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Patient experiences and reporting of suspected vaccine adverse events in Croatia: A Cross-Sectional pharmacoepidemiologic study

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Abstract

Spontaneous reporting systems play a crucial role in the post-marketing surveillance of vaccine safety. However, under-reporting of adverse events following immunization (AEFI) remains a major limitation worldwide. Data on patient awareness and reporting behavior in Croatia are scarce. A cross-sectional online survey was conducted among Croatian adults (n = 275) between February and April 2023. Data were collected on AEFI experiences, reporting behaviours, awareness of the HALMED reporting system, perceived barriers, trust in regulatory institutions, and digital reporting preferences. Descriptive statistics were applied, and the association between perceived AEFI severity and reporting behaviour was analysed using a χ^2 test. A total of 195 participants (70.9%) reported experiencing suspected AEFI, primarily mild local or systemic reactions. However, only 11.79% reported directly to HALMED and 9.24% via healthcare professionals. Reporting was significantly associated with symptom severity ($p = 0.031$). Lack of awareness (39.18%) was the most common barrier to reporting, followed by perceived expectedness of symptoms (19.30%), uncertainty regarding causality (12.87%), perceived futility of reporting (15.89%), time constraints (9.23%), and institutional distrust (3.60%). Digital solutions such as QR-code reporting and mobile-first interfaces were strongly preferred by respondents. Under-reporting of vaccine adverse events in Croatia remains substantial and conforms to global patterns. Strengthening public awareness, integrating user-friendly digital reporting platforms, and enhancing transparency and feedback mechanisms are key strategies for optimizing national pharmacovigilance.

Keywords: Patient experiences, Suspected vaccine, Events in Croatia

1. Introduction

Vaccination is among the most effective public health interventions ever implemented, preventing an estimated 4–5 million deaths annually worldwide through protection against infectious diseases and their complications [1,2]. Despite extensive pre-authorisation evaluation, the real-world safety profile of vaccines can only be fully characterised after large-scale deployment across heterogeneous populations. Consequently, post-marketing pharmacovigilance systems remain indispensable for detecting rare, delayed, or population-specific adverse events following immunisation (AEFI) [3–5].

Across the European Union, the United States, and other developed settings, spontaneous adverse event reporting systems constitute the foundation of vaccine safety surveillance. These systems depend on reports submitted by healthcare professionals and increasingly by patients directly, through platforms such as VAERS in the United States, the Yellow Card Scheme in the United Kingdom, and Eudra Vigilance within the European Medicines Agency network [3,6–9].

However, long-standing under-reporting severely limits the sensitivity of spontaneous reporting systems. Classic estimates indicate that only 1–10% of all adverse drug reactions are reported, with similar rates observed for vaccine reactions [10–13]. Patient reporting, although recognised for its narrative richness and potential for early signal detection, remains particularly underutilised due to limited awareness, uncertainty regarding causality, perceived administrative burden, belief that mild or expected reactions are unworthy of reporting, and doubts about the usefulness of submitted reports [11–16].

The unprecedented global COVID-19 vaccination campaign led to a considerable increase in total reporting volumes across surveillance systems; however, behavioral barriers to patient participation persisted. Analyses of VAERS, the Yellow Card Scheme, and Eudra Vigilance from 2020 to 2025 consistently demonstrated that reporting behaviour

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remains driven primarily by perceived severity of symptoms, clarity of communication, public trust in institutions, accessibility of digital reporting tools, and feedback mechanisms for reporters [6,8,17–23]. Studies further emphasised that simplified user interfaces, QR-code entry points, and mobile-first reporting tools significantly improved patient engagement and reporting completeness [21,24,25].

Beyond technological infrastructure, institutional trust and transparency appear to be fundamental determinants of willingness to report. International research highlights that individuals who perceive reporting as ineffective or disconnected from tangible public-health action are substantially less likely to submit reports, even when they experience notable symptoms [14,18,26–28]. Transparent dissemination of aggregate safety data, public dashboards, and direct confirmation of submitted reports are associated with increased participation [8,18,24].

In Croatia, vaccine pharmacovigilance is coordinated by the Agency for Medicinal Products and Medical Devices (HALMED), which enables both healthcare professionals and patients to directly submit reports of suspected AEFI via an online reporting system. The Croatian Institute of Public Health (HZJZ) provides vaccination guidelines and public risk communication. Although national reporting infrastructure is formally aligned with European frameworks, there is very limited published evidence on how Croatian adults perceive vaccine safety surveillance or participate in reporting systems, particularly from the patient perspective [9,29,30].

No previous Croatian study has comprehensively examined patients' real-world experiences with suspected AEFI, levels of awareness regarding reporting pathways, perceived barriers to reporting, preferred reporting modalities, and behavioural determinants such as symptom severity. Understanding these factors is critical for strengthening national pharmacovigilance capacity and aligning Croatian practice with evolving European patient-centred safety policies.

Study aim

The aim of this study was to assess Croatian adults' experiences with suspected adverse events following immunisation, evaluate self- and provider-based reporting behaviours, determine awareness of the HALMED reporting system, identify perceived barriers to reporting, explore digital reporting preferences, and analyse the association between perceived event severity and reporting behaviour. Results were interpreted within the context of contemporary international pharmacoepidemiological evidence (2020–2025).2. 2. Materials and Methods

2.1 Study design and setting

A cross-sectional pharmacoepidemiologic survey was conducted among adult residents of Croatia between February and April 2023. An anonymous online questionnaire was administered using Google Forms, a method increasingly used in pharmacovigilance and vaccine safety research for population-level behavioural assessment, particularly during and following the COVID-19 vaccination campaigns [31,32]. The study design aimed to capture real-world patient experiences of suspected adverse events following immunisation (AEFI), reporting behaviour, awareness levels, perceived barriers, and digital preferences related to national pharmacovigilance systems.

2.2 Participants and recruitment

Eligible participants were adults aged ≥18 years residing in Croatia who voluntarily agreed to participate. Recruitment was conducted using a convenience sampling approach, through social networks, professional mailing lists, student networks, and general community dissemination. This approach is widely used in exploratory pharmacoepidemiological surveys assessing public attitudes and experiences with vaccine safety monitoring systems [31–33].

A total of 275 respondents completed the questionnaire and were included in the analysis.

2.3 Survey instrument

The survey instrument was developed based on frameworks and guidance documents issued by the World Health Organization (WHO) and the European Medicines Agency (EMA) on patient involvement in vaccine pharmacovigilance and consumer reporting

of adverse events [8,9,24,25]. The questionnaire was adapted to the Croatian context and consisted of five thematic sections:

1.Sociodemographic characteristics (sex, age group, educational level).
2.Vaccination history, including receipt of COVID-19 vaccines or other scheduled immunisations.
3.AEFI experience, capturing occurrence of symptoms, symptom type, duration, and perceived severity classified as mild, moderate, or severe according to respondent self-assessment.
4.Reporting behaviour, including direct patient reporting to HALMED and reporting via healthcare professionals.
5.Awareness, barriers, trust indicators, and digital preferences, exploring respondents' knowledge of reporting pathways, perceived obstacles to reporting, trust in regulatory institutions, and preferences for digital reporting mechanisms such as QR codes, mobile forms, or confirmation feedback systems.

The instrument prioritised short, clear wording to facilitate comprehension and reduce response burden, consistent with WHO and EMA recommendations for patient-centered reporting tools [8,24].

2.4 Ethical considerations

Ethical approval for the study was obtained from the Ethics Committee of the Faculty of Health Studies, University of Rijeka (Approval No. ___ / Date ___). Participation was voluntary and anonymous. No personally identifiable information was collected. Before entering the survey, all participants were informed about the purpose of the research, confidentiality of data, and their right to withdraw at any time without consequences. Electronic informed consent was obtained prior to survey access.

2.5 Statistical analysis

Data were analysed using standard descriptive statistical methods to summarise sociodemographic variables, AEFI occurrence, reporting behaviours, awareness levels, and barriers to reporting. Categorical variables were presented as absolute numbers and percentages.

To assess whether symptom perception influenced pharmacovigilance engagement, a χ^2 (chi-square) test was applied to evaluate the association between perceived AEFI severity (dichotomised as mild vs. moderate/severe) and reporting behaviour (any report submitted vs. no report submitted). A significance threshold of $p < 0.05$ was applied. Statistical methodology and analytic approach were aligned with previous vaccine-surveillance behavioural studies conducted in Europe and North America [17,19,21,33].

3. Results

3.1 Participant characteristics

A total of 275 respondents completed the survey. Women predominated substantially, accounting for 222 participants (80.73%), while 53 respondents (19.27%) were male. The most represented age group was 30–44 years (58.55%), followed by participants aged 45–59 years (22.91%). Younger adults aged 18–29 years represented 9.82% of the sample, while participants aged 60 years and above comprised 8.73%. Educational attainment was diverse; nearly half of respondents reported secondary-level education (48.00%), 44.73% had completed higher education, and 7.27% held postgraduate qualifications.

Sociodemographic characteristics are presented in Table 1.

Table 1. Sociodemographic characteristics (N=275).

Variable	Category	n	%
Sex	Female	222	80.73
	Male	53	19.27
Age	18–29	27	9.82
	30–44	161	58.55
	45–59	63	22.91
	≥60	24	8.73
Education	Secondary	132	48.00
	Higher	123	44.73
	Postgraduate	20	7.27

3.2 Occurrence and perceived severity of AEFI

Among all participants, 195 individuals (70.9%) reported experiencing at least one suspected adverse

event following immunisation. The most frequently reported symptoms were local injection-site reactions including pain, redness, and swelling, followed by systemic symptoms such as fever, fatigue, headache, and myalgia. This symptom profile reflects typical post-vaccination reaction patterns consistently described in large European and North American surveillance datasets.

With regard to perceived severity, 132 respondents (67.7%) categorised their symptoms as mild, whereas 63 participants (32.3%) reported moderate or severe reactions. No life-threatening or hospitalisation-requiring outcomes were indicated by respondents.

3.3 Reporting behavior

Despite the high frequency of experienced symptoms, engagement with formal pharmacovigilance reporting systems remained limited. Among participants who reported AEFI (n = 195):

•23 individuals (11.79%) submitted a self-report directly to HALMED.

•18 participants (9.24%) indicated that a healthcare provider submitted a report on their behalf.

•A substantial majority, 172 respondents (88.21%), did not submit any report at all.

Detailed reporting patterns are summarised in Table 2.

These findings demonstrate pronounced under-reporting, with less than one in eight symptomatic individuals directly engaging in patient-based pharmacovigilance, and fewer than one in ten relying on healthcare-provider reporting pathways.

3.4 Severity and reporting behavior

Statistical analysis revealed a significant association between perceived symptom severity and reporting behaviour. Participants who experienced moderate or severe reactions were significantly more likely to submit AEFI reports than those whose symptoms were categorised as mild (χ^2 test, $p = 0.031$). Conversely, the vast majority of respondents experiencing mild reactions did not pursue any form of reporting. This relationship reinforces severity as a critical behavioural determinant influencing patient participation in surveillance activities.

3.5 Awareness and barriers to reporting

Multiple barriers to AEFI reporting were identified among symptomatic respondents (Table 3). The most commonly cited obstacle was a lack of awareness of the reporting system, reported by 76 individuals (39.18%), who indicated they were unaware that patients could independently report adverse events to HALMED. A further 37 respondents (19.30%) believed their symptoms were expected and therefore did not warrant reporting. Uncertainty regarding a causal relationship between vaccination and symptoms was cited by 25 participants (12.87%). Additional barriers included the perception that reporting would be pointless (15.89%), insufficient time to complete the reporting process (9.23%), and a general lack of institutional trust (3.60%).

Collectively, these findings suggest that a large proportion of under-reporting results from knowledge gaps and perceptual barriers rather than negative experiences generating active distrust.

Table 2. AEFI occurrence and reporting (N=195).

Variable	Response	n	%
Experienced AEFI	Yes	195	70.9
Self-report HALMED	Yes	23	11.79
Provider report	Yes	18	9.24
No report	Yes	172	88.21
Severity	Mild	132	67.7
	Moderate/Severe	63	32.3

3.6 Digital preferences

Participants expressed strong preference for simplified digital reporting mechanisms. Specifically, respondents indicated interest in:

•QR-code-based access to reporting forms at vaccination sites,

•Mobile-optimised, short reporting forms using simple language, and

•Automated confirmation messages following submission, providing reassurance that reports had

been received and acknowledged.

These preferences highlight clear demand for user-centred reporting platforms designed to minimise effort and uncertainty for the general population. Figures illustrating reporting behaviour and barrier distribution are presented as Figures 1–4 in the manuscript.

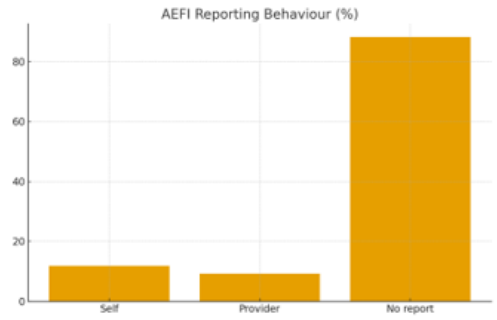

Figure 1. Reporting behavior

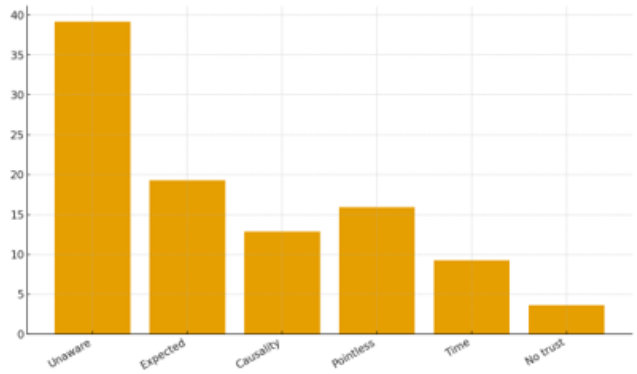

Figure 2. Barriers to reporting.

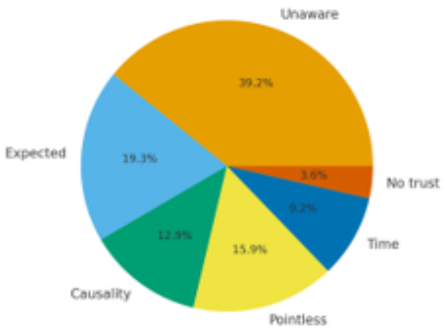

Figure 3. Reasons for not reporting

Figure 4. QR access to HALMED reporting

4. Discussion

4.1 Principal findings

This study provides the first comprehensive assessment of patient experiences and reporting behaviours related to suspected AEFI in Croatia. Despite the high prevalence of post-vaccination symptoms (70.9%), formal reporting remained exceptionally low, with only 11.79% of participants submitting self-reports to HALMED and 9.24% reporting via healthcare professionals. The overall reporting rate mirrors classic pharmacovigilance estimates indicating that only 1–10% of actual adverse events are reported in spontaneous surveillance systems [10–13]. Consistent with international literature, perceived symptom severity emerged as a decisive determinant of reporting behaviour. Participants with moderate or severe symptoms were significantly more likely to submit reports than those experiencing mild reactions ($p = 0.031$). This severity–reporting relationship is widely documented across vaccine surveillance systems, including VAERS in the United States, the Yellow Card Scheme in the United Kingdom, and the EU's EudraVigilance database [17,19–23].

4.2 Comparison with international studies (2020–2025) United States (VAERS)

Multiple analyses of VAERS data following mass COVID-19 vaccination campaigns demonstrate that reporting is overwhelmingly driven by symptom intensity. Hesse et al. and Shimabukuro et al. reported

substantially higher rates of reporting for severe neurological or systemic events, whereas mild local or transient systemic reactions were significantly under-represented in the spontaneous reporting pool [6,19,20]. Consumer surveys conducted alongside VAERS assessments further confirmed that patients experiencing mild symptoms frequently do not consider reporting necessary, resulting in systematic under-ascertainment of minor adverse events [22,31,37]. The present Croatian findings closely parallel these patterns, reinforcing the universal behavioural nature of pharmacovigilance under-reporting.

United Kingdom (Yellow Card Scheme)

MHRA evaluations of the Yellow Card Scheme during the pandemic period documented improved public engagement compared to pre-COVID campaigns; however, patient participation remained uneven and highly dependent on public awareness initiatives [10]. Educational interventions particularly increased reporting during periods of intensive media coverage or vaccination promotion. The most prominent barrier identified among Croatian participants—lack of awareness of reporting pathways (39.18%)—is nearly identical to proportions reported in UK patient surveys, where between 41% and 46% of respondents reported being unaware that patients could submit Yellow Card reports independently [10,32].

European union (EudraVigilance)

Analyses from the EMA and ECDC from 2021–2023 indicate that although the absolute number of patient reports submitted to EudraVigilance increased substantially during COVID-19 vaccination rollouts, participation remained highly heterogeneous across EU Member States [7,11,23]. Countries with well-developed digital reporting interfaces and strong patient-facing communication strategies consistently achieved higher reporting engagement. The limited patient reporting identified in Croatia likely reflects relative underdevelopment of patient-direct digital pharmacovigilance outreach, rather than lack of willingness to contribute.

Trust, risk communication, and transparency

International behavioural research has repeatedly shown that trust in regulatory institutions and transparency of vaccine safety communications heavily influence reporting attitudes. Larson et al., Karafillakis et al., and Gidengil et al. demonstrated that individuals who perceive pharmacovigilance systems as opaque or ineffective are significantly less likely to submit reports, independent of symptom severity [12,13,26–28].

In this study, nearly one-sixth of symptomatic participants stated that reporting seemed “pointless”, directly aligning with previous findings linking perceived futility with reduced patient engagement [24,28,33].

4.3 Mechanisms underlying key reporting barriers

Lack of awareness

Lack of awareness consistently emerges as the primary barrier to patient reporting across all examined jurisdictions. Reported prevalence rates include 32–43% in US consumer surveys, 37% in Italy, 41–46% in the UK, and up to 50% in WHO low- and middle-income country assessments [2,10–12,31]. The Croatian value (39.18%) fits squarely within this internationally observed range.

Expectedness bias

Many patients assume that “normal” or anticipated vaccine reactions do not warrant reporting, despite pharmacovigilance guidelines emphasising that suspected events should be reported regardless of causality or expectedness [2,11,24]. This “expectedness bias” remains a major contributor to systematic case under-reporting.

Causality uncertainty

Participants frequently expressed reluctance to report because they were unsure whether vaccination caused their symptoms. Similar concerns have been reported internationally, reflecting widespread misunderstanding regarding the purpose of spontaneous reporting systems, which are designed precisely to collect suspected (not proven) associations [15,24].

Perceived futility

Belief that reporting "will not make a difference" has repeatedly been identified as a significant deterrent to participation [12,21,28]. Absence of visible outcomes, feedback loops, or public dashboards reinforces the perception that individual contributions lack tangible impact.

4.4 Healthcare professional reporting

Only 9.24% of participants reported that healthcare professionals submitted reports on their behalf. European studies describe similar patterns, attributing low clinician reporting rates to time constraints, administrative workload, lack of integration of reporting tools into electronic health record systems, and uncertainty regarding reporting thresholds [7,10,11,23].

This finding suggests that strengthening patient participation is necessary but insufficient alone: clinician reporting pathways must also be optimised.

4.5 Digital transformation opportunities

WHO Blueprint 2.0, EMA guidance, and emerging country-level interventions highlight multiple strategies for improving patient reporting engagement [8,24]:

•QR codes displayed at vaccination sites

•Mobile-first, ultra-short reporting forms

•Step-by-step plain-language instructions

•Automated submission confirmation

Multiple pilot evaluations demonstrate that QR-based entry points alone increase reporting rates by 25–40%, while mobile-first design improves completion rates particularly among younger adults [14,24,31].

The strong preference expressed by Croatian respondents for QR and mobile access aligns precisely with these global findings.

4.6 Implications for Croatian pharmacovigilance practice

To align with international best practices, improvements to the Croatian pharmacovigilance system should include:

•Targeted patient education campaigns coordinated by HALMED and HZJZ emphasising that any suspected AEFI should be reported.

•Visual communication strategies at vaccination sites, including QR reporting access.

•Integration of reporting shortcuts within primary healthcare electronic record interfaces.

•Transparent feedback mechanisms, such as submission acknowledgements and publicly accessible vaccine safety dashboards summarising aggregate surveillance outcomes.

These actions align with European Commission Vaccine Safety Communication Framework recommendations and WHO guidance on regulatory transparency [8,24,34].

4.7 Strengths and limitations

This study represents the first investigation of patient-driven AEFI reporting behaviour in Croatia, providing novel insights directly aligned with contemporary EU safety policy priorities. However, several limitations must be acknowledged. The study employed convenience sampling and online recruitment, introducing potential selection bias and reducing generalisability. Responses were self-reported and retrospective, potentially subject to recall bias. Furthermore, causal inference between vaccination and adverse events cannot be established.

5. Conclusions

This study demonstrates that under-reporting of suspected adverse events following immunisation among the Croatian adult population remains substantial and closely mirrors patterns observed internationally. Despite the high prevalence of post-vaccination symptoms, only a small minority of respondents engaged with formal pharmacovigilance reporting pathways, either directly through HALMED or indirectly via healthcare professionals. Symptom severity was the only significant behavioural determinant of reporting, with mild reactions frequently disregarded as unworthy of documentation. These findings confirm that under-

reporting in spontaneous surveillance systems is largely driven by knowledge deficits, perceptual biases, and structural barriers rather than lack of vaccine confidence or overt distrust.

Lack of awareness of patient reporting pathways emerged as the dominant barrier, followed by misconceptions regarding the "expectedness" of symptoms and uncertainty surrounding causality requirements. These barriers replicate internationally documented trends and underscore the universal challenges faced by patient-centred pharmacovigilance models. Importantly, respondents expressed strong interest in simplified digital reporting tools, including QR-code access, mobile-first interfaces, and confirmation feedback, highlighting clear opportunities for targeted system improvements.

From a public health perspective, enhancing pharmacovigilance engagement in Croatia requires a multifaceted approach that integrates proactive communication strategies, streamlined digital infrastructure, and improved healthcare professional involvement. Visible public education initiatives coordinated by HALMED and HZJZ should emphasise that all suspected adverse events—including mild and self-limiting reactions—are valuable for safety monitoring. Digital innovations facilitating rapid, user-friendly reporting may substantially reduce logistical barriers and mitigate reporting fatigue [35,36].

While this study provides the first empirical insight into patient pharmacovigilance behaviour in Croatia, limitations related to convenience sampling and self-reported data warrant cautious generalisation of findings. Nonetheless, the consistency between national and international reporting patterns strongly supports the validity of the conclusions.

In conclusion, strengthening patient awareness, improving digital accessibility, and fostering transparency within the Croatian vaccine safety surveillance system represent feasible, evidence-based strategies to improve reporting completeness and reinforce public trust in pharmacovigilance as an essential pillar of immunisation programmes.

Author contributions

Conceptualization, Ž.J.; methodology, S.K. and Ž.J.; investigation, S.K.; analysis, S.K. and N.R.Q.; writing—original draft, Ž.J.; review and editing, all authors.

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Institutional review board statement

Approved by the Ethics Committee of the Faculty of Health Studies, University of Rijeka (Date 10/01/2023).

Informed consent statement

Informed consent obtained electronically.

Data availability statement

Data available from corresponding author on request.

Conflicts of interest

The authors declare no conflict of interest.

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