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# A study on user willingness to participate in an adverse drug event information sharing system

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## Abstract

**Background** To prevent the recurrence of Adverse Drug Events (ADEs), particularly drug allergies, it is essential to avoid re-exposure to causative drugs. Awareness of previous ADEs is crucial for patients because they can share accurate information with healthcare providers (HCPs). This study aims to assess users' willingness to share ADE information and evaluate the factors related to this willingness by utilizing a prospective ADE information-sharing system currently under consideration in South Korea.

**Methods** In September 2023, a self-administered questionnaire was collected from a sex-, age-, and regionally stratified nationwide convenience sample of adults recruited through a commercial panel in South Korea. Factors contributing to the willingness to share ADE information and create electronic ADE cards (e-ADE cards) were investigated using multivariate logistic regression analysis.

**Results** Among the 1,000 respondents, 458 (45.8%) were willing to share ADE information, and 521 (52.1%) were willing to create e-ADE cards. The willingness to share personal ADE information and create e-ADE cards was positively associated with the perceived benefits of sharing ADE, trust in HCPs and positive experiences. Notably, older adult patients demonstrated a higher willingness to share information and use e-ADE cards, with rates of 56% and 62%, respectively.

**Conclusions** Our findings indicate that the approach to sharing personal ADE information should be distinct from that of sharing comprehensive health information. Notably, users are likely to willingly disclose their personal information even if they are not anonymized, owing to the significant perceived benefits of sharing. The findings of this study can enhance awareness about sharing personal ADE information and contribute to the successful establishment of an ADE information-sharing system, thereby improving the patient safety environment.

**Keywords** Adverse drug event (ADE), ADE information-sharing system, Patient safety, Healthcare outcomes, Personal health records

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## Background

The World Health Organization defines adverse drug reactions (ADRs) as a noxious and unintended response to a drug that occurs at doses normally used for prophylaxis, diagnosis, or therapy of disease or for modifying physiological function. This represents a significant concern within the healthcare system, affecting patient safety and healthcare outcomes globally [1]. According to the Institute of Medicine report, 2.2 million people experience serious adverse drug reactions each year, and the direct costs associated with ADRs are estimated to be $177.4 billion annually [2]. Recent studies in Europe also reported a significant economic burden associated with ADRs, which increased with the severity of ADRs [3]. Therefore, preventing and managing ADR is an important issue in the healthcare system.

A key strategy for preventing the recurrence of serious ADRs is to avoid re-exposure to the causative drug, particularly for drug allergy prevention. To avoid re-exposure to the causative agents of ADR, patients must be aware of their previous adverse drug reactions, and they should share accurate information with healthcare professionals as a critical preventive measure [4]. In this context, various countries have made diverse efforts to facilitate the sharing of ADR information through allergy passports, drug allergy alert cards, and smart health cards [5–7]. In South Korea, several hospitals issue ADR alert cards to patients who have experienced ADRs to prevent their recurrence [8]. However, a critical weakness of these methods is that providing ADR information becomes difficult if the patient does not carry a card, and the information can be restricted because of the physical space limitations of the card.

Advancements in information technology have facilitated the seamless sharing of health information between medical institutions [9]. The prevailing tool for sharing today is personal health records (PHR), through which individuals manage and share their health information and self-generated health data with other institutions [9, 10]. Information on adverse drug events (ADEs) is necessary for comprehensive healthcare information sharing. As part of the efforts, Fast Healthcare Interoperability Resources, a web-based standard for exchanging, integrating, and sharing healthcare data, includes the "AllergyIntolerance" resource for drug allergies, facilitating rapid and easy exchange of information related to ADEs [11]. Recently, South Korea also introduced a national-level PHR system, with plans to establish a national PHR service (My HealthWay) by 2022 [9, 12]. Efforts are underway to prevent ADEs by sharing information through My Healthway. In addition, the National Drug Utilization Review (DUR) service has been implemented in all healthcare settings, including hospitals and pharmacies, in real-time in Korea [13]. It could serve as an additional route for sharing information about ADEs. Information for some patients who experience severe ADRs is currently being shared through the DUR system. The use of QR codes and/or mobile applications (electronic ADE cards and e-ADE cards) is another effective method for sharing ADE information. These digital solutions provide a convenient and accessible way for patients to share their ADR information, enhancing their ability to prevent ADRs, even when physical cards are not available. By scanning a QR code or using a dedicated application, healthcare providers can quickly access up-to-date allergy information, ensuring more accurate and timely clinical decisions. These approaches improve patient safety and streamline the communication of critical health information across healthcare settings. Notably, Korea is considering introducing a national system to share information on ADEs [14].

Irrespective of the method employed, understanding users' willingness to share information via the system is crucial for establishing a successful system. Furthermore, identifying and considering the factors that influence this willingness can facilitate the successful implementation of the system. Previous studies in Australia, Europe, and Japan have indicated that the digitalization of medical records, patient reluctance, and privacy concerns are significant issues associated with the sharing of personal health data [15–17]. A previous study in the United States indicated hesitance to share digital health information, mainly because of privacy concerns [18]. In Korea, factors such as performance expectancy, social influence, and facilitating conditions are associated with PHR platforms [19]. Additionally, the previous study by Kim et al.. investigated patient willingness to report de-identified ADE data to spontaneous reporting systems such as the Food and Drug Administration Adverse Event Reporting System (FAERS) and the Korea Adverse Event Reporting System (KAERS) that are not ADE information sharing systems [20]. Therefore, this study did not address the direct sharing of identifiable ADE information among healthcare providers. To the best of our knowledge, no studies have evaluated the willingness of patients to share ADE information in Korea despite ongoing efforts to share ADE information. Based on the aforementioned background, this study aims to assess the willingness of South Korean users to share ADE information and evaluate the factors influencing this willingness. The willingness to use e-ADE cards and factors influencing this willingness were also evaluated.

## Methods

### Study design and population

We conducted a cross-sectional study using an online survey to assess current attitudes toward the implementation of an ADE information sharing system. The study population was recruited using a web-based consumer panel from the Panel Marketing Interactive Company, the largest panel in South Korea, with approximately 1.5 million consumers, as detailed in a previous publication [20, 21]. The nationwide convenience consumer panel sample was selected using a stratified sampling method that reflects the sex, age, and regional proportions of the population distribution in South Korea. Age was classified into 10-year bands, and regions were categorized into administrative divisions.

The eligibility criteria for the participants included consumers aged 19 years and older who used medications. Healthcare professionals (HCPs) were excluded, and considering the characteristics of the online panels, individuals over the age of 70 were excluded because of the need for ease of web use. To assess attitudes toward the disclosure of ADE information among consumers frequently exposed to medications, at least 50% of the participants had long-term medication use (more than 3 months). Participants accessed a self-administered questionnaire on their websites. All the participants provided informed consent before participating in the study. Survey data were collected in September 2023. The Institutional Review Board of Seoul National University approved the study protocol (IRB No. 2308/004–004). Our study was conducted in compliance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement (Table S1) [22].

### Questionnaire development

The questionnaire used in this study was developed based on a modified privacy-calculus model [15]. This theoretical model is appropriate for explaining willingness to share information related to privacy issues, such as personal health information. In addition to the privacy concerns, perceived benefits, and risks included in the traditional privacy calculus model, this model incorporats the following factors [15]: (1) privacy concerns: evaluating the impact of potential privacy breaches on trust in the ADE sharing system; (2) perceived benefits: assessing the agreement with the potential benefits of ADE sharing system; (3) perceived risks: assessing the privacy risks of sharing ADE information; (4) personal health concerns: addressing the perceived importance of health risks to individuals; (5) trust in healthcare providers: measuring the mutual trust regarding the confidentiality of ADE information. Each factor was tailored to the context of ADE information sharing.

Moreover, variables influencing the willingness to share personal health information such as prior privacy invasion experiences and perspectives on those invasion, prior positive experience and perspectives on those experience, personal health status, and information sensitivity, were incorporated into this theoretical model [23, 24]. Questions related to prior privacy invasions were based on the premise that negative experiences reduce the willingness to share personal information, while positive experiences enhance it [23, 25, 26]. Additionally, we included assessments of personal health status and information sensitivity while considering that individuals' perceptions of their health and the sensitivity of the information influence their sharing behavior [23, 27, 28]. The information collected as baseline characteristics included sex, age, residential area, monthly income, education level, occupation, medication use, history of ADEs, presence of HCPs among family members, concerns about drug safety, and ADE knowledge [20]. Responses to all items were measured on a 5-point Likert scale ranging from strongly agree (5 points) to strongly disagree (1 point), except for prior positive and negative experiences, which were measured on a binary scale.

#### *Willingness to share ADE information*

The willingness of users to share ADE information was measured on a 5-point Likert scale, with responses ranging from "Strongly Agree", "Agree", "Neutral", "Disagree", to "Strongly Disagree" as adapted from Cherif et al. [15]. Responses of "Strongly Agree" or "Agree" were considered "willing to share", whereas all other responses were considered "not willing to share". The same response structure was applied to the willingness to create electronic ADE cards (e-ADE cards) [15, 29], and this willingness was assessed in the same manner as the willingness to share ADE information.

### Facial validation and pilot test

Face validation was conducted with three HCPs and 12 non-HCPs, with three individuals representing each 10-year age group (20s, 30s, 40s, and 50s and over) to review the clarity, appropriateness, and readability of the questionnaire [30]. Based on the feedback from the face validation, several specific changes were made to improve the questionnaire. These included rephrasing complex medical terminology to make it more understandable to non-HCPs, adjusting the wording of certain questions to reduce ambiguity, and modifying the layout to enhance readability.

Following these adjustments, an additional pilot test was conducted on 65 adult non-HCP users. This pilot test aimed to assess the internal consistency and comprehension of the revised questionnaire. The data collected from the pilot study were not included in the final analysis. Instead, feedback from this pilot test was used to make minor refinements, such as ensuring a consistent interpretation of questions across different demographic groups. The final questionnaire, incorporating all the modifications, is presented in Table S2.

### Sample size

Based on the survey results indicating that 50% of participants had reported a willingness to share emergency room digital data, a sample size of 1,000 subjects was calculated as adequate to detect a difference of 10% with 95% power and 5% α-error (Epi Info™ 7.2.2.6, Centers for Prevention and Control, Atlanta, GA) [31].

### Statistical analysis

Descriptive statistics were used to summarize the baseline characteristics of the respondents and variables related to their willingness to share ADE information. The variables included in the analysis were considered complete data. The survey was programmed to ensure that progress to the next question was impossible without recording a response, thereby ensuring a 0% missing rate for all items and confirming completion of the data.

Internal consistency of the questionnaire was assessed using Cronbach's α coefficient (cutoff criterion ≥ 0.7) [30]. To meet the prerequisites for using Cronbach's alpha as a reliability coefficient, the relevant items were presented on the same Likert scale, and the data were verified to be normally distributed [32]. An exploratory factor analysis was conducted to assess construct validity. The criteria for factor analysis included a Kaiser-Meyer-Olkin measure ≥ 0.7 and a p-value < 0.001 in Bartlett's test of sphericity. The number of factors was determined using a scree plot with eigen values of greater than 1. Items with a loading ≥ 0.4 were considered as the corresponding factors [33, 34].

Predictive factors affecting the willingness to share ADE information and create e-ADE cards were estimated using multivariate logistic regression analysis, with the results presented as odds ratios (ORs) and 95% confidence intervals (CIs). To evaluate multicollinearity, we assessed variance inflation factors (VIFs) before conducting the logistic regression analysis. The VIF values were well within the acceptable limits (<5), thus confirming that multicollinearity was not an issue in our analysis [35].

Sensitivity and subgroup analyses were performed on the respondents with subgroups based on sex, age group, residential area, occupation, educational level, and income. All statistical analyses were performed using SAS version 9.4 (SAS Institute Inc., Cary, N.C., USA), and the statistical significance level was set at $P<0.05$.

**Table 1** Baseline characteristics of respondents. ($N=1{,}000$)

| Characteristics | *N* (%) |
|---|---|
| Sex | |
| Male | 509 (50.9) |
| Female | 491 (49.1) |
| Age, years | |
| mean ± SD | 47.7 ± 13.7 |
| 19 – 39 | 346 (34.6) |
| 40 – 59 | 450 (45.0) |
| 60 – 69 | 204 (20.4) |
| Residential area | |
| Capital | 190 (19.0) |
| Metropolitan cities | 247 (24.7) |
| Provinces | 563 (56.3) |
| Education level | |
| Master's degree or higher | 120 (12.0) |
| College or graduated higher | 699 (69.9) |
| High school diploma or below | 181 (18.1) |
| Occupation | |
| Office job | 572 (57.2) |
| Non-office job | 211 (21.1) |
| Unemployed | 217 (21.7) |
| Income (monthly average) | |
| 1st quartile (lowest) | 78 (7.8) |
| 2nd quartile | 184 (18.4) |
| 3rd quartile | 319 (31.9) |
| 4th quartile (highest) | 419 (41.9) |
| Chronic medication use (≥ 3months) | 526 (52.6) |
| Recent medication use (within the last year) | 780 (78.0) |
| History of adverse drug events | 188 (18.8) |
| Presence of healthcare professionals in the family | 187 (18.7) |

## Results

### Study population and baseline characteristics

A total of 1,000 respondents participated in the study, reaching the target number of respondents. The mean age of the respondents was 47.7 years, and 20.4% were aged ≥ 60 years (Table 1). The study population consisted of 509 males (50.9%) and 491 females (49.1%). Overall, 43.7% resided in capital or metropolitan cities, and over 80% had at least a college education. Among the respondents, 52.6% had experienced long-term medication use, 78.0% had used medication in the previous year, and 18.8% had experienced ADEs.

### Reliability and validity

The items' internal consistency was assessed using Cronbach's alpha (Table 2). Cronbach's α coefficient was above 0.7 for all items except for those for personal health status (0.69). All items were suitable for exploratory factor analysis, satisfying a Kaiser-Meyer-Olkin measure ≥ 0.7 and a p-value ($P<0.001$) in Bartlett's test of sphericity. The factor loadings for these items are listed in Table 2. The results of the factor analysis revealed that all items corresponded to a single factor, explaining a total variance ranging from 52 to 68% (Table 2). Factor analysis also indicated that the lowest eigenvalue was 1.87, with all other variables exceeding 2.5. The scree plot indicates the presence of a single factor.

**Table 2** Internal consistency reliability and factor loading on the items for willingness toward sharing adverse drug events information

| Items | Total correlation coefficient | Factor 1 |
|---|---|---|
| Perceived benefit (0.84) [a] | | |
| BFT1 | 0.65 | 0.80 |
| BFT2 | 0.69 | 0.83 |
| BFT3 | 0.69 | 0.83 |
| BFT4 | 0.69 | 0.83 |
| Eigenvalue | | 2.73 |
| Cumulative variance explained (%) | | 68.23 |
| Trust in healthcare providers (0.85) [a] | | |
| TIHP1 | 0.64 | 0.78 |
| TIHP2 | 0.65 | 0.78 |
| TIHP3 | 0.67 | 0.80 |
| TIHP4 | 0.66 | 0.79 |
| TIHP5 | 0.67 | 0.80 |
| Eigenvalue | | 3.11 |
| Cumulative variance explained (%) | | 62.25 |
| Perceived risk (0.80) [a] | | |
| RK1 | 0.59 | 0.77 |
| RK2 | 0.61 | 0.79 |
| RK3 | 0.63 | 0.81 |
| RK4 | 0.60 | 0.78 |
| Eigenvalue | | 2.49 |
| Cumulative variance explained (%) | | 62.19 |
| Privacy concern (0.90) [a] | | |
| PC1 | 0.70 | 0.80 |
| PC2 | 0.76 | 0.84 |
| PC3 | 0.65 | 0.75 |
| PC4 | 0.76 | 0.84 |
| PC5 | 0.74 | 0.83 |
| PC6 | 0.71 | 0.80 |
| Eigenvalue | | 3.95 |
| Cumulative variance explained (%) | | 65.86 |
| Personal health concerns (0.74) [a] | | |
| PHCHT1 | 0.61 | 0.82 |
| PHCHT2 | 0.63 | 0.83 |
| PHCHT3 | 0.43 | 0.64 |
| PHCHT4 | 0.49 | 0.72 |
| Eigenvalue | | 2.29 |
| Cumulative variance explained (%) | | 57.29 |
| Concerns for drug safety (0.82) [a] | | |
| PHCDE1 | 0.59 | 0.75 |
| PHCDE2 | 0.60 | 0.76 |
| PHCDE3 | 0.71 | 0.84 |
| PHCDE4 | 0.58 | 0.74 |
| PHCDE5 | 0.56 | 0.72 |
| Eigenvalue | | 2.90 |
| Cumulative variance explained (%) | | 57.98 |
| Personal health status (0.69) [a] | | |
| PHS1 | 0.52 | 0.66 |
| PHS2 | 0.56 | 0.77 |
| PHS4 | 0.46 | 0.55 |
| Eigenvalue | | 1.87 |
| Cumulative variance explained (%) | | 62.28 |
| Information sensitivity (0.84) [a] | | |
| IS1 | 0.64 | 0.80 |
| IS2 | 0.69 | 0.83 |
| IS3 | 0.70 | 0.84 |
| IS4 | 0.65 | 0.81 |
| Eigenvalue | | 2.69 |
| Cumulative variance explained (%) | | 67.36 |
| Knowledge of ADEs (0.77) [a] | | |
| ADE_K1 | 0.54 | 0.72 |
| ADE_K2 | 0.57 | 0.75 |
| ADE_K3 | 0.62 | 0.79 |
| ADE_K4 | 0.58 | 0.75 |
| ADE_K5 | 0.44 | 0.61 |
| Eigenvalue | | 2.64 |
| Cumulative variance explained (%) | | 52.87 |

[a] Cronbach's alpha values were presented

The measures for prior positive experience and prior privacy invasion, each consisting of a single item, could not be subjected to Cronbach's alpha reliability analysis or factor analysis

For perspectives on prior privacy invasion and perspectives on prior positive experience, each measured by two items, Cronbach's alpha values were 0.78 and 0.74, respectively; however, factor analysis could not be performed due to the limited number of items

ADEs, Adverse drug events

### Attributing factors for willingness to share adverse drug event information

A total of 458 participants (45.8%) were willing to share ADE information (Table 3). The factors contributing to willingness to share personal ADE information are presented in Table 3. Respondents aged 60 years or older were more likely to share ADE information (adjusted OR [aOR], 1.8; 95% CI, 1.1–2.9). Additionally, perceived benefit (aOR, 7.5; 95% CI, 4.6–12.4), trust in HCPs (aOR, 2.2; 95% CI, 1.5–3.2), and perspectives for prior positive experience (aOR, 2.1; 95% CI, 1.4–3.0) were significantly associated with willingness to share ADE information. Prior privacy invasion (aOR, 2.4; 95% CI, 1.4–4.3), personal health concern (aOR, 1.6; 95% CI, 1.1–2.3), and knowledge of ADE (aOR, 1.4; 95% CI, 1.0–2.0) also significantly increased the sharing willingness.

### Factors contributing to the willingness to create electronic adverse drug event cards

As many as 521 respondents (52.1%) were willing to create an e-ADE card, which was higher than the proportion of respondents willing to share ADE information (Table 4). The factors contributing to willingness to create e-ADE cards are listed in Table 4. Similar to the willingness to share ADE information, the respondents aged 60

**Table 3** Factors associated with the willingness to share personal adverse drug event information

| **Predictors** | **Willing to share ADE information** [a] | | **crude OR (95% CI)** | **aOR** [b] **(95% CI)** |
|---|---|---|---|---|
| | **Yes (*n* = 458)** | **No (*n* = 542)** | | |
| Perceived benefit | 3.9 ± 0.6 | 3.6 ± 0.6 | **22.1 (14.6 – 33.6)** | **7.5 (4.6 – 12.4)** |
| Trust in healthcare providers | 3.5 ± 0.7 | 3.2 ± 0.6 | **8.2 (6.0 – 11.1)** | **2.2 (1.5 – 3.2)** |
| Perceived risk | 3.5 ± 0.7 | 3.5 ± 0.6 | 1.1 (0.9 – 1.3) | 0.7 (0.5 – 1.1) |
| Privacy concern | 3.8 ± 0.7 | 3.7 ± 0.7 | **1.3 (1.1 – 1.6)** | 1.4 (1.0 – 2.1) |
| Personal health concern | 3.7 ± 0.6 | 3.5 ± 0.6 | **3.3 (2.6 – 4.2)** | **1.6 (1.1 – 2.3)** |
| Concerns for drug safety | 3.2 ± 0.7 | 3.1 ± 0.7 | **1.5 (1.3 – 1.8)** | 0.8 (0.6 – 1.1) |
| Information sensitivity | 3.0 ± 0.8 | 3.1 ± 0.7 | 0.8 (0.7 – 1.0) | 1.1 (0.8 – 1.4) |
| Personal health status | 3.0 ± 1.0 | 2.9 ± 0.9 | **1.3 (1.1 – 1.5)** | 1.0 (0.8 – 1.2) |
| Knowledge of ADE | 3.8 ± 0.6 | 3.7 ± 0.6 | **2.7 (2.1 – 3.4)** | **1.4 (1.0 – 2.0)** |
| Prior positive experience | 244 (53.3) | 104 (19.2) | **4.8 (3.6 – 6.4)** | 1.2 (0.8 – 2.0) |
| Perspectives for prior positive experience | 3.4 ± 0.7 | 3.1 ± 0.6 | **5.2 (4.0 – 6.7)** | **2.1 (1.4 – 3.0)** |
| Prior privacy invasion | 77 (16.8) | 45 (8.3) | **2.2 (1.5 – 3.3)** | **2.4 (1.4 – 4.3)** |
| Perspectives for prior privacy invasion | 3.3 ± 0.7 | 3.2 ± 0.7 | **1.3 (1.1 – 1.5)** | 0.8 (0.6 – 1.1) |
| Sex | | | | |
| Female (ref. male) | 210 (45.9) | 281 (51.8) | 0.8 (0.6 – 1.0) | 0.8 (0.5 – 1.1) |
| Age | | | | |
| 60 above (ref. 20–30 s) | 115 (25.1) | 89 (16.4) | **1.9 (1.4 – 2.7)** | **1.8 (1.1 – 2.9)** |
| 40–50 s (ref. 20–30 s) | 204 (44.5) | 246 (45.4) | 1.2 (0.9 – 1.6) | 1.2 (0.8 – 1.8) |
| Residential area | | | | |
| Capital (ref. provinces) | 83 (18.1) | 107 (19.7) | 1.0 (0.7 – 1.3) | 0.8 (0.5 – 1.3) |
| Metropolitan cities (ref. provinces) | 124 (27.1) | 123 (22.7) | 1.3 (0.9 – 1.7) | 1.1 (0.7 – 1.6) |
| Education level | | | | |
| Master's degree or higher (ref. high school diploma or below) | 65 (19.7) | 55 (10.1) | 1.6 (1.0 – 2.5) | 1.0 (0.5 – 2.0) |
| College/university or graduated higher (ref. high school or below) | 315 (22.7) | 384 (70.8) | 1.1 (0.8 – 1.5) | 1.1 (0.7 – 1.8) |
| Occupation | | | | |
| Office job (ref. unemployed) | 268 (58.5) | 304 (56.1) | 1.2 (0.9 – 1.7) | 1.0 (0.6 – 1.6) |
| Non-office job (ref. unemployed) | 99 (21.6) | 112 (20.7) | 1.2 (0.8 – 1.8) | 0.9 (0.5 – 1.5) |
| Income (monthly average) [c] | | | | |
| 1th (lowest) (ref. 4th) | 27 (5.9) | 51 (9.4) | 0.5 (0.3 – 0.8) | 1.0 (0.5 – 2.3) |
| 2th (ref. 4th) | 130 (28.4) | 189 (34.9) | 0.6 (0.5 – 0.9) | 1.0 (0.4 – 2.1) |
| 3th (ref. 4th) | 84 (18.3) | 100 (18.5) | 0.8 (0.6 – 1.1) | 1.2 (0.6 – 2.5) |
| Chronic medication used (≥ 3months) | 263 (57.4) | 263 (48.5) | 1.4 (1.1 – 1.8) | 1.0 (0.7 – 1.4) |
| Recent medication use (within the last year) | 70 (15.3) | 150 (27.7) | 0.5 (0.3 – 0.6) | 0.8 (0.5 – 1.2) |
| History of adverse drug events | 373 (81.4) | 439 (81.0) | 1.0 (0.7 – 1.4) | 1.2 (0.7 – 1.9) |
| Presence of healthcare providers in the family | 374 (81.7) | 439 (81.0) | 1.0 (0.8 – 1.4) | 1.2 (0.8 – 1.9) |

[a] Predictors are presented as mean ± standard deviation, or n (%)

[b] The odds ratios (aOR) were presented as adjusted for all variables listed in the table

[c] Incomes (monthly average) are presented by quartiles. The 1st quartile represents the lowest 25%, and the 4th quartile represents the top 25%

aOR, Adjusted odds ratio; CI, Confidence interval; OR, Odds ratio

years or older were more likely to share ADE information (aOR, 2.2; 95% CI, 1.3–3.8). Perceived benefit (aOR, 11.0; 95% CI, 6.4–18.8), trust in HCPs (aOR, 2.8; 95% CI, 1.9–4.3), and perspectives for prior positive experience (aOR, 2.0; 95% CI, 1.3–3.0) were also significantly associated with the willingness to create e-ADE cards. Moreover, the presence of HCPs (aOR, 1.8; 95% CI, 1.1–2.9) was significantly related to the willingness to create e-ADE cards (Table 4). A total of 372 respondents expressed a willingness to both share ADE information and create e-ADE cards. Consistent with the overall findings, the willingness of these respondents was positively associated with the perceived benefits of ADE sharing, trust in healthcare providers, and previous positive experiences.

## Subgroup analysis

Upon analyzing the willingness to share ADE information and the willingness to create an e-ADE card categorized by subgroups based on sex, age group, residential

**Table 4** Factors associated with the willingness to create electronic adverse drug event cards (e-ADE cards)

| **Predictors** | **Willing to create e –ADE cards** [a] | | **crude OR (95% CI)** | **aOR** [b] **(95% CI)** |
|---|---|---|---|---|
| | **Yes (*n* = 521)** | **No (*n* = 479)** | | |
| Perceived benefit | 4.2 ± 0.4 | 3.5 ± 0.6 | **28.5 (18.4 – 44.4)** | **11.0 (6.4 – 18.8)** |
| Trust in healthcare providers | 3.9 ± 0.6 | 3.2 ± 0.6 | **10.5 (7.6 – 14.5)** | **2.8 (1.9 – 4.3)** |
| Perceived risk | 3.5 ± 0.8 | 3.5 ± 0.6 | 1.0 (0.9 – 1.2) | 0.75 (0.8 – 1.15) |
| Privacy concern | 3.8 ± 0.8 | 3.7 ± 0.7 | **1.3 (1.1 – 1.6)** | 1.27 (0.8 – 2.0) |
| Personal health concern | 3.9 ± 0.6 | 3.5 ± 0.6 | **3.3 (2.6 – 4.2)** | 1.3 (0.9 – 2.0) |
| Concerns for drug safety | 3.4 ± 0.8 | 3.1 ± 0.7 | **1.6 (1.4 – 2.0)** | 1.1 (0.8 – 1.5) |
| Information sensitivity | 3.0 ± 0.8 | 3.1 ± 0.7 | 0.8 (0.7 – 0.9) | 1.0 (0.7 – 1.2) |
| Personal health status | 3.1 ± 1.0 | 2.8 ± 0.9 | **1.4 (1.2 – 1.5)** | 1.0 (0.8 – 1.2) |
| Knowledge of ADE | 3.9 ± 0.5 | 3.7 ± 0.6 | **2.3 (1.8 – 2.8)** | 1.0 (0.7 – 1.37) |
| Prior positive experience | 273 (53.3) | 75 (53.3) | **5.9 (4.4 – 8.0)** | 1.5 (1.0 – 2.4) |
| Perspectives for prior positive experience | 3.7 ± 0.7 | 3.0 ± 0.6 | **6.4 (4.8 – 8.4)** | **2.0 (1.3 – 3.0)** |
| Prior privacy invasion | 79 (16.8) | 43 (16.8) | **1.8 (1.2–2.7)** | 1.1 (0.6 – 2.0) |
| Perspectives for prior privacy invasion | 3.3 ± 0.7 | 3.2 ± 0.7 | **1.4 (1.2 – 1.7)** | 1.0 (0.8 – 1.4) |
| Sex | | | | |
| Female (ref. male) | 236 (45.9) | 255 (45.9) | 0.7 (0.6 – 0.9) | 0.7 (0.5 – 1.0) |
| Age | | | | |
| 60 above (ref. 20–30 s) | 126 (25.1) | 78 (25.1) | 2.1 (1.4 – 2.9) | **2.2 (1.3 – 3.8)** |
| 40–50 s (ref. 20–30 s) | 243 (44.5) | 207 (44.5) | **1.5 (1.1 – 2.0)** | 1.8 (1.2 – 2.7) |
| Residential area | | | | |
| Capital (ref. provinces) | 98 (18.1) | 92 (18.1) | 1.1 (0.8 – 1.5) | 1.0 (0.6 – 1.7) |
| Metropolitan cities (ref. provinces) | 145 (27.1) | 102 (27.1) | **1.5 (1.1 – 2.0)** | 1.4 (0.9 – 2.1) |
| Education level | | | | |
| Master's degree or higher (ref. high school or below) | 74 (14.2) | 46 (14.2) | **2.0 (1.3 – 3.3)** | 1.9 (1.1 – 3.2) |
| College/university or graduated (ref. high school or below) | 367 (68.8) | 332 (68.8) | 1.4 (1.0 – 1.9) | 1.6 (0.8 – 3.4) |
| Occupation | | | | |
| Office job (ref. unemployed) | 309 (58.5) | 263 (58.5) | **1.5 (1.1 – 2.0)** | 1.1 (0.7 – 1.8) |
| Non-office job (ref. unemployed) | 115 (21.6) | 96 (21.6) | 1.5 (1.0 – 2.2) | 1.1 (0.6 – 2.0) |
| Income (monthly average) [c] | | | | |
| 1th (ref. 4th) | 27 (5.9) | 51 (5.9) | **0.4 (0.2 – 0.6)** | 1.6 (0.7 – 3.4) |
| 2th (ref. 4th) | 150 (28.4) | 169 (28.4) | **0.6 (0.5 – 0.8)** | 1.3 (0.5 – 2.8) |
| 3th (ref. 4th) | 98 (18.3) | 86 (18.3) | 0.8 (0.6 – 1.1) | 1.5 (0.7 – 3.2) |
| Chronic medication used (≥ 3months) | 309 (57.4) | 217 (57.4) | **1.8 (1.4 – 2.3)** | 1.4 (0.9 – 2.1) |
| Recent medication use (within the last year) | 82 (15.3) | 138 (15.3) | **0.5 (0.3 – 0.6)** | 0.9 (0.5 – 1.4) |
| History of adverse drug events | 415 (81.4) | 397 (81.4) | 0.8 (0.6 – 1.1) | 0.7 (0.4 – 1.1) |
| Presence of healthcare providers in the family | 432 (81.7) | 381 (81.7) | 1.2 (0.9–1.7) | **1.8 (1.1 – 2.9)** |

[a] Predictors are presented as mean ± standard deviation, or n (%).

[b] The odds ratios (aOR) were presented as adjusted for all variables listed in the table

[c] Incomes (monthly average) are presented by quartiles. The 1st quartile represents the lowest 25%, and the 4th quartile represents the top 25%

ADE, Adverse drug event; aOR, Adjusted odds ratio; CI, Confidence interval; e – ADE cards, Electronic adverse drug event cards; OR, Odds ratio

area, occupation, and income level, the trends were generally similar to those of the total respondents (Fig. S1, Fig. S2).

Regarding the willingness to share ADE information, the subgroup with education levels equal to high school education or below revealed not only perceived benefits and trust in HCPs but also perceived risks (OR, 0.05; 95% CI, 0.01–0.37) and privacy concerns (OR, 24.51; 95% CI, 3.30–181.92) were significantly related, unlike the subgroup with college education or higher levels. Moreover, among non-chronic medication users, unlike chronic medication users, not only perceived benefits and trust in healthcare providers but also personal health concerns (OR, 2.39; 95% CI, 1.28–4.49) and personal ADE concerns (OR, 0.53; 95% CI, 0.62–0.89) significantly influenced the willingness to share (Fig. S1, Table S3).

Furthermore, regarding the willingness to create e-ADE cards, within the subgroup of high school graduates or below, perceived risk (OR, 0.24; 95% CI, 0.07–0.76) was additionally significantly related, unlike the subgroup with college education or higher levels (Fig. S2, Table S4).

## Discussions

In this study, we found that nearly 46% of the participants were willing to share ADE information, and 52% were willing to create e-ADE cards. The willingness to share personal ADE information is driven mainly by the perceived benefits of ADE sharing, trust in HCPs, and positive experiences. Similarly, willingness to create e-ADE cards was positively correlated with the perceived benefits of ADE sharing, trust in HCPs, and positive prior experiences. Notably, older adult patients showed a higher willingness to share information and use e-ADE cards (56% and 62%, respectively). Our study suggests that the approach to sharing personal ADE information differs from sharing comprehensive health information. Importantly, with the considerable perceived benefits of sharing, users will willingly disclose their personal information even if it is not anonymized. To the best of our knowledge, this is the first study to investigate willingness to share personal ADE information.Previous survey studies that investigated the willingness to share personal health information adopted the privacy calculus theory to understand privacy concerns [15, 23, 24]. This theory is considered one of the most practical for analyzing individuals' privacy and information security among information system users [36] and has been widely employed in studies related to privacy disclosure or information sharing [37]. This theory posits that, while individuals may be reluctant to share their health information because of privacy concerns, they will disclose their personal information if the perceived benefits outweigh the perceived risks associated with privacy. Cherif et al. (2021) proposed a modified privacy calculus model by integrating new factors, such as trust in HCPs and personal health concerns, into traditional theory to explain individuals' willingness to share health information [15]. By applying the modified privacy calculus model [15], our study confirmed that several factors that could not be evaluated with traditional privacy calculus models were associated with the willingness to share information on ADEs.

Previous studies focused on willingness to share personal health information reported privacy concerns as a major contributing factor [23]. However, our study determined that privacy concerns did not significantly affect willingness to share ADEs. This finding aligns with those of previous studies in other countries that identified 'trust' as a critical factor for determining attitudes toward sharing of health information [38, 39]. South Korea's centralized healthcare data collection system may have instilled confidence in users regarding privacy protection [40]. A previous study comparing the UK and the US reported that the majority of respondents in the UK, with its socialized single-payer healthcare system, were willing to share data, whereas more than one-third of respondents in the US, with its privatized healthcare system, were reluctant to do so [39]. Given the substantial effect size of perceived benefits and a previous study indicating that privacy concerns can be mitigated by trust in institutions managing health data [41], individuals may still share ADE information if the perceived benefits outweigh the risks and there is trust in healthcare providers. In a similar context, perceived risks were unrelated to willingness to share. This could be attributed to the low perceived risk of privacy invasion among South Korean users, possibly due to the government-led healthcare system, high digitalization of the medical system, and advanced technical security systems [42]. This can be explained by the observation that privacy attitudes and behaviors are deeply influenced by cultural values. Individuals in collectivistic cultures generally place more trust in institutions and are more willing to share personal information, often due to the social or communal benefits that such sharing can provide. Privacy concerns in these cultures may be less pronounced, particularly when sharing information within trusted networks or for collective benefits [43]. For example, during the COVID-19 pandemic, South Korea was able to implement stringent public health measures, including extensive personal data collection for contact tracing, unlike many Western countries [44, 45]. This underscores that the key factors to consider when implementing an information-sharing system may vary depending on the cultural context.

Our study demonstrated that trust in healthcare providers, positive experiences regarding the sharing of health information, perspectives on prior privacy invasion, personal health concerns, and knowledge of ADRs were factors related to the willingness to share ADEs. However, perceived benefits overwhelmingly affected this willingness, and this aligns with the outcomes of previous studies [15]. Contrary to previous studies indicating that individuals become more reluctant to share health information with an increase in privacy-invasion experiences [23, 46], our findings suggest a higher tendency to share ADE information with more prior privacy breaches. This can be explained using the privacy paradox. This exemplifies the typical behavior in which individuals primarily value privacy concerns but paradoxically share their information easily in practice [47, 48]. Despite privacy concerns, individuals often disclose their personal digital information for relatively minor benefits, a phenomenon known as the privacy paradox [47, 48].

Meanwhile, our study revealed that older adults were more inclined to share information about adverse effects than younger adults. This tendency can be attributed to social exchange theory, wherein, for older adults, the benefits of disclosing ADE information, such as receiving valuable assistance, are perceived to be greater than for younger individuals [49, 50]. Older adults may have heightened concerns regarding their health status and thus place greater value on the assistance garnered through sharing health information. Alternatively, in line with the digital health divide, older adults may be less acquainted with online settings, rendering them less apprehensive about online privacy protection or more disposed to share health information online [51].

Our findings demonstrate uniformity in the willingness to create e-ADE cards, with no variation in the trends observed across both primary and subgroup analyses. Perceived benefit, trust in healthcare providers, and perspectives on prior positive experiences were positively correlated with the willingness to create e-ADE cards. However, unlike the willingness to share ADE information, prior privacy invasion was not associated with the willingness to create e-ADE cards. It is difficult to explain the differences in the factors associated with ADE information sharing and e-ADE card creation.

Establishing a governmental system to share individual ADE information can facilitate efficient information sharing. However, ADE information is sensitive and carries potential risks of privacy breaches. Unlike existing DUR, determining the participants' willingness to share information is a prerequisite for system development. This study is significant as it identifies the factors influencing users' willingness to share information. For successful system utilization, implementing measures such as education and promotion of these factors is essential. Thus, our findings can be used to enhance attitudes toward personal ADE information-sharing systems. Promotional efforts could focus on the benefits of sharing ADE information, positive experiences, and trust in HCPs, tailoring the direction of promotions accordingly.

Our study has several limitations that warrant attention. First, the survey was conducted among South Koreans; thus, its findings may not be applicable to other populations. Second, a significant majority of the participants (81.9%) were college graduates or had attained higher levels of education. This is notable because, as of 2020, only 43.4% of South Korea's adult population had achieved similar educational levels [52]. Therefore, result interpretations within the subgroup of high school or below are necessary. This discrepancy suggests that the online survey might have introduced a selection bias, favoring participants with greater internet accessibility. Third, despite aligning with national demographics in terms of sex, age, and region, the sample's representativeness may still be insufficient. Fourth, the recruitment of participants through an online panel inherently excluded individuals without internet access and those aged over 70 years. This decision may limit the generalizability of our findings to older adults who often have distinct medication usage patterns and may be more susceptible to ADEs. However, considering the higher willingness to share ADE information observed among participants in their 60s in our study, we believe that the willingness of older adults aged over 70 years may not differ [49, 51]. Fifth, the exclusion of healthcare professionals from the participant pool may have introduced a bias toward the consumer perspective. While the focus on consumers was intended to gauge their willingness as primary system users directly, the insights of healthcare professionals could provide a more holistic understanding of the system implications across all user groups. To address this limitation, future studies should include a broader demographic range, particularly including healthcare professionals and older adults, and they should use methods suitable for the target population. Sixth, self-administered questionnaires inherently possess limitations such as potential misunderstandings of questions and recall bias that can impact their reliability and validity. To enhance its validity, our questionnaire was designed based on the robust theoretical framework of the modified privacy-calculus model. We also conducted face validation and a pilot test with 65 participants to refine the questions and instructions, thereby minimizing ambiguity and ensuring consistent interpretations by the respondents. Although participants who choose to participate may differ systematically from those who do not [53], self-selection bias is likely to be minimal, as we used a nationwide consumer panel sample familiar with online surveys. Unlike in-person surveys, we could not control the environment in which the online survey was conducted, and this may have affected the reliability of the responses. However, the self-administered format allowed the participants to complete the questionnaire at their own pace, thereby reducing the likelihood of incomplete responses. Respondents were also encouraged to contact the research team for clarification, thus further reducing potential misunderstandings.

## Conclusions

This study offers critical insights into the willingness of South Korean users to share ADE information and to create e-ADE cards. The findings suggest that perceived benefits, trust in healthcare providers, and prior positive experiences significantly influence users' willingness to engage in ADE information sharing and e-ADE card creation. Targeted education and promotion of the benefits of sharing ADE information can enhance the implementation of ADE information-sharing systems.

### Abbreviations

| | |
|---|---|
| ADE | Adverse Drug Event |
| ADR | Adverse Drug Reaction |
| aOR | Adjusted Odds Ratio |
| CI | Confidence Interval |
| DUR | Drug Utilization Review |
| e-ADE card | Electronic Adverse Drug Event card |
| EHR | Electronic Health Record |

| | |
|---|---|
| FAERS | Food and Drug Administration Adverse Event Reporting System |
| HCP | Healthcare Provider |
| KAERS | Korea Adverse Event Reporting System |
| IT | Information Technology |
| OR | Odds Ratio |
| PHR | Personal Health Record |
| STROBE | Strengthening the Reporting of Observational Studies in Epidemiology |
| VIF | Variance Inflation Factor |
| WHO | World Health Organization |

## Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12889-024-20353-8.

Supplementary Material 1

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Not applicable.

### Author contributions

All authors contributed to the conception and design of this study. JS, MGK, and JYL performed the material preparation, data collection, and analysis. SL, YMA, and YMY wrote the first draft of the manuscript, and all authors commented on previous versions. All the authors have read and approved the final version of the manuscript.

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### Data availability

All data generated or analysed during this study are included in this published article and its supplementary information files.

## Declarations

### Ethics approval and consent to participate

This study was approved by the Institutional Review Board of Seoul National University (IRB No. 2308/004–004) and was conducted in compliance with ethical guidelines, including adherence to the Declaration of Helsinki.

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.

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