its emphasis on public health research. Although a full analysis of all present funding for health research in India and what it is spent on is not available, the funding from both domestic and international sources has increased substantially in India over the past decade.4

What then are the key goals that policy should address to boost research towards health care for all in India? First, a national research tracking mechanism should be developed to guide funding and commissioning of high-quality research into the major under-represented causes of disease burden and into neglected health-system issues. Second, a systematic plan is needed to make research initiatives more interactive with policies and implementation of health programmes, so that research is more relevant for the health system and policy, and the knowledge generated is used more often by policy makers. Third, rigorous evaluation research should become an essential component of all major population health programmes and policies, to understand how these could be refined to improve health outcomes and how the underserved segments of the Indian population could be better reached to improve health equity. For these goals to be achieved, the major national organisations attempting to strengthen health research in India should come together to provide effective stewardship. These organisations should collaboratively develop mechanisms that enable agreement on tangible medium-term and long-term targets for health research in the country, a plan of action, and methods to track progress in research utilisation to achieve health care for all in India. Although solutions for India will have to be tailored to its circumstances, there are useful lessons to be learnt from the systematic efforts of other countries aimed at matching research with public health priorities to more effectively improve population health.11,12

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The case for a global rare-diseases registry

Rare diseases are a clinically heterogeneous group of about 6500 disorders,1 and in fewer than 200 000 individuals in the USA.2 They are commonly diagnosed during childhood, often inherited, and can have deleterious long-term effects. Although any one condition is rare, their cumulative public health burden is substantial, with 6–8% of people having a rare disease at some point during life.3

Because of the rarity, no single institution, and in many cases no single country, has sufficient numbers of patients to do generalisable clinical and translational research. Geographic spread of patients has been a major impediment to recruitment into clinical trials. Most rare diseases do not have a specific International Classification of Diseases code, which hampers research that uses existing databases.1 Before the USA, the

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European Union, and Asian countries passed orphan-drug legislation more than 20 years ago, the drug industry gave little attention to the development of drugs for these diseases. Although these laws increased the pace of orphan-drug development, most rare diseases still have no medical therapy.

In recognition of these barriers and the moral and public health imperatives to advance knowledge on the best ways to improve the health and wellbeing of patients with rare diseases, recent conferences in the USA and Europe called for wide expansion of access to registries for such patients. The US meeting called for the creation of the infrastructure for a global registry.

Once the population has been defined, various data types can be added. Data can be entered by patients, clinicians, researchers, or be imported from electronic health records. Scientists and drug companies are more likely to research a rare disease if they find a registry in place. Registries enable the formation of infrastructures for various types of research, education, and outcomes improvement (panel).7,8

Less than a fifth of rare diseases have registries, and most of these are operated by patients’ organisations or researchers. Although most registries are country-specific, there are a few international efforts (eg, in cystic fibrosis9 and neuromuscular diseases10) that are showing the benefits of combining data across international boundaries.

We believe that now is the time to design and develop the infrastructure to foster global rare-disease registries. The increasing mobility of populations and the globalisation of lifestyles and food products make it clear that disease knows no boundaries. Some rare diseases occur so infrequently (<1 per 1 000 000 population) that only by forming international populations can sufficient numbers of patients be accrued. Because funding has been a key obstacle to establishing and maintaining registries, economies of scale that can be developed by forming a global rare-disease infrastructure would improve access to registries for many patients.

Registries are infrastructure, not research projects, and as for so many global concerns, there is no single funding source. A federated model in which several registries for the same disease are linked will most probably be needed to form a global infrastructure. A federated model requires that individual registries are developed or, for those already in existence, transformed to ensure that they are interoperable (ie, data are defined in the same way, use the same standards, and are stored in the same vocabularies).

For registry developers, there is no established forum for sharing experiences. Each time a new registry is developed, it starts from scratch.1 Information on best informatics practices and common data templates would go a long way toward reducing the start-up costs associated with developing a registry. Some data elements might be common to all rare diseases (eg, sociodemographics, diagnosis, genetics, growth, medications, services), which raises the possibility of creating a core dataset that can be incorporated into all rare-disease registries.

A single individual, group, or even country will not lead the movement toward formation of a global rare-disease registry. As in the open-source software community, an open-science community for rare diseases is needed. Such a community would ensure that the conditions necessary for data exchange are addressed by defining common datasets, data standards, and vocabularies, and would provide a forum for exchange of experiences and knowledge. The biggest hurdle to our vision of a global registry is not technical, but rather the

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**Panel: Research functions to enable a patients’ registry for rare diseases**

- **Knowledge dissemination**: distribution of information to patients and their clinicians on new therapies, best practices, and safety issues
- **Patients’ recruitment**: providing patient-population information for designing trial protocols that optimise size and length of trials
- **Clinical epidemiology**: population descriptive statistics, natural history of disorders, medical practice variation
- **Clinical effectiveness**: evaluation of the effects of preventive, diagnostic, and curative interventions delivered in real-world settings
- **Safety monitoring**: orphan drugs are generally not tested in large phase 3 studies, which makes the need for postmarketing safety surveillance via registries even more important than with conventional drugs
- **Quality and outcomes improvement**: enhancing patients’ outcomes by standardising practice and reducing practice variation
- **Genotype/phenotype association studies**: the registry provides phenotypic data which can be linked to genetic and other exposure data
- **Linkage to biospecimens and biorepositories**: to detect phenotypic correlates of cell and tissue biology
cultural obstacles to collaboration and data sharing across academic institutions and international boundaries.

Overcoming these hurdles is extremely important. A global infrastructure for a rare-disease registry will inject new energy into the effort to deliver more fully on the promise of orphan-drug legislation. Such a registry will draw new interest in rare diseases from academic researchers and the drug industry because it will enable the design of more effective clinical trials and effectiveness studies and the recruitment of patients much faster and at much lower cost.

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Why not send your best cardiology papers to The Lancet? The Lancet is planning a special issue to coincide with the European Society of Cardiology’s meeting to be held in Paris, Aug 27–31, 2011. We will consider high-quality original research papers that describe the results of randomised trials and will influence clinical practice. HotLine papers will be considered for fast-track review at the journal to allow publication immediately after the presentation. For HotLine papers only, the deadline for submission is July 18, 2011. The deadline for other submissions is May 23, 2011. Please state in your covering letter that the submission is in response to this call for papers.

Stuart Spencer
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A thank you to all our peer reviewers in 2010

Today we publish as a webappendix our annual list of clinical and statistical peer reviewers from many different countries and specialties who helped us choose and improve papers in 2010. Those who reviewed more than five papers are marked with an asterisk. By publishing their names, we hope that some small recognition of an important academic task can be given to those who give their time, knowledge, and expertise. While the academic community ponders on the best way to do peer review, a much more urgent question for those who design research assessment exercises is: how can this time-consuming yet undervalued activity be more formally appreciated and incorporated into the assessment of an academic’s work? As journal editors, we highly regard and respect our trusted reviewers. Thank you all!

Sabine Kleinert
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