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A journey into the unknown: An ethnographic examination of drug-resistant epilepsy treatment and management in the United States

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ABSTRACT

Patients often recognize unmet needs that can improve patient–provider experiences in disease treatment management. These needs are rarely captured and may be hard to quantify in difficult-to-treat disease states such as drug-resistant epilepsy (DRE). To further understand challenges living with and managing DRE, a team of medical anthropologists conducted ethnographic field assessments with patients to qualitatively understand their experience with DRE across the United States. In addition, healthcare provider assessments were conducted in community clinics and Comprehensive Epilepsy Centers to further uncover patient–provider treatment gaps. We identified four distinct stages of the treatment and management journey defined by patients' perceived control over their epilepsy: Gripped in the Panic Zone, Diligently Tracking to Plan, Riding a Rollercoaster in the Dark, and Reframing Priorities to Redefine Treatment Success. We found that patients sought resources to streamline communication with their care team, enhanced education on treatment options beyond medications, and long-term resources to protect against a decline in control over managing their epilepsy once drug-resistant. Likewise, treatment management optimization strategies are provided to improve current DRE standard of care with respect to identified patient–provider gaps. These include the use of digital disease management tools, standardizing neuropsychiatrists into patients' initial care team, and introducing surgical and non-pharmacological treatment options upon epilepsy and DRE diagnoses, respectively. This ethnographic study uncovers numerous patient–provider gaps, thereby presenting a conceptual framework to advance DRE treatment. Further Incentivization from professional societies and healthcare systems to support standardization of the treatment optimization strategies provided herein into clinical practice is needed.

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1. Introduction

Drug-resistant epilepsy (DRE) poses an increased risk of hospitalizations, medication non-adherence, and poor quality of life (QoL) [1–11]. A multitude of factors could account for why patients have unaddressed DRE, such as gaps in disease education, socioeconomic and societal limitations to healthcare access, lack of care-

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giver involvement, and healthcare provider (HCP) reluctance to move beyond pharmacological therapies, among others [12,13]. Furthermore, HCP knowledge gaps can lead to underestimations of the damage incurred by DRE and an overestimation of the risks of surgery [14]. These gaps put patients at greater risk of serious adverse clinical events that ultimately contribute to the overuse of healthcare resources [15,16].

Identifying unmet needs between patients and HCPs could address 'patient–provider' treatment gaps: resource and educational deficiencies that adversely impact patients' treatment course. Fully embracing a patient-centered treatment approach, thereby further distancing from a hospital-centric approach to strengthen the patient–provider relationship has been advocated for to address some disease management gaps [17,18]. Despite acknowledgment of this issue, there still exist multiple intervention points along a patient's epilepsy journey where addressable gaps occur [19]. In-depth observations through ethnography, an observational science to qualitatively understand the needs of patients could help identify and address these gaps, especially for DRE treatment management.

A comprehensive patient perspective to fully understand existing treatment gaps is needed to advance DRE standard of care. Formally examining these gaps with an observational science also holds the potential to institute large-scale change. Despite its need, a comprehensive ethnographic examination of patients' journey from their first seizure to managing DRE is unfortunately absent [20,21]. We therefore mapped their epilepsy treatment and management journey to understand key experiences and challenges in living with and managing DRE through qualitative ethnographic field assessments in the United States. These assessments allowed us to study both patients and HCPs within their day-to-day context to reveal patient–provider gaps that significantly impact their experience with managing this difficult-to-treat disease.

2. Materials and methods

A contracted team of medical anthropologists from a major global management consulting company conducted ethnographic field assessments across the epilepsy care continuum in 2019 to understand the experiences of living with and caring for those with DRE (Fig. 1). A third-party recruitment company identified and enrolled study participants within pre-defined criteria (Fig. 1c). The study was double-blinded to reduce potential biases from both the study sponsor and participants.

2.1. Patient recruiting criteria & ethnographic assessments

Ethnographic field assessments were conducted with patients, their families, and applicable caregivers across the United States (Fig. 1a). Patients were asked to self-identify themselves as fitting pre-defined criteria for the study to qualify (Fig. 1c). Patients were also recruited from an equal spread across CECs and community clinics. The duration of patients' epilepsy before receiving a DRE diagnosis and the number of anti-seizure medications prescribed to them at study initiation were not considered. Subject diversity was ensured by including patients with a mix of commercial and government funded insurance. Regional and socioeconomic representation across the country in Massachusetts, California, Nebraska, and Pennsylvania attempted to account for individual, as well as insurance and reimbursement policy differences. Because of its long-standing use, a patient's knowledge of and/or experience with the vagus nerve stimulation (VNS) Therapy® was used to assess their knowledge of antiepileptic neuromodulation treatment modalities [22] (Fig. 1c).

Approximately 40 h of total observation and discussion in patients' homes were performed. Ten patients (5 adult, 5 pediatric) between 4 and 65 years old, 50% female, all diagnosed with DRE and at least focal epilepsy, and with different time horizons of DRE diagnoses (2 months-30 years) residing across the United States were identified and included in the study. Assessments were in-home, lasted approximately four hours, and included observations, semi-structured interviews, and journey mapping exercises (Fig. 1b).

2.2. HCP recruiting criteria & ethnographic assessments

Qualitative ethnographic assessments with 20 HCPs (6 neurologists, 7 epileptologists, 4 neurosurgeons, and 3 nurse practitioners) were conducted in the United States at both community clinics and level 3 and 4 Comprehensive Epilepsy Centers (CECs) representing adult and pediatric specialties (Fig. 1a,b). A qualitative assessment relative to the number of patients with DRE an HCP saw per year and VNS Therapy prescribing behavior was used to assess non-pharmacological treatment experience. Approximately 25 h of observation and discussion in clinics and CECs was conducted, representing a mix of on-site assessments (four to eight hours) and telephone interviews with key stakeholders involved in the DRE care ecology. Other HCP assessment activities included touring facilities and meeting key HCPs across the epilepsy care continuum, roleplay of the patient-family experience, and group exercises to identify synergies and frictions between different HCP groups (Fig. 1c).

2.3. Constructing the journey of a patient with epilepsy

Four stages of the epilepsy journey were defined by patients and their families (Fig. 2). The average duration of how long patients spend within each stage was derived from ethnographic fieldwork assessments. Combined methods of data analysis, including inductive and deductive analyses, journey mapping, and needs clustering were used to illustrate an aggregate of the patient journey. The "y-axis" of the patient journey was generated through a process of inductive reasoning whereby an intensive vocabulary analysis of key words and phrases was performed.

2.4. Ethical considerations

A confidentiality agreement and consent to recordings was signed by each study participant. The study sponsor (LivaNova) was blinded to study participants and was labeled as "an anonymous medical technology company." This study was conducted following the ethical standards outlined by the International Chamber of Commerce International Code on Market, Opinion and Social Research and Data Analytics (ICC/ESOMAR).

3. Findings

Both patients and their families identified words used repeatedly when describing their experiences with epilepsy. These phrases led us to deduce that a 'perceived sense of control' was how patients and caregivers tolerate living with and managing this disease. This conceptual framework allowed us to qualitatively identify four unique stages of patients' epilepsy treatment and management journey. Ethnographic assessments from HCPs allowed us to provide clinical context to patient experiences. 'Moments of meaning', or critical inflection points that highlight notable patient–provider gaps are also presented within each stage (Suppl. Figs. 1-5).

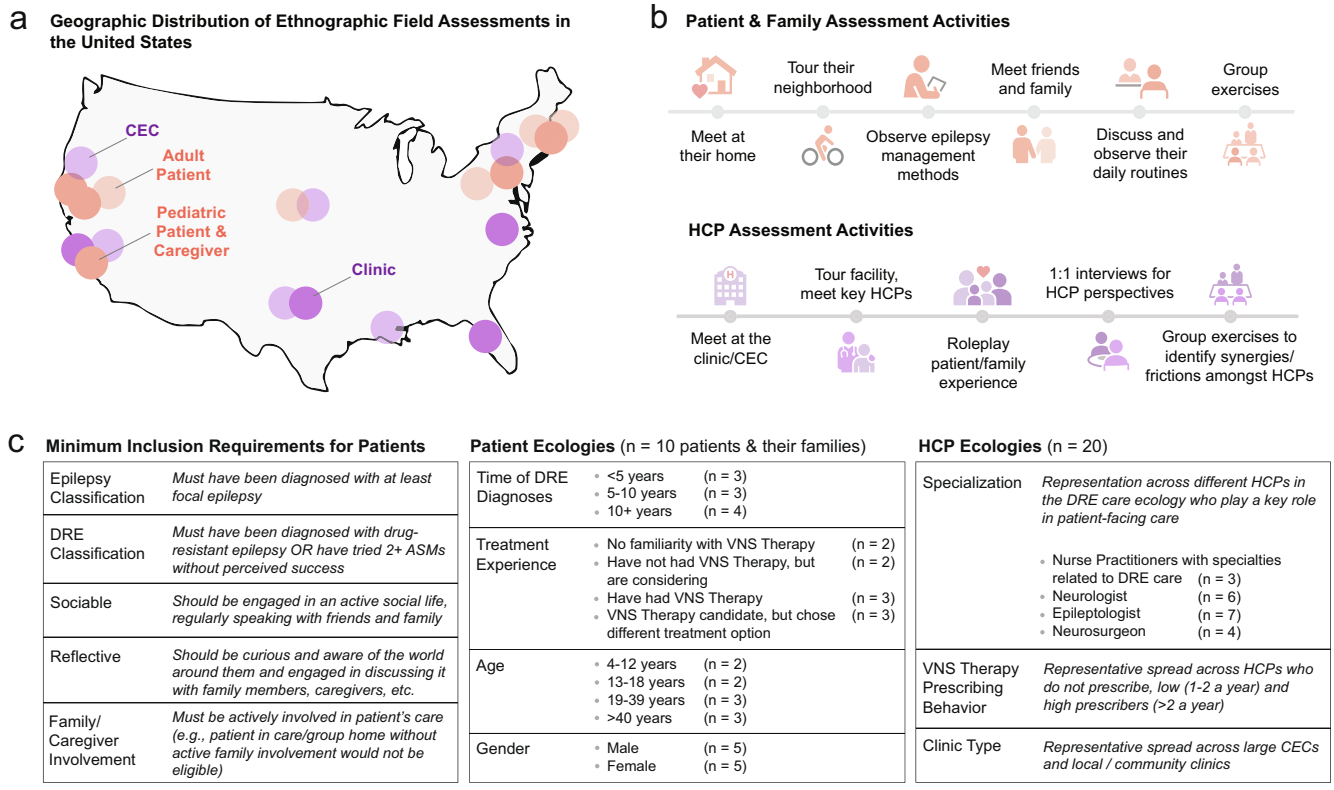

Fig. 1. Geographic distribution and overview of ethnographic field assessments. (a) Geographic distribution of patient, family, and HCP ethnographic field assessments in the United States. (b) Activities performed during ethnographic field assessments. Top: In-home assessments were conducted with patients and their families through observations, semi-structured interviews, and journey mapping exercises. Bottom: Assessments with HCPs in clinics and CECs included interviews, roleplaying of the patient and family experience, and group exercises. (c) Demographics and key recruiting criteria for patients and HCPs included in ethnographic assessments. Left: Minimum study inclusion requirement for patients and their family/caregiver. Middle: Patients in the study were 4–65 years old, mix genders (50% female), all diagnosed with DRE with at least focal epilepsy, and with different time horizons of DRE diagnoses (2 months-30 years). To further ensure patient diversity, we assessed a patient's exposure and experience with VNS Therapy®. Right: A spread of low and high VNS Therapy prescribers were included based on an internal qualitative assessment relative to the number of patients with DRE an HCP saw per year. Recruited HCPs came from a spread of community clinics and CECs (level 3 and 4 centers), as well as from both adult and pediatric specialties. Abbreviations – Anti-seizure medication, ASM; Comprehensive Epilepsy Center, CEC; drug-resistant epilepsy, DRE; Healthcare provider, HCP; Vagus nerve stimulation, VNS.

3.1. Stage I – Gripped in the panic zone

The first stage encompasses a patient's first seizure experience and their subsequent search for answers (Fig. 2, Panel I). This stage often lasts between one month and two years where an initial seizure rocks the very foundation of families (Suppl. Fig. 1). Though a diagnosis of epilepsy is often quickly received, families grapple with an up-hill battle to understand more about what kind of epilepsy they have. We observed that children appear to access and cycle through diagnostic tests faster than adults during this stage because of parent advocates (Fig. 2, Panel I). Healthcare providers expressed that patients who do not advance beyond this stage after six months can signify inappropriate treatment management, lack of open communication with their neurologist, or an attempt to seek numerous consultations for a second opinion before initiating treatment.

Although the first seizure is different for everyone, patients describe it as a moment that was utterly destabilizing (Suppl. Fig. 1). Clinical trial results and information from internet forums are how patients and their families most frequently fill in knowledge gaps between what HCPs tell them and what they do not understand. Adults struggle to balance their work, family priorities, and loss of independence with getting tests conducted quickly to start treatment. Parents can struggle from support network and socioeconomic standpoints. We observed most parents will shift their priorities entirely to focus on ensuring that their child undergoes the necessary testing (Fig. 2, Panel I). Epilepsy treatment is undoubtedly a family affair.

3.2. Stage II – Diligently tracking to plan

Patients reaching a high perceived sense of control over their epilepsy is an entry milestone of Stage II (Fig. 2, Panel II). This control is achieved when patients feel they have been presented with an initial 'game plan' from their care team for starting to manage their epilepsy with medication. Patients are hyper-focused on 'tracking according to plan' during this stage – often keeping detailed diaries of seizure type, frequency, and triggers to make sense of their seizures and gauge medication efficacy. Seizure diaries act as a gateway for patients to build literacy around their seizures while serving as a means by which to share valuable insights with their care team (Suppl. Fig. 2). Many patients had stories of how they record their seizure activities in unique ways, giving them a sense of empowerment over what was happening (Fig. 2, Panel II).

However, many patients expressed they did not have the seizure vocabulary necessary to effectively communicate their experiences with their care team despite achieving a heightened sense of control over their epilepsy during this stage (Fig. 2, Panel II). This lack of literacy or mastery of the 'seizure lexicon' significantly hindered both timely care and patients' ability to explain their epilepsy to co-workers and friends to avoid stigmatization.

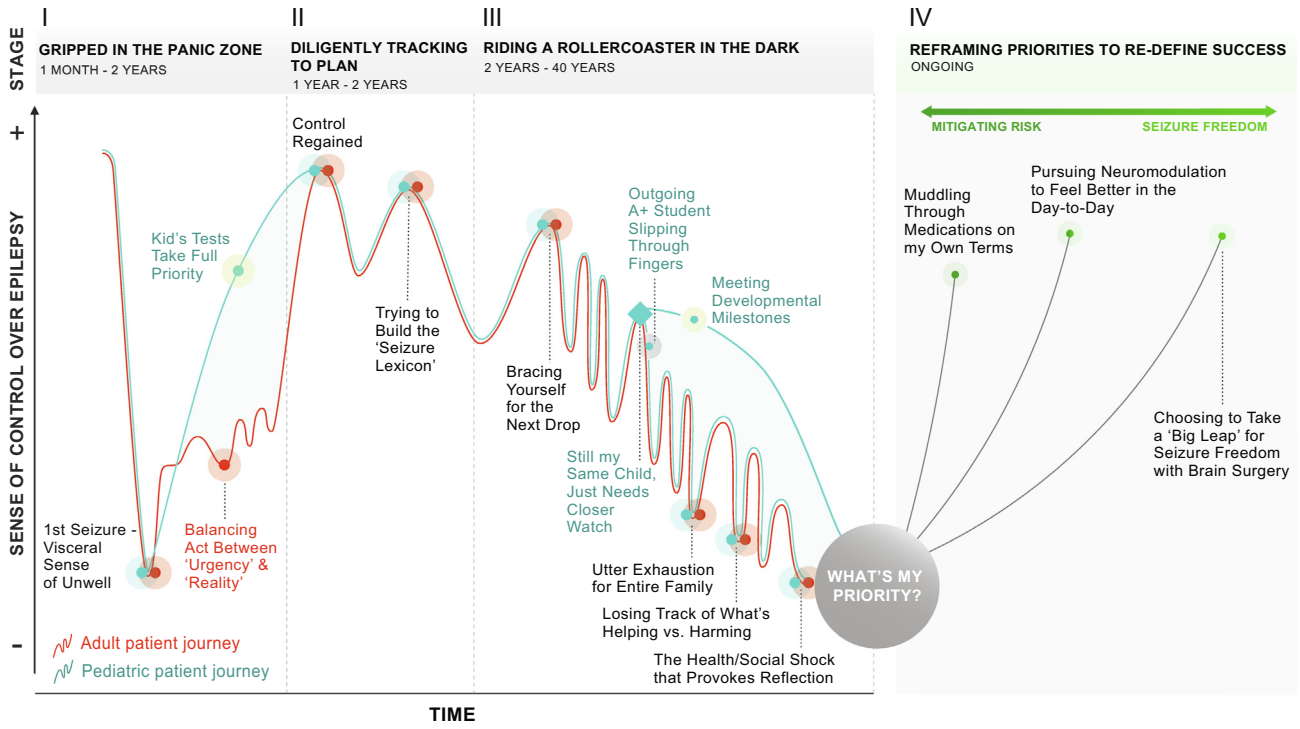

Fig. 2. Epilepsy treatment and management journey. Conceptual framework of adult and pediatric patient epilepsy treatment and management journeys (pediatric, teal lines; adult, red lines). Journeys are plotted across time with respect to ethnographically identified stages. Each stage includes 'Moments of Meaning' (circles), or critical inflection points that reflect pediatric (teal circle) and adult (red circle) patients' unsatisfied disease-related needs (Suppl. Figs. 1-5). The Y-axis of the journey represents a patient's 'sense of control' over their epilepsy experience, with higher elevations representing more control both socially and emotionally. The average duration of how long patients spend within each stage was derived from ethnographic fieldwork assessments (top). Yellow circles signify Moments of Meaning where pediatric patients' sense of control is uniquely heighted compared to adults. Shaded teal area illustrates difference between pediatric and adult patient journeys. (I) *Stage I – Gripped in the Panic Zone*. Stage I (1 month to 2 years) encompasses a patient's first seizure experience and the subsequent search for answers marked by a rapid decline in patients' sense of control. Pediatric patients and families regain their perceived sense of control quicker than adult patients due to parental treatment advocacy (yellow circle). (II) *Stage II – Diligently Tracking to Plan*. Patients in Stage II (1 to 2 years) establish a heightened sense of control over their epilepsy after they start keeping detailed seizure diaries in an attempt to make sense of their seizures by building their seizure lexicon. (III) *Stage III – Riding a Rollercoaster in the Dark*. Patients struggle with the unstable and unpredictable nature of their seizures and coincides with receiving a DRE diagnosis. Patient's sense of control by the end of Stage III reaches a low level comparable to when they experienced their first seizure. (IV) *Stage IV – Reframing Priorities to Redefine Success.* Patients who reach this stage arrive at a critical junction in their journey where they seriously contemplate their priorities for 'living a good life' with epilepsy. Though still seeking control, patients start to navigate along a new axis of control, between 'seizure freedom' and 'mitigating risk'. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

We discovered that adults desire additional tools for disease management, likened to the supportive role parents and caregivers serve for children during Stage I (Fig. 2, Panel I).

3.3. Stage III – Riding a rollercoaster in the dark

Families feel like they are 'riding a rollercoaster in the dark' as they cycle through overlapping medications and doses by Stage III, struggling with the unstable and unpredictable nature of their seizures and side effects. We observed that this stage has the largest range of 2–40 years and coincides with receiving a DRE diagnosis (Fig. 2, Panel III). Patients struggle with the perception of the constantly changing nature of their seizures and describe them as a 'black box' (Suppl. Fig. 3). As the impact of accumulated iatrogenic effects manifest, patients report feeling that what is 'harming' and what is 'helping' becomes blurred as they abandon previous efforts to track and understand their seizure activity. Not surprisingly, a substantial decrease in patients' sense of control over their epilepsy is observed moving through this stage (Fig. 2, Panel III).

For parents, Stage III represents a key decision when they observe a noticeable change in their child's cognition and social skills. Fearing that it may signify a permanent disruption in their child's ability to meet developmental milestones, many parents take immediate action to research new doctors and treatment options (Suppl. Fig. 3). This vigilance allows children to move through this stage faster than others (Fig. 2, Panel III). Similarly, we found that patients who were treated at a CEC experienced a swifter progression through this stage versus those treated at community clinics. For other parents we met, they believe their child is not really that dissimilar from the person they were before the seizures and medications started (Suppl. Fig. 3).

Most families complained of the extreme stress and fatigue that sets in at this point. Relationships between spouses and siblings become increasingly strained as families try to cope by making structural changes to their homes and routines – specifically optimizing sleep: the loss of which is described as the most torturous part of the experience in living with a loved one with epilepsy (Suppl. Fig. 3). From a treatment standpoint, some patients report that surmounting medication side effects may be counterbalancing any improvement in seizure frequency. There are clear patterns on perceptions of 'irreversibility' that can manifest on both physiological and social levels (Suppl. Fig. 4). This is a significant turning point where patients, in their search for more control over their epilepsy, begin to actively weigh whether they want to continue chasing seizure freedom or instead, focus more on mitigating risk and improving their QoL. A drastic decrease in patients' sense of control over their epilepsy may lead them to consider surgical treatment options for the first time.

3.4. Stage IV – Reframing priorities to redefine treatment success

Patients who reach this stage arrive at a critical junction in their disease trajectory where they contemplate their priorities for 'living a good life' with epilepsy. Patients start to navigate along a new axis of control, between 'seizure freedom' and 'mitigating risk' (Fig. 2, Panel IV). After years spent counting seizures and chasing seizure freedom, some patients feel exhausted and believe they have put their lives on hold to achieve something they no longer believe is attainable. Patients begin to redefine ideas of 'success' with seizure management and contemplate different trade-offs (e.g., accepting a few seizures if they can reduce the impact of medication side effects). 'Success' for many centers around optimizing their QoL between seizures.

While some patients are still hoping for seizure freedom as a form of control, they are weighing that form of control against a fear of what they may lose (Fig. 2, Panel IV). Patients who made the decision to stay on medications found a routine that worked for them by readjusting their priorities to maximize the moments between seizures (Suppl. Fig. 5). By this point, they had become familiar enough with their seizure symptoms that they built routines and practices in their lives to accommodate seizures as and when they happened: an unfortunately perceived complacency. Patients who pursued a neuromodulation therapy reported their decision was motivated by the desire to assume more control over their day-to-day seizure rhythms (Suppl. Fig. 5). Finally, patients who opt for brain surgery have reached a point where they 'feel like they do not have a lot of options anymore' (Suppl. Fig. 5).

4. Discussion

Epilepsy disrupts biological, mental, emotional, and social domains of a patient's life from their very first seizure. The eventual panic observed in patients with DRE and their families from disruptions in these domains undermines self-confidence due to an ever-present perception of threat to their health, independence, and sense of wellbeing. Furthermore, the spatiotemporal pattern of recurring seizures across one's lifespan can significantly degrade their QoL. Our ethnographic assessments allowed us to build a conceptual framework to qualitatively illustrate that disease severity is internally reflected in patients' sense of control over managing their epilepsy (Fig. 2). Identifying bottlenecks in both epilepsy and DRE treatment and management while addressing ethnographically identified patient–provider gaps with strategies to optimize care can potentially help ameliorate these issues.

4.1. Ensure early treatment & establish support networks upon 1st seizure

Enacting treatment optimization strategies, even as early as their first seizure, may help patients achieve a long-lasting control over their epilepsy. One prominent unmet need after a patient's first seizure revolves around access to testing (Suppl. Fig. 1). Assistance for patients to physically get to and from clinics, paired with education on the importance of prompt testing can prevent treatment delays (Fig. 2, Panel I). The latter is especially needed for patients whose seizures are less severe or infrequent. At-home testing options, dedicated travel assistance programs and enhanced education on the importance of testing through foundations and clinics can promote earlier intervention (Fig. 3). Even in the clinic, the need to streamline testing into a single-session can reduce the duration and cost of presurgical epilepsy evaluations [23].

Epilepsy surgery is currently underutilized despite offering the highest probability of seizure freedom early in a patient's treatment journey [24–29]. Surgical underutilization could be caused by several factors, from late incorporation into center's treatment algorithms and procedure-related knowledge gaps among HCPs, to a misunderstanding of its risks [14]. As identification of surgical candidacy early in the disease process is essential for better outcomes, it is important for patients to be educated on and evaluated for neurosurgical options early in their epilepsy treatment journey. This could potentially be achieved by standardizing the incorporation of neurosurgeons into patients' initial care team. If a surgical candidate, patients should be empowered to select their care team, provided access to a second opinion, and thoroughly educated on procedure expectations (Fig. 3a).

Technological advances can potentially revolutionize epilepsy testing and surgical evaluation by providing reliable information about disease etiology, periodicity, and burden. Accurate biometrics from machine learning and artificial intelligence analyses of electroencephalography data, for example, have the potential to provide rapid clinical insights on surgical candidacy, seizure forecasting, and rapid acknowledgment of medication efficacy and failure [30,31]. Advances in remote long-term video monitoring facilitated by family members or caregivers for identification of nonepileptic seizures could protect patients from undergoing unnecessary treatments [32]. Such technological advances have the potential to create a future paradigm shift by introducing novel epilepsy treatment and management pipelines throughout a patient's journey [33–35] (Fig. 3a, dashed yellow lines). These advances have yet to be fully adopted or realized, however.

From a patient perspective, consequences unique for teens and adults after their first seizure can be social and vocational (Suppl. Figs. 3 & 4). Support in the form of a care package with social, legal, and financial information should be readily available to protect patients against a decline in control early in their epilepsy treatment journey (Fig. 3b). Virtual peer-to-peer information exchanges, participation in groups like the Epilepsy Learning Healthcare System, and hospital facilitated educational sessions can serve as strong support network venues for patients [36]. We observed that parents also lack support networks, highlighting the need for epilepsy-specific training programs to both cope with and become more involved in their child's treatment [37–40]. Finally, implementing cognitive and behavioral interventions, in addition to incorporating a psychiatrist into patients' long-term care team, will standardize mental health evaluations and potentially heighten their QoL [41,42].

4.2. Digital tools to improve education, communication & treatment

Increased disease process-centered education, empowerment through shared decision-making, and digital tools to enhance patient–provider communication can further guard against a decline in patients' control over their epilepsy [43,44] (Fig. 2, Panel III). Patients agree that a streamlined digital tool to report seizure breakthroughs directly to their HCP would be beneficial. Digital seizure diary applications can also help patients learn more about their seizures, improve patient–provider communication, and provide smart, actionable analytics to inform clinical decision making [45–47]. Additionally, virtual appointments through electronic patient portals could increase treatment access, especially for difficult to reach rural and group home patient populations [48].

Patients during our assessments expressed the desire to better understand the spectrum of providers and treatment options available to them. A potential solution is a patient-friendly geographic guide to epilepsy care facilities to empower patients to take a lead role in building their care team (Fig. 3b). Likewise, a dedicated patient navigator can further empower patients who face socioeconomic and healthcare system barriers when trying to access quality care [49]. More importantly, patients need enhanced education

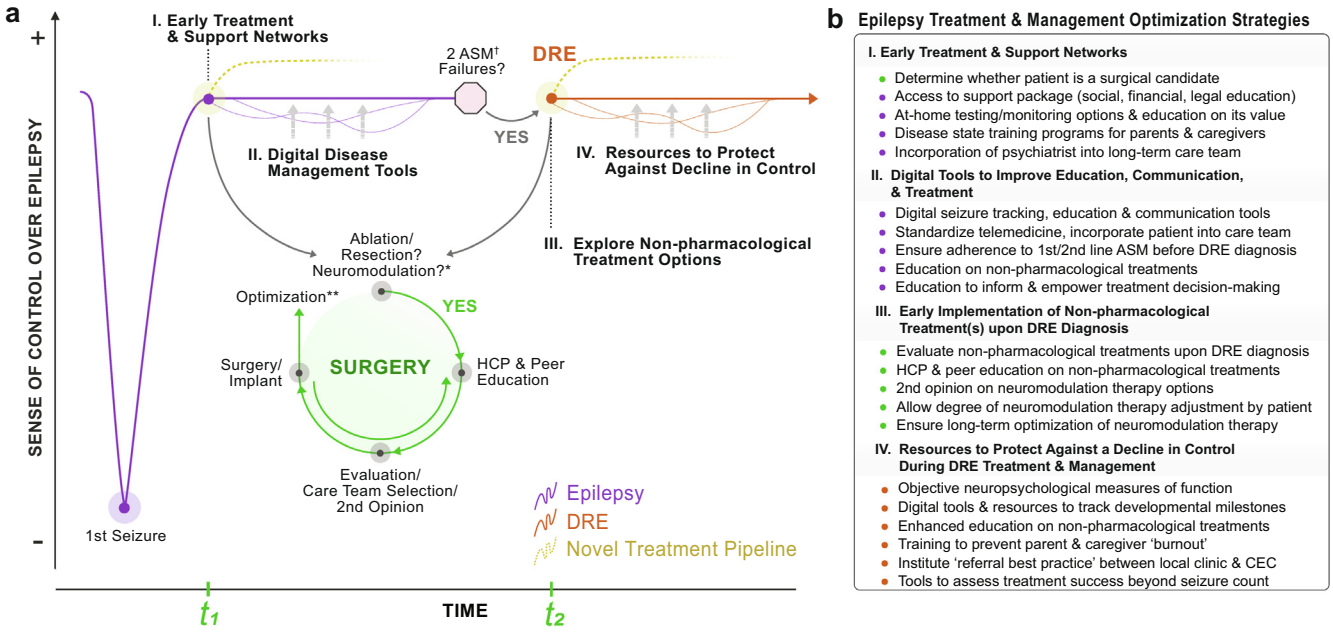

Fig. 3. Reimagined journey of a patient with epilepsy with respect to treatment and management optimization strategies. (a) Reimagined journey of a patient with epilepsy. After a patient's first seizure, early treatment initiation supplemented by support networks will help patients establish a heightened sense of control over their epilepsy (purple line). Surgical candidates should be identified and evaluated in this stage to ensure early treatment (green lines). Digital disease management tools to improve education and patient–provider communication will guard against a decline in control throughout a patient's epilepsy journey. If a patient receives a DRE diagnosis (orange line), non-pharmacological treatment options should be considered the gold standard, including neuromodulation therapies (green lines). To further protect against a decline in control when drug-resistant, additional resources should be provided to optimize quality of life. t1 and t2 along the x-axis represent optimal surgical intervention or neuromodulation implantation time points during a patient's epilepsy treatment and management journey. Future paradigm shifts through technological advances in epilepsy and DRE treatment and management have the potential to further heighten patients' sense control (yellow circles and dashed lines). Vertical arrows signify protection against a decline in control by employing treatment and management optimization strategy implementation. (b) Descriptions of epilepsy treatment and management optimization strategies. Colored dots correspond to journey stage in panel 'a'. *Evaluation for neuromodulation therapy when drug-resistant. **Optimization of neuromodulation therapy if applicable. † DRE is defined as failure of adequate trials of two tolerated, appropriately chosen and used ASM schedules (whether as monotherapies or in combination) to achieve sustained seizure freedom [58]. Abbreviations: anti-seizure medication, ASM; Comprehensive Epilepsy Center, CEC; drug-resistant epilepsy, DRE; healthcare provider, HCP. (For interpretation of the references to color in this figure legend, the reader is referred to the web version of this article.)

on what it means to be drug-resistant and the non-pharmacological treatment options available to them. Empowerment through these resources could increase active patient participation in their own care team and further democratize the patient–provider treatment decision process.

4.3. Non-pharmacological treatments as the gold-standard upon DRE diagnosis

Patients may spend years cycling through unsuccessful anti-seizure medications before re-defining what 'success' means for them when they are drug-resistant (Fig. 2, Panel IV). In fact, this medication cycling may account for the delay in reaching Stage IV we observed in patients treated at community clinics verses CECs. Though there is an implicit but unmet need to promptly identify patients with DRE much like the need for early treatment initiation upon a patient's first seizure (Fig. 3a). Coupled with this is a need to increase epilepsy surgery utilization in the United States for drug-resistant patients, with only 4–8% of surgical candidates undergoing procedures [50,14]. It is still to be determined what factors influence this delay in time to surgery but may be multifactorial [51].

Like surgery, the use of neuromodulation in the therapeutic armamentarium is underutilized in the DRE population and was reflected in our field assessments [52,53] (Suppl. Fig. 5). Clarity about seizure burden reduction and associated side effects of each neuromodulation therapy was of particular concern for patients. We also found the pathway to accessing therapeutic resources in clinics for pre- and post-operative support was unclear. Providing a step-by-step illustrative guide of each neuromodulation treatment journey to better understand the surgical procedure, expectations, and side effects would help patients when choosing the most appropriate therapy.

4.4. Resources to protect against a decline in control during DRE management

Resources after a patient's DRE diagnosis are needed to protect against the decline in control observed in Stage III (Fig. 2). A specific impasse for pediatric patients observed during this stage revolves around their inability to reach cognitive and social milestones. Working closely with pediatric HCPs for education regarding these milestones, referrals for academic support, and ensuring that individualized education programs or 504 plans are being followed will enhance their standard of care. Digital tools much like seizure diary applications can be introduced to track and further understand these milestones coupled with formal neuropsychological evaluations as objective measures of function to assess success beyond seizure count [54,55] (Fig. 3b).

Patients that have been referred to a CEC want to feel more confident in the unity of their care team. If referred back to a community neurologist, patients sought continuity in the information being provided. Fostering referral best practices between community clinics and CECs by inviting community providers to epilepsy conferences and establishing a direct line of communication to HCPs at CECs can ensure a closed-loop care team. Family caregivers should also be recognized as members of a patient's care team, who often experience burnout during the later stages of the epi-

lepsy treatment and management journey (Suppl. Fig. 4). Therapy and guidance using the Kübler-Ross model as a foundation can help family caregivers cope with, accept, and even improve their care responsibilities [56].

5. Limitations

Limitations of this study include the selective recruitment of patients with focal epilepsy, allowing patients to self-identify as having focal epilepsy and DRE for study inclusion without confirmation by an HCP, the lack of controls for potential comorbidities, and the potential selection bias introduced by measuring knowledge of or experience with VNS Therapy as a gauge for neuromodulation familiarity. It is therefore yet to be determined to what extent our ethnographic results can be generalized to other epilepsy types or syndromes. Furthermore, we acknowledge that these results may not be representative of all patients with DRE and warrants additional investigation. Another limitation is the potential patient experience bias introduced geographically, where most patients were chosen from the Western or Northeastern United States. This bias could influence our results on Stage II and III trajectories due to the unique experience these patients have from healthcare systems and social safety networks that may differ from the rest of the country (Fig. 2). A larger sample size is needed to address these limitations. Lastly, the conceptual framework of the journey of a patient with epilepsy represents an aggregate of collected experiences and may not be representative of all patients.

6. Conclusions

Ethnographic assessments of difficult-to-treat disease states have successfully identified patient–provider gaps not accessible by quantitative means [57]. By employing this observational science, we discovered the profound impact of untimely disease management leading up to and after receiving a DRE diagnosis. This delay manifests itself after patients are formally given the diagnosis of being drug-resistant, when missed disease education and non-pharmacological treatment opportunities are finally recognized. By identifying unique stages of the journey of a patient with epilepsy, we present treatment and management optimization strategies that could improve patients' sense of control over their epilepsy and empower them to become more active participants in their care. These strategies include incorporating resources to streamline patient–provider communication and introducing surgical treatment options earlier in patients' treatment journey (Fig. 3). Importantly, non-pharmacological treatments should be recognized as the gold-standard upon a patient's DRE diagnosis. Further Incentivization from professional societies and healthcare systems to support standardization of these strategies in clinical practice is needed.

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Author contributions

G.D.R.W contributed to ethnographic data analysis, figure construction, and drafting the initial draft of the manuscript. All authors contributed feedback on figure construction, the discussion section, and approval of the final draft of the manuscript.

Declaration of interest

G.D.R.W and E.C.H are employees of LivaNova.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.yebeh.2021.108319.

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