Name of Project: Activating Messages to Enhance Primary Care Practice (AMEP2)

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Research question(s):
This study seeks to improve recognition and treatment of depression in primary care by facilitating patient information and activation using brief multimedia interventions. An earlier phase of the study involved the development of a public service announcement (PSA) and an interactive multimedia computer module (IMCP). The current phase of the study is an RCT designed to test the two interventions. It is anticipated that the interventions will result in improved recognition of depressive symptoms by patients, reduction in patient feelings of stigma around depression, and increased self-efficacy to approach physicians about depression. Subsequently, it is also anticipated that the interventions will improve primary care physician recognition of depressive symptoms, and result in improved outcomes for patients.

Research staff will first recruit physicians who are willing to take part in the study. They will then obtain (via IDX) lists of patients who have upcoming appointments scheduled with participating physicians. Each physician will be shown the list, and given the opportunity to inform the study if there are any patients on the list who should not be contacted. The remaining patients will then be sent an opt-out letter, informing them that they will be receiving a phone call to see if they are interested in the study. If a patient does not wish to participate, he or she will be given a number to opt out of study participation. If the patient agrees to be screened for the study and is recruited, he or she will be asked to meet with study staff in the waiting area one hour prior to the scheduled appointment time. During this time, the patient will be consented, and will complete some preliminary questionnaires. The patient will be provided with headphones to complete one of the randomized interventions (the PSA or IMCP) or watch a control video on sleep hygiene. The patient will then complete the appointment with their physician, and then remain for a few additional minutes to complete a post-visit questionnaire.

Brief Background/Significance:

Background
Clinical depression is a major public health problem and is commonly addressed in primary care settings. Primary care has become the de facto mental health treatment system for adults (depression prevalence in these settings is at least 10-15%), yet depression often goes undiagnosed, and even detected depression is often under-treated. The proposed study will be conducted in primary care settings, where patients often suffer from co-morbid physical illness (an NIMH target) and where the majority of U.S. depression-related care is actually delivered.

Stigma is a significant barrier to effective diagnosis and treatment of depression in primary care (in the form of both public stigma and self-stigma). Stigma is an important conceptual lynchpin in our study; the targeted PSAs and the tailored IMCP will aim to reduce depression stigma among depression sufferers and others in their social network.

Patient-level interventions to improve quality of care for depression may complement
physician- and system-level approaches. Several well-designed studies conducted over the past decade have demonstrated the value of multi-faceted interventions to improve depression care quality. Key components of effectiveness include screening tools, reminders, practice guidelines, collaborative care models, structured follow-up, and organizational reform. However, dissemination and implementation has been slow. Patient-level interventions constitute a set of complementary approaches with the virtue of portability. Interventions targeting patients have improved quality and outcomes for chronic diseases such as diabetes, chronic lung disease, heart failure, arthritis, cancer-related pain, and depression. Most of these interventions aim to increase patients’ self-efficacy, transforming patients into active communicators able to change their own behavior and that of their physicians. In this study, carefully crafted PSAs and an IMCP will encourage patients to recognize their distress as potentially treatable, seek care, and ask for needed treatment.

Social marketing can potentially reduce depression-related stigma and disparities. Social marketing is defined as the design, implementation, and control of programs which attempt to increase the acceptability of a social idea or practice in a target group. In communication and marketing theory, targeting refers to the design and delivery of messages to fit the needs, expectations, and cultural norms of specific audiences defined by age, gender, race/ethnicity, or other readily identifiable social variables. Previous research such as the “Real Men, Real Depression” campaign indicates that targeting may be essential for reaching populations at risk for depression. An earlier phase of the study was dedicated to using principles of effective social marketing campaigns to develop targeted PSAs that encourage patients to seek depression care and request information or action.

Personally tailored, interactive multimedia computer programs (IMCPs) show promise for improving depression care. A growing body of evidence suggests that interventions that are personally tailored to individual mediators or modifiers of health behavior are superior to non-tailored interventions in improving various health behaviors and outcomes across a broad array of patient populations and target conditions, including depression in primary care. Studies have shown that tailored health messages are better remembered, read, and perceived as relevant. In this study, we use 3 tailoring hinges suggested by previous research: 1) type and severity of depressive symptoms; 2) illness representations; and 3) information processing style. Tailoring to symptoms facilitates message personalization, so that users will receive feedback tailored to their own illness experience (e.g., depressed vs. non-depressed, somatic vs. emotional symptoms). Tailoring to illness representations (explanatory model of illness) supports the construction of messages that are consonant with patients’ pre-existing mental models (e.g., biological, cognitive, or external). Tailoring to information processing style enhances social-cognitive “fit,” which has been shown to amplify persuasiveness. The IMCP exploits two well-recognized advantages of computer-based programs that extend beyond tailoring: 1) interactivity (promoting increased user involvement, which helps individuals stay on task) and 2) adaptive assessment (which can shorten questionnaire length, increase user comfort with sensitive items, and permit real-time measurement of cognitions and emotions).

Significance

This study asks whether an empirically grounded, theoretically informed process of PSA and IMCP development can support the production of targeted and tailored tools that will improve depression care and outcomes at the interface of medicine and public health. We test both marketing and social-psychological approaches to patient activation. The effectiveness of the PSA intervention at the individual person level may be relatively small, but the intervention is well-suited to reach families as well as individuals and the overall public health impact is potentially great. The effectiveness of the IMCP approach may be greater at the individual level, supporting future efforts to develop more intensive and reinforcing IMCP packages. Generalizability will be substantial since the principles involved in developing the PSAs and
IMCP can be applied to a variety of medical conditions. Implementation will not be limited to clinical settings with trained health educators, since the PSAs and IMCP could be used in any physician office setting equipped with a computer. Further, the PSAs will be transportable to non-clinical settings, so that they could reach a much larger segment of society, facilitating readiness to enter treatment when appropriate, and reducing stigma among those without depression. For example, the IMCP could be disseminated in doctors’ offices on CD-ROM, or directly to patients via health portals on the Internet, while the PSAs could be disseminated as part of a waiting room “infotainment” package, on commercial television, or on limited distribution networks (e.g., as part of in-air programming on commercial airlines). Through an aggressive outreach or advertising campaign, PSAs could potentially reach 50% of at-risk patients and their families, whereas traditional clinic-based interventions achieve penetration rates that are often an order of smaller magnitude. By encouraging active patient participation in care (which tends to be lower among men and minorities), the intervention also has the potential to diminish gender and racial/ethnic disparities in care.

Inclusion/exclusion criteria (list):

**Inclusion:**
Physician eligibility criteria: Faculty primary care physicians (Internal Medicine and Family Practice) and residents in their second or third year of training who practice primarily adult medicine.

Patient eligibility criteria: Patients must see an enrolled physician for their index visit; be between ages 25-70, currently not taking antidepressant medication in doses considered adequate for depression and/or not currently undergoing psychotherapy; judged by the RA as able to read and speak English; have a telephone and permanent mailing address; have adequate vision, hearing and hand function to watch a brief video and complete self-administered questionnaires on a laptop computer.

**Exclusion:**
Physician Exclusion Criteria: Physicians and residents who do not work in primary care settings (Internal Medicine or Family Practice) or do not practice primarily adult medicine will be excluded from the study.

Patient Exclusion Criteria: Patients younger than 25 or older than 70, currently taking antidepressant medication in doses considered adequate for depression and/or undergoing psychotherapy, who report not being comfortable completing a questionnaire in English, who are too sick to participate, or who refuse to proceed further will be entered into a log and excluded from the study.

**Method of contact/recruitment (be specific):**
Study research assistants will access the appointment schedules of physicians who have consented to take part in the study, and generate lists of their patients with upcoming primary care appointments. Physicians will be given the opportunity to review these lists and inform the study if any patients should not be contacted. All other patients will receive a letter (see attached) describing the study. These letters will include a “opt in” / “opt out” phone number, which the participant will be instructed to call. Patients who “opt in” will be contacted first by an interviewer to discuss the study with them and assess their eligibility and interest in participating. Then patients who have not called the number to “opt out” will be contacted no sooner than 7 days after the letter mailing. A study research assistant will schedule a baseline telephone interview with all eligible and interested participants as soon as possible after the
initial contact.

Benefits/burden for participants (clearly identify potential for harm):
Patients may experience emotional distress as they answer questions relating to depression and/or viewing a brief depression-related video. We have instituted the following measures are in place to reduce this risk: (a) the questionnaire will ask a variety of health questions in addition to depression; (b) the intervention videos are sensitive to the nature of depression and are designed to mitigate negative attitudes toward depression; and (c) patients who are suicidal will be excluded from this study (suicidality will be screened by completion of PHQ-9 items by the patient on the laptop computer). Therefore, we feel the risk of emotional distress is low. It is possible, though unlikely, that patients who report minimal-to-absent depressive symptoms at the baseline interview may ask for and receive a prescription for an antidepressant from their primary care physicians. We have added language to the Patient Consent Form notifying patients that medications including antidepressants may have risks and side effects, and that they should discuss these with their physician before making any decision to take medications.

Any benefits or burden to DGIM practitioners?
Physician enrollees may experience increased visit times if their patients bring up any of the issues discussed in the intervention materials; however, past studies on patient activation have shown improved visit efficiency, so this risk is considered unlikely.

Timeline for recruitment (projected start and stop dates):
The RCT is projected to begin on 6/1/2010, with a recruitment end date of 6/1/2011. We will recruit no more than 10 patients per participating physician.

Funding source: NIMH

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular):
N/A

Do you agree to notify us when recruitment is completed? Yes.

Date form completed: 5/14/2010