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11/16/2010 Draft Quantitative Questionnaire, Phase II

Parameters

Proposed Study Design and Protocol

$$2 \times 2 \times 2 + 1 + 1$$

Administration (online, paper) x Context (yes, no) x format (bubbles, OTC) + online control + paper control

N = 1300; n per cell = 130

Online administration:

$$2 \times 2 + 1$$

		Format		
		Bubbles	OTC	
Context	Yes			+ Control (Med Guide)
	No			

Paper administration:

$$2 \times 2 + 1$$

		Format		
		Bubbles	OTC	
Context	Yes			+ Control (Med Guide)
	No			

Participants will be randomly assigned to conditions. Each participant will see only one version of the patient information.

The sample will be limited to people 18 years of age or older who have been diagnosed with:

- Rheumatoid arthritis,
- Juvenile rheumatoid arthritis,
- Ankylosing spondylitis, or
- Plaque psoriasis

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Participants will be prescreened to obtain a range of literacy levels and a relatively even gender split. Protocol will take place via Internet administration.

The computer program should have the capability to record time spent on any screen.

[PROGRAMMER: We need to record time in milliseconds spent on each screen (including questions and introductory screens) throughout protocol.

• Notes in red are for design purposes only and should NOT be visible to participants]

Protocol

Informed Consent Procedure (Participants will be blind to FDA's sponsorship).

[PROGRAMMER: First screen. Please include "Click to continue" button at bottom of each screen]

Thank you for agreeing to help us with this project today.

[PROGRAMMER: New screen]

Please make sure you are comfortable and can read the screen from where you sit. This project is about information that patients get with their prescription drugs. You will see a patient information sheet for a new drug called Rheutopia and then you will be asked some questions about it. You will be able to look at the information sheet as long as you like and return to it if needed at any point in the project. Your answers are kept private. This means that no one will ever connect your name with your answers. Your help is important and we thank you.

[PROGRAMMER: New screen]

When you have finished reading this screen, go on to the next screen to see a patient information sheet about a prescription drug. Please imagine that you have just picked up this prescription drug from the pharmacy and you are looking at the printed information that comes with it. Please look at the information sheet as long as you like and continue to the next screen to complete the project. You may view the information sheet in a pop-up screen as you go through the project, looking at it if you like.

[PROGRAMMER: Show participants randomly assigned version of information and record time spent. When participants click to next screen, give them method to access information again as needed.]

Now please answer the following questions based on the information you read in the patient information sheet.

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Q1. What does Rheutopia treat?
(open-ended)

Possible codes:

- Rheumatoid arthritis
- Juvenile rheumatoid arthritis
- Plaque psoriasis
- Osteoarthritis
- Acne
- Other (list)

[PROGRAMMER: randomize Q2a-d]

Q2. (Behavioral Intention) Imagine your doctor has recommended that you take Rheutopia. When you picked up the prescription, you received this patient information sheet along with the Rheutopia.

Please rate how likely you are to do each of the following five things.

	1 Very unlikely	2	3 Neither likely nor unlikely	4	5 Very Likely
a. Contact your doctor’s office to ask a question about Rheutopia				^	^
b. Look for more information about Rheutopia on your own				^	^
c. Ask your pharmacist a question about Rheutopia					
d. Start taking Rheutopia as prescribed	*	*			

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*Q2e. [PROGRAMMER: Ask only of participants who selected 1 or 2 in response to Q2d; open-ended]

How did you decide on your answer?
(open-ended)

Possible Codes:

- *Risks*
- *Too expensive*
- *Don't know why they need it*
- *Other*

^Q2f. [PROGRAMMER: Ask only of participants who selected 4 or 5 in response to Q2a or Q2b; open-ended]

What additional information would you look for?
(open-ended)

Possible Codes:

- *Side effects*
- *How well it works*
- *Drug interactions*
- *How long it takes to work*
- *Other*

(Self-efficacy)

Q3. How confident are you that you can read and understand the information on this sheet?

1	2	3	4	5
Not at all confident		Somewhat confident		Very confident

(Perceived risk)

[PROGRAMMER: Randomize Q4-Q8]

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Q4. Based on the patient information sheet, would you be worried about getting a side effect from Rheutopia?

Yes
 No

[PROGRAMMER: If yes to Q3, ask Q3a]

Q4a. How *worried* would you be about getting a side effect from Rheutopia?

1	2	3	4	5
Not at all worried		Somewhat worried		Very worried

Q5. Based on the patient information sheet, how safe would Rheutopia be for you?

1	2	3	4	5
Not at all safe		Somewhat safe		Very safe

Q6. Based on the patient information sheet, how *risky* would Rheutopia be for you?

1	2	3	4	5
Not at all risky		Somewhat risky		Very risky

Q7. How likely do you think you are to get a serious infection if you were to take Rheutopia?

1	2	3	4	5
Not at all likely		Somewhat likely		Very likely

Q8. How likely do you think you are to have side effects like headache, redness or runny nose if you were to take Rheutopia?

1	2	3	4	5
Not at all likely		Somewhat likely		Very likely

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(Perceived benefit)

Q9. Based on the patient information sheet, how *well* would Rheutopia *work* for you?

1 2 3 4 5
Not at all Somewhat Very well

Q10. How likely is it that Rheutopia would improve your symptoms of [insert condition]?

1 2 3 4 5
Not at all likely Somewhat likely Very likely

Please answer the following questions the best you can based on the information sheet you have.

[PROGRAMMER: Randomize order of Q11-Q17 and randomize response options within each question except for the “not sure” answers, which should always be last]

Q11. Mary has been taking Rheutopia for 4 weeks. She woke up and noticed that her vision is blurry. She is about to take her next dose of Rheutopia. According to the patient information sheet, what should Mary do?

- Take her next dose
- Take her next dose then call her doctor
- Not take the next dose and call her doctor
- Not sure

Q12. Ted takes Rheutopia. He noticed an area on his skin that was warm, red and painful. According to the patient information sheet, what should Ted do?

- Soak the area in warm water
- Soak the area in warm water and take a pain medicine
- Take the next dose of Rheutopia and call his doctor
- Not take the next dose and call his doctor
- Not sure

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Q13. According to the patient information sheet, people who take Rheutopia can develop dry skin.

- True
- False
- Not sure

Q14. The patient information sheet says Rheutopia can affect your immune system. Because it affects your immune system, what can happen if you take Rheutopia?

- Nothing
- The Rheutopia will help you fight infection
- You may develop a bad infection and could die
- Not sure

Q15. Rosie went to the pharmacy and picked up her prescription for Rheutopia. She has never given herself a shot before and no one has taught her how. According to the patient information sheet, what should Rosie do?

- Wash her hands before giving herself the shot
- Get instructions online on how to give herself a shot
- Call her doctor to get instruction on how to give herself a shot
- Not sure

Q16. Jack missed his dose of Rheutopia. According to the patient information sheet, what should Jack do?

- Take two doses as soon as he remembers
- Take the missed dose as soon as he remembers then take the next dose at his regularly scheduled time
- Skip that dose and take the next dose on time
- Not sure

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Q17. According to the patient information sheet where should Rheutopia be stored?

- In the medicine cabinet
- In the freezer
- In the refrigerator
- Not sure

Q18. (Recognition of uses) Please check which of the following were mentioned in the information sheet as reasons you might take Rheutopia.

[PROGRAMMER: *randomize*]

	Yes	No
a. Rheutopia reduces painful and swollen joints.	x	
b. Rheutopia treats rheumatoid arthritis in adults.	x	
c. Rheutopia slows joint damage.	x	
d. Rheutopia treats juvenile rheumatoid arthritis (JRA).	x	
e. Rheutopia treats ankylosing spondylitis.	x	
f. Rheutopia improves mobility.	x	
g. Rheutopia treats plaque psoriasis.	x	
h. Rheutopia clears up areas of skin with psoriasis.	x	
i. Rheutopia treats aplastic anemia.		x
j. Rheutopia treats Lou Gehrig's disease.		x
k. Rheutopia increases lung capacity.		x
l. Rheutopia reduces hyperactivity.		x
m. Rheutopia promotes hair growth.		x
n. Rheutopia slows bone loss.		x

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Q19. Based on the information in the patient information sheet, what should you tell your healthcare provider about before taking Rheutopia? [PROGRAMMER: randomize] (Contraindications)

	Yes	No
a. If you think your in-grown toenail is infected.	x	
b. If you have ever tested positive for TB (tuberculosis).	x	
c. If you have recently lived in France.	x	
d. If you have nervous system problems	x	
e. If you have ever had a heart attack.	x	
f. If you are taking the medicine Kineret	x	
g. If you just had a vaccination.	x	
h. If you have kidney problems		x
i. If you have migraine headaches		x
j. If you have recently mowed grass or trimmed trees		x
k. If you recently had surgery		x
l. If you sometimes have blurry vision		x
m. If you have a family history of high cholesterol		x

Q20. James developed redness around the skin where he has given himself a Rheutopia shot. According to the patient information sheet, is redness something that can happen when taking Rheutopia?

Yes
 No
 Not sure

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Q21. Kate has been taking Rheutopia for 4 weeks. She has noticed that she has a headache right after she takes Rheutopia but it goes away in few hours. After her last dose of Rheutopia Kate developed a headache that got worse and has lasted for several days. According to the patient information sheet, what should Kate do?

- Take pain medicine before her next scheduled dose
- Stop taking Rheutopia and take a pain medicine
- Call her doctor
- Not sure

Q22. (Recognition of warnings/side effects) Please check which of the following were mentioned in the information sheet as possible side effects of taking Rheutopia.

[PROGRAMMER: *randomize*]

	Yes	No
a. lowered ability to fight infections	x	
b. TB (tuberculosis)	x	
c. vision problems	x	
d. swollen lymph nodes	x	
e. sudden weight gain	x	
f. redness and swelling where injection was given	x	
g. headache	x	
h. blindness		x
i. hearing problems		x
j. muscle weakness		x
k. increased chance of kidney failure		x
l. MS (multiple sclerosis)		x
m. stomach pain		x

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[PROGRAMMER: Randomize order of Q23a-b]

Q23. (Ease of understanding) Please answer each of the statements below.

	1 Not at all Clear	2	3 Somewhat Clear	4	5 Very Clear/
a. The information about the risks of Rheutopia in the patient information sheet is...					
b. The information about the uses of Rheutopia in the patient information sheet is...					

[PROGRAMMER: Randomize order of Q24a-b]

Q24. (Ease of understanding) Please answer each of the statements below.

	1 Easy to Understand	2	3 Somewhat Easy to Understand	4	5 Hard to Understand
a. The information about the risks of Rheutopia in the patient information sheet is...					
b. The information about the uses of Rheutopia in the patient information sheet is...					

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[PROGRAMMER: randomize Q13-Q15]

Q25. (Subjective health literacy) How often do you have someone (like a family member or friend) help you read instructions, pamphlets, or other written material from your doctor or pharmacy?

- Never
- Occasionally
- Sometimes
- Often
- Always

Q26. (Subjective health literacy) How confident are you filling out forms by yourself?

- Extremely
- Quite a bit
- Somewhat
- A little bit
- Not at all

Q27. (Subjective health literacy) How often do you have problems learning about your medical condition because of difficulty understanding written information?

- Never
- Occasionally
- Sometimes
- Often
- Always

[PROGRAMMER: For the next several questions, please insert the appropriate medical condition based on the screener data]

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Q28. How long ago did a healthcare provider tell you you had *[insert medical condition]*?

- Six months ago or less
- More than six months ago but less than a year ago
- A year ago or more but less than five years
- Five years ago or longer

Q29. Are you taking a prescription medicine now for *[insert medical condition]*?

- Yes
- No
- I'm not sure

Q30. How severe is your *[insert medical condition]* now? Would you describe it as:

- Very mild
- Mild
- Moderate
- Serious
- Very serious

Q31. In general, how much would you say you know about *[insert medical condition]*? Would you say you know:

- Nothing at all
- Only a slight amount
- Some
- More than some but not a lot
- A lot

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Q32. In general, how much would you say you know about treatments for [*insert medical condition*]? Would you say you know:

- Nothing at all
- Only a slight amount
- Some
- More than some but not a lot
- A lot

The next few questions about you.

Q33. Are you:

- Hispanic or Latino
- Not Hispanic or Latino

Q34. Which of these best represents your race? You may choose one or more. Would you say that you are:

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

Q35. Gender

- Male
- Female

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Q36. How many years of education have you had?

- Some grade school
- Completed grade school
- Completed middle school
- Some high school
- Completed high school or GED
- Some college
- Associate's Degree (2-year)
- Bachelor's Degree (4-year)
- Some postgraduate work
- Postgraduate degree (M.A., Ph.D., M.D., J.D., etc.)

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The next and final set of questions focuses on topics related to health and health care. First, you will read, view, or hear some health-related information. Then you will be asked some questions related to the information. The purpose of these questions is to find out what most people think and understand about some health care issues. If you do not know the answer to a question, then it is okay to check the box that says “Don’t know.” Some of the questions use names of people who are not real.

Q37. Cholesterol: Know What Your Level Means

<p>Cholesterol: What Your Level Means</p> <p>What is cholesterol?</p> <p>Cholesterol is a waxy substance the body uses to protect nerves, make cell tissues and produce certain hormones.</p> <p>Are there different types of cholesterol?</p> <p>Yes. Cholesterol travels through the blood in different types of packages, called lipoproteins.</p> <p>Low-density lipoproteins (LDL) deliver cholesterol to the body. High-density lipoproteins (HDL) remove cholesterol from the bloodstream.</p>	<p>Total cholesterol level</p> <ul style="list-style-type: none">• Less than 200 is best.• 200 to 239 is borderline high.• 240 or more means a person is at increased risk for heart disease. <p>LDL cholesterol levels</p> <ul style="list-style-type: none">• Below 100 is ideal for people who have a higher risk of heart disease.• 100 to 129 is near optimal.• 130 to 159 is borderline high.• 160 or more means a person is at a higher risk for heart disease. <p>HDL cholesterol levels</p> <ul style="list-style-type: none">• Less than 40 means a person is at higher risk for heart disease.• 60 or higher greatly reduces a person’s risk of heart disease.
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Please answer the following questions based on the information in the text.

Which set of low density lipoprotein (LDL) and high density lipoprotein (HDL) levels is best?


Select one answer only

- LDL of 134 and HDL of 61
- LDL of 98 and HDL of 82
- LDL of 140 and HDL of 50
- LDL of 165 and HDL of 80
- Not sure

Q38. Medical Center Information—audio recording

7. Medical Center Information - audio recording

Please listen to the recording below before proceeding to the next screen.



Please answer the following questions based on the information in the audio clip.

[Click here if you would like to listen to the recording again.](#)

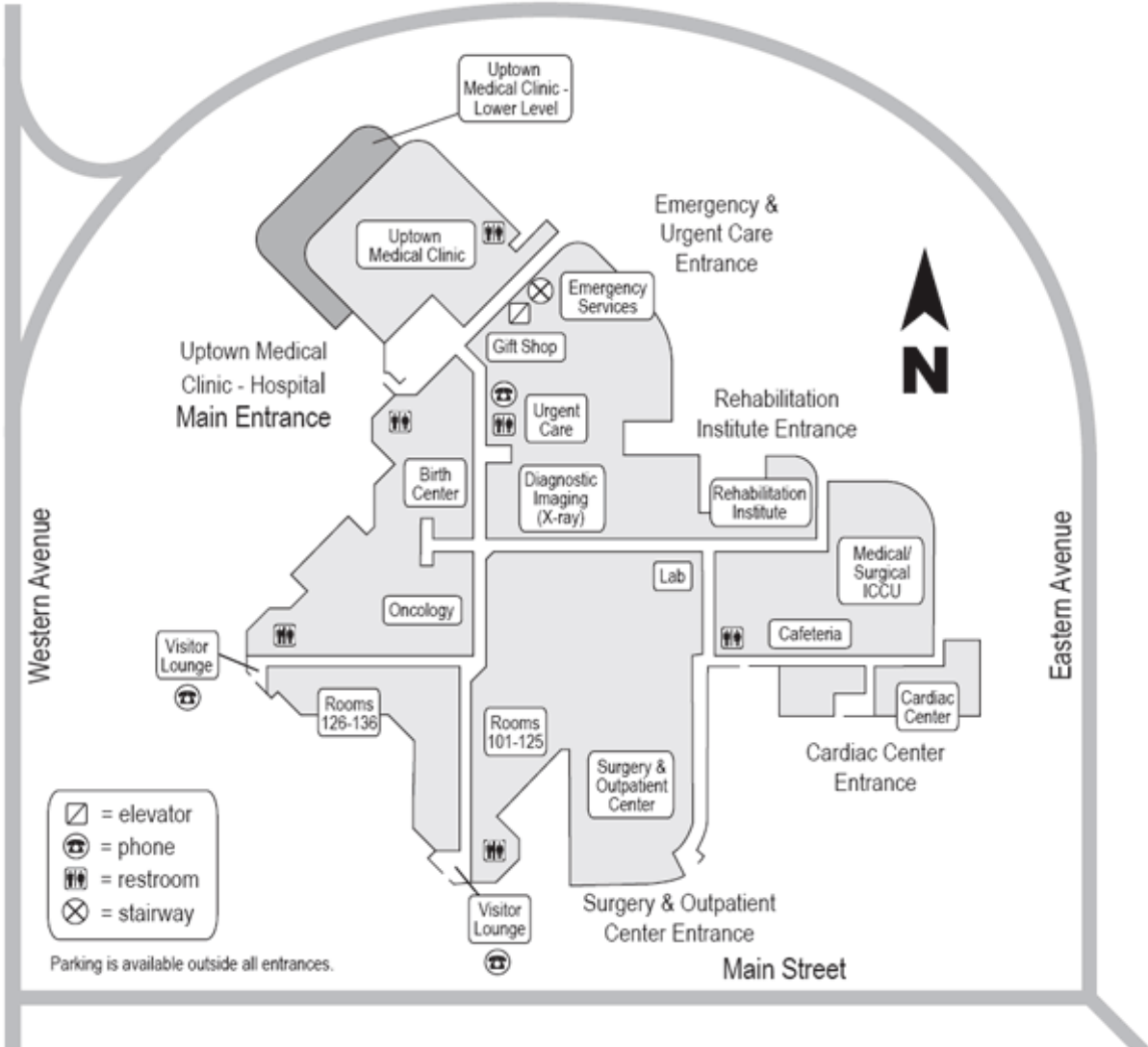
If a person was worried about his cough, what number should he press?

Select one answer only

- 1
- 2
- 4
- Call 911
- Not sure

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Q39. Hospital Map



Please answer the following questions based on the information in the map.

Which of the following entrances is closest to the elevator?

Select one answer only

- There is no elevator
- Surgery & Outpatient Center Entrance
- Rehabilitation Institute Entrance
- Main Entrance
- Don't Know

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Q40. Medicine Record

Be an Active Member of Your Health Care Team
My Medicine Record



Name: _____ Birth date: _____

	What I'm Using Rx-brand & generic name; OTC-name & active ingredients	What It Looks Like color, shape, size, markings, etc.	How Much	How to Use / When to Use	Start / Stop Dates	Why I'm Using / Notes	Who Told Me to Use / How to Contact
<i>--- Enter ALL prescription (Rx) medicine (include samples), over-the-counter (OTC) medicine, and dietary supplements ---</i>							
Ex	XXXX/xxxxxxxxxx	20 mg pill; small, white, round	40 mg; use two 20 mg pills	Take orally, 2 times a day, at 8:00 am & 8:00 pm	1-15-06	Lowers blood pressure; check blood pressure once a week; blood test on 4-15-06	Dr. X (800) 555-1212
1							
2							
3							
4							
5							
6							
7							
8							

www.fda.gov/usemedicinesafely/my_medicine_record.htm

(888) INFO-FDA
www.fda.gov/usemedicinesafely

These are my medicines as of: _____

FORM FDA 3664 (8/07)

Please answer the following questions based on the information in the chart.

In the example listed in the first row of the table, when should the medicine be taken?

Select one answer only

- Two times a day anytime between 8 a.m. and 8 p.m.
- At 8 a.m. or 8 p.m. each day
- At 8 a.m. and 8 p.m. each day
- Don't Know

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Q41. Calories burned

Please read the questions below, then visit the following website to answer the questions. Answer the questions based on the information in the website.

<http://www.healthwise.net/rti/Content/StdDocument.aspx?DOCHWID=tx4394>

Interactive Tool: How Many Calories Did You Burn?

What does this tool measure?



Click here to [find the number of calories you burn during exercise and daily physical activities](#).¹

This interactive tool measures how many calories are burned during common activities. The food you eat is measured in calories. The energy you use every day is also measured in calories. You are using energy all the time, even at rest. The more vigorous the activity and the longer the time you do it, the more calories you burn.


This tool also uses your weight to calculate calories burned, because a heavier person burns more calories during activity than a lighter person.

Author: [Debra Colonna, MD](#)
Medical Review: [Adam Laskovic, MD - Family Medicine](#)

Last Updated: [July 28, 2009](#)

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Please answer the following questions based on the information in the website.

Kate weighs 150 pounds. Which activity would burn the most calories?

Select one answer only

- Walking at a medium pace for 30 minutes
- Raking the lawn for 30 minutes
- Bowling for 30 minutes
- Don't Know

Q42. Signs of a stroke

Signs of a Stroke

My mother is alive today because a police officer knew the signs of a stroke. You can save a life, too, if you learn these signs.

Mom was on her way to the dentist when a police officer noticed she was driving strangely and started to follow her. She pulled over on the highway. When the officer approached her, she told him she had a blinding headache. But she said that she had to get to her dentist appointment on time.

The officer also noticed that mom just wasn't acting right. Some of her speech was confused. And she was a little dizzy.

Mom said she felt fine, but that didn't stop the officer. He quickly called 911. That call saved my mother's life.

Knowing the signs of a stroke could help you save a life, too. Remember, some people have all of these signs, but my mom only had a few.

If you or someone else has even a few of these signs, get help fast!



Five Signs of a Stroke

- Sudden numbness or weakness of the face, arm or leg, especially on one side of the body
- Sudden confusion, trouble speaking or understanding
- Sudden trouble seeing in one or both eyes
- Sudden trouble walking, dizziness, or loss of balance
- Sudden, severe headache

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Please answer the following questions based on the information in the flyer.

Which of the following is NOT a sign of a stroke?

Select one answer only

- Shaking chills
- Blurred vision
- Bad headache
- Numbness on one side
- Don't Know

Q43. Portion Control for Weight Loss

Expanding portions

Are you eating a variety of healthy foods, exercising and still struggling with your weight? Some people may need to pay closer attention to portion control — managing the amount of food that they eat — as their total calorie intake determines their weight.

A serving isn't what they happen to put on their plate. It's a specific amount of food defined by common measurements, such as cups, ounces or pieces. The serving sizes represented here are part of the Mayo Clinic Healthy Weight Pyramid — a food pyramid designed to promote weight loss and long-term health. Use these serving sizes in conjunction with a diet based on a variety of healthy foods. Add the right amount of regular physical activity, and a person will be well on their way to enjoying good nutrition and controlling their weight.

Vegetables

Until they're comfortable judging serving sizes, you may need to use measuring cups and spoons. A half a cup of cooked carrots, for example, equals one serving. Here are the recommended serving sizes for other vegetables:

Food	Serving size
Raw leafy vegetables	= 2 cups
Raw vegetables, chopped	= 1 cup

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Chopped, cooked = 1/2 cup
or canned
vegetables



Meat and beans

Familiar objects can help a person picture proper portions for meat, poultry, fish and beans. For example, a 3-ounce serving of fish is about the size of a deck of cards. Here are the serving sizes for meat and meat substitutes:

Food	Serving size
Cooked skinless poultry or fish	= 3 ounces
Cooked lean meat	= 1 1/2 ounces
Cooked legumes or dried beans	= 1/2 cup or about the size of an ice cream scoop
Egg	= 1 medium



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Please answer the following questions based on the information in the text and charts.

A person is cooking dinner for himself and he wants to include one serving from the meat and beans group. What should he choose?

Select one answer only

- 1 ½ ounces of cooked lean beef
- 1 ½ ounces of cooked fish
- 3 boiled eggs
- 1 cup of cooked kidney beans
- Don't Know


Q44.

Lunge

Please watch the video below before proceeding to the next screen.

16. Lunge

Please watch the video below before proceeding to the next screen.



Consult your doctor before beginning a strength training program, especially if you've been inactive or you have any health conditions.

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Please answer the following questions based on the information in the video clip.

[Click here](#) if you would like to watch the video again.

What parts of the body do lunge exercises work?

Select one answer only

- Arms and shoulders
- Back and abdomen
- Legs and buttock
- Don't Know

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Q45. Food Nutrition Label

Nutrition Facts		* Percent Daily Values are based on a 2,000 calorie diet. Your daily values may be higher or lower depending on your calorie needs:	
Serving Size 140 grams (140g)		Calories: 2,000 2,500	
Servings Per Container 1			
Amount Per Serving			
Calories 140	Calories from Fat 70		
	% Daily Value*		
Total Fat 7g	11%		
Saturated Fat 2.5g	13%		
<i>Trans</i> Fat 0g			
Cholesterol 25mg	8%		
Sodium 300mg	13%		
Total Carbohydrate 9g	3%		
Dietary Fiber 2g	8%		
Sugars 3g			
Protein 8g			
Vitamin A 10% • Vitamin C 20%			
Calcium 4% • Iron 10%			

Ingredients: Tomatoes; Chicken; Mushrooms; White Wine; Celery; Onions; Green Bell Pepper; Flour; Butter; Olive Oil; Salt; Black Pepper.

Sherri Pinero, RD, www.recipeanalysis.com

Please answer the following questions based on the information in the label.

If a person is on a 2,500 calorie diet, what percent of the daily value of saturated fat would he get from one serving?

Select one answer only

- 10 percent
- 11 percent
- 12 percent
- 13 percent
- Not sure

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Q46. Prostate Cancer

Number of Men Out of 100 Who Die from Prostrate Cancer Versus Other Diseases



Please answer the following questions based on the information in the chart.

More men die from prostate cancer than from other causes. Based on the chart above, would you say this is true, false, or are you not sure?

Select one answer only

True

False

Not sure

[\[PROGRAMMER: New screen\]](#)

This concludes the survey. Our goal was to gather patient reactions to important information about prescription drugs. To get your true reaction to this information, we used a fake brand of drug in this project. Rheutopia is not a real drug and it is not available for use or sale. Please contact your healthcare provider for any questions about your health.

Thank you very much for your time.

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