Towards a safer, more regulated environment in

Cosmetic Surgery Services



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Although Cosmetic Surgery is a big industry in Ireland, estimated at around €30 million a year, it is still a branch of Medicine and as such has an immediate impact on Public Health.

For this reason it must be regulated

The primary aim of the industry must not simply be the maximisation of profits but moreover to provide safe services. Clients are not just customers but more importantly they are patients with enhanced rights.

Cosmetic Surgery, like any branch of Surgery can lead to complications sometimes serious or even life-threatening.

These proposals below, if implemented, will reduce but not eliminate the incidence of complications. More importantly when complications do occur they will help ensure that they are managed with best practice.

The three interlinked components that constitute the body of the Cosmetic Surgery industry are:

- 1 The Cosmetic Surgery Clinic/Company where consultations with the Surgeon and pre and post-operative care takes place.
- 2 The Practitioner/Surgeon who performs the Surgical or non-Surgical procedure.
- 3 The Hospital/Clinic where the procedure is performed.

I will examine each of these separately and suggest specific standards aimed at improving patient's safety.





Section 1: The Cosmetic Surgery Clinic

This is the Party that facilitates the liaison between Patient and Doctor.

In most branches of Medicine, a patient is referred by his GP to a specialist. However, in Cosmetic Surgery, ninety per cent of the patients are self-referred. That is, the Patients decide for themselves why, where and with whom to consult for a cosmetic issue.

The Clinic uses marketing tools to inform prospective customers of the services offered. Brochures, Websites, Advertising in the media and Press Releases are used to communicate and convey attributes of the products or procedures offered.

The Clinic personnel usually perform the following tasks:

- They attract enquiries from interested patients;
- They arrange the meeting between the prospective patient with the Surgeon;
- They follow-up any initial inquiry before and after the consultation with the Surgeon;
- They arrange for the surgical procedure to take place;
- They provide pre and post-operative care and guidance to the patient;
- They receive the agreed fees from the patient and in turn they pay the Hospital and the Surgeon while keeping a considerable percentage for their administrative costs.

Often in the patients mind the Clinic is the only identifiable component when referring to their surgical experience. The name of the Surgeon often cannot be recalled. This is because the Clinic, through the media exposure and activity, has a much more prominent profile than the Surgeon or the Hospital.

Conversely, it is in fact the Surgeon, who ultimately holds the responsibility and duty of care to the patient. Therefore, it is of paramount importance that such Clinics are regulated in order to safeguard patients' safety.

- Any Clinic offering cosmetic care should employ a suitably qualified Medical Director based on the attributes described under Section 2 of this proposal.
- This Medical Director must be named in all advertising material. He/She should be responsible for the quality of information provided, the Nursing care, and the adequacy of the Hospital premises as well as the vetting of Doctors and Nurses.
- The Clinic must have its own Medical Legal Indemnity Insurance independent of the Surgeon's and the Hospital's Cover.
- The Medical Director must be held responsible to make all necessary checks that all Medical and Nursing Practitioners hold the correct qualifications, hold up to date registrations with their professional bodies and hold valid Insurances.
- Any non-Medical/Nursing employee that comes in contact with the public must identify themselves as non-medically trained. Non-medical employees and in particular "Sales Executives" must never be allowed to discuss medical matters, give opinion or advice.
- Marketing tools such as "better price deals" must be outlawed. In particular statements such as the following should not be tolerated as they put undue subliminal pressure on a patient;
 - "20% off if you book in June"
- "500 Euros off if you have the surgery next week"
- "Bring a friend and you will receive a discount"
- "Have two procedures for less"

Such calls to action may be legitimate in other kinds of business but they can lure patients and definitely trivialise the risks of Surgery.

- It should be unlawful to have patient sign "contracts" where in the terms and conditions there are punishing Cancellation Policies.
- A "cooling-off" period of a minimum of two weeks between the date of first Consultation and the date of Surgery should be established so that the patient has the time to re-consider, discuss with significant others and assimilate all implications of the surgical process.
- The Clinic must be responsible for ensuring and advising its customers that the Surgeon involved:
- Is on the Specialist Register;
- Is permanently resident in Ireland:
- That there is Medical and Nursina back-up 24 hours a day seven days a week:
- All operations are performed in a regulated medical environment.
- No one should be offered Cosmetic Surgery under the age of 18.
- If there is any sign that there might be a serious psychological dimension to a patient seeking Cosmetic Surgery (such as Dimorphic Syndrome) they should be politely and with due sensitivity guided to seek psychological help.

To summarise:

Since the Clinic is the first port of call of the public and the easiest accessible source, where all concerns of a patient are dealt with, the Company must apply all reasonable care to safeguard the patients' health. Profits must become secondary to patient health and safety. The prospective patient might not understand fully the implications of applying proper standards but should feel confident that the Clinic has made sure that all correct procedures and checks are made on his behalf.

Section 2: The Surgeon

Surgeon's Qualifications

In Ireland, today, there is a lot of confusion about who is properly trained to safely perform Cosmetic Surgery. In most of Europe (with the exception of the UK), as well as in the USA, Australia, Japan and Singapore, there is a list of cosmetic procedures that a practitioner can perform according to his qualifications and formal training. In Ireland (and the UK) there are unofficial guidelines-recommendations but there is no legal framework.

Therefore, as long as a patient consents to have surgery performed by a specific Doctor, no matter what his qualifications are, then that Doctor is allowed to perform the procedure agreed. The problem arises because of the many and confusing titles that practitioners performing Cosmetic Surgery have. As a result the public does not have a clear idea of who is trained to do what.

The following titles are some of the ones used to indicate a practitioner who currently performs surgical and non-surgical cosmetic procedures:

- Plastic Surgeon;
- Cosmetic Surgeon;
- Aesthetic Surgeon;
- Cosmetic Doctor;
- Cosmetic Physician;
- Facial Plastic Surgeon;
- GP with interest in Cosmetic Surgery;
- Dermatologist;
- Cosmetic Dermatologist;
- Cosmetic Dentist;
- GP
- Nurse Specials in LASER, Injectables, Cosmetic Procedures;
- Cosmetic Practitioner;
- Aesthetic Practitioner.



In Ireland, any Doctor with a basic degree from a Medical School with no further training or Specialisation can perform legally any cosmetic surgical procedure, as long as their patient consents to it.

Unfortunately the public is not aware of the differences between the above titles.

Companies and Practitioners often prefer this confusion which allows anyone of the above to be referred to as a "Specialist".

Furthermore the public in Ireland is not fully aware of the difference between the General and the Specialist Register of the Irish Medical Council.

A Doctor can be on the General Register as long as he/she has obtained a primary Degree from a Medical School. No further qualification or training is necessary to be on the General Register.

A GP is also on the General Register but he/she had further training in General Practice.

The Specialist Register is the list of Doctors who following their graduation from Medical School, had formal training in one of the approved Specialities and sat successfully the exams of their Specialty.

The credentials of anyone on the Specialist Register have been checked by a committee of the Medical Council consisting of Consultants of the relevant Specialty.

Cosmetic Surgery is a sub-specialty of Plastic Surgery.

The full title of a Plastic Surgeon on the Specialist Register is: "Specialist in Plastic, Reconstructive and Aesthetic Surgery" Aesthetic being the Greek word for Cosmetic.

Cosmetic Surgery is not a recognised Specialty. It is a branch of Plastic Surgery. There is no specific training in Cosmetic Surgery only that applied through the formal training of Plastic Surgery. A Plastic Surgeon during his training in various sectors of his specialty will train in Burns, Breast Reconstruction, Hands, Trauma, Congenital Deformities, Head& Neck Cancer etc, and Cosmetic procedures.

As a result there is no formal title of "Cosmetic Surgeon" or "Cosmetic Doctor" etc. These are all titles that are made up, that one can call himself, but are not recognised by the Irish Medical Council (IMC).

The guidelines of the IMC, the ONLY professional and regulatory body concerning Doctors, are very clear:

- Only a Consultant Plastic Surgeon is qualified to perform Cosmetic Surgery.
- Only a Consultant Plastic Surgeon and a Consultant Dermatologist are qualified to perform non-surgical procedures.
- Everybody else has not been trained and should not perform the above.
- Some of the less invasive non-surgical procedures, such as certain LASER procedures and Injectables can be performed by a trained Nurse or Medical Practitioner but only under the guidance and overall responsibility of either a Plastic Surgeon or a Dermatologist.

Unfortunately the IMC has only an advisory role. In order for those guidelines to be implemented there has to be a law.

It is the responsibility of the Department of Health to inform the Irish Public and to protect it through legislation. If the above recommendation becomes Law, then not only the incidence of Complications will be reduced, but even when complications occur they will be dealt with by a practitioner who had the necessary training and experience.

GP's and Doctors with no specialisation or Consultants of other Specialties such as Dentists and Anaesthesiologists who are currently performing non-surgical procedures will have to prove their level of training before they are licensed.

A Certificate of Competence awarded by the IMC would allow Doctors to perform specific non-surgical procedures and such Certification should be prominently displayed, in the premises where those procedures are performed.

We have all seen various "Diplomas" and "Certificates" confirming the proficiency of a practitioner in the use of a product, such as dermal filler or a technique such as non-surgical Breast Augmentation.

Most of those "Diplomas" are awarded by the manufacturer of that product or the appliance used.

Half a day's training is usually more than enough for such a "Diploma" to be awarded. The aim of the manufacturer who awards such certificates is to maximise the market share and public awareness of their product. The manufacturer is prepared to "train" and distribute his products to practitioners who otherwise should not be eligible to perform such procedures.

Surgeon's Country of Residence

A practitioner should not only hold the necessary qualifications but should also be able to prove that he is capable of providing the necessary aftercare to his patients.

Clinics in search of Plastic Surgeons are prepared to bring a Visiting Surgeon. It is well documented that at present there is a significant number of Plastic Surgeons who fly in and out of the country simply to perform procedures.

- They come from all over Europe, South Africa, USA and Latin America.
- They are flown in by certain Clinics.
- They stay in Ireland for only a few days at a time.
- They consult "pre-selected patients" i.e. patients who have been through an initial consultation with a Nurse, at best, or sometimes, a non-medical, sales-executive.
- They operate on those patients.
- They fly out shortly after to return back after a few weeks.

Most of the time the patient is totally unaware that he/she will be treated by a visiting Surgeon.

If asked, the Clinic often try to persuade the prospective patient that there will be proper aftercare from the Nursing staff or another visiting Surgeon. There is therefore no continuity of care or a safety mechanism. This whole process is a disaster waiting to happen.

The practice of using visiting Surgeons is dangerous and it should be illegal to facilitate or employ such a person.

Section 3: The Hospital / Facility

In Ireland, today, any building can be called a Hospital without any form of inspection or approval and surgical procedures can be carried out.

The presence of the patient on the premises and the consent he/she signs prior to surgery, automatically legitimises an otherwise unregulated place as a medical environment where surgical procedures under General Anaesthesia can be performed.

Regulations are absent.

The licence to open a fast food restaurant is granted after inspections by the Food Hygiene Authority, Health and Safety Authority, Fire Brigade etc. Strict regulations have to be followed. This however is not the case with places where people are having surgery.

Naming a place "Hospital" or "Clinic" does not make it a safe medical environment.

There are buildings that are completely inadequate and dangerous, where people are sometimes lured through misinformation to have invasive surgery.

I know of instances where there have been "near misses" where patients had to be carried out of the operating theatre, in chairs, semi-conscious, as there was no lift to move the patient. I have seen operating theatres in basements or on top floors, accessible only through narrow staircases. No fire-escapes, no positive air-flows for infection control.

Instruments and High tech Anaesthetic appliances are old, worn out and often not even properly serviced. Sterilisation procedures can be ancient. In some cases sterilisation of instruments is performed using outdated techniques.

It is a miracle that we have not seen more tragic incidents.

Nursing staff in some places are employed on a part-time or even on an hourly basis in order to minimise costs.

The "Clinic" becomes a Clinic just 30 minutes before the arrival of the first patient who is having surgery on the day and stops being a Clinic 30 minutes after the discharge of the last patient the following morning. There is no continuity of care from the Nursing staff.

Purchase of consumables is done in a haphazard way where price and the need to minimise costs is the only parameter that counts.

Operating lists are enormous, going on well into the night. It is common practice for the last patient to enter the operating theatre at 9pm. This is done in order to maximise use of Nursing Staff.

Operators of these "Clinics" are business people who are not only ignorant about medical matters but resist any advice that will reduce their profits. Patients are discharged in a hurry to evacuate the bed for the next scheduled patient.

Rooms and WC facilities can be very basic. Patients might be stacked next to each other with barely enough space to move. Cleanliness is questionable. A medically clean environment is different to a clean house or office.

Resident Medical Officers through the night are non-existent; meanwhile the Surgeon is boarding the plane, a few hours after he has finished his last procedure.

Recommendations

These facilities must be properly regulated. The regulatory body that inspects and licenses these premises must have the right to perform routine as well as on the spot inspections. Complaints procedures must be clearly explained to the patient and "hot-lines" need to be available to advise.

Full diaries of routine operations, unforeseen incidents, near-misses and complications must be recorded with all other patients' records. The Data Protection Act must be followed.

Back-up electric generators and anaesthetic gases should be available and resuscitation equipment should be in full working order and Nurses must have an up to date Advanced Life Saving Certification.

Established contacts with Blood Banks and large Hospitals must be present in case a patient needs to be transfused or transferred in an emergency.

As a rule, in order for a surgical procedure to be performed in those premises there should be a certainty that the Medical/Nursing Staff and the Hospital facilities can cope with the most extreme complications that might occur for that specific procedure.

A fully qualified and Registered Nurse or a Medic must be the licence holder and should be employed full time by the Clinic.

She/he will be held responsible for the implementation of all the relevant guidelines. Their professional registration should be at risk if they are found negligent. Businessmen have no licences to lose and can always use the presence of medical professionals as an alibi. In the recent past when owners of such failing Clinics have been asked why they allowed dangerous conditions, they have answered that they were simply laypeople who knew nothing of safety practices in Surgery and since the Surgeons and Nurses were happy to continue to practice in their establishment, who were they to question this?

Section 4: The Regulatory Body

The need for a Regulatory Body is apparent.

The experiences of the National Care Standards Commission in the past, and the recent Care Quality Commission in the UK have shown that when regulation and inspections are introduced, standards of practice are improved enormously and unfavourable outcomes are greatly reduced.

If the above recommendations are followed and are embedded in a legal framework then Cosmetic Surgery can become a much safer and still remain a profitable business.

The Irish Government is there to safeguard the well being of the Irish Citizens. It should act now.



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