Author’s response to reviews

Title: Advance directives in France: Do junior General practitioners want to improve their implementation and usage? A nationwide survey

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Author’s response to reviews:

Dear editor, Dear reviewer,

Thank you for the opportunity to provide a revised version of our manuscript. We have carefully taken into account reviewer comments in the revised manuscript. Please find below our point-by-point response to reviewers’ comments.

1. The paper requires a thorough English-language edit; the misuse of some words in the text made it difficult to understand precisely what it was that the authors were saying; e.g., (note: the pages were not numbered so I have ascribed numbers to assist with this review, starting from the cover page as p1) on p4, line 5: what does the word “affections” mean? P4, line 9: what does “obstinacy” mean in this context? Obstinacy by whom? About what? P5 line 26: “make” should be “require”. There are many other examples throughout the paper.
- As suggested the whole manuscript was reviewed by an English native speaker

- Affection is “disease” is this context

- Obstinacy was used to express something as willfulness in curative treatment in patients whose prognosis is very pejorative

- On page 5 the modification was done

2. To assist readers to understand the points made in this paper it is necessary to know what the legal system in France is; a brief outline of the law relating to Advance Care Planning is required, including the title of the legislation that was passed in 2005. For example, are Advance Directives legally binding on medical practitioners in France? If so, under what conditions? What are the circumstances under which a medical practitioner can choose not follow an Advance Directive? Are there penalties for medical practitioners who do not follow the Advance Directive other than as above? Do Advance Directives only have authority once the patient has lost capacity? What is the role of substitute decision-makers?

The legal system in France recently changed (2016). At the time of our study the modification of the law was not yet effective and the general practitioner residents were asked about 2005 law (Leonetti’s Law 2005-370 of April 22, 2005). Advance directives and trusted person appeared in French law in 2005 (Baumann A. Crit Care 2009 13.1 204). There was no specific guideline in writing living wills, a free sheet of paper could be used and kept by the patient or his/her relatives. At that time advance directives should “be taken into account” but were not binding (there was a “priority of medical practice over patients’ preference”) (Horn RJ. Health care anal 2014 22 59). To be valid, they should have been less than three years.

Due to the specificity of the law, any clinician could decide not to take them into account in many situations which made their use unattractive for the population. In emergency situation, if physicians suppose patient to be incompetent, if physicians consider the situation to be rapidly reversible, and in other situations, they can consider AD not to be relevant, whatever was the patient’s wishes, considering.

Considering theses information, the risk of penalty was very low.

The French law still indicates that advance directive would be used “in case they are one day in a condition that prevents them from expressing their will”. In any other case, patient is considered as in capacity to express themselves their wishes about intensity of care.

In French law, the notion of trustworthy person can be a decision-maker for the patient, making decisions based on what he/she thinks of the patient's wishes and can own patient’s advance
directives even if this point is not mandatory. This person, designated by the patient can be part of his family or not belonging to the family circle.

To complete the description of French law it should be noted that since 2016, there is no more validity period for advance directive. On the other hand, advance directives are partially binding, as physicians have to apply them except in emergency situation and in case they are in contradiction with law or patient status.

We add a sentence to synthetize these data: “This first version of the law was not legally binding for physicians, but should “be taken into account” for ethical reflections when the patient is unable to express his opinion. There was, however, a priority of medical practice over patients’ preferences, and physicians were allowed not to take AD into account because of uncertainty in sustainability of patients’ choices or because of apparent discrepancy between patients’ status and AD, suggesting that the wishes expressed by the patient were not taken with sufficient knowledge, and AD must be less than three years-old to be valid.”

3. Abstract P3: in the Results section here and at the beginning of the Results section in the main text, the response rate of 21.1% should be stated. The reader should not need to go to the Limitations section of the Discussion to find this. Although the response rate is very low, this need not necessarily preclude the paper from publication, but it needs to be acknowledged “up front”.

The percentage of participants and the total population of GPR during the study period was added in the abstract and the “Result/population” part of the manuscript.

In France medical studies are constituted of two different periods: a first one (six years) of initial and common formation and a second one (“internat”) during which they choose a medical or surgical specialty, and work in different wards to lean specificity of their future job. This is probably close to “fellowship” in the US. This period lasts three years for general practitioners. This was our target population.

Total population was constituted of the 3 promotions from the beginning to the end of internship was constituted of 10942 GPR.
4. Methods: I note that the on-line survey remained open for 14 months; this is a very long time for a survey to remain open. Presumably this was because of the low response rate and a hope to improve that. Were reminders sent out? If so, how many? Were any other actions undertaken to try to improve the response rate? (e.g., an editorial or comment in a journal or College newsletter relevant to the intended target group?).

There is very little information about the actual questions that were asked or the possible response options for each question. This causes confusion in reporting the results – see below.

Absolutely, we keep the survey open for a long time hoping increase the responder proportion. No official promotion of the study was available and the two students in charge of finding and sending mails and calling the head of GPR in each university took a lot of time (notably finding individual mails). Three reminders mails were sent to each group of GPR (one group per City/University). Individual mails were also sent when they were available. We try to contact educational leaders without any answer.

5. Results:

a. Population:

(i) What was the estimated denominator for the total population?

(ii) It is stated that 74.4% of respondents were female: what was the proportion of female:male GPRs in France at the time? In the discussion the authors say that the “sex ratio (was) close to that of the total population” (presumably the population of GPRs?); if this is correct, that is a surprisingly high figure. It would be of assistance to the reader to know what the actual sex ratio of GPRs in France is.

b. AD potential use: given the very small percentage who “would systematically take AD into account”, again we need to know, what is the law with respect to this?

You will find in additional information the translation of the whole survey. This document could constitute a supplementary material of the paper function if you think it is relevant.
6. (Results, cont.): The summary on p8 and Figure 5 do not reflect the text provided in the Results to this point. For example, in the text (p7, line 22) we are told that only 17.9% of the respondents who said that they would inform their patients about AD would “systematically” take the AD into account. Now we are told that 71.8% of the total population would “systematically or most often” do so. As noted above in relation to Methods, readers need to know the questions that were asked, the responses available and, at the very least, in the Results we need to know what the percentage was for each response option (at least, if this is going to be included in the discussion and in the Figures). In addition, Figure 4 (which supposedly provides graphic evidence of responses to this question) is not only incomplete in relation to percentages missing from the segments but there are only 4 segments instead of 5, which makes it completely useless.

Again, on p7, line 24, we are told that “59.7% of GPR … would spontaneously transmit” the patient’s AD to hospital with them. Then in the summary statement on p8, line 5 we are told that 99.1% of GPR who would “systematically or most often” take the AD into account would transmit the AD to the hospital but in Figure 5 we are now told that 71.4% of the total population would transmit the AD to the hospital. So is the correct figure 59.7% or is it 71.4%?

Some of these problems could potentially be overcome if all of the questions asked (or at least those reported in this paper) with all response options, were presented in the Methods and then, in the Results, the percentages for each option were given.

The summary statement on p8 also provides new Results which have not appeared in the previous text, i.e., that “65.4% of the total population would include such AD in a collegial reflection about withdraw or withhold decision.” Apart from the fact that this statement belongs in the main part of the Results, not in the summary statement, again we do not know what the response options were: e.g., were the response options “Always/Sometimes/Never”? Were they only Yes/No? If the former what does 65.4% represent (i.e., a combination of Always and Sometimes?).

- What was the estimated denominator for the total population?

As noted previously in our answer, total population of GPR during the study period was constituted of the 3 promotions from the beginning to the end of internship was constituted of 10942 GPR.
- what was the proportion of female: male GPRs in France at the time?

The proportion of women among GPR for the three studies years was: 63.6%, 62.3% and 62.9%. The mean was: 62.9% of the whole population of interest.

We add brackets in the discussions section: “(mean percentage of women in the whole GPR population of interest during the study period: 62.9%)”

- AD potential use: very small percentage who “would systematically take AD into account”: what is the law with respect to this?

According to the 2005 French law, physician should have taken AD into account. Many doctors however considered that patients where not competent to decide what level of therapeutic intensity they should receive and affirm they would not apply these AD arguing of the impossibility to be sure the patient did not have change his/her mind since the AD were wrote, or considering the patient unable to take an “informed decision” due to the lack of information concerning ICU or surgery, etc… On the other hand, many clinicians were much more afraid of legal consequences of a therapeutic withdrawal or withholding than of an excess in intensity of care.

Our aim was to underline this point, showing the frailty of the law, because of this remaining uncertainty about the relevance of patients’ decisions.

- summary on p8 and Figure 5 do not reflect the text:

  o p7, line 22: only 17.9% of the respondents who said that they would inform their patients about AD would “systematically” and p8: 71.8% of the total population would “systematically or most often”

  o p7, line 24, “59.7% of GPR … would spontaneously transmit”. p8, line 5 : 99.1% of GPR who would “systematically or most often. Figure 5 : 71.4% of the total population would transmit the AD to the hospital

We do apologize for the complexity of our results presentation. Two parameters should be taken into account: the population of interest and the exact item as you underlined.

The question was : “if your patient has written AD, would you take them into account : never/systematically/Most often/only if they seems relevant and if you agree with patient
decisions/Only if you consider the patient to have understood the consequences of his/her decisions”.

Your remark led us to review the way in which the synthesis of the results was presented: rather than exclude each time the GPR who had answered the previous question negatively, we chose to give independent answers from the population total. The corrections of the figure and in the text were made from this new point of view.

- Figure 4 is not only incomplete there are only 4 segments instead of 5, which makes it completely useless

We suppressed figure 4 and complete the proportions of different response in the text.

- We need to know what the percentage was for each response option (at least, if this is going to be included in the discussion and in the Figures).

We suppressed figure 4 and complete the proportions of different response in the text.

- Summary statement on p8 also provides new Results: “65.4% of the total population would include such AD in a collegial reflection about withdraw or withhold decision.”

- Were the response options “Always/Sometimes/Never”? Were they only Yes/No?

The question was: “Do you think withdrawal and withholding decisions must be made after take AD into account? Yes/No”.

- If the former what does 65.4% represent (i.e., a combination of Always and Sometimes?).

To clarify our purpose we decide to suppress confusing data and to express only raw results. In the initial version of the results, the expressed percentage only consider part of the GPR who positively respond to previous exposed questions. As you underlined, this presentation was unclear so we choose to give the raw result independently of the other answers of the participants.

Figure 5 was modified and last sentence is now: “At last, 2095 (90.7% of total population) would include such AD in a collegial reflection about withdraw or withhold decision, the
remaining part of the participants considering AD not to have a place in these ethical reflections.”

7. Discussion: the final sentence in the Discussion, which says “that directives are less an official form than a reflection process involving the physician-patient relationship” uses as a reference for this statement a paper from 2002!! In many countries where Advance Care Planning is part of “the physician-patient relationship”, it is also covered by legislation that confirms patient-centred care and the binding nature of Advance Directives. Without an understanding of the legislation in France, the reader has no way of judging whether or not that final sentence is valid.

French law was recently modified (2016) and applying patients written wishes is now a legal duty. Two important elements should however be noticed:

First, as specified in response to question 2, previous law was unclear on the expected degree of consideration of patients’ advance directives.

Second, despite large modification in the current law, weaknesses remain, that lead French physician to keep some distance from AD. In emergency situation, “stabilization of the patient condition” could and (probably should) be done before taking AD into account, at least in case of uncertainty about patient status. Moreover, many semantic points remain unanswered, for example: AD are often considered as wished for “end of life” situation, but except for chronic diseases, this notion is far unclear leading to an excess of aggressive treatment of severe conditions even in case of DNR wishes of the patient; another example could be the notion of “refusal of therapeutic relentlessness” which does not mean anything, leaving the clinician to choose when the treatment becomes futile. These points of weakness of the law, this supposed difference between the text and spirit of the law and the fear of not doing enough (in curative cares) are favoring intensity instead of comfort care in many situations.

At last, scarcity of AD and ignorance about them of the population encourage the physician to decide when and how to implement a curative treatment for a patient.

We hope these explanations can help you understand the state of mind of French doctor concerning AD and AD application in daily clinical practice.
To shortly synthetize these notion we add (at the end of the cited sentence) : “at least in countries were the law is least restrictive”.