Colonoscopy performance measurement study

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Abstract

Aim: Examine ambulatory colonoscopy performance.

Methods: Participating organizations provided organizational, process, and follow-up patient data via surveys over six months.

Results: 98% of cases had adequate bowel preparation. 95% of organizations included all recommended pre-sterilization/ high level disinfection [HLD] processes. Less than 85% followed all sterilant fluid testing steps. Median pre-procedure time (check-in to "scope in") was 62 minutes. Median post-procedure time ("scope out" to discharge criteria met) was 40 minutes. 3% of cases were complicated/non-routine; 1.8% involved hypotension/hypoxia. 98% of patients would have another colonoscopy.

Discussion: Opportunities include decreasing procedure time variation and complying with sterilant testing guidelines.

Keywords: Colonoscopy, Ambulatory surgery center, Bowel preparation, Colonoscope processing, Procedure time, Complications, Non-routine cases, Hypotension, Hypoxia, Patient outcomes.

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Introduction

Colorectal cancer is the second leading cause of death due to cancer in the United States. [1] Colonoscopy is a sensitive method to detect colorectal neoplasia and prevent deaths from colon cancer. [2, 3] In 2006, of the almost 6.25 million colonoscopy procedures performed in the United States (US) in the ambulatory setting, approximately two thirds (almost 3.7 million) were performed in freestanding facilities. [4]

Among the issues studied was adequacy of bowel preparation. Recent reviews indicate that detection of polyps greater than 5 mm polyp size threshold would identify over 95% of subjects with advanced adenomas. [5] Inability to complete colonoscopies or identify polyps greater than 5 mm in size because of poor bowel preparation can lead to procedure cancellation or shorter follow up times. This not only raises the direct costs, but also increases the risk to patients. [6, 7, 8]

Colonoscope processing was also examined in this study. Colonoscope processing has been the subject of clinical practice guidelines from national professional societies and the United States government. [9, 10] Proper colonoscope processing is critical to prevention of healthcare associated infections and has been a persistent patient safety issue. Published estimated direct costs of failed colonoscope processing are based on healthcare-acquired infections (HAIs), with surgical site infection (SSI) and CDI (clostridium difficile) being most appropriate for colonoscopy-associated infections. The US Centers for Disease Control and Prevention reports low estimates of cost of SSIs of $10, 433 per infection in 2005 dollars and high estimates at $25,546 in 2002 dollars. For CDI the low estimate is $5,042 and the high is $7,179, in 2003 dollars. [11] In 2006, Nelson and Muscarella reported that "in the absence of defective equipment, every reported case of nosocomial infection associated with a contaminated GI endoscope has been linked to a specific breech or violation of at least one of several requisite reprocessing steps." [12] In their 2008 review of the literature, Seoane-Vazquez and Rodriguez-Monguio concluded that "although the risk of endoscopy-related infection is very low, continued efforts are needed to ensure that quality is maintained during endoscope reprocessing to reduce the incidence of endoscopy-related infections." [13] In 2009, the US Office of the Inspector General (OIG) of the Department of Veteran Affairs (VA) investigation of failures in endoscope processing at three facilities (2 involving colonoscope processing) uncovered several issues associated with endoscope processing. "Issue 1" was the "absence of colonoscope model-specific reprocessing SOPs (standard operating procedures) and/or competence records." Estimated VA colonoscope reprocessing compliance with competence was approximately 1 of 2 (50.2%) across VHA (Veterans Health Administration) colonoscope reprocessing units and compliance with SOPs was 77.9%; compliance with both was 47.4%. [14]

"Procedure times" were also studied. Procedure times may be indicative of not just efficiency but also safety and patient satisfaction. The pre-procedure or "wait" time can be associated with patient satisfaction. The post-procedure or "discharge time" (the patient meets discharge criteria—not when the patient's ride arrived) may signify over-medication during the procedure.

Data were also collected on intra-procedure complication rates. Certain published complication rates for colonoscopy are not high (for example: bowel perforation occurs in 1 in 1400 for overall colonoscopies and 1 in 1000 for therapeutic colonoscopies), while other rates, such as hypotension and hypoxia, have been acknowledged for a couple of decades and can reach or exceed 15%. [15, 16]

One of the measures of patient outcomes used in the study was patients' willingness to have another colonoscopy, if their physician recommended one. Because of the ability to detect colorectal cancer at early stages and prevent increased morbidity and mortality, it is important that patients are willing to have colonoscopies, as recommended in clinical practice guidelines. Despite some negative public perceptions about the nature of the procedure, recent literature shows high patient satisfaction. [17]

Methods

Participant Recruitment

The AAAHC Institute for Quality Improvement solicited, via mail and electronic mail (email), participation from the Accreditation Association for Ambulatory Health Care (AAAHC) accredited organizations, those who had participated in previous AAAHC

Institute colonoscopy studies, members of the American Gastroenterological Association (AGA), as well as the wider population through the AAAHC Institute website (www.aaahciqi.org). Seventy-six organizations voluntarily registered for the study. Sixty-five organizations (representing more than 255, 104 colonscopies annually) supplied data. Annual colonscopy volume ranged from 80 to 12,600. Almost four fifths (78%) of the participating organizations were single specialty centers; the rest were multi-specialty centers.

Data Collection

Data were collected, via standardized survey instruments, and entered in secure online internet surveys, from January through June 2010. All cases were collected during the same six-month period to avoid issues with "historical" factors such as changing prices and technology. Participating organizations completed a "General Information" survey, describing their organization and its practices, as well as "Procedure Specific" surveys, which included documentation of patient attributes (ASA classification [18] and indication for the procedure), specific procedures' processes of care, and patient outcomes, via a telephone follow-up survey with patients 72 hours post-procedure. Organizations were asked to complete surveys for at least 15 to 25 cases. [19] Cases matching the procedure codes were assigned by a manager, so that the organization submitted a sampling of procedures to form a composite profile of the practice. If organizations had more than one endoscopist, they were encouraged to use data from two or more of their endoscopists. To avoid retrospective chart reviews, and obtain the most complete and accurate data, all documentation of processes of care were completed concurrently (in real time).

Data Review

A total of 1991 completed colonoscopy surveys were entered online and reviewed for accuracy and completeness. Each case was reviewed in detail to ensure that the responses accurately represented a potential profile for the procedure identified. Cases that appeared to include inconsistent data or outliers, or that had a small number of missing values, were checked with participating organizations to maximize completeness and consistency. The 61 complicated or non-routine cases which were submitted were not included in analyses because they might skew results; however, these procedures are described in the Results section below. A total of 1930 submitted surveys were used for aggregate (grouped) analyses. In the benchmark (comparison) procedure time analyses, for which a minimum 15 cases per organizations was required by the AAAHC Institute, 1863 cases from 60 organizations were used. [19]

Patient Attributes

For 99% (1910/1930) of the cases, ASA classifications were assigned; 91% of patients were classified ASA 1 or 2. [18] All cases had indications for the procedure listed – many had multiple indications listed. The most frequently listed indication for the procedure was "preventive screening" (37%). Unexplained GI bleeding (hematochezia, non-upper GI source melena, fecal occult blood) and patient history of neoplastic polyp/treatable cancer were the second and third most frequently listed indications for the procedure.

Results

Results described here are part of a more extensive report. [20]

Adequacy of Bowel Preparation

The primary types of bowel preparation (used in 100 or more cases), were (in order of frequency): PEG (polyethylene glycol) solutions, Miralax, Moviprep, Dulcolax or Bisacodyl, and magnesium citrate. For 98% of cases (all but 26), bowel preparation was considered to be adequate. For the 26 cases with inadequate bowel preparation, 20 had a shorter recommended follow-up period and 6 had no change in follow-up. Four cases, which were cancelled due to poor bowel preparation, were included in the non-routine, complicated cases and not included in other analyses for this report.

Colonoscope Processing Prior to High Level Disinfection / Sterilization

For 61 (95%) of the 64 responding organizations, scope reprocessing includes all of the following clinical practice guideline recommended processes, prior to sterilization or high level disinfection (HLD) (numbers after each process indicate the number of organizations reporting that they employed that particular process): leak testing (63); cleaning with an enzyme cleaner that is compatible with the scope (62); flushing and brushing all channels and ports (62): cleaning all external surfaces and accessories (64); and cleaning residue/debris until no more debris appears on cleaning brushes (64).

Colonoscope Sterilant Testing and Replacement

Testing the liquid sterilant/high-level disinfectant to ensure minimal effective concentration of the active ingredient is also recommended by clinical practice guidelines. 53 (or 54 – please see the last line of this paragraph) of the 64 (83% or 84%) responding organizations indicated that they comply with all of the following recommended steps (numbers after each process indicate the number of organizations reporting that they employed that particular process): test at least every day of use (26) and(6)/or test prior to each cycle/use (32); use the manufacturer's recommended chemical indicator (55); document the results of testing (58); discard the solution if the chemical indicator shows the concentration is less than the manufacturer's minimum effective concentration (58); and discard the solution if it is beyond the manufacturer's recommended shelf or use- life (57). The last recommendation is from the Centers for Disease Control and Prevention (CDC) 2008 guidelines but is not addressed in the latest revisions to multi-society guidelines.

Pre-Procedure Time

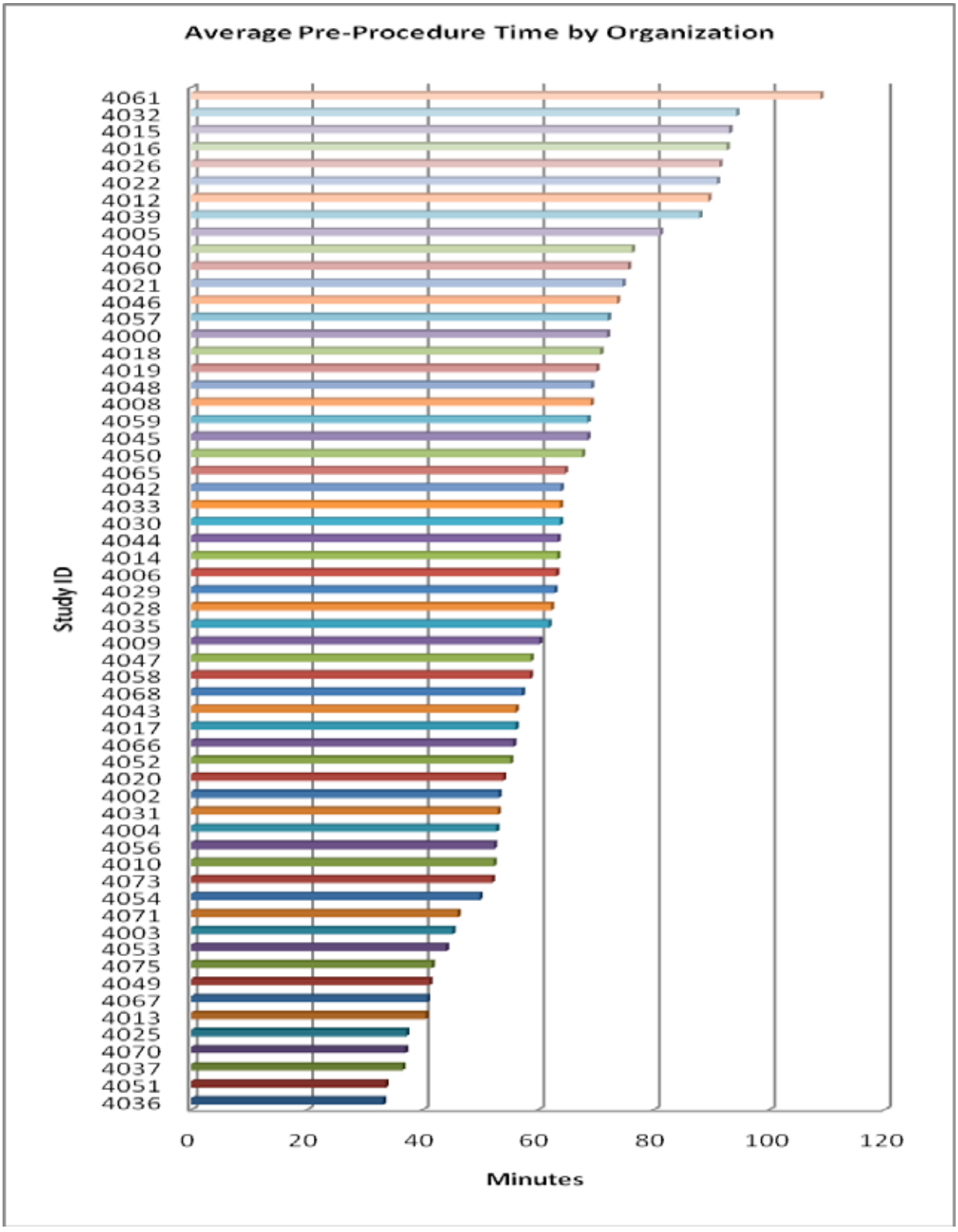
Pre-procedure time was defined as the time from the patient's checking into the facility to the time the procedure began (the scope is inserted). The median pre-procedure time overall was 62 minutes; the range was from 33 to 109 minutes. Please refer to Figure 1.

The time between when the patient has arrived at the procedure room and when the procedure starts is included in the "pre-procedure" time because some organizations may be shifting the wait time from the patient waiting area to the procedure room itself. If the wait in the waiting area is short, but the wait in the procedure room is long, patient satisfaction may suffer and facility times (and associated cost to the organization) will remain higher.

Pre-procedure time may be influenced by how early or late patients arrive. Patients who arrive very early may contribute to a longer average pre-procedure time, and those who arrive very close to the procedure time, or who are "moved up" in the schedule because of a cancellation, may decrease the average pre-procedure time.

At Organization 4036, which has the shortest average pre-procedure time:

- Patients come into the office to be worked up (i.e., medication list is obtained, medical history, etc.) prior to procedure day.
- Staff works together to turn rooms around for the next patient.
- Front desk staff communicates with endoscopy personnel with walkie talkies to let them know as soon as a chart is up and they may have the patient. There is an assigned "traffic director" each day to keep the flow going and make sure patients are brought back as soon as possible.



- Organization 4051 has the second shortest pre-procedure time. In addition to an efficient team, they attribute this to:
- Greeting the patient and their driver as soon as they arrive and check in.
- The nurse bringing the patient back to the admission area. This time is one half hour before the procedure is to begin.
- A "calming team" getting the patient changed, documents signed, intravenous lines started, procedure explained, etc.
- Two or more staff members helping to get the procedure room ready to expedite staying on time as scheduled.

At Organization 4037, which has the third shortest average pre-procedure time:

Nurses give patients courtesy calls prior to their procedures to remind them of their arrival time, review their history, and allow patients to express any concerns.

- The center instructs patient to arrive 30 minutes prior to their appointment to allow for intake and any patient delays.

- They have a computerized charting system that follows the patient from their primary physician visit to discharge from procedure. The system allows nurses and doctors to easily access patient information, make appropriate changes, and document the procedure.
- Patients' consents and concerns are reviewed and signed at the pre-procedure visit. The nurse only needs to address new concerns and questions prior to procedure.
- Their physicians are scheduled in blocks of time to allow minimal delays between physician schedules.
- If the pre-post-procedure nurse is available, she transports the patient to and from the pre-post-procedure area. Their technician assists the nurse with room turnover.

Discharge Time

Discharge time is defined as the time the procedure finishes (the scope is out) to the time the patient meets discharge criteria. The overall median discharge time was 40 minutes, with a range of 20 to 81 minutes. Please refer to Figure 2. Please note that the definition of discharge time used for this study is from the time the procedure finishes to the time the patient is ready for discharge – not to the time the patient's ride has arrived.

In addition to contributing to overall facility time (and the associated cost to the organization), longer discharge times may be indicative of inappropriate choices or levels of anesthesia for the patient, discharge criteria that are too strict, or staff not checking patients against discharge criteria frequently enough. Discharge times may also be longer if discharge instructions are being reviewed with patients/family for the first time or have not been provided in written form.

With the shortest average discharge time, at Organization 4039:

- The medicating nurse administers an initial intravenous sedation dose and titrates accordingly for patient comfort and moderate sedation until the cecum is visualized. Once the cecum is reached, no further sedation medication is routinely administered, unless ordered otherwise by physician.
- Immediately following procedure, the patient is taken to the recovery area by the medicating nurse and post-operative nurse.
- The post-procedure nurse then continuously uses verbal stimuli to wake the patient from sedation.
- The family is brought to the bedside to assist.
- The post-procedure nurse and post-procedure patient ratio is a one to one; this allows continuous bedside assistance (i.e. water, vitals, etc.).
- If no spontaneous flatus is present within an average of the first 10 minutes or so and/or the patient has discomfort or cramping, the post-operative nurse may place a rectal tube to assist with the removal of air.

Organization 4071 attributes its relatively low average discharge times to having an anesthesiologist onsite who delivers sedation. The majority of patients receive Propofol, for a quick onset and a very short half life. This helps the gastroenterologist facilitate the procedure due to additional relaxation of the colon and the patient recovers faster, with less nausea and vomiting, allowing the organization to discharge the patient earlier.

With the third lowest discharge time, Organization 4066, believes this is due to teamwork and:

- Physicians speaking after every procedure to family and ordering discharge in a timely manner.
- Excellent sedation management and delivery skills of the nurse.
- Having discharge nurses experienced in recognizing the signs and symptoms of sedation medications.
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Intra-Procedure Complications / Non-Routine Procedures

Four cases which were cancelled due to poor bowel prep were included in the non-routine, complicated cases and not included in other analyses for this report. 57 other cases were listed as complicated or non-routine. The three most frequent descriptions were:

- Hypotension (21 – 2 with hypoxia)
- Hypoxia (12)
- Extended recovery (11 – 1 with hypoxia, 3 with nausea, and 3 with retained gas)

Please note that oxygen was used in 83% of cases submitted (1603/1930). Most frequently mentioned reasons for oxygen use were:

- Routine or standard protocol (as a prophylactic, routinely, for all patients, with anesthesia or sedation, as policy, etc…) (1098).
- Maintenance of appropriate blood oxygen saturation/blood oxygen de-saturation was experienced (246).

Additionally, participating organizations were monitoring most patients for hypotension and hypoxia:

In nearly 100% (1,918) of cases, participants indicated that blood pressure was monitored.

- A pulse oximeter was used in 99% (1,903) of cases.

Another Colonoscopy

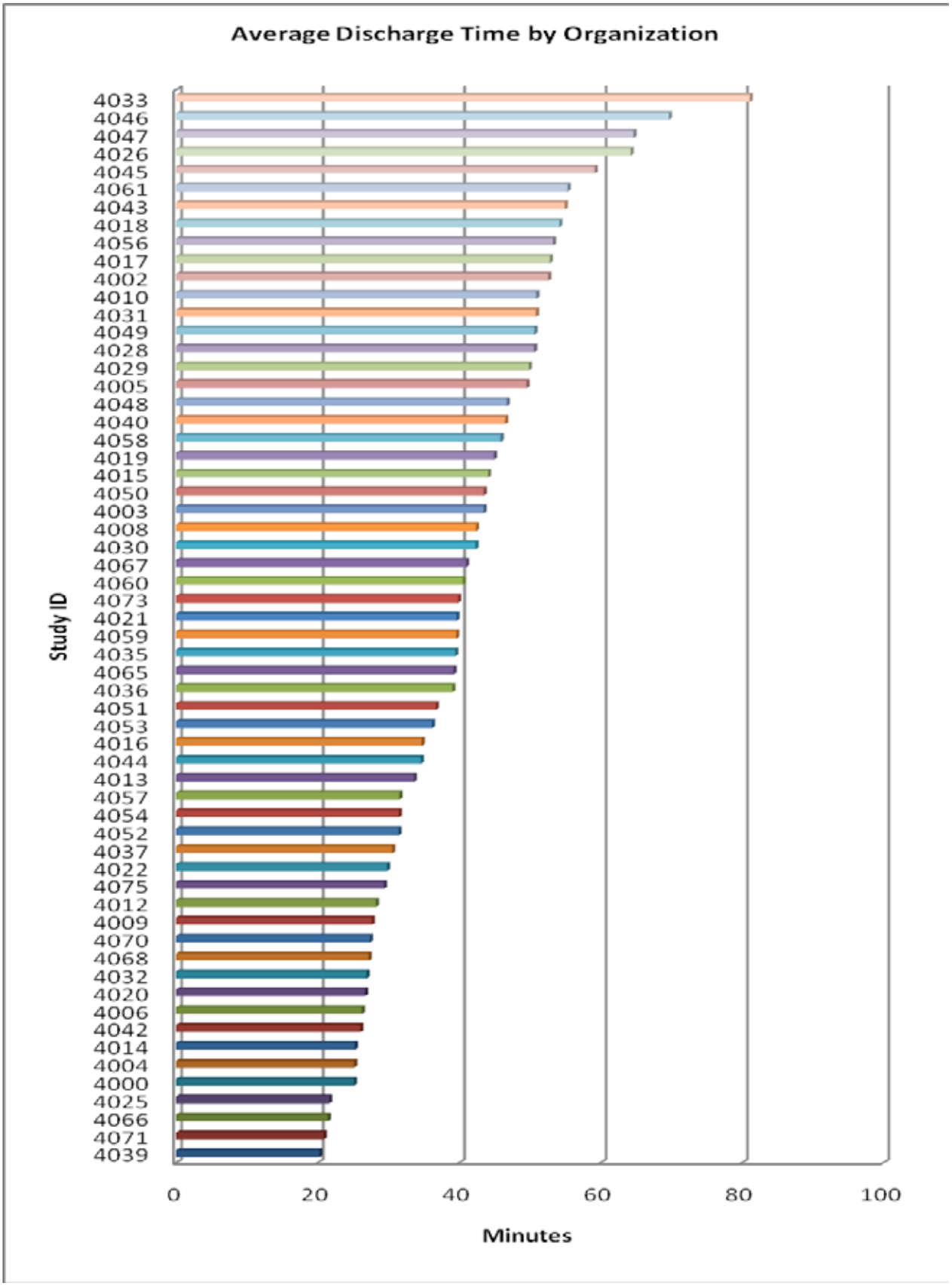
Within 72 hours of their colonoscopies, approximately 74% (1,419) of patients were contacted to obtain information about the outcomes of their procedures. In addition to several other questions, patients were asked: "If recommended by your physician, would you have another colonoscopy in the future?" "If 'no,' why?"

All but 5 patients answered this question. Of those who answered, 98% (all but 34) said they would do so. For those who would not have another colonoscopy, their reasons were:

- Bowel preparation (14)
- Past recommended age for colonoscopy (13)
- No reason (2)
- "Once was enough" and "don't want to do again" (2)
- Pain (2)
- "No need" (1)

Discussion

Adequacy of bowel preparation (98%) and compliance with recommended processes used to prepare colonoscopes for high level disinfection or sterilization (95%) is high. Also, patients' willingness to have the procedure again, if recommended by their physicians is very high (98%).



Monitoring blood pressure and blood oxygen saturation is almost uniform (nearly 100% and 99% respectively). Most of the "complicated" cases were those where patients experienced hypotension and/or hypoxia. Oxygen appears to be used in the majority of cases (83%); it is possible that a higher level of "routine" oxygen administration might lower the number of cases with hypoxia. [21, 22]

Areas with clear opportunities for improvement are sterilant testing/replacement and procedure times. Less than 85% compliance rates for sterilant or high level disinfectant fluid testing and replacement indicates the opportunity for additional education and improved performance. In addition, as Figures 1 and 2 show, there is great variation in average pre-procedure and discharge time by organization. Those organizations with the shortest times offer many

suggestions for decreasing these times, including common themes. Themes include preparing before the patient arrives and enough staffing to keep the patient moving through to the procedure room, as well as to use of sedation that allows the patient to be recovering when going into the PACU and attentive PACU staff.

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19. However, analyses indicate that 25 to 35 cases for the same procedure/diagnosis should provide a statistically accurate picture of a physician's practice regarding that procedure/diagnosis. This assumes organizations' patients are statistically independent, which is unlikely (Landon BE, Normand ST, Blumenthal D, Daley J. Physician Clinical Performance Assessment: Prospects and Barriers. ***JAMA*** 2003; **290**:1183–1189), so even larger samples would be necessary for statistical accuracy. Instead, organizations participating in AAAHC Institute studies are asked to review their performance from year to year to develop a composite of their performance.
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