

Development of Quality control — a model for collaborative working

By J. BASS, MSc, MRPHARMS, A. BEANEY, MSc, MRPHARMS, P. DEAN, MPhARMS, MRPHARMS, A. HALL, BPharm, MRPHARMS, R. LONGSHAW, DCC, MRPHARMS, and J. RHODES, PhD, MRSC

Quality control laboratories play an important role in maintaining high standards in pharmaceutical products. This article describes the evolution of one NHS laboratory

Stockton quality control laboratory (SQCL) is a National Health Service pharmaceutical quality control laboratory, based within North Tees and Hartlepool NHS Trust, which provides a wide range of microbiological, environmental and chemical testing. The service is primarily for hospitals in the northern sector of the former Northern and Yorkshire Regional Health Authority. The laboratory has a diverse range of clients and is continually expanding to support new developments, eg, the increasing use of pharmacy clean rooms for aseptic services. Microbiological environmental monitoring now forms the majority of its work.

Other similar NHS departments providing services to a number of trusts may find the management model of use.

BACKGROUND

The former Northern Region had a diverse geographical range from Cleveland in the South, up to the Scottish Border, and West to Cumbria. The regional quality control (QC) service was also diverse and fragmented, with many small specialist laboratories, which had special interests in chemistry, endotoxin testing and dressings testing.

Mrs Bass is chief pharmacist, Queen Elizabeth Hospital, Gateshead, Ms Beaney is regional quality assurance specialist (Northern and Yorkshire), Mr Dean is chief pharmacist, University Hospital, North Tees, Mr Hall is chief pharmacist, the James Cook University Hospital, Middlesbrough, Mr Longshaw is chief pharmacist, Freeman Hospital, Newcastle upon Tyne, and Dr Rhodes is laboratory manager, Stockton Quality Control Laboratory



Chemical testing: services such as this are essential for clinical governance

In 1973, SQCL was developed by the then Cleveland Area Health Authority to serve hospitals in the county of Cleveland. The management arrangements closely followed the subsequent NHS re-organisations.

In 1981, the laboratory was expanded to serve the region and a number of the smaller, hospital-based QC laboratories closed. The laboratory was managed by the area pharmaceutical officer but directed by the regional quality controller who was based at regional headquarters. The laboratory was funded by top-slicing the regional budget.

In 1983, with the abolition of area health authorities, management of SQCL transferred to North Tees District Health Authority, and the district pharmaceutical officer then managed the laboratory.

In the early 1990s, the Northern Regional Health Authority (RHA) reviewed the functions it should be managing directly, in the light of the creation of the NHS internal market. As a result, on 1 April 1991, SQCL commenced operation as a "trading agency" with a ring-fenced budget for three years. The regional documentation of the time showed that this was to establish a stable environment while managing the transition. The top-sliced money was nominally allocated to the new purchasers based on the current workload of the provider trusts. The aim of this approach was a gradual transition towards contracting. It was recognised that there would be changes in the service level between 1991/2 and 1994/5 as, for example, new pharmacies opened. However, irrespective of such changes it was agreed the charges would

continue to equal the allocation until 1994/5.

In order to ensure a period of stability, the funding was unchanged, except for inflationary increases, for three years. The speed necessary to introduce the purchaser/provider split resulted in a number of inaccuracies, which were later identified by chief pharmacists.

In 1992, in preparation for a full contracting model, staff from the laboratory started discussions on establishing service level agreements with users. By their nature, these time-consuming discussions led to different service level agreements for different users. This was mainly dependent on the level and nature of local QC control services available to chief pharmacists.

Devolution of the previously agreed ring-fenced allocations was due in 1994. However, the historical figures no longer reflected the reality of changing workloads. The nature of the work had also shifted. For example, some users had developed new aseptic services and downgraded traditional manufacturing activities. However, because of the service level agreements, the QC charges could not be altered to reflect the decline in manufacturing and the resultant decrease in chemical testing of raw materials and finished products. In general, the bigger users (with sub-regional manufacturing units) paid much higher charges. This meant that all users were no longer paying appropriate QC charges.

North Tees Hospital, in conjunction with the Northern RHA treasurer's department, adjusted the original (inflation-adjusted) allo-

cations to reflect the changed patterns of demand and were then mapped to "purchasing authorities" in proportion to trusts' overall revenue flows. These funds were subsequently consolidated into baseline revenues of health authorities, and, with the removal of ring-fencing, there were no earmarked QC funds. Chief pharmacists expressed concern that these changes occurred without consultation. This led to some conflict, because there was a belief that the opportunity to maximise resources had been lost.

By 1996, the laboratory had a significant number of problems. Externally, SQCL's relationship with its customers was fraught. The laboratory was not meeting its obligations with respect to chief pharmacists. There was a perceived lack of transparency about its activities and finances, a perception that services were not timely, and that the provision of quality assurance (QA) services was insufficient; overall, the service concentrated on analysis and environmental testing. The balance between analytical and microbiological services and QA services was wrong. The decline in traditional manufacturing and increase in aseptic preparation meant that there was a need to change the focus of QC control services in order to support the rapidly changing priorities of hospital pharmacy. In addition, users had a perception that the laboratory was focusing on commercial clients and generating income at the expense of its NHS customers.

Ironically, the reality of SQCL's financial situation was converse to users' perceptions, with the laboratory actually being overspent. Within the trust there was also a general lack of appreciation of the key role played by SQCL in supporting the activities of pharmacy departments. A serious lack of capital investment to enable necessary equipment upgrades was apparent, staff morale was low and questions were being asked about the continued viability of the laboratory within the trust. The laboratory was at that time not being managed within pharmacy services. From the point of view of the laboratory, the process of individually contracting with over 40 users was time consuming, expensive, led to disagreement about costs and did not allow for co-ordination of changes in standards and tests.

The competitive spirit engendered by the purchaser/provider split was not conducive to a consensual solution or open debate. This left the laboratory and its users in unsatisfactory positions, with users feeling isolated and disenfranchised, and SQCL being estranged from its users, the other QC facilities and the regional QA specialist.

THE SOLUTION

The first part of the solution was to accept that there was a problem and to encourage ownership. A solution was needed that would deliver transparency to users and engage them as customers. It was necessary

for all parties to work together to deliver these positive changes, to ask stakeholders to define the relationships required, and for SQCL to start to collaborate as part of the larger QC services.

In 1997, a chief pharmacist user group was established and adopted as a sub-committee of the Northern chief pharmacists network. This user group represented a mix of small and large trusts, and licensed and unlicensed units. As other hospitals from outside the northern sector requested services from SQCL, their representatives were asked to join the group to reflect the growing base of pharmacy users. The user group agreed the principles of a comprehensive contract, with equitable and transparent financial arrangements and, importantly, encouraged users to recognise QC services as an essential requirement for all trusts.

The user group oversaw the changes being made as SQCL revised and described its services in an up-to-date prospectus. Information on the annual workload, costs and budgets were shared with users. From this, prices could not only be shown transparently, but be predicted a year ahead as information was shared about potential changes in service provision, altered standards and predicted inflation. This streamlined the contracting process without creating an unnecessary bureaucracy. The user group thus allowed a phased approach to the shift of costs in a collaborative and equitable way.

The information generated from this process was shared with all users in order to ensure transparency. This had the unplanned effect of allowing a benchmark comparison to be made of the take up of QC services and standards between trusts. It also allowed SQCL and trusts to respond to changes in standards.¹⁻³

The collaborative approach allowed the laboratory a stable period in which to build its workforce, balance the budget, have access to capital funding and improve services.

THE CURRENT SITUATION

There is now an excellent working relationship between SQCL and the regional quality assurance specialist, and ownership of the laboratory by its customers. Results from the EL 96(95) internal audit,⁴ which was mandatory for all non-licensed aseptic units, revealed that units in the northern sector of Northern and Yorkshire Region performed well. In many respects, this can be attributed to the service provided by SQCL and the improved working relationships, which were taking place around the time of the audit. Since reporting of the results of EL 96(95)⁴ in EL (97)52,⁵ and the introduction of regular external audit by the regional quality assurance specialist, SQCL has increased its support for aseptic activity considerably, par-

ticularly in terms of microbiological and environmental testing.

SQCL now provides a wide range of pharmaceutical microbiology services such as sterility testing, settle plates, water and disinfectant monitoring. Laundering arrangements for clean room clothing in aseptic units in all trusts are administered through the laboratory, using the laboratory van service, which is also used for deliveries from the regional pharmacy store. Environmental testing services have recently been expanded to include routine testing of all facilities (both licensed and non-licensed) in the manned operational state.³ Additionally, this was one of the first areas in the country to implement this requirement. SQCL also supports the North East divisional drug contract, working closely with the regional quality assurance specialist and the contracting team, to ensure the purchase of products of acceptable quality and value for money.

CONCLUSION

The laboratory was forced to adapt to suit the changes in both user requirements and in the NHS environment. Having found that top-sliced and competitive models were unsatisfactory, this collaborative working model now meets users' needs, and a win-win situation has been achieved. User satisfaction with the changes has resulted in an equitable and sustainable cost base for SQCL. The cohesive QA arrangements now in place play a significant role in reducing risk to patients, both in the high-risk area of aseptic services and in many other aspects of pharmaceutical services.

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