Laycarers can confidently prepare and administer subcutaneous injections for palliative care patients at home: A randomized controlled trial

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Abstract
Background: Palliative care patients consistently nominate home as their preferred care environment. This is challenging without support from laycarers, especially if patients require subcutaneously administered symptom relief. Laycarers typically lack confidence with this task and request professional guidance.

Aim: To explore differences in laycarers’ confidence in administering subcutaneous injections depending upon whether a laycarer, registered nurse or pharmacist prepared injections for subsequent administration by laycarers.

Design: Prospective randomized controlled trial with three intervention arms: laycarer prepares, labels and stores injections; registered nurse prepares injections; and pharmacist prepares injections for later administration by laycarer.

Setting/participants: In all, 93 laycarers, from 24 urban and rural community services, completed the study.

Results: The primary outcome of interest was laycarer confidence with injection administration; analysis of variance revealed no significant differences between the three intervention arms; mean values ranged from 5.9 to 6.1 out of 7 (F(2, 90) = 0.50, p = 0.61). Comparison of confidence after laycarer preparation versus other (nurse or pharmacist) was not statistically significant (t = 0.7, df = 90, p = 0.49). Averaged over intervention arms, confidence levels increase significantly with injecting experience, from 5.3 to 6.1 (F(1, 75) = 47.6, p < 0.001).

Conclusion: Upskilled laycarers can confidently administer subcutaneous injections to relieve breakthrough symptoms in home-based palliative care patients, regardless of who has prepared the injections.

Keywords
Palliative care, injections, subcutaneous, pain management, randomized controlled trial

What is already known about the topic?
- Palliative care patients prefer to be cared for at home, but without a laycarer who can administer medications this can be difficult.
- Laycarers are motivated to provide breakthrough symptom relief but lack confidence to do so and request professional assistance.
- There are divergent professional opinions concerning whether laycarers should prepare and administer subcutaneous medications.

What this paper adds?
- This randomized controlled trial demonstrates that laycarers, when appropriately upskilled, can confidently administer subcutaneous injections to relieve breakthrough symptoms in home-based palliative care patients, regardless of who has prepared the injections.

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Implications for practice, theory or policy

- This study indicates that upskilled laycarers can add value to patient care by confidently administering subcutaneous injections to treat breakthrough symptoms in palliative care patients.
- Resource-stretched community services could integrate motivated laycarers into palliative care teams to improve both patient care and system outcomes.

Introduction

Palliative care patients consistently nominate home as their preferred place of care; however, without the support of at least one laycarer, such as a family member, this is difficult.1-5 In part, this is because symptoms in palliative care patients are prone to rapid and unpredictable escalation: severe symptoms can emerge at any time and if not optimally treated can necessitate transfer to inpatient settings.6-8 Laycarers often express a lack of confidence when called upon to assume responsibility for symptom management, particularly when it involves the preparation and administration of subcutaneous injections.9-12 Despite their lack of confidence, they remain motivated to help with symptom control as they believe their ability to provide injections adds value to patient care.4,7,8,13 The study described here explores the issue of laycarer confidence and subcutaneous medication preparation and administration.

It is known that structured education programmes for laycarers can result in positive patient and laycarer outcomes with respect to symptom management.2,13-15 In Queensland, Australia, an educational package that supports laycarers to administer subcutaneous medications was developed by a multidisciplinary group of specialist and non-specialist palliative care service providers, academics and laycarers.7,13 The package was evaluated favourably by laycarers,7,13 and implementation demonstrated that if laycarers are supported with material appropriate to their needs, they can indeed confidently, safely and competently administer subcutaneous injections.

Regardless, there is a degree of professional resistance, particularly from community nurses, concerning the involvement of laycarers in managing injections. In focus groups exploring clinician responses to the package described above, a recurrent issue concerned the safety and appropriateness of laycarers preparing injections that often include restricted medications with dangerous side effects, especially the possibilities that doses could be miscalculated or incorrect volumes drawn up.7 Opinions on the issue were diverse – some felt that with adequate support it was not only safe but necessary; others held that it was simply too burdensome to expect laycarers to fill this quasi-professional role. Furthermore, some opined that if laycarers are to be given responsibility for subcutaneous medication management, then syringes should be prepared by registered nurses and stored appropriately for later administration by laycarers.7

In terms of medication safety, it has been suggested that a community-based pharmacist should be responsible for the preparation and labelling of injectable medications that are used later in the home setting, and indeed, this is practised in other countries.16,17 Certainly, with respect to quality use of medicines, pharmacist preparation of injections represents a gold standard of practice. This possibility has not been researched in Australia.

This study utilized the package referenced above to investigate whether laycarers’ confidence, when tasked with treating breakthrough symptoms using subcutaneous injections, varied depending upon who prepared the injections – a laycarer or a professional. It was postulated that laycarers may be less confident if they had the added responsibility of preparing the injection as well as administering it. The impact of repeated experiences with injecting on laycarer confidence was also explored.

Method

The aim of this study was to explore possible differences in laycarers’ confidence in administering subcutaneous injections depending upon whether a laycarer, registered nurse or pharmacist prepared the injections for subsequent administration by the laycarer.

Ethics approval to conduct this randomized controlled study was obtained from six Human Research and Ethics Committees in Queensland, Australia:

1. Princess Alexandra Hospital Human Research Ethics Committee (Research Protocol: 2008/155; approved: 5 August 2008);
2. Cittamani Hospice Service Board (approved 10 September 2008);
3. Karuna Hospice Services Board (approved 18 September 2008);
4. BlueCare Human Research Ethics Committee (Reference number: Reymond 3808; approved 6 October 2008);
5. Mt Olivet Palliative Care Service (HREC #08/04; approved 7 November 2008);
6. St Vincent’s Hospital Human Research Ethics Committee (Spiritus HREC; approved 5 May 2009).

Recruitment occurred over the 7-month period from May to December 2009. Although the study is dated, the
issue of laycarers’ involvement in subcutaneous injection preparation and administration remains contemporary and contentious and requires resolution.

**Study design**

This prospective study was a randomized controlled trial. Laycarers were allocated to one of the three intervention groups:

1. A laycarer prepared, labelled and stored daily breakthrough medications for subsequent injection.
2. A registered nurse prepared and labelled daily breakthrough medications for laycarers to store for subsequent injection.
3. A clinical trial pharmacist prepared and labelled daily breakthrough medications for laycarers to store for subsequent injection.

Allocation was quasi-random because only laycarers who lived within the post codes surrounding the study pharmacy were considered for the pharmacy arm. Randomization to assign participants to the three intervention groups occurred via a computer-generated randomization sequence that allowed for consideration of post codes.

**Participants and procedure**

Laycarers who had volunteered to prepare and administer subcutaneous injections were targeted. Community-based service providers identified potential laycarer participants and asked whether they wanted to receive information about the study. If the laycarer agreed, a research team member then discussed the trial and obtained written informed consent in English. Table 1 lists laycarer inclusion and exclusion criteria.

| Inclusion criteria | Exclusion criteria |
|--------------------|--------------------|
| 1. Person considered capable by the clinical nurse to prepare and administer injections via a subcutaneous cannula for breakthrough symptom management should the need arise. This was an individual decision made by each clinical nurse | 1. Paid to provide care |
| 2. Over 18 years of age | 2. Previous experience or training in administering subcutaneous medications |
| 3. Able to read, write and understand the English language | |

When considered clinically necessary, nurses delivered the standardized education and resource package. All laycarers were taught to safely prepare, label, store and administer subcutaneous injections using a subcutaneous cannula and to use the daily diary for documentation relating to each injection administered. Post-education laycarers were allocated to one of the three intervention groups.

The community nurse then implemented their usual clinical practice to obtain subcutaneous medication orders from the patient’s general practitioner or specialist palliative care service provider. On each day of the trial period, the nurse contacted the laycarer, palliative care patient and treating medical officer (when appropriate) to discuss medication requirements and to continue to provide clinical support. Research staff telephoned or visited community nurses on a daily basis for the purpose of monitoring trial protocol.

Laycarers allocated to the first intervention group were instructed to draw up medications on a regular basis and store prepared medications for no longer than 72 h before safely disposing of unused injections. In the second intervention group, nurses prepared injections according to the same schedule during home visits. In the third group, pharmacy-prepared subcutaneous medications were delivered 7 days a week.

On the day that each laycarer commenced administering subcutaneous injections, he or she began a diary that was continued for a maximum of 2 weeks (the trial period). The first entry included laycarer demographics. Daily diary entries included the following:

- Ratings of their level of confidence after each injection administered using a 7-point Likert-type scale (with endpoints, not at all confident, 1 and extremely confident, 7) where 1–3 indicated low confidence and 5–7 indicated high confidence;
- Reason the injection was given;
- Medication name and dose;
- Time medication given;
- Effect of the injection on the patient’s symptom severity.

As a safety consideration, at every home visit, community nurses checked daily diary completion, medication remaining in the home, and whether the appropriate medication had been administered for the recorded symptom. These findings were reported to research staff.
Data collection and analysis

Quantitative data from the diaries were analysed using SPSS software version 22. Group differences in overall confidence in administration of injections were the outcome of primary interest. This was to be tested initially with analysis of variance, but a more focused comparison of relevance for a power analysis was whether confidence differed between those laycarers who had prepared the injections themselves (self) and those for whom another person (nurse or pharmacist: other) had prepared the injection. Assuming a ratio of 2:1 for other versus self, that a difference of one point on the 7-point Likert type confidence rating scale could be regarded as clinically significant and that the standard deviation of the confidence ratings was 1.25, the study would have a power of 80% to detect a difference of one point in overall confidence with a total sample size of 58 participants in a two-sided independent-samples t-test. To allow for the high attrition rate characteristic of palliative care studies, it was decided to recruit beyond the calculated sample size.

Results

Figure 1 illustrates laycarers’ progress through the study. In total, 106 participants were randomized to one of the three interventions. Ninety-three laycarers completed the
study, and reasons for study withdrawal are summarized in Figure 1. Consenting laycarers who completed the study were predominantly female (76%, 68) – spouses, partners or daughters – with a relatively even distribution of age and a mean age of 52 (standard deviation (SD) = 12.9) years, ranging from 21 to 77 years of age. Age characteristics and laycarer injecting experience within the study for the three intervention groups are listed in Table 2. In terms of geographical distribution, 98% (92) of participants were recruited from urban areas, with one person from a regional area and one from a rural population.

Laycarers maintained daily diaries of administered breakthrough injections and recorded their level of confidence in administering each injection. A total of 1429 daily diary sheets were returned by the 93 laycarers, all had been correctly completed. Of these, 123 were discarded as someone other than the laycarer (i.e. a health professional) had administered the injections during home visits. Community nurses reported to the researchers that diaries were always completed in their entirety, that medications and doses given for particular symptoms were appropriate to the patient and that the effectiveness of medications was always charted. No formal analysis of these reports was conducted. There were no incidences of infections at subcutaneous sites.

The average length of stay for participants on the study was 8.2 days. The number of days over which laycarers injected ranged from 1 to 14, with the total number of injections per laycarer ranging from 1 to 68. Analysis of variance revealed no significant differences between groups in number of days or number of injections administered.

Laycarer confidence depending on who prepared the injection

It was postulated that laycarers may be less confident if they had the responsibility of preparing the injection as well as administering it. Mean confidence levels across all injections over all days are shown in Table 3, and confidence levels are quite high (ranging from 5.91 to 6.09, where 7 is extremely confident) reflecting the benefits of the education package. Analysis of variance indicated that there were no significant differences between groups in level of confidence in their administration of the injection ($F(2, 90) = 0.50, p = .61$), and inspection of the mean values for level of confidence across groups supports this lack of significant difference.

The contrast of interest comparing confidence in administration of injection after preparation by self (laycarer) versus others (nurse or pharmacist) was not statistically significant ($t = 0.7, df = 90, p = 0.49$).

Development of confidence with experience: differences between the first injection and subsequent injections

To examine the possibility that confidence levels developed further after the first injection from an initial lower level, group changes in confidence ratings from the first injection administered to subsequent injections were examined in a repeated-measures analysis of variance, with experience as the repeated-measures variable and group as the between-subjects variable. Sample sizes are reduced somewhat as some participants administered only one injection. For the laycarer group, 24 provided relevant data, and mean confidence for the first injection was 5.4 (SD = 1.1); for the nurse group, mean confidence was 5.2 (SD = 1.3, $N = 26$); and for the pharmacist group, mean confidence was 5.3 (SD = 1.2, $N = 28$). For subsequent injections, the mean values for laycarers were 6.2 (SD = 0.7), 6.0 (SD = 0.56) for those in the nurse group, and 6.1 (SD = 0.73) for the group in which the pharmacist prepared the injections. The increase in confidence with experience of administering injections, from 5.3 for the first injection to 6.1 for subsequent injections, averaged over groups, is statistically significant ($F(1, 75) = 47.6, p < .001$). This approaches the specified clinically significant difference of 1 point on the Likert-type scale and can be interpreted as a meaningful change in confidence. However, neither the mean level of confidence nor the change in confidence over time differed significantly across groups ($F(2, 75) = 0.35, p = 0.71$, for overall group differences; $F(2, 75) = 0.06, p = 0.95$ for group $\times$ time interaction) – see Figure 2.

Table 2. Intervention group characteristics.

| Intervention Group | Carer | Nurse | Pharmacist |
|--------------------|-------|-------|------------|
| Laycarers age (years) | | | |
| Mean (SD) | 52.2 (13.7) | 54.0 (12.1) | 50.2 (13.1) |
| Minimum–maximum | 25–73 | 29–77 | 21–76 |
| Median | 53.0 | 53.0 | 48.5 |
| Injections during trial period | | | |
| Mean number of injections administered (min–max) | 14.6 (1–49) | 15.9 (1–66) | 12.0 (1–68) |
| Mean number of days injecting | 7.7 (1–14) | 6.0 (1–14) | 4.8 (1–14) |
Discussion

Main findings

This is the first randomized controlled trial to demonstrate that, with appropriate education and support, home-based laycarers can confidently administer subcutaneous injections to relieve breakthrough symptoms in palliative care patients, regardless of whether the laycarer, nurse or pharmacist prepares the injections. It also demonstrates that with experience, laycarer confidence in administering subcutaneous injections increases to a statistically significant extent. Furthermore, the study indicates that laycarers can be supported and educated to practice in accordance with aspects of best practice in their injecting process; according to community nurse reports, laycarers document appropriately, provide the right medication at the prescribed dose for particular symptoms and monitor the effectiveness of their interventions. These findings have important implications for patients, their carers and resource-poor community-based service providers.

Limitations of the study

Before discussing implications of the results, it is important to consider the limitations of the study. Only laycarers who could consent in English and who volunteered to provide subcutaneous injections were considered for the study. Presumably, these laycarers would have been better able to understand the resources presented only in English. Irrespective of language skills, those who volunteered for the study may have been personally better suited, more resilient and more motivated than the general population of carers to manage medications, thus making them more likely to succeed with the task of preparing and injecting medications. Also, only laycarers who lived within the vicinity of the clinical pharmacist were randomized to the third study group. This may have affected the results in some unknown way, although it is not immediately obvious how this urban cohort would differ from another urban cohort or the few non-urban participants.

Community-based service providers identified potential participants before inviting them to receive information about the study from the researchers. This process allowed for the possibility of 'gate-keeping' by over-protective service providers that could create a bias in the participant population.

It is difficult to know how these potential selection biases may have impacted the results, although one could surmise that they favoured laycarer outcomes.

Finally, although recruitment extended beyond the calculated sample size, the study was not powered to detect adverse side effects, such as infection at subcutaneous sites. Given the importance of such adverse, though rare, events, this may constrain attempts to generalize the findings.

What this study adds

Most Australian palliative care patients prefer to be cared for at home, and while 70% report that they want to die at
home, only 14% realize that outcome. One of the most frequent reasons that community-based patients are transferred to hospital is because their symptoms cannot be well controlled at home. If laycarers can be routinely educated and encouraged to manage breakthrough symptoms, more patients may be able to remain at home for longer and to die there, if that is their choice.

The value of laycarers in helping palliative care patients to remain at home cannot be underestimated. Laycarers provide psychosocial and physical care, but it needs to be remembered that they have real needs of their own. Palliative care service providers need to support laycarers so that they can be successful and robust in their caring role. This study demonstrates that skilling laycarers to provide subcutaneous injections gives them confidence and that this confidence increases significantly with experience. Embedding laycarers as part of the multidisciplinary community palliative care team, by teaching them to prepare and administer medications for breakthrough symptoms and monitor symptom relief, is likely to further empower them in their caring role.

Arguably, having a pharmacist prepare sterile subcutaneous injections represents the gold standard in terms of best practice for community-based palliative care. So, it is noteworthy, and counterintuitive, that laycarers’ confidence was not significantly higher when the pharmacist prepared the injections. Pragmatically, this is a favourable outcome because if laycarers are not confident to prepare injections, the patient and laycarer can be left in a vulnerable position, especially in the event of a sudden patient decline or symptom exacerbations occurring after business hours or on weekends. Pharmacy-prepared injections theoretically represent a lower infection risk compared to nurses or laycarers preparing injections using aseptic techniques. However, it is an expensive practice, and in Australia, the costs of such routine practice would be prohibitive both for healthcare organizations and individuals.

As mentioned, there was no difference in laycarer confidence depending on whether the laycarer or nurse prepared the injection. This finding may go some way to decreasing some community nurses’ concerns regarding recruitment of laycarers to assist with symptom control.

The aim of modern palliative care is to support palliative care patients to live and die within the setting of their choice, with optimal symptom control and a pattern of care that is supportive of patients’ caregivers. While, in Australia, there are no nationally consistent data on the volume of community services providing palliative care, it is known to be limited with services struggling to meet the increasing demand for palliative care. Globally, this situation is worsening as the population ages and public acceptance of palliative care for people with chronic illness and cancer grows. Increased capacity of community end-of-life services that are better coordinated and that collaborate with laycarers are required. This study indicates that community-based services could integrate motivated laycarers into the multidisciplinary symptom control team and that those laycarers are confident they can prepare and administer subcutaneous medications for their loved ones.

Acknowledgements

The authors thank the laycarers who participated in this study as well as the contribution from the pilot sites. Australian New Zealand Clinical Trials Registry (Registration Number: 083553 http://www.anzctr.org.au/).

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Funding

The author(s) disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: This work was supported by the Australian Government Department of Health and Ageing under the Supporting Carers of People Requiring Palliative Care At Home projects (grant MS846270).

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