Sheffield Formulary guidelines on the administration of medication to patients with dysphagia

Summary

Patients who present with dysphagia should have a medication review to assess the need for all their medication and to consider the most appropriate and cost effective medication for each condition. Following the step by step approach in Appendix 1 will ensure patients receive a tailored medication regime most suited to their needs; using licensed medicines wherever possible; and reserving the need for specials in those patients with a real need. All decisions made should be documented and reviewed at regular intervals, and patients kept fully informed.

Appendix 2 gives an overview on choosing medicines for patients unable to take solid dosage forms, and may also be used as a guide in managing medication in patients with swallowing difficulties.

Introduction

Dysphagia is likely to become an increasingly common problem with an aging population and these guidelines are intended to look at how to manage the administration of medication in such patients. Estimates suggest that almost 60% of elderly people have some degree of difficulty when swallowing medication. Dysphagia is associated with a plethora of problems; however the scope of these guidelines is only intended to look at ways of administrating medication to this group of patients; it will consider the steps that can be taken in assessing such patients and discuss possible solutions.

Diagnosis of Dysphagia

When a patient presents with swallowing difficulties the cause should be investigated, oesophageal cancer should be ruled out. There are many causes of dysphagia, which may be neurological (e.g. Parkinsons disease, motor neurone disease, stroke), mechanical (e.g. oesophageal cancer), psychological or medication related (e.g. any medication that can cause xerostomia.) Dysphagia may be a temporary condition (e.g. due to oral infections, dental pain) and as the degree of dysphagia can vary, any actions taken should be reviewed at regular intervals and documented.

If the dysphagia is felt to be significant; not just related to the taking of medication but also effecting eating and drinking - especially if nutritional intake is compromised, then referral to the Speech and Language Team may be indicated. The NICE guidelines for nutritional support in adults gives indicators as to when referral to healthcare professionals with relevant skills and training in the diagnosis, assessment and management of swallowing should be instigated.
Examples of indicators are:

- **Obvious indicators of dysphagia** - difficult, painful chewing or swallowing, regurgitation of undigested food, difficulty controlling food or liquid in the mouth, coughing or choking before, during or after swallowing, and unintentional weight loss.

- **Less obvious indicators of dysphagia** - wet voice quality, tongue fasciculation (may be indicative of motor neurone disease), change in eating – for example, eating slowly or avoiding social occasions, frequent throat clearing, recurrent chest infections and atypical chest pain.

**Management of patients with dysphagia experiencing difficulties in swallowing medication**

On presentation of a patient with swallowing difficulties that affects the administration of medication, a full medication review should be carried out to ascertain if there is still a current need for all the medication on the patients’ record. Any unnecessary medication should be stopped / temporarily suspended. This should be documented and reviewed appropriately. Once a list of medication necessary for the patient has been devised, each medicine should be looked at in turn to see whether the patient can swallow it in the present form prescribed (e.g. patients may be able to swallow capsules but not tablets).

Any medicines that cannot be taken by the patient in its current prescribed form should be looked at to see what alternative forms are available. Wherever possible, a licensed product should be prescribed.

**Consider the following when choosing the best option for patients**

- **Offer practical support to aid patient in swallowing.** Consider posture, head position, take one tablet at a time, swallow tablet with a thicker substance than water e.g. yoghurt or similar. For patients who require thickened fluids, oral liquid medicines, dispersible tablets or solid preparations dispersed in water prior to administration may be thickened with products such as Nutilis.

- **Side effects of current medication.** Is a patient taking medication that may be causing a dry mouth that is attributing to dysphagia? (See Appendix 3).

- **The size of the tablet.** A patient may be able to swallow a small bendroflumethazide 2.5mg tablet but not a larger paracetamol 500mg tablet.*
• **Is the medication available in a different oral form** e.g. dispersible tablets, liquid, capsules - take care to ensure dose equivalence is prescribed.

• **Administration of the medication via a different route** e.g. transdermal, sub-lingual or buccal tablets, suppositories, injectables, intranasal products – consider bioequivalence; dose adjustment, titration and monitoring may be needed.

• **An alternative drug in the same therapeutic group may be available in a form that could be administered to the patient** e.g. sertraline does not come in a licensed liquid form but other SSRIs such as fluoxetine and citalopram do. Be mindful of what doses are equivalent to the drug already being prescribed; dose titration and monitoring may be required.

• **Switching to a drug in an alternative therapeutic group.** Could an alternative drug be used to treat the same condition (e.g. Z-drugs such as zopiclone aren’t available in liquid form but temazepam liquid may be considered).

• **Using a licensed medication in an unlicensed manner.** Certain tablets can be crushed and dispersed in water; equally some capsules can be opened and the contents mixed with water / sprinkled on food. Altering a solid dose form in this way does change the legal implications of prescribing the medication. Greater liability rests with the prescriber as the product is being used outside of its marketing authorisation. Prescribers should make clear documentation of the reasons why this action is taken. The issue should be discussed with the patient – this should also be documented. Documentation in the patient’s care plan and /or labelling instructions should clearly state how the medicine is to be administered – if the form is altered it must be done immediately before administration. In general, care staff may only administer medicines in an unlicensed manner on the instruction of the prescriber but local procedures need to be taken into consideration. Patients should be aware of medication being administered; administering a crushed tablet in food for example is not designed to disguise the medication but to aid the patient swallowing it.

The manual dexterity and cognitive state of the patient should be borne in mind; is the patient able to administer the medication in this way? Not all tablets / capsules are suitable for crushing / opening. Appendix 4 lists preparations that are generally not suitable.* References 4 and 5 provide lists of many that can; the lists are not conclusive / exhaustive and are the opinion of the authors. Where different medicines are suggested, this does not necessarily imply therapeutic equivalence. Reference 4 offers advice on how to use licensed medication in unlicensed ways. Further information is available from the medicines management team, community pharmacies or reference sources provided.

• **Prescribing a special order product.** Products with a marketing authorisation - licensed products - are associated with less risk and are
generally less costly than special order products. Licensed medicines must meet quality standards for manufacture and be accompanied by appropriate product information and labelling. In order to be granted a marketing authorisation, a medicine must show evidence of quality, efficacy and safety.

If a licensed medicine is not available to meet the patient’s need a pharmaceutical special may be required. The Medicines Act allows prescribers to prescribe medicines without a licence providing they are happy to assume full liability for the prescription. If a medicine or pharmaceutical form is not listed in the British National Formulary (BNF) then it is likely to be unlicensed. The BNF lists some unlicensed products or off label uses of medicines but does clearly identify these.

Special order products

There are three main types of special order medicines (“specials”):

- Batch manufactured products – made by a specials manufacturer.
- Bespoke specials - made by a specials manufacturer as a single pack for a named patient.
- Extemporaneously prepared medicines – made in a community pharmacy under the pharmacist’s direct supervision.

Note: some medicines licensed in Europe and America may not be licensed in the UK; if they are imported into the UK they acquire the same legal status as specials.

Manufacturers of batch preparations must hold a Manufacturer’s Specials (MS) Licence granted by the licensing authority. Their manufacturing sites are inspected for compliance with Good Manufacturing Practice; this offers some reassurance around the quality of the manufacture. However specials have not been assessed for safety and efficacy by regulatory authorities and the products themselves are unlicensed.

Specials often carry a short expiry date, can incur a time delay when ordering the product and may be subject to special storage conditions. Unfortunately specials medicines are often subject to high costs (Appendix 5 shows examples of varying costs across Sheffield). Where alternatives are available, consideration should be made as to whether prescribing such products is making best use of public resources.

Legal differences

If a prescriber uses a medicine within the terms of the marketing authorisation e.g. at the stated dose and for the indication specified in the Summary of Product Characteristics (SPC - the agreed licensing conditions between the regulatory body and the pharmaceutical company), then any untoward effects are the legal responsibility of the manufacturer. If a patient experiences an adverse effect, even one not specified in the SPC, the patient would have grounds to prosecute the manufacturer. This is not the case for a
pharmaceutical special. As there is no SPC the prescriber takes full responsibility in law for any adverse effect caused by the medicine, unless it can be demonstrated that the medicine was faulty. Therefore it is important the prescriber can justify and feel competent in using such medicines.

Pharmacists share with the prescriber, accountability for supplying a special to a patient. They must be able to demonstrate that they have acted with due diligence in regards to patient safety, and that they have taken all reasonable steps to ensure:

- procurement from an appropriate source
- that the product is of appropriate quality
- that the product meets the particular clinical needs of the patient: this may require dialogue with the manufacturer, and if relevant the hospital pharmacy, about formulation, strength etc
- that relevant records are kept

Patients should be made aware that they are being prescribed a medication without a marketing authorisation. Appendix 6 is a document that may be given to patients to explain this.

*Both community pharmacists and the medicines management team will be able to advise on this.*

References

1. Introduction to Dysphagia. Rosemont Pharmaceuticals
   [http://www.rosemontpharma.com/education/healthcare-professional](http://www.rosemontpharma.com/education/healthcare-professional)
2. NICE CG32 2006 Nutrition support in adults.
3. Medicines Q & A 294.1 Therapeutic options for patients unable to take solid oral dosage forms. December 2009
4. From Calderdale and Huddersfield Trust Medication and Enteral Feeding Guidelines
5. Pharmacy Professional June 2010 Dealing with Specials

Date approved by APC July 2010
Appendix 1

See separate document:

Flow chart to assist in the prescribing for patients with dyspepsia

Available at: link to GI formulary when on intranet site

Appendix 2

See next pages – will also be available as a link so format is not lost
## Choosing medicines for patients unable to take solid oral dosage forms

Selecting suitable formulations for adult patients with swallowing difficulties or feeding tubes.

### A stepwise approach is suggested

#### STEP 1
**Use a licensed medicine in a suitable formulation.**

For example:
- Licensed liquid preparation
- Soluble tablets
- Powders or granules for suspension

In order to use a licensed medicine, consider switching to a different agent in the same class, or to a different route of administration.

For example, consider:
- Fluoxetine liquid (licensed preparation) as an alternative to sertraline tablets.
- Aspirin dispersible tablets instead of clopidogrel tablets.
- HRT patches instead of tablets.

### Why licensed status matters

To be granted a licence a medicine must meet quality standards and be shown to be safe and effective. Licensed medicines usually come with a patient information leaflet and are considered the safest choice.

Special-order medicines are unlicensed and are not required to meet the same standards as licensed medicines. Prescribers take greater responsibility when using them.

#### STEP 2
**Use a licensed medicine in an unlicensed manner, for example by crushing / dispersing tablets in water or by opening capsules.**

For example:
- Ramipril capsules can be opened and the contents mixed with water.
- Aspirin dispersible tablets can be dispersed in water.

Both the above examples are suitable for administration orally or via a feeding tube.

Not all medicines are suitable for administration in this way and it is important to check beforehand. See over for where to get advice.

As before, consider switching to a different agent or route of administration in order to use a licensed product.

#### STEP 3
**In the few situations where there is no licensed option, consider using a ‘special’.**

Special-order (‘special’) liquid medicines are unlicensed and expensive. They should only be used if there is no licensed medicine that meets the patient’s needs.

### Cost

Special-order medicines are often considerably more expensive than licensed medicines. They may have short shelf-lives compared with licensed alternatives and may need fridge storage.

For example, bendroflumethiazide liquid is 75 times more expensive than tablets:
- 28 doses of 2.5mg tablets costs 80p.
- 30 doses of 2.5mg/5ml liquid (150ml) costs £60.

NB: Bendroflumethiazide tablets can be dispersed in water for administration orally or via feeding tubes.

### Is it needed?

If the patient is taking medicines that aren’t needed or aren’t working, stop or change them.

### Care staff may only give licensed medicines in an unlicensed way if there is a written direction in the patient’s care plan.

Practical directions are overleaf.

### In most cases a licensed preparation will be available that meets the patient’s needs.

Licensed medicines should be used where possible. Special-order medicines are unlicensed and expensive and should only be used if there is no licensed alternative.

---

**Consider the patient’s method of feeding:**

- Patients on liquid feeds may take oral liquid medicines, dispersible tablets or solid preparations dispersed in water prior to administration. For patients on thickened fluids, liquid medicines can be mixed with products like Thick and Easy.
- Patients on soft-food diets may be able to swallow crushed tablets or the contents of capsules given with food.
- Patients with enteral feeding tubes may have oral medicines given by this route.

**Care staff may only give licensed medicines in an unlicensed way if there is a written direction in the patient’s care plan.**

Practical directions are overleaf.
Choosing medicines for patients unable to take solid oral dosage forms

Practical directions

- Crushing / dispersing tablets
  Many immediate-release tablets can be dispersed in water without crushing; some medicines need crushing first. Some tablets (e.g. modified release) are not suitable for crushing.
  For medicines that are suitable for crushing, crush using a pestle and mortar, a tablet crusher or between two metal spoons.
  Only crush medicines one tablet at a time; do not crush all the patient’s medicines together. Crushing or dispersal should only be performed immediately before administration.

- Opening capsules
  Some hard gelatin capsules can be opened and their contents mixed with water or administered with food. Some capsules are too small to manipulate. Capsules should only be opened immediately before administration.

- Giving medicines in soft food
  Some capsule contents or crushed tablets can be given with cold soft food such as a teaspoon of yoghurt or jam. Use a small amount of food to ensure the full dose is taken.
  Crushed tablets or capsule contents may taste very bitter to patients taking them orally. Mask the taste by giving with strong flavours such as blackcurrant.
  Medicines should only be administered in food with the patient’s knowledge and consent. Hiding medication in food is considered ‘covert administration’ and is only allowed in certain circumstances.

- Administering medicines via feeding tubes
  Feeding tubes should be flushed with water before and after each medicine is administered. If a liquid medicine is thick or syrupy, dilution may be required. Some patients are fluid restricted; this needs to be taken into account.
  When administering crushed tablets or opened capsules via a feeding tube, add the powder to 15-30ml water and mix well. Draw into a 50ml oral syringe and administer. If you have used a mortar or tablet crushe, rinse this with water and administer the rinsings also.

Suggested protocol for administering medicines via feeding tubes:
1. Stop the feed (leaving a feeding break if necessary).
2. Flush the tube with 30ml water.
3. Prepare the first medicine for administration, and give it.
4. Flush with 10ml water.
5. Repeat stages 3 and 4 with subsequent medicines.
6. Flush with 30ml water.
7. Re-start the feeding (leaving a feeding break if necessary).

Care staff may only administer medicines in an unlicensed manner on the instruction of the prescriber.
A written direction to crush or disperse tablets or to open capsules must be documented in the patient’s care plan.

Where can I get advice?

For advice on choosing appropriate dosage forms or to check if tablets or capsules can be dispersed, crushed or opened, contact your PCT medicines management team or UKMi medicines information centre.

Medicines Management team North – 0114 3051667
South 0114 2716430

Contact details for UKMi medicines information centres are available at www.ukmi.nhs.uk. Click on the map then search for your local or regional centre.

- Medicines Q&A
  This leaflet accompanies a Medicines Q&A document which provides further information and lists options available in several therapeutic areas for adult patients with swallowing difficulties or feeding tubes.
  Access it online via the National electronic Library for Medicines, www.nelm.nhs.uk (see bottom of the page for the full link).

- Reference texts
  Details of two respected texts are at the bottom of the page.

Only prescribe special-order medicines if there is no suitable licensed medicine available that meets the patient’s needs.
It may be appropriate to use a licensed medicine in an unlicensed way.
References:

- Smyth J. The NEWT Guidelines for administration of medication to patients with enteral feeding tubes or swallowing difficulties. Wrexham: North East Wales NHS Trust; 2006.

Date of preparation: January 2010
Appendix 3

Medication / conditions which may cause dry mouth.

- Any medication that has antimuscarinic (anticholinergic) properties:
  - Drugs for urinary incontinence (BNF 7.4.2)
  - Antimuscarinic drugs used in parkinsonism (BNF 4.9.2)
  - Antispasmodics (BNF 1.2 antimuscarinics)
  - Tricyclic antidepressants (BNF 4.3.1)
  - Some antipsychotics (BNF 4.2.1)
  - Sedating antihistamines (BNF 3.4.1)
- Diuretics (BNF 2.2)
- Some anti-epileptics (BNF 4.8.1)

NB. This list is not exhaustive and individual SPCs should be referred to if xerostomia is suspected. SPCs are available at: http://www.medicines.org.uk/emc/

- Irradiation of the head and neck
- Sjogren’s syndrome

See: BNF 12.3.5 Treatment of dry mouth http://bnf.org/bnf/bnf/current/29680.htm
## Appendix 4

### Examples of medication not suitable for crushing

<table>
<thead>
<tr>
<th>Type of medicine</th>
<th>Notes</th>
<th>Reason for not crushing</th>
<th>Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Modified release</td>
<td>Frequently identifiable by two letters, such as M/R, L/A, S/A, C/R, X/L, or S/R.</td>
<td>Medicine designed to be released over a prolonged period. Mechanism for slow absorption may be damaged.</td>
<td>Veramapil S/R Nifedipine M/R (Adalat retard)</td>
</tr>
<tr>
<td>Enteric coated</td>
<td>Usually identified by EN or EC.</td>
<td>Medication designed not to be released in the stomach, Enteric coating would be destroyed.</td>
<td>Diclofenac EC tablets Sulphasalazine EN</td>
</tr>
<tr>
<td>Hormonal Cytotoxic Steroidal</td>
<td>Risk assessment form requires completion if the drug is to be crushed before administration</td>
<td>Drug may go into the air by crushing, dose inadvertently received by administering person.</td>
<td>Tamoxifen Methotrexate Dexamethasone</td>
</tr>
</tbody>
</table>
Appendix 5

Examples of reimbursement costs for the top 10 liquid special prescriptions dispensed in quarter 3 0910 across Sheffield

<table>
<thead>
<tr>
<th>BNF name and quantity*</th>
<th>Cheapest reimbursement cost for quantity stated in column one</th>
<th>Most expensive reimbursement cost for quantity stated in column one</th>
<th>Possible solutions / alternatives to consider on an individual patient basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diazoxide Liquid 250mg/5ml (180 - 200ml)</td>
<td>£526.02</td>
<td>£786.35</td>
<td></td>
</tr>
<tr>
<td>Dipyridamole_Liquid Spec 100mg/5ml – 600ml</td>
<td>£79.18</td>
<td>£840.00</td>
<td>Dipyridamole modified-release capsules (Persantin Retard) may be opened and the modified-release granules mixed with water.** There is a risk that the granules could block a feeding tube. The granules must not be crushed. Administering the granules in soft food is not recommended; it is important not to chew the granules as this will damage the modified-release coating.</td>
</tr>
<tr>
<td>Simvastatin liquid 40mg/5ml – 300ml</td>
<td>£125.51</td>
<td>£221.88</td>
<td>Simvastatin tablets are film-coated but can be crushed and dispersed in water** for administration orally or via a feeding tube. Simvastatin suspension (sugar free) 20mg/5ml, 40mg/5ml are available as a licensed special from Rosemont, (May 2010) 150mL bottles, £99.50 and £152.00 respectively</td>
</tr>
<tr>
<td>Gabapentin_Liquid 250mg/5ml – 470ml</td>
<td>£108.10</td>
<td>£596.90</td>
<td>Gabapentin capsules can be opened and the contents mixed with water** for administration orally or via a feeding tube. The capsule contents can be mixed with soft food. The 100mg capsules are small and may be fiddly to open.</td>
</tr>
<tr>
<td>Spironol liquid 50mg/5ml – 125ml</td>
<td>£73.98</td>
<td>£260.67</td>
<td></td>
</tr>
<tr>
<td>Mag Glycerophos Tab 97.2mg – 168 tablets</td>
<td>£48.72</td>
<td>£260.40</td>
<td></td>
</tr>
<tr>
<td>BNF name and quantity*</td>
<td>Cheapest reimbursement cost for quantity stated in column one</td>
<td>Most expensive reimbursement cost for quantity stated in column one</td>
<td>Possible solutions / Alternatives to consider on an individual patient basis</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------------------------------------------</td>
<td>-------------------------------------------------------------</td>
<td>------------------------------------------------------------------</td>
</tr>
<tr>
<td>Midazolam_Liq Oromucosal 10mg/ml – 5ml</td>
<td>£45.87</td>
<td>£206.86</td>
<td></td>
</tr>
</tbody>
</table>
| Omeprazole_Liq 20mg/5ml – 150ml | £85.43 | £444.23 | Omeprazole dispersible tablets (Losec MUPS) -  
| Sertraline HCI_Liq 50mg/5ml – 150ml | £85.50 | £295.50 | Alternative SSRIs are available in liquid licensed form; e.g. fluoxetine, citalopram .  
| Simvastatin_Liq 20mg/5ml – 300ml | £102.00 | £441.00 | Simvastatin tablets are film-coated but can be crushed and dispersed in water** for administration orally or via a feeding tube. Simvastatin suspension (sugar free) 20mg/5ml, 40mg/5ml are available as a licensed special from Rosemont (May 2010), 150mL bottles, £99.50 and £152.00 respectively  

** Administering the medication in this way is unlicensed

**Note:**
- The cost of medication can vary depending on the quantity ordered and the pack size. For the purpose of true comparison, the table shows examples of identical pack sizes. The prices listed may not always be the cheapest or most expensive but is the cheapest and most expensive reimbursement cost.
Use of Unlicensed Medicines

PATIENT INFORMATION

What is this leaflet about?
You have been given this leaflet because a medicine that you have been prescribed does not have a licence, known as a marketing authorisation, issued by the Medicine and Healthcare Products Regulatory Agency (MHRA). This leaflet is intended to help answer any questions that you may have. Please talk to your doctor or pharmacist if there is anything further that you would like to know.

Pharmaceutical companies must hold a marketing authorisation for each medicine that they sell in the United Kingdom. The MHRA issue these licences only after they have assessed information on the quality, safety and efficacy of the medicine.

Why don’t all medicines have licences?
There are a number of reasons why a medicine may not have a licence, or marketing authorisation:

- It is currently undergoing clinical trials, but does not yet have a licence;
- The medicine used to be licensed in the UK, but is no longer available;
- It is only available from abroad and needs to be imported; or
- The medicine needs to be made specially

Why have I been given an unlicensed medicine?
You have been prescribed an unlicensed medicine because no suitable licensed alternative is available to treat your condition. However, the person treating you will have thought very carefully about prescribing the most appropriate medicine.

Should I be worried about taking unlicensed medicines?
The prescriber will have explained to you why they think that this medicine is the right one for you. If you are worried about taking this medicine, talk to your doctor or pharmacist about your concerns. They may be able to give you further information or help to put you in touch with a support group for your illness or condition.

If you do experience any unpleasant or unexpected effects whilst taking the medicine, you should report this to your doctor or pharmacist.

What else do I need to know?
Sometimes it will take longer for the pharmacist to order in an unlicensed medicine. In which case, you will need to allow one or two weeks for the pharmacist to obtain further supplies of your medicine. You should bear this in mind, if you need to get a repeat prescription from your doctor.