Dysphagia CPD Modules - Module 5

Dysphagia & Medicines Modification

Rosemont®

LEARNING OBJECTIVES

Welcome to Module 5
Dysphagia & Medicine Modification

This short training module focuses on the medication management of patients who have difficulty swallowing solid oral doses, specifically addressing the implications of modifying medicines.

Module 5 is intended to provide a general overview of the subject including the potential role of oral liquid medicines in addressing the problem. Upon completing the module, you should have a clearer understanding of:

The prevalence of dysphagia (swallowing difficulty)

Types of medicine modification and potential clinical implications

Medicine modification and patients with Enteral Feeding Tubes

Medicine modification and the Law

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THE PREVALENCE OF DYSPHAGIA (SWALLOWING DIFFICULTY)

Dysphagia, or difficulty swallowing, affects many people in the UK including 50% of the elderly[1] and up to 16% of the paediatric population.[2] Dysphagia is prevalent or a key concern in:

- Stroke patients[1]
- People with dementia[1]
- Patients with head and neck cancer[1]
- People with intellectual disabilities[3]

Up to 50% of elderly people suffer from dysphagia[1]

Up to 16% of paediatric patients are unable to swallow solid drug formats[2]

14-80% of patients with head & neck cancers have dysphagia.[4]

68% of those with dementia in care homes exhibit signs of dysphagia.[4]

Swallowing solid dose medication is particularly challenging for dysphagic patients as they need to be able to manage solid tablet/capsule and thin liquid at the same time.[5]

It can also have significant impact on the safe administration of oral medications.[5]

A patient who is unable to swallow medicines, is less likely to take them[6], which can compromise medicines adherence and therapeutic outcomes.[7]

TYPES OF MEDICINE MODIFICATION AND POTENTIAL CLINICAL IMPLICATIONS

Medicine manipulation is defined as the physical alteration of a pharmaceutical drug dosage form for the purposes of extracting and administering the required proportion of the drug dose.[8]

Manipulation of tablets and capsules, usually takes place at the point of administration[8] with a lack of pharmaceutical quality assurance[9].

25% drug loss can occur when using a pestle and mortar[10].

5.8% is the average drug loss when using a tablet crushing device[10].

There are various forms of manipulation which include[8]:

Splitting: tablet is split/broken/cut and a segment is given

Crushing: tablet is crushed and a proportion of the powder given

Dispersing: tablet is put in liquid and a portion of the liquid given

Capsule opening: a capsule is opened and a proportion of the powder given or content is mixed with liquid

TYPES OF MEDICINE MODIFICATION AND POTENTIAL CLINICAL IMPLICATIONS

Altering a medication can change the pharmacokinetic or bioavailability profile and may impact on efficacy and safety.[11]

Some solid dose medications should never be altered and advice from a pharmacist and/or the manufacturer would be needed.[12]

- Modified release
- Cytotoxic or steroidal
- Enteric coated
- Film and sugar-coated
- Hormonal

One survey revealed that **68%** of patients needed to open a capsule or crush a tablet to swallow their medication.[7]

Changing the presentation of a dosage form can:[11]

- Alter absorption characteristics
- Result in medicines instability
- Produce local irritant effects
- Cause failure to reach the site of action
- Produce occupational health & safety issues
- Result in a preparation with an unacceptable taste

MEDICINE MODIFICATION AND PATIENTS WITH ENTERAL FEEDING TUBES

A significant number of patients in hospitals and care homes temporarily depend on enteral feeding.[13] Research has shown that crushing solid medications can lead to avoidable blockages[14] in enteral tubes, with up to 45% of patients experiencing clogged PEG tubes.[15,16,17]

Re-siting an enteral tube, due to an obstruction, causes distress for the patient.[18]

The theoretical average cost per patient for admission and gastronomy tube replacement is estimated to be **£4,786** [19]

Modifying solid-dose medications should be considered only as a last resort, and only after consulting with a pharmacist.[12] Liquids are the preferred format for administration of medicine in patients with EFTs.[20]

MEDICINE MODIFICATION AND THE LAW

It is crucial for healthcare professionals to fully understand the seriousness and potential implications of modifying solid-dose medications. Altering these medications without proper consideration can lead to issues such as compromised efficacy or increased risk of side effects.[11] Ensuring that modifications are only made when absolutely necessary—and with the guidance of a pharmacist[12]—helps to safeguard patient safety and maintain the effectiveness of the treatment.

'Nurses have a responsibility to deliver safe and effective care based on current evidence, best practice and where possible validated research.'

The Nursing and Midwifery Council Code of Conduct 2008

'Altering a licensed medicine by crushing, suspending or dissolving a tablet or opening a capsule, results in the medicine becoming unlicensed.
You may become liable for any harm caused as a result of your actions.'

The Human Medicines Regulations 2012

•Verbal communication from the Prescriber asking you to do this may not remove you from this legal liability.
•Strict liability is removed and liability moves from the manufacturer to YOU.

Consumer Protection Act 1987

MEDICINE MODIFICATION AND THE LAW

‘The NPA Indemnity Insurance is unable to cover members (except in exceptional or emergency circumstances) who undertake PCT recommended alternatives to dispensing unlicensed specials – particularly where such recommendations result in the integrity of a licensed medical product being compromised e.g. by crushing, dispersing or breaking open (capsules) or which otherwise interfere with products in any other way.’

National Pharmacy Association Insurance

‘PDA guidance is that even if decisions are made in what is considered to be the best interests of patients, the supplying of a medicine in a manner or form which interferes with the integrity of its license is still undertaken at the personal risk of the Pharmacist’

Pharmacists’ Defence Association 2011

MEDICINE MODIFICATION AND THE LAW

‘Medicine management is a regulated activity under the Care Quality Commission which imposes essential standards for quality and safety of health services. Care providers have a duty to ensure medicines provided are appropriate and person centred.’

Health and Social Care Act 2012

‘Primary Care Trusts (PCTs) might be corporately liable for their crushing/dispersing policies if this amounts to a breach of duty to a patient and falls far below what can reasonably be expected of the organisation in the circumstances. Aggravating factors will include cost-cutting at the expense of safety and failure to heed warnings or advice.’

Corporate Manslaughter and Corporate Homicide Act 2007

Conclusion

People with swallowing difficulties often crush tablets or open capsules[7], but this can affect both efficacy and safety.[21] In some therapeutic categories, liquid medications are available.[21] Despite this, the practice of crushing tablets and opening capsules remains common.[7,21]
A survey indicated that the cost of liquid medication influences prescribing decisions for care home residents, even though liquid medications are generally considered a better option for those with swallowing issues.[21] It was therefore recommended that the patient's optimal formulation, rather than cost, should be the main consideration in prescribing.[21]

Solution

Liquid formulations are often associated with a higher acquisition price than solid dose formats. However, a study published in the *Journal of Medical Economics* indicates that, even with conservative assumptions, improved patient compliance could offset these additional costs.[22]

For example, the cost of preventing just one day's admission to a psychiatric hospital could cover the cost of liquid chlorpromazine for three patients for an entire year, rather than using a solid dose generic formulation.[22]

SWALLOWING DIFFICULTY TRAINING MODULES

Module 1
Swallowing Difficulties and Oral Liquid Medication

Module 2
Swallowing Difficulties and Epilepsy

Module 3
Swallowing Difficulties and Mental Health

Module 4
Enteral Administration and Oral Liquid Medicine

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