Barnsley Hospital NHS
NHS Foundation Trust

Position Statement on the MHRA Drug Safety Update:

(Spironolactone and renin angiotensin system drugs in heart failure: risk of potentially fatal hyperkalaemia)

The Drug Safety Update published on 17th February 2016 highlighted the risks of hyperkalaemia with concomitant use of spironolactone and renin-angiotensin system drugs, and made the following recommendations:

- Concomitant use of spironolactone with ACEi or ARB is not routinely recommended because of the risks of severe hyperkalaemia, particularly in patients with marked renal impairment.
- Use the lowest effective doses of spironolactone and ACEi or ARB if coadministration is considered essential.
- Regularly monitor serum potassium levels and renal function
- Interrupt or discontinue treatment in the event of hyperkalaemia
- Suspected adverse reactions should be reported on a Yellow Card.

In fact, the concomitant use of spironolactone and ACEI or ARB is routinely recommended in the treatment of heart failure with reduced left ventricular ejection fraction, and is an important evidence based step in the management of these patients to reduce hospitalisations and mortality.

Currently available guidelines for the management of heart failure with reduced left ventricular ejection fraction include clear recommendations on monitoring necessary to minimise the risks of hyperkalaemia. Hence, in line with the British Society for Heart Failure's response to this drug safety update, the Cardiologists would like to make the following recommendations:

- Routine monitoring of renal function and serum potassium is recommended in ALL patients taking a combination of spironolactone/eplerenone plus ACEI or ARB.
- Routine monitoring of U&E's is recommended at baseline and 1 - 2 weeks following initiation or any dose changes. Recheck at 1, 3 and 6 months after achieving a maintenance dose and at least 6 monthly thereafter.
- **Elderly patients and those with pre-existing renal dysfunction are at increased risk of hyperkalaemia and may warrant an increase in the frequency of monitoring to every 3 months.**
- For patients receiving 12.5mg doses, care is advised in ensuring that the patient is receiving the intended dose (since halving tablets may be difficult for patients with poor dexterity).

<u>What treatment is NOT appropriate?</u>

- Patients should not be given spironolactone or eplerenone if their eGFR is less than 30mls/min/1.73m^2
- Treatment with spironolactone, eplerenone, ACEi or ARB should be stopped or interrupted if the patient has a potassium level >5mmol/L
- Triple therapy with spironolactone or eplerenone, plus ACEi **and** ARB is not appropriate.

<u>References:</u>

1. MHRA Drug Safety Update, 17th February 2016: Spironolactone and renin angiotensin system drugs in heart failure: risk of potentially fatal hyperkalaemia. Accessed online via www.gov.uk/drug-safety-update/spironolactone-and-renin-angiotensin-system-drugs-in-heart-faiure-risk-of-potentially-fatal-hyperkalaemia
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4. Monitoring ACE inhibitor treatment in primary care, accessed online via www.gpnotebook.co.uk
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