In this issue…

Common problems can sometimes be difficult to treat. It is therefore important that the diagnosis is correct. The importance of a thorough history and examination is therefore emphasised in the articles by Gayle Fischer on childhood vulval disease, and by Mark Paine on dealing with dizziness.

While history and examination are essential for diagnosis, laboratory tests are indicated in some cases. Huy Tran tells us about the role of biochemical testing during pregnancy. The use of antidepressants is increasing. One reason for this rise is the use of the drugs for other indications such as those discussed by Lisa Lampe.
Intuitively the greatest benefit of a polypill is the simplicity of the regimen, resulting in improved adherence and better clinical outcomes, but surprisingly, few clinical trial data are available. Nevertheless, fixed-dose combinations of four or more medications are being developed for tuberculosis and HIV. For people with cardiovascular disease, in whom the separate ingredients are recommended, only a small minority receive the full combination. This may result from confusion due to complicated regimens, the sheer inconvenience of managing large numbers of pills, a reluctance to take (or prescribe) multiple medicines, and cost.

A polypill could be very inexpensive because its ideal components are now off-patent. World Health Organization (WHO) analyses show that combination therapy given to people at high absolute risk of cardiovascular disease is more cost-effective than current treatment patterns based on single risk factors (for example treating ‘hypertension’). Population approaches like salt reduction in foods are the most cost-effective of all, according to the WHO report. So why don’t we have a polypill already? Innovator companies are reluctant to invest, because profit margins are likely to be thin. Generic manufacturers do not have large research and development budgets. This leaves a gap that government agencies are not ready to fill. What is more, the regulatory hurdles for combinations of three or more ingredients are poorly defined. Despite all this, there are now ‘mini’ versions of the polypill. For example, last year the United States Food and Drug Administration approved a combination of amlodipine and atorvastatin. The authors of the BMJ paper have a patent on their version of the polypill, though it is difficult to know how defensible this would be, given the components are all generics and the concept is based on published evidence. At present there seems more heat than light in the polypill debate. It is time to move on and seek direct evidence from trials. Relatively small studies could investigate whether adherence is improved in patients with established indications for the component medications. An even bigger question is what works best for primary prevention; long-term trials with several thousand participants will be needed to show a reduced event rate. Before casting the polypill as ‘friend’ or ‘foe’, we need better information on acceptability, safety and effectiveness.

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References

Dr Rafter is applying for funding for a randomised controlled trial of combination cardiovascular medication.

Transparency – in the eye of the beholder?

**Editorial Executive Committee, Australian Prescriber**

Key words: drug regulation, drug industry.

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The Editorial Executive Committee of Australian Prescriber is concerned about the increasing difficulty of obtaining good information about new drugs. It is not unusual for a drug to be marketed in Australia despite a lack of published peer-reviewed information to support its manufacturer’s claims. This is particularly the case for adverse effects and for ‘head-to-head’ comparisons with older drugs used to treat the same conditions as the new drug. The data (both published and unpublished) may have been evaluated by drug regulatory authorities so there is a strong argument that their evaluations should be available to health professionals and consumers. A lot of prominence has recently been given to the need for ‘transparency’ in the drug regulatory system. For example, there have been calls for an international register of clinical trials so that unfavourable results are not hidden. Greater transparency in the process for subsidising drugs was also an important part of the free trade agreement between Australia and the USA. However, transparency means different things to different people.