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Published in:
Epilepsy and Behavior

DOI:
[10.1016/j.yebeh.2019.106514](https://doi.org/10.1016/j.yebeh.2019.106514)

Publication date:
2019

Document version:
Peer reviewed version

Link:
[Link to publication in PEARL](#)

Citation for published version (APA):

Newman, C., Ashby, S., McLean, B., & Shankar, R. (2019). Improving epilepsy management with EpSMon: A Templar to highlight the multifaceted challenges of incorporating digital technologies into routine clinical practice. *Epilepsy and Behavior*, 103, Article 106514. <https://doi.org/10.1016/j.yebeh.2019.106514>

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Improving epilepsy management with EpSMon: A Templar to highlight the multifaceted challenges of incorporating digital technologies into routine clinical practice

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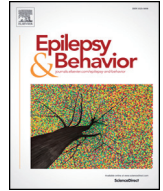
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Highlights

Improving epilepsy management with EpSMon: A Templar to highlight the multifaceted challenges of incorporating digital technologies into routine clinical practice

Epilepsy & Behavior xxx (2019) xxx – xxx

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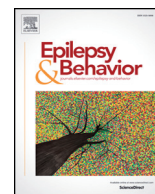
- People with epilepsy (PWE) are at significant risk of premature mortality.
- Physical, mental, & social changes can raise risk of premature mortality in PWE.
- **People with epilepsy** need to be given opportunities to self-monitor and be aware of risk change.
- The epilepsy self-monitor (EpSMon), a digital app, was created to facilitate this.
- The development, implementation, and validity studies for EpSMon **are** presented.

Table 1 Summary of evidence supporting EpSMon meeting NICE evidence standards framework for Digital Technology Solutions.



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Q1 Improving epilepsy management with EpSMon: A Templar to highlight the multifaceted challenges of incorporating digital technologies into routine clinical practice

Q3 Q2 Craig Newman^a, Samantha Ashby^b, Brendan McLean^c, Rohit Shankar^{d,e,*}

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ARTICLE INFO

Article history:

Received 20 August 2019

Accepted 21 August 2019

Available online xxx

Keywords:

Seizure risk

Communication

Management

Intervention

ABSTRACT

The digital epilepsy self-monitor (EpSMon) app was developed to address the challenge of improving risk education and management in the UK. The tool, which has emerged out of quality improvement methodology, demonstrates efficacy and has been met with peer-reviewed support and international awards. The focus of this paper is about the development and integration into care of a digital self-assessment epilepsy risk empowerment tool into the UK health system. This paper provides detail into the specific challenges of incorporating a digital epilepsy intervention into routine clinical practice. Despite a strong narrative and evidence, the engagement of commissioners, clinicians, and people with epilepsy is slow. A breakdown of the strategies used, the current governance landscape, and emerging opportunities to develop an informed implementation strategy is provided to support others who seek to create impact with digital solutions for people with epilepsy.

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1. Introduction

It has been consistently shown in population studies [1] that the risk of premature death is two to three times higher in people with epilepsy (PWE) than in the general population. This mortality risk is highest in the early years following diagnosis [2]. Various recognized and hitherto anticipated factors including nature, frequency and severity of epilepsy, demographics (gender, age), associated factors of genetics, antiepileptic drug compliance, physical, mental, and neurodevelopmental underlay, and social habits provide a complex mix of contributory reasons for premature mortality.

Unnecessary deaths [3,4] continue despite mounting evidence that articulates a narrative of increasing risk being linked to detectable markers [5,6]. Fundamental to this is that PWE remain ignorant to their holistic risk and more importantly change in risk characteristics. Three out of four (73%) PWE attending with a first episode of seizures are not given suitable management advice, 63% have no contact with services, and 71% are nonadherent to their medication from time to time [7]. There are 100,000 emergency department (ED) attendances annually in England [7] illustrating the reactive nature of care which

requires PWE to address problems only in perceived crisis. The issue is even more concerning given that more than half of the people attending ED get admitted but up to 60% of PWE reattend ED within 12 months [8]. This is a topical international problem where independent German and Spanish studies have identified similar concerns [9,10]. Looking at the burden of epilepsy across USA, Europe, and Brazil suggests that seizures, risks, quality of life, and costs are interdependent and current treatment options fail to capture and mitigate this burden [11].

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 unexpected deaths in epilepsy in the UK. A central theme of all these reports is a lack of awareness or underestimation of risk. In some places, a belief that was widespread in the 1990s persists that seizures are benign. A lack of national focus including the removal of epilepsy indicators from quality outcome framework (QOF) in primary care in the UK [12] belays the ambition to reduce amenable mortality.

The value of education has been demonstrated in other areas of health risk [13] with a demonstrated appetite for communication relating to epilepsy risk, from PWE [14].

The SUDEP and seizure safety checklist ("Checklist") venture is an example of a successful epilepsy safety education project [5,6]. In the last 9 years, the Checklist developed from identified risk factors for

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epilepsy mortality has slowly but successfully gained traction to be central to risk communication in the UK [5,6]. The success of the Checklist undertaking shows that the utilization of quality improvement methodology alongside charity sector support can create patient-centered care solutions, in this instance, an evidence-based, validated tool. The project has had success, in terms of clinician engagement, but challenges remain in it leading to direct patient empowerment.

The substantial body of work on epilepsy mortality while being brought together in a systemic manner for clinicians via the Checklist needed extending to PWE to enable a person-centered awareness of individual risk [15].

Given the lack of a UK wide systematic response and resources, solutions need to be frugal but still effective and have the opportunity to be accessed by every PWE. With the rise of technology and the availability of smart mobile phones, converting the evidence-based Checklist to a mobile application for PWE - EpSMon (epilepsy self-monitor) was the natural next step to address this gap [15,16].

2. Aim

This paper describes the development and integration of a digital self-assessment epilepsy risk empowerment tool (EpSMon), into the UK health service.

Epilepsy self-monitor as a patient facing tool and epilepsy as a condition offer unique insight to the multifaceted challenges to embedding digital technologies successfully into mainstream clinical practice, the lessons of which are generalizable to international audiences.

3. Developing EpSMon

Epilepsy self-monitor provides a digital version of the SUDEP and seizure safety checklist ("Checklist") [15,16] in the form of a self-administered risk e-checklist. The original EpSMon questionnaire was adapted by using patient and public co-design models from the Checklist questions to prompt for "yes or no" responses relating to health or lifestyle changes experienced in a three-month window, this period shown to be optimal for epilepsy risk retesting [17]. The cycle of design and consultation is represented in Fig. 1.

Highlights of development included co-design and co-production with the charity SUDEP Action which represented the combined viewpoint of people bereaved from the loss of a loved one to epilepsy. Thus, there was a high degree of lived experience and in-depth involvement at both design and implementation states. This model of 'bottom-up' involvement of the primary stakeholders in the form of a charity has helped not only to develop and disseminate the product but also to bring a level of credibility in clinical circles which commercial products struggle to do so.

Through this process, EpSMon delivered a number of features including self-assessment of risk, 3-monthly reminders, bespoke education (iterated around identified risk factors), recommended prompts to see a GP when indicated, and support line information. In addition to self-management, the app supports ongoing research via the remote collection of data relating to user demographics, epilepsy type, medication usage, and risk change over time. In 2016, the EpSMon app was released into the UK, available on Android and Apple devices (tablet and smartphone).

Epilepsy self-monitor adheres to a system of governance, where the evidence supporting the tool is reviewed 12-monthly utilizing the Checklist's Secretariat and evidence review process to ensure that the public facing EpSMon represents current evidence and practice. The app has been available since release for free to all PWE aged 16 and above.

3.1. PWE engagement

The original aim of the project was to increase the number of users at pace. In three years, 2483 PWE have registered to use the app. This is a

very small proportion of a potential pool of PWE, estimated around 600,000 in the UK. Uptake of the app was slow, but unsurprising, given the low uptake of risk communication observed to date [18].

However, a brief analysis of the available data conducted on September 2017 from these registered PWE reveals the opportunities and challenges faced by EpSMon at a patient engagement level. It highlights grave concerns clinically and shows significant lessons which must be learnt to better protect patients and enhance their education & self-management. Data showed that users have lived with epilepsy for a prolonged time (19 years on average). Only 30% (N = 751) had contact with an epilepsy specialist in the last 12 months. In fact, 21% (N = 531) of PWE had no clinical support in the last 12 months and were also the population who had higher levels of risk. The data also show an association of lower risk among those who reported to be educated on epilepsy risks. Yet what is highly concerning, given the avoidable nature of many epilepsy deaths [3,19], is that despite having had epilepsy for nearly two decades, almost half (45%, N = 1137) of the sample reported having had no risk education. There was an association of a total lower risk score with those who reported to be educated of SUDEP and seizure-related harm.

Patient engagement has been largely led by a charity sector partner SUDEP Action, with publicity campaigns and media opportunities around prizes and publications. The role of SUDEP Action in this project has been unique as they are partners to the product. Their work and contribution have been 'bottom-up' where they have played an equal role as clinicians in ensuring that the patient's voices have been heard and incorporated into the product.

3.2. Clinician engagement

Clinician engagement required awareness and trust building efforts in the context of no established clinical epilepsy network. The success of the project with respect to generating trust and peer recognition is evidenced in its objective peer review support and competitive standing against other national health innovations:

- An independent Cochrane review of SUDEP-related technologies which highlighted the relevance of EpSMon in managing seizures and associated factors to reduce deaths [20].
- An independent NIHR systematic review [21] of emerging technologies of epilepsy including experts and patients giving the app a score of 4/4.
- Two British Medical Journal (BMJ) Awards [22] wins (neurology 2016 and education team of the year 2019) and a BMJ Award commendation (Innovation 2017)
- First prize award from the Epilepsy Foundation America (2016) SUDEP Institute Challenge [23].
- A Health Service Journal Award [24] (2016) - Education and training in Patient Safety and a Health Business Award [25] (2017) for Healthcare IT.
- Provision of a BMJ quick tips video and RCGP training module [26] for epilepsy risk management.
- Signposting of the app by SUDEP Action via their clinical networks, clinical training sessions, and external projects. With a strong reputation built over 20 years, the charity's involvement and endorsement of the app aid in reassuring clinicians to promote the tool among patients.

3.3. Commissioner engagement

The National Health Service (NHS) is the publicly funded national healthcare system for England. In the UK, healthcare is procured by appointed clinically-led statutory NHS bodies who are the budget holder groups or boards, referred to Clinical Commissioning Groups (CCGs) also called as commissioners. The role of a CCG is responsible for the planning and commissioning of healthcare services for their

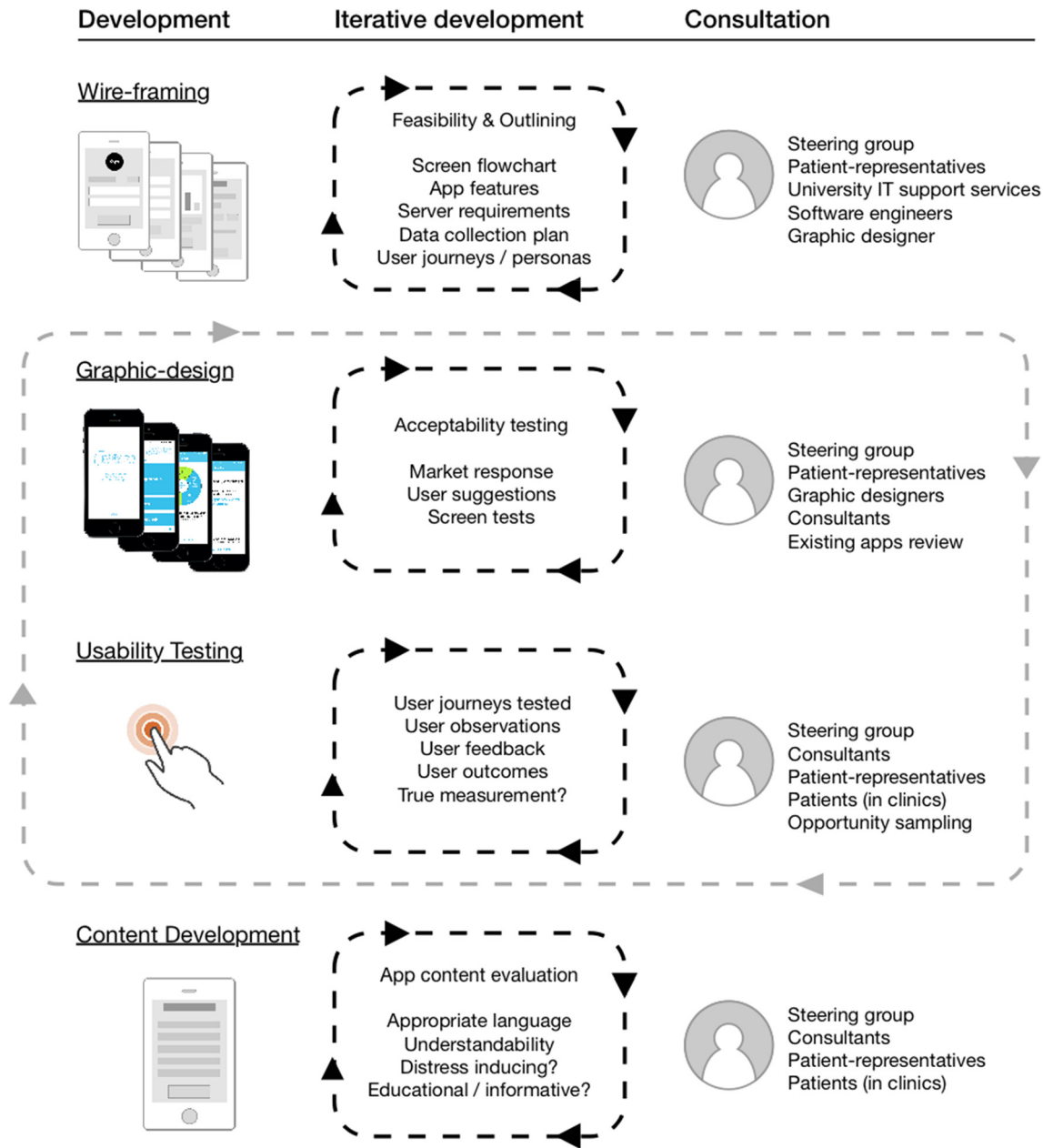


Fig. 1. Cycles of iterative development undertaken in creating EpSMon. (Taken from Newman et al. [16]).

205 local area for all conditions and to deploy available resource as per national goals and local priorities. A new scheme started in 2015 named the NHS Innovation Accelerator (NIA) [27] to help accelerate uptake of high-impact innovations for patient, population, and NHS staff benefit. Epilepsy self-monitor was one of seven chosen for 2016.

210 Clinical adoption, via the NIA, meant engaging with a procurement driven commissioning model which was a difficult match against the third sector funded initiative to provide the tool for free. Epilepsy self-monitor did not have a recognized procurement model that predicted 'year-in-savings', this being the dominant metric used by commissioners in the UK. Rather, it could lead to increased 'in-year-costs' as PWE who are identified at risk are prompted to get more support to address years of neglect.

218 The business case for EpSMon accommodates the potential to introduce long-term savings (via emergency call-outs and ED visits, increased drug adherence, risk management) and reduced lives lost. However, it is a difficult product to 'sell' as the market itself is

222 ambivalent about its need, represented in poor rates of risk communication in clinics [18] and the consequential absence of risk awareness in PWE [5]. It is also problematic to demonstrate actual 'lives saved' other than via risks reducing among PWE in the hope of avoiding potential mortality. In addition, evidence shows that PWE are not observed to engage with eHealth as of now [28].

227 Understanding how to attract commissioner commitment without procurement decisions is an ongoing engagement challenge. As NHS digital health systems are progressing, new opportunities are becoming evident, as discussed further below.

4. Learning and next steps

232 The app needs to be recommended to PWE as a component of evidence-based service provision, supported by use of the Checklist in clinical reviews (Fig. 2).

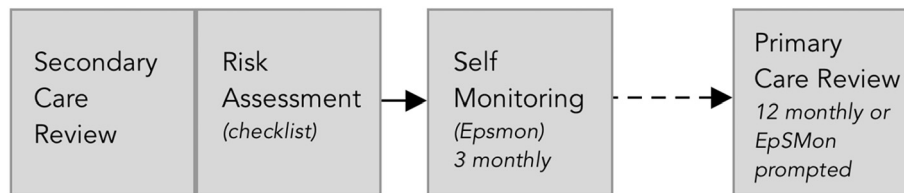


Fig. 2. Proposed epilepsy risk-management pathway, including the safety checklist and EpSMon.

A recent Public Health England report [29] highlighted the increase in epilepsy deaths in the UK in the period between 2001 and 2014. In response to these concerns, NHS England and associated organizations have developed pathways to aid PWE, clinicians, and commissioners to work together to deliver a seamless patient journey. Fundamental to this is the concept of an identified coordinator who would support the patient journey and post discharge if rereferred would again be the point of access. **Epilepsy self-monitor** which is suggested as good practice in these pathways could be a significant tool to understand person-centered changes at point of recontact.

To achieve a change in clinician behavior, the app needs health service promotion. Currently, it appears that clinicians and patients are pointed to reviews from recognized eHealth catalogues (e.g., www.orchacom) and the NHS app library. These stepping stones are relatively novel, and so understanding their worth has been difficult. It is increasingly apparent that health service testimonial is going to be essential, if culture change is the required route to adoption. This cross-organization benchmarking provides a platform to promote a solution, into clinical care.

5. Governance frameworks – UK

The launch of EpSMon occurred slightly ahead of a UK shift towards digital transformation. Inadvertently, the project represented a model of proposed best practice that is increasingly heralded as a solution in transforming services towards empowerment and self-managed care, worldwide. The gold standard for such care includes co-design with patients, accessibility, usability, education, empowerment, and synchrony with existing care pathways. Until recently, this was difficult to articulate as a formal standard for eHealth, which remained an abstract concept. Recent developments in clinical pathways particularly NHS Right care and NHS England led initiatives have strengthened the case for EpSMon. Both documents cite EpSMon as a good digital example of patient empowerment.

It is imperative that any new technology measures itself against an impartial set of regulations and requirements especially if patient facing. There is a lack of good practice guidelines for health technology internationally but in the UK in particular, the NICE has been looking to address this. The publication of the NICE evidence standards framework for Digital Technology Solutions [30] revealed a framework for assessing the validity and evidence for any eHealth option against the level of clinical risk. The NICE framework serves as a commissioner's evaluation toolkit and could prospectively aid projects such as EpSMon towards NHS implementation by acknowledging the relevance of previous research. On this basis, these standards have implications for the UK procurement of all epilepsy digital health solutions, existing and proposed.

In addition to the NICE standards, NHS digital created the NHS app library [31] which is supported by a self-completed Digital Assessment Questionnaire [32] and independent assessments provided from services such as Orcha [33]. These steps, along with the NICE guidelines previously mentioned, provide a roadmap towards NHS procurement and promotion. In the absence of a procurement model, promotion of a model that meets a broad range of PWE's needs and resonates with clinicians is imperative.

Epilepsy self-monitor when reviewed through NICE framework, offers a sample evaluation for others on how to map epilepsy innovations

onto national standards. This provides a UK centric analysis, representing the app's current home – however, similar models of inspection are emerging internationally. Beyond countries that have developed their eHealth sector to include this formal scrutiny, there are developing nations that may also seek to develop or adopt solutions such as EpSMon. This summary interpretation of the UK evidence requirements, alongside the evidence, can hopefully act as a reassurance and potential guide for such places – when considering this or another such innovation (see a full summary of the evidence against the NICE framework in the Supplementary information, Table 1).

5.1. NICE evidence standards framework for DHTs, 2018

Digital Health Technologies (DHTs), as referred by NICE, are evaluated firstly on function. The guidelines provide 3 tiers of functions, that link to evidence requirements that are either at a minimum or best practice standards, based on the level of risk to patients if the function was to fail. The tiers, 1, 2, 3a, and 3b, increase in evidence requirements as the impact on patient care increases. As the evidence requirement tier increases, all previous tiers must be met to demonstrate adequate evidence for commissioning. Fig. 3 shows the DHT function classifications proposed by NICE, stratified into evidence tiers.

Epilepsy self-monitor currently falls within evidence tier 2, as it meets the functional criteria for 'informing' and 'simple monitoring' patients (Supplementary Table 1). Informing is defined as, "provides information, resources, or activities to the public or activities to the public, patients, clinicians. It includes information about a condition or general health and lifestyle. Simple monitoring is defined as, "includes general health monitoring using fitness wearables and simple symptom diaries". **Epilepsy self-monitor** does not require tier 3a or 3b evidence as it does not enable self-treatment, but always promotes contact with clinicians alongside any risk detection, nor does it calculate or communicate any data to clinical teams.

The judgment around risk is an interesting consideration that is subjective, tasked to commissioners it seems, and context dependent. The guidelines ask the question, "How serious could the consequences be to the user if the DHT failed to perform as described?" With respect to EpSMon, it is possible that a failure to capture a positive confirmation of risk and appropriately communicate the clinical need of this risk back to the user could be negative as it can give false assurances. However, it is important to bear in mind that currently, a risk assessment is not provided at all for almost all patients with epilepsy at the recommended interval and definitely not in a structured manner. Further, in the context of an adequate NHS service with improved education, the risk of the app failing would be much less critical. For the purposes of this paper, as this is an unquantified area for EpSMon, the risk will be presumed to be high – requiring the 'best practice' evidence standard for all categories.

6. Implications

The standards of evidence are likely high for interventional epilepsy solutions such as seizure alarms in the UK, often needing to meet stringent research requirements and other governance requirements from the British Standards Institution [34], the HMRA [35], and NHS app library review [36].

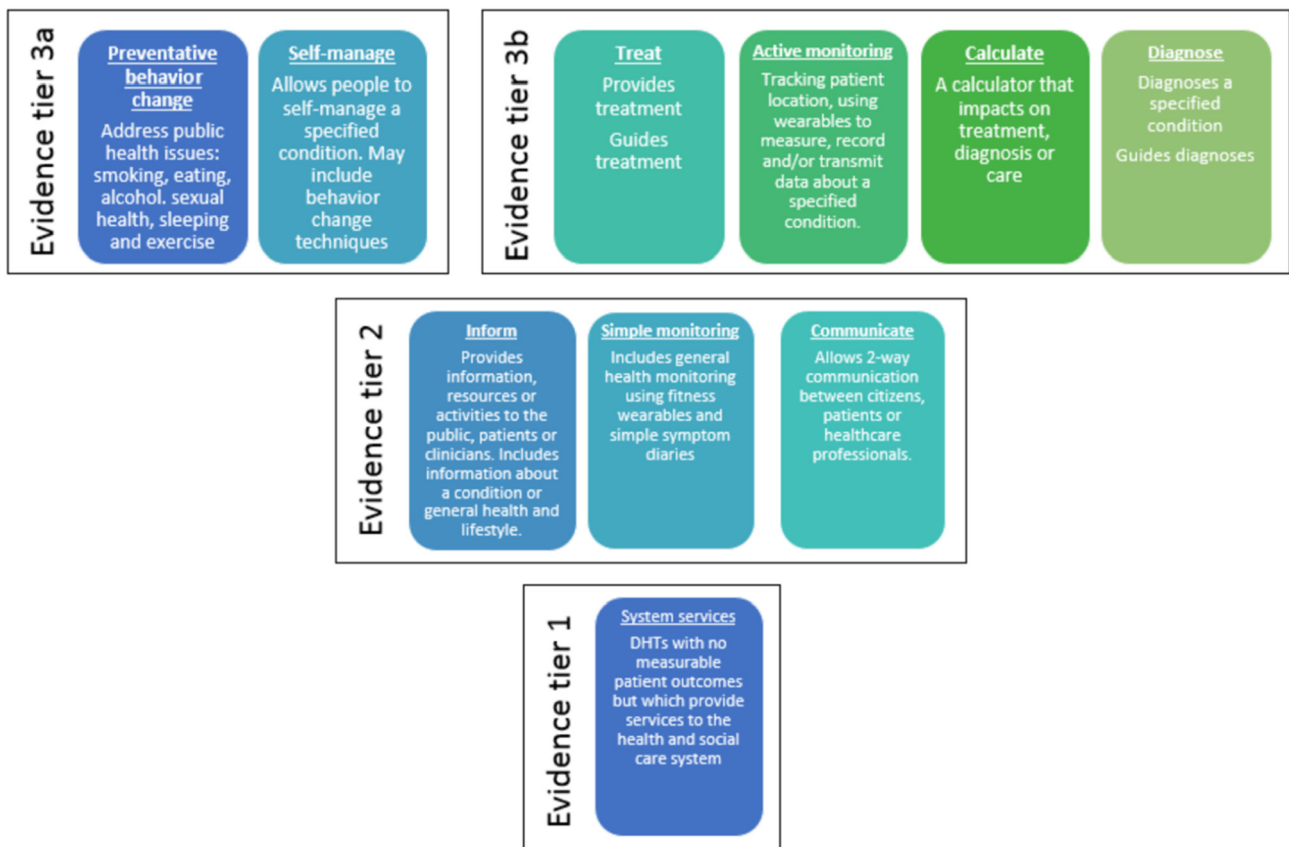


Fig. 3. DHTs classified by function and stratified into evidence tiers. (Taken from NICE [30]).

342 There is clear patient benefit in applying governance standards to
 343 eHealth proposals or to go beyond this and seek to bring solutions to-
 344 wards these standards to minimize risks in the lives of PWE. As an ex-
 345 ample, consider the many medication reminder app offerings. The app
 346 stores are satiated with solutions, most from unknown developers
 347 who are required to meet no standards of due diligence or software in-
 348 tegrity. A recent perusal of such apps showed that a commonly
 349 downloaded version was accompanied with user reviews describing
 350 the lack of reliability of the tool, with regular failures to remind. In
 351 these instances, it is left to users to rely on other user reviews for safety.
 352 Given what is known regarding epilepsy fatality risks, this is unaccept-
 353 able and hugely worrying. In the NICE framework, such a technology
 354 would require the highest evidence standards to be commissioned
 355 (tier 3b). There is currently no such app in the NHS health library.

356 Given the popularity of seemingly simple solutions such as medica-
 357 tion reminder apps, and the lack of engagement in areas of need such as
 358 epilepsy [37], it seems the responsibility of the NHS to attract or com-
 359 mission common solutions to its library and to apply a stamp of ap-
 360 proval. The same case can likely be made for numerous digital
 361 technologies, increasingly offered as risk reduction or treatment man-
 362 agement solutions for PWE without governance. Representing the risk
 363 of nongoverned solutions is in and of itself emerging as a need that re-
 364 quires communication to PWE, and the public more generally.

365 The UK offers a valuable testbed to the international community for
 366 emerging technologies. *Epilepsy self-monitor* is no different. If it can be
 367 structured to satisfy the NICE guidance, then it can also be used with
 368 minor adaptations internationally. However, the learning from the UK
 369 EpSMon project has been that the best framework to deliver such new
 370 technology and culture change is to have patient-focused organizations
 371 such as local epilepsy charities as key stakeholders as illustrated by the
 372 co-design and co-production model in the UK with SUDEP Action. Such

373 patient organizations will take responsibility of showcasing products in
 374 a measured manner ensuring the benefits, risks, and challenges that are
 375 highlighted to the end user, i.e., PWE.

7. Limitations

376 While attempts have been made to be impartial in the analysis, the
 377 authors accept that there could be lacunas particularly with regard to
 378 representing product weakness. The principal concern is of bias in the
 379 paper.

380 The engagement with technology in general and with EpSMon is
 381 now being recognized to be personality dependent and requires pa-
 382 tients to be highly motivated. Thus, those who have feedback might
 383 not represent the core group of people who have epilepsy. The app
 384 lacks some common features such as user feedback. This paper does
 385 not inquire into product variation, what would constitute 'stickiness'
 386 and does not provide focused evidence on what would be needed to
 387 make EpSMon from its current 'novelty' to 'necessity' for the patient.

388 Further, EpSMon is currently unrepresented in NHS care pathways.
 389 There are no current app prescribing models. There is a historical resis-
 390 tance to health technology culture in general.

8. Conclusion

391 *Epilepsy self-monitor* is pushing into a context of a continued need
 392 for epilepsy risk assessment and education [38], improved service care
 393 with respect to risk, increasing governance, and a digital health strategy
 394 that is yet to mature. The project has been successful with respect to its
 395 approach to evidence, proactively meeting tier one and two NICE stan-
 396 dards ahead of their release and capturing the support of academic,
 397 health, and third sector peers. While there are barriers to overcome
 398

400 for EpSMon, the recent data highlighting the significant minority who
401 are disenfranchised from routine monitoring and ignorant of risks
402 showcase the definite need of such a product to help redress the situa-
403 tion over time.

404 Supplementary data to this article can be found online at <https://doi.org/10.1016/j.yebeh.2019.106514>.

406 Ethical publication statement

407 We confirm that we have read the journal's position on issues in-
408 volved in ethical publication and affirm that this report is consistent
409 with those guidelines. No ethical approval was needed as this was a ser-
410 vice improvement project.

411 Declaration of competing interest

412 RS and BNMCL have received institutional and research support and
413 personal fees from LivaNova, UCB, Eisai, Special Products, Bial, and
414 Desitin outside the submitted work.

415 RS is a panel member of the NICE committee for the update of the
416 guidance for epilepsy.

417 References

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