



HealthSense Newsletter

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for Science and Integrity in Healthcare

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Events

Transparency campaigner to receive the 2023 HealthSense Award

Transparency advocate Dr Till Bruckner was the overwhelming favourite to receive the 2023 HealthSense award for his outstanding and hugely successful campaign to rescue hidden medical evidence.

Till started the [TranspariMED](#) initiative in 2017 to improve the public's and policy makers' understanding of how to effectively tackle the problem of unreported clinical trial results. He used his journalism and social media skills to heighten public understanding of the human and financial costs of medical evidence gaps, while educating decision makers and generating solutions for how to solve the problem in practice. He published dozens of reports revealing how many academic trial results remained hidden from view, and at the same time wrote a manual on improving clinical trial reporting that is now widely used by universities in the UK and across Europe.

Helped by his efforts, the UK recently put into place the world's first comprehensive clinical trial monitoring system, forever dispelling the long-standing myth that it is impossible to ensure that the results of all clinical trials are made public. Till holds a PhD in political science and is based in Bristol, UK.

Till has invited us also to recognise the efforts of his frequent collaborator Nicholas J DeVito, and we will be delighted to welcome him to the Awards evening too. A postdoctoral researcher in Applied Data Science at Oxford, Nick has significantly and sustainably improved clinical trial transparency in the UK, EU and US through the design and ongoing management of the EU Trials Tracker and the FDAAA Trials Tracker.

These continuously updated tools provide a detailed picture of which sponsors have failed to make public the results of what trials. The trackers have been widely used

not only by advocacy groups, but also by pharma companies, universities and hospitals worldwide to identify and address reporting gaps in their own portfolios. In both the US and EU, trial reporting rates increased from 50% to around 80% in the years since the trackers were launched – this would not have happened without the trackers. In addition, they have led to regulatory reforms in the UK, EU and US. Beyond the trackers, Nick has published a study on drug regulatory performance in Europe that has had a great impact.

We look forward to welcoming these young people who have driven research transparency for the benefit of patients everywhere.

Coming soon: HealthSense online AGM and in-person Awards Night

This year we will again run our annual events as two separate happenings – an online AGM for the business, and an in-person Awards Night very much for the pleasure – and we hope HealthSense members and friends, old and new, will join both.

Dates and times for both meetings are yet to be confirmed. HealthSense members will be informed by email, and news alerts will be posted publicly on this website, as soon as full details are known.

For the business side, our Annual General Meeting will be online-only so that HealthSense members far and wide will have the opportunity to watch the proceedings, take part and vote from the comfort of

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their own homes. Simple instructions on how to join the meeting on Zoom and how votes will be taken will be shared nearer the time on the [HealthSense news page](#) and to members' emails.

And for pleasure, following the popularity of last year's in-person awards, we will hold our HealthSense Award ceremony on a different night, at a venue to be confirmed. This is the event where we welcome our brilliant HealthSense Student Prize winners, and hear a presentation from this year's HealthSense Award Winner, Till Bruckner. The HealthSense Award ceremony will be streamed live on our [youtube channel](#) so it can be watched remotely by those unable to travel to London. A recording will also be made available afterwards.

News in brief

Our News in Brief section features latest achievements and news from our brilliant volunteers, and opportunities to get involved. Let us know what you are doing to promote good science and integrity in healthcare by emailing newsletter@healthsense-uk.org

Our letter on cancer screening hits The Times

After spotting some misinformation about breast cancer screening in a recent *Times* news article, Roger Fiskén made it onto the letters page with a feisty and evidence-based response.

Dr Fiskén, retired physician and HealthSense's chair, responded immediately he saw the article, and his letter was published on 16 May:

"Sir, Further to Kay Lay's report: 'NHS can't consider more breast screening' (News, May 12), there is enormous doubt that mammographic breast cancer screening saves lives. Studies have indicated that in large cohorts of screened women there is no reduction in all-cause mortality; in other words the small reduction in the number of breast cancer deaths is counterbalanced by a rise in deaths from other causes, some of them a result of surgery or chemotherapy for breast lesions that would never have caused death anyway.

"As techniques for treating breast cancer continue to improve, the value of screening – with its attendant harms of over-diagnosis, anxiety and overtreatment – becomes more and more questionable. Breast cancer screening does, however, waste precious NHS resources. The National Screening Committee has never carried out a full and proper evaluation of the UK's breast cancer screening programme; such a review is long overdue."

More about screening in "chicanery" letter

Roger Fiskén is also chasing the UK Department of Health and Social Care (DHSC) about their use of unpublished data to support a revamp of the ineffective and costly NHS Health Check programme. The best evidence shows that random, across-the-board

cardiovascular screening of the general population is a waste of time and money, as well as generating anxiety among those found to have a 'positive' screening test, and unnecessarily boosting general practitioners' workload.

Dr Fiskén had written to Professor John Deanfield (UCL Institute of Cardiovascular Science), who is to lead a UK government taskforce to identify new ways to prevent cardiovascular disease and reduce pressure on the NHS. Despite the avoidable causes of CVD being widely prevalent - smoking, obesity and inactivity - the unlikely strategy chosen by the DHSC is: "by modernising the NHS Health Check programme and by exploring and expanding the role of technology so that people can better look after their health and reduce the risk of CVD".

In his letter to Professor Deanfield, Dr Fiskén noted that the impressive data in the DHSC document which describes this work, including a table which reports substantial reductions in type-2 diabetes-related hospital admissions, CVD death and all-cause mortality, all comes from an unpublished report. He received a reply from Clare Perkins, deputy director of Personalised Prevention at the Prevention and Public Health System Directorate of DHSC, confirming that the data was indeed unpublished, and indicated no plans for its publication.

So Roger is pressing on with a further challenge to Clare Perkins, expressing dismay that the DHSC intends to pursue health checks: "According to the DHSC website the health checks programme is to be trialled in Cornwall but it is clear from the tone of the announcement that the purpose of the trial is to test the details of how to conduct the screening programme, not whether to put it in place at all.

"I have to say that my organisation regards this as both alarming and deeply unethical. You acknowledged to me in your email of the 12th of May that there is *no peer-reviewed, published evidence* to support the programme, yet the Department proposes to go ahead anyway."

His letter concludes: "HealthSense and its allies will do everything in their power, via the general news media and in other ways, to bring to the public's attention that this is not health care but chicanery and an expensive, and almost certainly worthless, project."

HealthSense-sponsored new science published, and an opportunity for student volunteers

TranspariMED, one of our partner organizations, is making huge strides in their global campaign to improve clinical trial transparency. The results of their latest – HealthSense-funded – project have just been made available as a [pre-print](#). Pre-print research is freely available online but not yet published in a peer-reviewed journal. In "Major UK non-commercial sponsors' efforts to reduce research waste: a mixed methods study" a team led by TranspariMED's Till Bruckner has generated a snapshot of research waste in

the UK. They looked into 145 historical clinical trials by ten major UK non-commercial sponsors, and found 18 of these trials had published no results. Non-publication means the knowledge gained is lost, and the contributions of the 637 patients involved – and the potential risks to which they may have been exposed – are all for nothing. They then contacted trial sponsors to press for their results to be shared, and were successful for 14 of the lost trials. Science saved! Read [more about the research](#) on the TranspariMED website.

For the next stage, Till Bruckner says: "We're planning to build on this pilot by starting to clean up the entire ISRCTN trial registry, chasing up over a thousand missing trial results." He is looking for volunteers – this is a great chance to improve medicine, learn useful skills, and get your name onto a scientific paper. As a volunteer, you will search the scientific literature to determine whether or not clinical trial results were made public. TranspariMED will then contact the institutions that ran the trials and ask them to make the results public. During past projects, volunteer teams have rescued large amounts of valuable medical evidence and preventing it from becoming research waste, including data from paediatric and cancer trials.

Find out more about TranspariMED's work at www.transparimed.org. If you are passionate about medical evidence and have good attention to detail, please get in touch with Till at: tillbruckner@gmail.com. No previous experience is needed and full training provided.

Surgeons get the story about our Student Prize

Last year's HealthSense Student Prize winners come under the spotlight in an article in The Bulletin, the newsletter of the Royal College of Surgeons of England (RCSEng), complete with colour photographs.

RCSEng is the organisation that generously supports our annual competition, so we were delighted to see them sharing our news with their members. The article appeared in the 28 February edition, vol 105, no. 2 and can be freely accessed [here](#).

Are menopause treatments being over-sold? Our experts online

A recent British Medical Journal webinar asked whether therapies for the effects of the menopause are being over-sold, and HealthSense experts played leading roles in the discussion. Our past chair Susan Bewley gave the opening remarks, while patron and past award winner Margaret McCartney was one of the presenters and gave an eye-opening talk about how the facts about hormone treatments are communicated – and miscommunicated – to women.

Originally run live on 25 May, the whole session is available online. The full recording lasts two hours, but if you're pressed for time, we advise you zone into the start of Dr McCartney's presentation at 1:16:25 and

watch for just a couple of minutes to learn about pharma's influence over parliamentary groups and the media coverage of menopause treatments (warning: you won't be able to switch off). Watch from the [BMJ Known Unknowns series page](#).

Margaret McCartney fronts the FT on today's reality for GPs

Dr McCartney has also sent a powerful message to politicians dabbling in healthcare, in "A GP's prescription for the NHS at 75", the Weekend essay which filled the front page of the Financial Times Life & Arts section on Saturday 8 July.

She rolled out the figures for the rising demand for appointments, and falling numbers of full-time equivalent practising GP's, in the context of the clear health benefits of continuity of care – which is also sharply in decline. Political initiatives have created time-wasting bureaucracy, used doctors as vote-fodder, and launched advertising campaigns that are plainly ridiculous. "General practice could be amazing. The choice to break it has been political, not professional."

She writes. "We need slower, more considered prescribing, reducing low-value tests, tablets and treatments — not subjecting people to an industrial healthcare model. We should be advocating for professionalism, holding doctors to account but starting with the presumption that the vast majority are trying to do their best with the resources they have. We should use evidence, not hot takes from focus groups, to guide us." FT subscribers can read the article in full online at [Financial Times Life & Arts](#).

Consilium Scientific opens up the news on Alzheimer's drugs

Alzheimer's Disease is a public health issue of the 21st century, yet the battle to figure out how the disease works and how to slow its dreadful progress has been going on for much longer. Where are we today? Is there real hope behind the new drugs that are making the headlines? Or is this just a hype promising billion-dollar earnings to Pharma? The 15 June seminar from our partner organisation Consilium Scientific:

["Alzheimer's future: is the amyloid hypothesis alive or is it on life support?"](#) gave answers from an array of experts from the US as well as a representative of the UK's Alzheimer's Society.

The recording is also available as a podcast, and a transcript and slides can be freely downloaded for swift reading if you don't have time to experience the full one-hour recording.

UK has been promised a national clinical trial 'directory'. Will the government deliver?

The UK government has announced that it will set up a national clinical trial 'directory' to provide continuously updated information on trials being conducted in the country. Currently, clinical trials run in the UK are either registered on the American ClinicalTrials.gov

registry or on the London-based ISRCTN registry. This fragmentation makes it difficult to get comprehensive oversight of all the research. The welcome announcement came in response to the 25 May report: 'Lord O'Shaughnessy review into commercial clinical trials in the UK.' The UK government accepted the recommendations and pledged immediate delivery backed by £81 million in funding over three years.

Dr Till Bruckner, of our partner organization TranspariMED, acknowledged how useful such a registry would prove, but sounded a caution: "This government has a history of making bold announcements about improving clinical trials and then failing to provide the resources required for implementation.

"For example, the government's #MakeItPublic strategy announced long ago that all clinical trials would be pre-registered directly by the Health Research Authority, but currently 8% of UK clinical trials are still not being pre-registered because the government has so far failed to deliver on that simple pledge. Providing monthly updates on the recruitment figures for each and every UK clinical trial would be far more challenging – and far more expensive – to implement.

"It is not acceptable that we are spending hundreds of millions of pounds each year on clinical trials and cannot properly account for whether it is delivering excellence or not. So, let's hope the government will use this latest initiative to finally, and fully, deliver on the transparency pledges set out in the #MakeItPublic strategy and in the government's [UK National Action Plan for Open Government 2021-2023](#)."

BMJ articles cite our experts

The British Medical Journal has had two hard-hitting news investigations recently into the thorny issue of medicine's conflicts of interests, and HealthSense provided go-to expert sources for both.

In July, investigative journalist Hristio Boytchev reported (1) that Royal Colleges in the UK have received more than £9 million in marketing payments from drug and medical devices companies since 2015, but do not always disclose the payments publicly. The biggest donor was drug company Pfizer, which donated £1.8 million.

Interviewed, Susan Bewley, past chair of HealthSense, said: "It is deeply disappointing that so many Royal Colleges negotiate these payments and don't even tell the full and detailed truth about them. Patients need to trust medical institutions that educate, or create and implement guidelines which should be based on best available evidence, not lobbying. (...) Sunshine, and full transparency are the very least," she says.

In a feature linked to this piece, (2) Margaret McCartney, GP, journalist and HealthSense patron, wrote: "Even if we are told the information is independent, funding skews the types of education or information that gets made. It means that we become

less independent, because we are not setting our own priorities, and that's bad for the profession."

In May, we were also quoted (3) in a piece on a forthcoming consultation on the public disclosure of industry payments to the healthcare sector. We have long called for there to be a central place where the public can look up payments made to doctors, but so far the General Medical Council has resisted.

In the article Susan Bewley was reported proposing that the voluntary register Disclosure UK, where health professionals can declare their interests, "should be mandatory, easily filled in, and searchable ... Making the 'right thing' into the 'easy thing' is key."

Leeza Osipenko, HealthSense vice-chair and chief executive of our partner organisation Consilium Scientific, a non-profit organisation aiming for transparency in clinical research, was also interviewed and told the BMJ: "Much can be done to improve information on industry payments, conflicts of interest, and implications for decision making."

1. Boytchev H. [Medical royal colleges receive millions from drug and medical devices companies](#). BMJ 2023;382:p1658
2. McCartney M. ["You have to be above reproach": why doctors need to get better at managing their conflicts of interest](#). BMJ 2023;382:1646.
3. Boytchev H. [UK will consult on disclosure of industry payments to doctors ahead of possible legislation](#). BMJ 2023;381:p1219 (paywalled)

Results of government's "worthless" 10-year Cancer Plan consultation are published

There is a warning on the webpage for the outcome of the government's [10-year Cancer Plan](#) call for evidence: "This report contains content that some readers may find upsetting ... " It is indeed upsetting, though perhaps not surprising, that the points made by HealthSense in our own submission have been overlooked.

Our members may recall that we were [publicly critical](#) of the shoddy quality of the consultation document, which was "so shot through with false assumptions, misunderstandings about the biology of cancer, and lack of awareness of public health priorities that we struggled to know where to start. What is more, the specific questions asked of respondents were vague and biased and can only deliver predetermined answers." The results of the consultation, published 17 May, support our misgivings. There is considerable emphasis on how to increase the uptake of cancer screening services, and none on consideration of potential harms or even of giving the public informed choice on whether to be screened.

Another top award for our 2021 HealthSense Award winner

Christina Pagel, winner of our 2021 Award for her brilliant efforts in explaining complex medical matters to the public, has scooped another great prize.

The [Royal Statistical Society](#) have made her the winner of their [2023 Excellence in Journalism Awards](#) in the category for the Best Statistical Commentary by a Non-journalist, for her feature ["Physics: Do girls avoid it because it's too hard?"](#) (BBC Science Focus, 9 May 2023). In the article she uses evidence to question a head teacher's assertion that girls are put off physics because they struggle with the maths. Spoiler alert: girls do better than boys at maths in both GCSEs and A levels, and the reasons for their low physics take-up are complicated – but Christina explains them clearly, as ever. Christina Pagel is professor of operational research and director at University College London, using mathematical tools to support delivery of health services. She leapt to our attention with her weekly live-streamed briefings during the early months of the Covid-19 pandemic. You can watch (or read) her 2021 presentation to us on the [Awards page of the HealthSense website](#).

WHO criticized for promoting pseudoscience

Another science advocate has criticized the World Health Organization (WHO) for its [Traditional Medicine Strategy 2014-2023](#), which seeks to integrate interventions such as Ayurveda, traditional Chinese medicine, naturopathy and anthroposophic medicine with evidence-based medicine.⁽¹⁾

Jonathan Jarry is a science communicator with the McGill Office for Science and Society, a US academic group dedicated to separating sense from nonsense on the scientific stage. In "The World Health Organization has a Pseudoscience Problem" he explains that the WHO's ambitious aim of ensuring everyone on the planet has access to health care becomes much easier to achieve if the definition of care includes traditional and complementary medicine. He concludes: "The WHO is continuing in the footsteps of Chairman Mao, promoting the integration of prescientific and often discredited ideas with actual medicine. They seem to believe it would be a great contribution to the world. I beg to differ."

Jarry's essay reminds us of concerns expressed in our own publication back in 2017, when Loretta Marron of Friends of Science in Medicine asked: ["Why is WHO guilty of WOO?"](#), in allowing their reports to be cited as evidence for the efficacy of acupuncture. Then, she called on the WHO to set the record straight for the sake of the poorest and most vulnerable. It seems little has changed.

1. Jarry J. [The World Health Organization has a pseudoscience problem](#). McGill Office for Science and Society, April 28, 2023

Critical Psychiatry textbook now freely available

Researcher and author Peter Gøtzsche, winner of our 2016 Award, has made his evidence-based Critical Psychiatry Textbook (2022) freely downloadable. "It describes a litany of misleading and erroneous statements in psychiatry textbooks used by students of medicine, psychology and psychiatry," he says. Go to the [Books page of the Institute for Scientific Freedom](#) to find out more.

Dr Gøtzsche has also collaborated to update an important international guideline aimed at improving the safety of randomised controlled trials of medical treatments. "Reporting of harms in randomised trials is usually vastly inadequate," he says. The updated guideline from the Consolidated Standards of Reporting Trials (CONSORT) group is clear on how randomised controlled trials should measure and report the harms – and not just the benefits – of health interventions.

Junqueira D et al. [CONSORT Harms 2022 statement, explanation, and elaboration: updated guideline for the reporting of harms in randomised trials](#). BMJ 2023;381:e073725

QRISK – what is the risk actually of?

A "letter of the week" in a recent print issue of the British Medical Journal flagged a remarkable lack of agreement between some apparently credible sources, on the subject of cardiovascular disease.

Cardiovascular disease (CVD) is the leading cause of death worldwide, so it's important to know what we are talking about.

York GP [Dylan Summers wrote](#) in response to a [BMJ article](#) about the latest NICE guidance on how to assess an individual's personal risk of developing CVD. Risk assessment uses a measure called QRISK, a method of calculating a person's likelihood of becoming ill with CVD in the next 5 or 10 years based on measures such as their age, sex, smoking history, blood pressure, and serum cholesterol.

The problem is, as Dr Summers makes clear, that different organisations have different ideas about what a particular QRISK score means. Is it, as NHS.net says, the risk of "coronary heart disease, stroke, TIA, peripheral artery disease and aortic aneurysm"? But NHS England's definition also includes "congenital heart disease and vascular dementia", he says. The Official QRISK website limits it to risk of heart attack and stroke alone in one page, but adds angina and transient ischaemic attack on another.

Dr Summers concludes: "Clinicians will struggle to offer informed choice to our patients amidst the welter of contradictory explanations currently on offer." We agree.

Charity harms

Abusing the public's trust in charities

By Les Rose

HealthSense maintains pressure on the [Charity Commission](#) regarding charities that mislead vulnerable people about health and disease.

Last year The Gerson Support Group, which promoted an extreme diet and coffee enemas to treat cancer, was wound up after my complaint to the Commission. Subsequently, the Gerson Support Group distributed its assets to other charities, including Together Against Cancer (charity 1123665), which was itself giving some dangerously misleading nutritional advice to cancer patients. When we approached them, Together Against Cancer told HealthSense that they had dismissed the 'nutritionist' involved and would review their policy on the advice they give. As they have cancelled my registration as a patient it's now impossible for me to check.

This is a small amount of progress from an effort that so far has taken over 10 years. For most of that time the Charity Commission has brushed aside complaints, claiming that they are not qualified to make judgments about evidence in health care.

"The Charities Act does not actually mention the word 'harm' or anything related to it"

The issue centres on the requirement in The Charities Act 2011 for all charities to operate for public benefit. The Act specifically states that public benefit is not simply to be assumed, but must be demonstrated. HealthSense asserts that a charity which provides advice based on scientifically implausible claims, and which have no supporting evidence, cannot meet this requirement.

On 20 June a video meeting was held with the Charity Commission, which I attended with Michael Marshall, project director at our partner charity The Good Thinking Society. The Commission was represented by senior personnel in their legal and risk departments. The purpose was to review progress with the regulatory cases which the Commission had opened largely as a result of our complaints, and which the Commission had shared with us last year.

There was a surprising outcome to this review. Several charities which had received "regulatory advice" from the Commission continued to make highly misleading claims at least a year later. We learned that the Commission does not undertake to monitor compliance with regulatory advice, and that if we still have concerns we should make further

complaints. This means that the onus is on the public to monitor compliance, because the Commission apparently does not have the resources to do so. So the process repeats, without a clear endpoint. This presumably is what the government calls "light touch regulation".

The Commission is extremely reluctant to take any action to remove a charity. This is mainly because of a failed attempt by the Commission to remove The Human Organ Preservation Research Trust (charity 1001750), which charges fees for the cryopreservation of dead bodies with a view to later resuscitation. A highly controversial tribunal judgment overturned the Commission's decision. This, coupled with very limited resources, seems to underlie the Commission's inertia on the matter of charities operating in the fringe health area.

We also gained some insight into the Commission's application of a threshold of harm, which they require to be met before they will act against the charity. The Charities Act does not actually mention the word 'harm' or anything related to it, it is only concerned with charitable purpose and public benefit. The Commission told us there is a body of case law that has established that harm has to be taken into account. We have yet to see this case law, but it comes up against a major problem when dealing with fringe health. Seriously ill victims of bad advice would rather die than complain about their practitioners. This is not a joke, it happens.

So, because of this policy of minimal regulation, we have a huge number of charities that could not possibly be providing any public benefit. There are even charities that campaign in the fields of so-called electrosensitivity, and astrology.

The Commission complains that it has too many charities to regulate, but has it made a rod for its own back, by admitting so many bad apples to the fold?

Les Rose

Clinical research scientist (retired), Salisbury

Research integrity

Murky territory indeed: prison for trachea researcher but key retractions still awaited

By Mandy Payne

Disgraced transplant surgeon Paolo Macchiarini is finally behind bars, yet his fraudulent research publications endure as a stain on the academic record and continue to place patients at deadly risk. HealthSense members are pushing vigorously for measures to protect patients from his dangerous legacy.

In June, an appeal court found Macchiarini guilty of gross assault against three patients on whom he tested synthetic tracheae.(1) The judges ruled that Macchiarini, then a surgeon at the Karolinska Institute,

"acted with criminal intent" in 2011-12 when he gave three patients synthetic windpipes seeded with stem cells from the patients' own bone marrow, despite being well aware that his experimental technique was problematical. All three patients died when the implants failed. At his original trial last year a Swedish district court had found Macchiarini guilty only of bodily harm. That time, he walked from court with only a suspended sentence. But when the disgraced surgeon tried to have even that reduced he gambled badly. Because at the same time, the Swedish Public Prosecutor was also appealing to increase his sentence, and both appeals were heard at the same hearing. Result: the appeals court in Stockholm upgraded the original judgement to gross assault and he was sentenced to 2 years and 6 months in prison.

"evidence of misrepresentation in research funding applications"

Meanwhile, medical and academic experts are aghast that the institutions that supported his deadly work shrink from the responsibility of having hosted a rogue surgeon. A [BMJ essay](#) published the day after the sentence was announced (2) reminds us that *The Lancet*, who published Macchiarini's 2008 paper and its five year follow-up, only made the smallest possible concession to its critics in February this year when they finally published an [expression of concern](#) (3) that was, the essay says: "so minimal that it fails to mention the reasons for concern." Well worth a read, the BMJ essay documents how a long list of world-leading universities and hospitals – including some in the UK – managed to distance themselves from the fraud.

HealthSense Newsletter readers will know that Dr Peter Wilmschurst, cardiologist and HealthSense's 2003 Award Winner for his fearless whistleblowing on research misconduct, has been documenting on his [blog](#) his own efforts to persuade *The Lancet* to retract Macchiarini's publications.

Now his fellow Award Winner (2010), Professor David Colquhoun, has been taking his own previous employer, University College London (UCL), to task for their role in the scandal. Macchiarini's co-investigator and co-author on the 2008 *Lancet* paper, Professor Martin Birchall, was employed by UCL at the time he was collaborating on the research that was to result in two of the deaths, at hospitals affiliated to the university. "Even if Birchall was originally ignorant that the 2008 paper had falsified clinical findings, there is no doubt that he has known since 2018. By then Macchiarini was discredited," wrote Professor Colquhoun, quoting from Dr Wilmschurst, (4) in his letter to Michael Spence, president and provost at UCL. He went on, also in Wilmschurst's words: "Birchall, as the other co-principal investigator, had the responsibility to correct the scientific record,

particularly because this research was causing patient deaths as further operations were attempted based on the false claims."

Colquhoun then cites evidence of Birchall having made misrepresentations in research applications, as uncovered by a major BBC investigation: "In one 2016 application to the European Medicines Agency, Martin Birchall is cited as saying Shauna's initial surgery was successful, but she suffered a 'fatal cardiovascular event six weeks following surgery' – whereas in fact she died after two weeks, because her trachea had collapsed."

"All this puts UCL in a terrible light and, worse still, it increases public distrust in science ... A word from you would make him do the honourable thing and request retraction of the 2008 paper and apologise for the misleading information in his 2012 follow up."

The provost of UCL, in his response, declined to get involved. He replied: "It is the *Lancet* which published the paper and therefore the decision on whether or not to retract it sits with them, and I would be wary of the precedent of the Provost putting pressure on an academic or their publisher about their work, which feels to me to take us into murky territory."

Nick Ross, president of HealthSense, remarks: "Whatever arguments there are about freedom of expression in academe there are no arguments in favour of scientific fraud or scientific illiteracy. If there is even plausible suspicion that a member of staff is or has been doing something wrong it might be argued that a top-class university has more than an option, more than a right, but a duty to investigate."

Mandy Payne
Editor, HealthSense Newsletter

References

1. Vogel G. [Transplant surgeon sentenced to prison for failed stem cell treatments](#). Science, 21 June 2023.
2. Rasko J, Power C. [The deadly legacy of a stem cell charlatan](#). BMJ 2023;381:p1367
3. The Editors of The Lancet. [Expression of concern: Clinical transplantation of a tissue-engineered airway](#). The Lancet 2023; 401(10376): 536
4. Wilmschurst P. [The Lancet's expression of concern – too little, too late](#). Dr Peter Wilmschurst, Blog. 1 Mar 2023

Students

Where is the evidence of evidence-based medicine at medical school?

By Lydia Shackshaft

Evidence-based medicine: supposedly a central tenet of our medical education and future medical practice. The ability to critically appraise evidence and apply it to the individual in front of us has become a crucial skill.

Our patients increasingly turn to 'Dr Google' for medical advice, are exposed to sensationalised media

reporting of medical 'breakthroughs', and use complementary and alternative medicine (CAM) with significant financial and potential health costs.

In the context of doctor-patient relationships evolving towards a shared decision-making model, our patients are coming to us with their own health beliefs and expectations. As medical professionals we need to be prepared to support our patients in assessing the vast quantities of information and misinformation presented to them. With knowledge constantly evolving and ever-increasing quantities of published research year-on-year,(1) we need the skills to appraise the evidence to update our medical practice throughout our careers. And as our population becomes increasingly elderly, multi-morbid, and subject to polypharmacy, we as clinicians need to be able to look beyond the guidelines, and use the evidence base in relation to the complex individual in front of us with their unique set of values and beliefs.

"I realised medical school was not teaching a questioning and analytical mindset"

Why then is teaching of evidence-based medicine (EBM) so neglected within the medical curriculum? My experience as a student at a UK medical school was that evidence-based medicine was often used as a buzzword, but with little time dedicated to teaching what this meant or how one might put this into practice. The teaching I received led me to believe that national guidelines were based on thorough reviews of the best available evidence, and that evidence-based practice (EBP) simply entailed following those guidelines (namely, those produced by NICE).

Indeed, EBP does involve making healthcare decisions "based on the best available, current, valid and relevant evidence",⁽²⁾ but we must still integrate this best available evidence with both "individual clinical expertise" and knowledge of the context of the individual patient with their unique "predicaments, right, and preferences".⁽³⁾

Limited understanding of EBP appears widespread amongst healthcare students,⁽⁴⁾ and is perhaps unsurprising; despite EBM being covered at most medical schools during the course, the extent of teaching is variable, and EBM and statistics are not consistently taught in every year of the curriculum.⁽⁵⁾ Opportunities to practice EBM skills and assessment of performance are also limited.⁽⁶⁾

Considering just the first fundamental component of EBM, learning how to engage with the medical literature was not a core aspect of my medical curriculum. Despite choosing Student-Selected Components in which this was required, there was a notable absence of teaching on how to appraise the evidence base and use it judiciously to inform my research and writing.

As a consequence, I naively assumed that any research published in a medical journal would be of sufficiently high quality to be included in my analyses. It was only through undertaking an intercalated BSc that I first learnt to critically appraise evidence presented to me, to question published research, and consider its methodology and findings instead of taking them at face-value.

As I became more involved in academic psychiatry and research I realised how easily data could be manipulated to support a hypothesis, the potential for biases at every stage of the research process, and the flaws of the peer review system. I realised that the science underpinning medicine may not be as infallible as I had once believed. I realised that medical school was not teaching a questioning and analytical mindset which would enable us to independently draw conclusions from the available information, but instead was teaching us how to memorise facts and follow guidelines.

For myself and for many of my peers, it was during preparation for academic foundation programme (AFP) interviews that it dawned on us how little medical school had taught us about critical appraisal. We sought to develop our own skills through self-directed learning, near-peer talks from current AFP doctors, and, in my case, through entering the HealthSense critical appraisal competition. The majority of students will, however, leave medical school without this experience or knowledge.

Now that I am practising as a junior doctor in a busy regional teaching hospital I find myself often questioning the strength of the scientific basis informing our actions as healthcare professionals. In my first year working on the wards I have seen how variable medical practice is, depending on the individual clinician, based on their years of personal experiences, and the development of their own mental schema and "way of doing things". As foundation doctors, we are continually learning from our own successes and mistakes, from observing the actions of our colleagues, and particularly from the direction and decisions of our seniors.

"many barriers to assessing and discussing evidence for answers to healthcare questions"

We are not alone in this: GP trainees primarily consult colleagues for answers to clinical queries, and rarely utilise research resources.⁽⁷⁾ US and Canadian resident doctors report many barriers to assessing and discussing the evidence to find answers to healthcare questions, making them more likely to consult more experienced clinicians; time limitations being highlighted as a primary barrier, but also lack of knowledge and skills, and fear of repercussions from colleagues resulting from the indirect insinuation that

their practice is outdated.(8) Of course, clinical experience is key to developing knowledge, and enables the application of this knowledge to each unique context and set of circumstances. Learning from our senior colleagues' experience is of huge value, but we must continually question and ensure that this does not come at the detriment of using the best available up-to-date evidence to inform our clinical practice.

The current state of EBP therefore appears to be one of disconnect between theory and reality; we recognise it needs to be included in medical curricula, but are yet to provide consistent, effective teaching across UK medical schools to equip young clinicians with the skills to translate this learning into practice. The reasons for this are many, but perhaps central to this issue is that education in EBM does not currently have a strong evidence base.

Several attempts at systematic review have highlighted the poor quality of studies of EBM education, and heterogeneity of outcome measures, preventing meaningful comparison.(9,10) However, the main conclusion is that no single method of teaching EBM appears superior to another.(10,11) There is also a notable lack of any evidence demonstrating that any observed improvement in knowledge and skills translates to improved clinical practice or patient outcomes.(9,12) Without evidence, it is difficult to provide guidance on how medical schools should implement EBM teaching.

What, therefore, might the future of EBM education look like? With recent changes to foundation programme applications such that additional achievements no longer count for additional merit, one must wonder how many students will continue to undertake costly intercalated BSc degrees, further reducing any exposure to critical appraisal skills. We will begin to see clinicians coming through the newly announced medical degree apprenticeships – will EBM be central to their education? This is a time of change for medical education, a time of evolving doctor-patient relationships, and a time of flattening of hierarchies within medical teams – a time, therefore, to ensure that the development of a questioning mind, and the skills to search and appraise the evidence to answer those questions, are central to the education of our future doctors.

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Public health

NHS England to revise bowel screening leaflet following complaint

By Mandy Payne

A complaint about the NHS' poorly worded [leaflet](#) on bowel cancer screening has prompted a review, reports Susan Bewley, emeritus obstetrician and past chair of HealthSense. NHS England have written to her to say that they have asked Public Health Commissioning Central team to undertake a full review after she alerted them that the leaflet is misleading and does not support informed choice. "This is a win", says Susan.

She had initially written to them in April this year about "NHS bowel cancer screening: helping you decide", a leaflet that is sent by post to people aged 60-74 years. It arrives with a covering letter that purports to come from "your trusted GP", although it does not, because it is actually generated by the NHS Bowel Cancer Screening Programme. In her complaint Susan wrote:

"I cannot trust your leaflets as they give me numbers in multiple formats. Although the leaflet proudly claims its commitment to the Plain English Campaign ... you do not use 'Plain Numbers' that members of the general public can understand."

The numbers supposedly "helping you decide" include:

- "8 out of 10 people diagnosed with bowel cancer are over 60"
- "bowel cancer screening reduces my risk of dying from bowel cancer by at least 25%"
- "about 2 in every 100 people have a 'further tests needed' result"
- "a colonoscopy causes a perforation in around 1 person in 1,700"

She went on: "It is against all principles of clear communication to give proportions, percentages and ratios using different denominators. The mixing and mingling of different formats acts as persuasive advertising or even coercion so as to avoid proper informed consent (which you don't check but just assume by return of the sample)." Better, she suggested, would be for the risks to be laid out in an evidence-based fact box, such as [those produced by the Harding Center for Risk Literacy](#), and comparing the risks both ways – including doing nothing first as it's always an option – and using a common denominator.

"I want trustworthy information on which I can base a decision, but I feel that I am being misled and bullied"

Susan had further complained about receiving an unsolicited telephone call from NHS staff hoping to persuade her to take part in the screening, but who were not able to answer her most basic questions. "What I need to know is the difference in my chance of dying with or without testing", she explained. "Instead, the caller offered me to opt out – I said I don't want to opt out – I want trustworthy information on which I can base a decision, but my problem is that I feel that I am being misled and bullied."

In their response, of 17 July, NHS England noted that the bowel screening leaflet is due for review later this year, and Bewley's comments will be shared with the team working with clinical advisors to update the leaflet. They also said, they had found her comments about the numerical representation of risk interesting and they have therefore requested the team look into the resources provided by the Harding Centre of Risk Literacy.

HealthSense will keep an eye out for any revised version and we look forward to being able to commend a new, intelligible leaflet that truly supports informed decision making on screening. Meanwhile, Susan is considering a further complaint. "Their letter to me says: 'we don't have targets', yet it goes on to say: 'we have to chase people up.'"

Such contradictions might be less surprising when you learn that the company subcontracted to doing the chasing is called "Catch 22".

Mandy Payne
Editor, HealthSense Newsletter

Last word

LAST WORD: Normal service has been resumed

By James May

Doctors are easily tempted by the notion that their treatments are effective. The placebo effect has therefore been a source of shame for some as it has seemed that much of the benefit of our treatment is illusory. That is to say, not that they do not work, but part of the way that they work is because of the illusion that they work.

But, what if we can boost the effectiveness of our treatments by turbo-charging the placebo effect? In practice this means that when recommending a treatment, or prescribing a medication, we do so with upbeat enthusiasm and confidence, the positivity of which augments the placebo effect. Placebo of course meaning 'to please', it seems a no-brainer to want to increase the effect to the benefit of the patient. This is particularly so, given that the size of the effect of the placebo often seems greater than the real effect of the drug.

The benefits of the placebo effect of course are not restricted to medications that work. If there is uncertainty about the true benefits of a drug, these doubts can be put to rest by the confidence that the placebo effect remains. A General Practitioner who does not recommend a cough mixture on the basis of a lack of evidence for efficacy can therefore be regarded as somewhat cruel, or perhaps unnecessarily nihilistic about what can be achieved if only they would be more positive about how patients can be made to feel.

But the dark side of the placebo effect begins to show its face here. Complementary therapies can easily be justified by the same enthusiasm. Why would we withhold the power of placebo, denying patients our optimistic vibes, by undermining the patient's strongly held convictions that chiropractic is doing wonders for their liver or their general sense of well being, posture, or various vague physical ailments? There is a dystopian possibility here too, that given the placebo effect is reported to be greater than the real effect of some drugs, one could legitimise the use of a drug that causes some minor harm, on the basis that it is outweighed by the benefit of the placebo. The thought experiment itself suggests that something is not quite right.

Despite the fact that the placebo effect has itself been shown to be very largely illusory (see [David Colquhoun's excellent blog](#), and [James McCormack's brilliant lecture](#)), the illusion that it is not illusory

persists, along with the desire to believe in illusions. It is therefore worth reviewing what we know. The studies that purported to show the placebo effect are both very old and very poorly conducted. Nevertheless, there is a gap between the proven benefits of a treatment and the improvement patients can expect from the point they are given the treatment. And this needs to be understood.

In General Practice patients come to see the doctor at a point of distress and concern about an illness. Not infrequently they verbalise it, 'But I don't normally feel like this'. The use of the conjunction, 'but' is worth noting. A typical scenario in which this sentence occurs is when a patient has attended with symptoms of a viral upper respiratory tract infection (a cold). Most patients know deep down that they do not need to make an appointment with a doctor if they have a cold. Therefore there is something about this particular cold that has led them to cross that line and which has an associated level of expectation (not to say expectation) attached to it. There is commonly a reference to particular symptoms like 'yellow phlegm', or that the cough, 'has gone to my chest' which makes them feel this is different from a "normal" cold. Sometimes a deadline at work, or an imminent holiday or wedding, has made their need for recovery unusually urgent.

"legalistic directives requiring same-day access suggests political agendas with limited clinical experience"

As interesting as the word 'but' is in the sentence, it is the word 'normally' which is most helpful. Healthy patients don't see the GP in their normal states, which is why maths matters.

Regression to the mean is a mathematical model which is simultaneously very important in medicine (to my mind the most useful statistical model bar none) and amounts to little more than tautology. It is the observation that aberrations from normality statistically return to normal with the passage of time. The day following an unusually hot summer's day is likely to be cooler. If a family has one child who is abnormally tall, then a subsequent child is likely to be shorter. This revelation is in fact little more than acknowledging that normal is normal. It is for this reason that a patient is likely to feel better the day after they have made the effort to book an appointment to see their GP. Please notice how carefully I phrased that sentence. I did not say the day after they have seen their GP, but the day after they have booked to see their GP. It is for this reason that unless the condition is urgent, when triaging my patients, and if appropriate, I try to

call them or see them 24 hours after they contact me.

Of course, access to GP services matters a lot, and I personally believe that good access can give patients the confidence not to contact the GP in the early stages of an illness because they know that it will be easy to get a timely appointment if needed later. However, the existence of legalistic directives requiring same-day access normally suggests political agendas with limited clinical experience.

Regression to the mean then, rather than the placebo effect, has tremendous power for clinicians and patients alike. It enables discussions about treatment options to appreciate that most of the time treatments are not a zero sum game where if you are treated you recover, and if you are not you do not. Very often there is some value added to medical interventions, but it may be considerably less than patients or clinicians are tempted to believe. This is not a bad thing. It means that the body has a wonderful habit of repairing itself, and that doctors are not gods. Conversations about harms and benefits of treatments can be had with greater honesty and less angst.

But a greater benefit, is that doctors can often choose to 'do nothing' – which in GP parlance has been called, 'masterful inactivity'. Using regression to the mean can help patients to understand their illness, and accept that treatments may not be helpful, but that anyway they will recover. It gives anxious doctors the confidence to 'wait and see', and review the patient only if they do not recover or improve (depending on the condition). The benefits of this are simply huge.

Unnecessary antibiotic prescribing can be avoided, decreasing the risk of resistance. Unnecessary tests can be avoided, because they can always be performed in a few days if still needed. Patients do not need to be seen repeatedly to follow up on minor conditions, because the clinician can feel confident that in all probability the patient will be just fine, and that the patient can be fully empowered to contact the GP at any time if things do not improve, whilst being safe in the knowledge that this is statistically very unlikely. Doctors can be more straightforward with their patients, not trying to 'enhance the placebo effect' by using positive spin, but sharing with patients that the medication may well not do very much, and that they are likely to feel better despite this.

The effect of understanding regression to the mean then is to use far less medicine, and far fewer clinical resources, empowering patients to cope with illness episodes without great anxiety, and increasing trust. The initial consultation can focus on excluding serious or urgent problems, and then adopting a wait and see approach, knowing that in all probability normal service will be resumed.

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- Consumer protection in regard to all forms of health care
- The highest standards of education and evidence-based health care by practitioners
- Better understanding by the public and the media of the importance of application of evidence from robust clinical trials

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