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Airport screening for Ebola

Will it make a difference?

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On 9 October the UK government announced that "enhanced screening" for Ebola virus disease will be implemented at Heathrow and Gatwick airports and Eurostar terminals. Details of how this will be done are not yet available, but the objectives presumably are to identify people arriving from Sierra Leone, Guinea, or Liberia who may have been exposed to Ebola, assess whether they have symptoms consistent with Ebola, test those who do, and isolate anyone with positive results.

Several practical difficulties will need to be overcome to achieve these objectives. As most direct flights to the UK from Sierra Leone, Guinea, and Liberia have been discontinued because of the epidemic, passengers will be arriving from various European cities, and itineraries will need to be carefully checked to identify passengers arriving from those countries. Those who are identified will be asked to complete a questionnaire stating whether they have been in contact with sick people or have attended funerals in west Africa, and whether they have symptoms such as fever, headache, diarrhoea, or vomiting.

People who answer "yes" to any of these questions will presumably be referred to a health official, which is likely to lead to considerable delays; this would not be an incentive to fill in the form honestly. A thermal scanning device may also be used to check passengers' temperature on arrival, but it is unclear what will happen to those found to have a fever. Most will not have Ebola. Even if testing facilities are on site, substantial delays to large numbers of passengers seem inevitable, and isolation of all passengers waiting for their test results may prove challenging.

The World Health Organization recommends that passengers on international flights out of Sierra Leone, Guinea, and Liberia should be screened for evidence of Ebola before boarding their flight. Those with symptoms or a raised temperature should not be allowed on the flight. Clearly, identifying people with Ebola before they board an international flight is a desirable objective. But how well does this system work in practice? Data are not available on the number of passengers denied entry to a flight during the current epidemic, but there are strong incentives for those wishing to fly to deny symptoms even if they have them and to take an antipyretic such as aspirin to bring down their temperature if they have a fever.

Hot and bothered

Lack of evidence

Is there any evidence that screening travellers arriving at international airports is an effective way of identifying those with serious infections? The data from Canada, which introduced airport screening during the SARS (severe acute respiratory syndrome) epidemic, are not encouraging. A total of 677 494 people arriving in Canada returned completed questionnaires, of whom 2478 answered "yes" to one or more question. A specially trained nurse referred each of these for in-depth questioning and temperature measurement; none of them had SARS. Thermal scanners were installed at six major airports. Of the 467 870 people screened, 95 were referred to a nurse for further assessment. None of them was confirmed to have a raised temperature. The cost of this unsuccessful programme was $CA17m (£9m; €12m; $15m).[1]

Why was this measure so ineffective, and could it work now? During the SARS epidemic a simple model was used to assess the fraction of cases that could be detected by entrance screening.[2] Assuming that people with symptoms are not allowed to board, entrance screening can only pick up those who develop symptoms while travelling. The longer the incubation period in relation to the flight duration, the lower the chance that this will happen, and the lower the yield from entrance screening.

The priority should be to provide information to all those who may be at risk on how and where to seek care

Updating the model using data on Ebola (incubation time 9.1±7.3 days[3]; direct flight from Freetown to London 6.42 hours), we estimate that, if everyone with symptoms was denied boarding, about 7 out of 100 people infected with Ebola travelling to the UK would have symptoms on arrival and hence be detectable by entrance screening (95% confidence interval 3 to 13). The other 93% would enter the UK unimpeded. If passengers arriving via Paris or Brussels (journey time about 13 hours) were not screened in transit, entrance screening in the UK could detect up to 13% of infected people (95% CI 7% to 21%). The majority would still enter the UK before developing symptoms. Only if patients are allowed to fly irrespective of symptoms would entrance screening be able to detect a substantial fraction of cases (43% if there is no direct flight, 95% CI 34% to 53%).

People who know they are at risk and develop symptoms will want to seek care immediately, as they will fear for their lives. The priority should be to provide information to all those who may be at risk on how and where to seek care. This would be as effective as screening at a fraction of the cost.

Adopting the policy of "enhanced screening" gives a false sense of reassurance. Our simple calculations show that an entrance screening policy will have no meaningful effect on the risk of importing Ebola into the UK. Better use of the UK's resources would be to immediately scale-up our presence in west Africa—building new treatment centres at a rate that outstrips the epidemic, thereby averting a looming humanitarian crisis of frightening proportions. In so doing, we would not only help the people of these affected countries but also reduce the risk of importation to the UK.

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The trial's negative result might lead us to question the widely accepted assumption of a causal chain linking the introduction of shared decision making to patient empowerment

Decision aids, empowerment, and shared decision making

Each works or fails to work in patient-clinician conversations

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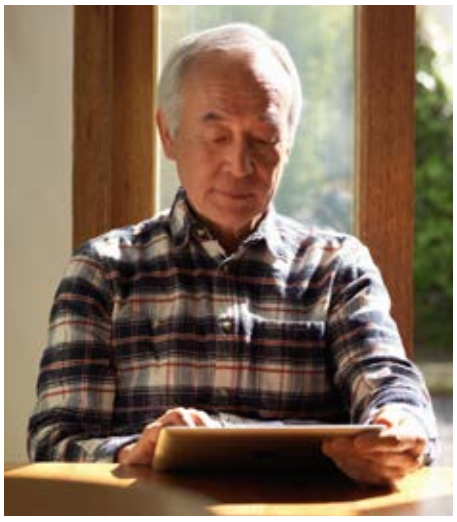
Finding unexpected results when testing our ideas is the basis of learning, experimentation, and scientific method. In a linked paper, Denig and colleagues report on a randomized trial of a decision aid for patients with type 2 diabetes.[1] After much well executed work in the development and testing of this decision aid, the authors concluded that it had a trivial, if any, effect on patient empowerment. What might we learn from this?

The trial tackles a real problem: the difficulties faced by patients and doctors in collaborating to target and control risk factors for adverse diabetes outcomes.[2] Targeting risk factors for diabetes requires commitment by both clinicians and patients, as it involves drug selection as well as the instigation of changes to patients' lifestyles. This care can be overwhelming,[3] and patients and clinicians should collaborate to prioritize the focus of treatment. Collaboration is, however, threatened by knowledge and power differences in the clinical encounter.

The hypothesis of the trial was that use of a decision aid would lead to patient empowerment, which would lead to patient involvement, which in turn would lead to greater adherence to treatment. This causal chain of empowerment is a reasonable idea. Indeed, it lies squarely within current thinking about shared decision making.[4] The negative results of this trial might lead us to conclude that there was some flaw in the design or the use of the intervention. They might also lead us to question the widely accepted assumption of a causal chain linking the introduction of shared decision making to patient empowerment.

Both lines of questioning focus our attention on what is happening in the clinical encounter. We do not know if Denig and colleagues' complex intervention succeeded in supporting the collaborative deliberation necessary for shared decision making. The trial set up the clinical encounter as a black box. The decision aid served as the input to the box, patient empowerment as the output of the box, and the researchers found little association between input and output. Inside the black box was the work of patients and clinicians coming together in conversation to make decisions about diabetes care. Without paying close attention to this interaction of patients and clinicians in the encounter it is impossible to fully appreciate the extent to which the decision aid has limitations in its design or use.



ROWAN ALLAN/SPL

Back to the drawing board

The authors report, for example, that several healthcare providers thought some of the information contained in the decision aid was unnecessary. Digging deeper into this suggestion requires looking at how the questionable information functions or fails to function in conversation—does it usefully contribute to patients and doctors talking through the problem at hand? With this focus, the decision aid and its constituents may be evaluated as factors operating internally, within the conversation.

Unexamined encounter

Why was the encounter left unexamined? While this study focuses on the problems of patient empowerment and involvement, its view of patient empowerment assumes that a patient's power to make decisions in clinical encounters is contingent on factors outside the clinical encounter. These factors external to the encounter include the content of the decision aid in both a paper based and an electronic format along with the training of doctors in motivational interviewing and risk communication. It follows from this assumption that the clinical encounter can be left unexamined.

We propose that the work of shared decision making—collaborative deliberation in the face of uncertainty[5]—happens within the encounter between patients and doctors. Decision aids function or fail to function in this environment. Successful decision aids enliven conversation and are at the same time enlivened by conversation, just as patients and doctors themselves may enliven conversation and be enlivened, or empowered, by conversation.[6] A decision aid, patient power, medical skill, and scientific evidence do not simply result in good decisions by being in a room together. Each may potentially contribute, but we think that their potential is drawn out and realized in conversation.

Following this line of thinking means paying closer attention to conversations between clinicians and patients when developing and evaluating decision aids. Researchers should deploy observational methods that try to identify those factors internal to the encounter that cause the decision aid to function as a decision aid—that is, to support interpersonal deliberation grounded in evidence, the real and particular problem being discussed, and the patient's context, preferences, and values.[7]

Denig and colleagues have advanced our understanding of how we should plan and conduct studies on shared decision making, decision aids, and other forms of patient centered care. Their meticulous work invites us to focus our attention on what is not seen. Their results advance the notion that testing shared decision making (and possibly patient empowerment) requires studying the logic of conversations between patients and their doctors.

This analysis should persuade researchers to partner with patients and doctors to enter and illuminate the black box of clinical encounters. In there, we shall find the conversations that shape health care.

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RESEARCH, p 13

Head-to-head comparisons may deviate from the truth by using unfair comparisons of doses, administration routes, or selective outcome reporting and analysis

Bias related to funding source in statin trials

The biases are clear if you know where to look

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One of the fundamental principles of pharmacology is that the effects of drugs (both efficacy and harms) are dose related. In a linked paper, Naci and colleagues use network meta-analysis as a technique to confirm that the effects of statins on serum levels of low density lipoprotein (LDL) cholesterol are dose related.[1] They also conclude that industry sponsorship of statin trials is not associated with increased efficacy estimates and that there are no differences in risks of bias between industry and non-industry sponsored trials. They incorrectly argue that this finding differs from our previously published study examining industry bias in drug-drug comparisons of statins.[2]

Like Naci and colleagues, we also found no differences in the results of industry and non-industry sponsored studies comparing statins with statins or other drugs. We did not include placebo comparisons. In addition, we found no differences in the adequacy of concealment of allocation, blinding, and inclusion of all subjects in the analysis between industry and non-industry sponsored studies.

Fortune favours the funder

However, we went on to analyse a pre-specified subset of studies—all of which were industry sponsored—to determine whether the results favoured the drug of the company sponsoring the study.[2] Naci et al did not make this comparison of studies funded by one company versus another. We found that the results of head-to-head comparisons favoured the product made by the sponsor of the study. Thus, for head-to-head comparisons, it is not industry sponsorship per se, but the company sponsoring the study that is associated with the bias.

We postulated that this favouritism was accomplished by testing the sponsor's drug at a higher dose than the competitor's drug. This assumption was based on evidence from a review of randomised controlled trials comparing the reductions in serum LDL cholesterol levels of two or more statins, which showed that almost all of the trials compared non-equivalent doses.[3] In head-to-head comparisons of drugs, "gaming the dose" is often used to demonstrate that one drug works better than another.[4-6] And, it's not just about the dose. The administration route of the drug[7] or the coding and analysis of outcomes[8] can also result in comparisons that favour one product over another.

Although the network meta-analysis conducted by Naci et al shows that the effects of statins are dose related, it does not investigate whether the studies funded by a particular company tested non-equivalent doses of the company's product compared with a competitor's product, or examine other differences in study design among the industry funded studies.[1]

Two studies, both alike in findings

So, we have two studies examining industry bias in statin trials with similar findings regarding the differences between industry and non-industry sponsored studies, but different conclusions about whether industry sponsorship biases study outcomes in favour of the sponsoring company's product. Part of this discrepancy is due to the definition of bias. Although Naci et al quote the Cochrane Collaboration definition of bias "as a systematic deviation from the truth, in results or inferences,"[9] they argue that differences in the frequency of statistically significant findings observed between industry and non-industry sponsored trials should not be referred to as bias.

As summarised in a Cochrane review, most studies of industry bias have examined the association between study funding source and "favourable" results, defined as those showing greater efficacy or less harm for the sponsor's product than for the comparator.[10] Naci et al argue that bias can only be evaluated based on the magnitude of the effect. The Cochrane review found that pharmaceutical industry sponsored studies were more likely to have favourable efficacy results and harm results than non-industry sponsored studies, but the findings for effect size were not consistent.[10] This is predictable because the studies of funding bias were conducted across a variety of drugs and indications and the effect sizes of different drugs vary widely depending on dose, the outcome being measured, and other factors such as the extent of reporting bias.[11] The direction of effect associated with industry funding is consistent. Independent of the effect size, overall, industry funded trials show treatments to be more efficacious and less harmful than non-industry funded trials.

Among studies of statins, industry bias is only apparent among head-to-head comparisons of statins funded by a single company. Network meta-analyses are a valuable tool for making indirect comparisons of drugs, but they can be difficult to interpret because of the complexity of their methods. The wide confidence intervals often shown for the relatively small number of indirect comparisons that can be generated make it difficult to detect meaningful differences.

Head-to-head studies that are sponsored by a company are far more common in areas where there is a commercial advantage to showing that one drug is better than another. These head-to-head comparisons are an example of research that can be used as marketing. Company sponsored head-to-head comparisons are presented to insurers, drug selection committees, and others who must decide which drug to recommend among competing products. These head-to-head comparisons may deviate from the truth (in other words, be biased) by using unfair comparisons of doses, administration routes, or selective outcome reporting and analysis. Despite their potential for bias, direct head-to-head comparisons can provide accurate information if comparative doses, routes of administration, and outcome measurement and analysis can be confirmed for the study.

Previously, I have argued that funding source should be considered a risk of bias.[12] Further empirical research on the association of industry funding with research outcomes is needed in order to understand possible mechanisms for the observed industry bias in the context of different types of test drug or study design. In the meantime, the potential for industry bias should not be ignored.

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RESEARCH, p 11

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The NHS in England and the 2015 general election

Will today's politicians rise to the challenge or consign necessary reforms to the "too difficult" box?

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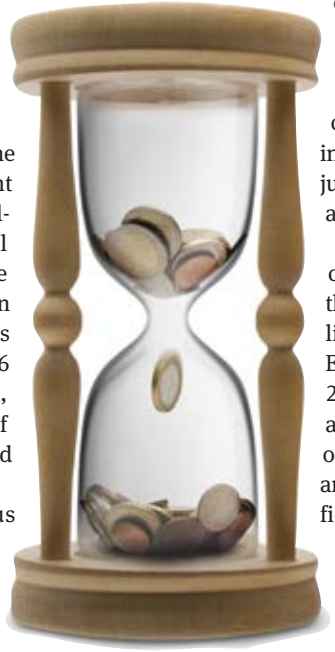
This autumn's party conferences offered some clues on how politicians are thinking about the NHS in preparation for next May's general election.

The Conservatives, Labour, and Liberal Democrats all made commitments to increasing funding for the NHS in a context in which NHS organisations are facing the prospect of growing deficits and difficulties in delivering key targets on patient care. Improving access to general practitioners and promoting closer integration of care were other areas on which the parties agreed.

Not surprisingly, they differed on the role of competition—most obviously in the Conservatives' continuing commitment to developing the market in healthcare whereas Labour is seeking to save money by reducing competition and making the NHS the preferred provider of services. The Liberal Democrats made their mark with a pledge to give priority to mental health.

The commitments made on funding varied in their specificity and generosity. The Conservatives promised to ensure a real terms increase in NHS funding, leaving open the question of whether this would be just above the level required to cover the costs of inflation, as in the current parliament, or more generous. Labour announced its plans to establish a "Time to Care" fund of £2.5bn (€3.2bn; $4bn), widely interpreted as over and above the annual inflation uplift for the NHS, although the full amount promised will not become available until 2017-18. The Liberal Democrats promised to increase funding in real terms by £1bn in 2016-17 and 2017-18, as well as reviewing funding for 2015-16 in this year's autumn statement, while holding out the prospect of bigger increases towards the end of the next parliament.



The beginning of a serious debate about NHS funding marks a welcome departure from what had seemed to be a conspiracy of silence among the political parties on the challenges facing the NHS. With further deep cuts in public spending planned for the next parliament whichever party is in power, and the outgoing head of the civil service warning that the most difficult decisions about public services have yet to be made,[1] politicians are understandably reluctant to promise more than they can realistically deliver. The risks of jeopardising plans to eliminate the deficit in the public finances by promising more money have to be weighed against the dangers of the NHS falling into crisis if current spending plans are not changed. For the time being at least, the political calculus favours additional investment in the NHS.

Whether the new found generosity towards the NHS will be matched by similar commitments on social care is not yet clear. Cuts in social care spending during this parliament mean that around one quarter fewer people are receiving publicly funded social care as local authorities tighten their eligibility criteria in order to live within their budgets. The coalition government has sought to cushion the effect of these cuts by transferring money from the NHS ring fenced budget to social care and the pooled health and social care budget, known as the Better Care Fund. Pooling budgets by transferring funds from the NHS is an understandable response to the interdependency of health and social care, although it substantially increases pressure on the NHS just when deficits are growing and targets are being missed.

It is also not clear that the commitments now made on the NHS will be sufficient. The likelihood is that the NHS in England will end up in deficit in 2014-15, perhaps by as much as £2bn. Putting NHS funding on a sustainable basis requires annual real terms increases sufficient both to cover inflation and to meet rising demands for care. It also requires additional funding for investment in new services that over time will result in less reliance on care in hospitals and care homes. This should be through a transformation fund covering health and social care.[2] A reasonable estimate of the required extra funding, recognising the scope to use existing budgets more efficiently, would be annual increases of around £4bn and a transformation fund of at least £1bn a year. This would provide the certainty needed to plan for the future and to implement new models of care.

The beginning of a serious debate about NHS funding marks a welcome departure from what had seemed to be a conspiracy of silence among the political parties

The more radical and desirable option would be to acknowledge the need for a new health and social care settlement fit for the 21st century—as set out by the Barker Commission in its recent report—rather than seeking to patch up a system that is creaking at the seams.[3] Such a settlement means aligning social care with the NHS by making social care for people with critical and substantial needs free at the point of use as the public finances recover and resources permit. Extra spending on health and social care would be funded through a combination of tax and national insurance increases, reallocating other forms of public spending, and the reform of prescription charges. Better-off pensioners would be expected to pay their share of these costs and would benefit from a more generous and integrated care system paid for through a single health and care budget.

A new, affordable settlement

If it is phased in over a decade, a new settlement is entirely affordable and would be as important as the post war reforms that created the current health and social care system. The unanswered question is whether today's politicians have the vision and the courage of their predecessors or, as seems more likely, prefer to consign major changes of this kind to the "too difficult" box.[4]

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