National Institute for Health and Care Excellence

IP915– Insertion of an epiretinal prosthesis for retinitis pigmentosa
Consultation Comments table
IPAC date: Thursday 12th February 2015

Com. no.	Consultee name and organisation	Sec. no.	Comments	Response Please respond to all comments
1	Consultee 1 Patient organisation - RP Fighting Blindness	**General**	Thank you for the opportunity to comment on this important issue. This is notable for RP patients as this is the first potential treatment for this currently incurable position. RP Fighting Blindness is pleased that NICE is considering epiretinal (and shortly sub-retinal) implants after considerable delay and expresses some concern that the application has taken this long to reach this point. We are aware of the changes within NICE and the NHS that have led to this.	**Thank you for comment**

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2	Consultee 2 Patient organisation - Royal National Institute of Blind People (RNIB)	**General**	About the RNIB: Royal National Institute of Blind People (RNIB) is the UK's leading charity providing information, advice and support to almost two million people with sight loss. We are a membership organisation with over 13,000 members throughout the UK and 80 percent of our Trustees and Assembly members are blind or partially sighted. We encourage members to get involved in our work and regularly consult them on matters relating to Government policy and ideas for change. As a campaigning organisation we act or speak for the rights of people with sight loss in each of the four nations of the UK. We also disseminate expertise to the public sector and business through consultancy on products, technology, services and improving the accessibility of the built environment. RNIB is pleased to have the opportunity to respond to this consultation	**Thank you for comment**

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3	Consultee 2 Patient organisation - Royal National Institute of Blind People (RNIB)	**General**	Accessible information: We believe this guideline should be culturally appropriate. It should also be accessible to people with additional needs such as physical, sensory or learning disabilities, and to people who do not speak or read English." The Equality Act expressly includes a duty to provide accessible information as part of the reasonable adjustment duty. Online information on websites should conform to the W3C's Web Accessibility Initiative Web Content Accessibility Guidelines (WCAG) 1.0, level AA, as required by the NHS Brand Guidelines and the Central Office of Information. With regard to the accessibility of print materials, including downloadable content such as PDF files, we would request that wherever possible they comply with our "See it Right" guidelines: http://www.rnib.org.uk/professionals/accessibleinformation/Pages/see_it_right.aspx	**Thank you for comment** The NICE website provides tools that enable individuals with sight loss to hear or view the text. NICE does not proactively produce braille versions of the guidance; however braille versions of this guidance are available on request from NICE's enquiry handling team at the following email address: nice@nice.org.uk

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4	Consultee 1 Patient organisation - RP Fighting Blindness	**1**	Though disappointing that NICE is not currently recommending that patients be given access to treatments, even on a highly restricted or specialised centre basis, we do understand the committees concerns that quality of life improvements could be better evidenced, and over the adverse events. However ... We ask that the committee asks itself again the question "Should the treatment be made available on a restricted basis to that small number of patients who would benefit?". This in the context that there is no other treatment. It is our view that well informed patients are in a position to make sensible judgements about the safety of the device, and will understand the adverse effects and the risk of them occurring.	**Thank you for comment** The IP guidance will not prevent access to the treatment but ensure that it is only provided within Research Governance. The Committee felt that in the context of such a small quantity and quality of published evidence, it would be inappropriate for patients to undergo the treatment without the safeguards of Research Governance. At the time of guidance development there were less than 150 patients in the published literature and it is likely that there was considerable overlap in the patient population included.
5	Consultee 1 Patient organisation - RP Fighting Blindness	**1**	This organisation and those patients with whom we have consulted recognise that the devices are expensive and that in the short term the costs are not likely to fall, if ever. There is some perception that the financial cost is the reason for the treatment not being made available in the UK. The device is approved for re-imbursement in Germany, Italy, France and the USA, with a very small number of operations taking place as a result. Other countries are in discussions.	**Thank you for comment** IPAC evaluates safety and efficacy. Cost-effectiveness is not part of the remit of the Programme. The Committee was not presented with any data on the cost of the procedure.

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6	Consultee 1 Patient organisation - RP Fighting Blindness	**1**	Further investment by Second Sight in UK research at the two centres of excellence (Moorfields EH and Manchester EH) may be jeopardised by the decision not to make treatment available. This may well disadvantage UK patients in the future. We urge that if this position is not reviewed as a result of the consultation that new evidence and/or technical advances lead to a fast tracking of any future review.	**Thank you for comment** NICE encourages further research and may review guidance when substantial evidence becomes available.

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7	Consultee 2 Patient organisation - Royal National Institute of Blind People (RNIB)	**1**	Specific comments pertaining to device RNIB welcomes further research into the insertion of an epiretinal prosthesis for retinitis pigmentosa. If the ophthalmology community is committed to using an epiretinal prosthesis for retinitis pigmentosa it is crucial to establish an acceptable safety and efficacy profile. We would like to see further research and information on: • Efficacy- The use of standardised methods and comparators • Pharmacovigilance services for medical devices - An epiretinal prosthesis for retinitis pigmentosa is associated with numerous ocular adverse reactions. Therefore, a continuous monitoring system should be established to ensure patient safety. Patients especially those with disabilities should know how to report adverse reactions and these should be available in accessible formats. • Patient study numbers- Study numbers range from n=6 to n= 30. Patient numbers need to be increased and efficacy and safety evaluated over longer periods of time. • Patients and carers view- The effect of an epiretinal prosthesis on daily living and emotional well being before and after the insertion of an epiretinal prosthesis.	**Thank you for comment** The Committee considered the comment and decided not to change the guidance. IPAC agreed with the RNIB that additional data are required before the procedure should be used outside of Research Governance. This will ensure that the follow-up suggested is maintained and that all adverse events are recorded. The available literature indicates that there is currently no standardised method of assessing the visual function of retinitis pigmentosa patients with severe sight-loss. IPAC has proposed that research outcomes should include the impact on quality of life, activities of day-to-day living, and durability of implants.

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8	Consultee 2 Patient organisation - Royal National Institute of Blind People (RNIB)	**1**	Practical and emotional support information- Information pertaining to device fitting and visual rehabilitation should be available in accessible formats. Post-implant clinical follow-up appointments- These should be monitored to avoid repeat postponement maybe through electronic share care records and patient registers.	**Thank you for comment** A Committee comment, in section 6, highlights the importance of patient selection, psychological counselling and post-implant follow-up. IPAC is unable to stipulate specific details on how these should be performed.
9	Consultee 1 Patient organisation - RP Fighting Blindness	**6**	We note the committees comments about the technology advancing further in the next few years. However many patients have been waiting for many years for treatments, have a poor quality of life now that could be improved, and there is a danger that they will be left with nothing whilst waiting for something that may or may not be better.	**Thank you for comment** Although the procedure is intended for patients who have no other treatment options, the Committee felt that, currently, there is no evidence that the minor improvements in metrics of vision result in substantial improvements in quality of life. Furthermore, the Committee noted that it may not be possible to replace or upgrade the epiretinal prosthesis once it has been implanted. It was concluded that further developments in the technology may result in substantial changes to outcomes.
10	Consultee 1 Patient organisation - RP Fighting Blindness	**6**	We are pleased to see recognised the need for counselling, training and support linked to the prospect of a restoration of some visual function and independence. We trust this will be reflected in future considerations of any treatment or therapy.	**Thank you for comment**

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11	Consultee 2 Patient organisation - Royal National Institute of Blind People (RNIB)	**6**	Retinitis pigmentosa affects peripheral and night vision affecting the ability: to perceive images, read, write and move and locate objects in the dark. The guidelines suggest that epiretinal prosthesis is intended for patients with advanced disease. We believe thresholds should not be set for this device and it should be a readily available treatment option for patients whose daily living and quality of life are negatively impacted by retinitis pigmentosa	**Thank you for comment** The Committee was advised that epiretinal prostheses are intended for patients with advanced disease. All available studies included patients with bare or no light perception and a visual acuity of worse than 2.9 logMAR in both eyes. Committee comment 6.2 was amended to state: The Committee recognised that the technology of epiretinal prostheses and related devices is evolving and that further developments may result in substantial changes to outcomes which may influence patient selection in the future.
12	Consultee 1 Patient organisation - RP Fighting Blindness	**NOTE**	I was present as observer at the committee meeting.	**Thank you for comment**