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Towards a Unified Research Agenda: International Consensus to Advance Understanding and Prevention of Sudden Unexpected Death in Epilepsy

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Abstract
Sudden unexpected death in epilepsy (SUDEP) is a significant research and community priority. In recent years, diverse stakeholders, including researchers, clinicians, charity organizations, people affected by epilepsy, and bereaved families, have collectively identified priorities and recommendations to accelerate understanding of SUDEP risk and prevention. Through comprehensive discussions, shared learnings and priorities have emerged across three broad areas, including clinical research, preclinical science, and awareness and education. To address these priorities, actionable recommendations that focus on providing better infrastructure, tools, data, access and education to advance prevention of SUDEP have been defined.

Keywords
SUDEP, epilepsy, preclinical, clinical, education

Introduction

Sudden unexpected death in epilepsy (SUDEP) is the most common cause of premature epilepsy-related mortality.[1] Defined as "death of a person living with epilepsy where no other cause of death is found post-mortem," SUDEP occurs when a person with epilepsy dies without warning.[2] SUDEP most often occurs at night and may happen during or following a seizure.[3,4] It is estimated that each year, one out of every 1000 people living with epilepsy and one of every 150 people with uncontrolled epilepsy die due to SUDEP.[5] These numbers are likely underestimated due to poor recognition, incomplete death records, and misattributed causes of mortality.[6] SUDEP ranks second only to stroke when considering potential life years lost.[7] To improve the lives of people with epilepsy, it is essential to understand risk factors of SUDEP, identify strategies to reduce risk, inform people about SUDEP, and provide support to bereaved families.

SUDEP research has expanded markedly, becoming a globally recognized issue.[8,9] This article provides a synthesis of international shared priorities,[10–12] recommendations and actionable outcomes to support the prevention of SUDEP.

Shared Priorities in SUDEP Research

Clinical Priorities

There is a clear need to better understand and inform people about the factors that increase the risk of SUDEP, with a specific focus on identifying and tracking modifiable factors to aid prevention efforts. Several clinical and environmental risk factors for SUDEP have been extensively studied, including the presence of generalized tonic-clonic seizures, nocturnal seizures, sleeping alone or unsupervised, and seizure frequency/control;[13–15] however, there is much to be learned about other risk factors.

For example, further research is required to examine the impact of cardiac and respiratory factors, genetics, electroencephalogram (EEG), and sleep[16] on SUDEP. Clinical datasets that capture these parameters and biospecimens are available for analysis to advance knowledge on factors that increase the risk of SUDEP (eg, Center for SUDEP Research). Similarly, it will be important to identify high-risk groups across critical life stages (eg, young adulthood, pregnancy) where tailored preventative approaches could be most effective.

To inform personalized risk prediction for SUDEP, there is an urgent need to utilize population level data across healthcare settings. In the United Kingdom (UK), efforts are underway to support the collection and linkage of routine epilepsy patient data across primary, secondary, and tertiary settings. In the United States (U.S.), efforts toward SUDEP data harmonization across healthcare settings are in their infancy. In both countries, infrastructure to improve data standardization and harmonization is needed to support risk identification and earlier intervention. Ensuring that electronic health records capture standardized information about seizures and clinical risk factors is essential for synthesizing and sharing risk information with patients.

Importantly, there is a need to consider the usefulness of wearable devices to aid seizure detection and prediction. To do so further research is required to evaluate the effectiveness of wearable devices in reducing SUDEP risk. This should be done in partnership with people affected by epilepsy, to support the feasibility, utility, and adoption of these devices in practice. Studies that evaluate the efficacy of alternative interventions to reduce the risk of SUDEP (eg, vagus nerve stimulation) are needed, in addition to SUDEP-specific clinical trial designs to examine SUDEP risk prevention.

Furthermore, it is evident that disparities in accessing healthcare and difficulties obtaining anti-seizure medications (ASMs) may place people at heightened risk of SUDEP. This barrier may be especially pertinent in the U.S., as well as low-income countries, as the cost of ASMs and absence of universal coverage can disproportionately disadvantage those experiencing greater economic restrictions. People with epilepsy who have limited access to care are at higher risk of mortality.[17] Research to inform the most effective ways to improve access to care and affordable ASMs is needed.

Preclinical Priorities

Preclinical research has advanced our understanding of SUDEP, implicating seizure-related disruptions in respiratory and cardiac function as potential contributors.[18–20] The precise biological mechanisms of SUDEP, however, remain unclear. Animal models, from mice to zebrafish, offer valuable insights, but variability in genetics, comorbidities, and lack of standardization in data collection and terminology across labs can hinder reproducibility and translatability to human SUDEP.[21,22] A clear definition of what constitutes a "SUDEP model" is required, as well as a curated, searchable registry of preclinical models, detailing strain, sex, age, seizure phenotype, circumstances of death, and distinguishing SUDEP from deaths due to status epilepticus, or unrelated causes. A key goal is to establish reporting standards that include synchronized EEG, electrocardiogram (ECG), and respiratory recordings, seizure semiology and duration, body position, and relevant pharmacology. Establishing this consistency would enable meaningful comparisons across laboratories and be a first step in facilitating the accumulation of data into a shared model ontology linked directly to human SUDEP registries.

To this end, CURE Epilepsy developed preclinical SUDEP common data elements (CDEs)[23–25] to support a standardized data reporting framework for the measurement and recording of key variables within preclinical SUDEP studies. Utilizing these and similar resources[26,27] will enable robust cross-lab aggregation and meta-analysis, transforming isolated datasets into a cumulative evidence base. Progress will be accelerated by shared infrastructure, including epilepsy brain banks, with protocols for retaining and sharing tissue from animals that

die during SUDEP-like events. Data repositories linked to model registries should include raw physiological signals, metadata, and analytic code, enabling re-analysis and pooled studies.

The biological themes pertinent for SUDEP include brainstem and arousal network failure, peri-ictal respiratory suppression, and autonomic instability. These processes should not be seen as isolated endpoints but as parts of an integrated cascade, with seizure activity triggering multi-system dysfunction. The field should strive towards simultaneous multi-system recordings (ECG-respiration-autonomic-video-EEG measures) in survival and terminal studies. An emphasis on brainstem spreading depolarization[28] as a potentially modifiable mechanism of cardiorespiratory collapse builds on evidence that seizure-induced spreading depolarization can invade brainstem nuclei controlling breathing and heart function. These mechanistic hypotheses should be tested within standardized model frameworks, using consistent physiological and behavioral endpoints.

In addition, a common priority includes the need for bidirectional translation between preclinical and clinical research. Animal models should be used to generate candidate biomarkers, such as heart-rate variability patterns, that can then be evaluated in patient cohorts, near-SUDEP cases, or high-risk individuals. Conversely, physiological features observed in clinical SUDEP or near-miss cases should be back-translated into animal studies for mechanistic investigation. Genetic models, particularly those involving ion channel and developmental encephalopathy variants, offer an avenue for probing mechanistic underpinnings shared with human epilepsy syndromes. Although their use may raise ethical and financial considerations, larger animal models may reproduce the complexity of human peri-ictal cardiorespiratory physiology, and could therefore be deployed strategically.

There is a critical need to aid researchers who are navigating regulatory requirements to conduct preclinical SUDEP research and also provide support for early-career researchers who are entering this field. Shared learnings in the U.S. have led to the development of a detailed blueprint for sustaining a SUDEP platform, including governance structures and funding models. Expanding and promoting the use of open-access platforms, such as Epilepsy. Science, can accelerate discovery through shared datasets and resources, and foster international collaborations. To effectively address geographic and resource-related disparities, data sharing is essential, an effort that will require broad adoption and commitment from the global research community.

Priorities in Awareness and Education

Globally, there is an urgent need to increase awareness of SUDEP and openly discuss SUDEP risk with patients and families impacted by epilepsy. In the UK, the National Institute for Health and Care Excellence guidelines state that SUDEP risk should be discussed following an epilepsy diagnosis. Research shows that only 20% of UK-based epilepsy professionals discuss SUDEP with affected individuals,[29] although this is higher than other European countries.[30] Despite U.S. guidelines on SUDEP stating that "clinicians should inform their persons with epilepsy that seizure freedom, particularly freedom from generalized tonic-clonic seizures, is strongly associated with a decreased risk of SUDEP,"[31] a survey of parents/legal guardians of children with epilepsy found that the topic discussed by neurologists and known about by parents the least was SUDEP (29.2% and 31.3%, respectively).[32] These findings highlight the critical need to raise awareness of SUDEP via alternative routes. Improvements in SUDEP education for professionals (eg, coroners, medical examiners, death investigators and healthcare providers) and people affected by epilepsy will increase awareness and support risk mitigation. There is also a need to provide education about epilepsy and SUDEP in broader contexts (eg, school and care settings) to raise awareness among the community.

Challenges around SUDEP risk communication is an important priority that requires further attention. The UK-based SUDEP Action developed the SUDEP and Seizure Safety Checklist and EpsMon App (https://sudep.org/about-research/epsmon-app/) to aid risk screening and support discussions between healthcare professionals and patients. Research has shown that this tool can lead to a reduction in individual risk factors for SUDEP.[33] In the U.S., clinical guidelines recommend discussing SUDEP within two medical visits following diagnosis although the implementation of this guideline differs greatly from practice to practice; SUDEP education and SUDEP-related legislation vary widely in the U.S.. Shared learnings across countries highlight the continued need to educate professionals about SUDEP and to identify the barriers that affect how risk is communicated (eg, language, timing, clinical judgement). There is also a greater need to understand patient preferences for communication, including for example direct communication about the topic of risk and death.[34] These steps are critical to ensure that people with epilepsy can implement strategies that will reduce their risk.

In the U.S., epilepsy organizations have highlighted inconsistencies in reporting SUDEP and the impact that this has on surveillance and risk identification. Similar challenges are observed in the UK. SUDEP reporting is captured through death registries or manually by healthcare providers if they are notified about a patient's death, but these efforts should be expanded. There is a pressing need to notify clinicians when a patient dies and to support the timely connection of bereaved families to support services and death registers (eg, SUDEP Action Epilepsy Deaths Register, North American SUDEP Registry). There is currently no mandatory reporting of SUDEP in the UK or U.S.; a standardized and systematic route for reporting SUDEP would inform risk-related research and ensure that patient records are updated.

Towards a Unified Actionable Agenda

Bringing together the shared international priorities for SUDEP research yields a more comprehensive, balanced roadmap to

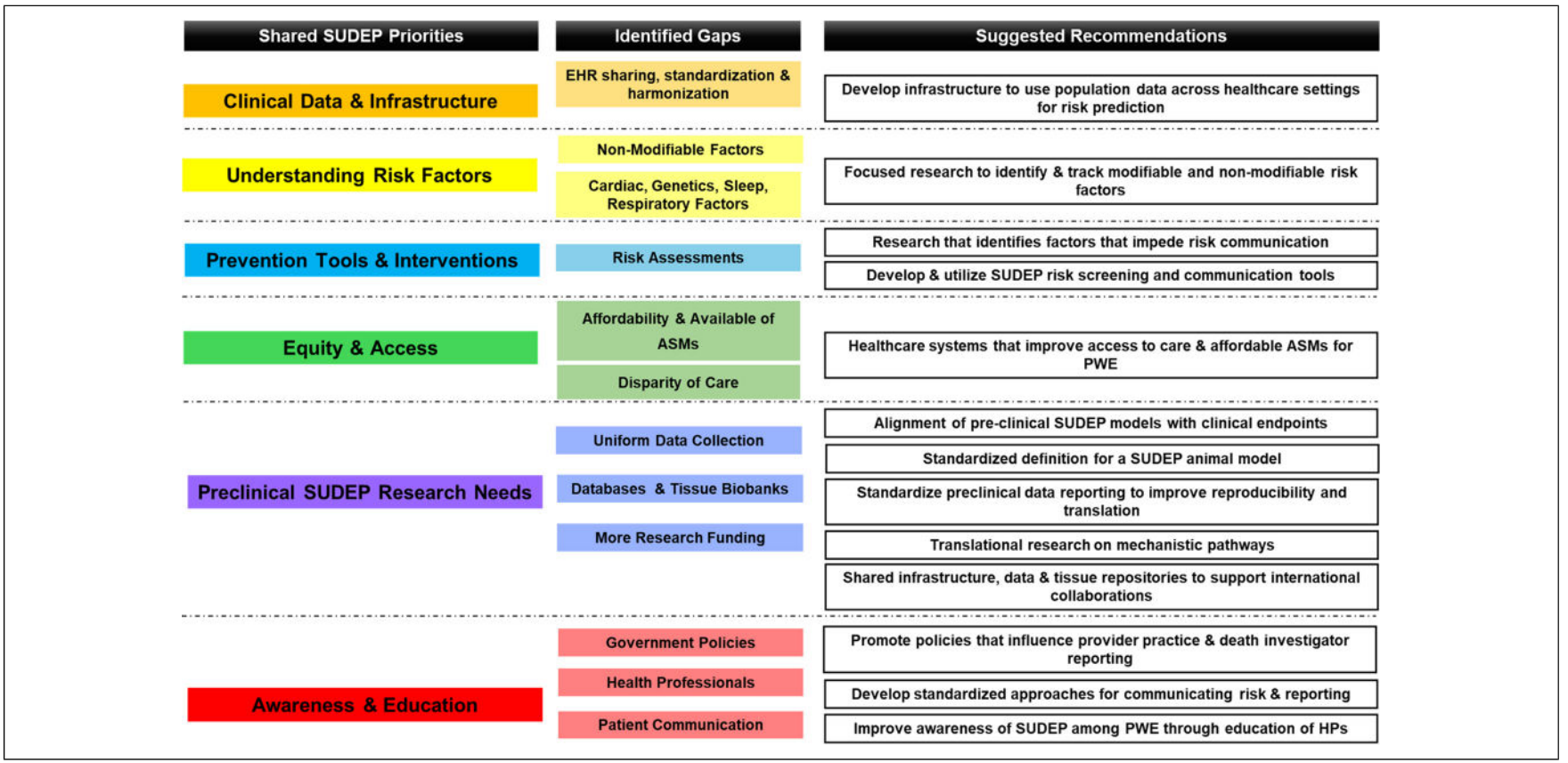

Figure 1. Shared SUDEP priorities and recommendations. Abbreviations: EHR = electronic health record; HP = health professionals; ASM = anti-seizure medication; PWE = people with epilepsy; SUDEP=sudden unexpected death in epilepsy.

actionable outcomes. A synthesis of unified recommendations across clinical, preclinical and awareness/education areas for SUDEP are outlined below (Figure 1).

Clinical

1. **Expand research** to investigate risk factors for SUDEP. New grant mechanisms and initiatives are required to drive transformation and accelerate research. Alongside this, recommendations to expand research on SUDEP form an integral part of the proposed National Plan for Epilepsy in the U.S., and similar efforts should be adopted globally.
2. **Develop personalized risk assessment tools** based on individual risk factors to provide tailored prevention approaches. Build tools based on known clinical and environmental risk factors and refine as new knowledge is generated. Capitalize and leverage population-based data to support the development of these tools.
3. **Drive research to investigate and improve the accuracy of wearable devices** for seizure detection in epilepsy to better understand their role in reducing rates of SUDEP. Subsequent initiatives could focus on improving access routes and technological advances that intervene when biological changes predispose someone for SUDEP.

Preclinical

1. **Adopt a shared model definition and reporting checklist,** including EEG/ECG/respiration monitoring and standard metadata, and deposit all qualifying studies into a curated, searchable registry linked to human datasets.
2. **Methodological,** multi-system physiological recordings should be encouraged, mapping the temporal cascade from seizure onset through post-ictal recovery or death.
3. **Pursue mechanistic targets with translational readthrough,** including brainstem/arousal circuits, serotonergic and adenosine signaling pathways, and brainstem spreading depolarization, while measuring corresponding biomarkers in clinical cohorts.
4. **Build tissue and data access infrastructure,** expanding epilepsy brain banks, promoting tissue retention after SUDEP-like animal deaths, and encouraging use of CDEs.
5. **Invest in people and platforms,** with specific funds allocated for early-career researchers and sustained support for core, well-governed repositories of SUDEP-related data and resources.

Awareness and Education

1. **Provide education on SUDEP and its associated risk factors to**
   (a) Government officials:
      (i) Promote information via the national plans for epilepsy worldwide.
      (ii) Ensure government health departments provide education on SUDEP to all.
   (b) Professionals:
      (i) Refine guidance to support SUDEP risk discussions. Review and build on existing guidance on risk communication and learning modules that have been successful in tackling the SUDEP awareness gap. Engage with healthcare professionals to develop new learning modules as needed and deploy materials for use in clinical settings.
      (ii) Encourage professionals to share information about SUDEP and its associated risks with their patients and incentivize where possible through reimbursement.
   (c) General public:
      (i) Educate the public about epilepsy and associated mortality risks, with an emphasis on SUDEP.
2. **Enhance communication of SUDEP risk** between healthcare professionals and people with epilepsy through the development and adoption of standardized tools that ensure information is delivered in a time-sensitive and effective manner. Where tools and guidance exist, ensure country-wide roll-out to accelerate implementation.
3. **Close the gap on reporting SUDEP within healthcare settings** by supporting registries to enable reporting of SUDEP and provide the infrastructure required for data linkage to electronic health records.

Future Directions

Together, this article summarizes internationally shared SUDEP priorities across three broad areas: clinical, preclinical, awareness and education. A set of actionable recommendations has been developed to accelerate our understanding of SUDEP risks and prevention. Recommendations include, but are not limited to, the creation of shared resources for tissue, data and methods, research that identifies and tracks modifiable and non-modifiable risk factors, and education to improve awareness of SUDEP. Although these offer a helpful starting point, it is important to consider a broader perspective to understand the worldwide impact of SUDEP and target diverse prevention needs. Working in partnership with international organizations and leveraging global expertise will playing a critical role in driving prevention efforts forward and implementing these recommendations for the benefit of people affected by epilepsy. Collaborations across sectors are required and should be prioritized to drive systematic change.

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Declaration of Conflicting Interests

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