

probably more pronounced when the inflammatory features prevail over the fibrotic process. On the other hand, Shanahan rightly observes that it is unlikely that a single probiotic is suitable for all patients. *Saccharomyces boulardii* is a promising agent in the maintenance treatment of Crohn's disease but its effects in ulcerative colitis remain unknown, being currently under investigation. Probiotic cocktails may well be the right solution, but the products successfully employed in pilot studies⁷—excluding Crohn's disease, so far—are not commercially available and we have no idea of their price until they are launched in the market.

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Survey of informed consent for endoscopy

EDITOR.—Informed consent is an integral part of good medical practice. The recently published Department of Health (DoH) reference guide to consent for examination or treatment lays out the most up to date recommendations for obtaining consent.¹ It includes guidance relating to the timing of consent and the provision of sufficient information for valid consent. For gastroenterologists, consent for procedures usually relates to endoscopy, and guidelines for this have also been produced by the British Society of Gastroenterology.² It is not clear how well endoscopists and endoscopy units perform in relation to these guidelines, and the guidelines themselves acknowledge the practical difficulty of achieving some of the standards. To attempt to assess current practice, a questionnaire was used to obtain information from endoscopy units.

A standard anonymous questionnaire was sent to the ward manager of each of the endoscopy units in the North West region

Table 1 Results of questionnaire

	Yes	No
Is a standard method of obtaining consent for endoscopy used by all consultant firms?	13 (76%)	4 (24%)
Are patients routinely given written information prior to attending for endoscopy?	16 (94%)	1 (6%)
If written information is given does this include information about procedural risk?	11 (65%)	6 (35%)
Are patients routinely advised that trainees (e.g. SHOs/SpRs) may perform procedures?	7 (41%)	10 (59%)
Are patients fully informed about procedures 24 hours or more before endoscopy?	10 (59%)	7 (41%)
Do patients sign the actual consent form immediately prior to the endoscopy?	16 (94%)	1 (6%)
Is there an opportunity for patients to ask any last minute questions immediately before the procedure?	17 (100%)	0
Do you use procedure specific consent forms (i.e. separate forms for gastroscopy, colonoscopy, and ERCP)?	1 (6%)	16 (94%)
Finally, is the same system of obtaining consent available for inpatients as outpatients?	12 (71%)	5 (29%)

asking about current practice in the unit with regard to consent for outpatient endoscopy. An accompanying letter explained the rationale for the questionnaire. Both district general and teaching hospitals were included. Seventeen of 20 units (85%) responded and each of the questionnaires returned was fully completed. Table 1 shows the results.

Although this simple questionnaire survey only examined one postgraduate region and did not cover a large number of units, there was a high response rate and so the results are representative of current practice within this region and probably reflect practice in the UK as a whole. It clearly demonstrates widespread variation in practice, both between individual units and to a lesser extent between individual doctors working at the same units. Present consent procedures appear to fall short of the ideal set out by the DoH guide and the GMC, particularly with regard to information about procedural risk, involvement of trainees in service provision, and allowing patients sufficient time to make informed decisions.^{1,3} The DoH guide recommends that consent should be sought well in advance and that information should be given about "significant" risks. Arguably the amount of information given about such matters as procedural risk may vary on a patient by patient basis. In a busy working environment, extra time spent explaining procedures may not appear productive but in the longer term will safeguard against complaints and even litigation.

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- 3 Seeking patients' consent: the ethical considerations. London: GMC, 1999.

Why measure thiopurine methyltransferase activity? Direct administration of 6-thioguanine might be the alternative for 6-mercaptopurine or azathioprine

EDITOR.—6-Mercaptopurine (6-MP) and its prodrug azathioprine (AZA) are effective in

inflammatory bowel disease (IBD), mainly by their active 6-thioguanine (6-TG) metabolites. Efficacy and also myelotoxicity of 6-MP and AZA seem to be related to the 6-TG levels achieved. Instead of activation to 6-thioguanine nucleotides, 6-MP and AZA can be inactivated to 6-methylmercaptopurine (6-MMP) by the enzyme thiopurine methyltransferase (TPMT). High interindividual variability in TPMT activity is known. Therefore, measuring TPMT activity could be used to adjust the dose of 6-MP or AZA to reduce myelotoxicity. However, levels of 6-MMP formed by TPMT seem to correlate with toxicity.¹

The issue in the commentary by Sandborn (*Gut* 2001;48:591-2) was rational dosing of AZA and 6-MP.² However, we would like to focus on direct administration of the active metabolite 6-TG. In a recent pilot study in IBD, patients treated with 6-TG had no methylated metabolites detected.³ 6-TG dosing is feasible without measuring TPMT activity.

Following intravenous administration of 6-TG, pharmacokinetic behaviour is biphasic: a distribution half life of 15 minutes followed by a terminal half life of 11 hours. Oral absorption of 6-TG is approximately 30%. Administration by oral suspension is possible in which the suspension is stable for almost three months.⁴ 6-TG tablets (Lanvis) have been available in our country since 1975 and registered for the treatment of acute and chronic myeloid leukaemia and acute lymphatic leukaemia.

We have started a prospective study of AZA or 6-MP in IBD patients with recurrent adverse events. The design is a non-randomised open label pilot study. The study medication will be 6-TG (Lanvis, Thioguanine Tabloid in the USA) in a starting dose of 40 mg orally per day.

The aim of the study is to obtain a clearer understanding of adverse events in conjunction with 6-TG serum levels in IBD, especially in patients with a history of skin rashes, fever, and pancreatitis related to AZA and 6-MP. Our first results are promising. However, we must evaluate 6-TG versus AZA and 6-MP in multicentre, prospective, randomised trials, leading up to FDA registration approval in the USA and Europe. Our major concern is that Glaxo Wellcome is not interested as the drug is out of patent, similar to the situation with beclomethasone for IBD in the past.⁵

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