Defining value in the mental illness space: Is caregiver burden considered in health technology assessments of treatments for depression and schizophrenia?

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Background

Caregivers of individuals with mental illnesses can face considerable burdens across various physical, psychosocial, and economic domains, and this can negatively impact their quality of life (QoL). We define caregivers here as partners, family members, and friends who provide unpaid, long-term care and support to patients. Chronic mental health disorders can put immense strain on caregivers' personal health and well-being, finances, and productivity, leading to wider societal costs. Moreover, traditional value frameworks used by health technology assessment (HTA) agencies may not fully capture these considerations.

Broader and more novel descriptions of value have been presented in the ISPOR Value Flower and include "family spillovers" which encompasses caregivers' QoL, yet this is inconsistently incorporated in value assessments (Figure 1).[1,2] A lack of consideration given to caregiver burden in the assessments of treatments for mental illnesses may result in innovations with the potential to impact patients, families, health systems, and society positively becoming underfunded or completely missed. This research explores whether HTA agencies consider caregiver burden in their decision-making when reviewing pharmaceutical treatments for mental disorders.

Figure 1: ISPOR Value Flower

Methods

HTA appraisals for pharmaceutical drugs indicated to treat depression (including major depressive disorder, treatment-resistant depression [TRD], and major depressive episodes [MDE]), schizophrenia, and bipolar disease published between January 2014 and June 2024 by the UK National Institute for Health and Care Excellence (NICE), French National Authority for Health (Haute Autorité de Santé, HAS), and German Federal Joint Committee (Gemeinsamer Bundesausschuss; [G-BA]) were reviewed. Evidence submitted by the manufacturer, and committee discussion regarding caregiver burden were analyzed to determine the extent of consideration by HTA agencies in their final decision.

Results

Between 2014 and 2024, only three pharmaceutical drugs for the treatment of depression, and two drugs for schizophrenia have been reviewed by NICE, HAS, and the G-BA. Bipolar disease was not included in our final evaluation since there were no new appraisals published for pharmaceutical drugs in this indication by the scope HTA agencies over the 10-year inclusion period.

Overall, there was no evidence to suggest that caregiver burden had a direct impact on the final HTA outcomes of any of the pharmaceutical drugs reviewed across all indications reviewed. HAS and G-BA did not mention caregiver burden in their assessments, and only NICE acknowledged the caregiver perspective in their assessments of treatments for MDE and TRD (Table 1).

Table 1: Summary of whether caregiver burden was considered in HTAs of treatments for mental disorders by country

Indication	NICE	HAS	G-BA
TRD	Esketamine, 2022	Esketamine, 2020	Esketamine, 2023
MDE	Vortioxetine, 2015	Vortioxetine, 2015 Agomelatine, 2015	Vortioxetine, 2015
Schizophrenia	Lurasidone, 2014	Lurasidone, 2014 Aripiprazole, 2022	Lurasidone, 2015

Blue = Caregiver burden was mentioned/discussed
Yellow = No discussion/consideration of caregiver burden

NICE highlighted the impact of MDE on the family and caregivers of patients in their assessment of vortioxetine[3]; however, this did not play a critical role in the final HTA decision. Greater consideration for the caregiver perspective was shown in a more recent NICE assessment of esketamine in TRD treatment, as the committee noted the negative effect of TRD on the families and caregivers of patients and acknowledged the importance of patients having support from caregivers to access treatments, eg, when traveling to and from hospital for certain treatments.[4]

Although NICE considered it appropriate to include caregiver disutility in the economic model for the effect of TRD on caregivers and families, the committee challenged the rigour of evidence considered necessary to show a direct effect on caregivers.[4] NICE further noted that caregiver disutility had not been considered in their previous assessment of vortioxetine for treatment of MDE.

Conclusions

Over the past decade, few new pharmaceutical drugs have been reviewed by NICE, HAS, and the G-BA for the treatment of mental illness, defined in this analysis as depression, schizophrenia, and bipolar disorder. Historically, these HTA agencies have not accounted for caregiver burden in their decision-making. Notably, in recent assessments, NICE has shown greater consideration for the caregiver perspective by acknowledging the impact of depression on caregivers and families when discussing the treatment pathway and economic models; however, this did not influence their final decision.

Overall, the findings from this research suggest a lack of consideration given by payers to the broader impacts of mental illnesses that extend beyond the patient to their caregivers. For innovative treatments to launch in this space, HTA agencies must evolve their existing assessment frameworks to adopt a wider definition of value that captures the benefits that novel drugs may bring, not only to the patient but also to their caregivers. Furthermore, there needs to be alignment in the methodological guidance across HTA agencies in order for caregiver burden to be consistently accounted for in HTA submissions and decision-making.

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