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A National Evaluation of Capacity in Intravenous Systemic Anti-Cancer Therapy (IV SACT) Preparatory Services

Professor Robert Duncombe, Emma Foreman, Jurga Biliune

Introduction

For several years, concerns have been expressed across the UK regarding pharmacy aseptic SACT services and their ability to meet the ever-increasing demand for intravenous systemic anticancer therapy (IV SACT). Within the London Region, working groups have been created at both regional and local levels, aiming to address these concerns and manage the pressure on IV SACT services. It is understood that similar groups are operational throughout the UK, as pharmacy teams try to manage what would appear to be a service approaching a crisis.

A combination of factors is believed to be creating a “perfect storm”:

- Commercial compounders unable to meet demand for products
- Increasing demand for IV SACT as hospitals fully recover from the COVID pandemic
- Reductions in local aseptic unit capacity as units close either due to facilities being no longer fit for purpose, or recruitment difficulties making it impossible to sustain a viable and safe service
- Recruitment and retention issues in pharmacy aseptic services affecting all grades of staff

While there has been much discussion of these issues, there has been insufficient data to establish a UK wide picture of the current situation, and no data to measure the impact of these issues on patients or staff working in SACT services (pharmacy and nursing).

This survey, which was conducted in June-July 2022, aimed to collect data from across the UK to demonstrate the extent of the problem, and for this information to support service leaders in taking steps to avert a situation where patient outcomes start to become affected by supply issues in pharmacy.

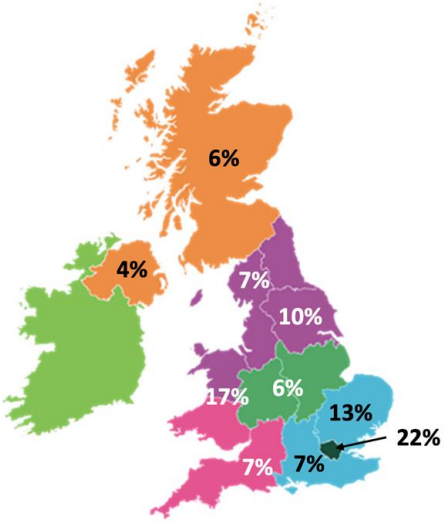
In this report, external suppliers of IV SACT are identified as being a significant contributing factor in some of the issues faced by hospital pharmacy teams. These suppliers are often confronting many of the same issues as small, local aseptic units. Commercial compounders play a key role in ensuring that patients receive access to medicines and the solutions to the concerns raised in this report are only going to be delivered through the combined efforts of all parties working together to improve the level of service provided and therefore the patient experience.

Method

To rapidly collect data from across the UK a Survey Monkey questionnaire was used. The survey was reviewed by senior pharmacy leaders from selected hospitals across the UK and

was further reviewed and endorsed by the Research Subcommittee of the British Oncology Pharmacy Association (BOPA). A copy of the survey is available on request. Approval to proceed with the survey was obtained from The Royal Marsden service evaluation committee. The survey was distributed nationally via the Chief Pharmacist network and via the BOPA mailing list from 23rd June to 5th July 2022. Reponses were anonymised and analysed using Survey Monkey and Microsoft Excel. Responders were asked to feedback on their experience of IV SACT delivery in the period January to June 2022.

Results



In total, 69 completed responses were received. The geographical distribution of these responses is shown in figure 1. The response rate was good, capturing responses from 50 SACT providers in England, 4 in Scotland 12 in Wales and 3 in Northern Ireland. Most responses were from NHS providers, however 2 responses were received from independent sector SACT providers (3%). It should be noted that not all respondents answered every question, therefore the total number of responses 'n' is quoted with each result.

Staffing levels

The first section of the survey related to staffing levels, including the number of posts included in the establishment, the number of vacancies and the number of 'hard to fill' posts (defined as a post which has been advertised at least once but not recruited to), broken down by AfC band. We have pooled the available data to give an overview (see tables 1 and 2).

In technical services the hardest to fill posts are band 3 and 4 positions while the highest percentage of vacant posts is at band 7. One respondent commented:

'we have significant concerns regarding staffing, and how we recruit/retain staff. It is proving very hard to retain technician/assistant staff, particularly with impending cost of living crisis'.

In clinical services the hardest to fill posts were in bands 7 and 8 and the highest percentage of vacant posts at band 4. It should be noted that in many oncology pharmacy teams, the same staff carry out both clinical and technical tasks as illustrated by this comment:

'We have a very lean team of pharmacists who are responsible for both the clinical and aseptic aspects of the service, and this can result in staffing challenges'

Table 1. Pooled data showing technical services staff establishment and vacancies (n=45)

Band	2	3	4	5	6	7	8
Total in establishment	95	199	132	156	96	75	101
Currently vacant	28	40	25	24	18	26	15
% Currently vacant	29%	20%	19%	15%	19%	**35%**	15%
Hard to fill=Y (% of responses)	18%	**44%**	**40%**	36%	24%	33%	27%

Table 2. Pooled data showing clinical services staff establishment and vacancies (n=50)

Band	2	3	4	5	6	7	8
Total in establishment	23	40	45	105	73	186	239
Currently vacant	4	6	14	12	16	40	43
% Currently vacant	17%	15%	**31%**	11%	21%	22%	18%
Hard to fill=Y (% of responses)	6%	10%	12%	14%	12%	**32%**	**30%**

Service quality

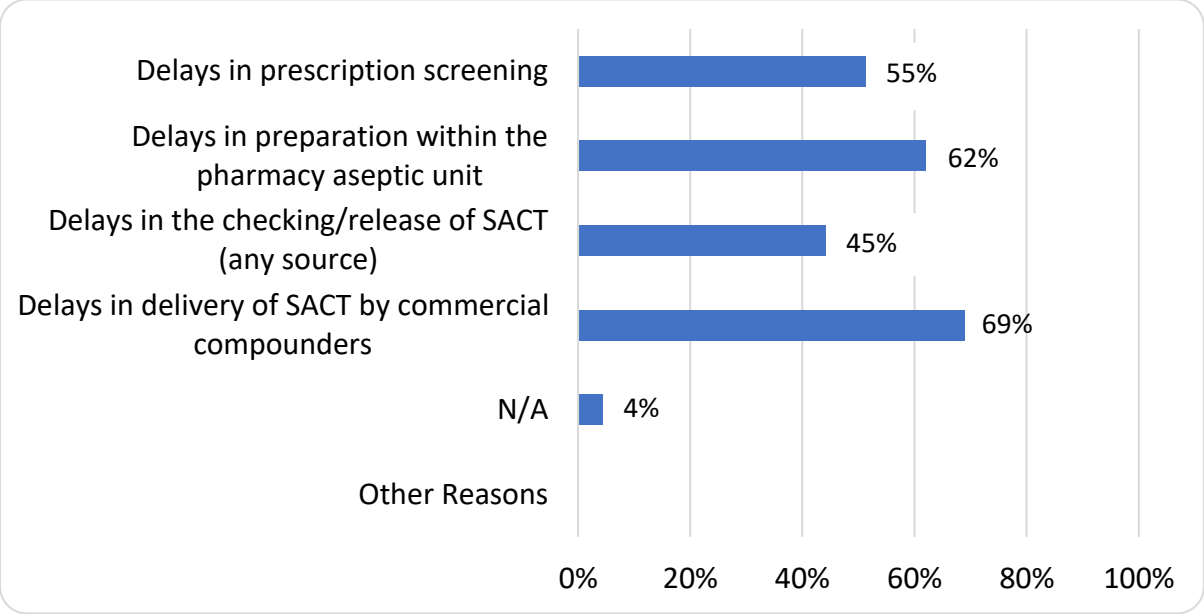
For any patient with cancer, time is valuable, and for those undergoing palliative treatment any time spent at hospital is time away from family and friends in what could be the last few months of their life. A delay in treatment delivery can impact disproportionately on a patient's quality of life. The survey sought to measure the level to which delays in pharmacy resulted in delays to treatment.

91% of respondents (n=58) reported that their pharmacy service had been responsible for 'same day' delays in treatment, defined as any occasion when a patient's IV SACT is not available at the scheduled administration time.

When asked how often pharmacy were responsible for same day delays, 45% reported this happened monthly, 27% weekly, and 16% reported delays on a daily basis (n=56).

The main causes of same day delays are shown in figure 2.

Figure 2. Main causes of pharmacy-related delays in delivery of IV SACT (n=55)

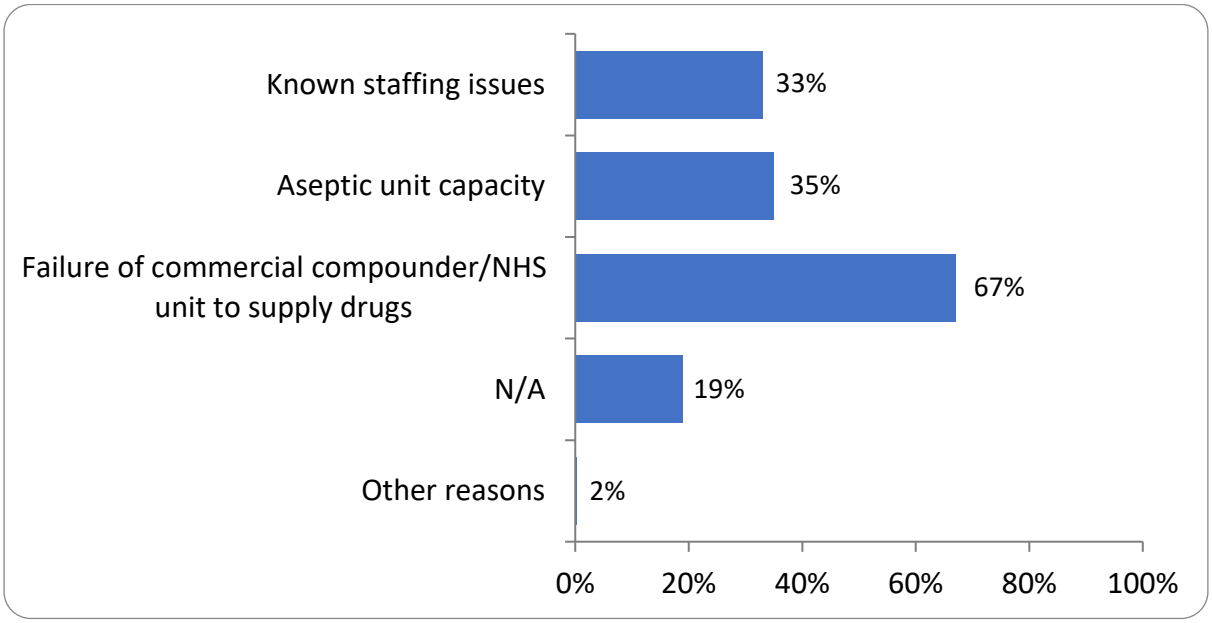


The most common cause of delay was a delay in the delivery of IV SACT by commercial compounders (69%), followed by delays in in-house preparation (62%) and delays in prescription screening (55%) (n=55).

On some occasions all these elements may come together to cause long delays for patients. A delay in screening could be followed by a lack of availability of commercially supplied product, which must then be made “in house” which could also be subject to delay.

The survey examined occasions where a patient’s treatment has had to be rescheduled to a different day due to pharmacy being unable to provide their IV SACT. 76% of respondents reported that this had happened at least once in the last 6 months (n=58) with 43% reporting this happened at least monthly and 24% at least weekly (n=54). The main causes for these delays are shown in figure 3.

Figure 3. Main causes of pharmacy-related delays resulting in rescheduled treatment (n=43)



Rescheduling of treatments, because of delays in the supply of chemotherapy, is a common occurrence. This inevitably has an impact beyond just the pharmacy service, as it requires the input of medical, nursing, and scheduling teams. Given the capacity constraints across most day-unit services, finding additional treatment slots for patients at short notice is challenging.

The most common cause of treatment rescheduling was the failure of commercial compounders to deliver the IV SACT (67%). Most respondents (74%) use a mixture of in-house preparation and outsourcing to commercial compounders, however 16% rely entirely on bought-in products, and therefore a failure to supply by a commercial compounder will directly result in a treatment having to be rescheduled. Only 10% of respondents still make all IV SACT in-house (n=49).

Of those respondents procuring IV SACT from commercial compounders 98% reported that they had experienced delays in receiving orders, 51% had had orders cancelled and 47% had orders changed (n=51). One respondent commented:

'Our trust do not have an aseptic unit, so we rely on commercial unit for IV SACT preparation. The delay of IV SACT delivery has become a norm rather than an exception every day with one of our commercial units……. We had a patient who was due cetuximab, the treatment was not delivered on the day before the treatment (as we planned), then it was not delivered the following day (i.e. the day of treatment), and then not the following day; so the patient end up having to be delayed for not once but twice for the treatment'

'We once had a 21yo with Hodgkin's lymphoma, being treated with ABVD. Understandably, it is a lot for a 21yo to take in having cancer and having to receive the treatment. He plucked up a lot of courage to come and have his treatment, but due to delivery failures, his first 3 treatments had all been delayed. It affected his morale so much, every time he had to have a few days to gather himself to receive treatment again'

In units where in house preparation is available, the failure of commercial compounders to fulfil orders can add strain to an already overloaded system as described by this respondent:

'critical supply issues from commercial compounders combined with the increase in overall activity has caused a huge spike in products required to be prepared aseptically. This pushes the aseptic capacity over resourced limits on an almost daily basis'

As would be expected, these service issues have resulted in a complaints.

76% of respondents said that their department had received informal complaints about the IV SACT service, and 25% had received formal complaints (n=51).

Day unit capacity

The third section of the survey tackled day unit capacity, and 40% of respondents said that their institutions were experiencing delays in getting patients started on IV SACT (n=51). These delays range from 1.4 days to 4 weeks. Of those that reported delays, 23% said the delay was less than 1 week, 45% said 1-2 weeks and 18% said 2-4 weeks (n=22).

40% of respondents indicated that their institution had put measures in place to help manage IV SACT demand (n=53). These included:

- Restriction of palliative cycles, low priority treatments, EAMS and compassionate access schemes. Use of the NICE COVID guidelines (NG161) to aid prioritisation.
- Favouring oral SACT options, using longest licensed dosing frequency
- Increased use of homecare and self-administration schemes
- Saturday opening
- Use of pre-assessment clinics and pharmacist prescribers to reduce delays in prescribing. Extending the validity period of blood tests to allow early confirmation.
- Collaboration with other units

The safe delivery of chemotherapy is a truly multidisciplinary endeavour, requiring input from teams and services across a hospital. When determining how to meet current and future demand it is essential that all services are involved in these discussions, as the service will only ever be as good as the capacity of the weakest service.

Disappointingly, only 45% (n=53) of respondents said that the pharmacy team were involved in capacity planning discussions at their institution, and only 8% reported that this input had resulted in any form of treatment capping (n=51).

Workload trends

The COVID pandemic initially resulted in a reduction of activity. In the early days of the pandemic, measures were taken to reduce hospital attendances, and in some cases the total number of treatment cycles administered was reduced or IV treatments were replaced with oral alternatives.

Post-COVID, activity levels have increased. 85% of respondents reported that workload had increased compared to pre-COVID levels (n=52), and 96% anticipate that it will continue to rise over the next 5 years (n=53). When asked to estimate the annual percentage increase in activity, most respondents estimated within the range of 5-15%. Only 25% expected an increase in staffing to manage this increase (n=51).

Participants were asked to rate how concerned they were about IV SACT services and their ability to continue to supply IV SACT to patients over the next 2 years on a scale of 1-10 (1=no concerns, 10=extremely concerned). The distribution of scores is shown in figure 4. The median score was 8 (n=51).

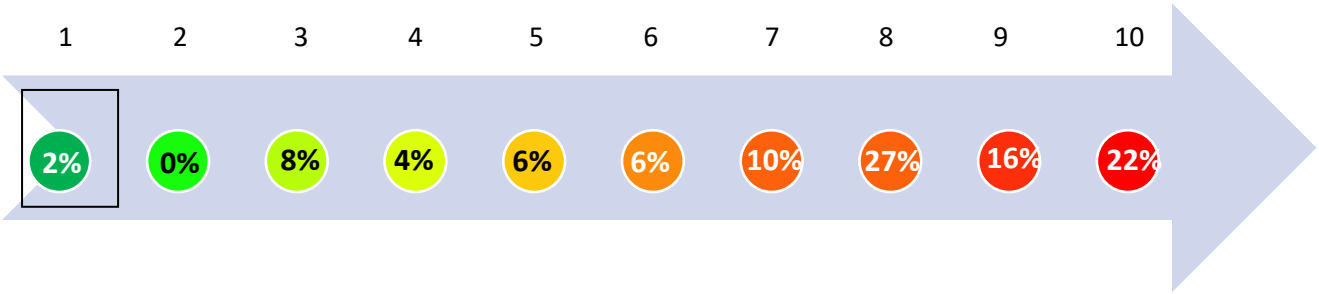


Figure 4. Likert scale showing levels of concern over IV SACT service capacity over the next 2 years (1=no concerns, 10=extremely concerned)

Respondents were also given the opportunity to contribute examples of how the current challenges in IV SACT services are impacting on patient care. See appendix 1 for their full responses.

Discussion

Pharmacy IV SACT services are under considerable strain, and approaching a crisis point. Currently, this is manifesting itself in poor patient experience, recruitment and retention problems, and treatment delays.

The key issues identified are:

1. The failure of commercial compounders to meet demand, and the subsequent delays and changes to orders meaning that patients are having treatments delayed or rescheduled. This creates additional workload for all staff involved in the treatment pathway.

2. High vacancy rates in both aseptic and clinical services mean that services are working at, or above capacity. Often these posts are hard to fill, with posts advertised several times before they are recruited into. Given the small numbers of staff entering aseptic services, the filling of a vacancy at one hospital is likely to result in a new vacancy at a neighbouring hospital.

3. When services are under strain, errors are more likely to occur. Aseptic preparation is inherently risky, and the consequences for patients of IV SACT errors can be severe. In the case of a clinical trial, this could result in the patient no longer being able to participate in the study. For other patients this could mean toxicity or a sub-optimal response to treatment. For staff involved in these errors there is a resulting loss of confidence and for some, a desire not to work in such a high-risk environment, further adding to existing workforce pressures.

4. When planning services, pharmacy capacity is not being taken into consideration by all providers, with an assumption that "pharmacy can cope". It may well be the case in the future that the rate-limiting factor in the provision of IV SACT is pharmacy's ability to provide the drugs.

There is a high level of concern amongst senior pharmacy leaders regarding the provision of IV SACT services and that the situation is outside of their control.

It was envisaged that commercial providers and larger, regional aseptic units would relieve the capacity shortfalls in hospital units. A key tenet of the 2016 Carter Report (Operational productivity and performance in English NHS acute hospitals: Unwarranted variations. An independent report for the Department of Health by Lord Carter of Coles) identified pharmacy aseptic services as falling into Infrastructure Services, which could / should be provided at a more regional level.

However, the commercial sector (which includes large, licensed NHS units) has been unable to meet the demand, and the unreliable supply has led to increased workload for in-house services and for those hospitals with no in-house provision, resulting in treatment

cancellations and delays. There are likely to be many reasons for this. Commercial compounders are likely to be experiencing the same workforce issues as NHS units. The competition for staff is fierce, and these staff, particularly when working in MHRA licensed units, take a long time to train. Quite rightly, the regulatory framework under which licensed units operate mean that product safety and integrity is placed over all other concerns.

New SACT treatments are being licensed and approved for use every year, including new technologies. There are currently 29 ATMPs and CAR-T therapies in the UK pipeline for approval (https://www.sps.nhs.uk/articles/annual-planning-advice-for-new-medicines-prescribing-outlook/). It is recognised that additional pharmacy resource will be required to ensure these highly specialist and complex therapies are implemented safely into routine clinical practice, yet we are currently unable to meet the existing demand for routine SACT treatments.

One of the limitations of this survey is that it does not cover oral SACT, which although it does not require aseptic preparation, is usually processed by the same team of pharmacy staff. Demand is also increasing for oral SACT, and oral options were actively encouraged during the COVD pandemic as described by this respondent:

'We're right on the edge! Currently just about managing demand but this is a daily shuffle between OP SACT unit, Ambulatory Care unit, supportive care day unit and wards. This survey doesn't take account of PO SACT services - this is having a huge impact on our clinical Pharmacy teams from a validation perspective - during COVID, we have had to double resource allocated to this activity'

Pharmacy IV SACT services are dependent upon having a trained and highly skilled workforce. The survey highlights that workforce issues are impacting upon the ability to provide a safe, efficient service. Vacancy rates are high across all staffing groups, and leaders are concerned about where the future workforce will come from. It is expected that demand for aseptic services will continue to rise, and without an increase in staffing (pharmacist, technician, qualified and unqualified) it is hard to see how future demand will be met.

It is noted that Health Education England are creating training programmes for new categories of pharmacy support staff (level 2 science manufacturing process operative and level 3 science manufacturing technician), however it will be a number of years before the results of these initiatives are seen.

The aseptic hub capital fund has allocated funding for hub and spoke pathfinder sites to improve capacity, but in the short term it is likely that these will be staffed from existing pools of NHS staff.

More work is required to understand the workforce shortages in hospital pharmacy and in particular aseptic services.

Recommendations

Concerns about pharmacy IV SACT services must be taken seriously. The high levels of treatment delays, deferrals and cancellations need to be taken as a warning sign that urgent action is needed to address the issues identified in this report. We recommend the following actions:

1. Recognition, outside of pharmacy, that this is a serious issue, with huge potential to affect the ability of hospital pharmacy teams to supply IV SACT.

2. The relationships with commercial compounders and larger licensed NHS units is key. Hospitals must work in partnership with these entities to ensure that all parties do everything they can to utilise optimally the limited aseptic compounding capacity available. All hospitals must fully adopt dose banding and standardisation in order that these products can be made in large volumes and truly become "off the shelf" products.

3. A clear plan must be developed to address both the short-term and long-term issues around IV SACT supply. Action is needed to address the workforce issues that are affecting all compounders of IV SACT.

4. A review of the regulatory environment in which hospital pharmacy aseptic units operate, to enable aseptic units with capacity to support other hospitals within their integrated care system (ICS) areas. There will always be a small number of products that have to be prepared locally on a patient-specific basis, and currently no mechanism exists for these products to be made, without relying upon commercial compounders.

5. Optimising the aseptic resources that we do have. Aseptic units should only be preparing those products that they have to prepare. Clear guidance is needed defining what should and should not be prepared within a hospital aseptic unit (e.g. standardising the preparation of some monoclonal antibodies in clinical areas) in order to make optimal use of the limited resources we have available.

6. Pharmacy teams must be part of all capacity planning discussions regarding IV SACT services. This may ultimately mean that alternative treatment options are followed in order that hospitals can provide all treatments to patients on curative treatment pathways.

Acknowledgments

We would like to thank everyone who has contributed to this survey, and in particular the members of the BOPA Research Subcommittee who reviewed the survey and the BOPA community who shared the survey.

Contact Details.

Professor Rob Duncombe. Robert.duncombe@rmh.nhs.uk. Tel 07817 385703.

Emma Foreman. Emma.foreman@rmh.nhs.uk

Jurga Biliune. Jurga.biliune@rmh.nhs.uk

Appendix 1. Responses to question 28: 'Please briefly describe how the current issues within pharmacy IV SACT services are directly impacting on patient care'

'The eroded resilience in Pharmacy SACT services is at best, also eroding the patient experience that we have worked so hard to improve (many more disruptive short notice delays, changes in treatment site, multiple deliveries or pickups for patients). At worst, the Pharmacy system is operating under such pressure that the risk to patients is increasing unacceptably; this is in terms of overall medication safety, but also of services falling over completely and treatments not being provided at all. There is no resilience in either NHS or Commercial services to pick up the slack of a unit failure; something we all fear.'

'Service has met demand to date but patients sometimes have to be rescheduled several times before a treatment slot can be confirmed. Not clinically significant but disruption is stressful for patients and staff alike. Service is now creaking at the seams, with detrimental impact on staff, manifesting as high turnover, staff dissatisfaction (NHS staff survey results), work-related stress, sickness absence etc. Problems compounded by a decade of sub-inflation pay rises affecting recruitment. NICE website horizon scanning suggests significant increases in workload heading our way, especially immunotherapies and gene therapy developments as well as traditional chemotherapy. We do not yet have a future capacity and workforce plan in place to meet this projected demand and are not confident that it will be adequately funded in any case'

'Due to 50% increase workload in the last 5 years, without the increase in staffing, we are unable to keep up with demand for pharmacy screening of SACT. Due to lack of NHS funding, we are unable to increase staffing numbers, current staff having to work overtime and use of NHSP to cover workload, which is not cost effective. Team has lots of proposals to improve skill mix cost effectively with additional low banded staff to release highly skilled pharmacists to do screening and extended roles to support the depleted medical workforce. Use of pharmacy staff for NMP is a cost effective skill mixed model to increase NHS capacity'

'Late delivery, some patients leave and need rescheduling, others stay which knocks on to chair time for rest of the session'

'Staff shortages, especially with Technicians is limiting ability to efficiently deliver chemotherapy and also limits ability to set up clinical trials, where this is required it may have a knock on effect with us being able to compound chemo in timely manner'

'They are having significant impacts on patient's experience of service, and all staff wellbeing. Complaints have been raised by both patient and staff bases regarding current service and capacity.'

'I have answered this survey on behalf of XXXXXXX merging data from our two sites that operate differently. Drug shortages of SACT have been increasing over the past few years and have led to delays in treatment and patients needing to change treatments which is not optimal. The lack of availability of bought in premade outsourced bags for items such as rituximab has increased the workload for the nursing staff at ward level when they are already stretched and this means the nursing staff have less time to spend with patients'

'we have significant concerns regarding staffing, and how we recruit / retain staff. it is proving very hard to retain technician / assistant staff, particularly with impending cost of living crisis'

'critical supply issues from commercial compounders combined with the increase in overall activity has caused as huge spike in products required to be prepared aseptically. This pushes the aseptic capacity over resourced limits on an almost daily basis. This peak in activity and lack of resourced capacity results in regular delays to patients treatments. We still have same day requests for chemotherapy which are given priority over some of those prescribed in advance, the issues described above mean that these advance patients are also the delayed due to the knock on capacity constraints. Continually working at or above resourced capacity pushes staff to the limit greatly increasing the chance of errors occurring and significantly increases the risk of patients being adversely affected'

'Lack of SACT prefilled bags/syringes availability from compounders is most problematic. Due to the reliance on compounders providing such SACT items pharmacy stockholding of raw materials is reduced.
Items not delivered by commercial compounders have to be manufactured in house. On occasions the raw ingredients cannot be obtained in time for appointments, increased aseptic team workload and risk or errors and upper limb disorders. Patient delays and subsequent complaints increased'

'We try very hard not to impact directly on patient care but this takes a lot of pharmacy time to manage ordering and supply. Local NHS unit in separate hospital has caused delays due to missed orders, lack of stock, lack of capacity which has resulted in patients travelling for treatment and then returning home without having received, due to 1pm delivery time - the patient can arrive before delivery of dose from NHS production unit'

'We have a very lean team of pharmacists who are responsible for both the clinical and aseptic aspects of the service, and this can result in staffing challenges'

'We're right on the edge! Currently just about managing demand but this is a daily shuffle between OP SACT unit, Ambulatory Care unit, supportive care day unit and wards. This survey doesn't take account of PO SACT services - this is having a huge impact on our clinical Pharmacy teams from a validation perspective - during COVID, we have had to double resource allocated to this activity'

'Staff recruitment and retention major issue leading to delayed training and service delivery to patients. Business cases long winded and very slow to take effect. Not all doses can be premade due to capacity/prescribing issues leading to delays on the day.'

'6 weeks delay in supply of dose banded products from commercial providers is a problem at the moment. In a district general hospital where we do not require large quantities we can only place our orders after it has been prescribed in order to avoid wastage. This makes it difficult to plan as 6 weeks is a long time to delay a patient's treatment'

'Delays cause increased stress for patients due to loss of dose intensity'

'Aspetic unit has outgrown the service, ideally need a new unit. Pharmacy are the limiting step to increasing capacity, as no resources to employ more staff for carrying out clinical work too'

'Our trust do not have an aseptic unit, so we rely on commercial unit for IV SACT preparation. The delay of IV SACT delivery has become a norm rather than an exception every day with one of our commercial units. It is to a point that we avoid ordering from them because we don't believe the orders would come in the following day, and it is a surprise to everyone if the products actually get delivered when we made an order. There are 2 specific poor examples. 1) We had a patient who was due cetuximab, the treatment was not delivered on the day before the treatment (as we planned), then it was not delivered the following day (i.e. the day of treatment), and then not the following day; so the patient end up having to be delayed for not once but twice for the treatment. 2) We once had a 21yo with Hodgkin's lymphoma and is being treated with ABVD. Understandably, it is a lot for a 21yo to take in having cancer and having to receive the treatment. He plucked up a lot of courage to come and have his treatment, but due to delivery failures, his first 3 treatments had all been delayed. It affected his morale so much, every time he had to be have a few days to gather himself to receive treatment again.'

'The main issues are delays to treatment either due to workload or poor procurement'

'Difficult to accommodate urgent patients, very little flexibility for delaying patients and severe restrictions on the times at which certain regimens can start. Adds pressure to the rest of the system'

‘My biggest worry is that we will not be able to fill vacant Support Worker and Technician posts as rates of pay at band 3 and 4 are particularly unattractive at the moment. It takes a big investment in time to train a support worker from scratch as they don’t usually have previous experience, yet this tends to be the staff group with the fastest turnover, resulting in constant training effort with a very short term or no pay back. This could be helped by having it be more normal to have band 3-4 progression for support workers. For technicians my worry is that there are no "new" technicians coming through with any aseptic (or other production) skills - so where will band 4s come from? I think this could be helped by having the SMT qualification leading to registration with the GPHC as a registered technician. In a DGH it is rare for an aseptic technician post not to have an element of "dispensary" time contracted eg Saturdays, late nights etc. If this was removed it would "give back" some aseptic capacity. eg My team loses approximately 0.5WTE of a technician per week to cover non aseptic/production activity (ie it is lost to the dispensary) I would like to see Registered pharmacy technicians be able to qualify for "advanced" status. eg clinical screening, being responsible for section 10 activities. This would enable pharmacists to be better supported so they could be prescribing in clinics which is something they struggle to get the time to do. Its high time that the profession and the law moves on’

‘Our service is extremely restricted and dependent on commercial suppliers of iv sact’

‘Aseptic capacity is going to be even more challenged by new molecules and technologies coming out e.g. Tebentafusp, Sacituzumab Govetican, Viruses, ATIMPs. Current aseptic compounders are focused on delivery of current demand and there is a lack of interest into future provision on new difficult to compound molecules’

‘Late prescribing happens occasionally and can impact on our ability to prepare treatments in advance, which can result in avoidable patient delays. -IV SACT is currently prepared in-house due to inconsistency of external providers to meet outsourcing demand. If there was a move from patient specific orders to batch orders of standardised products, more Trusts would be able outsource, freeing up capacity and improving patient care’

‘Due to staffing and facility, our aseptic service only can provide a morning SACT reconstitution (PN in the afternoon), at time this causes delay in patient treatment because the responsiveness of the aseptic service is reduced. Over the years, the SACT services had adapted to this arrangement and the delays is kept to the minimum’

‘Some drug shortages impact ability to deliver treatment e.g. supportive therapy, zoledronic acid Recruitment process takes a long time resulting in gaps in posts which impacts available staff health and wellbeing/sickness. Lack of sufficient medical prescribers results in late orders which has a knock-on effect on ability to deliver treatment at the scheduled appointment time. Delays in reporting of investigation results sometimes causes delays in prescribing SACT (pathology lab issues)’