addiction services has been long standing and consistent.

So what about the patient with alcoholic liver disease who has received a transplant and returns to alcohol consumption? From an addiction perspective, a patient who has fulfilled the criteria for a diagnosis of alcohol dependence is at risk of returning to previous levels of consumption when alcohol is taken, although whether this pattern is altered after a transplant is uncertain as transplantation itself may have a rehabilitative effect.[6] Most patients who have received transplants for alcoholic liver disease are unlikely to have met the criteria for a diagnosis of dependence, and resumption of drinking may therefore be less risky.

This leaves a dilemma regarding considerations from an addiction perspective for such transplant candidates. Some patients can return to some alcohol use after transplantation with no appreciable risk to the graft. People with a history of alcohol dependence, however, are unlikely to be able to resume moderate drinking without a risk of reverting to previous heavy levels of consumption. By insisting on lifelong abstinence for all, are we attempting to avoid all risk to the graft without considering quality of life and individual strengths and values? We should aim for harm minimisation and moderation for the majority and accept a risk to the graft for a small minority.

We do not have consensus on what constitutes a relapse or recidivism, and what degree of alcohol consumption, if any, is acceptable. After transplantation about 8-22% of patients relapse (consumption of any amount of alcohol) within six months and 10-30% relapse overall,[7] whereas with conventional treatment for alcohol dependence a 60-80% relapse rate at two years is common. Even in an era of donor shortage, the question should therefore not be whether patients with alcoholic liver disease should receive transplants but whether enough is being done to support such patients through a successful operation.

Concerns about the effects of relapse leading to recurrent graft damage and non-compliance are applied to patients who have received grafts for alcoholic liver disease but not other indications. For example, obesity may in itself result in end stage liver disease requiring liver transplantation, will accelerate the progression of hepatitis C virus disease, and may result in graft damage.[8] Should patients in whom obesity has had a role in the development of end stage liver disease be offered transplantation only if they lose weight before the procedure and agree to avoid over eating afterwards? Non-compliance with medication as a consequence of a return to drinking occurs in only a small proportion of drinkers who relapse.[9] In people with transplants, the greatest risk of non-compliance is not among those grafted for alcoholic liver disease but among teenagers.[10] Yet few argue that adolescents should not receive transplants because they might damage or lose their graft from non-compliance and in this event be denied a second graft.

Debate fuelled by uninformed comments will serve potential donors, their families, and recipients poorly. Those involved in transplantation need to show that donated livers are used wisely, ethically, and fairly and so should reassure the public to understand that selected people with alcohol induced liver damage are appropriate candidates for transplantation and that a rational basis is used to assess and treat such potential patients.

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Open access to industry's clinically relevant data

Urgently needed, but when will we get it, and in what form?

Last month GlaxoSmithKline announced that it would publish summaries of all its clinical trials of a new product once it had been launched.[1] This decision followed news of a lawsuit brought by New York State alleging that the company had concealed the results of trials of paroxetine because they might have spoilt marketing plans. GSK said it had been considering the move for some months. A similar sounding policy was announced by Glaxo Wellcome in 1998[2] but seems to have been quietly abandoned in 2000 after the merger with Smith KlineBeecham.

The arguments for free public access to all clinically relevant data on a company's drug have been stated

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many times: clinicians, patients, and the institutions that pay for health services all need the data to make good choices and to use drugs in the best ways, maximising their benefits and minimising harms. That is true not only for individual drugs and treatments, but also for the more efficient and speedy management of knowledge. Systematic reviews of treatments (both of individual treatments and of a range of treatment options for a problem) are bound to be biased if important studies are kept secret, and future research is misrouted or impeded if lessons from hidden studies cannot be assimilated.

The International Committee of Medical Journal Editors is considering requiring all clinical trials submitted for publication to be listed in a registry. The American Medical Association has decided to urge the Department of Health and Human Services to establish a comprehensive registry for all clinical trials and require every trial to have a unique identifier. Over 300 clinical trial registries currently exist: they are hard to use and not comprehensive.

Industry's argument against free access has always been that it has paid for the research and therefore owns the results, which are "commercially sensitive," a sweeping notion that covers trade secrets, "might help competitors," "could affect the share price." Competition thus rewards those who best keep secrets, not those who have the best drug and the data to prove it. It also means that anything to do with harms, which are sensitive commercially, tends to remain buried, and authors will feel less accountable. This denies the public interest and ignores the contributions of the participants, investigators, and the institutions where the work was done. Industry is beginning to recognise that secrecy is not "perceived" to be in the public interest. The Association of the British Pharmaceutical Industry (ABPI) launched its voluntary clinical trial register in May 2003. The register holds outline details of phase 3 trials of a licensed medicine in UK patients. So far only six member companies have registered 93 trials,[3] and the information about each is sparse. The ABPI seems satisfied, saying: "Since the launch it has been possible to refute a lot of the criticism about the perceived secrecy of the industry in the clinical trial area."

The US industry association, Pharmaceutical Research and Manufacturers of America (PhRMA), has acknowledged criticism in its statement on public disclosure of clinical trial results,[4] just updated.[5] This notes, however, that exploratory studies ("early phase or post-marketing") are often highly proprietary to the sponsoring company and of low statistical power, so that sponsors do not commit to publish the results of every exploratory study, nor "to make the … clinical trial protocols available at inception, as in a clinical trials registry." But now the momentum for meaningful disclosure has moved to a higher plane—partly fuelled by a succession of unexpected and worrying revelations about the harm caused by selective serotonin reuptake inhibitor (SSRI) antidepressants.

Even if other companies copy the policy announced by GSK we would lack much of the information we need. The data produced by the company would be abstracts that may well be incomplete and biased. Too many published clinical trials, whether industry-sponsored or not, do not comply with the CONSORT (consolidated standards of reporting trials) guidelines (www.consort-statement.org), and most are seriously deficient in detecting and reporting adverse events,[6] a problem to be addressed in the next revision of CONSORT.

To bring the reporting, interpretation, and dissemination of clinical trials into the 21st century will need a lot of work. Journal editors and participants in the Cochrane Collaboration are trying hard to improve matters, but others who should be concerned have shown little interest. Research ethics committees (institutional review boards) could contribute by pressing study investigators and sponsors to undertake to make the results—whether positive, negative, or inconclusive—publicly accessible within a reasonable time of completion (or abandonment). Regrettably, the new UK clinical trial regulations may prevent their making it a condition of approval.[7]

Drug regulatory agencies in particular could do most to help progress. They receive huge volumes of data to digest at speed. This may help to explain why the US Food and Drug Administration approves a drug if two studies of sufficient size establish its superiority over placebo, but then discounts the results from studies that show no evidence of drug efficacy.[8] Regulators should recognise that the data on which they base their decisions must be made available to the scientific community, clinicians, and the public as soon as a drug can be prescribed. They behave as if pharmaceutical companies were their primary customers. That will continue as long as industry funds drug regulation: government should fund it fully and independently as a vital part of public health, and separate bodies should deal with licensing and pharmacovigilance. UK law still forbids regulatory officials to disclose any information "obtained by or furnished to [them] in pursuance of" the Medicines Act, but this provision will be repealed next year. "Commercial confidentiality" should be confined to details of manufacture and formulation, not to clinical trial methods, data, or results. In the words of a former chairman of the Committee on Safety of Medicines, "the major proportion of individual [licence] applications, could, with little loss to anyone, be made publicly available."[9]

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