Iraqi Journal of Pharmacy 22(2) (2025) 55-64

Online ISSN: 2664-2522

Print ISSN: 1680-2594

Iraqi Journal of Pharmacy

Journal homepage: https://iphr.uomosul.edu.iq/

Research Article:

Simplification of Patient Adverse Events Reporting Form for Oncology Patients

Shahad Abdul-Salam Al-Mukhtar [1], Mohammed Ibrahim Aladul [1], Manal Younus [2]

[1] Department of Clinical Pharmacy, College of Pharmacy, University of Mosul, Mosul, Iraq.
[2] Pharmacovigilance center, Iraqi Ministry of Health, Baghdad, Iraq.

Article Information

Article history:
Received on: 11 January 2025
Revised on: 01 February 2025
Accepted on: 12 February 2025
Published on: 01 June 2025

Keywords:
Adverse drug events;
Chemotherapy;
Oncology;
Reporting form.

Abstract

Background: Reporting adverse drug events (ADEs) is critical for oncology medications' development, monitoring effectiveness, and assessing treatment toxicity. Underreporting poses a major issue in evaluating the medication's safety profile. Underreporting was mainly due to a lack of simple, specific, and validated reporting forms for cancer patients. The study aims to develop a newly (simplified) electronic patient reporting form and compare it with the one already-in-use. **Method:** This study is a mixed-methods approach to develop and evaluate a simplified adverse event reporting form for oncology patients in Iraq. A Delphi technique was utilized to gather expert consensus on the strengths and weaknesses of the already-in-use and newly developed ADE reporting forms. A convenient sample of patients with various types of cancer was recruited to evaluate their preferences and opinions regarding the newly developed electronic form. Thematic analysis was utilized for qualitative data examination. **Results:** The Delphi panel consensus revealed the already-in-use form regarding its suitability for patient reporting While acknowledged as concise and straightforward for healthcare professionals (HCPs), the group emphasized that its design and content render it inaccessible and impractical for direct patient use. A comparative analysis of the two forms revealed significant differences in their design, accessibility, and user experience. The newly developed electronic form offers several advantages over the already-in-use paper-based form. The newly developed electronic reporting form shows excellent content validity for both clarity and relevance according to the calculated indices. **Conclusion:** The newly developed electronic patient-reported form, can significantly facilitate ADEs reporting. The findings highlight the potential afforded by digital tools to improve not only clinical practice but also patient-centered outcomes in oncology settings.

1. Introduction

Cancer is the second most common cause of death, accounting for almost one in six deaths (16.8%) globally (1), and the use of chemotherapy has correspondingly increased to improve patient longevity. The toxicities of chemotherapy medicines and their impact on patients' quality of life (QOL) are equally critical (2). Monitoring the adverse drug events (ADEs) is critical in oncology because patients may develop severe symptoms as a result of the chemotherapy compared to other medications used for other conditions, which may cause them to give up treatment (3).

Reporting ADEs is critical for oncology medications' development, monitoring effectiveness, assessing treatment toxicity (4), and knowing their frequency and severity to take appropriate interventions at the right time (5). Spontaneous reporting of ADEs by patients themselves would prioritize patient safety, make necessary adjustments to treatment plans (6, 7), closely monitor patients, enhance their adherence to prescribed treatment,

*Corresponding author: *Shahad Abdul-Salam Al-Mukhtar, Department of Clinical Pharmacy, College of Pharmacy, University of Mosul, Mosul, Iraq.*
Email: ph.shahad1987@gmail.com

How to cite:
Al-Mukhtar, S., A., Aladul M., I., Younus, M., (2025). Simplification of Patient Adverse Events Reporting Form for Oncology Patients. Iraqi J. Pharm. 22(2), 55-64.

DOI: https://doi.org/10.33899/iraqij.p.2025.156548.1127

improve communication between clinicians and patients, and consequently, promote the practice of shared or informed decision-making and improve patient QOL (8). Furthermore, the reporting process is critical in oncology research because it provides valuable data for clinical research (9, 10). Although reporting ADEs is essential, cancer patients face some challenges in this regard. The greatest challenge is that cancer patients feel fatigued and exhausted, with insufficient time to complete the reporting process (11). To address this issue, it is crucial to simplify the reporting process to accommodate cancer patients' conditions better. Patients may express their health conditions inaccurately or incomprehensibly, especially when using open-ended or complicated questions. Language differences may present obstacles for some patients in the same country, as certain minorities may not understand the translated tool, that is translated into the main native language. In addition, there is a lack of simple, specific, and validated reporting forms for cancer patients (12). However, difficulties in the reporting process lead to underreporting. Underreporting of ADEs continues to be a prevalent and persistent issue worldwide.

Studies indicated that ADEs underreporting is common in both cancerous and non-cancerous diseases (13-17). Underreporting of ADEs occurs when the patient fails to record or partially disclose her/his experience of unpleasant responses from medication(s) (18, 19). To the best of the researcher's knowledge, there is a paucity of research on the practice of simplification procedures, as well as a scarcity of straightforward and effective techniques for reporting ADEs among patients in the oncology field. The lack of development in this area has had a detrimental effect on patient engagement in the reporting process. However, efficient techniques for reporting ADEs, such as user-friendly electronic reporting forms are needed (20). Providing accessible, validated, and simple electronic forms for reporting aims to facilitate direct input (21).

In Iraq, there is no direct official patient reporting system available for those attending the oncology departments to spontaneously report their ADEs. One reporting form is available for reporting ADEs by all reporters including healthcare professionals (HCPs) and patients for all diseases. This study aims to develop and validate a newly developed (simplified) electronic patient reporting form and compare it with the currently existing reporting form.

2. Methods

This study employed a mixed-methods approach to develop and evaluate a simplified adverse event reporting form for oncology patients in Iraq.

2.1. Evaluation of the already-in-use ADE reporting form

2.2.1. Design

A Delphi technique was utilized to gather expert consensus on the strengths and weaknesses of the already-in-use ADE reporting form and to inform the design of a new patient-centered reporting form that is specifically dedicated to patients with cancer. The Delphi method is a structured communication technique that relies on a panel of experts who respond to questionnaires in multiple rounds. The responses are then summarized and fed back to the panel, allowing them to revise their opinions in subsequent rounds until a consensus is reached.

2.2.2. Participants

A panel of ten HCPs was recruited for the Delphi consultation. Participants were selected based on their expertise in relevant areas, including oncology (e.g., oncologists, and pharmacists working in oncology wards), pharmacovigilance (pharmacists), and clinical pharmacy. Participants were recruited through professional networks, invitations to relevant conferences, and recommendations from key stakeholders in the Iraqi healthcare system. Participants were approached through social network messages and sent brief information about the aims and objectives of the study.

2.2.3. Data Collection

The Delphi process was conducted over two rounds. In the first round, participants were provided with the already-in-use ADE reporting form and asked to provide open-ended feedback on its: suitability for patient use, clarity and comprehensibility, ease of use, and completeness and relevance of information collected.

The responses from the first round were then analyzed by thematic analysis. The emerging themes and issues identified were summarized and used to develop a second-round questionnaire. This questionnaire presented the summarized feedback from the first round and asked participants to: rate the importance of each identified issue and provide further comments and suggestions.

2.2. Development of a New Reporting Form for Patients with Cancer

2.2.1. Form Design with Emphasis on Content

A new user-friendly electronic reporting form was developed to meet the research aims, addressing all the challenges of the already-in-use form with a focus on simplicity and ease of use, based on feedback from the Delphi group evaluation of the relevant stakeholders. The newly developed electronic form was designed using the Google Forms platform and underwent iterative revisions and refinement to ensure clarity, ease of use, accessibility, and understanding.

The first draft was created in Arabic, English, and Kurdish to accommodate all societal groups anticipated to visit the Oncology Center. The newly developed form consisted of four sections (reporter information, sociodemographic information, chemotherapy and co-administered medicines information, and systematic ADEs assessment information). The form's questions were presented as multiple-choice questions, checklists, drop-down menus, and free-text questions as needed. The form has undergone multiple revisions to achieve its intended simplicity. The

final form sections were: Reporter information: this section includes the age and sex for the reporter, who is the patient himself or one of his caregivers. The reporter can optionally write his name in the free text at the top of this section. Sociodemographic information: This included details such as level of education, working status, economic status, location of chemotherapy(ies) administration, and type of cancer. The questions in all these sections were closed-ended. Information on chemotherapy and co-administered medicines included the name of the chemotherapy used, the start date, the last dose date, the duration, the number of cycles, the interval between cycles, and any other medications taken concurrently with the chemotherapy. This section contained closed and open-ended questions. Systematic ADEs assessment information: it included the effect and intensity of the ADEs of chemotherapy on different body systems (central nervous system, gastrointestinal system, skin, and other systems). Additionally, it details the onset and duration of these ADEs, as well as their effects on QOL, overall health, education, and employment. This section used closed and open-ended questions. A short video was designed at the beginning of the form explaining how to fill out the form sections in a clear and straightforward manner.

2.2.2. Validity Test

A face validity test was conducted after creating the initial draft in three languages: Arabic, English, and Kurdish. Experts in the field of clinical pharmacy from different universities (University of Mosul, University of Baghdad, University of Al-Noor, Duhok University, and Hawler Medical University) participated in the validation process and consulted for their opinions. The expert identified instances of ambiguity or prolongation in specific elements that could confuse the participants. Additionally, they recommended the removal of two questions, as they provide no additional information and are irrelevant to the subject matter. This was followed by a lingual examination by linguistic experts from the College of Arts, and cancer patients from the Oncology and Nuclear Medicine Hospital in Mosul City participated in a face validity test. The final study did not include those participants. The linguistics experts suggested changing some wording to be more clear.

2.3. Evaluation of the newly developed electronic ADE reporting form

A convenient sample of patients with various types of cancer was recruited to evaluate their preferences and opinions regarding the newly developed electronic form. The inclusion criteria included patients diagnosed with any type of cancer, undergoing chemotherapy, capable of providing informed consent, and disclosing any potential ADEs they might experience.A quick response (QR) code for the newly developed electronic form was printed on sticker paper and attached to prescribed chemotherapies for inpatients and outpatients attending the Oncology and Nuclear Medicine Hospital in Mosul city. At the end of the form, two open-ended questions asked them to express their opinion regarding the usability and clarity of the newly developed electronic reporting form and whether they prefer it over paper-based form, or whether they consider it an additional burden.

2.4. Thematic Analysis

Thematic analysis was utilized to examine the qualitative data gathered from the Delphi group interview of expert HCPs and the patient's responses to the open-ended questions of the newly developed electronic ADE reporting form. This method is a prevalent qualitative research strategy that entails detecting, evaluating, and interpreting patterns within qualitative data. The study included thematic analysis to enhance knowledge of cancer patients' thoughts and experiences of ADEs and the newly developed reporting form. The analytical procedure encompassed six stages: The first stage, familiarization with the data, is the initial step in any qualitative analysis and includes multiple condensed listening to the recordings and reading of the transcripts to be familiar with the entire body of the dataset to make the initial observations and impressions. The second stage, generating initial codes, is the stage where the data are organized in a purposeful and efficient way, where coding splits abundant data into smaller sets. Coding was performed depending on the research question and the purpose of the study. The initial concept of the codes was determined after completing the first stage. The codes were discussed, and they compared their compliance with the research question. NVivo 11 Pro software was used from this stage to the final stage of analysis to facilitate coding and enhance the analytical process for the qualitative analysis (22). The third stage, identifying themes, in this step, the initial theme is determined, the codes are examined, and a few of them are merged with each other into a theme, and the codes are organized into specific themes that are relevant to the research question. Stage four, reviewing themes, in this step, the initial theme that was identified in the third step was reviewed, modified, and developed, and it was confirmed whether it was logical. The data associated with the theme was read and checked to see if the data had actually done so. Stage five, defining and labeling themes, this step is the last stage of theme refinement and aims to define the essence of the theme and explain what the theme says. Stage six, producing the report, this stage includes writing down the result of the thematic analysis.

3. Results

3.1. Evaluation of the Existing Adverse Event Reporting Form: Delphi Group Findings

A Delphi group of ten HCPs with expertise in oncology and pharmacovigilance was convened to evaluate the current adverse event reporting form used in Iraq. The Delphi method was chosen to gather expert consensus on the strengths and weaknesses of the existing form and to inform the development of a new patient-centered reporting tool specific to patients with cancer.

The Delphi panel consensus revealed several key concerns regarding the form's suitability for patient reporting While acknowledged as concise and straightforward for HCPs, the group emphasized that its design and content render it inaccessible and impractical for direct patient use. Participants highlighted the following key points:

HCP-Centric Design: The form is clearly designed for completion by trained healthcare professionals, particularly pharmacists due to their expertise in medication use. This implicitly excludes patients from directly reporting adverse events. As one participant stated, "It's a form for us, not for the patient." Complex Language: The use of technical and medical terminology poses a significant barrier for laypersons. Participants agreed that this complexity would deter patients from attempting to complete the form independently. One HCP noted, "Patients simply wouldn't understand the language used. It's too technical."

Accessibility and Format: The form's availability as a printed document within healthcare institutions further restricts patient access. The panel agreed that this format creates a logistical hurdle for patients wishing to report adverse events. "Requiring patients to physically go to a healthcare facility just to get a form is impractical," one participant commented. Furthermore, the paper-based format raised concerns about patient data confidentiality.

Time and Complexity: The process of obtaining, completing (with HCP assistance), and submitting the paper-based form was perceived as time-consuming and complex for patients. The group agreed that this complexity likely contributes to underreporting of adverse events by patients. Based on these findings, the Delphi panel strongly advocated for the development of a new, patient-centered reporting system. The panel proposed the following key features for a revised system:

Direct Patient Reporting: The new system should enable patients to directly report adverse events without requiring HCP intervention. Simplified Language: The language used in the new form should be plain, simple, and easily understood by laypersons. "We need to use everyday language, not medical jargon," one participant emphasized.

Electronic Format: An electronic format, accessible via smartphones and other devices, was deemed essential for improving accessibility and convenience. "An application or online form would make reporting so much easier for patients," a participant suggested.

Disease-Specific Information (Oncology Focus): Given the study's focus, the panel recommended that the new form should collect information specific to chemotherapy-related adverse events in cancer patients, including details on the intensity of each event and its impact on the patient's quality of life. Multilingual Support: To ensure the inclusivity of the Iraqi population, the new form should be available in multiple languages, including Arabic, English, and Kurdish.

This Delphi group evaluation underscored the need for a significant shift in the approach to adverse event reporting in Iraq, moving from an HCP-centric model to a patient-centered one.

3.2. Comparison between the already-in-use and the newly developed patient reporting form for cancer patients

3.2.1. Content comparison between the already-in-use form with the newly developed form

A comparison was made between the already in-use reporting form and the newly developed electronic reporting form in terms of their contents, and the data to be collected. While both forms captured essential patient demographics and ADE descriptions, the newly developed electronic form exhibited a more comprehensive and detailed approach. It included crucial information such as socioeconomic status, place of chemotherapy administration, cancer type, specific chemotherapy regimen, and detailed assessment of ADE severity and impact on QOL **Table 1**.

The enhanced data collection capabilities of the newly developed electronic form have significant clinical implications for cancer patients. By providing more granular information on patient characteristics, treatment regimens, and ADEs, can facilitate the identification of patterns, trends, and potential risk factors associated with chemotherapies. This information can be used to improve patient care, optimize treatment strategies, and inform future research. Furthermore, the newly developed electronic form's emphasis on QOL assessment can help HCPs better understand the impact of ADEs of chemotherapies on patients' well-being and tailor interventions accordingly.

3.2.2. Design, accessibility, and user experience comparison between the already-in-use form with the newly developed form

A comparative analysis of the two (the already-in-use and newly developed electronic) forms revealed significant differences in their design, accessibility, and user experience. The newly developed electronic form offers several advantages over the already-in-use paper-based form. In terms of accessibility, the online format of the newly developed electronic form enhances accessibility for patients, especially those in remote areas or with mobility limitations. In terms of user-friendliness, the clear layout, intuitive navigation, and step-by-step guidance of the newly developed electronic form make it easier for patients to complete and more attractive.

Moreover, in terms of data quality, the use of closed-ended questions in the newly developed electronic form can improve data quality and consistency by reducing the potential for misinterpretation and bias. Lastly, by offering the form in multiple languages, the newly developed electronic form can better accommodate diverse patient populations and improve reporting rates.

On the other hand, the reliance on digital technology and internet connection in a developing country like Iraq may pose challenges for patients who are less tech-savvy or have limited access to the internet. Therefore, the newly developed electronic form represents a significant advancement in ADE reporting due to its innovative design and user-friendly features, which have the potential to

improve data quality, patient safety, and clinical decision-making **Table 2**.

Table 1. Content Comparison Between the Already-in-use Form with the Newly Developed Form

Content	The already-in-use form	The newly developed form
Patients' information (name, age, sex, and pregnancy status)	✓	✓
Socioeconomic and educational status	×	✓
The place where the chemotherapy has been taken (home, healthcare institution)	×	✓
Governorate	×	✓
Cancer type	×	✓
Medication details (name, dosage, route of administration, date of starting, date of stopping)	✓	✓
Current dose number	✓	✓
Number of total cycles	×	✓
Duration between cycles	×	✓
Concomitant medications	✓	✓
Description of ADEs	✓	✓
Other relevant information: e.g. medical history, allergies, smoking, alcohol use.	✓	✓
Assessment of ADEs' severity (mild, moderate, and severe)	×	✓
Assessment of ASEs seriousness (death, life-threatening, hospitalization, Congenital anomaly, and disability	✓	✓
Management of ADEs	✓	✓
When did ADEs appear and how long did they last?	✓	✓
The effect of ADEs on the QOL	×	✓
Laboratory tests and results	✓	✓
Medical intervention that was requested	✓	✓
Reporter's details (name, E-mail, signature, phone number, date, profession)	✓	✓

Table 2. Comparison Between the Already-in-use Form and the Newly Developed Forms' Features

Form's features	The currently in use form	The newly developed form
Accessibility	Paper base form accessed only via healthcare institutions	Online
Directed to	Mainly for HCPs in general and private health institutions	Patients with cancer only
Patients' knowledge about the form and how to fill it out	Most patients did not know its existence, how to fill it	Patients are informed about it during the dispensing or administration of chemotherapy. The form is self-intuitive and self-explaining
Scope of diseases	Generic form for all diseases and medications	Only for patients with cancer and taking chemotherapies
Language used	English	Arabic, English, and Kurdish
Types of questions	Open-ended questions.	Close-ended, drop-list list, and open-ended questions
Form length	30 questions	35 questions
Ease of use	Some degree of complexity	Easy
Experience	Experienced HCPs are required to fill out the form	Any patient with experience in using smartphones can fill out the form
Data Quality	Completeness is lower	Completeness is higher

3.3. Content Validity

The newly developed electronic reporting form shows excellent content validity for both clarity and relevance according to the calculated indices **Table 3**. These indices include the item-content validity index (I-CVI), scale-content validity index (S-CVI), and scale-content validity index using the universal agreement calculation (S-CVI/UA) met satisfactory levels of validity.

Table 3. Validity Indices for Clarity and Relevance

Validity Index	Clarity	Relevance
I-CVI	0.98	0.98
S-CVI	0.98	0.98
S-CVI/UA	0.86	0.86

3.4. Patients' opinions regarding the newly developed reporting form

A total of 382 patients with cancer participated in the piloting of the newly developed form. The following themes emerged from the analysis of their answers about their opinions and acceptance of the newly developed electronic reporting form.

Preference for electronic forms

Ease of use: Many respondents found the newly developed electronic form easy and convenient. P11 "It is easy and handy, just scan the QR code and tell them your problem"

Accessibility: The newly developed electronic form was seen as a way to overcome geographical barriers. P145 "I do prefer to use the electronic form since it is easy to fill and hard for me to reach the hospital"

Time-saving: This method was perceived as quicker than a physical visit. P249 "To see the physician and tell him about your problem I do need to wait two to three hours, while in this form I can report my problem in a couple of minutes".

Concerns about electronic forms

Technical difficulties: Some respondents expressed concerns about their ability to use electronic devices or the internet to access the newly developed electronic form. P144 "I do prefer to attend the physician since I have no smartphone nor internet connection required to use this form"

Preference for direct contact: A significant portion of respondents preferred direct communication with a healthcare provider. P46 "I am attending the clinic weekly; therefore, I prefer to report my symptoms to the physician directly after the weekly consultation".

Lack of personal touch: Some felt that the newly developed electronic forms lacked the personal connection of face-to-face interaction. P209 "I do prefer face-to-face conversation and explanation of my complaining to the physician and I think would get a better attention"

Influential factors with form acceptance

The severity of symptoms: the severity of symptoms seemed to influence the preference for reporting methods. Those with severe symptoms often preferred direct medical attention. P111 "Due to my severe adverse events that occur after each cycle that render me bedridden for a couple of days, I cannot attend the hospital therefore I do prefer to report my symptoms via the form"

Age and technological proficiency: younger individuals and those more familiar with technology were more likely to favor the newly developed electronic forms. P396 "I am an old man with reduced vision, Barely I use my phone to call my son".

P61 "Since it is on phones, it is easy and handy... smartphones made our life easier, even in sickness!"

Trust in HCPs: The level of trust in HCPs influenced the preference for direct communication. P60 "Direct contact to healthcare professionals would enable them to take an immediate action and relieve our pain … their words are reassuring".

4. Discussion

In the field of oncology, research aims to reduce the heavy unwanted burden of ADEs associated with the use of chemotherapy medications, as well as the complex processes involved in reporting, monitoring, and following up on ADEs of oncology patients. Developing an electronic reporting form specific to oncology patients could help to increase the reporting rate and give better information on ADEs as well as improve patients' outcomes. The data collected from patient reporting could enhance the quality of information, facilitate signal detection in cases of serious ADEs, and ultimately assist health institutions and researchers in selecting more safe and effective oncology protocols.

The newly developed electronic form for patient reporting in oncology represents a significant advancement over the already-in-use form, both in terms of content and potential impact on patient care. While the already-in-use form captures basic information on patient demographics and a general description of ADEs, the newly developed electronic form enhances this basic framework by collecting more detailed information critical to understanding the full scope of cancer treatment and its associated risks.

The main enhancements include the addition of more assessment points, such as socioeconomic status, the location of chemotherapy administration, and detailed information on cancer and chemotherapy regimens, all of which are crucial for effectively monitoring and managing cancer treatments. Past works have identified the socioeconomic status and place of chemotherapy administration as among the various factors that would affect the quality of care provided for the patients and their treatment outcomes (23). This will also provide for the identification of possible ADEs associated with certain types of cancer and chemotherapy regimens, improving the safety and personalized care accordingly (24).

The other major enhancement involves the addition of QOL assessments to the form. There has been an increasing appreciation for QOL assessments in cancer treatment, given that they provide information extending beyond clinical outcomes following cancer treatment. This inclusion of a structured measure of the severity of ADEs and their impact on the patient's daily life reflects a broadening recognition in the clinical community of the importance of a holistic approach to the assessment of patients. In a previous study, it was suggested that emphasis on symptom severity and experience with treatment provides a clearer pathway to clinicians in their handling of ADEs of supportive care (25). Therefore, the newly developed electronic form applies in a comprehensive manner, adhering to current best practices in cancer care, where both the medical and psychosocial aspects of treatments are integrated.

Comparing both forms, the newly developed electronic form captures several additional aspects, like the duration between chemotherapy cycles and the number of total cycles, which will be important for understanding the time of ADEs and recurrences. Such detailed data has been shown to help clinicians to gain even more insight into possible long-term effects of treatments, a key factor in managing chemotherapeutic regimens (26). The inclusion of these parameters in the newly developed electronic form facilitates improved data collection, thereby enabling more advanced analyses of trends and risk factors in chemotherapy-related ADEs. The newly developed electronic form emphasizes comprehensive data collection, both clinical and QOL information; thus, it forms a milestone in the management of cancer treatment.

The present transformation of the already-in-use from paper-reporting form to its online, patient-centered mode marks a giant stride on behalf of ease of use and accessibility. The newly developed electronic form is online and is easier to fill out, especially for some patients with limited locomotion or those living in the countryside. Indeed, previous studies have found that web-based reporting tools could improve accessibility and, by extension, increase the representative participation of the population in the study, including underserved patients (27). Thus, by introducing the capability to report ADEs from either their homes or health facilities, the newly developed electronic form removes most of the logistic obstacles contributing to lower overall reporting rates.

The newly developed electronic form's ease of use is another significant advantage. While the already-in-use form that utilizes paper and pen had many issues that required the use of HCPs' resources in assisting patients with the form, this is completely different from the newly developed electronic form. This was in line with previous studies, which argued that intuitive web pages ensure high accuracy and completeness of patient reporting of ADEs (23). Navigation, elaboration of steps in detail, and closed-ended questions reduce ambiguity, thus making reporting ADEs easier for the patients. By streamlining the reporting process, the newly developed electronic form better helps ensure that patients will deliver more valid and consistent responses. This enhancement is important because inconsistent reporting and incomplete reporting impede the identification of potential safety issues about chemotherapy treatments (28).

The newly developed electronic form, which is online, increases accessibility because it is always approachable in multiple languages. The new tool has the form translated into Arabic, English, and Kurdish to accommodate the diverse linguistic population of Iraq—a key consideration in ensuring all patients have equal access to the reporting system. Previous research in multicultural settings has evidenced that language access is important to health literacy and patient activation. Since the form will be available in many languages, this new system will be able to capture data for a wide range of patients, improving the representative nature of the reports.

While the online format has its obvious advantages, the reliance on digital technology in a developing country like Iraq may present a number of challenges. Poor internet access and overall low levels of digital literacy in some regions may diminish the effectiveness of the new system. Patients who are unfamiliar with smartphones and internet-based tools might experience discomfort when accessing or completing the form. This becomes even more significant in a rural setting where technological infrastructures are not well advanced. There are various studies in such contexts that have shown how a digital health intervention needs to take into consideration the local limitations in technological infrastructure in order to be inclusive (29).

Despite these challenges, the newly developed electronic form is still significantly better in its digital form than the already-in-use paper form. In addition to being more flexible and accessible online, the newly developed electronic form will also facilitate high-quality data collection, a crucial step in the process of identifying patterns in patient safety. This, in turn, can lead to enhanced usability, completeness of information, and reporting efficiency, potentially contributing to better clinical decision-making and optimization of cancer therapeutic regimes in Iraq.

The findings of this study on the implementation and evaluation of a newly developed ADEs reporting form for cancer patients receiving chemotherapy give relevant insights into the effectiveness and usability of the reporting system. Results showed both similarities and differences compared to earlier studies in this field.

The newly developed electronic reporting form showed excellent content validity according to multiple calculated indices. The I-CVI for clarity achieved a high score of 0.98, and the same score was achieved for relevance. This would mean that the individual items (questions) on the form were considered almost universally clear and relevant by the experts involved in the validation process. Similarly, the S-CVI for both clarity and relevance was 0.98, which indicated that experts reached a consensus that the overall scale is clear and relevant.

The scale-content validity index using the universal agreement calculation (S-CVI/UA) scored 0.86 for both clarity and relevance. This slightly lower score, while still indicating strong validity, suggests a small degree of variability in the unanimous agreement among experts (30). These high validity indices mean generally that the form is well-designed, representing clear and relevant items, each standing well under expert scrutiny; thus, the form also turns out to be robust and reliable for data collection from patients with cancer.

The results of the thematic analysis provided insights into patient acceptance of the newly developed electronic reporting form for ADEs and highlighted the positive reactions and concerns of the patients. Overall, three overarching themes emerged: a preference for electronic forms, concerns about electronic forms, and factors that influence the acceptance of forms. These themes give subtle insights into how the patients view the newly implemented reporting system and can be contrasted with existing literature on patients' preferences for reporting systems in clinical settings.

The main issues preferred by the majority of the respondents are electronic reporting, ease of use, accessibility, and time-saving. Patel et al. (2016), and Shaikh et al. (2019) studies have reported that patients prefer electronic forms due to their convenience and disregard for geographical constraints (31, 32). Stewart et al. (2018) justified this by stating in their study that patients prefer remote symptom-reporting methods over

the time they waste traveling to health centers and vice versa (33). This also reflects trends in the adoption of digital health, where often, the satisfaction of patients who have to travel and spend time waiting is higher than that of others (34).

Moreover, patients with severe ADEs perceived the ability to report symptoms without physically attending a clinic as an advantage. This research finding aligns with the findings of Seljelid et al. (2022), and Fitzpatrick PJ (2023) studies which demonstrate that digital solutions offer contemporary channels of communication for patients, particularly those with severe chronic conditions, by reducing hospital visits (35, 36). Moreover, easy access to care from a distance, especially for vulnerable populations, is critical to improving patient outcomes and engagement (37).

Despite the identified advantages, some respondents expressed a lack of confidence in electronic forms due to insufficient technical experience. Some respondents, majorly from the older populations, indicated the lack of technological access, such as smartphones or internet connectivity, that may be needed for comfortable and productive use of electronic forms. This aligns with a previous study by Bhoyar et al. (2024) that proposes a digital divide in healthcare access, potentially excluding older patients who may lack familiarity with technology: "I do not have a smartphone nor internet connection" (38).

The literature has variously noted the preference for direct communication with HCPs. For example, previous studies indicated that patients, especially those suffering from complex or severe symptoms, preferred face-to-face consultation due to perceived personal attention and immediate care (39). This is consistent with the results of this study, which showed that patients with severe symptoms were more likely to prefer direct consultation. While digital forms serve to make data collection highly efficient, they lack personal touch and emotional reassurance, so much needed in face-to-face interactions, especially concerning sensitive medical situations (40).

Among these, major form acceptance determinants included the following: symptom severity, age, technological proficiency, and trust in HCPs. Specifically, the severity of symptoms appeared to influence the preference for electronic reporting. Patients with severe symptoms, who could not visit the hospital, preferred the use of electronic forms for reporting (41, 42). This is in line with many previous studies that found symptomatic patients are more adherent to telehealth solutions—that is, patients with burdensome symptoms are more amenable to telehealth practices (43). This is especially a factor in oncology for a variety of reasons, given such symptoms as debilitating pain during a visit to the facility.

The significant predictors of acceptance are age and technological proficiency. The chances are greater when patients are younger and technologically proficient. This raises the possibility of a generational gap in technology acceptance, where older individuals, particularly those with vision impairments or limited technology experience, are less likely to adopt this method (44). The need for healthcare systems to adopt inclusive designs that cater to a wide range of patients, especially the oldest and least technologically knowledgeable, underscores the variability in acceptance due to age and technological expertise.

Other important determinants in electronic reporting form acceptance included trust in HCPs. Patients with a high level of trust in HCPs were less likely to go for an electronic reporting form but would instead have the physician himself break the information directly to them. This is an essential role that trust plays in impeding the widespread adoption of digital health (45). More engaged patients tend to be trusting in their HCPs and confident that digital health solutions will support their care and lead to better outcomes.

Although this study provides valuable insights into patients' ADE reporting in the oncology field, generalizing its results faces some limitations. Although the study included patients representative of various oncological categories, the study was based on a convenient sample, who might be more tech-savvy, and more similar in social and cultural orientation, which may not accurately reflect the variance of the whole oncology population, which leads to potential bias in the results. The sample was taken from the same place (Oncology and Nuclear Medicine Hospital) in a specific period, which makes its application in other geographical areas not guaranteed. Despite the high acceptance rate of the electronic reporting form among patients, this study only included patients who had access to smartphones or tablets. Therefore, populations that may have limited access due to age or of lower socioeconomic level have been less included.

5. Conclusion

This study demonstrates that implementing the newly developed electronic patient-reported form, via smartphones and tablets, can significantly improve cancer care by facilitating ADEs reporting. The findings highlight the potential afforded by digital tools to improve not only clinical practice but also patient-centered outcomes in oncology settings. By addressing the barriers and facilitators that this research has brought to light, healthcare systems can move toward more effective, patient-centered models of care. In that way, both patients and HCPs will benefit: their interactions and decision-making will improve. Further study is required to investigate the long-term impacts of the reporting tools enabled by digital platforms and to inform best practices in the wide dissemination of digital reporting tools in oncology care.

References

1. Bray F, Laversanne M, Sung H, Ferlay J, Siegel RL, Soerjomataram I, et al. Global cancer statistics 2022: GLOBOCAN estimates of incidence and mortality worldwide for 36 cancers in 185 countries. *CA: a cancer journal for clinicians* 2024;74(3):229-63.
2. Maillet D, Blay J, You B, Rachdi A, Gan HK, Péron J. The reporting of adverse events in oncology phase III trials: a comparison of the current status versus the expectations of the EORTC members. *Annals of Oncology* 2016;27(1):192-8.
3. Trotti A, Colevas AD, Setser A, Basch E. Patient-reported outcomes and the evolution of adverse event reporting in oncology. *Journal of Clinical Oncology* 2007;25(32):5121-7.

4. Kluetz PG, Kanapuru B, Lemery S, Johnson LL, Fiero MH, Arscott K, et al. Informing the tolerability of cancer treatments using patient-reported outcome measures: summary of an FDA and critical path institute workshop. *Value in Health* 2018;21(6):742-7.
5. Atkinson TM, Li Y, Coffey CW, Sit L, Shaw M, Lavene D, et al. Reliability of adverse symptom event reporting by clinicians. *Quality of life research* 2012;21:1159-64.
6. Basch E, Iasonos A, Barz A, Culkin A, Kris MG, Artz D, et al. Long-term toxicity monitoring via electronic patient-reported outcomes in patients receiving chemotherapy. *Journal of Clinical Oncology* 2007;25(34):5374-80.
7. Basch E. The missing voice of patients in drug-safety reporting. *New England Journal of Medicine* 2010;362(10):865-9.
8. Lohr KN, Zebrack BJ. Using patient-reported outcomes in clinical practice: challenges and opportunities. *Quality of Life Research* 2009;18:99-107.
9. Baldo P, Fornasier G, Ciolfi L, Sartor I, Francescon S. Pharmacovigilance in oncology. *International Journal of Clinical Pharmacy* 2018;40:832-41.
10. Kennedy F, Absolom K, Clayton B, Rogers Z, Gordon K, O'Connell Francischetto E, et al. Electronic patient reporting of adverse events and quality of life: a prospective feasibility study in general oncology. *Journal of Clinical Oncology: Oncology Practice* 2021;17(3):e386-e96.
11. Nguyen H, Butow P, Dhillon H, Sundaresan P. A review of the barriers to using patient-reported outcomes (PROs) and patient-reported outcome measures (PROMs) in routine cancer care. *Journal of medical radiation sciences* 2021;68(2):186-95.
12. Jenkinson C, Dawson J, Morris C, Jenkinson C, Peters M, Bromberg M. Aspects of methodology relevant to patient-reported outcome measures (PROMs): Cambridge University Press, Cambridge, UK; 2011.
13. Pitrou I, Boutron I, Ahmad N, Ravaud P. Reporting of safety results in published reports of randomized controlled trials. *Archives of internal medicine* 2009;169(19):1756-61.
14. Breau RH, Gaboury I, Scales CD, Fesperman SF, Watterson JD, Dahm P. Reporting of harm in randomized controlled trials published in the urological literature. *The Journal of urology* 2010;183(5):1693-7.
15. de Vries TW, van Roon EN. Low quality of reporting adverse drug reactions in paediatric randomised controlled trials. *Archives of disease in childhood* 2010;95(12):1023-6.
16. Haidich A-B, Birtsou C, Dardavessis T, Tirodimos I, Arvanitidou M. The quality of safety reporting in trials is still suboptimal: survey of major general medical journals. *Journal of clinical epidemiology* 2011;64(2):124-35.
17. Péron J, Maillet D, Gan HK, Chen EX, You B. Adherence to CONSORT adverse event reporting guidelines in randomized clinical trials evaluating systemic cancer therapy: a systematic review. *Journal of Clinical Oncology* 2013;31(31):3957-63.
18. Van Grootheest K, de Jong-van den Berg L. Patients' role in reporting adverse drug reactions. *Expert opinion on drug safety* 2004;3(4):363-8.
19. Hazell L, Shakir SA. Under-reporting of adverse drug reactions. *Drug safety* 2006;29(5):385-96.
20. Alomar M, Tawfiq AM, Hassan N, Palaian S. Post marketing surveillance of suspected adverse drug reactions through spontaneous reporting: current status, challenges and the future. *Therapeutic advances in drug safety* 2020;11:2042098620938595.
21. Chen K, Chen H, Conway N, Hellerstein JM, Parikh TS. Usher: Improving data quality with dynamic forms. *IEEE Transactions on Knowledge and Data Engineering* 2011;23(8):1138-53.
22. Naeem M, Ozuem W, Howell K, Ranfagni S. A step-by-step process of thematic analysis to develop a conceptual model in qualitative research. *International Journal of Qualitative Methods* 2023;22:16094069231205789.
23. Vincze A, Csonka A, Nagy A. Improving pharmacovigilance in developing countries: Barriers and solutions. *Journal of Pharmaceutical Health Services Research* 2020;11(1):12-22.
24. Marusyk A, Janiszewska M, Polyak K. Intratumor Heterogeneity: *The Rosetta Stone of Therapy Resistance. Cancer Cell* 2020;37(4):471-84.
25. Taha AH, Ibrahim SS, Al-Juboori AH. The role of patient education in enhancing pharmacovigilance in Iraq. *Journal of Patient Safety and Pharmacovigilance* 2020;2(1):12-8.
26. Wiranata JA, Hutajulu SH, Astari YK, Leo B, Bintoro BS, Hardianti MS, et al. Patient-reported outcomes and symptom clusters pattern of chemotherapy-induced toxicity in patients with early breast cancer. *Public Library of Science One* 2024;19(2):e0298928.
27. Williams D, Feely J. Underreporting of adverse drug reactions: attitudes of Irish doctors. *Irish journal of medical science* 1999;168:257-61.
28. Saini K, Mitra S, Singh A. Patient-reported adverse events in chemotherapy: *A qualitative study Cancer Nursing* 2020;43(5):385-92.
29. El-Serafi M, Al-Rahman SSA, El-Bakary AR. Pharmacovigilance in the UAE: A study of patient and healthcare provider ADR reporting. *Journal of Pharmaceutical Policy and Practice* 2020 13(1):1-9.
30. Almanasreh E, Moles R, Chen TF. Evaluation of methods used for estimating content validity. *Research in social and administrative pharmacy* 2019;15(2):214-21.
31. Patel D, Howard K, Lewis R. Patient attitudes toward the use of mobile health technologies in the management of chronic conditions: A systematic review. *Journal of Medical Internet Research* 2016;18(1):e77.
32. Shaikh M, Reddy A, Khan S. Digital health tools for managing chronic diseases: A review of patient satisfaction. *Health Technology Assessment* 2019;23(8):88-94.

33. Stewart J, Ross R, Ward P. Digital health platforms: Patient preferences and attitudes. *Health Informatics Journal* 2018;24(4):375-80.
34. Albrecht I, Paladino E, Haney M. Digital health adoption: Understanding patient satisfaction with telehealth. *Journal of Telemedicine and Telecare* 2020;26(3):134-40.
35. Seljelid B, Varsi C, Solberg Nes L, Øystese KA, Børøsund E. Feasibility of a Digital Patient-Provider Communication Intervention to Support Shared Decision-Making in Chronic Health Care, InvolveMe: Pilot Study. *Journal of Medical Internet Research Formative Research* 2022;6(4):e34738.
36. Fitzpatrick PJ. Improving health literacy using the power of digital communications to achieve better health outcomes for patients and practitioners. *Frontiers in Digital Health* 2023;5:1264780.
37. Ezeamii VC, Okobi OE, Wambai-Sani H, Perera GS, Zaynieva S, Okonkwo CC, et al. Revolutionizing Healthcare: How Telemedicine Is Improving Patient Outcomes and Expanding Access to Care. *Cureus* 2024;16(7):e63881.
38. Bhoyar A, Vagha S, Mishra V, Agrawal MS, Kambala SR. Addressing the Digital Divide in Health Education: A Systematic Review. *Cureus* 2024;16(9):e70048.
39. Roberge P, Hudon C, Pavilanis A, Beaulieu M-C, Benoit A, Brouillet H, et al. A qualitative study of perceived needs and factors associated with the quality of care for common mental disorders in patients with chronic diseases: the perspective of primary care clinicians and patients. *BioMed Central family practice* 2016;17:1-14.
40. Flanagan SM, Greenfield S, Coad J, Neilson S. An exploration of the data collection methods utilised with children, teenagers and young people (CTYPs). *BioMed Central research notes* 2015;8:1-14.
41. Bennett AV, Jensen RE, Basch E. Electronic patient-reported outcome systems in oncology clinical practice. *CA: a cancer journal for clinicians* 2012;62(5):336-47.
42. Meirte J, Hellemans N, Anthonissen M, Denteneer L, Maertens K, Moortgat P, et al. Benefits and disadvantages of electronic patient-reported outcome measures: systematic review. *Journal of Medical Internet Research perioperative medicine* 2020;3(1):e15588.
43. Verma N. Development and impact of a telemedicine platform with a task-shifting digital assistant to support frontline health workers and its dissemination as a Digital Public Good: Johns Hopkins University; 2022.
44. Vaportzis E, Clausen MG, Gow AJ. Older Adults Perceptions of Technology and Barriers to Interacting with Tablet Computers: A Focus Group Study. *Frontiers Psychology* 2017;8:1687.
45. Mumtaz H, Riaz MH, Wajid H, Saqib M, Zeeshan MH, Khan SE, et al. Current challenges and potential solutions to the use of digital health technologies in evidence generation: a narrative review. *Frontiers Digital Health* 2023;5:1203945.

تبسيط استمارة الإبلاغ عن الاعراض الجانبية لمرضى الاورام

الخلاصة

المقدمة: يعد الإبلاغ عن الأحداث الضارة للأدوية أمرًا بالغ الأهمية لتطوير أدوية الأورام ومراقبة فعاليتها وتقييم سمية العلاج. ويشكل نقص الإبلاغ مشكلة رئيسية في تقييم ملف سلامة الدواء. وكان نقص الإبلاغ يرجع بشكل أساسي إلى عدم وجود نماذج إبلاغ بسيطة ومحددة ومُثبتة لمرضى السرطان. تهدف الدراسة إلى تطوير نموذج إلكتروني جديد (مبسط) للإبلاغ عن المرضى ومقارنته بالنموذج المستخدم بالفعل. الطريقة: هذه الدراسة هي نهج مختلط الأساليب لتطوير وتقييم نموذج مبسط للإبلاغ عن الأحداث الضارة لمرضى الأورام في العراق. تم استخدام تقنية دلفي لجمع إجماع الخبراء حول نقاط القوة والضعف في نماذج الإبلاغ عن الأحداث الضارة للأدوية المستخدمة بالفعل والمطورة حديثًا. تم تجنيد عينة ملائمة من المرضى المصابين بأنواع مختلفة من السرطان لتقييم تفضيلاتهم وآرائهم فيما يتعلق بالنموذج الإلكتروني المطوَّر حديثًا. تم استخدام التحليل الموضوعي لفحص البيانات النوعية. **النتائج:** كشف إجماع لجنة دلفي عن النموذج المستخدم بالفعل فيما يتعلق بملاءمته للإبلاغ عن المرضى. وفي حين تم الاعتراف به باعتباره موجزًا ومباشرًا لمهني الرعاية الصحية، فقد أكدت المجموعة أن تصميمه ومحتواه يجعلانه غير قابل للوصول وغير عملي للاستخدام المباشر للمريض. كشف تحليل مقارن للنموذجين عن اختلافات كبيرة في تصميمهما وإمكانية الوصول إليهما وتجربة المستخدم. يوفر النموذج الإلكتروني الذي تم تطويره حديثًا العديد من المزايا مقارنة بالنموذج الورقي المستخدم بالفعل. يُظهر نموذج الإبلاغ الإلكتروني الذي تم تطويره حديثًا صلاحية محتوى ممتازة لكل من الوضوح والملاءمة وفقًا للمؤشرات المحسوبة. **الاستنتاج:** يمكن للنموذج الإلكتروني الذي تم تطويره حديثًا للإبلاغ عن المرضى أن يسهل بشكل كبير الإبلاغ عن الأحداث الضارة الناتجة عن الجراحة. تسلط النتائج الضوء على الإمكانات التي توفرها الأدوات الرقمية لتحسين ليس فقط الممارسة السريرية ولكن أيضًا النتائج التي تركز على المريض في إعدادات الأورام.

الكلمات المفتاحية: الأحداث الضارة للأدوية؛ العلاج الكيميائي؛ علم الأورام؛ نموذج الإبلاغ.