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Aseptic Service Audits Performed Under EL(97)52

Background

During 1994 two children died in Manchester Children's Hospital as a result of receiving contaminated intra-venous feeding fluids prepared by the Pharmacy Department. The preparations were made under Section 10 exemption (to the 1968 Medicines Act) and therefore did not require a manufacturer's "special" licence (marketing authorisation) from the Medicines Control Agency (MCA). The granting of such a licence follows stringent inspection of the site and regular inspections thereafter.

An investigation by the Medicines Control Agency during 1995 showed serious deficiencies in many aspects of the aseptic (sterile) facilities and procedures adopted by the Pharmacy that led to microbiological contamination of the feeds from the sink located in the preparation room. A subsequent investigation throughout the United Kingdom performed by the MCA on behalf of Ministers found that an estimated 60% of NHS hospital had failings in their aseptic services that would present a risk to patient safety.

The NHS was then required to perform under EL(96)95 an internal audit of all hospitals preparing products under Section 10 arrangements. A report published in 1996 showed figures that agreed with the MCA.

During 1997 EL(97)52 was issued which required external audit, at an interval of 12 to 18 months, of all hospital pharmacy departments preparing injections under Section 10 exemption. Audits to be carried out by regional pharmacy quality assurance officers with reports made to trust chief pharmacists, trust and health authority chief executives and regional offices (for regional pharmacists and performance managers).

EL(97)52 was incorporated within Controls Assurance, Medicines Management, Criterion 5.

Present Position (within NHS England London Region, and NHS England South Region – South East Coast, Wessex and Thames Valley)

An audit programme is in place, maintained and with the work being performed by Regional Pharmaceutical Quality Assurance, Specialist Pharmacy Service based in the Guy's and St Thomas' NHS Foundation Trust.

The risks to patient safety since 1994 remain the same but the level of risk has been reduced through audit and this can be demonstrated. In more recent year's reduction in money to the NHS along with drives to improve efficiency have again raised the risk both in the condition and maintenance of aseptic units and their operation. These risks include:

- Aging and deteriorating poorly maintained facilities
- Inability to recruit and retain suitably experienced professional and technical staff
- Failure to train professional and technical staff
- Difficulties in retraining rotation staff
- Lack of succession planning for key staff
- New facilities poorly built and commissioned
- Poorly considered impact of trust mergers and rationalisation of services on pharmacy technical services
- Increasing work loads
- Poorly delivered provider services
- Failure to maintain sufficient workload to ensure staff competency

Another threat is changing requirements for a unit that take place within the life cycle of the new or refitted building project. This may be as simple as an increase in the preparation capacity required or a change in the requirements of the medicines being handled e.g. biological medicines.

On a similar note is the increasing requirement to purchase suitable unlicensed aseptic products where appropriate. These require additional space to receive, examine, store and dispense; this may be in the aseptic unit or elsewhere in the pharmacy. A driver for this is Medicines Optimisation that may see moves to once again to attempt to centralise NHS aseptic preparation and close the smaller, older and less efficient aseptic units. A caveat here is that closing a Trust's aseptic unit may impact on the ability of that Trust to participate in clinical trails requiring dispensed aseptic products or handle new biological medicines.

Martin Knowles
Director Pharmaceutical Quality Assurance 11 January 2017