Evaluation of a patient risk management tool and its impact on promoting patient safety in the physician's office :An IRB review

Background

- Nearly all patient safety research and improvement study has been conducted within the hospital setting, with only a small number of studies focused on the ambulatory practice setting
- One means of promoting a positive culture of patient safety in the ambulatory setting is to encourage patient-physician dialogue regarding the prevention of adverse medical events.

Specific aims

- To evaluate how a patient risk management tool at the time of a physician visit can promote a pro-active, risk management approach to patient safety in a physician's office.
- To quantify common self-reported patient safety risk factors

Design

- Quantitative survey of physician experience with a patient safety risk form
- Quantitative analysis of patient safety risk form responses

Setting

- Ambulatory family practice and internal medicine practices in southeastern Colorado

Participants

- Physicians and medical staff of the study practices
- Patients of the study practices

Intervention

- Twenty family medicine and internal medicine physicians will be recruited to participate in the clinical assessment of the Patient Risk Management Tool
- Each physician will be asked to recruit 20 patients to complete the risk management tool at the time of an outpatient office visit. Inclusion criteria for patient recruitment will include any established patient over the age of 18 who is responsible for their own health care. All patient risk management assessment forms will contain basic patient demographic information (gender, age) but will be not include any personal health information.
- Once the risk management tool is completed by the patient the physician will be asked to complete a response card regarding how the physician addressed risk assessment results.
- Two months after completing their patient recruitment, physicians will be sent an electronic survey instrument.

1. Date _____ Date of birth _____ Gender ___M ___F

1. How many DIFFERENT PRESCRIPTION medications do you currently take on a DAILY basis?

○ 0 ○ 1-2 ○ 3-4 ○ 5 or more

2. How many DIFFERENT OVER-THE-COUNTER (vitamins, pain relievers,etc.) medications do you currently take on a DAILY basis?

○ 0 ○ 1-2 ○ 3-4 ○ 5 or more

3. In the past 6 months have any of your medications changed as listed below (Check ALL that apply)

☐ No ☐ I had one or more new medications prescribed ☐ I had the dose of one or more medications changed ☐ I had one or more medications stopped

4. Do you take any of the following medications on a DAILY basis? (Check ALL that apply)

☐ None ☐ Coumadin (Warfarin) ☐ Pain medications (vicodin, percocet oxycodone) ☐ Insulin ☐ Digoxin (Lanoxin)

5. How often do you miss a dose of ANY daily medication?

○ Never ○ Less than once a month ○ Every Month ○ Every week ○ Every day

6. Do you carry a current list of your medications with you?

○ Yes ○ No

7. How many doctors do you see on a regular basis?

○ None ○ 1 ○ 2-3 ○ 4 or more

8. Do you carry a current list of your doctors with you?

○ Yes ○ No

9. Have you made any of the following medical visits in the PAST 6 MONTHS? (check all that apply)

☐ Emergency room visit ☐ Urgent care center ☐ Outpatient medical procedure ☐ Hospitalization for medical problem ☐ Hospitalization for surgery ☐ Not applicable

10. Is your current family physician aware of the medical visits you listed in question 9?

○ Yes ○ No ○ I don't know ○ Not applicable

Analysis

- Summary of physician surveys
- Summary of patient responses regarding frequency of patient safety risk factors

C-AHEAD Institutional Review Board (IRB) work sheet

Determination of exempt status

1) Does the research involve analysis of existing data (i.e., chart review, survey results, etc.)	Yes	No
2) Does the research involve collection of data through a survey process that is anonymous and de-identified and allows opting out of participation?		
3) Are anonymity, security, confidentiality, and privacy maintained?		
4) Is research exempt from IRB review (either items 1 or 2 AND item 3 "yes")		

Comments:

Full IRB review

1) Does the research involve special concerns? (Children, prisoners, mentally incapacitated)		
2) If research with children and > minimal risk, does it meet regulations?		
3) Does the research meet requirements and recommendations for trials?		
4) Are anonymity, security, confidentiality, and privacy maintained?		
5) Are all appropriate documents from other IRB(s) included?		
6) Will the research comply with best practices and government policies?		
7) Does scientific merit outweigh risk? For individuals, communities, and families, are risks minimized, benefits maximized, and justice ensured?		
8) Should the IRB waive all, or some elements of, informed consent?		
9) Should the IRB waive requirements to document informed consent?		
10) Are procedures adequate to negotiate and administer full consent?		
11) Are all necessary elements of informed consent included?		
12) Should the IRB seek reports of compliance from other than the PI?		
13) Should the IRB seek reports of compliance from other than the PI?		
14) Should it review the research sooner than annually, or monitor the process?		
15) Is the research more than minimal risk? *(needed for 'Annual' Reviews)*		

Comments