Drug Dilemmas for Dentists

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October 9th 2009
All Wales Special Interest Group
Llandrindod Wells
Outline

- Introduction to NWMIC
- Medicines and the law
- Drug interactions
- Warfarin and antiplatelets
- Corticosteroids
North West Medicines Information Centre (Liverpool)

- Part of the national UKM'i medicines information pharmacist network
- **UKM'i** specialist advisory centre for ‘Medicines in Dentistry’
- MHRA Regional Monitoring Centre for adverse drug reaction reporting
What do we do?

- Answer enquiries
  - Health professionals in the North West
  - Dentists in UK
  - NHS Direct
- Proactive information – bulletins, Q&As
- YCC North West – ADR reporting
- Teaching

Tel: 0151 794 8206
Email: druginfo@liv.ac.uk
Dental enquiries to NWMIC – 2008/9

- 901 / 3731 dental enquiries in 2008/9 (24%)
- 798 (89%) directly from dentists

- 36% - interactions/adverse effects
- 22% - endocarditis/prophylaxis
- 13% - antibiotic use/choice
- 11% - bisphosphonates
- 11% - availability/prescribing issues
- 10% - patients on warfarin/antiplatelets
- 6% - involved local anaesthetic use
- 6% - pregnancy or breast feeding
- 5% - controlled drugs
- 3% - managing patients on steroids
- 2.3% - fluoride
Recent issues

- Midazolam – ordering, storing, disposing of, SOPs
- Citanest availability
- Adcortyl in Orabase discontinuation
- Colophony in Duraphat varnish
Medicines, dentists and The Law
Medicines and the law

- Medicines Act 1968
- Misuse of Drugs Act 1971
- The NHS Act 1977
- Misuse of Drugs Regulations 2001
Medicines Act 1968

- Governs all aspects of medicinal products
  - Licensing of medicines
  - Requirements for packaging and labelling of medicines
  - Sale and supply of medicines
The basic principle of the Medicines Act is that medicines may only be sold or supplied by retail from registered pharmacies except those that are on the general sales list.

- Dentists are exempt from the requirement that all Non-GSL medicines must only be supplied from a pharmacy (private patients only)
- PoMs can be supplied from pharmacies only in accordance with a practitioner's prescription
Categories of Medicinal Products

Licensed medicines

- GSL (general sales list)
- P (pharmacy only)
- PoM (prescription only medicine)
Categories of Medicinal Products

- Unlicensed medicines
  - “Specials” – specially manufactured medicines e.g. tranexamic acid mouthwash
  - Imported medicines e.g. some latex free LAs
  - Unlicensed use of licensed medicines (“off-label use”) e.g. beclometasone inhaler or betnesol dispersible tabs for mouth ulcers
  - Most herbal and alternative medicines
Prescribing Outside the Product Licence

- The Medicines Act does not prohibit
- Alters and probably increases the prescribers professional responsibility and potential liability
- Patient explanation - explain the rationale for treatment
- Explain discrepancies in the Patient Information Leaflet (PIL)
Categories of Medicinal Products

- Medical Devices
- Not governed by Medicines Act BUT in the NHS prescribing restrictions apply
- Dentists cannot prescribe any devices, GMPs restricted to list Drug Tariff
  - e.g. Curasept mouthwash cannot be prescribed on an NHS prescription
  - Gengigel/Gelclair OK on WP10 but not WP10D
- [Most dental materials are Medical Devices]
What can dentists prescribe?
What can dentists prescribe?

- For NHS patients
  - Currently restricted to the drugs on the Secretaries of State list (see BNF)

- For private patients
  - There is no legal restriction
  - Ethically restricted to areas in which you are competent
Prescribing

- **NHS**
  - If you need to prescribe a medicine not on the DPF list, the GDS regs allow you to provide a private prescription to an NHS patient
  - Dentists must prescribe on WP10D Wales (or FP10D England, GP14 Scot, HS47 NI)

- **Private**
  - A private (not NHS) prescription must be used
Additions to DPF list since September 2008

- Alcohol free chlorhexidine mouthwash
- Antihistamines
  - Cetirizine
  - Loratadine
  - Chlorphenamine oral solution
- Proton pump inhibitors
  - Lansoprazole
  - Omeprazole
- Co-amoxiclav tabs/suspension
Supplying medicines
Supplying medicines

- **NHS patients** *(The National Health Service Regulations 2005)*
  - Only medications required for immediate use
  - Cannot supply PoM or P medicines

- **Private patients**
  - Can sell all PoM and P medicines
  - Must comply with labelling regs for dispensed medicinal products
  - Must comply with packaging regs
Duraphat toothpaste

Prescription Only Medicine both strengths prescribable on WP10D
Labelling regulations

The Medicines for Human Use (Marketing Authorisations Etc.) Regulations 1994 (Schedule 5 – Labelling)
Labelling regs for dispensed medicines

Medicines issued to a patient must be labelled with:

- the name of the product
- directions for use
- any precautions relating to the use of the medicinal product
- the name of the person to whom the medicine is to be administered
- the date of dispensing
Labelling regs – cont.

- the name and address of the dentist supplying the medicinal product
- the words “Keep out of reach of children” or words with a similar meaning
- the phrase “For external use only” if it is a preparation for external use only.

A container need not be labelled if it is enclosed in a package which is labelled with the required particulars.
Dental Care Professionals & Medicines responsibilities

- DCPs are competent to administer LAs by infiltration or IDB
- DCPs cannot prescribe medicines i.e. do not have the discretion and independence to decide
  - if and/or what LAs are to be used
  - if an antimicrobial should be used
- The dentist must prescribe/specify in writing the choice and dose of all medicines
Consultation

MLX 362: Sale, supply and administration of medicines by Dental Hygienists and Dental Therapists under a Patient Group Direction (PGD)

Issued: 28/08/09
Comments by: 20/11/09
DCP PGD consultation

- Named hygienists and therapists will be able to
  - Independently choose and administer local anaesthetics
  - Issue named medicines directly to patients e.g. fluoride preparations including Duraphat toothpaste
- All supplies must be labelled as dispensed medicines
Significant drug interactions in Dentistry
Drug interactions

Antibiotics

- Combined oral contraceptives
  - additional contraceptive measures should be used with all antibiotic courses (FPA advice, see BNF section 7.3.1)

- Warfarin
  - Possible potentiation of warfarin with all antibiotics (counsel patient about risk) but only metronidazole needs to be avoided if at all possible
Drug Interactions

Azole antifungals
(e.g. miconazole, fluconazole, itraconazole)

Warfarin

- An established and clinically important interaction leading to increased anticoagulant effect of warfarin. Monitor the INR if the combination is essential.
Drug interactions
‘Statins’
(e.g. simvastatin, atorvastatin)

- CONTRAINDICATED
  - Simvastatin + erythromycin
  - Simvastatin + miconazole

- Other combinations not contraindicated but warnings apply

- The interaction- macrolide antibiotics / azole antifungals
  - inhibit metabolism of statins leading to high blood levels and an increased risk of myopathy and rhabdomyolysis
Drug Interactions

Methotrexate

- Methotrexate and penicillin antibiotics
  - Methotrexate toxicity, combination not contraindicated but close monitoring is advisable

- Methotrexate and NSAIDs / paracetamol
  - Toxicity may be dose related and lowest risk in those taking low-dose methotrexate for psoriasis or rheumatoid arthritis with normal renal function.
Drug Interactions

NSAIDs

- Addition of NSAIDs to the following medicines can increase the risk of GI bleeding
  - Low dose aspirin
  - Selective serotonin reuptake inhibitors (SSRIs)
  - Warfarin
Drug interactions

Local anaesthetics

No clinically significant interactions occur with plain local anaesthetics at the small and localised doses used in dentistry.
Drug interactions

Vasoconstrictors

- Tricyclic antidepressants & MAOIs
  - No clinically important interaction

- Beta-blockers
  - Possibility of increased BP, although unlikely to be clinically important. The minimum amount of local anaesthetic containing the lowest concentration of adrenaline should be used.

- Diuretics
  - $K^+$ may be low due to diuretic action leading to possible increase in cardiotoxicity. The minimum amount of local anaesthetic containing the lowest concentration of adrenaline should be used.
Adrenaline

- Light physical work → 4mcg/ml adrenaline (plasma)
- Continuous IV infusion of 10mcg/ml adrenaline solution → 4mcg/ml adrenaline (plasma)
- 2mls lidocaine with 1:80,000 adrenaline = 25mcg adrenaline
- IV admin 25mcg adrenaline → <4mcg/ml (plasma)
- Anxiety and pain → ↑↑↑ adrenaline
What is the clinical significance of potential drug interactions with local anaesthetic preparations used in primary care dentistry?
Endocarditis prophylaxis guidelines
NICE endocarditis guidance
March 2008

- BUT …
- Still some controversy and confusion – cardiologists, dentists and patients
- Fear of litigation – but adherence to NICE affords robust legal protection
Post-NICE 2008: antibiotic prophylaxis prior to dental procedures for patients with pulmonary arteriovenous malformations (PAVMs) and hereditary haemorrhagic telangiectasia

C. Shovlin, K. Bamford & D. Wray

British Dental Journal 2008; 205: 531 - 533
Prophylaxis – not endocarditis?

- The principles established in the NICE endocarditis guidance can be extrapolated to most scenarios.
- Bacteraemia associated with tooth brushing and eating is $\geq$ that from tooth extraction.
- Therefore prophylaxis will not be required.
Patients on warfarin or antiplatelet therapy
Surgical management of the primary care dental patient on warfarin/antiplatelets

- 1999 - 50 calls in a year
- Confusion as dental texts, teaching and literature varied
- National haematology guidance not specific for dentistry
Surgical management of the primary care dental patient on warfarin/antiplatelets

### Summary

Warfarin does not need to be stopped before primary care dental surgical procedures

- The consensus from reviews on the management of dental patients taking warfarin is that patients requiring dental surgical procedures in primary care and who have an International Normalised Ratio (INR) below 4.0 should continue warfarin therapy without dose adjustment.
- Continuing warfarin during dental surgical procedures may increase the risk of postoperative bleeding requiring intervention.
- Most cases of postoperative bleeding are easily treated with local measures such as packing with a haemostatic dressing, suturing and pressure.
- Stopping warfarin increases the risk of thromboembolic events; the risk of thromboembolism after withdrawal of warfarin therapy outweighs the risk of oral bleeding as bleeding complications, while inconvenient, do not carry the same risks as thromboembolic complications.
- Stopping warfarin is no guarantee that the risk of postoperative bleeding requiring intervention will be eliminated as serious bleeding can occur in non-anticoagulated patients.

### Tranexamic acid mouthwash should not be used routinely in primary dental care

- Tranexamic acid mouthwash in primary dental practice is expensive, difficult to obtain and of no more benefit than other local haemostatic measures.
- When used alone with no local haemostatic dressing, tranexamic acid mouthwash reduces postoperative bleeding compared to placebo mouthwash.
- When used in combination with local haemostatic measures and suturing, tranexamic acid mouthwash provides little additional reduction in postoperative bleeding.
National Patient Safety Agency (NPSA)

Risk assessment of anticoagulant therapy
January 2006

2006
NPSA Patient safety alert

Actions that can make anticoagulant therapy safer

Anticoagulants are one of the classes of medicines most frequently identified as causing preventable harm and admission to hospital. Managing the risks associated with anticoagulants can reduce the chance of patients being harmed in the future.

This patient safety alert has been developed in collaboration with the British Society for Haematology (BSH) and a broad range of other clinical organisations and individual clinicians, patients and patient groups.

Action for the NHS and the independent sector

The National Patient Safety Agency (NPSA) is recommending that NHS and independent sector organisations in England and Wales take the following steps:

1. Ensure all staff caring for patients on anticoagulant therapy have the necessary vision, competencies. Any gaps in competency must be addressed through training to ensure that all staff are able to undertake their duties safely.
2. Review and, where necessary, update written procedures and clinical protocols for anticoagulant services to ensure they reflect safe practice, and that staff are trained in these procedures.
3. Audit anticoagulant services using the NPSA safety indicators as part of the annual medication management audit programme. The audit results should inform local actions to improve the safe use of anticoagulants and should be communicated to clinical governance, and trusts and management committees (or equivalent). This information should be used by commissioners and external organisations as part of the commissioning and performance management process.
4. Ensure that a patient’s target international normalised ratio (INR) is recorded on patient records and in written information at the start of therapy, at all hospital discharges, on the first anticoagulant clinic appointment, and when necessary throughout the course of their treatment. The ISD and the NPSA have updated their patient-held records templates for this (see www.isdrec.org.uk). Local targets should be set that reflect national targets if appropriate.
5. Promote safe practice with prescribers and pharmacists to check that patients’ blood clotting international normalised ratio (INR) is being monitored regularly and that the INR is safe before issuing or dispensing repeat prescriptions for oral anticoagulants.
7. Ensure that dental practitioners manage patients on anticoagulants according to evidence-based therapeutic guidelines. In most cases, dental treatment should proceed as normal and oral anticoagulant treatment should not be stopped or the dosage decreased inappropriately.

In some cases, patients on anticoagulant therapy have had their dental treatment delayed or cancelled, their anticoagulant therapy temporarily discontinued or their dose reduced. This has, in part, been due to a lack of understanding of evidence-based practice guidelines. In most cases, dental treatment can proceed as normal and oral anticoagulant treatment should not be stopped or the dosage decreased inappropriately.

The NPSA has been working with the British Dental Association and the BSH to produce a poster outlining safe practice guidelines for patients on anticoagulants requiring dental therapy. The NPSA is arranging to send a copy of this poster to every dental practice in England and Wales. A copy of this poster is available at www.npsa.nhs.uk/health/alerts
NPSA Patient safety alert

Actions that can make anticoagulant therapy safer

Managing patients who are taking warfarin and undergoing dental treatment

General guidelines
- If a patient is planned to undergo dental surgery while on anticoagulant therapy, certain precautions should be taken.
- Patients should be advised to bring their warfarin to the dental surgery.
- Dental surgeons should be aware of the risks associated with dental surgery.
- Patients should be advised to stop anticoagulant therapy prior to dental surgery.

Drug interactions
- There have been reports of warfarin interaction with other drugs, including aspirin, clopidogrel, and NSAIDs.
- Patients on warfarin should be monitored closely for changes in INR.
- Dietary changes should be avoided while on warfarin.

Cautions
- Patients should be advised to stop aspirin and clopidogrel prior to dental surgery.
- Patients should be advised to stop warfarin prior to dental surgery.
- Patients should be advised to stop NSAIDs prior to dental surgery.

Refer to specialist services.

Yes

Check the patient's INR two or more times in the 24 hours before the dental procedure.

No

Refer to specialist services.

Yes

Lisinopril and other renin-angiotensin inhibitors or angiotensin-converting enzyme inhibitors

Yes

Take prescription as normal.

No

Refer to specialist services.

Yes

Consider the timing of the procedure.
- If the procedure is scheduled for the morning, the patient should be anticoagulated.
- If the procedure is scheduled for the evening, the patient should be warfarin-free.

No

Refer to specialist services.

Yes

Use a local anaesthetic containing a vasoconstrictor, unless otherwise contraindicated.

No

Refer to specialist services.

Yes

If the patient is on warfarin, consider using an alternative repositioning technique.

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Refer to specialist services.

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Refer to specialist services.
NPSA - Information for dental patients on warfarin

General guidelines
It is important that you follow the advice in the booklet you were given when you started taking your anticoagulant medicine.

Taking anticoagulants can make it more difficult for your blood to clot. For this reason certain types of dental procedure, such as having a tooth removed, can cause bleeding more easily and for longer than other people.

Before your treatment
When you make an appointment, tell the dental team you are taking an anticoagulant medicine.

Remind your dentist before any dental treatment that you are taking a warfarin medicine.

Your dentist may ask you to have an extra blood test before your treatment. This test will indicate whether you need to take a blood test before the procedure. It is important that you attend the blood test because your dentist wants to have up-to-date information about how you will clot.

After your treatment
It is important that you look after the wound of the tooth for 2-3 days after the bleeding has stopped. You should:

- have a bath or shower instead of a shower if you have any bleeding
- avoid brushing your teeth with a toothbrush or using any other form of toothbrush for 24 hours after the treatment
- avoid shaving or any other oral care
- avoid eating or drinking hot or cold food for 24 hours
- avoid moving on the affected side until you are sure that you do not have any bleeding
- avoid brushing or any other oral care
- avoid eating or drinking hot or cold food for 24 hours
- contact your dentist if the bleeding does not stop

If you have excessive or prolonged bleeding you should contact:

- NHS 111
- the surgery
- the dental care team
- the pharmacist

Other medicines
Tell your dentist if you are taking any other medicines, herbal preparations or vitamin supplements including those that you have bought over the counter in a pharmacy or elsewhere.

Pain relief
Avoid taking medicines like ibuprofen or aspirin, or products containing these medicines. Your pharmacist will be able to advise you on this. Paracetamol should be used if you need pain relief, unless you are told otherwise.

Antibiotics
Your dentist may prescribe antibiotics to stop you getting an infection after your dental treatment. It is important that you take the dose prescribed. You must take the container with you when you go for a blood test so that the person monitoring you can read the information on the label.

If you or your dentist think that you may be taking antibiotics, you should inform your dentist or the pharmacist.

Contact your dentist if you have any doubts.

www.npsa.nhs.uk

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Guidelines for the management of patients on oral anticoagulants requiring dental surgery

In patients with a stable INR in the therapeutic range 2-4 (i.e. <4)

- Oral anticoagulants should not be discontinued in the majority of patients requiring out-patient dental surgery including dental extraction
- The risk of bleeding may be minimised by:
  - The use of oxidised cellulose (Surgicel) or collagen sponges and sutures
  - 5% tranexamic acid mouthwashes.
- An INR check is recommended 72 hours prior to dental surgery
- Patients taking warfarin should not be prescribed non-selective NSAIDs and COX-2 inhibitors
From BNF 55 (March 2008)

BNF now reflects NPSA/BDA/BSH guidance
Antiplatelets

- Antiplatelet meds increase the bleeding time (clopidogrel > aspirin)
  - Apply local measure to stop bleeding
- Aspirin + clopidogrel → ↑↑ bleeding time (anecdotally could be 45 -60 mins)
- Ask patient what happens when they cut themselves
- Timing of the procedure
- Refer ??? X
Do patients taking corticosteroids need any additional cover for dental procedures?
Corticosteroid cover?

- BNF Section 6.3

- ‘A suitable regimen for corticosteroid replacement, in patients who have taken more than 10 mg prednisolone daily (or equivalent) within 3 months of surgery, is:
  
  - *Minor surgery under general anaesthesia* — usual oral corticosteroid dose on the morning of surgery OR hydrocortisone 25–50 mg (usually the sodium succinate) IV at induction; the usual oral corticosteroid dose is recommenced after surgery
Corticosteroid cover?

What is minor surgery?

- Surgery undertaken under local anaesthetic and lasting under 1 hour

- The general anaesthetic is the biggest stress in minor surgery under GA
Corticosteroid cover?

- Below 10mg prednisolone suppression of HPA unlikely/limited: stress response will occur
- Above 10mg prednisolone there will be enough steroid ‘on board’ to protect the patient
- Carry out procedures first thing in the morning.
- **NB** this advice does **NOT** apply to patients with Addison's Disease
# Patients with Addison’s Disease

## ADDISON’S DISEASE (PRIMARY ADRENAL INSUFFICIENCY)

### POTENTIALLY LIFE-THREATENING STEROID DEPENDENCY

<table>
<thead>
<tr>
<th>Type of procedure</th>
<th>Pre-operative and operative needs</th>
<th>Post-operative needs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Long-term, major surgery with long recovery time (e.g., open heart surgery, major bowel surgery, procedures needing transfusion)</td>
<td>1000mg hydrocortisone i/m just before anaesthesia</td>
<td>Continue 100mg hydrocortisone i/m every 6 hours until able to eat &amp; drink normally, then taper the return to normal dose</td>
</tr>
<tr>
<td>Major surgery with rapid recovery (e.g., cataract surgery, hernia repair, papilloma)</td>
<td>1000mg hydrocortisone i/m just before anaesthesia</td>
<td>Continue 100mg hydrocortisone i/m every 6 hours for 24-48 hours or until nausea &amp; vomiting stop. Then double oral dose for 24-48 hours. Then return to normal dose</td>
</tr>
</tbody>
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### MEDICATION REQUIREMENTS FOR SURGERY AND DENTISTRY

*ADDISON’S CLINICAL ADVISORY PANEL (ACAP)*

*These guidelines have been prepared by Professor John Woods of the Chelsea College Hospital, Oxford, Dr. Irene Bennett of the Victoria Hospital, Huddersfield, Dr. Paul Rousby of the University Hospital, Nottingham, and Dr. Simon Pearce of the Royal Victoria Infirmary, Newcastle.*

ACAP is a non-profit organisation with an interest in adrenal medicine. It advises the Addison’s Disease Society on medical matters. Further information about ACAP is available on the Addison’s Disease Society website ([www.addisons.org.uk](http://www.addisons.org.uk)).

ACAP has issued emergency treatment guidelines for hypoglycaemia and adrenal crisis, available at [www.addisons.org.uk](http://www.addisons.org.uk)/publications.

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### SMALL HOSPITALS

**Rushmoor General Hospital**

**Skiptown General Hospital**

**Wrexham General Hospital**

**Other hospitals in the area**

**MEDICAL NOTES**

1. For any surgical procedure, please arrange an intravenous saline infusion to prevent dehydration and maintain plasma sodium levels. See [www.addisons.org.uk](http://www.addisons.org.uk) for further details.

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[www.addisons.org.uk](http://www.addisons.org.uk)
Patients with Addison’s Disease

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<td>Major dental surgery</td>
<td>100mg hydrocortisone i/m just before anaesthesia.</td>
<td>Double dose oral medication for 24 hours. Then return to normal dose</td>
</tr>
<tr>
<td>eg. dental extraction with general anaesthetic</td>
<td></td>
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<tr>
<td>Dental surgery</td>
<td>Double dose (up to 20mg hydrocortisone) one hour prior to surgery.</td>
<td>Double dose oral medication for 24 hours. Then return to normal dose</td>
</tr>
<tr>
<td>eg. root canal work with local anaesthetic</td>
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<tr>
<td>Minor dental procedure</td>
<td>Not usually required.</td>
<td>An extra dose only where hypoadrenal symptoms occur afterwards.</td>
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<tr>
<td>eg. replace filling</td>
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