FROM OTHER JOURNALS

Parents and proxy consent in paediatric clinical trials

With the increasing number of paediatric randomised controlled trials it is important to understand a parent's perspective about enrolling a child in a trial. In this qualitative study, the authors found that parents of children with a serious diagnosis were more anxious (than those with less seriously ill children) about the risks and outcomes of a trial. Parents who had little grasp over their child's disease sometimes felt excessively dependent on clinicians and expressed uneasiness in making an autonomous decision. Parents viewed "randomisation" negatively. They were concerned about the possibility that their child would be randomised to the less effective treatment and feared the guilt that they would feel if the child later deteriorated. However, trials in neonatology and childhood cancer have high participation rates, suggesting that parents are prepared to take greater risk for the hope of a cure.

The authors of this article note that researchers conducting trials with children would benefit from a better understanding of the special situations of parents and their particular needs. They could then help parents retain the sense that they had safeguarded their child's interests. The authors point out that research is needed on how this could be realised in practice.

Shilling V, Young B. How do parents experience being asked to enter a child in a randomised controlled trial? *BMC Med Ethics* 2009 Feb 16; 10:1

Ethical concerns of anonymous HIV surveillance in developing countries

Data collection for HIV surveillance is crucial to guide public health interventions, planning, and prevention efforts. One form of data collection is unlinked anonymous testing (UAT) which does not involve informed consent. UAT is an important form of HIV surveillance but raises ethical, epidemiological, and public health challenges in low-income countries. Historically, doctors and nurses have found it difficult to distinguish between HIV case finding and the public health context of HIV surveillance. This in low-income countries is aggravated by the shortage of health staff, lack of adequate training, weak public health infrastructure, and poor communication between local clinics and public health authorities.

Some ways of conducting UAT in the field violate the spirit of international ethical guidelines which maintains that besides blood samples and socio-demographic information, no additional information should be requested from the participant. In low-income country settings, behavioural questions of interest to regional health authorities are included within HIV surveillance. For example, women may be asked about sexual contacts with persons of another nationality, in regions where foreigners are suspected of transmitting HIV. Further, vulnerable populations like sex workers may be subject to unjust treatment by local health authorities during HIV surveillance initiatives.

The authors emphasise that conducting UAT in ethically and epidemiologically sound ways in low-income countries requires a multifaceted approach. This must include local capacity building, community engagement, and increased access to testing for HIV and sexually transmitted infections.

Rennie S, Turner AN, Mupenda B, Behets F. conducting unlinked anonymous HIV surveillance in developing countries: ethical, epidemiological, and public health concerns. *PLoS Med* 2009; 6 (1): 30-4

Seeking solutions to the globalisation of clinical research

The authors of this article emphasise that long-term solutions to problems arising from the globalisation of clinical research require collaboration from stakeholders in academia, industry and regulatory agencies around the world. They discuss various solutions including the need for sponsors to match trial populations with the intended markets for the drugs or medical devices being tested. They underscore the importance of publishing all clinical trial data. Further, the leadership of clinical trials must incorporate representatives of the key countries involved in the study. On the global front, the authors propose the creation of a formal mechanism for sharing regulatory oversight information of clinical trials. Government agencies could maintain a central statistical monitoring system to identify unusual data patterns in trial results that raise suspicion of fraud. They make a number of recommendations: a comprehensive study, by the Institute of Medicine or the World Health Organization, of issues related to the globalisation of clinical research; making greater use of centralised institutional review boards; encouraging mutual acceptance of proposal reviews in consortia, and developing streamlined best practices to reduce unnecessary work for investigators.

Glickman SW, McHutchison JG, Peterson ED, Cairns CB, Harrington RA, Califf RM, Schulman KA. Ethical and Scientific Implications of the Globalization of Clinical Research. *NEJM* 2009; 360 (8): 816-23

The health of a nation amidst an economic crisis

It may be common sense that losing your job causes mental anguish that might increase your risk of psychiatric disorder. This means job loss precedes the illness. However, research findings are not clear on the cause and effect relationship of such risks and their health consequences–and their implications for population health. For example, it is reasonable to suppose that when fewer people drive under the influence of alcohol–a risky behaviour–any overall reduction in injuries from traffic accidents must be due to that change in behaviour.

Likewise, when large numbers of people lose their jobs, they may eat less, consuming fewer calories, and this will reduce obesity.

On the other hand it is also possible that jobless people are forced to buy cheaper, less nutritious and positively unhealthy food–so that there is an increase in obesity and health problems. Or, if you look for a correlation between absenteeism and health, you might find that workers with a history of absenteeism try harder to stay healthy and avoid sick days so that they can compete with their healthy colleagues. On the other hand, workers with chronic diseases may try to work when ill and their health suffer more as a result. Studies have found that in a contracting economy, there is actually an increase in the number of people claiming disability insurance. People with disabilities for which they can receive compensation, stop fighting for jobs with low wages and accept the insurance instead. Further, as the economy goes downhill people neglect preventive health measures. For example, fewer people go for screening tests.

It might be better, the authors suggest, to focus on the questions that need to be asked: What can be done to reduce the suffering of job-losers and their family members who will neglect seeking help when they fall ill? How can they be encouraged to seek care? And if they do seek care, what needs to be done to pay for this care?

Catalano R. Health, medical care, and economic crisis. *NEJM* 2009; 360 (8): 749-51

Lessons in health policy from the Columbian Constitutional Court

Columbia is a middle income country, with economic inequality among the highest in the world. Two-thirds of its 46 million population lives below the poverty line. Yet it could give developing countries some lessons in health policy. Some dramatic changes took place, starting in the 1990s. These included the establishment of the constitutional court and mechanisms such as the tutela (protection writ) that granted protection to individual rights. This enhanced the public's access to the courts and helped enforce the right to health. Such changes were followed by the establishment of a two-tier system of health benefits, POS (Plan Obligatorio de Salud) and the POSS (Plan Obligatorio de Salud Subsidiado), for employed and unemployed people respectively. This increased healthcare coverage. The tutela's enabled people to turn to the courts to secure treatments and services that the state had agreed to provide under POS/POSS.

These mechanisms had a major impact on health policy-making, budgeting and the enforcement of existing laws. The Court ordered more transparency of health benefits. It also insisted on an annual restructuring of benefit plans with the direct participation of the medical community and users of the health system. It also ordered agencies to unify the POS and POSS plans, with the aim of realising universal coverage by 2010.

The Colombian example shows that increased access to courts may, under certain circumstances, enable people to assert their right to health, promote equity, ensure transparency in healthcare coverage, and encourage greater accountability within the health system.

Yamin AE, Parra-Vera O. How do courts set health policy? The case of the Colombian Constitutional Court. *PLoS Med* 2009; 6 (2): 1-4

Medicine, money and the market

In the wake of the current economic crisis, more attention has been focussed on containing costs in the healthcare system. Price tags are applied to every aspect of a doctor's day, creating an acute awareness of costs and reimbursement. Physicians are routinely provided with profit-and-loss reports reflecting their activity, with metrics measuring the cost-effectiveness of their work. This environment has got doctors focused on the market rather than on medicine's communal and social dimensions. The results from studies in behavioural economics and psychology suggest that performance metrics for doctors may actually reduce their productivity, impair the quality of their performance, and thereby increase healthcare costs. The authors highlight that the new business model cannot measure the quality that derives from the communal dimension of medicine. Finally, collegiality, cooperation, and teamwork are the cornerstones of medicine and must not be eroded by a marketplace environment.

Hartzband P, Groopman J. Money and the changing culture of medicine. *NEJM* 2009; 360 (2): 101-4

The patient's point of view of research done in emergency settings

Conditions such as stroke, sudden cardiac death, and major traumatic injury are major causes of morbidity and mortality. However, research on treatment given in these situations poses ethical concerns because it is difficult, if not impossible to get informed consent. In this qualitative study, survivors of sudden cardiac arrest were asked their views on whether research in emergency settings should be exempt from informed consent (EFIC). They found that patients were generally accepting of such research–more so than previous studies had predicted. Patients' concerns focused primarily on the study's risks and benefits and less on the question of waiving consent or randomisation. These findings indicate that there is a broad acceptance of EFIC research among people who have undergone emergency treatment for cardiac arrest. It suggests that the discussion should be focused on what risks are reasonable for non-autonomous subjects. The study also demonstrates that patients can provide valuable input on complicated and ethically challenging issues.

Dickert NW, Kass NE. Patients' perceptions of research in emergency settings: a study of survivors of sudden cardiac death. *Soc Sci Med* 2009; 68: 183-191

Visualising sexual assault: an exploration of the use of optical technologies in the medico-legal context

This paper explores the concept of "visualisation of sexual assault". They describe the evolution of specialised medico-legal knowledge and the technologies involved in medical forensic examinations. They put forward the theory that the principles and practices characterising medicine, science and the law are mirrored in the medico-legal response to sexual assault.

Specifically, they suggest that the demand for visual proof–such as DNA evidence–underpins the positivist approach taken in the pursuit of legal truth. Such evidence is generated to produce discrete empirical facts–removed from their context–through what are perceived to be objective technologies.

Drawing on interview and focus group data with 14 sexual assault nurse examiners (SANEs) in Ontario, Canada, the researchers examine perceptions and experiences of the role of visual information in sexual assault. They argue that some of the participants' comments support their theory that there is an institutional overemphasis placed on the physical damage to sexually assaulted women's bodies, and there is an increasing focus on developing technology for visual evidence documentation. This has implications when physical injuries are absent. They also expressed concerns about the problematic ways in which either the lack of visual evidence - or its particular nature - may play out in the legal context. The focus on documenting external and internal injuries created, for some, discomfort about the fragmenting and objectifying the bodies of those women these nurses must simultaneously care for.

White D, Du Mont J. Visualizing sexual assault: an exploration of the use of optical technologies in the medico-legal context. *Soc Sci Med* 2009; 68: 1-8

Perspectives on evidence-based healthcare in the context of oncology

Evidence-based medicine (EBM) is strongly shaping the nature and direction of biomedical practice and organisational culture. Clinicians are now expected to adopt the principles of EBM and evidence-based practice (EBP) whilst also maintaining professional autonomy, clinical judgement and therapeutic integrity. The authors of this study report on research drawing on in-depth interviews with 13 oncology consultants and 12 oncology nurses in Australia. They explore how oncology clinicians utilise and critique types of evidence and statistical probabilities; the organisational systematisation of care; and, wider policies of EBM. They report that the results illustrate significant variation in perceptions of EBM between the oncology sub-specialties examined in their study.

Broom A, Adams J, Tovey P. Evidence-based healthcare in practice: a study of clinician resistance, professional de-skilling, and inter-specialty differentiation in oncology. *Soc Sci Med* 2009; 68:192-200

Essential medicine lists for children in central Africa

This study set out to survey the inclusion of 20 medicines included in the WHO model list of essential medicines for children in national essential medicines lists (EMLs) in Central Africa. It also aimed to assess the availability and cost of these medicines in 14 countries in central Africa. Surveys were conducted in public and private sector medicine outlets in the capital city of each country. Although the majority of medicines in the WHO model list were considered to be "essential" as indicated by national EMLs, on average only half were available in the facilities surveyed. Overall, the average proportion of the survey medicines available varied from approximately 35% in primary health care clinics to approximately 50% in private retail pharmacies. Availability was higher in private or retail pharmacies (compared to public sector outlets) in all countries. However, there was substantial variability between countries. In Nigeria, for example, less than 20% of survey medicines were available in central medical stores.

There was considerable variability in prices, which tended to be higher in retail pharmacies. Findings were unclear on the demand side of the equation, the factors that determined prescribing practices and the cost of children's medicines. Authors conclude that the availability of key essential medicines for children was poor. Before improvements can be made, better understanding of the supply systems and patterns of demand in these countries is needed. Authors contend that medicines must be available, affordable and acceptable to patients, without which progress towards Millennium Development Goals will not occur without a major effort to improve access to medicines for children.

Robertson J, Forte G, Trapsidac JM, Hill S. What essential medicines for children are on the shelf? *Bull World Health Organ* 2009; 87:231-237

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