

# Elaboration and validation of an information manual for cardiac catheterization

Elaboração e validação de um manual informativo sobre cateterismo cardíaco

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## Keywords

Cardiac catheterization; Education, nursing; Nursing care

## Descritores

Cateterismo cardíaco; Educação em enfermagem; Cuidados de enfermagem

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## Abstract

**Objective:** To elaborate and validate an information manual for cardiac catheterization.

**Methods:** This was a methodological study. The manual was elaborated based on experience of researchers and data from the literature. The manual was validated by 8 nurses by using the Delphi technique; to be considered valid, agreement must reach 100%. Posteriorly, it was evaluated by 35 patients; at this stage the mean score must be 4 or greater.

**Results:** The manual covers the following topics: definition; location and time of conduction; how the procedure was done; and descriptions of care before, during, and after the procedure. A total of four rounds were needed to validate the manual with nurses. In the second step, all questions about the manual had a high mean score (4.83 to 4.91,  $p < 0.001$ ), making the manual valid for patients.

**Conclusion:** The manual was elaborated and considered valid by nurses and patients. The manual can be applied to different institutions.

## Resumo

**Objetivo:** Elaborar e validar um manual informativo sobre o cateterismo cardíaco.

**Métodos:** Trata-se de um estudo metodológico. O manual foi elaborado de acordo com a experiência dos pesquisadores e em dados da literatura. Foi submetido à validação por oito enfermeiros, utilizando a Técnica de *Delphi* e para ser considerado válido deveria alcançar 100% de concordância. Posteriormente foi avaliado por 35 pacientes e deveria alcançar uma média de pontuação igual ou superior a 4.

**Resultados:** O manual contém os tópicos: definição, local e tempo de realização, como ele é realizado e os cuidados antes, durante e após o procedimento. Foram necessárias quatro rodadas para validar o manual com os enfermeiros. Na segunda etapa observou-se que todas as questões sobre o manual tiveram médias altas (4,83 a 4,91,  $p < 0,001$ ), tornando o manual válido pelos pacientes.

**Conclusão:** O manual foi elaborado e considerado válido pelos enfermeiros e pacientes e, poderá ser utilizado por diversas instituições.

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## Introduction

In the United States, an estimated 85.6 million adults have one or more cardiovascular diseases.

<sup>(1)</sup> Among these diseases, the acute coronary syndrome (ACS) is of note. This disease is defined by an imbalance between supply and demand of oxygen to the heart, leading the patient to present signs and symptoms of acute myocardial ischemia. The main cause of this disease is the instability of an atherosclerotic plaque, but it also can result from an increased demand for oxygen by the heart. Three forms of ACS exist: acute myocardial infarction (AMI) with ST-segment elevation, AMI without ST-segment elevation, and unstable angina.<sup>(2)</sup>

In Brazil, an estimated 300,000 to 400,000 cases of AMI occur each year; for AMI, the coefficient of mortality per 100,000 inhabitants was 35.2 in 2002 and 39.36 in 2008, representing an increase of approximately 11%.<sup>(1)</sup> These diseases are diagnosed by electrocardiogram clinical signs and cardiac enzymes and are confirmed by cardiac catheterization.<sup>(2)</sup>

Because cardiac catheterization is an invasive diagnostic test, it often causes physiologic and psychological changes; anxiety and fear are the most common. According to an exploratory study on fear and anxiety in patients who underwent catheterization, the fear experienced before the procedure is related to concern about possible adverse events during exam, and anxiety results from the possibility of an unexpected diagnosis and prognosis. In addition, both the patient and his/her family member (or accompanying person) present anxiety before the procedure.<sup>(3-6)</sup>

Both feelings can cause physiologic changes in the patient, such as increased heart rate and blood pressure, which increase the consumption of oxygen and thereby worsen the development of the disease. In addition, these symptoms occur during invasive procedure, such as cardiac catheterization, and they can increase the duration of and may cause difficulties during the procedure, as well as leading to possible changes in the results of the exam and physical harm to the patient.<sup>(3)</sup>

A study showed that patients who underwent heart catheterization have gaps in knowledge about the procedure, mainly concerning the objective of the procedure,<sup>(4)</sup> which can generate more anxiety. In this context, health professionals must find ways to reduce these feelings and increase the knowledge of these patients.

There are many ways to reduce anxiety and fear and increase knowledge, such as nursing orientation. Nursing orientation reduces the insecurity of these patients and improves their understanding of future events. If the orientation is effective, it shows positive results in the nurse-patient relationship after the procedure.<sup>(7)</sup>

Orientation can be done verbally or by the use of alternative methods, such as information manuals.<sup>(7,8)</sup> An information manual aims to help professionals perform verbal orientation for patients and their family through health education. It enables a multidisciplinary team approach in the treatment process, recovery, and self-care; it also provides uniformity in orientation and better understanding of the individual in the health-disease process and steps to be taken for recovery.<sup>(8)</sup> In creating an information manual, social and cultural aspects of the target population must be considered.<sup>(9)</sup>

The objective of our study was to elaborate and validate an information manual for cardiac catheterization.

## Methods

This methodological study sought to elaborate and validate an information manual for cardiac catheterization. The elaboration and validation followed the steps described in other studies.<sup>(8,9)</sup>

According to Echer,<sup>(8)</sup> the first step is to seek existing scientific knowledge on the subject. Therefore, the manual was elaborated based on experience of researchers and data from the literature. We searched the literature indexed in PubMed, MEDLINE, LILACS and SciELO. Keywords used in LILACS and SciELO were “cardiac catheterization” and “care,” as well

as “cardiac catheterization” and “nursing.” In MEDLINE and PubMed, the keywords used were “cardiac catheterization” and “nursing,” including the boolean expression “and.”

Inclusion criteria were reports written in English, Portuguese, and Spanish; published between 2003 and 2014; and related to nursing care for cardiac catheterization. We excluded studies that lacked full text.

We selected four reports to elaborate the information manual.<sup>(10-13)</sup> In addition to the selected reports, we also included data from books on the subject.<sup>(14,15)</sup> After review of the literature, we elaborated a manual question-and-answer type that included the following items: definition, purpose, time of duration, local, care delivery before, during and after the procedure.

After elaboration of the manual, its content and format were validated. Validation was done in two steps: the first step was validation by nurses and the second step was done by patients. In the first step, a previous version of the manual was submitted to evaluation of eight nurses who agreed to participate in the study and who had a minimum of 2 years of experience in cardiology. Participants signed the consent form. The number of experts included depends on the phenomenon to be studied;<sup>(16)</sup> in our study we used the same number of experts used in another study.<sup>(9)</sup> We requested that nurses read and suggest changes to the content in order to improve the clarity (coherence) and language (appropriate language for the patient) of each topic of the manual. We also inquired about age, sex, educational level and area of professional activity.

The instrument used was a 3-point scale: 1, totally inadequate; 2, partially adequate; and 3, totally adequate. If the professional chooses a score of 1 or 2, he/she would suggest the changes needed. We evaluated the following items: definition; purpose; duration; care delivered before, during, and after the procedure; location where the procedure was carried out; how the procedure was done; and as the manual as a whole. In addition to the information contained in the

manual, nurses also evaluated the type of paper, the font size, illustrations, and accuracy. All these requirements had to be accepted by all nurses to be considered adequate.<sup>(9)</sup>

For validation in this first phase, we used the Delphi technique. This technique aims to achieve a consensus of opinion in a professional group about a specific topic. The Delphi technique uses questionnaires in a group of experts in the studied area, who must remain anonymous. Feedback with answers from the group and enhancement of the instrument are carried out to obtain the consensus of all professionals;<sup>(17)</sup> in the first study phase, this occurred when all items of the manual achieved a population of 3 (totally adequate).

Nurses were selected using the Lattes platform, which is an information system maintained by the Brazilian government to manage information on science, technology, and innovation related to individual researchers and institutions working in Brazil. In selecting the nurses, we considered the time they had worked in cardiology care (minimum of 2 years) and sought to include nurses from different hospitals. Afterward, patients were contacted and the objective of the study was explained to them. Once the nurses agreed to participate, the principal investigator applied the consent form, administered the assessment instrument, and gave the information manual to the professionals. The deadline to return the review was no later than 1 week.

After conclusion of the first stage, patients evaluated the final version of the manual; the convenience sample was composed of 35 patients. The sample size to verify the mean of each item of the information manual was greater than 4. The significance level was 5%; 95% confidence intervals were used; the standard deviation was 1.5; and the estimative error of 1 was of at least 26 interviewees.

Inclusion criteria were inpatients at a coronary unit who had already undergone cardiac catheterization and agreement to participate in the research. We excluded patients who had changes in

consciousness level, those who had vision problems, and those who were illiterate; all these patients were excluded because participants needed to read the content of the manual.

We used a 5-point scale Likert-type scale that evaluated the comprehensiveness of the manual. The minimum value was 1 (“I did not understand at all”) and the maximum value was 5 (“I fully understood and I do not have any doubt”). Patients had to evaluate the same topics that professionals did: the manual as a whole, definition, purpose, location, duration of the procedure, and care before and after the procedure. We also questioned about age, sex, level of education, and previous hospitalization.

Patients were approached personally by the principal investigator, and the objectives of the study were explained to them. Those who agreed to participate signed the consent form. After that, we gave participants the information manual and the assessment instrument. The principal investigator stayed close to the patient, but no further explanation was provided and no guidance about the content of the manual was given.

The manual was considered comprehensible when it achieved an average score of 4 or greater (“I understood almost everything”). We also evaluated the percentage of participants giving a score of 5 (“I fully understood and I do not have any doubt”), which must be 80% or greater.<sup>(9)</sup> To verify that means were higher than 4, we used the Wilcoxon test; to calculate the 95% confidence interval to maximal grades proportion (equal to 5), we used the binomial distribution.

Characteristics of the patients during the second stage of validation were analyzed in a descriptive form; we used absolute frequency (*n*) and relative frequency (%) for qualitative variables (sex, level of education, previous hospitalization) and mean, standard deviation, and minimal and maximal for quantitative variables (age). Software used for data analysis was R3.12; a significance level of 0.05 was used for all analyses.

The research project was approved by the Ethical and Research Committee of Hospital São Paulo (UNIFESP/EPM), number 542.492/14.

## Results

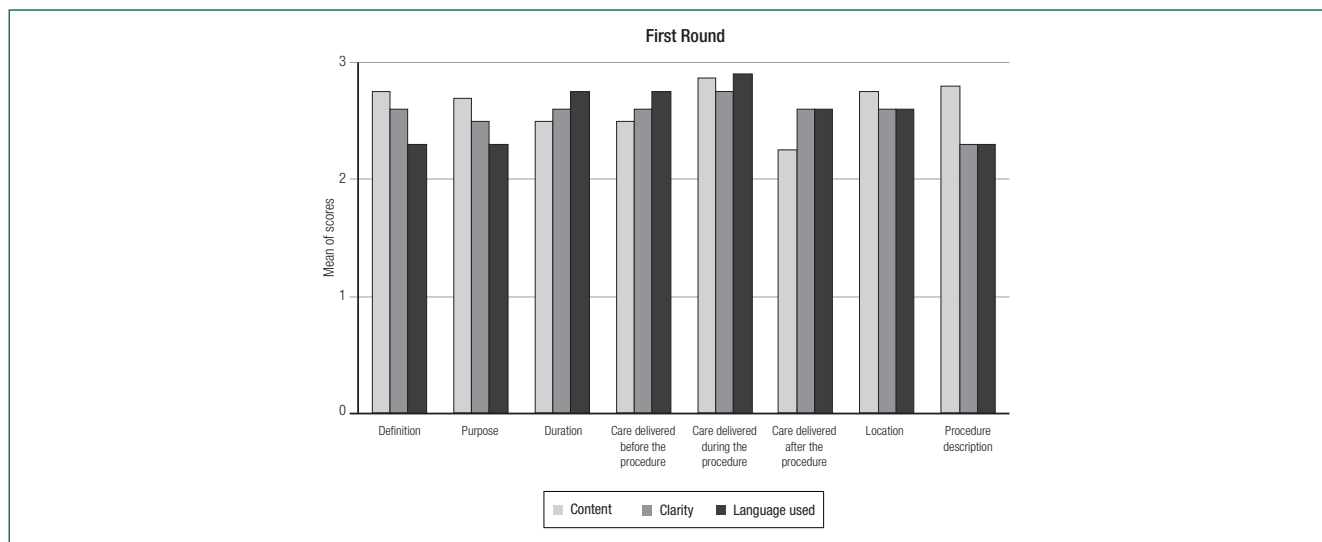
In the first validation, nurses ages ranged from 28 to 52 years, with mean age of 34.8 years. Seven nurses were women (87.9%). All nurses were specialized: 7 in cardiology (87.9%) and 1 in intensive care medicine (12.5%). Four had a master’s degree and 2 were attending a doctoral program. Most nurses had worked between 3 and 20 years in the area (mean, 10.5 years). Half of the professionals worked in an intensive care unit.

All nurses (100%) agreed that font size and type of paper of the manual were adequate in the first round. However, 37.5% (*n*=3) of professionals questioned the sharpness and purpose of the third figure; one nurse suggested more illustrations. To achieve 100% agreement, the third figure, which showed a nurse supporting the patient to be seated, was removed from the manual, once researchers reassessed and considered that this image was not in agreement with the content of the manual. Before removal of the figure, the manual was again forwarded to nurses, and all agreed removing the figure.

We used the Delphi technique to validate information content; four rounds were needed to obtain a consensus among experts.

In the first round, changes were suggested for 14 sentences: 1 about definition/purpose, 1 related to duration of the procedure, 3 about care before the procedure, 2 on care during the care, 4 on after the care, 1 on the location of the exam, and 2 on how the exam was carried out (Figure 1). We requested the inclusion of other care delivered before, during, and after the procedures, as well as inclusion of content on definition, location of the exam and how the procedure is carried out; a change was also suggested concerning the time needed to perform the procedure.

Sentences elaborated were redone according to the nurses’ suggestions. Only one change was not performed; this change was a request to replace “Sir/Madam” with “You,” but we decided not to make this change because most of the population performing the procedure is old and in Brazilian Portuguese the word “you” sounds informal. We chose to keep “Sir/Madam.”



**Figure 1.** Mean of score assessment of nurses on the first round of assessment of information manual

After reformulation, sentences were resubmitted for assessment of the professionals in a second round. We highlight that some paragraphs were divided into phrases to facilitate the analysis.

Following the second round, we suggested changes in 11 sentences (1 about definition, 1 about duration, 3 about care before the procedure, 3 about care during the procedure, 2 about care after the procedure, and 1 about location in which the exam was performed). Suggestions were mainly about changing words to improve understanding (language) and improve content of topics about care before, during, and after the procedure. Some suggestions were not implemented because they were related to protocols of different institutions, and researchers preferred to keep as much information as possible, such as time of resting after catheterization, which was kept as 3 to 6 hours. The 11 sentences were reformulated and reevaluated in the third round.

After the third round, 7 sentences (3 about care before the procedure, 1 about care after the procedure, 2 about care during the procedure, and 1 about location in which the exam was performed) were reformulated and resubmitted to another round. Suggestions concerned use of topic headings for better understanding instead of running text, and some suggestions referred to the content of sentences about care before and after the examination. For sentence 2, a professional suggested inserting a preceding sentence, which would be “Duration of the exam is approximately 30 to 50

minutes, but it can vary depending on each patient”; again the duration of hour of rest after the procedure was questioned. However, these changes were not made because these issues vary depending on the institution. Another suggestion not implemented regarded the removal of questioning the patient about allergy to seafood. This phrase was maintained because there was no consensus in the literature about relationship of seafood and allergy to contrast medium.

After the fourth round, there was a suggestion concerning the verbal agreement and not related with the content and; therefore, a new round was not needed. For this reason, the information manual was considered valid by experts.

After validation by professionals, the second stage entailed in assessment of the manual by 35 inpatients in coronary units who had already undergone cardiac catheterization.

The sample was predominantly composed of men (60.0%), almost half (48.6%) had finished high school or had a college degree, and more than half (51.4%) already had another admission modality. The mean age was  $55 \pm 11.19$  years (minimal, 32 years; maximal, 72 years).

The validation of the information manual showed that all questions about the manual had higher means (Table 1). Lower means were observed for items about care before, during, and after the procedure (means equal to 4.83). The Wilcoxon test rejected the hypothesis that these means are 4 or less.

**Table 1.** Hypothesis tests for information manual about cardiac catheterization

Variables	Mean	Median	Standard deviation	Minimal	Maximal	p-value*
Entire manual	4.86	5	0.43	3	5	< 0.001
Definition	4.89	5	0.32	4	5	< 0.001
Purpose	4.91	5	0.28	4	5	< 0.001
Time	4.86	5	0.36	4	5	< 0.001
Care delivered before the procedure	4.83	5	0.38	4	5	< 0.001
Care delivered during the procedure	4.83	5	0.45	3	5	< 0.001
Care delivered after the procedure	4.83	5	0.38	4	5	< 0.001

\*Wilcoxon test with null hypothesis of 4 or less and alternative hypothesis higher than 4

Table 2 shows the proportion of responses equal to 5 for each item, along with their confidence intervals. We verified that even in worse cases, for care delivered before and after the procedure, the proportion of equal responses to 5 was still high (83%; confidence interval, 66.35% to 93.44%).

Therefore, we observed that the manual had mean grades greater than 4 and that the proportion of maximal grades was higher, indicating that the manual was valid according to patients (Appendix 1).

**Table 2.** Percentage of responses of patients equal to 5 and confidence interval for the entire manual and the individual items

Variables	Proportion of 5's %	Confidence interval 95% *	
		Inferior %	Superior %
Entire manual	89	73.26	96.80
Definition	89	73.26	96.80
Purpose	91	76.94	98.20
Time	86	69.74	95.19
Care delivered before the procedure	83	66.35	93.44
Care delivered during the procedure	86	69.74	95.19
Care delivered after the procedure	83	66.35	93.44

\*Exact binomial confidence interval

## Discussion

Creating and validating information manuals is important for education of patients about therapeutic methods or complex diagnoses. The use of manuals is rising to facilitate the guidance of multidisciplinary teams, as well as to standardize the information by using simple language that helps improve patients' understanding, with proved efficacy.<sup>(7,8)</sup> For this reason, the present manual was elaborated

based on the literature and sought to provide relevant and necessary information on the procedure. Posteriorly, it was validated by nurses who worked with the phenomenon of the study and by patients who had undergone cardiac catheterization. A study that validated an educational guide on healthy diet during pregnancy also highlighted the importance of a literature search to guide the elaboration of the first version of the information manual, as well as to validate the content by experts in the area and by the target population.<sup>(18)</sup> The guidance material, when adequately elaborated, can change the lives of the specific population; thus, the information to be included must consider.<sup>(19)</sup>

The information manual was validated by nurses after four rounds. Similar results were identified in other studies showing validation of a manual after two to four rounds by using the Delphi technique.<sup>(9,20)</sup> Nurses made important modifications to the content. The content with more suggestions was the duration of bed rest after cardiac catheterization. Although the literature still shows no consensus regarding this issue, studies have investigated shorter bed rest and have shown no harms to the patient.<sup>(21-23)</sup> Regarding nurse characteristics, most nurses were female, corroborating the characteristics of the profession overall. All participants had, at the minimum, specialization that contributed to obtaining scientific knowledge added to clinical experience. A study emphasized the importance of validating specific content by specialists with clinical experience in the area.<sup>(24)</sup> Another topic to highlight is the professional diversity of nurses, once they were from different institutions that gathered different background knowledge about the studied topic.

There is no consensus in the literature about techniques used for assessment of information manuals.<sup>(18)</sup> The Delphi technique is one technique. The use of this technique allowed nursing professionals with specialization and different experiences to collaborate and achieve a consensus of opinion on a specific subject, thereby making a constructive decision and showing relevance for validation of instruments.<sup>(17)</sup>

Concerning the validation by patients, we observed that patients understood the manual in its entirety, and they ended up validating the instrument. Because most patients had not completed primary education, this result shows that the manual is easy to understand. Our study emphasizes the importance of adequate content expressed at the level of the culture and education of the patient, avoiding limitation of learning due to low educational level.<sup>(25)</sup> There is consensus that educational material must be written in a simple way that precisely communicates information.<sup>(18)</sup> Regarding the characteristics of patients undergoing cardiac catheterization, studies reported a mean patient age of 57 to 63 years, primarily men with a low educational level;<sup>(26,27)</sup> these findings agree with those reported in our study.

Items that reflected low patient understanding related to care delivered before, during, and after the procedure. We believe that this occurred because these items contained more information and this information had not been given to the patient before the procedure.

Participation of experts on the subject and individuals who received information increases the credibility and improves the content of information manuals, making the language more accessible.<sup>(25)</sup> We received new recommendations and information on cardiac catheterization, and therefore we believe that the manual must be reviewed and updated periodically.

An identified limitation factor in the second step of validation was the education level of the studied population. Their high degree of illiteracy and functional illiteracy delayed data collection because they were considered exclusion criteria.

Because our study was carried out in a cardiology unit and included a specific population, the same validations should be done while including other populations.

## Conclusion

The manual was elaborated and considered valid by nurses and patients. The manual can be used by a variety of institutions that treat these patients in order to instruct them about procedures that they will undergo.

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## Collaborations

Maciel BS, Barros ALBL and Lopes JL contributed to the conception of the study, interpretation of data, critical review relevant to intellectual content and approval of final version to be published.

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## Appendix 1. Information manual on cardiac catheterization

### What is a cardiac catheterization?

The exam verifies the presence of possible obstruction in vessels (arteries) of the heart, as well as other cardiac problems, and proposes an adequate treatment.

### Where the exam is done?

The exam is carried out at a special room that is cold because of the need to preserve the equipment. This room has a table for you (Sir/Madam) to lie down on and X-ray equipment so the physician can observe your heart.



Source: <http://www.centroalfa.com.br/empresa.html>

### How is the exam done?

You (Sir/Madam) will remain lying down and awake, and you must keep as still as possible during the entire exam to avoid contaminating the clothing that will cover you. Before beginning the catheterization, the physician or nursing team cleans up the site where the injection will take place (groin or arm) by using a product to reduce infection risk. Local anesthesia will be applied so that you (sir/madam) do not feel any pain. After local anesthesia, a catheter will be placed in a vessel of your arm or groin, and it will continue until it reaches the heart. Through the catheter, we will apply contrast material, which will enable the physician to visualize vessels and heart structures.

### How long is the exam?

The exam takes approximately 30 to 50 minutes, but this duration may vary.

### What preparation is required to perform the exam?

Care procedures before catheterization are:

- Fasting for at least 6 hours before the exam;

- Any blood pressure medicines should be taken with little water, even on the day of the exam;

- For diabetics, the medicine for diabetes should not be taken (*Metformin, Glucophage, Glucoformin, Dimefor, Glucovance*) for 24 hours before exam, and insulin should not be taken on the day of the exam, even if the patient has a high glycemic index;

- In case of use of anticoagulant (*Marevan, Coumadin, and Marcoumar*), patient should talk with his/her physician because the medication would be postponed 4 to 5 days before the exam.

You (Sir/Madam), if not hospitalized, must:

- Be accompanied by someone older than 18 years old;

- Bring your previous documents and exams;

- Communicate with the care team in case of allergy to iodine or seafood, medications and/or other food;

- Communicate the presence of bleeding and recent surgery or temporary heat throughout the body. This feeling is normal and will resolve in a few seconds.

- Removal of watches, bangles, earrings, necklaces, glasses, rings and dental prosthesis, if the patient has any of these items;

- Your arm/groin area hair will be shaved;

- Patient will use the hospital gown only, and it will be need to be removed in the exam room.



Source: <https://pixabay.com/pt/comer-bebida-proibido-n%C3%A3o-permitido-98633/>

### What steps should be followed during the exam?

You (Sir/Madam) must communicate anything you feel during the procedure, such as fast heart rate, chest pain, feeling as if you have to urinate, and

shortness of breath. If the team requests, you (sir/madam) should cough, breathe deeply and/or hold your breath.

**What steps should be followed after the exam?**

After finishing the exam, you (sir/madam) will be transferred to a recovery room and/or to hospital room. The physician will remove the introducer (catheter) from your groin or arm and will apply pressure to the site for approximately 20 minutes. Afterward, a bandage will be applied. It will be removed only according to the guidance of nursing team. If the exam was done using the groin area, you (sir/madam) will remain at rest without crossing your legs or raising the head of the bed, even to eat, for approximately 3 to 6 hours. If the exam

used the arm, it is important to keep the arm at rest and not bend it for approximately 4 hours; however you (sir/madam) can move your hand. After removal of the bandage, the site must be washed with soap and water. The physician may request that you (sir/madam) drink plenty of liquid. If you are willing to urinate, the nursing team should be requested to assist with that. The patient must communicate to the team (if hospitalized) or to seek medical assistance (after discharge) if he/she feels pain, discomfort and/or bleeding in the location of the exam, chest pain, or changes in the temperature or color of the location where the exam was done. Nursing team support should be requested for when the patient will stand for the first time after resting.