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Ethics analysis of light and vitamin D therapies for seasonal affective disorder

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Assessment

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Abstract

Objective. The aim of this ethics analysis was to highlight the overt and covert value issues with regard to two health technologies (light therapy and vitamin D therapy), the health technology assessment (HTA) and the disease of seasonal affective disorder (SAD). The present ethics analysis served as a chapter of a full HTA report that aimed to assist decision makers concerning the two technologies.

Method. First, we used the revised Socratic approach of Hofmann et al. to build overarching topics of ethical issues, and then, we conducted a hand search and a comprehensive systematic literature search on between 12 and 14 February 2019 in seven databases.

Results. The concrete ethical issues found concerned vulnerability of the target population and the imperative to treat depressive symptoms for the sake of preventing future harm. Further disease-related ethical issues concerned the questionable nature of SAD as a disease, autonomy, authenticity, and capacity for decision making of SAD patients, and the potential stigma related to the underdiagnosis of SAD, which is contrasted with the concern over unnecessary medicalization. Regarding the interventions and comparators, the ethical issues found concerned their benefit-harm ratios and the question of social inequality. The ethical issues related to the assessment process relate to the choice of comparators and the input data for the selected health economic studies.

Conclusions. The concrete ethical issues related to the interventions, the disease, and the assessment process itself were made overt in this ethics analysis. The ethics analysis provided an (additional) value context for making future decisions regarding light and vitamin D therapies.

Background

Health Problem at Stake

Seasonal affective disorder (SAD), also called autumn–winter depression, usually begins in autumn/winter and ends again in spring/summer (1). According to the International Statistical Classification of Diseases and Related Health Problems (ICD-10), SAD is a subtype of major depressive disorder (MDD) with a seasonal pattern (2). According to the American classification system Diagnostic and Statistical Manual of Mental Disorders (DSM-5), SAD occurs when depressive episodes occur for at least two consecutive years and cannot be explained by other circumstances, such as the loss of jobs for seasonal workers (3).

SAD patients not only suffer from typical symptoms of depression such as depressed mood, lack of drive, or loss of interest and joylessness (4), but they also often suffer from atypical symptoms such as anger attacks, hypersomnia (in 70–90 percent of SAD patients), increased appetite (in 70–80 percent), carbohydrate craving (in 80–90 percent), and weight gain (in 70–80 percent) (5). Most SAD patients experience mild-to-moderate depressive episodes and are less likely to experience suicidal ideations than nonseasonal MDD patients. Nonetheless, SAD continues to have a major impact on patients' private and professional lives (6;7). In general, the prevalence of SAD is higher in the north than in the south. In Europe and in the United States, the prevalence of SAD ranges between 1 percent and 10 percent. Long-term studies suggest that 22–42 percent of patients diagnosed with SAD still have SAD 5 to 11 years after diagnosis. Furthermore, 33–44 percent of SAD patients progress into a nonseasonal depression, whereas in 14–18 percent of SAD patients, the depressive symptoms disappear completely (8;9).

Technologies at Stake

Because of the fact that depressive episodes in SAD patients start in autumn/winter, a connection between the development of SAD and the decrease in hours of sunshine is suspected. The absence of sunlight could have an impact on the circadian rhythm, hormones, and the levels of neurotransmitters such as dopamine, norepinephrine, or serotonin (10). Light therapy and

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vitamin D therapy are thus two technologies at stake in this analysis. The list of comparators considered is placebo, no intervention, second-generation antidepressants, and psychotherapy.

Light Therapy

Due to its similarity to natural daylight, white fluorescent light (with ultraviolet radiation filtered out) is used most frequently for light therapy. SAD patients are recommended to carry out light therapy with an illuminance of 10,000 lux for about 30–45 min a day (11)—ideally in the morning right after waking up (12). The form of light therapy varies and the forms included in this analysis are light lamps (placed at a distance of 50–80 cm from the head), light devices (attached directly to the head), or light rooms (in which patients physically stay). It is important that SAD patients have their eyes open during light therapy, because the light is processed via the retinohypothalamic tract (5). Light therapy is expected to take effect after a few days to weeks and it is recommended to be carried out continuously in the winter months, as stopping it may lead to the return of depressive symptoms (7).

Vitamin D Therapy

Vitamin D is partly ingested through food, but for the most part, it is formed in the skin as a result of UV-B radiation from sunlight. It is, therefore, assumed that in the decrease of sunlight in the autumn/winter months, the lack of vitamin D may be related to SAD. In the present analysis, vitamin D therapy with vitamin D3 (cholecalciferol) (the most important physiological form of vitamin D) in various dosage forms (tablets and drops) and doses was examined.

This present article is the ethics chapter from a full health technology assessment (HTA) commissioned by the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG) and carried out by the Donau-Universität Krems in cooperation with the Austrian Institute for HTA and the University of Freiburg (13). The full HTA results will be submitted to a peer-reviewed journal separately (excluding this detailed ethics chapter). The present ethics analysis uses the revised Socratic approach (14) to analyze the interventions of light therapy and vitamin D therapy for SAD patients. It aims to highlight the overt and covert value issues with regard to the two health technologies, the disease, and the process of conducting the HTA itself and hence to inform the decision makers about the relevant value issues present in the HTA. The concrete ethical issues found concern the target patient population (vulnerability and beneficence), the disease (SAD as a disease, stigma, underdiagnosis, medicalization, and autonomy), the interventions and the comparators at stake (harm-benefit ratios), and the methodological limitations related to the assessment process.

Methods

Selection of Literature Used for the Ethics Analysis

Because ethical issues are independent of publication type, status, and study type, no limitation on the literature source was applied. Journal publications, monographs, project reports, but also relevant information on the Web sites of interest groups were considered in the ethics analysis. Throughout the text, the term *ethical issue* refers to any aspect related to the interventions, the disease, or the assessment process that is of ethical relevance. That is to say that it concerns ethical values, norms, or principles. Concerning ethical values, what is mostly meant is that an aspect of the health technology may not realize a value or impede access to a value (e.g., self-determination). Concerning norms and principles, what is mostly meant is that an aspect of the health technology may violate a norm or principle (e.g., respect for patient autonomy).

Data Gathering

For the sake of finding the relevant overarching ethical issues, the revised Socratic approach of Hofmann et al. was applied (14). The approach provides a set of questions that may assist in identifying overarching ethical issues with respect to the intervention, the disease, the patient group and other interest groups, as well as the actual assessment process of the health technology. The authors went through the set of questions and identified the relevant overarching ethical issues. The authors considered all questions from the revised Socratic approach and the decision on which ones were relevant was resolved by discussion.

Subsequently, once we identified the overarching ethical issues, we conducted an exhaustive hand search and a search for grey literature on the Web sites of interest groups. Because no articles were found that would specifically focus on the ethics of the two therapies and the disease, a comprehensive systematic literature search was conducted between 12 and 14 February 2019 in MEDLINE via OVID, CINAHL, ETHICSWEB, EthxWeb, PsychINFO, Belit, and Scopus. The search was not limited to the years of publication but was limited to sources published in English or German. The inclusion criteria for literature selection were defined using a Population-Intervention-Comparison-Outcome-(Study design) (PICO) model shown in Table 1. The search was kept broad for the sake of not missing out on articles related to the ethics of SAD and the two technologies at stake.

Furthermore, the studies included in the assessment of clinical benefit and the economic assessment of the full HTA were screened for ethically relevant issues.

Data Analysis

Gathering of all data and screening of all abstracts found by the systematic literature search was done by one person (MS). The selection of full texts from the systematic literature search was confirmed by a second person (CS). All concrete ethical issues necessary for the preparation of the ethics analysis were extracted in Table 2 by MS, which is structured as follows: (i) overarching questions from the revised Socratic approach, (ii) concrete ethical issues, and (iii) explanation/quote/reference. All the concrete ethical issues were constructed around the overarching questions set forth by the revised Socratic approach.

Results

The systematic literature search resulted in a total of 1,063 hits and the search strategies can be found in the Supplementary material. Data from a total of thirty-three documents were extracted for the purposes of the ethics analysis, and quotations from the relevant publications can also be found in Table 2.

Identified Ethical Issues

Based on the revised Socratic approach (14), we were primarily able to identify concrete issues related to disease and target groups, with only a few ethical issues related to the interventions. However, understanding the value context in which the

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Table 1. PICOs inclusion criteria

Population	Adult patients (≥18 years of age) suffering from major depressive disorder or seasonal affective disorder
	ICD-10 Code: F33
	MeSH-terms: Depression, Seasonal Affective Disorder, Depressive Disorder, Major
Intervention	• Light therapy (light lamp, light device, and light room) • Vitamin D therapy (vitamin D3) (in tablets or drops) • Combination of light and vitamin D therapies
	MeSH-terms: Phototherapy, Vitamin D
Control	• Placebo • No intervention • Light therapy (compared to vitamin D therapy) • Vitamin D therapy (compared to light therapy) • Second-generation antidepressants • Psychotherapy
	MeSH-terms: Phototherapy, Vitamin D, Antidepressive Agents, Psychotherapy
Outcomes	• Improvement in depressive symptoms • Quality of life • Social functioning • Number of (serious) adverse events • Autonomy • Withdrawal symptoms • Self-harm • Medicalization • Patient information • "Prozac defence" • Harm
Study type	No limitation

interventions apply is particularly important. There were no studies found that would directly report on the ethics of SAD, but as SAD is defined by ICD-10 as a subtype of MDD or bipolar disorder, ethical issues related to depression in general were taken to be on a par with particular SAD issues. This is also because of a pathophysiology model of SAD that assumes a *dual vulnerability* where "SAD develops when an individual has a combination of significant seasonal physiological symptoms (e.g. energy, sleep, appetite) [seasonality factor] and a vulnerability to develop secondary depression symptoms (e.g. low mood, guilt, anxiety, rumination) [depression factor]" (21). Individuals who have the depressive factor markedly higher than the seasonal one may not show the pattern of SAD because of their vulnerability to distress that "may manifest as non-seasonal depressive episodes (and other forms of psychopathology)" (21).

Ethical Issues Concerning the Target Patient Population

Vulnerability

As SAD is argued to have a major impact on the everyday functioning of a patient (5), the vulnerability of the SAD patient group is of particular ethical relevance here. Vulnerability is understood here as a quality of being able to be easily hurt or simply being at a higher risk of harm or wrong. According to Winkler et al., SAD affects approximately twice as many women as men, the onset is in early adulthood, and approximately half of the cases have a family history of psychiatric disease (19). Also, SAD patients tend to "exhibit comorbidity with other disorders linked to serotoninergic dysfunction, like premenstrual syndrome, alcohol abuse, and overweight" (20). SAD patients are, furthermore, vulnerable due to the disease's negative influence on individuals' health-related quality of life, their social functioning, and their employment status due to the frequency of sick leave being 0.36 days a month according to IC0-10 (6;40;41). Concerning employment and depression in general, people with depression are "twice as likely to be unemployed. They also run a much higher risk of living in poverty and social marginalization" (16).

Beneficence

The ethical imperative to treat depression is rooted in the principle of beneficence, which holds that there is an obligation for healthcare professionals to act in the best interest of patients. There is a need to treat depression because if goes untreated, it becomes increasingly debilitating—possibly resulting in brain damage caused by toxic levels of stress hormones (16;44) and increased risk of ischemic heart disease and myocardial infarction (45). It is particularly important due to the long-lasting nature of SAD as outlined above (8).

Ethical Issues Concerning the Disease

SAD as a Disease?

There is a certain ambiguity regarding the existence of the disease (46)—depression in general and SAD in particular—that is of ethical relevance. On the one hand, stands the biological explanation from above that SAD patients suffer from both the seasonal factor—coming with the change of autumn–winter seasons and the depressive factor—meaning that they develop secondary depression symptoms as a reaction to SAD (21). On the other hand, however, stands the general experience of winter fatigue that is experienced by many and the social theory of depression that interprets depression as a social bias against mildly dysthymic individuals (47). The argument is that depression is a result of the society creating norms that favor outgoing, friendly, and non-depressed personalities and that depression is potentially a *normal* response to pathological social structures (47). Hence, rather than curing *normal* emotional responses, it can be argued that we should change the disintegrating community structures (24;47). The reason why this ambiguity is ethically relevant is that it concerns societal norms or values that may be implicitly at play when diagnosing and then treating individuals with SAD or depression. Such inappropriate diagnosis may lead to inappropriate treatment that may result in unnecessary harm. Furthermore, the nonacceptance of SAD as a disease may have negative implications such as a lack of societal acknowledgment of SAD-related suffering or social inequality with respect to lacking access to covered SAD treatments.

Stigma

Concerning SAD and the experience of winter fatigue, SAD patients report a lack of awareness of SAD among physicians and especially, among general practitioners (15). Such a lack of awareness may be a contributing factor to patients' self-stigma as patients themselves report doubts whether listlessness, social withdrawal, and depressed mood are a normal part of winter (15). The physicians' lack of knowledge combined with the SAD patients' potential self-stigma may mean that opportunities to recognize and treat SAD are missed (16). The potential social barrier is also materialized in the form of lacking insurance coverage of SAD treatments and is well depicted in the Swedish context where patients diagnosed with SAD report experiencing "a dilemma because they knew the diagnosis [SAD] and the treatment [light therapy] were not considered legitimate in the

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Table 2. Identified ethical issues

Overarching questions from the revised Socratic approach	Concrete ethical issues	Explanation/quote/reference
1. What are the morally relevant issues related to the disease and the patient group?	The size of the burden of disease at stake in this assessment.	"**[SAD] affects 2–8% of the total population in Europe**, depending on latitude. In German-speaking countries approximately 2.5% of the population suffers from SAD. About 80% of those diagnosed with this illness will face a recurrent depressive episode the following winter, which has detrimental effects on their quality of life" (15).
		"Patients suffering from SAD exhibit typical depressive symptoms like low mood, lack of drive, decrease in interest and lack of concentration. In addition, patients tend to exhibit a specific symptom cluster related to atypical depression. These symptoms are **hypersomnia** (70–90% of SAD patients), **increased appetite** (70–80%), **carbohydrate craving** (80– 90%) and **weight gain** (70–80%). Furthermore, about three quarters of patients show increased irritability in fall/winter, and anger attacks seem to be especially prevalent in SAD" (5).
	Beneficence and the acute treatment of depression for the sake of preventing future harm.	"The longer depression goes untreated, the more debilitating the condition becomes, which in turn leads to even greater strain on national disability funds" (16).
		"One impact of severe depression is the possibility of **brain damage** caused by toxic levels of stress hormones" (17).
		"Depression is a risk factor for both **ischemic heart disease** and **myocardial infarction** … [and it] … is also associated with a worse prognosis in patients with unstable **angina**" (18).
		"After a period of 5–11 years from the initial diagnosis, 22% to 42% of patients were still suffering from SAD, as assessed by structured clinical interviews and collateral records, while 33% to 44% had **developed a non-seasonal pattern in subsequent episodes**. The remaining patients (−6%) had subsyndromal SAD, or the disorder resolved completely in 14% to 18% of the patients" (8).
	Vulnerability of patients who are the target of the interventions at stake.	"Frauen wiesen häufiger eine **komorbide psychiatrische Störung** auf als Männer (42.7% versus 19,0%; 'χ^2 = 25,553, df = 1, p<.001). Dieser Unterschied erklärt sich vor allem durch das Vorliegen eines PMDS (prämenstruelles dysphorisches Syndrom) bei 42.2% aller Frauen in unserer Studie." "Bei 48.8% unserer Patienten war eine **positive Familienanamnese für psychiatrische Erkrankungen** bei erstgradig Verwandten zu erheben. 40.0% gaben eine Erkrankung aus dem depressiven Formenkreis, 6.9% ein Alkoholabhängigkeitssyndrom, 2.1% eine schizophrene Erkrankung bei Verwandten 1. Grades an." "Das Durchschnittsalter bei der Erstuntersuchung betrug **41.1 ± 12.9** Jahre" (19).
		"According to our clinical experience, many SAD patients also exhibit **comorbidity** with other disorders linked to serotoninergic dysfunction, like premenstrual syndrome, alcohol abuse, and overweight" (20).
		" … the personality profile of patients with SAD appears distinct from that of non-seasonal depressed patients and norms. The combination of elevated openness and moderately elevated neuroticism was relatively specific to SAD and may be important in personality-based vulnerability to SAD." " … [it] can be interpreted in the context of a **dual vulnerability model** … [where] … SAD develops when an individual has a combination of significant seasonal physiological symptoms (e.g. energy, sleep, appetite) [seasonality factor] and a vulnerability to develop secondary depression symptoms (e.g. low mood, guilt, anxiety, rumination) [depression factor]." "Vulnerability to distress symptoms in response to seasonal changes in physiological symptoms is associated with neuroticism and is a component of the depression factor. Individuals with high levels of seasonality (openness) but too high of a loading on the depression factor (neuroticism) may not show a pattern of SAD because their higher level of **vulnerability to distress** may manifest as non-seasonal depressive episodes (and other forms of psychopathology)" (21).
		"The **influence of latitude** is sometimes unclear, though, but prevalence in North America is two times higher compared to Europe. A significant correlation between latitude and prevalence was found in North America, but in Europe only a trend in the same direction was found. Studies in some northern European countries have shown more mixed results" (22).
	The role of screening in preventing and limiting the burden of disease created by SAD and the challenge of false positives.	"Mounting evidence on the role of depression across diseases has resulted in an increased measurement of depression in research." "Reaching thresholds for depression on screening measures does not guarantee meeting the criteria for a diagnosis of depression. It is estimated that 59% of patients screening positive for depression are incorrectly identified as depressed, i.e. they have **false-positive results**" (23).

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Table 2. (*Continued.*)

Overarching questions from the revised Socratic approach	Concrete ethical issues	Explanation/quote/reference
2. What are the ethical, social, cultural, legal, and religious challenges related to the health technology?	Depression challenges individual autonomy especially in the context of the authentic personality of the depressed patient. It is thus connected to issues of identity, agency, and genuine free choice.	"Pathological depression damages **autonomy**, in varying degrees. It does so by reducing energy, enthusiasm, concentration, hope, optimism, self-esteem, and self-respect" (24;25).
		"Health care seeks to restore **autonomy** as **authenticity** … [it] seeks to restore the self that is threatened or disabled by disease and injury, whether physical or emotional" (26;27).
		"**Autonomy** is tied to **authenticity**. An essentialist view of authenticity says there is one true self for each of us, typically a higher self-defined in terms of a favoured value perspective (such as a particular religious viewpoint). A more plausible process view acknowledges that we can shape ourselves in many different directions" (25). "**Autonomy** has a role in personal decisions about the **identity** we affirm … drugs can substantially alter a personality, thereby raising the question, 'Whose autonomy are we out to preserve?' … Given our traditions of valuing individuality, presumably individuals have the right to make their decisions about whether to use legally prescribed drugs … The 'selves' at issue are not givens … The construction is never achieved once and for all. It is an ongoing struggle within the framework of one's past, social present, and projected future" (24;25).
		"**Authenticity** requires that 'actions faithfully represent the values, attitudes, motivations, and life plans that the individual personally accepts upon due consideration of the way he or she wishes to live'" (26).
		"In order to make an **autonomous decision**, an individual must have capacity—that is, the person's ability to make a decision must meet a certain minimum standard. If a person lacks capacity, their decision may be overridden as it will not be taken to reflect a **genuine free choice**." " … functional approach to **competence** … focuses on whether a person can demonstrate threshold decision-making ability, rather than … [focusing on] … the content of the decision (an 'outcomes' approach) or whether the decision-maker is one of a class of persons who are deemed to be incompetent (a 'status' approach)." "The '**agency**' requirement … [states that] … consideration should be given to the degree to which a person's expressed desire is consistent with stable and enduring desires … that are consistent over time" (28).
	Depression is associated with issues related to dignity, self-evaluation, and stigma.	"There is a well established link between depression and negative **self-evaluations**, including lowered self-esteem" (29).
		" … many people—including policy-makers and healthcare providers—hold negative attitudes towards people with depression resulting in isolation, **self-stigma** and a lack of services … Self-stigma undermines the ability of people to work towards their own recovery whilst stigma amongst health care providers means that opportunities to recognize and treat depression are missed" (16).
	In the Western understanding of depression, we project our social bias on people who deviate from the outgoing and friendly social norm.	"Our society favours **outgoing, friendly, non-depressed personalities**, and Prozac [2nd generation anti-depressant] highlights this cultural preference" (25). " … much of what psychiatrists 'call mental illness is nothing more than a political designation sold as science.' In particular, rather than a psychiatric disorder, **depression is a manifestation of the breakdown of community**. As such, it can be 'a normal response to pathological social structures,' and we should change those disintegrating community structures rather than 'cure' normal emotional responses to them. … depression arises out of an enormously complicated, constantly shifting, elusive concatenation of social circumstance, individual temperament, and biochemistry" (24;25). "The **social bias** against mildly dysthymic individuals can pressure them into using medication" (25).
		"People with depression, are twice as likely to be **unemployed**. They also run a much higher risk of living in poverty and social marginalization" (16).
		"Durch die Krankenbehandlung sollen die Gesundheit, die **Arbeitsfähigkeit** und die Fähigkeit, für die lebenswichtigen persönlichen Bedürfnisse zu sorgen, nach Möglichkeit wiederhergestellt, gefestigt oder gebessert werden" (30).
		"Some informants experienced a dilemma because they knew the diagnosis [SAD] and the treatment [light therapy] were not considered **legitimate** in the Swedish health care" (31).

(*Continued*)

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Table 2. (*Continued.*)

Overarching questions from the revised Socratic approach	Concrete ethical issues	Explanation/quote/reference
	The religious explanation sees depression as a moral issue.	"In general, much depression has both **health and moral dimensions**. Depression is a moral matter when it is a potentially meaningful encounter with troubled relationships, activities, values and self-respect. It is a therapeutic matter when it is a clinical syndrome of mood disorder, cognitive dysfunction, low self-esteem, and chemical imbalance." "Moorehead explained his **depression in terms of his religious tradition**. His problem arose from laziness, spiritual pride, and moral weakness, the affliction the Catholic Church once called acedia' and regarded as an occasion for spiritual self-scrutiny … [however,] to understand [Moorehead's] illness we need to consider synapses, not sin." "[Both] one-sided interpretations … neglect the possibility that **much depression is about both values and biology** … Alienated, self-doubting, and cut off from usual support systems, [Moorehead] was in a crisis that had moral, spiritual, and biological dimensions" (25).
	The experience of suffering associated with depression is argued to provide a sense of purpose.	"On both secular and theological accounts, the experience of suffering may either threaten or afford a **sense of purpose** that is constitutive of an authentic self" (26).
	Modifying CBT in line with patients' spiritual beliefs is argued to improve its effectiveness.	"Efficacy [of CBT] may be enhanced for some clients … by **modifying cognitive behavioural therapy with beliefs and values** drawn from clients' spiritual narratives. Potential enhancements include faster recovery, improved treatment adherence, lower post treatment relapse, and reduced treatment disparities" (32).
	Issues with distributive justice particularly concerning the question of justice in access to treatment.	" … patients often reported a **lack of knowledge** and awareness about SAD amongst their physicians, especially general practitioners. Upon noticing symptoms, most of the patients first consulted their general practitioners. However, none of the general practitioners consulted diagnosed SAD in the patients interviewed." " … patients described **difficulties in finding the 'right' psychotherapist** … [and] … finding a therapist within a reasonable timeframe was [also] challenging … [Furthemore,].. [c]osts of treatment play a role, especially with light therapy and psychotherapy. The lack of coverage in health insurance plans for light therapy devices and psychotherapy treatments posed barriers for patients … " "Physicians also reported that the **lack of health insurance coverage** for certain treatments was problematic for many patients. On the other hand, when services were offered free of cost, insurance coverage acted as a facilitator … " (15)
	Adverse events have an impact on patients' bodily functions and on quality of life.	"Adverse events associated with light therapy can he attributed in part to the parameters of light exposure, including dose (intensity and exposure duration), timing, spectral content, and method of exposure (diffuse, focused, direct, indirect, and angle of **incidence relative to the eyes**). Importantly, the emergence of **sleep disturbances** provides an important information toward adjustment of treatment timing: if evening light is scheduled too late, one often sees initial insomnia and hyper-activation. If morning light is timed too early, one often secs premature awakening with the inability to resume sleep" (11).
	SAD and the light therapy on SAD have an impact on patients' quality of life.	"Patients with SAD report markedly impaired QoL during the winter months. Treatment with light therapy or antidepressant medication is associated with equivalent marked improvement in perceived QoL" (33).
	Alternatives to Vitamin D therapy and light therapy are associated with benefits and harms.	"'**Sudden gains**' is a robust phenomenon that has been found to occur among a variety of psychotherapies, clinical conditions, settings, patient populations, and differing levels of therapist expertise. About 40% of patients receiving cognitive therapy for depression experience large symptom improvement following a critical session, and cognitive changes appear to account for these sudden and dramatic changes" (34).
		"Anti-depressive medications should be used only when they are necessary. Both patients and physicians like '**quick fixes**'. However, sometimes tablets should be replaced with other treatment modalities" (35).
		"Evidence for the effectiveness of second generation anti-depressants (SGAs) is limited to one small trial of fluoxetine compared with placebo, which shows a non-significant effect in favour of fluoxetine, and two small trials comparing fluoxetine against light therapy, which suggest equivalence between the two interventions. **The lack of available evidence precludes the ability to draw any overall conclusions on the use of SGAs for SAD**" (36).

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Table 2. (*Continued.*)

Overarching questions from the revised Socratic approach	Concrete ethical issues	Explanation/quote/reference
		"This is a side effect [of SGAs] referred to as **activation**; which is experienced as increased energy, anxiety, and/or agitation typically emerging several hours after taking the first dose. In individuals with this version of MDD, such acute-onset side effects often result in abrupt patient-initiated discontinuation (the side effects often scare patients and may make them very reluctant to go through another antidepressant trial). Thus, although after 4–6 weeks of treatment SSRIs often begin to significantly reduce both depression and anxiety symptoms, the initial few weeks of treatment can be very challenging and many patients drop out of treatment" (17).
3. What are the moral challenges with structural changes related to the health technology?	Medicalization of the appropriateness of depressive symptoms and the issue of 'mood elevators'.	"Experiences of depression often, as it is argued, sometimes '**appropriately**' accompany the real-life experiences of individuals and should not be medicalized simply because there may be an adequate treatment for that type of depression. Just as acute care medicine should resist the 'technological imperative'—if it is technically possible, it must be tried—the mental health professions should resist a 'treatment imperative' that treats conditions simply because it is possible to do so." " … it is deemed appropriate that someone who has lost a loved one goes through a period of mourning. A **mourner's pain**—encompassing sadness, longing, regret, disappointment, and anger—serves as a sign of the importance of the one lost to the one who now mourns." "In the past century, pharmacological and psychotherapeutic interventions have been developed to relieve emotional, psychic, and existential pain. The development and relative success of such medical modalities of relief has led some to question the **appropriateness** of 'treating our normal nihilism with Prozac', of medicalizing normal suffering" (26).
		"Peter Kramer coined the expression '**cosmetic psychopharmacology**' to refer to medicines used as mood elevators rather than cures for pathological conditions" (24;25).
	The issue of underdiagnosis of depression.	"More and more people are becoming unwell with depression and are **unable to access good quality support** when they need it that addresses the full range of symptoms. This would not be acceptable in any physical disease area and yet there is good evidence for cost-effective interventions, which can both prevent and treat depression" (16).
		"Despite these grim statistics and massive efforts to educate the public regarding depression, it is estimated that only **25%–33% of those who suffer seek treatment**" (17).
		"One major barrier patients encountered when searching for help, was that **general practitioners did not recognize SAD symptoms**. Consequently, SAD patients often remain mis- or underdiagnosed and continued to suffer from symptoms and functional disability" (15).
	Challenges for the relationship between healthcare professionals. Possible related issue of overprescription of antidepressant medication.	"Most drug treatment for depression takes place in **primary care medical settings**. 85% of prescriptions written in the United States for antidepressants are written by physicians and nurses that do not have specialty training in psychiatry. This is due in large part to managed care's efforts to cut costs … Yet, only 11% of those treated for depression in primary care receive adequate treatment (in terms of dosing, time to response, and follow-up)" (17).
		" … research suggests that the **treatment of depression in primary care is inadequate**. Resources are limited in primary care and access to psychological interventions is often not available. Hence, **antidepressants are the most commonly prescribed treatment, but are often not patients' preferred choice of treatment**. An estimated 20–30% of those identified as depressed in primary care settings receive adequate care and follow-up, and the majority of patients prescribed antidepressants discontinue them soon after initiation" (23).
		"Some contexts for ethical tension are inherited, such as the **split-care** model of pharmacotherapy and psychotherapy in the treatment of depression … " (37)
		" … when a patient calls a residency training clinic, a community mental health center or managed behavioral health care triage number requesting mental health services, there are often systems issues that cause a patient to see a psychiatrist first, rather than a non-physician clinician. Very often, it has to do simply with which clinician has the next available slot (most likely, a non-physician) or whether the patient is having acute symptoms (more likely, a physician slot). **If a patient first sees a non-physician clinician, then that person will decide whether the patient will be further evaluated for medications**. If the patient is first seen by a physician, then it will be up to the physician to decide if they will also provide psychotherapy or will refer the patient to another clinician for psychotherapy" (38).

(*Continued*)

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Table 2. (*Continued.*)

Overarching questions from the revised Socratic approach	Concrete ethical issues	Explanation/quote/reference
4. What are the moral issues related to the characteristics of the health technology?	Beneficence as the purpose of the intervention at stake.	The purpose of our interventions is to treat acute depressive episodes in SAD patients. This should improve the depression severity or even lead to being free of depression, which as a consequence should lead to better quality of life, better functioning in the private and social life.
		"Recovery does not refer to an end product or result. It does not mean that one is 'cured' nor does it mean that one is simply stabilized or maintained in the community. Recovery often involves a transformation of the self wherein one both accepts one's limitation and discovers a new world of possibility. This is the paradox of recovery i.e., that in accepting what we cannot do or be, we begin to discover who we can be and what we can do. Thus, recovery is a process. It is a way of life" (39).
5. What are the moral issues related to stakeholders?	Negative impact of depression on third parties, on social as well as working life.	" … there is a close association between depression and various domains of H-RQOL; depression has been associated with a decrease in experiencing positive well-being, **impairment in role functioning and disabilities in social functioning**" (40).
		"The winter depression affected not only the patients' subjective well-being but all important aspects of everyday life, that is, work capacity, recreational activities, and **relations with family and friends**. There were feelings of being 'alive' only half of the year (summer) and feeling like a robot the other half (winter)" (31).
		"The monthly excess of **days on sick leave due to SAD** was 0.24 days according to the OSM-5 and 0.36 days according to the IC0-10" (41).
6. What are the moral issues related to the assessment of the health technology?	Morally relevant issues with respect to the specific studies used in the economic analysis.	No relevant information regarding the vulnerability of the target population is mentioned in either one of the two health economics studies included in the analysis (42;43). Both health economics studies come from the US context and both included provider perspective and patient perspective (one to a lesser degree as it reported a reduced patient perspective in the form of provider costs + travel costs/income foregone (43)) (42;43). No other clinical outcome measures than Beck Depression Inventory-II were used in the cost-effectiveness analysis. No other crucial outcomes such as morbidity, mortality, or satisfaction were considered (42). No discount rates were used in either one of the studies. Only an inflation adjustment according to the relevant study year was made (42;43). No reference values were used in one of the studies (43).
	Relevant technologies not included in the assessment.	Related technologies that were not assessed were antidepressants (other than second generation), diet change, life style change, and other forms of psychological interventions.

Swedish health care" (6). "There is [furthermore] a well established link between depression and negative self-evaluations, including lowered self-esteem" (29) and the ambiguity regarding the existence of SAD has the potential to contribute to it even more.

Underdiagnosis

In light of the above, depression advocacy groups argue that such a lack of awareness would be unacceptable in any physical disease area (16). This is because a lack of awareness may lead to underdiagnosing SAD as a disease and, by implication, undertreating it. They argue on the grounds of fairness saying that a similarly severe case of a physical disease would receive more attention and thus would be less underdiagnosed. In general depression, it is furthermore estimated that only 25–33 percent of depressed patients seek treatment (44) and the appropriateness of the care pathway for those who do seek it is scrutinized. Illustrated by the US context, "85% of prescriptions…for antidepressants are written by physicians and nurses that do not have specialty training in psychiatry … [and] … only 11% of those treated for depression in primary care receive adequate treatment (in terms of dosing, time to response, and follow-up)" (16).

Medicalization

The question of underdiagnosis, however, needs to be put into contrast with the question of *medicalization* in order to avoid human conditions to be defined and treated as medical conditions. To the extent that SAD is *just* a form of winter fatigue that the patient can cope with without the need of healthcare support, we should resist the *treatment imperative* to medicalize *normal* reaction to winter just because of the fact that there is an adequate treatment for SAD (26). Kramer suggests that we should avoid *cosmetic pharmacology* where medicines are used as mood elevators, as opposed to cures for pathological conditions (24;47). Furthermore, with the aim of avoiding medicalization, it is suggested that depressed patients first go see a nonphysician clinician who evaluates whether medications from a psychiatrist are necessary (38).

The question of medicalization is also relevant in the context of religious views of depression. Religious perspectives may tend to see depression as a form of spiritual exercise as in the case of the Jesuit priest Moorehead who interpreted his experience with depression in the context of laziness, spiritual pride, or moral weakness—the affliction the Catholic Church once called *acedia* (28). Religious understanding of depression may thus see it as a moral matter

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"when it is a potentially meaningful encounter with troubled relationships, activities, values and self-respect" (47). In this respect, the religious interpretation may provide a sense of purpose for the experience of depression-related suffering.

Autonomy

One of the key ethical issues related to the experience and treatment of depression is associated with the notion of autonomy and the related challenges with authenticity and capacity for decision-making. Broadly speaking, the principle of autonomy here refers to individuals' capacity to make decisions for themselves that are aligned with their goals and it is understood as a precondition for holding individuals morally responsible for their actions. The experience of pathological depressive symptoms damages autonomy (in the sense of capacity to make decisions) by "reducing energy, enthusiasm, concentration, hope, optimism, self-esteem, and self respect" (24;47). The autonomous and authentic self that faithfully represents its values, desires, or life plans over time is precisely what health care aims to restore (26;27). However, in the case of depression, the question of authentic personality is particularly problematic. Although an *essentialist view* of authenticity sees only one true self that the anti-depression interventions are to restore, the *process view* acknowledges that the *self* is not a given and hence it changes all the time (24;47). With respect to the latter view, it is problematic to decide what *self* is to be restored or maintained—especially in the light of the self that changed through the use of antidepressants. For the sake of making autonomous and authentic decisions for which patients can bear moral responsibility, it is argued that individuals must possess a certain minimum standard of decision-making capacity, which may pose a challenge to patients at the heart of their depressive episodes (28).

Ethical Issues Concerning Interventions

Benefit-Harm Ratio of the Interventions at Stake

Even though both interventions (light therapy and Vitamin D therapy) are not particularly normatively challenging and hence are relatively uncontroversial, some ethical issues remain. Both interventions attempt to improve the baseline low quality of life (QoL) of seasonally depressed patients and their main issues concern the benefit-harm ratio and the question of social inequality. Regarding vitamin D therapy, although safety concerns are minor, there is insufficient evidence concerning its benefits. Regarding light therapy, the clinical benefits shown by the meta-analysis (13) need to be put in contrast with the potential side effects such as irritability, headaches, eye strain, sleep disturbances, and insomnia (11). Light therapy was also judged to be time-consuming by patients as it requires a commitment both in the morning and in the evening that is hard to be incorporated into daily routines and thus has the potential to disturb one's personal life (15). The issue related to social inequality is driven by the lack of insurance coverage and hence the need of out-of-pocket expenses. This is of particular relevance in case of purchasing the light therapy lamp that costs approximately 300 EUROS where patients also state that they get little guidance in the process of choosing the right lamp (15). Furthermore, the fact that, for instance, pharmacological therapy is covered by health insurance may have the potential to "nudge" SAD patients toward using pharmacological therapy instead of the less invasive options (such as light or vitamin D therapy), even though SAD patients tend to show preference toward nondrug therapies (15).

Benefit-Harm Ratio of the Comparators

Concerning the comparator interventions, the ethical issues with respect to second-generation antidepressants (SGAs) stem from their unclear clinical benefit profile and the risk of adverse events. The Cochrane systematic review of fluoxetine concludes a nonsignificant effect in favor of fluoxetine when compared to placebo and an equivalent effect when compared to light therapy (against the backdrop of low-quality evidence) (36). In contrast, the potential side effects of fluoxetine are many and they include drowsiness, dizziness, weakness, runny nose, sore throat, headache, flu symptoms, nausea, diarrhea, changes in appetite, weight changes, decreased sex drive, impotence, difficulty having an orgasm, dry mouth, and increased sweating (36). The insufficient clinical benefit profile of fluoxetine compared to the list of side effects seems to suggest a negative befit-harm ratio. With respect to the comparator of cognitive behavioral therapy (CBT), although there seem to be positive effects of CBT on SAD patients—especially when CBT is modified with respect to patients' beliefs and values drawn from their spiritual narratives—the time-consuming nature of person-centered therapy serves as an obstacle that may prevent patients from seeking this treatment alternative (15;32).

Ethical Issues Concerning the Assessment Process

Potential ethical issues with regard to the full HTA (13) are related to the choice of comparators and the health economic analyses. Relevant comparators that were not assessed in the full HTA are antidepressants other than SGAs, diet change, and lifestyle change. As these comparators were excluded from the analysis, a potential selection bias may be in place and relevant studies missed. This is of ethical relevance because gaps in the evidence base may change the conclusion of the HTA and hence the coverage decision. What is also ethically relevant are methodological mistakes in health economic studies, which may "incorrectly" deem an intervention cost ineffective and thus have a negative impact on patients. The main methodological concerns related to the health economic studies are that both health economic studies included come from the US context, and in the analysis, both included the healthcare provider view, whereas the patient view was included to a limited extent in one analysis, as it had a reduced patient perspective in terms of provider costs, travel costs, and income loss (48;49). No discount rates were used and reported in any of the studies and only inflation adjustments were made (48;49). In one of the studies, no reference values were used (48).

Discussion/Conclusion

In this article, we have analyzed the concrete ethical issues related to the interventions of light therapy and vitamin D therapy as well as those related to the assessment process and SAD as a disease. The ethical issues found concerned vulnerability of the target population and the imperative to treat depressive symptoms for the sake of preventing future harm. Further disease-related ethical issues concerned the questionable nature of SAD as a disease, autonomy, authenticity, and the capacity of SAD patients for decision making, and stigma related to underdiagnosis of SAD, which is contrasted with the concern over unnecessary medicalization that may redefine human conditions into medical ones. Moreover, only a limited number of ethical issues were found to be related to the interventions at stake—namely with respect to their benefit-harm ratios and the question of social inequality

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(due to the presence of out-of-pocket expenses). The benefit-harm ratio of the comparators was found to be of ethical relevance. Further ethically relevant issues were related to the assessment process, which concerned the choice of comparators and the input data for the selected health economic studies.

The main limitation of this ethics analysis lies in the methods used. First, it is questionable to what extent the PICO model applied to searching the medical databases can result in relevant hits, as PICO is an approach borrowed from especially clinical medicine and might thus not be fully suitable for searching and selecting ethically relevant literature. Secondly, the fact that only one person (MS) screened the abstracts without the quality check of the second person (CS) may cast doubts over the comprehensiveness of the literature included.

The present ethics analysis originally served as a chapter in a full HTA that assessed the safety and efficacy of the interventions at stake, as well as their economic, ethical, social, organizational, and legal implications (13). The concrete ethical issues that were found to be relevant to the interventions, the disease, and the assessment process were made overt in the present ethics analysis. The ethical issues outlined above are assumed to complement the medical-technical results of the clinical benefit assessment and so contribute to a broader assessment of value of the health technology. The ethics analysis yielded no ethical issues that would challenge the application of either of the two interventions. The IQWiG ThemenCheck is commended for conducting full HTAs that include the assessment of more issues than just those related to clinical benefit and safety. The value judgments embedded in the process of conducting an HTA need to be addressed in a transparent manner and ethics analyses can serve precisely this purpose.

Supplementary material. The supplementary material for this article can be found at https://doi.org/10.1017/S0266462320000884.

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