A framework is needed to guide the publication of lay summaries in medical journals

1. Why was this research needed?
There is a growing demand for lay summaries of clinical trial results, but very limited guidance exists for the preparation of lay summaries for publication in peer-reviewed medical journals.

2. What did we learn from this investigation?
A clearer process for creating a lay summary, including ideal timings alongside traditional manuscript preparation, needs to be established before embarking on content development.

3. What are the recommendations for the future?
Development of a framework is important to provide guidance to writers in preparing lay summaries, including training and use of examples, templates and a checklist.

### Background and Objectives
- Better health literacy plays an important role in improving patient outcomes in part by empowering patients to make informed decisions and being active in their own healthcare.
- Lay summaries can generate additional interest in the results of medical research in non-specialist language.
- In 2011 and 2013, a public lay requirement in the European Union for a lay summary of a clinical study to accompany the official clinical trial data was withdrawn.
- However, published journals are an important access point for the public in the Internet age, and lay summaries will increase accessibility of this material.
- While there are various guides to writing lay summaries, there is limited guidance for the preparation of lay summaries for peer-reviewed medical journals.

### Research Design and Methods
- A general literature search on PubMed and Google was performed to establish best available guidance using several terms: "layperson"-patient summary, and "patient communications".
- Google was also used to gather information on communicating to patients in the context of clinical trial data, including lay summary guidelines.

### Results
Patient Lay Summary Publishing Framework Development
- Recommendations from the senior publication and patient engagement expert review of the initial draft framework included the following:
  - Options for making the lay summary open-access should be discussed with the journal.
  - Consideration should be given to including a lay reviewer when developing the summary.
  - Priority should be given to trials/participants in the patientACCESS and patientWORM schemes.
  - Medical writers should be consulted for any auditing and training requirements.

### Discussion and Conclusions
- In this clinical research study was designed to find out if the drug, tabligliflozin (GLUCOEZE), could reduce the risk of fatal cardiovascular events and other CV-related side effects in people with type 2 diabetes and heart or vascular conditions.
- To find out whether:
  - Participants taking SGLT2 inhibitors may develop other CV-related side effects.

### References