

APPENDIX FOR CASE REPORT FORM

**Ketamine Infusion for
Paediatric Chronic Non-Cancer Pain and Cancer-related or
Pain associated with Medical Condition.
Series 42**

RAPID Pharmacovigilance in Paediatric Chronic Pain

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Faces Pain Scale – Revised (FPS-R)

In the following instructions, say "hurt" or "pain", whichever seems right for a particular child.

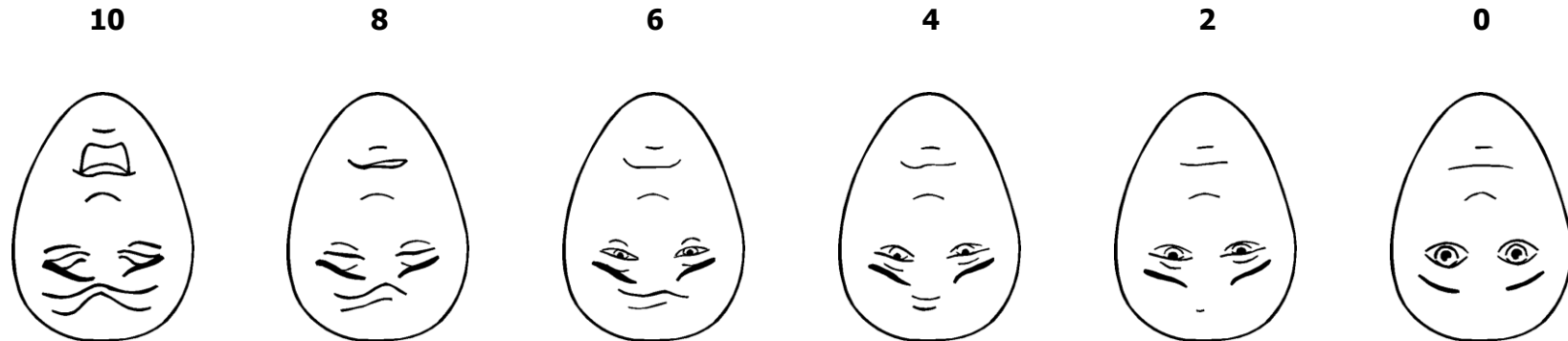
"These faces show how much something can hurt. This face [point to face on far left] shows no pain. The faces show more and more pain [point to each from left to right] up to this one [point to face on far right] - it shows very much pain. Point to the face that shows how much you hurt [right now]."

Score the chosen face **0, 2, 4, 6, 8, or 10**, counting left to right, so "0" = "no pain" and "10" = "very much pain". Do not use words like "happy" or "sad". This scale is intended to measure how children feel inside, not how their face looks.

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Sources. Hicks CL, von Baeyer CL, Spafford P, van Korlaar I, Goodenough B. The Faces Pain Scale – Revised: Toward a common metric in pediatric pain measurement. Pain 2001;93:173-183. Bieri D, Reeve R, Champion GD, Addicoat L, Ziegler J. The Faces Pain Scale for the self-assessment of the severity of pain experienced by children: Development, initial validation and preliminary investigation for ratio scale properties. Pain 1990;41:139-150.

(fold along
dotted line)



Symptom Severity Score – (Revised FLACC Scale)

Revised FLACC Scale SCORING			
Categories	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested, sad, appears worried	Frequent to constant quivering chin, clenched jaw, distressed looking face, expression of fright/panic
Legs	Normal position or relaxed, usual tone and motion to limbs	Uneasy, restless, tense, occasional tremors	Kicking, or legs drawn up, marked increase in spasticity, constant tremors, jerking
Activity	Lying quietly, normal position moves easily, regular, rhythmic respirations	Squirming, shifting back and forth, tense, tense. guarded movements, mildly agitated, shallow respirations, intermittent sighs	Arched. Rigid or jerking, severe agitation, head banging, shivering, breath holding, gasping, severe splinting
Cry	No cry (awake or asleep)	Moans or whimpers: occasional complaint, occasional verbal outbursts, constant grunting	Crying steadily, screams, sobs, frequent complaints, repeated outbursts, constant grunting
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to: distractible	Difficult to console or comfort, pushing caregiver away, resisting care or comfort measures

Each of the five categories (**F**) Face; (**L**) Legs; (**A**) Activity; (**C**) Cry; (**C**) Consolability is scored from 0-2, which results in a total score between zero and ten.

FLACC pain scale

The following table provides the criteria for the FLACC Behavioural pain scale.

Behaviour	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant quivering chin, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting, back and forth, tense	Arched, rigid or jerking
Cry	No cry (awake or asleep)	Moans or whimpers; occasional complaint	Crying steadily, screams, sobs, frequent complaints
Consolability	Content, relaxed	Reassured by touching, hugging or being talked to, distractible	Difficult to console or comfort

Instructions

Patients who are awake:

- Observe for at least 2-5 minutes.
- Observe legs and body uncovered.
- Reposition patient or observe activity; assess body for tenseness and tone.
- Initiate consoling interventions if needed.

Patients who are asleep:

- Observe for at least 5 minutes or longer.
- Observe body and legs uncovered.
- If possible, reposition the patient.
- Touch the body and assess for tenseness and tone.

Each category is scored on the 0-2 scale which results in a total score of 0-10.

Assessment of Behavioural Score:

0 = Relaxed and comfortable

1-3 = Mild discomfort

4-6 = Moderate pain

7-10 = Severe discomfort/pain

Reference: Merkel S, Voepel-Lewis T, Shayevitz JR, et al: *The FLACC: A behavioural scale for scoring postoperative pain in young children*. Pediatric nursing 1997; 23:293-797.

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TEENAGER REPORT (ages 13-18)

DIRECTIONS

On the following page is a list of things that might be a problem for you.

Please tell us **how much of a problem** each one has been for you

in the **LAST MONTH** by circling:

0 if it is **never** a problem

1 if it is **almost never** a problem

2 if it is **sometimes** a problem

3 if it is **often** a problem

4 if it is **almost always** a problem

There are no right or wrong answers.

If you do not understand a question, please ask for help.

In the ***LAST MONTH***, how much of a ***problem*** has this been for you ...

About My Health and Activities (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. It is difficult for me to walk more than 100 metres	0	1	2	3	4
2. It is difficult for me to run	0	1	2	3	4
3. It is difficult for me to play sport or do exercise	0	1	2	3	4
4. It is difficult for me to lift something heavy	0	1	2	3	4
5. It is difficult for me to have a bath or shower by myself	0	1	2	3	4
6. It is difficult for me to help around the house	0	1	2	3	4
7. I get aches and pains	0	1	2	3	4
8. I have low energy	0	1	2	3	4

About My Feelings (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

How I Get Along with Others (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. I have trouble getting along with other teenagers	0	1	2	3	4
2. Other teenagers do not want to be my friend	0	1	2	3	4
3. Other teenagers tease me	0	1	2	3	4
4. I cannot do things that other people my age can do	0	1	2	3	4
5. It is hard to keep up with other teenagers	0	1	2	3	4

About School (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my school work	0	1	2	3	4
4. I am away from school because I feel sick	0	1	2	3	4
5. I am away from school to go to the doctor or hospital	0	1	2	3	4

PedsQL™ - Paediatric Quality of Life Inventory: Version 4.0 – Australian English

CHILD REPORT (ages 8-12)

*In the **LAST MONTH**, how much of a **problem** has this been for you ...*

ABOUT MY HEALTH AND ACTIVITIES (problems with...)	Never	Almost Never	Sometimes	Often	Almost Always
1. It is difficult for me to walk a few houses from home (about 100 metres)	0	1	2	3	4
2. It is difficult for me to run	0	1	2	3	4
3. It is difficult for me to play sport or do exercise	0	1	2	3	4
4. It is difficult for me to lift something heavy	0	1	2	3	4
5. It is difficult for me to have a bath or shower by myself	0	1	2	3	4
6. It is difficult for me to help around the house	0	1	2	3	4
7. I get aches and pains	0	1	2	3	4
8. I have low energy	0	1	2	3	4

ABOUT MY FEELINGS (problems with...)	Never	Almost Never	Sometimes	Often	Almost Always
1. I feel afraid or scared	0	1	2	3	4
2. I feel sad	0	1	2	3	4
3. I feel angry	0	1	2	3	4
4. I have trouble sleeping	0	1	2	3	4
5. I worry about what will happen to me	0	1	2	3	4

HOW I GET ALONG WITH OTHERS (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. I have trouble getting along with other kids	0	1	2	3	4
2. Other kids do not want to be my friend	0	1	2	3	4
3. Other kids tease me	0	1	2	3	4
4. I cannot do things that other kids my age can do	0	1	2	3	4
5. It is hard to keep up when I play with other kids	0	1	2	3	4

ABOUT SCHOOL (<i>problems with...</i>)	Never	Almost Never	Sometimes	Often	Almost Always
1. It is hard to pay attention in class	0	1	2	3	4
2. I forget things	0	1	2	3	4
3. I have trouble keeping up with my schoolwork	0	1	2	3	4
4. I am away from school because I feel sick	0	1	2	3	4
5. I am away from school to go to the doctor or hospital	0	1	2	3	4

PedsQL™ - Paediatric Quality of Life Inventory: Version 4.0 – Australian English

YOUNG CHILD REPORT (ages 5-7)

Instructions for interviewer:

I am going to ask you some questions about things that might be a problem for some children. I want to know how much of a problem any of these things might be for you.

Show the child the template and point to the responses as you read.

If it is never a problem for you, point to the smiling face

If it is sometimes a problem for you, point to the middle face

If it is almost always a problem for you, point to the frowning face

I will read each question. Point to the pictures to show me how much of a problem it is for you. Let's try a practice one first.

	Never	Sometimes	Almost Always
Is it hard for you to click your fingers?	■	■	■

Ask the child to demonstrate clicking his or her fingers to determine whether or not the question was answered correctly. Repeat the question if the child demonstrates a response that is different from his or her action.

Think about how you have been for the last few weeks. Please listen carefully to each sentence and tell me how much of a problem this is for you. After reading the item, gesture to the template. If the child hesitates or does not seem to understand how to answer, read the response options while pointing at the faces.

Physical Functioning (problems with...)	Never	Sometimes	Almost Always
1. Is it hard for you to walk?	0	2	4
2. Is it hard for you to run?	0	2	4
3. Is it hard for you to play sport or do exercise?	0	2	4
4. Is it hard for you to pick up big things?	0	2	4
5. Is it hard for you to have a bath or shower?	0	2	4
6. Is it hard for you to help around the house (like pick up your toys)?	0	2	4
7. Do you get aches and pains? (<i>Where?</i> _____)	0	2	4
8. Do you ever feel too tired to play?	0	2	4

Remember, tell me how much of a problem this has been for you for the last few weeks.

Emotional Functioning (problems with...)	Never	Sometimes	Almost Always
1. Do you feel scared?	0	2	4
2. Do you feel sad?	0	2	4
3. Do you feel angry?	0	2	4
4. Do you have trouble sleeping?	0	2	4
5. Do you worry about what will happen to you?	0	2	4

Social Functioning (problems with...)	Never	Sometimes	Almost Always
1. Is it hard for you to get along with other kids?	0	2	4
2. Do other kids say they do not want to play with you?	0	2	4
3. Do other kids tease you?	0	2	4
4. Can other kids your age do things that you cannot do?	0	2	4
5. Is it hard for you to keep up when you play with other kids?	0	2	4

School/Preschool Functioning (problems with...)	Never	Sometimes	Almost Always
1. Is it hard for you to pay attention at school/preschool?	0	2	4
2. Do you forget things?	0	2	4
3. Is it hard to keep up with work at school/preschool?	0	2	4
4. Are you away from school/preschool because you feel sick?	0	2	4
5. Are you away from school/preschool because you have to go to the doctor or hospital?	0	2	4

How much of a problem is this for you?

Never



Sometimes



Almost Always



FUNCTIONAL DISABILITY INDEX						
When people are sick or not feeling well it is sometimes difficult for them to do their regular activities. In the past two weeks , would you have had any physical trouble or difficulty doing these activities?						
		No trouble	A little trouble	Some trouble	A lot of trouble	Impossible
1	Walking to the bathroom	0	1	2	3	4
2	Walking up stairs	0	1	2	3	4
3	Doing something with a friend (for example, playing a game)	0	1	2	3	4
4	Doing chores at home	0	1	2	3	4
5	Eating regular meals	0	1	2	3	4
6	Being up all day without a nap or rest	0	1	2	3	4
7	Riding the school bus or traveling in the car	0	1	2	3	4
<i>Remember, you are being asked about difficulty due to physical health</i>						
8	Being at school all day	0	1	2	3	4
9	Doing activities in gym class (or playing sports)	0	1	2	3	4
10	Reading or doing homework	0	1	2	3	4
11	Watching TV	0	1	2	3	4
12	Walking the length of a football field	0	1	2	3	4
13	Running the length of a football field	0	1	2	3	4

14	Going shopping	0	1	2	3	4
15	Getting to sleep at night and staying asleep	0	1	2	3	4