New diagnostic tests need more rigorous evaluation

Harms and benefits of new diagnostic tests should be fully evaluated and understood before they become available for use in clinical practice, argue Gluud and Gluud (p 724). They propose a four phase process of assessment,

mirroring that used for new drugs. Using brain natriuretic peptide for diagnosing heart failure as an illustrative example, they describe the four phases in diagnostic research. They claim the process is applicable to a wide range of tests including laboratory techniques, diagnostic imaging, pathology, evaluation of disability, electrodiagnostic tests, and endoscopy.

POEM*

False positive PSA is associated with increased worry

Question Do men who receive a false positive prostate specific antigen (PSA) test result worry more about prostate cancer than men who receive a negative result?

Synopsis For this prospective cohort study, the investigators identified 167 men from a group of consecutive men who had negative results of biopsy after a suspicious PSA test—a false positive PSA result. For comparison, they also identified 233 men who had a normal PSA result. The men were mailed a brief questionnaire about six weeks after they received their results. Overall, 85% of the men returned the survey, which is a very good response for a survey. Of the men who had a false positive result, 49% reported having thought about prostate cancer either “a lot” or “some of the time” compared with 18% of the control patients ($P < 0.001$). Compared with 8% in the control group, 40% of the men in the false positive group also worried “a lot” (7%) or “some of the time” (33%) about the possibility of developing prostate cancer. The false positive group did not worry more than the control group about dying soon. Sixty two percent of the men with a negative biopsy reported being “a lot” reassured by the result, despite the 10% false negative rate associated with biopsy. As with women who receive a false positive mammogram result, instead of being angry at the erroneous test result, men with a false positive PSA felt they had “dodged a bullet”: significantly more men in this group reported that their lives had changed for the better (31% v 13%; $P < 0.001$). And, as with women who have a false positive mammogram, the men in the false positive group were more likely to think their chance of getting prostate cancer was “much more” or “a little more than average” (36% v 18% in the control group; $P < 0.001$).

Bottom line False positive results of screening tests are not benign; they have a psychological cost. Men who received false positive prostate specific antigen test results reported having thought and worried more about prostate cancer despite receiving a negative follow-up (prostate biopsy) result. They also think that the false positive result makes them more likely to develop prostate cancer. Screening can be bad for our patients’ mental health.

Level of evidence 1b (see www.infoPOEMs.com/levels.html). Individual randomised controlled trials (with narrow confidence interval).

McNaughton-Collins M, Fowler FJ, Caubet JF, et al. Psychological effects of a suspicious prostate cancer screening test followed by a benign biopsy result. *Am J Med* 2004;117:719-25.

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* Patient-Oriented Evidence that Matters. See editorial (*BMJ* 2002;325:983)

Editor's choice

Heading where exactly?

“The hospital care was spread over three sites, delivered by six teams and by numerous members within each team, while the information passed to her GP was patchy.” So runs Craig Gannon’s sobering critique of the fragmented care delivered at his hospital to an elderly woman whose death from unaddressed renal failure could have been averted (p 737). How many such stories lurk in the corridors of today’s NHS, and what do they tell us?

Gannon says they tell us that, while individual clinicians are doing what they are asked, the UK’s new tick box, target driven culture means they are doing no more than is required. People are working in silos and without clear ownership of patients by a lead clinician, so there is no continuity of care. If this is, as Gannon implies, a result of recent reforms, what can we expect from the next phase of the government’s NHS improvement plan unveiled by Nigel Crisp last week?

Choice, we are told, will be the engine of the new patient led NHS. Patients needing elective procedures will choose from a menu of hospitals, including those in the private sector. A fixed national price for each procedure will mean that GPs and their patients make choices based on quality, not price. Payment by results will mean that hospitals get the money only if they get the business, which will encourage them to do a better job.

Won’t it be wonderful if it works? Better care is after all what we all want and it’s hard to argue against choice. But a report also published last week (p 691) voices concerns shared by many. Firstly, choice is not everyone’s cup of tea: apparently two rather large sectors of the population (men and people over the age of 55) prefer, in general, to leave decisions to their doctor. Private operators could skim off less difficult cases, leaving the NHS to deal with anything complex. Hospitals that patients choose not to use could close, which may not be in the public’s best interests. And rather than increasing equity as the government hopes, choice could unfairly advantage those better able to access and interpret information about a hospital’s performance.

And what types of information can properly hold health services to account? Quantitative measures like waiting times or death rates somehow adjusted for case mix? Or some qualitative measure of continuity of care? Not at any rate patient satisfaction, argues Barbara Stocking (p 736). Instead, well tested tools—such as simply asking patients whether their health is improved after care—could give a rational rather than a preference basis for decisions. Christian and Lise Lotte Gluud call for evidence based diagnosis (p 724), but where is the evidence for NHS policies? How do we know that they won’t result in more cases like the one described by Gannon?

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