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HealthWatch Newsletter

for Science and Integrity in Healthcare

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News

Over a decade pursuing a retraction

The blog RetractionWatch tracks and reports the taking down of scientific publications as a way of shining a light on how poor or mistaken science gets corrected. But a recent entry reminds us of one piece of research that is yet to be retracted, despite concerns raised by one of its own original investigators. It has been 13 years since the journal Circulation originally published the results of the MIST trial in which a heart device was used in a study to investigate links between a heart anomaly and migraine headache. At the time the principal cardiologist in the trial, Peter Wilmshurst, refused to be named as an author, citing concerns that the sponsoring company had withheld data from the study's authors. His investigations also uncovered evidence of questionable behaviours associated with the trial, including misrepresentation of data, and incomplete disclosure of financial links with the sponsoring company. Yet the MIST study paper remains online and, as recently as February 2021, the American Heart Association, who publish Circulation, have written to decline further involvement in the case. Dr Wilmshurst's integrity and pursuit of good science earned him the 2003 HealthWatch Award but has also made him the target of libel suits. Read the RetractionWatch article.

Webinar catchups

Metrics for evaluation of scientific output Traditional metrics are designed with commercial profit in mind – using them to measure the quality of individual scientists has corrupted science, says Professor David Colquhoun of University College London. Watch him explain why, in a new online seminar, hosted by the non-profit research organisation Consilium Scientific. Or, in another Consilium lecture, see Ian Tannock of the University of Toronto explain what makes some cancer research great but why some trials are just bad science. These talks are among a valuable library of expert-led seminars and debates on subjects ranging from clinical trials, conflicts of interests, academic publishing, and the profession of science, which is accumulating at Consilium Scientific. Just go to Consilium to find out more and register for a free account. Consilium Scientific aims to change the waste of resources, poor methodology and skewed incentives that mar the landscape of clinical trials. They run online seminars most weeks. HealthWatch has recently teamed up with Consilium and we look forward to joint initiatives in the future.

Information that should be free It is becoming increasingly difficult to obtain answers from government departments under the 2000 Freedom of Information Act, and the campaign group openDemocracy has found that requests are being screened and blocked. Hear some impassioned talk from politicians John McDonnell and David Davis, journalists, campaigners and FOI experts, as well as former Cabinet Office minister Lord David Clark who was behind the original Act, in a compelling 1hr recording of an online event held on 20 April. And if you are ready to start asking your own questions, the Campaign for Freedom of Information organizes excellent virtual "Using the FOI Act" courses. Learn what information you are entitled to ask for and from whom, how to draft an effective FOI request, how long to wait for an answer, and how to challenge refusals. The course lasts one day, takes place fully online with small groups and personal attention from experienced campaigners. Cost £95, or £55 for freelancers and small NGOs. We recommend checking their website for forthcoming course dates.

How drug companies affect medical knowledge Adriane Fugh-Berman's work to expose the less savoury aspects of drug company marketing has had a profound impact on doctors' perceptions of pharma-sponsored promotional activities. In a fascinating online seminar, she describes how shyness, underarm sweating and even laughter have been framed as medical conditions to promote drugs. Fugh-Berman leads the non-profit group PharmedOut, an initiative of Georgetown University Medical Center to promote evidence-based prescribing and educate health care professionals about pharmaceutical and medical device marketing practices. The 45-minute seminar was part of the University's Health and the Public Interest series. Watch it here.

Successful outcome from complaint about counselling research ethics

HealthWatch member Shirley Moore wrote recently (Newsletter 113 – Summer 2020) about her concerns over the ethics of research undertaken by students of counselling in some colleges and universities. She made a whistleblowing declaration to Abertay University Secretary related to misconduct by two MSc students, whose research project used SurveyMonkey to collect data from vulnerable individuals without obtaining ethical approval, or observing the rules on handling personal data. The University upheld five of Dr Moore's six complaints. They responded that the tutors were not fully

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aware of the students' activities because the course did not require any primary research to be conducted. Had they known such research was being attempted, they would have ensured ethics review was sought. The surveys have now been taken down, and measures have been put in place to improve oversight. Shirley feels the outcome was satisfactory. "I believe they have realized that this was a serious breach of ethics and they appear to have put things in place to ensure this doesn't happen again," she said.

Professional Standards Authority suspends the Society of Homeopaths

In January this year the Professional Standards Authority (PSA) suspended the accreditation of the Society of Homeopaths (SoH). The PSA, the government watchdog that regulates healthcare regulators and registers, found that the SoH "did not appear to have prioritised public protection over professional interests in its handling of complaints or governance processes, which undermined confidence in its ability to ensure its registrants were compliant with its own Code of Ethics and position statements". It concluded that the SoH's failings in this regard led to risks to the public from homeopathy being offered as an alternative for serious conditions. We congratulate the Good Thinking Society for their tenacity in highlighting the risks from the PSA lending credibility to organizations whose members make misleading claims.

The PSA has just published a report following their recent public consultation into the Authority's future direction. The report, titled "The future shape of the Accredited Registers programme" includes a quote from HealthWatch (see page 9): "If people put their faith in 'alternative' forms of treatment they may be deterred from seeking help from mainstream medicine and are clearly at risk of being harmed as a result." We were among several groups and individuals who had stressed the importance of considering evidence of treatments' effectiveness in deciding whether to accredit a practitioner. The PSA plan to publish more detailed proposals after May 2021.

UK govt "dragging its feet" over calls for registry of payments to doctors

This April saw yet another public call for a national registry to capture pharma and medical device industry payments and other benefits made to clinicians, healthcare organizations and patient support groups. David Phizackerley, writing in an editorial in the Drug and Therapeutics Bulletin, reminds us that a register of clinicians' interests was one of the key recommendations of last July's Independent Medicines and Medical Devices Safety Review (IMMDSR) into the avoidable harms caused by hormone pregnancy tests, sodium valproate, and pelvic mesh implants. The IMMDSR is rightly concerned that manufacturers' payments and incentives can impact on clinical recommendations. Most organisations that represent doctors support calls for mandatory reporting, writes Phizackerley, and several other countries – including the USA, France, Portugal and Latvia – already have systems in place. Yet, despite the UK Department of Health and Social Care's acknowledgement that it will consider the issue, it has not set out a timetable or a work programme to make sure that it happens. HealthWatch hopes that this will not be another missed opportunity.

Phizackerley D. Time for Transparency, Drug & Therapeutics Bulletin, 19 Apr 2021. DOI: 10.1136/dtb.2021.000008

What are the harms from wasteful treatments?

Treatments of questionable benefit are not just a waste of health resources, they can also jeopardize patient safety. But quantifying these harms is not always straightforward, and campaigns that focus on the cost of wasteful treatments can make patients think that their antibiotic prescription or prostate screening is being withheld due to unfair budget constraints. A BMJ Analysis turns a spotlight onto the problem of overuse of "low value healthcare", that is, tests and procedures that provide little or no clinical benefit, are unlikely to affect clinical decisions, and could risk patient harm. It calls for new research methods to quantify the harms of health service overuse and better collection of harms data from clinical studies.

Brownlee S, Korenstein D. Better understanding the downsides of low value healthcare could reduce harm. BMJ 2021;372:n117

Evidence database adds Guideline Grading feature

"Guideline grading" is a new project from the Trip Database which will aim to help health professionals sort the evidence-based guidelines from the opinion-based ones. This new feature will be added to Trip in the coming weeks. In case you are not familiar, Trip is a clinical search engine for high-quality research evidence to support practice. It uses a publication score, based on quality, to order results. As well as research evidence you can search for images, videos, patient information leaflets, educational courses and news. Trip is a small independent company that has been around since 1997, run by a team passionate about evidence.

Kindred spirits promoting critical thinking

The McGill Office for Science and Society website says it "aims to demystify science for the public, foster critical thinking, and separate sense from nonsense on the scientific stage". Kindred spirits, clearly. The project, run from the University of Montreal, Quebec and without external funding from vested interests, publishes blogs and short videos challenging pseudoscience and miscommunication. Take a look at https://www.mcgill.ca/oss/

New infographic on Covid-19 transmission

Campaigning charity Sense About Science has produced a new shareable infographic to explain the importance of indoor ventilation in reducing transmission of Covid-19. Public understanding has fallen far behind the accumulating evidence, they say. The infographic shows that transmission risk is eighteen times greater indoors than out, especially where ventilation is poor. By comparison, hard evidence that the virus may be caught from contaminated surfaces or food is lacking.

John Maddox Prize open for nominations

Nominations for the John Maddox Prize 2021 opened on 6th April. A joint initiative of the charity Sense about Science and the scientific journal Nature, the Prize has been awarded annually since 2012 to researchers who have shown courage and integrity in standing up for science and scientific reasoning against opposition and hostility. In 2019 there were over 200 nominations from 38 countries. Nominate for this year's prize at https://senseaboutscience.org/john-maddox-prize/.

Nutrition

Fermented foods and COVID

By David Bender

Since the pandemic broke it has become obvious that if you want to receive wide publicity and research funding one sure-fire way is to include "SARS-CoV-2", "COVID-19" or "coronavirus" among the key words. The outcome of most

research is negative, nevertheless, with these flags your ideas will spread on social media, and even in the reports of reputable journalists. In some cases (e.g., the promotion of the supposed curative properties of hydroxychloroquine) this can cause harm, but in others, for example the promotion of something useless but harmless, there are no adverse effects. This may be said of that idea that fermented foods protect you against COVID-19.

There has been an explosion of knowledge about the different species making up what is now known as the gut microbiome. Until about a decade ago, identification of intestinal flora was largely by culture of faeces – a difficult and often malodorous process – and many micro-organisms resisted culture. Nowadays, genetic sequencing techniques allow rapid identification of large numbers of bacterial species.

The human gastro-intestinal tract contains some 10^{14} microorganisms, belonging to more than 2,000 species, so that the gut microbiome contains 150- to 500-fold more genes than human DNA. There is a very considerable variation between individuals in the species diversity of their gut microbiome. To some extent this is genetic (identical twins have more similar microbiomes than fraternal twins), and to a great extent it depends on diet.

For some years now it has been known that a diet rich in dietary fibre, oligosaccharides and starch that is resistant to digestion in the small intestine nurtures the growth of (mainly beneficial) bacteria, which produce, among other products, short chain fatty acids that are a preferred fuel for the cells that line the intestinal wall and may offer protection against the development of colorectal cancer. The presence of flourishing communities of lactic acid-producing and other beneficial bacteria inhibits the growth of pathogenic organisms. We also know that there is considerable interaction between intestinal bacterial metabolites, immune system cells in the intestinal wall (and elsewhere) and indeed the central nervous system. The term prebiotic has been coined for the various oligosaccharides that promote intestinal bacterial growth.

All yogurt that has not been pasteurised will be a source of lactobacilli, not just those produced by Danone or Yakult, although these provide many times more bacteria than ordinary yogurt

The concept of encouraging a healthy intestinal microflora with lactic acid bacteria has a long history. At the turn of the 20th century, Elie Metchnikoff, who shared the 1908 Nobel prize with Paul Ehrlich for their work on cell mediated and humoral immunity, attributed the longevity of Bulgarian peasants to their consumption of yogurt. His ideas led to the establishment of Danone, originally a Spanish company, making and marketing yogurt in 1919. In 1930, Minoru Shirota in Japan identified what he called *Lactobacillus casei Shirota* (now *L. paracasei Shirota*) in miso, a fermented soy bean paste. In 1935 he began marketing Yakult, a drink made with milk fermented with this organism, and went on to establish the Tokyo-based Yakult Honsha company in 1955.

More recently there has been interest in other fermented foods as sources of potential probiotics (the potentially beneficial micro-organisms themselves). All yogurt that has not been pasteurised after fermentation will be a source of lactobacilli, not just those produced by Danone or Yakult, although these provide many times more bacteria than ordinary yogurt. For those who want something more exotic than yogurt, kefir has become popular. It is milk fermented with *L. kefiranofaciens* and the yeast *Saccharomyces turicensis*, as well as other bacteria and fungi. Of course, any cheese that has not been pasteurised after manufacture will also be a rich source of probiotics – and especially in the case of soft cheeses, the riper the cheese, the greater its probiotic content – with both bacteria and fungi.

Sauerkraut is European fermented cabbage, and a source of lactobacilli and other organisms. Again, for those who want something more exotic, there is spicy Korean kimchi: fermented cabbage, carrot, daikon radish, and spring onions with ginger and chili. Kombucha is made by fermenting sweetened tea with yeast and bacteria to produce a sparkling, slightly alcoholic and sharp tasting beverage.

Oddly enough, those who promote the benefits of sour dough bread as a fermented food ignore "ordinary" bread, which is also the result of yeast fermentation

Other fermented foods, for example sourdough bread, made using wild yeasts and lactic acid bacteria, are sometimes grouped in with those that contain probiotics. Fermentation may well change the proteins and other ingredients of the bread, but no micro-organisms will survive baking. Oddly enough, those who promote the benefits of sourdough bread as a fermented food ignore "ordinary" bread, which is also the result of yeast fermentation, albeit using standardised strains of yeast.

Similarly, beer, cider and wine are all the result of fermentation, but no living micro-organisms survive by the time we drink it. (It is noteworthy that in the past, when cholera was a problem due to contaminated drinking water, beer made using the same water was safe because the alcohol killed the pathogens.)

So, now we come to connection between COVID-19 and fermented foods. The tenuous reasoning might be as follows:

- SARS-CoV-2 enters cells by interaction of its spike protein with angiotensin converting enzyme II (ACE-II) on cell surfaces.
- ACE-II is found on the surface of many cells, including intestinal enterocytes.
- SARS-CoV-2 RNA is found in faeces.
- Different species in the gut microbiome may affect cell surface ACE-II.
- Different species in the gut microbiome may therefore affect SARS-CoV-2.
- Fermented foods containing live micro-organisms may modify the composition of the gut microbiome – this is mainly a transient effect; the introduced organisms rarely colonise the gut permanently.

One reviewer (1) sums up the potential (and the lack of evidence – the italics are mine): "…nutritional strategies to promote immunity against SARS-CoV-2, are being discussed. Certain fermented foods and probiotics ***may*** deliver viable microbes with the ***potential*** to promote gut immunity. Prebiotics, on their side, ***may*** enhance gut immunity by selectively stimulating certain resident microbes in the gut. Different levels of evidence support the use of fermented foods, probiotics and prebiotics to promote gut and lungs immunity. ***Without being a promise of efficacy*** against COVID-19, incorporating them into the diet ***may*** help to low down [sic] gut inflammation and to

enhance mucosal immunity, to ***possibly*** better face the infection by contributing to diminishing the severity or the duration of infection episodes."

The notes from a recent British Nutrition Foundation virtual event on nutrition and COVID-19 (2) say "Emerging research shows that gut health ***may be*** compromised by COVID-19 infection and, that gut microbiome status can influence health outcome in patients with COVID-19. Probiotics and prebiotics are ***purported*** to have a ***potential*** role in supporting the gut microbiome to help reduce severity of clinical outcomes of COVID-19. However more research is needed." Again the italics are mine.

David A Bender, Emeritus Professor of Nutritional Biochemistry, University College London

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Psychiatry

Why are antidepressants so overprescribed? And what to do about it?

By Allen Frances

It's so easy to start antidepressants, but so hard to stop them. That's why they are prescribed for about 12% of the population in both the UK and the US. In England the number of antidepressant prescriptions doubled between 2008 and 2018,(1) despite the fact that the pills are now off patent, which means that pressure from manufacturers to prescribe can likely be ruled out as a factor. There is no reason to believe that the incidence of psychiatric disorder has increased over time – so why are these pills so popular with practitioners and their patients?

The most important thing to understand is that general practitioners write most of the prescriptions. Often they must do so after rushed visits with patients they don't know very well; who frequently present on one of the worst days of their lives; with nonspecific symptoms of stress, depression, or anxiety. The quickest way to get a worried patient out of the consulting room is to write a prescription.

Half the patients who start an antidepressant continue to take the pills for at least two years – sometimes for decades, or even for life

Half the patients who start an antidepressant continue to take the pills for at least two years (2) – sometimes for decades, or even for life. This is often best practice for those with severe and recurring depressions. But it can be worst practice for the majority of patients who began with mild symptoms that likely would have disappeared on their own with time, stress reduction, placebo effect, and regression of symptoms to the mean. Previous research has shown that between one-third and half of patients taking antidepressants long-term have no evidence-based reason to be on them.(3)

Patients who don't really need antidepressants nonetheless often stay on them for two reasons: misattribution and withdrawal symptoms. A person who feels better after starting antidepressants understandably assumes it was the pills that caused improvement – not understanding that most mild symptoms are stress related, self-limited, and likely to go away on their own. Stopping pills that never were, or are no longer, necessary is hard to do once the person believes they have worked.

Self-report depression screening scales have become popular, but result in the massive overdiagnosis of clinical depression in the worried well

Withdrawal symptoms are most likely to occur when medications are stopped abruptly, after prolonged use, and at higher doses. Withdrawal can be very unpleasant and scary, causing lethargy, sadness, anxiety, irritability, trouble concentrating, sleep problems, nightmares, 'flu symptoms, nausea, dizziness, and strange sensations. They can also go on for a long time. Twenty-five per cent of users are still experiencing some symptoms after three months, and for some withdrawal can last six months.(4) Withdrawal occurs when doctors fail to deprescribe slowly enough or patients stop on their own. Partly because of the widespread misconception that antidepressants don't cause withdrawal, patients and doctors routinely misinterpret the symptoms as relapse – triggering what is often unneeded long term treatment.

Antidepressants are also increasingly being used in children and teenagers, in the UK as well as in the US,(5) despite considerable evidence they don't work in young patients and may even increase risk of suicide.(6) I think antidepressants should be used very rarely in kids, and only for very clear indications and when prescribed by a child psychiatrist.

Some highly publicized reviews of the depression literature have concluded that antidepressants are no more effective than placebo.(7) I would argue that this is an artefact caused by the fact that so many of the subjects included in these studies had only milder symptoms that are very placebo responsive. Severe depressions do not respond to placebo or psychotherapy and do require medication or even electro-convulsive therapy (ECT).(8) The trick is targeting – reducing medication use in those who don't need it, while identifying and treating those who do.

So what are possible solutions to the rampant over-prescription of antidepressants? The single most powerful intervention is giving general practitioners more time to know their patients and to explain why jumping to a prescription is not a good idea. For mild depressions, the best first steps are watchful waiting, normalization, advice, stress reduction, and a repeat visit after several weeks. For moderate or more prolonged depressions, psychotherapy should be tried first. Medication should always be started immediately for severe depressions, but should be only a last resort in those milder ones that persist, are impairing, and haven't responded to time or talk therapy.

Self-report depression screening scales have become popular in the offices of general practitioners. Unfortunately, they result in the massive overdiagnosis of clinical depression in the worried well, with resulting overuse of medication. It is important that we train GPs on the difference between severe and milder depressions and give them time to evaluate their

patients more thoroughly. Routine screening for depression is best reserved for high risk groups such as mothers in perinatal period, patients with chronic illness, and people with a history of mental illness or suicidal behaviour.

Better initial evaluation and more targeted treatment is certainly costly up front but should be weighed against the harms and costs of long term, unneeded medications and the consultations to prescribe them and deal with side effects.

Patients who don't need medication are much better off without them. They avoid the side effects and inconvenience of long term treatment and also gain the sense of mastery and resilience that comes from enduring and prevailing in the face of life's inevitable stresses.

Allen Frances, Professor and Chair Emeritus, Department of Psychiatry, Duke University, North Carolina, US; Chair, DSM-IV Task Force

Allen Frances is author of 'Essentials of Psychiatric Diagnosis' (pub. Guilford Press, 2013) and 'Saving Normal: An Insider's Revolt against Out-of-Control Psychiatric Diagnosis, DSM-5, Big Pharma, and the Medicalization of Ordinary Life' (pub. William Morrow, 2013)

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Research integrity

Error and fraud: the dark side of biomedical research

By Geoff Webb

I have been writing about major errors in the biomedical sciences since the late 1980s. My area of interest widened to include research fraud when I discovered that two authors who I had frequently cited in my own books and papers had been accused of fabricating their data.

A wide range of methods is available to the biomedical researcher: observational epidemiological methods, in vitro and animal studies and experimental studies using human subjects. Meta-analysis has become a very popular method of aggregating similar studies with the same outcome measures; it effectively combines them into a larger study of greater statistical power. Evidence hierarchies or pyramids are used by groups like NICE to decide whether the accumulated evidence favouring a hypothesis is sufficient to authorize treatments or other health-related behaviours. Nevertheless, errors or false theories escape scrutiny and not only reach publication but persist in the scientific and public health consciousness. For example:

- The almost unanimous belief that there was a huge and increasing shortfall in world protein supply (the protein gap) and that primary protein deficiency was the most common nutritional disorder in the world;
- The promotion of front sleeping for infants that led to a worldwide epidemic of cot deaths in the 1970s and 1980s;
- The belief that antioxidant supplements would substantially increase life expectancy even in well-nourished people; and
- The assertion that a defect in the heat-generating capacity of brown adipose tissue was a cause of human obesity and that thermogenic drugs were a promising therapeutic strategy.

Some scholars have proposed that the conclusions of most published research are wrong and that up to 85% of research expenditure is wasted, that is, that the four error case studies above are extreme examples at the tip of a very large iceberg of false theories and conclusions. One reason for such a pessimistic estimate is the pressure on academic scientists to publish. *Paper counting* refers to the metric whereby scientists are assessed by the number of their publications (*Editor's note: see News in Brief for a link to a talk by Professor David Colquhoun on this*). Responding to this demand are many predatory journals that will publish anything for a fee, even meaningless strings of computer-generated jargon. The result has been an avalanche of low value papers that will remain largely unread, sometimes even by peer reviewers who should be the gatekeepers for quality. This could give the impression that all of the advances in science and medicine stem from about 15% of research expenditure.

One deceived co-author of a fraudulent paper hanged himself after its exposure

As well as low value research, there are also cases of research misconduct, primarily the deliberate fabrication of results. I have encountered examples spanning 150 years and spread across the biological and medical sciences, perpetrated by doctors, dentists, biochemists, palaeontologists, botanists, zoologists and psychologists.

Detected cases of research fraud may be relatively few but have nevertheless caused serious and long-lasting harm. Many are committed serial offenders, sometimes with multiple offences spread over a decade or more; one would be unwise to accept any data that they have collected. Fraudsters squander and misuse scarce research resources, they mislead and waste the time and efforts of other researchers, they harm the careers of students and co-workers. One deceived co-author of a fraudulent paper hanged himself after its exposure.(1) Several have been responsible for inappropriate treatments or health advice being given, and fabricated or falsified research data has led to patient harm and deaths. How much of the current *vaccine hesitancy* can be blamed on the questionable research about the MMR vaccine causing autism?

Werner Bezwoda was an oncologist based at the University of Witwatersrand in South Africa until his dismissal in 2001. In 1995, he published clinical trial data which claimed to show that using high doses of chemotherapy (HDC) with *haematopoeitic rescue* increased survival time in some women with advanced breast cancer; it seemed to effectively cure almost a third of them. HDC uses high doses of multiple chemotherapeutic drugs in an effort to kill all of the cancer cells and so prevent recurrence. These cytotoxic drugs also destroy the bone marrow, so bone marrow (or peripheral stem cells) is harvested prior to treatment and then re-introduced after chemotherapy i.e., haematopoetic rescue. Tens of thousands of women underwent this very expensive, gruelling and potentially life-ending treatment for no discernible benefit. Some phase II trials had suggested that HDC increased average survival times but Bezwoda's trial was the only positive controlled trial published. Auditors were sent to South Africa when he presented data from a second positive trial at a 1999 conference in Atlanta; his positive data contrasted sharply with negative data presented by four other groups. A group in Seattle replicated Bezwoda's published treatment protocol in a small phase II trial. It was quickly abandoned as four of the first six patients suffered severe cardiac toxicity causing the death of two and severe, permanent cardiac damage in two others. He later admitted falsifying his results, and retracted the publication.(1)

What safeguards are there to prevent the publication of fraudulent and erroneous data? Peer review is traditionally seen as the key barrier to publication of flawed data but it was not designed to combat deliberate deception and is ineffective in preventing fraud. Co-authors must take responsibility for ensuring the integrity of data published under their names in which senior departmental figures uninvolved in the research are named as authors (so-called "gift authorship"). In some cultures this is deemed a courtesy, but is no longer acceptable. Some potential fraudsters might be dissuaded from misconduct if they believed that discovery was more probable and that the consequences were likely to be severe. Should this in fact include criminal prosecution and imprisonment?

Tens of thousands of women underwent this very expensive, gruelling and potentially life-ending treatment for no discernible benefit

Expert scrutiny of already-published papers has occasionally raised suspicion of data fabrication that was missed during peer review, but only rarely have major fraudsters been unmasked by either peer review or failed reproducibility – the traditional quality-control of published research. Whistle-blowers, colleagues or students who have reported suspicions of misconduct, have been responsible for unmasking many offenders. But some whistle-blowers whose accusations have ultimately been proven have been harassed, intimidated or had their career prospects blighted. Those who, in good faith, report suspicions of misconduct should be protected. Everything possible should be done to encourage potential whistle-blowers to report genuine suspicions.

Who should investigate cases of alleged research misconduct? Employers are often best placed to carry out any investigation and gain access to key data and co-workers. Some employer investigations are a credit to the institutions and should be a model for others to follow, with thorough, well-conducted and transparent investigations carried out by employers, professional bodies, journals and research funders. Other employers have abrogated their responsibilities in this regard, perhaps in an attempt to avoid adverse publicity.

A dilemma faces journal editors: how to disinfect the literature once misconduct has been identified and how to reduce further publication of fraud. Ideally, once one fraudulent paper is identified, all the guilty party's published work should be scrutinized for indications of misconduct and any suspect work retracted unless co-authors can demonstrate that the data was honestly generated. Retraction should become the default position for any suspect work of a fraudulent author. Research misconduct by an author is rarely a "one-off" aberration but often an indicator of a pattern of behaviour spread over many years.

It is common for retracted papers to continue to be cited positively after retraction

Journals must make it clear when a paper has been retracted – it is common for retracted papers to continue to be cited positively after retraction. Some journals print "RETRACTED" across every page of the electronic article whilst in other cases it is easy to miss the retraction notice. A few journals still charge readers to access retracted papers and commentaries relating to them. Ideally the reasons for a retraction should also be published.

Greater awareness of research fraud and some of its signs and symptoms would be an important step in reducing its prevalence. Credible accusations must always be seriously and thoroughly investigated. The aura of secrecy around accusations should be lessened and they should be handled as transparently as possible and the results of formal investigations made public. "Sunlight is the best disinfectant".

Geoffrey P Webb, Senior Lecturer, University of East London

Geoff Webb is the author of "Error and Fraud. The Dark Side of Biomedical Research", due to be published by Taylor and Francis at the end of May 2021. He blogs as Dr Geoff.

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Dentistry

Does your child really need braces? A personal view

By Keith Isaacson

The arresting title "Evidence and Orthodontics: Does your child really need braces?" headed an interesting and well researched paper (1) from Isobel Whitcomb, a brilliant investigative journalist in the on-line magazine "Undark" which circulates widely in the USA and is published by Massachusetts Institute of Technology.

The article questions the purported medical benefits of traditional orthodontics. In the USA Orthodontics is considered a medical speciality and the medical benefits are promoted. The American Association of Orthodontists suggests that a child should have an orthodontic consultation by the age of seven as "lack of treatment leads to dental

decay, gum disease, broken front teeth and loss of bone tissue". Persistent jaw pain and headaches are threatened if orthodontic treatment is not undertaken.

Many international researchers have failed to find any evidence to substantiate such claims. Dr Peter Vig, who is featured in the article, is a former colleague of mine who emigrated to work in the USA, and caused outrage in the American journals for criticising the claims of medical benefit. Despite his efforts, unsubstantiated claims continue to be made. He maintains there is a lack of scientific integrity in orthodontics.

Orthodontic treatment for such children is not just for the sake of appearance

Whereas all orthodontic treatment in the US is private, most treatment for UK children and teenagers is carried out within the NHS. A well-established 'Index of Treatment Need' based on specific clinical factors, determines whether NHS treatment is clinically justified. This eliminates patients with minor irregularities. Adults seeking Orthodontic treatment to enhance their appearance are treated privately.

Whilst much orthodontic research is on-going, trials can only compare different methods of treatment. It is not possible to initiate a trial comparing patients who have treatment with those who do not. Of the many claims made by the American Orthodontists, the only significant one is that prominent upper front teeth are at risk of being fractured. Orthodontic treatment can reduce this risk. Professor Kevin O'Brien of Manchester University has looked at the evidence for this.(2)

The question remains: Is orthodontics a medical speciality? I cannot give you any evidence, my response is purely anecdotal. Most of my career was spent as a Consultant Orthodontist in a large district NHS hospital where the patients included children with complex and handicapping malocclusions often needing jaw surgery and patients with cleft palates.

Working with cleft lip and palate patients from birth to late teenage years is very specialised and requires liaising closely with the plastic surgeons, ear nose and throat surgeons, and speech therapists.

We aimed to see all cleft palate patients with their parents as soon after birth as possible. It was often necessary to make feeding plates to cover the cleft so that the baby could swallow safely. Taking a dental mould on a premature baby was difficult and a potentially risky procedure. At an older age, bone grafting of the cleft usually required preliminary orthodontic treatment.

Most patients were treated with conventional orthodontic techniques. I will illustrate significant psychological enhancement in a few of them.

Severe malocclusions

All NHS patients attending the hospital were categorised according to the severity of need for treatment. Those accepted were in the 'worst' category. Children with less severe malocclusions were referred back to their general practitioner or to a specialist orthodontist for private treatment.

Treatment of the more severe cases frequently requires extraction of permanent teeth. This can be contentious if it involves extracting healthy teeth. Patients in the pubertal growth spurt can be treated using 'functional' appliances. These hold the lower jaw in a protruded position. They are not easy to wear but if successful can give dramatic results and often avoid the extraction of permanent teeth.

Significant prominence of the upper front incisors can be very disturbing for a young child especially as they change to a senior school. Orthodontic treatment for such children is not just for the sake of appearance. I received a letter from a patient that I treated over 40 years ago – her name is Tansy Summers (she asked me to quote from her letter and to give her name).

> "You may not remember me but back in 1975 we first met. I was 12 years old, you were a young Consultant, I was a very shy, unsure, introverted rather troubled individual undergoing a large amount of bullying and harassment at school due in the main to the state of my teeth. I was in a mess: a very upset young girl. After your initial examination, I had teeth removed, a fixed brace fitted complete with complex headgear. This remained in place until the treatment was finished. I came to see you on a monthly basis for the necessary adjustments for about 3 years followed by a retainer. I was determined to see it all through and on my 16th birthday the braces were removed and I started my first employment. The ugly duckling had turned into a Swan.
>
> "In all I've embraced life with vigour and fortitude and you enabled me to do so. And I thank you for that profusely. I procrastinated for 30 years but better late than never, hence my writing to you to say a sincere thank you for your past treatment of me Keith, I cannot thank you enough. Without you my life would have taken a very different course. You changed that: well done."

Jaw surgery

In some patients the discrepancy of size between the jaws is such that it cannot be corrected by orthodontics alone. A combination of orthodontics and surgery is the only answer to improve function and appearance. This work requires close collaboration with the maxillo-facial surgeons at each stage of the process. Once the patient has had the procedures explained and is prepared to have the necessary surgery (as with any surgical operation, this carries a risk). The planning of the process is frequently carried out by the orthodontist using specialised radiographs – and demonstrating to the patient the predicted change in both X-Rays and photographs. These are discussed with the patient and their parents at a multi-Disciplinary clinic with the orthodontist, maxillo-facial surgeons and (at my hospital) a consultant psychiatrist (to assess that the patient showed no evidence of being psychologically unsuitable for the treatment).

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Orthodontic treatment is commenced to arrange the teeth in the correct position and angulation prior to the surgical re-positioning of the jaws. At the operation, fixed braces are used to locate the new positions of the jaws and (I would normally be present to assist in this).

And finally, another patient whom I shall call Paula. I had seen her when she was about 13 years old, when she had a short lower jaw and prominent teeth. Treatment with a functional appliance was unsuccessful as she did not cooperate with it, so she was discharged. When five years later she was referred back to the hospital, it was for jaw surgery to advance her lower jaw. By then, Paula had become

rather introverted and, although the surgical planning was straightforward, she was interviewed by the psychiatrist to ensure she could cope with the surgery. I explained that I had failed to get a result by orthodontics alone. Coincidentally, as a teenager Paula had been a patient of the same psychiatrist. Knowing her family background, he understood why she had not cooperated with functional appliance treatment. He determined that now she could cope with the combined orthodontic and surgical treatment.

About two years later, an attractive, bright and personable young lady came into our multidisciplinary clinic, having completed treatment a year previously. While the surgeons were examining her, I was checking the dental models to see how her occlusion had been improved. I turned to the notes and showed them to the psychiatrist who was standing beside me. "It's Paula!" I exclaimed. Neither of us had recognised her and we could not believe that this was the same patient who we had been treating whilst a troubled teenager.

Cases such as these made my career in the hospital service so rewarding.

Keith Isaacson, Consultant Orthodontist (locum), Great Western Hospital, Swindon

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Stop press

The Tony Nicklinson Memorial Prize

A new annual award has been launched, sponsored by the grassroots non-profit organisation My Death, My Decision, and inspired by HealthWatch's long standing student competition for critical appraisals of clinical research protocols.

'The Tony Nicklinson Memorial Prize' is aimed at developing and fostering an interest in end-of-life choices and patient autonomy; it is named after the pioneering right-to-die campaigner Tony Nicklinson, who suffered from locked-in-syndrome, and sought to secure a lasting change in the law to permit assisted dying for adults of sound mind experiencing or facing incurable suffering. With permission from his family, this prize commemorates his legacy. The prize is £500 for the winning entry and a chance at publication in the New Humanist Magazine or British Medical Journal.

Entrants are invited to submit an original essay of no more than 2000 words entitled: "In a society that wants legal assisted dying, who should be eligible for a right to die?" The entries should be submitted in either word or pdf format to mail@mydeath-mydecision.org.uk before midnight, 31 May 2021 (UK time).

For full details of competition rules please see the website: https://www.mydeath-mydecision.org.uk/news/

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