Evaluating screening colonoscopy quality in an uninsured urban population following patient navigation

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A B S T R A C T

Patient navigation (PN) increases screening colonoscopy completion in minority and uninsured populations. However, colonoscopy quality is under-reported in the setting of PN and quality indicators have often failed to meet benchmark standards. This study investigated screening colonoscopy quality indicators after year-one of a PN initiative targeting the medically uninsured. This was a retrospective analysis of 296 outpatient screening colonoscopies. Patients were 45 to 75 years of age with no history of bowel cancer, inflammatory bowel disease, or colorectal surgery. The screening colonoscopy quality indicators: adenoma detection rate (ADR), cecal intubation rate (CIR), and bowel preparation quality were compared in 89 uninsured Federally Qualified Health Center (FQHC) patients who received PN and 207 University Hospital patients who received usual care. The FQHC PN and University Hospital cohorts were similar in female sex (69% vs. 70%; p = 0.861) and African American race (61% vs. 61%; p = 0.920). The FQHC PN cohort was younger (57 years vs. 60 years; p < 0.001). There was no difference in ADR (33% vs. 32%; p = 0.971) or CIR (96% vs. 95%; p = 0.900) comparing the FQHC PN and University Hospital cohorts. The FQHC PN patients had a greater likelihood of an optimal bowel preparation on multivariate logistic regression (odds ratio 4.17; 95% confidence interval 1.07 to 16.20). Uninsured FQHC patients who received PN were observed to have intra-procedure quality indicators that exceeded bench-mark standards for high-quality screening colonoscopy and were equivalent to those observed in an insured University Hospital patient population.

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1. Introduction

Colorectal cancer (CRC) continues to be a major public health problem that is responsible for >50,000 deaths each year in the United States (Society, n.d.). Completion of guideline-consistent CRC screening significantly reduces CRC related mortality (Lansdorp-Vogelaar et al., 2012; Zauber et al., 2012). Unfortunately, CRC screening rates are disproportionately lower within medically uninsured and minority populations, compared to insured white Americans (Murphy et al., 2014; Joseph et al., 2012; Kl bunde et al., 2011; Shapiro et al., 2008; Cooper and Koroukian, 2004; Bromley et al., 2015; Williams et al., 2016). CRC screening disparities are believed to be a major driver of the gaps in CRC related mortality observed among underserved populations (Lansdorp-Vogelaar et al., 2012; Cooper and Koroukian, 2004; May et al., 2015; Ayanian, 2010).

To combat disparities in CRC related mortality, numerous interventions have been undertaken to increase CRC screening use within uninsured and minority populations (Powe et al., 2010; Holden et al., 2010; Gawron et al., 2013). Among them, patient navigation (PN) interventions have proved to be an effective means of increasing screening test completion for fecal occult blood testing, sigmoidoscopy, and screening colonoscopy (Paskett et al., 2011). More specifically, within minority patient populations, PN interventions have increased screening colonoscopy completion rates by as much as 40% (Naylor et al., 2012).

Historically, PN interventions have utilized screening colonoscopy completion as their primary outcome measure (Ritvo et al., 2015; Percac-Lima et al., 2014; Jandorf et al., 2013; Myers et al., 2014; Braschi et al., 2014; Percac-Lima et al., 2009; Christie et al., 2008; Nash et al., 2006). However, the effectiveness of screening colonoscopy is dependent upon complete examination of the colon with intubation of the cecum and adequate mucosal inspection, thereby allowing for the detection of cancerous and pre-cancerous lesions. As a result, gastroenterology professional societies have promoted the cecal intubation rate (CIR) and adenoma detection rate (ADR) as quality indicators for...
screening colonoscopy (Rex et al., 2015). Cecal intubation is defined as the passage of the colonoscope tip to a point proximal to the ileocecal valve. A CIR of ≥95% is the suggested target for high quality screening colonoscopy. The ADR represents the proportion of patients undergoing a complete screening colonoscopy that have one or more adenomatous polyps. The ADR is the single most accepted CRC prevention related quality indicator and ADRs ≤20% have been associated with increased risk of interval CRC following screening colonoscopy completion (Rex et al., 2015; Kaminski et al., 2010; Baxter et al., 2011; Corley et al., 2014). Currently, a minimum target for overall ADR of at least 25% is recommended for average risk screening colonoscopy. When PN interventions have reported ADRs, the results have varied from as high as 27%, to as low as 8.1% (Lebwohl et al., 2011a; Chen et al., 2008; Lasser et al., 2011; Wolf et al., 2015; Lane et al., 2013; Xirasagar et al., 2014).

The CIR and ADR are directly impacted by the degree of bowel cleansing at the time of colonoscopy. Impaired mucosal inspection owing to suboptimal bowel preparation has been linked to decreased detection of both neoplastic lesions and pre-cancerous adenomas (Harewood et al., 2003; Froehlich et al., 2005). Furthermore, suboptimal preparation leads to increased healthcare-related costs due to prolonged procedure duration and the need for an early repeat colonoscopy (Rex et al., 2002; Lebwohl et al., 2011b). Several patient related factors have been identified as predictors of suboptimal bowel preparation including advanced age (Appannagari et al., 2014; Lebwohl et al., 2010), male sex (Appannagari et al., 2014; Lebwohl et al., 2010; Ness et al., 2001), African American race (Appannagari et al., 2014), public versus private insurance (Rex et al., 2002; Lebwohl et al., 2010; Nguyen and Wieland, 2010; Denberg et al., 2005), lack of health insurance (Rex et al., 2002), and the completion of an afternoon colonoscopy (Appannagari et al., 2014; Lebwohl et al., 2010; Ness et al., 2001). Uninsured and minority populations may inherently embody many of these risk factors thus increasing their likelihood of completing a colonoscopy that is limited due to suboptimal bowel cleansing. This is particularly pertinent to the use of colonoscopy as a CRC screening strategy within underserved communities where resource allocation and cost-containment are paramount.

Therefore, the objectives of this study were to assess the intra-procedure screening colonoscopy quality indicators: bowel preparation description, cecal intubation, and adenoma detection among uninsured patients from Federally Qualified Health Centers (FQHC) who received PN and University Hospital patients who received usual care.

2. Materials and methods

2.1. Study design

This study is a retrospective analysis of outpatient screening colonoscopy procedures scheduled or performed at the University of Chicago Medicine (UCM), beginning 08/01/2012 through 07/01/2013. The UCM institutional review board approved the research protocol (IRB13-0670). All patients who were scheduled for or completed an outpatient screening colonoscopy performed by either of two board-certified gastroenterologists between August 2012 and July 2013 were eligible for inclusion in the study. Screening colonoscopy procedures were identified through ICD-9 codes: V76.51 (Special screening for malignant neoplasms of the colon); V12.72 (Personal history of adenomatous polycy); V16.0 (Family history of malignant neoplasm of gastrointestinal tract); and V18.51 (family history, adenomatous colonic polyps). Exclusion criteria included: age <45 years or >75 years; history of inflammatory bowel disease; history of colon or rectal cancer; history of a hereditary colon cancer syndrome; history of colorectal surgery; incomplete colonoscopy due to complex anatomy (colon tortuosity); and a clinic encounter in the UCM Gastroenterology clinic within 6 months of their colonoscopy procedure date. A lower age limit of 45 years was utilized due to the predominately African American population, in accordance with 2008 American College of Gastroenterology CRC screening guidelines (Rex et al., 2009).

Colonooscopy-related sedation medications consisted of intravenous Midazolam and Fentanyl, which were administered by the attending gastroenterologist. A description of bowel preparation and photographic confirmation of cecal intubation were documented by the attending gastroenterologist using commercially available procedure documentation software, ProVation MD (ProVation® Medical Minneapolis, MN). The bowel preparation was described using the Aronchick Bowel Preparation Scale: excellent, good, fair, or poor (Aronchick et al., 1999). The procedure documentation software also included subjective bowel preparation descriptors such as adequate, inadequate, and unsatisfactory. In accordance with prior studies evaluating colonoscopy preparation, bowel preparation quality was dichotomized to either optimal (excellent, good, or adequate) or suboptimal (fair, poor, unsatisfactory, or inadequate) (Harewood et al., 2003; Lebwohl et al., 2011b). All patients who completed a colonoscopy were provided a procedure report detailing their exam findings and recommendations. Patients and their referring physicians were notified of pathology results by telephone or a mailed letter.

2.1.1. University hospital population

The UCM is a large tertiary-care medical center in Illinois, located within a primarily African American community area on the City of Chicago’s south side. Scheduling of outpatient endoscopy procedures was managed through an open-access endoscopy referral system (Eisen et al., 2002). Through the open-access referral system, UCM-affiliated physicians were able to request and schedule colonoscopies without pre-approval or consultation by a gastroenterologist. Scheduling of all open-access colonoscopies was managed through a dedicated scheduling telephone-line by procedure scheduling coordinators who were employed through the UCM Section of Gastroenterology. The standard practice for bowel preparation during the study interval was a clear liquid diet, 10 mg oral Bisacodyl, and either a single four-liter dose of polyethylene glycol (GoLYTELY®) or a single 238 g dose of MiraLAX® in 64 oz of a balanced electrolyte solution such as Gatorade. Single versus split-dosing of preparations was not recorded in the medical record. However, during the study interval, split-dosing was not standard practice and colonoscopy bowel preparation instructional handouts detailed single-dose preparation instructions exclusively.

2.1.2. FQHC patient navigation population

Beginning August 2012, the American Cancer Society (ACS) collaborated with hospitals throughout Illinois to sponsor the statewide Colorectal Cancer Screening Initiative (CRCSI). The goal of the CRCSI was to increase CRC screening among the medically uninsured. Participation in the CRCSI was open to all medically uninsured Illinois residents who were age appropriate for guideline-consistent CRC screening. CRCSI participants received education regarding CRC screening modalities including: fecal occult blood test, barium X-ray, flexible sigmoidoscopy, and screening colonoscopy. Participants were able to complete their preferred CRC screening test modality at no personal cost through their primary care provider or at CRCSI participating hospitals.

Through the CRCSI, the UCM Section of Gastroenterology established new partnerships with two Chicago south side based FQHCs, Englewood Community Health and Mercy Family Health Center, to provide screening colonoscopy services for CRCSI participants. The CRCSI sponsored UCM-FQHC partnership utilized community-based patient navigators, who were trained by the ACS to work closely with patients to reduce structural barriers to screening. The patient navigators were present on-site at the two partnering FQHCs. FQHC-based primary care providers identified their patients who were appropriate for average-risk CRC screening and directed them to meet with CRCSI navigators to discuss participation in the program. Patients who chose screening colonoscopy received on-site PN including: education regarding the colonoscopy procedure; review of bowel preparation instructions.
including dietary restrictions; assistance with procedure scheduling; as well as transportation assistance and appointment reminders. FQHC PN participants were given colonoscopy bowel preparation instructions to complete a single-dose four-liter GoLYTELY® preparation. The instructional handout was identical to the handouts used by University Hospital patients. FQHC PN participants did not have contact or communication with UCM gastroenterologists prior to the date of their screening colonoscopy.

2.2. Statistical analysis

Continuous variables were compared using the Kruskal-Wallis equality-of-populations rank test. Categorical variables were analyzed using the Pearson Chi-square, Fisher’s exact test, or logistic regression where appropriate.

The study covariates included patient demographic characteristics: age (years), sex (male or female), race (White, Black/African American, Asian/Pacific Islander, or Other), Insurance (Private, Medicare, Medicaid, Charity Care, or Uninsured), and participation in FQHC PN; screening colonscopy characteristics: indication (average risk, history of polyps, or family history of CRC), timing (morning or afternoon), bowel preparation medication (GoLYTELY® or MiraLAX®), endoscopist (endoscopist #1, endoscopist #2, or other); and the study outcomes: optimal bowel preparation (yes or no), cecal intubation (yes or no), and adenoma detection (yes or no). Covariates found to be significantly associated with optimal bowel preparation at p < 0.10 in univariate analysis were further examined using multivariate logistic regression. Finally, interaction terms were tested to examine the multiplicative effects of covariates on optimal bowel preparation. All analyses were performed using StataMP version 14 (StataCorp CP College Station, TX). A two sided p-value < 0.05 was considered statistically significant.

3. Results

During the study interval, a total of 456 outpatient-screening colonoscopies were completed. One-hundred-sixty-three colonoscopies did not meet the inclusion criteria. Of those, 100 University Hospital related colonoscopies were excluded due to patient age less than forty-five years or greater than seventy-five years and 58 colonoscopies were excluded as a result of non-screening related indications such as chronic diarrhea, anemia, hematochezia, etc. Overall, 2 FQHC-PN related colonoscopies were excluded; one due to history of a partial colon resection and one colonoscopy was incomplete secondary to tortuosity of the colon. Two-hundred-ninety-six colonoscopies satisfied pre-defined inclusion and exclusion criteria. Of those, 207 (70%) were colonoscopies completed on University Hospital patients and 89 (30%) were FQHC PN-related colonoscopies.

Patient demographics and colonoscopy characteristics are summarized in Table 1. The mean age of the study population was 59 years, 69% of patients were female, and 61% were of African American race. Thirty-nine-percent of patients were privately insured, 26% Medicare, 4% Medicaid, and 31% were uninsured. Of the 93 patients (31%) who were uninsured, 89 patients (30%) completed FQHC PN-related colonoscopies and 4 (2%) were University Hospital patients who received usual care. There was no difference comparing the FQHC PN and University Hospital cohorts with respect to female sex (69% vs 70%; p = 0.861) or the proportion of patients of African American race (61% vs. 61%; p = 0.913). The FQHC PN participants were of a younger mean age (57 years vs. 60 years; p = 0.001) compared to the University Hospital cohort.

The primary indication for colonoscopy was average risk CRC screening (78%). Overall in the study population, the timing of colonoscopy procedures were equally distributed in the morning and afternoon (50% vs. 50%). A greater proportion of FQHC PN-related colonoscopies were performed in the afternoon, compared to the University Hospital cohort (57% vs. 30%; p = 0.001). >80% of the total study population completed a GoLYTELY® based bowel preparation. Endoscopist #1 performed a greater proportion of the University Hospital-related colonoscopies than endoscopist #2 (69% vs. 31%), whereas the FQHC PN-related colonoscopies were divided between endoscopist #1 and #2 (46% vs. 51%).

3.1. Screening colonoscopy quality indicators

Table 2 summarizes the intra-procedure screening colonoscopy quality indicators: optimal bowel preparation, adenoma detection, and cecal intubation. The proportion of patients with optimal bowel preparation was greater for FQHC PN-related colonoscopies compared to the University Hospital cohort (66% vs. 49%; p = 0.007). Two-hundred-eighty-two of the 296 colonoscopies documented intubation of the cecum and/or ileum, resulting in an overall CIR for the study population of 95%. There was no difference in the CIR comparing the FQHC PN and University Hospital cohorts (p = 0.900). Lastly, 96 of the 296 colonoscopies included removal of one or more adenomatous polyps, resulting in an overall ADR for the study population of 32%. There was no difference in the ADR of FQHC PN-related colonoscopies compared to the University Hospital cohort (33% vs. 32%; p = 0.971).

A greater proportion of FQHC PN-related colonoscopies were observed to have an optimal bowel preparation and FQHC PN procedures were divided between endoscopist #1 and #2 (46% vs. 51%). However, endoscopist #1 performed a majority of the University Hospital related...
coloscopies (69%), which corresponded to 72% of the Medicare, 72% of the private, and 31% of the Medicaid/Charity care related procedures. To assess for the presence of confounding due to the unequal distribution of insurance types between endoscopists, the adjusted odds ratios for optimal bowel preparation stratified by patient insurance type or FQHC PN participation are summarized in Table 3. The adjusted odds ratios comparing endoscopist #2/other and endoscopist #1 for optimal bowel preparation were homogenous across strata ($\chi^2$ test of homogeneity = 5.91, $p = 0.12$). Additionally, the Mantel-Haenszel estimate for the common odds ratio was not significant for evidence of confounding related to patient insurance or FQHC PN participation (odds ratio [OR] 1.56, 95% confidence interval [CI] 0.94 to 2.58).

3.1.1. Univariate analysis

The univariate analysis of patient demographic and colonoscopy-related characteristics associated with optimal bowel preparation are presented in Table 4. Covariates with $p$-value < 0.10 were considered potentially significant and were included in a multivariate logistic regression. There were no differences in preparation quality related to patient sex, colonoscopy indication, or bowel preparation medication. Increasing patient age was associated with a lower likelihood of optimal bowel preparation (OR 0.95, 95% CI 0.92 to 0.98). Afternoon screening colonoscopy procedures had a greater likelihood of an optimal bowel preparation compared to procedures performed in the morning (OR 1.82, 95% CI 1.15 to 2.90). Patient race was significantly related to bowel preparation quality. Specifically, patients of Asian/Pacific Islander race had a greater likelihood of an optimal bowel preparation compared to patients of white race (OR 3.02, 95% CI 1.14 to 8.43). Additionally, compared to University Hospital patients with Medicare, FQHC PN participants had a greater likelihood of optimal bowel preparation (OR 4.17, 95% CI 1.07 to 16.20). Notably, there was significant interaction between the covariates insurance and endoscopist, indicating that undergoing a screening colonoscopy that was performed by endoscopist #1 tended to decrease the likelihood of optimal bowel preparation (OR 0.20, 95% CI 0.05 to 0.84).

3.2. Polyp findings

Of the 296 colonoscopies studied, 131 procedures included the removal of one or more polyps by biopsy forceps or snare polypectomy, resulting in an overall polyp detection rate for the study population of 44%. A review of pathology findings identified 96 patients with one or more adenomatous polyps; 33 with hyperplastic polyps; and 2 with inflammatory polyps. There was no difference in the ADR comparing patients of White and African American race (37% vs. 30%; $p = 0.279$). Of the 96 patients with adenomatous polyps, 22 polyps had characteristics consistent with advanced adenomas such as villous features and/or a size >10 mm. There was no difference in the proportion of advanced adenomatous polyps comparing FQHC PN participants and University Hospital patients (10% vs. 6%; $p = 0.249$). All identified polyps were successfully removed during the colonoscopy procedures and there were no adenocarcinomas diagnosed during the study interval.

4. Discussion

The objective of this study was to compare intra-procedure screening colonoscopy quality indicators in an uninsured FQHC-derived patient population who received PN and a University Hospital patient population who received usual care. The FQHC cohort was observed to have a greater proportion of patients with optimal bowel preparation compared to the University Hospital cohort (66% vs. 49%; $p = 0.007$). There was no statistically significant difference in CIR (96% vs. 95%; $p = 0.900$) or ADR (33% vs. 32%; $p = 0.971$) comparing the FQHC and University Hospital cohorts.

The study’s principal finding is that the uninsured FQHC cohort who received PN achieved equivalent screening colonoscopy quality

### Table 2

| Screening colonoscopy quality indicators. | Total | FQHC PN | University hospital | p-Value |
|------------------------------------------|-------|---------|---------------------|--------|
| **Optimal bowel preparation**            | 161 (54%) | 59 (66) | 102 (49) | 0.007 |
| Cecal intubation                         | 282 (95%) | 85 (96) | 197 (95) | 0.900 |
| Adenoma detection                        | 96 (32%) | 29 (33) | 67 (32) | 0.971 |

**Abbreviations:** FQHC PN-Federally Qualified Health Center Patient Navigation.

### Table 3

| Insurance                     | Optimal Prep. | Endos. #2/other | Endos. #1 | Odds Ratio (95% CI) |
|-------------------------------|---------------|----------------|-----------|---------------------|
| **Medicare**                  | 30 (19)       | 6 (6)          | 24 (55)   | 0.52 (0.17, 1.56)   |
| **Private**                   | 62 (38)       | 21 (32)        | 41 (83)   | 1.96 (0.83, 4.62)   |
| **Medicaid/charity care**     | 10 (6)        | 8 (11)         | 2 (5)     | 4.00 (0.35, 45.10)  |
| **FQHC PN**                   | 59 (37)       | 36 (48)        | 23 (41)   | 2.35 (0.93, 5.90)   |

Mantel-Haenszel estimate controlling for insurance odds ratio = 1.56; 95% CI 0.94 to 2.58; $p = 0.08$.

Test of homogeneity of odds ratios: $\chi^2 = 5.91; p = 0.12$.

Abbreviations: Endos-endoscopist; FQHC PN-Federally Qualified Health Center Patient Navigation.

CI-confidence interval.

* Column percent.
who performed the procedure. Significant interaction was observed between the covariates endoscopist and patient insurance type, where endoscopist #1 related procedures tended to have a lower likelihood of an optimal bowel preparation. One explanation for this interaction may relate to the subjective nature of bowel preparation characterization, which may differ across endoscopists. There was no evidence of confounding of the odds of optimal bowel preparation by endoscopist when stratified by patient insurance type or FQHC PN participation. Furthermore, participation in FQHC PN remained a significant predictor of optimal bowel preparation in multivariable regression after controlling for interaction between the endoscopist and insurance covariates. Altogether, the performance of the uninsured FQHC PN cohort is particularly noteworthy when considering that this patient population embodied multiple characteristics that have been previously linked with suboptimal colonoscopy preparation and low ADR including: lack of medical insurance, African American race, and completion of an afternoon colonoscopy procedure (Appannagari et al., 2014; Lebwohl et al., 2010; Ness et al., 2001). It is our belief that the in-person patient navigation services provided on-site at the participating FQHCs were instrumental in maximizing patient adherence to bowel preparation instructions, thereby promoting optimal bowel cleansing and polyp detection.

The benefits of high-quality screening colonoscopy on early detection and prevention of CRC have been clearly delineated (Rex et al., 2015; Kaminski et al., 2010; Baxter et al., 2011; Corley et al., 2014). In order to eliminate disparities in CRC-related mortality, it is paramount that uninsured and minority populations undergo high-quality screening examinations. In this study, screening colonoscopy quality indicators exceeded the currently recommended performance targets of an ADR of 25% or greater and CIR of 95% or greater in an uninsured FQHC patient population and a University Hospital patient population (Rex et al., 2015). These data depart from the literature in that among the uninsured FQHC cohort, the finding of an ADR of 33% surpassed the values for ADR previously reported in PN interventions that have included minority and uninsured patient populations, which have ranged from 8% to 27% (Lebwohl et al., 2011a; Chen et al., 2008; Lasser et al., 2011; Wolf et al., 2015; Lane et al., 2013; Xirasagar et al., 2014). This is particularly notable considering that 29 FQHC patients were found to have adenomatous polyps and of those, 9 patients (10%) had high-risk adenomas with villous features or size >10 mm. The detection of a substantial number of adenomas and advanced adenomas in the FQHC-derived cohort highlights the importance of achieving high-quality screening examinations in underserved and minority patient populations.

### 4.1. Limitations

This study was not a randomized control design and the majority of screening colonoscopies were performed by two gastroenterologists, thereby limiting the ability to assess the independent effects of PN and the overall generalizability of the study findings. Secondly, patient characteristics such as educational attainment, income, marital status, English language proficiency, and health literacy were not assessed due to the retrospective study design. In addition, information on patient race was not documented in the medical record for 6% of the study population, thereby limiting the ability to assess the independent effects of PN and the overall generalizability of the study findings. Lastly, patient use of single-dose versus split-dose bowel preparation was not examined, as split-dose bowel preparation was not standard practice during the study interval. Even so, the findings emphasize the potential role of PN in achieving high-quality screening colonoscopy in minority and underserved patient populations.

### 4.2. Conclusions

Patient navigation interventions have been instrumental in the efforts to increase CRC screening test utilization among uninsured and minority populations. To date, the majority of PN interventions that use
screening colonoscopy have reported colonoscopy procedure completion as their primary outcome. However, in order for patients to reap the full benefits of screening, colonoscopy examinations must meet bench-mark quality standards that have been linked to improved rates of early diagnosis and cancer prevention. In this study, uninsured FQHC patients who received patient navigation were observed to have intra-procedure quality indicators that exceeded the accepted standards for high-quality screening colonoscopy and were equivalent to those observed in an insured University Hospital-derived patient population. These findings underscore the potential benefits of PN among minority and uninsured patients, as well as the need for the inclusion of intra-procedure colonoscopy quality indicators as outcome measures in studies utilizing screening colonoscopy.

Conflict of interest statement

Keith Naylor, Cassandra Fritz, and Karen Kim declare that they have no conflicts of interest. Dr. Blase Polite reports personal fees from Astra Zeneca, grants from Merck, personal fees from GLC Consulting, personal fees from Bayer/Onyx, outside the submitted work.

Compliance with ethical standards

Ethical approval: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

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