PostScRxipt – PrimaRxy Care

NHS Greater Glasgow and Clyde

APRIL 2011

USE OF VACCINE SUBJECT TO TEMPERATURE STORAGE PROBLEMS:

Vaccines are 'thermolabile' medicines. This is reflected in a vaccine's Summary of Product Characteristics (SPC) or product licence, which states that vaccines should be stored at 2^0 to 8^0C.

For potentially heat damaged vaccines e.g. after a fridge breakdown or power failure, Pharmacy Public Health assess whether the vaccine remains suitable for use. Previously these vaccines could no longer be administered under a Patient Group Direction (PGD) however recent MHRA advice allows this, subject to good clinical governance procedures.

All NHS GG&C vaccines PGDs will be amended to reflect new MHRA guidance with the wording "Vaccine subject to excursion from the cold chain may continue to be used if it has been risk assessed and advised accordingly under the NHS GG& C Pharmacy Public (PPH) Health Standard Operating Procedure (SOP)."

Key points:

- **Vaccines must be stored at 2-8^{0}C**
- **Any temperature problems must be reported immediately to PPH to assess whether the vaccines remain suitable for use**
- PPH will issue a report to the practice with recommendations regarding continued use of vaccine for clinical governance purposes.
- The potential for continued use of vaccine under a PGD is a new development.
- Amendment will be made to NHS GG&C vaccine PGDs to reflect this.

Further information on storage of vaccines can be obtained from http://www.nhsggc.org.uk/content/default.asp?page=s1540_2 which details changes and practical points.

CHANGE IN ADVICE REGARDING ADDITIONAL CONTRACEPTION FOR WOMEN TAKING ANTIBIOTICS:

In their latest guidance on Drug Interactions with Hormonal Contraception, the Royal College of Obstetricians and Gynaecologists no longer advises that additional precautions are required when using combined hormonal contraception (CHC) with antibiotics that are non enzyme inducers. i.e. most commonly used choices. The advice to use additional precautions does however apply if vomiting or diarrhoea occurs as a result of the antibiotic or underlying illness.

For patients on enzyme inducing agents new contraceptive advice has been issued that takes into consideration the length of treatment with the inducing agent.

ANAPHYLAXIS:

A guideline for the adrenaline auto-injector has been developed by the Paediatric allergy service and is available on the above hyperlink.

A GGC adult guideline based on this is currently in development.

MHRA ADVICE ON HERBAL FLOS LONICERAE:

Advice to consumers not to use Herbal Flos Lonicerae capsules (Herbal Xenicol

The MHRA is advising consumers not to use the above unlicensed herbal product due to concerns about possible side effects. Anyone currently using this product should stop taking it and consult their healthcare professional immediately.

Promoted as a natural herbal product for weight loss, Herbal Flos Lonicerae was brought to the MHRA's attention when one patient was hospitalised and several other patients reported suffering a range of side affects including palpitations, severe gastritis/abdominal pain and insomnia after using the product.

The product has been tested and found to contain **sibutramine at a level twice those found in prescription dosages.**

Sibutramine was a Prescription Only Medicine (POM), however its marketing authorisation was withdrawn in January 2010 following a warning from the European Medicines Agency that it increased the risk of heart attacks and strokes.

ATYPICAL (SECOND GENERATION) ANTIPSYCHOTICS:

The MHRA recently issued advice on the use of atypical antipsychotics. GGC guidance is currently in preparation and will be published when available.

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.

Given that people with schizophrenia are at an increased baseline risk of cardiovascular morbidity and mortality, the following are needed during atypical antipsychotic treatment to support the physical health of the patient in the long term:

- early identification of modifiable risk factors
- monitoring for further development of metabolic adverse effects
- management of metabolic adverse effects.

EU DIRECTIVE ON TRADITIONAL HERBAL MEDICINAL PRODUCTS:

A recent issue of the Drug and Therapeutics Bulletin (DTB) featured an article on the new EU Directive on traditional herbal medicinal products, which comes into force in the UK on 30th April 2011.

The Directive states that no traditional herbal medicinal product shall be placed on the market unless a traditional herbal registration (THR) has been granted by the licensing authority. Apart from products with a THR, the only other manufactured herbal medical products that will be legally allowed will be those with a full marketing authorisation.

Although herbal practitioners will still be able to supply unlicensed herbal medicines direct to their patients, a statutory register for these practitioners has been called for, the intention being that only registered practitioners will be able to supply such medicines.

SELF MONITORING OF BLOOD GLUCOSE:

The National Electronic Library for Medicines NeLM have highlighted information on this topic by referring to NICE clinical guideline 66 (partial update 87) which states that:

Self Monitoring of blood glucose (SMBG) should only be offered **as an integral part of diabetes self-management education**, and should be available to:

- Those on insulin treatment
- Those on oral glucose lowering medications who may be at risk of hypoglycaemia
- Assess the impact of lifestyle and medication changes on blood glucose control
- Monitor changes during acute inter current illness
- Ensure safety during activities such as driving

Therefore patients with type 2 diabetes who are controlled by diet, metformin or glitazones should not routinely be offered SMBG.

Please refer to GGC guidance on the topic.

NEW LEARNING RESOURCE- UNDERSTANDING AND USING DRUG SAFETY INFORMATION:

The MHRA has introduced a new learning package on pharmacovigilance for clinical practitioners. Doctors, nurses, and pharmacists all stand to benefit from the pharmacovigilance module.

This self-directed learning resource covers:

- how information on adverse effects of medicines is produced
- how to seek up to date and authoritative information on the risk of individual medicines,
- how to fill out a Yellow Card and contribute to improving our knowledge about possible harms.

With time, more learning materials will be added to the MHRA's Learning Centre and existing materials will be reviewed and updated.

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