

Allow NHS doctors to prescribe cheap, safe and effective sight loss drug, says The BMJ

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NHS doctors should be allowed to prescribe a cheap, safe and effective drug for the degenerative eye disease, wet age related macular degeneration (AMD) - a leading cause of blindness among older patients, says an investigation by *The BMJ* today.

Editor in chief, Dr Fiona Godlee, says the new evidence "raises questions about the legal and regulatory positions that have skewed clinical practice, fuelled NHS drug costs, and left <u>doctors</u> confused about what they can and can't prescribe."

Dr Godlee says: "Doctors and academics have carried out <u>clinical trials</u> despite threats and intimidation - and doctors leaders should follow suit and not allow themselves to be bullied either. Patients have volunteered to participate in clinical trials thinking that their contribution might save the NHS millions of pounds. It is unethical not to act on their altruism."

She adds: "Doctors leaders also need to sort out the web of misinformation about drug prescribing that has been generated behind closed doors and is costing the NHS hundreds of millions of pounds a year by scaring doctors from using cheap and effective medicines."

The licensed treatment, Lucentis (ranibizumab) is estimated to cost \$1950 per dose compared with \$50 per dose for Avastin (bevacizumab), which is not licensed for AMD. Both drugs are owned by the same company (Roche), although Lucentis is marketed by Novartis in the UK.



Publicly funded trials have shown that bevacizumab is as safe and effective as ranibizumab - and allowing its use could release £102m a year that the NHS could re-invest in other frontline patient services.

Yet new evidence uncovered by *The BMJ* reveals a campaign by the drug manufacturers to "undermine and divert attention" from the results of these trials, even turning to the charity, Royal National Institute of Blind People (RNIB), for help.

Emails obtained under a freedom of information request show that clinicians with ties to Novartis urged some primary care trusts to pull out of one trial. *The BMJ* has also learnt of attempts by Novartis to "derail" a second publicly funded UK trial.

The trial's chief investigator, Alex Foss, a consultant ophthalmologist at Queen's Medical Centre, Nottingham told *The BMJ* how, during the trial's planning stage, a Novartis representative tried to divert him to Novartis funded work, with the prospect of future funds for personal research projects.

But while the studies have been ongoing, the General Medical Council (GMC) has told doctors it is unlawful to prescribe an "unlicensed" medicine on the grounds of cost.

This change of guidance has left doctors fearful of acting on the trial results.

The BMJ has learned that both the ABPI and the MHRA, acting on behalf of the government, lobbied against the proposed new clause. The RNIB has also lobbied the GMC against changing guidance to doctors that would allow more widespread use of off-label drugs.

In October, Royal College of Ophthalmology president, Carrie



MacEwan and Andrew Lotery, Professor of Ophthalmology in Southampton, called on NICE to appraise bevacizumab along with licensed drugs for the treatment of AMD.

"Given the overwhelming evidence for the effectiveness and safety of bevacizumab in the treatment of neovascular AMD, central government should act to overcome the bureaucratic hurdles that prevent it's use," they said.

In the US, surveys indicate that bevacizumab has about 60% of the market for ophthalmic use. The World Health Organization has also backed bevacizumab for ophthalmic use, adding the drug to its Essential Medicines List.

In an accompanying commentary, David Lock QC says there is nothing to suggest that a doctor who appropriately prescribes bevacizumab for someone with wet AMD acts in breach of criminal law.

He adds: "Doctors in the UK have been prescribing <u>bevacizumab</u> rather than ranibizumab for wet AMD for many years (both in the NHS and privately), and there is no record of any doctor being formally investigated by the GMC for doing so."

An editorial says it is time for a robust solution to this problem. Jeffrey Aronson, Honorary Consultant Physician at the Nuffield Department of Primary Care Health Sciences, and Robin Ferner, Director at West Midlands Centre for Adverse Drug Reactions, argue that, where there is sufficient evidence of quality, efficacy, and safety, "the cheapest product should be prescribable."

More information: Time to allow doctors to prescribe Avastin? www.bmj.com/cgi/doi/10.1136/bmj.h1659



Commentary: Avastin and Lucentis: a guide through the legal maze www.bmj.com/cgi/doi/10.1136/bmj.h1377

Editorial: A licence to cure www.bmj.com/cgi/doi/10.1136/bmj.h1723

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