日本ホスピス・緩和ケア研究振興財団　事業報告書
日本・韓国・台湾・香港・シンガポール　第３期共同研究事業

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Ⅰ　事業の目的・方法

1.　目的

アドバンス・ケア・プランニング（ACP）とは、意思決定能力を有する個人が、自分の価値観を確認し、重篤な疾患の意味や転帰について十分に考え、今後の治療やケアについての目標や意向を明確にし、これらを家族や医療者と話し合うことができるようにすることである。2017 年に欧州緩和ケアネットワーク（EAPC）から ACP の定義と推奨に関して国際的な専門家の合意が発表されたが、個人の自律性と同時に患者・家族の和を重んじる儒教文化の残るアジア諸国には必ずしもそぐわないような項目も含まれている。アジア諸国で国を挙げて ACP が推進され始めているが、アジアにおける ACP の望ましい在り方に関しては、国際的にも合意が得られていない。

本研究の主目的は、日本・韓国・台湾・香港・シンガポールの ACP の専門家の間で、これら 5 か国に適切な ACP の定義と推奨の国際合意を得ることである。

2.　方法

①対象

5 か国で ACP の臨床・研究・教育・政策等に係る計 23 名の多職種の専門家（がん医療、緩和ケア、一般内科、家庭医療、看護、心理学、倫理、法など）からなるタスクフォースを構成した。

②方法

1)　デルファイ研究。Round　1 と 5 は質的な方法を用い、2-4 は量的な評価を行う。合意プロセスにより Round の増減を決定する。月に 1-2 回のオンライン会議、時々の対面会議、メーリングリストを活用した検討を行う。現在、日本・韓国・台湾・香港で倫理委員会の承認を得ており、シンガポールではでる Round 1 完了後倫理委員会に提出する予定である。

2)　Round 1（準備）：5 か国の多職種で構成される国際的な ACP の専門家により、本研究のタスクフォースを組織し、アジア太平洋ホスピス緩和ケアネットワーク（APHN）とも連携している。神戸大学の木澤義之教授と、聖隷三方原病院の森雅紀が Co-Chair となり、研究成果や Professional　network から ACP の国際的な専門家を同定した。また、現在アジア諸国の ACP の系統的レビューを実施しているインドネシアの医師もタスクフォースに迎えた。各国のデータベースをもとに系統的レビューを追加し、抽出された定義・

推奨を参考に、ACP の定義・推奨を作成する。

Ⅱ　事業の内容・実施経過

①系統的レビュー

英文誌に掲載されていないエビデンスを包括的に把握することを目的に、ACP に関する定義や推奨項目に関して日本語、韓国語、中国語による系統的レビューを行った。アジアでは患者・家族等両者の関与が重要であること、法制化や指針作りの必要性が唱えられていることが明らかになった。

②デルファイ項目の検討

ACP の定義、推奨項目について、EAPC の項目をたたき台にし、アジアの文化に照らし合わせて大幅な加除修正を行った。月に 2 回のペースで Web 会議を開催し、ACP の定義と推奨項目の検討を一通り行った。また、2019 年 4 月では台北（招聘会議）で、8 月にはインドネシア（Asia Pacific Hospice Conference 2019）で、それぞれ対面での会議を行った。

③Relational autonomy

アジアにおける ACP を検討する上で、家族等周囲の人との関係性の中での自律性が話題になる。検討過程で Relational autonomy という概念が出された。日本国内で本概念についての理解を深める目的で、学際的な会議を行った。

Ⅲ　事業の成果

デルファイ研究を開始し、予定通り進められている。検討を通じ、アジア文化の独自性や各国の ACP の在り方に対する理解が深まった。また、できるだけ多数のタスクフォースメンバーの参加を促すために、Web 会議とメーリングリストでの議論のほか、タスクマネジメントのツールである Trello、SNS（WhatsApp）等を有効に活用し、効率的に多国間での議論を進めている。これらを通じて、日本・韓国・台湾・香港・シンガポール・インドネシアの緩和ケアの臨床家・研究者・教育者の先生方や、アドバイザーとなってくださっているオランダの研究者の先生方と顔の見える関係が形成された。

①　系統的レビューの学会発表

和文誌における ACP の系統的レビューを行い、その結果を共同研究者らが 23rd East Asian Forum of Nursing Scholars (EAFONS)で口演した（Chikada A, Takenouchi S, Nin K, Mori M. Recommended cultural considerations of advance care planning in Japan: A systematic review.）。

② 台北宣言

本事業を進める中で、検討内容を様々な形で発表する機会を得た。本事業の間接的な定義として、2019年台北宣言がある。本デルファイ研究に係るアジアの研究者らが中心となり、台北でアジアのACPに関する推奨を行う会議に招待された。検討内容をもとに、2019年台北宣言を発表し、Journal of Palliative Medicineに公開された（Lin CP, Cheng SY, Mori M, et al. 2019 Taipei Declaration on advance care planning: A cultural adaptation of end-of-life care discussion. J Palliat Med 2019;22:1175-77.）

③ デルファイ項目の作成

現在2巡目の検討中であるが、最終案として、下表のようなACPの定義と推奨項目案を作成した。左列が今回のデルファイ研究の元になったEAPCによる推奨項目であり、右列が今回の検討結果をもとにした2020年2月現在での最終版である。左列のEAPCの項目に対しては、タスクフォースメンバーにより、どの程度アジアのACPにおいて賛成されるかについて、探索的なWeb調査を行った（Strongly agree (SA), Agree (A), Agree somewhat (AS), Undecided (UD), Disagree somewhat (DS), Disagree (D), Strongly Disagree (SD)）。それをもとに、右列の項目を検討した。二つの定義（拡張版、短縮版）、６つのドメイン（推奨される要素、Relational autonomy、役割、タイミング、ポリシーと規制、評価）からなる計52項目の推奨項目から構成されている。アジアにおいては家族等信頼できる人の関与が必須であること、事前指示は必ずしも必須ではないこと、本人や家族等の感情に配慮することが重要であること、本人と家族等の気持ちの橋渡しを行うことも望ましいこと、多様な文化や宗教・信条があるためそれらを尊重することなどが共有された。

EAPC white paper items	**Suggested description (revisions underlined)**
Extended definition: Advance care planning enables individuals who have decisional capacity to identify their values, to reflect upon the meanings and consequences of serious illness scenarios, to define goals and preferences for future medical treatment and care, and to discuss these with family and health-care providers. ACP addresses	**Extended definition: Advance care planning is a process that enables individuals who have decisional capacity to identify their values, to reflect upon the meanings and consequences of serious illness scenarios, to define goals and preferences for future medical treatment and care, and to discuss these with family**

individuals' concerns across the physical, psychological, social, and spiritual domains. It encourages individuals to identify a personal representative and to record and regularly review any preferences, so that their preferences can be taken into account should they, at some point, be unable to make their own decisions. **(SA 11; A 4; AS 1)**	**and/or other closely related persons*, and health-care providers. ACP addresses individuals' concerns across the physical, psychological, social, and spiritual domains. It encourages individuals to identify a personal representative and to record and regularly review any preferences (as per local legal jurisdiction), so that their preferences can be taken into account should they, at some point, be unable to make their own decisions.**
Brief definition of ACP: Advance care planning enables individuals to define goals and preferences for future medical treatment and care, to discuss these goals and preferences with family and health-care providers, and to record and review these preferences if appropriate. **(SA 10; A 5)**	**Advance care planning is a process that enables individuals to define goals and preferences for future medical treatment and care, to discuss these goals and preferences with family and/or other closely related persons*, and health-care providers, and to record and review these preferences if appropriate.**
Recommended elements of ACP	**(New items)**
	1) The individual's preferences, and the preferences of the family and/or other closely related persons chosen by the individual, should be explored on the extent to which ACP is discussed, and who to include in the ACP discussions.
1. The ACP process includes an exploration of the individual's understanding of ACP and an explanation of the aims, elements, benefits, limitations and legal status of ACP. **(SA 8; A 4; AS 2)**	**2) The ACP process includes an exploration of the understanding of ACP among the individual and the family and/or other closely related persons* if the individual allows, and an explanation of the aims, elements,**

	benefits, limitations and legal status of ACP.
2. ACP should be adapted to the individual's readiness to engage in the ACP process. **(SA 7; A 5; AS 2)**	**3) ACP should be adapted to the individual's readiness to engage in the ACP process, and if allowed by the individual, the family and/or other closely related persons* may also be engaged in the ACP process.**
3. ACP includes the exploration of the individual's health-related experiences, knowledge, concerns and personal values across the physical, psychological, social and spiritual domains. **(SA 8; A 4; AS 1; DS 1)**	**4) ACP includes the exploration of health-related experiences, knowledge, concerns and personal values of the individual, and if allowed by the individual, the family and/or other closely related persons* across the physical, psychological, social and spiritual domains.**
4. ACP includes exploring goals for future care. **(SA 11; A 2; AS 1)**	**5) ACP includes exploring goals for future care.**
5. Where appropriate, ACP includes information about diagnosis, disease course, prognosis, advantages and disadvantages of possible treatment and care options. **(SA 10; A 4)**	**6) Where appropriate, ACP includes information about diagnosis, disease course, prognosis, advantages and disadvantages of possible treatment and care options.**
6. ACP might include clarification of goals and preferences for future medical treatment and care; if appropriate, ACP includes exploration of the extent to which these goals and preferences are realistic. **(SA 5; A 9)**	**7) ACP includes clarification of goals and preferences for future medical treatment and care; if appropriate, ACP includes exploration of the extent to which these goals and preferences are realistic.**
7. ACP includes discussing the option and the role of the personal representative,	**8) ACP includes discussing the option and the role of the personal representative,**

who might act on behalf of the individual when they are unable to express their preferences, as per local legal jurisdiction. **(SA 7; A 6; AS 1)**	**who might act on behalf of the individual when they are unable to express their preferences, as per local legal jurisdiction.**
8. ACP includes an exploration of the extent to which the individual allows their personal representative to consider their current clinical context in addition to their previously stated preferences when expressing preferences on their behalf. **(SA 5; A 6; AS 1; UD 1)**	**9) ACP includes an exploration of the extent to which the individual allows their personal representative to consider their current clinical context in addition to their previously stated preferences when expressing preferences on their behalf.**
9. ACP might include the appointment of a personal representative and documentation thereof. **(SA 5; A 4; AS 3; UD 1; DS 1)**	**10) ACP might include the appointment of a personal representative(s) and documentation thereof.**
10. ACP includes information about the option and role of an advance care directive (which is a document to record values, goals and preferences to be considered when the individual is unable to express their preferences) as per local legal jurisdiction. **(SA 7; A 4; AS 3)**	**11) ACP includes information about the option and role of an advance directive**, and might include its completion as per local legal jurisdiction.** **The term for "advance directive" to be confirmed by taskforce survey (will tentatively use "advance directive").**
11. ACP might include the completion of an advance care directive. **(SA 4; A 5; AS 3; DS 1)**	
	12) The content of ACP discussions should be documented every time.
12. ACP includes encouraging an individual to provide family and health-care professionals with a copy of the advance care directive.	**13) ACP includes supporting an individual to provide family and/or other closely related persons*, and health-care providers with a copy of document**

(SA 3; A 6; AS 4; DS 1)	related to ACP (→ ACP related document).
Recommended consideration for relational autonomy in ACP	
	14) Optimally, ACP discussions between the individual and healthcare providers should also include the family and/or other closely related persons, as chosen by the individual to engage in the ACP process.
	15) Health-care professionals should acknowledge that the individual's decision to consent or refuse treatment can be augmented by facilitating and encouraging that his/her relations to, and responsibility for, others are considered in decision-making process, and should keep the individual in the center of decision-making.
	16) Health care providers and family and/or other closely related persons should maximize support for individuals with physical or partial cognitive impairment to have meaningful participation in ACP.
	17) ACP should promote mutual understanding between the individual and family and/or other closely related persons regarding their values, wishes and preferences on the end-of-life care.
Recommended roles and tasks	
	18) Health-care providers should develop rapport with individuals and family and/or other closely related persons* before initiating ACP conversations.

	19) Health-care providers should determine that the individual has mental capacity to engage in the ACP process.
13. Health-care professionals should adopt a person-centered approach when engaging in ACP conversations with individuals and, if the individual wishes, their family; this approach requires tailoring the ACP conversation to the individual's health literacy, style of communication, and personal values. **(SA 11; A 2; AS 1)**	**20) Health-care providers should adopt a person-centered approach involving the family and/or other closely related persons* to the extent desired by the individual when engaging in ACP conversations with individuals and, if the individual wishes, their family and/or other closely related persons*; this approach requires tailoring the ACP conversation to the individual's health literacy, style of communication, and personal values and preferences.**
	21) Health-care providers should facilitate consensus building between the individual(s) and family and/or other closely related persons*, so that the individual's preferences are respected.
	22) Health-care providers should be attuned to emotions of individuals and family and/or other closely related persons* in the process of ACP.
14. Health-care professionals need to have the necessary skills and show an openness to talk about diagnosis, prognosis, death and dying with individuals and their families. **(SA 12; A 2)**	**23) Health-care providers need to have the necessary communication skills and show an openness to talk about diagnosis, prognosis, death and dying with individuals and their families and/or other closely related persons.**
15. Health-care professionals should provide individuals and their families with clear and coherent information concerning ACP.	**24) Health-care providers should provide individuals and their families and/or other closely related persons* with**

(SA 11; A 3)	**clear and coherent information concerning ACP.**
16. A trained non-physician facilitator can support an individual in the ACP process. **(SA 4; A 9; AS 1)**	**25) Multidisciplinary health-care team is encouraged to provide support in the ACP process, and can include health-care providers such as physicians, nurses, medical social workers, clinical psychologists, and/or trained non-clinician facilitators including lay health worker.**
17. The initiation of ACP (that is, the exploration of the individual's experiences, knowledge, personal values, and concerns) can occur within or outside of health-care settings. **(SA 5; A 5; AS 4)**	**26) The initiation of ACP can occur within or outside of health-care settings.**
18. Appropriate health-care providers are needed for clinical elements of ACP, such as discussing diagnosis, prognosis, treatment and care options, exploring the extent to which goals and preferences for future medical treatment and care are realistic and documenting the discussion in the medical file of the patient. **(SA 6; A 7; AS 1)**	**27) Appropriate health-care professionals are needed for clinical elements of ACP, such as discussing diagnosis, prognosis, treatment and care options, exploring the extent to which goals and preferences for future medical treatment and care are realistic and documenting the discussion in the medical file of the patient.**
	28) In supporting practice of ACP, there should be continual education of health-care providers about bioethical issues related to ACP.
	29) Health-care providers should provide appropriate information and support as needed by the individual based on interprofessional assessment. ~~need assessment of social and financial needs.~~

	(Add interprofessional nature in Discussion)
	30) Health-care providers should share contents of discussions upon the transition of care across settings.
	31) Palliative care team may help facilitate ACP process when other health-care providers need additional support.
	32) Health-care providers should apply a patient-focus and family-centric approach, and promote shared decision making between the health-care providers and individuals as well as family and/or other closely related persons. [Potential new item, here or in the Relational Autonomy domain]
	33) Health-care providers should ensure that both the individual and families and/or other closely related persons are involved to make informed decisions about care for the best interest of the individual.
	34) Health-care providers should respect the faith, belief system and culture of each individual and families and/or other closely related persons throughout the process of ACP.
Recommended timing of ACP	
19. Individuals can engage in ACP in any stage of their life, but its content can be more targeted as their health condition worsens or as they age. **(SA 9; A 3; AS 1; D 1)**	**35) Individuals can engage in ACP in any stage of their life, but its content can be more targeted as their physical or cognitive health worsens or as they age.**

20. As values and preferences might change over time, ACP conversations and documents should be updated regularly, such as if the individual's health condition worsens, their personal situation changes, or as they age. **(SA 10; A 3; AS 1)**	**36) As values and preferences might change over time, ACP conversations and documents should be updated regularly, such as if the individual's health condition worsens, their personal situation changes, their treatment plan changes, or as they age.**
21. Public awareness of ACP should be raised, including the aims and content of ACP, its legal status, and how to access it. **(SA 11; A 2; AS 1)**	**37) Public awareness of ACP should be raised, including the aims and content of ACP, its legal status, and how to access it.**
Recommended elements of policy and regulation	
	38) The government or health authorities should provide policy and ethicolegal guidance on ACP.
	39) ACP forms (e.g., advance directives) should be standardized, and a system built to capture these forms and make them visible across the healthcare continuum.
	40) A system of selecting a personal representative may need to be developed.
22. Advance care directives need both a structured format to enable easy identification of specific goals and preferences in emergency situations, and an open-text format so individuals can describe their values, goals, and preferences. **(SA 3; A 9; AS 1; UD 1)**	**41) Advance care directives need both a structured format to enable easy identification of specific goals and preferences in emergency situations, and any format that is acceptable within guidelines and/or laws of the country so individuals can describe their values, goals, and preferences.**

23. Health-care organizations should develop potential triggers for the initiation of ACP including, but not limited to, age, degree of illness, and transitions in care. **(SA 6; A 3; AS 5)**	**42) Health-care organizations should be aware of the importance of ACP and should develop potential triggers for the initiation of ACP including, but not limited to, age, degree of illness, and transitions of care.**
	43) Health-care organizations should develop a collaborative system to support decision making and training opportunities for multidisciplinary health-care professionals.
24. Health-care organizations need to create reliable and secure systems to store copies of advance care directives in the medical file so that these are easy to retrieve, transfer, and update. **(SA 12; A 2)**	**44) Governments and/or health-care organizations need to create reliable and secure systems to store copies of official or medical ACP related documents so that these are easy to retrieve, transfer, and update.**
25. Governments, health insurers and health-care organizations should secure appropriate funding and organizational support for ACP. **(SA 9; A 4; AS 1)**	**45) Governments should take initiatives to support and/or fund ACP.** **46) Health-care organizations should secure appropriate funding and organizational support for ACP including time, education, and training for health care professionals.**
26. Laws should recognize the results of an ACP process (such as surrogate decision making and advance care directives) as legally binding guidance of medical decision making. **(SA 7; A 4; AS 2; UD 1)**	**47) Governments and/or policy makers should recognize the results of an ACP process (such as surrogate decision making and advance care directives) as legally binding guidance of medical decision making.**
	48) A system should be established to realize individuals' end of life preferences in a region of their residence.

	49) A multidisciplinary collaborative system should be developed regarding home care and management of acute illnesses.
	50) Health-care systems should have processes in place to ensure that individual's preferences in ACP are shared with all those concerned with the individual's care.
Recommended evaluation of ACP	
27. Depending on the study or project aims, we recommend the following constructs assessed:	**51) Depending on the study or project aims, we recommend the following constructs assessed:**
A. Knowledge of ACP (rated by individuals, family, and health-care professionals) **(SA 7; A 7)**	**A) Knowledge of ACP (rated by individuals, family and/or other closely related persons*, and health-care professionals)**
B. Self-efficacy to engage in ACP (rated by individuals, family, and health-care professionals) **(SA 6; A 8)**	**B) Self-efficacy to engage in ACP (rated by individuals, family and/or other closely related persons*, and health-care professionals)**
C. Readiness to engage in ACP (rated by individuals, family, and health-care professionals) **(SA 9; A 5)**	**C) Readiness to engage in ACP (rated by individuals, family and/or other closely related persons*, and health-care professionals)**
	D) Willingness to engage in ACP discussions (rated by the individual, family and/or other closely related persons*and health-care professionals)
	E) Anxiety about thinking about death (rated by individuals, family and/or other closely related persons*, and health-care professionals)

	F) Prognostic awareness (rated by individuals, family and/or other closely related persons*)
D. Identification of goals and preferences **(SA 9; A 5)**	**G) Identification of values, goals and preferences**
E. Communication about goals and preferences with family **(SA 8; A 6)**	**H) Communication about goals and preferences with family and/or other closely related persons***
F. Communication about goals and preferences with health-care professionals **(SA 10; A 4)**	**I) Communication about goals and preferences with health-care professionals**
G. Identification of a personal representative **(SA 6; A 4; SA 4)**	**J) Identification of a personal representative**
	K) Individual decides on amount of flexibility/leeway in decision making to give surrogate
	L) Congruence between individual's stated wishes and surrogate's reports of individual's wishes
H. Documentation of goals and preferences **(SA 6; A 6; AS 2)**	**M) Documentation of goals and preferences**
	N) Documents and recorded wishes accessible when needed
I. Revision of ACP discussions and documents over time **(SA 7; A 5; AS 2)**	**O) Revision of ACP discussions and documents over time**
J. Extent to which ACP was considered meaningful and helpful (rated by individuals, family, and health-care professionals) **(SA 7; A 8; AS 2)**	**P) Extent to which ACP was considered meaningful and helpful (rated by individuals, family and/or other closely related persons*, and health-care professionals)**
K. Quality of ACP conversations (rated by individuals, family, and facilitators or health-care professionals, or both) **(SA 5; A 6; AS 3)**	**Q) Quality of ACP conversations (rated by individuals, family and/or other closely related persons*, and facilitators or health-care professionals, or both)**

L. Satisfaction with the ACP process (rated by individuals, family, and health-care professionals) **(SA 4; A 7; AS 2; DS 1)**	**R) Satisfaction with the ACP process (rated by individuals, family and/or other closely related persons*, and health-care professionals)**
	S) Decisional conflict (e.g., within individuals, among individuals, families and/or other closely related persons*, and/or health-care professionals)
	T) Decision control preferences, i.e.; control over decision making (rated by individuals and family and/or other closely related persons*) (may also be a moderator variable)
	U) Clinicians provide prognostic information tailored to individual/family readiness
	V) Psychological distress (rated by individuals, family and/or other closely related persons*, and health-care professionals)
	W) Peace (rated by individuals and family and/or other closely related persons*)
	X) Quality of life (rated by individuals, family and/or other closely related persons*, and health-care professionals)
	Y) Understanding of end of life care (rated by individuals and family and/or other closely related persons*)
	Z) Quality of end of life care
	AA) Psychological well-being of the bereaved
M. Use of health care **(SA 6; A 5; AS 2; UD 1)**	

	AB) Use of life sustaining treatment
N. Whether care received was consistent with the individual's expressed goals and preferences **(SA 9; A 5)**	**AC) Whether care received was consistent with the individual's expressed goals and preferences**
	AD) Place of death
	AE) Public awareness of ACP
	AF) Use of palliative care
	AG) A good death
	AH) Mutual understanding between the individual and family and/or other closely related persons regarding their values, wishes and preferences on the end-of-life care.
28. We recommend identifying or developing outcome measures based on these constructs so that results can be pooled and compared across studies or projects; these outcome measures should have sound psychometric properties, be sufficiently brief, and validated within relevant populations. **(SA 6; A 7; DS 1)**	**52) We recommend identifying or developing outcome measures based on these constructs so that results can be pooled and compared across studies or projects; these outcome measures should have sound psychometric properties, be sufficiently brief, and validated within relevant populations.**
Footnote	***Footnote:** **'Other closely related persons' are those trusted by an individual, and may include, but are not limited to, significant others, close friends, donees of a lasting power of attorney and court appointed deputies, as per local legal jurisdiction"** **** In sectors where an advance directive and/or surrogate are not**

	legalized, an 'advance directive' indicates ACP-related document(s) to record values, goals and preferences to be considered when the individual is unable to express their preferences; and a 'surrogate' indicates personal representative(s) who would make decisions for the individual's best interest when the individual loses his or her capacity.

Ⅳ　今後の課題

今後は、Round 1 を完成させ、以下の Round 2-5 を順次進めていく予定である。

- Round 1：デルファイ項目の完成、各国語への翻訳（順翻訳・逆翻訳を行う）。シンガポールでの IRB 承認。その後、Round 2 の準備として、デルファイパネル専門家の招聘、Web 調査の作成
- Round 2：デルファイパネル専門家の対象に、Round 1 で作成された項目についてどの程度同意できるかに関するウェブ調査を行う（7 件法）。
- Round 3：Round 2 に回答したデルファイパネル専門家のみを対象として、Round 2 の結果を示し、Round 2 と同様の 7 件法で回答を求める。
- Round 4：非常に強い賛成かつ非常に強い合意が得られた項目は受理される。その他の項目は、適宜修正し、タスクフォースのメンバーに評価を求める。
- Round 5：タスクフォースの最終的な意見をもとに、定義と推奨を修正し、APHN の理事会で承認を得る。

Ⅴ　事業の成果等公表予定（学会、雑誌等）

国内の系統的レビューは論文化を検討中である。5 か国のデルファイの成果は、2021 年に発表予定である。