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WORKING PARTY EXECUTIVE SUMMARIES

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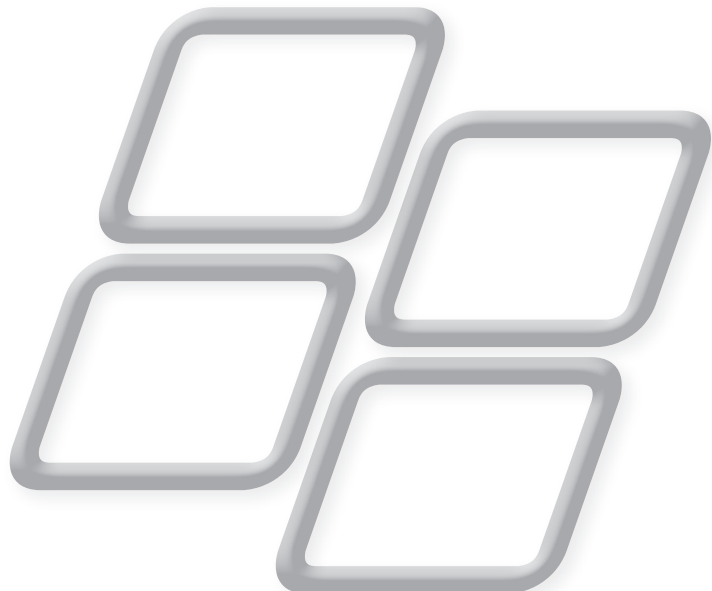
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For further information on the Working Parties please refer to the official congress website: www.gastro2009.org and the websites of the respective host societies:

www.uegf.org
www.worldgastroenterology.org
www.omed.org
www.bsg.org.uk





GASTROINTESTINAL NEUROMUSCULAR PATHOLOGY (GINMP) – CLASSIFICATION AND GUIDELINES ON HISTOLOGICAL REPORTING

Chair: Charles Knowles, UK

Co-Chair: Roberto de Giorgio, Italy

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Joanne Martin	John Hutson
Peter Milla	Sean Ward
Jan Huizinga	Michael Schemann
Colin Rudolph	Virpi Smith
Gianrico Farrugia	Vincenzo Stanghellini
Raj Kapur	Bela Veress
Karol Geboes	Tom Wedel

Since the successful bid to become a working party in 2007, significant progress has been made towards the objectives outlined. A final group of 13 WP members have contributed to the detailed guidelines published in the August edition of *Acta Neuropathologica*. This 'opus' spans 31 pages of the paper journal, has 172 accompanying references, numerous figures and tables as well as several key sets of reporting and referral recommendations to guide the general pathologist. Supplemental material is provided digitally. The full reference is:

Knowles CH, De Giorgio R, Kapur RP, Bruder E, Farrugia G, Geboes K, Gershon MD, Hutson J, Lindberg G, Martin JE, Meier-Ruge WA, Milla PJ, Smith VV, Vandervinden JM, Veress B, Wedel T. *Gastrointestinal neuromuscular pathology: guidelines for histological techniques and reporting on behalf of the Gastro 2009 International Working Group. Acta Neuropathol* 2009;118:271-301.

The same group is finalising a contemporary classification of gastrointestinal neuromuscular pathology based on defined histopathological criteria and using the guidelines as a platform. In recognition of its origins and first presentation in London at the World Congress of Gastroenterology 2009, this has been named 'The London Classification'. The classification should necessarily be viewed as a starting point for future modification as new data become available. It will have global applicability. We anticipate publication of this classification later this year in a major general gastroenterology journal.

The group has met in small groups in Europe (3 times) and the US (twice). The chairs have met on several further occasions in Bologna and London. Further correspondence has taken place by Email (over 1000 emails in relation to this project). These activities have taken place within the budgetary allocation of the group.

Future plans include the development of an international cooperative study group to delineate quantitative normative data for GINMP that are age, gender and region specific. The IWG identified this as the area of critical need for future research since the histopathological phenotypes defined by the guidelines were deliberately highly conservative based on the absence of adequate data to provide quantitative limits of normality in the individual.

EARLY RECOGNITION OF BARRETT'S OESOPHAGUS RELATED NEOPLASIA: THE BORN PROJECT

Chair: Prateek Sharma, USA

David Armstrong
Jacques Bergman
John Dent
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Michio Hongo
Yoshio Hoshihara
Janusz Jankowski
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Michael Vieth
Lisa Yerian

Some of the highlights of the project that have been completed thus far are:

- The first planning meeting of the BORN working group was held in Rabat, Morocco (January 2008). Issues related to study objectives, methodology, and outcomes were discussed.
- Subsequently, the working group including the investigators has had 3 face to face meetings during DDW, San Diego, CA. (May 2008) and UEGW, Vienna, Austria (October 2008) and DDW, Chicago, IL (June 2009). The core group of investigators has had several conference calls this year (2009) to plan for the London WGO meeting as well as to discuss ongoing challenges facing the project.
- The project received local Institutional Board clearance at each of the participating sites: Amsterdam (Netherlands), Kansas City (USA), Karlsruhe (Germany), Mainz (Germany) and Wiesbaden (Germany).
- Patients with Barrett's esophagus with high grade dysplasia, early cancer and mucosal changes have been enrolled at the multiple participating sites and the project is continuing to expand and grow.
- Images and videos using high quality endoscopes including high resolution and/or high definition endoscopes along with narrow band imaging, chromo-endoscopy and FICE capabilities have been obtained.



- A high quality teaching tool will be available for endoscopists for the recognition of early Barrett's neoplasia.
- The ability of expert and non-expert endoscopists' to recognize these early lesions will be tested.

THE LONDON POSITION STATEMENT OF THE WORLD CONGRESS OF GASTROENTEROLOGY ON BIOLOGICAL THERAPY FOR IBD WITH THE EUROPEAN CROHN'S AND COLITIS ORGANISATION

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When to start, when to stop and what to do in between?

Biological therapy is a significant advance in the management of inflammatory bowel disease. It is indicated for patients who have failed conventional therapy. Not all patients require biological therapy. Selection of patients appropriate for biological therapy depend on clinical characteristics, previous response to other medical therapy, phenotype and co-morbid conditions. Certain patient populations may derive greater benefit from the early introduction of biological therapy. Steroid-refractory or steroid-dependent Crohn's disease and complex fistulising disease are indications for early intervention, in conjunction with surgical drainage of any sepsis. The combination of infliximab with azathioprine is better than monotherapy for induction of remission and mucosal healing after 1 year in patients with Crohn's disease naïve to both agents. Whether this applies to other agents remains unknown. Infliximab is also effective for treatment-refractory, moderate or severe active ulcerative colitis. It is not known whether other anti-TNF agents are as effective. Patients who respond to induction

therapy benefit from systematic re-treatment, since this maintains response. Patients who have a diminished or loss of response to anti-TNF therapy may respond to dose adjustment of the same agent, or switching to another agent. Careful consideration should be given to the reasons for loss of response. Withdrawal of treatment can be considered in those who have complete mucosal healing and no biological evidence of inflammation after a year of anti-TNF therapy, but disease behaviour and the potential implications of relapse should be taken into account.

The choice of drug, adverse events and predicting response

Availability, local costs, or patient preferences guide the choice of the first line biological therapy for luminal Crohn's disease, so this should be tailored to the individual patient. Infliximab has the most extensive published clinical trial data, but studies with other agents (adalimumab, certolizumab pegol and natalizumab) suggest that they produce roughly similar benefits in Crohn's disease, although the study populations were different. For fistulising Crohn's disease, the efficacy of infliximab for induction of fistula closure is much better documented than for adalimumab or certolizumab pegol and suggests that infliximab should be the first line biologic for fistulising Crohn's disease until more data become available. The unique risks of natalizumab, while rare, account for its labelling as a second-line biologic agent in some countries. The search for predictive factors of refractoriness to biological therapy has examined clinical characteristics, serological markers and genetic factors, including mucosal gene signatures and molecular imaging, but none are sufficiently robust yet to be recommended for clinical practice. Although there is unequivocal evidence of an increased risk of serious infection among patients with rheumatoid arthritis treated with anti-TNF therapy, the evidence is less clear in Crohn's disease. The risk may be increased by combination therapy with steroids and/or immunomodulators.

Pregnancy and paediatrics

Anti-TNF therapy in pregnancy is considered to be low risk and compatible with use during conception in men and women, and during pregnancy in at least the first two trimesters. Infliximab is also compatible with breastfeeding, but safety data for adalimumab and certolizumab pegol are awaited. The risk of natalizumab during pregnancy is unknown. For children with Crohn's disease, infliximab is effective at inducing and maintaining remission. Episodic therapy is not as effective as scheduled infusions. Infliximab promotes growth in pre-pubertal and early pubertal Crohn's patients. Adalimumab is effective for children with active Crohn's disease and for maintaining remission, even if they have lost response to infliximab although there are fewer data. Vaccination of infants exposed to biologi-



cal therapy in utero should be given at standard schedules, except for live-virus vaccines such as against rotavirus. Inactivated vaccines may be safely administered to children with inflammatory bowel disease, even when immunocompromised.

THE DEVELOPMENT OF A HISTOPATHOLOGICAL CLASSIFICATION SYSTEM FOR GALL BLADDER CANCER AND PRECANCER

Chair: Robert Goldin, UK

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The first objective of this study were to assess the level of agreement between histopathologists, from different parts of the world, in classifying the pre-invasive stages of gall bladder cancer and, also, the individual histological features which contribute to the making of this diagnoses. The second objective was to develop an agreed, and validated, classification of the pre-invasive stages of gall bladder cancer. This will allow meaningful comparisons to be made between studies into the natural history of gall bladder cancer and its molecular pathology. Given the marked variation in the incidence of gall bladder cancer in different parts of the world it is clear that histopathologists in different countries will vary in their experience of it. It also cannot be assumed that pathologists in different countries mean the same thing when they use the same term (as has been shown to be the case with gastric cancer).

Images from the pre-invasive stages of cancer were posted on a dedicated, password-protected, website (www.gallbladderpathology.com). Pathologists from Chile, India, South Africa, Iceland and the United Kingdom took part in study. Each of them gave an overall diagnosis for each case and also assessed the presence or absence of individual architectural and cytological features.

The degree of inter-and intra-observer agreement was assessed using Cohen's kappa coefficient with geometric weighting. Taking all the participating pathologists together, very good levels of agreement were found for distinguishing normal mucosa from inflamed mucosa and dysplastic mucosa from invasive cancer. However, only moderate levels of agreement were seen in distinguishing inflamed mucosa, with reactive atypia, from dysplastic mucosa. It was found that not enough cases of metapla-

sia had been included to assess the reproducibility of this feature. Furthermore in distinguishing different degrees of dysplasia, very good levels of agreement were found when only two grades of dysplasia were used but only moderate levels when there were three grades. When individual histological features were studied the reproducibility of assessing increased mitoses and abnormal mitoses was very good. The reproducibility of nuclear enlargement, nuclear hyperchromasia and increased nuclear: cytoplasmic ratio was moderate. The reproducibility of distinguishing pseudostratification from loss of polarity was poor. When analysed against different the diagnostic categories it was found that the presence of increased and/or abnormal mitoses was the best criteria for distinguishing inflammation, with reactive atypia, from dysplasia.

Our provisional recommendations for the **London classification of pre-invasive gall bladder cancer** is that there should only be two categories of dysplasia, as is the case for gastro-intestinal malignancy in general, and that reproducible criteria for improving the reproducibility of the classification can be developed especially in distinguishing reactive atypia and dysplasia. More work needs to be done especially on the, relatively uncommon, adenoma-carcinoma sequence and to evaluate the significance of intramucosal adenocarcinoma in flat dysplasia.

GUIDELINES FOR EVALUATION OF NEW SCREENING TESTS: APPLICATION TO COLORECTAL AND GASTRIC CANCERS

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Alternative screening tests for gastrointestinal cancers are continually emerging with resultant confusion as to what evidence justifies their use. The evidence required to convince health-service providers that a new test can be justifiably used for screening is demanding. The need to compare accuracy, acceptance and cost requires rigorous evaluation beyond what is the case for diagnostic tests, as the goal of cancer screening is to reduce cancer-site-specific mortality in the targeted population. The goal of



this review has been to develop practical guidelines on how best to compare “new” with proven screening tests, the ideal context, the informative endpoints and the appropriate study design.

A systematic review of literature addressing strategies for comparing diagnostic or screening tests was undertaken together with a consensus approach involving experts.

Effectiveness of a new screening test requires demonstration of its impact on screening outcomes relative to a proven comparator test. Test accuracy backed up by programmatic population evaluation in the screening context, addressing acceptability and measurement of effectiveness on an intention-to-screen basis, are essential. Consequently, direct comparison of the new with a proven test is likely to be sufficient and not require cancer-specific mortality as an endpoint, provided that the comparator test has been proven effective by population randomized controlled trials and that the new test is based on a similar premise for detection. The effectiveness of guaiac-fecal occult blood tests has been convincingly demonstrated and the outcomes achieved with these tests represent the minimum standard to be achieved by a new test.

A four-phase stepwise approach to new test evaluation is proposed. An initial retrospective evaluation in cases with proven cancer (Phase 1), is followed by a prospective evaluation of performance across the continuum of neoplastic lesions (Phase 2) if phase 1 results are promising. Demonstration of adequate accuracy in prescreening phases justifies progression to more costly mass-population studies. These address programmatic outcomes at a prevalent screen on an intention-to-screen basis in unbiased typical screening populations (Phase 3), followed by evaluation of cost-effectiveness in on-going screening (Phase 4). Phase 3 outcomes are required to justify use of a test in an organized mass population screening program.

New screening tests will be efficiently evaluated by this stepwise comparative approach and will ensure that impact on population outcomes including mortality can be estimated relative to proven screening tests.

POST INFECTIOUS IBS: A GLOBAL PERSPECTIVE

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About 10–20% of IBS cases are supposed to begin after a gastrointestinal infection. The committee has set up a web-based survey for IBS patients to report the mode of onset of their IBS symptoms particularly any infection at onset and describe the evolution of symptoms over the next 5 years. Most patients (817) accessed the web site using a password provided by secondary care physicians 51 accessing without a password. So far we have 868 IBS patients registered, 274 male and 526 female from 34 countries (including 14 European, 9 South American, 3 North American, 2 African and 3 Australasian). The average age was 42(SD 15.0) years. As expected from an internet survey the subjects were mostly well educated, urban and middle class: 49% had completed secondary school and 40% had a university education. 46% lived in a city, 27% in a town with 23% living in a village. 34% had > 1 toilet per family, 16% shared a bed and 84% had running hot water in their childhood home. Only 7% had close contact with animals as a child.

144 (22%) met criteria for PI-IBS (onset of new IBS after acute illness with 2 or more of: fever, diarrhoea, vomiting or positive stool culture). Females were more likely to report PI-IBS, 24% versus 15% of males, $p=0.007$. Compared to IBS without an infectious origin (non-PI-IBS) there were no differences in bowel habit with similar number of days with pain, hard and loose stools and total number of bowel movements. However more PI-IBS reported previous treatment for depression PI-IBS 45/146(31%) v 103/524 (20%), $p=0.007$ and anxiety (44/146(30%) versus 113/524 (20%), $p=0.04$). There were no differences in age PI-IBS being 39.7(1.1) versus 41.8(0.7) years. Somatization, evaluated by the PHQ15 questionnaire, was significantly higher in PI-IBS 16.1(0.6) versus 13.3(0.3), for non-PI-IBS $p<0.0001$. There were no differences by region of birth nor whether they lived in a city or village. Childhood living conditions including having running hot water, sharing a bed with sibs or having animals around the home had no effect, but having more than 1 toilet per family increased the risk of reporting PI-IBS from 0.19 to 0.27, $p=0.015$.

When comparing Northern Europe and USA against the rest of the world there was no difference in the proportion beginning during travel nor in the severity of initial illness as judged by the presence of fever, vomiting or bloody diarrhoea which were reported overall in 62%, 65% and 24% respectively. Multivariate analysis suggests female gender, >1 toilet and low status occupation independently increase the risk of PI-IBS.

Conclusion: Our survey suggests that PI-IBS accounts for 22% of all IBS, occurs throughout the world with clinical features that are similar to non-PI-IBS. PI-IBS patients are more likely to be female with somatisation and previous treatment for anxiety and depression. Affluence may increase the risk.



THE NEGLECTED HCV GENOTYPES 4, 5 AND 6: AN INTERNATIONAL CONSENSUS REPORT

Chair: Nabil Antaki, Syria

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HCV genotypes 4, 5 and 6 represent 20% of all HCV infection cases worldwide. Genotype 4 is the most frequent cause of chronic hepatitis C in the Middle-East, North Africa and sub-Saharan Africa. It has recently spread to Europe particularly among IV drug users and in immigrants. Genotype 5 was initially reported in South Africa, where it represents 40% of all cases; However 4 pockets of genotype 5 have been found in France, Syria, Belgium and Spain. Genotype 6 is rare and confined to South East Asia, Asian Americans and Asian Australians. The response to treatment in HCV-genotype 4 is intermediate between HCV- genotype 1 and HCV-genotypes 2 and 3. Sustained viral response is obtained in 43% to 70% with PEG-IFN and ribavirin. It is higher in Egyptians than Europeans and Africans and is related to insulin resistance and to the severity of fibrosis. It increases to more than 80% with 24 weeks of therapy only if rapid viral response is achieved. In HCV- genotype 5, sustained viral response is obtained in more than 60% with 48 weeks of therapy. HCV- genotype 6 is also considered an easy to treat genotype reaching response in 60% to 85% of cases.

The experts of the working party would like to recommend the following:

1- HCV- genotype 4:

1. If RVR is achieved, treat for 24 weeks regardless of viral load at baseline
2. If complete EVR and if viral load at baseline is low and fibrosis mild, treatment for 36 weeks is an acceptable option. But if the patient tolerates the treatment and to increase his chance to obtain an SVR, treat for 48 weeks
3. If partial EVR is reached, treat for 48 weeks

2- HCV- genotype 5:

1. Treat for 48 weeks. If there is no EVR, consider discontinuation (good data are lacking for RVR and EVR)
2. Prospective study will determine if and when a shorter duration is possible

3- HCV- genotype 6:

1. Evidence of higher SVR with 48 weeks than 24 weeks
2. Treat for 48 weeks if EVR

THE LONDON OMED GUIDELINES FOR CREDENTIALING AND QUALITY ASSURANCE IN DIGESTIVE ENDOSCOPY

Chair: Doug Faigel, USA

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An OMED working party was organized to create guidelines for credentialing and quality assurance in digestive endoscopy. The working party reviewed existing guidelines and published articles in creating this document.

Credentialing and Granting of Privileges

It is the responsibility of healthcare institutions to grant privileges for endoscopic procedures only to competent individuals. Competency is the minimal level of skill, knowledge, and/or expertise derived through training and experience that is required to safely and proficiently perform a task or procedure, without assistance or supervision. Healthcare institutions should have written policies on granting endoscopic privileges, which should be time-limited, and also for their periodic renewal. Endoscopic training should provide an adequate case volume and mix, focusing on both technical and cognitive skills so that the competent endoscopist is capable of performing technically successful clinically indicated procedures, while minimizing risk, and is able to correctly interpret findings, use them for treatment planning, and provide communication to referring providers and to the patient. The endoscopist should also be able to perform common associated therapeutic procedures such as polypectomy and hemostasis techniques. Competency should be assessed by review of credentials (diplomas, certificates and other documents provided after successful completion of a period of education or training), review of the training director letter, completion of threshold numbers of procedures, direct observation, and, wherever possible, by objective measures.



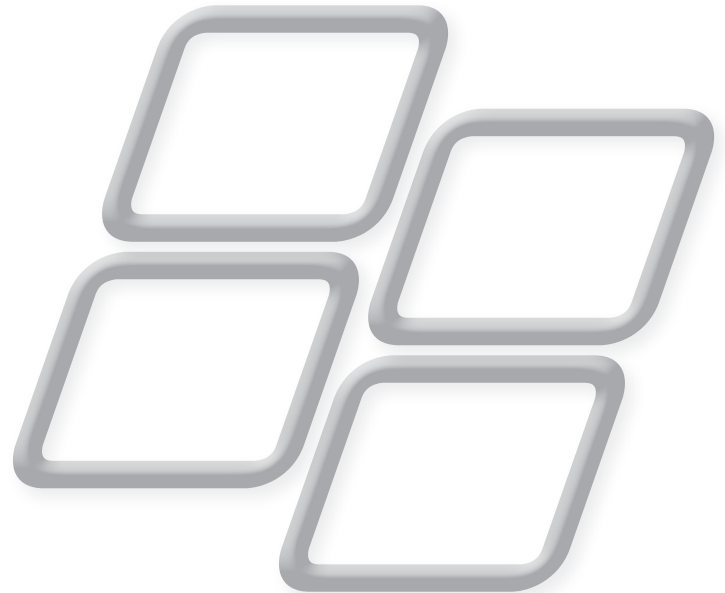
Quality Assurance and Improvement

The goal of maintaining and enhancing the quality of services should be addressed by a continuous process of measuring aspects of endoscopic performance. Quality improvement involves identification of areas of under-performance through quality measurement, initiation of an improvement plan, and then re-measurement to assess and document improvement. Endoscopy units should have a policy for quality improvement specifying a selection of individual indicators to be measured. Sentinel events (complications, adverse outcomes, departures from institutional policy) should be measured but are insufficient for documenting quality.

Quality indicators that may be measured include those common to all procedures, and those specific to individual endoscopic procedures (upper endoscopy, colonoscopy, ERCP). General indicators include: proper indication, informed consent, risk stratification, use of sedation reversal agents. Upper endoscopy indicators: biopsy of gastric ulcers, treatment of bleeding or high-risk ulcers, *H. pylori* testing of ulcer patients, use of variceal ligation. Colonoscopy indicators: post-polypectomy surveillance, cecal intubation rate, adenoma detection rate, withdrawal time, quality of the colon preparation. ERCP indicators: cannulation rates, pancreatitis rate, biliary stone extraction, biliary stent insertion.

Quality improvement should also focus on the endoscopy unit. Areas that may be monitored include: efficiency (e.g. wait times, room and staff turnover, no-show rates) to allow for the appropriate allocation of medical resources, and patient centered measures such as satisfaction surveys, receipt of written discharge instructions, post-procedure follow-up and plans for informing patients of biopsy and laboratory results.

Benchmarking entails measuring endoscopist or unit specific indicators in a reproducible manner and then comparing those results to other endoscopists or units in the database. The purpose is to determine levels of performance and benchmark one's own performance against others. This allows detection of areas of underperformance and rational planning for improvement as part of the continuous quality improvement process.



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