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Too much medicine; too little care

Time to wind back the harms of overdiagnosis and overtreatment

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Doctors are now so busy managing the proliferation of risk factors, "incidentalomas," and the worried well that they lack the time to care properly for those who are seriously ill. As the definitions of common conditions such as diabetes and kidney disease have expanded and the categories and boundaries of mental disorders have grown, our time and attention for the most worryingly ill, disturbed, and vulnerable patients has shrunk. Too much medicine is harming both the sick and well.

Much of the growth in apparent illness has escaped public attention. One striking example is the tripling of the incidence of thyroid cancer between 1975 and 2012,[2 3] during which time the death rate did not change. This dramatic rise is best explained by increased testing and improved diagnostic tools, than a real change in cancer incidence. It has been described as an epidemic of diagnosis rather than a true epidemic. Similar "epidemics" have occurred in conditions where there has been active screening, such as breast and prostate cancer.[4 5]

But perhaps the most important expansion in illness has been where definitions have changed and the dividing line between normal and abnormal has shifted. This has occurred with hypertension, diabetes, osteoporosis, high cholesterol, and cognitive impairment. Small changes in the boundaries can greatly expand the proportion of the population labelled as having disease (box).[6]

Of course, some newly diagnosed and treated "patients" will benefit, but others will experience the adverse effects of unneeded treatment and the anxiety and stigma caused by disease labels. Given the consequences and costs for healthcare and the impact on patients, there has been far too little discussion and debate of the pros and cons of how we detect and define disease.

To further the debate, this issue of the *BMJ* includes the first in an intermittent series of Analysis articles looking at the risks and harms of overdiagnosis in a broad range of common conditions.[7] The article by Weiner and colleagues on pulmonary embolism shows how the introduction of a new diagnostic technology, has been associated with an 80% rise in the detection of pulmonary emboli, many of which, the authors argue, don't need to be found. The series, together with the Preventing Overdiagnosis conference in September (www.preventingoverdiagnosis.net), is part of the *BMJ*'s Too Much Medicine campaign (www.bmj.com/too-much-medicine). Future articles will look at chronic kidney disease, dementia, attention-deficit/hyperactivity disorder, chronic obstructive pulmonary disease, depression, and thyroid cancer, and we welcome suggestions for other conditions to cover.

The series aims to promote understanding of how and why the apparent prevalence of disease has changed; the consequences for clinicians, patients, and policy makers; and how we might deal with the risks and harms of overdiagnosis.

A key question is how disease definitions are changed and by whom. Currently, there are no agreed standards for the constitution of panels that review or alter the definitions of diseases, including the mix of expertise represented and the methods to manage conflicts of interest. Nor are there clear criteria for when it is reasonable to change disease definitions. Such criteria should be sensitive to the need to balance potential health gains against the potential downsides of labelling, testing, and treating many more people. The recent controversy over the changes from DSM-IV (fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders*) to DSM-5 illustrates the case for debating internationally agreed processes.[8]

Meanwhile, what can clinicians do to minimise overdiagnosis? Besides maintaining healthy levels of scepticism about changing thresholds for defining disease and the use of "more sensitive" tests, there are several strategies that may help.

Investigation and screening should be selective and targeted. Guidelines are not diktat, and doctors should not order tests if they do not think they will aid patient management. Performance incentives can perversely encourage overtesting and overtreatment.[9] Unexpected abnormal findings should be considered within the context of the full clinical picture, and in most cases repeated or otherwise verified before a diagnosis is made or treatment considered. The approach advocated by Allen Frances, the former chair of DSM-IV, of a stepped process of problem formulation, watchful waiting, minimal interventions, counselling, and, finally, a definitive diagnosis if needed has much merit.[10]

Unfortunately, a diagnostic label is sometimes needed for reimbursement or referral. If so, it should be chosen carefully and be subject to reconfirmation and later review. We suggest using the terms "raised blood pressure" not "hypertension," "reduced bone thickness" not "osteoporosis," and "reduced kidney function" not "chronic kidney disease" when talking with patients.

Finally, we need to get better at sharing uncertainty with patients about disease definitions, the risks and benefits of testing, and the consequences of different management and treatment options so that decision making can be shared. Lay versions of the papers in this new series of *BMJ* articles are being produced by the US based consumer organisation, Consumer Reports, to aid this.

Although we hope that this new series will stimulate debate about this issue, more is needed. With the inexorable expansion in medical technologies and the "selling of sickness" for commercial gain,[11] action is needed on many fronts, including education and training, research, policy reform, and advocacy. With the economic crisis and the challenge of providing universal care, it's time to find ways to safely and fairly wind back the harms of too much medicine.

SIGNS OF OVERDIAGNOSIS AND QUESTIONS TO ASK

"Red flags" for possible overdiagnosis

The incidence is increasing while mortality stays the same

Labelling of a risk factor or biomarker to sound like a disease

Shift in diagnostic definitions or thresholds with no evidence that benefits are greater than harms

Some questions we might ask

Is this a risk factor or a symptomatic condition? Do the "labels" reflect that distinction?

Who has set the thresholds? Based on what evidence of benefits and harms?

Does this new test detect more or earlier "disease"? Do we understand the natural course of disease in those extra cases?

Competing interests: See bmj.com.
Provenance and peer review: Commissioned; not externally peer reviewed.
References are in the version on bmj.com.
Cite this as: *BMJ* 2013;347:f4247

ANALYSIS, p 18

Read blogs by Paul Glasziou at http://bit.ly/101gZns

bmj.com
Research: Reporting of industry funded study outcome data (*BMJ* 2013;346:f3981)

YODA and truth seeking in medicine

Making sense of the curious case of rhBMP-2

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Last month, *Annals of Internal Medicine* published a package of articles unveiling the first fruits of the Yale University Open Data Access (YODA) project. At the core of this novel concept is the idea of a coordinating organization—YODA—simultaneously commissioning two independent systematic reviews of patient level data for a medical product, and subsequently offering the data to researchers more broadly.[1-5]

The YODA project demonstrates one way to redress the problem of incomplete and distorted knowledge by asking industry to put its most detailed clinical trial data in the hands of an independent custodian. The two systematic reviews of data from trials on recombinant human bone morphogenetic protein-2 (rhBMP-2) obtained from Medtronic (Minneapolis, MN) are the first example of applying the YODA concept to seek the truth about the safety and effectiveness of a medical product.

The systematic reviews included trials that compared rhBMP-2 with iliac crest bone grafting, considered the gold standard for spinal fusion surgery. In 2011, a controversy erupted over the safety of rhBMP-2 amid accusations that Medtronic had understated the product's known harms.[6] This led to an unprecedented collaboration between industry and academia when Medtronic gave YODA data on trials of rhBMP-2 for researchers to conduct independent re-analyses.[5]

The two independent reviews concluded that rhBMP-2 was not superior to bone grafting in effectiveness outcomes such as pain or function. This seems surprising given the way in which rhBMP-2 had been previously described in the literature as superior to iliac crest bone grafting.[7] In contrast, Medtronic stated in a press release that "these [YODA systematic review] findings are consistent with those in the original clinical studies."[8]

Yet both systematic review teams found numerous problems with the published literature and "substantial evidence of reporting bias."[2] In a linked methodological research paper by one

of the systematic review teams, the researchers found that among published trials, only 56-88% of known effectiveness outcomes collected were reported.[9] Furthermore, six of Medtronic's 17 clinical trials remain entirely unpublished (three were randomized controlled trials).

Despite the under-reporting, interpretations about treatment effect based on patient level data and unpublished internal reports were no different from those based on published data alone. Although somewhat reassuring, it does not excuse under-reporting, and in other cases the situation could have been different.

But the safety of rhBMP-2 remains an open question. Only 23% of all adverse events recorded in the trials were mentioned in journal publications.[9] Even with all the data, neither review reached strong conclusions about the safety of rhBMP-2, although both reviews identified a possible increased risk of harms such as cancer. The reviewers reported that safety data were not systematically collected in the trials and adverse events were classified using Medtronic's own non-standardized "in house" coding system (developed in partnership with the Food and Drug Administration).[9]

These safety conclusions are not surprising; randomized controlled trials have limitations in evaluating the safety of healthcare interventions.[10] But can safety signals be better detected with access to complete trial data? The two systematic reviews of rhBMP-2 were conducted without the use of case report forms. In clinical trials, case report forms are the original forms on which participant data are collected. Original case report forms can allow systematic reviewers to use standardized terminology to categorize adverse events. These forms also could enable re-adjudication of adverse events when necessary, as the FDA has shown.[11] Finally, case report forms could contain sufficient information to fully understand adverse events at the individual level. Future systematic reviewers might consider these possibilities.

Eleven years after the FDA originally approved rhBMP-2 the two independent reviews seem unlikely to fundamentally change the community's understanding of the safety and effectiveness of rhBMP-2. Some may think that this shows that the current system of drug regulation, in which regulators are the only group that needs access to patient level data, works well. But this ignores the fact that rhBMP-2 was mostly used for indications not approved by the FDA. So physicians interested in knowing what the FDA thought of the product were out of luck—the FDA does not release its reviews of trials for unapproved indications.

Independent reviews of evidence for approved and unapproved indications seem both necessary and inevitable. Does this mean that when patient level data are available, systematic reviewers should treat them as the gold standard and forgo analysis of data from publications or internal reports? Unfortunately not; the *BMJ* analysis comparing the effects of rhBMP-2 and bone grafting yielded different meta-analytic effect estimates depending on the data source interrogated—internal reports, patient level data, or published data.[9] Thus, the take home message for systematic reviewers is that we still do not know what data source is trustworthy, and until we do, it seems prudent to ask for all the data and to rigorously analyze them.

Despite these two systematic reviews, and the availability of patient level data through YODA, the published literature on rhBMP-2 remains problematic. To reduce the possibility that future research will rely on these publications, Medtronic could restore the scientific record by publishing its unpublished trials and correcting misreported or under-reported trials.[12]

The rhBMP-2 case shows that responsible independent analyses of industry data are possible. With recent pledges from other companies to make their patient level data available, systematic reviewers have their work cut out for them.

Competing interests: : YODA paid all expenses for PD to join a June 2012 planning meeting to discuss YODA's forthcoming data sharing policy.
Provenance and peer review: Commissioned; not externally peer reviewed.
References are in the version on bmj.com.
Cite this as: *BMJ* 2013;347:f4251
RESEARCH, p 12

Predicted financial break even rests on an unlikely best case scenario in which technology problems have been overcome, professional concerns about confidentiality have been resolved, and power struggles and legal wrangles with suppliers have melted away

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Research: Effect of telehealth on use of secondary care and mortality (*BMJ* 2012;344:e3874)

England's national programme for IT

From contested success claims to exaggerated reports of its death

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The national programme for IT, which promised to revolutionise care in the English NHS, was originally planned to run for two years and nine months from April 2003.[1] Policy documents predicted that by the end of that period, a near paperless working environment would be the norm. This would include electronic systems for booking outpatient appointments, referring patients, producing discharge summaries, and transferring prescriptions between general practice and community pharmacies.[2-4] In emergency care, key clinical details would be available at the touch of a button wherever in the NHS the patient presented.[5] Patients would be "empowered" by remote access to their NHS records.[1 5]

The reality was different. Contracted deadlines for delivering key systems were repeatedly missed.[6-8] Technologies that were meant to make tasks and processes more efficient at the clinical frontline were more cumbersome and time consuming, and in some cases less safe, than their paper equivalent.[7-11]

Ten years on, only a handful of hospitals can be described as paperless, and most communication between NHS organisations still occurs by snail mail, fax, or patient messenger.[12] Extracts of patients' NHS records, stored on a national spine, have led to few if any dramatic life saving decisions. This is partly because they are little used; their accuracy and clinical value are contested; and many doctors view the risks of data breaches to be over-riding.[7 13] The patient portal to the NHS spine has been abandoned.[14]

The national programme for IT brought some genuine (although mostly non-cash releasing) benefits. There have been substantial improvements in the technical knowledge base underpinning information systems in the NHS, in organisational capacity to introduce any new IT system, and in information governance processes and procedures. Furthermore, some systems (notably those for archiving images) that are now used routinely are thought to work better than their pre-electronic equivalents.[12 15]

In view of this mixed picture, we should not be surprised that two competing narratives prevail. One, articulated on 2 June this year by Jeremy Hunt, secretary of state for health, is that the programme was a "huge disaster [that] became impossible to deliver."[16]

The other, expressed in a "final benefits statement" released by the Department of Health this month and based on data collected up to March 2012, claims that the programme has been broadly successful and is now on course to realise serious financial benefits.[17] That report acknowledges that its £7.3bn (€8.6bn; $11.3bn) costs substantially outweigh the £3.66bn estimated benefits, but predicts that, if we are prepared to wait until 2022, financial benefits may be £10.69bn, outweighing costs of £9.78bn.

Given these huge sums, it is not surprising that the public accounts committee asked the National Audit Office to review the estimates.[18] The office concluded that some possible costs had not been included and those that were included could well increase. Furthermore, two thirds of the predicted financial benefits are still to be realised and depend on successful implementation and continued use of the systems, which the office considers will be challenging to achieve.

Implementation, and measurement and attribution of costs and benefits, will have to be undertaken against the background of current (and any future) NHS reforms. At a public accounts committee hearing on 12 June 2013, it was revealed that hospital trusts installing systems that were part of the national programme for IT are given cash payments averaging £3m.[19] MPs pointed out that if the financial benefits were assured, these payments would not be necessary.

In sum, the financial break even for the national programme for IT is predicted to occur around 2021. It rests on an unlikely best case scenario in which technology problems have been overcome, professional concerns about confidentiality have been resolved, and power struggles and legal wrangles with suppliers have melted away. The Department of Health anticipates being able to control clinical behaviour remotely via expert systems from Whitehall, imposing order on a disorderly NHS.

We believe that NHS informatics sits at a strategic crossroads. One road has been mapped out in the secretary of state's proposed "information revolution," whose techno-utopian vision consists (once again) of paperless hospitals, remotely accessible online records, and a high degree of interoperability between sectors.[20 21] Notwithstanding Hunt's claim that informatics decisions will be locally controlled, his savings forecast of £4.4bn seems to rest on the assumption of universal uptake of preferred systems within the NHS, bug-free technology, and an unlikely harmony among the scheme's multiple stakeholders. There is a sense here of déjà vu, of failing to learn from history.[22]

The alternative route is a genuine bottom-up (or, perhaps, middle-out[23]) change model, freed from the fetters of heavy handed state control. The Cabinet Office is taking the lead, encouraging government departments to allow small contracts, in the order of tens of thousands of pounds, and with short delivery times.[24] But although the arguments in favour of this approach are powerful, the NHS's organisational memory relates to a "waterfall" model of large contracts and central standardisation. It does not currently have the technical or regulatory infrastructure, or indeed the culture, to encourage these more agile solutions to multiply rapidly (in the manner of smartphone apps).

Perhaps the most important first step in this uncertain territory is to abandon the utopian dream of ubiquitous, calm computing, easy to implement and able to transcend the realpolitik of a fragmented cash constrained NHS.[25] In this real world, money may be more productively spent on improving and augmenting the best of the NHS's current systems; exploiting mobile technologies and social media; and pinning down exactly where the costs, risks, and benefits of a new technically hybrid informatics service lie.

Competing interests: None.
Provenance and peer review: Commissioned; not externally peer reviewed.
References are in the version on bmj.com.
Cite this as: *BMJ* 2013;346:f4130

All countries, no matter what their level of development, need an explicit political commitment by government to promote wellbeing and health as well as to reduce inequality in decision making

Health in all policies

An approach that accepts that health is not created by ministries of health or healthcare systems

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"Health in all policies" has become the catchphrase for taking account of health and equity in the policies of other sectors. Launched last month on the occasion of the eighth International Conference on Health Promotion in Helsinki, a new book intends to provide "practical workable solutions in a range of settings for a range of problems."[1] It aims at a broad audience of policy makers and implementers worldwide, with examples spanning the globe from highly developed welfare states (Finland), to both middle income (Thailand) and low income countries. A welcome feature is the attention given to the global action needed to tackle common problems that span borders—for example, in relation to trade policies. A chapter is included on how development assistance can become more effective through health in all policies.

The book should contribute to a better understanding of how to go about tackling "wicked problems" and complexity in health.[2] Eight detailed policy examples—including ones relating to tobacco, alcohol, agriculture and food policies, work, and early child hood development—give a comprehensive overview, with concise short case studies. A special chapter considers the role and responsibilities of the health sector in health in all policies. It shows that ministries of health are not well prepared to play an active role across sectors and handle the conflicts and controversies that come with such a role. Another chapter maps out lessons that can be learnt from the association between environment and health to help achieve health in all policies.

Although this book complements other recent publications well I have some reservations. One is simple and easily corrected: the examples of health in all policies (possibly because they have mainly come from health promotion) tend to neglect the experiences gained in the field of infectious diseases. The lessons learnt from severe acute respiratory syndrome and H7N9 influenza are important examples of how to craft comprehensive policies under conditions of crisis and then prepare for the long term. Some short case studies indicate this, but more would have been useful.

My second reservation is that I would have liked all contributions to have followed more closely the analytical model introduced as a reference point—the Kingdon framework, which identifies three streams of the policy process (recognition of the problem, policies, and politics). This would have enabled better comparisons between policy examples.

My third reservation is more complex. Conceptually I much prefer the term "governance for health and wellbeing" or even more simply "public policies for better health." Why? In my view the term health in all policies leads to conceptual boundary problems, which also plague this publication. Despite careful editing the authors are not consistent in their use of the term. Health in all policies is used to mean many different things—an approach (which reflects the definition provided), a goal, and a strategy. For example, early child development is described as a "component of health in all policies" and the chapter on "Prioritizing health equity" does not even mention health in all policies; it refers to "action on the social determinants of health."

The authors state that most documented health in all policies cases are to be found in more developed economies and welfare states; they relate this to limited institutional and regulatory capacity in many developing countries. This is true for challenges such as tobacco or alcohol policies, which require not only public health institutions but regulatory systems and reliable fiscal mechanisms. However, they describe interventions such as the millennium villages project, examples of which can be found throughout the developing world, as "health in all policies-type interventions." Sometimes the book gives the impression that it is integrating a range of different approaches that involve other sectors into a concept with current currency, rather than extracting the essence of a health in all policies approach from the examples.

The prime minister of Finland's foreword provides clarity. He points out that all countries, no matter what their level of development, need an explicit political commitment by government to promote wellbeing and health as well as to reduce inequality in decision making. This mirrors the constitution of the World Health Organization, which states that "governments have a responsibility for the health of their people." It means entering the realm of politics and it links to my fourth reservation. Despite the use of the Kingdon framework, the book's analysis is weakest in relation to the political determinants of health. Health policy is referred to as a "key battleground" and—for example—the chapter on alcohol states clearly that weak alcohol policies can often be attributed to the central and dominant role of commercial interests in the policy making process. In her speech at the Helsinki conference, Dr Margaret Chan, the director general of WHO, also drew attention to the distortion of public policies by powerful industries. We still require better political analysis of how to win the "health wars."

Nonetheless, if this new focus means that after decades of medicalising health we accept that most of health is created not by the actions of health ministries or the healthcare system, but by many different policies and by actions in society and everyday life, that surely is progress. If health in all policies is successful as a proxy term to highlight that we need to govern health differently I am 100% on board.

Competing interests: I was an adviser to the World Health Organization on preparing for the Helsinki conference and helped draft the conference statement.

Provenance and peer review: Commissioned; not externally peer reviewed.

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Cite this as: *BMJ* 2013;347:f4283