

DOES AUDIT IMPROVE QUALITY IN A HOSPITAL MANUFACTURING UNIT?

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- **OBJECTIVE** - To establish whether auditing improves the overall quality of a hospital manufacturing unit
- **DESIGN**- Continuous assessment of the quality level of a hospital manufacturing unit using 14 quality indicators over a nine-month period, and two periods of audit carried out towards the beginning and end of the assessment period
- **SETTING** - The non-sterile manufacturing, sterile manufacturing and repackaging services areas at the pharmacy manufacturing unit at Queens Hospital, Burton-on-Trent
- **RESULTS** - Compliance ratings for the second audit were better than those for the first audit, but there was no overall improvement in quality over the study period
- **CONCLUSION** - Auditing probably improves compliance by focusing the minds of the staff involved, rather than by initiating a sustained improvement in overall quality

During the past decade, the definition and measurement of quality have been important issues within the NHS. Internal audits have been established as a method of measuring quality,¹ both at ward level and within specific departments such as pharmacy. Other methods include external audits, which are used for legislative purposes, for example inspections of pharmacy manufacturing units by the Medicines and Healthcare products Regulatory Agency.

As well as providing a means to measure quality, regular internal audit is believed to improve performance. For example, a study conducted in Greater Glasgow showed that 94 per cent of the staff questioned thought internal audits promoted improvements.² However, it is unclear whether improvements in compliance over a previous audit that are recorded during a subsequent audit are the result of a sustained improvement in quality, achieved because deficiencies have been recorded and acted upon, or if improvements are merely initiated when audit takes place and are followed by post-audit lapse.

The present study was designed to assess if the audit process developed within the manufacturing unit of the Pharmacy Department at Queen's Hospital in Burton-on-Trent produced a real positive effect on the level of quality of the department or merely influenced subsequent audit results by focusing attention on the audit process.

METHODS

Setting The study was performed in the three areas of the manufacturing unit (non-sterile manufacturing, sterile manufacturing and repackaging services) at Queen's Hospital in Burton-on-Trent. The non-sterile manufacturing section produces an average of 4,250 units a month (from a range of 152 products), the sterile manufacturing section produces an average of 1,872 units a month

(from a range of 38 products) and the repackaging section produces an average of 10,957 units (from a range of 107 products). The study period lasted for nine months.

Audit design Audits were conducted towards the beginning (January) and end (June) of the study period. The audits were designed using established standards (ie, rules and guidance for pharmaceutical manufacturers and distributors 1997, the quality manual of the production unit concerned and various regulatory requirements) to which the manufacturing unit should conform.

The model developed by the National Total Nutrition Service was adapted for use to avoid "reinventing the wheel", which is often seen in auditing.³ An audit was tailored for each of the three areas (non-sterile manufacturing, manufacturing and repackaging services) within the manufacturing unit. Sections on, for example, personnel, premises, equipment, documentation, quality control and quality assurance were included in the audit of all three areas. Additional sections on, for example, environmental acceptability and sterilisation were included where they were appropriate for the area.

A selection of audit questions was developed and phrased so the auditor could easily decide if the area being audited achieved compliance or not. The audit questions aided the auditor, by acting as a checklist, ensuring that important areas were not overlooked and that the audit was conducted in a systematic and structured manner. A written guidance document was produced, enabling the audit to be carried out in a concise manner. It was essential to the study that the results were reproducible and free from influences that could affect objectivity. The guidance ensured that each auditor assessed the unit by the same criteria. This enabled an accurate conclusion to be made from the audit results.

The audit definitions were written in lay terms to enable ease of understanding and accurate application. To comply with "The

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guide to good manufacturing practices for medicinal products 1997” and regulatory requirements, the aim of the audit was stated to the auditors. This was “to determine the conformity or non-conformity of the quality systems and operating procedures that are in place within the production unit”. The audit format also allowed for comments and remedial action for each of the audit questions.

To ensure no confusion was caused by the results rating scheme, the four possible outcomes to each audit question were defined as follows:

- **Compliance** Means that you cannot detect anything wrong with what is being examined (score of “1”).
- **Minor non-compliance** Means that you think that what is being examined is adequate but you can identify an improvement that can be made (score of “2”).
- **Major non-compliance** Means that you can see quite a wide range of faults within this area and can identify major improvements that need to be made (score of “3”).
- **Critical non-compliance** Means that what you see is not complying at all with the requirements and that immediate action is needed to rectify the situation (score of “4”).

For the audit to be completed, it was essential that there was a method for ensuring corrective action was taken in the event of non-compliance. A non-compliance form was completed if the auditor recorded a score of three or four to an auditing question. Corrective action schedules arising from both the written and oral non-compliance information were put into action within two weeks of the auditing process. Where a score of 2 was given, the reasons behind the score were explained to all staff members via a debriefing session and an internal memorandum, which listed all the minor non-compliances for each area audited and the corrective action proposed. This method was chosen to rectify minor non-compliances because it was quick and included all members of staff in the quality improvement technique. Corrective action schedules were put into operation within two weeks of the auditing procedure.

Over the two set auditing periods (each auditing period lasting two weeks), each of five auditors performed an audit in each of the three areas once in each audit period. Hence a total of 30 audits was performed. The five auditors chosen were all senior pharmacists or technicians working within the manufacturing unit.

The resulting compliance rating for each section from each auditor was determined by totalling the compliance score by an auditor for each question within a section of

the audit (the higher the score, the less compliant the section was). The compliance ratings for each of the audited sections performed were totalled to give the average compliance result for the audit.

Quality assessment The continual assessment of the three primary areas of the manufacturing unit was achieved by obtaining an actual overall weighted quality index value for the entire manufacturing unit for each month within the nine-month study period, and comparing it with a target overall weighted quality index value.

To obtain the actual and target overall weighted quality index values, 14 quality indicators were designed. These were chosen and designed to cover sections of the manufacturing process under direct control of the manufacturing department staff. For each indicator a target performance standard was set.

A “quality index” was then set up (see Panel 1). This comprised a series of performance standards, which translated into a quality index value. The index was set up such that the target performance standard generally translated to an index value in the middle of range (ie, 5 or 6) except where the target performance standard was either zero or 100 per cent, where the target quality index value necessarily corresponded to the end of the range (ie, 10). The better the performance, the higher the corresponding index value.

Weightings for the indicators were then established, according to how important achieving the relevant target performance standard would be to the customers or patient’s perception of the service they received, and to the department’s assessment

of the quality of the product produced. The highest weightings were given to indicators that could affect the quality of the product (for example, indicators 8–11). Lower weightings were given to the other indicators, which related to service issues. By multiplying together the relevant quality index value and weighting and dividing by 100, weighted quality index values were obtained. Adding together all 14 weighted quality index values gave an overall quality index value for the manufacturing unit (see Panel 2, p408).

RESULTS

Audit results There were large differences between the compliance ratings given by the different auditors (data not shown).

Table 1 (p409) shows a summary of all audit results produced by averaging the five auditors scores from each of the three sections of the manufacturing unit for both the initial audit (January) and the final audit (June).

It is evident that compliance increases (ie, scores decrease) between the two audits for all three sections. Repackaging services improved by 17.2 per cent, non-sterile manufacturing by 13.3 per cent and sterile manufacturing by 12.7 per cent. Although repackaging services showed the greatest improvement in compliance, non-sterile manufacturing with a deviation from total compliance of 17.9 per cent had the closest result to total compliance. Second was sterile manufacturing with 22.0 per cent and repackaging services was third with a deviation of 25.7 per cent from total compliance. These differences have to be interpreted carefully, because they do not take into account differences such as, for example,

Panel 1: The “quality index”

Quality indicator	Index value									
	1	2	3	4	5	6	7	8	9	10
1	40%	45%	50%	55%	60%	65%	70%	75%	80%	85%
2	55%	60%	65%	70%	75%	80%	85%	90%	95%	100%
3	91%	92%	93%	94%	95%	96%	97%	98%	99%	100%
4	91%	92%	93%	94%	95%	96%	97%	98%	99%	100%
5	50%	45%	40%	35%	30%	25%	20%	15%	10%	5%
6	82%	84%	86%	88%	90%	92%	94%	96%	98%	100%
7	91%	92%	93%	94%	95%	96%	97%	98%	99%	100%
8	45%	40%	35%	30%	25%	20%	15%	10%	5%	0%
9	1.8	1.6	1.4	1.2	1.0	0.8	0.6	0.4	0.2	0.0
10	1.9	1.8	1.7	1.6	1.5	1.4	1.3	1.2	1.1	1.0
11	5.5	5.0	4.5	4.0	3.5	3.0	2.5	2.0	1.5	1.0
12	55%	60%	65%	70%	75%	80%	85%	90%	95%	100%
13	64%	68%	72%	76%	80%	84%	88%	92%	96%	100%
14	55%	60%	65%	70%	75%	80%	85%	90%	95%	100%

The quality index comprises a series of performance standards relating to the 14 quality indicators, from which a quality index value can be read off. The target performance standard (see Panel 2) generally corresponded to a quality index value of 5 or 6, except where the target performance standard was either zero or 100 per cent, where the target quality index value necessarily corresponded to the end of the range (ie, 10)

Panel 2: Quality indicators, target performance standards, target quality index values, weightings and target weighted quality index values

Quality indicator	Target performance standard	Target quality index value	Weighting	Weighted target quality index value
1. Sufficient stock to complete orders within a one week delivery period	60 per cent of orders to completed within this period	5	2.5	0.125
2. Sufficient stock to complete orders within a two week delivery period	80 per cent of orders to completed within this period	6	2.5	0.15
3. Sufficient stock to complete orders within a four week delivery period	95 per cent of orders to completed within this period	5	2.5	0.125
4. Sufficient stock to complete orders within a six week delivery period	100 per cent of orders to be completed within this period	10	2.5	0.25
5. Complete fulfilment of orders on first delivery – no items to follow	Only 25 per cent of orders to have any items to follow	6	2.5	0.15
6. A comprehensive answer to be given to customers within 30 minutes of them telephoning	90 per cent of telephone queries to be answered within this time period	5	5	0.25
7. Extemporaneously dispensed items to be received by the customer within their required delivery date or by patients within a 30 minute period	95 per cent of items to be completed within these time periods	5	10	0.50
8. No work sheets should be incomplete at any stage in production on spot checks	No worksheets to be incomplete at any stage in production	10	15	1.50
9. Only limited errors to be present on repackaging worksheets	Only 1 “demerit” to be found on any worksheet	5	15	0.75
10. Only limited errors to be present on non-sterile manufacturing worksheets	Only 1.5 “demerits” to be found on any worksheet	5	15	0.75
11. Only limited errors to be present on sterile manufacturing worksheets	Only 2 “demerits” to be found on any worksheet	8	15	1.20
12. Items manufactured for outstanding orders should be manufactured within a seven day period	80 per cent of items to be manufactured within this time period	6	5	0.30
13. Items for outstanding orders should be tested within seven days for non-sterile and repackaging items and 20 days for sterile items	80 per cent of items to be tested within this time period	5	5	0.25
14. Raw materials and packaging components should be tested before the invoice is paid (30 days)	80 per cent of raw materials to be tested within this time period	6	2.5	0.15

Target overall weighted quality index value = **6.45**

The target overall weighted quality index value is calculated by multiplying the target quality index value and the weighting, dividing by 100, and adding together the 14 resultant weighted target quality index values. See text for details of how the quality index values and weightings were decided on. “Demerits” are errors found on worksheets, weighted according to severity and point of detection within the manufacturing process according to an internally revised schedule. The actual weighted quality index values can be calculated similarly, by using the quality index value appropriate to the performance standard achieved, as set out in Panel 1

differences in personnel. This could only be achieved using a complex weighting system which itself would be subject to its own variables.

Quality indices Over the monitoring period, overall quality index values (calculated from the 14 quality indicators as set out in Panel 1, p407) were produced for each of the nine months.

The results are tabulated below (Table 2). The two main points to be highlighted are that the results remain fairly constant over the nine-month period and that at no point over the monitoring period did the quality index reach the target quality index value of 6.45.

Table 3 shows the numerical difference between the results obtained for each of the 14 quality indicators to the target result. A zero depicts when the target result was achieved, a negative number when the result was below the target and a positive number when the result was better than the target figure.

This table can be used to highlight a number of trends. For example, quality indicator 8 (spot checking of in-process worksheets) indicates the biggest deficiency within the unit and it can also be seen that there is an overall decline in the standards of the worksheet over the second half of the monitoring period when compared to the first.

DISCUSSION

The large differences between the compliance ratings given by the different auditors reinforces the decision to have a number of auditors each audit the same area, so that a balanced picture is obtained, but any differences in results between areas cannot be attributed to differences in auditing personnel.

The improvement in compliance of the audited departments from the first to the second audit was to be expected because an effective programme of corrective action had been implemented between the two audits. In addition to this, areas not requiring cor-

Table 1: Overall audit results for the manufacturing areas

Area	Total required for compliance	Average score for January	Average score for June
Repackaging services	88	133.6	110.6
Non-sterile manufacturing	106	144.2	125.0
Sterile manufacturing	133	185.8	162.2

rective action were unlikely to deteriorate to a lower quality compliance rating.

That there was no corresponding improvement in quality throughout the period monitored suggests that the auditing process generally focuses the minds of the staff involved in the manufacturing processes being audited on, for example, good manufacturing practice during the time over which the audit is carried out, but that it does not lead to sustained quality improvements. Therefore, auditing alone cannot be expected to improve overall quality, except as part of an overall quality improvement package.

CONCLUSIONS

The auditing results show an improvement in the compliance of the audited departments from the first to the second audit, but there was no corresponding improvement in overall quality, as measured

using 14 quality indicators designed to cover sections of the manufacturing process under direct control of the manufacturing department staff.

This suggests that auditing influences subsequent audit results by focusing the attention of the staff involved on the auditing process itself, rather than by initiating sustained quality improvements.

REFERENCES

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Table 2: Overall weighted quality index values

Month number	Overall quality index value
1	4.625
2	5.550
3	5.500
4	5.425
5	4.350
6	4.975
7	3.650
8	4.200
9	4.575

Table 3: Numerical difference between the quality index result achieved and the target result

Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total
1	0	-1	2	-2	-3	2	5	-7	-5	-5	0	2	2	1	-9
2	1	0	0	-2	-1	5	0	-5	1	-5	2	3	-5	2	-4
3	-2	-3	-4	-2	0	0	5	-7	2	0	0	-2	-5	-1	-19
4	3	1	-1	-2	0	5	5	-6	1	0	-8	2	0	2	2
5	3	1	2	-4	0	5	5	-6	1	-5	-4	-4	1	-2	-7
6	1	0	-2	-2	0	5	1	-8	2	-5	-4	-2	-5	-2	-21
7	1	-1	-3	-2	-1	0	0	-8	0	0	-8	-2	-2	-2	-28
8	-1	-3	-5	-5	-2	0	5	-9	-2	1	-2	-3	-5	0	-31
9	-2	-3	-5	-5	-2	5	-4	-7	1	2	-3	-3	-2	0	-28
Total	4	-9	-16	-26	-9	27	22	-63	1	-17	-27	-9	-21	-2	