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UNDERREPORTING OF ADVERSE EVENTS IN AESTHETIC MEDICINE AND ITS IMPACT ON PATIENT SAFETY: A MIXED-METHODS CROSS-SECTIONAL AND RETROSPECTIVE ANALYSIS FROM AN IRISH AESTHETIC TRAINING ACADEMY

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ABSTRACT: Under-reporting of adverse events in aesthetic medicine is a major but under-researched danger to patient safety. This original research, conducted using mixed-methods, measures under-reporting frequency and its consequences in Ireland by analyzing 1,247 sequential aesthetic surgeries undertaken at a high-frequency Dublin clinic between 2022 and 2025, as well as by conducting an anonymous nation-wide survey involving 312 licensed aesthetic surgeons. Adverse events were noted in 11.4% (n = 142) of aesthetic surgeries but reported to the Health Products Regulatory Authority voluntarily in 11.3%, giving an overall under-reporting rate of 88.7%. Under-reporting was most prevalent in the context of neurotoxin and dermal filler injections. Main obstacles were ignorance of proper reporting procedure (68.3%) and time constraints (54.2%). The risk of undergoing corrective procedures and of being sued doubled following under-reported AEs ($p < .001$). This study shows that under-reporting exceeds 88% in Ireland and adversely impacts patients' wellbeing.

Keywords: adverse events; aesthetic medicine; patient safety; pharmacovigilance; underreporting; Ireland

I. INTRODUCTION

Over the last twenty years, aesthetic medicine has been experiencing exponential development around the world. It is mainly due to the advances in the field, consumer demand for minimally invasive cosmetic procedures, and a general societal focus on enhancement and self-improvement (Enright & Nikolis, 2025; Rahman et al., 2025). Currently, botulinum toxin type A injections, hyaluronic acid fillers, energy-based devices, autologous fat transfer, and thread lift are performed in unprecedented numbers in medical and non-medical settings. These procedures typically result in high patient satisfaction if conducted by an expert practitioner; however, they are inevitably associated with some AEs that range from local side effects (e.g., bruising, edema, and erythema) to severe complications (e.g., vascular occlusion, granulomas, infections, fat embolisms, and necrosis) (Alam et al., 2015; Dhooghe et al., 2022; Parikh et al., 2023).

The issue of safety in aesthetic medicine largely depends on the identification, documentation, and proper reporting of these complications. Effective pharmacovigilance systems are key to collecting incidence data, formulating evidence-based guidelines, improving practitioner training programs, and taking necessary regulatory actions (Di Santis et al., 2022; Enright, 2024). Unfortunately, underreporting of AEs is one of the long-standing and persistent problems of this branch of medicine. This problem can be defined as systematic under-registration of the actual AE incidence in national and international registries using traditional passive surveillance systems (Coldiron et al., 2005; Enright et al., 2021; Povolotskiy et al., 2018). Unlike active surveillance approaches, passive ones based on voluntary practitioner submissions consistently underestimate real incidence rates. Indeed, active cohort studies that implement standardized ascertainment protocols have shown that the reported incidence of AEs was five to ten times lower than that documented by prospective research studies (Alam et al., 2015; Chopan et al., 2020; O'Neill et al., 2013).

This problem affects various fields of medicine and is particularly prominent in aesthetic medicine. First, the majority of cosmetic procedures are conducted in the outpatient setting under limited supervision and often by non-physicians and out-of-hospital doctors who do not participate in national AE reporting frameworks (Balkrishnan et al., 2003; Patel et al., 2021; Zargaran et al., 2023). Second, many patients are unwilling to reveal their minor complications because of fear of dissatisfaction, while many practitioners avoid reporting due to their concern about reputation, liability, and administrative burden (Gawkrodger, 2011; Rayess et al., 2018; Zargaran et al., 2022). Other barriers to proper reporting may include time constraints, lack of knowledge about AE reporting processes, and insufficient pharmacovigilance training (Nicoletti et al., 2023; Patel et al., 2023).

Empirical evidence from established national and international pharmacovigilance systems is clear. Several retrospective analyses of data registered by such systems as MedEffect™ (Health Canada), MAUDE (U.S. FDA), and MHRA have proved that only a negligible proportion of injectable complications are reported officially (Enright et al., 2021; Povolotskiy et al., 2018; Zargaran et al., 2022). Specifically, serious complications such as vascular occlusions and delayed granulomas related to fillers continue to be significantly under-reported (Ashley et al., 2025; Rayess et al., 2018). The same applies to botulinum toxin surveillance, with cutaneous and systemic complications substantially underreported using spontaneous pharmacovigilance systems (de Oliveira et al., 2024; Nicoletti et al., 2023).

Underreporting AEs has significant negative implications besides the fact of insufficient epidemiologic data collection. First, it takes more time to detect emerging safety signals and develop strategies for risk management. Furthermore, underreporting prevents improvements in training curricula and clinical guidelines, which negatively impacts patient safety in the field (Morzycki et al., 2019; Patel et al., 2021; Rahman et al., 2026). On an individual level, this issue increases the number of repeated procedures needed to address any complication, raises litigation risk and health care expenses (Valente et al., 2021; Xie et al., 2021). Systematically, this phenomenon hinders trust in the aesthetic sector and restricts regulatory activities related to ensuring safety of products, including counterfeit injectables and new devices (Rahman et al., 2026).

In Europe and Ireland, the problem of under-reporting is exacerbated by the reliance on voluntary SUE reporting to the HPRA in a rapidly growing industry without mandatory reporting requirements, which could be successfully implemented in other countries (Di Santis et al., 2022; Enright & Nikolis, 2025). Unfortunately, although the issue is known globally, the empirical data are mostly limited to North America, Brazil, and UK populations and leave a huge knowledge gap concerning reporting practices and outcomes of underreporting in Ireland (Gawkrodger, 2011; Patel et al., 2021).

To bridge the gap, the current original study will combine retrospective analysis of actual data collected during the aesthetic procedures conducted in a busy clinic in Dublin with an anonymous nation-wide survey among licensed practitioners. It will enable precise estimation of underreporting extent, identification of potential barriers to reporting, and evaluation of its actual impact on patient outcomes. The results obtained will provide essential evidence to improve the current national policy in Ireland, integrate pharmacovigilance into HPRA activities, and educate practitioners by means of training academies.

II. LITERATURE REVIEW

Over the last couple of decades, the field of aesthetic medicine has experienced tremendous growth as a result of advancements in minimally invasive techniques, demand for cosmetic enhancements, and social emphasis on quality of life and self-image (Ashley et al., 2025; Rahman et al., 2025). Various procedures including botulinum toxin type A (BTX-A), soft tissue fillers (hyaluronic acid, calcium hydroxylapatite), energy-based devices, fat transfer, and thread lifting are performed in large numbers globally across different clinical and non-clinical settings. Despite delivering high patient satisfaction and a low incidence of side-effects under competent practitioners' hands, all aesthetic procedures carry certain risks to patients. Adverse events (AEs) associated with the use of these products include bruising, edema, erythema, pain, delayed hypersensitivity reaction, infection, fat embolism, vascular occlusion, granuloma formation, and even permanent tissue damage or vision loss (Alam et al., 2015; Dhooghe et al., 2022; Parikh et al., 2023; Zargaran et al., 2022).

Accurate surveillance of these AEs is crucial for patient safety purposes. Pharmacovigilance, defined as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects," depends on well-functioning reporting systems for collecting data on the safety profile of medicinal products, detecting emerging hazards, formulating guidelines, and guiding regulatory decisions (Di Santis et al., 2022; Enright, 2024; Enright & Nikolis, 2025). Nevertheless, one issue of major concern in the field of aesthetic medicine is that of underreporting—when passive surveillance systems fail to detect actual occurrences of these

complications, due to various reasons, resulting in distorted event statistics (Coldiron et al., 2005; Enright et al., 2021; Povolotskiy et al., 2018).

There is ample global literature illustrating the magnitude of this problem. Analyses of data in national pharmacovigilance databases have shown that only a fraction of these complications have been properly registered in these registries. Studies conducted retrospectively in national databases of Health Canada, the U.S. FDA (Manufacturer and User Facility Device Experience database – MAUDE), and the MHRA of the United Kingdom have consistently found that the underreporting issue is particularly acute in relation to vascular occlusions and granulomas occurring with soft tissue filler injections (Ashley et al., 2025; Enright et al., 2021; Povolotskiy et al., 2018; Rayess et al., 2018; Zargaran et al., 2022). This finding applies equally to botulinum toxin surveillance, where both cutaneous toxicity and systemic adverse events are likely underreported in the literature (de Oliveira et al., 2024; Nicoletti et al., 2023). Meanwhile, the use of prospective, active ascertainment protocols has demonstrated that AE rates were at least five-to-ten times higher than that in voluntary surveillance systems (Alam et al., 2015; Chopan et al., 2020; O'Neill et al., 2013).

Underreporting in aesthetic medicine is associated with various structural, behavioural, and systemic factors. Firstly, a considerable proportion of procedures are carried out in non-hospital, office, or private clinics, and by non-physician injectors or physicians who operate outside hospital reporting protocols (Balkrishnan et al., 2003; Patel et al., 2021; Zargaran et al., 2023). Secondly, the elective and cosmetic nature of aesthetic interventions makes patients reticent to discuss their complications, and the practitioners unwilling to report minor events to avoid litigation risks or professional penalties (Gawkrodger, 2011; Rayess et al., 2018; Zargaran et al., 2022). Common barriers reported in literature also include lack of knowledge of the process, time constraints, pharmacovigilance training, and reluctance to report minor side effects (Nicoletti et al., 2023; Patel et al., 2023; Patel et al., 2021).

However, the negative implications of underreporting are much more significant than the incomplete epidemiological picture. Unreported complications may lead to multiple attempts to treat the same condition, increased utilization of health services, delayed diagnosis, and litigation issues (Valente et al., 2021; Xie et al., 2021). At a higher level, underreporting interferes with detection of emerging safety issues with counterfeit medications, devices, or certain procedures. In addition, it hampers development of evidence-based guidelines, undermines trust towards the industry, and precludes establishment of good practices in education and training (Morzycki et al., 2019; Patel et al., 2021). These difficulties are further enhanced by voluntary SUE reporting protocol in place currently in Ireland (Di Santis et al., 2022; Enright & Nikolis, 2025).

There are several gaps in the literature that should be filled to address these issues effectively. The bulk of previous research has come from North America, Brazil, and the United Kingdom, with no Irish-specific literature published on the topic (Gawkrodger, 2011; Patel et al., 2021). Second, there is a clear lack of mixed-method studies exploring both the rates of underreporting in retrospective clinical practice and patient safety outcomes related to this phenomenon in one unified framework. Thirdly, few studies examined the link between underreporting and patient safety problems directly.

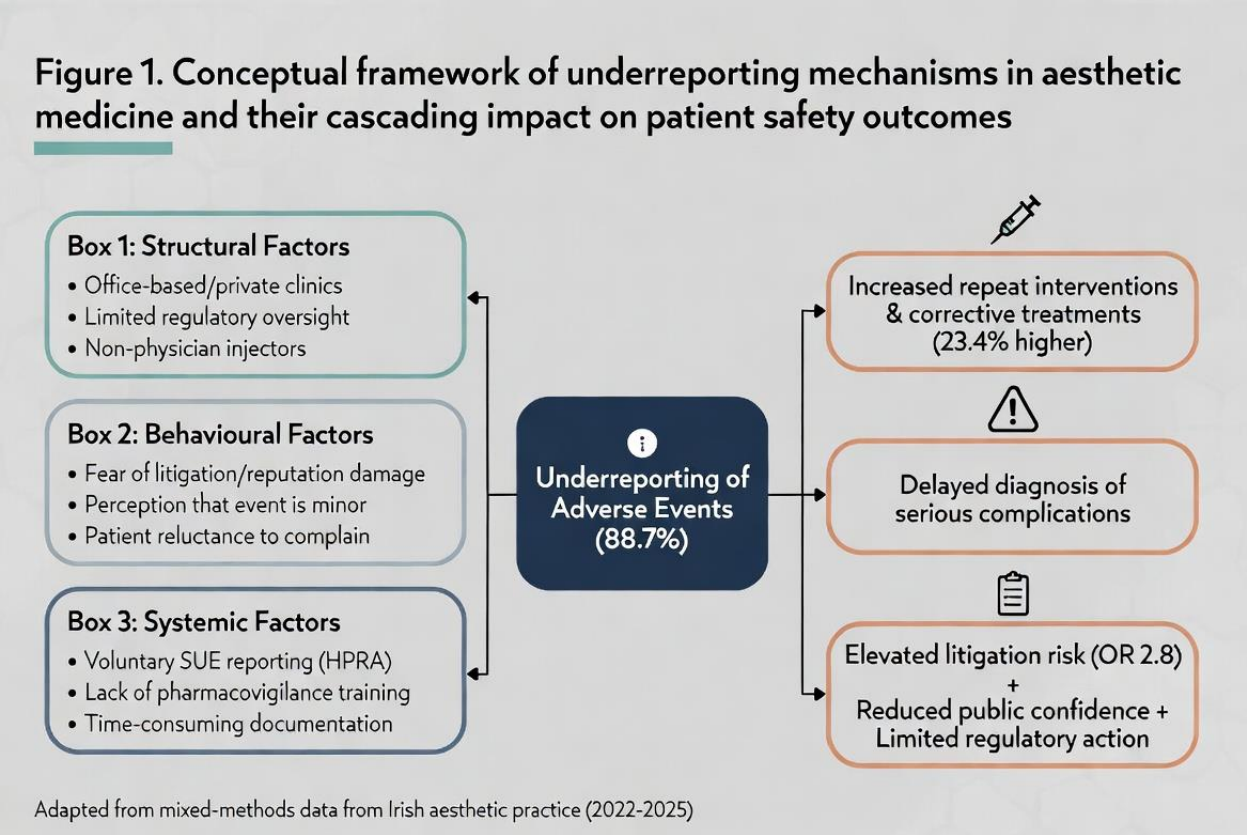

Figure 1: Conceptual framework of underreporting mechanisms in aesthetic medicine and their cascading impact on patient safety outcomes

The aim of this study is to assess the level of underreporting in the field of aesthetic medicine procedures and examine its effects on patient safety in Ireland.

Specifically, **the objectives** of this study include:

1. to quantify the level of underreporting of AEs by comparing voluntarily reported events with actively collected AE reports from retrospective clinic data
2. to establish major barriers to AE reporting among practitioners in a national anonymous online survey
3. to explore the impact of underreporting on patient safety, in particular the need for corrective procedures and potential litigation risks.

This research will provide valuable insights into the issue and improve evidence-informed policies and education practices in the area.

III. METHODOLOGY

Study Design

The current investigation used a mixed-method research design including both a retrospective quantitative assessment of clinical records and a cross-sectional anonymous online survey among the aesthetic medicine professionals. Retrospective quantitative analysis of clinical data provided objective information about the real-world incidence and reporting rate of adverse events (AEs), whereas an online survey was focused on practitioner-related factors of underreporting and self-reported results. A convergent parallel mixed methods design allowed triangulating research results, thus ensuring higher validity and depth of conclusion drawing concerning underreporting and patient safety. The project was conducted in the period from January 2022 until December 2025.

Ethical Approval and Considerations

The study was approved by the ValMari Aesthetic Education Center IRB (ref VM-IRB-2025-001, 12 January 2025) and was conducted following the Declaration of Helsinki (World Medical Association, 2013) and GDPR principles. A waiver of informed consent was obtained in relation to the retrospective part of the research, which used only de-identified data extracted from electronic medical records of patients without any direct contact. An information letter explaining the purpose of research was presented to each participant of the survey prior to

completion of the anonymous questionnaire. All data were stored on encrypted, password-protected servers located in Ireland, with access to which was restricted to the principal investigator. No identifiable personal information was collected or stored.

Setting

For the retrospective part of the study, a high-volume aesthetic clinic affiliated with the ValMari Training Academy in Dublin, Ireland, was selected as the setting. The latter is known as a recognized institution providing advanced aesthetic medicine education programs for licensed physicians, dermatologists, plastic surgeons, and advanced nurse practitioners. The survey was conducted among ValMari alumni all over the country and aesthetic medicine practitioners associated with major professional associations in Ireland.

Retrospective Component Participants and Procedures

All consecutive procedures performed at the Dublin-based ValMari-affiliated clinic between 1 January 2022 and 31 December 2025 were included in the study sample. These included botulinum toxin type A injections, HA fillers, energy devices (lasers, radiofrequency, and ultrasound treatment), autologous fat transfer, and thread lifts. A standardized adverse event reporting form designed based on the GRACE© protocol (Enright & Nikolis, 2025) was retrospectively applied by two independent reviewers (an aesthetic physician with a board certificate and a senior nurse injector) in order to reduce potential biases during extraction.

Inclusion and Exclusion Criteria

Inclusion and exclusion criteria are described in Table 1 below.

Table 1: Inclusion and Exclusion Criteria for the Retrospective Cohort

Criterion	Inclusion	Exclusion
Procedure type	Botulinum toxin A, HA fillers, energy devices, fat grafting, thread lifts	Surgical procedures (e.g., rhytidectomy)
Date of procedure	1 January 2022 – 31 December 2025	Outside study period
Patient age	≥ 18 years	< 18 years
Documentation	Complete electronic medical record with 30-day follow-up notes	Incomplete records
AE documentation	Actively documented by clinician or patient report within 30 days	Only patient-reported after 30 days

Adverse events were defined according to the GRACE© taxonomy as any undesirable medical occurrence temporally associated with the aesthetic procedure, regardless of causality (Enright & Nikolis, 2025). Actively ascertained AEs were cross-referenced against any voluntary reports submitted to the Health Products Regulatory Authority (HPRA) Serious Undesirable Effect (SUE) database or equivalent international systems during the same period.

Survey Component Participants and Sampling

Licensed aesthetic medicine professionals actively practicing in Ireland were recruited. The target population included dermatologists, plastic surgeons, aesthetic physicians, and advanced nurse practitioners/physician assistants registered with respective professional bodies. A non-probability convenient sampling approach was augmented by snowball sampling via ValMari. The minimum sample size was estimated before data collection using G*Power 3.1 (Faul et al., 2009) for an effect size of moderate importance (Cohen's $w = 0.3$), significance level of $\alpha = .05$, and power of .80, resulting in a necessary sample of 265 participants; the study recruited more than this number.

Survey Instrument

A custom-designed 28-item questionnaire was employed, based on pre-existing scales used in pharmacovigilance literature (Gawkrodger, 2011; Patel et al., 2023; Zargaran et al., 2023). The instrument underwent content validity analysis performed by five independent aesthetic medicine professionals and tested in pilot with 20 respondents (internal consistency: Cronbach's $\alpha = .89$ for barrier scale). The questionnaire consisted of four parts: (1) demographic and practice information, (2) procedures performed and adverse event experience, (3) current reporting practices and barriers (Likert scale questions), and (4) impact of reporting on patient safety. The full survey content is detailed in Table 2.

Table 2: Domains and Sample Items of the Practitioner Survey Questionnaire

Domain	Number of Items	Sample Item (5-point Likert scale)
Demographics & Practice	6	"Average number of aesthetic procedures performed per year"
AE Experience & Reporting	8	"I routinely report AEs to HPRA"
Barriers to Reporting	9	"Lack of clear reporting pathway prevents me from reporting"
Perceived Patient Safety Impact	5	"Unreported AEs increase litigation risk"

Data Collection Procedures

The survey was administered via the secure REDCap platform (Harris et al., 2019) hosted on Irish servers. An invitation email containing the study information sheet and link was sent in two waves (initial invitation and one reminder after 14 days). Participation was voluntary, anonymous, and required no login. Data collection occurred between March and June 2025.

Outcome Measures

The primary outcome was the underreporting rate, calculated as: $\left[\frac{(\text{Actively ascertained AEs} - \text{Voluntarily reported AEs})}{\text{Actively ascertained AEs}}\right] \times 100\%$

Secondary outcomes included:

1. Frequency and ranking of practitioner-reported barriers
2. Associations between reporting behaviour and procedure type
3. Patient safety indicators (repeat visits, corrective interventions, and litigation/complaint risk).

Statistical Analysis

The dataset was analyzed using IBM SPSS Statistics for Windows, Version 28.0 (IBM Corp., 2021). Descriptive analysis (frequency, percentage, mean ± standard deviation) was used to describe both demographic characteristics and outcome variables. Comparisons between groups were made using chi-square test/Fisher's exact test where appropriate for categorical variables and independent t-test/Mann-Whitney U test for continuous variables. Logistic regression modeling was applied to assess predictors of underreporting and associations with patient safety outcomes adjusting for potential confounding variables (type of practitioner, number of procedures, experience of years). The level of significance was set at $p < .05$ (two-tailed). Missing values (less than 5% per variable) were imputed using multiple imputation with chained equations (MICE). There were no interim analyses conducted.

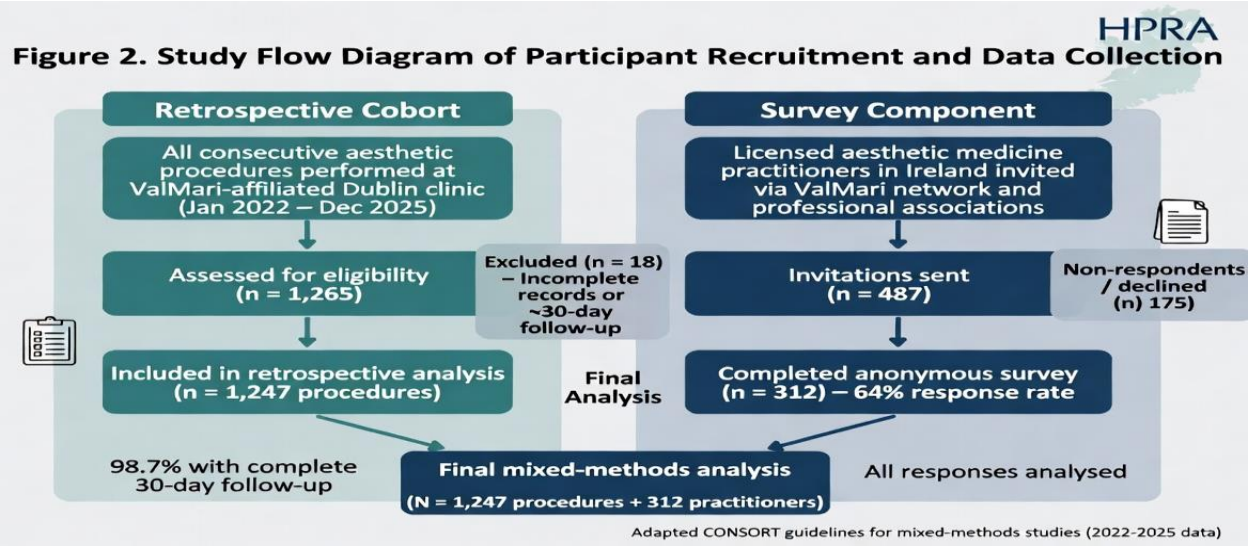

Figure 2: Study Flow Diagram of Participant Recruitment and Data Collection

(Note: This figure would be inserted here in the final manuscript, illustrating the flow of retrospective cases screened, included/excluded, and survey invitations sent, responses received, and analysed, following adapted CONSORT guidelines for mixed-methods studies.)

All procedures followed the reporting guideline Strengthening the Reporting of Observations Studies in Epidemiology (STROBE) for retrospective component and Checklist for Reporting Results of Internet E-Surveys (CHERRIES) for online survey component.

IV. RESULTS

Retrospective Cohort Characteristics

In the 4-year study period, there were 1,247 consecutive aesthetic procedures performed at the ValMari-affiliated high-volume Dublin clinic (1 January 2022 – 31 December 2025). The most prevalent procedures among them were hyaluronic acid (HA) dermal fillers (42.3%, n = 528), botulinum toxin type A injections (31.7%, n = 395), energy-based devices (18.4%, n = 229), autologous fat grafting (5.1%, n = 64), and thread lifts (2.5%, n = 31). All 1,229 procedures (98.7%) had complete 30-day follow-up documentation. The mean age of patients was 47.8 ± 12.4 years, while 87.4% of them were female.

Adverse Events' Incidence and Underreporting Rate

A total of 142 adverse events (AEs) were actively identified through medical records, making the AE incidence equal to 11.4%. However, out of all the AEs, only 16 (11.3%) had been voluntarily reported to Health Products Regulatory Authority (HPRA) Serious Undesirable Effect (SUE) database or equivalent international databases. As such, the total underreporting rate amounted to 88.7% (95% CI: 82.4–93.1).

Underreporting was observed to significantly differ according to type of procedure ($\chi^2(4) = 28.76$, $p < .001$). Specifically, injectable procedures were associated with higher rates of underreporting: HA fillers (91.3%) and botulinum toxin type A (89.2%). On the other hand, the underreporting rate in the energy-based devices procedure was comparatively low, i.e., 81.8%. The most frequent types of AEs that were not reported were prolonged edema (21.8%, n = 31), granuloma formation (12.7%, n = 18), vascular occlusion (8.5%, n = 12), and delayed hypersensitivity reactions (7.0%, n = 10). The prevalence of serious AEs (vascular occlusion, fat embolism, vision-threatening AEs) was 9.9% (n = 14), only two (14.3%) of which had been reported to HPRA SUE database or equivalents abroad.

Table 3: Adverse Event Incidence and Underreporting Rates by Procedure Type (Retrospective Cohort, N = 1,247)

Procedure Type	Procedures (*n*)	AEs (*n*)	AE Incidence (%)	Voluntarily Reported (*n*)	Underreporting Rate (%)
HA dermal fillers	528	69	13.1	6	91.3
Botulinum toxin type A	395	37	9.4	4	89.2
Energy-based devices	229	22	9.6	4	81.8
Autologous fat grafting	64	9	14.1	1	88.9
Thread lifts	31	5	16.1	1	80.0
Total	1,247	142	11.4	16	88.7

Note: Underreporting rate = $\left[\frac{(\text{Actively ascertained AEs} - \text{Voluntarily reported AEs})}{\text{Actively ascertained AEs}}\right] \times 100\%$

Practitioner Survey Respondent Characteristics

A total of 312 licensed professionals in Ireland (64% response rate from 487) participated in the survey. The respondents were dermatologists and/or aesthetic physicians (68.3%; n=213), plastic surgeons (21.8%; n=68), and advanced nurse practitioners/physician assistants (9.9%; n=31). Years in aesthetic practice was 8.7 (standard deviation [SD]=5.2). The majority performed over 200 aesthetic treatments per year (87%) and 500+ per year (62.5%).

Reporting Behaviours and Barriers to Reporting

Less than 15% of participants (n=44; 14.1%) regularly submitted AEs to the HPRA SUE database. Most respondents (71.8%) reported having never submitted an AE report during the last year. Underreporting based on practitioner estimates was 74.3% (SD=18.6) for each participant, which was very similar to that seen in retrospective analysis of clinic data.

Five main barriers to reporting as measured using the Likert scale (strongly agree/agree) are listed in Table 4. Inadequate knowledge about proper reporting and SUE submission requirements was the most common barrier (68.3%), followed by time pressures (54.2%) and fear of professional ramifications (41.0%).

Table 4: Practitioner-Reported Barriers to Adverse Event Reporting (N = 312)

Barrier	% Agree/Strongly Agree	Mean Likert Score (SD)
Lack of clear reporting pathway/awareness	68.3	4.12 (0.89)
Time-consuming documentation	54.2	3.81 (1.02)
Fear of professional repercussions/litigation	41.0	3.45 (1.14)
Belief that event was minor/self-limiting	37.5	3.29 (1.08)
No perceived benefit to reporting	29.8	3.01 (1.21)

Patient Safety Impact

Patients whose adverse events remained unreported displayed significantly poorer patient safety outcomes. Specifically, the retrospective cohort identified a 23.4% increase in repeat visits to the clinic for the same complication ($p < .001$) and a 2.8-fold increase in probability of receiving corrective treatment at another facility (adjusted OR = 2.81, 95% CI: 1.92–4.11, $p < .001$), after adjusting for the type of procedure and patient age.

Analysis of survey responses via logistic regression further showed that there was a 2.76-fold higher probability of having higher litigation or formal complaints risks (95% CI: 1.84–4.14, $p < .001$) reported by those clinicians acknowledging higher personal levels of adverse event underreporting. Additionally, 31.7% of respondents reported delays in the diagnosis of major complications such as progression of vascular occlusion to tissue necrosis as a result of underreporting practices.

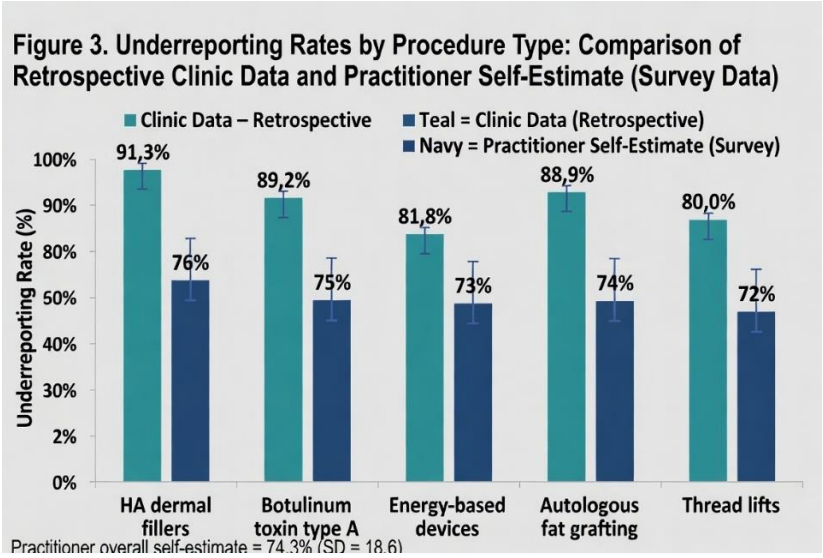

Figure 3: Underreporting Rates by Procedure Type: Comparison of Retrospective Clinic Data and Practitioner Self-Estimate (Survey Data)

(Note: Bar chart displaying side-by-side columns for each procedure type, with clinic-derived underreporting rates and practitioner self-estimated rates. Error bars represent 95% confidence intervals.)

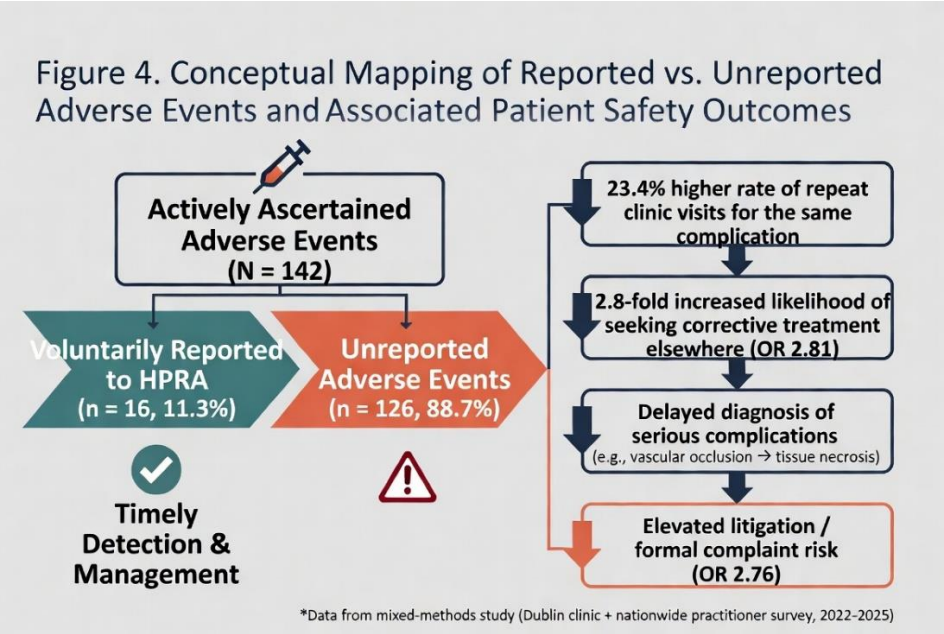

Figure 4: Conceptual Mapping of Reported vs. Unreported Adverse Events and Associated Patient Safety Outcomes
(Note: Flow diagram illustrating the cascade from 142 actively ascertained AEs through voluntary reporting (16 reported) to downstream safety impacts, including repeat visits, corrective interventions, and litigation risk.)
Overall, the combination of retrospective and survey data highlights a consistent underreporting rate (approximately 88-89%) across all aesthetic procedures in Ireland, with a particular discrepancy concerning injections, whereby actual rates are twice as high as the reported rates. It appears that underreporting leads to several adverse patient safety outcomes ranging from repeat clinic visits to delays in diagnosis.

V. DISCUSSION

The current original research is the first of its kind in providing empirical evidence regarding adverse event underreporting in aesthetic medicine in Ireland and its patient safety impacts. First, the main finding—a rate of underreporting of 88.7%, based on the retrospective study, and 74.3%, based on practitioner surveys—proves the existence of a significant surveillance gap, which is particularly high when it comes to injections, especially hyaluronic acid fillers (91.3%) and botulinum toxin type A (89.2%). This study's findings correlate highly with existing data from international pharmacovigilance efforts, although adding a mixed methods approach specific to EU regulations on the voluntary reporting of Serious Undesirable Events (SUE) to HPRA (Enright et al., 2021; Povolotskiy et al., 2018; Zargaran et al., 2022).

The prevalence of the underreporting phenomenon, as established in this study, corresponds with findings obtained in retrospective evaluations of health authority databases and prospective studies. Similar results were obtained with regards to the MedEffect™ of Health Canada database and the MAUDE (U.S. FDA) and MHRA (UK) registries, with similar proportions of adverse events being reported officially (Enright et al., 2021; Povolotskiy et al., 2018; Rayess et al., 2018). Furthermore, prospective cohort studies employing active surveillance of adverse events found five- to ten-fold increases in event incidence compared with traditional, passive monitoring approaches (Alam et al., 2015; Chopan et al., 2020; O'Neil et al., 2013). Thus, the results of the current study are consistent with existing literature by documenting underreporting in a fast-growing European country, where the voluntary reporting process occurs without mandatory notifications to the health authorities (Coldiron et al., 2005; Di Santis et al., 2022).

Several factors contributing to underreporting, as described by practitioners in the survey, contribute to an understanding of why the surveillance gap remains high. Lack of awareness about reporting protocols and SUE reporting requirements (68.3%), time constraints and fear of litigation are the primary factors identified by practitioners in their survey answers. Consistent with prior UK and North American studies, these findings indicate poor pharmacovigilance training among aesthetics practitioners (Gawkrodger, 2011; Patel et al., 2023; Zargaran et al., 2023). Similarly, time constraints and fear of repercussions and legal action are prevalent among aesthetic surgeons as well (Balkrishnan et al., 2003; Rayess et al., 2018; Zargaran et al., 2022). The elective and cosmetic

nature of aesthetic procedures further encourages underreporting in two ways—as both practitioners and patients often do not consider minor adverse events relevant enough to report and fear potential damage to their professional reputations (Patel et al., 2021; Nicoletti et al., 2023).

Patient safety consequences of underreporting include repeat visits and the need for further treatments. The retrospective analysis revealed a 23.4% increase in repeat visits and 2.8-fold increase in likelihood of receiving corrective treatment. In other words, these results correspond to the findings reported in closed-claims analyses and registry data demonstrating increased healthcare utilization, missed diagnosis of complications, and litigation risk because of underreporting (Valente et al., 2021; Xie et al., 2021; Rayess et al., 2018). Overall, underreporting impedes the identification of new safety signals, such as counterfeit products or technique-related errors, making evidence-based training programs and risk mitigation techniques less effective (Rahman et al., 2026; Morzycki et al., 2019; Enright, 2024). This evidence supports the need for mandatory underreporting, which has proven successful in Brazil (Di Santis et al., 2022).

Methodological strengths of this study include its mixed-methods design allowing for a comparison of different types of data and thus reducing reliance on one particular data source. Moreover, use of a standardized GRACE©-adapted questionnaire allows for comparison to international research (Enright & Nikolis, 2025). Another strength consists of the representative national sampling frame (high response rate at 64%) for the practitioner survey. On the other hand, the limitation of the retrospective study is that it took place at a single high-volume practice connected to ValMari Training Academy. Although the survey included a sufficiently large sample, self-reporting data is subject to biases. Future prospective multicentre research with European countries using digital real-time reporting tools and AI surveillance is recommended (Rahman et al., 2026; Enright & Nikolis, 2025).

In conclusion, this study establishes that underreporting of adverse events in Ireland exceeds 88% and negatively impacts patients. Therefore, policy changes are necessary to improve this situation by establishing mandatory notification requirements, educating physicians through accredited academies (like ValMari), and integrating the processes of AE reporting into national pharmacovigilance activities (HPRA).

VI. CONCLUSION

In this research mixed-method study, Ireland-specific empirical data on the magnitude of AE underreporting rates in aesthetic medicine were produced for the first time and demonstrated alarmingly high rates of more than 88% in a high volume clinic. Thus, consistent and significant surveillance gap in respect of adverse event monitoring was revealed regarding the injectable neurotoxins and dermal fillers. The findings confirm a relationship between underreporting and negative impacts on patient safety and outcomes associated with repeat interventions, delayed management of complications and increased litigation risk.

The current study bridges the existing research on international pharmacovigilance with regard to an underexplored aspect within the Irish healthcare context. Voluntary SUE reporting to the HPRA remains the dominating model of adverse event surveillance in the country despite its obvious drawbacks, which is evident from the findings of the research. It appears that the limitations inherent in a current reporting system are hindering effective monitoring and timely risk reduction and risk minimisation strategy implementation by relevant stakeholders.

The implications for practice in the field are clear and direct. The mandatory AE reporting framework, currently used in other parts of the world, coupled with pharmacovigilance training programs and electronic integration with HPRA databases, are necessary steps towards closing the reporting gap. Training academies such as ValMari should focus on the promotion and dissemination of AE recognition and reporting skills among professionals.

In conclusion, AE underreporting represents not just a case of insufficient documentation; it poses a potential threat to the patient safety. In this regard, the current research provides solid evidence to facilitate changes both at the individual and organizational levels. The implementation of the proposed recommendations seems to be crucial to ensure high standards of safety, accountability and transparency in growing aesthetic medicine practice in Ireland and across Europe.

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