The following are examples of reviews rated by Deputy Editors of JGIM. The reviews are rated on the following scale: 6=outstanding, 5=excellent, 4=very good, 3=good, 2=fair, 1=poor.

Manuscript #

Three sample reviews are given for each rating, beginning with the outstanding (6) reviews.

Nov 13, 2007

	JGIM Artic	le Re	view	Forn	n: CO	MME	NTS TO THE E	EDITOR
Reviewer:		10 10	711011	1 011			VISIO IIIE I	
INTERES	ST TO REAI	DERS	SHIP	OF	JGIM.	·		
	High	<u>1</u>	2	3	4	5	Low	
ORIGIN/	ALITY AND	CON	ITEN	T OI	FNEW	V INFO	ORMATION:	
	High	1	<u>2</u>	3	4	5	Low	
STUDY D		<b>.</b>	* c	ontair	ns mina	or flaw	sis serious	sly flawed
				onum	15 111111	51 11 <b>u</b> vv		ny nawea
	ICAL ANAI Appropriate			3	4	5	Inappropriate	or absent
	трргорписс	•	or-		<u>-</u>	Ü	ширргоргиис	or dopen.
	Recommend	revie	_		tical C	onsult	ant: _*_Yes	No
	Y OF CONC							
V ALIDI I		1		3	4	5	Invalid	
CLARIT	Y OF WRITI	ING:						
	High	1	<u>2</u>	3	4	5	Low	
RECOM	MENDATIO	NS:						
	ACCEPT	Γ:			_	_REJE	CT:	_*_RECONSIDER
	( ) as is							(*) with major
	( ) conditi	onal						( ) with minor
	IF RECOM	MEN	D AC	CEP.	TANC	E:		
	is the length	app	ropri	ate?	_	_*_Yes	3	Needs to be shortened
	Are there an	y <b>fig</b> ı	ures o	r tab	_*_YesNo			
	If yes, please	e spec	cify w	hich	tables	are unr	necessary:	
	figure 2 not	need	ed. Ta	able 2	and 3	could	be combined.	
	Do you feel	this s	hould	be re	ecomm	ended	for <b>Editorial?</b> _	*Yes (provided comments are address
	-						·	• •

CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)

The authors present interesting data about weight change following first year of new diagnosis of diabetes

based on retrospective review of electronic medical records of patients seen at XXX. The authors report that majority of diabetes patients lost some weight after diagnosis, but gained weight after a couple of months. Predictor factors for weight loss are also evaluated.

The manuscript is well written, has important clinical message, and should be of great interest to the readers. However, the results are not well presented and the statistical analysis would probably need to be revised. The authors utilized growth curve analysis used to categorize groups of patients into: higher stable weight, lower stable weight, weight gain, and weight loss. However, it would have been better to categorize them into clinically relevant groups such as: % of patients who lost > 10% of weight (weight loss group), gained > 10% of weight (weight gain group), and the rest (stable weight group). It would then make it easier to extrapolate the results to the clinical settings and would make more sense. Also, there are a couple of other minor issues that have been mentioned in the "comments to the authors". Overall, it is an important study, and should be considered for publication in JGIM, once the statistical issue has been resolved.

Please do not hesitate to contact me if you have any questions.

Nov 13, 2007 Manuscript #

#### Reviewer #6a

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

## Do not include recommendations regarding acceptance/rejection of manuscript.

The manuscript presents interesting and clinically important results. A few issues, however, need to be addressed:

#### **Abstract:**

- 1. Use of term "real-world data" appears odd.
- 2. Objective is too broad and should be narrowed down to the primary objective. i.e evaluate weight change and it's predictors following new diagnosis of diabetes
- 3. XXXX t should be mentioned in the abstract.
- 4. % of patients who lost clinically meaningful weight (> 10%) should be mentioned.
- 5. The auhotrs have identified a sub-group of population that may be particularly vulnerable to weight gain and therefore the last sentence of conclusion section should be changed to something like: patients with certain characteristics may need more support for weight loss and physicians should pay particular close attention the sub-group.

#### Methods

- 1. The reference for the sensitivity of the XXX registry should be mentioned (page 7, second para).
- 2. The authors limited the population to those with type 2 DM and the elgibile population decreased from 4,718 to 4,315 (page 8, last line of second para). Were all the rest type 1 DM? The line should be reframed to clarify such as: after excluding \_\_\_ number of patients with type 1 diabetes, the analytical cohort comprised of \_\_\_ patients with type 2 diabetes.
- 3. Kg (kilogram) is considered to be standard for international standards, and it might be better to report the outcomes in Kgs (page 8, last para)
- 4. Details of follow up of the patients should be provided (frequency and type of physician: endocrinologist versus primary care physician).
- 5. Information about use of other medications, besides metformin and sulphonylureas, such as thioglitazones, acarbose, should be provided, and included in analysis
- 6. Statistical analysis section is unclear. Why was growth curve analysis used to determine groups of patients as compared to clinically important outcomes, such as % of patients who lost > 10% of weight, gained > 10% of weight, and the rest.
- 7. Given that majority of the associations were statistically significant (given the large sample size), it might be better to consider p<0.01 as statistically significant.

## **Results**

- 1. The absolute weight change defining the categories: higher stable weight, lower stable weight, weight gain, and weight loss, should be mentioned (results section, first para). Again, these categories appear artificial and should be replaced by clinically meaningful outcomes.
- 2. There is a lot of switching between weight loss and weight gain as the comparison group. The authors should form one comparison groups, such as weight losers, and then report all data compared to that group (page 12, second and third para).
- 3. When was the HbA1c checked: at 3 months, 6 months, or at the end of the follow up period, and for those with multiple HbA1c which value was used (page 12, last para). It might be best to consider the last HbA1C value for those with multiple measurements.
- 4. Use of Metformin was higher among weight losers as compared to weight gainers in Table 2, but this was not a significant predictor of weight loss in the multi-variate analysis (table 4). Did the authors double-adjust for Metformin by including both Metformin alone and Metformin+sulphonylureas in the model?

## **Discussion**

Generally well written.

- 1. More details about similar studies should be provided.
- 2. Did the XXXX cater to predominantly urban based or rural based population.? This should be mentioned in the limitations.
- 3. The authors did not look at physician characteristics (endocrinologist versus primary care physician etc), and the frequency of follow up (those with closer follow up probably have higher weight loss), and this should be mentioned in the limitations (if the authors cannot provide data on the same).
- 4. Patients with certain characteristics may need more support for weight loss, should be mentioned in the conclusion section as well.

## Figures and Tables

- 1. Table 1: What constitutes "higher stable weight, lower stable weight, weight gain, and weight loss", should be mentioned.
- 2. Table 2 and 3 can be combined.
- 3. The variables that were adjusted in the logistic regression model should be mentioned.
- 4. Figure 1 is probably not needed as the methods section explains it well.

Jul 19, 2007 Manuscript #

JGIM Article Review Form: COMMENTS TO THE EDITOR

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

Reviewer	#6b									
INTERES	T TO READ High			P OF 2			5	Low		
ORIGINA	ALITY AND High		NTI x		OF NE'	W INF 4	ORM.	ATION: Low		
STUDY I		ıate		cor	ntains	minor	flaws	is seriously f	lawed	
STATIST	ICAL ANAI Appropriate		X		3	4	5	Inappropriate or a	absent	
	Recommend	l rev	iew	by St	atistica	al Con	sultant	:Yes _x_N	o	
VALIDIT	Y OF CONC Valid			NS:	3	4	5	Invalid		
CLARITY	OF WRITI High			2 x	3	4	5	Low		
RECOMN	MENDATIO	NS:								
	ACCEPT: ( ) as is ( ) conditional						EJEC	Γ:	_x_RECONSIDER ( ) with major (x ) with minor	
	IF RECOM	ME	ND	ACC	EPTA1	NCE:				
	is the length	n a	ppr	opriate	?	x	Yes		Needs to be shortened	
	Are there as	ny f	igur	es or t	ables	that a	re unn	ecessary:	Yesx_No	
	If yes, pleas	se sj	peci	fy whi	ch tab	les are	unnec	essary.		
	Do you feel	thi	s sh	ould b	e reco	mmeno	ded for	r Editorial ?	x_YesNo	
	If yes, who	m d	o yc	ou reco	mmen	d write	e the E	Editorial?_		

CONFIDENTIAL COMMENTS TO THE EDITORS: This is an important topic and one which appears to be somewhat conflicting in the literature. This secondary, stratified analysis of an RCT is provocative and clinically relevant, and adds to similar findings from some other studies. Most of the issues I identified with the study methods and results probably just require clarification of methods. However, the study could be improved in its discussion section significantly. Most importantly, the authors appropriately referenced a just-published RCT of alendronate after hip fracture in the discussion of the paper (Lyles NEJM 357:1799-1809). However, that paper showed reduction in mortality as well as fractures, and the authors should address it more fully. The level of evidence by that paper is strong, and probably merits a change in practice. The authors should compare their study with Lyles in greater detail for differences that might explain their opposing findings. They should also assist the reader in interpreting the clinical

message of their study as recommended below.

Furthermore, the authors do not grapple with the appeal of preventing BMD loss early. This appeal is both emotional (it must be better to treat things early) and scientific (eg belief that it is better to maintain microarchitectural elements that might be lost permanently, evidence that BMD can be maintained with bisphosphonates). Clinically, I find this plays a role in many patients' decisions. I did not ask the authors to address this because of space constraints and because their study does not address this question directly. However, an editorial addressing this study's clinical significance could also address the arguments for and against osteoporosis "prevention" vs "treatment".

Jul 19, 2007 Manuscript #

Reviewer #6b

JGIM Article Review Form: COMMENTS TO THE AUTHORS

Do not include recommendations regarding acceptance/rejection of manuscript.

**General**: This article addresses an important clinical topic in decision-making in osteoporosis treatment. While it is a secondary analysis, it is from a large RCT and is well-conducted. Some editing to clarify methodology as well as further place it in perspective, particularly for the practicing clinician, would add to the paper as detailed below.

**Title** is confusing. Perhaps something like "A history of non-vertebral fracture does not identify women without osteoporosis **who could benefit from treatment** to reduce incident non-vertebral fractures

**Methods-Analysis-**The goal of the unadjusted Cox model of the placebo patients is not clear in the methods suggestion. Is this to ensure that non-vertebral fractures were important risk factors in this cohort, and thus to justify their main analysis as suggested in the discussion? If so, this analysis seems reasonable and an adjusted analysis does not seem necessary. However, on first reading I expected to see an adjusted analysis, and a clarification of the goal of this model would be helpful to the reader.

While the analysis limited to fractures traditionally and strongly recognized as osteoporotic fractures is reasonable, a justification for this would add to reader understanding of the role of this analysis.

#### **Results:**

What is meant by the "mechanism" of fracture? This is not mentioned in the methods, and in fact there is a specific mention that patient was asked about "timing and location, but not "circumstances" of the fracture. Was mechanism derived from physician notes? How were these categorized? If this cannot be clearly stated, it should be dropped from the results.

#### Discussion

The authors appropriately cite past literature with similar findings to theirs, but the recent Lyles study and the McClung Hip trial (risedronate RCT) have the strongest level of evidence, so comparing their findings to these studies in particular would be most helpful to the reader. (The raloxifene trial is also strong evidence that clinical info alone does not allow risk-stratification of patients, but as it has little information about bone density it does not directly apply to the osteopenic patient with a fracture). How does this study population compare with the Lyles and McClung studies in size and study subject characteristics? If you hypothesize that your findings and perhaps the HIP trial occurred because "antiresorptives exert their action on bone density, turnover and quality, alone but not on other risk factors" how do you explain the Lyle results? Are there other possible hypotheses?

Finally, can you offer any conclusions based on your study to the clinician faced with a patient with osteopenia and a fracture? For example, should clinicians be treating osteopenic patients after hip or vertebral fractures but not after other fractures? Can other risk factors be used to aid in this decision?

## **Supplement #**

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer: #6c INTEREST TO READERSHIP OF JGIM: 3 5 High 1 Low ORIGINALITY AND CONTENT OF NEW INFORMATION: High 1 2 3 5 STUDY DESIGN: contains minor flaws X is seriously flawed is adequate STATISTICAL ANALYSES: Appropriate 1 5 Inappropriate or absent --or--Recommend review by Statistical Consultant: Yes X No VALIDITY OF CONCLUSIONS: Valid 3 5 Invalid **CLARITY OF WRITING:** 3 5 High 1 Low **RECOMMENDATIONS: REJECT:** X RECONSIDER ACCEPT: (X) with major () as is ( ) with minor revisions ( ) conditional IF RECOMMEND ACCEPTANCE: is the **length** appropriate? X Yes Needs to be shortened Are there any **figures or tables** that are unnecessary: If yes, please specify which tables are unnecessary. Do you feel this should be recommended for **Editorial** ? Yes If yes, whom do you recommend write the Editorial? **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to** 

## authors)

The absence of information regarding the study participants' actual involvement in their respective interventions is a critical omission that needs to be rectified (see "comments to the authors: Methods").

Also, I'm concerned about the amount of unsupported generalizations and speculations contained within this report. It feels as though the conclusion section was written before the results were uncovered - and that it was not adjusted to reflect the actual findings (e.g., the impression is that the authors champion the Internet for patient education w/o the benefit of data).

Without addressing these issues, I would not recommend this for publication.

Apr 13, 2007 Supplement #

#### Reviewer # 6c

## JGIM Article Review Form: COMMENTS TO THE AUTHORS

## Do not include recommendations regarding acceptance/rejection of manuscript.

Certainly the relative effectiveness of various modes of patient education materials is an important area of study. However, I have the following specific concerns with this particular study:

#### **Introduction:**

- 1. Beware of generalizations e.g., last sentence of 2<sup>nd</sup> paragraph on page 6 "Additionally, the Internet allows users to access health information easier and in a format that is most suited to their learning style; accounting for different levels of education, language and media". This statement makes a lot of assumptions (although some logical) that should at least be supported by citations.
- 2. Although you use Frosch et al 2003 as a justification for your study (see last paragraph page 6 w/carry-over to top of page 7) the explanation of this study and it's segue into your investigation is too abrupt. Your explanation of "decisional conflict" as an important outcome measure was convincing your discussion of Frosch deserves similar attention. Also of note, there is a typo in the second sentence of the first paragraph on page 7 (one of your "videos" should be "internet").

## **Methods:**

Did you assess how many people actually viewed/used the intervention materials (per group)? What about their level of participation? Unfortunately, we can't assume that all study participants interacted with the intervention materials equivalently. Moreover, we can't assume that all study participants were equally comfortable with the particular mode of patient education materials they received. You touch on this latter issue via "Internet Use" (as reported in Table 1), but all of these areas need to be explored given their potential to impact your outcome measures. This is a major issue.

#### **Results:**

See previous comment re: Methods. Need to report data on intervention completion rates.

#### **Discussion:**

The first paragraph of your discussion session is well stated. However, I had issue with much of the content in the paragraphs that followed. For example:

- 1. Last two sentences of the final paragraph on page 16: "The presence of psychosocial barriers often prevents men from accessing traditional sources of patient education. This inability to access high quality information can cause men to make uninformed medical decisions". By what evidence do we know either of these? And what exactly are psychosocial barriers? Clearly some psychosocial issues are more important regarding information access than others. Which are you talking about?
- 2. First paragraph on page 17, you talk about how the Internet "can circumvent the psychosocial barriers..." (again, which ones?) and in the sentence immediately following you state that "the Internet removes the psychosocial barriers..." This jump needs to be clarified and supported with evidence.
- 3. The second paragraph on page 17 is predominately speculative. That the majority of people driving the "proactive approach to healthcare" are younger patients is an example of such.
- 4. Lose the first paragraph of page 18. You shouldn't focus on generalized potentials of the Internet when your data doesn't support it.
- 5. Missing limitation is data on intervention participation (per group).

Dec 12, 2007 Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@iupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer:	#5a									
INTERES	ST TO REA	DERS	SHIP	OF .	JGIM:					
	High	1	2	3	4	5	Low			
ORIGINA							ORMATION:			
	High	1	2	3	4	5	Low			
STUDY I		ate	c	ontain	s mino	r flaw	sis seriously	flawed		
STATIST	TICAL ANA									
	Appropriate	1	2	3	4	5	Inappropriate or	absent		
	D 1		or-		. 10	1.		r		
					tical Co	onsult	ant: _Yes _N	10		
VALIDIT	Y OF CON Valid	CLUS 1			4	5	Invalid			
CLARIT	<b>Y OF WRIT</b> High			3	4	5	Low			
RECOM	MENDATIO	NS:								
	_x_ACCEP ( ) as is ( x ) cond		1		_	REJE	ECT:	RECONSIDER ( ) with major ( ) with minor		
	IF RECOM	MEN	D AC	СЕРТ	ANCE	):				
	is the lengtl	n app	ropria	ite?	_	_Yes		_x_Needs	to be shortened	
	Are there ar	ıy <b>fig</b> ı	ures o	r tab	les that	are u	nnecessary:	Yes	_x_No	
	If yes, pleas	e spec	cify w	hich t	ables a	re uni	necessary.			
	Do you feel	this s	hould	be re	comme	ended	for <b>Editorial</b> ?	Yes	No	
	If yes, whor	n do y	ou re	comn	nend w	rite th	e Editorial?			
CONFID							ORS: (Do not rep			

Well written and interesting. I would like to see the authors address some of my concerns (e.g., try to synthesize their findings with prior research, can they give PDs more specific and concrete suggestions about next steps). Also, the paper can be a bit shorter (1-2 pages).

authors)

Dec 12, 2007 Manuscript #

Reviewer #5a

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

## Do not include recommendations regarding acceptance/rejection of manuscript.

I found the article to be interesting and insightful, and particularly well written. I think the authors have tried to put their findings into context and many of my suggestions are for clarifications. The major points they should consider are the following:

- 1. This study was conducted prior to work hour rules going into effect (which puts some of the interns' comments in a new light). What effect might work hour changes have had on the findings? Does the study need to be replicated, in some way, in the post-work hours era?
- 2. It is clear that there has been prior work in this field, and the authors summarize the major findings from others and how the current study is unique and adds to what has been described. The difficulty that I have is trying to synthesize all of this information. The current study provides important insights but, quite frankly, what is a program director to do? PDs are overwhelmed by trying to comply with all of the regulations and guidance from the ACGME and I think some clearer direction about next steps would be helpful and welcome. Specifically, can the authors move beyond recommending that PDs implement courses/interventions/ideas to preemptively address what interns will experience to more concrete ideas of interventions that could be studied, in a collaborative manner?

## **Specific Comments:**

Abstract: No comments, well written.

#### Introduction

1. Intro is well written but needs to be a bit shorter; shorten the paragraph on metacognition. Perhaps combine second paragraph into the first by eliminating last sentence of first paragraph, shortening second. My concern is that the introduction is a bit too long and you'll lose the reader.

#### Methods

- 2. Bottom of page six, last paragraph: Seems you already had a framework going in of the interns' experience--should this be stated as a bias going into the study? You've already created a framework before you ask them their opinions.
- 3. Top of page 9, awkward sentence: Three residents expressed that their responses be kept confidential, and these not quoted in the results.
- 4. Middle page 9: "When consensus was reached with this sample, the remaining questionnaires were coded by the three investigators." Was this coding independent? as a group? divided up the remaining narratives?

#### Results

1. Top of page 12: A powerful quote but the authors might want to make clear that this was conducted before work hours rules went into effect

#### Conclusions

- 1. Page 21: Could you expand a bit more on how your study differed/added to Kasman's study? I'm looking for what your study adds to the literature/understanding. I get the point but I think a bit more (1-2 sentences) would be helpful.
- 2. Page 24: "Program directors use a combination of approaches to promote the professional development of the residents and to provide a forum for discussing challenges they may encounter." This works more effectively here than in the introduction so would consider dropping from intro to shorten it.
- 3. Limitations: Study also conducted prior to work hours--what effect might that have on critical incidents, particularly as they relate to sleep deprivation?

#### Table

1. <u>Table needs a title and a legend.</u> Might be easier to see as more of an organizational chart--or, make clear that the critical incident categories are the subthemes within each overall metacognition theme.

Nov 13, 2007 Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer: #5b INTEREST TO READERSHIP OF JGIM: 3 5 High 1 Low ORIGINALITY AND CONTENT OF NEW INFORMATION: High 1 2 3 4 5 Low STUDY DESIGN: contains minor flaws is seriously flawed is adequate STATISTICAL ANALYSES: Appropriate 1 5 Inappropriate or absent --or--Recommend review by Statistical Consultant: Yes No **VALIDITY OF CONCLUSIONS:** Valid 1 3 5 Invalid **CLARITY OF WRITING:** 3 5 High 1 4 Low **RECOMMENDATIONS: REJECT:** X RECONSIDER ACCEPT: ( ) with major () as is (X) with minor ( ) conditional IF RECOMMEND ACCEPTANCE: is the **length** appropriate? \_\_Needs to be shortened X Yes Are there any **figures or tables** that are unnecessary: X No If yes, please specify which tables are unnecessary. Do you feel this should be recommended for **Editorial** ? Yes If yes, whom do you recommend write the Editorial?

# **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)**

In general, a well done study that should be of interest to JGIM readers. However, I don't think the authors have made a strong enough case for why their work is important. A strengthened background and discussion section would be needed for acceptance. I would also like to see clearer terms used for their categories of patients, and these descriptions in the abstract, as some readers may only read the abstract.

Nov 13, 2007 Manuscript #

Reviewer #5b

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

Do not include recommendations regarding acceptance/rejection of manuscript.

This is a well done study that should be of interest to the readers of JGIM. I have a few minor concerns/recommendations, but my main criticism is that the authors have not made a strong enough case for why their study is important and adds to the literature. How can I apply these groupings of weight trajectories to my individual patients? Why bother looking in the first place? Because the rationale for the study is not stated clearly enough and the relevance of the findings do not seem applicable, some of the findings seem obvious. How does knowing that patients taking metformin are more likely to lose weight and patient stopping smoking are more likely to gain weight help me? I knew this already. Similarly, I am not surprised that patients who did not gain weight or lost weight had better improvements in glycemic control.

## Of the minor concerns that should be addressed:

- 1. What about medications other than metformin and sulfonylureas? Was no insulin used, which is known to cause weight gain. How about TZD's? If these are not formularly, then this should be stated.
- 2. I understand that main limitation of claims analysis is lack of data that would be in the chart. However, knowing whether or not diet and exercise what discussed seems like it would be very important. A chart review of a section of the data might have been helpful. Did diet and exercise counseling negate any weight gain affects of SU therapy?
- 3. Along those lines, it would be important to mention as a limitation that it is not clearly whether or not patients knew they had been diagnosed. This may have played an important role, since patients knowing they had a diagnosis might be more likely to be compliant.
- 4. I would seriously reconsider the terms used for the four categories. "Higher stable weight" patients actually had some weight loss, so this term does not adequately describe the group. Also, it is not clear what "higher" means, just from the term. How about "Heavy re-gainers" "light re-gainers" "gainers" and "losers." If you feel the term "losers" is two derogatory because of the double meaning, you could go with "weight gainers" and "weight loser." Regardless of which terms you use. I would highly recommend explaining the terms in the abstract, as this may be the only thing that readers actually read.

May 16, Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer: #5c INTEREST TO READERSHIP OF JGIM: 1 2 3 5 High Low ORIGINALITY AND CONTENT OF NEW INFORMATION: High 1 2 3 4 5 Low STUDY DESIGN: x contains minor flaws is seriously flawed is adequate STATISTICAL ANALYSES: Appropriate 1 3 5 Inappropriate or absent --or--Recommend review by Statistical Consultant: Yes No **VALIDITY OF CONCLUSIONS:** Valid 1 3 5 Invalid **CLARITY OF WRITING:** 1 3 5 High 2 4 Low **RECOMMENDATIONS: REJECT:** x RECONSIDER ACCEPT: (x) with major () as is ( ) with minor ( ) conditional IF RECOMMEND ACCEPTANCE: is the **length** appropriate? \_\_Needs to be shortened x Yes Are there any **figures or tables** that are unnecessary: Yes x No If yes, please specify which tables are unnecessary. Do you feel this should be recommended for Editorial? \_\_Yes If yes, whom do you recommend write the Editorial?

# **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)**

The topic is interesting and the data unique but the analyses need work and the interpretation needs refining. The conclusions are overstated. I don't think this work has the potential to inform the disparities literature in a meaningful way—the data are not sufficient for that. I am not sure the revised paper, with additional analyses and appropriate caveats, will say enough to make it worthy of publication in JGIM.

May 16, Manuscript #

Reviewer #5c

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

**Overview:** This paper uses data from WIHS to examine whether individuals who were informed that they were HCV positive in 1999 (n=1166) and were followed up in 2003 (n=681) remember that they are HCV positive in 2003; were offered a liver biopsy between 1999 and 2003; and (c) received a biopsy. About three fourths of the 681 HCV positive women who were followed up in 2003 remembered that they were HCV positive. About half who remembered they were HCV positive said that their provider recommended liver biopsy and about half of those reported having a liver biopsy.

## **Main Comments:**

(1) The study reports that about half of HCV positive women were offered a liver biopsy. The denominator is all women who were HCV positive and who were followed up in 2003, which implicitly assumes that all were candidates to be offered a biopsy. However, page 5 reports that "treatment guidelines recommend that all HIV/HCV co-infected persons be *evaluated and considered* for hepatitis C treatment." (emphasis added). But the guidelines (as paraphrased in the report) do not specifically indicate that all HCV positive patients or those with HIV/HCV be evaluated with a liver biopsy.

It thus seems plausible that some of the physician behavior observed (those who do not offer or recommend a biopsy) may be decisions about the appropriateness of the procedure for the particular individual based on the medical facts of the case. For example, physicians may not have referred individuals with particular co-morbid conditions that contraindicate a biopsy, or individuals who they thought might be overwhelmed at the prospect of adding an additional procedure to their medical regiem, or individuals who they thought should prioritize their HIV treatment or delay a biopsy until a more appropriate time.

Additionally, there is no measure of health insurance status of individuals included. Doctors might be reluctant to advise a test for uninsured individuals with no means to obtain the procedure or for individuals whose insurance may not pay for all/most of the costs of the treatment.

Moreover, the finding that most of those who were offered the biopsy went through with could be interpreted as the physician's having appropriately screened biopsy candidates.

Both health insurance status and factors such as comorbid medical conditions are likely to be correlated with race and SES. Thus, we may not be observing the effect of race on physician's referral behavior, but rather the effect of these other underlying factors. Consequently, the conclusions drawn are too strong; for example, page 14 concludes, "women's income, education, and substance abuse were negatively associated with referral-a measure of physician (or health system) behavior...this implies that non-medical factors influenced who as offered treatment." Page 15, similarly, "We have demonstrated.. that race/ethnicity and socioeconomic factors predict who is referred for HCV evaluation and treatment..."

Finally, it is questionable whether the women who did not remember their status should be included in the analysis. As it stands, the analysis assumes they were not offered a biopsy (page 12). However, they may have both forgotten their status and the offer of a biopsy.

(2) With no medical record validation of whether women were offered a biopsy or not, respondent reporting error could be substantial, and the finding that 1 in 4 women do not remember being told they were HCV positive substantiates the potential bias from reporting error.

The authors could in fact make use of information they have on reporting error by doing a multivariate analysis of who remembers and who doesn't. These same factors may be correlated with who remembers being offered treatment and who doesn't—if race and SES predict HCV non-remembrance, then we cannot be sure if the effect we observe of these factors on biopsy offering is related to reporting error or physician behavior.

On the other hand, if we find the same factors are associated with non remembrance of HCV status and with offering, another interpretation could be that doctors who are less inclined to remind their patients about their HCV status are also doctors who are less inclined to offer treatment.

The analysis bears doing and the interpretations bear comment, at a minimum.

A related question: Had any women been evaluated/treated for HCV prior to the 199 screening (and thus unlikely to have had a biopsy referral or procedure between 99 and 03?)

(3) The loss of many individuals to death is a potentially significant problem. Did the authors consider a competing hazard model where the outcomes are either death or referral for biopsy treatment?

## **Other Comments**

(1) In table 1 are the descriptors all measured as of 1999 (and not as of 2003)? If they are measured as of 2003 (e.g. alcohol use), these factors may be endogenous (affected by the knowledge of whether they are HCV positive or negative.

Did any of the women know prior to the 1999 screen that they were positive? If so, even if the factors were measured as of 1999, there could still be some endogeneity, which even if not correctable could be acknowledged.

- (1) Another limitation to note is that the sample is urban women and the results may not hold for those in rural areas or for men.
- (2) It would be useful to clarify how the Hep c virus is transmitted. The authors say on page 5 that there are "shared routes of transmission" with HIV, and that rates vary with age/geography/and origin of cohort, but do rates vary with route of transmission; e.g. are HIV users who were infected from a tainted needle more at risk than those who were infected through unprotected sex?
- (3) Page 14 says that "effective education about alcohol cessation is needed." But does education per se work or are there are things that induce people to change their behavior? Is it only about <u>education</u> or are there other things that have been shown to help alter behavior? In the following sentence, the authors mention alcohol or substance abuse treatment, but these treatments are aimed at heavy users, and not individuals who drink a little but should be completely abstaining.
- (4) Perhaps a limitation to note or something for further research, but outside of the WIHS, an issue is how many individuals with HIV are tested for HCV to begin with. This study cannot address that question, but clearly this precedes everything else—remembering, referral, and receipt of treatment.

## Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer: #4a INTEREST TO READERSHIP OF JGIM: 1 3 5 High Low ORIGINALITY AND CONTENT OF NEW INFORMATION: High 1 2 4 5 Low STUDY DESIGN: x contains minor flaws is seriously flawed is adequate STATISTICAL ANALYSES: Appropriate 1 5 Inappropriate or absent --or--Recommend review by Statistical Consultant: x Yes No **VALIDITY OF CONCLUSIONS:** Valid 5 Invalid **CLARITY OF WRITING:** 1 2 3 5 High 4 Low **RECOMMENDATIONS: REJECT:** x RECONSIDER ACCEPT: () as is (x) with major ( ) with minor ( ) conditional IF RECOMMEND ACCEPTANCE: is the **length** appropriate? Needs to be shortened x Yes Are there any **figures or tables** that are unnecessary: x No If yes, please specify which tables are unnecessary. Do you feel this should be recommended for Editorial? x Yes If yes, whom do you recommend write the Editorial?

# **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)**

An interesting observation limited by being a post-hoc, sub-set analysis (see Wang R et al NEJM 2007; 357: 2189-2194. As a result the conclusions of the authors are overstated. There study limitations need to be clarified and stressed and I would suggest a title change to: A post-hoc analysis of the Fracture Intervention Trial suggests that alendronate may not reduce incident non-vertebral fractures in women with a prior history of a not vertebral fracture but not osteoporosis by World Health Organization criteria." Without the changes suggested in the comments to the authors, the paper should not be accepted. If the authors are willing to make the changes, re-consideration and re-review are mandatory.

#### Reviewer #4a

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

## Do not include recommendations regarding acceptance/rejection of manuscript.

The manuscript XXXXXX by XXXXX et al is a post-hoc, subset analysis of women in the Fracture Intervention Trial who did not have a prevalent vertebral fracture at randomization. The authors conclude that alendronate "does not appear to reduce the risk for incident non-vertebral fractures who did not have a historical history of prior non-vertebral fracture or osteoporosis."

Manuscript #

The major concern this reviewer has with the manuscript is that because it is a post-hoc, subset analysis there are cofounders and selection biases that may lead to overstated and misleading conclusions. For example, both the title of the paper and statements in the conclusion make it appear that this is a definitive study, which it is not. I would suggest the authors consider modifying the title to state: "A post-hoc analysis of the XXXXX....." In addition, the conclusion is stated too definitively for a post-hoc, subset analysis and misleads the knowledgeable reader. The conclusion should be made cautious. Such as "using a post-hoc, subset analysis our data might suggest that alendronate may not appear to reduce.............as assessed by capturing non-vertebral fractures in a clinical trial."

Table 3 should also show the absolute number of fractures captured as AE's.

In the introduction, the authors should also state that the prevalence of osteoporosis is according to the 1994 World Health Organization (WHO) report at the femoral neck but they should also include the WHO prevalence calculations when based on combining 3 skeletal sites (hip, spine and forearm) of 30%.

Also, in the introduction, paragraph 1, line 5, the authors should clarify that more fractures occur in the osteopenic postmenopausal population than in the osteoperotic (by WHO criteria) population because there are simply more osteopenic than osteoperotic women; and, that additional non-BMD related risk factors also contribute to fracture risk.

On page 2, 1<sup>st</sup> sentence. In the risedronate hip trial the randomization for Group 2 was on the basis of 1 of several "clinical risk factors for frailty", not just falls alone.

In outcomes it should be stated that incident non-vertebral fractures were captured as AE's.

## Page 5 Results

The opening sentence:" given the randomized trial design" should be deleted. It misleads the reader. This is a post-hoc, subset analysis.

Page 5 Fracture Outcomes. State clearly of the 153 incident non-vertebral fractures how many were in the alendronate vs the placebo groups.

Discussion, line 6 should state "prior non-vertebral fractures captured as historical data......"

## **Supplement #**

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer	: #4b									
INTERE	ST TO REA	DERS	SHIP	OF J	GIM:					
	High	1	<u>2</u>	3	4	5	Low			
ORIGIN	ALITY AND	CON	NTEN	T OF	NEW	INFO	RMATIO	N:		
	High	1	<u>2</u>	3	4	5	Low			
STUDY I		e	co	ntains	minoi	r flaws	_ <b>X</b> _is s	eriously	flawed	
STATIST	ΓICAL ANA									
	Appropriate	1	2	<u>3</u>	4	5	Inappropi	riate or a	bsent	
	Recommend	revie	or- w by S		ical Co	onsulta	nt:Yes	s _x_N	lo	
VALIDIT	TY OF CON	CLUS	SIONS	S:						
	Valid	1	<u>2</u>	3	4	5	Invalid			
CLARIT	Y OF WRIT	ING:								
	High	1	<u>2</u>	3	4	5	Low			
RECOM	MENDATIC	NS:								
	ACCEPT	·:				_REJE	CT:		_x_RECO	NSIDER
	() as is () condit	ional							(x) with () with n	•
	IF RECOM	MEN	D AC	СЕРТ	ANCE	Ξ:				
	is the lengtl	h app	ropria	ite?	_	_Yes			Needs to	o be shortened
	Are there ar	ny <b>fig</b> i	ures o	r tabl	es that	t are ur	necessary:		Yes	No
	If yes, pleas	se spe	cify w	hich ta	ables a	ire unn	ecessary.			
	Do you feel	this s	hould	be rec	comme	ended 1	for <b>Edit</b>	orial ?	Yes	No
	If yes, whor								<del></del>	<del></del>
	J .,	•	,							

# **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)**

The author intended "to determine the feasibility" of the handheld computer in event reporting, but most of the findings presented seemed not relevant to "feasibility". Because it is a voluntary reporting of what a reporter experiences/encounters during his/her shift, the comparisons of reporting rates between different types of reporters do not tell us anything useful, and do not tell how feasible the handheld computer is (in comparison with what?).

Apr 05, 2007 Supplement #

Reviewer #4b

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

## Do not include recommendations regarding acceptance/rejection of manuscript.

This manuscript addresses a critical HIT question – integrating of event-reporting into larger HIT systems. The introduction establishes the motivation of this study clearly and strongly. But the Method, Results and Discussion sections seemed to have gone to a different direction.

Ideally for a feasibility study, one would, first, want to see comparisons between the handheld, "innovative" system and another, "traditional" system. It seemed at least one of the four hospitals has such a traditional system, based on the statement on page 4, "Comparative baseline reporting rates were calculated for one of the participating hospital sites using traditional event reports collected during the study period and average hospital staffing estimates." Second, feasibility could be judged based on (1) technological capacity (innovative systems do better or equally well, easier to use, etc.), (2) costs (cheaper both in real costs and operating times); and (3) outputs (more reports, more complete reports, etc.). In the end, the author would conclude that the new system does the job and is cheaper and easier to operate, therefore "feasible". The author provided little on either aspects of a feasibility study.

The characteristics of the participants (page 7) is determined by the recruitment process (page 4-5), and the statistical differences in participating days between different groups, for example, do not have any meaning beyond the study sample, so the p-values do not have usual statistical meaning (as statistical inferences). I also have trouble with reporting rates: are these rates suppose to reflect event occurrence during a shit or diligence of the reporter, or both? Again, because of the mixed implications of a specific "reporting rate", the comparison of reporting rates does not offer meaningful information.

There are lots of valuable information in this study: Handheld computer could be a valuable extension of HIT systems; there might be an opportunity for this study to show that handheld computer is cheaper and less time-consuming than "traditional" method in event reporting, as a result, physicians and nurses are more willing to report (more reports per shift), and report more completely; the authors could focus more on what data the system were able to collect (in comparison with other systems); and the information on how the 4 hospitals developed their system may provide lessons to other organizations.

## **Supplement #**

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@iupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer	:: #4c									
INTERE	ST TO REA	DER	SHIP	OF J	GIM:					
	High	1	2x	3	4	5	Low			
ORIGIN	ALITY ANI	) CO	NTEN	T OF	NEW	INFO	RMATION:			
	High	1x	2	3	4	5	Low			
STUDY	DESIGN:									
	_x_is adequ	ate	cc	ontains	minor	flaws	is seriously	flawed		
STATIS	ΓICAL ANA	LYS	ES:							
	Appropriate	1x	2	3	4	5	Inappropriate or	r absent		
			or-							
	Recommend	d revi	ew by S	Statisti	ical Co	nsulta	nt: _Yes _N	O		
VALIDI	TY OF CON									
	Valid	1x	2	3	4	5	Invalid			
CLARIT	Y OF WRIT									
	High	1x	2	3	4	5	Low			
RECOM	MENDATI(	ONS:								
	_x_ACCE					REJE	CT:		NSIDER	
	(x) as is		1					<ul><li>( ) with major</li><li>( ) with minor</li></ul>		
	( ) condi							( ) with	IIIIIOI	
	IF RECOM	IMEN	ND AC	CEPT	ANCE	•				
	is the <b>lengt</b>	h ap	propria	te?	_>	x_Yes		Needs	to be shortened	
	Are there a	ny <b>fi</b> g	gures o	r tabl	es that	are un	necessary:	Yes	_x_No	
	If yes, pleas	se spe	ecify w	hich ta	ables ar	re unn	ecessary.			
	Do you fee	l this	should	be rec	omme	nded f	for <b>Editorial</b> ?	Yes	_x_No	
	If yes, who	m do	you rec	comm	end wr	ite the	Editorial?			
CONFI	DENTIAL C	OM	MENTS	OT 2	THE E	THE	ORS: (Do not rene	eat comme	nts mada ta	

authors)

Even with the comments below to the authors, I feel the article is sufficient for use as-is.

Apr 12, 2007 Supplement #

Reviewer #4c

**JGIM Article Review Form: COMMENTS TO THE AUTHORS** 

Do not include recommendations regarding acceptance/rejection of manuscript.

Overall the study was very good; there was nothing major that I felt needed comment.

One thing was unclear in how the study was performed. It was mentioned in the beginning that the handheld application was being used alongside another system that was prompting the users for information, or that users could choose the application outside of the prompting. I was curious what the prompting application was asking the users (i.e., something related to medications or errors, or something completely different), and was also curious if people submitted most responses because they were prompted to do so, or because they chose to do so (by launching XXXX themselves). It seems like that would be relevant to developing future applications that take advantage of the findings here. In other words, is prompting/reminding necessary, or will they do it on their own? This prompting is mentioned in the discussion (talking about residents needing it) so I think it should be clarified.

Also interesting if available would be the accuracy with which different groups (nurses, attendings, residents) assigned blame. Specifically, it is mentioned that residents do not report for fear of professional or legal complications, so could it be that they focus too much on their role in the incident? Were attendings regularly reporting residents' mistakes, but not their own (it appears that's the case, as they were reporting mostly prescribing errors, but mostly stating that they weren't theirs)? There was a subjective "who was involved" question, but no mention of that in the article. Were different areas (peds, med, surg) reporting at different rates than the others?

The methods, results, and discussion sections were all sufficient and clear. The above comments may result in additional discussion elements.

It was mentioned in the discussion at one point that the use of the tool increased the reporting rate at one facility by 15 times. It would be interesting to know the numbers across the institutions, and if that was an anomaly or common across the studied institutions.

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Perspectives Review Form: COMMENTS TO THE EDITOR** 

Reviewer	:: #3a									
INTERE	ST TO REA									
	High	1	X	3	4	5	Low			
ORIGIN						INFO	ORMATION:			
	X 2	3	4	5	Low					
STUDY	<b>DESIGN:</b> _X_is adeq	uate		contair	ns mino	r flaw	sis seriousl	y flawed		
VALIDI	TY OF CON									
	Valid	1	X	3	4	5	Invalid			
CLARIT	Y OF WRI									
	High	1	2	X	4	5	Low			
RECOM	MENDATI	ONS:								
	_X_ACCE () as is (X) cond		al			REJE	CT:	RECONSIDER ( ) with major ( ) with minor		
	IF RECON	<b>MEN</b>	ID AC	СЕРТ	ANCE	:				
	is the <b>leng</b>	th ap	propri	ate?	, 	X_Ye	s	Needs	to be shortened	
	Are there	fig	gures (	or tab	les that	are u	nnecessary:	Yes	_X_No	
	If yes, plea	ise spe	ecify w	hich t	ables a	re unr	necessary.			
	Do you fee	el this	should	l be re	comme	nded	for <b>Editorial</b> ?	? _Yes	No	
	If yes, who	om do	you re	ecomn	nend wr	ite the	e Editorial?			
CONFID authors		COMN	MENT	'S TO	THE I	EDIT	ORS: (Do not rep	oeat commei	nts made to	

#### Summary

In general, this is a well-written manuscript that could be published in the JGIM. There is no clinical question, but instead poses an interesting question about the gap in translation from research to the individual clinician. Though the paper may seem "soft" to some readers, many research physicians may agree that there definitely exist barriers in helping overworked clinicians assess and remember a multitude of data in order to remain up to date. As an academic researcher, it never occurred to me to use representative stories to present research findings, which probably accounts for some of the dryness of my own work and presentations.

In general, I believe this manuscript merits publication, and have only a few comments and suggestions to the authors before publication:

#### Title:

The title says very little about the manuscript's point. I would suggest wording that more appropriately conveys the aim of the paper, perhaps "The use of stories to translate research data into clinical practice" or something similar.

#### Abstract:

No comment.

#### Introduction:

I would add a paragraph that touches on why the majority of researchers would not necessarily approve, or even understand, the use of fiction/nonfiction techniques to present data. It does seem to fly against the historical manner of writing research grants and manuscripts. The only example that comes to my mind is the use of expanded case reports, often using a fictionalized composite patient created to fit a clinical situation. This could be followed by a logical argument on how stories could be an adjunct for more traditional ways of presenting data.

The second paragraph is very powerful and eloquent in the way it summarizes in a few sentences how groups matter to research findings, but individual decisions are influenced by stories about individuals. Well done. Could the authors be more specific in how a researcher could take data from groups and effectively paint a portrait of a patient? This is done to a degree later on, but I'd rather see some kind of algorithm up front.

It would have been interesting to see a few concise examples from the cardiovascular disease, HIV, or diabetes. Substance abuse may have been a softer target since this disease state affects so many aspects of a patient's life negatively.

## Attributes of representative stories

This section is interesting, but could be tied together more efficiently. To a medical researcher, this section could be confusing, even foreign, when it comes to the "five attributes."

## Summary

I have read this paper several times, and will admit to being a bit lost in some of the jargon of writing, for lack of a better word. When a journal publishes not only a scientific manuscript, but an editorial as well, I look forward to reading both, as the editorial often clarifies data for me, especially if it is not in my area of expertise. I think that representative stories could accomplish the same, with even more powerful memory effect. I believe that the author has an excellent idea, and is very publishable, but my main criticism remains that the language of the paper is a bit unwieldy. I would have liked language that sounds a bit less "English major (of which I was once)" and more scientific. After all, the author is encouraging scientists to create stories, not for fiction writers to understand science. Perhaps more simple language, and a better step by step algorithm, would make this very intriguing paper more accessible to mainstream medical researchers.

Apr 16, 2007 Manuscript #

Reviewer #3a

**JGIM Article Review Form: COMMENTS TO THE AUTHORS** 

Do not include recommendations regarding acceptance/rejection of manuscript.

## Summary

In general, this is a well-written manuscript. There is no clinical question, but instead poses an interesting question about the gap in translation from research to the individual clinician. Though the paper may seem "soft" to some readers, many research physicians may agree that there definitely exist barriers in helping overworked clinicians assess and remember a multitude of data in order to remain up to date. As an academic researcher, it never occurred to me to use representative stories to present research findings, which probably accounts for some of the dryness of my own work and presentations.

In general, I have only a few comments and suggestions to the authors:

## Title:

The title says very little about the manuscript's point. I would suggest wording that more appropriately conveys the aim of the paper, perhaps "The use of stories to translate research data into clinical practice" or something similar.

#### Abstract:

No comment.

#### Introduction:

I would add a paragraph that touches on why the majority of researchers would not necessarily approve, or even understand, the use of fiction/nonfiction techniques to present data. It does seem to fly against the historical manner of writing research grants and manuscripts. The only example that comes to my mind is the use of expanded case reports, often using a fictionalized composite patient created to fit a clinical situation. This could be followed by a logical argument on how stories could be an adjunct for more traditional ways of presenting data.

The second paragraph is very powerful and eloquent in the way it summarizes in a few sentences how groups matter to research findings, but individual decisions are influenced by stories about individuals. Well done. Could the authors be more specific in how a researcher could take data from groups and effectively paint a portrait of a patient? This is done to a degree later on, but I'd rather see some kind of algorithm up front.

It would have been interesting to see a few concise examples from the cardiovascular disease, HIV, or diabetes. Substance abuse may have been a softer target since this disease state affects so many aspects of a patient's life negatively.

## **Attributes of representative stories**

This section is interesting, but could be tied together more efficiently. To a medical researcher, this section could be confusing, even foreign, when it comes to the "five attributes."

## Summary

I have read this paper several times, and will admit to being a bit lost in some of the jargon of writing, for lack of a better word. When a journal publishes not only a scientific manuscript, but an editorial as well, I look forward to reading both, as the editorial often clarifies data for me, especially if it is not in my area of expertise. I think that representative stories could accomplish the same, with even more powerful memory effect. I believe that the author has an excellent idea, and is very publishable, but my main criticism remains that the language of the paper is a bit unwieldy. I would have liked language that sounds a bit less "English major (of which I was once)" and more scientific. After all, the author is encouraging scientists to create stories, not for fiction writers to understand science. Perhaps more simple language, and a better step by step algorithm, would make this very intriguing paper more accessible to mainstream medical researchers.

May 25, Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer: #3b INTEREST TO READERSHIP OF JGIM: 1 5 High Low ORIGINALITY AND CONTENT OF NEW INFORMATION: High 1 2 3 4 5 Low STUDY DESIGN: x is adequate \_\_contains minor flaws \_\_is seriously flawed STATISTICAL ANALYSES: 5 Appropriate 1 Inappropriate or absent --or--Recommend review by Statistical Consultant: Yes No **VALIDITY OF CONCLUSIONS:** Valid 3 5 Invalid **CLARITY OF WRITING:** 1 5 High 2 Low **RECOMMENDATIONS: REJECT:** x ACCEPT: RECONSIDER ( ) as is ( ) with major (x) conditional ( ) with minor IF RECOMMEND ACCEPTANCE: is the **length** appropriate? \_\_Needs to be shortened x Yes Are there any **figures or tables** that are unnecessary: If yes, please specify which tables are unnecessary. Do you feel this should be recommended for **Editorial**? Yes If yes, whom do you recommend write the Editorial?

## CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to

**authors)** This is an interesting analysis of a rather complex public health issue that raises several important questions most of which are addressed by the authors. The fact that every study participant was told about her or his HCV status during a research interview, yet only 77% were aware of the diagnosis is perhaps the seminal finding of the study. While we can speculate on the reasons for the failure to remember/learn, it would seem fair to assume that the intensity of the educational effort in the research setting exceeds that which occurs in a primary care practice setting. This would seem to pose a significant challenge for the health care system, already stressed for time, to adequately educate patients with very complex disease as well as very complex social circumstances. I would like to see this issue addressed in the discussion; it is essentially ignored in the current iteration. The translational concern for me is what would happen in the busy/stressed primary care practice in a public hospital or health department where the vast majority of these patients will receive their care. Such could be an important 'lesson learned' with some suggestions or ideas for patient education strategies or system modifications.

An interesting paper to read and review with excellent information, especially of the above concerned are made a part of the discussion.

## May 25, Manuscript #

Reviewer #3b

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

## Do not include recommendations regarding acceptance/rejection of manuscript.

- 1. This is a generally well written article; there are a few typos (e.g. inconsistent caps for hepatitis) and at least one incomplete sentence second sentence of the Methods.
- 2. The various numbers of patient categories gets a bit confusing, which may be unavoidable with such a complex patient grouping, but would be worth trying to make clearer.
- 3. The fact that every study participant was told about her or his HCV status during a research interview, yet only 77% were aware of the diagnosis is perhaps the seminal finding of the study. This poses a translational concern for the study, namely, what would happen in the busy/stressed primary care practice in a public hospital or health department where the vast majority of these patients will receive their care. These patients had at least 2 shots at education about their HCV status, first through the study interview and then again from the PCP, yet a sizable minority either forgot, couldn't remember, etc. Perhaps one of the 'lessons learned' here is the formidable challenge of how can a stressed health care system, especially in the public setting, realistically and adequately meet the needs of these very complicated patients. Perhaps this issue could be discussed and some ideas shared.

Mar 23, 2007 Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer: #3c

INTEREST TO READERSHIP OF JGIM:

High 1-2

ORIGINALITY AND CONTENT OF NEW INFORMATION:

High 1-2

STUDY DESIGN:

XX is adequate

STATISTICAL ANALYSES:

Appropriate 1-2

--or--

Recommend review by Statistical Consultant: xx Yes

**VALIDITY OF CONCLUSIONS:** 

Valid 1-2

**CLARITY OF WRITING:** 

Low

**RECOMMENDATIONS:** 

XX Reconsider with rewrite of the following:

# **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)**

Summary: (1) recommendation not to title paper using the term "inertia" related to physician practice, thinking, etc., because of the possible derogatory implications of the use of this term. (2) recommendation to further research the peer-reviewed medical geriatric literature for non-aggressivenes of management of hypertension in the older geriatric population. (3) recommendation to more fully develop with a set of key references the notion of "cognitive mapping" and to discuss this concept in relation to the notion of "mental models."

Mar 23, 2007 Manuscript #

#### Reviewer #3c

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

## Do not include recommendations regarding acceptance/rejection of manuscript.

#### **Abstract**

- 1. The authors need to drop their use of the term "inertia" from their title, abstract, and body of paper becomes of the negative connotations associated with this term directed at physicians and their practice of medicine. The term "inaction" is highly specific (and less derogatory) and more suitable to the presentation in the authors' paper. Why start the title and abstract out with the term "inertia" which may be demeaning to physicians in general and why lose a possibly interested audience by the use of a negative phrase "inertia" at the start of the Abstract. As a reader, I would have never looked at this paper with its use of "inertia" in the title.
- 2. The authors will need to spend time with the Introduction of their manuscript to described the concept of "nominal group panels" of practicing physicians and provide references that the readers of JGIM could use to further explore this concept.
- 3. The authors' size of each of their three groups (N = 6, N = 7, and N = 9) will need further discussion within the Discussion section regarding the "representativeness" captured in such a small group size.
- 4. The notion of "cognitive mapping" will also need to be further elaborated upon the authors' introduction and a comparative description of where "cognitive mapping" fits into the conceptual framework of "mental models" further elaborated upon.
- 5. "The model shows that clinical inertia is a subset of all "inaction", much of which may be clinically appropriate." The authors will need to sit down and reconstruct sentences such as the above which is virtually meaningless as well as being derogatory because of the use of the term "inertia." The authors need to drop their use of the term "inertia" becomes of the negative connotations associated with this term. The term "inaction" is high specific and more suitable to the presentation in the authors' paper. Why start the title and abstract out with the term "inertia" which may be demeaning to physicians in general and why lose a possibly interested audience by the use of a negative phrase "inertia" at the start of the Abstract.

## Introduction, Methods, Discussion

6. The authors have not provided enough attention and need to perform a review of the peer-reviewed medical literature in geriatrics regarding the specifics of what has been studied in the misdirected attempts to bring older geriatric patient's blood pressure under "better" control.

This reviewer believes the authors need to rewrite their manuscript's Introduction and Discussion providing a more thoughtfully considered expression than "inertia." The fact that the term has been used in the title of one referenced publication is not sufficient to continue it further use in the title of a manuscript in the peer-reviewed medical literature.

The authors have not as yet provided a well-developed explanation of the concept of "cognitive map" or cognitive mapping."

The authors have not provided a sufficient review of the peer-reviewed medical geriatric literature on the reasons not to over-manage the older geriatric patient's hypertension medication which should be make a key component of this paper.

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** Reviewer: #2a INTEREST TO READERSHIP OF JGIM: 1 3 4 5 High Low ORIGINALITY AND CONTENT OF NEW INFORMATION: High 1 2 4 5 Low STUDY DESIGN: contains minor flaws is seriously flawed X is adequate STATISTICAL ANALYSES: Appropriate 1 5 Inappropriate or absent --or--Recommend review by Statistical Consultant: Yes No VALIDITY OF CONCLUSIONS: Valid 3 5 Invalid **CLARITY OF WRITING:** 3 5 High 1 4 Low **RECOMMENDATIONS: REJECT:** RECONSIDER X ACCEPT: (X) as is ( ) with major ( ) with minor ( ) conditional IF RECOMMEND ACCEPTANCE: is the **length** appropriate? X Yes Needs to be shortened Yes Are there any **figures or tables** that are unnecessary: X No

# **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)**

Do you feel this should be recommended for **Editorial**? Yes

If yes, whom do you recommend write the Editorial?

If yes, please specify which tables are unnecessary.

Failure to refer for treatment is a social and moral issue. Thus while the findings are not surprising, they warrant publication because of the role physician expectations based on patient demographics play in whether or not referrals are offered.

One additional limitation of note – the study sampled exclusively from urban areas. Thus it did not take into consideration the role of rurality in access to care. These findings could conceivably be somewhat different in a rural setting with different challenges in access, but also potential variations in both demographics and physician relations with patients.

May 22, Manuscript #

Reviewer #2a

**JGIM Article Review Form: COMMENTS TO THE AUTHORS** 

Do not include recommendations regarding acceptance/rejection of manuscript.

While the findings are not entirely new, they warrant continued attention because of the role that physician expectations, based on patient demographics, plays in whether or not referrals are offered and because lack of referral continues to take place.

One additional limitation of note – the study sampled exclusively from urban areas. Thus it did not take into consideration the role of rurality in access to care. These findings could conceivably be somewhat different in a rural setting with different challenges in access, but also potential variations in both demographics and physician relations with patients.

## Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Review	er: # <b>2b</b>											
INTER	INTEREST TO READERSHIP OF JGIM:											
	High	1	2	3	4	5	Low					
ORIGI	NALITY ANI	D CO	NTEN	T OF	NEW	INFO	ORMATION:					
	High	1	2	3	4	5	Low					
STUDY	DESIGN: _X_is adequ		ontain	s mino	or flaw	sis serious	y flawed					
STATIS	STICAL ANA	LYSI	ES:									
	Appropriate	e 1	2	3	4	5	Inappropriate of	or absent				
	_	Or										
Recommend review by Statistical Consultant:Yes _X_No												
VALID	ITY OF CON											
	Valid	1	2	3	4	5	Invalid					
CLARI	TY OF WRIT	ΓING	:									
	High	1	2	3	4	5	Low					
RECO	MMENDATIO	ONS:										
	_X_ACCE () as is (XX) co		onal		_	_REJE	CT:	RECONSIDER ( ) with major ( ) with minor				
	IF RECOM	1MEN	D AC	СЕРТ	ANCE	Ξ:						
	is the <b>leng</b> t	th app	propri	ate?	_	X_Ye	S	Needs to be shortened				
	Are there a	ny <b>fig</b>	ures (	r tabl	es that	t are u	nnecessary:	Yes _X_No				
	If yes, plea	se spe	cify w	hich t	ables a	re unn	necessary.					
	Do you fee	el this s	should	be red	comme	ended	for <b>Editorial</b>	?YesNo				
If	viham da var	****	an d	vvmita i	ha Edi	itaria19	) I dan't Irmary al	out this aspect of your journs				

If yes, whom do you recommend write the Editorial? <u>I don't know about this aspect of your journal</u>

## **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)**

This is an unusual paper in the sense that nobody, to my knowledge, has done anything like this successfully. I think the special aspect of the paper is the excellent curriculum they have developed and implemented. It looks like trainee physicians and psychologists can take to it easily. The authors need to define why it should be published in an internal medicine journal versus a psychiatry journal. Also, the authors should point out that this sort of curriculum, even for a year, may not produce stellar individual scientists and methodologists. Instead, this training provides enough skills to be able to discern garbage publications from valid ones!

Mar 28, 2007 Manuscript #

Reviewer #2b

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

## Do not include recommendations regarding acceptance/rejection of manuscript.

Dr. XXXX and his colleagues have put together a manuscript describing a new clinical research training program at the XXXX. In essence their new program, in part based on a program developed at the XXXX, was implemented at the XXXX for trainee physicians and psychologists for one year. As a 'control' they assessed similar trainees' skills in clinical research at two other comparable universities. The authors found that their training program was considerably superior in developing research competency than the other two programs at the end of the year.

In short, this is an interesting manuscript and research idea. However, a few things need to be addressed by the authors to enhance their manuscript. First, the authors need to define why this paper should be published in JGIM and not a primary psychiatry journal. In other words, the authors need to persuade themselves and others that their findings can be extended to other medical specialties.

Second, the authors do not truly have a 'control group'. The choice of going to the three institutions by the trainees may have been biased by multiple factors. The authors need to highlight that. Also, it is never clear if all of the trainees at the XXXX had to participate in the training or if it was only those who chose to do so! If the latter were the case, the findings of this study are much weaker.

Third, the authors seem overly focused on producing a group of scientific giants. Rather, the results of the study indicate that the trainees became much more sophisticated in understanding strengths and weaknesses of clinical research methodologies. In other words, they won't instead be educated by the pharmaceutical industry or other lobbying forces or groups, but can assess the strengths and weaknesses of clinical research as applied to clinical practice. Hopefully the trainees from programs such as these will be able to read scientific journals with ease and discern between wheat and chaff!

Lastly, the authors need to define why and how they chose their program in more detail.

## Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer: #2c INTEREST TO READERSHIP OF JGIM: 1 2 X 3 5 High Low ORIGINALITY AND CONTENT OF NEW INFORMATION: High 1 2X3 5 Low STUDY DESIGN: contains minor flaws is seriously flawed X is adequate STATISTICAL ANALYSES: Appropriate 1 5 Inappropriate or absent --or--Recommend review by Statistical Consultant: X Yes No **VALIDITY OF CONCLUSIONS:** Valid 1 2X3 5 Invalid **CLARITY OF WRITING:** 1 2X3 5 High 4 Low **RECOMMENDATIONS: REJECT:** ACCEPT: RECONSIDER () as is ( ) with major ( ) with minor (X) conditional IF RECOMMEND ACCEPTANCE: is the **length** appropriate? \_\_Needs to be shortened X Yes Are there any **figures or tables** that are unnecessary: If yes, please specify which tables are unnecessary. Tables could do with revision. For example Table 2 – within 90 – "day" needs adding Do you feel this should be recommended for Editorial? Yes X No If yes, whom do you recommend write the Editorial?

## **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)**

It is an every day issue for internists put in an interesting statistical format since an ED visit in older population is harbinger of adverse outcomes later. The statistics may need to be looked at and verified. The authors might explain Charlson Comorbidity Index and Score, and its implications for general readership. Under ED visit characteristics it might be informative to expand the common diagnoses beyond what the last sentence says. The study was conducted at one [teaching] VAMC for a short period and the study results should be interpreted with caution, as these may not be generalizable. What about non-VA environment? What about Veterans enrolled in VA primary care clinics primarily to get medications but who obtain major care from outside private doctors and go to non-VA EDs in emergencies that are not counted in this study? The article could be published with some improvements.

Apr 11, 2007 Manuscript #

Reviewer #2c

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

## Do not include recommendations regarding acceptance/rejection of manuscript.

My congratulations to authors for picking up an issue that is important every day issue for internists put in an interesting statistical format since an ED visit in older population is harbinger of adverse outcomes later. The statistics may need to be looked at and verified. The authors might explain terms like Charlson Comorbidity Index and Score, etc, for general readership – for the implications – what inference to derive, why these are important and why should one be concerned.

Under ED visit characteristics it might be informative to expand the common diagnoses beyond what the last sentence says, talk about types of adverse health outcomes and risk factors associated with adverse outcomes. Also was readmission associated with same or different diagnoses?

The study was conducted at one [teaching] VAMC for a short period of time and the study results should be interpreted with caution, as these may not be generalizable. What about non-VA environment? What about Veterans enrolled in VA primary care clinics primarily to get medications but who obtain major care from outside private doctors and go to non-VA EDs in emergencies that are not counted in this study?

## Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** 

Reviewer:	#1a										
INTERES	ST TO RE High	ADE 1	RSHII 2	<b>P OF</b> 3		5	Low	7			
ORIGINA	ALITY AN High	ND CO	ONTE 2	<b>NT O</b>	F NEW 4		ORMA Low				
STUDY I	<b>DESIGN:</b> _X_is adea	quate		_contai	ins mino	or flaw	rs _	_is seriously	flawed		
STATIST	TICAL AN Appropria	/ \	SES: 2		4	5	Inap	propriate or a	absent		
	Recomme	nd rev	iew by	y Statis	stical Co	onsulta	ant:	Yes _X_	No		
VALIDIT	T <b>Y OF CO</b> Valid	NCLI		<b>NS:</b> 3	4	5	Inv	alid			
CLARIT	Y OF WR	ITIN(	<b>5</b> : 2	3	4	5	Lov	w			
RECOM	MENDAT	IONS	:								
	_X_ACC ( X) as ( ) cond	is	al			REJE	CT:		RECON		
	IF RECO	MME	ND A	CCEP	TANCE	:					
	is the leng	gth a	ppropr	riate?		X_Ye	S		Needs 1	to be shorte	ened
	Are there	any fi	igures	or tab	oles that	are ui	nneces	ssary:	Yes	_XNo	
	If yes, ple	ease sp	ecify	which	tables a	re unn	ecess	ary.			
	Do you fe	el this	shoul	ld be re	ecomme	nded	for	<b>Editorial</b> ?	_X_Yes	No	
	If yes, wh	om do	you r	ecom	mend wr	rite the	e Edito	orial?	_		

**CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)** This was a well done study. It appears that there were some minor logistical issues with the survey distribution. Effectively integrates both quantitative and qualitative methods in their research design. Also, very helpful that their survey addressed barriers to fostering caring attitudes and that they addressed the need for faculty development.

The only thing I would add is the need to address GME strategies to promote caring attitudes. Students spend more time around residents than around faculty (especially in the clinical years) so what is being done to promote caring attitudes amongst the residents since they play a big role in defining the "hidden curriculum".

Mar 14, 2007 Manuscript #

Reviewer #1a

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

## Do not include recommendations regarding acceptance/rejection of manuscript.

An important and well conducted study. There were some minor logistical issues with the distribution of the survey but otherwise the methods used were very sound. I found it especially valuable to see how they intregrated and presented both their quantitative and qualitative study results. Additionally, it was important that the survey include the perceived barriers to promoting caring attitudes and the need for faculty development in order to foster these behaviors amongst the role models.

The only thing I would add is the need to address GME strategies to promote caring attitudes. Students spend more time around residents than around faculty (especially in the clinical years) so what is being done to promote caring attitudes amongst the residents since they play a big role in defining the "hidden curriculum".

## Manuscript #

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@iupui.edu

JGIM Article Review Form: COMMENTS TO THE EDITOR

Reviewer	: #1b										
INTERE	ST TO REA	DERS	SHIP (	OF JO	GIM:						
	High	1	X2	3	4	5	Low				
ORIGIN	ALITY AND	CON	NTENT	ΓOF N	NEW 1	NFOI	RMATION:				
	High	1	X2	3	4	5	Low				
STUDY	DESIGN:										
	Xis adequa	ate	co	ntains	minor	flaws	is seriously	flawed			
STATIST	ΓICAL ANA	LYSF	ES:								
	Appropriate X1			2 3 4 5 Inappropriate or absent							
			or								
	Recommend	revie	w by S	tatistic	cal Co	nsultan	t:Yes X1	No			
VALIDI	TY OF CON	CLUS	SIONS	:							
	Valid	1	X2	3	4	5	Invalid				
CLARIT	Y OF WRIT	ING:									
	High	X1	2	3	4	5	Low				
RECOM	MENDATIO	NS:									
	X ACCEP	T:			I	REJEC	T:	RECONSIDER			
	( ) as is							( ) with major			
	(X) cond	litiona	ıl					() with n	ninor		
	IF RECOM	MEN!	D ACC	CEPTA	NCE:						
	is the length	app	ropriat	te?	_X	_Yes		Needs t	o be shortened		
	Are there ar	ıy <b>fig</b> ı	ures or	· table	s that a	are unr	necessary:	X_Yes	No		
	If yes, pleas	e spec	eify wh	nich tal	oles ar	e unne	cessary.				
	Do you feel	this s	hould	be reco	mmer	nded fo	or Editorial?	Yes	X_No		
	If yes, whor	n do y	ou rec	omme	nd wri	te the	Editorial?				
CONFII authors)	DENTIAL CO						RS: (Do not repe	at commen	ts made to		

Nov 19, 2007 Manuscript #

Reviewer #1b

## **JGIM Article Review Form: COMMENTS TO THE AUTHORS**

Do not include recommendations regarding acceptance/rejection of manuscript.

This is a well written article that utilizes data regarding fracture rates in patients with osteopenia. One suggestion is revision of the title. It contains a double negative ("... fracture does not identify women without osteoporosis ..."); perhaps that could be revised for clarity.

The paper is well organized and well written. I could not find any substantial errors in style or grammar.

The authors have posed their hypothesis well. There is a question of the clinical relevance of the data—why the risk of fracture would not be reduced in women with osteopenia who received alendronate. This may be due to other reasons for fracture (besides low bone mass), such as fall risk, trauma, etc. The authors did discuss this briefly.

The authors state in the discussion that the statistical power was low, but I cannot find in the article what the stated power was. It may be that the power was too low to detect a difference if a difference in fact existed.

Note to Reviewers: Please return the completed form with comments (see Page 2) as a Microsoft Word attachment to jgimsupp@jupui.edu

**JGIM Article Review Form: COMMENTS TO THE EDITOR** Reviewer: #1c INTEREST TO READERSHIP OF JGIM: 1 2 3 4 5 High Low ORIGINALITY AND CONTENT OF NEW INFORMATION: High 1 4 5 Low STUDY DESIGN: contains minor flaws is seriously flawed x is adequate STATISTICAL ANALYSES: Inappropriate or absent Appropriate 1 3 4 5 --or--Recommend review by Statistical Consultant: Yes No **VALIDITY OF CONCLUSIONS:** Valid 1 2 3 5 Invalid **CLARITY OF WRITING:** 5 High 2 3 4 Low **RECOMMENDATIONS:** x REJECT: ACCEPT: RECONSIDER () as is ( ) with major ( ) conditional ( ) with minor IF RECOMMEND ACCEPTANCE: is the **length** appropriate? x Yes Needs to be shortened Yes Are there any **figures or tables** that are unnecessary: x No If yes, please specify which tables are unnecessary. Do you feel this should be recommended for **Editorial** ? Yes x No If yes, whom do you recommend write the Editorial?

## **CONFIDENTIAL COMMENTS TO THE EDITORS: (Do not repeat comments made to authors)**

Nice article that did not, in my opinion, adequately add to our fund of knowledge about this issue. It was a small study that would make a fine letter, if the authors found this to be an acceptable format.

Jan 12, 2007 Manuscript #

Reviewer #1c

**JGIM Article Review Form: COMMENTS TO THE AUTHORS** 

Do not include recommendations regarding acceptance/rejection of manuscript.

The paper is concise and easy to understand. The statistics are appropriate for the study. The findings are strong.

There was very little discussion of how this study fits into the context of other, similar studies, or in what way it contributed to the field beyond what other studies have shown.