Information letter

Palliative sedation practice and opinions in pediatrics

Dear colleague,

We invite you to participate in a study about palliative sedation in children. Please take time to read this information letter carefully and to ask questions if there are any uncertainties or if you require additional information.

1 DESCRIPTION AND PURPOSE OF THE STUDY

Switzerland is participating in an international study about palliative sedation in children with principal investigators from the Belgian UZ Ghent and the University of Ghent in collaboration with the End-of-Life Care Research Group, together with the UK, Portugal, The Netherlands, Norway, Italy, the Czech Republic and Switzerland.

The purpose of the study is to gain insight into opinions and practices of pediatric healthcare professionals regarding pediatric palliative sedation. We aim to explore attitudes and practices in pediatric palliative sedation of physicians responsible for caring for terminally ill children between 0 and 18 years old, investigate the conditions in which physicians would start up palliative sedation based on a vignette case, and examining international differences between attitudes, practices and intentions to start pediatric palliative sedation.

We kindly ask you to take the time to complete an online questionnaire for us. This will take approximately max. 20 minutes of your time. Target participants are physicians with experience in caring for terminally ill children, i.e. pediatricians, neonatologists, general practitioners or physicians with other subspecialties.

https://kwaliteitvanzorg.limequery.com/513855?lang=en

2 INFORMED CONSENT AND ETHICAL APPROVAL

Participation in the study is completely voluntary. Participants can stop filling out the questionnaire at any time. Informed consent to participate in the study will automatically be given by completing the questionnaire, which is done on a voluntary basis. If you do not wish to participate in the study, you do not need to do anything. You can stop participating or withdraw your answers at any time. If you do not or no longer wish to participate, this will have no further consequences.

This study was pre-approved by an independent Medical Ethics Committee, linked to the Ghent University Hospital and the Ghent University. The study is being conducted in accordance with the guidelines for good clinical practice (ICH / GCP) and the Declaration of Helsinki, developed to protect human participants in medical research.
In accordance with the General Data Protection Regulation (GDPR) (EU) 2016/679 of 27 April 2016 (in effect since 25 May 2018) and the Belgian Act of 30 July 2018 on the protection of natural persons regarding the processing of personal data and on the free

movement of such data, your privacy will be safeguarded, and you will be able to access the collected data. Your consent to participate in the study means that we process your data for the purpose of the clinical study. This processing of data is provided for by law based on Article 6, § 1, (b), (e) or (f) and Article 9, § 2(j) of the General Data Protection Regulation.

In Switzerland, the *Kantonale Ethikkommission, Kanton Zurich*, confirmed, that this research project does not fall within the scope of the Human Research Act (HRA) (BASEC-Nr.: Req-2024-00213).

If you consent to participate in this study, your personal data will be anonymised during the study (thus, there will no longer be any link back to your personal file). Only the anonymised data will be used for data analysis and in any documentation, reports, or publications (in medical journals or at conferences) regarding the study. If the results of the study are published, your identity will remain confidential. Personal data will be processed and stored for at least 20 years. The process manager is the institution of the study head researcher, Dr. Laure Dombrecht (Ghent University).

In view of data protection, the data will be processed by members of the research team, designated by and under the responsibility of the head researcher, including own staff of non-healthcare professions.

If you so wish, the Data Protection Officer can provide you with more information about the protection of your personal data.
Contact details: Hanne Elsen privacy@ugent.be .

The Belgian supervisory authority responsible for enforcing data protection legislation can be contacted via the contact details below:

Gegevensbeschermingsautoriteit (GBA) (Data protection authority)
Drukpersstraat 35 – 1000 Brussels
Tel. +32 2 274 48 00
e-mail: contact@apd-gba.be
Website: www.gegevensbeschermingsautoriteit.be

3 DATA ANALYSIS

Data will be processed anonymously, and results will be reported anonymously in accordance with the provisions of the law on personal data protection. Descriptive analyses will be performed using *SPSS statistics*.

4 CONTACT

If you would like to receive more information about this study, you can contact one of the investigators at any time during the course of the study:

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We sincerely thank you for your cooperation.
Respectfully yours,

Dr. S. Debulpaep	Dr. E. Vandecruys	Dr. L. Goossens	Prof. Dr. K. Beernaert	Dr. L. Dombrecht	Dr. Y. Aelvoet	PD Dr. E. Bergsträsser	Dr. D Gubler	H. Fischer
UZ Gent	*UZ Brussel*	*UZ Gent*	*Universiteit Gent*	*Universiteit Gent*	*UZ Gent*	*University Children's Hospital Zurich*	*University Children's Hospital Zurich*	*UZH*