



The ABCD Nationwide Dapagliflozin Audit - Objectives

Using modern technologies on the NHS N3 computer network to facilitate easy gathering of anonymised data, ABCD is setting up a nationwide audit of dapagliflozin (Forxiga) in real clinical use in the UK. The aim will be to ascertain whether the experience in real clinical use matches the data from phase 3 clinical trials. Clinicians using dapagliflozin will be invited to submit the data that they routinely collect as they monitor the progress of their patients (HbA1c, weight, side effects etc) to the nationwide audit. An IT tool has been developed on the NHS computer network, N3, 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 dapagliflozin. 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 **HbA1c reduction** occurs with dapagliflozin in real clinical use. Is this reduction durable over time in the real world?
- How much **weight loss** occurs with dapagliflozin in real clinical use. Is weight loss durable over time?
- What is the impact on **blood pressure** with dapagliflozin in real clinical use.
- What is the real world experience of **progression to insulin treatment** in patients treated with dapagliflozin? Is this delayed?
- What is the impact on **lipids** of dapagliflozin in real clinical use.
- What is the impact on alanine aminotransferase (ALT) of dapagliflozin – through weight loss and impact on lipids might dapagliflozin improve non-alcoholic fatty liver disease (**NAFLD**).
- Who are the patients **who respond** especially well to dapagliflozin in real clinical use – does it relate to initial HbA1c, weight, body mass index, duration of diabetes, initial age or sex, or particular other medications being used etc. Is it possible to predict the patients who are more likely to respond to dapagliflozin.
- Similarly, who are the patients **who don't respond** to dapagliflozin?
- What are the **side effects**? They seem to be relatively minor and tolerable in the clinical trials but is that also the case in real practice? Are there any important side effects that have not yet been identified?
- If there are **safety issues** with dapagliflozin 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 dapagliflozin 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 is the size of the problem of **hypoglycaemia** with dapagliflozin and insulin, or dapagliflozin and sulphonylureas. Is there a problem of worsening hyperglycaemia if insulin is reduced and dapagliflozin started? Are there guidelines that can be deduced from the nationwide experience with regard to how to add dapagliflozin to insulin and how to add dapagliflozin to sulphonylureas without inducing hypoglycaemia or hyperglycaemia.
- What percentage of patients **cannot tolerate dapagliflozin** in real clinical use?
- Is the clinical efficacy of dapagliflozin sustained in real clinical use? Does the weight loss continue with time or does it plateau off?