

Analysing

Aseptic preparation

– workload measurement and capacity planning

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The second part of this month's special feature discusses the part of a project carried out at trusts in the north west of England that focused on workload, collaboration and capacity issues

Establishing the workload and capacity of aseptic preparation units, as well as assessing the degree to which aseptic units collaborate in producing aseptic products, gives important information on the extent to which best use is made of available facilities.

Devising practical models to measure workload and collaboration, to which survey data can be applied, was therefore part of the project to analyse aseptic preparation carried out at trusts in the north west of England.¹ It is important to note that there are no generally accepted definitions of collaboration and workload, and so there are no set methods of calculating them.

COLLABORATION

The approach taken to measure collaboration was to adapt a model previously used by the then health authorities to describe catchment populations and patient flows.² When the adapted model (see Figure 1) was applied to the baseline survey results it showed that the average export figure across trusts (ie indicator II) was 15 per cent. The majority of trusts did not produce many or any products for other trusts (i.e. indicator II was less than 10 per cent). Five of the trusts exported more than 15 per cent of their products (indicator II was 16 to 35) ("high exporting units").

When applied to the quarterly survey results, the average export figure rose to

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$$I \quad \text{Percentage of products used locally that are imported from outside a trust} = C \times \frac{100}{(B + C)}$$

$$II \quad \text{Percentage of products produced locally that are exported from a trust} = A \times \frac{100}{(A + B)}$$

Figure 1: The model used to assess collaboration. "A" is the number of aseptic products that are produced by a trust and supplied to other trusts (exports), "B" is the number of aseptic products that are produced by a trust and used within the trust, and "C" is number of aseptic products that are bought in by a trust for local use (imports). Indicator "I" gives a percentage measure of imports, and indicator "II" gives a percentage measure of exports. Where the value of indicator "I" is higher than the value of indicator "II", the trust is a net importer. Where the value of indicator "II" is higher than the value of indicator "I", the trust is a net exporter. Trusts without an aseptic preparation unit should be excluded from the analysis.

27 per cent, with the four high exporting units that participated during the quarterly survey period increasing their exports, such that indicator II was between 51 and 70.

This suggests that collaboration generally increased throughout the 1998–2000 period, presumably the result both of the seven aseptic units starting to be replaced and of a consensus between trusts that collaboration should be increased. As mentioned previously,¹ the programme to replace the aseptic units did not proceed according to the planned timetable, and so it was impossible to establish its full effect on collaboration.

WORKLOAD MEASUREMENT

Workload (and therefore capacity) can be assessed using a variety of models that centre around equipment, staffing and

physical constraints. However, it would be unrealistic to assume that all NHS units can be staffed 24 hours a day. Therefore the steering group focused on measuring the work actually done, which by definition is staffed, and developed the following key indicators (calculated as per Figure 2, p343):

- Aseptic dispensing unit hours per week (ADUHW)
- Aseptic dispensing unit hours per week per cabinet (ADUHC)
- Cabinet hours per week per cabinet (CHWC)
- Average weighted time per product (AWTP)

These indicators are clearly linked with one another and can be used to provide a profile of the workload for each unit. They

enable comparative performance to be benchmarked and interpreted locally to inform the development of capacity or workload plans. The results from the baseline and quarterly surveys¹ provided much of the information needed to establish values for the indicators, although additional information on standard times and the number of cabinets was needed as well.

— STANDARD TIMES

The most common approach to standard times in the pharmaceutical industry is to use “unit time equivalents” (UTEs). These are measures of the time it typically takes to perform a particular activity, or a series of activities. For the purpose of the project, they cover the period from the receipt of a request or prescription or order to the approval of the finished product by the supervising pharmacist. They are suitable for use in benchmarking. The approach of using UTEs was adopted by the steering group.

Initially, it was thought that UTEs could be obtained through observation. Hence a work-study consultant was commissioned to observe aseptic unit operators and time each element of the established general procedure for aseptic manufacturing³ for each item prepared during the observation period. However, it soon became apparent that establishing UTEs by this method was not achievable.

First, there were issues about the consultant being present in the unit when aseptic preparation was taking place. For example, in order to maintain an aseptic environment, the consultant could not sit next to the pharmacist or technician preparing the products, and to be in the unit at all, the consultant needed to “gown up” and appropriately cover his monitoring equipment (for example, stopwatch, clipboard, paper). In the few units where CCTV existed, the whole of the cabinet was not in view, and so UTEs could not reliably be obtained from reviewing the footage. (That the whole of the cabinet is not covered by CCTV is not a problem during normal use because operators are trained to hold objects up to the camera, for example, for checking.)

Moreover, there were wide variations in the time taken to make up items in a particular product category both between units (often depending on the method of work) and within units. For example, one unit visited prepared 37 different types of pre-filled syringes, with the number of ampoules required to make one syringe varying considerably up to a maximum of 25. The process time involved in making similar products also varied depending on the speed with which solutions mix. It was clear that unless each item in each product category was individually timed and unless each product category in each unit was given its

own unique time, establishing UTEs by this method was not possible. Undertaking this work was not practical within the scope of the project.

Instead it was decided to develop the UTEs through an iterative process using the statistical techniques of “multiple perspectives” and “delphi”^{4,5} with as much cross-checking as possible. The process was as follows:

- A group of senior pharmacists produced preliminary (mean) UTE values for the list of products using a range of evidence and personal experience.
- These UTE values were circulated to pharmacist members of the steering group together with a number of pharmacists who worked in trusts outside the north west of England.
- All aseptic unit managers at trusts in the north west of England were surveyed to establish their views on the preliminary UTE values. They were asked to indicate whether they agreed or disagreed that each UTE value was reasonable. If they disagreed then they were invited to offer an alternative mean UTE value. They also had the opportunity to indicate what they thought were the shortest and longest mean times that might apply to each product, in order to appreciate the degree of variability that may apply. (This process obtained a 69 per cent response rate.)
- The degree of agreement with the preliminary UTE values was substantial. Over half of the product categories got an agreement level of at least 70 per cent. The remaining product categories had agreement levels of between 40 and 60 per cent. The differences in UTE values between aseptic unit managers seemed largely attributable to differences between licensed and unlicensed aseptic preparation. The former involves more batch work whilst the latter deals with the same product on an individual basis, taking more time. Therefore it was decided that each product should have two UTE values – one for where production is licensed and one for where it is not.
- The final values for the UTEs were determined statistically from the survey results with regression analysis being used to establish minima and maxima values for the UTEs.

The finally determined UTE values are shown in Table 1 (p343). There is considerable variation in UTEs between the different product categories. It is notable that the products produced in high numbers (minibag plus, minibag/infusion and pre-filled syringes) have low UTE values. It was made clear to trusts that UTEs were meant to be reasonable mean times to be used for information and were not fixed performance targets – hence the use of the term “marker UTE”.

$$\text{ADUH} = \left(\frac{\text{number of cardioplegia solutions produced per year} \times \text{UTE}}{\text{UTE}} \right) + \left(\frac{\text{number of cytotoxics produced per year} \times \text{UTE}}{\text{UTE}} \right) + \left(\frac{\text{number of epidural injections produced per year} \times \text{UTE}}{\text{UTE}} \right) \text{ etc}$$

$$\text{ADUHW} = \frac{\text{ADUH}}{52}$$

$$\text{ADUHC} = \frac{\text{ADUHW}}{\text{Number of cabinets}}$$

$$\text{CHWC} = \frac{\text{ADUHC}}{3}$$

$$\text{AWTP} = \frac{\text{ADUH}}{\left(\frac{\text{number of cardioplegia solutions produced per year}}{\text{UTE}} \right) + \left(\frac{\text{number of cytotoxics produced per year}}{\text{UTE}} \right) + \left(\frac{\text{number of epidural injections produced per year}}{\text{UTE}} \right) \text{ etc}}$$

Figure 2: Diagram showing how the key workload indicators (staffed) are calculated for a given unit. "ADUH" is aseptic dispensing unit hours, "ADUHW" is average aseptic dispensing unit hours per week, "ADUHC" is aseptic dispensing unit hours per week per cabinet, "CHWC" is cabinet hours per week per cabinet, and "AWTP" is averaged weighted time per product. "UTE" is unit time equivalent. It is important to use the appropriate UTE, tailored for the product and type of unit (licensed or unlicensed) as indicated in Table 1. "Etc" indicates that the relevant figure for the other product types listed on Table 1 needs to be added appropriately. A year is taken for illustration – other periods require appropriate adjustment

CABINETS

The steering committee determined that the number of cabinets (i.e. laminar air flow cabinets and pharmaceutical isolators) was critical to measuring performance, rather than the number of associated workstations. This is because, in practice, in the aseptic units involved, only one

operator would carry out aseptic manipulation in multiple-workstation cabinets at a time.

While attempting to establish UTEs through observation (see p340), a work-study consultant had established that cabinet time accounted for between 25 and 40 per cent of the time of the whole aseptic preparation process. It was therefore decided to

assume that aggregate cabinet times would be approximately one third of the total aggregate activity time (see the calculation of CHWC in Figure 2, where "3" is the denominator).

Cabinets not regularly in use within the work of a unit, and those retained for emergency use, were excluded from the calculations.

Table 1: Marker unit time equivalent (UTE) values, with minima and maxima, for the various products prepared in licensed and unlicensed aseptic units

Product	Licensed unit			Unlicensed unit		
	Marker UTE	Minimum	Maximum	Marker UTE	Minimum	Maximum
Cardioplegia solutions	10.0	7.5	15.0	15.0	12.0	23.0
Cytotoxics	6.0	4.8	10.0	10.0	7.5	15.0
Epidural injections	5.0	4.0	8.0	7.5	6.0	12.0
Eye drops/eye irrigations	5.0	4.0	8.0	7.5	6.0	12.0
Irrigations (non-ophthalmic)	5.0	4.0	8.0	7.5	6.0	12.0
Minibag plus	1.0	0.8	2.0	1.5	1.2	7.0
Minibag/infusion	3.0	2.4	3.0	5.0	4.0	8.0
Injection devices	12.0	9.0	19.0	18.0	14.0	26.0
Prefilled syringes	6.0	4.8	10.0	10.0	7.5	15.0
TPN:adult compounded	20.0	15.0	29.0	30.0	24.0	41.0
TPN:adult simple	10.0	7.5	15.0	15.0	12.0	23.0
TPN:paediatric	30.0	24.0	41.0	45.0	36.0	60.0
Other	5.0	4.0	8.0	4.0	6.0	12.0

"UTE" means unit time equivalents (measured to nearest 0.5 min). The term "marker UTE" was chosen to indicate that UTEs are for information and not fixed performance targets. Minima and maxima figures were established using regression analysis.

Table 2: Application of marker unit time equivalent (UTE) values to the baseline survey results for licensed units

Unit	ADUHW	Number of cabinets	ADUHCW	CHWC	Total products produced	AWTP
1	113.52	3	37.8	12.61	17,077	20.7
2	84.32	3	28.1	9.37	59,941	4.4
3	45.97	2	23.0	7.66	40,783	3.5
4	79.95	4	20.0	6.66	85,976	2.9
5	56.07	3	18.7	6.23	28,173	6.2
6	35.05	2	17.5	5.84	18,086	6.0
7	50.15	3	16.7	5.57	63,279	2.5
8	112.91	7	16.1	5.38	88,626	4.0
9	80.47	5	16.1	5.36	100,538	2.5
10	26.10	3	8.7	2.90	46,932	1.7
11	6.50	1	6.5	2.17	3,730	5.4

Table 3: Application of marker unit time equivalent (UTE) values to the baseline survey results for unlicensed units

Unit	ADUHW	Number of cabinets	ADUHCW	CHWC	Total products produced	AWTP
1	137.2	2	68.6	22.9	46,382	9.2
2	126.8	2	63.4	21.1	39,575	10.0
3	348.0	7	49.7	16.6	98,494	11.0
4	72.4	2	36.2	12.1	64,814	3.5
5	130.9	4	32.7	10.9	33,377	12.2
6	92.8	3	30.9	10.3	18,488	15.7
7	66.6	3	22.2	7.4	21,888	9.5
8	54.2	3	18.1	6.0	19,644	8.6
9	50.4	3	16.8	5.6	20,184	7.8
10	28.9	2	14.5	4.8	18,903	4.8
11	23.3	2	11.7	3.9	7,520	9.7
12	21.7	2	10.8	3.6	8,719	7.8
13	10.3	1	10.3	3.5	2,561	12.6
14	27.4	3	9.1	3.1	5,304	16.1
15	17.8	2	8.9	3.0	4,901	11.3
16	16.9	2	8.4	2.8	3,437	15.3
17	23.6	3	7.9	2.6	7,786	9.5
18	13.8	2	6.9	2.3	4,755	9.1
19	6.5	1	6.5	2.2	791	25.5
20	16.0	3	5.3	1.8	8,389	6.0
21	15.4	3	5.1	1.7	3,550	13.5
22	7.3	2	3.7	1.2	2,167	10.5
23	5.1	2	2.6	0.9	1,969	8.1
24	1.8	2	0.9	0.3	449	12.2

“ADUH” is aseptic dispensing unit hours, “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, “AWTP” is average weighted time per product

WORKLOAD RESULTS

The key results from applying the marker UTEs to the baseline survey results are shown in Tables 2 and 3.

The results showed that there was wide variation in the use made of aseptic dispensing unit facilities. For example, ADUHW

ranged from 7–114h for licensed units and from 2–348h for unlicensed units. The number of cabinets was a clear factor, and when this was taken into account (ie by using ADUHCW) there was greater consistency, although the variations were still marked (7–38h for licensed units and from 1–69h for unlicensed units). The highest

ADUHCW figure was for a licensed unit that only produced TPNs (which have high marker UTEs). The highest ADUHCW figures for unlicensed units were for high volume units. This was not surprising because producing a large number of products enables efficiencies in processes to be effected, and these efficiencies are not accounted for in the UTE values for unlicensed units. It may therefore be appropriate for high volume unlicensed units to use the marker UTEs for licensed units, but this is something for the units themselves to consider when assessing their performance internally.

When considering the time spent using the cabinets, only seven units seemed to use each of their cabinets for more than two hours per day. Even if the figure of 40 per cent (the top of the range of cabinet time observed by the work study consultant) was used to calculate CHWC, only one additional unit would meet this level of usage. It should be appreciated that the CHWC figure is by definition an

average over a week and that there are necessarily variations in the workload, with Thursdays and Fridays generally having the highest workloads in preparation for the weekend. This points to the cabinets being used sparingly at other times. It should also be noted that it is unrealistic for some smaller units to increase their workload significantly, because they essentially perform an “insurance” role – in other words, they are there to provide an essential but irregularly used aseptic facility and must be maintained in an operational state in case a patient need arises.

— CAPACITY

As with collaboration and workload, there is no consensus about a definition of capacity. It is generally viewed as a measure of a unit’s ability to maximise its workload. Various factors influence capacity. Those that tend towards increased capacity include having:

- Continuous operation and support
- A high number of isolators and cabinets
- Long and flexible opening times
- An appropriate skill mix between pharmacists and technicians and between senior and junior staff
- An appropriate level of information technology support and automation

Factors that tend to decrease capacity include the time taken to:

- Clean facilities (“down time”)
- Monitor (eg, environmental monitoring)
- Validate processes
- Train operators
- Rectify non-compliance with quality assurance standards
- Undertake checks

Any proposed formula for calculating capacity would ideally take into account all of the above (and other) factors, but this

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would lead to numerous combinations. Various models were evaluated but none provided a satisfactory definition of capacity. The lack of consistency in aseptic unit design was a major constraint.

In addition, considerably more information would need to be collected than was collected in the baseline survey to take full account of the numerous factors (especially on staffing and staff mix) that influence capacity. Collecting this large amount of information for all the trusts involved would be difficult in terms of ensuring data quality and consistency. Also, even if the data could be collected, there would still be issues about how it should be used. Without clarity about the benefits and use of additional data, it is important to minimise the demands on pharmacists for data. Instead, the steering group decided that the appropriate way forward was for each unit or trust to develop its own capacity plan. The model developed by the NHS pharmaceutical production committee is a good example for

use, and is currently being revised (for further details contact Mike Lillywhite on mike.lillywhite@bartsandthelondonon.nhs.uk). The plan should make explicit, for example, the trust's assumptions, resources and constraints. Although capacity plans should be developed locally, they should be open to external scrutiny, particularly where collaborative arrangements are in place.

The data collected in the baseline and quarterly surveys and the subsequent workload measures provide a basis for constructing such capacity plans through a benchmarking approach. It also enables relativities between trusts to be highlighted, and can be used by trusts to inform and justify their local capacity plans, taking local factors into account.

CONCLUSION

Practical models for measuring workload and collaboration, which could be applied throughout the NHS, were developed.

A specific single statistical definition of capacity was not feasible, and so individual capacity plans for trusts, using a benchmarking approach, are proposed instead.

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