

Smart Solutions For HCAI



STUDY REPORT

An Evaluation of MedMat[®] 700 and MedMat[®] 1100 Dressing Fields in Terms of Practical Application and Perceived Impact on Infection Control in a Range of healthcare Settings

Development Phase:	Post marketing NHS Service Evaluation
Investigational Products:	MedMat [®] 700 and MedMat [®] 1100
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Study Start Date:	9 March 2009
Study Completion Date:	31 May 2009
Final Report Date:	14 th June 2010
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GLOSSARY OF TERMS AND ABBREVIATIONS

BCHS	Bristol Community Health Services
HCAI	healthcare associated infections
IEC	Independent Ethics Committee
IV	Intravenous
NHS	National Health Service
NRES	National Research Ethics Committee
MedDRA	Medical Dictionary for Regulatory Activities
MRSA	Meticillin-resistant <i>Staphylococcus aureus</i>
SD	Standard Deviation

1 SYNOPSIS

Title of Study: An Evaluation of MedMat[®] 700 and MedMat[®] 1100 Dressing Fields in Terms of Practical Application and Perceived Impact on Infection Control in a Range of Primary healthcare Settings

Investigators: The Principal Investigator was Wendy Briggs, Infection Prevention & Control Specialist Practitioner, Bristol Community Health Services (BCHS). MedMat[®] evaluations were performed by 30 primary healthcare professionals (nurses and practitioners) in a wide range of community healthcare settings within BCHS.

Study Location(s): Community healthcare settings within BCHS: treatment rooms, podiatry clinics, wound care clinics, patient homes, prison service healthcare, walk in treatment centres, other primary care facilities

Publication (reference): None at the time of this report.

Date of First Evaluation: 9 March 2009

Date of Last Evaluation: 31 May 2009

Objectives:

To identify the procedures and/or patient groups where the use of MedMat[®] 700 and MedMat[®] 1100 were most appropriate.

To quantify the potential impact that MedMat[®] technology has on infection control related issues.

To understand how MedMat[®] can help to facilitate an improvement in procedure standards and in particular how MedMat[®] can lead to a more aseptic approach to procedures.

To evaluate the product performance in practice:

- Is MedMat[®] simple and easy to use?
- Is the product able to deal with fluid load and clinical waste effectively compared to existing dressing fields in use?

Methodology: Over a 3-month period, MedMat[®] 700 (550 x 450 mm) and MedMat[®] 1100 (855 x 690 mm) dressing fields were used for a range of clinical procedures such as wound care or catheterisation, by primary healthcare professionals in patients' homes, treatment rooms, podiatry clinics, wound care clinics, prison service treatment rooms, walk in treatment centres, and other primary care facilities,.

At the conclusion of each clinical procedure using a MedMat[®] dressing field, the healthcare professional (evaluator) completed an evaluation form (Form A) on which they recorded procedural details and rated 4 performance characteristics (absorbs fluids; average procedure time; achieves an aseptic approach to the procedure; maintains a sterile field) against those of current practice according to a 5 point scale (1 = much worse; 2 = worse; 3 = same; 4 = better; and 5 = much better).

At the end of the 3-month period, evaluators recorded summary information on their experience using MedMat[®] dressing fields on an end of study evaluation form (Form B) and rated the 11 performance characteristics of MedMat[®] against those of current practice using a 5-point scale (1 = strongly disagree; 2 = disagree, 3 = same; 4 = agree; and 5 = strongly agree). Performance characteristics rated were: is fit for the purpose; is simple to use; encourages good practice; improves overall performance; is a useful product to help to prevent and contribute towards controlling healthcare associated infections (HCAIs); improves the standard of asepsis; maintains a sterile field; isolates waste material for all procedures carried out; is able to absorb fluids for all procedures carried out; reduces the average procedure time; I would like to continue using the MedMat[®]

Additionally, at the end of the study a *TrusTECH* representative and Smart Solutions for HCAI representative interviewed a selection of evaluators to obtain further information on their experiences with MedMat[®] and views on product performance.

Number of Evaluations: It was planned that approximately 100 MedMat[®] 700 and MedMat[®] 1100 dressing fields were to be evaluated in each clinical setting over the 3-month period of the study. In total 650 MedMat[®] dressing fields were used by 30 evaluators. Form A evaluation forms were completed for 495 (76%) of the dressing fields used; 419 MedMat[®] 700 and 73 MedMat[®] 1100 (3 evaluators did not enter size of MedMat[®] on the evaluation form).

Test Products: MedMat[®] 700 (550 x 450 mm, equivalent to a standard hospital dressing trolley) and MedMat[®] 1100 (855 x 690 mm, equivalent to the width and a third of length of standard hospital bed) dressing fields (Ergomedica, Bucks, UK) were evaluated. MedMat[®] consists of a double-layered, latex-free, protective mat that is used to cover, and prevent contamination of surfaces during clinical procedures. Following removal of the top layer of the mat, which is absorbent to allow fluid capture, the second layer provides a clean sterile surface for follow up procedures such as wound dressing. An integral sealable waste bag is included to ensure effective disposal of all non-sharp contaminated waste, including the protective mat.

Statistical Methods: Data from Forms A and B for each MedMat[®] performance characteristic were summarised by number and percentage for each rating score 1 to 5. The mean and standard deviation (SD) of each performance characteristic rating were also calculated. Forms A and B scores were analysed using the Wilcoxon signed-rank test. If scores were significantly higher than 3 (= same as current practice) MedMat[®] was assumed to be statistically significantly superior. Additionally, for Form A scores the Mann-Whitney test was used to determine if there was a difference in performance rating between MedMat[®] size (700 vs 1100), and the Kruskal-Wallis test was used to compare performance rating for type of clinical procedure and the amount of fluid involved in the procedure.

Results: The most frequent settings for use of MedMat[®] were patients' homes (50%) and podiatry clinics (33%), with the remaining (17%) locations being treatment rooms, wound care clinics, prison service treatment rooms, and walk in centres. MedMat[®]s were most commonly placed on beds (39%) and the floor (35%). Wound dressing was the most common procedure, with 66% of MedMat[®]s used for small wound dressing and 24% used for large wound dressing. Only 1% was used for urinary catheterisation, none were used for IV cannulation, and 10% were used for other clinical procedures (not specified). Half (51%) of MedMat[®] use involved small volumes of body fluid, 41% did not involve body fluids, and 8% of procedures involved large volumes of body fluid.

The Form A performance characteristics showed that the primary benefit offered by MedMat[®] as rated by evaluators is its ability to absorb fluids, although there were also statistically significant findings for other criteria evaluated (average procedure time, achieving aseptic approach to the procedure, maintaining a sterile field). There was no difference in the ratings of MedMat[®] 700 and 1100 in the ability of these different size systems to absorb fluids. However, significantly more evaluators rated MedMat[®] 700 more effective than current practice at achieving an aseptic approach and maintaining a sterile field, than MedMat[®] 1100.

The final 3-month global evaluation (Form B) showed MedMat[®] to be superior for all performance characteristics except for average procedure time which was viewed the same as current practice, and continued use of the product for which there was no clear preference expressed by evaluators. Nearly three quarters of evaluators agreed that MedMat[®] dressing fields were simple to use, 82% agreed that they were able to absorb fluids for all procedures carried out, and 69% agreed that MedMat[®] isolates waste material.

Conclusions:

- The primary advantage offered by MedMat[®] dressing fields over current practice is their effectiveness in absorbing fluids, particularly for those procedures involving moderate to large volumes of fluid, such as in large wound dressing.
- No differences in evaluators' opinions of MedMat[®] 700 and MedMat[®] 1100 for fluid absorption were observed. However, compared to the larger MedMat[®] 1100 significantly more evaluators rated the smaller MedMat[®] 700 more effective at achieving an aseptic approach and maintaining a sterile field than current practice.

Date of Report: 12 April 2010

2 ETHICS

The National Research Ethics Committee (NRES) was consulted to determine whether or not the study required full ethical approval. In the opinion of the NRES, the study was a National Health Service (NHS) evaluation and did not require ethical approval.

The study was conducted according to the protocol and guidelines laid down by the European Union and the NHS, and the investigators ensured that the conduct of study was in full conformity with the October 2008 revision of the 1964 Declaration of Helsinki.

Each evaluator (primary healthcare personnel who evaluated MedMat[®] dressing fields) participating in the final interviews was asked to sign a consent form indicating that:

1. They consented to being recorded during the final study evaluation interview.
2. All the information they provided during the study could be included in the analysis of the study outcome.

3 INVESTIGATORS AND STUDY ADMINISTRATIVE STRUCTURE

The study was sponsored by *TrusTECH* Innovation Unit, Manchester, UK, as part of the Smart Solutions for healthcare Associated Infections (HCAI) programme.

The Principal Investigator for the study was Wendy Briggs, Infection Prevention and Control Specialist Practitioner, Bristol Community Health Services (BCHS), UK. Evaluation of the performance of MedMat[®] dressing fields in primary healthcare settings was performed by healthcare professionals within BCHS.

MedMat[®] dressing fields were manufactured by Ergomedica, Bucks, UK, and distributed by Sunlight Clinical Solutions, Rhondda Cynon Taff, UK. Training in the use of MedMat[®] dressing fields and support for the BCHS healthcare personnel involved in the study was provided by the distributor.

Data was entered into the study database by the *TrusTECH* Market Research Manager, and data analysis was conducted by Paul Bassett of Statsconsultancy Ltd. The study report was prepared on behalf of Smart Solutions for HCAI by Remo, Southampton, UK.

4 STUDY OUTLINE

4.1 Programme Background

As part of continued efforts by the Department of Health to improve hospital infection control and reducing healthcare associated infections, a programme of evaluating technologies with the potential to help prevent cross-contamination and spread of infection is in progress.

The technology under investigation in this study, MedMat[®] 700 and MedMat[®] 1100 dressing fields (Ergomedica, Bucks, UK), was evaluated as part of the Smart Solutions for HCAI programme; a national programme run by *TrusTECH*, The North West of England NHS Innovations Hub, on behalf of the Department of Health's HCAI Technology Innovation Programme, and supported by the NHS National Innovation Centre.

Smart Solutions for HCAI aims to bring forward new technologies generated by businesses in healthcare or other commercial sectors, that are not currently in use, or have not been widely adopted, within the NHS, but have the potential to be transferred into the NHS to help control the spread of infection.

Ergomedica's new dressing fields were 1 of 9 new technologies selected for evaluation in the Smart Solutions for HCAI programme following a national competition in 2008. The technology was selected for further evaluation due to the potential to reduce cross-contamination of patients undergoing healthcare procedures in the primary healthcare setting.

4.2 Technological Background

MedMat[®] dressing field has been designed to protect both patients and healthcare personnel from cross-contamination by providing an aseptic, practical work surface, and integral waste disposal system, for carrying out clinical procedures such as dressing changes and podiatry in the field setting.

MedMat[®] dressing field consists of a double-layered, latex-free, protective mat that is used to cover, and prevent contamination of surfaces during clinical procedures. Following removal of the top layer of the mat, which is absorbent to allow fluid capture, the second layer provides a clean sterile surface for follow up procedures such as wound dressing. MedMat[®] also contains an integral sealable waste bag to ensure effective disposal of all non-sharp contaminated waste, including the protective mat.

MedMat[®] dressing fields are available in two sizes; MedMat[®] 700 (550 x 450 mm) which covers a surface equivalent to a standard hospital dressing trolley and is suitable for procedures creating a small to medium quantity of waste; and MedMat[®] 1100 (855 x 690 mm) which covers a surface equivalent to the width and a third of the length of a standard hospital bed, and is therefore suitable for patients who are bed bound or having continence difficulties.

4.3 Study Rationale

Colonised and infected patients represent the important risk to of infection control, with transmission mainly by person-to-person contact via the hands of healthcare workers. The rationale for this study was to identify whether the use of MedMat[®] 700 or MedMat[®] 1100 have the potential to help in the reduction of levels of cross contamination and infection transmission.

Thus the aims of this study were to evaluate MedMat[®] 700 and MedMat[®] 1100 in terms of practical application and perceived impact on infection control related factors such as fluid absorbance, procedure time, aseptic approach and sterility. No attempt

was to be made to make a direct correlation between infection rates and the use of MedMat[®] 700 or MedMat[®] 1100.

4.4 Benefit-Risk and Hazard Evaluation

MedMat[®] 700 and MedMat[®] 1100 dressing fields are Class 1 CE marked products, certifying that they are safe and of a guaranteed good quality.

No potential health and safety risks to either the patients or healthcare personnel were identified when these products were used in accordance with the instructions provided in the study protocol (Appendix 1).

5 STUDY OBJECTIVES

The objectives of this study were:

- To identify the procedures and/or patient groups where the use of MedMat[®] 700 and MedMat[®] 1100 dressing fields were most appropriate.
- To quantify the potential impact that the MedMat[®] technology has on infection control-related issues.
- To understand how MedMat[®] dressing fields can help to facilitate an improvement in procedure standards and in particular how they can lead to a more aseptic approach to procedures.
- To evaluate the product performance in practice:
 - Is MedMat[®] simple and easy to use?
 - Is the product able to deal with fluid load and clinical waste effectively compared to dressing fields already in use?

6 INVESTIGATIONAL PLAN

6.1 Method

This was a large-scale, open, uncontrolled field study in which primary healthcare personnel evaluated the performance of MedMat[®] 700 and MedMat[®] 1100 dressing fields when used during routine clinical procedures in a range of primary community healthcare settings.

The MedMat[®] distributor, Sunlight Clinical Solutions provided training for all healthcare personnel involved in the study on the use of MedMat[®] 700 and MedMat[®] 1100.

The dressing fields were deployed, using a standardised procedure, in patients' homes, treatment rooms, podiatry clinics, wound care clinics, prison service treatment rooms, walk in treatment centres, and other primary care facilities, over a 3-month period starting on 9 March 2009 and ending on 31 May 2009.

MedMat[®] dressing fields were available for use as appropriate during wound care, urinary catheterisation, venous catheterisation, and other clinical procedures.

Evaluators of MedMat[®] were primary healthcare personnel (e.g. nurses and practitioners). At the conclusion of each clinical procedure, the evaluator recorded procedural details on a post-procedure evaluation form, and rated their view of performance characteristics of MedMat[®] compared with those of current practice, using a 5-point rating scale (see Section 10).

The following procedural information was recorded:

- Healthcare setting (Treatment room/Podiatry clinic/Wound care clinic/Patient's home/Prison service treatment room/Walk in centre/Other)
- Working surface used for the procedure (On the bed/Dressing trolley/Floor/Other)
- Size of MedMat[®] dressing field used (MedMat[®] 700/MedMat[®] 1100)
- Type of clinical procedure carried out (small wound dressing/large wound dressing/urinary catheterisation/IV cannulation/other)
- Amount of body fluid involved in the procedure (No fluid/Small volume/Large volume)
- Did the MedMat[®] waste bag accommodate all the waste produced during the procedure (Yes/No)

At the end of the 3-month study period, evaluators recorded summary information on their use of MedMat[®] dressing fields on a global evaluation form, and rated the performance characteristics of MedMat[®] dressing field against those of current practice, using a 5-point rating scale (see Section 10).

The following procedural information was recorded on the global evaluation forms:

- healthcare setting for the procedures (Treatment room/Podiatry clinic/Wound care clinic/Patient's home/Prison service treatment room/Walk in centre/Other)
- Number of MedMat[®] 700 dressing fields used during the study period (less than 10; 10 – 50; 50 – 100; Over 100)
- Number of MedMat[®] 1100 dressing fields used during the study period (less than 10; 10 – 50; 50 – 100; Over 100)

A number of evaluators were interviewed by a panel consisting of a *TrusTECH* representative and a Smart Solutions for HCAI representative to obtain further information on the evaluators' experiences with MedMat[®] dressing fields, and their views on the performance of the product.

6.2 Discussion of Study Design

The aim of this study was to evaluate MedMat[®] 700 and MedMat[®] 1100 dressing fields in terms of practical application and perceived impact on infection control related factors in the day to day work of community health nurses and practitioners. No attempt was to be made to make a direct correlation between infection rates and the use of MedMat[®] 700 and MedMat[®] 1100.

To enable evaluation of the overall practicality of MedMat[®] dressing fields, the products were used on a large-scale in a wide range of clinical settings for a broad range of routine healthcare procedures. Evaluators, who were primary healthcare personnel (e.g. nurses and practitioners), followed a standardised procedure when using the dressing field to reduce variations that might have occurred as a result of using different practical techniques.

The performance of MedMat[®] dressing fields was evaluated at the end of each clinical procedure to enable assessment of the effectiveness of the product when used for different healthcare procedures. The evaluators also completed a global evaluation of the performance of the products at the end of the 3-month study period to enable assessment of the overall performance of the products.

Bristol Community Health Services were selected as the location for this study because from the size of the patient population it serves it was anticipated that a sufficient number of dressing fields would be evaluated during the 3-month study period.

6.3 Investigational Products

MedMat[®] 700 and MedMat[®] 1100 dressing fields are manufactured by Ergomedica, Bucks, UK, and distributed by Sunlight Clinical Solutions, Rhondda Cynon Taff, UK. Details of the composition of the layers of the mat and waste bag of the dressing fields are shown Table 1.

Table 1 MedMat[®] Dressing Field Technical Specifications and Batch Numbers

Product	MedMat [®] 700	MedMat [®] 1100
Batch number(s)	Lot No. 0109408	Lot No. 0109409
Size	550 mm by 450 mm	855 mm by 690 mm
Top layer	Glue laminated 20 gsm PE ¹ + 60 gsm paper + 30 gsm PP ²	
Second layer	20 gsm PE ¹ + 28 gsm Viscose	
Waste bag	74 gsm PE ¹ film lined inside with 1 piece of 28 gsm Viscose	
Manufacturer	Ergomedica	

¹ polyethylene; ² polypropene

7 STUDY ASSESSMENTS

7.1 Primary Outcome Variable: Performance of MedMat[®] After Each Healthcare Procedure (Form A)

The primary outcome variable of the performance of MedMat[®] compared with current practice was rated using a 5-point rating scale by the evaluator at the conclusion of each clinical procedure on a post-procedure product evaluation form (Form A).

The following performance characteristics were rated:

1. "Absorbs fluids"
2. "Average procedure time"
3. "Achieves an aseptic approach to the procedure"
4. "Maintains a sterile field"

The 5-point rating scale was as follows: 1 = Much worse; 2 = Worse; 3 = Same; 4 = Better; and 5 = Much better.

If the use of MedMat[®] dressing fields was prematurely ended during a procedure, the evaluator was asked to provide additional information on the post-procedure product evaluation form.

7.2 Secondary Outcome Variables

7.2.1 Global Evaluation of MedMat[®] (Form B)

At the end of the 3-month study period evaluators performed a global evaluation of performance characteristics of MedMat[®] compared with current practice. The ratings using a 5-point rating scale were recorded on a global product evaluation form (Form B).

The following performance characteristics were evaluated:

1. "Is fit for the purpose"
2. "Is simple to use"
3. "Encourages good practice"
4. "Improves overall performance"
5. "Is a useful product to help to prevent and contribute towards controlling HCAs"
6. "Improves the standard of asepsis"
7. "Maintains a sterile field"
8. "Isolates waste material for all procedures carried out"
9. "Is able to absorb fluids for all procedures carried out"
10. "Reduces the average procedure time"
11. "I would like to continue using the MedMat[®]"

The 5-point rating scale was as follows: 1 = Strongly Disagree; 2 = Disagree, 3 = Same; 4 = Agree; and 5 = Strongly Agree.

7.2.2 End of Study Interview

At the end of the 3-month study period, a number of evaluators were interviewed by a panel comprising a *TrusTECH* representative and a Smart Solutions for HCAI representative.

At the start of the interview the respondent (evaluator) signed a form stating that they did or did not agree to the interview being recorded. If the respondent agreed, the interview was recorded and transcribed.

The interview lasted for approximately 15 minutes, and consisted of an informal semi-structured conversation between the interviewers and respondent during which the respondent was asked questions from the evaluation questionnaires, and questions about the respondent's experiences with, and opinions of, the MedMat[®] dressing fields.

Further information on the structure and content of the interview is provided in the amended study protocol (Appendix 1).

7.3 Quality Assurance

Healthcare procedures

When using MedMat[®] dressing fields, a standardised procedure was followed by the evaluators. A comprehensive training in the use of MedMat[®], product literature and supporting materials were provided by the distributor (Sunlight Clinical Solutions).

7.4 Statistical Methods

Full details of the statistical analyses are provided in the Statistical Report (Appendix 2).

All numerical data were summarised and tabulated. The non-parametric Wilcoxon signed-rank test was used to examine whether the performance of MedMat[®] as reported in the responses to the questions on Form A (rating of performance of MedMat[®] after each procedure) and Form B (global evaluation MedMat[®] after using for 3 months) was rated significantly differently to current practice.

The non-parametric Mann-Whitney test was used to determine whether responses differed for the two MedMat[®] dressing sizes (700 and 1100). To compare responses by the type of clinical procedure and by the amount of fluid involved in the procedure, the non-parametric Kruskal-Wallis test was used.

7.5 Changes in the Conduct of the Study Including Changes to the Planned Analyses

The protocol was amended to include post-study interviews (Section 7.2.2).

8 RESULTS

8.1 Data Sets Analysed

In total 650 MedMat[®] dressing fields were used by 30 evaluators over the 3-month study period. However, Form A was only completed for 495 (76%) of the dressing fields used.

Twenty-two evaluators incorrectly completed Question 1 (“Absorbs fluids”) on Form A for clinical procedures that did not involve body fluids. The incorrect responses were not included in the statistical analyses of the study data.

8.2 Use of MedMat[®]

8.2.1 Healthcare Settings

Information on the use of the 495 MedMat[®] dressing fields is shown in Table 2 and Figure 1. The data shows that 419 (85%) were MedMat[®] 700 and 73 (15%) were MedMat[®] 1100. In 3 cases size of the dressing field was not stated.

Half (249; 50%) of the dressing fields were used in patients’ homes, a third (163; 33%) were used in podiatry clinics, and the remaining 63 (17%) were used in treatment rooms, wound care clinics, prison service treatment rooms, walk in centres, and other locations.

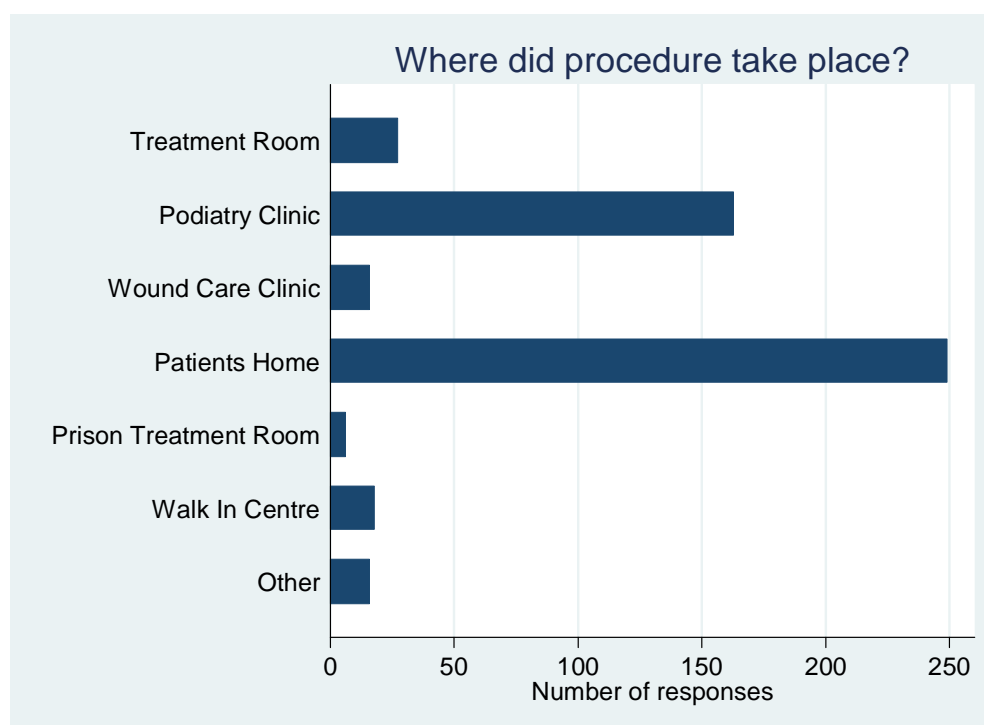
One hundred and ninety-three (39%) of MedMat[®] dressing fields were used on beds; 173 (35%) were used on the floor; 76 (15%) were used on other work surfaces; and only 50 (10%) were used on dressing trolleys.

Table 2 Use of MedMat[®] dressing fields (Form A)

Variable	MedMat [®] dressing fields (completion of Form A) N = 495
	n (%)
Dressing field used:	
MedMat [®] 700	419 (85)
MedMat [®] 1100	73 (15)
Not recorded	3 (-)
Clinical setting:	
Treatment room	27 (5)
Podiatry clinic	163 (33)
Wound care clinic	16 (3)
Patients’ homes	249 (50)
Prison service treatment room	6 (1)
Walk in centre	18 (4)
Other	16 (3)
Work surface:	
Bed	193 (39)
Dressing trolley	50 (10)
Floor	173 (35)
Other	76 (15)
Not recorded	3 (-)

Source: Table 1, Statistics Report; Appendix 2

Figure 1 Where MedMat[®] procedures took place (Form A)



The results obtained from asking each evaluator how many of each size of MedMat[®] dressing field they had used during the study are shown in Table 3. Most evaluators (20; 69% for MedMat[®] 700 and 18; 95% for MedMat[®] 1100) had each used up to 50 MedMat[®]s over the 3 month period of the study.

Table 3 Use of MedMat[®] dressing fields (Form B)

Estimated number used	Number of evaluators N = 30	
	MedMat [®] 700	MedMat [®] 1100
Less than 10	8 (28)	10 (53)
10 – 50	12 (41)	8 (42)
50 – 100	8 (26)	1 (5)
Over 100	1 (3)	0 (0)
Not recorded	1 (-)	11 (-)

Source: Table 6, Statistics Report; Appendix 2

8.2.2 Clinical Procedures

Information on the use of MedMat[®] in clinical procedures is shown in Table 4.

Three hundred and seventeen (66%) MedMat[®] dressing fields were used for small wound dressing, 114 (24%) were used for large wound dressing; 6 (1%) were used for urinary catheterisation, and 47 (10%) were used for other clinical procedures. No MedMat[®] dressing fields were used for IV cannulation.

Half (241; 51%) of MedMat[®] dressing fields were used for procedures involving small volumes of body fluid, 193 (41%) were used for procedures involving no body fluids, and 39 (8%) were used for procedures involving large volumes of body fluid.

Table 4 Number of MedMat® used for each clinical procedure

Procedure type:	Numbers used: n (%)
	N = 495
Clinical procedure	
Small wound dressing	317 (66)
Large wound dressing	114 (24)
Urinary catheterisation	6 (1)
IV cannulation	0 (0.0)
Other	47 (10)
Not recorded	11 (-)
Body fluid volume	
No fluid	193 (41)
Small volume	241 (51)
Moderate	1 (0.2)
Large volume	39 (8)
Not recorded	21 (-)

Source: Table 1, Statistics Report; Appendix 2

8.3 Primary Outcome Variable: Performance of MedMat® After Each Healthcare Procedure (Form A)

8.3.1 Performance of MedMat® Against Current Practice (Form A)

Evaluators rated 191 (67%) MedMat® dressing fields better or much better than current practice for absorbing fluids, as compared to 5 (2%) rated worse than current practice. Just over half (240; 51%) of MedMat® dressing fields were rated better or much better at achieving an aseptic approach, compared to 53 (11.2%) rated worse or much worse and 185 (39%) were rated the same. Similarly, evaluators rated 247 (51%) MedMat® dressing fields better or much better at maintaining a sterile field, compared to 73 (15.4%) rated worse or much worse. All three of these results were statistically significant ($p < 0.001$) in terms of mean scores.

Although average procedure time was statistically significant ($p < 0.001$), only 106 (22%) MedMat® dressing fields were rated better or much better than current practice for average procedure time, compared to 36 (7%) rated worse or much worse. Most evaluators rated procedure times for using MedMat® dressing fields the same as current practice (344; 71%).

A comparison of the performance of MedMat® dressing fields against current practice is presented in Table 5 and Figures 2, 3, 4, and 5.

Table 5 Performance of MedMat[®] against current practice (Form A)

Performance characteristic	Score	Number (%) N = 495	Mean score (SD)	P-value
1. Absorbs fluids?				
Much worse	1	0 (0)	3.8 (0.7)	<0.001
Worse	2	5 (2)		
Same	3	90 (31)		
Better	4	157 (55)		
Much better	5	34 (12)		
2. Average procedure time?				
Much worse	1	0 (0)	3.2 (0.5)	<0.001
Worse	2	36 (7)		
Same	3	344 (71)		
Better	4	102 (21)		
Much better	5	4 (1)		
3. Achieves an aseptic approach to the procedure?				
Much worse	1	1 (0.2)	3.5 (0.8)	<0.001
Worse	2	52 (11)		
Same	3	185 (39)		
Better	4	199 (42)		
Much better	5	41 (9)		
4. Maintains a sterile field?				
Much worse	1	2 (0.4)	3.4 (0.9)	<0.001
Worse	2	71 (15)		
Same	3	156 (33)		
Better	4	207 (43)		
Much better	5	40 (8)		

Source: Table 2, Statistics Report, Appendix 2

Figure 2 Ability of MedMat[®] to absorb fluids compared to current practice (Form A)

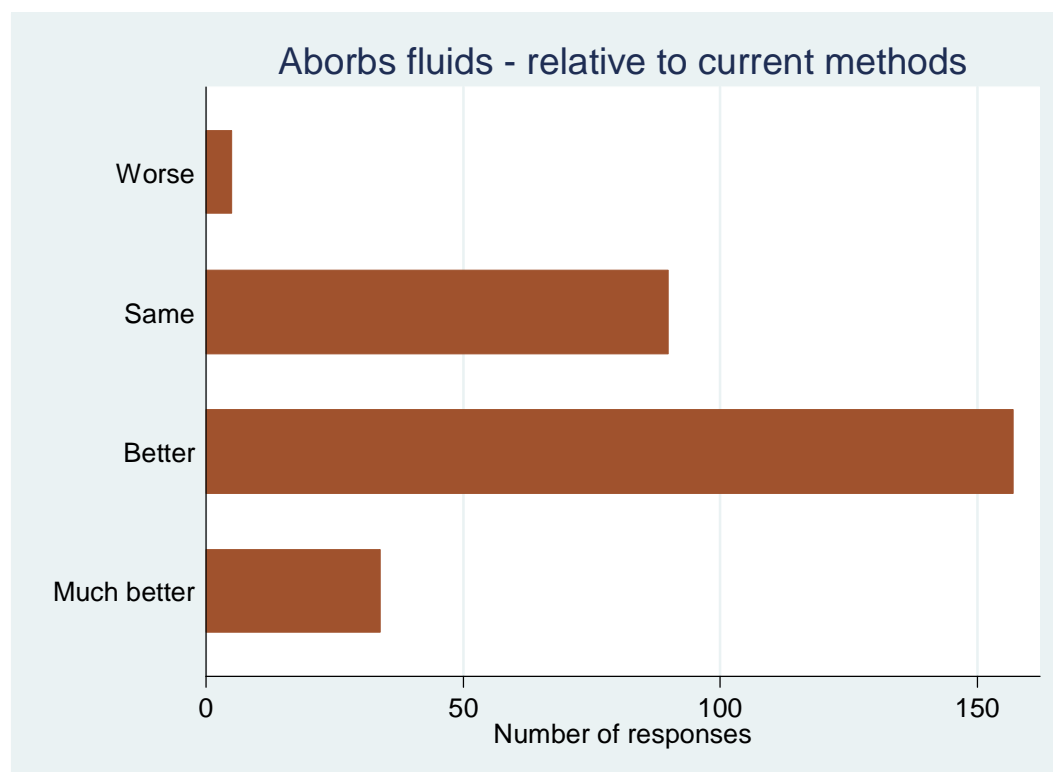


Figure 3 Average procedure time associated with the use of MedMat[®] compared to current practice (Form A)

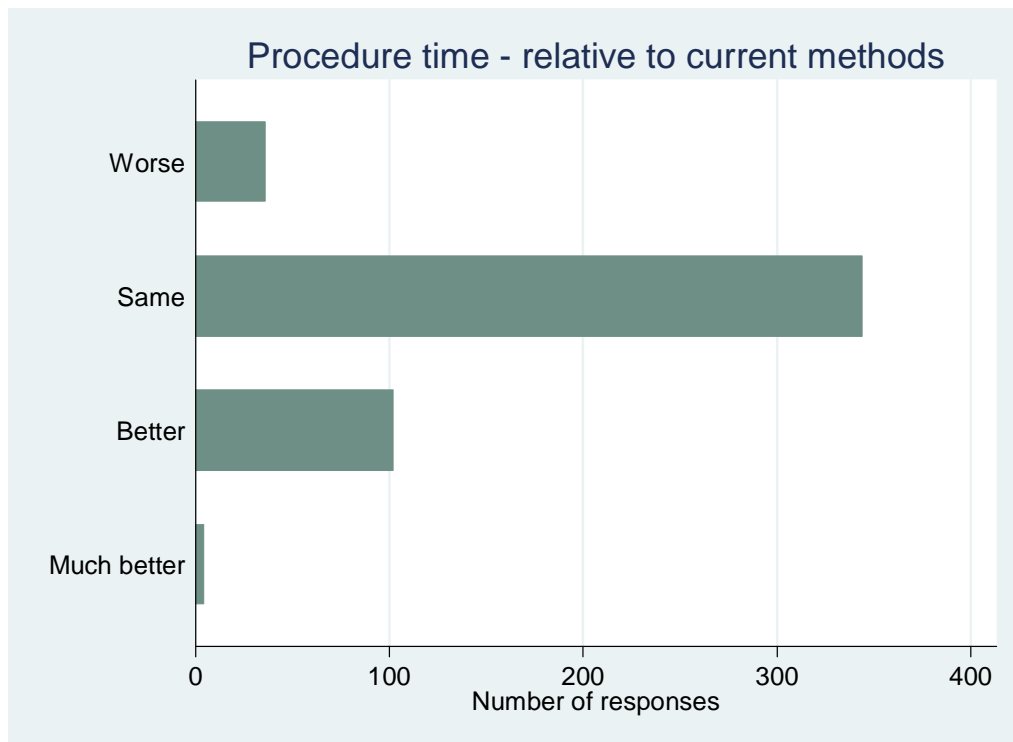


Figure 4 Whether users considered that MedMat[®] achieves an aseptic approach to the procedure compared to current practice (Form A)

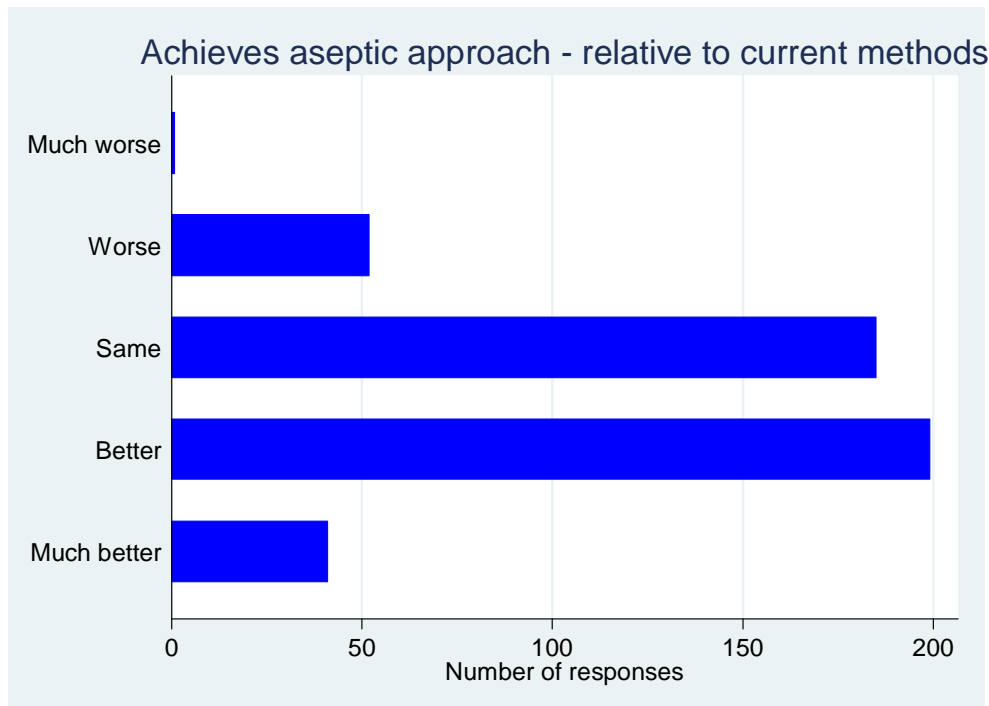
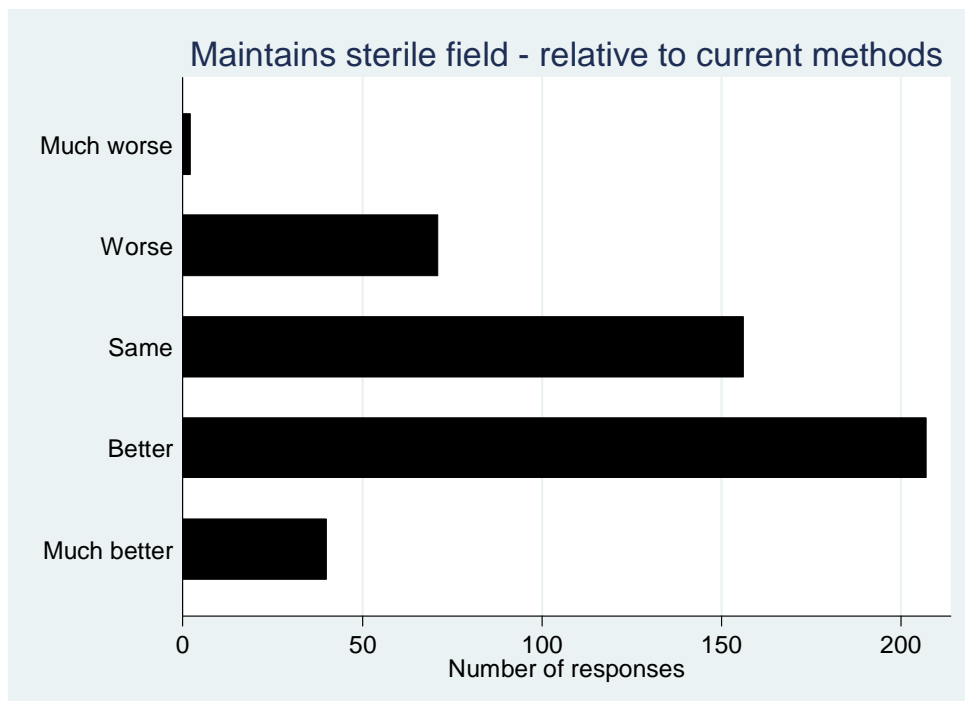


Figure 5 Whether users considered that MedMat[®] maintains a sterile field compared to current practice (Form A)



8.3.2 Comparison of Performance of MedMat[®] 700 and MedMat[®] 1100 (Form A)

A comparison of the performance of MedMat[®] 700 and MedMat[®] 1100 dressing fields is presented in Table 6.

Statistical comparison showed that there was no significant difference between the mean rating scores between MedMat[®] 700 and MedMat[®] 1100 in their ability to absorb fluids ($p = 0.11$) or their effect on average procedure time ($p = 0.36$). MedMat[®] 700 was however rated significantly more effective at achieving an aseptic approach ($p = 0.01$) and maintaining a sterile field ($p = 0.02$) compared with current practice, than shown for MedMat[®] 1100. Evaluators rated 214 (53%) MedMat[®] 700 dressing fields as better or much better at maintaining an aseptic approach, compared to 26 (36%) MedMat[®] 1100. Similarly, 217 (53%) MedMat[®] 700 were rated better or much better in maintaining a sterile field, compared to 28 (41%) MedMat[®] 1100.

Table 6 Comparison of the performance of MedMat® 700 and MedMat® 1100 (Form A)

Performance characteristic	Dressing field N = 495		P-value
	MedMat® 700 n (%)	MedMat® 1100 n (%)	
<i>1. Absorbs fluids?</i>			
Much worse	0(0)	0(0)	0.11
Worse	5 (2)	0 (0)	
Same	78 (33)	11 (22)	
Better	122 (53)	34 (67)	
Much better	28 (12)	6 (12)	
<i>2. Average procedure time?</i>			
Much worse	0(0)	0(0)	0.36
Worse	29 (7)	6 (8)	
Same	289 (70)	53 (74)	
Better	89 (22)	13 (18)	
Much better	4 (1)	0 (0)	
<i>3. Achieves an aseptic approach to the procedure?</i>			
Much worse	0 (9)	0 (0)	0.01
Worse	45 (11)	7 (10)	
Same	145 (36)	39 (54)	
Better	174 (43)	25 (35)	
Much better	40 (10)	1 (1)	
<i>4. Maintains a sterile field?</i>			
Much worse	1 (0.3)	0 (0)	0.02
Worse	57 (14)	14 (19)	
Same	127 (32)	28 (40)	
Better	179 (44)	26 (38)	
Much better	38 (9)	2 (3)	

Source: Table 3, Statistics Report, Appendix 2

8.3.3 Comparison of the Performance of MedMat® After Each Procedure (Form A)

The results obtained from evaluation of the overall performance of MedMat® dressing fields at the end of each clinical procedure are summarised in Table 7 and Figure 6.

As there were few responses in the urinary catheterisation category it was combined with the “other” category for the purposes of statistical analysis.

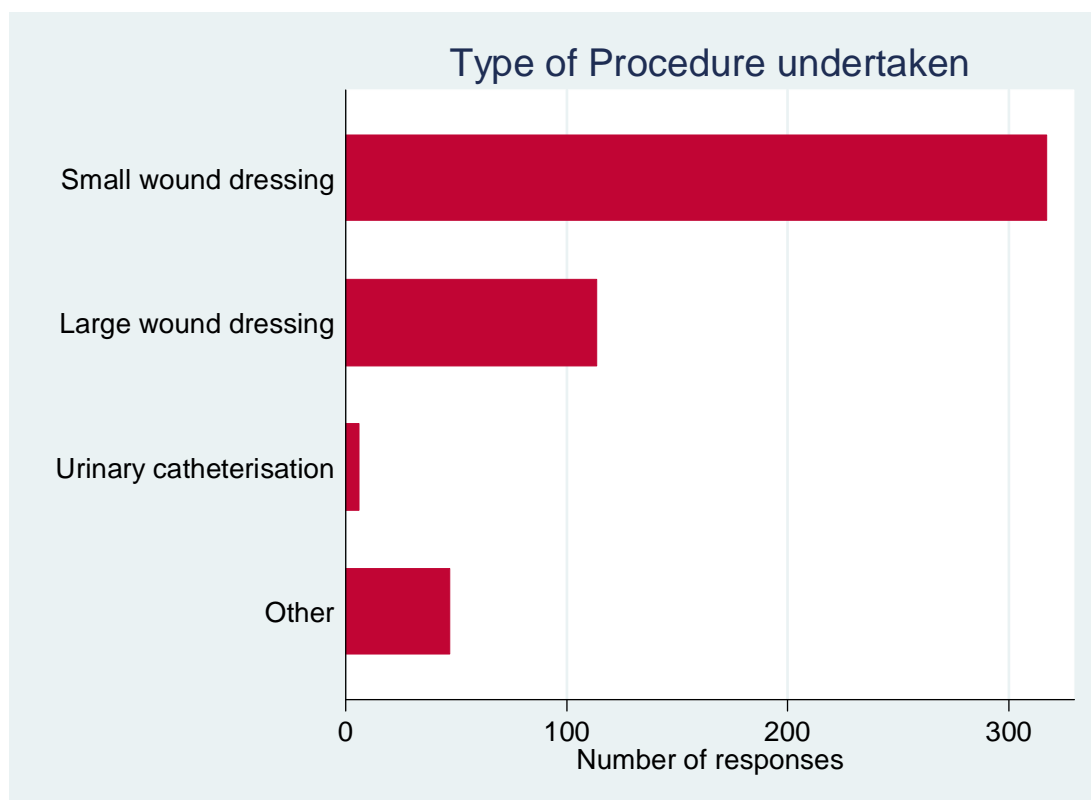
Analysis of the evaluators’ reports on MedMat® dressing fields for each type of clinical procedure indicated that the only statistically significant difference between MedMat® and current practice ($p = 0.007$) was in the effectiveness of MedMat® at absorbing fluids. Evaluators rated 68 (79%) MedMat® as better or much better for managing large wound dressings than current practice, as compared to 109 (61%) rated better or much better for small wound dressings. Of the 17 MedMat® dressing fields used in other clinical procedures, 12 (71%) were rated better or much better than current practice, and the remainder (5; 29%) as the same.

Table 7 Performance of MedMat® during each type of clinical procedure (Form A)

Performance characteristic	Clinical procedure N = 495			P-value
	Small wound dressing n (%)	Large wound dressing n (%)	Other n (%)	
<i>1. Absorbs fluids?</i>				
Much worse	0 (0)	0 (0)	0 (0)	0.007
Worse	2 (1)	3 (3)	0 (0)	
Same	67 (38)	15 (17)	5 (29)	
Better	96 (54)	50 (58)	9 (53)	
Much better	13 (7)	18 (21)	3 (18)	
<i>2. Average procedure time?</i>				
Much worse	0 (0)	0 (0)	0 (0)	0.23
Worse	24 (7)	10 (9)	2 (4)	
Same	211 (68)	84 (75)	40 (75)	
Better	74 (24)	17 (15)	10 (19)	
Much better	2 (1)	1 (1)	1 (2)	
<i>3. Achieves an aseptic approach to the procedure?</i>				
Much worse	1 (0.3)	0 (0)	0 (0)	0.28
Worse	31 (10)	13 (11)	8 (15)	
Same	118 (38)	50 (46)	12 (23)	
Better	132 (48)	36 (33)	26 (50)	
Much better	25 (8)	10 (9)	6 (12)	
<i>4. Maintains a sterile field?</i>				
Much worse	1 (0.3)	0 (0)	1 (2)	0.08
Worse	40 (13)	24 (22)	7 (13)	
Same	101 (33)	38 (35)	13 (24)	
Better	140 (46)	38 (35)	24 (45)	
Much better	23 (8)	9 (8)	8 (15)	

Source: Table 4, Statistics Report, Appendix 2

Figure 6 Type of procedure in which MedMat[®] was used (Form A)



8.3.4 Evaluation of Performance of MedMat[®] by Amount of Fluid Involved in the Clinical Procedure (Form A)

The results obtained from evaluation of the overall performance of MedMat[®] dressing fields by the amount of fluid involved in the clinical procedure are summarised in Table 8.

In total 32 (82%) MedMat[®]s were rated better or much better than current methods for absorbing fluid when a moderate or large volume of fluid was involved in the procedure, compared with 155 (70%) for procedures involving a small amount of fluid.

Evaluators rated average procedure time better or much better than current practice for 80 (34%) MedMat[®]s for procedures involving small volumes of fluid compared to no fluid (24; 12.5%) or moderate to large volumes of fluid (2; 4%). However, evaluators rated average procedure time the same as current practice for 144 (60%) MedMat[®]s involving use of small volumes of fluid, as compared to no fluid (147; 78%) or moderate to large volumes of fluid (37; 93%).

For achieving an aseptic approach and maintaining a sterile field, overall the evaluator's rating of MedMat[®] was better or much better than current practice when a small volume of fluid was involved in the procedure.

Evaluators rated 147 (62%) MedMat[®] dressing fields better or much better at achieving an aseptic approach when small volumes of fluid were involved, compared with 17 (43%) when moderate or large volumes were involved and 72 (38%) when no fluid was involved. Similarly, 150 (64%), MedMat[®]s were rated better or much better at maintaining a sterile field for procedures involving small volumes of fluid,

compared to when a moderate or large amount of fluid was involved (17; 43%) and when no fluid was involved (75; 40%).

Table 8 Comparison of the performance of MedMat® by volume of fluid involved in the procedure (Form A)

Performance characteristic	Volume of fluid involved in the procedure N = 495			P-value
	None N (%)	Small n (%)	Moderate/large n (%)	
<i>1. Absorbs fluids?</i>				
Much worse	0(0)	0(0)	0 (0)	<0.001
Worse	0 (1)	2 (1)	3 (8)	
Same	18 (82)	62 (28)	4 (10)	
Better	4 (18)	130 (59)	23 (59)	
Much better	0 (0)	25 (11)	9 (23)	
<i>2. Average procedure time?</i>				
Much worse	0 (0)	0 (0)	0 (0)	<0.001
Worse	18 (10)	16 (7)	1 (2)	
Same	147 (78)	144 (60)	37 (93)	
Better	23 (12)	78 (33)	1 (2)	
Much better	1 (0.5)	2 (1)	1 (2)	
<i>3. Achieves an aseptic approach to the procedure?</i>				
Much worse	0 (0)	1 (0.4)	0 (0)	<0.001
Worse	19 (10)	26 (11)	4 (10)	
Same	96 (51)	62 (26)	18 (46)	
Better	64 (34)	118 (50)	15 (38)	
Much better	8 (4)	29 (12)	2 (5)	
<i>4. Maintains a sterile field?</i>				
Much worse	0 (0)	2 (1)	0 (0)	<0.001
Worse	33 (18)	27 (11)	10 (26)	
Same	78 (42)	57 (24)	12 (31)	
Better	65 (35)	124 (53)	15 (38)	
Much better	10 (5)	26 (11)	2 (5)	

Source: Table 5, Statistics Report, Appendix 2

8.3.5 Additional Comments on Form A

Additional comments were provided on Form A by a number of users after using the MedMat® dressing fields for individual procedures. The comments were reviewed and summarised by the TrusTECH and Smart Solutions for HCAI representatives. The resulting summary is shown below.

Maintaining a sterile field

One user noted that MedMat® provided a larger sterile field than currently available and another commented that MedMat® was useful in maintaining a sterile field as it is much harder wearing than a paper dressing towel.

However, users also commented that MedMat® did not maintain a sterile field as one user needed to lean on the mat to treat a leg wound, whereas another stated that it is impossible to keep a sterile field when there are large amounts of fluid.

Cross infection prevention

Fluids

One user commented that MedMat[®] was useful as it absorbed the saline used for cleaning a heel wound, whereas another noted that fluid ran off the bottom of the MedMat[®] they were using and on to the floor.

Waste bag and isolating waste materials

One of the users noted that the attached waste bag was useful. However other users noted that they had some trouble using the waste bag. The bag was too small for all the bandages from bilateral leg ulcer wounds and one user had to squash down waste materials into the bag with their hands.

More than one user found that they needed to put their hands into the bag to put contents in, especially if the bag was on the floor or not hanging down, and it was also noted that they had to put their hands in to seal the bag.

Users also noted that they found it difficult to peel off the strip and seal the bag or found that the bag would not seal.

Layered fields

Some of the users noted that they found the layered fields in the MedMat[®] dressing field cumbersome and thought it complicated the process making the procedure longer than necessary. However, one user noted that they found MedMat[®] very effective and easier to use once they got used to the new procedure.

The users also commented that two layers of sterile field are not always needed for every procedure, which made MedMat[®] wasteful in some circumstances such as dressing smaller wounds.

Several users stated that they did not like the layering of the sterile fields, as this meant putting dirty dressings on top of what is going to become the new sterile field and commented that they would prefer the layers to be separate or detachable for this reason.

Suitability of procedures and environments

One user stated that MedMat[®] was very easy to use and very effective in a clinical setting.

Users noted that they found MedMat[®] particularly beneficial when compared to the usual non-sterile paper towel or certain procedures including cleaning and dressing heel wounds, urinary catheter procedures, and dressing pressure ulcers. Users also noted that MedMat[®] is too big for wound dressings and smaller wounds and there is not always need for two layers and they produce a lot of waste.

Further comments

Size

Users noted that they had accidentally chosen the wrong size of MedMat[®] to use for the procedure and therefore it was not suitable on that occasion. Some users also commented that the large size makes it difficult to work with, whereas others considered MedMat[®] too small for some wound dressings and for use in the community or in patients' homes.

Waste disposal

Users repeatedly stated that they thought MedMat[®] produced too much unnecessary waste when used for smaller wounds and that it took up more space than current materials in the waste disposal which is not very environmentally friendly.

Gloves

More than one user commented that they had to use additional items including gloves and would like an extra pack of sterile gloves included in the MedMat®.

8.4 Secondary Outcome Variables

8.4.1 Global Evaluation of MedMat® Performance (Form B)

The results obtained from global evaluation at the end of the study, of the overall performance of MedMat® dressing fields compared to current practice are summarised in Table 9.

Table 9 Global evaluation of the performance of MedMat® (Form B)

Performance characteristic	Evaluator rating N = 30					
	Strongly disagree n (%)	Disagree n (%)	Same n (%)	Agree n (%)	Strongly agree n (%)	Not done n (%)
1. Is fit for the purpose?	0 (0)	3 (10)	5 (17)	18 (60)	4 (13)	0 (-)
2. Is simple to use?	0 (0)	2 (7)	6 (20)	16 (53)	6 (20)	0 (-)
3. Encourages good practice?	1 (3)	3 (10)	6 (21)	15 (52)	4 (13)	1 (-)
4. Improves overall performance?	0 (0)	2 (7)	16 (53)	11 (37)	1 (3)	0 (-)
5. Is a useful product to help to prevent and contribute towards controlling HCAs?	0 (0)	1 (3)	15 (50)	12 (40)	2 (7)	0 (-)
6. Improves the standard of asepsis?	0 (0)	3 (10)	12 (40)	10 (33)	5 (17)	0 (-)
7. Maintains a sterile field?	0 (0)	2 (7)	15 (50)	8 (27)	5 (17)	0 (-)
8. Isolates waste material for all procedures carried out?	1 (3)	3 (10)	5 (17)	15 (52)	5 (17)	1 (-)
9. Is able to absorb fluids for all procedures carried out?	0 (0)	1 (4)	4 (15)	15 (56)	7 (26)	3 (-)
10. Reduces the average procedure time?	3 (10)	10 (34)	15 (52)	1 (3)	0 (0)	1 (-)
11. I would like to continue using the MedMat.	2 (7)	5 (18)	10 (36)	9 (32)	2 (7)	2 (-)

Source: Table 7, Statistics Report ; Appendix 2

The findings for each performance characteristic are summarised as follows.

Is fit for the purpose?

Twenty-two (73%) of the evaluators agreed or strongly agreed that MedMat® dressing fields were “fit for purpose”, 5 (17%) thought that that they were about the same as current practice, and 3 (10%) disagreed.

The majority of the evaluators therefore agreed that MedMat® dressing fields were “fit for purpose”.

Is simple to use?

Twenty-two (73%) of the evaluators agreed or strongly agreed that MedMat® dressing fields were “simple to use”, 6 (20%) found no difference, and 2 (7%) disagreed.

The majority of the evaluators therefore agreed that MedMat[®] dressing fields were “simple to use”.

Encourages good practice?

Nineteen (65%) of the evaluators agreed or strongly agreed that MedMat[®] dressing field “encourages good practice”, 6 (21%) thought that there was no difference, and 4 (13%) disagreed or strongly disagreed.

The majority of the evaluators therefore agreed that MedMat[®] dressing fields encouraged good practice.

Improves overall performance?

When asked if MedMat[®] dressing fields “improves overall performance”, 12 (40%) of evaluators agreed or strongly agreed, 16 (53%) thought the performance was the same as with their current practice, and 2 (7%) disagreed.

Therefore, just over half the evaluators agreed there was no difference in overall performance dressing fields compared with current practice, but a significant minority (40%) agreed that MedMat[®] improves overall performance.

Is a useful product to help prevent and contribute towards controlling HCAIs?

Just under half (14; 47%) of evaluators agreed or strongly agreed that MedMat[®] “is a useful product to help prevent and contribute towards controlling HCAIs”. Half (15; 50%) of evaluators considered it to be the same as current practice, and 1 (3%) disagreed with the statement.

Improves the standard of asepsis?

Half of the respondents (15; 50%) agreed or strongly agreed that MedMat[®] dressing fields “improves the standard of asepsis”, 12 (40%) reported that it was the same, and 3 (10%) disagreed.

Maintains a sterile field?

When asked if MedMat[®] dressing fields “maintains a sterile field”, 13 (44%) of the evaluators agreed or strongly agreed that they did, 15 (50%) felt they were about the same as their current practice, and 2 (7%) disagreed.

Isolates waste material for all procedures carried out?

Twenty (20; 69%) of the evaluators agreed or strongly agreed that MedMat[®] dressing field “isolates waste material for all procedures carried out”, 5 (17%) thought there was no difference from their current practice, and 4 (13%) disagreed or strongly disagreed.

The majority of evaluators therefore agreed that MedMat[®] dressing fields isolated waste material for all procedures carried out.

Is able to absorb fluids for all procedures carried out?

Twenty-two (82%) of the evaluators agreed or strongly agreed that MedMat[®] dressing field was “able to absorb fluids for all procedures carried out”, 1 (4%) disagreed, and 4 (15%) thought that there was no difference compared to their current practice.

The majority of evaluators therefore agreed that MedMat[®] dressing fields were able to absorb fluids for all procedures carried out.

Reduces the average procedure time?

Only 1 (3%) respondent agreed that MedMat[®] dressing field “reduces the average procedure time”, as compared to 15 (52%) who thought it was the same, and 13 (44%) who disagreed or strongly disagreed.

Almost all of evaluators therefore thought that MedMat[®] dressing fields did not reduce the average procedure time.

I would like to continue using the MedMat

Eleven (39%) agreed or strongly agreed that they “would like to continue using the MedMat[®]”, 10 (36%) expressed no preference, and 7 (25%) disagreed or strongly disagreed.

8.4.2 Additional Comments on Form B

A number of users provided additional comments on Form B during their global evaluation of the use of MedMat[®] dressing fields. The comments were reviewed and summarised by the TrusTECH and Smart Solutions for HCAI representatives. The resulting summary is shown below.

Improve the standard of asepsis and asepsis technique

One user commented that using MedMat[®] does make you really think about your aseptic technique.

Cross infection prevention

Fluids

One user commented that the absorbency of MedMat[®] dressing field is useful.

Waste bag and isolating waste materials

The users noted that it was difficult to seal the bag without putting your hands inside the waste, but that the bag was excellent to secure waste with.

Layered fields

The users commented that the dirty and clean fields need to be completely separate. The users noted that the fields should be detachable so that they can be placed in different areas for use which would also make the product less fiddly to use.

The users noted that not all the wounds dressed warrant two layers of sterile fields.

Suitability of procedures and environments

One user stated that the waste bags are good for patient’s homes, as users already have waste bags attached to their trolleys in treatment rooms. However, some users commented that the waste is too bulky for the community and that the product is too wasteful for smaller dressings.

One user noted that they found MedMat[®] ideal for VAC therapy due to size of the waste bag. Another suggested that MedMat[®] would be useful for podiatry ulcer clinics, but would want the fields to be detachable. One user found that MedMat[®] was not appropriate to put the patient on and would probably be more appropriate for treating a wound on a leg or an arm.

Further comments

Size

The users commented that they liked the size and durability of MedMat[®] and would like a smaller size for smaller wounds, but found the current sizes big and bulky to carry around.

Gloves

More than one user commented that they would like a pair of gloves included in pack as they needed to use separate gloves during the procedure.

8.4.3 Summary of End of Study Interviews

Fourteen (41%) of the evaluators were interviewed at the end of the 3-month study period by representatives from *TrusTECH* and Smart Solutions for HCAI. The transcripts from the interviews were evaluated by the *TrusTECH* and Smart Solutions representatives. A summary of their findings is provided below.

Improve the standard of asepsis and asepsis technique

Maintain sterile field

One user agreed that MedMat[®] did maintain a sterile field, commenting that it was better than current normal practice which uses just one sterile field.

Several of the users advised that you do not need a sterile field for all procedures such as leg ulcers. Therefore, it is not really necessary to use a sterile area and when in people's homes users do not carry out sterile dressings, but "clean" dressings.

The users also advised that it can be difficult to maintain a sterile field when you are in a patient's home compared to a clinical area or treatment room and often users need to use the floor. Many found MedMat[®] covered a large area on the floor and provided a good sterile field in the home for them to spread out and have a bigger area to work in.

In a clinical area or treatment room users also advised that they found MedMat[®] provided a good sterile field when using a trolley with the waste bag hanging at the side.

Users commented that the MedMat[®] sterile field is bigger than those currently used but some did not think there was much difference between current materials and the MedMat[®]. One user commented that the MedMat[®] was nicer because it was a bit thicker than the current materials.

Users noted that by folding the dirty area in to the waste bag you could be contaminating the sterile area and once you have contaminated your sterile field underneath you could not use it as a sterile field.

Users were also concerned that during procedures the sterile field underneath the top layer could be contaminated, one example given by a user was when removing very wet dressings fluid could pour down the leg and run under the edges of the top layer and onto the field underneath.

Many users would have preferred to separate the two fields, not all thought it was ideal for the clean dressings and clean field to be next to the wound, dirty dressings and dirty field and would rather they were separate or detachable.

The users suggested detaching the absorbent mat, or having a perforated edge to detach the waste bag to ensure they could maintain a sterile field.

Cross infection prevention

Fluids

The majority of users commented on the absorbency of MedMat[®] and noted that it was particularly useful for washing legs and feet, including irrigating the leg and changing leg and foot ulcer dressings. These can often be pouring and involve a large amount of fluid and users mentioned MedMat[®] helped prevent spillage and mess left in the patients home.

There were no examples given by any of the users where MedMat[®] had failed to absorb all the fluid. Users advised that MedMat[®] was much better at absorbing fluids

compared to what they currently use, which is usually blue paper towel and white paper.

One user commented that the absorbency is very useful for infection control.

Waste bag and isolating waste materials

Some users considered the MedMat[®] system an improvement to current working practice as all the processes are in one compact area. The users commented that they do not have to move around, the dirty area is contained and that clearing away debris is a lot more effective because it is sealed into a bag, rather than be wrapped up in a paper towel for disposing of later.

One user commented that there is a greater need to know how to dispose of dressings and MedMat[®] was a good thing because waste was not hanging around waiting to be disposed of.

The majority of the users found that the waste was contained by the attached waste bag; one user gave the example of using MedMat[®] 1100 for a dressing change on both legs where there were a lot of wet dressings and the waste bag accommodated all the dressing waste.

However, one user advised that they did not always manage to fit all the waste into the attached bag and they had to use extra bags. This has been mainly for double leg ulcer dressings with lots of bandages.

A number of the users commented that they had needed to put their hands inside the waste bag to push rubbish down, put back rubbish that had spilled out when the bag was lying flat on the floor rather than hanging, push rubbish down which was occluding the bag to fit all the rubbish in, and pull the peel off sticky tab to seal the bag. The users were not sure that they should be putting their hands into the bag or near the contaminated waste while they are still touching the patient.

Some users stated that the bags did not always close properly, especially when filled with heavily soiled bandages and dressings because it was so full (especially the smaller MedMat[®] 700) and that the tape does not always seal the bag completely.

Users suggested separating the bag or perforating the edge of the bag as they would prefer it if once the dirty dressings have gone into the bag that it could be separated to keep the dirty dressings away from the clean area. Another suggestion was to have the bag free standing rather than lying flat.

Layered fields

Some users commented that using the layered fields was different to their current practice of having a separate sterile field. As discussed some users considered the MedMat[®] system an improvement but not all the users thought having the layered fields was ideal.

One user advised that they had been using the top layer predominantly then using the second layer but not as an aseptic procedure and another user advised that they did not use the second layer, as they forgot about it.

Several of the users felt that by having dirty dressings on the top layer and rolling the this layer into the bag once the dressing has been taken down you touch the bottom layer and lose the sterile field underneath. They would prefer to detach the top layer and commented that it would be nice to have the sterile field separate, even as a little pack inside as they would like a sterile field and a dirty field to put dirty dressings and instruments on.

The users also noted that it would be useful to perforate the top layer for procedures on certain parts of the body, for example, when a patient is in bed it would be easier to use just one layer as it is tricky to get under the patient to remove the top layer.

Suitability of procedures and environments

The majority of the users commented that MedMat[®] was good for wounds with a large amount of fluid and dressings. In particular, the users noted that MedMat[®] was used for leg ulcers and washing the legs and noted it was very useful for this procedure and other leg wounds.

One user noted that it can be difficult working in patient's homes but found taking down a dressing, washing the leg ulcer and redressing it not a problem using MedMat[®].

Other users noted that they only really found MedMat[®] useful for large patients with leg wounds and would only use it for this as they found this procedure was improved. However, one user noted that they would not use MedMat[®] again for chronic leg ulcers because the waste bag was not big enough to take all the waste from this procedure.

One user used MedMat[®] for re-catheterisation and found it useful to be able to lay all the testing equipment down for urine testing and the sterile bits and pieces on the mat and as soon as they had finished put the old catheter and waste in the waste bag. Another noted that their catheterisation pack was much more wasteful than the MedMat[®] and so using this instead was much better and less wasteful and it had a larger field to fit the long catheter on comfortably.

Another user found catheterisation more awkward, as you have to remove the top layer from underneath the patient. They also considered that MedMat[®] was not necessary for catheterisation if you fit the bag onto the catheter before inserting it as there should be no leakage.

Users also found that MedMat[®] was useful at the podiatry clinic, especially for carrying out debridement of patients' feet as this can be done straight into waste bag for ease and containment. The users commented that it is better than what they are currently using and the absorbent material was useful for irrigating the wounds.

However, podiatrists use a tripod foot stool for home visits and one user found that MedMat[®] is not as useful when used with the foot stool as it is too large and cumbersome. Therefore the mat needed to be tethered onto something to prevent it from moving. The user advised that they stuck it to their leg across their lap, but this left them restrained in their position and suggested something smaller would be more appropriate.

Another user found MedMat[®] useful for abdominal wounds, abdominal cavities and the thoracic area as you can put the field under the patient and irrigate an area without making such a mess.

Another user found MedMat[®] useful for VAC dressings as it is good to have a large field as there is a lot of waste with the VAC and they found that MedMat[®] dressing fields are very thick and durable.

The users commented that some areas on the body are too difficult to use with MedMat[®] including under arms, heads, faces and you would not be using that sort of sterile field on the wounds.

Several users also commented that MedMat[®] is not appropriate for smaller dressings such as toes, arms, and elbows because it is too large and would be wasteful.

One of the environments that users commented it could be difficult to use MedMat[®] was if a patient was in bed at home. The users found it difficult to lay out a MedMat[®] and use the waste bag in this situation. It was also difficult to place the mat under the patient then lift them to remove the top layer.

Many evaluators used MedMat[®] on the floor in patients' homes and in a hospital or treatment room setting where it can be used properly on a trolley or work bench.

One of the users noted that in the home environment MedMat[®] made the procedure a lot tidier.

Further comments

Size

The users frequently commented that they like the large size of the mat and that it covers a large area on the floor, although they also note that this can be its limitation.

Several users suggested making a smaller MedMat[®] for smaller wounds, for example an arm laceration or perhaps a hand, almost half the size of the MedMat[®] 700.

Procedure time

Some users found that the procedure time was about the same as current practice because the same procedures are still being carried out as before.

Some users found using MedMat[®] quicker, reducing procedure times because they had not had to move away from the patient and had a large dressing area with enough room to lay everything out. One user noted that it was quicker but only for patients with both legs being dressed.

However, one user thought it took longer once the mat was, opened, stuck down, and the waste bag conveniently positioned.

Waste disposal

Most of the users commented that there is a lot more extra waste.

Some of the users noted that a lot of the patients do not like MedMat[®] because it is too big and they do not like that much waste going into their bins.

Also, in clinical settings users noted that a repercussion of using MedMat[®] is the quite bulky waste and consequently they took up a lot of space in clinical waste bags.

Gloves

Several users also commented that they were using an additional pack of sterile gloves as well as using the MedMat[®] and would like a pair of gloves included in the MedMat[®] system to save using two packs. One user suggested a pair of gloves and an apron.

9 DISCUSSION AND OVERALL CONCLUSIONS

MedMat[®] is a discrete dressing field designed to provide an aseptic, practical work surface for healthcare personnel carrying out procedures such as dressing changes and podiatry in the field setting, and thus should help prevent cross-contamination and the spread of infection during these types of procedures. In this community-healthcare based 3-month evaluation of the performance of the two sizes of MedMat[®] (700 and 1100) the primary advantage offered by the MedMat[®] over current practice was found to be its effectiveness in absorbing fluids, and the effectiveness with those clinical procedures involving moderate or large volumes of fluid, such as large wound dressing.

In the study, 495 of MedMat[®] 700 and 1100 were evaluated by 30 healthcare workers within Bristol Community Health Services NHS Trust. In common with normal day to day practice, the most frequent settings for use of MedMat[®] were patients' homes (50%) and podiatry clinics (33%), with the remaining (17%) used in locations such as treatment rooms, wound care clinics, prison service treatment rooms, and walk in centres. The most common places for using a MedMat[®] were beds (39%) and the floor (35%), with MedMat[®]s used most frequently in wound dressing.

Four performance characteristics of MedMat[®] that were important in improving infection control were compared to current practice, and quantified on a 5-point scale. These showed that above all fluid absorption had the most favourable ratings with a mean (SD) score of 3.8 (0.7). In total 67% of the MedMat[®] dressing fields used were rated better or much better than current practice at absorbing fluids, as compared to 31% rated the same and 2% rated worse than current practice. Indeed analysis of the evaluators' reports on the MedMat[®] dressing fields for type of clinical procedure (mainly wound dressing) indicated that the only performance characteristic rating that was statistically significant different from current practice ($p = 0.007$) was in the effectiveness of MedMat[®] at absorbing fluids. In line with this finding, evaluators rated 79% of MedMat[®]s used as better or much better for large wound dressings, a procedure that frequently may involve more fluids. Further to this, 82% of MedMat[®]s were rated better or much better at absorbing fluids than current methods when a moderate or large volume of fluid was involved, compared with 70% for procedures involving a small amount of fluid. In particular, some users found MedMat[®] particularly useful when washing and irrigating legs and feet. Regarding the two sizes of MedMat, no significant difference was noted for fluid absorption.

Evaluators rated just over half (51%) of MedMat[®] dressing fields as better or much better at achieving an aseptic approach and maintaining a sterile field. Indeed, the mean scores of 3.5 (0.8) and 3.4 (0.9), respectively, were statistically significant ($P < 0.001$). For achieving an aseptic approach and maintaining a sterile field, overall the evaluator's rating of MedMat[®] was at least better than current practice when a small volume of fluid was involved in the procedure for 62% and 64% of MedMat[®]s, respectively, which was higher than for procedures involving moderate to large amounts of fluid (43%). This result may have come about because of the view that it was more difficult to achieve aseptic conditions or sterility with procedures involving larger volumes of fluids. Additionally, several of the evaluators pointed out that a sterile area is not required for all procedures, for example treating leg ulcers. They also said that it is difficult to maintain a sterile field in a patient's home compared with a clinical area in a treatment room. It is noted that possibly because of its smaller size and use for more discrete procedures, MedMat[®] 700 was rated more effective for achieving an aseptic approach and sterility.

Although average procedure times for using the MedMat[®] dressing fields were rated mainly the same (71%) as current practice, 22% were considered at least better than

current practice with a resulting mean score for average procedure time of 3.2 (0.5) ($P < 0.001$).

The final 3-month global evaluation showed that MedMat[®] dressing fields were considered by evaluators to be generally better than current practice, although no clear preference was expressed for continued use of the product compared with current practice. Nearly three quarters of evaluators agreed that MedMat[®] dressing fields were simple to use, and 82% agreed that they were able to absorb fluids for all procedures carried out. Importantly, 69% of evaluators agreed that MedMat[®] isolates waste material. However, most of the users commented that there is a lot more extra and bulky waste compared with other practices after using MedMat[®], which could lead to concern at the space taken up in patients' waste bins and in clinical waste bags.

Conclusions

- The primary advantage offered by MedMat[®] dressing fields over current practice is their effectiveness in absorbing fluids, particularly for those procedures involving moderate to large volumes of fluid, such as in large wound dressing.
- No differences in evaluators' opinions of MedMat[®] 700 and MedMat[®] 1100 for fluid absorption were observed. However, compared to the larger MedMat[®] 1100 significantly more evaluators rated the smaller MedMat[®] 700 more effective at achieving an aseptic approach and maintaining a sterile field than current practice.

10 APPENDICES

10.1 Protocol

Smart Solutions For HCAI



Smart Solutions for HCAI

Protocol for Evaluating MedMat

Introduction

Smart Solutions for HCAI is a national programme run by *TrusTECH*, the North West of England NHS Innovation Hub, on behalf of the Department of Health and NHS Purchasing and Supply Agency (NHS PASA) and supported by the NHS National Innovation Centre.

Smart Solutions is an NHS programme to find new ways to help combat healthcare associated infections (HCAIs).

The Smart Solutions programme - aims to identify new technologies generated by businesses in healthcare or other commercial sectors that are not currently in use, or have not been widely adopted, within the NHS. Once identified, the products and technologies will be applied in a real-life environment to evaluate their potential to help further reduce levels of infection, especially MRSA and *C. difficile*.

Nine products have been selected for evaluation:

UV Lighting Equipment Range - UV Light Technology Ltd

Medixair - GE Healthcare

The AD (air disinfection unit) -Inov8 Science Ltd

AirManager, driven by Close Coupled Field Technology (CCFT) - Quest International (UK) Ltd

Recombinase Polymerase Amplification - TwistDx

MedMat - Ergomedica

Liquid glass layering technology - Nanopool

Formula 429 and Formula 429 plus - Chemspec Europe

V-link luer-activated device with VitalShield protective coating - Baxter Healthcare.

www.smartsolutionsforhcai.co.uk

MedMat is medical procedure device providing a two layer sterile field system for undertaking a variety of medical procedures, for example dressing changes, catheter changes, line changes etc. MedMats integrated waste bag enables the efficient and immediate disposal of all non sharp clinical waste created by the procedure including the product packaging, used bandages and the actual layers of the MedMat.

MedMat has two distinct surfaces to enable the application of aseptic techniques during the different stages of the procedure, separating the “dirty” from the “clean” elements of each process.

MedMat provides a protective barrier to the surface where the procedure is undertaken, for example a surgical trolley or patient's bed. The top layer where the “dirty” elements of a procedure are conducted, for example removing a soiled wound dressing, is highly absorbent to fluids but also laminate backed therefore preventing any strike through onto the second layer of the MedMat.

When the first stage of the procedure is complete the top layer is disposed of into the integrated waste bag revealing the clean, absorbent bottom surface ready for the next stage of the procedure, for example applying a new wound dressing. A peel off adhesive strip efficiently and conveniently seals the waste bag which is then disposed of as per the clinical waste guidelines of the Trust.

MedMat is available in two sizes, the 700 covers a standard hospital trolley and the 1100 approximately one third of a hospital bed.

MedMat is a CE marked product, certifying that it is safe and of good quality, and is designated as a Class 1 device.

www.medmat.co.uk

Bristol Community Health Services - is responsible for local NHS health services in Bristol, taking over from the previous Bristol South and West and Bristol North PCTs. Covering a population of around 400,000 people with a budget of over £600 million.

Services include GP Practices, pharmacies, dentists, opticians, a range of community nursing and therapy services.

The dedicated Infection Control Team consists of 2 Infection Prevention and Control Specialist Practitioners, one of which will be the Principal Investigator for this evaluation.

www.medmat.co.uk

Aim

The aim of this study is to evaluate MedMat in terms of practical application and perceived impact on infection control related issues. The purpose of this evaluation is to undertake a feasibility study (there will not be an attempt to make a direct correlation between infection rates and the use of the MedMat).

Objectives

- To identify the procedures and / or patient group where the use of MedMat is most appropriate
- To quantify the potential impact that MedMat has on infection control related issues
- To understand how MedMat can help to facilitate an improvement in procedure standards and in particular how MedMat can lead to a more aseptic approach to procedures.
- Evaluate product performance in practice - Is MedMat simple and easy to use; is the product able to deal with fluid load and clinical waste effectively compared to existing dressing fields in use?

Methodology

Bristol Community Health Services will deploy the technology in the following areas:

- District Nurse team for use for various procedures in patients home.
- Wound Care Service.
- Walk in centres
- Practice Nurses for various procedures in a Health Centre Treatment Room.
- Practice Nurses predominately for use during urinary catheterisations.
- Prison Service Healthcare.
- Podiatry.
- Intermediate care setting; predominately for intravenous venous cannulation.

Approximately 100 MedMats will be evaluated per setting for various procedures over a 12 week period.

Comprehensive product training will be provided by the MedMat distributor, along with all ordering details, product literature and supporting materials such as instruction posters. The training will be tailored to suit the needs of the PCT clinical staff involved in the evaluation process; these needs will be specified by the Principal Investigator.

In addition to the MedMat being used in different clinical settings it will be used for different procedures, user feedback will be gathered on an evaluation form. Two evaluation forms have been developed; a short questionnaire (appendix 1) for use by the evaluator following every procedure undertaken using the MedMat and a more detailed questionnaire (appendix 2) for completion by each evaluator at the end of the evaluation period.

The Principal Investigator will facilitate the collection of data and will collate the survey findings. At the conclusion of the evaluation period, a detailed final evaluation report will be prepared by a third party, identified and managed by the Smart Solutions Programme Manager.

Key Contacts / Stakeholders

Wendy Briggs	-	Principal Investigator– Infection Prevention and Control Specialist Practitioner, Bristol PCT Tel: 0117 900 2622
Emma Malpeli		Programme Manager – Smart Solutions for HCAI Tel: 0161 276 5970
Charlotte Butterfield	-	Marketing Director – Ergomedica Tel: 07823 880272
Karen Park	-	Rocialle Product Manager – MedMat Tel: 07825 382805

Ethics

Following guidance from the local Research and Development Department and the Comprehensive Research Network it has been agreed that this study is an 'in use feasibility evaluation' and therefore ethical approval is not required.

Health and Safety / Risk Analysis

No potential risks to patient, clinician or health and safety have been identified in relation to use of the MedMat, when used in accordance with instructions listed in appendix 4.

All other risks associated with the overall evaluation project are highlighted in appendix 3.

Suggested actions and timelines

There will be a phased approach to evaluation commencement; as clinical areas agree to participate; training will be provided; stock will be delivered and the evaluation will commence. There is no requirement for one common start date. The key stages in the evaluation are listed below:

1. Agree evaluation protocol for data collection – 28 Jan 2009
2. Agree specific procedures and or clinical areas where MedMat is to be evaluated – 8 Jan 2009 - Ongoing
3. Identify key internal link nurses from the participating departments – 8 Jan 2009– Ongoing
4. Legal contracts agreed and signed – 6 Feb 2009
5. Deliver Staff training – week commencing 9 Feb 2009 - Ongoing
6. Collate the data and forward to the Smart Solutions Programme Manager on a monthly basis for the duration of the evaluation. First data collection to be sent week commencing 9 March 2009.

10.2 Statistical Report

Smart Solutions For HCAI



Smart Solutions for HCAI

Statistical Report

Introduction

This report details the results of a study performed to examine the effectiveness of the MedMat medical device.

STATISTICAL METHODS

The statistical analysis of the data was undertaken in several stages. Initially a descriptive summary of the results obtained is reported. All information collected was measured on a categorical scale, and so the results were summarised by the number and percentage of values in each category. If no answer was given, the results were omitted from the analysis. In addition some results were displayed graphically using bar charts.

The second stage analysed the responses to the questions that compared MedMat to existing procedures. Responses to these questions were recorded on a 5 point scale from:

MedMat worse than existing methods (score of 1)

up to

MedMat better than existing methods (score of 5).

If the scores were significantly higher than 3 (MedMat same as existing methods) then MedMat can be assumed to be statistically better than the existing products. These analyses were performed using the Wilcoxon signed-rank test. This is a 'non-parametric' test, which is ideally suited to data of this type (ordinal data), where the order of the 5 categories is known, but the actual values attributed to each of the categories (1-5) are slightly arbitrary.

For the Part 1 data, the responses to the questions comparing MedMat to existing methods were associated with a number of other factors. Analyses were performed to examine whether the responses varied by MedMat size, by the type of procedure and by the amount of fluid. There were two MedMat sizes, and so the Mann-Whitney test was used to compare between sizes. The other two variables had more than two categories, and so the Kruskal-Wallis test was used for the analyses. These are two additional 'non-parametric' tests that are used to compare ordinal outcomes between groups.

Results

a) Part 1 - Analysis of data collected via the user evaluation forms that were completed for each use of a MedMat during the MedMat trial.

i) Summary of procedure

This initial analysis is a summary of all the data collected in the trial and is presented in Table 1. The figures reported are the number of responses in each category, together with the percentage of the total number of responses.

Table 1: A summary of all the data collected in the MedMat trial

Variable	Category	Number	Percentage
Where did procedure take place?	Treatment room	27	5%
	Podiatry clinic	163	33%
	Wound care clinic	16	3%
	Patients home	249	50%
	Prison treatment room	6	1%
	Walk in centre	18	4%
	Other	16	3%
Where was it used?	On the bed	193	39%
	Dressing trolley	50	10%
	Floor	173	35%
	Other	76	15%
MedMat size	MedMat 700	419	85%
	MedMat 1100	73	15%
Type of procedure	Small wound dressing	317	66%
	Large wound dressing	114	24%
	Urinary catheterisation	6	1%
	Other	47	10%
Amount of fluid	No fluid	193	41%

	Small volume	241	51%
	Moderate volume	1	0.2%
	Large volume	39	8%
MedMat waste bag accommodate waste	No	50	10%
	Yes	433	90%

Note: The total number of observations is 495. Due to missing values, the total number of responses for each variable may be less than this figure.

These results indicate that half of all procedures were performed in the patients' own home, whilst a third was performed in the podiatry clinic. No other location was particularly popular. This result is shown graphically in a bar chart in Figure 1.

MedMat was most commonly used on the bed (39% of all procedures), and also commonly used on the floor (35% of procedures). It was less commonly used on the dressing trolley. This result is shown in Figure 2.

MedMat 700 was the most commonly used size as it was used in 85% of procedures.

Figure 1: A bar chart summarising the location of where the MedMat procedures took place.

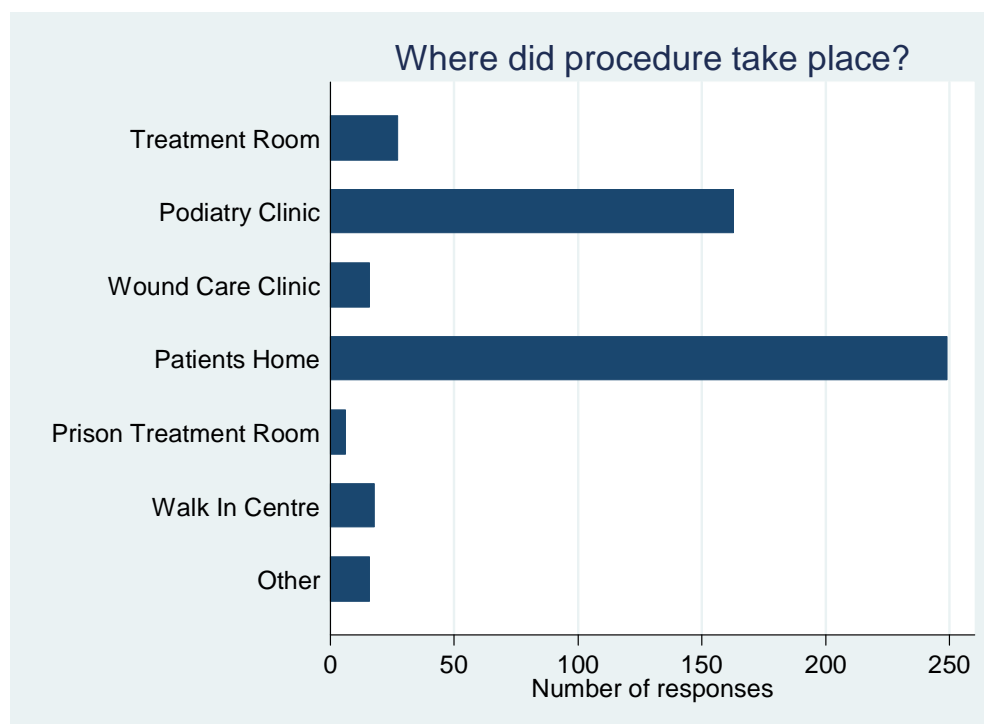
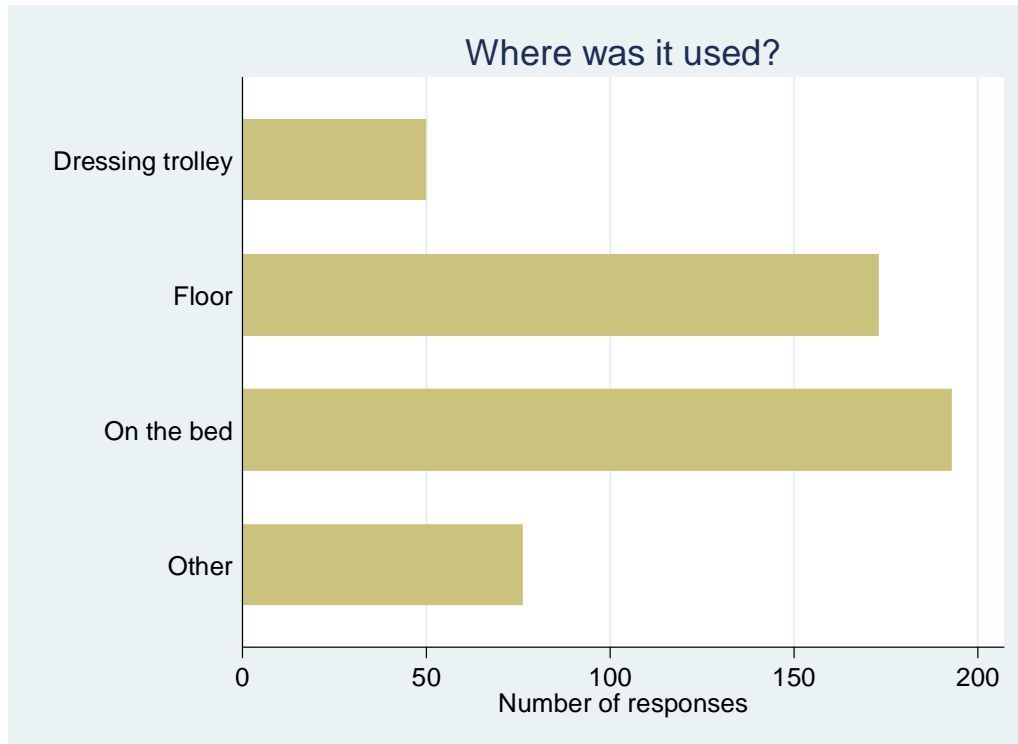


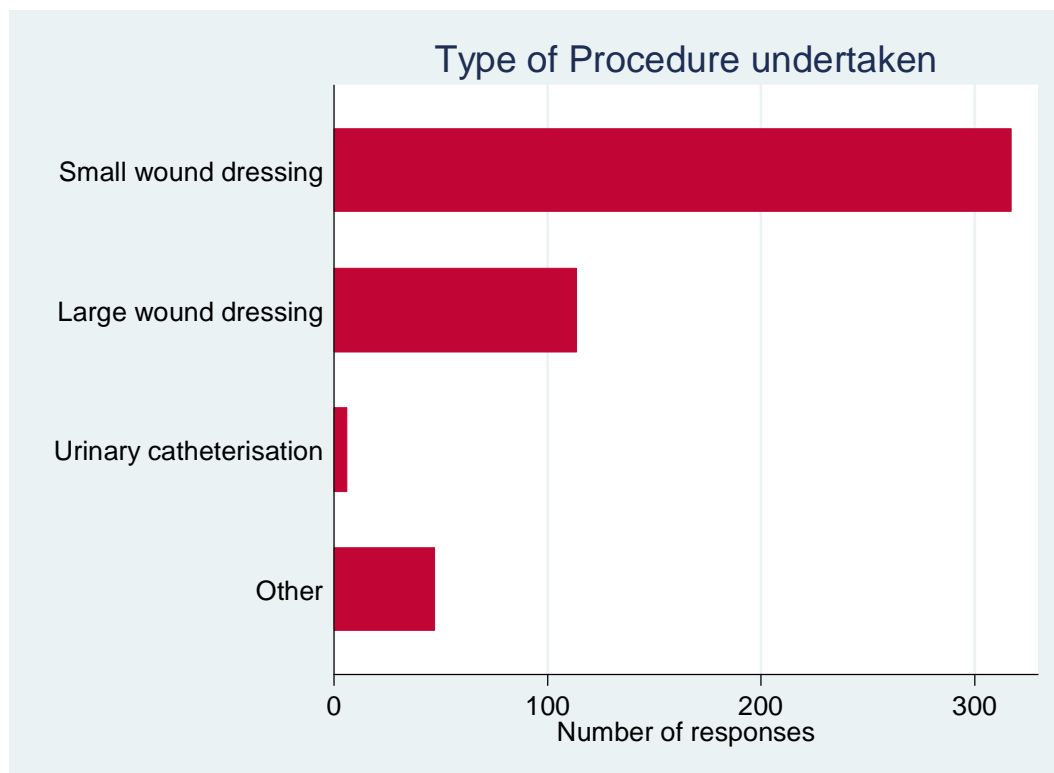
Figure 2: A bar chart summarising the surfaces on which the MedMat procedures took place.



MedMat was used with a small wound dressing in two-thirds of the procedures, and the majority of the remaining procedures involved large wound dressings. This result is displayed graphically in Figure 3.

There was no fluid in 41% of cases, with a small amount of fluid in just over half of cases. Less than 10% of procedures had a moderate or large amount of fluid.

Figure 3: A bar chart summarising the type of procedures in which MedMat was used.



ii) Analysis of the performance of MedMat compared to existing methods

The following analysis examines the performance of MedMat relative to existing materials, products and procedures. The analyses were performed using the Wilcoxon signed-rank test, and the results are summarised in Table 2. The figures reported are the number and percentage in each response category, and also the mean and standard deviation score (on a 1-5 scale). The p-values indicating the significance of the results are also reported.

Table 2: Analysis of the performance of MedMat relative to existing methods.

Variable	Comparison with existing procedure	Score	Number (%)	Mean Score (SD)	P-value
Absorbs fluids	Much worse	1	0 (0%)	3.8 (0.7)	<0.001
	Worse	2	5 (2%)		
	Same	3	90 (31%)		
	Better	4	157 (55%)		
	Much better	5	34 (12%)		
Procedure time	Much worse	1	0 (0%)	3.2 (0.5)	<0.001
	Worse	2	36 (7%)		
	Same	3	344 (71%)		
	Better	4	102 (21%)		
	Much better	5	4 (1%)		
Achieves aseptic approach	Much worse	1	1 (0.2%)	3.5 (0.8)	<0.001
	Worse	2	52 (11%)		
	Same	3	185 (39%)		
	Better	4	199 (42%)		
	Much better	5	41 (9%)		
Maintains sterile field	Much worse	1	2 (0.4%)	3.4 (0.9)	<0.001
	Worse	2	71 (15%)		
	Same	3	156 (33%)		
	Better	4	207 (43%)		
	Much better	5	40 (8%)		

Note: The total number of observations is 495. Due to missing values, the total number of responses for each variable may be less than this figure.

The results indicate that the use of MedMat was significantly different from existing procedures on all four of the parameters measured. In each case MedMat was preferred to the current methods. 65% of responses indicated that MedMat performed better than existing methods, 51% of responses indicated that MedMat achieved a better aseptic approach, whilst 51% of responses indicated that MedMat

was better at maintaining a sterile field than existing methods. These three results are shown graphically in Figures 4, 6 and 7.

Whilst significant, the results were less convincing for procedure time. The majority of responses (71%) suggested that procedure times were the same as for existing procedures, but most of those who expressed a preference suggested that MedMat was better. This result is displayed in Figure 5.

Figure 4: A bar chart indicating the ability of MedMat to absorb fluids relative to existing methods

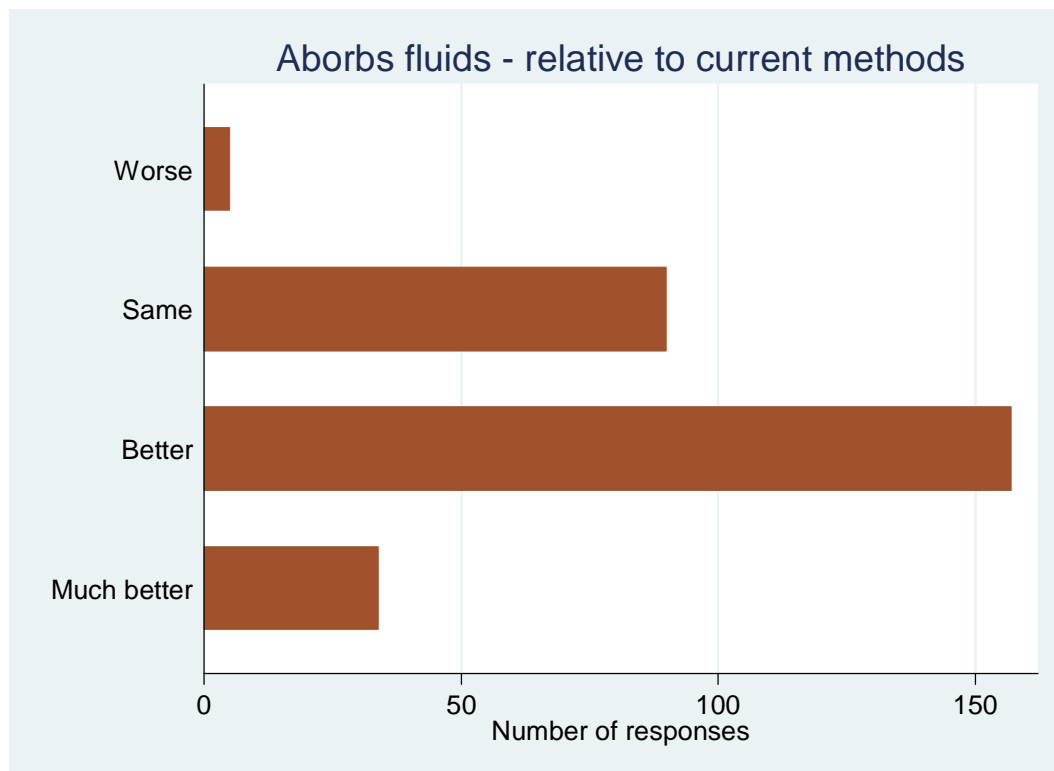


Figure 5: A bar chart indicating the average procedure time associated with the use of MedMat relative to existing methods

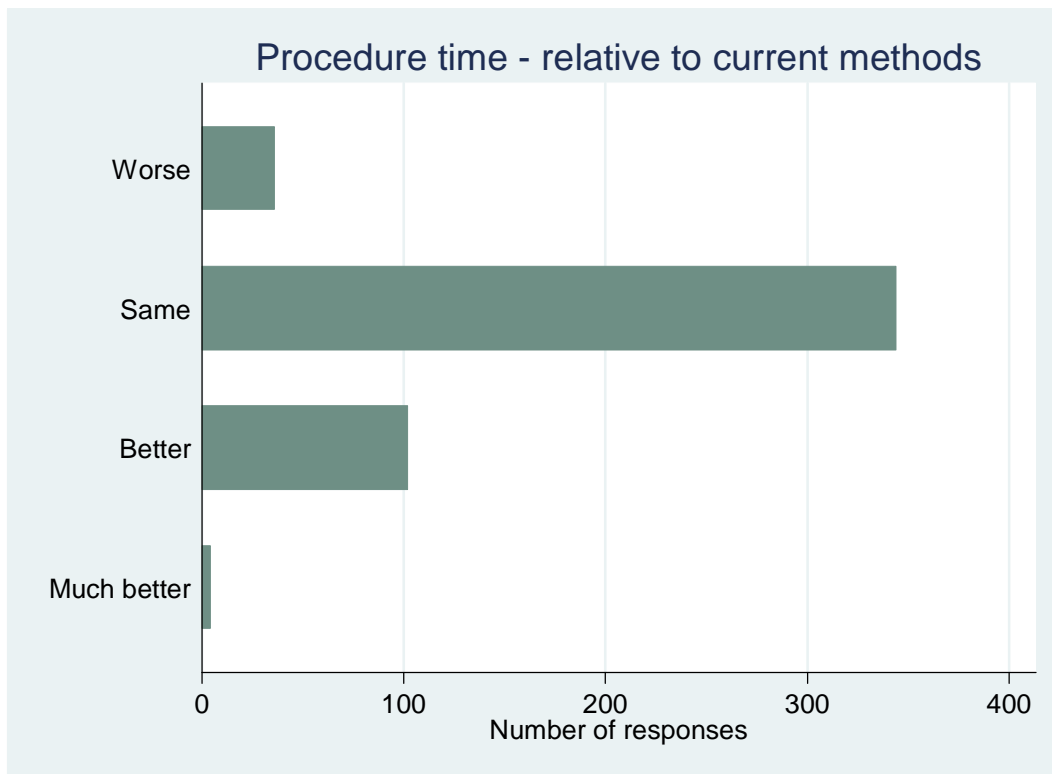


Figure 6: A bar chart indicating whether users considered that MedMat achieves an aseptic approach to the procedure relative to existing methods

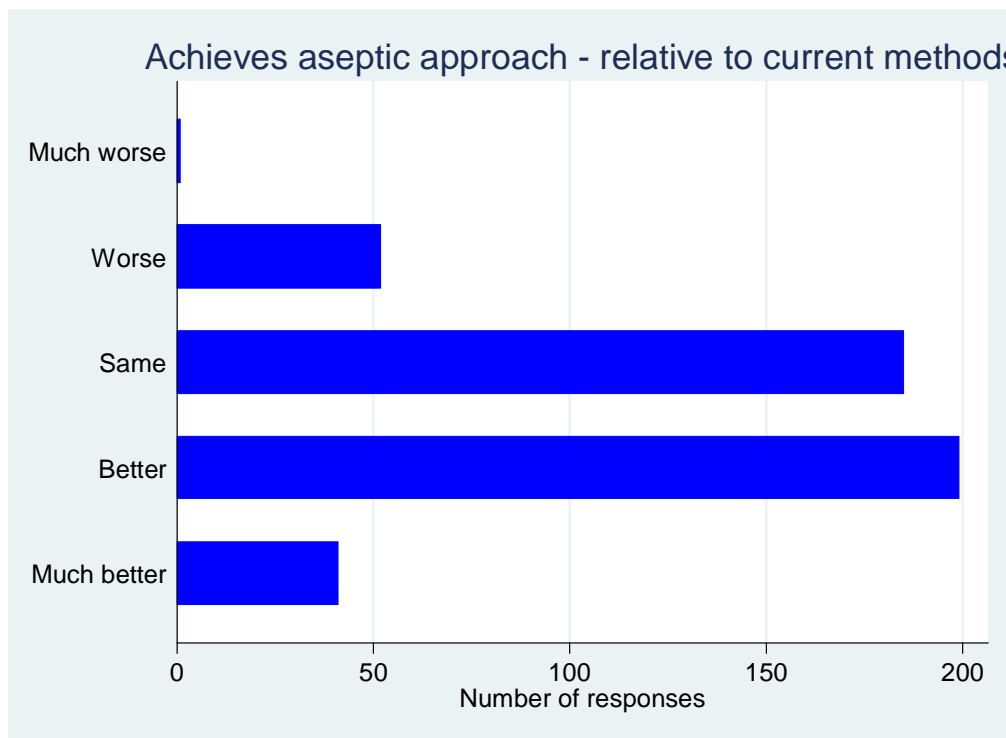
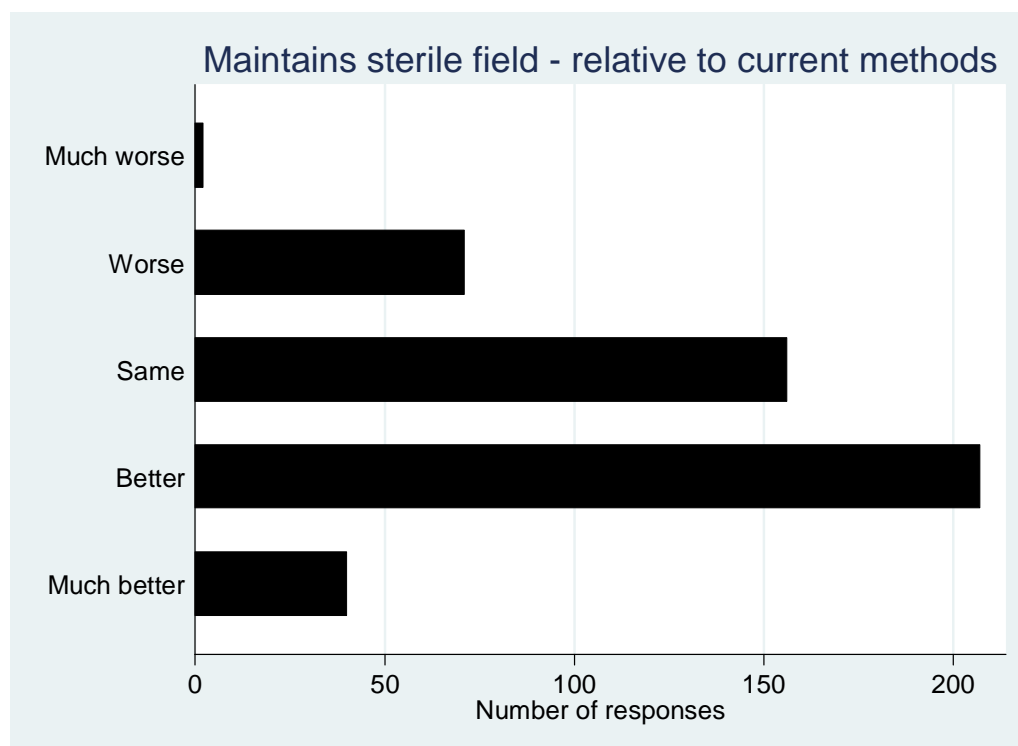


Figure 7: A bar chart indicating whether users considered that MedMat maintains a sterile field relative to existing methods



iii) Analysis of the effect of other factors on users perceptions of MedMat

This analysis examines if the users responses were dependant on other factors such as the size of the MedMat used or the medical procedure.

The difference between the two MedMat sizes was examined using the Mann-Whitney test. A summary of the responses is given in Table 3. This gives the number and percentage of responses in each group for each of the two MedMat sizes.

Table 3: Analysis of results by MedMat size

Variable	Category	MM 700 Number (%)	MM 1100 Number (%)	P-value
Absorbs fluids	Worse	5 (2%)	0 (0%)	0.11
	Same	78 (33%)	11 (22%)	
	Better	122 (53%)	34 (67%)	

Procedure time	Much better	28 (12%)	6 (12%)	0.36
	Worse	29 (7%)	6 (8%)	
	Same	289 (70%)	53 (74%)	
	Better	89 (22%)	13 (18%)	
	Much better	4 (1%)	0 (0%)	
Achieves aseptic approach	Worse	45 (11%)	7 (10%)	0.01
	Same	145 (36%)	39 (54%)	
	Better	174 (43%)	25 (35%)	
	Much better	40 (10%)	1 (1%)	
Maintains sterile field	Much worse	1 (0.3%)	0 (0%)	0.02
	Worse	57 (14%)	14 (19%)	
	Same	127 (32%)	29 (40%)	
	Better	179 (44%)	27 (38%)	
	Much better	38 (9%)	2 (3%)	

Note: Compared to the numbers in Table 2, 3 additional observations are omitted from all analyses, as MedMat size wasn't recorded

These results suggest that there is no significant difference between MedMat sizes in terms of either the ability to absorb fluids or procedure time.

However, there are differences in both the ability to achieve an aseptic approach and maintaining a sterile field. The MedMat 700 was more likely to be better than existing methods, with 53% indicating this was better compared to only 36% of responses for the MedMat 1100. The MedMat 700 was also more likely to maintain a sterile field, with 53% of procedures rated as better than existing methods, compared to only 41% of procedures for the MedMat 1100.

The Kruskal-Wallis was used to compare the responses between the types of procedure. As there were few responses in the urinary catheterisation category, this was combined with the 'other' category for the purposes of analysis. The results are summarised in table 4.

Table 4: Analysis of results by procedure type

Variable	Category	Small Wound	Large Wound	Other	P-value

		N (%)	N (%)	N (%)	
Absorbs fluids	Worse	2 (1%)	3 (3%)	0 (0%)	0.007
	Same	67 (38%)	15 (17%)	5 (29%)	
	Better	96 (54%)	50 (58%)	9 (53%)	
	Much better	13 (7%)	18 (21%)	3 (18%)	
Procedure time	Worse	24 (8%)	10 (9%)	2 (4%)	0.23
	Same	211 (68%)	84 (75%)	40 (75%)	
	Better	74 (24%)	17 (15%)	10 (19%)	
	Much better	2 (1%)	1 (1%)	1 (2%)	
Achieves aseptic approach	Much worse	1 (0.3%)	0 (0%)	0 (0%)	0.28
	Worse	31 (10%)	13 (11%)	8 (15%)	
	Same	118 (38%)	50 (46%)	12 (23%)	
	Better	132 (43%)	36 (33%)	26 (50%)	
	Much better	25 (8%)	10 (9%)	6 (12%)	
Maintains sterile field	Much worse	1 (0.3%)	0 (0%)	1 (2%)	0.08
	Worse	40 (13%)	24 (22%)	7 (13%)	
	Same	101 (33%)	38 (35%)	13 (24%)	
	Better	140 (46%)	38 (35%)	24 (45%)	
	Much better	23 (8%)	9 (8%)	8 (15%)	

Note: Compared to the numbers in Table 2, 11 additional observations omitted from all analyses, as procedure type wasn't recorded

These results suggest that the user's perception of the ability of the MedMat to absorb fluids varies significantly between the procedure types. The results show that when comparing the fluid absorption ability of the MedMat with existing methods, the MedMat was more likely be rated better than existing methods for large wound procedures (79%) than for small wound procedures (61%).

There was no evidence of a difference between procedure types for the three other variables.

The Kruskal-Wallis test was also used to compare the responses between different amounts of fluid used. These results are displayed in Table 5.

Table 5: Analysis of results by amount of fluid involved in the procedure

Variable	Category	Amount of fluid involved in the procedure			P-value
		No fluid N (%)	Small volume N (%)	Mod/Large volume N (%)	
Absorbs fluids	Worse	0 (1%)	2 (1%)	3 (8%)	<0.001
	Same	18 (82%)	62 (28%)	4 (10%)	
	Better	4 (18%)	130 (59%)	23 (59%)	
	Much better	0 (0%)	25 (11%)	9 (23%)	
Procedure time	Worse	18 (10%)	16 (7%)	1 (2%)	<0.001
	Same	147 (78%)	144 (60%)	37 (93%)	
	Better	23 (12%)	78 (33%)	1 (2%)	
	Much better	1 (0.5%)	2 (1%)	1 (2%)	
Achieves aseptic approach	Much worse	0 (0%)	1 (0.4%)	0 (0%)	<0.001
	Worse	19 (10%)	26 (11%)	4 (10%)	
	Same	96 (51%)	62 (26%)	18 (46%)	
	Better	64 (34%)	118 (50%)	15 (38%)	
	Much better	8 (4%)	29 (12%)	2 (5%)	
Maintains sterile field	Much worse	0 (0%)	2 (1%)	0 (0%)	<0.001
	Worse	33 (18%)	27 (11%)	10 (26%)	
	Same	78 (42%)	57 (24%)	12 (31%)	
	Better	65 (35%)	124 (53%)	15 (38%)	
	Much better	10 (5%)	26 (11%)	2 (5%)	

Note: Compared to the numbers in Table 2, 11 additional observations omitted from all analyses, as the amount of fluid wasn't recorded

This analysis shows that the responses varied by the amount of fluid used during the procedure for all four of the outcomes.

When considering the ability of the MedMat to absorb fluids, the results indicate that MedMat was more likely to be considered better than existing methods when fluid was present, and particularly when there was a large volume of fluid. When no fluid was present, MedMat was considered to be better than existing methods for 18% of

procedures, compared to 70% of procedures when there was a small amount of fluid, and 82% of procedures when there was a large volume of fluid.

For the three remaining outcomes, the user's perception of MedMat were most positive when a small volume of fluid was used during the procedure. For example, MedMat was more likely to maintain a sterile field than existing methods for 64% of procedures where there was a small amount of fluid, compared to 40% of procedures with no fluid, and 43% of procedures with a large volume of fluid.

b) Part 2 – Analysis of the data collected from the user feedback forms that were completed at the end of the MedMat trial

The second set of data was collected from each MedMat user at the end of the evaluation period.

A summary of where the procedures took place and the number of procedures evaluated are summarised in Table 6.

Table 6: Summary of data collected at the end of the MedMat trial.

Variable	Category	Number	Percentage
Where procedures take place?	Treatment room	4	13%
	Podiatry clinic	3	10%
	Wound care clinic	0	0%
	Patients home	11	37%
	Prison treatment room	1	3%
	Walk in centre	0	0%
	Other	11	37%
Number MedMat 700 evaluated	Less than 10	8	28%
	10 - 50	12	41%
	50 - 100	8	26%
	More than 100	1	3%
Number MedMat 700 evaluated	Less than 10	10	53%
	10 - 50	8	42%

	50 - 100	1	5%
	More than 100	0	0%

Note: The total number of observations is 30. Due to missing values, the total number of responses for each variable may be less than this figure.

The Wilcoxon signed-rank test was used to examine whether the performance of MedMat was significantly different to existing methods. The results are summarised in Table 7. The results presented are the number and percentage of responses in each category, the mean and standard deviation score, and also the p-values indicating the significance of the results.

Table 7: Performance of MedMat relative to existing methods.

Variable	Category	Score	Number (%)	Mean (SD)	P-value
Fit for purpose	Strongly disagree	1	0 (0%)	3.8 (0.8)	<0.001
	Disagree	2	3 (10%)		
	Same	3	5 (17%)		
	Agree	4	18 (60%)		
	Strongly agree	5	4 (13%)		
Simple to use	Strongly disagree	1	0 (0%)	3.9 (0.8)	<0.001
	Disagree	2	2 (7%)		
	Same	3	6 (20%)		
	Agree	4	16 (53%)		
	Strongly agree	5	6 (20%)		
Encourages good practice	Strongly disagree	1	1 (3%)	3.6 (1.0)	0.002
	Disagree	2	3 (10%)		
	Same	3	6 (21%)		
	Agree	4	15 (52%)		
	Strongly agree	5	4 (13%)		
Improves overall performance	Strongly disagree	1	0 (0%)	3.4 (0.7)	0.007
	Disagree	2	2 (7%)		
	Same	3	16 (53%)		
	Agree	4	11 (37%)		
	Strongly agree	5	1 (3%)		
Useful product to help prevent HCAIs	Strongly disagree	1	0 (0%)	3.5 (0.7)	<0.001
	Disagree	2	1 (3%)		
	Same	3	15 (50%)		
	Agree	4	12 (40%)		

Improves standard of asepsis	Strongly agree	5	2 (7%)	3.6 (0.9)	0.003
	Strongly disagree	1	0 (0%)		
	Disagree	2	3 (10%)		
	Same	3	12 (40%)		
	Agree	4	10 (33%)		
	Strongly agree	5	5 (17%)		
Maintains sterile field	Strongly disagree	1	0 (0%)	3.5 (0.9)	0.004
	Disagree	2	2 (7%)		
	Same	3	15 (50%)		
	Agree	4	8 (27%)		
	Strongly agree	5	5 (17%)		
Isolates material waste	Strongly disagree	1	1 (3%)	3.7 (1.0)	0.002
	Disagree	2	3 (10%)		
	Same	3	5 (17%)		
	Agree	4	15 (52%)		
	Strongly agree	5	5 (17%)		
Able to absorb fluids	Strongly disagree	1	0 (0%)	4.0 (0.8)	<0.001
	Disagree	2	1 (4%)		
	Same	3	4 (15%)		
	Agree	4	15 (56%)		
	Strongly agree	5	7 (26%)		
Reduces procedure time	Strongly disagree	1	3 (10%)	2.5 (0.7)	0.001
	Disagree	2	10 (34%)		
	Same	3	15 (52%)		
	Agree	4	1 (3%)		
	Strongly agree	5	0 (0%)		
Continue using	Strongly	1	2 (7%)	3.1 (1.0)	0.41

MedMat	disagree				
	Disagree	2	5 (18%)		
	Same	3	10 (36%)		
	Agree	4	9 (32%)		
	Strongly agree	5	2 (7%)		

Note: The total number of observations is 30. Due to missing values, the total number of responses for each variable may be less than this figure.

When compared with existing materials, products and procedures, the results indicate that the user's perceptions of MedMat were significantly different to existing methods for almost all the variables examined.

The results indicate that the respondents considered MedMat was preferable to existing methods for the following variables:

- fit for purpose
- simple to use
- encourages good practice
- improves overall performance
- useful product to help prevent HCAs
- improves standard of asepsis
- maintains sterile field
- isolates waste material
- able to absorb fluids.

MedMat was particularly preferred for being able to absorb fluids, where 82% of respondents indicated that MedMat had the better performance. This result is shown graphically in Figure 8. Being simple to use and fit for purpose were two parameters where MedMat also scored highly, with 73% of respondents agreeing that MedMat was better on each of these two measures. These results are shown in the form of bar charts in Figures 9 and 10.

Figure 8: Is MedMat more able to absorb fluids relative to existing methods

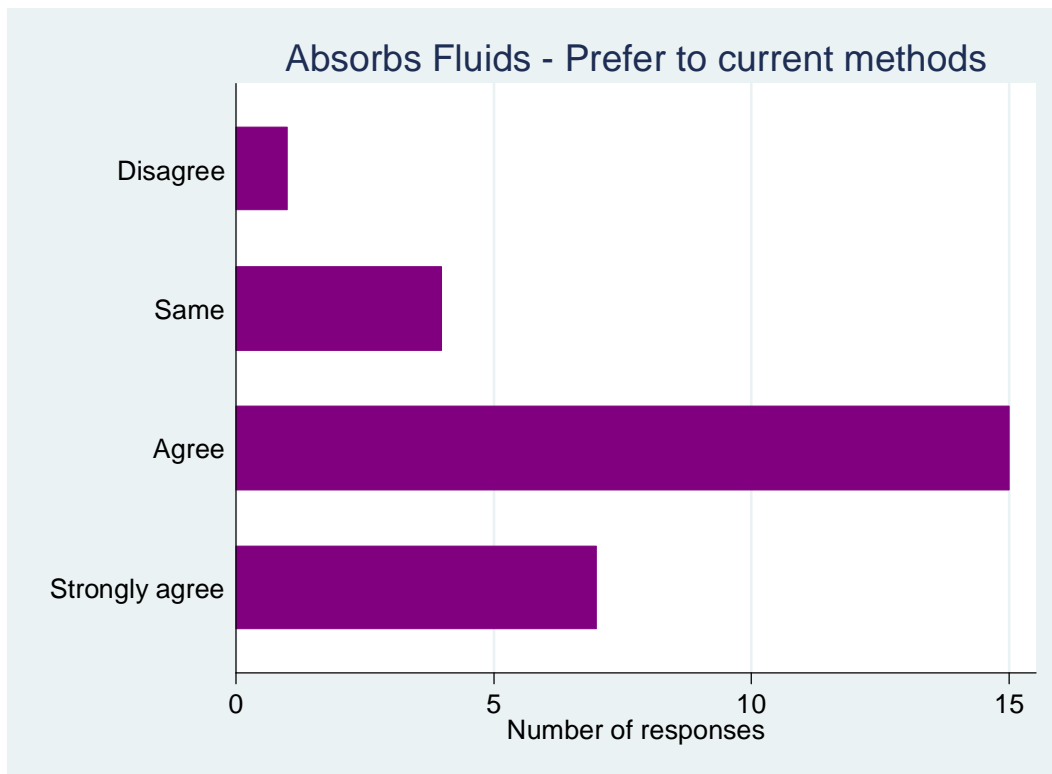


Figure 9: Is MedMat simpler to use than existing methods

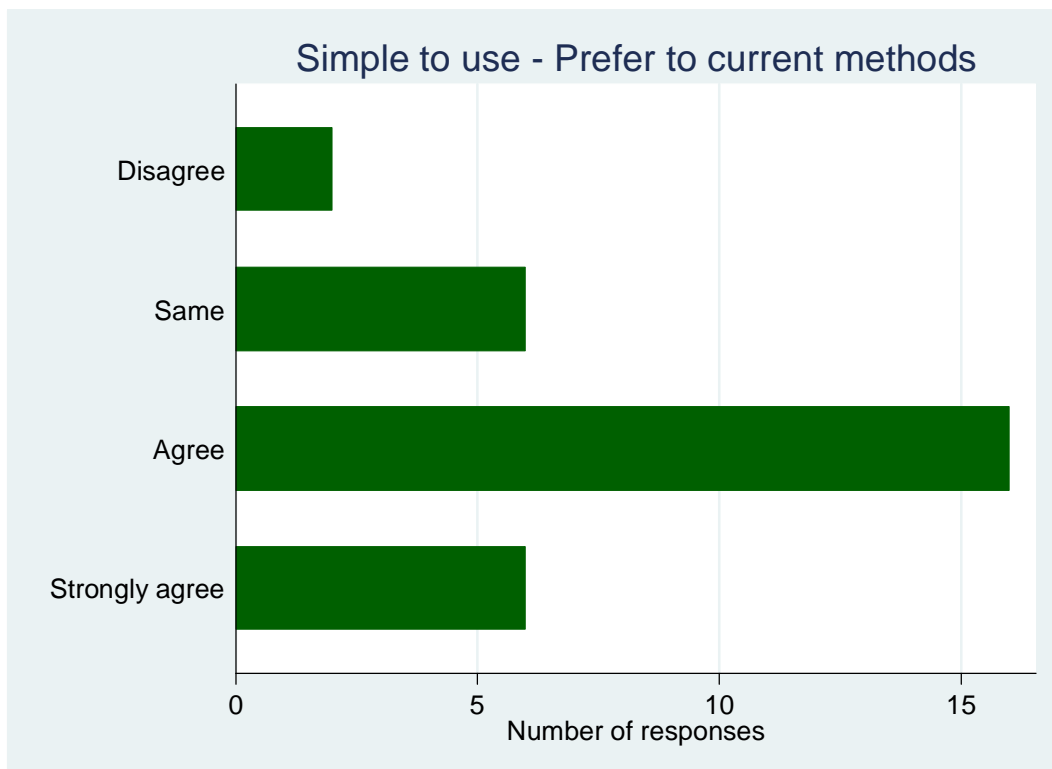
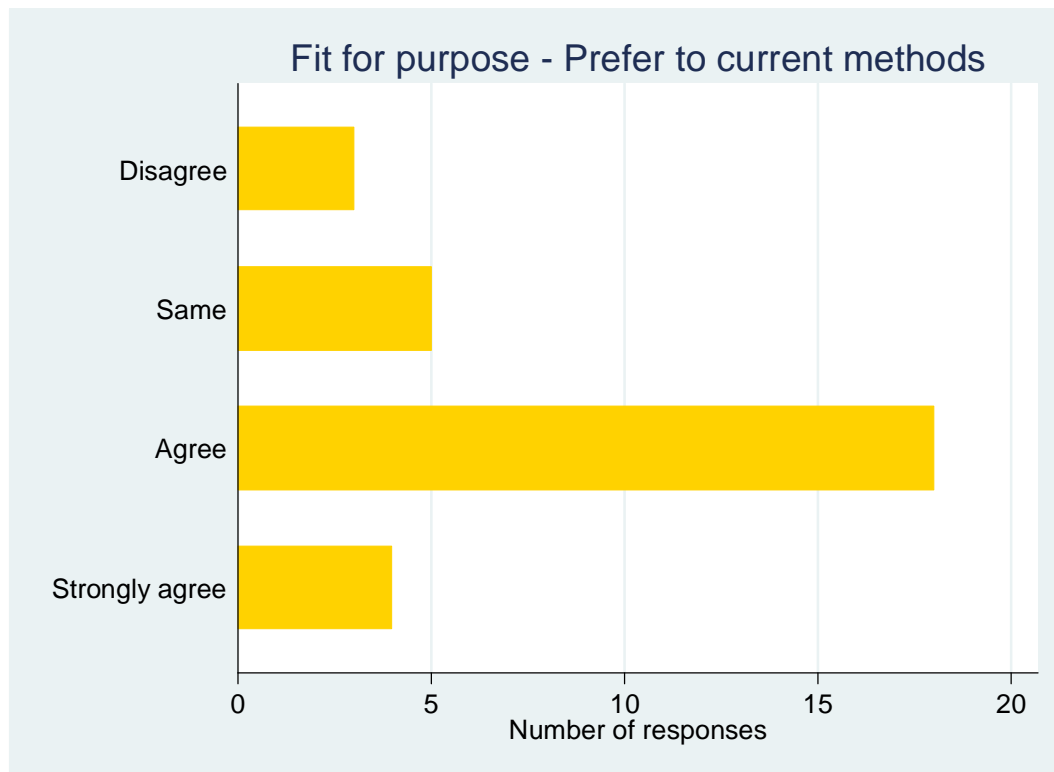


Figure 10: Is MedMat more fit for purpose than existing methods



There was also a statistically significant result for reducing procedure time. However, for this measure, respondents considered that MedMat performed worse than current methods. Overall, 44% of respondents disagreed that MedMat reduced procedure times, with 52% indicating procedure times were the same as current methods. This result is illustrated in Figure 11.

There was no significant difference with current methods in terms of the continuing use of MedMat. In other words, there was no suggestion that respondents were any more or less likely to use MedMat in the future compared to existing methods.

Figure 11: Does MedMat reduce procedure times compared to existing methods

