Toul 400-2 Mobile Laminar Airflow Unit

1. Executive Summary

This Clinical Innovations Report summarises the background to this new technology, the process for the extended trial at 8 BHL sites and the learning outcomes for the Network.

Based on the data submitted from the 8 trial hospitals, it is evident that the Toul Meditech Mobile Laminar Airflow Unit (MLAF) is a viable alternative to a traditional ceiling mounted system.
The introduction of innovative medical technology will always provoke a debate. The four month trial of these units within BHL has enabled Orthopaedic Consultant users within the Network to use and comment on this new product. Any issues arising as result of this trial have been addressed by the BHL Support Team for this product. The team comprises of:

Jan Clement	Head of Clinical Services – BHL
Gavin Hookway	National Head of Theatre Services / Theatre Manager - BHL Portsmouth
Matt Calver	Nurse Consultant Clinical Governance
Mark Barnes	Theatre Manager – BHL Southampton
Jonathan Tucker	National Estates Manager - BHL
Dr David Tompkins	National Microbiology Advisor - BHL
Tony Coleman	Product Specialist , Maquet UK Ltd

Maquet have the rights to distribute this unit in the United Kingdom and have offered BHL an exclusivity agreement until the end of 2005. In working with Maquet as First Market Movers for this innovative product, BHL has been offered a distinct advantage over our competitors.

As part of the current wave of GSupp2 work awarded to BHL, TransMedica have agreed via their Medical Director, Dr Henrik Jacobsen that they will perform all joint surgery using the Toul MLAF device.

The MLAF unit offers the option to BHL to increase the utilisation and productivity of theatre suites by removing the limitation on orthopaedics being conducted in single speciality use theatres and also enables a wider range of surgery to be performed in ACAD and, potentially, some Endoscopy units. Furthermore, the MLAF enables a cost-effective extension of the range and volume of BHL Network surgery undertaken in ultra clean air conditions, delivering improvements to customers, both patients and consultants.

It is our recommendation, that following a successful 4-month trial period, the Toul 400-2 Mobile Laminar Airflow Unit has demonstrated that it is fit for purpose and offers BHL Network a distinct advantage over our competitors.

We, therefore, recommend investment in the purchase of additional MLAF for BHL Network.

Jan Clement
Head of Clinical Services
BUPA Hospitals

June 2005

Gavin Hookway
National Head of Theatre Services
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June 2005

2. Background

Laminar flow (Ultra Clean Ventilation–UCV) theatres are considered the industry standard for operations involving implantation of implants / prosthesis, for example joint replacements and spinal surgery.

MLAF units are a new product for the UK market. They are manufactured by a Swedish company Toul Meditech and marketed in the UK by Maquet. They have been used since 2001 in Scandinavian countries. Sales have recently grown in Italy, France and Spain. They can be used immediately following delivery and installation (subject to a commissioning phase). The units can be flexibly used in different locations within a hospital, and potentially between hospitals within the Network.

The need for orthopaedic operations involving implants / prosthesis to be undertaken in ultra clean air theatres is increasingly becoming a regulatory issue. As of April 2005 the Department of Health expected all joint surgery to be performed in ultra clean conditions and this has also been made a condition of bidding for GSupp2. The use of these MLAF units will enable release of this key constraint on the orthopaedic capacity in several hospitals.

Across the BHL Network, 24 of 25 hospitals have at least one ultra clean air theatre, with 41 clean air theatres out of the 83 total. This means that orthopaedic operations, including joint replacements, are regularly being performed in non UCV theatres, as the Network has gaps in provision of clean air theatres:

- Alexandra does not have clean air provision at all, and have estimated a capital cost of installation for both theatres at over £130k

- Leeds, Edinburgh, Norwich, Wirral, Wellesley, South Bank, Southampton, Tunbridge Wells and Redwood have only a single clean air theatre

Until now the only technological option for provision of ultra clean ventilation conditions in operating theatres has been the installation of ceiling mounted laminar flow systems. These cost between £70k and £100k per theatre, and installation also requires a 3-4 week downtime with the resulting adverse business impact.

Jonathan Tucker has advised that the ceiling mounted systems have an expected lifespan of 10 years, and has identified the need for a rolling replacement programme for the Network because of the 41 units in total:

- 24 are less than 10 years old;
- 3 are between 10 and 15 years old;
- 9 are over 15 years old;
- 5 that are 20 years or older.

Following an initial trial of MLAFs at Southampton in 2004, an expert group led by Jan Clement, involving theatre managers and group purchasing evaluated the equipment in action and recommended the purchase of 8 machines for an extended trial across the Network. The purpose of this extended trial was:

- Examination of the MLAF to ensure that the basic principles of the Hospital Infection Society guidelines on '*Microbiological Commissioning and Monitoring of Operating Theatre Suites*' (1999) were adhered to. As HTM2025 has no provision for the use or testing of Mobile Laminar Airflow Devices, BHL will use the HIS Documentation and advice of Dr David Tompkins to ensure that the testing of these devices is as thorough as would be expected if it were to comply with HTM2025

- Use of the MLAF within BHL Network to test supplier efficacy in practice against manufacturers specifications

- Identification of opportunities for business growth and improved clinical standards via the addition of ultra clean air facilities across the Network through use of this technology

3.1 Placement of Units

Eight Toul 400-2 MLAF units were delivered to BHL in February 2005, following a launch of the device at a Theatre Managers Conference (BUPA House – 8 February 2005). After careful consideration, the units were delivered to the following sites:

BUPA Alexandra	BUPA South Bank
BUPA Leeds	BUPA Southampton
BUPA Norwich	BUPA Washington
BUPA Portsmouth	BUPA Wirral

Each of these Hospitals was issued with setup / training guides from the manufacturer and BUPA Hospitals D&D team. A support team of 'super users' was identified to assist the Hospitals in the successful introduction of these units.

3.2 Air Sampling

Dr David Tompkins (National Microbiology Advisor, BHL) was engaged to advise on the process for air sampling these devices during the initial commissioning stage. This part of the process was critical, as currently HTM2025 (Ventilation in Healthcare Premises, 1994) does not mention the use / testing of Mobile Laminar Airflow units, focusing purely on Fixed UCV. At this stage of the process, a delay was experienced as the method of testing was deliberated. Originally, it had been agreed that the use of Agar 'Settle' plates would be an appropriate method of sampling, but after consideration it was decided that air sampling should be set at the same standard required for UCV Theatres (HTM2025).

In the initial commissioning period, 3 groups of air samples were required to be taken. Air was sampled from within the Ultra Clean airflow (x3) and from the periphery (x1), so that effective comparisons of the air quality could be made. The sample plates were incubated at 'local' Microbiology facilities, read and the results were forwarded to Dr David Tompkins for interpretation.

It was agreed that once the results had been interpreted and ratified by Dr Tompkins, the units could be used within the clinical environment.

3.3 Engineering Considerations

Jonathan Tucker, National Estates Manager, BHL evaluated the Toul MLAF against the requirements of the Hospital Infection Society (1999) and HTM2025 documents. The following points required consideration:

Paragraph 4.104 of the document requires *"...differential pressure transducers to be provided to monitor and alarm on excessive filter pressure drop"*

Paragraph 6.95 states that *" ...UCV systems will additionally require .... Dirty terminal filter indication and alarm".*

The current design of the Toul MLAF unit does not incorporate such a system, relying on an indicator which identifies how many hours the filter has been in use. This system does not indicate the quality / status of the HEPA filter.

After consultation with the Product Support Team, Maquet and Toul Meditech a pressure gauge and visual alarm will be retrospectively fitted to the 8 units currently being used by BHL, ensuring that the requirements listed in the paragraph(s) above, are fulfilled. All further units delivered to BHL will have the pressure gauge and alarm fitted as standard with no additional cost.

3. Clinical Data

Following his analysis of the air sampling results from 7 of the 8 units, Dr Tompkins has commented that

" ...considering all the results from all centres to date, the TOUL system obviously is effective in reducing the bacterial contamination in air to a level equivalent to an ultra clean theatre...."

In total, there have been a reported 171 Orthopaedic cases completed across the trial sites using the Toul unit. The breakdown of these cases is as follows

MAJOR + Cases **Total : 58** **Percentage : 34%**

Procedure	OPCS Code	Hospital Category	Total Cases
Total Knee Replacement	W4210	MAJOR+	18
Back Surgery	V3310	MAJOR+	18
Total Hip Replacement	W3710	MAJOR+	15
Total Shoulder Replacement	W5000	MAJOR+	5
Total Elbow Replacement	W5510	MAJOR+	1
Arthroscopy Hip	W8620	MAJOR+	1

MAJOR Cases **Total : 56** **Percentage : 33%**

Procedure	OPCS Code	Hospital Category	Total Cases
Arthroscopy (Knee)	W8500	MAJOR	26
Foot	W0860	MAJOR	16
ACL / PCL	W7420	MAJOR	5
Lower Limb	T5540	MAJOR	3
Arthroscopy (Ankle)	W8600	MAJOR	2
Sub Acromial Decompression	W8190	MAJOR	2
Arthroscopy Wrist	W8600	MAJOR	1
Pelvic Surgery	W0940	MAJOR	1

INTERMEDIATE Cases **Total : 43** **Percentage : 25%**

Procedure	OPCS Code	Hospital Category	Total Cases
Carpal Tunnel Release	A6510	INTER	28
Upper Limb	T7230	INTER	7
Trauma (rem. Metalwork)	W2830	INTER	7
Exploration Joint	W8150	INTER	1

MINOR Cases **Total : 14** **Percentage : 8%**

Procedure	OPCS Code	Hospital Category	Total Cases
Hand	T4510	MINOR	11
MUA/Arthrogram	X2380	MINOR	2
Injection Joint	W9030	MINOR	1

There have been no reported incidences of infection from these cases as a result of using the MLAF unit.

The new equipment has enabled Consultant Orthopaedic Surgeons to perform many of these cases in facilities other than the designated traditional orthopaedic operating theatre, and to perform joint surgery in theatres that do not have ceiling mounted laminar airflow units.

Therefore, as well as delivering improvements in service quality, the trial has also demonstrated business growth as many of these cases would not have been able to be performed in BHL Hospitals without the increased flexibility and capacity for orthopaedics the MLAF units have created.

4. Learning Outcomes

The following are the learning outcomes from the extended 4 month trial:

- The MLAF has clearly demonstrated that it offers flexible, mobile Ultra Clean Airflow at a fraction of the cost of traditional ceiling mounted devices. Test results have proven that the MLAF reduces the bacterial contamination in the air to a level expected in an Ultra Clean theatre environment. The extended trial has demonstrated that the MLAF unit now meets the requirements of the Hospital Infection Society guidelines, and is considered safe for patient use.

- The HEPA filter on the unit is both delicate and expensive. If the units are to be considered for transportation between Hospital sites, then some form of protective cover is required to protect the filter mechanism. This cover is soon to be available from Toul/Maquet.

- The process of air sampling for the units across 8 sites has demonstrated the need for a standardised Network approach. To comply with the instructions of Dr Tompkins and the requirements of the Hospital Infection Society (and indeed HTM2025) it would be sensible to suggest that an independent company be sub-contracted to undertake the sampling process of the units on a monthly basis. When additional hospitals are likely to receive MLAF units, this would ensure that the testing process is of a standard approach. This is currently being investigated via a company with links to Sheffield University and would provide BHL with an instantly accessible database of sample results / status. This process is at final quotation phase. (Quotation expected w/c 13 June 2005)

- While the units are primarily being considered for Orthopaedic procedures, there has been interest in some Hospitals for the MLAF units to be used for other specialities. Although these procedures have not be performed in UCV environments in the past there would appear to be a demand for all surgery to be performed in 'clean air' environments in the future. Whilst these units do not prevent or eradicate infections such as MRSA, it is considered that the combination of good surgical technique allied with clean air conditions can lead to a reduction surgical site infections.

The British Orthopaedic Association (1999) note that early joint surgery performed in non-laminar airflow theatres, lacking modern day surgical techniques and precautions had an infection rate approaching 11%. Infection rates in modern theatres fitted with clean air systems can be expected to be less than 1 – 2%. Hughes and Anderson (1999) draw conclusion that there is *"clearly a relationship between the quality of air within the operating theatre and the degree of sepsis encountered".*

This may have potential for the BHL customer proposition, for example in Cosmetic Surgery. Further work to now assess this potential is recommended.

5. Conclusion

To enhance BHLs existing facilities in this manner would be advantageous for the customer proposition and would offer a unique selling point, enhancing the patient experience and journey.
BHL would clearly have competitor advantage and demonstrate innovation in leading healthcare delivery.

Jan Clement
Head of Clinical Services
June 2005

Gavin Hookway
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June 2005

6. References

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