**DGIM Project Summary**

**Name of Project:** Outpatient factors in medication safety

**Investigator(s):**
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**Research question(s):**
**Specific Aims:** The aims of this pilot study are:
1. To determine the frequency of medication related encounters at the outpatient level with:
   a. Providers (physician, nurse practitioner, physician assistants, nurse, any traditional and non-traditional health care provider).
   b. Pharmacies (for procuring routine, non-routine, prescription and non-prescription medications).
   c. Patient symptoms and/or non-therapeutic laboratory values when medication self-management is indicated.
2. To describe the frequency of potential and actual medication related error/harm.
3. To assess the nature of the medication related outpatient’s encounters by describing influencing outpatient factors that contribute to potential or actual medication harm. These factors will be categorized as: provider, pharmacy, system, and patient specific factors.

**Brief Background/Significance:**
Prescription medication remains the foundation and mainstay of therapeutic interventions in outpatient care. Nearly 2.5 billion prescriptions were dispensed by U.S. pharmacies in 1998, and the percent increase in primary care office visits that involved the initiation or continuation of medication therapy increased from 61% to 72.6% from 1995 to 2005. There is increasing concern about safe medication use by outpatients as healthcare trends toward outpatient care and an aging population increases and self-management of medications becomes increasingly complicated. Coordination of care across multiple providers, facilities, pharmacies, and medication self-management by the patient when encountering preventive or symptomatic health conditions introduces multiple points at which medication error/harm can occur. However, the frequency of these encounters and the patient’s perspective that influences decisions around self-management in the outpatient setting has not been explored.

**Inclusion/exclusion criteria (list)**
**Inclusion Criteria:**
Outpatient care 2) Age over 60 years, 3) Takes at least 2 prescription medication 4) English speaking, 5) Sufficient visual, hearing, and cognitive ability to complete the Short Test of Functional Health Literacy in Adults STOFHLA and interview, 6) Ability to complete the interviews as indicated by the Mini Mental Status Examination (MMSE) (screening exam), 7) May have other co-morbid conditions, including diabetes, 8) Have access to make or receive telephone calls.

**Exclusion Criteria:**
Patients who do not obtain a score of 24 or higher on the MMSE will be excluded. Patients with MMSE scores of 24 or higher will receive the STOFHLA, a paper and pencil test. Patients who score at the Marginal or Inadequate Functional Health Literacy level (score of less than 23) will be asked if they can get someone to fill out the Encounter Log (a diary of healthcare visits) for them. Patients who are unable to suggest someone who can help him or her will be excluded. Patients who do not meet these inclusion criteria will not be enrolled.

**Method of contact/recruitment (be specific)**
Clinic health care providers will be sent a cover letter explaining options for provider
participation in patient recruitment for the study, including non-participation. Additionally, flyers explaining the study will be posted at the outpatient areas and information sheets explaining the study will be placed in the patient waiting areas. Patients may either contact the researcher directly or patients may give their providers permission for the researcher to contact them. Keeping with HIPPA regulations, patients who respond to invitations made by participating healthcare providers during a clinic visit and give permission, will be contacted by the PI or the RA (an experienced RN) and the healthcare provider will document the patient’s consent in the medical chart. Patients may contact the researcher directly in response to a flyer, an information sheet, or as an encouragement to participate in the study from either participating or non-participating providers. When patient expresses a willingness to learn about the research project, the PI or the RA will explain the study, determine study eligibility, and answer any questions that the patient may have. Potential subjects will be asked to explain the study activities back to the PI or the RA to determine patient understanding of the project. If participant demonstrates clear understanding and indicates their consent, a mutually agreeable time will be set up to conduct an office interview in a private space at UCSF. If necessary, the interview will be interrupted for any other provider visit and resumed following the visit.

Benefits/burden for participants (clearly identify potential for harm)
This pilot study has minimum risk with inconvenience of having to stay for 60-90 minutes to take the battery of tests in the clinic and to respond to once a week calls (10 to 20 minutes each) for a maximum of four weeks. Attempting to take advantage of wait times and suspending and resuming activities around clinic appointments will minimize the inconvenience to the patient and the clinic. Similarly, telephone calls will be arranged at a mutually agreeable time.

Any benefits or burden to DGIM practitioners?
Benefits to participating DGIM practitioners include participation in this important study and preliminary data results with minimum burden to provider in determining study eligibility and documenting patient’s consent to have researcher contact patient. Providers burdened with clinic time may provide a study information sheet and have the patient contact the researcher directly to determine study eligibility and provide study information. There is no burden to DMIG practitioners as provider participation with recruitment and/or eligibility determination is voluntary and patients of non-participating providers may participate in the study by contacting the researcher directly.

Timeline for recruitment (projected start and stop dates)
This study has received CHR approval and will start immediately upon approval of the DGIM committee. The pilot study is expected to take 3 to 6 months to recruit 50 patients with an expected enrollment of 30 patients.

Funding source:
None

Potential for DGIM collaborators? (We encourage DGIM resident and fellow involvement in particular)
Currently, this project is in collaboration with Dr. Susan Janson in the GMC clinic. Anyone with interest in the area of outpatient medication safety is welcome.

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

Date form completed
September 22, 2008