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An audit of the quality of orthodontic consent form completion among IIUM postgraduate residents: first-cycle findings

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Abstract

Informed consent (IC) is both a legal and ethical requirement in clinical practice and holds particular importance in orthodontics due to the long-term nature of treatment. Comprehensive documentation of the consent process supports patient autonomy, enhances communication, and ensures professional accountability. This audit aimed to assess the quality and completeness of informed consent documentation within the Doctor in Orthodontics (DrOrth) postgraduate programme at the International Islamic University Malaysia (IIUM), as part of a Continuous Quality Improvement (CQI) initiative. A retrospective audit was conducted on 360 randomly selected patient records, managed by eight postgraduate residents between February and June 2024. Nine target criteria were assessed based on the Malaysian Medical Council's Guidelines for Consent for Treatment, with each criterion benchmarked against a 100% compliance standard. The sample represented approximately 45% of the total eligible patient population. All active orthodontic cases under postgraduate care were included. While the presence of consent forms was documented in 96.1% of cases, overall adherence to the nine target criteria varied between 84.7% and 96.1%. The highest compliance was observed for patient/guardian signatures and clinician documentation. However, the 'Benefits and Risks' section showed the lowest completion rate (84.7%), indicating a potential gap in documenting the treatment implications. Additionally, good effort found in 23.3% of forms which included documentation of 'Additional Specific Risks'. Consent forms were present in the majority of cases, the audit identified areas requiring improvement in the completeness of documentation. Targeted improvements, particularly in risks documentation, are recommended to enhance compliance with informed consent standards in orthodontic care.

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Introduction

Consent, as defined by Oxford University Press, refers to the act of giving permission for something to take place or agreeing to do something. In the context of healthcare, Informed Consent (IC) extends this concept by requiring that patients are adequately informed of the potential risks, benefits, and consequences of a proposed treatment before providing their agreement (Chougule *et al.*, 2025). Historically, medical practice was dominated by a paternalistic model, where decisions were primarily made by clinicians under the assumption that the

doctor knew best. Over time, this approach has evolved toward a patient-centred model of care that prioritises patient autonomy and shared decision-making (Bora *et al*., 2020; Yaakob, 2023).

In orthodontics, IC holds particular significance due to the long-term nature of treatment, which often spans several years. This necessitates sustained communication between clinicians and patients to ensure that individuals remain informed and actively involved in their care (Hazelan & Jahn Kassim, 2018; Meade *et al*., 2019). Such engagement aligns with the ethical duty to respect patient autonomy. Obtaining IC is both a legal and ethical obligation in clinical practice. As part of professional transparency and the duty of candour, healthcare providers are required to furnish patients with adequate information regarding the proposed treatment. The use of a written consent form serves as a standardised method to document that this process has been completed. Typically, these forms are filed within the patient's clinical records or notes as part of routine documentation. Given the ethical and legal significance of IC particularly in long-term treatments like orthodontics, it is essential to ensure that consent practices are not only performed but also properly documented, with all mandatory sections are appropriately filled, in accordance with established standards.

This audit, the first conducted following the commencement of the Doctor in Orthodontics (DrOrth) postgraduate programme at the International Islamic University Malaysia (IIUM) in 2021, was undertaken as part of the department's ongoing quality improvement activities to improve and maintain high standards of clinical practice. The DrOrth postgraduate programme at the IIUM is accredited by both the Malaysian Qualifications Agency (MQA) and the Royal College of Surgeons of Edinburgh (RCSEd)**.** Among its core educational outcomes is the cultivation of a strong duty of candour, reflecting a commitment to ethical transparency, patient-centred care, and professional integrity, principles that are fully aligned with the World Health Organization (WHO) standards for quality and safety in healthcare.

Aims

This audit was conducted to evaluate the quality of consent form completion and to identify areas for improvement as part of the Continuous Quality Improvement (CQI) process within the DrOrth postgraduate programme at the IIUM. Serving as the first cycle of a structured quality improvement initiative on informed consent, it aims to identify existing gaps, implement appropriate corrective measures, and strengthen compliance with Malaysia Medical Council (MMC) consent standards, thereby contributing to the continual enhancement of clinical governance and patient care quality within the programme.

Materials and Methods

The audit was conducted on patient records managed by the first and second cohorts of the DrOrth postgraduate programme at IIUM. Using the Raosoft sample size calculator, a minimum sample size of 260 was determined based on an estimated population of 800 patients with 99% confidence level. A 99% confidence level was chosen to ensure a higher degree of statistical certainty and to minimize the likelihood of Type I error (false positives), thereby enhancing the reliability and robustness of the findings, which is an important consideration for audits or studies aimed at informing clinical standards and quality improvement initiatives.

For confidentiality purposes, each consent form and its corresponding postgraduate residents were anonymised and identified using codes A to H, representing postgraduate residents 1 to 8. To ensure unbiased sampling, patient folders were randomly selected from the records room using the patient's name list of cases managed by the postgraduate residents, with 45 records retrieved for each postgraduate resident. An inter-rater check

was conducted to ensure the rigor and consistency of data extraction.

The documentation was assessed against the standards outlined in the "*Guidelines for Consent for Treatment of Patients by Registered Medical Practitioners"* issued by the Malaysian Medical Council (MMC).

A total of nine target criteria were assessed from the consent forms retrieved from the patients' records. All patients undergoing active treatment, under the care of postgraduate residents were included in the audit. No exclusion criteria were applied.

The audit aimed for 100% compliance with each criterion, which included the documentation of:

1. Presence of consent form in all active cases
2. Patient details
3. Treatment plan
4. Benefits and risks
5. Identification details of the patient or parent or guardian details
6. Signature of the patient or parent or guardian
7. Identification details of the treating clinician
8. Signature of the clinician
9. Corresponding date

Results

A total of 360 patient records across eight orthodontic residents were reviewed retrospectively from February till June 2024. These records were randomly selected, representing approximately 45% of the total eligible patient population. Overall, adherence to the target criteria was not fully met. Completion rates varied ranging from 84.7% to 96.1% (Figure 1) indicating that while certain items were well-documented, others showed notable gaps. The 'Consent form present' was the most consistently completed item, with a compliance rate of 96.1%, followed closely by 'Signature of Parent/Guardian' (94.2%), 'Clinician Signature' (93.6%), and 'Clinician Details' (92.5%). Documentation of 'Patient Details' (91.7%), 'Parent/Guardian Details' (91.3%), and the 'Treatment Plan' (89.4%) also showed relatively high completion rates. However, the 'Benefits and Risks' section was present in only 84.7% of the forms, highlighting a significant shortfall in communicating the full scope of treatment implications. The 'Presence of Date' was recorded in 88.6% of cases. In addition to the pre-determined audit target criteria, it was observed that 'Additional Specific Risks' were documented in the 23.3% of the consent forms reviewed.

Discussion

The findings from this audit align with those of previous pre-intervention studies, which similarly reported varied levels of completeness in informed consent documentation (Leng & Sharma, 2016; Prado & Waring, 2019; Tham *et al*., 2023). Overall, the audit demonstrated encouraging findings with consistently high completion rates across most of the target criteria. More than 90% of forms had key components completed including presence of consent form (96.1%), documentation of patient details (91.7%), clinician details (92.5%), inclusion of signatures from both clinicians (93.6%) and parents/ guardians (94.2%). This reflects commendable level of compliance with procedural documentation protocols. legal and ethical standards.

A particularly encouraging observation from this audit was the documentation of patient-specific or additional risks in 23.3% of cases. Although this was not part of the initial audit criteria, the presence of such entries is noteworthy. The documentation of risks specific to individual patients reflects a more patient-centred approach in consent. This not only supports ethical principles such as respect for autonomy and shared decision-making but also reinforces the legal validity of the consent process. Furthermore, it provides a useful reference for managing concerns, especially in cases where complications arise or where the adequacy of consent is later questioned.

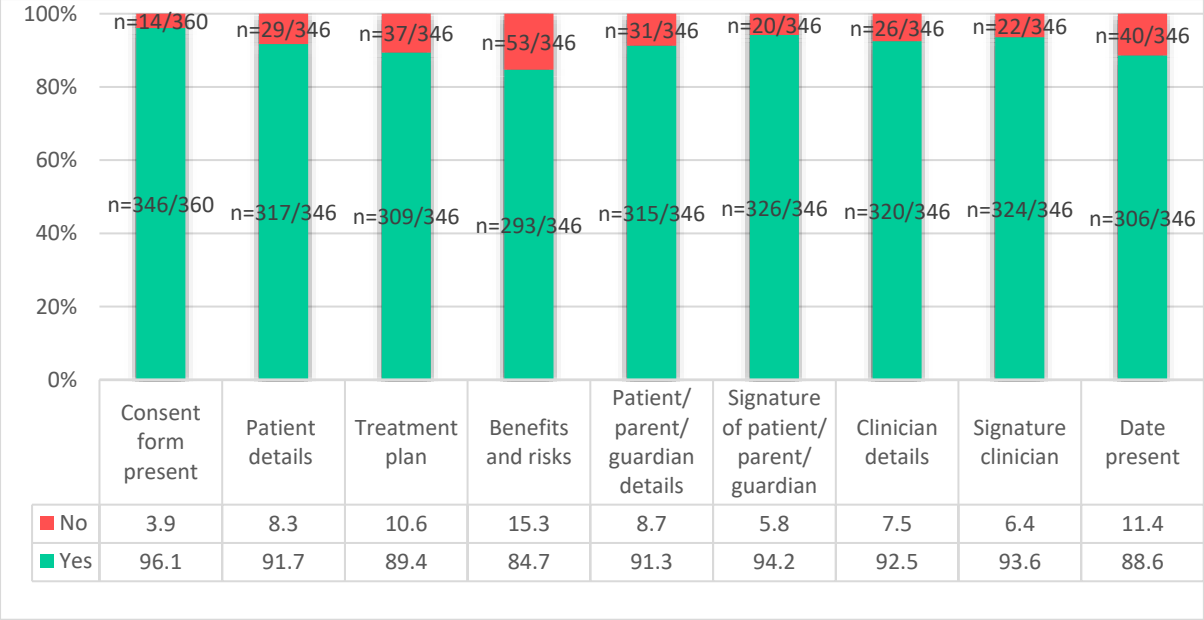

Figure 1. Bar chart illustrating the overall result of the first cycle. Results are presented mainly in percentages (supported by values). For all items following 'Consent form present', percentages were calculated based on the subset of cases where a consent form that was present.

Among the assessed criteria, the lowest level of compliance was observed in the documentation of 'Benefits and Risks' (84.7%). This may reflect an implicit reliance on the pre-printed general risk statements included in the consent forms which residents may have perceived as adequate. Extending beyond this specific issue, the reasons underlying incomplete or missing consent forms are likely multifactorial (Tham *et al.*, 2023). Suboptimal consent practices may stem from time constraints as well as a lack of awareness regarding the medico-legal and ethical significance of thorough informed consent documentation. It is important to note that incomplete documentation on the consent form does not necessarily imply that residents failed to communicate those elements during the informed consent process (ICP).

Nevertheless, a fully completed form functions as an important safeguard, enhancing both medico-legal protection and clarity in patient communication. A properly completed consent form, free from alterations or tampering reflects good clinical practice. Thorough documentation enhances legal defensibility by providing clear evidence that the patient was adequately informed and that consent was voluntarily given. The significance of precise and thorough documentation during the consent process has been emphasised in the medico-legal literature. For instance, a review in the context of orthopaedic surgery highlighted that proper recording and integration of consent forms into patient records were linked to a reduction in indemnity-related claims *(Bhattacharyya et al.*, 2005).

A key strength of this audit was its relatively larger sample size compared to previous audit in orthodontics (Prado & Waring, 2019). Large sample size allows generation of more representative and generalizable results. Nevertheless, it is important to acknowledge the limitations of this study. As a single-centre audit, the findings may not be fully applicable or transferable to other institutions with differing clinical practices or documentation systems. Furthermore, being a retrospective review, the analysis was dependent on the completeness and accuracy of existing records, which may have introduced information bias or limited the depth of interpretation.

Recommendations and Future Direction

In light of the audit findings, several strategies were proposed to improve the quality and completeness of informed consent documentation in orthodontic practice. One key recommendation was the integration of Continuous Dental Education (CDE) sessions aimed at raising awareness among residents and clinical staff regarding the audit outcomes. These sessions included guidance on the steps necessary to achieve full compliance with documentation standards while reinforcing the ethical and medicolegal importance of comprehensive IC practices. Additionally, the use of index dividers within patient records was recommended to facilitate quick access to consent forms during clinical procedures. This simple yet effective measure helps to streamline clinical workflow, enhances record organisation, and promote greater compliance with consent form completion.

To complete the audit cycle and assess the effectiveness of these proposed interventions, a follow-up audit is planned. This subsequent review will aim to achieve 100% completion rates across all existing criteria. Furthermore, the audit will introduce a tenth evaluation criterion i.e., the documentation of additional specific risks with a target of at least 50% inclusion. This new benchmark reflects a commitment to enhancing the quality of patient-centred care through more individualised and transparent consent practices.

By implementing these targeted, practical, and cost-effective measures, the orthodontic department can move towards improved compliance and a more robust informed consent process, ultimately contributing to better clinical outcomes and stronger patient-provider relationships.

Although this audit was conducted within a single institution, its findings provide valuable insights that may be applicable to other postgraduate clinical programmes. The recommendations emphasise the importance of consistent adherence to IC standards and structured quality improvement processes, which can be adapted by other institutions seeking to strengthen their clinical governance frameworks.

Conclusion

This audit identified areas for improvement in the completion of informed consent forms. All audit standards could be further enhanced. Targeted and low-cost strategies have been proposed to enhance documentation and clinical effectiveness. A follow-up audit will be conducted to assess the impact of these interventions and complete the audit cycle.

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Declaration of Conflicting Interests

The author(s) declare that there are no potential conflicts of interest with respect to the audit, authorship, and/or publication of this report.

Ethics

This audit was undertaken as a component of a larger research project approved by the IIUM Research Ethics Committee (IREC) under ID No. IREC 2024-033, at the International Islamic University Malaysia.

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