surrounding genetic modification and the failure of the EU regulatory system to process applications to license new GM products.

A common reaction to such controversy is to commission subject reviews or meta-analyses[1] that assess the weight of evidence for certain effects across many individual studies. Ideally, reviewers would use processes similar to those deployed in the Cochrane Reviews that inform decision-making in health care[9].

But reviews also contain pitfalls. First, they risk amplifying rather than eliminating systematic bias — which could be more common in some subjects than others. Second, they can be affected by the increasing tendency not to publish 'negative' results[4]. Meta-analyses can compound the prevalence of false positives in the literature, and can be blind to unreported true negatives. We need rules for how to deal with these issues when compiling literature reviews for policy-relevant research.

SEAL OF APPROVAL

Strict procedures govern experimental design and the evidence standards for trials that are used to determine the efficacy and safety of GM organisms, pesticides or drug therapies. But once products are licensed for use, they are often subject to less formal investigations. The same relaxation of rules applies to testing the efficacy of policy interventions. Ad hoc studies, with all the problems outlined above, can then carry disproportionate political weight when their results question the operational integrity of a licensed product, or the effectiveness of a policy[10]. Quality-control criteria are needed for these studies that are outside a regulatory framework.

We need an international audited standard that grades studies, or perhaps journals. It would evaluate how research was commissioned, designed, conducted and reported. This audit procedure would assess many of the fundamental components of scientific studies, such as appropriate statistical power; precision and accuracy of measurements; and validation data for assays and models. It would also consider conflicts of interest, actual or implied, and more challenging issues about the extent to which the conclusions follow from the data. Any research paper or journal that does not present all the information needed for audit would automatically attract a low grade.

"What I propose augments rather than replaces peer review."

Such a system would provide policy officials and others with a reliable way of assessing evidence quality, and it would drive up standards in scientific research to reverse the worrying trends that suggest underlying bias[1–4,7].

Critics will counter that my proposed certification standard would be subjective and would shift the job of assessing quality away from expert peer reviewers. But in its current form, peer review fails to set a consistent standard. What I propose augments rather than replaces peer review, and assessment could be carried out on behalf of authors, journals or users of information through the use of third-party certified auditors.

I do not underestimate the challenge of establishing such a system, but it would bring standards to scientific publishing that are common practice in other disciplines. Ultimately, this will increase the rigour and transparency around the scientific literature that is used in policy decisions. ■

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Bring on the evidence

It is time to probe whether the trend for patient and public involvement in medical research is beneficial, say **Sophie Petit-Zeman** and **Louise Locock**.

Involving patients and the public as partners in medical research — from deciding what to study to influencing how results are used — is an emerging force. For some, the approach is based on common sense and justice[1]. Others, such as the chief medical officer for England, Sally Davies, feel that the advice of patients and the public "invariably makes studies more effective, more credible and often more cost efficient"[2].

The Seventh Framework Programme (FP7), the European Union's current research-funding instrument, stresses[3] the importance of patient and public involvement, known as PPI. And the Patient-Centered Outcomes Research Institute in Washington DC has allocated US$68 million to a research network predicated on the principle that "the interests of patients will be central to decision-making"(see go.nature.com/mdhy6i).

PPI is a prerequisite for much UK government research funding and it is spreading among funders, health-care organizations and charities[4]. The James Lind Alliance (JLA), with which one of us (S.P-Z.) has worked since its inception in 2004, enables patients, carers and clinicians to agree on what research matters most. It explicitly excludes the pharmaceutical industry and pure researchers. After a decade of arms-length government support, the JLA is now part of the National Institute for Health Research (NIHR) based in Southampton, UK, and JLA partnerships are complete or underway for 25 medical conditions (see go.nature.com/twhvxz). For example, the NIHR Oxford Biomedical Research Centre is running partnerships in spinal-cord injury and joint-replacement surgery, and it is the first major research institution to be appointing staff to use the JLA method 'in house', closing the loop between what matters to patients and what is researched in their name.

This international growth of PPI is rightly paralleled by unease at the paucity of evidence for its impact. And the evidence there is, including the findings that PPI improves recruitment to studies and changes what is researched[2,5], is weak. As Simon Denegri, the United Kingdom's first national director for public participation and engagement in research, put it: "The evidence-base for PPI's impact is meagre, patchy and largely observational."

SELF-EXAMINATION

Those of us working in PPI must robustly examine our own practices with a common set of tools. Otherwise, we will struggle to answer PPI sceptics, such as one researcher who asked: "Why should patients have useful opinions about what directions research should take?"[6].

ILLUSTRATION BY CHRIS RYAN/*NATURE*

A first crucial step is to ensure consistent, accurate reporting of what PPI has been done and how. We can assess whether an activity is useful only if it is clear what it was.

This challenge is being addressed through GRIPP[7] (Guidance for Reporting Involvement of Patients and Public), a checklist published in 2011 for studies that include PPI to help authors and readers to critically appraise the work. GRIPP is being used to generate consensus through the EQUATOR Network, an international initiative that promotes the development and spread of guidelines for health-research reporting[4].

A key element of reporting PPI is to make clear who was involved, in part to allow us to gauge when it matters to distinguish between public and patient input. One demonstrable effect of PPI is that it helps to create user-friendly information, questionnaires and interview schedules for patients[5]. But this sort of reality check about jargon differs from gathering and heeding patient experiences.

We must also probe whether PPI is valuable for all research types. Will it ever, for example, have a place in basic science? Anecdotal evidence suggests that it might, in part because patients push for research into causes. The UK Alzheimer's Society, the only funder that works with people with dementia and their carers to select research projects, backs work from the lab bench to the clinic. And priorities in sight-loss research, identified through the JLA approach, revealed patient interest in causation, as well as treatments using stem cells and gene therapy.

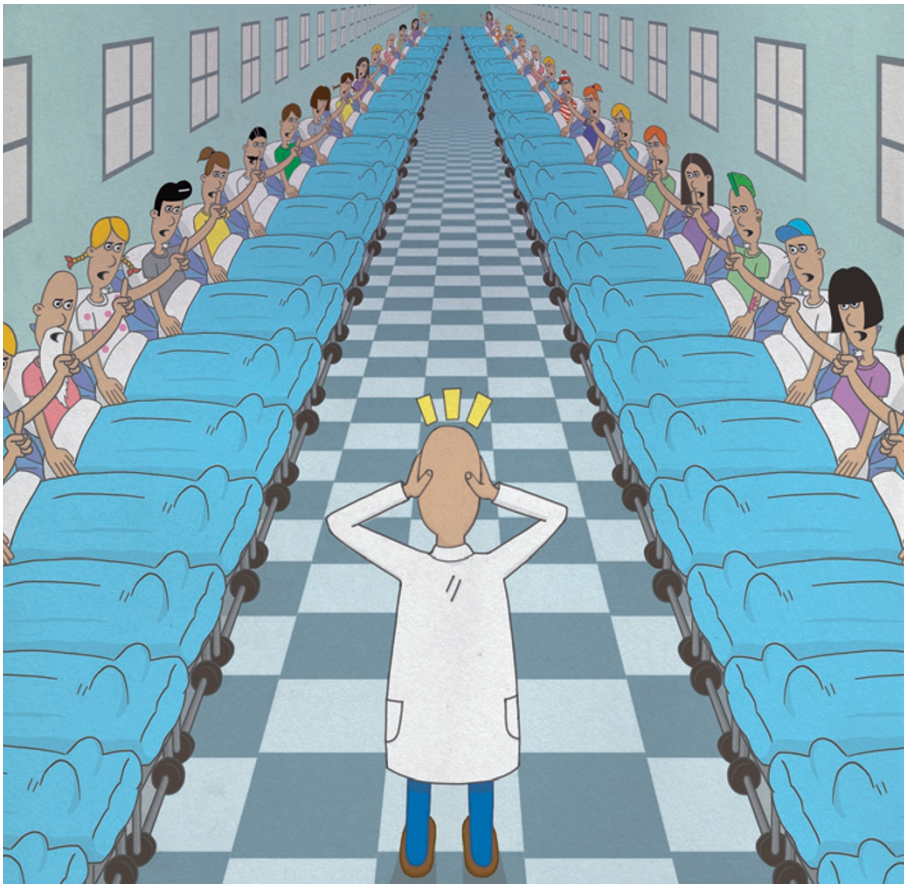
One of the knottiest problems in PPI is how to best weigh up anecdotes and evidence. How are the patients involved chosen? Do they bring more than their own views? Are diverse voices heard, or just those that are loudest?

Ignore such questions, and PPI might unwittingly perpetuate power imbalances. Patients can achieve involvement through existing networks, but not all will be part of these, or they might be chosen by a researcher who is keen to work with a kindred spirit. The most well-meaning approaches can simply extend input from educated, middle-class professionals to input from educated, middle-class patients.

Yet we must also avoid double standards. Just as people will always want the best researchers or clinicians, we must not exclude the most informed or articulate patients[8].

There is no easy fix, but the ability of involved patients to represent wider views can be optimized through routes such as the website www.healthtalkonline.org, led by the University of Oxford's Health Experiences Research Group (HERG), where one of us (L.L.) is deputy research director.

Healthtalkonline and its sister site, www.youthhealthtalk.org, contain video, audio and written records of nearly 3,000 people's experiences of more than 75 health-related issues. The websites allow patients and professionals to broaden their knowledge of what it is like to be ill or to make difficult health-care decisions.



Using qualitative research, interviews with subjects continue until no major new themes emerge, indicating that a comprehensive set of views has been gathered. As Sue Ziebland, HERG's research director, explains: "Supporting patients involved in research to draw from a pool of views helps defend them from accusations that they bring only their own agenda."

BUILDING A CASE

Gathering the evidence base for PPI will take time. The methodological issues described here must be addressed, and the crucial question — whether research using PPI makes life better for patients — is complex. A project funded by the UK Medical Research Council last week launched its Public Involvement Impact Assessment Framework, a resource to support research teams to develop impact-assessment tools appropriate for their work.

As PPI matures, we must find ways to ensure that those who do it, be they professionals, patients or public participants, are offered support and training — perhaps most crucially to help them to understand each others' worlds. We must then report, dissect and assess involvement, devising impact measures with patients as partners, in ways that optimize the potential of patient-centred science. ■

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