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Monitoring global health: time for new solutions

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leukaemia[16]) were not predicted by animal studies using similar doses of vector.

One set of questions on toxicology related to gene transfer arises because most studies in humans—as with many other trials of hazardous agents—enrol participants with advanced illness. Such participants are likely to misinterpret the purpose of the trial as providing therapy rather than producing generalisable knowledge.[17] Enrolment in studies on the safety of gene transfer is therefore susceptible to being based on "misinformed" consent. Also, participants who perceive a trial as providing therapy may be less willing to comply with intrusive procedures (for example, long term follow up and autopsy) that are aimed at testing safety. By policing consent procedures for language that promotes misconceptions about therapy, investigators may encourage participants to cooperate with a trial's toxicological aspects.[18]

Premarketing studies of drugs often have insufficient power to expose rare adverse events[19]; the collection of toxicity data is further hampered because gene transfer trials generally enrol participants with severe illness. For instance, attributing causes for adverse events is confounded by underlying medical conditions. Moreover, such populations are unlikely to survive and experience theoretically predicted latent adverse events. Therefore, many risks will only be characterised once gene transfer extends to populations with less severe medical conditions; patients and the public (rather than trial participants) will likely bear many of the risks involved in characterising latent toxicity.

Owing to the uncertainties and inexperience surrounding risks from gene transfer, systems may need to be established for postmarketing surveillance (for example, registries) and the long term follow up of trial participants. In the United States, such long term follow up is not mandatory, and anecdotal evidence indicates that it is not widely practised.[18] In contrast, the United Kingdom[20] and Australia (www7.health.gov.au/nhmrc/research/gtrap.htm) track the medical records of recipients of gene transfer. Follow up and postmarketing surveillance are potentially costly, can medicalise people's lives, and infringe on their privacy. Nevertheless, spontaneous reporting of adverse events is unreliable for detecting latent adverse events,[19] and more active measures may be necessary to protect the public, and patients and their descendants, should gene transfer expand to milder medical conditions.

Although recent trials confirm the feasibility of gene therapy, they also highlight that its risks are poorly understood. The task for researchers in gene transfer will be to characterise these risks while attending to the complex ethical challenges of conducting gene transfer studies in humans.

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Corrections and clarifications

The next small step

The author of this article in our Christmas issue, Kevin Fong, has notified us that his email address is missing its first full stop (*BMJ* 2004;329:1441-4, 18-25 Dec). His correct address is k.fong@ucl.ac.uk.

Monitoring global health: time for new solutions

The authors of this Education and Debate article (who argued that a new global health monitoring organisation is needed to replace the World Health Organization) would like to clarify for readers that they have all had recent links with WHO (*BMJ* 2004;329:1096-100, 6 Nov). Christopher J L Murray worked for WHO until 15 September 2003, Alan D Lopez worked for the organisation until 1 January 2002, and Suwit Wibulpolprasert has served on a number of advisory committees to WHO.

If the honey doesn't get you, the bees will

A lapse in concentration by Harvey Marcovitch, the author of the summaries on the BMJ Family Highlights page, led to the inadvertent omission of the word haemorrhagic in this summary on the BMJ Family Highlights page (*BMJ* 2004;329:1368, 11 Dec). The third sentence should have read: "Computed tomography of the head and magnetic resonance imaging of the brain showed a large right temporo-occipital haemorrhagic infarct."

Cadavers as teachers: the dissecting room experience in Thailand

In this article by Andreas Winkelmann and Fritz H Güldner in our Christmas issue, we forgot to carry out the authors' wishes that we acknowledge Professor G H Schumacher from Rostock, Germany, as the provider of the photograph (*BMJ* 2004;329:1455-7, 18-25 Dec).