Digi-HTA Recommendation

Kaiku Health Service for symptom management of cancer patients

PRODUCT AND ITS INTENDED PURPOSE	
The Kaiku® Health service is a digital system that can be used to monitor the well-being of a patient with cancer. This service can be accessed via either a web browser or a mobile application. Through the service, the patient fills in symptom monitoring and a quality of life meter, and if necessary, the system sends information about the deterioration of well-being to the treating organization. The end user and the hosting organization can send non urgent messages through the system. The device has a CE-mark. The device is a Class IIa medical device (Medical Device Directive (MDD) 93/42/EEC).[1] The manufacturer of the product is Kaiku Health Oy.[1] The company has an ISO 13485 quality management system in use.[1]	
RECOMMENDATION	
Date of Recommendation	23.6.2020
	The Kaiku Health service is suitable for monitoring the well-being of a patient with cancer during and after active cancer treatments. The service can help the patient manage their symptoms and get treatment when severe symptoms occur.

SUB AREAS OF ASSESSMENT		
Effectiveness	Five people participated in the pilot study from the Kaiku Health service. These participants had head or neck cancer. Based on the research, the Kaiku Health service is suitable for monitoring the side effects and quality of life of radiotherapy during and after radiotherapy.[2] In addition to the pilot study, a few other studies have used the Kaiku Health service to monitor patients. The system was found to be easy to use when monitoring multiple myeloma (MM) patients. During the study, 80.1% of the patients completed weekly symptom follow-up. Health-care workers pointed out that symptom monitoring caught symptoms that would otherwise have gone unnoticed; in addition, the number of calls to the health-care unit was smaller.[3] The Kaiku Health service has also been used to monitor patients with prostate cancer.[4] Based on the research, good commitment to using the system was observed. Weekly symptom follow-up was completed by approximately 80% of the respondents, and every other week, symptom follow-up was completed by more than 90% of the respondents.[3, 4] Experiences from Other Similar Systems Similar types of systems are in use in other countries. Basch's study (2016) found that the system used in the study had positive effects on the patients' quality of life compared to the control group. The patients had fewer visits to the emergency room, cytostatic therapy continued for a longer period, and overall survival time was longer. The participants were divided into subgroups in terms of computer skills. Inexperienced users benefited more from the system. The background information of the group differed from that of the group of experienced users (e.g., they were older, less educated, and male), but the effect of these background factors on outcome variables was not investigated in the study.[5, 6] Denis (2017) studied the use of a similar system in France in 121 lung cancer patients. Those who used the system had a longer overall survival time and underwent fewer medical imaging studies. For those who used the system, the recurrence of the disease was observed in ⅔ of the cases among the agreed controls, while in the control group, this was observed in only ⅓ of the cases.[7] During the midterm review period, a statistically significant difference in mortality was observed between the groups. Based on this information, the study was discontinued, and the control group participants were transferred to use the system.[8] Warrington (2019) reviewed similar systems from which research data was available. All the studies used some patient-centered outcomes to evaluate the effectiveness of the system, often quality-of-life indicators, symptom surveys, and psychosocial outcome measures. The systems can help patients manage the side effects of cancer treatments and can have positive effects on patient-centered outcome variables such as quality of life and overall survival. Good commitment to using the systems was observed.[9] From the patients' perspective, different systems have been reported to improve communication between the patient and the health-care worker, helping patients treat their symptoms and increasing the	

	patients' sense of safety when symptom monitoring is performed between appointments.[10–12] For the health-care organization, the use of systems can be a cost-effective way to monitor the symptoms and quality of life of cancer patients.[13, 14] During the assessment (June 2020), several studies were underway on Kaiku Health and other similar systems.[15]	
Safety	The safety of the Kaiku Health service is at a satisfactory level, although end-user activity can increase or decrease some risks. The company constantly monitors error messages and takes the necessary actions to improve safety. No adverse events related to the use of the product have been reported. The company's risk assessment report is comprehensive.[16, 17]	
Cost	The use of the Kaiku Health service involves an initial cost and a monthly usage fee. The initial cost is reasonable and tied to the number of modules to be acquired. The monthly usage fee depends on the number of modules and patients. The organization that is procuring this service is responsible for these costs. The manufacturer does not charge the end user. Presumably, customer organizations do not charge end users for using the system.[1]	
Data Security and Protection	The Kaiku Health service fulfills the data security and protection requirements well. The service supports interfaces to several different systems. Those interfaces have not been considered in this assessment, so we recommend that these interfaces be included in the data security and protection assessment at the time of procurement.[18] Please also note that the organization considering the acquisition is responsible for data protection as it acts as a data controller and that Kaiku Health Oy acts as a data processor.	
Usability and Accessibility	During the assessment (June 2020), the Kaiku Health service did not meet all the requirements set by the Act on the Provision of Digital Services (WCAG 2.1., level A ja AA).[1] Deviations are reported in the accessibility statement.[19] The regulations for websites will enter into force in September 2020 and for mobile applications in June 2021.[20] Users with different kinds of disabilities have been considered in the product's design. The service has been tested with real users, and the company has a process in place that takes usability development needs identified based on customer feedback to become part of the product development process.[1]	
Other Things to Consider When Using This Product	The Kaiku Health service is a Software as a Service (SaaS) solution, which can be used with the following web browsers: Apple Safari, Google Chrome, Microsoft Internet Explorer (11 or newer), and Mozilla Firefox. The mobile app is available for Android and iOS.[1] Currently, the product has an integration to the suomi.fi authentication service and the following health care systems: Acute ja Uranus (patient records), Varian ARIA (radiotherapy patient records), MOSAIQ (oncology patient records), Oberon (patient management), and Mylab (laboratory information systems).[1]	

	Questionnaires related to the Kaiku Health service can be integrated with third-party services through iframe and JWT token authentication.[1] The Service Utilizes Artificial Intelligence The Kaiku Health service utilizes artificial intelligence (AI) based on machine learning for the functions of both the end user and the operating organization. AI utilizes symptom assessments entered by the end user. In addition, the accuracy of the prognosis can be improved by making use of laboratory test results and information on treatment measures accumulated in patient information systems. Based on this information, the AI generates personalized predictions and, if necessary, sends an alert to the operating organization.[1] It is a continuously learning system that is retrained manually while monitoring its performance. The AI algorithm does not require any special actions from the staff to operate.[1] Training and Product Support Before deployment, Kaiku Health will provide user training for the care organization. End users do not need training before use.[1] Product support for the service is available on weekdays from 9:00 a.m. to 5:00 p.m. (EET/UTC+02: 00) in Finnish, English, German, French, and Swedish, either via the Kaiku Health service or by email (support@kaikuhealth.com).[1] Widespread Use of the Service The Kaiku Health service is used by more than forty oncology clinics in Finland, Sweden, Switzerland, Germany, Italy, and the Netherlands. The first version of the product was introduced in 2012.[1] Other Available Recommendations for the Product When the COVID-19 pandemic spread in the spring of 2020, ESMO recommended the use of remote monitoring systems to monitor the well-being of cancer patients to reduce exposure to COVID-19.[21]
References	1 Digi-HTA, information provided by manufacturer. Not publicly available. 2 Peltola et al 2016. A Novel Digital Patient-Reported Outcome Platform for Head and Neck Oncology Patients- A Pilot Study. Clinical Medicine Insights: Ear, Nose and Throat 2016:9 1-6. Doi: 10.4137/CMENT.S40219 3 Putkonen et al 2018. Web-based symptom tracking of Multiple Myeloma patients. Available from: http://arxius.infosalut.com/infosalut/2018/program_ebmt2018_hsll.pdf Luettu 17.6.2020 4 Kairemo et al 2018. Web monitoring tool for ^{177}Lutetium-PSMA treatments in prostate cancer patients. Available from: https://epos.myesr.org/poster/esr/ecr2018/C-1065 Luettu 17.6.2020 5 Basch et al 2016. Symptom Monitoring With Patient-Reported Outcomes During Routine Cancer Treatment: A Randomized Controlled Trial. J ClinOncol 34:557-565. Doi: 10.1200/JCO.2015.63.0830 6 Basch et al 2017. Overall Survival Results of a Trial Assessing Patient-Reported Outcomes for Symptom Monitoring During Routine cancer Treatment. Jama 2017; 318(2): 197-198. Doi: 10.1001/jama.2017.7156

	7 Denis et al 2017. Randomized Trial Comparing a Web-Mediated Follow-up With Routine Surveillance in Lung Cancer Patients. JNCI J Natl Cancer Inst 2017;109(9(:djx029. Doi: 10.1093/jnci/djx029. 8 Denis et al 2019. Two-Year Survival Comparing Web-Based Symptom Monitoring vs Routine Surveillance Following Treatment for Lung Cancer. Jama 2019; 321(3):306-307. 9 Warrington et al 2019. Electronic Systems for Patients to Report and Manage Side Effects of Cancer Treatment: Systematic Review. J Med Internet Res 2019;21(1):e10875. Doi: 10.2196/10875 10 McCann et al 2009. Patients' Perceptions and Experiences of Using a mobile Phone-Based Advanced Symptom Management System (ASyMS) to Monitor and Manage Chemotherapy Related Toxicity. Eur J Cancer Care 2009; 18(2):156-64. Doi: 10.1111/j.1365-2354,2008.00938.x 11 Jensen et al 2013. Review of Electronic Patient-Reported Outcomes Systems Used in Cancer Clinical Care. Journal of Oncology Practice 2013;10(4):e215-e222. Doi:10.1200/JOP.2013.001067 12 Snyder et al 2019. A PRO-cision Medicine Methods Toolkit to Address the Challenges of Personalizing Cancer care Using Patient-Reported Outcomes. 13 Lizee et al 2019. Cost-Effectiveness of Web-based Patient-Reported Outcome Surveillance in Patients With Lung Cancer. Journal of Thoracic Oncology 2019;14(6):1012-1020. Doi: 10.1016/j.jtho.2019.02.005. 14 Nixon et al 2018. Cost-effectiveness of symptom monitoring with patient-reported outcomes during routine cancer treatment. Journal of Cancer Policy 2018;15:32-36. Doi: 10.11016/j.jcpo.2017.12.001 15 Ongoing studies. Available from: https://clinicaltrials.gov/ct2/results?cond=Cancer&term=ePRo&cntry=&state=&city=&dist= Cited 18.6.2020 16 Kaiku Health - risk management report 17 Kaiku Health - Incident management and complaint handling process 18 The data security and protection requirements of the Northern Ostrobothnia Hospital district (PPSHP, the National Emergency Supply Agency's Cyber Health project 2018-2019, University of Tampere Jari Seppälä). Available from: https://www.kyberturvallisuuskeskus.fi/en/ncsc-news/instructions-and-guides/information-security-and-data-protection-requirements-social 19 Kaiku Health, accessibility statement 10thJune 2020 20 The Act on the Provision of Digital Services 306/2019 21 ESMO. Guidelines. Cancer Patient Management During The Covid-19 Pandemic. Available from: https://www.esmo.org/guidelines/cancer-patient-management-during-the-covid-19-pandemic Cited 17.6.2020
Assessment Team	Petra Falkenbach, Senior Planning Officer, FinCCHTA Jari Jääskelä, Research Assistant, OUSPG, University of Oulu Timo Kolehmainen, Artificial Intelligence Specialist, University of Oulu, Faculty of Medicine Jari Haverinen, Specialist, University of Oulu, Faculty of Medicine

Key Assessment Domains

Points	Effectiveness	Safety	Cost	Data security and protection	Usability and accessibility
2	Sufficient	Sufficient	Reasonable	Sufficient	Sufficient
1	Promising but the information is scarce	Probably at a sufficient level but not known well enough	High	Minor shortcomings	Minor shortcomings
-4	Weak or unknown	Weak or unknown	Unreasonably high	Shortcomings	Shortcomings

Recommendation Scale

Total score	Definition
10	USE OF THE PRODUCT IS RECOMMENDED The use of this product is recommended because of strong evidence for its effectiveness. Safety, data security and protection, and usability and accessibility of the product are at an adequate level. The cost of using the product is reasonable.
9	THERE IS ONE THING TO CONSIDER WHEN USING THE PRODUCT An organization considering the deployment of the product should note that in one key area there are things to consider. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
7-8	THERE ARE A FEW THINGS TO CONSIDER WHEN USING THE PRODUCT An organization considering the deployment of the product should note that in two or three key areas there are things to consider. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
5-6	THERE ARE MANY THINGS TO CONSIDER WHEN USING THE PRODUCT An organization considering the deployment of the product should note that in four or five key areas there are things to consider. Information about the effectiveness of the product could be promising, but the information is scarce. Product safety could be at a sufficient level but not known well enough. Product costs may be high. There could be minor shortcomings in the product's data security and protection or in usability and accessibility.
≤4	THERE ARE CRITICAL THINGS TO CONSIDER WHEN USING THE PRODUCT An organization considering the deployment of the product should note that there are shortcomings in one or more key areas. Information about the effectiveness of the product is untrustworthy or of low quality. There may be shortcomings in the product's safety, or information related to it may be unreliable or of low quality. Product costs may be prohibitively high. There could be shortcomings in the product's data security and protection or in usability and accessibility.