The Law of Unintended Consequences: The Joint Commission Regulations and the Digital Rectal Examination

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Study objective: The Joint Commission (TJC) recently issued stringent regulations about quality control testing of waived laboratory tests. Many hospitals subsequently instituted detailed procedures for performing, evaluating, documenting, and tracking point-of-care testing for fecal occult blood testing. We hypothesize that implementing this policy would generate an "opportunity cost" because busy physicians would need to compensate for this additional time required by reducing the frequency of digital rectal examinations or fecal occult blood testing.

Methods: We designed a before/after study to measure use of digital rectal examination and fecal occult blood testing in a single-center study between 2002 and 2003. The experimental intervention was implementation of TJC-based hospital policy requiring physicians to manually document fecal occult blood testing quality control data. Charts were screened for 6 a priori established index diagnoses: abdominal pain, gastrointestinal bleeding, chest pain, constipation, diarrhea, and syncope/presyncope. Trained data extractors recorded the presence or absence of digital rectal examination and fecal occult blood testing by using explicit medical record review methods, and rates of both digital rectal examination and fecal occult blood testing were calculated.

Results: We screened 3,337 charts and 788 met our inclusion criteria. For the primary outcome, physicians performed 16.7% fewer digital rectal examinations after implementation of the policy (41.3% versus 24.6%). Fecal occult blood testing decreased by 18.7% (38.5% versus 19.8%).

Conclusion: TJC-inspired point-of-care testing policy was negatively and unintentionally associated with physician examinations, most notably the performance of a digital rectal examination. Institutional regulations designed for patient safety may unintentionally influence patient care. Economists describe this paradoxic phenomenon as the Law of Unintended Consequences. The costs and benefits of such policies should be analyzed before implementation and enforcement of new medical regulations. [Ann Emerg Med. 2008;51:197-201.]

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INTRODUCTION

Background

The Joint Commission (TJC) recently issued more stringent regulations about quality control testing of waived laboratory tests.[1] The new guidelines, which evolved from the Clinical Laboratory Improvements Amendments of 1988,[2] require that appropriate quality control and test records be centrally maintained for point-of-care tests. Many hospitals subsequently instituted standardized procedures for performing, evaluating, documenting, and tracking bedside fecal occult blood testing.

Importance

Well-meaning governmental regulations designed for safety can paradoxically affect individual behavior. Economists describe this phenomenon as the Law of Unintended Consequences.[3] A classic example was the requirement for infant car seats on domestic airline flights, a seemingly sensible regulation designed to save children's lives. But the unintended

Editor's Capsule Summary

What is already known on this topic

Systematic changes designed to improve quality can have paradoxic effects.

What question this study addressed

This single-site before-after study examined whether a new requirement that physicians document quality control data every time they test for occult fecal blood changed how often they performed rectal examinations and tested feces for occult blood.

What this study adds to our knowledge

The percentage of 788 eligible patients who received a rectal examination and testing for occult blood decreased by one sixth after implementation of the quality control scheme.

How this might change clinical practice

This study points out that there may be negative untoward consequences of actions designed to improve the quality of care.

consequence became apparent as parents chose not to pay for the additional airfare and to instead drive to their destination. Because flying is safer, the policy induced a theoretical net increase in infant trauma mortality because of diversion to highways.[4] TJC policy may similarly have unintended influence on clinical practice, especially in the highly regulated environment of an emergency department (ED).

Goals of This Investigation

We hypothesized that implementing this policy would generate an "opportunity cost" because busy physicians would need to compensate for the additional time required to do the testing by reducing the frequency of digital rectal examinations and fecal occult blood testing.

MATERIALS AND METHODS

Study Design

We developed a before-after study design to measure performance of digital rectal examination and fecal occult blood testing. The primary outcome was frequency of digital rectal examinations. Secondary outcomes included frequency of fecal occult blood testing and compliance with the applicable point-of-care testing policies. The experimental intervention was implementation of TJC-based local hospital policy requiring physicians to manually document into a central log the patient's demographics, fecal occult blood testing card number, reagent lot number, and fecal occult blood testing quality control test results. Physicians were given specific instructions for the new policy by demonstration, e-mail, handouts, and both group and individual counseling. Clinicians were blinded to the existence of this study. The study was approved by the institutional review board.

Setting

The setting was an academic ED with approximately 50,000 patient visits annually. This ED uses a handwritten chart with separate sections for chief complaint, medical history and physical examination, and final diagnosis. The old policy on point-of-care testing required the clinicians to record on the patient chart only the phrase "QC OK" to indicate that they had performed a quality control test on the fecal occult blood testing card. The new TJC-based point-of-care testing policy changes required physicians to manually document into a central log the patient's demographics, fecal occult blood testing card number, reagent lot number, and fecal occult blood testing quality control test results; alternatively, physicians could send a confirmatory fecal occult blood testing card to the central laboratory for testing.

Data Collection and Processing

The new policy was implemented in May 2003. We identified a 100-day window from August 1 to November 8 in 2002 and 2003. These identical windows a year apart were chosen to avoid a possible bias such as the "July phenomenon" of new residents beginning their academic year.[5] We allowed 4 months to inform and train the clinical providers about the change before we collected data. The written charts at our hospital are filed by calendar dates; physicians in our ED work 3 8-hour shifts in a 24-hour period. We randomly selected 20 calendar dates for each year's window, correlating to 60 shifts. The 100 days were divided into 25-day blocks, and 5 days were randomly selected from each block to ensure a reasonable spread of sampling throughout the 100-day window.

Selection of Participants

All charts were explicitly screened for 6 a priori established index diagnoses for which a digital rectal examination would reasonably be indicated: abdominal pain, gastrointestinal bleeding, chest pain, constipation, diarrhea, and syncope (which a priori included presyncope, nonspecific dizziness, and generalized weakness). Explicit chart extraction criteria were used to define the index diagnosis from either the final written ED diagnosis or the chief complaint. We excluded major trauma activations, abdominal pain as a result of pelvic pain or vaginal bleeding, patients leaving against medical advice, and dizziness as a result of vertigo.

Methods of Measurement

Using a practice set of 160 medical records, 3 chart abstractors (K.M., S.A.B., and J.D.) were trained by the principal investigator in explicit chart review methodology before the start of the study.[6] Explicit definitions for inclusion and exclusion criteria and clinical outcomes were standardized (see Appendix E1, available online at http://www.annemergmed.com). A single investigator (K.M.) was

present and acted as the direct supervisor during all chart review sessions and monitored the performance and reliability of the other abstractors. Abstractors were not blinded to the study hypothesis. However, they were trained to review for inclusion/exclusion criteria first before assessing for the primary outcome. We held monthly meetings to review study definitions and monitor compliance with the methodology. We dual recorded onto a standardized abstraction form and a computer spreadsheet the following: patient demographics, disposition status, level of emergency physician (resident or attending), presence or absence of emergency physician digital rectal examination, presence or absence of fecal occult blood testing, and current use of any antiplatelet or anticoagulation medications. Compliance with the old ("before") point-of-care testing policy was determined to be present if either of the phrases "quality control OK" or "QC OK" were recorded on the chart. Compliance with the new ("after") policy was determined to be present if the physician either entered the patient's demographics into the centralized department log or sent the fecal occult card to the laboratory for confirmatory testing.

Primary Data Analysis

Descriptive statistics with 95% confidence intervals (CIs) were calculated for the primary and secondary outcomes.

RESULTS

Characteristics of Study Subjects

We screened 3,337 charts and found 788 that met our inclusion criteria. No patients refused a digital rectal examination. For the before cohort, 60.6% of the patients were female, 78.2% were examined by resident emergency physicians, and 21.8% were examined by attending physicians. For the after cohort, 57.8% of the patients were female, 78.5% were examined by resident emergency physicians, and 21.5% were examined by attending physicians. Age trended older in the before cohort (Table 1). The average age of the before and after cohorts was 50.1 years (SD=22.7 years) and 44.3 years (SD=22.8 years), respectively.

The diagnostic makeup of each cohort was similar with respect to their distribution of index diagnoses (Table 2). The admission rate for patients with the index diagnoses was 41.9% and 33.4% in the before and after cohorts, respectively. The overall admission rate for all patients within the selected shifts was 20.4% in the before cohort and 16.1% in the after cohort. Subset analysis of admissions showed a proportionately higher admission rate for chest pain and gastrointestinal bleeding in the before cohort and a proportionately higher admission rate for abdominal pain in the after cohort (Table 2). Medications with gastrointestinal bleeding risk, either long-term medications or administered in the ED, are summarized in Table 3. The before cohort had relatively more anticoagulants and especially antiplatelet agents.

Main Results

For the primary outcome, physicians performed 16.7% fewer digital rectal examinations after implementation of the policy (before cohort=41.3%, 95% CI 36.2% to 46.6% versus after cohort=24.6%, 95% CI 20.6% to 29.0%). Fecal occult blood testing decreased by 18.7% (before cohort=38.5%, 95% CI 33.1% to 43.3% versus after cohort=19.8%, 95% CI 16.2% to 24.0%).

Table 1. Percentage of digital rectal examination performed in the before and after groups, by age decile.

	Before Cohort		After Cohort	
Age Decile	Percentage of Cohort	DRE Performed, %	Percentage of Cohort	DRE Performed, %
1st	4.1	33.3	5.2	25.0
2nd	7.2	33.3	12.2	23.4
3rd	12.1	17.1	14.1	16.7
4th	6.9	40	11.2	20.9
5th	16.6	31.3	13.8	18.9
6th	13.4	51.3	13.3	29.4
7th	14.1	41.5	14.1	35.2
8th	15.9	52.2	8.6	24.2
9th	9.7	60.7	7.0	18.5
10th	0	0	0.5	50

DRE, Digital rectal examination.

The drop-off in digital rectal examination performance was most pronounced for patients with abdominal pain, chest pain, or syncope (Table 2). Compliance of the before and after cohorts was 44.3% and 18.3%, respectively, with the old policy. However, compliance with the new policy itself was 2.9% in the after cohort.

LIMITATIONS

We cannot determine whether any patients experienced harm by not receiving a rectal examination or fecal occult blood test, because our study did not provide clinical outcome data. It is possible that the regulation actually encouraged physicians to be more appropriately selective in performing rectal examinations. Also, the observed decrease in digital rectal examination and fecal occult blood testing reported may really only be a decrease in the chart documentation of these procedures and not necessarily a decrease in the actual performance of the procedures. Although the actual role of the digital rectal examination in the ED has come under scrutiny,[7-9] many authorities still believe it is indicated for evaluating certain urgent chief complaints.[10,11] Regardless, changes in clinical practice should be deliberately based on scientific evidence and not inadvertently from the unforeseen consequences of policy. Another limitation of the study is that patients in the before cohort were older, received more anticoagulants, and were more likely to be admitted. This by itself could have accounted for the more frequent rectal examinations in that group. It is not clear why the cohorts varied in this respect, but perhaps the patient mix changed during the course of 12 months, or admission decisions may have become more restrictive.

Table 2. Prevalence, admission rate, number, and percent (with 95% CI) for each of the index diagnoses for the before and after cohorts.

	Before Cohort						After Cohort					
Index Diagnosis	Total Cases	DX as Percentage of Cohort	Admission, %	DRE Performed, No.	DRE Performed, %	95% CI	Total Cases	DX as Percentage of Cohort	Admission, %	DRE Performed, No.	DRE Performed, %	95% CI
Abdominal pain	116	32.1	15.5	55	47.4	38.1-56.9	156	36.5	23.7	47	30.1	23.1-38.0
Chest pain	133	36.8	65.2	38	28.6	21.1-37.1	148	34.7	47.0	11	7.4	3.8-12.9
Diarrhea	25	6.9	0.0	11	44.0	24.4-65.1	32	7.5	0.0	14	43.8	26.4-62.3
Constipation	2	0.6	15.4	2	100.0	29.0-100	6	1.4	12.9	5	83.3	35.9-99.6
GI bleeding	15	4.2	55.6	14	93.3	68.2-100	21	4.9	16.7	19	90.5	69.6-98.8
Syncope	70	19.4	47.8	29	41.4	30.6-53.1	64	15.0	43.3	8	12.5	5.6-23.2
Totals	361	100.0	41.6	149	41.3	36.2-46.6	427	100.0	33.5	104	24.4	20.4-28.7

DX, Diagnosis; *GI*, gastrointestinal.

DISCUSSION

Implementation of TJC-based hospital policy was associated with unintended decreases in both digital rectal examination and fecal occult blood testing. This change in physician behavior seemed to be particularly evident for the evaluation of chest pain, abdominal pain, and syncope. This observation we believe actually strengthens the association by demonstrating essentially a dose response. Marginally indicated diagnoses (eg, chest pain) would be the first examinations to be curtailed with increased regulation.

In the wake of widely publicized diagnostic errors in laboratory cancer screening, the Clinical Laboratory Improvements Amendments of 1988 and ensuing TJC guidelines were developed to ensure quality laboratory testing and to reduce point-of-care testing diagnostic errors. Ironically, our study suggests that a well-meaning (but evidently burdensome) policy may have altered the physician's clinical examination by actually decreasing digital rectal examinations and fecal occult blood testing.

Compliance with the new point-of-care testing mandate was extremely low, presumably because physicians found the new procedure onerous. Regulations often result in not only additional time requirements but also a work burden, or "hassle factor." We find it particularly interesting that both compliance and performance of digital rectal examination and fecal occult blood testing decreased. If the clinicians essentially ignored the new policy entirely, this should not have affected the performance of digital rectal examination and fecal occult blood testing. Instead, we observed 2 unintended consequences: noncompliance with the policy and a negative effect on digital rectal examination/fecal occult blood testing. A similar pattern has been described with institution of overly conservative lower speed limits when drivers may both paradoxically increase their fatal accident rates (by, for example, bypassing safer freeways for dangerous back roads) and break the law by speeding anyway.[12-14]

Similar consequences to TJC policies have just recently been reported in the context of community-acquired pneumonia. Kelen and Rothman[15] stress that EDs must divert precious resources to ensure "adherence to weak practice standards." Likewise, this current policy was designed to ensure that physicians properly performed point-of-care diagnostic testing for fecal occult blood. But in reality, this bedside test is simple, accurate, and almost instantaneous.[16] Rather than comply with these seemingly nonsensical requirements, physicians may have skipped the test altogether. External control of clinical practice cannot always take into account competing factors for limited resources in the ED. Likewise, this point-of-care testing policy, while endeavoring to improve diagnostic accuracy, paradoxically resulted in the decrement of physician examination.

Table 3. Antiplatelet or anticoagulant medications of subjects.

	Before Cohort				After Cohort			
Medication Class	**Total Cases**	**Percentage of Cohort**	**DREs Performed, No.**	**DREs Performed, %**	**Total Cases**	**Percentage of Cohort**	**DREs Performed, No.**	**DREs Performed, %**
None	171	47.4	72	42.1	255	59.7	70	27.5
NSAID	42	11.6	11	26.2	47	11.0	10	21.3
Antiplatelet	115	31.9	48	41.7	97	22.7	18	18.6
Anticoagulant	33	9.1	18	54.5	28	6.6	6	21.4

NSAID, Nonsteroidal anti-inflammatory drug.
Aggregate of either home medications or medications given in the ED. In cases of multiple medications the number was attributed to the higher risk category.

In Retrospect

We would like to have obtained specific survey data to more fully explain why the physicians altered their behavior.

Summary

Well-meaning regulations designed for patient safety may yield unintended consequences to daily medical practice. The opportunity costs and benefits of such policies should be carefully analyzed before implementation and enforcement of new medical regulations.

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Appendix E1. Supplemental Instructions for Chart Reviewers

A.) Index Diagnoses (inclustion criteria) will be defined as:
1. Abdominal Pain
2. Gastrointestinal Bleeding
3. Chest Pain and/or Acute Coronary Syndrome (ACS)
4. Constipation
5. Diarrhea
6. Weakness/Dizziness/Syncope/Pre-Syncope/AMS

B.) We will exclude the following:
1. Trauma Charts
2. Left Without Being Seen (LWOBS) Charts
3. Patient eloped or left AMA
4. Urgent Care Clinic Charts
5. Patient refused DRE (not "deferred")
6. Vaginal Bleeding/Pelvic Pain
7. Dizziness secondary to vertigo

C.) Explicit Rules for Data Extraction and Chart Review
1. Analyze data from all charts (SF 558) that meet the above inclusion criteria but do not have any of the exclusion criteria listed (see below for more specifics).
2. Include the chart if at least one or more of the index diagnosis is listed anywhere in the "Chief Complaint" or "Diagnosis" boxes of the SF 558.
3. Abdominal pain can also be defined as stomach or mid-epigastric pain. We will also include the diagnoses of appendicitis, diverticulitis, gastroenteritis, and colitis under this subset.
4. Flank or back pain does not qualify as abdominal pain.
5. Pelvic pain and/or vaginal bleeding, when found as isolated complaints, should be excluded.
6. We will accept the following patient complaints for dizziness: "passed out", "blacked out", pre-(or near) syncope, syncope, and "loss of consciousness" (LOC). We will also include "weakness" or "generalized weakness".
7. Dizziness, when found as an isolated complaint and diagnosed as secondary to vertigo, should be excluded.
8. Circle any of the selected home medications if they are listed under the "Medications" section of the SF 558.
9. Circle any of the emergency department course (EDC) medications if they are listed on the "Orders" section of the SF 558.
10. List the physician who performed the DRE based on handwriting comparison.
11. If no rectal exam was recorded, assume it was not done.
12. If a DRE is noted, but no hemoccult results are documented, circle "Not Recorded".
13. "No gross blood" on the rectal exam without any further hemoccult testing will be noted as "Not Recorded".
14. Assume that "deferred" means that the rectal exam was not done (circle "No").
15. If the rectal exam is illegible, circle "No" for rectal exam performed.
16. The DRE should only be counted if it was done on that particular ED visit.
17. If the DRE was noted as "trace positive", circle "Trace" under hemoccult results.
18. Note that "guaiac" signifies hemoccult testing.
19. Circle "Yes" for "QC OK" if it was noted next to the DRE results.
20. Circle "Yes" if it was noted that the hemoccult results were noted in the ED logbook or in CHCS.

Note:

Gilbert EH, Lowenstein SR, Koziol-McLain J, et al. Chart reviews in emergency medicine reserch: Where are the methods? *Ann Emerg Med*. 1996;27:305-308.