ROMANIAN CCC* CORNER

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Excellence Centers in Inflammatory Bowel Disease in Romania: a Measure of the Quality of Care

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INTRODUCTION

The notion of quality of care is an important and controversial topic in today's medicine: its detractors suggest that strict quality measures and guidelines affect "the art of medicine", while its supporters believe that it increases the delivery of evidence-based care to all patients. The process of quality improvement requires a clear definition of adequate and inadequate care markers. This requires valid metrics and clearly established mechanisms to provide feedback in a dynamic manner that will lead to future improvement in the quality of care. The choice of quality indicators is based on existing scientific evidence or expert consensus. The chosen indicators should be readily applied and monitored to continuously evaluate and improve the quality of care.

Over the past decade, efforts to improve the quality of care in inflammatory bowel disease (IBD) patients have been made in many regions of the world. This was mostly done by creating evidence based guidelines and centers of excellence in the field. Increasing evidence suggests that creating such expert/excellence centers will ultimately lead to the better quality of care. There is still a debate regarding the characteristics of a center of excellence even though guidelines regarding diagnosis, treatment, managing complications and patient follow up have been released by different academic societies and generally been accepted by the community of caregivers.

The types of quality indicators generally used at the moment are the structural measures (indicators on the center providing care in IBD: specialized staff - gastroenterologists with interest in IBD, specialized surgeons, nurses, nutritionists, equipment, electronic medical records, a multidisciplinary approach); the process measures (indicators of the process of providing care: diagnosis, investigations, treatment, complications, and patients' interaction) and the outcome measures (indicators that assess the outcome of patients: mortality, morbidity, quality of life, patient satisfaction) [1].

The Romanian Task Force for IBD, under the auspices of the IBD 2020 initiative, decided to evaluate and to propose a comprehensive set of quality of care indicators of structure, process, and outcomes for defining and evaluating an excellence center in the field. After careful evaluation of the literature and panel discussions, a set of quality indicators and criteria required for an excellence center were recommended for Romanian specialized centers.

EXPERT PHYSICIANS AND GUIDELINES ADHERENCE: THE NEED FOR CENTERS OF EXCELLENCE

Evidence is growing that specialized centers are providing better care for their patients. In a Spanish survey, the degree of adherence to guidelines was high in both general and tertiary centers but the use of imaging techniques in diagnosis and follow-up significantly differed. In perianal disease for example, IBD specialized gastroenterologists used magnetic resonance and surgical exploration under anesthesia more frequently than the general gastroenterologists do. Also, the IBD specialists showed significantly higher adherence to the guidelines in certain therapeutic areas: less use of thiopurines in refractory cases and increased use of methotrexate in corticoid-dependent, azathioprine-intolerant patients and also in patients under biological treatment. Requests for infection studies and vaccinations at diagnosis or prior to treatment were also more common in the specialized centers [2].

In another study where the use of certain criteria (appropriate frequency of blood tests during the initiation/maintenance of immunosuppressive treatment, bone protection when oral steroids were given, screening colonoscopy at 8-10 years of ulcerative colitis, annual serum urea and creatinine concentrations in patients prescribed 5-aminosalicylates, annual liver function tests, annual haematinics in patients with Crohn‘s disease) were assessed to monitor the quality of care, the specialist IBD clinics had better results than the non-specialist general gastroenterology clinics. Even in the specialist clinic, however, the care of a minority of patients did not fulfill certain criteria, emphasizing the need for a critical audit of outpatient management of IBD [3].

Separating physician members of the American Gastroenterology Association (AGA) into "non-expert" and "expert" groups, based on whether a practice consisted of >50% patients with IBD, showed that experts are more comfortable using a broader array of medical therapy than non-expert physicians. Although both groups had similar concerns regarding the side-effects of anti-TNFα therapy, expert physicians were much more likely to have managed a broad range of complications in their patient population [4].

These studies confirm that having access to established guidelines is not enough and that we need specialized teams working together in centers with interest in IBD, in a multidisciplinary approach. This approach will permit easier access to the use of advanced diagnostic techniques and to physicians with supreme knowledge of therapeutic choices.

Creating such centers will allow easier access to our patients to modern diagnostic tools, treatment optimization and avoidance of treatment side effects. Better colon cancer screening and expert histopathology in the field of IBD are other advantages of such an excellence center.

MEASURES TAKEN AND REQUIRED CRITERIA

To overcome the widespread variations in the care of IBD patients, certain measures have been implemented in recent years.

In the United Kingdom, a multidisciplinary panel developed a set of IBD Standards. Although not all these standards are evidence-based, they reflect a general multidisciplinary expert consensus on what defines quality care for patients with IBD, and include both structural standards (the setting in which care is delivered, specialists number etc.) and measures reflecting the process of care [5].

In the USA, the AGA convened a taskforce which defined process measures in conjunction with the American Medical Association‘s Physician Consortium for Quality Improvement. After public debate and comment these measures were accepted in 2012. The criteria are presented in Table I [6]. This was accomplished by starting with more than 500 potential quality indicators culled from all IBD guideline and position articles from 2006 to 2011.

A multidisciplinary panel composed of gastroenterologists representing the Crohn's Colitis Foundation of America (CCFA), the AGA and the American College of Gastroenterology (ACG), a colorectal surgeon, and patients convened for the 3 in-person moderated panels that ultimately voted on the 10 process and outcome quality indicators that composed the final measure set for adult IBD care. The main criteria defining an expert center according to CCFA are listed in Tables II and III.

Table II. Measurable quality outcome indicators for IBD (expressed as proportion or number). Adapted with agreement from: Melmed et al 2013 [1] and Siegel et al 2013 [7]

1. Patients with steroid-free clinical remission for 1 year
2. Patients currently taking steroids (excluding those diagnosed within the past 16 weeks)
3. Days per month/year lost from school/work attributable to IBD
4. Days per year in the hospital attributable to IBD
5. Emergency room visits per year for IBD
6. Patients with malnutrition
7. Patients with anemia
8. Patients with normal disease-targeted, health-related quality of life
9. Patients currently taking narcotic analgesics
10. Patients with nighttime bowel movements or leakage
11. Patients with incontinence in the past month

APPLICABILITY IN PRACTICE IN ROMANIA

Can we translate these measures into clinical practice in Romania? And will they improve our patient care in IBD?

In order to identify and implement effective quality indicators, a Romanian task force for IBD analyzed the current situation, the existing scientific evidence and the particularities of the country. A set of measures to improve quality of care was proposed. This task force reunited some of the experts in the field of IBD in Romania, and had the authorities (health ministry and house of insurance) and patient associations' support.

Current practice

General gastroenterologists

An important number of gastroenterologists in Romania are interested in the field of IBD. Few have extensive

Table I. Initial assessment criteria of an IBD patient (modified after Melmed et al 2013) [6]

Precise documentation of IBD type, anatomic location, and activity
Indication for corticosteroid-sparing agents in patients unable to taper off corticosteroids
Strategies to avoid corticosteroid related iatrogenic injury (e.g. evaluation and treatment of bone loss among patients at risk)
Screening for tobacco use and cessation if relevant
Recommendation for influenza, pneumococcal immunization
Assessment of hepatitis B virus status before anti–TNF therapy and immunization if necessary
Screening for latent tuberculosis before initiating anti–TNF therapy

Table III. Quality process indicators in IBD. Modified from Melmed et al 2013 [1] and Siegel et al 2013 [7]

Treatment	• Before initiating anti-TNF therapy, tuberculosis risk assessment should be documented, and tuberculin skin testing or interferon-gamma release assay should be performed
	• Before initiating therapy with anti-TNF, risk assessment for hepatitis B virus should be documented and vaccination provided if necessary
	• If a patient with IBD requires at least 10 mg prednisone (or equivalent) for 16 weeks or longer, then an appropriately dosed steroid-sparing agent or surgery should be recommended
	• In a hospitalized patient with severe colitis who is not improving on i.v. steroids within 3 days, sigmoidoscopy with biopsy should be performed to exclude cytomegalovirus, and a surgical consultation should be obtained
	• If a flare of IBD is suspected with new or worsening diarrhea then the patient should undergo *C. difficile* testing at least once
	• If a patient with IBD is initiating 6-MP/AZA, then thiopurine methyltransferase testing is recommended and should be performed
Surveillance	• In confirmed low-grade dysplasia in flat mucosa, proctocolectomy or repeat surveillance within 6 months should be offered to the patient
	• In a patient with extensive ulcerative colitis or Crohn's disease involving the colon, who has had the disease for 8–10 years, then surveillance colonoscopy should be performed every 1–3 years
Health care maintenance	• Patients with IBD on immunosuppressive therapy should be educated about appropriate vaccinations, including the following: annual inactivated influenza, pneumococcal vaccination with a 5-year booster, and general avoidance of live virus vaccines
	• In an active tobacco smoker with Crohn's disease, smoking cessation should be recommended, and treatment should be offered or a suitable referral provided at least annually

experience; some have some experience but all wish to improve their current practice. Their educational efforts have had a substantial support from the pharmaceutical industry which permitted an increased number of meetings and scientific symposia, courses and scholarships.

It is our belief that there is an increased interest and awareness to IBD specific problems that will lead to the improvement in the quality of care and to an increased adherence to the guidelines.

Existing "expert" centers

At the moment several centers have extensive experience and expertise in IBD. This is related to their tradition but also to a constant preoccupation in the field. They can serve as models, as they have successfully started to provide practical courses on IBD management in the last two years with the support of the Romanian Society of Digestive Endoscopy (SRED) and Romanian Crohn's and Colitis Club (RCCC).

Although there are great differences between centers regarding the infrastructure (number of beds, emergency rooms, types of hospitalization, availability of the diagnostic tools as HD endoscopy, capsule endoscopy, echo-endoscopy, modern radiological techniques) due to a constant effort of physicians and close collaboration between centers (state or private) a complete patient evaluation is possible in the majority of cases.

The process of creating expert centers and improving quality of care is seen as a friendly and healthy competition. The ability to overcome differences, to reach scientific consensus and to work together for the benefit of the patients has greatly improved in the last years in the field of gastroenterology in Romania.

One of the aspects pointed out by members of our group was the necessity of advanced endoscopy techniques in order to become an expert center, especially access to HD endoscopy and narrow band imaging. This point of view is not supported by all experts: first of all with the current funding it will be difficult to have such equipment in all centers, also the current data is still conflicting. Although the potential benefits of newer optical and digital dye-less chromoendoscopy (DLC) techniques over traditionally used dye based chromoendoscopy (DBC) are substantial, only DBC can currently be recommended to improve dysplasia detection in long-standing IBD. In contrast, DLC has the potential to quantify disease activity and mucosal healing in IBD [8].

The constant underfunding of the health system also poses serious barriers to any center wanting to have the newest diagnostic tools. It is our impression that even in large university centers, there is not only limited access to HD endoscopy but also a limited number of radiologists/imagists and also pathologists with experience and specific training in IBD.

Prescription

One of the main threats is the lack of predictability of the health system, its constant underfunding and reimbursement problems that ultimately pose a threat to our patients

The prescription of biologic therapy is performed within a legal frame of national protocol, mostly similar to the ECCO guidelines. Although the prescription is possible for every certified gastroenterologist, there is a formal recommendation for the patient to have an evaluation in a university center. The patient file is also analyzed by a Commission of the Health Insurance, which has both a regulatory and clinical function: it ascertains that the protocol is respected and that the therapeutic decision is for the best interest of the patient but also within the legal protocol framework. However, data in the patient file, their accuracy and the therapeutic decision is the responsibility of the prescribing physician.

Although regarded by some as a constraint, this kind of regulatory prescription will also help with increased adherence

to diagnostic and therapeutic guidelines and also will increase the quality of care offered to the patients.

Proposed criteria

Based on international models and the current situation in Romania, simple and quantifiable measures were proposed in order to obtain accreditation of the existing centers as excellence centers (Table IV). A simplified version of the current international criteria adapted to the local "reality" and milieu was realized. Interestingly, our debate and set of measures are quite similar to the recent initiative by a Spanish expert group in the IBD field, which had support from patients' associations and authorities to publish their conclusions [9].

Accreditation and auditing

Each center will apply online and will receive a certificate of excellence from the task force/RCCC if proven to fulfill more than 80% of the established criteria. This initiative is intended to improve the quality of care, to increase the number of participants providing "good" care and is neither an instrument to exclude centers or physicians nor a way to narrow the current practice.

The auditing process, using the same measurable criteria and adherence to the measures will take place every two years. Similar to the AGA measures, the data will be published and a list of centers and physicians will be available at all times. Publishing the data will maintain the standard of quality of care due to increased efforts to remain in the "excellence league". This will create some healthy competition and ultimately will continue to improve the quality of care.

CONCLUSIONS

Our initiative identified a set of quality of care indicators that will serve for evaluating and certifying excellence centers in IBD. This will help establishing clear goals and targets to different teams, ultimately leading to better care for the IBD patients.

The strongest recommendation is the need for management of IBD in a multidisciplinary setting with respect of national/

Table IV. Measures proposed for an excellence center in Romania

Structural measures	• Emergency room/ short term/long term hospitalization available
	• Dedicated staff with interest in IBD: gastroenterologists, pathologists, surgeons, radiologists, specialized nurses
	• Access to new techniques: HD endoscopy, capsule endoscopy, endoscopic ultrasound, entero CT and entero MRI
	• Electronic medical records
	• Participation to the national registries and IBD databases
Initial assessment of IBD patients	• Exact documentation of IBD type, anatomic location, and activity
	• Screening for latent tuberculosis and assessment of HBV, HCV and HIV status should be done routinely (at a certain moment patients may need anti–TNF therapy urgently)
	• Recommendation for influenza and pneumococcal immunization
	• Avoidance of live virus vaccines is strongly recommended if on immunosuppressive therapy
	• Screening for tobacco use and cessation if relevant
	• If a patient requires > 10 mg prednisone (or equivalent) for more than 4 months a steroid-sparing agent or surgery should be considered
	• If a hospitalized patient with severe colitis fails to improve after 3 days of i.v. steroids then sigmoidoscopy with biopsy should be performed to exclude cytomegalovirus, and surgical consultation should be obtained
	• All IBD flares with new or worsening diarrhea requires *C. difficile* testing at least once
	• Thiopurine methyltransferase testing is recommended before initiating 6-MP/AZA
	• Confirmed low-grade dysplasia in flat mucosa in a ulcerative colitis patient imposes a proctocolectomy or repeat surveillance within 6 months with a second opinion
	• For extensive ulcerative colitis or Crohn's disease involving the colon for > 8–10 years, surveillance colonoscopy should be performed every 1–3 years
Outcome Quality Indicators	• Number of emergency room visits per year for IBD
	• Number of hospitalizations attributable to IBD
	• Proportion of patients with steroid-free clinical remission for 1 year
	• Proportion of steroid dependent patients
	• Proportion of patients with anemia and malnutrition
	• Proportion of patients currently taking narcotic analgesics
	• Proportion of patients with nocturnal bowel movements, fecal incontinence or leakage
	• Proportion of patients with incontinence in the past month
	• Periodical assessments of quality of life through IBD QoL questionnaires
	• All death attributable to IBD or complications should be discussed multidisciplinary in staff

international guidelines. Participation in the national registry is paramount. The IBD team should include specialized IBD nurses, gastroenterologists, radiologists, surgeons and endoscopists. Both outpatient and inpatient care should be offered. An important measure should include the patients' involvement in decision making and participation in their own care. Ultimately, this initiative can lead to better funding of the centers. An honest discussion between centers and a constant debate within the RCCC should assure the transparency and the scientific weight of such an initiative, allowing negotiation with funding authorities.

We hope that all of those involved in the care of IBD patients will continue to work collaboratively in this process of improving quality of care, and that the creation of excellence centers can be a first step in the effort to deliver better care to our patients.

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