

Aseptic preparation

– survey design and data assessment

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This month's special feature sets out the methods and findings of a project carried out at trusts in the north west of England. This first part examines trends in the production and use of aseptic products



Preparing a prefilled syringe – one of the product categories analysed as part of a project to assess trends in aseptic product preparation and use at trusts in the north west of England

Preparing aseptic products in a hospital pharmacy, rather than in a clinical area, is generally considered to reduce the risk of patients receiving pharmaceutical products that have been contaminated during preparation or reconstitution.¹⁻⁴ Pharmacists and trust managers are therefore interested in transferring as much of the preparation

of aseptic products as possible from clinical areas to specialised suites in hospital pharmacies.

Before this can be done, and before money is spent investing in new facilities, it is important to analyse the extent to which existing units are used.

To this end, a survey of aseptic facilities was carried out at trusts in the north-west of England (the then North West region) in 1995/96. This original survey showed wide variations in the use made of local aseptic units. The results (and design) of the survey were published in *Hospital Pharmacist* in 1998.⁵

The survey results prompted a senior review of aseptic risks⁶⁻⁸, leading the then NHS Executive North West to fund a programme to replace seven aseptic units in the area with larger and more modern units. It also funded other initiatives to promote collaboration between trusts in producing aseptic products. Funding was also provided for a project⁹ to build on the original survey design and results, and to look in more detail at methods of measuring workload, collaboration and capacity, which are examined in the next part of the special feature.¹⁰

The project was also designed to monitor trends in aseptic preparation and use and

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Panel 1: Types of relevant data

Data	Comment or explanation
● Product category	Minibag or pre-filled syringe, for example
● Ingredients	Constituents of product
● Patient type	Child or adult
● Administration site	Leg or arm, for example
● Administration route	Intravenous or intramuscular, for example
● Administration rate	
● Place of preparation	Local aseptic unit, clinical area or bought in
● Assembly	Nurse or pharmacist, for example

assess the impact of the programme to replace the aseptic units. This aspect of the project (which was overseen by a multidisciplinary steering group) had the following general approach:

- Deciding what data should be collected
- Establishing whether or not existing pharmaceutical information systems routinely provided such data
- Determining a sound, practical method of collecting the data for a full financial year, which could then act as the baseline survey for the project
- Analysing the results of the baseline survey, and comparing them with the results of the original survey
- Evaluating the design of the baseline survey

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- Agreeing a survey design for collecting five subsequent quarters of data
- Analysing the results of the quarterly surveys to determine trends and to assess the impact of the replacement aseptic units

It was important that the methods used should be capable of being applied throughout the NHS, so that trusts in other parts of the country could similarly analyse their patterns of aseptic product preparation and use.

DATA TO COLLECT

A variety of health care professionals from both the NHS and private sectors met at a workshop to determine the types of data that were most relevant to the project (see Panel 1).

After considering the options, the steering group decided that activity should basically be quantified by product category, rather than at a more detailed level.

EXISTING SYSTEMS

A data audit of nine trusts was undertaken to determine whether existing pharmaceutical information systems used throughout the area (Ascribe, JAC, HORIS and MDIS) could provide the necessary data. The primary purpose of such systems is to support the operation of pharmacies (for example, generate labels) rather than to generate detailed data for analysis, so it was important to find out what, if any, additional input would be needed.

The audit established that existing systems could either provide the target data automatically, or at worst, might require some manual input or other processing. This input or processing was considered achievable, providing sufficient notice was given.

The audit also established that trusts could configure the same basic systems differently to reflect their local requirements. This gave potential for differences in product definition, coding systems, report formats and data export facilities between the systems used at the various trusts throughout the area. However, it was considered that such factors would have only a limited impact on the project because it quantified activity by product category, rather than at a detailed level.

BASELINE SURVEY DESIGN

The baseline survey comprised three forms (see Panel 2). Data for each product category (see Panel 3, p333) were collected on the appropriate form. Radiopharmaceuticals and terminally sterilised products were excluded from the project.

Following an evaluation of the original survey,⁵ it was thought that data about the number of commercially acquired licensed products used in all clinical areas should be included – hence the inclusion of form 3. It was also thought that breaking down the product categories for cytotoxics, CIVAS (central intravenous additive service) products and TPN (total parenteral nutrition) products might be appropriate to reflect the different demands on resources that the different manipulations made.

Panel 2: Forms used in the baseline survey

Form 1	Data about the products prepared or manufactured in pharmacy aseptic preparation units
Form 2	Data about the source of aseptically prepared unlicensed products used in the trust
Form 3	Data about the use of commercially acquired licensed products used in a trust without further manipulation in a pharmacy aseptic unit before administration to a patient

Panel 3: Product categories used in the baseline survey

- Cytotoxics
 - infusions
 - syringes
 - devices
- Total parenteral nutrition products
 - adult: compounded
 - adult: simple addition
 - neonatal/paediatric
- Central intravenous additive service products
 - cardioplegia solutions
 - epidural injections
 - minibag plus
 - minibag/infusion
 - injection devices
 - pre-filled syringes
- Eye-drops/eye irrigations
- Irrigations (non-ophthalmic)
- Other

Forms 2 and 3, together with guidance documents, were sent to the chief pharmacists at all 37 trusts in the then North West region. In addition, form 1, together with guidance documents, was sent to those 31 trusts with units that aseptically prepared products. Trusts with multiple aseptic units filled in a form for each unit, making 35 units in total.

To maintain confidentiality, each unit (or trust, where the trust had no unit) was allo-

cated a unique code. The data collected were for the financial year 1998/99.

— BASELINE SURVEY RESULTS

All 37 trusts asked to contribute data did so. In broad terms, the situation was similar in 1998/99 to that in 1995/96.³ The total number of products produced in aseptic dispensing units in trusts in the north-west of England dipped from approximately 1.1 million to approximately 1.0 million, while the total number of products used increased from approximately 1.0 million to approximately 1.1 million (see Table 1 (below) and Table 2, p335, for a breakdown of the 1998/99 results). The most popular items produced were minibag plus, minibag/infusion and prefilled syringes, which together totalled 767,745 products and accounted for 77 per cent of all the products produced.

The variation in the number of products produced at the different aseptic units was considerable. Production was generally dictated by whether or not the unit held a manufacturer's "specials licence" (see Table 3, p335). The seven units that each produced over 50,000 products accounted for 58 per cent of all the products produced in the area.

— BASELINE EVALUATION

Throughout the baseline survey period, trusts were invited to comment on any problems they came across when providing the data requested. The steering group took these responses into account when evaluat-

ing the design of the survey and made appropriate changes to the format for the five quarterly surveys.

A particular problem with the baseline survey design was that it distinguished whether a cytotoxic was an infusion, syringe or device. The data available from pharmacy computer systems did not necessarily provide this level of detail, so pharmacists had to estimate the split. In the circumstances, the steering group decided that, on balance, the benefits of subdividing the cytotoxics category did not outweigh the disadvantages, and so a single cytotoxics category was proposed for the quarterly surveys. No similar problems were found in providing the data split for TPNs and CIVAS, so those subdivisions were retained.

Data about commercially-acquired licensed products (form 3) also caused problems. The intention had been to gain an appreciation of the volumes of products, such as TPNs, bought into trusts and issued directly to clinical areas, where they were either administered directly to the patient or manipulated by ward staff, so it could be established whether any increase in TPN production in aseptic units represented an overall increase in the use of TPNs or simply a switch from manipulation being carried out in clinical areas. Unfortunately, it was not possible to establish a clear definition of the commercially-acquired licensed products the steering group wanted information on, and so the data received was inconsistent. In addition, the forms that were returned indicated that the number of these products used in the trusts was

Table 1: Total number of products prepared in aseptic units at trusts in the north-west of England during the baseline survey period, with information as to end-user

Product	Number used within trust	Number used by other NHS user	Number used by non-NHS user	Total
Cytotoxics	107,906 (97)	456 (0)	2,454 (2)	110,816
TPN:adult compounded	15,558 (51)	4,192 (14)	10,491 (35)	30,241
TPN:adult simple	13,490 (96)	484 (3)	48 (0)	14,022
TPN:neonatal/paediatric	14,004 (72)	5,201 (27)	364 (2)	19,569
Cardioplegia solutions	109 (15)	600 (85)	0 (0)	709
Epidural injections	9,001 (100)	0 (0)	0 (0)	9,001
Minibag plus	237,839 (77)	69,573 (23)	23 (0)	307,435
Minibag/infusion	235,426 (98)	5,359 (2)	0 (0)	240,785
Injection devices	5,494 (92)	7 (0)	480 (8)	5,981
Prefilled syringes	209,364 (95)	4,296 (2)	5,865 (3)	219,525
Eye drops/eye irrigations	9,106 (91)	850 (9)	5 (0)	9,961
Irrigations (non-ophthalmic)	15,444 (86)	2,437 (14)	28 (0)	17,909
Other	2,617 (23)	8,574 (76)	43 (0)	11,234
Total	875,358 (88)	102,029 (10)	19,801 (2)	997,188

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. Figures in parentheses indicate the percentage (to the nearest whole number) of products of that particular type that are prepared by the trusts and used by the particular user, compared with all users.

Table 2: Total number of products used by trusts in the north west of England during the baseline survey period, with information as to source

Product	Number acquired from own trust	Number acquired from licensed unit at other trust	Number acquired from unlicensed unit at other trust	Number of unlicensed product acquired from commercial source	Total
				62,759 (36)	
Cytotoxics	107,906 (62)	2,295 (1)	149 (0)	387 (2)	173,109
TPN:adult compounded	15,558 (73)	3,955 (19)	1,453 (7)	2,703 (16)	21,353
TPN:adult simple	13,490 (82)	227 (1)	0 (0)	0 (0)	16,420
TPN:neonatal/paediatric	14,004 (75)	3,075 (16)	1,625 (9)	0 (0)	18,704
Cardioplegia solutions	109 (100)	0 (0)	0 (0)	3,285 (16)	109
Epidural injections	9,001 (43)	8,474 (41)	0 (0)	0 (0)	20,760
Minibag plus	237,839 (82)	52,590 (18)	0 (0)	1,863 (1)	290,429
Minibag/infusion	235,426 (94)	14,186 (6)	0 (0)	3,000 (35)	251,475
Injection devices	5,494 (65)	0 (0)	0 (0)	24,116 (10)	8,494
Prefilled syringes	209,364 (84)	11,543 (5)	3,293 (1)	2,502 (17)	248,316
Eye drops/eye irrigations	9,106 (63)	2,942 (9)	0 (0)	21,821 (58)	14,550
Irrigations (non-ophthalmic)	15,444 (41)	153 (0)	102 (0)	317 (5)	37,520
Other	2,617 (45)	2,792 (48)	44 (1)		5,770
				122,753 (11)	
Total	875,358 (79)	102,232 (9)	6,666 (1)		1,107,009

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. Figures in parentheses indicate the percentage (to the nearest whole number) of products of that particular type that are used by the trusts and acquired from that particular source, compared with all sources.

relatively small, and so it was agreed that form 3 would not be used in the quarterly surveys.

— QUARTERLY SURVEY DESIGN

The design of the project was such that data for five quarters would be surveyed, covering the period from April 1999 to June 2000 (inclusive). The main reason for having quarterly (rather than annual) surveys was so that the expected changes in the production and usage of aseptic products at trusts in the north west following the replacement of seven aseptic units with larger and more modern units could be monitored and quantified at a fairly detailed level. Any changes in collaboration¹⁰ between trusts over that period could also be analysed.

Given the need for five quarters of data, a computer disk method was used. This enabled routine data collection in a way that automatically aggregated the data for the quarterly totals from daily, weekly or monthly figures. All 37 trusts included in the baseline survey were invited to take part again.

— QUARTERLY SURVEY RESULTS

Ten of the 37 trusts did not submit any quarterly data or there were significant shortfalls in the data that they submitted. Some of the "non-responding" trusts had closed their units, and trusts that did not have aseptic units generally did not respond this time. These trusts were excluded from the analysis. The trusts fully included in the quarterly surveys accounted for 71 per cent of all

aseptic dispensing units and 63 per cent of the aseptic dispensing unit activity across the area according to the baseline survey.

Trends in the total number of products produced and used at participating trusts throughout the survey period are shown in Table 4, (p337). Overall there had been a 25 per cent increase in the number of products up until the end of quarter 3, followed by a dip. The fall in the last two quarters was largely due to production at one trust being reduced as its aseptic unit was being replaced with a new unit. If production in that aseptic unit were to return to its quarter 3 level when the new unit opened, the overall increase in production across the trusts would have been around 32 per cent. Such patterns highlight the important point that aseptic units may have to close (albeit temporarily) when changes, developments and problems occur.

Data from individual trusts (not shown) fluctuated dramatically from one quarter to the next. A small number of trusts showed a reduction in production (other than those that were being upgraded), but otherwise there were notable increases. This perhaps points to better use being made of the units, for example, by some moving of activity from clinical areas.

In terms of monitoring the effect of the new units, a large complication was that the replacement programme did not progress to the planned timetable. Only two of the seven aseptic units that were scheduled to be replaced were actually replaced during the period covered by the quarterly surveys, and

Table 3: Number of products produced by licensed and unlicensed units at trusts in the north west of England

Number of products	Number of licensed units producing that number of products	Number of unlicensed units producing that number of products
More than 50,000	6	1
25,000 to 50,000	3	3
18,000 to 25,000	1	5
9,000 to 18,000	0	0
Fewer than 9,000	1	14

The total number of units adds up to 34 (and not 35) because the data from two units at the same hospital (and not just the same trust) were amalgamated

Table 4: Trends in the total number of products (of all types) produced and used by trusts in the north west of England throughout the survey period

Quarter	Products produced	Products used
Baseline	156,928	158,231
Quarter 1	162,659 (104)	158,551 (100)
Quarter 2	168,485 (107)	165,967 (105)
Quarter 3	195,617 (125)	173,567 (110)
Quarter 4	183,289 (117)	164,822 (104)
Quarter 5	177,497 (113)	156,685 (99)

Figures in parentheses represent the percentage of products produced or used by trusts in the north-west of England, compared with baseline. To determine the baseline, activity figures for the trusts that fully participated in the quarterly surveys were taken from the baseline survey results (which covered one year) and divided by four

one of these was right at the end. This meant that the overall impact of the programme could not be fully determined. Although disappointing, this was not thought to invalidate the work, because it was important to establish how trends could be measured and monitored.

CONCLUSIONS

The data collected during the survey periods enabled trends in the preparation and use of aseptic products at trusts in the north-west of England to be monitored.

By addressing issues in the baseline survey design, the steering group believes that it has established the practical limits of what data could readily and sensibly be collected. There seems to be no reason why the final survey design and methods should not be employed more widely in the NHS.

Moreover, the data provides a platform for the measurement of workload, collaboration and capacity.¹⁰

Contributing material to Hospital Pharmacist

General advice to contributors, together with specific advice on submitting letters, news items, meeting reports, details about future events, papers and articles (including information about the appropriate format for references, figures, tables and photographs) can be obtained from www.pjonline.com/about/advicehp.html.

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