

Breast cancer screening

With the publication of Gøtzsche's latest Cochrane review warning of the overdiagnosis of breast cancer by screening programmes, one might have hoped that a consensus would appear [1]. However, the lively debate shows some are still accusing his analyses of methodological flaws, while others provide supporting evidence. Governments are naturally reluctant to cut public screening programmes, having gone to great lengths to set them up and advertise them, when the majority of medical opinion does not agree with his conclusion: one in three breast cancers detected in a population offered organised screening is overdiagnosed.

Congratulations to the BMJ for making this paper and the surrounding debate available free of charge.

A study from Ontario, Canada, concludes that for a theoretical population of 10,000 women between the ages of 50 and 69 years, the addition of clinical breast examination would lead to the detection of breast cancer in only four women whose cancer would be missed by mammography. However, adding clinical breast examination would also lead to false-positive results for an additional 219 women [2]. In the US, PSA screening for prostate cancer has resulted in 1.3 million cases of treatment, and most of these were false positives [3].

1. BMJ. 2009;339:b2587 doi:10.1136/bmj.b2587
2. J Natl Cancer Inst. 2009;101(18):1236-43.
3. J Natl Cancer Inst. doi:10.1093/jnci/djp278.

Raltegravir non-inferior to efavirenz

On 15 September 2009 the EU granted a licence extension for raltegravir (Isentress) to be used for treatment of antiretroviral-naïve adult patients. Raltegravir, the first and only approved integrase inhibitor, had already been approved in more than 80 countries across six continents for use in combination with other antiretrovirals in treatment-experienced patients.

According to the findings of a non-inferiority trial published early online in *The Lancet*, initial treatment of HIV-1 infection with therapy based on the integrase strand transfer inhibitor raltegravir is non-inferior to efavirenz-based therapy in terms of viral suppression at week 48. The time to achieve such viral suppression was shorter for patients on raltegravir than on efavirenz (log-rank test $p < 0.0001$). Significantly fewer drug-related clinical adverse events occurred in patients on raltegravir ($n = 124$ [44.1%]) than those on efavirenz ($n = 217$ [77.0%]; difference -32.8%, 95% CI -40.2 to -25.0, $p < 0.0001$). Serious drug-related clinical adverse events occurred in fewer than 2% of patients in each drug group.

The inclusion of raltegravir among recommendations for first-line therapy will offer more choice to patients beginning treatment. This may be important for women of child-bearing potential whose choice to start treatment has been limited by concerns about the teratogenicity of efavirenz.

The Lancet. doi:10.1016/S0140-6736(09)60918-1

The bacterial challenge — time to react

In a joint report, the European Centre for Disease Prevention and Control and the EMEA highlight the gap between the burden of infections due to multi-drug resistance and the development of new antibiotics to tackle the problem. The main findings are:

- resistance to antibiotics reaches 25% in several EU Member States among Gram-negative and Gram-positive bacteria that cause serious infections
- resistance in *E. coli* is increasing
- extra healthcare costs and productivity losses cost at least Euros 1.5 billion a year
- fifteen new antibiotics with the potential to tackle multidrug resistance are in an early stage of development. However, they are mostly for bacteria for which treatment is already available.
- there is a particular need for new targets or mechanisms of action to be found for multi-resistant Gram-negative bacteria. Two likely agents are in an early stage of development.

The report calls for European and global strategies and will be examined by the Commission with the encouragement of the present Swedish presidency.

www.emea.europa.eu/whatsnewp.htm

Rituximab approval

The European Commission has approved rituximab (MabThera) for use in patients with relapsed or refractory chronic lymphocytic leukaemia (CLL). The approval was based on data from the REACH study, which showed that the median progression-free survival (primary endpoint) was longer in patients with relapsed or refractory CLL who were treated with rituximab in combination with chemotherapy (fludarabine and cyclophosphamide) compared to those treated with chemotherapy alone (30.6 months vs. 20.6 months).

www.roche.com/media/media_releases/med-cor-2009-09-03.htm