RIAT MOVES FOR TRIAL TRANSPARENCY

PRESSURE ON pharmaceutical companies to make available their unpublished clinical trial data moved up a gear in June with the launch of the RIAT (Restoring Invisible and Abandoned Trials) initiative by British Medical Journal, PLoS and researchers. It is a call to action to companies and academic funders to publish, or update already published, findings from trials they sponsored. The initiators of RIAT say they will make public all the confidential information they hold about missing and abandoned trials in one year’s time if trial sponsors fail to publish it themselves.

This latest news is a high point from the AllTrials campaign’s roller-coaster ride of recent months. A low came on 25th April when the European Court issued an injunction stopping the European Medicines Agency from releasing information from clinical trials conducted by two pharmaceutical companies, InterMune and AbbVie, who had challenged the EMA’s decisions to grant access to clinical study reports from drug trials. The wider effect of the injunction has been to chill other requests for clinical trial information. There are at least 100 pending requests seeking trial results.

The outlook improved on 29th May when MEPs voted unanimously in favour of proposals to increase the transparency of clinical trials. UK Labour MEP and Health Spokesperson Glenis Willmott drafted the report which includes obligations for clinical trial sponsors to publish their Clinical Study Reports.

Commenting on the EMA injunction, Peter Doshi, Fellow in Comparative Effectiveness Research, Johns Hopkins University, said: “I am not aware of any evidence that any harm to public health has ever resulted from the sharing of clinical trial data.”

Mandy Payne

Contents

**NEWS**  A sad farewell to HealthWatch’s friend and past treasurer; News in Brief ............................................. 2

**CLINICAL**  Murali Varma on the misunderstandings surrounding that most feared of diagnoses ............................ 3

**SLIMMING**  A weight loss plan and its promises: David Bender goes head to head with Alizonne .......................... 4, 5

**WOMEN’S HEALTH**  New egg-freezing technology—less liberation, more heartbreak: Miriam Zollobserves .............. 6

**RESEARCH**  Edzard Ernst research that has crossed the line—not just poor, but unethical .................................... 7

**LAST WORD**  Campaigners celebrate the birth of a new law after the 21st Century’s most successful campaign ........ 8

PLANS FOR NEW EXETER CAM POST

COMPLEMENTARY AND Alternative Medicine could soon have more research devoted to it. There are moves to establish a new post at Exeter University to continue the pioneering work of Prof Edzard Ernst who retired earlier this year. HealthWatch’s President, Nick Ross, has been in discussions with Exeter’s Medical Dean, Steve Thornton, since Prof Ernst first announced he would be stepping down, and together with the science writer Simon Singh has been seeking potential candidates and funding.

Professor Ernst developed a global reputation for his candid assessment of CAM treatments, demonstrating that some had scientific plausibility and a few could be shown to be effective. However, he upset many alternative practitioners by questioning the evidence behind complementary therapies, including homeopathy, which he had learnt early in his medical career whilst at a homeopathic hospital in Munich. He showed most CAM therapies caused no demonstrable benefits beyond placebo, and some were positively dangerous. He was at the centre of a row in 2005 over a report commissioned by the Prince of Wales which advocated complementary medicine and which Prof Ernst described as, “deeply flawed”.

The controversies caused problems for Exeter but according to Nick Ross, ‘The university is standing by its guns. It is keen in principle to build on Edzard’s work. But the endowment that paid for Edzard’s centre has now run out of cash. The big question now is how we can fund a new post in these very difficult times for university finances’. Ross and Singh are approaching charitable trusts and other agencies and have been considering crowd-sourcing to get the new post up and running.

See page 6 for an article by Edzard Ernst.

Fiona Godlee, editor in chief of the British Medical Journal since 2005, and the journal's first female editor, has agreed to accept the 21st HealthWatch Award at this year’s Annual General Meeting. Mark your diaries for the evening of Thursday 24th October at the Medical Society of London
JOHN HANFORD: A SAD FAREWELL

IT WAS WITH enormous sadness that the HealthWatch Committee learned recently that our good friend and former treasurer, John Hanford, died on 3rd March 2013.

John was well loved by all who knew him through HealthWatch. His friends echoed the sentiments expressed by Walii Bounds who remembered him as “a thoroughly nice and decent man, and a very effective treasurer”. He was originally introduced to HealthWatch by his long-standing friend John Garrow, then chairman of HealthWatch, who writes:

“Our family moved into a house on Pinner Hill because I was going to work in the new MRC hospital in Harrow instead of going into St Bartholomews Hospital, and Katharine wanted to work as a GP in Watford. We soon discovered that there were no children on the hill—our neighbours were all elderly and affluent people who had been ‘something in the City’. No one played with toys.

“It was therefore wonderful when after a few weeks the Hanford family took over the house exactly opposite ours, and their children were of the same age as ours. Our two families got on very well, and (best of all) John modestly said he was quite familiar with financial records, and could probably act as the HealthWatch treasurer. He did have some slight problems with the records, because something in the punctuation seemed to be missing. I was able to help, because when he saw an entry £749 he thought that represented Seven hundred and forty-nine thousand pounds, (or even £749 million), but of course it was just £749. It was revealed that John was a director of a company that provided international pipelines, so his ledgers dealt only in millions of pounds.

“The Hanfords were good friends for our family, and John was a very good friend to HealthWatch. As we all got older our children disappeared from the nest, and the Hanford parents went on long trips overseas, so he could not maintain the job of treasurer. We have been lucky again with the volunteer who has taken over this role.”

Mandy Payne

NEWS IN BRIEF

CAMBRIDGE University Press have agreed to sponsor the 2014 HealthWatch Student Prize. They will take over from past HealthWatch chairman Professor John Garrow, for whose kind sponsorship of the 2013 prize we thank him.

NOMINATIONS ARE now open for the 2013 John Maddox Prize for Standing up for Science. Sir John Maddox, whose name the prize commemorates, was a passionate and tireless champion and defender of science, engaging with difficult debates and inspiring others to do the same. As a writer and editor, he changed attitudes and perceptions, and strove for better understanding and appreciation of science throughout his long working life. The prize is a joint initiative of Nature, where Sir John was editor for 22 years; the Kohn Foundation; and Sense About Science, where Sir John served as a trustee until his death in 2009. The prize: £2000. The award is presented in November and an announcement of the winner will be published in Nature. Nominations online.


THE DEPARTMENT for Work and Pensions is under investigation for administering questionable psychometric tests to the unemployed, allegedly under threat of loss of benefits if they did not complete them, reports the Guardian. The Health and Care Professions Council (HCPC) is investigating why jobcentres were permitted to trial the 48-question character test, called My Strengths, which was devised by the government's Behavioural Insights Team but has been criticized by psychologists as lacking in concrete evidence.


THE NHS HAS been criticized for taking payments from companies in exchange for access to pregnant women, such as via the distribution of “Bounty Bags”. The Bounty company reportedly pays the NHS £2.3m a year for the right to distribute 2.6 million bags of samples and advertisements, and sales staff collect commercially valuable data from mothers still in the maternity ward. Writing in the British Medical Journal, Glasgow GP and past HealthWatch Award-winner Margaret McCartney says, “The lack of knowledge about what signing over your details means is troubling in a hospital environment, which should take consent and confidentiality seriously. The hours after birth are hardly an optimal time to obtain formal consent. And is the presence of a nonessential Bounty worker on the ward desirable?”

BMJ 2013;346:f3448 (28 May 2013) http://www.bmj.com/content/346/bmj.f3448

A GLOBAL movement is calling for an end to industry-promoted disease-mongering that manipulates health concerns and harms through practices that medicalise normal life. Learn more about the Call to Action on Selling Sickness on their website.

http://sellingsickness.com/final-statement/

TWO NEW books just published will be of interest to HealthWatch members:

Me Medicine vs. We Medicine: Reclaiming Biotechnology for the Common Good by Donna Dickenson, is published 3 July by Columbia University Press (hardcover, 304 pages, £19.95 (£14.00 Kindle)). Dickenson writes, “Backed up by the glamour of new biotechnologies such as direct-to-consumer genetic testing or neurocognitive enhancement, personalized medicine—what I call ‘Me Medicine’—appears to its advocates as the inevitable and desirable way of the future. By contrast, what I term ‘We Medicine’—public health programs such as flu jabs or childhood vaccinations—is widely distrusted and highly vulnerable to austerity cutbacks.”

Crime, how to solve it and why so much of what we’re told is wrong by Nick Ross was published 29 May by Biteback Publishing. (Hardcover, 384 pages. RRP £17.99, £8.75 Kindle). Nick Ross’ new book draws on evidence-based medicine as a model to review social policy, in this case crime. Based on his twenty years experience working with victims and police, and ten years research to find out what makes crime rates ebb and flow, he proposes a radical re-think of crime policy and exposes the way that facts about crime are continually manipulated to serve the needs of politicians and the media.

http://sellingsickness.com/final-statement/
CANCER: WHAT’S IN A NAME?

This has undoubtedly contributed to the general perception of cancer. However, rapid advances in diagnostics, surgery and oncology has resulted in a much higher proportion of cancers being detected at an early stage and patients being cured. In some instances, such as some cancers of the testis and childhood leukemias, even patients with advanced disease can be effectively treated and cured of the disease.

However, the current public misperception of cancer is not solely related to the improvements in clinical outcome. There are also more fundamental issues related to the public understanding of cancer; some of which are related to the different ways in which the word “cancer” is used and understood by the general public, patients and various medical professionals. To paraphrase Lewis Carroll in Alice’s Adventures in Wonderland, a word can be made to mean so many different things to so many different people. This article explores issues related to cancer terminology/phraseology and their impact on the public perception of cancer.

“Most laymen would think of cancer as a life threatening disease; for them there is no ‘harmless cancer’.”

Cancer is not a single disease but a group of diseases with very different risks of adverse outcome. While some almost never pose any risk to life, others are almost invariably fatal even if detected at an early stage. Even phrases such as “breast cancer”, “thyroid cancer” and “lung cancer” are unhelpful as each includes a number of very different diseases ranging from the relatively harmless to the deadly. The spectrum of thyroid cancer ranges from “papillary microcarcinoma”, which generally has little effect on life expectancy to “anaplastic thyroid cancer”, which has a dismal prognosis for most patients surviving no more than a few weeks. Similarly, basal cell carcinoma of the skin is relatively harmless while other skin cancers such as malignant melanoma have a significant risk of metastasis and death. Thus, it would be more appropriate to refer to this group of diseases in the plural (“cancers” rather than “cancer”) and to state that an individual patient is suffering from “a breast cancer” rather than “breast cancer”. This is more than just semantics; it reduces the risk that a young woman diagnosed with a slow growing form of cervical cancer would assume that she is suffering from the same aggressive disease that resulted in the highly publicised death of Jade Goody.

In this respect, “cancer” is analogous to “infection”. Patients suffer from an infection that may be relatively harmless (e.g., the common cold) or invariably deadly (e.g., rabies); while lung infections range from a viral bronchitis that usually requires no treatment, to a bacterial pneumonia that is generally easily cured with antibiotics, to severe infections such as SARS that carry a significant risk of mortality. It is generally unhelpful to discuss the need to “find the cause of cancer” or “discover a cure for cancer” as different cancers have different causes and require very different approaches for treatment.

Another major issue is the differing perceptions of what constitutes cancer. Most laymen would think of cancer as a life threatening disease; for them there is no “harmless cancer”. On the other hand, doctors identify most cancers based on the microscopic appearance of the tumour supported, if necessary, by an array of special tests; this includes some lesions that pose very little risk to patients. Thus, patients with some incidentally detected tiny low-grade proliferative conditions of the thyroid gland, breast and prostate are diagnosed as suffering from cancer even though these lesions have negligible risk of causing harm. It would be useful if the nomenclature of some low risk lesions could be changed so that they are no longer designated as cancers. For example, it has been suggested that some low-risk thyroid cancers should be renamed “tumours of uncertain malignant potential”.

Another potential source of confusion is related to the nomenclature of non-invasive (“in-situ”) lesions such as ductal carcinoma in situ (DCIS) of the breast. The latter is often referred to as a form of breast cancer, as in the high profile case of the tennis star Martina Navratilova. However this is misleading, as these non-invasive “cancers” themselves have no potential for causing harm until and unless they progress to an invasive cancer. Thus, DCIS is a pre-cancerous condition rather than a true cancer. This confusion regarding the nomenclature of non-invasive lesions is not limited to laymen. Several scientific publications have analysed DCIS as a form of breast cancer and many non-invasive tumours of the urinary bladder are currently designated as bladder cancer. There has more recently been a welcome trend towards changing the terminology of certain types of non-invasive proliferations. For example, “carcinoma in situ” of the cervix is now labelled “cervical intraepithelial neoplasia”, thereby avoiding the emotive word “carcinoma” (a type of cancer).

CURRENT medical practice involves detailed discussion by specialist oncology teams with patients who have been diagnosed with cancer. However, this discussion would be greatly facilitated if these patients already had a general understanding of cancer as a heterogeneous group of diseases. Patients who perceive a diagnosis of cancer as a death sentence are likely to panic and opt for aggressive treatments that are not really necessary. Aggressive therapy is not a risk-free approach as cancer therapy itself can have significant side effects, including in some cases the induction of new cancers. Hence, better public education regarding the nature of cancer is required. This need for public education is most acute for those considering cancer screening because in addition to discovering clinically significant cancers modern diagnostic screening techniques may also detect low-risk lesions resulting in anxiety and confusion.

Murali Varma
Consultant Histopathologist
University Hospital of Wales
Cardiff
SELLING MORE THAN JUST WEIGHT LOSS

ALIZONNE HAS transformed my life”—weight reduction, skin retraction and contour shaping without surgery. The words headlined an advertisement in the Metro paper on January 14th. My initial reaction was that this was promoting the lipase inhibitor Orlistat, which is marketed as a prescription medicine under the name Xenical, and sold over-the-counter under the trade name Allitame.

There is good evidence for the efficacy of Orlistat in weight loss regimes. However, when I went online to http://www.alizonne.co.uk, I discovered I had confused the similar-sounding names. Alizonne is a completely different approach to weight loss.

The website gives some very sound information on the difficulty of dieting for weight reduction. This is something we all know—if it was easy to reduce food intake and lose weight then the multi-million pound market in diets and slimming aids would collapse, and we would not face the problems for the NHS of two thirds of the population being overweight, and a quarter clinically obese. Nevertheless, it is good marketing to start the information about Alizonne with a discussion of how difficult it is to lose weight. We could find ourselves imagining that we are going to be offered something that will be quick and easy.

Alizonne therapy for contour shaping and weight reduction consist of three elements: a diet, and two types of non-surgical contour shaping. The diet seems fairly conventional; it is based on vegetables that can be consumed in more or less unlimited quantities. There is also a protein and amino acid supplement. I am not convinced of the need for protein supplements, but there are sound metabolic reasons why a relatively high protein intake increases metabolic rate and therefore aids weight reduction.1

"Perhaps I would be disappointed to be told that my personal rate of weight loss would be less than 6 kg/month."

I am less happy with the claim that you can lose 6–12 kg/month. If you starved totally and maintained your usual physical activity, you can calculate that you would lose no more than 2.3 kg/week as a sustained weight loss. This is simple arithmetic, based on energy expenditure of 2500 kcal/day and the energy yield per kg of adipose tissue. However, we are told that each patient is given his/her predicted rate of weight loss at the initial consultation. Perhaps I would be disappointed to be told that my personal rate would be less than 6 kg/month.

Claims for rate of weight loss on dietary restriction can risk being misleading. It is certainly true that weight can seem to melt away quite rapidly during the first few days of a diet programme. The human body responds to calorie restriction by burning up its most readily accessible stores of energy, the carbohydrate glycogen, which is stored in the liver and muscles, and contains a large amount of water in its structure. This release of glycogen-associated water accounts for the immediate rapid weight loss that all dieters experience and is a source of much joy. Alas, it is over quickly and cannot be sustained—subsequent fat loss by calorie restriction is a long, slow process with no short cuts. It is also true that the rate of weight loss, especially during these early days, depends to a large extent on the individual. Broadly speaking men, and those who are heavier to begin with, lose weight more rapidly than women and those who are closer to normal weight. Claims for rates of weight loss that are based on unrepresentative experiences are not looked upon kindly by the Advertising Standards Authority, whose Code of Advertising Practice states in this regard, “For those who are normally overweight, a rate of weight loss greater than 2 lbs (just under 1 kg) a week is unlikely to be compatible with good medical and nutritional practice. For those who are obese, a rate of weight loss greater than 2 lbs a week in the early stages of dieting [my emphasis] could be compatible with good medical and nutritional practice."2

The next part of the therapy gave me pause for thought. Contour shaping consists of ultrasound treatment that is apparently set at a frequency and intensity to disrupt subcutaneous fat cells. This worries me. If you disrupt my adipose tissue cells then presumably the contents (fat) will leak out. The lipids (fats) in my bloodstream are contained within protein shells—these are the plasma lipoproteins, and especially the low-density lipoprotein that my GP is concerned about. If you just release the fat from adipose tissue cells into the bloodstream, you will have an oil that does not mix with blood plasma. The result would be disastrous.

Furthermore, I am concerned about the effect of ultrasound on red blood cells. Clinically, highly focussed beams (of high intensity) ultrasound are used to break up kidney stones. The ultrasound used for imaging is at a very low intensity, does not disrupt cells, and is considerably less hazardous than X-rays. However, if you are going to disrupt subcutaneous fat cells with ultrasound then it must be relatively unfocussed, and will presumably also act also on red blood cells in blood vessels near the surface. This is worrying—if you want to disrupt red blood cells in the laboratory then one way of doing so is to use ultrasound. If you disrupt red cells in the body the you release haemoglobin which can have a damaging effect on the kidneys, quite apart from causing haemolytic anaemia if you disrupt enough cells. The crisis provoked by haemolysis in people suffering from the genetic disease favism is potentially fatal.

Finally, we are told that there is an additional non-surgical technique to treat the skin over the whole body. This is to stimulate fibroblasts to produce collagen and elastin, so as to firm and tighten the skin. This sounds desirable—I certainly do not want saggy skin where I have lost weight, but I know that the skin will go back to its normal elastic state quite happily after weight loss without any additional treatment, the same as it does after pregnancy. The website3 does not give any further information on this technique.

David A Bender
Emeritus Professor of Nutritional Biochemistry
University College London

References
3. Alizonne (UK). See: http://www.alizonne.co.uk
Alizonne’s medical director and physician, Dr Mark Palmer, was invited to respond to points made in the article opposite and we are pleased to publish his comments:

Regarding concern about the claim that some customers can lose 6–12 kg/month:

Whilst understanding his concerns, these are not unreasonable estimates of weight loss on our programme. They are average figures based on the collation of many thousands of sets of patient data and analysis of the weight loss they have achieved.

Unlike most other weight loss programmes, our programme is closely medically supervised by our own fully registered doctors. Every patient that we treat has an in depth one hour consultation and assessment by one of our doctors before they commence their treatment and at regular intervals throughout their treatment programme.

As part of this assessment their resting metabolic rate is measured with an FDA approved device. Their body composition is also analysed in detail using multi-frequency bioelectrical impedance analysis. These data help our doctors to determine the expected rate of weight loss for each individual patient prior to treatment, therefore each patient is given personalised, individualised and realistic information.

Regarding concerns about the use of ultrasound treatment:

It is correct that lipids are transported in the bloodstream bound to proteins, otherwise, as is correctly stated they would be insoluble. On our weight loss programme, the weight loss is achieved by manipulation of the patient’s nutritional intake, not though the use of ultrasound.

In order to address the cosmetic aspect of weight loss, which is important for the patient’s psychological state, ultrasound is used to improve the patient’s body contour in certain body areas as adipocytes in areas of poorly perfused and relatively avascular hypertrophic subcutaneous adipose tissue do not respond well to dietary manipulation.

The application of ultrasound energy to this tissue increases the permeability of the adipocyte cell membrane through a process of stable-cavitation. The triglyceride thus released enters the extracellular space and not the bloodstream. There it is enzymatically cleaved into glycerol and free fatty acids which enter the lymphatic system, which is a lipid containing fluid compartment.

Patients’ blood lipids are monitored before and at regular intervals throughout their treatment programme and in all cases there is a dramatic fall in total cholesterol, LDL and triglycerides and a rise in HDL, i.e., we always see a very significantly improved and healthier profile.

This is because the manipulation of the patient’s nutritional intake dramatically improves the blood lipid profile and the use of the ultrasound energy does not have any adverse effect on this.

Regarding the effect of ultrasound on red blood cells and speculation that the consequences of red blood cells leaking haemoglobin would be undesirable:

It is correct that clinically, highly focused and high intensity ultrasound is used to break up kidney stones. It is also correct that the ultrasound used for imaging is of a very low intensity and does not disrupt cells. Ultrasound is a form of sound energy and is not part of the electromagnetic spectrum, therefore it does not cause damaging ionizing changes to cells unlike some frequencies of electromagnetic energy such as ultra violet rays, x-rays and gamma rays. It is safely used during pregnancy for this reason.

Ultrasound currently used in medicine to treat adipose tissue can either be focused or unfocused. Some devices currently on the market focus the ultrasound energy onto a small target area. In this case, a lot of heat is produced at the target site within the subcutaneous adipose layer and the adipocytes are destroyed via a process of thermal ablation. Treatment in this way is time consuming, as the energy has to be progressively delivered to small adjacent target areas until all the treatment area has been covered. It can be painful for the patient and there is the theoretical potential for causing ablative damage to other structures if the energy is not precisely focused within the adipose layer.

We, therefore, use non-focused ultrasound energy, which produces no significant heat at the target site and no ablation of the tissue occurs. The energy is applied at a specific frequency and intensity, which induces a process of stable-cavitation within the adipocytes. This increases the permeability of their cell membranes and triglyceride leaks out. This does not affect other cell types due to their different structure and composition. Adipocytes are unique in being composed nearly entirely of lipid and therefore, having different acoustic properties, they respond differently to the application of this type of ultrasound energy.

Regarding processes that might stimulate fibroblasts to produce collagen and elastin, so as to firm and tighten the skin:

To address the elasticity of the skin, we use mechanical cellular stimulation with a LPG device. The patient receives regular treatment from the very start of the weight loss over their entire body, covering the majority of their skin surface area.

The LPG device has many published studies supporting its efficacy, including some which show a reduction in circumference measurements as a result of skin and tissue tightening, independently of weight loss, even in some patients who gained some weight during the study period. Despite this, even those patients have been shown to have a reduction rather than the expected increase in circumference measurements.

The mechanical cellular stimulation targets the fibroblast cells in particular, both in the dermis of the skin and in the subcutaneous fibro-septal network. This is a cross-over matrix of connective tissue fibres running multi-directionally throughout the subcutaneous adipose layer. When the fibroblast cells are exposed to multi-directional, mechanical tractional forces, of sufficient intensity, they respond with increased output of collagen and elastin, which increases the firmness and elasticity of the dermis and the subcutaneous fibro- connective tissue matrix.

Fibroblast cells are the cells, which produce collagen and elastin and they are the main cell type involved in wound healing and tissue repair. In unwounded tissue they are in an almost dormant state and their output of collagen and elastin is very low. This is their normal state.

The fibroblast cells react to the mechanical cellular stimulation as a form of cellular injury and they react, as they would in the case of tissue wounding, with a wound healing response and an increased and sustained output of collagen and elastin.

Dr Mark Palmer MB ChB T(GP), MBACD
Medical Director and Physician
Alizonne

Editor’s note: as at time of publication, no references have been supplied, but should Alizonne take up our offer to publish full references we will be pleased to include these on our website www.healthwatch-uk.org
While Richards’ decision appears to have clearly provided her with a sense of hope and temporary emotional equilibrium, it may very likely prove to be illusory. Sadly, as millions of women can attest, including me, the vast majority of assisted reproductive technologies (ART) fail: In 2012, of the 1.5 million treatments reported globally, approximately 1.1 million failed—a 77 per cent failure rate. In the United States in 2010, the overall failure rate was 68 per cent. Once optimistic and hopeful about the promise of reproductive science, I endured four failed IVF cycles, including one miscarriage, and two failed donor egg attempts. Ironically, both donors were diagnosed as being infertile, a painful discovery that further eroded my confidence in the experts I had trusted and made me realize how few consumer protections are in place for women undergoing treatments.

But it is no wonder that Richards believes she will be able to bear children with her frozen eggs whenever she wants to. A $4 billion dollar industry1 is driving the public discourse about often unproven discoveries through a lens that focuses attention on the majority of successes rather than the whole messy, complicated story. Growing up in a culture that reveres science, she has been bombarded with overly optimistic and often one-sided media stories touting the sensationalized miracles of creating babies in laboratories. The truth is, many women signing up for treatments do not realize until later the extent to which they are participating in a vast experiment, where evidence-based medicine has yet to establish a reasonable foothold.

The only current independent effort to track the health of all women going through treatments remains largely invisible to patients who might sign up to have their health—and that of their offspring—tracked over time. This voluntary registry—the Infertility Family Research Registry (www.ifrr-registry.org)—is based at the Dartmouth Hitchcock Medical Center and is funded in part by the American Society for Reproductive Medicine (ASRM). To date, the vast majority of large fertility centers in the United States are not displaying the registry’s placard in their waiting rooms, greatly reducing the potential benefits such a long-term study would provide.

Richards’ desire to protect her ability to bear a biological child is heartfelt, and her willingness to undergo egg freezing procedures that were considered experimental at the time speaks to her commitment—and her panic—to try anything to preserve that opportunity. But her statement that this decision was “the best investment” she ever made is premature, to say the least.

The general public knows virtually nothing about the failure and success rates of vitrification—a new flash freezing technique that has been used to preserve the eggs of women younger than 30 who are facing life-threatening illnesses. While an estimated 1000 babies have been born from this technology worldwide, there is virtually no data that tells us if these live births were the result of 3,000 or 10,000 trials. We have no idea how many miscarriages or stillbirths may have ensued, and there are few, if any, long-term infant health studies evaluating how flash freezing half of a child’s DNA might affect them later in life. The one study Richards cites found that 900 babies exhibited no more risk of birth defects than babies conceived naturally by young mothers, but is one study really enough?

Apparently the ASRM believed it was proof enough for them last fall to lift the “experimental” label from this still young science. Its Practice Committee said it was not yet ready to endorse widespread use of egg freezing for elective treatments and, while randomized controlled studies were rare, the committee did find sufficient evidence to “demonstrate acceptable success rates in young, highly selected populations.” Citing a lack of data on safety, efficacy, cost-effectiveness, and potential emotional risks, their report states, “Marketing this technology for the purpose of deferring childbearing may give women false hope and encourage women to delay childbearing. Patients who wish to pursue this technology should be carefully counselled.”

As would be expected, once their decision became public, their caution about women’s age and infant health was obscured and eventually obliterated by the dust kicked up by a stampede of panicked but hopeful 30 and 40-something women running to the nearest fertility clinic to have their eggs harvested for future use—for anywhere between $10,000 and $15,000 or more.2

One must wonder why the ASRM felt so compelled to provide a stamp of approval for a procedure still lacking in reliable safety and efficacy data. As legal scholars Debora Spar and Naomi Cahn have written in their books, The Baby Business and Test Tube Babies, respectively, in the context of an unregulated industry in the United States, it is virtually impossible to separate the medical and market forces at play when new techniques and procedures are advertised to potential clients. The blurred boundaries between fertility clinics wanting to provide patients with safe, evidence-based procedures while also needing to generate business to meet their bottom lines puts that much more pressure on consumers to know what they are signing up for.

But when evidence and information is scarce, biased or non-existent, well-heeled consumers like Richards feel they have no choice but to close their eyes, write a check, and jump off that technological cliff called Hope. For Richards’ sake, I hope she succeeds. If not, she may well join the ranks of millions of men and women who, since the first IVF baby was born in Britain 35 years ago, have inadvertently experienced involuntary biological childlessness as a result of delaying parenthood and relying on science for last minute miracles.

Miriam Zoll
Writer

Award-winning US writer Miriam Zoll’s new book, Cracked Open: Liberty, Fertility and the Pursuit of High Tech Babies was published 1 April 2013 by Interlink Books, paperback £12.99. Her article shown here originally appeared on the American reproductive health website RH Reality Check http://rhrealitycheck.org/ and appears with the author’s kind permission.

References (and continued on facing page)
WHERE IS THE LINE BETWEEN POOR AND UNETHICAL RESEARCH?

Indian homeopaths recently published a clinical trial aimed at evaluating homeopathic treatment in the management of diabetic polyneuropathy. The condition affects many diabetic patients; its symptoms include tingling, numbness, burning sensation in the feet and pain, particularly at night. The best treatment consists of adequate metabolic control of the underlying diabetes. The pain can be severe and often does not respond adequately to conventional pain-killers. It is therefore obvious that any new, effective treatment would be more than welcome.

The new trial is a prospective observational study which was carried out from October 2005 to September 2009 by the Indian Central Council for Research in Homeopathy at its five institutes. Patients suffering diabetic polyneuropathy (DPN) were screened and enrolled in the study, if they fulfilled the inclusion and exclusion criteria. The Diabetic Distal Symmetric Polyneuropathy Symptom Score (DDSPSS), developed by the Council, served as the primary outcome measure.

A total of 15 homeopathic medicines were identified after repertorizing the nosological symptoms and signs of the disease. The appropriate constitutional medicine was selected and prescribed in the 30, 200 and 1M potencies on an individualized basis. Patients were followed up for 12 months.

Of 336 diabetics enrolled in the study, 247 patients who attended at least three follow-up appointments and baseline nerve conduction studies were included in the analysis. A statistically significant improvement in DDSPSS total score was found at 12 months. Most objective measures did not show significant improvements. Lycopodium clavatum (n = 132), Phosphorus (n = 27) and Sulphur (n = 26) were the most frequently prescribed homeopathic remedies.

From these results, the authors concluded that: “homeopathic medicines may be effective in managing the symptoms of DPN patients.” Does this study tell us anything worth knowing? The short answer to this question, I am afraid, is no. Its weaknesses are all too obvious:

1. There was no control group.
2. Patients who did not come back to the follow-up appointments—presumably because they were not satisfied—were excluded from the analyses. The average benefit reported is thus likely to be a cherry-picked false positive result.
3. The primary outcome measure was not validated.
4. The observed positive effect on subjective symptoms could be due to several factors which are entirely unrelated to the homeopathic treatments, e.g., better metabolic control, regression towards the mean, or social desirability.

Anyone who had seen the protocol of this study would have predicted the result; I see no way that such a study does not generate an apparently positive outcome. In other words, conducting the investigation was superfluous, which means that the patients’ participation was in vain; and this, in turn, means that the trial was arguably unethical.

This might sound a bit harsh, but I am entirely serious: deeply flawed research should not happen. It is a waste of scarce resources and patients’ tolerance; crucially, it has a powerful potential to mislead us and to set back our efforts to improve health care. All of this is unethical.

The problem of research which is so poor that it crosses the line into being unethical is, of course, not confined to homeopathy. In my view, it is an important issue in much of alternative medicine and quite possibly in conventional medicine as well. Over the years, several mechanisms have been put in place to prevent or at least minimize the problem, for instance, ethic committees and peer-review. The present study shows, I think, that these mechanisms are fragile and that, sometimes, they fail altogether.

In their article, the authors of the new homeopathic study suggest that more investigations of homeopathy for diabetic polyneuropathy should be done. However, I suggest almost precisely the opposite: unethical research of this nature should be prevented, and the existing mechanisms to achieve this aim must be strengthened.

Edzard Ernst
Emeritus Professor of Complementary Medicine
Exeter University


This article first published 4th June 2013 in Edzard Ernst’s blog http://edzardernst.com/ and appears here with his kind permission.

2. ART factsheet. European Society for Human Reproduction and Embryology. See: http://www.esreh.eu/ESHRE/English/Guidelines-Legal/ART-factsheet/page.aspx/1061. Author’s note: derived from figures in 3rd paragraph: 350,000 live births out of 1.5 million treatments; hence 1,150,000 million = 76.6% of attempts do not result in live births.
3. 2010 Assisted Reproductive Technology Report. US CDC. See: http://www.cdc.gov/art/ART2010/index.htm Authors’ note: derived from figures of 147,260 cycles performed resulting in 47,090 live births; hence 100,170 = 68.1% of attempts do not result in live births.
SPEECH IS FREER: A NEW LAW IS BORN

THIS TIME four years ago the science writer, Simon Singh, was fighting a libel action brought against him by the British Chiropractic Association in response to his comments about chiropractic in a newspaper article. On 18th May 2009 a group of well-known scientists, comedians and writers assembled at the Penderel’s Oak pub in Holborn, London, on the initiative of young lawyer David Allen Green, to object to the treatment of scientists. The atmosphere was very different, though no less exhilarating, in the basement of that very same pub on the evening of 16th May 2013. Sense About Science hosted the party and the now victorious Simon Singh unveiled a brass plaque which commemorates the historic event and what happened next.

As most HealthWatch members now know, the original 2009 meeting led to the formation of the Libel Reform Campaign—a coalition of three charities: Index on Censorship, English PEN and Sense About Science, who together led a general protest against the use of libel to stifle valid scientific comment. The LRC’s call to reform England’s libel laws grew to involve 60,000 bloggers, publishers, scientists and authors and more than 100 organizations including including Citizens Advice, Nature, Mumsnet, Global Witness, Which?, Amnesty, Society of Authors and the Royal College of GPs in what has been described as one of the most successful campaigns of the 21st century.

The Defamation Act became law on 25th April 2013. The new bill’s provisions include:

· A statement is not defamatory unless it has caused or is likely to cause serious harm to the reputation of the claimant.

· Commercial entities must show that the words complained of caused or are likely to cause serious financial loss.

· The time period to bring a libel action starts with the first publication and cannot be restarted with subsequent publications, unless the material is published in a materially different manner.

· A libel action against a person who does not live in Europe can only be heard in London if the claimant can show that England is the most appropriate place.

The guests who celebrated in the packed basement of the Penderel’s Oak last month heard statements from supporters including celebrities Dara O’Brian and Professor Brian Cox, who exclaimed, “I’m amazed that rational thought should be a niche activity!”; MPs Evan Harris and Rob Flello, as well as Simon Singh and some of their fellow victims of libel actions, among them Dr Peter Wilmshurst, consultant cardiologist and defendant in NMT Medical vs Wilmshurst. Peter Wilmshurst’s optimism was cautious: “I hope that the Defamation Act will make it easier for scientists, doctors and others to openly discuss concerns of public interest without being sued for libel, but I fear that so long as the legal process in England remains unbelievably expensive, those with the most money will continue to silence ordinary people with limited resources who wish to raise concerns.”

Mandy Payne

Further information

HealthWatch promotes:
1. The assessment and testing of treatments, whether “orthodox” or “alternative”.
2. Consumer protection of all forms of healthcare, both by thorough testing of all products and procedures, and better regulation of all practitioners;
3. Better understanding by the public and the media that valid clinical trials are the best way of ensuring protection.

HealthWatch welcomes membership enquiries from those who share its aims. Membership costs £30.00 per year, including hard copy newsletter sent by post (£40.00 for members outside Europe); or £25.00 for members anywhere in the world who agree to receive the newsletter only in pdf form by e-mail. Student membership, which includes the newsletter by e-mail only, is free. Questions about membership should be sent to membership secretary Kenneth Bodman, at kenneth.bodman@btinternet.com

Extra newsletter copies are available at £5.00 each.