Institution: Cardiff University		
Unit of Assessment: Allied Health Professions, Dentistry, Nursing and Pharmacy (3)		
Title of case study: A new international standard, and commercial growth for a leading UK manufacturer of antibacterial wipes		
Period when the underpinning research was undertaken: 2006 – 2020		
Details of staff conducting the underpinning research from the submitting unit:		
Name(s): Jean-Yves Maillard	**Role(s) (e.g. job title):** Professor of Pharmaceutical Microbiology	**Period(s) employed by submitting HEI:** 01/10/2004 – present
Period when the claimed impact occurred: 2013 – 2020		
Is this case study continued from a case study submitted in 2014? No		

1. Summary of the impact (indicative maximum 100 words)

Many antimicrobial wipes, used to minimise the spread of bacteria in hospital settings, are ineffective and could inadvertently contribute to the spread of potentially fatal pathogenic bacteria. Cardiff researchers developed a new testing protocol for antimicrobial wipes allowing their efficacy to be accurately evaluated in real-life clinical situations, aligned to improved infection control. The Cardiff protocol for the testing and use of antibacterial wipes was adopted as an American Society for Testing and Materials (ASTM) International Standard and enabled a leading UK wipe manufacturer, GAMA Healthcare, to develop new products, drive sales and develop a new £4M R&D facility. These activities delivered £8M in new revenue for the company since 2013.

2. Underpinning research (indicative maximum 500 words)

According to NHS England, healthcare-associated infections are estimated to cost the NHS approximately £1 billion a year. Antimicrobial wipes are used for the decontamination of surfaces in healthcare settings to minimise the risk of patients acquiring infections, however, little was known about the efficacy of these anti-bacterial products and which were most effective in eliminating microbial pathogens. There was also no evidence to inform how wipes should be used in a clinical setting for effective infection control.

2.1 Investigation into the efficacy of anti-bacterial wipes in Welsh Intensive Care Units

In 2006, the Welsh Government approached Maillard, following his extensive research expertise on antimicrobial biocides and microbial resistance, to investigate the effectiveness of antimicrobial wipes for infection control in Welsh Intensive Care Units.

Prior to Cardiff's research, the evaluation of anti-bacterial wipes was based solely on the efficacy of the chemical biocide, but not when the biocide was incorporated into a wipe. Cardiff researchers assessed a range of factors, including the nature and concentration of the biocide used in the wipe, the wipe material itself, the nature of the surfaces that needed to be decontaminated, the target pathogens, and the way in which the wipe was being physically used by health care and cleaning staff in clinical situations **[3.1, 3.2]**. This research:

- enabled accurate evaluation of antimicrobial wipe performance **[3.1]** and delivered quantitative reporting outcomes including: the percentage of microbial bioburden removed from surfaces; microbial transfer prevented from wipes to surfaces; and the percentage kill of the target microorganisms that were collected within the wipe;
- revealed that the claims provided by wipe manufacturers around antimicrobial efficacy of their wipes were not substantiated by their products **[3.1, 3.2, 3.3, 3.4]**. Maillard explored the ability of the commercially available sporicidal wipes to remove *Clostridioides difficile* spores from an inanimate surface and showed a wide range in efficacy between all wipe products **[3.3]**. One wipe did not remove any spores and none of the wipes demonstrated high sporicidal activity within 5 minutes of contact

time, except for a control wipe soaked in 5,000-ppm sodium hypochlorite. All but one commercial wipe demonstrated that spores could be repeatedly transferred to other surfaces. Light-scattering data provided evidence that some wipes were able to break up spore aggregates, potentially releasing more pathogenic spores onto the surface **[3.3]**;

- demonstrated the superiority of one antimicrobial product in particular, produced by GAMA Healthcare, in removing spores from a surface **[3.3]**;
- highlighted a significant risk of the spread of harmful bacteria associated with both ineffective wipe products and the misuse of antimicrobial wipes **[3.2, 3.3, 3.4]**.

These findings raised significant concern that the wipes themselves, and the methods of using these wipes adopted by healthcare and cleaning staff, could not be relied upon to provide a safe environment within healthcare settings.

2.2 Development of a biocide wipe protocol

The research outlined in Section 2.1 also identified the need for users of the wipes, including nurses, healthcare assistants and cleaning staff, to follow a clear procedure to avoid cross-contamination and the spread of bacteria. Maillard worked with the inventors of a textile testing device called the Wiperator® to inform adaptations of this device so that it could assess the effectiveness of wipes with different biocide formulations and when real-life use conditions were applied (e.g., applied force, rubbing speed and duration of wiping). Previously the Wiperator® could only test the material used in wipe manufacturing but with Cardiff's input, the device has become an innovative tool for robust microbial wipe efficacy testing **[3.5]**. Using this adapted appliance, the Cardiff team developed a new protocol for the testing and clinical use of antimicrobial wipes. They showed that even when a wipe product is proven to be capable of eliminating bacteria, it must be used in a specific way to be effective in minimising the spread of bacteria i.e. one wipe, used on one surface and in one direction, in order to prevent the wipe from spreading bacteria from one surface to another or from one area to another when used on numerous surfaces or in various directions **[3.6]**. This protocol clearly demonstrated which products were effective and how they should be used safely to minimise the spread of potentially fatal pathogenic bacteria.

3. References to the research (indicative maximum of six references)

[3.1] Williams GJ, Denyer SP, Hosein IK, Hill DW and **Maillard J-Y**. (2007) The development of a new three-step protocol to determine the efficacy of disinfectant wipes on surfaces contaminated with Staphylococcus aureus. *Journal of Hospital Infection* 67(4): 329-335. DOI: 10.1016/j.jhin.2007.08.012

[3.2] Williams GJ, Denyer SP, Hosein IK, Hill DW and **Maillard J-Y**. (2009) Limitations of the efficacy of surface disinfection in the healthcare settings. *Infection Control and Hospital Epidemiology*, 30(6); 570-573. DOI: 10.1086/597382

[3.3] Siani H, Cooper CJ and **Maillard J-Y**. (2011) Efficacy of 'sporicidal' wipes against Clostridium difficile. *American Journal of Infection Control*, 39(3), 212-218. DOI: 10.1016/j.ajic.2011.01.006

[3.4] Ramm L, Siani S, Wesgate R, and **Maillard J-Y**. (2015) Pathogen transfer and high variability in pathogen removal by detergent wipes. *Amer J Infec Control*, Jul 1;43(7):724-8. DOI: 10.1016/j.ajic.2015.03.024

[3.5] Sattar SA, Bradley C, Kibbee R, Wesgate R, Wilkinson MAC, Sharpe T, and **Maillard J-Y**. (2015) Disinfectant wipes are appropriate to control microbial bioburden from surfaces: use of a new ASTM standard test protocol to demonstrate efficacy, *Journal of Hospital Infection*, 91(4), 319-325. DOI: 10.1016/j.jhin.2015.08.026

[3.6] Siani H, Wesgate R, and **Maillard J-Y**. (2018) Impact of antimicrobial wipes compared with hypochlorite solution on environmental surface contamination in a health care setting: A

double-crossover study. *Amer J Infect Control*, 46(10), 1180-1187. DOI: 10.1016/j.ajic.2018.03.020

4. Details of the impact (indicative maximum 750 words)

Maillard's research resulted in a new American Society for Testing and Materials (ASTM) International Standard for testing pre-wetted anti-bacterial wipes and led to substantial commercial growth for a leading manufacturer of anti-bacterial cleaning products.

4.1 Evidencing a new ASTM International Standard

ASTM is an international organisation that develops and publishes technical standards for materials, products, systems, and services. Since May 2015, following the Cardiff-led developments to the Wiperator® device **[3.5]**, the Wiperator® has formed the basis of ASTM International standard E2967-15 for testing pre-wetted towelettes in accredited laboratories to evaluate the wipe product's ability to decontaminate surfaces that contain pathogens. The introduction to the ASTM states*: "This standard, formulated after a critical review of available wipe test methods (5-8) and published standards, is based on the use of a mechanical device (the Wiperator; Appendix X1) designed to wipe HITES [High-Touch Environmental Surfaces] under controlled conditions and also to test the transfer of acquired microbial contamination to clean surfaces"* **[5.1,** p1**]**. Maillard's research forms 7 of 13 research references cited in the ASTM International Standard E2967 document **[5.1]**.

As well as informing adjustments to the Wiperator® device (as outlined in Section 2.2), the inventor of the Wiperator®, Antony Sharpe, noted that "*Prof. Maillard also was instrumental in testing this new (MK2) Wiperator® in ring trial with multiple laboratories in Canada and in the UK. The trial results were successfully published (Sattar et al.* J Hosp Infect *2015;91:319-325) and the Wiperator® MK2 is the equipment mentioned in the ASTMEN2967-15 standard"* **[5.2]**.

In addition, Dr Syed Sattar, Professor Emeritus of Microbiology at the University of Ottawa and recipient of the ASTM's Award of Merit for distinguished service to the standards-setting organisation, stated: "*Prof. Maillard was instrumental in approaching sponsors and getting the funding to conduct a multi-national collaborative to generate data on the reproducibility and repeatability necessary for a standard submission to ASTM International"* **[5.3]**.

4.2 Underpinning the commercial growth of GAMA Healthcare (£8M since 2013)

GAMA Healthcare is a leading antimicrobial wipe manufacturer in the UK and Australia. Via his research, Maillard identified the superiority of GAMA Healthcare's wipe products against the pathogen *Clostridioides difficile* **[3.3]**. This led to a long-term collaboration between Cardiff University and GAMA Healthcare, supported via four Knowledge Transfer Partnerships (KTPs, January 2012 – June 2014, January 2015 – November 2016, February 2016 – April 2019 and May 2018 – present) from Innovate UK. GAMA Healthcare benefited from Cardiff research in the following ways:

a. Testing GAMA Healthcare's products to increase profits and ensure these products met new EU regulations

According to Dr Guy Braverman and Dr Teresa Layer from GAMA Healthcare, "*Cardiff-led enhancements to the Wiperator® device were instrumental in enabling GAMA to test and develop 18 novel formulations"* and *"Three of the novel formulations developed by GAMA and tested using the refined Wiperator® device were commercialised within eight months of conception, generating at least £1million in their first 2 years on the market for Gama Healthcare"* **[5.4]**.

By providing the means to test and prove the efficacy of GAMA Healthcare's products, Maillard enabled GAMA to develop new products, including a product to address biofilm removal in sinks and showers in hospitals, called Clinell Drain Disinfectant **[5.5]**. In addition, between May 2015 and March 2019, and via two KTPs, GAMA Healthcare worked with Cardiff University to ensure that its formulations were effective in meeting new EU regulations (EN13697:2015; EN17126:2018; EN13704:2018; EN14476:2018; EN1499:2013;

EN13624:2013; EN14348:2005) allowing the company to enter new markets within the EU. As Dr Layer (GAMA Healthcare's Science and Innovation Director) confirmed: "*The collaboration with Cardiff has enabled GAMA Healthcare to test its products and develop formulations to meet new EU regulatory requirements well ahead of their implementation"* **[5.5]**.

b. Informing GAMA's sales and marketing materials

GAMA Healthcare used Cardiff's robust scientific evidence to drive its sales and marketing activities **[5.4]** and to train healthcare professionals in effective use of their products, as stated by Dr Braverman and Dr Layer: "*An important driver of GAMA's Healthcare business is also the provision of excellence in product training and usage to Healthcare Professionals. Data from research collaborations with Cardiff University supporting product claims is referenced in expert marketing materials utilised by GAMA Sales Professionals and is freely available on our website"* **[5.4]**. Cardiff research is also cited throughout GAMA Healthcare's marketing and sales brochures **[5.6**; p3, **p7**, **5.7**; p3, **5.8**; p3**]**. Consequently, GAMA's global presence grew by over 50% between 2012 and 2017 **[5.4]** and the use of Cardiff's research findings proving the efficacy of their products has allowed GAMA Healthcare to win new business in over 54 international markets including in Europe and Australia **[5.5]**. GAMA's Dr Braverman and Dr Layer confirmed that "*The research and testing to prove the superiority of GAMA's sporicidal formulations has led to commercial growth leading to £8.0mn revenue generated since 2013 and growing steadily 13% yoy [year on year]"* **[5.4]**.

c. Development of GAMA's in-house Research and Development (R&D) facility

At the start of the collaboration between GAMA Healthcare and Cardiff, GAMA Healthcare's long-term ambition was to develop its own R&D facility **[5.4, 5.5]**. GAMA's Managing Director, Dr Braverman stated: "*The first plan was set out during the first KTP with Cardiff University, and Prof Maillard provided valuable advice and guidance in the establishment of the facility"* **[5.4]**. Data provided by Cardiff was used to build a database of its formulations and their effectiveness against different bacteria. This collaboration, alongside GAMA Healthcare's significant commercial growth, enabled investment of £4M in a new in-house R&D department in Halifax, Yorkshire **[5.4, 5.5]**. This R&D facility currently employees 20 multi-disciplinary scientists (with an agreed expansion to a team of 35 in 2021 **[5.4]**) and Dr Braverman and Dr Layer noted that "*100% of Gama Healthcare's microbiology staff received training at Cardiff University"* **[5.4]**. With this facility in place, GAMA Healthcare can now test its product formulations internally and this has so far resulted in cost savings of £23,000 compared with services offered by external accredited labs **[5.4]**.

According to Dr Layer, GAMA's collaboration with Cardiff is "*a key strategic partnership supporting development of highly innovative new products in the infection prevention and control space"* **[5.5]**. GAMA's Chief Executive Officer (and Managing Director) Dr Braverman also summarised the benefit of Cardiff's research for GAMA Healthcare as follows: "*This partnership has included developing rigorous testing methods, product development and commercialisation, academic publications, training and knowledge transfer"* and he added that the collaboration *"has been a core part of our growth and success"* **[5.9]**.

In summary, Cardiff research underpinned a new ASTM International Standard for testing and use of antimicrobial wipes and played a significant role in driving competitive advantage and commercial growth of a leading anti-bacterial wipe manufacturer, GAMA Healthcare. Cardiff research additionally led to improved infection control measures globally, helping to minimise healthcare acquired infections.

5. Sources to corroborate the impact (indicative maximum of 10 references)

[5.1] ASTM E2967. Test Method for Assessing the Ability of Pre-Wetted Towelettes to Remove and Transfer Bacterial Contamination on Hard, Non-Porous Environmental Surfaces Using the Wiperator. ASTM International 2015

[5.2] Testimonial: Antony Sharpe – inventor of the Wiperator, corroborating Cardiff's direction on the development of the Wiperator device.

[5.3] Testimonial: Dr Syed Sattar, Professor Emeritus of Microbiology at the University of Ottawa

[5.4] Testimonial: Dr Guy Braverman, GAMA Healthcare CEO and Managing Director and Dr. Teresa Layer, GAMA Healthcare's Science and Innovation Director

[5.5] Testimonial: from Dr. Teresa Layer, GAMA Healthcare's Science and Innovation Director

[5.6] GAMA Healthcare marketing brochure: Clinical and Laboratory Evidence p.3, p.7

[5.7] GAMA Healthcare marketing brochure: Drain Disinfectant Brochure p.3

[5.8] GAMA Healthcare marketing brochure: Clinell Sporicidal Wipes p.3

[5.9] Testimonial: Dr Guy Braverman, GAMA Healthcare CEO and Managing Director