FROM OTHER JOURNALS

Traditional birth attendants can save lives

Traditional birth attendants (TBA) have generally been regarded with a degree of distrust. However, recent studies have found that if TBAs are offered training, support and resources, they are often effective in lowering the perinatal and neonatal mortality rates. This is especially true in low-income countries where skilled birth attendants (such as nurses, midwives and obstetricians) might not always be available. Studies have also shown that, notwithstanding the heterogeneity of the interventions made towards training TBAs, in general, the support and care provided by them during childbirth have worked towards reducing maternal morbidity and mortality. The author of this editorial argues that in the past six years, despite efforts, there has been little progress towards achieving Millennium Development Goals Four and Five. Most countries are aware of what constitutes safe and effective care for pregnant women but the challenge for them lies in implementing this, especially in resource-poor settings. The author observes that the World Health Organisation is ideally placed to help countries in translating this knowledge into action. As of the present, only Brazil has resorted to legislation on the subject; the government of Brazil has enacted a 'companion law' which states that all women have the right to companionship during labour and childbirth. When the fundamental aim is to provide for better support for pregnant women and babies, it becomes all the more important to involve trained TBAs in this endeavour

Hodnett E. Traditional birth attendants are an effective resource: strategies to ensure their training and support in all settings are key. *BMJ*. 2012;344:e365.

The future of ASHA

Accredited Social Health Activist (ASHA), the flagship programme under the National Rural Health Mission (NRHM) has been inspired by the concept of Community Health Workers (CHW) known by different names in different parts of the country. The role envisaged for the CHW is to prioritise health needs in the community by mobilising community participation. Authors Joshi and George describe three programmes- the Comprehensive Rural Health Project, Jamkhed, Maharashtra; the Comprehensive Health and Development Project, Pachod and the Mitanin Programme of Chattisgarh to give an idea about the CHW programmes. The paper is based on a study conducted on ASHAs in a tribal area in Maharashtra and it looks at the implementation as well as the roadblocks faced by the programme. The question of "incentives" has been central to the ASHA programme. The study reveals that there is a strong connection between incentives earned and the performance of ASHAs, as a majority of them are from low income families and view the "voluntary" ASHA work as their main source of income. The insistence on ASHAs being "activists" and not being on a regular pay roll has had its effect in ASHAs favouring those activities offering higher incentives. The authors also indicate that the major focus of ASHA workers is on providing curative care by assisting health workers, distributing medicines and providing referral services while neglecting other activities like counseling and community meetings. This defeats the purpose of the programme aimed at converting ASHAs into "agents of change" as it reduces them to a mere extension of the existing health system. The authors warn that ASHAs could also end up as Rural Medical Practitioners in the future. The ASHAs have failed to engage with the community due to their inability to rise above "class-caste-power" equations in the community; also due to their lack of involvement in other development activities. It is interesting to note that while the NRHM training guidelines talk about holding community meetings, they are silent on the process of initiating or even conducting them, leaving the onus completely on the ASHA workers. Without addressing the key issues related to incentives, services and community involvement, the ASHA programme is unlikely to achieve what it was originally intended to achieve.

Joshi SR, George M. Healthcare through community participation Role of ASHAs. *Econ Pol Wkly*. 2012 Feb 25; 47(10):70-6.

The consequences of inaccurate internet information

The use of dietary supplements is a subset of complementary and alternative medicine (CAM) which consists of probiotics, selenium, chamomile and other teas, flax seed, macrobiotics, St. Johns Wort, etc. Educated people surf the internet for credible health-related information. However, the danger is that much of such information is inauthentic. Unproven claims and promotions may generate interest and hope in people, particularly seriously ill people who are vulnerable to such claims.

The authors report on a cross sectional study with people living with HIV/AIDS, contemplating the use of dietary supplements. One out of four respondents was using dietary supplements and, among them, a representative number reported that they used the internet to seek information on these supplements. The researchers also note that two out of three passages taken from the internet made false claims of treating and curing AIDS; a significant number of dietary users believed and trusted the content from all the three passages.

Though the findings of this study cannot be generalised, they highlight the fact that the trend of using CAM by chronically and terminally ill patients is on the rise. It is important for healthcare professionals to communicate with patients on this aspect, counsel them and provide them with credible information or reliable sources.

Kalichman S, Cherry C, White D, Jones M, Kalichman M, Detorio M, Caliendo A, Schinazi R. Use of dietary supplements among people living with HIV/AIDS is associated with vulnerability to medical misinformation on the internet. *AIDS Res Ther*. 2012 Jan; 9(1):2-8.

De-anonymising donor information

In the era of assisted reproductive technologies (ARTs), the number of individuals conceived with the use of donated sperm and/or ova is on the rise. The writer calls for the right of such individuals to know their genetic history. Existing laws – the article focuses on the laws in the US – prevent donors and their genetic children from contacting each other, for reasons of confidentiality. However, it has been argued in recent times that the absence of genetic information can have negative consequences for donor-conceived individuals. Even within the group that stands for the de-anonymisation of information, there is a difference of opinion. Some hold that the demand for access to information is related to an individual's right to know about his or her identity; for others, such access has medical and ethical consequences. Medical claims are generally easier to justify given the importance of knowing one's genetic and family history for medical purposes. However, the demand for de-anonymisation does not imply that all forms of information should be available; what is being suggested is a mechanism that makes it possible to track a donor/donor-conceived individual when desired. For instance, in one case the donor-conceived person developed a serious problem with a genetic base. However, the family was unable to trace the donor to ask him not to donate in the future. A related concern is that donors are typically young adults and several genetic disorders do not affect them till middle age; but when they do, a tracing mechanism would also make it easier for donors (or their oocyte bank) to contact their genetic children and warn their families about the risk of a disorder manifesting itself later. In an era of ARTs, it is particularly important to have a regulatory mechanism that can address these concerns through a customised disclosure of donor identity.

Ravitsky V. Conceived and deceived: the medical interests of donor-conceived individuals. *Hastings Cent Rep*. 2012;42(1): 17-22.

GlaxoSmithKline and clinical trial standards

The ethical standards used while conducting multinational clinical trials, especially with vulnerable populations, have always been a matter of debate. An ongoing case in Argentina has again raised certain important questions. Recently, Argentinian courts fined GlaxoSmithKline (GSK) US$92,000 for irregularities in the conduct of a clinical trial to assess the efficacy and safety of a vaccine against *Streptococcus pneumoniae* and acute otitis media caused by non-typeable *Haemophilus influenzae*. The study was conducted between 2007 and 2008, in the rural areas of three provinces of Argentina and involved 400 health professionals. 17,000 children were to be recruited for this purpose.

In 2007, a paediatrician raised issues regarding possible irregularities in the informed consent given by the parents on behalf of their children who had been recruited. The Syndicate Federation of Argentinian Health Professionals investigated the complaint and found irregularities related to the informed consent procedure. These were reported to the Argentinian National Administration of Drugs, Food and Medical Technology (ANMAT). However, GSK had maintained that these problems were identified through their self monitoring system, which they had reported to ANMAT first. An investigation carried out by ANMAT confirmed that there were problems related to the informed consent process. Later, the trial was resumed with more stringent measures to ensure that there are no irregularities. During the course of the trial, 14 infants who were recruited died. Since all of them were from the placebo group, ANMAT and GSK concluded that the trial could continue. The trial was successfully completed with an 18% decrease in the number of recruitments and the vaccine was approved by ANMAT.

As there were irregularities in the informed consent procedures, ANMAT fined GSK. In the three provinces of Argentina where the trial was conducted, courts issued rulings fining GSK for these irregularities. GSK appealed these rulings in the Supreme Court and won its appeal in one of the provinces, and lost the appeal in one. In the third province the court is yet to rule. The irregularities in this trial have led to a number of changes in Argentina, from the setting up of a trial registry, to draft legislation banning clinical trials involving children. However, many larger ethical questions around the outsourced clinical trials remain unanswered.

Fuertes N, GSK malpractice case raises questions about trial standards. *Lancet*. 2012 Feb 11; 379(9815):508.

Gender and the HLEG report

This article analyses the High Level Expert Group (HLEG) report on universal health care (UHC) from a gender perspective. The writers note that a major achievement of the report is to give gender a firm place in the agenda of healthcare. The report has recommendations aimed at reducing out-of-pocket expenditure, making essential medicines available and increasing access to primary healthcare, all of which will have a positive impact on women's health. However, the national health package, which will include all services to be provided free under UHC, is gender sensitive only to a certain extent, and has not covered the needs of specific groups like transgender people, homosexuals, etc. Further, the report has failed to look beyond and address the non-financial barriers to access healthcare. Policy makers must look beyond Indian public health standards to a more comprehensive gender and rights perspective when examining the quality of services. The report also fails to look at inequities in the health workforce from a gender perspective. There is also no effort to gear national health information technology towards gendered policies and programmes.

While the HLEG report has a separate chapter on gender and health, it fails to discuss gender-related issues in other areas, and this is pointed out as a major lacuna. The chapter on gender and health fails to understand the underlying gender dimensions of the different barriers identified, and restricts itself to "addressing different needs of different genders". Though the report starts with a vision of health as a human right, it fails to incorporate a sexual and reproductive rights framework. The recommendation of the chapter includes improving access to all genders, enhancing women's role in the healthcare sector, making the system capable of recognising and addressing gender concerns, and empowering women, girls and other vulnerable groups. The writers concluded that while the report has "brilliantly" addressed the issues of gender in parts, the approaches and recommendations are mostly vague and mediocre.

Ravindran TKS, Nair MR. Gender in the HLEG report: missed opportunity. *Econ Pol Wkly*. 2012 Feb 25; 47(8):70-3.

The right to abortion

This comment looks at the current issues around abortion practices. While there is stagnation in the abortion rates globally, there is a steady increase in unsafe abortions around the world. This is despite the fact that the procedure is legal in many countries. The reasons are a combination of stigma, politics, religion and (lack of) access to facilities. Efforts to address this problem are also constrained by questions regarding the reliability of data on abortion services from countries where it is illegal, where there is a significant presence of private healthcare providers and with the increasing dependence on medical abortion.

The authors point out that unsafe abortion is one of the leading causes of maternal mortality, which is a paradox; considering that abortion is a relatively safe procedure with less risk than childbirth. Not surprisingly, this entire burden of death due to unsafe abortions is shared between Asia, Africa and Latin America. The authorities who deny access to safe and legal abortion services are contributing to this burden. The authors point out that irrespective of the legal status of this procedure, women who wish to terminate their pregnancy will do so, often at risk to life. Addressing the issue of unsafe abortion is crucial to achieving the millennium development goals addressing maternal mortality. It is equally significant to recognise that abortion is most unsafe in those countries where it is illegal.

Winikoff B, Sheldon WR. Abortion: what is the problem? *Lancet*. 2012 Feb 18;379:594-5.

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ERRATA

1. We regret that there were errors in the passage below on page 30, columns 1 to 2, of *IJME* Jan-Mar 2012. In the Comment entitled: "Finding and using evidence that you can trust" by Prathap Tharyan. The relevant corrected passage appears below:

However, if one inspects the graphical display of results in Figure 1, it is easily apparent that in Jessani 2005, the RR of 5.60; 95% CI 2.27 – 13.81 indicates that drug B was far more effective than drug A; a result that is in the opposite direction to the RR estimates of the other four trials. In the graphical display and the numerical description, the confidence limits in Jessani 2005 also clearly do not overlap with those of the other trials. Non-overlapping confidence intervals, especially if accompanied by effect estimates that differ in the direction of effects, are clear indications that the results from all the trials included in the meta-analysis are inconsistent with the pooled result, raising the possibility of statistical heterogeneity.It is possible (though unlikely given the clear difference in the direction of effects) that this inconsistency in results is due to chance. The chi-square test for homogeneity shown in the second last row reveals a very small p value, indicating that one can be 99.99999% sure that this inconsistency is not due to chance but due to differences in the trials (clinical or methodological heterogeneity).

Just as with the previous example, the p value from the chi square test only provides us the certainty of excluding chance as an explanation of a result, and does not reveal how much of this inconsistency is actually important. The final notation in the second last row of the figure reveals an I^2 value of 87%. The I^2 statistic is derived from the chi square test and reinterprets this to indicate the proportion of inconsistency that is due to true heterogeneity in the trials. The I^2 value of 87% indicates that only 13% of the inconsistency observed is due to chance and 87% is due to differences in the way the drug works in the trials. This degree of inconsistency is too large to ignore; and it would be unreasonable to assume that the pooled effect estimates provide a realistic average effect of drug A. Had this value been less than 25%, one might be less worried about heterogeneity in the meta-analysis since more than 75% of the differences in results of the five trials occurred by chance.

2. The following was inadvertently omitted on page 17 of *IJME* Jan-Mar 2012 from the article on "International collaborative trials, placebo controls and The Declaration of Helsinki: need for clarification in Paragraph 32" by AY Malik and F Ghafoor:

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