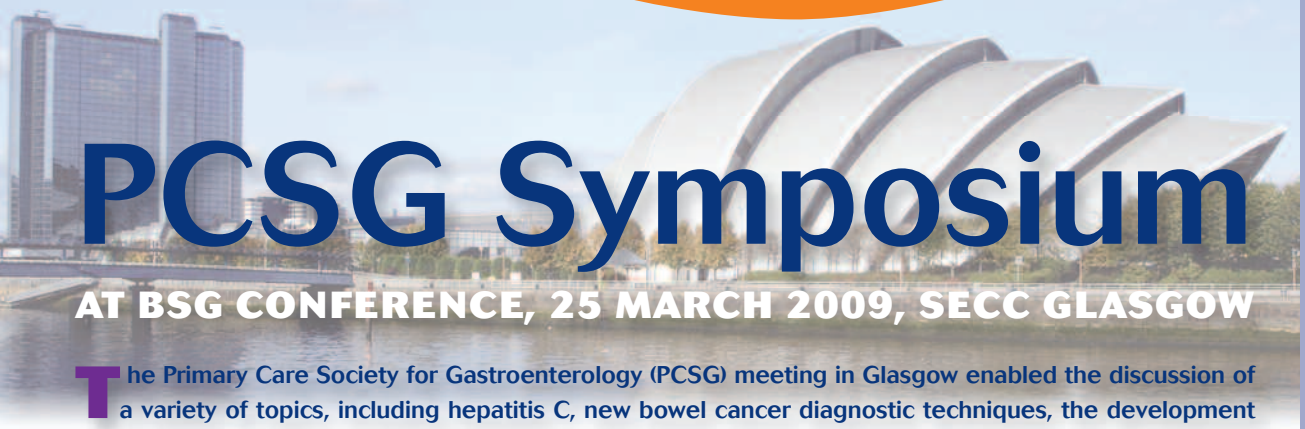
MAY 2009

Gastroenterology IN PRIMARY CARE

JOURNAL OF THE PRIMARY CARE SOCIETY FOR GASTROENTEROLOGY



PCSG Symposium

AT BSG CONFERENCE, 25 MARCH 2009, SECC GLASGOW

The Primary Care Society for Gastroenterology (PCSG) meeting in Glasgow enabled the discussion of a variety of topics, including hepatitis C, new bowel cancer diagnostic techniques, the development and evaluation of a decision support system within primary care, as well as the new IBD National Service Standards, which were launched in February this year.

Hepatitis C: the epidemic that didn't happen?

Dr Martin Philips, Norwich

Hepatitis C is a global concern and accounts for a significant proportion of liver disease worldwide. The highest levels of hepatitis C are currently found in Egypt, reaching as high as 14.5%. This followed a vaccination program where the same needle was used on multiple patients. It is also highly prevalent in Southeast Asia, including India (1.5%), Malaysia (2.3%) and the Philippines (2.3%). It is estimated that there are around 170 million cases worldwide - approximately 3% of the population.

Prior to 1991, most cases of hepatitis C in the UK were contracted through blood transfusion. Intravenous drug users now represent the largest single risk group. As with HIV, the sharing of contaminated needles and syringes increases the chance of infection dramatically. Sexual contact has been clearly identified as a means of transmitting hepatitis C, but is relatively rare in the UK.

The incidence of hepatitis C within the UK has been growing steadily since 1960, with an initial peak occurring around 1985.[1,2,3,4] However, cumulative laboratory reports from 1992-2007 suggest that the problem is continuing to grow, with a steady increase in the number of hospital episodes of hepatitis C. Currently, there are increasing numbers of patients with end-stage liver disease and hepatic cell carcinoma, and listing for liver transplantation has doubled in ten years. The Hepatitis C Trust Report estimates that there are 466,000 cases of hepatitis C in the UK but that only around 65,000 of these have been diagnosed.[3]

A significant proportion of patients with acute infection go on to develop chronic infection (Figure 1). It is difficult to identify these patients because the early symptoms of hepatitis C are difficult to recognise. Low level infection, in which the infected individual is virtually asymptomatic but still highly contagious, may continue for years, even decades, before progressing significantly.

The therapy for chronic hepatitis C has evolved steadily. At the present time, the optimal regimen appears to be a 24-week or 48-week course of a combination of pegylated alpha interferon and ribavirin. Treatment is highly effective and results in 50-80% cure rates.

Previously, NICE recommended that only patients with moderate/severe disease should be treated and that all patients (except haemophiliacs) needed a liver biopsy. Now, NICE guidelines recommend that anyone who has mild chronic hepatitis C can be treated without a liver biopsy. The problem remains, however, in identifying these patients. Only a small proportion of patients are identified and treated within the UK (Figure 2). This is partly due to the stigma associated with hepatitis C, as well as patient ignorance about the disease, both of which appear to be better managed in other European

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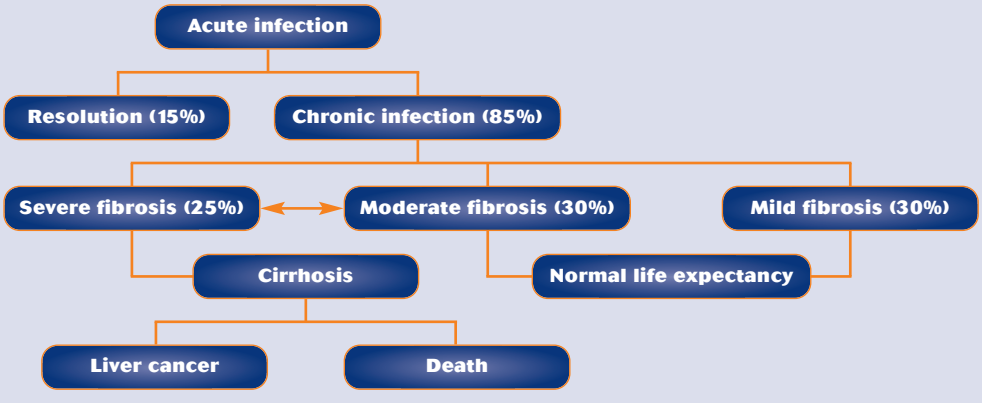
FIGURE 1 HEPATITIS C: DISEASE PROGRESSION



This issue...

EDITORIAL

The recent PCSG session at the BSG in Glasgow highlighted the changes in the medical landscape in which we practice. Increasingly the role of primary care is developing into new areas that demand the development of our skills and expertise.

Martin Phillips points out the number of undiagnosed patients with hepatitis C in our practice population; surely there has never been such a good case for primary care to actively screen for this condition!

Richard Driscoll (CEO NACC) and John O'Malley (GP and PCSG committee member) spoke on the IBD standards that will inform the care of patients with this condition for years to come. The point is that primary care has a central role to play in the management of these conditions. Roger Jones's IMAGE study is also likely to underline the crucial role of primary care in the management of patients with a variety of gastrointestinal conditions. However, we cannot manage these conditions in isolation and engaging with secondary care and nurse specialists will be a requirement for holistic care. Kay Greveson, a nurse specialist from the Royal Free, points out the key role of specialist nurses.

One must not forget the role of the patient in the scheme of things. This has been addressed in the IMAGE study and we should be thinking about closer engagement with patients and patient organisations. Secondary care recognises the value of working more closely with primary care, nurse specialists and patient organisations and we must not let this change in the culture go unrecognised.

This, in many ways, is a change in emphasis for the society and it is important not to forget that many members are endoscopists. The society is actively involved in piloting revalidation for GP endoscopists. This is under the auspices of the National Endoscopy team and will, in the future, form the basis of revalidation for all endoscopists whatever their calling. It is important that members realise that, not surprisingly, this will form the basis of their contract with their PCT. As the process develops the PCSG will keep you informed but it is fair to say that there will be a Directly Observed Procedure (DOPs) by two assessors, a review of a personal learning plan which will include engagement with the educational programs and meetings designed to fulfil the requirements for revalidation. I would

urge all endoscopists to access the PCSG website regularly for details of the meetings but I will endeavour to inform all members by email when the revalidation process has been agreed.

Dr Jamie Dalrymple

KEY FACTS 5 Iron Deficiency Anaemia (IDA)

Topic/Definition

- Anaemia is defined as a haemoglobin (Hb) level lower than the normal range for the laboratory performing the test. Iron deficiency results in microcytic, hypochromic erythrocytes on the blood film, a reduced mean cell volume (MCV) and mean cell haemoglobin (MCH). A reduced serum ferritin is the most powerful marker of iron deficiency.

Prevalence/Incidence

- The prevalence of IDA is 2-5% among adult men and post menopausal women in the UK. The prevalence is 5-12% in healthy pre-menopausal women usually due to menstrual loss, increased demands in pregnancy/breast feeding or diet. Iron deficiency without anaemia (hypoferritinaemia) is three times as common as IDA.

Common symptoms/signs

- Symptoms of anaemia include fatigue, headaches, faintness, breathlessness, palpitations, angina and intermittent claudication.
- History should include GI symptoms, especially alarm symptoms, diet, use of NSAIDs, family history of anaemia, blood donation and menstrual history in women.
- Signs specific to IDA include brittle nails and hair, spoon-shaped nails (koilonychia) atrophic glossitis and angular stomatitis.
- Urinalysis should be done as 1% of patients with IDA have a renal tract malignancy.

Investigations

- FBC and Ferritin
- Hb electrophoresis in patients with appropriate ethnic background
- B12 and Folate in patients with a normal MCV but low ferritin.
- All men and post-menopausal women/women over 50 years old should be considered for GI investigation. Pre-menopausal women under 50 without GI symptoms should be screened for Coeliac disease with serology only unless there is a further indication for investigation.
- 1-10% have dual pathology in upper and lower GI tracts and therefore complete investigation must be undertaken with OGD plus duodenal biopsies and either colonoscopy or flexible sigmoidoscopy with barium enema.
- Small bowel investigation is not required unless IDA is transfusion dependant.
- Only post menopausal and men over 50 years should have GI investigation of iron deficiency without anaemia (hypoferritinaemia).
- Faecal occult blood testing is of no benefit in the investigation of IDA

Do's and don'ts of treatment

- Treat the underlying cause of IDA to prevent a recurrence
- Given oral iron supplements to correct anaemia. Oral iron needs to be continued for 3 months after the Hb has returned to normal so body stores are replenished fully
- Ascorbic acid (250-500mg bd) may be given to enhance absorption
- Blood transfusion is only required for patients with or at risk of cardiovascular instability as a result of their anaemia.

Follow up

- Repeat FBC and ferritin at 3 monthly intervals for one year and then again after a further year.
- Further iron should be given if the Hb or red cell indices fall below normal.
- Further investigation is only required if the Hb or red cell indices cannot be maintained in this way

Review articles

- BSG guidelines for the management of iron deficiency anaemia; A F Goddard, M W James, A S McIntyre and B B Scott.

Dr Mark Follows

Maintenance treatment of inflammatory bowel disease

PATIENT ADHERENCE AND CURRENT PRACTICE

Abstract

Crohn's disease and ulcerative colitis are chronic idiopathic diseases characterised by periods of exacerbation and remission, where the lining of the intestine becomes inflamed and ulcerated. Peak incidence is between 10 and 40 years but it can affect people of any age (Forbes 2001). Diarrhoea, rectal bleeding and abdominal pain are the predominant symptoms depending on the site of disease.

Medical treatment aims to provide rapid effective relief from symptoms, modify the disease process and improve quality of life (BSG 2004). 5-aminosalicyates are used as maintenance treatment for mild to moderate disease, and corticosteroids for moderate to severe active disease; while immunosuppressant and biological therapies are usually reserved for disease refractory to conventional medication (ECCO 2006, 2008). Medication regimes can be complex and only offer disease remission rather than a cure. Maintenance treatments not only have a role in the prevention of disease relapse, but also a proven role in the long term prevention of disease related complications such as colorectal cancer by up to 75% (Eaden 2003, BSG 2004).

The choice of 5-ASA formulation depends on the site and extent of disease, patient tolerance and concordance with suggested treatment. Proprietary prescribing (by trade name) is recommended over generic but consensus states that drug choice should be based on route of delivery, dose frequency, cost and availability rather than efficacy alone (ECCO 2008). A combination of oral and topical mesalazine has been proven more effective for distal/extensive colitis than oral mesalazine alone, although patient acceptability may limit the use of topical therapy (ECCO 2006, 2008).

Any chronic disease is a risk situation for non-adherence to treatment, with adherence being a major factor in the successful control of disease and the prevention of hospital admission and readmission (Lopez-Sanroman & Bermejo 2006). Risk factors associated with non-adherence in inflammatory bowel disease include disease duration, male gender, and three times daily dosing (Sewich et al 2003, Kane 2001, Shale & Riley 2003). Oral mesalazine has been cited as having the worst adherence rate, with many studies citing non-adherence rates of around 50% (Kane 2001, Bernal et al 2006, Shale & Riley 2003). The primary reasons for non-adherence include forgetfulness and number of pills therefore addressing these issues may lead to enhanced adherence rates.

Recent advances have seen the introduction of new mesalazine formulations aimed at reducing pill burden by offering the convenience of once or twice daily dosing (Shire pharmaceuticals 2007, Dr Falk Pharma 2008, P&G Pharmaceuticals 2007, Ferring pharmaceuticals 2008). These can be more expensive than existing mesalazine preparations but this cost may be offset with improved compliance and therefore better disease control and outcomes as a result of once daily dosing (Kane 2007). The benefit of newer once daily 5-ASA preparations includes lower pill burden and simple dosing regimen that may optimise medication adherence due to convenience (Hussain et al 2001). Research has shown that compliance with prescribed medication improves with once daily dosing compared with twice daily, but that this improvement is even greater when switching from three times daily to twice daily dosing regimen (Eisen et al 1990). The available research suggests that the efficacy of a product may depend more on compliance with the product than the delivery system (BSG 2004), with once daily dosing regimes offering comparable efficacy and improved adherence (ECCO 2008). Failure to take prescribed medication is well recognised and associated with greater risk of symptomatic relapse and long term complications (Kane et al 2003, Van Staa et al 2005). As a result of this costs will be incurred due to greater utilisation of health care resources, particularly if this entails hospitalisation (Kane 2007, Bassi et at 2004).

Patient education is key to improving awareness and compliance, particularly in respect of explaining the disease process, and benefits and risks of treatment, therefore enabling patients to make informed decisions (Robinson 2004, RCN 2007). Research shows that patients who feel responsible for symptom control are more likely to adhere to treatment regimens, particularly if they have been involved in the decision making process (Robinson 2004). The clinical nurse specialist is in a unique position to take simple steps that will improve adherence rates and thus increase the efficacy of prescribed therapy. Extended roles such as independent prescribing and patient group directive (Department of Health 2006b) have enabled the specialist nurse role to develop and be pivotal in addressing and aiding medication adherence. Physicians and Nurse Prescribers must balance evidence based prescribing decisions with patient preference in order to optimize patient involvement and adherence (Pendleton et al 2003)

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Royal Free Hospital NHS Foundation Trust

The full version of this article can be downloaded from www.pcsg.org.uk

References: The list of references can be obtained from the PCSG Secretariat.

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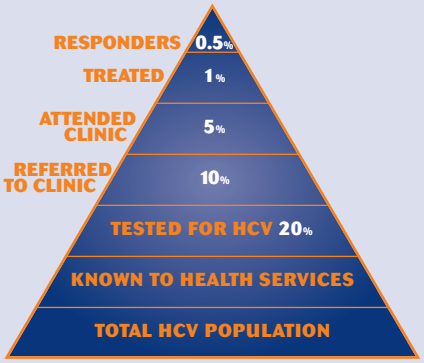
FIG 2 UK HEPATITIS C POPULATION



countries and leading to proportionally more patients being treated.

The problem of identification lies not only with the patients. The average GP, with 2,000 registered patients, will have around 10-15 patients with hepatitis C. Of these, only 2-3 will be diagnosed and only one patient will be on antiviral treatment. The average GP often does not have the necessary knowledge to expertly identify and manage this disease and an increased awareness of hepatitis C within primary care is needed. The drive to do this would be supported by the quality and outcomes framework, where QOF points can be gained by case finding in high risk populations by checking for blood transfusions given before 1991 or potential intravenous drug use.

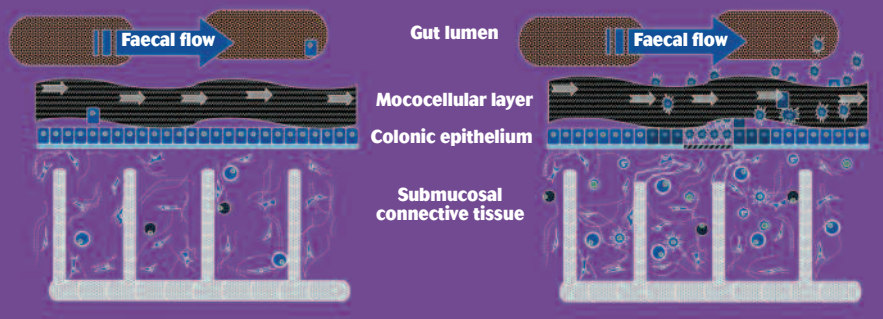
If patients are diagnosed early enough, hepatitis C can be cured in the large majority of cases. However, up to 86% of people infected with hepatitis C in the UK are currently undiagnosed. It is estimated that the future costs of Hepatitis C will amount to £8 billion per year. The UK is far behind other European countries in diagnosing and treating patients with hepatitis C and service delivery needs to change to meet the needs of these patients.

Colonocytes: the new diagnostic tool in bowel cancer

Dr Jeremy Gibson, Taunton

Normally, few colonocytes exfoliate into the mucocellular layer covering the colorectal mucosa. However, in the case of malignant cells, exfoliation increases, the cells remain in the mucocellular layer and are transported towards the rectum (Figure 3). Based on this observation, it has been suggested that direct collection of exfoliated cells from rectal mucosa could provide material for secure quantitative discrimination between colorectal cancer (CRC) patients and cancer-free individuals.

FIGURE 3 EXFOLIATION OF COLONOCYTES FROM THE MOCOCELLULAR LAYER



Determination of total Deoxyribonucleic Acid (DNA) amounts in samples of exfoliated colonocytes (DNA scores) by PicoGreen assay and real-time Polymerase Chain Reaction (PCR), show that abnormal DNA scores are higher in patients with cancer and inflammatory bowel disease compared to those with no abnormalities detected, diverticular disease and small polyps ($p<0.001$ for PicoGreen assay; $p=0.002$ for real-time PCR).[5]

A device has been developed for the easy collection of colonocytes from the rectal mucosa. It incorporates an inflatable and retractable elastic membrane, which is deployed during proctoscopy without bowel preparation. Once the cells have been collected, the elastic membrane is deflated and the sample is mixed with a cell lysis buffer (Figure 4).

A pilot clinical trial found pronounced nuclear polymorphism in exfoliated colonocytes collected from the surface of rectal mucosa of a patient with ascending colon carcinoma. Analysis of DNA score distribution showed that DNA scores in normal volunteers largely fell below 5.0.

In a subsequent case-control study in clinically healthy (asymptomatic) volunteers (age over 50) and CRC patients, sensitivity and specificity was found to be better for distal CRC (sensitivity 0.79.; specificity 0.90) compared with proximal colon malignancies (sensitivity 0.44; specificity 0.90) with a DNA score of 4.5 or less.

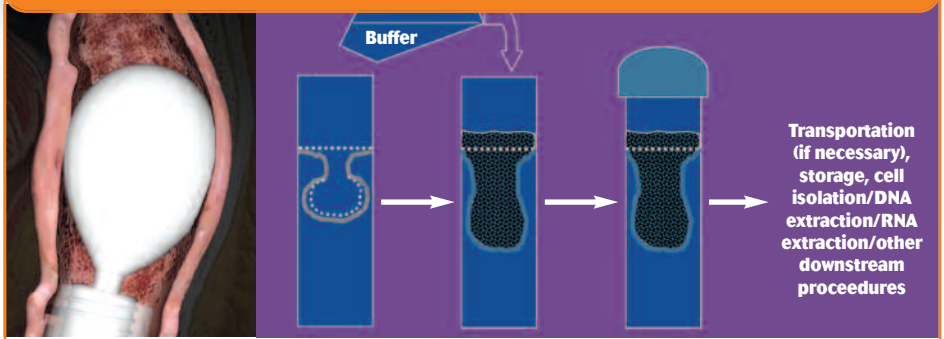
A number of studies are ongoing, including a prospective study in patients referred as having red flag symptoms at University College, London; a prospective and blinded study of all patients referred from primary care with suspicion of lower gastrointestinal pathology in Exeter (CANCCER study); and a study using cell preserving buffer looking at genetic markers in Cambridge.

In the London study, preliminary results indicate a sensitivity of 100% and a specificity of 70.8% for CRC.

The CANCCER study has enrolled over 2,000 patients and data is expected from this study towards the end of 2009.

This new diagnostic tool allows for a simple, safe and reliable procedure providing uniquely valuable biological material. The exfoliated cells directly collected from colorectal mucosa can be successfully used in numerous biomedical applications, both clinical and research-oriented. It is hoped that the quantitative DNA analysis can be used for CRC mass screening and early diagnosis. This would provide a new test, which

FIGURE 4 COLONIX® CELL SAMPLING DEVICE



STEPS FOLLOWING TOUCH-PRINT EXFOLIATED CELL SAMPLING FROM RECTAL MUCOSA

A Cell-sampling device with exfoliated cells on the cell-collecting membrane after cell collection

B Addition of a specific buffer (fixed volume) depending on further requirements

C Preparation for sample transport-ation and storage

D Further down-stream procedures for screening/ diagnostic or/and research purposes

could be considerably more sensitive and specific than currently employed faecal occult blood testing.

Dr James Dalrymple presented **'Quality criteria for primary care gastroenterology: development and evaluation of a decision support system'** on behalf of **Professor Roger Jones, London.** However some of the material contained within the talk has been submitted for publication so will be available to PCSG members in a future issue of GiP.

Inflammatory Bowel Disease (IBD) Standards, a new framework of care

Richard Driscoll, London and Dr John O'Malley, Wirral

Currently, there is a variable speed of access to specialist care for IBD patients. Clinics are often overwhelmed and it is not uncommon for diagnosis to be delayed as a result.

It is hoped that the implementation of the new IBD National Service Standards **(Table 1)**,[6] which reflect the findings of the 2006 National Audit of Adult IBD Services and Care,[7] will soon be achieved at a local level and will deliver improvements in the quality of care for IBD patients.

TABLE 1 THE SIX STANDARDS OF IBD CARE

High quality clinical care

High quality, safe and integrated clinical care for IBD patients based on multidisciplinary team working and effective collaboration across NHS organisational structures and boundaries

Local delivery of care

Care for IBD patients that is delivered as locally as possible, but with rapid access to more specialised services when needed

Maintaining a patient-centred service

Care for IBD patients that is patient-centred, responsive to individual needs and offers choice of clinical care and management where possible and appropriate

Patient education and support

Care for IBD patients that assists patients and their families in understanding IBD and how it is managed and that supports them in achieving the best quality of life possible within the constraints of the illness

Information technology and audit

An IBD service that uses IT effectively to support patient care and to optimise clinical management through data collection and audit

Evidence-based practice and research

A service that is knowledge-based and actively supports service improvement and clinical research

The results of the second IBD audit have shown that many aspects of IBD care have improved since the last audit. This includes the provision of dedicated gastroenterology wards and an increase in both the number of IBD Clinical Nurse Specialists and the time that they dedicate to IBD care. However, meetings between physicians and surgeons are happening less frequently than before, which may be a reflection of the time pressures imposed by other multidisciplinary team meetings. Provision of dietetic services, toilet facilities and psychological support remains at unacceptably low levels and are key priorities for improvement.

The IBD Standards were launched in February 2009. However, in order to gain support for their implementation, political support is needed through communication with local health trusts or boards and by questions to parliament.

Several objectives have been set on a national, as well as UK country specific level, and progress is being made in a number of areas. Nationally, the IBD Standards and audits are supported by the health departments and audit results are being used within quality inspection processes. The needs of IBD patients are also understood by those planning services for long-term conditions. In England, NICE have included the IBD Standards in the NHS Evidence Portal and the Health Quality Improvement Partnership have included the IBD audit in their national programme. In addition, the Care Quality Commission included the IBD audit results in their annual health check and the Department of Health's commissioning unit are getting involved. In Scotland, meetings have been arranged with Quality Improvement Scotland and the Head of the Long-term Conditions Unit. In Wales, meetings have been arranged with senior policy officials. In Northern Ireland, there is still an urgent need for specialist nurses.

Integrated care is vital to improve IBD services and will ensure that patients are placed at the centre of their care, regardless of organisational structures and boundaries. There is also a need for clarity of the role of GPs. Education to help identify IBD patients earlier and improve communication between healthcare providers and IBD patients is needed. As a consequence of these needs, a number of potential roles within primary care have been suggested **(Table 2)**.

TABLE 2 POTENTIAL ROLES WITHIN PRIMARY CARE

GP with Special Interest

- Has designated sessions working within the IBD Service.
- Providing aspects of the IBD Service.
- Lead GP for liaison between secondary care service and GPs?

Engaged GP or Practice

- Engages with education opportunities and service developments for IBD patients
- Active participant in shared care

All GPs

- Do not particularly engage in IBD
- Undertake shared care monitoring if required

Improving the interface between primary and secondary care will allow patients the choice of the type of care they want, whether it be hospital-based, shared care or supported self management. Primary care can also play a key role in monitoring of prescriptions and immunosuppressive medication, providing annual reviews, as well as giving access to IBD nurses at a local level. Patients not undergoing regular follow up can also be flagged up and checked by their GP, then added to the follow up system.

Commissioners can play a role by ensuring that all IBD patients are known and receive appropriate healthcare services. This can be done by setting up an IBD register so that all patients can be reviewed annually.

Eventually, it is hoped that an integrated IBD service will be available for all patients, where roles are clear and patient needs are fulfilled.

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Process mapping in GASTROENTEROLOGY SERVICE DESIGN

One of the practice based commissioning consortia in Bristol had discussed their aspirations to develop a community based gastroenterology service with NHS Bristol and in the summer of 2008 I was asked to develop a model of care for this service. The aim of the service was to provide assessment and treatment of defined gastroenterological conditions including uncomplicated diagnostic endoscopy in the community setting, which would equal or exceed in quality that provided in secondary care.

The proposal for this service had been driven by GPs in the city and fitted well with the Primary Care Trust's Strategy for delivering care closer to home and improving equitable access for patients.

A small project group was set up and it soon became clear that there was a desire to go beyond the provision of a community endoscopy service to develop a more holistic model which would include assessment, advice and guidance for referrers and patients and some treatments for defined conditions.

I felt that the best way to develop the model within the timescale required was to apply the commonly used service improvement technique of process mapping.

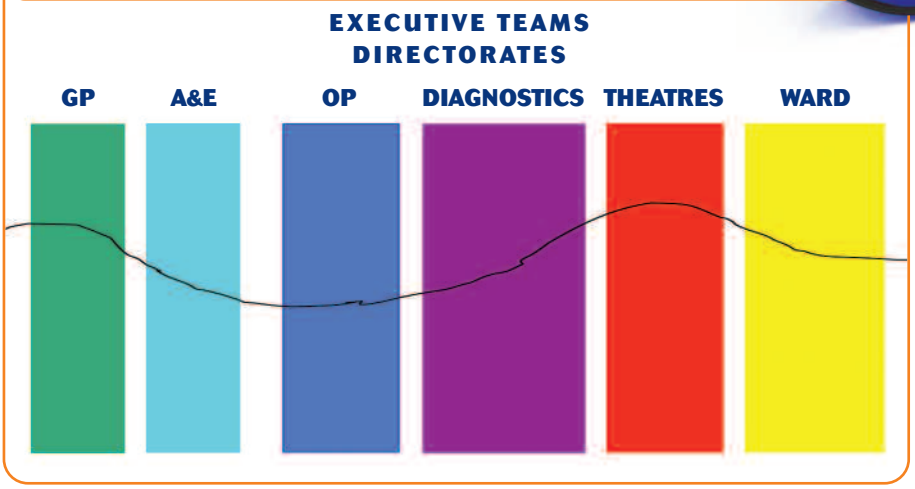
So what is a process map?

Essentially it is a visual representation of a series of connected steps or actions to achieve and outcome. Any process can be represented in this way, from making a cup of tea to the manufacture of a top of the range car. Mapping is a tool that helps us really to **see** the process and the technique has been increasingly applied in health care over recent years.

The advantage of the visual representation of a process map is that any potential blockages in the system or unnecessary steps in the process quickly become obvious to those involved and ways to improve the process become clear.

When I cast my mind right back to how we used to organise processes and systems in the NHS it was clear that mostly we designed them very much in silos with a vertical top down approach (Figure 1).

FIGURE 1 VERTICAL TOP DOWN APPROACH



Different departments and functions within primary care and acute hospitals all had their own way of working and there was little collaboration or co-operation between them. This must have been incredibly difficult for the patient (represented by the black line in figure 1) who had to navigate through all these different worlds as they travelled through the health care system and who suffered from the inevitable duplication and delays that a system like this created.

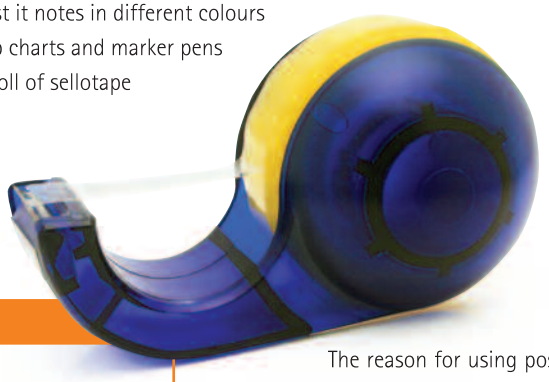
With the advent of the patient centred, integrated care pathway (ICP) approach which really began to take off in the mid 1990s, service design has moved on to develop processes from a patient's view point and has really focused on the cross over points where patients move from stage to stage in the pathway. The process mapping technique facilitates this approach to service design.

The work to develop the model of care for the primary care acre gastroenterology service was carried out with a small team consisting of three GPs with a special interest in gastroenterology, two patients, a service improvement facilitator from the PCT (who happened to have a background as a radiographer) and myself.

The first step was to define the scope of the pathway - the first step and the last step in the process. It was agreed to map the pathway of the patient from presentation at a GP surgery with a gastroenterology condition to discharge back to the GP following assessment, diagnostics and treatment. The mapping of the service model was in two initial stages, firstly to map a current state (where we are now) and then a future state (where we want to be).

The resources needed for process are very basic:

- A roll of brown paper or wall paper to record the map on
- Post it notes in different colours
- Flip charts and marker pens
- A roll of sellotape



The reason for using post it notes is that they can be easily moved as discussion and debate occurs so that the end product is a true representation of the process. Other issues inevitably arise and these can be collected on the flip chart and 'parked' to inform the further development of the model. In this way the discussion does not get sidetracked and remains focused on the development of the process map.

At the conclusion of the session the sellotape is a vital resource to secure the post it notes in place!

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Mezavant XL with Multi Matrix System® Technology (MMX®) goes beyond symptom control to induce complete remission, a stringent treatment standard comprised of both clinical and endoscopic remission[2,3]

Prescribing information:
(Please refer to full Summary of Product Characteristics [SPC] before prescribing). **Mezavant® XL 1200mg, gastro-resistant, prolonged release tablets. Presentation:** Mesalazine provided as 1200mg gastro-resistant, prolonged release tablets. **Uses:** For the induction of clinical and endoscopic remission in patients with mild to moderate, active ulcerative colitis. For maintenance of remission. **Dosage and administration:** Oral. Tablets to be taken once daily (o.d.). Tablets must not be crushed or chewed and should be taken with food. ***Adults/Elderly:*** For induction of remission: 2.4 to 4.8g (two to four tablets) should be taken once daily. The highest dose of 4.8g/day is recommended for patients not responding to lower doses of mesalazine. When using the highest dose (4.8g/day), the effect of the treatment should be evaluated at 8 weeks. For maintenance of remission: 2.4g (two tablets) should be taken once daily. ***Children:*** Not recommended. **Contraindications:** History of hypersensitivity to salicylates (including mesalazine) or any of the excipients of Mezavant XL. Severe renal impairment (GFR <30ml/min/1.73m2) and/or severe hepatic impairment. **Special Warnings and Precautions:** Use with caution in patients with confirmed mild to moderate renal impairment. All patients should have an evaluation of renal function prior to initiation of therapy and at least twice a year. If there is suspicion of blood dyscrasia, treatment should be terminated. If acute intolerance syndrome is suspected, prompt withdrawal of mesalazine is required. Caution should be used in prescribing to patients with hepatic impairment, patients with chronic lung function impairment, especially asthma (due to risk of hypersensitivity reactions), patients allergic to sulphasalazine, or patients with conditions predisposing to myo- or pericarditis. Organic or functional obstruction in the upper gastrointestinal tract may delay onset of action. See SPC for full details on warning and precautions. **Interactions:** Caution is recommended with concomitant use of known nephrotoxic agents including non-steroidal anti-inflammatory drugs (NSAIDS). Mesalazine inhibits thiopurine methyltransferase and caution is recommended for concurrent use of mesalazine with azathioprine or 6-mercaptopurine. Administration with coumarin type anticoagulants could result in decreased anticoagulant activity. **Pregnancy and Lactation:** Only use during pregnancy when clearly indicated, using caution with high doses. Caution should be exercised if using mesalazine whilst breastfeeding. **Undesirable Effects:** Approximately 14% subjects experienced treatment emergent adverse drug reactions in clinical trials with Mezavant XL, the majority being transient and mild or moderate in severity. Events reported as common (>1% and <10%) were flatulence, nausea or headache. Uncommon events (>0.1% and <1%) to Mezavant XL were: decreased platelet count, dizziness, somnolence, tremor, ear pain, tachycardia, hypertension, hypotension, pharyngolaryngeal pain, abdominal distension, abdominal pain, colitis, diarrhoea, dyspepsia, pancreatitis, rectal polyp, vomiting, increased alanine aminotransferase, abnormal liver function test, acne, alopecia, prurigo, pruritus, rash, urticaria, arthralgia, back pain, asthenia, face oedema, fatigue, pyrexia. Mesalazine has also been associated with the following; agranulocytosis, aplastic anaemia, leukopenia, neutropenia, pancytopenia, thrombocytopenia, neuropathy, myocarditis, pericarditis, allergic alveolitis, bronchospasm, cholelithiasis, hepatitis, angioedema, systemic-lupus erythematosus-like syndrome, myalgia, interstitial nephritis, nephrotic syndrome. **Overdose:** Conventional therapy for salicylate toxicity may be of benefit. Hypoglycaemia, fluid and electrolyte imbalance should be corrected and adequate renal function maintained. **Basic NHS price:** £62.44. **Legal category:** POM. **Marketing Authorisation number:** PL 08081/0040. **Marketing Authorisation holder:** Shire Pharmaceuticals Contracts Limited, Hampshire International Business Park, Chineham, Basingstoke, Hampshire, RG24 8EP, UK. **Date of revision:** June 2008. Further information is available from: Shire Pharmaceuticals Limited, Hampshire International Business Park, Chineham, Basingstoke, Hampshire, RG24 8EP, UK. Tel: 01256 894000. MEZAVANT is a trademark of Shire LLC in the UK.

ONCE-DAILY
mezavant® XL
mesalazine 1200mg
gastro-resistant, prolonged release tablets

Discover complete remission

Adverse events should be reported. Reporting forms and information can be found at www.yellowcard.gov.uk. Adverse events should also be reported to Shire Pharmaceuticals Ltd on 01256 894000.

Reference: 1. Mezavant XL. Summary of Product Characteristics. January 2007. **2.** Kamm MA, Sandborn WJ, Gassull M, et al. Once-daily, high-concentration MMX mesalamine in active ulcerative colitis. *Gastroenterology.* 2007; 132: 66-75. **3.** Lichtenstein GR, Kamm MA, Boddu P, et al. *Clin Gastroenterol Hepatol.* 2007; 5: 95-102. Date of preparation: December 2008. UK/MEZ/08/0196

Shire

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Continued...

The roll of the facilitator is to question and clarify every step. It is often useful for the facilitator to have little knowledge of the subject, as they will challenge what might seem to be the obvious to the participants. It is usually necessary for the facilitator to tease out the detailed breakdown of a process, as those working in a service will not always see every step because the process has become such routine practice for them.

The draft model produced at the end of this process can be seen in Figure 2.

Having completed this initial phase the group identified the next steps which included the parts of the process which needed to be mapped in more detail. We had established the conditions that could be referred into the service and agreed to individually map three clinical pathways in more depth:

- Dyspepsia and Reflux
- Irritable Bowel Syndrome
- Rectal bleeding

This work was used to inform the development of clinical guidelines for the service.

The group had produced a draft model of care, three pathways which were then sent out for wide consultation with identified stakeholders and external clinical advisors to test the robustness of the design. The viability of the model was then scrutinised through financial and activity analysis and a business case was produced for consideration by the NHS Bristol who have agreed to commission this service.

The benefits of using process mapping are many:

- It is a good starting point to articulate an improvement project visually.
- It is a great opportunity to bring multidisciplinary and multi-organisational teams and service users together to stimulate discussion and questioning on where or why a process works or does not work. This, in turn, encourages buy in and ownership and creates ambassadors for the project.

It is a technique that will eliminate waste and ensure that every step adds value for the patient.

Babs Williams
Head of Service Design, NHS Bristol

Event Diary

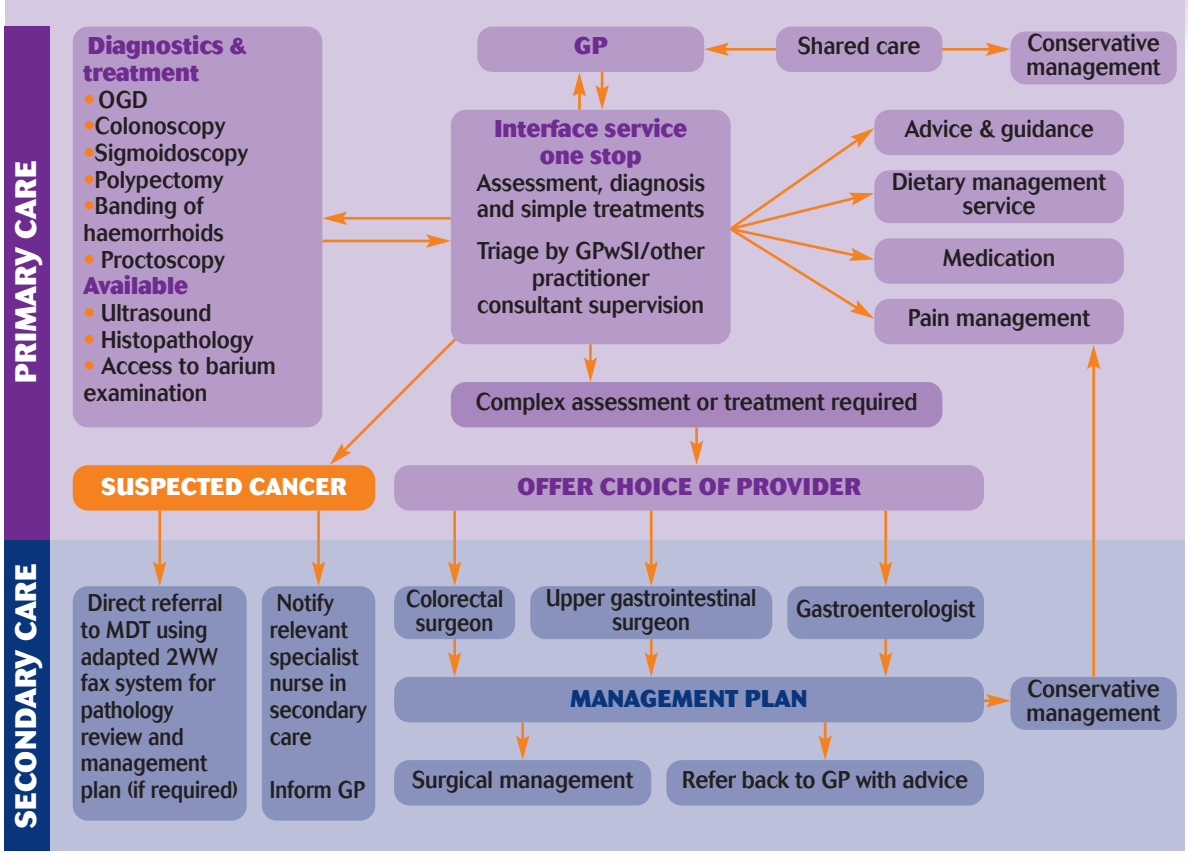
25 Sept 2009
PCSG ASM and AGM
Chandos House, Central London.
Contact: Kirsty Moulsley
020 7836 0088
secretariat@pcsg.org.uk

13-14 Oct 2009
BAPEN Annual Conference
Cardiff International Arena
Contact: Correen Finney
01527 457850
bapen@sovereignconference.co.uk
www.bapen.org.uk

21 Nov 2009
Endoscopy Meeting
East London.
Contact: Kirsty Moulsley
020 7836 0088
secretariat@pcsg.org.uk

21-25 Nov 2009
GASTRO 2009
UEGW/WCOG
ExCel, London
www.gastro2009.org

FIGURE 2 DRAFT MODEL OF CARE



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