Lawyers attempt to silence Liverpool scientists

There has been outrage at news that the University of Liverpool has been threatened with libel action after two of their scientists reported concerns about potential research misconduct at another university. The issue concerns research into transplanted tracheas seeded with the patient’s own stem cells, a technique which has been used experimentally in a number of operations at University College London (UCL) and, in one case, Great Ormond Street Hospital (GOSH).

The scientists who spoke out are Patricia Murray, professor of cellular and molecular physiology at the University of Liverpool, and her colleague Raphael Lévy, senior lecturer in nanotechnology and imaging. Murray and Lévy had submitted a complaint to UCL alleging that a request for approval of studies of the technique had included insufficient safety and efficacy data, and further alleging that ethics committee approval had been based on false information.

According to a report in the British Medical Journal, after Murray and Lévy pressed UCL for a response, a letter was received by the vice chancellor of Liverpool University, from lawyers for Videregen, a company planning clinical trials in collaboration with UCL. The letter was said to claim that statements made by Murray and Lévy may cause damage to Videregen’s reputation and its ability to conduct research, and invited the university to avoid litigation by dissociating itself from the scientists’ comments. Videregen has received research grants totalling almost £8m from the European Commission and Innovate UK, says the BMJ report.

Murray and Lévy also referred to their concerns in their submission to the 2017 Science and Technology Committee enquiry into research integrity. According to the BMJ, UCL responded to this by saying that the evidence offered was “highly selective”.

HealthWatch is not in a position to comment on whether UCL’s response was justified or not. But we object to any body using litigation to silence scientific debate, on the grounds that it is a threat to science and to patients.

We are indebted to Peter Wilmshurst for bringing this story to our attention. Dr Wilmshurst is the cardiologist who himself spent years fighting libel suits after reporting cases of research misconduct. “The fight for libel reform goes on, I think”, he commented.

For more information see: Hawkes N. Academics who raised concerns about research misconduct are threatened with lawsuit. BMJ 2018;362:k3100.

News

HealthWatch Symposium: debunking false health news

HealthWatch was fighting ‘fake news’ in relation to health before the term was invented. As the converse of evidence-based medicine it is the focus of our existence. Earlier this year a paper published in Science (The spread of true and false news online) revealed that false news actually travels faster than truth. Beyond acknowledge that we have a problem can we do anything to correct it?

Following in the footsteps of previous popular HealthWatch, debates, we have organised a meeting for the evening of Thursday 4th October 2018 to discuss ways to combat mis- and dis-information. (We are consigning ‘fake’ to Trump and twitter.) It will be led by two researchers with a special interest in the subject. Geoff

Continued on next page
Walton, from Manchester Metropolitan University has studied how young how people form judgements on information, and Jens Koed Madsen says he feels passionate about the potentially harmful (my word) effects of misinformation. They will be joined by award-winning medical journalist and GP, Faye Kirkland. We will also be inviting authors, researchers and representatives of institutions concerned with the issues involved to come to offer informed contributions from the floor. The meeting starts 19:00 at King’s College, London. Attendance, as always, is free and open to all. Book tickets at https://www.healthwatch-uk.org/symposium2018

2018 HealthWatch Award goes to the doctor in the House

The 2018 HealthWatch Award will be presented to Sarah Wollaston, who is both a GP and the Conservative Member of Parliament for Totnes. In choosing this year’s awardee, we were impressed by Dr Wollaston’s personal integrity and her track record in Parliament in support of evidence in medicine: advising about the ill-considered Saatchi Bill, supporting minimum unit pricing for alcohol, chairing the government’s Health Select Committee, and working to protect patients’ confidential information.

Dr Wollaston will receive her award from HealthWatch’s president, the author and broadcaster Nick Ross, at our next annual general meeting on Wednesday 31st October. The evening starts as usual with a reception at 6.30pm, and is free to attend and open to all, although only members may vote at the AGM.

The venue will be the Medical Society of London, Lettsom House, 11 Chandos Street, Cavendish Square, London W1G 9EB. The after-meeting buffet, at £45 a head, must be pre-booked – for more information and a link to book places at dinner go to:


UK Science & Technology Committee research integrity inquiry: report published

Last year HealthWatch, in partnership with TranspariMED and other parties, responded to the government’s consultation on research integrity. The report was published on 11 July. It covered academic research only – surprisingly there was no attention given to commercially funded research, though it comprises two-thirds of the UK’s R&D expenditure and has integrity issues of its own.

UK universities came in for much criticism. Although all had signed up to the 2012 Concordat to Support Research Integrity, six years on around a quarter of universities are not fulfilling its most basic requirement. Further, while compliance with the Concordat should be pre-requisite for funding, no funding actions have been taken against non-compliant institutions.

The Committee’s chair, Norman Lamb MP, called for a national Research Integrity Committee to champion integrity in the sector and drive implementation of a tightened Research Integrity Concordat. See: Science & Technology Committee, 6th report of session 2017-19, Research Integrity. HC 350.

UKRIO call for volunteer advisors

One of the recommendations of the UK Science & Technology Committee’s report into research integrity (above) was to encourage all universities to subscribe to the UK Research Integrity Office, which gives free independent advice on matters relating to research integrity. and offers support to the public, researchers and organisations to further good practice in academic, scientific and medical research. UKRIO is currently expanding its adviser base and is calling for volunteers. See: http://ukrio.org/

BMJ publishes Good Thinking’s cancer fundraising investigation

Three cheers for the Good Thinking Society for getting great media coverage of their year-long investigation into crowdfunding appeals for ineffective cancer treatments.

The team had searched fundraising sites such as JustGiving and GoFundMe, looking for appeals from UK patients which referenced unproven or disproven cancer treatments, and identified where the treatments were being administered.

They found that since 2012, 540 crowdfunding appeals have raised in excess of £8m to send patients for unproven or disproven alternative cancer treatments. Most were to overseas clinics in Germany, Mexico, and the US. Half of the appeals benefited from positive coverage in the local or national media. More than 140 of the patients involved in the fundraisers have subsequently passed away.

Good Thinking’s project director Michael Marshall said “Crowdfunding platforms need to do more to prevent funds being channelled to clinics offering unproven and sometimes dangerous therapies. If they want to continue to benefit from the goodwill of their users – and, indeed, to profit from the fees they charge each of their fundraisers – they have a responsibility to ensure that they do not facilitate the exploitation of vulnerable people.”

The investigation was published in The BMJ, and was covered in media including the BBC, The Times, The Telegraph, The Daily Mail, The Independent, and Newsweek.


HealthNewsReview.org’s 12-year run to end

We are sad to learn that an award winning health news critiquing website looks likely to fold in December. HealthNewsReview.org is an independent source for journalists and the general public. Its team of expert reviewers pick up on topical health news stories and respond with quality features with reliable information. Press releases about research results are given star ratings, and the team even offers a free pre-publication review service for press release writers. You can still sign up for HealthNewsReview’s excellent weekly e-mail news at: https://www.healthnewsreview.org/

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Their recent special feature: “Screening: How overdiagnosis and other harms can undermine the benefits” is worth bookmarking for its clear and accurate explanations of all the issues and misconceptions surrounding screening.

CAM use linked to worst outcomes in cancer
Cancer patients who use complementary medicine are more likely to refuse conventional cancer treatments, and as a result increase the risk of dying from their condition. US scientists who studied matched cohorts of cancer patients found that those who used complementary treatments had a mortality risk two-fold that of those who only took conventional cancer treatments. The risk appears to have resulted not from the therapies themselves, but from the users’ greater propensity to refuse to take conventional cancer therapies alongside them. The work suggests caution should be exercised over so-called ‘integrative medicine’ in which complementary therapies are tried along with conventional ones. See: Johnson SK et al. Complementary medicine, refusal of conventional cancer therapy, and survival among patients with curable cancers. *JAMA Oncol* July 19, 2018. doi:10.1001/jamaoncol.2018.2487

False Positives on SYSK
If you like listening to podcasts you might have come across ‘Stuff You Should Know’ (SYSK), a long-running American weekly audio series in which journalists Josh Clark and Charles W ‘Chuck’ Bryant take a dive into a topic and subject it to a very relaxed, rangey conversation over the course of around an hour. On March 29 this year the two non-scientists tackled ‘False Positives’, exploring testing and screening inaccuracies and associated costs and harms – difficult stuff made into easy listening for non-scientists while still being reasonably accurate. The podcasts can be downloaded from their website or direct onto your podcast app. Listen from about 3:30 minutes in: https://www.stuffyoushouldknow.com/podcasts/what-are-false-positives.htm In the episode Josh and Chuck also give a welcome shout out to Choosing Wisely (http://www.choosingwisely.org/), an international initiative that advises against unnecessary medical testing and treatments.

Treatments

Safety of multi-needle prostate biopsy needs urgent investigation
There is a widespread belief that multi-needle prostate biopsy is safe and does not cause local tumour extension. Experience and evidence suggest otherwise, and risks should be assessed. It is possible that extension of prostate cancer following needle biopsy might account for poor results of radical surgery and PSA screening.

Clinical trials, and the procedures used within them, must be adequately assessed for their safety before they receive ethical approval. My experience as a patient in 2001 led me to suspect that systematic 10-needle biopsy of the prostate has the potential to cause extra-capsular tumour spread.


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found to have a raised prostate specific antigen (PSA), I underwent a 10-needle transrectal ultrasound-guided biopsy. During the procedure the consultant urologist showed me an abnormal-looking area of the prostate beneath an intact capsular margin. Histology confirmed malignancy.

Fortunately, he was one of the few urologists who always carried out a second ultrasound examination to reassess the capsular margin of the prostate before proceeding to radical prostatectomy. This repeat ultrasound scan showed a defect in the capsular margin overlying the abnormal area, with tumour extending out through it. I requested a magnetic resonance image (MRI) scan, which showed bilateral tumour extension through capsular defects, presumably caused by needle punctures.

I was encouraged to raise my concerns about the safety of the prostate biopsy with the ProtecT study team. The responsible clinicians and lead investigator assured me there was no evidence that prostate biopsy caused local tumour spread, and hence no need to investigate the issue.

The ProBE sub-study

The aims of the ProBE sub-study (2) of ProtecT were, “to measure the effects of adverse events within 35 days of transrectal biopsy, to estimate associated healthcare resource use and to develop a classification scheme for reporting adverse events following prostate biopsy”. Despite my having raised concerns about biopsy safety with the chair of the responsible ethics committee, this safety issue was not considered by the ProBE Study, nor in the BMJ editorial accompanying its publication (3). In a letter to the BMJ (4) I suggested that, in view of the potential of a multi-needle ‘mapping’ biopsy with 30 to 40 needle cores (9), was approved by the NICE Interventional Procedures Committee for use in patients with suspected prostate cancer who have had negative or equivocal results from other biopsy methods (10).

In the past two years there have been five published reports of poor results of radical surgery for ‘early’ intra-capsular prostate cancer as assessed pre-operatively. In 2016 two studies, from Queensland (11,12) and Chicago (13), compared the results of robot-assisted laparoscopic prostatectomy with open surgery, and the ProtecT study evaluated the effectiveness of treatment for clinically localised prostate cancer (14).

In all three studies a high incidence of inaccurate pre-operative staging of the local tumour extent was found when the excised glands were examined histologically; with extra-capsular extension between 20% and 34% and positive surgical margins between 12 and 29%. [“Positive surgical margins” refers to the microscopic evidence of the possibility that some cancer cells may have been left behind after surgery, these may or may not result in recurrence.]

In a letter to the New England Journal of Medicine (15) I suggested that, in view of the potential of a multi-needle biopsy to cause extra-capsular tumour extension, it was essential for the prostate capsular margin to be re-assessed.

I was repeatedly re-assured that there was no evidence that the biopsy caused harm and so no need to investigate its safety.

This potential risk of multi-needle biopsy was not assessed within the 2008 NICE Prostate Cancer Guideline (7), or its 2014 Update (8), as it was regarded as a standard procedure in widespread use. In 2012 a multi-needle ‘mapping’ biopsy with 30 to 40 needle cores (9), was approved by the NICE Interventional Procedures Committee for use in patients with suspected prostate cancer who have had negative or equivocal results from other biopsy methods (10).

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Continued on next page

### Table 1: Histology results following radical prostatectomy for early prostate cancer

<table>
<thead>
<tr>
<th>Study</th>
<th>Number of patients</th>
<th>Incidence of non-organ confined disease</th>
<th>Incidence of positive surgical margins</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Total %</td>
<td>Total %</td>
</tr>
<tr>
<td></td>
<td>Number</td>
<td>%</td>
<td>Number</td>
</tr>
<tr>
<td>Queensland (11,12)</td>
<td>308</td>
<td>104</td>
<td>104</td>
</tr>
<tr>
<td>Chicago (13)</td>
<td>96,935</td>
<td>19,839</td>
<td>20.5</td>
</tr>
<tr>
<td>ProtecT (14)</td>
<td>391</td>
<td>114</td>
<td>114</td>
</tr>
<tr>
<td>National Prostate Cancer Audit (16)</td>
<td>2450</td>
<td>862</td>
<td>35.0</td>
</tr>
<tr>
<td>Learning Curve Study (17)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Surgeon A</td>
<td>First 50</td>
<td>12</td>
<td>24.0</td>
</tr>
<tr>
<td></td>
<td>Second 50</td>
<td>19</td>
<td>38.0</td>
</tr>
<tr>
<td>Surgeon B</td>
<td>First 50</td>
<td>19</td>
<td>38.0</td>
</tr>
<tr>
<td></td>
<td>Second 50</td>
<td>25</td>
<td>50.0</td>
</tr>
<tr>
<td>Surgeon C</td>
<td>First 50</td>
<td>27</td>
<td>48.0</td>
</tr>
<tr>
<td></td>
<td>Second 50</td>
<td>3</td>
<td>6.0</td>
</tr>
</tbody>
</table>
by an imaging technique, such as MRI, before clinical management decisions were made. The main authors of the ProtecT study report replied that they “were not aware of an association between local tumour spread and biopsy”, though they agreed that the use of multi-parametric MRI to target or reduce biopsies might be helpful.

In 2016 the National Prostate Cancer Audit (16) reported that, following radical surgery in men assessed as having early intra-capsular tumour, at histologic examination of the excised prostate glands, non-organ confined disease was found in 35% and positive surgical margins in 33%.

More recently a trial was reported assessing the learning curve of three surgeons for the robot-assisted radical prostatectomy procedure (17). Again, there was a high incidence of inaccurate local staging of tumour extent (27 to 44%) and positive surgical margins (22 to 28%) as found at histology. The results of these five studies are summarised in Table 1 (see previous page).

Finally, the PROMIS Study (18) is a clinical trial of two prostate biopsy procedures to compare their efficacy in detecting early prostate cancer, in which patient safety was received scant consideration. All participants underwent both a trans-perineal mapping biopsy (30-40 cores) and trans-rectal ultrasound-guided 10-needle biopsy. They were not warned that so many biopsy cores might cause extra-capsular tumour extension and it was not looked for. Of further concern is that if the biopsy was positive the results of tests were given to patients, and they then ‘followed standard care according to the outcomes of the tests’ (18, see p8, para 1.2). There is no suggestion that after receiving so many needle biopsies the state of the capsular margin, and assessment of any possible extra-capsular tumour extension with an Mp-MRI scan, was not considered.

**Conclusion**

Urologists continue to believe that multi-needle prostate biopsy is safe and does not cause significant extra-capsular extension of tumour tissue. The five recently reported studies of the results of radical surgery for ‘early intra-capsular tumour’ as assessed at the time of biopsy, suggest that this paradigm should be challenged. In all five studies a high incidence of inaccurate staging of tumour and extra-capsular tumour was found at histology of the excised glands, together with many instances of positive surgical margins, indicating that this radical and life-changing surgery was unsuccessful.

In view of this evidence and my own experience I propose that, following a positive prostate biopsy, further imaging of the prostate should always be done to assess local disease stage as accurately as possible before determining appropriate treatment. Perhaps the results of surgical treatment and PSA screening will then improve.

Acceptance that multi-needle biopsy can cause local tumour extension may also influence the management of men who are monitored by active surveillance, and who undergo repeated biopsies, every one of which may cause local tumour spread.

Novel diagnostic techniques must not be advertised and promoted without adequate assessment of their potential benefits and harms – and particularly their safety.

Of greatest concern has been my difficulty over seventeen years, in finding any individual, professional organisation, or NHS department prepared to acknowledge that the safety of multi-needle prostate biopsy should be investigated.

G David Stainsby FRCS (England)
Consultant Orthopaedic Surgeon (retired)

**References**

10. Transperineal template biopsy and mapping of the prostate. Interventional procedures guidance [IPG364]. Published: October 2010 (see para 1.1).
16. Annual Report 2016 – National Prostate Cancer Audit, Royal College of Surgeons of England (see Table 2.10, p29).
Good Vibrations? Machines that talk to your body

“It is a generally accepted theory in Quantum Physics, that everything in the universe is in vibration and has a frequency. Bio-resonance equipment first appeared during the 1970’s and there are many different makes, each with its own particular development path. Bio-resonance equipment is to find imbalances and then re-balance them. The equipment identifies the various frequencies that are affected then triggers restoration of healthy oscillation for the recipient. The skill of the practitioner is in knowing all the subtleties of the equipment to tune each session and get the best results for the recipient.”

Who can spot the errors here? The quotation comes from a directory of bio-resonance therapists (1). I am not a physicist, but even I can see the confusion between the quantum and macro levels. The writer appears to claim that certain machines can detect vibrations at the quantum level, and match these to known patterns of vibration. Can they sort out patterns of vibrations from countless (literally) numbers of atoms and molecules, all as we well know oscillating out of phase and at different frequencies?

What about electron orbitals, which are actually standing waves? What sort of machine can detect those? Maybe they can even detect oscillating superstrings?

The word ‘quantum’ seems to give certain ‘therapists’ licence to make a wide range of claims, but I very much doubt if any of them understands quantum mechanics. Nobel Laureate physicist Richard Feynman is often quoted as saying: “If you think you understand quantum mechanics, then you don’t.” I would not claim to be among those who do.

Nevertheless in the last 20 years or so ‘bio-resonance’ machines have proliferated. Not only are they claimed to be diagnostic, but also therapeutic. As seen above, they can apparently correct imbalances, although what is out of balance is never clearly defined. Note that it all depends on the skill of the operator, which leads me to think that the process is determined by whatever the ‘therapist’ thinks and does, and the machine may have little to do with it.

As the quotation above says, these machines have been in existence for decades. Let me take a well-known example, the Vega machine. A practitioner’s website (2) says:

“Ill health begins on an informational/energetic level and, therefore, symptoms of an imbalance of energy (functional disturbances) can and do occur long before any pathological morphology is evident.”

Needless to say no references are given in support of this, nor for any of the other claims. Alarm bells might have already rung for the site visitor, as the practitioner also says that the technology “has its origins in acupuncture and homeopathy”. Hardly a foundation based on science.

Any attempt to categorise the many such machines on the market will frustrate any rational person, but the Institute of Bioenergetic and Informational Healthcare (IBIH) has done so (3). Now although I have tried to focus on machines described as using ‘bio-resonance’, the long list on this site includes over 30 products, with only half of them in the ‘bio-resonance’ category. Reading the descriptions however renders the categories pretty much meaningless, as they are all as far as I can see nonsense. The functions claimed include diagnosis of abnormalities, some of which are recognisable (e.g. presence of bacteria and viruses), and some which are not (e.g. nebulous ‘imbalances’). Some devices are biofeedback machines, not an entirely an unscientific concept, but with usually grossly overblown claims. One device, the Zyro, combines galvanic skin response with voice analysis “to optimize all areas of human performance”. Impress the descriptions however renders the categories pretty much meaningless, as they are all as far as I can see nonsense. The functions claimed include diagnosis of abnormalities, some of which are recognisable (e.g. presence of bacteria and viruses), and some which are not (e.g. nebulous ‘imbalances’). Some devices are biofeedback machines, not an entirely an unscientific concept, but with usually grossly overblown claims. One device, the Zyro, combines galvanic skin response with voice analysis “to optimize all areas of human performance”. Impress.

Most of these products rely on a vast library of patterns or signatures, to which the machine’s readings for any one patient are matched. I had an interesting exchange with the manufacturer of the Qest4 (4), a product not on the IBIH list. Specific medical claims are not immediately apparent in the website text, but careful reading identifies them. First off, they say on the home page:

“Bringing a new dimension to your health and wellness consultations with state-of-the-art energetic resonance equipment”

So it seems to be aimed at health care practitioners. That Continued on next page
brings the device within the health regulatory arena. In among all the flannel about ‘energy’ etc, it’s possible to work out what they are claiming. The word ‘test’ appears here:

“Energetic testing with our QEST4 bioresonance equipment complements your clinical training, experience and insight by giving you the ability to test the client’s response to thousands of recorded signatures and receive immediate feedback”.

So far we have established that this is a test device for health care practitioners. But it is more:

“Having identified an individualised set of signatures, the QEST4 Bioenergetic equipment imprints the information into a physical medium of your choice which is given to your client, or applied using the included low-energy laser.

“The imprint process has been called ‘digital homeopathy’ and it serves to feed back the signals or resonances identified during the test and response process to the body-mind system”.

So it also makes treatments. If they were to claim that these are homeopathic, then to supply them to patients would be illegal, if they were found to be unlicensed homeopathic products.

But what are the 40,000 ‘signatures’ that they provide? This list is of one of the so-called ‘libraries’:

**PHARMACEUTICAL AGENT RESONANCES**
- Anesthetics
- Antidepressants
- Antifungals
- Antihistamines
- Antipsychotics
- Anxiolytics
- Chemotherapy Agents
- Contraceptives
- Diuretics
- Fertility Medications
- Mood Stabilizers
- Statins

I chose this library because the items listed would be familiar to readers, though it is not clear what exactly is meant by ‘signature’ – does this refer to supposed ‘dame’ done by those drugs, or treatments that the machine could suggest to replace the conventional medical treatments? There is also a library containing Color Filters, Crystal Signatures, Geopathic Stress, Matter/Energy Disruptions, Polarity Disturbance, etc. I have no idea of what they mean by these terms. I asked the manufacturer for rigorous research evidence that the machine actually can test for the factors listed. Here is what they said:

“Energetic testing is only ever ‘asking a question’, and recording a response, in this case galvanic skin response. Conclusions drawn would come from the expertise of the practitioner, when combined with observations, client history and whatever else. The vast majority of practitioners entirely understand this, though you may find one or two where the wordings on their websites suggest otherwise, which we are happy to take up with the practitioner.

“If an operator subscribes to the belief that outputting an encoded signal by low-power radio transmission can prompt a meaningful physiological/psychological response, it is then also the responsibility of the operator to decide how to interpret that response. The system is not marketed with the claim that it can ‘detect of the presence of an agent within the body’ or ‘detect intolerance to an agent’, but merely collate galvanic skin measurements that occur when sequences of signals are output.”

I could not understand this, so I took another example, a library of genuine medical conditions (including mycoplasma, viruses, and fungi). I asked what, if the result was dependent on the practitioner, was the point of the machine? I asked if the machine could detect a signal that matches with say the ‘prion signature’, another one in the same library. I’d be pretty impressed with identifying a prion non-invasively. I received no reply.

Some manufacturers include a disclaimer. Here is the one from Qest4:

“QEST International and its products do not diagnose, care, prevent or treat disease. If you have a medical condition or concern, please consult an appropriate health care professional. QEST and its claims have not been evaluated by any government agency or regulatory organization.”

This of course directly negates the claims which I have outlined above. A court of law will always consider what the reader will understand to be the claim, and disclaimers have very little legal force. Unusually, Qest4 is a UK company so it should be easier to challenge their claims.

So what is the regulatory status of these products? Two years ago another example, the QXCI machine, caught my eye (5). The acronym means Quantum Xeroid Consciousness Interface and, try as I might, I can’t find any explanation of what ‘xeroid’ means in this context. I asked the MHRA Devices Compliance Unit whether this device was licensed. Here is their reply (for which I had to wait two months):

“I can inform you, that unlike medicines, European Union directive 93/42/EEC and the Medical Device Regulations 2002 state that you do not require a license to market a medical device. You are required to register with MHRA if you are a manufacturer of class I medical devices or if you intend to act as a UK based authorised representative for a manufacturer based outside of the European Union. If you are a manufacturer of a class IIa, IIb or III devices then you would require approval from an authorised European Notified Body to legally market the product in the EU and would not feature on the MHRA manufacturer register. Therefore, the product would not necessarily appear on any database contained within the MHRA.

“We are currently investigating whether the QXCI product meets the definition of a medical device. If

Continued on next page
through our inquiries it is deemed to be a medical device, then it would be required to conform with European Union directive 93/42/EEC and the Medical Device Regulations 2002.

“As we stated in our initial response, we have not felt able to disclose further information due to restrictions on disclosure under section 237 of the Enterprise Act. The inappropriate disclosure of such information could result in the prosecution of the individual or organisation that discloses it, furthermore, it could compromise any investigation that the Agency may be undertaking.”

Two years later I still don’t know the answer, and I am not going to get it because of The Enterprise Act according to the last paragraph above. More recently I challenged the MHRA again, and they said that the legislation for both medicines and devices includes this provision, so they are not allowed to release any information about a product that is subject to an enquiry. Readers might remember an article by Roger Fisken in the Summer 2016 issue, about the MHRA’s lack of transparency over another such device, the Asyra. The MHRA response can be found on the HealthWatch website (6).

I first encountered the QXCI device at http://thewellbeingclinic.org, a practitioner in Wiltshire. Since my enquiries to the MHRA the relevant page on the site has disappeared. For the reasons given above, it’s impossible to know if enforcement action was taken. I still don’t know the product’s regulatory status, and this is at least in part because many such products are made abroad, and directly imported by practitioners. It’s the latter who are often responsible for repeating misleading claims to a UK audience. The manufacturers presumably train the purchasers, and leave them to deal with the regulators of advertising directed to consumers.

There are so many of these devices out there, that they constitute a major problem for consumer health regulation. Vulnerable people might rely on them for providing diagnostic information, or they might rely on the ‘remedies’ they are claimed to make. The MHRA Device Compliance Unit has told me that this is a ‘grey area’, which to my mind means that regulation is inadequate. Bio-resonance machines are little more than skin conductance meters. None of the manufacturers approached has provided me with any validation of their claims that their products can generate useful health information, and how the multitudes of so-called ‘signatures’ were derived remains a total mystery. The Advertising Standards Authority has dealt effectively with complaints against a few practitioners, whose claims seem to be more direct and easily challenged, but it really is for the national statutory regulator to do something about manufacturers and importers. It’s time the grey area was rendered black and white.

Les Rose
Retired Clinical Research Consultant

References
1. Findatherapy.org: Bioresonance Therapy Practitioners https://www.findatherapy.org/bioresonance_therapy
4. QEST 4: The next evolution in bio-energetic testing https://www.QUEST4.eu/

Alternative therapies

The polarisation of chiropractors: science versus lucrative fantasy? Report from FSM, Australia

The founder of the chiropractic profession, Daniel Palmer, was convinced that “ninety-five percent of all diseases are caused by displaced vertebrae”. He suggested that an “innate intelligence” provided a “guiding energy” source that ran up and down the spinal column. If the bones of the spinal column were even mildly displaced they could interfere with this energy which was responsible for whole of body health.

The displacements involved what he called “subluxations”. By “adjusting” these displacements, health could be restored. Here was a treatment for deafness, heart disease, sexually transmitted disease and even measles! With modern knowledge of spinal anatomy and physiology we know this theory was nonsense and should be of historical interest only.

Surprisingly and regrettably there is evidence to suggest that many chiropractors here in Australia accept this fantasy as fact and use it to justify claims that they can treat diseases that have nothing to do with the spine including autism, asthma and developmental problems. There is an emphasis on treating children. Adherents refer to their approach to chiropractic as “vitalism”. Of course, there are many chiropractors who are appalled with this situation and restrict their practice to care that is evidence-based. In Australia, chiropractors are registered as health professionals and their board, established by government to oversee the profession, does not support the vitalistic

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Evidence based dentistry

Advertising Standards Authority shows its teeth

Orthodontic treatment is widely used and becoming increasingly popular. No longer are braces the prerogative of teenagers but many adults are also now having treatment. According to the latest survey by the British Orthodontic Society (1), most practitioners are seeing a rise in the numbers of adult patients, with a sizeable number reporting that their patients’ treatment decisions have been influenced by celebrities or social media. The fact that so many famous personalities admit to having had orthodontic treatment and are even pictured wearing appliances, has made the treatment more acceptable. Popular magazines and social media effectively promote this.

Not only are the media responsible, but relaxation of advertising by health professionals has given dental practices more freedom to promote ‘healthy smiles’. I have written before about the promotion of ‘six-month smiles’ which is, I argue, not a satisfactory form of treatment as it usually only involves the front teeth and ignores the way teeth bite. It is also frequently accomplished by filing the teeth to reduce their width, which if done to excess, can cause the death of the tooth.

Fixed appliances are the most efficient way of moving teeth, however it is a slow process and treatment usually takes up to two years to complete. With this in mind I have been most impressed that in recent years the ASA has made three rulings on claims relating to the speed of orthodontic treatment. They have gone into the evidence in considerable detail, examining the trials that were put forward to substantiate the claims.

The first two judgments related to the websites of two different orthodontic practices in London, both of which were promoting a type of orthodontic attachment called Damon™ braces for which they claimed the following:

“Damon braces offer a new generation of treatments ... which all produce results fast! Conventional braces have elastic 'ties' which cause friction and pressure. Damon braces feature a sliding mechanism over the bracket that helps to reduce this friction and any potential discomfort as teeth move ... Not only do Damon braces result in quicker treatment times but lighter forces on the teeth providing a more comfortable treatment experience ... less [sic] visits to the practice and on average, 4-6 months less in their treatment times.” (2)

And from a second practice website:

“[Damon braces] deliver faster treatment, fewer appointments, greater comfort, and consistent high-quality results ... Light high-technology shape-memory wires that move teeth faster and require fewer adjustments ... A new clinically proven treatment approach that aligns your teeth and enhances your facial aesthetics-usually without extractions ...” (3)

In both cases Ormco Corporation, the manufacturer of Damon braces, replied on the practices’ behalf. The ASA were not convinced by their evidence. The papers included unpublished master’s theses and commercial surveys. Four studies had been conducted using models of the mouth rather than human subjects. Clinical trials comparing the effect of the Damon system with traditional braces all exhibited methodological issues, said the ASA, such as potential sample selection bias, reporting errors and a lack of randomisation in treatment allocation.

According to the ASA, a body of evidence should
include at least one independently and well-designed randomised controlled trial to ensure conclusions were unbiased and objective. Overall, they concluded that the claims had not been substantiated and were therefore misleading.

A more recent ruling was against an advertisement for “AcceleDent®”. Patients wearing braces or aligners could purchase this small device to hold in their mouth for 20 minutes a day. The theory is that the device’s vibrations when applied to the teeth are transmitted to the roots and surrounding bone, helping them to move faster, so reducing treatment times. The ASA investigated two claims made in the advertisement:

“When used with braces or aligners, AcceleDent is clinically proven to move teeth up Hopefully [sic] to 50% faster”

“AcceleDent is also clinically proven to reduce the pain and discomfort associated with braces and aligners by up to 71%” (4)

Study evidence was supplied by the manufacturer, but again the ASA was critical of the methodologies. In the pain study, they noted that there had been no placebo device. The study stated that it could not have used a “sham” device because that may have influenced the reporting of pain. The ASA remarked that this was the very purpose of having a placebo. The ASA found that for both claims the evidence supplied was inadequate and they were asked to remove from their advertisements the claims that the device could reduce pain or treatment times.

Results? Encouraging for the clinics – both of those investigated last year have now amended their websites. AcceleDent also seems to have acted quickly and removed the offending claims from their website. But a quick google of the text of those claims reveals that many private clinics who supply the device are repeating them verbatim on their own websites.

The work continues …

Keith Isaacson
Emeritus consultant orthodontist

References

Book review

The importance of being Ernst

SCAM: So-called Alternative Medicine by Edzard Ernst. Imprint Academic, Exeter, UK; June 2018

The title says it all: SCAM, Edzard Ernst is the world’s only professor of complementary and alternative medicine, a former practitioner himself, and has carried out more research on it than anyone. He is always worth listening to even if - perhaps especially if - you’re a believer.

In one sense his latest book is simply refining the definition. After all, CAM is neither an effective complement to real medicine nor an acceptable alternative. It would be unremarkable had he described its practitioners as ‘so-called healers’. But by applying the same logic to the practice as a whole – by insisting on ‘so-called complementary and alternative medicine’ – he is no longer an academic observer of fringe treatments. The resulting acronym is a declaration of war.

Just as Prince Charles seems to wish to fudge the distinction between science and pseudoscience by calling it ‘integrative medicine’, Edzard Ernst has turned the tables by name-calling of a different sort. And his devastatingly pejorative title is likely to catch on.

Indeed, his name-calling is much more accurate than that of his opponents, whose bizarre range of ancient remedies and modern silliness is anything but integrated. Homeopaths do not refer their patients to herbalists, and acupunctureists tend not to believe in chiropractic subluxation. Each is its own religion, usually, as Ernst points out, much like a cult. Few believe in the beliefs of the other disciplines, much less practise them. What they have in common is not an integrated logic or methodology but a shared belief in belief itself. And the principal thing that nowadays brings these strange bedfellows together is a collective sense that they are under attack.

Indeed they are. Ernst was brought up in a CAM household and began his professional life applying CAM as a qualified doctor. His job as the world’s first professor of CAM was paid for by a CAM adherent and his appointment was greeted by the CAM fraternity with acclamation. It was the evidence that failed to live up to their, or his, expectations. Here and there a few CAM treatments seemed to work, at least to a small degree – acupuncture for lower back pain, for example – but as more and more results came in the
clearer it became that most CAM really was a scam.

This book retells that story but Ernst has grown tired of simply rehashing the same old evidence, or even supplementing it with new. SCAM is more a debunker of the thinking (and lack of thinking) behind the quack beliefs. He ridicules its ambivalence to knowledge where research is warmly welcomed when it supports a belief but condemned as the work of the devil when it doesn’t. He rakes through the ‘shoddy quality’ of sometimes ‘nonsensical’ research conducted by CAM adherents. He lambasts the ‘quackademia’ – the lazy greed and intellectual indolence which led so many universities to offer degrees in pseudoscience (sometimes, as Ernst points out, awarding BScs for anti-science). He excoriates SCAM for the harm it does, not least by cuddling up to anti-vaxers, the conspiracy-theorists whose irrational fear of inoculation leads to so much suffering and unnecessary death. But what now really fascinates him is how and why so many seemingly sensible people are swept up in this parallel universe of wishful thinking.

No doubt money oils the alternative machine, and SCAM is a reproach to the multibillion dollar industry that cons the worried well as much as the worried sick. Many practitioners are straight charlatans embracing a lucrative mantra that requires the patient to return again and again and again. Many businesses, like the British ‘neutraceutical’ company Vitabiotics, profit from selling supplements which deftly circumvent advertising restrictions on health claims. (I sometimes wonder if multimillionaire Tej Lalvani, one of the stars of the BBC’s Dragon’s Den, pops the largely pointless pills he so cleverly sells to others.) Investors in Holland & Barrett, the global ‘health food’ chain, might honestly believe it makes the world a better place. But I strongly suspect the last superintendent of pharmacy at Boots the Chemist knew perfectly well that his stores were selling many ineffective products whose packaging gave the impression they had health-giving properties. Perhaps that’s why he was replaced with someone more attuned to marketing? Almost every pharmacy in the world now relies for much of its income on merchandise which almost every pharmacist knows to be pretentious gimmicky.

Yet my own experience of CAM believers – whether practitioners, vendors or buyers – is that they are mostly sincere, often passionately so. To write them all off as scammers is unfair. They are credulous, true; but that is the defining feature of holding a belief. They are often scientifically illiterate, and sometimes wilfully so. Some of them make their living out of flimflam. But mostly they do believe.

Real medicine also has its failings, of course. In fact its very potency is problematic, and tens of thousands of people are injured or even killed each year through avoidable medical error. What’s more, as Edzard Ernst concedes, it has become increasingly impersonal. In a postscript to his 200 pages of lacerating criticism he notes there are ‘positive sides’ to SCAM, not least that it, ‘might finally force conventional healthcare professionals to remember that time, compassion and empathy are some of their core values which cannot be delegated to others.’

Yet there is a vast, inescapable and, to any rational analyst, undeniable difference between what we now call conventional medicine (which is actually adventurous and where research seeks unconventional new answers) and so-called CAM (which, paradoxically, clings tightly to orthodoxy). One really works, the other mostly gives some people the impression that it works. Faith healing has never shown any improvement in mortality or morbidity of any population at any time in history. Yet since the dawn of the Age of Enlightenment, with the development of scientific methods and the adoption of evidence-based medicine, human health and longevity have risen to a phenomenal degree and in steeply rising cadence. Set against the astounding and measurable achievements of real medicine, so-called complementary and alternative medicine really is a scam.

This is why, to the dismay of honest fools and the disdain of manipulative charlatans, I suspect that Ernst’s new name for quackery will stick.

Nick Ross
Author and broadcaster, president of HealthWatch
London

It’s on the label – triumphs of design over utility

Our cat is not a fussy eater, although he makes a fuss when he wants to be fed. However, we like to give him a variety of different flavours of meat or fish in jelly, and he seems to like one brand that offers four different pairs of fish or meat in each dozen packs of food.

On the back of each pack of food is a list of the contents (e.g. salmon and saithe, or turkey and liver) in 24 languages. This could be very useful for me when travelling, if I bothered to memorise the list, so that I would at least know some basic menu items. There is a problem with one of the flavours – the panel that contains English and the other languages that I recognise is printed in white on a yellow background, so that it is completely unreadable.

Perhaps more seriously, a couple of months ago we were

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on a family holiday in a large apartment, and it was my turn to cook dinner. The apartment offered a very limited range of cooking utensils, so I decided that chicken mini-fillets in a cheese and tarragon sauce would be easiest. I went to buy some cheese sauce granules in the supermarket, then remembered that one of the family was gluten intolerant, so checked the ingredients. Quite correctly, there was a list of ingredients, in order of quantity, and with possible allergens in bold type. Unfortunately, the whole package was in a Gouda cheese rind yellow, with the printing in white – again completely unreadable.

Some years ago my then local council produced a very useful leaflet of services available to visually impaired people. It was printed in cyan on white. Readable with moderate difficulty by someone with good eyesight (but much improved by reading through rose-tinted spectacles to darken the pale blue ink). However, for someone with impaired vision, and especially if using blue tinted spectacles to reduce UV damage to the eye, it was completely unreadable. The recent NHS Health Check leaflet “Change your life in 20 minutes” is at least printed in black, but with a shaded blue background, so reducing readability on the left hand side of each page.

Then there is the problem of information overload on the label. My 57g tin of mustard powder contains full nutritional information, starting with the nutrient content per 100g (as is legally required) – that is almost two tins of mustard powder. It then gives the information per 2.5g serving, which is more useful, and finally the percentage of the reference intake of an average adult in a 2.5g serving. Too much information for something that is a condiment eaten in small amounts rather than a food, but at least it is printed clearly in black on yellow.

Finally, something that has nothing to do with diet or health, but is another triumph of design over utility – the text book that I had difficulty paying for in the bookshop because the bar code was printed in red on a white background – and bar code readers use a red laser.

David Bender
Emeritus Professor of Nutritional Biochemistry
University College London