A consultant pharmacist in Leicester is taking the lead in prescribing medicines such as omalizumab and methotrexate for patients with asthma and working to tackle issues around adherence to therapy.

Manage patients with difficult-to-control asthma in a specialist clinic

By Anna Murphy, Msc, MRPharmS

Two major challenges for healthcare professionals are to ensure local adherence to national prescribing guidelines and to help patients achieve optimal adherence to treatment themselves and engage in good self-management behaviours.

Glenfield Hospital, part of the University Hospitals of Leicester NHS Trust, is a tertiary referral centre for adult patients with difficult-to-control asthma. Currently, over 700 patients have been referred to the hospital’s “difficult asthma clinic” (DAC), with most of these individuals being followed up on a regular basis.

The asthmatic population attending the clinic has particularly severe disease, with high levels of morbidity — over a quarter of patients have had previous life-threatening exacerbations requiring admission to an intensive care unit and most patients are prescribed oral corticosteroids on a regular basis to maintain asthma control, prevent exacerbations and, ultimately, reduce their risk of dying.

The DAC is a multidisciplinary service and I have an active role as the pharmacist providing clinical and medicines support. Over the years I have developed this role and now have three key responsibilities, namely:

- An omalizumab clinic
- A high-risk medicines clinic
- Adherence assessment and support

Omalizumab clinic

Omalizumab is a monoclonal antibody that is used as add-on treatment for adults and young people with severe, persistent allergic (IgE-mediated) asthma. In 2008 a pharmacist-led clinic was set up to assess patients’ suitability for, and objectively measure outcomes of, this high-cost treatment.

Initially I led the development of a guideline to ensure the drug’s appropriate and safe use and

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establish a structured approach to its prescribing and monitoring. Now the physicians refer directly to me any patient they identify as being potentially suitable for omalizumab treatment. In the clinic I:

- Ensure the patient meets the restrictions of the UK product licence and the criteria set by the National Institute for Health and Clinical Excellence
- Confirm that the patient is currently prescribed optimum asthma treatment (or that this has been adequately attempted in the past)
- Check that the patient is adhering to their regular asthma medicines (assessed by discussion with the patient, plasma levels and repeat prescription dispensing records)
- Confirm that the patient is not a smoker
- Apply for funds for the 16-week trial period and potential long-term treatment with omalizumab (especially applicable for those patients who are referred from outside the local primary care trust)
- Ensure that the patient is discussed at the DAC multidisciplinary team meeting and that two consultants agree the patient is suitable for treatment

Once the omalizumab treatment is approved, the patient is invited to attend my medicines management clinic. The purpose of this clinic is to ensure that all clinic. The purpose of this clinic is approved, the patient is invited to attend my medicines management treatment and the potential adverse effects are discussed.

To try to maintain asthma control and reduce the overall doses of oral corticosteroid used, medicines such as methotrexate or ciclosporin can be co-prescribed with corticosteroids. Our use of such corticosteroid-sparing medicines has increased substantially as the number of patients referred to the DAC has risen. However, both published and our own local data show that not all patients prescribed methotrexate or ciclosporin benefit from the treatment. Because of the potential toxicity of these drugs, it is essential for therapy to be individualised so that the patient fulfils initial prescribing criteria and only those with a profound clinical response continue treatment.

At Glenfield Hospital, all patients with respiratory disease who are considered for these "high risk" medicines are referred to me.

When patients attend the clinic, I complete an initial assessment of their respiratory symptoms and take a full drug history, including capturing use of herbal and over-the-counter medicines. This helps to identify potential drug interactions and provides an opportunity to suggest any changes to regular medicines.

For each patient it is my responsibility to:

- Confirm the suitability of the proposed high-risk drug
- Highlight the potential benefits and risks
- Provide patient information
- Document the patient’s understanding and consent to start treatment in his or her medical notes
- Order the required blood tests and provide blood test forms for subsequent monitoring
- Prescribe the medicine
- Provide my contact number so that the patient can phone for support if required
- Send details of the consultation to the referrer and to the patient’s GP (including, if required, local "shared-care agreements" for the medicine in question); the community pharmacist will also be sent details if the patient agrees
- Monitor the results of further blood tests

An audit of adherence to asthma medicines

During July and August 2009, I investigated the adherence behaviours of adult asthma patients attending the "difficult asthma clinic". GPs were contacted to obtain retrospective prescription refill data for asthma medicines. Prescribing data from the local hospitals were also accessed. Patient information such as age, sex, smoking history and number of rescue courses of prednisolone was collected. Asthma severity, lung function and asthma symptom score were examined to evaluate the possible clinical implication of non-adherence. Adherence to medicines was defined as more than 80% of prescription refill rate (calculated as the number of doses refilled out of the number of doses prescribed, expressed as a percentage, for a mean duration of 12 months).

The audit included 115 patients. Poor adherence was identified in 75 patients (65.2%) prescribed inhaled corticosteroids. Patients with poor adherence to inhaled corticosteroids had a lower post-bronchodilator forced expiratory volume in one second (FEV₁) and higher sputum eosinophils than those who had adequate adherence. There were no significant differences in age, gender, racial origin, smoking history or courses of rescue oral prednisolone between these two groups, but patients with poor adherence to inhaled corticosteroids were more likely to have been ventilated for asthma (19.2% versus 2.6%; P=0.02).
In the clinic we routinely measure patients' differential sputum eosinophil count and exhaled nitric oxide concentrations (FeNO) to assess airway inflammation. A raised sputum eosinophil count (>2%) or FeNO (>25 parts per billion at 50ml per second) is seen in 70–80% of patients with untreated asthma. The number of eosinophils in sputum is associated with asthma severity and decreases following treatment with inhaled or oral corticosteroids. In addition, inhaled corticosteroids can achieve a dose-dependent reduction in FeNO in asthmatic patients. These physiological markers can be useful for assessing patients' adherence to corticosteroids but may not provide a complete picture and should be used in conjunction with other assessments.

Surrogate measures (eg, pharmacy prescription refills or repeat prescribing records) have been found to be useful for identifying non-adherence.

I currently use a combination of both clinical and surrogate methods when assessing medicines adherence among patients attending the DAC. This information is collated and reported back to the consultant physician.

Increased awareness of the issues surrounding non-adherence has changed our clinical practice — patients are now given more opportunities to talk about their concerns, beliefs, needs and expectations regarding their asthma and its treatment. Issues affecting adherence are discussed openly with patients.

If an individual admits to, or is suspected of, not adhering to his or her prescribed asthma medicines, this is explored and plans are agreed to try to improve the situation.

References