

SUPPORTING EVIDENCE FOR THE  
DEVELOPMENT OF THE COLON CANCER  
DECISION AID

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Table of Contents

Introduction ..... 3

Development Team ..... 4

The Development Process ..... 5

Benefits and Risks..... 6

Patient Feedback Table ..... 7

Expert Panel Feedback Table ..... 11

References ..... 27

## Introduction

Colon cancer is the second leading cause of cancer-related deaths in the US. However, most deaths are preventable with routine colon cancer screenings.<sup>1</sup> The United States Prevention Services Task Force (USPSTF) recommends colorectal (CRC) cancer screening for asymptomatic people aging from 50-75, yet more than a third of Americans are overdue for screening.<sup>2-4</sup> There are several types of screening tests for CRC including invasive imaging tests and less invasive stool blood testing.<sup>5</sup> The USPSTF does not recommend one test over the other but emphasizes the importance of screening.<sup>6</sup>

Decision aids (DAs) are an evidence-based strategy to support patients making colon cancer screening choices, and many colon cancer decision aids are currently available.<sup>7</sup> Offering patients a choice in screening options increases overall screening rates.<sup>8</sup> However, CRC DAs often do not achieve their intent to offer choice due to challenges in implementation including strong physician bias and recommendations towards colonoscopy.<sup>9</sup> To overcome these barriers we developed a novel CRC DA that clearly emphasizes physician preference for colonoscopy but also acknowledges patient choice in screening methods. The DA includes:

1. Paper Decision Aid-A four-page DA detailing screening options for CRC. The DA states that physicians prefer and recommend colonoscopy but also encourages and emphasizes the importance of getting screened.
2. Video Decision Aid-The 6 minute video mirrors the information presented in the paper DA.

## Development Team

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### The Development Process

Fuzzy trace theory (FTT) guided the development of the DA. FTT suggest that patients make decision based on the bottom-line meaning they derive from information.<sup>10</sup> DAs using a FTT framework focus on presenting information using gisted, or summarized, statements that convey the main points. FTT de-emphasizes the importance of quantitative heavy DAs by arguing patients lack the numeracy skills to accurately interpret numerical risk and tend to make decisions based on their gist interpretations.<sup>10</sup>

Additionally, our DA uses elements of shared decision making by offering choice in a method that highlights patient values. A feature that distinguishes our DA from an information pamphlet is that in addition to information, the DA supports patients in clarifying their values to determine what is important to them. We incorporated elements of behavior change theory (self-efficacy, relative risks for benefits etc.) to help guide patients towards a screening decision. We chose to only describe colonoscopy and stool blood testing because research suggests that more options actually creates confusion<sup>8</sup> and because we recognize that colonoscopy is the preferred choice of most physicians.

We used a stepwise process of DA development which conforms to the International Patient Decision Aid Standards (IPDAS).<sup>11,12</sup> We created a paper and video DA incorporating feedback from patients (See Table 1) and expert advisors (see Table 2). We developed several iterations of the DAs and revised each version based on feedback received. We gave careful consideration to health literacy and numeracy in the DA development. We followed the recommendations for clear communication which ensured both the paper and video versions are written at a 5<sup>th</sup> grade level (Using Flesch-Kincaid analytics available in Microsoft word).<sup>13-15</sup>

### Benefits and Risks

The overall goal of this DA is to increase CRC screening rates. CRC is largely preventable with regular screening.<sup>1</sup> Although, FTT recommends against risk statistics, we felt it necessary to provide some screening risk and benefit statistics to highlight the risk of dying from CRC without screening. CRC risk statistics are typically presented in 10-year survival increments. We felt this was confusing and difficult for the lay person to understand, therefore, we used lifetime risk statistics. This decision was received well by patients (see Table 1) and poorly from experts (see Table 2). Since the target audience of the DA is they lay patient we feel justified in this decision. The lifetime risk statistics were taken from the National Cancer Institutes SEER database<sup>16</sup> and the USPSTF which sets the national guidelines and recommendations for CRC screening.<sup>6</sup>

## Patient Feedback Table

Date	Patient #	Suggestion/Comment	Response/Outcome
04/18/2014	001	<ul style="list-style-type: none"> <li>• No age range for screening</li> <li>• Table is too confusing-not enough information on FIT prep</li> <li>• Do not understand the 10 year risk</li> </ul>	<ul style="list-style-type: none"> <li>• Age range (50-75) was added</li> <li>• We added and deleted elements from the table</li> </ul>
09/19/2014	002	<ul style="list-style-type: none"> <li>• Start off with characteristics of cancer</li> <li>• Add info to table about recovery time from test</li> <li>• Do not understand 10 year risk</li> <li>• What are symptoms of colon cancer?</li> </ul>	<ul style="list-style-type: none"> <li>• Added a fact section about colon cancer to front of DA</li> <li>• Added statement about recovery time</li> <li>• Symptoms are listed on back of DA</li> </ul>
09/25/2014	003	<ul style="list-style-type: none"> <li>• Language on DA is to technical</li> <li>• Table is confusing and needs to be reorganized</li> </ul>	<ul style="list-style-type: none"> <li>• We reworked highly technical or medical language into lower literacy or laymen's terms</li> </ul>

Patient Feedback Table Cont.

Date	Patient #	Suggestion/Comment	Response/Outcome
09/30/2014	004	<ul style="list-style-type: none"> <li>• No comments</li> </ul>	
Spring 2015		<ol style="list-style-type: none"> <li>1. We majorly revised DA. We added 2 pages to expand document to 4 pages.                             <ul style="list-style-type: none"> <li>• We added basic background info and a description of colon cancer</li> <li>• We reorganized and cleaned up language on table</li> <li>• We change to lifetime risk vs 10 year risks</li> <li>• We added a comment and question page for patients to take to doctor</li> </ul> </li> <li>2. We also turned the DA into a short 6 minute video</li> </ol>	
08/13/2015	005	<ul style="list-style-type: none"> <li>• I do not understand the scales and how they relate to the faces</li> <li>• Needs stronger language to convey importance of screening “this life or death”</li> <li>• “I don’t like the choice. Colonoscopy is better.”</li> <li>• Page 2 (table) is best part</li> </ul>	<ul style="list-style-type: none"> <li>• We will work to clarify scales</li> <li>• Agreed this is life or death decision but the idea is to offer choice and not force colonoscopy</li> </ul>

Patient Feedback Table Cont.

Date	Patient #	Suggestion/Comment	Response/Outcome
09/04/2015	006	<ul style="list-style-type: none"> <li>• “I don’t like the video!”                             <ul style="list-style-type: none"> <li>○ Pictures stay on screen too long</li> <li>○ You should better demonstrate how to use test</li> <li>○ Too much blue, don’t like the font</li> <li>○ Speaker has a nice voice</li> </ul> </li> <li>• I don’t understand the scales and some of the other graphics</li> </ul>	<ul style="list-style-type: none"> <li>• We plan to re-film the video</li> <li>• We deleted the scales because they caused too much confusion</li> <li>• We will look into revising other graphics</li> </ul>
09/15/2015	007	<ul style="list-style-type: none"> <li>• Why doesn’t the DA explain how serious colon cancer is?</li> <li>• Colonoscopy is the more definitive test</li> <li>• Overall liked the video and narrator</li> <li>• Did not like the fonts and colors</li> </ul>	<ul style="list-style-type: none"> <li>• The DA focuses on screening for cancer not the cancer itself</li> <li>• Doctors prefer colonoscopy but the USPTF does not recommend one test over the other</li> <li>• We plan to re-film the video to address stylistic concerns</li> </ul>

Patient Feedback Table Cont.

Date	Patient #	Suggestion/Comment	Response/Outcome
	008	<ul style="list-style-type: none"> <li>• Get rid of man graphic on page 3</li> <li>• Page 2 has too much on it</li> <li>• Add doctors email address</li> <li>• Did not like video                             <ul style="list-style-type: none"> <li>○ Did not like colors or fonts</li> <li>○ Did not like narrator</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• We changed the graphic on page 3</li> <li>• Most patients like 2<sup>nd</sup> page. We will work to streamline and edit but not eliminate</li> <li>• We will re-film the video</li> </ul>
02/19/19	UCLA GI Team	<ul style="list-style-type: none"> <li>• UCLA contacted us and requested we remove language specific to UCHealth from the video so that they could implement in their HC system</li> </ul>	<ul style="list-style-type: none"> <li>• We are thrilled there is interest in the tool. We removed UCHealth specific contact info and reposted on our website.</li> </ul>
03/14/19		<ul style="list-style-type: none"> <li>•</li> </ul>	<ul style="list-style-type: none"> <li>• Spanish translation of the tool is complete. Spanish version posted on website.</li> </ul>
03/27/19	Development Team	<ul style="list-style-type: none"> <li>• Annual review of facts and statistics in document</li> </ul>	<ul style="list-style-type: none"> <li>• We conducted a thorough review of the statistic presented in the tool. We found our stats are still current and the tool does not require revisions at this time.</li> </ul>

Expert Panel Feedback Table

Expert ID:	What is the purpose of the decision aid?	Comment:
MS	To inform patients that they have a choice between 2 options for colon cancer screening and what the options are and what they entail	
BC	To help patients make the screening decision that's right for them	
WSR	The decision aid provides a structured framework for patients to compare two different screening tests for colon cancer	
DR	To encourage patients to be screened for colon cancer and to help them decide which test is best for them	
CL	It is pretty clear that the purpose is to provide information about 2 screening options for colon cancer.	
MM	To help people decide if they should undergo colon cancer screening and what the test options are.	
SS	help people decide between colonoscopy and fobt	
JL	To inform patients about options other than colonoscopy	
LS	To encourage people to do some form of colon cancer screening.	
PS	Informing patients and encouraging them to be screened	

Supporting Evidence For The Development of the Colon Cancer Decision Aid

Expert ID:	Which test, if any, is emphasized as being a better choice?	Comment:
MS	It does say colonoscopy may be a little bit better than Stool Blood Test but I do not think this message comes out	
BC	The decision aid doesn't suggest one over the other	
WSR	My interpretation is that the decision aid favors fecal occult blood testing	
DR	I think it is pretty balanced	
CL	I don't think there is a true emphasis; the table on page 2 makes colonoscopies sound like a bigger deal - prep, sedation, need family support; of course it is because these are more invasive. I think the info on page 3 puts the risk/preference into greater perspective and more evenly presented (based on pt preference)	
MM	It is subtle, but colonoscopy appears to be emphasized as being better.	
SS	Neither - seems balanced to me	
JL	neither	
LS	I felt this was quite well balanced.	
PS	I don't think it presents either test as better. Very balanced	

Expert ID:	What is the bottom-line message of the decision aid?	Comment:
MS	Schedule one of the tests for your health.	
BC	screening is a good idea, either test is reasonable and of similar efficacy	
WSR	The decision aid emphasizes the importance of screening for colon cancer	
DR	WE RECOMMEND SCREENING FOR COLON CANCER. YOU HAVE A CHOICE ABOUT HOW TO GET SCREENED	
CL	there are choices for CC screening and presents the differences	
MM	To get screened for colon cancer you don't always have to choose colonoscopy as your screening modality.	
SS	YOU SHOULD GET SCREENED, AND YOU SHOULD CHOOSE THE MODALITY THAT BEST ALIGNS WITH YOUR PREFERENCES	
JL	DO ONE OR THE OTHER	

Supporting Evidence For The Development of the Colon Cancer Decision Aid

LS	I feel like the message of this decision aid is that getting a test, of some type, to look for colon cancer, is important to do.	
PS	Same.	

Expert ID:	Do you agree or disagree with the presentation of screening risks? Why?	Comment:
MS	Yes, although “some people need several days to recover completely” seems qualitatively high to me. Few, if any, of my patients require more than a day to recover	
BC	Yes I think it’s fair. I usually emphasize to patients that the major downside of stool based testing is the chance they’ll need a colonoscopy. So to say its harmless doesn’t seem completely accurate, but it does mention that there is a chance that colonoscopy would be needed if pos.	
WSR	I think that the decision aid somewhat over plays the risks associated with sedation and colonoscopy. In the section titled "how long the screening test takes" I would change the last sentence under colonoscopy to read "rare people need several days to recover completely." Under the section "with the screening test findings" I would recommend changing the description under colonoscopy to read "precancerous polyps and colon cancer" in the next section IA would consider adding “diverticuli” in addition to “polyps that are not cancer”.	
DR	YES	
CL	Overall, I agree. Table 2 feels one-sided; but once again, that is probably bc the risk between scopes and FIT are different.	
MM	Yes, I agree. Seems to be an accurate representation of people’s choices and the risks and benefits.	

SS	<p>—&gt; YOU STATE: "3 people will have complications requiring hospitalization"; SHOULD THIS BE "ER VISIT OR HOSPITALIZATION"? THERE IS NO DISCUSSION OF PSYCHOLOGICAL RISKS (EG, WORRY ABOUT POSITIVE STOOL TEST)</p>	
JL	<p>a. I HOPE 3/1000 IS AN OVERSTATED RISK FOR HOSPITALIZATION AT UCH. IT IS CLOSER TO 1/1000-1/2000 AT DH. DESCRIPTION OF PREP IS INCORRECT. EVERYONE USES A SPLIT PREP NIGHT BEFORE AND MORNING OF PROCEDURE. NEEDING TO GO TO THE BATHROOM IS A EUPHAMISM – YOU WILL HAVE A LOT OF DIARRHEA IS MORE ACCURATE. THE TEST FROM INTAKE TO DISCHARGE IS CLOSER TO 2 HOURS, A DAY OFF FROM WORK, AND REQUIRES A COMPANION TO TAKE THEM HOME. THOSE ARE THE MOST SIGNIFICANT 'RISKS' OF COLONOSCOPY.</p> <p>b. I AM NOT AS COMFORTABLE WITH THE HEADLINE STATEMENT 'WHO DO NOT WANT A COLONOSCOPY.' IF THEY REALLY DON'T WANT A COLONOSCOPY THEY SHOULD DO NOTHING. MENTIONING THE NEED FOR COLONOSCOPY IN ANYONE WITH BLOOD ON THE FIT IN SMALL</p>	d.

	<p>PRINT IN A TABLE DOESN'T HAVE THE MEMORY IMPACT OF THE HEADLINE.</p> <p>c. I WOULD PUT 'WHY SHOULD I GET SCREENED' ABOVE WHAT ARE MY OPTIONS AS THAT IS THE LOGICAL PROGRESSION.</p>	
LS	I do agree with this. The only thing I still emphasize with patients is that if they have a stool test that shows blood, they will need to accept the risks of colonoscopy and move ahead with the testing.	
PS	<p>I like the fact that it just presents the risk of injury, which just applies to colonoscopy.</p> <p>Some would argue for the risk of overtreatment or false positive, but I am not attracted by that approach, in part since it is just too complicated.</p> <p>Our da does include some information about the risk of stool testing having a false negative for polyps and even for cancers, but I have very mixed feelings about that.</p>	

Expert ID:	Do you agree or disagree with the presentation of mortality statistics? Why?	Comment:
MS	Yes, Lee meta-analysis of FOBT data	
BC	I don't agree with the stated RRR of 64%, not sure its needed unless the aim is to promote screening. I	

	usually say the chance of avoiding death over 10 yrs of regular screening with FOBT is about 1/1000 and with colo its about 1/500. Looks like the frame here is lifetime risk which is probably simpler than a 10 yr frame but if we agree that colo is at least as good as sigmoidoscopy (RRR 30%) and FOBT has RRR 15% then is it more accurate to suggest absolute benefit closer to 1/100? I guess the bottom line that the benefit is close either way and humans probably struggle with difference between 1/100 and 2/100	
WSR	I agree with the presentation on mortality statistics.	
DR	Disagree. Both relative and absolute benefits are too high in the pictogram and text. Relative mortality reductions for fecal testing are in the 15-32% range, not 64% percent. Absolute mortality reduction is lower than note	
CL	I think its ok, but pts may be confused when they see the difference is 2 people out of 100, but see the data of 64% risk reduction (I assume this is relative risk reduction - if so, that can be misleading)	
MM	I had to look them up as I more frequently talk about 10 year risks. The RRR although accurate overinflates the value of screening.	
SS	Seems reasonable	
JL	We don't include mortality as a risk of the procedure. The risk is less than 1:10000	
LS	I do agree with this presentation. I also find it helpful, however, to present incidence statistics. For many people, just knowing that you could prevent a colon cancer occurrence, and its subsequent morbidity, is just as important as preventing a colon cancer death.	

PS	<p>I like the simplicity and focusing on just mortality reduction. We ended up including incidence reduction, and even sensitivity for cancer. I like the fact that you kept the denominator 100 and rounded up the post-screening mortality rate to 1. That is a nice approach.</p>	
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Expert ID:	Is our presentation of the importance of colon cancer screening consistent with how you present information to your own patients about screening?	Comment:
MS	<p>yes  <b>a. What elements are consistent?</b>                      Generally do not give them this much information. Just tell them it can help them live longer but has some risks...Generally recommend colonoscopy and if pt is not willing to go or doesn't go I strongly recommend stool testing (but explain they would have to go for colonoscopy if positive)  <b>b. What elements would you present differently?</b>                      A stool blood test generally requires some preparation in terms of possibly modifying one's diet in the days before (ie avoid red meat)</p>	
BC	<p><b>a. What elements are consistent?</b>                      - all are consistent with exception of presentation of benefit as above. I recommend CRC screening but also give an option to not screen though recognize that's not a choice in this DA/project</p>	

	<p><b>b. What elements would you present differently?</b>                  - I would present benefits differently, probably avoid RRR but that's just my opinion on this particular issue. This overall looks great</p>	
WSR	<p><b>a. What elements are consistent?</b>                  The emphasis on the importance of colon cancer screening and reduction in morbidity and mortality.</p> <p><b>b. What elements would you present differently?</b>                  In the final two graphics I would rephrase the headings of your population figures to read "Without screening, 3 out of 100 will die of colon cancer" and "With screening, 1 out of 100 will die of colon cancer" The way it is currently phrased is ambiguous.</p>	<b>c.</b>
DR	<p>ASIDE FROM THE MORTALITY STATISTICS ISSUE ABOVE, YES.</p> <p><b>a. What elements are consistent?</b></p> <p><b>b. What elements would you present differently?</b> MORTALITY STATISTICS. ALSO, PATIENTS OFTEN WANT TO KNOW ABOUT COSTS. IT MIGHT BE GOOD TO PUT SOMETHING IN THEIR ABOUT COSTS, EVEN IF IT IS BRIEF (LIKE TESTS ARE REQUIRED TO BE COVERED).</p>	
CL	<p>It is consistent, but more detailed - which is why a tool like this is needed</p>	
MM	<p><b>a. What elements are consistent?</b> Risks and benefits of the two options. What happens if you have a positive stool card. I usually tell patients that colonoscopy is better.</p> <p><b>b. What elements would you present differently?</b> None</p>	

SS	<p><b>a. What elements are consistent?</b> —&gt; THAT THE 2 TESTS ARE EQUALLY EFFECTIVE IF PERFORMED REGULARLY; TRADEOFFS (ANNUAL VS Q10 YEARS, INVASIVE VS NONINVASIVE, ETC)</p> <p><b>b. What elements would you present differently?</b> —&gt; THE “WHICH TEST IS RIGHT FOR ME” TABLE CONTAINS ALOT OF TEXT; I WOULD BE CONCERNED THAT PATIENTS WOULD ABSORB ONLY A FRACTION OF THIS</p>	
JL	<p>I AM NOT IN THE POSITION TO DO THIS EXCEPT IN RARE PATIENTS WITH SIGNIFICANT HEALTH PROBLEMS.</p>	
LS	<p><b>a. What elements are consistent?</b> I also emphasize that the best test is the one that gets done. I present the pros and cons in a very similar way, particularly mentioning that the benefit of a colonoscopy is that you don't have to think about it every year, and that it may give greater peace of mind as a result. I present the pros of the stool test that it spares you from having an invasive test if you don't need it or want it, but that you will have to be vigilant about testing every year.</p> <p><b>b. What elements would you present differently?</b> I usually do emphasize that colon cancer screening reduces your chances of getting colon cancer significantly, not just the risk of death. I think this is an important component to convey, as the benefit is even more impressive when the incidence reduction is emphasized.</p>	
PS	<p><b>a. What elements are consistent?</b></p> <p><b>b. What elements would you present differently?</b></p>	

	<p>Well, do you mean my patients in clinic? They get a three sentence presentation, basically -- crc is important and screening saves lives, colonoscopy is great but requires a procedure, stool testing is probably almost as good and much easier, but might lead to colonoscopy. That's basically all i say, given the time constraints.</p>	
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<b>Expert ID:</b>	<b>Any additional feedback you have is appreciated. Thank you again for reviewing the decision aids and providing your thoughts.</b>	<b>Comment:</b>
MS	<p>Have you checked the reading level? Patients tend to have a hard time with the word screening. Sometimes screening is used and sometimes testing is used in the pamphlet.</p> <p>After “requires help from family or friend” the answer “yes, you will be given...” doesn’t seem to cognitively flow. Could say yes, you will need someone to drive you home after the test because of the medications given during the test.</p> <p>“Every 10 years, if no polyps are found.” This is not completely accurate. Instead, “if no concerning polyps are found.” Otherwise all my patients with hyperplastic polyps will think they need their next colonoscopy sooner.</p>	

	<p>“3 people will have complications requiring hospitalization” seems vague, would be more specific.</p> <p>Would bold first page: “This info is for you... through have not had colon cancer”</p> <p>If you want to persuade pts to be screened keep “in other words, either test lowers your chance of dying from colon cancer by about 64%.” Otherwise, if you want more balance could cut.</p> <p>Could cut: “Screening is important for everyone, but not everyone has the same questions or concerns”</p>	
BC	<p>For what its worth, this version is easier to read than the last version I saw. Nice work!</p>	
WSR		
DR	<p>IT IS VISUALLY APPEALING AND IT LOOKS LIKE YOU’VE DONE A GOOD JOB KEEPING IT UNDERSTANDABLE FOR LOW LITERACY PATIENTS</p>	
PS	<p>Shorter than other brochures? There are some short brochures out there. I agree that some of the das have been too long and complex to be workable or useful. There is a lot of information in here, in the table, so that is one potential issue, but I think it's well done.</p> <p>Oh, and one small proof reading thing: The copyright / licensing disclaimer at the end refers to LV assist devices, so should be changed</p>	

<p>I should mention that in terms of quantitative information, you give almost the same limited set of numbers that we gave in my pilot study that led to the PCORI grant. We're resubmitting the manuscript based on that data later this month, and happy to send it then. We gave just:</p> <ul style="list-style-type: none"><li>- icon chart of baseline risk of getting and dying of CRC</li><li>- risk reduction in lifetime mortality in CRC from FIT (based on the SimCRC model for average risk) - i.e. from 30 per 1000 to 6 per 1000.</li><li>- risk reduction in lifetime mortality in CRC from colonoscopy (based on the SimCRC model for average risk) - i.e. from 30 per 1000 to 4.6 per 1000.</li><li>- complication rate from colonoscopy (I think we gave 2 per 1000, I can't remember right now)</li><li>- rate of positive FIT cards (I think we gave 50 per 1000, can't remember.)</li></ul> <p>Anyway, that's pretty similar to what you are doing with numbers. As I mentioned, on the PCORI grant, we got push back from reviewers to give more numbers, and we are. Just sensitivity of FIT and colonoscopy for CRC, and risk reduction in getting colon cancer.</p> <p>We also directly address more clearly in our DA than you do in yours (and than we did in our pilot version) the chance that FIT can miss polyps and why it isn't so bad to miss polyps.</p>	
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	<p>SO, bottom line is what I said before: I like what you are doing with numbers and think it is very defensible. Of course, the recommendations from IPDAS in 2006 and sort of reiterated in the chapter in 2012 do recommend MORE numbers than we are doing, and I'd like to dial that expectation back a bit. Some numbers OK, or even maybe just optional, but don't go overboard. Obvious!</p> <p>2) I should add that I really like that you do your values clarification implicitly, not explicitly. There are many prominent voices calling for explicit values clarification but I am quite impressed by the LACK of evidence for this position. So, again, hear hear to you.</p>	
SE	<p>Thank you for the opportunity to comment. I certainly agree with the approach to increase colon cancer screening in the population. I feel strongly that the message to our patients should be that screening colonoscopy is the best test. Performing high quality colonoscopy for colon cancer screening is our mission and our division's adenoma detection rate and complication rate would suggest that in our population a colonoscopy performed at UCH or Lone Tree by our physicians is the best test available for preventing death from colorectal cancer.</p> <p>I object to the language below.</p> <p>"Colonoscopy may be a little bit better than Stool Blood Test, but it has</p>	

	<p>some risks. The best test is the one that gets done.”</p> <p>It could be stated:</p> <p>Colonoscopy is the best test. If you decide not to do the best test then doing something else is better than not doing anything to protect you from colon cancer.</p>	
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