FULL TITLE: "What else can we do?" - Provider perspectives on treatment-resistant depression in late life

SHORT RUNNING TITLE: Treatment-resistant late-life depression

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KEY POINTS

- The North-American psychiatric system does not meet the needs of older adults with treatment-resistant depression (TRD).
- Primary care providers and psychiatrists desire integrated care models that allow them to work together for this population.

WHY THIS MATTERS

Better treatment will improve the lives of older adults with TRD.

ABSTRACT

Background: Treatment-resistant depression in late-life (TRLLD) is common. Perspectives of primary care providers (PCPs) and psychiatrists treating TRLLD could give insights into the challenges and potential solutions for managing this condition.

Methods: To identify perspectives of providers who treat TRLLD, we conducted a qualitative descriptive study using semi-structured interviews *with* providers treating older adults with TRLLD in 5 locations across North America (Los Angeles, New York City, Pittsburgh, St. Louis, Toronto). We conducted semi-structured interviews with 50 care providers (24 Primary Care Providers (PCPs), 22 Psychiatrists, and 4 Depression Care Managers). Interviews elicited providers' perspectives on treatment options for TRLLD, including treatment within the primary care setting and referral to psychiatry, and sought suggestions for improvement.

Results: We identified 4 themes. (1) Treating TRLLD takes an emotional toll on providers. (2) Existing psychiatric services are inadequate to meet the needs of patients with TRLLD, mainly because of lack of access. (3) PCPs often attempt to treat TRLLD, even when they are not comfortable doing so. (4) To better meet the needs of patients with TRLLD, providers recommend integrated care models involving PCPs, psychiatrists, and psychotherapists, potentially made more feasible by the growth of telehealth.

Conclusions: Findings from these qualitative interviews show the challenges in providing care for TRLLD. These findings can guide knowledge dissemination to psychiatrists, PCPs, policy-makers, and other stakeholders involved in the mental health system. They can also inform structural changes to clinical practice that may increase the implementation of the best treatment strategies across settings to improve long-term outcomes for TRLLD.

Key words: older adults, treatment-resistant depression, antidepressant, psychotherapy, provider perspectives, qualitative research

INTRODUCTION

Less than half of depressed older adults respond to an initial trial of an antidepressant medication, with even lower response rates for subsequent trials.[1,2] When defining treatment-resistant depression (TRD) as not remitting to two or more trials of antidepressant treatments, TRD in late life (TRLLD) is associated with substantial personal, social, and economic costs.[2] TRLLD is a complex condition and its management requires consideration of both multiple treatment options (e.g., switch vs. augmentation strategies, psychotherapy, brain stimulation) and concerns about polypharmacy and comorbidities including cognitive impairment.[3,4] The management of TRLLD is further impeded by systemic issues in the health care system, including a dearth of geriatric psychiatrists and a lack of embedded psychiatric services in most primary care settings.[5-7] Prior research has shown that patients with TRLLD are most often seen in primary care settings,[8-11] where primary care physicians (PCPs) have to address up to six different topics over an average 17-minute visit, with mental health accounting for less than 5% of the total visit time.[12]

These structural realities of the health care system impact not just patients but also providers. However, to our knowledge, no study has documented the emotional impact of caring for TRLLD. Increasing the understanding of both providers' experience and systemic challenges associated with TRLLD will help to improve its care and outcomes. Thus, we conducted qualitative interviews with PCPs, psychiatrists, and depression care managers involved in the ongoing Optimizing Outcomes in Treatment-Resistant Late-Life Depression (OPTIMUM) study, a pragmatic clinical trial evaluating the benefits and risks of antidepressant strategies (augmentation vs. switch) in TRLLD.[13] These interviews assessed the experience of providers treating TRLLD and elicited their suggestions to address the impediments they face in doing so. This report describes the salient themes which emerged from these interviews.

METHODS

The methods of the OPTIMUM study have been reported previously.[13] We interviewed both patients and providers involved in OPTIMUM. In this report, we present only data from providers. We summarize our methods here, with additional details in Supplement 1.

Following a qualitative descriptive approach, our overall goal was to describe the perspectives of providers.[14] We developed an interview guide focusing on provider experience of treating TRLLD (see Supplement 1). Sample size for qualitative interview studies is driven by thematic saturation (i.e., when additional interviews no longer yield additional insights), which typically occurs after interviewing 8-16 participants.[15] Thus, we planned to interview 50 providers (10 from each of the 5 OPTIMUM sites), allowing us both to reach thematic saturation and to identify potential site-variations in perspective. Each site referred providers who had referred patients to the OPTIMUM study and we included the first 50 providers who agreed to participate.

Phone interviews were recorded and transcribed verbatim, with identifying details redacted. Transcripts were analyzed with the assistance of Atlas.ti software. We inductively developed a codebook based on the content of the interviews. To establish intercoder reliability, two experienced qualitative coders coded 10 interviews. Cohen's kappa scores were calculated for each code, with an average score of 0.71 indicating substantial agreement.[16] After a single coder coded the remaining interviews, she and the qualitative methodologist (MH) conducted content and thematic analyses. Resulting themes were discussed with all of the authors as a form of investigator triangulation, to ensure the credibility of the interpretation.[17-19]

This study was reviewed and approved by the University of Pittsburgh IRB.

RESULTS

Fifty interviews were completed between November 2018 and June 2019, with 75% of providers approached agreeing to be interviewed. Participating providers comprised PCPs (n=24), depression care managers (n=4), and psychiatrists (n=22) (see Supplement 2 for the distribution of providers across the 5 sites). We present below the four major themes identified and reference quotes parenthetically (e.g., Quote_1A); themes are common across the three types of providers unless a type is specified (see Supplement 3 for additional quotes supporting each theme). Key points are represented in Figure 1.

Theme 1: Treating patients with TRD takes an emotional toll on providers.

All providers reported they were invested in treating TRLLD but it exacted an emotional toll on them. All PCPs expressed a desire to help their patients with TRLLD and described using first- and second-line pharmacotherapy and potential therapy referrals. However, either patient resistance to initiate recommended treatments (Quote_1A) or non-response to initiated treatments resulted in PCPs feeling "stuck" (Quote_1B), "worried" (Quote_1C), or "nervous" (Quote_1D), particularly when they perceived the needed treatment as outpacing their knowledge, or available time and other resources. One PCP said "I'm not sure that one can be fully comfortable with the experience of working with a patient who is suffering so much and can be very difficult to reach with treatment." Similar sentiments were echoed by a depression care manager: "It gets to a point that it's sort of like, what else can we do here?" Although psychiatrists reported being more familiar with treating TRLLD and having more treatment tools at their disposal, they also described addressing TRLLD as "challenging" (Quote_1E), "grinding" (Quote_1F), "frustrating" (Quote_1G), or "uncomfortable" (TOR006). They

emphasized struggling with TRLLD despite their desire to see their patients improve and the risk of suicide in this group.

Theme 2: Available psychiatric services do not meet the needs of patients with TRLLD.

Providers at all sites described a mental health system that is difficult for them and their patients to access and navigate. PCPs often characterized accessing psychiatric care for their older patients negatively, describing it as "not a good one" (Quote_2A) or a "nightmare" (Quote_2B). The most common barrier described was a lack of psychiatrists, including geriatric psychiatrists, psychiatrists taking new patients, or psychiatrists who accept Medicare. Reported wait-times to see a psychiatrist were 1-6 months. US providers also described restrictions related to insurance, including out of network psychiatrists (typically those who opted out of Medicare; Quote_2F). The lack of an updated list of approved psychiatrists accepting new patients led one PCP to comment, "Referring my patients to mental health is […] one of the most taxing things in my job." These difficulties are compounded by differing requirements to obtain prior authorization to see a psychiatrist (Quote_2C), lists of preferred or covered medications and associated copays (Quote_2D), and payment restrictions for treatment such as group therapy or telehealth (Quote_2E).

Additionally, providers described that some patients with TRLLD, particularly when compounded by cognitive impairment, have difficulty making and attending appointments, and that mental health specialists are unforgiving of these difficulties. One New York depression care manager noted that patients who struggled to keep psychiatric appointments were discharged due to noncompliance (Quote_2G). Thus, even when patients find a psychiatrist who accept their insurance, they may not be able to remain in treatment due to difficulties caused by the condition

that requires treatment in the first place. Many barriers were similar at all five sites, indicating a system in which timely access to psychiatric care for TRLLD is often beyond reach.

Theme 3: Because psychiatry is difficult to access, PCPs often attempt to treat TRLLD beyond their level of comfort.

Lack of access to psychiatrists results in PCPs treating TRLLD (Quote_ 3A), with varying degrees of confidence. Some PCPs described being "forced" to treat patients they do not feel qualified to treat (Quotes_3B, 3C), with some reporting this resulting in increased comfort (Quote_3D). Many PCPs however feel uncomfortable treating TRLLD due to a lack of experience (Quote_3G) or knowledge of what to prescribe, concerns about drug-drug interactions (Quote_3H), or lack of time (Quote_3I). Whether or not they were comfortable managing TRLLD, most PCPs needed to refer some of these patients to psychiatrists, including those presenting with severe symptoms, risk of self-harm, psychiatric comorbidities such as bipolar disorder or psychosis (Quote_3E), or non-response to medications the PCP was comfortable prescribing (Quote_3F).

Psychiatrists described both expertise and experience with TRLLD. Several mentioned that as psychiatrists at large academic medical centers, most of their patients are referred to them by PCPs or community-based psychiatrists because of treatment-resistance. However, as noted in Theme 1, they still reported TRLLD as a major challenge (Quote_3J).

Theme 4: Providers made specific suggestions to better address TRLLD.

Providers described a variety of approaches to improve care for TRLLD: (1) increasing the number of psychiatrists; (2) improving collaborations among PCPs, psychiatrists, and therapists, with embedded mental health professionals in PCP practices; (3) providing treatment

algorithms tailored to PCPs; and (4) increasing access to psychotherapy, in addition to pharmacotherapy.

Given the shortage of psychiatrists and the wait-times discussed above (Theme 2), providers felt that increasing the number of psychiatrists (particularly those who accept Medicare) would have a positive impact (Quote 4A). They also emphasized telehealth to improve access, in particular for patients with transportation, mobility, or motivational difficulties (Quote 4B). Integrated care was viewed as helpful, starting with increased communication between psychiatrists and referring PCPs. Both types of providers desired this increased communication, with psychiatrists commenting on the lack of detailed reasons for referrals, and PCPs on the poor feedback regarding diagnosis or progress; they said that formalizing and improving communication could reduce this disconnect and identified integrated electronic health records as one way of achieving this. PCPs desired more concrete collaboration, including routine partnering with psychiatrists, or embedding psychiatric care within their practices (Quote_4C).

In addition to closer collaboration, PCPs desired treatment algorithms for TRLLD, detailing which medications to use in which order and recommended dosages. They also wanted education in managing medications with more complex adverse effect profiles (Quote_4D) and increased availability of psychotherapy, noting that, beyond medications they could prescribe, their patients could benefit from counselling (Quote_4E).

Lastly, though less frequently, some PCPs wished for senior centers that would provide socialization to prevent or reduce depression. One Pittsburgh PCP stated, “general loneliness in the society is part of the reason for TRD in older patients”; a LA PCP wanted to see social and physical activities like “meditation, yoga, [and] bridge” as part of mental health treatments.

DISCUSSION

Eliciting the perspectives on TRLLD of PCPs, psychiatrists, and depression care managers, we identified four themes that encompass the problematic state of care for this condition: (1) treating TRLLD takes an emotional toll on providers; (2) existing psychiatric services are inadequate to meet the needs of patients with TRLLD, mainly because of lack of access; (3) PCPs attempt to treat TRLLD, even if they are uncomfortable doing so. (4) To better meet the needs of patients with TRLLD, providers recommend integrated care models involving PCPs, psychiatrists, and psychotherapists, made more feasible by the growth of telehealth.

Insufficient access to psychiatric services was noted by all providers in this study. While 20% of the US population will soon be over the age of 65, there are fewer than 1,800 board-certified geriatric psychiatrists in the US.[20-22] The aging of the population and the associated increasing rate of TRLLD magnifies this lack of geriatric specialists.[23] Providers in our study also noted that many geriatric psychiatrists opt out of Medicare due to inadequate reimbursement,[24] thereby creating a financial barrier for patients who cannot afford out of network care. PCPs also commented on the difficulty identifying specialists accepting new patients and the insurance they accept. Finally, given that TRLLD itself results in poor treatment adherence and missed appointments, providers noted that stringent rules related to missed appointments lead to premature discharges and having to start over in a difficult-to-navigate system.

Providers in this study reported that the complexity of treating TRLLD increased their frustration associated with access issues. Many PCPs and depression care managers were concerned that the needs of their patients with TRLLD surpassed their knowledge and experience. PCPs provide 60% of psychiatric care occurring and almost 80% of antidepressant

prescriptions.[25,26] The participating PCPs reported discomfort and a lack of experience with the implementation of complex strategies for TRLLD (e.g., combining or augmenting antidepressants), compounded by legitimate concerns about inadequate treatment and adverse effects. For example, the Beers criteria from the American Geriatrics Society updated in 2012 listed selective serotonin reuptake inhibitors (SSRIs) as potentially inappropriate medications for use in older adults due to fall risk.[27] As we have noted previously,[28] this results in some PCPs choosing not to use SSRIs, despite a lack of a causal link between SSRIs and falls.[28,29] Focusing exclusively on the risk of adverse effects ignores the risks of untreated or undertreated depression in late life: poor adherence to treatment for physical comorbidities, and increased morbidity and mortality. According to PCPs we interviewed, these issues contribute to the worry, frustration, and discomfort associated with the management of TRLLD.[30,31] While participating psychiatrists reported managing TRLLD as central to their practice, they also found it emotionally taxing due to the tension between their desire to see their patients improve and a frequent lack of improvement despite the deployment of the full pharmacotherapeutic armamentarium.

To address challenges with access to, and implementation of, treatment for TRLLD, providers suggested a variety of recommendations including a shift towards integrated care, improved education and dissemination of evidence-based treatment algorithms, and the use of technology such as telehealth and electronic health records (Table 1). These unsurprising recommendations should be considered in the context of two insights from our interviews: first, the emotional toll that treating TRLLD has on providers with, as discussed above, its different causes in PCPs and psychiatrists; second, the counterproductive rules in psychiatric practices when patients miss initial or follow-up visits. Telehealth has the potential to alleviate some of the

emotional toll reported by providers managing TRLLD and to address many of the barriers to the attendance of care visits experienced by patients with TRLLD. However, while telehealth care has been shown to be feasible in older adults with mental disorders, its implementation has been slow.[32,33] The COVID-19 pandemic is creating a systemic shift towards telehealth; a recent report estimated that US physicians are seeing 50-175 times more patients via telehealth than they did prior to the pandemic.[34] Several changes in Medicare are enabling this shift: equalization of reimbursement for telehealth and in-person services; ability to receive telehealth services in any location without requiring an established relationship with a physician; and physicians being allowed to see patients in state in which they are not licensed.

What was a priority for physicians and patients prior to the pandemic[35] is shifting to an imperative in the face of the pandemic.[36,37] If Medicare changes are maintained following the pandemic, they can mitigate some of the barriers reported in this study. Patients with TRLLD would be able to access via telehealth psychiatrists located in different geographic areas, which would particularly benefit remote or rural locations. Also, patients with TRLLD would be able to keep appointments despite motivation, mobility, or weather issues. Telehealth may also facilitate the implementation of integrated care models which have been shown to be more effective than usual care for the treatment of depression and suicidality, both in those with and without significant medical comorbidities.[38-41] However, the implementation of these models is challenging, in part because of barriers similar to those reported in this study.[7,11] Telehealth decreases the need for physical space, creates access to a larger geographically-dispersed group of mental health specialists, and is linked to a system to access and create health records remotely, including simple measures to monitor treatment progress and outcomes.

This study has some limitations. First, the sample was drawn entirely from providers who participated in a large clinical trial, either as referral sources or as treatment providers, with urban academic sites. Thus, they may have more experience with treating TRLLD or working with multidiscipline teams and our results may underestimate the situation in less-resourced settings. Additionally, while we made multiple attempts to reach providers, we ultimately interviewed the providers whom we could reach and were willing to participate. This could have biased the sample towards providers who had more concerns and complaints, inflating the reported emotional impact of treating TRLLD. However, we described participants' perspectives as they expressed them, as is the goal of qualitative description. Third, we included depression care managers because of their involvement in one trial site, but the small number of them we interviewed (n=4) precludes making any comprehensive conclusions about their perspectives in comparison to those of PCPs and psychiatrists. Finally, this qualitative study was part of a larger pharmacotherapy clinical trial defining TRLLD as two failed adequate antidepressant trials during the current episode. This may have skewed the participating providers towards medication interventions as opposed to psychotherapy or brain stimulation. These limitations are offset by strengths including participating providers' geographic and role diversity and a focus on individual providers' perspectives. Also, our sample size is fairly large, and our findings were consistent across geographical regions and provider types, underscoring the need to improve care for TRLLD.

In conclusion, interviews of providers involved in a pharmacotherapy trial for TRLLD identified four themes related to challenges in the management of TRLLD: insufficient access to psychiatric services, limits of psychiatric management in primary care, a desire to improve the outcomes of TRLLD met with worry and frustration when treatment fails. Providers made

recommendations for improving the care of TRLLD. These recommendations comprise a renewed focus on training geriatric psychiatrists, nurse practitioners, psychologists, and social workers to meet society's demographic changes; the expansion of telehealth to provide access to existing and new providers; and the design of new treatment strategies that can be implemented in the primary care setting.[42]

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Conflicts of Interest

Dr. Karp has served as a scientific advisor in 2020 for NightWare, prepared and delivered a webinar (disease-state, not product-focused) for Otsuka in 2020, serves as scientific advisor for Aifred Health with potential for future equity, and receives compensation for editorial duties from Physician's Postgraduate Press and from American Journal of Geriatric Psychiatry. Dr. Lavretsky receives grant support from the NIH (NCCIH and NIMH), Forest Research Institute and the Alzheimer's Research and Prevention Foundation. Dr. Lenze has received research support from NIH, FDA, McKnight Brain Research Foundation, Taylor Family Institute for Innovative Psychiatric Research, Barnes Jewish Foundation, Takeda, and Lundbeck. Dr. Mulsant holds and receives support from the Labatt Family Chair in Biology of Depression in Late-Life Adults at the University of Toronto. He currently receives research support from Brain Canada, the Canadian Institutes of Health Research, the CAMH Foundation, the Patient-Centered Outcomes Research Institute (PCORI), the US National Institute of Health (NIH), Capital Solution Design LLC (software used in a study founded by CAMH Foundation), and HAPPYneuron (software used in a study founded by Brain Canada). Within the past five years, he has also received research support from Eli Lilly (medications for a NIH-funded clinical trial) and Pfizer (medications for a NIH-funded clinical trial). He has been an unpaid consultant to Myriad Neuroscience. The other authors report no conflicts of interest.

Author's Contributions

Study concept and design: Hamm, Brown, Karp, Lavretsky, Lenard, Lenze, Mulsant, Reynolds, Roose,

Acquisition, analysis, and interpretation of data: Brown, Cameron, Dawdani, Hamm, Karp, Lenze

Drafting of the manuscript: Brown, Hamm, Karp, Lenze, Mulsant

Critical revision of the manuscript for important intellectual content: Brown, Cameron, Dawdani, Hamm, Karp, Lavretsky, Lenard, Lenze, Mulsant, Pham, Reynolds, Roose

Obtaining funding: Lenze, Karp, Lenard, Lavretsky, Mulsant, Reynolds, Roose

Administrative, technical, or material support: Lenard

Supervision: Brown, Hamm, Lavretsky, Lenze, Mulsant, Reynolds, Roose

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436 LEGEND

437 Figure 1 F1: Infographic – Older Adults with Treatment Resistant Depression: Provider

438 Perspectives

439 Table 1 T1: Barriers to Care and Suggested Solutions

440 Supplementary Text S1: Methodological Supplement

441 Supplementary Text S2: Providers Interviewed by Site

442 Supplementary Text S3: Representative Quotes for Each Theme

443