

BMJ Open Protocol for a randomised crossover trial to evaluate patient and nurse satisfaction with electronic and elastomeric portable infusion pumps for the continuous administration of antibiotic therapy in the home: the Comparing Home Infusion Devices (CHID) study

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ABSTRACT

Introduction Previous studies comparing satisfaction with electronic and elastomeric infusion pumps are limited, and improvements in size and usability of electronic pumps have since occurred. The Comparing Home Infusion Devices (CHID) study plans to assess patient and nurse satisfaction with an elastomeric and electronic pump for delivering intravenous antibiotic treatment in the home. Secondary objectives are to determine pump-related complications and actual antibiotic dose administered, evaluate temperature variation and compare pump operating costs.

Methods and analysis The CHID study will be a randomised, crossover trial. A trained research nurse will recruit patients with infectious disease aged ≥ 18 years and prescribed ≥ 8 days of continuous intravenous antibiotic therapy from the Royal Adelaide Hospital (RAH) (Adelaide, Australia). Patients will be randomised to receive treatment at home via an elastomeric (Baxter Infusor) or an electronic (ambIT Continuous) infusion pump for 4–7 days, followed by the other for a further 4–7 days. Patient satisfaction will be assessed by a 10-item survey to be completed at the end of each arm. Nurse satisfaction will be assessed by a single 24-item survey. Patient logbooks and case notes from clinic visits will be screened to identify complications. Pumps/infusion bags will be weighed to estimate the volume of solution delivered. Temperature sensors will record skin and ambient temperatures during storage and use of the pumps throughout the infusion period. Costs relating to pumps, consumables, antibiotics and servicing will be determined. Descriptive statistics will summarise study data.

Ethics and dissemination This study has been approved by the RAH Human Research Ethics Committee (HREC/16/RAH/133R20160420, version 6.0, 5 September 2016). Study results will be disseminated through peer-reviewed

Strengths and limitations of this study

- Crossover randomised trial design to determine patient and nurse satisfaction with elastomeric and electronic infusion pumps for continuous infusions in the home setting.
- Measurement of ambient and skin temperature throughout the infusion period.
- Recording and analysis of pump, vascular access device and antibiotic complications, plus estimation of dose delivered.
- Home nursing staff have more experience using elastomeric infusion devices in comparison to electronic infusion devices.
- Unable to detect early emptying of elastomeric devices.
- Internal infusion solution temperature cannot be ascertained.

publications and conference presentations. The CHID study will provide key insights into patient and provider satisfaction with elastomeric and electronic infusion pumps and inform future device selection.

Trial registration number ACTRN12617000251325; Pre-results.

BACKGROUND

Ambulatory intravenous infusion of analgesics, chemotherapy and antimicrobials enables suitable patients to be treated in the home care setting, as an alternative to inpatient hospital care.^{1 2} This reduces demand on hospital beds, provides cost savings and

improves patient well-being.^{3–6} The administration of antibiotics in the outpatient setting is well established worldwide,⁶ and in a 7-year Australian-based study antibiotics were administered to more than 70% of patients.⁷ A range of ambulatory infusion pumps are available for use in the home setting, including mechanically powered disposable pumps and electronic reusable pumps. Each device type has key differences in functionality and operation.

Disposable elastomeric pumps are widely used for home infusions, both in Australia⁵ and internationally.¹ Elastomeric pumps contain a fluid reservoir made of a flexible elastomer that is stretched when filled, creating a high driving pressure. The flow rate is set by narrow bore tubing, known as a flow restrictor, in the line.¹ Advantages of elastomeric pumps include ease of operation, lightweight, silent operation, disposability and independence from an external power supply.^{2 8–12} The limitations of elastomeric pumps include a predetermined flow rate,^{1 8 13 14} variability of infusion duration,^{10 15} diluent restrictions,¹³ absence of warnings or alarms if the infusion occludes,^{10 14 16} and limited peer-reviewed data on antibiotics compatible with the elastomeric reservoir material at temperatures observed in the home.^{17 18} These pumps typically have a stated accuracy in the range of $\pm 15\%$ under a specific set of conditions, but flow rate can be affected by a range of factors including variation in temperature, pump height, viscosity, filling volume and storage conditions.^{1 9 19} Difference between clinical and calibrated conditions may result in flow rate variations of up to $\pm 50\%$.^{5 15}

Portable electronic pumps use a battery source to power a fluid pumping mechanism connected to a reservoir of infusion solution. Electronic pumps offer more accurate flow rates, with a stated accuracy in the order of 5%–8%.^{12 20} Built-in alarms alert users to any changes in flow and/or occlusion, enabling healthcare providers to identify and respond to problems in a timelier manner.¹⁴ Other advantages include programmable options,^{20 21} the ability to vary infusion rates without interrupting the infusion or disconnecting the closed intravenous system,²² and more reservoir options.²⁰ Potential disadvantages with the use of electronic infusion pumps include programming and user interface errors,²¹ pump noise¹³ and greater capital purchase cost of the pump.¹

Pump selection may have implications for satisfaction with care and clinical outcomes among patients treated in the home. Reductions in flow rate with an elastomeric pump due to variation in temperature, for example, might contribute to a poor clinical response or extended treatment duration. Higher than expected flow rates have the potential for toxic medication levels, especially for those with a narrow therapeutic window.²³ Poor patient satisfaction with a larger pump may lead to reduced patient adherence² or a reduction in mobility.²⁴ Although both elastomeric and electronic infusion pumps are used in the home setting, few studies have compared user preferences. One small crossover trial comparing

the elastomeric Baxter Infusor to the electronic CADD-1 for continuous infusion of fluorouracil among 10 outpatients reported that all patients preferred the elastomeric pump.²³ The time spent by nurses with each pump was assessed, but the nurses were not questioned about their satisfaction or pump preference. A comparative study assessing satisfaction with the elastomeric Baxter LV5 Infusor and two electronic alternatives (Graseby 9300 Ambulatory Infusion Pump and Microjet Infusion Pump) among 68 patients showed very good satisfaction with the Baxter and Graseby pumps; however, pump crossover was not incorporated into the study design.²²

Elastomeric pumps are often stored in a refrigerator prior to use¹⁸ and following connection to a patient, elastomeric pumps and infusion reservoirs are exposed to the home environment for the duration of the infusion. However, there is limited recent data available regarding temperature variation in the home setting where infusions take place.¹⁸ Changes in temperature can impact on drug stability,^{18 25} infusion solution viscosity and elastomeric infusion duration^{18 26} due to its impact on elastomeric material properties. Also, during use, the restrictor element of an elastomeric pump is taped to the patient's skin, relying on that skin temperature to regulate flow rate and further data on skin temperature variation during infusion is required.

Similarly, few studies have compared the operating costs associated with elastomeric and electronic pumps and recent data is lacking. A narrative review of studies published between 1989 and 2001 showed no clear cost advantage of one type of pump over another.¹ However, there was considerable variation in the methods used to compare costs, and an up-to-date comparison is required.

The Comparing Home Infusion Devices (CHID) study will compare and contrast an elastomeric infusion pump with an electronic infusion pump for delivery of continuous intravenous antibiotics in the home setting. The primary aim of this study is to evaluate both patient and nurse satisfaction with each type of pump. Secondary aims are: (A) determine complications relating to the infusion pump, vascular access device (VAD) and antibiotic therapy during home infusions; (B) estimate average flow rate and dose of the antibiotic administered with each pump; (C) examine variation in ambient temperature during storage, and variation in skin and ambient temperatures during continuous home infusion; and (D) compare the operating costs associated with each type of pump.

METHODS

Study design and setting

The CHID study is a single-centre, prospective, randomised, crossover trial with 1:1 allocation of patients to receive either a portable electronic pump for 4–7 days, followed by an elastomeric pump for 4–7 days, or vice versa, to deliver a continuous intravenous antibiotic infusion in the home setting (figure 1). The crossover trial

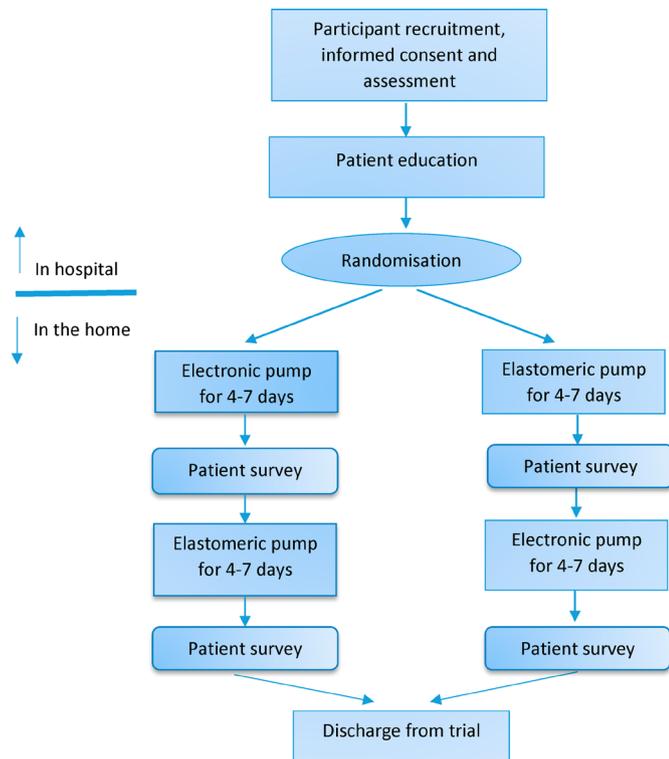


Figure 1 Flow diagram of crossover study design.

design was chosen to enable direct comparison between both pump types by patients and home nursing staff. Due to the nature of the study and the visibility of the infusion pumps, this will be an open-label study.

Patients will be recruited from the inpatient wards of the Royal Adelaide Hospital (RAH), a 640-bed public teaching hospital in Adelaide, South Australia. An external home nursing service provider, Royal District Nursing Service (RDNS) South Australia, will provide home care to participants as per current practice for metropolitan-based patients. In Australia, antibiotics administered via intravenous infusions in the home setting are generally administered as a continuous infusion over a 24-hour period, with nursing staff visiting once per day. During the home visit, the nurse will disconnect the previous pump, assess the line and dressings, attach the new infusion pump and attend to any other clinical needs of the patient. No patients will undertake self-administration while enrolled in the CHID study.

This trial has been registered with the Australian New Zealand Clinical Trials Registry at <http://www.anzctr.org.au/> (ACTRN12617000251325) (table 1).

Participants

Patients

Patients aged 18 years or older with approval from the RAH Infectious Diseases (ID) unit to receive intravenous antibiotic therapy in the home via a continuous 24-hour infusion for a minimum of 8 days will be eligible for inclusion. Patients who are unable to provide informed consent, those who are unable or unwilling to complete the study logbook and survey in English, pregnant women

and patients who are immobile or require 24 hours nursing care will be excluded. Patients with a skin allergy or contact dermatitis to stainless steel will also be excluded from the study.

Home nursing staff

Nurses who have provided home care for one or more study participants will be eligible to complete a survey.

Study procedures

Patient recruitment

A trained research nurse will liaise with the RAH ID unit during weekdays and obtain a list of hospital inpatients approved to receive continuous intravenous antibiotic treatment in the home setting. The research nurse will assess each patient to determine if the patient meets the study entry criteria and provide eligible patients with verbal and written information about the trial. Written informed consent will be obtained prior to leaving hospital.

Randomisation

After obtaining written consent, patients will be randomised to receive either the elastomeric or electronic infusion pump to deliver the first week of intravenous antibiotic therapy, followed by the alternative pump for the subsequent week. Randomisation will be undertaken by the RAH Pharmacy Department when the discharge prescription is received. Patients will be randomly allocated to either crossover arm by a computer-generated sequencing program.

Infusion devices

The two specific brands of infusion pumps to be compared in the CHID study are the Baxter Infusor (Baxter Healthcare Corporation, Illinois, USA) and the ambIT Continuous (Summit Medical Products, Utah, USA) (figure 2).

The Baxter Infusor is a single-use, elastomeric, portable infusion pump and consists of an elastomeric membrane within a ridged outer shell. The integrated administration line is primed at the time of dispensing or at the patient bedside and is attached via a luer lock connector to the patient's VAD. Varying sizes and flow rates are available; however, the CHID study will only use the devices marketed to provide a 24-hour continuous infusion. A commonly used version has dimensions of approximately 170 mm in length by 68 mm in diameter, and weighs 65 g when empty. Elastomeric pumps have a silent operation with no alarms. Confirmation of fluid delivery is approximated by examining the size of the fluid reservoir within the clear, hard casing.

The ambIT Continuous infusion pump is an electronic reusable portable device. The dimensions of the pump are 55×36×175 mm and it weighs 181 g (including two AA batteries). Flow rates can be programmed between 0.1 and 125 mL/hour and will be set to deliver a 24-hour continuous infusion. The pump mechanism is a micro-processor-controlled rotary peristaltic with some audible pump noise. Visual and audible alarms occur for the

Table 1 Trial registration data

Data category	Information
Primary registry and trial identifying number	Australian New Zealand Clinical Trials Registry (https://www.anzctr.org.au) Ref No. ACTRN12617000251325
Date of registration	17 February 2017
Public title	Comparing Home Infusion Devices for antibiotic treatment—CHID Study
Scientific title	A randomised crossover trial evaluating patient and nurse satisfaction of the electronic portable infusion device (ambIT Continuous) versus elastomeric delivery (Baxter Infusor) for the continuous administration of antibiotics in the home in patients with infectious disease
Trial acronym	CHID
Health conditions	Any infectious disease requiring intravenous antibiotic therapy and suitable for treatment via a continuous infusion in the home setting
Study type	Interventional
Intervention code	Treatment: devices
Control treatment	Treatment administered via an elastomeric infusion pump
Key inclusion criteria	Suitable for ambulatory home antibiotic therapy as approved by infectious diseases specialist Inpatient of Royal Adelaide Hospital Can provide informed consent Require 8 days minimum therapy Able to provide feedback through questionnaire and logbook 18 years of age or older
Key exclusion criteria	Patient is unable or unwilling to fill out the patient questionnaire survey and or logbook Skin allergy or contact dermatitis to stainless steel Patient's primary clinician is unwilling to enrol patient Pregnancy Patient is totally dependent on care for all daily needs and/or is immobile The following antibiotics are excluded due to restricted shelf life: ceftazidime, ticarcillin/clavulanate
Recruitment state	South Australia
Recruitment hospital	The Royal Adelaide Hospital—Adelaide
Funding source 1	Government of South Australia, Department of Further Education, Employment, Science and Technology (now Department of State Development)
Funding source 2	CPIE Pharmacy Services, Findon, South Australia
Primary sponsor	Flinders University, Bedford Park, South Australia
Other collaborator	CPIE Pharmacy Services, Findon, South Australia
Ethics committee	Royal Adelaide Hospital Human Research Ethics Committee, Approval No. R20160420

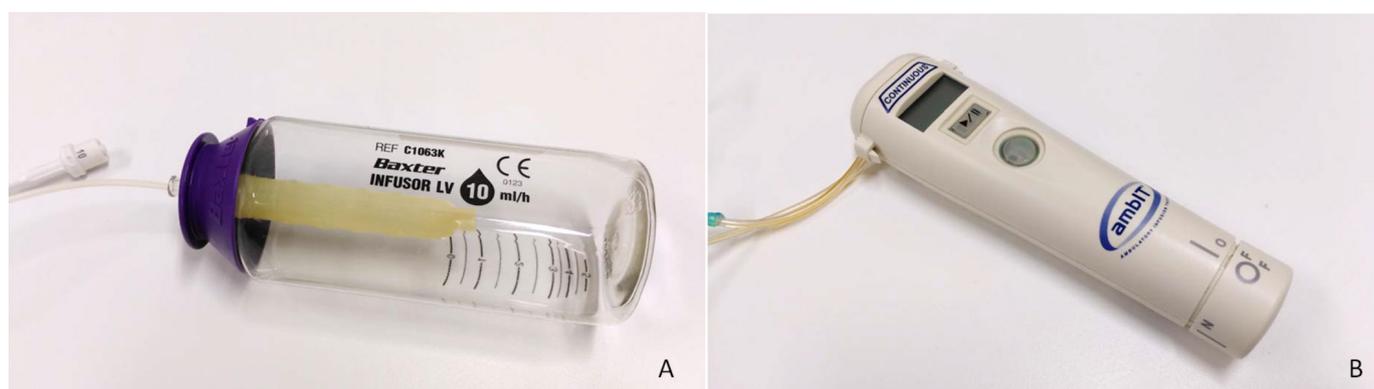
**Figure 2** Infusion pumps used in the Comparing Home Infusion Devices study. (A) Baxter Infusor. (B) ambIT Continuous.

Table 2 Patient timeline

	In hospital	Day 1 (day of leaving hospital)	Home period 1	Clinic visit 1	Home period 2	Clinic visit 2
Eligibility	x					
Informed consent	x					
Demographic data	x					
Randomisation	x					
First infusion device connected		x				
Temperature sensor applied to patient's forearm		x				
Home nursing staff visit patient			x	x	x	
Patient completes logbook		x	x	x	x	x
Clinical progress assessment				x		x
Patient completes satisfaction survey				x		x
Patient crossover to other infusion device				x		
Discharge from trial and patient handover						x

following conditions: occlusion downstream, cassette not mounted, low battery, dead battery, malfunction and infusion complete. The ambIT Continuous is connected to a filled infusion container prior to infusion.

Supply of the infusion device and antibiotic

Prefilled elastomeric pumps will be sourced from the manufacturer and dispensed by the RAH Pharmacy Department, as per standard practice at the RAH. CPIE Pharmacy Services (Adelaide, Australia) will prefill the infusion containers, attach and program the electronic pump at a fixed flow rate and dispense for the individual patient. (CPIE Pharmacy Services are providing the loan of the electronic pumps and the labour involved with the preparation of electronic infusions as in-kind support for the trial.) Pumps will be supplied to the patient at the time of leaving hospital (day 1) and at clinic visit 1 (table 2). Antibiotics prescribed will be those which have sufficient stability for a 24-hour continuous infusion and are commonly used in the home setting in Australia. These may include: flucloxacillin, ceftriaxone, cephalothin, cephazolin, clindamycin and vancomycin.

Patient education and monitoring

All patients will receive education regarding their VAD and antibiotic therapy as per normal hospital practice. Participants will receive written information sheets produced by the pump manufacturers and verbal education from the study nurse relating to each pump type prior to leaving hospital. Patients will also be given information about the temperature sensor that will be placed on the skin, and how to care for it.

The first infusion pump will be connected to the patient on the day of leaving hospital (day 1; refer to table 2). From day 2 onwards, patients will be reviewed daily in their home by an RDNS nurse. Patients will also attend a clinic appointment with a RAH ID doctor at least weekly for routine clinical monitoring, pump and VAD checks, and any blood tests deemed necessary by the ID doctor.

The ID doctor will review any adverse events experienced during the study period and document in the hospital case notes as per standard practice. The ID doctor will assess treatment response during the clinic visits and may amend the duration of antibiotic therapy if required. This is standard care for patients receiving home treatment with antibiotic therapy who are under the care of the ID unit at the RAH.

Nurse training and clinician support

Elastomeric infusion pumps are the most common type of infusion pump used for delivering continuous antibiotic infusions in the home setting in South Australia; however, home care nurses may have no previous experience using the ambIT Continuous electronic infusion pump. To ensure competency, all RDNS nurses providing a home visit for patient(s) enrolled in the trial will receive training on the ambIT Continuous pump via a short, custom-made, online video that will be disseminated through the RDNS training platform. The video was developed with input from the clinical educators employed by the device distributor, CPIE Pharmacy Services and the RDNS. All steps that were deemed essential for the use of the ambIT Continuous electronic infusion pump in the CHID study were covered in the video. The content was validated and refined based on input from the CHID study investigators, pharmacists, nursing staff and laypersons. The final version of the video was approved by the nursing provider. The home nurses will also receive an information sheet about the CHID study, the temperature sensor and the elastomeric pump used in the trial. This training material will be provided prior to enrolment of the first participant.

Home nurses will also be provided with a communication pathway to access technical assistance during the trial period. Home nurses and other health professionals providing care for patients enrolled in the study will be encouraged to contact the 24-hour telephone technical

support service should a pump-related issue occur during the study period (eg, alarm with the ambIT Continuous).

Logbooks

All patients will be asked to complete a logbook daily, to record details of any concerns or complications related to the infusion pump, any alarms that occurred and any phone calls that were required during the study period. In addition, patients will be asked to record the time each pump is connected and disconnected. Nurses will be asked to review the logbook each day and all logbooks will be reviewed weekly by the research nurse during the clinic visit.

Patient and nurse satisfaction surveys

Each patient will be asked to complete a survey at their clinic visits (table 2) to assess their experience and satisfaction with the type of pump most recently used. The patient surveys (see online supplementary materials 1 and 2) for each device include 10 questions addressing pump characteristics (weight, size, noise), the ability to perform daily activities, ease of use of the pump and usefulness of the information sheet, answered with a Likert scale. There is also a free-text section to report problems with the pump, and room for general comments. The survey to be completed following treatment with the electronic device includes an additional question on the pump alarms.

All home care nurses who provide care for any patient enrolled in this study will be invited to complete a 24-item nurse satisfaction survey (see online supplementary material 3). Nurses will be asked to respond to questions regarding their experience and satisfaction with each pump type using the Likert scale provided.

The patient and nurse survey questions were initially developed by two clinician members of the research team using the existing literature^{2 21 23} as a guide. The questions were revised following input from other members of the research team and a statistician. The face and content validity of the revised survey questions were then assessed by 10 people, including pharmacists, nurses, researchers and laypersons, who were asked to provide feedback on clarity and whether all desired information would be captured using the surveys. Following this, minor revisions were made to improve readability of the surveys.

Weight of elastomeric device and infusion containers

To estimate the delivery accuracy of the infusion pumps, all elastomeric pumps and infusion containers attached to the electronic pumps will be weighed pre and post-administration. The difference in weight will be used to calculate the total volume infused, based on the density of the drug and diluent in the infusion container or pump. The volume infused will be determined by dividing mass by density. This, along with the start and stop times of each pump recorded in the patient logbooks, will allow calculation of an average flow rate throughout the infusion period.

Temperature sensors

Patient skin temperature will be continuously monitored throughout the trial period using an iButton DS1921H (Maxim Integrated, CA, USA) digital temperature sensor. The iButton has previously been validated for accuracy, response time²⁷ and skin reaction.²⁸ With an accuracy of $\pm 1^{\circ}\text{C}$ and a temperature range of $+15^{\circ}\text{C}$ to $+46^{\circ}\text{C}$, the iButton will record patient skin temperature every 10 min. The temperature sensor will be applied by the research nurse to the patient's forearm on the day of leaving hospital and kept in place using the same adhesive dressing that is used to attach the VAD to the skin. The sensor will be replaced during the ID clinic visit 1 (table 2) and removed during the ID clinic visit 2.

Ambient temperature surrounding the infusion pump will be monitored continuously using the iButton DS1921G (Maxim Integrated) digital temperature sensor. This sensor has a temperature range of -30°C to $+70^{\circ}\text{C}$. The temperature sensor will be attached to the outside of the elastomeric pumps and to the outside of the infusion containers connected to the electronic pumps at the time of dispensing. Temperature will be monitored at 10 min intervals.

Data will be downloaded at the end of each week from all sensors using Thermodata Viewer software (Thermodata, Victoria, Australia).

Patient handover

At the end of the trial period, patients will revert back to the standard clinical care under the RAH, and be discharged or continue antibiotic therapy as required.

Data collection and monitoring

Demographic and clinical information will be extracted from the hospital medical records for each participant at baseline and after each ID clinic visit using a standardised data collection form. Data from the temperature sensors, along with the pre and postweight data of the pumps and infusion containers, will be collated by the research nurse for analysis.

A protocol steering committee comprising study investigators and an independent ID physician will regularly review study progress and monitor recruitment, protocol adherence, antibiotic type and safety-related matters. An internal study monitor will inspect the case record files during the study period. Any serious adverse events occurring during the study will be immediately reported to treating clinicians and the RAH Human Research Ethics Committee.

STUDY OUTCOMES

Primary outcome

The primary outcome is to evaluate patient and nurse satisfaction with an elastomeric and electronic infusion pumps for delivery of intravenous antibiotics in the home setting. This will be determined using responses to the patient and nurse satisfaction surveys described above. Subquestions will be averaged and means compared

between the two pumps. In the patient survey, participants are asked to rank their satisfaction for the 'ability to carry out the following activities' with each pump type. The activities addressed are the ability to shower or bathe, sleep, sleep due to noise level and perform other daily activities. There is also a question on the overall experience with the pump, including attributes such as ease of use, easy to carry, reliability, feeling of safety and overall performance. A question addressing attributes that may affect patient satisfaction asks about the size, shape, weight and noise of the pump.

The nurse survey asks participants to rank their satisfaction with both devices with reference to safety of the pump, ease of use of the pump and overall satisfaction. They are also asked to consider various characteristics of each pump including: acceptable size for healthcare staff, ease of attaching/detaching to the patient, ease of determining fluid flow and reservoir emptying.

Secondary outcomes

Complications

Data collected from the two patient surveys, logbooks and hospital case notes will be assessed to identify the prevalence of complications relating to each of the infusion pumps or the VAD, including leaks, occlusions and incomplete infusions, as well as medication-related complications, unplanned phone calls or extra home visits that were required.

Dose delivered

The dose of antibiotic received by the patient over a 24-hour period will be estimated based on the volume of infusion solution delivered by the infusion pump. The estimated dose received will be compared with the total daily dose prescribed by the ID physician. The average flow rate each day will be approximated based on the volume of infusion solution delivered and the connection and disconnection times recorded in the patient logbook.

Temperature

The average and peak ambient temperatures surrounding the infusion pump will be determined during (1) storage prior to patient connection and (2) while connected to the patient. Temperature data recorded from the patient's skin will be compared with calibration conditions for peripheral skin temperature used by manufacturers of elastomeric pumps.

Device costs

Data on purchase cost of pumps, disposables (including batteries) and antibiotics will be obtained from the RAH Pharmacy Department and CPIE Pharmacy Services. Service and cleaning cost of the reusable electronic pump will be recorded by CPIE Pharmacy Services. The estimated volume remaining in returned pumps and infusion containers, together with consideration of the connection and disconnection times, will be used to estimate the cost of any remaining (underinfused) medication. Additional medication costs relating to wastage due to dose not administered or due to prescription

changes made during the study period will also be determined.

ANALYSIS

Given the limited number of studies comparing patient satisfaction with infusion pumps to guide a sample size calculation, and on the advice of a consultant statistician, a post hoc power analysis will be performed after enrolment of the first 10 patients to estimate the minimum number of patients required for the trial. Descriptive statistics will be used to summarise patient characteristics, responses to surveys and temperature variation. Patient and nurse satisfaction between devices will be assessed individually using the Wilcoxon signed-ranks test of survey data and any variation in exposure time between devices accounted for as necessary. The influence of nurse prior experience on satisfaction will be assessed using the Kruskal-Wallis test. Complication types and frequency will be compared using χ^2 test or Fisher's exact test. Dose delivered will be compared using a paired t-test for normally distributed data or Wilcoxon signed-rank test for non-normally distributed data. Analysis of variance will be used to determine effects of temperature on average flow rate. All survey data for patients who have completed a minimum of 4 days with each device will be included. Patients who do not complete a questionnaire will be excluded from the patient satisfaction analyses, but data will still be included in the temperature analysis. Quantitative data will be analysed using Stata Statistical Software (StataCorp, College Station, TX).

Thematic analysis will be used to analyse any responses in the free-text boxes of the surveys. Two members of the research team will carefully read all free-text responses to establish familiarisation and identify common themes. The researchers will categorise the free-text responses according to these themes and discuss to reconcile any disagreement. Specific quotes from the free-text sections of the survey may be used to illustrate results from the thematic analysis.

ETHICS AND DISSEMINATION

The CHID study has been approved by the RAH Human Research Ethics Committee (Reference No. HREC/16/RAH/133R20160420). Any protocol changes will be communicated to ethics, trial registry and investigators as required.

Data collected as part of this study will be treated confidentially and stored securely at the RAH ID Unit in accordance with hospital guidelines for clinical trial research. Paper-based study documents will be securely locked and will be accessed only by the research team. Electronic data will be stored in a password-protected database. Data will be stored in a reidentifiable manner (using a unique patient identifier) should a patient withdraw consent. Final data set access will be limited to study investigators.

Study results will be disseminated through peer-reviewed publications and conference presentations. Clinicians participating in this research will have access to a copy of a final report summarising key study findings. Research participants will be able to request a lay summary of findings.

DISCUSSION

The CHID study is the first study to assess patient and nurse satisfaction with the Baxter Infusor elastomeric pump and the ambIT Continuous electronic pump for delivery of continuous intravenous home antibiotic therapy. Comparison of patient satisfaction between a hospital in the home service and inpatient treatment shows that patients generally are more satisfied with home treatment^{29 30} as they preferred their home environment and could resume daily activities. Research into the human factors that influence the success of home healthcare includes personal, environmental and technology aspects, as well as the tasks that need to be undertaken.³¹ Physical and technical attributes of the device such as its size, portability and instructions must be considered along with the capabilities of the user and their familiarity with the tasks, to gain user acceptance and user competence.^{31 32} However, there are few studies that compare satisfaction between two infusion pumps, and ask questions about the device attributes that influence patient and/or nurse satisfaction. We identified one cross-over study in which all patients preferred the elastomeric over the electronic pump, with the main reasons attributed to increased size and weight of the electronic pump.²³ However, the CADD-1 electronic pump assessed in this study weighed 425 g, whereas the ambIT Continuous is one of the lighter electronic infusion pumps available at 181 g.³³ Developments in electronic pump design (including weight reduction) since these studies were published indicate the need to revisit patient and staff preferences. This study will provide key insights into patient and provider satisfaction with elastomeric and electronic infusion pumps which is particularly important given that few studies have done this directly. User's perspectives on technology that is used in the home should inform future device design to improve user-friendliness.³²

The main advantage of electronic pumps is a more accurate flow rate but elastomeric pumps are perceived to be cheaper and easier to use.¹ Elastomeric pump accuracy also degrades with multiple environmental factors and this has raised clinical concerns. In a previous study where elastomeric pumps were weighed several times a day during an inpatient infusion, the estimated flow rate exceeded the manufacturer's stated accuracy of $\pm 15\%$ in 47% of infusions for the elastomeric EasyPump and 35% of infusions for the elastomeric Infusor LV5.¹⁶ The CHID study will weigh all infusion pumps and containers before and after use, and connection times will be recorded in logbooks. This will enable us to estimate the dose of antibiotic delivered and average flow rate for each type of infusion pump.

The CHID study will also provide comprehensive information on the home environment in which these pumps are used. It will build on a previous study assessing ambient autumn temperature data collected from six healthy volunteers in the home (conducted in Adelaide, South Australia), where infusion solution temperatures could exceed 30°C.¹⁸ This is important for understanding how temperature influences flow rate and pump accuracy, as well as providing valuable data for future drug stability studies.

Another strength of the CHID study is the ability to record skin temperature variation during continuous home infusions. Variations in temperature of the restrictive element taped to the skin will alter the flow rate of an elastomeric pump.³⁴ Sarabia *et al* reported wrist temperature in healthy subjects can vary by up to 6°C over 24 hours under normal living conditions.³⁵ This natural variation alone would exceed the stated $\pm 15\%$ accuracy of the elastomeric pump used in this study. Recorded skin temperature data will inform future bench testing of these pumps.

There are several limitations with our study design. The elastomeric pump used for the CHID study is the current standard of care for this patient cohort, so the home nurses are likely to have greater familiarity with its use. Home nurses will be educated about the use of the electronic pump and have access to technical assistance, but nurse satisfaction may be biased due to differences in prior experience and the recent timing of training. The home nurses will have access to written educational materials and an online video regarding the use of the electronic pump; however, one of the limitations in the study design is that we could not provide hands-on training for all nurses employed by the home nursing organisation. Furthermore, although patients and staff will be educated regarding the use of the logbook, and adherence checked at each clinic visit, it is possible that recording may diminish over time, leading to an underestimation of complications and unexpected call-outs. Incomplete recording of connection and disconnection times may also impact on complete capture of data for analyses relating to average flow rates and cost. A further limitation is that the CHID study will not be able to detect rapid infusions (early emptying), as the elastomeric pump or infusion container will only be weighed before and after the infusion takes place. Finally, data will be limited to the external temperature of the elastomeric pump or infusion container and not the internal temperature of the solution.

In conclusion, the CHID study will provide important information regarding patient and nurse satisfaction with elastomeric and electronic infusion pumps, and will elucidate differences in patient safety and treatment costs to inform future device selection. Skin and ambient temperature data collected for the CHID study will provide a basis for expanded drug stability studies and flow rate bench testing of elastomeric infusion pumps.

TRIAL STATUS

Planned patient recruitment from February 2017 to October 2017.

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