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A Randomized Controlled Pilot Trial of the Functional Assessment Screening Tablet to Engage Patients at the Point of Care

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BACKGROUND: Healthcare providers play an important role in encouraging healthy behaviors and improving health-related quality of life (HRQoL). They are most effective when they partner with informed, engaged patients.

OBJECTIVE: To examine the impact of a new health-information technology intervention (FAST-Feedback) that provides patients with immediate, personalized, guideline-based feedback regarding tobacco use, physical activity, and HRQoL, and encourages patients to initiate discussions regarding these topics with their primary care physician.

DESIGN: A pilot, randomized controlled trial clustered by resident physician, with patients as the unit of analysis.

PARTICIPANTS: Resident physicians and their outpatients in a single academic health center between May and October 2011.

INTERVENTION: Patients received (intervention) or did not receive (control) FAST-Feedback prior to the clinical encounter.

MAIN OUTCOME MEASURES: Primary outcomes were patient reports of initiating any discussions regarding tobacco use, physical activity, and HRQoL. Subgroup analyses examined patient reports of discussions regarding tobacco use, physical activity, and HRQoL, respectively.

KEY RESULTS: Thirty of the 36 eligible resident physicians (83%) agreed to participate; 173 of their 415 eligible patients (42%) expressed interest in the study and 99 (24%) consented to participate. Compared to controls, a higher percentage of intervention patients reported initiating any discussion with their resident physician, although this difference was not statistically significant (40% vs. 27%; p=0.12). For subgroup analyses regarding specific topics of discussion, patients in the intervention group reported initiating more discussions regarding mental HRQoL than controls (23% vs. 0%; p=0.02). There was no difference in patient reports of initiating discussions regarding smoking, physical activity or physical HRQoL.

CONCLUSIONS: Providing patients with immediate, personalized, guideline-based feedback prior to the clinical encounter can increase patient-initiated discussions regarding mental HRQoL. Future work should test FAST-Feedback in a larger population and evaluate the impact on tobacco cessation, increased physical activity, and improvements in HRQoL.

KEY WORDS: patient engagement; patient-centered outcomes research; smoking cessation; physical activity; quality of life.

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BACKGROUND

Healthcare providers can play an important role in encouraging their patients’ behavior change. Brief physician encouragement and counseling increases physical activity1 and decreases smoking behavior.2 Similarly, health-related quality of life (HRQoL) can be improved when physicians address conditions that cause impairment.3–5

While there are differences between patient and physician reports of counseling, even during the same encounter,6 physicians’ rates of behavior change counseling for physical inactivity and tobacco use are low, regardless of the reporter and despite the clear need to address such behaviors. In one study, fewer than 30% of patients reported receiving advice regarding physical activity. Among those who did receive advice, only 38% reported receiving help formulating an activity plan.7 While up to 66% of primary care encounters identify patients’ tobacco use status, referral to smoking cessation programs is provided at low rates.8 In a 2007 Association of American Medical Colleges survey, only 13% of US physicians reported referring patients to smoking cessation programs.9

Part of the problem may be due to lack of time. For instance, it is estimated that delivering all of the care recommended by the United States Preventive Services Task Force would take a clinician over 7 hours, which underscores a significant disconnect with the typical primary care appointment of...
15 minutes or less. Newer, efficient methods are needed to help physicians deliver recommended primary care.

Activating patients to partner with their physicians is a core component of both the Chronic Care Model, which emphasizes system changes to facilitate care teams partnering with patients, and the Patient Activation Model, which posits that patients’ knowledge, skills, and confidence for self-management are associated with more positive health behaviors. Patient activation is one possible solution to remove barriers to behavior change—activated patients are more able to understand their care needs and work with their physician to address those needs. Providing patients with feedback regarding their health has long been used to activate patients to undertake behavior change, and can make them more engaged partners in their healthcare. Innovative uses of health information technology (HIT) to provide personalized feedback may help patients take a more proactive role in their healthcare, and allow physicians to focus on patient-identified areas of need.

We designed a new HIT-based tool called FAST-Feedback, which builds on our FAST tablets and provides immediate, guideline-based feedback to patients regarding their self-reported health behaviors (smoking and physical activity) and health-related quality of life (HRQoL) prior to their clinical encounter. A pilot study was conducted to examine the impact of FAST-Feedback on initiation of discussions about these topics by patients during a clinical encounter. We hypothesized that such an intervention could increase patient initiation of discussions regarding smoking, low physical activity, and HRQoL, and serve as a model for patient engagement.

METHODS

Design

A cluster randomized controlled trial, with resident physicians as the unit of randomization and patients as the unit of analysis, was conducted between May and October 2011 to test the impact of providing patients with guideline-based feedback regarding their health behaviors and HRQoL (FAST-Feedback) immediately prior to their office visit. All resident physicians from a single academic health center practice were recruited for this study. Resident physicians who agreed to participate were consented and randomized (1:1, in blocks of four generated in STATA) to the FAST-Feedback (intervention) arm or the usual care (control) arm. All patients of a resident physician in the intervention arm received FAST-Feedback, while patients of resident physicians in the usual care arm (control) did not. The allocation was embedded in the Functional Assessment Screening Tablet (FAST) program, described below.

The University of Pittsburgh and RAND Santa Monica institutional review boards (IRBs) approved this study and it was registered with ClinicalTrials.gov (NCT01080183).

The FAST Tablets. Since 2003, patients in this large academic primary-care practice have completed general intake information, including health behaviors, HRQoL, and family and past medical history, at the time of their appointment using a tablet computer-based system, the FAST. The FAST is a brief, computerized clinical intake form that provides physicians with longitudinal patient-reported information at the time of the clinical encounter.

Smoking status is gathered by asking patients if they smoke cigarettes (yes or no) and if they do, how many packs of cigarettes per day. Information regarding physical activity is collected using a single item based on the Centers for Disease Control and Prevention guidelines that asks if patients engage in at least 30 minutes of moderate physical activity, 5 days per week. HRQoL is collected using the RAND-36 Health Status Inventory. The RAND-36 has a mental and physical health composite score (MHC and PHC respectively) both normed to means of 50 and standard deviations of 10.

Intervention: FAST-Feedback

In addition to completing the FAST, medical assistants provided all patients (irrespective of visit type) seeing intervention resident physicians with a personalized information sheet (FAST-Feedback, Fig. 1). FAST-Feedback was generated from the patients’ prior and current FAST responses and provided them with guideline-based feedback regarding health behaviors and HRQoL. To leverage the benefits of physician advice, feedback included a statement that the specific physician who the patient was seeing that day agreed with the recommendations.

Feedback regarding smoking was only provided to current and former smokers. Current smokers received information about the health risks of smoking and encouragement to quit smoking, former smokers received positive feedback on quitting, and individuals who had relapsed to smoking since their last visit received encouragement to try to quit again.

Feedback regarding physical activity was based on current Centers for Disease Control guidelines for 150 minutes of moderate physical activity per week. It incorporated information regarding the patient’s physical activity level and the benefits of moderate physical activity. For smokers, a statement was included linking the benefits of moderate physical activity to the prevention of weight gain associated with smoking cessation.

Feedback regarding HRQoL graphically placed an individual’s mental and physical HRQoL scores in the context of general population normative data. Individuals with poor mental (MHC ≤ 38) or physical HRQoL (PHC ≤ 42) were encouraged to think about possible contributors, such as changes in family and work life (mental HRQoL) or injuries and chronic medical conditions (physical HRQoL), and to speak with their doctors about possible interventions.

Patients of control physicians continued to receive usual care, including completing the FAST, but with no feedback.
Patient Participants

After completing the FAST, patients of participating resident physicians received, or did not receive, FAST-Feedback based on their resident physicians’ group assignment. All of these patients, regardless of race or gender, were invited to participate in this study. Patients who indicated on the FAST that they were interested in participating were approached by research staff and were engaged in the informed consent process. We did not collect data regarding reasons for non-participation. Figure 2 shows the flow of participants through the study.

Measures

After each visit, enrolled patients and their resident physicians completed a survey with questions regarding discussions of smoking, physical activity, and mental and physical aspects of HRQoL. For each topic, they were asked if a discussion occurred (yes or no), who initiated the discussion (patient, resident physician, or not discussed), and if the discussion was useful to the patient (1: not at all useful, 2: a little useful, 3: somewhat useful, 4: useful, 5: very useful, 0: not discussed). Perceived usefulness was analyzed as a dichotomous variable (based on the distribution of responses): at least somewhat...
useful (3–5) vs. less than somewhat useful (1, 2). All assessors were blinded to intervention assignment.

Health behaviors and HRQoL data were used to determine if a discussion should occur (i.e., any necessary discussion). For example, a patient who had never smoked would not be expected to have a discussion about smoking, whereas a patient who was a current or former smoker would. These were summarized into any necessary discussion vs. no necessary discussion. These data, along with patient age and gender, were abstracted from the FAST. We also collected basic demographic information including age, gender, and post-graduate year (1, 2, or 3) for the resident physician.

Patient participants received $10 compensation for completing study questionnaires. Resident physicians received no compensation.

**Statistical Analysis**

Sample size calculations assumed an intra-class correlation of 0.05 and anticipated that 29 of the 36 resident
physicians (80 %) would participate, with an average of three patient participants per resident physician (n=87). This results in 80 % power to detect an absolute difference of 25 to 32 % in the patient-initiated rate of discussions between the intervention and control arms, assuming a baseline patient-initiated rate of discussion of 20 to 40 % (two-sided, α=0.05).

Participant characteristics were summarized using frequencies and measures of central tendency. Logistic regression, clustered by resident physician, was used to compare rates of patient report of initiation of any necessary discussion in the intervention and control groups, our primary outcome. The patient perspective was chosen as the primary analysis, because the patient’s understanding of what happens during the clinical encounter is at the heart of a patient-centered perspective,6 and therefore is the priority in understanding what the patient takes away from the clinical encounter. Similar analyses were conducted for secondary outcomes, including resident physician report of patient initiation of any necessary discussion, as well as patient and resident physician perspectives on whether a necessary discussion (regardless of initiator) occurred, and whether the discussion was useful to the patient. In sensitivity analyses, only individuals with current smoking, current physical inactivity, current low mental HRQoL, or current low physical HRQoL (as opposed to including immediate former smokers and individuals who had increased their activity level) were identified as being eligible for any necessary discussion.

In subgroup analyses, we used Fischer’s exact test to examine patient and resident physician perspectives on patient initiation of discussion, discussion occurrence (regardless of initiator), and if the patient found the discussion helpful for each health behavior (smoking and physical activity) and aspect of HRQoL (mental and physical). Because of small numbers, it was not possible to cluster these analyses by physician.

The correlations between patient and resident physician reports regarding discussions were also estimated. To account for clustering by resident physician, mixed effects models and our observed data were used to simulate correlations (rho) between patient and resident physician responses regarding if a necessary discussion was (1) patient initiated, (2) occurred at all, and (3) was at least somewhat helpful to the patient.

Logistic regressions and Fischer’s exact test were conducted using STATA, version 11 (Stata Corp, College Station, TX). Correlation simulations were conducted in R (R version 2.12.2, http://www.R-project.org). Given the pilot nature of this study, we sought to balance the risk of both type 1 and type 2 error. Consistent with Feise’s recommendations, we chose a single primary endpoint and did not apply corrections for multiple comparisons.23 Analyses were conducted in 2012 and finalized in 2013.

RESULTS

Enrollment and Intervention Delivery

Of the 36 resident physicians eligible to participate in this study, 30 (83 %) enrolled and 29 (14 in the intervention group and 15 in the control group) had at least one patient participate in the study. Of the 415 patients who received, or did not receive (based on group assignment) HIT feedback, 173 (42 %) expressed interest in the study. Ninety-nine of these 173 (57 %, 24 % overall) patients enrolled in this study and 98 completed questionnaires. There was no difference in the age or gender of patients who participated versus those who did not (p=0.27 and 0.86, respectively). These 29 physicians and 98 patients form the basis for our analyses.

Baseline Demographics and Clinical Characteristics

Resident physicians in both groups were on average 29 years of age (standard deviation [SD]: 2.1, range 24–33) and 55 % were female. There were more post-graduate year 2 physicians in the control group, but these differences were not statistically significant (Table 1). On average, resident physicians had 4.9 (SD: 2.8) patient participants (median: 5, inter quartile range 3–7).

Forty-eight patients were seen by resident physicians in the control group and 50 were seen by resident physicians in the intervention group. Patients had an average age of 46 years (SD: 12.7, range 22–85 years). Slightly more intervention participants were female and slightly more control participants had any relevant health behavior or aspect of HRQoL to discuss; neither of these differences were statistically significant (p=0.15 and 0.32, respectively) (Table 1).

Patient Reports of Initiation of Discussions

Patient report of initiating any necessary discussion, the primary outcome, was higher among intervention than control patients,

| Table 1. Resident and Patient Participant Characteristics [% (%)] |
|---------------------------------|-----------------|-----------------|
| **Resident**                     | **Intervention** | **Control**     |
| Age (years, mean (sd*))          | 29 (2.4)        | 29 (1.8)        |
| Female                           | 8 (53)          | 8 (57)          |
| Post graduate year               |                 |                 |
| 1                                | 6 (40)          | 3 (21)          |
| 2                                | 4 (27)          | 7 (50)          |
| 3                                | 5 (33)          | 4 (29)          |
| **Patient**                      |                 |                 |
| Age (years, mean (sd*))          | 45 (12.9)       | 46 (12.5)       |
| Female                           | 35 (70)         | 26 (54)         |
| Any relevant PRI                 | 43 (86)         | 45 (94)         |
| Smoking                          | 25 (50)         | 23 (48)         |
| Low physical activity            | 25 (50)         | 22 (46)         |
| Low mental HRQoL                 | 27 (54)         | 33 (69)         |
| Low physical HRQoL               | 32 (64)         | 38 (79)         |

SD Standard deviation; PRI patient-reported information; HRQoL health-related quality of life
but this difference did not reach statistical significance [16 (40 %) vs. 12 (27 %), respectively; \( p=0.12 \)] (Table 2).

Similarly, there was no significant difference between the intervention and control groups in secondary outcomes. The proportion of patients reporting the occurrence of any necessary discussion, regardless of the initiator, was not different between the intervention and control groups. Among those reporting that discussions occurred, there was also no difference in the proportion finding them at least somewhat helpful. Sensitivity analyses limited to individuals with current smoking, current physical inactivity, current low mental HRQoL, or current low physical HRQoL yielded the same results (data not shown).

Subgroups according to each health behavior and aspect of HRQoL were also examined. Among patients with low mental HRQoL, those in the intervention group were more likely to report initiating discussions regarding low mental HRQoL (23 % vs. 0 %; \( p=0.02 \)). More smokers in the intervention than the control group reported initiating a discussion related to smoking, but this difference did not reach statistical significance (28 % vs. 5 %; \( p=0.08 \)) (Table 3).

**Physician Reports of Initiation of Discussions**

There were also no significant differences in resident physician reports of any necessary discussions. Resident physicians in the intervention group compared to the control group did not report that any necessary discussions occurred more frequently, were more likely to be initiated by the patient, or that their patients found the discussions at least somewhat helpful (Table 2).

Resident physicians in the intervention group reported that a higher proportion of their patients with low physical HRQoL initiated discussions regarding physical HRQoL than did those in the control group (65 % vs. 32 %; \( p=0.04 \)) (Table 3).

**Patient–Resident Physician Agreement Regarding Discussions**

The correlations between patient and resident physician reports were \( \rho=0.25 \) for relevant discussion occurring, \( \rho=0.21 \) for discussion being initiated by the patient, and \( \rho=0.58 \) for the patient finding a discussion helpful. This emphasizes that patient and resident physician perspectives regarding discussions of health behaviors and HRQoL differ at the same patient encounter and are not interchangeable.

**DISCUSSION**

In this pilot study, we provided patients, in addition to physicians, with immediate, personalized, guideline-based feedback regarding health behaviors and HRQoL prior to the clinical encounter. Among the patients who agreed to complete study questionnaires, patients who received this FAST-Feedback reported significantly higher levels of self-initiation of discussions of mental HRQoL than those who did not. However, there were no significant differences observed between the two groups in patient-initiated discussions regarding smoking, physical activity, and physical HRQoL. Resident physicians reported significantly higher levels of patient initiation of discussions of physical HRQoL, but not smoking, physical activity, or mental HRQoL, among patients receiving FAST-Feedback compared to those who did not. This study was conducted in the context of all patients being queried about these topics prior to their physician encounters and resident physicians already systematically receiving the information before the encounter.

These findings are consistent with other work that promoted patient engagement by feeding patients’ own reports of health behaviors and HRQoL back to them with contextual information. Detmar and colleagues provided HRQoL information to oncology patients and providers or providers alone prior to the clinical encounter. They found an increase in communication (by review of audiotaped recordings) regarding social, fatigue, and dyspnea aspects of HRQoL among patients and providers. In addition, a larger proportion of patients who received HRQoL information had improved mental health and role functioning compared to those for whom only the physician received this information.\(^{24}\) The Bank of America retiree health promotion study was conducted without the involvement of healthcare providers. Participants completed health risk assessments and then received, or did not receive, personalized recommendation letters and general self-management

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<th>Table 2. Patient and Resident Reports Regarding any Discussion Related to Smoking, Low Physical Activity, Low Mental HRQoL,* or Low Physical HRQoL</th>
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<td>Intervention n (%)</td>
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\*HRQoL Health-related quality of life; \( p \) values based on logistic regression models with clustering by resident physician
materials and health promotion books. Participants in the intervention group had improved health risk scores and lower healthcare costs than the control group. Outside of the health care setting, technology-based interventions have shown promise as well, including decreasing problem drinking and gambling.

In contrast to other studies in primary care that collected health behaviors and HRQoL from patients and provided it exclusively to physicians, this study engaged patients in their care by providing them with personalized feedback prior to the clinical encounter. Patients in this study were activated to initiate discussions with their resident physicians regarding health behaviors and HRQoL. Particularly encouraging is that patients who received FAST-Feedback reported initiating more discussion regarding the particularly challenging area of mental health. Given the existence of evidence-based interventions, providers could readily access the tools necessary to assist their patients in health promotion in response to patient initiation of discussions.

It is notable that reports regarding patient initiation of discussions of smoking, physical activity, and HRQoL differed between resident physicians and patients. In this study, there are no direct observations of the patient–resident physician encounter. While we had planned to audiotape encounters, no patient participant consented to audiotaping. However, consistent with the findings of this study, prior work has shown that all of these perspectives (patient, provider, and direct observation) provide differing views of what occurred. We focused on the patient perspective, as our priority was to understand what the patient takes away from the physician–patient encounter.

We did not find that patients who received FAST-Feedback found discussions with their resident physicians to be more helpful than those who did not. This pilot study was underpowered to see these differences. In addition, we did not provide additional training to the resident physicians regarding the intervention. Finally, the study was cross sectional; longitudinal feedback providing multiple opportunities for discussion may be necessary to reinforce both patient and physician behavior. Future work should include training for the physicians, longitudinal intervention, and tracking of patient behavior change.

### Limitations

This study has a number of limitations that deserve mention. First, this pilot study was underpowered to detect differences between groups. Given the effect sizes, it is estimated that twice as many patients would be needed to see a significant difference between groups; future work will include a larger sample size.
sample of both patients and providers. Only 25\% of the patients who received, or did not receive, FAST-Feedback agreed to answer questions regarding their clinical encounters, possibly limiting the generalizability of the study. Future work should track behavior change in all patients of participating physicians. Neither the patient nor the resident physician was blinded to the intervention. To minimize contamination, the intervention was clustered by resident physician—all patients of the resident physician received or did not receive FAST-feedback, regardless of the patient’s enrollment to complete study questionnaires. Finally, the study was conducted in a resident physician practice setting. As such, these physicians and their patients may not be representative of the practice overall or broader practice settings. For example, patients seen by resident physicians are more likely to have public insurance or be uninsured than patients seen by faculty. However, these resident physicians practice within the same physical setting as the faculty, and have access to the same resources.

CONCLUSIONS
In this pilot study, immediate, guideline-based feedback regarding health behaviors and HRQoL was delivered to patients prior to an encounter. Results suggest that it activated patients to engage with their health providers regarding mental HRQoL. These topics can be difficult to discuss during the clinical encounter; the approach that a provider takes to these discussions depends on the patient’s readiness to address the issue. Placing these topics on the patient’s agenda (in addition to the physician’s agenda, as we did with the FAST) and allowing him or her to initiate the discussion presents the provider with a context within which to begin counseling. If larger studies confirm that this model is successful at creating behavior change, it would help to decrease the morbidity and mortality associated with poor mental HRQoL. The framework could then provide a model for a variety of conditions that require patient self-management.

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