





Laboratory investigative report to evaluate microbes on theatre caps

July 8 **2021** 

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**Date of Report:** 21st December 2021







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#### 1. Introduction

#### 1.1 About DEMAND Hub

The Data-Enabled Medical Technologies And Devices (DEMAND) Hub project is funded by the European Regional Development Fund as part of the European Structural and Investment Funds Programme 2014-2020 – Priority Axis1: Promoting Research and Development. The project is delivered by the University of Birmingham in strategic partnership with University Hospitals Birmingham NHS Foundation Trust. The DEMAND Hub programme will run until June 2023 and will support SME businesses in, or looking to enter, the healthcare market by delivering scientific services and commercial pathway support. In addition, there will be a strong focus on the utility of patient reported outcomes and healthcare data in guiding product design, testing and development, removing barriers for innovative businesses and stratifying product development.

The distinctive offering of the DEMAND Hub is characterised by the creation of new academic-clinical-innovation pathways between our existing Birmingham Health Partners expertise in medical technologies, health data and clinical trials, working with established medical technology companies as well as innovative digital SME companies, to enable them to access the opportunities within the regional medical and healthcare sector so as to facilitate development of new technologies across systems software, devices, algorithms, AI solutions and beyond.

#### 1.2 Company

WarwickMed have designed and created latex-free, customised, reusable "name and role" cloth caps for the NHS in a bid to change from single use, disposable theatre caps. The company claim they boost staff morale and reduce patients' anxiety as they enable everyone to identify the people around them, quickly and easily.







#### 1.3 Hypothesis

Multiple disposable cloth hats are currently presented loosely in an open container that clinical staff pick out by hand. Disposable hats may therefore become microbially contaminated before use.

Personalised re-useable cloth hats could replace disposable hats, thereby reducing waste going to landfill and enabling staff to be identified. The cloth hats may be washed and returned clean directly to the end user.

#### 2. Summary

As part of DEMAND Hub (Data-Enabled Medical technologies ANd Devices Hub), Dr Gillian McNab designed the laboratory investigation based on her extensive experience and interest in the development of the translation of ideas, technologies and pharmaceutical products to the clinic as effectively as impossible. The experiments were led by a Senior Scientist in the Healthcare Technologies Institute and the School of Biochemical Engineering laboratories at the University of Birmingham, who has led a team of technicians for more than 7 years at a leading UK Pharmaceutical and Fast-Moving Consumer Goods (FMCG) manufacturer. In addition, Dr Ts'ong Sui facilitated with the experiments. Dr Sui is a Research Fellow in DEMAND Hub and this research was based on his extensive academic and industrial research experience and interest in technologies and biomedical products. The team specialised in microbiological tests to examine if there was a difference in the number of contaminants of unused and worn paper disposables theatre hats compared to unused and washed cloth hats. In addition, the microbes were sent off for identification to get an idea of the range of species on the hats.

As part of the laboratory investigations, DEMAND Hub provided a package for WarwickMedical Ltd in the form of this written report, comprising the microbial testing of the theatre hats, the methods used, results and discussion of the tests, as well as recommendations for future work.







#### 3. Samples

One anaesthetist and two theatre nurses were given six fabric hats each: -

- 3 black hats that were made from normal Alba 2 fabric
- 3 blue hats were made from treated *antimicrobial* fabric

The anaesthetist was given bandana style cloth hats to wear, as was their preference, and the two nurses medium elastic back hats. In addition, the subjects were given a disposable hat to wear for one day during surgery.

At the end of their time in theatre, the worn hats were either: -

- placed inside plastic pockets and the hours spent in theatre with each hat recorded on each
  bag plus the type of surgery taking place
- or 2 of the 3 cloth hats were washed at the subject's home, in a wash bag as they normally would, at either 30 °C or 60 °C.

Therefore, each subject was given: -

- Clear pocket for 1 used disposable hat
- Clear pocket for 1 used and UNWASHED fabric **black** hat
- Clear pocket for 1 used and WASHED at 30°C fabric **black** hat
- Clear pocket for 1 used and WASHED at 60°C fabric **black** hat
- Clear pocket for 1 used and UNWASHED fabric **blue** hat
- Clear pocket for 1 used and WASHED at 30°C fabric **blue** hat
- Clear pocket for 1 used and WASHED at 60°C fabric **blue** hat

Total = worn 18 fabric hats and 3 worn disposable hats

Additionally, as controls for the laboratory tests, the anaesthetist sent 3 unworn disposable hats taken from a half full box dispenser in a clinical setting, the company sent 3 unused cloth hats and 3 unused disposable mob caps were taken from laboratory cleanroom stock.







#### 4. Method and materials

Each hat was sampled by applying a 55mm diameter TSA contact plate (Oxoid, Part Number PO0678D) onto the central surface of the opened hat. Contact plates were incubated for 7 days at 30°C after which the colonies were counted.

Selected colonies were isolated and sub-cultured onto individual Tryptone soya agar (Oxoid, Part number PO0821D or agar prepared by HTI laboratory from TSA powder (Oxoid, CM0131) for further analysis. These isolated colonies were sent away to an independent laboratory for Gram stain analysis (Helvic/Tentamus).

#### 5. Results

Subject 1 – scrub nurse, Subject 2 – anaesthetist, Subject 3 – scrub nurse

Table 1: Hours each subject spent in theatre, with the type of surgery taking place and the time hats spent in wash

	Subject 1			Subject 2			Subject 3		
	Time	Type of	Detergent	Time	Type of	Detergent	Time	Type of	Detergent
	worn	surgery	used	worn	surgery	used	worn	surgery	used
	(h)			(h)			(h)		
worn disposable								A&E,	
hats	10	Urology	n/a	12	General	n/a	10.5	Vascular	n/a
worn unwashed		Breast,			Upper				
black cloth hats		Bronchoscopy			GI,				
	10	list	n/a	13	Urology	n/a	10	Breast	n/a
worn black cloth									
hats washed at		Urology,	Persil: 30			Persil: 60			Persil: 30
30°C	10	breast	min wash	12	General	min wash	10	Breast	min wash
worn black cloth									
hats washed at			Persil: 59			Persil: 60		Upper	Persil: 59
60°C	12.5	Urology	min wash	9	Dental	min wash	12.5	GI	min wash
worn unwashed		Vascular and						Breast,	
blue cloth hats	12	A&E	n/a	12	Vascular	n/a	12.5	General	n/a
worn blue cloth								Upper	
hats washed at			Persil: 59		Upper	Persil: 60		GI,	Persil: 59
30°C	12.5	Urology	min wash	14	GI	min wash	12.5	Vascular	min wash
worn blue cloth									
hats washed at			Persil: 59			Persil: 60			Persil: 59
60°C blue	10	Breast	min wash	10	Urology	min wash	10	A&E	min wash







Table 2: Summary of all microbes found on disposable and cloth theatre hats from the subjects (n=3)

	Average colony count per sample	Number of	
	(range)	samples	Types of species
			Positive cocci, Negative rod
unworn mob hats from clean room	1 (0-2)	3	and mould
unworn cloth hats	1 (0-2)	3	Positive cocci and Positive rod
unworn disposable hats	19 (1-49)	3	Positive cocci
			Positive cocci, positive rods
worn disposable hats	40 (2-108)	3	and yeast
			Positive cocci, positive rods
worn unwashed black cloth hats	7 (5-9)	3	and yeast
worn black cloth hats washed at			Positive cocci, positive rods
30°C	35 (4-90)	3	and yeast
worn black cloth hats washed at			Positive cocci, positive rods
60°C	29 (6-71)	3	and yeast
			Positive cocci, positive rods
worn unwashed blue cloth hats	36 (1-94)	3	and yeast
worn blue cloth hats washed at			Positive cocci, positive rods
30°C	75 (46-90)	3	and yeast
worn blue cloth hats washed at			Positive cocci, positive rods
60°C blue	14 (7-26)	3	and yeast

Figure 1: Overall results from the subjects showing the average microbial colony counts from the hats tested

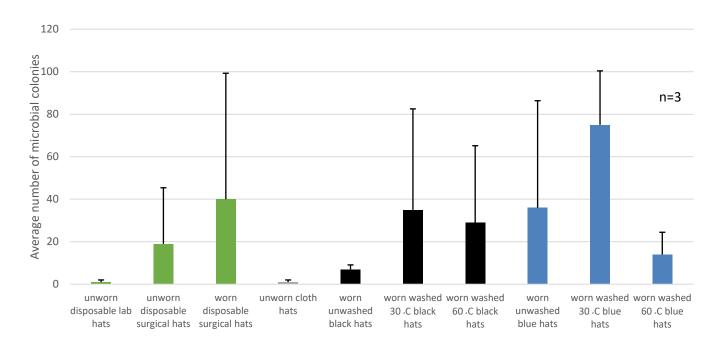




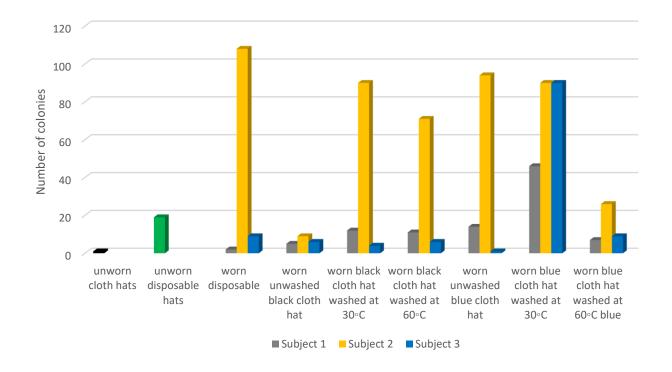




Table 3: Colony counts on the unused and worn disposable and cloth hats from each subject

	Av. Colony counts	Colony Counts		
	n=3	Subject 1	Subject 2	Subject 3
unworn cloth hats	1 (0-2)			
unworn disposable hats	19 (1-49)			
worn disposable		2	108	9
worn unwashed black cloth hat		5	9	6
worn black cloth hat washed at 30°C		12	>90	4
worn black cloth hat washed at 60°C		11	71	6
worn unwashed blue cloth hat		14	94	1
worn blue cloth hat washed at 30°C		46	>90	>90
worn blue cloth hat washed at 60°C blue		7	26	9

Figure 2: Individual colony counts from each subject on the disposable and cloth hats









#### 6. Discussion

As seen in Table 1, each of the hats were worn in various types of surgery for an average 11 hours (range 9-14h). Two of the three subjects (the scrub nurses) washed their black hats for 30 mins at 30°C but this did not an increase in the number of colonies detected. All the other washes were performed at either 30°C or 60°C for about 60 mins using Persil as the detergent.

Of the three unworn disposable hats taken in clinic from the centre of a used box, only a single hat was found to be heavily contaminated with Gram positive cocci bacteria (49 colonies) as shown in Table 2. The type of bacteria found on this hat was consistent with being handled, as Gram positive cocci are typically found in large numbers on the surface of the skin (i.e. hands).

Relatively few colonies were found on the unworn cloth hats (on average 1 colony per hat, n=3) or the mob hats taken from the HTI cleanroom (1 colony per hat, n=3). The type of species found on the unworn cloth hats included Gram positive cocci and also Gram positive rods (Table 2). Gram positive rods are found widely in the general environment.

The HTI cleanroom mob hats were included as an additional control for disposable hats. The mob hats were taken from an open bag that had been dipped into by multiple users; however, in this case, the users must always sanitise their hands before picking up a hat.

After use, both the cloth hats and disposable surgical hats were found to be contaminated with a range of Gram positive cocci, Gram positive rods and yeast (Table 2). The amount of contamination (colony forming units - cfu/plate) found per sample was on average slightly greater on the disposable hats compared to the unwashed black or unwashed blue cloth hats (Figure 1). However, this may have been due to the very high counts for the disposable hat worn by subject 2 (the anaesthetist) as seen in Table 3 and Figure 2.

It should be noted that there was a huge variation in the number of colonies counted between the subjects. The hats worn by Subject 2 (the anaesthetist) had the highest colony counts on the worn disposable and both worn black and blue cloth hats. This may be due to the more hands on and "up close to the patient work" the anaesthetist performed in theatres compared to the scrub nurses.







Of the hats worn, subjects 2 and 3 had less microbial contamination on either of their worn unwashed black or blue cloth hats when compared to the worn disposable hats, as seen in Table 3 and Figure 2.

However, washing the cloth hats at 30°C was found to generally increase the average number of viable colonies found on the both the black and blue cloth hats compared to the worn, unwashed cloth hats in Figure 1 and the washing time (30 or 60 mins. wash at 30°C) did not affect the amount of contamination (Table 1).

Washing the cloth hats at 60°C rather than 30°C did reduce the average levels of microbial contamination for the used blue hats when compared to the unwashed used blue hats (Figure 1), more specifically so in subjects 1 and 2 (Figure 2), but this higher temperature wash did not return the hats to the condition that they had been in prior to use as seen in Figures 1 and 2. Following washing, the used black and blue hats still had a range of Gram positive cocci, Gram positive rods and yeast species but the blue hats had less contaminants than the black cloth hats in subjects 1 and 2 washed at the same temperature and the used blue hats washed at 60°C had similar levels of microbial contamination as the unworn disposable hats (Figure 2).

#### 7. Conclusions

It was confirmed that disposable hats can become contaminated when presented in an open box for users to dip their hands into. It is also possible that, as theses hats are not marketed as sterile, they may also be microbially contaminated on receipt too. The hats in the cleanroom, where users sanitise their hands before taking a hat, also contained a low level of microbial contamination but this was similar to the unworn cloth hats.

Prior to use the cloth hats contained low numbers of Gram positive cocci and Gram positive rods. After use the hats contained, in general, a larger number of Gram positive cocci, Gram positive rods and yeast. There was also a greater range of species found in the worn hats compared to the unworn hats. The range of species found included gram positive bacteria (both rods and cocci) and yeast (only in used and used wash hats so suspect that the yeast had come from one of the subjects). The Gram positive cocci and yeast should be killed with an anti-microbial washing detergent and heat. The Gram positive rods maybe less so as these







species tend to form temperature and disinfectant resistant spores but happily very few of these species are known to be pathogenic.

Washing, even at 60°C, did not reduce the amount of microbial contamination back to their original unworn levels and, in the case of the cloth hats washed at 30°C, even increased the amount of microbial contamination. However, the blue hats that are made from treated antimicrobial fabric and were worn by the three subjects, had similar or lower numbers of microbial colonies to the unworn disposable hats. It might be unrealistic to assume washing the cloth hats at 60°C would reduce the contamination levels back to the original unworn cloth hat numbers. It would be fair to say that subject 2 (the anaesthetist) had more outliers than the other two subjects (although one scrub nurse also had one very high reading). To be fair to subject 2, this happens to everyone sometimes as everyone goes through phases of shedding/moulting. Also, the results for the 30°C wash seem to be pretty high for all subjects (except one very low outlier). More subjects will help to iron out the outliers but as a hospital laundry is was not used to do the washing, focussing on getting the washing cycle fixed should be a priority.

The question needs to be asked as to whether the cloth hats need to be washed with approved antimicrobial detergents or by a professional hospital laundry. Unless using a validated wash cycle, with approved detergents or in a carefully maintained clinical grade washing machine, whilst washing may remove visible stains and odours from items of clothing, it may not actually kill bacteria, yeasts or mould.

A recommendation would be to get more data on whether a 60°C wash with a disinfectant detergent returns the hats to pre-use state maybe using something like the Dettol washing detergent which claims to kill 99.9% bacteria at home to see if the kill can be improved at 60°C in a domestic washing machine. In addition, tumble drying the cloth hats may be beneficial.

Finally, scientific literature has discovered that during mock operations, the bouffant hats and the disposable surgical skullcaps had similar airborne particle counts. However, cloth skullcaps do not exhibit a porous crown compared with their disposable counterparts and they outperformed bouffant hats, showing lower particle counts and significantly lower microbial shedding at the sterile field compared to bouffant hats<sup>1</sup>. It has also been reported that there is no relationship between the type of surgical hat worn and the infection rates in terms of incidence of postoperative wound events<sup>2</sup>.







#### 8. References

- Cloth Caps More Effective Than Disposable Caps at Preventing Contamination in the OR. https://www.infectioncontroltoday.com/view/cloth-caps-more-effective-disposable-caps-preventing-contamination-or.
- 2. Haskins, I. *et al.* Is there an association between surgeon hat type and 30-day wound events following ventral hernia repair? *Hernia* **21**, 495-503 (2017).



