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Is capacity to consent to healthcare a uniformly defined concept? Insights from a document analysis of laws and national guidelines across six European countries

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ABSTRACT

Background: Capacity to consent or *decision-making capacity* to healthcare is a key prerequisite for a valid informed consent. A clear understanding of this concept is important to protect patients' autonomy. Without it, clinical assessments may vary, jeopardising patients' participation in decisions about their care and increasing the risk of delayed, denied or harmful treatment. Despite substantial international debate and reforms concerning norms on capacity assessment, there remains a paucity of scholarly literature comparing national approaches, which could enable countries to learn from one another. This study aimed to explore how the concept of capacity to consent to healthcare and the assessment is described in documents, guiding healthcare professionals, issued by health authorities in: Norway, England and Wales, Belgium, France, Sweden and Ireland.

Methods: Explorative qualitative document analysis of health laws, national guidelines and recommendations published by national health authorities in each country.

Results: There is no uniform description of the concept of capacity to consent to healthcare across all countries, although some commonalities exist, such as the functional approach and some countries are more conceptually aligned. The level of descriptive detail on the assessment varied, and in some countries the documents did not include such descriptions.

Discussion/conclusion: To protect patients' autonomy, it is important that healthcare professionals are provided with a comprehensive guidance document to support their understanding of the concept of capacity to consent to healthcare and how to assess this capacity. The findings indicate that several countries lack such provisions. This could threaten patient safety and wellbeing and make research and clinical practice development more challenging.

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1. Introduction

Informed consent is central in all healthcare practice and aims to safeguard against bodily violations and breaches of personal integrity (Beauchamp & Childress, 2019, pp. 118–123; Vansweevelt & Glover-Thomas, 2020, p. 269). It is a countermeasure against paternalism in healthcare and it is central to ethical research, protecting autonomous choice (Beauchamp & Childress, 2019, p. 118). The ability to safeguard one's own interests is an important condition for a valid informed consent. This ability is generally called *capacity to consent* or *decision-making capacity* and is also understood as a gatekeeper for the right to autonomy (Beauchamp & Childress, 2019, pp. 112–113; De Sabbata, 2020; Donnelly, 2010, pp. 90–91). However, capacity to consent (henceforth referred to as CC) is not a straightforward concept and has been the subject of discussion in the medical, ethical and judicial literature for decades (Donnelly, 2010, pp. 90–130). The determination of a patient's CC can have major consequences for the patient concerned, those close to them such as family, healthcare professionals and the wider society.

This problem is becoming increasingly relevant as the number of people aged 65 years or older is expected to double by 2050 (United Nations Department of Economic Social Affairs Population Division, 2020). Globally it is estimated that nearly 9.9 million people develop dementia each year (World Health Organization, 2017). For older people and individuals with cognitive impairment like dementia CC may fluctuate, further increasing the complexity of CC assessments (Donnelly, 2010, p. 120). Given the growing prevalence of dementia, a clear theoretical and practical account of CC is increasingly important. As cognitive decline progresses people with dementia commonly need to be supported to be able to exercise their autonomy (Alzheimer Europe, 2020; Arstein-Kerslake, 2016).

Autonomy is often defined as *self-determination*, referring to the capacity of a rational person to make decisions that are well informed and free from coercion (Manda-Taylor et al., 2016). In Western society, liberalism is highly influential, also affecting the concept of autonomy, with an emphasis on individual interests, rights, freedom and privacy. Autonomy is often considered the dominant value in medical ethics (Donnelly, 2010, pp. 14–15). However, it is often in conflict with the principle of beneficence in care for patients, which can be linked to paternalism (Manda-Taylor et al., 2016). The assessment of CC is highly relevant to this ethical dilemma, frequently addressed in healthcare. When an individual is not able to fulfil their autonomy, they still have the right to healthcare and to be protected from harm and neglect (Mackenzie, 2013). Thus, the concept of CC is an important safeguard.

There are different approaches to capacity assessments such as the status approach, the outcome approach and the functional approach (Law Reform Commission, 2006). The status approach assumes a person lacks capacity based on a diagnosis or condition and the outcome approach evaluates capacity based on the reasonableness of the decision made i.e. judged by the consequences of the decision. In contrast, the currently dominant functional-based approach focuses on the person's decision-making abilities in relation to a specific decision and on the process of decision making rather than the outcome (Law Reform Commission, 2006). Different jurisdictions define cognitive abilities necessary for CC differently, however, the four abilities outlined by Grisso and Appelbaum (1998) has been influential. This approach is based on assessing the ability to understand relevant information, to appreciate the information and its personal relevance, to reason with the information, and to communicate a choice.

Functional capacity assessments are centred around cognitive abilities, but critics would argue that the emphasis on rational decision-making does not reflect how people actually make decisions in real life (Hawkins, 2024; O'Connor, 2010). A more relational model for decision-making recognises the context and the relationships that could influence a person's capacity, both enabling and constraining the process of making decisions (O'Connor, 2010). It also emphasises supported decision making. The UN Committee on the Rights of Persons with Disabilities, reasoning on the basis of Article 12 of the UN Convention on the Rights of Persons with Disabilities (CRPD, 2006) challenges the idea of questioning a person's capacity to make valid decisions for themselves (including in relation to healthcare and medical treatment). It declares that all states parties should abolish laws allowing forced treatment and substitute/best interests decision-making, requiring them instead to provide support mechanisms that respect the person's will and preferences (Committee on the Rights of Persons with Disabilities, 2014). Although the CRPD is considered as an important convention that protects the rights of disabled persons such as people with dementia, it is also criticised on the basis that the radical interpretations of CRPD could be difficult to implement into practice (Dawson, 2015). However it could also provide new solutions and improvements in healthcare, especially for people with dementia (De Sabbata, 2020), such as the strong emphasis on replacing substituted decision making with supported decision-making.

Several studies show a wide variation in the proportion of individuals who have been assessed as having CC among those receiving treatment in somatic or psychiatric hospitals, also across jurisdictions (Curley et al., 2022; Lepping et al., 2015; Marcó-García et al., 2024). This may partly be due to the diversity in the instruments and criteria used to assess capacity (Marcó-García et al., 2024). Many instruments have been developed to assist healthcare professionals in their assessment of CC; however, several instruments have limited evidence of validation, may be time-consuming to use, or only applicable to specific groups (Amaral et al., 2022; Lamont et al., 2013a). Nevertheless, the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) is often described as the "gold standard" among these instruments and recommended as suitable to a variety of populations. However, such instruments should be used as a support and guide to healthcare professionals' clinical judgement, rather than as standalone assessment tools (Lamont et al., 2013a). CC is often seen mainly as a legal concept, however in healthcare it is primarily healthcare professionals who undertake the assessments and thus decides whether a person is to be considered to have capacity or not regarding treatment decisions (Donnelly, 2010, p. 131). The responsibility of performing these assessments is recognised among healthcare professionals (Murrell & McCalla, 2016), although they may not always be equipped to undertake these assessments (Donnelly, 2010, pp. 161–169; Lamont et al., 2013b). A Norwegian study, on the use of coercion in nursing homes, found that healthcare professionals had a lack of knowledge and felt unsure on the concept of CC and the assessments (Pedersen et al., 2013). Some studies have shown high rates of disagreement between healthcare professionals in their conclusions regarding CC (Kim et al., 2011), although this can be mitigated to some extent by greater education and training (Marson et al., 2000). Such variability could lead to false assumptions of incapacity which would threaten the patients right to autonomy, or it could lead to false assumptions of capacity which could lead to missed care or neglect and at worst, death.

In addition to education, training and tools, which may vary or be missing, healthcare professionals' understanding may be impacted by documents provided by the healthcare authorities to regulate and guide clinical practice. As long as the doctrine of informed consent is a part of the health legislation, and a valid consent presupposes CC, such documents should provide healthcare professionals with a comprehensive description of the concept of CC for healthcare, helping to ensure that healthcare professionals are well-equipped to perform assessments when needed. Without a shared understanding there is a high risk that the assessments of CC will vary among healthcare professionals. Implicit and vague use of the concept of CC, may lead to violations of fundamental human rights, as well as hidden and arbitrary variations in practice. Norms on capacity assessments has been at the centre of international debate and reforms. Despite this, there is a lack of scientific literature comparing differences and similarities between national approaches. Such studies would enrich the debate by highlighting the

lessons one country could learn from another. If divergent descriptions of CC across countries are not acknowledged, arbitrary variations may arise, which could make international collaboration and research more challenging. To our knowledge, there is little or no research that has studied the concept of CC in such documents.

The aim of this study is to explore how the concept of CC to healthcare and its assessment is described in central documents issued by the health authorities in six European countries (Norway, England and Wales, Belgium, France, Sweden and Ireland), highlighting both similarities and differences, including the level of descriptive detail and to explore whether a uniform description of the concept and its assessment exist in these documents across countries.

2. Design and methods

The research questions were as follows: 1: how is the concept of CC to healthcare described in relevant health care policy, e.g., health laws, national guidelines and recommendations published by the central health authorities in Norway, England and Wales, Belgium, France, Sweden and Ireland? 2: how is the assessment of this capacity described in these documents?

A document analysis was conducted following the four steps of the *READ approach* by Dalglish et al. (2020), enabling a systematic procedure for collecting and gaining information from health policy documents, comprising of; ready the material, extracting the data, analysing the data and distil the findings (Dalglish et al., 2020). The analysis was inspired by the *Practice-oriented document analysis* method by Asdal and Reinertsen (2022) and the methodological move of studying *document issues,* exploring how words and texts shapes how issues is portrayed in and between documents (Asdal & Reinertsen, 2022, pp. 102–123). Thus, comparing and contrasting texts as well as examining how the concept was modified across different texts, was important. The selection of countries to this study was led by the aim to include a variety of western countries to broaden the understanding of the concept of CC. The countries were purposively selected to ensure variation in national context and legal system, allowing for comparative insights into how CC is described across jurisdictions.

2.1. Data collection

A group of researchers and experts in the field of dementia studies, law and ethics were established prior to the start of the project. This group was established to ensure sufficient variation (see above), building on previous research collaboration and connections made at international conferences, and inviting complementary expert knowledge where needed. In October 2024, the group met to discuss the research questions, inclusion criteria and search strategy. The aim of the search was to retrieve documents issued by national health authorities, or by organisations authorised to advise healthcare professionals, which guide the understanding and the assessment of CC to healthcare, including legislation that describes CC to healthcare and informed consent. To narrow the scope of our study, we did not perform a comprehensive comparative analysis of the legal frameworks in the countries, consequently, we excluded sources such as parliamentary preparatory documents, case law and legal doctrine. Furthermore, we did not examine statutory principles or legal definitions of mental capacity as they apply to decision making outside the healthcare context. Rather, this study explores the pertinent documents that is guiding healthcare professionals in their practice.

A spreadsheet with a search instruction based on the aims the study, inspired by Dalglish et al. (2020), was developed as a guide for the document search in each country (See Appendix A). The authors, CS, JS, IR, HB, GN, MD, SOK, IHF, conducted the document search in their respective countries. All the relevant documents were sent to the first author IHF and stored systematically. Then IHF and BL selected the documents to include in the final analysis. During the analysis process, a change to the Norwegian Patient and User Rights Act (§ 4-3) addressing CC was enacted by the Norwegian Parliament. This law will not come into effect until 01.06.2026 but was included in the analysis. Additionally, key summary points and chapter 6 from a research report from Belgian Health Care Knowledge Centre (KCE) was included as it was addressed to practitioners with the aim to guide them in their understanding of the concept of CC to healthcare and the assessment. The data collection period lasted from October 2024 till February 2025. 31 documents were selected (see Table 1 and Table 2) comprising of 2181pages. Since legislation can change and wording may be modified, only the current version of each document was included in the analysis.

2.2. Data analysis

In the second step we extracted the relevant data. First, all documents were read by IHF and BL to get an overall impression. We examined the documents scope, completeness, internal contradictions, represented perspectives and document authority. All the documents were analysed in their original language. The documents were imported to NVivo 14 software (Lumivero, 2023) for further analysis and relevant parts of the document describing CC and the assessment was extracted, including sections describing informed consent. Although the analysis focused on these extracted parts, the entirety of the document was studied when needed for clarification. Document analysis is a form of fieldwork and an iterative process which begins as early as the initial search for documents (Asdal & Reinertsen, 2022, pp. 198–200; Dalglish et al., 2020). To ensure that no important insights or reflections were overlooked, a record of thoughts, ideas, and plans for further work was written down in a memo throughout the entire process, used to inform the subsequent analysis.

The third step involved a closer analysis of the data inspired by the methodological move of studying document issues (Asdal & Reinertsen, 2022, pp. 102–123). We applied a combined inductive and deductive approach led by the two research questions. This involved an active reflection on the text, looking for how *the issue*, CC and the assessment, was described both explicitly and more implicitly, and how this description could be part of clarifying an understanding of the concept (Asdal & Reinertsen, 2022, pp. 104–108). It was guided by questions such as: What is the description of CC? Are there similarities and differences in how CC is described within or across documents? How are various aspects emphasized? We looked for words used to describe CC and compared these across documents. In a similar way we scrutinized descriptions of the assessment of CC, such as how the assessment should be performed, who should perform the assessment and in which situations. The absence or paucity of texts also provided important information on the subject of investigation and was noted (Asdal & Reinertsen, 2022, pp. 107–108; Bowen, 2009).

The fourth step involved a writing and revising of results to clarify analysis findings and compile them. In this step the group met again to discuss the results, revised the draft of the article, before it was finalised.

2.3. Ethical considerations

All the documents included in this study are official, publicly available documents, thus ethical approvals were not required to conduct this study

3. Results

The results of the document analysis are presented according to the two research questions of the study divided into; 3.1: the concept of CC to healthcare, 3.2: the assessment.

Table 1
Laws.

Country	Law		Date of entry into force
Norway	Patient and User Rights Act *(Lov om pasient- og brukerrettigheter (pasient- og brukerrettighetsloven)*).	Chapter 4: Consent to Healthcare	01.01.2001
Norway	Act relating to the provision and implementation of mental health care, with later amendments (Mental Health Care Act) (*Lov om etablering og gjennomføring av psykisk helsevern (psykisk helsevernloven))*	Chapter 2: Special Provisions Regarding Consent	01.01.2001
Sweden	Patient Act (*Patientlag (2014:821)*)	Chapter 4: Consent	01.01.2015
France	Law No., 2002-303 of March 4, 2002, on Patients' Rights and the Quality of the Healthcare System. (LOI n° 2002-303 du 4 mars 2002 relative aux droits des malades et à la qualité du système de santé LAW No. 2002)	Chapter I: Information for Users of the Health System and Expression of Their Will (Articles L1111-1 to L1111-31)	05.03.2002
France	Act No. 94-653 of 29 July 1994 on Respect for the Human Body *(Loi n°94-653 du 29 juillet 1994 relative au respect du corps humain.)*.	Chapter II: Respect for the Human Body (Articles 16 to 16-9)	29.07.1994
Belgium	Law on Patients' Rights *(Loi relative aux droits du patient)*	Chapter III: Patient Rights	22.08.2002
Belgium	Act on Palliative Care *(Loi relative aux soins palliatifs)*	Articles 2 and 7	14.06.2002
England &Wales	Mental Capacity Act 2005	Part 1: Persons who lack capacity, section 1- 4	07.04.2005
Ireland	Assisted Decision-Making (Capacity) Act 2015 as amended by Assisted Decision-Making (Capacity) (Amendment) Act 2022	Part 1: Section 3 and Part 2: Section 8	26.04.2023

3.1. The concept of CC as a recognized concept though not explicitly described across all countries

All countries included in this study have a legal requirement that healthcare must be provided with the informed consent of the adult patient as the main rule. However, whether CC is described as a criterion for a valid consent, or not, differed. Although health laws in Belgium, France and Sweden (see Table 1) provide descriptions of the informed consent, they lack any detailed description or direct reference to the concept of CC to healthcare, what it entails and how it should be assessed. Both Belgian and French health laws refer to an inability or capability to express a will, but with no specification of what it means. According to the French *LAW No*., 2002-*303 of March 4, 2002, on Patients' Rights and Quality in the Health System, art. L. 1111-4*:

> No medical act or treatment can be performed without the free and informed consent of the person, and this consent can be withdrawn at any time. When the person is unable to express their will, no intervention or investigation can be carried out, except in emergencies or if impossible, without consulting the trusted person designated in Article L. 1111-6, or the family, or of this is not possible, one of their close relatives.

The concept of CC to healthcare is described in the Norwegian, English and Welsh, and Irish health laws (see Table 1). Ireland and England and Wales have specific legislation on mental capacity that explicitly describes CC, while in Norway descriptions of CC is incorporated within the Patient and Users Rights Act.

Although the Swedish, Belgian and French health laws do not explicitly describe the concept of CC to healthcare or indicate what the patient must be capable of, the issue is addressed in guidance documents issued by the health authorities (see Table 2). However, several of these documents provide only a limited description of the concept. In a Swedish handbook, *Your obligation to Inform and make the Patient Involved,* which outlines the legislation, regulations, and advice regarding patients' rights to self-determination the issue of CC to healthcare is described in one paragraph under the headline "Decision-making capacity":

> To evaluate different treatment options and provide valid consent to care, the patient must have the ability to understand the information provided and foresee the consequences of their decision. This ability is often referred to as decision-making competence. Healthcare must provide good and safe care to all patients (Section 2a, HSL). Good care includes respecting the patient's wishes. This can be relatively unproblematic when the patient clearly shows that the information has been understood and can express their will. However, many times, especially when a patient is in a crisis situation, the ability to absorb and process information can be affected and their will may fluctuate. It can then be difficult to assess the patient's decision-making competence. (National Board of Health and Welfare, 2015, p. 14).

However, even though it is recognised as difficult to assess, there is little description of the concept of CC or of assessment methods. In contrast, we did find several guidance documents describing CC in Norway, England and Wales, and Ireland (see table 2), and all countries had guidelines with a complete description of the concept and the assessment.

Overall, across countries, documents differ in type, the extent to which they address various aspects of the concept of CC and the assessment, and their style. For example, in Norway, the guideline *The Patient and User Rights Act with Comments* are more bound by legal terms, with less elaboration or explanation of the concept while other guidelines such as *The Mental Capacity Act 2005 Code of Practice* in England and Wales have dedicated more space to explain the concept and the assessment. Thus, our results also reflect this difference. The most detailed descriptions of CC are presented together below, including descriptions of some differences between countries.

3.1.1. Capacity to consent: A dynamic concept safeguarding autonomy

Overall, the documents exhibit several similarities in how the concept of CC to healthcare is described, alongside notable differences. The presumption of capacity applies to every adult, meaning that an individual must be assumed to have capacity unless it is proven otherwise, based on the balance of probabilities in England and Wales, and in Norway. Consequently, it must be more likely than not, that a person lacks CC. Sweden, Belgium, France and Ireland have no descriptions of the applicable standard of proof. The person questioning capacity has the responsibility to provide sufficient evidence of a lack of capacity according to the Irish documents. Thus, the person's autonomy can be overridden if evidence demonstrates that the person lacks capacity to exercise it.

CC is described as the ability to make a decision. The capacity is decision or case specific, which implies that CC at the same time could be intact for some decisions and not for others. It may also vary in time for the same decision. CC is described as consisting of several abilities which people apply in making a decision. These abilities may vary depending on circumstances and fluctuate over time. In England and Wales, the lack of capacity must be caused by an impairment of the mind or brain. In contrast, while acknowledging that an illness or impairment may influence a person's capacity, determination of a lack of capacity does not require a causative nexus in Ireland and the recent amendment

Table 2
Documents describing CC and the assessment.

Country	Document title	Author	Year	The purpose of the document. Short description
Norway	The Patient and User Rights Act with Comments.	Norwegian Directorate of Health	2015	Circular. Provides interpretations the Act, how it should be understood and applied into practice. Each paragraph of the law is accompanied by comments.
Norway	The Mental Health Care Act with Comments.	Norwegian Directorate of Health	2017	Circular. Provides interpretations the Act, how it should be understood and applied into practice. Each paragraph of the law is accompanied by comments.
Norway	Legal protection when using coercion and force against certain people with mental disabilities. Act of 24 June 2011 No. 30 relating to municipal Health and care services, Chapter 9	Norwegian Directorate of Health	2015	Circular. Provides interpretations the Act, how it should be understood and applied into practice.
Norway	Template for Decisions on Somatic Health Care (under Chapter 4A of the Patient and User Rights Act).	Norwegian Directorate of Health	2019	A decision template. The form complies with legal requirement. Also, with a short guidance to each of the requirements.
England & Wales	Mental Capacity Act 2005. Code of Practice.	Department for constitutional Affairs	2007	Practical guidance to support the Act. Statutory force. Offers examples of best practice.
England & Wales	The Mental Capacity Act 2005. Guidance for providers.	Care Quality Commission	2011	Summarises the Code of practice. Help providers understand their responsibilities under the Act and check if they are meeting them.
England & Wales	Decision-making and mental capacity. NICE guideline.	National Institute for Health and Care Excellence	2018	Recommendations from NICE, based on available evidence.
England & Wales	Decision making and mental capacity. Quality standard.	National Institute for Health and Care Excellence	2020	Description of prioritized areas for improvement. Quality of care
Ireland	Code of Practice for Supporting Decision-Making and Assessing Capacity.	Decision support service	2023	Statutory Code. Provide guidance. The Code applies to anyone performing a function under the Act.
Ireland	Code of Practice for Healthcare Professionals.	Decision support service	2023	Statutory code. Guidance to healthcare professionals performing functions under the Act.
Ireland	HSE National Consent Policy v1.2.	The Health Service Executive	2024	Professional Guidance for employees of the HSE. Healthcare workers must comply with the guidance provided in the policy.
Ireland	Guide to Professional Conduct & Ethics for Registered Medical Practitioners	Medical Council of Ireland	2024	Professional guidance. Guide differentiates between absolute duty and best practice description.
Ireland	Capacity statement template.	The Health Service Executive	2023	Guidance for professionals preparing functional capacity assessments in connection with court applications
Sweden	Your obligation to Inform and Make the Patient Involved.	National Board of Health and Welfare	2015	A handbook with a comprehensive overview of the legislation and regulation on patients' rights. Ensure more consistent application nationwide.
Sweden	National Guidelines for Care and Support in Dementia – Support for Governance and Management.	National Board of Health and Welfare	2017	Guidelines, provide recommendations for care and treatment for people with dementia.
Sweden	Information Sheet: Coercive and Protective Measures in Care and Support for Adults.	National Board of Health and Welfare	2013	A circular, outlines the regulations to consider when addressing coercive and protective measures for adults.
Belgium	The adult patient lacking decision-making capacity.	Belgian Order of Physicians	2025	Fact sheet with answers to frequently asked questions. Covers answers about rules and procedures regarding the treatment of individuals with a lack of capacity and the physician's role.
Belgium	2018 Medical Code of Ethics, Article 17 and 18 with comments.	Belgian Order of Physicians	2018	To provide physicians with a framework for professional conduct and ethical practice.
Belgium	Assessment and support of decisional capacity in persons with dementia or mental health problems.	Belgian Health Care Knowledge Centre (KCE)	2022	KCE report. A research report covering the issue of capacity to consent. Literature review, interviews and a review of the legislation, with a summary of key points to each topic discussed.
France	Chapter VII: Professional Ethics (Articles R.4127-36 to R.4127-37).	French Parliament	1995	Defines the core ethical duties of physicians in France, including respect for patients, professional responsibility, and independent clinical judgment.
France	Clinical practice guidelines: Emergency involuntary commitment of a mentally disordered person.	French National Authority for Health (HAS)	2005	A guideline. Outline the procedure for determining whether emergency involuntary hospitalization of a person with mental disorders is warranted.
France	Informed Consent and Information for Persons Undergoing Care or Participating in Research: Advice 58.	National Consultative Ethics Committee (CCNE)	1998	Opinion 58 of the French National Consultative Ethics Committee addresses the issue of information and consent in care and research. Addresses the current legal situation and recommendations.

to the Norwegian Patients' and Users' Rights Act abolished this causative nexus. There are no descriptions of a causative nexus in the documents from Belgium, France and Sweden.

CC is described as a dynamic concept that can fluctuate, often influenced by external and internal factors. These factors can be an illness, medication or drugs, pain, mental health problems, stress or a strong feeling of anxiety. Many of those factors can however be altered, which means that the CC could improve. The risk of individuals being deemed as lacking capacity due to inadequate support, influencing factors, misconceptions, stereotypes, or judgement based solely on their condition is recognised as a significant concern.

3.1.2. Improving capacity with support

The emphasis on providing support to the person and its potential influence on CC varied across the documents. As an example, the support principle is one of the statutory principles of the Irish and English and Welsh laws. Here, support must be provided before an assessment of capacity is performed and applying support to maximise capacity is described as a duty of healthcare professionals. Furthermore, a lack of capacity cannot be established until the support principle is sufficiently applied. The Irish *Code of Practice for Healthcare Professionals* states that: "Where capacity is in question, you should take steps to maximise a relevant person's capacity to help uphold their decision-making rights, safeguard their autonomy and give effect to their will and preferences" (Decision Support Service, 2023a, p. 6). Capacity is thus described as something that could be dependent on the support available to the person. Hence, support is important in fulfilling the individual's right to make their own decisions and if possible, avoid substituted decision making. The Irish guideline *Code of Practice for Supporting Decision-Making and Assessing Capacity* also acknowledges that you could build capacity to make a decision, as "Some people may need to be supported to learn to make a decision for themselves, for example where they have never done it before" (Decision Support Service, 2023b, p.18). Furthermore, will and preferences is described as an essential part of supported decision-making, as "You should respect and give effect to a relevant person's known will and preferences in all interactions with them" (Decision Support Service, 2023b, p. 11). The support principle is recognised by the Norwegian law *Patient and User Rights Act* as important to exercise autonomy, however, is given less emphasis in the accompanying guideline *The Patient and User rights Act with Comments* when describing the concept of CC. As an example, the support principle is only described thorough a few variations of the phrase "…the patient's ability to give consent must be optimised" (Norwegian Directorate of Health, 2015, p. 89). Although the importance of tailored information and patient involvement are described in more detail in other parts of the document, it is not explicitly related to supporting the individual's capacity and there are scarce descriptions of capacity as something that could be improved with support, especially compared to the English and Welsh, and Irish documents. Similarly, supporting patients is in general emphasised and described as important to ensure autonomy in the French and Swedish guidance documents; however, descriptions of measures to support and improve CC are scarce. The Belgian KCE report elaborates on this issue giving examples of ways to improve CC, however, referring to English guidelines and literature.

3.2. The assessment of CC to healthcare: A lack of common understanding and standards

We identified several differences between countries in their description of how CC should be assessed and, in the instructions, given to healthcare professionals for facilitating an assessment. The assessment of CC to healthcare is described in the English and Welsh, and Irish legislation (see Table 1) and the assessment is also given a considerable amount of space in the guidelines. There are no specific descriptions of the assessment of CC to healthcare in the Belgian, French and Swedish health laws. However, we did find guidance documents describing the assessment in these countries (see Table 2), although, the issue was just briefly mentioned in the Swedish and French documents. Neither the Norwegian health law describes how the assessment should be undertaken, though it is described in more detail in guidelines.

3.2.1. The assessment mainly based on the functional approach

The guidance documents from Norway, England and Wales, Belgium, France and Ireland describe the functional approach to an assessment of capacity. The emphasis of the assessment is on the process of how a person makes a decision and the steps involved in their decision-making. This involves an assessment of four abilities described either as understanding, retaining, using or weighing information about the decision, and communicating a decision: or as understanding, appreciation, reasoning, and expressing a choice. Some differences were evident in the description of these abilities and in the amount of guidance given to understand the requirements for these abilities. In some of the guidance documents, such as the French *Clinical practice guidelines: Emergency involuntary commitment of a mentally disordered person,* there is no elaboration on how the abilities should be assessed. These abilities are also discussed in the KCE report *Assessment and support of decisional capacity in persons with dementia or mental health problems,* from Belgium, however stating that: "In contrast to some other countries, the Belgian patients' rights law does not indicate what a patient must be capable of or on the basis of which criteria decisional capacity must be assessed. Also in the parliamentary preparatory works little attention is paid to it" (Vinck et al., 2022, p. 135). We did not find any descriptions of the approach to the assessment or which abilities that should be assessed in the Swedish documents.

3.2.2. Who should assess CC and when

Healthcare professionals responsible for the provision of care or treatment are generally described as responsible for the assessments. However, in England and Wales, and Ireland it is acknowledged that the assessor could also be the person "…who is directly concerned with the individual at the time the decision needs to be made" (Department for Constitutional Affairs, 2007, p. 53). This person should have a clear understanding of the decision to be made and the context of this decision.

There was a difference in the descriptions of when to conduct an assessment. In the Belgian KCE report the issue of when to conduct an assessment is discussed referring to the law which do not specify in which situations a formal assessment should be carried out, and the fact that a formal assessment could be distressing. However, recommending that:

> Decisional capacity must be assessed for each medical intervention (even if this is often implicit in practice). An explicit/formal assessment of decisional capacity is only necessary if there is sufficient reason to formally examine decisional capacity and if the advantages of such an examination outweigh the disadvantages. It is part of the professional autonomy of the healthcare provider to decide when such an assessment is required.(Vinck et al., 2022, p. 148)

According to the Norwegian guideline *The Patient and User Rights Act with Comment* "Capacity to consent must be assessed specifically for the healthcare that is to be provided… (Norwegian Directorate of Health, 2015, p. 89). However, with no more specification on when or if CC to healthcare should be assessed. According to the Swedish guideline *Your obligation to Inform and Make the Patient Involved*, CC assessment may also be required "…before one, at the patient's initiative, refrains from initiating a certain treatment" (National Board of Health and Welfare, 2015, p. 44). According to the English and Welsh guideline *The Mental Capacity Act 2005. Code of Practice* capacity assessment is to be carried out if a person's capacity is in doubt. Furthermore, it states that "There are a number of reasons why people may question a person's capacity to make a specific decision" (Department for Constitutional Affairs, 2007, p. 52). Reasons for this could be; behaviour or circumstances that cause

doubt, concerns from others, or a previous condition/diagnosis affecting capacity and"…it has already been shown they lack capacity to make other decisions in their life" (Department for Constitutional Affairs, 2007, p. 53). In contrast, capacity assessments are clearly described as a "last resort" in the Irish *Code of Practice for Healthcare Professionals,* stating that " You must have a valid reason before assessing a relevant person's capacity" (Decision Support Service, 2023a, p. 9). When determining the need for a capacity assessment, the urgency of the situation should be considered, potential risks or harm, and whether supportive measures have failed. Moreover, in both England and Wales, and Ireland the person should also consider if the decision and the assessment could be postponed to a more favourable time. Postponing the decision if possible is also addressed in the Belgian KCE report. There are no descriptions of postponing the assessment in the documents from Norway, France and Sweden. Although the Norwegian guideline, *The Mental Health Care Act with Comments,* recognises that fluctuations in CC may necessitate ongoing assessments.

Furthermore, consent to an assessment is addressed in some of the countries. The Irish guideline *HSE National Consent Policy v1.2* states that:" The healthcare worker assessing capacity must seek the consent of the person to undertake the capacity assessment" (The Health Service Executive, 2024, p.32). However, they should try to facilitate an assessment even though a patient may refuse, but ultimately must respect a refusal and, if necessary, apply to court for a declaration that the person lacks capacity based on the evidence before the court, notwithstanding the absence of an assessment. Situations where the patient may refuse to undergo an assessment are also described in several of the English and Welsh documents. In contrast, the question of consent to an assessment and situations where the patient may refuse to be assessed is not specifically addressed in the documents from Norway, France or Sweden. There are no descriptions of informing the patient about the assessment or the right to refuse an assessment. However, these state that the patient and their next of kin must be informed immediately if the assessment concludes with a lack of capacity. Consent to an assessment is addressed in the Belgian KCE report, however referring to the English and Welsh context.

3.2.3. Information, dialogue and reflexivity in the assessment process

There was a difference between documents regarding how much emphasis was placed on facilitation an assessment and the responsibilities of the assessor. The person responsible for assessing an individual's CC seems to be held more accountable for the process in some of the documents. This means being well-prepared and taking responsibility to ensure that external factors which could influence the capacity assessment are minimised. As an example, the Irish *Code of Practice for Supporting Decision-Making and Assessing Capacity* has allocated an entire chapter to detailed descriptions on preparations for the assessment. This includes descriptions of the responsibilities of the assessor to facilitate an assessment that considers and eliminates factors that may influence the assessment, and preparing the person being assessed.

In contrast the Norwegian guideline *The Patient and User Rights Act with Comments* focuses on the assessment of the patients' abilities and provides examples of questions. However, there is little description of the assessor's reflexivity, which includes how their understanding of the assessment process, the issue at stake, their relationship with the patient and their preconceptions, might influence the assessment outcome. Moreover, some documents emphasised information disclosure as a patient right, while others also highlighted the importance of dialogue and how the quality of that dialogue could influence the patient's CC. The importance of dialogue is illustrated by this excerpt from the Irish *HSE National Consent Policy v1.2:*

> The manner in which the healthcare worker discusses the intervention with the person is as important as the information itself. The relationship between the healthcare worker and the person should be a partnership based on: Openness; Trust; Clear communication. Obtaining consent often involves and requires ongoing communication with the person rather than a 'once-off' discussion. It is essential that communication occurs at a time and place and in a manner that will maximise the person's ability to: Understand the information required for a valid consent; Communicate their choice. (The Health Service Executive, 2024, p. 23)

3.2.4. The issue of unwise decisions and risks

The issue of unwise decisions and risks is emphasised in the English and Welsh, and Irish documents when describing the assessment of CC. In both, the legislation states that a person is not to be considered to lack capacity merely because they make what others may consider an unwise decision. This issue is highlighted by descriptions of how decisions may seem unwise to some but not to others. Such perceived unwise decisions are not justified as a reason for deciding that an individual is lacking CC, although it could be a reason to assess their capacity, especially as stated in the Irish *Code of Practice for Supporting Decision-Making and Assessing Capacity* if "…the person makes a unwise decision that is not aligned with their known will and preference" (Decision Support Service, 2023b, p. 18). However, an unwise decision is neither something that justifies or automatically requires an assessment. Risk is described as a possible reason to conduct an assessment, especially if the person makes a decision that puts him/her or others at risk however; "Before proceeding with further investigations, you should balance the perceived risks associated with the decision against respecting the relevant person's right to make it" (Decision Support Service, 2023b, p. 18). Moreover, the individual considerations concerning what constitutes as a risk are also addressed. The complexity of the situation is relevant according to the Irish C*ode of Practice for Supporting Decision-Making and Assessing Capacity,* as "Different decisions require different levels of capacity, depending on the complexity of the decision to be made and the urgency of the decision" (Decision Support Service, 2023b, p. 16). It could also require more support. According to the English and Welsh *Mental Capacity Act 2005 Code of Practice*, "More complex decisions are likely to need more formal assessments" (Department for Constitutional Affairs, 2007, p. 54). Decisions with serious consequences are described as a reason to conduct an assessment in the Belgian KCE report. The Norwegian guideline *The Mental Health Care Act with Comments* states that "…the requirement for the ability to understand is strengthened where the consequences of accepting (consenting to) the healthcare, or of refusing it, are considered to be significant. This means that the patient must consider additional information as well as making difficult assessments and trade-offs, which will place greater demands on the ability to understand" (Norwegian Directorate of Health, 2017, p. 20). In the French and Swedish documents this issue of unwise decisions and associated risks in a CC assessment is not specifically elaborated upon, although risk disclosure is important. However, situations where the healthcare professionals do not agree with the patient are recognised and, in such cases, their decision must be respected.

4. Discussion

This study has shown that there is no unified description of the concept of CC to healthcare and its assessment in documents guiding healthcare professionals across all countries. However, all countries share some commonalities, such as the functional approach. Some countries such as England and Wales, and Ireland have quite unified and detailed descriptions of the concept and its assessment, however also with notable differences such as the causal link and the conceptualisation of support. Some countries, such as Norway and England and Wales share some concept commonalities, while the level of descriptive detail differ. While there is a common ground in the requirement for a valid informed consent, some of the countries lack a clear description of CC to healthcare in these documents. Furthermore, our findings indicate a lack

of a common standard for assessing CC and in some countries the responsibility of setting standards for this assessment seems to be left to healthcare professionals. Here we will discuss these central findings with an emphasis on some of the differences found in these documents and their clinical implications.

4.1. CC and the assessment in light of relational vs. classical liberal conceptions of autonomy

We found that CC is described as a dynamic concept that can fluctuate with internal and external factors, but the emphasis placed on providing support to the patient differed. Some documents emphasised information disclosure, while others focused on how information exchange and how the quality of a dialogue could influence capacity. We further identified differences in how responsibility for the assessment was portrayed. To understand these differences a reflection on the differences between the liberal and relational accounts of autonomy and thus also CC could give some insights (Donnelly, 2010, pp. 49–130). The classical liberal account of autonomy has its primary focus on the individual as a rights holder free from interference, and describes autonomy as an inherent attribute of the individual (Beauchamp & Childress, 2019, pp. 400–404; Donnelly, 2010, pp. 19–22). The relational account of autonomy understands autonomy as socially embedded and dependent on the context, power dynamics and views autonomy more as an achievement focusing on the process (Donnelly, 2010, pp. 41–47; Mackenzie, 2013; O'Connor, 2010). It recognises that CC is decision-specific and fluid, and because it depends on changing contextual factors, it places greater responsibility on healthcare professionals to support understanding and participation (Donnelly, 2010, pp. 110–114; O'Connor, 2010). Thus, the assessor is an active participant, not a neutral observer, that must foster meaningful participation, protect the person's well-being, and take practical steps to maximise their capacity (O'Connor, 2010). The liberal approach can result in either under- or over-estimation of the patient's CC, whereas the relational approach carries the risk of over-estimation of CC or undue influence of the patient's choice.

In contrast to a cognitive model, the relational approach to assessing CC adopts a strengths-based perspective that seeks to preserve and build on remaining abilities rather than assuming loss (O'Connor, 2010). Thus it seeks to move away from a mere testing of capabilities and rather investigate how a person is capable and how this could be supported (Donnelly, 2010, p. 113). The emphasis on providing information would align with the liberal account of autonomy, focusing on ensuring enough information that would enable an autonomous choice and non-interference (negative liberties) (Beauchamp & Childress, 2019, p. 404). Protecting those who cannot protect themselves (Donnelly, 2010, p. 91). Merely giving information alone does not ensure understanding and thus risks an incorrect CC assessment (Beauchamp & Childress, 2019, pp. 130–135; O'Connor, 2010). The patient may be overwhelmed or confused by the information given (Beauchamp & Childress, 2019, p. 133; O'Keeffe, 2008). With an emphasis on dialogue and support, the healthcare professional is not just an information provider but also responsible for facilitating understanding of the decision at hand and how the context could enable CC. Emphasis on the dialogue could enable more understanding and would also be more responsive to patients needs and thus more in line with the protection of autonomy (Donnelly, 2010, pp. 110–111). Supporting decision making is required under the CRPD (Arstein-Kerslake, 2016; CRPD, 2006). The person supporting the patient should attempt to be as neutral as possible to allow the true will and preferences to be expressed (Arstein-Kerslake, 2016). The fear of undue influence and paternalism is a relevant concern; however influence is not inherently negative (Beauchamp & Childress, 2019, pp. 136–138). Influence is an inevitable part of the relational approach; however, it becomes undue when the influence is hard to resist or undermines the person`s autonomy. Respecting autonomy requires active measures, not merely a respectful attitude; it goes beyond non-interference to include positive obligations such as support, ensure understanding and remove barriers (Beauchamp & Childress, 2019, pp. 104–105, 130–135). However, supportive measures require a framework that safeguards the relationship (Arstein-Kerslake, 2016). Even though support is required, it may not be fulfilled in practice if the mechanisms for endorsing support are not sufficient.

4.2. Functional assessment and a lack of consensus about when to perform an assessment

The functional, task specific approach to CC assessments seems to be adopted in most countries. This approach is an important corrective to the outcome and status approach (Law Reform Commission, 2006) and aims to maximise decision making freedom (Donnelly, 2010, p. 92). Because assessments are inherently normative, an assessor's values and biases may influence the outcome (Donnelly, 2009). Moreover, a functional task specific approach to CC may pose difficulties where decisions in healthcare are linked together or related to ongoing treatment decisions, thus making assessments in situations of fluctuating capacity particularly challenging (Donnelly, 2010, p. 120). Additionally, a frequent criticism is that the approach fails to account for how values and emotions are an essential part of decision-making and should be considered in the assessment (Harcarik et al., 2025; Hawkins, 2024). Traditional cognitivist approaches have tended to see emotions as impeding decision-making and failed to recognise that values and emotions can play a positive role in decision-making (Charland, 1998a, 1998b). An overly cognitive approach to assessments could also be culturally biased (O'Connor, 2010). Our findings indicate that the abilities required are by large similar to either the four abilities from the common law test for capacity (understanding, retaining, using or weighing information about the decision and communicating a decision) or the four abilities described by Grisso and Appelbaum (1998) (understanding, appreciation, reasoning and expressing a choice). There is, however, a risk of insufficient clarity regarding the requirements and boundaries of these abilities (Donnelly, 2010, pp. 133–147). Misconceptions exists and it could be difficult to differentiate between them (Jorem et al., 2025). Abilities such as understanding rely on adequate information given by the healthcare professional in a way that facilitates understanding (Donnelly, 2010, p. 137). Patients not subject to capacity assessment may also fail to understand the information about their treatment, which places those who are assessed, because of an impairment of the mind or brain, at a disadvantage (Donnelly, 2010, p. 137). Also, assessments that require reasoning and justifying choices can disadvantage patients with reduced cognitive or verbal skills (Donnelly, 2010, pp. 145–146). Some may also make decisions based more on emotions and less on rational thinking. Thus, it is essential that these and other nuances are described in an appropriate manner.

As the ethical dilemma between autonomy and beneficence often involves CC assessments, the issue of outcome and risk is central. However, our findings suggest that the emphasis on this differed. We also found differences in the descriptions of the evidentiary requirement for a finding of incapacity. CC assessments serves as a gatekeeping test to decide who is above or below a threshold (Beauchamp & Childress, 2019, pp. 112–118). A high threshold may lead to more patients being found incapable, while a low threshold risks allowing more patients to make harmful decisions. The threshold could depend on the task at hand and the associated risks. Thus, risk-related factors could influence a CC assessment. Some scholars favour a sliding scale strategy where the abilities varies with the associated risks (Grisso & Appelbaum, 1998, pp. 138–141). It is, however, argued that decisions involving risks do not necessarily require more decision making abilities (Beauchamp & Childress, 2019, pp. 117–118). However, higher-risk decisions often demand greater care in assessing capacity correctly. Moreover, risks and what constitutes a considerable risk are regarded as an individual concern. Some would argue that judgements of CC are more often borderline or unsure than strictly binary (O'Keeffe, 2008). For people

with conditions such as dementia a strictly binary division can be problematic, as their condition and their CC may fluctuate.

We also found that there seems to be no consensus regarding when to perform an assessment. Capacity assessments place extra cognitive and communicative demands on the person undergoing them, and a criterion of impairment of the mind or brain could impose a disadvantage on those possessing it by making a diagnosis itself a reason to subject them to capacity assessment (Donnelly, 2010, p. 137). Capacity assessments are often prompted by disagreements between the patient and the healthcare professionals, typically treatment refusal, or by a request by family members (Beauchamp & Childress, 2019, p. 115). Yet, if a patient lacks capacity and assessment is delayed or omitted, they may risk not receiving timely, necessary treatment. A lack of a clear definition on when to carry out a capacity assessment could lead to inappropriate assessments or a failure to assess when needed, thus a clear guidance on when to conduct an assessment is needed. Furthermore, our results demonstrate that several countries do not mandate informing patients in advance of capacity assessments. Since a capacity assessments and conclusion of incapacity could have a significant impact on their lives (Donnelly, 2009), several argue that the patient needs to be informed of the reason for their capacity being called into question and potential consequences of the assessment outcome (O'Keeffe & Donnelly, 2024). For people with cognitive impairments such as dementia this may cause distress, that may influence the assessment. Thus, healthcare professionals may be reluctant to inform the patient of the assessment. However, active participation from the patient in the assessment is important (O'Connor, 2010).

4.3. A lack of common understanding and standards for assessing CC

Our results have shown that the descriptions of the assessment of CC differs across countries. In understanding this variation, it is necessary to be aware that definitions of CC to healthcare can be found in different kinds of health-related legislation. In England and Wales, and Ireland, CC is defined in stand-alone capacity legislation, while in Norway, Belgium, France and Sweden it is part of laws governing patient rights and informed consent. This context is relevant to the role played by CC. For example, where CC is defined only in the context of the doctrine of informed consent it may function as a more abstract concept than in specific capacity legislation, and where CC is defined in mental health legislation, it is not the ultimate determinative factor regarding whether or not treatment is provided. In countries where the statutory definitions of capacity is drafted in more general terms, giving courts greater interpretive latitude in healthcare cases, that definition nonetheless remains fully binding and determinative. Nevertheless, it remains of critical importance that the judiciary`s understanding of the concept is properly communicated to healthcare professionals who is responsible for undertaking such assessments in a clinical context. Furthermore, an important finding was the lack of documents addressing the complexity of CC and how this complexity should be approached in several countries. This could lead to undesirable variations in practice, with a risk of unequal protection of patients from harm and abuse. Recent reforms in healthcare law have aimed to strengthen patients' rights, among the most important being the right to informed consent to healthcare and thereby mitigating paternalistic practices in healthcare (Beauchamp & Childress, 2019, p. 118). However, the strong emphasis on self-determination without necessary support mechanisms may expose vulnerable people, such as those with dementia, to neglect and danger with a high risk of not being offered essential treatment (Guenna Holmgren et al., 2024; Mattsson & Giertz, 2020). Thus, safeguards are important to ensure that vulnerable individuals who cannot fully protect their autonomy can exercise it and at the same time have their rights upheld. Interventions on the basis of incapacity is a form of soft paternalism on the grounds of beneficence to avoid nonvoluntary conduct (Beauchamp & Childress, 2019, p. 233; Donnelly, 2010, p. 90). In countries where health laws require valid consent but do not describe the concept of CC or criteria for the assessment, clinical and legal uncertainty could arise on when to assess capacity, and by which standards. CC serves as an important gatekeeper for autonomy, despite its limitations, but it functions as a safeguard only when assessed correctly (Donnelly, 2010, pp. 272–274). Some argue that clinical judgments should not be replaced by an excessive emphasis on standardisation of clinical practice (Sinsky et al., 2021). However, as the concept of CC is complex and the assessment is prone to variations, it is important to provide healthcare professionals with sufficient guidance on how to assess this capacity, in addition to training and ongoing education. Healthcare authorities must acknowledge the complexities of healthcare and create guidelines balancing between standardisation and the important role of clinical judgements in their efforts to translate the law and the concept of CC into practice.

4.4. Strengths and limitations of the study

It is a limitation that our study reflects perspectives only from Western countries. These perspectives are shaped by the values and cultural norms predominant in this part of the world, often with a strong emphasis on individual autonomy as an inherent trait in humans. Furthermore, the interpretations of the findings are informed by a healthcare perspective. However, a multidisciplinary group of researchers, comprising of nurses, doctors, lawyers, a sociologist and a psychologist, with practical experience, combined with in-depth knowledge on the subject matter brings a diversity to the study findings. This study reflects on a part of a likely diversity that exist within Europe adding to the transferability of the results.

To ensure the rigour and the transparency of the study, a systematic approach was used to retrieve documents and to conduct the analysis. Two researchers conducted the main analysis. Both read all the documents and had several meetings to discuss the findings. Further, to enhance quality and avoid misinterpretations of the data, all the authors met to discuss the results leading to a revising of the results. The documents retrieved met the purpose of the study and gave us sufficient information to answer the research questions. However, a limitation of this study is the relatively small number of countries included and thus the representativeness of these findings. The included documents differ in style and scope which may affect a cross-country comparison, but they are themselves a key finding. Our analysis is limited to documents and does not assess how these provisions are implemented in practice; consequently, we cannot report on actual clinical practice.

5. Conclusion

Our study demonstrates that documents issued by healthcare authorities across six European countries to guide healthcare professionals lack a unified description of CC to healthcare and a consistent framework for its assessment, although some commonalities exist, such as the functional approach, and some countries are more conceptually aligned than others. However, our findings can offer a nuanced and enriched understanding of the concept of CC. Some countries lack guidelines that clearly describe the concept and its assessment. Thus, in some countries, the responsibility for establishing such standards appears to rest with individual healthcare professionals. Our study of these documents from a perspective of healthcare professionals is an important contribution to inform healthcare authorities of the need to critically review their guidelines in line with their own legal framework. Healthcare professionals should be provided with sufficient guidance documents to understand the complexity of the concept of CC to healthcare and to support healthcare professionals in their assessments of CC to healthcare. This is important to reduce undesirable variations in practice and to avoid unequal protection from harm, abuse and neglect. Failing to recognise the concept of CC undermines the very purpose of protecting individual autonomy. There is a need for more international collaboration and research that addresses these questions.

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Declaration of competing interest

No potential conflict of interest was reported by the authors.

Appendix A. Supplementary data

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