PAIN-OUT

Improvement in
Postoperative PAIN OUTcome

STANDARD OPERATING PROCEDURES (SOPs)

January, 2019

Project schedule updated in January 2021; included here, January 2022

I need help? Whom do I contact ?

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Selecting a surveyor for the project

The hospital will allocate 2-4 people to carry out data collection.

The person collecting data -

1. Can be a student (nursing or medical) \ nurse \ resident;
   - They may use the data to promote their studies , e.g. degree &\or publication.
2. Will not – as much as is possible – have clinical duties on the ward where he\ she is collecting data
   - This is done to prevent patients from feeling obliged to please the surveyor in the answers they give when filling in the questionnaire.
3. Will be fluent in reading English;
4. Will be given time to undergo **training** about methodology of the project. This includes:
   i. Reading the project manual (SOPs) and filling in a quiz;
   ii. Collecting 10-15 trial patient datasets & entering the data into the PAIN OUT mask – can be done only once ethics approval obtained;
   iii. Attending the kick off meeting for additional training.
5. Will be given time **to collect data** for the project in 1 or 2 wards.
   i. # patients: 80-120 patientsX2 phases, lasting 4 months each ->~30 patients\month ->~7\week;
      - ~ 15% of patients approached for participation might refuse to participate.
   ii. Time required : 20-30 minutes per patient -> ~ 3-4h \ week for 8 months of data collection.
6. **As training for data collection AND gaining experience with data collection are both time consuming --> aim, as much as is possible, that the same surveyors remain for the duration of the project.**

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IMPORTANT

4.0 Examples of entries with missing data

Part 1 PAIN OUT concept & current project

1.1 PAIN OUT concept & current project

This manual is intended as a guide for staff participating in the project *'An initiative assisting healthcare providers optimize management of postoperative pain in South Africa by continuous quality improvement'*.

This manual has 3 aims :

(1) Providing background information about the project;

(2) Describing the items in the PAIN OUT questionnaires;

(3) Offering guidance:

- How to collect the data items from patients and from their medical records
- How to input the data into the web-based server.

1.2 What is the goal of PAIN OUT?

To improve management of peri-operative pain, worldwide.

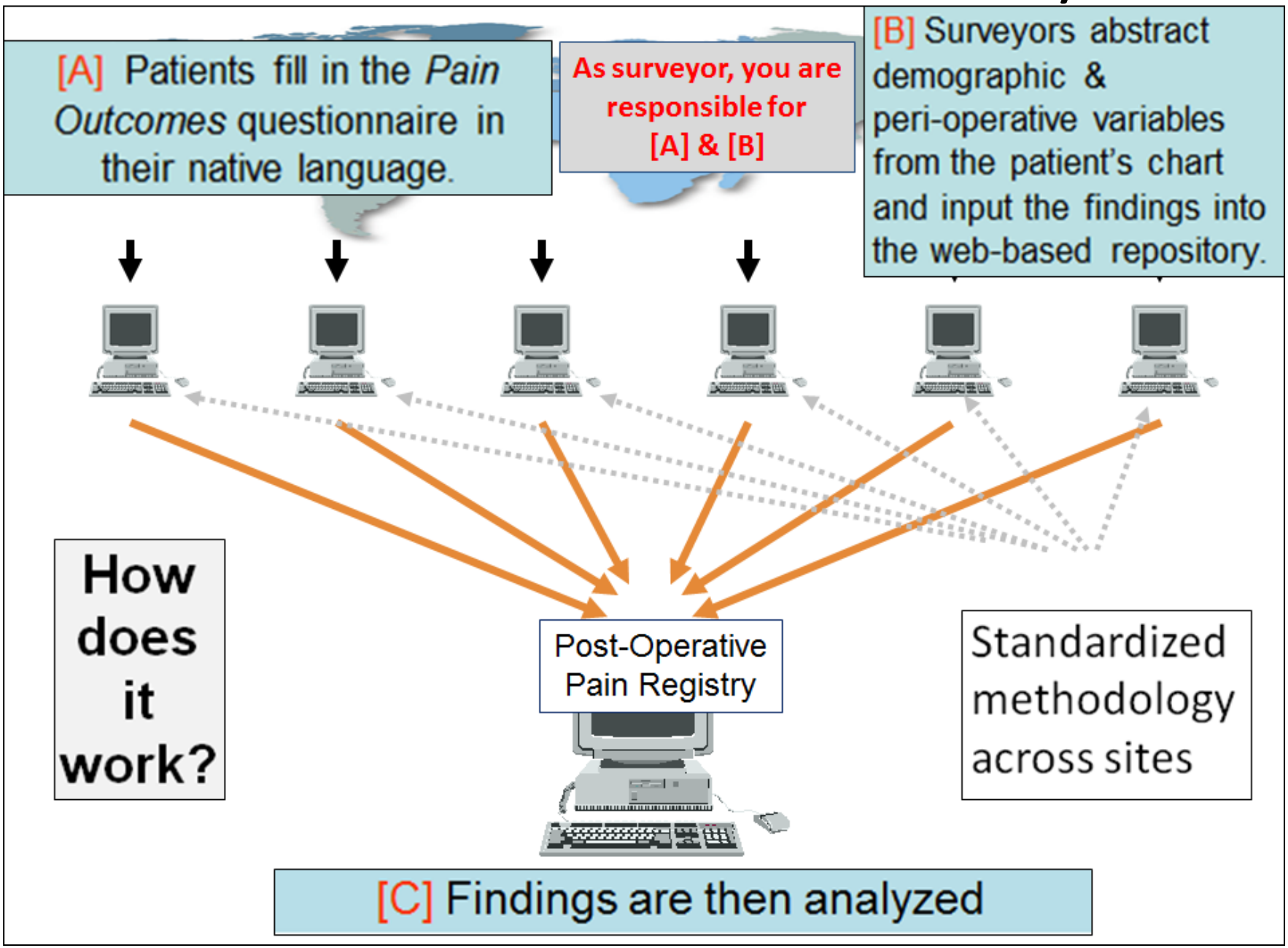
HOW?

- By **collecting data** about peri-operative pain management from patients in surgical wards,
- **Pooling** the data into one database (=registry),
- Providing **feedback** to staff in each center about how they are managing their patient's pain,
- **Benchmarking** the data to allow comparison with similar patients in other wards & hospitals.
- Carrying out **quality improvement** projects with single- or multiple- centers.

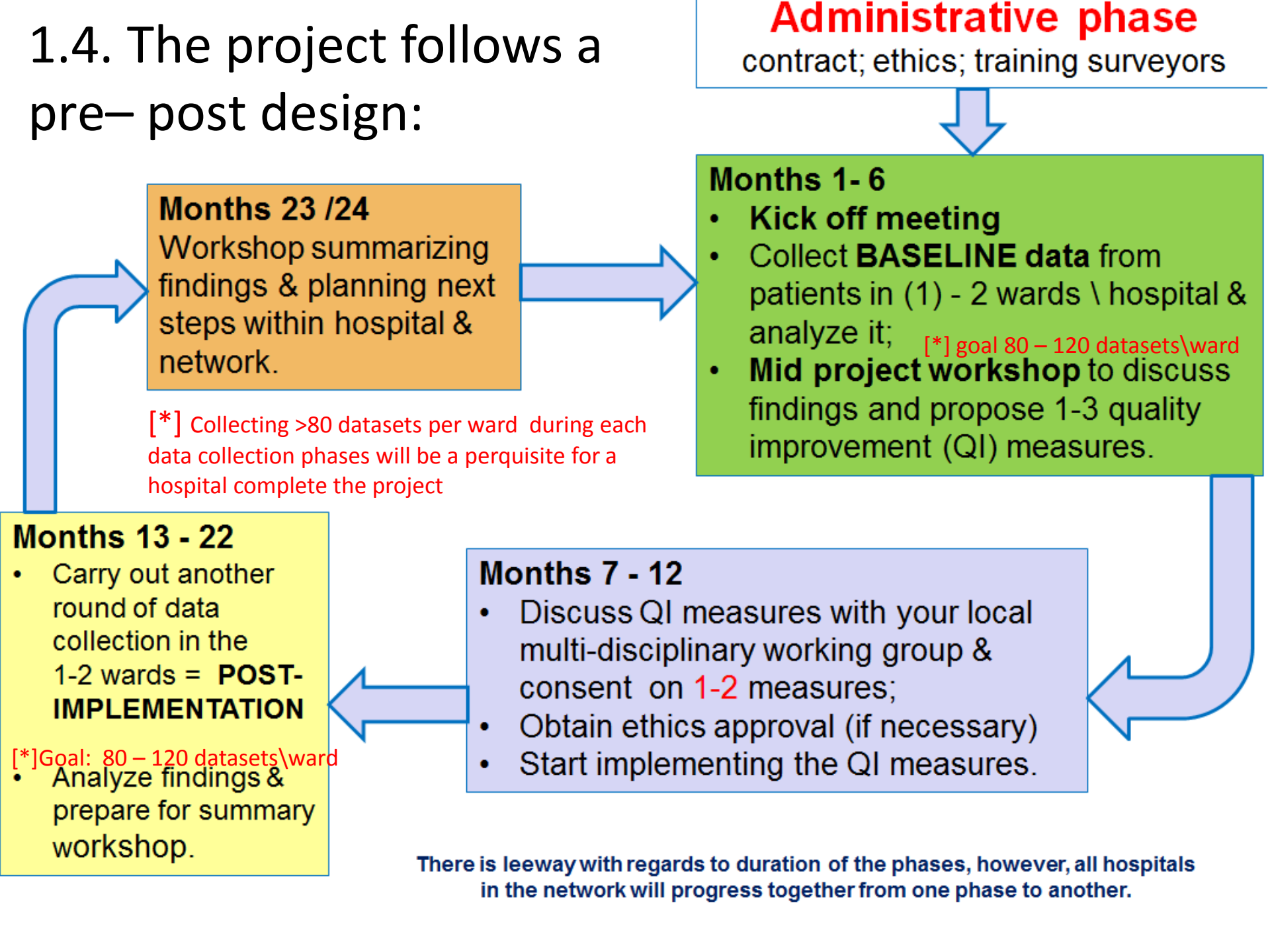
The data can used as the basis for observational studies.

Activities such as these should give healthcare providers information about appropriateness and effectiveness of the treatments they provide.

1.3 How does it work & what do surveyors do?



1.4. The project follows a pre– post design:



1.5 Training for data collection in PAIN OUT

(1) Read the information here.

(2) Fill in the quiz.

(3) Once you pass the quiz AND a contract is signed with your hospital , Claudia will send you:

- A **Surveyor Code**. It is unique to you. Mark all the questionnaires you collect with this code and enter this for all the datasets you enter into the benchmark server.
- Your hospital will receive a **username and password** providing you with access to the project's website and data entry mask.

(4) **Collect datasets from 10 -15 patients** (both process and outcomes questionnaires) and enter the findings into the data entry mask.

- Notify Claudia that you have done this.
- We will review the data and check that it is consistent with the project's methodology.

(5) During the KICK OFF meeting, we will review the project's data collection methodology once again.

Collecting data from patients and entering it correctly into the benchmark server is a learning process.

The quality of the data entered into the database depends on your work.

1.6 Quality of data is crucial

How to get quality data?

- Become acquainted with the project's methodology.
- Make sure that the data you enter into the web-based mask is accurate
  - E.g. for benchmark group, date of birth, height, for medication doses
- Avoid missing data – when collecting it and when inputting it into the web-based mask.
  - Make sure that all cells are filled in.

Like THIS	☒ yes ☐ no ☐ not possible to obtain the information
NOT like this	☐ yes ☐ no ☐ not possible to obtain the information

- **When in doubt - contact us.**

1.7 Randomization

If you have time to approach all patients who comply with the inclusion criteria on the day you are collecting data - you need not randomize.

You need to randomize if there are too many patients on a the ward for you to collect in one day.

Randomization is a 3-step process:

Step 1 Get a list of patients on the ward who are on the first post-operative day.
If the list is not numbered, number it.

Step 2 Create a set of randomized numbers.
Use a randomizer such as www.randomizer.org or draw numbers from a box.

Step 3 Select the patients according to the numbers on the randomization table and the length of time you have for data collection.

1.8 How Many Cases to Collect?

- One case counts if you have filled in **both** the Process AND Outcomes questionnaires.
- You need to collect a minimum of 80 cases (*) during the BASELINE and POST- INTERVENTION phases in each ward participating in the project;
  - each phase will last about 4 months.
- As not all patients you approach, will agree to participate, and so you will need to approach an additional ~15 %.
  - -> approach ~ 25 -30 patients a month OR ~ 7 a week.

(*) Might differ according to requirements from your local ethics committee

1.9 Time to collect data for one case?

Once you have gained experience, it will take ~ 20 - 30 minutes to collect data for one case.

– i.e. both the process and outcomes questionnaires.

What is the best time to go to a ward to collect data ?

– This depends on the routine of the ward.
– Some surveyors go early in the morning before rounds begin.
– Some surveyors prefer to go once morning rounds are over and before patients are discharged.
– Try to coordinate this with the Head Nurse.

Your time will be better spent – collecting fewer, high quality datasets but within the required number – rather than 10s of datasets and have little time to maintain quality.

1.10 How to obtain PAIN OUT questionnaires ?

New sites joining the project will get these materials together with their login addresses.

It is also possible to download questionnaires from the web site.

- This is particularly relevant when you need a patient outcomes questionnaire in a language other than normally used in your country.
- See next page.

1.11 Accessing the PAIN OUT website for questionnaires

Navigation

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- → How to join
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Application

Downloads

- » PAIN OUT outcome questionnaires in all languages: Download
- » PAIN OUT process questionaire: Download
- » PAIN OUT standard operating procedures: Download

- » PAIN OUT data dictionary: Download. To use the data dictionary, please unzip the downloaded file. Then, open the unzipped directory and open the file index.html. Choose the table with the variables you desire on the left side. It can further help to download the annotated process questionnaire, where the names of all variables are linked to their respective question: Download
- » PAIN OUT annotated process questionnaire Download
- » PAIN OUT annotated english outcomes questionnaire Download

Part 2 PAIN OUT questionnaires

2.1 Overview of questionnaires for assessing quality

Avedis Donabedian, a pioneer in research of Public Health systems, described three distinct aspects of quality in health care. These include:

- Outcomes
- Processes
- Structures

The three questionnaires are described in more details in the following slides.

Surveyors in each site are responsible to coordinate that the 3 questionnaires are filled in by the appropriate persons and that the data is inputted into the benchmark server.

2.2 PAIN OUT questionnaires

The **Process Questionnaire** comprises of 5 sections:

- Administrative information
- Screening / Inclusion criteria
- Demographics
- Medical history
- Medication

The data is collected from the **medical record**.

Can be filled in directly to the web-based server if Wifi connection in available on the ward.
Use this option only when you have gained proficiency in collecting data – you will not have a paper back up to rely on

The **Outcomes Questionnaire** consists of 13 questions:

- Pain intensity
- Pain interference
- Affective impairment
- Adverse effects of treatment
- Perceptions of care
- Non-medical pain treatment
- Chronic pain

The questionnaire is usually filled in **by the patient**.

The **Hospital Structural Questionnaire** relates to information about organizational structures in an institution or ward.

The questionnaire is filled in once by the **responsible persons** for PAIN OUT in the ward being observed

2.3 The Process questionnaire

The PROCESS questionnaire consists of 5 sections:

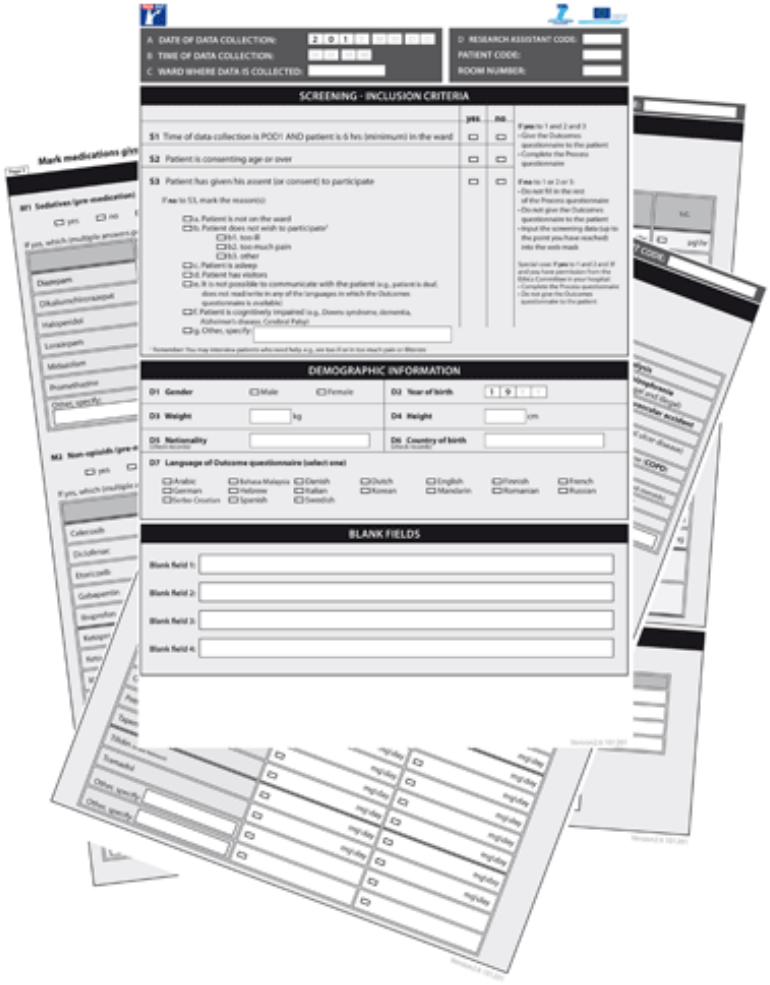
(1) Administrative information

(2) Screening / inclusion criteria

(3) Demographics

(4) Pain-related medical history

(5) Perioperative medications



2.4 Where to obtain the data from?

Obtain the information for the PROCESS questionnaire from the medical record only.

Do not interview patients for this information.

2.5 Options for answers (i)

Most of the items in the Process Questionnaire have 3 options for an answer: "YES" / "NO" / "NOT POSSIBLE TO OBTAIN THE INFORMATION"

Select 'NO' when the form used to record a particular treatment is in the medical record but the category has not been filled in.
Example: you find the form for pre-medication orders but there are no instructions about administering pre-medication.

Select 'Yes' when you find positive information for the data item.

Then either select one of the listed options, or if it is not listed, write the information in 'Other'

M1 Sedatives (pre-medication)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	p.o.	i.v.
Diazepam	☐ mg	☐ mg
Clorazepate dipotassium	☐ mg	☐ mg
Other, specify:	☐ mg	☐ mg

2.5 Options for answers (ii)

Select 'Not possible to obtain the information' when the form used to record a particular treatment in your hospital is missing from the medical record.
EXAMPLE: you find no form about pre-medication in the medical record. Select

Please note:
Use 'other' ONLY when you are CERTAIN that the option is not listed already in the table above.

M1 Sedatives (pre-medication)

☐ yes ☐ no ☐ not possible to obtain the information

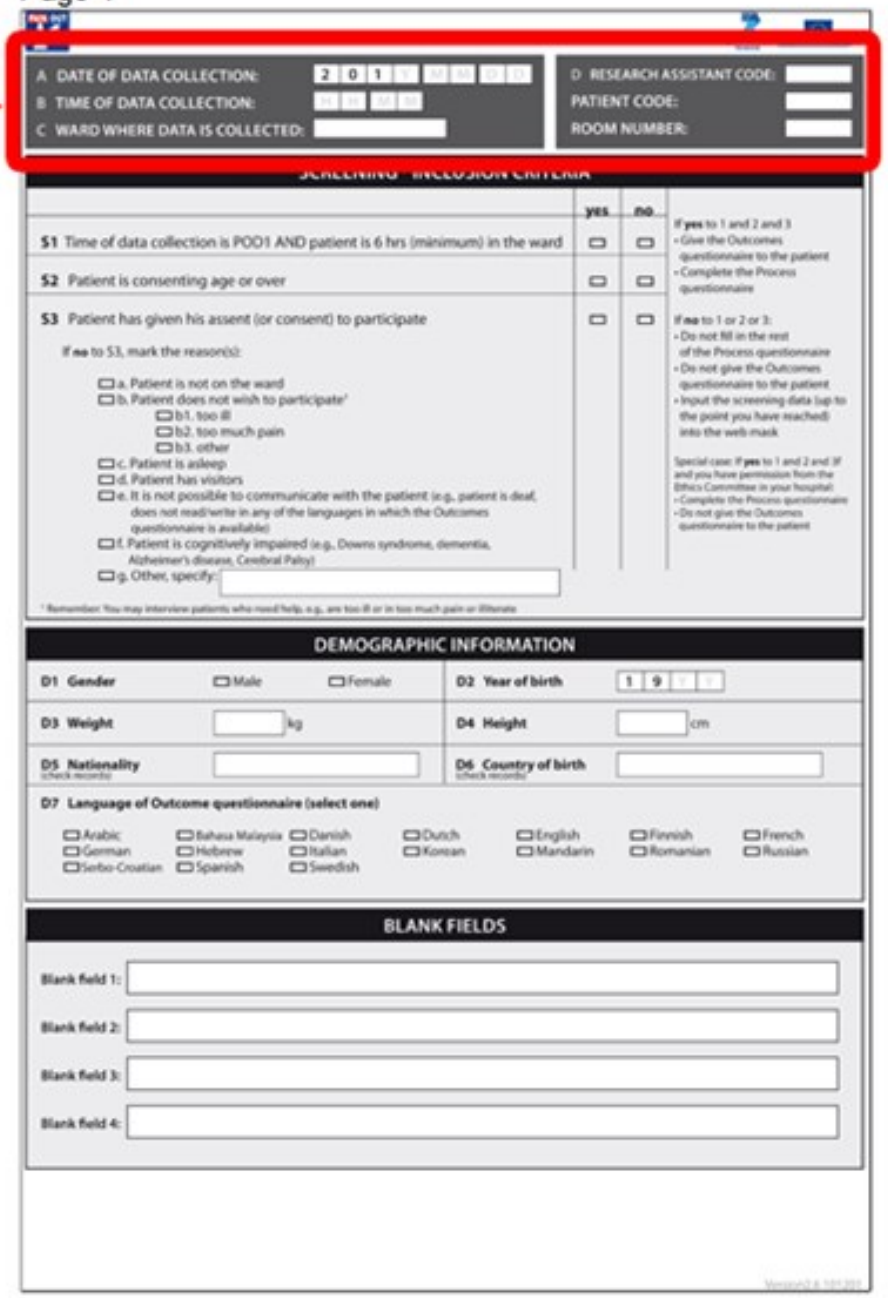
If yes, which (multiple answers possible):

	p.o.	i.v.
Diazepam	☐ mg	☐ mg
Clorazepate dipotassium	☐ mg	☐ mg
Other, specify:	☐ mg	☐ mg

2.6 Administrative information

SECTION 1

Page 1



A DATE OF DATA COLLECTION: 2 0 1 _ _ _ _ _

B TIME OF DATA COLLECTION: _ _ : _ _

C WARD WHERE DATA IS COLLECTED:

D RESEARCH ASSISTANT CODE:

PATIENT CODE:

ROOM NUMBER:

SCREENING - INCLUSION CRITERIA

	yes	no
S1 Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward	☐	☐
S2 Patient is consenting age or over	☐	☐
S3 Patient has given his assent (or consent) to participate	☐	☐

If **yes** to 1 and 2 and 3
- Give the Outcomes questionnaire to the patient
- Complete the Process questionnaire

If **no** to 1 or 2 or 3:
- Do not fill in the rest of the Process questionnaire
- Do not give the Outcomes questionnaire to the patient
- Input the screening data (up to the point you have reached) into the web mask

Special case: If **yes** to 1 and 2 and 3 and you have permission from the Ethics Committee in your hospital:
- Complete the Process questionnaire
- Do not give the Outcomes questionnaire to the patient

If **no** to S3, mark the reason(s):

- ☐ a. Patient is not on the ward
- ☐ b. Patient does not wish to participate*
  - ☐ b1. too ill
  - ☐ b2. too much pain
  - ☐ b3. other
- ☐ c. Patient is asleep
- ☐ d. Patient has visitors
- ☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
- ☐ f. Patient is cognitively impaired (e.g., Downs syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
- ☐ g. Other, specify:

* Remember: You may interview patients who need help, e.g., are too ill or in too much pain or illiterate

DEMOGRAPHIC INFORMATION

D1 Gender ☐ Male ☐ Female

D2 Year of birth 1 9 _ _

D3 Weight _____ kg

D4 Height _____ cm

D5 Nationality (check records)

D6 Country of birth (check records)

D7 Language of Outcome questionnaire (select one)

☐ Arabic ☐ Bahasa Malaysia ☐ Danish ☐ Dutch ☐ English ☐ Finnish ☐ French
☐ German ☐ Hebrew ☐ Italian ☐ Korean ☐ Mandarin ☐ Romanian ☐ Russian
☐ Serbo-Croatian ☐ Spanish ☐ Swedish

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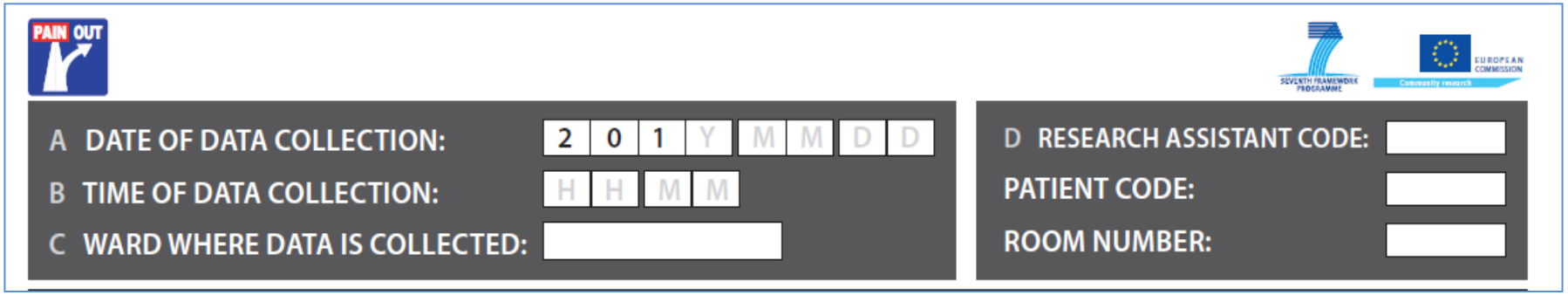
Blank field 2:

Blank field 3:

Blank field 4:

2.7 Administrative information: items A - C



A Date

Relates to the date of when you are filling in the questionnaire.

Coded as year-month-day: 201y mm dd, e.g. 20120801 (= 2012 August 1).

B Time

Time of day that the questionnaire is being filled in.

Data should be collected between **08:00 to 18:00**.

The time is coded as hour-minutes: hh mm, e.g. 1426 (= 2.26 pm).

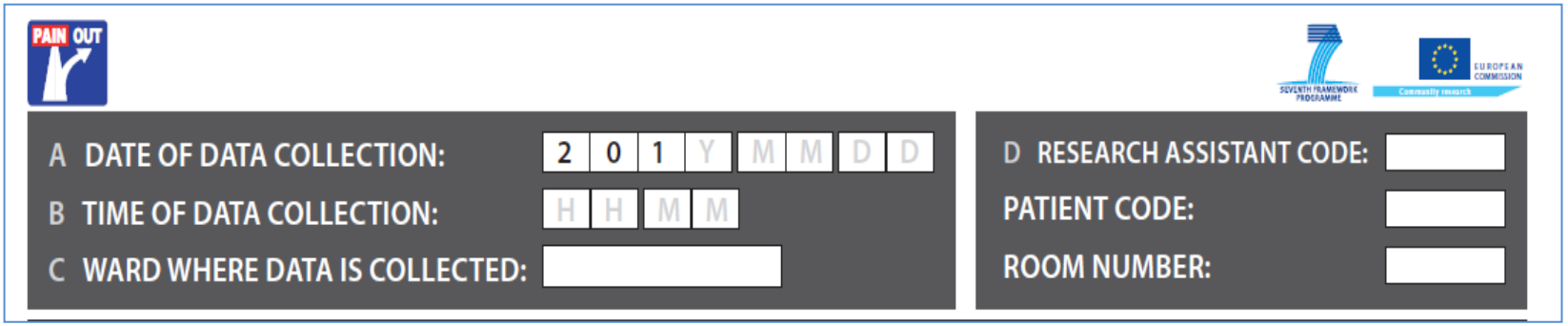
C Ward

The ward is where you collect the data.

Use the name given to you by PAIN OUT.

When entering the data into the web-based mask – make sure you are entering the data into the correct benchmark group.

2.8 Administrative information: item D, patient code & room number



D Surveyor code (=written as 'Research assistant' on the form)

You will receive a code from PAIN OUT. The code is yours only.
Do not pass it on to other persons collecting data for PAIN OUT.

Mark your code on all questionnaires that you collect and on all questionnaires you input into the web-mask.
Be consistent the way you enter the code into the data entry mask.
e.g. if your code is '01' enter '01' ; if '1', enter '1'.

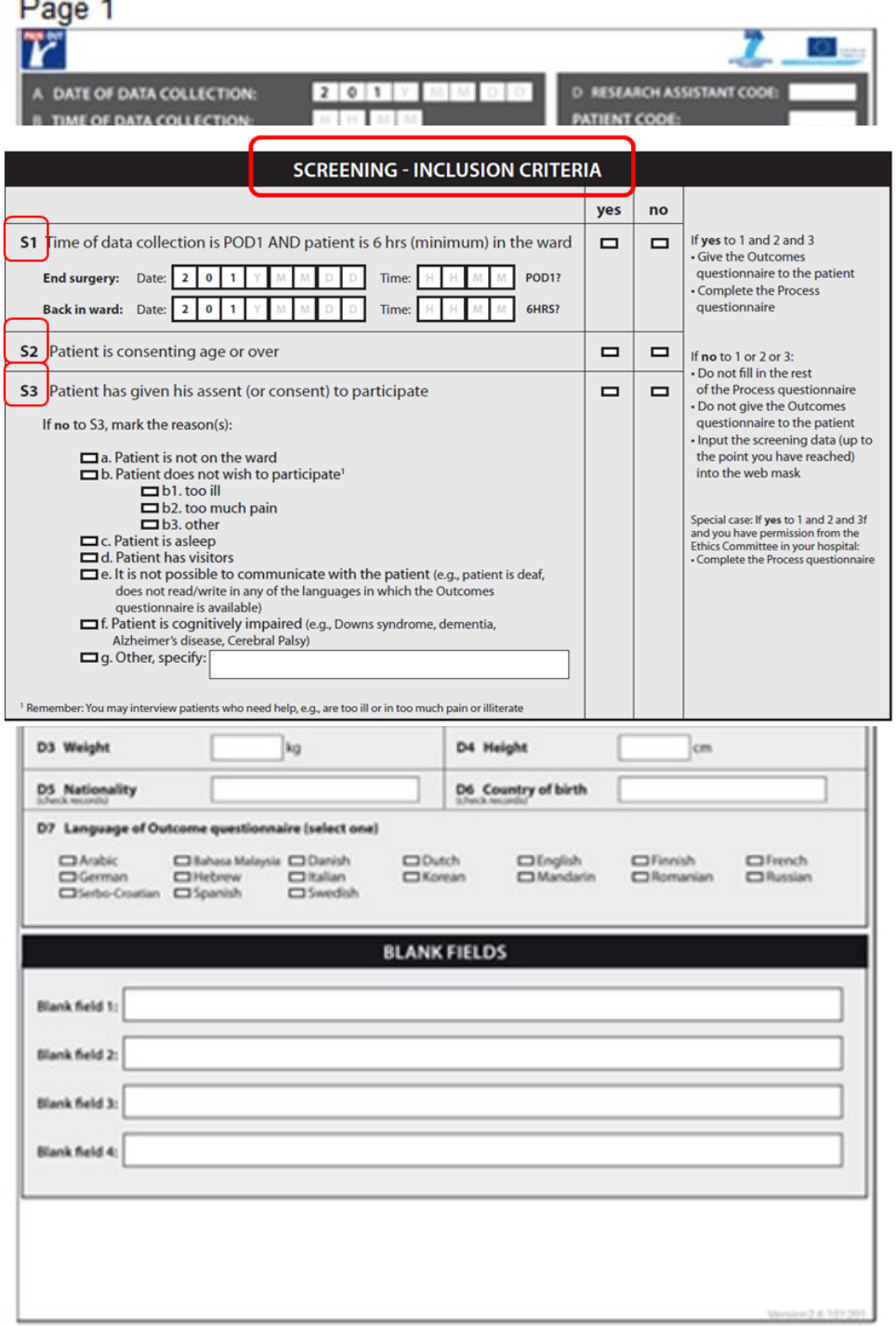
Patient code & Room number

These are for your use, to help you keep the Process and Outcomes Questionnaires of an individual patient together and to help you find the room of the patients to whom you have given the Outcomes Questionnaire. These items will **not** be entered into the PAIN OUT registry

When you enter the data into the web-based mask – a unique identifier will be automatically created for each patient.

2.9 Screening: inclusion criteria

SECTION 2



Page 1

A DATE OF DATA COLLECTION: 2 0 1 Y M M D D

B TIME OF DATA COLLECTION: H H M M

C RESEARCH ASSISTANT CODE:

PATIENT CODE:

SCREENING - INCLUSION CRITERIA

		yes	no
S1	Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward **End surgery:** Date: 2 0 1 Y M M D D Time: H H M M POD1? **Back in ward:** Date: 2 0 1 Y M M D D Time: H H M M 6HRS?	☐	☐
S2	Patient is consenting age or over	☐	☐
S3	Patient has given his assent (or consent) to participate	☐	☐

If **no** to S3, mark the reason(s):

- ☐ a. Patient is not on the ward
- ☐ b. Patient does not wish to participate[1]
  - ☐ b1. too ill
  - ☐ b2. too much pain
  - ☐ b3. other
- ☐ c. Patient is asleep
- ☐ d. Patient has visitors
- ☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
- ☐ f. Patient is cognitively impaired (e.g., Downs syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
- ☐ g. Other, specify:

[1] Remember: You may interview patients who need help, e.g., are too ill or in too much pain or illiterate

If **yes** to 1 and 2 and 3
- Give the Outcomes questionnaire to the patient
- Complete the Process questionnaire

If **no** to 1 or 2 or 3:
- Do not fill in the rest of the Process questionnaire
- Do not give the Outcomes questionnaire to the patient
- Input the screening data (up to the point you have reached) into the web mask

Special case: If **yes** to 1 and 2 and 3f and you have permission from the Ethics Committee in your hospital:
- Complete the Process questionnaire

D3 Weight ☐ kg

D4 Height ☐ cm

D5 Nationality (check one only)

D6 Country of birth (check one only)

D7 Language of Outcome questionnaire (select one)

☐ Arabic ☐ Bahasa Malaysia ☐ Danish ☐ Dutch ☐ English ☐ Finnish ☐ French
☐ German ☐ Hebrew ☐ Italian ☐ Korean ☐ Mandarin ☐ Romanian ☐ Russian
☐ Serbo-Croatian ☐ Spanish ☐ Swedish

BLANK FIELDS

Blank field 1:

Blank field 2:

Blank field 3:

Blank field 4:

SCREENING - INCLUSION CRITERIA

	yes	no
S1 Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward **End surgery:** Date: 2 0 1 Y M M D D Time: H H M M **POD1?** **Back in ward:** Date: 2 0 1 Y M M D D Time: H H M M **6HRS?**	☐	☐
S2 Patient is consenting age or over	☐	☐
S3 Patient has given his assent (or consent) to participate	☐	☐

If **no** to S3, mark the reason(s):

- ☐ a. Patient is not on the ward
- ☐ b. Patient does not wish to participate[1]
  - ☐ b1. too ill
  - ☐ b2. too much pain
  - ☐ b3. other
- ☐ c. Patient is asleep
- ☐ d. Patient has visitors
- ☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
- ☐ f. Patient is cognitively impaired (e.g., Downs syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
- ☐ g. Other, specify: _____

[1] Remember: You may interview patients who need help, e.g., are too ill or in too much pain or illiterate

If **yes** to 1 and 2 and 3
- Give the Outcomes questionnaire to the patient
- Complete the Process questionnaire

If **no** to 1 or 2 or 3:
- Do not fill in the rest of the Process questionnaire
- Do not give the Outcomes questionnaire to the patient
- Input the screening data (up to the point you have reached) into the web mask

Special case: If **yes** to 1 and 2 and 3f and you have permission from the Ethics Committee in your hospital:
- Complete the Process questionnaire

2.10 S1: Time after Surgery & Time on the Ward

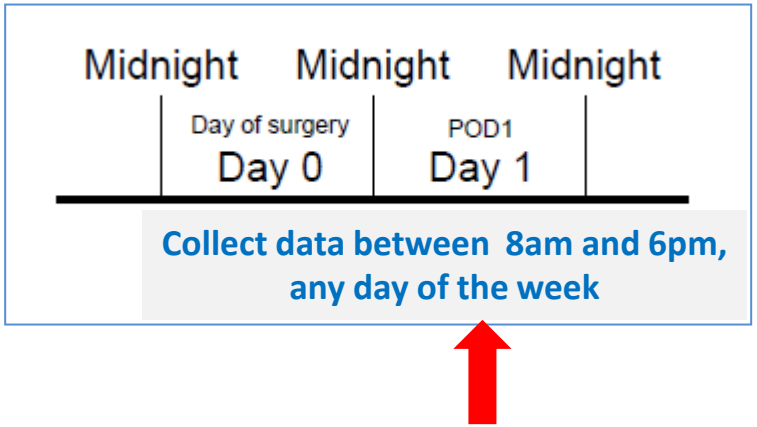
	yes	no
S1 Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward	☒	☐
End surgery: Date: 2 0 1 Y M M D D Time: H H M M **POD1?**		
Back in ward: Date: 2 0 1 Y M M D D Time: H H M M **6HRS?**		

A patient can be recruited to the survey if he/she:

(1) is on the first post-operative day AND

(2) is back on the ward from surgery for at least 6 hours.

(1)



(2) In PAIN OUT, we aim to assess how the staff are managing the patient's pain on the ward after surgery. The patient, therefore, needs to be back on the ward for a minimal duration of time. We have chosen that this will be 6 hours.

2.11 S2: consenting age and over

	yes	no
S2 Patient is consenting age or over	☒	☐

The patient has reached consenting age or over in his country of residence.

In most countries age of consent is 18 years.

2.12 S3: patient has given consent to participate

You need to ask the patient whether he/she agrees to participate in the PAIN OUT survey.

Many sites accept ORAL assent (= the patient says that he agrees to participate). However, some ethics committees require that patients sign a letter of consent.

You need to check the requirements in your hospital.

Consent is an important legal and ethical issue.

If a patient is not interested in participating, you should not exert any pressure on him to do so.

Neither should members of staff, family or friends do so.

2.13 If assent / consent is not given, mark the reason for this

	yes	no
S3 Patient has given his assent (or consent) to participate	☐	☒

If **no** to S3, mark the reason(s):

- ☐ a. Patient is not on the ward
- ☐ b. Patient does not wish to participate[1]
  - ☐ b1. too ill
  - ☐ b2. too much pain
  - ☐ b3. other
- ☒ c. Patient is asleep
- ☐ d. Patient has visitors
- ☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
- ☐ f. Patient is cognitively impaired (e.g., Downs syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
- ☐ g. Other, specify: _____

[1] Remember: You may interview patients who need help, e.g., are too ill or in too much pain or illitera

Use 'Other' only if the reason is NOT listed above. Please check & re-check !

2.14 Make a decision – include or exclude

Once you review S1 & S2 & S3 for a patient – you will need to decide whether the patient can be included or not in the survey:

If you have marked YES in all items (S1 + S2 + S3) -> the patient can be included.

1. Give the Outcomes Questionnaire to the patient.
2. Complete the Process Questionnaire.

If you have marked NO for any of the items S1 and/or S2 and/or S3, then the patient must be excluded.

In this case:

1. Do *not* give the Outcomes Questionnaire to the patient.
2. Do *not* fill in the rest of the Process Questionnaire.
3. **Do SAVE the form and input the information about S1 & S2 & S3 into the web-based mask. All publications require information about the number of patients approached, those who were not included (and reasons) and those recruited. It is, therefore, important to collect information about the patients who were not recruited.**

2.15 Special case of 'Patient does not want to participate‘ [i]

When a patient does not wish to participate in the survey due to feeling too ill or being in too much pain (or any other reason), you can offer to assist by reading the questions in the Outcomes Questionnaire out loud (= make an interview).

In the event of an interview:

- Select ‘YES’ for assent (or consent) in S3;
- Do NOT select S3b;
- At the end of the Outcomes Questionnaire, select YES indicating that the patient was interviewed and the reason why
  - **see next slide.**

2.15 Special case of 'Patient does not want to participate‘ [ii]

See text in the previous slide

S3 Patient has given his assent (or consent) to participate

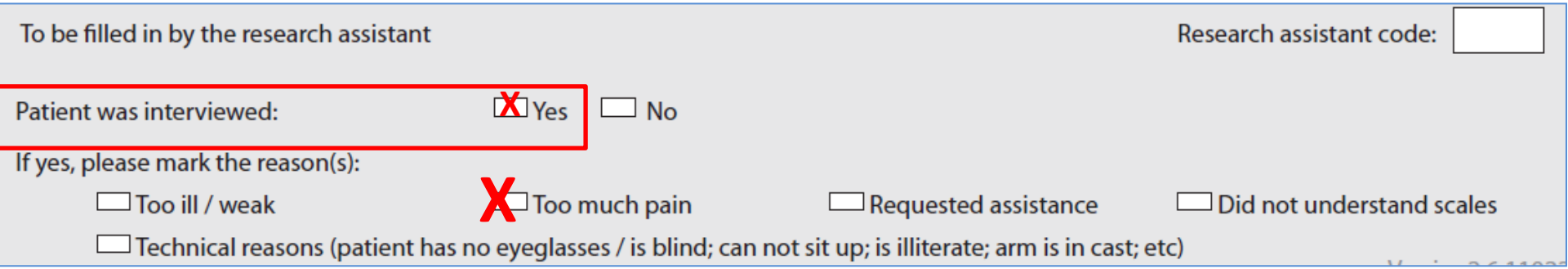
If **no** to S3, mark the reason(s):

- ☐ a. Patient is not on the ward
- ☐ b. Patient does not wish to participate[1]
  - ☐ b1. too ill
  - ☐ b2. too much pain
  - ☐ b3. other
- ☐ c. Patient is asleep
- ☐ d. Patient has visitors
- ☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
- ☐ f. Patient is cognitively impaired (e.g., Downs syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
- ☐ g. Other, specify: _____

[1] Remember: You may interview patients who need help, e.g., are too ill or in too much pain or illiterate

2.15 Special case of ‘Patient does not want to participate’ [iii]

If you interviewed a patient, mark this and the reason for the interview at the **end** of the outcomes questionnaire.


To be filled in by the research assistant

Research assistant code:

Patient was interviewed: [X] Yes [ ] No

If yes, please mark the reason(s):

[ ] Too ill / weak [X] Too much pain [ ] Requested assistance [ ] Did not understand scales

[ ] Technical reasons (patient has no eyeglasses / is blind; can not sit up; is illiterate; arm is in cast; etc)

2.16 Special case: cognitively impaired patients

If a patient is cognitively impaired he cannot give consent.

Usually you would have to exclude this patient.

However, if the ethics committees in your hospital has given permission, you may obtain process data from this patient´s medical record.

This means:

- Mark YES for S3.f
- Complete the Process Questionnaire
- Do not give the Outcomes Questionnaire to the patient.

What is the rational of collecting this type of data ?

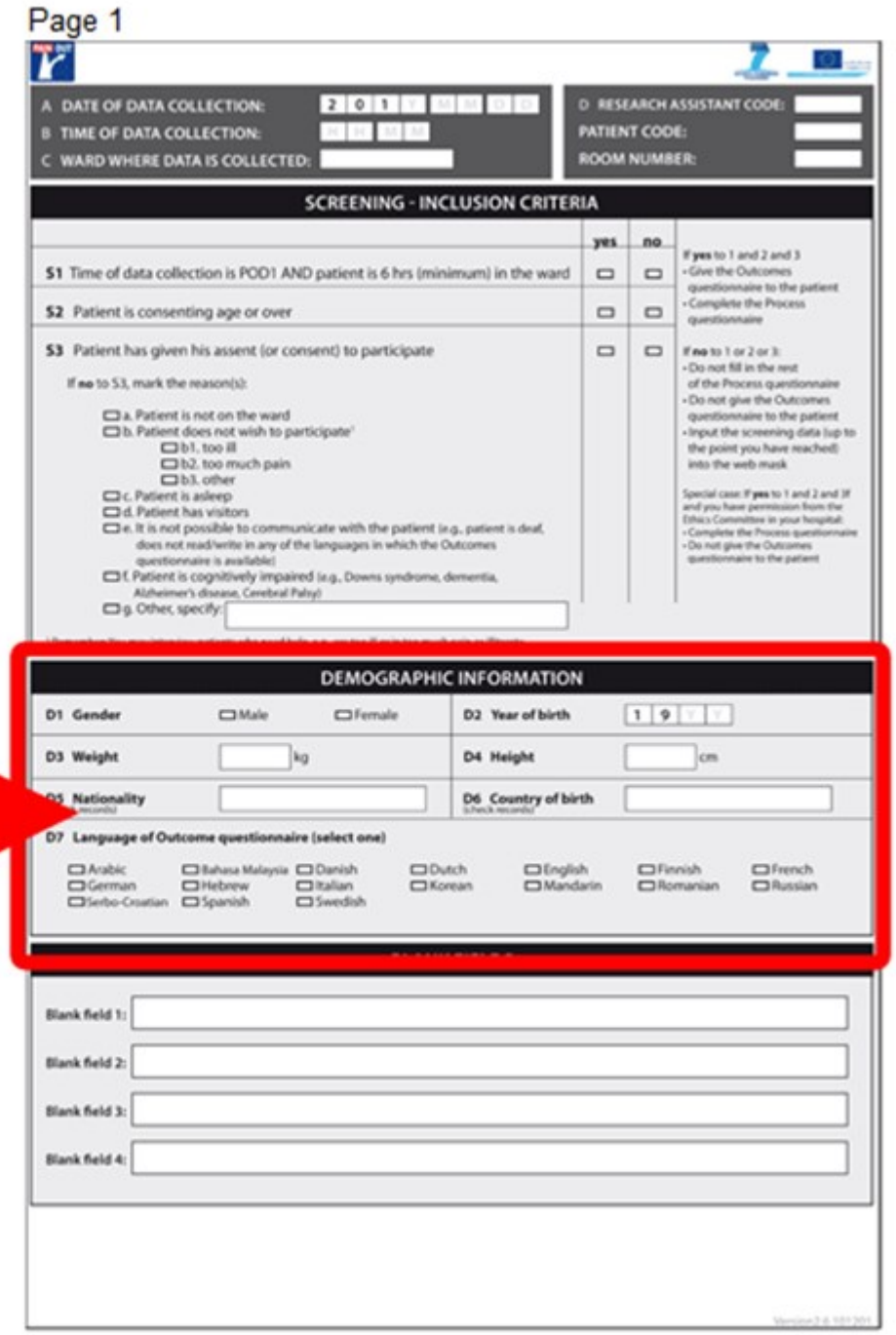
To assess how your hospital manages pain in vulnerable populations.

2.17 Demographics

This section consists of 7 items:

D1 Gender
D2 Year of birth
D3 Weight
D4 Height
D5 Nationality
D6 Country of birth
D7 Language of the Outcomes questionnaire

SECTION 3


Page 1

A DATE OF DATA COLLECTION: 2 0 1 Y M M D D
B TIME OF DATA COLLECTION: H H M M
C WARD WHERE DATA IS COLLECTED:

D RESEARCH ASSISTANT CODE:
PATIENT CODE:
ROOM NUMBER:

SCREENING - INCLUSION CRITERIA

	yes	no
S1 Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward	☐	☐
S2 Patient is consenting age or over	☐	☐
S3 Patient has given his assent (or consent) to participate	☐	☐

If yes to 1 and 2 and 3
- Give the Outcomes questionnaire to the patient
- Complete the Process questionnaire

If no to 1 or 2 or 3:
- Do not fill in the rest of the Process questionnaire
- Do not give the Outcomes questionnaire to the patient
- Input the screening data (up to the point you have reached) into the web mask

Special case: If yes to 1 and 2 and 3 and you have permission from the Ethics Committee in your hospital:
- Complete the Process questionnaire
- Do not give the Outcomes questionnaire to the patient

If no to S3, mark the reason(s):

☐ a. Patient is not on the ward
☐ b. Patient does not wish to participate
  ☐ b1. too ill
  ☐ b2. too much pain
  ☐ b3. other
☐ c. Patient is asleep
☐ d. Patient has visitors
☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
☐ f. Patient is cognitively impaired (e.g., Downs syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
☐ g. Other, specify:

DEMOGRAPHIC INFORMATION

D1 Gender ☐ Male ☐ Female
D2 Year of birth 1 9 Y Y
D3 Weight ☐ kg
D4 Height ☐ cm
D5 Nationality (check records)
D6 Country of birth (check records)
D7 Language of Outcome questionnaire (select one)

☐ Arabic ☐ Bahasa Malaysia ☐ Danish ☐ Dutch ☐ English ☐ Finnish ☐ French
☐ German ☐ Hebrew ☐ Italian ☐ Korean ☐ Mandarin ☐ Romanian ☐ Russian
☐ Serbo-Croatian ☐ Spanish ☐ Swedish

Blank field 1:
Blank field 2:
Blank field 3:
Blank field 4:

2.18 Demographics: D1 – D 4

D1 Gender
Tick male or female

D2 Year of birth
It is coded as year: "19yy", e.g. "1970“

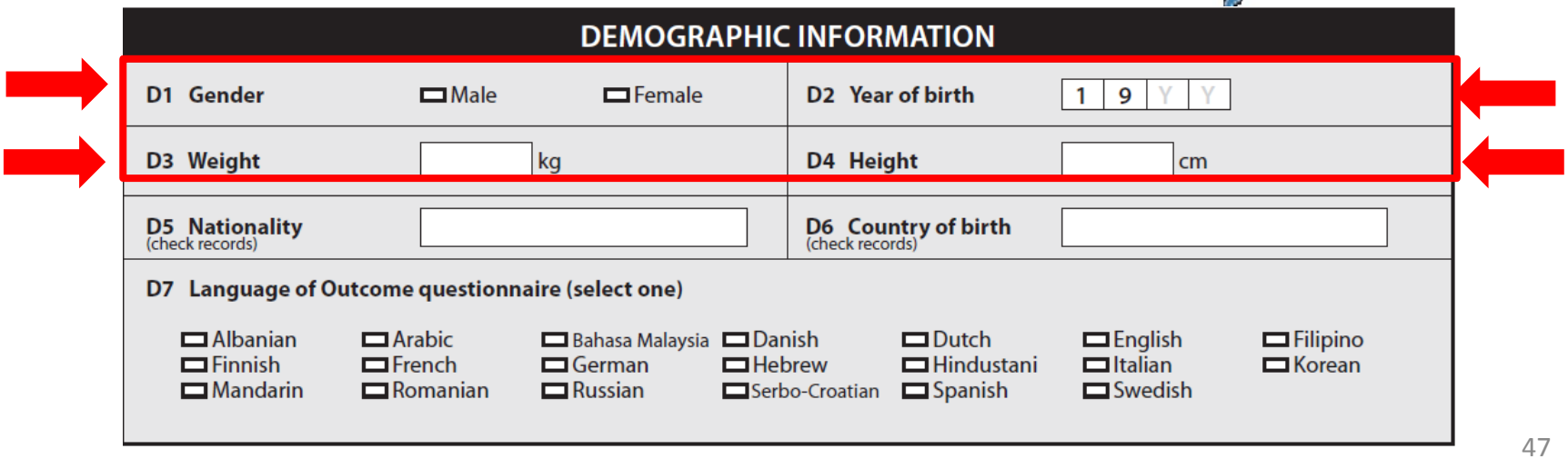
D3 Weight
Fill in weight in kilograms

D4 Height
Fill in height in centimeters

What to do if information about
weight / height / nationality / country of birth
is missing from the medical record?

Leave the box in the **Process Questionnaire** empty.

Later, when you input the data into the web-based mask,
select „NOT POSSIBLE TO OBTAIN THE INFORMATION“.



2.19 Demographics: D5 – D7

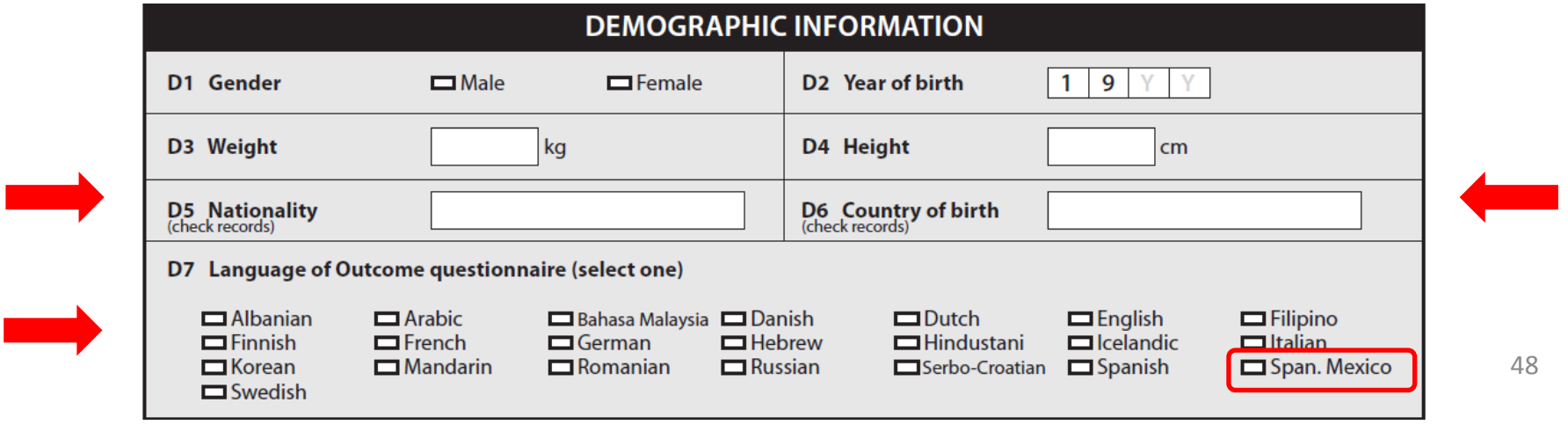
D5 Nationality
Obtain this information only if it is available in the medical record.

D6 Country of birth
Obtain this information only if it is available in the medical record.

D7 Language of Outcomes Questionnaire
Tick the language in which the patient will fill in the Outcomes Questionnaire.

Patients should receive the Outcomes Questionnaire in their native language. This should make it easier for them to understand the questions and to give reliable answers.

You will find a library of multilingual questionnaires in the project´s website.



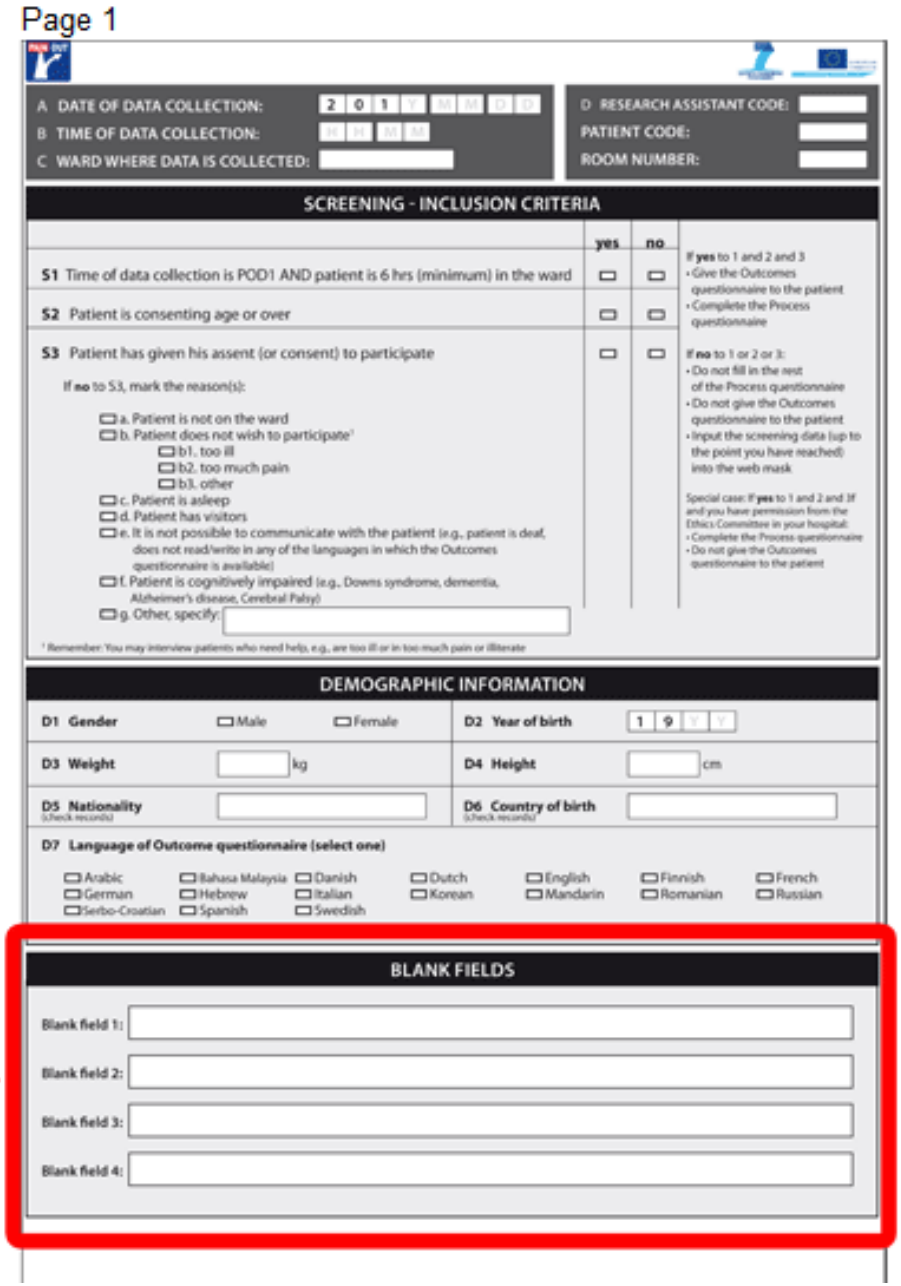
DEMOGRAPHIC INFORMATION

D1 Gender	☐ Male ☐ Female	D2 Year of birth	1 9 Y Y
D3 Weight	kg	D4 Height	cm
D5 Nationality (check records)		D6 Country of birth (check records)	

D7 Language of Outcome questionnaire (select one)

☐ Albanian	☐ Arabic	☐ Bahasa Malaysia	☐ Danish	☐ Dutch	☐ English	☐ Filipino
☐ Finnish	☐ French	☐ German	☐ Hebrew	☐ Hindustani	☐ Icelandic	☐ Italian
☐ Korean	☐ Mandarin	☐ Romanian	☐ Russian	☐ Serbo-Croatian	☐ Spanish	☐ Span. Mexico
☐ Swedish						

2.20 BLANK FIELDS


Page 1

A DATE OF DATA COLLECTION: 2 0 1 Y M M D D
B TIME OF DATA COLLECTION: H H M M
C WARD WHERE DATA IS COLLECTED:

D RESEARCH ASSISTANT CODE:
PATIENT CODE:
ROOM NUMBER:

SCREENING - INCLUSION CRITERIA

	yes	no
S1 Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward	☐	☐
S2 Patient is consenting age or over	☐	☐
S3 Patient has given his assent (or consent) to participate	☐	☐

If yes to 1 and 2 and 3
- Give the Outcomes questionnaire to the patient
- Complete the Process questionnaire

If no to 1 or 2 or 3:
- Do not fill in the rest of the Process questionnaire
- Do not give the Outcomes questionnaire to the patient
- Input the screening data (up to the point you have reached) into the web mask

Special case: If yes to 1 and 2 and 3 if and you have permission from the Ethics Committee in your hospital:
- Complete the Process questionnaire
- Do not give the Outcomes questionnaire to the patient

If no to S3, mark the reason(s):

☐ a. Patient is not on the ward
☐ b. Patient does not wish to participate*
  ☐ b1. too ill
  ☐ b2. too much pain
  ☐ b3. other
☐ c. Patient is asleep
☐ d. Patient has visitors
☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
☐ f. Patient is cognitively impaired (e.g., Downs syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
☐ g. Other, specify:

* Remember: You may interview patients who need help, e.g., are too ill or in too much pain or illiterate

DEMOGRAPHIC INFORMATION

D1 Gender ☐ Male ☐ Female
D2 Year of birth 1 9 Y Y
D3 Weight kg
D4 Height cm
D5 Nationality (check records)
D6 Country of birth (check records)

D7 Language of Outcome questionnaire (select one)

☐ Arabic ☐ Bahasa Malaysia ☐ Danish ☐ Dutch ☐ English ☐ Finnish ☐ French
☐ German ☐ Hebrew ☐ Italian ☐ Korean ☐ Mandarin ☐ Romanian ☐ Russian
☐ Serbo-Croatian ☐ Spanish ☐ Swedish

BLANK FIELDS

Blank field 1:
Blank field 2:
Blank field 3:
Blank field 4:

Blank fields are used to collect data items which are interesting to your site.

Personnel in the site collecting this data will be responsible for defining the data items.

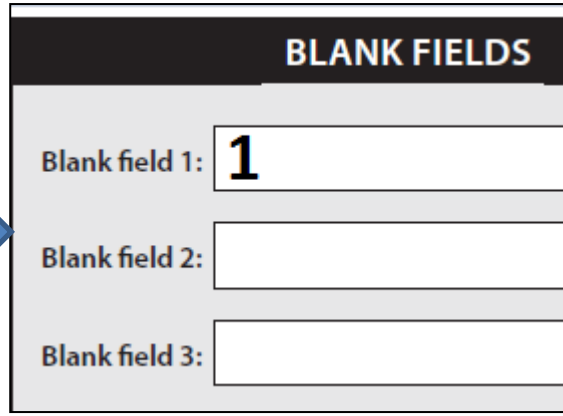
This information will be entered into the web-based mask, available for offline analysis.

See the next slide for examples of how to carry this out.

The following are EXAMPLES on how to use the Blank Fields:

In your site you would like to record whether Caesarean Sections are carried out as emergency or scheduled procedures.

1. Allocate Blank Field 1 to record this information.
2. Create a code: Emergency = 1; Scheduled = 2.
3. When you come across a patient who underwent Caesarean , write in Blank Space 1, '1' if this was an emergency procedure and '2' if scheduled.
4. Inform the other surveyors working with you about this coding scheme so they will follow this practice when they are collecting data.



In your hospital you are following patients after radical prostatectomy. The ICD9 codes do not differentiate between the open vs laparoscopic approaches. You can do this using a Blank Field.

1. Allocate Blank field 2 for this; code : Open = 3; Laparoscopic = 4.
2. When you come across a patient who underwent radical prostatectomy , write in Blank Space 2, '3' if this was an open procedure and '4' if laparoscopic.
3. Inform the other surveyors working with you about this coding scheme so they will follow this practice when they are collecting data.

In your hospital you would like to assess the effect of providing different modes of information to patients about their pain treatment options.

1. Allocate Blank field 3 for this; code the different methods you will be using to provide information: Leaflet = 1; video = 2; app sent to patient's phone = 3;
2. Inform the other surveyors working with you about this coding scheme so they will follow this practice when they are collecting data.

2.21 Medical history

This section consists of 3 items:

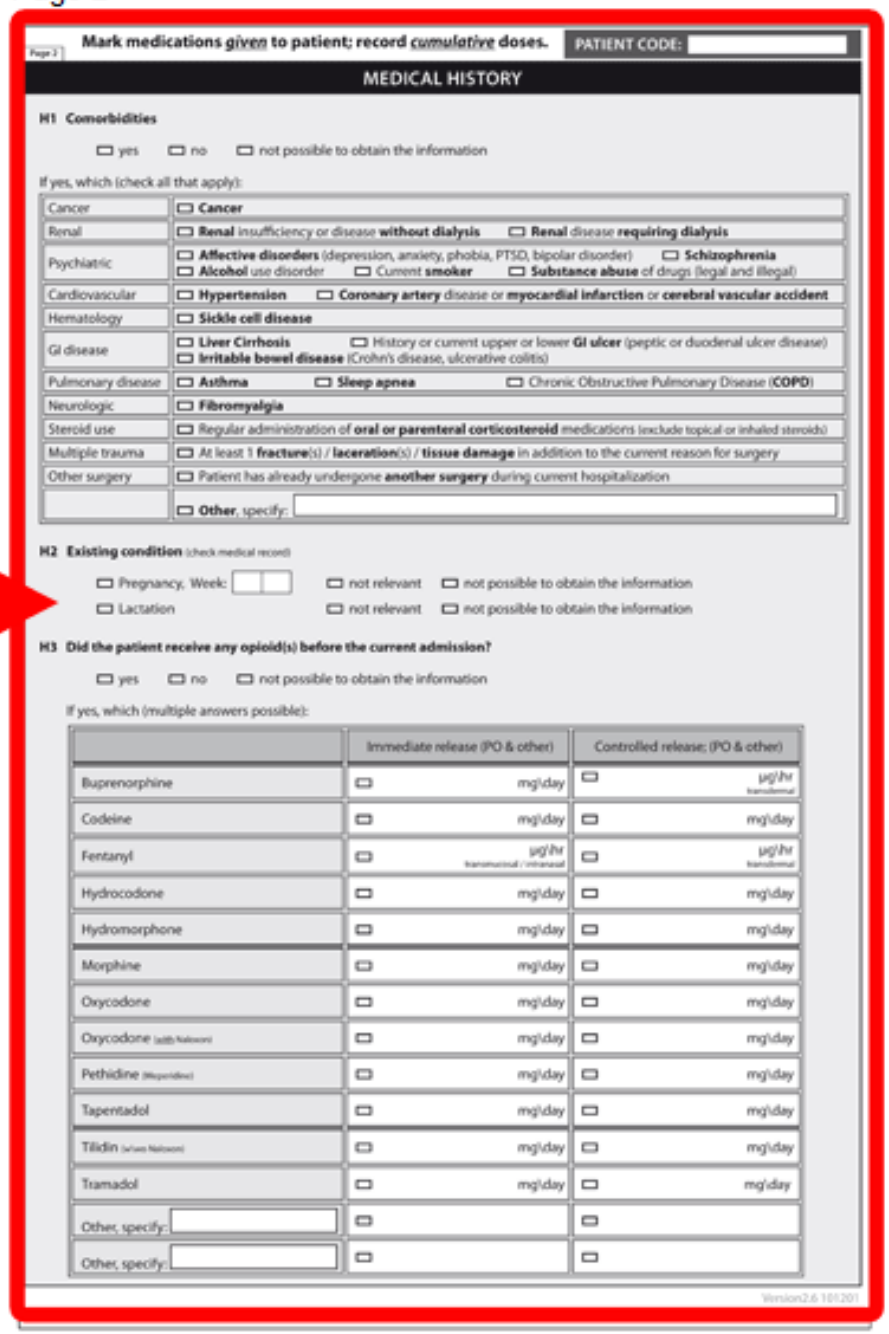
H1 Comorbidities

H2 Existing condition

H3 Opioids before current admission

SECTION 4

Page 2



Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE:

MEDICAL HISTORY

H1 Comorbidities

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (check all that apply):

Cancer	☐ **Cancer**
Renal	☐ **Renal** insufficiency or disease **without dialysis** ☐ **Renal** disease **requiring dialysis**
Psychiatric	☐ **Affective disorders** (depression, anxiety, phobia, PTSD, bipolar disorder) ☐ **Schizophrenia** ☐ **Alcohol** use disorder ☐ Current **smoker** ☐ **Substance abuse** of drugs (legal and illegal)
Cardiovascular	☐ **Hypertension** ☐ **Coronary artery** disease or **myocardial infarction** or **cerebral vascular accident**
Hematology	☐ **Sickle cell disease**
GI disease	☐ **Liver Cirrhosis** ☐ History or current upper or lower **GI ulcer** (peptic or duodenal ulcer disease) ☐ **Irritable bowel disease** (Crohn's disease, ulcerative colitis)
Pulmonary disease	☐ **Asthma** ☐ **Sleep apnea** ☐ Chronic Obstructive Pulmonary Disease (**COPD**)
Neurologic	☐ **Fibromyalgia**
Steroid use	☐ Regular administration of **oral or parenteral corticosteroid** medications (exclude topical or inhaled steroids)
Multiple trauma	☐ At least 1 **fracture**(s) / **laceration**(s) / **tissue damage** in addition to the current reason for surgery
Other surgery	☐ Patient has already undergone **another surgery** during current hospitalization
	☐ **Other**, specify:

H2 Existing condition (check medical record)

☐ Pregnancy, Week: ☐☐ ☐ not relevant ☐ not possible to obtain the information

☐ Lactation ☐ not relevant ☐ not possible to obtain the information

H3 Did the patient receive any opioid(s) before the current admission?

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	Immediate release (PO & other)	Controlled release; (PO & other)
Buprenorphine	☐ mg\day	☐ µg/hr transdermal
Codeine	☐ mg\day	☐ mg\day
Fentanyl	☐ µg/hr transmucosal / intranasal	☐ µg/hr transdermal
Hydrocodone	☐ mg\day	☐ mg\day
Hydromorphone	☐ mg\day	☐ mg\day
Morphine	☐ mg\day	☐ mg\day
Oxycodone	☐ mg\day	☐ mg\day
Oxycodone (with Naloxone)	☐ mg\day	☐ mg\day
Pethidine (Meperidine)	☐ mg\day	☐ mg\day
Tapentadol	☐ mg\day	☐ mg\day
Tilidin (when Naloxone)	☐ mg\day	☐ mg\day
Tramadol	☐ mg\day	☐ mg\day
Other, specify:	☐	☐
Other, specify:	☐	☐

Version2.6 101201

2.22 Medical history: H1 Comorbidities, definition

The section refers to co-morbidities which are related to management of pain after surgery. As the literature does not provide a classification which was considered suitable for PAIN OUT, we devised the following:

To quality for inclusion, a condition needs to strongly impact on how the patient's pain is managed after surgery.
e.g., renal failure leading to restriction of non-steroidal anti-inflammatory drugs OR sleep apnea leading to restriction of opioids
AND
the condition is one that is typically documented in a patient's medical record in a standardized manner.

2.23 Medical history: H1 list of Comorbidities

Cancer	☐ **Cancer**
Renal	☐ **Renal** insufficiency or disease **without dialysis** ☐ **Renal** disease **requiring dialysis**
Diabetes	☐ **Diabetes Type I** ☐ **Diabetes Type II** ☐ **Diabetes Type unknown**
Psychiatric	☐ **Affective disorders** (depression, anxiety, phobia, PTSD, bipolar disorder) ☐ **Schizophrenia** ☐ **Alcohol** use disorder ☐ Current **smoker** ☐ **Substance abuse** of drugs (legal and illegal)
Cardiovascular	☐ **Hypertension** ☐ **Coronary artery** disease or **myocardial infarction** or **cerebral vascular accident**
Hematology	☐ **Sickle cell disease**
GI disease	☐ **Liver Cirrhosis** ☐ History or current upper or lower **GI ulcer** (peptic or duodenal ulcer disease) ☐ **Irritable bowel disease** (Crohn's disease, ulcerative colitis)
Pulmonary disease	☐ **Asthma** ☐ **Sleep apnea** ☐ Chronic Obstructive Pulmonary Disease (**COPD**)
Neurologic	☐ **Fibromyalgia**
Steroid use	☐ Regular administration of **oral or parenteral corticosteroid** medications
Musculoskeletal	☐ **Osteoarthritis** ☐ **Rheumatoid arthritis**
Multiple trauma	☐ At least 1 **fracture**(s) / **laceration**(s) / **tissue damage** in addition to the current reason for surgery
Other surgery	☐ Patient has already undergone **another surgery** during current hospitalization
	☐ **Other**, specify:

2.24 Medical history: H1 Comorbidities, how to fill in

- Check the patient’s medical record for comorbidities.
- If comorbidities are listed, check if they match any of the ones listed in H1.
- If there is at least one match:
  - Select "YES" and mark the appropriate terms.
  - You can select multiple terms.
- If no comorbidities are listed in the medical record or none match the ones listed in H1 select "NO".

DO NOT INTERVIEW PATIENTS TO OBTAIN THIS INFORMATION - IT MUST BE PRESENT IN THE PATIENT'S FILE.

2.25 Medical history: H1 Comorbidities, some definitions

Here are cues to help select some of the comorbidities.

'Multiple Trauma' refers to other injuries (e.g. fracture[s] or laceration[s] or tissue damage) that resulted in the patient's current hospitalization, e.g., a patient has had a motor vehicle accident and has a fractured femur AND/OR laceration of the spleen AND/OR burns in 30% of the body surface area.

'Substance Abuse' In some countries it might be difficult to obtain information about Substance Abuse Disorders, as the information is not recorded in the medical record.

'Current smoker' Select this if you can find information in the medical record that indicates that the patient currently smokes cigarettes (independent of the number of cigarettes) or stopped within the last month.

'Cancer' Select this if you find the term 'cancer' or synonymous terms such as malignancy, malignant neoplastic disease, malignant tumor, or neoplasm.

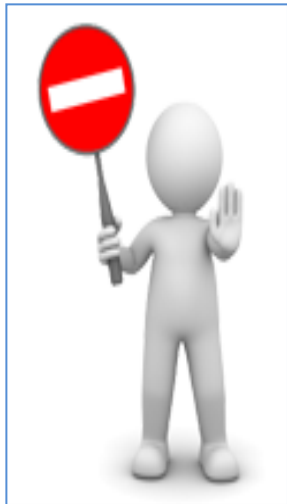
2.26 Medical history: H1 Comorbidities, when to use ‘OTHER’?

Before you enter an entry into ‘Other’, check:

[1] Are you sure the condition is not already listed in the H1 table?

[2] Are you sure it’s a comorbidity that is relevant to management of pain after surgery?

[3] Remember – conditions in ‘Other’ are rarely analyzed – don’t waste your time entering this information unless you have considered that it is relevant !



2.27 Medical history: H2 Existing condition

H2 Existing condition (check medical record)

☐ Pregnancy, Week: ☐☐	☐ not relevant	☐ not possible to obtain the information
☐ Lactation	☐ not relevant	☐ not possible to obtain the information

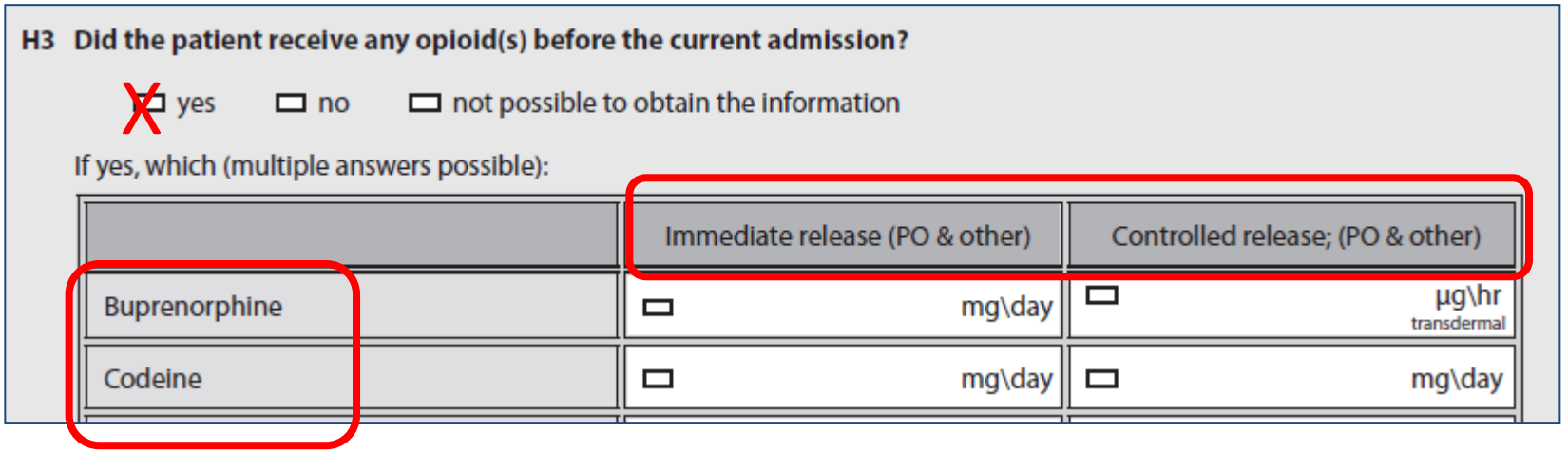
- **This section is relevant to female patients only.**
- The data is collected as there is little information on how to treat the pain of pregnant women undergoing surgery / after giving birth and planning to breastfeed.
- If the woman is pregnant or lactating, select the relevant answer.
- Select "NOT RELEVANT“: if the woman is over childbearing age OR the patient is a MALE.
- Select "NOT POSSIBLE TO OBTAIN THE INFORMATION“, if the woman is of childbearing age and information is about pregnancy is not registered in the medical record.

How do you know
if the woman is of childbearing age?

Make an estimate!
Do not ask her.

2.28 Medical history: H3 Opioids before current admission

If the patient received an opioid, when at home, before being admitted to hospital and the opioid is listed in the medical record, select "YES".
Record the name of the medication and the total daily dose.



H3 Did the patient receive any opioid(s) before the current admission?

☒ yes ☐ no ☐ not possible to obtain the information

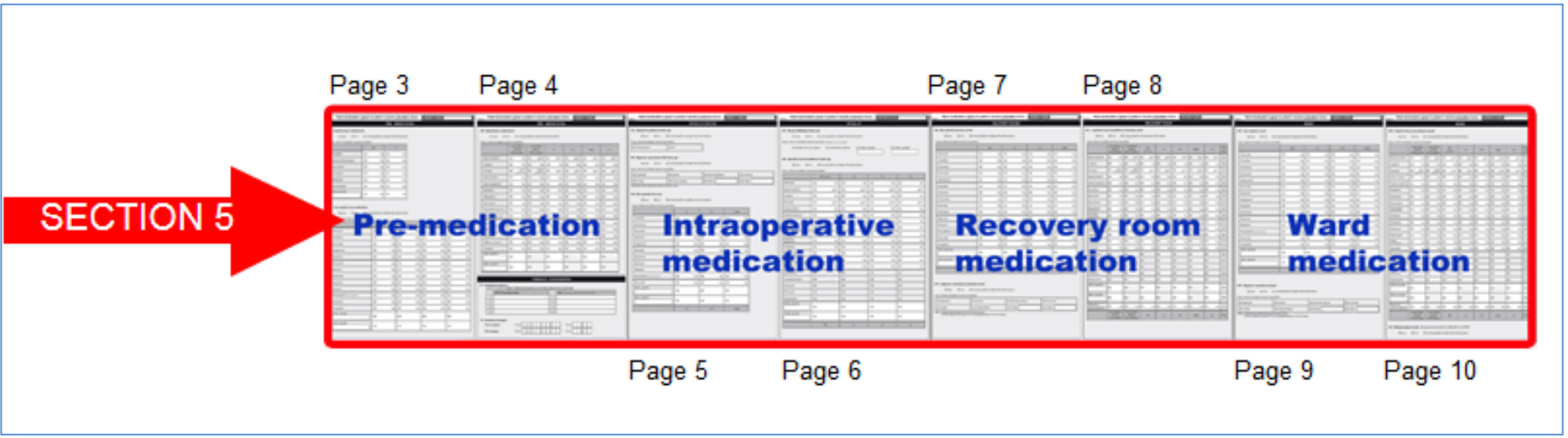
If yes, which (multiple answers possible):

	Immediate release (PO & other)	Controlled release; (PO & other)
Buprenorphine	☐ mg\day	☐ µg\hr transdermal
Codeine	☐ mg\day	☐ mg\day

- Opioids before admission might typically be given to orthopedic patients. This is likely to vary considerably in different countries.
- Opioids before admission might not be well documented.
  - Check the patient's medical record and the nursing records.

The list of opioids in H3 is not exhaustive. If you can't find the opioid, list it in "OTHER".
Use 'OTHER' – ONLY after you have checked the list and can't find the medication listed.

2.29 Perioperative medications & surgical procedure



The section deals with medications given to the patient during the different perioperative phases AND with coding the surgical procedure:

M1- M3	Pre-medication
P1 - P2	Surgical Procedures
M4 – M8	Intra-operative
M9 - M11	Recovery room OR Post Anesthesia Care Unit (PACU).
M12- M15	Ward

2.30 Types of perioperative medications

Record the following medication groups related to treatment of pain:

- Sedatives (only when given as pre-medication)
- Non-opioids
  - non-steroidal anti -inflammatory,
  - Paracetamol and dipyrone / metamizole,
  - clonidine,
  - Gabapentinoids
  - ketamine
- Opioids
- Local anesthetics

At first glance, this section of the process questionnaire, which consists of 8 pages, seems to be the most complex.
Stick to a few principles and it should be straightforward to handle.

2.31 How to record the perioperative medications

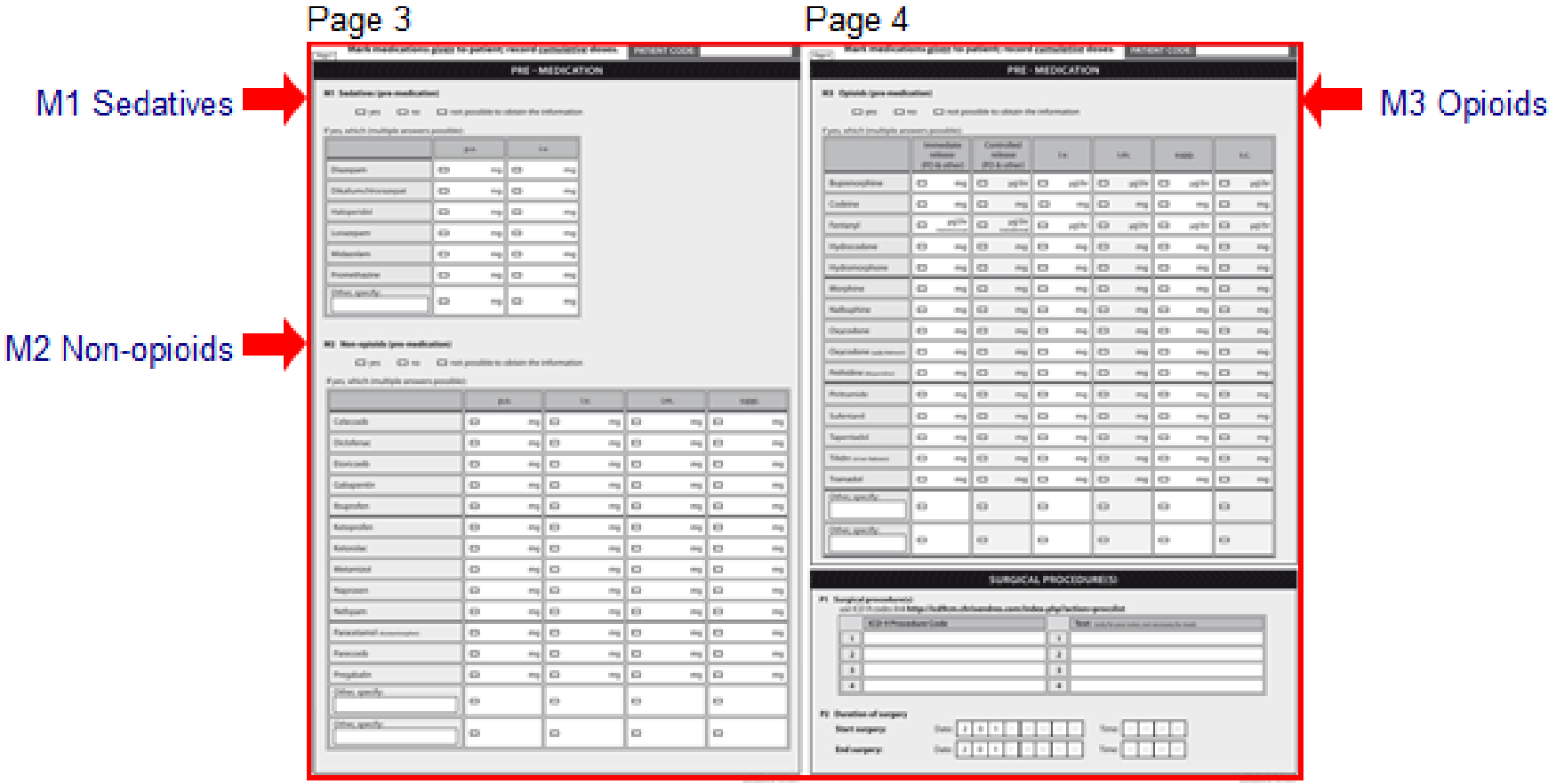
- Record medications ***given*** to patient e.g., IV morphine 5 mg.
- Do NOT record those *prescribed* e.g., IV morphine every 10 min.
- Record ***cumulative*** **doses** given in each perioperative phase.
- Record ***generic*** and NOT brand names.

There are situations which require that you carry out **complex dose calculations**, e.g., if the dose is written as mg/kg/hr OR if a medication is given via a PCA pump continuously with boluses taken by the patient.

In these cases, you can choose to:

- Record the name of medication & route of administration but **NOT** the dose.
- Record the total dose only if you are confident that the calculation is correct.

2.32 Perioperative medications: pre-medication



These are medications given to the patient on the evening, night, morning and/or afternoon of surgery, up until induction of anesthesia.

2.33 P1 Surgical procedure code & P2 Duration of surgery

Before continuing with the next section of the 'intra-operative' medications, you're asked to address:

- P1 Surgical procedure
- P2 Duration of surgery: day & time of the start & end of surgery.
  - Do not confuse this with the beginning and end of anesthesia.

P1 Surgical procedure(s)
use ICD-9 codes link **http://icd9cm.chrisendres.com/index.php?action=procslist**

	ICD-9 Procedure Code		Text (only for your notes, not necessary for mask)
1		1	
2		2	
3		3	
4		4	

P2 Duration of surgery

Start surgery:	Date:	2	0	1	Y	M	M	D	D	Time:	H	H	M	M
End surgery:	Date:	2	0	1	Y	M	M	D	D	Time:	H	H	M	M

2.34 P1 Surgical procedure: how to code

Surgical procedures are classified using a variety of systems.
For uniformity, PAIN OUT uses the **ICD-9 coding system**.

- If ICD-9 codes are used in your hospital -> use these codes.
- If a different code is used -> convert to ICD-9.
- If the procedure is described using text - > use this information to look for the ICD9 code.

Websites for finding ICD9 codes:
http://icd9.chrisendres.com/; make sure you are looking at 'procedures'.

https://www.findacode.com/icd-9/icd-9-cm-diagnosis-codes.html, make sure you select vols 1-3 and are looking at the ICD9 codes (not ICD10)

When registering ICD9 codes – every digit can change the type of procedure being recorded !

A patient's ICD9 code was written in the PAIN OUT mask as '81'.

81 is one procedure and 81.0 is another.

ICD-9 v3 CHPT/SEC	**81** Repair and plastic operations on joint structures
ICD-9 v3 CHPT/SEC	**81.0** Spinal fusion

For another patient – it was written as '84'.

84 or 84.0 ?

84.0 is Amputation of upper limb
84 is Other procedures on musculoskeletal system

If a patient has 2 or more procedure codes - >
the first code – should be of the principle surgical procedure.

2.35 Perioperative medications: Intra-operative

This section addresses 5 items:

- M4 General anesthesia
- M5 Regional anesthesia
- M6 Non-opioids
- M7 Wound infiltration
- M8 Opioids and local anesthesia

2.36 Perioperative medications: Intra-operative,anesthesia

If **general anesthesia** was used, mark YES in M4 and select the method, inhalational and/or intravenous.
If **regional anesthesia** was used, mark YES in M5 and the approach used.
If the patient received a **combination** of general and regional anesthesia - > mark YES in both M4 and M5.

M4 General anaesthesia (intra-op)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☐ Inhalational	☐ IV

M5 Regional anaesthesia (RA) (intra-op)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☐ Epidural	☐ Spinal	☐ Brachial plexus	☐ Femoral
☐ Sciatic	☐ Paravertebral	☐ Transv. Abdom. Plane (TAP)	☐ Other:

Mark the medication(s) used for RA in M8

Do not forget

2.36 How to record General Anesthesia in M4

Inhalational Anaesthetics

For reference, here are the most commonly used inhalation anesthetics:

- Desflurane
- Enflurane
- Halothane
- Isoflurane
- Nitrous oxide (laughing gas)
- Sevoflurane

M4 General anaesthesia (intra-op)

☒ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☒ Inhalational	☐ IV

Intraveneous Anaesthetics

IV relates to Total Intravenous Anesthesia (=TIVA).

M4 General anaesthesia (intra-op)

☒ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☐ Inhalational	☒ IV

2.37 Perioperative medications: Intra-operative, non-opioids

M6 If the patient received a non-opioid, select "YES".

Then select the name and route administered.

Write the dose, if known.

M6 Non-opioids (intra-op)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	i.v.	i.m.	supp.
Clonidine	☐ mg	☐ mg	☐ mg
Diclofenac	☐ mg	☐ mg	☐ mg
Ibuprofen	☒ 400 mg	☐ mg	☐ mg
Ketamine	☐ mg	☐ mg	☐ mg
Ketoprofen	☐ mg	☐ mg	☐ mg

2.38 Perioperative medications: Intra-operative,wound infiltration

M7 Wound infiltration

If the surgical wound was infiltrated,

- either by the surgeon (=single shot)
- and/or by an indwelling catheter
- and/or by another method select "YES".

Multiple answers are possible.

Do not record the type of medication used.

M7 Wound infiltration (intra-op)

☒ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible; analgesic is not recorded):

☐ Single shot by surgeon ☐ Indwelling catheter ☐ Other, specify: ☐ Other, specify:

2.39 Perioperative medications: Intra-operative, opioids & local anesthetics

M8 Opioids and local anesthetics and clonidine

If the patient received any of the medications in the list, select "YES". Then choose the appropriate medications and the route administered.

- For opioids record the dose, if possible.
- For local anesthetics, dose is not necessary.
- For medications given by a regional anesthetic technique , mark the method in M5 (Regional anesthesia).

M8 Opioids & local anaesthetics (intra-op)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	RA (see M5)	i.v.	i.m.	s.c.
Alfentanil	☐ mg	☐ mg	☐ mg	☐ mg
Buprenorphine	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr
Codeine	☐ mg	☐ mg	☐ mg	☐ mg

2.40 Perioperative medications: Recovery room, M9–M11

Recovery room medication relates to 3 items:

- M9 Non-opioids
- M10 Regional anesthesia
- M11 Opioids and local anesthetics and clonidine

2.41 Perioperative medications: Recovery room, M9 & M10

Page 7

Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE:

RECOVERY ROOM

M9 Non-opioids (recovery room)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	p.o.	i.v.	i.m.	supp.
Celecoxib	☐ mg	☐ mg	☐ mg	☐ mg
Clonidine	☐ mg	☐ mg	☐ mg	☐ mg
Diclofenac	☐ mg	☐ mg	☐ mg	☐ mg

M9 If the patient received a **non-opioid** in recovery**,** select "YES". Then mark the name, route & dose.

M10 Regional analgesia (recovery room)

☐ yes ☐ no ☐ not possible to obtain the inform

If yes, which (multiple answers possible):

☐ Epidural	☐ Spinal	☐
☐ Sciatic	☐ Paravertebral	☐

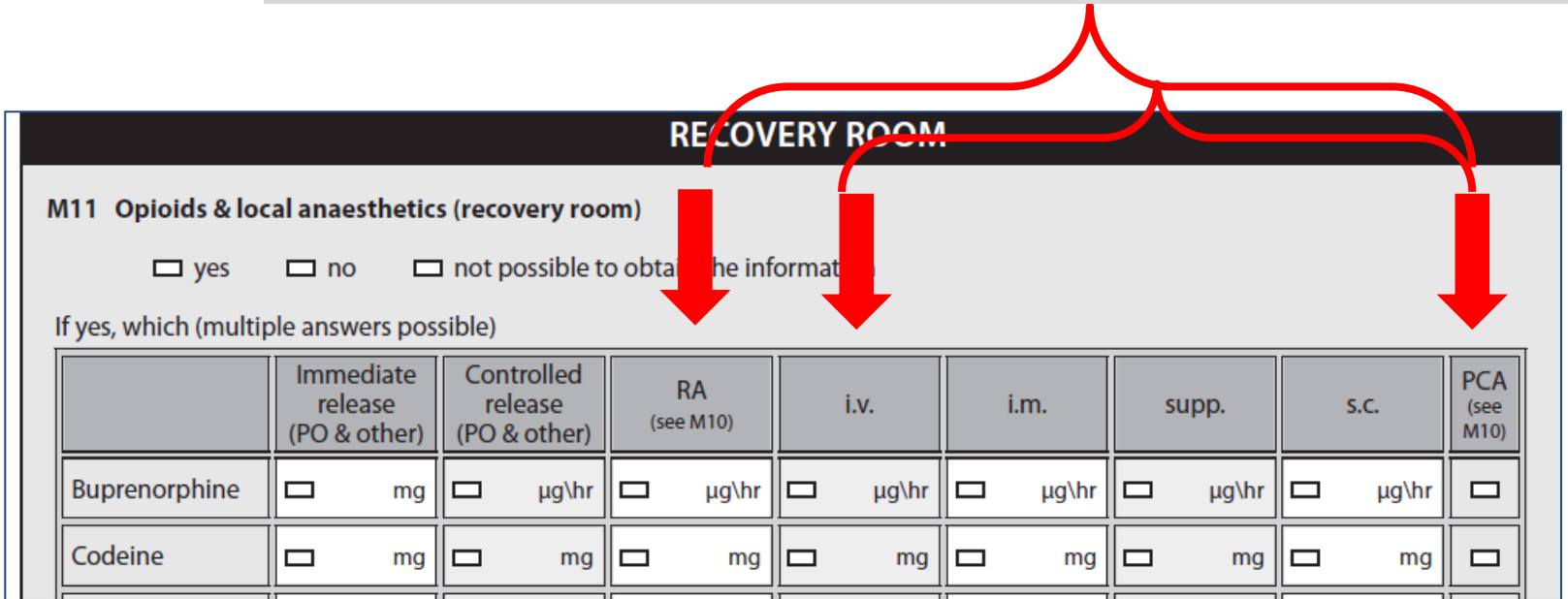
n M11: (1) Mark the RA medication(s) given in the RA column
(2) If the medication was given as PCA, tick appropriate box in the PCA column

M10 If the patient received regional anesthesia in recovery, select "YES". Mark the approach. Remember to add information about the medication in M11 AND PCA, if it was used.

2.42 Perioperative medications: Recovery room, M11

M11 Opioids and anesthetics and clonidine
If the patient received one or more of these medications, select "YES". Then select the medication name and route.
For **opioids**, record the total dose, if possible. If the calculation is complex – do not include this information.
For **local anesthetics** -> do not record the dose.
Naloxone is listed at the bottom: only mark this if the patient received naloxone for treatment of respiratory depression.

If patient controlled analgesia (PCA) was used: mark it in the appropriate box and also the route used, e.g. IV or regional analgesia.



RECOVERY ROOM

M11 Opioids & local anaesthetics (recovery room)

☐ yes ☐ no ☐ not possible to obta he informat

If yes, which (multiple answers possible)

	Immediate release (PO & other)	Controlled release (PO & other)	RA (see M10)	i.v.	i.m.	supp.	s.c.	PCA (see M10)
Buprenorphine	☐ mg	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐
Codeine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐

2.43 Perioperative medications: Recovery room, RA & PCA

How to mark epidural fentanyl with PCA administered in the recovery room?

M10 Regional analgesia (recovery room)

■ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

■ Epidural	☐ Spinal	☐ Brachial plexus	☐ Femoral
☐ Sciatic	☐ Paravertebral	☐ Other:	☐ Other:

In M11: (1) Mark the RA medication(s) given in the RA column
(2) If the medication was given as PCA, tick appropriate box in the PCA column

AND

RECOVERY ROOM

M11 Opioids & local anaesthetics (recovery room)

■ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible)

	Immediate release (PO & other)	Controlled release (PO & other)	RA (see M10)	i.v.	i.m.	supp.	s.c.	PCA (see M10)
Buprenorphine	☐ mg	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐
Codeine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Fentanyl	☐ µg\hr transmucosal	☐ µg\hr transdermal	■ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	☐ µg\hr	■

2.44 Perioperative medications: Ward

Ward medication includes 4 items:

- M12 Non-opioids
- M13 Regional anesthesia
- M14 Opioids and local anesthetics
- M15 Measurement of pain

Follow same principles as in Recovery, see sections 2.40 – 2.43

2.45 Perioperative medications: Ward, pain measurement

M15 Measurement of pain

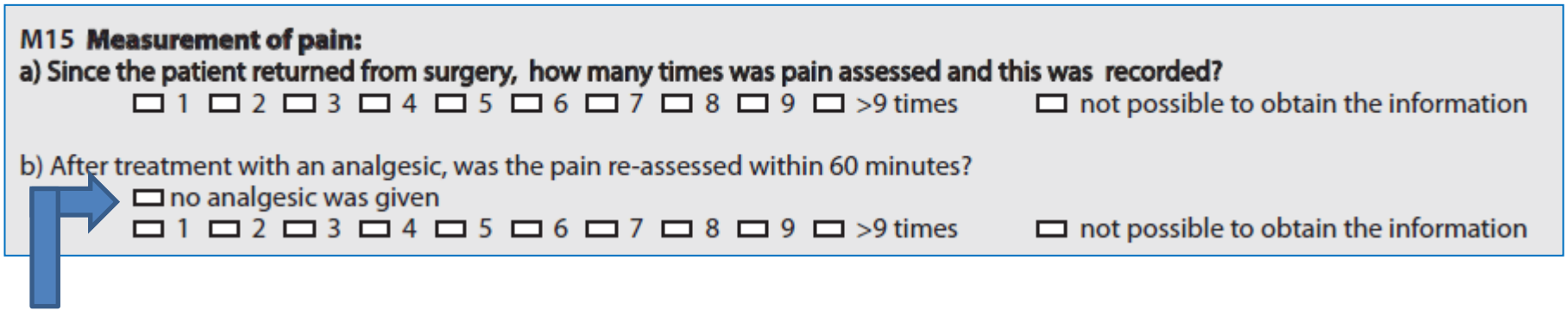
This item evaluates whether, once the patient is back on the ward after surgery, pain was assessed by the nurses and how often.

The item consists of two sub questions :

In **(a)** mark **IF** and **HOW OFTEN** was pain assessed & recorded by the nurses on the ward;

In **(b)** mark if the patient received an analgesic, was the pain **re-assessed** & this recorded within 60 minutes of treatment.

If yes, **how many times** was the reassessment carried out?



M15 Measurement of pain:

a) Since the patient returned from surgery, how many times was pain assessed and this was recorded?

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ >9 times ☐ not possible to obtain the information

b) After treatment with an analgesic, was the pain re-assessed within 60 minutes?

☐ no analgesic was given

☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ >9 times ☐ not possible to obtain the information

If the patient was not given any analgesics, once back on the ward, select this option.

2.46 Question 1

When at home, Jacob generally takes 7.5 mg Midazolam p.o. at night for severe sleeping problems.

The anesthesiologist prescribed 2 mg Lorazepam p.o. as medication for the night before surgery.

What would you record in **M1 Sedatives (pre-medication)**?

1. Midazolam 7.5 mg p.o. and Lorazepam 2 mg p.o.
2. Midazolam 7.5 mg p.o.
3. Lorazepam 2 mg p.o.

Answer # 3 is correct .

2.47 Question 2

Jacob underwent knee surgery. He was given a sedative and analgesic as pre-medication. He was ventilated by a laryngeal mask. Additionally a femoral nerve block catheter was placed to administer local anesthetics.

Which type of anesthesia do you record in M4 and / or M5?

1. General anesthesia in M4
2. Regional anesthesia in M5
3. General and Regional anesthesia in M4 and M5 AND the type(s) of medications administered in M8.
   - See next slide.

option #3 is correct.

Question 2, continued

Page 5

Mark medications *given* to patient; record *cumulative* doses. PATIENT CODE:

INTRA-OPERATIVE

M4 General anaesthesia (intra-op)

☒ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☒ Inhalational	☐ IV

M5 Regional anaesthesia (RA) (intra-op)

☒ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

☐ Epidural	☐ Spinal	☐ Brachial plexus	☒ Femoral
☐ Sciatic	☐ Paravertebral	☐ Other:	☐ Other:

In M8: Mark the RA medication(s) given in the RA column

M8 Opioids & local anaesthetics (intra-op)

☒ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	RA (see M5)	i.v.	i.m.	s.c.
Alfentanil	☐ mg	☐ mg	☐ mg	☐ mg
Buprenorphine	☐ µg	☐ µg	☐ µg	☐ µg
Codeine	☐ mg	☐ mg	☐ mg	☐ mg
Fentanyl	☒ µg	☐ µg	☐ µg	☐ µg
Hydrocodone	☐ mg	☐ mg	☐ mg	☐ mg

2.48 Question 3

Rachel underwent colon surgery. She had an epidural catheter with local anesthetics and fentanyl. On the ward, she received a PCA with continuous administration and boluses throughout the first post-operative day.

A. How would you record this on the ward?

M13 Regional analgesia (ward)

☐ yes ☐ no ☐ not possible to obtain the information — If yes, which (multiple answers possible):

☒ Epidural	☐ Spinal	☐ Brachial plexus	☐ Femoral
☐ Sciatic	☐ Paravertebral	☐ Transv. Abdom. Plane (TAP)	☐ Other:

In M14: (1) Mark the RA medication(s) given in the RA column
(2) If the medication was given as PCA, tick appropriate box in the PCA column

M14 Opioids & local anaesthetics (ward)

☐ yes ☐ no ☐ not possible to obtain the information

If yes, which (multiple answers possible):

	Immediate release (PO & other)	Controlled release (PO & other)	RA (see M13)	i.v.	i.m.	supp.	s.c.	PCA (see M13)
Buprenorphine	☐ mg	☐ µg\hr	☐ µg	☐ µg	☐ µg	☐ µg	☐	☐
Codeine	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐
Fentanyl	☐ µg transmucosal	☐ µg\hr transdermal	☒ µg	☐ µg	☐ µg	☐ µg	☐ µg ☐ µg	☒
Hydrocodone	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐ mg	☐

See next slide

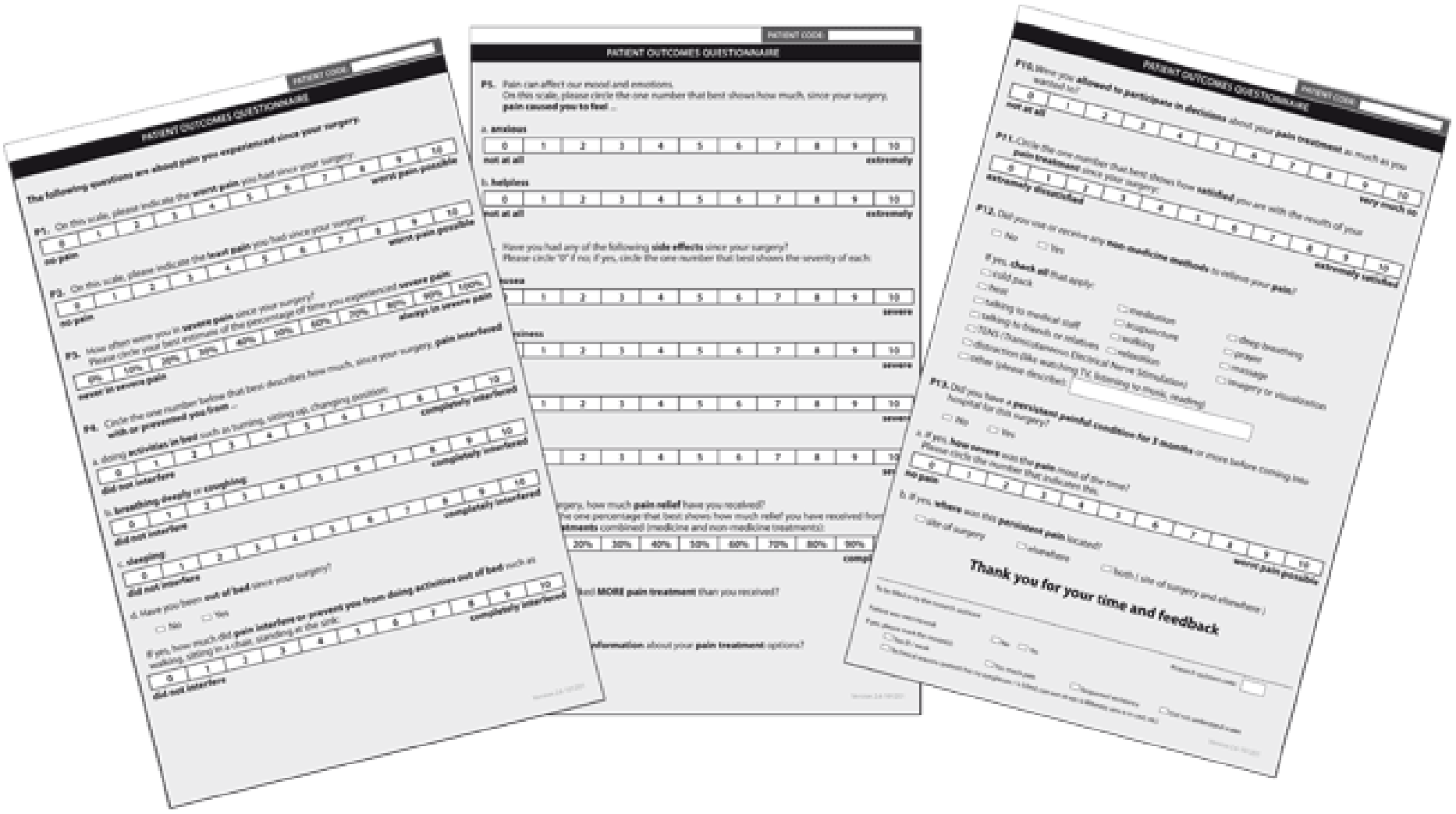
2.48 Question 3 (cont.)

B. Which dose would you record for the PCA?

1. Only dose given as bolus
2. Only dose given continuously
3. Combined doses given as bolus and continuously
4. Dose is not necessary

Option # 4 is the correct one;
Do NOT enter dose for local anesthetics;
It can be complex to calculate the dose for continuous infusion and boluses – best to leave out.

2.49 Outcomes Questionnaire



2.50 How to provide information and how to **obtain** consent ? [i]

Providing information In all countries, the ethics committee [(EC), or Institutional Review Board (IRB)] of each hospital will require that you provide the patient with information about the nature of the survey.

The information can be given either in written format or orally when the surveyor approaches the patient to recruit him.

Obtaining consent In some countries it is enough that patients give **oral agreement** about their participation, this is called **'assent'** (= to agree to, give approval to).

In some countries, the EC requires that the patient provide their agreement in written form. In this case, you will need to give the patient a **consent form**; ask the patient to read the form and to sign.

Both factors, i.e. how to inform patients and how to receive their consent, are determined by the local ethics committee in each hospital.

2.50 Obtaining informed consent. cont.

In the next slide, we describe the format of a letter that you may use for patients in your site. However, some ethics committees will require that collaborators compose and use a letter based on specifications given by the local ethics committee.

2.51 An example of a Patient Information & letter of consent

Dear Sir \ Madam

We would be grateful if you would participate in our survey on how patients feel after surgery. The aim of the survey is to improve the management of pain after surgery in this department.

Your participation is voluntary and the information you provide will be made anonymous once you hand in this questionnaire. This means that your name or other form of identification will be deleted from the questionnaire after you hand it in and will not be included in any records we will hold.

Your answers in this questionnaire will **not** be shared with your medical or nursing team.

Your team will treat you in the same way whether or not you choose to participate in our survey.

Many thanks for considering to take part in this survey.

The letter addresses:

[1] Type and aim of study

[2]Participation is voluntary

[3] Anonymity will be kept

[4] Same quality of treatment

2.52 [1] **Type** and **aim(s)** of study

TYPE The data collected in PAIN OUT falls under the category of 'Quality Improvement' or 'non-interventional ‘ or ‘observational’ or 'descriptive’ studies or 'surveys'.

AIM(s) Primary aim: The information will be used to improve how pain is managed in this department. The findings may also be used to assess how to improve management of patients undergoing similar procedures in other hospitals.

2.53 [2] Participation is voluntary

Patients can be recruited only if they do so voluntarily, out of their own free will.

No one should force or coerce a patient to take part, not the patient's relatives or friends or a member of staff.

2.54 [3] Anonymity will be kept

Patients should be assured that their answers will be dealt with anonymously. This means that once the data for each patient is entered into the web-based database, it will be difficult to trace answers back to him / her.

How? PAIN OUT does not record patient identifiers: name, full date of birth or hospital identification number.

Patients may be concerned that the doctors or nurses caring for them will be notified about the answers they gave. This is mostly relevant if a patient is critical or displeased with his treatment.

Assure patients that: (1) you do not belong to the team treating him (when this is true) and that (2) staff receive only summarized data; not findings about individual patients.

The code used to match the Outcomes Questionnaire of an individual patient with the Process Questionnaire of that patient is an internal hospital code, it is not inputted into the database.

2.55 [4] Same quality of treatment

Assure patients that the quality of treatment they receive will not be affected in any way

if the choose not to participate in the survey.

2.56 Recruiting patients

Approach patients using a standardized procedure.
Here is a summary of the steps you should carry out.

STEP 1 Introduce yourself and PAIN OUT.

STEP 2 Ask for consent.

STEP 3 If consent is given, give the Outcomes Questionnaire.

STEP 4 Patient fills in the questionnaire / Leave the room.

STEP 5 Return to collect the Outcomes Questionnaire.

2.57 **STEP 1** Introduce yourself and PAIN OUT

‘Hello, Mr/Mrs X, my name is Y. I am from the K department. We are carrying out a survey to assess how patients feel after surgery. Our aim is to improve management of pain after surgery.’

2.58 **STEP 2** Asking for consent

After informing the patient about the survey, ask for consent.

Since this is an observational study, many sites accept oral consent = the patient says that he agrees to participate. However, some ethics committee require that patients sign a letter of consent.

Watch clip on:

https://www.youtube.com/watch?v=Y1wKxibHOn8

2.59 **STEP 2** When a patient does not consent

If a patient is not interested in participating, do not exert any pressure on him to do so.

Neither should other members of staff, family or friends do so.

2.60 STEP 2 When a patient cannot give consent

There are different reasons for patients not giving consent. See those listed in S3 of the Process Questionnaire.

S3 Patient has given his assent (or consent) to participate

If **no** to S3, mark the reason(s):

- ☐ a. Patient is not on the ward
- ☐ b. Patient does not wish to participate[1]
  - ☐ b1. too ill
  - ☐ b2. too much pain
  - ☐ b3. other
- ☐ c. Patient is asleep
- ☐ d. Patient has visitors
- ☐ e. It is not possible to communicate with the patient (e.g., patient is deaf, does not read/write in any of the languages in which the Outcomes questionnaire is available)
- ☐ f. Patient is cognitively impaired (e.g., Downs syndrome, dementia, Alzheimer's disease, Cerebral Palsy)
- ☐ g. Other, specify: _____

[1] Remember: You may interview patients who need help, e.g., are too ill or in too much pain or illiterate

If a patient is not recruited – remember to record the reason(s) for this AND to enter the information into the web-based mask.

2.61 **STEP 2** Asking for consent: Check yourself

Surveyor : ‘Would you be willing to participate in a survey assessing how patients feel after surgery?’

Patient: ’I don´t feel like filling in questionnaires. Please leave me alone.’

How should you answer?

1. ’No problem. The survey is voluntary.’
2. ’I would appreciate if you would re-consider. It will only take some minutes and is likely to help future patients.’
3. ’OK. I will come back later, maybe you’ll feel different then.’

1 is the correct answer

2.62 **STEP 3** If consent is given, give the Outcomes Questionnaire

Hand out the Outcomes Questionnaire.
Ask the patient to fill it in.

Tell the patient that you will leave him/her to fill in the Outcomes Questionnaire.
Give an approximate time as to when you will come back to collect it.

Come back the same day!

2.63 STEP 4 Filling in the questionnaire

Language of the Outcomes Questionnaire

Patients should receive – as far as is possible -the Outcomes Questionnaire in their native language.

This should make it easier for them to understand the questions and to give reliable answers.

For patients who live in a country where their native language is not spoken, find out which language of the questionnaire they prefer. Even if a patient has been residing in their adopted country for years and is fluent speaking the language, they may prefer reading in their native language, particularly in times of stress, such as after surgery.

Ask the patient which language of the questionnaire they prefer to have.

See video clip: https://www.youtube.com/watch?v=XBKol0adsW4

Download questionnaires in multiple languages from the PAIN OUT website.

D7 Language of Outcome questionnaire (select one)

☐ Albanian	☐ Arabic	☐ Bahasa Malaysia	☐ Danish	☐ Dutch	☐ English	☐ Filipino
☐ Finnish	☐ French	☐ German	☐ Hebrew	☐ Hindustani	☐ Icelandic	☐ Italian
☐ Korean	☐ Mandarin	☐ Romanian	☐ Russian	☐ Serbo-Croatian	☐ Spanish	☐ Span. Mexico
☐ Swedish						

Versions in Afrikaans / Xhosa / Zulu are being prepared

2.64 STEP 4 But the patient has visitors

The Outcomes Questionnaire seeks to find out how patients perceive their pain after surgery. We aim that patients fill in the questionnaire on their own, with no help from the surveyor OR family member OR friend. Under these conditions, patients' answers probably be based on their own judgment and minimally influenced by the need to please others, e.g. they might feel that by reporting high pain scores they are being critical of their healthcare providers.
There are exceptions to this – described in the slides that follow.

Watch clip on:
https://www.youtube.com/watch?v=uCHgdRVIysk

2.65 **STEP 4** Does the patient need help?

When giving out the questionnaire, evaluate the patients´ need for help.

Some will need:

1. NO help filling in the questionnaire;

Others will need:

2. help with a few questions;
3. help with all questions (= interview).

2.66 STEP 4 No help required

Situation 1: Needs no help filling in the questionnaire.

Most patients will be able to read the questions independently and write the answers on their own.

Why do we aim that they do this?

PAIN OUT seeks to find out how patients perceive pain, side-effects and

impact of the pain on their mood, amongst other items.

These assessments are easily influenced by others.

The wish to please a member of family or member of staff can alter a patient´s evaluation of how he feels.

Therefore, the Outcomes Questionnaire should be filled in by the patient on his own, with no help from others.

Once you hand out the questionnaire to the patient, leave the room.

2.67 STEP 4 Help required with a few questions

Situation 2: Needs help with a few questions

If a patient does not understand a question
read it out loud once, using the same text as in the question.

If he / she still does not understand the question after you have done this, mark it as un-answered.

This applies to all questions in the Outcomes Questionnaire.

You may come across this situation once the patient has gone over the questionnaire and you have come back to collect it.

2.68 **STEP 4** When is it an interview

Situation 3: patient needs help with all questions

If a patient requests that you help him with the entire questionnaire, you can carry out an interview.

When is it an interview?
It is when you hold the Outcomes Questionnaire in your hands, read out all the questions to the patient and write down his answers for him.

Helping a patient with 1 - 3 questions does not qualify as an interview.

2.69 **STEP 4** Situations a patient needs help

There are medical and technical reasons why a patient might require help filling in the Outcomes Questionnaire. For example:

Medical

- is too weak,
- in too much pain,
- arm is cast

Technical

- eye-glasses are unavailable,
- does not understand the scales for evaluating answers.

Please assist patients who request help -> excluding them could bias the findings.

2.70 [i] **STEP 4** Guidelines to conduct an interview

Translate text here

If a patient **cannot read:**

- Read out each question exactly as it is. **Do not change the text!**
- Let the patient reply. Write down his/her answer.

If a patient **cannot write:**

- Let the patient read the questions on his/her own
- Write down his/her answer.

Do not comment.
Do not be judgmental about the patient's answers.

2.70 [ii] **STEP 4** Guidelines to conduct an interview

If you carried out an interview, mark this on the back of the Outcomes questionnaire.
Select "YES" and mark the reason.

2.71 Question yourself

The patient can´t find his glasses.

He says: ’Sorry. I can´t participate. I am too nearsighted to read the text.’

How should you answer?

1. ’You can participate. We’ll ask your daughter can help, she can read the questions out loud for you.’
2. ’You can participate, I will help you by reading the questions out loud to you. Do you agree?’
3. ’That´s true, sorry. In this case, you cannot participate.’

Option #2 is correct.

2.72 **STEP 5** Picking up the Outcomes questionnaire

Go over the Outcomes Questionnaire and check if all the questions have been filled in.

If the Outcomes Questionnaire is complete, thank the patient and leave the room.

2.73[i] STEP 5 Reviewing the questionnaire

If after reviewing the questionnaire, you find it is **incomplete**, ask the patient whether:

1. He / she has left out the answers unintentionally OR
2. Does not want to answer the question(s) OR
3. Needs help.

If the patient does not want to answer and asks for no assistance, then leave the question unanswered.

If the patient asks for assistance with a few questions (e.g up to 3-4):

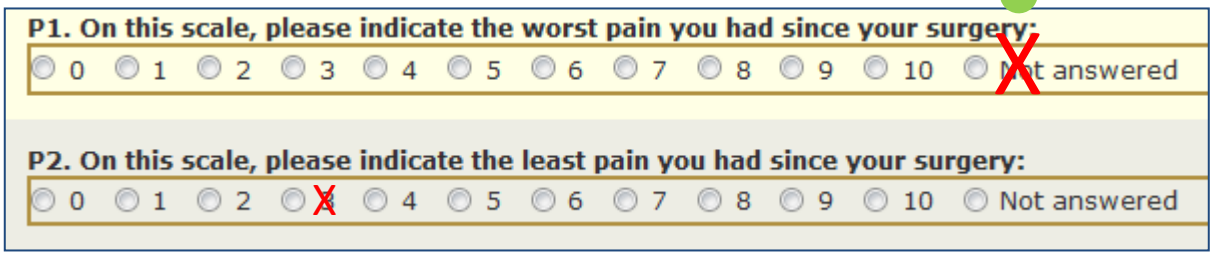
1. Read out the question once.
2. Do not change any of the text.
3. Do not provide any explanations.
4. Let the patient reply and write down his answer.

This does not constitute an interview.

If the patient does not understand the question(s) after you have done this, mark it / them as unanswered.

Later, when you enter the data into the web-mask, mark these question(s) as 'Not answered'. See next slide.

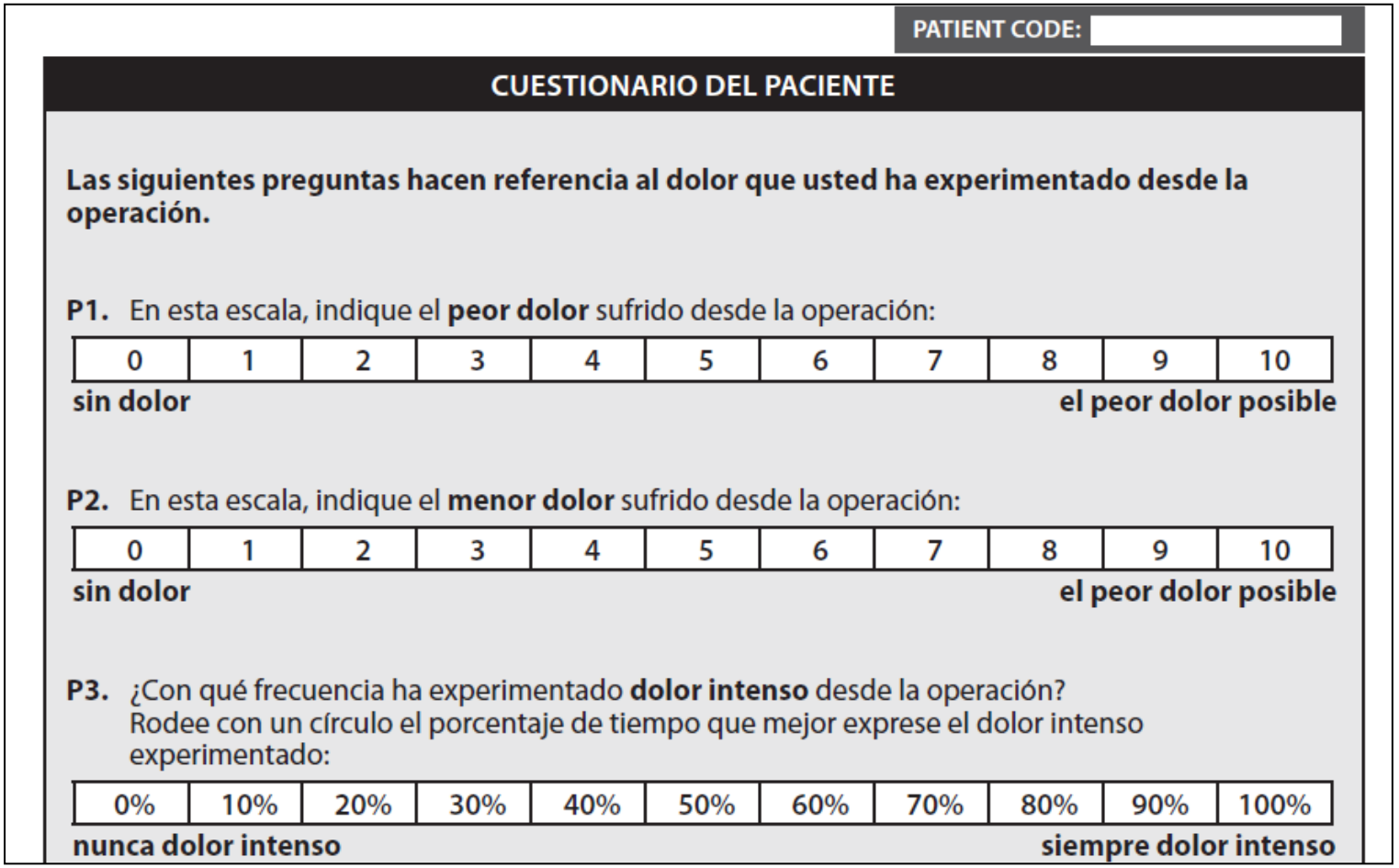
2.73[ii] **STEP 5** Reviewing the questionnaire



When you enter the data into the web-mask, mark question(s) which the patient left un-answered as 'Not answered'.

See previous slide.

2.74 Background, structure & items in the patient reported outcomes questionnaire



PATIENT CODE:

CUESTIONARIO DEL PACIENTE

Las siguientes preguntas hacen referencia al dolor que usted ha experimentado desde la operación.

P1. En esta escala, indique el **peor dolor** sufrido desde la operación:

0	1	2	3	4	5	6	7	8	9	10

sin dolor **el peor dolor posible**

P2. En esta escala, indique el **menor dolor** sufrido desde la operación:

0	1	2	3	4	5	6	7	8	9	10

sin dolor **el peor dolor posible**

P3. ¿Con qué frecuencia ha experimentado **dolor intenso** desde la operación? Rodee con un círculo el porcentaje de tiempo que mejor exprese el dolor intenso experimentado:

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

nunca dolor intenso **siempre dolor intenso**

2.75 Outcomes for patients to assess their experience of pain after surgery

In the International Pain Outcomes questionnaire, patients use the following outcomes to assess the management of pain they received after surgery:

- Intensity or severity of pain,
- Interference of pain with activities in and out of bed and with emotions,
- Adverse effects related to anesthesia and opioids ,
- Perception of care related to pain, given by the healthcare providers.
- Chronic pain before surgery: existence, intensity and location.
  - Chronic pain can have an effect on pain experienced after surgery.

The American Pain Society published its first version of a questionnaire asking patients to assess pain-related outcomes in 1995. Since then, the questionnaire has been revised a number of times. The questionnaire used in PAIN OUT is adapted and based on the 2010 vision. It is also based on experience gained from the German acute pain registry, QUIPS.

2.76 Validation of the questionnaire

The International Pain Outcomes questionnaire was validated in English.

The work is described in:

Rothaug et al. Patients' perception of postoperative pain management: validation of the International Pain Outcomes (IPO) questionnaire. J Pain. 2013 Nov;14(11):1361-70

Validity

Validity refers to the degree in which the test truly measures what it claims to measure. The Outcomes Questionnaire has good validity.

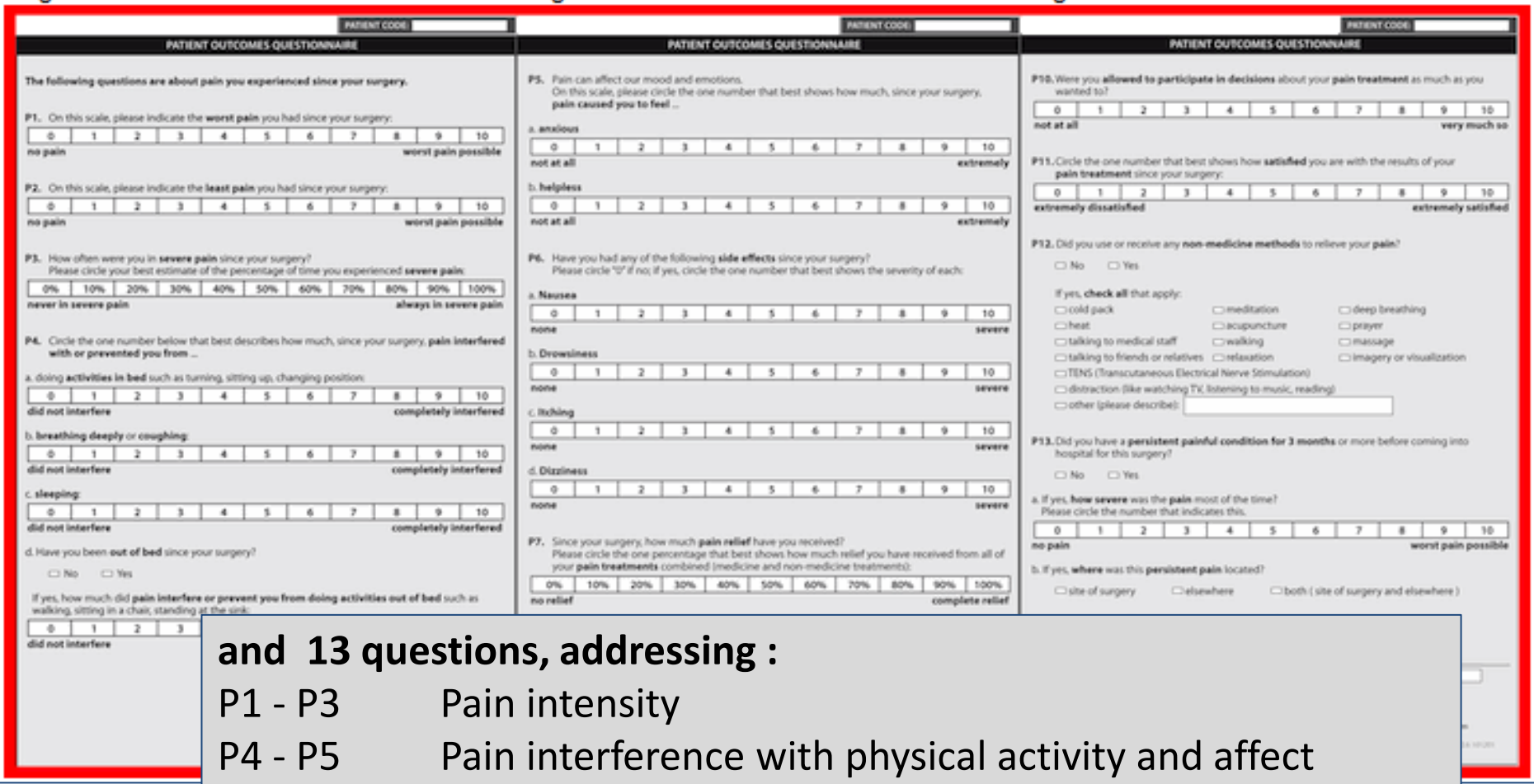
Reliability

Reliability refers to the repeatability or consistency of the test. The Outcomes Questionnaire has a high internal consistency

Translations from the original English version to other languages is carried out following a standardized procedure of *translation and back-translation* by a clinician and professional translator. The two versions are then compared and consolidated.

2.77 The patient questionnaire consists of 3 pages

Page 1 Page 2 Page 3



PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

The following questions are about pain you experienced since your surgery.

P1. On this scale, please indicate the **worst pain** you had since your surgery:

0 1 2 3 4 5 6 7 8 9 10

no pain — worst pain possible

P2. On this scale, please indicate the **least pain** you had since your surgery:

0 1 2 3 4 5 6 7 8 9 10

no pain — worst pain possible

P3. How often were you in **severe pain** since your surgery?
Please circle your best estimate of the percentage of time you experienced **severe pain**:

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

never in severe pain — always in severe pain

P4. Circle the one number below that best describes how much, since your surgery, **pain interfered with or prevented you from** ...

a. doing **activities in bed** such as turning, sitting up, changing position:

0 1 2 3 4 5 6 7 8 9 10

did not interfere — completely interfered

b. **breathing deeply** or **coughing**:

0 1 2 3 4 5 6 7 8 9 10

did not interfere — completely interfered

c. **sleeping**:

0 1 2 3 4 5 6 7 8 9 10

did not interfere — completely interfered

d. Have you been **out of bed** since your surgery?

☐ No ☐ Yes

If yes, how much did **pain interfere or prevent you from doing activities out of bed** such as walking, sitting in a chair, standing at the sink:

0 1 2 3

did not interfere

PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

P5. Pain can affect our mood and emotions.
On this scale, please circle the one number that best shows how much, since your surgery, **pain caused you to feel** ...

a. **anxious**

0 1 2 3 4 5 6 7 8 9 10

not at all — extremely

b. **helpless**

0 1 2 3 4 5 6 7 8 9 10

not at all — extremely

P6. Have you had any of the following **side effects** since your surgery?
Please circle "0" if no; if yes, circle the one number that best shows the severity of each:

a. **Nausea**

0 1 2 3 4 5 6 7 8 9 10

none — severe

b. **Drowsiness**

0 1 2 3 4 5 6 7 8 9 10

none — severe

c. **Itching**

0 1 2 3 4 5 6 7 8 9 10

none — severe

d. **Dizziness**

0 1 2 3 4 5 6 7 8 9 10

none — severe

P7. Since your surgery, how much **pain relief** have you received?
Please circle the one percentage that best shows how much relief you have received from all of your **pain treatments** combined (medicine and non-medicine treatments):

0% 10% 20% 30% 40% 50% 60% 70% 80% 90% 100%

no relief — complete relief

PATIENT CODE:

PATIENT OUTCOMES QUESTIONNAIRE

P10. Were you **allowed to participate in decisions** about your **pain treatment** as much as you wanted to?

0 1 2 3 4 5 6 7 8 9 10

not at all — very much so

P11. Circle the one number that best shows how **satisfied** you are with the results of your **pain treatment** since your surgery:

0 1 2 3 4 5 6 7 8 9 10

extremely dissatisfied — extremely satisfied

P12. Did you use or receive any **non-medicine methods** to relieve your **pain**?

☐ No ☐ Yes

If yes, **check all** that apply:

☐ cold pack ☐ meditation ☐ deep breathing
☐ heat ☐ acupuncture ☐ prayer
☐ talking to medical staff ☐ walking ☐ massage
☐ talking to friends or relatives ☐ relaxation ☐ imagery or visualization
☐ TENS (Transcutaneous Electrical Nerve Stimulation)
☐ distraction (like watching TV, listening to music, reading)
☐ other (please describe):

P13. Did you have a **persistent painful condition for 3 months** or more before coming into hospital for this surgery?

☐ No ☐ Yes

a. If yes, **how severe** was the **pain** most of the time?
Please circle the number that indicates this.

0 1 2 3 4 5 6 7 8 9 10

no pain — worst pain possible

b. If yes, **where** was this **persistent pain** located?

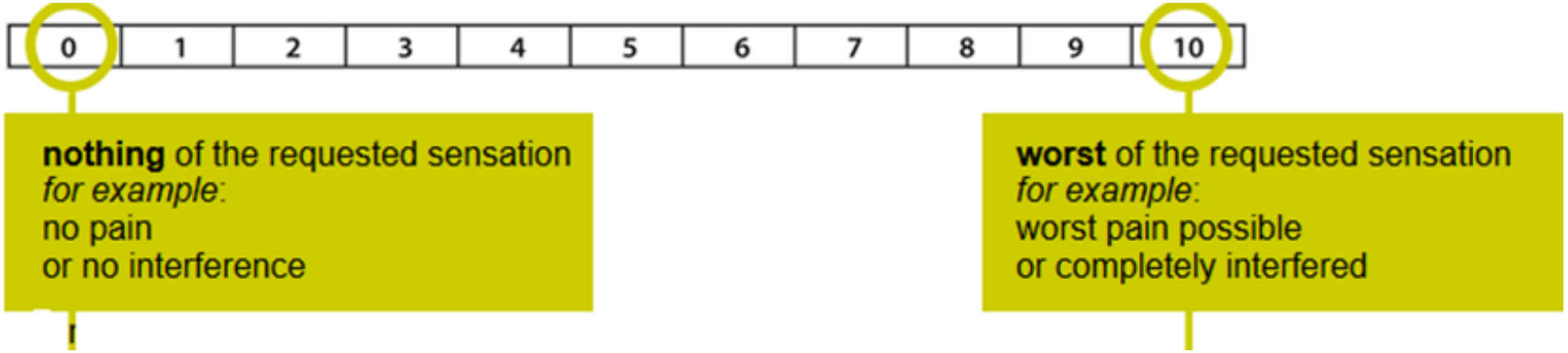
☐ site of surgery ☐ elsewhere ☐ both (site of surgery and elsewhere)

and 13 questions, addressing :

P1 - P3	Pain intensity
P4 - P5	Pain interference with physical activity and affect
P6	Adverse effects
P7 - P11	Perceptions of care
P12	Non--pharmacological treatment of pain
P13	Persistent pain

2.78 Scales used for assessment

[1] Patients rate most of the items using a **Numerical Rating Scale**



[2] Two questions are assessed using a **percentage scale**

[3] A number of items are assessed using **YES / NO**

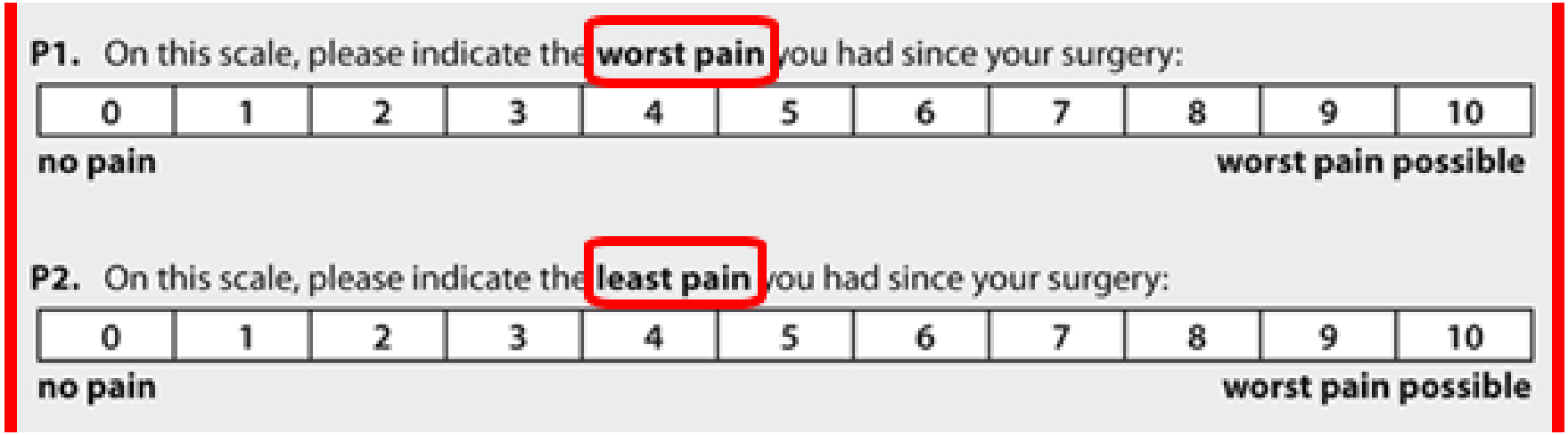
2.79 Pain since your surgery …

Note that in all questions, except for the last one, P13, patients are asked to reflect on how they felt since their surgery.

The following questions are about pain you experienced since your surgery.

This is to remind patients to relate each question to the pain or sensation which is associated with the surgery they underwent.

2.80 P1–P2 Pain Intensity



P1. On this scale, please indicate the **worst pain** you had since your surgery:

0	1	2	3	4	5	6	7	8	9	10

no pain **worst pain possible**

P2. On this scale, please indicate the **least pain** you had since your surgery:

0	1	2	3	4	5	6	7	8	9	10

no pain **worst pain possible**

Questions P1 and P2 ask patients to assess the **worst** and **least** pain intensity they experienced since surgery.

Measuring worst and least pain helps evaluate the full range of pain experienced during rest (when people typically experience least pain) and when carrying out activities which typically induce severe pain.

At times, patients confuse between 'worst' vs 'least' pain and fill in their assessment for least in worst and vice versa.
When picking up the questionnaire – please review – is the evaluation of least > worst AND have all the questions been answered. If yes, point out to the patient and ask them to address this.

2.81 P3 Pain intensity

P3. How often were you in **severe pain** since your surgery?
Please circle your best estimate of the percentage of time you experienced **severe pain**:

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

never in severe pain **always in severe pain**

In P3, patients are asked to assess how much of the time, since surgery, they spent in **severe** pain. They assess this as a **percentage**.

In **P1** patients are asked to assess what the intensity of their **worst** pain was – this could be momentary pain, e.g. when moving or taking a deep breath.

In **P3** patients are asked to assess how much **severe** pain they experienced over time. Patients would need to define for themselves what they regard is their 'worst' pain and what is 'severe' pain.

Patients often find that using the percentage scale is challenging.
You can point out that they should make an estimate – this is not meant to be a precise calculation.
If a patient still experiences difficulties:

1. You can read the question out loud once.
2. If this is not sufficient to clarify the question, leave it un-answered

When you enter the data into the web-mask, mark "Question un-answered"

2.82 P4 Interference of pain with activities

P4. Circle the one number below that best describes how much, since your surgery, **pain interfered with or prevented you from ...**

a. doing **activities in bed** such as turning, sitting up, changing position:

0	1	2	3	4	5	6	7	8	9	10
did not interfere										**completely interfered**

b. **breathing deeply** or **coughing**:

0	1	2	3	4	5	6	7	8	9	10
did not interfere										**completely interfered**

c. **sleeping**:

0	1	2	3	4	5	6	7	8	9	10
did not interfere										**completely interfered**

d. Have you been **out of bed** since your surgery?

☐ Yes ☐ No

If yes, how much did **pain interfere or prevent you from doing activities out of bed** such as walking, sitting in a chair, standing at the sink:

0	1	2	3	4	5	6	7	8	9	10
did not interfere										**completely interfered**

P4 a, b addresses activities in bed which typically induce higher levels of pain and so may be difficult to carry out.

P 4 d is relevant only for those patients who have already gotten out of bed by the time they answer the questionnaire.

2.83 P5 Effect of pain on affect

P5. Pain can affect our mood and emotions.
On this scale, please circle the one number that best shows how much, since your surgery, **pain caused you to feel ...**

a. **anxious**

0	1	2	3	4	5	6	7	8	9	10
not at all										**extremely**

b. **helpless**

0	1	2	3	4	5	6	7	8	9	10
not at all										**extremely**

2.84 P6 Adverse effects

P6. Have you had any of the following **side effects** since your surgery?
Please circle "0" if no; if yes, circle the one number that best shows the severity of each:

a. **Nausea**

0	1	2	3	4	5	6	7	8	9	10
none										severe

b. **Drowsiness**

0	1	2	3	4	5	6	7	8	9	10
none										severe

c. **Itching**

0	1	2	3	4	5	6	7	8	9	10
none										severe

d. **Dizziness**

0	1	2	3	4	5	6	7	8	9	10
none										severe

P6 a-d ask about adverse effects that are typical of the anesthesia and treatment with opioids.

Constipation is a common adverse effect of opioids. It is not included here as it is un-likely to develop during the first post-operative day.

2.85 Perceptions of care

P7 – P11 addresses ‘perception of care’, i.e. asks patients to assess how they regard

the pain management given to them by their healthcare providers.

2.86 P7 Degree of pain relief received

P7. Since your surgery, how much **pain relief** have you received?
Please circle the one percentage that best shows how much relief you have received from all of your **pain treatments** combined (medicine and non-medicine treatments):

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%
no relief										**complete relief**

Patients are asked to assess the degree of relief they received from all the pain-related treatments they received.
Patients are asked to carry out this assessment using a percentage scale.
0 % indicates no relief - 100 % indicates complete relief.

Patients often have difficulties using the percentage scale.
If a patient experiences difficulties:
1. Read the question out loud once. You can try to clarify it by saying 'Think back to all the treatments you received for pain.
Can you estimate much relief do you received?'
2. If this is not sufficient to clarify the question, leave it un-answered

Mark "Question un-answered" when you enter the data into the web-mask later.

% scale – worth paying attention

P3. How often were you in **severe pain** since your surgery?
Please circle your best estimate of the percentage of time you experienced **severe pain**:

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

never in severe pain **always in severe pain**

In **P3**, when assessing % time in severe pain – 100 % represents the most PAIN;
In **P7**, when assessing pain relief – the 100 % represents the most RELIEF.

P7. Since your surgery, how much **pain relief** have you received?
Please circle the one percentage that best shows how much relief you have received from all of your **pain treatments** combined (medicine and non-medicine treatments):

0%	10%	20%	30%	40%	50%	60%	70%	80%	90%	100%

no relief **complete relief**

2.87 P8 & P9: More treatment & providing information

P8. Would you have liked **MORE pain treatment** than you received?

☐ Yes ☐ No

P9. Did you receive any **information** about your **pain treatment** options?

☐ Yes ☐ No

2.88 P10 & P11 Allowed to participate & satisfaction

P10. Were you **allowed to participate in decisions** about your **pain treatment** as much as you wanted to?

0	1	2	3	4	5	6	7	8	9	10
not at all										**very much so**

P11. Circle the one number that best shows how **satisfied** you are with the results of your **pain treatment** since your surgery:

0	1	2	3	4	5	6	7	8	9	10
extremely dissatisfied										**extremely satisfied**

Some patients find question P10 difficult to answer.
Do not provide explanations, leave un-answered.

Mark "Question un-answered" when you enter the data into the web-mask later.

Note that In P11 'Satisfaction' relates to pain management and NOT to other features of the patient's stay in hospital.

2.89 P12 non-pharmacological management of pain

P12. Did you use or receive any **non-medicine methods** to relieve your **pain**?

☐ Yes ☐ No

If yes, **check all** that apply:

☐ cold pack	☐ meditation	☐ deep breathing
☐ heat	☐ acupuncture	☐ prayer
☐ talking to medical staff	☐ walking	☐ massage
☐ talking to friends or relatives	☐ relaxation	☐ imagery or visualization

☐ TENS (Transcutaneous Electrical Nerve Stimulation)

☐ distraction (like watching TV, listening to music, reading)

☐ other (please describe): _____

P12 asks patients to record the types of non-pharmacologic strategies that they might have used to control their pain and / or that they might have received from their healthcare providers. Providing patients with non-pharmacologic treatment strategies is recommended by some clinical treatment guidelines for some conditions , e.g. cold pack for various orthopedic procedures is accepted as a standard of care in some countries and hospitals. These treatments are often not documented in the medical record which is why patients are being asked to record them.

If a patient writes an intervention in OTHER which appears in the list, please select that when entering data into the mask. Information in OTHER is rarely accessed or assessed.

2.90 P13 Persistent Pain

P13. Did you have a **persistent painful condition for 3 months** or more before coming into hospital for this ~~surgery?~~

☐ Yes ☐ No

a. If yes, **how severe** was the **pain** most of the time?
Please circle the number that indicates this.

0	1	2	3	4	5	6	7	8	9	10

no pain **worst pain possible**

b. If yes, **where** was this **persistent pain** located?

☐ site of surgery ☐ elsewhere ☐ both (site of surgery and elsewhere)

P13 asks patients whether they had **persistent pain** for 3 months or more before surgery. "Pain for three months or over" is one definition for chronic pain.

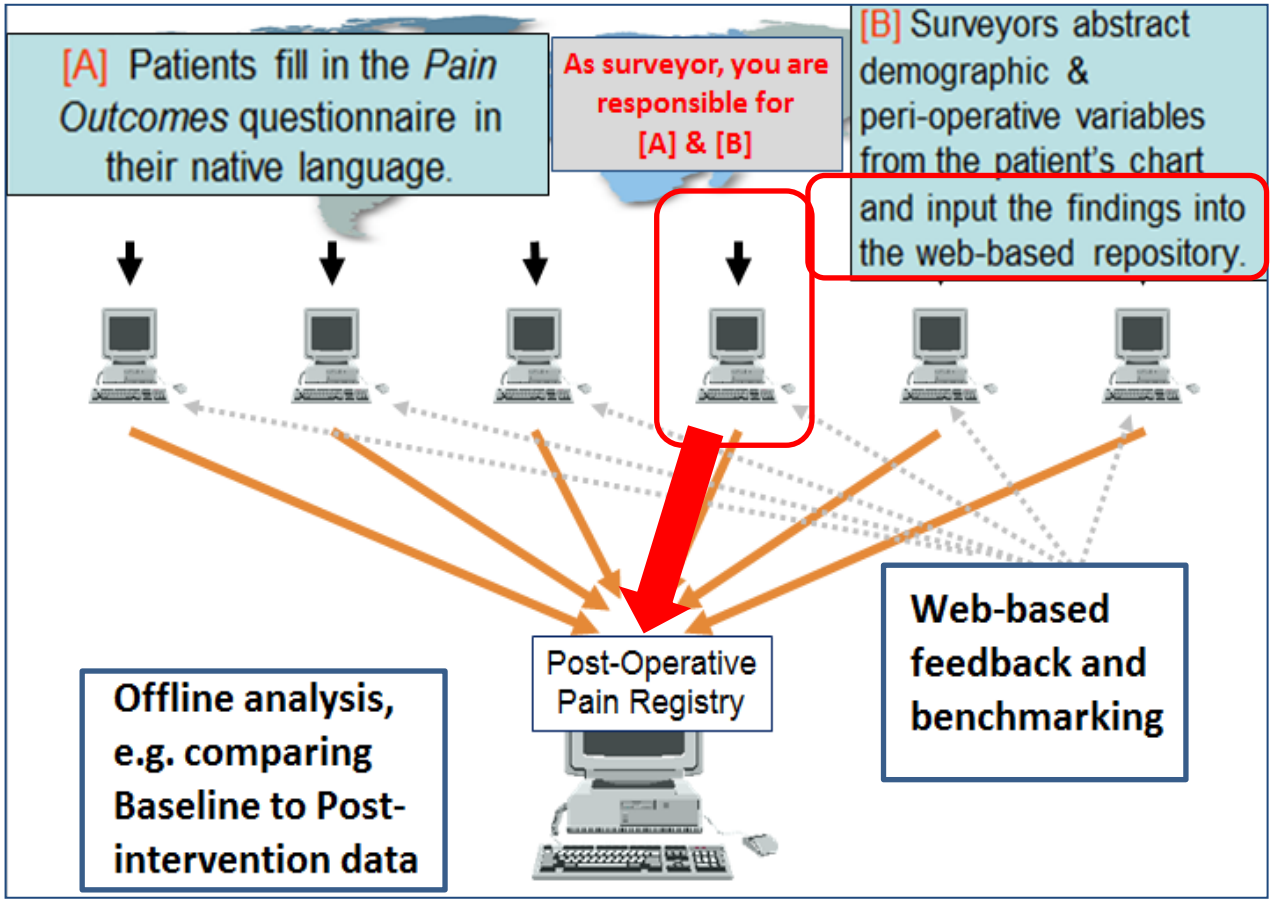
If "YES" the patient is asked to characterize the pain regarding
(1) intensity; (2) region on the body.

Having pain before surgery can impact on the severity of pain in the early post-operative period. This may also be one of the many factors which influence development of chronic pain after surgery.

2.91 Structural Questionnaire

- A member in your team will be asked to fill in a short questionnaire evaluating structures in your hospital, e.g. type of hospital (governmental or private) and number of beds.
- This will be carried out when you join the project.
- Please help to verify that this questionnaire was filled in.

Part 3: Inputting data into the web-based mask

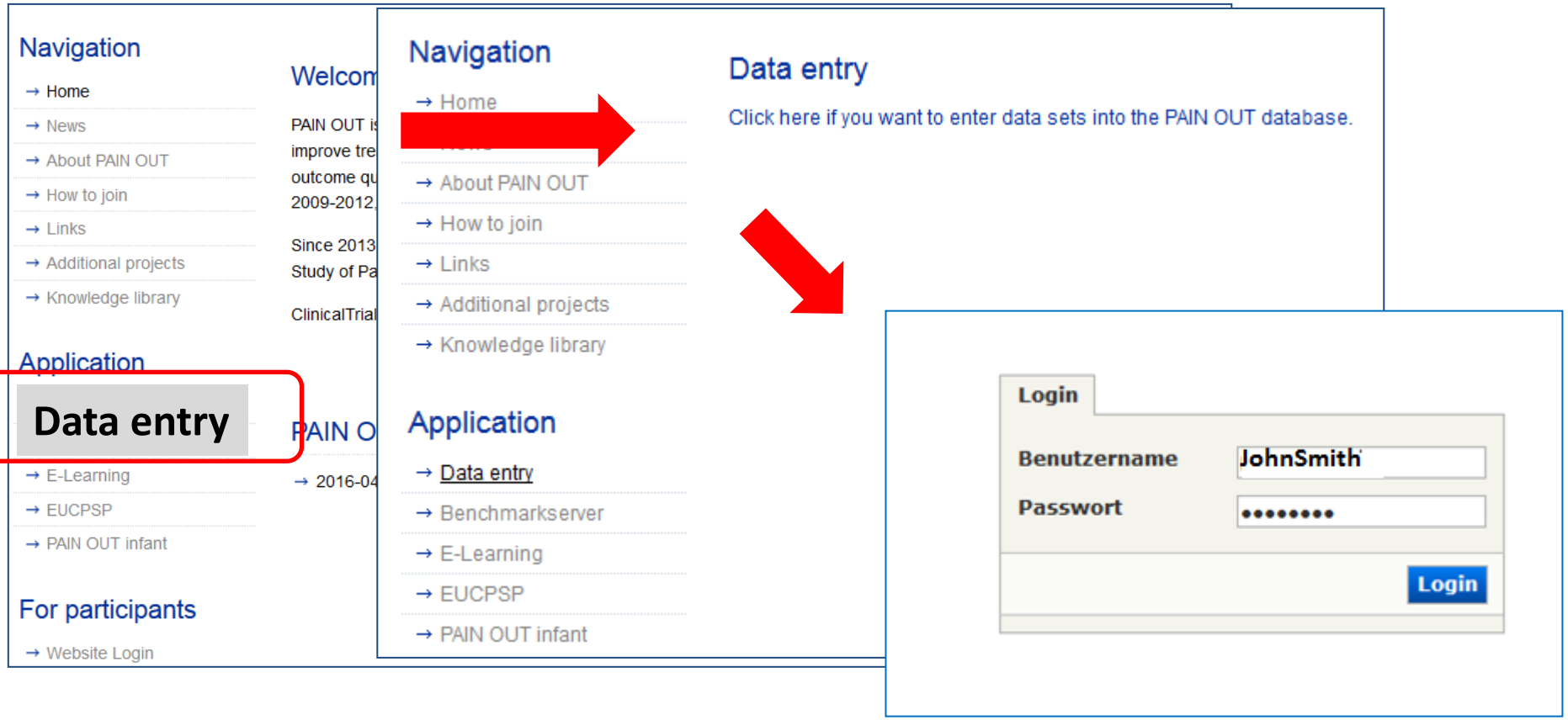


Now that you have collected Outcomes and Process questionnaires from a number of patients, you can enter the findings into the web-based mask.

The findings will then become available for web-based feedback and also for analysis offline.

3.1 Accessing the data entry mask [i]

1. Access the PAIN OUT web site through http://pain-out.med.uni-jena.de/
2. Find ‘Data entry’ and log in.

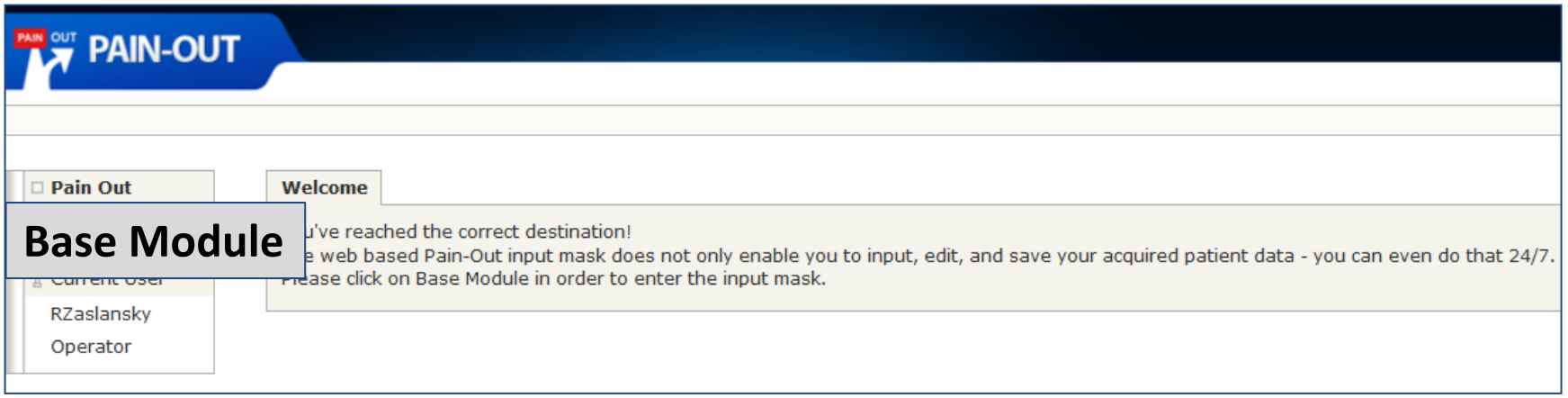


3.1 Accessing the data entry mask [ii]

Obtain the passwords for the PAIN OUT website and for data entry from Claudia.

You can change the password you receive to one which is convenient for you to use.

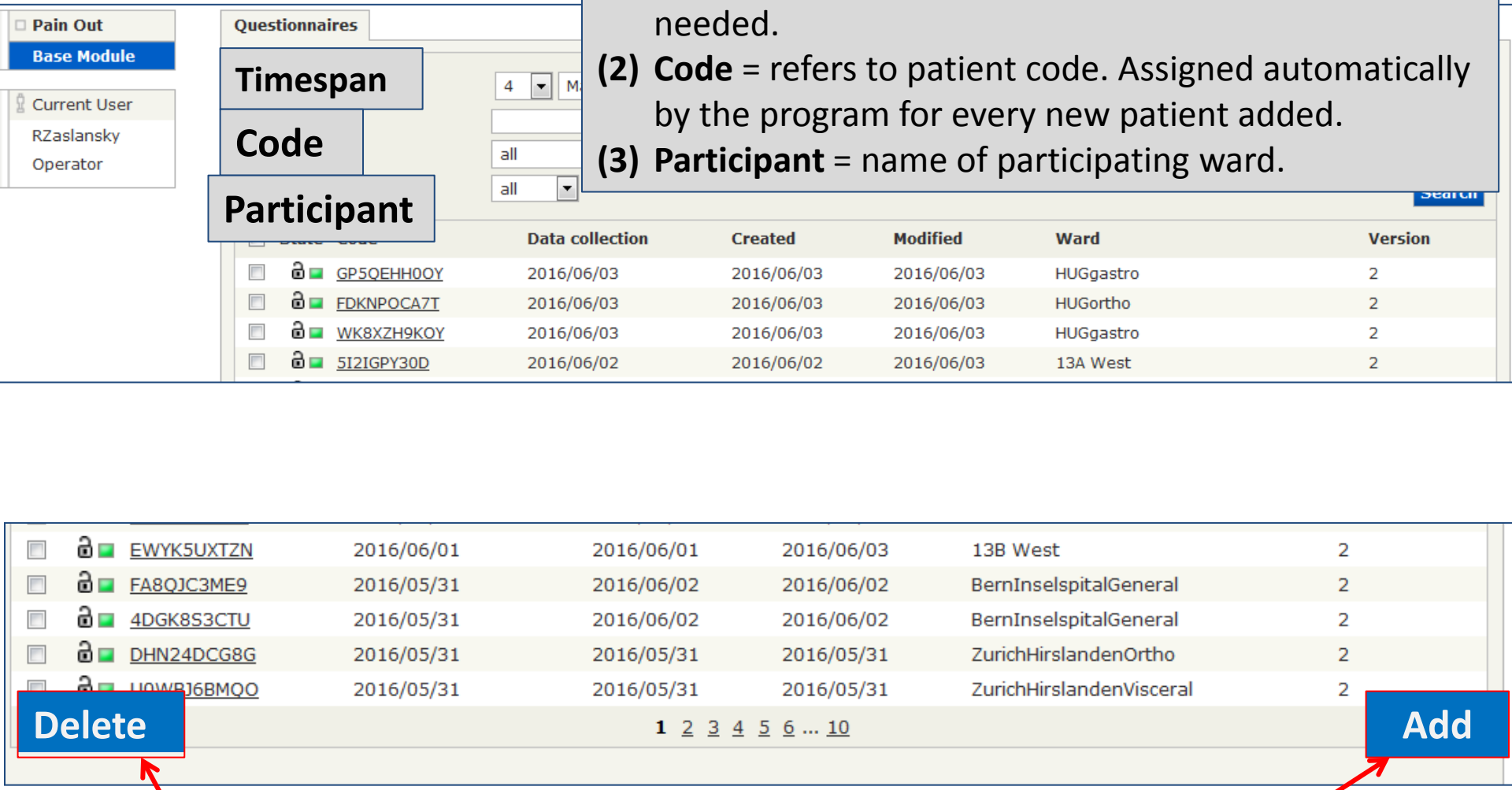
3.1 Accessing the data entry mask [iii]



Select "Base module" to input, edit or save the data.

3.2 Accessing the mask to input data

(1) **Timespan** = dates during which data for your site is displayed. The default is 3 months; increase as needed.
(2) **Code** = refers to patient code. Assigned automatically by the program for every new patient added.
(3) **Participant** = name of participating ward.



To delete a file

To add a new data file

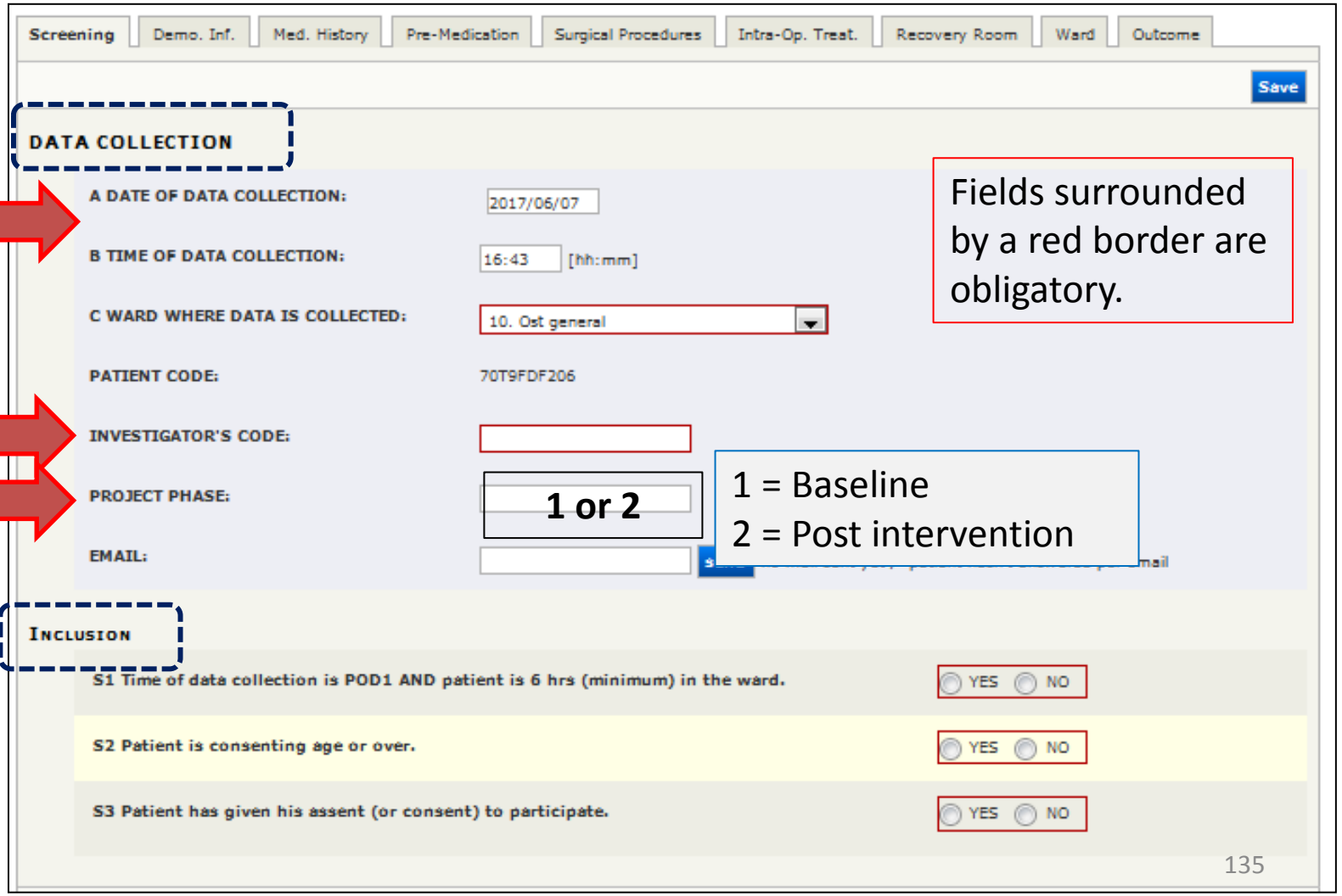
3.3 Creating a new dataset [i]

To create a new data file, click on the 'add' button (bottom right of the screen; see previous slide). You will access the screen below. The information corresponds to that obtained by the Process questionnaire. So that, **DATA COLLECTION** corresponds to the **Administrative information** in the Process questionnaire; **INCLUSION to Inclusion, etc**.

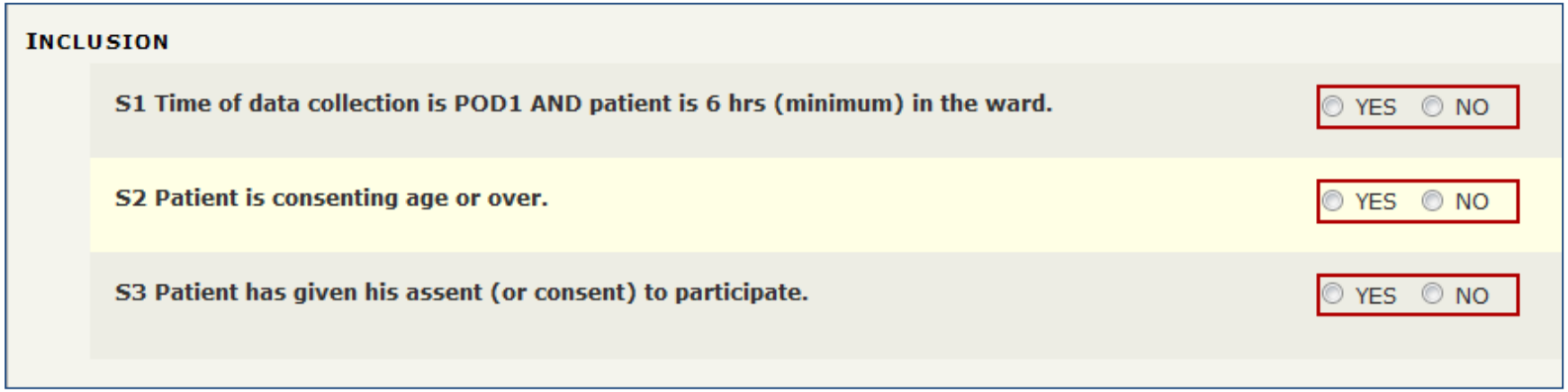
Enter time and date of data **collection**

Enter your surveyor's code

Enter the project phase



3.3 Creating a new dataset[ii]



If the patient is **included** (i.e., you have entered 'YES' for S1 & S2 & S3), you will next go through each of the tabs and input all data items relevant for this patient that you collected in the Process and Outcomes questionnaires.
If the patient was **excluded** in one of the Screening - Inclusion Criteria steps, save the information and proceed to the next patient.

TABS

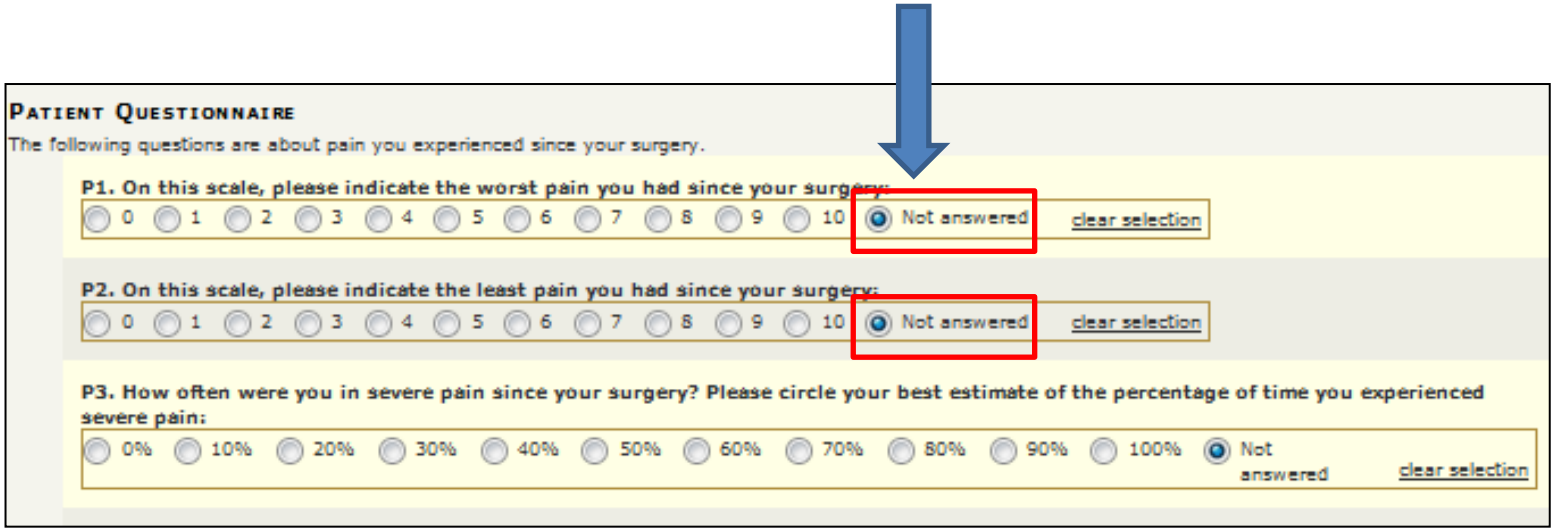
Demo Inf / Med History / Pre medication / Surgical procedures / Intra-op treat / Recovery Room / Ward / Outcome

Save

Remember to SAVE while you work !
The system does not save the data automatically - it is up to you!

3.4. ‘Not answered’

If a patient did fill in a reply to a particular question –mark this as ‘not answered’ when entering the data into the mask.

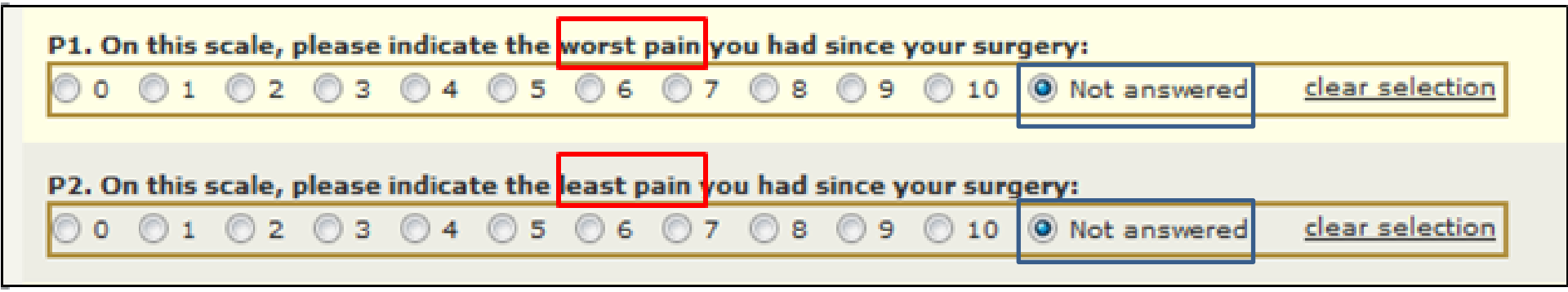


3.5. Is least pain > maximal pain ?

At times patients misread ‘worst’ and ‘least’ pain and record the maximal score in ‘least’ and least in ‘worst’.

The best way to address this mistake is to review the questionnaire when picking it up from the patient and asking him / her if this was intentional – if yes, leave; if not ask them to correct.

If you were unable to detect at an earlier stage – record as ‘Not answered’.



3.6 Data sets are open for 8 weeks

Datasets are automatically closed eight weeks after they are created.

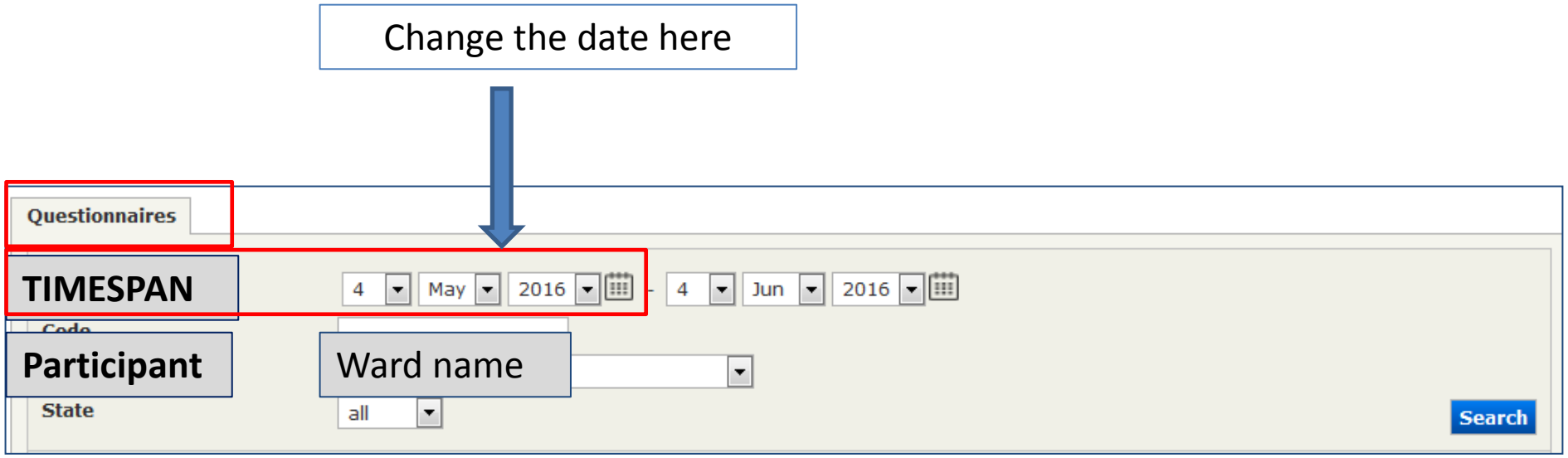
Once closed, you cannot edit them any longer (*).

-> Make sure you enter all data within this 8 week period.

(*) In the event that it is necessary to access a file to make corrections -> contact the PAIN OUT office and we will make the file accessible for editing.

This is a time consuming procedure – therefore, aim to make corrections within the first 8 weeks of creating a patient file.

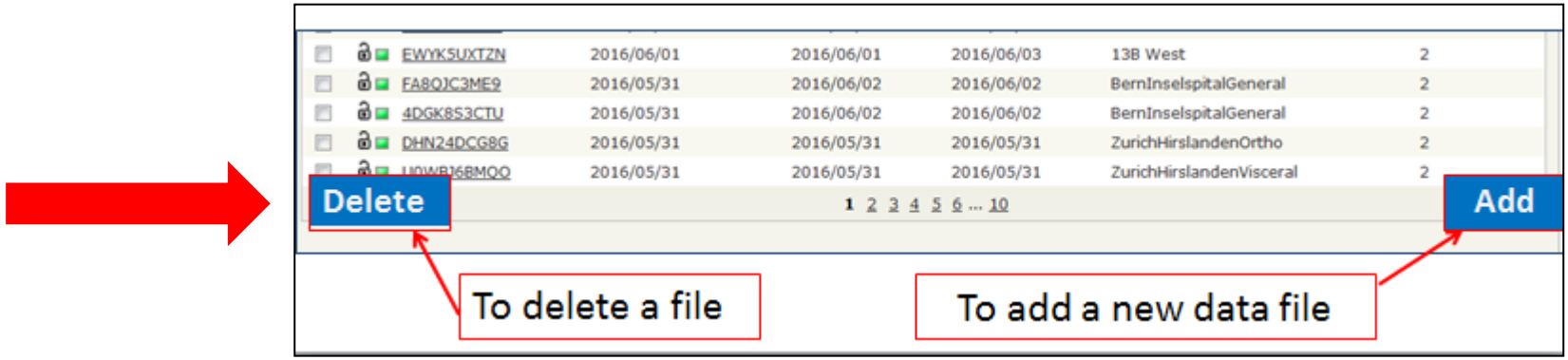
3.7 Finding previously entered datasets



Sometimes people have trouble finding questionnaires they entered already.
In the 'Questionnaires' screen, increase the filter related to TIME SPAN '.
The default time span is THREE months; data entered before this date will not appear.
Once you increase the TIMESPAN, you should see the data.

3.8 Gaining experience with data entry

When you start learning how to use the web-based mask, save and reopen one or two data sets that you inputted and check if the data was saved correctly. You can delete datasets if you find they are faulty.



3.9 Please pay attention – enter data into the correct benchmark group [i]

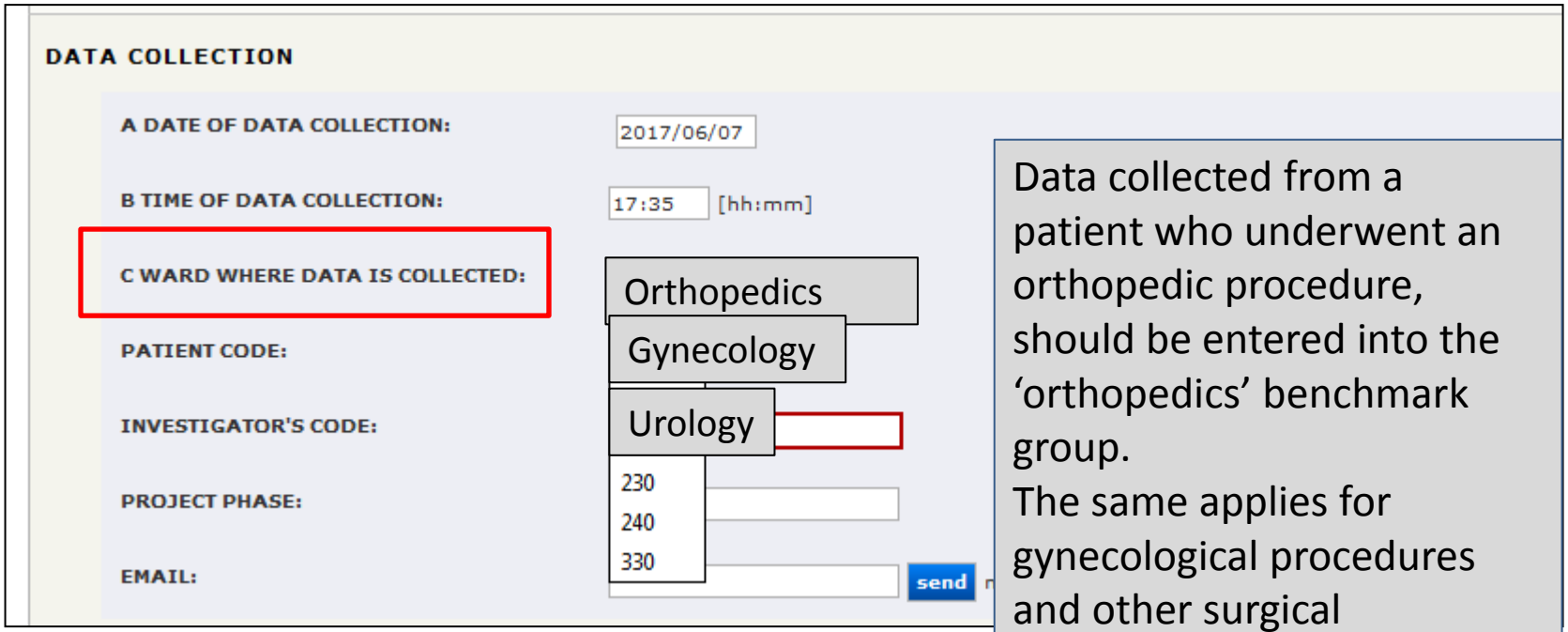
When entering data, pay attention that you are entering it into the **correct** benchmark group.
The names of the wards Claudia will give you will be related to the specialty (=benchmark group) you will be collecting.
e.g. orthopedics or gynecology or general surgery or urology.

For a patient undergoing an orthopedic procedure, enter his / her data ONLY into the relevant benchmark group, i.e. the orthopedic group.

Entering this data into gynecology benchmark group will result in contaminating that group with irrelevant data; you and your colleagues will not have reliable data for your own feedback and for benchmarking.

See next slide

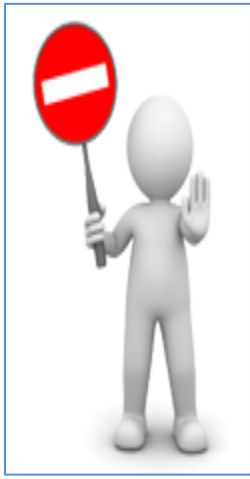
3.9 Please pay attention – enter data into the correct benchmark group [i]



Data collected from a patient who underwent an orthopedic procedure, should be entered into the 'orthopedics' benchmark group.
The same applies for gynecological procedures and other surgical specialties.

See previous slide

3.7 Please pay attention - review all tabs [ii]



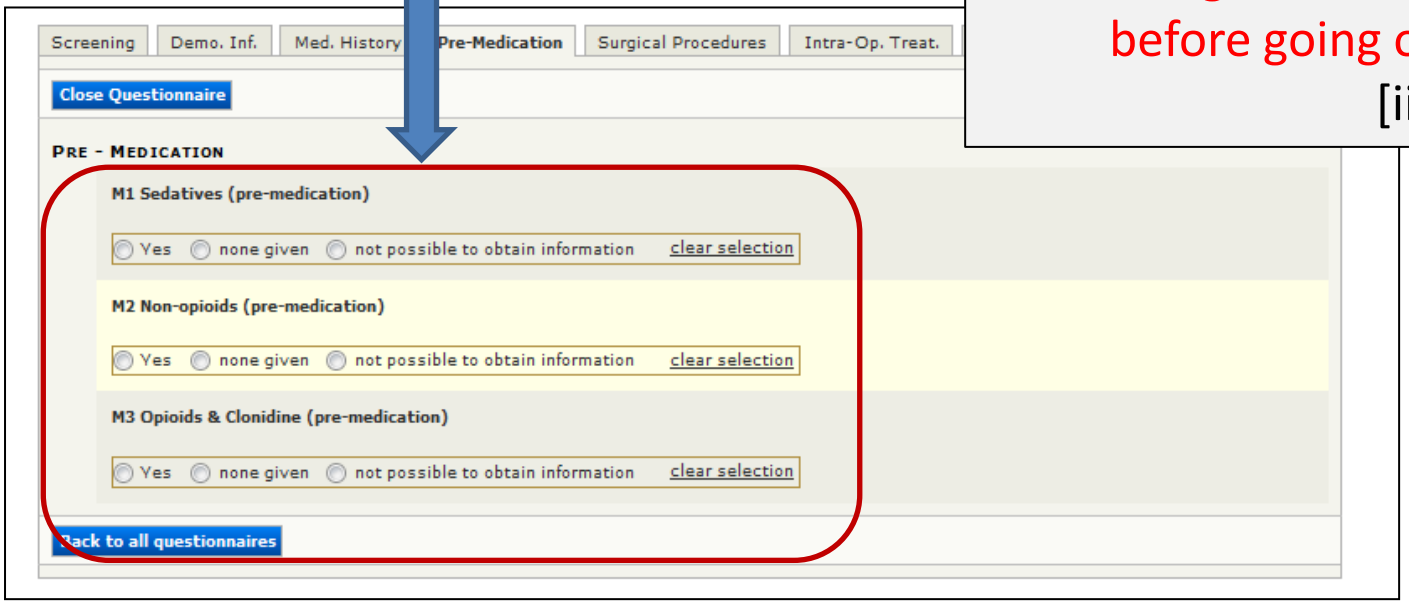
Once you have finished entering data for one patient – review all the tabs to ascertain that all data elements have been inputted.

Missing data – i.e. cells which have been left empty, reduces quality of the data in the repository.

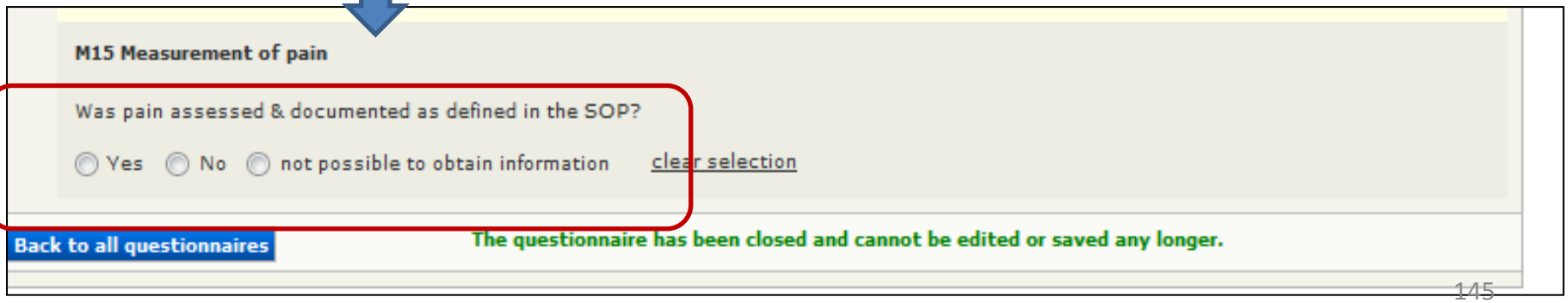
-> see next slide.

3.7 Please pay attention review entries in all tabs once you finish entering data for one patient and before going onto the next.
[ii]

Missing data



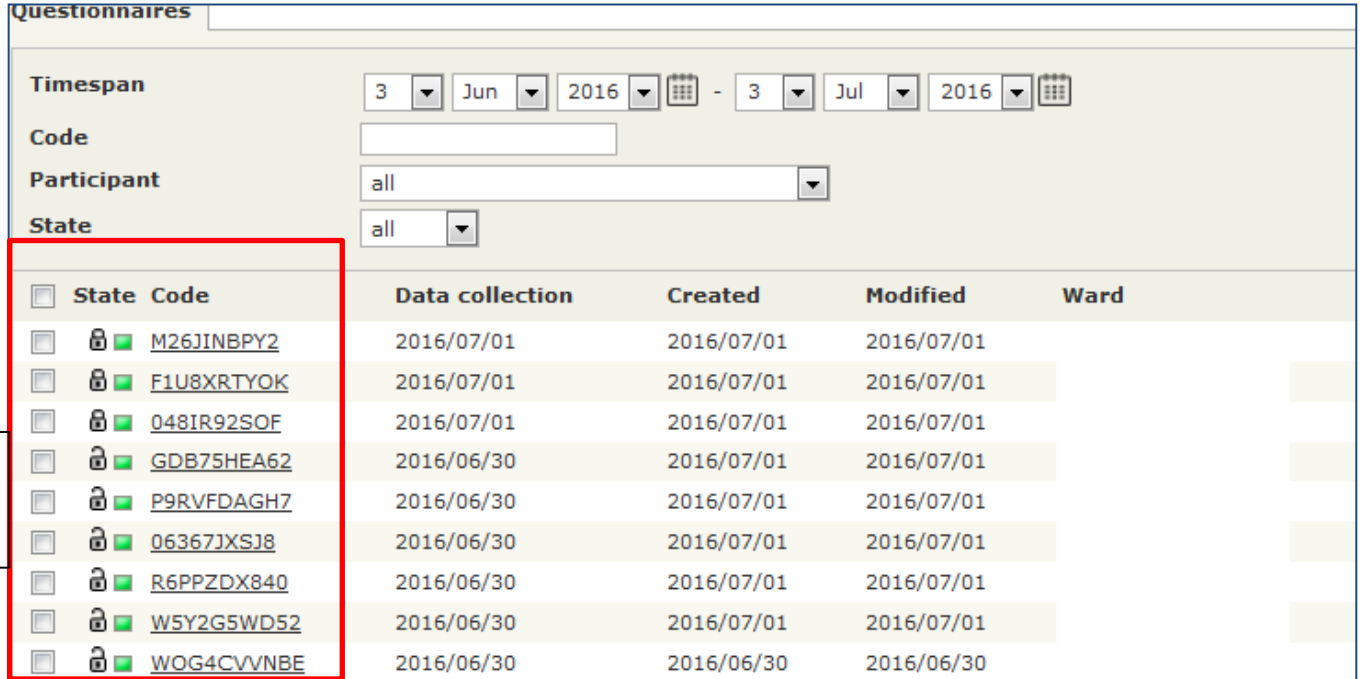
Missing data



The first 10 data sets

- Once you have finished going over these slides, fill in the quiz.
- After this, you will be given access to the PAIN OUT tools (questionnaires, password, a code which identifies you, the 'Investigator Code')
- Collect & input 10 -15 datasets into the data entry mask
  - Make a list of all the anonymized patient codes & send them to Claudia
  - We will review these datasets and write back to you with feedback
  - Once OK, you can start collecting data routinely, based on the schedule of your network.

Anonymized patient codes:



Accessing the QUIZ

1. Go to the PAIN OUT home page: www.pain-out.eu
2. Scroll to the bottom of the page, select 'QUIZ'

3. Your answers will be sent to the PAIN OUT team. We will write back to you with feedback.

Timeline for the project in the South Africa PAIN OUT network. REVISED Jan 2021

Month of project	Month	Activity
~ 0-8	Complete by end of July 2021	Administrative preparations for joining the project.
		2-3 surveyors from each hospital will submit a quiz AND 10-15 practice datasets AND they will be assessed AND corrected, as necessary
1		Kick off meeting
2 – 7	August 2021 – Feb 2022	• Surveyors collect BASELINE DATA • PIs carry out descriptive analysis of the findings (assisted by the network leader, PAIN OUT).
	March 2022	Mid-term workshop
7 - 10	April 2022 – June 2022	Staff discuss options for quality improvement measures with the local working groups; carry out the necessary preparations for implementing the measures
11 -17	July – Dec 2022	POST INTERVENTION DATA COLLECTION.
18 - 22	Jan – Feb 2023	Analysis of findings and preparations for the summary workshop.
23 or 24	April 2023	Summary workshop

Request that project completion is deferred to 30 April 2023

Thank you for your time.

If you have questions about anything related to the quiz or the project – please contact us.

We hope you will find that participating in the South African network of PAIN OUT will be useful to you and to your patients.

April 2019 updates include:

- Section 1.4, p 18 – Schematic updated
- Section 2.10, p 38 – Days of week for collecting data
- Section 2.20, p 50-51 – Blank fields
- Section 2.23, p 54 – Comorbidities
- Section 2.36, p 69 – Inhalational anesthesia vs TIVA
- Section 2.45, p 78 – Measurement of pain – variables changed

January 2021 update:

Project schedule