

major bottlenecks for successful policy reform. We hope to stimulate debate on rigour in health-systems research. By identifying some of the issues, we aim to encourage better understanding of this field of work among the broader health-research community, as well as better research.

*Anne Mills, Lucy Gilson, Kara Hanson, Natasha Palmer, Mylene Lagarde

Department of Public Health and Policy, London School of Hygiene and Tropical Medicine, London WC1E 7HT, UK
anne.mills@lshtm.ac.uk

We declare that we have no conflict of interest.

- 1 Alliance for Health Policy and Systems Research. Strengthening health systems: the role and promise of policy and systems research. 2004. http://www.who.int/alliance-hpsr/resources/Strengthening_complet.pdf (accessed Oct 17, 2008).
- 2 Pawson R, Greenhalgh T, Harvey G, Walshe K. Realist review—a new method of systematic review designed for complex policy interventions. *J Health Serv Res Policy* 2005; **10** (suppl 1): 21–34.
- 3 Walt G, Gilson L. Reforming the health sector: the central role of policy analysis. *Health Policy Plan* 1994; **9**: 353–70.
- 4 Kelly MP, Morban A, Bonnefoy J, Butt J, Bergman V. The social determinants of health: developing an evidence base for political action. Final report to the World Health Organisation Commission on the Social Determinants of Health from the Measurement and Evidence Knowledge Network. 2007. http://www.who.int/social_determinants/resources/csdh_media/hskn_final_2007_en.pdf (accessed Oct 17, 2008).
- 5 Lavis JN, Becerra Pasada F, Haines A, Osei E. Use of research to inform public policymaking. *Lancet* 2004; **364**: 1615–21.
- 6 Fulop N, Allen P, Clarke A, Black N, eds. Studying the organisation and delivery of health services: research methods. London: Routledge, 2001.
- 7 Habicht JP, Victora CG, Vaughan JP. Evaluation designs for adequacy, plausibility and probability of public health programme performance and impact. *Int J Epidemiol* 1999; **28**: 10–18.
- 8 Ravallion M. The mystery of the vanishing benefits: an introduction to impact evaluation. *World Bank Econ Rev* 2001; **15**: 115–40.
- 9 George AL, Bennett A. Case studies and theory development in the social sciences. Cambridge, MA: MIT Press, 2005.
- 10 Walt G, Shiffman J, Schneider H, Murray SE, Brugha R, Gilson L. "Doing" health policy analysis: methodological and conceptual reflections and challenges. *Health Policy Plan* 2008; **23**: 308–17.
- 11 Diop F, Yazbeck A, Bitran R. The impact of alternative cost recovery schemes on access and equity in Niger. *Health Policy Plan* 1995; **10**: 223–40.
- 12 Litvack J, Bodart C. User fees plus quality equals improved access to health care: results of a field experiment in Cameroon. *Soc Sci Med* 1993; **37**: 369–83.
- 13 Lagarde M, Palmer N. The impact of user fees on health services utilization in low- and middle-income countries—how strong is the evidence? *Bull World Health Organ* 2008; published online Oct 31. DOI:10.2471/BLT.07.049197.

Scaling up research and learning for health systems: time to act

Recent years have seen a growing recognition of the importance of health systems in achieving the health-related Millennium Development Goals (MDG) by 2015, and the constraints related to systems short-falls which have hindered progress. These complex constraints are more easily understood through single-dimension diagnoses, such as a global shortage of over 4 million health workers,¹ or out-of-pocket payments for health care that push 100 million persons annually into poverty.²

These systems shortfalls are now being recognised at the highest level in global policy circles, as witnessed by their inclusion in the G8 follow-up Framework for Action, the Accra Agenda for Action,³ and the MDG High Level Taskforce follow-up.⁴ The Global Fund for AIDS, Tuberculosis and Malaria, the GAVI Alliance, and other major global-health initiatives are now encouraging countries to include activities for health-systems strengthening in their applications for support. These efforts coincide with other efforts specifically aimed at encouraging greater private-sector and civil-society involvement, strengthening information systems and health workforces at the country level, and aligning global partners around countries' health plans.^{5–8}

This intense activity raises the question of where we stand in systems learning and draws attention to the consensus statement of an earlier Ministerial Summit on Health Research in Mexico in 2004.⁹ In today's *Lancet*, Sara Bennett and colleagues¹⁰ report a stocktaking exercise. This analysis notes increases in funding, but points to underinvestment in researchers in low-income countries, fragmentation of global efforts, and a research agenda that lacks focus. These concerns prompted WHO's Director-General to convene a high-level consultation in June, 2008, to explore how research and learning on health systems could be scaled up.¹¹ In follow-up, a WHO-convened Task Force is preparing a set of recommendations for consideration at the Bamako Ministerial Forum on research for health in November, 2008.

These recommendations aim to raise the global profile of health-systems research but also emphasise several priority areas. One of these relates to better understanding of how health systems and programmes funded by global-health initiatives interact to influence demand, service delivery, health-system functioning, and outcomes. Indeed, a recently launched initiative, "Maximizing Positive Synergies between Health Systems

See [Editorial](#) page 1519

See [Health Policy](#) page 1571

The printed journal includes an image merely for illustration

Health-care worker talking to mother at outdoor health clinic in Mali

and Global Health Initiatives”, brings together researchers from academia, civil society, and implementing countries to systematically explore how these interactions occur in various contexts.¹² A second priority area is on systems design to deliver universal and equitable services, especially in relation to health financing, health workforce, information systems, governance, and supply-chain management. A third area relates to learning, specifically in effective use of monitoring and evaluation at the country level and evaluative research to enhance learning and decision making.¹³ The rapid growth in evaluative research offers opportunities for better coordination of efforts, methodologies, and cross-learning.

However, strong ownership by countries and leadership is vital if health-systems research is to succeed and yield meaningful evidence to inform policy and practice to save lives. Greater direct access to funds for country-based researchers and investment in robust systems for monitoring and evaluation are fundamental first steps, coupled with investment in academic institutions, civil society, and appropriate agencies in the public and private sectors in countries to develop analytic and learning capacity. A first order of business is to develop, as global public goods, common frameworks for health-systems research, methods, instruments, and measures to assess health-systems strengths and weaknesses.¹⁴ The second is to develop institutional arrangements that enable systematic

analysis and learning in countries and South-South cooperation. The growing interest in health-systems observatories could provide a common institutional platform for building research and learning capacity at the country level. A common framework can be an incentive for official development agencies to earmark contributions. In addition to strengthening systems learning at the country level, such an approach would also honour the commitment to harmonisation and alignment embodied within the Paris Declaration on Aid Effectiveness¹⁵ and its recent reiteration at the Third High Level Forum on Aid Effectiveness in Accra.¹⁶

The global funding environment is conducive to realising this vision. As part of their proposals to the Global Fund, countries can request funding for monitoring and evaluation, and relevant (local and international) technical assistance to develop analytic capacity to contribute to efforts to strengthen health systems. Other global funders, such as the Bill & Melinda Gates Foundation and the US President’s Emergency Plan for AIDS Relief, are investing substantially in operational research related to health systems. The recently launched US\$100 million Africa Health Initiative of the Doris Duke Foundation¹⁷ and the Global HIV/AIDS Initiatives Network¹⁸ are providing research funds and facilitating capacity strengthening through twinning arrangements.

Scaling up research and learning for health systems, led by researchers from countries and backed up with appropriate global support offers, a rich harvest in terms of accelerated health achievement, strengthened health systems, and better value for money that Ministers in Bamako just cannot afford to ignore.

**Timothy Evans, Sania Nishtar, Rifat Atun, Carissa Etienne* Information Evidence and Research, WHO, 1211 Geneva 27, Switzerland (TE); Heartfile, Chak Shahzad, Islamabad, Pakistan (SN); Global Fund to Fight AIDS, Tuberculosis and Malaria, Geneva, Switzerland (RA); Business School, Imperial College London, London, UK (RA); and Health Systems and Services, WHO, Geneva, Switzerland (CE)
evanst@who.int

We declare that we have no conflict of interest.

- 1 WHO. The World Health Report 2006: working together for health. <http://www.who.int/whr/2006/en> (accessed Oct 17, 2008).
- 2 Xu K, Evans DB, Kawabata K, Zeramdini R, Klavus J, Murray CJL. Household catastrophic health expenditure. *Lancet* 2003; **362**: 111–17.
- 3 OECD. Accra Agenda for Action. Aug 11, 2008. <http://siteresources.worldbank.org/ACCRAEXT/Resources/4700790-1217425866038/AAA-Final-Draft-11-August-2008.pdf> (accessed Oct 9, 2008).

- 4 MDG Gap Task Force. Delivering on the Global Partnership for Achieving the Millennium Development Goals. 2008. http://www.un.org/esa/policy/mdggap/mdg8report_engw.pdf (accessed Oct 17, 2008).
- 5 WHO. Health Metrics Network. 2005. <http://www.who.int/healthmetrics> (accessed June 27, 2008).
- 6 WHO. Global Workforce Alliance. 2005. <http://www.ghwa.org> (accessed June 27, 2008).
- 7 Rockefeller Foundation. The role of the private sector in health systems. 2008. http://www.rockfound.org/library/020108private_sector_health.pdf (accessed June 27, 2008).
- 8 Department for International Development. International Health Partnership. Sept 5, 2007. <http://www.dfid.gov.uk/news/files/ihp/default.asp> (accessed June 27, 2008).
- 9 The Mexico Statement on Health Research: Knowledge for better health: strengthening health systems. Nov 16–2004. http://www.who.int/rpc/summit/agenda/en/mexico_statement_on_health_research.pdf (accessed June 4, 2008).
- 10 Bennett S, Adam T, Zarowsky C, et al, Alliance STAC. From Mexico to Mali: progress in health policy and systems research. *Lancet* 2008; **327**: 1571–78.
- 11 Chan M. Scaling up research and learning for better health: opening remarks at the high-level consultation, Divonne les Bains, France. June 2, 2008. <http://www.who.int/dg/speeches/2008/20080602b/en> (accessed July 1, 2008).
- 12 WHO. Maximizing positive synergies between health systems and Global Health Initiatives. May, 2008. <http://www.who.int/healthsystems/GHlsynergies/en> (accessed July 1, 2008).
- 13 Murray CJ, Frenk J, Evans T. The Global Campaign for the Health MDGs: challenges, opportunities, and the imperative of shared learning. *Lancet* 2007; **370**: 1018–20.
- 14 Strengthening health systems capacity and leadership. <http://www.columbia-icap.org/bellagio2/index.htm> (accessed Oct 17, 2008).
- 15 OECD. The Paris Declaration. http://www.oecd.org/document/18/0,2340,en_2649_3236398_35401554_1_1_1_1,00.html (accessed Oct 20, 2008).
- 16 Accra High Level Forum. Accra agenda for action. <http://www.accralh.net/WBSITE/EXTERNAL/ACCRAEXT/0,,contentMDK:21690826~menuPK:64861649~pagePK:64861884~piPK:64860737~theSitePK:4700791,00.html> (accessed Oct 20, 2008).
- 17 Doris Duke Charitable Foundation. Operations research. <http://www.ddcf.org/page.asp?pagelid=486> (accessed Oct 9, 2008).
- 18 Global HIV/AIDS Initiatives Network. <http://www.ghinet.org> (accessed Oct 9, 2008).

En route to international clinical trial transparency

Substantial progress has been made since the Ministerial Forum on Health Research in Mexico when the notion of making information about a clinical trial publicly known before it had started recruiting participants was still relatively novel and unpopular.¹ Their call to “establish a platform linking a network of international clinical trial registers to ensure a single point of access and the unambiguous identification of trials” has now been realised. WHO’s International Clinical Trials Registry Platform includes the WHO Registry Network and an online Clinical Trials Search Portal (CTSP) that allows users to search WHO’s trial-registration dataset provided by registries meeting WHO’s standards for quality control and content.^{2,3} More than 72 000 records have been provided to WHO by registries in Australia, the UK and USA, and data from China, Germany, India, Japan, the Netherlands, and Sri Lanka will soon be added to this list.

Despite good progress, important challenges remain. As of Oct 13, 2008, only 3.1% of the 25 015 trial records on the CTSP with the status “recruiting” were doing so in low-income countries (6.8% in lower-middle-income countries), compared with 90.6% in countries of the Organisation for Economic Co-Operation and Development. Only 2.5% of all trial records on the CTSP have ever or are currently recruiting participants in low-income countries (figure). Because it has

been estimated that 30–40% of clinical trials involve low-income and lower-middle income countries,⁴ a large proportion of clinical trials research conducted in these countries seems to be unaccounted for.

Without international legislation to make registration of a clinical trial in a publicly accessible registry legally binding, enforcement mechanisms can only be determined and implemented within national borders. Enforcement within a country can be achieved through national legislation (such as that in Brazil), or by making registration a requirement for ethics approval.⁵ Countries may choose to use existing infrastructure

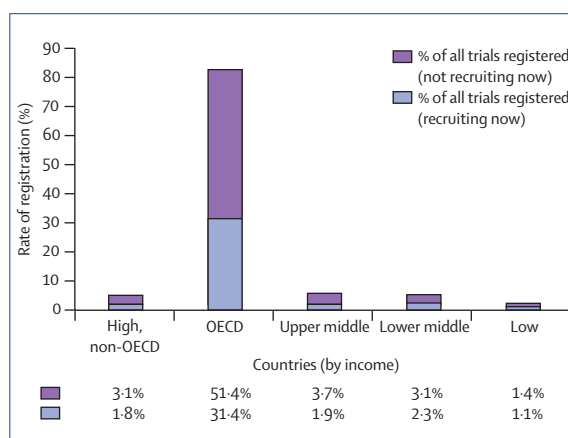


Figure: Rate of trial registration by World Bank income level
 OECD=Organisation for Economic Co-Operation and Development. Results of search of ICTRP clinical trials search portal, Oct 13, 2008.