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Developing and evaluating a dental incident reporting system: a user-centered approach to risk management

Kiti Siriwatana[1*] and Sathirakorn Pongpanich[2]

Abstract

Background Patient safety is critical in healthcare, and adverse events (AEs) in dental care require tailored reporting systems for accurate documentation and risk management. Generalized systems fail to address the unique needs of dentistry, necessitating a specialized approach. This study introduces the dental incident reporting system (DIRS), a user-centered framework designed to overcome the barriers in dental incident reporting.

Methods This mixed-methods study was conducted in three phases. Phase 1 involved the development of a comprehensive classification system for dental AEs using 752 patient safety incidents reported over 5 years at the Dental Hospital, Faculty of Dentistry, Chulalongkorn University. Phase 2 involved the design and refinement of the DIRS, integrating features such as automated risk assessment and classification assistance, validated through heuristic evaluations. Phase 3 comprised usability testing with 16 end users using the system usability scale (SUS) and user acceptance test (UAT) to assess perceived effectiveness, usefulness, and satisfaction.

Results The classification system categorized dental-specific AEs, aligning with the hospital accreditation standards. The DIRS achieved a mean SUS score of 69.7, indicating above-average usability. The UAT showed high user ratings for effectiveness (mean, 3.15; SD, 0.49), usefulness (mean, 3.15; SD, 0.51), and satisfaction (mean, 3.38; SD, 0.48). Strong reliability (intraclass correlation coefficient, 0.91; 95% CI, 0.81–0.96) was demonstrated across the evaluations.

Conclusions The DIRS addresses gaps in dental incident reporting by offering a user-friendly, standardized system. Its potential to enhance reporting accuracy and foster a culture of transparency highlights its significance for improving dental patient safety. Future efforts should focus on refining usability, expanding testing, and exploring scalability for broader adoption.

Keywords Dental patient safety, Incident reporting system, Adverse events, Usability testing, Risk management, System usability scale

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Background

Patient safety is a critical component of quality healthcare, and adverse events (AEs) can have significant effects on patient outcomes, healthcare costs, and overall safety culture in healthcare institutions. Incident reporting systems (IRSs) are fundamental to improving patient safety by serving as tools for identifying, analyzing, and mitigating risks within healthcare settings. Moreover, an effective IRS promotes a culture of transparency and accountability, empowering healthcare professionals to learn from incidents and enhance their practices without fear of blame or retribution.

The World Health Organization (WHO) recognizes the critical role of robust IRS in patient safety strategies [1, 2]. Despite advancements in many healthcare sectors, dentistry faces unique challenges in incident reporting. Complex workflows, specialized equipment, and nuanced provider–patient interactions contribute to the difficulties in adapting general medical IRS to dental settings. Existing systems often fail to adequately capture dental-specific AEs, leading to incomplete documentation and limited utility in improving patient safety.

Several factors exacerbate these challenges. First, existing IRS frameworks lack the specificity required for dental settings [3, 4]. Dental-specific AEs, such as wrong tooth extraction, equipment malfunction, and procedural complications, require a tailored classification system that accurately captures the nuances of dental practice. Second, underreporting remains a pervasive issue, hindering the comprehensive documentation of AEs and limiting the effectiveness of risk management strategies (5–7). Studies have shown that dentists often find reporting systems overly complex or fear potential repercussions, further discouraging active participation [8, 9]. This underreporting limits the ability to identify the true incident patterns and hinders the development of targeted interventions to improve patient safety. Therefore, this study aimed to develop and evaluate a dental incident reporting system (DIRS) tailored to improve reporting accuracy, usability, and risk management in dental healthcare.

Methods

This mixed-methods study employed a multistage approach to develop and evaluate the DIRS. Qualitative analysis of narrative incident reports informed the development of a comprehensive classification system tailored for dental settings. Quantitative methods were then used to assess the frequency of the reported incidents, evaluate expert consensus on the classification system, and assess user experience (UX) with the DIRS. The primary aim was to address the need for a standardized system to report and analyze dental AEs. Aligned with Thailand's National Reporting and Learning System (TNRLS) standards [10, 11], this system facilitates structured data entry, enhances the accuracy of incident categorization, and supports detailed analysis for risk management. The DIRS was then developed to incorporate this classification system, enabling the automated reporting and analysis of dental AEs.

Phase 1: development of the comprehensive classification system

The primary investigator developed the DIRS classification system through a multistep process based on the qualitative analysis of 752 narrative incident reports and existing frameworks. An expert panel verified and refined the framework using a structured Delphi process. The approach consisted of the following steps:

Initial framework development

Sources and foundations The initial framework was informed by two main sources: The first source was the limited dental-specific classifications available in the academic literature [3, 4, 12–16], which provided examples of AE types specific to dentistry. The second source was the broader categories outlined by TNRLS [10, 11], including "safe surgery," "infection prevention and control," "medication and blood safety," "patient care process," "emergency Response," etc. The Conceptual Framework for International Classification for Patient Safety [17] of the WHO was used as a reference to ensure international alignment in the categorization criteria.

Preliminary categories Examples from the dental literature, such as procedural complications (e.g., wrong tooth extraction), equipment malfunctions, and medication errors, were combined with TNRLS's broader classifications to form the initial event categories.

Indicators of classification included

- *Type of event*: Nature of the adverse incident (e.g., procedural, equipment, and medication-related events).
- *Severity*: Based on patient harm (e.g., minor, moderate, and severe).
- *Likelihood*: Assessed using historical frequency data.
- *Risk*: Derived using a risk matrix combining severity and likelihood.

Thematic analysis of the narrative reports

A qualitative analysis was conducted on 752 narrative incident reports, excluding duplicates and incomplete reports, collected from the Dental Hospital, Faculty of Dentistry, Chulalongkorn University, spanning from December 2018 to August 2023. Thematic analysis

allowed the identification of specific patterns and subcategories within the broader AE types. For example, procedural-related complications were further subcategorized into nerve injuries, perforation-iatrogenic, pulp exposure-iatrogenic, etc. Equipment-related issues included equipment failure, missing or broken instruments, etc.

Validation of the initial classification

Iterative refinement

The primary investigator conducted iterative refinement using incident data from the most recent reporting year (2023). This process involved testing the initial framework to ensure that it captured all relevant incidents. Subcategories were adjusted to address the gaps and inconsistencies identified during testing.

Expert consensus and finalization

Delphi method

The Delphi method was employed to validate the comprehensive classification framework for dental AEs and key DIRS features. A panel of 13 experts, including clinicians, patient safety officers, and healthcare risk managers, with an average of 7.6 years of experience, participated in a single-round Delphi process given the high level of initial agreement. The panel included a balanced gender distribution and representation from both academic and clinical institutions.

Two sets of structured questionnaires were utilized to gather feedback. The first set employed a 7-point Likert scale for quantitative assessment, allowing experts to rate the clarity, comprehensiveness, and applicability of the classification system and DIRS features. The second set included open-ended questions for the collection of detailed qualitative feedback and suggestions for refinement. Quantitative data were analyzed using mean scores and interquartile ranges to assess agreement levels, whereas qualitative responses were subjected to thematic analysis to identify common themes and areas for improvement. Consensus was defined as a mean score ≥ 5.5 with an interquartile range ≤ 1. Scores meeting these criteria were considered agreed upon, whereas items with discrepancies were refined based on the qualitative feedback.

Refinements to the classification system included adjustments to subcategories and the addition of clarifying descriptions based on expert suggestions. Thus, to ensure alignment with practical and theoretical considerations, key refinements were then discussed with the panel.

Final adjustments

Based on the consensus reached through the Delphi method and expert feedback analysis, the final classification framework included 28 main categories and additional subcategories that addressed the nuances of dental practice, ensuring clarity and usability.

Final testing

The final framework was retrospectively applied to all 752 incidents to validate its applicability and consistency across diverse dental scenarios.

Summary of indicators for classification

The finalized classification framework was based on the following indicators:

- *Type of event*: Procedural, equipment-related, medication errors, etc.
- *Severity*: Harm level categorized as insignificant, minor, significant, major, or severe.
- *Likelihood*: Frequency determined by retrospective analysis as rare, unlikely, possible, likely, and frequent.
- *Risk assessment*: Combined severity and likelihood using a standardized matrix.
- *Context*: Consideration of environmental, procedural, and patient-specific factors.

The final classification system provides a structured, reliable framework that categorizes dental AEs by type, severity, and context. This framework forms the foundation for the DIRS developed in subsequent phases, ensuring the usability and effectiveness of the system in addressing safety challenges in patients with dental problems.

Phase 2: design and development of the DIRS

The DIRS was designed and developed through a user-centered approach, emphasizing usability and alignment with risk management principles. The development process was informed by theoretical frameworks such as the health belief model (HBM) [18] and the technology acceptance model (TAM) [19], which guided the integration of features to foster ease of use and perceived usefulness. Usability-focused design, adherence to usability principles, and rigorous evaluation methodologies are the key stages in the development process.

Adaptation to National standards

To ensure scalability and alignment with broader healthcare goals, the DIRS was designed in compliance with TNRLS standards [10, 11]. This alignment facilitated the integration of the system into existing frameworks, supporting its potential for broader adoption and application in various healthcare settings.

Core features of the DIRS

The key features of the DIRS were initially identified based on the lead author's experience in risk management over a decade. The DIRS was developed with several key features to enhance its functionality and UX:

- **Dashboard with feedback**: A real-time dashboard provides updates on the reporting status, enabling users to track their submissions and receive early feedback.
- **AE classification assistance**: This feature guided users in categorizing incidents accurately, reducing the risk of misclassification.
- **Severity assessment support**: A structured severity assessment tool that standardized the evaluations of incident effect and likelihood.
- **Automated risk level assessment**: Automated calculations of risk levels facilitated the timely identification of high-priority incidents.
- **Automated notifications**: Notifications were sent to relevant personnel based on the severity of the reported incidents, ensuring prompt interventions.
- **Standardized reporting**: Generates summary reports aligned with accreditation standards.
- **Customizable reporting options**: Users can generate tailored reports to meet specific organizational requirements, supporting targeted risk management efforts.

These features collectively addressed the challenges in dental incident reporting, such as complexity, underreporting, and lack of standardization. By aligning with user needs and regulatory requirements, the DIRS provided a robust solution for improving reporting accuracy and fostering patient safety.

Table 1 Likelihood grading for patient adverse events

Likelihood	Description	Likelihood assessment criteria based on the incident reporting frequency	Likelihood score
Frequent	Expected to occur frequently.	An average of ≥ 4 incidents monthly or ≥ 48 incidents annually ($X \geq 4$)	**5**
Likely	High probability of occurrence.	An average of 2 to < 4 incidents monthly or 24–47 incidents annually ($2 \leq X < 4$)	**4**
Possible	Moderate probability of occurrence.	An average of 1 to < 2 incidents monthly or 12–23 incidents annually ($1 \leq X < 2$)	**3**
Unlikely	Low probability of occurrence.	An average of 0.5 to < 1 incident monthly or 6–11 incidents annually ($0.5 \leq X < 1$)	**2**
Rare	Uncommon or infrequent occurrence.	An average of < 0.5 incidents monthly or < 6 incidents annually ($X < 0.5$)	**1**

Privacy and confidentiality measures

In development and evaluation of the DIRS, maintaining data privacy and confidentiality was a critical priority. To achieve this objective, the following protocols were implemented:

- **Data encryption**: All data, both in transit and at rest, were encrypted using advanced security protocols to prevent unauthorized access.
- **Role-based access control**: Access to the system was restricted based on user roles and responsibilities. Only authorized personnel can view or modify sensitive data.
- **Anonymization**: Identifiable patient information was anonymized during data collection and analysis. This ensured that sensitive details were not directly linked to specific individuals in the incident reports.
- **Audit trails**: The system maintained comprehensive audit logs, documenting all access and actions taken within the system. These logs enabled the monitoring and compliance with institutional data protection policies.

These measures were designed in alignment with Thailand's data protection standards and international best practices for healthcare data security, thereby reinforcing trust and compliance among system users.

Risk assessment framework

The risk score for AEs was determined using a 5×5 risk matrix based on two key components: likelihood and severity. This methodology adheres to the hospital accreditation standards of Thailand, ensuring alignment with national frameworks for risk management and patient safety.

Likelihood assessment

The likelihood is graded on a 5-point scale, reflecting the frequency of incident occurrences as outlined in Table 1:

- **Frequent (5)**: Expected to occur frequently (≥ 4 incidents monthly or ≥ 48 incidents annually).
- **Likely (4)**: High probability of occurrence (2–3.9 incidents monthly or 24–47 incidents annually).
- **Possible (3)**: Moderate probability of occurrence (1–1.9 incidents monthly or 12–23 incidents annually).
- **Unlikely (2)**: Low probability of occurrence (0.5–0.9 incidents monthly or 6–11 incidents annually).

- **Rare (1)**: Uncommon or infrequent occurrence (< 0.5 incidents monthly or < 6 incidents annually).

The default values for the likelihood criteria were derived from historical data on incident reporting from this study. However, healthcare facilities can customize these criteria to better reflect their operational contexts and emerging trends.

Severity grading

Severity was graded on a 5-point scale based on the effect on the patient, as detailed in Table 2:

- **Insignificant (1)**: No harm or injuries to the patient.
- **Minor (2)**: Mild and temporary discomfort or harm.
- **Significant (3)**: Injuries requiring medical attention with limited treatment.
- **Major (4)**: Irreversible injuries requiring ongoing medical treatment.
- **Severe (5)**: Results in patient death.

Risk matrix

The risk matrix (Table 3) combines the likelihood and severity scores to produce a composite risk score. For example, an event with a likelihood score of 5 (frequent) and a severity score of 4 (major) results in a risk score of 20.

Table 2 Severity grading for patient adverse events

Impact level	Description	Impact score
Insignificant	No harm or injuries to the patient	1
Minor	Causes mild and temporary discomfort or harm	2
Significant	Causes injuries or illnesses that require medical attention with limited treatment	3
Major	Causes irreversible injuries or illnesses that require ongoing medical treatment	4
Severe	Results in patient death	5

Risk level classification

The calculated risk score is categorized into risk levels based on the predefined thresholds, as outlined in Table 4:

- **Very low risk**: Minimal or negligible effect.
- **Low risk**: Requires monitoring but no immediate intervention.
- **Medium risk**: Demands further investigation and monitoring.
- **High risk**: Requires immediate corrective action.
- **Severe risk**: Demands urgent, systemic interventions.

Example application

An example of the risk calculation process is as follows:

Table 3 Risk matrix for patient adverse events

Impact		Insignificant	Minor	Significant	Major	Severe
Likelihood		**1**	**2**	**3**	**4**	**5**
Frequent	**5**	5	10	15	20	25
Likely	**4**	4	8	12	16	20
Possible	**3**	3	6	9	12	15
Unlikely	**2**	2	4	6	8	10
Rare	**1**	1	2	3	4	5

Table 4 Risk level classification

Risk level				
Very low risk	Low risk	Medium risk	High risk	Severe risk

- An **accidental soft tissue damage** incident results in the patient requiring additional treatment, such as wound suturing. This event is classified as having an **effect level of significant (3)**.
- The incident occurs **12 times annually**, which corresponds to a **likelihood score of possible (3)**.
- Using the **risk matrix**, the combination of likelihood (3) and severity (3) gives a **risk score of 9**, which is categorized as **medium risk**.
- This categorization highlights the need for monitoring and further investigation to mitigate similar events in the future.

System customization and default configuration

The DIRS allows healthcare institutions to adapt its default configuration to meet their unique needs. For this study, the default likelihood assessment criteria were derived from the incident reporting data analyzed. As institutions gather more data and identify patterns specific to their operations, they can recalibrate the likelihood and severity parameters within the DIRS. This flexibility ensures that the system remains relevant and responsive to changing organizational requirements, supporting sustained improvements in risk management.

The ability to customize foundational data, such as default likelihood thresholds and severity criteria, ensures that the DIRS can accommodate a wide range of institutional preferences while remaining aligned with Thailand's hospital accreditation standards.

User-centered approach

The DIRS design prioritized user engagement and practicality by incorporating principles from the HBM and TAM. These models were integrated to shape the system's design, emphasizing the ease of use and perceived usefulness to encourage active engagement. The HBM inspired features such as feedback mechanisms and simple reporting processes, whereas the TAM principles ensured that the system's usability promoted positive attitudes toward incident reporting.

Usability design and standards

The DIRS adhered to established usability principles, particularly Nielsen's 10 usability heuristics [20]. The system's design focused on key usability aspects such as the visibility of system status, error prevention, and user control. Expert and heuristic evaluations were incorporated to ensure compliance with usability standards.

Heuristic evaluation and iterative refinement

The heuristic evaluation (usability heuristics) involves assessing the usability of a system by expert evaluators, distinct from usability testing conducted with actual end users. Unlike end-user usability testing, which focuses on observing how real users interact with the system in real-world scenarios, heuristic evaluations involve expert analysis based on established usability principles (heuristics). This approach offers a cost-effective and efficient way of identifying usability issues during the early stages of system development. A heuristic evaluation was conducted to assess and refine the usability of the DIRS, utilizing Nielsen's 10 usability heuristics as the evaluation framework.

Development and content validity testing of the heuristic evaluation questionnaire

The heuristic evaluation questionnaire was designed to cover 10 usability aspects, with questions on key criteria such as visibility of system status, error prevention, and user control. The initial questions were reviewed for content validity by a panel of four experienced faculty members in dental and healthcare informatics. Each question was assessed for its relevance and appropriateness in evaluating the usability aspects, using the item-content validity index and scale-content validity index metrics.

Heuristic evaluation process

A heuristic evaluation was performed to assess the usability of the DIRS. The evaluators were three IT professionals with extensive expertise in information and communication technology. This selection aligns with established recommendations in the usability evaluation literature, particularly Nielsen's guideline that 3–5 evaluators can uncover approximately 75–80% of usability issues (Nielsen) [20]. The number of evaluators was chosen to balance practicality and effectiveness, ensuring comprehensive feedback within resource constraints while adhering to methodological standards.

Each evaluator independently assessed the system using a validated questionnaire based on Nielsen's usability heuristics. This evaluation framework facilitated a systematic and detailed assessment of the DIRS, focusing on key usability dimensions such as error prevention, system feedback, and ease of navigation. The evaluation produced consistently high usability scores, ranging from 3.00 to 3.67, with strong ratings for error prevention and automated feedback features. These results highlight the system's alignment with the core usability principles.

Reliability analysis of the heuristic evaluation

To ensure the robustness of the heuristic evaluation findings, reliability analyses were performed using the intraclass correlation coefficient (ICC). These statistical measures were employed to confirm the consistency and agreement of the evaluators' ratings, providing a quantitative foundation for the qualitative insights obtained.

Phase 3: usability and user acceptance testing with sample end users

The evaluation process is summarized in Fig. 1, illustrating the key stages from the heuristic evaluation to end-user testing through the SUS and UAT. Each stage was designed to ensure the usability, effectiveness, and alignment of the DIRS with risk management principles.

System usability scale

The system usability scale (SUS) [21, 22] was utilized to quantitatively evaluate the overall usability of the DIRS. This standardized tool provides a reliable measure of UX and allows benchmarking of the system's usability against established performance thresholds. This method is widely recognized for its reliability in evaluating information systems and providing quantitative scores to benchmark system performance and is valuable for its ability to provide quick and robust insights into system usability across diverse user groups [22].

User acceptance testing

The user acceptance testing (UAT) is a critical phase in the software development lifecycle to ensure that the developed application meets the needs and expectations of its intended users [22, 23]. Recognizing its importance, the UAT was conducted to evaluate the perceived effectiveness, usefulness, and overall satisfaction of the DIRS among end users.

To address the complexities of reliably assessing user satisfaction, as highlighted by Melin et al. (2020) [23] in their study on mHealth apps, significant efforts were made to develop a robust UAT questionnaire. To enhance its content validity, the questionnaire was carefully reviewed by four experts. This review process ensured that the questionnaire accurately captured user perceptions, thereby strengthening its reliability and applicability for the evaluation of the DIRS.

The UAT was conducted to evaluate the perceived effectiveness, usefulness, and satisfaction of the DIRS among end users. A five-point Likert scale was employed with the following descriptors:

- 1: Strongly disagree.
- 2: Disagree.
- 3: Neutral.
- 4: Agree.
- 5: Strongly agree.

A benchmark score of > 3.0 was defined as positive user acceptance. This threshold aligns with prior research, where scores > 3.0 are interpreted as indicative of agreement and satisfaction:

- Kaur et al. reported a mean satisfaction score of 3.8 in a healthcare setting, interpreting it as "good" [24].
- Aldossary et al. reported an overall satisfaction score of 3.61 in a dental care context, also interpreted as high [25].

These examples highlight the suitability of the > 3.0 benchmark in evaluating healthcare systems.

Objectives of the UAT and SUS

The integration of the UAT and SUS served complementary purposes:

• SUS

- Provided a quantitative measure of the system's overall usability, benchmarking it against standardized thresholds.
- Offered comparative data to identify usability strengths and weaknesses.

• UAT

- Assessed subjective user perceptions regarding the system's effectiveness, usefulness, and satisfaction.
- Provided qualitative insights into areas of improvement based on user feedback.

By combining the UAT and SUS, the evaluation process captured both subjective and objective dimensions of usability, ensuring a comprehensive understanding of the DIRS performance and UX.

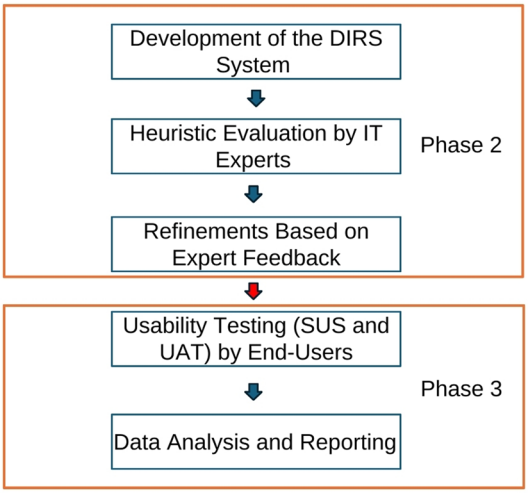


Fig. 1 Evaluation process for the dental incident reporting system

Development and content validity testing of the UAT questions

For the UAT, specific questions were formulated to evaluate key usability aspects, such as perceived effectiveness, usefulness, and satisfaction with the DIRS. These questions were reviewed for content validity by a panel of four faculty experts (two associate professors and two assistant professors), who assessed the questions based on relevance and appropriateness.

Translation and validation of the SUS questions

To adapt the SUS questions [21] for Thai-speaking participants, a meticulous translation and validation process was conducted:

1. Initial translation: This was done by two linguists.
2. Synthesis of translations: The two linguists collaborated to synthesize their versions into a single, cohesive Thai version.
3. Back translation: This was done by a third linguist who was not involved in the initial translations.
4. Finalization of the Thai SUS: All three linguists reviewed the back-translated English version alongside the original and synthesized Thai versions.

Sample selection and testing scenarios

The sample for usability testing was selected from personnel across 21 departments and clinics within the Faculty of Dentistry. These departments and clinics represent various units involved in providing dental care services, including general dentistry, specialized care units (such as oral surgery, orthodontics, and pediatric dentistry), and supporting units such as radiology and pharmacy. The inclusion of participants from diverse units ensured a comprehensive evaluation of the DIRS by capturing perspectives from a wide range of operational contexts.

In total, 17 individuals responded to the invitation, of which 16 met the inclusion criterion of having at least 2 years of incident reporting experience. This criterion ensured that participants possessed sufficient familiarity with reporting processes to provide meaningful and actionable feedback on the usability and functionality of the system. Their collective experience allowed for a nuanced understanding of the system's strengths and areas for improvement, particularly in the context of real-world dental care workflows.

According to established guidelines for usability testing, a sample size of approximately 16 ± 4 participants is considered adequate to capture a wide range of usability issues and provide reliable insights into system performance when using standardized tools such as the SUS (Faulkner, 2003; Alroobaea, 2014) [26, 27]. This sample size was chosen to balance practicality and statistical reliability, ensuring that the testing could effectively identify major usability concerns and offer a comprehensive evaluation of the UX.

To familiarize participants with the system and its functionalities, all participants were provided with a short instructional video outlining the system's features and an overview of the reporting workflow. Following this, the participants accessed the system through a web-based interface using preassigned credentials.

Before the SUS evaluation, the participants were presented with simulated dental AEs. These scenarios were carefully selected and adapted from real incident reports collected in previous research phases to ensure authenticity and relevance. The simulated events were designed to reflect a range of common and significant AEs encountered in dental settings, such as wrong tooth extractions, equipment malfunctions, and adverse drug reactions.

Hands-on interaction

Participants directly activated the DIRS during the testing phase, completing specific tasks related to reporting the simulated AEs. This hands-on interaction allowed participants to experience the system's features first-hand, navigating through the interface, inputting incident details, and utilizing the risk assessment tools. By actively engaging with the system, participants gained a realistic understanding of its functionality and workflow, ensuring that their experiences reflected actual usage.

After completing the tasks, the participants evaluated the system using the SUS and UAT, focusing on perceived effectiveness, usefulness, and satisfaction.

Data analysis

- **Usability testing (SUS analysis)**: SUS scores were analyzed quantitatively to evaluate the overall system usability and identify areas for improvement.
- **UAT Analysis**: Descriptive statistics were used to evaluate UAT results across dimensions such as perceived effectiveness, usefulness, and satisfaction.
- **Reliability analysis for the UAT**: ICC analysis was performed to assess the consistency of user ratings in the UAT.
- **Correlation analysis**: Pearson correlation analysis was conducted to explore the relationship between participant demographics, particularly years of incident reporting experience, and their UAT scores.

Ethical considerations

Results

Phase 1: development of the comprehensive classification system

The analysis of 752 patient safety incident reports from the Dental Hospital, Faculty of Dentistry, Chulalongkorn

University, revealed a diverse range of AEs, categorized as follows: [28]

- **Procedural complications** (43.75%): The most frequent category included implant failures, tooth fractures during extractions, and nerve damage.
- **Medication-related issues** (18.88%): Such as adverse drug reactions and medication errors.
- **Patient falls** (10.24%): Accidents occurring within dental care settings.
- **Equipment malfunctions** (7.18%): Issues such as malfunctioning dental chairs and faulty handpieces.
- **Infections** (4.26%): Including postoperative infections and cross-contamination cases.
- **Other incidents** (15.69%): Including burns, allergic reactions, and communication errors.

The classification system was developed systematically, ensuring the comprehensive coverage of AEs based on this dataset. Testing the system with retrospective data over 5 years confirmed its ability to classify all reported incidents accurately and consistently. Refinement through expert validation using the Delphi method ensured alignment with hospital accreditation standards and relevance to dental patient safety needs.

Consensus process overview

The classification system underwent rigorous expert review and feedback:

- **Initial Review and Feedback**: The experts were provided with the proposed classification system and asked to evaluate its comprehensiveness, relevance, and alignment with the accreditation standards. The evaluation was conducted using a 7-point Likert scale, where 1 indicated "strongly disagree" and 7 indicated "strongly agree." Feedback was collected on its clarity, applicability to dental-specific AEs, and potential for standardization across dental settings.
- **Consensus achievement**: High agreement was reached during the initial rounds of evaluations, exceeding expectations for a two-round process. The average Likert scale scores ranged from 5.85 to 6.00 across key dimensions, such as clarity, comprehensiveness, and alignment with risk management practices. The strong consensus achieved in the first round highlighted the robustness and applicability of the classification system. Minor refinements were made based on individual suggestions to ensure that the system addressed all critical aspects of dental patient safety effectively.

This expert validation demonstrated that the classification system was meticulously developed, achieving high levels of agreement among experts. It underscored the system's potential to standardize incident reporting, facilitate detailed analysis, and enhance patient safety management across diverse dental care settings.

Phase 2: design and development of the DIRS

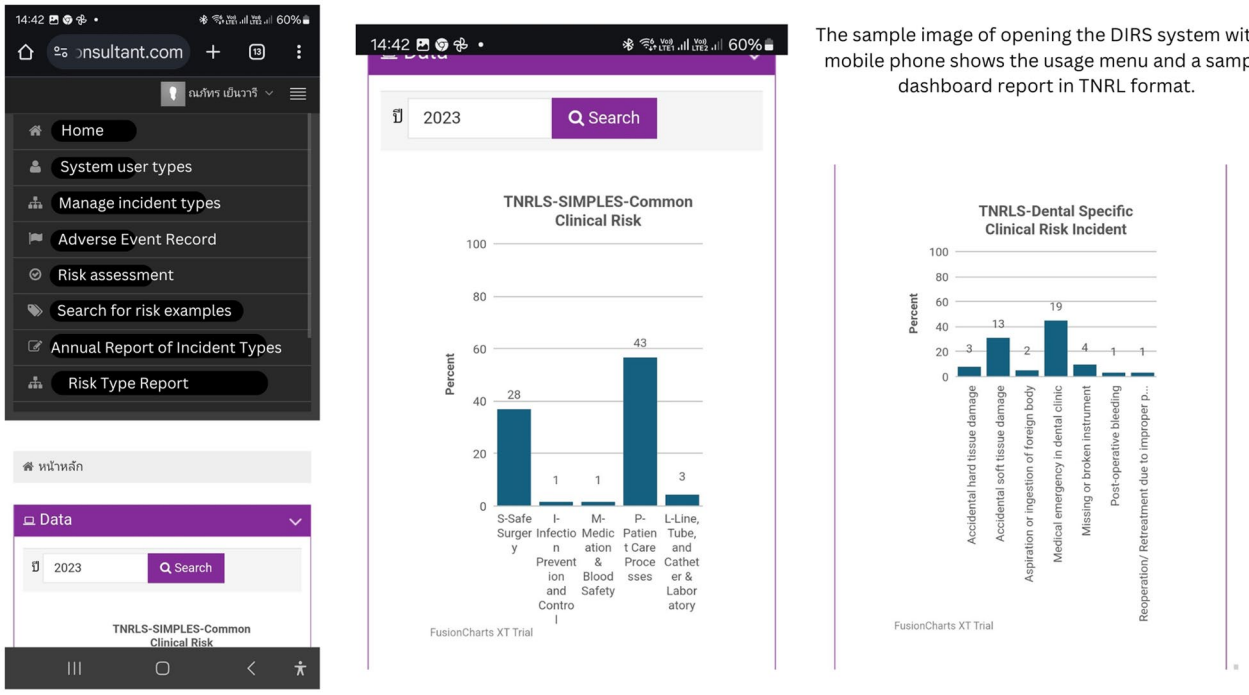
Building on the classification system, the DIRS (Figs. 2, 3 and 4) was developed as a user-centered digital tool to improve the documentation and analysis of dental AEs. It integrates features that enhance risk management, promote reporting efficiency, and align with TNRLS standards. The system was developed following a structured process informed by the comprehensive classification system from Phase 1, expert feedback, and iterative refinement through heuristic evaluations.

System design and feature integration

The DIRS was equipped with a robust set of features, refined through collaborative discussions and expert consensus:

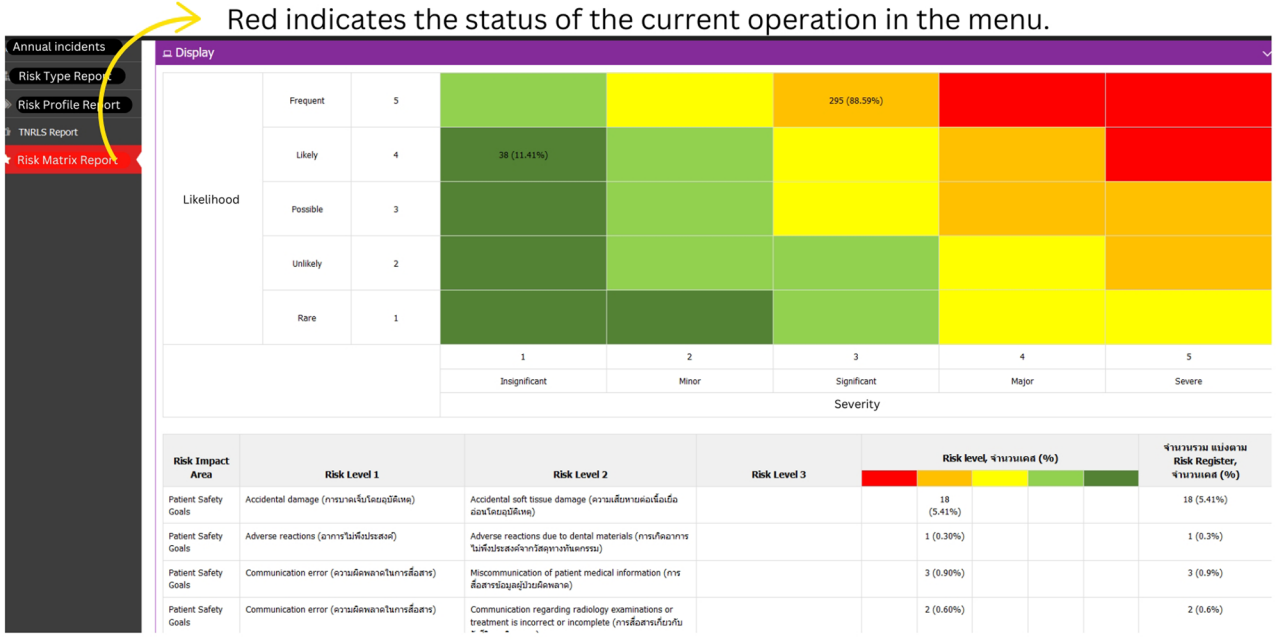
1. **Dashboard with feedback**: Provides real-time updates on reporting status, allowing users to track their submissions and receive early feedback, promoting transparency and engagement.
2. **AE Classification assistance**: Guides users in selecting appropriate categories for AEs, reducing errors, and ensuring accurate categorization based on the classification system developed in phase 1.
3. **Severity assessment support**: This supports users in evaluating the severity of incidents using predefined criteria, enabling standardized assessments across users.
4. **Automated risk level assessment**: This involves automatic calculation of risk levels by analyzing the likelihood and effect of events, providing a risk score to identify high-risk incidents requiring immediate attention.
5. **Automated notifications**: Sends alerts to relevant personnel based on the severity of incidents, facilitating timely interventions for high-risk events.
6. **Standardized reporting**: Generates reports aligned with hospital accreditation standards, supporting comprehensive analysis of incident trends.
7. **Customization for risk managers**: Allows risk managers to customize reports to meet organizational needs, focusing on specific areas of interest or concern.

Through collaborative discussions with the programmer, additional features were incorporated to enhance the adaptability and functionality of the DIRS:



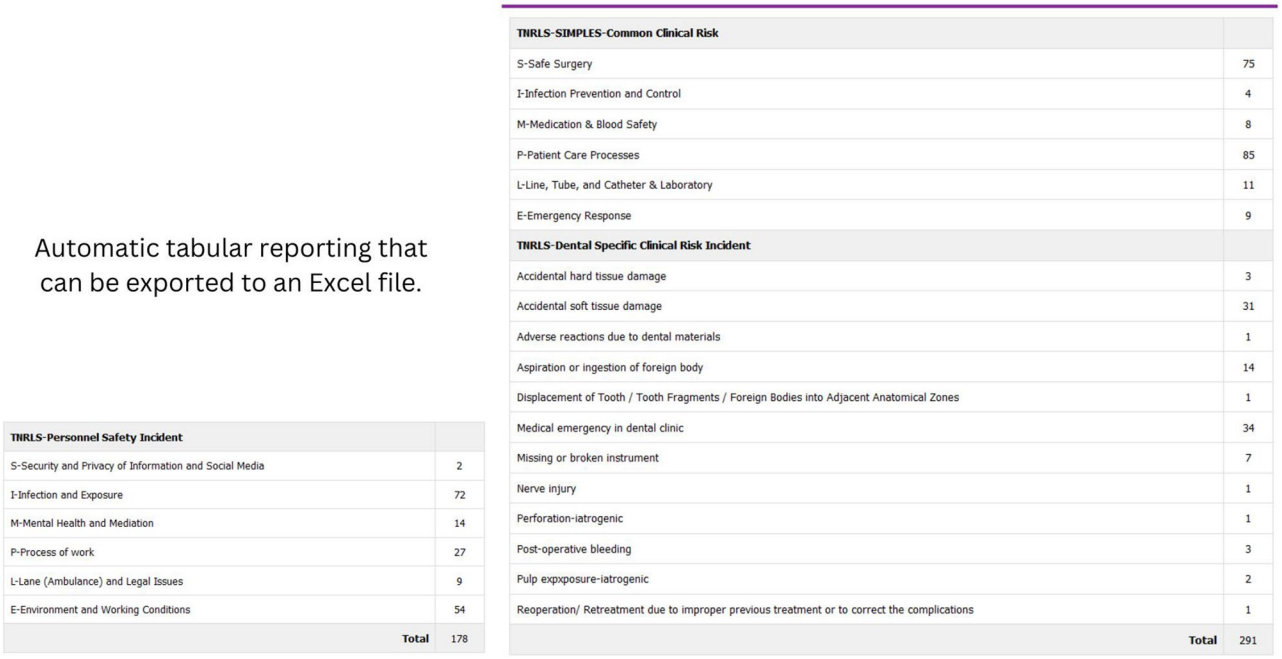
The sample image of opening the DIRS system with a mobile phone shows the usage menu and a sample dashboard report in TNRL format.

Fig. 2 Screenshots of the dental incident reporting system menu and sample dashboard on a mobile phone



Automatic presentation of risk assessment from system data and presented in a Dashboard format according to the time period specified by the system user.

Fig. 3 Screenshot of the dental incident reporting system displaying the dashboard in a risk matrix format



TNRLS-Personnel Safety Incident	
S-Security and Privacy of Information and Social Media	2
I-Infection and Exposure	72
M-Mental Health and Mediation	14
P-Process of work	27
L-Lane (Ambulance) and Legal Issues	9
E-Environment and Working Conditions	54
Total	178

TNRLS-SIMPLES-Common Clinical Risk	
S-Safe Surgery	75
I-Infection Prevention and Control	4
M-Medication & Blood Safety	8
P-Patient Care Processes	85
L-Line, Tube, and Catheter & Laboratory	11
E-Emergency Response	9
TNRLS-Dental Specific Clinical Risk Incident	
Accidental hard tissue damage	3
Accidental soft tissue damage	31
Adverse reactions due to dental materials	1
Aspiration or ingestion of foreign body	14
Displacement of Tooth / Tooth Fragments / Foreign Bodies into Adjacent Anatomical Zones	1
Medical emergency in dental clinic	34
Missing or broken instrument	7
Nerve injury	1
Perforation-iatrogenic	1
Post-operative bleeding	3
Pulp expxposure-iatrogenic	2
Reoperation/ Retreatment due to improper previous treatment or to correct the complications	1
Total	291

Fig. 4 Screenshot of the dental incident reporting system displaying automated tabular reporting

1. **Risk profile summaries**: Summarizes risk profiles, highlighting areas with higher frequencies or severities to prioritize risk mitigation strategies.
2. **Risk type classification**: Enables the categorization of incidents by risk type, facilitating trend analysis and targeted interventions.
3. **Risk register report generation**: Maintains a risk register and generates reports for the risk management committee to support decision-making and track risk management efforts.
4. **Adaptability for future updates**: Designed with flexibility to accommodate evolving requirements, ensuring that the system remains relevant and capable of integrating new features over time.

System workflow

The DIRS follows a structured workflow that encompasses the key stages of incident reporting and management:

- **Reporting form**: Users begin by submitting detailed incident reports through a standardized reporting form, capturing essential data related to patient, personnel, or organizational safety incidents.
- **Verification by risk manager**: Submitted incidents are reviewed by a risk manager to ensure data accuracy and completeness before proceeding to the next stage.
- **Categorization and risk assessment**: Incidents are categorized into specific types (e.g., AEs and near misses) and assessed for severity and effect using predefined criteria. Risk scores are generated based on severity and likelihood, guiding prioritization.
- **Database storage and dashboard integration**: Verified incidents are stored in a database and made accessible via the dashboard. This allows users to track incident trends, monitor high-risk cases, and generate summary reports.
- **Automated response activation**: For high-risk incidents, the system automatically notifies designated personnel to facilitate immediate intervention.
- **Reporting system and risk register**: The DIRS generates comprehensive reports for organizational review and updates the risk register to support ongoing risk management activities.

Automated notification system

The DIRS includes an automated notification system designed to alert relevant personnel in real-time. When an incident is reported, the system evaluates its severity and type to trigger appropriate notifications. These notifications are sent via email and SMS to key stakeholders such as department managers, safety officers, and risk management personnel.

The system aims to support immediate interventions by ensuring that high-severity incidents are promptly brought to the attention of the responsible parties. For example, if a critical incident such as a medical emergency is reported, a notification is automatically sent to the risk management team to coordinate a rapid response. The integration of these notifications into the

DIRS helps maintain a proactive approach to risk management and safety improvements.

However, although the system currently excels in alerting personnel to new incidents, it does not yet document follow-up actions or their outcomes within the system. Future updates include features for tracking these follow-up actions, enhancing the system's role in comprehensive risk management.

Incident tracking and feedback process

In its current state, the DIRS relies on manual data entry and oversight by risk managers to manage the incident lifecycle. This includes the generation of reports and maintaining a risk register that supports the risk management committee in their review and follow-up processes. Incident status tracking, root cause documentation, and feedback to incident reporters are performed manually through meetings and internal communications.

Although the system does not yet have automated tracking and feedback mechanisms, the following improvements are under consideration for future iterations:

- **Incident status tracker**: A feature to monitor the real-time progress of incident investigations.
- **Root cause analysis documentation**: Automation of the analysis and action plan documentation.
- **Feedback to reporters**: Direct notification to reporters regarding the status and outcome of their reported incidents.

These enhancements will be designed to accommodate the operational needs and regulatory requirements of healthcare facilities, ensuring that patient data privacy and confidentiality while improving the efficiency of risk management workflows.

Intersystem compatibility

The DIRS is designed with intersystem compatibility, offering institutions the ability to integrate data exchange processes without requiring direct integration with hospital information systems. Organizations can facilitate data sharing through database import/export functions, allowing risk managers to incorporate incident reports and relevant information into their existing risk management frameworks.

This compatibility supports various deployment models, including the following:

1. **Standalone use**: The DIRS can function independently, providing complete incident tracking and reporting capabilities.
2. **Customized integration**: Institutions can adapt the DIRS to existing systems by aligning its features with their specific data handling and reporting requirements.
3. **Data exchange**: By enabling data import/export, the DIRS promotes interoperability, minimizing redundant data entry and enhancing risk analysis processes across departments.

These flexible deployment options emphasize the adaptability and practical application of the DIRS in diverse organizational settings, improving efficiency and supporting continuous risk management.

Heuristic evaluation

The heuristic evaluation, conducted by three IT experts using a 5-point scale, demonstrated the strong usability of the DIRS. The individual heuristic scores ranged from 3.00 to 3.67, with particularly high scores for error prevention and system feedback. These results indicate that the DIRS effectively guides users and provides clear information throughout the reporting process. Iterative refinements addressed key issues, including visual design and navigation flow, further enhancing overall usability, and ensuring a seamless UX. The evaluation results were within acceptable ranges, and due to budget constraints, no further modifications were made to the system before proceeding to testing with end users in the next phase.

Reliability of the heuristic evaluation

The reliability of the heuristic evaluation was measured using the ICC, which yielded a value of 0.91 (95% CI, 0.81–0.96). This indicates a high level of agreement among the evaluators, confirming the robustness and reliability of the usability assessments.

Phase 3: usability testing with the sample end users

The usability and acceptability of the DIRS were evaluated through testing with 16 end-users from the Faculty of Dentistry, representing diverse departments and roles in dental patient care.

System usability scale results

The SUS scores from 16 end users were administered to quantitatively assess the usability of the IRS. The average SUS score was 69.6875. This result suggests above-average usability, although specific areas may benefit from further refinement. According to Bangor et al. [29], this places the DIRS to fall near the "OK" to the "good" range on the adjective rating scale. It indicates a system with acceptable usability but room for improvement.

User acceptance test results

The UAT results demonstrated positive user acceptance across all the evaluated dimensions:

- **Usefulness**: Mean = 3.15 (SD = 0.49).
- **Effectiveness**: Mean = 3.15 (SD = 0.51).
- **Satisfaction**: Mean = 3.38 (SD = 0.48).

These scores indicate that users generally agreed that the system was effective, useful, and satisfactory. According to studies on system usability and satisfaction in healthcare, scores > 3.00 suggest positive user acceptance and overall satisfaction with the system's performance [24, 25] . However, continued improvements, particularly in ease of use and customization, could further enhance the UX. Although the sample size was relatively small, involving 15–20 participants is consistent with best practices for usability testing, often sufficient to identify key issues and assess user perceptions effectively [26].

Reliability of the UAT results

The reliability of the UAT was assessed using Cronbach's alpha and the ICC to evaluate internal consistency and agreement among participants. The Cronbach's alpha for the UAT was calculated at 0.93, indicating excellent internal consistency, as values > 0.9 are generally considered to demonstrate strong reliability (Nunnally & Bernstein) [30].

The ICC, measuring the agreement across user ratings, was calculated at 0.91 (95% CI, 0.776–0.967, $p < 0.001$). This value indicates a high level of agreement among participants and further supports the robustness of the evaluation process. According to Cicchetti (1994) [31], ICCs > 0.75 indicate excellent reliability, confirming that the UAT provided consistent results across the sample.

The high reliability metrics demonstrate that the UAT effectively captured user perceptions regarding the perceived effectiveness, usefulness, and satisfaction of the DIR, providing significant and dependable results.

Correlation analysis

Pearson correlation analysis was performed to examine the relationship between the participants' years of incident reporting experience and their UAT scores across the dimensions of effectiveness, usefulness, and satisfaction. The results are summarized as follows:

1. **Effectiveness and usefulness**:

- A significant positive correlation was observed between **effectiveness** and **usefulness** ($r = 0.834$, $p < 0.01$). This indicates that participants who rated the system as effective also found it highly useful, suggesting that these dimensions are closely related.

2. **Effectiveness and satisfaction**.

- A significant positive correlation was found between **effectiveness** and **satisfaction** ($r = 0.831$, $p < 0.01$), demonstrating that participants who perceived the system as effective were also satisfied with its overall performance.

3. **Usefulness and satisfaction**.

- A strong positive correlation was identified between **Usefulness** and **Satisfaction** ($r = 0.786$, $p < 0.01$), indicating that the more useful the participants found the system, the more satisfied they were.

4. **Experience and UAT dimensions**.

- No significant correlation was found between participants' years of experience and any of the UAT dimensions (effectiveness, $r = 0.090$, $p = 0.740$; usefulness, $r = 0.283$, $p = 0.289$; satisfaction, $r = -0.021$, $p = 0.938$). This suggests that the DIRS was perceived as equally effective, useful, and satisfactory, regardless of the participants' prior experience with incident reporting.

Interpretation of the statistical significance

The significant correlations observed between the UAT dimensions (effectiveness, usefulness, and satisfaction) at $p < 0.01$ indicate a strong and significant relationship [32]. This reinforces the robustness of the DIRS design, showing that participants found the system effective, useful, and satisfying consistently. The lack of a significant correlation between experience and UAT scores highlights the accessibility and usability of the system across a diverse range of users, irrespective of their backgrounds.

Integrated summary of the key outcomes

The study confirmed the following:

1. The classification system comprehensively addressed dental-specific AEs and provided a reliable framework for structured documentation.
2. The DIRS prototype incorporated user-centered features, aligning with both usability principles and national standards, to improve reporting processes.
3. Usability testing validated the effectiveness, usefulness, and satisfaction of the DIRS among end users, promoting a culture of transparency and continuous improvement in dental patient safety.

These findings support the potential of the DIRS for broader implementation in national and international dental care settings, offering a scalable solution to enhance patient safety and reporting efficiency.

Discussion

This study underscores the critical importance of developing a DIRS tailored to the unique characteristics of dental care [9]. By addressing the limitations of existing generalized medical IRS, the DIRS enhances the ability to document, analyze, and mitigate dental-specific risks, thereby promoting patient safety.

Analysis of reporting patterns and the need for improvement

The analysis of AE reports from the Dental Hospital revealed critical insights into the current state of incident reporting. Over 5 years, 752 incidents were reported, a number disproportionately small compared with the estimated 200,000 patients with dental problems treated annually at the Faculty of Dentistry. This suggests potential underreporting due to the lack of definitive benchmarks for the expected AE rates in dental settings. Existing studies highlight that patient safety in dentistry is underexplored, complicating the assessment of reporting adequacy and emphasizing the need for standardized systems and benchmarks to improve safety practices [33, 34].

The data indicate a pattern of selective reporting, with severe incidents like medical emergencies consistently documented, whereas minor complications such as alveolar osteitis were often underreported despite their higher frequency. This reflects barriers such as complex reporting processes and the limited emphasis on documenting noncritical events.

These findings underscore the importance of developing a robust, user-friendly DIRS to simplify reporting, foster transparency, and ensure comprehensive documentation of all incidents, regardless of severity. The DIRS is designed to address these challenges, promoting a culture of safety and enabling meaningful analysis of AEs in dental care.

Significance of a DIRS

IRSs are indispensable tools for improving patient safety; however, the unique context of dental care presents challenges that generalized systems fail to address comprehensively [13]. Dental-specific AEs, such as procedural complications, equipment failures, and adverse drug reactions, require specialized categorization frameworks to ensure accurate documentation and meaningful risk analysis.

The DIRS addresses critical barriers such as underreporting by offering a simplified and intuitive interface that reduces reporting complexity and promotes active engagement. By fostering transparency and minimizing the fear of repercussions, the system aligns with global patient safety strategies. In addition, the technical guidance of WHO on patient safety incident reporting and learning systems [35] highlights the importance of adapting reporting frameworks to the specific contexts of different healthcare settings to ensure effective documentation and analysis of incidents.

This approach does not advocate for creating isolated systems but emphasizes the need to adapt and expand existing frameworks to encompass the nuances of dental practice. By integrating the DIRS into broader systems, such as TNRLS, dental incidents can be effectively captured and analyzed. Such integration ensures that the reporting process is inclusive and compatible with national and institutional safety goals, promoting a comprehensive approach to patient safety while avoiding disruption to existing system structures.

Development process as a model

The development process for the DIRS provides a replicable model for other specialized fields in healthcare:

1. **Comprehensive classification system**: Historical incident data and expert insights informed a robust framework for categorizing dental-specific AEs, aligned with accreditation standards.
2. **User-centered design**: Input from dental professionals and IT experts ensured a practical and user-friendly system.
3. **Iterative refinement**: Systematic usability testing and heuristic evaluations allowed for continual improvement to meet the end-user needs.

The heuristic evaluation in phase 2 identified usability challenges, particularly in navigation and visual design. However, owing to budget constraints, these issues were not fully addressed before proceeding to phase 3. As a result, although the usability testing with end users using the SUS indicated that the system was in the "acceptable" range, it fell short of achieving higher usability ratings. Despite these limitations, the UAT by end users yielded positive results.

This outcome highlights the cascading effect of unresolved issues from the heuristic evaluation on subsequent usability assessments. In future iterations, addressing these challenges during the heuristic testing phase could significantly enhance end-user satisfaction and usability metrics, ensuring a smoother and more intuitive UX. By employing iterative refinements and aligning feedback from both experts and end users, the DIRS can better meet the needs of all stakeholders and achieve its full potential as a tool for improving patient safety.

Key features and their effect

The DIRS includes features designed to address the challenges faced by dental healthcare personnel (DHCP) in incident reporting:

- **AE classification assistance**: Ensures accurate categorization of AEs, establishing a foundation for standardized documentation.
- **Automated risk assessment**: Provides consistent and actionable data by reducing the variability in severity evaluations.
- **Real-time feedback and notifications**: Facilitates prompt reporting and timely interventions.
- **Customizable reporting options**: Adapts to the specific needs of dental settings while remaining compatible with institutional and national standards.
- **Data visualization and dashboards**: Offers accessible, real-time insights into incident trends for targeted risk management.

These features collectively promote the usability and relevance of reporting systems, encouraging higher participation rates and comprehensive documentation of incidents. Importantly, the DIRS integrates seamlessly into institutional and national risk management practices without creating silos.

Comparative analysis of existing frameworks

The DIRS addresses several key limitations observed in the existing incident reporting frameworks:

- **Lack of dental specificity** [16, 36, 37]: Unlike other healthcare IRSs, the DIRS features a comprehensive classification system tailored for dental AEs, ensuring accurate and relevant reporting.
- **Underreporting due to fear of repercussions** [38–42]: The DIRS fosters a non-punitive reporting culture and offers anonymous reporting options to encourage participation, addressing the common issue of underreporting due to staff fears of blame or punishment.
- **Complex and time-consuming reporting processes** [43–46]: The DIRS simplifies reporting through a user-friendly interface with streamlined forms and automated risk calculations, mitigating the complexity and time constraints that often discourage reporting in other systems.
- **Insufficient feedback and follow-up** [39, 43, 47–49]: The DIRS incorporates real-time dashboards and automated notifications to ensure timely feedback and follow-up on reported incidents, addressing the common failure of many systems to provide adequate feedback.
- **Limited data analysis capabilities** [50–52]: The DIRS integrates advanced analytics tools for trend identification and risk assessment, supporting data-driven decision-making and overcoming the limitations of systems that struggle to analyze and learn from collected data.
- **Inadequate support for learning and improvement** [53–55]: The DIRS includes features for generating customized reports and sharing insights to support a culture of continuous improvement in dental safety practices, addressing the limitations of systems that focus solely on data collection without facilitating organizational learning.

The DIRS also offers additional features that enhance risk management capabilities:

- **Risk profile summaries**: Enables the identification of high-frequency or high-severity areas to prioritize risk mitigation strategies.
- **Risk categorization**: Aids in trend analysis and targeted interventions.
- **Risk register report generation**: Supports decision-making and tracks risk management efforts for risk management committees.

By addressing these limitations, the DIRS presents a more comprehensive and effective approach to incident reporting in dental settings. Its dental-specific design, user-friendly interface, and advanced analytics capabilities make it well-suited to improve patient safety and quality of care in dental practices.

Practical applications and recommendations

The DIRS offers practical pathways for enhancing dental patient safety and organizational learning:

1. **Integration with existing systems**: Institutions can adopt the classification framework into current reporting systems to improve specificity and functionality.
2. **Adoption as a reference model**: The DIRS can serve as a template for developing tailored IRSs by leveraging its critical features and workflows.
3. **Direct deployment**: Organizations may deploy the system directly through collaboration with developers, enabling immediate improvements in incident reporting.
4. **Intersystem compatibility**: Facilitating data exchange between the DIRS and existing systems through database integration and import/export functions.

Implications for broader adoption

The DIRS prototype's submission to the dental hospital enables real-world testing and adaptation. Although the heuristic evaluation results indicated acceptable usability, budget constraints limited further refinements. Despite this, the UAT results demonstrated positive feedback regarding the system's effectiveness, usefulness, and

satisfaction. Addressing usability issues identified during the heuristic evaluation could improve the SUS scores and broader end-user acceptance. Future iterations should prioritize user interface/ UX (UI/UX) improvements to enhance navigation and visual appeal.

Implications for policy and practice

The findings highlight several dimensions where the DIRS can inform policy and practice:

1. **Foundational importance of a classification system**.

The structured classification system developed as the backbone of the DIRS ensures robust incident documentation and analysis. It supports:

- **Comprehensive data collection**: By standardizing incident categories, dental institutions can systematically capture diverse AEs across various care settings.
- **Meaningful analysis**: The granularity of the classification aids in identifying trends, root causes, and risk factors.
- **Alignment with accreditation standards**: The system's design complies with Thailand's Hospital Accreditation standards, demonstrating its adaptability to both national and international reporting frameworks.

2. **Integration of usability testing in system development**.

The iterative development process emphasized usability testing at multiple stages:

- Addressing navigation complexity and visual design challenges during heuristic evaluations can enhance end-user satisfaction.
- Iterative refinements improve the UX and broaden adoption.

3. **Addressing budget constraints in development**.

Allocating resources for UI/UX enhancements and advanced analytics is essential for scalability.

4. **Practical applications of the DIRS**.

The DIRS provides actionable pathways for enhancing dental patient safety and organizational learning:

- **System integration**: The classification system can augment existing reporting platforms.
- **Adaptability**: The DIRS serves as a model for developing tailored IRSs across various institutions.
- **Scalability**: With further development, the DIRS can be integrated with broader healthcare systems to foster nationwide improvements in patient safety.

5. **Policy recommendations**.

To maximize the effect of the DIRS, policymakers should consider the following:

- **Investing in usability**: Allocate resources for UI/UX refinements to address heuristic findings.
- **Promoting organizational learning**: Embed the DIRS into broader risk management strategies to foster a culture of safety.
- **Standardizing reporting practices**: Advocate for the nationwide adoption of the classification framework of the DIRS.
- **Encouraging technology adoption**: Provide training to overcome barriers and build confidence in the system's utility.

6. **Broader impacts on usability and adoption**.

The SUS and UAT findings affirm the potential of the DIRS to meet user expectations:

- **Streamlining workflows**: Simplified navigation and enhanced visual appeal can further improve user satisfaction.
- **Building trust in technology**: Reliable feedback mechanisms reinforce user confidence in the adoption of IRSs.

Limitations and future directions

Despite its promise, the DIRS has the following limitations:

- **Limited sample size**: small number of usability test participants (16 end users) may limit the generalizability. Expanding the sample size in future studies could provide broader insights.
- **Short development cycle**: Time constraints limited refinements. Future iterations should focus on comprehensive evaluations.
- **Budget constraints**: Esthetic and advanced functionality enhancements require additional funding.

Future iterations of the DIRS should incorporate user feedback and allocate resources to address the identified limitations. By doing so, the DIRS can evolve into a benchmark system for incident reporting in dentistry,

contributing to sustained improvements in safety and risk management.

Integration and future applications

The DIRS has the potential to complement existing hospital and national reporting systems, addressing gaps in dental-specific incident reporting. To maximize its effect, future iterations could:

- **Enhance adaptability**: Improve the system's adaptability to enable integration with international benchmarks and diverse reporting requirements.
- **Foster collaboration**: Promote global collaboration in dental incident reporting to facilitate shared learning and continuous patient safety improvements.

Conclusions

This study highlights the development and validation of the DIRS, a tailored tool designed to address the unique challenges of incident reporting in dental settings. By integrating a comprehensive classification system and user-centered design principles, the DIRS enhances the accuracy and efficiency of AE documentation while aligning with national standards.

Key findings and their significance

The study identified three critical outcomes:

1. **Comprehensive classification system**: The developed classification framework encompasses the spectrum of dental-specific AEs, ensuring systematic and standardized documentation. This foundation enhances risk management and supports compliance with accreditation standards.
2. **Moderate usability and positive user acceptance**: A mean SUS score of 69.6875 reflects "acceptable" usability, indicating that users found the system functional and moderately easy to use. While heuristic evaluations identified navigation and interface design as areas needing improvement, the UAT results indicated positive user acceptance, demonstrating alignment with the practical needs of dental healthcare personnel, particularly in terms of effectiveness and functionality.
3. **Promoting transparency and reporting Culture**: By simplifying reporting processes and minimizing the fear of repercussions, the DIRS encourages active engagement, fostering a culture of safety and continuous improvement in dental patient care.

Practical applications

The DIRS prototype has been submitted to the Dental Hospital, Faculty of Dentistry, for consideration and real-world testing. If adopted, the system could:

- Promote incident documentation and reporting efficiency across dental institutions.
- Serve as a reference model for developing tailored incident reporting tools in other specialized healthcare settings.
- Provide actionable data to inform organizational learning and policymaking.

Limitations and future directions

Several limitations and areas for future development were identified:

1. **Usability and interface refinement**: While the system demonstrated acceptable usability, the heuristic evaluation revealed areas for improvement in the UI and navigation design. Future iterations should prioritize these refinements to enhance UX and satisfaction.
2. **Sample size**: The usability testing involved a relatively small group ($n = 16$), which may limit the generalizability of the findings. Expanding the participant pool in future research will provide broader insights and ensure that the system meets diverse user needs.
3. **Longitudinal impact assessment**: Further studies are needed to evaluate the long-term effect of the DIRS on reporting rates, risk management outcomes, and patient safety improvements in dental settings.
4. **Budget constraints**: Limited development funding affected aspects such as visual design and advanced analytics features. Addressing these constraints in subsequent development cycles will allow the system to reach its full potential.

Future implications

The DIRS holds significant potential for nationwide adoption, serving as a supplementary tool to enhance existing incident reporting frameworks. Refinements in the UI/UX design and broader usability testing will enable the system to meet higher standards of user satisfaction and effectiveness. In addition, the DIRS could contribute to establishing standardized reporting practices in dental care globally, promoting data-driven decision-making and fostering a proactive approach to patient safety.

In conclusion, the DIRS exemplifies how a tailored, user-centered approach can overcome the barriers in dental incident reporting. Although the current findings highlight areas for improvement, the system demonstrates strong functionality and alignment with user

needs, providing a scalable and sustainable model for improving safety practices and advancing patient care in dentistry.

Abbreviations

AEs	Adverse events
DIRS	Dental incident reporting system
DHCP	Dental healthcare personnel
ICC	Intraclass correlation coefficient
IRS	Incident reporting system
HBM	Health belief model
SUS	System usability scale
TAM	Technology acceptance model
TNRLS	Thailand's National Reporting and Learning System
UAT	User acceptance test
UI	User interface
UX	User experience
WHO	World Health Organization

Supplementary Information

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Supplementary Material 1

Supplementary Material 2

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Author contributions
K.S. and S.P. conceptualized and designed the study. K.S. analyzed and interpreted the data and wrote the manuscript. All authors read and approved the final manuscript.

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Data availability
The data that support the findings of this study are available from the corresponding author upon reasonable request.

Declarations

Ethics approval
for this study (HREC-DCU 2023-078) was obtained from the Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University, Bangkok, Thailand. The need for informed consent was waived by the Human Research Ethics Committee of the Faculty of Dentistry, Chulalongkorn University, owing to the retrospective nature of the study and the anonymization of all data.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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