

Translated from *Rev Prescrire* May 2008; 28 (295): 377

Distinguishing between research and clinical care

In theory, the earlier cancer is detected, the more effective and less aggressive the treatment, and the greater the chance of survival. Unfortunately, this is not always the case.

The impact of breast cancer screening mammography on overall mortality is uncertain (1). For example, screening has not been found to reduce the number of total mastectomies in countries where this outcome has been measured (1).

Mass screening for colorectal cancer prevents some deaths due to colorectal cancer but does not reduce the overall mortality rate (2). The utility of prostate cancer screening remains to be proven (3). And the list goes on.

Expectations remain high, fuelling the search for new and patentable screening tests.

Consequences of screening tests. In France, an Inserm (National Institute for Health and Medical Research) researcher and the Inserm director general decided to create a private company in order to commercialise a technique capable of detecting tumour cells in blood (4).

In 2007, when a dispute arose between the researchers and the company, the French National Consultative Ethics Committee for Health and Life Sciences (CCNE) was asked to intervene. In an opinion dated September 2007, CCNE reiterated that inadequately validated tests “can provide results that are difficult to interpret and that might have deleterious consequences for the physical and mental well-being of the tested subjects if they were extended to mass screening” (5). CCNE recommended that assess-

ment by an independent health authority was “a crucial prerequisite for the marketing of any diagnostic test or procedure”.

Inform patients about uncertainties. The CCNE ethics committee also recommended that a clear distinction be made between research and clinical care, stating that: “as the development of a technical tool is not an end in itself, independent of the future use of the tool [...], it is not the technique itself that should dictate its use” (5). And when this type of test is suggested, patients should be “properly informed of the uncertainties surrounding the real significance of the presence of one or several circulating tumour cells”.

The roles of researchers and clinical care providers clearly differ. Research and development of a laboratory test, along with its marketing, require systematic planning. Similarly, a new screening strategy must be properly evaluated in terms of its expected benefits and potential dangers for patients participating in the screening procedures.

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Selected references from Prescrire’s literature search.

- 1- Prescrire Editorial Staff “Mammography screening for breast cancer” *Prescrire Int* 2008; 17 (93): 24-27.
- 2- Prescrire Rédaction “Dépistage du cancer colorectal. Efficacité modeste, risques acceptables” *Rev Prescrire* 2007; 27 (290): 923-926 + 28 (292): inside front cover.
- 3- Formindép “Dépister le cancer de la prostate?” *Rev Prescrire* 2006; 26 (269): 151.
- 4- “Le directeur de l’Inserm accusé de “conflit d’intérêts”” *Le Figaro*, 15 October 2007: 2 pages.
- 5- Comité consultatif national d’éthique (CCNE) “À propos d’un test (ISET-Oncologie) visant à détecter dans le sang des cellules tumorales circulantes” Opinion n° 99, 13 September 2007. www.ccne-ethique.fr accessed 8 February 2008: 8 pages.

