Report on the review of evidence regarding the contamination of wash-hand basin water taps within augmented care units with Pseudomonads

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Document Purpose	For Information
Gateway Reference	17819
Title	Report on the review of evidence regarding the contamination of wash-hand basin water taps within augmented care units with Pseudomonads
Author	DH
Publication Date	29 June 2012
Target Audience	NHS Trust CEs, Care Trust CEs, Foundation Trust CEs , Medical Directors, Directors of PH, Directors of Nursing, Allied Health Professionals, Communications Leads, Emergency Care Leads
Circulation List	PCT CEs, SHA CEs
Description	The Report is for information only. It was produced by the Pseudomonas Working Group in August 2011, the recommendations have informed the Pseudomonas work programme currently being undertaken by the Department of Health.
Cross Ref	Gateway Ref 17334: Water sources and potential Pseudomonas aeruginosa contamination of taps and water systems. Advice for augmented care units. Gateway Ref 17216: Pseudomonas aeruginosa bacteria preventing and controlling contamination. Gateway Ref 14720 Water sources and potential for infection from taps and sinks
Superseded Docs	N/A
Action Required	N/A
Timing	
Contact Details	NHS Estates & Facilities Policy Branch Department of Health Room 3N09, Quarry House Leeds LS2 7UE
For Recipient's Use	

First published June 2012

Published to DH website, in electronic PDF format only.

www.dh.gov.uk/publications

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Foreword

In August 2010 the Department of Health commissioned a review of evidence relating to contamination of hospital water supplies with Pseudomonads, following outbreaks of Pseudomonas in Wales. The output of this work was considered by the Chief Medical Officer, Professor Dame Sally Davies, in August 2011. This report reflects information available at that time.

The evidence review was conducted by the Pseudomonas Working Group, which comprised representatives from professional organisations, NHS, Royal Colleges, Health Protection Agency, Health and Safety Executive, Water Research Centre (WRc), Drinking Water Inspectorate, Water Regulations Advisory Scheme (WRAS), the Devolved Administrations, BuildCert and manufacturer's trade associations. The membership and terms of reference of the working group are detailed in Annex A.

The output from the review exercise helped inform the development of the Department of Health's action plan and programme of work to address Pseudomonas contamination of water sources and water systems. This culminated in the production of new advice and guidance in 2012[1, 2]. The March 2012 technical guidance provides new guidance for those healthcare organisations providing patient care in augmented care units, such as paediatric and adult critical care, neonatal and burns units, and provides advice on:

i) assessing the risk to patients if water systems become contaminated with *Pseudomonas aeruginosa* or other opportunistic pathogens
ii) protocols for sampling, testing and monitoring water for *Pseudomonas aeruginosa*
iii) what actions to take if water systems become contaminated with *Pseudomonas aeruginosa*
iv) developing local water safety action plans

The Department is currently undertaking additional work to inform the development of an addendum to the existing Estates guidance, Health Technical Memorandum 04-01: *The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems* to address issues relating to *Pseudomonas aeruginosa.* This publication is expected to be available in March 2013.

[1] February 2012 - Pseudomonas aeruginosa bacteria preventing and controlling contamination http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_132536

[2] March 2012 - Water Sources and Potential for Pseudomonas aeruginosa Infection from taps and water systems; Advice for augmented care units http://www.dh.gov.uk/health/2012/03/technical-guidance-pseudomonas/

Contents

This report has been superseded by guidance issued in March 2012

Executive summary

In July 2010, the Department of Health for England became aware of a number of reports of incidents emanating from English NHS Trusts and information on two incidents in Wales concerning outbreaks of infection with pseudomonads. The incidents had occurred in adult intensive care units though the scope of this work was extended to cover augmented care wards (eg high dependency, adult & neonatal critical care, renal and burns units etc.)

The Department commissioned an investigation into this problem the outcome of which has informed the development of a report to the Chief Medical Officer (CMO) and this subsequent publication.

The report to the CMO reviewed the evidence available at the time, identified gaps in the knowledge base and made seven recommendations to address the issue.

1. Recommendation 1 - production of a policy document, aimed at both clinical staff and hospital engineers, on infection control measures to reduce the risk of these infections and an associated “top tips” poster.

2. Recommendation 2 - seek a view from NICE on the need for a quality standard for water quality in healthcare.

3. Recommendation 3 - for a national survey to gather additional evidence to establish how common such contamination is.

4. Recommendation 4 - a sampling and records protocol for routine monitoring of pseudomonal contamination within high risk units.

5. Recommendation 5 - research on modelling of tap & water system colonisation and a call for research proposals

6. Recommendation 6 - identifies a potential need for research on tap design. Calls for a discussion with professional bodies to identify research gaps.

7. Recommendation 7 - proposes a revision of HTM 04-01: *The control of Legionella, hygiene, “safe” hot water, cold water and drinking water systems* to include a wider focus on water quality.

Report on the review of evidence regarding the contamination of wash-hand basin water taps within augmented care units with Pseudomonads

In August 2010 the Department issued a Dear Colleague letter "Water sources and potential for infection from taps and sinks" to NHS Trusts reminding them of the importance of assessing the risk of infection from taps and sinks to their patients and ensuring the appropriate use of hand hygiene controls[3].

Evidence gathering visits were made to University Hospitals of South Manchester and Centre Hospitalier Universitaire (CHU) - Amiens. There were also visits to centres of expertise in England and to two manufacturers of specialist taps and thermostatic mixing valves. In addition, a meeting was held with the Chief Inspector of the Drinking Water Inspectorate.

Full details of the evidence supporting these recommendations and the discussion by the Working Group, which led to these recommendations, are detailed in Annex B.

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http://www.dh.gov.uk/en/Publicationsandstatistics/Lettersandcirculars/Dearcolleagueletters/DH_119169

Introduction

This publication records the findings and recommendations of the Pseudomonas Working Group and the evidence available, prior to the completion of the report in August 2011, which underpinned their conclusions and recommendations. The report's recommendations were subsequently prioritised by the Department and an action plan put in place.

Since the completion of the report, there have been further developments in the evidence base and knowledge, gained from the outbreaks in neonatal units in Northern Ireland during 2011/12 associated with taps contaminated with *Pseudomonas aeruginosa*, which have led to the development of additional guidance for healthcare providers on this issue.

The Department is undertaking further work to develop the evidence base to close existing gaps in the current knowledge base. This work will be used to inform the development of an addendum to the existing guidance document, Health Technical Memorandum 04-01: *The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems* to address issues relating to *Pseudomonas aeruginosa.* This publication is expected to be available in March 2013.

Throughout this document we have referred to pseudomonal strains, this is in recognition of the fact that although Pseudomonas aeruginosa is the predominant organism implicated. All pseudomonal species are inherently antimicrobial resistant.

Background, Findings and Initial Actions Taken

a) In response to requests for information, increasing numbers of reports of incidents from England, and the other home nations, followed the first reports from Wales.

b) There is published evidence relating to pseudomonal contamination incidents and infection outbreaks in other countries, including Austria, France, Australia, Ireland, United States of America, Hungary, Switzerland, Norway, Greece, Italy and Germany.

c) Previously the National Patient Safety Agency (NPSA) reviewed their records and made the Department aware of an outbreak in a dermatology clinic where leg ulcers were cleaned with tap water.
The project team is also aware of an outbreak of otitis externa in primary care where ears were syringed with tap water. In addition, several centres have drawn the attention of the Department to the problem of pseudomonas contamination related to medical devices, particularly nebulisers used with cystic fibrosis.

d) Epidemiological data from voluntary surveillance of bacteraemias, collected by the Health Protection Agency (HPA) from microbiology laboratories, suggests that numbers of *Pseudomonas aeruginosa* bacteraemia have risen slowly in recent years. However, no systematic prospective survey data on wider pseudomonal

infection has been collected. It is not possible, from the existing evidence, to determine if the anecdotal reported outbreaks of HCAI pseudomonal infections are part of a widespread trend or simply sporadic instances of a low-level HCAI contributor.

In some, but not all, instances genotyping has shown that the contaminating isolates found in the taps were indistinguishable from those giving rise to colonisation and infection in patients. However, this does not confirm causation.

e) Available sources of utilisable carbon will support bacterial growth in the presence of other supporting factors. There are several reported instances, within the literature, that relate specifically to Pseudomonas in this regard.

Reports show the use of certain synthetic rubber formulations, that include some based upon ethylene propylene diene monomer (EPDM), can be sources of utilisable carbon within taps/thermostatic mixing valves (TMVs) and water distribution systems. There are specific literature references to this with respect to pseudomonas.

f) It is clearly established, within the literature, that Pseudomonas is a successful organism in terms of biofilm formation and colonisation.

In addition, evidence suggests that the presence of microorganisms within a biofilm substantially increases the problems associated with decontamination of those water systems. This has led to work within industry to examine aspects of design within taps and associated plumbing in order to reduce the rate or extent of biofilm build up.

g) Substantively the literature and the experiential evidence support the need for clear “clean – dirty” separation in reducing the risk of acquiring organisms from the environment and water as a common media. There is limited observational evidence to the effect that such separation is not always achieved in practice and may give rise to wash-hand basin contamination.

The use of wash-hand basins for disposing of patient wash water and the rinsing of respiratory equipment may increase risk of contamination from patient sourced organisms. The risk of spreading contamination to other patients from the wash-hand basin via contact or droplets has been observed.

Whilst the increased provision of wash-hand basins with non-touch tap systems is likely to reduce some HCAI risks this effect may be countered if general purpose sinks and clean utilities are less available. It is also possible that the increased provision of hand hygiene stations has reduced the frequency of use and hence added to the risk of colonisation.

h) Much of the emphasis in recent years has centred on sensor/non-touch taps as part of hand-wash facilities that act as a point source of pseudomonal risk. This has influenced the approach of healthcare and design engineers. Those non-touch tap systems using thermostatic mixing valve-infra red operated systems (TMV-IRs) have been implicated in Pseudomonas outbreaks. However, the evidence

available does not conclusively single out TMV or solenoid devices from a broader pattern of risk (see *Annex C,* weblinks e) and f), for papers on examples of similar discussions in the United States of America in relation to TMV-IRs).

i) The extent of contamination within taps and associated pipework (including flexible pipework/tails) has been the subject of local studies in England and other nations specifically including France. The findings from these studies do exhibit a degree of consistency. However, the sampling strategies used vary between centres and this makes more detailed comparison difficult.

j) Pseudomonal colonisation is often restricted to the last 1.5 to 2.0 metres length of the plumbing system measured back from the tap outlet. Centre Hospitalier Universitaire (CHU) - Amiens reported that in 9 out of 10 reported pseudomonal contamination incidents within their healthcare facilities the contamination did not extend beyond 1 metre from the tap.

k) In many instances the residual water present within a tap, TMV and adjacent pipework, when the tap is closed, is found to be contaminated with planktonic (free living and mobile rather than constrained within a biofilm matrix) organisms. These planktonic contaminants, including pseudomonads, are the most likely source of risk to be transferred to patients.

l) Safety alert (DH (2010) 03 : Flexible water supply hoses) was issued in May 2010 to assist in combating the risks associated with legionella, and pseudomonas, from the use of synthetic rubber based components (such as some formulations of EPDM rubber) in flexible water supply hoses. Trusts complying with the safety alert may have replaced EPDM flexible hoses with standard rigid plumbing or components lined with genuine WRAS approved polyethylene (PE), cross-linked polyethylene (PEX), linear low-density polyethylene (LLDPE) and post-chlorinated poly vinyl chloride (PVC C). These actions are likely to have countered pseudomonal colonisation risk although no specific published report has been located to date

m) In an extension of the above thinking, some estates groups have replaced TMV-IR / non-touch taps with more conventional elbow or knee actuated devices. Reports from infection prevention and control groups suggest that these actions are coincident with an end to the outbreak and associated contamination for the reported period. It should be noted that this may not establish a permanent solution.

   The replacement of taps would be expected to give particular emphasis to infection prevention in the practices of staff, at least for a period of time. This factor gives rise to difficulty in concluding that tap replacement itself is effective in risk reduction over the medium term (see also *Annex C,* weblinks e) and f)).

n) Additional chlorination and/or the use of high temperature hot water supply and tap flushing techniques have been shown in published literature to be effective in suppressing pseudomonal contamination, at least temporarily. A periodic, controlled and monitored strategy may be effective in longer term risk suppression

o) Materials used in manufacture. These are detailed in "*BS 6920*, *Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water".* Part 2.4 is concerned with testing the ability of materials to support bacterial growth. The method described is one of measuring oxygen utilisation from which biological activity is inferred.

   It needs to be established if BS 6920 Part 2.4 is appropriate in respect of suitability for use in healthcare specific water distribution systems and whether revision or specialisations may be necessary in material selection and specification. It is understood that a new standard is under development in Europe that includes the current Dutch, German and UK test methods.

p) There is some evidence to suggest that final Quality Assessment (QA) testing of specialist taps, at the end of the manufacturing process, using recycled water may be a source of pseudomonal contamination. Some manufacturers, concerned on this issue, have introduced UV disinfection of the water used in the QA process or initiated post manufacture disinfection processes to reduce contamination. However, this may not eliminate contamination and the vulnerability to subsequent microbiological proliferation may remain.

   It is likely that current precautions in the installation of these specialist taps within healthcare buildings are not fully effective in removing or preventing the pseudomonal contamination. This issue may be usefully addressed in an amended HTM 04-01.

q) One anecdotal report revealed an outbreak shortly after the commissioning of a unit, raising the possibility that contamination occurred during the installation or commissioning process and was not detected. Unusually subsequent widespread contamination of the water distribution system was observed in this instance, i.e. not localised to any unit or device

r) Reports suggest errors in the set-up and adaptation of firmware/software used to control some taps may have contributed to a loss of useful characteristics in respect of suppression of pseudomonal contamination.

s) Typical cost for replacement of infrared sensor tap and clinical washbasin assembly on a like for like basis is in the region of £2500. NB: excludes chlorination costs and assumes no additional electrical wiring requirements/modifications. The opportunity cost for clinical unit closure, for tap replacement, is difficult to estimate but may be substantial.

t) Published and private communication shows that terminal filtration of water delivered from taps contaminated by pseudomonas to be highly effective in constraining infection risk from this point source. The cost of such provision for a typical large ITU with 32 taps would be about £50k per annum* (costs will increase or decrease dependant upon the number of outlets and subsequent testing and replacement schedules implemented). However, it would provide immediate control of dissemination from a tap and could be applied to specific outlets on a risk assessed basis, which may reduce the outlay costs. This cost compares with a current public health evaluation of a QALY as £30k. It does not include the benefit

of the prevention of additional patient bed days with their associated costs, which typically range from £225 to £400 per bed day** dependant upon the type of clinical care being administered

* source- University College London Hospitals NHS Foundation Trust.
**source - NHS Institute for Innovation and Improvement.

Recommendations

- **Immediate actions**

Recommendation 1

a) Production of a specific policy document on infection prevention and control applied to the reduction of risk to patients associated with pseudomonal contamination of water systems. This to be supported by a brief guidance package for regulators (Monitor, HSE), commissioners, quality inspectorates (CQC) and providers.

HSE cooperation has been established in this matter.

b) Provision of a *"Top-Ten-Tips"* document and poster to care providers, focused within the constraints of reliable evidence, on key engineering measures and clinical practices which will support prompt risk reduction in this area.

- **Short term action**

Recommendation 2

a) Issue a request to the National Institute for Health and Clinical Excellence (NICE), or academic institutions, for further evaluations of the evidence base for potential construction of a Care Standard related to water quality and the protection of the patient against infection. This may be related to specific care pathways, which involve augmented care, and the care of immunocompromised patients.

This action adds emphasis to the urgent response, and helps to ensure a further good quality evaluation of the evidence.

- **Short to medium term actions**

a) Additional evidence gathering.

Despite a substantial base of evidence, key questions remain difficult to answer. There is a requirement for the gathering of additional evidence to establish how common such contamination is and to evaluate the likely impact of mitigating measures.

The requirements are as follows:

Recommendation 3

i) A prospective national survey which affords data allowing the challenge and impact of pseudomonas incidents and contamination of taps, and their associated water supply systems and apparently related patient infection to be understood in quantitative terms. This would be particularly valuable in regard of assessing the magnitude of response which healthcare commissioners and providers may make.

The Advisory Committee on Antimicrobial Resistance and Healthcare – Associated Infection (ARHAI) offered only qualified support to commissioning a national survey. Several members preferring an approach based on a more active investigation of reported outbreaks.

Recommendation 4

ii) Development of a sampling and records protocol for routine monitoring of pseudomonal contamination, for application within “at risk units.” This to be supported by the development of protocols for use when an outbreak of infection related to contamination is observed. This would further comply with the recommendations received from ARHAI.

Recommendation 5

iii) Developing from i) above and in order to understand how the movement of contaminated water, equipment and materials might lead to the colonisation of patients; a modern Monte Carlo/ movement vectors modelling exercise has been proposed. Appropriate research groups have been identified and will utilise data from recorded outbreaks of pseudomonal contamination and associated infection in patients. It is expected to incorporate appropriate operational (nursing activities, methods and movements) studies.

Recommendation 6

iv) The commissioning of laboratory based controlled research studies on the relationship, if any, between pseudomonal contamination risk and key tap/supply design parameters (materials, surfaces, water flow, water temperature, flushing regimes, etc) for six generic arrangements of taps and thermostatic mixing valves (TMVs):

- Thermostatic Mixing Valve -Infra Red operated(TMV-IR) (commonly known as sensor or non-touch taps);
- Conventionally operated tap with integral TMV
- Conventionally operated tap with remote TMV;
- Conventionally operated tap with no TMV
- Patient showers with TMV
- Patient baths with TMV

(NB: it may also be necessary to compare monobloc outlet units versus individual hot and cold outlets)

Members of the major trade organisations have emphasised the importance of a systems approach in which tap design, manufacture, decontamination and other factors are seen as a coherent whole. This broad approach may be expected to be robust in terms of risk control.

Narrow, isolated options, such as the replacement of existing taps without supporting actions, may prove to be expensive and counter productive

These actions should be pursued in cooperation with commercial bodies and appropriate research groups.

- **Medium term action**
  Recommendation 7
  a) In order to draw the attention of regulators, commissioners and providers to the risk of harm to patients from contaminated water in units where vulnerable patients are cared for, there is a requirement to rewrite Health Technical Memorandum (HTM) 04-01: *The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems*. This will facilitate a focus on overall water quality and safe hot and cold water systems across a broad spectrum of potential risk in clinical environments. The resultant document will focus on issues specific to healthcare.

     Learned and commercial bodies have recommended that any revised document should be able to assist the care providers in focussing on individual Trust needs in respect of infection risk reduction and clinical usability/efficiency at a local level.

Supporting evidence for the above recommendations is located in Annex B

Annex A

Agreed Terms of Reference (TOR) - 16 August 2010
Project team and supervising board.
Risks associated with Pseudomonas contamination in water taps used within Healthcare facilities.

Background

The formation of a small team drawn from within the Department and supervised by a two person SCS board is to be completed urgently in response to reported instances of potentially pathogenic Pseudomonas contamination in water supply taps primarily those located in Intensive Therapy Units (ITUs).

Initial reports emanated from Welsh Health Estates and Public Health Wales, these have been followed by reports of contamination of taps at a number of acute units in England.

This document considers the setting-up and TOR for a fixed-life team charged with specific duties regarding the above issues. Where appropriate the TOR is extended to cover the tasks which the team will be expected to complete and the products that are needed.

Aims and Objectives

To work with the Health Departments of the other UK administrations to achieve the prevention and control of infection from strains of Pseudomonas in connection with water supply and taps used in Healthcare. There shall be particular emphasis on departments within acute units where infection vulnerable patients are cared for including Intensive Therapy Units and other facilities identified from post surgical, burns and serious illness care protocols.

The current defined objectives are to:

a) Gather and summarise the available evidence on Pseudomonas and other bacterial infections related to the provision and use of taps at wash-hand basins and sinks in the above mentioned facilities. This shall specifically include:
   - i) Epidemiological trends and the identification of the strains involved with particular emphasis on drug resistance where present.
   - ii) Technical data related to the design and function of taps found to carry Pseudomonas contamination. Specifically the structures within the tap, which become contaminated and the contamination dynamics (rate of growth or multiplication).
   - iii) The effectiveness or otherwise of techniques intended to mitigate the contamination. This shall include flushing, pasteurisation (thermal and chemical) and the application of filtration.

b) Consider the above evidence in terms of risk estimation. Nature, severity and probability. Consideration of consequences for staff, public and patient safety. The derivation of policy options intended, where necessary, to reduce or mitigate the

risk of tap contamination and the consequent infection of persons. In addition to general contamination risks, special consideration shall be given to the possibility of contamination of taps and structures internal to taps by MDR strains of Pseudomonas arising from patients undergoing care in the facilities considered.

c) Consider reports related to the engineering of the taps specifically including but not limited to types using thermostatic mixing valve (TMV) technologies combined with infra-red transducer based control systems. Consider the characteristics of these taps, that may give rise to contamination risks, which are in excess of those encountered from alternative available technologies. These reports shall contain recommendations for actions designed to reduce risk through engineering measures, where appropriate and in line with policy options presented under b) above.

d) Consideration, where necessary, of risk reduction through operational and care protocols applied on the ITU and other facilities thought to be at potential risk from this source of infection. This shall include items such as: nursing procedures; cleaning and maintenance; monitoring and microbiological testing.

Associated workstreams.

At the outset the following areas of work are identifiable as being required to meet the aims and objectives given above.

T1) Literature reviews and report reviews to cover epidemiology, infection characteristics and drug resistance related to Pseudomonas and water supply from taps. This will be accomplished working with Public Health Wales as appropriate. Engineering evidence reviews based on published material and reports received from Healthcare Estates organisations as appropriate again with emphasis on the work of Welsh Health Estates. Collection of reports from hospitals where contamination has been detected and further reports on infection should this be present.

T2) In the event that the evidence search, described above, reveals relevant and significant deficiencies in understanding then a laboratory-based short research undertaking will be pursued. At the time of writing, work on routes of contamination entry, characteristics of internal tap structures in terms of supporting contamination / colonisation and quantification of decontamination techniques appear to be of potential interest.

T3) Drafting and evaluation of policy options for risk reduction etc as required. These shall be sufficiently broad in consideration as to include other potential risk sources such as scalding. Due attention shall be given to existing BSI/EN and ISO standards where relevant.

T4) Consultation with industry to include manufacturers of taps and fitting, trade associations, regulators and those providing codes.

T5) Liaison. Firstly with the Health and Safety Executive (HSE) as necessary to establish satisfactory evaluation of evidence as related to staff and public safety. Consultation on policy options where appropriate. Similar considerations related to

patient safety in regard of the National Patient Safety Agency (NPSA). The extension of this short consultation process to include appropriate Advisory Committees shall be considered as necessary. At least some consultation with the Advisory Committee on Dangerous Pathogens may be thought appropriate but in-view of the short time scales envisaged this may take the form of Chairman's action and retrospective reports.

T6). Drafting of policy options, interim and final reports (see products below).

Products.

Interim report.

It is envisaged that once the evidence gathering and where needed consultation work is complete an interim report will be generated covering at least the following topics –

a) A summary of the instances of contamination and possible related infections reported at least for Wales and England.
b) Brief consideration of the background epidemiology and the strains present including their drug resistance characteristics.
c) Overview of the key scientific and engineering considerations for supply and tap design. To include features thought to promote contamination and colonisation.
d) Risk analysis in terms of potential for contamination and colonisation by Pseudomonas and associated hazards for staff and the patient.
e) Proposed policies and assessment of costs, risk reduction impact and practicality.
f) Statement on any further resources, which the team may need in order to complete the drafting of a final report.

It is envisaged that this interim report would be ready, at least in draft form by mid-September. The team will pass the report to the SCS supervisors for their consideration and instructions. This draft will also be shared with Wales and other home nations, as appropriate but will not be published. The current "lines to take" will be revised at this point.

Final report.

The contents of this report will be a development of that given in the interim case and will also include –

g) Recommendation on policy selection and a brief description of advantages and impact with particular attention to risk reduction and cost implications.
h) Further revised press statement and "lines to take."
i) Outline engineering specifications and protocols for risk control as may be required by the recommended policy. These should be such that they can be developed by outside organisations (HPA / industry /teaching hospital NHS trusts) into a mature directly applicable form.
j) Further draft derived from this work, which is suitable for publication if required.

The final report in draft is expected by the end of September. This will be subject to consideration by all 4 home nations as they may wish. The report will form the basis for Estates Alerts and CMO letters as may be indicated by the chosen policies. Although it is hoped that the nations may agree common policy and approach the arrangements will allow for different approaches as needed.

Confidentiality

The majority of the evidence used in the generation of risk considerations and reports within this project will be public domain. However, reports on contamination and infection within specific institutions shall be regarded as restricted.

The draft and final reports shall be designated as restricted until such time as the supervising board may indicate that circulation and / or publication is appropriate.

List of Working Group Members and Contributing Experts

Dr Crispin C Adjidé - Centre Hospitalier Universitaire - Amiens
Philip Ashcroft – Department of Health
John Ashworth - Water Regulations Advisory Scheme
Emma Boakes – National Patient Safety Agency
Tim Boswell – NHS Nottingham University Hospitals
David Burns - DHSSPS Northern Ireland
Naresh Chada – DHSSPS Northern Ireland
Professor Jeni Colbourne - Drinking Water Inspectorate
Paul Featherstone – University Hospitals South Manchester
Dr Guy Franklin – WRc-NSF
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Isabelle Gaillard - Université de Picardie Jules Verne
Rose Gallagher – Royal College of Nursing
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John Newbold – Health & Safety Executive
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Robert Pitchers - WRc
Nigel Porter - Welsh Health Estates
Terry Rowbury – British Electrotechnical & Allied Manufacturers Association
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ANNEX B

Supporting Evidence, Grading and Discussion
The extent of the known problem

1. Current situation in England/United Kingdom

a) The Chief Medical Officer (CMO) Wales issued a letter in August 2010 with regard to two separate outbreaks of pseudomonal infection in augmented care related to hand hygiene stations. Evidence presented to the project team indicated that both human derived and environmental strains were involved.

b) In England, The Department of Health issued a 'Dear Colleague' letter in August 2010 outlining the recent reports from Wales and highlighting the appropriate steps to be taken.

c) Increasing numbers of reports of incidents from England and the other home nations have now followed the first reports from Wales. To date we have been made aware of similar outbreaks or contamination occurring with this organism at the several major centres in England. Although these episodes have been investigated locally, we are unaware of recent published reports from England.

   Anecdotal evidence from members of the working group indicates that there are likely to be many more incidents that may have occurred, but which have not been reported.

d) In addition, the National Patient Safety Agency (NPSA) is aware of an outbreak in a dermatology clinic where leg ulcers were cleaned with tap water. A member of the project team is also aware, through a personal communication, of an outbreak of otitis externa in primary care where ears were syringed with tap water. In addition, several centres have drawn the attention of the Department to the problem of pseudomonas contamination related to medical devices, particularly nebulisers used with cystic fibrosis.

e) Epidemiological data from surveillance, collected by the HPA, suggests that numbers of hospital / healthcare associated pseudomonal bacteraemias have risen slowly in recent years (see Published Evidence below and also *Annex C)*.

2. Current guidance and protocols.

a) The requirements of the Code of Practice on the prevention and control of infections and related guidance are applicable to the contamination of taps/plumbing system by pseudomonas and related outbreaks of infection.

b) CMO for Wales, and the DH Directors for Health Protection and Estates & Facilities, have issued letters to their respective NHS communities urging a precautionary approach to pseudomonal infection control specifically related to augmented care units and tap contamination.

c) A Safety Alert relating to flexible synthetic rubber based plumbing components and the risk of legionella and other bacterial infection (DH (2010) 03: Flexible water supply hoses) was issued in May 2010.

d) An extant Health Technical Memorandum (04-01: The control of Legionella, hygiene, "safe" hot water, cold water and drinking water systems) has guidance content on reducing risk of bacterial contamination of hospital/healthcare water supplies. However, this guidance does not deal specifically with tap and plumbing system design/cleaning/maintenance specifically related to pseudomonal contamination.

e) The Health and Safety Commission has an Approved Code of Practice* backed by guidance from the Health and Safety Executive on Legionella contamination of water supplies/ systems.

HSC/E L8 The control of Legionella bacteria in water systems Approved Code of Practice and Guidance.

3. Evidence (General observations)

a) Throughout this document we have referred to pseudomonal strains, this is in recognition of the evidence that although *Pseudomonas aeruginosa* is the predominant organism implicated, other species and other Gram negative organisms may also be of concern. All pseudomonal species are inherently antimicrobial resistant. Where strains contaminating taps have originated from human strains there is concern that they will have acquired additional antimicrobial resistance

b) Many anecdotal/sporadic reports of patient infection with a wide range of strains/types of pseudomonas and other gram-negative bacteria have been received. The infections are reported in relation to augmented care units (ITU and Cardiac ITU) and some other areas where immunosuppressed patients are housed and receive care. Many of these incidents/outbreaks are associated with coincident detection of pseudomonal contamination of taps and pipework within the care area including hand wash systems.

c) There are many anecdotal and semi-systematic reports of contamination of taps and pipework and associated outbreaks of pseudomonal infection from many countries throughout Europe. Increasing numbers from England and the other home nations have now followed the first reports from Wales.

d) As alluded to in (b) above the contamination and infection instances cannot, in any obvious way, be correlated to any specific strain either at the local or national level. (Strain types have not been assessed in all circumstances).

e) Broadly, the literature supports the need for clear "clean – dirty" separation in reducing the risk of acquiring organisms from the environment and human waste. There is limited observational evidence to the effect that such separation is not always being achieved and that the use of hand basins for disposing of wash water and rinsing respiratory equipment, may put the wash-hand basins

at risk of contamination from patients and indeed will increase the risk of contaminating the patient from the hand basin.

Whilst the increased provision of wash-hand basins with non-touch taps is likely to reduce HCAI risks, this effect may be countered if general purpose sinks and clean utility rooms are less available.

The significance of high water exposure procedures – bed baths, cleaning of medical devices in clinical areas, etc may expose patients to "infectious doses" of organisms such as *P. aeruginosa*, therefore a focus primarily on taps, associated pipework, and hand hygiene as the only approach maybe unwise. The interruption of transmission by sound hygienic and IC practice which are risk assessment based is the fundamental issue which must be adhered to, and all processes designed and maintained to separate "clean from dirty" in units where vulnerable patients are nursed.

It is also possible that the increased provision of hand hygiene stations will reduce the frequency of flushing because of a lower frequency of use and hence add to the risk of colonisation.

4. Evidence (Class 2-3 and above)* (see footnote in Section 5 for evidence key)

a) In some but not all instances, typing has shown that the contaminating isolates found in the taps are indistinguishable from those giving rise to colonisation and infection in the patients (2/3).

b) Available sources of utilisable carbon will support bacterial growth and promote bacterial growth in the presence of other supporting factors (1).

c) The use of certain grades of synthetic materials including some ethylene propylene diene monomer (EPDM) rubbers used in tap valve seals / solenoid assembly and flexible couplings/pipes can be evidentially associated with bacterial contamination specifically pseudomonas. It is thought that this relates to these materials being a source of utilisable carbon in bacterial metabolism. Although evidence conflicts it may be reasonable to assume that smaller, low surface area components potentially offer a reduced potential for available carbon release leading to enhancement of microbial growth (2/3)

d) It is clearly established that Pseudomonas is a successful organism in terms of biofilm colonisation.

e) Terminal filtration of water delivered from taps potentially subject to pseudomonal contamination by point of use filters appears, from published and private evidence, to be highly effective in constraining infection risk from this point source. (2)

A risk based approach for selective use of point of use filters may be appropriate.

f) Additional chlorination and / or the use of high temperature hot water supply and tap flushing techniques have been shown to be effective in suppressing pseudomonal contamination, at least temporarily. A periodic, controlled and monitored strategy may be effective in risk suppression*. (2/3)*

5. Evidence (Class 3-4)

a) Much of the emphasis, in engineering terms, has centred initially on non-touch taps, acting as point source as part of hand-wash facilities within the care units affected. Of this general type, those taps using TMVs have been emphasised. Further coincident/anecdotal/associative evidence of *P. aeruginosa* colonisation is also associated with Infrared (IR) controlled taps. (4)

b) In some cases, local prevention and control of infection teams working with estates professionals have acted to reduce perceived infection risk levels by removal of the TMV-IR taps and their replacement with conventional elbow or knee-operated types.

A number of reports from prevention and control groups suggest that these actions have resulted in an end to the current local outbreak and associated contamination. However, the Department lacks information on longer term outcomes from these actions.

There are several, good quality reports, e.g. Centre Hospitalier Universitaire (CHU) - Amiens, that indicate this measure has been effective in the short term but that the problem can reoccur even after exchanging taps for new non-TMV units. *(4)*

c) The extent of contamination within taps and associated pipes has been the subject of many local studies in England and other nations specifically including France. The findings from these studies exhibit a good degree of consistency. However, the sampling strategies used vary greatly between centres and this makes detailed comparison difficult. Key indications include: –

i) Contamination is often restricted to the last 1.5 to 2.0 metres length of the plumbing system measured back from the tap outlet. (3) This may be related to temperature or biofilm distribution but no specific correlating evidence has been found.

ii) Some contamination of whole or more extensive sections of water systems including storage tanks has been seen. Whilst many of the reports point to common non-humanised strains / types as involved it is not possible to exclude the possibility of drug-resistant and humanised organisms being present as no relevant studies have been performed. (4)

iii) In many instances residual water present within tap and TMV structures, when the tap is closed, is found to be contaminated. (4)

iv) Contamination levels or densities/occurrence are assumed to vary widely and show only limited, if any, correlation with outbreak probability on very limited data. (4)

d) In response to some instances involving legionella outbreaks, and in adopting the recommendations of DH (2010) 03 – Flexible Water Supply Hoses, local teams have reacted to outbreaks with strategies which involve the removal of EPDM based pipes / lines serving wash-hand basins and sinks. These components have then been replaced by standard rigid plumbing or components lined with as polyethylene (PE), cross-linked polyethylene (PEX), linear low-density polyethylene (LLDPE) and post-chlorinated poly vinyl chloride (PVC C). These actions are likely to have countered pseudomonal contamination to some limited extent(3/4)

e) There is some evidence to suggest that final Quality Assessment (QA) testing of specialist taps, at the end of the manufacturing process, using recycled water may be a source of Pseudomonas contamination. Some manufacturers, concerned on this issue, have introduced the use of biocides, UV disinfection of the water used in the QA process or initiated post manufacture disinfection processes in an effort to reduce contamination. (4)

* The evidence classification used in sections 4 and 5 of this document is categorised into levels 1-4 as follows:

Levels of Evidence	
Level 1	*Meta-analyses, systematic reviews of randomised controlled trials, or randomised controlled trials.*
Level 2.	*Systematic reviews of case-control or cohort studies, or case-control or cohort studies*
Level 3	*Non-analytic studies, e.g. case reports, case series.*
Level 4:	*Expert opinion (in the absence of any of the above). This includes the views and experiences of patients and their carers.*

Note: The evidence grading exercise for this document was not subjected to systematic review

6. Published evidence

a) The Health Protection Agency (HPA) has recorded an increase in pseudomonal bacteraemias in England (http://www.hpa.org.uk/web/HPAwebFile/HPAweb_C/1281952800376):
"From 2005 to 2008, there was a 20% increase in the number of Pseudomonas spp. bacteraemias reported to the HPA (3,297 reports in 2005 compared with 3,957 reports in 2008), reducing slightly by 2% in 2009 to 3888 reports. In 2009, 90% of Pseudomonas spp. Isolates from bacteraemia were identified to species level (3,483 reports), with 93% of these identified as P. aeruginosa."

b) The published literature contains reports of similar problems from other countries in Europe, the Americas and the Far East. (see *Annex C* for bibliography of published literature)

Discussion - The extent of this problem and any relationship with increased episodes of bacteraemia within the health service in England is unknown. Although a number of outbreaks in major units are known it is not possible to assess the potential for future harm. A survey is required to establish the extent of the problem.

7. Potential contributing factors

a) Design and maintenance issues

i) Temperature of circulating water. To control the proliferation of legionellosis hot water is stored at 60°C with a requirement that the return temperature is no lower than 50°C. The system should be designed so that the hot water temperature at the inlet to TMVs and water outlets is 55°C at the most distant outlets. The current guidance for the health service is contained within HTM 04-01.

Anecdotal evidence has been presented that many hot water distribution systems are badly designed, maintained or installed leading to problems in ensuring the correct hot water temperature is maintained throughout the system.

Discussion - Control of biofilm is an important factor in the prevention of the proliferation of legionellosis and pseudomonas. However care should be exercised in assuming that maintaining a temperature regime that is effective for the control of legionellosis will also control pseudomonas to the same extent, i.e. there are reports of strains of pseudomonas adapting or evolving to become temperature tolerant (Université de Picardie Jules Verne (University of Amiens)).

Thermal disinfection has been utilised in certain healthcare establishments (e.g. Centre Hospitalier Universitaire de Tours) as a control mechanism as either a routine task or when sampling reveals pseudomonas contamination of an outlet.

In areas of augmented care such as intensive care units, consideration should be given to circulating hot water within the distribution system above 60°C (this could possibly be achieved by having a local hot water system dedicated to the intensive care unit). In addition, if a survey indicates extensive contamination of these systems additional supervision and maintenance will be necessary.

ii) Use of TMVs that are compliant with the BuildCert TMV3 Scheme. To further reduce the risk of scalding these valves have been introduced so that water at the outlet does not exceed 41-43°C. The design of these valves may have inadvertently increased the risk of the formation of biofilms by the use of:

- plastics and rubbers that release utilisable carbon sources and may not withstand prolonged periods of pasteurisation above 80°C, however some manufacturers state that their equipment

can be safely exposed to higher temperatures, certainly to 85°C;

- low pressures that discourage a level of turbulence that might minimise the formation of biofilms are of interest, however, a full systems analysis would be necessary for each type as the tendency to turbulence is unlikely to be related to pressure in a simple linear way;;
- residual volumes within the valve that would encourage stasis and bacterial growth.

Discussion - Manufacturers should be encouraged to seek alternative designs that reduce the risk from the above problems by minimising the use of materials (including reduction of surface area) that may release utilisable carbon and by designs that do not leave residual volumes of water and will withstand a higher level of chemical and heat disinfection.

iii) Use of solenoids and infrared switch operation. In its desire to reduce hand contact points to control MRSA, many augmented care units have moved to infrared operated taps, which are switched by the use of a solenoid. These devices usually require the use of an artificial rubber diaphragm which because a greater surface area will further increase the amounts of utilisable carbon sources available and the area on which biofilm can locate.

iv) Materials used in manufacture. These are detailed in "*BS 6920*, *Suitability of non-metallic products for use in contact with water intended for human consumption with regard to their effect on the quality of the water".* Part 2.4 being concerned with testing the ability of materials to support microbial growth. The method described is one based on measuring dissolved oxygen utilisation.

The appropriateness of BS 6920 part 2.4 for use in critical health uses has been questioned. It is understood that a new European standard for assessing Enhancement of Microbial Growth, containing the current national methods used in Germany, the Netherlands and the UK, is currently being considered in Europe. The national drinking water regulators for France, Germany, the Netherlands and the UK are currently considering whether the test methods being prepared by CEN could be used in the development of mutually acceptable approval of products for use with drinking water within these four Member States.

In the light of the known problems they should be encouraged by the appropriate authorities to consider issues in relation to augmented care situations in healthcare establishments with respect to materials approval and microbial growth, and whether more demanding test criteria should be developed for these situations

v) Delivery of non-colonised, pathogen free devices (TMVs and taps). Post manufacture all devices will, in all probability, have been tested using a test rig which will have introduced water into the valve. There is no recommendation that taps or TMVs should be delivered, installed and commissioned in a clinically clean manner.

Discussion – Note: there is no definition of "clinically clean", the devices when delivered should be non-colonised, pathogen free and installation should not introduce contamination (this implies special precautions to obtain something approaching aseptic conditions). The level of maintenance and supervision within intensive therapy units should be increased to detect potential problems. It remains a requirement that all fixtures should be capable of successful decontamination post installation

The manufacturers questioned the requirement to deliver non-colonised, pathogen free products. They raised the issues of TMVs and taps being installed as part of construction and renovation of healthcare premises where any disinfection process at the factory would be wasted.

(also see above (5 e)) regarding observations in relation to the use of water in the QA testing of specialist taps, at the end of the manufacturing process)

b) Practice issues.

i) Clearly, the use of a hand hygiene basin for disposal of any fluids or for washing patient equipment (i.e. anything other than hand washing) will risk contaminating both the outlet and the tap.

ii) The absence in many organisations of dedicated 'decontamination facilities' at the local clinical level to support effective decontamination of items such as reusable and single patient use medical devices

iii) Using contaminated water to rinse clinical equipment such as respiratory equipment or to manufacture ice for physiotherapy are recognised hazards.

iv) The use of terms such as single patient use, common for example in respiratory equipment, is known to be a challenge for best practice in decontamination due to the logistical issues associated with compliance with the decontamination cycle in dedicated facilities. The use of single use equipment carries financial and environmental risks

v) Clinical wash-hand basins and other water outlets should be cleaned in the correct order to prevent contamination with *P. aeruginosa.*.

vi) The use of water from a contaminated source to carry out bed bathing will pose a greater risk than using the water for hand hygiene.

Discussion - Clinical practice guidelines require review to ensure that the use of water within intensive therapy units minimises the risk of contaminating the patient with potentially harmful organisms. The increase in the number of hand hygiene sinks may also have led to low usage adding to stagnation and increased risk. The extensive use of alcohol hand rubs may also be a factor in this consideration (also see Recommendations and section 3 e) above)

8. Constraint of bacterial contamination of water supply

Utilisable carbon sources *(NB: many published papers show pseudomonas is particularly evolved towards the utilisation of carbon sources)* - to grow planktonically a bacterial requires a carbon source which might originate from:

a) the mains supply, this will depend on the sources e.g. groundwater, borehole etc;

b) within the hospital water distribution system (storage tanks, pipework, TMVs, tap outlets);

c) extrinsic sources at the point of use, in the case of hand hygiene stations this could be the use of chemicals such as chlorhexidine gluconate or the condensation of isopropyl alcohol (Poynter and Mead 1964. J Applied Bact, 27 (1); 182–195).

Discussion - This area has not been explored in recent years and changes in engineering in clinical practice will not have taken this into account. Because the potential contributing factors are not fully understood it is necessary to explore the part played by carbon sources to this problem. Research into this area is required to establish whether external carbon in the mains water or extrinsic sources or neither contribute to the colonisation of water resources in health care

The following points provide further observation and discussion in relation to Design and maintenance issues and Constraint of bacterial contamination of the water supply.

d) Reduction of biofilm mass/integrity/thickness

If the evidence of a connection between pseudomonal contamination and biofilm build-up is seen as persuasive then biofilm suppression may be regarded as a relevant factor. This has implications for design and choice of materials used in tap construction (see h) and i) below) and pipework fabrication (including flexible pipework). In addition, preventative maintenance techniques, which remove biofilm, are of potential interest.

Several groups within industry strongly advocate the use of a holistic Quality Systems approach in the matter of biofilm suppression in water delivery

systems (NB: This is also the course of action laid down in HTM 04-01 and L8).

e) Reduction of available carbon

A wide range of potential carbon sources may be present. These include environmental contributors as well as those related to the construction of the taps, associated TMVs and plumbing system. Reduction in the release of available carbon or its removal by filtration may be influential in reducing pseudomonal contamination risks.

At least one tap/TMV manufacturer has developed a pressure based flow control system (for the USA) such that thermal control can be maintained without the use of valves with synthetic seats/seals. Not yet approved for the TMV3 approvals scheme

f) Suppression techniques

There is evidence to support the use of additional chlorination techniques as a way of interrupting a contamination/colonisation cycle. However, the evidence on any lasting effect, within plumbing systems, is equivocal. In addition, careful control is necessary in order to avoid the risk of corrosion.

TMV and tap manufacturers have also expressed concerns regarding the compatibility between certain biocides and the materials used in the construction of taps/TMVs and pipework. Incorrect use of biocides can cause damage to the internal components of the water distribution system, including TMVs and taps. It can lead to the provision of roughened surfaces through pitting that can aid bio-film proliferation.

The use of high-temperature flushing has also been used, particularly in France, where the hospital water supply technology supports the technique. Several references support the application of flushing at 70 C at outlet for 30 minutes. This however, has implications for staff safety. In England, local supplementary heating of hot water supplies in affected areas may be viable but DH is not aware of any concerted pilot to date. Variations on this technique including the use of steam injection have been used.

Other techniques including UV irradiation of water close to tap outputs were postulated within the project working groups as an area for possible targeted development by industry. Recent information has indicated that one manufacturer has developed this technology for legionella control (trial ongoing in Belfast). The manufacturer has offered to participate in trials with two English Trusts to determine the efficacy with respect to pseudomonas.

The use of local production of copper/silver ions has been proposed for planktonic pseudomonas control, it is currently utilised for legionella control in some UK hospitals. However, concerns exist on the effects of perturbation by other ionic species including calcium in hard water areas or when such water is imported to supplement local supplies.

g) Disinfection techniques and contamination.

Concerns have arisen from anecdotal evidence concerning techniques used to clean wash-hand basins. The possibility that pseudomonas bacteria are contaminating cleaning cloths/materials which are then being brought into contact with tap outlets (spout) has been raised though no direct evidence of this effect has been seen.

At least one manufacturer of tap systems is moving to offer taps with interchangeable spouts, which may be single use, or in other designs suitable for steam sterilisation. There is no doubt that these techniques will remove the local contamination but may leave organisms present in adjacent pipework. To counter this one manufacturer has engineered their system such that the whole tap and adjacent pipework assembly can be removed, replaced by a spare unit and the original system steam sterilized.

h) Design factors in taps and related plumbing systems

The primary aims of development within some tap/TMV manufacturers programmes embrace the reduction of biofilm deposition and minimisation of residual water volumes present when the tap is closed.

Work is being done on the biofilm deposition and indeed scavenging characteristics in relation to water flow patterns within the tap systems. This is a subtle area with some design engineers promoting linear flow as a means of avoiding deposition whilst others advocate the deliberate induction of turbulence to scavenge the pipe/tap internal walls. Similar arguments apply to surface finishes with both smooth and roughened finishes being evaluated.

The business of minimising residual water within the tap, TMV and pipework is complex. In addition, the availability of utilisable carbon within these wet, potentially contaminated structures appears to be a powerful compounding factor (i.e. oxygenation when air is present). Manufacturers are pushing to minimise these volumes and to develop means of flow control, which do not depend on a valve closure onto a synthetic rubber seat or seal.

Additionally flushing patterns, in some cases under firm or software control are used to displace residual water particularly in systems subject to intermittent or infrequent use. Some manufacturers, particularly in France, have combined this flushing with the use of high-temperature hot water to provide an additional decontamination effect. Where this is practice is utilised precautions are required to protect against scalding, as the protective effect of the TMV is not in play during programmed flushing.

i) Materials employed for tap and plumbing system construction

The choice of materials used in the construction of tap, TMV and pipework is the focus of interest in view of the potential bacterial suppression

available from copper and the potential converse effect from synthetic rubbers.

Private evidence was presented to the DH team on the effect of certain alloy compositions on the bacteraemia contamination levels seen when taps are not used for periods of time. This suggests that marked effects can be obtained particularly when combined with flow characteristics, which minimise biofilm build-up and the use of pressure based flow control systems, which do not require synthetic rubber seats.

j) Water quality considerations.

Pseudomonal contamination might be seen as one part of a larger picture of water quality and fitness for purpose. The World Health Organisation (WHO) and the UK Drinking Water Inspectorate both provide (very similar) standards on potable water quality suitable for drinking and general purposes. However, these standards primarily apply to the water supply to the site/building (at point of entry) and may not always clearly relate to water discharged from a tap at the point of use. (Utilisable carbon limits within standards may be significant here).

The French Health Ministry provide guidelines on water quality within healthcare premises in their technical guide *L'eau dans les établissements de santé.* A similar set of guidelines for use by healthcare providers in England and the Devolved Administrations may be advantageous.

9. Development of Policy and guidance options.

The existing provisions are described in "Current guidance and protocols" above. Within the current Policy structures, any new guidance etc. would need to be:

a) Based on properly evaluated evidence.

b) Related to outcomes in terms of patient (staff) safety and experience of care.

c) Be directed towards commissioners and the commissioning process as well as the needs of care providers.

d) Have clauses related to measurable parameters, which may be assessed at audit and used in Care Quality Commission (CQC) licensing and inspection processes.

e) Allow a range of options, for local choice (in the structure of a CFPP), in terms of the measures taken and how they are applied to a given care process within a specified environment. (e.g. selective application of filtration following monitoring results)

f) Be derived from work contributed by learned, professional and industrial bodies within a policy and directive framework provided by DH. Much of this would relate to the requirements of the 2010 revision of the Code of Practice on the prevention and control of infections and related guidance.

g) Subject to constant upgrade as required by evidential changes or alterations in care practices.

h) Cost per Quality Adjusted Life Year (QALY) saved.

ANNEX C

References

Web-links

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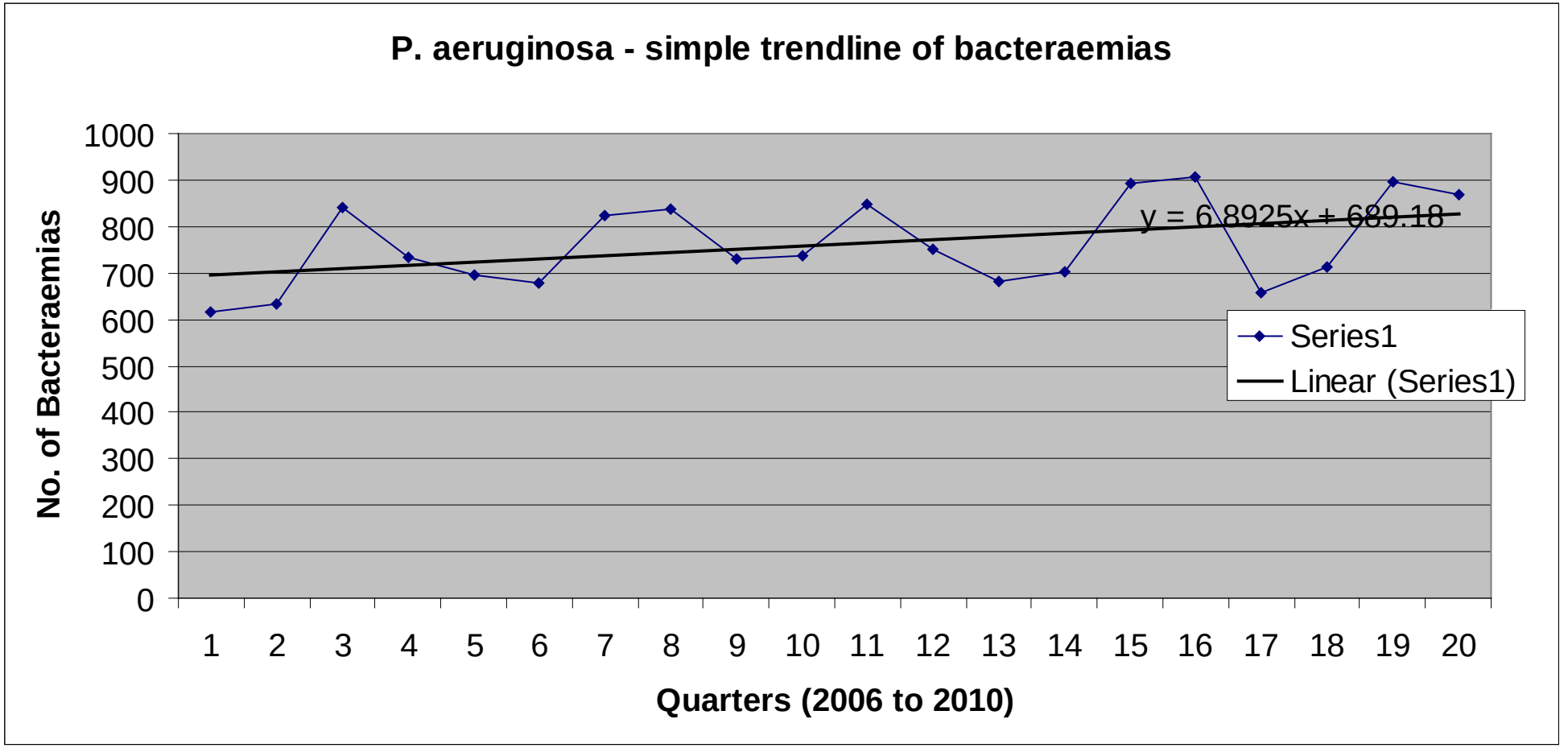

The data utilised to produce the chart above was supplied to Dr M Kelsey by Dr A Johnson (HPA Centre for Infections) on 4th March 2011

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