

# comment

Numerous government papers and strategies in this field have proved to be false dawns

**ACUTE PERSPECTIVE** David Oliver

## Are we really prioritising prevention?

Last week Matt Hancock, health and social care secretary for England, gave a speech launching a government document, *Prevention is Better than Cure: Our Vision to Help You Live Well for Longer*. After much advance publicity I was curious to see its contents. I'm enthused by the focus and I don't doubt his sincerity but, without cogent detail of meaningful investment, policy levers, and implementation plans, visions don't come true.

There's a framing preamble, the restatement of established expert consensus on prevention and public health, key facts and figures, and a series of ambitions. But the paper offers little tangible new policy, funding, or even a hint at workforce planning to deliver them.

It has a low cost focus on nudging and supporting people to take personal responsibility for their health and lifestyle risks, which ignores the evidence about the effects of wider environmental factors on individual choice. Crucially, it says nothing about increasing funding for public health or local authorities—or about tackling low pay, welfare, or benefits systems to reduce the socioeconomic disparities that beget health inequalities.

Hancock wants to “prioritise investment in primary and community healthcare,” but the paper lacks detail on how to do this and how quickly. It mentions developing an alcohol strategy with no hint at a publication date, it ducks the issue of minimum unit pricing, and it says little on the serious under-provision of cessation services or any meaningful regulation of the food and drinks industry.

It discusses shifting more resources into primary and community care but doesn't mention the serious workforce gaps, any timetable or mechanisms to



achieve this, or the hospital sector's struggle with capacity and demand.

The one truly visionary flourish is some speculation about the untapped potential of genomics, precision medicine, and predictive algorithms to target prevention. But this is very much a work in progress, whose costs and benefits are yet to be realised.

The paper mainly groups together a range of existing national policy programmes whose impact is currently uncertain. But it fails to deal with serious structural and funding shortfalls or radical solutions, and it shifts responsibility from local or national government onto individuals and employers.

Of course, not all prevention lies in formal public health services, but public health budgets have been serially cut since 2010, and the Health Foundation's analysis of the budget estimated further cuts of £1bn, as any additional funds for the NHS go into service provision and capital expenditure. If wider communities, local government, and voluntary services are to be key agents of change in the shift towards prevention—well, their budgets have been similarly cut, affecting social care and support for people to remain healthy and independent. We'll have an idea, after the next spending review and the long awaited social care green paper, whether any of this will be reversed.

I commend the health secretary for highlighting prevention. But we've had numerous government papers and strategies in this field before that have proved to be false dawns. Without being adequately resourced and backed by evidence based policy levers with teeth, there'll be another one in five years—and another *BMJ* columnist describing its limitations.

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## Time to put workplace rivalry to rest

No one is, by definition, a better doctor just because they don't work at St Elsewhere

**N**owadays remembered as the title of a 1980s US TV drama, when I was at medical school “St Elsewhere” was a disparaging term used to describe hospitals that we considered inferior to our own. That is to say, pretty much all other hospitals.

One of the less savoury aspects of our not-so-hidden curriculum was a disdain bordering on contempt for those less fortunate individuals who worked or studied in places other than our own.

This was expressed in various ways. I remember being told that a particular patient had been assaulted twice, once by a man in a pub and the second time by the surgeons at St Elsewhere who had tried to finish him off.

Perhaps conversations like that still take place. We are all programmed to see the world in relative terms and maybe making disparaging comments about others provides a shortcut to boosting our own self esteem.

I met a consultant who moved from a teaching hospital to a post in a smaller rural hospital and was astonished to find that, within weeks, colleagues at the local specialist centre were starting to patronise him, when they had only recently been coming to him for advice. It seems that the respect we feel due to colleagues is in some irrational way connected with the place in which they work.

### Strained relations

The lack of respect sometimes shown by staff in one hospital towards those in others carries echoes of the



### Let's take pride in our institutions, but not by demeaning colleagues in other places

sometimes strained relations between doctors in primary and secondary care. Others have called out the strange phenomenon by which a newly qualified doctor can feel it right

to take a superior tone with an experienced GP trying to make a referral for specialist advice.

Does it matter? Is this just a whinge from someone who works at the far end of a distant peninsula and has a corresponding chip on his shoulder?

It matters because of current moves in many disciplines,

## Why didn't the budget include tax rises to pay for the NHS funding boost?



In June the prime minister promised that NHS funding would increase by about £4bn in each of the next five financial years. Yet in the chancellor's budget last month there was no increase in income tax, VAT, or national insurance to fund this.

The Office for Budget Responsibility is admirably clear about where this extra money was found in the absence of tax rises: there were better than expected tax receipts. “The budget spends the fiscal windfall rather than saving it,” it said.

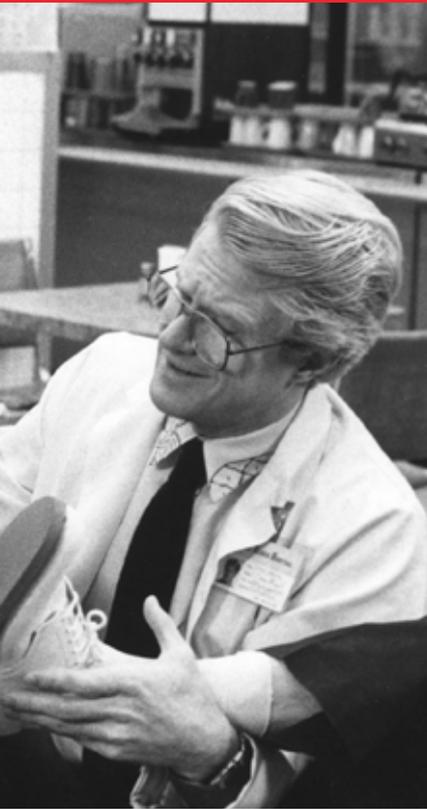
It is unclear that other parts of the public sector will be able to continue coping with the funding settlements agreed for them. In England local government funds social care and organises

public health and many other services that affect demand on the NHS, but its own funding has been hugely cut since 2010. The National Audit Office warns that “the current pattern of growing overspends on services and dwindling reserves exhibited by an increasing number of authorities is not sustainable over the medium term.”

Analysis by the Institute for Fiscal Studies found that “even a minimal definition of ending austerity would require an additional £19bn in 2022-23.” Paul Johnson, the institute's director, noted, “Health is taking a bigger and bigger share of public service spending, up from 23% in 2000 to 29% in 2010 and planned to hit 38% by 2023. At



**Undeliverable plans are not a desirable way to run a health service**



NBC-TV/KOBAL/SHUTTERSTOCK

**The fictional St Eligius Hospital was the setting of the US television drama St Elsewhere**

a number of difficult hospital trust mergers.

Having visited many hospitals over the past few years, the disparities in the physical environment, infrastructure, and resources available are often striking—you might look and feel pretty cool driving your Ferrari, but have a go in my old banger and see how you get on.

It's surely time to put these pretensions to rest. No one is, by definition, a better doctor (or nurse or radiographer) simply because they work at a particular site. By all means let's take pride in the institutions in which we work, but not by expressing demeaning and usually unwarranted opinions about colleagues in other places.

After all, you might think that you work in a world leading centre of excellence, but from where the rest of us stand it's just... St Elsewhere.

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including radiology, to encourage collaboration in networks. A network relies on mutual respect between parties to a much greater extent than a traditional hierarchical model of institution based care. Building that respect requires investment of time and effort—a lesson which should, by now, have been learnt from

some point this is going to require higher taxes. We can't just keep squeezing everything else."

### Provider sector deficit

The cause of the deficit in the provider sector of the NHS in England is not mysterious, as analysis by Sally Gainsbury of the Nuffield Trust has shown. "The root cause of the NHS provider deficit is that provider costs now systematically outstrip their income," Gainsbury says. "It costs more to treat each patient, on average, than the income hospitals and other providers receive to carry out those treatments. We can view that mismatch between expenditure and income as a trading gap, which has emerged as a direct

consequence of deliberate NHS policy over the last decade."

The budget conveyed a message that voters' taxes do not have to rise to support increased public spending. This is an interesting political judgment at a time when surveys indicate that most people think the government should spend more on public services.

The risk facing the NHS is that its imminent 10 year plan will be burdened with expectations that the extra money simply cannot support. Undeliverable plans are not a desirable way to run a health service. And they are a real and present danger.

Andy Cowper is editor of *Health Policy Insight*

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## BMJ OPINION Rob Hughes

### Toxic air: the risk factor we're forgetting to ask patients about

When was the last time the clinicians reading this asked a patient about smoking? Or how many units of alcohol they drink? I'm prepared to guess that one or both of these routine questions trip off the tongue many times every day.

Now, when did you last ask about whether the child with a respiratory infection lives on a busy road? I guess you advised the newly pregnant woman in your clinic about the benefits of folic acid, but did you recommend that she tries to walk on quieter roads or green routes during rush hour? Did you share with her the fact that breathing dirty air can lead to low birthweight, undermine neurodevelopment of the fetus, and increase the risk of developing asthma?

I hope I'm wrong, but I worry that too many doctors are forgetting this risk factor. That needs to change. Fast. Around 93% of children globally are right now breathing toxic air (and this rises to 98% if you live in a low or middle income country). This problem is big and it's getting bigger. As the world urbanises, I find it hard to think of a more pressing challenge for us all—especially doctors—to engage with.

The good news is that we know what to do about air pollution, and doing it will bring other benefits too.

Tackling dirty air can help prevent climate breakdown at the same time as saving millions of lives. Every one of us has a part to play. Here are three ideas for what you can do as a health professional and as an individual:

**It's hard to think of a more pressing challenge for doctors to engage with**

1) Ask about toxic air as a risk factor: build it into your consultations and forms. Include (and expect) a lot of "don't know" answers, but use these to raise awareness of this often invisible problem. Advise patients (particularly the most vulnerable) on how to reduce exposure.

2) Advocate as health professionals: doctors remain the most trusted professionals. Engage with this matter; put it on the agenda of your local, national, and global meetings. Advocate for policy change related to sources of pollution where you live and work.

3) Engage as citizens: campaign for change locally through community and parent groups and write to your local representatives. Be part of the solution and choose more active forms of travel.

The duties of a doctor extend well beyond the clinic or operating theatre. The promotion and protection of the public's health isn't optional—it is central to our duties as doctors. Tackling toxic air that kills millions of people is a perfect illustration of why we must put this into practice.

Rob Hughes is a senior fellow at the Children's Investment Fund Foundation (CIFF)



# Reporting harms more transparently

Clinical trials of cancer drugs often use terms that downplay the seriousness of adverse events.

**Bishal Gyawali and colleagues** call for greater clarity and transparency

The clinical trial report of ribociclib, a drug for breast cancer, mentions in its discussion that “most patients had an acceptable adverse-event profile.”<sup>1</sup> A report of a trial of liposomal irinotecan in pancreatic cancer states in the concluding paragraph that it “has a manageable and mostly reversible safety profile.”<sup>2</sup> And a trial of tasquinimod in patients with prostate cancer reports “the tolerability was good overall.”<sup>3</sup>

All three studies were published in top medical journals. Naturally, readers would take these statements to be true. However, a look at the data for adverse events doesn't paint such a good picture.

In the first study, more than twice as many patients in the ribociclib arm as in the control arm experienced severe (grade 3 or higher) adverse events (271/334 v 108/330).<sup>1</sup> The difference in treatment related serious adverse events (leading to death, life threatening condition, hospital admission, disability or permanent damage, congenital anomaly or birth defect, or that required medical or surgical intervention to prevent one of the other outcomes<sup>4</sup>) was nearly five times higher (25 v 5).

The trial of liposomal irinotecan shows that five patients in the intervention arm died from toxicities versus none in the control.<sup>2</sup>

In the trial reporting overall good tolerability of tasquinimod, the incidences of severe and serious adverse events compared with control were 42.8% v 33.6% and 36.0% v 23.6%, respectively.<sup>3</sup>

These three studies are only representative examples. The adverse event profiles of many new cancer drugs are hidden behind similarly general or subjective terms that obscure their harms. We therefore investigated how often publications of cancer drug trials downplayed



## Terms used to downplay the harms of cancer drugs and reasons for avoiding them

*Acceptable*—Acceptable to whom? Were the patients asked if the toxicities were acceptable to them?

*Manageable*—Serious events and deaths can never be considered manageable. Even manageable toxicities incur burden and decrease patients' quality of life

*Feasible*—What is the threshold for feasibility of a treatment? Will the mention of “the treatment is feasible” be enough to obtain patient's consent to a treatment?

*Favourable toxicity profile*—Favourable compared with what? Threshold of enduring toxicities and thus favourability is different from patient to patient

*Tolerable or well tolerated*—Only the patient can decide whether any side effect is tolerable

*Safe*—Any cancer treatment that has resulted in a treatment related death cannot be considered safe

harms. We defined downplaying as use of the following terms or their derivatives to describe adverse events: tolerable, favourable, acceptable, manageable, feasible, and safe. The box above explains why their use is inappropriate, irrespective of whether the toxicities were increased or decreased.

We examined all phase II or III randomised trials published during 2016 in the five major medical journals—based on their impact factors—that publish cancer drug trials (*New England Journal of Medicine*, *Lancet*, *Lancet Oncology*, *Journal of the American Medical Association*, and *Journal of Clinical Oncology*). These five capture most randomised trials of cancer drugs, and almost all trials of cancer

drugs that get approved and make it to the market. We chose trials published in 2016 as it was the most recent calendar year (this research was conducted in 2017). We looked for the identified terms and any others that could imply downplaying of harms. Disputes, or the discovery of a new term that seemed to downplay the toxicities, would be resolved by discussion and consensus among the authors.

We then assessed how harms in the experimental arm were reported. We extracted the data on severe and serious adverse events and deaths for both the experimental and control cohorts from these trials. All the study eligibility confirmations and data extractions were done twice—once by BG and once by KH, who remained blinded to each other's data—and finally double checked by TS.

## Description of harms

We identified 122 trials of cancer drugs in the journals, of which 53 (43%) contained terms that downplayed harms. Fourteen of the 53 studies did not report any data on severe adverse events, 22 had no data

## KEY MESSAGES

- Many reports of cancer drug trials use subjective terms to describe harms, especially in abstracts and conclusion
- Vague and subjective terms can lessen the perception of harm and influence decisions about treatment
- All cancer trials should fully report adverse events and avoid subjective terms
- Assessments of quality of life or asking patients about acceptability of a treatment would provide a better guide for treatment

on serious events, and two had no data on deaths. Such under-reporting of harms is common in oncology trials.<sup>5,6</sup> However, when trials mention an acceptable, tolerable, or favourable toxicity profile in the experimental treatment arm, it seems wrong not to report the supporting data.

In the trials that did report data, the rates of severe adverse events were higher in the experimental arm than in the control arm for 77% of trials (30/39), serious adverse events were higher in 84% of trials (26/31), and deaths in 66% of trials (34/51). Thus, despite using terms such as favourable, the trials often showed a greater number of harms than in the control arms.

### Why is transparency important?

Not fully reporting harms is of particular concern because cancer drugs usually provide modest benefits at high costs—in terms of both price and toxicities.<sup>7</sup> Downplaying harms can suggest a better risk-benefit profile than actually exists.

Describing harms as acceptable or tolerable in trials is unacceptable, irrespective of incidence and risk, as it makes a subjective judgment. Whether harms are acceptable is for patients to decide rather than physicians or trial stakeholders, and the threshold for tolerability to harms will differ from person to person. Without collecting data from patients on what they would acknowledge as acceptable or tolerable toxicities, we believe that investigators cannot put those labels on the experiences of our patients. Furthermore, any cancer drug that has ever had a treatment related death should not be described as safe or as having “manageable toxicities.”

We do not intend to promote or discourage a certain drug as safe or unsafe. Indeed, one trial cannot provide enough data on safety; ongoing real world data as well as physicians’ and patients’ experience of a drug should guide discussions of toxicity in clinical practice. However, unambiguous and complete reporting of harms data is an important step to appropriate clinical practice, more so in oncology where many new drugs are used that are yet to have adequate safety information from long term studies.

The subjective terms we found were used in the abstract, conclusion, or discussion (or in the “Research in context” box in *Lancet* and *Lancet Oncology*). These are arguably the most widely read sections in a research paper and may make a lasting impression on readers, who often lack the time to read the results section for further information.

## Whether harms are acceptable is for individual patients to decide rather than physicians or trial stakeholders

Although we focus on randomised trials, the use of subjective terms to describe harms is also common in phase I or II non-randomised studies as well as in conference presentations. The use of such terms in non-randomised studies is particularly concerning as readers do not have a control to make comparisons.

No data are available on whether the harms reporting in oncology trials is worse than in other specialties, but the under-reporting of harms is a well known problem irrespective of discipline.<sup>6,7</sup>

### Better reporting

We consider the lack of harms reporting and the use of subjective terms to describe harms to be poor reporting practice. The CONSORT statement for reporting of harms has a table listing common poor reporting practices.<sup>8</sup> The first item reads: “Using generic or vague statements, such as “the drug was generally well tolerated” or “the comparator drug was relatively poorly tolerated.”

All trial reports should avoid using vague and subjective terms. The trade-offs between benefits and harms will vary, and though benefits might outweigh the risks, no cancer drugs are completely “safe,” so we propose that this term should not be used.

Our study supports other evidence that reporting of adverse events is poor in cancer drug trials, with some failing to report the incidences of severe, serious, and fatal adverse events. These events should be documented in all trial reports. Although brevity may be cited as one reason for using general terms to describe toxicities in conclusions or abstracts, we propose two more accurate ways to tackle this problem. The first is to ask patients about acceptability. All trials of cancer drugs could collect data from patients on whether they consider the toxicities are tolerable or acceptable. The abstract conclusions could then state “64% of patients in the trial considered the drug to have tolerable toxicities” rather than using non-objective statements. Non-randomised trials could also use this approach.

A second solution is to report quality of life. For cancer drugs, quality of life information is an indirect indicator of harms and is also an important measure of clinical benefit. Thus, instead of “toxicities were manageable,” the report could conclude that there was “no effect on patients’

quality of life” or that “quality of life was improved,” based on objective assessment using validated tools.

However, quality of life reporting in cancer drug trials may also be subject to the risks of spin. For example, even though adjuvant sunitinib after resection of high risk renal cell cancer worsened quality of life in the S-TRAC trial, it was reported as “patients on sunitinib did report increased symptoms and reduced [health related quality of life], but these changes were generally not clinically meaningful, apart from appetite loss and diarrhoea, and were expected in the context of known sunitinib effects.”<sup>9</sup>

In another example when olaparib did not improve the prespecified primary quality of life analysis in patients with ovarian cancer, this was reported as “not having a significant detrimental effect.”<sup>10</sup> Furthermore, many randomised trials of cancer drugs do not report quality of life end points and negative quality of life information is reported less often than positive outcomes.<sup>8</sup>

Some trials already report harms more transparently. For example, a recently published trial of rituximab plus lenalidomide versus rituximab plus chemotherapy reported in its abstract conclusion that “the safety profile differed in the two groups.”<sup>5</sup> Although this statement is not very informative, it is at least an objective description and readers can look at the adverse effect profiles and frequencies for themselves. Another trial abstract concluded: “The rate of high-grade adverse events in the cabozantinib group was approximately twice that observed in the placebo group.”<sup>11</sup>

Medical journals can also help to improve reporting of harms in cancer drug trials. The use of subjective terms must be discouraged, especially in the abstracts and conclusions. Editors and reviewers should ask for detailed harms data and encourage authors to report numbers and incidence rather than the vague statements to describe the harms. As readers, physicians and patients should look at the toxicities data in the tables rather than trust generalised terms. Proper risk-benefit assessment of any cancer drug should be made with actual harms and efficacy data, and not based on general concepts of safe, tolerable, or intolerable.

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## OBITUARIES

### Peter Bruggen

Founder and consultant psychiatrist Hill End Adolescent Unit, St Albans, and consultant psychiatrist Tavistock Clinic, London (b 1934; q Edinburgh 1957; FRCPsych), died after



a short illness with prostate cancer and Alzheimer's disease on 20 September 2018

"I went to Edinburgh as a medical student at age 17. I did not like it but learnt to be strategic. I wandered through junior jobs until I found psychiatry and learnt more about myself. I had weekly psychotherapy with occasional LSD sessions, legal with safe procedures. The Department of Health tried to remove me from my consultant job because I didn't fill enough beds, had no waiting list, and worked with a systemic reason for admission and discharge. I sometimes dangerously pursued one theory to the exclusion of others, until I understood that they were merely ways of seeing things. I leave Joan, my wife since 1964; three daughters; and four grandchildren."

Peter Bruggen

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### Margaret McGarrity

Clinical assistant in sexual health Sandyford Unit, Glasgow (b 1965; q Aberdeen 1988; DFFP), died from metastatic breast cancer on 1 June 2018



Margaret McClymont married John McGarrity, a fellow doctor whom she had met during house jobs at Airdrie Hospital, in 1990. Their children were born in the following years. In 1997 Margaret applied for a job in genitourinary medicine in Inverclyde. Her patients liked her clear, concise, non-judgmental communication skills, and her colleagues soon realised she could cope with a busy clinic. She moved to the Sandyford Unit in Glasgow, where she worked full time. Margaret never defined herself as a doctor—she was more content when she was being creative. She was a talented dressmaker and excelled in crafts and problem solving. In 2005 she was diagnosed with grade 3 breast cancer and in 2007 with multiple bone secondaries. She leaves John, five children, and five cats.

John McGarrity

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### Alan Gibson

Consultant psychiatrist (b 1926; q St Mary's Hospital, London, 1949; FRCP Ed, DPM, FRCPsych), died from a stroke on 2 September 2018



In 1963 Alan Gibson moved to St Ann's Hospital in Poole to set up a new psychiatric service for Bournemouth. Of the initial 400 inpatients, only 43 remained when he left 18 years later. The rest had died or were cared for in the community, with the help of the community nursing service that he personally set up. In 1981 Alan left the NHS and was medical director of Bowden House Clinic in Harrow on the Hill for three years. He left to do locums and work as visiting psychiatrist at HMP Wormwood Scrubs. From 1989 he served on the Parole Board and was a member of the Mental Health Review Committee. Predeceased by his wife in 2011, he leaves three children, seven grandchildren, and four great grandchildren.

Alan Gibson, Janet Morrison, Sally Norman, Jane Turton

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### Samuel William Babington Newsom

Microbiologist (b 1932; q Westminster Hospital Medical School 1956; MD, FRCPATH, DTM&H), d 28 August 2018



Samuel William Babington Newsom ("Bill") was appointed consultant microbiologist to Papworth and Addenbrooke's hospitals in 1967. He became a leading authority on infective endocarditis and infections complicating cardiac transplantation. He was the first person to discover an important  $\beta$ -lactamase enzyme, PSE-4, in *Pseudomonas*. He published some 160 papers and editorials. He was particularly pleased to be at the forefront of antibiotic research, giving the first dose of cefuroxime and ciprofloxacin in the UK. He sat on national and European committees for safety cabinets and hospital disinfection and was a founder member of the Hospital Infection Society. He leaves Rose, his wife of 59 years; two sons; and five grandchildren.

Richard Newsom

Cite this as: *BMJ* 2018;363:k4435

### Isobel Anne Tait

Consultant in genitourinary medicine Liverpool (b 1936; q Edinburgh 1959; MD, DObst RCOG), died from renal failure on 3 October 2018



Born Isobel Anne Ritchie in Dunfermline, Fife, our mother was encouraged to develop her full potential by her own mother, Jessie, who banned her from learning shorthand or typing, so that she could better resist any pressure to follow a secretarial route. Educated at St George's School, Edinburgh, she graduated from Edinburgh University in 1959, took a series of placements in the region, and then moved to Liverpool, where she spent the rest of her career and married Robin Tait in 1964. Anne gained an MD from her alma mater in 1982. In retirement she returned to Edinburgh, where she combined public service and her Christian faith as a volunteer at St Giles' Cathedral. She leaves her husband, Robin; two sons (the authors of this obituary); and a grandson.

Nick Tait, Andrew Tait

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### Anzhela Krol

Advanced biomedical scientist (b 1970; q Uzhgorod State University, Ukraine, 1995), died from metastatic gastric adenocarcinoma on 24 September 2018



Anzhela Krol ("Angela") was born and educated in Uzhgorod, Ukraine. After postgraduate training in forensic medicine in Kiev from 1995 to 1997, she worked as a specialty trainee in forensic histopathology in Ukraine. In 1999 she moved to the UK and got married. She had a career break after having two children, and then studied for a BSc in biomedical science at the University of Portsmouth. She later worked at the Queen Alexandra Hospital in Portsmouth until her diagnosis of metastatic gastric adenocarcinoma late in 2017. Angela had a wide circle of friends, who appreciated her positive outlook on life. She was committed to her family and her Christian faith. She leaves her mother, her husband, and two children.

David Poller, Marino Krol

Cite this as: *BMJ* 2018;363:k4360

# Barney Carroll

The “conscience” of psychiatry

**Bernard J Carroll (b 1940; q 1964; MD, PhD), died from cancer on 10 September 2018**

A pioneer in biological psychiatry, more recently Bernard Carroll (“Barney”) became a withering critic of its compromised ethics and corruption by industry. Shortly before his death, he helped prepare this obituary—his last chance to help correct the perverse incentives that too often influence the conduct and reporting of scientific research.

Barney’s scientific contribution to psychiatric research was to introduce neuroendocrine techniques. He independently discovered the value of the dexamethasone suppression test (DST) as a biomarker of melancholia—the classic, biologically driven subtype of depression. This was the first, and remains one of very few, biomarkers in psychiatry. Barney’s 1981 paper on the DST was among the most highly cited papers in psychiatry. Its impact was immediate, with many replications and extensions.

Another of Barney’s enduring contributions was to educate colleagues in the discipline of proper clinical decision making. He clarified the Bayesian principle that context counts—that is, prior conditional probabilities greatly influence the utility of any clinical feature or laboratory test in making a diagnosis. Throughout medicine, biomarkers and clinical diagnostic features perform with much greater utility in high risk groups than in general populations. He criticised the *Diagnostic and Statistical Manual* for innumerate failures to clarify the performance of diagnostic criteria.

## Scientific scepticism

Barney rejected grand biological theories that offered neat, simple-but-wrong explanations of psychopathology. Ever aware of the complexity of the human brain, he was an early rejecter of blind optimism that any simple imbalance of monoamine transmitters could

account for the wide variety of mental disorders. More recently, he deplored the ubiquitous hype that suggested that genetics or neuroimaging or big data mining could provide simple answers to deeply complex questions. He predicted—presciently—that these powerful new tools would have great difficulty in producing solid, replicable findings that could be translated to clinical practice.

Barney had a wide range of research interests, never lacked for creative ideas, always had abundant funding from the National Institute of Mental Health (NIMH), and never depended on commercial drug trials. Even though he consulted disinterestedly with many drug companies, he joked that his main job was to dissuade them from wasting money on feeble drugs and foolish research.

Barney trained in Australia and at the University of Pennsylvania. In 1983 he accepted the chair of psychiatry at Duke University, North Carolina. He turned a respected department of psychiatry into a great one—recruiting faculty members, increasing external grant support 10-fold (raising it to sixth in the US), improving clinical services, and forging research and residency training partnerships with the public sector.

During the past 20 years, Barney became a critic of weak science, of ethical lapses, and of industry’s corruption of the research enterprise. He coined the term “experimercial” to describe clinical trials that were really disguised exercises in marketing. He relentlessly exposed undisclosed conflicts of interest, hidden commercial promotions, inadequate research designs, biased analyses, misleading conclusions, exaggerated claims, and ghost writing. He became the conscience of psychiatry. With the frequent collaboration of Robert Rubin, he outed many high profile academic opinion leaders who had been co-opted by commercial interests.

Barney never flinched in his David and Goliath battle to restore truth and



**Barney Carroll felt that DSM-5 sacrificed scientific improvement in its pursuit of sales**

integrity to the psychiatric research enterprise. He especially deplored the hijacking of nosology by the American Psychiatric Association and felt that DSM-5 sacrificed scientific improvement in its pursuit of sales. He liked to say nobody owns diagnostic criteria.

## Recalibrating ethics standards

Barney’s “right” prevailed against institutional and commercial “might.” He helped to force the current upgrades of editorial oversight and full disclosure now demanded by Nature Publishing Group, by AMA journals, and most journals. The publicity surrounding Barney’s exposés triggered the conflict of interest inquiries conducted by Charles Grassley, chair of the US Senate Finance Committee, which had a profound impact on recalibrating ethics standards in all medical specialties. As he left us, Barney was encouraged by current trends towards improving transparency and increased integrity. Barney leaves his wife, Sylvia, and two children.

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Barney Carroll

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## SURGICAL MESH AND SAFETY

**Don't ignore lessons from the commercial sector**

The mesh scandal is all too familiar (Editor's choice, 13 October). It joins a growing list of scandals where commercial conflicts of interest (COIs) and effective marketing of a defective product have led to serious injury and loss of life. What is needed to prevent a disturbing pattern from repeating itself? Where will the leadership come from, given that sectors of the medical community are enmeshed with private industry?

Politicians might step up. But the US Sunshine Act did not solve the problem. Unbeknown to many, the act reflected how Wall Street and politicians manage their own commercial COIs. Disclosure has failed to prevent ongoing scandals underpinned by commercial COIs, including the worldwide banking crisis of 2008.

Managing financial relations through disclosure has allowed politicians to have their cake and eat it too. They say that it does not compromise their ability to act in the public interest. It's a familiar response, heard on Wall Street and in many areas of medicine. Self denial has helped to sustain the status quo.

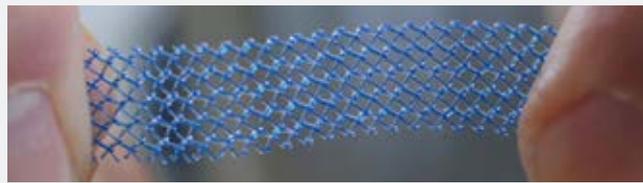
Until politicians end their own financial conflicts through legislation, scandals in both medicine and in the marketplace will likely remain a familiar—albeit disturbing—pattern. We need to go beyond disclosure in tackling commercial COIs. And we need to start at the top.

Mark Wilson, bioethicist, Ontario  
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## VITAMIN D AND BONE HEALTH

**Ample data exist**

The experts' comments in the news article about our systematic review on the effects of vitamin D supplementation are incorrect or mistargeted (This Week, 13 October).



## LETTER OF THE WEEK

**NICE responds to surgical mesh article**

NICE first made recommendations about mesh in its interventional procedures guidance in 2005. This was cautious advice with requirements for notifying clinical governance leads, informing patients about safety uncertainties, and the need to audit outcomes.

Heneghan and Godlee refer to NICE guidance as “ineffectual” (Editorial, 13 October), and we agree that it should have had more impact. Responsibility for implementing guidance does not rest with NICE but requires a system-wide approach. A systematic approach after our recommendations in 2005 could have identified more quickly, or avoided, many of the adverse outcomes of mesh.

Recommendations on interventional procedures should be seen as mandatory rather than advisory. Mechanisms to reinforce these recommendations include oversight by the regulator to ensure effective governance structures, and trusts' appraisal systems should ensure that clinicians take due account of our guidance. Clinicians should comply with requirements for consent, data collection, and audit, and should report complications.

Data submitted to national registers must be properly analysed and published to ensure that patterns of complications or harms are identified quickly. Coherent and coordinated action can then be taken to reduce future risks to patients.

Gillian Leng, deputy chief executive; Kevin Harris, director of interventional procedures programme, NICE

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Clarke's comments are wrong. He says that the trials in our meta-analysis had too few participants, used an insufficient dose of vitamin D, and had an insufficient duration of treatment. The trials in our review comprised >34 000 participants, 3534 fractures, 870 hip fractures, and 14 139 falls. Almost all recent trials used >800 IU/day vitamin D, and 17 trials of falls and fractures lasted >12 months. He suggests waiting for more trial results, but ample data exist. Trial sequential analyses show reliable evidence that vitamin D supplementation does not have clinically relevant beneficial effects on falls, fracture, or bone density.

Martineau says that supplementing the entire UK population with vitamin D will prevent the most extreme

complications of rickets. This is not relevant to our review. We specifically stated that people at high risk of rickets and osteomalacia should receive vitamin D. But supplementing adult populations to maintain or improve musculoskeletal health will not prevent rickets. It will mean that many people take vitamin D supplements for no benefit.

Mark J Bolland, associate professor of medicine, Auckland; Alison Avenell, professor of medicine, Aberdeen; Andrew Grey, associate professor of medicine, Auckland

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## GPS AND “FIT NOTES”

**Sick certification by GPs is an unethical COI**

Rimmer reports that “fit notes” may become part of GP training in England (RCGP

Annual Conference, Glasgow, 13 October). I had my primary training in the Netherlands, where sick certification was assigned to social security and occupational physicians. It was considered an unethical conflict of interest for the treating doctor, who should be dedicated to the cause of the patient, not of an employer, insurer, or government authority.

The Dutch Medical Association still says that treating doctors should not offer advice on fitness for work or issue attendance certificates for employment purposes. It is not only unethical, but GPs do not have the training, knowledge, or expertise to do this (unremunerated) work competently. On top of all the other arguments, it places another penalty on general practice in areas of social deprivation.

Hendrik J Beerstecher, GP, Sittingbourne

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**All doctors need to learn the process**

I share concerns about the usefulness of fit notes and the role of the treating doctor in completing them. But as long as the responsibilities for sickness certification remain as they are, it seems unhelpful to underline the role of GPs, when fit notes can and should be completed by all doctors.

I frequently see patients who report very specific advice about time off work from hospital colleagues but have been given a more limited length of fit note or no fit note at all. Moreover, there is often no relevant letter available or only a letter that does not mention time off work. Dealing with this wastes valuable GP appointments.

It would be hard to train as a GP without substantial learning about fit notes as they are a part of daily practice. All doctors should receive any further training that is to be offered, not just GPs.

Deborah A White, GP, Stockton on Tees  
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