NHS
South East Staffordshire and Seisdon Peninsula
Clinical Commissioning Group

NHS
East Staffordshire
Clinical Commissioning Group

NHS
Stafford and Surrounds
Clinical Commissioning Group

NHS
Cannock Chase
Clinical Commissioning Group

Medicines Optimisation Team Prescribing Audit
Simple cost-effective medication switches

Aim

To ensure cost effective choices of medicines across South Staffordshire. The Joint South Staffordshire QIPP Group will consider any changes to suitable alternative lower cost acquisition medicines.[2,3]

Rationale

Due to recent changes in Information Governance legislation, under section 251 (NHS RHA 2013)[1], CCG employees are not authorised to review patient identifiable data unless it is for direct patient care. Therefore the Medicines Optimisation Teams is unable to extract and review patient data relating to "simple switches". The CCG has seconded the Medicines Optimisation Team to practices to enable them to undertake these switches whilst complying with legislation.

This generic Standard Operating Procedure has been produced to outline responsibilities regarding undertaking these "simple switches".

Definition of "Simple switches" are : (this list is not exhaustive)

- Switching branded medicines to generic equivalents
- Switching generic medicines to branded equivalents
- Switching tablets to capsules of the same drug
- Switching capsules to tablets of the same drug
- Switching to a high strength of the same drug – dose optimisation
- Switching to a lower strength of the same drug – dose optimisation
- Switching same drug to a different formulation e.g. diclofenac potassium to diclofenac sodium

Anything out of the scope of the above is classed as a more complex prescribing audit and would have a separate Standard Operating Procedure.

Examples of more complex audits (this list is not exhaustive)

- Switching drugs within the same therapeutic class
- Switching drugs from standard preparation to MR and vice versa
- The discontinuation of drugs
- Switching drugs to the correct formulary choice.

Version 4 revised April 2015 Authored by East Staffs CCG To be revised April 2017
Joint Medicines Optimisation Group Approved:

G:\East Locality 2\ESCCG_Medicines Management (New)\Admin\Minutes and Submissions to Meetings\PA & Tech\Approved SOPs\SOPs to Lesley\Simple switches Standard Operating Procedures.doc

Roles and Responsibilities

The practice manager (or another member of practice staff) is responsible for ensuring the member of the Medicines Optimisation Team undertaking the work is given appropriate resource and sufficient access rights in order to undertake the medication switch and generation of patient letter. They also need to ensure that the Medicines Optimisation Team member signs a confidentiality agreement (as per practice policy).

The Medicines Optimisation Team :

- Undertakes a search of patients for simple switches not in the list that require "special consideration" (see further below for list) and
- Presents this as a data collection form for the nominated GP, to check patients are still appropriate to switch) together with an action sheet (for the nominated GP to sign off).

The practice pharmacist is to clinically check audit work undertaken by the prescribing support technician of simple switches that require "special consideration" before presenting to the nominated GP for final check and authorisation.

The nominated GP authorises each individual switch to be carried out in the practice (working toward a TWO working week turnaround).

N.B Practices can adapt this Standard Operating Procedure for their own use where input done Medicines Optimisation Team is no required

Audit criteria

- Patient ID
- Patient Surname
- Patient Forename
- Registered / usual /prescribing GP [as per practice]
- Patient Age
- Current repeat of the particular medicine under review
- Any relevant examinations or blood result & date
- Current medication for gastro protective agent (PPI, H2RA or misoprostol)
- Past medication for the suggested alternative medications, reason stopped and date stopped
- Pharmacist recommendations
- GP action/recommendations

Exclude the following patients:

- *Who have received suggested alternative medication(s) previously but stopped it due to poor response or not tolerated.*
-
- *Patients that have recorded allergies for example soya, peanut.*
- *Who have declined a switch to the suggested alternative medication medication(s) previously*
- *If there is any uncertainty about whether a patient is suitable for switching to the suggested alternative medication, e.g. Patient is visually impaired and lives alone, language barrier etc.*
- *The authorising GP (or patient's own GP) feels that the patient is unsuitable for a reason not documented in the patient notes.*

Document in patient notes if they are not suitable and the reason if not already detailed together with a read code, e.g. drug declined by patient (8B3O).

Method

Step 1: Medicines Optimisation Technician /pharmacist performs initial search in accordance with the audit criteria.

Step 2: Medicines Optimisation Pharmacist clinically reviews patients highlighted in search and recommends actions for the GP.

Step 3: Medicines Optimisation Team gives completed audit to GP practice team to either action or to be signed off to be actioned by Medicines Optimisation Team.

Step 4: Medicines Optimisation Team performs changes if required by GP practices.

Step 5: Interventions captured and reported

Notes for Practice Pharmacist:

Reference:

1) National Health Service Health Research Authority (2013). What is Section 251? Available online: http://www.hra.nhs.uk/hra-confidentiality-advisory-group/what-is-section-251/ (Date accessed: August 2013). NHS HRA
2) Medicines and Healthcare products Regulatory Agency. Patient Information Leaflet. How does licensing and authorisation work?
3) Generics Manufacturers Association. Generic medication FAQ

Appendices

1a Patient switch letter- Sept 2014
2a Generic FAQ British Generic Manufacturers Association

Signature	Name	Title	Date
	Mrs Susan Bamford	Head of Medicine Optimisation	11.12.15
	Mrs Judith Crosse	East Staffs CCG Prescribing Lead	9.12.15

Important Information about a Change in Your Repeat Medication

Dear

We are currently reviewing the medicines that we prescribe with a view to using the most cost effective medicines.

Therefore we have felt it was appropriate to change your
XXXXXXXXXXXX

to

XXXXXXXXXXXX

These are both exactly the same drug and should be taken exactly in the same way.

To avoid waste, please carry on taking your **<<insert drug A name here>>** until you need to order your next prescription. As this change will be activated when you request your next repeat prescription from the practice.

Even though the medicine may look slightly different you can be assured that it is as safe and effective as your usual prescription. You should not notice any change or new side effects.

Please do not hesitate to contact the practice if you would like more information or discuss this change.
Yours sincerely,

... .

Generic medication: Frequently Asked Questions (FAQs)

Produced by the British Generics Manufacturers Association

What exactly is a generic medicine?

A generic medicine contains the same active medicinal substance as an originator pharmaceutical product. Because it acts in the same way in the human body, it is interchangeable with the originator product. Generic medicines are launched when the originator product's patent has expired.

In the EU a generic medicine is identified either by a company name plus its International Non-proprietary Name (INN), or by its own invented brand name. Generic medicines are increasingly used by general practitioners, specialists, and hospitals as equally effective alternatives to higher-priced originator pharmaceuticals.

Is there a difference between generic medicines and originator medicines?

Generic medicines contain the same active ingredients as originator pharmaceuticals and act in the same way on patients. Equivalent generic medicines may contain different non-active ingredients (such as colourings, starches, sugars, etc) and they may differ in size, colour or shape, but none of these have any impact on the therapeutic effect, i.e., the way they work in the patient's body. In some cases, the active ingredient in generics and originators may also differ in salts and esters. And just as when originators modify the non-active ingredients, salts or esters in their products, these differences must not affect the therapeutic equivalence between the different products.

Who checks the quality, safety and efficacy of a generic medicine?

In the EU, all medicines, originator or generic, have to be authorised before they may be produced and distributed to patients. The medicines agency of each EU Member States, or the European Medicines Agency (EMEA) in London, does this by assessing the quality, safety and efficacy of the medicine. To receive market approval, a generic medicine must be 'bioequivalent' to the originator product - i.e., it must work in essentially the same way in the patient's body. Generic medicines are subject to the same European procedures as originator products and are carefully scrutinised by the competent authority.

Are generics really as good as their originals?

Yes. Generic medicines must comply with exactly the same standards of quality, safety and efficacy as all medicinal products. They are produced in inspected plants under what is known as 'GMP' or 'Good Manufacturing Practice'. And, just like originator products, once a generic medicine is sold on the market, it must be monitored by the manufacturer in case any adverse reactions are reported.

Are generic medicines really less expensive?

Yes and the savings are significant. Generic medicines cost 20% to 90% less than the original price of their brand-name equivalents. In addition, competition from rival generic products forces originators to reduce their own prices after - or sometimes before - patent expiry.

How do generic medicines benefit patients and the national healthcare systems?

When we use generic medicines, our national healthcare systems save considerable sums of money - many billions of Euros. This frees up money to pay for other, more expensive treatments and services that patients need, including funding the research into new treatments and medicines.

Generic competition also acts as an important stimulus for originator companies to focus on new research to create new patented medicines.