

BEST PRACTICE IN PHARMACY MANAGEMENT

DOOP Kit, Domestic Bin Or Watery Grave? A Study Investigating Disposal Practices Of Transdermal Drug Delivery Products In Care Homes

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Abstract

Title

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Background

The issue of opioid use and misuse is current and topical at present with reports of opioid epidemics in the USA and the increasing use of opioids in other parts of the world. The New Scientist asserted that America was in the throes of an opioid epidemic with reports of fatalities linked to physical contact with fentanyl. Discussions have progressed from an American focus to speculating on the spread of this issue to UK cities, Glasgow in particular. Safety issues have more recently come to light regarding the physical application and management of specific drug forms e.g. opioid transdermal patches (OTPs). The prescribing, application and safe disposal of OTPs within both healthcare settings and personal dwellings is critical to the effective use of these products. Healthcare professionals have a duty of care and responsibility to ensure the safe application and disposal of OTPs.

Aims

The aims of this study were to 1) gain insight into current practices of healthcare professionals regarding OTPs (fentanyl and buprenorphine) disposal practices and 2) identify

knowledge and system awareness surrounding the disposal of these products in care home settings.

Methods

We decided to focus on care homes due to the estimated high prevalence of prescribing of OTPs in these care settings. The study was undertaken by the University of Bradford School of Pharmacy in 2015 and the participant sample focussed on the North of England (UK).

Results

The findings (based on 56 survey responses) displayed a significant variation in current disposal practices and a lack of specific working policies. We unearthed anomalies in the participants' knowledge of the active ingredient volume held in depleted patches which, if not disposed of correctly, can lead to harm. This has highlighted the need for more thorough training and education on the safe and effective management of OTPs.

Conclusions

Further education and training is needed regarding safe disposal practices of OTPs, with the suggestion of pharmacist-led interventions. This will minimise confusion and reinforce safe disposal practices (denaturing products) and support the reduction of unsafe disposal practices (domestic waste or flushing).

Keywords: opioid transdermal patches, care homes, disposal practice, training.

Introduction

Background

The issue of opioid use and misuse is current and topical at present with reports of opioid epidemics in the USA and the increasing use of opioids in other parts of the world. The New Scientist asserted

that America was in the throes of an opioid epidemic¹ with reports of fatalities linked to physical contact with fentanyl. Discussions have progressed from an American focus to speculating on the spread of this issue to UK cities, Glasgow in particular.^{2,3} Safety issues have more recently come to light (June 2018)

regarding the physical application and management of specific drug forms e.g. opioid transdermal patches (OTPs).⁴ The prescribing, application and safe disposal of opioid transdermal patches (OTPs) within both healthcare settings and personal dwellings is critical to the effective use of these products.



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THE SAFE DISPOSAL OF FENTANYL PATCHES IN CARE HOMES IS MOST IMPORTANT: Remove backing, fold over on itself and place in a waste disposal or sharps bin - or use a CD denaturing kit.

Healthcare professionals have a duty of care and responsibility to ensure the safe application and disposal of OTPs.

There has been a steady increase in the prescribing and use of transdermal patches, especially in the elderly population who maybe dependent on caregivers to manage their medications in particular for chronic conditions.⁵ Research by Rene et al found that 94.3% of caregivers preferred the administration of a transdermal patch over oral rivastigmine for the treatment of Alzheimer's disease due to ease of application of the patch over administering oral medication and reduced interference with the caregivers' daily routine.⁶ Patient compliance and acceptance were also increased when using transdermal patches over other routes of administration.⁷ Whilst the transdermal delivery system has many benefits, it has also been the source of numerous patient safety incidents often relating to their unsafe application and disposal.^{8,9,10,11,12}

The main focus in this study was to investigate disposal practices of transdermal opioid patches, which have been subject to numerous Medicines Healthcare products Regulatory Agency (MHRA) medication safety alerts. Particularly concerning have been reports of accidental exposure to fentanyl patches where cases have been reported of patients swallowing patches or the risk of them being transferred to other individuals because they have not been disposed of safely. The incorrect disposal of patches by patients or healthcare professionals has the potential for patches to be diverted for misuse. Reports are emerging where active ingredients from OTPs have been extracted and used by individuals with substance misuse problems. This highlights the importance of raising awareness about the safe and effective disposal practices in both the patient and healthcare professional communities.

In December 2015, NHS Wales issued a patient safety notice to all healthcare

professionals highlighting reports of ineffective application, removal and disposal practices with fentanyl patches. The alert made specific recommendations advising healthcare professionals, including those in nursing homes, to ensure that patients and/or carers were advised about safe disposal practices.¹³ The Care Quality Commission (CQC), in 2012, recommended that healthcare professionals needed further training and education around safe prescribing, administration and, importantly, disposal of fentanyl patches.¹⁴ The literature demonstrates that the use of fentanyl patches is high on the agenda of medicines and health regulatory bodies and has been for the past ten years with the consistent theme of patient harm emerging due to many factors, one being inappropriate disposal of these products. The introduction of Controlled Drug Accountable Officers into healthcare settings has reinforced the priority of good and managed practice relating to the use and safe disposal of these products.¹⁵ Internationally, in 2012, the US Food and Drug Administration (FDA) reinforced the quality of information provided to patients and caregivers regarding disposal of fentanyl patches after 26 case reports of paediatric accidental exposure to fentanyl over the past 15 years have resulted in 10 deaths and 12 hospitalisations.¹⁶

Incorrect disposal of OTPs has led to paediatric fatalities due to accidental exposure via ingestion and application of patches. Alarms have been triggered regarding these products based on incidents such as OTPs being disposed in a general waste bin within the home¹⁷ and poor disposal practices in a care home which led to the death of a 2 year old boy, Blake, who placed a discarded fentanyl patch in his mouth during a visit to his great grandmother.¹¹ In June 2018 a further case of a 15 month old child dying from accidental exposure to fentanyl was reported widely in the media.⁴ Although not directly a disposal issue it does highlight the importance of correct disposal practices, which can

prevent further such cases. A recent study by Breen et al regarding disposal practices in UK care homes reported a need for the implementation of training materials and standardisation of guidelines across the healthcare sector.¹⁸

Due to toxicity associated with OTPs their effective disposal is essential for the prevention of accidental exposure as used patches still contain a high proportion of active pharmaceutical ingredient. Research has shown that there can be up to 80% of residual drug remaining in a fentanyl patch after three days continuous use.¹⁹ The current practice for the disposal of OTPs as reported in multiple healthcare settings is, once removed from the patient, to fold the patch with the adhesive side inwards, place the OTP back inside the original sachet and dispose of it via clinical waste or return it to the supplying pharmacy. A reported variation on this is that the folded patch should then be placed back inside the original sachet and disposed of via domestic waste.

Within care homes the expected practice is to remove the backing and fold the patch over on itself. The patch would then be placed into a waste disposal bin or a CD denaturing kit²⁰ or a yellow sharps bin.²¹ This is contrary to FDA guidance in the home which recommends disposing of used patches by folding them in half with the sticky sides together, and then flushing them down a toilet. They should not be placed in the domestic waste where children or pets can find them.²²

Despite many safety alerts issued by MHRA and FDA advising healthcare professionals and patients on the safe disposal of OTPs, there is a critical need to safeguard patients/carers against accidental pharmacological exposure

with these products through raising awareness around correct disposal practices, which will also limit the inadvertent diversion of these products for misuse purposes. The focus of this study was to examine opioid transdermal patch disposal in care homes and gain a detailed understanding of systems, knowledge and practices in relation to disposal of OTPs. To our knowledge, we are not aware of any study that has specifically looked at OTP disposal practices in the UK or internationally despite numerous studies looking at disposal of medicines broadly.²³

Methods

We approached participants for this study and asked them to share their views on OTP application, disposal and education between September 2015 and December 2015. The participants who contributed to this study were healthcare professionals working within a care home setting who were involved with medicines administration. Potential care homes with or without nursing were identified through the website 'www.carehomes.co.uk' in the following areas: Bradford, Leeds, Manchester. This yielded a very large number of care home contacts; Bradford 79 leads, Leeds 172 leads and Manchester 185 leads, which totalled 336 potential care homes that could be included in this study. The authors (EM and SI) then telephoned each care home to ascertain willingness to participate and this yielded an interest of 85 care homes. Interested parties were then sent out study information documentation and consent forms based on personal preferences (electronic or paper). Once consent documents were received the questionnaire was released to the

individuals based on personal preference either electronically through Google forms or a paper version posted out. Two weeks after receiving the questionnaires care homes were followed up by telephone by EM and SI to check on progress with completing the questionnaire.

To ensure that all the information gathered was of high quality a mixture of qualitative and quantitative research methods for the development of the questionnaire were used, which enabled a broader and deeper understanding of the project and provided scope for a more detailed analysis. A variety of both closed-format and open-format question types were used to encapsulate both methodologies such as Guttman scaling, Likert scaling, multi-choice and single option questions. Thematic analysis was undertaken to determine common areas of focus as per the respondents' responses.

The questionnaire was piloted by healthcare professionals (5 individuals) including both nurses and pharmacists. The feedback included improving the clarity of answers and the appropriate wording of questions. The pilot was used to further develop the questionnaire before being finalised and sent out to care homes.

Ethical approval was granted by the University of Bradford ethics committee (Ref: EC2172).

Results

The number of respondents who participated in the study is shown in Table 1. The respondents were all healthcare professionals with the responsibility of administering OTPs within their role in care homes. It is not possible to

“ . . . there is a critical need to safeguard patients/carers against accidental pharmacological exposure with these products through raising awareness around correct disposal practices . . . ”

accurately note the response rate for the online surveys therefore only the completed online numbers are mentioned in Table 1.

OTP Disposal Practice

The care home staff were asked a number of questions pertaining to their knowledge of current disposal practice of OTPs (specifically fentanyl and buprenorphine patches) and product related characteristics that impacted on safe and risk averse disposal. Following patch removal from a patient's skin,

participants were asked what their initial course of action would be. Responses provided indicated that:

- 1) 63% of the staff fold the patch inwards:
- 2) 30% immediately dispose of the patch through clinical waste
- 3) 4% place the patch back into its original packaging
- 4) 3% cut the patch in half or immediately dispose of it through general waste.

Folding was not reported in options 2 and 3 - but that is not to say that it did not happen.

Participants were asked how they disposed of unwanted and used OTPs within their care homes. Responses are indicated in Figure 1. Responses listed as 'Other' were disposal via a DOOP Kit.

Participants were asked to select the percentage range of residual drug remaining in a patch once used for full duration of treatment to check their knowledge and understanding of OTP product characteristics. The responses are shown in Table 2.

On the subject of ongoing training, participants were asked if their care home provided training relating to disposal of medicines, and more explicitly relating to OTPs, which informed the staff of correct OTP disposal procedure. The majority (66.7%) of participants said that within their workplace they did not undergo training in order to safely dispose of patches as part of their continuous professional development.

Participants were asked if they were aware of the MHRA safety update issued in 2014. The results showed that only 47.2% of the respondents were aware of the update, with 52.8% unaware.

The questionnaire further explored the views of participants to see if they were aware of any policies or procedures within the care home setting for OTP disposal. 58.2% of participants stated they were aware of specific policies, with 41.8% unaware of any policies in place. When asked if there was a designated lead person within the healthcare team responsible for the disposal of unwanted medicines, 53.7% of participants said 'no', while 46.3% of participants were aware of a staff member tasked with safely disposing of medicines. When discussing final collection of OTP waste, the practice reported again varied: 69% of respondents stated that collections took place on a monthly basis, 17% on a weekly basis, 4% on a daily basis and

Table 1: Surveys completed

Survey Format	Number of Responses
Online	36
Paper	20
Total	56

How do you dispose of any unwanted/used patches in your care home?

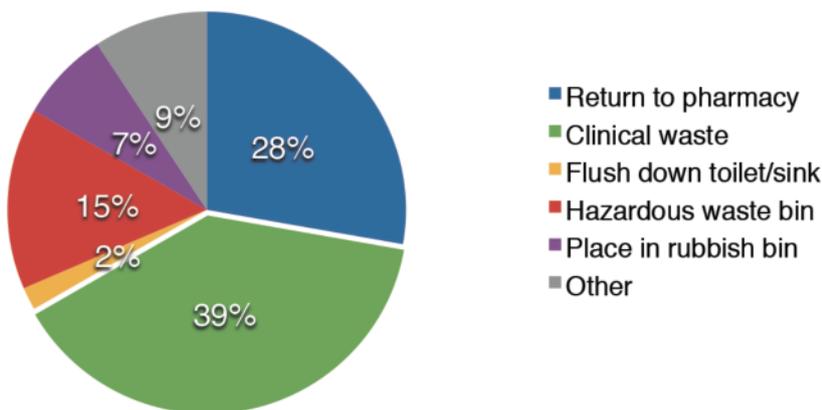


Figure 1: OTP Disposal profile as determined by participant responses

Table 2: Participants' views on active drug levels in used OTPs

Amount of residual drug in OTP once removed for disposal	Percentage of participants who agreed to the residual figure
0-9%	65%
10-30%	21%
31-50%	8%
51-80%	2%
80-100%	4%

10% said that these waste products were not collected at all.

Discussion

Although this study is small scale it does provide a brief snapshot of activity in UK care homes relating to fentanyl and buprenorphine patch disposal practices. The results of this study yielded the following insights, which are discussed below in the five key themes shown.

1) OTP disposal – practice and process

The correct disposal of OTPs is vital in preventing patient safety incidents from occurring. Participants in this study were asked to comment on how they dispose of unwanted/used patches in their care setting. A variety of responses were recorded. The results showed that 39% of respondents disposed of patches through clinical waste and 28% disposed of patches by returning them to the pharmacy. The diverse responses in disposal practice is not surprising considering, as mentioned above, the lack of guidance health care professionals have in terms of disposing OTPs.

Of particular concern within this study was how divided respondents were regarding their knowledge of the quantity of residual active ingredients once an OTP was removed for disposal. This is an issue as previous research has demonstrated that the amount of drug remaining in a patch following three days of continuous use can fall within the range of 28.84% to 84.4% of the original drug content.²³ In this study, 86.6% of respondents believed there was less than 30% of drug remaining in a patch after use. There is a possibility that healthcare professionals may perceive OTPs as obsolete products after use and

not give due care and attention to disposal because they do not perceive that harm can occur. This aspect of the OTP raises another ‘red flag’ concerning not only the risk of harm of ineffective OTP disposal to the patients/carers or family but the magnitude of this risk (e.g. the adverse impact to a patient or child or patch ingestion or adhesion) and increases the urgency within the NHS to ensure that safe disposal procedures are formulated and effective practice is utilised in all care homes and healthcare settings.

2) OTP disposal – system knowledge and awareness

A number of points raised within this study are a cause for concern. Healthcare professionals who are not aware of the considerable amount of drug remaining in a patch once it has been used may register these products as lower risk and hence take less safety precautions. This, coupled with the fact that used/discarded OTPs are stored by the majority of healthcare sites for a month prior to collection (which appears to be the industry norm), can carry additional risk.

The professionals’ responses were split equally on the employment of a lead staff member responsible for OTP disposal. If this person was in post they would ensure that the risk attached to the product use, retention/storage, disposal/collection was managed and reduced (akin to the role of a Controlled Drugs Accountable Officer). However, care home providers at times are resource deprived and therefore the more practical solution may be to train and upskill all, or at least the majority of staff, in OTP safe disposal as a standard element of their job.

At the time of collecting this data (September to December 2015) only 7.5% of respondents were aware of any adverse incidents regarding the application and disposal of these products (as an aside to the MHRA alert in 2014). This again reinforces the need for accurate and timely provision of information that informs health professionals, patients and carers of the risks attached to OTPs and the correct method of opioid patch disposal to avoid personal risk and environmental pollution.

3) Communication

The results of the study indicated that 52.8% of care staff were unaware of the recent safety update issued in July 2014 by the MHRA in regards to fentanyl patches, which highlights a gap in communication between healthcare professionals and external governing bodies, a weakness in in-company communication strategies or both. Healthcare providers should have systems in place and procedures where medicine alerts which come through the Central Alerting System can be accessed by all healthcare professionals within the organisation and appropriate action can be taken within a timely manner. The MHRA alerts are released to practicing healthcare professionals, including pharmacists. A strong emphasis is placed on pharmacists to remind carers and patients of the potential risk of accidental patch transfer if patches are not disposed of safely. As the majority of respondents were unaware of this update, it indicates room for improvement for this information to cascade through the different healthcare settings and may support a case for the use of community or practice pharmacists to go into healthcare settings to reinforce this message.

“of particular concern . . . was how divided respondents were regarding their knowledge of the quantity of residual active ingredients once an OTP was removed for disposal.”

The wider implication of this finding is twofold: 1) the results have shown the deficiency and inaccessibility of medicines or patient safety alerts to healthcare providers/professionals resulting in potential patient harm and 2) the question of accountability and responsibility to ensure the alerts are acted upon and whether support is required through a pharmacist to ensure implementation. From a regulatory perspective the Care Quality Commission core standards of inspection require healthcare providers to have systems in place that ensure patient safety notices, alerts and other communications concerning patient safety that require action are acted upon within required timescales.

4) Training

Staff training regarding how to effectively dispose of OTPs (fentanyl and buprenorphine) was also raised as a potential area of focus to reduce risk of harm not only to patients but carers and family members. The importance of safe disposal of patches within care homes and the wider impact on family was highlighted through the tragic case of Blake who died 2 days after visiting his great grandmother.¹¹ The design of good procedures and protocols, and compliance with these, would reduce any risk of harm and therefore all used patches could be accounted for and signed to say they have been safely disposed. Tools to support OTP application and disposal (recording of the date, time and site of application, removal and disposal of the OTP by a healthcare professional) will significantly reduce the risk around unaccounted patches that have the potential to cause harm.

5) Pharmacists as experts in medicines management guidance and support

The findings of this study indicate that 61% of care staff would refer to pharmacists as their first port of call if they required any further information on application or disposal of patches. The role of a pharmacist can be described as an educator, particularly in care homes

where better utilisation of the pharmacist's skills and knowledge can bring various benefits not only in improving medicines management processes but also medicines optimisation. Pharmacists can raise awareness of the impact of incorrect disposal methods/routes e.g. risk of soil and water contamination and/or risk of third parties accessing used OTPs and purposefully using them by extracting their active ingredients for subsequent injection or reusing patches. Furthermore, the results from this study indicate that care homes have no adequate guidance or systems in place for staff to follow in relation to OTP disposal. Pharmacists can be used to develop robust systems around the safe and effective disposal of OTPs.

The value of a pharmacist's knowledge and skills is further supported by the new plans set out by the NHS in employing pharmacists in local GP surgeries in patient-facing roles highlighting the potential pharmacists have in providing additional support as well as delivering advice to patients. This has been reinforced by the introduction of pharmacists into care homes to support medicines optimisation and advise on better medicines systems for care homes to reduce waste and inefficiency.²⁴

Conclusions

This study and subsequent analysis was done in response to risks identified as a result of poor OTP management within the healthcare environment e.g. accidental paediatric exposure and patch transfer from elderly patients have been reported by the MHRA (2008 and 2014) and Greater Manchester Combined Authority (2017). This study is by no means comprehensive but aims to highlight a significant risk attached to the disposal of transdermal opioid patches.

The results indicate the diversity in current policies across different healthcare settings as well as the disjointed knowledge concerning the practices currently being used when

disposing of patches. Only 9% of respondents used the denaturing process (DOOP Kit) to safely dispose of OTPs. Other practices such as disposal via flushing and domestic waste are totally unacceptable and cause potential harm to patients, the environment and society. The returns to pharmacy and disposal via clinical and hazardous waste were all favoured disposal methods but the disparity of practice exhibited is of concern.

The study also indicated that there is awareness of the level of residual active ingredients in OTPs at the point of disposal, and there is limited mandatory guidance provided regarding product use and disposal. From a system perspective there does not appear to be consistent training and practice regarding the safe disposal of this product range and the information channels whereby alerts and vital information regarding these products are passed to healthcare professionals are underdeveloped.

This study presents preliminary but cautionary findings, and on this basis the authors recommend that the following elements be considered when effectively managing OTP products (fentanyl and buprenorphine):

- The main tool that can educate patient/carers and healthcare professionals on the correct and most effective method of patch disposal is the Patient Information Leaflet (PIL). Manufacturers should ensure that the information needed to dispose of such products is clear and can be acted upon by carers and staff and should make this a separate document to the PIL.
- There is a need for a guidance document which can be used in all healthcare settings dictating the mandatory practice to be followed regarding OTP disposal.
- As part of the medicines management training all healthcare professionals receive, particular focus should be placed on the disposal of transdermal opioid patches. This training could be delivered by pharmacists who have

expert knowledge about safe disposal practices of medicines.

- A tool should be developed which fully audits the stages of application, removal and most importantly disposal of the patch. This will ensure unaccounted patches are located and thus disposed of safely.
- We suggest that further research be undertaken by Central Alerting System to look at the best channel of communication to ensure these alerts reach all healthcare professionals, not just managers, and, most importantly, that they are acted upon. Several alerts issued identified healthcare professionals who were best

positioned to remind patient/carers of safe disposal practices and this information is not being cascaded down. This study has identified this from an OTP perspective but the finding is generalisable to all alerts concerning medicines and their implementation.

- More research needs to be undertaken into the prevalence of OTP safety incidents, incident recording mechanisms, root cause analysis and prevention mechanisms. This data can be used to inform guidance and process design.
- Improved knowledge and understanding, coupled with training

and education of OTP disposal, should be considered to mitigate and reduce the risk of harm from these products. Pharmacists can play a key role, working with other healthcare professionals, to create essential guidance and training materials regarding the safe disposal of OTPs in care home and other healthcare settings.

Declaration of interests

The authors have nothing to declare.

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