

1.3% of the sampled population were not paying social health insurance premiums even though their incomes were high enough to be taxable. If this proportion could be extrapolated, about 1.6 million people would not have insurance, which might bring into question Japan's status as a country with universal coverage. In addition to these non-payers, the benefits of those enrollees who have not paid premiums for more than 18 months in the citizens' health insurance are severely restricted (pay full amount first, and get reimbursed later).³⁶ 1.6% of people enrolled in citizens' health insurance have this status.

All three difficulties have been exacerbated by the fragmentation of social health insurance plans by employment and residential status, and the increasing disparity in income levels and age structure among the plans. This disparity could be compensated for by increasing subsidies from general revenues, which would require taxes to be increased. However, every government in Japan that has raised or attempted to raise value added taxes (VAT) has subsequently lost the next election, the most recent being Prime Minister Kan losing control of the upper house in July, 2010, because he made an ill-timed announcement on the need to raise VAT.³⁷ The Great East Japan Earthquake might lead to a bipartisan movement to increase taxes, but this money would mostly be allocated to rebuilding the devastated regions and to paying back the huge deficit, and would probably not lead to a real increase in funding for health care.

Panel 3: Debate on the insurance scheme for late elders

A new insurance scheme for people aged 75 years and older (late elders) was introduced in April, 2008. All those aged 75 years and older, irrespective of where they had been enrolled previously, joined the Later Elders' Health Insurance. Because the needs and risk of medical service use are distinctively higher in late elders than in other age groups, an age-specific scheme seemed to be more valid because risk pooling would become homogeneous, services covered could be made more appropriate for this group, and financing responsibility could be made more explicit.

However, the new scheme became a political fiasco for the government led by the Liberal Democratic Party at the time. The media reported on the administrative difficulties of introduction of the new scheme and the outrage expressed by people whose premiums increased, but the greatest public outcry was towards its perceived ageism aspect. This feature was exemplified by the introduction of an end-of-life consultation fee only for late elders. Accusations were made that it would not be consultation, but persuasion, so that it had to be delisted from the fee schedule only 2 months after its introduction.

The present government, led by the Democratic Party of Japan, came to power in September, 2009, with a pledge to abolish the scheme by 2013. The services listed only for late elders in the fee schedule were formally abolished in April, 2010, during one of its scheduled revisions (every 2 years). To replace the plan for late elders, in December, 2010, the government committee recommended a two-stage reform. The first was to revert back to the enrolment rule that existed before the plan for late elders: people aged 75 years and older who are dependants of employees or are themselves employees would continue to be enrolled in the employee-based plan (20%), the rest would be enrolled in citizens' health insurance (80%). The second was to consolidate citizens' health insurance within prefectures. However, even if the reform is implemented, the disparity between and within tiers will remain.

Another possible solution would be to reduce the benefits covered by social health insurance to a basic package, with the rest to be paid out of pocket or to be covered by supplementary private health insurance. The Regulation Reform Council composed of industry leaders and economists backed by Prime Minister Koizumi attempted such a reform in 2004. However, opposition from the Ministry of Health, Labour and Welfare and the Japan Medical Association resulted in a compromise in 2005, which largely left intact the regulations restricting extra billing and balance billing, while giving more flexibility to hospitals wanting to provide new technology not yet listed in the fee schedule.³⁸ Although advocates of deregulation will always exist, if equal access is not to be sacrificed Japan should continue to impose broad and complex restrictions on extra billing, as Canada and some European countries have done.³⁹

Consolidation of social health insurance plans

From our analysis, we believe that the way forward would be to consolidate social health insurance plans. Consolidation would equalise premium contribution rates across plans, increase total funding by raising the contribution rates of plans currently set at a low level, and improve administrative efficiency by expanding risk pools. Three options exist for consolidation.

The first is to allow everyone to choose the plan that they prefer, after adjustment of the basic premium rate for income, age, and other factors that affect the risk profile of the individual. Such structural adjustments would decrease differences in contribution rates and increase the pressure for plans to consolidate, as has occurred in Germany.⁴⁰ However, this approach would not work in the Japanese context because most social health insurance plans do not operate as independent entities. They are administered as de-facto divisions of the company's personnel department in most society-managed health insurance plans, and of the municipal government in the citizens' health insurance plans.

The second is national unification of all social health insurance plans, as has been done in South Korea.⁴¹ This option has the advantages that risk pooling occurs nationally, the contribution rate is the same for all, and the administrative costs would be lower. However, such unification would be contrary to present efforts to decentralise the national government's functions and would ignore the differences in per-head health expenditure after adjustment for age structure in the 47 prefectures.⁴²

The third is to unify social health insurance plans regionally and untie insurance coverage from employment status. Canada and many European countries have a history of provincial autonomy and have organised their systems on a regional basis. The advantages are that the health insurance contribution rate would be indicative of the medical expenditure of the region, after the national government has standardised regional differences in

income, age, and other factors on the demand side. By doing so, popularly elected regional governments would have an incentive to increase efficiency of service delivery.

In view of the difficulties associated with the first two options, we believe that regional consolidation is the most appropriate solution for Japan. A bonus is that enrolment of everyone within a prefecture in the same plan would facilitate improved tracking of the uninsured. This option has recently become more realistic since the Ministry of Health, Labour and Welfare announced its intention to consolidate the citizens' health insurance within the 47 prefectures as the second stage in its goal of abolishing the plan for those aged 75 years and older (panel 3). However, unless employee-based plans are consolidated as the third stage, because contribution rates in most citizens' health insurance plans are already high, no substantial increase in funding would be achieved.

We assessed the effect of expansion of the risk pool by analysing the variance in per-head annual inpatient medical expenditures if plans were to be consolidated within prefectures, on the basis of data for individuals from all social health insurance plans in 2005 (see webappendix p 4 for technical notes). As figure 5 shows, when the number enrolled exceeds 1.5 million in the consolidated citizens' health insurance plans and 4.5 million in these plans and employee-based plans, further consolidation would bring only a small incremental benefit when compared with national consolidation. Nine prefectures would exceed this level and their combined population would compose slightly more than half the total. The population of the remaining prefectures would still be less than the economically efficient level, but further consolidation would necessitate mergers of the prefectures themselves.

We are aware of formidable political and institutional obstacles to merging employee-based plans with community-based citizens' health insurance. Consolidation would be opposed by the employee-based plans, particularly the society-managed health insurance plans with fairly young, high-income enrollees. They will argue that increased contribution rates would reduce the global competitiveness of Japanese products, but this fear is unfounded. Germany has managed to maintain its competitive advantage despite a contribution rate that is twice the average for society-managed health insurance.⁷ Another obstacle is that the method of premium calculation differs between the employee-based plans and citizens' health insurance. Moreover, among citizens' health insurance plans, not only does each municipality use a different method to calculate contribution, but also the extent to which subsidies are provided from the municipality's general revenues budget differs.

However, these obstacles could be overcome, especially now that solidarity has been strengthened after the Great East Japan Earthquake. Structural reform will result in all households within the same prefecture contributing the same percentage of their income as premiums,

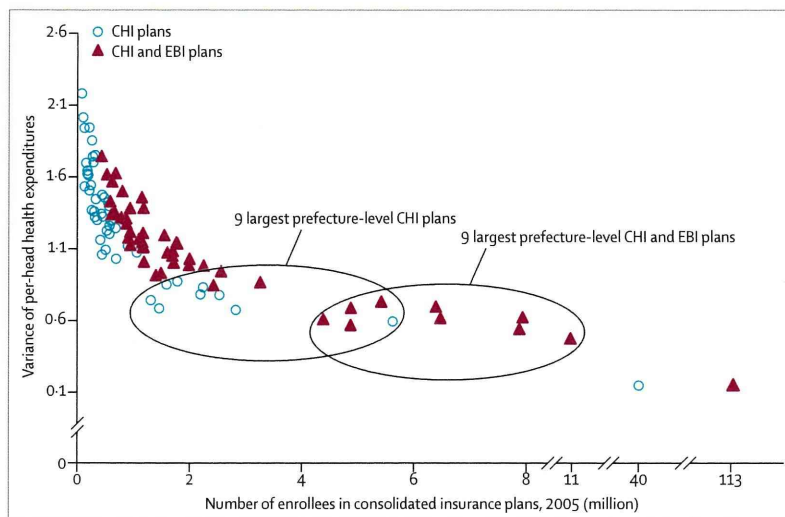


Figure 5: Size of consolidated citizens' health insurance plans and employee-based insurance plans, and variance of per-head annual inpatient health expenditures (ratio of standard error to the mean [%]) in Japan, 2005
The circle and the triangle on the far right show the variance if the plans were consolidated nationally. CHI=Citizens' health insurance. EBI=Employee-based insurance. Data from Ministry of Labour, Health and Welfare (unpublished).

Panel 4: Public assistance and safety net for the poor

Definition of individuals who cannot afford any contribution is a prerequisite for universal coverage by social health insurance. In Japan, people on public assistance are not enrolled in any social health insurance plan, and are exempted from both premium contribution and co-payment. Medical expenditures paid by public assistance contribute about 3–4% of the total. The medical services to which people with public assistance are eligible are the same as for social health insurance enrollees, and providers are paid at the same fee schedule rate.

Although all individuals who meet the nationally defined criteria should be eligible for public assistance, in practice, the hurdle is high. Municipal governments have been reluctant to provide coverage because they have to fund 25% of expenditure from their general revenues—which amounted to 17% of Osaka City's budget in 2010—and because they are aware of the public outcry should any abuse be reported by the media. Applicants are told to first seek assistance from family members who are legally bound to help under the civil code. However, municipal governments do not have any means of enforcing family support.

The number of people on public assistance has increased by 10% compared with 2010, to 2 million in 2011, a record high. The national government has tried to lower the proportion they currently fund, 75%, and have pointed out the 11-times difference in the per-head number of those on public assistance even between prefectures. However, the municipalities have so far successfully resisted, arguing that because ensuring basic livelihoods is a constitutional right, the national government should be primarily responsible, and that prefectures that have high proportions of people on public assistance are metropolitan areas with a higher prevalence of people without homes than in rural areas.

The livelihood allowance provided by public assistance is higher than the basic pension amount, which has added another layer of complexity because its reform is linked to pension reform. In health care, it is linked to the next layer of poverty: those who will be exempt from co-payment among those enrolled in the citizens' health insurance, which is also a decision made by municipalities. Thus, the safety net for the poor is doubly at risk when the municipality faces fiscal difficulties.

irrespective of employment status. Income would be calculated from all sources, and not restricted to wages as is currently the case for employee-based plans. This

approach will adjust to further changes in employment patterns, including an increased number of pensioners working. Additionally, the co-payment rate should be lowered for all households with low income—not only elderly people—to improve inequities in access. Where to set the line to exempt people from contributing premiums and making co-payments should be considered in the context of public assistance reform (panel 4).⁴³

Consolidation within prefectures does not mean that the national government would abdicate its responsibility. On the contrary, the government should continue to play a major part in deciding the services to be covered and their prices in the fee schedule, in setting national standards of quality and professional qualifications, and in subsidising prefectures with low average incomes, a higher proportion of elderly people, and so forth. However, key decisions about investment in and restructuring the delivery system would be made by prefectural governments. This devolution of authority and fiscal responsibility would be in line with the ongoing trend in the public sector in Japan.

Global lessons

Japan's major accomplishment with social health insurance, from a global perspective, has been its successful pursuit of the normative goals of expansion of coverage and containment of costs while improving equity in the health system over time. Japan offers several lessons for other countries.

The first is that attainment of universal coverage on the one hand and achievement of equity in benefit packages and rates of co-payments and contributions on the other, are different goals and need different long-range strategies.⁴⁴ Before universal health coverage was achieved in 1961, community-based plans adopted the fee schedule of employee-based plans in 1959. The co-payment rate became uniform, except for elderly people and children, only in 2003. However, contribution rates still differ by more than three times between the social health insurance plans. Reform is a continuous process that will never be completed.

The second is the importance of political driving forces to move countries forward on the path to universal coverage. For Japan, the political forces for expansion of social health insurance coverage were the goals of achieving a wartime state in the 1930s and 1940s, and a welfare state in the 1950s to 1970s. For the welfare state, Japan's post-war democracy had a crucial role, providing both popular support and political party competition that motivated efforts to decrease inequities in the different rates of co-payment between social health insurance plans. Successful egalitarian reforms have been undertaken in South Korea and Taiwan after the election of democratic governments.⁴⁵

The third is the inherent weakness of a social health insurance system that is fragmented by employment and residential status as in Japan. Because each plan

will differ in risk profile and income level, economic and political incentives against policy change are created.⁴⁶ This difficulty will be exacerbated if local governments are allowed to choose their own method of setting contribution rates. Countries that might consider adopting Japan's model of social health insurance should plan in advance to address its weaknesses before opposition to structural reform becomes deeply entrenched.

Contributors

B-KY, HH, MM, AB, and RW contributed to the data analysis. B-KY, HH, MM, AB, HO, KS, B-MY, and MRR commented on the report, and MRR revised the report. All authors contributed to the discussion and have seen the final version of the report.

Conflicts of interest

We declare that we have no conflicts of interest.

Acknowledgments

We thank John Creighton Campbell and Keizo Takemi for their valuable comments, Megumi Kasajima for technical assistance in the statistical analysis, Andrew Stickley for his technical edits, and Tomoko Suzuki and Tadashi Yamamoto for their administrative support. This work is in part funded by the Bill & Melinda Gates Foundation and the China Medical Board, and in part by a research grant from the Ministry of Health, Labour and Welfare (H22-seisaku-shitei-033). The views and opinions expressed by the independent authors in this publication are provided in their personal capacity and are their sole responsibility.

References

- 1 Saltman RB, Busse R, Figueras J, eds. Social health insurance systems in western Europe. Maidenhead: Open University Press, 2004.
- 2 Hsiao WC. Design and implementation of social health insurance. In: Hsiao WC, Shaw RP, eds. Social health insurance for developing nations. Washington, DC: World Bank, 2007: 21–41.
- 3 OECD. OECD Health data 2011. Paris: Organisation for Economic Co-operation and Development, 2011.
- 4 Hashimoto H, Ikegami N, Shibuya K, et al. Cost containment and quality of care in Japan: is there a trade-off? *Lancet* 2011; published online Sept 1. DOI:10.1016/S0140-6736(11)60987-2.
- 5 WHO. World health report. Geneva: World Health Organization, 2010. <http://www.who.int/whr/en> (accessed April 20, 2011).
- 6 Ministry of Finance, Japan. International comparisons of debt as percentage of GDP. 2011. <http://www.zaisei.mof.go.jp/pdf/4-2.pdf> (accessed July 20, 2011).
- 7 Shimazaki K. Health care in Japan—institutions and policies. Tokyo: Tokyo University Press, 2011 (in Japanese).
- 8 Campbell JC, Ikegami N. The art of balance in health policy: maintaining Japan's low-cost, egalitarian system. Cambridge: Cambridge University Press, 1998.
- 9 Fuse S. History of doctors—Japanese characteristics. Tokyo: Chuou Kouronsha, 1979 (in Japanese).
- 10 Higuchi T. Medical care through social insurance in the Japanese rural sector. *Int Labour Rev* 1974; 109: 251–74.
- 11 Takagi Y. Citizens' health insurance and regional welfare—addressing issues in long-term hospitalization and stabilizing citizens' health insurance. *Kikan Shakai Hoshou Kenkyu* 1994; 30: 239 (in Japanese).
- 12 Shakai Hoken Kenkyusho. Progress in social insurance. Tokyo, Japan: Shakai Hoken Kenkyusho, 1991 (in Japanese).
- 13 Federation of Health Insurance Societies. Health security seen from figures and tables (in Japanese). Tokyo: Gyoshei, 2010: 8–9.
- 14 Katsumata Y. Comparison of health expenditure estimates between Japan and the United States. In: Ikegami N, Campbell JC, eds. Containing health care costs in Japan. Ann Arbor, MI: Michigan University Press, 1996: 19–33.
- 15 Ministry of Health, Labour and Welfare. Patient survey report 1950–2008. Tokyo: Health, Labour and Welfare Statistics Association, 2010.

- 16 Babazono A, Tsuda T, Yamamoto E, Mino Y, Une H, Hillman AL. Effects of an increase in patient co-payments on medical service demands of the insured in Japan. *Int J Technol Assess Health Care* 2003; 19: 465–75.
- 17 Ohnuki-Tierney E. *Illness and culture in contemporary Japan: an anthropological view*. New York, NY: Cambridge University Press, 1984.
- 18 Tamiya N, Noguchi H, Nishi A, et al. Population ageing and wellbeing: lessons from Japan's long-term care insurance policy. *Lancet* 2011; published online Sept 1. DOI:10.1016/S0140-6736(11)61176-8.
- 19 Ministry of Health, Labour and Welfare. Status of insurance and pensions. *J Health Welfare Stat* 2010; 57: 46–47.
- 20 Ikegami N. My plan to reform health insurance for elders. *Shakai-hoken Junpo* 2010; 2410: 16–21 (in Japanese).
- 21 Kakwani N, Wagstaff A, van Doorslaer E. Socioeconomic inequalities in health: measurement, computation, and statistical inference. *J Econometrics* 1997; 77: 87–103.
- 22 O'Donnell O, van Doorslaer E, Rannan-Eliya RP, et al. Who pays for health care in Asia? *J Health Econ* 2008; 27: 460–75.
- 23 Wagstaff A, van Doorslaer E, van der Burg H, et al. Equity in the finance of health care: some further international comparisons. *J Health Econ* 1999; 18: 263–90.
- 24 van Doorslaer E, O'Donnell O, Rannan-Eliya RP, et al. Catastrophic payments for health care in Asia. *Health Econ* 2007; 16: 1159–84.
- 25 van Doorslaer E, Koolman X, Jones AM. Explaining income-related inequities in doctor utilisation in Europe. *Health Econ* 2004; 13: 629–47.
- 26 Lu JF, Leung GM, Kwon S, Tin KY, Van Doorslaer E, O'Donnell O. Horizontal equity in health care utilization evidence from three high-income Asian economies. *Soc Sci Med* 2007; 64: 199–212.
- 27 All-Japan Federation of National Health Insurance Organizations. *Seeking stability in national health insurance*. Tokyo: All-Japan Federation of National Health Insurance Organizations, 2010 (in Japanese).
- 28 Federation of Health Insurance Societies. *Fiscal year 2007—data of health insurance societies*. Tokyo: Federation of Health Insurance Societies, 2008.
- 29 Ministry of Health, Labour and Welfare. *Basic data about health insurance*, 52nd edn. Tokyo: Ministry of Health, Labour and Welfare, 2007.
- 30 Ministry of Health, Labour and Welfare. *For reference: cost burden. Council for the reform of health system for elders*. Tokyo: Ministry of Health, Labour and Welfare, 2010.
- 31 Tamura M. Why does the general public oppose the introduction of disparity in healthcare? *Shakai Hoken Jynpou* 2003; 2192: 6–15 (in Japanese).
- 32 Ministry of Health, Labour and Welfare. *Data 3: projections for national medical expenditures*. Tokyo: Ministry of Health, Labour and Welfare, 2005.
- 33 Vogel SK. *Japan remodeled: how government and industry are reforming Japanese capitalism*. Ithaca, NY: Cornell University Press, 2006.
- 34 Ministry of Public Management, Home Affairs, Posts and Telecommunications. *Historical data 10: employee by age group and type of employment—whole Japan labour force survey*. 2011. <http://www.stat.go.jp/data/roudou/longtime/zuhyou/lt52.xls> (accessed April 12, 2011).
- 35 Ministry of Public Management, Home Affairs, Posts and Telecommunications. *Results of the industrial classification. Labour force survey*. 2011. <http://www.stat.go.jp/data/roudou/sangyo.htm> (accessed April 12, 2011).
- 36 Ministry of Health, Labour and Welfare. *Results of a survey on the issuing of certificates of status*. <http://www.mhlw.go.jp/houdou/2008/10/h1030-2.html> (accessed July 19, 2011).
- 37 Anonymous. *Even with VAT at 10% still not able to pay for social security*. Tokyo: The Nikkei, 2011.
- 38 Ikegami N. Should providers be allowed to extra bill for uncovered services? Debate, resolution, and sequel in Japan. *J Health Polit Policy Law* 2006; 31: 1129–49.
- 39 Flood CM, Haugan A. Is Canada odd? A comparison of European and Canadian approaches to choice and regulation of the public/private divide in health care. *Health Econ Policy Law* 2010; 5: 319–41.
- 40 Moynihan R. *Focus on health policy in times of crisis, competition and regulation, evaluation in health care*. Gütersloh: Bertelsmann Stiftung, 2010.
- 41 Kwon S. Healthcare financing reform and the new single payer system in the Republic of Korea: social solidarity or efficiency? *Int Social Security Rev* 2003; 56: 75–94.
- 42 Regional Disparity Study Group. *Disparity of healthcare expenditures*. Tokyo: Toyo Keizai, 2001 (in Japanese).
- 43 Honda R. *Reportage on public assistance*. Tokyo, Japan: Chuoukouron Shinsha, 2010 (in Japanese).
- 44 Bump J. *The long road to universal health coverage: a century of lessons for development strategy*. Seattle, WA: PATH, 2010.
- 45 Wong J. *Healthy democracies: welfare politics in Taiwan and South Korea*. Ithaca, NY: Cornell University Press, 2004.
- 46 Pierson P. Increasing returns, path dependence, and the study of politics. *Am Political Sci Rev* 2000; 94: 251–67.

Science and consensus for health policy making in Japan



After World War 2 and the Korean War, Japan gained political stability by merging two conservative parties in 1955, then capitalised on this stability to promote economic growth. What emerged was an interdependent system that satisfied major political groups by funding benefits from tax money rather than by weighing objectively social benefits and costs. This system succeeded in an era of prosperity, but Japan now has a rapidly ageing population, enormous financial deficits, and slow economic growth. Japan needs to reform policy making to be geared to the interests of society as a whole.¹

Can evidence-based policy making in health be the solution? Partly, yes. Such an approach should provide: (1) direction for health policy making on the basis of available evidence (the most thoughtful, objective, balanced, and useful information about available choices), which facilitates wider consensus than that without evidence; (2) an environment in which consensus among various stakeholders and with the general public can be achieved; and (3) a safeguard against undue influence from biased political or lobbyist groups. However, an evidence-based approach does not solve all problems, nor does it necessarily always provide the right answer. It is limited by the availability of evidence, which is shaped by funding opportunities, ease of doing research, and interpretation of uncertainty. Not all the political decisions previously made in Japan that were not evidence based were necessarily wrong. However, the likelihood that health policy direction will be appropriate increases with an evidence-based approach.^{2,3}

There are several prominent examples from which Japan can draw lessons, because the task of crafting sound health policy is a global challenge. The Netherlands has a highly regarded health-insurance system.⁴ However, this system did not arise at a single moment, but was a result of several reforms driven by different parliaments, on the basis of principles that were developed in the 1980s. The Australian Pharmaceutical Benefits Scheme has a long history of policy development on the basis of research synthesis and cost-effectiveness analyses.⁵ However, this method of policy development is politically palatable in a country where virtually all medicines are imported and there are fewer powerful stakeholders in the form

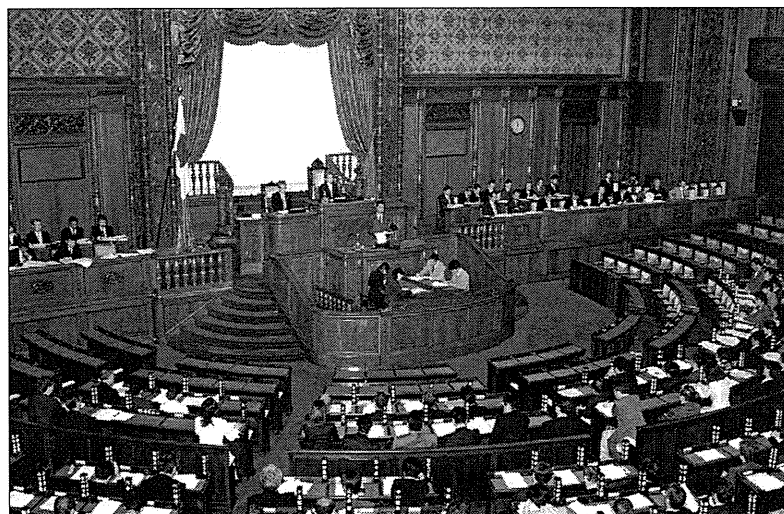
of domestic pharmaceutical companies. The Cochrane Collaboration provides a platform for researchers around the world to contribute high-quality reviews of studies in health care. The Collaboration is purposely detached from political decisions and Cochrane Reviews often give no clear guidance for health policy makers. The UK's National Institute for Health and Clinical Excellence (NICE) was created by the Labour Government. NICE makes consensus building a part of its methodology by including wide consultation with stakeholders, multidisciplinary approaches, and involvement of patients and the public. The US Institute of Medicine provides another model. In its consensus studies to guide health policy, the Institute goes to great lengths to avoid conflicts of interest, expose any biases, and to base its conclusions and recommendations on science and evidence.

If Japan were to create a new organisation to develop health policies on the basis of available evidence with political neutrality, two key elements would be needed: robust methodology to develop policies (eg, research synthesis of high-quality comparative studies, timely and accurate epidemiological data, decision analysis, and formal consensus methods, implementation strategies, and audit cycles); and a governance structure that informs key stakeholders (including professional organisations, patients' groups and consumers, government representatives, and industry) about policy needs but keeps their vested interests separate from the assessment of evidence

Published Online
September 1, 2011
DOI:10.1016/S0140-6736(11)60820-9

See Online/Comment
DOI:10.1016/S0140-6736(11)60274-2 and
DOI:10.1016/S0140-6736(11)61189-6

See Online/Series
DOI:10.1016/S0140-6736(11)61176-8 and
DOI:10.1016/S0140-6736(11)61098-2



leading to policy. Although publicly funded, the new organisation should be separate from the government. It should operate on principles of transparency and conflict of interest management, and dissemination and communication should be emphasised. The central idea is to create an organisation that can remain neutral and grounded in evidence when doing studies, but that involves all key stakeholders in defining issues of concern and encouraging implementation of evidence-based solutions.⁵

One fundamental concern is the present capacity of pertinent technical expertise. As of 2009, there were only 55 researchers in Japan who had contributed to Cochrane Reviews, and there are only a handful of health economists in Japan who can do cost-effectiveness analyses. To fulfil the potential of a new policy advisory organisation, greater technical capacity will need to be developed.

If Japan is to overcome the unprecedented challenges of a rapidly ageing society, enormous financial deficits, and diminished economic growth, it needs to incorporate new values in health policy making. Japan can come to rely more on science as a guide to health policy by establishing a new quasi-public organisation with appropriate stakeholders represented in its

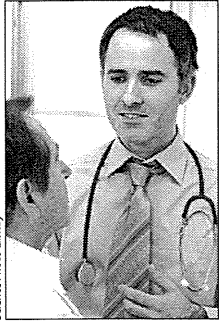
governance, but with policies and procedures that assure robust methodology untainted by conflicts of interest, and grounded in science and evidence. The organisation should have a two-tiered design of an oversight council that includes representatives of stakeholders and an operating agency that is structured to operate without conflicts of interest to serve the purpose.

*Rintaro Mori, Keizo Takemi, Harvey V Fineberg

Department of Global Health Policy, Graduate School of Medicine, University of Tokyo, 7-3-1, Hongo, Bunkyo-ku, Tokyo 113-0033, Japan (RM); School of Political Science and Economics, Tokai University, Kanagawa, Japan (KT); and Institute of Medicine, Washington, DC, USA (HVF)
rintaromori@gmail.com

We declare that we have no conflicts of interest.

- 1 Ikegami N, Yoo B-K, Hashimoto H, et al. Japanese universal coverage: evolution, achievements, and challenges. *Lancet* 2011; published online Sept 1. DOI:10.1016/S0140-6736(11)60828-3.
- 2 Dobrow MJ, Goel V, Upshur REG. Evidence-based health policy: context and utilisation. *Soc Sci Med* 2004; 58: 207-17.
- 3 Niessen LW, Grijseels EW, Rutten FF. The evidence-based approach in health policy and health care delivery. *Soc Sci Med* 2000; 51: 859-69.
- 4 Exter A, Hermans H, Dosjak M, et al. Health care systems in transition: Netherlands. 2004. http://www.euro.who.int/__data/assets/pdf_file/0006/95136/E84949.pdf (accessed April 10, 2011).
- 5 Chalkidou K, Tunis S, Lopert R, et al. Comparative effectiveness research and evidence-based health policy: experience from four countries. *Milbank Q* 2009; 87: 339-67.



Telling culturally construed truth in clinical practice

Your Editorial entitled "Truth telling in clinical practice" (Oct 1, p 1197)¹ raises an old, albeit contentious, issue in medicine. Any caring physician knows how important it is to inform the patient about the diagnosis and prognosis of a disease, and the treatment options. Since culture creates the context within which individuals experience life, illness, suffering, and death, cultural and moral meanings of diseases profoundly affect clinical medicine. Thus the ethics of truth telling in medicine is embedded in cultural meaning and construction of what is understood as truth.

In traditional Hindu teaching, truth has three qualities or attributes—*satyam*, *shivam*, *sundaram*—and thus for something to be regarded as the truth it has to be true in fact (*satyam*), good in nature (*shivam*), and beautiful or aesthetically appealing (*sundaram*). Disclosure of the painful reality of a fatal disease to a suffering patient—honouring individual autonomy but with total disregard for his or her emotional state of mind or the role of the family—might be neither good nor appealing. In the art of compassionate medicine, telling the truth might thus demand—at least in some cases—non-disclosure of some of the factual information about a disease, and communication of the limited information that is true, good, and appealing. Further, truth telling is not necessarily a one-time act; rather it might be a continued process of sharing over a period of time with respect for the feelings and needs of patients.

I declare that I have no conflicts of interest.

Subrata Chattopadhyay
linkdrsc@yahoo.com

Department of Physiology, Sikkim Manipal Institute of Medical Sciences, Tadong, Gangtok, Sikkim 737102, India

1 The Lancet. Truth telling in clinical practice. *Lancet* 2011; **378**: 1197.

Vaccine-associated paralytic poliomyelitis in Japan

Despite WHO's recommendation to switch the poliomyelitis vaccine from oral polio vaccine (OPV) to inactivated polio vaccine (IPV) in countries where polio elimination has been achieved, Japan has continued to use OPV. In Japan, OPV is given twice to children aged from 3 to 18 months.¹ More than 10 years after the elimination of wild polio virus, tragic cases of vaccine-associated paralytic poliomyelitis (VAPP) continue to be reported every year—most recently in May, 2011. The Ministry of Health, Labour and Welfare claims that IPV is still being developed by Japanese vaccine companies and that it will not be available until the end of 2012 at the earliest. The growing tension between the Government, which persists with domestically produced OPV, and the parents, who request IPV to avoid VAPP, has evoked huge media attention.

To understand OPV perceptions and practices among parents, we did a survey of 260 parents whose children attend day care or one of two nursery schools in Kanagawa Prefecture. 50 parents (19%) thought that OPV was dangerous and 81 (31%) wanted their children to take IPV. Because of the growing fear of OPV, the coverage of OPV has been decreasing. According to the Ministry, OPV coverage from April to June, 2011, was 17.5% lower than in the previous year.² A paediatrician in the urban area of Tokyo has said that the inoculation rate is only about 50% there, which indicates an increased risk of re-transmission of poliovirus once it is imported.³

Despite such concerns, the Japan Pediatric Society recommends that people should take OPV until domestically produced IPV becomes available.⁴ However, some paediatricians have begun to import IPV

and administer it if parents are willing to pay out-of-pocket expenses of US\$160–240. The Governor of Kanagawa Prefecture also announced the establishment of a system to provide IPV to respond to the needs of residents, despite strong opposition from the Government.

Japan has been a major driver of the Global Polio Eradication Initiative,⁵ but the lack of consistency between its domestic and global health policies is harming its own people. How long will the Japanese people need to wait for safe IPV to become available?

This study was reviewed by the Office of Human Research Administration of the Harvard School of Public Health. Protocol number 21402-101: "Polio vaccination status and parents' perception on polio vaccine." We declare that we have no conflicts of interest.

**Miwako Hosoda, Hajime Inoue, Yasuo Miyazawa, Eiji Kusumi, Kenji Shibuya*
miwhosoda@gmail.com

Seisa University, Yokohama, Kanagawa 227-8522, Japan (MH, HI, YM); and University of Tokyo, Tokyo, Japan (EK, KS)

- 1 Ministry of Health, Labour and Welfare. Basic information on polio and poliomyelitis vaccine. <http://www.mhlw.go.jp/bunya/kenkou/polio/qa.html#q6> (accessed Dec 5, 2011).
- 2 Anon. Government should introduce IPV immediately. *Akita Sakigake* Nov 18, 2011. <http://www.sakigake.jp/p/editorial/news.jsp?kc=20111118az> (accessed Dec 5, 2011).
- 3 Horigome K. Record of polio information session for the National Diet Members: November 15, 2011. http://lohasmedical.jp/blog/2011/11/post_2509.php (accessed Jan 31, 2012).
- 4 Japan Pediatric Society, Committee of Immunization and Communicable Disease. Policy statement on polio vaccine. http://www.jpeds.or.jp/saisin/saisin_111114.pdf (accessed Dec 5, 2011).
- 5 Anon. Japan to provide 900 million yen to fight polio. *Asahi Shimbun* Oct 26, 2011. http://ajw.asahi.com/article/behind_news/politics/AJ2011102615766 (accessed Dec 5, 2011).

Prevalence and risk factors for third- and fourth-degree perineal lacerations during vaginal delivery: a multi-country study

F Hirayama,^a A Koyanagi,^a R Mori,^a J Zhang,^b JP Souza,^c AM Gülmezoglu^c

^a Department of Global Health Policy, Graduate School of Medicine, University of Tokyo, Tokyo, Japan ^b MOE-Shanghai Key Laboratory of Children's Environmental Health, Xinhua Hospital, Shanghai Jiao Tong University School of Medicine, Shanghai, China ^c Department of Reproductive Health and Research, World Health Organization, Geneva, Switzerland

Correspondence: Dr A Koyanagi, Department of Global Health Policy, Graduate School of Medicine, University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033 Japan. Email koyanagai@yahoo.com

Accepted 7 October 2011.

Objective To investigate the prevalence and risk factors of third- and fourth-degree perineal lacerations in 24, mainly developing, countries.

Design Analysis using cross-sectional data from the WHO Global Survey on Maternal and Perinatal Health.

Setting Seven African, nine Asian and eight Latin American countries.

Population Women at admission to hospital for delivery in 373 facilities between 2004 and 2008.

Methods We estimated the country-wise prevalence of third- and fourth-degree perineal lacerations, and conducted region-wise multivariate logistic regression analyses to identify its risk factors.

Main outcome measures Prevalence and risk factors of third- and fourth-degree perineal lacerations.

Results A total of 214 599 women who underwent vaginal delivery were analysed. The prevalence of third- and fourth-degree

perineal lacerations ranged widely across countries [from 0.1% (China, Cambodia, India) to 15.0% (Philippines)] and facilities (from null to 76.3%). After the deletion of facilities reporting no third- or fourth-degree perineal lacerations, and also highly outlying facilities, the range in prevalence was 0.1% (Uganda) to 1.4% (Japan). Forceps-assisted delivery, nulliparity and high birthweight were significant risk factors in all three regions. Vacuum-assisted delivery was also a significant risk factor in Africa and Asia.

Conclusions Misdiagnosis of third- and fourth-degree perineal lacerations in developing countries may be common. Correct recognition and diagnosis may lead to timely treatment and fewer sequelae. Risk factors of third- and fourth-degree perineal lacerations in developing countries were similar to those previously reported from developed countries.

Keywords Developing countries, multi-country study, third- and fourth-degree perineal lacerations.

Please cite this paper as: Hirayama F, Koyanagi A, Mori R, Zhang J, Souza J, Gülmezoglu A. Prevalence and risk factors for third- and fourth-degree perineal lacerations during vaginal delivery: a multi-country study. BJOG 2012;119:340–347.

Introduction

A third- or fourth-degree perineal laceration or tear is a serious adverse outcome of vaginal delivery. If left untreated it may lead to persistent perineal pain, sexual and urinary problems, and fecal incontinence.¹ These sequelae severely affect the physical and psychological well-being of postpartum women.² Previous studies have reported the prevalence of third- and fourth-degree tears to be between 0.1 and 10.2%,^{1,3–13} and most studies have consistently reported

instrumental delivery,^{4–6,8–16} macrosomia,^{3,4,6,8,9,13–17} nulliparity,^{3,6,8,9,15} and episiotomy^{4,6,8–10,12–14,16,17} as risk factors of third- and fourth-degree tears. All of these prevalence and risk factor studies were conducted in developed countries and, to date, there are no data from developing countries. Therefore, we conducted secondary data analysis from a large multi-country data set (WHO Global Survey, GS) to describe the prevalence and risk factors of third- and fourth-degree tears in 24 mainly developing countries in Africa, Asia and Latin America.

Methods

Study design

The detailed methodology of the GS has been published elsewhere.^{18–20} Briefly, the GS was a facility-based multi-country cross-sectional study, with the objective of creating a global data system on maternal and perinatal health services. The study involved 373 health facilities from 24 countries, and was conducted between 2004 and 2005 in Latin America and Africa, and between 2007 and 2008 in Asia. The 24 countries in the survey were: Algeria, Angola, Democratic Republic of Congo, Niger, Nigeria, Kenya and Uganda (Africa); Cambodia, China, India, Japan, Nepal, Philippines, Sri Lanka, Thailand and Vietnam (Asia); and Argentina, Brazil, Cuba, Ecuador, Mexico, Nicaragua, Paraguay and Peru (Latin America). A stratified multistage cluster sampling design was used to obtain a sample of health institutes. The capital city in each country was included in the project sample. In addition, two provinces or regions in each country were randomly selected using a computer. Next, a census of all facilities handling more than 1000 births per year and those conducting caesarean sections was obtained. If there were fewer than seven facilities in a country, all facilities were selected. If there were more than seven facilities, seven facilities were selected randomly. The duration of data collection was 3 months in institutions that had <6000 expected deliveries per year and 2 months in institutions that had 6000 or more expected deliveries per year.¹⁹ Written consent was obtained from all ministries of health of the participating countries and from the directors of the selected facilities.¹⁹ All individual data were obtained from medical records without the identification of participants. The Ethics Review Committee of the WHO and that of each country independently approved the protocol.¹⁹

Data collection

All pregnant women who gave birth at the facilities during the period of data collection were included in the study. Data on demographics, third- and fourth-degree tears, maternal body mass index (BMI), infant birthweight, maternal age, parity, induction of labour using oxytocin, misoprostal or other prostaglandins, and mode of delivery were obtained from medical records, and a structured questionnaire was completed using this data. Maternal weight in Africa and Latin America referred to that of the last antenatal care visit, whereas in Asia it referred to the last weight before delivery.

Statistical analysis

Statistical analysis was conducted using STATA 11.1 (Stata-Corp LP, College Station, TX, USA). The analysis consisted of three different samples (Table 1). Firstly, the caesarean

section rate was based on the 290 499 women for whom information on mode of delivery was available. Secondly, a total of 214 905 women underwent vaginal delivery, but 306 had no information on third- and fourth-degree tears, and thus the prevalence of third- and fourth-degree tears was calculated based on the remaining 214 599 women. As the variation in the prevalence of third- and fourth-degree tears among facilities was extremely high, ranging from null to 76.3%, we reasoned that there is substantial misclassification, and consequently excluded facilities with no third- and fourth-degree tears, and also facilities with an exceptionally high prevalence of third- and fourth-degree tears, defined as >1.5 (interquartile range, IQR, from the 25th to the 75th percentile) above the 75th percentile of the total analytical sample after the exclusion of facilities with no third- and fourth-degree tears (Figure 1). This cut-off point corresponded to a prevalence of >4.16%. This method of identifying outliers has been described in previous literature.²¹ By doing so, we intended to exclude the facilities in which third- and fourth-degree tears were not recognized and facilities where third- and fourth-degree tears were over-diagnosed. This exclusion resulted in a remaining sample of 146 403 women from 204 facilities. Next, we conducted multivariate logistic regression analyses to identify the risk factors for third- and fourth-degree tears at a regional level. Adjusted odds ratios for third- and fourth-degree tears were obtained after accounting for the confounding effects of mode of delivery, induction of labour, parity, infant birthweight, maternal age and BMI, and country. Also, because 33.6% of the data on BMI from the analytical sample were missing from Africa, we included a missing category only for this region. This variable was included explicitly in the model because data is likely to be missing preferentially from resource-limited facilities in Africa, where, for example, tape measures and scales were not available. These facilities are likely to have unusually poor childbirth outcomes, and the explicit inclusion of the missing data variable in the model enabled at least a partial adjustment of the effects of these resource limits in the model. The models were also adjusted for the clustering effect within facilities, using the clustered sandwich estimator. $P < 0.05$ was considered to be statistically significant.

Results

Table 1 illustrates the prevalence of caesarean section and third- and fourth-degree perineal lacerations by country using the three different sample populations (i.e. all women, including those with caesarean section; only women with vaginal delivery; and a subsample of women who underwent vaginal delivery after the exclusion of facilities suspected of over- and under-diagnosis of third- and fourth-degree tears). Based on all 214 599 women who

Table 1. Prevalence of caesarean section and third- and fourth-degree perineal lacerations by country

Region	Country	Total sample*		Total analytical sample (vaginal delivery)**			Analytical subsample***			
		<i>n</i>	Caesarean section (%)	Total no. of facilities	No. of facilities with no 3rd and 4th degree perineal lacerations	<i>n</i>	3rd and 4th degree perineal lacerations (%)	Total no. of facilities	<i>n</i>	3rd and 4th degree perineal lacerations (%)
Africa	Algeria	15 887	13.8	18	8	13 654	7.2	7	5542	1.1
	Angola	6410	1.7	20	11	6298	0.7	9	4886	0.9
	DRC	9009	13.0	21	6	7834	0.9	14	5639	1.0
	Kenya	20 334	16.1	20	8	17 063	1.1	11	12 112	0.4
	Niger	8435	5.4	11	1	7976	2.8	9	6047	0.7
	Nigeria	9185	14.9	21	10	7813	1.4	8	2415	0.5
	Uganda	14 104	13.9	20	15	12 132	0.6	4	7969	0.1
Asia	Cambodia	5642	14.7	5	2	4812	0.1	3	3715	0.2
	China	14 709	46.5	21	19	7867	0.1	2	1148	0.4
	India	24 977	17.9	20	7	20 519	0.1	13	14 868	0.2
	Japan	3355	20.8	10	1	2656	1.7	8	2195	1.4
	Nepal	8575	20.5	8	2	6817	0.5	5	5594	0.4
	Philippines	13 432	19.0	17	1	10 879	15.0	7	6216	1.1
	Sri Lanka	15 157	30.8	14	3	10 494	0.4	11	8672	0.4
	Thailand	9838	34.4	12	1	6454	0.9	11	6294	0.9
	Vietnam	13 412	35.8	15	8	8607	0.3	6	4734	0.3
Latin America	Argentina	10 869	35.8	14	3	6753	0.3	11	5733	0.4
	Brazil	15 361	30.1	19	6	10 720	0.7	12	7812	0.4
	Cuba	12 769	35.8	17	8	8195	0.4	8	6101	0.3
	Ecuador	12 484	40.4	18	7	7437	2.2	9	4756	1.2
	Mexico	21 053	38.1	21	5	13 028	0.8	16	10 735	0.9
	Nicaragua	5675	31.1	8	4	3912	0.4	4	2276	0.8
	Paraguay	3514	42.2	6	2	2024	1.6	3	1259	1.0
Peru	16 263	34.5	17	4	10 655	0.3	13	9685	0.4	

DRC, Democratic Republic of Congo.

*Total sample includes caesarean section. Women missing information on mode of delivery were excluded.

**Total analytical sample and subsample only include women who underwent vaginal delivery and had information on third- and fourth-degree perineal lacerations.

***Facilities reporting no third- or fourth-degree perineal lacerations were excluded. Facilities with a prevalence of third- and fourth-degree perineal lacerations > 1.5 (IQR) above 75th percentile, after exclusion of facilities without third- and fourth-degree perineal lacerations, were excluded.

underwent vaginal delivery, the countries with the lowest prevalence of third- and fourth-degree tears were China (0.1%), Cambodia (0.1%) and India (0.1%), whereas those with the highest prevalence were the Philippines (15.0%), Algeria (7.2%) and Niger (2.8%) (Table 1). After the exclusion of facilities with suspected over- and under-diagnosis of third- and fourth-degree tears, the countries with the lowest prevalence were Uganda (0.1%), Cambodia (0.2%) and India (0.2%), and the highest prevalences were observed in Japan (1.4%), Ecuador (1.2%), Algeria (1.1%) and the Philippines (1.1%) (Table 1).

Table 2 presents the prevalence of third- and fourth-degree perineal lacerations by maternal and infant characteristics by region in women who underwent vaginal deliv-

ery after the exclusion of facilities suspected of over- and under-diagnosis of third- and fourth-degree tears. The overall mean maternal age (SD) was 25.8 (6.0) years, and a high maternal BMI was common in Latin America (BMI \geq 30 kg/m² 25%). Women in Africa tended to have higher parity than in other regions. Prevalence of birth-weight \geq 4000 g ranged from 1.1% (Asia) to 4.3% (Africa). Forceps and vacuum-assisted delivery together constituted between 1.5% (Africa) and 3.6% (Asia) of all vaginal delivery. Induction of labour was common in Latin America (12.3%) and Asia (12.8%), but was not so frequent in Africa (3.5%). The overall prevalence of third- and fourth-degree tears among women who gave birth to babies weighing <4000 and \geq 4000 g were 0.6 and 1.1%,

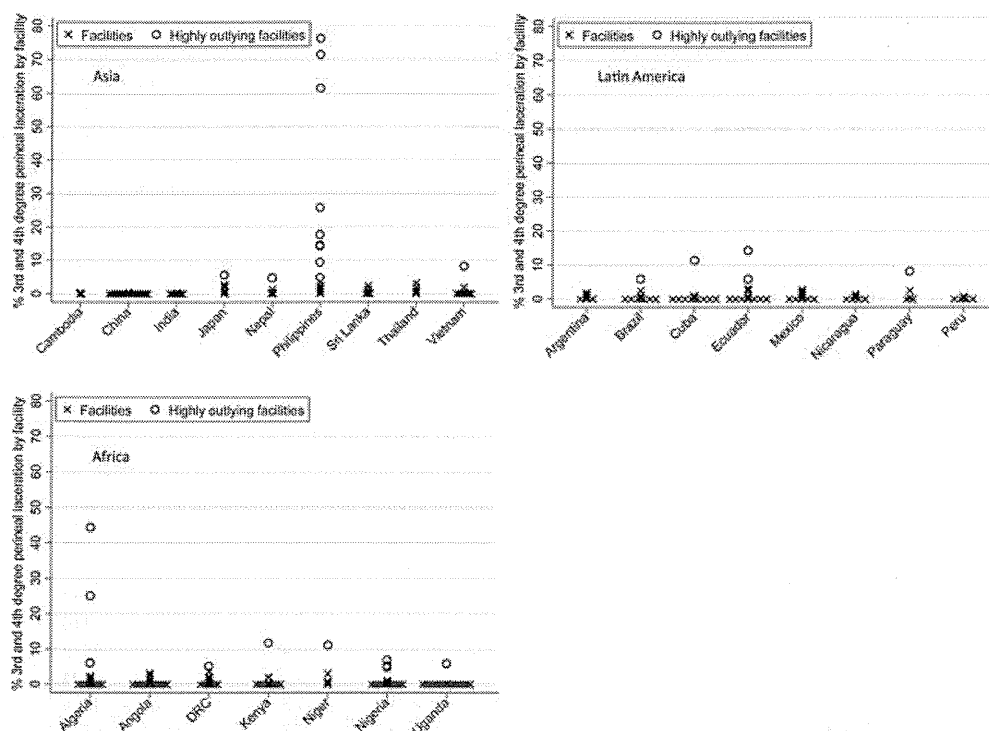


Figure 1. Facility-specific third- and fourth-degree perineal laceration rates by country and region.

respectively. The corresponding figures for nulliparous and multiparous women were 0.8 and 0.4%, respectively. Across regions, prevalence was particularly high among women who underwent forceps-assisted delivery (ranging from 2.4% in Asia to 4.0% in Africa and Latin America), and vacuum-assisted delivery in Africa (4.0%) and Asia (2.3%).

Table 3 illustrates the results of the multivariate logistic model of predictors of third- and fourth-degree perineal lacerations. Maternal age and BMI were not associated with risk of third- and fourth-degree perineal lacerations, but nulliparity, high birthweight and forceps-assisted delivery significantly increased the risk in all three regions. Compared with nulliparous women, multiparous women (parity 1 or 2) had a significant 58%, 46%, 61% lower risk of third- and fourth-degree tears in Africa, Asia and Latin America, respectively. The risk of third- and fourth-degree tears was between 1.98 (Africa) and 2.99 (Asia) times higher among women with infants with birthweight ≥ 4000 g compared with women with normal birthweight babies (2500–3999 g). Forceps-assisted delivery was also a significant risk factor, where the OR ranged from 3.72 (Africa) to 9.28 (Latin America), and so was vacuum-assisted delivery [ORs 5.59 (Africa) and 4.17 (Asia)]. The OR for Latin America could not be calculated because there were no third- and fourth-degree tear cases in the vacuum-assisted delivery group. Finally, a non-significant trend for

higher risk of third- and fourth-degree tear was observed for those who underwent induction of labour (Africa, OR 1.53 95% CI 0.79–2.98; Asia, OR 1.38, 95% CI 0.90–2.11; Latin America, OR 1.38, 95% CI 0.88–2.15).

Discussion

To the best of our knowledge, this is the first multi-country study to investigate the prevalence and risk factors of third- and fourth-degree perineal lacerations in developing countries. The strength of the study is the large sample size from multiple countries, which allowed a direct comparison of prevalence and risk factors across regions. Also, the large sample size allowed for the investigation of multiple risk factors, which cannot be achieved with small sample size because of the generally low prevalence of third- and fourth-degree tears.

When all facilities were included, the prevalence of third- and fourth-degree tears ranged from 0.1% (China, Cambodia, and India) to 15.0% (Philippines). Out of the 373 facilities included in our study, 142 reported no cases of third- and fourth-degree tears. Suspected under-reporting was highly prevalent in countries such as China and Uganda, where 90.5 and 75.0% of the facilities, respectively, did not report any cases of third- and fourth-degree tears. On the other hand, suspected over-reporting was common

Table 2. Prevalence of third- and fourth-degree perineal lacerations by maternal and infant characteristics*

Characteristics	Category	Africa		Asia		Latin America	
		<i>n</i>	%	<i>n</i>	%	<i>n</i>	%
Age (years)	<20	7037	0.9	4054	0.6	9356	0.9
	20–34	31 971	0.6	45 001	0.5	34 616	0.5
	≥35	5128	0.4	4381	0.7	4366	0.6
	Missing	474	0.4	0	NA	19	0.0
BMI (kg/m ²)**	<30	25 250	0.7	48 104	0.5	28 845	0.7
	≥30	4391	0.6	3598	0.5	9488	0.6
	Missing	14 969	0.4	1734	1.4	10 024	0.5
Parity	0	15 529	1.0	25 936	0.7	19 891	0.9
	1 or 2	16 780	0.5	23 839	0.4	22 009	0.4
	≥3	12 043	0.3	3635	0.5	6409	0.5
	Missing	258	1.2	26	0.0	48	2.1
Birthweight (g)	<2500	4643	0.5	8078	0.3	3639	0.6
	2500–3999	37 732	0.6	44 799	0.5	42 746	0.6
	≥4000	1885	1.0	559	1.4	1910	1.1
	Missing	350	1.0	0	NA	62	0.0
Mode of delivery***	Spontaneous	43 938	0.6	51 541	0.4	47 242	0.5
	Forceps	446	4.0	614	2.4	1066	4.0
	Vacuum	226	4.0	1281	2.3	49	0.0
Induction of labour****	No	42 930	0.6	45 559	0.5	42 224	0.6
	Yes	1533	1.2	6676	0.7	5920	0.8
	Missing	147	1.4	1201	0.8	213	1.4

Regions of study: Africa includes Algeria, Angola, Democratic Republic of Congo, Kenya, Niger, Nigeria and Uganda; Asia includes Cambodia, China, India, Japan, Nepal, Philippines, Sri Lanka, Thailand and Vietnam; and Latin America includes Argentina, Brazil, Cuba, Ecuador, Mexico, Nicaragua, Paraguay and Peru.

*Facilities with no third- or fourth-degree perineal lacerations were excluded. Facilities with a prevalence of third- and fourth-degree perineal lacerations > 1.5 (IQR) above the 75th percentile after exclusion of facilities without third- and fourth-degree perineal lacerations were excluded.

**Maternal BMI in Africa and Latin America refers to that of the last antenatal care visit, whereas in Asia it refers to the last weight measured before delivery.

***No missing category, as analysis was restricted to women with no missing variable for mode of delivery.

****Induction by oxytocin, misoprostal or other prostaglandins. Missing category also includes women who had induction by other methods.

in the Philippines, where three out of 17 facilities reported more than 60% of women having third- or fourth-degree tears. The overall prevalence in our study was 0.6% (range 0.1–1.4%) when facilities with suspected under- and over-reporting were excluded, and this figure is comparable with previous studies that included both nulliparous and multiparous women, where results ranged from 0.1% to 10.2% (UK,³ USA,^{4–9} Japan¹⁰ and Finland¹¹).

The previously reported risk factors of third- and fourth-degree tears in developed countries were mostly similar in our study in mainly developing countries. We focused on six main risk factors of third- and fourth-degree tears, based on past findings: maternal age,^{8–10,13,14} BMI,²² parity,^{3,6,9,10,15} infant birthweight,^{3,6,14,15} instrumental delivery (forceps or vacuum),^{4–6,8–16} and induction of labour.¹⁰ First, we did not find any significant associations between maternal age and third- and fourth-degree tears, although there was a tendency for older women to have higher ORs in Asia and Latin America. The results of previous studies

are mixed but most have reported a significant or non-significant higher risk of third- and fourth-degree tears among older women,^{9,13,14} with the exception of one study.⁸ Secondly, no significant associations between BMI and third- and fourth-degree tears were identified in our study, although there was a non-significant trend for those with higher BMIs to have a lower risk in all three regions. Although most previous studies have reported no association between BMI and third- and fourth-degree tears,²³ lower risks of third- and fourth-degree tears have been reported in a large study from the USA, where a dose-dependent significant protective effect was observed with higher BMIs at admission to labour/delivery only among nulliparous women.²⁴ The authors of this study postulate that higher caesarean section rates among obese women and extra soft tissue around their perineum might explain why obesity is protective against third- and fourth-degree tears. Thirdly, multiparity was associated with a significant dose-dependent protective effect against third- and fourth-degree tears, compared with

Table 3. Multivariate logistic model of predictors of third- and fourth-degree perineal lacerations*

Characteristics	Africa		Asia		Latin America	
	Category	Adjusted OR (95% CI)**	Category	Adjusted OR (95% CI)**	Category	Adjusted OR (95% CI)**
Country***	Algeria	1.13 (0.34–3.78)	Cambodia	0.37 (0.14–1.01)	Argentina	0.37 (0.17–0.82) ^a
	Angola	1.28 (0.38–4.31)	China	0.80 (0.35–1.84)	Brazil	0.44 (0.19–1.05)
	DRC	1.25 (0.40–3.86)	India	0.52 (0.23–1.16)	Cuba	0.23 (0.11–0.50) ^c
	Kenya	0.43 (0.11–1.61)	Japan	2.54 (0.99–6.52)	Ecuador	1.80 (0.89–3.67)
	Niger	1.00	Nepal	0.84 (0.31–2.25)	Mexico	1.03 (0.51–2.06)
	Nigeria	0.50 (0.17–1.47)	Philippines	3.03 (0.99–9.27)	Nicaragua	1.00
	Uganda	0.15 (0.05–0.40) ^c	Sri Lanka	1.00	Paraguay	1.00 (0.33–3.05)
			Thailand	1.94 (0.70–5.44)	Peru	0.46 (0.25–0.84) ^a
Age (years)	20–34	1.00	20–34	1.00	20–34	1.00
	<20	1.02 (0.68–1.52)	<20	0.64 (0.40–1.03)	<20	0.99 (0.70–1.40)
BMI (kg/m ²)****	≥35	0.94 (0.53–1.64)	≥35	1.12 (0.74–1.71)	≥35	1.19 (0.70–2.02)
	<30	1.00	<30	1.00	<30	1.00
Parity	≥30	0.87 (0.59–1.28)	≥30	0.86 (0.52–1.44)	≥30	0.86 (0.66–1.13)
	Missing	0.91 (0.51–1.64)				
Birthweight (g)	0	1.00	0	1.00	0	1.00
	1 or 2	0.42 (0.24–0.74) ^b	1 or 2	0.54 (0.38–0.77) ^b	1 or 2	0.39 (0.26–0.58) ^c
Mode of delivery	≥3	0.22 (0.14–0.35) ^c	≥3	0.56 (0.25–1.24)	≥3	0.47 (0.27–0.79) ^b
	2500–3999	1.00	2500–3999	1.00	2500–3999	1.00
Induction of labour*****	<2500	0.65 (0.41–1.02)	<2500	0.43 (0.23–0.82) ^a	<2500	1.02 (0.57–1.83)
	≥4000	1.98 (1.29–3.03) ^b	≥4000	2.99 (1.29–6.91) ^a	≥4000	2.54 (1.45–4.46) ^b
Mode of delivery	Spontaneous	1.00	Spontaneous	1.00	Spontaneous	1.00
	Forceps	3.72 (1.64–8.45) ^b	Forceps	4.21 (2.01–8.84) ^c	Forceps	9.28 (6.56–13.11) ^c
Induction of labour*****	Vacuum	5.59 (2.07–15.13) ^b	Vacuum	4.17 (2.48–7.02) ^c	Vacuum	NA
	No	1.00	No	1.00	No	1.00
	Yes	1.53 (0.79–2.98)	Yes	1.38 (0.90–2.11)	Yes	1.38 (0.88–2.15)

DRC, Democratic Republic of Congo.

*Facilities with no third- or fourth-degree perineal lacerations were excluded. Facilities with a prevalence of third- and fourth-degree perineal lacerations > 1.5 (IQR) above 75th percentile, after the exclusion of facilities without third- and fourth-degree perineal lacerations, were excluded.

**Adjusted for all covariates in the model and clustering within facility.

***Reference category is country with prevalence closest to overall 3rd and 4th degree perineal laceration prevalence in that region.

****Maternal BMI in Africa and Latin America refers to that of the last antenatal care visit, whereas in Asia, it refers to last weight measured before delivery. The missing category for BMI was only included for Africa, as 33.6% of the data on BMI was missing.

*****Induction by oxytocin, misoprostal or other prostaglandins.

Statistical significance: ^a*P* < 0.050; ^b*P* < 0.010; ^c*P* < 0.001.

nulliparity in all three regions. The results accord with previous studies from the USA and UK that have reported a significant 3.0–7.3 times higher risk of third- and fourth-degree tears among nulliparous women, compared with multiparous women.^{3,6,9,15,24} Nulliparity is a well-known risk factor for third- and fourth-degree tears,⁸ and the most biologically plausible mechanism is the lack of elasticity of the perineum among nulliparous women.^{3,10,15} Fourthly, birthweights of ≥4000 g were associated with a significant 1.98, 2.99 and 2.54 times higher risk of third- and fourth-degree tears, compared with normal birthweights in Africa, Asia and Latin America, respectively. These findings are comparable with previous literature, which have all

reported lower birthweights to be protective against perineal laceration.^{3,6,15,24} Next, forceps-assisted delivery was associated with a 3.72–9.28 times higher risk of third- and fourth-degree tears compared with spontaneous delivery in all three regions. Vacuum-assisted delivery was also associated with a significant 4.17 and 5.59 times higher risk in Asia and Africa, respectively. These results are consistent with numerous studies that report forceps and vacuum-assisted delivery to be risk factors for third- and fourth-degree tears (OR 3.0–15.5 for forceps;^{6,9,10,14,15} OR 2.6–9.5 for vacuum-assisted delivery^{9,10,14}). Finally, we observed a 1.53, 1.38 and 1.38 times higher risk of third- and fourth-degree tears among those who underwent induction com-

pared with those who did not in Africa, Asia and Latin America, respectively, but the results were not significant in any of the three regions. There are conflicting results regarding induction of delivery in the literature. A large study in Japan reported a significant 2.19 times higher risk of third- and fourth-degree tears among women who underwent induction of labour,¹⁰ but others, including a large study in the USA, have found no such effect.^{3,24}

Although results were similar across regions, some differences in the magnitude of the association between the risk factors and third- and fourth-degree tears were observed. This may be attributable to the different caesarean section rates ranging from 1.7% in Angola to 46.5% in China. If women with a high risk of third- and fourth-degree tears were more likely to undergo caesarean section in some regions, and thus not be under risk of third- and fourth-degree tears, this could at least partially explain the regional differences observed.

Prevention, early detection and treatment of third- and fourth-degree tears are essential. The large variability in rates of third- and fourth-degree tear among facilities warrants attention. Indeed, 38.1% (142/373) of the facilities in our study did not report any cases of third- and fourth-degree tears, and some facilities reported a prevalence of over 60%, which is far from the prevalence of third- and fourth-degree perineal laceration considered to be normal. Under-recognition of third- and fourth-degree tears is unacceptable, as if left untreated, it may result in persistent perineal pain, urinary and fecal problems, and sexual dysfunction.^{1,25} On the other hand, over-diagnosis may lead to unnecessary treatment. In order to overcome this problem, clinicians must be aware of the devastating consequences of untreated third- and fourth-degree tears, and the introduction of standardised guidelines to promote correct diagnosis at the clinical scene may be important. In terms of prevention, avoidance of unnecessary instrumental delivery and possibly induction of labour during delivery may contribute to a reduction in third- and fourth-degree tears, as high rates of unnecessary instrumental delivery and induction of labour have been reported,^{26,27} at least in developed countries. The magnitude of this problem in developing country settings remains largely unknown, and is an area for further research.

Some limitations of this study should be noted. First, as this was a facility-based study, the results may not be generalisable to the general population, especially in countries where the rate of hospital delivery is low. Second, there was probably substantial over- or under-reporting of third- and fourth-degree tears in some countries, resulting in unreliable estimates. We excluded facilities with no third- and fourth-degree tears and facilities with a prevalence higher than 1.5 (IQR) above the 75th percentile in our analytical sample in order to exclude facilities with

suspected over- and under-reporting. We cannot be certain about how much the misclassification was reduced by this procedure. However, despite potential misclassification, the effects of most risk factors were in line with previous publications. Future studies should be conducted with strict diagnostic criteria. Thirdly, we did not have information on some reported risk factors of third- and fourth-degree tears, such as episiotomy,^{25,28} inherent predisposition (e.g. short perineal body),²⁵ prolonged second stage of labour,^{25,28} previous anal sphincter tear²⁵ and female genital mutilation.²⁹ Therefore, the independent and confounding effects of these factors remain unknown. Finally, the inclusion of a missing category is known to induce biases in parameter estimates, and thus the inclusion of a missing category for BMI in Africa may have induced some level of bias. However, the analysis without a missing category yielded similar results (data not shown), and thus we believe that this is not a major limitation.

Conclusion

In conclusion, over- and under-diagnosis of third- and fourth-degree perineal lacerations in developing countries may be common. Training of medical personnel to facilitate the early detection and treatment of postpartum women with third- and fourth-degree perineal lacerations may be important in reducing sequelae. Most risk factors previously reported from developed countries were similar in our context of mainly developing countries. Studies using strict diagnostic criteria for third- and fourth-degree perineal lacerations are warranted in developing countries to obtain more accurate estimates on prevalence and risk factors.

Disclosure of interests

We declare that we have no conflicts of interest.

Contribution to authorship

HF wrote the article. AK analysed the data and contributed to writing the article. RM, JPS and AMG contributed to data collection and provided advice. JZ contributed to data analysis and interpretation. All authors read and approved the final version of the manuscript.

Details of ethics approval

The Ethics Review Committee of the World Health Organization (WHO) and that of each country independently approved the protocol. Individual informed consent was not obtained because this study was a cluster-level study in which data was collected from medical records without any individual identification. WHO/RHR Scientific and Ethical Review Committee, 25 April 2003, ref. no. A25176.

Funding

This study was financially supported by: the Department of Making Pregnancy Safer, the United States Agency for International Development (USAID); UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (HRP), Department of Reproductive Health and Research (RHR), WHO, Geneva, Switzerland; Ministry of Health, Labour and Welfare of Japan; Ministry of Public Health, Beijing, China; and the Indian Council of Medical Research, Delhi, India.

Acknowledgements

The authors thank all those who made contributions to the study design and implementation. The authors also thank the study coordinators, data collectors and staff of the Ministries of Health and WHO offices, the participants of the study and Stuart Gilmour for his statistical advice. ■

References

- Dahlen H, Homer C. Perineal trauma and postpartum perineal morbidity in Asian and non-Asian primiparous women giving birth in Australia. *J Obstet Gynecol Neonatal Nurs* 2008;37:455–63.
- Yip SK, Cardozo L. Psychological morbidity and female urinary incontinence. *Best Pract Res Clin Obstet Gynaecol* 2007;21:321–9.
- Eskandar O, Shet D. Risk factors for 3rd and 4th degree perineal tear. *J Obstet Gynaecol* 2009;29:119–22.
- Goldberg J, Hyslop T, Tolosa JE, Sultana C. Racial differences in severe perineal lacerations after vaginal delivery. *Am J Obstet Gynecol* 2003;188:1063–7.
- Carroll TG, Engelken M, Mosier MC, Nazir N. Epidural analgesia and severe perineal laceration in a community-based obstetric practice. *J Am Board Fam Pract* 2003;16:1–6.
- Christianson LM, Bovbjerg VE, McDavitt EC, Hullfish KL. Risk factors for perineal injury during delivery. *Am J Obstet Gynecol* 2003;189:255–60.
- Williams MK, Chames MC. Risk factors for the breakdown of perineal laceration repair after vaginal delivery. *Am J Obstet Gynecol* 2006;195:755–9.
- Edwards H, Grottegut C, Harmanli OH, Rapkin D. Is severe perineal damage increased in women with prior anal sphincter injury? *J Matern Fetal Neonatal Med* 2006;19:723–7.
- Kudish B, Sokol RJ, Kruger M. Trends in major modifiable risk factors for severe perineal trauma, 1996–2006. *Int J Gynaecol Obstet* 2008;102:165–70.
- Nakai A, Yoshida A, Yamaguchi S, Kawabata I, Hayashi M, Yokota A, et al. Incidence and risk factors for severe perineal laceration after vaginal delivery in Japanese patients. *Arch Gynecol Obstet* 2006;274:222–6.
- Raisanen S, Vehvilainen-Julkunen K, Gissler M, Heinonen S. The increased incidence of obstetric anal sphincter rupture—an emerging trend in Finland. *Prev Med* 2009;49:535–40.
- Payne TN, Carey JC, Rayburn WF. Prior third- or fourth-degree perineal tears and recurrence risks. *Int J Gynaecol Obstet* 1999;64:55–7.
- Hornemann A, Kamischke A, Luedders DW, Beyer DA, Diedrich K, Bohlmann MK. Advanced age is a risk factor for higher grade perineal lacerations during delivery in nulliparous women. *Arch Gynecol Obstet* 2010;281:59–64.
- Angioli R, Gomez-Marin O, Cantuarua G, O'Sullivan MJ. Severe perineal lacerations during vaginal delivery: The University of Miami experience. *Am J Obstet Gynecol* 2001;182:1083–5.
- Samarasekera DN, Bekhit MT, Preston JP, Speakman CT. Risk factors for anal sphincter disruption during child birth. *Langenbecks Arch Surg* 2009;394:535–8.
- Marchand MC, Corriveau H, Dubois MF, Watier A. Effect of dyssynergic defecation during pregnancy on third- and fourth-degree tear during a first vaginal delivery: a case-control study. *Am J Obstet Gynecol* 2009;201:183. e1–6.
- Lowder JL, Burrows LJ, Krohn MA, Weber AM. Risk factors for primary and subsequent anal sphincter lacerations: a comparison of cohorts by parity and prior mode of delivery. *Am J Obstet Gynecol* 2007;196:344:e1–5.
- Shah A, Faundes A, Machoki M, Bataglia V, Amokrane F, Donner A, et al. Methodological considerations in implementing the WHO Global Survey for Monitoring Maternal and Perinatal Health. *Bull World Health Organ* 2008;86:126–31.
- Lumbiganon P, Laopaiboon M, Gulmezoglu AM, Souza JP, Taneepanichskul S, Pang RY, et al. Method of delivery and pregnancy outcomes in Asia: the WHO global survey on maternal and perinatal health 2007–08. *Lancet* 2010;375:490–9.
- Betran AP, Gulmezoglu AM, Robson M, Meriardi M, Souza JP, Wojdyla D, et al. WHO global survey on maternal and perinatal health in Latin America: classifying caesarean sections. *Reprod Health* 2009;6:18.
- Pirson M, Dramaix M, Leclercq P, Jackson T. Analysis of cost outliers within APR-DRGs in a Belgian general hospital: two complementary approaches. *Health Policy* 2006;76:13–25.
- Halperin O, Raz I, Ben-Gal L, Or-Chen K, Granot M. Prediction of perineal trauma during childbirth by assessment of striae gravidarum score. *J Obstet Gynecol Neonatal Nurs* 2010;39:292–7.
- Heslehurst N, Simpson H, Ellis LJ, Rankin J, Wilkinson J, Lang R, et al. The impact of maternal BMI status on pregnancy outcomes with immediate short-term obstetric resource implications: a meta-analysis. *Obes Rev* 2008;9:635–83.
- Landy HJ, Laughon SK, Bailit J, Kominiarek MA, Gonzalez-Quintero VH, Ramirez M, et al. Characteristics associated with severe perineal and cervical lacerations during vaginal delivery. *Obstet Gynecol* 2011;117:627–35.
- Power D, Fitzpatrick M, O'Herlihy C. Obstetric anal sphincter injury: how to avoid, how to repair: a literature review. *J Fam Pract* 2006;55:193–200.
- Nichols CM, Pendlebury LC, Jennell J. Chart documentation of informed consent for operative vaginal delivery: is it adequate? *South Med J* 2006;99:1337–9.
- Dublin S, Lydon-Rochelle M, Kaplan RC, Watts DH, Critchlow CW. Maternal and neonatal outcomes after induction of labor without an identified indication. *Am J Obstet Gynecol* 2000;183:986–94.
- Fernando RJ, Williams AA, Adama EJ. The management of third and fourth degree perineal tears. *RCOG Green-top Guidelines No 29* 2007;1–11.
- Utz-Billing I, Kentenich H. Female genital mutilation: an injury, physical and mental harm. *J Psychosom Obstet Gynaecol* 2008;29:225–9.

