Comparing 3 Values Clarification Methods for Colorectal Cancer Screening Decision-Making: A Randomized Trial in the US and Australia

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PURPOSE: To compare the effects of three methods of values clarification (VCM): balance sheet; rating and ranking; and a discrete choice experiment (DCE) on decision-making about colorectal cancer (CRC) screening among adults in the US and Australia.

METHODS: Using online panels managed by a survey research organization in the US and Australia, we recruited adults ages 50–75 at average risk for CRC for an online survey. Those eligible were randomized to one of the three VCM tasks. CRC screening options were described in terms of five key attributes: reduction in risk of CRC incidence and mortality; nature of the screening test; screening frequency; complications from screening; and chance of requiring a colonoscopy (as initial or follow-up testing). Main outcomes included self-reported most important attribute and unlabeled screening test preference by VCM and by country, assessed after the VCM.

RESULTS: A total of 920 participants were enrolled; 51 % were Australian; mean age was 59.0; 87.0 % were white; 34.2 % had a 4-year college degree; 42.8 % had household incomes less than $45,000 USD per year; 44.9 % were up to date with CRC screening. Most important attribute differed across VCM groups: the rating and ranking group was more likely to choose risk reduction as most important attribute (69.8 %) than the balance sheet group (54.7 %) or DCE (49.3 %), $p<0.0001$; most important attribute did not vary by country ($p=0.236$). The fecal occult blood test (FOBT)-like test was the most frequently preferred test overall (55.9 %). Unlabeled test choice did not differ meaningfully by VCM. Australians were more likely to prefer the FOBT (AU 66.2 % vs. US 45.1 %, OR 2.4, 95 % CI 1.8, 3.1). Few participants favored no screening (US: 9.2 %, AU: 6.2 %).

CONCLUSIONS: Screening test attribute importance varied by VCM, but not by country. FOBT was more commonly preferred by Australians than by Americans, but test preferences were heterogeneous in both countries.

KEY WORDS: values clarification; colorectal cancer screening; patient decision support.
J Gen Intern Med 29(3):507–13
DOI: 10.1007/s11606-013-2701-0

NIH Trial Number: NCT01558583

Electronic supplementary material *The online version of this article (doi:10.1007/s11606-013-2701-0) contains supplementary material, which is available to authorized users.*

Received July 27, 2013
Revised October 10, 2013
Accepted October 21, 2013
Published online November 23, 2013

INTRODUCTION

Colorectal cancer (CRC) is one of the most important causes of cancer incidence and death worldwide, particularly for developed countries such as the US and Australia.[1] In 2010, CRC was the second leading cause of cancer incidence and third leading cause of cancer deaths in Australian adults.[2] In 2012, CRC is estimated to be the third leading cause of cancer incidence and deaths for US adults.[3] CRC screening can reduce CRC incidence and mortality.[4] Several different methods of screening are available but no single method has been shown to be clearly superior to others. Available options [fecal occult blood testing (FOBT), sigmoidoscopy, colonoscopy, radiologic screening] differ in several important regards, making CRC screening a good area for decision support.[5–7]

Decision support interventions, including decision aids (DAs), can help patients make a decision where multiple reasonable options exist. Consensus recommendations suggest DAs should include some values clarification method (VCM).[8] VCMs are "methods to help patients think about the desirability of options or attributes of

options within a specific decision context, in order to identify which option he/she prefers."[9] Several different VCMs are available for health choices, including cancer screening.[10] Potential options include **implicit techniques** (e.g., balance sheet), in which patients receive information about the relevant characteristics of a decision and are able to consider their potential value on their own, and **explicit techniques** (e.g., rating, ranking, discrete choice methods including conjoint analysis) in which patients are asked specifically to compare the relative importance of relevant characteristics of a decision. It is not clear whether these different VCMs may affect patient reported values and preferences. If different VCMs produce similar results, using shorter, simpler VCMs (e.g., ranking and rating) should be sufficient for research and practice; if, however, they give divergent results, research is needed to understand which VCM leads to better clinical and decision-making outcomes. We have previously shown that two VCMs, the discrete choice experiment (DCE) and rating and ranking, produce somewhat different patterns of attribute importance, but no difference in preferred testing modality, in a small sample of US adults considering CRC screening.[11] Additionally, some previous research outside of the health-care setting has shown that different VCMs yield different attribute importances.[12]

Most developed countries recommend and have implemented CRC screening, either through organized programs or on an ad hoc basis, with variable decisions about which test or tests to offer.[13] Ideally, the type of program implemented in a given country should reflect the majority of its citizens' values, including screening versus no screening as well as the different screening options and their attributes. Some studies have found considerable variation in how people value different attributes, but have not assessed variation across different countries.[11,14,15]

By studying the US and Australia, we were able to examine how values and preferences for screening differ in two countries with similar wealth but with differences in how CRC screening has been implemented. US guidelines recommend several options for screening, but implementation has been ad hoc.[6,16] Australia recommends FOBT-based screening and has partially implemented an organized screening program.[17,18] Our primary objective in this study was to compare three VCMs: a balance sheet of test characteristics, a rating and ranking exercise, and a DCE, about CRC screening; and, second, to examine how the values of: (1) US and Australian adults and (2) previously screened and not previously screened respondents may differ.

METHODS

Overview

We performed a randomized trial among members of an online survey panel in the US and Australia to examine CRC and prostate cancer screening decisions. This article reports on the CRC screening component; we have previously reported the findings of the prostate cancer screening component.[19] Participants completed a baseline questionnaire, reviewed information about the screening decision, completed their assigned VCM, and then completed a post-VCM questionnaire that assessed most important attribute and preferred screening test choice.

Selection of Attributes and Levels

CRC screening options were described in terms of five key attributes: reduction in risk of CRC incidence and mortality; nature of the test (including time required, whether the test was performed at home or at a facility, and whether it was invasive; tend to be highly correlated); screening frequency; complications from screening; and chance of requiring a colonoscopy (as initial or follow-up testing). The attributes and levels of the attributes included were based upon the existing literature, including simulations[20] and our own previous work.[11] We represented the effectiveness of CRC screening tests over time rather than in one single application. CRC screening tests have similar long-term risk reduction; thus, we described all tests as having the same level of risk reduction.[7] (Table 1)

Balance Sheet Task

The balance sheet used the key attributes and levels described above. The four commonly available testing options (FOBT, sigmoidoscopy, colonoscopy, and radiologic testing) were described using the attributes and levels described above, and participants were instructed to select their preferred screening test or no testing (Appendix Figure 1, available online).

Rating and Ranking Task

The rating and ranking task asked participants to rate (on a scale of 0 = not important at all to 5 = very important) and then rank the three most important screening test attributes from the same set of key attributes described above (Appendix Figure 2, available online).

Discrete Choice Experiment

The DCE method is based on the concept that goods and services, including health services, can be described in terms of a number of separate attributes and that an individual's valuation of the good or service depends on the combination of those attributes. In DCE, respondents are asked to complete a series of choice tasks. In each task, they choose between

Table 1. Attributes and Levels

Attribute	Screening levels	No screening levels
Nature of the test	No preparation time, requires taking a stool sample, no discomfort, no preparation time Half day preparation time, invasive test in a medical facility, mild-moderate discomfort, 1 h recovery time Full day preparation time, invasive test in a medical facility, mild-moderate discomfort, 24 h preparation time	No preparation time, no discomfort, no recovery time
Frequency of testing	Every year Every 5 years Every 10 years	Never
Chance of complications from screening over 10 years	6 in 1,000 8 in 1,000 10 in 1,000	0 in 1,000
Chance of needing a colonoscopy as a result of screening over 10 years	45 % 60 % 100 %	0 %
Ability to reduce mortality from CRC	Your risk of getting colon cancer is reduced from about 6 % to 3 % and your risk of dying from colon cancer is reduced from about 3 % to 1.5 %	Your risk of getting colon remains about 6 % and your risk of dying from colon cancer remains about 3 %

hypothetical alternatives, each defined by a set of attributes and levels within these attributes. The levels of each attribute are varied systematically in a series of questions. Respondents choose the option that they prefer for each choice task/question. We used NGENE (www.choice-metrics.com) to generate a statistically efficient DCE design that minimized sample size.[21,22] Our design required all participants in the DCE group to complete a set of 16 choice scenarios, each of which included a "no testing" option (Appendix Figure 3, available online).

Pretesting

All instruments were pre-tested as described elsewhere.[19]

Participant Eligibility and Recruitment

Participants were members of an online panel maintained by Survey Sampling International (SSI). We aimed to recruit 900 adults with an even representation by gender (450 men and 450 women) and country (450 US, 450 Australia). Participants were average risk (no personal or family history of CRC) and between the ages of 50 and 75. Prior testing history was assessed but not used to determine eligibility. Those with visual limitations or inability to understand English were excluded.

Study Flow

The entire study was performed online. After eligibility was determined and consent obtained, participants received basic information about CRC and CRC screening (Appendix Figure 4, available online), completed basic demographic questions, and were randomized by SSI on a 1:1:1 basis, stratified by country, to: (1) an implicit VCM (a balance sheet of key test attributes); (2) a rating and ranking task; or (3) a DCE. Within each VCM group, participants were randomized to five different attribute orders to account for potential ordering bias. Upon task completion, participants completed a questionnaire.

Study Outcomes

Our main outcome of interest was the *participant's self-reported most important attribute*. We chose this outcome to determine whether the VCM itself influenced how individual participants valued key features of the decision. We assessed this outcome after the VCM by asking each participant to indicate "which ONE feature of colon cancer screening is most important to you?" with responses chosen from a list of attributes including: (1) reduction in risk of CRC incidence and mortality, (2) the nature of the test, (3) screening frequency, (4) complications from screening, and (5) chance of requiring a colonoscopy (as initial or follow-up testing).

Key secondary outcomes included *unlabeled test preference*, based on a question assessed after the VCM that included four unlabeled options (designed to represent FOBT, sigmoidoscopy, colonoscopy, and radiologic testing), described in terms of the appropriate levels of key attributes listed above, plus the option of not being screened (Appendix Figure 5, available online). Respondents also completed the *values clarity* subscale of the Decisional Conflict Scale (DCS), which ranges from 0 to 100, with lower scores suggesting better clarity, and a single question about *intention to be screened for colon cancer*, based on a Likert scale (from strongly disagree to strongly agree, with agree and strongly agree considered as positive intent).[23]

ANALYSES

Main Analyses

We performed initial descriptive analyses with means and proportions, pooled across VCM groups. We then used chi-squared, ANOVA, and logistic regression for bivariate analyses first across the three VCM task groups and then between US and Australian participants and between participants who had and had not previously completed any CRC screening test (previous screening status).

Because there were some baseline differences across country and previous screening groups, we performed multivariate analyses using logistic or linear regression, adjusted for age, race, education, and income.

Ethical Considerations

This study was approved by the University of North Carolina Institutional Review Board on April 28, 2011 (study number 11-0861) and is registered through ClinicalTrials.gov site (NCT01558583).

RESULTS

Enrollment

We screened 3,076 individuals from October 12–27, 2011. Of these, 2,010 were ineligible or declined participation, and 1,066 were randomized. Of these 1,066 individuals, 920 (86.3 %) completed the full survey.

Baseline Characteristics

The mean age was 59 (range 50–72), 49.9 % were female, and 87 % were white. There were no important demographic differences across the VCM task groups. We observed several differences in baseline characteristics between US and Australian participants: Australian respondents were more likely to be white ($p<0.0001$), less well-educated ($p<0.0001$), and less likely to be up to date with screening ($p<0.0001$) (Table 2). Those who had not previously completed any CRC screening test were slightly younger than those who had previously completed a screening test (57.7 vs. 59.8 years, $p<0.0001$).

Main Outcomes

Most Important Attribute. The majority of respondents across all VCM groups (57.9 %) chose risk reduction as most important attribute.

By VCM. The individual-level choice of most important attribute differed by VCM. We found that those who received the rating and ranking exercise were the most likely to choose risk reduction over any other attribute (OR=1.92; 95 % CI 1.38, 2.67) (Table 3).

By Country. Most important attribute did not differ by country in adjusted or unadjusted analyses (Table 3).

By Previous Screening History. After adjusting for VCM task, country, and demographic characteristics, we found

Table 2. Participant Characteristics by Task Group and by Country

	Overall	Balance sheet	Rating and ranking	DCE	US	AUS
	n=920	*n*=309	*n*=305	*n*=306	*n*=452	*n*=468
Mean age (SD)	59 (5.6)	58.93 (5.8)	58.94 (5.6)	59.14 (5.6)	58.8 (5.8)	59.2 (5.5)
	%	%	%	%	%	%
Female	49.9	47.6	49.5	52.6	50	49.8
Country						
USA	49.1	48.5	49.5	49.4	–	–
Australia	50.9	51.5	50.5	50.6	–	–
Race/ethnicity						
White	86.9	87.7	86.9	86.3	79.9	93.8
Non-white	120	12.3	13.1	13.7	20.1	6.2
Education						
<HS	6.5	5.8	7.2	8.6	1.8	11.1
HS grad/some college	59.2	61.8	54.8	61.1	53.5	64.7
College grad or more	34.2	32.4	38.0	32.3	44.7	24.2
Income						
<$30,000	24.9	24.9	24.9	24.8	25.4	24.4
$30,000–59,999	32.1	33.3	31.8	31.1	32.5	31.6
>$60,000	34.5	33.7	35.7	34.0	36.3	32.7
Prefer not to answer	8.6	8.1	7.6	10.1	5.8	11.3
CRC testing						
Up to date	44.9	49.2	42.3	43.14	54.0	36.1
Previously screened, not up to date	16.3	12.6	18.7	17.65	11.5	20.9
Never screened	37.2	37.2	37.4	36.9	33.4	40.8
Don't know	1.6	1.0	1.6	2.3	1.1	2.2

Table 3. Most Important Attribute by Task Group and by Country

	Overall	Balance sheet	Rating and ranking	DCE	US	Australia
	n=920	*n*=309	*n*=305	*n*=306	*n*=452	*N*=468
Attribute	%	%	%	%	%	%
Nature of the test	18.5	20.1	14.8	20.6	19.0	18.0
Frequency of the test	12.7	12.9	8.5	16.7	11.3	14.1
Chance of complications	6.5	5.8	3.9	9.8	7.5	5.6
Chance of needing a colonoscopy over 10 years	4.4	6.5	3.0	3.6	6.2	2.6
Reduction in risk of getting or dying from colon cancer	57.9	54.7	69.8	49.3	56.0	59.8

that those who had not completed screening in the past, compared to those who had, were much less likely to choose risk reduction as most important attribute over any other attribute (OR=0.45; 95 % CI 0.34, 0.61).

Unlabeled Test Preference. The majority of respondents in all VCM groups chose the FOBT-like test (55.9 %), and the fewest chose the radiologic-like test (7.4 %). Additionally, very few respondents chose the "no testing" option (8.1 %) (Table 4).

By VCM. No meaningful differences in test preference emerged based on VCM task (Table 4).

By Country. Australians were more likely than US respondents to choose the FOBT-like test among the unlabeled testing options (AU: 66.3 % vs. US: 45.1 %) (Table 4). This relationship did not change after controlling for task, previous screening status, and demographic characteristics.

By Previous Screening Group. No meaningful differences emerged based on whether or not the individual had previously completed any CRC screening test. However, among the previously screened, those who had previously completed an FOBT, compared with any other screening test, were much more likely to choose the FOBT-like test (OR 2.2, 95 % CI 1.49, 3.25), controlling for task and demographic characteristics.

Values Clarity

Mean post-task values clarity score was 20.45, suggesting generally clear values. This result did not differ meaningfully across VCM group or country.

By Previous Screening Group. In bivariate analysis, the mean values clarity score for those who had not previously completed screening was significantly higher (lower clarity of values) than for those who had previously completed screening (not previously screened: 24.2; previously screened: 18.1; $p<0.0001$). This relationship did not change after controlling for task, country, and demographic characteristics.

Intent to be Screened

Most respondents across all VCM task groups reported that they intended to be screened (70 %), and this result did not differ across VCM groups or countries.

By Previous Screening Group. Those who had never been previously screened, compared to those who had, were much less likely to intend to be screened in the future. Nearly half (49.6 %) of those who had not previously completed screening did not intend to complete screening in the future compared to 17.6 % of those who had ($p<0.0001$). The relationship did not change after controlling for task, country, and demographic characteristics (OR 0.19, 95 % CI 0.14, 0.27; $p<0.0001$).

Table 4. Unlabeled Test Preference by Task Group and by Country

	Overall	Balance sheet	Rating and ranking	DCE	US	Australia
	n=920	*n*=309	*n*=305	*n*=306	*n*=452	*n*=439
Test	%	%	%	%	%	%
FOBT	55.9	54.7	57.5	55.23	45.1	66.3
SIG	16.9	15.5	16.4	18.6	18.4	15.4
COLO	14.3	13.4	8.5	11.7	16.8	6.8
RAD	7.4	8.9	7.2	7.8	10.4	5.3
No testing	7.7	8.1	3.6	11.4	9.3	6.2

DISCUSSION

To our knowledge, this is the first large, multicountry, randomized trial comparing different VCMs related to CRC screening. We found that different VCMs produced different results in terms of an individual's most important CRC screening test attribute but did not affect unlabeled test preference, post-task values clarity, or intent to be screened. Australians were more likely to select the FOBT-like test among unlabeled test options than US participants, perhaps reflecting this test's higher profile in Australia. Intent to be screened was high in both countries, suggesting that informed participants generally favor screening. Comparing people who had and had not previously completed CRC screening revealed differences in most important attribute, post-task values clarity, and intention to complete screening in the future.

These findings suggest that the VCM affects how respondents report what attributes of CRC screening they value most. Previous research has shown that how patients value features or attributes of CRC screening varies widely, but few, if any, studies have considered the effect of specific VCM.[11,14] In this study, slightly more than half of respondents selected risk reduction as most important. Those who did not may have perceived the risk of CRC and the reduction in risk as being very small and thus did not consider this attribute to be "important." Those who completed the rating and ranking task were the most likely to select risk reduction as most important over any other attribute. This is consistent with previous studies that included a rating and ranking task for CRC and other cancer screening decisions.[11,19,24] This relationship may suggest that VCM influences how respondents balance attributes of CRC screening. Additionally, rating and ranking tasks may not promote as much deliberation about the attributes and their relationships with each other, potentially promoting selection of the most accessible attribute, risk reduction, as most important.[25] Regardless, if the method of assessing values affects reported values, as our results suggest, it becomes important to understand what such differences mean, perhaps through qualitative methods.

Interestingly, despite differences in self-reported most important attribute by VCM, unlabeled test preference did not differ by VCM. This may have been influenced by the portrayal of risk reduction as the same across all screening modalities. We did find that Australians were much more likely to prefer the FOBT-like test than Americans. This may suggest that the emphasis on FOBT in the Australian screening program is reflective of the values of Australians. Alternatively, it could reflect Australians increased familiarity with FOBT, as it is the only recommended screening test in Australian guidelines and in the Australian national screening program.[26,27] Finally, we saw previous experience with screening affected attitudes about screening. Those who had not previously been screened were much less likely to select reduction in risk of mortality as most important and were less likely to intend to be screened in the future compared to those who had been screened previously. This may suggest an underlying difference in understanding of mortality risk from CRC in people who have not previously completed screening, but additional research would be necessary to further understand this relationship.

Our study adds to the limited body of research examining the effects of explicit values clarification methods versus no values clarification, implicit methods, or other explicit methods, on decisions about CRC screening or other health conditions. Other current research has shown inconsistent effects of values clarification, and little research has compared the effects of different values clarification methods.[11] Because there are several effective options for CRC screening that differ in risks and benefits, it is important that an individual's values are represented when a decision is made. We observed a similar result for prostate cancer screening decisions, finding that different values clarification methods produce different patterns of attribute importance and different preferences for screening when presented with an unlabeled choice.[19] This study represents an early attempt to understand how different values clarification methods could be used to help patients make a values-concordant decision.

Although useful, this study has several limitations. First, the study sample was relatively highly educated and primarily White, and our findings may not be generalizable outside of these populations. Second, we chose not to include out-of-pocket cost as an attribute of CRC screening. Given our goal to compare across countries, we could not make the attributes or levels country-specific. The cost structure for CRC tests differs between the US and Australia, and we could not resolve this difference. Third, while we were able to detect differences in selection of most important attribute across VCM, we cannot draw any conclusions on which method produces the most accurate choice. Finally, this study was hypothetical and did not follow respondents forward in time to look at actual screening choices.

In conclusion, we found that different VCMs produced different results in terms of most important attribute, but not in terms of unlabeled test preference, values clarity, or intention to be screened. Unlabeled test preference differed across countries, and attitudes about screening differed according to past experience with testing. Future research should include a qualitative component to begin to understand perceptions of the results of different VCM tasks, including which results are most accurate. Studies should also include longitudinal follow-up to determine whether different VCMs produce differences in actual completion of CRC screening, test choice, and long-term outcomes. Finally, future research should explore differ-

ences in values between actively (specifically chosen not to be screened) and passively unscreened people.

Acknowledgments: *Dr. Brenner was supported by an AHRQ NRSA Training Grant [previous: 5T32 HS 13853-9 (University of Washington School of Public Health, Department of Health Services); current: 5T32-HS000032 (University of North Carolina at Chapel Hill, Cecil Sheps Center for Health Services Research)]. Dr. Brenner was affiliated with the University of Washington while completing this manuscript. Dr. Pignone and Ms. Crutchfield were funded by the University of North Carolina Cancer Research Fund and by Established Investigator Award K05 CA129166 from the National Cancer Institute. The sponsors had no role in the design, implementation, or analysis of the study. This manuscript was presented in part at the International Cancer Screening Network 2012 Biennial Meeting in Sydney, Australia (October 23–25, 2012).*

Conflict of Interest: *The authors declare that they do not have a conflict of interest.*

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