

**Health and Social Care Overview and Scrutiny Committee, January 17<sup>th</sup>, 2008**

**Report of the Director of Public Health, Dudley PCT/MBC**

**Report on health care standard C4c, Decontamination**

**Purpose of Report**

To provide reassurance to the Committee regarding Dudley PCT's ongoing actions towards compliance with the Healthcare Standard on Decontamination of Medical Devices.

The Standard, C4c, is one of those in the Healthcare Commission's Standards for Better Health - First Domain – 'Safety'.

The standard states:

Health care organisations keep patients, staff and visitors safe by having systems to ensure that: all reusable medical devices are properly decontaminated prior to use and that the risks associated with decontamination facilities and processes are well managed.

**Background**

The PCT has a responsibility, under The Health Act 2006: Code of Practice for the Prevention and Control of Healthcare Associated Infections, to ensure that their own and commissioned providers comply with all the national standards on decontamination when providing services.

The process of decontamination of medical devices in healthcare setting has remained unchanged and largely unchallenged for decades. The word decontamination is used to encompass three processes which may be used jointly or alone to rid an object of harmful substances; it comprises the processes of cleaning, disinfection and sterilisation.

In Dudley PCT, and many other community health settings across England, the current decontamination processes for high risk instruments (which require sterilisation), no longer comply with the National Standards on decontamination. The National Standards are predicated on the requirements for decontamination of the highest risk instruments in the highest risk settings.

The current national standards have been developed primarily to ensure protection of staff and patients from Transmissible Spongiform Encephalopathy (TSE) producing agents, known as Prions.

The exact mode of transmission of prions is unknown in many instances, but there is evidence of its transmission to humans through the consumption of affected meat (Mad

cow disease) and transmission of the agent to recipients of blood transfusion and donor organs has been proved.

Prions are unlikely any other infectious agents. Most infections are caused by micro-organisms which are 'alive' and have DNA or RNA. Micro-organisms which cause disease are known as Pathogens. Pathogens can be killed by various means. Some pathogens are more fragile than others. Many are killed or deactivated by cleaning with detergents alone, others require the addition of disinfectants to kill or deactivate them while others require cleaning and sterilisation.

Theoretically infectious agents and organisms can be transmitted to patients via contaminated medical devices.

The common pathogens which cause Healthcare associated infections; such as MRSA, *Clostridium difficile* and other bacteria are susceptible to routine decontamination processes, and in many cases are killed by cleaning with detergent alone.

Prions are, however not killed, even by sterilising since they are not alive. They do not have any DNA or RNA, they exist as protein only. The mechanism by which they replicate and 'infect' a host is largely unknown.

There is a theoretical risk that sterilising instruments, that may still have prion protein on them, may 'fix' the prion to the instrument. The emphasis on decontamination has therefore now been placed on the cleaning process which needs to take place before instruments are sterilised.

The greatest risk of prion transfer is from devices used on patients known to have prion disease, and from devices used on these patients for certain procedures.

The highest risk of prion transmission is on instruments used for neurosurgical, ophthalmic and central lymphoid tissue (tonsil and adenoid) surgery. However with the knowledge that prions have been transmitted by blood transfusion there is an argument that there is potential risk from all instruments contaminated by blood. The science regarding the level of risk of prion disease is not exacting and much is unknown about this infectious agent.

Dudley PCT has conducted infection control audits of its healthcare premises and found that by applying the new decontamination standards (which apply to hospital sterile service departments) the scores were low.

Based on her knowledge of the limited world-wide knowledge on prion disease the Nurse Consultant in Communicable Disease made an assessment of risk for the procedures and medical devices used by the PCT.

The PCT does not perform any procedures involving neurosurgical, ophthalmic or lymphoid surgery, although we may commission other providers to perform these procedures and have a responsibility to ensure they comply with the extensive and rigorous recommendations in this regard.

Most of the procedures performed by the PCT staff and PCT provider services would be classed as low risk for prion transmission – but that does **not** mean no risk.

The majority of 'surgical' procedures performed by PCT service providers are Dental Surgery, Contraceptive and Sexual Health (C&SH) related procedures and podiatric procedures.

As stated earlier the science and knowledge is uncertain regarding the true risk and transmission potential for prions.

### **Highest to Lowest Risk (for the PCT activities)**

The highest risks within the PCT settings lie with instruments used in deep body cavities or where the likelihood of the instruments being contaminated with blood and body fluids is high.

#### **Dental Surgery**

The highest risk, for the PCT, sits with instruments used for Dentistry.

#### **C&SH procedures**

The next highest risk is with instruments used by the C&SH service for insertion or removal of intrauterine devices since these instruments access a sterile body cavity and are likely to be contaminated with blood and proteinaceous material.

#### **Podiatry**

The lowest risk (**not** No risk) is with instruments used on skin and subcutaneous tissue – such as those used in podiatry.

The risk assessment was raised within the PCT and the Executive Management Team actioned the production of Business Cases from the Provider services outlining resource requirements in order to comply with the standards.

### **Finance**

5. The estimated annual costs of ensuring compliance with national decontamination standards in PCT premises and services was estimated to be approximately £700,000 for the year 2007/08, with over 90% of this sum being recurrent annual costs.

The business case compiled by Community and Primary Care Directorate was taken to Executive Management Team on 2<sup>nd</sup> May 2007.

The following decisions were made:

1. The MT wished to move to full compliance with current decontamination guidance on a phased basis, as funding will allow.
2. There was £0.3m recurring revenue available from 07-08 onwards.

### **Law**

6. All NHS bodies must comply with the legislation laid down in The Health Act 2006: Code of Practice for the Prevention and Control of Healthcare Associated Infections.

### **Equality Impact**

7. The standards and policies relating to decontamination of medical devices apply to all persons working or living in Dudley, regardless of race, disability, gender or other relevant group.

### **Recommendation**

8. It is recommended that the Committee note the contents of the report.

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### **List of Background Papers**

The Health Act 2006: Code of Practice for the Prevention and Control of Healthcare Associated Infections. Department of Health. October 2006.

Decontamination of Surgical Instruments Dudley Primary Care Trust Premises – Position Statement, January 2007

Decontamination Report to Executive Management Team, 2<sup>nd</sup> May 2007

Towards Compliance - The Health Act 2006 - Code of Practice for the Prevention and Control of Health Care Associated Infection, PCT Board 6<sup>th</sup> August 2007