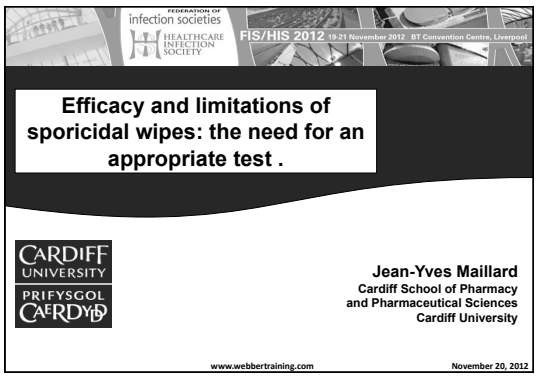
Decontamination – Efficacy & Limitations of Sporicidal Wipes
Prof. Jean-Yves Maillard, Cardiff University, Wales
Broadcast live from the HIS/FIS conjoint conference www.hisconference.org.uk



CONTENT

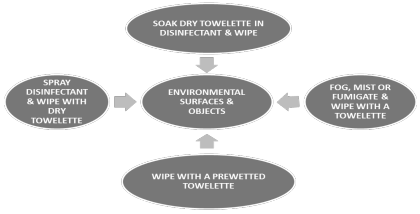
- Role of surfaces in microbial transmission
- Sporicidal wipes and claims
- Test requirement and development

ANTIMICROBIAL WIPES

ANTIMICROBIAL WIPES

Possible scenarios for decontaminating high-touch environmental surfaces by wiping

Sattar and Maillard *Am J Infect Control, in press*



ROLE OF SURFACES IN MICROBIAL TRANSMISSION

ROLE OF SURFACES IN MICROBIAL TRANSMISSION

Surfaces as reservoirs of microorganisms

Paucity of direct scientific evidence to link microbial pathogens found on a particular surface with a specific clinical outbreak

Dancer. *J Hosp Infect* 2004; 56: 10-5
Hota. *Clin Infect Dis* 2004; 39: 1182-9
Talon. *J Hosp Infect* 1999; 43: 13-7

Current evidence

•common surfaces/articles within the hospital environment can become contaminated with pathogenic microbes

•hands (gloved or un-gloved) can become contaminated with these organisms after touching such a surface.

Contamination of common hospital surface is often anecdotal

- •Room door handles
- •Mops
- •Healthcare workers pens
- •Taps
- •Telephones
- Sterile packaging
- Ward fabrics and plastics
- Keyboards
- Stethoscopes

A Webber Training Teleclass
www.webbertraining.com

Decontamination – Efficacy & Limitations of Sporicidal Wipes
Prof. Jean-Yves Maillard, Cardiff University, Wales
Broadcast live from the HIS/FIS conjoint conference www.hisconference.org.uk

ROLE OF SURFACES IN MICROBIAL TRANSMISSION

Sites	Bacterial Load	References
Hospital ward surface Ward floor	< 3 cfu/cm^2 < 5 cfu/cm^2	Rutala *et al. J Clin Microbiol* 1983; 18:683–8.
Stethoscope membrane	In > 54% of cases > 5 cfu/cm^2; in 18% of cases > 29 cfu/cm^2	Bernard *et al. Infect Control Hosp Epidemiol* 1999; 20:626-8.
Hospital ward surfaces	2.5 to 40 cfu/cm^2; ward cleaning reduced this to <2.5 cfu/cm^2	Griffith *et al. J Hosp Infect* 2000; 45:19– 28.
Hospital kitchen surfaces	2 to 294 cfu/cm^2	Aycicek *et al. Int J Hyg Environ Health* 2006; 209:203–6.
Nurse workstation Under ward bed	< 9 cfu/cm^2 < 25 cfu/cm^2	Hardy *et al. J Hosp Infect* 2007; 66: 360–8.
Hospital ward surfaces	55 to 80% of sampled sites had > 5 cfu/cm^2	White *et al. Int J Environ Health Res* 2007; 17: 285–95.

Adapted from Page *et al. J Mat Chem* 2009;19: 3819-31.

HIS/FIS 2012

ROLE OF SURFACES IN MICROBIAL TRANSMISSION

Observations	Hospital 1	Hospital 2
% observations where staff washed hands	28	20
% observations where staff used alcoholic hand rub	**30**	**9**
Of those incidences where no gloves worn, % incidences where staff used alcoholic hand rub	41	14
% staff wearing no gloves and used no AHR, but washed hands	17	19
% staff using no protection/skin sanitisation	19	46
% potential staff to object cross- contamination	30	59
% potential staff to patient cross-contamination	4	0
% potential object to object cross- contamination	70	88
% potential object to patient cross-contamination	20	9
% potential patient to object cross-contamination	17	9

Cheeseman *et al. J Hosp Infect*, 2009; 72: 319-25.

- **Low frequency of hand sanitisation, particularly with use of AHR lead to high incidence of potential cross contamination**

HIS/FIS 2012

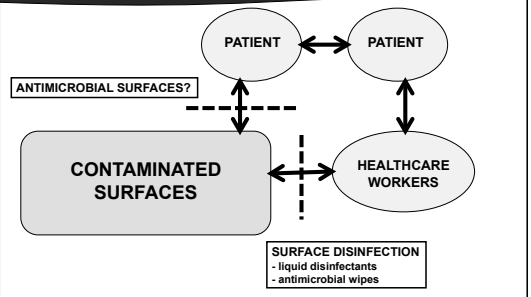
ROLE OF SURFACES IN MICROBIAL TRANSMISSION

Prevalence of *Clostridium difficile*

- Floors, commodes, toilets, bed pans, bed frames
  Vonberg *et al. Clin Microbiol Infect* 2008; 14: 2-20.
- *C. difficile* spores persistence on surfaces : 5 months
  Kramer *et al. BMC Infect Dis* 2006; 6:130-8.
- *C. difficile* incidence data correlated with the prevalence of environmental spores in 1 out of 2 wards.
  Fawley *et al. Epidemiol Infect* 2001; 126: 343-50.

HIS/FIS 2012

ROLE OF SURFACES IN MICROBIAL TRANSMISSION



HIS/FIS 2012

SPORICIDES AND SURFACE DISINFECTION

LABEL CLAIMS - wipes

Siani *et al. AJIC* 2011; 39(3):212-8.

WIPES	INGREDIENT DISCLOSED ON LABEL	CLAIM ON LABEL
Clinell® sporicidal wipe	Inorganic peroxygen generator, tetra acetyl ethylenediamine, surfactants	Sporicidal
Trigene Advance	<1% polymeric biguanide hypochloride, alkyl di-methyl benzyl ammonium chloride, didecyl dimethyl ammonium chloride	Sporicidal
AzoMaxActive™	QAC, PHMB and bronopol	Bactericidal claim and claim against *Clostridium difficile* on label
Sani-Cloth® Rapid	Didecyl dimethyl ammonium chloride 0.45%	Sporicidal
Activ8™	Composition not disclosed; "effective against *C. difficile* spores under 30 seconds with mechanical action of cleaning"	Sporicidal
SuperNova®	Didecyl ammonium chloride, laurakonium chloride, polyaminoporopyl biguanide, 2-bromo-2-nitro-para1-3-diol	Sporicidal
Tuffie	"impregnated with low-level biocides" 5% cationic surfactant, amphoteric surfactant and EDTA	Sporicidal
Enduro Patient wipes	Composition not disclosed	Sporicidal

HIS/FIS 2012

SPORICIDES AND SURFACE DISINFECTION

LABEL CLAIMS - wipes

WIPES	INGREDIENT DISCLOSED ON LABEL	CLAIM ON LABEL
	IMPREGNATED WIPES	
Clinell® sporicidal wipe	Inorganic peroxygen generator, tetra acetyl ethylenediamine, surfactants	Sporicidal
DuoMax	synergistic blend containing a core biocide, surfactants and organic wetting/cleaning agents	*C. difficile* spores (*C. difficile* bacteria)
Ecosan	Hypochlorous acid	*C. difficile*
PDI – sanicolth Chlor +1000ppm	Chlorine	Sporicidal
	SPRAY-ON WIPES	
Difficil-S	Chlorine dioxide	*C. difficile* (including spores)
Chlorclean	1000 ppm av chlorine (sodium dichloroisocyanurate)	Sporicidal
Dispatch	Bleach 6500 ppm (sodium hypochlorite)	No sporicidal claim
Tristel jet	Chlorine dioxide	Sporicidal
Actichlor	1000 ppm av chlorine (sodium dichloroisocyanurate)	*C. difficile*

A Webber Training Teleclass
www.webbertraining.com

Decontamination – Efficacy & Limitations of Sporicidal Wipes
Prof. Jean-Yves Maillard, Cardiff University, Wales
Broadcast live from the HIS/FIS conjoint conference www.hisconference.org.uk

SPORICIDAL – SPORISTATIC ACTIVITY AND CLAIM

PRODUCT A

"Sporicidal, kill *Clostridium difficile* (C.diff) spores (EN 1276 & EN 14347), started with 15,300,000 c. diff spores and were reduced in one minute contact time to less than 10 C. diff spores in both clean & dirty conditions"

EN1276
Bactericidal NOT sporicidal

EN14347
BASIC sporicidal test
NO soiling

PRODUCT B

" EN 1276: *Campylobacter jejuni*, *E. coli*, *E. hirae*, *Klebsiella pneumoniae*, *Listeria monocytogenes*, MRSA, *Mycobacterium avium*, *Pseudomonas aeruginosa*, *Proteus vulgaris*, *Vibrio cholerae* and *Clostridium difficile* (spores & vegetative)"

HIS/FIS 2012

SPORICIDAL – SPORISTATIC ACTIVITY AND CLAIM

PRODUCT C

"Product C achieved a 100% kill of vegetative cells of *Clostridium difficile* ATCC 9689 (1.1×10^7) dried out on a 12 inch square stainless steel test surface. (Wipe time: 30 seconds)"

Validation of Product C efficacy against *Clostridium difficile* ATCC 9689 – surface test

Methodology:

"The test organism was inoculated into 9ml of cooked meat medium (Biomerieux) and incubated at 37°C for 48 hours to obtain a culture containing approximately 10^8 cells/ml (actual count = 1.1×10^8/ml). A 12 inch square test surface was marked out on a stainless steel plate and one ml of inoculum was spread over the test surface and allowed to dry for 30 minutes. The Product C was wiped systematically over the test surface for 30 seconds. Suspensions were taken from the surface of the test site and from the wipe itself, plated out on HBA plates and incubated in an anaerobic jar for five days at 37°C ."

NO MENTION THAT THE TEST WAS CONDUCTED ANAEROBICALLY!!

HIS/FIS 2012

SPORICIDAL – SPORISTATIC ACTIVITY AND CLAIM

UNDERSTANDING *Clostridium difficile*

By ATS Labs on November 1, 2012

"Because the dormant spore form found in the health care environment causes concern for the infection control process, the EPA requires that all disinfectant products registered for use against *C. difficile* must be effective against the spore form of the organism, not the vegetative form.

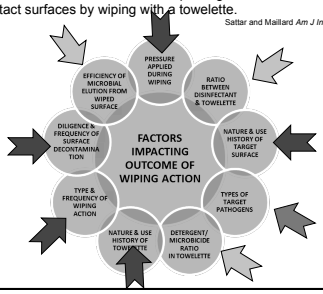
However, testing is difficult because these strains don't readily sporulate to high populations (>10^8 spores/mL) using standard propagation methods and growth media."

HIS/FIS 2012

FACTORS AFFECTING ANTIMICROBIAL WIPES & USAGE

The combined effect of various factors impacting the outcome of decontamination of high-contact surfaces by wiping with a towelette.

Sattar and Maillard *Am J Infect Control, in press*



HIS/FIS 2012

FACTORS AFFECTING ANTIMICROBIAL WIPES & USAGE

FACTORS			COMMENTS	
Wipe	Type		Affect ability to pick up spores soiling	Affect ability to retain spores
	Material			
	Size, sickness			
	Formulation	Biocide/wipe ratio	Affect activity	
		Detergent/biocide ratio		
		Release of biocide	Affect activity -residual	
Wipe Action	Type and frequency of wipe action		Affect ability to pick up spores/soiling	
	Pressure			
Contact Time			Affect activity	
Surface			Affect ability to pick up spores/soiling	
RH, temperature			Affect loss of wetness	
Neutralisation			Test procedure	
Recovery from carrier			Test procedure	

TESTING WIPES EFFICACY

Sattar and Maillard *Am J Infect Control, in press*

AOAC International 961.02	10-60 inoculated glass slides sprayed with biocide for 10 min: For a 'pass' 10/10 slides must show no growth, and no more than one 'failure' is allowed with 60 slides	Wiping not controlled Contact time
ASTM international 32908*	Petri plates with dried inoculum	Wiping not controlled Does not differentiate wiping from biocide efficacy
ASTM International E2362	10 inoculated glass carriers wiped with one wipe	Wiping not controlled Relevance to the field?
EN 4-Field test (phase 2, step 2)	1 test area inoculated, wipe back on forth over remaining 3 test area; test area sampled	Pressure controlled, wiping movement not controlled, relevance of back and forth movement?
3-Stage Test	Test ability to remove bioburden from surface, ability to transfer following wiping and efficacy of wipe	Wiping controlled, contact time appropriate

* Under development/work item

HIS/FIS 2012

A Webber Training Teleclass
www.webbertraining.com

Decontamination – Efficacy & Limitations of Sporicidal Wipes
Prof. Jean-Yves Maillard, Cardiff University, Wales
Broadcast live from the HIS/FIS conjoint conference www.hisconference.org.uk

TESTING WIPES EFFICACY

Sattar and Maillard *Am J Infect Control, in press*

US EPA		
Virucidal activity	10 glass carrier inoculated with feline calicivirus in soling	Wiping not controlled Relevance to the field?
Draft Interim Guidance for Non-Residual Sanitization of Hard Inanimate Food Contact Surfaces Using Pre-Saturated Towelettes	Based AOAC standard 961.02. Aims to demonstrate a 5 log reduction in viability	Flexibility to test carrier, 30 sec contact time Wiping not controlled
Mycobacteria	Based on AOAC standard 961.02	Wiping not controlled Contact time
Method for Disinfection Using Pre-Saturated Towelettes	10-60 inoculated slides wiped; . For a 'pass' 10/10 slides must show no growth, and no more than one 'failure' is allowed with 60 slides.	Wiping not controlled Contact time

HIS/FIS 2012

TESTING WIPES EFFICACY: 3-STAGE TEST

Antimicrobial wipe usage

Williams *et al. J Hosp Infect* 2007; *67: 329-35*

Observation of usage in practice –cleaning staff in ITUs

- use of wipes – surface area
- contact
- rotation

Wipe Number	Surface initially wiped	Time applied (seconds)	Number of consecutive surfaces wiped (other surfaces)
1	Bed Rail	4	5 (bedside table, monitor X2, monitor stand)
2	Steel Trolley	6	2 (both shelves on the trolley wiped)
1	Monitor	4	5 (monitors, two keypads, monitor stand)
2	Bed rail	7	4 (table, monitor, keypad)
3	Bedside table	10	4 (folder, two bed rails)

HIS/FIS 2012

TESTING WIPES EFFICACY: 3-STAGE TEST

ROLE OF WIPES

Williams *et al. J Hosp Infect* 2007;67:329-35

Remove bioburden from a surface — Stage 1 – bacterial removal
How good are the wipes in removing microbial contaminants? (not killing effect)

Prevent transfer of bioburden from the wipe to other surfaces — Stage 2 – bacterial transfer "adpression tests"
Can the wipes transfer survivors to other surfaces (i.e. cross-contaminate)?

Where antimicrobial is present – kill the microbial bioburden — Stage 3 – Antimicrobial activity
Can the wipes kill the bacteria they remove?

HIS/FIS 2012

TESTING WIPES EFFICACY: 3-STAGE TEST

SPORICIDAL EFFICACY – efficacy testing against *C. difficile* NCTC12727

Siani *et al. AJIC* 2011; 39(3):212-8.

Wipes	Bacterial Removal (log_{10} cfu/disk ± SD) 500 g surface pressure	Bacterial transfer following 10 s wiping time at 500 g surface pressure
Negative control	1.13 (± 0.36)	5 consecutive transfers. TNTC
Hypochlorite soaked wipe	2.02 (± 0.21)	5 consecutive transfers. TNTC
Clinell® sporicidal wipe	4.09 (± 0.79)	No spore transferred
TriGene Advance	0.22 (± 0.07)	**5 consecutive transfers. From 0 to TNTC**
AzoMaxActive™	1.30 (± 0.33)	**5 consecutive transfers. From 0 to TNTC**
Sani-Cloth® Rapid	0.57 (± 0.07)	**5 consecutive transfers. From 1 to TNTC**
Activ8™	+0.08 (± 0.08)	5 consecutive transfers. TNTC
SuperNova®	1.14 (± 0.65)	5 consecutive transfers. From 83 to TNTC
Tuffie	0.67 (± 0.11)	5 consecutive transfers of ≤43 bacteria
Enduro Patient wipes	0.88 (± 0.13)	5 consecutive transfers. From 2 to TNTC
NewGenn	0.84 (± 0.66)	5 consecutive transfers. From 40 to TNTC

HIS/FIS 2012

TESTING WIPES EFFICACY: 3-STAGE TEST

SPORICIDAL EFFICACY – efficacy testing against *C. difficile* NCTC12727

Siani *et al. AJIC* 2011; 39(3):212-8.

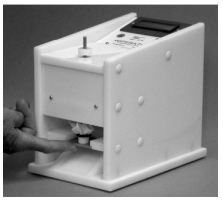
Wipes	Claim on label	Sporicidal effect (log_{10} reduction ±SD)	
		10 s contact time	5 min contact time
Clinell® sporicidal wipe	Sporicidal	0.11 (± 0.15)	1.54 (± 0.84)
TriGene Advance	Sporicidal	0.04 (± 0.05)	+0.84 (± 0.03)
AzoMaxActive™	Bactericidal claim and claim against *Clostridium difficile* on label	1.41 (± 0.14)	+0.92 (± 0.15)
Sani-Cloth® Rapid	Sporicidal	1.77 (± 0.27)	0.01 (± 0.44)
Activ8™	Sporicidal	0.99 (± 0.14)	+0.70 (± 0.15)
SuperNova®	Sporicidal	1.96 (± 0.09)	+0.66 (± 0.13)
Tuffie	Sporicidal	0.37 (± 0.23)	+0.50 (± 0.19)
Enduro Patient wipes	Sporicidal	0.41 (± 0.10)	+0.66 (± 0.10)
NewGenn	No sporicidal claim on label	0.31 (± 0.15)	+0.82 (± 0.14)
Hypochlorite soaked wipe	5000 ppm	+0.14 (± 0.49)	5.39 (± 0.00)

Sporistatic

HIS/FIS 2012

TESTING WIPES EFFICACY: 3-STAGE TEST



HIS/FIS 2012

A Webber Training Teleclass
www.webbertraining.com

Decontamination – Efficacy & Limitations of Sporicidal Wipes
Prof. Jean-Yves Maillard, Cardiff University, Wales
Broadcast live from the HIS/FIS conjoint conference www.hisconference.org.uk

WIPES AND RESIDUAL ACTIVITY

DETERMINING RESIDUAL EFFICACY

S. aureus: 4.78 - 5.12 $\log_{10}$ bacteria/disc

A. baumannii: 4.37 – 4.80 $\log_{10}$ bacteria/disc

Mechanical rotation: 10 s at 60 rpm against surfaces exerting a weight of 500 ± 5 g. Bacterial inoculation after 30 min of initial wiping; 5 min exposure time

S. aureus

PRODUCT	LOG_{10} REDUCTION
Control wipe	0.92 ± 0.12
Control wipe + 5000 ppm NaOCl	0.87 ± 0.10
Wipe A	2.78 ± 0.00*

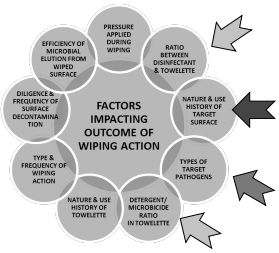
A. baumannii

PRODUCT	LO_{G10} REDUCTION
Control wipe	0.42 ± 0.07
Control wipe + 5000 ppm NaOCl	1.39 ± 0.34
Wipe A	2.37 ± 0.00*

HIS/FIS 2012

ANTIMICROBIAL WIPES – ??

BETTER UNDERSTANDING



HIS/FIS 2012

ANTIMICROBIAL WIPES – ??

BETTER UNDERSTANDING

Sattar and Maillard *Am J Infect Control, in press*

Should towelettes be tested against individual types and species of pathogens?	Careful use of surrogate Keep the claim label uncomplicated and user friendly
If and what type of soil load should be used in testing the decontaminating activity of towelettes?	reasonable amount of added soil load and type to better simulate the practice
Should test organisms be recovered from the towelette used for decontamination?	Recovering the test organism from the contaminated towelette is neither easy nor needed
Should product labels not specify the ratio between disinfectant volume and the surface area to be decontaminated by wiping?	end-user is hardly ever provided with guidance on how large a surface area to be decontaminated with a given towelette
What controls should be included in testing the decontaminating activity of towelettes?	(a) The number of viable organisms placed on each carrier to be wiped (b) assessment of loss in viability of the test organism during the initial drying of the carriers (c) physical removal of the test organism from the carrier by a control or blank towelette

HIS/FIS 2012

THANK YOU

HIS/FIS 2012

A Webber Training Teleclass
www.webbertraining.com