



Tallaght Hospital

Completing Self Inspection Audits in the Pharmacy Aseptic Unit (AU)-The Tallaght Experience

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INTRODUCTION

H/PICs are national Irish guidelines of professional practice developed by pharmacists working in aseptic compounding units. Chapter 9 advises that 'a self-audit programme should be established and conducted in an independent and detailed way by designated, trained, competent people'¹. In order to adhere to these guidelines a self-audit of the premises and equipment section (Chapter 3) of the H/PICs was completed. This section was selected as the aseptic unit (AU) was built in 1998 and guidelines have changed since this time.

OBJECTIVES

To complete a self-audit against chapter 3 of the H/PICs guideline.

To implement changes where possible.

To escalate issues to the hospital's executive management team (EMT) where required.

METHODS

Training courses specifically geared for personnel working in pharmacy AUs were sourced and attended. Skilled auditors within the hospital setting were identified and these auditors were shadowed. This in turn led to the further training with this core group of experts.

An audit checklist was designed using a combination of templates presented at training courses. (See table 1)

An audit was completed in March 2015.

Non conformances (NC) were graded and actions required were detailed.

Corrective and preventative actions (CAPA) were put in place where possible. (See table 2)

Major/critical NCs not corrected in the pharmacy were escalated to the EMT for their support.

Unresolved NCs were escalated to hospital group level and placed on the Dublin Midlands Hospital Group risk register.

RESULTS

Training courses enabled the author to acquire the skills to complete this self audit. Identifying and linking in with skilled auditors in the laboratory enabled local support.

RESULTS (continued)

A checklist for the premises and equipment section of the H/PICs was prepared (see table 1). The statement, taken from the guideline was converted into individual questions. Using this template an audit was completed. The evidence to support compliance was documented. The type of assessment completed was listed. The result indicated the level of compliance with the guideline and it was graded according to the key in table 1. The scoring system applied was discussed with an audit inspector from Northern Ireland at a follow up training day. The proposed actions were detailed.

Table 1-Completed Checklist-Chapter 3 Premises & Equipment H/PICs

There were 32 sections in this chapter and 15 NCs of various grades identified. 9 of these were rectified within pharmacy department resources. For example (see table 1) the particle counter used as part of the quality management system was in itself, a potential source of contamination. The device was old, difficult to clean and contained paper. This device was graded as a major NC under a number of statements. The corrective action (action taken to eliminate the cause) was to only use this equipment during downtime to avoid the contamination risks. The preventative action (action taken to eliminate the cause before it happens) was to source a new model which complied with the guideline. A business case was prepared and the product was purchased.

The results of the audit were presented to individual members of the EMT. NCs requiring financial support, for example purchasing closed systems, updating the current facility and increasing staffing levels were highlighted (see table 2).

RESULTS (continued)

Guideline No.	Risk	Non-Compliance Grade	Corrective Action (CA) or Preventative Action (PA)	Date completed by	Preventative Action (PA)	Action to date	Final Outcome
3.2.2	Are careful and aseptic working techniques employed to reduce the risk of contamination?	Minor Non-compliance	Prepare MABs in separate isolator	11/05/15	Purchase a closed system which reduces the prevent risk of cross contamination. EMT on 24/05/15. Cost €10,000 but system would pay for itself due to associated viral savings.	Business case presented to EMT on 24/05/15.	Waiting final financial approval.
3.2.1	In the capacity (total and usable) sufficient to enable a logical workflow?	Major Non-compliance	Maximize throughput by improving process improvement tools. Decrease cost neutral products. Prioritize compounding over all other activities.	Ongoing	Upgrade the infrastructure of the AU to support the workflow.	No capital funding available in 2015.	Placed on Dublin Midlands Hospital Group Risk Register
	AU capacity plan identified indicates a staffing deficit of 1 FTE pharmacist & 2 A/PE technicians based on workload.	Major Non-compliance			Increase staffing levels to support the workflow.	Business case presented to EMT in December 2015. Escalated with changes to 2016/16.	Waiting final approval.
3.2.4	Are washing and cleaning activities a	Critical	Identify QC SOPs in place which monitor the microbial activity in this location.	Ongoing	Upgrade AU to comply with guidelines.	No capital funding available in 2016.	Placed on Dublin Midlands Hospital Group Risk Register

Table 2 –Actions Taken in Response to NCs

There are major staffing deficits in the AU and a business case to rectify these shortages was prepared. This awaits final approval by the EMT. The audit highlighted many deficiencies in the infrastructure of the AU. It was built in 1998 when activity was 200 item/month, it is now 1000. There are no change facilities (table 1) and there is a sink adjacent to the preparation room (table 2). These structural risks/constraints could not be remedied despite consultation with facilities and estates department. It is agreed that a new AU is needed, however this requires significant capital funding (>€2 million). This upgrade has been highlighted at hospital group level and with the NCCP. In the meantime the risks have been added to the Dublin Midlands Hospital Group risk register by the EMT detailing the controls currently in place.

CONCLUSION

Self-audit is an invaluable tool and aids compliance with H/PICs guidelines. It allows the identification of high risk activities. Grading NCs assists in the prioritisation of process improvement projects. Audit supports the feedback of performance against recognised guidelines to management. This has assisted in raising their awareness and gaining their support. It has resulted in positive changes for the AU and highlighted future needs.

REFERENCE

1. H/PICs National Guidelines for Aseptic Compounding in Irish Hospital Pharmacy Practice

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