

Should We Keep or Drop the Terminal-Only Rule?

Satoshi Kodama (Dept. of Ethics, Kyoto University)

The Terminal-Only Rule (TOR)

- In Japan, only patients in the terminal phase are allowed to have life-sustaining treatments terminated. (TOR)
- A similar situation exists in South Korea but not in Taiwan or the UK (Tanaka et al. 2020).
- TOR is analogous to the Dead-donor rule in organ transplantation (Kodama 2007).
- Abuse or gerrymandering of TOR is occurring.
- **Should Japan keep the rule or drop it? - Drop it.**

1. Fussa Dialysis Case 2018



Tanaka and Kodama (2020)

<https://mainichi.jp/articles/20190312/k00/00m/040/323000c>

- A 44-year-old chronic kidney disease (CKD) patient died a week after terminating dialysis treatment in a public hospital in Tokyo in August 2018.
- The patient's attending physician suggested several treatment options, including kidney transplantation and permanent vascular catheter. According to the independent enquiry conducted by **the Japanese Society for Dialysis Therapy (JSDT)**, the patient's medical condition **was not considered terminal** since she could have lived at least another six months had the dialysis been continued.

1. Fussa Dialysis Case 2018

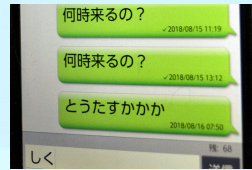


Tanaka and Kodama (2020)

<https://medical.nikkeibp.co.jp/leaf/mem/pub/report/1332/201904/560717.html>

- The patient indicated she understood the physician's explanation that she would die within two weeks if dialysis were terminated. Nonetheless, after several discussions with the medical team and her husband, the patient signed a consent form to authorise the termination of dialysis, which was stopped shortly afterwards.
- According to the hospital's report and the investigation conducted by local government officials, the patient experienced pain and panic the day after the dialysis treatment was stopped and rescinded her wish to terminate treatment due to respiratory distress.

1. Fussa Dialysis Case 2018



Tanaka and Kodama (2020)

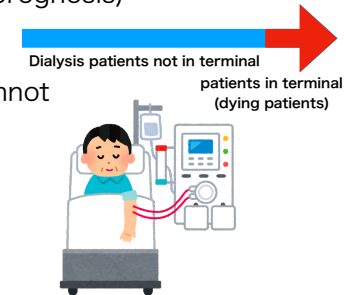
<https://mainichi.jp/articles/20190307/k00/00m/040/004000c>

- Nurses calmed her down with breathing exercises, and the attending physician administered a sedative. The patient only indicated a wish to treat the respiratory discomfort and did not insist on resuming dialysis. In response, the physician offered pain relief without reinitiating dialysis. The patient died shortly afterwards.
- The JSDT's recommendations [2014] allow withholding and withdrawing hemodialysis **only if a patient's general medical condition is extremely poor [i.e. terminal]**.

2. Guidelines and Dialysis

MHLW's Guidelines and JSDT's Recommendations (2014) adopt TOR

1. Only patients in the terminal phase can have life-sustaining treatments (LST) terminated. (TOR)
2. Patients on dialysis are not in the terminal phase. (except for those with very poor prognosis)
3. Therefore, patients on dialysis cannot have their LSTs terminated.



MHLW's guidelines for end-of-life decision-making process

- Created in 2007 (「終末期医療の決定プロセスに関するガイドライン」)
- Outlines the decision-making process for end-of-life care (informed consent, proxy consent, best interest)
- There is no definition of "end-of-life (terminal phase)"
- Emphasises procedural justice
- Recommends for clinical ethics consultation
- Prohibits active euthanasia
- Changed its name from "end-of-life (terminal) care" to "the final stage of life" in 2015 (人生の最終段階の決定プロセスに関するガイドライン)
- Revised in 2018 and emphasises ACP and nursing care (人生の最終段階における医療・ケアの決定プロセスに関するガイドライン)

MHLW's Guidelines do not define or give criteria for the terminal phase (=the final stage of life)

<https://www.asian-eolc-ethics.com/>

注4 人生の最終段階には、がんの末期のように、予後が数日から長くとも2-3ヶ月と予測が出来る場合、慢性疾患の急性増悪を繰り返し予後不良に陥る場合、脳血管疾患の後遺症や老衰など数ヶ月から数年にかけ死を迎える場合があります。どのような状態が人生の最終段階かは、本人の状態を踏まえて、医療・ケアチームの適切かつ妥当な判断によるべき事柄です。また、チームを形成する時間のない緊急時には、生命の尊重を基本として、医師が医学的妥当性と適切性を基に判断するほかありませんが、その後、医療・ケアチームによって改めてそれ以後の適切な医療・ケアの検討がなされることになります。

*Note 4: The last stage of life includes cases where the prognosis is predictable from a few days to a few months at most, such as the terminal stage of cancer; cases where the prognosis is poor due to repeated acute exacerbations of chronic diseases; and cases where death occurs over several months to several years, such as the sequelae of cerebrovascular diseases and senility. The last stage of life should be determined by the proper and valid judgment of the medical and nursing care team based on the patient's condition. In an emergency situation where there is no time to form a team, the physician has no choice but to make a decision based on medical validity and propriety with respect for life, after which the medical and nursing care team will again consider proper medical treatment and nursing care for the patient.

JSDT's initial view on the Fussa Case

Okada 2019

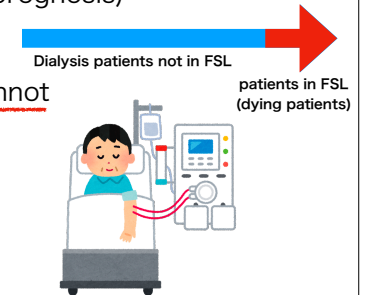
- The major issue in this case was that the physician proposed discontinuing dialysis for the non-terminal patient with end-stage kidney disease undergoing maintenance dialysis. Despite the patient's desire to resume the suspended dialysis, it was not restarted. Additionally, the medical team did not carry out shared decision-making and advance care planning.
- For non-terminal patients, the medical team should refrain from proposing the option of forgoing dialysis at the start and during the continuation of treatment...
- Dialysis is considered a life-prolonging treatment for patients with end-stage kidney disease; however, for patients who can achieve long-term survival through the initiation or continuation of dialysis, it should be regarded not as life-prolonging treatment, but simply as treatment.

Guidelines and Dialysis

MHLW's Guidelines and JSDT's Recommendations (2014) adopt TOR

1. Only patients in the final stage of life (FSL) can have life-sustaining treatments (LST) terminated. [TOR]
2. Patients on dialysis are not in FSL (except for those with very poor prognosis)

3. Therefore, patients on dialysis cannot have their LSTs terminated.



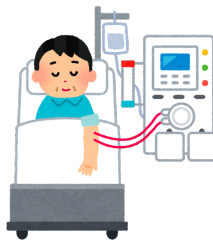
3. Enter JSDT's new recommendations (2020)

透析会誌 53(4) : 173~217, 2020

日本透析医学会 (the Japanese Society for Dialysis Therapy)

透析の開始と継続に関する 意思決定プロセスについての提言

2020年

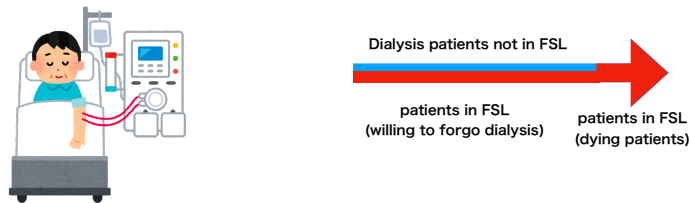


Determination of the final stage of life: Joint decision model JSDT (2020: 187, 207)

- In this report, we will use the term 'final stage of life' in accordance with recent guidelines from the MHLW, rather than 'terminal phase'. The determination of whether a patient is in the final stage of life should be made by a physician, taking into account the patient's overall condition, including dialysis-related complications and other diseases. **The final stage of life begins when the patient, or the patient's family if the patient lacks decision-making capacity, understands and accepts this diagnosis.**
- **ESKD requiring dialysis alone does not constitute the final stage of life.** However, patients with ESKD who require dialysis to sustain life but choose comfort care measures and discontinue dialysis have a high probability of death within several days to weeks, even though they are not medically considered to be in the final stage of life...

Determination of the final stage of life: Joint decision model JSDT (2020: 187, 207)

- Therefore, **when a patient**, or the patient's family if the patient lacks decision-making capacity, **requests the medical team to discontinue dialysis, the final stage of life begins from the point at which a physician diagnoses the patient with ESKD requiring dialysis to sustain life permanently.**



JSDT's revised view on the Fussa Incident

Okada et al (2022)

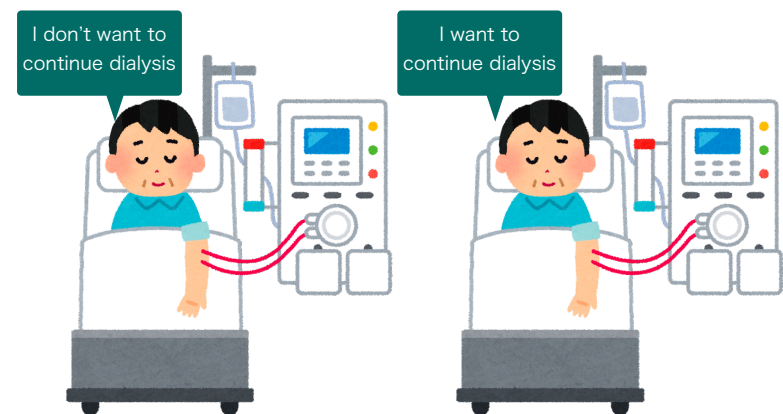
- Under the new JSDT's recommendations, while dialysis patients are not considered to be in the final stage of life, when **a patient with decision-making capacity requests the medical team to discontinue dialysis**, and a physician diagnoses the patient with ESKD requiring permanent dialysis to sustain life, **and the patient or their family understands and accepts this diagnosis**, the final stage of life is deemed to have commenced. **Therefore, the civil lawsuit [Fussa] case in question falls under the category of being in the final stage of life.**

4. Discussion: Is the joint decision model of FSL coherent?

- Judgment of the terminal phase (or FSL) seems medical, independent of the patient's wish or understanding. (Objective-medical model)
- Compare: "**Stage 4 cancer** begins when the patient, or the patient's family if the patient lacks decision-making capacity, understands and accepts this diagnosis." This would be very odd.
- Implication 1: Of two exactly similar ESKD patients on dialysis, one may be in the FSL and the other not in the FSL.
- Implication 2: If the ESKD patient changes his mind, he can be in and out of the final stage of life without any change in his medical conditions.

Implication 1

Two exactly similar ESKD patients on dialysis

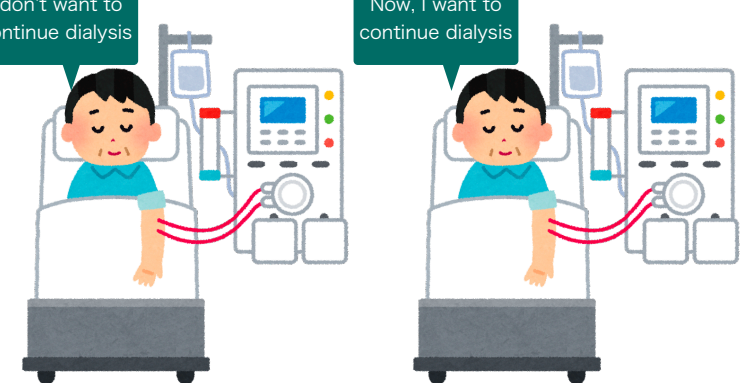


Pt1 is in the final stage of life
⇒allowed to discontinue dialysis

Pt2 is not in the final stage of life
⇒not allowed to discontinue dialysis

Implication 2

ESKD patient on dialysis changes his mind



I don't want to continue dialysis

Now, I want to continue dialysis

Pt3 is in the final stage of life one day

Pt3 is **not** in the final stage of life another day without any change in his medical conditions

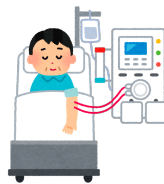
4. Discussion: Is the joint decision model of FSL coherent?

- Consistency 1: Should we apply the same logic to ALS (MND) patients and PVS patients and allow discontinuation of LSTs?
- Consistency 2: Healthy people can die within a few days if they don't eat and drink at all. Should physicians consider healthy people to be in the final stage of life if they decide not to eat and drink?



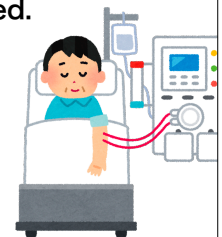
Joint decision model leaves 1. (TOR) untouched but tinkers with 2. to make termination possible

1. Only patients in the final stage of life (FSL) can have life-sustaining treatments (LST) terminated. (TOR)
2. **Patients on dialysis are not in FSL.** (except for those with very poor prognosis)
3. Therefore, patients on dialysis cannot have their LSTs terminated.



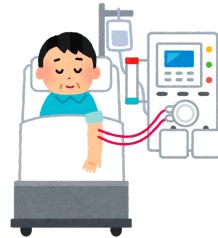
Joint decision model leaves 1. (TOR) untouched but tinkers with 2. to make termination possible

1. Only patients in the final stage of life (FSL) can have life-sustaining treatments (LST) terminated. (TOR)
2. Patients on dialysis are not in FSL. (except for those with very poor prognosis)
⇒ **Patients on dialysis are in FSL only if they wish to have LSTs discontinued.**
3. Therefore, patients on dialysis **can** have their LSTs terminated.



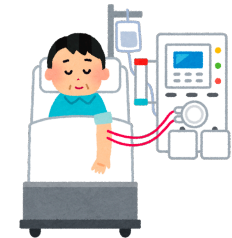
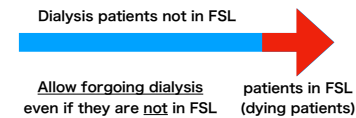
We should challenge 1. (TOR)

1. Only patients in the final stage of life (FSL) can have life-sustaining treatments (LST) terminated. (TOR)
2. Patients on dialysis are not in FSL. (except for those with very poor prognosis)
3. Therefore, patients on dialysis cannot have their LSTs terminated.



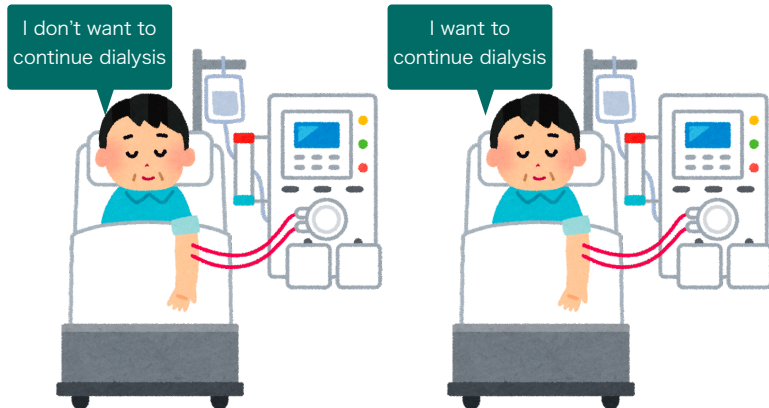
Patient autonomy and the right to refuse treatment

- If we as a society allow dialysis patients to end their treatment, we should not do so by changing the definition or interpretation of “terminal phase” to bypass TOR.
- Instead, we should abandon TOR and recognise the right to refuse treatment for non-terminal patients, even if that may result in their death.



Right to refuse treatment

Two exactly similar ESKD patients on dialysis



Pt4 is **not** at the final stage of life
⇒allowed to discontinue dialysis

Pt5 is **not** at the final stage of life
⇒allowed to continue dialysis

Conclusions

- The Terminal-Only Rule (TOR) is one of the ethical principles in Japan's end-of-life care.
- The Fussa Dialysis Case in 2018 appeared to violate TOR.
- JSDT's new recommendations have adopted the joint decision model to determine the terminal phase, enabling non-terminal dialysis patients to “choose” to be terminal.
- JSDT's strategy carries several unpalatable implications.
- Recognising the right to refuse treatment is a simpler way to allow non-terminal patients to discontinue dialysis.

References

- JSDT (2014). 日本透析医学会血液透析療法ガイドライン作成ワーキンググループ. “維持血液透析の開始と継続に関する意思決定プロセスについての提言.” 透析会誌 47 (5): 269–85.
- JSDT (2020). 透析の開始と継続に関する意思決定プロセスについての提言作成委員会. (2020). 透析の開始と継続に関する 意思決定プロセスについての提言. 透析会誌, 53(4), 173–217, at 186-7. In Japanese
- Okada, K. (2019). 日本透析医学会 「維持血液透析の開始と継続に関する意思決定プロセスについての提言」 —— その後の実態調査 ——. 日本透析医会雑誌, 34(1), 110–116. In Japanese
- Okada, K., Tashiro, M., Iwaki, M., Inoue, T., Shima, H., Minakuchi, J., & Kawashima, S. (2022). 透析の見合わせに関する現状と課題—全国実態調査より—. 透析会誌, 55(10), 555–561. In Japanese
- Kodama, S. (2007). “デッド・ドナー・ルールの倫理的検討.” 生命倫理 17 (1): 183–89. In Japanese
- Tanaka, Miho, Satoshi Kodama, Ilhak Lee, Richard Huxtable, and Yicheng Chung. (2020). “Forgoing Life-Sustaining Treatment – a Comparative Analysis of Regulations in Japan, Korea, Taiwan, and England.” BMC Medical Ethics 21 (1): 1–15.
- Tanaka, Miho, and Satoshi Kodama. (2020). “Ethical Issues Around the Withdrawal of Dialysis Treatment in Japan.” Asian Bioethics Review 12 (1): 51–57.

Thank you for listening

