1. TITLE PAGE:

TITLE: eCoach: Development and pilot testing of a decision aid for prostate cancer

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2. STRUCTURED ABSTRACT:

Purpose. Prostate cancer is treated with different approaches, including surgery, radiation, and active surveillance, with similar outcomes but varying side effects. These options create challenges in communication and informed decision-making. The purpose was to Investigate the usability and feasibility of an embodied conversational agent (eCoach) to facilitate shared decision making in men with localized prostate cancer. **Scope**. A pilot study was conducted to solicit input from patients to design the eCoach tool. The tool was then evaluated by the same group of patients, plus clinicians. **Methods**. Baseline evaluation of health literacy was performed with focus groups of men diagnosed with localized prostate cancer, held at Emory University and Grady Memorial Hospital, a safety net hospital in urban Atlanta. Modifications to the eCoach tool were evaluated again by the same groups along with quantitative data about the usability, feasibility, and comprehension of eCoach information. **Results**. Early input about the eCoach tool varied by study site. Modifications to the tool were well-received and the tool was found to have high feasibility and acceptability among both patients and clinicians. Many participants, however, stated a preference to obtain information needed for treatment decision-making from their own providers rather than from an electronic tool.

Key Words. Patient decision-making; prostate cancer; decision aids.

3. Purpose (Objectives of the study)

The purpose of the study was to investigate the usability and feasibility of an embodied conversational agent (eCoach) to facilitate shared decision making in men with localized prostate cancer. **Study Aims** were: 1. To conduct a pilot study to develop and test an embodied conversational agent (eCoach) that could be used to facilitate decision-making by men with early stage prostate cancer and their significant others; and 2. To evaluate the acceptability, usability, feasibility, and comprehension of information related to the eCoach tool.

4. Scope (Background, Context, Settings, Participants, Incidence, Prevalence)

Background. The treatment of prostate cancers remains on the forefront of United States healthcare as the overall population continues to age. Overall, prostate cancer is the most common cancer diagnosed among U.S. men and ranks second as a cause of cancer mortality. With the advent of widespread use of prostate-specific antigen (PSA) for screening, along with greater emphasis on detection within the medical community, incidence rates for prostate cancer have increased significantly leading to the detection of early stage disease. Men with localized (stage I or II; T1-2, NX-O, MO) prostate cancer have many choices for treatment, including active surveillance, brachytherapy, radical prostatectomy, and external beam radiation therapy. Unlike moderate and high-grade prostate cancer, scientific evidence does not provide clear benefit between each treatment option for early stage disease. In addition, while the incidence of prostate cancer has increased, overall mortality has been decreasing from 2005 to 2009. The optimal treatment, or avoidance of treatment, for early stage disease remains unclear since survival benefits are similar with each option. However, adverse events for different treatments vary from each other and include urinary and bowel incontinence and sexual dysfunction, and each treatment modality is associated with changing risk profiles for each approach to varying degrees. Treatment side effects have been shown to impact health–related quality of life (HRQOL), may be long-term, and may cause greater harm to HRQOL than the actual cancer, which potentially may be very indolent. This degree of uncertainty increasingly makes selecting a treatment a significant dilemma for patients and their treating physicians. Biases among specialists in urology, radiation oncology, etc. manifest in counseling patients for a given treatment, leading to divergent, and even contradicting, recommendations. Patients are left possibly having to decide between quality of life factors and their length of life.

With the conundrum in selecting an appropriate treatment, research has shown that a growing discrepancy exists between meeting patient preferences and the medical care they receive. Researchers have found that while patient preference for their prostate cancer care did not predict treatment choice, the treating physician (radiation oncology vs. urology) did. Additional studies also support this finding disparity in prostate cancer[i] and other diseases.

To help mitigate this discrepancy, preference-sensitive care is one means to help patients having to make significant tradeoffs affecting his quality and/or length of life. In conjunction with shared decision making, patients and providers could work in an environment that would lead to a discussion based on the best available evidence, the patient's values, preferences, and healthcare goals. In an ideal setting, patients would arrive to a clinic visit willing and prepared to candidly discuss their disease management. They would have earlier determined their goals for treatment and subsequently understood their physician's advice based on a discussion of treatment options between the treating physician and the patient. Additionally, the physician, to facilitate treatment decision-making by the patient, would optimally provide patients with easy to understand information, free from bias, that accurately explains possible risks and benefits of each treatment options. In addition, an optimal clinic visit would

allow sufficient time to address any possible questions that may arise during the patient interaction. Unfortunately, there are many barriers that prevent this ideal approach from occurring, including physician factors (time, inability to detect patient's lack of understanding, etc), patient factors (trust, health literacy and numeracy, and varying degrees of willingness to participate in decisions) and system factors (patient-provider communication, power imbalance, insufficient time for discussion).

To help address these problems, decision aids are a potential tool that could be used by providers to assist patients and family members in their decision-making activities. Decision aids have been shown to evoke more realistic expectations in patients, lessen decisional conflict, reduce the proportion of patients assuming a passive role in the decision process and aid patients in improving their knowledge. The majority of aids provide information in a written or multimedia form. Despite the large number of aids available, none provide risk based or other patient-specific factors compiled using validated risk prediction tools.

Context. Health literacy, the constellation of skills needed to function effectively in the health care environment, remains a subject of little importance in decision aid development. The National Assessment of Adult Literacy (NAAL) carried out by the US Department of Education found that 14% of adult Americans had below basic health literacy skills and 22% had basic skills. Average health literacy levels were lowest among certain groups, including members of underrepresented minority populations – more than half of African American adults and two-thirds of Hispanic adults have limited health literacy, compared to less than one-third of white adults. Considering that many tasks in the health care setting (including comprehension of consent forms) require at least intermediate proficiency, it is reasonable to say that more than half of underrepresented minority patients in this country face challenges interfacing with the health care system.

Settings. In this study, the goal was to determine if a virtual decision aid (eCoach) specifically made to address many of the aforementioned gaps in low risk prostate cancer treatment selection, was a viable alternative to currently available tools. Due to the paucity of data involving decision aids and risk/benefit analysis, another aim of the study was to determine how best risk can be expressed with a decision aid when evaluated in the context of the patient's health literacy scores. Finally, this study ultimately sought to re-establish the need for providers to tailor their patient education to the health literacy and healthcare access specific to their patients by examining two healthcare systems, one a tertiary care, academic hospital (Emory University Healthcare), and the other a safety-net healthcare institution (Grady Health System) in urban Atlanta. Emory Healthcare includes a National Cancer Institute-designated cancer center (Winship Cancer Institute) where prostate cancer treatment is given in the context of multi-disciplinary care. The Emory Clinic represents the largest, most specialized group practice in all of Georgia. Grady Memorial Hospital was established with a mission to provide healthcare to medically under-served residents of Atlanta. Today, it serves as Georgia's largest safety-net provider and as the Level 1 Trauma Center for the majority of the region. Previous research has demonstrated a high prevalence of low health literacy at Grady with 13% of patients with marginal health literacy and 35% of patients with inadequate health literacy. Grady Hospital provides both outpatient and inpatient care to the medically indigent populations of Fulton-DeKalb counties in Georgia, as well as many others.

Participants. Subjects enrolled in the study to participate in one of three focus groups held at Emory Healthcare, or one of three focus groups at Grady. Following IRB and Grady Hospital research approvals, the study was opened at both Emory and Grady institutions. Participants were recruited to participate in the study by research assistants (RAs). Eligibility criteria included men with a diagnosis of early stage prostate cancer; age between 45-74 years; English speaking, and the subject needed to be physically available in the patient waiting rooms at

either the Grady Health Systems Urology Clinic or Emory Clinic Urology Center. All men had to be capable of completing a demographics form and health literacy questionnaire.   Data obtained in the demographics paperwork included gender, age, address, and home or cell phone numbers. The health literacy evaluation also contained three questions to determine the patient's own assessment of how well they navigate their healthcare. A few patients also brought their significant other to participate in the discussions since prior research has demonstrated the importance of significant others in decision-making for prostate cancer treatment.

5. Methods (Study Design, Data Sources/Collection, Interventions, Measures, Limitations)

Regulatory Review. The study was reviewed and approved by both the Clinical Translational Research Committee of the Winship Cancer Institute and the IRB for Emory University, and the Grady Research Oversight Committee.

Study Design. This study involved a mixed methods study design. Quantitative data were collected using validated tools related to health literacy, numeracy, as well as instruments to measure acceptability, feasibility, and comprehension of information. Qualitative data were gathered from the focus groups (FG) and structured interview questions as part of the post-development evaluation of the eCoach tool.

Qualitative data collection consisted of six FG conducted as part of the initial development of the eCoach tool. The original eCoach prototype, designed by collaborators at the Georgia Institute of Technology, was presented to participants at each of the initial FG for comment and feedback. These qualitative data from the FG were analyzed and fed back to the Georgia Tech team to then modify the eCoach tool accordingly. The final eCoach tool was then presented to one FG held at each of the two study sites. Participants at these later FG had also been previously part of the initial FG so they were all familiar with the eCoach prototype and later version.

 Quantitative data was collected from the demographic form and health literacy and numeracy assessment tools as part of the FG. During the final eCoach evaluation sessions, additional quantitative data related to acceptability, usability, feasibility, and comprehension of information were also collected.

Qualitative data were collected during 90 minute semi-structured focus group (FG) sessions led by a designated moderator. Prior to the beginning of each FG, participants were informed of the purpose of the study and a full explanation of both their informed consent forms and HIPPA waivers were completed prior to signing. During each session, a semi structured interview style was used to gather each participant's assessment of the eCoach. An experienced moderator led each focus group using IRB approved questions to steer facilitate the discussion. The same moderator led each of the six focus group meetings. RAs also attended each focus group to serve as recorders and generate notes to supplement transcribed materials. Each focus group member received a $25 incentive, approved by the IRB, for assisting in the study. All focus groups were audio recorded and later transcribed.

Data Analysis. Overall, 46 total men attended a total of six focus groups, three for patients treated at Emory and three for patients treated at Grady. All identifying information was kept confidential and participants remained anonymous during data collection.

Qualitative Data Analysis. This study used a qualitative inductive content analysis as it allows for systematic categorization of data. Using inductive content analysis methodology, open coding of the transcripts was completed first by one reviewer, followed by coding conducted by a second reviewer, leading to the creation of all categories that appropriately

described the written content. Next, using the previously compiled categories, the dominant themes of each FG were recorded to serve as overall thematic assessments of each transcript. To maintain or confirm the validity of the coding, a second reviewer independently created an index of themes based on additional assessment of the transcript. Any discrepancy in themes observed in the reviewer's analysis of the data was discussed and changes made accordingly. If a discrepancy continued to exist, a third reviewer was brought in to decide on the correct theme. Participant quotes were selected by both reviewers to help emphasize a specific theme.

        Quantitative Data Analysis. The quantitative data was analyzed using descriptive statistics, primarily frequencies and univariate analysis. The small sample size overall prevented extensive quantitative data analysis using inferential statistics and the primary analytical approach was designed to be focused on the qualitative data from the FG discussions.

Intervention. The main intervention was the eCoach tool. As a pilot study, the purpose was to develop and evaluate the tool as a potential decision aid in early stage prostate cancer. The eCoach tool was essentially a cartoon character of a physician presenting the information about prostate cancer. The tool was animated, with the avatar "talking" to the participant, with mouth moving and hand gestures. Specific information about prostate cancer, e.g. a detailed drawing of prostate anatomy or illustrations of surgery and radiation therapy, was included. The "talking" by the "eCoach" avatar was provided as a voice-over narration, so the participant could visually see the information as well as hear the information said aloud. This was helpful for those users who might be visually impaired, those with limited literacy and/or health literacy, and those who learned better through visual aids.

        Technical Methodology. The methodology used to develop the avatar and eCoach tool was designed by the team from the Georgia Institute of Technology. Briefly, the animation, primarily the movement of the mouth and hand gestures, was designed to sync with the other aspects of the tool, including drawings. Specific information was linked to an underlying database containing a variety of information. For example, if the user clicked on an unfamiliar word on the screen, the program would show the definition of that word from the database.

        SCRIPT DEVELOPMENT: The script was reviewed by clinicians, researchers, patients, and the technical group developing the accompanying algorithm for the animation. After input from all stakeholders, the final script was approved, to be used to develop the final algorithm for the eCoach conversations and interactions.

        Using the script approved, the technical team then developed the accompanying animation, screens, and interactive ability of the eCoach tool. This entailed 1) having the avatar move his mouth and make gestures in concert with the script; 2) developing the animated diagrams that went along with the words and to detail the anatomy of the prostate gland and the mechanisms behind each treatment modality, e.g. radiation; 3) allowing the patient/user to choose the direction of the conversation, e.g. to go over terms that were unfamiliar or to explain surgery first, etc, by clicking on "buttons" related to different choices, and 4) integrating other functions into the presentation, such as buttons to pause, replay, go to frequently asked questions, or exit.

        The working version of the final eCoach prototype was then tested using a group of patients who had been diagnosed and/or treated for prostate cancer who had also been part of the earlier focus groups that originally provided input about the eCoach tool's creation. These men evaluated the final prototype in terms of feasibility and acceptability and made recommendations regarding further improvements and changes.

        AVATAR DEVELOPMENT. The avatar was designed to be capable of body and facial gestures and poses as well as rudimentary lip synching (i.e. mouth movements will be driven by speech audio amplitude changes only, not phoneme recognition). The final avatar included

posable eyes, mouth and eyebrows along with hand and arm gestures. An animated and posable avatar allowed the matching of tone and content of the dialog with appropriate body language and facial gestures (i.e. expressing concern, hopefulness, seriousness, etc.)

The avatar's mouth animation was driven by a custom algorithm which analyzes the sections of the recorded script being presented and changes the avatar's mouth in response, currently using amplitude only. Other animations were hand-authored and timed to the final dialog in order to ensure that they are appropriate for the material being presented. This scriptable animation system works in conjunction with the existing dialog tree structure developed earlier on the project. Using the script approved, the technical team then developed the accompanying animation, screens, and interactive ability of the eCoach tool. This entailed 1) having the avatar move his mouth and make gestures in concert with the script; 2) developing the animated diagrams that went along with the words and to detail the anatomy of the prostate gland and the mechanisms behind each treatment modality, e.g. radiation; 3) allowing the patient/user to choose the direction of the conversation, e.g. to go over terms that were unfamiliar or to explain surgery first, etc, by clicking on "buttons" related to different choices, and 4) integrating other functions into the presentation, such as buttons to pause, replay, go to frequently asked questions, or exit.

Examples of what the participant would see on the screen as part of the intervention are below.
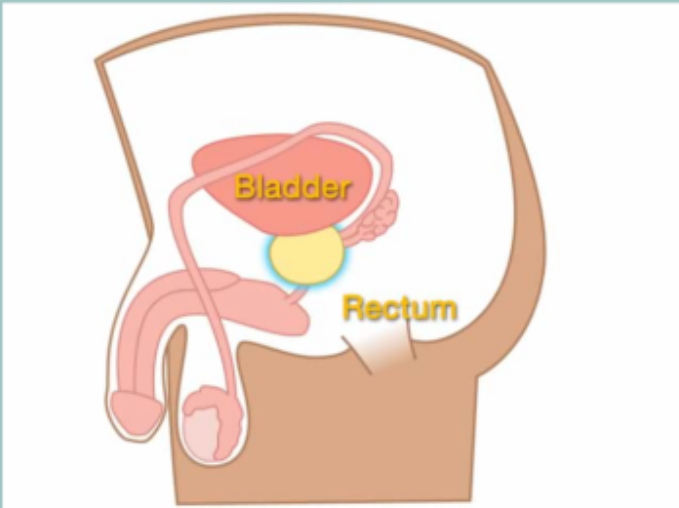
Examples of Screen Shots from the eCoach Program
The eCoach "avatar" both spoke to the user and had the conversation and highlights written on the screen.
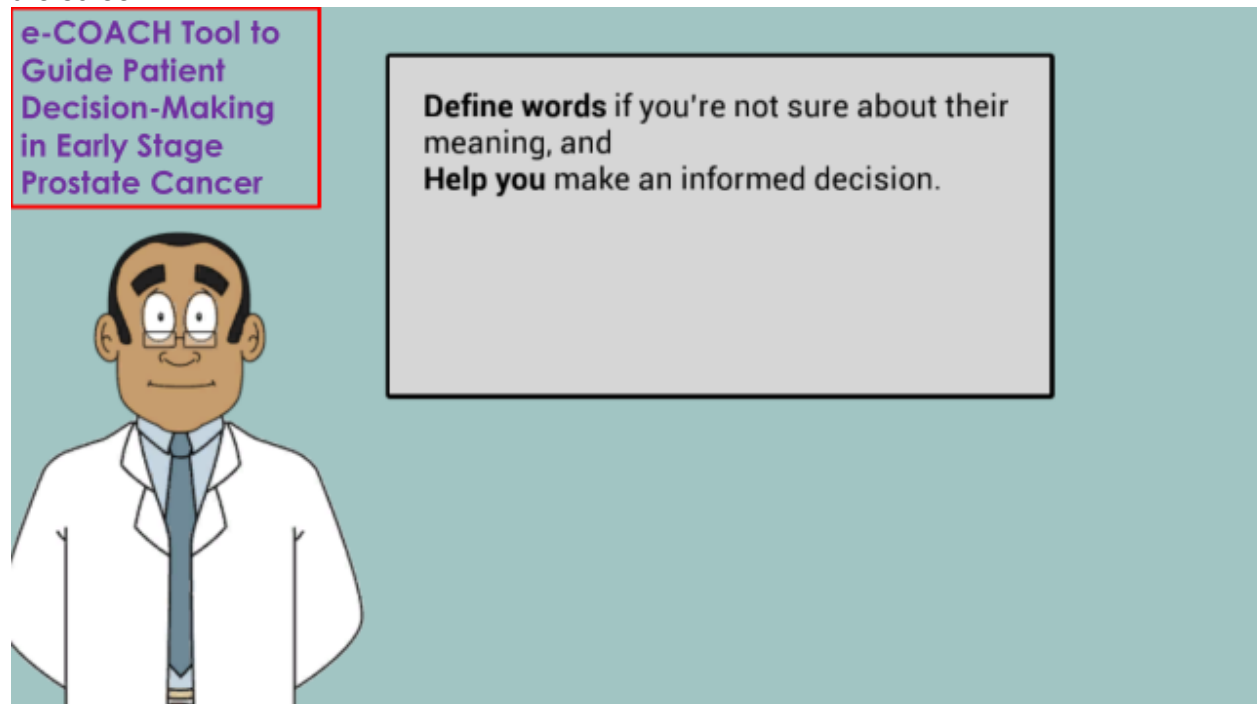
In response to the initial feedback, the eCoach program included animated diagrams of anatomy and physiology related to prostate cancer.

The eCoach program also included animations related to each type of treatment described for prostate cancer, to enhance comprehension of how each treatment worked.

The eCoach tool tested and modified its approach to risk communication based on feedback from participants. An example of a screen shot discussing risk is below.
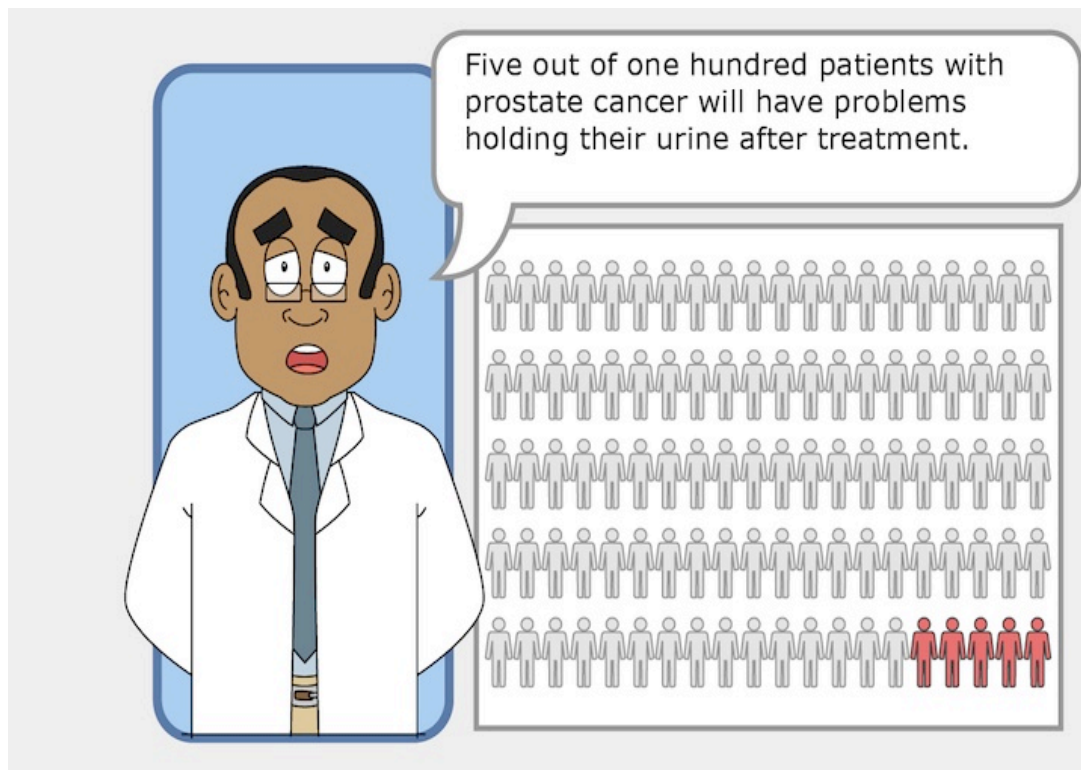
Measures. The key outcome measures for this pilot study were acceptability, feasibility, usability, and comprehension of information. Both quantitative and qualitative data were collected for each of these measures. Data related to the measures for the initial "draft" eCoach tool were used to modify and redesign the final eCoach tool, and the same outcomes were evaluated at the end of the study using a subset of the original focus group participants.

Limitations. As a pilot study, the aims were designed to develop, assess the outcomes related to the initial tool with a series of focus groups, and evaluate the final eCoach tool, rather than actually compare the effectiveness of the eCoach to other decision aids, to standard physician-patient communication, to online information, or other sources used in treatment decision-making for early stage prostate cancer. In the original application, the plan was to also integrate risk calculation tools into the process, so that a specific patient could use the eCoach tool while also incorporating risks specific to his own Gleason score, tumor size, age, etc. However, the complexity of the eCoach tool design process, and the various iterations required based on the initial focus group feedback, made it clear led to the decision to limit the project to the eCoach tool development and evaluation.

RISK CALCULATION: The original plan called for integration of several risk calculators into the eCoach tool, to be completed prior to the patient accessing the tool, and done by a mid-level provider in the clinic setting (Nurse, nurse practitioner, physician's assistant). The risk calculators and web access to the Cleveland Clinic tools were obtained and pre-tested by the investigators. However, the decision was made not to proceed with the integration of the risk calculators for several reasons:

1) the risk calculators are not universally or consistently used by clinicians and their practical application to clinical decision making in prostate cancer is unclear and not supported by much evidence;

2) the ability of the other clinic staff to complete the information to be entered into the risk calculator, and to interpret the data correctly was questioned and determined this activity would be highly variable based on the individual provider. Thus, this would create issues with trying to evaluate the calculation if inaccurate data were being entered by staff.

3) the use of the risk calculator introduced a level of complexity to the eCoach tool overall that takes time and other resources away from the key aims of this project, and did not benefit the project overall, nor contribute to the main goals very much.

4) the ability to insert a validated risk calculation model, which would also require the collection, validation, and use of each patient's own personal pathology and other risk data, was beyond the scope of the project, particularly for the cohort of participants from Grady Memorial Hospital.

6. Results (Principal Findings, Outcomes, Discussion, Conclusions, Significance, Implications)

Principal Findings. The key findings for each outcome measure are described here.

Acceptability - The original eCoach tool, as developed by the Georgia Tech investigators, consisted of an "avatar" to present the information that was essentially a cartoon character of a physician presenting the information about prostate cancer. Regarding acceptability:

1. Participants at both Emory and Grady sites expressed very negative views about the cartoon aspects of the eCoach tool. Comments included "prostate cancer is not funny" and "a cartoon character is not appropriate for cancer." These initial comments led to the rapid development of additional prototypes of the physician/coach avatar, including examples that were more "realistic" in appearance. Through additional testing, the more realistic-looking avatar was chosen by the participants and incorporated into later renditions of the eCoach tool.

2. The participants at Grady, more so than at Emory, expressed less acceptance of the eCoach tool. This diminished acceptance was related in part to the lack of comfort with or access to computers. However, the more important reason for lack of acceptance by the Grady participants was due to an expressed need for greater direct communication with providers at Grady. The participants universally felt the communication between patients and providers at Grady was suboptimal and that the eCoach tool, while helpful in general, should not be used as a substitute for that direct doctor-patient communication that the patients reinforced was greatly needed but all too often missing at the Grady clinics.

A subgroup of the original focus group members were recruited to test once more the acceptability of the eCoach tool, after it had undergone significant revisions based on the focus group feedback. This group consisted of two focus groups, with patients from both the Emory and Grady Hospital sites. Feedback from the second focus groups demonstrated qualitatively:

1) The program was easy to navigate, although they were unable to maneuver fast forward or move backward although it could repeat information
2) The participants thought it was easy to move from one section to another but the Question [?] button was not entirely clear.
3) The users reported a high level of comfort in using the program, even if they did not regularly work on a computer

4) The font of the words on the screen and the buttons included for navigation were considered large enough and readily accessible
5) The spoken parts of the program were clear, the volume and speech were readily understood. Questions were asked about whether eCoach would be translated into other languages.
6) The grade level of the entire program was considered on point and very well understood

Feasibility: The eCoach tool, as determined through focus group discussions at both Emory and Grady sites, was found to be feasible. Whether used on a laptop, a tablet/pad, as a kiosk, or similar, the focus group feedback was positive about how this information might be used. In addition, feedback from clinicians regarding the feasiblity of the eCoach tool as part of patient education and in the context of urology clinics was also positive.

Quantitative data related to **Feasibility** and **Acceptability** of eCoach:

On scale of 0-6, for each question, the mean score was:
1. How liked the eCoach tool overall? (mean =4.6)
2. How likely would recommend to other institutions? (4.75)
3. How likely would recommend eCoach to other patients? (4.75)
4. In terms of how much time the eCoach program took compared to average amount of time taken using other approaches to informed decision making for prostate cancer, the time taken by eCoach program: took shorter amount of time
5. How helpful overall was eCoach communicaiton about prostate cancer and its treatment? (4.5)
6. How much do you think information provided by eCoach could affect or change decisions made by patients diagnosed with prostate cancer? (4.0)
7. How important do you think it is to develop eCoach program for patients, even if cost more time or money than usual? (5.5)
Usability: The focus groups were held in two different sites and represented two distinct populations: at Emory, the population was assessed as having higher health literacy and numeracy scores, higher socio-economic status, and was primarily Caucasian. At Grady Memorial Hospital, the population was assessed as having significantly lower health literacy scores and lower socio-economic status compared to the Emory groups. The Grady participants were also primarily African American. The Emory groups had a higher level of facility and familiarity with computer-based programs compared to the Grady groups. The Grady groups either had no access to computers, or had access but were less comfortable in using a computer-based tool and preferred one-on-one communication with their healthcare provider. However, overall, members of focus groups at both sites were willing to utilize a computer-based tool to aid in decision-making about prostate cancer if the tool was simple and readily understood by the user.

The algorithms linked to the database were re-designed to enable the end user (the patient) to move seamlessly from one section of the eCoach tool, e.g. the ability to access the vocabulary, frequently asked questions etc., to another section, such as the treatment specific discussion conducted by the eCoach avatar. Several redesigns were pursued so this process to appeared to be seamless by the user in order to make the program truly effective and to more closely mirror an actual discussion with a healthcare provider.

Focus groups were held with patients previously diagnosed/treated with prostate cancer who had participated in the original focus groups advising about the eCoach initial development.

Participants were provided hands-on experiences to truly test the usability of the tool. The initial and subsequent focus groups were asked questions about usability.

Findings related to usability, on a scale of 1-6, reported the following mean scores for each of the measures:
1. Easy to use (mean = 5.8)
2. Answered questions readily (4.2)
3. Easy to understand (5.8)
4. Important to use for treatment decision-making (4.2)
5. Important to use to improve quality of prostate cancer care (5.4)
6. Think that being informed is important (6.0)
7. Think that prostate cancer at institution where treated is the highest possible (4.8)
8. Satisfied with the way eCoach tool can be used (5.0)
9. Think quality of care delivered could be improved (5.0)
10. Satisfied with eCoach tool as a means to improve quality of care (5.2)

Comprehension - Specific feedback from the focus group participants was solicited as it related to understanding the eCoach information as well as the way in which the information was presented. Some key findings related to comprehension of information were:

1. Graphical representation of risks was viewed as helpful, with preference given to specific graphs that emphasized individual risks, e.g. "5 men out of 100 men could experience this side effect" rather than a numerical representation.
2. Anatomical drawings were perceived as very useful to enhancing comprehension of other information about prostate cancer.
3. Not all the information presented was easily comprehended by the focus group members. The feedback indicated that specific vocabulary (e.g. "incontinence", "impotence", etc) should have the option for the user to focus on these words and receive more detailed explanation of their meaning in the context of the eCoach tool, prior to moving on to the next section.
4. Feedback also recommended that information be presented as BOTH written words on the screen AND as an audio recording to promote learning that might depend on different sensory intake.

In terms of comprehension, the patients generally reported they found the information easy to understand. In addition, the ability to access frequently asked questions, to pause the program, and to repeat the information as many times as they needed all contributed to high levels of comprehension. Additional features that participants suggested to improve the product included a glossary of terms, updating the information included in real time to reflect new advances in prostate cancer treatment, and to bookmark the information for ease of resuming the program after a pause or interruption.

Outcomes - **Quantitative Data Analysis.** As related to Aim 2, specific outcome measures as measured at each study site are described in Table I below.

Table I - Quantitative Data by Study Site

Variable	Grady (mean score)	Emory (mean score)
Satisfaction with eCoach [0-6 scale]		
Easy to use	6	5.8

Answered questions about prostate ca	6	4.2
Easy to understand	6	5.8
Important for treatment decisions	6	4.6
Important for quality of PCa care	5.83	5.4
Being well informed is important	6	6
PCa care at this institution is highest possible	6	4.8
Satisfied with way could use eCoach	6	5
Quality of eCoach as tool is best possible	4.16	5
Satisfied with eCoach as means to improve quality of PCa care	6	5.2
Feasibility & Acceptability of eCoach Tool [0-6.5]		
How well liked tool overall	4.6	4.2
Would recommend to other institutions to use	4.75	5.3
Would recommend to other patients to use	4.75	5.5
How effective eCoach would be as pt decision aid	2.5	3.2
How helpful was communication with providers about PCa decision making	4.1	3.8
How likely eCoach might be to affect decisions	3.9	3.7

How effective eCoach might be compared to usual care	4.0	5.5
Barriers to decision-making identified	Lack of understanding, risks & benefits, fear of death, getting to clinic	Emotions (fear), lack of knowledge & info, doctor bias, too many options
Time required for eCoach vs usual approach	50% = shorter	Shorter
Had direct communication w providers for PCa decision making	66% yes; 33% no	60% yes; 40% no
Type of communication re: PCa w physicians	Varied; talked before & after treatment; also not at all	Varied; talked before & after treatment; also not at all

Outcomes - **Qualitative Data Analysis.** As related to Aim 2, specific outcome measures with notation of qualitative data from each study site are described in Table II below.

Table II - Qualitative Data by Site

Qualitative Comments re: eCOACH	Grady	Emory	Suggested Change
How Hard/Easy to Use the Program?	Easy to navigate but couldn't back up; very comfortable using computer; able to read words without problem; narration clear	Liked touch screen, facile, easy to use, unable to move back or forward, words big enough, very comfortable with using, could find buttons, volume of narration would vary from softer to louder, appropriate grade level	Change so able to move forward or backwards; fast fwd; bookmark so can go back to that place; need to update info in real time; frequent updates; login so can resume program where left off; have menu at program start; ? button not clear, translate to other languages
eCOACH Program Itself	Figure (avatar) ok, program helped focus info; rather use coach than explore on own; took fear out of DM; liked having different options presented; not boring; FAQs helpful; diagrams inaccurate re: surgery; tx options need revision	Prefer real person, not cartoon; coach was professional; figure was non-descript didn't draw attention from text; eventually stopped looking at figure & just focused on text & voice over; needed more info re: options presented, missing other options; boring, confusion re: start	If figure is "coach" have it as a general health professional NOT as a doctor; whatever figure or method must be able to be updated frequently; add glossary of terms, bibliography, other websites; need to drill down to more detail esp re: specific treatments, too superficial; make clear where to start
eCOACH Content & Comprehension	Perfect amt of info, very easy to understand, helped	Content limited & out of date; need to add cryoablation, robotics,	include more tx options; reflect newest advances in treatment; add more about

of Content	figure out what questions to ask, understood entire program	focal laser; need to include all tx options not just some; good for newly diagnosed; add how long various treatments & recovery take; good starting point but need more data, detail, deeper information	Gleason & staging; missing content: robotics, laser, cryoablation; want more detail, ways to learn more in-depth
Specific Information related to Treatment Options	Liked all sections, helped show different risks/benefits of each treatment, esp increased awareness of AS	Info on surgery very limited, didn't discuss different types of surgery; gave enough info to start to ask questions; good to include AS but didn't say much; choice of African Americans in the animation pictures	Expand specific info related to treatment options, esp surgery, also add in newer options; say more about AS
How Might Use eCOACH if you were a Patient with a New Diagnosis of PCa	Should be required viewing for all pts; watch program first then know what to ask; watch after mtg with dr; program better than learning from other website, better than talking with dr, watch while waiting to see dr, see before PCP mtg, program better than talking with other PCa survivors; all high rankings for overall feasibility, acceptability, & satisfaction	Should view before talking to dr; should be given to pt AFTER talking with dr; want to view in privacy of home with as much time as you want; give CD/DVD to view at home; download from website; biggest problem in PCa decision making is pressure to do something immediately- self-pressure to do something, program should emphasize more that we can take time; Include info from *ACS Prostate Cancer Quick Facts*, & *Prostate Ca for Dummies*	Give pt a brochure with the website where he can access or download the program at home or in private or give CD/DVD to use later; after pt gets diagnosis, direct him to eCoach first

 Discussion
Both quantitative and qualitative findings were very informative to the project and understanding the patient/user perspective with this tool.
1. It was clear that the participants from Emory, who were generally better educated, more computer savvy, with higher socioeconomic status, had very different views compared to the Grady patients, who tended to be African American, of lower socioeconomic status, and many were uncomfortable with using computers although most everyone had access to a computer, either personally or through some other shared resource.
2. The Emory patients were clear that the tool, and the doctor-patient conversations, needed to be more sophisticated, and include real-time information about the latest treatment options, data, and recommendations. These participants were most concerned that users would be able

to access a variety of online and other types of educational resources, and tended to be independent information seekers overall.

3. The patients seen at Grady Hospital, while often having access to computers where they could potentially conduct the same online learning or searches as described by the Emory patients, were less enthusiastic about having their education related to treatment options relegated to an online resource. These patients, without exception, really wanted to talk directly with their physicians. They did not want the eCoach tool to substitute for a one-on-one conversation with their actual provider, with whom they could dialogue. They were agreeable to have the eCOACH tool as a means to complement the physician-patient interaction, but not at the cost of reducing or eliminating time spent in discussion with the provider.

4. Neither Grady nor Emory patients saw the eCoach tool as being significantly effective as a treatment option decision tool (mean score=2.8). They thought the tool was likely to be effective as an educational piece to augment the provider discussion, and should be viewed by patients either before the conversation with the provider to raise awareness of concerns and information, and/or to be viewed after the provider discussion, in order to reinforce the physician/provider discussion. There was some discussion as to whether the eCOACH tool would work better to be viewed before or after the discussion with the provider. This timing seemed to be somewhat patient-specific.

Conclusions

The participants in the study expressed the need for a centralized, easy to use information source for men with low risk prostate cancer. The majority felt the aid would have helped their decision-making at the time of diagnosis.   The technical aspects of the eCoach tool, including presentation style, information included, and hands-on use, were found to have a high degree of feasibility, acceptability, and usability among all participants. In addition, the tool enhanced comprehension of information needed for informed decision making for prostate cancer treatment options. However, the men strongly disagreed on the type of eCoach to use, as well as the depth of information necessary to ensure its effectiveness. This disagreement was largely linked to population demographics and study site that reflected specific demographics. These findings support the conclusion that "one size does not fit all" regarding patient needs for education and intervention and patient education for prostate cancer must be tailored to the individual, keeping in mind the health literacy and preferences of the individual patient.

Significance

.   The concerns raised by many of the participants, especially that they preferred to obtain their information needed for treatment decision-making from their own providers rather than from an electronic tool, brings to the forefront findings that have been suggested by other investigators previously as needing attention in the eHealth domain. Other studies have asked: *What is the optimal "space" in which eHealth patient education tools and decision aids should operate*? An assumption has been made in many cases that eHealth or online educational interventions are always more useful, effective, and efficient that depending on busy practitioners to take the necessary time to explain treatment choices and assist patients in making these decisions. However, when asked directly, diverse patients agree that physicians have the most important role in understanding treatment options while other materials are more helpful in laying the groundwork for those conversations, or for clarifying the discussion with the provider after that discussion has been completed

Implications

Even when patients with lower health literacy have adequate computer access and skills, they may not prefer to use a computer to aid in the decision-making (DM) process. For many patients, human interaction remains preferable for the actual DM process than use of interactive

decision aids (DA), even if the DA could be used at a pace and over a period of time that the user most prefers. This study highlights gaps in evidence, including such key questions as impact on clinical consultation time, costs, and content, that are vital to pursue. Thus, further research should focus on these gaps, including key outcomes, e.g. adherence, that lack evidence that these result from using DA of any type. Even if a patient has higher health literacy, computer literacy, and higher socioeconomic status, as well as access to computers/internet, it cannot be assumed that they are comfortable using computers as means for informed DM; OR that they wish to use electronic DA. The common practice of providing websites, even if known to be accurate, as the primary means to facilitate informed DM, is not an optimal approach regardless of patient literacy level. Electronic, web-based, or print DA may be useful as *adjuncts* to the DM process, but they cannot substitute entirely for direct physician-patient communication. Direct communication with the physician and healthcare team was preferred by all participants vs. other DA, regardless of other patient characteristics. This included both the higher SES patients at the Emory site as well as the lower SES population seen at Grady Hospital system. Decision aids, of any style, may be most effective if used as preparation *before* consultation with the physician, or as reinforcement or further exploration *after* consultation. Lastly, as an important practice implication, knowledge and assessment of an individual patient's literacy, health literacy, numeracy, and preferences regarding the optimal approach to patient education is essential. To facilitate this critical assessment, in the absence of adequate time generally included in a clinic appointment, a basic assessment can be performed using three simple questions that have been validated in other studies:

- HEALTH LITERACY: *"Do you have trouble filling out medical forms?"*
- NUMERACY: *"Do you have a hard time working with numbers/fractions/percentages?"*
- GENOMIC LITERACY: *"What is the highest level of education you completed?*

Clinicians need to tailor information provided – including omitting or reducing numeric information or present visually, using both words AND percent, using absolute risk, and evaluating written materials for literacy. As examples:

 "Your risk of this outcome is ~ 5% or 1 in 20 patients; 'low risk'"; "You could decrease your risk by 50% (relative risk) - from 6% to 3% (absolute risk) - by this intervention; your risk of (3 out of 100 patients) is considered low risk".

Clinicians should ask the patient: "How would you prefer to receive information about this_____ (treatment/intervention/drug, etc) we are discussing today?" and then provide the information as they prefer – as numbers, visual, words, or from an available range of presentation styles for informed consent and decision making. Decision making and decision aids could build on meaningful use of the electronic medical record (EMR) which could provide an opportunity to tailor information to individual patient needs & preferences. In addition, patient reported outcomes should be integrated routinely into the EMR electronically, and key data about patient educational level, literacy, etc. should be automatically added to the regular patient history and physical assessment in the EMR.

7. List of Publications and Products (Bibliography of Outputs) from the study.

PRODUCTS:

An interactive decision aid using an embodied conversational agent (eCoach): qualitative study. This paper, which summarizes the findings of the focus groups for the project, was developed by the research team and submitted to the Emory University School of Medicine as partial completion of the requirements of the School of Medicine's Discovery Phase for a medical student who worked on the project (Derrick Ashong).

Ashong D, Gillespie T, Mohan A. eCoach: Assessing the Need and Development of an Interactive Decision Aid for Prostate Cancer. Manuscript revision under review. [*Patient Education and Counseling*]

Results of the first phase of testing of eCoach and the qualitative data from the focus groups were presented as a poster presentation at the Emory University School of Medicine's Medical Student Research Day in April 2014 by Derrick Ashong.

Scott Robertson, Rob Solomon, Mark Riedl, Arun Mohan, Toni Chociemski, Viraj Master, Theresa Gillespie. The Visual Design and Implementation of an Embodied Conversation Agent in a Shared Decision Context. *Conference Proceedings HCI International 2015.*

Impact of Providers on Quality of Care and Patient Outcomes in Prostate Cancer
Urology Grand Rounds – October 30, 2014
Presented by Theresa W. Gillespie, PhD, MA

Decision-Support Tools for Early Stage Cancer: Prostate Cancer as a Model
Winship Grand Rounds – February 25, 2015
Presented by Theresa W. Gillespie, PhD, MA

Theresa Gillespie, Derrick Ashong, Viraj Master, Scott Robertson, Rob Solomon, Mark Riedl, Toni Chociemski, Arun Mohan. Use of an interactive treatment decision aid for early stage prostate cancer: eCoach evaluation. Manuscript submitted and under review.