Welcome to the July edition of the Area Drug and Therapeutics Committee (ADTC) Collaborative newsletter. In this edition, we'd like to share with you some of our current work with ADTCs.

Previous editions of our newsletters are still available on the Healthcare Improvement Scotland website here.

If you have any comments on the new look or if you have issues viewing the newsletter, please contact us at hcis.adtc-collaborative@nhs.net

Valproate in children, young people and adults: summary of NICE guidance and safety advice

A useful summary of NICE guidance and safety advice on Valproate in children, young people and adults was published in March.

The guidance can also be found in the Tools and Resources tab of Clinical Guideline 137 CG137: Epilepsies: diagnosis and management.”

The ADTCC wish to highlight that the MHRA have published a Drug Safety Update on the Valproate Pregnancy Prevention Programme. This is available here.

The update highlights:
the feedback from a patient survey indicating further action is required to comply with the goals of the Pregnancy Prevention Programme,
changes that have been made to the Annual Risk Acknowledgement form and
resources that are available to support healthcare professionals.

ADTCs may find it useful to consider this update and communicate this to relevant healthcare professionals if considered appropriate.

Pre-HTA Free of Charge Stock scheme Process

Guidance on the national process for the once for Scotland review and implementation of pre-health technology assessment (HTA) Free of Charge (FOC) Stock schemes has been added to the ADTCC website.

Going forward, details of schemes reviewed and implemented will be included in the PAS register which is shared with Boards on a monthly basis. For support in relation to this process or to give any comments on the process please contact the PASAG Secretariat at nss.np-pasag@nhs.net

Prescribing following Private Consultation – NHS Tayside

NHS Tayside joined us at our ADTCC webex in March to present their newly developed Policy for Prescribing following Private Consultation.

“This is intended to support prescribers in their decision making when they receive a request to prescribe from non-NHS healthcare providers. It outlines a number of possible options for on-going prescribing as well as suggestions for early discussion with patients when they are considering seeking private treatment.”

(Hazel Steele, Lead Pharmacist, Prescribing Support and Jill Nowell, Head of Prescribing Support Unit, at Kings Cross Hospital, Dundee)
DOAC Alert Card and Booklet

Colleagues from NHS Greater Glasgow and Clyde joined the ADTCC webex in March to share their work in developing patient resources including an Alert Card and Booklet for Direct Oral Anticoagulant (DOAC) therapy. This work was well received and has been shared with the Scottish Patient Safety Programme for consideration for their future work programme.

Electronic versions of the card and booklet can be found at http://www.ggcmedicines.org.uk/DOACS/

Presentation available on request – please email hcis.adtc-collaborative@nhs.net

(Cristina Coelho, lead pharmacist, Clinical Effectiveness Medicines Information, NHS GREATER GLASGOW AND CLYDE)

Extending on the core benefits of Hospital Electronic Prescribing

Richard Cottrell gave a presentation at the ADTCC webex, giving an overview on some of the ongoing work being done by NHS Ayrshire & Arran. The HEPMA team have been working with their Hospital ePrescribing system and associated data to deliver additional benefits beyond those associated with core ePrescribing. This included details on:

- Easy access to hospital prescribing & administration information for primary care
- Tools developed to support clinicians during ward rounds
- Discharge letter whiteboards to streamline the pharmacy discharge process
- Automated sharing of discharge information with community pharmacies where relevant
- ePrescribing data driven whiteboard displays, driving dramatic improvements in the timely administration of Parkinson’s medicines
- Automated referrals to primary care pharmacy teams
- Tool to assist in poly-pharmacy reviews within the hospital setting
These tools have been developed and assessed locally within NHS Ayrshire & Arran and are available for sharing with other NHS Scotland ePrescribing sites either now or in the near future.

Presentation available on request – please email hcis.adtc-collaborative@nhs.net

(Richard Cottrell, Senior Clinical/ePrescribing Pharmacist, NHS Ayrshire & Arran)

**New ultra-orphan pathway**

The new ultra-orphan pathway is now fully operational. This new approach allows promising new medicines for extremely rare conditions to be made available more quickly to patients in Scotland. SMC will continue to assess medicines validated as ultra-orphan at the point of licensing but the Committee will no longer make a decision on access at this initial stage. After this assessment, provided pharmaceutical companies offer their medicines at a discounted price, the medicine will be made available for a three year period during which further data on its clinical benefits will be collected. After the three years, the SMC will assess all the available evidence, including experience of use in Scottish patients, and make a final decision on routine availability.

More information can be found in the [Scottish Government’s guidance on the new approach](#) and also on the [SMC webpage](#).

**Nusinersen (Spinraza)** for the treatment of spinal muscular atrophy (SMA) is the first medicine to be available through the new pathway. Nusinersen was accepted for routine use in patients with SMA type 1 in May 2018. It was validated as an ultra-orphan by SMC in December 2018 and can now also be prescribed for patients with types 2 and 3 SMA under the ultra-orphan pathway through a phased approach beginning with children before moving to use in adults.

SMC has recently received the first submission for a validated ultra-orphan medicine, **voretigene neparvovec (Luxterna)** for the treatment of vision loss due to inherited retinal dystrophy caused by confirmed biallelic RPE65 mutations. The SMC Ultra-orphan Medicine Assessment Report (UMAR) for voretigene is due to be published at the end of the year.

(Jan Jones, Principal Pharmacist, SMC, Healthcare Improvement Scotland)
Ultra-Orphan Pathway

UO validation outcome in confidence to Boards

PAS

Company submission for initial assessment (UO framework)

NDC

SMC

UO assessment report (UO framework)

Company submission for reassessment (UO framework)

NDC

SMC

SMC advice
- Accepted
- Restricted
- Not recommended

PAS – Patient Access Scheme
NP – National Procurement
PACE – Patient and Clinician Engagement meeting

Opportunity for early Engagement with SMC/NP

Key uncertainties

Evidence generation – ‘Lived experience’

Data collection plan (company led)

Stage 1
8 weeks

Stage 2
≈18 weeks

Stage 3
5
Data collection ≤3 years

Stage 4
≈22 weeks

Appendix 2
PACS Tier 2/National Review Panel Data Analysis

“PACS Tier 2 and the National Review Panel (NRP) was established in June 2018 with the policy intent to increase the access to medicines that are not routinely available in Scotland. The following data analysis is taken from health board submissions to the Scottish Government over this time.

In summary a total of 258 PACS2 requests had been considered with an overall acceptance of 90.3% with a single national review being heard. A number of medicines that were considered under PACS2 have subsequently been accepted by the Scottish Medicines Consortium (SMC) for use representing 43% of medicines that had been not been agreed at local review.

This data analysis has been shared within the ADTC Collaborative for information and is included in the current Scottish Government review (Peer Approved Clinical System (Tier Two: Six Month Review and Next Steps, 26th June 2019)”

Presentation available on request – please email hcis.adtc-collaborative@nhs.net

(Stephen Bowhay, Clinical Lead for the PACS Tier 2 National Review Panel, Healthcare Improvement Scotland)

ADTC Collaborative Team news

We currently hold regular webexes to provide updates, share information and good working practice. However, from January 2020 we will be using Skype for Business instead. Details on how to join meetings using this method can be found here. Everyone is welcome. Future dates are provided below:

<table>
<thead>
<tr>
<th>ADTC webex dates</th>
<th>Formulary Network Scotland webex dates</th>
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<tbody>
<tr>
<td>27th August 2019</td>
<td>3rd September 2019</td>
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<tr>
<td>6th November 2019</td>
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