> I'm not so interested in who is telling me that they are a leader. I'm more interested in who does things or says things worth noting or emulating

NO HOLDS BARRED Margaret McCartney

Troubling leadership

Keith McNeil resigned as chief executive of Addenbrooke's Hospital in 2015 shortly before the Care Quality Commission rated it inadequate.[1] He was popular and highly regarded. But, like many other chief executives before him, he resigned after a short tenure, having found nurse recruitment expensive and difficult and in "challenging" financial circumstances.[2 3] His colleagues wanted him to stay. If the NHS is so toxic that the leaders who are wanted can't stay, we have a problem.

Calls to be a "leader" are endemic in the service. The NHS and a plethora of private providers run many courses aimed at clinicians and health service managers. Some are costly. Some promise career advancement.

I know many NHS staff with "leader" in their job title who are kind, clever, and fantastic at their job. But what I find troubling is not just the lack of evidence for meaningful outcomes in such courses but also the concept and practice of "leadership" in the first place.

The NHS supposedly has a shortage of leaders and has created a Leadership Academy. A tension exists, however, between leaders with an agenda based on evidence, professionalism, and experience, and "leaders" with tasks to implement, whether or not this is the best thing for patients and staff.

Broadly, leadership courses seem to say little about how to evaluate the evidence for the changes that are being implemented. Many contain pseudoscience. Not long ago, I discussed the evidence for a service re-disorganisation with a "leader for change management." I explained how this intervention had been tried before, had made things worse, and had eventually been changed back. But it was clear that her job was to enforce the change—not to decide whether it was worth making.

The people who have led me to think better and more clearly—or, uncomfortably, about what I'm doing and why—have held several roles, and many have been at odds with the establishment.

The author Samuel Shem explained hospital medicine to me when I was a junior and still has much to say about the goodness of general practice ("Connection heals. Even in dying").[4] In his 1978 novel *The House of God* he explained that compassionate care involves breaking senseless rules: "The delivery of good medical care is to do as much nothing as possible."

Shem is an inspirational doctor, but he was initially shunned by a medical establishment disgusted at the curtains being lifted on greedy, hypocritical healthcare. Unpopularity in some quarters may be a sign of someone who, if not defined by the NHS as a leader, should be.

Margaret McCartney is a general practitioner, Glasgow
margaret@margaretmccartney.com
Follow Margaret on Twitter, @mgtmccartney
Cite this as: *BMJ* 2016;353:i2645

MORE ARTICLES ON THEBMJ.COM ABOUT NURSE STAFFING LEVELS (See David Oliver, p 316)

- Fall in 1:1 nursing ratios in neonatal ICUs is linked to higher death rate (*BMJ* 2016; 52:i828)
- Higher nurse to patient ratio is linked to reduced risk of inpatient death (*BMJ* 2016;352:i797)
- Government blocked guidance that urged minimum staff ratios in emergency departments (*BMJ* 2016;352:i385)

PERSONAL VIEW Silvio Garattini

The EMA is too close to industry

The European drug regulator still fails to put patients' interests first

Fifteen years ago I raised criticisms about the policy and attribution of the then young European Medicines Agency (EMA) and its Committee for Medicinal Products for Human Use (CHMP).[1]

With the same aim of encouraging this institution to put the interests of patients and public health services first, I now offer an updated picture (see table).

The current supervising directorate general of the European Commission is certainly more appropriate than before: first it was DG Enterprise, which also represents drug companies—a considerable conflict of interest. Today it is DG Sanco, which is responsible for health and consumers.

Withdrawal by a company of an application for marketing authorisation no longer precludes the publication of a negative opinion by the CHMP with its reasons. And now, when the CHMP does not unanimously approve a medicinal product, it publishes the minority opinion.

Access to data

Each dossier supporting an application for a drug's approval used to be completely confidential; now the public has some access to the data, for instance in redacted clinical trial reports.[2] Making dossiers and assessment processes public would improve openness further.[3 4]

Some of the EMA's problems have not been solved, and the situation is essentially unchanged. For example, the criteria for evaluating drugs are still quality, efficacy, and safety, but a previous suggestion was to include "added therapeutic value" to require comparisons with the best treatments available for the same indication. Today it's still possible to obtain approval without studies of comparative efficacy: trials of superiority versus placebo and of non-inferiority versus active comparators are still welcome, as is the clinical evidence supporting marketing authorisations that relies too often on surrogate outcome measures.

Nobody receiving 80% of a salary from industry would be admitted to any committee that deals with drug evaluation

The fact that independent pivotal trials are not required favours an incredible conflict of interest: even today, only studies promoted by industry are accepted for evaluation. The documentation accompanying the marketing authorisation—that is, the summary of product characteristics and the leaflet—is still prepared by the industry and omits important information for doctors and patients, such as comparison with other drugs of the same therapeutic class.

Unfortunately, some aspects of the EMA are getting worse. For instance, the contribution from industry was once about €39m (£30.2m; $44.1m), equal to 71% of its whole budget; today it is about €250m (83%). This dependence is incompatible with the

ACUTE PERSPECTIVE David Oliver

Nurse staffing levels are still not safe

Setting out his vision to make the NHS "the safest in the world," Jeremy Hunt has discussed the need for a less bureaucratic, more people centred system using data.[1] But endless bureaucratic flip-flopping and political meddling over safe nurse staffing levels illustrate the emptiness of his rhetoric.

In the final 2013 report of his public inquiry into Mid Staffordshire Hospital,[2] Robert Francis specifically recommended that "minimum safe staffing and skill-mix levels should be drawn up by the National Institute for Clinical Excellence [NICE] and policed by the Care Quality Commission

Use local discretion over the safe staffing evidence after all

[CQC]."[3] In 2013 the Department of Health evaded this.[4] After pressure in professional publications,[5] it reluctantly agreed to commission NICE,[6] which works independently of government and issues statutory and credible guidelines.

Safe nurse staffing was a concern before Francis and beyond England. For instance, the Royal College of Nursing had produced evidence reviews and recommendations.[7 8] The Safe Staffing Alliance has campaigned tirelessly.[9] The Welsh Assembly has a safe staffing bill.[10] NICE had a body of academic research to call on, and the University of Southampton reported a detailed systematic review.[11] This analysed links between patient outcomes, care processes, nurse staffing, and skill mix in 35 primary studies, with clear associations demonstrated.

Then NHS England subverted NICE's traditional independence by effectively stopping its work, getting its chief nurse to defend the decision to her peers.[12] This was driven by fear that a national "formula" might prove unaffordable and inflate costs, but this wasn't explicitly acknowledged.

Meanwhile, the CQC was on the case, criticising many hospitals for inadequate nurse to patient ratios.

BELLE MELLOR

EMA being seen to be independent. Nobody receiving 80% of a salary from industry would be admitted to any committee that deals with drug evaluation.

Too much power

Today the CHMP concentrates even more functions and too much power. For substantial fees it gives scientific advice to industry figures to help them prepare studies that are then judged by the committee itself. It considers appeals against its own decisions. And it is responsible for pharmacovigilance and the withdrawal of drugs that it has authorised. Scientific advice, appeals, and withdrawals should be dealt with by committees independent of the CHMP.

It used to be that drugs could be approved under exceptional circumstances—that is, despite a lack of comprehensive evidence of efficacy and safety. Today we also see "conditional approvals," which are often not followed by the studies that the EMA requires from the manufacturer.[5] The agency is also starting an adaptive licensing process described as ". . . a prospectively planned, flexible approach to regulation of drugs,"[6] which, in essence, aims to allow medicines to the market more quickly and is based on lower evidence requirements than under a conventional marketing authorisation. This may be dangerous for patients, in that it further shifts the burden of evidence from pre-marketing to post-marketing.[7]

More than 20 years have elapsed since the decision to have a single agency consider drug approvals, with a view to facilitating the preparation of dossiers by the industry and harmonising the availability of drugs in Europe.[8] Unfortunately, however, the economic interests of member states and the industrial lobby have so far hampered the adoption of legislation and rules that favour the interests of patients.

Silvio Garattini is director, IRCCS Istituto di Ricerche Farmacologiche Mario Negri, Via Giuseppe La Masa 19, 20156 Milan, Italy
silvio.garattini@marionegri.it

I thank Vittorio Bertele' for contributing to this article, and I thank Judith Baggott for editing.

Cite this as: *BMJ* 2016;353:i2412

No need for an army of inspectors to tell it that nine in 10 establishments are short of their own target that was driven by post-Francis transparency and safety.[13]

Now NHS England has belatedly acknowledged, only after invocation of the Freedom of Information Act, the true scale of the nursing workforce crisis that ministers previously played down.[14 15]

Another information request in 2015, integrity, and courage from NICE's non-executive directors, led to the *Health Service Journal* releasing the staffing guidelines for settings including emergency departments and mental health being drawn up before they were killed off.

Most recently, the chief nurse of the new oversight body, NHS Improvement, told local services to use local discretion over the safe staffing evidence after all—which is where this story started.[16 17] The chief nurse also pushed the highly contentious suggested metric of "care hours per patient day."[18] The same body has told hospitals to reduce head count and cap agency spending,[19] which will hardly help nurse to patient ratios.

Confusing, isn't it. How's that vision working out, Mr Hunt?

David Oliver is a consultant in geriatrics and acute general medicine, Berkshire
davidoliver372@googlemail.com
Twitter @mancunianmedic

Cite this as: *BMJ* 2016;353:i2665

THEBMJ.COM BLOGS Billy Boland

A quality forum

Discussing quality improvement (QI) with colleagues at my trust has been really rewarding. We've set up a few different resources for people to use. My favourite of these so far is something we're calling a QI forum: essentially, an unstructured meeting where we discuss QI in general with whoever turns up. We're finding that people have varying needs, understandings, and interests, so it's been useful to get a sense of where we are as an organisation. We also take the opportunity to give a short presentation of our evolving QI approach. Our vision is to come up with a common QI language that we can all unite around, one that facilitates collaboration.

I had arrogantly imagined myself as a sort of modern day quality improvement prophet, ministering the good news to the good people

We've found lots of QI work going on that we've not been sighted on as an organisation—some really excellent stuff. Looking back, I think that I had arrogantly imagined myself as a sort of modern day quality improvement prophet, ministering the good news to the good people and welcoming them on board. But none of the forums so far has been like that. Each time we have heard examples of staff working on issues methodically in innovative ways, to resolve problems in the system or create opportunities. Typically, it takes a little while for these stories to come out, but each one has been a delight that I've been keen to celebrate. But these examples have also made me think about why the work hasn't reached me already. Why have I learnt about it only through the forum? Why hasn't the learning been shared more widely in the trust in other ways?

It has often come down to modesty. I was heartened to find that hardworking, motivated clinicians see quality improvement as a core part of their role. A "must- do." Something that's intrinsic to their work. As such, many don't see it as something to shout about—they're just doing their job. Some don't want to put themselves out there as if to suggest that they're better than others: they see their colleagues driving quality improvement too.

Therein lies a wonderful dilemma: how not to disrupt people's private passion for QI, yet find a way to foster cooperation and shared learning across an organisation. We've not got that totally figured out yet, but it is a joy trying.

Billy Boland is a consultant psychiatrist and associate medical director for quality and safety at Hertfordshire Partnership University NHS Foundation Trust

You can follow him on Twitter @originalbboland

Read this in full at bmj.com/blogs

ANALYSIS

"Informed choice" in a time of too much medicine

Minna Johansson and colleagues argue that preventive medicine and expanding disease definitions have changed the ethical premises of informed choice and our good intentions may inadvertently advance overmedicalisation

The idea of informed patients who make reasoned decisions about their treatment based on personal preferences is appealing. Rightly, many doctors now reject paternalism. They prefer to elicit the patient's preferences and embrace an open discussion of risks and benefits of different options within a shared decision making approach.[1] However, the rise of preventive medicine, the transformation of risk factors and common life experiences into diseases, and the lowering of diagnostic thresholds have changed the ethical premises of informed choice by pushing responsibility on to often ill prepared citizens.[2-5] We call for careful reflection on the potential downsides of trusting informed choice to resolve ethical problems and complex value judgments in an era of "too much medicine."[6]

New pathways to informed choices

When the clear cut needs of a patient to solve a health problem set the framework for the medical consultation, the ethics of informed choice can be fairly unambiguous. A patient with osteoarthritis consulting a doctor because of serious, long lasting knee pain that inhibits daily function may exemplify this. Most of us would appreciate being informed about the pros and cons of knee replacement surgery and other options, including doing nothing, and thereby being enabled to make an informed choice based on personal preferences. In such situations, informed choice is clearly better than previous paternalistic approaches. However, in medicine today, the path towards an informed choice is often far more tortuous.

Dangers of diagnostic cascade

Consider a middle aged man who consults his general practitioner because of a mild headache, dizziness, and a feeling of strong heartbeats. Among other things, the doctor measures his blood pressure, which is moderately raised. Although the man's blood pressure is unlikely to cause the observed symptoms, and a reasonable response might be to set aside this finding after exploring the personal history further, many doctors will feel pressure from guidelines[7] or quality measures to proceed to medical action. After the diagnosis is confirmed through monitoring ambulatory blood pressure, the patient's risk of cardiovascular disease is assessed in accordance with current guidelines.[7] He is given individualised information on the potential benefits and harms of treatment for hypertension and hyperlipidaemia and encouraged to make an informed choice about whether to start potentially lifelong preventive drugs.

KEY MESSAGES

- Informed choice is increasingly considered as the best way to determine appropriate care
- Providing information does not tackle the deeper drivers of overdiagnosis and overtreatment
- Requiring an informed choice can cause harm when controversy exists about treatment or diagnostic thresholds
- Without critical reflection our good intentions may enhance medicalisation and too much medicine

Providing information to make "informed choices" does not address the many deeper drivers of medical excess

In the process of medical work-up, the doctor explores the patient's symptoms further. These are obviously stress related. Based on a short questionnaire and the conversation that took place at the consultation, the doctor diagnoses moderate depression and provides the patient with information on the pros and cons of selective serotonin reuptake inhibitors, perhaps combined with cognitive therapy. After exploring the patient's preferences the doctor facilitates a decision on whether to start treatment. As doctors, we are taught to feel proud of ourselves in this situation; we took the time to make sure that the person was informed and to explore personal preferences. We thus respected our vulnerable patient's autonomy.

However, we see major ethical problems arising from this approach, which in this case might smoothly transform a person in temporary distress into a lifelong patient, or at least someone who for the rest of their lives has "previous, medically treated depression." A common consultation for symptoms such as those discussed above, with strong ties to stressful life circumstances, can evoke a diagnostic cascade that to some extent is legitimised by offering choices about medical treatment, choices demarcated by an unquestioned framework of medical interpretation and classification.

There is increasing complexity in making choices about the many disease labels and interventions that bring only marginal benefit and considerable harms

Screening asymptomatic citizens

Mass screening programmes further complicate informed choice. Here, the initiative arises from within the healthcare system. Asymptomatic citizens are offered an examination they have not asked for. In a best case scenario, potential participants receive balanced information on both the pros and cons of the intervention and can then make a choice. But who considers the ethics of presenting such a complex choice in the first place?

Expanding disease definitions

Expanding disease definitions present another major challenge for informed choice. Conventionally, people are informed about the pros and cons of different treatment options—but who is charged with discussing the validity of the underlying diagnostic label? There are now important controversies about whether thresholds for diagnoses and risk factors have become too low across a range of conditions, including pulmonary embolism,[11] osteoporosis,[12] chronic kidney disease,[13] and hypertension.[14]

Similarly, more and more of life's challenging experiences are turned into diagnoses through the inexorable expansion of the number of and criteria for mental disorders.[16] This is exemplified by the fourth edition of the Diagnostic and Statistical Manual of Mental Disorders including the controversial "hypoactive sexual desire disorder" in women.[17] Our biomedical framework for understanding disease makes us sort our patient's illnesses and suffering into diagnoses that are technically correct but not necessarily existentially meaningful in the sense of enhancing the patient's ability to engage in life.[4]

Informed choice—a fake fix?

We argue that general reliance on informed choice to resolve ethical problems and closely balanced value judgments in contemporary medicine might be a fake fix. There are five main reasons for this, as discussed below.

Doubts about personal preferences—In a cultural context permeated by the belief that "more is better,"[18 19] it is doubtful whether we can expect people to make truly informed choices when considerable uncertainty exists about the benefits and harms of interventions and diagnostic labels.

Transfer of responsibility—There are downsides to being forced to make informed choices. For example, if patients choose not to have their risk factors treated, they may feel guilty if they are later affected by the condition.[22] Such feelings of guilt are amplified by the "prevention is better than cure" dogma but are ethically objectionable and uncalled for, given that a preventive intervention makes no difference for the majority. Additionally, there is a risk that informed choice transfers responsibility for treatment harms from the health professional to the patient.

Information can cause trouble—Informed choice implicitly suggests that information is inherently good, a view reinforced by a reluctance in our societies to accept uncertainty. But information is not the same as insight. Information can be harmful if it leads to unjustified distress or interventions that eventually inflict harm. Additionally, information about our risk of getting a symptomatic disease based on asymptomatic risk factors can negatively influence the perception of our health and quality of life.[4-24]

No neutral territory—Inherent to the idea of informed choice is an ideal of the doctor as a professional conveyor of neutral information. However, the practice of medicine inevitably includes many value judgments, both implicit and explicit. Furthermore, the idea of a neutral doctor contrasts with the fundamental importance of the interaction and relationship between the doctor and the patient. The strong focus on individual autonomy and informed choice may divert attention from some of the underlying, unspoken premises and assumptions that are fundamentally important to clinical decisions.[4]

Opportunity costs—Facilitating genuinely informed choices in the context of preventive medicine will consume much time and money. This risks redistributing ever more scarce resources to healthy individuals when these resources could instead be spent on people with the greatest need: those who are already ill.[5]

Call for reflection

What we do in medicine is inevitably value laden; it reflects the values of the surrounding society all the way from the choice of research questions to the choice of information to provide in the individual consultation.[25]

A relevant response to the man with increased blood pressure in the example above might be to sit back and really listen. Among the myriad reasons for his symptoms might be a poor relationship with a family member or imminent downsizing at the workplace. Such problems are not resolved by use of antidepressants or assessing cardiovascular risk. A more laidback and listening approach from the doctor might favour salutary choices with great importance to health and might represent greater respect for individual autonomy then offering medical choices the patient did not ask for.

We are not opposed to providing information or involving patients in decisions. But we want to raise a note of warning; there is increasing complexity in making choices about the many disease labels and interventions that bring only marginal benefit and considerable harms. Most importantly, providing information to make "informed choices" does not address the many deeper drivers of medical excess, be they technical, professional, commercial, or cultural. Moreover, it imposes new ethical questions that healthcare providers and policy makers are yet to consider.

Minna Johansson, PhD student, Department of Public Health and Community Medicine, Institute of Medicine, University of Gothenburg, Gothenburg, Sweden; and Research Unit and Section for General Practice, FoUU-centrum Fyrbodal, Vänersborg, Sweden minna.johansson@vgregion.se

Karsten Juhl Jørgensen, senior researcher, Nordic Cochrane Centre, Rigshospitalet, Copenhagen, Denmark

Linn Getz, professor, General Practice Research Unit, Norwegian University of Science and Technology, Trondheim, Norway

Ray Moynihan, senior research fellow, Centre for Research in Evidence Based Practice, Bond University, Australia

Cite this as: *BMJ* 2016;353:i2230

Find this at: http://dx.doi.org/10.1136/bmj.i2230

Margretta Eleanor Addis-Jones

General practitioner (b 1928; q Welsh National School of Medicine, Cardiff, 1959), died from a spindle cell sarcoma on 8 March 2016.

Born into a house that frequently provided hospitality to Aneurin Bevan, the local MP, Margretta Eleanor Addis-Jones ("Lynne") was always anxious to practise medicine. In 1951 she finally obtained a place in Cardiff and later married Clive, a fellow medical student. In 1962 she took a position as a registrar in the radiotherapy department at St Luke's Hospital, Guildford, and later joined Clive in a small general practice in Guildford that grew to Guildford's largest. When the medical centre was set up at the newly inaugurated University of Surrey, she became one of its medical officers, specialising in family planning. She retired in 1992. Lynne was a former chair of the local BMA. She leaves her husband, Clive, and two children.

Clive Addis-Jones

Cite this as: *BMJ* 2016;353:i2421

Francis Anthony Almond

Former general practitioner Garforth and Aberford, West Yorkshire (b 1926; q St Bartholomew's Hospital, London, 1951), died from pneumonia complicating Hodgkin's lymphoma on 18 August 2015.

Francis Anthony Almond ("Frank") was called up for national service within weeks of his marriage to Diana. The couple lived in Trieste and subsequently Berlin. On returning to England he took a training post in Brentwood. His first role as a principal was in Southend, but he subsequently took over a singlehanded dispensing practice in west Yorkshire. Additional duties included police surgeon, and on industrial injury disablement boards. He retired in 1988 but continued to undertake locum work and adjudicating on medical appeals. Diana died in 1998. He leaves three daughters, three grandchildren, and three great grandchildren.

Janet Almond, Katie Leslie, Patricia Bell

Cite this as: *BMJ* 2016;353:i2424

Barbara Cushnaghan

Former clinical research physician (b 1928; q Leeds 1951; DObst RCOG, DA Eng, MFPM RCP (UK)), d 2 August 2015.

Barbara Campbell Edwards married Andrew Cushnaghan in 1960. They met when she was ship's surgeon with the Clan Shipping Line on the *Clan McIntosh*, where Andrew was the ship's junior second engineer. They had two children. Barbara took a job as family planning medical officer, and further senior hospital roles in anaesthetics followed in Glasgow and the south of England, before she worked in the pharmaceutical industry in clinical research. Andrew and Barbara moved to the Isle of Man in the late 1980s, where she continued working in pharmaceutical consultancy and in women's health. Barbara had bequeathed her body to medical science at Newcastle University, so a short memorial service was held for her, with the funeral service pending the completion of the studies at Newcastle. Andrew died in January 2016, when the studies had been completed, and the two of them had a joint funeral service on 17 February 2016.

Orlanda K H Allen

Cite this as: *BMJ* 2016;353:i2425

Jerome Gerald Lewis

Former consultant physician Edgware General Hospital (b 1926; q London Hospital Medical School 1951; MD, FRCP), died from complications of pneumonia on 28 November 2015.

Jerome Gerald Lewis ("Jerry") worked in junior posts at the Hammersmith, Royal Free, and Brompton hospitals, culminating in a senior registrar position at Charing Cross Hospital. He received an MD in 1960 and was appointed consultant physician at Edgware Hospital in 1964. Jerry had a special interest in clinical pharmacology and was an adviser to the *BNF* committee. His publications included a handbook for house physicians and notes on therapeutics. He was an examiner for London University, the Royal College of Physicians, and the GMC, and he belonged to several medical societies. His enthusiasm for teaching led to an association with the newly formed St George's University School of Medicine in Grenada. He leaves Blanche, his wife of 59 years, and two children.

Gerald Bevan

Cite this as: *BMJ* 2016;353:i2435

Kenneth Haddon Trigg

Former general practitioner Merstham, Surrey (b 1921; q King's College Hospital, London, 1954; DObst RCOG, FRCGP), d 17 February 2016.

Kenneth Haddon Trigg served with the Royal Artillery in the Far East in the second world war. He was captured and held as a prisoner of war in Borneo for three and a half years. He trained in medicine after his liberation and worked as a family doctor in Merstham until 1986. An active member of the Royal College of General Practitioners, he established his local vocational training scheme and served as provost of the college's South West Thames faculty. He was precise and meticulous and had a great appreciation of things of beauty and craftsmanship. His many interests included woodwork, photography, music, and horticulture. He had met his wife, Sylvia, at King's. They married after they had both qualified in 1955. He leaves Sylvia, four children, and three grandchildren.

Jennifer Trigg, Hilary Trigg , Cecilia Trigg, Miles Trigg

Cite this as: *BMJ* 2016;353:i2420

Katherine Nola Williams

Former associate specialist geriatrics St David's Hospital, Bangor, Gwynedd (b 1921; q 1944), died from colon cancer on 17 August 2015.

Katherine Nola Bentley was the first female medical undergraduate at Birmingham University. She met Mostyn Williams, a general practitioner in Bethesda, when she was a house surgeon at the Caernarvonshire and Anglesey Infirmary and Dispensary in Bangor. She joined the Royal Army Medical Corps and was posted to India for two and a half years. On demobilisation she returned to north Wales, married Mostyn in 1947, and worked as medical officer in the student health department at Bangor University for seven years before becoming a full time associate specialist in geriatrics, a post she held until she retired in 1986. Enthusiastic in all her many interests, she retained an inquisitive mind and was a keen golfer, playing almost to the end. Predeceased by Mostyn, she leaves a son, Edward.

June Cooper, William Roberts

Cite this as: *BMJ* 2016;353:i2422

Krysztof Krawczyński and Elżbieta Gürtler-Krawczyńska

A husband, a viral hepatitis expert, and wife, a cardiologist and radiologist, died in a car crash

Krysztof Krawczyński (b 1938, q Warsaw 1962) and his wife of 55 years, Elżbieta Gürtler-Krawczyńska (b 1938, q Warsaw, 1962), both died on 28 January 2016 from injuries caused by a car accident.

On Thursday 28 January 2016, Elżbieta Gürtler-Krawczyńska and her husband, Krysztof Krawczyński, were driving through the evening darkness toward their home near Atlanta in the United States. It was her 79th birthday, and they had earlier enjoyed a celebratory dinner in a restaurant.

Kris and Elizabeth, as they were called by their American friends, were both born in Poland. They had both studied at what is now called the Medical University of Warsaw. In 1984, as political tensions grew in Poland, they both emigrated to the US for a new start in life.

Elizabeth, professor emeritus of radiology at Emory University, was active in Atlanta's Polish community and in the Catholic Church. Kris was internationally renowned as an expert in viral hepatitis. During his 31 years at the Centers for Disease Control and Prevention (CDC), he investigated pathological, immunological, and virological aspects of hepatitis B, hepatitis C, and hepatitis E infections. He was the author of more than 130 scientific papers and wrote numerous chapters in various textbooks.

Unknown to Kris and Elizabeth as they were driving home from the birthday dinner, police had spotted a suspicious looking car a few miles away. The officer tried to get the driver to stop. Instead, the driver fled at high speed with the police car in pursuit.

Documentary

Elżbieta Grażyna Gürtler-Krawczyńska was born in Warsaw. Her mother was a doctor and her father worked in a government ministry. When she was 2, Elżbieta—along with her mother and grandmother—was among the 1.7 million Polish citizens forcibly deported by the former Soviet Union to labour camps in central Asia and Siberia. Elżbieta, her mother, and her grandmother were sent to Kazakhstan. When Soviet officials learned that Elżbieta's mother was a doctor, they put her to work. Elżbieta and her grandmother were allowed to return home to Warsaw in 1946. In 2005 Elizabeth helped arrange for a documentary about the mass deportations to be shown in Atlanta. "I just need to tell people what happened, and to pray for all the lost life," she said at the time.

After qualifying Elżbieta trained in cardiology. She would become deputy head of the Department of General Cardiology at the Institute of Cardiology in Warsaw. In the early 1980s she served as treasurer and secretary of the Warsaw division of the Polish Society of Cardiology. After the move to Atlanta, she was awarded a research fellowship in nuclear medicine at Emory University and was later named assistant professor of radiology. Her work focused on clinical trials in nuclear imaging of the heart.

PAWEL LOJ

Kris's investigations included experimental studies on non-human primates, Elżbieta's on nuclear imaging of the heart

Pathomorphology

Krysztof Zygmunt Krawczyński met Elżbieta in his first year at Warsaw University. The couple married in late 1961. After qualifying Krysztof worked at the Department of Immunopathology of the National Institute of Hygiene in Warsaw, where he received a doctorate and higher doctorate, specialising in pathomorphology. He completed his postdoctoral training in New York City at Cornell University Medical School's research laboratories at New York Hospital, now part of New York-Presbyterian Hospital. By 1970, even though he was working behind the so called iron curtain in eastern Europe, he had coauthored papers published in the *Lancet*. In 1983 he lectured at the Royal Free Hospital in London on the relevance of morphological aspects of experimental viral hepatitis to the natural history of the disease. After he joined the CDC, he collaborated with the National Institutes of Health, the US Food and Drug Administration, and research centres around the world. His investigations included numerous experimental studies on non-human primates, including an investigation into antiviral immunity against the hepatitis B virus infection. He also studied the potential for developing a hepatitis E vaccine. Kris officially retired from the CDC in May 2015.

A few minutes before Kris and Elizabeth would have safely arrived home, the unthinkable happened. Their car entered an intersection and was crushed by the vehicle that was fleeing police.

Elizabeth and Kris were mourned by hundreds at a funeral mass in Atlanta, followed by a celebration of their lives. Two weeks later in Warsaw, a mass was attended by lifelong friends and colleagues, and they were laid to rest at Powazki cemetery. They leave their daughter and two grandaughters.

Ned Stafford, Hamburg
ns@europefn.de

Cite this as: *BMJ* 2016;353:i1854

ELECTRONIC CIGARETTES

Nicotine has deleterious effects on wound healing

We endorse any measure that reduces public health harm from smoking (Analysis, 30 April), and considerable evidence suggests that smoking is associated with poor wound healing. This is important in many types of surgery, irrespective of specialty, and smoking is contraindicated before some elective plastic surgery procedures. Nicotine affects wound healing through increased vasoconstriction. Recent data show reduced cutaneous blood flow after using e-cigarettes.

Therefore patients should refrain from using all nicotine containing products before non-urgent operations.

Christopher S Davies (christopher.davies9@nhs.net), Amir Ismail

Cite this as: *BMJ* 2016;353:i2709

DEPRESSION IN PREGNANCY

Paucity of data on the safety of drug treatments

The "What you need to know" box in the clinical review of depression in pregnancy (26 March) deserves comment.

Drug safety is a major problem—benefit to harm ratio and dosing data are mostly lacking and often overlooked by prescribers. Patient information leaflets must be improved and clinicians better trained in drug safety.

Cognitive behavioural therapy (CBT) and antidepressants are similarly effective against major depression but CBT has fewer adverse effects. CBT should be first line treatment in major depression, not just in mild to moderate cases.

Fluoxetine (not just paroxetine) also increases the risk of cardiac anomalies, and selective serotonin reuptake inhibitors should not be first line for women of childbearing age because teratogenicity can occur before women know they are pregnant.

Well designed research on congenital anomalies, autism spectrum, and attention deficit disorders is needed so that we can offer women the information to make a shared decision on treatment for depression.

Alain Braillon (braillon.alain@gmail.com), Susan Bewley

Cite this as: *BMJ* 2016;353:i2582

Authors' reply

We are developing an online aid for women and providers making decisions about drugs during pregnancy. Because of the rapidly changing harms-benefits literature on antidepressants during pregnancy, national guidelines are preferable to patient information leaflets.

Psychological treatments should be offered for depression of all severity, but because they are not universally accessible antidepressants are an alternative for women with moderate-severe depression, as recommended by NICE.

Most selective serotonin reuptake inhibitors (SSRIs) (not just paroxetine and fluoxetine) have been associated with small increased risks of various child outcomes. Therefore, the most cautious approach is that no SSRI is more acceptable during pregnancy than another. The exception of paroxetine relates more to its short half life and severe withdrawal effects than to cardiac anomalies.

We agree that more research is needed.

Simone N Vigod (simone.vigod@wchospital.ca), Claire A Wilson, Louise M Howard

Cite this as: *BMJ* 2016;353:i2583

ALAMY

LETTER OF THE WEEK

E-cigarettes: beware the rocket in your pocket

The recent report on e-cigarettes and tobacco harm reduction missed an important point (Analysis, 30 April). We recently published the first case series of burn injuries from exploding rechargeable lithium ion batteries in e-cigarettes—thigh burns that required hospital admission and surgical debridement. Both patients described their e-cigarettes as bursting into flames like a "rocket in my pocket." The devices were not second hand, counterfeit, or damaged and were purchased from UK high street stores. A Google search identified an epidemic of e-cigarette related fires and explosions, with at least eight serious burn injuries in the UK during 2016.

These batteries currently pose a real risk of explosion, fire, and serious injury. Urgent consumer guidance is needed on the safe storage and charging of these devices. We welcome any device regulation that would come with licensing, because this should drive improvements in product safety and quality. It is completely unconscionable that public users are currently being sold devices with the potential to explode spontaneously and cause serious injury. It would also be inexcusable to prescribe such a device to a patient without guarantee of safety. Given e-cigarettes are being proposed for use by some of our young and potentially most vulnerable patients, these concerns need to be considered as a matter of urgency.

Aidan M Rose (a.m.rose@dundee.ac.uk), Kenneth J Nicoll, Omar Quaba, Alastair G Lowrie

Cite this as: *BMJ* 2016;353:i2712

MIGRANTS' HEALTHCARE RIGHTS

Limits to what European health systems can provide

What about the economics of providing healthcare (Personal view, 23 April)? EU healthcare systems rely on "risk pools," known populations for which managers plan and finance care. Mass migration expands these pools, making existing funding arrangements unsustainable.

European healthcare is already changing as a result of austerity measures. The NHS, as a comprehensive system that provides near universal access based on residency, is vulnerable in an EU of over 500 million people in which free movement could quickly expand the population covered.

Free healthcare for all comers presents daunting challenges. It requires extra funding through redistributive fiscal policies, a route that few countries are likely to take. Instead, already creaking healthcare systems will be stretched to cope with rising demand. If Western welfare states collapse, models that developing countries look towards when reforming their systems will be discredited at great global cost. Realistically, we must accept limits on what European healthcare systems provide.

David Hughes (d.hughes@swansea.ac.uk)

Cite this as: *BMJ* 2016;353:i2679