National Institute for Health and Clinical Excellence

Ranibizumab for the treatment of macular oedema caused by retinal vein occlusion (RVO) (ID328)

Royal College of Nursing

Introduction

The Royal College of Nursing (RCN) was invited to review the Appraisal Consultation Document (ACD) of Ranibizumab for the treatment of macular oedema caused by retinal vein occlusion (RVO).

Nurses caring for people with macular oedema reviewed the documents on behalf of the RCN.

Decision Support Unit (DSU) Report – RCN Response

The Royal College of Nursing's Ophthalmic Nursing Forum welcomes the opportunity to comment on this report. As with all clinicians, our duty of care is to ensure that our patients receive the best treatment and care available to us.

The Bevacizumab V Ranibizumab debate has been a 'hot topic' for a number of years and following reading this document we still have concerns re-evidence base medicine and safety.

So much of the 'clinician study data' was inconsistent. The number of patients recruited, or analyzed retrospectively are low, there is variance in bevacizumab dosage and number of injections that patients received,

demonstrating that clinicians are still unsure of the best treatment regimen to use.

The DSU report refers to the possibility that adverse events in Bevacizumab patients are possibly only a chance finding, yet the most robust data reported in the IVAN and CATT studies highlight a higher incidence in the bevacizumab group compared to the ranibizumab group. As a result of this UK IVAN study centers have recently had communication from the Safety Committee requesting that patients be informed of the increased risk and offered the chance to withdraw from the study. This has had an impact on patient's confidence in the safety of the drug and may impact on the uptake if it were to become the NHS drug of choice.

We also have issues around the potential for contamination from 'mulitple vial use' of Bevacizumab and the lack of robust safety data. We acknowledge that the report highlights larger scale manufacturing units are more recent and carry out repackaging in bulk under tightly controlled conditions but this is still inferior to that of industrial manufactured drugs which have been subjected to regulatory directives. This is clearly a concern to us as patient safety is paramount.

It is historical NHS practice for clinicians, in the best interest of their patients, to administer drugs that are 'off label', but usually only when there is no licensed alternative. We feel it would be hard to justify the use of bevacizumab for pathology that already has an approved licensed drug i.e. – Ranibizumab for neovascular age-related related macular degeneration.

Also, knowing the numbers of patients with retinal pathology suitable for anti-VegF therapy is vast; the potential for adverse events from an unlicensed drug is greatly increased. Hence the financial saving from using a 'cheaper' drug for the 'greater good' may actually result in an overall loss from potential litigation!

In conclusion, at this point in time, we would have difficulty advocating that Bevacizumab becomes an NHS approved drug for ophthalmology for pathology that has a licensed alternative.