

TAYS PEDIATRIC PILOT TRIAL CLINICAL END REPORT

SOENIA™ Medical Diary & Cloud

Study information:

Pilot name: "*BrainCare-omaseurantasovelluksen pilotointi*"

Pilot duration: 8/2018 – 3/2019

Tampere University Hospital, Pediatric Neurology Polyclinic

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Background information

At present, epilepsy patients report their seizure outcomes and possible treatment related adverse effects to neurologists in order for them to make an informed treatment decision. Documentation and explanation of the seizures and side effects are performed in one or more of the following ways: 1) oral explanation during an office visit without any documentation, 2) through a pen-and-paper diary hand delivered during office visits, 3) through pre-scheduled phone consultations with a specialist nurse, or 4) through unscheduled patient-initiated phone consultations with a specialist nurse. In general, the phone consultations are time consuming, especially the unscheduled ones.

Present Method of Epilepsy Patient Management

In TAYS Pediatric Neurology there are two types of pediatric patients. Seizure-controlled pediatric epilepsy patients usually have on average 1-1.33 polyclinic visits per year with frequency of visits every 9-12 months. Refractory pediatric patients usually average 4-5 polyclinic visits per year with frequency varying between 1-3 months.

Neurologists make treatment decisions based upon what they learn from the patients themselves, their parents or caretakers, and information collected via the nurses. After the decision is made to do an intervention, follow-up phone consultations are scheduled with a nurse. Usually the scheduled phone consultations are made every four weeks during the intervention follow-up phase usually lasting 3-6 months. These scheduled phone consultations typically have durations of 15 minutes but can last up to 30 minutes per call per patient.

Only some patients keep a hand-written seizure diary, which is presented during the visits to the polyclinic. In the pediatric treatment chain, the phone calls (both scheduled and unscheduled) are the main way of reporting seizures, and it is usually reported by the pediatric patient's parents. Therefore, the parents need to make time to call the polyclinic during their work day during the polyclinic's phone consultation hours. These unscheduled phone consultations typically have durations of 15 to 30 minutes per call per patient. The pediatric polyclinic typically receives 2-10 unscheduled phone consultations per day, averaging to 5-6 unscheduled phone consultations per day and 100 unscheduled phone consultations per month. At present, the nurses must manage 50 hours per month of unscheduled phone consultations into their regular schedules.

Pilot Rationale & Schedule

Piloting a New Solution for Epilepsy Patient Treatment Chain Management

SOENIA® Suite offers a novel solution to provide standardized clinical data and save time for the Pediatric Epilepsy Polyclinic. SOENIA® Suite includes SOENIA® Medical Diary (previously called SOENIA™ Epilepsy Diary) and SOENIA® Cloud (previously called SOENIA™ Epilepsy Cloud) as complementary products to offer a solution for reducing the number of scheduled and unscheduled phone consultations and also reduce the amount of time needed for pre-scheduled phone consultation for pediatric epilepsy polyclinic patients. The solution modernizes the epilepsy patient treatment chain. The treatment chain is changed by patients providing the required information on seizures through a smartphone application, SOENIA® Medical Diary, which securely delivers the seizure information to a regulatory-compliant cloud based system, SOENIA® Cloud. The specialist nurses could then review the enrolled patient's seizures in nearly real time and schedule a contact if needed. Additionally, the aim for the neurologist is to make treatment decisions based upon this standardized data collection process when needed.

Pilot Schedule and Duration

The pilot was agreed to start during late spring 2018 and the pilot duration was set to be three (3) months, after which the parties (service provider and the polyclinic) agreed to write an end report. Due to circumstances beyond the pilot, the pilot enrolled its first patient in August 2018 and reached all ten pilot patients during week 50 of 2018; therefore, the pilot ran with all ten patients during 01/2019 – 03/2019 in order to understand the value and benefits of the new solution.

It is worth noting that the smart phone application was called SOENIA™ Epilepsy Diary when the pilot began, and the rebranding only began during 03/2019 to be called SOENIA® Medical Diary. Therefore, the pilot has been unaffected by the name change because all patients had the smart application installed before this time.

Pilot Methodology

During the pilot the following steps were taken:

1. BrainCare Oy provided the link for patients to download the smart application from the Apple App Store and Google Play Store.
2. During all scheduled patient visits, the nurses introduced SOENIA® Medical Diary to the patients. Installation and user instructions were included.

3. BrainCare Oy trained two new staff members and enrolled them to the SOENIA® Cloud. Additional support was and is available at support@braincare.fi.
4. The nurses were advised to spend 0 to 30 minutes per week or every second week, reviewing online all of the enrolled patients. This time was made available through reduced and/or shortened phone consultations from patients asking about their situations.
5. The patients were asked to download and use the SOENIA® Medical Diary during the pilot so that their or their child's seizure history was available online to the Hospital Users (i.e., nurses and doctors) via the SOENIA® Cloud.
6. BrainCare Oy fulfilled all IT requirements to hold a patient registry during the pilot.
7. BrainCare Oy gathered feedback from the nurses throughout the Pilot Trial to learn about possible ways to improve the Service.

Therefore, the epilepsy treatment process change during the pilot expected the enrolled patients (or their parents) to have an Android or iOS phone, who are capable and willing to use smart applications, to document their seizures in a repeatable standardized way via the SOENIA® Medical Diary. The Hospital Users (doctor & nurses) monitored these pilot epilepsy patients through the SOENIA® Cloud.

Pilot Results

Improved Clinical Outcomes

The results of the pilot included the following improved clinical outcomes:

1. There is **faster and better decision making** regarding each patient's individual care. The polyclinic can more quickly reduce patient adverse side effects and ineffective treatment cycle time over the course of the treatment. The polyclinic directly benefited from knowing what the status is of all the refractory patients in the pilot.
2. The polyclinic **improved its quality of care** by reducing the overall reaction time required to report a pediatric patient's adverse side effects. The overall reaction time is from when the parents or caretakers consult the nurse and then from the nurse to consult with the neurologist on duty, which enables the polyclinic to **more quickly schedule an emergency visit if necessary** for pediatric patients due to a recent treatment change. In the specific case documented in Appendix 1, the emergency visit was scheduled an estimated 12-15 hours sooner than using the standard protocol because the nurse notified the neurologist about an unusual seizure after a treatment change before the parent would have called during the

consultation hours the next day. Faster reaction times typically translate to faster intervention feedback, which also reduces the risk of medical complications caused by the seizures.

3. There was **more detailed, accurate, and standardized** seizure reporting. The template seizure entry in the SOENIA® Medical Diary improved the overall quality of reporting across the pilot patients, especially for those that do not document well their seizure history such as type, triggers, location, time of day, etc. This is an improvement over the hand-written diaries because the nurse would usually provide only a summary overview in the medical records.
4. Reduced the errors in reporting -- missing and illegible diary entries were replaced in the pilot group with the SOENIA® Cloud, which provided bar graphs, numeric seizure totals and text of all reported seizures from each patient.

Economic Savings through Saved Time

The time saved can be counted in multiple ways that benefit the polyclinic:

1. Shorten the duration of scheduled and unscheduled phone calls by 50% to 66%, reducing 30 minute consultations to 15 minutes and 15 minute consultations to 5 minutes. The time is saved because the seizures are already entered into the system. The current protocol requires the nurse to ask about the details of the seizures and then to document them into the hospital records, which may be done during or after the phone call.



2. The nurse estimated that there were on average 2-3 scheduled phone consultations per week from the pilot patients that yielded approximately 30-45 minutes per week or 2-3 hours per month saved time from scheduled phone consultations.

3. The nurse estimated that there was on average 1 less scheduled phone consultations per set of 3 scheduled calls per pilot patient that had a treatment change. Currently, there is no way to send a message through the SOENIA® Medical Diary to indicate that the call has been cancelled so a short phone call needs to be made. This is a suggested feature to implement and improve the Service. One less scheduled phone consultation



saves 30 minutes, minus one short call to notify the patient about the eliminated call in total saving 25–29 minutes.

4. Once ten patients were enrolled in the system, the nurse estimated that the number of unscheduled phone consultations reduced by approximately 20% to 25%. This percentage is based upon the fact that the monthly average of 100 unscheduled phone consultations before the pilot started reduced to 75 to 80 unscheduled phone consultations per month after the ten patients were enrolled. Therefore, the nurse saves on average at least 10 hours per month from a reduced number of unscheduled phone consultations.



5. The nurse reported that she saved about 15 minutes per office visit per pilot patient. This time was saved by eliminating the interview portion of the visit that is usually spent on counting or estimating the number of seizures each patient had since the previous encounter (either phone consultation or office visit). If there are on average 2 pilot patients (of ten pilot patients) with office visits per month, then approximately 30 minutes can be saved during office visits per month.

In total, the monthly estimated time saved from the nurses is **12–14 hours per month** from 10 patients in the system.

Feedback from Parents according to the Nurse

According to the head nurse, the parents of pediatric epilepsy patients prefer the smart application and are very satisfied with it. Parents detail the seizures very well in an informative way so usually there is no need to call for further information. Currently, only one parent (or patient) may be logged into the application at a time. The nurse indicated that compliance with the smart application is much better than the paper diaries because the paper diaries are typically forgotten.

Lastly, one teenage patient declined to put the app on his/her phone. We believe that the teenager may not have wanted to disclose that he/she has epilepsy. Once BrainCare Oy learned about this possible issue, the team began updating the regulatory documentation to include support for headaches and migraines in order to minimize and mitigate patients from being stigmatized for having a chronic neurological illness.



Feedback from the Nurse

The only setback that the nurse identified is that the nurses have to carry around a USB-key because the system is not currently integrated into the hospital's system. If the system would become integrated, nurse Katja Nieminen would be very excited for this new tool to better manage their refractory epilepsy patients.

Conclusion

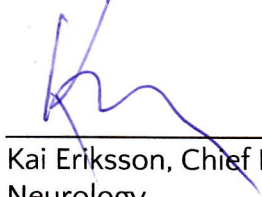
Based upon the improved clinical value and the time saved, Dr. Kai Eriksson and Katja Nieminen both recommend the SOENIA® Suite as an effective tool for epilepsy seizure management and would request that the system be taken into continuous usage.

Signatures:

In Tampere on 31.5.2019

In Tampere on 31.5.2019

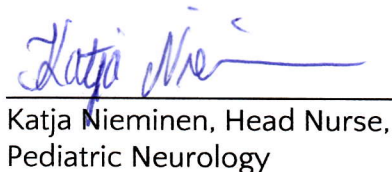
Pirkanmaan sairaanhoitopiirin kuntayhtymä BrainCare Oy



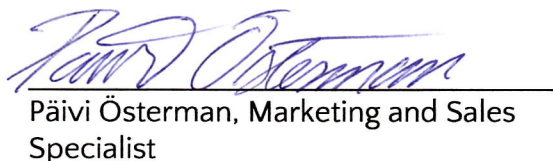
Kai Eriksson, Chief Physician of Paediatric Neurology



Katrina Wendel-Mitoraj, CEO




Katja Nieminen, Head Nurse,
Pediatric Neurology





Päivi Österman, Marketing and Sales
Specialist



Appendix 1 - Pediatric Clinical value signed document

SOENIA™		BRAIN CARE	
BRAIN CARE OY (LTD.)			
PEDIATRIC SINGLE CASE REPORT OF CLINICAL TRIAL			
SOENIA™ Epilepsy Diary & Cloud			
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SOENIA™ by BrainCare Oy, websites: in English: www.soenia.com , Finnish: www.soenia.fi , and Swedish: www.soenia.fi/svenska.html			
BrainCare Oy Biokatu 6, 33520 Tampere Business ID: 2554390-9 VAT: FI25543909		CONFIDENTIAL Case study 17.08.2018 Page 1 of 2	
www.braincare.fi info@braincare.fi ISAN FIBS 1146 3001 1437 64 SWIFT: BIC: NOEAFINHH			

SOENIA™		BRAIN CARE	
Pediatric single patient case report using the SOENIA™ Epilepsy Diary & Cloud			
The pediatric neurology polyclinic in Tampere University Hospital reported, that one of the parent's of a pediatric patient in their pilot study reported a seizure, and the nurse at the pediatric polyclinic was able to see the seizure and take action immediately. The nurse's actions included contacting and notifying the doctor the same day, instead of waiting for the parent to call the next day.			
Clinical value:			
<ol style="list-style-type: none">1. More detailed and real-time seizure data.2. Faster and better decision making regarding each patient's individual care.3. In this specific case the emergency visit was scheduled and estimated 12-15 hours sooner than using the standard protocol.			
Cost-effective/economical value:			
<ol style="list-style-type: none">1. Saved time from parents calling and reporting in via phone.2. Cost-effective scheduling based on seizure activity.			
Signature			
			
Date & Place		Katja Nieminen, neurology nurse Tampere University Hospital, Pediatric Neurology	
BrainCare Oy Biokatu 6, 33520 Tampere Business ID: 2554390-9 VAT: FI25543909		CONFIDENTIAL Case study 17.08.2018 Page 2 of 2	
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Appendix 2 - Clinical opinion by Dr. Kai Eriksson in Finnish

Original text in Finnish:

Ylilääkäri Kai Eriksson pyysi välittämään minun kauttani kokemuksia Soenia sähköisestä epilepsia päiväkirjasta.

Tässä kokemuksia ranskalaisin viivoin:

- Käyttäjiä meillä on tällä hetkellä 10 (näillä ei ole saatu kohtaustilannetta täysin hallintaan, niillä Soenia tarpeeton niillä joilla kohtaustilanne on hallinnassa.)
- Soenia kulkee helposti kännykässä mukana, vanhemmat tähän tyytyväisiä, helppo ja nopea kirjata kohtaukset, niiden tyypit, oireet ennen, jälkioireet, olotila, tuntemukset. Lisätieto kohta hyvä johon voi kirjottaa omin sanoin pitkänkin kertomuksen
- reaaliaikainen ilmoitus hoitajalle/ lääkärille joka näkee heti kun kohtaus on merkitty kalenteriin ja voi toimia samantien.
- yhdellä nuorella on ollut kynnyskuusmyksenä ottaa Soenia sovellus kännykkään. Ei tiedetä syytä mutta olisiko niin että ei halua kavereiden näkevän.

Hyöty:

- vanhemmat haluavat että kohtaustilanteeseen puututaan saman tien ja usein soittavat vaikka laittavat kohtauksen päiväkirjaan. Päiväkirjassa ei ole mahdollista infota vanhempia että asia on huomioitu, joten päiväkirja ei ole loppujen lopuksi ihan hirveästi soittoja puolin jos toisin vähentänyt.
- Soenia kulkee perheen mukana kännykässä eikä tarvitse kantaa paperia ja kyniä eli kohtausten muistiinpanojen merkitsemisen vaivattomuus (kännykkä aina mukana jollakin perheen jäsenistä)

Soenia ei kuitenkaan ole korvannut poliklinikka käyntiä. Soenia ei keskustele sairaalamme käyttöjärjestelmän kanssa mikä hankaloittaa sitä että kaikkien hoitohenkilökunnasta ei ole mahdollista nähdä ilman että käyttää tikkua, joka pitää laittaa keskusyksikköön. Myös tikun kuljettaminen, siirtäminen paikasta toiseen talossa hankalaa koska se pitäisi olla aina mukana.