STANDARD OPERATING PROCEDURES (SOPs)

v4.0 - January 2018
I need help? Whom do I contact?

Contact your national network leader – see next page

OR

Claudia Weinmann, PAIN OUT administration
Claudia.Weinmann@med.uni-jena.de
Network leaders

- Belgium: Professor Patrice Forget, forgetpatrice@yahoo.fr
- France: Professor Valeria Martinez, valeria.martinez@aphp.fr
- Ireland: Professor George Shorten, Dr Brona Fullen
  - G.Shorten@ucc.ie
  - Brona.fullen@ucd.ie
- Italy: Professor Caterina Aurilio, Professor Rita Melloti
  - caterina.aurilio@unicampania.it
  - ritamaria.melotti@aosp.bo.it
- Netherlands: Rianne vanBoek, Dr Monique Steegers,
  - Rianne.vanBoekel@radboudumc.nl
  - Monique.Steegers@radboudumc.nl
- Serbia: Dr Dusica Stamenkovic, dusicastamenkovic@yahoo.com
- Spain: Dr Hermann Riberia, Dr Jaume Garcia
  - hermannribera@gmail.com
  - jaumegarcia@gmail.com
- Switzerland: Professor Ulrike Stamer, ulrike.stamer@dkf.unibe.ch
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
     - To prevent patients 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 trial patient datasets & entering the data into the PAIN OUT mask;
     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: ~130 patients X 2 phases, lasting 4 months each -> ~ 33 patients\ month -> ~ 8 \ 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, to keep the same surveyors for the duration of the project.
Contents [summary]

Part 1. Getting started
Part 2. Project questionnaires
Part 3. How to input data into the web-based mask
Part 4. The quiz

A detailed Table of Contents follows to ease finding specific items in this file.
Table of Contents

Part 1. Getting Started
1.1 PAIN OUT concept & current project
1.2 What is the goal of PAIN OUT?
1.3 How does it work & what do surveyors do?
1.4 An additional component this project: Plan–Do–Study–Act cycle(s)
1.5 Training for data collection in PAIN OUT
1.6 Quality data is crucial
1.7 Randomization
1.8 How many cases to collect?
1.9 How long does it take to collect one case?
   What time of day is it best to go to a ward to collect data?
1.10 How to obtain the questionnaires?
1.11 Accessing the PAIN OUT website for documents
Part 2. Project questionnaires

2.1 Overview of questionnaires for assessing quality
2.2 PAIN OUT questionnaires
2.3 The process questionnaire
2.4 Where to obtain the data from?
2.5 Options for a reply (i), (ii)
2.6 Administrative information
2.7 Administrative information: items A - C
2.8 Administrative information, item D, patient code & room number
2.9 Screening: inclusion criteria
2.10 S1: Time after Surgery & Time on the Ward
2.11 S2: consenting age and over
2.12 S3: patient has given consent to participate
2.13 And if no consent is given, mark the reason
2.14 Make a decision – include or exclude
2.15 Special case of ‘Patient does not want to participate’ [i - iii]
2.16 Special case: cognitively impaired patients
2.17 Demographics
2.18 Demographics: D1 – D 4
Part 2 (cont.), process questionnaire

2.19 Demographics: D5 – D7
2.20 BLANK FIELDS
2.21 Medical history
2.22 Medical history: H1 Comorbidities, definition
2.23 Medical history: H1 Comorbidities – list of
2.24 Medical history: H1 Comorbidities, how to fill in
2.25 Medical history: H1 Comorbidities, some definitions
2.26 Medical history: H1 Comorbidities, when to OTHER?
2.27 Medical history: H2 Existing condition
2.28 Medical history: H3 Opioids before current admission
2.29 Perioperative medications & surgical procedure
2.30 Types of perioperative medications
2.31 How to record the perioperative medications
2.32 Perioperative medications: pre-medications
2.33 P1 Surgical procedure code & P2 Duration of surgery
2.34 P1 Surgical procedure: how to code
2.35 Perioperative medications: Intra-operative
Part 2 (cont), process questionnaire

2.36 Perioperative medications: Intra-operative, type anesthesia
2.37 Perioperative medications: Intra-operative, non-opioids
2.38 Perioperative medications: Intra-operative, wound infiltration
2.39 Perioperative medications: Intra-operative, opioids & local anesthetics
2.40 Perioperative medications: Recovery room, M9–M11
2.41 Perioperative medications: Recovery room, M9 & M10
2.42 Perioperative medications: Recovery room, M11
2.43 Perioperative medications: Recovery room, RA & PCA
2.44 Perioperative medications: Ward
2.45 Perioperative medications: Ward, pain measurement
2.46 Question yourself - question 1
2.47 Question yourself - question 2
2.48 Question yourself - question 3
2.49 Outcomes questionnaire

2.50 Obtaining informed consent

2.51 An example of a Patient Information & Consent letter

2.52 [1] Type and aim of study

2.53 [2] Participation is voluntary

2.54 [3] Anonymity will be kept

2.55 [4] Same quality of treatment

2.56 Recruiting patients

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

2.58 **STEP 2** Asking for consent

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

2.60 **STEP 2** When a patient cannot give consent

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

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

2.63 **STEP 4** Filling in the questionnaire

2.64 **STEP 4** But the patient has visitors

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

2.66 **STEP 4** No help required

2.67 **STEP 4** Help required with a few questions

2.68 **STEP 4** When is it an interview?
The Outcomes questionnaire (cont.)

2.69 **STEP 4** Situations a patient needs help
2.70 **STEP 4** Guidelines for an interview [i,ii]
2.71 Question yourself
2.72 **STEP 5** Picking up the Outcomes Questionnaire
2.73 **STEP 5** Reviewing the questionnaire
2.74 Background, structure & items in the patient reported outcomes questionnaire
2.75 Outcomes for patients to assess their experience of pain after surgery
2.76 Validation of the questionnaire
2.77 The questionnaire consists of 3 pages
2.78 Scales used for assessment
2.79 Pain since your surgery ... 
2.80 P1 – P2 Pain Intensity
2.81 P3 Pain intensity
2.82 P4 Interference of pain with activities
2.83 P5 Effect of pain on affect
2.84 P6 Adverse effects
The Outcomes questionnaire (cont.)

2.85 Perceptions of care

2.86 P7 Degree of pain relief received

2.87 P8 & P9: More treatment & providing information

2.88 P10 & P11 Allowed to participate & satisfaction

2.89 P12 non-pharmacological management of pain

2.90 P13 Persistent Pain

2.91 Structural questionnaire
Part 3: Inputting data into the web-based mask

3.1 Accessing the data entry mask [i,ii,iii]
3.2 Accessing the mask to input data
3.3 Creating a new dataset [i,ii]
3.4 Question ‘not answered’.
3.5 Is least pain > maximal pain
3.6 Datasets are open for 2 weeks
3.7 Finding previously entered datasets
3.8 Gaining experience with data entry

**3.9 Please pay attention – the correct benchmark group [i]**
**3.9 Please pay attention – review all tabs [ii]**

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 in hospitals participating in the EFIC - PAIN OUT project ‘Optimizing management of perioperative pain: a multi-centre project in 8 countries in Europe’

This manual has 3 aims:

(1) Providing background information about the project;
(2) Describing the items in the PAIN OUT questionnaires;
(3) Giving 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,
• Providing feedback to staff in each center about how they are managing the pain of their patients,
• Benchmarking the data to allow comparison with similar patients in other wards & hospitals.

The data is also used to carry out observational studies OR separate group pre- post- intervention studies (EFIC project)

These activities give healthcare providers information about appropriateness and effectiveness of the treatments they provide.
1.3 How does it work & what do surveyors do?

[A] Patients fill in the *Pain Outcomes* questionnaire in their native language.

As surveyor, you are responsible for [A] & [B]

[B] Surveyors abstract demographic and peri-operative variables from the patient’s chart and input the findings into the web-based repository.

---

Post-Operative Pain Registry

How does it work?

Standardized methodology across sites

[C] Findings are then analyzed
1.4 The EFIC project has another component...

... a Plan – Do – Study – Act cycle

<table>
<thead>
<tr>
<th>ACT phase, months 23 /24</th>
</tr>
</thead>
<tbody>
<tr>
<td>Workshop summarizing findings and planning next steps within hospital &amp; network</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PLAN phase, months 1- 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kick off meeting</td>
</tr>
<tr>
<td>Collect BASELINE data from patients in 1-2 wards \ hospital &amp; analyze it;</td>
</tr>
<tr>
<td>Mid project workshop to discuss findings and decide objective(s) of the project; propose 1-3 intervention(s).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DO phase, months 7 - 12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Discuss interventions with local multi-disciplinary working group &amp; consent on 1-2 to implement;</td>
</tr>
<tr>
<td>Obtain ethics approval (if necessary)</td>
</tr>
<tr>
<td>Start implementing the intervention(s).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>STUDY phase, months 13 - 22</th>
</tr>
</thead>
<tbody>
<tr>
<td>Carry out another round of data collection in the 1-2 wards.</td>
</tr>
<tr>
<td>Analyze findings &amp; prepare for summary workshop</td>
</tr>
</tbody>
</table>

There is leeway with regards to duration of the phases, however, all hospitals in the network will progress together from one phase to another.
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 at least 10 patients (both process and outcomes questionnaires) and enter the data into a training benchmark group.
   - 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 in the database depends on your work.
1.6 Quality data is crucial

How to get quality data?

– Become acquainted with the project’s methodology.
– Standardize the methodology you and your colleagues use.
– Avoid missing data – when collecting it and when inputting it into the web-based mask.
   - Make sure that all cells are filled in.

- 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 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 130 cases (*) during the BASELINE and POST-INTERVENTION phases; each phase will last about 4 months.

- As not all patients will agree to participate, you will need to approach an additional 20 – 30%.
  - -> about 38 – 42 patients a month OR about 10 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.
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

www.pain-out.eu
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 **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 **Hospital Structural Questionnaire** relates to information about organizational structures in an institution or ward.

The data is collected from the medical record.

Can be filled in directly to the web-based server if Wifi connection is 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 questionnaire is usually filled in by the patient.

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.
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'.
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.
2.6 Administrative information
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

<table>
<thead>
<tr>
<th>S1</th>
<th>Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward</th>
</tr>
</thead>
<tbody>
<tr>
<td>S2</td>
<td>Patient is consenting age or over</td>
</tr>
<tr>
<td>S3</td>
<td>Patient has given his assent (or consent) to participate</td>
</tr>
</tbody>
</table>

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., Down syndrome, dementia, Alzheimer’s disease, Cerebral Palsy)
- g. Other, specify:

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

---

**SECTION 2**

<table>
<thead>
<tr>
<th>D3</th>
<th>Weight</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>kg</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D4</th>
<th>Height</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>cm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D5</th>
<th>Nationality (check one)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Arabic</td>
</tr>
<tr>
<td></td>
<td>Bahasa Malaysia</td>
</tr>
<tr>
<td></td>
<td>Danish</td>
</tr>
<tr>
<td></td>
<td>Dutch</td>
</tr>
<tr>
<td></td>
<td>English</td>
</tr>
<tr>
<td></td>
<td>Finnish</td>
</tr>
<tr>
<td></td>
<td>French</td>
</tr>
<tr>
<td></td>
<td>German</td>
</tr>
<tr>
<td></td>
<td>Hebrew</td>
</tr>
<tr>
<td></td>
<td>Italian</td>
</tr>
<tr>
<td></td>
<td>Korean</td>
</tr>
<tr>
<td></td>
<td>Mandarin</td>
</tr>
<tr>
<td></td>
<td>Norwegian</td>
</tr>
<tr>
<td></td>
<td>Romanian</td>
</tr>
<tr>
<td></td>
<td>Russian</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>D6</th>
<th>Country of birth (check one)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>D7</th>
<th>Language of Outcomes questionnaires (select one)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Arabic</td>
</tr>
<tr>
<td></td>
<td>Bahasa Malaysia</td>
</tr>
<tr>
<td></td>
<td>Danish</td>
</tr>
<tr>
<td></td>
<td>Dutch</td>
</tr>
<tr>
<td></td>
<td>English</td>
</tr>
<tr>
<td></td>
<td>Finnish</td>
</tr>
<tr>
<td></td>
<td>French</td>
</tr>
<tr>
<td></td>
<td>German</td>
</tr>
<tr>
<td></td>
<td>Hebrew</td>
</tr>
<tr>
<td></td>
<td>Italian</td>
</tr>
<tr>
<td></td>
<td>Korean</td>
</tr>
<tr>
<td></td>
<td>Mandarin</td>
</tr>
<tr>
<td></td>
<td>Norwegian</td>
</tr>
<tr>
<td></td>
<td>Romanian</td>
</tr>
<tr>
<td></td>
<td>Russian</td>
</tr>
</tbody>
</table>

**BLANK FIELDS**

- Blank field 1:
- Blank field 2:
- Blank field 3:
- Blank field 4:
### SCREENING - INCLUSION CRITERIA

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time of data collection is POD1 AND patient is 6 hrs (minimum) in the ward</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>End surgery: Date:</td>
<td>2</td>
<td>0</td>
</tr>
<tr>
<td>Back in ward: Date:</td>
<td>2</td>
<td>0</td>
</tr>
</tbody>
</table>

| 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
  - [ ] 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., Down’s 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
2.10 **S1: Time after Surgery & Time on the Ward**

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.

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

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

<table>
<thead>
<tr>
<th>S3</th>
<th>Patient has given his assent (or consent) to participate</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>If no to S3, mark the reason(s):</td>
</tr>
</tbody>
</table>

- 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.

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 questions (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** in any of the questions S1 and/or S2 and/or S3 the patient must be excluded.
1. Do not give the Outcomes Questionnaire to the patient.
2. Do not fill in the rest of the Process Questionnaire.
3. **And don´t forget**: Save the form and input the information about S1 & S2 & S3 into the web-based mask.
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
  - 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.

<table>
<thead>
<tr>
<th>To be filled in by the research assistant</th>
<th>Research assistant code:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient was interviewed:</strong></td>
<td></td>
</tr>
<tr>
<td>[ ] Yes</td>
<td>[ ] No</td>
</tr>
<tr>
<td>If yes, please mark the reason(s):</td>
<td></td>
</tr>
<tr>
<td>[ ] Too ill / weak</td>
<td>[ ] Too much pain</td>
</tr>
<tr>
<td>[ ] Requested assistance</td>
<td>[ ] Did not understand scales</td>
</tr>
<tr>
<td>[ ] Technical reasons (patient has no eyeglasses / is blind; can not sit up; is illiterate; arm is in cast; etc)</td>
<td></td>
</tr>
</tbody>
</table>
2.16 Special case: cognitively impaired patients

If a patient is cognitively impaired he cannot give consent. Usually you have to exclude these patients.

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
2.18 Demographics: D1 – D4

**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

<table>
<thead>
<tr>
<th>DEMOGRAPHIC INFORMATION</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>D1 Gender</strong></td>
</tr>
<tr>
<td>□ Male</td>
</tr>
<tr>
<td>□ Female</td>
</tr>
<tr>
<td><strong>D2 Year of birth</strong></td>
</tr>
<tr>
<td>1970</td>
</tr>
<tr>
<td><strong>D3 Weight</strong></td>
</tr>
<tr>
<td>[ ] kg</td>
</tr>
<tr>
<td><strong>D4 Height</strong></td>
</tr>
<tr>
<td>[ ] cm</td>
</tr>
<tr>
<td><strong>D5 Nationality</strong></td>
</tr>
<tr>
<td>(check records)</td>
</tr>
<tr>
<td><strong>D6 Country of birth</strong></td>
</tr>
<tr>
<td>(check records)</td>
</tr>
<tr>
<td><strong>D7 Language of Outcome questionnaire (select one)</strong></td>
</tr>
<tr>
<td>□ Albanian</td>
</tr>
<tr>
<td>□ Arabic</td>
</tr>
<tr>
<td>□ Bahasa Malaysia</td>
</tr>
<tr>
<td>□ Danish</td>
</tr>
<tr>
<td>□ Dutch</td>
</tr>
<tr>
<td>□ English</td>
</tr>
<tr>
<td>□ Filipino</td>
</tr>
<tr>
<td>□ Finnish</td>
</tr>
<tr>
<td>□ French</td>
</tr>
<tr>
<td>□ German</td>
</tr>
<tr>
<td>□ Hebrew</td>
</tr>
<tr>
<td>□ Hindustani</td>
</tr>
<tr>
<td>□ Italian</td>
</tr>
<tr>
<td>□ Mandarin</td>
</tr>
<tr>
<td>□ Russian</td>
</tr>
<tr>
<td>□ Serbo-Croatian</td>
</tr>
<tr>
<td>□ Spanish</td>
</tr>
<tr>
<td>□ Swedish</td>
</tr>
</tbody>
</table>
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.
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.

EXAMPLE – you are interested to follow up specific comorbidities or medications which are not listed in the questionnaire, eg diabetes.
2.21 Medical history

This section consists of 3 items:

H1  Comorbidities
H2  Existing condition
H3  Opioids before current admission
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 qualify 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

<table>
<thead>
<tr>
<th>H1 Comorbidities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cancer</strong></td>
<td></td>
</tr>
<tr>
<td>Renal insufficiency or disease without dialysis</td>
<td>Renal disease requiring dialysis</td>
</tr>
<tr>
<td>Psychiatric</td>
<td></td>
</tr>
<tr>
<td>Affective disorders (depression, anxiety, phobia, PTSD, bipolar disorder)</td>
<td>Schizophrenia</td>
</tr>
<tr>
<td>Alcohol use disorder</td>
<td>Current smoker</td>
</tr>
<tr>
<td>Substance abuse of drugs (legal and illegal)</td>
<td></td>
</tr>
<tr>
<td>Cardiovascular</td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>Coronary artery disease or myocardial infarction or cerebral vascular accident</td>
</tr>
<tr>
<td>Hematology</td>
<td></td>
</tr>
<tr>
<td>Sickle cell disease</td>
<td></td>
</tr>
<tr>
<td>GI disease</td>
<td></td>
</tr>
<tr>
<td>Liver Cirrhosis</td>
<td>History or current upper or lower GI ulcer (peptic or duodenal ulcer disease)</td>
</tr>
<tr>
<td>Irritable bowel disease (Crohn's disease, ulcerative colitis)</td>
<td></td>
</tr>
<tr>
<td>Pulmonary disease</td>
<td></td>
</tr>
<tr>
<td>Asthma</td>
<td>Sleep apnea</td>
</tr>
<tr>
<td>Chronic Obstructive Pulmonary Disease (COPD)</td>
<td></td>
</tr>
<tr>
<td>Neurologic</td>
<td></td>
</tr>
<tr>
<td>Fibromyalgia</td>
<td></td>
</tr>
<tr>
<td>Steroid use</td>
<td></td>
</tr>
<tr>
<td>Regular administration of oral or parenteral corticosteroid medications</td>
<td></td>
</tr>
<tr>
<td>Multiple trauma</td>
<td>At least 1 fracture(s) / laceration(s) / tissue damage in addition to the current reason for surgery</td>
</tr>
<tr>
<td>Other surgery</td>
<td>Patient has already undergone another surgery during current hospitalization</td>
</tr>
</tbody>
</table>

- **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.
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: [ ] [ ]
- Lactation

- **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 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.

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

M1- M3  Pre-medications
P1 - P2  Surgical Procedures
M4 – M8  Intra-operative OR Post Anesthesia Care Unit (PACU).
M9 - M11  Recovery room
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,
  - simple analgesics,
  - clonidine,
  - Gabapentinoids
• Opioids
• Local anesthetics

At first glance, this section of the process questionnaire, which consist 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.
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)


<table>
<thead>
<tr>
<th>ICD-9 Procedure Code</th>
<th>Text (only for your notes, not necessary for mask)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td></td>
</tr>
<tr>
<td>4</td>
<td></td>
</tr>
</tbody>
</table>

**P2** Duration of surgery

Start surgery:  
Date: 2017-01-01  
Time: HH:MM

End surgery:  
Date: 2017-01-01  
Time: HH:MM
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.

<table>
<thead>
<tr>
<th>ICD-9 v3</th>
<th>81 Repair and plastic operations on joint structures</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHPT/SEC</td>
<td>81.0 Spinal fusion</td>
</tr>
</tbody>
</table>

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)

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
<th>not possible to obtain the information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If yes, which (multiple answers possible):

<table>
<thead>
<tr>
<th>Method</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalational</td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td></td>
</tr>
</tbody>
</table>

### M5 Regional anaesthesia (RA) (intra-op)

<table>
<thead>
<tr>
<th></th>
<th>yes</th>
<th>no</th>
<th>not possible to obtain the information</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If yes, which (multiple answers possible):

<table>
<thead>
<tr>
<th>Method</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Epidural</td>
<td></td>
</tr>
<tr>
<td>Spinal</td>
<td></td>
</tr>
<tr>
<td>Brachial plexus</td>
<td></td>
</tr>
<tr>
<td>Femoral</td>
<td></td>
</tr>
<tr>
<td>Sciatic</td>
<td></td>
</tr>
<tr>
<td>Paravertebral</td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
</tr>
<tr>
<td>Other:</td>
<td></td>
</tr>
</tbody>
</table>

Mark the medication(s) used for RA in M8

Do not forget
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

**Intravenous Anaesthetics**

IV relates to Total Intravenous Anesthesia (TIVA). We are using a definition for “TIVA” that does not exclude use of inhalational gases. This means that if a patient was given BOTH inhalational gases and IV medications (= ’balanced analgesia’), select both boxes: Inhalational AND 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.

<table>
<thead>
<tr>
<th>Non-opioids (intra-op)</th>
<th>i.v.</th>
<th>i.m.</th>
<th>supp.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clonidine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Diclofenac</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ibuprofen</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketamine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ketoprofen</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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.
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).
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

**M9 Non-opioids (recovery room)**

- **If yes**, select "YES" and mark the name, route & dose.

<table>
<thead>
<tr>
<th>Medication</th>
<th>p.o.</th>
<th>i.v.</th>
<th>i.m.</th>
<th>sup.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Celecoxib</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Clonidine</td>
<td>no</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Diclofenac</td>
<td>no</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
</tbody>
</table>

**M10 Regional analgesia (recovery room)**

- **If yes**, select "YES" and mark the approach. Remember to add information about the medication in M11 AND PCA, if it was used.

- **Epidural**
- **Spinal**
- **Brachial plexus**
- **Sciatic**
- **Paravertebral**
- **Other:**
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.
2.43 Perioperative medications: **Recovery room, RA & PCA**

How to mark epidural fentanyl with PCA administered in the recovery room?
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
2.45 Perioperative medications: Ward, pain measurement

M15 Measurement of pain

Ask the Head Nurse whether there is a departmental guideline or a standard tool for measuring pain.

If the pain was recorded at least once since the patient was back on the ward after surgery on the patient’s chart AND the assessment was carried out using a standard tool, select "YES".

If assessments were not carried out as described above, select "NO".

If there is no form related to assessment of pain in the medical record, select "NOT POSSIBLE TO OBTAIN THE INFORMATION".

M15 Measurement of pain: Was pain documented as defined in the SOPs?

☐ yes  ☐ no  ☐ not possible to obtain the information
2.46  Question 1

When at home, Jacob 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.
Question 2, continued

**INTRA-OPERATIVE**

**M4 General anaesthesia (intra-op)**
- X yes  □ no  □ not possible to obtain the information

If yes, which (multiple answers possible):
- X 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  X 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):

<table>
<thead>
<tr>
<th></th>
<th>RA (see M5)</th>
<th>i.v.</th>
<th>i.m.</th>
<th>s.c.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfentanil</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buprenorphine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fentanyl</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Question 2, continued

Mark medications **given** to patient; record **cumulative** doses.

### INTRA-OPERATIVE

**M4 General anaesthesia (intra-op)**

- [x] yes
- [ ] no
- [ ] not possible to obtain the information

If yes, which (multiple answers possible):

- [x] Inhalational
- [ ] IV

**M5 Regional anaesthesia (RA) (intra-op)**

- [x] yes
- [ ] no
- [ ] not possible to obtain the information

If yes, which (multiple answers possible):

- [ ] Epidural
- [ ] Spinal
- [ ] Brachial plexus
- [x] Femoral
- [ ] Sciatic
- [ ] Paravertebral
- [ ] Other:

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

**M8 Opioids & local anaesthetics (intra-op)**

- [x] yes
- [ ] no
- [ ] not possible to obtain the information

If yes, which (multiple answers possible):

<table>
<thead>
<tr>
<th>RA (see M5)</th>
<th>i.v.</th>
<th>i.m.</th>
<th>s.c.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alfentanil</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Buprenorphine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fentanyl</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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?

<table>
<thead>
<tr>
<th>Opioids &amp; local anaesthetics (ward)</th>
<th>Immediate release (PO &amp; other)</th>
<th>Controlled release (PO &amp; other)</th>
<th>RA (see M13)</th>
<th>i.v.</th>
<th>i.m.</th>
<th>supp.</th>
<th>s.c.</th>
<th>PCA (see M13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>mg</td>
<td>µg/ hr</td>
<td>µg</td>
<td>µg</td>
<td>µg</td>
<td>µg</td>
<td>µg</td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
</tr>
<tr>
<td>Fentanyl</td>
<td>µg transmucosal</td>
<td>µg/ hr</td>
<td>µg</td>
<td>µg</td>
<td>µg</td>
<td>µg</td>
<td>µg</td>
<td>µg μg</td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
<td>mg</td>
</tr>
</tbody>
</table>

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 collect dose for local anesthetics;
It can be complex to calculate the dose for continuous infusion and boluses – best to leave out.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Immediate release (PO &amp; other)</th>
<th>Controlled release (PO &amp; other)</th>
<th>RA (see M13)</th>
<th>i.v.</th>
<th>i.m.</th>
<th>supp.</th>
<th>s.c.</th>
<th>PCA (see M13)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buprenorphine</td>
<td>mg</td>
<td>µg/hr</td>
<td></td>
<td>µg</td>
<td>µg</td>
<td></td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>Codeine</td>
<td>mg</td>
<td>mg</td>
<td></td>
<td>mg</td>
<td>mg</td>
<td></td>
<td>mg</td>
<td></td>
</tr>
<tr>
<td>Fentanyl</td>
<td>µg transmucosal</td>
<td>µg/hr transdermal</td>
<td>X</td>
<td>µg</td>
<td>µg</td>
<td></td>
<td>µg</td>
<td></td>
</tr>
<tr>
<td>Hydrocodone</td>
<td>mg</td>
<td>mg</td>
<td></td>
<td>mg</td>
<td>mg</td>
<td></td>
<td>mg</td>
<td></td>
</tr>
</tbody>
</table>

ANSWER TO PREVIOUS SLIDE

And also select ‘epidural’ in M13
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.
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.
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.
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 they 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=Y1wKxibHOo8
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
  - □ 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:

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

---

1 Remember: You may interview patients who need help, e.g., are too ill or in too much pain or illiterate
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.’
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!
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 a "new" country for years and is fluent speaking the language, he is still likely to prefer reading in his / her native language, particularly in times of stress, such as after surgery.

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

Download questionnaires in multiple languages from the PAIN OUT website.
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 will 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.

Could you please leave the room for a few minutes so that Mrs M can fill in the questionnaire or her own. I will help, if this is necessary.

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

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

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

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:

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>sin dolor</td>
<td>el peor dolor posible</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>sin dolor</td>
<td>el peor dolor posible</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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:

<table>
<thead>
<tr>
<th>0%</th>
<th>10%</th>
<th>20%</th>
<th>30%</th>
<th>40%</th>
<th>50%</th>
<th>60%</th>
<th>70%</th>
<th>80%</th>
<th>90%</th>
<th>100%</th>
</tr>
</thead>
<tbody>
<tr>
<td>nunca dolor intenso</td>
<td>siempre dolor intenso</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
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. The questionnaire has been revised a number of times, since then. 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 8 languages. The process of validation included the following:

Translations from the original English version were 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. This was followed by assessing the validity and reliability of the translated versions.

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.

The work is described in:

Subsequent additional translations are carried out using the same procedure but without assessing validity and reliability of the new translation.
2.77 The questionnaire consists of 3 pages 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**

![Numerical Rating Scale Example](image)

- *nothing* of the requested sensation
  - for example: no pain or no interference
- *worst* of the requested sensation
  - for example: worst pain possible or completely interfered

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

![Percentage Scale Example](image)

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

[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.
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. If it occurs, point out to the patient and ask them to correct this.
2.81 P3 Pain intensity

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 would 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 have difficulties using the percentage scale. You can point out that they should make an estimate – this is not meant to be a precise calculation.

If a patient experiences difficulties:
1. You can read the question out loud once.
2. If this is not sufficient to clarify the question, leave it un-ananswered.

Mark "Question un-answered" when you enter the data into the web-mask later.
2.82 P4 Interference of pain with activities

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 ...

<table>
<thead>
<tr>
<th></th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. anxious</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>not at all</td>
<td>extremely</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>b. helpless</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>not at all</td>
<td>extremely</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
2.84 P6 Adverse effects

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.
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

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.
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?

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>not at all</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>very much so</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>extremely dissatisfied</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>extremely satisfied</td>
</tr>
</tbody>
</table>

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

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

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

To be updated
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 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 add a new data file:

- **Timespan**
- **Code**
- **Participant**

To delete a file:

- **Delete**
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.

![Screen capture of data collection form]

- **Enter time and date of data collection**
- **Enter your surveyor’s code**
- **Enter the project phase**
- **Use a uniform format for entering the data, i.e. ‘01’ or ‘1’**.

**Fields surrounded by a red border are obligatory.**
3.3 Creating a new dataset

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

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 did not detect this – record as ‘un-answered’.
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.
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 TIMESSPAN, 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.
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 to review entries in all tabs once you finish entering data for one patient and before going onto the next.

(ii) Missing data

- M1 Sedatives (pre-medication)
- M2 Non-opioids (pre-medication)
- M3 Opioids & Clonidine (pre-medication)

(iii) Missing data

- M15 Measurement of pain
  - Was pain assessed & documented as defined in the SOP?
    - Yes
    - No
    - not possible to obtain information

Back to all questionnaires

The questionnaire has been closed and cannot be edited or saved any longer.
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.
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 EFIC - PAIN OUT project will be useful to you and to your patients.