TB tests under WHO fire

By ACSH Staff — July 21, 2011

Tuberculosis (TB) test-kit manufacturers were castigated [1] by the World Health Organization (WHO) yesterday, while their sales in developing countries were placed under immediate ban due to unacceptable levels of wrong results and perverse financial incentives to boost sales, according to a WHO statement.

The tests were produced mainly by Western manufacturers and sold to 17 poorer countries; now, a year-long analysis by the WHO has found that the tests produced either false-positive or false-negative results in at least 50 percent of the cases. The WHO stated that most of the tests, on sale since the mid-1990s, have no published evidence to support their claims of accuracy, and that they were targeted at countries with weak regulatory mechanisms for diagnostics, where questionable marketing incentives can override the interest of patients.

Allowing these tests to remain on the market seems like an egregious oversight, according to the WHO statement, says ACSH s Alyssa Pelish.

And such a high rate of false test results seems pretty radical, adds ACSH s Dr. Ruth Kava, since that means that there are thousands of people who were inaccurately diagnosed with TB and are now going through treatment and experiencing side effects for no reason. What s worse, there are thousands of people with TB who don t know it and aren t being treated!

What ACSH's Dr. Gilbert Ross finds most difficult to believe is that a test marketed for such a widespread, lethal disease as TB, which kills 1.7 million people annually, lacks a peer-review publication assessing its predictive value in diagnosing or ruling out active TB. The implied claim of what is basically fraud is quite disturbing. If private companies are promoting a test that has a poor capacity to correctly diagnose TB, especially among poorer countries where TB is a major public health concern, then a serious investigations is warranted, including harsh penalties, he says.

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