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for Science and Integrity in Healthcare

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Worldwide, fundamental problems with all electronic patient records

Whenever electronic patient records (EPRs) are used for 'Patient Encounter Assistance' - rather than just for faster and higher quality reporting of laboratory tests and imaging results, or for the retrospective analysis of data for management or research, there are at least seven areas of continuing concern.

1. The inter-operability Impasse: humans (especially clinicians) talk to each other, or send complex, mainly free text, letters, faxes or e-mails to each other. At present every healthcare EPR system, everywhere, consists of incompatible databases which are created by fiercely competitive IT organisations. Not one of these, in their existing format, will ever be able to communicate with any other database as effectively as humans do every day. No programmer, however expert, can now, or probably at any time in future, overcome this fundamental problem.
2. Virtually no senior person controlling IT budgets in politics or healthcare management has yet learnt to accept the simple fact that "anyone working in the IT industry needs a feeling for the intractable nature of the industry's basic resource, and only personal experience can create that awareness."(1)
3. To be fully useful every item of EPR data must be recorded in a structured way. But converting the complexity of life into a fully structured electronic pattern almost always takes longer than jotting down free text. Big Data, Deep Mind, Artificial Intelligence initiatives and all similar algorithms depend on someone, somewhere on the front line spending extra time entering information in a structured way. And for every such item of data, account needs to be taken of the time spent entering that information. And every minute taken re-entering incompatible data is time taken away from individual patient care.
4. Humans communicate most effectively when talking face to face. But in every country, patients comment how the increasing use of VDU's detract from personal interactions with their care providers. Few in Harley Street use an electronic medical record.
5. While some things can become virtually paperless, it needs to be recognised by all those in authority that digital records cannot, and should not, totally replace paper records. The quality of paper throughout the NHS is just as important as the quality of electronic records. They work in different but complementary ways (see my paper (2) and writings of Richard Lilford, Professor of Public Health at the University of Warwick).
6. Every other industry, apart from healthcare, uses customers to enter basic data themselves. Why is this still so rare in healthcare?(3)
7. Virtually every source of IT training for clinicians and healthcare managers is totally dependent on sponsorship by those selling IT systems. As if the only source of information about drugs was that provided by the pharmaceutical industry. Not healthy. Bad Pharma but a thousand times worse!

The Result

"The blunders (of government) documented so far are small change, however, compared with the amount wasted on what has been – at least so far – the veritable ... RMS Titanic of IT disasters, the doomed-from-the-beginning

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NHS National Programme for IT ... That particular fiasco deserves a book of its own..."(4)

Insanity is sometimes defined as "Doing the same thing over and over again and expecting a different result". Yet everywhere, worldwide, those in budget authority promise "we will do better next time" before they repeat the same mistakes. The result: vast sums of taxpayers' money are still spent ("invested"?) on repeating the same mistakes again and again, in a manner which continues to cause serious damage to every part of the healthcare industry everywhere.

Our most important priority remains the need to reduce the incompatibility impasse and this can only be overcome by accepting the fact that electronic patient records will only attain their true potential for improving the quality of patient care and reducing the risk of human error, without crippling data re-entry overload when, in each speciality and sub-speciality – following intense, open, web-based discussions – bit by bit their detailed, logically and chronologically arranged, flow-patterned questions and the

full range of all allowable answer-options – including free text in appropriate set contexts (always including, whenever needed, "Unknown – Free Text" and "Other – Free Text") – are, by stages, taking into account as many interested parties as possible, individual question by individual question, internationally standardised, IN PLAIN ENGLISH.

Rupert Fawdry, FRCS (Ed), FRCOG

Retired gynaecologist, interested in medical computing since 1982, when he wrote his first computer programme to use the mother's history to predict the baby's due date.

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News

New "liquid biopsy" test currently poor at screening

Recent reports suggested that a sophisticated blood test for cancer,(1) represents an important step forward in the battle against this group of diseases. The new test, which examines cancer-related DNA and proteins in the blood, reportedly yielded a positive result about 70% of the time across eight common cancer types in more than 1000 patients whose tumors had not yet spread,

The test has been named CancerSEEK, and is being developed by doctors at Johns Hopkins University in Baltimore, who recently reported on their work in the journal *Science*. The authors of the study (and several commentators) hope that the test will be able to catch tumours early, enabling a better chance of cure. One of the authors (Dr Papadopoulos) is quoted as saying "a test does not have to be perfect to be useful". When it comes to population screening, though, the devil is in the imperfections, as we illustrate below.

In the subgroup of patients who were not yet showing symptoms, the sensitivity was reduced to around 43%. So, not only is the current version of the test fairly insensitive, but it also seems to have tempted commentators, and perhaps even the investigators who reported it, into the so-called "Prosecutor's Fallacy".

The reported false-positive rate for the test is 7 in 812. So let us do the sums: suppose that early, pre-symptomatic cancer (PSC) has a prevalence of 1 in 500 in the population (a generous estimate). So, in a group of 100,000 people, 200 will have PSC. Of these, 43%, or 86 people, will have a positive test result. 99,800 people in this population will not have PSC. They will generate false-positive results in $99,800 \times (7 \div 812)$ instances, i.e. approximately 860 false positives. Therefore the total number of positive results, true and false, will be $860 + 86$, i.e., 946.

But out of these 946 only 86, or 9%, are true positives, so if the screening programme comes up with

a positive test result in a random individual, the likelihood that s/he has cancer is just 9%, or less than one in ten!

Sadly, it's suitability as a screening test is still way into the future.

Roger Fiskén

Retired consultant, Northallerton, N Yorks

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1. Kaiser J. 'Liquid biopsy' promises early detection for cancer. *Science*, 18 January 2018. <http://www.sciencemag.org/news/2018/01/liquid-biopsy-promises-early-detection-cancer>

Dr Roger Fiskén is the newest member of the HealthWatch Committee. He trained in medicine in Oxford and Birmingham, and later specialised in diabetes and endocrinology, with further studies in the area of calcium metabolism and hypercalcaemia. He was a hospital consultant in Northallerton, North Yorkshire, from 1991 until his retirement in 2010. Since joining HealthWatch he has written for the newsletter and helped judge the HealthWatch Student Prize competition.

News

Join the HealthWatch googlegroup

IF YOU'RE a HealthWatch member, and you have an e-mail address, you're eligible to join our googlegroup to keep up to date and take part in member discussions. It's a benefit exclusive to HealthWatch members, so make the most of it. Join by e-mailing your request to membership@healthwatch-uk.org

2017 was another bad year for homeopathy

NHS PRESCRIPTIONS for homeopathy are down by 91% in the UK since 2000, says the latest post from the Nightingale Foundation, which challenges misleading health claims. The number of NHS prescriptions written for homeopathic remedies has slumped to just 3% of what it was at the height of its popularity in the mid-1990s.

HealthWatch's David Bender noted on the googlegroup that, if homeopaths believe less is better, they might welcome this progressive dilution of their sales.

<http://www.nightingale-collaboration.org/news/195-yet-another-bad-year-for-homeopathy.html>

AllTrials unreported clinical trial of the week

EVERY WEEK the *BMJ* is naming and shaming a clinical trial that is late in reporting its results. Non-reporting of

clinical trials is a global health problem, because it deprives healthcare professionals of the evidence they need to make treatment decisions.

The US Food and Drug Association recently updated trial reporting requirements under the FDA Amendment Act (FDAAA 2007), so that now certain types of clinical trials registered in the public database ClinicalTrials.gov must report results there within 12 months of trial completion. The FDA are not publicly tracking compliance, so Ben Goldacre and the EBMDatalab team at Oxford University created the FDAAA TrialsTracker tool to do this (see <http://fdaaa.trialstracker.net/>). Launched in January, it currently shows 120 trials are overdue or have reported late.

The initiative is working already. When the team flagged up a trial from researchers at Columbia University on pain relief in labour, a week later the researchers submitted results. Support the campaign at:

<https://www.justgiving.com/campaigns/charity/senseabout-science/alltrialsmissingtrials>

BMJ Blogs, 29 March 2018

<https://blogs.bmj.com/bmj/2018/03/29/it-is-time-to-fix-the-problem-of-unreported-clinical-trials/>

Chairman's report

Making our vision a reality

This year we have been working to explore further and implement ideas that came out of last year's vision meeting, as well as continuing our ongoing work in diverse areas. I am grateful as ever to the work of the committee. To David Bender, our secretary, Anne Raikes our treasurer, Alan Henness our membership secretary, Debra Bick, Malcolm Brahams, Diana Brahams, Keith Isaacson, John Illman, John Kirwan, Les Rose and Philippa Pigache, with co-opted members Tom Moberly and student representatives, Sofia Hart, Andrew Fulton.

We have sadly said goodbye to Diana Brahams and Debra Bick this year, who have all contributed a lot to the committee over several years, even decades. We are looking forward to our new members joining us this year. Some of the committee who live far outside London have been using Teleconferencing to contribute to the meetings.

On the afternoon before last year's AGM our vision meeting produced a great many helpful ideas. The committee had an extra ad hoc meeting to discuss these, and voted on priority areas to focus on: improving communications, specific projects, and student outreach.

As a result we have improved the website, and decided to publish our excellent newsletter online immediately so that it is accessible to everyone. We now have online membership, and I should remind those still on standing orders to ensure they are paying the current fee of £30.

Twitter is an increasingly useful way of communicating what we are doing. We are also pursuing setting up HealthWatch student groups based in medical schools, in the hope that they will be able to pursue projects in line with our aims, improve evidence based teaching in

medical schools, and maintain a long term commitment to our aims and objectives.

We are also aiming to pursue a defined range of ongoing projects, alongside trying to improve our ability to respond quickly to consultations or issues picked up in journals or the media as a formal HealthWatch response.

Les Rose has continued to pursue the CPR2 project with trading standards. The Trading Standards Review journal has been reluctant to publish the results of the study, seemingly because they are perceived as critical of Trading Standards. We are currently working on a conciliatory approach which sees that they are working on our side, but are seriously under-resourced, which we hope might find ways of helping Trading Standards to find it easier to evaluate fraudulent claims and implement decisions, where for example the same product is simply removed from one website and sold on another.

We have submitted responses to consultations both as individual members of HealthWatch and as an organisation. Les Rose has worked hard to persuade the

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Charity Commission to consult on homeopathic charities and how they should be evaluated. We produced a number of responses in great detail on this. We have also collaborated with TranspariMed and others on a consultation on the need for better regulation of research using an National Audit system for clinical trials.

We proposed a debate on the evidence for harms and benefits for e-cigarettes as a globally important public health question. However, we were unable to find debaters against e-cigarettes, and so abandoned the debate. We are currently looking for topics for a debate or discussion for Spring next year, and would value any suggestions.

We are hoping that our website will make it easier for members and others to contribute to HealthWatch activity. If you haven't checked the website recently then please have a look and complete the focus questionnaire which is

an opportunity to feed in your ideas. Please also consider joining the googlegroup to keep up to date with developments. We have significant financial resources to spend on projects in line with our aims. If you have ideas then please apply for this funding, or feed in your ideas for our developing student groups to work on.

We believe that our focus on strategy and systems within HealthWatch over the past year will increasingly enable us to have a wider impact, and to draw in a rejuvenated membership of students and new doctors who are as passionate about evidence as we are.

James May

James May now hands over as chair of HealthWatch to Susan Bewley.

HealthWatch Award winner 2017

Poking your nose in where it's not wanted: the dark side of investigating healthcare

The 25th HealthWatch Award was presented to the former *BMJ* Investigations Editor Deborah Cohen, in recognition of her courageous reporting of medical issues in the face of attack from vested interests. She received her award from HealthWatch president Nick Ross at the 2017 HealthWatch AGM on Tuesday 17 October 2017, and the following text is adapted from her presentation.

It has meant a lot to me to know that others recognise that you're reporting in the face of vitriol and attacks from vested interests.

The first big story I did was in 2009. HealthWatch members will already be familiar with the Tamiflu story



and how the Cochrane Collaboration struggled to access clinical trial data for their review of this flu drug. The investigation into the missing data ended in my in-tray. I have degrees in medicine and medical journalism, so it was something to get my teeth into, and it turned out to be an interesting journey. As you'll recall, the lead authors of the clinical trials had told us they didn't have access to the primary data. The manufacturers, Roche, gave us observational data. But not the clinical trial data.

One of the privileges of working at the *BMJ* is you have access to some really good academics who will drop everything to help you out – they know who they are. So we set them to work making sense of this observational data that we had. Roche maintained that Tamiflu not only reduces the incidence of secondary complications by 67%, but it also reduced the rate of hospital admissions by 61%. But when we re-analyzed the observational data we found it didn't say that. We published our report,⁽¹⁾ and the allegations we made were quite controversial. No satisfactory explanations had been given for the missing clinical trial data. Yet there were journalists who'd been covering the flu pandemic for a while, who'd taken it at face value that Tamiflu must be effective enough to merit the UK government stockpiling it – at a cost of £424m between 2006 and 2013.

Conflicts and controversies

In the course of our search we came across whistleblowers who had written up the clinical trial paper that was published in *The Lancet*. We were told they'd been instructed to include key words and phrases that were important for the marketing of the drug.

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It also became apparent that the people who were involved with the companies marketing the product were also key advisors to the World Health Organization (WHO), the European Medicines Agency (EMA), and others. Roche, together with some other manufacturers of influenza drugs, are the funders of a group called the European Scientific Working Group on Influenza (ESWI). This industry-funded group wrote WHO's first influenza pandemic preparedness plan. So, as a result of this investigation we did a follow up piece about the conflicts of interest of the advisors.(2) This proved even more controversial than the first, and we came under attack. The WHO would not release any information about whether their advisors declared conflicts of interest or not. The scientists said they had, but WHO would not confirm or deny.

Embarrassingly I ended up on an American "shock jock" show, where they took the line that this is a big pharma conspiracy, which was very far from what we had intended with this story. We'd been very careful to make the point that when you are making policy decisions, which could have huge impact in terms of finances and patient harm, should you really be using the people who have been marketing the drug? You would think not.

But the attacks continued. Nature did an exposé,(3) and people tweeted that our research had been discredited. In our article there had been a sentence that maybe could have been worded more carefully, so we ended up conceding one or two points in relation to the story, and the result was taken as an admission that our story was wrong, starting a back and forth between Nature and the BMJ. It became one of the most read articles on the BMJ website at the time.

Hip devices

The next thing we looked into was medical device regulation. We started with the European Union directives, which took some reading. Ours was a joint investigation between the BMJ and Channel 4's *Dispatches*, so we had a whole team to help us go through the directives. Then in 2011 a very useful study was published by a group at the Cleveland Clinic, in Ohio. They looked at the US Food and Drug Administration (FDA)'s regulatory system for medical devices. The FDA have two processes, one is pre-market authorisation, and the other is called 510(k). To get a device onto the market using pre-market authorisation you have to have clinical evidence, such as from randomised control trials, or a case control study. But for 510(k) you only need to show something called equivalence, which means that your new device is "substantially equivalent" to an old one, a predicate device, that is already authorised. It is possible to trace the history of some 510(k)-authorised devices, and to track the tweaks and changes that have been made to the design over time, so that a device approved in 2015 might not have had any clinical studies to support it, and gone through so many changes since, say, 1980, when the original version was approved, that you can end up with

virtually a whole new device but without any clinical evidence for it. The Cleveland team's study found that two thirds of device recalls were in respect of devices that had gone through the 510(k) route, that is, there was no direct clinical evidence for those versions of the devices.(4)

Working with the Centre of Evidence based Medicine at Oxford University, we thought it would be interesting to replicate this study in Europe. But we couldn't. Because we kept coming up against the words: "commercial, in confidence".

Devices come in different risk categories. In Class I, you have low-risk items like plasters and syringes; in Class II there are insulin pumps. Class III is for hip implants, pacemakers, things that need surgery to get them in place. I phoned the Medicines and Healthcare Regulatory Authority (MHRA) and asked if they had a list of Class III devices that are used in the NHS.

And they said "No". No such list exists.

We knew that some implants must have been causing problems, so we put in a freedom of information request

to look at reported harms. Again, "commercial in confidence". We learned that under the Freedom of Information Act you can get clinical data related to pharmaceutical trials, but you can't get it for medical devices.

So, we were thwarted from the outset by a lack of transparency. We wrote a story(5) about a hip implant called the ASR, which is made by DePuy, a subsidiary of Johnson & Johnson, and which was recalled in 2010. The ASR was used for two types of orthopaedic surgery – total hip replacement (ASR XL) and hip resurfacing (ASR resurfacing). The ASR in the United States had gone through 510(k) for total hip replacements. For the hip-resurfacing application it should have gone through the full pre-market authorisation process, but the FDA had called a halt to the approval because of problems with the trial. That didn't happen in Europe. It has been used in tens of thousands of patients.

We later looked at all large diameter metal on metal total hip replacements. We reviewed the medical literature, and whole 510(k) daisy chains, and found that among an entire class of implants there was no publicly available clinical data to support their use. Now, bear in mind that these are made of cobalt and chromium. In the 1970's and 1980's surgeons were debating the toxic effects of cobalt and chromium, and in 2007 a comment piece in the *Lancet*(6) pointed out that little is known about the transport, distribution, excretion of metal ions in the body; toxic effect thresholds have not been characterised. So wouldn't you think there would be a need to proceed with caution? We know a lot about the local effects of metal ions in the body, but about the systemic effects we know very little because if we're talking about pharmacovigilance of medical devices like you have with drugs, well, it just doesn't happen.

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"... under the Freedom of Information Act you can get clinical data related to pharmaceutical trials, but you can't get it for medical devices"

Under cover

My question was, in this article, surely we should proceed cautiously with these devices, given that there is no known toxic threshold for these compounds? In the media it became, the BMJ hip replacement cancer scare, which had not been our intention at all. Suffice to say, that the bullying I encountered as a result gave me a glimpse into the business side of orthopaedic surgery and how things run when there is a great deal of money at stake, and some of it is very unsavoury.

After that, we went under cover. I should point out that it is actually really hard to get clearance to go under cover. There has to be a strong public interest reason, and you have to demonstrate that you can't get the information any other way. We had a good reason – this was health. We created a fake metal hip. We called it the TMH (total metal hip) and tried to get our metal hip onto the market. We had a fake dossier, and gave it some disastrous data, failures, ions all over the place.

The system here in Europe is that you have to go through what are called notified bodies. There were about 70 of these, they are private organisations, and these are where manufacturers go to get a CE mark. Once they have this mark they can sell the device anywhere across Europe. The various regulators in the different countries then regulate those bodies. It's an incredibly complex system.

You have to pay these bodies to review your dossier, before they decide if it should receive a CE certificate. That already seems like a conflict of interest, as these companies are paid for approving the device and then are paid again to do follow up audits every few years. An officer at one of the notified bodies in the Czech Republic admitted to us that it is “on the side of manufacturer and their products, not on the side of patients.”

We set up a fictitious company called Changi, and we hawked our new device around notified bodies, pretending to be their PR people. We found that not only are regulators out-sourcing the regulation of medical devices to private companies, but some of these private companies are further out-sourcing their device regulation activities to other private companies. We found ourselves at a branch of a Czech notified body which was in South Korea, where a small group of companies came together to operate as a one-stop-shop. Device manufacturers would go to one for advice about how to create their dossier, then another to receive the CE certificate, and then the next company offered marketing. We were told that it is easy to get products approved in Europe, and they are not worried about inspections by European officials, though they were really scared of the FDA.

We got our design approved for a CE certificate for our non-existent hip implant. That investigation had an impact.(7) We presented our evidence at the Science and Technology Committee and at the European Parliament when they were updating their medical device regulations.

Sugar and water

We were at a meeting just before the 2012 Olympics, when sports medics told us that sports drinks are one of the most controversial things ever. What could be controversial about sweetened water? Again working with the Centre of Evidence based Medicine, we decided to take the top 10 best selling UK and US sports and fitness magazines, and pulled out the adverts to see what health claims they were making for sports drinks. Then we looked at the references to see what evidence we could find to support them. Then we tried the manufacturers' websites to find references, before approaching the companies for evidence to support their claims.

We were told things like, water doesn't quench thirst. Anecdotally, we heard that one company was telling kids that if they drank water rather than sports drinks they would get cerebral oedema. An idea had been created, that of 'exercise induced dehydration'. Now, any doctor who has treated someone with genuine dehydration, well, it's not quite about jumping on the treadmill and getting a bit thirsty. But this idea had been created that if you exercise you get exercise-induced dehydration, and the solution is to drink more sports drinks. This then led to a genuine

health concern which is, hyponatremia – a reduction in the body's electrolyte levels due to drinking too much, which was leading to cerebral oedema, and there was a study in the *New*

England Journal of Medicine that looked at the Boston Marathon and people who had had exercise-induced cerebral oedema, because they'd actually been taking in too much fluid.(8)

The backlash against our “The truth about sports drinks”(9) was incredible. The attacks kept on coming. One company held up what they said were over 100 clinical trials that underpinned their science. We critically appraised all of them, and found that most were poor quality and didn't support the main claims made.

Fertility clinics

We did a programme with BBC's Panorama about in vitro fertilisation (IVF).(10) You get to a certain age and lots of your friends are going through IVF, and if you listen to their stories you find they're all having different kinds of treatments and also being sold extras, on top of IVF, so-called “add-ons”. We again teamed up with Oxford University, we scraped lots of websites from fertility clinics looking at the claims made for add-on treatments, and then looked at the evidence. We found very few were able to support their claims that these add-ons could actually improve your chances of having a baby. We used undercover again – and came under criticism for this – to look at the lack of fully informed consent for these treatments, and the lack of evidence, and how poorly regulated they are by the HFEA. Needless to say we experienced a backlash from private clinics in the UK.

There are times when you get home, shut the door, and you're looking at the door, wondering what's going to happen next. You can take the professional attacks, but worse than that is the sexual harassment. As a female

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“We got our design approved for a CE certificate for our non-existent hip implant.”

reporter on a heavyweight subject I have my authority questioned, because I'm young and female, and I am constantly challenged about my ability to carry out these investigations. It's a constant battle, and that is probably the biggest challenge in this area.

Based on Deborah Cohen's presentation at the HealthWatch 2017 AGM, adapted by Mandy Payne

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Alternative therapies

The 'rise and rise' of Traditional Chinese Medicine

When the Australian Government signed an \$18bn Free Trade Agreement with China in 2014, Traditional Chinese Medicine (TCM) was singled out for special attention.(1) However, with no definitive evidence to support claims that TCM can cure any disease or disorder, why is Australia embracing TCM?

TCMs are among the fastest growing 'health' products. The growth of TCM in Australia has been facilitated by both governments, by international agencies, including the World Health Organization (WHO), by our regulators and even by our universities.

TCM is a \$40 billion industry in China.(2) TCM products are among the most profitable of all Chinese exports. However, it has been on the decline in China in recent decades, with some estimating that as many as 80% of Chinese people now rely on western treatments.(3)

In 2016, the State Council released a "Strategic Development Plan for Chinese Medicine (2016-2030)"(4) seeking to spread knowledge of TCM into campuses, homes and abroad. In July 2017 a new Chinese law, promising equal status for TCM and western medicine, came into effect. Provisions include encouragement to hospitals to set up TCM centres.

China is using its national power "to protect its interests and people overseas; to gain leadership of international governance".(5) Huang Wei, the deputy director of the National People's Congress Standing Committee's commission for legislative affairs, stated "The new law on traditional Chinese medicine will improve global TCM influence, and give a boost to China's soft power".(6)

Traditional Chinese Medicine is not safe. In 2014, 230,000 reports of adverse reactions were received by China's 'National Adverse Drug Reaction Monitoring'. In 2015, DNA analysis of imported TCM products found that

nearly nine in ten contained some form of undeclared substance – including strychnine, arsenic, snow leopard, pit viper, warfarin and Viagra.(7) A 2017 review of nearly 500 TCM products by Hong Kong hospital toxicologists found that most contained modern, pharmaceutical-grade anorectics, stimulants and anti-inflammatories.(8)

The 'Chinese Dream' is to revitalise their nation.(5) Part of their strategy is to initiate children in the traditional practice. Despite many parents' seeing it as useless, and teaching it a waste of precious school time, 12-year-olds are being taught about TCM and how to administer

acupuncture – seen by government as a way to boost confidence and pride in China. Over 700,000 TCM textbooks are being distributed to schools.(9)

Acupuncture is included within TCM, but it doesn't work.

Cochrane reviews are the 'Gold Standard' for evidence-based medicine. Almost 50 reviews have failed to find robust evidence. A rigorously scientific review of the evidence by non-acupuncturists concluded that it was a theatrical placebo.

America's National Institutes of Health looked at 70 systematic reviews of TCM treatments. In 41, the trials were too small or badly designed to be of use. In 29, the studies showed possible benefits, but problems with sample sizes and other flaws meant that the results were inconclusive.(10) Most systematic reviews suggest that there is no good or consistent evidence for effectiveness, but there are too few high-quality studies to make a

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definitive statement. And because negative results tend not to be published, the majority of studies from China report efficacy of TCM.

Acupuncture is practised globally in 103 countries besides China.(11) In the late 1970s, WHO recognised the ability of acupuncture and Oriental medicine to treat nearly four dozen common ailments.(12) Quoted worldwide as “evidence”, a 2002 WHO publication on acupuncture claimed that acupuncture was “clinically proven to be effective” or “effective” for over 90 diseases and disorders.(13) These include depression, dysentery, induction of labour, rotating babies in the breech position, rheumatoid arthritis, stroke and whooping cough.

For the past decade, Margaret Chan was director-general of WHO. A Chinese-Canadian physician, she uses TCM. She urged the Chinese government to promote TCM world-wide, claiming it was a way to “reduce the burden on health services”.

The regulators are supporting TCM claims. As part of the Department of Health, the Australian Therapeutic Goods Administration’s role is to safeguard the health of the Australians “through effective and timely regulation of therapeutic goods.”(14) However, the latest proposed changes to their advertising code include over 1000 TCM and traditional indications, such as “Harmonise middle burner (Spleen and Stomach)”, “Unblock/open/relax meridians”, “Balance Yin and Yang”, “Renal tonic” and “Helps healthy liver regeneration”.

Collaboration with Chinese institutions is bringing millions of dollars into our universities. They aim to integrate TCM “research into a clinical setting”, supposedly to “accelerate the development of more effective treatments for the most pressing and costly chronic health problems facing the world”.

Here in Australia, Friends of Science in Medicine has made some progress. The links to the acupuncture report have been removed from the WHO website. Following more than 1,000 complaints by Friends of Science in Medicine (FSM), in July 2017, the Chinese Medicine Board of Australia (CMBA) stated publicly “acceptable evidence to support advertising claims needs to be based on findings obtained from quantitative methodology such as systematic reviews of randomised, and high quality controlled trials”.(15) The Australian Health Practitioners Regulation Agency,(16) whose role is to support the National Boards in their primary role of protecting the public, is currently assessing 477 complaints about Chinese medicine practitioners’ advertising – representing 10% of CMBA registrants.

With no way to modify TCM practitioners’ scope of practice, however, it will remain ‘business as usual’ for those who venture into their local TCM clinic.

China wants to grow its exports of TCM(17) by influencing governments, universities and regulators. Australian business wants to tap into the \$170 billion global TCM market.(18) At the 19th Chinese Communist Party Congress, President Xi Jinping stated that his vision was to “continue to increase our country’s influence”. This is not about improving our health and wellbeing, but about growing Chinese business influence internationally and

boosting the Chinese economy. The chronically ill and other vulnerable patients pay the price.

Loretta Marron

Friends of Science in Medicine can be found at <http://www.scienceinmedicine.org.au/> where you can also subscribe to their e-mail updates and newsletter.

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Students

Sixteen years of the HealthWatch Student Prize

How can the public be protected from ineffective and potentially harmful treatments? They and their healthcare professionals are inundated with reports of new and better products that are claimed to have been “clinically proven”, when on closer examination the evidence to support such claims is often unreliable and misleading because of poor-quality research.

For the past 16 years, the HealthWatch Student Prize competition has been gaining insight into the way our future healthcare professionals are learning to distinguish between good quality research and poorly designed studies. Each year students are invited to appraise four hypothetical research protocols and rank them according to which is most likely to provide a reliable answer to the stated aim of the trial. The protocols are designed to contain scientific, methodological and ethical flaws. Students have to write a short essay to explain their reasons for assigning their ratings and suggest ways in which the protocols could be improved.

This year's HealthWatch Student Prize protocols

- Mefenamic acid for pain control in IUD (Intra-Uterine Device) fittings
- Cranial osteopathy for childhood colic
- Breast screening age extension programme
- Raspberry leaf for use in pregnancy

The competition is open to all medical, dental, nursing and midwifery students, and students of professions allied to medicine, in the UK. To qualify for a prize, students must achieve at least 70% of the maximum possible score, based on correctly commenting on the presence or absence of key protocol design features. All entries from those who assigned the protocols in the correct order, are assessed blind by a panel of judges. Winners receive a cheque for £500, and up to five runners-up receive £100 each.

This year's results are an improvement over last year's in that, of the total number of 73 entries, 31 (42%) had placed the protocols in the correct order, whereas in 2016 only 8 (12%) of 67 students had done so. It was encouraging to note that the 31 correct entries included three nurses, of whom one received a 'special commendation' for her extra efforts, whereas no nurses ranked the protocols correctly in 2016. It was also noted that this year, more students had paid attention to ethical

considerations, commenting on the absence of ethics committee clearance and lack of informed consent in some protocols, compared with previous years. Many correctly criticised the 'Breast Screening Age Extension' protocol for only having 'implied consent' and considered this to be unacceptable. These are welcome observations, as are students' comments on how the protocols could be improved, e.g. by giving clearer entry criteria and better-defined endpoints (Raspberry study). These and other comments suggest that students have given careful thought to protocol-design, but there remains apparent confusion among some students over specific protocol features, like what constitutes 'informed consent', or what is meant by 'selection bias', wrongly assuming this could be overcome by means of randomisation. Despite this year's generally encouraging results, there remains much need for better education of healthcare professionals, including nurses, who frequently are the first port of call for patients asking about 'the latest wonder-drug' publicised in the media.

To the winner and runners-up, we extend our admiration and congratulations and wish them well in their careers.

*Walli Bounds, SCM, Hon.FFSRH
Student Prize Committee, HealthWatch*

Congratulations to

Winner Julius Kremling – Medical Student, Ruhr University Bochum, Germany

Runners-up

Dominic Allen – Medical Student, Imperial College London

Jungwoo Kang – Medical Student, Queen Mary's College, London

Sumir Chawla – Medical Student, University of Southampton

Special Commendation Arleah Laidley – Nursing Student, University of Southampton

HealthWatch extends its thanks to Cambridge University Press for their generous sponsorship of the 2017 competition. Our thanks also go to David Bender, Walli Bounds, Roger Fiskens and John Kirwan for administrative and scientific contributions.

Poem

The Quack Doctor *a poem by Caroline Richmond*

For I will consider the quack doctor, for his treatment cures every symptom known to humankind.

For this he performs in ten degrees.

For Firstly, he parades a flock of grateful patients who insist that they have been ill and misunderstood for years but now have been cured.

For Secondly, he works outside the medical establishment and the National Health Service, and weeps into his bank statements for grief that his treatment isn't available to all sufferers.

For Thirdly, he claims that the National Health Service would save billions of pounds if they adopted his treatment.

For Fourthly, his treatment is not reimbursable by the private health insurance companies, though he may tell intending patients that it is.

For Fifthly, he adopts the posture of martyrdom when other doctors cast doubt on his methods.

For Sixthly, he never subjects his diagnoses or treatments to the scrutiny of his peers.

For Seventhly, he says he is kinder and more understanding (more holistic) than other doctors, who are brutes.

For Eighthly, he diagnoses his specialty condition in every punter who comes through his door.

For Ninthly, the nature of the treatment is such that the punter has to keep coming back.

For Tenthly, he fixes up articles about his miracle cures in the newspapers, contravening the General Medical Council's regulations on canvassing.

For he usually gets away with this.

For the GMC takes no action unless someone swears a complaint before a lawyer, which they rarely do.

For he will call himself a specialist even if he has the minimum qualifications required to practise medicine.

For he is a cuckoo who invades the domains of qualified specialists.

For his chosen territory may be allergy, cancer, neurology, aging, psychiatry, rheumatology, or neurasthenia.

For, whichever it is, he will prescribe a diet which is ghastly and quite impossible to follow.

For he understands the nature of placebo effects.

For, when the patient relapses, he can say that she didn't follow the diet properly.

For it is a sad fact that the patient is usually a woman.

For women who are put upon by their families and others seek refuge in sickness.

For when the punter is a man he is usually introverted and hypochondriacal.

For the quack's diets are considered avant-garde by everyone except nutritional therapists.

For he will prescribe absurd doses of food supplements, for which he is paid commission.

For he will dazzle his patients with pseudoscience.

For if he is a cancer quack, the patients spend the rest of their lives visualising their white cells and chopping up carrots.

For if the cancer returns he can say they did not visualise their white cells clearly, or chop enough carrots.

For if his specialty is psychosomatics, the patients initially improve, and he puts them on a stricter diet and sells them more supplements when they relapse.

For if it is psychosis, the patient eats the diet and is still mad.

For if it is arthritis, the patient first attends when the pain is severe and improvement is therefore likely to follow.

For when the pain relapses they will return for more treatment.

For if it is neurology or aging, the patients will perceive themselves as stronger, or looking younger, for a few weeks.

For if he chooses food allergy he may give people appalling injections over large areas of their skin.

For this is certain to make anyone come up in weals.

For, in his pseudoscience, he may put their blood cells to fight foods in a test-tube, or sell them bogus homemade neutralising vaccines.

For he may stretch his patients' credulity, putting food in their belly-buttons and seeing if their limbs go wobbly.

For he may suspend their credulity still further, diagnosing diseases by waving a pendulum over a sample of blood or hair.

For he may diagnose hypoglycaemia, myalgic encephalomyelitis, electromagnetic sensitivity, or *Candida albicans* for good measure.

For he will say their immune system is depressed.

For he will take unethical commissions by selling them vitamins, or minerals, or enzyme tablets.

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For though his papers are rejected by journals that have high standards and pay no fee, he and his allies may start a journal of their own and distribute press releases about it.

For he makes good money writing paperback books, which are widely read and bring in more punters.

For his books are paraphrased from the books of his fellow quacks.

For these books are easy to write, and reinforce the message of the other books.

For though I have described the quack as he, some quacks are women.

For history shows that quacks often have the support of the highest in the land.

For the rich, the royal, and the famous seem often to take pride in folly.

Caroline Richmond
Author and medical journalist, London

This verse was originally published in The Lancet, vol 336, pp 1367-8, on 1 December 1990, and appears here with the kind permission of the author. As she explains, it is a parody of "my Cat Jeoffry", part of "Jubilate Agno" by Christopher Smart (1722-1771). Smart, educated at Durham School and Cambridge, published two volumes of poems; a paraphrase of the psalms, the "Song to David", to King David as poet and author of the Psalms; and translations of Phaedrus and Horace. His poem, the "Hilliad", parodied Alexander Pope's translation of the "Iliad" and satirised John Hill, a quack doctor. Smart went mad and died, a pauper, in Bedlam.

Last word

Erotic tendencies of Trappist monks

OK, that caught your attention – all will be explained later...

When I started my PhD in 1968, the only way to do a literature search was to go through your predecessor's thesis and supervisor's grant proposal, then resort to Chemical Abstracts or Index Medicus. It took me some time to realise that the index to Chemical Abstracts was the last of twenty or so large thick volumes for each year.

This meant looking up key words in the index, then humping each (usually dusty) volume onto the desk and look for the relevant abstract numbers. At least this gave me the abstract of the paper, so I could decide whether it was worth trawling the library shelves or not. Index Medicus only gave references, not abstracts, so at least there were fewer volumes, but the print was small and it was a very tedious task.

The only way to keep up with the current literature then was to go to the library and scan the contents pages of relevant journals, or wait for the departmental copy of Current Contents to circulate to me. Current Contents was a small publication (I think monthly) that printed facsimiles of the contents pages of a large number of biomedical journals – not all of which were in our library. Then someone invented the Key Words in Context (KWIC) index. The idea was that it took the title of a paper and shifted the reading frame one word (or part word) at a time. Under this list of frame-shifted titles was the journal reference. The late Prof John Jepson was an extremely well read person, and one day shouted out in delight at a paper that appeared in the KWIC index as "Erotic Tendencies of Trappist Monks". He dashed over to the library, retrieved the journal and found the full title was "Atherosclerotic Tendencies of Trappist Monks". Much less exciting. (This was the period when people were looking for new factors that appeared to be associated with atherosclerosis – I think they had about 600, one of which

was religious observance, which was apparently protective).

Many years later, when I was researching material for "Nutrition – a Reference Handbook", published in 1996, I still had to use Index Medicus, then chase to several libraries to find the journals. Indeed, about that time I was asked to referee a paper that reported the effects of an altered diet on experimental animals. This manuscript did not report the composition of the diet, but cited another paper (by the same authors). That journal was in a different library, and did not report the diet composition, but cited yet another paper, in a journal that was in a different library. That paper led me to yet another library, a 20 minute walk away – and it was a cold January day. When I found no information on the diet in that journal, I decided that enough was enough, and I recommended rejecting the paper, since we were not told what diet had been fed to produce the results.

Now, of course, it is very much easier. The third edition of 'Amino Acid Metabolism' (2012) contains over 50 pages of references, as well as half a page of 'further reading' at the end of each chapter – and I did not set foot in the library at all. Bibliographic software like EndNote and Reference Manager allows you to search PubMed or other on-line sources and download the reference and abstract; sometimes there is also a direct link to the full



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text of the paper. Even better, you can format the references in any one of many different styles for different journals, then set up a bibliography in whatever order you want or need. You can even 'cite as you write' by letting EndNote link to Word.

Some years ago a referee criticised one of my papers for omitting to cite two "key publications in the field", saying that in these days of PubMed there was no excuse for this omission. Of course, I sought out and read these two papers, then cited them in the revised manuscript. In my covering letter I apologised for the omission, but pointed out that PubMed at that time only went back 10 years, and these two papers were older than that.

Recently, ResearchGate has started to email me several times a week to tell me that someone has just cited or read one of my publications. I have been surprised to see citations of some of my papers that were so old that I had forgotten that I had done the work. Somewhat depressingly, each time they tell me about these citations, they ask me to invite my co-author(s) to join ResearchGate – would that I could with the three now deceased co-authors.

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We stand for:

- The assessment and testing of all medical and nutritional treatments, products and procedures
- Consumer protection in regard to all forms of health care
- The highest standards of education and evidence-based health care by practitioners
- Better understanding by the public and the media of the importance of application of evidence from robust clinical trials

We are against:

- Misleading advertising of health products
- The sale of unproven remedies to the vulnerable and desperate
- Unethical marketing by pharmaceutical companies
- Misconduct in clinical trials
- Media misinformation on health and nutrition
- Government promotion of health and screening programmes unsupported by evidence

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