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# Screening, ethics, and the law

## *Ensure that subjects know what's going on*

In traditional medical practice patients ask doctors for advice and treatment for their complaints. The doctor's duty is to do only that for which the patient has given informed consent and to provide care conforming to the standards set by a reasonable body of medical opinion. The patient usually understands, and is often reminded, that diagnostic procedures and treatment may have adverse effects. Screening for asymptomatic or occult disease differs from this: the contact is initiated by health care providers, who seek out people who believe themselves to be well with an offer to optimise their future health. By offering to screen, however, the doctor assumes the same duty of care as if the patient had initiated the contact.

Screening programmes should be regarded as research procedures until their value and safety are firmly established. Review by a local research ethics committee before their introduction is therefore mandatory.[1] The committee must first consider the proposal in the light of the long established criteria for screening tests and programmes laid down by Cochrane and Holland,[2] and Wilson and Jungner.[3] These criteria require that the condition that is to be screened for should be sufficiently important to make screening worthwhile, that its natural history should be known, and that treatment at the presymptomatic stage should favourably influence outcome. Anyone invited to undergo a screening test is entitled to assume that these requirements have been met.

When a proposal is made to introduce a new screening test the ethics committee may be confronted with an ethical dilemma. To determine the natural history of a condition and to evaluate the potential benefits of early treatment it may be necessary to gather a sample of people whose condition is at the presymptomatic stage. To do this, however, may require the testing or examining of a large population of apparently healthy people.[4] Clearly, if ethics committees insist that all Wilson and Jungner's criteria are fulfilled before permitting research programmes to start, the necessary data will never be obtained. In these circumstances ethics committees should encourage researchers to gather the necessary epidemiological data, but the temptation to intervene should be resisted, until the natural history of the condition has been clarified and the predictive value of the investigations is known. To give informed consent, therefore, subjects must understand that participation in the research programme will not benefit them, although the results may help others in the future.

Failure to obtain informed consent for a screening procedure is not only ethically unacceptable[5] but also exposes the health authority to the risk of litigation. When assessing a proposed new screening programme ethics committees should not be content with assurances that subjects will receive a clear oral explanation. Only by insisting on a clear information sheet or leaflet and reading it carefully can they assess whether all questions will be honestly answered. Furthermore, the adverse psychological consequences of screening may be minimised if subjects understand precisely what the screening programme offers.[6] Whoever obtains consent should note in the medical record what information has been given to the subject. The time taken to obtain genuinely informed consent must be included when calculating the cost of any screening programme, whether it is established practice or still at the research and development stage.

Failure to provide adequate information for the subject to give informed consent may not only result in an action for negligence but also lead to an action for trespass against the person.[7] To give consent subjects must understand the nature of the screening process. They should be told what the test is for and—if known—its false positive and false negative rates. The consequences of a positive result must be explained. In some circumstances—for example, antenatal screening tests for congenital abnormality—these can be serious,[8] entailing extensive investigations and perhaps culminating in the loss of a normal infant because of a false positive result or a complication of the diagnostic procedure.

A false negative result may delay diagnosis, and the subject must be warned that screening tests can never be perfect. For example, congenital deafness is easily missed in infancy because the screening test is difficult to do well. If parents are told that the child has "passed" they may dismiss any concerns they have about the child's hearing so that screening may delay rather than facilitate the diagnosis.[9] Even more disturbing, in the context of antenatal screening, is the possibility that a false negative result may be followed by the birth of a severely handicapped child, with disastrous emotional and legal consequences.

A subject who has suffered unpleasant or hazardous procedures as a result of a screening test, or who was wrongly reassured by a false negative result, might bring a successful action if he or she could show that the nature and limitations of the screening process had not been adequately explained or

that the test had not been correctly performed. In the case of the false negative result the subject would also have to show that loss or damage had been sustained as a result of the delayed diagnosis. A health authority might also be judged negligent if substandard laboratory reagents or techniques resulted in an incorrect result or if staff failed to respond appropriately to a positive result.

Screening has an intuitive appeal. Nevertheless, health authorities may be reluctant to continue or embark on screening programmes that have not been adequately researched or that expose them to a risk of litigation. They must consider what might go wrong with a screening programme, how a court might react in the event of a mishap, how informed consent can best be obtained, and how hazards can be minimised. At the same time they should remember that, though failure to provide and promote a particular health care measure is not necessarily actionable, it might become so if a substantial body of medical opinion came to believe that such a measure was necessary.

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# Americans retreat on SI units

## *Turn again, New England Journal of Medicine*

After a decade of trying, American doctors are giving up on the new fangled Système International (SI) units. The *New England Journal of Medicine* has announced that it will no longer use them alone.[1] Instead it will use conventional units and give SI units in parentheses "as a courtesy to our many overseas subscribers who are used to them." This backward step is much regretted both within the United States and outside and is akin to the World Health Organisation deciding that trying to eradicate polio is just too tiring.

The case for the superiority of SI over conventional units has been made many times, and the *New England Journal of Medicine* makes it again in the first paragraph of its back-tracking editorial: they are scientifically more informative and they simplify international communication. The health systems of most countries and most medical journals began using them in the 1970s, and even most English speaking countries gave up their grains, rods, perches, furlongs, and scruples in the '80s. Indeed, the International Committee of Medical Journal Editors, which includes the editor of the *New England Journal of Medicine*, agreed that measurements should be reported in SI units, and most American journals began to do so in the '80s.

The *New England Journal of Medicine* is retreating because most of its American readers don't use and don't understand SI units. This move to give readers what they want rather than what editors think will be good for them is in many ways admirable. Medical journals have for too long had a tradition of ignoring their readers' needs, but medical journals also have a job to lead—and the *New England Journal of Medicine* has often done so. When a journal of its influence retreats on something as important as SI units then whatever movement there is to SI units in the United States will be slowed or even stopped. The journal should be shaping the future, not retreating into the past.

In some ways this retreat is symptomatic of the broader ills of the United States. For a time Americans could choose to ignore the rest of the world. Their economy was so powerful that they had no need to worry about foreign markets. Now it is threatened by Japan and the European Community, and American business schools are internationalising their curriculums as fast as they can and schoolteachers are encouraging their pupils to look beyond the United States. The *New England Journal of Medicine* should be doing the same, not encouraging the mentality of "Fortress America." Perhaps some American doctors hope that if change is necessary to ensure international standards it will be the rest of the world that will have to change. Given today's world, this is an unrealistic dream.

Another American ill that this episode illustrates is the difficulty of making change right across the board. The intentional division of power among the executive, legislature, and judiciary, which is repeated in every state, stymies attempts to tackle broad issues like reform of the health care system and improving the environment. Whereas Britain and the Nordic countries could introduce SI units everywhere after broad consensus was reached, such a move is simply not possible in the United States. The slow, halfhearted way of gradually implementing the change has been the greatest hindrance to the Americans' adoption of SI units. But jumping over a fence cannot be done in several small leaps.

Finally, there is the need for leadership, which Americans should understand, given that they lead the world in "leadership studies" and their bookshops usually devote a whole section to the topic. The rest of the world looks to the *New England Journal of Medicine* to provide leadership for medicine, and being let down is painful. It's fine for Miss Adelaide to sing of "a bushel and a peck" in *Guys and Dolls*, one of America's greatest musicals, but the phrase doesn't belong in the country's greatest medical journal.

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