Study showing Copper Infused Pyjamas versus Standard Hospital Textiles

The average stay in a UK hospital is 7 days\(^1\), where the main clothing of the in patient is pyjamas. It has been emphasised that microbial shedding from our body occurs all the time and is greater in patients\(^2\). The moisture and temperature in the textile micro-environment promote its proliferation when a bacterium is shed into a textile fabric between the patient and the bed, either on the pyjamas or directly onto the sheet\(^3\). Pyjamas are the main barrier covering your skin area, where we are most at risk of contracting a HAIs or Nosocomial infections, through broken or compromised skin\(^4\), also well known is that people can contract MRSA from dust containing contaminated skin particles that may be carrying bacteria on it\(^5\). Nosocomial infections can affect any part of the body but 24.3\% of all nosocomial are through the skin or surgical wound site\(^6\) (see Appendix B).

Micro-organisms enter the tissues of the skin and other body tissues, often at the site of compromised skin such as a sore, ulcer or a cut, to cause symptoms such as redness, swelling and/or pus\(^7\). Several studies\(^8\) - \(^{10}\) indicates that people are most at risk of serious infections include:

1. Elderly people (due to dermatological changes)
2. People with wounds or abnormal skin sites
3. Those whom are already ill may have lowered immunity or being immunosuppresed
4. Those that are already carrying *staphylococcus aureus* or MRSA
5. Those that are hospitalised for a length of time
6. Surgery
7. Diabetics
8. Previous anti-biotic use
9. Previous MRSA colonization


\(^7\) Public Health England *What is a health care associated infection.* http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/HCAI/GeneralInformationOnHCAI/ (accessed 17/05/2013)


MRSA exists throughout the community, it is more common in hospitals where people are having medical procedures and are being cared for. Recent research also shows that nasal MRSA carriage in diabetic patients is a significant risk factor for foot ulcer MRSA infection\textsuperscript{10}. MRSA infection occurs when the bacteria enter the body through a wound, or when the bacteria enter the bloodstream\textsuperscript{11}. Cross infections are not always the cause of MRSA, as bacteria can enter the body through a wound or any compromised skin. \textit{S.aureus} is just one of a family of staphylococcal bacteria. Their normal home is on human skin and nose, and some of them, such as \textit{S. epidemidls} are seen as part of the normal commensal flora of the human body\textsuperscript{12}. About 30\% of the general population are colonised by \textit{S. aureus}. A carrier can be a source of infection for themselves (e.g. they can infect themselves if they have a wound), especially those with a compromised immune system, or those on immuno supresses, but they can also infect others when the bacteria are passed on either on someone's hand (normally a healthcare worker's) or on infected equipment\textsuperscript{13}. In about one tenth of these carriers (3\% of the population overall), the \textit{S. aureus} is MRSA. Carriage sites are most commonly the nose and the skin, especially in folds such as axilla (armpit) or groin\textsuperscript{14}.

It is estimated that approximately 70\% of older people in the UK experience skin problems, many of which are preventable\textsuperscript{15}. Age-related changes in the skin mean older people are at increased risk of skin breakdown and should be supported to maintain good skin health\textsuperscript{16}.

Copper complexes and copper fabrics which deliver copper ions are well known to be used in wound healing, and angiogenesis (VEGF) is believed to be the most prevalent. VEGF expression is sensitive to copper ions and that the angiogenic potential of copper may be harnessed to accelerate dermal wound contraction and closure\textsuperscript{17}. As well as rejuvenating skin texture. Copper-sensitive pathways regulate key mediators of wound healing and skin rejuvenating such as angiogenesis and extracellular matrix remodelling. Copper-based therapeutics (copper ions) represents a feasible approach to promote dermal wound healing\textsuperscript{18} (see Appendix D). A sufficient level of copper appears to be required for angiogenesis. Copper availability has played a fundamental role in growth regulation throughout evolution and that is the reason that so many

\textsuperscript{11}MRSA Action UK. http://mrsactionuk.net/babiesandmrsa.html. (accessed 20/05/2013).
\textsuperscript{17}Barralet, J. et al. (2009). \textit{Angiogenesis in Calcium Phosphate Scaffolds by Inorganic Cipper Ion Reese}. 15(7): 1601-9.
angiogenic promoters appear to be dependent upon copper levels. Borkow, et al summarised the importance of copper, stating that:

"Copper is an essential trace element involved in numerous human physiological and metabolic processes. It plays a key role in many of the processes that together comprise of wound healing, including induction of endothelial growth factor, angiogenesis and expression and stabilization of extracellular skin proteins".

Copper as opposed to silver (which has now had its anti-microbial status withdrawn in the USA) is essential for the normal function of many tissues, gene expression and many metabolic processes. This study shows that copper fabrics continuously kill disease causing microbes. It is shown that just 2.3% copper oxide impregnated polypropylene nonwoven fabric and the internal copper contained within the fabric both release Cu++ ions (containing 3% copper oxide plated fibres) of test dressings have, potent antibacterial and anti-fungal properties. The damage to micro-organisms is exerted within a matter of minutes of their exposure to the copper containing fabrics. Although most hospitals provide pyjamas of normal cotton, these are not known to prevent the spread of nosocomial infections, where as copper fabrics have the ability to kill pathogens. Copper fabric should be used as close to the skin as possible for effective, odour control, improved hygiene and promote healthier skin tone and texture.

Bamboo, which is the fastest-growing plant and requires no pesticides, is touted as an environmentally friendly material. Lab results show that bamboo fabrics is more than 9 times more effective at killing bacteria than fabrics treated with chemicals to kill bacteria, even after 50 commercial washings.

The bamboo and copper infused pyjamas should be provided to supplement other hospital protocols and become part of an overall risk management program to control HAIs. Another advantage over the cotton hospital supplied pyjamas or pyjamas brought from home (not known when last laundered) is that the copper ions released by the copper plays an essential role in

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angiogenesis\(^\text{28}\) (the growth of new capillaries). Capillaries are designed to provide maximum nutrient efficiency so as an increase in the number of capillaries allows the micro-circulation network to deliver more nutrients and oxygen in the same amount of time. The greater number of capillaries allows for greater oxygen exchange, feeding the skin and preventing dry cracked skin by the rapid promotion of collagen and elastin, which in turn dramatically helps rehydration of the skin and can aid in the prevention of skin pathologies\(^{29}\). Angiogenesis in turn can help to stop the skin from being further compromised and skin rejuvenating\(^{30}\), reducing the patient’s chance of contracting MRSA through open sores, broken skin or other skin pathologies, especially those in wards for longer periods.\(^{31}\) Another preventive modality would be for those who are going to hospital for elective surgery (especially those who have skin pathologies) could wear these pyjamas as normal at home prior to hospitalisation, this would promote healthier skin tone and texture through (angiogenesis). Copper demonstrates a critical effect in the processes of wound healing, including induction of endothelial growth factor, angiogenesis, antimicrobial potency and expression and stabilization of extracellular matrix\(^{32}\). And would ensure the decolonisation of microbes\(^{33}\). It is also known that the bacteria can delay dermal healing by competing with host cells for already depleted nutrients and oxygen. MRSA may remain as reservoirs on hospital equipments, for example, beds, which is a particular issue where pressure or diabetic ulcers are common. It is important to remember that chronic wounds often develop due to an alteration in blood-flow (micro-circulation) to the infected area, and the use of systemic antibiotics has very little or no affect on the wound site as the reduction of the capillaries that were able to deliver blood are sometimes broken, split or withdrawn, this can prevent access of the antibiotic to the affect area\(^{34}\).

Our copper and bamboo pyjamas that give off copper ions (see Appendix E), have potent anti-fungal and anti-bacterial properties, which will totally destroy micro-organisms and will not allow them to mutate or even enter the VBNC state\(^{35}\). They can also promote angiogenesis, rejuvenated skin and can be produced with an anti-static finish (which will repel dust). As dust and skin cells are known to carry MRSA\(^{36}\).

Most importantly, copper infused fabric costs just a fraction more than cotton fabrics alone.

\(^{28}\)Pan, Q., et al. (2002). *Copper Deficiency Induced by Tetrathiomolydate Suppresses Tumor Growth and Angiogenesis. Cancer Research*, http://cancerres.aacrjournals.org/content/62/17/4854.long (accessed 26/05/2013).


Ladies and Men's Pyjamas

We recommend daily use, as the pyjamas are designed around a breathable fabric that can be worn 24 hours a day. Additionally, the pyjamas should be worn as much as possible both in and out of bed, and close to the skin as possible. When at risk of a nosocomial infection or otherwise as normal in bed.

39.3% copper fibre content and 60.7% bamboo viscose are very coefficient materials which we have bought together and manufactured into male and female bed wear, pyjamas. Humans are very tolerant of copper and it is in many different foods, nearly all vitamin tablets, and is easily metabolised and utilised by the body when absorbed either orally or through tissues\(^37\).

Human skin, in contrast to micro-organisms, is not sensitive to copper and the risk of adverse reactions due to dermal exposure to copper is extremely low. Copper is not only considered safe for humans, as demonstrated by the widespread and prolonged use of copper intrauterine devices (IUDs) by women\(^38\). Additionally, bamboo fibre’s natural anti-bacterial qualities do not cause skin allergy as chemical anti-microbial sometimes can. Besides, copper and bamboo fabrics are known to be safe, copper fabrics have passed standard allergencity and skin irritation test which have been shown to be safe for using fabrics for personal use by the Environment Protection Agency of the USA with registration number 84542-6\(^39\).

The Pyjama fabric has been the subject of 50 commercial wash cycles with no special detergents or bleaching type agents keeping a normal PH level of 6.2 and at a water temperature of only 21 degrees carried out by accredited lab (ATTC 10231).

Copper fabrics in vitro tests showed them to be anti-microbial with significant log reductions with very little or no leaching (see Appendix F: In Vitrol Anti-microbial Certificates).

What is it that is innovative/new?

Copper and its anti microbial properties are neither new nor innovative, nor are infusing acrylic fabric with Nano copper.

What is new is the way the copper, polyester and bamboo (viscose) have been infused and engineered to be a breathable fabric, so comfortable and non clammy. The methodology of manufacture, i.e. the bringing together in one fabric, two coefficient fibres for both a practical and very functional use.

Our fabric is now used on a daily basis by the Chinese military with over 4 million troops having socks, underwear and towels etc. There has NOT been one report of dermal intolerance (both male and female).

Also the Army in the USA has standard issue Cu29 infused socks, being nearly 2 million people. These are issued not only for the anti microbial properties alone, but for the preventative modality of foot skin pathologies or when skin in that area is compromised an infection is far less likely.

NASA journey to international space station has chosen copper infused garments, socks, underwear, T-shirts, towels, bed sheets, etc., not only will this decrease the weight from nearly 1 ton estimated of standard fabrics, down to a fraction of this weight. The study showed that the garments were totally anti-microbial and more comfortable to wear than the previous garments.36

The pyjamas are new and innovative by British design, also what is relatively new is the functionality of anti-microbial, anti-static/ anti-dust and promotes angiogenesis which can enhance wound closure, skin rejuvenation, promotion of collagen and elastin and are anti-odour.

How will this product contribute to reducing hospital acquired infections?

One of the problematic HAIs is MRSA or VRSA which is transmitted by touch but very quickly mutates and becomes resistant to its surroundings\textsuperscript{40}. There is no evidence that microbes would become resistant on copper. Horizontal gene transfer (HGT) is largely responsible for increasing the incidence of antibiotic-resistant infections worldwide. In addition, rapid death of both antibiotic-resistant strains and destruction of plasmid and genomic DNA were observed on copper, which could be useful in the prevention of infection spread and gene transfer\textsuperscript{41}.

The Cu and Bamboo pyjamas will act as a barrier both for the staff handling of the patient, as microbes live on fabric surfaces and there for mutate. These pyjamas will not allow the microbes to survive and completely destroys them, within minutes without chemicals by the exposure to copper ions that penetrate the harmful bacteria/ fungus destroying the DNA\textsuperscript{42}.

The microbes cannot become copper tolerant on the fabric containing copper fibres that produce copper ions\textsuperscript{43}.

For the patients, especially those with compromised immune functionality or those who are immunosuppressed can easily contract a HAI just through their own skin flora\textsuperscript{44}. Those whom are hospitalised for longer period of time would also benefit from the angiogenesis process which plays a central role in wound healing and also accelerate the healing of any dermal skin pathologies and wound contraction and closure\textsuperscript{45} (providing the pyjamas cover the area of skin). Those whom have a breech in the skin (for example, bed sores, ulcers, or dry cracked skin), which may become breached just from swelling, pressure sores, or surgical wound sites are at risk of infection. Skin conditioned with nutrients and oxygenated blood supply from vascular endothelial growth factor (VEGF) newly formed capillaries in their micro-circulation would greatly improve skin texture reducing the chance of the patient contracting a HAI in the first place\textsuperscript{46}.

The fabric contains approx 2.5-3\% copper (Cu++) in 40\% of the fibres and have potent antibacterial, gram- positive and gram negative bacteria and anti-fungal properties. The pyjamas cover 90\% of the body and present a greatly improved modality in the reduction of Skin pathologies (by way of Angiogenesis) giving skin rehydration nutrients and oxygen that is needed for the skins well being. It is well known that copper ions (Cu++) show a pro angiogenic

\begin{itemize}
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action favouring the development of new vessels\textsuperscript{47}, also having a natural ability to destroy microbes in a very short period of time. Patients shed skin cells and bacteria in their pyjamas, the temperature and humidity between the patients and the bed are appropriate conditions allowing for effective bacterial proliferation. We suggest that hospital textiles, especially those that come in contact with the patients, such as patients’ sheets, pillowcases, robes, and pyjamas, are an important source of micro-organisms, that may infect susceptible patients either by endogenous transmission, indirect contact or through airborne transmission (dust) when these fabrics are handled by the hospital staff. The use of pyjamas could reduce prolonged hospitalisation, decrease the use of antibiotics and the very high costs associated with increased periods of hospitalisation\textsuperscript{48}.

**Guidelines or protocols to which this product relates**

At present, the only guidelines for night wear are to have clear markings on the label keep away from fire. We recommend that they are not washed with fabric conditioner. The pyjamas only need to be washed in water 20-25 degrees, no bleach or any substance, likely to be outside standard recognised PH value between 5-8.

**Why is this product more effective in reducing healthcare associated infection than other similar class of products in the market?**

The only comparable product is nano silver fabric, which is not anti-microbial\textsuperscript{49}. It is been observed in studies that silver treated cotton fabric leach and have zones of inhabitation that are least minimum 24mm and maximum 29mm for gram positive bacteria and minimum 14mm and maximum 18mm for gram negative bacteria\textsuperscript{50}. Silver fabric has limited durability and has the potential to cause a variety of other problems when used in garments. As the garments are washed the silver dosage depletes from its original anti-bacterial state reducing efficiency. If too little is left in the garments after washing the bacteria colonisation are not controlled and can mutate, cause rashes and other skin irritation in users\textsuperscript{51}.

Silver does have anti-bacterial function but the copper as opposed to silver is essential for the normal function of many tissues, gene expression and many metabolic processes. Copper unlike silver, is readily metabolised and utilised by the body when absorbed either orally all through tissues, it is found that in many food types and nearly all multi-vitamins. The R.D.A is 2mg daily\textsuperscript{52}.


\textsuperscript{48}Borkow, G. and Gabbay J. (2010). *Preventing Pathogens Proliferation and Reducing Potential Sources of Nosocomial Infections with Biocidal Textiles in Developing Countries*. The Open Biology Journal, 3:81-86.


\textsuperscript{51}European Food Safety Authority (2009). *Scientific Opinion on the Substantiation of Health Claims related to*
Relevant comparator(s)

Cotton pyjamas or other types of fabric manufactured into night wear (that patient may bring from home).

In our studies, in vitro results showed that in the analysis of antimicrobial properties of fabric according to ISO 20743: 2007, what was used as a control was clean laundered cotton NHS hospital gown (standard issue) shows that there is significant log reduction (see the lab results shown in orange highlight with the Doc. No. COA-FMT-S3678-02). (see Appendix G: NHS Gown Fabric Versus Copper)

What is the mechanism of action?

The direct effect of destruction comes from the release of copper ions which degrade the DNA of a cell and inhibit its respiration. The indirect effect is even more rapid. On a dry surface, copper interacts with the bacteria's metabolism to generate very potent free radicals, which are even quicker than copper itself at destroying the DNA and inhibiting respiration\(^53\).

Horizontal gene transfer (HGT) in bacteria is largely responsible for the development of antibiotic-resistance, which has led to an increasing number of difficult-to-treat healthcare-associated infections (HCAIs) – copper prevents this process from occurring and rapidly kills bacteria on contact\(^54\).

Composition of the compound (if applicable) or appropriate information to ensure assessment of risk and safety:

Viscose bamboo 60.7% and copper infused polyester 39.3% the CTTC report No.: BA13000894, dated on 15/05/2013.

Copper is known to be very safe and is in fact the only solid surface material registered as safe and poses no threat to human safety. It has been widely used in water pipes, and copper surfaces have recently been shown to cut down on nosocomial infections in a four year study at 3 major hospitals in the USA. By as much as 58%\(^55\) (see Appendix H: 58% HAIs Reduction USA Trial).

May, I remind you that I.U.D's (Female Coil) are mostly made from copper and have approval to be inserted in the female body for 10 years at a time\(^56\).

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Safety information on use of product:

Copper fabrics have widely been studied in one form or another been used around the world without any known reports of dermal intolerance.

NASA USA, the international space station have spent millions of dollars researching copper infused garments and have given the official approval that the cosmonauts will wear copper infused fabrics whilst on the space station\(^57\). Under the H.R.P. Keep astronauts healthy and functional during deep space, the budget allocated was $ 165 million for 2013.

Also the USA Army of 2 million wear copper socks and the Chinese Army of nearly 4 million are given copper socks, copper pants, and copper towels (all copper infused fabrics).

**In vitro activity of the compound**

A U.K.A.S. Laboratory has carried out AATC147 Standard, anti-microbial on MRSA and Candida. This was carried out 8 times in the UK and twice in a Chinese textile laboratory.

In the UK, we used international standard method EN ISO 20743\(^58\) which would stand up the best to scrutiny as it is an international standard method and the test is performed in triplicate to remove any element of doubt to the inherent biological variability that comes with any microbiological method.

a) Absorption method (an evaluation method in which test bacterial suspension is inoculated directly onto samples);

Samples using method A includes; Laboratory certificate No.:

05042  
05043  
05044  
05228  
05229  
05230

b) Streak method (an evaluation method in which test bacteria are placed on an agar plate and transferred onto samples); Laboratory certificate No.

04543  
04544  
04985  
04986  
04987  
04988

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Please note that test No. 05228-05230 have got cotton control results, which show the significant difference between copper infused fabrics and cotton control (see Appendix G: NHS Gown Fabric Versus Copper)

Published or other evidence of impact, of product/process on health-care associated infections:

The pyjamas would be an asset in the fight against HAIs. There is evidence provided within that MRSA microbes can infect and also cross infect. There is also evidence to suggest that people are more at risk of getting MRSA in a hospital setting. Our pyjamas were engineered to reduce the bio burden on a clinical setting or hospital environment by both a preventative modality healthier rehydrated skin (less likely to get an infection). Also engineered to be anti-static (will not attract dust or skin cells) demonstrated to carry MRSA. The pyjamas cover a vast area of your skin flora which in turn kills any microbes, either on your skin or on the fabric which will in turn reduce cross infection.
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( accessed 24/05/2013).


APPENDIX

Appendix A: A Recent Study of Skin Pathologies
(will open a complimentary document)

Appendix B: Patient MRSA at NHS Croydon

Appendix C: Case Studies Cu Fabric Socks for Diabetic Foot MRSA Risk
(will open a complimentary document)

Appendix D: Compromised Skin at Risk of MRSA

Appendix E: Copper Infused Pyjamas

Appendix F: In Vitrol Anti-microbial Certificates
(will open a complimentary document)

Appendix G: NHS Gown Fabric Versus Copper
(will open a complimentary document)

Appendix H: 58% HAIs Reduction USA Trial
(will open a complimentary document)
Appendix B: Patient MRSA at NHS Croydon
Appendix D: Compromised Skin at Risk of MRSA

**CELLULITIS**
These pictures were taken 23 days apart, wearing Cu++ socks only with no other medical intervention, creams or topicals.

*Before*  
*After*

**FUNGAL INFECTION**
These pictures were taken 15 days apart wearing Cu++ crew neck, long sleeve top. No other medical intervention, creams or topicals.

*Before*  
*After*  
*Before*  
*After*