Review Article

Regulatory frameworks in plastic and cosmetic surgery: a comparative scoping review across Australia, United Kingdom, and Italy

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Background: The regulatory landscape for plastic and cosmetic surgery across the country plays a crucial role in shaping the practices within its premises, ensuring patient safety, and maintaining ethical standards in the medical community. This review examines the distinct regulatory frameworks that govern Australia, United Kingdom (UK), and Italy practices, focusing on the nuances that influence the professional accountability and safety measures in place.

Methods: A comprehensive scoping review was conducted, exploring the legal and regulatory frameworks governing plastic and reconstructive surgery in Australia, the UK, and Italy. Databases such as PubMed, Scopus, and Google Scholar were searched for relevant studies from infinity to May 2024, which were then analyzed to compare regulatory practices, qualification requirements, and their implications on patient safety and professional accountability.

Results: Each country presents a unique set of regulations that reflect their individual medical, legal, and cultural contexts. In Australia, the Australian Health Practitioner Regulation Agency (AHPRA) and the Medical Board of Australia impose stringent criteria for differentiating between "cosmetic surgeons" and "plastic surgeons". The UK's approach, governed by the General Medical Council (GMC), emphasizes ethical conduct, informed consent, and transparent advertising. Italy's regulatory framework varies slightly with a specific focus on the qualifications and titles of practitioners.

Conclusions: The study underscores the importance of stringent regulations in plastic and cosmetic surgery, advocating for enhanced regulatory measures and comprehensive education on the qualifications of practitioners. It is imperative that these standards are maintained and adapted as necessary to protect patients in the rapidly evolving landscape of cosmetic and plastic surgery across the different regions.

Keywords: Regulatory framework; governance; clinical; management

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Introduction

The legal framework governing plastic and reconstructive surgery, particularly cosmetic surgery, is critical due to the enduring ramifications these procedures can have on patients. In an era where the demand for cosmetic enhancements continues to escalate, the necessity for stringent regulations becomes paramount to ensure patients' safety and uphold ethical standards within the medical community. These legal stipulations must be meticulously crafted and enforced to mitigate risks and foster trust between patients and practitioners, ensuring that the outcomes of cosmetic surgeries are aesthetically satisfactory, medically sound, and ethically conducted (1-3).

One of the central bodies overseeing Australian medical practitioners is the Australian Health Practitioner Regulation Agency (AHPRA) alongside the Australian Medical Association (AMA) (4). In the United Kingdom (UK), the General Medical Council (GMC) plays a central role in regulating all medical practitioners, including those specializing in plastic and cosmetic surgery (5). The GMC's stringent guidelines help ensure that all medical professionals maintain the highest standards of practice and ethics (5). The Italian framework is known as the Associazione Italiana Chirurgia Plastica Estetica (AICPE), which focuses exclusively on aesthetic plastic surgery, promoting education and practice in this specific field among qualified surgeons (6).

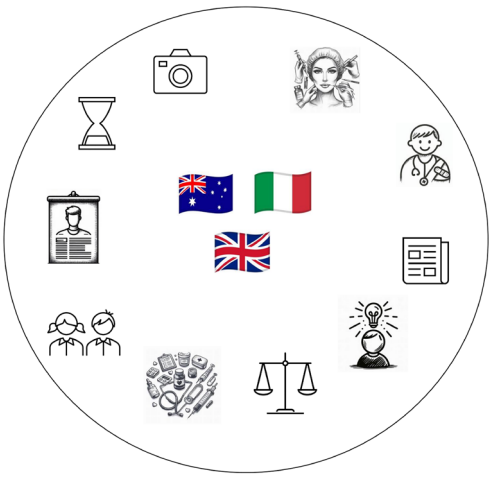

Figure 1 Diagram showing the various aspects of legal frameworks.

Australia, the UK, and Italy each have distinct regulatory frameworks that govern the practice of cosmetic and plastic surgery. These frameworks ensure that each country maintains high standards of patients' safety and professional accountability in the rapidly evolving field of cosmetic and plastic surgery (*Figure 1*). In this scoping review, we meticulously examined the legal and regulatory frameworks governing plastic and reconstructive surgery across Australia, the UK, and Italy. By scrutinizing these frameworks, we gain valuable insights into how each nation safeguards patient welfare and upholds ethical standards within the realm of cosmetic and plastic surgery. We present this article in accordance with the PRISMA-ScR reporting checklist (available at https://gs.amegroups.com/article/view/10.21037/gs-24-244/rc).

Highlight box

Key findings

- This review identifies key differences in the regulatory frameworks for plastic and cosmetic surgery across Australia, United Kingdom (UK), and Italy, particularly in terms of patient safety and professional accountability. Australia's regulations distinctly differentiate between cosmetic and plastic surgeons, the UK's regulations emphasize ethical conduct and transparency, while Italy prioritizes practitioner qualifications and titles.

What is known and what is new?

- It is known that regulatory standards vary globally, impacting the quality of care and safety in plastic surgery.
- This manuscript adds new insights into how regulations in each country are influenced by specific medical, legal, and cultural contexts, providing a comparative analysis of the regulatory frameworks in Australia, the UK, and Italy.

What is the implication, and what should change now?

- The findings suggest that enhanced regulations and comprehensive education on practitioner qualifications are essential. The study advocates for immediate actions to tighten regulations and improve public awareness, ensuring patient protection in the rapidly evolving field of plastic surgery.

Methods

This scoping review aims to elucidate the distinctions between cosmetic and plastic surgeons, along with the associated ethical and legal considerations in Australia, the UK, and Italy. As a scoping review, no strict selection criteria were employed. Instead, cited articles were discussed among the authors to ensure eligibility based on relevance and quality. Various databases, including PubMed, Scopus, Web of Science, Embase, Google Scholar, and the Cochrane Library, were searched, considering data available up to May 2024. The collected data were shared among

Table 1 Regulatory frameworks in plastic and cosmetic surgery across Australia, the UK, and Italy

Aspect	Australia	UK	Italy
Regulatory entities	AHPRA, Medical Board of Australia	GMC	AICPE, SICPRE
Qualification requirements	Specialization and fellowship from the RACS	Certification in the GMC specialist register	Specialization in plastic and reconstructive surgery
Title differentiation	Distinction between plastic surgeons and cosmetic surgeons	Distinction between plastic surgeons and cosmetic surgeons	Distinction between plastic surgeons and cosmetic surgeons
Informed consent	Requires at least two pre-operative consultations, mandatory cooling-off period	Detailed discussion and mandatory reflection period	Detailed and understandable, including psychological assessment
Cooling-off period	At least 7 days	Specified to provide time for reflection	Not specified
Advertising	Regulated by AHPRA to prevent misleading practices	Regulated by GMC, must be truthful and transparent	Prohibition of misleading or sensational advertising
Patient suitability evaluation	Comprehensive evaluation including psychological conditions, referral requirement	Thorough medical and psychological assessment	Rigorous medical and psychological evaluation
Minors	Requires psychological evaluation and 3-month cooling-off period	Treatments only if in the best interest of the minor	Aesthetic surgery not performed on individuals under 18 years, psychological evaluation required for reconstructive surgery
Use of medical devices	Information on devices provided to patients	Regulated by MHRA	Follows EU regulations, CE marking
Legal recourse	Complaint with AHPRA, civil lawsuits for negligence	Complaints handled through GMC and civil lawsuits	Possible recourse for negligence and lack of professional ethics, complaints to SICPRE

UK, United Kingdom; AHPRA, Australian Health Practitioner Regulation Agency; GMC, General Medical Council; AICPE, Italian Association of Aesthetic Plastic Surgery; SICPRE, Società Italiana di Chirurgia Plastica Ricostruttiva ed Estetica; RACS, Royal Australasian College of Surgeons; MHRA, Medicines & Healthcare products Regulatory Agency; EU, European Union; CE, Conformité Européenne.

the authors and analyzed to compare regulatory practices, qualification requirements, and their implications on patient safety and professional accountability in different countries (*Table 1*). This comprehensive examination seeks to map existing evidence, identify inconsistencies among national regulations, and highlight areas with insufficient regulatory oversight.

Results

Distinction between cosmetic surgeons and plastic and reconstructive surgeons

A key legal distinction that exists between 'cosmetic surgeons' and 'plastic surgeons' is the differentiation not just of semantics but of significant training and accreditation. Plastic surgeons must complete years of specialized training and residency, culminating in a fellowship from the Royal Australasian College of Surgeons (RACS). This ensures they are proficient in both aesthetic and functional reconstructive procedures, adhering to high safety and ethical standards. Conversely, the term 'cosmetic surgeon' can be used by doctors with varied medical training who have not undergone the specialized surgical training that certified plastic surgeons have. This can lead to differences in expertise and outcomes in procedures focused solely on aesthetic enhancements. Legally and ethically, this distinction affects regulation and advertising. AHPRA requires clear communication about qualifications, and the AMA enforces strict advertising guidelines to prevent misleading claims (4). This is crucial for patient safety and informed consent, ensuring practitioners meet the expectations of medical integrity and quality in surgical outcomes. Plastic surgeons receive comprehensive training and are recognized by the RACS equipping them with

the expertise needed for both complex reconstructive and cosmetic procedures (5). In contrast, the term 'cosmetic surgeon' may refer to practitioners with varying levels of expertise, some of whom may not have specialized training (7-11).

In the UK, surgeons performing cosmetic procedures must hold certification in their respective specialty within cosmetic surgery, necessitating inclusion in the GMC specialist register in a relevant surgical field and meeting rigorous criteria demonstrating professional competence, clinical proficiency, and practical experience (5). Furthermore, maintaining competence and performance across all aspects of cosmetic surgery is obligatory, involving regular participation in activities for professional development and staying updated on relevant laws, clinical standards, and ethical guidelines (5). Actively seeking and incorporating patient feedback, alongside feedback from peers, is crucial for practice improvement and ensuring patient satisfaction and well-being (12-14).

In Italy, the distinction between cosmetic surgeons and plastic surgeons is emphasized by the requirements for practice and the type of procedures they are allowed to perform. Plastic surgeons are typically required to have extensive training and certification in plastic, reconstructive, and aesthetic surgery. They are expected to stay updated with the latest medical advancements and maintain a high level of professionalism and competence (6).

Cosmetic procedures, on the other hand, might not always require such extensive medical training and can include non-surgical treatments such as Botox injections or fillers. The ethical code implies a professional boundary that Società Italiana di Chirurgia Plastica Ricostruttiva ed Estetica (SICPRE) members should respect by ensuring they only practice within the scope of their specialized medical training (6).

The legal liabilities associated with cosmetic surgery primarily stem from medical negligence due to inadequate training, insufficient supervision, and a lack of expertise, which can lead to higher complication rates and diminished patient satisfaction. These practitioners, if not adequately trained, may not manage surgical complications effectively, which can result in severe consequences for patients. This highlights a major legal concern, as patients might pursue litigation for negligence, leading to substantial legal repercussions for practitioners. The ethical responsibility to ensure patient safety and satisfaction further intensifies the need for stringent regulatory oversight of training and credentials in the cosmetic surgery industry. Ensuring that practitioners meet these rigorous standards is essential not only for patient safety but also for maintaining the integrity and reputation of the medical profession (15-17).

Individuals considering cosmetic surgery are advised to meticulously research their practitioner's credentials. Cosmetic procedures, ranging from surgical interventions like breast augmentations, rhinoplasty, and liposuction to non-surgical treatments such as dermal fillers and laser hair removal, aim to modify the appearance, texture, or structure of bodily features for a more desirable look. While cosmetic surgery primarily focuses on enhancing appearance by altering normal body features, reconstructive surgery, which is not covered by these guidelines, aims to restore form and function to body structures affected by congenital defects, diseases, or injuries.

Patient suitability

In Australia, the process of assessing patient suitability for cosmetic surgery is comprehensive and multidimensional, focusing on ensuring the safety and well-being of the patient (4). It begins with a prerequisite for all patients seeking cosmetic surgery to have a referral, ideally from their usual general practitioner (GP) or another medical specialist who operates independently of the surgeon performing the procedure. This requirement ensures an unbiased evaluation of the patient's need for surgery. The surgeon must then delve into the patient's motivations, distinguishing between external pressures, such as societal expectations, and internal desires related to self-perception. This discussion aims to align the patient's expectations with realistic outcomes (4).

Another critical aspect of the assessment involves evaluating the patient for psychological conditions, notably body dysmorphic disorder (BDD), using validated screening tools. This step is essential, as psychological conditions can significantly impact the patient's perception and satisfaction with the surgery's outcome. If a patient is found to have underlying psychological issues, a referral to a psychologist, psychiatrist, or GP for further evaluation is necessary. Additionally, the surgeon must explore and discuss alternative options with the patient, including different treatments or the decision against undergoing surgery, ensuring the patient is fully informed of all possibilities (4,13,18,19).

The consultation process itself mandates at least two pre-operative consultations 1 week apart, with at least one being in person with the performing surgeon to facilitate a

thorough understanding and rapport between the patient and surgeon. Consent forms should not be signed during the first consultation, underscoring the importance of giving patients adequate time to consider their options. A crucial component of this process is the cooling-off period of at least 7 days following the second consultation and informed consent, allowing the patient time to reflect on their decision without pressure. This structured approach ensures that both the physical and psychological aspects of patient suitability are thoroughly evaluated, prioritizing patient safety and the ethical practice of cosmetic surgery (4,15,20).

The UK guidelines for patient suitability in cosmetic surgery emphasize the need for a thorough evaluation of each patient's medical and psychological profile. Before any cosmetic procedure, surgeons must assess a patient's medical history, general health, age, existing co-morbidities, ongoing medications, and any other planned procedures. This medical assessment ensures that the surgeon can determine if the patient is a good candidate for the proposed intervention, taking into account any potential risks or complications that could arise from their current health status (5).

Additionally, the psychological state of the patient is a critical factor in determining their suitability for cosmetic surgery. Surgeons are required to evaluate whether the patient has realistic expectations about the outcomes of the procedure and whether there is a psychological vulnerability that could impact their satisfaction post-surgery. For instance, if a patient has a history of repeated cosmetic procedures with dissatisfaction, or if their mental health history suggests possible psychological disturbances, the surgeon might decide to defer the surgery or refer the patient for a psychological assessment. This careful screening process is vital to ensure that the intervention is likely to be beneficial and that the patient is well-informed and prepared for the possible outcomes (5,14,21,22).

In Italy, the ethical standards demand that members carefully evaluate the suitability of patients for plastic or cosmetic procedures. This includes considering the patient's physical health and psychological readiness for surgery. Surgeons must ensure that the intentions behind seeking cosmetic enhancements are appropriate and that patients have realistic expectations. Preoperative evaluations, including psychological assessments, when necessary, are crucial to determine suitability.

Surgeons under AICPE are required to adhere to strict ethical guidelines that include assessing patient suitability (6). This includes ensuring that patients have appropriate intentions and realistic expectations before undergoing aesthetic procedures (12,23-26).

Consent and patient aiming to prevent misleading claims and ensure the integrity of medical advice.

Informed consent encompasses a wide range of considerations, from detailed discussions about the surgery itself, including anaesthesia, venue, potential outcomes, alternatives, and specific risks, to a clear explanation of the financial implications covering the total cost, additional treatments, and the policy on refunds. It also necessitates a mandatory cooling-off period of at least 7 days to ensure patients make unpressured, reflective decisions. Additionally, consent for the use of patient images, whether for medical records or advertising, must be explicitly obtained, with patients having the right to refuse or withdraw their consent at any time. This process is not just about obtaining permission but ensuring that patients are fully aware of what the surgery involves, its risks, and the financial commitment, alongside respecting their privacy and autonomy. Medical practitioners are tasked with the responsibility to ensure patients understand all provided information, necessitating a direct consultation at least 7 days before the surgery and reconfirmation on the day, thereby upholding the highest standards of ethical medical practice and patient care (5,16,17,27,28).

Informed consent—Australia

Comprehensive information disclosure

To achieve genuine informed consent, the medical practitioner must ensure that the patient is thoroughly briefed on what the surgery entails. This includes a detailed discussion on the type of anaesthesia and pain management to be used, the venue of the surgery (hospital or day procedure centre), and whether the surgery incorporates new or experimental techniques. Importantly, the discussion should cover the potential range of outcomes, highlighting those results may vary and that achieving a 'perfect' outcome is not guaranteed. This conversation must be devoid of any language that glamorises the surgery or understates its complexity and possible risks (2,5,13,29).

Understanding risks and recovery

A crucial aspect of informed consent involves detailing the short- and long-term risks associated with the surgery, tailored to the patient's specific health context, including any comorbidities. The possibility of needing revision

surgery or additional treatments in the future must be communicated, along with realistic recovery times and care requirements during the recovery phase.

Financial informed consent

Informed financial consent is critical, requiring disclosure of the total cost of the surgery, including any associated costs such as implants, assistant surgeon and anaesthetist fees, and facility charges. The patient should be informed about deposit requirements, payment schedules, and the policy regarding refunds. Follow-up care costs, potential expenses for allied health services post-operatively, and further costs for revision surgeries or additional treatments should also be discussed. Patients must understand that cosmetic surgery is generally not covered by Medicare, highlighting the importance of being fully aware of the financial commitment involved (5).

Consent for use of images

Consent extends into the domain of privacy, particularly concerning the use of photographs or videos of the patient (1). Patients must be informed about the intended use of any images taken, including their use in advertising or medical records. Explicit consent must be obtained for each distinct use, with the patient retaining the right to refuse or withdraw consent at any time (1). This consent must be documented, emphasizing the separation between consent for surgery and consent for the use of images (5,6).

The cooling-off period

A mandatory cooling-off period of at least 7 days after giving consent and before undergoing the surgery is essential. This period allows patients to reflect on their decision, seek further information, or consult with other professionals, ensuring that their consent is not only informed but also deliberate and unpressured (4).

Ensuring understanding

The medical practitioner is responsible for ensuring that the patient fully understands all information provided. This includes taking steps to deliver information in a language and manner that the patient comprehends. Consent must be obtained through a direct consultation (either in-person or via video) at least 7 days before the surgery and reconfirmed on the day of surgery. Documentation of consent is critical, with a copy of the signed consent form provided to the patient for their records (4,5).

This comprehensive approach to informed consent respects the patient's autonomy, promotes ethical medical practices, and safeguards against legal implications arising from misunderstandings or unmet expectations. It emphasizes the importance of transparency, communication, and mutual respect in the patient-practitioner relationship.

Informed consent—UK

The GMC also mandates that consent for cosmetic procedures must not only be obtained but also thoroughly documented and discussed, ensuring patients are well-informed of the possible outcomes and risks associated with their chosen interventions. According to the GMC, the surgeon must directly handle the consent process, preventing delegation to ensure that the patient fully understands the procedure's risks, benefits, and limitations. This includes a mandatory discussion led by the surgeon who will either perform or supervise the procedure. The guidelines advocate for a detailed and patient-centric approach, giving patients adequate time to reflect on the provided information, including a specified reflection period that allows them to consider the invasiveness and risks involved comprehensively. Patients are also reminded that they can withdraw consent at any time, reinforcing the voluntary nature of their decision.

For more complex scenarios, such as patients lacking the capacity to consent, the GMC guidelines require adherence to specific legal frameworks like the Mental Capacity Act 2005 or the Adults with Incapacity Act 2000. Surgeons must involve close contact with the patient and consider the patient's prior expressed wishes to guide the consent process. The aim is to respect patient autonomy while ensuring all decisions are made in their best interests, with the surgeon required to document all aspects of the consent process thoroughly, including the financial costs and any discussions about alternative options or the possibility of not proceeding with the surgery at all (5).

Informed consent—Italy

The AICPE has an ethical code that its members must adhere to, which sets norms for responsible and ethical professional practice (3). This includes guidelines on advertising, informed consent, and patient privacy management, ensuring that patient rights are always respected, and that care is provided with the highest standards of quality and medical ethics.

Consent is a cornerstone of medical ethics, particularly

in elective procedures such as plastic and cosmetic surgery. The SICPRE ethical code requires that surgeons provide detailed information about the risks, benefits, and possible outcomes of the surgery. This information must be communicated in a clear, comprehensive manner, allowing the patient to make an informed decision. Surgeons must also respect patient privacy and confidentiality, adhering to legal standards for handling personal health information. The AICPE's ethical code underscores the significance of informed consent, guaranteeing patients receive thorough and comprehensible details regarding their forthcoming procedures, while also prioritizing patient privacy and confidentiality (6,23).

Regulation of advertising practices

The marketing dynamics within the cosmetic surgery industry significantly differ from the rest of the healthcare sector, primarily due to the elective nature of cosmetic procedures (30,31). Unlike services driven by medical necessity, the demand for cosmetic surgery is heavily fuelled by advertising and marketing strategies, with social media platforms and upselling tactics being particularly influential. These methods aim to reach a broad audience and shape consumer preferences and decisions in cosmetic surgery. This commercial approach treats potential patients akin to consumers in a retail space, focusing on generating demand rather than addressing healthcare needs. Such practices raise ethical concerns, especially when the marketing strategies employed may not fully align with the best interests of the patients.

Misleading advertising in cosmetic surgery presents significant risks, as it can create unrealistic expectations, push individuals towards unnecessary procedures, minimize the perceived seriousness and risks of surgery, and gloss over the recovery process (30,31). The implications of such advertising are not trivial; they can lead to individuals making poorly informed decisions, potentially resulting in dissatisfaction with outcomes or, worse, serious health complications (17). It is equally important to educate potential patients on the importance of seeking accurate, comprehensive information and consulting with qualified professionals to make informed healthcare decisions. In doing so, the industry can better safeguard patient safety and uphold ethical standards in the promotion and practice of cosmetic surgery.

The advertising of cosmetic and plastic surgery services is subject to strict regulations under AHPRA guidelines in Australia. These rules are designed to protect patients from misleading or deceptive marketing practices. Advertisements cannot make unfounded promises of outcomes, use sensational or unrealistic depictions of before and after scenarios, or offer financial inducements such as discounts for surgery if acted upon within a certain timeframe.

Cosmetic surgeons must also acknowledge that the demand from individuals may deem them unsuitable for cosmetic surgery due to psychological conditions like BDD, and recognize the possible harm to such individuals. Advertising must not target these vulnerable groups or offer financial incentives that could unduly influence the decision to undergo surgery. Furthermore, practitioners are tasked with ensuring the clarity and honesty of information regarding costs, insurance coverage, and their qualifications, experience, and competence in advertising. This includes clear, unambiguous information about their medical registration and qualifications to prevent misleading the public. Ultimately, the paramount consideration in all practitioner-patient interactions, including advertising, must be the duty of care towards the patient, prioritizing their safety, well-being, and informed consent above financial gains or marketability of cosmetic procedures (2,4,13,21,29,32).

The GMC enforces rigorous standards regarding the advertising and promotion of medical services, particularly for cosmetic interventions. Practitioners are required to adhere strictly to honesty and integrity, ensuring all promotional materials accurately reflect their qualifications, experience, and the nature of their services. Regulatory codes and guidelines set by the Committee of Advertising Practice must be followed without exception. This includes making sure that any advertised information is verifiable, factual, and does not exploit the vulnerabilities or lack of medical knowledge among potential patients. The intent is to prevent deceptive practices that could mislead patients about the practitioner's capabilities or the efficacy and safety of the procedures offered.

Moreover, the marketing of medical services must responsibly convey the risks associated with cosmetic interventions, explicitly stating that such procedures are not risk-free. If a medical assessment is required prior to an intervention, this must be communicated in the marketing material to avoid patients being misled about the accessibility of the service. Additionally, practitioners are prohibited from using promotional tactics that might pressure or rush potential patients into making hasty decisions, such as offering services as prizes or guaranteeing

specific results. The guidelines also stipulate that physicians must disclose any financial or commercial interests that could potentially influence their clinical decisions. This transparency is crucial to maintaining trust and ensuring that patient care decisions are made based on medical best practices rather than financial incentives, thereby safeguarding the integrity of medical advice and treatment recommendations (5).

The Italian ethical code is similarly strict about advertising practices. Surgeons are forbidden from engaging in any form of deceptive or sensational advertising. This includes avoiding exaggerated claims about the results and benefits of cosmetic procedures. The aim is to prevent the trivialization of medical procedures and ensure that any advertising is grounded in factual, verifiable information. Surgeons are also advised against using any promotional methods that could mislead patients about the quality or safety of the services offered. The AICPE requires its members to abstain from misleading advertising practices. Surgeons must avoid communications that can create unrealistic expectations or that trivialize the seriousness of medical procedures (6).

Ethical and responsible healthcare advertising is crucial in the realm of cosmetic surgery, serving as a safeguard by equipping individuals with accurate, balanced information, thereby enabling informed decision-making. Good practice in cosmetic surgery advertising is underscored by the provision of balanced and accurate information that avoids misleading impressions. It ensures the depiction of realistic outcomes, candidly presents the risks and recovery processes and acknowledges that results vary based on individual characteristics. Moreover, it encourages a positive portrayal of normal body variations, steering clear of pathologizing normal appearances or suggesting surgery as a remedy for natural body diversity. These guidelines outline what is considered acceptable, aiming to meet professional obligations and adhere to good medical practice, although an exhaustive list of appropriate versus inappropriate advertising practices cannot be feasibly provided. Examples mentioned serve to facilitate understanding and are not the sole instances of potentially misleading or unacceptable advertising.

Special considerations for patients under 18 years of age

When providing cosmetic surgery to patients under the age of 18 years, medical practitioners face additional responsibilities beyond the standard requirements outlined in cosmetic surgery guidelines. AHPRA mandates that such patients must be well-versed and compliant with the legislation specific to their jurisdiction regarding cosmetic surgery on minors. A critical part of this process involves assessing whether the minor can consent to the procedure, which often involves referencing Gillick competence, a legal principle stating that minors capable of understanding the procedure and its implications may consent independently, regardless of age (32). This evaluation considers the minor's maturity and comprehension of risks and alternatives. While Gillick competence guides the decision, involving parents or guardians where possible ensures additional support and perspectives, prioritizing the minor's well-being in cosmetic surgery decisions. This assessment should not only consider the minor's ability to understand and weigh the implications of surgery but also, where practicable, incorporate the perspectives of the patient's parents or guardians regarding their support for the surgery (4,32).

Furthermore, it is required that all minors be referred to an independent psychologist, psychiatrist, or GP for an evaluation aimed at uncovering any significant underlying psychological issues that may render them unsuitable for the surgery. This step underscores the importance of ensuring the patient's mental health is thoroughly considered before proceeding with any cosmetic interventions.

In addition to the psychological assessment, a mandatory cooling-off period of at least 3 months is required for patients under the age of 18 years from the time informed consent is provided until the surgery can be performed (1). This period serves multiple purposes: it allows time for the patient to reflect deeply on their decision, to consider the potential long-term impacts of the surgery, and to discuss their reasons for wanting the surgery with their GP. This dialogue with a healthcare professional outside of the cosmetic surgery context may provide additional insights or support, further ensuring that the decision to undergo cosmetic surgery is made with the utmost care and consideration for the patient's well-being. These added measures for minors recognize the unique considerations and potential vulnerabilities associated with making such significant decisions at a young age, emphasizing a cautious and thoroughly evaluated approach to cosmetic surgery (4,33-38).

The GMC has established stringent guidelines for treating children and young people regarding cosmetic interventions. These guidelines stress the importance of providing treatment in environments suited to pediatric care and often necessitate collaboration with multidisciplinary

teams experienced in treating minors. This approach ensures that both the physical and emotional needs of the child are addressed, emphasizing a setting that is safe and appropriate for their developmental needs.

For consent involving minors, the GMC dictates that interventions must only be performed if they are in the best interests of the child. Children who are capable of understanding the procedure should be encouraged to involve their parents in the decision-making process, but their own consent is central. If a child cannot consent, parents may do so on their behalf, but the child's willingness to undergo the procedure must be considered—if they are opposed to it, the procedure should not proceed. Additionally, the guidelines specifically prohibit marketing cosmetic interventions to children and young people, safeguarding them from potentially manipulative advertising.

For minors, the Italian ethical code is equally stringent. Non-essential aesthetic surgeries are not performed on individuals under 18 years to protect this vulnerable group from unnecessary medical procedures (3). In cases where reconstructive surgery is needed (for example, due to congenital defects or accidents), it requires thorough consultation with the minor's guardians and often a psychological evaluation to ensure that the minor is mentally and emotionally prepared for the outcomes of the surgery (5).

Authorized use of specific equipment

In Australia, prior to undergoing any cosmetic surgery involving an implantable device, it is imperative that the patient receives the Therapeutic Goods Administration approved patient information leaflet, while post-surgery, they should be provided with the patient implant card pertaining to the device (4).

The administration and enforcement of medical device regulations in the UK fall under the jurisdiction of Medicines & Healthcare products Regulatory Agency (MHRA), which wields various investigatory and enforcement powers to ensure their safety and quality. Manufacturers intending to supply medical devices in the UK must adhere to regulations such as the Medical Devices Regulations 2002 (UK MDR 2002) and the General Product Safety Regulations 2005, both under the Consumer Protection Act 1987, subject to investigation by MHRA for compliance (12). MHRA conducts market surveillance activities, responds to non-compliance, and may issue enforcement notices, if necessary, under the UK MDR 2002 or the General Product Safety Regulations 2005, potentially leading to prosecution for serious offenses (12). Inspections, guided by the Consumer Rights Act 2015, may be conducted to ensure compliance, with confidentiality protocols in place as per relevant legislation such as the UK MDR 2002 and the Enterprise Act 2002.

At the European level, the introduction of medical devices such as implants for aesthetic enhancement is governed by the Conformité Européenne (CE) marking, which certifies a product has met European Union (EU) safety and health requirements. An instance of such regulation was the ban on the use of Macrolane for breast volume enhancement due to safety concerns, followed by the revocation of its approval by several European regulatory agencies, including Italy (39).

Legal recourse for unsatisfactory outcomes

Patients who experience unsatisfactory outcomes or complications from cosmetic or plastic surgery have several avenues for legal recourse. These include lodging a complaint with AHPRA, seeking a civil lawsuit for negligence or breach of contract, and, in some cases, pursuing claims through consumer protection laws.

The legal process for addressing such complaints aims to provide a fair resolution for affected patients, including possible compensation for damages and measures to address the practitioner's future conduct. This system underscores the legal and ethical responsibilities of surgeons to uphold the highest standards of patient care and safety (5).

If dissatisfied with the care provided by a doctor, the GMC advises patients to first address the concern or complaint directly with the doctor or their affiliated organization. However, if there are concerns regarding patient safety or significant deviations from expected standards, individuals are encouraged to visit https://www.gmc-uk.org/patientshelp. Here, one can access guidance outlining the standards doctors must adhere to, available at https://www.gmc-uk.org/cosmetic (24,28).

While the Italian code does not detail specific legal recourses available to patients, it outlines the professional expectations and the disciplinary measures that can be taken against surgeons who fail to meet these standards. If a patient experiences unsatisfactory outcomes due to incompetence or unethical behavior by a surgeon, the patient may file a complaint with the SICPRE or the relevant medical board. This could lead to disciplinary action, including temporary suspension or permanent

expulsion from the medical society, and potentially legal action for malpractice or breach of contract. Although specific details on legal recourse for unsatisfactory outcomes have not been detailed, the AICPE's ethical code emphasizes the maintenance of high professional and ethical standards. In cases of non-compliance, disciplinary measures may be implemented, which can include suspension or expulsion from the association (6,23).

Discussion

There are several limitations in the scoping review process. Firstly, the study sample and the absence of strict selection criteria might introduce bias and variability in the selection of articles. This can result in studies with varying levels of quality and relevance, potentially affecting the robustness of the review's conclusions. The reliance on discussions among authors to ensure eligibility based on relevance and quality may introduce subjectivity. Moreover, we only focused on Australia, the UK, and Italy while other countries were excluded.

Secondly, the process of sharing and analyzing collected data among the authors could introduce inconsistencies, especially if clear guidelines and standardized methods for data extraction and synthesis were not established. Comparing regulatory practices, qualification requirements, and their implications across different countries (Australia, the UK, and Italy) can be challenging due to variations in healthcare systems, legal frameworks, and cultural contexts. This complexity might limit the ability to draw definitive conclusions.

Conclusions

The study highlights the critical need for stringent regulations in the practice of plastic and cosmetic surgery across Australia, the UK, and Italy. Our review underscores the importance of clear distinctions between cosmetic surgeons and plastic surgeons to ensure patient safety and professional integrity. Enhanced regulatory measures and comprehensive education on the qualifications of practitioners are essential to uphold high standards of care and protect patients in the evolving landscape of cosmetic and plastic surgery.

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Footnote

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