Official Title: The Mathematics of Breast Cancer Overtreatment: Improving Treatment Choice Through Effective Communication of Personalized Cancer Risk

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Purpose of the Study

Implement a RCT to test the main hypothesis that the use of personalized decision aids leads to (i) an increase in the proportion of women who would consider active surveillance as a viable management strategy for DCIS, and (ii) an increase in knowledge of the associated risk trade-offs.

The central hypothesis is that communication of model-based personalized risk projections leads to an improved understanding of the trade-offs associated with different management strategies for DCIS.

Background & Significance

Overtreatment in Breast Carcinoma in Situ (DCIS).

Each year in the United States alone, approximately 60,000 women will be diagnosed with DCIS (10). More than 97% of diagnosed women will choose immediate treatment, either surgery alone, or surgery in combination with radiation or chemotherapy (11). Since it is estimated that only 20-30% of DCIS lesions eventually become invasive (12, 13), this year, as many as 45,000 women will undergo radical surgery for a lesion that would not cause any harm in their remaining lifetime. The treatments, and thus the consequences of current DCIS management, are similar to those of treatment for invasive cancers. Consequences include pain (14-16), reduced quality of life (17, 18), increased risk of angiosarcoma and ischemic cardiac disease (due to radiation) (19, 20).

Scientific Premise for Active Surveillance in DCIS.

The concept of AS was introduced to manage prostate cancer, because many men die with their prostate cancer, rather than from it, and treatment can be associated with profound morbidity. In AS, definitive therapy is not implemented at diagnosis. Instead, decisions about whether and when to intervene are based on subsequent disease behavior during surveillance over time (21). The AS approach allows the biologic behavior of a monitored tumor to dictate therapy, thus effectively reducing overtreatment by reserving aggressive interventions only for those likely to derive benefit from them. Because it is a non-invasive lesion with unknown malignancy potential, DCIS is comparable to early-stage prostate cancers for which AS is effective. However, currently only 3% of patients diagnosed with DCIS elect AS (22). Retrospective studies suggest that surgery may not improve survival for low-grade DCIS (23); however, prospective data remain scarce.

Empowering Patients through Personalized Decision Aids (DA).

In the absence of prospective data for AS in patients with DCIS, the current paradigm of surgical treatment is unlikely to change in the near future. Since randomized controlled trials (RCTs) on AS have only recently started (7-9), relevant data is a long way off. At the same time, there is a great wealth of existing clinical and biological data on DCIS. However, because these resources are dispersed across a large number of data and knowledge sources, they remain largely inaccessible to patients and their physicians. To overcome this information barrier, the proposed research is expected to yield the best-possible individualized risk and uncertainty projections for patients diagnosed with DCIS, and to effectively communicate these projections via personalized DAs. This contribution is significant because it is expected to enable future DCIS patients to evaluate the trade-offs associated with different management strategies, and to make an informed decision that is aligned with their personal risk tolerance. By increasing the acceptability of AS through effective communication of personalized risks, the proposed research has a significant impact on the NIH's mission to reduce morbidity and enhance health.

Design & Procedures

Implement an RCT to test the main hypothesis that the use of personalized decision aids leads to (i) an increase in the proportion of women who would consider active surveillance as a viable management strategy for DCIS, and (ii) an increase in knowledge of the associated risk trade-offs. The consents and associated documents will be uploaded for review and approval before recruitment/consent.

Introduction. The objective of this study is to evaluate the impact of the DA on the understanding and acceptability of AS. For ethical reasons, we will test the main hypothesis in a hypothetical scenario in women without a personal history of cancer. The rationale for this aim is that, if successful in women with no personal history of cancer, we will advance towards the long-term goal of reducing overtreatment of DCIS. This aim will be informed by both the cognitive interviews (Aim R2a) and DA pre-testing (Aim R2c). All documents that will be used during this aim will be uploaded to this application once they are developed. We will submit modifications before beginning any data collection. Materials and consent documents will be developed for both the 202 participants for the RCT as well as for the beta-testing portion. All documents will be uploaded to the IRB once they are developed. No participants will be recruited/consented until an amendment is reviewed and approved by the IRB.

Justification & Feasibility**.** Because there is no clear distinction between attitude and choice in a hypothetical scenario, the commonly used evaluation measure of informed choice (39, 48) is unsuitable. We focus instead on the proportion of women who would choose AS as their preferred treatment option. Our working hypothesis is that the personalized DA will increase this proportion, because DCIS-specific mortality under AS is comparable to early-stage prostate cancer-specific mortality under AS (49), and 35-50% of men diagnosed with early-stage prostate cancer choose AS (50-52). Thus, it is plausible that AS could be considered a viable option for DCIS if the trade-offs for different management strategies are effectively communicated. Similar to previous DA evaluations (40, 53), we will use an RCT design. Since many women are unaware of AS in breast cancer (54), the control arm plays a crucial role by accounting for potential novelty priming.

Research Design**.** A parallel-arm double-blind RCT of 202 women to evaluate DST (decision support tool) with AS as an option (intervention) vs. DST without AS as an option (control) for a hypothetical diagnosis with low-grade DCIS. The primary outcome is treatment choice (binary: AS vs non-AS). Secondary outcomes include: acceptability of the different treatment options; perceived riskiness of the AS option, and pre- vs post-knowledge about DCIS (self-reported). Using the secure web portal REDCap, eligible consented women will complete three phases: randomization, baseline, and endline. Randomization phase: 1:1 randomization to control (surgery options only) or intervention (surgery options plus active surveillance option) arms, stratified by age group (< 65, 65+) to ensure balance of age-specific mortality risks. Block randomization (k=6) will be used. Baseline phase: all women will receive information about a hypothetical DCIS diagnosis and complete: 1) a baseline questionnaire about breast cancer and DCIS knowledge. Endline phase: after self-directed exploration of provided content, primary and secondary outcomes will be measured by questionnaire. A series of additional covariates and personality scales will also be elicited with the questionnaire. Each woman is expected to take at most one hour to complete the entire study task. In addition to the questionnaire, the team will collect basic website user analytics such as the order in which the website is explored, and how long participants spend on each page. Eligibility. Consented female participants of age 50-79 years, with no history of breast cancer and with a negative mammographic screen within the preceding 12 months. A financial incentive will be provided. Beta-testing. Before roll-out of the RCT, beta-testing of the evaluation will be conducted in 30 women (15 in each trial arm).

Expected Outcomes**.** An RCT-validated DA that improves understanding of the trade-offs associated with different management strategies for DCIS, and that increases acceptability of AS as a viable management strategy.

Rigor and Transparency**.** Rigor in DA evaluation is achieved by using a parallel-arm, double-blind randomized controlled trial design. Highest possible robustness and transparency of the approach will be achieved by registering the trial with clinicaltrials.gov and adhering to CONSORT guidelines for analysis.

Potential Problems & Alternative Approaches**.** Our working hypothesis is that the use of a personalized DA will increase the proportion of women who consider AS a viable management strategy for DCIS. Although our model projections (60) solidly support this hypothesis, it may not be confirmed here. In this unlikely case, we will analyze secondary outcomes and baseline risk measures to determine whether the lack of effect was due to poor understanding of DA content or was associated with low personal risk tolerance. Because the DA provides projections for all management modalities, it remains valuable even for women who are opposed to AS.

Selection of Subjects

Sex: Female
Age: 50-79 years
Has had a negative mammographic screen in the past 12 months
No personal history of breast cancer

Subject Recruitment and Compensation

For beta-testing (n=30) and the full randomized study (n=202), a total of 232 women will be recruited from the Duke Mammography Clinic. We will use a MaestroCare MyChart recruitment invitation to help identify potential participants. Potential subjects are identified via a report generated within MaestroCare by the DOCR MaestroCare Analyst team. A recruitment invitation will be sent by a DOCR analyst to potential subjects via MyChart. The patient will indicate if they are interested and the study coordinator will be sent an Inbasket message (MaestroCare internal message) if they are interested. Only key personnel who are delegated the task of patient identification/recruitment will have access to the Inbasket messages. Only patients who express interest will be contacted by key personnel, who will then follow the recruitment process approved by the IRB for this study. The study coordinator may follow-up (up to 3 times) with patients (by phone, email, or via MyChart message) if they expressed initial interest in the study. Patients who have opted out of research contact, via yellow dot in Maestro, will not be contacted. Patients will not be contacted more than three times, including via phone and email. If a patient states they would like to opt out, the study team will follow the Duke Recruitment and Engagement policy.

RCT beta-testing and randomized study compensation: $25/survey

Subject's Capacity to Give Legally Effective Consent

Not applicable, only subjects capable of giving consent themselves will be eligible for inclusion in the study.

Risk/Benefit Assessment

The potential risks to RCT participants (Aim R3) include accidental disclosure of their identity or identifiable responses. This would result in the disclosure of the participant's identity, their opinion about the utility of the decision aid for communicating risk, and the self-reported effect of decision aid material on their perceived acceptability of active surveillance as a management strategy for DCIS. Because the participants have had a negative mammogram within the past 12 months and have no personal history of breast cancer, the risks of psychological harms by engaging with the decision aid content is expected to be minimal. Because there are few anticipated risks, in our opinion, the benefits driven from the causally strong conclusions of the trial outweigh the very minimal risks to the participants.

Only self-reported participant data and basic demographics will be collected for this study. The planned procedures for protecting against and minimizing potential risks include: use of a secure system for data collection; storage of data in a secure relational database requiring two-factor authentication.

Benefits:

Potential direct benefits of the research to research participants include intellectual satisfaction in participating in the pre-testing of a decision aid for breast cancer patients, and the satisfaction of contributing to the advancement of knowledge about decision aid development for breast cancer patients. The benefits to cancer care and society include the potential to generate new knowledge about informed decision making, and the potential for this work to steer future research in the management of breast carcinoma in situ. The minimal risks to subjects are considered reasonable in relation to the anticipated benefits to research participants and society overall.

Costs to the Subject

There are no costs that the subject will incur as a result of participation

Data Safety and Monitoring

The DA will be evaluated in women without a personal history of breast cancer. Participants will be presented with a hypothetical DCIS diagnosis scenario only, and the study does not involve medicinal products or medical devices. Furthermore, the DA will be developed following best practice guidelines from the Society of Medical Decision Making and with input from an expert in the user experience design industry. Most importantly, we will seek to minimize potential psychological risks to participants in the study. Based on these considerations, we anticipate minimal risks to the participants and very low risk of (serious) adverse events. In the case of an adverse event, however, it will be reported in accordance with Duke IRB guidelines.

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Appendix 1: Decision Support Tool Questionnaire

Survey: Decision support website

0% 100%

In this survey, we will ask you to explore a decision support website.

The website is designed for patients diagnosed with ductal carcinoma in situ (abbreviated as DCIS). It is okay if you have never heard of DCIS before. The website will provide plenty of information about it.

After exploring the website, you will be asked to answer questions about your experience and what you learned.

0% 3% 100%

2 One quick note before you get started: Please be sure you are on a laptop or desktop computer (not a tablet or phone), using one of the browsers listed below. Microsoft Explorer is not supported.

o Google Chrome (Windows/Mac): Install Chrome
o Apple Safari (Mac): Install Safari
o Microsoft Edge (Windows): Install Edge

Please remember that to receive compensation for this study, you need to complete the survey. Information to provide compensation will be collected at the end of the survey.

0% 6% 100%

Before exploring the website, we have a couple of questions to help us understand how much you currently know about breast cancer and DCIS.

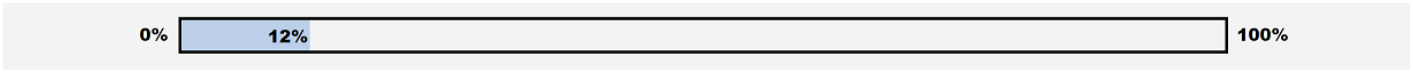
0% 9% 100%

Please rate on the scale, how much do you know about breast cancer?

◯ 1 I know very little about breast cancer
◯ 2
◯ 3
◯ 4
◯ 5 I know a lot about breast cancer

Please rate on the scale, how much do you know about ductal carcinoma in situ, abbreviated as DCIS?

- ◯ 1 I know very little about DCIS
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 I know a lot about DCIS



For this study, we would like you to imagine you were just diagnosed with DCIS.

With this in mind, we will ask you to carefully explore the DCIS website. To make your life easier, we will show you the website content in three separate links on the following pages.

When you are done exploring all three sections of the website, you will be asked to make a treatment decision.

Below is the link to the first section to explore, the Guide. It will open in a new window. When you are done exploring, return back here and click 'Next Page.'

Please click the link below and use the following access code: [record-name]

Click Here (Link 1 of 3): Guide

Below is the link to the second section to explore, the Decision Support Tool. It will open in a new window. When you are done exploring, return back here and click 'Next Page.'

Please click the link below and use the following access code: [record-name]

Click Here (Link 2 of 3): Decision Support Tool

I confirm that I have finished exploring the Decision Support Tool.

- ◯ Yes, I am ready to continue

Below is the link to the last section to explore, the Information Center. It will open in a new window. When you are done exploring, return back here and click 'Next Page.'

Please click the link below and use the following access code: [record-name]

Click Here (Link 3 of 3): Information Center

I confirm that I have finished exploring the three links provided and I am ready to continue the survey.

(If not, please finish exploring the three links; they are provided at the bottom of this page)

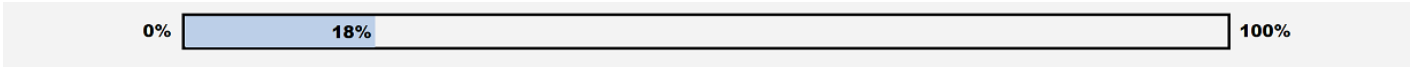
Keep in mind, you can revisit any of the sections at any time while completing the survey (your access code: [record-name])

Guide

Decision Support Tool

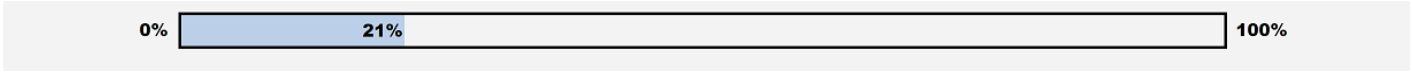
Information Center

- ◯ Yes, I am ready to continue



If you were a patient diagnosed with DCIS, what treatment option would you choose?

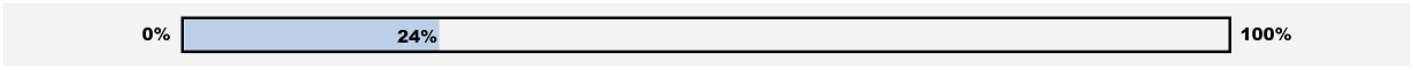
- ◯ Active monitoring
- ◯ Lumpectomy
- ◯ Lumpectomy with radiation
- ◯ Mastectomy



Why did you choose this treatment option? (You may list several reasons)

Please rate, how confident are you in your treatment choice?

- ◯ 1 Not at all confident
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Very confident



How comfortable would you be with active monitoring as your initial treatment for DCIS?

- ◯ 1 Not at all comfortable
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Very comfortable

How comfortable would you be with lumpectomy as your initial treatment for DCIS?

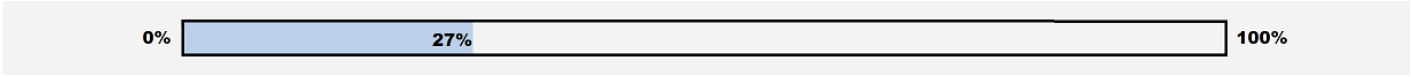
- ◯ 1 Not at all comfortable
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Very comfortable

How comfortable would you be with lumpectomy with radiation as your initial treatment for DCIS?

- ◯ 1 Not at all comfortable
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Very comfortable

How comfortable would you be with mastectomy as your initial treatment for DCIS?

- ◯ 1 Not at all comfortable
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Very comfortable



If you choose active monitoring as your treatment, how likely is it that your DCIS will progress to invasive cancer within 10 years after diagnosis?

- ◯ 1 Not at all likely
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Very likely

Please note: for the rest of the survey when we use the term 'DCIS website', we are referring to the collection of all three links you reviewed (Guide, Decision Support Tool, and Information Center).

After you have reviewed the DCIS website, how much do you know about ductal carcinoma in situ, abbreviated as DCIS?

- ◯ 1 I know very little about DCIS
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 I know a lot about DCIS

What do you think about the amount of information on the DCIS website?

- ◯ 1 Too little information was provided
- ◯ 2
- ◯ 3
- ◯ 4 The amount of information was just right
- ◯ 5
- ◯ 6
- ◯ 7 Too much information was provided

How clear was the information on the DCIS website?

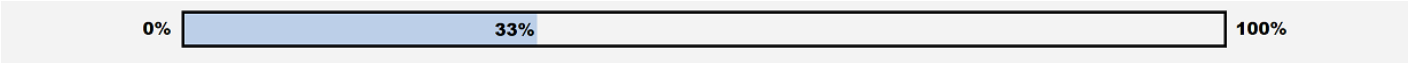
- ◯ 1 Not at all clear
- ◯ 2
- ◯ 3
- ◯ 4 Somewhat clear
- ◯ 5
- ◯ 6
- ◯ 7 Extremely clear

How helpful was the information on the DCIS website for making a decision about DCIS treatment?

- ◯ 1 Not at all helpful
- ◯ 2
- ◯ 3
- ◯ 4 Somewhat helpful
- ◯ 5
- ◯ 6
- ◯ 7 Extremely helpful

Would you recommend the DCIS website to a friend diagnosed with DCIS?

- ◯ 1 No
- ◯ 2
- ◯ 3
- ◯ 4 Not sure
- ◯ 5
- ◯ 6
- ◯ 7 Yes



How likely might a breast biopsy miss invasive cancer?

- ◯ A biopsy will always show correctly if there is invasive cancer
- ◯ There is about a 1-5 % chance that biopsy misses invasive cancer
- ◯ There is about a 6-10 % chance that biopsy misses invasive cancer
- ◯ There is about an 11-15 % chance that biopsy misses invasive cancer
- ◯ There is a more than 15% chance that biopsy misses invasive cancer

Is DCIS the same as invasive breast cancer?

- ◯ Yes
- ◯ No

The following options are used to treat DCIS patients (choose all that apply):

- ☐ Active monitoring
- ☐ Endocrine therapy
- ☐ Lumpectomy
- ☐ Mastectomy
- ☐ Chemotherapy
- ☐ Radiation

For a woman diagnosed with DCIS, how much does waiting 3-4 weeks to make a treatment decision affect her chances of survival?

- ◯ A lot
- ◯ Somewhat
- ◯ A little or not at all

With active monitoring, about how many women diagnosed with DCIS do you think will die of breast cancer in 10 years?

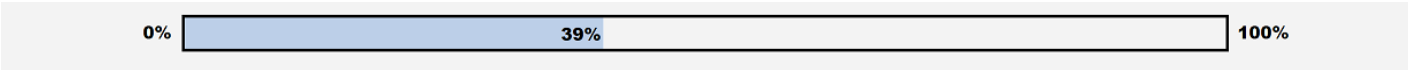
- ◯ Most will die of breast cancer
- ◯ About half will die of breast cancer
- ◯ Most will NOT die of breast cancer

After which treatment is it more likely that women will need to have a second surgery to remove leftover tumor cells?

- ◯ Lumpectomy
- ◯ Mastectomy without reconstruction
- ◯ Equally likely for both

Which treatment option does NOT affect the appearance of the breast?

- ◯ Active monitoring
- ◯ Lumpectomy
- ◯ Lumpectomy with radiation
- ◯ Mastectomy



On average, which DCIS patients do you think have the highest chance of being diagnosed with invasive cancer in the same breast, within 10 years of diagnosis?

- ◯ Women who choose active monitoring
- ◯ Women who choose a mastectomy
- ◯ Women who choose a lumpectomy with radiation
- ◯ There is no difference between the above options

After a lumpectomy, what is the traditional schedule for radiation treatment?

- ◯ 1 day a week for 5 to 6 weeks
- ◯ 3 days a week for 6 weeks
- ◯ 5 days a week for 3 weeks
- ◯ 5 days a week for up to 10 weeks

Out of 100 women who have radiation treatment after lumpectomy, how many will have serious side effects, such as another cancer, heart problems, or lung problems?

- ◯ Fewer than 2
- ◯ 2-4
- ◯ 5-10
- ◯ 11-20
- ◯ More than 20

Mark whether some women have this side effect from radiation treatment after lumpectomy (choose all that apply):

- ☐ Fatigue
- ☐ The breast skin might change color
- ☐ The breast feels harder and thicker
- ☐ Migraines

In your opinion, does the DCIS website...

...help women recognize that a treatment decision needs to be made?

- ◯ Not at all
- ◯ A little
- ◯ Somewhat
- ◯ Quite a bit
- ◯ A great deal

...prepare women to make better treatment decisions?

- ◯ Not at all
- ◯ A little
- ◯ Somewhat
- ◯ Quite a bit
- ◯ A great deal

...help women think about the pros and cons of each treatment option?

- ◯ Not at all
- ◯ A little
- ◯ Somewhat
- ◯ Quite a bit
- ◯ A great deal

...help women think about which treatment option pros and cons are most important?

- ◯ Not at all
- ◯ A little
- ◯ Somewhat
- ◯ Quite a bit
- ◯ A great deal

In your opinion, does the DCIS website...

...help women know that the treatment decision depends on what matters most to them?

- ◯ Not at all
- ◯ A little
- ◯ Somewhat
- ◯ Quite a bit
- ◯ A great deal

...help women recognize their own thoughts about the treatment decision?

- ◯ Not at all
- ◯ A little
- ◯ Somewhat
- ◯ Quite a bit
- ◯ A great deal

...help women think about how involved they want to be in the treatment decision?

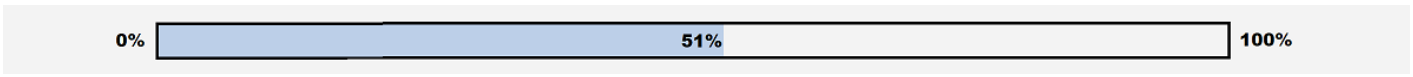
- ◯ Not at all
- ◯ A little
- ◯ Somewhat
- ◯ Quite a bit
- ◯ A great deal

...help women identify questions they want to ask their doctor?

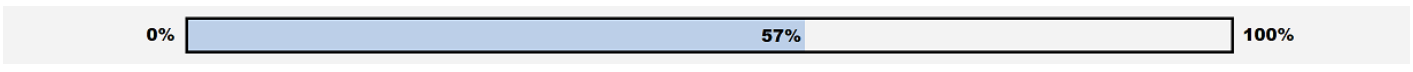
- ◯ Not at all
- ◯ A little
- ◯ Somewhat
- ◯ Quite a bit
- ◯ A great deal

...prepare women to talk to their doctor about what matters most to them?

- ◯ Not at all
- ◯ A little
- ◯ Somewhat
- ◯ Quite a bit
- ◯ A great deal



To help us improve the DCIS website, please recommend what we could change: _____



Now, we would like to ask you questions about you. While answering questions from now on, please think about yourself and your personal experiences.

How often do you need someone to help you when you are given information to read by your doctor, nurse, or pharmacist?

- ◯ Rarely
- ◯ Sometimes
- ◯ Often

When you need help with medical information can you easily get a hold of someone to assist you?

- ◯ Rarely
- ◯ Sometimes
- ◯ Often

Do you need help to fill in official medical documents (such as an insurance application)?

- ◯ Rarely
- ◯ Sometimes
- ◯ Often

Are you someone who likes to find out different information about your health?

- ◯ Rarely
- ◯ Sometimes
- ◯ Often

How often do you think carefully about whether health information makes sense in your particular situation?

- ◯ Rarely
- ◯ Sometimes
- ◯ Often

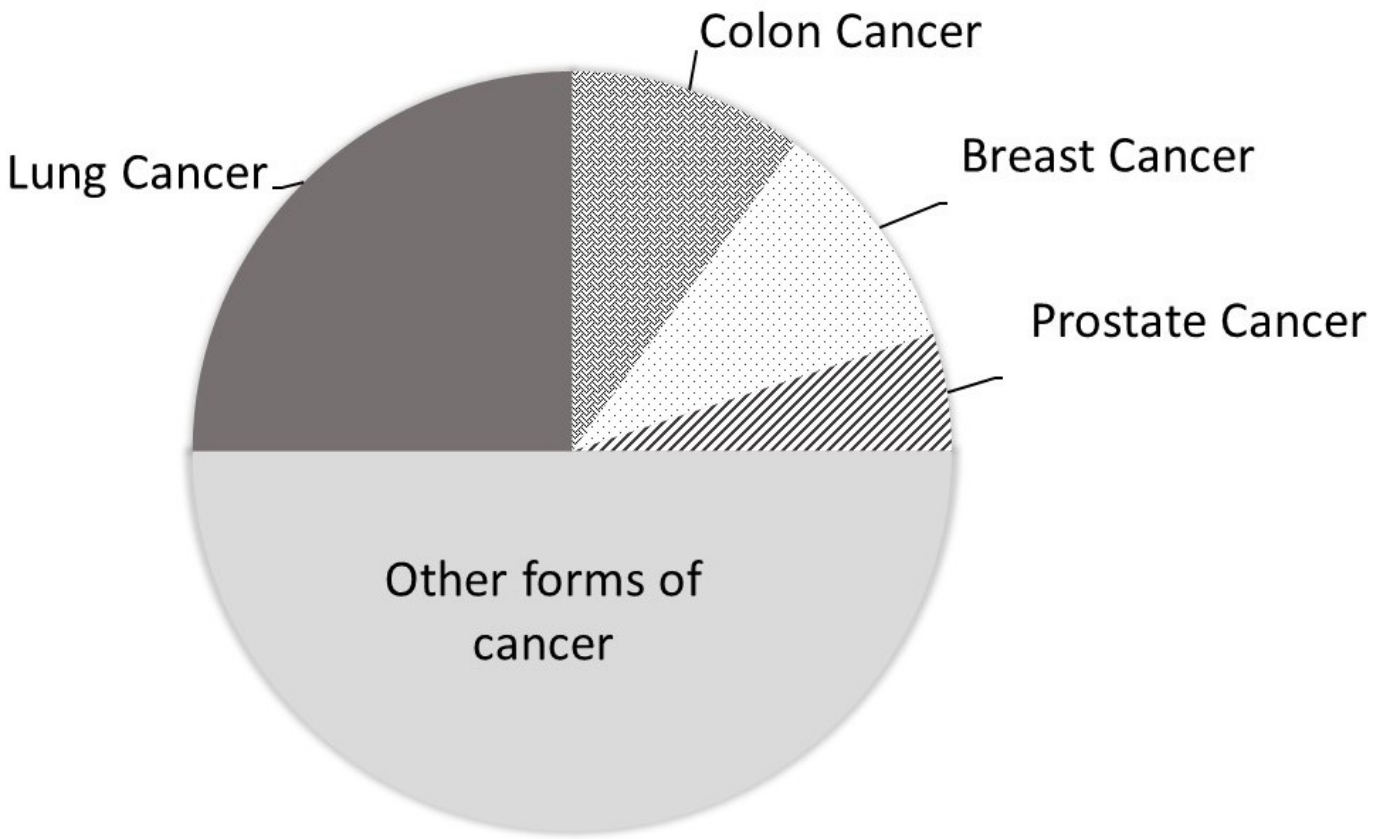
How often do you try to find out whether information about your health can be trusted?

- ◯ Rarely
- ◯ Sometimes
- ◯ Often

Are you the sort of person who might question your doctor or nurse's advice based on your own research?

- ◯ Rarely
- ◯ Sometimes
- ◯ Often

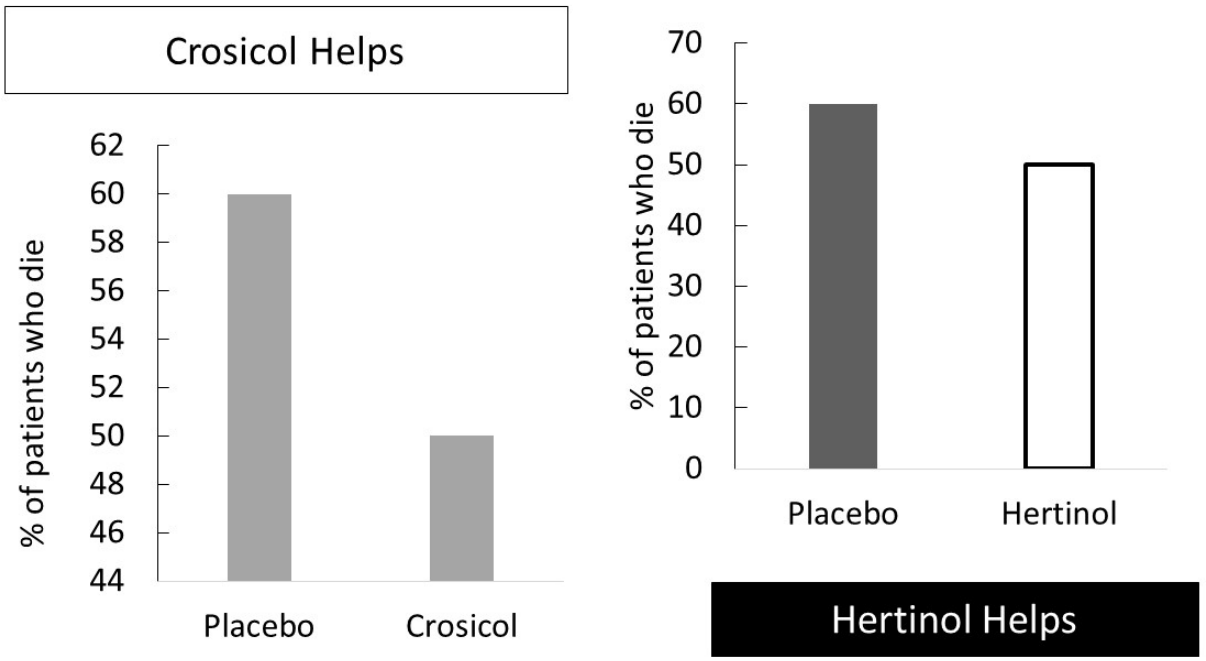
On the graph below, you see the percentage of people that die from different forms of cancer.



Approximately what percentage of people who die from cancer die from colon cancer, breast cancer, and prostate cancer taken together?

◯ 100%
◯ 25%
◯ 75%
◯ 50%
◯ Can't say

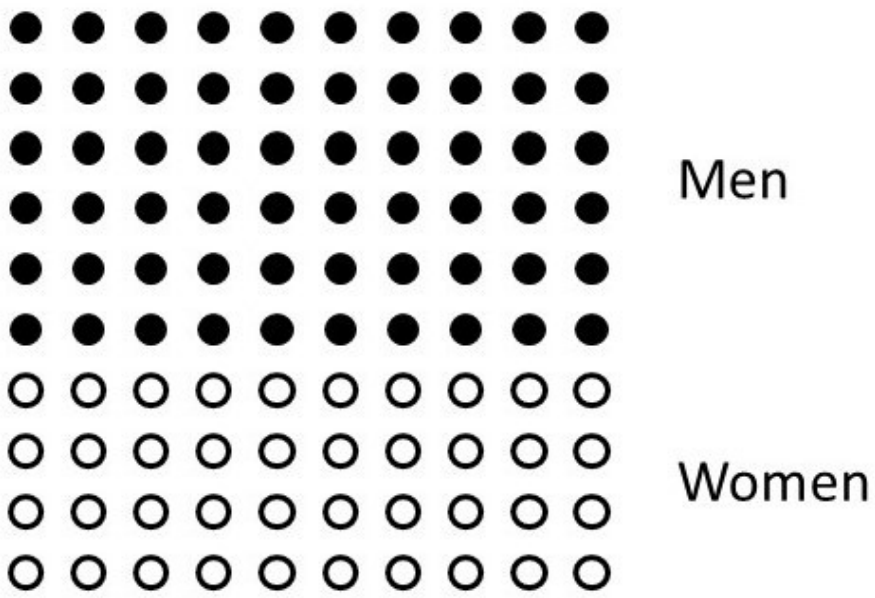
In a magazine, you see two advertisements, one on page 5 and another on page 12. Each is for a different drug for treating heart disease, and each includes a graph showing the effectiveness of the drug compared to a placebo (sugar pill).



Compared to the placebo, which treatment leads to a larger decrease in the percentage of patients who die?

- ◯ Crosicol
- ◯ Hertinol
- ◯ They are equal
- ◯ Can't say

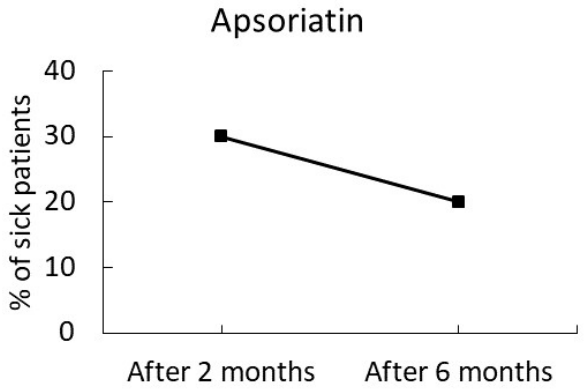
The following figure shows the number of men and women among patients with disease X. The total number of circles is 100.

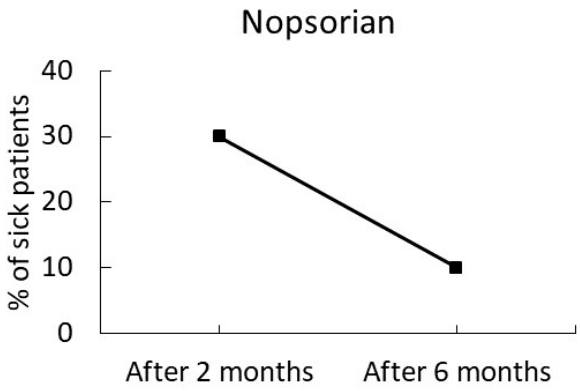


How many more men than women are there among 100 patients with disease X?

◯ 100
◯ 60
◯ 40
◯ 20
◯ 80
◯ Can't say

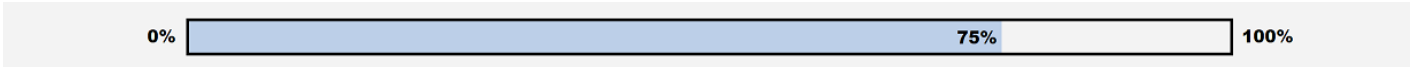
In the newspaper you see two advertisements, one on page 15 and another on page 17. Each is for a different treatment of psoriasis, and each includes a graph showing the effectiveness of the treatment over time.





Which of the treatments contributes to a larger decrease in the percentage of sick patients?

◯ Apsoriatin
◯ Nopsorian
◯ They are equal
◯ Can't say



Sometimes, medical action is clearly necessary, and sometimes it is clearly not necessary. Other times, reasonable people differ in their beliefs about whether medical action is needed.

In situations where it's not clear, do you tend to lean towards taking action or do you lean towards waiting and seeing if action is needed?

◯ I strongly lean toward waiting and seeing
◯ I lean toward waiting and seeing
◯ I somewhat lean toward waiting and seeing
◯ I somewhat lean toward taking action
◯ I lean toward taking action
◯ I strongly lean toward taking action

Taking risks makes life more fun.	◯ 1 Strongly disagree ◯ 2 ◯ 3 ◯ 4 ◯ 5 Strongly agree
My friends would say that I'm a risk taker.	◯ 1 Strongly disagree ◯ 2 ◯ 3 ◯ 4 ◯ 5 Strongly agree
I enjoy taking risks in most aspects of my life.	◯ 1 Strongly disagree ◯ 2 ◯ 3 ◯ 4 ◯ 5 Strongly agree
I would take a risk even if it meant I might get hurt.	◯ 1 Strongly disagree ◯ 2 ◯ 3 ◯ 4 ◯ 5 Strongly agree

Taking risks is an important part of my life.	◯ 1 Strongly disagree ◯ 2 ◯ 3 ◯ 4 ◯ 5 Strongly agree

I commonly make risky decisions.

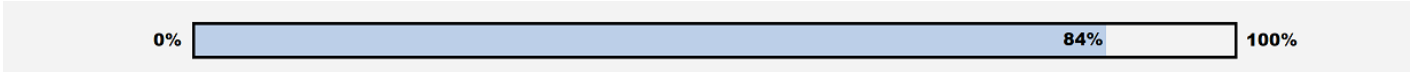
- ◯ 1 Strongly disagree
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Strongly agree

I am a believer of taking chances.

- ◯ 1 Strongly disagree
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Strongly agree

I am attracted, rather than scared by risk.

- ◯ 1 Strongly disagree
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Strongly agree



Pain seems to cause my heart to pound or race.

- ◯ 0 Never
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Always

When I hurt I think about pain constantly.

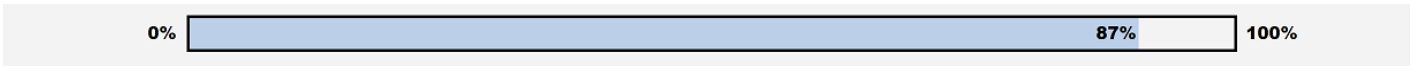
- ◯ 0 Never
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Always

I dread feeling pain.

- ◯ 0 Never
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Always

As soon as pain comes on, I take medication to reduce it.

- ◯ 0 Never
- ◯ 1
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Always



Having a thin body shape is...

- ◯ 1 Not at all important compared to other things in my life
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6 The very most important thing in my life

Being physically attractive to other people is...

- ◯ 1 Not at all important compared to other things in my life
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6 The very most important thing in my life

My personal appearance is...

- ◯ 1 Not at all important compared to other things in my life
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6 The very most important thing in my life

Feeling good about the way I look is...

- ◯ 1 Not at all important compared to other things in my life
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5
- ◯ 6 The very most important thing in my life

Think about you and your attitude toward cancer in your life.

How worried are you about getting cancer someday?

- ◯ 1 Not at all
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Almost all the time

How much does your worry affect your mood?

- ◯ 1 Not at all
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Almost all the time

How much does your worry affect your ability to perform your daily activities?

- ◯ 1 Not at all
- ◯ 2
- ◯ 3
- ◯ 4
- ◯ 5 Almost all the time

To help you classify how healthy you feel, we have drawn a scale for you to report how good or bad your health is in general; 100 being the best health for someone your age and 0 being the worst health for someone your age.

To indicate how healthy you feel, please use the slider to select the value that corresponds to your response.

0 = Worst health for someone your age

50

100 = Best health for someone your age

(Place a mark on the scale above)

What is your current marital status?

- ◯ In Relationship
- ◯ Married
- ◯ Divorced
- ◯ Separated
- ◯ Single
- ◯ Other

What is your age in years?

◯ 50	◯ 51	◯ 52	◯ 53
◯ 54	◯ 55	◯ 56	◯ 57
◯ 58	◯ 59	◯ 60	◯ 61
◯ 62	◯ 63	◯ 64	◯ 65
◯ 66	◯ 67	◯ 68	◯ 69
◯ 70	◯ 71	◯ 72	◯ 73
◯ 74	◯ 75	◯ 76	◯ 77
◯ 78	◯ 79	◯ 80	

Are you Hispanic or Latina?

- ◯ Yes
- ◯ No

With which of the following groups do you most closely identify (check all that apply)?

- ☐ White
- ☐ Black or African American
- ☐ American Indian or Alaska Native
- ☐ Asian or Pacific Islander
- ☐ Other

If "Other," please specify

_____

What is your highest level of education?

◯ Some high school
◯ High school
◯ Bachelor's degree
◯ Master's degree
◯ Professional degree (e.g., MD, JD)
◯ Doctorate degree (e.g., Ph.D.)

How would you describe your household's financial situation right now?

◯ After paying the bills, you still have enough money for special things you want
◯ You have enough money to pay the bills, but little spare money to buy extra or special things
◯ You have money to pay the bills, but only because you have cut back on things
◯ You are having difficulty paying the bills, no matter what you do

Do you have a personal history of cancer (any type)?

◯ Yes
◯ No

Do you have a family history of cancer? (here, by family we mean those related to you by blood)

◯ Yes
◯ No

If yes please choose among options below, (you may choose several options):

☐ My parent
☐ Grandparent
☐ Sibling
☐ Other

If "Other," please specify:

_____

Is English your main language at home?

◯ Yes
◯ No