



REPORT ON COMPARATIVE EVALUATION OF GRASEBY SYRINGE DRIVER REPLACEMENTS

Cardinal Alaris AD and Niki T34

Carey Fletcher October 2009
(on behalf of the Project Team)

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Acknowledgements

Brenda Forder and the Team from REM systems for the hire of 4 Niki T34 pumps to conduct this evaluation

All North Shore Hospice Nursing Staff who assisted with this audit

Report on comparative evaluation of Graseby Syringe Driver replacements

Cardinal Alaris AD and Niki T34

INTRODUCTION

This report describes an audit project undertaken at North Shore Hospice to compare two proposed alternatives to the soon-to-be withdrawn Graseby Syringe Driver, the Cardinal Alaris AD and the Niki T34. Both devices have been approved for use in a palliative care setting therefore the only aim is to assess the impact of each on patients, carers and nurses, predominantly in the community setting but also in the Inpatient Unit. This audit will not affect the care given to patients, the types and strengths of medications they are prescribed or their clinical outcomes.

It is intended that this audit will answer the questions generated by Clinicians at North Shore Hospice regarding the ease of use and acceptability of the proposed alternative devices to patients and their carers in the home environment. Results will inform decision making with regard to the purchase of further devices in addition to those already procured and in use in the Inpatient Unit. Following careful consideration of the evaluation data in the report published by District Health Boards New Zealand (DHBNZ) it has already been determined that either alternative device is safe and no further audit of this is necessary.

To conclude the report, a recommendation will be made regarding the syringe driver that North Shore Hospice should purchase to complete the transition and phase out of the Graseby. This will be the device which most appropriately meets the needs of the North Shore Hospices' patient population. It will be for other Hospice Service Providers to draw their own conclusions with regard to the device they will purchase if they have not already done so.

BACKGROUND

General

Graseby Syringe Drivers have been used in a variety of Health Care settings for 30 years. Their versatility and simplicity make them universally acceptable. It is primarily recognized as a device for use in palliative care settings, its portability making it suitable for community use. An innovation in the mid 1970s, it made it possible for medication to be delivered continuously and in a manner that did not rely on the oral route which can often be compromised in terminally ill patients. In the 30 years since inception, medical technology has advanced beyond the Graseby's capabilities and requirements for safety in medical devices have become more exacting with the result that it no longer meets the standard.

Smiths Medical ceased supplying both formats of Graseby Syringe Drivers in October 2007 in Australia and New Zealand but undertook to provide support and parts for existing devices for up to five years. It became imperative to seek an alternative. Medsafe, which licenses and regulates medical devices issued an advisory notice to District Health Boards to give immediate consideration to sourcing an alternative (Health Procurement, 2009). A Syringe Driver Advisory Group, comprising Clinical, Technical and Procurement representatives (SDA) was assembled to seek alternatives and evaluate them. This group worked closely with DHBNZ to gain a national procurement agreement to ensure consistency of the alternative pump implementation. At the conclusion of the evaluation process in early 2009, the pump selected was the Cardinal Alaris AD. This is a new device initially launched into the UK market in early 2008. It is largely unknown elsewhere however is being used in some centres in Australia.

Syringe Driver use in Palliative Care

Using syringe drivers in palliative care to manage symptoms is accepted practice and there are many benefits for patients (Ministry of Health, 2009). Palliative care takes place across the Health Care Continuum and any replacement should meet the requirements of these diverse settings but also be acceptable to a vulnerable patient group for whom a small degree of independence may be the only semblance of normality they retain.

These pumps may be used:

- In patient's homes
- Residential Aged Care Facilities
- Hospice Inpatient Units
- Acute Care Settings

In 2008, The Syringe Driver Advisory Group produced a discussion document. In it was stated:

The ideal device for use in an acute hospital ward may not be ideal in the community where family members and untrained personnel may be helping with care. It is essential that any device intended for use across care settings is acceptable for community use

(McLennan, 2008)

This statement is particularly pertinent to Hospice settings as syringe driver use in the home is prevalent and is regarded as a standard tool of palliative care. What is especially interesting is the syringe driver selected as the national replacement for the Graseby, the Alaris AD was not evaluated for community use during the selection process. A potentially significant oversight given that the home is where it is likely to be used most frequently. The Graseby syringe driver is acknowledged as not meeting international safety standards for a medical device and that there have been a number of critical incidents relating to its use. The question remains whether the Alaris AD is the ideal replacement for use in the community and whether it is suitable for untrained persons to be involved, even with a low level of responsibility, in its management.

Preparation

Existing evaluation documents for both pumps were obtained through an internet search and reviewed for any potential area which requires further investigation. Both devices were evaluated according to functionality, safety and acceptability to Clinicians who were using them. Neither were evaluated for patient acceptability and lifestyle impact – an important factor when considering quality of life for dying people. Some questions were answered by these documents but many more were not. Technically, there is little to choose between the devices and so the main points of difference may lie in their usability and acceptability to patients.

In considering these points, a list of questions which required an answer was assembled and incorporated into two audit tools, one for patients and one for Clinical Staff involved in the use of the devices. The audit was carried out in two settings, the IPU and the Community and involved both patients and staff in each area.

Training

Before commencement of the project all Community Nurses and the Team Leader undertook training in the use of the Niki T34 and a refresher of the AD. The Clinical Coordinator(s) had Super User training. Staff had access to on-line, interactive Training Packages for both pumps as follows:

- Niki T34:
 - <http://www.mckinleymed.co.uk/online-training/>
 - Log in: rem2008
 - Password: careyf

- AD Syringe Driver:
 - On the 'common' drive (intranet), in the 'Syringe Driver –AD pump' folder

AUDIT DESIGN

The intention of this audit was to determine how acceptable and useable the alternative pumps were to patients and carers predominantly in home environments. In order to do this, several issues of interest were identified for which opinion would be sought:

- Weight and size of pump
- Convenience of use
- Impact on quality of life.

Another focus of the audit was to determine ease of use and acceptability to nursing staff using the alternative pumps. This examined, primarily the operating of the pumps with some subjective analysis of what was liked and disliked about both pumps.

In order to achieve this two audit tools were developed which sought both quantitative and qualitative data. (See Appendix 1 and 2) A protocol was written by the project advisory group (appendix 3) which outlined the audit approach, how data would be collected, collated and reported upon.

It was planned that the audit would run from August 1st 2009 – 30th September 2009 with the data collection period extending for six weeks in between those dates. Completed surveys would be reviewed at intervals to ensure it was delivering sufficient data in both quantity and quality from which to draw conclusions. This plan was confounded by circumstances which are explained in more detail in the section on limitations.

The intention was that all participants, if possible should use both devices for a period of time, the minimum period being 4 days and the ideal 7. At the transition of one to another, each patient would be navigated through the audit tool by the Clinical Coordinator. Despite these intentions, unfortunately, some patients were not able to use both devices.

It was intended that every endeavour be made to ensure there be an equal number of evaluations for each pump and that the quality of the data collected was of a comparable standard however, this proved difficult to achieve in the confounding and very limiting circumstances. Staff evaluations were completed by all CPC Nurses who had involvement in caring for the patients participating in the audit and throughout the audit period all participants received usual care.

RESULTS AND DISCUSSION

There were 7 patient participants in the audit. The ideal number was twelve but unfortunately, during the data collection period there were few patients requiring syringe drivers, which was very disappointing. Not all of the seven completed the audit in the designated manner and there were several more evaluations completed for the Niki T34 than the Alaris AD. Objective patient data of either pump is limited however, staff evaluations comprise both quantitative and qualitative data which were helpful in determining experiences and views of both pumps.

Some of the patients involved in the Audit had already had experience of the Graseby Syringe driver and it should be acknowledged that from a patient's point of view, neither of the available alternatives are as small, as light or as uncomplicated as this. This deserves mention as at least one of the patients evaluated both alternatives in the context of previous knowledge and in one case, the audit was abandoned so the patient could return to using the Graseby.

Data was collected from 5 patients regarding the Niki T34 and from 3 patients regarding the Alaris AD. In only two cases was it possible to collect data regarding both pumps from the same patient. In the quantitative data from these patients there was little to choose between the two however, their comments indicated that their preference was the Niki T34. One patient commented that the charging cradle of the Alaris AD was very limiting and the other commented that the Alaris AD was a little too big to carry under clothes. Results are visually displayed in graphs as percentages of the total responses for each pump as this was the most effective way of demonstrating a comparison.

There were some negative responses regarding the Niki T34 and these were largely focused on the security of the Infusion. In a number of cases, the device had been used without a lock box or a carry pouch and this gave both Nurses and patients a feeling of insecurity. Where lock boxes were used, the view was overwhelmingly in favour of the Niki. Several comments were made by nurses that patients were able to tamper with the keypad of the Alaris AD if they wished to.

Both pumps were considered too heavy by some patients and some made a comparison with the Graseby which is lighter than both the alternatives. Only the Alaris AD was considered too large to be carried discreetly under clothing or to be negotiated through clothing.

Comment was made regarding battery use by the Niki T34. Batteries were requiring to be changed every 3 days which does have cost implications however, can be mitigated by the use of rechargeable 9 volt batteries. There were also issues regarding the charging cradle for the Alaris AD and it caused a number of challenges for patients and nurses. The most notable being the difficulty that one patient had in finding a convenient power point to plug it into. An elderly lady living on her own was not able to manage the requirements of the battery recharging.

With regard to patient responses, The Alaris AD performed better than the Niki in some criteria but overall, patients found the Niki T34 more acceptable. For nursing staff, there is no question which pump has been identified as most suitable for use in a community environment.

Results are visually displayed in charts on the next 3 pages.

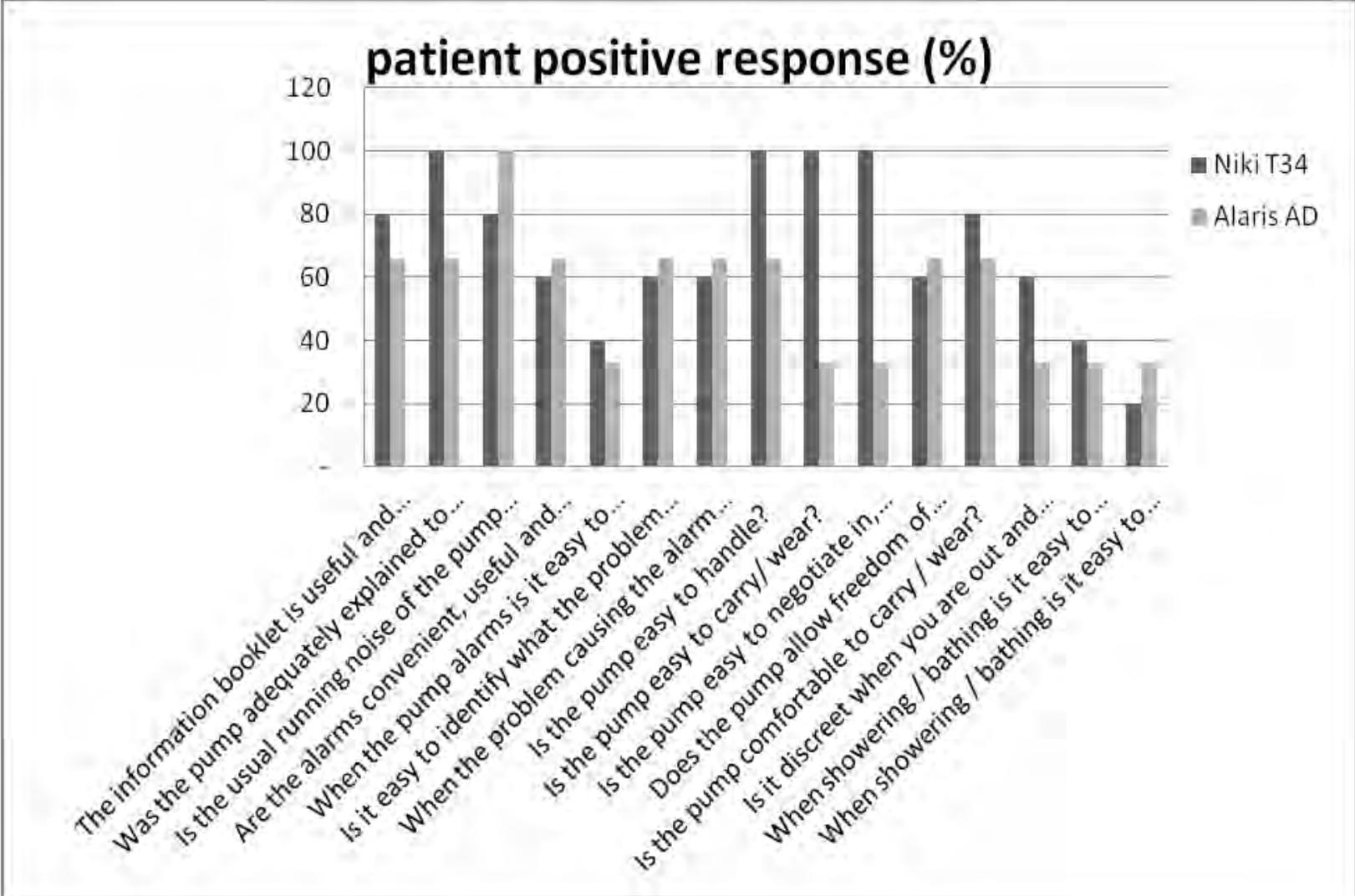


Figure 1

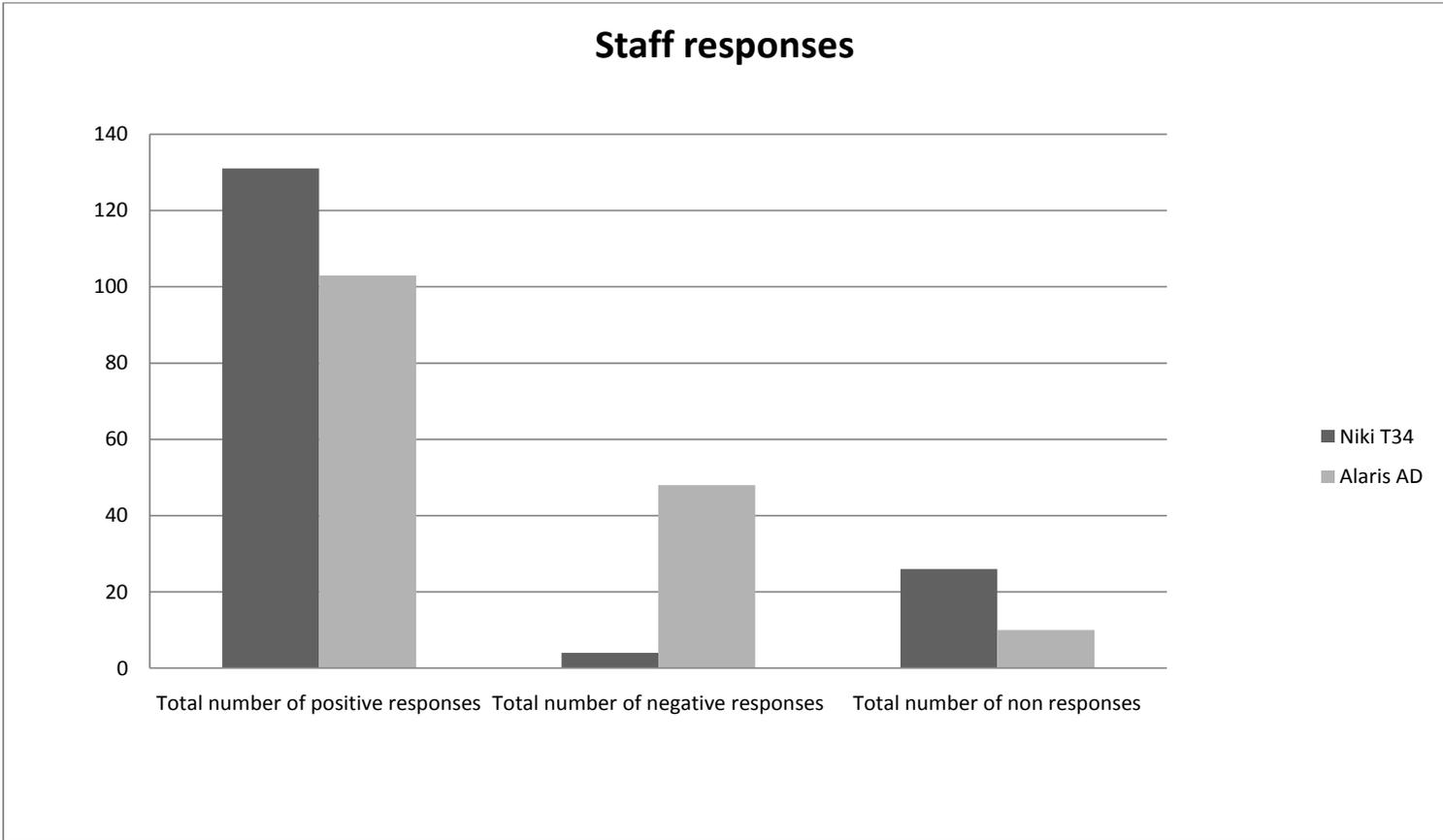


Figure 2

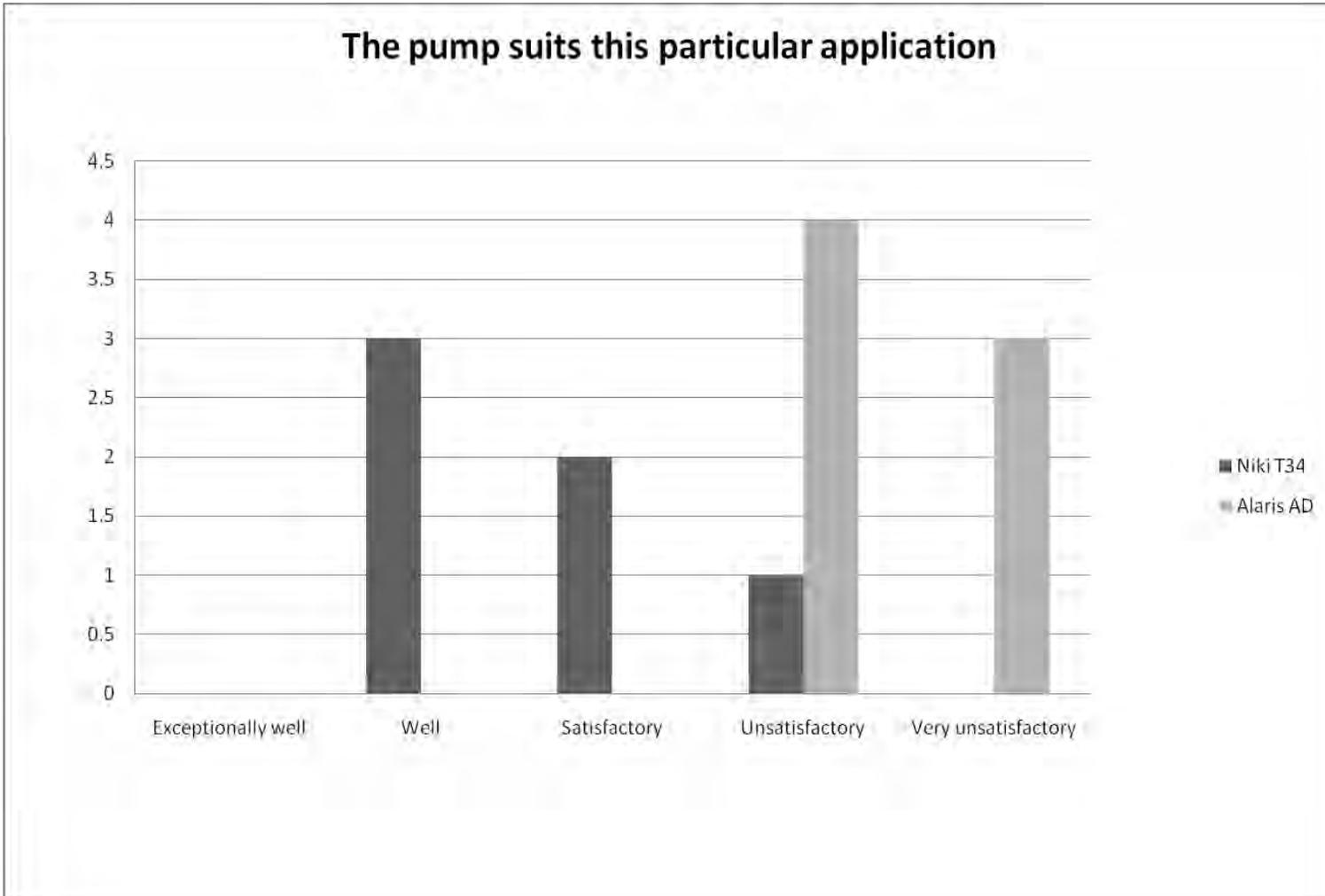


Figure 3

LIMITATIONS

The design of this audit involved patients experiencing both pumps for a period of time in order to make a comparison. This was a major challenge as some patients were only able to experience one and it was apparent at the end of the data collection period that more information had been collected from patients regarding the Niki T34. The lack of comparative data from the Alaris AD and the small amount of quantitative patient data from either pump has made it difficult to draw conclusions based solely upon it. Fortunately, the audit comprised two data sources which means information collected from staff who have been involved in caring for patients using the pumps can be included in the results which gives a clear outcome and identifies preference of device.

Time was limited for this project which meant it was not possible to extend the audit period beyond a few days and this has contributed to the lack of excellent data. During the audit and data collection period there was a lack of patients requiring a syringe driver who met inclusion criteria and this is the most significant limitation to the audit however the tools developed would make it possible to replicate the audit.

In order to obtain good data on both pumps, the time frame was a minimum of eight days. In practice, for symptom management a syringe driver is rarely required for that length of time, six days being common. As this was an audit, normal practice was continued therefore it became clear that the full eight days was unlikely to be achieved.

Patients considered to be in the last 48 hours of life were excluded from the audit however, determining this is not always possible and unfortunately 3 participants died before any data was able to be collected.

RECOMMENDATIONS

Despite the limited number of patient evaluations, there were sufficient staff evaluations of both pumps to make a recommendation. It is clear that the Niki T34 represents more closely a like for like alternative to the Graseby and staff were more comfortable using it than the AD in a community setting. A number of patients had previously experienced the Graseby and found neither alternative as light, small and as simple to use as that but acknowledged that of the two alternatives, there were less challenges with the Niki T34.

In conclusion, on the basis of the results of this audit, we recommend the purchase of REM systems Niki T34 pump with lock boxes or the soft carry pouch to ensure the safety and security of both the infusion and the device.

REFERENCES

Health Procurement, (2009). *DHBNZ Syringe Pump Evaluation Report*. Wellington: Author

MacLennan, A., (2008). *Discontinuation of Supply of Graseby MS16A and MS26 Syringe Drivers: Discussion Paper*. Wellington: Syringe Driver Advisory Group

Ministry of Health, (2009). *Guidelines for Syringe Driver Management in Palliative Care in New Zealand*. Wellington: Ministry of Health

PROJECT TEAM

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APPENDICES

Patient Questionnaire

Staff Questionnaire

Audit protocol

Comments Tables

Audit to evaluate Alaris AD and Niki T34 syringe driver pumps

Pump being evaluated

Alaris AD

Niki T34

Circle one

Department IPU

CPC

Participant Identifier.....

Patient Questionnaire		Yes	No	Not applicable
1	Is the information booklet useful and easy to understand?			
2	Was the pump adequately explained to you when it was set up?			
	If not, what further information would have been useful?			
Pump Functioning				
3	Is the usual running noise the pump makes acceptable to you?			
4	Are the pump alarms convenient, useful and unobtrusive?			
5	When the pump alarms it is easy to silence it?			
6	Is it easy to identify what the problem is when the pump alarms?			
7	When the problem causing the alarm has been identified is it easy to rectify it?			
	Comments regarding any of the above 5 points			
Acceptability / convenience				
8	Is the pump easy to handle?			
9	Is the pump easy to carry / wear?			
10	Is this pump easy to negotiate in, around and under clothing? (think about when you are dressing and undressing)			
11	Does the pump allow relative freedom of movement?			
12	Is the pump comfortable to carry / wear?			
13	Is it discreet when you are out and about?			
14	When showering / bathing is it easy to disconnect and reconnect this pump?			
15	When showering / bathing is it easy to pause and restart the infusion with this pump?			

	Comments regarding any of the above 8 points
Weight, shape and size	
16	<p>We would appreciate your comments on the weight of the pump. Some points to consider are:</p> <p>Does the weight of the pump affect your ability to handle it?</p> <p>Does the weight of the pump affect your ability to mobilise / participate in usual activities?</p> <p>Does the weight of the pump allow you to carry it comfortably?</p> <p>Comments:</p>
17	<p>We would appreciate your comments on the size and shape of the pump. Points to consider are:</p> <p>Do the size and shape of the pump affect your ability to handle it?</p> <p>Do the size and shape of the pump affect your ability to mobilise / participate in usual activities?</p> <p>Do the size and shape of the pump allow you to carry it comfortably?</p> <p>Comments:</p>
18	How easy to use is the charging cradle? (Alaris only)
19	How easy is it to identify when the battery needs changing and to change it? (Niki T34)
20	<p>Has the pump been dropped?</p> <p>What factors contributed to this?</p> <p>What was the outcome when the pump was dropped?</p>
21	What impact has this pump had on your lifestyle? In other words, not withstanding your illness and medications how much or how little has this pump restricted you?

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Overall rating of pump and final comments					
22	What I liked about this pump				
23	What I disliked about this pump				
24	This pumps meets my needs				
	Exceptionally well Could not be better	Well. Some minor improvements needed	Satisfactory	Unsatisfactory. Major improvements required	Very unsatisfactory. I do not want to use this pump again

<p>On completion of evaluation of both pumps, and further to what you have already told us, please tell us the main differences between both pumps and which one you would prefer to continue using</p>

Many thanks for your assistance with this

Audit to evaluate Alaris AD and Niki T34 syringe drivers

Pump being evaluated

Alaris AD

Niki T34

Circle one

Department IPU

CPC

Staff identifier

Staff Questionnaire						
1.	Training for using this device was	Very good	Good	Adequate	Inadequate	Poor
2.	Operating manual / Instructions provided for use of this device is	Very good	Good	Adequate	Inadequate	Poor
3.	Comments regarding the above points					
Device Functioning / appropriateness						
4.	This device is suitable for the intended use	Very good	Good	Adequate	Inadequate	Poor
5.	Battery life is	Very good	Good	Adequate	Inadequate	Poor
6.	The size of the pump is	Very good	Good	Adequate	Inadequate	Poor
7.	The weight of the pump is	Very good	Good	Adequate	Inadequate	Poor

8.	<p>The robustness of the pump is:</p> <table border="1" data-bbox="386 231 1307 367"> <tr> <td data-bbox="386 231 568 294">Very good</td> <td data-bbox="568 231 750 294">Good</td> <td data-bbox="750 231 932 294">Adequate</td> <td data-bbox="932 231 1114 294">Inadequate</td> <td data-bbox="1114 231 1307 294">Poor</td> </tr> <tr> <td data-bbox="386 294 568 367"></td> <td data-bbox="568 294 750 367"></td> <td data-bbox="750 294 932 367"></td> <td data-bbox="932 294 1114 367"></td> <td data-bbox="1114 294 1307 367"></td> </tr> </table>	Very good	Good	Adequate	Inadequate	Poor					
Very good	Good	Adequate	Inadequate	Poor							
9.	<p>Comments regarding any of the above 5 points points for consideration –</p> <ul style="list-style-type: none"> • use of the charging cradle – Alaris; • battery life and ease of changing battery – T34) • Ease of negotiating the pump around / through patient’s clothing 										
Loading and setting up the device											
10	<p>The loading procedure for the device is</p> <table border="1" data-bbox="386 714 1307 856"> <tr> <td data-bbox="386 714 568 777">Very good</td> <td data-bbox="568 714 750 777">Good</td> <td data-bbox="750 714 932 777">Adequate</td> <td data-bbox="932 714 1114 777">Inadequate</td> <td data-bbox="1114 714 1307 777">Poor</td> </tr> <tr> <td data-bbox="386 777 568 856"></td> <td data-bbox="568 777 750 856"></td> <td data-bbox="750 777 932 856"></td> <td data-bbox="932 777 1114 856"></td> <td data-bbox="1114 777 1307 856"></td> </tr> </table>	Very good	Good	Adequate	Inadequate	Poor					
Very good	Good	Adequate	Inadequate	Poor							
11	<p>The priming procedure for the device is</p> <table border="1" data-bbox="386 924 1307 1066"> <tr> <td data-bbox="386 924 568 987">Very good</td> <td data-bbox="568 924 750 987">Good</td> <td data-bbox="750 924 932 987">Adequate</td> <td data-bbox="932 924 1114 987">Inadequate</td> <td data-bbox="1114 924 1307 987">Poor</td> </tr> <tr> <td data-bbox="386 987 568 1066"></td> <td data-bbox="568 987 750 1066"></td> <td data-bbox="750 987 932 1066"></td> <td data-bbox="932 987 1114 1066"></td> <td data-bbox="1114 987 1307 1066"></td> </tr> </table>	Very good	Good	Adequate	Inadequate	Poor					
Very good	Good	Adequate	Inadequate	Poor							
12	<p>The ease of setting syringe brand and size is</p> <table border="1" data-bbox="386 1134 1307 1276"> <tr> <td data-bbox="386 1134 568 1197">Very good</td> <td data-bbox="568 1134 750 1197">Good</td> <td data-bbox="750 1134 932 1197">Adequate</td> <td data-bbox="932 1134 1114 1197">Inadequate</td> <td data-bbox="1114 1134 1307 1197">Poor</td> </tr> <tr> <td data-bbox="386 1197 568 1276"></td> <td data-bbox="568 1197 750 1276"></td> <td data-bbox="750 1197 932 1276"></td> <td data-bbox="932 1197 1114 1276"></td> <td data-bbox="1114 1197 1307 1276"></td> </tr> </table>	Very good	Good	Adequate	Inadequate	Poor					
Very good	Good	Adequate	Inadequate	Poor							
13	<p>The ease of setting the rate is</p> <table border="1" data-bbox="386 1344 1307 1486"> <tr> <td data-bbox="386 1344 568 1407">Very good</td> <td data-bbox="568 1344 750 1407">Good</td> <td data-bbox="750 1344 932 1407">Adequate</td> <td data-bbox="932 1344 1114 1407">Inadequate</td> <td data-bbox="1114 1344 1307 1407">Poor</td> </tr> <tr> <td data-bbox="386 1407 568 1486"></td> <td data-bbox="568 1407 750 1486"></td> <td data-bbox="750 1407 932 1486"></td> <td data-bbox="932 1407 1114 1486"></td> <td data-bbox="1114 1407 1307 1486"></td> </tr> </table>	Very good	Good	Adequate	Inadequate	Poor					
Very good	Good	Adequate	Inadequate	Poor							
14	<p>The ease of setting the Volume to be infused (VTBI) is</p> <table border="1" data-bbox="386 1554 1307 1696"> <tr> <td data-bbox="386 1554 568 1617">Very good</td> <td data-bbox="568 1554 750 1617">Good</td> <td data-bbox="750 1554 932 1617">Adequate</td> <td data-bbox="932 1554 1114 1617">Inadequate</td> <td data-bbox="1114 1554 1307 1617">Poor</td> </tr> <tr> <td data-bbox="386 1617 568 1696"></td> <td data-bbox="568 1617 750 1696"></td> <td data-bbox="750 1617 932 1696"></td> <td data-bbox="932 1617 1114 1696"></td> <td data-bbox="1114 1617 1307 1696"></td> </tr> </table>	Very good	Good	Adequate	Inadequate	Poor					
Very good	Good	Adequate	Inadequate	Poor							
15	<p>The ease of navigating the control panels is</p> <table border="1" data-bbox="386 1764 1307 1892"> <tr> <td data-bbox="386 1764 568 1827">Very good</td> <td data-bbox="568 1764 750 1827">Good</td> <td data-bbox="750 1764 932 1827">Adequate</td> <td data-bbox="932 1764 1114 1827">Inadequate</td> <td data-bbox="1114 1764 1307 1827">Poor</td> </tr> <tr> <td data-bbox="386 1827 568 1892"></td> <td data-bbox="568 1827 750 1892"></td> <td data-bbox="750 1827 932 1892"></td> <td data-bbox="932 1827 1114 1892"></td> <td data-bbox="1114 1827 1307 1892"></td> </tr> </table>	Very good	Good	Adequate	Inadequate	Poor					
Very good	Good	Adequate	Inadequate	Poor							

16	The visual displays are	Very good	Good	Adequate	Inadequate	Poor

17	The clarity of messages is	Very good	Good	Adequate	Inadequate	Poor

18	The noise level whilst running is	Very good	Good	Adequate	Inadequate	Poor

19	The running indicator clarity is	Very good	Good	Adequate	Inadequate	Poor

20	The display of rate / VTBI during infusion is	Very good	Good	Adequate	Inadequate	Poor

21	The alarm messages are	Very good	Good	Adequate	Inadequate	Poor

22	The alarm tone is	Very good	Good	Adequate	Inadequate	Poor

23	The appropriateness of alarms is	Very good	Good	Adequate	Inadequate	Poor

24	The safeguards against tampering are					

		Very good	Good	Adequate	Inadequate	Poor
25	The ease of stopping, disconnecting and restarting the pump for showering is					
		Very good	Good	Adequate	Inadequate	Poor

Weight, shape and size

26	<p>Has the pump been dropped? What factors contributed to this? What were the consequences of the pump being dropped?</p>
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Overall rating of pump and final comments

27	What I liked about this pump
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28	What I disliked about this pump
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29	This pump suits this particular application				
	Exceptionally well. Could not be better	Well. Some minor improvements needed	Satisfactory	Unsatisfactory. Major improvements required	Very unsatisfactory. I do not want to use this pump again

Are there any further comments you would like to add?

SYRINGE DRIVER EVALUATION AUDIT PROTOCOL JULY – SEPTEMBER 2009

PURPOSE – The purpose of this comparative evaluation is to determine patient and staff preference for an alternative to the Graseby Syringe Driver which will be withdrawn at the end of 2009. This will be achieved by initiating a robust process which comprises 6 stages and will inform decision-making regarding future purchases of replacement pumps. There are external stakeholders awaiting the results of the evaluation audit.

INTRODUCTION

There are two main device options to replace the Graseby, they are the AD Syringe Driver supplied by Cardinal Health (also known as the 'Alaris') and the Niki T34 supplied by REM Systems (known as the McKinley T34 in Europe). Both of these pumps have been approved as "fit for purpose" by the Syringe Driver Advisory Group.

There has been extensive searching and reading of current information and evaluations already written on both pumps to inform any work undertaken here. It is acknowledged that in functioning, both pumps are superior to the Graseby in their accuracy of delivery and safety but it appears no account has been taken of patient comfort and acceptability. In the evaluation commissioned by DHBNZ conducted in 2008 by the Syringe Driver Advisory Group, there was scant evaluation of both alternative devices in the community. The AD Syringe Driver is new to the market and has not had extensive use anywhere in the world. The T34 has been available for several years and is used in the UK, Australia and in some areas of New Zealand. Based on appearance, the T34 appears closest in resemblance to the Graseby although functioning is more sophisticated, more accurate and less susceptible to the risk of tampering.

In palliative care, a basic tenet is to improve quality of life for dying people. It would therefore, be indefensible to use a pump for which there is a lack of clear evidence to support this tenet. To our knowledge the evaluation we are advocating and preparing has not been conducted in New Zealand. A project team has been assembled to provide the expertise and oversight to ensure the data collected is valid and can be interpreted clearly and effectively. The team consists of Educators, Team Leaders and Clinical Manager as the Advisory Group and Clinical Coordinators who will run the clinical aspects of the trial and navigate patients through the process.

As both pumps have been approved for use in a palliative setting, this audit is only aiming to evaluate the patient and staff acceptability of each pump. Therefore this audit will not affect the care given to patients, the types and strengths of medications they are prescribed or their clinical outcomes.

PREPARATION

Existing evaluation documents for both pumps were obtained through an internet search and examined for any potential area which requires further investigation. Both devices were evaluated according to functionality, safety and acceptability to Clinicians who were using them. Neither were evaluated for patient acceptability and lifestyle impact – an important factor when considering quality of life for dying people. Some questions were answered by these

documents but many more were not. Technically, there is little to choose between the devices and so the main points of difference may lie in their usability and acceptability to patients.

In considering these points, we have assembled a list of questions which require an answer and incorporated these into two audit tools, one for patients and one for Clinical Staff involved in the use of the devices. The audit will be carried out in two settings, the IPU and the Community and involve both patients and staff in each area.

Further documentation to support the project includes

- Information leaflets for patients regarding both pumps
- Information regarding the audit and consent form to participate.

All patients will be assisted in the navigation of the documentation and the evaluation by the Clinical Coordinators.

Regular meetings of the Advisory Group and the Clinical Coordinators will be held in preparation and during the project to:

- assess progress and measure against timeline
- ensure the project remains focussed and on task
- assess preliminary findings and adjust information and data gathering if required
- revisit inclusion criteria if sampling is not meeting the needs of the project

PARTICIPANT INCLUSION / SELECTION CRITERIA

To ensure the process is robust and valid, an ideal number of 12 participants has been set as a total number across both settings. Each Patient and Staff participant will be given a unique, project identifier to maintain confidentiality and to facilitate the reporting of results. All IPU patients and staff will be prefixed with the letter I and all CPC patients and staff will be prefixed with the letter C.

In order to replicate normal practice as near as possible all patients will be considered potential participants with the exception of:

- Patients who are considered to be in the last 48 hours of life
- Patients who are unable to give consent in English.

TRAINING

Before commencement of the project all Community Nurses and the Team Leader will have training in the use of the Niki T34 and a refresher of the AD. The Clinical Coordinator(s) will have SuperUser training. Staff will have access to on-line, interactive Training Packages for both pumps as follows:

Niki T34:

<http://www.mckinleymed.co.uk/online-training/>

Log in: rem2008

Password: careyf

AD Syringe Driver:

On the 'common' drive (intranet), in the 'Syringe Driver –AD pump' folder

METHODOLOGY

Nursing staff will approach potential participants for inclusion in the trial and will give them a brief overview of the project and its purpose. The Clinical Coordinator will then visit the patient and explain in more detail and obtain consent. The order the pumps will be trialled in will be entered onto their information sheet and be available for all Hospice Staff to review. If in doubt, any member of the Advisory Group or the Clinical Coordinator can be contacted for clarification. Participants should be reassured of continuing support throughout the audit.

All participants, if possible will use both devices for a period of time. Minimum time period is 4 days and the ideal is 7 days using each. At the transition from one to another, each participant will be navigated through the audit tool by the Clinical Coordinator in which opinion will be sought regarding the pump's impact on life. At the end of the audit, each participant will be asked which pump he / she would prefer.

Some patients may not be able to use both devices. Every endeavour will be made to ensure there is an equal number of evaluations for each pump and that the quality of the data collected is of a comparable standard. It is anticipated that evaluations may be completed by more than one staff member and this will be dependent on who has been caring for the participants.

Each participant has the right to withdraw from the audit at any time and to have the data collected withdrawn from collation and returned to them if they wish.

Details of the audit process including patient identifier will be recorded on the white board in the CPC office for the duration of the project.

Raw data, when collected will be reviewed by the Advisory Group for completeness and then securely stored until it is collated. Once all data has been extracted, original documentation will be destroyed.

IMPLEMENTATION AND CLINICAL SUPPORT INCLUDING AFTER HOURS TROUBLE SHOOTING AND TRIAGING

All issues that participants have with the trial pumps will be recorded separately from other records Recording / register. All call ins and call outs will be identified separately from other calls.

Each device will be issued to a participant with a fully charged battery and the charger cradle in the case of the AD pumps and a new 9 volt battery in the case of the T34.

DATA COLLATION / ANALYSIS

Data from participants will be collated separately from staff as will information gathered from CPC and IPU. It is believed that the issues facing patients in the community when managing devices are unique and must be demonstrated as clearly as possible. Information gathered from patients in the IPU will provide added depth and validation to the evaluation particularly if the results regarding impact on activities of daily living are similar.

Quantitative Data will be visually displayed following collation to give a direct comparison of both devices. There will be some thematic analysis of the qualitative data.

REPORT

The results of the audit will be written up and reported to the Chief Executive and the Executive Team by the beginning of September. It will subsequently be disseminated to other stakeholders.

C. Fletcher

July 2009

Appendix 4

Table displaying positive comments for both pumps (patients)

Niki T34	Alaris AD
feels happy with the pump – it has not caused any trouble	Generally okay - just noticed it once when I was reading, I noticed the weight
The weight of the pump is okay, quickly got used to it	The shape and size were okay
It feels far better than taking lots of medication orally.	Charging cradle is easy to use
Easier than oral medication, unobtrusive, quiet, convenient size and weight	Delivers medication unobtrusively
Good weight	It has been good having the pump easier than lots of oral medication
It is good to know that the pump is there delivering medication in a good way.	Found it very acceptable
Easy to use	The charging cradle is okay

Table displaying positive comments for both pumps (Staff)

Niki T34	Alaris AD
Easy to set up	Easy to set up
Pump not complex and was accessible for patient Dealt with a phone call and managed to triage and trouble shoot over the phone	Both training and operating manual very good
The instructions were easy to follow, it did not seem too different from what I have used previously. It calculated the rate of medication to be administered and appeared to accurately display what was left before we changed it, Also liked the battery indicator	
I have limited involvement with the T34 but it has been no problem when I have used it.	
Pump dropped without adverse consequences I liked the easy to read running indicator	
I liked robustness – similarity to Graseby in appearance and size	
There had been a gap of several weeks between the original instruction and when I had to change the medication for the Niki. The instructions were easy to follow	
Battery easily checked I liked that it was easy to programme	
A syringe driver suitable for the community needs to be as simple as possible, no complicated display panels, robust and not attached to a recharging cradle	
I liked the coloured buttons as a guide to show patient what to press	

Table displaying negative comments for both pumps (patients)

Niki T34	Alaris AD
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Attachment. Can't be bothered getting fully dressed Feel it needs more robust protection. Not improved from Graseby	Upon completion of setting up of Alaris AD pump, the patient decided she would prefer to go back to the Graseby. Just all too overwhelming and importantly, the need for the pump to be on a charger was very difficult / impossible for an elderly lady on her own to manage. Power Socket was difficult to access in the lounge and there was no socket in the bedroom suitable / no extension cable.
Heavier than Graseby – willing to get used to it	Patient did not like this pump if it was taken down and replaced with a Graseby.
Would have liked to have felt in better health to fully understand information and explanation Syringe (30ml) protruding in front of unit. Would benefit from a cover.	Unable to see screen in sunlight. Large, heavy Carer today thought T34 less complicated, more mobile and easier to change patient's clothing
Battery changed yesterday at 27%. Low battery alarmed today at 11.30hr	When explained and demonstrated AD to patient and family members, they did not want to proceed with it as too complex
Would have liked to have more control over the pump but carers were willing to help	Too difficult for patient on own to set up for showering.
Pump fell off side of bed whilst patient asleep which caused it to alarm. Not turned off as CPC nurse due to visit	It is a little too big to wear under clothes
	It has restricted my lifestyle
	It is a little noisy and makes sounds all the time

Table displaying negative comments for both pumps (staff)

Niki T34	Alaris AD
Only 27% battery life after 3 days although tester in SD box said battery life was good Needs a case. Awkward for patients as syringe catches on clothes, bag, etc	Too bulky
Not very robust without a cover	Called in a 04.00hr to replace AD with Graseby as IPU nurse unable to triage any further regarding pump settings. Family distressed – pump display saying it needed to be reset. Not appropriate for me to do this safely at 04.00hr with no previous experience of the pump.
Disliked that it didn't have a cover	More practical experience needed, personally found the manual quite difficult to follow
Patient had difficulty reading the screen as she was unwell and frail with no other family No idea why it alarmed although patient was vomiting. Perhaps line had kinked	Too large and cumbersome
Patient asked about a cover to protect it from being dropped.	Heavy for patient to carry
I disliked that fact that it used up a lot of battery very quickly. It seemed less robust and more vulnerable to the environment without a cover.	Reports of pump case breaking and several AD pumps have needed to go for repair
Because this pump didn't have a plastic cover I was aware of bumping or moving the parts that protrude. Whilst I did not bump or move them, this could have been a problem.	Pump easily falls off the cradle. To find suitable power points in some houses difficult. Large to negotiate through clothing
I didn't like not having a plastic cover	Visual displays poor in sunlight
I didn't like that it was slightly heavier	Cumbersome, heavy. Digital programming far too difficult for patient and majority of carers / family to manage. Screen far too small, can't see at all in bright sunlight Location of power source difficult to access in many homes
The weight was managed adequately by a young man. It is certainly heavier than the Graseby and could be a problem for a frail elderly person	This syringe driver does not suit the community environment. Patients are obviously very unwell and anxious, many carers are elderly and regular / irregular family members attending to patient are anxious also. This kind of pump adds to their anxiety.
I disliked that it is heavier and bulkier than the Graseby T34 battery lasts 3 days – each visit easy to assess battery level on driver – easy to change battery.	I did not like: the size, the smallness of the display, complexity of troubleshooting for patients
Battery doesn't last long and when we changed the battery (at 24%) I checked it on the battery indicator and it registered fully charged	Needs to be charged – too complicated for relatives and poorly patients
No covering – easy to access	Way too big
	Relatives feel it's not clear enough and they are not sure if it is running
	Have to press button to light up screen
	If you wanted to get into it you probably could
	Very poor for stopping and restarting for showering
	I disliked the stress caused to carers due to it being complicated. The fact that it needs charging
	Too heavy in comparison to others
	A pump should be something the patient / carer does not really need to think about
	The mains connection is very easily dislodged as it was with one patient and they were not

	aware that it wasn't charging. Fortunately, the battery did not run out
	Bulky. Not an easily accommodated shape
	Feels heavier than the Niki
	Frustrating because it needs such frequent recharging
	The screen is blank unless there is a problem
	Screen dark until activated
	Very bulky. Heavy. The need for the pump to be constantly recharged therefore needing a 3 point socket by the bed.
	not suitable for community use
	Too large and cumbersome
	Okay for staff but for patients a little heavy
	Pump had alarmed twice that morning with an occlusion and he had 'sorted it'. Advised to ring Hospice and not guess what to do. Patient could only sit on bed to recharge battery. Need to consider location of plug socket making re-siting of cannula difficult
	Patient did not like the fact he had to sleep with the pump in the charger. Found it too restrictive. Pump was about to work on emergency battery although had been sitting on cradle all night. Unless you get it on right it does not charge correctly. Can easily be moved. As battery was low it would not work correctly. I had to keep turning it off and starting again. took too long to set up - time consuming
	Too difficult for patients and family to stop and restart pump for showering
	Too complicated for patients in the community
	Because of the low battery, this visit took me about an extra 20 - 25 minutes. Do not like the AD - something simple is needed for community patients
	When not using the AD frequently, one relies upon clear instructions to explain the use of the device in order to be safe and deliver a high standard of care
	Pump size bulky therefore more difficult to negotiate sleeves in patient's clothing compared with the Graseby. Charging cradle looks and feels brittle and may crack if dropped on the floor. This is a risk when used at home with pets and children in the house. Pump and cover feel insufficiently robust. Lockable cover can be opened with a paper clip therefore not secure.
	Patient able to press buttons - not good