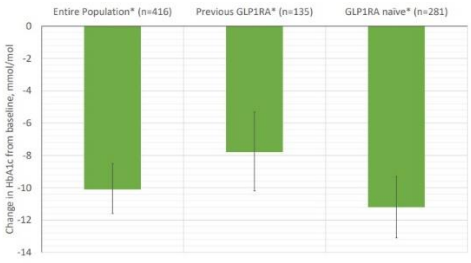

Association of British Clinical Diabetologists

The ABCD Nationwide Oral Semaglutide Audit - Objectives

ABCD is setting up a nationwide audit of oral semaglutide (Rybelsus) in real clinical use in the UK. The aim will be principally to ascertain whether the experience in real clinical use matches the data from phase 3 clinical trials. Clinicians using oral semaglutide will be invited to submit the data that they routinely collect as they monitor the progress of their patients (HbA1c, weight etc) to the nationwide audit. Based on technologies used in previous such audits, a secure, on-line, encrypted, IT tool is being developed to make this process as easy and user friendly as possible. It will also facilitate easy analysis of locally collected data by the local clinicians. ABCD hopes to gain insight into both the safety and efficacy of semaglutide. ABCD hopes that the data from the nationwide audit will inform future practice and guidelines.

From the data submitted in the audit ABCD hopes it might be able to quantify and analyse in detail:

- How much ***weight loss*** occurs with oral semaglutide in real clinical use. Is weight loss durable over time?
- How much ***HbA1c reduction*** occurs with oral semaglutide in real clinical use. Is this reduction durable over time in the real world?
- What percentage of patients achieve both ***HbA1c reduction*** and ***weight loss*** with oral semaglutide as opposed to just one or neither of these parameters?
- In our liraglutide audit the efficacy appeared to be less with ***duration of diabetes*** – does this also apply to oral semaglutide?
- What is the real world experience of ***progression to insulin treatment*** in patients treated with oral semaglutide?
- What is the impact on ***lipids*** of oral semaglutide in real clinical use?
- What is the impact on alanine aminotransferase (ALT) of oral semaglutide – through weight loss and impact on lipids might semaglutide improve non-alcoholic fatty liver disease (***NAFLD***)?
- Who are the patients ***who respond*** especially well to oral semaglutide in real clinical use – does it relate to initial HbA1c, weight, body mass index, duration of diabetes, initial age or sex, ethnicity or particular other medications being used etc. Is it possible to predict the patients who are more likely to respond to oral semaglutide?
- Similarly, who are the patients ***who don't respond*** to oral semaglutide?

- What percentage of patients using oral semaglutide have a ***history of cardiovascular disease***? How much cardiovascular benefit are we likely bringing to our patients if we consider the benefits found in the SUSTAIN 6 and PIONEER 6 trials? How does that benefit compare with that predicted by the UKPDS risk engine?
- What are the ***side effects***? Oral semaglutide may be more effective than previous GLP1 receptor agonists – are the side effects worse as a result of a more potent medication?
- If there are ***safety issues*** with oral semaglutide which may come out in due course, we hope to get some forewarning of these now through pooling the national experience.
- To what extent does oral semaglutide allow avoidance of insulin and continuation in their jobs for ***professional drivers***, or regaining of their jobs for such workers who have lost them through insulin?
- What impact does oral semaglutide have on ***diabetic retinopathy*** as assessed in the NHS national diabetic retinopathy screening programme? Does it get worse, better or stay the same after oral semaglutide? Does the impact depend on the initial state of retinopathy at commencement of treatment? What is the relationship between the size of the HbA1c fall and the impact on retinopathy?
- If patients ***switch to oral semaglutide from another GLP-1 receptor agonist*** is there further reduction in HbA1c and weight?
- What percentage of patients ***cannot tolerate oral semaglutide*** in real clinical use?
- Is the ***clinical efficacy*** of oral semaglutide sustained in real clinical use? Does the weight loss continue with time or does it plateau off?
- Are there benefits, or otherwise, in combining other medications such as ***SGLT2 inhibitors*** and/or ***thiazolidinediones*** and oral semaglutide

ABCD, June 2021