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Registered Charity No 1003392

HealthSense Newsletter

for Science and Integrity in Healthcare

Issue 122, Spring 2023

Obituary: Professor Sir Michael Rawlins: 1941- 2023

An EBM champion extraordinaire

We were saddened by the news that Professor Sir Michael Rawlins, a patron of our charity since 2012, died on 1 January 2023. An involved and enthusiastic supporter, he took part, with fellow patron Professor Steve Jones, in our first ever public debate at King's College London back in 2013, and again in our debate on Lord Saatchi's Medical Intervention Bill in 2015.

By John Illman

In October 1999, the Labour government's newly founded National Institute for Clinical Excellence (NICE) generated extreme anger of a kind very rarely expressed so openly and vehemently by visitors to No.10 Downing Street. It also provoked fury throughout the pharmaceutical industry and widespread public concern about the onset of rationing.

Glaxo Wellcome chair Sir Richard Sykes stormed through the famous front door, reportedly "incandescent". In its first decision, made even before it was fully up and running, NICE had recommended that the NHS in England and Wales should not prescribe Relenza, Glaxo's new influenza treatment.

Sykes expected to be listened to. He had been the architect of Glaxo's transformation into Europe's biggest drug maker, first through the merger with Wellcome shortly after he became chief executive in 1993 (and later through the merger with SmithKline).

Relenza set the stage

As the first chair of NICE (later the National Institute for Health and Care Excellence) Professor Michael Rawlins was potentially vulnerable. Glaxo Wellcome was a significant foreign currency earner for Britain and one of its most prominent companies. Sykes threatened that if the 'ludicrous' decision was not reversed, Glaxo Wellcome, then Britain's biggest pharmaceutical company, would consider leaving the UK.

Tony Blair was a relatively new prime minister, only two and a half years into the job but, briefed by his health secretary Frank Dobson, he steadfastly defended NICE's decision.

In *A Terrible Beauty: A Short History of NICE (2017)* Rawlins recalled: "We were incredibly lucky with Relenza. It was the first big test, although I didn't realise at the time quite how big a test it was. It set the stage.

"It was blatantly obvious that the drug only reduced influenza symptoms by about a day, which wasn't a big deal. It cost an arm and a leg (£24 for a five-day course). And doctors were horrified at the prospect of finding themselves either running round everyone with flu to give them a prescription, or all the flu patients coming to their waiting rooms and spreading their germs around everyone else in the room. So the GPs were on side with the decision, and the newspaper leaders in the lay press were broadly supportive.

Decisions would be based on evidence

"It showed we were an evidence-based organisation, and that we would make decisions on the available evidence, not on a wing and a prayer or a promise."

Relenza, Rawlins said, was "precisely the sort of problem that we had been set up to sort out". His revolutionary role was to make him one of the most controversial figures in medicine — and a world leader in health and social care guidance and medicine evaluation. NICE, which now has nearly 700 employees, has been admired and imitated by many countries.

Early NICE critics were not restricted to big pharma. They included Dr Richard Smith, then BMJ editor, who, some five years later, said: "NICE may prove to be one of Britain's greatest cultural exports

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along with Shakespeare, Newtonian physics, the Beatles, Harry Potter, and the Teletubbies."

Rawlins, chair between 1999 and 2013, was a major factor in what was and is an inspiring success story.

Professor Gill Leng CBE, former NICE chief executive (2020-2022), said: "Sir Mike Rawlins was a wonderful human being who combined warmth and humanity with a razor-sharp intellect. He had vision, drive and a passion to improve healthcare, always with patients at the centre. He leaves a huge imprint on the history of medicine. It was a privilege to have worked with him."

A formidable challenge

The challenge in 1999 was formidable. New expensive treatments such as beta interferon for multiple sclerosis, had created a postcode lottery. Fair-mindedness demanded that a state-funded NHS should provide individual medicines for all or none.

The rationale for NICE was easy to understand: it would give doctors the necessary evidence to provide effective care and control costs. Who could possibly object, apart from big pharma? But asked if he thought it would work, Dobson, a refreshingly honest politician, replied: No. "But we'll give it a bloody good shot."

Concern was not restricted to industry. NICE, critics said, would encourage rationing and threaten clinical freedom, the right of doctors to prescribe as they saw fit.

Rawlins, however, helped to make evidence-based medicine (EBM) part of the fabric of healthcare. A charming man with a gift for winning people over, he resolved that all stakeholders should have their say, if not necessarily their way; and that NICE should be robust, inclusive, transparent, independent and contestable.

Cool under pressure

Rawlins was also cool under pressure. When the NICE board met in 1999, within hours of its launch, it lacked a chief executive. Rawlins told the board that he had a suitable applicant waiting outside. They had ten minutes to make up their minds. Enter Andrew Dillon, then chief executive of St George's healthcare NHS trust, and an inspired choice. He went on to lead NICE for more than 20 years.

NICE worked because it was an advisory body. The NHS was not obliged to implement its recommendations — a point noted by Glaxo Wellcome in 1999 when it ran an advertising campaign in the medical press to encourage Relenza prescribing. But just 212 Relenza prescriptions were dispensed between September 1999 and January 2000. In the absence of NICE, there could have been hundreds of thousands.

Rawlins was the first of two sons of the Rev Jack Rawlins, vicar of Northwood-on-Trent, Staffordshire, and his wife, Evelyn (née Douglas-Hamilton), a nurse. Jack died when Michael was about five. Sone 13 years later Evelyn married Dr Headley Boardman, a single-handed GP, who became a "wonderful, supportive stepfather", encouraging young Mike "to look at the patient behind the pathology and to think more about the sociological aspects of medicine."

After attending Uppingham school in Rutland, Rawlins read medicine at St. Thomas' hospital, London where his mother had trained. Although he completed an intercalated degree in anatomy, the basis for his interest in science and research, he was not a model medical student. His academic work suffered, he later admitted, because of his passion for conducting an orchestra and staging operas. He also played the piano, violin and viola.

Making up for time lost to music, he reasoned that if he could "understand" pathology, he would "understand" medicine. In his final year he attended post-mortems almost every morning. Talking with Professor David Webb, president of the British Pharmacological Society in June 2018, he recalled: "I was the only student there. The pathologists loved having me there and were teaching me pathology all the way through. It stood me in wonderful stead."

After completing house jobs in Portsmouth, St Thomas's and the Brompton in London, he decided "an organ specialty wouldn't be much fun". Chest medicine, he reasoned, was all about asthma and chronic bronchitis, while neurology "was all about headaches and so on".

Giving one another fevers

William Cranston, professor of medicine at St Thomas's and later chair of the Committee for the Safety of Medicines (CSM), hired Rawlins to research temperature regulation and the mechanism of action of aspirin.

He and a PhD student did 'terrible things to one another' by giving one another fevers and treating them. This may not sound attractive, but in his memorable interview with Webb, Rawlins explained: "That was my career as it were — made for me — pharmacology and general medicine."

He undertook post-graduate training in clinical pharmacology and general medicine at the Hammersmith Hospital and the Karolinska Institute, Stockholm.

At the extremely young age of 32, he started 33 years (until 2006) as the Ruth and Lionel Jacobson professor of clinical pharmacology at Newcastle University. His apprenticeship, in effect, for his role with NICE included 18 years on the CSM, five as chair (1993-1998).

After stepping down from NICE, he chaired the Medicines and Healthcare products Regulatory Agency (MHRA) from 2014 to 2020. He also chaired the Advisory Council on the Misuse of Drugs (1998-2008), was president of the Royal Society of Medicine (2012-2014) and chairman of UK Biobank (2012-2019).

Rawlins' marriage in 1963 to Elizabeth Hambly, a nurse, ended in divorce in 2005. He is survived by their

three daughters: Victoria, Lucy and Susannah, eight grandchildren and a great-grandchild.

It might seem astonishing that a leading EBM advocate was a lifelong smoker, but *The Guardian* reported that the night before an ambulance took him to hospital for the last time, Rawlins sat in bed chatting to his daughter with a glass of whisky in one hand and a cigar in the other.

John Illman
Medical journalist and author, London

News in brief

Student resources now online!

We have created a unique set of free online resources to equip healthcare students with the skills needed to critique clinical trial protocols. The new Student Resources were developed by HealthSense volunteers including doctors and our enthusiastic student team. They draw on our experience of more than a decade of running an annual Student Prize competition that encourages students to test their research skills.

The new resources are under the 'Students' tab of the HealthSense website and consist of:

Evaluating research protocols – an example of a short, simple clinical trial protocol and some examples of good critiques. These have just enough detail to help students develop their own evaluative framework, which can then be applied to both research protocols and published research papers.

Recommended reading – has links to books, websites, journal articles, worksheets, and other free resources that support learning about aspects of quality clinical research.

These resources will be a goldmine for students entering the HealthSense Student Prize competition. Remember, the deadline for this year's entry is midnight on Sunday 30 April 2023.

Finally – transparency to be UK law

After ten years of dogged campaigning by many groups including HealthSense, the government's response to its consultation on clinical trial legislation was published on 21 March. We heartily welcome its proposals for new legal requirements on transparency: all UK clinical trials will be required to register publicly prior to starting, and publish a summary of results within 12 months of trial completion, as well as sharing results with participants. The campaign was begun in 2013 by Ben Goldacre (who had already come to our attention and received our award in 2006); and taken up by many groups of which one of the most dedicated and energetic was our partner TranspariMED. The UK is already making good progress on clinical trial reporting, but the Health Research Authority reports that a stubborn 8% of trials continue to violate this ethical requirement. We hope that the new laws will help close these gaps.

Reading the rest of the government's report, the government's plans to create a "proportionate and flexible regulatory environment" and to "provide a framework that is streamlined, agile and responsive to innovation" could raise concerns. Could they be loosening controls in order to help generate profits for those with a commercial interest?

Telegraph correction over liquid biopsy article

A complaint by HealthSense ex-chair Susan Bewley has led to a correction in *The Daily Telegraph*. In an article on 16 January, health editor Laura Donnelly had written enthusiastically about "revolutionary" tests which she and her fiancé had – at £1250 each – which she said could "vastly improve early diagnosis rates". These liquid biopsies could, she wrote, detect up to 70 types of cancer years before symptoms emerge. She didn't clarify whether she or *The Telegraph* had paid for the test. In fact, the clinic – the Cancer Screening Trust (CST) – had paid. Susan Bewley's letter called out the uncritical coverage and the undisclosed conflict of interest. Replying to Bewley, Rachel Welsh, head of editorial legal & compliance at the Telegraph Media Group said: "We accept that the article should have made clear that CST paid for the consultations and tests. This oversight has now been corrected and the article states: "Our tests and consultations were paid for by The Cancer Screening Trust." Unfortunately the article is behind a paywall, so the correction can only be seen by those with a paid subscription to the newspaper.

Subscription blood test claims judged "misleading"

The Advertising Standards Agency (ASA) has upheld a complaint from HealthSense patron Margaret McCartney against a company that advertised an at-home blood test. Numan's Fear Nothing Blood Test, which costs from £98 for a three-month subscription, claims to be "FREE if we don't find anything". But the Glasgow GP and broadcaster objected to their advertisements which implied that something was medically wrong if a result was outside the 'normal' range, and were not clear about how much they cost. The ASA agreed with her concerns, finding that at least 90% of people using the test would have a result of at least one biomarker outside the 'normal' range, while there was no information given about the test's accuracy or risk of false positives. Unvalidated screening tests can cause harm by making people worry and seek unnecessary and potentially harmful treatment after supposedly abnormal results.

And more on blood tests for cancer – new Consilium video

For a more balanced view on the subject of novel blood tests for cancer screening, see Multi-modal screening tests: hype or hope? In this 45-minute talk, US research scientist Paul Pharaoh uses the example of the 'Galleri' test to illustrate both the potential and the problems, with the questions that will need to be answered before tests like this can be used in clinical practice. The event was organized by our partners, Consilium Scientific. If

you are too busy to watch the whole video, remember that this and all new Consilium recordings are accompanied by a transcript. From Consilium's homepage, pull down the KNOWLEDGE tab to see the full list of past seminar recordings.

The Lancet issues 'expression of concern' over Macchiarini papers

Five years after publication fraud in their journal had been brought to their attention, *The Lancet* has now issued an 'expression of concern' relating to two articles by the disgraced surgeon Paulo Macchiarini. In his latest blog, Dr Peter Wilmshurst argues that the journal's action is inadequate, and goes on to detail the shocking history of patient deaths following Macchiarini's discredited trachea-transplant experiments. Wilmshurst had brought the surgeon's research misconduct to the journal's attention in 2018 but *The Lancet* steadfastly refused to retract the paper, even after MPs Norman Lamb and Dr Sarah Wollaston intervened. Dr Peter Wilmshurst writes in his latest blog, "Once it is confirmed that a publication is fatally flawed, retraction is the only acceptable course, whether the faults resulted from honest error or falsification. In this case, there is no doubt that both Lancet papers were falsified." An expression of concern is called for when the accuracy or integrity of a publication are called into serious question and are under investigation. An alert with link to the expression is now visible to anyone accessing the original papers.

The Editors of The Lancet. Expression of concern: Clinical transplantation of a tissue-engineered airway. Lancet 2023;401(10376):536

An easy way to save NHS money

When nurses' strikes were announced, HealthSense Committee member Keith Isaacson sent the brief letter below to his local MP, Laura Farris, Member of Parliament for Newbury. She responded to say she has forwarded it to the Secretary of State for Health. We await Steve Barclay's response with interest, and in the meantime we are sharing Keith's letter below so that HealthSense members may like to send a similar one to their own MPs:

Dear [your MPs name]

A large, worthwhile saving for the NHS

I understand the government's reluctance to increase the pay for public sector workers. Amongst such workers, I believe the public has the most sympathy for nurses. The Prime Minister made it clear to the Secretary of Health that any extra money must come from the existing health budget.

My suggestion is that a worthwhile saving can be made by cancelling the extra £10 million pledge to provide 29 new NHS breast screening units, plus upgrades to existing services, or even the whole programme. It sounds attractive to the public, but unfortunately there is NO EVIDENCE that this screening programme saves lives (overall deaths), or reduces advanced cancers of the breast (which it should if it 'worked'). On the contrary, it gives rise to many false positives in healthy women, increases the risk of mastectomy and is an unnecessary added burden to the NHS, diverting resources from the sick to the well. Do see the factbox here:

https://www.hardingcenter.de/en/transfer-and-impact/fact-boxes/early-detection-of-cancer/early-detection-of-breast-cancer-by-mammography-screening

I'd be happy to supply more references and information.

Please advise how you can help make this happen.

Signed

[Add your personal address to prove that you live in the catchment area of your MP]

New books by Peter Gøtzsche

Physician and medical researcher Peter Gøtzsche, who received our award in 2016, has published prolifically in recent years. For a list and description of some of his latest publications see the Institute of Scientific Freedom website. His recent book, *The Chinese virus: Killed millions and scientific freedom*, tells the story of alleged cover-ups over the origin of the COVID-19 pandemic and the chilling effects on scientists.

Misinformation – a leading cause of death?

Can misinformation be 'cured'? A new article argues that most attempts to 'cure' public opinion are untested or out of line with best evidence. The pandemic brought the dangers of rushed and ill-conceived public health messages to the fore and left the scientific community vulnerable to reputational damage, the authors explain. An interesting long read, this viewpoint in the *American Medical Association's Journal of Ethics* was written by US experts in science communication, and includes suggestions for better ways ahead.

Freiling I, Krause NM, Scheufele DA. Science and Ethics of "Curing" Misinformation. AMA J Ethics. 2023;25(3):E228-237

Bad news game

On the subject of misinformation, it seems that a good way to fight fake news is to 'inoculate' people by teaching them how they might be manipulated. An online game developed at the social decision-making lab at Cambridge University lets you explore how easy it is to create and spread misinformation. The game, Bad News, encourages players to try their hand at writing deceptive social media posts and headlines. When tested afterwards, the team found players had, in the process of playing the game, become more immune to false claims. Try it!

Innovations

Polygenics: the latest chimera

By Roger Fisken

There is an old Danish saying, often attributed to the physicist Niels Bohr, but almost certainly in use before his time, that it is difficult to make predictions, especially about the future.

Despite the obvious truth of this statement, researchers, doctors and politicians continue to seek a definitive answer to the question: "Will I get cancer and, if so, of which organ and when?". Attempts to take this further have led to a number of screening programmes aimed at detecting diseases as early as possible in hope of achieving better outcomes. Regular readers of this newsletter will be aware of how badly this idea has gone wrong in relation to mammographic screening for breast cancer, despite the success of other screening programmes such as those for cervical cancer.

Molecular genetics has advanced hugely in the last 40 years. One result has been the idea that healthy people could be screened for harmful genetic variants that are linked to certain diseases that develop later in life, giving the opportunity for early action to improve their outcomes. This concept, when applied to screening for a large panel of genetic variants, is called polygenics. But does it work? Is it actually better than other screening methods? Answers to these questions are found in a recent *BMJ* Analysis by a group led by Amit Sud of London's Institute of Cancer Research.(1)

Its authors explain that polygenic scores look at thousands of variants across a person's genome to estimate their risk of developing a specific disease. Each individual genetic variant has a small effect on a person's risk. However, it is hoped that by looking at all the variants together, something clinically meaningful might be said about that individual's overall lifetime risk of developing that disease. The two areas in which polygenics have been used most extensively are cancer and coronary artery disease.

Limited ability to predict disease

According to Sud et al, "enthusiasm surrounds government reports on polygenic scores, with the *Genome UK* report describing them as offering a step change in treatment for disease".(2) However, as they go on to say, polygenic scores are limited in their ability to predict disease and if we do not set our expectations accordingly they could harm rather than help.

One of the major drawbacks of polygenic scores is that they do not give any weight to the effects of environmental or other non-genetic factors that contribute to most common diseases. Thus, when Zhang et al (3) calculated the maximum predictive ability achievable with polygenic scores for a range of cancers they hit a ceiling. For example, in the case of breast cancer, with specificity set at 95% (i.e., where only a small number of false positive results would be seen) the best achievable sensitivity (rate of picking up those who truly have the disease) would be 19%. This is about 4% better than current scores, but still poor as far as a screening test goes.

One approach to addressing the shortcomings of polygenic scores is to try and integrate them into other disease risk scoring systems, for example the QRISK score for atherosclerotic cardiovascular disease. However, adding polygenics only improves the predictive accuracy of QRISK by around 3 to 4% over ten years.(4,5) Putting it another way, using this integrated risk tool and giving a statin to all those judged to be at increased risk would mean that 8713 people would need to be tested by means of the integrated programme, and those at higher risk be given statins, in order to prevent one additional coronary artery disease event. A recent cost effectiveness analysis of polygenic scores in coronary artery disease prevention concluded that the incremental cost effectiveness ratio of this approach was $140,000 per quality-adjusted life year, even assuming 100% adherence to statin treatment.(6)

Did the test save Matt Hancock's life?

Those who have reason to think unkindly of a previous Secretary of State for Health who was in office during much of the Covid-19 pandemic may be interested to know that he believes that having a polygenic score for prostate cancer "may have saved [his] life".(7) In a speech to the Royal Society in 2019, Matt Hancock announced that the test led to him being told that his risk of developing prostate cancer before the age of 75 was 15%, and that he would now make sure he didn't "miss any screening appointments in the future". He was perhaps unaware that the average lifetime risk in UK males born after 1960 is actually 18%, but he should have known that there is, in any case, no current UK screening programme for prostate cancer.

In summary, the paper by Sud and colleagues gives many similar examples of problems with the use of polygenic risk scores. Their final conclusion is that "contrary to what many people might expect … , a high polygenic score will generally have a rather underwhelming impact on absolute risk and both clinicians and the public need to know this."

Roger Fisken
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Roger is chair of HealthSense

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Complementary and alternative medicine

Is so-called alternative medicine compatible with Christian beliefs?

By Edzard Ernst

Is so-called alternative medicine (what I like to call SCAM) compatible with Christian beliefs? I must admit, this is not a question that robs me of my sleep all too often. Yet it seems an interesting issue to explore.

So, I did a few searches and found a group called the Christian Medical Fellowship had published a 'Christian Checklist' as applied to SCAM.(1) Since it is not long, I present it to you in full on the next page.

1. Taking into consideration the lack of scientific evidence available, can it be recommended with integrity?
2. What are its roots? Is there an eastern religious basis (Taoism or Hinduism)? Is it based on life force or vitalism?
3. Are there any specific spiritual dangers involved? Does its method of diagnosis or practice include occult practices, all forms of which are strictly forbidden in Scripture.

Now, let me try to answer the questions that the checklist poses:

1. No! – particularly not, if the SCAM endangers the health of the person who uses it.
2. Most SCAMs have their roots in eastern religions, life force, or vitalism. Very few are based on Christian ideas or assumptions.
3. If we define 'occult' as anything that is hidden or mysterious, we are bound to see that almost all SCAMs are occult.

What surprises me with the 'Christian Checklist' is that it makes no mention of ethics. I would have thought that this might be an important issue for Christians. Am I mistaken? I have often tried to point out that the practice of SCAM almost invariably violates fundamental rules of ethics.(2)

In any case, the checklist makes one thing quite clear: by and large, SCAM is nothing that Christians should ever contemplate employing. But the following quotes, taken from an *Independent* article about a Vatican-backed exorcism course, would seem to raise some concerns.(3)

The article quotes Swiss exorcist Father Cesare Truqui saying that the course, "attended by exorcists, priests and lay people, was vital in order to raise awareness and hone priests' skills in fighting evil."

It goes on to note that: "In 2012 it emerged that the diocese of Milan, the biggest in the world, had installed an exorcism hotline to cope with demand. Monsignor Angelo Mascheroni, Milan's chief exorcist, said that his diocese had doubled the number of exorcists from six to 12 to cope with the 100 per cent rise in the number of requests for help over the last 15 years.

The late Father Gabriele Amorth, the Vatican's chief exorcist who is said to have performed 160,000 exorcisms over 60 years, reportedly took a "dim view of fantasy novels and yoga. Practising the latter, he once warned, was 'satanic'; it leads to evil just like reading Harry Potter'."

Perhaps you take such statements not all that seriously; the scorn of the Vatican does not concern you?

Yet, the 'Christian Checklist' also raises worries much closer to home. King Charles is the head of the Anglican Church. Undeniably, he also is a long-term, enthusiastic supporter of many of those 'quasi-satanic' SCAMs.(4) How are we supposed to reconcile these contradictions, tensions, and conflicts? I am sure many Christians must worry about this question.

Edzard Ernst
Emeritus Professor, University of Exeter

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Transparency update

Progress on clinical trials: UK, Germany and USA

By Till Bruckner

A few years ago, HealthSense called on the UK government to put into place a system to ensure that all clinical trials are registered and their results reported.

That system is now being implemented according to plan, making the UK the first country worldwide to put an end to

this form of research waste in clinical trials. Keep an eye on the Health Research Authority's website for the #MakeItPublic conference, planned for later this year, which will bring together funders, institutions and researchers to exchange best practices in clinical trial transparency.

Meanwhile, the UK's system has caught the eye of health groups in Germany. TranspariMED is currently working with Cochrane Germany and other groups to develop a blueprint for a similar national system. Over the coming months, the coalition will push German policy makers to put a watertight system into place. Check out the video of the workshop kicking off the campaign, in which key UK players explain why and how the UK system was developed.

Finally, in the USA, the world's largest medical research funder, the National Institutes of Health, (NIH) has begun cracking down on research waste. NIH policies have required all trials to be registered and reported since 2017, but a recent study found that NIH had failed to monitor and enforce compliance, leading to hundreds of millions of dollars in research waste. Following pressure from Congress, NIH now appear to be getting serious about curbing research waste. Details are still unclear. TranspariMED has filed two Freedom of Information requests to find out more.

Like HealthSense, TranspariMED has no core funding and relies on donations to keep the lights on. You can support its work to get all clinical trial results reported by making a small monthly contribution here: https://consilium-scientific.org/incubator/transparimed

Till Bruckner is a member of HealthSense and the founder of TranspariMED

Book reviews

Bad Data

By Philippa Pigache

"Bad Data: How Governments, Politicians and the Rest of Us Get Misled by Numbers" by Georgina Sturge is published by The Bridge Street Press (3 Nov 2022). Hardcover, RRP £20.00

The Covid pandemic forced us to grapple with statistics. How many died? What percentage were infected? Which country managed the disease best? Accurate data had never been more important. Even with David Spiegelhalter holding our hands, many didn't trust the figures they were shown. Here comes Georgina Sturge to confirm our worst fears.

As a statistician at the at the House of Commons Library, she has the spec on how our government's attempts to count, survey, measure and project frequently yield bad data. They fail because they don't ask the right questions, they change the way they measure things, make the wrong assumptions, construct inaccurate models and don't spend enough money. But governments need data to demonstrate that their policies work, or will work as planned. Because if they don't they will be punished at the ballot box.

In 1085, when William the Conqueror wanted to discover from whom he could best raise money in his new realm, he sent out commissioners to record all the people, all the animals and all the land. It took a long time and cost a lot, but was probably worth it in order to collect his taxes. These days HMRC attempts to contact everyone to calculate their income and wealth with the same objective, but it doesn't spend enough and the wealthy pay experts to avoid or evade paying up.

A football fan

Sturge, who is a football fan, contrasts what government spends with what happens in sport. "There is data on exactly how many times Harry Kane made an on-target goal attempt with his left foot in the last Premier League season." This is possible, she explains, because there are companies that pay whole teams of people to manually record what happens in every game in England's top league.

King William's Domesday Book is usually regarded as the forerunner of the modern decennial census, which was first taken in 1801. In the census, information is gathered by means of a survey: by asking everyone in the country on a particular day exactly the same questions. Since asking everyone is vastly expensive, between censuses we estimate by sampling the population to be counted. To be meaningful, samples must be large enough to be representative of the populations they stand for. In Britain the total population is estimated between censuses by deleting the number of registered deaths, adding in the number of births plus, or minus, a number for net migration. Since 1961 this last was calculated using the International Passenger Survey (ITS), which Sturge points out, represented a small, unrepresentative sample based on a false assumption.

Making migrant numbers add up

The ITS interviews about 800,000 travellers each year. Those saying they intend to stay are counted as immigrants and those planning to leave, as emigrants. In 2019, just before the UK left the EU, only 3000 (one in every 267) were classed as migrants. This was a rather a small number to be representative of a country with free movement within the EU. And it was because the ITS only counted migrants passing through three major airports: Heathrow, Gatwick and Manchester. It had overlooked completely the mushrooming of low-budget, no frills airlines like easyJet, Ryanair and Wizz Air, set up to cater for increased traffic to and from Europe and using smaller, regional airports like Luton, Birmingham and Leeds to keep down costs. In preparation for EU expansion, the UK government had asked its researchers to predict how many people might migrate to this country each year. The answer, says Sturge, was, 'Probably between 5000 and 13,000,' The reality was more than twenty times that number.

Similar miscalculations, based on equally mistaken assumptions, continue to bedevil the statistics on immigration and asylum seeking. The UK has no remotely accurate way of counting resident foreign nationals, who include children born here to foreign nationals, since there is no automatic birthright citizenship in the UK.

Many of the things government tries to measure are intangible. How do you define poverty, which depends not just on income but on who and what it has to support? You can define it absolutely or relatively, as a percentage of average income, or by a surrogate marker of poverty like the number of children on free school meals. This leads to some strange contradictions. In 2020, the leader of the opposition claimed that there were now 600,000 more children living in poverty than at the end of the last Labour government. The Prime Minister refuted this by claiming there were 100,000 *fewer* children living in *absolute* poverty. Both claims were supported by official figures.

Crime statistics

In crime statistics problems of definition overlap with the distortion caused when the people who record crime are also the ones tasked with reducing it. One police force showed a 27 percent reduction in "theft from a motor vehicle", which did have a policing target, but a 407 percent increase for "vehicle interference", which didn't. This sort of inconsistency makes it difficult to say with any certainty whether crime is going up or down. But since 1980 we have had an alternative to data from police-recorded crime. The Crime Survey for England and Wales gathers data on crime *not* reported to the police, and it shows a consistency absent from police-recorded data.

Sturge points out that data is only collected when it is recognised as important. But governments need to predict the effect of new measures. In the absence of data, models are constructed. During the Covid pandemic these came in for justifiable stick. Sturge urges the advantage of unifying existing data on population in a single database rather than storing them in silos guarded closely by the NHS, the DHHS, HMRC and local authorities. In Holland, where population data are linked, the last census was carried out by 15 people from their desks, at a cost of £1.4 million, whereas the 2012 Census of England and Wales cost £900 million.

I enjoyed *Bad Data*. It's full of interesting, important information, written in a lively, untechnical style that doesn't bamboozle statistical novices like me. But all those numbers still swirl around in my head when I try to sleep.

Philippa Pigache
Medical journalist and author
Philippa is secretary of HealthSense

How rotten is drug regulation in India?

"The Truth Pill: The Myth of Drug Regulation in India" by Dinesh Singh Thakur and Prashant Reddy Thikkavarapu was published 10 October 2022 by S&S India. Kindle edition £9.49

Over the past decade, India's drug exports have doubled to over $24 billion per year. While its long-established and rapidly growing generics industry has earned the country the accolade of 'pharmacy of the world', Indian companies are now also running clinical trials and developing new innovative products, including one of the world's first nasal Covid vaccines. In other words, India has become firmly established as a global player in medicines.

However, India's rise as a global hub of pharmaceutical production and innovation has not been without hiccups, to put it mildly.

Concerns about vaccines and generics

Last year started off with the company behind India's flagship home-made Covid vaccine Covaxin, Bharat Biotech, going through the courts to force an investigative outlet to take down 14 stories critical of the vaccine's development and approval process. Eventually, additional reporting confirmed that India's drug regulator had approved the vaccine based on a rushed clinical trials programme that did not meet established national standards.

In the meantime, the World Health Organisation suspended the procurement of Covaxin by UN agencies due to concerns about subpar manufacturing practices.

Also in 2022, the European Medicines Agency suspended the marketing authorisations of dozens of generic medicines due to "irregularities" in bioequivalence studies conducted by an Indian contract research organisation, Indian generics manufacturers came under fire for apparently concealing clinical trial results, and dozens of children in Gambia and Uzbekistan were reported to have died after taking contaminated cough syrup made in India. Substandard generic versions of a paediatric cancer drug have reportedly also been exported from India, harming children worldwide.

Rotten apples or a rotten system?

Pharma critics often jump on isolated instances of corporate malfeasance or regulatory failure to argue that the entire system is rotten. The authors of *The Truth Pill: The Myth of Drug Regulation in India*, are veteran industry critics. They argue that in the case of India, the charge of "a rotten system" is fully justified.

Drawing on in-depth legal and regulatory analyses, numerous case studies and responses to hundreds of Freedom of Information requests, they exhaustively document glaring gaps in India's legal framework and severe shortcomings in regulatory oversight and enforcement. For example, the monitoring of drug quality is the responsibility of the 28 individual states within India, some of which have devoted woefully insufficient resources to the task and show little appetite for prosecuting offenders.

This allows manufacturers to take advantage of lax local oversight of production facilities while retaining access to India's huge domestic market, and the ability to export generics to low-income foreign countries that do not systematically control the quality of imported drugs. The authors cite multiple studies that have found major discrepancies between drug content stated on packaging, and actual content contained within pills, including for antibiotics.

Dodgy drugs and broken rules

Regarding newly developed drugs: on paper India has adopted evidence standards that broadly mirror those in the United States. However, in practice these standards were not consistently upheld during the pandemic. India's drug regulator approved Covid drugs and vaccines based on an 'accelerated pathway' that removed the requirement for presenting data from phase III clinical trials – but that 'pathway' had no basis in national law.

Overall, the book achieves its objective of demonstrating that there are severe structural flaws in Indian drug regulation that go beyond the malfeasance of individual companies, bureaucrats or judges. The authors' obsessive attention to detail, backed up by copious referencing, has produced a comprehensive overview on what is amiss with drug regulation in India. Sadly, the sheer wealth of detail means that the length of the resulting tome makes it unlikely to attract a broad audience.

Opportunities for reform?

Where do we go from here? Refreshingly, the final chapter offers policy recommendations that appear to be politically feasible and grounded in realism.

One angle that remains unexplored is the wisdom of exposing Indian policymakers' apparent belief that lax regulation confers competitive advantages on domestic drug companies.

A few more headlines about dead children could quickly turn the 'Made in India' label into a toxic brand with consumers overseas, especially if Indian stakeholders' response is to smear whistle-blowers as unpatriotic rather than to take corrective action.

The Indian government recently announced that it will invest $80 million into strengthening its drug regulatory system.

Similarly, the WHO's continuing suspension of Covaxin illustrates that lax domestic oversight can have consequences. If foreign regulators come to view all Indian data and products as inherently untrustworthy, Indian companies may find themselves blocked from moving up the global value chain from generics manufacturing into developing highly profitable new medicines.

Regulatory scientists must now take these authors' excellent work further by placing it into an international context.

We need a truly global regulatory science

Substandard medicines and vaccines are now a major global health problem that directly affects patients around the world and fuels antimicrobial resistance. Today, what happens in India (or China, or America) no longer stays in India (or China, or America). Also, just as India is not unique in having regulatory problems – see the Implant Files scandal – nor do Europe and America have a monopoly on regulatory solutions.

We urgently need a truly global regulatory science that moves beyond Western navel-gazing and systematically compares and evaluates regulatory approaches across all major jurisdictions. Hopefully, such comparisons will not only dwell on failures, but will also identify successful innovations in India, China, Japan, and elsewhere that regulators everywhere can learn from.

 Till Bruckner is the founder of the TranspariMED campaign. He can be contacted on tillbruckner@gmail.com

Last word

A rose by any other name

By Caroline Richmond

I used to write medical obituaries for the *Independent* newspaper. About ten years ago they asked me to write an obit of Dr Mortimer Sackler, leading light of Purdue Pharma, who make oxycontin.

Oxycontin is a highly addictive opioid prescription painkiller that is widely abused in America and does tremendous harm. Purdue promoted it ruthlessly as being non-addictive, and they gave kickbacks to doctors who prescribed it.

They made masses of money and whitewashed their reputation by donating to art galleries around the world, funding improvements and insisting they bore the Sackler name. The Royal Academy has a Sackler gallery, and Glasgow's Theatre Royal has a Sackler staircase.

The dark side was hidden

A few hours after commissioning the obit the Independent rang to say they'd been sent one, unsolicited. It was by Tam Dalyell, Scottish Labour MP, parliamentary correspondent of *New Scientist*. I knew him slightly, a very nice and very decent person, now dead. It was uncritical, as mine would probably have been, as the dark side of Purdue was well hidden at the time.

Shortly after, I bought two pink climbing roses to cover an arch in my garden. They were called Mortimer Sackler. I recognised the name. They're still going strong, scented, very pretty and healthy, and with few thorns. As the Purdue scandal unfolded I became increasingly unhappy about them. But it would have been asinine to dig them up and replace them.

In February I saw the documentary film, *All the Beauty and the Bloodshed*, about Purdue Pharma and oxycontin. And when I got home I emailed Patrick Radden Keefe, the New Yorker investigative journalist who wrote the book about Purdue Pharma and oxycontin, *Empire of Pain*. I asked him to ask the campaigners, if he's still in touch with them, to lobby The Royal Horticultural Society and suchlike, to change the rose's name. I realised this was a long shot.

A few days later he replied, saying that because of the Purdue scandal the rose had recently been renamed Mary Delany.

A rose by any other name will smell as sweet. N'est-ce pas?

Caroline Richmond
Author and journalist, London

Footnote:

Shropshire rose breeders David Austin Roses kindly sent us details of the change from their press announcement last year:

"We are pleased to confirm a change in name of one of our most beautiful and popular English Climbing Roses. 'Mary Delany' (Ausorts) is the new name for the rose variety formerly known as 'Mortimer Sackler'. There is no other change to the rose variety, whose appellation remains the same.

"In light of the opioid scandal surrounding the Sackler name, and along with many other organisations world-wide, we have taken the decision to re-name this rose for the talented and forward-thinking 18th Century English artist, gardener, writer and 'bluestocking', Mary Delany. Known for her invention of 'decoupage' or paper cutting, also known as 'paper mosaiks', Ms Delany created the most intricate botanical illustrations – 985 in all – most of which are housed at the British Museum, by donation from her family."

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Thanks We acknowledge with thanks the work of lawyer Thomas West of Richard Slade & Company, London, who checks our newsletter for potential legal concerns pre-publication; and HealthSense Secretary Philippa Pigache for her careful checking and subbing of the draft.

We stand for

- The assessment and testing of all medical and nutritional treatments, products and procedures
- 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

We are against

- Misleading advertising of health products
- The sale of unproven remedies to the vulnerable and desperate
- Unethical marketing by pharmaceutical companies
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- Media misinformation on health and nutrition
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