ANALYSIS

The responses to the “cancer drugs scandal” must fully involve patients—an essay by Tessa Richards

After finding that most new cancer drugs appear to confer little clinical benefit, *The BMJ*'s Tessa Richards reflects on her cancer journey and argues that decision making in cancer must improve, to involve patients at every level

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It sometimes feels as though the frequency of “healthcare scandals” is increasing. The veil is lifted, and the public gets disturbing new insight into healthcare’s harsher realities. The Mid Staffordshire scandal was a notable example¹; the US opioid crisis is a more recent one.² Last month, what might be termed a “cancer drugs scandal” hit the headlines.

The trigger was a package of articles in *The BMJ* laying bare that the approval of most cancer drugs by the European Medicines Agency and the US Food and Drug Administration in 2009–13 was based on “flimsy or untested surrogate outcomes.” To the limited extent that the impact of these drugs has been studied over time, they seldom appear to deliver “clinically meaningful benefit.”³ A *Mail Online* headline was blunt: “The costly cancer drugs that don’t help patients.”⁴

A second worrying message, not picked up by newspapers, came from an oncologist in a response to *The BMJ*'s articles: that “production line systems adopted by the NHS . . . encourage doling out of chemotherapy without thought.”⁵

These messages warrant wide debate and should give pause for thought to those lobbying for accelerated access to new cancer medicines, including patient organisations. The cost to the public purse is mind boggling⁶; the cost to patients who directly bear the burden of ineffective and toxic treatments, incalculable.

The struggle to cope with debilitating side effects

As a patient and patient advocate I repeatedly hear, read, and observe stories of bravery, disillusion, and despair. Many patients and carers, including me,⁷ are deeply traumatised by their cancer journey. Fellow travellers describe the shock of diagnosis, the fear, and then often a determination to “beat cancer” by taking unpronounceable drugs and other treatments. Next comes the exhausting struggle to “comply” with complex regimens, access disjointed and often distant services, and cope with distressing and debilitating side effects. Finally, the progressive loss of morale and hope that comes with advancing

disease, the inexorable erosion of quality of life, and the realisation that treatment will not deliver on its promise.

The options here are seldom easy, of course, and no one forces patients to embark on chemotherapy, aggressive or otherwise. Indeed, oncologists argue that patient pressure is what makes them prescribe—an apologia I don’t find wholly convincing. Patients may be desperate for “magic bullets,” but they still take doctors’ advice seriously. It’s a professional responsibility to present people with uncomfortable truths, to be transparent about the limitations of the evidence and how “effectiveness” of cancer treatments is judged, and to be objective about information on risks, harms, and benefits.

A couple of years ago I was invited to a meeting convened by a doctor who specialises in dealing with the abdominal side effects of cancer treatment. It was an eye opening experience. The consultant, who later diagnosed and treated the candida oesophagitis I got after radiotherapy, said that “colleagues don’t like me holding this meeting, for they say it gives oncology a bad name, and [that] cancer treatments will become less toxic and more effective in time.” Oh—and meanwhile, let’s not frighten the horses?

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Inadequate discussions about treatment

Undeniably, many new cancer treatments are highly effective, and the issue for patients is often getting access to them. New research and personalised medicine have opened up exciting avenues. But we live in the present, and what seems a near universal message is that discussions about treatment are often woefully inadequate.

Patients may get their diagnosis, prognosis, and proposed treatment laid out in a couple of short outpatient sessions. Although this may be deemed efficient, a recent report from

Macmillan suggests that about a quarter of people with a cancer diagnosis don't fully understand what's wrong with them and that half are not fully informed about side effects.⁸ In an eloquent response, Ceinwen Giles, a member of *The BMJ's* patient panel, has underlined how getting a diagnosis is "numbing" and how patients need time to formulate the questions they need answering.⁹

Shortage of time is a big problem, but it's not the only one. Decision making in oncology has evolved into a production line affair. Patients packaged as "cases" are processed through multidisciplinary teams. The focus is on scan and test results and treatment options. Consensus on "recommended" treatment may be reached with little or no reference to patients' goals, hopes, fears, or preferences at the current stage in their cancer journey. The voice of upbeat interventionists tends to trump the cautious and can fuel more aggressive treatment.¹⁰

When a panel of experts has come to a decision it's hard to even question it, let alone row back on it. I've tried this and found that it doesn't endear you to your clinicians. Nor does asking to attend the multidisciplinary meetings at which your case is discussed, to get an understanding of the rationale for decisions. A recent request I made was met with surprise and a sharp, "No, we are not set up to include patients." When I declined chemotherapy that was recommended by a consultant I'd never met before (on the basis of a discussion about my case that I didn't even know was taking place), his conclusion, incorrectly, was that I lacked the will to live.¹¹

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As a doctor I know about practice variation and why expert views may differ, but it's bewildering when you encounter it as a patient. When I presented with a fourth recurrence of my adrenal cancer in the caudate lobe of the liver 18 months ago, various lines of treatment were suggested by the different consultants I saw. They included: immediate surgery (deemed very risky); adjuvant chemotherapy, with a view to shrinking the tumour a bit prior to surgery; joining a phase I clinical trial (I was advised to "chase this option fast" but weeks later was told that I didn't fit the eligibility criteria); undergoing a second course of abdominal radiotherapy (my first was more than 10 years ago); and taking a long used, but notoriously hard to tolerate, "holding" drug for adrenal cancer, called mitotane.

Evidence on the likely outcomes of pursuing these options was not clear. I struggled to make a decision and, while I did so, I discovered other therapeutic possibilities through independently supported "crowdsourcing." These included new forms of endoradiotherapy and percutaneous NanoKnife ablation. (I plumped for radiotherapy and, when this failed to shrink the tumour, then underwent NanoKnife treatment privately, to good effect.)

Decisions must consider patient preferences

The option to do nothing was not proffered, although I wanted to explore it. I knew that I couldn't face major surgery again and was opposed to taking toxic drugs that were unlikely to confer benefit and guaranteed to undermine my quality of life. So, I summoned the courage to ask the oncologists about the likely endgame. About a year, they said, looking rather uncomfortable—with jaundice and ascites or with severe pain associated with invasion of the coeliac plexus before death. I mulled things over and, on the advice of a trusted medical friend, went to the GP to ask for referral for an early discussion about

palliative care. She seemed flummoxed: "I don't know the palliative care doctors," she said. "You could maybe get in touch with them at the hospice yourself. We refer people at the end of life."

Sometimes insight into healthcare is an advantage; sometimes not. When I'm below par or awake at night I sometimes relive stressful hospital episodes and churn over healthcare's wicked problems in relation to my own journey. Commercialisation of healthcare, fragmentation of care, "too much medicine," "inequity in access," managerial diktat, burnt-out clinicians,^{12 13} "staff shortages," and "professional turf wars." Most patients experience the impact of these, and Victor Montori, professor of medicine at the US Mayo Clinic, analyses and illuminates them in a new book, which calls for kind, careful, and minimally disruptive care.¹⁴

When I'm well, as I largely am now, I park apprehension. Knowing that your time's limited is a great spur to "seize the day" and pursue things that matter to you. For me this includes advocacy for established movements and campaigns, which are integral to the wide responses we need to the "cancer drugs scandal."

Better approval and oversight of cancer drugs is a clarion call.¹⁵ But so too should be the call for mutually well informed and fully shared decisions. Progress on this front is generally encouraging,¹⁶ but there's a long way to go—not least in cancer care, where the stakes are high and the therapeutic line between benefit and harm is often thin.

The quality of decision making will improve when we resolve the power imbalance regarding access to information. The case for integrated records is well accepted, but the case for giving patients full, real time access to their own health records and test results, as well as control over how their health data are used, is still a logistical and ideological battle in progress despite accumulating evidence of benefit.¹⁷⁻¹⁹

The right to a second opinion is something else I support. Patients surely have a right to question doctors, explore options, and have personal views on "best" treatment. Those who do their own research, and who seek the wisdom of the crowd through networked patient communities, should not be branded overdemanding or difficult. The Ashya King case should have taught all of us lessons.²⁰

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Patient involvement in research is crucial

Above all, the "cancer drugs scandal" makes it imperative that patient and public involvement in the research enterprise continuum becomes robust and well embedded. The frameworks are there, particularly in the UK, US, Canada, and the Netherlands, with growing agreement on best methodologies, not least with respect to co-creating the research agenda.²¹ A recent report, suggesting that patient involvement in clinical trials yields massive economic benefit, will no doubt accelerate progress.²²

Had co-creation of research been well established in 2009-13 it would doubtless have ensured more focus on answering the questions and determining the outcomes that matter most to patients. The weak methodology and poor reporting of data on quality of life, particularly in cancer trials, is hard to defend, suggests Mel Calvert, director of the Centre for Patient Reported Outcome Research at the University of Birmingham (<http://bit>.

ly/2zTL5iZ), who has conducted a study of such trials for Macmillan.

Strengthening the rights of patients who participate in research studies is also vital. “Guinea pig” status, as described in a recent lacerating article by Paul Wicks (another member of *The BMJ*’s patient panel), is not acceptable.²³ It’s also important to extend and open up the debate among researchers and health professionals about the nature and drivers of the eye watering high level of avoidable waste in the biomedical research enterprise.^{24 25} There are “scandals” here including bias, error, non-publication, and fraud, which have a direct bearing on the “cancer drugs scandal.” Patient and public awareness of the issues—and their input—can help in a collective drive to tackle these problems, just as patient input is vital in assessing the value of healthcare.²⁶ Implementing the call for #PatientsIncluded in medical conferences will help on both fronts.²⁷

But no campaign can deliver what most patients seek—and it’s not a patient right. It’s a doctor we know and trust and who knows and understands us, and who helps us to weather the storms, including the final one. I have had a couple in the past; I now feel the lack of one keenly.

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Biography

Dr Tessa Richards is a senior editor at *The BMJ* and leads the journal's patient partnership initiative. Her professional interest in patient partnership has been advanced by her experience as a carer for close family members with rheumatoid arthritis, dementia, and blindness. Tessa herself had adrenal cancer diagnosed in 2004 and underwent thoraco-abdominal surgery, followed by further surgery to remove metastases.