

# GIP

Gastroenterology in Primary Care  
November 2010 edition



Primary Care Society for Gastroenterology

## Editorial

I hope you have all had a great summer. And what a summer of change! The White Paper and the implications for general practice came, to use a baseball metaphor, completely from left field. To extend the metaphor further, we can either let the ball hit us full in the face with all the attendant pain and disfigurement or use it to our advantage and score a home run. Yes, I know, but being a Liverpudlian means that baseball and the Boston Red Sox are uppermost in our minds. With that in mind, John Galloway has written an article for this issue on how he sees the future of primary care gastroenterology in the next few years. As the summer faded from memory, we moved into Autumn and, of course, the PCSG ASM. This year's Annual Scientific Meeting was somewhat special with some excellent speakers. Half the day was based on liver disease and the other on colorectal cancer. Sandwiched in between these two pieces of artisan bread we had the filling of our AGM. We now have a new (and first) patron in Lynne Faulds Wood who has raised our profile almost immediately with interviews name checking us in the Yorkshire Post and Radio York. To mark the changes and celebrate the Society's 25th anniversary, Jamie follows this editorial with a review of the past and a look to the future. In this issue of GiP we have a smorgasbord of articles, but in future, I would like to theme the issues with the next issue centring on IBD and the subsequent one on Liver disease. So any contributions gratefully received. I hope you enjoy this edition and, as always, any comments are welcome.

John O'Malley

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### **THE PCSG: THE FUTURE**

This year the PCSG is 25 years old and it seems an opportune time to present a retrospective of the society and a comment on its future. In 1985 a group of GPs with an interest in primary care gastroenterology formed the nucleus of the society supported by a now defunct pharmaceutical company, Thomas Morson. Over the next few years the society, supported by a succession of companies, assumed the mantle of representing the GP endoscopist and this identity persisted for a number of years. I suppose that the heyday of the society was during fundholding when many GPs opened their own endoscopy units, spearheaded by the likes of John Galloway. At the same time the society proved to be the source of advice and direction for gastroenterology in primary care and produced many documents relevant to the provision of care in the community. Throughout our history we have been actively involved in research and this activity persists today.

Over the past few years the direction of the society has changed with an increasing emphasis on the provision of care for patients with gastroenterological illnesses in the community. This has come about for a number of reasons. Changes in funding streams, the requirements for decontamination as well as the NICE dyspepsia guidelines have meant that there has been a steady attrition of GP-led endoscopy units however, with the advent of practiced-based commissioning, this trend may reverse. At the same time these changes mean that the society is well placed to provide a lead in commissioning pathways.

The White Paper and the proposed changes to the Health Service have raised the profile of the PCSG to pharmaceutical companies, commissioners and secondary care alike.

For example, research supported by the PCSG (the IMAGE study - led by Roger Jones) has produced a wealth of research data on the standards of care required and care pathways in four index conditions, GORD, IBS, coeliac disease and IBD. This information is gold dust and forms the basis of commissioning pathways: information that the Department of Health, secondary care and commissioners do not have. Thus there is a growing realisation that we are the experts in this field and our expertise is being sought from many quarters. In other areas, such as the DoH's programme to tackle the burgeoning problem of liver disease, the society is well represented on the Liver Strategy group at the Department of Health under the chairmanship of John O'Malley.

Gastroenterology has been notable by its absence in the Quality Outcomes Framework. The society, in conjunction with the BSG, the Coeliac society and Crohn's and Colitis UK, has lobbied NICE to redress this imbalance and we have drawn on our experience and knowledge to inform this bid. At the same time we have formed closer links with these societies and this bodes well for our future role in advising on a range of gastroenterological activities in primary care.

These wide ranging activities are proving to be more than the current membership of the society can support. We are, as a result, trying to identify all GPs in the UK with an interest in Gastroenterology and invite them to join the PCSG which will be free to all eligible members.

Our constitution has recently been revised to encompass this change in ethos and we are trying to raise our profile by inviting public figures to become Patrons of the Society. This will ensure that our views are heard when the care of patients with gastroenterological illnesses is debated. With the increasing integration of patient care, between hospitals and the community, we need to have our opinion brought to the attention of the BSG. To achieve this we are supporting the creation of the primary section of the BSG; this will be composed of healthcare professionals working in primary care gastroenterology and importantly there will be representation on the BSG's council. Members of the primary

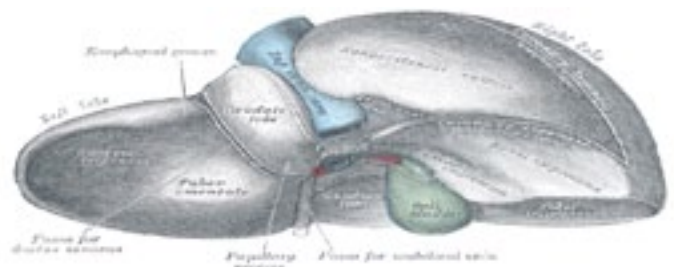
care section of the BSG will have automatic membership of the PCSG but our society will remain independent of the BSG. Thus our views will have a direct impact on the deliberations of the BSG.

I hope that this article has given you an overview of the evolution of the society but more importantly reflect the increasing influence of the society in the changing landscape of health care provision. There is no doubt that we have a vital part to play in the future of integrated care for patients with gastroenterological illnesses but the strengths of our society lies with knowledge, expertise and commitment of its members. I hope that you continue to support the society and help to further influence the future of primary care gastroenterology.



Jamie Dalrymple

The Role of the Nurse in Hepatic disease.



I am a nurse consultant in hepatology at the Royal Liverpool University Hospital. I qualified at the Royal Liverpool University Hospital in March 1991. Once I qualified my first job was working on a busy surgical Gastroenterology ward, with rotation onto a 5-bedded high dependency oesophageal varices unit. After 12 months I went to do voluntary work in an Infectious Diseases Children's Hospital in Romania. On my return I got a job working on the Gastroenterology Unit back at the Royal Liverpool hospital. As the unit expanded and new jobs became available I progressed to work as a Nurse Trainer / Educator in Endoscopy and

then in 1996 I was appointed as a Gastroenterology Specialist Nurse working with patients with upper GI cancer and liver disease.

In August 2006 I was appointed as Nurse Consultant in Hepatology and am continuing to develop my role in all aspects of liver disease and now am competent in undertaking ultrasound guided liver biopsies. The service has now expanded and as well as a nurse consultant, there are also two other specialist nurses in hepatology and very recently a hepatitis C nurse has been employed to work in local GP practices to set up a community hepatitis treatment service. I guess what first led me in hepatology was my experiences as a staff Nurse on a surgical gastroenterology ward and subsequent experience on a oesophageal varices HDU. Seeing the profound and sometime lethal effect of liver disease and wish to improve the life of these patients led me into endoscopy and by a circuitous route into hepatology.

I have a special interest in Hepatitis C. I take part in a nurse led service providing a variety of treatments, for example, weekly subcutaneous pegylated interferon and daily ribavirin. We give people 24 or 48 week courses depending on the genotype of the virus. But we provide more than just medication but also support and education. Many patients with Hepatitis C often are intravenous drug users and have a mixed experience of health care providers and it is important that they are not victimised and seen for what they are; patients. They are often seen as challenging and need dedicated time explaining treatment options and giving them the support they need to be compliant with medication. They are seen weekly for 4 weeks and then monthly but also patients have access to us via phone so they can let us know if they are struggling. Although Hepatitis C is a major part of our work, we also see patients with all forms of chronic liver disease (CLD) from AIH to PBC. We also monitor post transplant patients.

With the constantly changing background of hospital life, the important thing, we provide, I think, is continuity of care. Every patient with chronic liver disease is a person and building a rapport is an essential part of the treatment. They know they don't have to go through all their personal information each time they come to see us which often happens with a series of rotating doctors.

I can only see our workload increasing in hepatology as the big three problems associated with CLD increase, namely Hepatitis C, alcohol and obesity. The best way forward is via prevention and education. The problem we find is that education on hepatology is not a priority in primary care despite the massive challenges it present and this strikes as strange when thinks of the increasing burden, hepatology is placing on the health economy. I suspect this is partially to do with the absence of liver disease in the QOF. We do run education sessions with local practice nurses and we try and work closely with local GPs. We also run courses in interpretation of LFTs for practice nurses as part of their diagnostic course.

However, an interesting initiative has been started locally funded out of saving from Practice Based Commissioning. The practice closest to the hospital employs a viral hepatitis nurse and she is being used to identify Hep C patients in three practices and offer referral. Such novel ways of working may well be the future in hepatology.

Helen Caldwell

### ***Will the White paper on health have a beneficial effect on gastroenterology in primary care?***



Few GPs will have read the white paper "Equity and excellence Liberating the NHS" in its entirety. Most will have read headline articles in the national press and GP publications such as Pulse.

The cornerstone of the new NHS will be a fundamental change in the way services are provided with GP consortia responsible for commissioning services, which better serve the population. In particular there will be an emphasis on pathways of care that will ensure a timely response to illness management across

the NHS. Overseeing the GP consortia will be a NHS commissioning board, which will give guidance to the consortia. Current PCTs will be phased out, as the GP consortia will replace their role in commissioning. This process is meant to cut bureaucracy and administrative costs.

GP consortia should define what services they want in consultation with providers. Providers could be hospital trusts, the private sector and GPs themselves. It is this fundamental change, which could have an effect on the provision of gastroenterology services. We have long wished for a QOF in gastroenterology but such standards of care have been more difficult to define than in other areas.

The obvious care pathways in Gastroenterology would include dyspepsia, rectal bleeding and changes in bowel habit, investigations of iron deficiency anaemia, management of IBD, management of coeliac disease and hepatology. With all these conditions there are investigations to be commissioned and once a diagnosis has been made an agreed care plan and follow up with the most appropriate health professional. There are good examples of some of these pathways already established in the country and best practice needs to be shared between consortia.

Many areas of gastroenterology are considered to be outside the remit of primary care mostly because of lack of access to appropriate investigations.

Endoscopy in the primary care setting became quite popular in the fundholding era of the 1980s. Savings made by entrepreneurial fund holding practices could be reinvested into the provision of new services. In 2000, there were nearly thirty primary care endoscopy units offering upper gastrointestinal endoscopy, flexible sigmoidoscopy and colonoscopy with some of these units being in modified health centres and others in community hospitals.

The numbers of these units has dwindled for a variety of reasons. These have included loss of contracts with PCTs, dwindling numbers of GP endoscopists, inability to comply with the new tough regulations that surround endoscope decontamination and meeting the stringent requirements made of endoscopy units by the endoscopy modernisation group and the global rating scale. The administration of the global

rating scale has now been taken over by JAG (the Joint advisory group for gastrointestinal endoscopy).

There is a national tariff for these procedures, which look generous. An example of this would be nearly £800 for a colonoscopy.

However any unit providing endoscopy needs to have a recovery area, positive and negative airflow for the clean and dirty areas and a separate clean and dirty area for endoscope decontamination. Also unisex lists have to be accommodated.

Endoscopes are expensive and a minimum of three endoscopes for each procedure is necessary. To set up a unit in the community requires considerable investment and space.

As a consequence GP commissioning groups would need to agree on the placing of such contracts before such an investment could be made. There are companies looking at a fully managed service where endoscopes are provided pre decontaminated for a list, so this may be the way forward provided the cost is economically viable.

GP endoscopists are dwindling in number because most GPs do not have the time to train up to JAG requirements which would still not be adequate for practicing in isolation. However it may be possible that our consultant colleagues would be prepared to work in community units along side their GP colleagues.

This would appear to put a negative view on primary care endoscopy from one who practices it. However I know of the pitfalls and have had the advantage of running a thriving unit in the community for 16 years and if faced with the setting up of such a unit now I would struggle with the enormity of the task.

The new White paper certainly provides the mechanism for the enthusiast who is capable of jumping the hurdles. Patients score a high satisfaction rate when using primary care units, which can provide a timely and efficient service. The announcement of a once off flexible sigmoidoscopy by the government for colorectal cancer screening will put an enormous strain on hospital endoscopy units and it is quite possible that community units would be the ideal setting for such procedures where the day to day pressures of a hospital unit could not interfere with the smooth running of screening lists.

The white paper certainly provides GPs with a special interest in gastroenterology a chance to design pathways of care in collaboration with secondary care and patient interest groups. In particular the Image study and work by NACC (The National Association for Colitis and Crohn's Disease, now known as Crohn's and Colitis UK) and Coeliac UK have defined standards of care in gastroenterology which GP commissioning groups can base their decisions on for the future.



John Galloway

## **The GUTSY Group**



In June 2010 I attended the annual North Wales and Western Cheshire Cross-Border Oesophago-Gastric Cancer Research & Audit Day, which this year was entitled 'The Patient Journey'. Ann Camps, the Macmillan Upper GI Nurse Specialist for Wrexham, gave a talk introducing the Gutsy Group, of which she is the lead for patient information and user issues. This group seems to provide an excellent service for patients, which I thought would be of interest to PCSG members.

'Gutsy' is a support group for patients in North Wales and West Cheshire who require, or have had, surgery for oesophago-gastric cancer, and their relatives.

It was launched at an inaugural meeting in March 2007, and since then has held quarterly meetings and published a series of newsletters.

Its aims are to enable patients to meet staff and fellow patients, to learn from the experiences of other patients, and to provide feedback resulting in service improvements. After appropriate training, Gutsy members provide a 'buddying' service for newly diagnosed patients.

It now has over 150 members; between 40 and 50 members typically attend the meetings, which also involve medical staff – surgeons, specialist nurses, physiotherapists, dieticians

and occupational therapists. Mr Jonathan Pye, the lead Upper GI Consultant Surgeon based in Wrexham, attends regularly and provides a question and answer session which is greatly valued by patients and relatives alike. In addition, group members choose guests they would like to invite.

At a recent meeting these included the North Wales Macmillan GP advisor, whose work involves promoting improvements in the quality of cancer and palliative care provided by GPs and primary health care teams, including improving communication between care providers.

Late in 2009 a website was established: [www.gutsy-group.org.uk](http://www.gutsy-group.org.uk) for the benefit all patients, especially those unable to attend meetings, and this year a laptop was donated by BT Community Connections to enable patients without internet access at home to use cancer related websites during group meetings.

Group members have participated in focus groups to provide feedback about the service they receive. These, together with the annual satisfaction survey of palliative as well as surgical patients, have resulted in improvements in the patient journey with reduced numbers of hospital visits due to better co-ordination, outreach visits to patients by clinical team members, and new pathways for discharge management. Involving patients in this way can highlight gaps in the service, reveal near misses, promote healing & reconciliation, allow patient voices to be heard & keep patients and their families at the heart of their care.

Ann described the group's latest new project, which is to record patients' 'digital stories'. She played video recordings of three patients describing their experience of diagnosis, surgery and life after their operations. They all emphasized the positive effect of detailed pre- & post-operative explanation by the surgeon. I was especially struck by a quote describing an appreciation of surgeons & nurses 'sitting on the bed'.

The newsletters have drawn my attention to the wide range of information booklets published by Macmillan and available via their website [www.macmillan.org.uk](http://www.macmillan.org.uk)

Dorothy King, Chester.

# When prescribing oral mesalazine, when would you expect to see symptom relief for your moderately active ulcerative colitis (UC) patients?

An advertisement feature by Warner Chilcott UK Ltd

The clinical symptoms of moderately active UC can be debilitating and can negatively impact patients' lives. Improvement of symptoms is a key treatment goal both from a clinician's and a patient's point of view.<sup>1</sup>

## Symptom relief for moderately active ulcerative colitis (UC) patients in 14 days?

The three ASCEND Phase III, double blind, clinical trials with Asacol (mesalazine) showed that a high percentage, up to 72%, of patients with moderately active UC achieved treatment success (complete remission or clinical response to therapy) at 6 weeks.<sup>2-4</sup>

With high dose mesalazine treatment an improvement of symptoms can be expected within 14 days. This is consistent with the European Crohn's and Colitis Organisation (ECCO) consensus for the management of UC.<sup>5</sup>

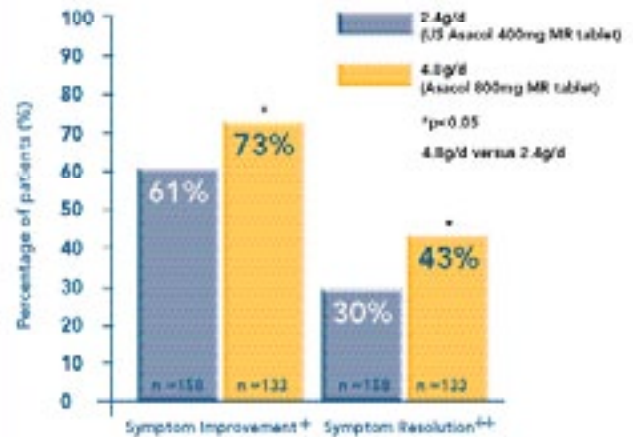
A recent post hoc analysis of data from the ASCEND I and II trials showed that, for patients with moderately active UC, when treatment was initiated with Asacol 800mg MR tablets dosed at 4.8g per day:<sup>6</sup>

- 73% of patients demonstrated symptom improvement at day 14 compared with baseline
- 43% demonstrated complete symptom resolution at day 14 compared with baseline

### ASCEND Studies: clinical parameters

- \* Symptom improvement: a decrease in symptom score from baseline of at least 1 point
- \*\* Symptom resolution: cessation of rectal bleeding and normalisation of stool frequency

## Symptom improvement or resolution with Asacol (mesalazine) MR tablets at day 14<sup>6</sup>



A post hoc analysis of pooled moderately active UC patient population from ASCEND I and II. Symptoms: rectal bleeding and stool frequency combined

This was a significantly higher proportion of patients than in the group receiving mesalazine 2.4g per day (delivered using US Asacol 400mg MR tablets).

The clinical equivalence of Asacol 400mg MR tablets and US Asacol 400mg MR tablets has not been established.

**Start treatment at 4.8g per day with Asacol 800mg MR tablets, to help moderately active UC patients achieve symptom relief at 14 days.**

vs mesalazine 2.4g per day delivered using US Asacol 400mg MR tablets.

Combined Asacol 400mg MR Tablet and 800mg MR Tablet PL  
Presentation: Asacol 400mg MR Tablets, PL 10947/0011; each modified release tablet contains 400mg mesalazine (5-aminosalicylic acid). Bottles of 120, £39.21. Bottles of 90, £29.41. Asacol 800mg MR Tablets, PL 10947/0012, each modified release tablet contains 800mg mesalazine (5-aminosalicylic acid). Bottles of 180, (£117.62). Indications: Ulcerative colitis: Treatment of mild to moderate acute exacerbations. Maintenance of remission. Crohn's ileo-colitis: Maintenance of remission. Dosage and administration: ADULTS: 400mg Tablets: Acute disease: 6 tablets a day, in divided doses, with concomitant corticosteroid therapy where clinically indicated. Maintenance therapy: 3 to 6 tablets a day, in divided doses. 800mg Tablets: Mild acute exacerbations: 3 tablets a day in divided doses. Moderate acute exacerbations: 6 tablets a day in divided doses. Maintenance of remission of ulcerative colitis and Crohn's ileocolitis: Up to 3 tablets a day, in divided doses. ELDERLY: The normal adult dosage may be used unless renal function is impaired. CHILDREN: Not recommended. Contra-indications: A history of sensitivity to salicylates or renal sensitivity to sulfasalazine. Confirmed severe renal impairment (GFR <20ml/min). 400mg Tablets only: Children under 2 years of age. 800mg tablets only: Hypersensitivity to any of the ingredients. Severe hepatic impairment. Gastric or duodenal ulcer, haemorrhagic tendency. Precautions: Use in the elderly should be cautious and subject to patients having a normal renal function. Asacol should be used in extreme caution in patients with confirmed mild to moderate renal impairment. Renal function should be monitored (with serum creatinine levels measured) prior to start of treatment, and periodically

during treatment, taking into account individual history & risk factors. Mesalazine should be discontinued if renal function deteriorates. If dehydration develops, normal fluid & electrolyte balance should be restored as soon as possible. Serious blood dyscrasias (some with fatal outcome) have been very rarely reported with mesalazine. Haematological investigations including a complete blood count may be performed prior to therapy initiation, during therapy, and are required immediately if the patient develops unexplained bleeding, bruising, purpura, anaemia, fever or sore throat. Stop treatment if suspicion or evidence of blood dyscrasia. Lactulose or similar preparations which lower stool pH should not be concomitantly administered. Concurrent use of other known nephrotoxic agents, e.g. NSAIDs & azathioprine, may increase risk of renal reactions. 400mg tablets only: Only use during pregnancy if benefits outweigh the risk. Avoid during lactation unless essential. 800mg Tablets only: Mesalazine should be used with caution during pregnancy and lactation when the potential benefit outweighs the possible hazards in the opinion of the physician. If neonate develops suspected adverse reactions consideration should be given to discontinuation of breast-feeding or discontinuation of treatment of the mother. Discontinue treatment immediately if acute symptoms of intolerance occur including vomiting, abdominal pain or rash. Patients with the rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine because of the presence of lactose monohydrate. Standard haematological indices (including the white cell count) should be monitored repeatedly in patients taking azathioprine, especially at the beginning of such combination therapy,

whether or not mesalazine is prescribed. Undesirable Effects: Common: Nausea, diarrhoea, abdominal pain, headache. Rare reports of leucopenia, neutropenia, agranulocytosis, aplastic anaemia, thrombocytopenia, peripheral neuropathy, pancreatitis, abnormalities of hepatic function and hepatitis, myocarditis, pericarditis, alopecia, lupus erythematosus-like reactions and rash (inc. urticaria), drug fever, interstitial nephritis and nephrotic syndrome with oral mesalazine treatment, usually reversible on withdrawal. Renal failure has been reported. Suspect nephrotoxicity in patients developing renal dysfunction. Very rarely, mesalazine may be associated with exacerbation of the symptoms of colitis, Stevens Johnson syndrome, erythema multiforme. 400mg only: Rare reports of allergic and fibrotic lung reactions. 800mg only: Common: vomiting, arthralgia / myalgia. Rare reports of vertigo, bronchospasm, eosinophilic pneumonia, bullous skin reactions. Very rarely, interstitial pneumonitis. Legal category: POM. Marketing Authorisation Holder: Warner Chilcott UK Ltd, Old Belfast Road, Millbrook Road, Larne, County Antrim, BT40 2SH, UK. Asacol is a trademark. Refer to Summary of Product Characteristics before prescribing. Date of preparation August 2010. AS8397. Reference: 1. Van Assche G, et al. J.Crohn's and Colitis. Suppl.2008:2:abstract 47. 2. Hanauer SB, et al. Can J Gastroenterol. 2007; 21: 827-34. 3. Hanauer SB, et al. Am J Gastroenterol. 2005; 100: 2478-85. 4. Sandborn WJ, et al. Gastroenterology. 2009; 137: 1934-1943. 5. Travis SPL, et al. Journal of Crohn's and Colitis 2008; 2: 24-62. 6. Orchard T. R. et al. J. Crohn's and Colitis 2009:3(1); Pg S48: Abstract P095, and poster presentation at ECCO 2009. Date of Document Preparation October 2010. AS8472/62620.12

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Adverse events should also be reported to Warner Chilcott UK Ltd on 0800 0328701.

**Asacol**  
**800mg MR tablets**  
(MESALAZINE)

**WC WARNER CHILCOTT**