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Unreported medical device trials in the UK: mission in progress

While universities and NHS Trusts across the UK have significantly improved their reporting of the results of drug trials in recent years, it seems that results of trials of medical devices are trailing far behind, even though their results may be of equal or even greater importance to patients. A HealthWatch-funded research project aims to change this, by flagging instances of undisclosed trial results to their institutions.

In early April, project lead Till Bruckner of TranspáriMED filed Freedom of Information (FOI) [requests](#) with the 15 universities and five NHS Trusts in the country with the largest number of non-drug trials in their portfolios.

Out of the 20 institutions contacted only four have so far provided the requested details of their non-drug trials completed or terminated between 2006 and 2015. To date, a further four have yet to respond while 12 refused the request outright, arguing that gathering the data would involve a workload exceeding the limits set out by FOI legislation.

It is likely that university and NHS Trust portfolios contain a significant number of non-drug trials that have never made their results public. This “research waste” is not only costly in terms of resources, but trial participants will needlessly have been exposed to risks. Previous TranspáriMED research suggests that NHS Trusts alone have [left the results of around 500 clinical trials unreported](#), putting medical research worth over £250 million at risk of becoming research waste.

The FOI responses received suggest that during the period in question most of the institutions did not have any central oversight over non-drug clinical trials – a factor that is often associated with late or absent reporting of clinical trial results. Following a 2018-2019 [parliamentary enquiry](#), many UK institutions overhauled their clinical trial policies and processes, but typically only for future trials, and many did not include medical device trials in their scope, which means that few institutions now have central oversight of non-drug trials that were completed many years ago.

Why are trials of medical devices being neglected?

The 2018-2019 [parliamentary enquiry](#) focused almost exclusively on drug trials because data on institutions’ compliance with regulations on timely publication of clinical trials of drugs was readily available through the [EU Trials Tracker](#). Comparable data on their reporting of device trials did not exist, so gathering it would have required time-intensive manual searches. As a result, political and public pressure on universities and NHS Trusts was focused on bringing reporting of drug trials up to date, while other trials stayed under the radar.

Clinical trials of drugs (so-called CTIMPs) are regulated differently from non-drug trials in the UK and across the European Union. Drug trials must be registered on the [European trial registry](#), and the institutions running them are obliged to later upload their results onto that same registry. In contrast, trials of medical devices and other non-drug interventions may be registered on a variety of other [WHO primary registries](#), and there is no regulatory obligation to make their results public.

Over the coming months, TranspáriMED will continue its efforts to identify [medical device trials](#) left unreported by UK universities and NHS Trusts.

The 20 universities and NHS Trusts will then, we hope, be able to receive lists of their completely unreported non-drug trials so that they can take action before their medical research results are lost forever.

This work is part of a project funded by HealthWatch as part of its mission to promote science and integrity in healthcare. The article is adapted from [TranspáriMED blog](#) of 12 June 2020 by Till Bruckner.

In this issue:

NEWS	<i>Unreported medical device trials; our take on the Cumberlege Review; and News in Brief</i>	1-4
PSYCHOLOGY	<i>Ethics concerns over student research activities, by Shirley Moore</i>	4-6
NUTRITION	<i>Adam Daly on why Nutrition needs a re-brand</i>	6-8
UNPROVEN TREATMENTS	<i>Bioresonance comes under fire from opposite sides of the globe</i>	8-10
BOOK REVIEW	<i>Sex Robots & Vegan Meat, eye-opening review by Caroline Richmond</i>	10-11

Medical devices

Cumberlege Review – apologies, but what next?

There were apologies from Health Minister Nadine Dorries and Health Secretary Matt Hancock, on behalf of the NHS, to families who suffered “avoidable harm” as a result of medical procedures. The Independent Medicines & Medical Devices Safety (IMMDS) Review’s publication ended a two-year investigation into our healthcare system’s response to decades of concerns raised by patients and families over the catastrophic harms resulting from three medical interventions. The verdict from former Secretary of State for Health and Social Care, Jeremy Hunt, on the system’s response was understated: “not good enough”. But, point made. What happens next?

“First do no harm” is the title of the 277-page Review, published on 8th July 2020, which can be read in full on the IMMDS website. It addresses concerns over three medical interventions: the hormone pregnancy test Primodos; the anti-epileptic drug sodium valproate; and pelvic mesh. The Review team, led by Baroness Julia Cumberlege, consulted patient groups, manufacturers, regulators, clinicians and policy makers. You can read about HealthWatch’s involvement here. Below HealthWatch chair Susan Bewley responds to reading the Review.

“The report deals with longstanding issues of harms from drugs and devices, explains why simple negligence law doesn’t work for most people, and the potential for harm in conflicts of interests and biases. Survivors were not taken seriously, and found themselves up against a massive, complex system. The Review team clearly listened to distressed people, who have had ‘little voice’. Their report describes the complexity of the fragmented landscape with 126 or so bodies with regulatory responsibilities, but limited visions and powers; and particularly it makes note of the insidious conflicts of interest.

“Although there are only nine ‘headline’ recommendations (of which two are ‘fulsome apology needed’ and ‘task force to ensure implementation’), there are many more scattered in the text. Many, like ‘standard information nationally’ and decision aids (including recorded consultations about consent) will be music to HealthWatch’s ears.

“The Medicines and Healthcare products Regulatory Agency (MHRA) will need an obligation towards patient safety, and legislation will be required to compel the General Medical Council to keep a register of doctor’s

interests. The Review also asks for registers of implantable devices, together with surgeons’ details and their consent to track – measures that HealthWatch have previously called for – and joining up prescribing in pregnancy with school records. NICE comes in for praise for governance, even though we have seen how it too is subject to pressures over transparency, and tendency towards redacting key information in ‘academic’ as opposed to ‘commercial’ confidence.

“The report reveals industry influences on the MHRA, ineffective systems of ‘self-declaration’ of financial interests, problems with integrity of journals, and data collection. Data collection and sharing is a common issue – for example, at the moment patient-reported outcomes only happen for hip and knee implants..

“HealthWatch heartily welcomes the report and its recommendations. But the detail of how a system of redress for avoidable harm will work is lacking. There is recognition that litigation leads to defensive practices, hence the need for something non-adversarial. But will there be a backlash, and can the vision for improvement happen? How can we ensure #learnnotblame is embedded? It requires leadership, funding, and creative thinking so as not to create just another layer of people with jobs.

“I guess no one wants to harm others, they just are ‘willfully blind’ or unable to connect the dots. We have to keep banging on that innovation in itself is not good, especially where secrecy, status and the power of money dominate. In addition transparency alone is not enough, although it will be vital to unbiased science & integrity.

“The proof of the pudding will be in the implementation.”

News in brief

The “unfortunate experiment” was not?

A new analysis has called into question claims that dozens of women died as a result of a cervical screening study in the 1960s. Gynaecologist Herb Green had introduced ongoing surveillance in place of surgery for women with abnormal cervical screen tests at a hospital in Auckland, New Zealand. Contrary to subsequent reports that the study had involved withholding lifesaving treatment from women, the controversial techniques had avoided major surgery and preserved women’s fertility. The new findings appear in the June issue of the [Journal of Clinical Epidemiology](#) and are explained in an accompanying

[Commentary](#) by Iain Chalmers of the [Oxford Centre for Evidence Based Medicine](#).

Registering doctors’ interests

Doctors’ leaders have called on the General Medical Council to set up a central searchable register on which all doctors would declare their financial interests. The letter’s 11 signatories included HealthWatch Award winners Iain Chalmers and Ben Goldacre, and our newest patron, Sarah Wollaston, who is immediate past chair of the Commons Health Select Committee, as well as long-standing HealthWatch patron Margaret McCartney and our chair

Susan Bewley. “Transparency is a patient safety matter”, Dr Wollaston [told the BMJ](#); Dr McCartney called for moral leadership among doctors. “People with undeclared conflicts may be small in number but are disproportionate in effect.”

Accessing info on EMA

The European Medicines Agency (EMA) currently does not permit submission of Freedom of Information (FOI) requests by email, which is a breach of European transparency regulations. Requests of other European bodies can be submitted via the widely-used [AsktheEU.org](#). HealthWatch linked up with [Access Info Europe](#) and other health organizations, doctors and scientists in a letter to the EMA to request this be changed to meet the standards of transparency essential to share knowledge and combat fraud and corruption.

Consultations update

In recent months HealthWatch has continued to prepare responses to public consultations on issues in line with the charity’s aims. Most recently we have contributed to:

- *Parliamentary Select Committee on Health & Social Care: Enquiry into how to manage non-Covid health care during the Covid-19 pandemic*
- *Competition and Markets Authority consultation on information provided by private IVF clinics to potential clients*
- *Department of Health and Social Care consultation on storage of embryos, eggs and sperm.*

We acknowledge with thanks the work of HealthWatch committee member Roger Fiske for preparing and managing these consultation responses.

Skin deep

Entry requirements for the [postgraduate healthcare qualifications PgDip ENT and PgDip Dermatology](#) at the RILA Institute for Health Sciences (a partner provider institution of the University of Plymouth, according to the university’s website), include: “Be in possession of a BHMS (Bachelor of Homeopathic Medicine & Surgery) from an accredited institution”. In April we notified the University of Plymouth on twitter of our concern over this apparent consideration of a qualification in homeopathy as being appropriate for a course at an institute of Health Sciences. No response from the University of Plymouth has been received to date.

Farewell to Frank Odds

We were sad to learn of the death of a longstanding HealthWatch member, [Professor Frank Odds](#), on 7th July, aged 75. We will miss his insightful contributions to the HealthWatch Newsletter and googlegroup. Professor Odds was a world expert on medical mycology, latterly at the University of Aberdeen, and he played the piano to concert standard.

Members publish

New publications from HealthWatch members to look out for: [“How Evidence-based is dentistry anyway? From evidence-based dentistry to evidence-based practice”](#) in

(*Br Dent J* 2020; 229:12–14); dentist Shaun Sellars of Bury St Edmunds, Suffolk, calls for less research and for the research that is done to be more evidence-based.

HealthWatch chair Susan Bewley, emeritus professor at the Department of Women & Children’s Health, Kings College London, co-authored [“Sex, gender and gender identity: a re-evaluation of the evidence”](#) (*BJPsych Bulletin* 2020;1-9) which sensitively considers evolving terminology around transgender health and the uncertainties facing clinicians. We encourage members to share news of their latest publications – send details to the editor at newsletter@healthwatch-uk.org

Supermarket shelves cleared of WDDTY

A magazine slated for promoting dangerous health misinformation has been withdrawn by its editors from the shelves of supermarkets and will now be available only by subscription. The magazine formerly known as “What Doctors Don’t Tell You”, latterly re-branded as “Get Well” with the strapline “Alternative Treatments Proven to Work” recently came under heavy fire from charities for its December 2019 cover story which apparently claimed craniosacral therapy and chelation could “reverse autism”. Read more at [The Good Thinking Society](#). Good Thinking has also worked with the BBC on a 30-minute film [“False Hope? Alternative Cancer Cures”](#), now available online.

Cost of Correcting Bad Science

To be trustworthy and rigorous, science needs to be correctible. But academic science and traditional publishing models are not built for that. If you missed this 8th July webinar in which publishers and early career scientists explored how to straighten out science, the recording can now be seen on [YouTube](#) and the programme and slides are all at the group’s [OSF Page](#). The 150 minute session was organised jointly by the international journal clubs initiative [ReproducibiliTea](#), Kings College London’s [RIOT Science Club](#) and the [Francis Crick Institute](#).

Communicating Covid

If the prime minister really wants the UK to be “normal by Christmas”, the government will have to improve its communication about Covid-19, says an article in [the Spectator](#) (July 22nd) by Tracey Brown, director of [Sense About Science](#), and Carl Heneghan of Oxford’s Centre for Evidence Based Medicine. They recently [called on ministers](#) to be more frank with the public about low risk age groups and settings, and honest about evidence and how they have calculated trade-offs.

Skeptical Inquiry talks online

Recordings are now freely accessible online of presentations from the last convention of the Committee for Skeptical Inquiry, CSICON 2019. Look out for 30-minute talks by American writer, scientist, and former naturopathic doctor Britt Hermes [“Do not harm. But first, nature”](#); and gynaecologist Jennifer Gunter [“Modern wellness, women, and the religion of pseudoscience”](#). These are made available by the international non-profit [Center for Inquiry](#).

Myth-busting in psychology

The Association for Psychological Science has put together a new resource for consumers who like their psychology to be evidence-based. There are lay research summaries on myth-laden topics such as “Too much sugar makes children hyperactive”, and “Traumatic memories are often repressed” as well as clear explanations of latest research into why people believe misinformation and how to correct it. [“Myths and Misinformation” resource page](#) also has lesson plans for instructors.

New Covid-19 Evidence Hub

The US consumer advocacy group, Center for Science in the Public Interest (CSPI), has launched a new website to aggregate all Covid-19 evidence databases in one place on an easy-to-navigate table that distinguishes whether they are new, ongoing or a combination of the two. It details whether they include drugs, vaccines and/or public health interventions; also what trial designs are included. [Covid-19 Evidence Hub](#) is updated every two weeks.

Psychology

Student surveys in counselling and psychotherapy courses – are they “research”? Are they ethical?

Counselling and psychotherapy are not regulated professions; indeed, practitioners are still arguing over the definitions of both terms (neither of which is protected) and who is better than who. Optional membership bodies have ethical codes and basic qualification and CPD requirements, however the level of training and experience of an individual counsellor is highly variable – Groupon offers an online [“Counselling Skills Advanced Diploma”](#) (special offer £29), says Shirley Moore (*see below*).



This article is not about standards in practice, it is about quality of research in counselling and psychotherapy and the level of attention given to established ethical and legal principles from both students and qualified counsellors.

It is acknowledged that all counsellors and psychotherapists need to be able to understand research evidence, apply it to practice and be able to monitor and evaluate individual/service performance. It is also accepted that they may engage in formal research to contribute to the evidence base of their profession.(1) Notwithstanding the Groupon courses, counselling qualifications are offered at all levels from further education diplomas at local colleges, to degrees and postgraduate qualifications at established universities. Most will offer some introduction to research methods although usually only university courses will have the research ethics policies and committees to facilitate primary research.

The British Association of Counselling and Psychotherapy (BACP) is one of the largest (voluntary) membership bodies for counselling and psychotherapy and publishes comprehensive research guidelines which explicitly state that researchers must have appropriate training and skill and that all research must undergo ethical review in advance, either through a formal academic, NHS or social care research ethics committee or an independent review panel.(2)

Social media provides a variety of online groups for trainee and qualified counsellors and is also commonly used as a recruitment tool for research with humans. Unfortunately, the ease of accessing potential study participants has encouraged an explosion of counselling “research projects” which, despite collecting sensitive information from potentially vulnerable individuals via online surveys, have not been through any formal ethical approval process. Some of these surveys collect personal data such as gender identity, ethnicity, and email addresses along with client experiences of therapy or counsellor experiences of working with specific groups of people. Individuals with specific diagnoses or disabilities can be easily targeted via online groups serving these populations, for example the autistic community.

Most of the surveys I have seen have come from students on diplomas at private institutes or further education colleges, where the tutors may not have the relevant level of research knowledge or experience to teach the subject or advise on ethics. Rather than concentrating on the critical appraisal of primary studies to answer a research question, they are allowing students to undertake poorly designed surveys which do not take informed consent or General Data Protection Regulation, (GDPR) into consideration. In a 2009 paper West and Byrne discuss their own concerns about the

Author background

I retired from medicine five years ago but still have a keen interest in education and evidence-based healthcare. I am a new member of HealthWatch but I was the second ever (joint) winner of the HealthWatch prize for the critical appraisal of clinical research protocols. I am still very proud of this, even though as a student I was too poor to make the journey from Scotland to receive my award! I have always been interested in communication, human factors and the individual patient story, which is why I decided to undertake a diploma in “Person-Centred Counselling and Psychotherapy”; partly as a self-development exercise and partly to explore it as an alternative career choice.

Shirley Moore

appropriateness of counselling research and suggest that students with little training should stick to secondary research to inform their practice.(3)

I have written to a number of individuals within these institutions to express my concerns and, while some have been receptive and have promised to investigate, others have replied that these surveys are not considered research, simply student projects. There is limited appreciation of the potential for harm from insensitively written questionnaires and the processing of personal data, making informed consent essential.

Figure 1

To what extent counsellors and psychotherapists are open to incorporate evidence-based hypnotherapy in their work?

1. Dear Colleague,

Page 1 of 2

I am researching whether trainee or qualified practitioners are open to incorporate evidence-based hypnotherapy (sometimes called 'clinical hypnosis') into their therapeutic work.

Evidence-based hypnotherapy refers to a therapeutic intervention where the client actively or voluntarily splits their consciousness to access the unconscious self through feelings, memories or sensations. It excludes non-therapeutic hypnosis (forensic or entertainment).

This research project is part of my Diploma in Integrative Counselling at City Lit.

The Head of Faculty at Kirklees College was prompt and courteous in his response to my concerns about a student survey concerning sexual abuse survivors, stating that it went against their internal ethical policies and that the survey would be taken down, the data disregarded and an internal review undertaken.

On the other hand the Director of Bedonwell Training responded to my concerns about a survey on counselling clients with Post Traumatic Stress Disorder (PTSD) with: "I have discussed your concerns with our course tutor responsible for the conduct of the research project who has confirmed to me that all of our students' research procedures are informed by professional body and course accreditation organisation guidelines." I took my concerns further to SEG (Skills and Education Group) Awards through whom institutions (including Bedonwell) provide their ABC counselling diploma. SEG Awards agreed to update its guidance for the 'Conduct of Research in Counselling' to state that research participants will participate "on the basis of explicit informed consent" and to follow up my concerns with Bedonwell Training. Their updated advice does not yet seem to have reached all students, as I recently came across a further survey, from a student on an ABC counselling course at Wakefield College. My email to SEG Awards following this discovery has not yet been answered.

City Literary Institute stated in their response to a freedom of information request that "the College does not conduct any research activities" and that "trainee counsellors ... are required to demonstrate a basic understanding of some counselling research principles... assessed via a literature review and research proposal, and this is largely theoretical". Yet an online survey research project for a Diploma in Integrative Counselling (see screenshot in figure 1) collected personal information along with responses to how well participants agreed with statements such as "The mental health of clients improves miraculously after experiencing evidence-based hypnotherapy".

Some of these research projects form part of higher/postgraduate education programmes from established universities, where there should be no excuse for lack of understanding of ethical research practice. What seems most shocking, however, is not that research projects seem not to have been through the appropriate ethical procedures, but that when concerns were raised they were not upheld. A common response is that the projects had not been through ethical approval because they were not considered research – despite apparently meeting the universities' own definitions of research.

I raised my concerns about an MSc project at Abertay University on "Autistic Clients [sic] Experiences in Counselling/Psychotherapy". This project employed a SurveyMonkey questionnaire to ask a series of personal and sensitive quantitative and qualitative questions. There was no participant information sheet, no explicit informed consent, no acknowledgement of a potential for harm and I could find no evidence that the survey had been through any ethical approval process or was GDPR compliant. The response to my concerns stated that the survey was "not part of a research project, not intended to collect data within a research context and will not transmit or provide data towards any analysis or other research-based activity." It said it was part of a "project where students create an idea for a practitioner or client resource" and that "Students are asked to talk to people who are both counsellors and clients about what would be helpful to them." The response stated that the Chair of the University Ethics Committee did not consider ethical approval to be required "for a survey, in the place of a face to face or more informal inquiry". It is not clear whether the Chair had actually seen the survey.

Interestingly, although this was not acknowledged in the response from Abertay University, the online survey was edited shortly after I raised my concerns, to include slightly more information, and to state that the survey was not intended to generate quantitative research data, rather to "gather experiences" to "provide insights". This was

Figure 2

Autistic Clients Experiences in Counselling/Psychotherapy: An Anonymous Questionnaire

This questionnaire has been created by [redacted] an MSc Counselling student at University of Abertay in Dundee, Scotland. The intention is for it to be used to inform two MSc research projects - one by [redacted] and one by [redacted].

This questionnaire is intended to gather experiences of individual autistic clients in counselling. It is not intended to generate quantitative research data. The sole use of any information submitted will be to provide insights for two final year MSc projects - looking at ways in which counselling can be adapted to better meet the needs of clients on the autism spectrum.

then followed by the same quantitative and qualitative questions as before, which would call that initial statement into question. The survey also specifically referred to the project as a “research project”.

Does what we are seeing indicate confusion over what constitutes research and research misconduct, or actual furthering of the misconduct by failing to address it?

Either way it seems that there is little that can be done to stop it through the formal channels. The Head of Research at the British Association for Counselling & Psychotherapy (BACP) has assured me she was as concerned as I was “about research that has not been through a rigorous ethical review process when it is necessary, and the potential this has to harm vulnerable participants” and that she would be raising these concerns along with some of her own ideas about how to address them at the next meeting of their research committee. The response from Abertay University stated that “the Programme Lead ... has been consulted on this matter and supports the position of the School and the University that these were not research projects ...” The Programme Lead “is, incidentally, the Chair of the BACP Research Committee”. I hope they take note.

In a slightly different vein, when I raised my concerns about the inappropriateness of a consent form for a 5000-word client case study, I was informed by the Dean of Research for the University of the Highlands and Islands that “While I agree that students involved in the case study aspect of the programme are applying research-based methodologies ... it is clear to me that students ... are not actually undertaking this work as a research project. It is not akin to, for example, the honours level project of an undergraduate degree which is specifically entitled a ‘research project’.

Are the definitions of research in these universities’ ethical codes redundant? It is difficult to escape the impression that by avoiding the word ‘research’, lengthy

and inconvenient applications to research ethics committees can be bypassed.

Bizarrely, Twitter has proved a more effective way to raise concerns than formal processes. The Abertay survey went offline less than 24 hours after I tweeted “*Saying a project does not generate quantitative research data (when it clearly does) to avoid going through ethics approval is unethical. #actuallyautistic participants may be particularly vulnerable*” to @AbertayUni and some prominent figures in autism research. The survey was removed but the insistence it was not research remained. “This was a student questionnaire for a piece of coursework rather than a research project. We apologise for any unintentional confusion or ambiguity. The questionnaire has now been removed and all data deleted.”

Counselling is often dismissed by medical professionals as harmless or ineffective therapy for the “worried well”. I believe it has so much more to offer, in the hands of trained psychotherapists; however, if counselling and psychotherapy wish to be taken seriously within the mental health field, they need to take their research ethics seriously too.

Dr Shirley Moore, Portfolio Careerist, Perth, Scotland

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Nutrition

“Nutrition” as a subject and profession: time for a rebrand?

The words “Nutrition” and “Nutritionist” summon wildly different connotations and definitions depending on who’s being asked. To some, it means specialist scientists and their research, but to many more, nutrition appears to be an abstract, open subject for non-academics selling diet and therapy books. In both academia and practice, the heterogeneity of even basic conceptual understanding extends far beyond what is acceptable and is symptomatic of a problem that has plagued the field for decades.(1,2) Adam Daly reports.

Rather than a standard case of anti-science disruption, this fate is embedded in nutrition’s history, subculture, and the variety of academic pathways identifying under the

banners of ‘nutrition’, ‘nutritional science’ or, occasionally, ‘nutritional therapy’. Often, they pilot starkly



contrasting theories and generate a confusing conglomerate of professions.

With a field so closely bound to public food choice, disease management, and ultimately public health, the war between the various paradigms and professions fighting to operate under this group of labels threatens to undermine the overarching goal of health promotion, and generates an unfounded public perception of ambiguity, leading to fatalism that can be challenging to revert.

Nutritional Science

Since most ‘micronutrients’ were discovered and characterised in the 19th and early 20th Centuries, explaining endemic deficiency diseases such as beriberi, nutritional science has been a discipline within biochemistry. The science is interested in the interface between health and the physical world – especially the complexity of biomass transfer and the homeostatic systems that govern metabolism, growth, and development. However, as

nutritional scientists, we must also take heed of how human and societal factors such as culture, taste, and cooking skills play a huge part in nutrition and diet-related disease.(3)

Indeed, before we had nutritional science, food was an academic subject in the context of such factors. We have come a long way since this. Nutrition is now firmly established as a hard bioscience. But the public perception has failed to shift alongside it.(4) The subject’s various origins: biological chemistry, home economics, physical geography, and nursing, have generated a confused and uncoordinated path and identity for the field of nutrition, where even today, educators and practitioners alike interpret and define it in very different ways, with nutrition students studying ‘creative confectionary’ at one institution and cellular metallomics at another.(5,6)

This transdisciplinarity may generate more harm than good. If academia can’t decide what ‘nutrition’ is as a subject, then how can we expect the public to respect it as a science? Moreover, what does this mean for the perception of nutrition-related health professionals?

Alongside this, a ‘modern pathology’ threatens its integrity further: ‘nutrition hobbyists’ from outside the scientific community have expanded into passionate fandoms, cultures, and communities. Mono-faceted enthusiasms such as veganism, naturopathy, or paleolithism are incubated in online echo-chambers without scientific rigour, then flood the public domain and exacerbate any lack of clarity that existed before.(7,8) This rhetoric is now so pervasive throughout society that the very concept of ‘nutrition expertise’ is met with scepticism from the general public. Whilst one may be pleased by public awareness that much of the information circulating about nutrition is dubious, mistrust in pseudoscientists doesn’t solve the problem when that mistrust is also extended to public health campaigns and clinical dietetic advice. This partly explains the poor adherence to medically advised nutrition interventions.(9)

Dietetics

Dietetics is a respectable and regulated health profession, predominantly describing the medical application of nutritional science, from providing advice for specific medical conditions in hospitals, such as managing diabetes or cancer treatments, to providing and monitoring parenteral (intravenous) nutrition in critical care units. Dietitians are an integral part of any health system and have years of theoretical and practical education in the biosciences pre-registration.(10) (*Hooray!*)

Overall, protecting the academic integrity of nutrition and dietetics is a growing challenge, with naturopathic and acupuncture colleges delivering “Master of Science” degrees under the inconspicuous titles of ‘Nutrition’ or ‘Nutritional Therapy’ whilst their lecturers sell ‘detoxification-promoting’ artichoke solutions on the side.(11,12,13) Meanwhile, education regulators appear reluctant to take action.(14) For example, the Northern

College of Acupuncture which offers an MSc in ‘Nutrition Science and Practice’ was reviewed by the Quality Assurance Agency for Higher Education (QAA). Their glowing report praised academic standards and student learning opportunities, yet there was no recognition or corresponding

assessment of the scientific accuracy of the content of the course, which proudly teaches from a ‘functional medicine’ perspective. Much of the content effectively appears to be pseudoscience. This raises concerns over the risk graduates present to their future clients as well as to the integrity and reputation of the wider nutrition field.(14,15)

Similarly-motivated groups are now trying to infiltrate clinical dietetics. The University College of Osteopathy has applied to the Health & Care Professions Council (HCPC) to launch an undergraduate ‘Integrated Nutrition and Dietetics’ programme. The HCPC has released a non-approval recommendation for the course, citing that learning environments are “not suitable to support the achievement of the [regulatory] learning outcomes”. However, if subsequent inspections confer HCPC approval, students would be eligible to register as dietitians upon graduation, and treat NHS patients.(16)

Whilst the regulatory demands of the profession of dietetics are harder to circumvent, the title “nutritionist” is currently unregulated. An effort to protect the commonly abused title in the way the titles ‘dietitian’ or ‘medical doctor’ are protected in law, is under way by the Association for Nutrition (AfN), an evidence-based regulatory body for traditional nutrition graduates interested in non-clinical areas rather than dietetics. The AfN’s proposed authority over the term ‘nutritionist’ is being undermined at every turn by alternative practitioners, but their petition to establish a new ‘Royal College of Nutrition’ which would award chartered status across dietetics and nutritional science seems like a promising route. It would however rely on an ambitious public awareness campaign and government backing to

“naturopathic and acupuncture colleges delivering “Master of Science” degrees ... whilst their lecturers sell ‘detoxification-promoting’ artichoke solutions on the side”

serve its function of clearly separating the scientifically from the alternatively educated.(17)

Consequently, we should focus our attention on promoting the legitimacy of dietetic and governmental guidance. To do this requires the strengthening and harmonisation of existing nutrition curricula beyond current regulatory guidance.

This should be supported by a public programme of lifelong education both on nutrition/medicine and on the concept of seeking evidence. Secondary school children should fully engage with nutrition through a reformed secondary science curriculum with much greater emphasis on research methods and critical thinking. The response to this multi-cause problem must be equally multi-strategic.

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Unproven treatments

Bioresonance 1: Devices span the globe defying health warnings and good sense

Below is an update from Loretta Marron in Australia who is CEO of Friends of Science in Medicine. This is followed by a UK perspective provided by HealthWatch's most active campaigner for good science, Les Rose.

In March 1991, the [Australian College of Allergy](#) published an article in the *Medical Journal of Australia (MJA)* about a ‘bioresonance’ device for allergy testing entitled [“VEGA testing in the diagnosis of allergic conditions”](#), it stated that it was “an unorthodox method of diagnosing allergic and other diseases” with “no established scientific basis” and “no controlled trials to support its usefulness”.

The article raised concerns that this test “may lead to inappropriate treatment and expense to the patient and community”. VEGA is one of nearly 30 ‘energy medicine’ devices, some of which continue to cite Therapeutic Goods Administration (TGA) listing in their marketing. (Such listing means a medicine or device has been assessed for quality and safety, though not efficacy).

With each of these computerised devices costing upwards of AU\$34,000, the advertisers tell practitioners the machine can earn them up to AU\$150,000 annually.

Referring to ‘bioresonance’ as [“the medicine of the future”](#), they claim that all toxins, viruses and bacteria have unique ‘frequency patterns’, which, when ‘neutralised’ by the device, restore the patient to health.

They may also claim that it can [cure addictions to alcohol, cocaine, crack, nicotine, heroin, opiates, cannabis, spice, ‘legal highs’ and other medications](#). Some claim that it can cure cancer, hay fever, allergies, auto-immune diseases, behavioural problems, smoking addiction and that they can kill parasites – the list goes on.

The devices are said to be ‘based’ on acupuncture, homeopathy and ‘quantum physics’. Yet more than 60 Cochrane reviews (considered the ‘Gold Standard’ for evidence-based medicine systemic review), [have failed to find robust evidence for clinically significant outcomes for acupuncture for any disease or disorders](#). Australia’s National Health & Medical Research Council has concluded, “[there are no health conditions for which there is reliable evidence that homeopathy is effective](#)” and that quantum physics “is not at work”.

In February 2020, nearly 30 years after that original *MJA* article, the TGA’s cancellation of [two of these devices](#) saw the last of them removed from Australia’s Register of Therapeutic Goods, but not from permissible advertising or practice.

From 2014 to 2018, Friends of Science in Medicine (FSM) had repeatedly written letters and submissions to the TGA asking for these devices to be investigated. Meeting with the TGA’s national manager in 2016, we were told that these devices could not be cancelled because they were ‘biofeedback’ devices, which had a legitimate place in health care. In 2018, FSM sourced comments from informed experts here and overseas. These disputed the ‘biofeedback’ claim. FSM sent screenshots from more than 200 websites to the [TGA advertising complaints](#).

In 2019, after issuing a [warning on bioresonance](#), the TGA closed the complaints and commenced an ‘education campaign’. They also engaged a credible Australian scientific organisation to review the evidence provided by eight ‘sponsors’ marketing 12 bioresonance devices listed in the Australian Register of Therapeutic Goods.

All devices have now been cancelled by their sponsors or by the TGA. The ‘education campaign’ continues. Even though the devices are still widely used, and [courses](#) still being run, FSM considers this a modestly satisfactory outcome.

Informed opinions on Bioresonance devices

“Having reviewed the specifications of the BICOM device, I find that its inclusion on the ARTG as a ‘biofeedback device’ is erroneous.” *Michelle G Anifetos Fellow, Biofeedback Certification International Alliance*

“The BICOM device does not fit the criteria of a legitimate biofeedback device.” *Dr Tania M. Slawecki, Energy and the Environment Laboratory (formerly Materials Research Lab), Penn State University, USA (Author of “How to Distinguish Legitimate Biofeedback/Neurofeedback Devices”)*

“The claims of how the BICOM and CyberScan work are preposterous. ‘Quantum physics’ is not at work.” *Dr Stephen J Roberts, Consultant on electronic devices*

“The BICOM is NOT a biofeedback device and should be cancelled...The description of this device makes it crystal clear that **it cannot possibly have any effective diagnostic or therapeutic function**, and certainly has nothing at all to do with biofeedback...The claims made for the device amount to the worst kind of psychological manipulation, and their sole purpose is to mislead and exploit vulnerable people for financial gain. As a civilised society, we should not allow this kind of immoral exploitation to continue and the device should be banned forthwith.” *Emeritus Professor Joseph P Forgas, FASSA, Scientia Professor, Psychology, UNSW.*

“Bioresonance is not biologically plausible, not of proven effectiveness, potentially harmful and associated with exorbitant costs. I cannot recommend it for anyone or any purpose.” *Emeritus Professor Edzard Ernst*

Loretta Marron

CEO, Friends of Science in Medicine

Bioresonance 2: A UK Perspective

The UK situation is much worse. Most of the many ‘bioresonance’ devices on the market have CE marking. Manufacturers may claim that this is a mark of regulatory approval, but it only means “This product complies with EU safety and EMC directives”. No such product has any approved diagnostic or therapeutic applications.

For the vast majority of devices CE is self-certified, which means that the manufacturer or seller simply slapped on the CE sticker, without any involvement of a notified body or other certification agency (a notified body is an independent organisation that is approved by the EU to assess regulatory submissions from manufacturers).

In practice it is very difficult to find out the regulatory status of any medical device, because the UK’s Medicines & Healthcare products Regulatory Agency (MHRA) does not keep records of any approvals by notified bodies outside the UK. So, when investigating one bioresonance device making false claims I was referred by the MHRA to the relevant regulator in the Czech Republic. I received no reply.

The MHRA does not regulate marketing claims – it says

that any complaints must go to the Advertising Standards Authority. Excellent as the ASA is, it applies only a voluntary code and manufacturers are not compelled to act. In my experience, they don’t.

So, although the MHRA is the statutory regulator of medical devices, and these products make medical claims, it does not regulate the products at all. Hence any adverse ruling by the MHRA, along the lines of the TGA ruling discussed above, would be ineffective because the MHRA never approved them in the first place.

Self-certification used to be allowed for Class 1 medical devices, which means that these devices were not life-critical and could not present hazardous voltages or currents to the patient. Devices in higher classes, however, did require certification by a notified body. As of 2017, higher

standards applied as per the Medical Device Regulation (MDR), and these are actually mandatory for all existing and newly designed devices as of 26th May 2020.

Unfortunately, not only is there a huge waiting list with the notified bodies for devices to get registered and approved, with at least a six-month backlog, but some of the guidelines and regulations are so poorly defined as to be practically unworkable. And, now that the MHRA no longer reports under EU regulations, any clarity with regard to regulations is further out of reach.

I have engaged with manufacturers, asking clear questions. On the matter of diagnostic claims, they often reply: “this is not a diagnostic device”, despite offering long lists of abnormalities that their devices can “detect”. I have asked: “You say your device can detect electrical signals from the body, based on ‘vibrations’ at the cellular level. How does the device decode the signals from trillions of cells, into something intelligible?” Nobody has ever answered that, and the conversation always stops there.

As well as what the manufacturers themselves say – and they are as we have seen not reticent about medical claims – there is also the matter of what practitioners claim. The manufacturers provide training for their customers, and of course we can’t see the contents of their courses without paying. It appears likely that, even if a manufacturer or importer were to stop advertising claims, they would make the same claims in customer training. This seems to be borne out by what practitioners say.

The established means of regulatory enforcement are not fit for purpose. The ASA is rigorous and evidence based, but has no legal force and manufacturers ignore it. Its ‘legal backup’, Trading Standards, is hopelessly under-resourced, as HealthWatch has previously found. The MHRA largely ignores this business sector.

Call to Action

We have put together a list of actions that HealthWatch members could take:

- Compile a list of bioresonance and related devices marketed in the UK, including their regulatory status and marketing claims.
- Compile a list of bioresonance practitioners operating in the UK, any diagnostic and therapeutic claims made, and membership of professional bodies.
- Access customer training provided by manufacturers and importers. It might be necessary to pay for some course material, and even to attend a course.
- Test a number of devices and/or practitioners to see if they consistently detect the abnormalities they claim. Again this would require funding.
- Compile a report on the bioresonance market in the UK, to submit to regulators. Note that the Competition and Markets Authority (CMA) regulates unfair trading practices, although it does not respond to specific complaints. The CMA may be able to advise on which regulator should be overseeing this market.
- Engage with relevant journalists. A topical hook would be the widespread claims that bioresonance has a role in the coronavirus pandemic.
- Engage with interested politicians.

We would be interested to hear from members interested in joining this project, by e-mail to newsletter@healthwatch-uk.org

Les Rose, HealthWatch trustee and Clinical Science Consultant (retired), Salisbury, Hants

Contributions from Richard Rasker, biomedical electronics engineer, are gratefully acknowledged

Book review

Sex Robots & Vegan Meat: Adventures at the Frontier of Birth, Food, Sex & Death

by Jenny Kleeman. July 2020, by Picador. Hardcover £11.52, also ebook, reviewed by Caroline Richmond

Jenny Kleeman is a television journalist who has investigated current controversial R&D. She writes about sex robots, vegan meat, artificial human wombs, and assisted dying. Sex robots are already here, and men with money can buy, for upwards of \$6000, computerised animated dolls customised to suit their tastes. They look like surgically enhanced porn stars.

The leading company offers 17 different torsos, 34 faces, 42 styles of nipple, and different skin colours and hair. The more you pay, the more you get for your money. The dolls have PVC bones with steel joints. Some are programmed to make limited conversation: when asked what they would like, one drones prettily that she wants to please the interrogator: “Ten minutes without you feels like an eternity,” she adds.

Kleeman has visited factories where the dolls are made and been shown the options: dolls with a range of vaginas with removable washable linings. There’s a range of

mouths, all with silicone rubber teeth that won’t hurt. Would-be rapists can buy a ‘modest’ doll who doesn’t want to be penetrated. A rival maker, Roberto in Vegas, makes plaster casts of real women and his dolls can supposedly perform 20 sex acts. Some dolls and dildos can be hacked, aargh.

Chinese and Japanese companies make child sex dolls which it’s illegal to import into Britain. I’ve lost track of which manufacturer boasted, “she can be beaten without feeling a thing,” and I don’t want to ask Google.

There are online clubs of users who detest women, claiming they rule the world unfairly and grossly.

So, what about the customers? Davecat, who works in a call centre, is an embarrassment-free spokesman for many. He owns a RealDoll, who has purple hair with dark roots, and sports a black corset. She's his "lovely wife of 16 years", bought when he was 27. He also owns Elena, who's Russian, and Miss Winter, who's Chinese. He gets "romantic" with all of them and he's proud of his harem.

And so we move on to vegan meat. This isn't about fake meat – veggie burgers that bleed beetroot juice when you bite them – but about growing animal muscle cells in a laboratory. A research centre Kleeman visited is run by vegans who want to avoid the cruelty of factory farming, where animals are confined ankle-deep in their own excrement and have to be fed antibiotics to avoid the infections that would result. But the developers, though vegan, are not against using animals for their research. They grow cells in the serum of aborted calves. The serum costs £50 a litre, and you need 50 litres to produce one burger.

Another factory, with no concept of irony, fed Kleeman on vegan scrambled egg, which tasted of nothing except the butter they'd cooked it in. And a third factory fed her on a single chicken nugget made with huge difficulty. The "chicken" (actually frog) cells are somewhat liquid and were held together with a synthetic felt. Kleeman gagged on it. The good news is that vegan meat isn't going to hit the market in the foreseeable future.

So, what of artificial wombs? One argument for them is that, since men can become parents without being pregnant and giving birth, why can't women have this

freedom? There's surrogacy, which is fraught with problems. So why not raise a baby for nine months in a test tube and incubator?

For a start, it's hugely difficult. Most very premature babies, with the best possible care, grow up with damaged brains, livers, kidneys, intestines, and live short and very dependent lives. Put them in a bath of artificial amniotic fluid and try to deliver nutrients through the umbilical cord, and they try to pull out the tubes, so they have to be sedated. So the Philadelphia children's hospital, known as CHOP, is researching on lambs. Like the fetal calves in the vegan meat lab, they are cut untimely from the mothers' wombs. Unlike human prems, they can't pull out the tubes.

Kleeman, who has a toddler, did this research after having several miscarriages and very shortly after losing a perfect baby at 20 weeks gestation because she had septic appendicitis. She interviewed researchers without revealing this.

The final section of the book is about assisted dying, but there's nothing brave-new-world about this. There have always been people who have wanted to cut short a prolonged or painful death.

This review is based on a PDF, so it was impossible to leaf through the pages for the bits I wanted to return to, or to annotate it easily. I may not have done justice to the book, which is a gripping but uncomfortable read. Kleeman writes carefully, thoughtfully and movingly. She asks questions that many would shrink from asking. When I finished it my cheer-yourself-up mechanism kicked in and I recalled Billy Connolly's complaint about his inflatable sex doll: "I want ma money back. I gave her a wee love bite and she farted and flew oota the window."

Caroline Richmond

Medical journalist, London

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- The highest standards of education and evidence-based health care by practitioners
- Better understanding by the public and the media of the importance of application of evidence from robust clinical trials

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