

## Knowledge is power

Effective diagnostics are of paramount importance to the successful management of infectious diseases, yet their development and use, particularly in the developing world, remains a neglected area. To address this deficiency, TDR and *Nature Reviews Microbiology* have joined forces to produce a series of user-friendly diagnostic evaluation guides.

Regular readers of our editorials will be well aware of the shameful statistics that quantify the huge burden that infectious diseases continue to inflict on the developing world. These diseases kill more than 14 million people each year, 90% of whom live in resource-poor regions. Equally well documented are the recent public-private partnerships that are tackling the so-called neglected diseases, and such initiatives are to be warmly welcomed, even if they fall short in terms of the amount of funding that the United Nations feels is necessary to tackle the situation effectively.

One issue that receives less attention relates to the research priorities drawn up by these partnerships. Perhaps not surprisingly, there is a tendency to focus on vaccine research and drug development as these are key components of any infectious disease control strategy. However, of equal importance as a basic tenet of all disease-management programmes is the availability of effective and quality-assured diagnostics. Early and accurate diagnosis ensures that patients receive appropriate treatment, which in turn ensures a reduction in the risk not only of the patient developing long-term complications but also the risk of transmitting the disease to other members of the community. Reliable diagnostics are also crucial for effective monitoring of disease-control efforts and for the enhancement of disease-surveillance capacity.

Unfortunately, the evidence suggests that infection diagnostics and their development remains a neglected component of disease management, particularly for those diseases that are common in the developing world. For example, in the case of malaria, investment in diagnostics receives less than 1% of the overall funding for malaria research and development, compared with 37% for drug development<sup>1</sup>. The problems that blight the effective and widespread use of diagnostics in poorer regions include a lack of adequate regulatory controls on the quality of diagnostics, the predominance of relatively small manufacturers in this market with an associated lack of resources, and the prevalence of inadequate and unverifiable performance-evaluation data. The end result of these failings is that the onus falls on health workers to evaluate the potential of a new test, based on information

provided either in the product insert or on published data from incomplete or flawed study designs.

To address the need for stricter controls on the introduction and use of diagnostic tests in national public health programmes, the UNICEF/UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases (TDR) assembled a Diagnostic Evaluation Expert Panel (DEEP) to generate recommendations for best practice in the design and conduct of diagnostic trials for selected diseases of public health importance. Their work included the generation of a set of general principles for the design and conduct of diagnostic evaluations, and a series of disease-specific recommendations on how the necessary methodological standards could be applied to the evaluation of diagnostics that are relevant to a particular disease.

As part of our ongoing collaboration to promote and disseminate information on infectious diseases that disproportionately affect developing nations, *Nature Reviews Microbiology* and TDR have joined forces to produce a series of user-friendly operational guides based on the recommendations of DEEP. We hope that this information will support the relevant regulatory, procurement and international health agencies and, more importantly, enable health workers and scientists working on disease control in the developing world to evaluate diagnostic tests in accordance with international standards.

Included with this issue of the journal is the first instalment of the 'Evaluating Diagnostics' series of guides. This supplement focuses on the evaluation of diagnostic tests relevant to malaria, a disease that kills at least 1 million people every year. *Nature Reviews Microbiology* is proud to be associated with this initiative and we thank TDR for their support in the production of this supplement. In recognition of the importance of this information to healthcare personnel working in severely resource-constrained environments, the supplement will be freely accessible on our website (<http://www.nature.com/nrmicro/supplements>) and is also available from TDR (print and online: <http://www.who.int/tdr>).

1. Malaria R&D Alliance. *Malaria Research and Development – An Assessment of Global Investment* [online], <http://www.malaria vaccine.org/files/RD%20Report%20complete.pdf> (2005).

“...diagnostics and their development remains a neglected component of disease management...”