Comhairle na nDochtúirí Leighis
Medical Council

Doctor & Patient views on reforming the Complaints Model

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1. Background

The primary objective of the *Complaints Model Framework* project is to develop a policy that informs and makes recommendations on a re-envisioned complaints model. It will enable the Medical Council to reflect on existing approaches and explore how to rebalance its regulatory model through the adoption of a proportionate, risk-based and agile approach. The aim is to create a pathway to manage complaints appropriate to risk.

The reform of our complaints model is occurring at a time when medical regulators worldwide are increasingly focusing on the experience of doctors and patients. Indeed, regulators such as the General Medical Council (GMC) and the Australian Health Practitioner Regulation Agency (Ahpra) have strategically implemented fundamental reforms to their complaint's models.

To support development of this policy, an in-depth rapid research analysis was undertaken of regulatory models and approaches to complaints in international jurisdictions[1]. This paper identified key themes including transformative reforms and developments, varieties in processes, potential for bias and marginalisation of the public from regulatory powers. It recognised that within the extensive body of research into doctor and patient experiences there is clear symmetry of priorities and concerns for both groups - fairness, transparency, communication, timeliness and empathy. This is also reflected across five reports undertaken and commissioned by the Medical Council that explore and analyse Irish complaints data from 2008-2023.

This research study seeks to build on the above body of knowledge in order to support and inform the *Complaints Model Framework* project. It explores and considers both the doctor and patient experience together. Giving voice to our stakeholders is crucial to help ensure that the new complaints model fosters transparency and garners support for implementation. It enables the identification of key concerns, needs, and opportunities for improvement, thus enhancing the model's effectiveness and acceptance.

This study ensures appropriate and meaningful engagement from patients and doctors by using a Patient and Public Involvement (PPI) approach, taking the form of facilitated focus groups with both cohorts of stakeholders. PPI can be defined as, '*research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them'* (National Institute for Health and Care Research, 2021). PPI is now understood as a cornerstone of health research, with the Irish Health Research Forum describing PPI as, *'occurring when individuals meaningfully and actively collaborate in the governance, priority setting and conduct of research, as well as in summarising, distributing, sharing and applying its resulting knowledge.'* (Health Research Charities Ireland, 2018).

PPI can help focus questions on areas that patients/public consider to be important. It can improve the quality and relevance of models and services for the end users. Asking the right

[1] Council received an in-depth paper presenting a rapid research analysis of regulatory models and approaches to complaints in international jurisdictions.

research questions and addressing issues that patients and public view as important, whilst using methodologies that they are more likely to engage with, can all ensure that processes and approaches are more efficient, and resources are optimally utilised. Importantly, meaningful PPI in this project will clearly signal the Medical Council's commitment to engaging the voice of patients/public and doctors, as set out in our Statement of Strategy and business plan objectives.

2. Research Objective

To facilitate engagement and discourse by patients and doctors on key issues relating to the Medical Council's complaints process with a view to exploring and informing a revised complaints model that fosters transparency, efficiency, effectiveness and acceptance by key stakeholders.

3. Method

3.1 Design

A qualitative research design was employed with data collected using in-depth focus groups and a subsequent guided reflection (see appendix 1), which yielded further data. A purposive sampling technique was used to recruit doctors and patients and to facilitate maximal diversity. Data were analysed using Braun and Clarke (2019) model for reflexive thematic analysis.

3.2 Participants and Recruitment

Patient participants were sought through patient representative and advocacy groups, including the Irish Platform for Patient Organisations, Science and Industry (IPPOSI), Patient Advocacy Liaison Service, HSE National Patient & Service User Forum and Patients for Patient Safety. An information leaflet seeking patient participation was distributed to patients through the above group (see appendix 2). Patients contacted the research team to express interest in the focus group. They were advised that would participate in their capacity as patients and members of the public, rather than representing a specific patient issue or patient advocacy agenda.

Doctors were recruited through Irish Hospital Consultants Association (IHCA), Forum of Postgraduate Training Bodies, NCHD Lead, CareDoc, North Doc, South Doc, ICGP, Train Us for Ireland (TUFI), the Association of Irish Pakistani Physicians and Surgeons (AIPPS), as well as indemnifiers including Medisec and Medical Protection Society (MPS). An email was distributed to the above providing information on the focus group, and interested doctors contacted the research team for further details.

Potential participants were asked to respond within a two-week timeframe if they were interested in participating. Feedback from doctors indicated that an online option only for the focus group

would be preferable, as it would be more accessible and inclusive, while patient representative groups suggested that an in-person approach would be more constructive as their knowledge of the role of the Council was likely to be limited and they may need more guidance and support to engage interactively.

A total of 12 patients expressed an interest in participating and all were invited to join. In total, over the two-week period, 48 doctors expressed interest in participating and were invited to indicate their availability for specific times and dates. Only 19 of these were available at the times specified. Attention was given to ensure representativeness of the sample of doctors in terms of demographics, division of the Register, area of practice, and 13 doctors currently registered with the Medical Council were invited to attend two online focus groups.

All participants received an information pack (see appendix 3) in advance of the focus group meeting, containing details about the nature of the focus group, parameters of the discussion, including specific areas and topics to be explored. Also included were privacy and confidentiality statements, prepared by the Head of Information Governance, and practical details including directions to the Medical Council's office.

A total of 9 patients attended the focus group, which consisted of 3 males and 6 females, from a wide geographical area, including counties Sligo, Clare, Dublin, Galway, Westmeath. A number of patients had particular health needs which required support on the day of the focus group.

The doctor focus group comprised two parts, each lasting one hour on two subsequent evenings, and the same cohort of doctors attended each focus group. 11 doctors attended the first and 9 attended the second focus group, with two unavailable due to work and personal circumstances.

Doctor characteristics are presented in Table 1.

Table 1. *Doctor characteristics.*

Sex	**N**
Female	5
Male	6
Division	
Specialist	8
Trainee Specialist	1
General	2
Qualification Category	
Irish	8
International	3
Area of Practise	
General Practise	5
Occupational Medicine	1
Psychiatry	2
Paediatrics	1
Radiology	1
Anaesthesiology	1
Previous Complaint	
Yes	5
No	6

3.3 Consent Considerations

Participants were introduced to the research study through information via email and were issued a privacy notice, explaining that focus groups would be recorded and transcribed (see appendix 4). All participants were assured that personal data would be anonymised and personal identifiers removed. Data would be processed and stored securely in line with General Protection Data Regulations (GDPR). All participants gave signed consent to the privacy notice in advance of participating in the focus groups.

3.4 Data Collection

The data were collected during early June 2024 through focus groups and subsequent guided reflections, which participants received via email. The patient focus group took place in the Medical Council's office on 4th June from 10.30am-2pm. The doctor online focus groups took place on 5th June from 8pm-9pm and 6th June, 8pm-9pm with the same cohort of doctors. All focus groups were audio recorded and transcribed verbatim. The focus groups were facilitated by Kathyan Kelly, Independent Research Consultant, with considerable experience facilitating focus group research and engaging the voices of the public. Members of the Research Team were present and took detailed notes and responded to any questions on Medical Council processes and supported patients with particular needs.

The focus groups commenced with an overview of the objective and outline of ground rules. The patient focus group included a detailed explanation of the role and remit of the Medical Council and its complaints procedures. Doctors demonstrated an understanding of the above and many were keen to describe their experiences. In both instances, broad, open-ended questions were used to encourage and facilitate narration. For example, the facilitator asked participants about their perceptions and experiences of engaging with the Medical Council and followed up with supplementary questions. Participants were presented with vignettes or real-life case studies (see appendix 5) based on data already gathered by the Medical Council relating to doctor and patient experiences of the complaints process, and these provided useful prompts for discussion. These case studies were prepared from discussions with the Complaints and Investigations and Fitness to Practice teams. They highlighted the journey of doctors and patients though the complaints process, building in key themes and challenges identified in our complaints reports, 2008-2023. Participants were invited to respond to the vignettes and openly share their perceptions of what a balanced and proportionate approach to our complaints could look like. They were supported and encouraged to engage in a design thinking process involving problem-solving and creatively exploring ideas and practices in smaller break-out groups.

The in-depth nature of the topic and limited time for discussion proved challenging and in order to gain further insight and details, participants were asked to provide feedback and input in the form of a subsequent guided reflection. This exercise was useful in prompting participants to reflect on their and other participants perspectives and perceptions and draw further insights.

Guided reflections were emailed to all participants a week after the focus group and responses were provided by five doctors and seven patients within a two-week timeframe.

3.5 Data Analysis

The focus group data were analysed using qualitative reflexive analysis as described by Braun and Clarke (2017). NVivo, a qualitative data analysis package, was used to support analysis, generate codes and identify themes.

First phase: The first phase involved becoming familiar with the data through listening to the audio files, reading transcripts thoroughly, including guided reflections, and generating initial ideas of what was in the data and what was interesting about it.

Second phase: Phase two involved generating initial codes using NVivo and notes from the focus groups. The data were approached with an inductive orientation. A long list of initial codes from the data was produced; for example, "need to meet KPIs", "support dialogue", "empathy and involvement". Separately, the guided reflections helped corroborate the data, thereby enhancing the validity and reliability of the findings.

Third phase: In this phase, themes were constructed using codes as building blocks. They were constructed from the previous initial codes used to categorise the data. Themes were defined, named and checked against the dataset to ensure the data related to a central organising concept.

Fourth phase: During this phase the guided reflections were used as a means of triangulation, and this helped develop a comprehensive understanding of key issues relating to the Medical Council's complaints process. Themes were reviewed against the entire dataset to potentially rework themes, create new themes and validate themes.

Fifth phase: This involved writing up the analyses of patients and doctors experiences. The findings were discussed among the research team to ensure consistency. Themes and subthemes were revised to clarify their content and to develop a richer more nuanced reading of the data. Although this appears as a linear process, the analysis process involved a constant back and forth movement between the whole and the parts of the data.

4. Research Findings

4.1 Thematic Analysis of Doctor Focus Group

The necessity of a formal complaints process for serious cases was evidently expressed during the focus groups. However, the need to improve the current model was also stark; this was required for the Council, patients and doctors. A number of themes were generated from the discussions during the focus groups including the complaints process being an emotionally taxing experience, which needs to include support for doctors. In addition to this, strong themes identified included the need for alternate informal processes prior to the complaints procedure, streamlined processes, improved communication and increased accountability. These themes have many linkages and are discussed with illustrative quotations below.

Emotionally Taxing Experience

The prospect of receiving a complaint from the Medical Council elicited a strong emotional response among doctors. One doctor spoke about carrying this as a concern every day for their career while others spoke about the constant fear of being complained about.

> *"I am not knowledgeable in the sense I have not had a complaint, but would have been committed to being part of this because of the awareness I've had of how I carried it as a concern every day for my 37 years since I qualified."*

Other doctors shared the *"shock"*, *"anxiety"*, and *"stress"* of receiving a complaint. It became clear that this was often an *"isolating experience"*.

Receiving a complaint had a negative impact on a doctor's mental health. One doctor shared feeling dehumanised by the process, another spoke about suicide risk during the process and others spoke about how emotionally traumatising it is to be complained about and to undergo a lengthy investigation.

> *"the Medical Council has an ethical duty to look after doctors because doctors under complaint are at risk of suicide"*

> *"it's very emotionally traumatising as well at the time to find out that ok, you saw this patient a few months ago and suddenly you have this complaint against you and you had no idea that, you know, something had happened."*

The impact of the complaint was emphasised when doctors described being *"subjected to"* or *"suffered from"* a complaint. This may be worsened by poor communication and information around timelines.

"Well, I suppose the thing is not knowing when the outcome is going to be or... I know I was given no timeline or anything as well. It's just kind of there in the back of your head the whole time."

It is important to note that the doctor may be dealing with several other factors in their personal lives and the doctor's family may also be impacted by the complaint.

There was often a level of shame and secrecy associated with being complained about whereby doctors did not feel comfortable sharing this information with other colleagues. Beyond the personal impacts, the professional impacts in terms of hindering career progression and training opportunities and practising cautious medicine were also clear. Importantly, doctors experienced some of these concerns about complaints even if they had not received one, and doctors who had their case closed with no further action also shared how emotionally taxing the experience was, irrespective of if the complaint was open for seven months or three years. Many of these doctors also described their complaints as *"grievous"* or *"misguided"* and there was a sense that sometimes patients can be challenging and more likely to present a complaint.

Support for Doctors

Due to the strong emotional impact a complaint can have on doctors there was a sense that this process needs to be handled with caution and care. The current complaints process, in the eyes of doctors, was lacking in support for doctors. There was also a sense that the remit of the Medical Council, from a legislative perspective, is protecting patients and the public, not doctors. Many of the participants felt that the Medical Council has an ethical duty to support doctors, even if it is not outlined in the legislation.

"But like in fairness, the Medical Council, without being disrespectful, doesn't care about doctors. It's not its remit. Its remit is to look after patients and the public."

"Ethically, the MC now knows that the process is negatively impacting on doctors and is still not acting."

Supports at varying levels of complexity were suggested by doctors, ranging from better signposting to key workers within the Council, peer support services and counselling services. Importantly, these supports need to be immediately outlined and clearly communicated to the doctor. This should therefore be explained in the initial notification and the website should clearly outline what the doctor can access and where they can access it. While no major issues with website navigation were outlined during the focus groups, having a sample of doctors to navigate the website to test if this is easily accessible was suggested by one doctor.

Key Worker Support

The first line of support suggested was a *"key worker"* within the Medical Council, beyond the current case officer. Case officers were described as helpful, but they cannot support the doctor as they are a neutral point of contact for both the doctor and the complainant and carry out a number of the investigations as directed by the PPC. This key worker should be a single point of contact for the doctor that can support them with all logistics. This includes keeping them updated on the status of the complaint, signposting to mental health supports, supporting communication with other doctors involved in the complaint or enabling access to medical notes if the doctor has moved to a new place of employment, as is often the case with NCHDs. These key workers need to be identified in the initial notification, knowledgeable of the process, have excellent communication skills and an ability to display genuine empathy towards people.

"I think it should be that if there is, you know, once there's a specific person from the Medical Council appointed to that person, to that case even, that they act as, you know, a connection between different people and they are able to, you know, talk to the person and guide further even that, ok, this has happened and now this is the next step, and this is what you do."

"there would be like a key worker appointed by the Medical Council who works in the Medical Council to communicate with the doctor in a sympathetic and, you know, to just give them updates and advice, that they would have a phone number and a contact and an email of somebody in the Medical Council that they could liaise with."

Counselling Service

The need for a counselling service was also identified. Doctors had different opinions about how this would work best but generally suggested phone counselling option to begin with the opportunity to move to in person sessions if required. Doctors also suggested that this be available outside of office hours or 24/7 if possible, that the counsellors are accredited by the Irish Association of Counsellors and Psychotherapists (IACP), that the number of sessions are not limited, and that ideally support is also available to the next of kin and family as they are also impacted by the process.

Peer Support

There were also suggestions of an official independent peer support service, similar to a UK service for doctors (Doctors Support Service). This should be funded by the Medical Council, with proper structures in place so that peer supporters receive appropriate supervision, training and support. Peer supporters should be available upon request to all doctors going through the complaints process. This may involve both doctors who have been through the process who want to volunteer their time and doctors without personal experience that still wish to support colleagues. Becoming a peer supporter would also allow interested doctors to give back and support colleagues.

"My sense is that a confidential peer support group would be the most welcome format. Most doctors feel great empathy for a colleague working through a complaint and support from a colleague is always welcome due to shared fears, concerns and common experiences. Training is critical to ensure unbiased and professional boundaries are maintained."

"I believe doctors like myself who work diligently daily through their career to manage risk in their own personal work and to support safe practice throughout the patient service they work in, would welcome the opportunity to formally train as a peer support."

Junior and International Doctor Support

It was suggested that certain cohorts of doctors may need additional supports and may find themselves in a more vulnerable situation if they are newly qualified or newly arrived in the country. NCHDs in hospital settings often do not have their own private insurance and the HSE indemnity will not cover them if they are complained about. Several doctors suggested that the Medical Council, or other relevant bodies, should advise these doctors around getting their own insurance. However, one doctor acknowledged that they may not be in the financial position to do so, and the Medical Council may just need to acknowledge and account for this vulnerability in some way, while another doctor suggested the HSE should increase their cover for these doctors.

"I suppose really what struck me yesterday evening was the young doctors who, the Clinical Indemnity Scheme from the HSE doesn't cover them for Medical Council complaints. They don't seem to know that, particularly if they didn't qualify here and it's just, I mean it beggars belief to think of a young doctor, perhaps not Irish, who's come here and ends up with a complaint and there's nobody to help them. And they have no legal support either because you need to know how to respond to a Medical Council complaint."

"But I am really aware of that horrible misnomer, non-consultant hospital doctors, where people are defined by what they're not. I never understand it, but you know, I'm very aware that, you know, when you're in training, you've so much pressure going on. You don't really understand things. You often won't have enough money to be paying extra to a medical defence society"

Doctors shared that medical indemnity insurance was extremely helpful in navigating the process, but that it was limited to dealing with the complaint and could not provide the support required. Doctors often felt that they must remain professional in their response to the complainant and go through their legal support, even when they found the complaint upsetting.

"I've always found the MPS to be very good. They do help you. They kind of want you to, they just want to kill it. They don't want anything to go ahead and they just want you to say you're sorry and that'll be the end of it. But they do give very good advice, but the Medical Council itself generally tells you nothing."

Alternative Resolution Processes

There was a sense that a complaint can sometimes originate from a patient not being listened to, or from a misguided understanding of the remit of the Medical Council or the purpose of the complaints process. There are also instances where doctors have a difficult relationship with patients whereby supports could be provided. In some cases, the doctors felt it was too easy to complain. In these cases, alternative methods of resolution to the formal, legalistic complaints procedure were suggested.

- Facilitated Conversation

Doctors wanted to encourage some form of step down, or a more *"amicable solution"* than the formal complaints process where patients discuss their issue at a local level before pressing the *"nuclear button"* and submitting a formal complaint. One doctor shared that whenever there is a difficulty identified in the patient doctor relationship at their practice, they encourage their patients to engage in conversation, and to bring a family member with them to help articulate their concerns. This was implemented by a colleague from the UK, and has proved constructive and beneficial. Promoting such initial conversation was welcomed by most doctors.

- Local Resolution

Various suggestions were offered around this such as promoting local resolution on the website so that de-escalation and potentially quick action should be actively encouraged by the Council where appropriate. Patients may also be encouraged to bring someone with them, potentially a family member, especially if one had a medical background, to discuss their concerns.

"encourage on the website or some other way for people to discuss in a respectful and confidential way their annoyance or their you know, for those minor things with somebody before they press that button and make the complaint"

The need for very clear criteria around what would be suitable for resolution outside of the Medical Council complaints process and the involvement of the Medical Council was identified.

"So it needs to be very clear. There needs to be a code of practice of what exactly you can resolve informally and how you should do it."

- Mediation and Tiered Approach

There was extensive discussion about mediation and who would be appropriate to act as a mediator, with suggestions around a medically trained mediator or a generally trained mediator and avoiding potential bias. Various different suggestions around a *"tiered process"* were made, with the overall sentiment was that it should be facilitated and structured. A potential tiered approach might involve a helpline at level one, with trained Medical Council staff to advise patients on the expected process after they make a complaint and the list of possible outcomes, and with a view to managing expectations. Following on from this a mediation service would be useful which might involve either one or two levels. One important consideration would be whether the patient is encouraged to bring a family member or advocate with them to help them articulate their concerns. The second level could be a trained mediator or facilitator without a medical background, and following on from this at level 3, a mediator with a medical background. While exact details were not fully teased out, it was agreed qualified and trained mediators would be needed at both levels. Further granular suggestions were made, for example, whereby the patient's GP could be trained in mediation to resolve disputes with hospital doctors or a patient's GP might resolve disputes with out-of-hours doctors.

"that if they're non-medical, it should be a two-step process. So realistically, if it is not soluble at the mediator non-medical level, that a medical mediator would be the next step in the process."

- Avoidance of Legal Processes

The avoidance of Medical Council and legal processes until all other options were exhausted were suggested as the goal here.

"Keeping it a bit away from the formality of the Medical Council. That's where the, that's I think where the issue is. There seems to be a big Chinese wall at the Medical Council. Once you go across it, you're in a big, long process. And we're trying to keep things outside the wall maybe."

Local resolution without formal legal processes was perceived as leading to better outcomes for both doctor and patient.

"the results are much better for the patient. The relationship can often be saved. I would imagine a lot of your patients going through the Medical

Council would feel they lost their doctor and that may be very much a specialist or a long family relationship."

It was acknowledged that open disclosure meeting may help enable this whereby doctors can apologise and admit some level of guilt. However, it was observed that protecting and defending oneself may be a limitation to mediation, and this would need consideration.

"Everyone's, you know, just so aware that, you know, if anyone says anything, how do I word this? How do I defend myself to the utmost? You know, even if it comes to a mediation, there's a certain degree of everything has to be carefully worded to defend yourself from the fact later on."

Streamlined Processes

The need to streamline processes was evident, as the time taken to deal with complaints was identified as a huge source of frustration and concern for doctors. This also increased the impact that the complaint or prospect of a complaint had on doctors' mental health and their person life.

"And as far as I know anecdotally, it is the biggest grievance of doctors. Time taken."

"I think what you'll find across the board is the primary concern about doctors isn't, like isn't the nature that at some point in time, we might get a complaint. It's the duration to actually closing out that complaint or getting an answer from the PPC as to whether or not you're moving forward to the FTP. I think that, you know, as everyone said before, justice delayed is justice denied for everybody."

Doctors felt that processes to streamline complaints at PPC was very important as the time taken was often overly lengthy. The new processes at PPC to close trivial, vexatious, without substance or made in bad faith complaints was acknowledged but there was a sense that many complaints are still open for a number of months. There needs to be a better process in place to categorise and address complaints based on levels of seriousness, thereby helping to eliminate burdensome timelines. Timelines need to be developed, communicated and adhered to, and furthermore, if they are not being observed this needs to be communicated and explained to doctors. Any duplication of effort should be identified and reduced as this increases both time and cost. One doctor shared that when dealing with complaints legal teams were often requesting the same information.

"The MC needs to be more open and honest about how long a complaint will take, this needs to be set out clearly, and these timelines need to be reduced. If timelines were improved mental health and self-concerns would not be such an issue."

Improved Communication

The Medical Council was perceived as a poor communicator that often emits a distinctly unfriendly attitude in their communications. Doctors felt this both within and out of the complaints process and suggested communicating in a more considerate way. It was evident that the Medical Council needs to be an excellent communicator.

"Not alone the complaints process, even the process of renewal of annual registration is adversarial in the language and accusatory tone of the questions."

"In my experience the medical council is a very poor communicator. They are almost impossible to contact by phone, emails take weeks to be responded to, feedback forms are not acted upon. This needs vast improvement."

Regarding the complaint the initial communication should be reviewed in terms of content, tone, timing and transparency, and this should be considered from the earliest communication. Doctors felt it was crucial that the initial notification was not received at a potentially distressing time for doctors. Generally, it should therefore not be emailed outside of 9am and 4pm Monday to Thursday, so the doctor can contact the Council after the notification. Therefore, it may be important to consider this initial notification further.

"So not only will the Medical Council obviously have to look in at the processes, but they'll also have to be cognisant of sort of when a communication is made, what time of year it is, be it during someone's summer holidays or Christmas, but also how that is framed and that communication is delivered in a sort of considerate way, you know."

"Avoiding an envelope or email being opened causally in circumstances far from ideal or safe e.g., enroute into theatre, while consulting with patients still in the waiting room, at a time of family bereavement, while alone caring for children, etc."

Different suggestions were offered around this initial notification; some doctors suggested an initial phone call followed by an email containing further information, others suggested email only while one suggestion was to capture each individual's preferred method of contact. Beyond the initial notification, doctors also suggested that the Medical Council should be cognisant of the

timing of follow-up communication, for example this may not be appropriate the week before Christmas as it could cause stress for a doctor when they cannot act on the information.

The content of the email with the complaint also needed review. Doctors shared how an unfiltered complaint could be emotionally distressing and drew parallels to other situations, for example receiving feedback from a Human Resources department.

> *"Just that struck me while we were talking was about in HR. You couldn't give feedback to someone by simply sending them the whole feedback on them in any work-related situation. You'd have to agree a meeting time, agree did they want someone with you, all of that, and yet someone can open a 70-page letter about them, you know."*

Since a complaint is likely to cause some discomfort regardless of method of the notification there were suggestions to make this as safe and humane as possible. Some suggested avoiding *"data dumping"* all the information in an email without sufficient warning.

> *"So how that happens, you know, is there an initial communication that says, you know, you have been assigned a key worker in the Medical Council? Your key worker is this person. Please make contact with them and, you know, please do not be unduly alarmed because no matter what, you know, you have ongoing responsibility. You know, some language. And then you move from that to, you know, do you need support to see those notes? Do you need support to communicate with other people involved? Do you need mental health support because we acknowledge these are difficult things?"*

The Medical Council also needs to communicate realistic and expected timelines to the doctors. If NCHDs are having difficulty communicating with other parties involved or the hospital the Medical Council should also enable this and remove any blockages. The Medical Council should also communicate that this is a possibility to NCHDs, one doctor shared that their colleague was taking annual leave and travelling long distances to access medical notes through a secretary at a previous place of employment. If the Medical Council can facilitate this access doctors need to be informed and access should be given in a timely fashion.

Greater Accountability

There was a sense that the Medical Council needs to demonstrate greater accountability and be more responsive to feedback.

> *"Doctors feedback to the Irish Medical Council must always be acknowledge and in a timely manner. Only by demonstrating respect and good*

communication can the Council foster a good working relationship with patients and doctors and improve and enhance their processes."

The Medical Council needs to start being transparent and open in sharing information and data on timelines, which will encourage accountability. Data on the number, types and nature of cases, and those involved in disciplinary actions and court proceedings would also be informative for doctors going through the process, providing a transparent view and helping to manage expectations.

"The other thing is just publication of data. So like the Medical Council publishing data across the board about the complaints, the duration that they're taking, between PPC, FTP, the specialities that are typically being complained about, the levels, be it NCHD or consultant. Because I think ultimately that holds both parties to account."

4.2 Thematic Analysis of Patient Focus Groups

The patient focus group drew on case studies of patient and doctor experiences of the complaints process to generate their views and concerns regarding the complaints process. Overall, patients had less awareness and understanding of the complaints process compared to the doctor cohort, as none had been directly involved in the complaints procedures. However, some patients displayed regulatory literacy, a familiarity with legislation and guidelines for the regulation of the medical profession. Nonetheless, it was evident that the patient cohort had read and learned about the complaints model prior to the focus group. A number of themes were generated from the discussions during the focus groups including the need to redefine a complaint, a perceived power imbalance between patient and both doctor and Medical Council structures. Similar to doctors, improved communication, empathy and humanness were emphasised as crucial, along with early mediation prior to engaging in the complaints process.

Inefficient Processes

The complaints process was perceived as inadequate and inefficient in many ways. Patients pointed out that it was unjustifiably and excessively long, mentioning for example the numerous PPC meetings required to arrive at a decision. Reflecting on one of the case studies, which was forwarded to Fitness to Practise for a formal inquiry but resulted in an outcome of no findings, a participant expressed:

"Well, I think they did very badly from the Medical Council's point of view. It took two and a half years and it was brought up at six PPC meetings."

Referring to the entire length of this case study another patient succinctly stated:

> *"Six [years]…the timeline is ridiculous, is far too long".*

Comments were also made highlighting the excessive financial cost and adversarial nature of the process. Moreover, the process was viewed as overly legalistic, at the expense of being more approachable, empathetic, and humane:

> *"Many patients will not have the knowledge, skills and confidence to engage in a process that can appear overly legalistic or intimidating. It is important to approach the patient with empathy. A vast majority of complaints are made for genuine reasons."*

In addition, the complaint form itself was regarded as not easily accessible and complicated, a sentiment that was common among the participants:

> *"Access to the complaints form should be easy, and it should always be worded in user-friendly language, with the minimum number of steps needed to access the complaints form. The complaints forms themselves should not feel as though they have been written by a legal professional, but rather by a specially trained complaints officer of the medical council. Keeping it simple and non-complicated is always important."*

Imbalance of Power

From the patients' perspective, significant social capital is required to undertake the complaints process, with the risk that those who are better educated being more likely to engage with the complaints process.

> *"People don't have the knowledge, skills and competence, especially when they're experiencing trauma, to go through with a complaint".*

Limited literacy among patients and the feeling of being vulnerable arising from an adverse experience can deter patients from engaging with the complaints process. Patients expressed the view of an unfair power imbalance favouring doctors.

> *"risk on patients' part to making a complaint, especially if it's a small practice, as it can affect how you're treated and perceived."*

Another felt that those with a medical card are less likely to raise a concern or complaint and question whether raising a complaint was *"worth the emotional impact"* especially if one is already ill.

Patients questioned whether the Medical Council truly serves the interests of patients and queried if it is biased in favour of doctors, as succinctly described by a patient as,

> *"A medical body for doctors, not for patients".*

Patient expectations and knowledge of healthcare have increased, and many no longer expect to be passive recipients of healthcare but rather to be actively involved and informed. Patients feel that many doctors are operating through a paternalistic lens and are not open to communicating and sharing knowledge with patients. However, it was noted that younger doctors are more willing to engage.

Feeling *"unsafe", "uncertain"* and feeling unfairly *"dismissed"* by a doctor were cited by patients as factors that might lead them to make a formal complaint, as were care and treatment. Feeling that a doctor was not taking their concern seriously, was treating a symptom rather than the patient, was indifferent to or nonchalant about their issue was raised. Some felt that raising a complaint *"to protect other patients"* from a similar experience was also an important consideration.

Constructive Conversation

From the patients' perspective, a complaint, as defined by the Medical Council, does not begin as a complaint. It was suggested that the term 'complaint' be replaced with *"discussion"* or *"conversation",* given that this is what is required at this early stage- a discussion between doctor and patient, facilitated by a designated person,

> *"Conversations that need to be had"*

Another patient defined a complaint as *"a missed opportunity"* to deal with and address an issue. Patients focused attention on the early outset, stripping back the term 'complaint' to define it as,

> *"A complaint is a query, a level of inquiry about one's own health…a possibility that could be avoided".*

Participants expressed dislike of the term 'complaint', suggesting it is an *"adversarial"* term, with negative connotation that implies fear and anxiety. Efforts should be made to de-escalate what can potentially become a complaint by bringing patient and doctor together,

"How do we nudge doctors and patients to talk to each other?"

Improved Communication

The importance of good communication was underlined throughout the discussions with participants. There were discussions regarding communication between the Medical Council and the patient, and between the doctor and the patient. It was noted that sometimes patients are not even interested in raising a complaint, but what they really want is to be heard and acknowledged:

"It is widely acknowledged that most people wish to be heard and understood. One of the people in the workshop (focus group) stated that they did not want to make a complaint, but was told that it was the only process available."

Participants mentioned doctors need to have more conversations with patients, explain to patients about decisions made for their care (e.g. tests, procedures), and set expectations. The doctor-patient partnership is viewed as essential to *"establish and maintaining trust"*.

Closely related to communication, some participants expressed concern over specific language, such as *"trivial"* and *"vexatious"*. Regarding the word *"trivial"* it was understood this was innocuous in legal parlance, but the term was perceived as disrespectful and offensive for the patient who wants their concerns to be taken seriously:

"Trivial in a legal sense means a situation or offence hasn't reached a level to be considered by a court. As the court's time is too important, wouldn't be able to legislate etc. In everyday English it is offensive. Can you say, 'needs to be dealt with in a lower forum, needs to be referred back to mediation'? There isn't a less offensive word for trivial. Unimportant or minor are equally offensive. I think the whole approach here has to be rephrased."

"vexatious" and "trivial" are very hurtful words for any person to hear. I don't think any replacement label is even needed to be honest. Why label or judge at all? "The patient state…" "Person X stated…" "Such and such a request/response was made/accepted/declined.." State the facts as they occur, honestly and without judgement."

These concerns point to the need for more empathetic language as another tool to address concerns with patients in a more humane way, rather than maintaining the current approach which is understood as cold and impersonal.

Furthermore, suggestions were made in relation to the Medical Council website and more generally about the information that is provided. Information should be presented in a clear and simple manner, in plain English, and keeping accessibility in mind. The possibility of videos, infographics or other visual materials was also discussed. Information provided in this way should educate patients on how to make a complaint in simple terms and outline available options and supports.

Empathy and Involvement

Participants drew much attention to the need for a truly empathetic approach to the complaint process that actively involves patients and their families. It was underlined that efforts should be made to understand and support the patient from an early stage in the process. Patients expressed the need and expectation for *"empathy, friendlier communication"*, rather than rigid, cold processes. Some talked about the importance of empathy in comforting and reassuring a patient who may be feeling vulnerable.

It should be acknowledged that the complaint process can have an extremely stressful impact on the patient and therefore supports should be tailored according to each patient's circumstances, in the form of counselling and patient advocacy services. Participants were positive about being involved in discussions with the Medical Council and thought this was fundamental. The prevalent view was that engaging with patients would be beneficial for all.

"there is a great need for the Medical Council to continue engaging with the patient/partner engagement process, because it will keep the council well-grounded and engaged with a well-principled organisation, with a good base of people who have a wide diversity of health experiences.

"If there is a will within the Medical Council to engage with this group of people, along with their recommendations, the council has a good chance of changing the public's perception."

Involving the patients' families was pointed out as a constructive means of improving the process and making a valuable addition to the conversation:

"...you end up in this, a paper chase, so paper goes in, goes to the Council. The Council do the paper. Where is the point where the Council invites the family and enables them to tell their story and supports them to tell their story to get out the bits that maybe aren't captured on paper? And therefore if we include within the complaint process an impact statement on the family that is captured. You know, that's kind of written within a guidelines type piece. So the family is there within the complaint."

Mediation as Alternative

The possibility of engaging in some type of mediation as a first step in dealing with patients' complaints/concerns came up as a strong theme among patients in general. Mediation was seen as a way to address queries and diffuse possible conflict between patients and doctors, and to engage more closely and efficiently with the Medical Council. Reflecting on one of the case studies presented to the group, a participant commented:

> *… "So if we can come back to the discussion that was in the room earlier where we were saying ok, mediation could possibly, you know, resolve some of these issues. This is a classic example where if mediation has been introduced, at stage one, probably would have calmed [patient] down a bit."*

This was echoed by other members of the focus group, for instance, on a subsequent guided reflection:

> *… "mediation should be available as an option before escalating to formal complaints procedure."*

Participants shared more specific details on how mediation could look like. It was proposed that it could be a local service akin to health boards dealing with different regions. Mediation should be an independent process, with an independent mediator, conducted through a board, including the affected patient, family members, patient advocates, healthcare representatives, and doctors.

It was also pointed out that mediation could take a restorative approach aiming at repairing the patient-doctor relationship, whereby all parties could learn from the experience. For these suggestions to materialise, training and resources should be offered to Medical Council executive, as well as relevant information being available online for patients and doctors.

It was emphasised that mediation does not replace the legal process, but that it is an alternative previous to it. Similarly, it was pointed out that doctors should be encouraged to reach out to the patient first, and this requires better soft skills or *"people skills"* that may be underutilised by doctors.

5. Discussion of Findings

5.1 Interrelation between Doctor and Patient Views

The six themes described in relation to patients focus groups should be seen as closely related to each other, representing an informative and coherent message from patients. The general discontent with a perceived inefficient complaints process, which was seen as lengthy, complicated, and legalistic, appears to have led patients to prioritise the suggestion that the Medical Council adopts a more empathetic approach that genuinely listens to and involves the patient. For this approach to materialise, improved communication among all parties is key, including between doctors, patients, and the Medical Council. Good communication should be embedded at an early stage, even before a concern can be escalated into a complaint. In turn, mediation was identified as a popular and potentially powerful alternative, discussed in detail.

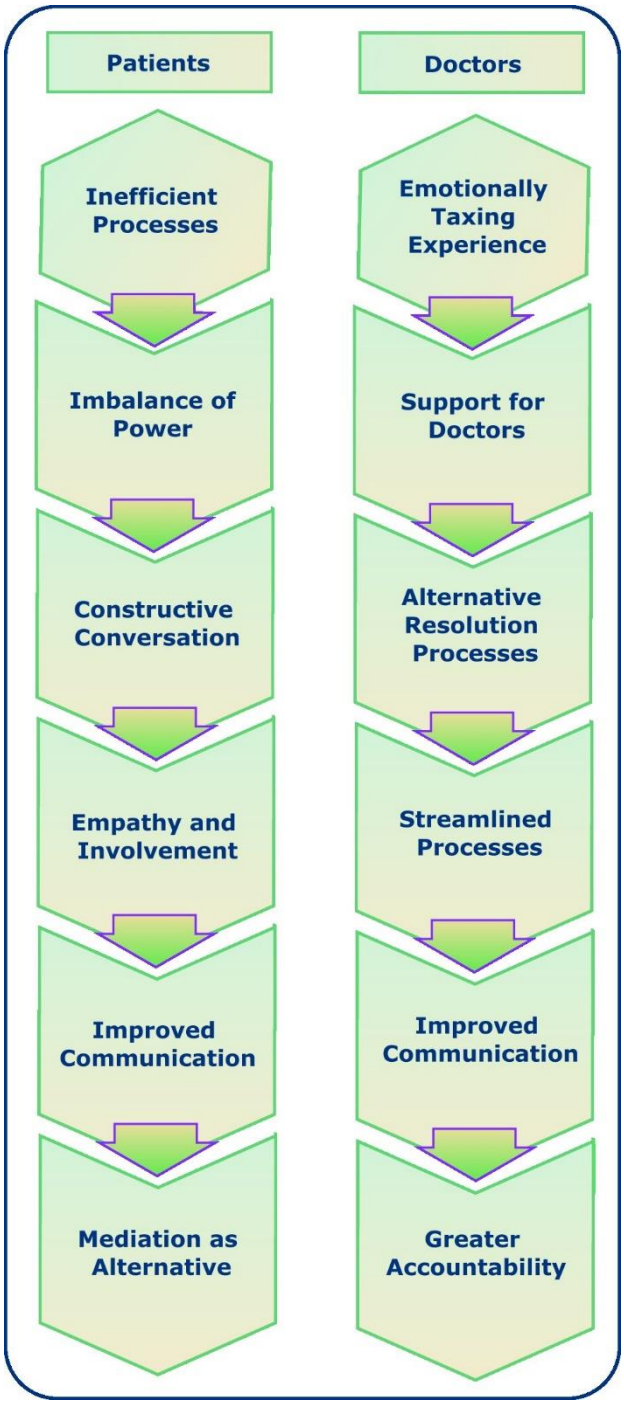
Among doctors, there is keen awareness and understanding of the intricacies of the complaints process and eagerness to share the emotional toll of their experiences. Doctors offered significant insight regarding how the process should be revised and what it should look like. The figure below illustrates the synergy of themes emerging from the doctor discussion:

The findings indicate strong convergence between doctor and patient views of the regulatory complaints process. Both cohorts emphasised the point of pre-complaint and intervening in a timely way at the earliest point to de-escalate and resolve, preventing a formal complaint occurring. Significant discussion centred on current inefficiencies and particular dissatisfaction was raised regarding overly lengthy timelines. While both cohorts emphasised the need for mediation and timely communication, doctors provided greater insight into what this should entail. Patients expressly challenged the general understanding of a complaint, calling for a re-definition of the term and the need for more inclusive conversation between doctor and patient.

There was distinct divergence of doctor and patient views in two specific areas: Doctors viewed the Medical Council as being biased in favour of patients and their interests, while patients perceived the Council and its structures as benefiting doctors over patients. In another instance, patients expressed that there were too many barriers to making a formal complaint, including literacy levels, skills and competence. However, doctors felt that it was too easy and quick for patients to make a complaint. Interestingly, both of these differing views are noted in international research on patient and doctor experiences of the regulatory complaints processes.

The figure below is an illustration of the synergy of the themes emerging from the patient and doctors focus group discussions.

Figure 1. *Main Themes from Patient and Doctor Focus Group Discussions*



5.2 Learnings from International Insights

Our previous research paper presented a rapid analysis of regulatory models and approaches to complaints in international jurisdictions, noting the complex and multifaceted nature of reformative processes. The paper sought to understand and define a good experience for both patient and doctor from an international perspective. The feedback and insight presented in this paper from both doctors and patients in an Irish setting has helped further define this experience

and identify specific areas for improvement to ensure that our regulatory system is robust, responsive, humane and efficient. These lived experiences corroborate and validate international research, providing constructive insight into how the Medical Council might consider changing current practices to improve efficiencies and ensure fairness, trust and confidence in its regulatory processes.

There are numerous corroborated examples between international research findings and those from our focus groups including early and timely resolution, supporting immediate dialogue and seeking to resolve complaints at local level rather than through official legal procedures. Perhaps unsurprisingly, the adverse impact of the complaints process on the psychological and emotional wellbeing of doctors was emphasised by respondent doctors, and accompanying feelings of stress, anxiety, shame, frustration and anger. The broader impact on family and personal life and also on doctors' capacity to care for patients while enduring such stress has been highlighted both in the doctor focus group and in external research. The doctors' perspectives echo Australian research findings that many perceive the complaints process as unfair and punishing, that they were treated as guilty until proven innocent.

While none of the patient participants had personally experienced the Medical Council's complaints process, they expressed concern and dissatisfaction with the overall management and process involved, particularly in relation to timeliness, communication and perceived fairness. This was similarly expressed by doctors along with a sense of lack of transparency and too infrequent communication, also mirrored in extensive international research. Research indicates that an individual's experience of the regulatory process strongly influences the *perceived* fairness of the result or outcome of the process. Perceived unfairness and dissatisfaction were strongly emphasised by doctors and patients. Chamberlain (2017) indicates that greater attention should be paid to examining whether doctors and patients report greater satisfaction with the process, even when the outcome does not find in their favour. This would help generate better understanding of conceptions of fair treatment and impartiality, within the domain of fitness to practise hearings (Case, 2011).

Judgemental bias identified in international research results in the regulator being more likely to take up cases from individuals who clearly articulate their concerns, an issue reflected by patient participants. Also highlighted in the focus groups and in international research is regulatory illiteracy on the part of the public, whereby the remit of the Council and threshold of seriousness is poorly understood. Processes of *"institutional epistemic injustice"* (Anderson, 2012; Fricker, 2007) undermine the credibility of those with limited formal education. The marginalisation of the general public from *"symbolic power"* (Bourdieu, 1989) to define what matters in medical professional regulation is alluded to by patients. O'Donovan and Madden (2018) in their analysis of *complaints* to the Irish *Medical Council argue that some action may be effective such as effectively disseminating information about the role of the regulator. Indeed, this can include* addressing the degree of misunderstanding amongst the general public about the role and function of the Medical Council whether through public awareness, improved website information and content that is accessible by people with diverse needs. However, f*urther changes may challenge the regulator's institutional thinking, as this demands moving beyond understanding emotional evidence as an oxymoron, "Most challenging of all, however, are*

remedial actions aimed at ensuring socially disadvantaged complainants and those with limited cultural and symbolic power are heard and have their complaints taken seriously" (O'Donovan and Madden, p.103).

The research literature refers to defensive medicine as an unintended consequence of the complaint process. This was raised in the doctor feedback, as a means by which doctors seek to protect themselves from patient complaints. In practising over-cautiously and defensively, the best interest of the doctors lies in avoiding issues with patients, rather than ensuring the best medical care and this can represent a direct risk for patient safety.

5.3 What Does Good Look Like?

Arising from the thematic analysis, this section defines the nature of the desired experience for patients and doctors, setting out a 'good' experience. This is centred around principles that include transparency, timeliness, communication- regular and empathetic, and accountability.

1. Implement Alternative Early Resolution Processes

Where appropriate the patient-doctor issue could be resolved locally and in a timely way. This may allow all parties to learn from the experience and may lead to better outcomes for patients, doctors and the Council.

Doctor	**Patient**
Facilitated conversation and local resolution • Promote initial conversation • Define and encourage local resolution pathways • Identify criteria for local resolution	Facilitated conversation in place of complaint • "Nudge" patients and doctors into conversation • Listen to and acknowledge <u>all</u> patients including those with limited literacy and disabilities
Mediation and Tiered Approach • Create tiered approach of informal layers before PPC Layer 1: Helpline to advise on process and expectations Layer 2: Mediation between parties with trained facilitator (not a medical doctor) Layer 3: Mediation by trained facilitator (who is also medical doctor or has a medical background) • Potential learnings from processes used in SouthDoc with focus on de-escalation and local pathways.	Independent mediator • Restorative approach, aiming at repairing the patient-doctor relationship

2. Support Structure

There are supports that the Medical Council can facilitate that might help support patients and doctors. The Medical Council has a legislative basis for protecting patients and the public but ethically has a duty to support doctors.

Doctor	**Patient**
Key worker • Communicate and liaise with empathy from outset	Key worker
Counselling • Qualified therapists • Out of office hours/ 24/7 availability	Counselling
Peer support • Voluntary support network, akin to British Medical Association • Peer support training	Advocacy support • Tailored to meet patient needs
Junior/International Doctor Support • Indemnity advice by Council provided on point of registration	

3. Communication and Transparency

It is incumbent on the Medical Council that it is an excellent and exemplary communicator from the initial outset throughout the entire complaints process.

Doctor	**Patient**
Communication should be filtered and tailored, in place of excessive information that is unfiltered and potentially distressing • Flag an issue/complaint via phone call before an email with info is sent • Follow up with further information at a time that allows the doctor to consider the issue • Provide timely advice on self-care and signposting • Appoint key worker immediately who can provide additional supports and advice • Tone of all communication should be considered and supportive	Communication should be emphatic and humane • Specific legal terms should be re-considered • Website should be improved- easy-to-read language • Complaints form should be more accessible with plain English • Simple videos, infographics, visual materials • Clarify local pathways and supports • Tone should be friendly and empathetic
Statistical data be made available • Data on timelines, numbers and types of cases should be clearly stated on the website	

• KPIs should be set out and progress in relation to international jurisdictions.	

4. Streamlined Processes

The Medical Council should implement processes to streamline complaints at PPC and reduce times to process complaints. Current timelines cause concern and may increase the impact on all parties.

Doctor	**Patient**
Addressing and reducing timelines should be prioritised • Implement triage to effectively categorise complaints and eliminate non-serious complaints	Timelines viewed as unjustifiably and excessively long, and requiring streamlining

6. Conclusions

This research study highlights the value of systematically collecting feedback from doctors and patients about the Medical Council's complaints model, with both groups reporting significant concerns about their experiences and perceptions. This qualitative thematic analysis has enabled us to provide rich and detailed descriptions of experiences and perceptions of the Medical Council's regulatory complaints model. A key advantage of this form of qualitative analysis is that it highlights and draws attention to a broad range of issues which can then form the basis of the development of a policy that informs and makes recommendations for revising the Medical Council's complaints model. The symmetry of concerns for both groups; namely, transparency, communication, timeliness, empathy, expectations, fairness; highlight the importance of understanding the combined experience. Understanding these lived experiences is invaluable to creating a pathway to good practice. These concerns can and should contribute to improvements in the Medical Council's complaints process. Ensuring both the public and medical doctors have trust and confidence in the Medical Council is crucial for effective, efficient and humane regulation that contributes to patient safety and doctor wellbeing.

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Appendices

1. Appendix 1 – Guided Reflection

MEDICAL COUNCIL COMPLAINTS PROCEDURE
GUIDED REFLECTION FOR DOCTOR PARTICPANTS

Thank you for your very constructive, honest and open participation in our recent workshops on the Medical Council Complaints procedure.

A number of issues arose in Workshop 1 which were discussed in breakout rooms in Workshop 2.

We would appreciate it if you could take some time to fill out this guided reflection which outlines the proposed solutions to these issues under the following headings.

Issue 1: Care and Support
a. Care and Empathy for Doctors. Counselling service – broadly welcomed but noted that it needs to be available 24/7, have qualified therapists, no limit to amount of sessions, and that families and next of kin would have similar support. Is there anything you feel would add to this support? Do you have an opinion as to whether this can be achieved online/by phone or if it needs to be in-person?
Your response:
b. Enable establishment of support group for Doctors Similar to British Medical Association – Peer Supporters need to be trained to allow them to journey with the Doctor; Medical Council key worker appointed to communicate/liaise with Doctor. Do you feel this would work well? Do you have ideas on how this could be set up and managed?
Your response:
c. Particular support for newly arrived/young Doctors (esp around indemnity issues) How should the Medical Council act to recognise the vulnerability of newly arrived/young Doctors? Is it sufficient to advise them that HSE indemnification/legal support will not cover them if they are the subject of a complaint or does more need to be done and if so, what are your opinions on how that should look?
Your response:

Issue 2. Communication and Transparency
a. Communication Medical Council seen as a poor communicator. Communication is unfiltered – when notified of a complaint this should be flagged to a doctor in advance and followed up at an appropriate time. How should this be done? Phone, email, both? What advice should be given

around self-care and mental health and how should this be imparted? Would the appointment of a Medical Council keyworker help and if so, who should that person be?
Your response:
b. Feedback forms on doctors' views of the complaints process are not responded to/acted upon. Is there any feedback in particular that you feel is crucial to capture and report on at this stage? How would you like to see this acknowledged and/or presented? Phone, email, written report?
Your response:
c. Statistical data on complaints not freely available What statistical information do you feel is important to have on the Complaints procedure as it stands? What data should the Medical Council share (for example timelines for complaints, specialty of doctors involved, etc please provide as much granular detail as possible)? How would you like this to be communicated to you?
Your response:
d. Medical Council Website
Some comments were made about the website being too text heavy. Can you recommend changes to this? Is there additional information that needs to be made available? If so, what would that be? How would you like this information communicated?
Your response:

Issue 3. Alternatives to the Medical Council Complaints Procedure
Alternatives to the current process were discussed and two options were suggested. Option 1: Create more informal layers – create a tiered approach before the complaint goes to PPC *Layer 1*. Medical Council should provide a helpline to answer questions manned by someone with capacity to respond *Layer 2*. Mediation between Doctor and Patient with trained facilitator (not a medical doctor) – enable a level of discussion between Doctor and patient *Layer 3*. Intervention by Doctor at Medical Council level *Layer 4*. Formal Complaint
Do you have any further suggestions about how this might work at an operational level? Are there any changes you would make?
Your response:
Option 2: Adopt process similar to that used in SouthDoc – eg resolve issues locally
Layer 1. Discussion between SD Doctor and patient GP *Layer 2*. If not resolved, discuss with Medical Directors with patient and GP *Layer 3*. If on GMS Scheme, involve HSE service
How could this local resolution be achieved? What involvement should the Medical Council have here? Is recommending local solution enough or are there any further steps that the Medical Council could consider?
Your response:

Option 1 and 2 were both discussed in the workshops. Which of these two approaches do you feel would work best? If you think a combination of both is a good solution, please provide an outline of how this might work at an operational level. If you feel neither option is appropriate, can you advise on an alternative method of how the Medical Council could deal with complaints – eg triage etc?
Your response:

4. Other Issues
a. Fee It was suggested that the Medical Council should introduce a fee applicable to patients making complaints. This would seem to be a divisive issue. What is your opinion on this?
Your response:
b. Liaison with other organisations/IHCA Particularly in discussion with the provision of support of newly arrived/young Doctors starting out and issues over indemnification. Do you feel this would be helpful and how would it work?
Your response:
c. Front line work v HSE Managers It was stated that, as public-facing professionals, you bear the brunt of decisions/allocations often made by HSE Managers. While this may be outside of the remit of the Medical Council, we would like your views on how engagement/communication with the HSE could be improved and what you would seek to change.
Your response:
d. Future involvement Do you feel there a role for more open dialogue with Doctors within the Medical Council? How do you feel this should work? Please also specify if you would like to be involved in the future and what you would like your level of involvement to be.
Your response:
e. Other issues Are there other issues that did not arise during the Workshop that you have subsequently thought of? Please let us know.
Your response:

MEDICAL COUNCIL COMPLAINTS PROCEDURE
GUIDED REFLECTION FOR PATIENT PARTICPANTS

Thank you for your very helpful and enthusiastic participation in our recent workshop on the Medical Council Complaints procedure.

A number of issues arose during the day and we would like to gather some more detailed information on these topics.

We would appreciate it if you could take some time to fill out this guided reflection based on your input on the day.

PATIENT PARTICIPANT GUIDED REFLECTION
1. Alternatives to the current Complaints Procedure It is clear from the conversation that there are a number of issues around the procedure as it stands, and that most patients would prefer not to be engaged in what is ultimately a protracted legal process if there was an alternative. Mediation has been suggested. How would you see this working? (eg at a local level, involving independent/medical facilitator/family member etc?)
Your response:
2. What supports does the Medical Council need to put in place for patients making a complaint? (eg psychological counselling, access to information about the process etc)
Your response:
3. Language and Communication There are a number of issues around how the Medical Council communicates with patients. In what ways would you like to be communicated with? (eg email only, phone only, combination of email and phone, online). Also, words such as 'Complaint' 'Vexatious' or 'Trivial' are seen to be problematic. Can you suggest alternatives?
Your response:
4. Create a more person-centred process Complaints need to be viewed from a more holistic and personal perspective acknowledging that while the matter may seem small to a Doctor it may be very significant to an individual. How can we change that?
Your response:
5. Power imbalance Many patients will feel vulnerable making a complaint, or unwilling to do so as care choices can be limited. Is there a way to address this?
Your response:
6. Access to information/website Participants felt that the Medical Council website was overly textual and that it was difficult to find information, uninviting and that took many steps were required to find, for example the

complaints form. How can we improve this? How can we better communicate our role to patients/public?
Your response:
7. The Complaints Form We would appreciate your input into how to improve the Complaints Form. Can you please comment on use of language, accessibility, ease of use, length etc. Would it be useful to signpost to alternatives at the start of the form? If so, what should those alternatives be? (eg phone/local mediation/alternative bodies etc)
Your response:
8. Future involvement Do you feel there a role for patient participation within the Medical Council? How do you feel this should work? Please also specify if you would like to be involved in the future and what you would like your level of involvement to be.
Your response:
9. Other issues Are there other issues that did not arise during the Workshop that you have subsequently thought of? Please let us know.
Your response:

2. Appendix 2 - Information Flyer

Medical Council of Ireland
Call for Patient & Public Voices

Who is the Medical Council?

The Medical Council is the regulatory body for doctors. It sets the standards for medical education and training in Ireland. The Medical Council is also where the public may make a complaint against a doctor. If the complaint is serious and raises concerns over a doctor's fitness to practise, the Council can restrict the doctor's registration.

What is this work about?

The Medical Council can investigate complaints from the public about a doctor's fitness to practice medicine. The Council is planning to change the way its complaints process works because there are challenges and inefficiencies in how complaints are currently handled. The Council wants to improve its complaints process and build public trust, enhance patient safety and ensure the wellbeing of doctors.

Why is the Medical Council calling for patient involvement?

We believe patient input is essential to the work of the Council. We know that the input of people who use health services can help us inform and design policy and services that work better and meet the needs of people who use them. The Medical Council is therefore seeking patients to provide input on how we can improve our handling of complaints.

Patient Involvement
Factsheet

Role of the patient
Patient representatives to join an in-person focus group at the Medical Council. There will be approximately 8-10 patients in attendance.

Meeting and duration
The focus group will take place at on **4th June from 10.30-1.30pm**. It will be held at the Medical Council's office in Dublin (Kingram House, Dublin 2). It will be in-person only. The focus group will last 3 hours, approximately.

Expectations for patient partner participation
We want to hear patient's views on the development of a new complaints model and the contribution of patient views is essential to the work of the Council.

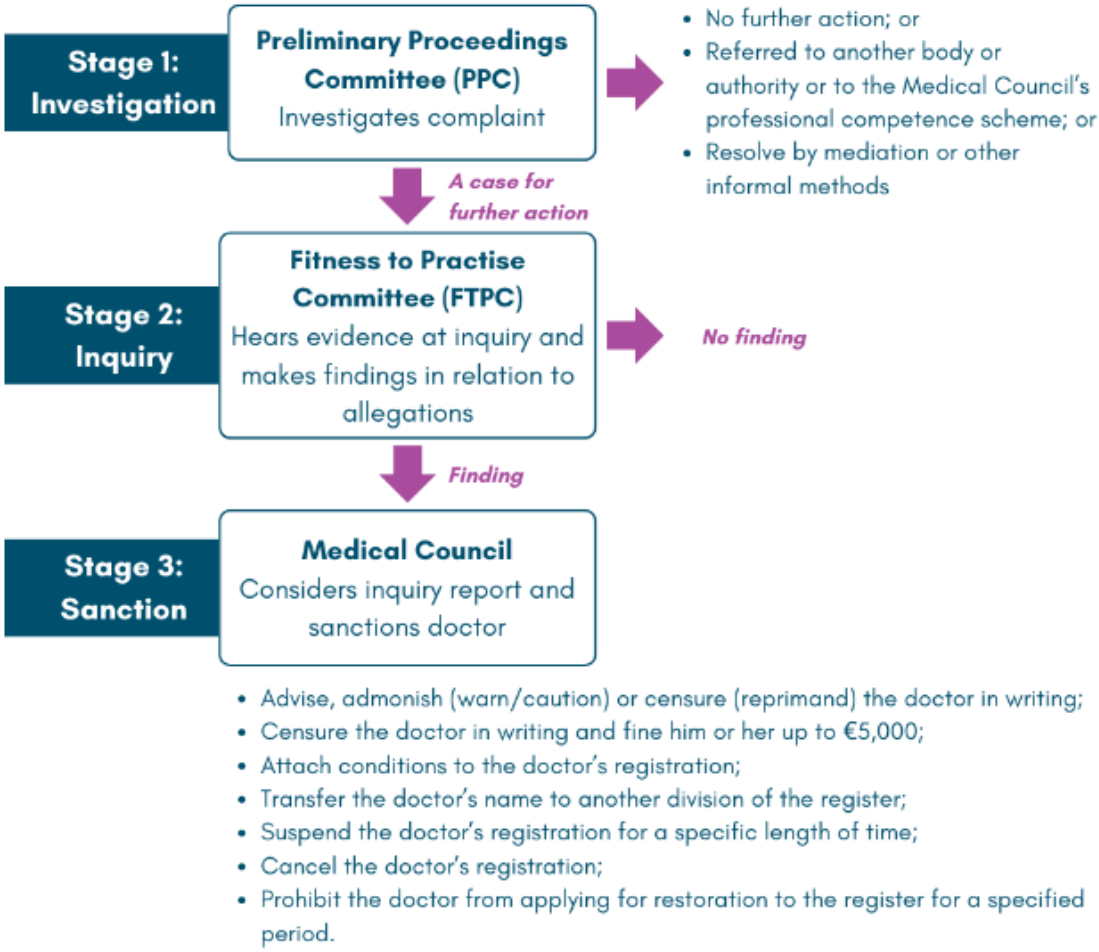
Reimbursement
Patients will be paid €50 for their time plus travel costs. Refreshments and lunch will be provided during the focus group.

Contact
If interested, please contact Bernadette Rock (Bernadette.rock@mcirl.ie) by the 22nd May.

3. Appendix 3 - Information Pack

A brief diagram of the complaints model, below, was accompanied with an in-depth discussion and explanation of the complaints process during this focus group. This detailed how complaints and currently examined and assessed, the roles of the PPC and FPC, and legislative remit of the Medical Council. Also provided were data on complaints, including the average number of complaints per annum and number of those that proceed to PPC and FPC.

Medical Council Complaints Process



4. Appendix 4 - Privacy Notice

Privacy Notice – Participants in Focus Group Discussions

The Medical Council recognises the importance of transparency when processing your personal data. It is important for the Council to outline how we may use any information you provide, details about your own experiences or your views or suggestions on existing processes and how they may be improved. The purpose of this focus group is not to record any personal data about you but to help the Council as it seeks to reform its complaints process. All personal data will be anonymised in any report created and any identifiers will be removed.

The focus group is being facilitated by Kathyan Kelly, Researcher in the School of Social Work and Social Policy, Trinity College, who is bound by confidentiality clauses. Some Medical Council staff, mainly from our Research Team, will be present for the duration of the focus groups and will take handwritten notes as a memory aid to later write up reports. A mobile phone will record the audio for the in-person focus group and the online focus group held on Microsoft Teams will be recorded through Teams. All recordings will be transcribed and will be subsequently permanently destroyed.

The Medical Council's legal basis under the General Data Protection Regulations 2016/679 (hereafter "the GDPR") to process your personal data, though noting that any published or externally circulated report etc. will be anonymised, falls under Article 6(1)(e) i.e. *'Processing shall be lawful only if and to the extent that at least one of the following applies: processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller'*. The aim of the focus group is to support and inform the Medical Council in revising and reforming its complaints model.

The Medical Council considers our obligations under the GDPR and other relevant legislation very seriously. We have numerous policies and procedures in place to ensure the continued safeguarding of any personal data. The Council has a dedicated Information Governance team who ensures our continued compliance with relevant data protection and Freedom of Information legislation. Any records produced as part of this focus group are subject to the Freedom of Information Act 2014 though bearing in mind that the Act does not permit the issuance of any third party information to the public as a result of a request received. The Council also has a dedicated ICT team who ensure the continued technical security of any personal data we process. Further information is available on our website.

In participating in the focus group, I note that all personal data and anything that may identify me will be stored securely in line with the Council's obligations under the GDPR. Any personal data that may be published in any report or evaluation or used to shape our future processes will be anonymised and any additional identifiers will be removed.

_____

Signed:
Date:

5. Appendix 5 -Case Studies

- Case Study 1: Communication Difficulties and Fees for Routine Blood Tests as a Medical Card Holder
- Case Study 2: Serious Failings - Issuing Prescriptions, History Taking and Note Keeping
- Case Study 3: Communication Issues and Failure to Conduct Appropriate Health Tests

Case Study 1: Communication Difficulties and Fees for Routine Blood Tests as a Medical Card Holder

Background

This case refers to a single incident between a patient with a medical card under the general medical services (GMS) scheme 'John' and a General Practitioner (GP). 'John' attended the GP for the first time due to a variety of symptoms including swelling and pain in their joints and spine, a decrease in their height and injuries after very minor physical activity.

What Happened?

The Patient's Complaint: 'John'

John attended their GP and requested a body density (DEXA) scan as they were concerned that they may have some form of arthritis or other issues with their bone health. John claims that he expressed his concerns and that the GP suggested a blood test which would cost €25. John also claims that the doctor **offered pain killers to help manage the pain** although John would have preferred a DEXA scan. John noted that the doctor **did not dress professionally.**

John initially agreed to come back for a blood test but believed that **as a medical card holder he should not have to pay the €25**. After the appointment he contacted the HSE and claims that the HSE confirmed that as a medical card holder he cannot be charged for a blood test, if it is necessary. John rang the doctor to relay this information and also shared that he did not want a blood test if it was not necessary. John claims that the doctor told him over the phone that if he did not want a blood test not to get one and **abruptly ended the conversation**. John has been **unable to contact the GP** since and has no choice but to continue to attend this practice as no other GPs nearby are taking on medical card patients.

John previously lodged this complaint with other bodies including the HSE.

The Doctor's View: GP in a single-handed practice

"I am sorry to see that 'John' was unhappy with his interactions with me at the practice. I never intended to cause any upset or inconvenience."

The GP in question explained that at the time of this appointment this was a single-handed practice with only a part-time secretary and that as a result sometimes answering the phone was limited. This doctor now has secretarial cover for four days a week and this issue has improved. They apologised for potentially missing the call and were sorry to hear the patient was unhappy with the experience.

The GP shared that at the consultation they agreed to get a full file transfer from the patient's previous GP. The doctor agreed that the patient requested a DEXA scan as they found it recommended online. The GP did not believe this scan was the best first line investigation based on the issues John was presenting with and explained that a blood test for particular markers was more appropriate. The doctor claimed that John was informed that a DEXA scan could be considered in the future if necessary. The doctor said they did not prescribe pain killers but may have suggested taking some to alleviate pain.

The doctor confirmed that they informed the patient of a €25 euro fee for a blood test, as the provision of routine blood tests is not covered under the current GMS contract for medical card holders. The doctor also claimed that they offered the option of referral to outpatient blood test services which would have been free of charge and they could have reviewed the results. The doctor also shared that they would have been happy to deal with the complaint locally and that the clinic was walk-in so John could have attended any day if the phone was not answered. The doctor also stated that they always dress professionally at work.

"If 'John' had written to me directly regarding his concerns I would have been happy to try and address them at a local level initially and try resolve the issue."

Outcome

- Complaint was open for 6 weeks and considered at one Preliminary Proceedings Committee meeting.
- Committee confirmed that this blood test is not covered under the current GMS contract for medical card holders.
- Committee ultimately decided no further action should be taken by the Medical Council as they were of the view that the complaint was ***"trivial and without substance*** *in the circumstances where it did not raise any clinical concerns or patient safety issues and was bound in law to fail as it was incapable of ever reaching the threshold of seriousness to warrant a referral to the Fitness to Practise Committee"* ("FTPC").

Case Study 2: Serious Failings - Issuing Prescriptions, History Taking and Note Keeping

Background

This complaint is about the prescribing pattern of a General Practitioner (GP) and was lodged by a community pharmacist. A patient attended a pharmacy with a prescription for medication, which has a potential for addiction and withdrawal, if not prescribed and taken appropriately. The pharmacist doubted the validity of this prescription due to the handwriting, high quantity and nature of the medication.

What Happened?

The Complainant View: Community Pharmacist

A patient presented to a pharmacy with a prescription for 90 Diazepam tablets (10mg) and 30 Dalmane tablets (30mg). These are a type of medication with addiction and withdrawal potential. The pharmacist had **concerns over the validity of the prescription** and they attempted to contact the prescribing doctor directly. The pharmacist searched for the doctor's number online in case the number on the script was fraudulent. They could not contact them at their clinic but later contacted them through the mobile number initially included on the prescription. The **doctor confirmed the prescription was valid, and claimed it was for a 3-month supply**. The pharmacist claims that the doctor refused to explain why there was no clear indication of the dose per day or why they did not request 3 x 30 tablets on repeat rather than simply 90 tablets. The pharmacist also claims the patient told them it was a one-month supply. The pharmacist **found the prescription to be valid but found it difficult to decide whether or not to supply it**.

"I completely felt like [the doctor] knew what they were doing was wrong"

This pharmacist had over 10 years' experience and complained as they believed it was their professional duty. They consulted some colleagues and claimed that they all agreed that this did appear to be a 3-month supply (90 days together) and that they had never experienced any doctor prescribing 3 months of this tablet together. The Medical Council was the first place they lodged this complaint.

"It takes time off all of our busy schedules but I still felt I had to email the alert"

The Doctor's View: Specialist General Practitioner in Busy Urban Setting

The doctor in question responded suggesting the complaint was ***"just a misunderstanding".*** The doctor explained that they have an excellent knowledge of pharmacology and that they knew how to appropriately treat patients with complex mental illnesses.

The doctor explained that:

- the prescription was handwritten as they do not use printers for prescriptions in their practice
- they prescribed the Diazepam for 3 months and Dalmane for 1 month because both have an addictive potential (1 tablet daily for each)
- they consulted a few pharmacists and they confirmed that this was an appropriate prescription
- these medicines can be prescribed for long periods, such as 3 months, especially when the patient suffers from mental illness

Upon review the doctor realised that they had issued the same prescription to this patient two weeks apart due to an administrative error. Upon further correspondence the doctor shared that they were being threatened by some patients and that they had decided to stop prescribing for psychiatric patients and were now sending them elsewhere (to an alternate GP or consulting psychiatrist).

Preliminary Proceedings Committee Request:

Based on all the information provided by the complainant and the doctor the Preliminary Proceedings Committee (PPC) requested a report by an independent expert witness. This expert witness was a GP with significant experience in urban and socially disadvantaged areas, and had extensive experience in addiction management.

Expert Witness Report

This expert witness prepared a report based on **this complaint** and the **treatment of 70 additional patients** under the care of this doctor. The expert witness stated that the issues in this complaint can be divided into issues relating to:

- history taking and note keeping,
- practice administration, and
- issuing of the prescriptions

The expert witness reviewed the two files that the doctor had recorded for the patient in question:

- The doctor had recorded both as if they were their first consultation, and the mental health issue was recorded differently in both files for the same patient ('panic attacks' vs 'depression, anxiety and insomnia').
- Both files failed to record the current mental health status of the patient, any social circumstances, any addiction history or medication history, previous GP or consultants, or have any record of discussing the addiction, tolerance and withdrawal potential associated with the medication.
- The expert witness believed this was a **serious failing** in terms of history taking, note keeping and issuing the prescriptions and not to the required standard of a GP working in Ireland.

The expert witness then examined the records of 70 additional patients treated by this doctor. A similar trend was observed in the majority of these cases. There was a **serious failing** in issuing prescriptions, nearly always for benzodiazepines, history taking and note keeping for 66 of these patients.

Based on these cases the expert witness also noted that:

- documentation did not improve after the complaint was received;
- there was a slight change in prescribing behaviour after the complaint was received whereby the doctor began to prescribe lower doses for shorter time periods. However, there were still serious failings, and the doctor did not stop treating patients with mental illnesses as suggested; and
- no case considered non-benzodiazepine treatment, made any addiction or counselling referrals or documented attempting to contact the patient's previous GP.

Outcome

- Complaint was investigated by the PPC for 3 years. This involved the case being considered at 8 PPC meetings, numerous investigations by case officers and consulting an independent expert witness. This independent report cost €7,500.
- PPC Committee formed the opinion that there was a prima facie case to warrant further action being taken in relation to the complaint as the matter was sufficiently serious. On that basis, the PPC referred the matter to the Fitness to Practise Committee ("FTPC") on the grounds of poor professional performance and/or professional misconduct.
- This case was with FTPC for a further 3 years and heard at a private inquiry. The associated Legal and Counsel fees at FTPC were €20,000.
- The doctor took an undertaking **not to repeat the conduct** and **to consent to being censured** by the Council pursuant to Section 67(1) of the Medical Practitioners Act.
- This doctor also undertook to voluntarily withdraw from the Register immediately following the conclusion of the complaint and to never apply to rejoin the register of Medical Practitioners in Ireland. This doctor ultimately retired early and emigrated.
- In total, this case took 6 years to resolve.

Case Study 3: Communication Issues and Failure to Conduct Appropriate Health Tests

Background
This complaint is about a deceased patient who was under the care of a cardiologist. The complaint was made by the patient's wife who felt that concerns were not listened to and appropriate health tests were not carried out. The patient's death was the subject of a coroner's enquiry and the complaint involved an expert witness.

What Happened?

The Complainant View: Wife of patient, 'Tom', patient with cardiac history
Tom was a patient with a history of cardiac problems. Tom was experiencing sharp stabbing pains, and tightness and pressure in his chest. He attended his local GP surgery where he was assessed and referred to the local A&E department immediately. A consultant on duty in A&E ran several tests including X-ray, blood tests, ECG and concluded that Tom had ***'stable angina'.*** His wife noticed that one of the records written by hand stated in quite large handwriting ***"ON MY OWN – TOO MANY PATIENTS".*** Tom was given a prescription (GTN spray) and was told that this would relieve any discomfort in his chest, and subsequently went home. Tom's wife believes her husband should have been transferred to a cardiac hospital that same day and seen by a cardiologist for a thorough examination before being discharged.

As Tom's symptoms continued, he made an appointment to see his private cardiologist. He had a stent procedure and was told that if he felt chest pains he could use the GTN spray as required. However, symptoms continued and worsened, including sharp stabbing chest pains, tightness in his chest, as well as fatigue, shortness of breath, insomnia, loss of appetite, anxiety, heavy nose bleeds, severe headaches and heartburn/indigestion. Tom and his wife tried to have his next appointment scheduled sooner, but was informed the cardiologist was too busy, and the secretary seemed to be impatient in explaining this. His wife could see Tom's health was deteriorating every day and was extremely worried. At the next appointment the cardiologist insisted the pain was not cardiac-related and suggested the nose bleeds and headaches were also unrelated, perhaps caused by a cold. He refused to carry out further tests, as requested by the patient and his family. Tom passed away exactly two weeks later. His family want to know why his symptoms were not properly investigated, ***"How could a cardiologist dismiss chest pains without even taking any tests?"***

"We tried so hard to explain to medical professionals that his health and well-being was deteriorating every day in front of our eyes while under their medical professional care, especially within the last two months prior to his death. I strongly believe that death was preventable... There are too many issues not addressed and we are unable to move forward with our lives without this clarification".

Tom's wife also highlighted other concerns:

- New medications prescribed for her husband were not monitored for side effects;
- Prescribed too many blood thinners while taking his usual medication;
- Tom should have had more frequent appointments to monitor his cardiac health.

"Words cannot express the sadness in our hearts that will always be there. We desperately need answers to all our concerns and need to know why this happened so that we can get some sort of closure."

The Doctor's View: Long-term Treating Consultant Cardiologist 'Dr Mahon'

"Tom was a long-standing patient of mine with a history of hypertension, atrial fibrillation, in-sile pacemaker, cardiomyopathy and a probable history of stroke with no neurological sequela".

Tom's doctor shared that they had no involvement in Tom's discharge from A&E with sharp, stabbing chest pain and tingling down his right arm but that the medication offered at the time was normal. The doctor subsequently saw Tom at their clinic and determined that he had two syndromes:

- "sharp stabbing pain" which was not cardiac, and
- "tightness" which was exercise related

The doctor admitted Tom for a diagnostic angiogram and started him on ***"triple therapy",*** Aspirin, Clopidogrel and his Warfarin. The symptoms Tom described were in keeping with angina so the doctor brought him back for an angioplasty and Tom was successfully stented. According to the doctor, there was no indication that Tom needed any further intervention for that symptom set. When Tom came back he was complaining of sharp, stabbing chest pain which the doctor diagnosed as similar to what he had before, without any tightness in his chest. The doctor shared that sharp, stabbing chest pain is not cardiac in origin and is most often musculoskeletal. The doctor told Tom that there was no requirement for admission to hospital to investigate stabbing right sided chest pain and that as his exercise induced tightness had resolved and that they expected that the stabbing pain would resolve on its own. Tom also reported having some nosebleeds on the combined three medications. At that appointment in keeping with guidelines and in the setting of nosebleeds, the doctor stopped his Aspirin, started him on Apixaban. Unfortunately Tom died suddenly the following Monday.

Independent Expert Witness

Based on details submitted, the PPC requested an independent expert witnesses report. The expert witness reviewed all relevant material and identified a **'serious failing'** in one area of Tom's care. This concerned the failure to assess chest pains that Tom was complaining of following his stenting procedure.

"In my opinion, Dr Mahon should have considered the significant concerns of Tom and his family and in order to get objective evidence to support his subjective assessment that the chest pains were non-cardiac, he should have considered further cardiac investigations."

The expert witness noted that this was a difficult judgement to make based on a chart/document review like this but on balance "***that the failure to proceed with further investigations represent a serious failure by Dr Mahon."***

The expert witness felt that it was ***"important to acknowledge and highlight that this was a single episode of concern"*** and ***"that the care provided by Dr Mahon was to the high standard that I would expect from any consultant cardiologist."***

The patient's wife expressed concern about changes in his medication. However, the expert witness reported that the medications and drugs were appropriate and consistent with guideline recommendations and there were no failings. The patient's wife also felt that Tom should have been kept under more frequent review and had more frequent investigations. However, the expert witness agreed with the management approach of Tom and did not find any evidence of significant failings in this regard.

Outcome

- Complaint was investigated by the PPC for 2 and a half years. This involved the case being considered at 6 PPC meetings, numerous investigations by case officers and consulting an independent expert witness. This independent expert witness cost €5,000.
- The PPC Committee formed the opinion that there was a case to warrant further action and referred the matter to the Fitness to Practise Committee ("FTPC") on the ground of poor professional performance.
- This case was with FTPC for a further 3 years. The associated Legal, Counsel and expert fees at FTPC were €40,000.
- No findings were made, no evidence of poor professional performance.

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