IBDIS validation study – Report

The IBDIS validation project received one of the ECCO grants 2008. According to the plan, the first line was accomplished in January 2009. 58 IBD experts from all over the world participated in this project and 42 of them contributed by capturing 15 patient records. Significance tests about distribution of data (validation of data) will lead to an improvement of IBD-relevant parameters. The final results are expected for April 2009.

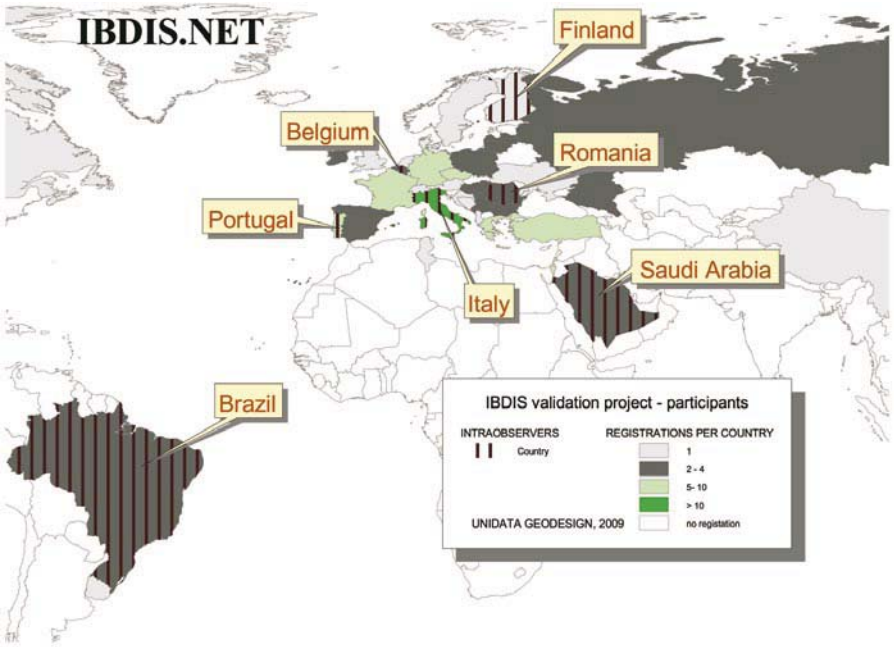

Fig. 1 Participating countries.

Our objective:
Improving the quality of IBDIS
Comparability of data needs standardized and harmonized tools and services. The Inflammatory Bowel Disease Information System, IBDIS, was designed and developed to document all single issues and the course of disease of IBD patients. The current validation study examines each parameter for variability of interpretation within a group of observers (interobserver) and among 7 individual observers (intraobserver). The results of the analysis will affect the contents and the definitions of the parameter table of IBDIS.

Participants
The list of persons comprises IBD experts from all over the world – from Uruguay and Brazil to Tunisia and Israel, nearly all European countries, Russia and the People's Republic of China. Although ECCO is a European organisation, 13 persons who registered for participation were from non-European countries. This is an indication for the worldwide understanding of the necessity of validated tools and services and for the acceptance of ECCO. Participation was restricted to individual ECCO members (particularly members of Young ECCO (YECCO)) and members of the Council of National Representatives. The registration period lasted 2 months and started in July 2008. The randomised election of 7 intraobservers took place in January 2009 and was controlled by the IBDIS statistician.

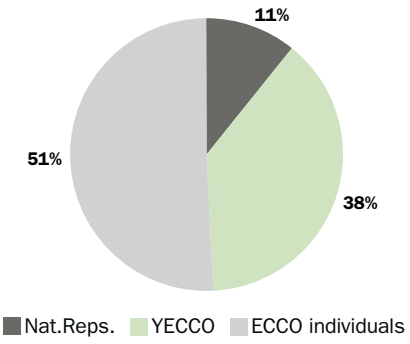

Fig. 2 Recruitment of participants.

Contents of patient files
IBDIS assigns the contents (actions) of each patient file to blocks e.g. Block B Location or Block C Phenotype. Each single action is assigned to a corresponding block (e.g. examination *Radiology* assigned to Block B Location or *Montreal Classification* assigned to Block B Location or *Bone density* assigned to Block G Comorbidity). The data capture process of the IBDIS validation project shows the following results:

Assigned Block	Actions
A Epidemiology	1026
B Location	8444
C Phenotype	929
D Course of disease	868
E Complications	836
F Intestinal Surgery	673
G Comorb / Risk	808
H Pregnancy	994
I Therapy	2315

Fig. 3 Summary of activities: 42 observers captured up to 15 patient files each.

Statistics
Interobserver agreement (IOA) analysis is an accuracy analysis that calculates the percentage (standard deviation, SD, or the 95% confidence interval, CI) of observer agreement with a predetermined reference observer. The agreement between the mode (the most frequently assessed value) and the reference is expressed as a percentage. Statistical characterization of the strength of interobserver agreement will be determined using Cohen's kappa (k). In the study each patient file will be considered as an independent observation. The strength of agreement is considered poor with a k statistic of less than 0.2, fair with a k of 0.21 to 0.4, moderate with a k of 0.41 to 0.6, good with a k of 0.61 to 0.8, and very good with a k of more than 0.8.

Intra-observer agreement analysis
The intra-observer agreement analysis (retest reliability) is an accuracy analysis calculating the percentage of agreement between first and second observation of the 7 selected observers. They will be asked to re-evaluate 7 medical records after another 12 weeks. Furthermore, different tests as e.g. test of homogeneity, test of coincidence, chi-square-tests, odds-ratio

Facts & Figures

123	persons registered in the validation project.
58	persons decided to participate as observers.
42	Users entered 15 patient files.
1	User entered 13 or 14 Patient files each.
0	Users entered 4, 6, 7, 8, 9, 10, 11 or 12 Patient files each.
3	Users entered 3 or 5 Patientfiles.
5	Users entered 1 or 2 Patientfile.

and pooled kappa-tests will be used to detect influences of geographical and linguistic areas.

Outlook

As the knowledge about IBD is constantly growing, IBDIS needs to be validated several times. Supporting gastroenterologists with up-to-date documentation systems and keeping downward compatibility of functions and data, establishing new standards together with the scientific community and improving the quality of IBD-related data, these are our main objectives for the future. The current validation project is as yet another step to achieve this goal.

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Links:
https://documentation.ibdis.net
http://www.ibdis.net

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IBDIS chosen for Saudi Arabian incidence registry of IBD patients

Background

Longitudinal studies over the last 50 years have shown an increasing incidence of ulcerative colitis (UC) and crohn's disease (CD) worldwide (1,2). The incidence rates markedly differ geographically and among different ethnic groups presumably due to genetic and environmental factors (3). Epidemiological data coming from Saudi Arabia are very limited. Alghamdi et al (4) only recruited 77 CD cases from 1982–2002 at King Khalid University Hospital (KKUH), Riyadh, Saudi Arabia. In 2005, we have collected 42 cases of CD in only 2 years (2004 and 2005) at the same centre which indicating a very rapid increase of CD incidence. Currently we are following about 600 IBD cases in our centre (KKUH). Riyadh city has 6 tertiary hospitals as well as many gastroenterology private centres which serve an area of approximately 4,000,000.

Based upon these preliminary data of striking increase of IBD incidence, we planned to join the IBDIS platform in order to register our patients according to a validated documentation tool for IBD patients. By capturing all of our incident IBD cases and by following them for at least one year will help us to learn on the natural course of IBD in our country and to compare this experience with data from Europe.

Fig. 1 Map of Saudi Arabia with locations of participating.

New incidence registry of IBD

Knowledge about incidences of diseases necessitates stable and reliable data pools. Dr. Aljebreen and Nikolaus F. Pedarnig, IBDIS project manager at UNIDATA GEODESIGN, met at UEGW 2008 in Vienna and discussed a proposal concerning an IBD incidence registry for Saudi Arabia. It was evident to use the existing IBDIS parameter catalogue to design a comprehensive and easy-to-use eCRF.

Data management

According to the IBDIS online software (*https://documentation.ibdis.net*) the new eCRF uses the same modules (anamnesis, epidemiology, phenotype, diagnosis, course of disease, medication, complication and surgery). All data is stored in a database, operated and controlled by UNIDATA staff.

Aims

To capture the natural course of incident IBD cases in the Kingdom Saudi Arabia, a country in which the second generation of IBD cases is currently observed.

Participation

All Saudi Arabian IBD centres are planned to participate in the trial. Interested physicians and clinicians are kindly requested to contact the authors.

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References:

1. Bjornsson S. Inflammatory bowel disease in Iceland during a 30-year period, 1950-1979. Scand J Gastroenterol Suppl 1989; 170:47-49.
2. Fellows IW, Freeman JG, Holmes GK. Crohn›s disease in the city of Derby, 1951-85. Gut 1990; 31(11):1262-1265.
3. Moum B, Ekbom A. Epidemiology of inflammatory bowel disease--methodological considerations. Dig Liver Dis 2002; 34(5):364-369.
4. Al Ghamdi AS, Al Mofleh IA, Al Rashed RS, Al Amri SM, Aljebreen AM, Isnani AC et al. Epidemiology and outcome of Crohn›s disease in a teaching hospital in Riyadh. World J Gastroenterol 2004; 10(9):1341-1344.

Second YECCO Workshop in Hamburg

How to set-up and perform a clinical trial

On February 4 the ECCO Education Committee and YECCO organized the second YECCO workshop. This workshop was organized prior to the recent ECCO Congress in Hamburg and was attended by ECCO Course attendees as well as 35 YECCO members. Prior to the meeting, all participants had to prepare a short proposal for a study evaluating the efficacy of anti-TNF agents in the treatment of chronic refractory pouchitis.

Old Board: Gionata Fiorino & Marc Ferrante.

New Board: Marc Ferrante & Jan Wehkamp.

During the first part of the workshop several speakers gave a lecture about divers topics necessary to set-up a good clinical trial. Daan Hommes started with an animated talk on study goals and endpoints. The second lecture on statistics was given by Peter Jüni. Concepts as sample size, type I and type II errors became logical and understandable for all attendees. Prior to the break, Yehuda Chowers discussed some critical ethical issues and finally Wolfgang Russ introduced us in the basics of good clinical practice.

The last part of the meeting existed of a very interactive discussion between Daan Hommes, the participants and the other lecturers. During this 45 minutes the attendees improved their prepared study proposal and a very solid study protocol came out.

We would like to thank all speakers and all attendees for this very successful event. We hope to continue this collaboration with the ECCO Education Committee in the future. Ideas for new YECCO workshops are more than welcome.

New YECCO Board

During the YECCO meeting in Hamburg a new YECCO board was inaugurated. After two and half years of hard work Gionata Fiorino (Rome, Italy) stepped down as YECCO Chair. Gionata was the engine behind YECCO in the early days and we are very grateful for the courage he had at that time. During the past two years he and some other founding members achieved the inclusion of YECCO in the ECCO structure and started with some very nice YECCO initiatives. Although he'll not be a board member anymore, we're sure that Gionata will continue his hard work for our young organization.

The past YECCO Co-Chair, Marc Ferrante (Leuven, Belgium), has been elected as new YECCO Chair. He will collaborate with Jan Wehkamp (Stuttgart, Germany) who was elected as YECCO Co-Chair. Silvio Danese (Milan, Italy) will keep his position as YECCO representative in the ECCO Scientific Committee, while Charlie Lees (Edinburgh, United Kingdom) was elected by the ECCO Education Committee as the first YECCO Representative.

Looking forward to a great future of YECCO.

MARC FERRANTE
YECCO Chair

JAN WEHKAMP
YECCO Co-Chair