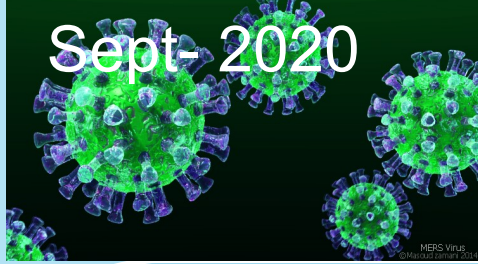


Sept- 2020



PRIMUS NEWSLETTER

Primary care **M**anagement of lower **U**rinary tract **S**ymptoms:

COVID-19 Changes to protocol

Addition of medication review for recruitment pathways - GP Practices will run read codes, based on uroselective medications that patients are currently prescribed. Patients currently prescribed these medications will be invited by the practice for review. If patients report bothersome symptoms, you can explore whether study entry would be suitable.

Consent and Study Visit Part A can take place remotely: Due to the current situation with COVID-19, signing of consent will be a flexible process. Patients can receive, sign and send back the consent form electronically or via post. We will also accept verbal consent for Study Visit Part A (whereby the research nurse/HCA will go through each statement and confirm consent verbally, signing off on their behalf). However, these patients will then need to re-confirm and sign off consent when attending for their urodynamics appointment (you will need to let the urodynamic nurse know if this is the case). *Sites should only use consent forms (triplicate/electronic) with Pre-Populated Patient ID Number on the top of the consent form. You can request these from PrimUS@cardiff.ac.uk.*

Electronic Study Packs and Site Files: All localised GP and Mail Out Packs have been uploaded onto the WIKI page. Potential Participant Letter can be pre-populated and the study packs can be sent to potential patients electronically. All documentation that can be filed in your site file is available to download from WIKI. Please use the current documents list to ensure you are using correct versions.

Urodynamics

- UDS nurses will complete a risk assessment with every patient prior to booking patients into clinic
- UDS nurses will have the appropriate PPE
- Patients will wear a mask
- UDS nurses may have to find out the air changes per hour from the practice manager

This months issue— Coronavirus

- COVID-19 Changes to protocol
- Study restart
- Urodynamics
- SAE Reporting

Study Restart

We have received Ethical Approval and R&D/HRA Approval to RESTART. If you are able to RESTART recruitment for PrimUS, please confirm with the PRIMUS INBOX, so that we can maintain oversight of GP Practices resuming activity.

SAE Reporting

Patients who are already on the study and have been awaiting urodynamics may have experienced unrelated SAEs due to being hospitalised for COVID-19 (or other). Please ask all existing patients whether they have been hospitalised and then please report using the SAE Report Form or call the study manager to discuss this.

You may not be made aware of an SAE until after the SAE has resolved, this is absolutely okay, you just need to report it as soon as you are made aware of it.

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