Promoting informed consent in a children's hospital in Tabriz, Iran: a best practice implementation project

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ABSTRACT

Introduction: Informed consent is a continuous and dynamic process. It is a crucial part of healthcare procedures that becomes more complex in a pediatric clinical practice, where parents must make decisions for their children.

Objectives: The aim of this implementation project was to evaluate the current practice and implement the best practice related to obtaining informed consent in a children's hospital in Tabriz, Iran.

Methods: A clinical audit was undertaken using the JBI Practical Application of Clinical Evidence System (JBI PACES) tool. Five audit criteria representing the best-practice recommendations for informed consent were used. A baseline audit was conducted, followed by the implementation of multiple strategies. The project was finalized with a follow-up audit to determine change in practice.

Results: The compliance rate of all criteria improved from baseline to follow-up audit. Criteria 1 (obtaining informed consent prior to all nursing procedures) and 5 (provision of information related to the necessity of the treatment) reached 97% compliance in the follow-up cycle. Criterion 4 (provision of information related to the nature and effect of the treatment) achieved 74% compliance. Both criteria 2 and 3 (provision of information related to alternative treatments and consequences of refusing treatment) reached 57% in the follow-up cycle. To improve compliance, meetings were organized with the heads of departments, nurses and residents regarding informed consent. Also, staff were encouraged to report cases where informed consent was not obtained.

Conclusion: The audit results indicated an improvement in obtaining informed consent in the included departments. The interventions that were employed can facilitate the implementation of evidence into clinical practice.

Keywords Best practice; clinical audit; evidence-based practice; informed consent

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Introduction

Informed consent is a serious issue in medical ethics.[1] It involves patients obtaining comprehensive information about their health before making an autonomous decision about their care. This is considered a continuous and dynamic process rather than an isolated one.[2] Recently, the interest in informed consent has increased among medical professionals due to the development of new guidelines for doctors.[3] One benefit of informed consent is enhanced trust in clinical practice, which is the foundation of the relationship between patients and healthcare professionals.[4] Through informed consent, patients receive necessary information about medical procedures, such as the nature of the procedure, potential benefits and adverse events, alternative treatment options and consequences of not undergoing the procedure.[5] Findings from a literature review showed that the number of patients who obtained information about the possible risks and complications of health procedures was low, especially in older patients. However, written materials and discussions between patients and physicians have

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been shown to improve patients' knowledge about procedures.[6] Documents of informed consent and patient education materials should be stored in the electronic medical record, or other methods where possible.[7]

Informed consent becomes more complex in pediatric clinical practice, where parents must make decisions for their children.[8] Parents are more vulnerable when their children require a medical procedure, and they may find the timing of an informed consent discussion inappropriate. However, to demonstrate respect for parents' decisions, health professionals should offer comprehensive and understandable information to parents.[9] They should also provide appropriate information to children and their families, and consider a patient's spectrum of intellectual disability.[10]

Nurses are at the forefront of patient-provider interactions as advocates for patients and should support patients' rights to be fully involved in the healthcare decision-making process.[11] In order for nurses to be patient advocates, they need to improve their communication skills, as well as clinical and ethical knowledge.[12] There is lack of information in the literature around informed consent in nursing procedures.[13] In this audit project, we considered parental consent in medical, surgical and nursing procedures.

The status of informed consent in Iran has been shown to be unacceptable. For example, results of one study from Iran showed that the status of informed consent in the included hospitals was poor, and patients considered the provided information to be insufficient.[14] A similar study in Iran also showed that patients did not have appropriate information about their own rights, and the status of informed consent was unsuitable in the included hospitals.[15] Another study in Iran declared that patients' knowledge before and after completing the informed consent form was low, which is the responsibility of the healthcare provider.[16]

Aims and objectives

The aim of this project was to evaluate current practice and implement the best practice related to promoting informed consent in nursing and medical procedures, as well as surgical consent in a pediatric hospital in Tabriz, Iran. The specific objectives were:

- To determine current compliance with evidence-based criteria regarding informed consent by carrying out an initial audit.
- To implement strategies for obtaining informed consent in order to address non-compliance with criteria.
- To conduct a follow-up audit to determine improvements in compliance with evidence-based criteria regarding obtaining informed consent.

Audit question

To what extent are nurses and medical staff (physicians or residents) in compliance with obtaining informed consent according to JBI recommended practice?

Methods

The current evidence-implementation project used the JBI Practical Application of Clinical Evidence System (PACES) and Getting Research into Practice (GRiP) audit and feedback tool, which involves three phases of activity:

i) Establishing a team for the project and undertaking a baseline audit based on the criteria informed by the evidence.
ii) Reflecting on the results of the baseline audit, and designing and implementing strategies to address non-compliance found in the baseline audit, informed by the GRiP framework.
iii) Conducting a follow-up audit to assess the outcomes of the interventions implemented to improve practice, and identify future practice issues to be addressed in subsequent audits.

The project was undertaken in the ear, nose and throat (ENT) and surgical wards of a children's hospital in Tabriz, Iran. The ENT ward has 30 beds and 32 nurses, and the surgical ward has 28 beds and 30 nurses. Because the children were younger than nine years, parental informed consent was the subject of this audit project.

This project was submitted and approved by the Ethics Committee of the Tabriz University of Medical Sciences (No. IR.TBZMED.REC.1396.1262).

Phase 1: Team establishment and baseline audit

The audit team consisted of a lecturer, physician, nurse, PhD students in health policy, the quality control expert of the pediatric hospital, and research staff. The audit criteria, which were derived from the best available evidence,[17] included the following five items:

i) Informed consent obtained prior to all nursing procedures (that are not emergency situations) is documented.

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ii) The patient's family has been provided with information by staff related to alternative treatments.
iii) The patient's family has been provided with information by staff related to the consequences of refusing treatment.
iv) The patient's family has been provided with information by staff related to the nature and effect of the treatment.
v) The patient's family has been provided with information by staff related to the necessity of the treatment.

These criteria were developed by JBI and were translated to Persian by two of the researchers. A meeting was conducted to familiarize the members with the project and to discuss the audit criteria and data collection methods. The baseline audit to detect current practice of obtaining informed consent in ENT and surgical wards was conducted in April 2018. Forty families of children with a hospital stay of more than one day who had signed the consent form to participate in the study were selected randomly. Table 1 shows the evidence-informed audit criteria used in the project (baseline and follow-up audit) as well as a description of the sample and approaches to measuring compliance with the best practice for each audit criterion.

Phase 2: Design and implementation of strategies to improve practice (GRiP)

A four-month implementation period was conducted from June 11 to October 22, 2018. Results were analyzed following the baseline audit to identify gaps between the current practice and the best practice recommendations. The project team summarized areas of excellent (greater than 75%), moderate (50%-75%) and low (less than 50%) performance. We used the JBI GRiP tool to identify barriers in practice and suggest strategies for improvement. The necessary resources for the implementation of strategies were discussed by the audit team. The GRiP report was discussed in face-to-face meetings, and

Table 1: Audit criteria, sample and method employed to measure compliance with parental informed consent

Audit criterion	Sample*	Method used to measure percentage compliance with best practice
It is documented that informed consent is obtained prior to all nursing procedures (that are not emergency situations).	Baseline: 40 families of children Follow-up: 35 families of children	Documentation audit – review of child's records
It is documented that staff have provided the patient's family with information related to alternative treatments.	Baseline: 40 families of children Follow-up: 35 families of children	Interview child's family Documentation audit – review of child's records
It is documented that staff have provided the patient's family with information related to the consequences of refusing treatment.	Baseline: 40 families of children Follow-up: 35 families of children	Interview child's family Documentation audit – review of child's records
It is documented that staff have provided the patient's family with information related to the nature and effect of the treatment.	Baseline: 40 families of children Follow-up: 35 families of children	Interview child's family Documentation audit – review of child's records
It is documented that staff have provided the patient's family with information related to the necessity of the treatment.	Baseline: 40 families of children Follow-up: 35 families of children	Interview child's family Documentation audit – review of child's records

*All children were younger than nine years of age.

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opinions of key stakeholders were gathered. Stakeholders were informed about the results of the audit and any other details about the process through ongoing communications.

Phase 3: Follow-up audit post implementation of change strategy

A follow-up audit was conducted in November 2018 using the same criteria as the baseline audit to evaluate changes in nurses' and medical staffs' compliance.

Results

Phase 1: Baseline audit

Forty families of children participated and were surveyed for the audit criteria at the baseline audit. Data are presented in graphic form using the JBI PACES (Joanna Briggs Institute, Adelaide, Australia) in Figure 1. Compliance with two of the five criteria (criterion 1: Obtaining informed consent prior to all nursing procedures, and criterion 5: Provision of information by staff related to the necessity of the treatment) was greater than 75%; one was 53% (criterion 4: Provision of information by staff related to the nature and effect of the treatment); and two were less than 50% (criterion 2: Provision of information by staff related to alternative treatments, and criterion 3: Provision of information by staff related to consequences of refusing treatment).

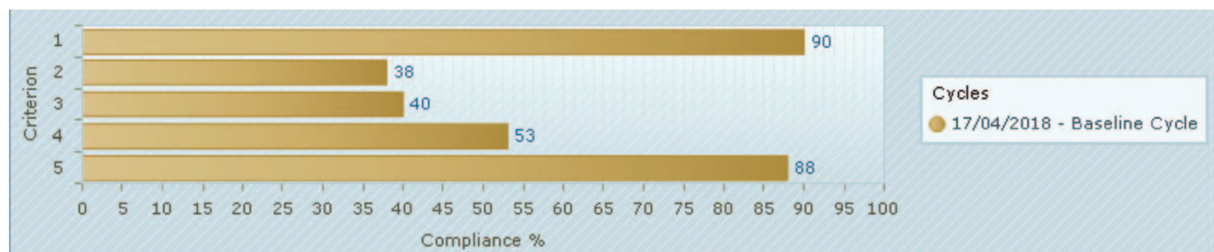
Phase 2: Strategies for Getting Research into Practice (GRiP)

In this phase, we used the PDCA (plan, do, check, act) cycle.[18] First, we planned what was required to affect the desired change, and then we implemented the strategies with the staff of the two wards. We held meeting sessions with nurses, residents and heads of the two departments. Then, we convinced staff to report cases where informed consent was not obtained. Next, we tracked the outcomes of the interventions, and finally, we ensured that the implemented changes continued to have the sustained desired effect.

Four barriers to compliance with best practice were identified, and strategies to overcome these barriers (as summarized in Table 2) were formulated and then implemented.

Barrier 1: Non-commitment of the department heads to obtain informed consent from patients before surgery.

For this strategy, we attempted to persuade physicians to obtain informed consent by organizing a meeting with the heads of the departments. We highlighted the legal issues of informed consent to convince the heads of departments and other physicians to obtain informed consent from the patients before surgery. The resources required included a meeting room and lecture content to persuade and motivate the physicians. The resulting outcome was



Criteria legend

1. It is documented that informed consent is obtained prior to all nursing procedures (that are not emergency situations). (40 of 40 samples taken)
2. It is documented that staff have provided the patient's family with information related to alternative treatments. (40 of 40 samples taken)
3. It is documented that staff have provided the patient's family with information related to the consequences of refusing treatment. (40 of 40 samples taken)
4. It is documented that staff have provided the patient's family with information related to the nature and effect of the treatment. (40 of 40 samples taken)
5. It is documented that staff have provided the patient's family with information related to the necessity of the treatment. (40 of 40 samples taken)

Figure 1: Compliance (%) with best practice for audit criteria for parental informed consent at baseline

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Table 2: Getting Research into Practice matrix

Barrier	Strategy	Resources	Outcomes
Non-commitment of the department heads to obtain informed consent from patients before surgery.	Organize a meeting with the heads of departments.	Meeting room, educational content	Department heads demonstrated commitment and willingness to obtain informed consent from patients.
Inattention and unwillingness of residents to obtain informed consent.	Organize a meeting with residents.	Meeting room, educational content	The number of residents who obtained informed consent increased.
Inattention of nurses to obtain informed consent.	Organize meeting with nurses.	Meeting room, educational content	The nurses demonstrated increased accuracy and attention to obtaining informed consent.
Identify surgeries without informed consent.	Convince personnel to report lack of informed consent cases.	Worksheet, computer, statistical software	The surgeries without informed consent were identified and analyzed, and feedback was provided.

commitment and willingness of the department heads to obtain consent from patients.

Barrier 2: Inattention and unwillingness of residents to obtain informed consent.

The strategy to overcome this barrier involved organizing a meeting with residents. In teaching hospitals, the informed consent is usually obtained by the residents; therefore, it was necessary to organize a separate meeting to emphasize the importance of obtaining informed consent. A meeting room and lecture content to increase the motivation of residents to obtain informed consent were required. The outcome was that the number of residents who obtained informed consent increased.

Barrier 3: Inattention of nurses to obtain informed consent.

A meeting with nurses was organized to overcome this barrier. Because the patient's documents are completed before going to the operating room, the nurses must carefully check the documents and inform the physician if informed consent is not obtained. The operating room nurses should also check the patient's document before surgery. A meeting room and lecture content to increase the motivation of nurses to carefully check the patient's documents were required. The resulting outcome was increased accuracy and attention to obtaining informed consent by nurses.

Barrier 4: Identify surgeries without informed consent.

This strategy required convincing personnel to report cases where informed consent was not obtained. To identify these cases, we enlisted the help of the department's personnel to review the statistics of each department and physician, and send the required feedback to them separately. The resources involved included a worksheet for reporting cases, additional personnel to review and analyze reports, and computer with statistical software. The outcome was that surgeries without informed consent were identified and analyzed, and feedback was provided.

Phase 3: Follow-up audit

Figure 2 presents the follow-up audit results compared with the baseline results. The compliance rate of all criteria improved. Criteria 1 and 5 reached 97%, criterion 4 achieved 74%, and both criteria 2 and 3 reached 57% in the follow-up cycle.

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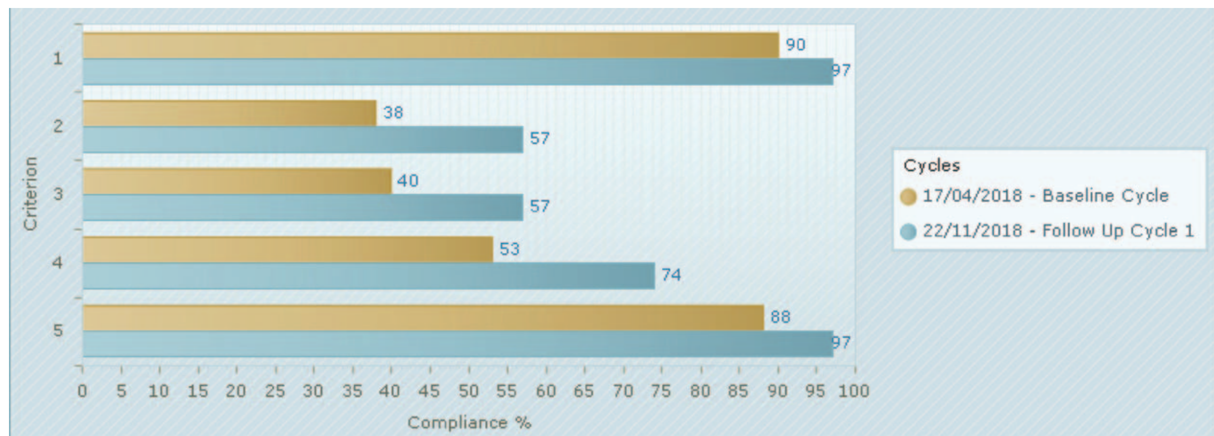

Criteria legend

1. It is documented that informed consent is obtained prior to all nursing procedures (that are not emergency situations). (35 of 35 samples taken)
2. It is documented that staff have provided the patient's family with information related to alternative treatments. (35 of 35 samples taken)
3. It is documented that staff have provided the patient's family with information related to the consequences of refusing treatment. (35 of 35 samples taken)
4. It is documented that staff have provided the patient's family with information related to the nature and effect of the treatment. (35 of 35 samples taken)
5. It is documented that staff have provided the patient's family with information related to the necessity of the treatment. (35 of 35 samples taken)

Figure 2: Compliance (%) with best practice for audit criteria for parental informed consent at baseline and follow-up audits

Discussion

Providing information about alternative treatments (criterion 2) was one of the criteria with poor compliance with best practice in the baseline audit (38%); however, compliance improved to 57% in the follow-up audit. Results from one study showed that some of the challenges of obtaining informed consent are the complexity and uncertainty of the information about alternative treatments and advanced technologies, which make it difficult to explain the expected risks, benefits and outcomes.[19]

Findings from this project indicated that post-implementation compliance with obtaining informed consent prior to all nursing procedures (criterion 1) and providing information related to the necessity of the treatment (criterion 5) were good (97% after follow-up). This is in contrast to results of a study that showed poor compliance with obtaining informed consent before surgical procedures in Iran. Additionally, the quality of the acquisition of informed consent was inappropriate.[20] Moreover, another study from Iran showed that obtaining informed consent was done inappropriately, and patients did not receive information related to their educational level.[21]

The information provided related to consequences of refusing treatment (criterion 3) had a low compliance rate in the baseline audit (40%); however, compliance improved to 57% in the follow-up audit. Grauberger *et al.*[22] showed that, in a retrospective cohort study, failure to explain risks and adverse effects of surgery, and alternative treatment options, were the most common allegations by patients in medical malpractice claims.[22] A similar study indicated that 85% of the patients undergoing total knee arthroplasty did not obtain any information about alternative treatments from the providers, and only 28% of the patients received information about possible complications of the procedure.[23] Along the same lines, a study from Southern Ethiopia found that 73.9% of participants did not receive any information about alternative treatment options.[24] Badsar *et al.*[25] and Shaker *et al.*[26] reached similar results in Iran. Alternative treatment options and their success rates are components to be disclosed by the informed consent form.[27]

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Compliance with providing information about the nature and effect of the treatment (criterion 4) improved from 53% in the baseline audit to 74% in the follow-up audit. A study from Iran showed that most of the patients did not receive information about possible complications of the surgical procedure, such as death. The most important factors of this criterion included the patient's level of education and type of surgery.[28]

Results of this implementation project showed that organizing meetings with nurses and residents about the informed consent improved results in the follow-up phase of the audit. Similarly, results from one study found that residents participating in educational programs about informed consent became more confident in their ability to obtain informed consent. Including the informed consent training in the surgical residency curriculum appeared to contribute to better results.[29] One qualitative study showed that inadequate education and training of staff about the informed consent process could lead to deficiencies in this process.[30]

Common barriers in obtaining informed consent relate to communication between healthcare provider and patient, such as cultural and lingual barriers and the patient's level of education.[31] To resolve these barriers and improve the quality of informed consent, informed consent should be included in medical students' curriculum.[32] Also, educating healthcare providers and creating policies and strategies for obtaining informed consent in hospitals would help overcome these barriers.[33,34]

Conclusion

This best-practice implementation project used a clinical audit process to monitor the informed consent process in a pediatric hospital setting. The audit results indicated an improvement in all criteria. The implemented strategies included organizing meetings with the heads of departments, all nurses and residents regarding informed consent, and convincing staff to report the lack of informed consent cases. These strategies can facilitate the implementation of evidence into clinical practice. Future research should focus on wider settings to ensure that more patients with different types of diseases and surgeries are included. Further audits should be conducted to monitor practice and the effect of best-practice changes.

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