

MONITORING THE PHYSICAL HEALTH OF PATIENTS WITH SERIOUS MENTAL HEALTH ISSUES

The MHRA highlighted in April's Drug Safety bulletin (www.mhra.gov.uk/Safetyinformation/DrugSafetyUpdate/CON111764) the need for ongoing monitoring of the physical health of those receiving atypical antipsychotics. People with schizophrenia are three times more likely to die prematurely from natural causes (mainly cardiovascular disease) compared with people without mental health disorders. Schizophrenia also seems to be associated with modifiable and non-modifiable risk factors for cardiovascular morbidity and mortality (eg smoking, poor diet, sedentary lifestyle and family history of cardiovascular disease).

Some atypical (second-generation) antipsychotics are associated with significant weight gain (>7% of baseline), dyslipidaemia and hyperglycaemia (metabolic adverse effects). Individual atypical antipsychotics differ in their propensity for metabolic adverse effects: available data suggest that clozapine, olanzapine and quetiapine are especially implicated.

NHSGGC Mental Health Services are about to launch a physical health care policy to ensure that mental health service users have access to the same quality of physical health care as the general population. Escalating evidence clearly indicates that the physical health care needs of people with a serious mental illness (SMI) are as important as the individual's mental health care needs and should be considered and addressed as part of a holistic package of care.

Secondary specialist services for mental health need to work closely with primary care services and patients to ensure that those with a SMI have their physical health monitored and managed effectively. This new policy aims to ensure that the systematic assessment of mental and physical health and the health improvement needs of service users should be embedded in the provision of inpatient and community mental health services and address issues appropriate to the individual's quality of life and well being.

GP practices have established registers for people with severe long-term mental health problems, such as schizophrenia, bipolar disorder and other psychoses, as part of the general medical services contract. Most GP practices in Greater Glasgow & Clyde provide annual health screens for patients on their mental health registers. The clinical care provided for under the contract potentially meets the basic needs for evidence-based, routine physical health reviews for most individuals with these conditions.

Monitoring effects of drug therapy

Any prescribing physician, including the psychiatrist, has responsibility for physical health monitoring in long-term

PostScript

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Website

<http://www.ggcformulary.scot.nhs.uk>

therapy. Prescribers should actively monitor patients for physical side effects of psychotropics in the short and long term. Specific guidance has been produced for some high risk medicines such as atypical antipsychotics:

- Prescribing psychiatrists in GG&C Mental Health Services should take a personal and family history of cardiovascular problems and/or diabetes and define ethnicity prior to recommending atypical antipsychotics.
- Various good practice guidelines suggest that when commencing an atypical antipsychotic, weight, BMI and/or waist circumference, glucose and lipids should be monitored. It is important to identify people with metabolic problems and treatment-related weight gain early on, enabling steps to be taken to address any significant problems.
- Most practitioners agree that most physical health monitoring is best performed in primary care, although treatment setting and patient choice will determine the best arrangement. The prescriber should ensure that physical screening has taken place. GPs should be asked to ensure the patient is on their mental health register to trigger an annual review thereafter.
- A record of current and previous smoking status is desirable as well as assessment of readiness to quit.
- If cardiovascular risk is a concern then a baseline ECG is desirable, and repeat if clinically indicated. These can be arranged for outpatients at any local ECG department.
- Enquiry as to medication-related sexual dysfunction is desirable, with consideration given to checking prolactin levels where raised prolactin is suspected.

Mental Health Services encounter patients with a range of co-morbidities. The guidance stresses that due consideration must be given to any ongoing physical health monitoring requirements for inpatients, especially those with prolonged stays. The routine admission of a psychiatric patient should always be accompanied by a detailed physical assessment encompassing systems enquiry, physical examination, investigations and a follow-up plan where necessary. A list of suggested blood tests for the monitoring of specific conditions or for treatment with particular medications is provided in the guidance.

The full policy is due to be posted on Staffnet later in the summer.

Latest ADTC decisions

Go to [www.ggcformulary.scot.nhs.uk/Latest news/formulary update bulletin.pdf](http://www.ggcformulary.scot.nhs.uk/Latest%20news/formulary%20update%20bulletin.pdf) for full details of all ADTC decisions and links to SMC recommendations.

Added to the *Formulary*

Calcium and Vitamin D3 (Adcal-D3 Dissolve®) Adjunct therapy for osteoporosis and supplementation of calcium and vitamin D. Total *Formulary*. Restricted to use in those patients who cannot tolerate other calcium and vitamin D preparations.

Ensure® Enteral feeding *Formulary* (Preferred List).

Febuxostat (Adenuric®) Treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a history, or presence, of tophus and/or gouty arthritis). Total *Formulary*. Restricted to symptomatic patients whose uric acid levels have failed to respond adequately despite optimal dosing of allopurinol (for which the maximum licensed daily dose is 900mg daily).

Ⓢ **Fentanyl buccal tablets (Effentora®)** Treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. Total *Formulary*. Restricted to patients who are unsuitable for other short-acting opioids. Fentanyl buccal/sub-lingual preparations are not interchangeable and should be prescribed by brand name.

Ⓢ **Fentanyl sublingual tablets (Abstral®)** Management of breakthrough pain in adult patients using opioid therapy for chronic cancer pain. Use of sublingual fentanyl tablets should be restricted to patients who are unsuitable for other short-acting opioids eg oral morphine. Total *Formulary*. Restricted to patients who are unsuitable for other short-acting opioids. Fentanyl buccal/sub-lingual preparations are not interchangeable and should be prescribed by brand name.

Non-Formulary

• **Calcium and Vitamin D3 (Cacit D3® sachets)** Adjunct therapy for osteoporosis and supplementation of calcium and vitamin D. Removed from the *Formulary* following consultation with the GGC Osteoporosis Group.

• **Carmellose Sodium (Optive®)** Dry eyes.

• **Fentanyl nasal spray (Instanyl®, PecFent®)** Management of breakthrough pain in adults who are already receiving maintenance opioid therapy for chronic cancer pain.

• **Fortisip®, Calshake®, Scandishake®** Enteral feeding. Removed from *Formulary* following contract change.

Ⓢ **Filgrastim (Zarzio®)** Reduction in duration and incidence of neutropenia and febrile neutropenia, mobilisation of peripheral blood progenitor cells (see SMC advice for full details of indications considered). Total *Formulary*.

Ⓢ **Hydromorphone capsules (Palladone®)** Severe pain in cancer. Total *Formulary*. Restricted to use in palliative care patients who are unable to tolerate other opioids in accordance with local protocol.

Hydroxypropyl guar eye drops (Systane®) Dry eyes. Total *Formulary*.

Macrogol Oral Powder (Laxido Orange®) Chronic constipation in adults and adolescents and faecal impaction in adults and adolescents. Total *Formulary*.

Ⓢ **Memantine (Ebixa®)** Management of Alzheimer's disease. Total *Formulary*. Restricted to use in accordance with local protocol (under review).

Ⓢ **Omalizumab injection (Xolair®)** Omalizumab is indicated in adults, adolescents (12 years of age and older) and children (6 to <12 years of age) with convincing immunoglobulin E mediated asthma. Total *Formulary*. Restricted to patients who are prescribed chronic systemic steroids and in whom all other treatments have failed.

Sertraline tablets Treatment of depression. *Formulary* (Preferred List).

Ⓢ **Venlafaxine modified-release preparations** Treatment of depression. Total *Formulary*. Restricted to initiation only on the advice of a consultant.

• **Macrogol Oral Powder (Movicol®)** Chronic constipation in adults and adolescents and faecal impaction in adults and adolescents. Removed from *Formulary* following addition of alternative preparation.

• **Moviprep®** Bowel cleansing agent.

• **Quetiapine (Seroquel®, Seroquel® XL)** Treatment of major depressive episodes in bipolar disorder.

• **Tadalafil (Adcirca®)** Treatment of pulmonary arterial hypertension classified as WHO functional class II and III, to improve exercise capacity.

Ⓢ specialist use only

Ⓢ specialist initiation only

NHSGGC palliative care guidelines

A new set of palliative care guidelines has been approved for use in the Health Board and reflects a consensus of opinion about best practice in patients with a life-limiting disease. The guidelines are available in an A5 pocket size which contains an abbreviated set of guidelines and an A4 folder with a more complete set of guidelines. All of the guidelines and some patient information leaflets can be accessed via www.palliativecareguidelines.scot.nhs.uk For local Palliative Care information, please access www.palliativecareggc.org.uk.

For hard copies, please contact your local palliative care team or Elayne Harris (elayne.harris@ggc.scot.nhs.uk).

Fentanyl for breakthrough pain in cancer

After discussion with the Palliative Care Managed Clinical Network, fentanyl buccal tablets (Effentora®) and fentanyl sublingual tablets (Abstral®) have been added to the Total *Formulary* for the treatment of breakthrough pain in adults with cancer who are already receiving maintenance opioid therapy for chronic cancer pain. Use is restricted to patients who are unsuitable for treatment with other short-acting opioids such as morphine. Fentanyl buccal and sublingual preparations are not interchangeable and should be prescribed by brand name. Fentanyl citrate lozenges are already on the Total *Formulary* restricted to initiation by hospital palliative care and cancer specialists.



New treatment for gout added to Total Formulary

Febuxostat (Adenuric®) is a new medicine licensed for the treatment of chronic hyperuricaemia in conditions where urate deposition has already occurred (including a

history, or presence, or tophus and/or gouty arthritis). It is a 2-arylthiazole derivative that selectively inhibits xanthine oxidase, thereby decreasing uric acid.

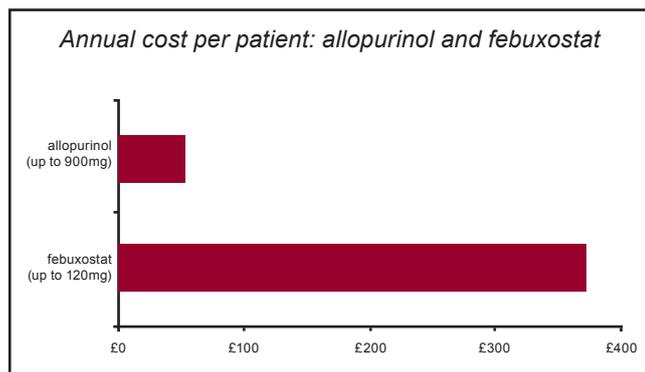
SMC has accepted febuxostat for use in NHS Scotland when treatment with allopurinol is inadequate, not tolerated or contra-indicated. Although febuxostat was shown to be superior to allopurinol 300mg daily in reducing serum uric acid, it did not demonstrate increased effectiveness in terms of preventing recurrence or reducing overall size of tophi, and its efficacy compared with higher doses of allopurinol is unknown.

Its place in therapy has been clearly defined for NHSGGC Formulary:

- **Use is restricted to symptomatic patients whose uric acid levels have failed to respond adequately despite optimal dosing of allopurinol. Prescribers are reminded that the maximum licensed dose of allopurinol is 900mg. In clinical practice, doses above 300mg are infrequently used but titration to higher doses, if tolerated, should be tried prior to consideration of febuxostat. Allopurinol should be given in divided doses where more than 300mg daily is prescribed.**
- **Febuxostat is not recommended for patients with ischaemic heart disease or heart failure. The manufacturer has made a commitment to conduct a post-marketing comparative cardiovascular safety study of febuxostat and allopurinol due to the higher incidence of cardiovascular events observed in the clinical trials.**
- **Febuxostat is not recommended in patients with creatinine clearance <30mL/min.**

The starting dose of febuxostat is 80mg daily. This can be increased to 120mg daily after four weeks if the serum urate still exceeds 360micromol/L. As with allopurinol treatment, prophylaxis for flares of gout should continue for the first six months. Liver function testing is recommended prior to the initiation of therapy with febuxostat and periodically thereafter based on clinical judgement.

The relative costs of these medicines are illustrated below.



Reminder of safety issues and Formulary restrictions on Spiriva® Respimat®

Tiotropium (Spiriva®) is a long-acting antimuscarinic bronchodilator licensed for the maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD). An initial four week trial of tiotropium is recommended and should only be continued long term if the patient shows symptomatic benefit.

Tiotropium is available in two different inhaler devices:

- Spiriva 18mcg inhalation powder capsules: ONE dose to be inhaled via HandiHaler® once daily.
- Spiriva Respimat 2.5mcg/ metered inhalation: TWO doses to be inhaled ONCE daily.

Spiriva HandiHaler is the first line choice of device. The NHSGGC Formulary and the SMC restrict prescribing of Spiriva Respimat to patients with poor manual dexterity who have difficulty using the HandiHaler.

Usage figures from NHSGGC suggest that the Formulary restrictions are being adhered to with 3.5% and 5.5% of use attributed to Respimat in acute care and primary care respectively.

In 2008, the UPLIFT study confirmed the safety of tiotropium delivered via the HandiHaler device. However, a recent study comparing Spiriva Respimat with placebo in patients with COPD has been highlighted in a MHRA Drug Safety update which gave the following advice:

Information and advice for healthcare professionals

- Recent analyses found that Spiriva Respimat was associated with a non-significant increase in all-cause mortality compared with placebo. By contrast, Spiriva HandiHaler was associated with a decrease in all-cause mortality compared with placebo. The underlying reasons for the apparent difference are unclear and may be a chance finding; further studies are ongoing.
- Spiriva Respimat should be used with caution in patients with known cardiac rhythm disorders.
- Patients with COPD who use tiotropium should be reminded not to exceed the recommended once-daily dose of:
 - one Spiriva HandiHaler 18-microgram capsule, or
 - two puffs Spiriva Respimat 2.5 micrograms.
- Please remember to report suspected adverse reactions to any formulation of tiotropium on a Yellow Card at www.yellowcard.gov.uk

Meningococcal meningitis: Change in prophylaxis

The Health Protection Agency has recently updated guidance on antibiotic prophylaxis. This now recommends a single dose of ciprofloxacin is used instead of rifampicin for all patient groups. This is contrary to usual advice that ciprofloxacin is contra-indicated in children and pregnancy, but the guidance explains why single dose use is appropriate for all groups.

For more details see the Public Health Protection Unit newsletter at www.library.nhs.gov.uk/mediaAssets/PHPU/nhs.gov.uk/phpu_newsletter_vol10iss04.pdf

Helping patients on bisphosphonates prevent BONJ: New guidance

Bisphosphonates have an important role in the prophylaxis and treatment of osteoporosis and corticosteroid-induced osteoporosis. They are also used in the treatment of Paget's disease, hypercalcaemia of malignancy and in bone metastases in breast cancer. As we highlighted in *PostScript 57* (May 2010), bisphosphonate-related osteonecrosis of the jaw (BONJ) is an extremely rare, but very serious, condition in which the bone of the maxilla or mandible becomes irreversibly damaged.

Due to their effect on bone turnover, patients taking bisphosphonates are at increased risk of oral health complications, namely BONJ. Concern over the lack of clarity about providing dental care for patients taking bisphosphonates has prompted the development of new guidance by the Scottish Dental Clinical Effectiveness Programme (SDCEP).

Maintaining good oral health helps to minimise the risk of BONJ developing. Being primarily directed towards primary care dentists, the new guidance provides clear and practical advice on how to advise and care for patients prescribed these drugs, focusing on the prevention of BONJ.

Part of the guidance is specifically aimed at doctors and pharmacists who prescribe or dispense bisphosphonates because it is particularly important that patients receiving these drugs are encouraged to attend for appropriate dental care.

The guidance for anyone who prescribes or dispenses bisphosphonates is straightforward:

"Advise the patient:

- **that the medication they have just been given is a bisphosphonate and it is associated with a very small risk of BONJ,**
- **to make an appointment with a dentist as soon as possible to ensure they are dentally fit (this includes patients who have dentures),**
- **to tell their dentist that they are taking a bisphosphonate."**

By following this guidance, patient awareness of the potential oral health implications of taking bisphosphonates will be raised and preventive dental care is more likely to be provided at an early stage. As BONJ is an extremely rare condition, it is very important that patients are not discouraged from taking their bisphosphonate or from undergoing dental treatment.

The new guidance, entitled *Oral Health Management of Patients Prescribed Bisphosphonates*, can be viewed at the SDCEP website (www.sdcep.org.uk/index.aspx?o=3017).

SDCEP is an initiative of the National Dental Advisory Committee and operates within NHS Education for Scotland. For further information go to www.sdcep.org.uk, e-mail scottishdental.cep@nes.scot.nhs.uk or telephone 01382 425751.

"If I could change one thing . . ."

The treatment of opiate misuse has changed dramatically in the last 40 years. The numbers of people receiving treatment are far greater than would have been imagined.

In NHS Greater Glasgow & Clyde, there are almost 20,000 prescriptions for methadone, Subutex® or Suboxone® every month. Prescribing systems have also changed dramatically in that time with use of IT now standard and the introduction of supplementary prescribing by nurses and pharmacists for drug misuse. Unfortunately, the legislation which governs how these medicines are prescribed dates back to the early 1970s. A healthcare professional involved in the treatment of addiction would like to see that legislation changed.

If I could change one thing, I would rewrite the Misuse of Drugs Act and have it made fit for the prescribing and dispensing practices of the 21st century.

It would be less prescriptive about use of specific wording so that it is easier to make supplies to cover periods when a pharmacy is closed without having to send the prescription back to the prescriber to be altered. This would recognise the fact that pharmacists are highly educated and trained professionals who are capable of exercising sound professional judgements for the benefit and safety of patients. It would also cause less delay for the patient who should receive the medicine and cause fewer problems for the prescriber who inadvertently has not annotated the prescription correctly.

Any update should also change the requirements around instalment prescribing. Currently it is not enough to list the daily dose and then the intervals at which dispensing should occur. So saying dose 40ml daily, supply daily is not permitted. The script must state not only that the dose is 40ml daily but that 40ml must be supplied daily and 80ml to be supplied on a Saturday to provide a supply for when the pharmacy is closed on the Sunday. This duplication of information is very frustrating for prescribers who only have a limited number of characters allowed in electronic prescribing systems such as GPASS and EMIS.



Area Drug & Therapeutics Committee
Chair: Dr J Gravid

Communications Sub-group
Chair: Mrs A Thompson

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PostScript Editor: Mrs A Thompson
Prescribing Team, NHS Greater Glasgow & Clyde
Pharmacy & Prescribing Support Unit
Queen's Park House, Victoria Infirmary, Langside Road
Glasgow G42 9TY Tel: 0141 201 5214 Fax: 0141 201 5217
E-mail: audrey.thompson@nhs.net

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