FROM OTHER JOURNALS

Cancer treatment: is it about survival alone?

The authors of this essay discuss an ethical framework for comparative effectiveness research in the management of cancer.

Over the past decade, oncology has undergone revolutionary changes with the advent of new drugs and techniques to combat cancer, and many types of cancer are now considered chronic diseases. However, the chronic disease exemplar, which emphasises the management of the disease by the patient with support from the clinician, fails in the case of cancer, where treatments may change as the disease progresses.

Comparative effectiveness research is sought after by oncologists for the management of chronic cancer. Clinical trials in this field have compared the effectiveness of new drugs against old drugs and of combination regimens versus single drugs in sequence. A review of data from clinical trials suggests that the decision on the treatment regimen should be based on a consideration for the patient's quality of life and the therapeutic index (the ratio of the quantity required to produce the desired effect to the quantity that will produce dangerous side effects). The authors cite a number of studies to argue that effectiveness cannot be defined solely on the basis of progression-free survival. Factors such as overall survival, toxicity of the new regimen, costs and other burdens are also significant while judging the effectiveness of a regimen. Effective treatment should also encompass palliative care for relieving toxicity associated with the treatment regimen.

Further, with the availability of data online, patients and their relatives are also equipped with more knowledge and will have their own assessments of a regimen's effectiveness and the options. Comparative effectiveness research can actually improve the patient-provider interaction and facilitate an informed decision making process for patients while choosing a treatment. The authors bring to close the essay with this noteworthy conclusion: "The story of living with a chronic disease is the patient's own story. The disease's natural history and how it responds to interventions is part of this story. By defining 'effectiveness' with reference to life as it is lived, oncologists support the practice of informed decision-making and honor the story in progress."

Berlinger N, Flamm AL. Define "effective": the curious case of chronic cancer. *Hastings Center Report*. 2009 Nov-Dec;39(6):17-20.

Genetic information: balancing civil rights and the public good

On August 30, 2009, the University of Akron in the USA approved an addition to the employee background review policy. It asked for blanket criminal background checks, including DNA sampling, for all prospective employees excluding student employees. This new rule led to widespread protests and was eventually amended, shifting the role of pre-employment DNA screening to law enforcement authorities.

The first federal law against genetic discrimination, the Genetic Information Nondiscrimination Act (GINA), came into effect in November 2009. GINA prohibits employers from seeking DNA material from employees even for criminal background checks. It also precludes any discrimination based on genetic information. The US Equal Employment Opportunity Commission also prevents the collection of, and discrimination based on, genetic information. The only law enforcement exception that GINA has pertains to forensic laboratories and to those seeking identification of human remains, and to detect sample contamination. But there is still lack of clarity as to how GINA will apply to law enforcement agencies acting on behalf of employers.

There is also the dimension of screening potential employees to identify risks to the security of other employees and students. But many consider that such a blanket check would be discriminatory against certain socioeconomic and ethnic groups. Compulsory DNA sampling would produce sensitive information about the health status of employees and their family members. There are logistical issues pertaining to the presence of trained personnel, properly equipped, monitored and secure laboratory facilities, and appropriate policies for managing the samples. If linked to a law enforcement agency, the employee DNA database gets linked to criminal databases, exposing more people to the risk of false positive matches and also to constant surveillance. The authors opine that simply avoiding the practice of DNA identification will not be a solution to the larger issue at stake. There should be a balance between the privacy concerns of the employee, the security interests of the employer and law enforcement.

Callier SL, Huss J, Juengst ET. GINA and preemployment criminal background checks. *Hastings Center Report*. 2010 Jan-Feb;40(1):15-9.

The equity efficiency trade-off

The argument about tradeoffs between equity and efficiency while scaling up programmes is an age-old one. One of the key issues in scaling up is whether to maximise coverage across the whole population (which may result in greater use by those with more access, who are frequently the wealthier as well) or to target resources to reach poor and vulnerable groups. The first approach would result in a widening of the existing inequalities between the different socioeconomic groups.

The author argues that the cost effectiveness of a chosen treatment strategy influences the cost and constraints associated with scaling up and thereby the costs of broader coverage. The point is illustrated with examples from the

efforts to scale up HIV treatment in South Africa. The financial as well as logistical feasibility of scaling up programmes should be an important consideration for health policy makers. In the case of cost constraints, a more cost effective programme might improve potential coverage among those in need of the services. However, the ethical dilemma in such an approach is that very often the more cost effective treatment (producing the greatest impact for the amount of money spent) might not be the most effective one (having the greatest impact regardless of the cost) and vice versa. The author argues that in a resource strapped setting, if equitable access to effective forms of treatment is unavailable, then a more cost-effective form of care with higher access to those who are in greater need of services should be sought.

Cleary SM. Trade-offs in scaling up HIV treatment in South Africa. *Health Policy and Planning*. 2010 Jan;25:99-101.

Palliative care awareness in urban and rural areas

Palliative care which began in the hospice movement got established as a hospital-based programme in the 1980s in the United States. It is still a relatively new concept in Indian society. A study was undertaken in rural and urban areas of a district in Kerala to assess the knowledge and attitude of the public towards palliative care. Only 20.5% urban and 5.4% rural participants had heard about palliative care, with the major source of information being newspapers. The study also found that all the rural and more than 90% of the urban population felt that the treating physician should honestly inform the patient about his/her illness. But while urban participants believed that the patient should be the first recipient of the bad news, rural participants were in favour of informing the family first. The authors opine that this could be due to the greater value attributed to the family in rural areas. There was a great keenness expressed by study participants, both rural and urban, to know more about palliative care. Awareness measures through the mass media about palliative care should be scaled up and the services should be made more easily available to those in need. The authors argue that the concept of palliative care should be customised to meet the specific needs of the Indian community and more healthcare providers, including grassroots level health workers, should be given training to meet the increasing needs of palliative care.

Joseph N, Jayarama S, Kotian S. A comparative study to assess the awareness of palliative care between urban and rural areas of Ernakulam district, Kerala, India. *Indian Journal of Palliative Care*. 2009 Jul-Dec;15(2): 122-6.

UN resolution against medical torture

There have been many reports, from all over the world, of the involvement of doctors in torture and the inhumane treatment of refugees and prisoners. Because of strong political and social pressure, or in the course of fulfilling their professional obligations during their tenure in the military or police of a state agency, doctors are often forced to overlook their ethical obligations and be part of torture indirectly, by tampering with medical reports, more directly by medicating prisoners to keep them alert during torture, and so on.

In March 2009, the United Nations Human Rights Council passed a resolution to curb medical torture. The resolution calls on states to initiate steps to prevent the involvement of doctors in torture and to protect those doctors who take an open stand against torture. The resolution, which also addresses the healthcare professional and the UN special rapporteur, giving him more authority on medical torture-related issues, has adapted ideas from the ethical principles of the World Medical Association, the Hippocratic Oath and the Declaration of Tokyo. This resolution wields more power and can be enforced in a court of law. It is also an expression of a non binding commitment to take action against medical torture. Medical associations worldwide will find it easier to implement and adhere to the principles of the new resolution as the states are also involved in the process.

Polatin PB, Modvig J, Rytter T. Helping to stop doctors becoming complicit in torture. *BMJ*. 2010;340:c973

Financial incentives to the research team

There are many factors influencing the conduct of biomedical research. Financial remuneration is one incentive for the researcher to participate in research. This factor gains much significance with the growth of industry-sponsored clinical trials. The authors of this paper explored the question of whether financial remuneration influences the research team in recruiting patients for a particular study and also what the factors are behind the decision of patients to participate in a study. They investigated the recruitment and informed consent rates for two clinical trials with identical inclusion criteria in a neonatal ICU setting in a hospital in Canada. Study 1 was a multi-centred, funded study involving an 18-month-follow up and providing financial remuneration to respiratory therapists who were to enrol participants in the study. Study 2 was a single-centre, non-funded study which offered no remuneration to the research team.

The authors found that the rate at which parents were approached was higher for the first study but the consent rates by parents were significantly higher for the second study. Participation rates were similar in both studies. None of the researchers reported financial incentive as a motivation for higher approach rates but they mentioned that they were more motivated to ensure success of the bigger multicentre trial. Institutional ethics committees now oppose remuneration to the research team to enrol eligible participants and many IECs have made it mandatory that the financial ties of the researcher be clearly stated in the informed consent form. Clinical research should be encouraged but remunerations to researchers should not undermine the ethical conduct of research.

Unger S, Wylie L, Fallah S, Heinrich L, O'Brien K. Motivated by money? The impact of financial incentive for the research team on study recruitment. The *Hastings Center Report IRB: Ethics and Human Research*. 2010;32(1):16-9.

Exhibition of plastinated corpses

This editorial comments on the controversy surrounding a unique exhibition in Birmingham, UK. Bodies Revealed, an exhibition of plastinated corpses, was banned in Venezuela and the subject of a lawsuit in the USA. The lawsuit forced the exhibitors in the US to display a disclaimer saying that the bodies on display were those of Chinese residents or citizens received by the Chinese bureau of police. However, they did not mention that the bodies might be those of Chinese prisoners.

At the Birmingham exhibition the exhibitors did not display any information about the origin of the bodies. According to the website of the exhibitors, the bodies were of people who died of natural causes and they were donated with their relatives' consent for educational purposes. However, the exhibitors failed to independently verify the origins of the bodies. The writers of this editorial point out that informed consent is not required in the case of imported tissues as per the 2004 Human Tissue Act which is the legal framework for the storage and use of human bodies, tissues and organs in the UK. The editorial calls for action so that proof that human tissue was obtained with informed consent is made mandatory for public display of human remains irrespective of whether they are of UK or foreign origin.

Editors. Bodies revealed, but whose? *Lancet*. 2010 Feb 20;375:612.

Research data sharing

Sharing of health data has immense benefits in the field of public health research. But there are significant technical, ethical and professional obstacles that must be overcome to make data sharing a standard practice. The major ethical impediment in data sharing is regarding the maintenance of confidentiality of participants. The pressure on researchers to publish also prevents them from sharing their data. There is also a need to improve data management standards in developing countries.

International funding agencies and journals are trying to make the process of data sharing routine in research. Disclosure of data sharing plans is part of many grant requisition forms of funding agencies, and journals are asking for a replication data set with articles. But it is equally important that secondary users and funding agencies work at building capacities among primary researchers from developing countries, and in developing and expanding data management and archiving standards in the primary research settings. The authors emphasise that "fair trade and not free trade" should be the driving force behind international data sharing initiatives.

Pisani E, Whitworth J, Zaba B, Abou- Zahr C. Time for fair trade in research data. *Lancet*. 2010 Feb 27; 375:703-5.

Compiled by Divya Bhagianadh
drdivyabhagianadh81@gmail.com

Healthcare rationing conference, Rotterdam, The Netherlands, December 9-10, 2010

The Erasmus Observatory on Health Law has organised an international conference on healthcare rationing. Participants will discuss questions arising from the Dutch government's experiments with "regulated competition" in social health insurance. Some of these questions are: Who is responsible for rationing? How does it function? What are relevant and acceptable selection criteria? To what extent is current rationing just? What can be done to make it more just? How will healthcare rationing affect equal access to healthcare? What is the relationship between healthcare rationing and differences in health status?

Each conference day will open and close with plenary sessions with keynote presentations and debate. During each day, the conference will host parallel sessions addressing certain defined questions. The conference language is English.

A special poster session for young researchers is planned for Friday, December 10.

For more information, write to: info@erasmusobservatoryonhealthlaw.nl