

An alcoholic patient who continues to drink: endoscopic treatment is preferred

EDITOR—Patients like Mr Bond in the last interactive case report are increasingly common and present difficult clinical decisions.¹ Leon and McCambridge highlighted the large increase in deaths from cirrhosis in the United Kingdom between 1987-91 and 1997-2001.² Mortality doubled (104% increase) in men in Scotland during that time, and per capita alcohol consumption also doubled in the UK between 1960 and 2002. Treatment of Mr Bond's variceal haemorrhage and associated decisions on how far to go with intervention should be based on clinical need, balanced with the probability of a beneficial outcome for Mr Bond, rather than his continued drinking or other lifestyle issues.

When Mr Bond presented with a further variceal bleed he was successfully treated endoscopically. At this point a transjugular intrahepatic portosystemic shunt is not clinically indicated. Eleven randomised controlled trials have compared endoscopic treatment with a shunt for recurrent bleeding. A meta-analysis of these studies showed that although a portosystemic shunt is better at preventing recurrent bleeding, it is associated with a much higher incidence of hepatic encephalopathy and no improvement in mortality.³ As such the shunt is usually reserved for salvage therapy in patients with refractory bleeding.

The prognosis in variceal bleeding is directly related to the severity of the underlying liver disease and the prevention of complications. Studies have consistently shown a poor outcome in patients undergoing a transjugular intrahepatic portosystemic shunt who have associated hyperbilirubinaemia, coagulopathy, or renal impairment. The model end stage liver disease (MELD) score (calculated from the serum bilirubin concentration, international normalised ratio, and serum creatinine concentration), which is now used in the United States to prioritise patients for liver transplantation, was developed as a prognostic model for patients having a shunt.⁴

A recent study of 312 cirrhotic patients admitted to intensive therapy units, 65% of whom had alcoholic liver disease, found an overall mortality of 65% at 6 weeks. The factors independently associated with survival were fewer organs failing (patients with three or more organs failing had over 90% mortality) and with lower fractional inspired

oxygen, lactate, urea, or serum bilirubin concentrations at admission.⁵

The above data, although not ideal, allow us to make informed decisions on the clinical management of patients with alcoholic liver disease. Liver transplantation in this setting is different. In the UK we currently do not offer liver transplantation to patients with alcoholic hepatitis. In the elective setting a period of abstinence, although not predictive of drinking behaviour after transplantation, does allow assessment of the potential for hepatic regeneration and may avoid the need for liver transplantation.

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- 1 McPherson S, Rees CJ. An alcoholic patient who continues to drink: case outcome [with commentaries by A Bond with C Rees; P Haber; E Peiler; J Gillies, M Sheehan]. *BMJ* 2005;332:276-9. (4 February.)
- 2 Leon DA, McCambridge J. Liver cirrhosis mortality rates in Britain from 1950 to 2002: an analysis of routine data. *Lancet* 2006;367:52-6.
- 3 Burroughs AK, Vangeli M. Transjugular intrahepatic portosystemic shunt versus endoscopic therapy: randomized trials for secondary prophylaxis of variceal bleeding: an updated meta-analysis. *Scand J Gastroenterol* 2002;37:249-52.
- 4 Malinchoc M, Kamath PS, Gordon FD, Peine CJ, Rank J, ter Borg PC. A model to predict poor survival in patients

undergoing transjugular intrahepatic portosystemic shunts. *Hepatology* 2000;31:864-71.

- 5 Cholongitas E, Senzolo M, Kwong K, Patch D, Nikolopoulou VN, Leandro G, et al. Survival at six weeks of cirrhotic patients admitted to an intensive care unit. *Gut* 2005;54(suppl 2):A77.

The incidence of gastroschisis

Research urgently needs resources

EDITOR—Kilby says that gastroschisis shows an increasing temporal trend in the number of affected babies born in the United Kingdom,¹ a trend that has also been observed in other parts of the world.²

We evaluated the data of 25 registries of members of the International Clearinghouse for Birth Defects Surveillance and Research (ICBDSR) with more than seven years of data—a homogeneously ascertained and reliable dataset on termination of pregnancies.³ Fourteen registries showed a significant increasing temporal trend of gastroschisis (table). No similar trend was observed in the 36 malformations analysed in the dataset. We excluded the possible bias of a simultaneous decreasing trend in omphalocele indicating changes in reporting nomenclature or coding.

The increasing trend of gastroschisis is worldwide—namely, Japan, Australia, North-Central-South America, North-Central Europe—but not universal. For example, in Italy four regional birth defects registries (all

Rates of gastroschisis in 14 members' registries of International Clearinghouse for Birth Defects Surveillance and Research with significant temporal trend

Registry	Rate per 10 000		P trend (χ^2 test)
	First three years	Last three years	
Japan (1974-2003)	0.96	2.58	<0.01
Australia:			
Western Australia (1980-2003)	1.53	4.30	<0.01
Victoria (1983-2003)	0.71	2.44	<0.01
Canada Alberta (1980-2003)	1.57	3.53	<0.01
USA Atlanta (1974-2003)	0.85	2.48	<0.05
Mexico (RYVEMCE) (1980-2003)	1.44	5.11	<0.01
South America (ECLAMC) (1974-2003)	0.04	2.92	<0.01
Norway (1974-2003)	1.34	2.74	<0.01
Finland (1993-2003)	1.70	3.73	<0.01
Ireland Dublin (1980-2003)	0.13	2.05	<0.01
England and Wales (1995-2003)	1.52	2.05	<0.01
France:			
Paris (1981-2003)	0.18	3.44	<0.01
Central East (1978-2003)	0.42	1.60	<0.01
Slovak Republic (1995-2003)	0.55	1.10	<0.05

RYVEMCE=Mexican Registry and Epidemiological Surveillance of External Congenital Malformations. ECLAMC=Estudio Colaborativo Latino Americano de Malformaciones Congénitas.

The 11 registries with non-significant temporal trend (mean rate per 10 000 of the period): USA Texas 1996-2002 (3.85); Netherlands North 1981-2003 (0.81); Germany Saxony Anhalt 1987-2003 (1.54); Hungary 1982-2003 (0.38); Italy North-East 1981-2003 (0.51); Italy Emilia Romagna 1978-2003 (0.81); Italy Tuscany 1992-2003 (0.42); Italy Campania 1991-2003 (0.58); Malta 1993-2003 (1.02); Israel Birth Defects Monitoring System 1978-2003 (0.29); United Arab Emirates 1996-2003 (0.79).

with a rate between 0.4 and 0.8 per 10 000) have not seen any increase in the past 25 years.

Any explanation of this worldwide epidemic should consider the rate variation around the world, the increasing rate experienced worldwide but not universally, and the consistent increased risk in young mothers found in all studies performed. Aetiological research should be concentrated on large enough material, such as only an international collaboration can provide. Unfortunately, almost all birth defects registries are experiencing a chronic lack of funds, and no such study can be planned.

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- 1 Kilby DM. The incidence of gastroschisis. *BMJ* 2006;332:250-1. (4 February.)
- 2 Di Tanna GL, Rosano A, Mastroiaco P. Prevalence of gastroschisis at birth: retrospective study. *BMJ* 2002;325:1389-90.
- 3 International Clearinghouse for Birth Defects Surveillance and Research Centre. *ICBDSR annual report 2005*. International Clearinghouse for Birth Defects Surveillance and Research Centre, 2005.

Is also increasing in Spain, particularly among babies of young mothers

EDITOR—Kilby drew attention to the increasing incidence of gastroschisis in the United Kingdom, particularly among babies of young mothers.¹ This has also been shown by Donaldson and by Mastroiaco et al (previous letter).²

In the Spanish collaborative study of congenital malformations (ECEMC), an ongoing case-control study and surveillance system,³⁻⁵ we have also observed an apparent increasing trend in the birth prevalence of gastroschisis in Spain among mothers younger than 20 but not among older mothers (table).

Our results do not reach significance, although the sample sizes are small, so we cannot rule out that the observed increase was by chance. However, termination of pregnancy after detecting fetal anomalies has been legal in Spain since 1985, and data on such terminations cannot be obtained routinely. This implies that the apparent

increase in young mothers over time could be more striking, because of the termination of some pregnancies in which fetuses had gastroschisis.

Although the increasing frequency in young mothers is not universal in all published studies,³ the relation between gastroschisis and young maternal age is consistently found in all of them. Some maternal or environmental risk factors related to young women seem to be changing with time in some areas of the world. This could be associated with many other changing factors. The way forward to deal with this challenge is collaborative research,¹⁻³ if possible comparing factors in areas with and without increasing frequency of this rare congenital anomaly.

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- 1 Kilby DM. The incidence of gastroschisis. *BMJ* 2006;332:250-1. (4 February.)
- 2 Donaldson L. *Gastroschisis: a growing concern*. London: Department of Health, 2004. www.dh.gov.uk/assetRoot/04/11/57/82/04115782.pdf (accessed 4 Jan 2006).
- 3 Martínez-Frías ML, Salvador J, Prieto L, Zaplana J. Epidemiological study of gastroschisis and omphalocele in Spain. *Teratology* 1984;29:377-82.
- 4 Martínez-Frías ML. Gastroschisis: is the prevalence increasing? *Am J Med Genet* 1994;49:128.
- 5 Martínez-Frías ML, Rodríguez-Pinilla E, Prieto L. Prenatal exposure to salicylates and gastroschisis: a case-control study. *Teratology* 1997;56:241-3.

Assessing fitness to practise

Common sense approach to revalidation/accreditation

EDITOR—The controversial and impractical route for revalidation proposed by the General Medical Council based on legislation is for doctors to provide evidence that they are up to date and fit to practise. Ever since, the debate has ranged from how this might be achieved to questioning the validity of revalidation itself. I prefer the more complimentary “accreditation” to “revalidation.”

Government and regulatory bodies must ensure that the patients’ trust in their doctors is not betrayed.

Many assessment protocols have been devised to evaluate a wide range of activities, but these require validation for the accreditation of doctors. Baker argues for the establishment of detailed criteria based on standards expected of a doctor.¹ But Wakeford believes that patients will have no confidence in a system in which a doctor’s skills and standards of practice are reduced to a few sets of tick boxes.¹ But what trust will patients have in a system declared unworkable by the experts?² Rather than becoming embroiled in the academic arguments for and against these extreme views could we not resort to a time honoured, routinely

practised, common sense approach to this problem?

An appointment, entry into medicine, or the granting of an award invokes varying degrees of objective and subjective judgments. If accreditation is based on the principles of clinical governance in which a doctor is held responsible and assessed for delivering a high quality of service and maintaining the means to achieve it, then it would be eminently amenable to a similar approach. This is how we recognise a good workman—by the quality of his work.

The clinical excellence awards scheme is a good, simple, cost effective model on which to base the accreditation of doctors.

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Competing interests: AEAJ has a passionate interest in accreditation for the safety of the patients and the professional development of doctors.

¹ Baker R. Developing standards, criteria and thresholds to assess fitness to practise [with commentary by R Wakeford]. *BMJ* 2006;332:230-3. (28 January.)

Revalidation is a long and winding road

EDITOR—The road to revalidation is proving long and winding because of the complexity in setting standards described by Baker and Wakeford,¹ as well as problems with defined leadership and a professional cultural inertia.

In the current hiatus of leadership, the NHS Clinical Governance Support Team continues to promote the concept of useful revalidation for all doctors registered with the General Medical Council. In 2004 we worked with the Royal College of General Practitioners to define measures that any general practitioner could provide as useful indicators of fitness to practise.² The college used these when finalising its college portfolio.³ We sought collaboration with the Academy of Royal Medical Colleges to make these measures generic for all doctors.

Revalidation requires clearly defined evidence, and we are producing a portfolio suitable for all doctors. Our approach is to ensure that all doctors can identify learning from audit, important events, complaints, and feedback from patients and peers— aspects of professional behaviour that are essential to all doctors.

We support a clearly defined link between appraisal and revalidation: the evidence provided for revalidation, although signed off externally, can be screened in appraisal and used as a basis for the appraisal discussion.⁴ We have therefore produced an advisory framework for the quality assurance of appraisal.⁵

We believe that a broad alliance of stakeholders should lead this process. It is an opportunity to improve the quality of the medical profession because it seeks to quantify that which is currently not measurable. When the standards have been set, we should participate energetically for society

Birth prevalence of gastroschisis per 10 000 newborn infants (with 95% confidence intervals) in two age groups in Spain between 1980 and 2004

Maternal age	1980-5	1986-99	2000-4
<20*	1.57 (0.43 to 4.02)	2.24 (1.16 to 3.91)	2.99 (0.97 to 6.98)
≥20†	0.48 (0.28 to 0.76)	0.30 (0.20 to 0.42)	0.27 (0.15 to 0.46)

*Total population surveyed=95 814.
 †Total population surveyed=1 949 593.

to have the demonstrably excellent profession it deserves.

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- 2 NHS Clinical Governance Support Team. Defining the evidence for revalidation—supporting the Royal College of General Practitioners. 2004. www.gpappraisal.nhs.uk/files2/11092004090353defining_the_evidence_for_revalidation_pdf_late_edit.pdf (accessed 1 Feb 2006).
- 3 Royal College of General Practitioners. *Portfolio of evidence of professional standard for general practitioners*. www.rcgp.org.uk/corporate/consultation/eval_menu.asp (accessed 1 Feb 2006).
- 4 Conlon M. Appraisal and revalidation: can the circle be squared? *Clinician Manage* 2004;12:197-202.
- 5 NHS Clinical Governance Support Team. Assuring the quality of medical appraisal. www.cgsupport.nhs.uk/News/Assuring_the_Quality_of_Medical_Appraisal.asp (accessed 1 Feb 2006).

Conscientious objection in medicine

Author did not meet standards of argument based ethics

EDITOR—Savulescu's account of conscientious objection in medicine is a bold statement that requires all obstetricians to perform abortions, regardless of any moral convictions that they may have to the contrary.¹ Unfortunately, he violates the standards of argument based ethics.^{2,3}

He claims that professional commitments, what should be provided to patients, are based on law and the just management of resources. To say the least, this is a contentious claim in contemporary medical ethics and therefore must be argued. Having claimed law and responsible resource management as the ethically authoritative sources of doctors' professional obligations, Savulescu is methodologically obligated to provide an account of relevant law and an ethical justification for why and how it should guide doctors' clinical judgment, decision making, and behaviour.⁴ He is also methodologically obligated to provide a rigorous ethical analysis of the very slippery concept of inefficiency in the management of resources to show why it is always, as he puts it, an inequity that is unjustifiable.⁵

He does neither. In all cases of conflict with the principles of individual conscience of "would-be conscientious objectors," the professional commitments of doctors, Savulescu concludes, should control clinical judgment, decision making, and behaviour. The intellectual and moral authority of this sweeping conclusion is a function of the argument given to explain and justify the commitments of the profession. No such argument is provided.

Savulescu's failure to meet the standards of argument based ethics means that the five constraints that are necessary to ensure the legal, equitable, and efficient delivery of health care spring fully armoured from the head of Savulescu. Readers timorous enough to expect argument should, instead, genuflect and accept these constraints,

simply on Savulescu's unargued, albeit vigorous and witty, assertion of them. After all, *initium sapientiae timor domini*. Thus is medical ethics reduced to saying it is so.

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- 1 Savulescu J. Conscientious objection in medicine. *BMJ* 2006;332:294-7. (4 February.)
- 2 McCullough LB, Coverdale JH, Chervenak FA. Argument-based medical ethics: a formal tool for critically appraising the normative medical ethics literature. *Am J Obstet Gynecol* 2004;191:1097-102.
- 3 DeGrazia D, Beauchamp TL. Philosophy. In: Sugarman J, Sulmasy DP, eds. *The methods of medical ethics*. Washington, DC: Georgetown University Press, 2001:31-46.
- 4 Hodge JG Jr, Gostin LO. Legal methods. In: Sugarman J, Sulmasy DP, eds. *The methods of medical ethics*. Washington, DC: Georgetown University Press, 2001:88-103.

Doctors' freedom of conscience

EDITOR—Since visiting Auschwitz, I have grappled with the question of how I would have behaved as a doctor in Nazi Germany or Stalinist Russia. I hope I would have had the moral courage to refuse to participate in the various perversions of medicine that these regimes demanded—for example, respectively, eugenic "research" and psychiatric "treatment" of dissidents.¹

I hope, but not being a very courageous person, I'm not at all sure. My chances of behaving honourably would have been greatest if I had felt part of an independent medical profession with allegiance to something higher and more enduring than the regime of the day. They would have been least if Savulescu's opinions had prevailed (which, I suppose, they did).²

The most charitable interpretation of Savulescu's article was that he wanted to criticise doctors who obstructed women's requests for abortion. If so, he could have made an interesting case on ethical grounds. But by widening his argument, first to the usual suspects of Christians and Americans, and then to anyone who dissents from the current state ideology, he destroyed it. A happy, but unintended, consequence.

Savulescu is entitled to his opinions, but they shouldn't have been presented as received wisdom. Presumably the *BMJ* published his piece because it is radical and challenging. That's okay, but there are at least 100 000 practising doctors in this country, and, although we are generally intelligent, caring, and skilful, many of us are surprisingly sensitive. We need to be supported as well as challenged. Perhaps the journal could include some encouraging articles from time to time?

After 30 years of reading the *BMJ*, Savulescu's article was the first one to make me feel physically sick.

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- 2 Savulescu J. Conscientious objection in medicine. *BMJ* 2006;332:294-7. (4 February.)

The ethics of responding to bird flu

EDITOR—We question Savulescu's statement that a specialist valuing her own life more than her duty to her patients during a bird flu epidemic would be demonstrating values "incompatible with being a doctor."¹

By 6 February 2006 the World Health Organization had received reports of 165 confirmed cases of avian influenza in humans, of whom 88 had died (mortality 53%).² The Department of Health's influenza pandemic contingency plan estimates an attack rate of 25% and a case fatality rate of 0.37%.³ Healthcare staff are likely to be particularly at risk, with estimated sickness absence rates double the rate of the general population.³

But if the department's estimates are seriously overoptimistic, and the case fatality rate remains high, at 25-50%, treating infected patients arguably would represent a grave risk to a doctor's physical welfare.⁴ Furthermore, a substantial mortality among trained healthcare professionals would remove a vital resource for treating people in need and damage the future viability of the health service. Horton makes a strong case for clinicians adopting a virtue based framework and retaining professionalism in their practice.⁴ But the exercise of virtue requires integrating Aristotle's phronesis—practical wisdom or prudence—with compassion and altruism as endorsed by the Royal College of Physicians.⁵

In this context, recklessly to treat a highly contagious individual without taking adequate precautions would be imprudent and irresponsible. Equity and fairness requires a professional to judiciously balance the needs of one patient with the needs of others, including those of his or her own family.

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- 1 Savulescu J. Conscientious objection in medicine. *BMJ* 2006;332:294-7. (4 February.)
- 2 World Health Organization. Epidemic and pandemic alert and response (EPR). www.who.int/csr/disease/avian_influenza (accessed 7 Feb 2006).
- 3 Department of Health. *UK health departments' influenza pandemic contingency plan (October 2005 edition)*. London: Department of Health, 2005.
- 4 Horton R. Medicine: the prosperity of virtue. *Lancet* 2005;366:1985-7.
- 5 Royal College of Physicians Working Party. *Doctors in society. Medical professionalism in a changing world*. London: RCP, 2005.

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