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HealthWatch Newsletter

for Science and Integrity in Healthcare

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GP-investigator scoops 2019 HealthWatch Award

Last year's winner was a doctor in politics – this year we've chosen another medic to receive the HealthWatch Award, but this one is making waves in the world of investigative journalism.

IN just four years, GP Faye Kirkland progressed from graduating with a diploma in journalism to being awarded best newcomer from the Association of British Science Writers (2016), to Freelance of the Year from the Medical Journalists' Association (2018) ... while still working as a GP.

Faye qualified with a BSc (Neuroscience) in 2002, and Medicine in 2005 at Birmingham, following this with a postgrad Diploma in Broadcast Journalism from Cardiff in 2014. Her journalism is widely recognised to combine a respect for scientific evidence and statistics with the interviewing skills of a GP. She is in every way a worthy recipient of this year's HealthWatch annual award.

She has done exclusive investigations for Panorama, BBC News, BBC Breakfast, Victoria Derbyshire programme, BBC Radio 4, BBC 5 Live, and for the Guardian. Faye's reporting has led to changes in clinical practice, sparked national and local inquiries and prompted parliamentary questions in The House. In August 2018 she presented a Panorama exposing online prescribing of unregulated drugs, and in February of this year took up the contentious prescribing of puberty-blocking drugs to trans kids: issues which are among HealthWatch's live concerns. She has also exposed a lack of funding for HIV testing in the UK and leaked A&E winter performance figures for England. And she contributed to the 2018 HealthWatch symposium Debunking False Health News and Views by explaining how myths and distortion travel more swiftly than truth on social media.

Karen Wightman, deputy editor of Panorama, says Faye effortlessly combines her two roles "with her particular brand of care and integrity"; and that they have been impressed by "her dedicated attention to detail; her ability

to put interviewees from all walks of life at their ease, and her boundless energy in the pursuit of important medical stories in the public interest."

Was this "effortless combination" an accident or a deliberate goal? Faye replies, "I had always wanted to do some writing alongside general practice but it took time for me to understand that I would benefit from journalism training. Only when I was doing the diploma did I realise that I could use my training in the two disciplines to expose issues that would ultimately benefit patients. Of course, it's a privilege to help individual people, but in working to highlight concerns over patient care you can influence national change which can improve care for so many more."

This year's HealthWatch AGM will take place on Tuesday 29 October 2019 at 19:00 (drinks reception from 18:30) at the Medical Society of London, Lettsom House, 11 Chandos Street, Cavendish Square, LONDON W1G 9EB. The meeting is free and open to all; but the buffet meal that follows must be booked and paid for in advance. For more information see: <https://www.healthwatch-uk.org/agm2019.html>



Dr Faye Kirkland

Philippa Pigache

Medical Journalist & HealthWatch Committee member

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News in brief

If you like Twitter you'll love ...

Wanted – someone who loves doing social media and who is passionate about HealthWatch. If you are interested in helping engage with others who love evidence, and can spare a few minutes here and there for tweeting and facebooking, go to https://www.healthwatch-uk.org/Social_Media_Editor.pdf to find out more about this volunteer position.

Talking gender evidence on Newsnight

Susan Bewley, HealthWatch's chair, talked to BBC's Newsnight about concerns over a study that involved prescribing puberty blocking drugs to transgender children under the age of 16. Read more:

<https://www.bbc.co.uk/news/health-49036145>

Independent experts journalists can trust

Our chair has also just gained a place on the list of more than 100 independent experts collated by *HealthNewsReview.org*. This resource was started 11 years ago to help journalists find industry-independent experts to use as sources in their stories. See:

<https://www.healthnewsreview.org/2019/09/we-help-journalists-avoid-reliance-on-sources-with-financial-conflicts-of-interest/>

Active on consultations

In recent months HealthWatch has contributed to public consultations on topics ranging from the Research Integrity Concordat to NHS Patient Safety and the Medicines and Health Products Regulatory Agency's relationship with the public. Committee member Roger Fiskien has been co-ordinating and submitting these often detailed and lengthy documents. We welcome suggestions from members on any consultations that should be including HealthWatch's voice. Let us know via the HealthWatch Google Group (members join by e-mailing membership@healthwatch-uk.org).

Teasing out toxins

Les Rose continues to take on charities whose promotion of unproven therapies cannot possibly be of benefit to the public. The HealthWatch committee member and retired clinical scientist recently challenged one UK charity, the Gerson Support Group, whose programme is widely claimed to treat cancer. His efforts to get them to name any of the toxins their regime aims to remove, are here: <https://majikthyse.wordpress.com/2019/08/13/gerson-therapy-and-toxins/>

Partnering Students 4 Best Evidence

HealthWatch are really pleased to be included as a partner organization of this busy student-run online group that promotes understanding of evidence and good science to

their peers, via blogs, workshops and sharing of quality information. Find out more at:

<https://www.students4bestevidence.net/>

New journal on scientific integrity

Submissions are being welcomed for the new Journal of Scientific Practice and Integrity. It's independent, open access, and – unusually for today's journals – free to publish. Worth a look: <https://www.jospi.org/>.

Whistleblowing at Evidence Live

Hear Peter Wilmshurst talk at this year's Evidence Live congress, free on YouTube. The cardiologist and 2003 HealthWatch Awardwinner, speaks for 30 minutes about his experiences as a fearless caller-out of research misconduct. Go to: <https://youtu.be/Xze-yPubFIY>

Farewell to a skeptic

We were sad to hear of the death of Willem Betz, on June 8th after a long illness. Professor Betz was a GP for 20 years before becoming a teacher and researcher at Belgian university Vrije Universiteit Brussel. He co-founded SKEPP, the Belgian skeptical society, and campaigned vigorously against pseudo-medicine. Read more: <https://edzardernst.com/2019/06/willem-betz-1943-2019/>.

Au revoir, sugar pills

The French Government will stop reimbursing homeopathy treatment from 2021. The announcement follows publication in March of an official report which called for an end to the payments by health insurers until proof of medical benefit is demonstrated; and to the issuing of university degrees in homeopathy by medical or pharmaceutical faculties. See: [France to stop reimbursing patients for homeopathy](#) *The Guardian*, 10 Jul 2019.

Free evidence stats courses

Two new online courses on communicating treatment evidence to patients are now available from Cambridge University's Winton Centre for Risk & Evidence Communication. Each 2-hour course includes self-test questions and video consultation case studies, and has been accredited by the relevant UK Royal Colleges. Go to: <https://moodle.wintoncentre.uk/>

Google has banned ads for unproven meds

This September Google updated its Healthcare and medicines policy to prohibit advertising for speculative and experimental medical treatments. The policy will apply globally, banning companies from using Google to promote treatments such as stem cell therapy, gene therapy, biohacking, DIY genetic engineering products and gene therapy kits. See: <https://support.google.com/adspolicy/answer/9396731>

Research integrity

A Case of Bad Analysis: The Semenya Ruling

In 2018 the International Association of Athletics Federations (IAAF) introduced new eligibility regulations for female athletes with higher levels of testosterone. A female athlete falling under this classification, Caster Semenya, a South African middle-distance runner and Olympic gold medallist, challenged the IAAF in the Court of Arbitration for Sport (CAS). In 2019, 3 judges ruled (majority 2-1) in favour of the IAAF, keeping the regulations in place.



Grace Stamate, left, and Hannah Bewley

THESE regulations state that any athlete who is legally recognised as either female or intersex in a certain category of Differences of Sex Development (DSD), with an endogenous (i.e., naturally produced) blood testosterone concentration >5 nmol/L, must reduce and maintain blood testosterone concentration below this level. Semenya was born with XY chromosomes and her circulating blood testosterone is above this level. She is and always has been physically female.

The groundwork began in 2014 when another female athlete, the Indian sprinter Dutte Chand, was banned from competing for having “unnatural levels of testosterone”. The IAAF had introduced regulations that required female athletes to take testosterone-suppressing medication if they had an endogenous blood concentration level >5 nmol/L. After Chand appealed the ban, CAS suspended the IAAF regulations because there was not enough scientific evidence to support a competitive advantage from high testosterone levels.

In order to reinstate and enact their regulations, IAAF commissioned research into testosterone and sport performance. The

key conclusion from Berman and Garnier’s (2017) paper (BG17), was that “female athletes with high fT [free testosterone] levels have a significant competitive advantage over those with low fT”.(1) This conclusion led directly to CAS’s Semenya ruling, which has been heavily criticised throughout the scientific community.

The World Medical Association stated it has “strong reservations about the ethical validity of these [IAAF] regulations ... they are based on weak evidence from a single study, which is currently being widely debated by the scientific community”. The analytical methodology of BG17 has raised ethical concerns and contains systemic data errors.

The BG17 research was funded and conducted by IAAF.(2) It is highly unusual for regulations to be based on research paid for by the regulatory body itself. The full dataset is not publicly available for reasons of personal identifiability, hence it cannot be externally verified.

A subset of data was eventually sent to other researchers in order to replicate BG17’s results. When they tried to recreate the statistics in the original paper for the four

events central to the new regulations, Pielke, Tucker and Boye (2019) identified three types of error: duplicated athletes; duplicated times; and phantom times where no athlete could be found for the result reported.(2) They found that 17–33% of the data were problematic and speculated that similar problems were likely to be found in the rest of the unshared data. Moreover, they concluded the problematic data is “significant and consequential for the results” of BG17; when the errors are corrected the results change for all outcomes in all events.

The BG17 research is predicated on the assumption that testosterone improves athletic performance, though no consistent or conclusive evidence supports this. Furthermore, many assumptions about the effect of testosterone arise from studies only using males and it is inappropriate to apply conclusions to females.

Individuals have very different responses to the same amount of testosterone; it is just one element of a complex neural pathway system that means the level of testosterone in one person have might have completely different effects on someone else. A good example are

women with Complete Androgen Insensitivity Syndrome who are born with XY chromosomes, internal testes and high levels of testosterone, yet who develop as female as their tissue is not responsive to their elevated testosterone levels. These women are also over-represented amongst elite athletes, but given that their receptors are unresponsive to testosterone, it cannot follow that their athletic advantage results from the raised levels of the hormone.

Does testosterone affect performance, or does performance affect testosterone?

Emerging evidence shows behavioural and environmental factors can determine hormone levels. Higher athleticism maybe associated with higher testosterone levels without causality. Female and male athletes at competitions have been shown to experience a rise in testosterone, but pre-competition testosterone levels do not predict an athlete’s performance on the field.(3)

There is no side-effect-free medical method to reduce circulating testosterone levels. The IAAF currently use oral contraceptives which can have career limiting effects

“The regulations are based on ‘a flawed scientific foundation’ which has been called a ‘comprehensive failure of scientific integrity’”

on an athlete; anti-androgens have a number of side effects such as diuretic effects that can cause excessive thirst, urination, electrolyte imbalances, disruption of carbohydrate metabolism, headache, fatigue, nausea and liver toxicity. Furthermore, there is inconclusive evidence these methods actually reduce testosterone levels successfully. Studies have shown oral contraceptives reduce testosterone levels in saliva but not competition associated levels.(4) The IAAF ask female athletes to do something harmful which doesn't necessarily achieve their intention.

BG17 contains multiple errors in methodology that led to unreliable and unreproducible results (above), but the analysis itself is also problematic. The paper groups the cohort into low, intermediate and high testosterone levels, and then compares the average performances in the high and low testosterone groups. The only statistically significant result (which may no longer hold given the data errors) is between the lower and upper female category, and not in all the events considered. There is no reported statistically significant effect between the middle and lower, and middle and upper categories, and no significance whatsoever in the male categories; a significant result in 1 of a possible 6 combinations. Furthermore, this is not a conventional method and type of statistical analysis that would normally be used and was not subjected to sensitivity testing. A more appropriate test would have been to report the raw correlation between testosterone levels and performance in the BG17 sample as a whole.

GIVEN the sample sizes and number of statistical tests conducted, an estimate of 24% was made of finding a correlation by chance, i.e., that it could have been a 'false positive'.(5) This well-studied problem in statistical sciences has many proposed solutions: the authors used none. Their critics found none of the differences would be statistically significant after controlling for multiple hypothesis testing. Moreover, it is important to note that the BG17 analysis could only ever indicate an association between high fT and athleticism, not causality.

The IAAF regulations and judgement only apply to athletes in the category of women with the chromosomal characteristic 46XY DSDs. But elevated testosterone levels can also occur in another 46XX category of DSD, and also those without DSDs, such as women with polycystic ovaries. This suggests that the court and governing body see more than just elevated testosterone levels at play. The ruling only applies to women with elevated testosterone plus a specific genetic composition. The only evidence used to support the ruling is IAAF-commissioned research which solely concerns testosterone levels and athletic performance, not specific genetic makeup. So, the research did not even examine the relevant analytical question.

Lastly, there was a lack of relevant control variables (or confounders). There is no control for fluctuation of hormones in the menstrual cycle (proven to affect sporting performance and therefore the performance times used). BG17 only controls for oral contraceptives, when there are over 5 types of hormonal contraceptive that could be used. The type of oral contraceptive was not stated. Given the wide range, all of which contain varying levels of estrogen, progestogen and androgens, this could exert a strong effect on performance. Additionally, there is no control for androgen insensitivity and no mention of the importance of this associated issue.

Ethically, if we did consider the assumption that higher natural levels of testosterone improve athletic performance, what about other high performing athletes with natural genetic advantages? Michael Phelps' double jointed ankles bend 15 degrees more than most swimmers meaning they act as flippers. Phelps is able to dominate his

sport by producing less lactic acid than his rivals, allowing him to recover quicker, winning many gold medals in quick succession. Why does the IAAF restrict participation for certain

athletes and not others?

The CAS ruling against Caster Semenya to uphold the IAAF regulations is based on an analysis that does not hold up to scrutiny. The regulations are based on "a flawed scientific foundation" which has been called a "comprehensive failure of scientific integrity".(2)

*Grace Stamate and Hannah Bewley
Economists, London*

References

1. Berron S, Garnier P. Serum androgen levels and their relation to performance in track and field: mass spectrometry results from 2127 observations in male and female elite athletes. *Br J Sports Med* 2017;51:1309-1314. <http://dx.doi.org/10.1136/bjsports-2017-097792>
2. Pielke R, Tucker R, Boye E. Scientific integrity and the IAAF testosterone regulations. *Int Sports Law J* 2019;19:18. <https://doi.org/10.1007/s40318-019-00143-w>
3. Karkazis K, Jordan-Young R, Davis G, Camporesi S. Out of Bounds? A Critique of the New Policies on Hyperandrogenism in Elite Female Athletes *Am J Bioeth* 2012;12(7):3-16. <https://doi.org/10.1080/15265161.2012.680533>
4. Edwards DA, O'Neal JL. Oral contraceptives decrease saliva testosterone but do not affect the rise in testosterone associated with athletic competition. *Hormones and Behavior* 2009;56(2):195-198. <https://doi.org/10.1016/j.yhbeh.2009.01.008>
5. Franklin S, Betancurt J, Camporesi S. What statistical data of observational performance can tell us and what they cannot: the case of Dutee Chand v. AFI & IAAF. *Br J Sports Med* 2018;52:420-421. <http://dx.doi.org/10.1136/bjsports-2017-098513>

Surgery

Pelvic mesh – surgery’s dirty secret

In a remote corner of Europe in the late 1990s, a Swedish professor created a sling made from plastic mesh to treat women’s incontinence. The plastic material already had FDA approval to fix hernias. What could possibly go wrong?

NEWS of the invention soon spread and its creator received an offer he couldn’t refuse. Professor Ulf Ulmsten assigned the patent of his procedure, known as tension-free vaginal tape (TVT), to a company he set up called Medscand. An agreement followed with Ethicon (a subsidiary of global medical giant Johnson & Johnson) who paid Medscand \$1,000,000 – [reportedly](#), on condition a new study would demonstrate TVT’s efficacy (Johnson & Johnson do not confirm that this condition was in the contract). J&J later bought Medscand and all its TVT assets for a cool \$25 million.

The sling would end up wreaking havoc for thousands of women across the globe for the next 20 years and be [labelled](#) a bigger scandal than thalidomide.

The mesh and sling surgery grew in popularity helped by enthusiastic promotion from industry – a number of US states have since taken out [lawsuits](#) in relation to the promotion of the devices, [one citing](#) “unlawful, unfair and deceptive marketing practices associated with their surgical mesh devices.”

The mesh kits were particularly lucrative in private practice. Industry giants were quick to spot a gap in the market for pelvic organ prolapse mesh and in 2002 these were added to the surgeon’s tool kit. [All were approved](#) via a flimsy regulatory system whereby market authorization is given simply because it is similar to something else already being used. Women’s mesh kits were seen as “similar to hernia mesh.”

The warnings began to roll in, including from American Professor Lewis Wall, who [in 2009 said](#): “Before the advent of mesh kits, there was little commercial interest in gynaecologic surgery aside from the sale of sutures or catheters, but now there are operation-specific kits, huge profits are on the table. Almost everything you need to operate – except good clinical judgment and technical skill – is right there, fresh out of the box.”

But Wall, and others like him, were ignored.

ALSO ignored were women who began reporting that the polypropylene plastic product could become brittle once implanted, acting like a knife inside, cutting into tissue, nerves, organs and slicing through vaginal walls, cutting partners during sex.

Mesh sling surgery is performed blind, using guesswork and a giant set of hooks. A contentious concept, considering women have varying anatomies, especially after childbirth, the most common cause of incontinence and prolapse. Inserting mesh, particularly the incontinence slings, was always going to be a steep learning curve.

Despite all this, mesh kits were [labelled “gold standard”](#), and surgeons welcomed an operation that took less than half an hour compared with traditional repairs of up to three hours.

The savings for the UK NHS initially seemed considerable. The reality was that women and their families paid the ultimate price.

Long term, the NHS must be feeling a financial punch, too. Professor Carl Heneghan, director of the centre for evidence-based medicine at the University of Oxford, [says](#) that in nine years, outpatient appointments for mesh injured women have cost the NHS a whopping £245 million. That is before adding up the cost of mesh removals, medication, scans and primary care appointments.

Scientific studies on mesh surgery came thick and fast, but the majority focused on efficacy. Outcomes included

the laughable “pad test”: if a woman no longer wears an incontinence pad post op she is logged as a successful outcome. This meant nobody picked up a worrying global trend of

pain, loss of sex life, urinary infections and reactive conditions to the plastic implant, such as lupus, fibromyalgia and psoriasis.

[Sling the Mesh](#), with more than 7,700 members in its Facebook support group, has many members in mobility scooters, with bladders or bowels removed where mesh has ripped into them. Sex lives are destroyed, marriages are on the rocks. Many can no longer work and suffer severe depression as a result. Yet, because they no longer wet themselves or have a prolapse problem, their surgery is deemed a success.

We feel the British Society of Urogynaecology (BSUG) has let women down by not maintaining a detailed and comprehensive record of surgical complications. In doing so, they have failed to capture the scale of possibly the biggest health scandal of our generation.

[Their database](#) collects data on surgeries for urinary incontinence and pelvic organ prolapse from the UK. But the data reporting, despite being recommended by NICE, is self-reported and voluntary. The “Global Impression of Improvement” outcome that it uses to record outcome of surgery is the clearly inadequate “pad test”. Furthermore, submission of data to the BSUG database is only open to BSUG members. It is hardly surprising to find that data on only a third of surgeries have been reported to the BSUG database. The black hole of missing data is shocking.



“nobody knows the true scale of this human disaster because nobody recorded the complications”

Much of the research on the subject has been [commercially funded](#). Some trials had very small participant numbers, or only of short duration when most complications occur years after implant. Too many had large percentages of women dropping out, leading to bias in the results. Others used only older women – these trials are vulnerable to yet more bias in that new pain may be attributed to age.

Many papers claim the mesh disaster is only a small minority of women suffering. In reality, nobody knows the true scale of this human disaster because nobody recorded the complications. The inevitable result for women is an inability to give fully informed consent, and a downplaying of the suffering that leaves them feeling distressed, depressed, vulnerable, with trust shattered.

Bridgette York, criminal defence lawyer and former NHS guideline development panel member for Women's Health, is shocked at the ongoing suffering of mesh harmed women. "In the 25 years I've researched health I have never seen this level of suffering and pain for any treatment in women's health. Medical journals and mesh enquiries were aware of the high risks of severe complications but many women weren't told. The NHS needs a patient led, patient safety committee.

"What happened to informed consent and choice? Any doctors saying the 'vast majority' of mesh patients are fine, when they've only followed up 5 per cent at one year, makes no sense."

Dr Phil Hammond, renowned for his work exposing the Bristol baby heart scandal, said: "Women have every right to be angry at being disabled and trying to get voices heard and being misdirected from their course by softly spoken meetings people, instead of getting their evidence on record.

"What saddens me is that we don't learn the lessons of the past. It's a pattern that repeats again and again, and we need to learn to listen to difficult stories at an early stage so we can step in and intervene earlier. Medical devices and implants need to be subjected to the same rigours as

drug testing, with proper compulsory registers and monitors."

London surgeon Suzy Elneil, who has been supporting women suffering mesh complications since 2005, said: "One of the main issues when dealing with women suffering with mesh complications is hearing the continual narrative of denial.

"From the outset it became apparent that not only did women not know what was being done to them for incontinence treatment, many were never offered any alternative to mesh.

"As a consequence, when problems occurred they struggled to get anyone to accept they had a problem. The process of denial started at the GP and went all the way to the implanting surgeon and their support colleagues. They were denied they had chronic pain, autoimmune features and mesh distortion. Instead they were told it was

'premature menopause', 'depression', 'fibromyalgia of unknown cause' and other similar diagnoses. It is imperative the woman is listened to and her symptoms acknowledged. Then, and only then, can we as a profession understand the breadth

of the mesh disaster and address its consequences in a holistic manner."

The use of vaginal mesh in incontinence surgery is currently [suspended](#) across the UK while a safety review is carried out by Baroness Julia Cumberledge. NICE has now banned a type of vaginal prolapse mesh, but only following strong criticism from campaigners. But with a shortage of surgeons trained in traditional repairs, the ban is not popular with many in the medical establishment.

Professor Heneghan said: "Twenty years after mesh was introduced we still have no understanding of its impact on women's quality of life, the long-term complications and who has been harmed. It is therefore vital that NICE's national registry starts with the thousands of women who have already had mesh. Vast numbers of patients are informing how to improve healthcare; it's about time we, the health system, listened."

Kath Sansom

Sling The Mesh (<https://slingthemesh.wordpress.com/>)

HealthWatch is taking action on medical devices

The [HealthWatch Symposium 2019: Evidence, Healthcare and Medical Devices & Implants](#), held on 17th June this year, hosted presentations by experts including Carl Heneghan of the Oxford Centre for Evidence-Based Medicine, and welcomed stakeholders from doctors and patients, to regulators and manufacturers. An afternoon of presentations and round table discussions explored the challenges to evidence based healthcare in the field of medical devices and implants, and aimed to identify areas where HealthWatch and similar organizations might most productively concentrate their efforts.

As a result of the symposium HealthWatch launched a consultation to identify opportunities to engage with industry, regulators, academia and media and patient groups to tackle the problems. A proposal is in preparation for actions to HealthWatch to take forward. Our website now has a dedicated [Medical Devices](#) project page for this work where you can read more about the symposium and its outcomes, and find links to materials including the important background report prepared for us by TranspariMed leader Till Bruckner. We would urge members to take a look and get involved.

Dentistry

The ethics of evidence-based dentistry

“Delivering Better Oral Health” is Public Health England’s flagship document on preventative dentistry. And yet, only 48 of its 113 recommendations (42%) are based on strong evidence. The majority of Cochrane reviews also demonstrate that a large amount of evidence produced in the dental field is of low quality with a moderate to high risk of bias.



WHILE evidence-based medicine has been increasing in acceptance since the 1970s, evidence-based dentistry (EBD) is still in its infancy. Dentistry could even be considered to be an orphaned field of medicine, both in regard to the amount of research being carried out and the quality of data generated. In addition to this the interlink between EBD and ethics has received little attention.

EBD can be considered as an approach to dental practice which links a practitioner’s expertise with patients’ needs and preferences taking into consideration the latest and most relevant scientific evidence. It aims to improve both patient outcome and patient autonomy, by enabling greater choice of treatment by the patient, and allowing the practitioner to carry out the most clinically effective treatment. However, this somewhat oversimplifies the concept both clinically and from an ethical viewpoint.

There are clear implications for the benefit to patients. If the quality and quantity of evidence is low, any benefits of interventions are uncertain. This introduces unknowns into the risk-benefit balance, and the treatment that is intended to benefit a patient may end up causing harm.

It may be that evidence-based practice is a more difficult concept in dentistry than in medicine. A broken tooth, unlike a broken bone, will not heal

itself. The nature of the dental industry is such that there is a constant flow of new and ‘better’ materials and techniques which, at times, tend to have only short follow-up periods in clinical research. This research is often funded by the dental industry and therefore more likely to be biased. Designing randomized controlled trials of different treatment modalities or uses of different materials is challenging. Because of this, much of the data collected comes from observational trials, and is subsequently at risk of being of lower value.

This reduced quantity of data – often of lower quality – provides further challenges. As it stands, practitioners are free to choose to perform treatments based on their own clinical expertise and training. If we try and limit our clinical interventions to only those with clear therapeutic effects, patients may suffer. New and innovative treatment modalities are likely to have a reduced evidence base, so if only high evidence treatments are allowed, the newer treatments cannot be applied. This could stifle new research, and limit subsequent improvement of the evidence base, and in turn any potential for new treatments to benefit patients.

Numerous organizations, including the Faculty of General Dental Practice UK (FGDP) and Scottish Dental Clinical Effectiveness Programme (SDCEP), have produced evidence-based guidelines to aid in clinical practice. Problems arise when these guidelines are seen as laws to be followed. In the case of dentistry, clinical guidelines could be upheld somewhere between laws and more generalist ‘rules of thumb’. This *prima facie* approach to guidelines allows practitioner interpretation of the guidelines to suit individual patients.

The formulation and introductions of evidence-based guidelines into practice should, theoretically, help improve patient outcomes. However, dentists often mistrust the results of academic research and tend to trust their own clinical experience over clinical trials. This view of “it works in my hands” is one of the biggest stumbling blocks to the acceptance of EBD into routine practice. It ignores any cognitive biases which affect how we judge our own experiences. As with other areas of healthcare, practitioners need to be aware of the biases which may

influence their decision making. Without this skill, both treatment choices and treatment outcomes can be compromised. There is a definite lack of teaching on these ‘softer skills’ in comparison to clinical techniques.

Within dentistry, and in comparison to medicine, there is an evidence gap. A large amount of research is being concentrated on complex procedures, such as implant success rate. In comparison, there is less research going into basic dentistry such as toothbrushing technique and prevention of decay. This raises ethical questions as practitioners are unable to provide a truly beneficial service to patients if they are unsure that the treatment they are able to provide is effective.

Patient autonomy, an increasingly important factor, is similarly affected. If there is no way to know which treatment option is shown to be most effective, then patients cannot make a fully informed decision. From a funding point of view, money may be being wasted on ineffective treatments, but there is no way to know without good quality evidence. In a system where funding often comes from a limited government budget, this can create an uncertainty in equality, where some patients may be receiving more expensive but less effective treatment.

Limiting use of effective but superseded practices may benefit patients. This would, though, require the profession to train in new and updated practices. Although this may

“This view of ‘it works in my hands’ is one of the biggest stumbling blocks to the acceptance of evidence-based medicine into routine practice.”

be expensive and logistically taxing, it is one way of ensuring that effective treatment that has been proven to benefit patients, is being fully implemented. Focusing on the effectiveness and the importance of EBD is paramount at all levels of training and education starting from undergraduate dental students and throughout all aspects of continuous professional development for experienced practitioners.

EBD is without doubt of overall benefit to the profession and patients. It is key to delivering success to both practitioners and patients by aiding in providing interventions that are proven to be effective and thus reducing harm to patients and increasing patients trust in the profession.

Striving to improve the quality of evidence available for all, should be one of the main priorities of the dental profession. 'Practice based research' should be encouraged and well funded. This duty could be shared between the government and other independent bodies. Perhaps it's time to set up an Independent Primary Care Research fund to which the industry is encouraged to contribute? Emphasis on EBD should be an integral part of the undergraduate curriculum as well as training on how to conduct and interpret clinical trials to ensure that dentistry is never viewed as an orphaned branch of medicine.

*Shaun Sellars, Dental Surgeon
Hingham, Norfolk*

Clinical trial transparency

The Transparency Clause after-party: what's next for clinical trials reporting?

Following the conclusion of the 72nd World Health Assembly (WHA) held in Geneva in May, governments reiterated their support for transparency in medicines research and development (R&D). Indirectly, at centre stage of the Assembly, was the issue of clinical trials. This was where governments debated the "transparency clause". It would mean that companies would have to disclose the actual costs of researching and manufacturing of medicines.

CLINICAL trials are at the heart of that process. Whilst this is a great next step forward in clinical trials reporting, knowing the costs of research, it is not far enough. To ensure stronger clinical trials reporting, here are three further needed reforms:

- 1) **Strengthen accountability mechanisms and actively enforce current legislation** Currently, in America and in Europe, the Food and Drug Administration Amendments Act (FDAAA) requires that all trials report their findings within a year of their completion. Failure to do so would result in a fine. Yet according to the [FDAAA Trials Tracker](#) (at the time of writing) only 66.6% of complete trials have been reported. The estimated fines that the government should impose amounts to \$3,209,5541,394. And yes, you read that correctly. Europe has an even lower rate of 57.2% of reported trials, according to the [EU Trials Tracker](#). Universities are often the worst offenders – for example, The Medical University of Vienna is listed with a reporting rate of 7.4%. Even leading universities in America struggle to report their trials. Dr Jeffrey Popma of the Harvard affiliated BAIM institute was quoted as saying: "We have been on the forefront of academic publications over the past two decades, and strive for the transparency of publishing all clinical trial results". Yet while Harvard university was a key driver behind the 2007 FDAAA legislation, it has not enforced its promise with its affiliate institutions. The Brigham and Women's Hospital has only [reported on 3 of its 9 trials](#). If the legislation is to be taken seriously then accountability measures need to be enforced.
- 2) **Sponsors and trialists must take responsibility** They must maintain their registry entries of trials and keeping

them up to date. Trials are completed, but the results aren't published, and registers don't show the progress of the trial. The implications of this are wide-ranging, from unnecessarily duplicated experiments to slowing down patients' access to information on treatment choices. Researchers have a scientific commitment to share their results in a timely manner, and this principle forms the basis of the World Health Organisations (WHO) [statement](#) on Public disclosure of Clinical Trials Results. Also, neglected records make it harder for potential trial participants to find active recruiting trials, and for trialists to find participants. The whole research process is slowed and medical innovation stifled.

- 3) **Apply rigour and methodology in R&D** Often when clinical trials are published, they have inconsistent data or are badly reported, reducing the readability and benefit of the trial. Sloppy writing and reporting can result in unnecessary duplication of research, wasting resources and hiding the validity of trial findings. A solution would be to adopt and enshrine the recommendations of the [CONSORT Statement](#) (Consolidated Standards of Reporting Trials). CONSORT comprises a 25-item checklist and a flow diagram which can be followed to ensure randomized trials are reported according to recognized standards. CONSORT is endorsed by leading scientific journals. These standards help ensure the trial results – whether positive and negative – are accessible.

The 72nd WHA made a brave step in introducing transparency into medical drug research and pricing. However, it should have gone further, calling for: strengthening of accountability mechanisms and enforcement of the current legislation, maintaining trial

registers by sponsors and trialists and finally, adoption of the CONSORT standards for clinical trial publishing. “Chalking it up to a win” doesn’t cut it in an age and industry that relies on facts and accuracy.

Josselin Canevet

Health Initiative Intern at Transparency International

Last word

Thank you, Mr Hevert!

Yes, critics of homeopathy are deeply indebted to Mr Mathias Hevert, CEO and President of Hevert Arzneimittel, a Germany-based manufacturer of homeopathic and naturopathic remedies. He may have intended otherwise, but he spread the message that “efficacy of homeopathy does not exceed placebo” more thoroughly than we possibly could have done in months or even years.

MR Hevert used a sophisticated two step approach to shed all doubts. First, clarify that there is no homeopathic remedy in the market that could claim valid scientific proof of efficiency beyond placebo. Second, once this was established, make sure many people would get to know this.

In more detail: drugs of science-based medicine have to undergo a three-step procedure to gain approval as medication to be sold in pharmacies. A key step is to provide valid scientific data from clinical trials to prove effectiveness. We all know that homeopathic preparations generally are registered only, a method provided in German drug legislature especially for homeopathy where this requirement for proving the effectiveness is dropped.

But, to the discomfort of all skeptics, quite a number of homeopathic preparations have “approved” status. How is this? Do they contain a substantial portion of mother tinctures, that is the starting material usually diluted out of the process by potentation? Or are these remnants from times before the current legislation was in place?

Here comes Mr Hevert’s first action: a cease and desist letter was filed to Professor Glaeske, a well-known German pharmacologist.(1) In a TV feature on weight loss and dietary products, Glaeske had stated that “there is no homeopathic preparation with proved effectiveness”. He never mentioned Hevert or any of their products nor were any visible on screen. Nevertheless, Glaeske was requested to desist from repeating such a statement “because it is not true”. And Mr Hevert was right: there are approved homeopathic drugs and so there must be some evidence available.

Upon digging into that matter we found German drug legislation holds more than one pitfall for patients. Approval for medications of scientific medicine is different from approval of homeopathic preparations. German drug legislature provides, that for approval “the medical experience of the medical system is to be taken into account.” Consequently, the Federal Institute for Drugs and Medical Devices, which is authorized to issue

approvals and registrations, has a committee of twelve experts, eight of whom are trained or practising homeopaths.(2) And they may recommend a homeopathic remedy for approval, for the treatment of minor or medium medical conditions, based on long term use, the availability of case studies or homeopathic provings, literature reviews and the like – but no clinical study. In their last annual report, the Federal Institute stated that they never had relied on the results of clinical studies for their approvals of homeopathic preparations.(3) Hence, approved status, in the case of homeopathic medications, is not evidence of effectiveness.

With this issue cleared beyond any doubt, now we may spread the news with more enthusiasm and enhanced vigor. And here Mr Hevert proved very helpful once again.

Natalie Grams, one of the speakers of

Informationsnetzwerk Homöopathie (INH) and the most prominent critic of homeopathy and other alternative treatments in Germany gave an interview to the *Rheinpfalz*, a small local daily newspaper. Grams herself had practised as a homeopath in

Heidelberg for several years before she came to oppose the practice and is now a prominent sceptic. Amongst other things, she stated that homeopathy is not effective beyond placebo – without referring to any product or company in particular – and received the next cease and desist letter from Mr Hevert(1) even though, again, neither product nor company had been named in the interview. She would be liable to pay €5,100 for any instance in which she would repeat that statement.

Of course, this request is ridiculous. It is general knowledge based on any amount of scientific findings of numerous major scientific bodies, that the best evidence says that homeopathy is no more effective than placebo. Starting from the EASAC, the advisory council of the European academy of sciences, the UK National Health Service, down to all available systematic reviews. Even RT Mathie, affiliate of the Homeopathy Research Institute, could not find reliable positive evidence in his long lasting

“Reporters repeatedly pointed out how ridiculous and far-fetched the tenets of homeopathy are, especially the claim to heal with nothing but dried water on sugar pills.”

project to evaluate the clinical evidence.(5) It is surely safe to say: This absence of quality scientific evidence of homeopathic efficacy is a fact.

Consequently, Grams refused to sign this letter, and made it public. With her popularity in the German media, many journalists picked up this story and detailed in various ways how far-fetched and strange Hevert's request really was. If you criticize cars as being detrimental for the environment – should you beware of receiving cease and desist letters from car manufacturing companies? Will Mr Macron, the French President receive such a letter after he decided to stop his health system reimbursing homeopathy for lack of effectiveness? And what about Hevert himself? His company sells products to the US, and are required to indicate precisely this information on their packages.(6)

FIRST medical papers carried the news, but before long mainstream media (online versions) picked it up. *Der Spiegel* reported the story online as did the *Frankfurter Allgemeine Zeitung*, and *Handelsblatt* or *Medical Tribune*. Many reports featured interviews with Natalie Grams and other critics of homeopathy. In fact, this story was widespread for a few weeks locally and abroad. And reporters repeatedly pointed out how ridiculous and far-fetched the tenets of homeopathy are, especially the claim to heal with nothing but dried water on sugar pills.

And then something happened that nobody expected: Jan Böhmermann, the most scathing of German comedians (yes, German comedians really do exist) took up the story in the show *Neo Magazin Royale*, and for a full twenty minutes he dissected homeopathy, repeating over and over again that homeopathy does not show an effect beyond placebo, with a counter in the corner of the screen accumulating the money it was costing him every time he

said the offending statement. Natalie Grams, and Christian Lübbers, made appearances, and I demonstrated a way to prepare a homemade homeopathic potentiation. "Diluting, shaking, talking bullshit" were, he said, the three basic principles of homeopathy and he gave his proper mailing address for cease and desist letters.(7)

No, Mr Hevert, without your support, sceptical views of homeopathy could not have achieved this popularity. Maybe your colleagues do not approve of your course of action but at least you made the name of your company ring in many ears. However, we doubt that this will help to increase your sales.

Dr.-Ing. Norbert Aust

Engineer, Informationsnetzwerk Homöopathie,
Schopfheim

References

1. Köppe J. Pharmafirma geht juristisch gegen Homöopathie-Kritiker vor. Spiegel-Online 03-06-2019.
2. Bundesinstitut für Arzneimittel und Medizinprodukte: "Kommission nach § 25 Abs. 6, 7 und 7a Satz 8 AMG für den humanmedizinischen Bereich, homöopathische Therapierichtung (Kommission D)".
3. Bundesinstitut für Arzneimittel und Medizinprodukte: "Jahresbericht 2017/2018", p. 40.
4. Eine "Quasi-Religion". Die Rheinpfalz, May 3, 2019.
5. Randomised controlled trials of homeopathy: examining the evidence. Website of the Homeopathy Research Institute. <https://www.hri-research.org/hri-research/learning-more-from-existing-evidence/systematic-review-programme/>
6. Stoye E. Homeopathic Medicine Labels Now Must State Products Do Not Work. Scientific American, 22 Nov 2016. <https://www.scientificamerican.com/article/homeopathic-medicine-labels-now-must-state-products-do-not-work/>
7. Homöopathie wirkt. Neo Magazin Royale mit Jan Böhmermann - ZDF Neo. <https://www.youtube.com/watch?v=pU3sAYRl4-k>

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