

Evaluating the impact of major investment in aseptic preparation on capacity and collaboration

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- **OBJECTIVE** — To evaluate the effect of a major capital investment programme for aseptic units in the north-west of England.
- **METHODS** — Aseptic products production and use data for the financial year 2003/04 were collected and analysed. Data were compared against those recorded in the financial year 1998/99 and against targets that were put in place at the start of the capital investment programme.
- **RESULTS** — The number of aseptic products produced at trusts in the north-west of England has increased by 48 per cent and the number used has increased by 45 per cent. The number and proportion of licensed units has increased and cabinets are being used more intensively. Indicators suggest that there is more collaboration between trusts. Production targets were exceeded at two of the eight trusts to receive monies, and production increased, although not by as much as projected, at the other six trusts.
- **CONCLUSIONS** — Beneficial changes relating to the way aseptic production facilities are used have been made, seemingly as a result of the investment programme. The programme also seems to have acted as a catalyst for improvements in production performance across all 36 acute trust sites in the north-west of England. Lessons learnt from trusts in the north-west of England are likely to be useful where similar investments are planned elsewhere.

The mid-1990s saw renewed focus on aseptic dispensing and product preparation in the NHS,¹⁻³ including the need to reduce the risks to patients of microbiological contamination and medication errors. It was recognised that, wherever possible, preparation should be carried out in suitable facilities under the control of pharmacy staff.⁴⁻⁷

To make early local progress, the NHS Executive Office for the north-west of England provided a £3m investment (the capital programme) in order to:

- Increase the production capacity of aseptic units across the north-west of England
- Improve collaboration between trusts to obtain best value in the production and use of products
- Shift the balance of high-risk aseptic preparation away from clinical areas towards pharmaceutical units (thereby reducing risk to patients)

Under the capital programme, monies were directed to aseptic units at eight of the 36 trust sites in the north-west of England. Five of the units to receive funds were already licensed, with the other three becoming licensed as part of the investment plan. Targets were set in terms of projected increases in production and capacity.

Previous research had established practical ways to measure aseptic production, use and collaboration, for the purposes of capacity planning.⁸⁻¹⁰ Data were therefore collected for all the trusts in the north-west of England for the financial year 2003/04, with a view to comparing it with that obtained in the financial year 1998/99.^{8,9} Such evaluation would be useful to determine whether value for money from the capital programme had been achieved and for accountability purposes. Particular focus was given to evaluating the effects of licensing status and of separating out cytotoxic preparation in dedicated cabinets.

Any lessons learnt from trusts in the north-west of England would be timely, given that the Department of Health, under the Modernisation of NHS manufacturing project¹¹ has invested £46m nationally — aseptic preparation schemes accounted for

just under half of the investment in London trusts and broadly two-thirds of that for trusts in the south of England (excluding London).

Methods

Production, use and capacity data A modified version of the two forms already developed^{8,9} was used to collect data, based on the recommendations of pharmacists who had been collecting ad hoc data in the intervening period. It combined the two forms into one and reduced the number of product source categories by merging the “minor” categories. The data collected for each product category were therefore the number of products:

- Prepared within pharmacy facilities for use within own trust
- Outsourced from other trusts
- Acquired from commercial sources (unlicensed products)
- Prepared within pharmacy facilities for other NHS trusts and other users

One of the product categories, cardioplegia solutions, was dropped from the original form, with its production or use being recorded under “other”. (There were only 709 cardioplegia solutions produced in 1998/99,⁸ and these were accordingly aggregated with “other” from that survey to ensure valid comparisons with the 2003/04 data. All of the data necessary for calculating the workload measures^{8,9} were retained.)

Where organisational and other changes had taken place over the period (such as the merging of trusts, the closure of hospital sites and the closure of aseptic units) the 1998/99 baseline data for the trusts involved was aggregated to form the 1998/99 activity for the new trust. An important caveat is that any exchange of products between the merging trusts in 1998/99 would be ignored but, given the trusts concerned, this was seen as having minimal effect on the overall figures.

Data relating to the projected workload for units that received capital monies used the targets quoted in their submitted business cases.

The marker “unit time equivalents” (UTEs) previously developed by the authors

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were applied to the data collected to translate it into the workload measurements of:⁹

- Aseptic dispensing unit hours per week
- Aseptic dispensing unit hours per week per cabinet (ADUHC)
- Cabinet hours per week per cabinet (ie, ADUHC divided by 2.5 for cytotoxics, since cabinet time accounts for approximately 40 per cent of the time of the whole aseptic preparation process, or ADUHC divided by 3 for other products)
- Average weighted time per product

The consensus among pharmacists at trusts in the north-west of England was that there had been no changes in the UTE values, for either licensed or unlicensed products, and so they were appropriate to use on the 2003/04 data.

Collaboration between trusts Collaboration between trusts in the production and use of aseptic products was measured by applying the methods previously developed by the authors.^{9,10} These calculated the percentage of products used locally that are imported (indicator I) and the percentage of products produced locally that are exported (indicator II), for each of the trusts.^{9,10}

Moving production from clinical areas Projections of the total demand for products from figures based on finished consultant episodes (FCEs), admissions and bed-days were made. The actual use of products that had been prepared at trust units, as recorded in the current survey, was then subtracted from these projections, to determine the amount of products prepared in clinical

Table 1: Distribution of aseptic dispensing units in the north-west of England by licensing type and production volume in 2003/04

Number of products produced	Number of licensed units producing that number of products	Number of unlicensed units producing that number of products
More than 50,000	9	1
25,000 to 49,999	4	3
18,000 to 24,999	3	0
9,000 to 17,999	2	3
Fewer than 9,000	1	6

Equivalent figures for 1998/99 are available (*Hospital Pharmacist* 2003;10:335). Two unlicensed units had been closed over the period, one because of rationalisation and one as a result of the hospital site itself closing. One (now licensed) unit that was temporarily closed during 1998/99 was fully operational in 2003/04.

areas. This figure was then calculated as a percentage of the total demand and compared with figures obtained for 1998/99.⁸⁻¹⁰

Results

Production and capacity All 36 acute trust sites provided data, including those that did not have an aseptic dispensing unit. This represented full coverage of acute services in the north-west of England.

Table 1 shows the distribution of aseptic dispensing units in the north-west of England by licensing type and production volume in 2003/04. There were eight more licensed units than there had been in 1998/99, increasing the proportion of such units from 35 to 59 per cent. Licensed units accounted for 55 per cent of the products produced in 1998/99 and 84 per cent in 2003/04.

Table 2 shows the number of products produced and used by trusts in the north-west of England. From 1998/99 to 2003/04, overall aseptic production in pharmacy facilities increased by 48 per cent and clinical use also increased by 45 per cent. At strategic health authority level, production more than doubled in Lancashire, increased by two-thirds in Greater Manchester and increased by 5 per cent in Cheshire and Merseyside.

The number of products acquired from commercial sources increased by 89 per cent between 1998/99 and 2003/04, with such products accounting for 14 per cent of all products used in 2003/04.

Table 3 (p223) summarises the aggregate increases in production for each product type, for the eight aseptic units that received monies from the capital programme, and

Table 2: Total number of products aseptically prepared in and used by trusts in the north-west of England in 2003/04, with some information as to source

Product category	Number of products produced in aseptic preparation units	Number of products used by trusts from all sources	Number of products used from commercial sources
Cytotoxics	171,569	243,849	74,389
TPN:adult compounded	30,558	18,471	941
TPN:adult simple	23,157	23,843	21
TPN:neonatal/paediatric	20,466	21,364	650
Epidural injections	16,622	31,409	10,740
Minibag plus	646,720	678,878	102,978
Minibag/infusion	191,656	236,288	33,754
Injection devices	8,685	6,042	350
Prefilled syringes	328,506	316,996	6,555
Eye drops/eye irrigations	5,082	8,338	1,209
Irrigations (non-ophthalmic)	2,184	2,225	0
Other	9,658	9,717	0
Total	1,454,863	1,597,420	231,587

Equivalent figures for 1998/99 are available (*Hospital Pharmacist* 2003;10:334-5). For TPN (total parenteral nutrition), the "adult compounded category" is where there is aseptic transfer of fluids and injections from original containers into a previously empty 2 or 3L polyvinylchloride or ethyl vinyl acetate bag and the "adult simple addition" is where there is a previously prepared product consisting of stable bulk fluids to which low numbers of injections are added.

compares them with the increases originally planned. The increased production in units that did not have such schemes was 239,000 products. Six of the eight units did not achieve their individual targets, with under-shoots ranging from 1,000 to 165,000 for 2003/04. The other two units each exceeded their targets by 50,000 products.

Capacity issues Figure 1 shows the percentage change in the key indicators used for workload measurement for each category of aseptic unit from the financial years 1998/99 to 2003/04. The total number of cabinets (laminar flow cabinets and pharmaceutical isolators) at trusts in the north-west of England increased from 100 to 106. Eight licensed units installed new cabinets (12 cabinets in total) and four units closed cabinets (six cabinets in total).

All but five units had both general and dedicated cytotoxics cabinets. It was found that the measured intensity of use of cabinets varied considerably for general cabinets on their own (ie, excluding cytotoxics) from when all cabinets were combined together (by between -49 and +97 per cent for individual units). Excluding a specialist TPN unit, all licensed units had average weighted time per product values below 8.0, and all unlicensed units had values above 8.0.

Collaboration between trusts Figures 2 and 3 (p224) provide diagrammatic presentations of the collaboration indicators,⁹ setting out collaboration for individual product types in total for 1998/99 and 2003/04. Overall collaboration between trusts increased over the period. The proportion of products exported (indicator II) increased from 12 per cent in 1998/99 to 27 per cent in 2003/04. The proportion of products imported (indicator I, which includes commercially acquired products) increased from 21 per cent to 33 per cent over the same period. Regarding individual trusts, in 2003/04, five trusts exported more than 25 per cent of production, with one trust exporting nearly 60 per cent.

Moving preparation from clinical areas The percentage of aseptic preparation in clinical areas decreased from 77 per cent in 1998/99 to around 67 per cent in 2003/04, when bed-days were used as proxy. If admissions or FCEs are used (which are generally deemed less appropriate to use than bed-days), the 2003/04 figures are 68 and 70.

Discussion

The data suggest that the following changes relating to the way aseptic production facilities were used and aseptic products were used occurred from 1998/99 to 2003/04:

- The number and proportion of licensed units has increased

Table 3: Projected and actual production levels for aseptic units at trusts participating in the capital investment programme

Product category	Actual change in the number of products produced (A)	Planned change in the number of products produced (P)	Difference between A and P
Cytotoxics	2,547	4,000	-1,453
TPN (all types combined)	1,770	5,750	-3,980
Epidural injections	4,770	0	4,770
Minibag plus	223,820	155,000	68,820
Minibag/infusion	- 43,753	129,000	-172,753
Injection devices	795	0	795
Prefilled syringes	56,856	163,000	-106,144
Eyedrops/eye irrigations	- 5,138	100	-5,238
Irrigations (non-ophthalmic)	- 3,313	200	-3,513
Other	-6,290	3,000	-9,290
Total	232,064	460,050	-227,986

- Greater use is being made of commercial sources, where this is appropriate
- Use of the available facilities (in terms of cabinets) has been rationalised, with cabinets generally being used more intensively
- There have been major changes in (some of) the export/ import patterns of the different product types
- Cytotoxics production has increased by over half, presumably reflecting the implementation of the National Cancer Plan¹²
- More of the time-intensive products (which possibly involve most risk to patients) are being prepared in aseptic

units (which is what would be expected if production was moving away from clinical areas)

Another likely change is that there is greater consistency in the relationship between how intensively cabinets are used and the mix of the products prepared, in line with whether a unit is licensed or not (with licensed units tending to increase the production of products with shorter preparation times, and unlicensed units tending to produce the more complex and/or higher risk products). Evidence for this is seen when scattergrams of the average weighted time per product against aseptic dispensing hours per week per cabinet are produced.

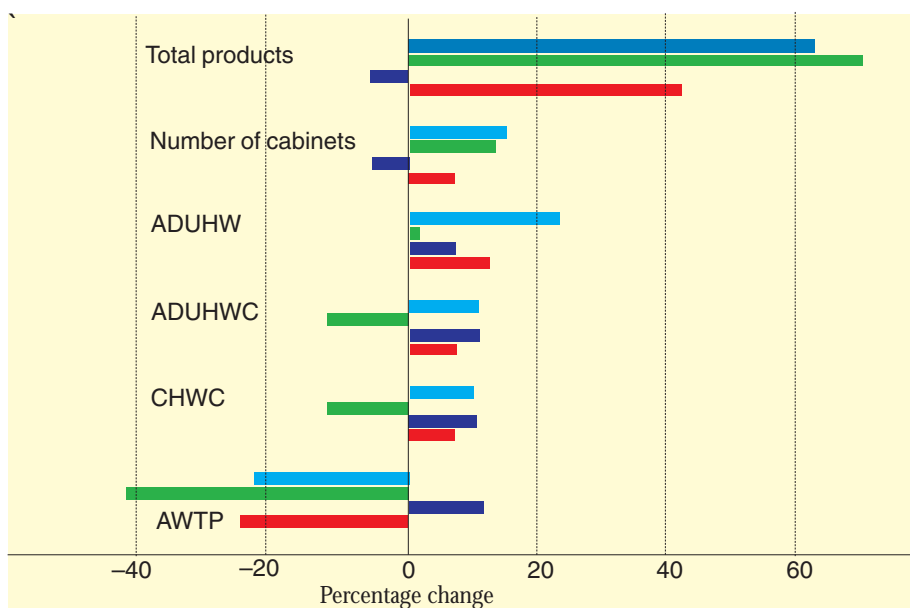


Figure 1. The percentage change in the key capacity-related indicators between 1998/99 and 2004/05 for each category of aseptic unit. "ADUHW" is aseptic dispensing unit hours per week, "ADUHCW" is aseptic dispensing unit hours per week per cabinet, "CHWC" is cabinet hours per week per cabinet (see text, p222, for explanation) and "AWTP" is average weighted time per product. Key: ■ are units that were licensed in 1998/99 and 2003/04; ■ are units that were licensed in 2003/04 but not in 1998/99; ■ are units that were unlicensed in 1998/99 and in 2003/04 and ■ is the aggregate of all units.

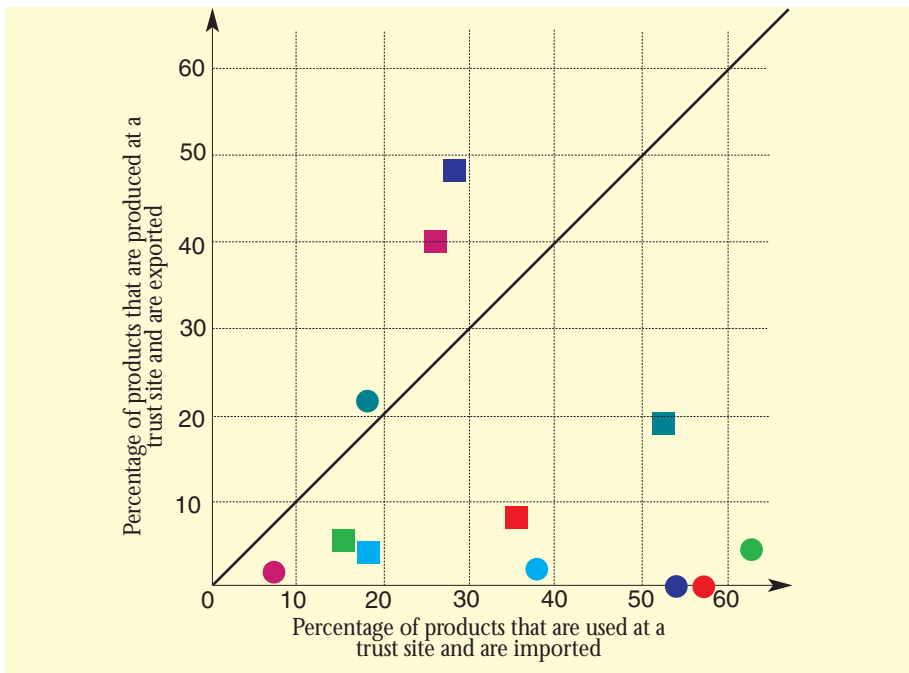


Figure 2. Diagrammatic representation of the percentage of products that were produced at a trust site and exported (indicator II) and the percentage of products that were used at a trust and were imported (indicator I), by product type, during 1998/99. Key: ● are cytotoxics; ● are epidural injections; ● are eye drops/irrigations; ● are irrigations (non-ophthalmic); ● are minibags plus; ● are minibag/infusions; ■ are injection devices; ■ are prefilled syringes; ■ are TPNs:adult compounded; ■ are TPNs:simple; ■ are TPNs:paediatric and ■ are other products. See Tables 2 and 3 for an explanation of the various total parenteral nutrition (TPN) products

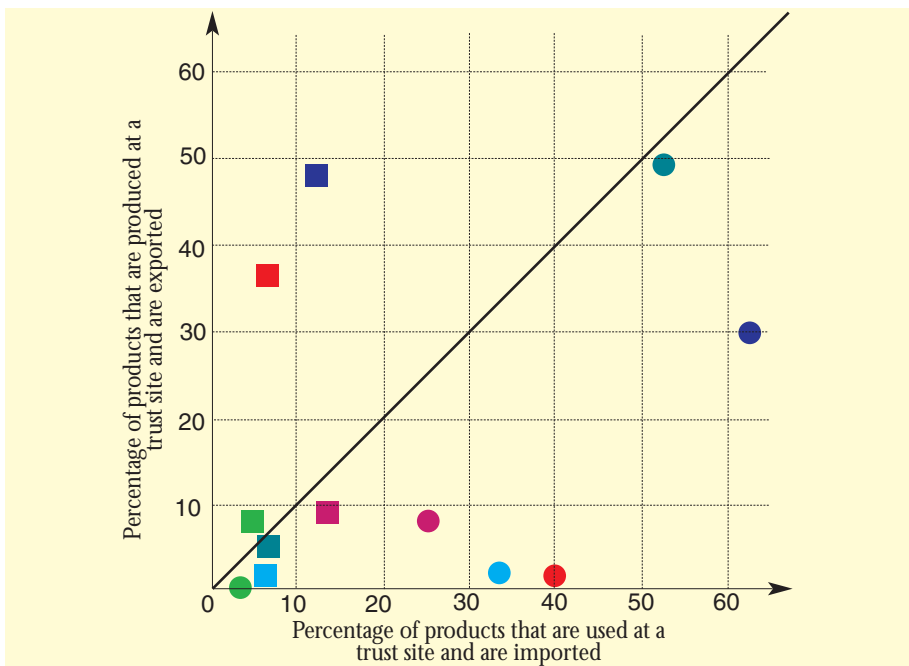


Figure 3. Diagrammatic representation of the percentage of products that were produced at a trust site and exported (indicator II) and the percentage of products that were used at a trust and were imported (indicator I), by product type, during 2003/04. Key: ● are cytotoxics; ● are epidural injections; ● are eye drops/irrigations; ● are irrigations (non-ophthalmic); ● are minibags plus; ● are minibag/infusions; ■ are injection devices; ■ are prefilled syringes; ■ are TPNs:adult compounded; ■ are TPNs:simple; ■ are TPNs:paediatric and ■ are other products. See Tables 2 and 3 for an explanation of the various total parenteral nutrition (TPN) products

The scattergram for 1998/99 (data not shown) pointed to there being little relationship between the mix of products produced and the intensity of cabinet use, with data for unlicensed units in particular

being widely spread. However, when the scattergram was repeated for 2003/04 (data not shown) the units were comparatively concentrated into a small number of groups of the same licence status.

The changes set out above cannot be solely attributed to the capital programme, which took place within the context of a rapidly changing NHS, which is undergoing modernisation and is becoming increasingly influenced by market conditions. Yet there seems to be no doubt that the programme acted as the catalyst for improved production and performance across all of the 36 trust sites in the north-west of England, and not just those that received funds. Changes to equipment and buildings as a result of the capital programme increased both production and capacity in the participating units, to the extent that if all the unused capacity from this investment had been fully taken up and used within trusts in the north-west of England, then a further 328,000 products would have been made; aseptic production would have increased by 81 per cent instead of 48 per cent; aseptic use would have increased by 75 per cent instead of 45 per cent; and the percentage of products prepared in clinical areas would have reduced to around 60 per cent.

That most of the units that had received monies from the capital programme had not achieved their projected targets was of concern. There were various reasons for this. For example, at one trust a member of the aseptic unit staff suffered from repetitive strain injury and the advice from local occupational health staff meant that one particular type of product could no longer be produced there.

However, the main problem was one of timing and economics. When the capital programme was conceived, chief executives committed their trusts to (a minimum of) two years' business for the additional production volumes. Unfortunately, the work carried out at the eight trusts covered a five-year period, rather than the 18 months originally anticipated, which effectively negated the commitment to buy two years' worth of products. Trusts had to acquire the products they needed from elsewhere, to support the treatment of patients, if they were not available from their contracted source. Those units that had increased their capacity in the early stages, and which had established transport and supply links, therefore had increased numbers of buyers whom they could not reasonably refuse. (The two units that produced 50,000 more products than originally projected both fell into this category). In addition, some purchasing trusts were not necessarily realistic about what they should pay for products made in other NHS organisations. The producing trusts were not going to produce more products without commitment — trust boards will not approve investment in staff for increased production, unless there are guaranteed purchasers.

There are therefore lessons to be learnt from the experiences of trusts in the north-west of England:

- Planning the evaluation of such investment programmes is essential from the outset, so that the degree to which objectives have been met can be determined on completion, for accountability purposes.
- Changing a unit's status from unlicensed to licensed can precipitate significant improvements in production and performance because, for example, this brings increased opportunities for batch production and skill mix.
- It is important to separate out any cytotoxics production data for relevant analysis, where there are both general and dedicated cytotoxic cabinets. Cytotoxics production is set to increase, in line with the implementation of the National Cancer Plan,¹² and this could mask trends in production in other areas.
- Capital programmes must not be considered in isolation, as they can act as the catalyst to changes in aseptic production and use across a whole health economy. Therefore any evaluation of aseptic production and use should examine the whole of the health economy, as well as individual schemes.
- It follows that a co-ordinated, collaborative approach across trusts is essential, and this should include making better use of existing facilities

and commercial sources, as well as capital investment.

- Where significant capital schemes are envisaged, getting guaranteed commitment from customers is vital and the schemes must be delivered on time.
- The sheer magnitude of aseptic preparation that takes place outside pharmacies¹⁰⁻¹² in the NHS is such that trusts need to have clear risk management and capacity plans that suitably address the issue locally, within a clinical governance framework. Even with significant capital investment and increased collaboration between trusts, it is unrealistic to envisage the complete removal of aseptic preparation from clinical areas, within the foreseeable future. Therefore trusts need to set themselves practical targets and milestones for moving the balance of production away from clinical areas towards pharmacy facilities. This should be based on risk assessment of clinical area preparation activities and prioritisation of transfer of high-risk products. The National Patient Safety Agency has recently carried out a consultation exercise on proposals to carry out such risk assessments throughout the NHS.¹³

Since 2003/04, the development of pharmacy aseptic services across the north-west of England has continued apace. A number of new hospital aseptic facilities have been opened, along with a new aseptic unit by a commercial company providing local services on a partnership basis. It is expected that the forthcoming NPSA risk assessments of preparations in near-patient areas will result in the identification of further high-risk activities which should be transferred into pharmacy facilities. Our methodology will be useful for assessing capacity and activity changes resulting from these initiatives both for individual schemes and for the health economy as a whole.

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