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NHS

Elastomeric Devices

Delivering 24-hour IV antibiotics in patients' homes

Information pack for health and care stakeholders to support adoption and spread

December 2022

Contents

Elastomeric Devices Delivering 24-hour IV antibiotics in patients' homes

Oxford Academic Health Science Network

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The challenge

Pressure on inpatient hospital beds is a longstanding issue. Through the virtual ward / hospital at home programme, alternative ways are being actively sought to:

- treat patients safely and appropriately without needing to admit them to hospital, and
- reduce the time patients spend in hospital by facilitating safe discharge at an earlier stage in their treatment pathway

Elastomeric devices are small, single use pumps used to administer medication such as intravenous (IV) antibiotics or chemotherapy. As these pumps can be used at home, they have the potential to help relieve pressure on hospital beds by facilitating earlier discharge for medically stable patients who would otherwise remain in hospital to receive their IV therapy, or support patients to remain at home and avoid admission.

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Our aim and how we can help

This information pack has been compiled by the Oxford University Hospitals NHS Foundation Trust (OUH) and the Oxford Academic Health Science Network (AHSN) to provide information, guidance and learning to organisations who may be interested in introducing the elastomeric device for delivering 24-hour IV infusions in patients' homes.

The guidance in this document is based on the experiences of OUH, who introduced elastomeric devices for use in patients' homes in November 2019. Other organisations may have different arrangements and services in place, so implementation may vary.

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Outpatient Parenteral Antimicrobial Therapy Services

Outpatient parenteral antimicrobial therapy, or OPAT, services enable the delivery of IV antibiotics to patients, who are medically stable, within their own homes. OPAT is becoming increasingly used as a means of treating patients who need IV antibiotics, but who do not need to stay in hospital for other reasons.

There is no single model of care, with some services being delivered in community clinics and others in patients' homes, depending on the local available healthcare resources. As the health service increasingly moves to an integrated care service model and with growing hospital at home services, this could be an attractive approach to providing suitable and safe care outside of the acute hospital setting.

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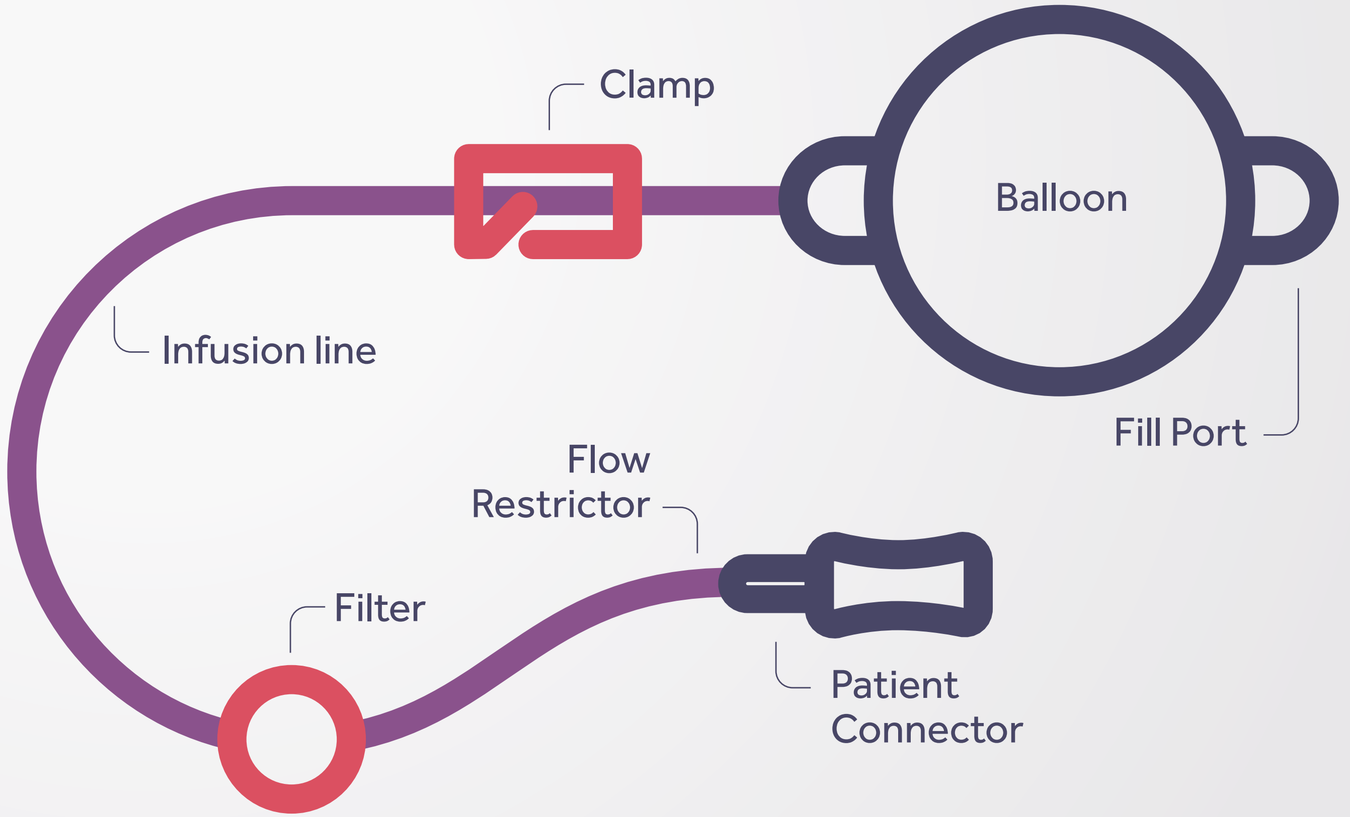
What is the elastomeric device?

Elastomeric devices are small, single use pumps used to administer medication such as IV antibiotics or chemotherapy. The pumps are needle-free and do not require electricity or gravity to administer the medication. Instead, the pressure required to administer the drug comes from the elastomeric membrane inside the pump. The membrane is stretched when the pump is filled, the force of which is used to deliver the medication. The pumps are available in many different sizes with differing flow rates.

The device can deliver medication over a constant time period, such as 12 or 24 hours, and the rate of administration remains constant. Empty devices can be procured which are filled by trained staff using the aseptic non-touch technique (ANTT) when they visit the patient or in an aseptic unit. Alternatively, devices can be purchased pre-filled and stored in the fridge.



Why use the elastomeric device?

OPAT services are a suitable model of care for patients who would otherwise remain in hospital purely to receive IV antibiotics. The use of elastomeric devices enables a greater number of suitable, medically stable patients to be discharged earlier, or prevent admission of patients, as they can receive the necessary ongoing care within their own home. This in turn will release bed days back into the acute hospital system which will reduce the burden on inpatient beds and improve the flow of patients through the hospital.

OUH service

The introduction of the elastomeric device within OUH increased the capacity of the ambulatory nursing team. By reducing the number of home visits required to one a day, the team were able to safely provide care to a greater number of patients, thereby saving a greater number of bed days. Furthermore, the use of the device has enabled a wider group of patients to benefit, as previously the ambulatory nursing team were only able to provide care to patients requiring up to two times a day IV infusions. The use of the elastomeric device has enabled the ambulatory nursing team to care for patients who previously would have needed three to four times a day IV infusions.

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24-hour infusions via elastomeric devices

The British Society of Antimicrobial Chemotherapy (BSAC) OPAT Drug Stability Testing Programme provides evidence on the stability of drugs and devices used in infection management practice, particularly those used in OPAT services.

The critical factor for 24-hour infusions via elastomeric devices is that the drug must remain stable for 24-hours at 32°C within the device. OUH have used the following three drugs within the elastomeric device for 24-hour infusions in patients' homes:

- Piperacillin/Tazobactam
- Flucloxacillin
- Ceftolozane/Tazobactam

However, BSAC is continually testing and updating stability data for 24-hour infusions. Please refer to their website for the latest guidance.

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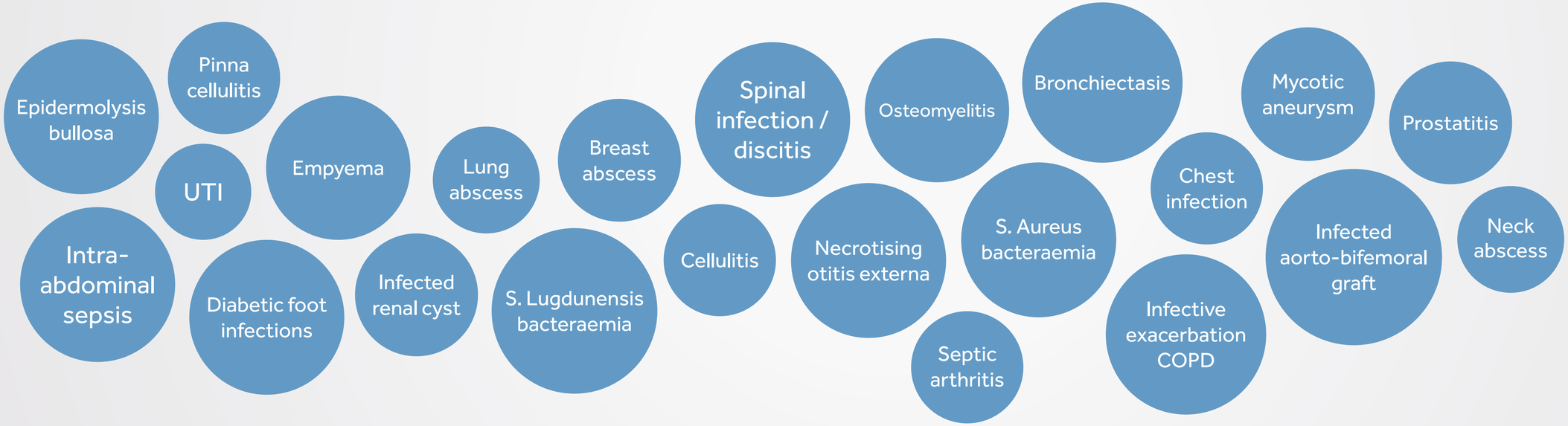
Patient suitability and eligibility criteria

There are no defined cohorts of patients who could benefit from the elastomeric device, as the anti-microbials used for 24-hour infusions treat a wide range of conditions. Conditions treated via the OUH service include:



The device can be used with any patient who is receiving one of the IV antibiotics outlined above multiple times a day. Following identification of patients receiving the appropriate IV medication, patients will need to be reviewed to ensure they are medically stable and suitable to be discharged home with an elastomeric device to continue their treatment at home.

Patient suitability and eligibility criteria

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OUH service

OUH has developed criteria by which staff can assess patients for suitability, and is outlined below:

Inclusion criteria

Patient understands & can consent to ambulatory treatment using elastomeric device

Patient is medically stable as deemed by clinical team caring for them

Patient has suitable CVAD; midline is minimum suitable standard

Patient is receiving treatment in appropriate environment with access to appropriate medical team

Patient has received at least one dose of prescribed antibiotic without reaction prior to being initiated on 24-hr infusion

Caution criteria

Patient has history of drug abuse

Patient has psychiatric illness, severe depression, suicidal tendencies

Patient has physical disabilities which may prevent self-administration; should be assessed on individual basis

Children or vulnerable adults at home and may have access to medicines

Exclusion criteria

Patient is at risk of self-harm

Safeguarding concerns

Patient is deemed unable to participate due to lack of capacity as defined under the Mental Capacity Act (2005)

Patients must also be counselled regarding the elastomeric device to ensure they are fully informed to consent to the administration of the IV infusion via an elastomeric device. A patient information leaflet must also be given to the patients to explain this form of treatment.

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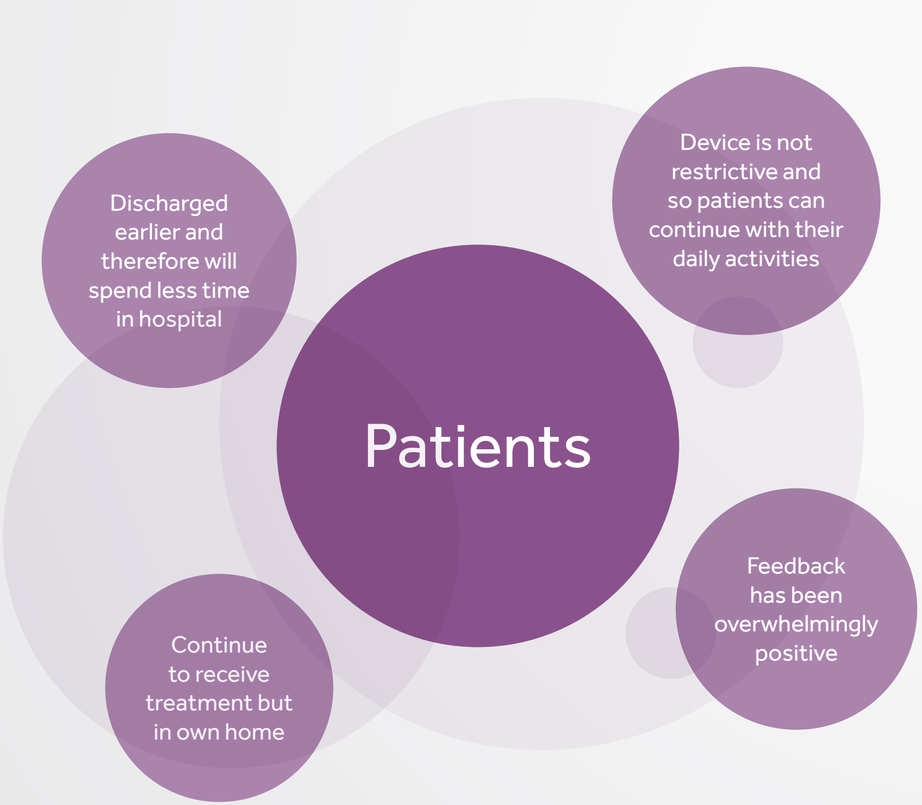
Potential benefits

There are many benefits for both patients and the health system that could be realised from using elastomeric devices:



Service models

There are different ways a Trust can realise the benefits associated with elastomeric devices, depending on the resources that may already be available. The different options for preparing and administering the device are outlined below.

Options for preparing the device

1 Purchase empty elastomeric devices – filled by nursing staff using ANTT

Trusts will need to have a process to fill the devices appropriately. Depending on the particular device, nursing staff could fill the device using the Aseptic Non-Touch Technique.

- Benefit: greater flexibility for responding to patient needs as staff can fill devices as and when required, which in turn ensures medicines are not wasted
- Drawback: device needs to be connected to patients within one hour of filling

2 Purchase empty elastomeric devices – filled by aseptic or CIVAS unit

This option would be viable if a Trust has an aseptic or CIVAS (centralised intravenous additive services) unit.

- Benefit: the benefit of devices being filled as required but with the additional benefit of providing longer expiry times than if the device was prepared out the aseptic environment. The capacity and responsiveness of the aseptic or CIVAS unit would need to be considered

3 Purchase pre-filled elastomeric devices

Pre-filled devices can be purchased and stored in a fridge for up to 10 days. These devices would be subject to pharmacy quality procedures and would need to be dispensed by pharmacy before use.

- Benefit: convenience of pre-filled devices and no requirement by Trust staff to fill the device prior to administration
- Drawback: potential wastage of medicines if the devices are not used in time. Usage will depend on the need of patients, which can be difficult to predict. The cost of pre-filled devices will also be greater than empty devices

4 Use a homecare company to provide the medication

A homecare company can provide the specific medication against a prescription, which can be delivered direct to patients' homes or to the hospital pharmacy. This could be a model of care for predictable discharges or long-term antibiotic usage.

- Benefit: the Trust does not need to use resources to prepare and transport the devices
- Drawback: there is usually a delay of approximately 48 hours between the prescription being sent and medications being delivered. This would result in patients having to wait longer in hospital and so the full benefit of realising bed days would not be realised. The method of administering the devices to patients would need to be carefully considered

Options for administering the device

1 Hospital at Home service

Clinical staff will visit a patient in their own home to deliver care. Within OUH, the Trust provides this, with nursing staff filling the device in hospital before transporting to a patient's home. Alternatively, community Trusts, who provide a hospital at home service, could undertake this or possibly district nursing teams. Clear governance arrangements would need to be in place regarding which Trust has oversight of the patients and who patients should contact if they have any concerns or issues.

This model of care could be delivered with devices that are filled by the nursing team, pre-filled devices or devices delivered direct to patients' homes.

2 Patients attend ambulatory ward / outpatients / community clinics each day

This model would see patients attending the hospital or community clinic each day to have the device changed. This has the advantage of not requiring a hospital at home service, but consideration would need to be given to the impact on patients being required to travel to daily appointments, plus the additional nursing resources required to administer the devices to patients in clinic.

3 Patients self-administer devices

Patients are taught to administer the device themselves. This option would require pre-filled devices to be delivered to patients' homes (or patients could take a week's supply home). Patients would need clear guidance on how to store and dispose of devices, and a clear escalation plan for any issues or concerns. Additional consideration would need to be given to patient selection as this option would require patients to be particularly vigilant for potential signs of concern, plus patients' dexterity would need to be considered to ensure they could change the device. While this model would not require daily visits by the clinical team, a weekly visit or hospital appointment would be required to take observations, blood tests and dressing changes for the line.

Trusts will need to work through the different options and decide on the best model of care based on staffing, infrastructure and costs.

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OUH patient pathway

The diagram below highlights the key steps in a patient's journey at OUH.

Inpatient reviewed by ID/microbiology team for suitability → Referral made to the Acute Hospital at Home (AHAH) team → PICC or mid line inserted, if not already in situ → AHAH team reviews and consents patient on ward

↓

On day of discharge, AHAH nurse administers first device on ward → Post discharge, AHAH team reconstitutes device in hospital and travels to patient's home (device must be connected within 1 hour of filling) → AHAH nurse visits patient daily to administer new device → AHAH nurse takes obs at visit:
Daily: temp / HR / BP
Weekly: blood test / dressing change

↓

Weekly MDT held to review patients, ensure they are responding to treatment, discuss issues & ensure appropriate follow-up plan is in place → On final visit, nurse will remove device and line → Discharge summary sent from AHAH team to patient's GP

Concerns can be raised with nurse at daily visits; these can be escalated to clinical lead or original inpatient medical team if necessary. Urgent issues outside of working hours that cannot wait until next visit, patients advised to contact 111 or 999 as appropriate

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Approval process for introducing into clinical practice

The approval process will vary between Trusts. However, the key steps to consider are:

1 Approval by new technologies committee

This group could be the first step in the approval process, particularly if your organisation does not use elastomeric devices already. Such a group will be interested in the device itself, including technical specifications, CE marks and approval for use in healthcare.

At OUH, this committee required the clinical team to undertake an inpatient pilot. This was to see the device delivering IV antibiotics over a 24-hour timeframe within the hospital setting, to identify if there were any issues prior to approval for use within patients' homes.

2 Approval by medicines management committee

It is important for the medicines management committee to be involved in the approval process, as this model of care involves delivering IV antibiotics in a different way and in a different setting.

3 Business case approval

A business case may be required for this service development. This case will outline the service proposal, benefits and risks, alongside the cost effectiveness of the proposal. Data will be a key component of the case as it will be essential to demonstrate the potential number of patients who could benefit from the service.

Data considerations

There are a few key pieces of information that will be needed in order to build the business case:

a) The number of patients who could potentially benefit from the service. To do this, look initially on the electronic prescribing system for the number of patients on Piperacillin/Tazobactam, Flucloxacillin, and Ceftolozane/ Tazobactam. These patients will need to be assessed to understand how many are medically stable and suitable for discharge to continue treatment at home. This is likely to need a review on the ward with the clinical team, and you may want to repeat this over a period of time to gather more data.

b) If you already have access to at Hospital at Home or OPAT service, there is other information that is relevant to the case. Questions you may wish to ask are:

- Does the H@H or OPAT service accept patients on more than once a day antibiotics?
- If yes, how many patients are on 3 or more times per day antibiotics (Piperacillin/Tazobactam, Flucloxacillin, and Ceftolozane/ Tazobactam)?
- How many referrals for these antibiotics have not been accepted due to capacity reasons?

This data will help to show the potential for increased efficiency within the service that could be realised if patients were able to be discharged with elastomeric devices.

4 Governance arrangements

As with any service, a clear governance structure is crucial. The service should have clear lines of clinical and managerial responsibility, and if patients cross between acute and community organisations, it is important there is clarity on which organisation has responsibility and oversight for patients and the service. The governance arrangements should detail the robust method of monitoring the outcomes of patients during their treatment, such as daily and weekly observations and MDT review meetings. Furthermore, there should be clarity on how patients can escalate concerns both during and outside of normal working hours, and which team has responsibility for addressing these concerns.

The BSAC has developed good practice recommendations for OPAT services, which includes an assessment tool for services to self-assess against recommendations: **http://e-opat.com/wp-content/uploads/2020/06/BSAC_OPAT_GPR_Tool_FINAL_100320.pdf**

Approval process for introducing into clinical practice

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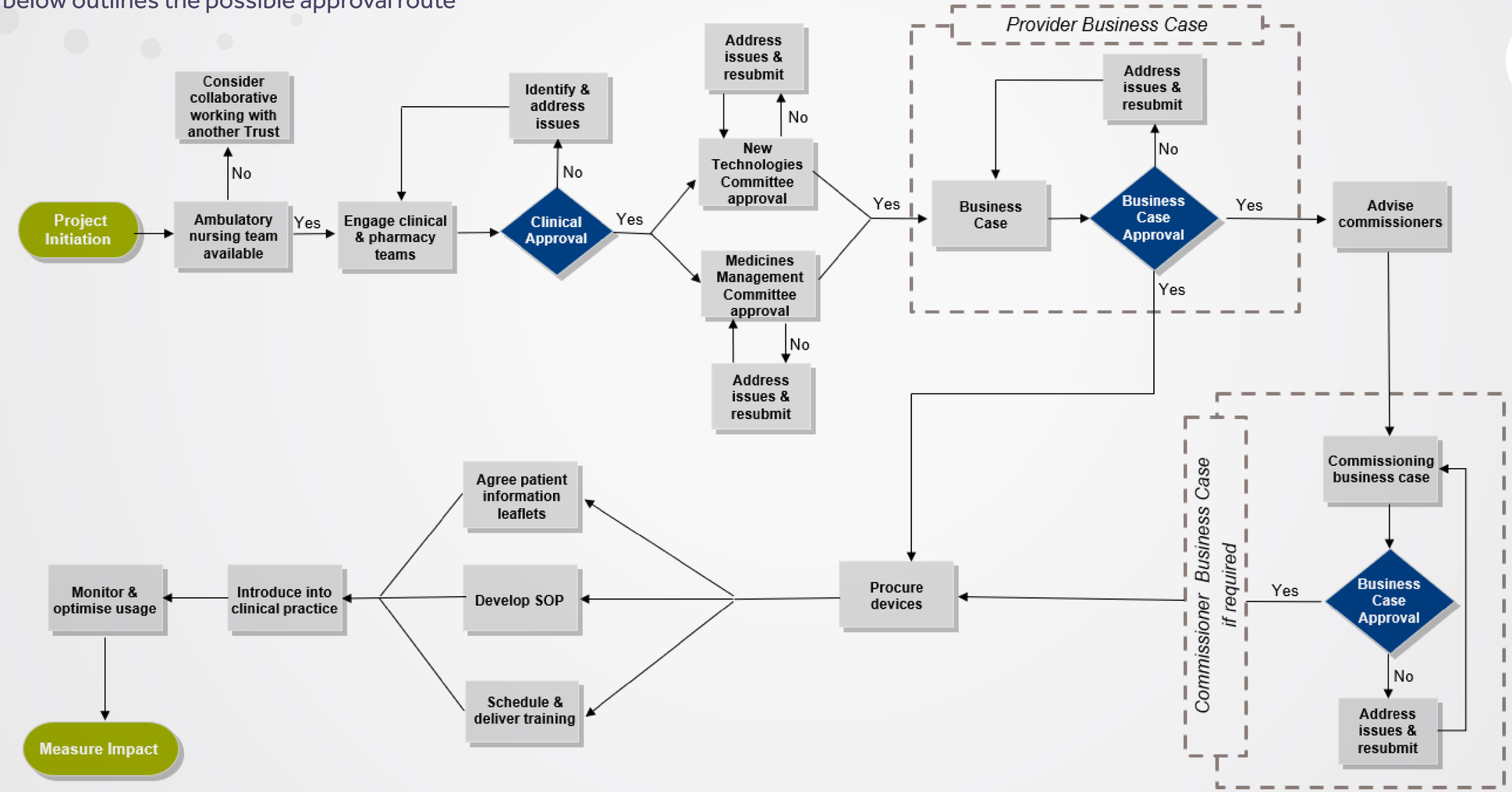
The diagram below outlines the possible approval route



Training

Training provided by the supplier may vary depending on the company.

OUH experience

The supplier provided a training session to staff, part of which included the company observing the staff filling the device. Following this session, a member of staff already competent in administering the devices observed nursing staff administering 3 devices to patients in hospital (i.e. on the day of discharge), following which staff were signed off as competent.

Staff must be competent in using ANTT to prepare the device. In OUH, this is prepared at the hospital site and transported by the nursing team to the patients' homes.

Competency will need to be reassessed if nursing staff do not administer the devices for an extended period of time.

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Monitoring impact

It is important to be able to demonstrate the benefits the service has brought to both patients and the health system.
There are two strands to this – outcome monitoring and patient experience.

Outcome monitoring

Maintaining a record of patients discharged home with elastomeric devices is crucial. It is therefore crucial to maintain a record of patients going through the service. Data captured should include patient numbers, indication treated and medication used, IV treatment duration via elastomeric device, and the overall outcome. Below is an example of the data gather by OUH:

Sex	Age	Days id device	Medication	Indication	IV treatment duration (days)	Outcome	Admission date
Female	63	14	Pip/taz 13.5g	Bronchiectasis	14	Course complete	30.06.2020
Female	71	5	Flucloxacillin 8g	S. Aureus bacteraemia	14	Switched to oral due to AKI	05.09.2020
Male	57	36	Pip/taz 13.5g	Diabetic foot	42	Course complete	07.12.2021

This will enable the service to provide activity data, including bed days saved. The overall outcome is important as this will enable the service to monitor outcomes and review patient selection, if needed.

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Bed days saved

At OUH, the bed days saved per patient is calculated as (this may vary depending on the service model implemented):

- Number of elastomeric devices used – 1 (as first device is administered on day of discharge)

Financial savings

Once the number of beds saved has been calculated, the cost avoidance can be calculated:

Bed day cost – service costs

Service costs include:

- Elastomeric device
- Buffered saline
- Staffing cost (time to reconstitute device, travel time, time spent in patient's home)

Drug costs are not included as these are incurred regardless of whether the patient receives the drug in hospital or at home.

Each Trust will have their own bed day cost, please refer to your finance team for this.

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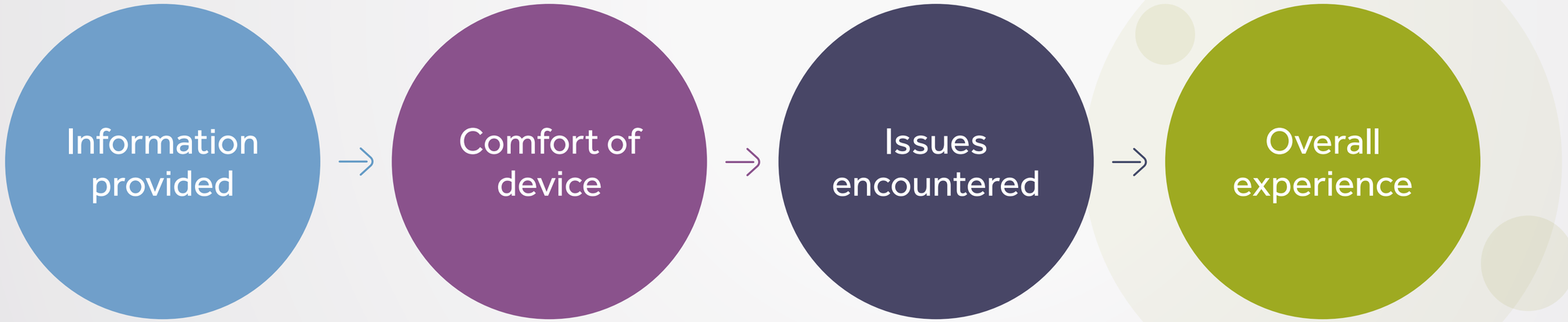
Patient experience

Patient feedback provides valuable data for any service, and it is important this is factored into your service design and processes.

OUH created a feedback questionnaire which is included in the patient information pack given to all patients on discharge. Patients are asked to complete this at the end of their treatment and hand it to the nurse on their final visit. The questionnaire covers a number of areas:



As a result of patient feedback, OUH made changes to the patient information to provide more detail on how to care for the device and how to address potential issues.

Patient information

Provision of clear and detailed patient information, delivered both in person and written, is crucial to give patients the confidence to take a more active role in their treatment and care. While there are many patient benefits some patients may be anxious about this model of care. As such it is important staff take the time to discuss and provide clear information to patients about how to look after the device and themselves, and what to do should issues be encountered.

OUH Patient Passport

OUH has developed a patient passport which provides information on:

- The pump and how to look after it
- What to expect each day from the nursing team
- Who to contact if issues arise

Suppliers of the device will have patient information leaflets which could be used, but Trusts may wish to develop bespoke information leaflets for their patients.

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Procurement

There are many companies who supply elastomeric devices, although not all are suitable for nursing staff to fill using ANTT. Elastomeric devices are available via the NHS Supply Chain's framework.

Please note that alongside the cost of the device, there is a small cost for buffered saline (required for reconstitution and flushes) and the drug.

NHS Supply Chain

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Lessons from OUH Implementation

The main learning points from the OUH implementation are:

1. Engage with the Infectious Diseases and Microbiology teams from the outset of the project
2. Ensure all necessary approvals, including governance, are in place prior to introducing the device into clinical practice
3. Provide patients with a bag to carry the device which will help to keep it warm and in turn help maintain the flow (bags can be provided by the supplier or equally a walking sock can work!)
4. It is important to ensure there is a steady flow of patients using the device, as sporadic use will make it difficult for the nursing team to maintain competency levels
5. Have a data collection process in place from the outset, to be able to demonstrate impact
6. Have a clear Standard Operating Procedure agreed prior to usage

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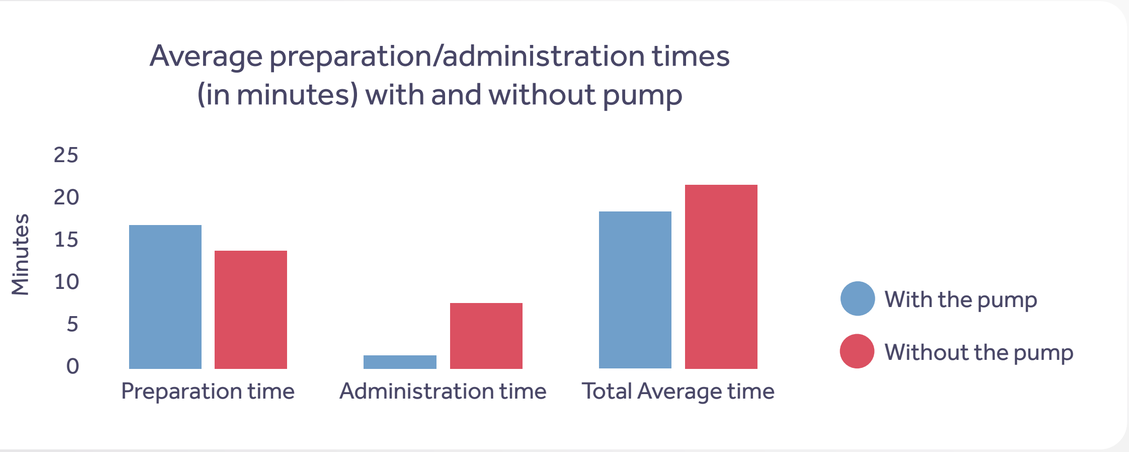
Outcomes from OUH

The following section provides details of the activity and outcomes at OUH.

Time in motion study

A time in motion survey was undertaken to be able to compare the preparation and administration times when the elastomeric device was used and not used. The graph below shows the differences with preparation time taking slightly longer when the pump is used, but this is more than offset by the reduced administration time. This is due to only once a day administration when the pump is used. Overall, the total average preparation and administration time is shorter with the elastomeric device.



Activity and outcome data

From November 2019 to August 2022, a total of 180 patients have been discharged with the elastomeric device, and subsequently completed their treatment. This has resulted in 2478 bed days being saved, with a cost avoidance of over £780,000.

Below is a breakdown of the patients, devices used, bed days saved and cost avoidance, up to August 2022.

Total number of patients	180
Male	110
Female	70
Average age	67 years
Age range	19 – 94 years

Total number of devices	2658
Average number of devices per patient	15
Range of devices used	2 – 42
Bed days saved	2478
Cost avoidance	£781,363

Outcomes from OUH

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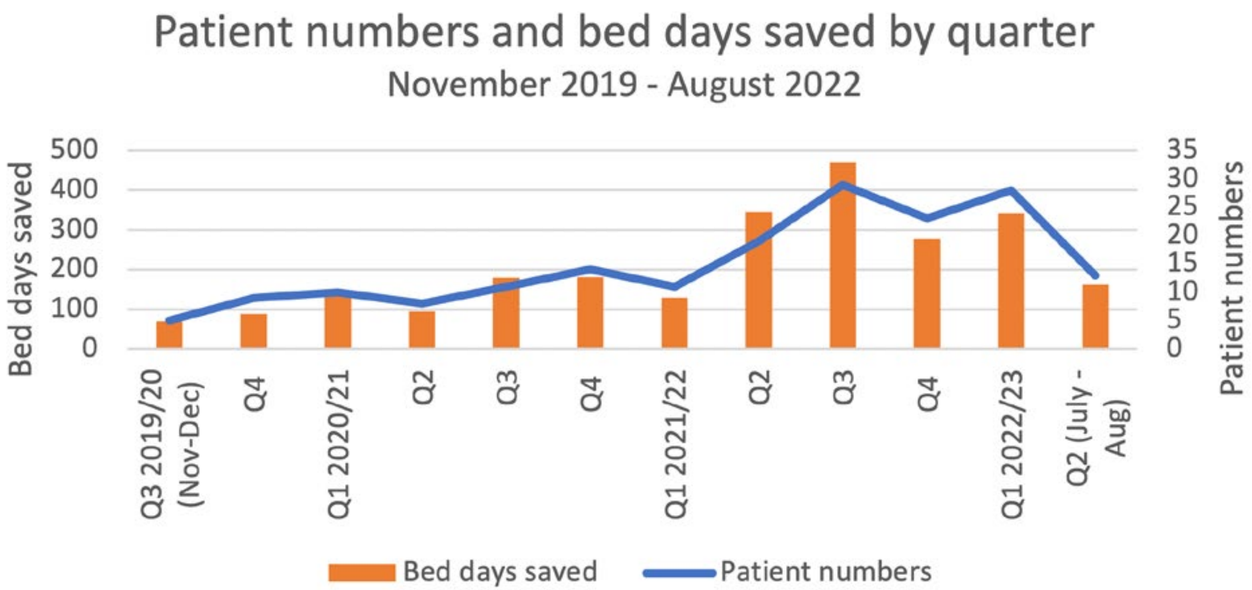
Activity and outcome data

The chart below provides a breakdown of patient numbers and bed days saved per quarter.



The indications treated were:

- Bronchiectasis
- Staph aureus bacteraemia
- Cellulitis
- Breast abscess
- Diabetic foot infections
- Epidermolysis bullosa
- Mycotic aneurysm
- S. Lugdunensis bacteraemia
- Pinna Cellulitis
- Prostatitis
- Intra-abdominal sepsis
- UTI
- Spinal infection/discitis
- Infected aorta-bifemoral graft
- Lung abscess
- Septic arthritis
- Empyema
- Necrotising Otitis Externa
- Osteomyelitis
- Infective exacerbation COPD
- Chest infection
- Infected renal cyst
- Neck abscess

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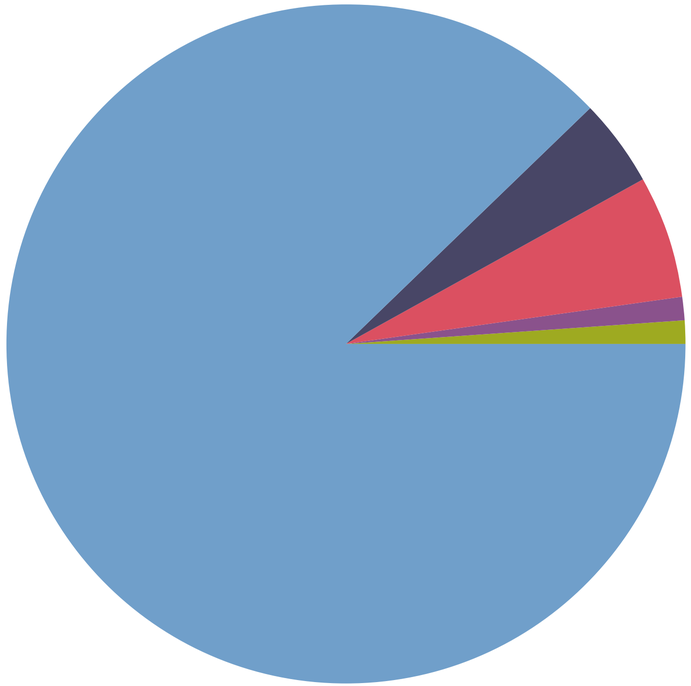
Activity and outcome data

The majority of patients discharged with the elastomeric device completed their course of treatment at home, as shown in the chart below.



Patient outcomes (all years)

- 88%: Course complete
- 6%: Readmitted
- 4%: Drug change
- 1%: Allergic reaction
- 1%: Stopped due to non-compliance

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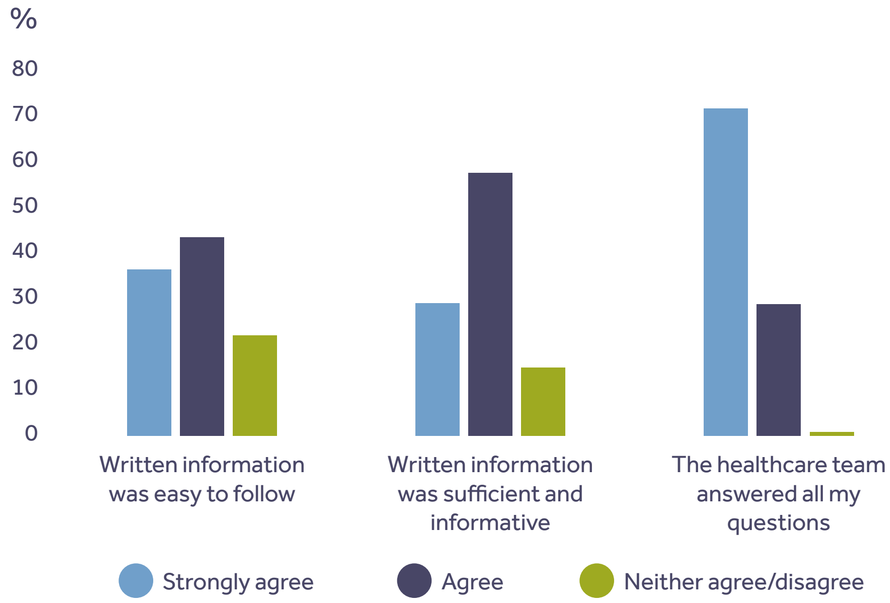
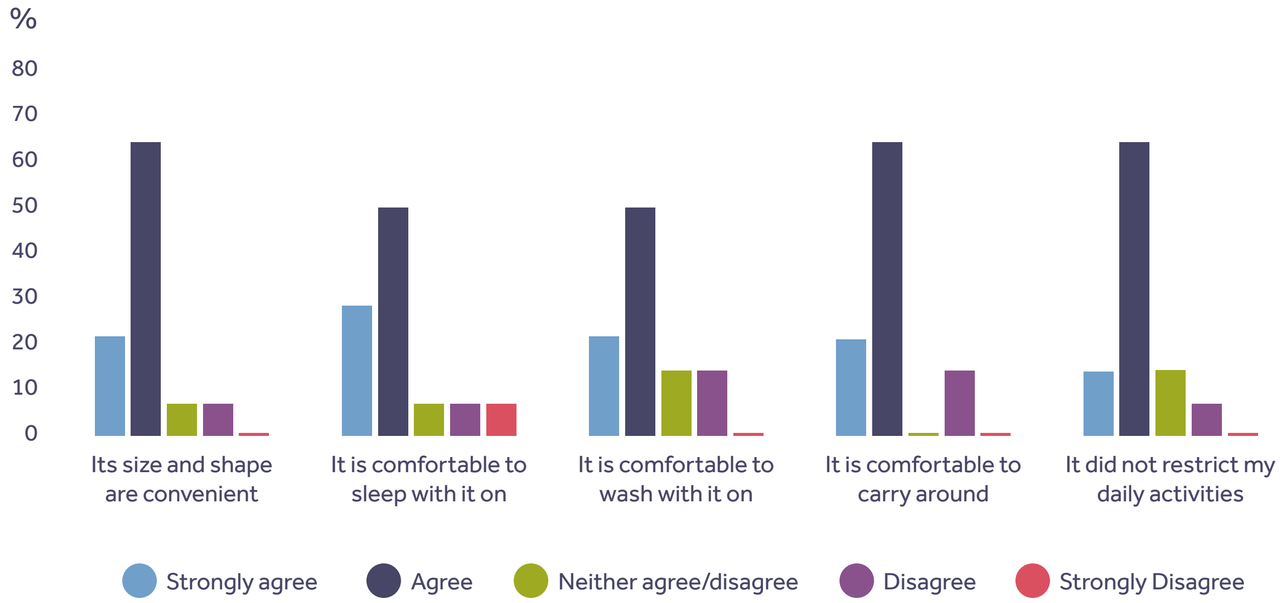
Patient Feedback

The charts below provide a summary of the patient feedback received.
Patient feedback has been extremely positive.

Patient satisfaction with written information



Patient satisfaction with comfort of device



Outcomes from OUH

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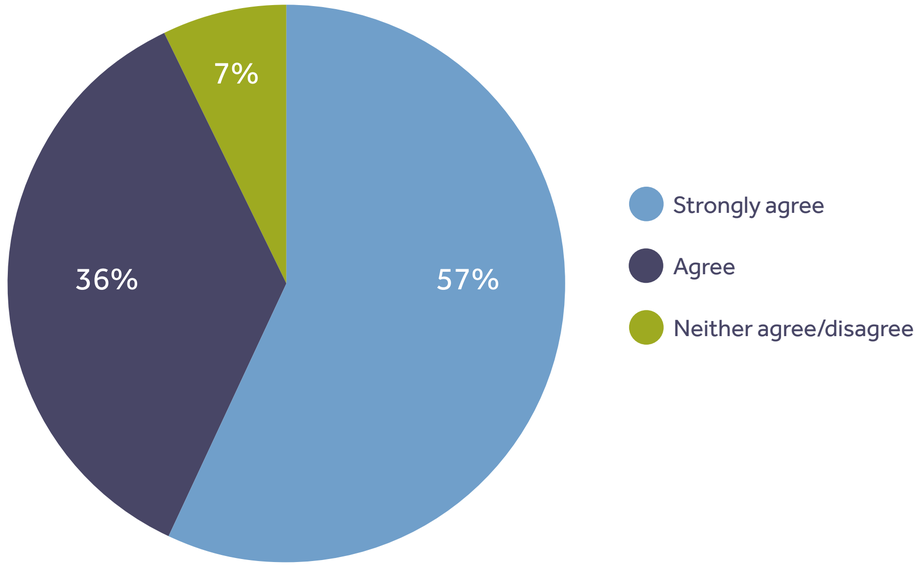
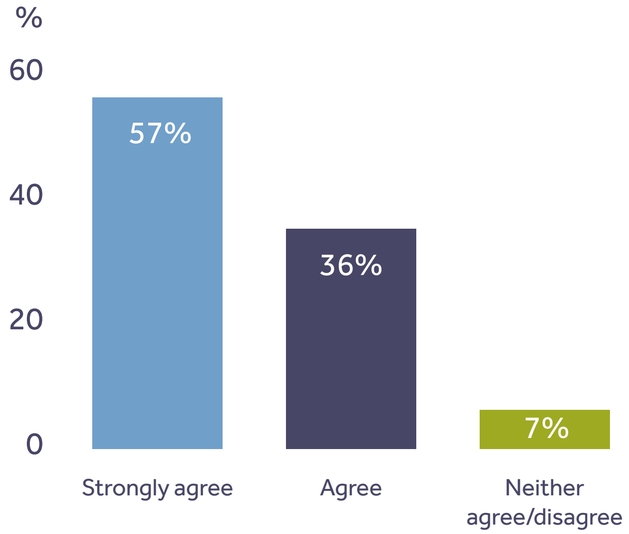
Patient Feedback

Patients would use the Accufuser® pump again



Patients satisfaction with experience of using the Accufuser® pump



Issues encountered

Issues that have been encountered include:

- Device stopping suddenly
- Device emptying before completing the 24-hours
- Device taking longer than 24-hours to fully administer the medication

The reasons for these issues included a kink found in the midline, a clamp being inadvertently on, and the device being cold.

The primary risk of a full dose not being given is that a patient would be under-dosed, meaning the infection is not treated and/or it could lead to antimicrobial resistance. However, the antibiotics used have wide therapeutic windows so if the full dose is not delivered, there is confidence that a sufficient amount of drug has been administered that falls within the therapeutic window. Furthermore, patients are monitored daily and have weekly blood tests. These results are discussed at the weekly MDT alongside any issues that have arisen. There were no clinical concerns that insufficient drug delivery may have led to failure of treatment.

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Helpful Resources

Yellow Covered Document Standards

- Yellow Covered Document Standards

OUH's Standard Operating Procedure

- OUH's Standard Operating Procedure

British Society for Antimicrobial Chemotherapy

- Good practice recommendations
- Self-assessment tool

OUH's Patient Passport

- OUH's Patient Passport

NHS Supply Chain Value Based Procurement Case Study with OUH

- NHS Supply Chain Value Based Procurement Case Study with OUH

Series of information videos to explain elastomeric devices and how to introduce into practice

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Relevant Publications

- Optimising patient safety when using elastomeric pumps to administer outpatient parenteral antibiotic therapy
  Oliver 2016 (abstract): https://pubmed.ncbi.nlm.nih.gov/27792443/
- Health economic assessment – OPAT vs inpatient care. Dimitrova et al 2021: https://bmjopen.bmj.com/content/11/9/e049733
- Challenges and opportunities of OPAT services. Chapman 2013: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5873703/
- Updated good practice recommendations for OPAT in UK. Chapman et al 2019: https://academic.oup.com/jacamr/article/1/2/dlz026/5554098
- How to develop a successful business case for OPAT services (United Lincolnshire Hospitals NHS Trust)
  Leo2020: https://www.pmhealthcare.co.uk/uploads/imagelib/pdfs/Journal_articles_by_issue/JoPM%20Oct%202020/Outpatient%20Parenteral%20Antimicrobial%20Therapy.pdf
- Challenges and solutions to starting and managing OPAT services (USA based)
  Halilovic et al 2014: https://www.dovepress.com/managing-an-outpatient-parenteral-antibiotic-therapy-team-challenges-a-peer-reviewed-fulltext-article-TCRM
- The Comparing Home Infusion Devices (CHID) study (Australia based). Hobbs et al 2017: https://bmjopen.bmj.com/content/7/7/e016763
- Safety and effectiveness of home intravenous antibiotic therapy for multidrug-resistant bacterial infections
  Mujal et al 2015 (abstract): https://pubmed.ncbi.nlm.nih.gov/25655757/
- Safety and effectiveness of outpatient parenteral antimicrobial therapy in older people
  Mujal et al 2016: https://academic.oup.com/jac/article/71/5/1402/1750752?login=false

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