FINCCHTA
Finnish Coordinating Center for Health Technology Assessment

UNIVERSITY OF OULU

Digi-HTA Recommendation

Hygga Flow Enterprise Resource Planning System

PRODUCT INFORMATION
Hygga Flow is a real time enterprise resource planning (ERP) system for health care. It is used for managing patient appointment reservations, timely invitations, indicating treatment period lengths, and managing patient flow. The product contains a web-based service for health care unit personnel. The product is intended for both dental and primary health care. According to the notice from the manufacturer the product is not a medical device, and therefore it should not be used for purposes designated for medical devices. Platform: ☐ Android ☐ IOS ☒ MS Windows ☒ Browser ☐ Other Language: ☒ Finnish ☒ Swedish ☒ English ☒ Dutch Certificates: ☐ CE-marked ☐ Medical device, level ☐ US FDA Information security management system: ☐ ISO 27001 ☐ ISO 27701 ☐ Other Quality management system: ☐ ISO 13485 ☐ Other Manufacturer/Distribution: Hygga. https://hyggasolutions.com/en/

RECOMMENDATION 18.3.2022
9 THERE IS ONE THING TO CONSIDER WHEN USING THE PRODUCT The Hygga Flow enterprise resource planning system is suited for planning the enterprise resources of health care units. Adopting the system requires significant change in how a unit operates. The recommendation is based on the information provided by the manufacturer.

SUBAREAS OF ASSESSMENT		
Subarea	**Assessment**	Points
Effectiveness	**Sufficient** The aim of the enterprise resource planning (EPR) system is to care for the patients so that their whole treatment is completed in one visit. It is intended to help shorten patient treatment periods, reduce patient travel costs and enhance the organisation's business. Many names are used to refer to the business model: the one-visit model, the fix-all-in-one model, or the flexible patient treatment model.[1] A study by Aalto University compared a private single-visit dental clinic to two municipal dental clinics. The single-visit clinic treated more patients and conducted more weighted procedures than the municipal dental clinics, proportionate to the number of staff. The distribution of professions among the staff of the single-visit clinic differs slightly from that of the municipal clinics, which affects the amount of patients and procedures. Comparing the amount of visits between similar patients, the patients of the single-visit clinic had an average of 1,4 visits, whereas those of the municipal clinics had an average of 2,3 visits. The average length of treatment periods between similar patients was 27 days for the single-visit clinics and 71 and 73 days for the municipal clinics. 73 % of all patients at the single-visit clinic had treatment periods of one day, whereas in the municipal clinics 49 % and 44 % of all patients had one-day long treatment periods. The clientele of the single-visit clinic and the municipal clinics are slightly different, however, according to the analysis circa 70 % of the municipal clinics' adult clients could become clients of the single-visit model.[2] **Practical experiences** One dental clinic in the Jyväskylä region implemented the single-visit model on trial. During the trial, the dental clinic completed 48 % more procedures than in other units and the patients' treatment periods became shorter. At the end of the trial over half of the unit's patients were new, whereas in other units 29 % were new patients.[3]	

	Transitioning to this operational model has increased productivity and reduced the number of visits per patient in the South Karelia social and healthcare region. The customers' treatment period lengths have become significantly shorter and customer satisfaction has increased.[1] In the Satakunta region implementing this model has improved productivity and made the business more flexible. The scope has remained smaller than originally planned, which may have affected the economic productivity. Customer satisfaction has been high and staff wellbeing has improved.[1] The model is used in the Örebro region in Sweden. During the monitored period the productivity has been better than in the control organisation. 69 % of the patients had a maximum of 3 treatment visits and 72% of the patients were treated during one visit.[1] **Changes in the organisation** Bringing out the effectivity of the operational model demands going through a transitional process, which entails the training of all participating staff and committing to a new way of doing things. The need for a transitional process has been taken into account and the company has an introduction project plan[1]. The organisation's experiences of the single-visit operational model have for the most part been positive: treatment periods have become shorter, the staff are satisfied and customer experiences have been positive.[4]	
Safety	**Sufficient** According to the company their risk management system follows the principles of the ISO 14971 standard[1]. According to the company, the organisations who have used the product have not reported a single safety issue during the time they have used the product[1]. In a risk analysis the main risks related to the product have been comprehensively dealt with and the necessary measures to eliminate or minimise them have been specified[1]. The company has the necessary processes and notification practices as well as designated persons in charge of ensuring the safety of the product[1].	

Costs	**Reasonable** Adopting the service entails costs, the scale of which depends on the service agreement of the client organisation. The training costs related to the use of the service are included in the introduction costs.[1] Using the service has a monthly fee which is tied to the size of the client organisation and the fixed level of service.[1] Based on the information given by the service provider, it appears that the cost of using the service is reasonable when compared with the provision of an equivalent service in another way.	
Data security and data protection	The assessment was carried out using the list of data security and data protection requirements for social welfare and health care procurement and the response material provided by Hygga[1,5]. **Sufficient** Based on the response material delivered by the company the Hygga Flow service fulfils the information security and protection requirements. **Risk management and information security testing** The service producer has risk management processes in place. The producer also has processes to identify vulnerabilities in third-party software as well as tests to ensure the validity of the license containment practices. **Log management** Tracking logs of the use of information are maintained and stored on client-specific servers. At the time of the evaluation the producer is building a centralised log management environment. **User management** The service supports role-based management of licensing. It is possible to add support for one-time login as an integration project, through which multi-step identification can be supported. The service supports RFID identification. The service supports traditional minimum strength requirements for passwords. Support for client organisation-specific password requirement definitions is being developed at the time of evaluation.	

	Telecommunication The telecommunication between the Hygga Flow end devices and the server is encrypted. In addition connections can be restricted by IP address. **Data protection** The client organisation acts as the record holder and Hygga acts as the information processor. Personal information is stored on client organisation-specific servers in Finland and information is not processed outside of ETA. A data protection impact assessment has been conducted for the server. Data links are encrypted. The information databases are not encrypted at rest. **Other considerations** Hygga Flow uses the SaaS delivery model. The Hygga Flow service can be integrated into external systems. These external systems are not included in this evaluation. **General instructions for purchases** During the purchase phase it is important to always be in contact with the IT management, data security specialist and data protection specialist of your own organisation. Please discuss with them whether this product fulfils your requirements. In addition we recommend that health care districts utilise the European Union Agency for Cybersecurity's (ENISA) data security manual for purchases[6].	
Usability and accessibility	**Minor shortcomings** The product includes a web browser-based user interface for health care professionals[1]. According to the notice from the company the system has been developed in cooperation with clinicians[1]. New functions for the product are tested and trial run in a separate demo environment with product developers and clinicians as the testers[1]. The terminology of the product bases itself on health care jargon and does not include hard-to-understand terminology[1]. Health care professionals participate in checking the terminology[1]. Submitting and handling customer feedback related to the accessibility and usability of the product is realised through customer service channels, monthly meetings between the	

	company and client organisation, as well as bi-annual events organised for clients[1]. No actual accessibility evaluation of the product has been conducted, neither is there any accessibility statement of the product[1]. Although no accessibility evaluation against the WCAG 2.1 criteria, according to the company the product partially meets the following accessibility categories: noticeability, manageability, intelligibility, and reliability[1]. **General instructions for purchases** The purchasing organisation must take into account the accessibility requirements laid out for digital services and keep in mind that fulfilling the requirements is the responsibility of the service provider[7,8,9]	
Other things to consider when using the product	The product is available for Microsoft Windows and iOS operating systems, as well as for the Linux8 operating system if needed. **Interoperatibility** The system can be integrated into other systems such as the patient information systems of customers through interfaces provided by the company. At the moment, the product has integration to the LifeCare/Effica patient information systems and the Titania work shift planning program and self-enrolment devices.[1] **Technical functionality** The company has defined and implements testing processes as part of ongoing product development[1]. The company has notification channels with their clients in case of potential error notifications as well as processes to fix them[1]. During the past six months, the product has not been out of use or operating insufficiently due to a failure[1]. The timing of system updates is agreed on with the client and changes are gone through with the help of a change log[1]. A system update may cause a short break in the operation of the service, but the aim is to time it so that the client does not have any activity at that time[1]. **Training and technical support** Before adopting the system, the company will arrange the necessary trainings, and they offer intensified support for the client organisations after the introduction as needed (usually around 2-3 weeks after the	

	introduction). The company has a project plan ready to help support the introduction of the product. The training can be arranged in Finnish, Swedish or English. The company offers product support by phone or email.[1] **Distribution** The company has customers in several Finnish cities as well as abroad in Sweden, Holland and Belgium. The product has been in use in Hygga's own dental health unit since 2010.[1]
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Key Assessment Domains

Points	Effectiveness	Safety	Cost	Data security and protection	Usability and accessibility
2	Sufficient	Sufficient	Reasonable	Sufficient	Sufficient
1	Promising but more evidence is needed	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.