

Effect of reminder for alcohol screening in patients age 65 or older in a primary care clinic setting during initial encounter.

A: Study Purpose and Rationale

The purpose of this study is to assess the effectiveness of providing a paper reminder to clinicians to screen for alcohol use disorders during initial encounter in patients age 65 or older who report alcohol use.

Alcohol use disorders are a relatively common problem among older adults and are far more prevalent than any other addictive disorder in elderly individuals, including the abuse of prescription drugs. Alcohol use disorders can range from potentially risky use to alcohol dependence. Although prevalence of alcohol use disorders is less in the elderly than in younger people, rates may be underestimated due to less intensive screening leading to under-detection and misdiagnosis. Co-morbid medical illness, increased biological sensitivity to effects of alcohol, alcohol-medication interactions leave the elderly at unique risk for alcohol use disorders. Given the aging population of the world, the number of older people with alcohol use disorders is expected to increase. Health care providers can help elderly patients avoid serious health consequences by screening for alcohol use disorders.

In the 2001 to 2002 National Epidemiologic Survey on Alcohol and Related Conditions, 37% of women and 55% of men who were ≥ 65 years of age reported that they currently used alcohol (Balsa et al). Prevalence of alcohol use disorders in the elderly is difficult to determine and rates vary widely depending on definition of risk drinking or alcohol abuse, population studied (inpatient, community, nursing home), and depending on methodology. Exact definition of alcohol misuse, and diagnostic criteria used, has varied from study to study.

Results from the Canadian Study of Health and Aging yielded estimates of alcohol abuse of 8.9% among persons who were ≥ 65 years of age in a clinical sample (Thomas and Rockwood 2001). A study on community dwelling persons age 60-94 showed 62% of subjects drank alcohol, with heavy drinking in 13% of men and 2% of women (Rigler 2000). According to the American Geriatrics Society (AGS) 2003 Clinical Guidelines for Alcohol Use Disorders in Older Adults, alcohol use may be potentially risky behavior in up to 15% of older adults and alcohol abuse or dependence is present in 2-4%. A study done as a secondary analysis of the 2005 and 2006 National Survey on Drug Use and Health conducted in 2009 by Blazer and Wu found that in the 65 or older age group, 13% of men and 8% of women reported at-risk alcohol use, and more than 14% of men and 3% of women reported binge drinking (Blazer & Wu, 2009). Studies on community prevalence rates for alcohol dependence also show a wide range of results.

Even with studies showing variable prevalence of alcohol use disorders in the elderly, it is clear that alcohol use disorders are of concern in this population. Various studies show that alcohol use disorders are under-detected and misdiagnosed in the elderly. Primary care clinics are particularly important for such screening given that a large proportion of elderly patients see a physician.

Reasons for under screening and under-detection are likely multifactorial. The presentation of elderly people with alcohol use may be atypical (falls, confusion, depression, cognitive or self-care deficits), or masked by co-morbid physical or psychiatric illness. Clinicians may be unaware of the extent of how significant alcohol use disorders are in the elderly population or may be unaware of how new social situations faced by elderly patients may put them at risk for late onset alcohol use disorder. Clinicians may be less inclined to ask questions about alcohol use behaviors or formally screen elderly patients because they are unaware of positive treatment outcomes. The rate of screening for alcohol in health care settings in the general population remains lower than 50 percent (Fleming 1997). There is limited data to quantify screening practices for alcohol use disorders in elderly patients in a primary care setting.

The United States Preventive Services Task Force and other organizations recommend systematic alcohol screening of all adults in medical care settings. The systematic screening of all patients reduces the chance that alcohol overuse will be missed. Given that alcohol use disorders are prevalent but under diagnosed in the elderly, that there are significant consequences from alcohol use disorders in the elderly, that there are available treatments that have been shown to work in the elderly population, and that screening is cost effective, all elderly patients should be screened for alcohol use patterns at a primary care level.

Unfortunately, knowledge of screening guidelines is not sufficient to change physician practices. Studies focusing on physician behavioral change show that prompting can facilitate behavioral change. This study will examine prompting in the form of a paper reminder.

Detecting alcohol abuse and dependence early in the course of disease enables clinicians to get people the help they need, either by initiating a brief intervention or by referring the patient to treatment. Even patients who do not have an alcohol disorder, but who are drinking in ways that are risky or harmful (i.e. interactions with medications) can benefit from screening and brief intervention. In general, treatment outcomes are as good or better for older patients compared to younger ones. As a group, the elderly are more likely to be compliant and remain in longer-term outpatient programs. Given that intervention can have a significant impact on health and quality of life, screening should be routinely performed in patients 65 and older.

Any intervention that would increase rates of screening would be beneficial to this patient population. The impact of a reminder to a clinician to screen for alcohol use disorders in patients age 65 and older will be assessed by this study.

B. Study Design and Statistical Analysis

Hypothesis: We hypothesize that residents that receive reminder to formally screen patients 65 or greater who endorse alcohol use will have a higher rate of screening than residents who don't receive the reminder.

Null: There will be no difference in screening with this intervention.

Study Overview: The study will be conducted at the Columbia University Medical Center AIM Clinic (Resident Clinic). This will be a prospective randomized, controlled trial to determine the effect of an intervention, providing reminders to screen for alcohol use, in patients age 65 or older, during an initial encounter with a resident clinician. The primary objective assess the there is a significant increase in screening in the group randomized to receive a reminder to screen.

Statistical Analysis

Studies focused on the general population report alcohol screening rates in health care settings ~ 50%. Studies specifically on inpatients have found that physicians record alcohol use history for only ~ 1/3 of patients. Studies that document rates of alcohol screening are limited in the elderly are limited. Studies specifically focusing on screening of elderly specifically in a primary care setting are also lacking. Thus, rates of alcohol screening for patients age 65 or older in primary care setting are not well quantified in literature. Most data related to screening in this population is in the setting of an intervention designed to increase screening practices.

Studies that do quantify screening practices in older populations are usually embedded in analysis of an intervention designed to increase screening. Rates of screening in the control/ non-intervention group in various studies focusing on older populations in a primary care setting range from 10-75%.

For power analysis calculations, type I error rate α , was set at 0.05. Type 2 error rate, β was set at 0.2, with a power of 80%.

For the purpose of effect size calculations an unpaired t-test will be used for analysis. Assuming enrollment of 80 residents in AIM Clinic, and 40 randomized to each arm, n is 40. Given a range of 65%, and the small sample size, the standard deviation is 16.25% . This results an effect size of 10%.

Residents have about 40 clinic sessions throughout the year. They may carry about 80 total patients. Given that 13% of general population is age 65 or greater, if that is represented in our clinics, we would expect that residents carry around 10 patients that are age 65 or greater. However, it is more likely that our clinic has an older patient population and that our patient population seen in clinic age 65 or older is more that 13%.

A rough estimate would be that each resident carries about 10 patients age 65 or greater. Studies show variable data on prevalence of alcohol use in patients age 65 or greater, with rates 50-60%. Given these numbers, one would expect that residents would encounter patients age 65 or greater than endorse alcohol use that would be eligible for screening.

Study Design:

80 medicine residents will be involved in the trial, with 40 residents randomized to each arm.

1. 40 residents will be randomized to receive a paper reminder (sheet of paper in the paper chart handed to them prior to patient encounter) to screen for alcohol abuse in patients age 65 and older. Sheet will be placed in chart of every patient age 65 or older during initial visit/encounter with that provider.
2. 40 Residents will not receive a reminder.

Randomization: Residents/Providers will be stratified based on clinical year and will be assigned to control vs. intervention group using computer randomization.

The intervention will be ongoing for a 1 year time period. All charts on patients 65 or older being seen for a first time encounter seen by all study residents will be evaluated. The clinic note from that initial patient encounter will be looked at. We will look initially for documentation regarding alcohol use in these patients. Patients who deny alcohol use will be noted. In patients that did report alcohol use, we will then look for documentation of a formal screening test performed during that initial visit.

“Formal screening” can include mention or documentation of CAGE, any other formal screening test (i.e. MAST or AUDIT, ARPS), and will also include documentation of specific quantity of drinks over a specific time period. Three examiners will review the charts. What constitutes “formal screening” will have to be agreed upon by at least 2/3 examiners. The examiners can be any individual that is not part of the study; possibly 3 attendings.

We will assess and compare the rates of documented screening in the control and intervention/reminder arms using an unpaired t test. We will analyze if there is a difference in screening rates in patients in the intervention group.

For the analysis of the primary outcome, we will also assess physician practice and patient level variables considered potential confounders. On the provider level we can assess if factors like age, sex affect baseline screening. On the patient level we will assess age, gender, co-morbid illness, medications.

C. Study Procedure: No additional procedures will need to occur. The study will run for the duration of 1 academic/clinical year. The subjects will participate for the duration of the year.

D: Study Drugs: NA

E: Medical Device NA

F. Study questionnaire: NA

G: Study Subjects:

Inclusion Criteria: Columbia Internal Medicine resident AIM clinic providers from year PGY-1-3.

Exclusion criteria: none

H: Recruitment of Subjects: Subjects will be recruited from AIM clinic.

I: Confidentiality of Study:

All data obtained will be stored on a password protected computer in a password protected file. Resident subjects will be assigned a study number to protect their identity. We will need access to patient records, specifically initial clinic visit note of patients seen by residents involved in the trial. Patients involved in the study by virtue of being seen by a provider that is participating in the study will also be assigned a study number to protect their identity.

J: Potential Conflict of Interest: none

K: Location of Study: Columbia/NYP AIM Clinic

L: Potential Risks: Risks to resident participants are minimal. For patients involved by virtue of being seen by a clinician participating in the study the only potential risk would be disclosure of protected health information, although steps will be taken to prevent this by assigning a study number to each patient chart to be reviewed.

M. Potential Benefits: There may or may not be increased screening of patients at the end of the study.

N: Alternative therapies: none

O: Compensation to subjects: none

P: Cost to Subjects: There will be no cost to the study subjects.

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