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Keeping patients with epilepsy safe: a surmountable challenge?

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Abstract

This quality improvement project was inspired as an answer to a problem that intellectual disability teams have been struggling to manage whilst caring for people with epilepsy (PWE). The issue was that despite guidance to discuss the possibility of sudden unexpected death in epilepsy (SUDEP) be discussed with a newly diagnosed PWE this is rarely done. Additionally when, how, and what to discuss about SUDEP and reduce its risk is arbitrary, non-person centred, and with no structured evidence.

Prior to initiating changes a discussion of SUDEP was recorded in just 10% of PWE. We introduced a check-list to help identify risk factors for SUDEP. We then modified the check-list, and then used it via telehealth, a way of contacting patients and their carers over the phone using the check-list approach. Following interventions, discussions of SUDEP are now recorded in 80% of PWE. Feedback from patients, carers and primary and secondary care professionals has been positive.

We are now developing an app so that patients and carers can monitor their own risk factors, thus empowering them and increasing their knowledge and awareness of SUDEP.

Problem

UK has 600,000 people with epilepsy (PWE), 30% being treatment resistant with a 42% sudden unexpected death in epilepsy (SUDEP) lifetime risk. Sudden death is 20 times higher in PWE to general population. Epilepsy is the 5th highest cause of life-years lost. Forty-two percent of deaths are considered avoidable.[1] Epilepsy NICE guidelines 2004 and 2012 [2] recommend discussion of SUDEP with newly diagnosed PWE. This is rarely followed and until recently only 4% PWE had a recorded SUDEP discussion.[3] In their current publication of the NHS Outcomes Framework, the Government prioritizes the prevention of amenable mortality, making it a core focus for NHS services. Epilepsy mortality features in new NICE Standards as well as NICE Clinical Guidelines. The public health burden of SUDEP alone is estimated as second only to stroke among neurological conditions.[4]

However, the dilemma remains of when, how, and what to discuss about SUDEP. Meaningful structuring of its risk is arbitrary, non-person centered with no evidenced mechanism.

At the two epilepsy services locally in Cornwall for people with intellectual disability (ID), as well as in the general population, the recorded discussion of SUDEP was less than 10%.

In Cornwall, the local community was motivated by the sudden unexpected death of a young nurse. Kt's Fund commissioned SUDEP Action to work in partnership with local researchers and epilepsy clinicians of Cornwall. A strong local partnership of stakeholders with input from national experts including specialists, general practitioners (GPs) and the HM Coroner has embraced this project. All PDSA cycles have involved local and national epilepsy experts, service users, national epilepsy charities, and GPs.

Background

There is a substantial body of work on SUDEP.[5, 6] While no definitive mechanism or factors have been categorically identified, research has shown that there are various factors which can influence risk of an adverse outcome. A detailed literature review was done to identify the nature of the problem and the available evidence. It concluded that evidence of risk factors exist but that this has not been brought together in a systemic manner to help patients, and that clinicians have a person centred discussion of individual risk.

In clinical practice the lack of any tools to support risk management is of concern. Risk management has been highlighted as vitally important to reducing avoidable epilepsy-related deaths, both in research and reporting, but also via prevention of future death reports and fatal accident inquiries held by those investigating sudden and unexpected deaths (www.sudep.org/epilepsy-deaths-reports).

A central theme of all these reports is a lack of awareness or underestimation of risk. In some places the idea that seizures are benign persists, a myth that was widespread in the 1990's. SUDEP occurs today in the context of the reduction of GPs Quality and Outcomes Framework (QOF) payments for epilepsy and in many areas pressures in hospitals to discharge patients early [7] all impacting on the care for those with epilepsy.

Baseline measurement

In 2010 a specialist epilepsy service of 350 complex PWE and ID were reviewed for any discussion on SUDEP. Less than 10% had a

recorded discussion of SUDEP. There was less than 1% of a recorded discussion of a person centred discussion of SUDEP looking into specific patient risk and characteristics in order to empower patents and their family to take safety measures. People with epilepsy want information on risk.[8, 9] While there is some evidence that communication of risk is improving, it is very slow.[10]

Design

The team involves NHS Trusts, universities, primary and secondary care, international epilepsy experts, local specialists, GPs, national epilepsy charities, and service users.

The problem required a solution which was evidenced based, simple to use in a clinical setting, could be easily re-adopted across a range of settings and practices, and would be easy to communicate with patients/carers with clear outcomes for change. It also needed to be modifiable to change and lend itself to a range of applications.

A detailed literature review was undertaken to determine SUDEP contributory risk factors. A total of 18 factors were identified of which 11 were deemed modifiable and having the potential to influence the SUDEP risk. A SUDEP safety checklist [5, 6] to help communicate and quantify risk was postulated taking account the epilepsy factors (duration of epilepsy, seizure increase in frequency and intensity), psychological factors (depression, anxiety), social factors (alcohol intake, compliance, nocturnal surveillance) and biological factors (sleep disturbances, recent medication changes, co-morbid physical health diagnosis etc). This was populated onto an A4 checklist. A safety checklist supports the goal of patient safety by focusing on the modifiable factors and guiding treatment. It can also be a tool to open a person centred discussion with patients that outlines how individual behaviours could impact on risk (for example, lack of compliance, alcohol misuse, etc) and to help engagement between doctors and patients.

Strategy

PDSA cycle 1: The SUDEP safety checklist developed from literature review was used as the data collecting tool for a retrospective study incidentally the largest epidemiological study for SUDEP in England.[11] The study was completed in Cornwall with the coroner and looked at the risk factors of all deaths linked to epilepsy 2003 -2012, helping to confirm and improve aspects of the tool to make it more patient focused. It helped confirm risk factors for worsening of epilepsy control and SUDEP. It additionally highlighted the presence of modifiable risk factors identifiable three to six months prior to the demise of the individual, which when not corrected had a potential cumulative effect on the individual’s seizure control and risk.

The study found that only 20% of people with epilepsy who died suddenly appeared to have been contact with specialist services in the previous year. For those with tonic-clonic seizures (a risk factor for SUDEP), in about 90% of the deaths there was a noted increased in seizure frequency three to six months before their death. One half had a record of alcohol misuse, and a quarter had been taking drugs to treat depression or anxiety.

This cycle highlighted the identifiable presence of modifiable risk factors three to six months prior to demise, which going uncorrected had a potential cumulative effect on seizure control and risk.

PDSA cycle 2: The checklist has now been in use for two years as routine practice in epilepsy clinics in Cornwall and Plymouth, with feedback from over 200 PWE/carers. Ninety eight percent responded positively, and 2% were neutral. Feedback was reviewed and assimilated. Those who scored highly said it would make them think about the issues they could address. Those with low scores, and who were previously aware of SUDEP, said it was a relief to be told. Interestingly this challenges the popular preconception that it would upset patients to discuss SUDEP. It appears a structured approach pays dividends in focusing individuals on items within their locus of control.

Clinical use of the safety checklist with the "at risk population" and subsequent feedback from PWE and their carers showed 98% positive and 2% neutral feedback for the quality of consultation provided using the checklist. High scorers on the checklist said it made them think of issues to address and modify esp. with life style choices.

In the last two years 80% of PWE accessing Cornwall epilepsy services have had their SUDEP risk assessed and recorded. Prior to this locally only 8% of patients were assessed in this systematic way and the percentage is much lower in other areas.

PDSA cycle 3: A telehealth pilot of proactive checks using the checklist was implemented on 15 high risk patients defined as having treatment resistant seizures for over 10 years but stable in the community from an eligible 90 patients with epilepsy from a large GP surgery having a catchment population of 16,000. Every three months a telehealth nurse calls up the registered patients and runs the checklist with them. All results are then communicated to the GP in a timely way. Telehealth services in what was considered a stable "at risk" population led in practice to 17% receiving several interventions in the last one year that would not have happened without the tool. Clinicians across primary and secondary care have reported that this is working well as an intervention to raise awareness and improve the management of high risk patients proving a useful system for clinicians and an improvement on previous clinical practice.

PDSA cycle 4: We are developing a mobile app "EpsMon" that incorporates the risk factors identified and tested in the previous PDSA cycles with a view to empowering service users to monitor their own risk. It is being done in association with Plymouth University and SUDEP Action UK, a national charity.

Results

There have been zero sudden unexpected death in epilepsy in the ID epilepsy service in the last five years. This is from data at the coroners where every death that is epilepsy linked is now

examined. In the last two years, 80% of PWE accessing Cornwall epilepsy services have had their SUDEP risk assessed compared with 8% in the past. Clinical use showed the feedback as 98% positive and 2% neutral. High scorers said it made them think of issues to address.

Telehealth services offered to 15 PWE led to 14 consenting and requesting to take it up. Routine checks using the service and the safety checklist in a stable "at risk" population led to 17% receiving several interventions that would not have happened without the tool. Both the primary and secondary care doctors felt the checklist raised awareness and management of high risk patients.

Our results also challenge the popular preconception that discussing SUDEP would upset patients. A structured approach pays dividends in focusing individuals on items in their locus of control. There is developing evidence of improving safety by indicators of A/E admissions, clinicians, patients and carer feedback and SUDEP reduction.

Lessons and limitations

The tool is used by epilepsy clinicians across Cornwall UK, dispersed to other parts of the UK (Plymouth, Birmingham, etc) and centres in New Zealand, France, Canada, Brazil, Netherlands, etc. Publications were in the top five downloaded for the journal Seizure (Impact Factor 2) in the first three months of publication. The safety checklist has been populated into a Microsoft Excel® spreadsheet.

An initial risk assessment is conducted with the patient during their first consultation in order to gain an individual baseline SUDEP risk rating for the patient. When the patient returns for a follow up or there is a change of treatment/medication then the risk assessment will be undertaken again. Epilepsy clinicians have found the tool simple and quick to use (five minutes in clinic). The assessment is stored in the patient's medical notes. When risk is increasing clinicians can intervene to mitigate. Costs in time and resources are negligible.

Limitations: Changing cultural stereotypes takes a generation. Awareness of the public burden of SUDEP has improved in recent years, but has not been translated into communications with patients. While the SUDEP checklist is being used in many places across the UK and internationally it is still not in the common professional/clinical psyche of the practicing epilepsy clinician. Till date there is ongoing debate of the need and value to inform PWE of SUDEP.[12] However, our work challenges this view.

Conclusion

From governance perspective, knowing how people feel about risk is essential for effective regulation. In this information rich world people increasingly want to know more about their medical conditions, treatment, and their risks. This five minute risk assessment checklist serves to inform PWE about their risk factors and how some lifestyle changes; for example, medication compliance and surveillance at night can have a positive impact on mitigating their individual risk of SUDEP. The evidence based checklist identifying the major risk factors helps both clinicians and patients to focus on minimizing certain risk factors and promotes safety by focusing on the modifiable factors and guides treatment. It is a tool to open person centered discussion and to outline how individual behaviors could impact on risk. It provides documentary evidence for the clinicians on the impact the treatment plan over a period of time and demonstrates effective clinical governance while enhancing patient safety.[13]

While there is no proven intervention or national surveillance of epilepsy mortality, the safety checklist is a simple and practical tool that can be used to demonstrate effective clinical and corporate governance while enhancing patient safety. It can also help give some assurance to bereaved families that every effort was made to reduce risk and prevent a fatality.

It also lends itself to a variety of templates such as paper A4 sheets, Excel format to monitor risk longitudinally, telehealth services and is being developed into a patient self-monitoring mobile app, EpsMon.

While the safety checklist was developed for SUDEP risk, factors such as non-adherence, depression, and substance misuse appear to closely overlap with the findings on risk from literature on all causes of epilepsy mortality.[14-16] The safety checklist, updated to take account of latest evidence, will be available in the spring of 2015.

The updated checklist is available from www.sudep.org. The Checklist risk factors will be reviewed every two years by a committee of international experts in epilepsy brought together by SUDEP Action who would revisit the relevance of each risk factor as per current evidence and if appropriate recommend removal of out dated factors or addition of new relevant factors.

A peer reviewed editorial discussing the application of technology for PWE where in the SUDEP Checklist project utility is discussed has been accepted in the British Journal of General Practice.[17]

The release of EpsMon would raise awareness of epilepsy risk among people with epilepsy who would then approach their health professionals to help them assess and understand risk. In addition the SUDEP checklist has been discussed to be part of the national commissioning tool kit for epilepsy to evidence safety. Promotional events and peer reviewed presentations at epilepsy conferences have been planned or conducted to increase awareness nationally and internationally.

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Declaration of interests

Nothing to declare.

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Ethical approval

Ethics approval was not requisite to this project. Prior commencement of work with the coroner a discussion was held with the regional REC who have given written confirmation of this. Other parts of the project were service improvement issues.