PostScript

Issue 76, July 2013 ◆ Produced by NHS Greater Glasgow and Clyde Area Drug and Therapeutics Committee

This edition contains articles on:

Major developments to immunisation programmes

There is a significant programme of changes to routine immunisation programmes across the UK. These will have substantial workload implications for many groups of staff including GP practices and community pharmacies

Rotavirus immunisation is scheduled to start from July 2013. Rotavirus infection causes severe diarrhoea and vomiting in babies and young children leading to dehydration requiring hospital treatment. The virus spreads easily by hand-to-mouth contact. It can be picked up from surfaces like toys, food or nappies. A two dose vaccine will be offered to all babies when they attend their GP for childhood immunisations. The vaccine is given orally as a liquid and protects against the most common strains.

NHS Education for Scotland in partnership with Health Protection Scotland has produced a number of educational resources to support healthcare practitioners involved in rotavirus immunisation.

Meningococcal infection most commonly presents as meningitis and / or septicaemia. It may affect all age groups, but rates are highest in children under 5 years with a secondary peak in those 15 - 19 years of age. Changes in the Men C vaccination programme have been made to offer improved protection in adolescents and young adults. Educational resources describing these changes have also been produced.

The changes to the immunisation programme include:

- Rotavirus immunisation added to the infant programme from 1st July. It is given orally at 2 months and at 3 months.
- Men C vaccine is now given at 3 months and at secondary school S3 booster appointment.
- From August 2014 a limited catch-up programme to offer Men C vaccine to first-time university entrants less than 25 years.
- Shingles vaccine introduced in September 2013 for people aged 70 years (routine cohort) and 79 years (catch up cohort) this year.
- Seasonal flu programme will be extended to healthy children aged 2 to less than 17 years with phased implementation beginning autumn 2013. Vaccination will be offered to 2 and 3 year olds, accompanied by a limited pilot involving primary school children.

Further information will follow, but these changes will double the number of people being offered vaccination. The expansion of the seasonal flu programme delivered in a few weeks in the autumn will require careful cold chain management. Further information about the full range of immunisations and vaccines in Scotland is available on the public information website.

Midazolam for conscious sedation

Midazolam was the subject of a National Patient Safety Agency (NPSA) Rapid Response Report.

- Use of inappropriate doses can result in patient harm or death
- New guidelines have been approved for conscious sedation to minimise these risks.

Midazolam is a sedative agent used to alleviate anxiety and ensure patient comfort and cooperation during potentially uncomfortable procedures such as endoscopy and colonoscopy. Midazolam is normally used safely and effectively, however, in 2008 the NPSA highlighted that 498 incidents had been reported to them over a four year period where an inappropriate dose had been administered to a patient. Three deaths had occurred. It was recommended that local guidelines should be developed to aid the safe use of sedation and of midazolam in particular.

One of the early actions taken locally was to rationalise the range of products used in NHSGGC and to ensure that the high dose product used for palliative care (10mg/2ml) is stored safely and only

in those clinical areas where necessary. Work has been done with GP computer systems to reduce the risk of prescribing the wrong product; the palliative care setting is the only expected use of midazolam by GPs. Primary Care Dental Practitioners may use low strength midazolam for conscious sedation.

Guidelines for use of midazolam in conscious sedation have now been approved after extensive consultation and make recommendations on a variety of areas of care. These should be used in combination with any national guidance particular to the relevant specialty or procedure. The full guideline is available here and summarised below.

Staff
Staff should be suitably trained in the administration of sedation including monitoring and resuscitation of the patient. Staff should be trained in at least Basic Life Support and higher levels of training are desirable. Administration of procedural sedation requires two trained personnel as a minimum.

Patient Selection
A patient's co morbidities and concurrent medication should be assessed before sedation to allow an informed decision about safety and ensure patients are given appropriate information on the expected effects. High risk cases may require the assistance of an anaesthetist. Patients with an American Society of Anaesthetists (ASA) grading of three or greater should only be sedated in a hospital.

Equipment
Areas where sedation is administered should have the following equipment immediately to hand: a sufficient supply of oxygen, suction, facilities to hand ventilate the patient, emergency drugs including appropriate reversal agents, a defibrillator and appropriate airway adjuncts. Beds and trolleys must be capable of being tipped head down.

Monitoring
Pulse oximetry should always be used, with non-invasive blood pressure and ECG monitoring immediately available in hospital areas and used as standard in high risk patients (ASA 3 and above). There should always be a nominated member of staff to monitor and record the patient's physiological variables, including consciousness level. If verbal contact is lost, an anaesthetist must be called as the patient needs care equal to that of general anaesthesia.

Drugs and Dosing
Midazolam 5mg/5ml is the only product that should be used for conscious sedation. If an opioid is required for analgesia, it should be administered first then a lower dose of midazolam is given. Midazolam doses should reflect age, weight, concomitant drug therapy and co-morbidities as per the SmPC.
Midazolam overdose may be treated with flumazenil. This drug has a shorter half life than midazolam, which may result in the patient becoming re-sedated after the flumazenil has worn off. This is especially important in the elderly. Reversal agents should be available for emergency use but should not be used to hasten recovery to allow earlier discharge.

Recovery and discharge
Patient monitoring and oxygen therapy should continue during recovery with adequate staff present and resuscitation equipment available. Discharge criteria relating to the patient's clinical condition and home circumstances should be met before discharge.

ADTC decisions summary

See the website for full list of medicines and details of indications and restrictions.

Some additions to the *Adult Total Formulary*:
- Aflibercept: age related macular degeneration
- Ipilimumab: metastatic melanoma
- Linaclotide: irritable bowel syndrome (see below)
- Mirabegron: overactive bladder (see below)

The following medicine was removed
- Tiotropium (Spiriva) Respimat® (see below)

Change to the *Adult Preferred List*
- Piroxicam 0.5% gel replaces Movelat® cream/gel

The following medicines were among those added to the *Paediatric Formulary*
- Lisdexamfetamine: attention deficit hyperactivity disorder

Polypharmacy: pause button for prescribing

Doing our bit to reduce inappropriate polypharmacy (and related side effects)
The NHSGGC Mindful Prescribing Strategy was launched in December 2012 in response to national polypharmacy guidance (CEL 36 (2012)). The strategy aims to support engagement with prescribers and patients to encourage a mindful approach to medication with less inappropriate polypharmacy.

Polypharmacy is a necessary feature of modern therapeutics. It is not without risk, and elderly or frail patients are especially vulnerable. Four out of five people aged over 75 years take a prescription medicine and more than a third take at least four.

Patients on multiple medicines are more likely to suffer side effects, regardless of age. Being on

multiple medications is accompanied by a clear and steady increase in the number of admissions to hospital with side effects from medicines.

During pilot work, clinician views around processes and tools were vital in assisting the development of a GP practice Local Enhanced Service (LES). One tool which was considered to be extremely valuable was the **Drug Review Process** (see website) which highlights seven key criteria to be considered when reviewing medicines. Laminated copies of the drug review process can be provided on request.

The Polypharmacy LES aims to promote safe, effective, evidence based use of medicines. It aims to increase GP provision of medication reviews involving the patient or their carer. The main target is review of patients on ten or more medicines to reduce the level of inappropriate polypharmacy.

252 out of 261 practices have now opted in to the polypharmacy LES which will provide reviews for approximately 33,000 patients this year. Practices will use Read codes for patients who receive a polypharmacy LES review. This information will appear on GP referral letters and the Key Information Summaries to alert clinicians in other care settings that a review has taken place and that medicines may have been adjusted with full patient engagement.

Next steps include

- Raising awareness across all settings of the medication review activity in primary care so that decisions made with the patients to adjust medicines are not 'undone' during acute admission or outpatient attendance.
- Raising awareness of the need to adopt a mindful prescribing attitude when prescribing specialist medicines recognising that even one or two (more) medicines may not be appropriate for your patient.
- Raising awareness of the role that all prescribers have to play in undertaking holistic medication review, sharing best practice and quality tools to support the review process.

So… before you add on just one more drug, take a mindful prescribing approach and think about how your patient manages (or doesn't manage) what they are already prescribed.

For further information please contact Graeme MacPhee, Consultant Physician or Noreen Downes, Lead Clinical Pharmacist.

New drug: mirabegron

Mirabegron has been added to the total Formulary for symptomatic treatment of urgency, increased micturition frequency and/or urgency incontinence in overactive bladder (OAB) syndrome.

It is the first of a new therapeutic class of medicine, thought to enhance urine storage by stimulating beta 3-adrenoceptors in the bladder. The Preferred List choices (oxybutynin, solifenacin and tolterodine) should be tried first.

The evidence of efficacy and safety comes from a series of short clinical trials showing a modest reduction in the mean number of micturitions and incontinence episodes per 24 hours compared to placebo. There is no direct comparative data but an indirect comparison concluded similarity in efficacy to most other options.

The different mechanism of action results in a different adverse effect profile which includes a lower incidence of dry mouth. This is often a limitation with antimuscarinic agents, and may give mirabegron an advantage in these patients.

New drug: linaclotide

Linaclotide has been added to the Total Formulary after being accepted by SMC for restricted use in patients with moderate to severe irritable bowel syndrome with constipation (IBS-C).

A diagnosis of IBS-C requires abdominal discomfort or pain with ≥2 of the following features for ≥12 weeks:

- relief with defecation
- onset associated with a change in frequency of stool, and
- onset associated with a change in form [appearance] of stool.

This medicine should be reserved for patients who have not responded adequately to or cannot tolerate all other suitable options including laxatives, antispasmodics and off-label use of antidepressants.

Almost half the patients in the trial did not fully respond to treatment so it is very important to assess the need for continued treatment. The SmPC advises that patients who have not experienced improvement in their symptoms after 4 weeks should be re-examined and the benefit of continued treatment reconsidered.

New guidelines

The clinical guidelines below were posted onto Staffnet.

- Guideline for the use of rivaroxaban for the treatment of DVT or PE
- Management of invasive procedures for patients receiving:
- Rivaroxaban
- Apixaban
- Dabigatran

What difference do yellow cards make?

The Yellow Card Scheme acts as an early warning system for the identification of previously unrecognised adverse reactions. It also provides valuable information on recognised adverse reactions, allowing the MHRA to identify and refine the understanding of risk factors that may affect the clinical management of patients. The value of the scheme has been demonstrated many times and it has helped to identify numerous important safety issues. The MHRA have published information here which shows safety issues which Yellow Card reports have helped to identify. Some examples of changes made are shown below. Many of these, and the benefits of the yellow card system, have been reported in PostScript.

Sign up for Drug Safety Update on the MHRA website.

Date	Medicine	Adverse Reaction	Resulting action or advice
Aug 2012	Simvastatin	Drug interactions	Updated warnings and contraindications with maximum dose recommendations
Jun 2012	Tacrolimus oral products	Toxicity and graft rejection due to switching	Recommendations for routine brand prescribing and dispensing for oral tacrolimus products
Apr 2012	PPIs	Hypomagnesaemia	Long-term use warnings and measurement of magnesium levels

Safety update: Strontium ranelate

In April 2013, MHRA issued a drug safety alert on strontium ranelate. A review raised concern about its cardiovascular safety beyond the already recognised risk of venous thromboembolism. An analysis of RCT data has identified an increased risk of serious cardiac disorders, including myocardial infarction. For advice on the ongoing management of patients who require a change in therapy, contact the falls pharmacy team on 0141 201 5313.

Spiriva Respimat®: Removed from Formulary

The MHRA has reported potential cardiac adverse effects with this inhaler device. A 2012 meta-analysis indicated that it was associated with a universally increased risk of overall death compared with placebo, Spiriva HandiHaler®, long-acting beta2 agonists and long-acting beta2 agonists plus inhaled corticosteroids in combination. The risk of cardiovascular death was greater in patients with severe COPD and at higher dose. The product has been removed from the GGC Formulary but has not been withdrawn.

Primary care implications

Patients prescribed Spiriva Respimat should be reviewed and other treatments considered at the next opportunity.

www.ggcprescribing.org.uk

Contact us:
postscript@ggc.scot.nhs.uk

0141 201 5348