Author’s response to reviews

Title: Medical staff opposition to a deep and continuous palliative sedation request under Claeys-Leonetti law

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Dear Maria Zalm,

Please find enclosed a new version of our paper entitled: «Medical staff opposition to a deep and continuous palliative sedation request under Claeys-Leonetti law» (PCAR-D-18-00040) by C. Vitale et al., which we would like to submit again to BMC Palliative Care.
Revision has been undertaken taking into account the comments of the reviewers.

Reviewer 1: Simon Woods, PhD:

1. "The English is not adequate for an English language publication and I would suggest seeking assistance with the translation and proof-reading."

The article was read by a native speaker for the translation and proof-reading so that the article is written in an adequate English language publication.

2. "The piece needs a more extensive background/introductory section which should include a clear account of the change of law to the Claeys-Leonetti Law - as for example the case study reported by de Noneville et al Case Rep Oncol. 2016 Sep-Dec; 9(3): 650-654 which you cite. You really need to explain the significance of these changes and perhaps in particular how the law distinguishes between deep continuous sedation and sedation that is otherwise permitted and how both differ from euthanasia. You might also refer to other literature in palliative care such as the EAPC position paper on sedation."

We developed background/introductory section with inclusion of a clear account of the change of the Leonetti law to the Claeys-Leonetti law. Furthermore, we explained the meaning of these changes and in particular how law distinguishes between deep and continuous sedation at the patient’s request and sedation, but also euthanasia. We also referred to EAPC position paper on sedation. The background has been modified accordingly, pages 3 and 4 (L. 69-106).

“In February 2, 2016, the French Government passed a law called the Claeys-Leonetti law (1), after the re-examination of questions related to the patients’ support at the end of life and euthanasia. The first law concerning the rights of patients at the end of life and called Leonetti law (2) was unable to respond to public debate on the issue of euthanasia and appeared limited concerning patient’s rights. Indeed, if the Leonetti law allowed terminal sedation, it did not allow deep sedation to continue until death at the patient's request. Thus, terminal sedation was already authorised by the Leonetti law when a patient experiences acute complications with immediate vital risk. These situations can be cataclysmic haemorrhages, asphyxia respiratory distress and refractory symptoms or when the patient is no longer able to express his will and as a refusal of
unreasonable obstinacy the doctor decides to terminate the maintenance treatment (respirator). According to the European Association for Palliative Care (EAPC) “Palliative sedation was defined in analogous ways in all guidelines, that is, as an intervention instituted solely for the purpose of refractory symptom control. It could be light (or superficial) or deep (patient is asleep and unresponsive). This could be intermittent and temporary, or continuous until death” (3).

The Claeys-Leonetti law, that always forbade euthanasia or slow-euthanasia (described as occurring “when clinicians sedate patients approaching the end of life with the primary goal of hastening the patient’s death” (4)), maintains terminal sedation, but also increased patients’ autonomy by strengthening the value of advance directives and extending the spectrum of unreasonable obstinacy to the sustainment of vital treatments (5). Claeys-Leonetti law improved end-of-life conditions by establishing, under certain conditions, the right to deep and continuous sedation at the request of palliative patients, consisting of sedative treatment, and analgesic treatment if needed, leading to a profound and continuous change of vigilance to death, associated with the cessation of all life-sustaining treatments including artificial nutrition and hydration (6).

The set-up of this law forces doctors, after discussing the case in palliative multidisciplinary meetings, and in accordance with the French Oncology Coordination Centre recommendations to implement it, at the patient’s request, under conditions. The establishment of deep and continuous sedation at patient’s request is permitted by law in only two situations. First, deep and continuous sedation at the patient’s request, is initiated when a seriously ill and incurable patient with a short-term prognosis (this term is not made concrete in the law) experiences refractory symptoms. Secondly, when an incurable patient with a short-term pathology prognosis takes the decision to stop a treatment that could result in a short term life-threatening and/or potential unbearable suffering (artificial hydration has only been considered to be a life-sustaining treatment since the application of Claeys-Leonetti law).”

3. "The case study needs some additional detail as well as some editing of the technical medical terminology (consider the international non-specialist readership) - in particular you ought to give some account of how the patient's status was evaluated and in particular how their request was judged."

We were more clear concerning the patient’s request by providing more explanations and by defining more precisely the terms used. We also gave some account on how the patient’s status
was evaluated and how this request was judged. The case presentation was modified accordingly, page 5 (L. 132-143).

“Apart from the fear he expresses, the patient has no symptoms of anxiety, depression or pain after the introduction of appropriate treatments. On the other hand, he clearly states that he refuses to live again knowing that his death is approaching and that he is apprehensive of suffering. He said he wanted to speed-up the process to his death. For us, this is a request for assisted-suicide (active help from a third party for the administration of a lethal product) or euthanasia (act of a third party which intentionally provokes the death of another to put an end to his sufferings), rather than a real demand for deep and continuous sedation. It seems important to note that the patient’s requests for deep and continuous sedation until death are not registered officially. The law does not impose a written request. Thus, the request is most often made orally in the presence of several doctors and clinicians.” (L. 132-143)

● "You seem to suggest that there was some doubt about the terminal nature of the presenting condition but the patient died within 10 days."

We developed further the difficulties encountered in determining the short-term prognosis, as well as the ambivalence of the patient to know the degree of evolution of his cancer despite our proposals of CT scan. The changes were made pages 5 and 6 (L. 147-168).

“Indeed, prognosis appeared not short term committed (no visible clinical progression of the disease, which commits for sure the short-term vital prognosis), symptoms were managed with appropriate treatments and no life-sustaining treatment arrest could lead to potential unbearable sufferings. Regarding the short-term criterion of life-threatening prognosis, the patient was offered a CT scan to measure the progression of the disease. Indeed, no imaging had been performed for one year (time of diagnosis of recurrence). The patient refuses this proposal. The request for deep and continuous sedation was reiterated several times by the patient, who was still refusing any investigations to define the progression of his cancer and wanted parenteral hydration to be maintained. Daily, he questioned each caregiver about the rationale for the refusal of his request. How can the medical staff be sure that his prognosis is not a short-term compromise? Why could his psychological distress not be considered as refractory?

One week after refusing further investigation, the patient finally agrees to undergo a CT scan. Three days after the exam he died peacefully, according to our team (no specific questionnaires or objective elements to judge the quality of death exists), of a not predictable respiratory distress
certainly linked to the evolution of his cancer of the hypopharyngeal region, without the introduction of deep and continuous sedation, but with continuous midazolam treatment for anxiety. Opiates were not introduced because the patient was not in pain. The CT scan results, unknown at the time of death, reveal nothing conclusive (pulmonary metastases, but no lymph node involvement) and would have required additional analysis.” (L. 147-168)

● "What palliative care did the patient receive if not deep continuous sedation was it opiates and milder sedation? Was the death judged to be peaceful for example?"

We were more specific on that point pages 5 and 6 (L. 160-166).

Also, according to us the patient dies peacefully, even if regrettably there are no specific questionnaires or objective elements to judge the quality of death. This one is always difficult to assess and depend on the person subjectivity.

“One week after refusing further investigation, the patient finally agrees to undergo a CT scan. Three days after the exam he died peacefully, according to our team (no specific questionnaires or objective elements to judge the quality of death exists), of a not predictable respiratory distress certainly linked to the evolution of his cancer of the hypopharyngeal region, without the introduction of deep and continuous sedation, but with continuous midazolam treatment for anxiety. Opiates were not introduced because the patient was not in pain.” (L. 160-166)

4. "Your title raises the question of medical staff opposition but you don't actually discuss the grounds of that opposition which is particularly important in this case. You could be much more specific about your criticisms of the current law (this would be easier if you described it in more details as suggested above)."

We further discussed the ground of the medical staff opposition to the patient’s request and we were much more specific about our criticisms of the current law, particularly about its lacks of reference to palliative care literature.

The discussion has been modified accordingly pages 6 and 7.
“Moreover, our clinical case raises the question of intention in deep and continuous sedation until death at the patient’s request. The problem of intention, already put into work for sedation, has been partly resolved by the principle of double effect. Here, it exacerbated by the fact that the patient is asking for sedation.” (L. 180-184)

“The difficulty of evaluating a “refractory symptom”, is accentuated when it comes to so-called psychological or existential symptoms and is put forward by the European Association for Palliative Care (EAPC).

After defining the refractory symptom as precisely as possible, the EAPC framework discusses the relevance of considering the physicians or other clinicians being in the best position to determine whether a symptom is refractory. Finally, the EACP framework recognises the “subjectivity of refractoriness”, but refractory existential and psychological suffering not being a sufficient criterion for sedation (10). This problem is unresolved regarding deep and continuous sedation until death at the patient’s request. Thus, it seems necessary to clarify the law in this place, but also to define more clearly in a framework what is meant by psychic or existential suffering at the end of life, to objectify the criteria.” (L. 195-207)

“In order to reduce this lack of objectivity, it would be interesting to develop more prediction software in order to specify the short-term prognosis (as machine learning for example), but also strengthen palliative multidisciplinary meetings in the presence of physicians or clinicians who do not know the patient. Considerable variation was observed in physician-reported performance and decision-making (13), highlighting the importance of providing clearer guidance on the specific needs of the context in which continuous deep sedation until death is to be performed. Moreover, there are major gaps in end-of-life laws knowledge among medical specialists involved in end-of-life (14). Ongoing training is needed to ensure that specialists have up-to-date knowledge of the law to avoid compromising patient care or putting medical practitioners at legal risk.

Finally, through our case report, and the presented patient’s case request to accelerate death, we questioned the impact of the uncertain perception of deep and continuous sedation at patient’s request on the medical decision. In fact, it appears that the patient’s request to provoke or hasten his death could influence our decision to refuse or accept deep and continuous sedation, because it questions the grounds of the intention of physicians and clinicians in setting up sedation. Often, the difference between relieving and giving death is tenuous. Thus, for the sake of practices’ homogenisation and to prevent potential drifts due to the lack of precise criteria and objectives of the Claeys-Leonetti law. We could recommend, in addition to some degree of
Reviewer 2: Kenneth Chambaere:

1. INTRO

- "need for more clarity in the description of the legal situation (important for readers to understand the context fully)"

We developed background/introductory section with inclusion of a clear account of the change of the Leonetti law to the Claeys-Leonetti law. Furthermore, we explained the meaning of these changes and in particular the differentiation between deep and continuous sedation at the patient’s request and sedation, but also euthanasia. We have thus clarified the legal situation in order for the readers to fully understand the context. The background was modified accordingly, pages 3 and 4 (L. 69-106).

“In February 2, 2016, the French Government passed a law called the Claeys-Leonetti law (1), after the re-examination of questions related to the patients’ support at the end of life and euthanasia. The first law concerning the rights of patients at the end of life and called Leonetti law (2) was unable to respond to public debate on the issue of euthanasia and appeared limited concerning patient’s rights. Indeed, if the Leonetti law allowed terminal sedation, it did not allow deep sedation to continue until death at the patient's request. Thus, terminal sedation was already authorised by the Leonetti law when a patient experiences acute complications with immediate vital risk. These situations can be cataclysmic haemorrhages, asphyxia respiratory distress and refractory symptoms or when the patient is no longer able to express his will and as a refusal of unreasonable obstinacy the doctor decides to terminate the maintenance treatment (respirator). According to the European Association for Palliative Care (EAPC) “Palliative sedation was defined in analogous ways in all guidelines, that is, as an intervention instituted solely for the purpose of refractory symptom control. It could be light (or superficial) or deep (patient is asleep and unresponsive). This could be intermittent and temporary, or continuous until death” (3).

The Claeys-Leonetti law, that always forbade euthanasia or slow-euthanasia (described as occurring “when clinicians sedate patients approaching the end of life with the primary goal of
hastening the patient’s death” (4), maintains terminal sedation, but also increased patients’ autonomy by strengthening the value of advance directives and extending the spectrum of unreasonable obstinacy to the sustainment of vital treatments (5). Claeys-Leonetti law improved end-of-life conditions by establishing, under certain conditions, the right to deep and continuous sedation at the request of palliative patients, consisting of sedative treatment, and analgesic treatment if needed, leading to a profound and continuous change of vigilance to death, associated with the cessation of all life-sustaining treatments including artificial nutrition and hydration (6).

The set-up of this law forces doctors, after discussing the case in palliative multidisciplinary meetings, and in accordance with the French Oncology Coordination Centre recommendations to implement it, at the patient’s request, under conditions. The establishment of deep and continuous sedation at patient’s request is permitted by law in only two situations. First, deep and continuous sedation at the patient’s request, is initiated when a seriously ill and incurable patient with a short-term prognosis (this term is not made concrete in the law) experiences refractory symptoms. Secondly, when an incurable patient with a short-term pathology prognosis takes the decision to stop a treatment that could result in a short term life-threatening and/or potential unbearable suffering (artificial hydration has only been considered to be a life-sustaining treatment since the application of Claeys-Leonetti law).”

● "'right to deep and continuous sedation": is this really a right? So physicians cannot deny DCS if patient fulfils all criteria?"

Yes, it is really a right and physicians cannot deny deep and continuous sedation until death if patient fulfils criteria. We highlighted this further in our remarks page 4 (L. 96-98)

“…The set-up of this law forces doctors, after discussing the case in palliative multidisciplinary meetings, and in accordance with the French Oncology Coordination Centre recommendations to implement it, at the patient’s request, under conditions.”

● "'analgesic treatment": so this can be given alone, without sedatives, to achieve DCS? this I would find very strange"
We were not precise enough in our remarks. In fact, analgesic treatment cannot be given alone, without sedatives, to achieve DCS. So we have specified this sentence page 3 (L. 91-94)

“consisting of sedative treatment, and analgesic treatment if needed, leading to a profound and continuous change of vigilance to death, associated with the cessation of all life-sustaining treatments including artificial nutrition and hydration (6).”

● ""if the patient is likely to suffer pain": so DCS can only be given for pain and no other symptom such as dyspnea eg? And the patient does not have to suffer (pain) presently, ie DCS can be provided for anticipated pain? This would also be highly unusual"

By being more precise on the criteria of the Leonetti law and the Claeys-Leonetti law, we showed that sedation could already be put in place for other symptoms than pain.

DCS can only be implemented in anticipation when the patient with a pathology short-term prognosis take the decision to stop a treatment that could result in a short term life-threatening and/or potential unbearable suffering. We were clearer on these points page 3 (L. 75-80) and page 4 (L. 102-106)

“Thus, terminal sedation was already authorised by the Leonetti law when a patient experiences acute complications with immediate vital risk. These situations can be cataclysmic haemorrhages, asphyxia respiratory distress and refractory symptoms or when the patient is no longer able to express his will and as a refusal of unreasonable obstinacy the doctor decides to terminate the maintenance treatment (respirator).” (p. 3)

“Secondly, when an incurable patient with a short-term pathology prognosis takes the decision to stop a treatment that could result in a short term life-threatening and/or potential unbearable suffering (artificial hydration has only been considered to be a life-sustaining treatment since the application of Claeys-Leonetti law).” (p. 4)

● ""short-term prognosis": is this term not made concrete in the law? eg two weeks?"
No, short-term prognosis’ term is not made concrete in the law, which is the main problem. We added this precision page 4 (L. 101-102)

“patient with a short-term prognosis (this term is not made concrete in the law)”

● "Secondly, when patient with a serious and incurable condition take the decision to stop a treatment that could result in a short term life-threatening and/or potential unbearable suffering": so in this case a short-term prognosis is not necessary? and the treatment COULD result in death or suffering: this could mean even with a very low likelihood?"

In fact our sentence was ambiguous: a short-term pathology prognosis is necessary. We modified this sentence page 4 (L. 102-106).

“. Secondly, when an incurable patient with a short-term pathology prognosis takes the decision to stop a treatment that could result in a short term life-threatening and/or potential unbearable suffering (artificial hydration has only been considered to be a life-sustaining treatment since the application of Claeys-Leonetti law).”

2. CASE PRESENTATION

● "Line 111: is 10 days not short-term death (prognosis)?"

Ten days is in fact a short-term prognosis, but unfortunately, we had no objective element that would allow us to consider the patient’s death in such a short time. We developed this more pages 5 and 6 (L. 146-167).

“Indeed, prognosis appeared not short term committed (no visible clinical progression of the disease, which commits for sure the short-term vital prognosis), symptoms were managed with appropriate treatments and no life-sustaining treatment arrest could lead to potential unbearable sufferings. Regarding the short-term criterion of life-threatening prognosis, the patient was
offered a CT scan to measure the progression of the disease. Indeed, no imaging had been performed for one year (time of diagnosis of recurrence). The patient refuses this proposal. The request for deep and continuous sedation was reiterated several times by the patient, who was still refusing any investigations to define the progression of his cancer and wanted parenteral hydration to be maintained. Daily, he questioned each caregiver about the rationale for the refusal of his request. How can the medical staff be sure that his prognosis is not a short-term compromise? Why could his psychological distress not be considered as refractory?

One week after refusing further investigation, the patient finally agrees to undergo a CT scan. Three days after the exam he died peacefully, according to our team (no specific questionnaires or objective elements to judge the quality of death exists), of a not predictable respiratory distress certainly linked to the evolution of his cancer of the hypopharyngeal region, without the introduction of deep and continuous sedation, but with continuous midazolam treatment for anxiety. Opiates were not introduced because the patient was not in pain. The CT scan results, unknown at the time of death, reveal nothing conclusive (pulmonary metastases, but no lymph node involvement) and would have required additional analysis.

● "Is refractory psychological distress not an acceptable reason for DCS? or did the patient not present this distress after adequate treatment?"

Refractory psychological distress could be an acceptable reason for DCS, but does not seem to be. We developed it in the discussion after modifications (pages 6 and 7, L. 195-207).

“The difficulty of evaluating a “refractory symptom”, is accentuated when it comes to so-called psychological or existential symptoms and is put forward by the European Association for Palliative Care (EAPC).

After defining the refractory symptom as precisely as possible, the EAPC framework discusses the relevance of considering the physicians or other clinicians being in the best position to determine whether a symptom is refractory. Finally, the EACP framework recognises the “subjectivity of refractoriness”, but refractory existential and psychological suffering not being a sufficient criterion for sedation (10). This problem is unresolved regarding deep and continuous sedation until death at the patient’s request. Thus, it seems necessary to clarify the law in this place, but also to define more clearly in a framework what is meant by psychic or existential suffering at the end of life, to objectify the criteria.”
The patient also not present this distress after adequate treatment, what we specified page 5 (L. 131-133).

“Apart from the fear he expresses, the patient has no symptoms of anxiety, depression or pain after the introduction of appropriate treatments.”

● "Unclear to me: did the patient request a hastened death by DCS? Or did he instead ask to be kept sedated in his final days? This is an important issue to clear up in this case presentation, in light of the entire paper"

Because this is important to clear up in this case presentation and in light of our entire paper, we explained more precisely the request of the patient. He wanted a hastened death and not to be kept sedated in his final days. He hoped that being kept sedated will hastened his death. We modified the case presentation in order to be more clear page 5 (L. 133-139)

“On the other hand, he clearly states that he refuses to live again knowing that his death is approaching and that he is apprehensive of suffering. He said he wanted to speed-up the process to his death. For us, this is a request for assisted-suicide (active help from a third party for the administration of a lethal product) or euthanasia (act of a third party which intentionally provokes the death of another to put an end to his sufferings), rather than a real demand for deep and continuous sedation.”

3. DISCUSSION

● "The authors pinpoint the difficulty of objective and/or measurable criteria but do not offer suggestions on how to tackle the issue. The authors could suggest a solution based on the case presentation? What about the "palliative multidisciplinary board", would it be worthwhile to propose this as a good system to review eligibility of DCS requests, eg through some degree of consensus among practitioners? And how do the authors feel about the idea of oversight via reporting DCS to the central authorities, or via registration at regional hospitals? Would they recommend this, or rather not? What other solutions can be imagined?"
You will find, in our modified text, some suggestions on how to tackle the issue pages 7 and 8 (L. 205-207) (L. 213-217) (L. 224-235).

“Thus, it seems necessary to clarify the law in this place, but also to define more clearly in a framework what is meant by psychic or existential suffering at the end of life, to objectify the criteria.” (L. 205-207)

“In order to reduce this lack of objectivity, it would be interesting to develop more prediction software in order to specify the short-term prognosis (as machine learning for example), but also strengthen palliative multidisciplinary meetings in the presence of physicians or clinicians who do not know the patient.” (L. 213-217)

“Finally, through our case report, and the presented patient’s case request to accelerate death, we questioned the impact of the uncertain perception of deep and continuous sedation at patient’s request on the medical decision. In fact, it appears that the patient’s request to provoke or hasten his death could influence our decision to refuse or accept deep and continuous sedation, because it questions the grounds of the intention of physicians and clinicians in setting up sedation. Often, the difference between relieving and giving death is tenuous. Thus, for the sake of practices’ homogenisation and to prevent potential drifts due to the lack of precise criteria and objectives of the Claeys-Leonetti law. We could recommend, in addition to some degree of consensus among practitioners in palliative multidisciplinary meetings, that there is an oversight in reporting requests in cases of deep and continuous sedation until death within the central authorities, at least at the regional hospitals level first of all.” (L. 224-235).

4. GENERAL

● "Some English language corrections are needed, please let a native speaker read through the paper."
The article was read by a native speaker for the translation and proof-reading so that the article is written in an adequate English language publication.

We now hope that our paper is suitable for publication in BMC Palliative Care and we look forward to hearing from you.

Kind regards,

Claire Vitale.