National Institute for Health and Clinical Excellence

Colistimethate sodium powder and tobramycin powder for inhalation for the treatment of pseudomonas lung infection in cystic fibrosis

Royal College of Nursing

Introduction

The Royal College of Nursing was invited to submit evidence to inform the above technology appraisal. With a membership of over 400,000 registered nurses, midwives, health visitors, nursing students, health care assistants and nurse cadets, the Royal College of Nursing (RCN) is the voice of nursing across the UK and the largest professional union of nursing staff in the world. RCN members work in a variety of hospital and community settings in the NHS and the independent sector.

The request was circulated to nurses involved in the care of people with cystic fibrosis.

Evidence submission

The Royal College of Nursing welcomes the opportunity to submit evidence to inform the multiple technology appraisal of the use of colistimethate sodium powder and tobramycin powder for inhalation for the treatment of pseudomonas lung infection in cystic fibrosis (CF).

Current practice

Colistin or tobramycin for inhalation have been nebulised via a compressor machine for many years as an anti-pseudomonal treatment for CF. They have never before been available as a dry powder. Healthcare professionals occasionally prescribe gentamicin and tazocin for a minority of patients. Nebulised Colistin has been used historically as the first line treatment for Pseudomonas infection, due to cost, but for those who are intolerant of Colistin or who do not respond to it, they would be offered tobramycin.

We are currently not aware of any geographical differences of prescribing.

The method of delivering this nebulised antibiotic will vary geographically in the compressors that are currently used. *E-flow* rapid nebuliser compressors and iNebs are currently the most commonly used methods of delivery. Both are easy to use and relatively quick to deliver the drug but for many people with CF this new proposed technology would be infinitely preferable for patient use, due to speed of delivery and portability.

Depending on genotype and phenotype, and clinical course, the condition and prognosis in CF can vary from patient to patient.

We have not identified any differences in the capacity of different subgroups to benefit from or those that could be put at risk by the technology. It will only be appropriate for use in children over six years of age who are able to use the device. The new technology would only be prescribed for those patients whose clinical signs indicate a need for the antibiotic, for example, if Pseudomonas aeruginosa were to be cultured in the sputum.

The technology could be used in a variety of settings, including home, hospital, work, school. It is smaller and more portable than current devices available.

As far as we are aware, no additional professional input has been identified for the use of this technology.

As this is a new technology, which is not currently used in cystic fibrosis, we are not aware of any variation of its use in the NHS. As always, financial implications will be a consideration.

An advantage of this new technology is that it would be very easy to use and would be acceptable to patients.

With regards to additional sources of evidence, as far as we are aware, very little literature has been published to date. We consider that there will be a need for a comparative study to be done at some stage if this is not already being done.

Equalities issues

In Scotland, adult CF care is funded by the National Services Division, which is a Scottish Executive Government department. This money is ring fenced and used solely for the care of CF patients. As a result, all adult patients in Scotland are treated in the same way and are not affected by "postcode lotteries". The National Service Division do require national and standardised protocols for antibiotic treatment, and would currently see nebulised colistin as first line therapy to be followed by TOBI should it be necessary. All adult patients in Scotland with CF are treated at one of the 3 main specialist centres as well as being regularly reviewed at a district hospital as necessary.

In the UK there has historically been a postcode lottery for prescribing medications and the regional variation is reflected in local care pathways and management protocols, involving specialist pharmacists where required.

Implementation issues

We consider this technology to be innovative in the treatment of CF. It would need to be priced comptetively compared to current therapy and be as effective and well tolerated as current therapy. However, the benefits to the patients could be very significant in terms of adherence, quality of life and length of time between chest exacerbations. There is a significant problem currently with compliance with CF patients which this new technology could help to address.

Staff would need initial training and education in using the new technology but after this, there would be no additional requirements in terms of staffing resources etc. All patients would need to be taught how to use the new device, but we anticipate that it would be simpler and easier to use than the current technology.

Appraising the value of innovation

- *Do you consider the technology to be innovative in its potential to make a significant and substantial impact on health-related benefits and how it might improve the way that current need is met (is this a 'step-change' in the management of the condition)?*

We consider that this technology would have a significant impact on health related benefits. The benefits to the patients could be substantial in terms of adherence, quality of life and length of time between chest exacerbations.

Conclusion

Currently colistin is the first line choice of nebulised medication but some patients are unable to tolerate this medication (i.e. they get a wheezy or tight chest on administration) and we would then try tobramycin via nebuliser. All patients who currently nebulise antibiotics will be keen to try these new devices, as they will be quicker and easier for them to use. All patients who are receiving a new medication which is directly inhaled into the lungs have a supervised test dose in a hospital setting.

"Adherence to treatment" should be added as another outcome measure, as there could be potentially quite a dramatic improvement in adherence for patients using this device. Adherence is a complicated measurement and whether to rely on patient (self) measures of adherence is a contentious issue.

We consider that BMI probably would be an appropriate outcome measure. There is consistent evidence to show that fewer chest infections result in better nutritional status and a higher BMI results in fewer exacerbations.

This technology could be innovative in the treatment of CF. It would need to be priced comptetively compared to current therapy and be as effective and well tolerated as current therapy.

The benefits to the patients could be very significant in terms of adherence, quality of life and length of time between chest exacerbations. There is a significant problem currently with compliance with CF patients which this new technology could help to address.