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ONE HUNDRED FOURTEENTH CONGRESS

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June 3, 2015

Carolyn M. Clancy, M.D.
 Interim Under Secretary for Health
 U.S. Department of Veterans Affairs
 810 Vermont Avenue, NW
 Washington, DC 20420

Dear Dr. Clancy,

According to a letter from Dr. Jeffrey A. Murawsky (former VISN 12 Network Director), dated December 21, 2012, VA approved a quality improvement grant to VA employee, Dr. Saul Weiner, to be used at the Edward Hines, Jr. VAMC, the Jesse Brown VAMC, and other VA health care facilities. This work is purportedly at a cost of at least \$900,000. The purpose of the quality improvement study is "To improve staff and provide attention to Veterans' individual circumstances and needs, or 'contest,' when assisting them or planning their care." Dr. Weiner's overall research on the patient/physician experience has been ongoing since 2006, and his work has been published in the *Annals of Internal Medicine* (20 July 2010, Vol. 153, No.2), a peer reviewed journal. See enclosures.

The Committee has learned that, according to Dr. Weiner's own admission, actors were hired to portray Veterans throughout this study. The actors wore hidden microphones to capture the physician-patient interaction; feigned symptoms that took real appointment slots from Veterans and tied up facility resources, such as lab tests, while health care professionals sought answers to the actors' fake maladies. VA physicians were forewarned that "patients" would be "wired" in order to capture the physician-patient dialogue.

As the study progressed and after concerns were voiced by Veterans about the misuse of resources, Dr. Weiner purportedly began enlisting actual Veterans from facility waiting rooms. According to complaints filed with the local union, some Veterans did not want to participate, but in at least one instance, a Veteran was badgered at least four times to do so. Veterans noted concerns that, if they did not participate, they would be "flagged" as uncooperative and might be retaliated against by the facility. In these instances, those Veterans who did participate alerted the physician by handwritten note that they were being recorded during the physician-patient interaction. Apparently, none of the Veterans used in this study signed a consent form to participate.

I wanted to bring this situation to your attention for a number of reasons. Firstly, the improper use of VA resources for actors' fake maladies is beyond comprehension given VA's wait times scandal and wasteful spending scandal, both problems that continue to occur across VA.

Secondly, the potential that a VA employee received a \$900,000 grant to perform a study on the quality of VA's physician-patient experience is questionable at best given other priorities. Thirdly, Dr. Weiner's research, presumably for publication in a peer review journal, is based on the conversations between physicians and patients, the former who were alerted that patients would be wearing a microphone, thus introducing a bias into the outcome of the study. Finally, one thing that is not measurable, and is apparently not even a consideration in the conduct of this study, is the damage done to the physician-patient trust relationship.

Within the Department's limited resources, how did this project receive approval since it was determined that an Institutional Review Board was not required? Also, how will you address this issue moving forward?

If you have any questions, please contact Mr. Eric Hannel, Staff Director for the Subcommittee on Oversight and Investigations, at (202) 225-3569.

Sincerely,



MIKE COFFMAN
Chairman
Subcommittee on Oversight and Investigations

cc: Ann Kuster, Ranking Member

MC/jh

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Response to Information Request – Quality Improvement project in Patient-Centered Decision Making

- *Documentation on the date this project was approved and implemented, when did it cease to be a research project and become a QI project? The union was not notified of this program, which is a change in working conditions.*

Response: Please see attached “Determination by IRB of QI status not Research” (tab 2) dated Feb 7th, 2013. This is the date on which the Hines Institutional Review Board determined that “this is a quality improvement project, not research.”

Question: What aspect of this project constitutes a “change in working conditions”? Employees are not given any new responsibilities, there are no new claims upon their time, the project has no implications for their compensation, the data is de-identified and not available to any department official, and there is no monitoring of or consequences for physicians who are not interested in improving their care. Nevertheless (see below) physicians have been using this data for two years (and routinely requesting it) as a safe resource for improving their care – and (see below) it is measurably improving the care Veterans’ receive. We welcome an opportunity to present this project to anyone and would be pleased to do so to union members who are interested.

- *Copy of the IRB application and approval both nationally and local if applicable.*

See IRB letter (tab 2) referenced above. This is a quality improvement, not research. This is an important distinction. Specifically the project is intended exclusively for the purpose of improving the care of Veterans, not for any kind of experiment or study to discover new knowledge. There are no research subjects. Hence, per the IRB there is no indication for an IRB application.

- *Specifically, what authority is the researcher utilizing to circumvent the voluntary requirements of a signed informed consent from the providers? It is my believe that this issue already in policy as both an interactions and interventions of protection of human subjects – under VA 1200.05. Henceforth, a copy of legal authority that rumps that requirement.*

Please see above. As determined by the IRB this is not research and there is no researcher involved and no human subjects.

- *Funding source of the research*

Please see above. This is not research and, hence there is no research funder

- *Solicitation of volunteers*

Veterans are invited to volunteer for this project. Attached is the handout (tab 3) given by QI staff in the waiting area before their appointments that informs them of the project (see attached “Patient Information Sheet.”)

- *Copy of the federal notice establishing the system of records that has been established by the department for recording this information.*

Reviewing the Master Agreement, section on quality improvement, I can't see what this is referring to, specifically. I don't see any reference to Federal Notice for QI projects. Notice of the project itself is in the minutes of the QI Council. It's also recorded by the IRB.

- *Access rights for providers and patients to those recordings, or system of records, if they voluntarily participated in the study, or the study is completed.*

Again, please note, this is not a study. It's QI and QI is protected from disclosure of data. See below under 38 U.S.C. "Confidentiality of Medical Quality Assurance Records." Data cannot be disclosed outside the quality management system. Also, in the patient handout sheet it says that "The purpose of this project is to collect audio-recorded information from clinic visits so that Hines doctors can better understand how their communication with Veterans can either improve or limit the quality of care Veterans receive. *The audio-recordings are not for any other purpose.*"

Hence, doctors are protected by laws governing quality improvement from the risk that their patients could request and obtain the audio recordings.

Particularized Need:

Per Master Agreement, Article 17, section 4 Use of Recording Devices

"Information obtained in conflict with this Section will not be used as evidence against any employee".

- *The union needs information on any electronic recording and evidence of consent or lack of consent by bargaining unit members. Is participation in this project mandatory and a condition of employment?*

Article 17, section 4 states that "no electronic recording of any conversation between a bargaining unit employee and a Department official may be made without mutual consent..." This project does not involve any such recording. The recording is done by a Veteran who volunteers to collect data for the purpose of providing the physician with data on their own care. The medical teams are fully aware of this project and understand that the information will only be used to help them improve patient care. They also understand that all identifiers, both of medical team and patient, will be removed from any data before it is shared outside of the Quality Improvement team so that there is no harm either to Veterans or doctors as a result of any material recorded. About every two months we will present the information from many visits to our medical staff. All identifying information about the veteran and the medical team will be removed before any of this information is shared. At the meeting the medical teams will have a chance to talk about what they are doing well and where they could improve, based on what they learn from the notes and records of the audio-recordings.

- *Per the Provider Information Sheet, "Audio recorded information would never be disclosed with identifiers unless it contained evidence of behavior that is illegal or flagrantly violates VA standards". What are the VA standards?*

Staff have an ethical obligation to report violent behavior, sexual assault or other obvious harm to Veterans. For instance, the Jesse Brown manual "Standards of Behavior" states that "neither,

Response to Information Request – Quality Improvement project in Patient-Centered Decision Making

violence, disruptive behavior; physical or verbal in nature towards anyone; veteran, employee, visitor, internal or external customer will not be tolerated.”

This would not apply to QI data collected from the audio. 38 U.S.C. “Confidentiality of Medical Quality Assurance Records” which is specified within VHA Directive 2010-025 states that data collected *“as part of a facility’s quality management program may not be disclosed outside of the quality management process.”* The directive also states that *“As long as confidentiality is maintained consistent with 38 U.S.C § 5705 and appropriately documented, data from peer reviews for quality management can be aggregated and communicated to the organized professional staff so that trends are understood and opportunities for improvement identified.”*

3. Title 3

Article 47 Section 1. C “As appropriate, the Union may initiate mid-term bargaining at all levels on matters affecting the working conditions of bargaining unit employees”.

This project does not impact compensation, there are no assigned duties, there are no consequences for ignoring the data. It is essential to understand how this project serves Veterans by giving physicians data they use to improve their care.

Despite lack of any requirements that physicians use the data collected for them, they are listening and using the data to improve their care because of their personal commitment to professional development. They are able to get continuing medical education credit (CME) if they wish, and most of them have. Note this CME is no different than any other CME. It has been approved by the ACCME which accredits all physician CME, it is entirely voluntary. Physicians can complete “quizzes” emailed to them about the topic and get CME credit if they wish.

The attached QI report (tab 4) illustrates data they receive.* The blue line show the proportion of visits with Veterans in which the care plan specifically addressed challenges Veterans are facing in managing their care (e.g. homelessness, lack of transportation, competing job responsibilities). The red line tracks “probing” which refers to physicians noticing and asking about indicators of Veterans’ challenges (such as homelessness, loss of transportation etc...). In addition the report includes examples both of missed opportunities to address the Veteran’s life context in the care plan as well as examples of excellent care that addresses Veterans’ needs. Note that the report uses the following terms:

*A “Contextual Flag” is a clue that a Veteran is struggling – for instance their hemoglobin A1C has gone up indicating they are struggling to manage their diabetes. A “probe” refers to a physician showing interest and asking the Veteran about the struggle they are facing. A “contextual factor” is what the Veteran the shares about their life that they struggling with. A “contextual plan of care” is a care plan that addresses those challenges (e.g. referring the Veteran to a homelessness program, or to social work etc...)

Note: I would be happy to meet with any union members to present the project and answer questions.



DEPARTMENT OF VETERANS AFFAIRS
VA Great Lakes Health Care System
Veterans Integrated Service Network 12
Tower Four Westbrook Corporate Center
11301 West Cermak Road, Suite 810
Westchester, IL 60154

December 21, 2012

To: IRB #4, UIC
R&D Committee, JBVAMC
R&D Committee, Hines VA Hospital

From: Jeffrey A. Murawsky, MD
Network Director, VISN 12

Subject: VISN 12 Quality Improvement Project: Patient Centered Decision Making

1. Since 2006 a team of our investigators, led by Dr. Saul J. Weiner, have been developing and testing methods for assessing physician performance at planning care that takes into account patients' individual circumstances and needs, or context. This process of "patient centered decision making" (PCDM) is foundational to VHA#1 Strategic Goal of Delivering Personal, Proactive, and Patient-Driven Health Care to our Nation's Veterans."

2. A seminal publication in Annals in 2010 by Dr Weiner's team, illustrates how frequently clinicians – even those who are excellent at applying evidence based guidelines – overlook the implications of contextual factors such as patient's competing responsibilities, economic circumstances, social support, and cognitive limitations, when planning their care.

3. VISN 12 is committed to applying this knowledge to a quality improvement project designed to improve patient centered care of our veterans. The project will be initially introduced at JBVA and Hines. The project will be implemented by QI teams, at JBVA and Hines, with the aim of providing a process that is effective in delivering feedback to providers, and is regarded as a welcome and safe tool for professional development and quality improvement. The personnel, processes and procedures involved will be those in place for all QI projects, to maximize efficacy and safety. Attached is a Charter for the project at Jesse Brown. A similar Charter is being developed for Hines VA Hospital.

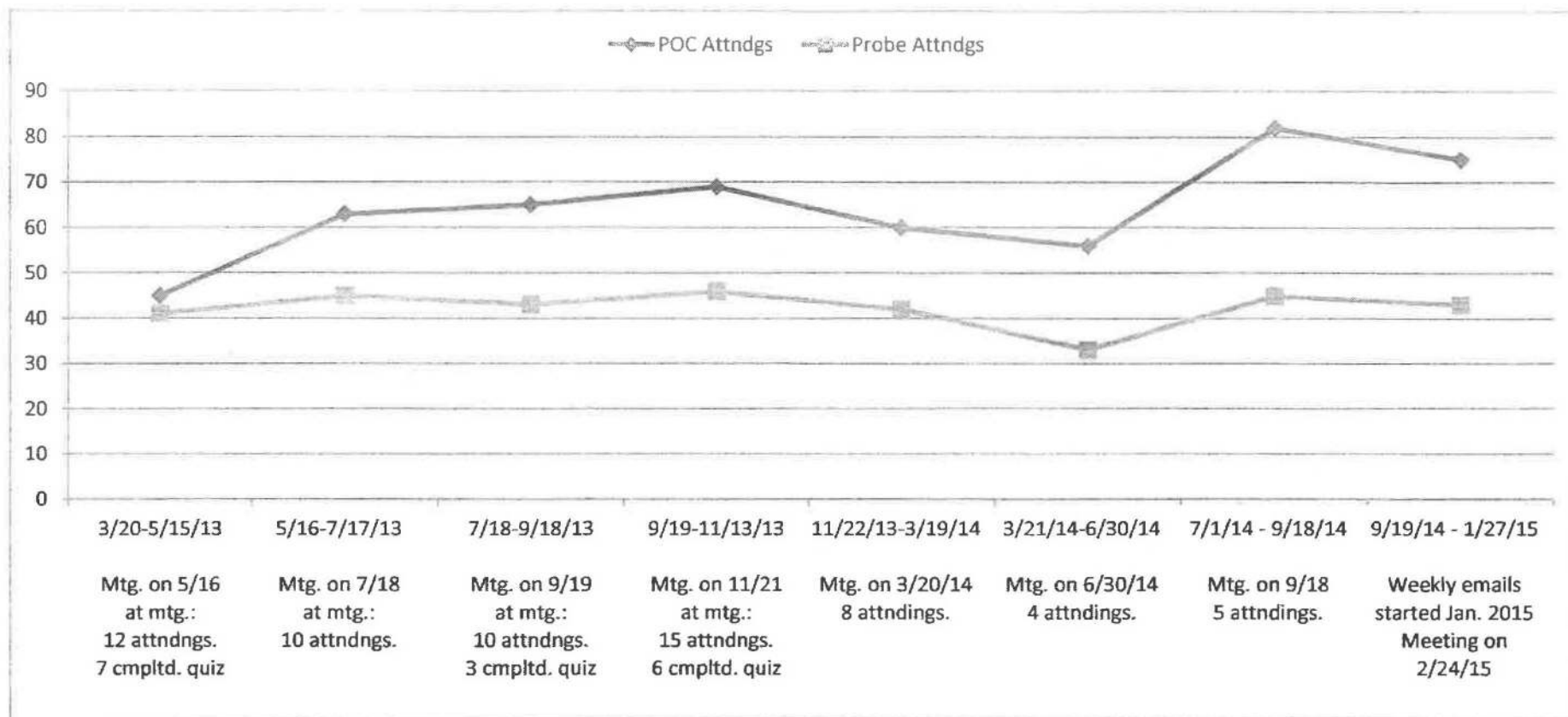
Sincerely,

A handwritten signature in black ink, appearing to read "J. Murawsky".

Jeffrey A. Murawsky, MD

Patient Centered Contextual Decision Making QI Report

2/24/15



PROVIDER EXAMPLES

Examples of no probing:

- 1.) **Contextual Flag:** High A1C (12.0)
No Probe: The provider did not inquire why the patient's A1C was elevated. (The provider reviewed the list of prescribed medications, but did not ask if the patient was taking them as prescribed.)
- 2.) **Contextual Flag:** The patient missed 13 of the last 24 scheduled appointments.
No Probe: The provider didn't inquire why the patient missed so many appointments. Missed opportunity to see if there are factors affecting the patient's ability to attend appointments that the provider could address.
- 3.) **Contextual Flag:** The patient refused the flu vaccine.
No Probe: The provider didn't inquire why the patient refused the vaccine. Missed opportunity to see if there are factors affecting the patient's acceptance of vaccines that the provider could address.

Examples of no probing, patient revealed contextual factors, no plan of care:

- 1.) **Contextual Flag:** High A1C (9.9)
No Probe:
Contextual Factor Revealed by Pt.: The patient stated he had been working overtime and his employer was providing unhealthy food.
No Plan of Care: The provider did not address the patient access to healthier choices with his schedule change. Missed opportunity to strategize options, for example, suggest contacting employer to request fruit instead of pastry.
- 2.) **Contextual Flag:** The patient missed a scheduled eye exam.
No Probe:
Contextual Factor Revealed by Pt.: The patient stated he has been having memory problems.
No Plan of Care: The provider did not address the patient's ability to attend scheduled appointments. Missed opportunity to strategize options, for example, writing down upcoming appointments, suggesting putting reminders into patient's cell phone.
- 3.) **Contextual Flag:** The patient refused the flu vaccine.
No Probe
Contextual Factor Revealed by Pt.: The patient revealed that he thought the vaccine contained a live virus and would make him sick.
No Contextual Plan of Care made: The provider didn't address the patient's understanding of how the flu vaccine works. Missed opportunity to inform the

patient that the flu vaccine does not contain a live virus and has a low risk of making him ill.

Examples of physician probe, contextual factor revealed, no plan of care made:

- 1.) **Contextual Flag:** High A1C (12.8)
Probe: The provider asks the patient if he is taking his medications as prescribed.
Contextual Factor: The patient reveals he “lost all discipline” during a recent family celebration.
No Contextual Plan of Care: The provider didn’t address the patient’s environmental factors during family celebrations. Missed opportunity to strategize options for the patient to remain “disciplined” during family occasions, for example, bring healthy choices to events, or review a restaurant’s menu online before going out to eat.
- 2.) **Contextual Flag:** The patient missed two scheduled appointments in the last four months.
Probe: The provider asked why the patient stopped following up with a specialty clinic.
Contextual Factor: The patient responded that he recently started attending school and was unable to attend the appointments.
No Contextual Plan of Care: The provider didn’t address the patient’s competing responsibility interfering with attending appointments. Missed opportunity to strategize ways for the patient to attend future appointments, for instance, comparing the patient’s school schedule with clinic hours.
- 3.) **Contextual Flag:** The patient refused the flu vaccine.
Probe: The provider asked the patient why he didn’t want the flu vaccine.
Contextual Factor Revealed by Pt.: The patient revealed that he thought the vaccine made him sick last year.
No Contextual Plan of Care made: The provider didn’t address the patient’s understanding of how the flu vaccine works. Missed opportunity to inform the patient that the flu vaccine does not contain a live virus and has a low risk of making him ill.

Examples of no physician probing, patient revealed contextual factor, contextual plan of care:

- 1.) **Contextual Flag:** High A1C (9.9)
No Probe:
Contextual Factor Revealed by Pt.: The patient mentions that he feels like he is “near death” after a recent stroke and doesn’t see why he should control his sugars. He explained that his experience with people who have had strokes is

that they end up no matter what very incapacitated with "drool coming out of their mouth".

Contextual Plan of Care: The provider addressed the patient's emotional state and misunderstanding about strokes saying that many patients live full lives after a stroke and recover without outward signs. The provider went on to counsel the Vet that a strategy to avoid future strokes was to control his blood glucose level. The patient agreed to work on controlling his diabetes.

- 2.) **Contextual Flag:** The patient missed 5 appointments in the last four months.

No Probe:

Contextual Factor Revealed by Pt.: The patient stated that he was informed that the specialty clinic he was to visit only saw patients on Wednesdays and that interfereContextual with his work schedule.

Contextual Plan of Care: The provider informed the patient that he was given erroneous information and that the clinic was in fact open on Mondays when the patient could attend.

- 3.) **Contextual Flag:** The patient refused the flu vaccine.

No Probe:

Contextual Factor Revealed by Pt.: The patient stated that his sister always gets a headache after getting the flu shot.

Contextual Plan of Care: The provider addressed the patient's understanding of the flu vaccine by informing the patient that he shouldn't base his decision on other people's perception of the effects of the vaccine.

Examples of physician probing, no contextual factor:

- 1.) **Contextual Flag:** High A1C (10.4)

Probe: The provider asked the patient, "What do you remember about learning about your diabetes?" and "What has changed (since the last visit)?"

No Contextual Factor: The patient was following the previously discussed plan of care by modifying diet and taking medications as prescribed.

- 2.) **Contextual Flag:** The patient missed 2 appointments in the past 4 months.

Probe: The provider asked, "What happened? Did they send you a letter?"

No Contextual Factor: The patient did not reveal any contextual reason for missing the appointments.

No Contextual Plan of Care Necessary

- 3.) **Contextual Flag:** The patient refused the flu shot.

Probe: The provider asked, "Why?"

No Contextual Factor: The patient stated that it was his preference to not get the flu shot.

No Contextual Plan of Care Necessary

Examples of a physician probing, contextual factor revealed; contextual plan made.

- 1.) **Contextual Flag:** High A1C (10.6)
Probe: The provider asked the patient if he was taking his insulin as prescribed.
Factor: The patient revealed that he was not taking regular dosages of insulin because he was unable to afford food and he was instructed to take his insulin with food.
Contextual Plan of Care: The provider addressed the patient's financial situation by referring him to a VA Social Worker.

- 2.) **Contextual Flag:** The patient missed an appointment.
Probe: The provider asked the patient why he missed the appointment.
Contextual Factor: The patient stated that he missed the appointment and then wasn't sure how to reschedule the appointment – he wasn't sure how to contact the provider.
Contextual Plan of Care: The provider addressed the patient's understanding of how to reschedule appointments by providing him with the phone number to use, also schedules an appointment for the patient while he is in the room.

- 2.) **Contextual Flag:** The patient refused the flu vaccine.
Probe: The provider asked, "Why not?"
Contextual Factor: The patient stated that he thought the flu shot would make him "jittery."
Contextual Plan of Care: The provider addressed the patient's understanding of the flu shot and its side effects.

CODER OBSERVATIONS –

Probes that reveal another Contextual flag should be probed further (happens quite a bit):

At times, providers probe a contextual Contextual flag, but when the patient responds with another contextual Contextual flag, the provider does not probe further. In some cases, continuing to probe will reveal an issue that the provider can address.

For instance:

Contextual Flag: Poorly controlled diabetes (A1C 10.9)
Probe: Provider: "Are you taking your medications as prescribed?"
(This is a contextual probe, but a closed question.)
New Contextual Flag: Patient: "I sometimes skip taking my insulin."

The provider stopped the line of questioning. The provider did not ask why the patient skipped dosages of insulin. It's possible that there is a contextual factor the provider could address. Perhaps the patient has issues remembering his meds and the provider could recommend strategies for remembering to take insulin – alarm on phone, post-it notes, etc.

Example of provider following up on new Contextual flag:

Contextual Flag: Poorly controlled diabetes (A1C 9.1)
Probe: Provider: Why is your A1C higher?
New Contextual Flag: Patient: "I've been bad."
Probe New RF: Provider: "Do you mean your diet?"

The patient went on to reveal that he'd been eating more candy and carbohydrates. The provider and patient strategized ways to eliminate the candy and carbs.

Anticipating a problem:

Occasionally a patient will mention a contextual factor that isn't a problem, but could be a problem in the future.

Example: A patient mentioned that he and his wife have tried to quit smoking, but they were unsuccessful. The patient requested a smoking-cessation medication to try. The provider suggested that the patient's wife also see her physician to start the same medication, counselling the patient that it would be difficult to stop smoking if his wife continued to smoke.

Communication Skills:

Some providers type while talking or while the patient is talking. Some providers are able to handle the EMR efficiently while others miss what the patient is saying or lose track of what they are saying.

Good communications skills help diffuse patient's frustration with the system.

Example: A patient had left an appointment with a VA specialist because the wait was very long and he felt disrespected. The provider:

- Listened to the patient's story without interrupting
- Apologized that he had that experience
- Empathized appropriately

Because this provider used effective communications skills, the patient's anger and frustration dissipated quickly and they were able to conduct the encounter.

Effective communications skills (quite often these don't occur during an encounter):

- Introduction at the beginning of the encounter (saying "Hello" and giving patient your name)
- Asking permission before some physical exam procedures
- Explaining physical exam procedures
- Communicating results of physical exam procedures
- Asking patient if they have any questions
- Excusing self if there is an interruption
- Closing the encounter professionally (saying "Good bye")

Hannel, Eric

From: Germaine Clarno <gc0039@gmail.com>
Sent: Tuesday, May 12, 2015 11:03 AM
To: Hannel, Eric
Subject: Fwd: Audio recording of physician appointments
Attachments: QI Response.pdf; QI Reponse IRB Chairperson letter.pdf; QI Response Provider information sheet.pdf; QI Response Patient Information Sheet.pdf; QI Response VISN 12 Lettr.pdf; QI Response QI Report.pdf

Eric,

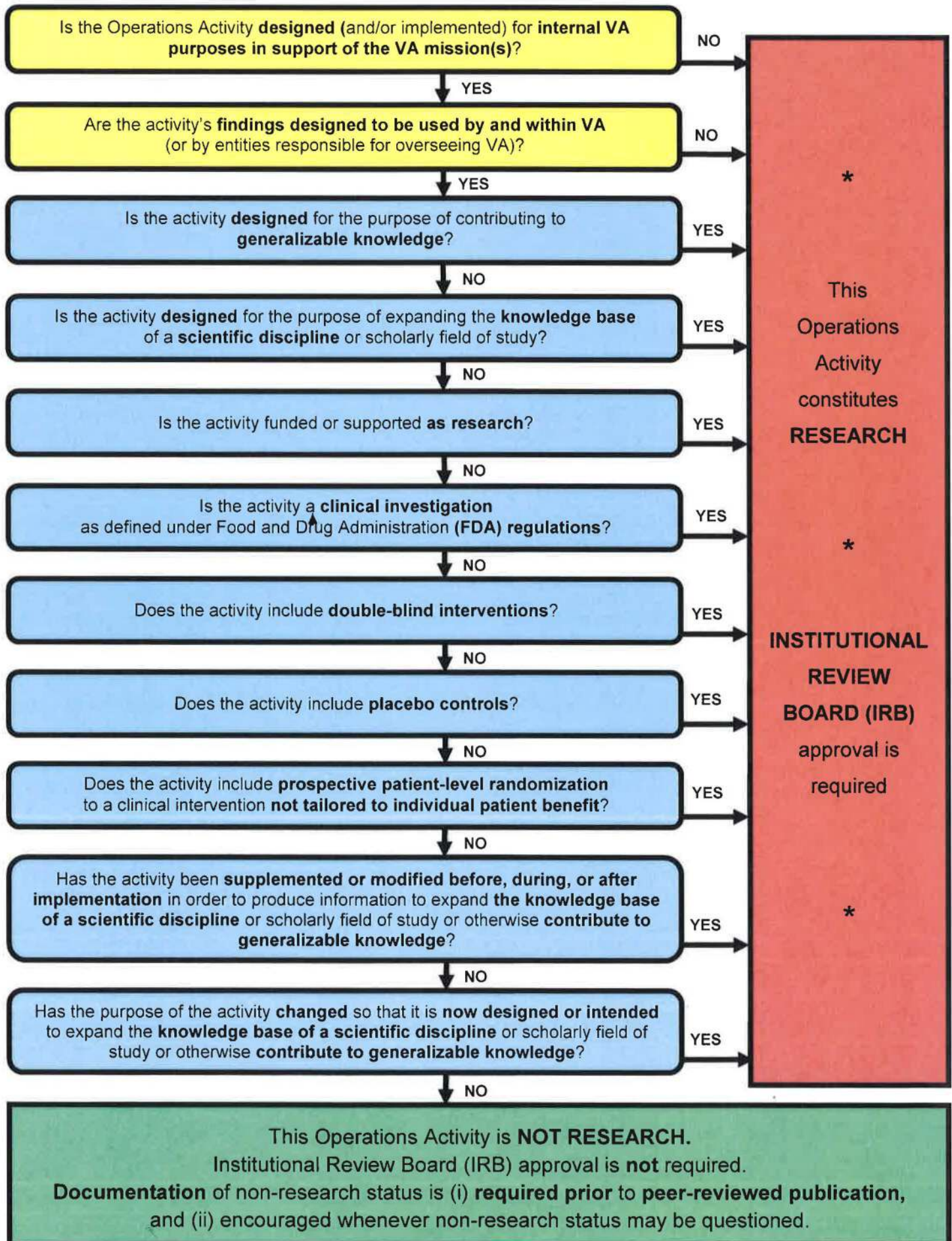
Here is some information about this "QI" project. I will be sending you more about the conflict of interest as well.

Drs. Weiner and Pawlikowski do not believe veterans should be paid or provide a signed informed consent form prior to the recording. Further, the recording is done randomly, so the doctor is not aware. The veterans are approached at random in the waiting room. Many speak with their doctor and show them the recorder or place stickies on their hands telling the doctor he/she is being recorded undercover. There are no metrics to know which veterans solicited by the program are able to grant consent (e.g. they are incompetent). Again, NONE OF THE 1000 VETERAN PARTICIPATES SIGNED ANY INFORMED CONSENT FORMS per Dr. Weiner; only the actors involved signed such forms and were paid.

Thanks,

Germaine

VHA Operations Activities That May Constitute Research



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Entity Details

File Number: **4576902** **Incorporation Date / Formation Date:** **07/18/2008**
(mm/dd/yyyy)

Entity Name: **INSTITUTE FOR PRACTICE AND PROVIDER PERFORMANCE IMPROVEMENT, INC.**

Entity Kind: **CORPORATION** **Entity Type:** **GENERAL**

Residency: **DOMESTIC** **State:** **DE**

Status: **GOOD STANDING** **Status Date:** **03/31/2015**

TAX INFORMATION

Last Annual Report Filed: **2014** **Tax Due:** **\$ 0.00**

Annual Tax Assessment: **\$ 175.00** **Total Authorized Shares:** **100**

REGISTERED AGENT INFORMATION

Name: **CORPORATION SERVICE COMPANY**

Address: **2711 CENTERVILLE RD SUITE 400**

City: **WILMINGTON** **County:** **NEW CASTLE**

State: **DE** **Postal Code:** **19808**

Phone: **(302)636-5401**

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Saul J. Weiner, MD
Founder and Principal

Saul Weiner is a board certified internist and pediatrician with practice, leadership, and research experience in a variety of health care settings. He has served as a residency program director, academic division head, clinic director, and health services investigator. Dr. Weiner is a former Generalist Physician Faculty Scholar of the Robert Wood Johnson Foundation. He has served as a principal or co-investigator of studies of health systems improvement, health surveys, medical decision making and provider communication funded by the Robert Wood Johnson Foundation, the National Institutes of Health, the National Science Foundation, and the Veterans Administration. Over the last 5 years he has focused on developing and refining methods that employ incognito standardized patients to collect performance and quality of care data in a broad range of health care settings.

Alan Schwartz, PhD

Founder and Principal

Alan Schwartz is a cognitive psychologist with expertise in medical decision making, organizational behavior, and measurement with over a decade of experience evaluating and training health care providers to improve quality. His research in medical decision making and evidence-based medicine has been funded by the National Science Foundation, the National Library of Medicine, the National Board of Medical Examiners, and the Robert Wood Johnson Foundation. He serves on the editorial board of the journal Medical Decision Making. His most recent book, published by Cambridge University Press, is Medical Decision Making: A Physician's Guide.



Amy Binns-Calvey

Standardized Patient Coordinator

Amy Binns-Calvey oversees all aspects of the training and oversight of our actors in the field. To date she has overseen over 300 (and counting) unannounced visits in the field to dozens of physicians and practices throughout Chicago and Milwaukee. She extensively trains and supervises standardized patients in the educational, testing and research arenas. Amy brings 30 years of professional theater experience (including directing an off-Broadway production) to her with standardized patients. She has been an instructor and program designer for The Art Institute of Chicago's Young Artists Studios and an Illinois Arts Roster artist in residence. Her proficiency with improvisational techniques uniquely qualifies her for training SPs to remain undetected during unannounced encounters. Amy has first-hand experience as an unannounced SP, working undercover.

Gunjan Sharma
Project Manager



Gunjan Sharma oversees and coordinates projects, working closely with our clients to assure seamless communication. She has extensive experience setting up unannounced standardized patient visits in numerous health settings ranging from small group practices to large hospital clinics and clinic networks. She has served as a the project director of a large federally funded study involving nearly 400 unannounced standardized visits to over 100 physicians and practices throughout the Midwest. Previously, she served as a research associate conducting studies on safety across high consequence industries, including aviation, with an emphasis on safety culture in high reliability organizations.

Gunjan has a Ph.D in Business Commerce and Industrial Psychology from the University of Jammu, India.

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Research

I3PI investigators are on the cutting edge of research to measure and improve quality, particularly with the application of simulated visits. Drs. Weiner and Schwartz recently completed a large federally funded study of over 100 physicians in practices in two large metropolitan areas using simulated patients to collect data on variations in approaches to management and quality of care. Actors are trained to reproduce the same scenarios, behaviors and dress, enabling the research team to examine the influence of length of visit, physician experience, and many characteristics of the practice environment that could influence quality of care. The study has been published in *Annals of Internal Medicine*. A video demonstration of the unannounced standardized method use in that study is available [here](#).

A follow-up study by the team demonstrating an educational approaches to reducing errors in doctors-in-training appeared in *JAMA*, and a demonstration of the added value of simulated patients in the real practice environment vs. "known" simulated patients appeared in the *Joint Commission Journal on Quality and Patient Safety* in 2013.

Staff have also developed and validated a methodology for measuring how effectively care is individualized in the primary care setting. This coding method was used to show that individualizing care is associated with improved patient outcomes in a 2013 study in *Annals of Internal Medicine*.

Meet our
Leadership
Team

I3PI Founder Dr. Saul Weiner was interviewed about research in individualizing care in the October 2008 issue of *The Hospitalist* journal, in the July 20, 2010 issue of the *Chicago Tribune*, and on Chicago Public Radio's *Eight Forty-Eight* show. I3PI Founder Dr. Alan Schwartz has spoken about individualizing care on NPR's *Talk of the Nation* Science Friday and been quoted in several television and newspaper stories on the topic.

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Patients go undercover to record encounters with doctors

Sherri McGinnis González

April 15, 2013

Patients' health outcomes improve when physicians individualize care and take their patients' life circumstances into account, according to a new study by the University of Illinois at Chicago and the U.S. Department of Veterans Affairs.

The study is the largest ever to be conducted using real patients to collect data about their doctors' behavior using concealed audio recorders. It appears in the April 16 issue of *Annals of Internal Medicine* and was funded by the U.S. Department of Veterans Affairs.

"What our study really tells us is that the information that patients divulge during appointments about their life situation is critical to address and take into account if we're looking for optimal health care outcomes," said Dr. Saul Weiner, professor of medicine, pediatrics and medical education at UIC and staff physician at the Jesse Brown VA Medical Center, who was lead author of the study.

A goal of the study was to determine if patient-centered decision making — identifying clinically relevant information about a patient's circumstances or behaviors — impacted health care outcomes.

The study recruited 774 real patients who secretly audio recorded their visits with 139 resident physicians at two Chicago VA facilities. The doctors had all agreed to participate in the study but were not told which patients were recording them.

"Incognito audio recording provides accurate information about how doctors practice that you can't obtain any other way," said Alan Schwartz, professor and associate head of medical education at UIC, a methodologist and co-author of the paper.

The researchers developed a coding method to score physicians based on whether they individualized a patient's care plan by taking into account key contextual factors, such as financial hardship, transportation problems, competing responsibilities, social support and other factors. Inattention to such issues leads to what are called "contextual errors" in patient care.

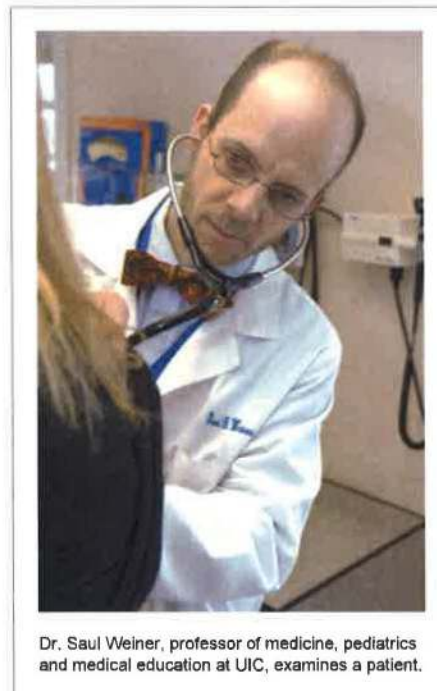
For example, if a patient had missed a lot of appointments that would be a red flag. In other words, it is something the physician should be asking about because it is clearly interfering with the patient's care.

"If the patient has, for example, a chronic condition like diabetes or hypertension that's going out of control we would say that that's also a contextual issue and probably a sign that something is going on in that patient's life that needs to be addressed," Weiner said.

In the study, the researchers reviewed the patient's medical record and evaluated the recordings to determine if a care plan was patient-centered by answering three questions: Are there contextual red flags? If so, did the physician recognize the red flags and question the patient about contextual factors that could be addressed in a care plan or did the patient volunteer such information? If so, did the physician address the contextual factors in the recommended care plan?

The patients were followed for up to nine months to evaluate their health care outcomes and determine if the original red flag had been partially or fully resolved.

Each participating physician was repeatedly audio recorded until the researchers obtained three encounters with contextual red flags. The final data included 403 encounters with a total of 548 red flags. Among the 548 red flags, 208 contextual factors were confirmed either when physicians probed or patients volunteered information.



Dr. Saul Weiner, professor of medicine, pediatrics and medical education at UIC, examines a patient.

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When contextual factors were essential to the care plan, physicians made a contextualized care plan 59 percent of the time; 41 percent of the time they did not.

In the cases where the physician made a contextualized care plan, there was a good outcome in 71 percent of the cases and a bad outcome in 29 percent of cases. When physicians did not develop a contextualized care plan, a good outcome occurred in 46 percent of cases and a bad outcome occurred in 54 percent of cases.

Weiner said while it may seem intuitive that if a patient is missing appointments and the physician discovers it's because the patient lost their transportation and refers them to a clinic-supported van service, it will result in fewer missed appointments. "But this is the first study to document an association between contextualizing patient care and patient care outcomes," he said.

Other co-authors include Ilene Harris and Amy Binns-Calvey of the UIC College of Medicine; Dr. Amit Dayal, Frances Weaver and Brendan Kelly of Hines Veterans Affairs Hospital; Gunjan Sharma and Naomi Ashley of Jesse Brown Veterans Affairs Medical Center; and Dr. Sonal Patel of Durham VA Medical Center.

[An extended interview as MP3 audio file and transcript.]

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Identifying and Predicting Contextual Errors in Medical Decision Making

Abstract

Relevance: Overlooking critical information about a patient's life and unique circumstances — their "context" — can have predictable and avoidable adverse effects as significant as those anticipated from an incorrectly diagnosed but treatable condition. When such oversights result in "the failure of a planned action to be completed as intended, or the use of a wrong plan to achieve an aim" they represent instances of medical error, as defined by the Institute of Medicine. Such "contextual errors," however, are usually missed using current methods to identify or predict medical error.

Objectives: Using a factorial design, this study will test hypotheses and explore mechanisms of how physicians under-prioritize contextual, relative to biomedical, information during the processes both of history taking and of planning patient care. It also will attempt to identify the cognitive processes associated with avoidance of contextual error, and the characteristics of physicians and the medical encounter that influence the likelihood of contextually appropriate care.

Procedure: The experiment involves using unannounced standardized patients and four scripted cases, each with four variations, three of which are embedded with biomedical and/or contextual information that is essential to care. At the start of the study, 112 fully trained internists at four VA hospitals and their university-affiliated medical centers, will provide data on their education, practice experience, and sociodemographic background. They will then be randomized to receive one of four variations from each of the four cases, appearing as new patients in their practice some time over a study period of 18 months. Eight actors, four African American and four Caucasian, will be paired in groups of two with each pair assigned to one case and its variants. The first variant, known as the baseline, consists of a patient presenting with a straightforward clinical problem, typical of what a primary care physician might encounter routinely in the office setting. In the second, appropriate questioning will uncover atypical features pointing to an unexpected biomedical condition requiring alternative management. In the third, appropriate questioning will uncover atypical features pointing to an unexpected psychosocial, or contextual, situation requiring alternative management. In the fourth, appropriate questioning will uncover both the biomedical and contextual "qualifiers," requiring a multifactorial approach to management. The encounters will be audiotaped and analyzed using checklists and interaction analysis. Outcome variables are whether the physician attempts to elicit the embedded information in the atypical cases and, if they do, whether their treatment recommendations incorporate that information. Analysis across the groups and cases will allow comparisons of subjects' priorities and interpretive abilities for managing biomedical and contextual complexities in patient care. Factor analysis of data from the interaction analysis will be used to develop a latent factor score of contextual reasoning for each case of each subject. A path analysis will test a predictive model of contextual reasoning skills, physician characteristics, and encounter conditions that influence the outcome variables.

Significance: This study will elucidate the mechanisms of medical errors caused by failures to gather or use information about patients' life context. It will also attempt to identify the characteristics of clinicians (particularly their cognitive skills) and the encounter conditions that predict contextual error-making. Finally, by introducing a methodology for identifying contextual errors it will enable future study of interventions to reduce their frequency.

Affiliated Center/Program

[Health Promotion Research Program \(/center/health-promotion-research-program\)](#)

Principal Investigator

[Saul J. Weiner, MD \(/researcher/saul-j-weiner-md\)](#)

Funding Agency

[Veterans Administration Health Services Research and Development \(http://www.hsrd.research.va.gov/\)](#)
(investigator-initiated merit award)

Start date

10/01/2006

End date

08/31/2009

Contextual Errors and Failures in Individualizing Patient Care

A Multicenter Study

Saul J. Weiner, MD; Alan Schwartz, PhD; Frances Weaver, PhD; Julie Goldberg, PhD; Rachel Yudkowsky, MD, MHPE; Gunjan Sharma, PhD; Amy Binns-Calvey; Ben Preyss, BA; Marilyn M. Schapira, MD, MPH; Stephen D. Persell, MD, MPH; Elizabeth Jacobs, MD, MPP; and Richard I. Abrams, MD

Background: A contextual error occurs when a physician overlooks elements of a patient's environment or behavior that are essential to planning appropriate care. In contrast to biomedical errors, which are not patient-specific, contextual errors represent a failure to individualize care.

Objective: To explore the frequency and circumstances under which physicians probe contextual and biomedical red flags and avoid treatment error by incorporating what they learn from these probes.

Design: An incomplete randomized block design in which unannounced, standardized patients visited 111 internal medicine attending physicians between April 2007 and April 2009 and presented variants of 4 scenarios. In all scenarios, patients presented both a contextual and a biomedical red flag. Responses to probing about flags varied in whether they revealed an underlying complicating biomedical or contextual factor (or both) that would lead to errors in management if overlooked.

Setting: 14 practices, including 2 academic clinics, 2 community-based primary care networks with multiple sites, a core safety net provider, and 3 U.S. Department of Veterans Affairs facilities.

Measurements: Primary outcomes were the proportion of visits in which physicians probed for contextual and biomedical factors in response to hints or red flags and the proportion of visits that resulted in error-free treatment plans.

Results: Physicians probed fewer contextual red flags (51%) than biomedical red flags (63%). Probing for contextual or biomedical information in response to red flags was usually necessary but not sufficient for an error-free plan of care. Physicians provided error-free care in 73% of the uncomplicated encounters, 38% of the biomedically complicated encounters, 22% of the contextually complicated encounters, and 9% of the combined biomedically and contextually complicated encounters.

Limitations: Only 4 case scenarios were used. The study assessed physicians' propensity to make errors when every encounter provided an opportunity to do so and did not measure actual error rates that occur in primary care settings because of inattention to context.

Conclusion: Inattention to contextual information, such as a patient's transportation needs, economic situation, or caretaker responsibilities, can lead to contextual error, which is not currently measured in assessments of physician performance.

Primary Funding Source: U.S. Department of Veterans Affairs Health Services Research and Development Service.

Ann Intern Med. 2010;153:69-75.

www.annals.org

For author affiliations, see end of text.

Clinical decision making has been described (1) as answering the question, "What is the best next thing for this patient at this time?" To be effective and safe, care plans must be tailored to a patient's individual circumstances. Intensifying the medication regimen for a patient with poorly controlled asthma who cannot afford his or her current medications is an example of ordinarily appropriate provider behavior that represents inappropriate care under the circumstances.

According to the Institute of Medicine (2), an inappropriate plan of care is a medical error. We refer to decision-making errors that occur because of inattention to patient context as *contextual errors* (1, 3). By patient context, we mean those elements of a patient's environment or behavior that are relevant to their care, including their economic situation, access to care, social support, and skills and abilities. Contextual errors represent a failure to individualize care (4). All other decision-making errors may be classified as *biomedical errors* (3).

Decision-making errors can occur if clinicians do not identify clinically essential information or do not correctly incorporate essential information into the plan of care. In a previous study (5), we developed and tested a method

for assessing physician propensity to make contextual or biomedical errors in clinical encounters with standardized patients. In this study, we applied that method in a multicenter field experiment by using unannounced, standardized patients to assess how well-experienced internal medicine physicians can probe for contextual and biomedical factors in response to hints (red flags) and incorporate their findings into the plan of care.

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Appendix Table
Video supplement
Conversion of graphics into slides

Context

Understanding a patient's individual situation or context is essential to planning appropriate care.

Contribution

In this study, standardized patients visited physicians, reported a medical problem, and gave hints of contextual and biomedical complicating factors. Their responses to probing revealed no complicating condition or an underlying contextual or biomedical issue (or both) that would lead to management errors if overlooked. Physicians probed fewer contextual than biomedical hints. They provided error-free care more often in the uncomplicated encounters (73%) than in the biomedically (38%), contextually (22%), or biomedically and contextually (9%) complicated encounters.

Implication

High error rates may occur when physicians face complicated situations that require attentiveness to individual patient context.

—The Editors

METHODS

Eight actors were trained by the University of Illinois at Chicago Dr. Allan L. and Mary L. Graham Clinical Performance Center, a specialized facility for standardized patient training and testing, with 2 actors (1 white, 1 black) assigned for each of 4 cases. The actors presented as real patients and followed scripts that contained hints of clinically significant biomedical or contextual issues that, if confirmed, would be essential to address to avoid error. The only way a physician could know whether the hints were clinically significant was to recognize them as red flags that warranted follow-up and probe for additional information. A video describing the study methods is available at www.annals.org.

We designed our study to track whether biomedical or contextual errors occurred because of a physician's failure either to notice the hints or to incorporate what they had heard into the plan of care. We also sought to explore potential predictors of error, including physician demographic characteristics, such as practice experience; visit characteristics, such as time spent with a patient; and 1 patient characteristic—whether the actor was black or white.

During the consent process, we informed the physician-participants that this was a study of "decision making" and that up to 4 incognito standardized patients would visit them over the next 18 months and surreptitiously make audio recordings of each encounter. Actors were entered into the scheduling system as actual patients. All visits occurred between April 2007 and April 2009. The institutional review boards of the University of Illinois

at Chicago, the Jesse Brown Veterans Affairs Medical Center, and all site affiliates approved the study.

Physician Sample

We approached 152 attending physicians in primary care internal medicine at 14 practice locations, including 2 medical center–based academic clinics, 2 community-based groups with multiple sites, a core safety net provider, and 3 large primary care facilities within the U.S. Department of Veterans Affairs (VA) system, situated in 2 metropolitan areas. After each encounter, a copy of the physician's note was forwarded to the project team, and we then contacted participants by e-mail and asked whether they believed the patient had been real or an actor (6).

Case Scenarios

Each case had 4 variants: uncomplicated, biomedically complex, contextually complex, or both biomedically and contextually complex. Each actor was trained to present all variants of a case and instructed on which one to enact on any given visit.

At the beginning of any variant, the actor presented a baseline story that suggested a common ambulatory condition that warrants pursuing a standard evaluation or treatment. For example, one case involves a man, aged 42 years, with long-standing asthma that has worsened recently despite the prescription of a low-dose inhaled glucocorticoid (video available at www.annals.org). With no other clinically relevant information, appropriate care would include intensifying the treatment (for example, by prescribing a higher dose of medication) or adding a second agent, such as a long-acting β -agonist.

In addition to the baseline story, the actor also mentions both a biomedical and a contextual red flag, each suggesting a more complex presentation that requires an alternative approach to care. For the biomedical red flag in the asthma case, the actor says, "Sometimes I wake up wheezing or coughing at night," which suggests that his worsening asthma is due to the onset of gastroesophageal reflux symptoms. This red flag is intended to prompt the physician to probe further on whether confirmatory symptoms of reflux are present, including heartburn; hoarseness; cough; or increased symptoms after large, fatty meals. For the contextual red flag, the actor says, "Things have been tough since I lost my job," which suggests that his symptoms are worsening because he cannot pay for medications. This red flag is intended to prompt the physician to probe further on whether the patient has become medically indigent and cannot adhere to the prescribed pharmacotherapy. The Appendix Table, available at www.annals.org, provides an overview of each of the 4 cases and their biomedical and contextual red flags.

For the uncomplicated version of each case, if the physician attempts to elicit more information about either red flag, the actor provides reassurance that the complicating condition is not present. In the asthma example, questions

about reflux yield a negative review of symptoms. The intended conclusion is that the patient does not have reflux, only nocturnal symptoms related to poorly controlled asthma. Questions about possible loss of health insurance yield a reassuring response that the patient is covered by his wife's plan and is not having difficulty affording his medications as prescribed.

In the biomedical variant, elicitation yields confirmatory evidence of the complicating biomedical condition: The patient reports having sufficient symptoms of gastroesophageal reflux disease to warrant a management plan for that condition. In the contextual variant, elicitation yields confirmation from the patient that he cannot take his medication daily because of the cost, which indicates that instructions to take a higher dosage or more medication would not be effective or appropriate. In the combined biomedical and contextual variant, probing for each red flag is rewarded with the clinically significant information. For these complicated case variants, failure to attend to any relevant underlying biomedical or contextual issue that the patient presents constitutes inappropriate care (or error) for that variant.

Our criteria for appropriate versus inappropriate care for the uncomplicated and biomedically complex variants reflect current standards of care. For example, we based our criteria for inadequately controlled asthma that warrants intervention on international guidelines (7). We developed our criteria for appropriate versus inappropriate care for the contextually complex variants on the basis of an iterative process that involved 16 experienced internal medicine primary care physicians who were not part of the study population. We randomly assigned them to review scripts independently until each physician agreed with all the others who reviewed the same case variant and disagreed with those who reviewed different variants of the same case regarding appropriate management, when all contextual information was revealed. We considered a case to be a valid instrument for assessing physician performance when including the contextual information was certain to prompt a sample of Board-certified physicians to recommend non-baseline care (5).

The **Appendix Table** illustrates the errors that would result from continuing to provide baseline care in the setting of a biomedically or contextually complicated variant. For example, not treating the patient with asthma for gastroesophageal reflux disease despite 4 symptoms of the condition would constitute a biomedical error. Similarly, recommending increased dosages of asthma medication despite 4 indicators that the patient cannot afford his current therapy would constitute a contextual error. The **Appendix Table** also summarizes baseline errors that occurred, such as taking no action to address inadequately controlled asthma in the baseline version of that case; such errors were relatively uncommon.

Allocation and Outcomes Assessments

We used an incomplete randomized block design. Physicians were assigned by computer-generated random number to 1 of 16 permuted blocks that combined 4 cases and variants in a partial factorial arrangement, so that each physician was assigned to receive 1 of each of the 4 cases with a different variant in each (a total of 4 visits per physician). To reduce suspicion, we typically scheduled the first visit for several months after a physician was enrolled. We scheduled the remaining visits over approximately 1 year on the basis of appointment availability.

We report 2 primary outcomes: success or failure to probe contextual or biomedical red flags and success or failure to implement the appropriate care plan for the case variant. We also assessed the costs of errors (data not shown).

Trained coders used checklists to score the probing from the audio recordings of the encounters. The coders also audited the actor's portrayal to ensure that scripts were precisely followed. Physicians were given credit for probing with either closed or open-ended questions in response to red flags. For example, when the patient with poorly controlled asthma volunteered that "Things have been tough since I lost my job," a physician would get credit for either "Are you having trouble affording your medications now?" or "How has it been tough for you?" but not for "I'm sorry to hear that."

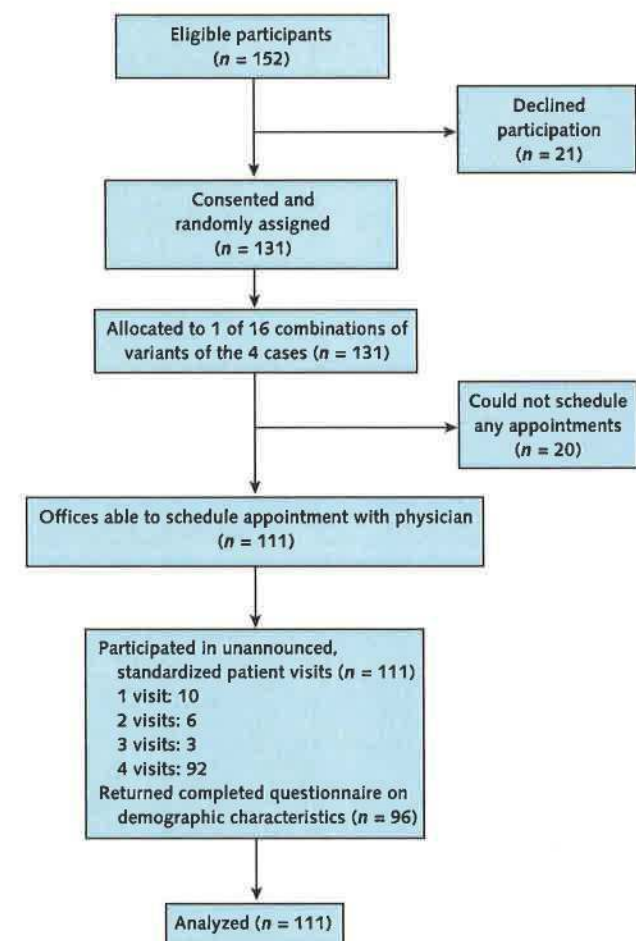
The care plan was scored from the physician's note (or from his or her recorded statement of the plan of care to the patient when the note was unavailable), again by coders who used a checklist and were blinded to the case variant—although the variant could be inferred when physicians correctly adapted their care plan to the case variant. We predefined the criteria for appropriate care as avoiding particular errors (**Appendix Table**).

We sent physicians questionnaires to collect data on potential predictors of physician performance, including age, race, sex, medical school location (United States, Canada, or other), previous formal communication training (yes or no), years since residency, and number of half-days of clinical time. We sent the questionnaires after each physician's final completion of study visits. For all visits, total and face-to-face times were documented, as was actor ethnicity and physician-actor concordance of ethnicity (when physicians provided demographic data).

Statistical Analysis

We compared rates of probing of contextual and biomedical red flags across cases by using the McNemar test of correlated proportions, with particular attention to the uncomplicated baseline variant. We compared the proportion of correct treatment plans among uncomplicated, biomedically complicated, contextually complicated, and combined biomedically and contextually complicated variants by using chi-square tests. On the basis of pilot studies, we determined that a sample size of 52 physicians would provide

Figure 1. Study flow diagram.



80% power to detect an absolute difference of 25 percentage points in the rate of biomedical versus contextual probing. Similarly, 25 visits per condition would provide 80% power to detect absolute differences between variants of 20 percentage points in correct treatment plans; on the basis of the assumption that probing would not occur on all visits, we sought to perform at least 75 visits per condition.

In addition, we fitted 3 mixed-effects logistic regression models that predicted biomedical probing, contextual probing, and treatment plan outcomes to test the independent effects of multiple predictors while controlling for case differences and clustering of visits within clinicians. We used the PROC GLIMMIX command in SAS, version 9.2 (SAS Institute, Cary, North Carolina), to fit the models, with physicians as random effects and compound symmetry in the working covariance matrix (8). We fitted the models with full likelihood estimation (METHOD = QUAD). Fixed design effects in the models included whether the variant included a complicating biomedical diagnosis, complicating contextual diagnosis, or both; the

actor's race (black or white); visit site; and case presented. Additional fixed effects included whether the physician reported that they believed the patient was a real patient (if they responded to the follow-up e-mail) and the amount of face time during the visit. We tested demographic predictors, as well as a dummy variable that represented failure to return the demographic questionnaire, for their relationship with design and outcome variables; because we found none, we did not include demographic predictors in the model.

Statistical analysis was performed primarily by 1 investigator. We did not exclude any participants. If a physician could not participate in all 4 planned visits, we included the data from those in which he or she did participate in the mixed model analysis. We also included a dummy variable for each physician in the analysis to indicate whether the physician had completed all 4 visits (9). Usually, when physicians did not complete all 4 visits, it was because they had moved or changed practices; however, 4 physicians requested to discontinue seeing further standardized study patients (1 after a single visit and 3 after 2 visits). We treated missing visits as resulting from a missing-at-random mechanism, because we found no relationship between completing all visits and other model variables, no effect from requesting to discontinue the study, and substantially similar results from an analysis that included only physicians who completed all 4 visits (not reported).

Role of the Funding Source

Our study was funded by the VA Health Services Research and Development Service. The funding source was not involved in the formulation of study questions, data collection, statistical analysis, manuscript preparation, or decision to submit the manuscript for publication.

RESULTS

Participants and Visits

Eighty-six percent of eligible physicians agreed to participate in the study, but we could not schedule visits with 20 of them because they closed their practice or relocated after study initiation (Figure 1). The Table shows the demographic characteristics of the remaining physicians who returned the questionnaire (96 of 111 [86.5%]). We coded 399 unannounced standardized patient visits for probing of biomedical and contextual information. Coding was based on the audio recordings (380 visits) or, if the recorder failed, on checklists completed by the actors (19 visits). Coding of plan of care was based on physician notes (382 visits) or on the recording if the notes were missing (16 visits); visits for which neither the note nor the recording was available (because of recorder failure) were not coded.

A second rater reviewed a sample of 15% of the recordings (63 visits) from all cases and variants to score the probing. We resolved minor discrepancies in the coding of

5 visits by discussion. Two raters coded all 398 care plans for appropriateness and resolved 12 discrepancies (mostly due to note illegibility) by listening to the recordings. Physicians responded to the postvisit suspicion question for 189 visits; 153 physicians (81%) indicated that they believed they were seeing a real patient during the visit.

Visits were conducted over 2 years. The mean time between the closest subsequent visits to the same physician was 63 days (SD, 50), the median was 59 days, and 80% of subsequent visits took place 3 to 144 days apart. The mean time between the first and last visit to the same physician was 334 days (SD, 144), the median was 343 days, and 80% of first and last visits took place 127 to 521 days apart.

Probing

Physicians probed fewer contextual red flags (51%) than biomedical red flags (63% across all visits) (McNemar test chi-square, 12.4; $P < 0.001$), and also fewer contextual red flags (32%) than biomedical red flags (53%) in the 107 baseline or uncomplicated variant visits (McNemar test chi-square, 10.4; $P = 0.001$). Figure 2 shows that the unadjusted rates of probing varied among the 4 case scenarios. The overall rate of contextual probing was higher than the rate of biomedical probing in contextual variants, whereas the opposite was true in biomedical variants. This resulted from standardized patients responding to open-ended questions with a comment related to that variant, which often prompted physicians to probe if they had not done so already. For instance, in the contextual variant of the asthma case, in response to "Any other problems?" the standardized patient could elaborate on his or her financial situation but not on symptoms of gastroesophageal reflux disease that were not present. This disclosure, in turn, would often precipitate a probe for which the physician would receive credit.

Results of mixed logistic regression models showed no effect of site, patient ethnicity, or physician belief that they had seen an actor on outcomes. Of note, physicians who probed contextual (but not biomedical) red flags were more likely to respond to the follow-up e-mail, regardless of whether they believed they had seen an actor. Greater face time increased the likelihood of probing both the biomedical red flag (adjusted odds ratio [OR] per minute of time, 1.08 [95% CI, 1.03 to 1.12]) and the contextual red flag (adjusted OR per minute of time, 1.05 [CI, 1.02 to 1.09]). As suggested by the unadjusted rates, probing differed for the case scenarios ($P < 0.001$). Also, biomedical probing was higher in the biomedical variants ($P < 0.001$) and contextual probing was higher in the contextual variants ($P < 0.001$).

Plan of Care

Overall, physicians provided error-free care in 73% of the uncomplicated baseline encounters, 38% of the biomedically complicated encounters, 22% of the contextually complicated encounters, and 9% of the combined biomedically and contextually complicated encounters (overall, chi-square, 100 [$P < 0.001$]; for the comparison be-

tween biomedical and contextual variants, chi-square, 6.07 [$P = 0.014$]). Figure 3 shows that the unadjusted rates of appropriate treatment plans varied among cases.

Eliciting biomedical or contextual information was usually necessary but not sufficient for appropriate treatment in complicated variants. Of the 191 biomedically complicated encounters, physicians planned appropriate treatment in 42 of the 136 encounters (31%) in which elicitation occurred and 3 of the 55 (6%) in which it did not. Of the 185 contextually complicated encounters, physicians planned appropriate treatment in 24 of the 120 encounters (20%) in which elicitation occurred and 2 of the 65 (3%) in which it did not.

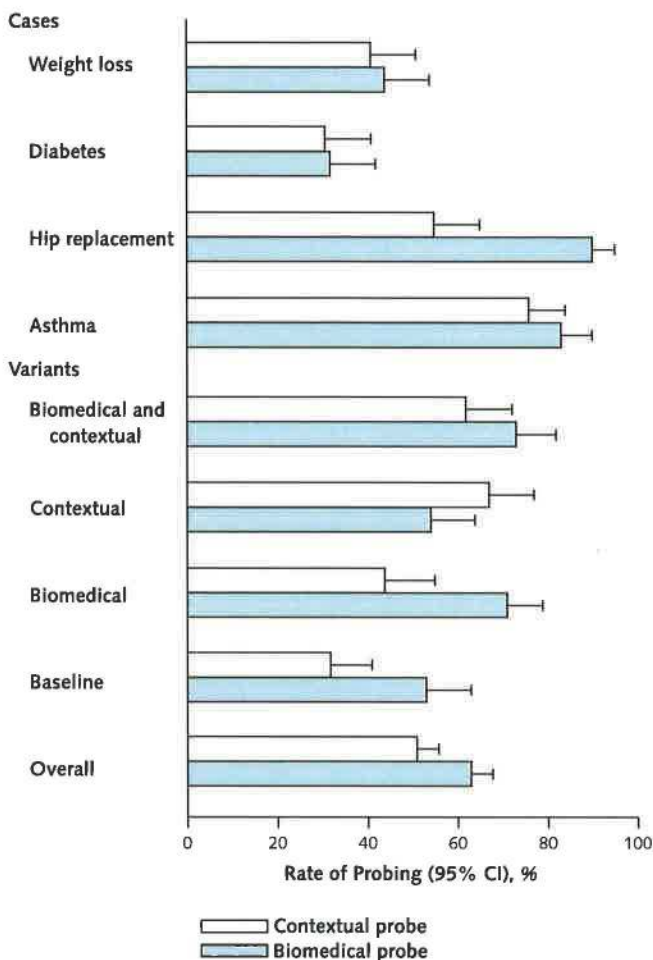
Our mixed logistic regression model found that error was more likely when the variant included a biomedical qualifier

Table. Demographic Characteristics of Participating Physicians

Characteristic	Physicians
Sex, n (%)	
Male	48 (50)
Female	48 (50)
Age, n (%)	
25–34 y	13 (15)
35–44 y	56 (58)
45–54 y	17 (18)
55–64 y	10 (10)
Race or ethnicity, n (%)	
White	57 (59)
Asian	28 (29)
Hispanic	4 (4)
Black	2 (2)
Native American	2 (2)
Multiracial or other	3 (3)
Medical school location, n (%)	
United States	81 (83)
Canada	2 (2)
Other	13 (14)
Time since completion of residency, n (%)	
1–5 y	20 (21)
6–10 y	29 (30)
11–15 y	29 (30)
16–20 y	5 (5)
21–25 y	12 (13)
>25 y	1 (1)
Formal communication training, n (%)	
Yes	9 (9)
No	87 (91)
Mean half-days of clinic per week (SD), n	6.0 (2.4)
Practice site affiliation, n (%)	
U.S. Department of Veterans Affairs	36 (32)
Other	75 (68)
Board-certified in internal medicine, n (%)*	
Yes	104 (94)
No	7 (6)

* On the basis of American Board of Internal Medicine Web site verification.

Figure 2. Unadjusted rates of probing, by case and variant.



Error bars show the upper boundary of the 95% CI.

(adjusted OR, 7.88 [CI, 3.33 to 18.7]), a contextual qualifier (adjusted OR, 16.3 [CI, 6.82 to 39.1]), or a biomedical qualifier that was not elicited (adjusted OR, 6.35 [CI, 1.57 to 25.6]). We found no interaction between the presence of biomedical and contextual qualifiers and no effects on outcomes from patient ethnicity, VA versus non-VA site, physician belief that he or she had seen an actor, case, or face time.

DISCUSSION

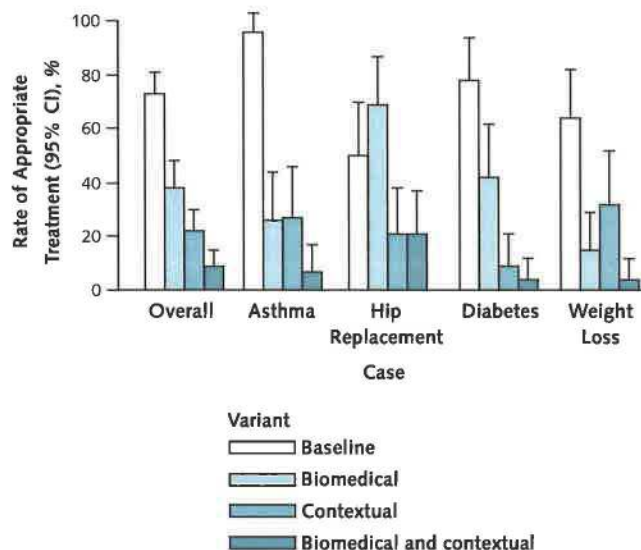
We found high error rates among physicians who were confronted with clinical situations that required attentiveness to a patient’s context. Although the physicians in this study provided error-free care 73% of the time when presented with unannounced, standardized patients who had uncomplicated ambulatory complaints, that percentage decreased to 22% when we introduced complicating contextual factors that required an alternative plan of care. For example, even when a patient with hypoglycemic episodes indicated poor health lit-

eracy and stated, “It’s hard for me to keep numbers straight,” physicians frequently recommended only adjustments in insulin dosing. Two fifths of the time, contextual errors occurred because physicians did not probe in response to contextual red flags. In the remainder of these instances, physicians adhered to a standard, algorithmic approach to care despite eliciting additional evidence of overriding contextual issues.

A MEDLINE search of the English-language literature from the past 5 years reveals instances in which the term *contextual error* has been adopted by others (10, 11) to describe failures to “incorporate patient-specific information into systematic and structured evidence” and as “misconstruing guidelines as standards to be followed rather than knowledge to be incorporated.” Breslin and colleagues (12) refer to the avoidance of contextual error through attention to patients’ circumstances as “contextualization,” and Stange (13) describes it as “the personalized application of the best scientific evidence, tempered by the best evidence from personal context.” Kim and colleagues (14) postulate that “[i]ndividualizing clinical decisions based upon the contextual knowledge of a patient’s beliefs and values as well as responsibilities at work, home, or school” has particular importance for certain high-risk groups of patients, such as those with addiction problems.

Sackett and colleagues (15) define evidence-based medicine as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.” A conscientious and judicious approach requires that physicians investigate indicators of clinically important patient contextual factors and adapt their care plan accordingly. Our study illustrates that physicians frequently fall short of this goal.

Figure 3. Unadjusted rates of appropriate treatment plan, by case or variant.



Error bars show the upper boundary of the 95% CI.

The high error rates we observed could be explained in several ways. First, we designed our study to assess physician propensity to make errors when every encounter provided an opportunity to do so, not to measure actual error rates. We do not know the proportion of encounters in which inattention to context would lead to medical error in, for example, primary care. Second, we developed and validated only 4 cases for this experiment, and probing outcomes varied across cases. These cases may have been unusually challenging or atypical of most patients seen in primary care. Nevertheless, the contextual issues we selected—low health literacy, inability to afford medications, caretaker responsibility, and nutritional deprivation—are all well-documented problems in large segments of the American population (16–19). Third, the hints that the actors offered of underlying contextual issues may have been too subtle. When we developed the cases, we did not have a mechanism to validate whether our expectation that physicians would pursue the red flags was reasonable, only that the underlying contextual information was indeed essential to avoiding an error when planning the patient's care. Fourth, because all of our unannounced standardized patients presented as new patients, we examined physician performance at individualizing care only during first encounters. Error rates could be different in a long-term physician–patient relationship. Finally, we could not fully overcome the logistical challenges of conducting an unannounced, standardized patient study, which resulted in some missing data and loss of subterfuge.

Although tracking physician adherence to guidelines as a quality indicator is straightforward, determining whether physicians are appropriately individualizing care is not. Broadening the assessment of physician performance to include this metric unmasks serious performance problems. Strategies that address the challenge of individualizing clinical decisions through both provider education and new measures of performance are urgently needed.

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Disclaimer: The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the U.S. Department of Veterans Affairs or the U.S. government.

Acknowledgment: The authors thank Simon Auster, MD, JD, Uniformed Services University of the Health Sciences, and Michael Berbaum, PhD, University of Illinois at Chicago, for their constructive input, particularly during the planning and analysis stages of the study.

Grant Support: By the Department of Veterans Affairs Health Services Research and Development Service (grant IIR 04-107).

Potential Conflicts of Interest: Disclosures can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M10-0665.

Reproducible Research Statement: *Study protocol and statistical code:* Available at www.cmc3.research.va.gov. *Data set:* Not available.

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Obtaining of funding: S.J. Weiner, F. Weaver, J. Goldberg.

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Collection and assembly of data: S.J. Weiner, J. Goldberg, R. Yudkowsky, G. Sharma, A. Binns-Calvey, M.M. Schapira, S.D. Persell, E. Jacobs.

Appendix Table. Case Presentations With Criteria for Defining Errors*

Case Presentation	Biomedical Red Flag	Contextual Red Flag	Criteria for Medical Error for Each Variant		
			Baseline Error	Biomedical Error	Contextual Error
Man aged 43 y with recent persistent asthma symptoms despite being prescribed a low dose of a high-cost, brand-name, inhaled glucocorticoid	"Sometimes I wake up wheezing or coughing at night."	"Things have been tough since I lost my job."	No intervention to address inadequately controlled asthma symptoms	Not treated for gastroesophageal reflux despite 4 symptoms of the condition	Patient advised to increase dosage of current medications without consideration of cost, despite 4 indications that he cannot afford them
Woman aged 47 y presenting for preoperative assessment of hip replacement reports mild hypertension and overweight	Mentions recent weight gain, constipation, and heavy menses	"I'm looking forward to the surgery so I can take better care of my son."	No discussion of possible risk factors of surgery	Not evaluated for hypothyroidism despite 4 symptoms of the condition	Physician raises no concerns about surgery despite patient's first priority being to care for an adult child who has end-stage muscular dystrophy and depends on her fully
Diabetic man aged 59 y presents with 2 presyncopal episodes after previous physician increased insulin dosage	"Felt some pounding in my chest when it happened."	Confuses dosages and says, "It's hard for me to keep numbers straight."	No adjustment of insulin dosing or discussion of changes in diet to prevent hypoglycemia	No electrocardiography, event monitor, or stress test ordered in patient with 4 symptoms of arrhythmia	No discussion of or plan to address obstacles to self-care in patient with 4 indications of learning or cognitive disability that impairs his capacity to correctly dose his medication since he left a community where he had assistance
Man aged 72 y with unexplained weight loss	Shows signs of being depressed	Seems impoverished and possibly homeless	No evaluation for cancer in patient with unexplained weight loss for whom depression and malnutrition have been ruled out	No treatment or referral for depression in patient with 4 symptoms of depression	No discussion of or plan to address malnutrition in patient who provides 4 indications of inadequate access to food

* Presentations and red flags were the same for all variants of a case. The biomedical and contextual variant (not shown) was always a combination of the biomedical and contextual variants.

CORRECTION

In the recent article by Weiner and colleagues (1), there were 2 errors in the Editors' Notes sidebar. The Contribution section should have begun with "In this study," and should have included the paragraph in the Caution section. The online version has been corrected.

Reference

1. Weiner SJ, Schwartz A, Weaver F, Goldberg J, Yudkowsky R, Sharma G, et al. Contextual errors and failures in individualizing patient care. A multicenter study. *Ann Intern Med.* 2010;153:69-75.

January 22, 2014



Saul J. Weiner, M.D.

Saul J. Weiner, M.D., Associate Director of the HSR&D Center of Innovation (COIN) for Complex Chronic Healthcare, has been named by the University of Illinois at Chicago (UIC) as a recipient of the 2013 Distinguished Researcher Award. This award is presented by the UIC Office of the Vice Chancellor for Research, and is given to five researchers who have demonstrated outstanding research achievements in their field of expertise.

Dr. Weiner's research focuses on issues of access to care, the impact of culture and ethnicity on self-report of health indicators, and on medical decision making and the physician-patient relationship. He has extensively examined the problem of "contextual errors" in physician decision making, which occur when providers overlook factors specific to patients' life circumstances that are essential to planning appropriate care. Dr. Weiner received the award for groundbreaking research on causes of failures in physicians' ability to provide patient-centered or contextualized care. He and his UIC colleague, Alan Schwartz, Ph.D., pioneered a method for creating and validating standardized patient (SP) cases by using standardized patients played by professional actors. In work funded by VA HSR&D, Weiner and Schwartz performed an experiment using SPs visiting physicians undercover and wearing hidden audio recorders. The results of this study were published in the *Annals of Internal Medicine* and revealed that contextual errors were pervasive and they further characterized the pattern of errors and costs of errors. This was the largest study using covert observation of physicians by SPs, a method receiving increasing attention from policymakers as a way to promote quality and patient safety.

In addition to his role with HSR&D, Dr. Weiner is also a Professor of Medicine, Pediatrics and Medical Education, and Vice Provost for Planning and Programs at the University of Illinois-Chicago. He currently receives funding as a principal investigator from the Veterans Administration, and as a co-investigator from the National Board of Medical Examiners, National Science Foundation, National Institutes of Health, and Robert Wood Johnson Foundation Generalist Physician Faculty Scholars Program.