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Research Article

Implementing e-Bilingual Informed-Consent with e-Signature in EHR at Johns-Hopkins Aramco-Healthcare, Saudi Arabia: Quality-Improvement Initiative

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Abstract

Background: Patient involvement in healthcare decisions is essential, with informed consent (IC) being a legal requirement before any admission, surgery, or high-risk treatment. In Saudi Arabia, the local Saudi central board for accreditation of healthcare institutions (CBAHI) and the MOH mandate the use of IC forms in both English and Arabic to support the 2030 Vision.

Objective: To implement a bilingual electronic informed consent (e-IC) with e-signature functionality in the EHR, Epic, aiming to comply with accreditation and MOH requirements and achieve patient satisfaction ≥90% and staff satisfaction ≥75% within two years post-implementation.

Methods: This quality improvement initiative employed an implementation-focused design. All manual, paper-based IC forms were translated into Arabic, and bilingual ICs were integrated into the EHR. Retrospective data were collected to assess baseline practices, while prospective data were collected to measure improvements using several metrics, including patient satisfaction and staff satisfaction, after implementation. Data analysis was performed using SPSS v.30, with a statistical significance level set at $p \leq 0.05$.

Results: Between January 2023 and December 2024, manual IC forms significantly decreased to 4.7% ($p < 0.001$), while e-IC usage rose to 95.2% ($p < 0.001$). Documentation deficiencies revealed a statistically significant 98.5% reduction ($p < 0.001$). Additionally, assessed patient satisfaction reached 92.5% while staff satisfaction reached 75.5%, exceeding the set targets.

Conclusions: Implementation of an e-bilingual IC with e-signatures streamlined the consent process, minimized documentation deficiencies, and enhanced patient and staff satisfaction. Healthcare institutions can adopt a standardized approach that supports accreditation compliance, promotes efficient, patient-centered care, and provides a sustainable model for healthcare institutions seeking prompt, measurable improvements in quality and safety.

Keywords: Bilingual Informed Consent; e-Informed Consent; e-Signature; Electronic Health Record (EHR)

Introduction

The importance of informed consent in healthcare has garnered growing attention in recent decades. Informed consent is the process through which a patient voluntarily agrees to undergo medical treatment or participate in a clinical research study, based on sufficient knowledge and understanding of the procedures involved [1]. Informed consent is grounded in the ethical principles of respect for individual autonomy, beneficence, nonmaleficence, and justice [2,3]. Patient involvement in healthcare decisions is essential, and accreditation bodies require informed consent before admissions, surgeries, invasive procedures, and high-risk treatments. It supports high-quality care by ensuring patients and their families understand the risks, benefits, and alternatives, while upholding patient autonomy. Joint Commission International (JCI), under Patient-Centered Care (PCC.03.00), mandates that informed consent follow a hospital-defined process conducted by trained staff in a manner and language the patient or surrogate can understand [4].

Furthermore, informed consent is both an ethical and legal obligation for medical practitioners in the Kingdom of Saudi Arabia. Like JCI, the Saudi Central Board for Accreditation of Healthcare Institutions (CBAHI) mandates parallel requirements under the Patient and Family Rights standard (PFR.10). Documentation on consent form details plays a crucial role in protecting the rights of both patients and healthcare practitioners should a medico-legal dispute arise [5]. This comprehensive process must be clearly outlined in hospital policies and adhere to relevant legal and regulatory frameworks. Saudi Guidelines for informed consent issued by the Ministry of Health (MOH) emphasize the importance of providing informed consent forms in both English and Arabic (as the country's native language), aligning with the nation's Vision 2030 to improve patient satisfaction and engagement [6].

Advances in technology have rendered traditional paper-based consent processes increasingly outdated, driving the adoption of digital approaches in clinical and research settings [7]. Digital platforms can address longstanding challenges with paper consent, including illegibility, omissions, lack of standardization, and the risk of lost documentation [8,9]. Electronic Health Records (EHRs) further enhance efficiency by enabling rapid access to patient information, improving communication, supporting continuity of care, and strengthening overall quality [10]. However, implementing electronic informed consent (e-IC) requires robust security- and privacy-by-design measures to safeguard sensitive patient data [11]. Evidence on the transition from manual to electronic informed consent in clinical settings remains limited, leaving uncertainties regarding its effects on efficiency, data integrity, user experience, and overall care quality [12]. The extent of these benefits is influenced by the quality of the underlying EHR systems [13]. Nonetheless, studies indicate that digital transformation in healthcare can enhance operational efficiency, improve patient comprehension and information recall, increase satisfaction, and strengthen patient–provider engagement in both research and clinical environments [14-17].

Johns Hopkins Aramco Healthcare (JHAH), a JCI, CBAHI, and Planetree (Person-centered Care) accredited hospital in Saudi Arabia's Eastern Province, was cited in its reaccreditation survey visit for lacking a bilingual (English/Arabic) informed consent process. In response, a quality improvement project was launched to develop a bilingual electronic informed consent (e-IC) with e-signature integration into the EHR (Epic), leveraging LEAN principles to streamline workflow. The initiative aimed to meet accreditation and MOH requirements while maintaining high levels of patient and staff satisfaction, targeting ≥90% and ≥75%, respectively, by the end of 2024.

Methods

Ethical considerations

The study proposal was approved by the Institutional Review Board (IRB) at our organization (IRB 24-08-100).

Previous practice (Area for improvement)

Until 2021, our hospital employed a manual, paper-based informed consent process that did not include Arabic translation for procedures, surgeries, anesthesia, treatment, and transfusions. Whenever necessary, a translator would explain the consent details to the patient and sign the form in accordance with hospital policy, though. The signed informed consent form is then scanned and uploaded into Epic for secure documentation.

Quality improvement project design

Utilizing the technological capacity and our EHR (Epic) platform stability in our hospital, this Quality improvement initiative

designed to implement electronic dual-language (English/Arabic) informed consents (e-IC) into Epic, with electronic signatures (e-Sign) functionality starting 2022, whereas 2023 planned as the year for optimization and sustainability, through a collaborative teamwork between both accreditation team and Epic support team in JHAH.

Translation

The accreditation team at JHAH collaborated with the Epic team in January 2022 to plan the project, beginning with a feasibility assessment. The project effectively started in February 2022 by collecting informed consent forms from various services and departments, including Operating Rooms (OR), Day Surgery (DS), Outpatient Procedural Areas (OPPA), Anesthesia Clinic, Dental Clinic, Interventional Radiology (IR), Inpatient wards, and Outpatient specialty clinics where invasive procedures might be performed. Initially focusing on the top ten surgeries/procedures, it soon expanded to include the majority of procedures performed at our organization. Using the DeepL artificial neural network [18], all elements of informed consent were translated from English to Arabic. These translated forms were then reviewed by Arabic-speaking physicians and clinicians from each department, serving as subject matter experts, to ensure the accuracy of medical information and the clarity of language, thereby meeting patients' needs.

EHR (Epic) implementation

The translated and approved informed consents were sent to the Epic support team between March and September 2022 for integration into the EHR. Two SOFT LIVE events were conducted during September and October. However, the actual GO-LIVE, with tip sheets and full instructions, was initiated in November 2022, focusing on testing and optimizing functionality, as well as training end users, through the end of the year.

E-signature pads

E-signature pads (Topaz) were initially used in selected areas of our hospital, but not throughout the entire facility. To support the transition to a fully electronic process, the required number of e-sign pads was promptly purchased with the IT support team's help, ensuring coverage across all targeted areas, clinics, and districts.

Training End-users

Several awareness sessions were conducted during the go-live period to promote the proper use of the e-IC and e-Sign, and to address all end-user queries about the process. These sessions included both virtual and in-person, hands-on support from the Epic support team and clinical super users.

Quality Improvement Measures

The outcome measures included:

- **Percentage Reduction of Manually Scanned Informed Consents**: This metric is used to reflect the use of the previous paper-based consent process. It is calculated as: (Number of manually scanned consents /Total number of consents during the study period) x 100.
- **Percentage Increase of e-Signed e-Informed Consents:** This metric is used to reflect the adoption of the newly implemented e-consent process and is calculated as: (Number of e-signed e-informed consents/Total number of consents during the study period) x 100.
- For the above two measures, the pre-implementation period is Q4 2022, and the post-implementation period spans over two years from January 2023 to December 2024.
- **Percentage Reduction in Informed Consent Deficiencies**: This metric was calculated post-implementation as follows: [(Number of informed consent deficiencies pre-implementation – Number of deficiencies post-implementation)/Number of deficiencies pre-implementation] x 100.
- **Patient Satisfaction**: This metric was used to assess patients' satisfaction levels pre- and post-implantation. The survey, developed in June 2024, comprised seven questions covering multiple domains (See Supplement 1). It was distributed manually to patients visiting selected clinical and surgical units, using a convenience sampling approach of patients who visited the hospital during that month. The data were collected over one month.

مركز جونز هوبكنز أرامكو الطبي
Johns Hopkins Aramco Healthcare

Dear valued JHAH patients, Kindly, I would appreciate if you could take a few minutes of your time to fill the below satisfaction questionnaire in regards to "Obtaining the informed consent process", your honest feedback is valued.	عزيزنا مريض مركز جونز هوبكنز أرامكو الطبي ، من فضلك، سنكون ممتنين لو أمكنك تخصيص بضع دقائق من وقتك لملء استبيان الرضا أدناه فيما يتعلق بـ " الحصول على عملية الموافقة المستنيرة"، فنحن نقدر لك التعليق بصدق.
The results will be strictly used for understanding patient's experiences and opinions in regards to the newly implemented "Bi-lingual e-Informed consent with e-signature" in Epic. The information will be anonymous.	سيتم استخدام النتائج بشكل صارم لفهم تجارب المرضى وآرائهم فيما يتعلق بـ "الموافقة الإلكترونية المستنيرة ثنائية اللغة مع التوقيع الإلكتروني" التي تم تنفيذها حديثًا .وكذلك فأن المعلومات ستعامل ب سرية تامة بدون ذكر أسماء.
Please feel free to add any suggestion or comment you would like.	لا تتردد في إضافة أي اقتراح أو تعليق ترغب فيه
We cordially thank you in advance for your participation.	***ونحن نشكرك جزيلا مقدما على مشاركتك***

Usability and Interface

1-I found the electronic consent & e-signature pads user-friendly.	قد وجدت أن منصات الموافقة الإلكترونية والتوقيع الإلكتروني سهلة الاستخدام
○ Disagree/ لا أوافق ○ Neutral/ حيادي ○ Agree/ أوافق	

Efficiency and Workflow

2-The electronic consent made the process of obtaining consent more efficient compared to the traditional manual process.	أصبحت عملية الحصول على الموافقة المستنيرة أكثر كفاءة مقارنة بالعملية اليدوية التقليدية السابقة
○ Disagree/ لا أوافق ○ Neutral/ حيادي ○ Agree/ أوافق	
3-The electronic consent & e-signature pads save my time when signing an informed consent.	توفر لوحات الموافقة الإلكترونية والتوقيع الإلكتروني وقتي عند التوقيع على الموافقة المستنيرة
○ Disagree/ لا أوافق ○ Neutral/ حيادي ○ Agree/ أوافق	

Communication and Clarity

4-The electronic consent is effective in facilitating a clear communication about my procedure/surgery.	تعتبر الموافقة الإلكترونية فعالة في تسهيل التواصل الواضح حول الإجراء/الجراحة التي أجريتها
○ Disagree/ لا أوافق ○ Neutral/ حيادي ○ Agree/ أوافق	
5-The electronic consent supports a clear understanding before giving my consent.	تدعم الموافقة الإلكترونية الفهم الواضح قبل إعطاء موافقتي
○ Disagree/ لا أوافق ○ Neutral/ حيادي ○ Agree/ أوافق	

Security and Privacy

6-I am confident that electronic consent system can protect my information, privacy and secure my data.	أنا واثق من أن نظام الموافقة الإلكترونية يمكنه حماية معلوماتي وخصوصيتي وتأمين بياناتي
○ Disagree/ لا أوافق ○ Neutral/ حيادي ○ Agree/ أوافق	

Overall Satisfaction

7-Overall, I am satisfied with the electronic consent process with electronic signature.	بشكل عام، أنا راض عن عملية الموافقة الإلكترونية مع التوقيع الإلكتروني
○ Disagree/ لا أوافق ○ Neutral/ حيادي ○ Agree/ أوافق	

Any Suggestion/Comment	**أي اقتراح/تعليق**

Supplement 1: Patient satisfaction survey questions.

- **Staff Satisfaction**: This metric was used to compare employees' satisfaction levels pre- and post-implantation. The survey, created in June 2024, consists of 12 questions covering several domains (See Supplement 2) and was distributed to all surgeons and clinicians authorized/ privileged to perform surgeries or invasive procedures, as well as anesthesiologists, via JHAH e-mail using Microsoft Forms. The data were collected over one month using convenience sampling methodology.

مركز جونز هوبكنز أرامكو الطبي
Johns Hopkins Aramco Healthcare

Dear JHAH medical Staff,

Kindly, I would appreciate if you could take a few minutes of your time to fill the below employee satisfaction questionnaire in regards to "Obtaining the informed consent process", your honest feedback is valued.

The results will be strictly used for understanding of staff experiences and opinions in regards to the newly implemented "Bi-lingual e-Informed consent with e-signature" in Epic, an initiative to meet accreditation and MOH requirements in addition to LEAN the process. The information will be absolutely anonymous.

Please feel free to add any suggestion or comment you would like to.

We cordially thank you in advance for your participation.

Usability and Interface

1- I found the electronic consent with e-signature platform user-friendly.

○ Disagree ○ Neutral ○ Agree

2- I rarely encounter technical issues while using, accessing or retrieving e-consent forms from Epic.

○ Disagree ○ Neutral ○ Agree

Training and Support

3- I was provided with adequate training to use the e-consent system effectively.

○ Disagree ○ Neutral ○ Agree

4- There is an ongoing support available when I have questions or problems with the e-consent.

○ Disagree ○ Neutral ○ Agree

Efficiency and Workflow

5- The e-consent made the process of obtaining consent more efficient compared to the traditional manual process

○ Disagree ○ Neutral ○ Agree

6- The e-consent with e-sign saves my time when obtaining consent from patients.

○ Disagree ○ Neutral ○ Agree

Communication and Clarity

7- The e-consent is effective in facilitating clear communication with patients about the procedure/surgery.

○ Disagree ○ Neutral ○ Agree

Accuracy and Documentation

8- The e-consent is reliable in recording and storing patient consents.

○ Disagree ○ Neutral ○ Agree

Security and Privacy

9- I am confident that e-consent system's ability to protect patient privacy and secure their data.

○ Disagree ○ Neutral ○ Agree

Adoption and Change Management

10- The transition from paper-based to the electronic consent forms was smooth.

○ Disagree ○ Neutral ○ Agree

Overall Satisfaction

11- Overall, I am satisfied with the e-consent process with e-signature.

○ Disagree ○ Neutral ○ Agree

Comparision with OLD MANUAL process

12- What your overall satisfiction with the previuos process using the hardcopy cons

○ Disagree ○ Neutral ○ Agree

Any Suggestion/Comment

Supplement 2: Staff satisfaction survey questions.

The reliability of the survey instrument was evaluated using Cronbach's alpha test to ensure internal consistency and suitability for the JHAH context. Content validity was confirmed through expert review, with a Content Validity Index (CVI) ranging from 0.1 to 0.5 guiding the refinement and finalization of the survey tool. Both satisfaction surveys used a 3-point Likert Scale (3 = Satisfied (Agree), 2 = Neutral, and 1 = Dissatisfied (Disagree)).

Statistical analysis

Paired t-test and Mann-Whitney U tests were used as appropriate via SPSS v.30.0.0, with a statistically significant level set at $p \leq 0.05$.

Results

Data collected from January 2023 to December 2024 for all the measures showed the following.

Percentage reduction of manually scanned informed consents

Data analysis showed a statistically significant decrease in the number of scanned informed consent (IC) forms, from 7,889 out of 9,470 (83.3%) total ICs in Q4 2022 (Pre-implementation) to 5,406 out of 114,414 total ICs between January 2023 and December 2024 (Post-implementation). This represents a substantial drop to 4.7% ($p < 0.001$), indicating a marked reduction in the use of the manual paper-based informed consent forms following the adoption of the new electronic process (Figure 1).

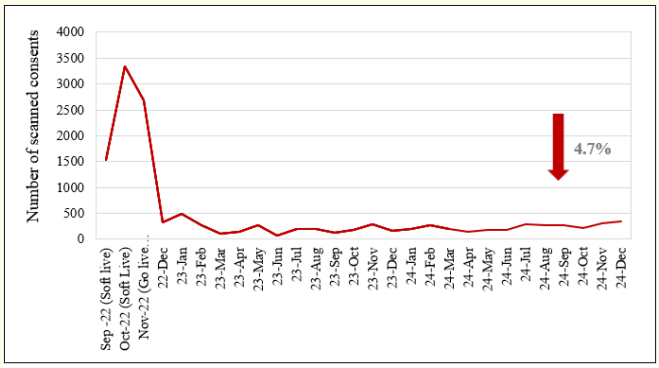

Figure 1: The number of scanned consents that are signed manually and uploaded into Epic has decreased to 4.7% after two years of implementation.

Percentage increase of E-Signed E-informed consents

Analysis revealed a statistically significant increase in the use of e-signed/electronic informed consents (e-IC), rising from 1,581 out of 9,470 (16.7%) total ICs in Q4 2022 (Pre-implementation) to 108,966 out of 114,414 total ICs between January 2023 and December 2024 (Post-implementation). This represents a sharp increase to 95.2% ($p < 0.001$), demonstrating the strong commitment of our medical staff to adopting the new electronic process (Figure 2).

Percentage reduction in informed consent deficiencies

Analysis of pre- and post-implementation data demonstrated a statistically significant reduction in informed consent

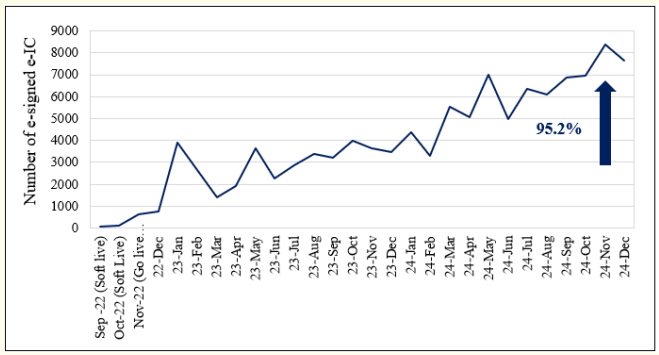

Figure 2: The number of e-signed e-ICs that are integrated in Epic has increased to 95.2% after two years of implementation.

deficiencies. Deficiencies decreased from 63,267 in Q4 2022 (Pre-implementation) to 949 deficient elements (among 114,414 consents over the two-year post-implementation period; January 2023 through December 2024). This represents a 98.5% reduction of deficiencies ($p < 0.001$), with the highest number of deficiencies recorded at 186 and the lowest at eight throughout the study period, highlighting the effectiveness of the e-consent system (Figure 3).

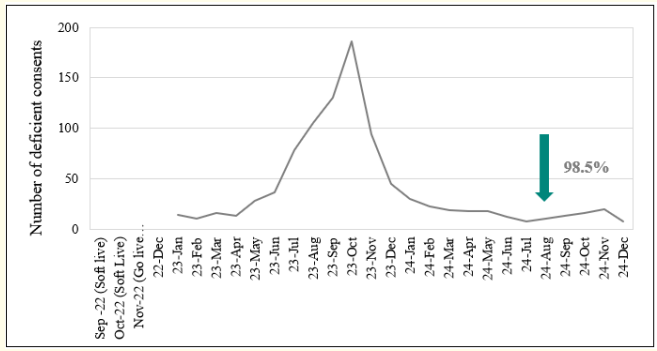

Figure 3: The number of deficient consents detected after two years of implementation has decreased by 98.5%.

Patient satisfaction

Cronbach's alpha was computed across all survey domains and yielded a reliability coefficient of r = 0.79, indicating acceptable reliability. Data were collected over one month, resulting in (n=418) completed responses, representing approximately 27.9%

of the average total outpatient visits (N=1500) to the selected units during that period, and a 100% response rate among the approached targeted patients. Analysis revealed an overall patient satisfaction rate of 92.5% ($p < 0.001$), meeting our target (Figure 4).

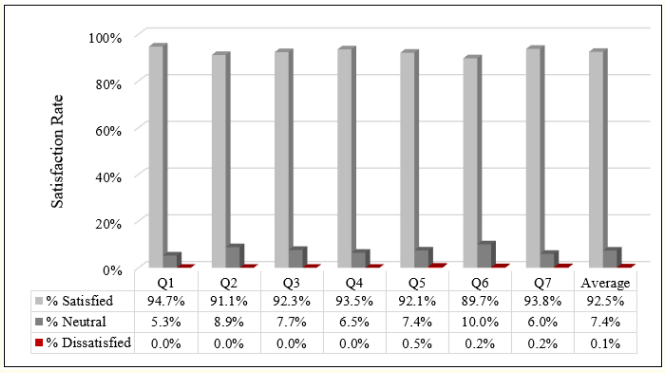

Figure 4: Patient satisfaction rate maintained at an average of 92.5% after two years of implementation (n = 418).

The overall patient responses mean score was 2.92 ± 0.016 (95% CI: 2.89–2.95). Most participants provided positive feedback, appreciating the new electronic consent process. However, four patients (0.96% of respondents) suggested implementing e-sign pads with thumbprint recognition to better accommodate elderly or illiterate users.

Staff satisfaction

Cronbach's alpha was computed across all survey domains and yielded a reliability coefficient of r = 0.84, indicating acceptable reliability. Microsoft Forms facilitated the feedback collection from (n=104) medical staff members, including surgeons and clinicians authorized/privileged to perform surgeries or invasive procedures (N=82), as well as anesthesiologists (N=38) in our organization. The response rate reflects 86.7% of the targeted medical staff. The average staff satisfaction rate rose from 8.7% to 75.5% ($p < 0.001$), meeting our target (Figure 5). Notably, in October 2025, the same survey was distributed to medical staff, and the data collected showed a statistically significant increase in staff satisfaction to 99.2% ($p < 0.001$), exceeding the primary target and indicating sustained improvement and higher staff satisfaction with the new process.

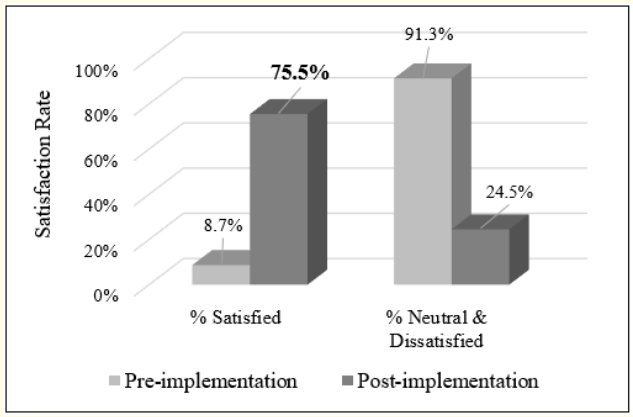

Figure 5: Employee satisfaction rate maintained at an average of 75.5% after two years of implementation (n = 104).

Nevertheless, survey responses from 104 medical staff members revealed an overall mean score of 2.7± 0.18 (95% CI: 2.4-3.0) (Figure 6), reflecting a favorable perception of the new process, compared with a mean score of 1.4 ± 0.65 (95% CI: 1.0-1.9) under the previous system ($p < 0.001$), demonstrating a marked enhancement in staff satisfaction.

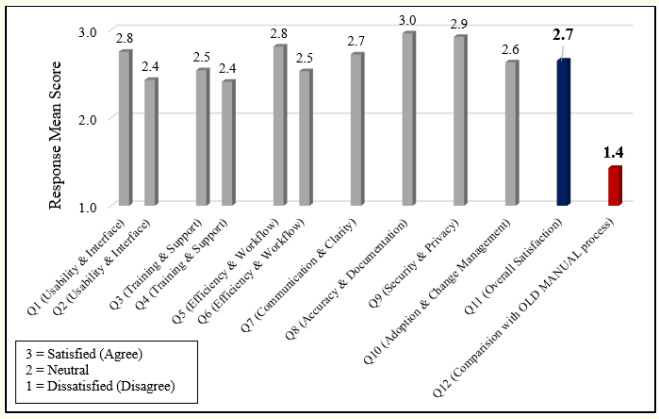

Figure 6: Medical staff satisfaction: Among 104 staff respondents, the overall mean score was 2.7, indicating a generally positive perception of the new process, compared with a mean score of 1.4 under the previous process.

Project obstacles

Analysis of the medical staff satisfaction survey revealed that 34% of respondents reported challenges, primarily technical issues and system glitches, causing delays in the informed consent process (Usability/Interface and Efficiency/Workflow domains). Additional feedback emphasized the need for pre-implementation training (Training and Support domain). Specific issues included malfunctions with the e-sign pad (Topaz), BC connectivity issues, and non-functional portable devices. Among patients, 10% provided comments, and 0.96% requested e-sign pads with thumbprint support.

Project success story

On the other hand, success stories included positive end-user experiences; most respondents provided free-text descriptions of accomplishments, workflow improvements, and improved record-keeping. A variety of themes emerged from both patients and staff, such as:

- The electronic consent has removed issues of illegibility, unclear entries, and the need for handwritten documentation.
- The e-consent made a significant improvement in the spelling error and saved time.
- It becomes much easier to obtain consent readily available at any time.
- I am happy with the system; the only problem is that sometimes when the patient signs the consent, we need to pull and insert the USB cord again, and it takes time to connect.
- Very satisfied with the consent.
- Thanks to the nursing staff for their good care and for protecting my confidentiality, in addition to the physician for giving me detailed information about my surgery.
- Many thanks for all the improvements that have been seen during the past period, and looking for more.
- Electronically stating the exact procedure/surgery that is going to take place.
- Great initiative.

Discussion

With the expansion of Healthcare Information Technology (HIT), Electronic Health Records (EHRs) have become central to healthcare delivery, though maintaining patient data security remains critical. Traditional informed consent processes are often manual, time-consuming, prone to illegibility, and may cause patient dissatisfaction [19]. A literature review identified limited studies on the implementation of e-informed consent (e-IC) in academic, research, and cancer centers, primarily aimed at enhancing the patient experience. These studies reported about 80% functionality, with varying adoption levels depending on EHR integration [20,21]. In the US and Europe, e-signatures must comply with federal regulations (21 CFR 11c), requiring unique, verifiable identifiers [20]. Some Institutional Review Boards (IRBs) expressed uncertainty about the validity of e-signatures, applicable laws, and secure storage [22].

Integrating a bilingual electronic informed consent (e-IC) with e-signature into the EHR was the primary aim of this quality improvement initiative, addressing documentation challenges while ensuring security and auditability. LEAN principles were applied to streamline workflow, maintain compliance with accreditation and MOH requirements, and enhance both patient and staff satisfaction. Through this initiative, we wanted to transition to an entirely paperless informed consent system by the end of 2022. Data analysis showed high staff adoption of the e-IC. At the same time, paper-based consents were retained only for illiterate patients who require thumbprints, as current e-sign pads do not support this feature. By Q4 2024, manually signed and scanned consents had decreased significantly to 4.7%, while e-signed e-ICs had increased dramatically to 95.2% ($p < 0.001$). In contrast, St. John., *et al*. reported continued reliance on paper-based consents despite digitalization efforts [23].

Additionally, the e-IC implementation resulted in a 98.5% reduction in consent deficiencies, compared to the high error rates observed with the old paper-based process. Similarly, Dyke., *et al*. found that 62% of paper consents omitted key risk elements, compared with <2% using e-consent forms [24], with comparable improvements reported in other surgical specialties [25]. Literature supports that e-consent systems reduce variability and

ensure standardized, procedure-specific information, consistent with the outcomes of our study [26].

Patient satisfaction reached 92.5% post-implementation, while medical staff satisfaction was 75.5%, reflecting strong engagement with the new e-process that required substantial effort to secure employee buy-in [27]. Interestingly, data collected later in 2025 showed staff satisfaction rising to 99.2%, indicating sustained improvement. In our study, data were collected anonymously, without recording participants' ages, unlike Chen., *et al*. who found that younger users were more satisfied with technology-based consent [20]. While ongoing initiatives continue to address identified gaps, for instance, procuring e-sign pads with thumbprint support and enhancing overall patient and staff experience, beginning of 2025, these devices have been successfully applied, ultimately further improving patient satisfaction. Consistent with two published efforts by Buckley., *et al*. our e-IC platform exemplifies an innovative, lean operational model that enhances patient engagement, education, and compliance with the consent process regulations [28,29].

Although this study had limitations, including its single-center design and the absence of financial data, these factors restricted our ability to compare the efficiency and cost-effectiveness of paper-based versus electronic informed consent within JHAH or to benchmark against similar institutions. However, the successful adoption of the e-IC with e-Signature at JHAH demonstrates a scalable model for healthcare settings with comparable infrastructures, with witnessed benefits of the e-IC process offering a potential best-practice framework for broader adoption.

Conclusion

Our quality initiative demonstrated that integrating an electronic bilingual informed consent form with e-signature functionality has streamlined the informed consent workflow, eliminating paperwork. This approach has effectively reduced deficiencies in consent documentation while enhancing satisfaction for both patients and medical staff. It also supports improved access to care, equity, and a person-centered approach to healthcare quality and safety.

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