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New NICE guidance on referral for cancer

Monumental, evidence based, but not “less is more”

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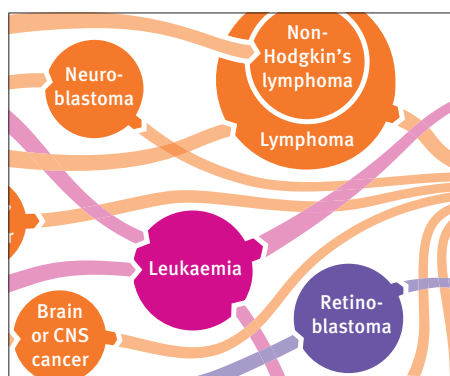
It is difficult to recall the 1990s, when patients in the United Kingdom with suspected cancer sometimes waited months for investigation. In 2000 the Department of Health introduced guidelines for referral, structured pathways, and a waiting time target of two weeks for patients with suspected cancer. Fifteen years later guidelines published by the National Institute for Health and Care Excellence (NICE) represent an enormous overhaul, which reflect monumental scholarship and are unique in the world.¹⁻³ This latest guidance differs greatly from its forebears in methodology, form, tone, and content.

The authors have painstakingly trawled the literature to pin down the positive predictive values of many of the presenting features of cancer. Adults with clinical features that are associated with a positive predictive value of 3% or more for cancer (less for children) should be referred urgently for investigation.

The wording is less prescriptive than in previous guidance. Many patients with cancer do not fit the classic referral criteria but still need easily accessible investigation—currently only about half of cancers are diagnosed via the suspected cancer pathway.⁴ The authors distinguish between advice supported by evidence and recommendations to “consider” investigation where the evidence is thin. In primary care symptoms that are of concern are often “unexplained” or “persistent,” and these words, surprisingly absent from previous guidance, occur more frequently here. Hoarseness, for example, has to be unexplained and persistent rather than merely being present for three weeks as previously stated.

This guidance appears in the UK amid concern that cancer survival is poorer than in other developed countries.⁵ This is sometimes ascribed to delayed referral by general practitioners who act as “gatekeepers” to resources.⁶

Yet the truth is that primary care, for better or for worse, has soaked up a great deal of clinical risk in low risk clinical scenarios, which is how the NHS has survived with limited resources.⁷



See infographics at <http://bit.ly/1Ckn8j2> and <http://bit.ly/1GlpEV>

As a GP (and as a potential patient) I have a few unanswered questions. Currently, around 11% of patients referred urgently with suspected cancer have the disease—that is, nine urgent referrals for one new case of cancer.⁴ If all GPs refer at 3% risk there will be 33 urgent referrals for each new case of cancer. As a patient, if I am investigated at a threshold of 11% risk I will have about six investigations (colonoscopies, prostatic biopsies, or the like) before I have a 50% chance of being diagnosed with cancer ($0.89^6=0.5$), whereas at a 3% threshold of risk I will be investigated 23 times. However, I also face future risks from other cancers, arterial disease, neurodegenerative disease, chronic kidney disease, and so on. One concern is that I will retire from general practice and spend my remaining years in hospital outpatient clinics.

The problem becomes greater with patients who have multiple symptoms or who always answer positively to a direct question. These are a vulnerable group, and one role of GPs is to protect them from over-investigation.

This identifies a problem with over-reliance on positive predictive values rather than clinical judgment. The way most positive predictive values are calculated probably substantially overestimates them. Studies often derive such values using databases of Read coded symptoms entered into the general practice computer system. But if GPs preferentially code the clinical details they think are important, rather than the

entire blizzard of symptoms often encountered in a single consultation, then the positive predictive value may be substantially inflated. Symptoms such as fatigue, hoarseness, cough, or abdominal bloating occur very frequently in consultations, yet may be preferentially recorded only when the GP suspects major disease.

Clinical common sense

An over-reliance on the positive predictive value of symptoms could miss subtleties of presentation that alter their importance. There is probably a big difference between the predictive value of a volunteered symptom (“When I swallow my food sticks here”) and an elicited symptom (“Do you ever feel your food gets stuck?” “Well, yes actually.”) Experience also suggests that previous health seeking behaviour makes a large difference to the predictive value of symptoms. Although the authors state that they are making “recommendations not requirements, and [they] are not intended to over-ride clinical judgment,” their advice often reads like requirements, and courts might interpret their advice this way.

Another limitation of the guidance is that it does not really reflect current concerns about over-investigation. For example, it advocates investigating unexplained deep vein thrombosis for cancer despite evidence of low pick-up rates (though just above the authors’ 3% threshold).⁸⁻⁹ The use of CA125 as a diagnostic tool in women with bloating remains, though I suspect many doubt its efficacy. Faecal occult blood testing is introduced as a diagnostic rather than a screening test. Yet despite these concerns over the methodology, these evidence based recommendations do largely seem to converge with clinical common sense, which is reassuring for practitioners of evidence based medicine.

This game changing guidance should be welcomed. It incorporates as much evidence as is available and is explicit about risk thresholds. It is less didactic and more nuanced than previous guidance. However, it does not buck the seemingly inexorable trend of advocating more intervention at ever lower levels of risk. My preference would have been to be even less prescriptive, to improve access to investigation and specialist opinion, and to rely on improving clinical skills.

Cite this as: *BMJ* 2015;351:h3640

It is only recently that researchers acknowledged antibiotic prescribing as a complex behaviour

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► News: UK lags behind other countries on cancer survival but outperforms on low antibiotic prescribing (*BMJ* 2015;351:h3618)

► Research: Feasibility and effectiveness of a low cost campaign on antibiotic prescribing in Italy (*BMJ* 2013;347:f5391)

Contribution of behavioural science to antibiotic stewardship

Belated recognition of its importance

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The prospect of a world without effective antibiotics has galvanised public and professional opinion on the need to conserve this precious resource.¹ Unfortunately, how to do this most effectively is far from clear. Just as with climate change, the threat seems for most people to be largely societal and in the future—exemplifying the so called “tragedy of the commons” (where individual action to maximise personal benefit results in harm to the interests of the population as a whole²). While many people are already experiencing the negative consequences of antimicrobial resistance, taking remedial action has perceived adverse consequences now, with many patients wanting the strongest possible antibiotic to cure their current infection.

Antimicrobial stewardship programmes have been designed to promote the effective use of antimicrobials by limiting overuse, underuse, or misuse. In the UK, example programmes include the TARGET toolkit for primary care³ and the “start smart then focus” programme for secondary care.⁴

Overprescribing

The prescription of potentially unnecessary antibiotics is one target of these programmes. Most antibiotics are prescribed in primary care for suspected infections, particularly respiratory tract infections. Many of these prescriptions offer little to no clinical benefit and expose patients to unnecessary risk of harm.^{5 6} Interventions to decrease overuse have the potential to conserve antibiotics, enhance patient safety, and reduce antimicrobial resistance.

A recent report by the Department of Health and Public Health England summarised the evidence on behavioural change and antibiotic prescribing in healthcare settings.⁷ The most depressing thing about this excellent report is its identification of the lack of underpinning



Tragedy of the commons

psychological theory and behavioural science in most of the studies done so far.

It is only recently that researchers acknowledged antibiotic prescribing as a complex behaviour, carried out by an informed individual making a (subjectively) rational choice. Indeed, some clinicians justify the “socially responsible” use of broad spectrum antibiotics early on in respiratory illness to achieve a rapid cure and avoid hospital admission.⁸ This recognition of the central role of behaviour in antimicrobial stewardship has led to attention being focused on the individual, either clinician or patient, and the multiple influences on behaviour rather than the historical focus on education to fill a presumed “knowledge deficit.” The influences on behaviour can be either external, in terms of the environment in which prescribing decisions are made, or internal, in terms of clinicians’ motivation to practise “good medicine” and follow guidelines or to accede to patients’ requests for antibiotics. Behavioural science can identify such influences and can inform and direct complex interventions aimed at specific behavioural mechanisms to change antibiotic prescribing.

Evidence of success

Interventions using behavioural science have been effective at changing antibiotic prescribing. One intervention, based on social learning theory, aimed to increase clinicians’ motivation to change their prescribing and their confidence in their ability to change.⁹ The trial showed a significant fall

in antibiotic prescribing for all causes at a practice level over one year, with no significant changes in hospital admissions, repeat consultations, or costs. More recently, in a trial informed by multiple behavioural science theories clinicians were trained in using a near patient test, communications skills in conjunction with a patient booklet, or both.^{10 11} The trial found a significant decrease in antibiotic prescribing across six European countries for both the booklet and the near patient test, with a greater decrease when doctors received training in the two interventions.

Despite these successes, antibiotic prescribing in primary care remains unacceptably high.¹² It is important that researchers recognise the value of theory based strategies that are aimed at both patients and prescribers and are tailored to the population of interest.¹¹ Tailoring of interventions is best informed by qualitative, exploratory research in the initial stages and can ensure that materials are acceptable to audiences and feasible for use.^{13 14}

Although this approach requires time and resources, it is crucial in identifying the key determinants of behaviour. Trials of interventions should include not only clinical outcomes to assess effectiveness in terms of antibiotic use but also measures of beliefs, attitudes, and motivation to change behaviour in order to understand how interventions have worked.¹¹ A detailed understanding of how the components of an intervention work to change behaviour may allow us to identify components that could be interchangeable. Such a choice would offer greater flexibility in implementing interventions in different contexts.

We strongly support the call in the government report for the use of behavioural science in tackling antibiotic prescribing.⁷ Using a theoretical framework, the report identifies 15 intervention approaches that could improve antibiotic stewardship. Behavioural interventions that are informed by theory, are tailored for a specific context and audience, and can be tested and evaluated effectively have the potential to benefit many. Such an approach is crucial in reducing unnecessary antibiotic prescribing and promises to have future benefits for antimicrobial resistance, attendance in primary care, and empowering patient self management of acute illness.

Cite this as: *BMJ* 2015;350:h3413

We have a global opportunity to generate an evidence base of the predictive performance of human symptoms

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► Research News: Primary care telephone triage does not reduce workload (*BMJ* 2014;349:g4958)

► Research: Following celebrities' medical advice: meta-narrative analysis (*BMJ* 2013;347:f7151)

Fifty million people use computerised self triage

A global opportunity, not a threat

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Self help triage is not new,¹ and most doctors have probably been tempted to use Google to check a patient's symptoms.² After reading the study of self help triage tools by Semigran and colleagues in this issue,³ some doctors may advise patients to use these tools when clinical support is hard to access—for example, while on a plane, holidaying abroad, or working on an oil rig. But few doctors would want politicians to see these tools as a cheaper and more accessible substitute for face to face out of hours services. So, what is the role of self help triage and how should we respond to the current findings?

In Semigran and colleagues' study, the mean accuracy of self help triage tools was only 58%,³ but several arguments still favour self help over telephone or face to face triage. These tools could change the lives of people who are too shy or dysarthric to use telephone triage or too frail to access a walk-in centre. A study in 1976 showed that people are more honest about their alcohol intake to a computer than to a doctor,⁴ and in a 1992 trial, pregnant women shared more antenatal problems with a computer than they did with an obstetrician.⁵ Studies using simulated patients showed that clinical advice from a health professional can be biased by patients' sex, age, race, or assertiveness.⁶ A cabinet office study of 120 UK councils in 2012 revealed that typical services cost 15p (€0.21; \$0.23) when provided through the internet, a 60th of the £8.60 cost of a face to face contact (www.gov.uk/government/publications/digital-efficiency-report). Therefore accessible, non-judgmental, and affordable symptom triage by computer will attract many patients—as well as politicians.

Four challenges

However, before universal self help triage can be advocated, four challenges need to be considered.

A tool's accuracy tells little about its impact on patient outcomes or service use. For medicolegal reasons many self help tools are risk averse and fail safe. One tool in Semigran and colleagues' study told all users to consult a doctor, for exam-

ple.³ Although people often ignore incorrect advice⁷ they can also ignore correct advice, so good accuracy in a tool may not translate into more efficient use of primary care or emergency services, let alone better clinical outcomes in serious conditions where delays matter. Surprisingly, implementation of a related technology, online personal health records, increased attendances at primary care by 26% and hospital admissions by 38%.⁸ So evidence is needed on how self help triage is used, by whom, and how users respond to outputs (and how to optimise these responses⁹), followed by randomised trials to evaluate the effects on patient outcomes and healthcare resources.¹⁰ Given that 50 million people already use self help triage annually (projection based on Semigran and colleagues' supplementary table 3), and given the large potential for benefit or harm, this evidence is needed urgently.

Clinical rapport remains important. Every clinician remembers patients who seemed unduly anxious about their relatively innocent symptoms and unburdened themselves when prompted: "Is something else worrying you?" This sixth sense persists when nurses triage by phone but is neutralised by a simple shift to triage by computerised instant messaging.¹¹ It will be a long time before automated cyberdoctors emulate such rapport.¹²

Triage tools may not reflect the way patients describe their symptoms or focus on the symptoms that matter. We know that patients and professionals describe symptoms differently (as do professionals among themselves¹³). These differences must be handled carefully in triage tools and in studies that evaluate them. In Semigran and colleagues' study,³ non-clinical researchers entered data into triage tools from hypothetical clinical scenarios, but real patients might have used a different narrative or emphasised different symptoms. In a telephone triage service, nurses and call handlers can translate from patient to algorithm

language, but self help triage tools cannot do that until "affective computing" (https://en.wikipedia.org/wiki/Affective_computing) arrives.

We do not yet have the right evidence to build more accurate, safer, and more effective tools. A decade ago, NHS Pathways sought studies on the association between symptoms and related outcomes to help design triage algorithms for NHS 111 but found few. This still applies. Evidence pioneer Dave Sackett's final initiative before retiring was the global CARE collaboration to promote large studies to validate clinical signs,¹⁴ and this initiative needs to encompass symptoms too. Symptoms are a core component of both clinical expertise and self management tools. Good evidence is needed from inception cohort studies,¹⁵ linking people's descriptions of their symptoms with appropriate triage "dispositions" (such as self care, or presentation to an

emergency department) and diagnoses. Accumulating this kind of evidence could be a global "Human Phenome" enterprise comparable to that of the Cochrane Collaboration or the Human Genome Project.

It would be easy for clinicians to dismiss self help triage tools as a trendy innovation driven by cost not quality. It seems unwise to substitute self help for clinical triage right now, but the current study³ shows that some tools are ready for randomised trials and could then become part of a "mul-

tichannel" triage strategy. However, the study also suggests that we have a global opportunity to generate an evidence base of the predictive performance of human symptoms, which can be used to develop a new generation of self help triage tools, and also inform education, practice, and self management. Seizing that opportunity is arguably a core professional responsibility as important as maintaining the evidence base for treatment effectiveness.¹⁶

Cite this as: *BMJ* 2015;351:h3675

► RESEARCH, p 11



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► Analysis: Women, children, and global public health: beyond the millennium development goals (*BMJ* 2015;350:h1755)

► Analysis: What should follow the millennium development goals? (*BMJ* 2013;346:f1193)

“Beyond aid” investments in private healthcare in developing countries

The UK government’s investment in commercial hospital chains merits greater scrutiny

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An inquiry by the House of Commons International Development Committee published in February 2015 proposed a transition to “beyond aid” policies.¹ The rationale for this transition was clearly stated: traditional forms of aid address the symptoms of poverty “at a substantial short-term cost.” In contrast, beyond aid policies aim to tackle underlying causes of poverty and “would be good for the UK in the short run as well as in the long run.”

Beyond aid policies emphasise the use of loans and equity investments to support the growth of a range of private sector companies. In December 2014, for example, the secretary of state for international development, Justine Greening, described a transition towards “returnable capital investments” in Indian health and education sectors.² A month later the Department for International Development’s investment arm, CDC Group, announced a \$48m (£32m; €42m) investment in Narayana Health, an Indian corporate hospital chain.³

The UK government’s interest in capital investments in the private hospital industry is part of a troubling wider (and poorly documented) international trend. We used a combination of online project databases and annual reports to conduct a preliminary mapping of investment commitments to private hospitals and clinics by the CDC Group and other similar development financing institutions.^{4–10} We identified commitments that totalled at least \$2.3bn, of which \$1.9bn was committed within the past eight years. The World Bank’s International Finance Corporation is the largest investor in such private hospitals and clinics, but our data suggest that other development financing institutions (in particular those of France, Germany, the UK, and Sweden) have also become increasingly supportive in this sector.

The biggest recipients of investment have been large commercial hospital chains in the emerging economy countries. Our data sug-



Beneficiary of the UK’s largesse

gest that nearly two thirds of commitments went to companies in India (\$470m), Turkey (\$345m), Brazil (\$232m), China (\$176m), Russia (\$123m), and South Africa (\$100m). Of the nine hospital corporates to receive commitments of at least \$50m since 2007, five are international chains (Saudi German Hospitals, Apollo Hospitals, Fortis Healthcare, IHH Healthcare Berhad, and Life Healthcare) and four are national chains (Max Healthcare, Acibadem Healthcare Group, Medicina, and Rede D’Or).

Direct investments in private hospitals by the UK government’s CDC Group have grown since a strategy change in 2012. Its two direct investments between 2000 and 2012 (\$6.1m in Prime Cure Clinics, South Africa, and \$5m in Apollo Hospital Dhaka, Bangladesh) have been dwarfed by investments of some \$65.5m since (in Rainbow Hospitals and Narayana Health, both India), which are expected to enable these hospital chains to expand to new cities.

Costs and distortions

Investments by development financing institutions tend to be made using criteria of job creation and returns on investment. It would seem that their effects on health systems, health equity, and poverty have largely avoided scrutiny until now. But easy assumptions about the contribution of the commercial sector to improving health coverage for poor people need to be challenged. High throughput models of profitable healthcare treatments are being rapidly rolled out in the absence of

robust evidence of their affordability or appropriateness. A recent rigorous review found “very limited evidence” that such models offer good prospects for extending services to the poor in the future.¹¹

Impoverishment caused by healthcare costs is also a documented concern in many countries.¹² Although catastrophic costs can be incurred in public sector hospitals that have user fee systems, the problem is far greater in the profit generating sector. In India alone an estimated 2.5 million households are pushed below the poverty line each year by the costs of inpatient care.¹³ We also know from research supported by the Department for International Development that many more users of private healthcare are impoverished each year in India than users of the public sector (48% compared with 15% incur catastrophically high out of pocket health spending).^{14 15}

This situation is compounded by the distortions in the provision of care that are known to be encouraged by commercial interests. Interestingly, it is the World Bank that has become the latest voice to draw attention to a worldwide epidemic of medical overuse—the prescribing of unnecessary medical tests, procedures, hospital admissions, and operations—citing the role of “aggressive marketing of services by hospitals, pharmaceutical firms and the medical device industry” and “incentives inherent in the way providers are paid for their services.”¹⁶ The bank highlights the marginal benefits of many procedures and notes that they can lead to unnecessary suffering, particularly among frail and elderly people.

This scenario arouses concerns that a transition to beyond aid in the health sector as currently envisaged may undermine attempts to achieve equitable universal health coverage. Greater scrutiny is required of beyond aid investments in commercial hospital chains and other related areas in order to better determine their effect on poor people’s access to healthcare, on catastrophic out of pocket health expenditure, and on opportunities for developing countries to create unified health systems with an appropriate focus on prevention and on primary healthcare.

Cite this as: *BMJ* 2015;350:h3012