February 2015

Prescribing....

For new diseases

- There is increasing concern about whether or not some "new" indications are valid and require treatment, or are part of the normal ups and downs of life.
- Patients recently diagnosed with diseases may take more time off work and report reduced wellbeing.
- A recent article in the BMJ reported that a large proportion of people prescribed antipsychotics do not have diagnosed psychosis or bipolar disease.

What is the background to this ?

Clinical treatment usually follows a set pattern. A patient consults a healthcare professional, symptoms and signs are discussed, concerns are aired and shared, a diagnosis is made, treatment options are discussed and drug therapy is prescribed as and when indicated.

Information to support the choice of drug is readily available from the *British National Formulary*, technical drug details are published in the Summary of Product Characteristics, and both publications describe the indications for each drug. Although we spend much time and effort analysing key aspects of drug safety, efficacy and cost-effectiveness, do we pay as much attention to the licensed indications for that drug? How sure are we that the indication itself is valid as a diagnosis?

Over the last few years, therapeutic developments have often manifested in finding new indications for existing drugs. There is a huge economic benefit for drug companies to extend the licensed indication of branded products that are protected by patent. Such indications may well be widely accepted, with the drug providing another useful approach in the treatment of the condition. Increasingly, however, the indication itself is controversial, falling close to medicalising normal ups and downs of life.

The extension of the indication for testosterone for the treatment of reduced female sex drive has been controversial, with debate over what the diagnosis really means. More recently, the development of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-5) has given certainty to diagnoses which have attracted considerable criticism as to their real validity. These include concerns that reactions such as grief or toddler temper tantrums will become medical conditions that require pharmacological intervention; and that labelling age-related forgetfulness will result in a large number of people with a diagnosis of Minor Neurocognitive Disorder. In addition, many members of expert panels making decisions about definitions or diagnostic criteria for common conditions have declared links to pharmaceutical companies.

Does this really matter?

After all, if the patient feels X is a problem, then surely it must be so and it would be considered arrogant of doctors to say X is actually normal. However, modern medicine is about understanding the health of a whole person in a social situation. We need to be careful, therefore, to recognise where the boundary between normal and abnormal lies, and not to redefine the former as simply being the absence of distress. Doctors have long tried to get away from the belief of 'a pill for every ill'.

But does it cause any harm ?

There have been many new diagnoses in mental health in recent years. It is not yet known if treating these conditions causes any harms. And there are undoubtedly some patients who will have been helped by effective treatments for distressing conditions.

The frequently off-license use of antipsychotics in the extremely difficult area of managing the behavioural and psychological symptoms of dementia is a concern, given their potentially serious side effects in older people.

A recent study published in the BMJ found that less than half of UK prescriptions for these drugs are being issued for the serious mental illnesses for which they are mainly licensed. Researchers reported that they are often prescribed off-label to older people with conditions such as anxiety and depression. They are sometimes recommended for complex cases of depression or for short term use in mental health crises. Prescribing rate was significantly higher for women than for men. People aged over 80 years were twice as likely to be given an antipsychotic than people aged 40 to 49. Those living in areas of deprivation were more than three times likely to be prescribed one of these drugs than those in more affluent areas. Amongst the diagnoses were anxiety, depression, dementia, sleep and personality disorders.

On a wider theme, labelling something as 'abnormal' itself produces problems. In one study one group of patients were "diagnosed' with mild hypertension even though their blood pressure was normal. They were found to take more time off work and report less wellbeing in the following year that the group that were told, correctly, that their blood pressure was normal.

Drugs have to go through substantial hurdles to get a license for an indication and some are subject to even further meticulous assessment before they are granted States funding. It is time that the validity of the indication is subject to an equally rigorous assessment process. The harms, benefits and opportunity costs associated with changing diagnostic criteria and thresholds require independent and impartial evaluation.

References : Drugs and Therapeutics Bulletin July 2014 52:7 73 , British Medical Journal December 2014

Written by: Geraldine O'Riordan, Prescribing Advisor Tel: 01481-732460