that has been used for many years to treat children and adults with chest infections unrelated to AIDS. Studies in adults with HIV additionally showed that the drug reduces other complications from bacterial infections.[7]

When preliminary evidence showed that the infections in children with HIV might also be reduced, a group of British researchers got together with colleagues in Zambia to assess the effects of co-trimoxazole as a possible preventive medicine in a large study. The trial, which started in 2001 and lasted about two years, compared the antibiotic with a placebo in over 500 children. The results became clear sooner than anticipated when it was shown that the drug cut AIDS-related deaths by 43% (74 deaths in the co-trimoxazole group compared with 112 in the placebo group) and also reduced the need for hospital admissions. At this point the independent committee scrutinizing the results recommended that the trial be stopped.

One immediate outcome was that all children in the trial were given co-trimoxazole as part of a Zambian government initiative. A wider consequence was that the World Health Organization and UNICEF promptly altered their advice on medicines for children with HIV.[8, 9]

These organizations continue to recommend co-trimoxazole as an inexpensive, life-saving and safe treatment for such children.[10]

BAD RESEARCH

Psychiatric disorders

Regrettably, research is not always well done or relevant. Take the example of a distressing condition known as tardive dyskinesia. This is a serious side-effect associated with long-term use of drugs called neuroleptics (antipsychotics), which are prescribed for psychiatric disorders, especially schizophrenia. The most prominent features of tardive dyskinesia are repetitive, involuntary movements of the mouth and face – grimacing, lip-smacking, frequent poking out of the tongue, and puckering or blowing out of the cheeks. Sometimes these are accompanied by twitching of the hands and feet. One in five patients taking a neuroleptic for more than three months experiences these side-effects.

In the 1990s a group of researchers began exploring, systematically, what treatments had been used for tardive dyskinesia over the preceding 30 years. Writing in 1996, they were rather surprised to have identified about 500 randomized trials involving 90 different drug treatments. Yet none of these trials had produced any useful data. Some of the trials had included too few patients to give any reliable results; in others the treatments had been given so briefly as to be meaningless.[11]

Members of the same research group went on to publish a comprehensive survey of the content and quality of randomized trials relevant to the treatment of schizophrenia in general. They looked at 2,000 trials and were disappointed in what they found. Over the years, drugs have certainly improved the prospects for people with schizophrenia in some respects. For example, most patients can now live at home or in the community. Yet, even in the 1990s (and still today), most drugs were tested on patients in hospital, so their relevance to outpatient treatment is uncertain. On top of that, the inconsistent way in which outcomes of treatment were assessed was astonishing. The researchers discovered that over 600 treatments – mainly drugs but also psychotherapy, for example – were tested in the trials, yet 640 different scales were used to rate the results and 369 of these were used only once. Comparing outcomes of different trials was therefore severely hampered and the results were virtually uninterpretable by doctors or patients. Among a catalogue of other problems, the researchers identified many studies that were too small or short term to give useful results. And new drug treatments were often compared with inappropriately large doses of a drug that was well known for its side-effects, even when better tolerated treatments were available – an obviously unfair test. The authors of this review concluded that half a century of studies of limited quality, duration, and clinical utility left much scope for well-planned, properly conducted, and competently reported trials.[12]

Epidural analgesia for women in labour

The importance of assessing outcomes that matter to patients is clearly illustrated – in a very negative fashion – by early trials of epidural analgesia given to women for pain relief during labour.