Research in Social and Administrative Pharmacy 13 (2017) 717–726

Contents lists available at ScienceDirect

Research in Social and Administrative Pharmacy

journal homepage: www.rsap.org

The knowledge, attitudes and beliefs of patients and their healthcare professionals around oral dosage form modification: A systematic review of the qualitative literature

Aoife Mc Gillicuddy [a, *], Maria Kelly [a], Abina M. Crean [b], Laura J. Sahm [a, c]

[a] Pharmaceutical Care Research Group, School of Pharmacy, University College Cork (UCC), Cork, Ireland
[b] School of Pharmacy, University College Cork (UCC), Cork, Ireland
[c] Pharmacy Department, Mercy University Hospital, Cork, Ireland

ARTICLE INFO

Article history:
Received 20 September 2016
Accepted 20 September 2016

Keywords:
Healthcare professionals
Patients
Medicine manipulation
Oral administration
Qualitative research
Systematic review

ABSTRACT

Objectives: The objective of this systematic review was to synthesize the available qualitative evidence on the knowledge, attitudes and beliefs of adult patients, healthcare professionals and carers about oral dosage form modification.
Design: A systematic review and synthesis of qualitative studies was undertaken, utilising the thematic synthesis approach.
Data sources: The following databases were searched from inception to September 2015: PubMed, Medline (EBSCO), EMBASE, CINAHL, PsycINFO, Web of Science, ProQuest Databases, Scopus, Turning Research Into Practice (TRIP), Cochrane Central Register of Controlled Trials (CENTRAL) and the Cochrane Database of Systematic Reviews (CDSR). Citation tracking and searching the references lists of included studies was also undertaken. Grey literature was searched using the OpenGrey database, internet searching and personal knowledge. An updated search was undertaken in June 2016.
Review methods: Studies meeting the following criteria were eligible for inclusion; (i) used qualitative data collection and analysis methods; (ii) full-text was available in English; (iii) included adult patients who require oral dosage forms to be modified to meet their needs or; (iv) carers or healthcare professionals of patients who require oral dosage forms to be modified. Two reviewers independently appraised the quality of the included studies using the Critical Appraisal Skills Programme Checklist. A thematic synthesis was conducted and analytical themes were generated.
Results: Of 5455 records screened, seven studies were eligible for inclusion; three involved healthcare professionals and the remaining four studies involved patients. Four analytical themes emerged from the thematic synthesis: (i) patient-centred individuality and variability; (ii) communication; (iii) knowledge and uncertainty and; (iv) complexity. The variability of individual patient's requirements, poor communication practices and lack of knowledge about oral dosage form modification, when combined with the complex and multi-faceted healthcare environment complicate decision making regarding oral dosage form modification and administration.
Conclusions: This systematic review has highlighted the key factors influencing the knowledge, attitudes and beliefs of patients and healthcare professionals about oral dosage form modifications. The findings suggest that in order to optimise oral medicine modification practices the needs of individual patients should be routinely and systematically assessed and decision-making should be supported by evidence based recommendations with multidisciplinary input. Further research is needed to optimise oral dosage form modification practices and the factors identified in this review should be considered in the development of future interventions.

1. Introduction

Medication represents one of the most common and most important therapeutic interventions of modern medicine.

* Corresponding author.
E-mail addresses: a.mcgillicuddy@umail.ucc.ie (A. Mc Gillicuddy), 113223823@umail.ucc.ie (M. Kelly), a.crean@ucc.ie (A.M. Crean), l.sahm@ucc.ie (L.J. Sahm).

http://dx.doi.org/10.1016/j.sapharm.2016.09.004
1551-7411/

However, key to optimising drug therapy is ensuring that the right patient receives the right drug at the right dose by the right route at the right time.[1] Although oral dosage forms (ODF), such as tablets and capsules, are preferred by both healthcare professionals (HCPs) and patients, modifications may be necessary to facilitate administration of the right dose or to allow administration via the oral route. ODF modification can be defined as, "any alteration of an oral dosage form that can be performed at the point of administration".[2] These modifications are undertaken to facilitate medicine administration to patients with difficulty swallowing the intact dosage form (e.g. crushing tablets or opening capsules) or to facilitate fractional dosing (administration of part of an ODF to allow administration of a lower dose e.g. splitting tablets). Studies have shown that between 24.1% and 31.0% of all tablets prescribed for adult patients in primary care are split prior to administration,[3,4] with data from long term care indicating that 35.4% of older adults receive at least one split medication.[5] ODF modifications to overcome swallowing difficulties are also prevalent, with up to one third of all occasions of medicine administration to older patients in long term care facilities involving ODF modification.[6] Data from primary care suggest that between 9.0% and 37.4% of adult patients experience difficulty swallowing tablets and capsules, with the majority of those affected modifying the dosage form to overcome these difficulties.[7,8]

There are a number of safety and efficacy concerns around modified medicines such as reduced dose accuracy, reduced drug stability and the potential to affect the pharmacokinetic and pharmacodynamic profile of the drug *in vivo*.[9–14] Guidelines advise that modifications should only be undertaken as a "*last resort*"[15] when "*other methods have been considered*".[16] Additionally, there is growing concern amongst regulatory agencies about fractional dosing.[17,18] However, despite this, evidence shows that ODF modifications are a routine part of clinical practice.[3,19,20] While modifications may be necessary due to a lack of appropriate licensed formulations,[4,5,19] it is clear from the literature that modifications occur even in situations where alternative formulations are available[3,4,21] and/or in situations where the modification is expressly prohibited by the manufacturers guidelines.[3,4,20,21]

Whilst quantitative studies have provided useful evidence on the prevalence of ODF modifications and highlighted concerns, they have not elucidated the factors that influence the decision to modify. HCPs prescribe, dispense and administer modified ODF,[4,22] and patients modify medicines without the knowledge of their healthcare providers.[4,22,23] These studies have shown that both HCPs and patients: have concerns about the appropriateness of modifications; experience difficulty when modifying medicines and; display significant knowledge deficits about ODF modification.[4,20,22,24] Qualitative research methods can provide an insight into the knowledge, attitudes and beliefs of those who modify to gain a deeper understanding of the factors that influence behaviour and practice. Qualitative studies have been undertaken to investigate ODF modification, but to date, no systematic review of this literature has been conducted.

2. Aim

The aim of this systematic review is to synthesise the available qualitative research on the knowledge, attitudes and beliefs of adult patients, healthcare professionals and carers about ODF modification.

3. Methods

Details of the protocol for this systematic review were registered on PROSPERO and can be accessed at http://www.crd.york.ac.uk/PROSPERO/display_record.asp?ID=CRD42015023494.

3.1. Search strategy

A systematic literature search of the following databases, from inception to September 2015, was undertaken: PubMed, Medline (EBSCO), EMBASE, CINAHL, PsycINFO, Web of Science, ProQuest Databases, Scopus, Turning Research Into Practice (TRIP), Cochrane Central Register of Controlled Trials (CENTRAL) and Cochrane Database of Systematic Reviews (CDSR). No language or time restrictions were placed on the initial search. A comprehensive search strategy was devised, using index and free-text terms, related to (i) patients, healthcare professionals or carers, (ii) medicine modification, (iii) knowledge and (iv) qualitative research. The search strategy was initially developed by the primary author (AMG) and subsequently approved by a qualified medical librarian prior to undertaking the searches. The reference lists of included studies were hand-searched to identify additional relevant studies. Citation tracking of included studies was also undertaken. A search for grey literature was completed; by searching the OpenGrey database, internet searching and using personal knowledge to identify further potentially relevant sources. The initial search was undertaken in September 2015 and an updated search was undertaken in June 2016.

3.2. Study selection

Titles were screened by one reviewer (AMG) to remove studies that did not meet the eligibility criteria. Each abstract was independently screened by two reviewers (AMG-full set and LJS or AMC). The full-text of articles identified as potentially eligible based on the abstract were obtained and assessed independently by two reviewers for inclusion (AMG and LJS or AMC) according to *a priori* inclusion and exclusion criteria. In the case of any discrepancies between reviewers at any stage, a third reviewer independently examined the study and following discussion, a consensus on inclusion was reached by all three reviewers.

3.3. Eligibility criteria

Studies were eligible for inclusion if they met the following criteria: (i) used qualitative data collection and analysis methods; (ii) the full-text was available in English; (iii) included adult patients (18 years or more) who required ODF to be modified to meet their individual needs; (iv) included carers or HCPs (doctors, nurses, pharmacists, speech and language therapists) of patients who require ODF to be modified. For studies undertaken using mixed methods, only the qualitative component was included. Debate exists as to whether survey data is considered qualitative or quantitative, which has posed an issue in previous qualitative systematic reviews.[25] It was decided *a priori* that surveys would be excluded if the results were purely quantitative in nature, as this data lacks the necessary "*conceptual depth and richness*",[26] which is an approach that has been utilised previously.[27] Quantitative studies, systematic reviews, meta-analyses, meta-syntheses, editorials, commentaries, letters and conference abstracts were excluded. The primary outcomes of interest were patient, HCP and carer knowledge, attitudes and beliefs about the modification of ODF.

3.4. Data extraction

The data extraction form developed by the National Institute for Health and Care Excellence[28] was modified by one reviewer (AMG) to meet the requirements of the systematic review. Data from the