

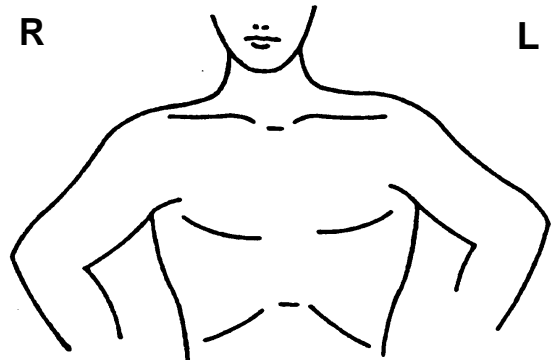


ID: _____

Date: ____ / ____ / ____

Baseline Rose Questionnaire – Angina

Visit: SV1 02

- | | Yes | No |
|---|---|--------------------------------------|
| 1. In the past month , have you had any pain or discomfort in your chest? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2
→ Stop |
| 2. Do you get this pain or discomfort when you walk uphill or hurry? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2
→ Stop |
| 3. Do you get this pain when you walk at an ordinary pace on the level? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2 |
| 4. When you get any pain or discomfort in your chest, what do you do? | stop <input type="checkbox"/> 1
slow down <input type="checkbox"/> 2
continue <input type="checkbox"/> 3 | <input type="checkbox"/> 3
→ Stop |
| 5. Does it go away when you stand still? | <input type="checkbox"/> 1 | <input type="checkbox"/> 2
→ Stop |
| 6. How soon? | 10 minutes or less <input type="checkbox"/> 1
>10 minutes <input type="checkbox"/> 2 | <input type="checkbox"/> 2
→ Stop |
| 7. Where do you get this pain or discomfort?
(mark the place(s) with X in the diagram) | <div style="display: flex; justify-content: space-between; align-items: center;"> R  L </div> | |

Office use

8. Outcome: *Positive 1
Negative 2

* If positive, refer to clinician and complete follow up worksheet.

Reviewed by (staff ID): _____
Entered by (staff ID): _____

Rose Questionnaire-Angina

Overview

The purpose of this interviewer-administered form is to identify individuals with angina of effort. This form may be self administered if it is thoroughly explained to the participant. If it is self-administered, it is suggested that the first question be interviewer-administered, and the questionnaire only handed out to participants who answer “Yes” to the first question.

The form will be used at SV1 to identify participants with suspected peripheral vascular disease who need physician approval to continue in the study. This form is also used during intervention as part of safety monitoring. When uncertainty remains after reviewing a question with these instructions, please indicate this on the questionnaire and send to the study clinician for review.

Administration Instructions

Using a blue or black pen, check the appropriate box to designate which visit this form (#06) was administered: SV1, 3, 6, 12, or 18 month.

Place ID label on page 1.

This form can be self administered but due to its complexity you may wish to administer it in an interview format.

<u>Page</u>	<u>Question</u>	<u>Special Administration Instructions (if any)</u>
1	1	If Yes, Q2 should be completed. If No, Stop. Severe indigestion should be coded as Yes.
	2	If Q1 = “Yes“, this question may not be left blank. If Yes, Q3 should be completed. If No, Stop. Climbing stairs counts as walking uphill.
	3	If both Q1 and Q2 = “Yes“, this question may not be left blank. Q4 should be completed regardless of the response selected in Q3. This question is to be used by the study clinician to help determine severity. It is not used in determining outcome.
	4	If both Q1 and Q2 = “Yes“, this question may not be left blank. If answer is “Stop” or “Slow Down“, Q5 should be completed. If answer is “Continue“, Stop.
	5	If both Q1 and Q2 = “Yes“ <u>and</u> Q4 = “Stop” or “Slow Down“, this question may not be left blank. If Yes, Q6 should be completed. If No, Stop.
	6	If Q1, Q2 and Q5 all = “Yes“, <u>and</u> Q4 = “Stop” or “Slow Down“, this question may not be left blank. If “10 minutes or less“, Q7 should be completed. If “>10 minutes“, Stop.

Page Question

1

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Special Administration Instructions (if any)

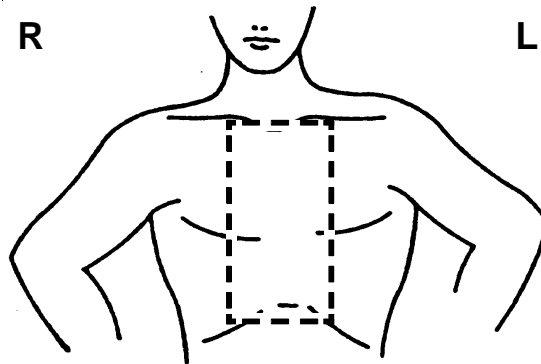
If Q1, Q2, and Q5 all = “Yes,” Q4 = “Stop” or “Slow Down”, and Q6 = “10 minutes or less”, this question may not be left blank. Participant should mark, using an “X”, all places where the pain or discomfort occurs. Valid response = at least one ”X” in any area. Staff person should complete Q8.

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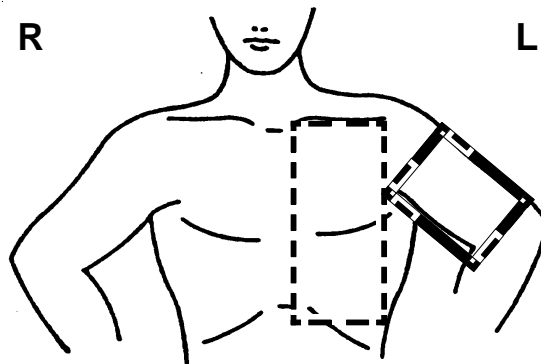
Should be filled out for all participants. If participant reached a “stop” outcome above, enter “Negative”. If at least one “X” appears on the diagram in either of the following areas: the center third of the chest (from clavicle to xiphoid) –OR- if both on the left side of the chest and the left arm, enter “Positive” and complete the worksheet.

See diagrams below for the allowable marking locations for a positive result. “X’s” must be in the dashed box(es) indicated on the diagrams.

For any other pattern of “X’s” enter “Negative“, regardless of participants’ responses to the other questions.



Positive (version 1):
X must be inside the area marked by the dashed box.



Positive (version 2):
An X must be inside the area marked by **each** dashed box (a total of 2 X’s).

Coding Instructions

Make sure all corrections are initialed and dated with an explanation.

When filling out the “Reviewed by” and “Entered by” box, be sure to use the correct staff ID number. The “Entered by” staff ID number should not be filled in until the form is entered.

Review Instructions

If the participant is Negative for Angina (Q8 = Negative), confirm that a “stop” outcome occurred on the form or Q7 has “X’s” on the diagram, anywhere, except in the center third of the chest (from clavicle to xiphoid) – OR – on “both on the left side of the chest and the left arm.” Enter “Negative” on the SV1 Visit Form (#03) for the Rose Questionnaire-Angina outcome.

If the participant is Positive for angina (Q8 = Positive), all of the following conditions must be met:

? Q1, Q2, = Yes

? Q4 = “Stop” or “Slow Down”

? Q5 = Yes

? Q6 = “10 minutes or less”

? Q7 = At least one “X” appears on the diagram in the center third of the chest (from clavicle to xiphoid) – OR – “X’s” appear on the diagram both on the left side of the chest and the left arm.

Note: Right chest pain alone does not make the outcome of this questionnaire positive, even if all other previous conditions are met. Left chest pain does not make the outcome of this questionnaire positive unless left arm pain is also marked. Jaw pain alone does not make the outcome of this questionnaire positive.

When all the above conditions are met (Q8 = Positive), staff must complete the Positive Angina screening worksheet.

If all of the above items look acceptable, enter your Staff ID number in the “reviewed by” section at the bottom of page 1, and enter “Positive” on the SV1 Visit Form (#03) for the Rose Questionnaire-Angina outcome.

Additional Instructions

For follow up visits, all positives trigger an AE form (#30). Study clinician must review all forms to determine if it is a false positive. If not, a serious AE form(#xx) must be completed.

Positive Angina Worksheet – Screening

This worksheet is to be completed for every participant who is coded as POSITIVE on Q8 of the Rose Questionnaire – Angina **during screening**.

Steps for all participants

- Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.

Referral Date: _____

Physician Name (if known): _____

Physician Phone (if known): _____

- Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM
- Does participant wish to continue in the trial? (circle one) YES / NO
(If YES, then go on to the following section. If NO, close the participant out as a “Refusal” on the visit form or on a closeout form if between visits).

Steps for participants who wish to continue in the trial:

- Contact participant’s physician to get approval for participation in the study. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. Approval requires a letter indicating that patient has had a negative stress test within the last 6 months, and that the physician approves of their participation in the study.

Physician Name: _____

Physician Phone: _____

Date of contact: _____

Date of physician contact: _____

Outcome of contact (circle one): EXCLUDE / OK TO CONTINUE

Notes: _____

- Study clinician reviews study chart

Study Clinician Name: _____

Date of Review: _____

Outcome of review (circle one): EXCLUDE / OK TO CONTINUE

Study Clinician Signature: _____

Notes: _____

(If both the participant’s physician and the study clinician say the participant is “OK to continue,” enter an outcome of “Eligible” on the Pre-Randomization Checklist. Otherwise, enter an outcome of “Ineligible.” To close the participant out prior to completing the Pre-Randomization Checklist, you can enter a closeout form with the reason coded as “Investigator discretion for safety”)

Positive Angina Worksheet – Follow Up Visits – Repeat Positives

This worksheet is to be completed for every participant who is coded as POSITIVE on Q8 of the Rose Questionnaire – Angina during a follow up visit, and has previously been POSITIVE.

Steps for repeat positives

- Study clinician reviews study chart for any signs that participant's condition has changed.

Study Clinician Name: _____

Date of Review: _____

Outcome of review (circle one): NEEDS REFERRAL* / OK TO CONTINUE

Study Clinician Signature: _____

Notes: _____

*If study clinician decides that participant needs referral:

- Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.

Referral Date: _____

Physician Name (if known): _____

Physician Phone (if known): _____

- Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM

Positive Angina Worksheet – Follow Up Visits – New Positives

This worksheet is to be completed for every participant who is coded as POSITIVE on Q8 of the Rose Questionnaire – Angina during a follow up visit, and has not previously been POSITIVE.

Steps for new positives

- Ask participant to refrain from participating in the exercise portion of the intervention until the follow-up has been completed.
- Refer the participant to their personal physician. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. If they do not have a personal physician, help them to find a physician.

Referral Date: _____

Physician Name (if known): _____

Physician Phone (if known): _____

- Confirm participant saw physician: (circle one) CONFIRMED / UNABLE TO CONFIRM
- Contact participant's physician to get approval for their continued participation in the exercise component of the intervention. Before contacting the physician, refer to the Participant Information Form (#100) to be sure you have permission to contact the physician. Approval requires a letter indicating that patient has had a negative stress test within the last 6 months, and that the physician approves of their participation in exercise component of the intervention.

Physician Name: _____

Physician Phone: _____

Date of contact: _____

Date of physician contact: _____

Outcome of contact (circle one): STOP EXERCISE / OK TO CONTINUE

Notes: _____

- Study clinician reviews study chart

Study Clinician Name: _____ Date of Review: _____

Outcome of review (circle one): STOP EXERCISE / OK TO CONTINUE

Study Clinician Signature: _____

Notes: _____

(If both the participant's physician and the study clinician say the participant is "OK to continue," inform participant that they can resume the exercise component of the intervention. Otherwise, notify participant that it has been decided that they should continue to refrain from the exercise component of the intervention.)