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A fresh approach to administering medication in the palliative care environment

Elizabeth Lewis

University of Technology, Sydney, Australia

Review

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Corresponding Author:
Elizabeth Lewis
info@elizabethlewisdesigns.com

Abstract

This area of study has been developed as a response to the needs of patients living in a palliative care setting, whilst also exploring the overarching levels of care in regards to the surrounding support networks such as nursing staff, family and friends and allied health professionals.

Of particular interest is the way the design of syringe drivers influences the administration of pain management medication and the ways in which administration of medication can be improved.

QCap is a subcutaneous syringe driver for palliative care patients. The syringe driver delivers up to four medications from a specifically designed syringe at a set time to dose ratio through the use of a micro air compression pump. Devices that currently fulfil the same or similar function are difficult and tedious to use, require several operations for start up and maintenance, are time inefficient for operators and are cumbersome and awkward for patients.

Possible consequences of human and mechanical error in the operation of current models of syringe drivers can result in overdose/under dose, mismanagement of pain and discomfort. The research and design of a fresh alternative is directed at addressing and eliminating these risks, creating a more time and labour efficient set of processes whilst offering a new perspective on the relationship between the operator, patient and device.

This product solution involves three core elements: the design of a drawing snap off syringe, the design of a compact housing and the development of an online interface. Each element has been carefully considered to ensure best practise standards through all stages of operation whilst allowing monitored and intentional adaptability to meet individual patient needs. This device offers added value to all avenues of the palliative care environment.

Key Words
Design, palliative, syringe driver

Introduction

Design has infiltrated so many aspects of our lives, but when exploring the products used in the palliative care environment, they appear foreign and sterile in their functionality. As time passes attitudes and values change, a new generation of people move into palliative care carrying new expectations based on their relationship with technology. So how do we approach developing this area of medical design? What strategies do we employ in meeting individual needs? How can these facets of design progress to meet patients' personal experiences in the unfamiliar context of end of life care?

This paper aims to explore and question a new design approach to the development of medical devices in the palliative care environment, in particular the redesign of medication administration devices. This process has led to the product solution, QCap, which aims to provide a new direction and possibility for the design of subcutaneous syringe drivers. It will act as a tool and an augury to the aspirations of design practise in relation to palliative care. These processes enable us to consider the value of closely incorporating design practise and research within the palliative care environment.

The palliative care environment as a design context

The palliative care environment is complex and dynamic and provides a support framework for the resident and a central long term care system for health professionals and family members. [1] It is a multidisciplinary approach to care that encompasses the physical, emotional and spiritual needs of patients.[2] When exploring the physical attributes of such an environment, whether a nursing home, hospice, hospital or one's own home, it is

important to consider how devices, products and systems are utilised together, their operation, functions, needs and primary purposes. It is these considerations that lead us to determine how a physical device meets criteria within its prescribed environment and assessing its performance. This process of review often acts as a catalyst for new designs and inventions. For the purpose of this study, palliative is defined as alleviating pain and symptoms without eliminating the cause.

Among the greatest challenges for designers working in the palliative care field is envisioning a pain management product for an experience and an environment which for the greater part they have little personal experience. It is about creating empathy for and relationship with patients.

Noell (1995) states that we should be seeking to "Highlight the quality of human experience and shift medical services and dehumanising equipment into the background", and that " A physical environment for older people must be designed to celebrate life". [2]

Pain Management as an origin for design solutions

The goals of palliative care as outlined by *The Therapeutic Guidelines – Palliative Care – of Australia* (2005) lists the provision of relief from pain and other distressing symptoms as a primary goal. [3] The management of pain through pharmacological means acted as a stimulus for the conceptualisations, problem analysis and development explored in this paper and highlighted the genuine need for the creation of next generation subcutaneous syringe drivers.

The subcutaneous syringe driver

Syringe drivers are used in a palliative approach as a primary way of conducting pain management for patients who suffer from chronic pain. The medication is administered through the subcutaneous route and reduces the need for constant injections whilst allowing regulated levels of pain medication. Syringe drivers aim to assist patient mobility and independence through a compact device. The primary benefit for nurses is the facility to mix together 3-4 drugs in a syringe and set the device for 24 hours, improving time management. Patients can perform daily routines such as sleeping without the worry of self-regulating pain medication.

Currently there is a predominant model used within the Australian market, the Graseby, with four core models used internationally. Each model can be evaluated for both its positive and negative attributes, with each model possessing distinct qualities. These models are shown below to provide visual stimuli for the following discussion.

Image 1: Graseby MS26 (Wikipedia, 2009) measured in mm/24hrs[4]

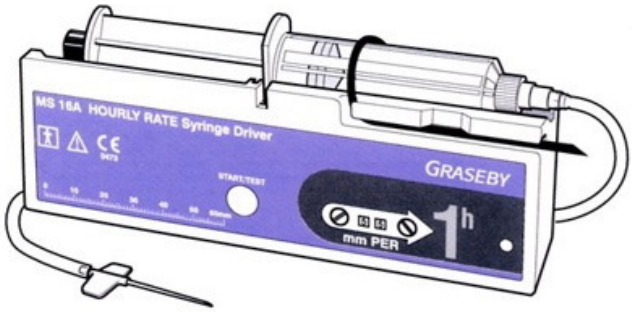

Image 2: Graseby MS16A (Queensland Government, 2008*)* measured in mm/hr[6]

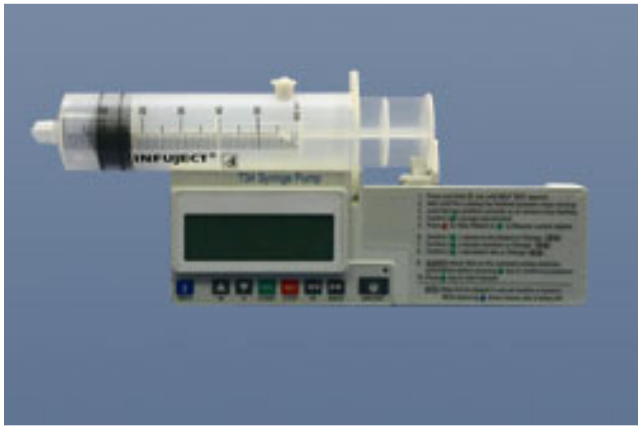

Image 3: Niki T34 Syringe Driver (Caesarea Medical Electronics Ltd) [8]

Image 4: Gemstar Syringe Driver (Hospira Pty Ltd)[7]

Image 5: CADD Legacy Syringe Driver (SAI Infusion Technology, 2009)

Problem analysis

In November 2007, Palliative Care Australia released a document titled "Report on Subcutaneous Infusion Devices".[5] Within the document it states that Graseby syringe drivers will no longer be available on the Australian market. Palliative Care Australia described the reason on page 1 as "…these devices are no longer compliant with the best practise standards for contemporary devices as set by the Therapeutic Goods Administration and have been voluntarily withdrawn from the market."

These devices are no longer available for purchase on the Australian market, however the manufacturer Smith Medical will continue to provide service support and maintenance and repairs of devices for a further five years (Palliative Care Australia, 2007).[5]

The palliative care sector has, at present, the opportunity to review syringe drivers currently on the international market and to specify technical and clinical requirements for the future development of syringe drivers. The aim of redevelopment and innovation in this area is to offer solutions that do not progress in slow iterations but rather in large leaps whilst also demonstrating the potential and breadth of design possibilities that exist in palliative care.

Consideration of the problem in a creative and innovative framework provides the opportunity to re-evaluate the purpose, function and clinical requirements of these types of devices. The integration of emerging innovations in technology and a greater understanding of the psychological needs of patients as well as pressures placed on carers can help form and progress the design of infusion devices.

This approach aims to supersede that which is currently on offer whilst utilising next generation technology and design strategies. The solution posed in this report, *QCap*, deals with the problems evaluated both in the environment and current devices, but also hypothesises the way in which medical practise will operate in years to come.

***QCap*, subcutaneous syringe driver for palliative care**

Image 6: *QCap* subcutaneous syringe driver

This product solution is based around the development of the syringe design, the housing design and the digital interface. It also extends to a larger system of products and the extension of the *QCap* brand. The systems approach aims to provide a solution that encompasses the multidisciplinary, ever changing environment in which the driver is used. Ultimately this solution aims to improve the quality of life of the patient through improved operations and interactions through all areas of use. Each of the listed areas will be discussed in further detail

The housing design

The exploration and design of the housing or casing revolves around two core facets; the ability to house functional and technical elements as well as the aesthetic appearance of the housing. Both develop simultaneously and govern materials selection, manufacturing processes, size and weight, the way the product feels in the hand and detailed elements such as the positioning of lights and buttons. The external components reflect the internal components and work harmoniously to produce a product solution.

Complex problems and relationships are added to the design process when elements and components of the product must change, be removed or altered as dictated by rituals of use. For example if a product that is electronic is used in the shower, it must be waterproof. The accommodation of such factors can be seen a large scope of products, including the syringe driver.

Current devices are awkward in shape, size, weight and visual language and have previously been governed by specific driving mechanisms and internal componentry. This has a significant impact on the patient experience. The practise of care may be influenced by manufactured features in both a psychological and physical sense.

Therefore the primary motivation in design is to gain a greater understanding of the experiences of these patients and to implement emerging technologies that will promote a sense of ownership and acceptance of the device. The design process involves formulating a relationship between the user experience, the technology, the functional requirements, manufacturing opportunities and material selection.

The *QCap* form derived firstly from the shape of the syringe, which is housed within, and then developed slightly to fit internal components and mechanisms. The device is to be powered through the use of an air compression pump and motor. Information is received from the circuit board unit. The compression unit then calibrates to the appropriate pressure. This force is then placed on the syringe plunger and moves the plunger down the barrel. The force is applied through correct placement of the syringe and the application of an elastomer seal.

Supplementary components for the operation of the device include a central processing unit, a 555 timing chip, a sound chip, a Bluetooth chip, circuit board and a Thinenergy battery. Including polypropylene housing and internal components it is estimated that the device would weigh 150g and measure 108mm in length and at maximum diameter 38mm.

Patient mobility and mental capacity varies which led to the provision of options and adaptability. The capabilities of the device should not define the daily experiences of the patient but rather allow movement freely and without limitation.

Several options have been contemplated in regards to the relationship between the body and the device. Solutions such as holding the device and placing the device in a pouch or silicon case are fairly common alternatives for mobile medical devices and may be applied in this situation.

However, the ability to adhere the device to the body for short periods is a new proposal in the realm of syringe drivers. The reduction in weight and size, has afforded *QCap* the ability to experiment with new adhesion systems. This initial adhesion proposal occurs through a simple dressing. The dressing has been designed to wrap around the device and then adheres to the body in two places. The design is simple and effective for short transfers and allows patients to utilise both hands during movement.

Image 7: *QCap* within context

The following illustrations demonstrate the way in which the dressing application occurs.

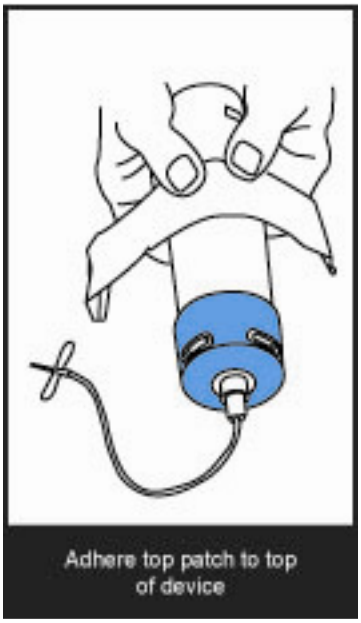

Image 8: Dressing instruction 1

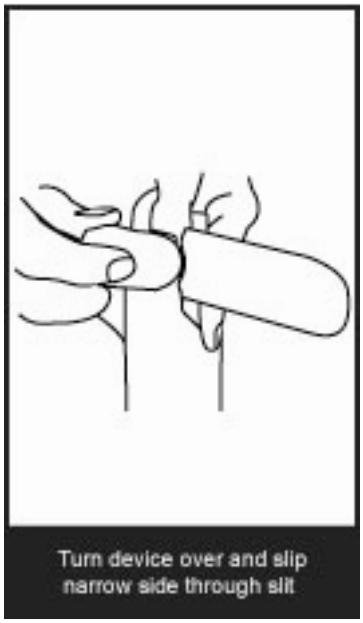

Image 9: Dressing instruction 2

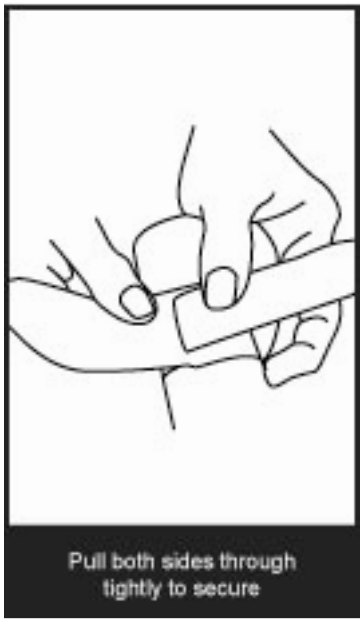

Image 10: Dressing instruction 3

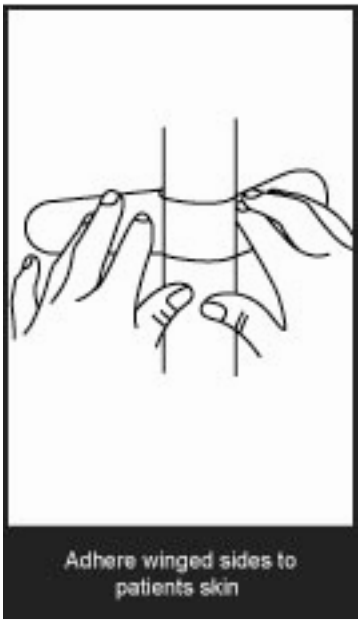

Image 11: Dressing instruction 4

Syringe design

A key problem identified in the use of generic syringes was the difference in diameter to length ratios. This was highlighted in a "Patient Safety Alert" (Queensland Government, 2008), whereby a 10mL BD-Plastipak syringe was used within the Niki T34 device. This syringe did not align correctly and became dislodged several times resulting in incorrect infusion rates.

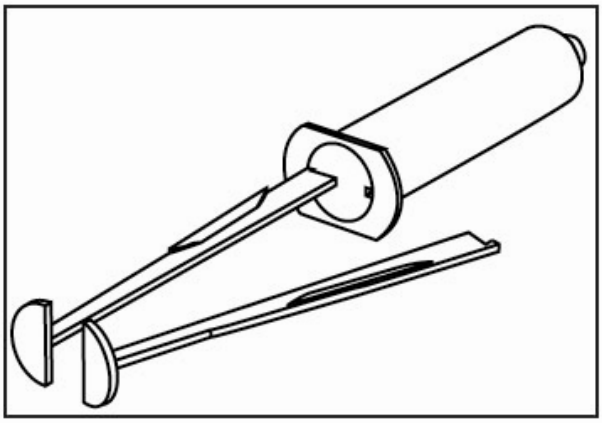

Image 12: Illustration of snapped syringe

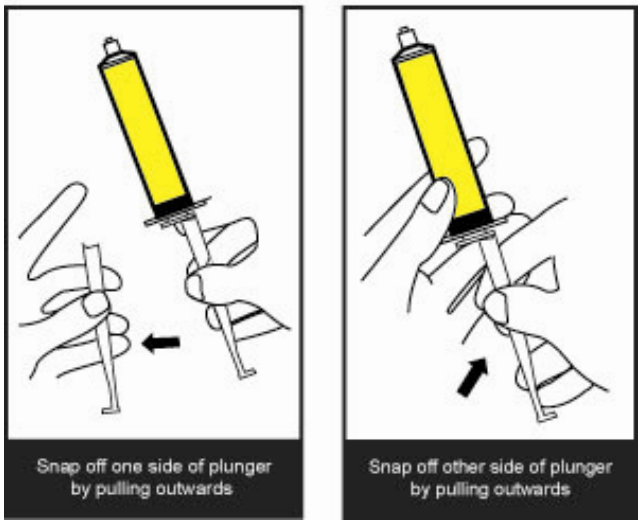

Image 13: Illustrated instructions for snapping plunger

The design feature in the redesign of the *QCap* syringe was the implementation of a snap off plunger. This feature was developed to not only reduce the size of the syringe, thus allowing a smaller driver overall, but also acted as a key design strategy in ensuring that a brand specific syringe was used to eliminate the problems created by differences in generic syringes.

Current prototypes have been developed in 20mL size syringes, which offer the ability for the syringe plunger to snap at any point within the barrel due to the snap hinge design. The design of the device housing does not at this stage allow for the use of multiple or larger syringes. This design problem is to be investigated in the next iteration of design development.

Extensive user testing through the development of prototypes has been undertaken to ensure that the plunger snaps accurately, efficiently and with confidence. The simplicity of the snap marks the success of the design.

Digital Interface

The emergence of digital interface within medical design and programming has led to the development of comprehensive and highly detailed interactions between the user and the product. The display of information, the way in which information is sought and programmed through gestures and visual interactions as well as the placement of interfaces in relation to the overall form has led to highly complex rituals of use.

When exploring the palliative environment from a multidisciplinary view, there is often movement of devices between locations, patients and health professionals. Technology now provides the opportunity to program these types of devices via an external database or software program that is linked to internal computer systems. The primary motivation for a movement towards this form of programming is to allow enhanced communication amongst health care professionals. Information can be shared, stored and evaluated in a digital format, improving efficiency. Design of such a database occurs congruently with the visual cues provided on the device.

The overall design for each resident database has been developed around three core quadrants. The top left shows resident information, bottom left device information and the right quadrant guides the user through programming. This template was developed as it allows an overall picture of the functioning of the device in one glance. It is important that the resident can be identified at all times throughout the interface. Therefore the top left quadrant remains consistent throughout all the pages. The placement of icons along the bottom bar promotes the use of external resources.

As this is a software program, the development would be occurring alongside expert computer programmers, whereby conditioning of security and protection of personal information would be at the forefront.

Levels of Operation

Medical device systems are used interchangeably and often require specific knowledge in regards to operation and implementation. Due to the safety and functional requirements of syringe drivers, it is difficult to simplify the actions and operations needed for use. There are ways, however, in which the complexity of learning can be eased. An example that has been implemented in this design is the placement of finger grips on the syringe plunger to indicate the direction of pull. The operation path for this driver has been illustrated in 20 simple drawings that indicate the intention for use.

Development Status

The development of this design solution is at proof of concept stage. All elements require development, testing and prototyping to ensure accuracy and tolerances. The current *QCap* design has been developed alongside professional practise, particularly within a nursing home setting. The solution has been guided by nursing staff, specialised geriatric doctors, pharmacist and nursing unit managers. Some of the requirements set by the Australian Therapeutic Goods Administration are:

- AS 1094.2004 – Sterile hypodermic syringes for single use, syringe for manual use
- AS 1600.1 – Medical equipment, conical fittings with 6% Luer Taper for syringes, needles and certain other medical equipment
- AS 3200.2 – Medical electrical equipment, general requirements for safety
- AS 14160 – Sterilisation of single use medical devices
- AS 4940-2002 – User applied identification labels for use on fluid bags, syringes and drug administration lines

Conclusion

Design research and practise in a multidisciplinary environment allows for the development of innovative solutions that are deeply embedded in the user experience. The incorporation of design practise within the palliative care environment has led to the design solution, *QCap*, which has been devised to specifically to meet the needs of both care providers and patients. Through this solution we are able to anticipate the enormous influence that emerging technologies and innovation will have for patients within palliative care and ultimately improving quality of life.

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Written consent for publication was obtained from the patient or their relative (Image 7).

PEER REVIEW

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CONFLICTS OF INTEREST

The author declare that they have no competing interests