

## Quality Assurance and Patient Safety in the Gastroenterology Unit

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### Editorial

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### Introduction

Hospital in general and gastroenterology unit in particular is a dangerous place. Patients are hospitalized, examined and treated for a very good reason, with a positive effect on their survival and quality of life, but at the same time have adverse events and complications of endoscopic and surgical procedures, missed diagnosis or drug side effects that achieve the opposite. In 3.7% of hospitalizations adverse events may occur, and cause death in 13.6% of them. About third of the mortality cases are associated with negligence [1]. Complications and potential harm of procedures and treatment occur in 12 cases out of 100 hospitalizations; 28% of them are preventable and 1% lethal [2]. Every year 44000 to 98000 patients die in the USA because of adverse events, or 1.8% to 2.4% of 2.4 million hospitalizations every year [3].

This sad information lead the World Health Organization to declare: "To Err is Human", to advance patient safety regulations, quality assurance programs, quality improvement plans, quality indicators development and measurements, and to encourage accreditation organizations around the world.

### Patient Safety

Patients referred to gastroenterology are in danger of miss diagnosis, wrong treatment, and complications of endoscopic procedures. In the first 2 issues gastroenterology service is similar to any other clinical field based on good clinical practice that is medical history, proper physical examination, laboratory tests, and radiological investigation. In this regard, medicine should be based on updated evidence based data and clinical guidelines. Endoscopic procedures are different, and should be treated separately. The process of endoscopy is divided into many stages, and every stage is in danger of failure and unwanted adverse event or side effect. A failure in any stage of this process may end in a bad result, such as perforation in colonoscopy, or massive bleeding after gastric polypectomy. Proper indication, patient pre-sedation and pre-procedure assessment, safety measures of the procedure, proper sedation, and recovery after the procedure will minimize the danger of unwanted events. "Time Out" check list that includes the International Patients Safety Goals (IPSG): patient identity, prevention of infection, prevention of fall, the right patient and procedure, staff communication, and high-risk drug monitoring, is now mandatory in most of the endoscopic units in the Western world. Patient should be followed after the procedure, given useful instructions and open routes for communication with the operating team.

### Quality Assurance

Patients' complains, criticism, or improvement recommendations should be properly addressed. Periodical tracers with a validated questionnaire is recommended, which include retrospective as well as prospective evaluation of team performance. Regular staff meetings are required to collect staff recommendations and to compare experience. Every team member should know and understand the unit function and particular his/her function as a team member. Every team member should be evaluated annually, and his role clearly addressed in the department strategy plan.

Complicated procedures such as stent insertion, endoscopic mucosal resection, endoscopic sub mucosal resection, papilotomy, papilectomy, biopsy through endoscopic ultrasound, are prone to adverse events. Thus, in these procedures only highly trained physicians and nurses should be allowed to participate. When a new procedure is started in the hospital, every step is rehearsed and repeated till all team members know their part. The leader of the new procedure should be trained in an experienced site or bring an experienced endoscopist from outside the hospital to help at the first steps. Committees of the hospital or outside organizations such as the Ministry of Health or JCI are periodically inquiring adverse events or sentinel events in the endoscopy unit. Any deviation from international, national or local benchmarking should be thoroughly examined, and failures corrected.

### Quality Plan

Annual quality improvement plan (QI) is required and includes clinical protocols, instructions for endoscopic procedures and patients and staff safety regulations. Mapping of every step in the following endoscopic procedures is needed: Upper endoscopy, colonoscopy, sigmoidoscopy, endoscopic retrograde cholangio pancreaticography (ERCP), linear and radial endoscopic ultrasound (EUS), biopsy and cytology, histology processing, read back tool for critical results, time-out check list before the procedure, post-procedure assessment (including Aldrate score and falls). Potential failure should be assessed in every step, and a safety solution is mandatory. Benchmarking for success is needed for every procedure. For example, in colonoscopy the preparation quality, complete examination to the cecum or the terminal ileum, retroflexion in the rectum to avoid missing peri-anal lesions, adequate polyp or adenoma finding and removal, American Society of Anesthesiology (ASA) score for every patient and proper sedation, cleaning the endoscopes according to the most demanding guidelines – all these are essentials for a safe and high quality colonoscopy. A new QI is needed every year for continually improving efforts in the endoscopy unit. Prevention of endoscopy complications such as perforation, bleeding and sepsis and of sedation adverse events

is the utmost goal of the QI as the achievement of the clinical aims, such as prevention of cancer development.

## Quality Indicators

Quality indicators help the professional team to assess the quality of clinical processes, and to improve constantly in diagnosis, treatment and safety. There are clinical indicators for process, outcome and service, as well as for patient safety. For the last decade there is emphasize on endoscopy associated indicators, but clinical process other than endoscopic procedure should also be in focus. Thus, every unit should concentrate on several chosen quality indicators which include procedures, service measurements, outcomes and safety and are considered accountable [4,5]. Examples are: Bone mineral density in patients with inflammatory bowel disease [6-11], gastro-protective agents given for high risk patients on non-steroidal anti-inflammatory drugs [12-15], colonoscopy following positive fecal occult blood test [16-18], gastroscopy in patients with reflux and Barrett's esophagus [19-22], documentation of family history of colorectal cancer [23-27], and colonoscopy in these patients [28-30], complete colonoscopy and cecal description or photos, colonoscopy withdrawal time, polyp/adenoma detection rate and proper report and recommendation for follow up [31]. Special projects to improve the indicators, such as enhancing compliance of patients with a positive result of fecal occult blood test to undergo colonoscopy or screening for occult hepatitis C infection, can be performed as part of the department QI.

## Risk Management

Malpractice claims against physicians and health institutions are increasing continuously in the Western world, and become a serious problem in health economy. Strategies for decreasing these claims and reducing financial losses have become an important part of every health plan. Many physicians, avoiding the unpleasant experience of being sued because of negligence, practice defensive medicine, such as assurance behavior or avoidance behavior, as was reported recently among specialists and gastroenterologists from North America and Japan [32,33].

Reporting adverse events and complications should be an integral part of daily routine work in the gastroenterology unit and endoscopy. This strategy is important for preparation of potential claims, assigning dedicated sums of money by the insurance company, establish the benchmarking for adverse events, and for education and systematic improvement of patient safety [34-36].

## Conclusion

Patient safety, quality assurance and risk management are integrated issues of the gastroenterology unit and should be part of daily activity. Every gastroenterology unit should adopt quality indicators and quality improvement plan for advancing the safety of the patients.

## References

1. Leape LL, Brennan TA, Laird N, Lawthers AG, Localio AR, et al. (1991) The nature of adverse events in hospitalized patients. *New Engl J Med* 324: 377-384.
2. Bates DW, Cullen DJ, Laird N, Petersen LA, Small SD, et al. (1995) Incidence of adverse drug events and potential adverse drug events. Implications for prevention. ADE Prevention Study Group. *JAMA* 274: 29-34.
3. Kohn LT, Corrigan JH, Donaldson M (1999) To err is human: Building a safer health system. Washington DC, Institute of Medicine.
4. Cohen AD, Dreier J, Regev-Rosenberg S, Yakovson O, Lieberman N, et al. (2010) [The quality indicators program in Clalit Health Services: the first decade]. *Harefuah* 149: 204-209, 265.
5. Chassin MR, Loeb JM, Schmaltz SP, Wachter RM (2010) Accountability measures--using measurement to promote quality improvement. *N Engl J Med* 363: 683-688.
6. Miheller P, Lorinczy K, Lakatos PL (2010) Clinical relevance of changes in bone metabolism in inflammatory bowel disease. *World J Gastroenterol* 16: 5536-5542.
7. Schulte C, Dignass AU, Mann K, Goebell H (1998) Reduced bone mineral density and unbalanced bone metabolism in patients with inflammatory bowel disease. *Inflamm Bowel Dis* 4: 268-275.
8. Bjarnason I, Macpherson A, Mackintosh C, Buxton-Thomas M, Forgacs I, et al. (1997) Reduced bone density in patients with inflammatory bowel disease. *Gut* 40: 228-233.
9. Lewis NR, Scott BB (2007) Guidelines for osteoporosis in inflammatory bowel disease and celiac disease. London: British Society of Gastroenterology, and World Gastroenterology Organization Global Guideline: Inflammatory bowel disease: a global perspective. *Munich* 1: 23.
10. Bishop N, Brailon P, Burnham J, Cimaz R, Davies J, et al. (2008) Dual-energy X-ray absorptiometry assessment in children and adolescents with diseases that may affect the skeleton: the 2007 ISCD Pediatric Official Positions. *J Clin Densitom* 11: 29-42.
11. Bernstein CN, Fried M, Krabshuis JH, Cohen H, Eliakim R, et al. (2010) World Gastroenterology Organization Practice Guidelines for the diagnosis and management of IBD in 2010. *Inflamm Bowel Dis* 16: 112-124.
12. Pilotto A, Franceschi M, Leandro G, Paris F, Cascavilla L, et al. (2004) Proton-pump inhibitors reduce the risk of uncomplicated peptic ulcer in elderly either acute or chronic users of aspirin/non-steroidal anti-inflammatory drugs. *Aliment Pharmacol Ther* 20: 1091-1097.
13. Yilmaz S, Bayan K, Dursun M, Canoruç F, Kiliç N, et al. (2007) Does adding misoprostol to standard intravenous proton pump inhibitor protocol improve the outcome of aspirin/NSAID-induced upper gastrointestinal bleeding?: a randomized prospective study. *Dig Dis Sci* 52: 110-118.
14. Antman EM, Bennett JS, Daugherty A, Furberg C, Roberts H, et al. (2007) Use of nonsteroidal antiinflammatory drugs: an update for clinicians: a scientific statement from the American Heart Association. *Circulation* 115: 1634-1642.
15. Abraham NS, Hlatky MA, Antman EM, Bhatt DL, Bjorkman DJ, et al. (2010) ACCF/ ACG/AHA 2010 expert consensus document on the concomitant use of proton pump inhibitors and thienopyridines: a focused update of the ACCF/ACG/AHA 2008 expert consensus document on reducing the gastrointestinal risks of antiplatelet therapy and NSAID use. A Report of the American College of Cardiology Foundation Task Force on Expert Consensus Documents. *J Am Coll Cardiol* 56: 2051-2066.
16. Smith RA, Cokkinides V, von Eschenbach AC, Levin B, Cohen C, et al. (2002) American Cancer Society guidelines for the early detection of cancer. *CA Cancer J Clin* 52: 8-22.
17. US. Preventive Services Task Force (2002) Screening for colorectal cancer: recommendation and rationale. *Ann Intern Med* 137: 129-131.
18. (2010) National Committee for Quality Assurance (NCQA) HEDIS® 2011: Healthcare Effectiveness Data and Information Set. Volume 1, narrative Washington (DC): National Committee for Quality Assurance (NCQA).
19. (2007) American Gastroenterological Association Institute, Physician Consortium for Performance Improvement®, National Committee for Quality Assurance. Gastro esophageal reflux disease (GERD) physician performance measurement set. Chicago (IL): American Medical Association, National Committee for Quality Assurance 9: 9.
20. Grover M, Strickland C, Kesler E, Crawford P (2006) How should patients with Barrett's esophagus be monitored? *J Fam Pract* 55: 243-247.

21. Sampliner RE, Practice Parameters Committee of the American College of Gastroenterology (2002) Updated guidelines for the diagnosis, surveillance, and therapy of Barrett's esophagus. *Am J Gastroenterol* 97: 1888-1895.
22. (2000) Management of Barrett's esophagus. The Society for Surgery of the Alimentary Tract (SSAT), American Gastroenterological Association (AGA), American Society for Gastrointestinal Endoscopy (ASGE) Consensus Panel. *J Gastrointest Surg* 4: 115-116.
23. Sifri RD, Wender R, Paynter N (2002) Cancer risk assessment from family history: gaps in primary care practice. *J Fam Pract* 51: 856.
24. Emery J, Rose P (1999) Expanding the role of the family history in primary care. *Br J Gen Pract* 49: 260-261.
25. Smith RA, von Eschenbach AC, Wender R, Levin B, Byers T, et al. (2001) American Cancer Society guidelines for the early detection of cancer: update of early detection guidelines for prostate, colorectal, and endometrial cancers. *CA Cancer J Clin* 51: 38-75.
26. Murff HJ, Greevy RA, Syngal S (2007) The comprehensiveness of family cancer history assessments in primary care. *Community Genet* 10: 174-180.
27. Qureshi N, Wilson B, Santaguida P, Carroll J, Allanson J, et al. (2007) Collection and use of cancer family history in primary care. *Evid Rep Technol Assess (Full Rep)* 1-84.
28. Armelao F, Orlandi PG, Tasini E, Franceschini G, Franch R, et al. (2010) High uptake of colonoscopy in first degree relatives of patients with colorectal cancer in a healthcare region: a population-based, prospective study. *Endoscopy* 42: 15-21.
29. Menges M, Fischinger J, Gärtner B, Georg T, Woerdehoff D, et al. (2006) Screening colonoscopy in 40- to 50-year-old first-degree relatives of patients with colorectal cancer is efficient: a controlled multicentre study. *Int J Colorectal Dis* 21: 301-307.
30. Hlavaty T, Lukac L, Huorka M, Bezayova T, Duris I (2005) Positive family history promotes participation in colorectal cancer screening. *Bratisl Lek Listy* 106: 318-323.
31. Kahi CJ, Vemulapalli KC, Johnson CS, Rex DK (2014) Improving measurement of the adenoma detection rate and adenoma per colonoscopy quality metric: the Indiana University experience. *Gastrointestinal Endoscopy* 79: 448-454.
32. Studdert DM, Mello MM, Sage WM, DesRoches CM, Peugh J, et al. (2005) Defensive medicine among high-risk specialist physicians in a volatile malpractice environment. *JAMA* 293: 2609-2617.
33. Hiyama T, Yoshihara M, Tanaka S, Urabe Y, Ikegami Y, et al. (2006) Defensive medicine practices among gastroenterologists in Japan. *World J Gastroenterol* 12: 7671-7675.
34. Niv Y, Gershtansky Y, Kenett RS, Tal Y, Birkenfeld S (2011) Complications in endoscopic retrograde cholangiopancreatography (ERCP) and endoscopic ultrasound (EUS): analysis of 7-year physician-reported adverse events. *Drug Healthc Patient Saf* 3: 21-25.
35. Niv Y, Gershtansky Y, Tal Y, Kenett R, Birkenfeld S (2011) Analysis of 7-year physician-reported adverse events in colonoscopy. *Eur J Gastro Hepathol* 23: 492-498.
36. Niv Y, Gershtansky Y, Tal Y, Kenett RS, Birkenfeld S (2012) Analysis of 7-year physician-reported adverse events in esophagogastroduodenoscopy. *J Patient Saf* 8: 65-68.