A year ago The BMJ committed to setting up an international panel of patients, patient advocates, and clinicians to help us develop a strategy to advance the “patient revolution” in healthcare. This week we are launching it, with due thanks to the members of our advisory panel. Over the past six months they have stimulated, provoked, steered, and supported us to make landmark changes to our editorial processes. Changes that we hope will add to national and international efforts to improve the quality, safety, value, and sustainability of health systems through realising the transformative potential of working in partnership with patients, their families, communities, and advocacy groups. So what have we done?

Firstly, we have embedded patient peer review of research papers. We started with randomised controlled trials and have now extended it to all research papers where patient input would clearly be helpful. We are also calling for the submission of robust research papers that advance the science, art, implementation, and assessment of the impact of patient partnership, shared decision making, and patient centred care. Authors of research papers are being asked to document if and how they involved patients in defining the research question and outcomes, the design and implementation of the study, and the dissemination of its results.

We are also asking them to comment on the burden on patients of new interventions. This is not intended to be a box ticking exercise, but to encourage and properly report on collaborative research between patients and investigators.

Secondly, we are inviting more analysis and comment articles to extend the debate and add to the evidence on the benefits and barriers to patient participation in all of its spheres, including the design and delivery of services, medical education, health policy, and the setting of the research agenda. The National Institute for Health Research and the Patient Centred Outcomes Research Institute already involve patients in setting research priorities, but the power of networked patients to independently initiate research and influence its conduct is growing. Best practice for collaborative working has yet to be defined but should pay dividends.

Co-production is more than a buzz word and it describes a third important change that we have made. Authors of clinical reviews and other educational articles, including selected editorials, are being asked to obtain input from patients and document their contribution. We are working towards our first patient co-authored “state of the art” review. Educational articles will also be reviewed by patients. You can help to build up our database of patient reviewers by extending this invitation to them.

The BMJ’s interest in patient partnership is not new. In 1999 we published a theme issue on the topic and a year later an issue led and written by patients. We may do this again, but our current initiative is not about one off gestures. We want partnership to become integral to how we work and think, as well as being something we advocate in healthcare. New expert patients on our editorial board and a newly appointed patient editor will help us in this quest and in time will enable us to meet a fourth pledge: to have patients participating in internal decision making committees. They are already flagging up innovative initiatives and helping us to get the patient’s voice into the journal more. Past articles written by patients underline the self evident truth that people with experience of illness and of navigating health services have much to teach us.

No tokenism

Our advisers have issued some clarion calls. One is to avoid tokenism. Initiatives to promote patient involvement and provide patient centred care are all too often poorly informed by patients and don’t promote partnership. A second is “do it well.” The failure to systematically collect and use the data on patient experience of care has been criticised.

We want partnership to become integral to how we work and think

A third is to get the “authentic” voice of patients heard; not just that of the articulate minority. This is a challenge that we all grapple with, and one that is recognised by our patient advisers. We will continue to publish individual perspectives but are extending our links with patient networks and advocacy organisations to help tap into collective views. As we do this we recognise the importance of transparency. As in academic medicine, commercial influences are pervasive, and we are requesting and publishing conflict of interest statements from patient reviewers and authors exactly as we do with medical authors and reviewers.

The fifth tranche of our strategy is a campaigning one. We support patient control or co-ownership of personal health records and the “Patients included” initiative. Patients are thin on the ground in medical forums (the time and expense of attending deters many) and not routinely invited as speakers, or on to steering committees. Here again our plan is to lead by example.

Our new strategy aligns with our “too much medicine” and “open data” campaigns and our support for “minimally disruptive medicine.” The BMJ remains a journal for doctors, but with Consumer Reports, which is partnered with the Choosing Wisely initiative, we are providing input into lay versions of the papers in our “overdiagnosis” series, to promote public awareness of the commercial and technological drivers shaping healthcare. Patients’ rights are another focus. Recent emphasis has been put on the right to be empowered to self manage chronic conditions.

Worldwide, the big issue remains the right to access good quality, affordable healthcare.

Patient partnership is a lot easier to talk about than to realise. It demands mutual respect and understanding. Our strategy is being implemented incrementally and will evolve as we evaluate its impact. But we are excited by its potential and hope readers will be too.

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We can actively support public awareness campaigns and make information and resources to help people start future care planning more widely available

Why is talking about dying such a challenge?

Much more needs to be done to encourage the conversation

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Most patients and doctors still struggle to deal with the challenges posed by deteriorating health and thinking about dying. How and where people die depends not only on their disease but on their circumstances, options, choices, expectations, values, and beliefs. Open, early discussions about what matters when people are dying are vital if we are to act on the growing list of policies, good practice guidance, and recommendations.

A recent survey of 2055 British adults found that about half knew about their partner’s end of life wishes. Just 6% had written down their own preferences. A parallel study found some improvement in the proportion of GPs who had initiated a conversation with patients about end of life care (75% in 2014 v 65% in 2012). A Scottish primary care study found that patients with cancer or other advanced illnesses were being identified for a palliative care approach only in the last weeks of life. Fewer than one in five patients with organ failure, dementia, or frailty were on practice palliative care registers when they died.

The results of these studies mirror outcomes of advance care planning initiatives in other healthcare systems, where some people embraced opportunities to think and plan ahead while others preferred a “day to day” approach to living well with advanced illnesses. This is particularly true of patients with multiple advanced conditions or non-cancer illnesses, such as chronic obstructive pulmonary disease.

However, even in cancer care, where death is an acknowledged reality, chemotherapy is commonly offered in the last months of life and is associated with an increased risk of the patient having a medicalised death in hospital. By contrast, early palliative care that facilitated a gradual shift in prognostic awareness led to improved quality of life and even prolonged survival in patients with lung cancer.

The situation in secondary care is similarly problematic, as shown by an audit of 149 hospitals in England. Although hospital staff recognised most of those patients entering the last days of life, documented discussions, particularly with patients, about impending death and treatments such as clinically assisted hydration and nutrition seemed to be lacking in many cases. Many factors contribute to this state of affairs, including a focus on investigations and treatment, uncertainty about prognosis, and concerns about how to communicate with patients and families who have diverse information needs, expectations, and coping strategies.

Cardiopulmonary resuscitation is another source of controversy, and there have been calls for greater clarity about how decisions are made and who should be consulted. In the United Kingdom, doctors complete a “do not attempt cardiopulmonary resuscitation” form if a cardiac or respiratory arrest is an expected part of the dying process. Resuscitation would then be unsuccessful and prevent a dignified death.

It is essential to talk with patients and their families about shifting goals of care to focus on ensuring patients’ comfort as they are dying, but detailed discussions about the process of cardiopulmonary resuscitation may be distressing and unwarranted. Where there are doubts about the outcomes of resuscitation, the risks and benefits need to be discussed with the patient, any nominated proxy, and family members able to provide insight into the patient’s wishes. The poor outcomes of cardiopulmonary resuscitation in people with advanced life limiting conditions and the adverse consequences of attempts at resuscitation need to be highlighted.

Increasing public awareness should help

So what more can be done to encourage better conversations about care at the end of life? We can actively support public awareness campaigns and make information and resources to help people start future care planning more widely available. Evidence points to a need for specific training in effective ways to raise the subject of dying well before the last phase of life. Professionals who are comfortable with sharing information at a pace that people can tolerate and in ways that preserve their ability to function in the world will be less worried about causing loss of hope and distress (box).

The World Health Assembly recently endorsed a resolution calling for palliative care to be fully integrated into healthcare in every setting and throughout the course of advanced illnesses. Palliative care specialists offer expertise and support, but ensuring that we provide good care for the 1% of the general population and the 30% of hospital inpatients who are in the last year of their lives is everybody’s business.

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EDITORIALS
Can palliative care teams relieve some of the pressure on acute services?

All the evidence points that way; commissioners take note

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Specialist palliative care teams are those with palliative care as their core daily work. They are multidisciplinary teams, have specialist skills and experience, and deliver palliative care both directly and indirectly; directly by providing care to patients and families, and indirectly by supporting other professionals to deliver such care.1 Providers, commissioners, and funders of health services need to know whether specialist palliative care teams make a difference and, if so, how. In this issue of The BMJ Seow and colleagues report a retrospective cohort study from Canada which suggests that community based specialist palliative care teams are effective in reducing use of acute care services (hospitalisation and emergency department attendance) in the last weeks of life.2 This adds to growing evidence that specialist palliative care teams not only improve patients’ symptom control, quality of life, and satisfaction with care, but can change patterns of acute care use, supporting health services in their urgent need to do things differently and more cost effectively.

Illness in the last year of life places a major burden on patients and families, and considerable resource burden on health services. Between 69% and 82% of those who die need palliative care,3 and up to a quarter of health-care expenditure is spent in the last year of life,4 mainly on inpatient care.5 In the face of ageing populations, growing numbers of people with multiple long term conditions, and major funding deficits for health systems internationally, the way frontline healthcare is delivered has to change. Reducing use of acute services such as hospitals is at the heart of this change, and reducing ineffective or futile use of acute interventions near end of life is also a factor.6

There is good evidence from controlled trials that specialist palliative care teams (whether in the community, hospital, or inpatient hospices) consistently deliver better symptom control, more satisfaction with care, improved quality of life, and better outcomes for families.7,8 In a recent Cochrane review, Gomes et al also found clear and reliable evidence that home based palliative care increases the likelihood of dying at home, in accordance with the preferences of many for death at home.10

Cheaper, too?

But do specialist palliative care teams also make a difference to the patterns (and therefore costs) of acute care use? This is important, since if they reduce hospitalisations towards end of life, and deaths in hospital, there may be an opportunity to relieve some of the current pressures on acute services, while at the same time delivering better care and meeting many patients’ preferences for place of death.

There is some early evidence that provision of palliative care can lead to cost savings,1,11 largely through reduction in hospital admissions, and reduction in acute interventions near end of life. To further consider use of acute services, Seow and colleagues use propensity score matching to reduce confounding and better test the effects of 11 community based specialist palliative care teams against usual care.2 Their carefully considered use of both administrative databases and propensity score matching enabled them to make robust conclusions; that delivery of community based, specialist palliative care (regardless of size of team or geography) is associated with significant reductions in patients’ use of acute services in the last two weeks of life.

If the associations reported by Seow and colleagues are causal, access to a palliative care team cuts hospitalisations by a third, use of emergency departments by a quarter, and risk of hospital death by a half, compared with usual care. The size or exact configuration of the community palliative care team didn’t seem to matter, but the teams were specialist; delivering palliative care as their core work, being multidisciplinary (with at least nursing and medical input), with specific palliative care skills and experience, and being closely integrated with primary care teams (so delivering indirect as well as direct care).

One of the limitations in this study is the focus on use of health services alone; the design and data sources did not allow for reporting of important outcomes such as symptoms, satisfaction with care, quality of life, and family or caregiver outcomes. It would be a major advance to know whether community based specialist palliative care teams can deliver—within the same cohort or study population—better symptom control, more satisfaction with care, improved quality of life, and better family outcomes while simultaneously reducing acute care use (hospitalisation and emergency department attendance).

This would require linked administrative and research datasets with detailed clinical outcomes, but would be an important next step in advancing the evidence. There is particular concern that, in delivering end of life care at home, the physical, emotional, and financial burden may fall on family caregivers.12 It is critically important, therefore, to include measures of family impact and outcomes in future studies.

There is, however, a clear and welcome message here for providers, commissioners, and funders of health services. In the intense pressure for healthcare services to do things differently and more cost effectively, specialist palliative care teams may have a central role in delivering better care and outcomes while reducing acute care use in last weeks of life. They should be resourced and commissioned to do so.

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RESEARCH, p 14
Efforts to improve the infrastructure for data collection in the postmarketing period are essential, as current initiatives are insufficient

Digging for data on harms in duloxetine trials

Detection of harms caused by drugs must be considered on a continuum through their life cycle

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The biomedical research enterprise devotes enormous amounts of time and money to determining how well a medicine works. By contrast, few resources focus on discovering the harms a given drug may cause. Even the randomized trial, our so called gold standard, is notoriously poor at detecting serious drug related harms. Some reasons for this are well known: trials are usually too small, too short, or enroll participants who are “too healthy”—which collectively means that relatively uncommon, but none the less real and possibly serious side effects may not occur with sufficient frequency (or at all) during a clinical trial to demonstrate convincing evidence of harm.

Despite their limitations, however, randomized trials remain a critical element in assessing potential harms, especially as randomization assures serious attention by researchers interested in the “causality” game. But credible use of trial data requires confidence in the quality of the reporting of trial results. In two linked papers, the Nordic Cochrane Centre sheds further light on this topic by dealing with the most nettlesome problem of recent psychopharmacology: the relation between antidepressants and suicidality.

The first study by Maund and colleagues provides evidence that coding dictionaries used within clinical trials may themselves help obscure adverse events. The authors’ research, based on access to 13 729 pages of clinical study reports for nine trials of duloxetine for the treatment of major depressive disorder in adults, reveals a system with more subjectivity than many might be prepared to accept. The study shows, for example, that while trial investigators recorded two cases of “suicidal ideation” (the verbatim term), these events essentially vanished from the trial dataset after being coded as “depression.”

Code wrong
The authors attribute this to an inherent limitation of the medical dictionary used to code adverse events in six of the nine trials. That dictionary—known as COSTART (Coding Symbols for a Thesaurus of Adverse Reaction Terms)—matched terms such as suicidal tendency, melancholia, and depression neurotic to the code “depression.” This means that readers of journal articles and trial registries would only have seen “depression.”

The good news is that COSTART has been superseded by MedDRA (Medical Dictionary for Regulatory Activities), a dictionary for which Maund and colleagues did not discover the same problems (at least for suicidality). The bad news is that until the harms data from older trials using COSTART are recoded, systematic reviewers and guideline committees remain vulnerable to the problems identified. Access to detailed records from clinical trials, such as completed case report forms, can help extant data to be reassessed. Verbatim terms can be recoded, adverse events can be adjudicated, and possibly new and robust conclusions can be drawn—or at a minimum, inform the design of post-marketing studies.

The other study by Maund and colleagues compared the consistency of reporting of duloxetine trials across different media: journal publications, trial registries, and clinical study reports. Their study adds to the growing body of research on reporting biases, which documents the gross underreporting of adverse event data in such sources.

Maund and colleagues’ papers may leave readers with the distinct impression that boozy traps abound: despite what seems like an impeccable study design (the randomized trial), the nuances and complexity in interpreting adverse event information are a recipe for endless debates over whether or not a drug is “causally linked” to a given type of adverse event. In this light, it is perhaps unsurprising that after so many clinical trials, the relation between duloxetine and suicide apparently remains unclear.

Despite drugs being approved in the United States as “safe and effective” on the basis of “adequate and well-controlled” investigations, randomized trials are largely designed to test prespecified efficacy hypotheses—not harms. While there remains an imperative to enlarge and diversify the population in premarking studies, it is unlikely that they will ever be long enough to assess all serious harms. Also, it is unethical to randomize participants to solely assess suspected harms. Efforts to improve the infrastructure for data collection in the post-marketing period are essential, as current initiatives are insufficient.

The largest of these systems is the US Food and Drug Administration’s MedWatch. But its database is populated by a mixture of voluntary and mandatory reports, which lack a population denominator, are often poorly coded, and lack important details of the events.

The FDA’s newer Sentinel Initiative ostensibly improves on MedWatch (FAERS, the FDA Adverse Event Reporting System) by providing measureable exposure to the drug that permits population based assessment of harm. However, Sentinel’s value is unclear as it has “yet to detect a substantial new drug risk that resulted in a safety withdrawal, a contraindication, or a warning.” In addition, the lack of public access to Sentinel data remains a concern. Competing interests and references are in the version on bmj.com.

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