Independent Neurology Inquiry

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CHAPTER 9 – CONCERNS

Introduction

9.1 The Terms of Reference of the Inquiry specifically task the Inquiry with reviewing the handling of complaints or concerns identified or received prior to 2016, which should have alerted the Belfast Trust to instigate an earlier and more thorough investigation over and above the extant arrangements. A separate chapter looks at the formal process of complaint within the Belfast Trust, but the Inquiry wished to also consider concerns that were apparent in the years prior to November 2016.

9.2 The Inquiry encountered concerns raised by General Practitioners ("GPs"), other neurologists, nursing staff and their interaction with those in medical management.

9.3 This chapter sets out the concerns raised by the various categories of medical professionals who interacted with Dr Watt during the relevant period, the nature of those concerns, to whom they were communicated and what action, if any, was taken. The chapter focuses on 11 separate concerns or series of concerns, which were raised in relation to Dr Watt at times during the relevant period between 2006-2016.

CONCERNS RAISED BETWEEN 2006-2016 BY THE MEDICAL PROFESSION:

General Concerns about Dr Watt's Practice by a General Practitioner - 2013:

9.4 Dr Paul Conn, a much-respected GP in the Ballygomartin Practice, gave evidence to the Inquiry on 30th October 2018. Tragically, he subsequently lost his life in an accident on 27th July 2019.

9.5 He told the Inquiry that his first concerns about Dr Watt surfaced in 2007/2008. One of his patients had presented at casualty with signs of a stroke. Dr Conn knew the patient well and was convinced from the patient's history that her symptoms were functional, rather than organic. Dr Watt had diagnosed a stroke. As a result of his concerns, Dr Conn arranged to see Dr Watt. He told the Inquiry Panel:

> So I actually went to see Michael [Watt]. This was in 2007/2008. I went up to his clinic. He and his nurse were there. We went through everything you know and I just didn't feel he was reflecting on his diagnosis if you like. But anyway we couldn't come to an agreement but we did come to an agreement that we would continue to manage her as if she had a stroke so at least she felt we were all together and that sort of solved that problem.

Dr Conn indicated that he had never before or since gone to a consultant directly.

9.6 Dr Conn told the Inquiry Panel that his concerns about Dr Watt continued. In his evidence he stated: *"Then you know in 2012/2013/2015 a few patients of ours, not just of mine came through with unusual diagnoses"*. Dr Conn told the Inquiry Panel that his Practice had sent two letters to Dr Watt during this period, as they were concerned over the diagnoses. One of the cases involved a patient who was applying for life insurance. He had been given a diagnosis of probable migraine by a different doctor, but Dr Watt felt his symptoms may have been due to cerebral ischaemia. Because of the patient's age, a diagnosis of thromboembolic cerebrovascular disease rather than migraine would have financial implications for the patient.

9.7 Dr Conn explained to the Inquiry Panel that the Ballygomartin Practice had a box, which contained unusual letters from other medical professionals. The GPs in his Practice tended to talk regularly amongst each other about patients and their care. Dr Conn told Professor Mascie-Taylor, the Co-Panellist:

> **Professor Mascie-Taylor:** At around 2012 you had a special Dr Watt box?
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> **Dr Conn:** Well, it was just somewhere if I got a letter and I thought that doesn't sound right, I would have put it in there to look at later. There were more Dr Watt letters than any other, not a lot but there were.

9.8 Although the partners in Ballygomartin Practice had devised a useful system of checking with each other on potential problems, there was, unfortunately, no systematic way of actioning letters from Dr Watt that had been placed in the box. It was the case that two specific letters about patients in the Practice had been sent to Dr Watt. Dr Conn indicated that there were, in total, about eleven letters in the 'Practice box' and about half of them related to Dr Watt. He stated that the partners had discussed their concerns on several occasions, on the basis that the GPs felt he was *"over-diagnosing and over-treating"*.

9.9 Dr Conn then informed the Inquiry Panel that he called Dr Donagh MacDonagh, who then held a part time post as Associate Medical Director in the Belfast Trust with responsibility for liaising with Primary Care. Unfortunately, the Inquiry Panel has been unable to identify the precise date of the conversation that took place between Dr MacDonagh and Dr Conn. The best estimate is that it was in or around 2013 which was a particularly significant time, as outlined in the 2012-13 Missed Opportunities chapter. Another Associate Medical Director in the Belfast Trust, Dr Ken Fullerton, and Dr Ray Hannon had been asked at different times by the Medical Director, Dr Tony Stevens, to review Dr Watt's practice and there were numerous other complaints received at or about this period.

9.10 Dr Conn explained that he and Dr MacDonagh had been on the Eastern Local Medical Committee. He indicated that he had known Dr MacDonagh for some time and felt that he was *"an amazing source of information"*. Dr McDonagh was not aware during the phone call that Dr Conn had a range of concerns about Dr Watt that went back over a number of years. Dr Conn indicated in his evidence that his reason for ringing Dr MacDonagh was that he wanted to find out if there were any further concerns about Dr Watt. Dr MacDonagh's response was, according to Dr Conn, that he should put his concerns in writing. He stated:

> You know, he quite rightly said "if you have concerns you need to put them in writing to me". That just was, you know, it was a step at that time I didn't want to take, and you will ask me why. I wasn't sure what would happen after that, to be honest. You are right, Northern Ireland is a small place and, in fairness, I didn't do anything.

Dr Conn stated that Dr MacDonagh was unable to give him any reassurance:

> **Mr Lockhart QC:** Did he give you any reassurance in that regard?
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> **Dr Conn:** No. Well I don't think he was able to, to be fair.

9.11 Dr Conn was uncomfortable with raising what he termed as "soft concerns" and wanted to have some reassurance that putting things in writing would be justified. As he put it to the Inquiry Panel:

> **Dr Conn:** It was either the full two barrels or nothing. There was nowhere could you have a look and ask.
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> **Mr Lockhart QC:** There didn't appear to be a safe place in order to get reassurance.
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> **Dr Conn:** They are not soft issues, but I mean as far as there are appraisals every year, there are revalidations every five years, there must be some kind of governance behind what areas in the hospital do and reflections, reviews, audits following local guidelines. I just assumed that these things would go on within the organisation. You know, I think one of the other issues in neurology is you are kind of super specialised so maybe your colleagues don't deal with any of your patients. What happens when he is on holiday, who sees his patients? I don't really know.

9.12 Dr Conn informed the Inquiry Panel that whilst, on reflection, he should have raised the matter officially with either Dr MacDonagh or the Medical Director in the Belfast Trust, he did have concerns about the implications of putting something in writing. He stated to the Inquiry Panel:

> In terms of Northern Ireland being a small place and, you know, I am not a colleague, I don't work in the hospital, but I could have personally taken a lot of flack had it turned out that actually we were the only practice, or somebody found there was nothing going on, or whatever.

9.13 Essentially, what Dr Conn had hoped would happen was that Dr MacDonagh would have made some discrete enquiries and if he had found that there were other problems, he would, at that point, have been prepared to put the matter in writing. Dr Conn confirmed that he did not give the patients' names to Dr MacDonagh and that Dr MacDonagh's approach was that unless he was prepared to put the matter in writing, nothing could happen. Dr Conn's recollection of their phone call differs slightly in detail, but not in substance to that of Dr MacDonagh. Dr MacDonagh recalled that he could not progress the matter without the names of the patients. Whether it was a request for the names or a request for the matter to be put in writing, the result was the same. The concerns were not recorded and/or escalated to the Medical Director or anyone else in the Belfast Trust.

9.14 Dr Conn did indicate that subsequently his Practice did not refer patients to Dr Watt if at all possible. In retrospect, he believed that this was something that might have been discussed by his other GP partners and, after an informal discussion the decision was taken not to refer private patients to Dr Watt. In retrospect, Dr Conn was not surprised that general practice had picked up concerns in relation to Dr Watt because of the number of outpatients involved with neurological services. When the news broke of the recall and Dr Watt's suspension, Dr Conn indicated that his Practice had reflected on what had happened:

> **Mr Lockhart QC:** Whenever it broke what was the attitude within the practice?
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> **Dr Conn:** We were right all along was what we thought, and we did actually reflect on it.
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> **Professor Mascie Taylor:** What did you think?
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> **Dr Conn:** That we should have been the ones raising the flag.

9.15 Dr Conn was also clear that, at times, the partners would have discussed Dr Watt. He told Professor Mascie-Taylor:

> **Professor Mascie Taylor:** As a practice you discussed Dr Watt and his practice essentially on one occasion or a number of occasions.
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> **Dr Conn:** A number of occasions. It seemed that he was over diagnosing and over-treating.

> **Professor Mascie Taylor:** I understand why you were doing it.
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> **Dr Conn:** It would have been, if he had been misdiagnosing, under-diagnosing, under-treating that would probably have been a higher priority.

9.16 Dr Conn was clear that he felt he should have done more:

> **Mr Lockhart QC:** In ease of you it is fair to say that you were not the only GP who tried to take steps. You probably got further than most. Other GPs tried even more oblique ways of trying to bring to the attention of other authorities their concerns. So it is important that in us asking you to reflect and do that we also make it clear that there were many aspects of your practice in particular that were exemplary. We do get the point that many other doctors kept their concerns to themselves, didn't do anything and just ignored it, what I term a kind of 'Nelsonian blindness' and yet when all emerged, people began to realise that the laconic and short letters and everything else was indicative of something far more problematic …
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> **Dr Conn:** The easy thing is to do nothing about it.
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> **Professor Mascie-Taylor:** Precisely.
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> **Dr Conn:** You know, nobody will ever catch you out on that one. I mean I feel, we do feel as a practice, me personally that I should have done more.

9.17 In his response to Dr Conn's evidence, Dr MacDonagh, who gave evidence to the Inquiry Panel on 13th September 2018 and 6th December 2018, indicated that he wanted Dr Conn to go to Dr Watt. He was clear that he had informed Dr Conn that if he was not prepared to disclose the names, he did have a duty to say to the consultant, by writing to him, about the issues he had raised. He was satisfied that Dr Conn had, in fact, raised his concerns in writing with Dr Watt.

9.18 Dr MacDonagh informed the Inquiry Panel that he was doing about three sessions per week with the Belfast Trust as Associate Medical Director for Primary Care. He came into post in 2011. He was quite clear that no one else had raised a specific query about Dr Watt to him during his time in post and again emphasised that he did not think there was a mechanism for handling what he referred to as 'soft concerns'. It was specifically put to Dr MacDonagh that both variances and concerns are matters, which should be raised with the Medical Director's Office and that the absence of a name would not have prevented investigation:

> **Mr Lockhart QC:** We talked to the Medical Director's Office, half a concern, half a variance, they want to know about it. If you don't give them a name, that's fine, they will look at it themselves. You didn't get trained.

> **Dr MacDonagh:** I didn't get trained. Any training I got was when there was a memo circulated about NCAS

9.19 Dr MacDonagh felt that, in the current climate, it was sometimes easier for GPs to say nothing. The Inquiry Panel asked Dr Tony Stevens, the then Medical Director, about the reticence of Dr MacDonagh to escalate the matter:

> **Mr Lockhart QC:** One of the key moments may well also be when Donagh MacDonagh got the information from Paul Conn and the cases could have been looked at, and, unfortunately, he did not get that across the line to the Medical Director's office.
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> **Dr Stevens:** I think that —. Again, I'll be careful: Donagh's given his evidence, and I don't want to just be saying, "He said. I said". I'm surprised he didn't take advice, and I can find no evidence that he took advice. And he said he was intimidated by me. I will personally question that, but I accept he said it genuinely. But he could have spoken to Cathy Jack [then Deputy Medical Director] He shared an office with Peter Watson. [Senior Manager in the Medical Director's Office].
>
> He could have spoken to [Ken Fullerton] then Associate Medical Director. [Dr McDonagh] was a full member of my team. He attended all the Associate Medical Director's meetings, and he attended the Medical Director's advisory group.
>
> What would the advice have been? I don't know. The other question —. Paul Conn, sadly, isn't here — to reflect on this. But Paul is well known to everybody. Paul ran our out-of-hours service; he was an employee of the Trust and well known to senior management. The two of them could have taken advice, and both of them chose not to, and that's —. They were good guys; they're not bad guys. They didn't have the experience. They didn't take the advice. My advice would have been — I think that my advice to Paul would have been, "Paul, quietly let us have a look at the cases". Because that's what I —. I know what I would've done: I would have got someone to have a look at them. "Give me their names, and I'll get somebody to have a quiet look at them".
>
> And I would probably have done that under the radar. Because sometimes, strictly speaking, you shouldn't do those sort of things, but just go in under the radar, have a look, "Should we be worried about these?" Then, if somebody came back and said, "Yes", you'd have been into a new ball game. So, it probably was a missed opportunity.

9.20 Dr MacDonagh, in his evidence, indicated that the concern was only expressed on the phone and that, in his recollection, the phone call from Dr Conn was ostensibly about other matters. Dr MacDonagh, however, was clear that he informed Dr Conn that he had a professional duty to approach Dr Watt:

> **Dr MacDonagh:** just to be clear, I did say to [Dr Conn] … that if he wouldn't give me the names or letters, he had a professional duty to say to [Dr Watt] the consultant by writing to him about the issues raised, and he very clearly did that.

9.21 The Inquiry is quite satisfied that Dr Conn did approach Dr Watt. Dr MacDonagh, however, accepted candidly that, with hindsight, he could have done more:

> **Mr Lockhart QC:** What we are saying is clearly the best thing to do in the role of Associate Medical Director is if you get a hint of something, you do something about it.
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> **Dr MacDonagh:** In defence, I don't like using the word defence because if there is criticism to come out of this Inquiry levelled at me, if it is fair criticism, I will quite happily take it.
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> **Mr Lockhart QC:** That is why we are trying to be as fair as possible.
>
> **Dr MacDonagh:** In my defence, lots and lots of things coming at me, some of them you could argue like this I could have done more about. Some of them they were just personality issues or workload issues being batted around. When GPs are speaking on the phone about other doctors, particularly consultants, they can use language they wouldn't dream of writing down. Allowing for the retrospective scope could I have done more? Of course I could. Would you have a system that allows GPs to report and soft concerns to be explored? I would love to see it.
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> **Mr Lockhart QC:** Again, this is something we are really concerned about, because this was not the only incident with GPs. GPs tried various ways to raise concerns. Dr Conn was not the only GP to raise concerns.

9.22 The Inquiry Panel formed the view that GPs were apprehensive about raising concerns generally. This is conspicuously apparent in the evidence of the late Dr Conn and in the testimony of Dr MacDonagh. There are many reasons for this, but at its core, a general practitioner will tend to hesitate before criticising or querying the approach of a specialist. The distinction by Dr MacDonagh between soft concerns and any other concern is not valid. All medical practitioners have a professional duty to properly escalate concerns, whether they consider them to be soft or not. The primary concern must always be the safety of the patient. The Inquiry Panel does note, however, that Dr MacDonagh did raise an index concern in June 2017 with the Belfast Trust regarding a patient who had been prescribed Sativex by Dr Watt. This particular case did have some influence on the decision by Dr Jack to fully restrict Dr Watt from clinical practice in July 2017. More detail on this issue is contained in the chapter on November 2016 - May 2018.

9.23 Dr Conn's evidence and the actions that he took, together with Dr MacDonagh's response, highlight a major concern for this Inquiry. Both doctors gave their evidence to the Inquiry Panel straightforwardly and candidly, but the problems that they both faced illustrate graphically a deeper difficulty with medical culture in Northern Ireland. This is considered in greater detail in the chapter on Medical Culture.

9.24 The Inquiry Panel believes that the evidence of Dr Conn, both specifically and more generally, would have been highly relevant to the investigation carried out by Dr Fullerton. It is unfortunate that Dr Conn did not give the names and addresses of the patients to Dr MacDonagh, but more important that, Dr MacDonagh did not escalate the matter to the Medical Director's Office in any event. All doctors have an existing professional obligation to raise concerns in circumstances where they believe patient safety may be compromised, as set out in The Good Medical Practice ("GMP") published by the General Medical Council ("GMC") in 2013.

Concerns raised by a GP during an Appraisal:

9.25 Another GP who raised a concern was Dr Peter MacSorley, who was practising in North Belfast and was involved with the INI 5 case, which is commented upon in detail in the Complaints chapter. In his role as her GP, he had written to INI 5 and indicated in that correspondence *"I should have told you the drug that you were prescribed had as one of its possible side effects the psychosis"*. Dr MacSorley indicated to the Inquiry Panel in his evidence of 2nd October 2018 that, in general, he too had felt uncomfortable about challenging the decisions of consultants, who were specialists in their field. He highlighted the position of GPs generally in relation to prescription advice notes. In effect, these are directions from a consultant to prescribe a certain drug although GPs retain an overall responsibility for the prescription.

9.26 At his appraisal in 2013, Dr MacSorley raised with his appraiser, Dr George O'Neill, 3 cases in relation to Dr Watt where steroids had been prescribed. One of the cases involved a patient with MS and the other two referred to cases in which the tests, including CT and MRI scans, did not reveal evidence of MS. Dr MacSorley set out, in general terms, the details of the prescribing. He was concerned about the diagnoses and the fact that he was, as a GP, being asked to prescribe the medication recommended by Dr Watt. Dr MacSorley informed the Inquiry Panel that he had never before, in his years of practice, been troubled about a specific consultant. He felt that the medical culture was such that it was difficult to raise concerns with confidence. He indicated to the Inquiry Panel: *"in Northern Ireland you tread very*

warily". Dr MacSorley was of the view that the difficulties in raising concerns did impact on patients' safety.

9.27 When reflecting on the appropriateness of raising concerns about Dr Watt in his appraisal, Dr MacSorley commented:

> **Mr Lockhart QC:** And can I just follow that up by asking you the question as to whether, if you did have a concern about a secondary care provider, was it your view that one way to deal with that is to utilise the appraisal system as a method by which you could reflect and raise concerns?
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> **Dr MacSorley:** It was, I mean, at the end of the day, it was almost like peer review. And the thing about it is, is I am just an ordinary GP and, you know, and I wouldn't say necessarily that my views were any more valid than anyone else's.
>
> **Mr Lockhart QC:** Well, this is what is concerning me, if you had a concern would you even know, and I don't mean this pejoratively in the slightest, but would you know what you would do with that concern, leaving aside the appraisal would you, I mean have you ever, for instance in 30 years gone to the Belfast Trust, or the Medical Director, or any of these organisations and said, "I have a concern about a secondary care provider"?
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> **Dr MacSorley:** …In Northern Ireland you tread very warily.
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> **Mr Lockhart QC:** This is why I am asking the question because we have interviewed other GPs, who don't even know who to go to.
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> **Dr MacSorley:** It appears to me to be, in effect, deeply entrenched systemic bullying, if you could describe it as that.
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> **Mr Lockhart QC:** That's very helpful. And would it be fair to say that, how do you think that impacts upon patient safety?
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> **Dr MacSorley:** Very significantly … in terms of clinical governance, you know, why has nobody been, I think it's really to do that probably in Northern Ireland there are not the same checks, effective checks and balances as there would be in Scotland, England and Wales

9.28 Dr MacSorley's appraisal papers raised concerns about a number of matters and clinicians, but the papers themselves did not identify any of the clinicians by name. In correspondence sent to the Inquiry on 5th January 2022, Dr O'Neill stated that at no point was he made aware of the identity of Dr Watt or of the patients, though this was not accepted by Dr McSorley. Dr O'Neill pointed out that the purpose of GP appraisal was to review personal development plans. He accepted concerns about a colleague could be raised at an appraisal, but to do so would require the appraiser

to be privy to the identity of the patients and clinicians. The Inquiry Panel is not clear on whether Dr O'Neill sought this information from Dr MacSorley. Dr O'Neill also commented that he would have made it clear that it was the responsibility of Dr MacSorley to escalate his concerns directly with the colleague involved or, failing that, with the employer. The Inquiry Panel has been unable to determine whether Dr O'Neill knew that the concerns being raised related to Dr Watt or not, but it is clear that neither Dr MacSorley nor Dr O'Neill ensured that the concerns were escalated further.

9.29 In his appearance before the Inquiry Panel on 19th November 2018, Dr O'Neill commented on the general reticence of doctors to raise concerns. He highlighted the fact that when he commenced his medical career, there was, as he put it, almost total silence, but that things had moved on and he mentioned the Hyponatraemia Inquiry. Dr O'Neill commented: *"there is a lot of pressure on the profession to be open and transparent, to put your hands up. The population at large now accept that we do make mistakes"*.

9.30 In terms of raising concerns, Dr O'Neill advised that if a young GP had a concern, they should initially approach the consultant and if that is not satisfactory, then escalate the concern to the Medical Director or the Chief Executive. When asked by Professor Mascie-Taylor whether he thought that most GP's knew how to raise a concern, Dr O'Neill responded: *"probably not. The other fear is the fear of rocking the boat or causing waves and that is a difficulty"*. Dr O'Neill was clear that if a GP raised a concern during an appraisal, he would tell the appraisee that they have the responsibility to report their concerns.

9.31 In Dr O'Neill's view, the real key to progress was in creating an environment where medical practitioners were comfortable in raising "soft concerns". The reference to such concerns was also utilised by other doctors. The Inquiry Panel considers that any distinction between concerns is unhelpful. The key question is whether there is a risk to patient safety.

9.32 The Inquiry Panel also examined the question of raising concerns with Dr Margaret O'Brien, the Responsible Officer for General Practitioners. Dr O'Brien informed the Inquiry Panel, in her evidence of 20th June 2020, that there was a system in place for GPs to raise concerns:

> By and large a lot of GP's who aren't associated to other roles within the Trusts aren't really *au fait* with how the system works but they do know, and I do have mechanisms in place for any GP be it if they are concerned about another GP either within their practice or a surrounding practice, or if they have concerns

> about any other medical practitioners. We do have mechanisms for the GP's to raise that and they do.

9.33 Dr O'Brien indicated that she did have concerns raised with her in her role as Responsible Officer. A majority of concerns related to secondary care and the problems with waiting lists, a lack of communication and failure to appropriately advise around changes in medication. When asked specifically whether she got concerns about misdiagnoses, she confirmed that such matters had been brought to her and gave to the Inquiry Panel a recent example. Dr O'Brien stated:

> Yes I would have to say from my own experience and what GP's are now coming to me with has improved, yes, over the years. We are finding that we are getting a lot more coming through our proper processes to highlight difficulties not just with other GP's but secondary care colleagues and their performance.

9.34 The Inquiry Panel then put to Dr O'Brien a scenario, which was similar to what had occurred between Dr MacSorley and Dr O'Neill during appraisal. Dr O'Brien stated that it remained the responsibility of the GP with the concern to go through the processes in place, even if the matter had been raised with an appraiser. She did, however, indicate that there was also an escalation process in place so that if issues were identified in appraisal, these could be raised with lead appraisers. Dr O'Brien stated:

> We have formal escalation processes, albeit they are aligned more to maybe a particular issue with a GP themselves in the appraisal, but they also accommodate if a concern has been raised or they want to raise something else. The lead appraiser may feel they are not in a position to do that, but they can pass that on to their regional appraisal co-ordinator who can pass it on to me.

Registrar Concerns about the Diagnosis of Epilepsy in Women who were Pregnant – 2013:

9.35 Dr Ellen Campbell conducted research as a registrar with the then Clinical Lead, Dr Jim Morrow, from August 2011 to August 2013. She explained to the Inquiry Panel the nature of her duties with Dr Morrow:

> I did his seizure clinic on a Tuesday afternoon, and I did his joint epilepsy/obstetric clinic on alternate Thursday mornings. It was in the pregnancy clinic that a couple of cases came through that I was a bit concerned about the standard of care. The setting of the joined-up epilepsy/obstetric clinic — I'm not sure if you're aware of the run of the clinic.

Dr Campbell also described the nature of the clinic:

> In consultant practice, you have very little crossover. I see my patients, John Craig sees his patients and, unless you refer to each other, then you don't really see each other's patients outside of an inpatient setting. Joint epilepsy/obstetrics, we see any pregnant patient with epilepsy that looks for antenatal care in the Royal Maternity Hospital. So, if I do that clinic next Thursday, there might be some of my patients come through, but there will be a significant number of John [Craig's] Stephen [Hunt's], Paul McMonagle's cases, cases that don't that attend a neurologist coming through that I take care of while they're pregnant. And obviously, amongst those cases, patients of Dr Watt would've come through. As a registrar in that clinic, I was supernumerary. It's, again, unlike other clinics in that there is a template, but it is adhered to very loosely because how busy the clinic is depends on how many people are pregnant at the time, and you can't really control for that. So we see patients with epilepsy sort of at 12, 20-ish, 28 and then every four weeks after that until the end. Sometimes the clinic is busy; sometimes it is not. When it was busy, I would have been seeing patients in another room from Dr Morrow. In the majority of the cases, I would have been an observer in his clinic room.

9.36 Dr Campbell told the Inquiry Panel about two of Dr Watt's patients with which she had particular concerns sometime in 2013:

> Both cases came through over a period of a few months; they were pregnant at similar times. They had a label of epilepsy and were on anti-epileptic drugs. One of the cases, I felt, was slightly borderline. There were aspects that were suggestive of epilepsy and aspects that seemed a bit more atypical. Whereas the other case was, I felt, more straightforward in that the things that the lady described were absolutely incompatible with a diagnosis of epilepsy. And I recall there being in the clinic room myself and Dr Morrow at that stage, and I remember there being some discussion, and all of us — well, I had the impression; I can't speak for Dr Morrow — but I had the impression that all of us agreed that the diagnosis was unclear in those cases. Later on, during both pregnancies, the babies were diagnosed, after the 20-week scan, with two different types of congenital malformations, which it is impossible to know if there's a link. But it's a potential link. I wasn't satisfied at the time that the care that they'd been given was to a sufficiently high standard.

9.37 While one of the cases may have been borderline, Dr Campbell was clear that, in the other case, the symptoms were not compatible with a diagnosis of epilepsy. Given the potential implications of this development, Professor Mascie-Taylor immediately followed both these cases up with the Medical Director, Dr Cathy Jack, to ensure that both patients had been properly cared for and were aware of the

issues. What was of particular interest to the Inquiry Panel was the fact that the cases were assessed by Dr Morrow and, in an open discussion with Dr Campbell, there was a clear dissatisfaction expressed as to the level of care received by the patients. Dr Campbell informed the Inquiry Panel:

> I was told by my consultant [Dr Jim Morrow] that he would discuss these two cases directly with Dr Watt. I saw [Dr Morrow] a week or so later, and I was told that that discussion had taken place and that he was satisfied with the outcome of it. I wasn't expecting, as a registrar, to be informed about the outcome of the discussion.

9.38 Dr Campbell emphasised her respect for Dr Morrow, both as a clinician and as a supervisor. She also highlighted that Dr Morrow was known to be very candid with patients. She was not aware, however, of what action was taken as a result of the concerns raised.

9.39 The Inquiry Panel also heard evidence from Nurse Beth Irwin on 16th November 2020. Nurse Irwin had previously attended the Inquiry on 12th March 2019 and had indicated that, although the consultants with a sub-specialty in epilepsy would have worked slightly differently, she had no inkling that there was anything untoward with Dr Watt's patients as opposed to other consultants. Following Dr Ellen Campbell's evidence to the Inquiry Panel, it became apparent that Nurse Irwin was present with Dr Ellen Campbell and Dr Jim Morrow when the concerns about the two pregnant patients had arisen. Nurse Irwin was asked to re-attend the Inquiry. The following exchange took place during her second attendance:

> **Mr Lockhart QC:** Okay. Do you recall Dr Campbell's distress about the matter?
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> **Nurse Irwin:** Oh, vaguely, now you mention it. I mean, I get distressed every time any of my patients, even as a midwife, had a foetal abnormality. I don't recall her initial distress about … I do recall Dr Morrow going through the history … Okay. As I say, the joint clinic runs very specifically, so you are seen at specific times. I do remember that we were all upset when we discovered the baby had a foetal abnormality. I do know that Dr Morrow did try to take her off treatment and the patient declined. I know that was earlier on. I do know he had a discussion with her that he felt, like
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> Dr Craig, one of her previous neurologists, he didn't feel it was epileptic in nature, but obviously her current consultant did.
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> **Mr Lockhart QC:** Were you aware that Dr Morrow was going to talk to Dr Watt about it?

> **Nurse Irwin:** I do remember, I think it probably was about 28 weeks when we see them back and we discovered, I do remember Dr Morrow saying, 'I'm going to take this further', and knowing Dr Morrow he will have done that.
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> **Mr Lockhart QC:** You were aware that he was extremely concerned about it, according to Dr Campbell?
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> **Nurse Irwin:** I know, like all of us, he was upset, because, looking back on her history and the fact that it was Dr Craig who had diagnosed non-epileptic attack disorder, because that's significant with him being an epilepsy specialist. He was annoyed. I know he did have a meeting. I know Dr Morrow, being Dr Morrow, would have followed the proper protocols and procedures … I do recall that he told Dr Campbell and myself that he had that meeting, but I don't recall who was at it or what was said.
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> **Mr Lockhart QC:** Yes. Would you have been under any illusion at all that this was a major concern being raised?
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> **Nurse Irwin:** No, I wouldn't have been -- yes, it was.
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> **Mr Lockhart QC:** It clearly was a major concern.
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> **Nurse Irwin:** It was.
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> **Mr Lockhart QC:** And that concern would have been related to the fact that Dr Watt had diagnosed epilepsy when not just Dr Morrow, but Dr Campbell and Dr Craig had said these are non-epileptic in nature?
>
> **Nurse Irwin:** … It would have been because he felt that -- well, it wasn't because of Dr Morrow and Dr Campbell, it was because Dr Craig had previously diagnosed her as non-epileptic, and she had been treated in her previous pregnancies.

9.40 It is unfortunate that Nurse Irwin did not recall this incident when she first gave evidence. Nevertheless, on the second occasion when she attended the Inquiry Panel, her evidence was clear and corroborative with what had taken place with Dr Campbell and Dr Morrow.

9.41 The Inquiry Panel was extremely concerned about the care given to both these patients and their management. At the very least, there was reason for the matter to be fully investigated and documented. Dr Morrow was unable to give evidence to the Inquiry Panel because of his own medical condition, so has not had the opportunity to respond to the issues raised. The Inquiry Panel is not aware of what Dr Morrow discussed with Dr Watt or what action, if any, was taken. No evidence was received that any escalation or investigation took place. On the face of it, however, both these cases were evidence of a potential serious misdiagnosis and mistreatment, and

comprehensive action should have been taken in respect of these 2 patients and any other patients identified.

9.42 It is wholly insufficient for the matter to be handled by way of a private conversation if that is, in fact, what occurred. This incident occurred at a critical time when other aspects of Dr Watt's practice, more generally, were being considered. It is clear, however, that this information did not reach Dr Fullerton, the Associate Medical Director, or Dr Stevens, then Medical Director, and, therefore, could not inform other investigations. This was a significant concern, which does not appear to have been handled in an appropriate manner by Dr Morrow[1]. It should have been escalated, investigated and the outcome of any investigation documented. The Inquiry Panel has not seen any evidence that any of these actions occurred.

Concerns about Dr Watt's Practice raised by a Registrar - Late 2013:

9.43 Dr Ingrid Hoeritzauer completed her training as a registrar in Belfast in 2016. She subsequently took up a neurology consultant's post in Edinburgh. As with every registrar, she was specifically asked by the Inquiry Panel if she had noticed anything about Dr Watt's practice during her registrar training. In her evidence to the Inquiry Panel of 6th May 2019, Dr Hoeritzauer made a distinction between registrars chatting informally about consultants and raising a specific concern formally. In relation to Dr Watt, she highlighted how pleasant and likeable he was and how patients were fond of him because they felt valued by his approach. It was because of this that she found raising concerns when she was a registrar to be particularly difficult. Nevertheless, despite her anxieties, Dr Hoeritzauer, did bring concerns about Dr Watt to the Clinical Director, Dr John Craig, probably in the second half of 2013. She told the Inquiry Panel that she was conscious of her own limitations as a younger neurologist and that she was challenging someone who was popular and well liked. As far as Dr Hoeritzauer was concerned, she felt that the problem must be with her and not with her consultant colleague.

9.44 Dr Hoeritzauer had specific concerns. She referred to young people who had transient neurological symptoms where the relevant test had not shown up any abnormality. She felt that too many were being diagnosed as something ischaemic and were being prescribed Aspirin and Clopidogrel. She also noted young people being put on Warfarin. She stated to the Inquiry: *"Nobody else was doing that and it wasn't in anything I was reading and it just felt concerning"*. This would have been

1 It should again be reiterated that Dr Morrow who is medically unwell did not have an opportunity to comment on the matters raised in this chapter.

in or about early 2013. Dr Hoeritzauer felt that she was very junior to be raising such concerns. She noted, however, that most neurologists stayed quite close to the guidelines and that, in contrast, Dr Watt did not carry out the same level of investigation or acquire the same degree of certainty before making a diagnosis. She stated to the Inquiry Panel that he did not exhibit diagnostic uncertainty, even when it was quite clear there was an uncertainty.

9.45 Dr Hoeritzauer highlighted that one of the incidents, which had spurred her on to raise a concern was because of the treatment of a patient, who had an intrathecal baclofen pump. She indicated to the Inquiry Panel that the patient had a neurological degenerative condition for which there was no diagnosis. She told the Inquiry Panel on 6th May 2019:

> As is sometimes the case with neurology, you just watch patients for a long period of time, you support them, and you don't necessarily have a specific name for it. But he'd been very thoroughly investigated. So, he had this intrathecal baclofen pump, and he was very much in pain. He was worried about seeing the pain team, because he was worried that they were going to take some of his medications off him. He said, "Can you do anything else for me?" and Dr Watt had said, "Well we can put some morphine into your pump" and [Dr Watt had asked me to do that. I didn't know how morphine and baclofen would interact. I didn't know what amount to give. You know- it felt like a massive decision and it felt also, like a massive decision where another consultant would've said, I know you're really worried about the pain team, but "I'll be with you" or "I'll get the registrar to come with you". You know, there are ways around that. Dr Watt just said, "No. Let's just give you the morphine into the pump". So, I didn't do that, and then one of the other registrars did, and [the patient] ended up becoming very unwell with the morphine and had respiratory compromise.

9.46 When she was asked to fill the pump, she indicated that she would need to talk to the Pharmacist before she administered the treatment. Eventually one of the other registrars carried out the procedure. This resulted in the patient's breathing being compromised. This was ultimately reversed when Dr Jamie Campbell became involved and administered Naloxone. Dr Hoeritzauer remembers feeling upset about this incident and although she did not write down the details of what had happened in any log, this was one of the cases that encouraged her to go to the Clinical Director, Dr Craig. Commenting more generally about why she felt that she must go to Dr Craig about Dr Watt's practice, Dr Hoeritzauer also gave evidence about her experience at TIA clinics with Dr Watt:

> We were at TIA clinics, you know, and there would just be these young people. They were young, and they had these transient neurological symptoms.

> Sometimes, in neurology, you have to just say, "I don't know. We've done the tests, and this - it could be nothing; it could be something. We don't know. We'll see you again or we'll not see you again unless this happens again". Sometimes, it's all sorts of funny forms of migraine, you know, but there are these patients, and then there are similar patients in other neurology clinics you know? The way that they were dealt with, even by other people in the clinic, but certainly, in other clinics, you know, was very different. You know, everybody was diagnosed with something ischaemic, and everybody was getting aspirin and clopidogrel. And they were young people, you know? And then also, sometimes, you would see people on warfarin and aspirin, if they came back with recurrent neurological symptoms. You know, nobody else was doing that, and it wasn't in anything I was reading. And it just - that felt concerning.

She summarised her concerns as follows:

> The things I was concerned about: TIA clinics, on call, sometimes, patients admitted to the ward that you would see being investigated and managed very differently. There were some examples that, actually, I talked to [my lawyer] about before I actually got the report. The things were, as I said, the TIA clinic, young people, anticoagulants- warfarin & aspirin the epilepsy clinic … People like to stay very closely to the guidelines, whereas, with Dr Watt, there just wasn't the same level of investigation or certainty required for a diagnosis. And then the patients on the ward: it was, again, things like the diagnoses. You know, other people would want an MRI scan and a lumbar puncture and something else before you make this life-altering diagnosis to somebody, whereas, with Dr Watt, it wasn't like that. You could have one thing that's sort of, maybe, a soft sign that somebody else might've said, "This could be". There was no diagnostic uncertainty: it was, "You have this", even when there was quite of lot of diagnostic uncertainty.

9.47 Dr Hoeritzauer talked over her proposed course of action with her friend Dr Carolynne Doherty, another registrar in neurology. She told the Inquiry Panel:

> I talked to my really good friend Carolynne Doherty. We would have conversations after work in her car about, you know, life, the world and everything, at the end of a long shift. I spoke to her, and I said, "I'm worried, and I don't know if I'm wrong". She was a year more junior than I was, and she just said, "Those are really serious allegations. You need to think very carefully about them" and that was our conversation. It was just an informal discussion but I was saying "I'm worried" and she was just saying, "This is a very serious thing you're thinking about.

9.48 Dr Doherty confirmed to the Inquiry Panel, in her evidence of 24th May 2019, that there had been a conversation with her friend Dr Hoeritzauer, prior to Dr

Hoeritzauer's discussion with Dr Craig about clinical concerns in relation to Dr Watt. She could not recall the detail of the clinical concerns, nor the fact that it was Dr Craig but did remember that Dr Hoeritzauer was anxious about raising the matter.

9.49 Dr Hoeritzauer also described her apprehensions at raising the matter with Dr Craig, whom she described as: *"fair, clinically excellent and very knowledgeable"*. She was anxious to state that she did not want to be a troublemaker and was extremely nervous. In her own mind, there was a distinction between chat in the registrars' room about consultants and a serious concern about someone's practice. She told the Inquiry Panel:

> I think it's very important to make a very clear distinction between a bit of chat in the reg. room about who you like and who you don't and saying, "I think this person might be dangerous". Those are worlds apart, those are worlds apart. I think one of them is a very dangerous thing to say, and one of them you've got to be really — before you open your mouth, you've got to be very sure about what you're saying, and the other is just normal life, you know, who you — you know, just normal chit-chat.

9.50 She indicated that when she spoke to Dr Craig, he wanted to know whether the matter could be explained by a difference in practice between neurologists. Was it, for instance, a personality difference on the spectrum of various neurologists and personalities? Dr Hoeritzauer was quite clear that it was not a personality thing. Dr Craig thanked Dr Hoeritzauer for coming to see him and, in her recollection, stated to her that another registrar had come to him with similar concerns. In relation to the manner in which she raised the concern with Dr Craig, Dr Hoeritzauer stated:

> I think I just said, "I'm worried and I've got four names here. If you want to look at their notes, I think these show why I'm worried. [Dr Craig] didn't ask about specifics; he just said, "Is this within the remit of normal clinical practice and just different personalities, or is this very far away from that? and I said, "No this is definitely something outside of personality, outside of variance in clinical practice".

9.51 According to Dr Hoeritzauer, Dr Craig indicated that he did not need the notes and undertook to look into the matter himself. Dr Hoeritzauer described feeling *"massively relieved"*, because Dr Craig had taken the matter seriously. She also recalled being reassured that Dr Jamie Campbell, who she considered to have excellent clinical acumen, had raised similar concerns. She indicated that it was Dr Craig who had informed her that the other registrar with similar concerns was Dr Jamie Campbell.

9.52 Dr Jamie Campbell, in his evidence of 9th January 2020, confirmed that he did have a discussion in the registrars' office with Dr Hoeritzauer about their mutual concern regarding Dr Watt's practice of neurology, probably sometime towards the end of 2013. He was, however, quite clear that he had not personally talked to Dr Craig about his concerns.

9.53 On his second appearance before the Inquiry Panel on 9th January 2020, Dr Campbell had been able to consider the evidence of Dr Hoeritzauer and was keen to clarify the timings. He believed that his discussion with Dr Hoeritzauer and their mutual concern about Dr Watt must have occurred before he left for Brighton, in September 2013. He did recall, however, the case involving the intrathecal morphine was in April to May 2013.

9.54 Dr Campbell had reflected on the discussion in the registrars' office with Dr Hoeritzauer. He was able to confirm that Dr Hoeritzauer had, in the course of their discussion, revealed that she had been to see Dr Craig because she had concerns about Dr Watt's practice and that she had relayed these to Dr Craig in person. Dr Campbell told the Inquiry Panel:

> She didn't discuss the cases [causing her concern] in detail, I don't recall, though we did, in the context of the conversation, discuss the intrathecal morphine case. It was quite exceptional, as you'll appreciate, and one to certainly recall. We discussed a little bit about concerns more generally and what one should do about that — what one could do and what one could expect to happen, perhaps, having raised those concerns.

9.55 Dr Campbell recalled that both he and Dr Hoeritzauer had agreed that it had been appropriate for Dr Hoeritzauer to approach Dr Craig. They both talked about what would happen next and how they, as trainees, might not get direct feedback about subsequent discussions or measures that were put in place. Dr Campbell also remembered that they would have had some discussion about functional cases as Dr Hoeritzauer was developing a sub-specialist interest in such cases. The Inquiry Panel then asked Dr Campbell specifically whether he had also raised concerns about Dr Watt with Dr Craig. His evidence is set out below:

> **Mr Lockhart QC:** [Dr Hoeritzauer]'s got the impression that she was reassured when she went to John Craig, because John Craig had said, "Oh, I've already spoken to Jamie Campbell about that". Do you recall that at all?
>
> **Dr Campbell:** I hadn't — I think I can say with some confidence I hadn't gone to Dr Craig in the manner in which Ingrid did. I didn't make a formal meeting. I think that's something I would've recalled and would probably be on record.

> Clearly, from Ingrid's account, she's, at the very least, got the perception that Dr Craig and I had had a discussion. She doesn't outline what that discussion was or was in relation to. I can only make assumptions or draw inferences from that. I'm not sure specifically what he was referring to in that discussion. I can only assume it's been on the back of discussions we've had about individual cases wherein, if Dr Craig was on call, for example, and a patient had presented to hospital or, perhaps, was in the neurology ward and he was ultimately responsible overnight, we would've discussed that case. I'd always sought — if there were cases that I was uncertain about, I was worried about, I would've raised that with the relevant consultant on call. The weekends, for example, would've been the most likely scenario, where we maybe had a more detailed discussion about the current inpatient cohort, and he may have drawn an inference from some of those as to some disquiet".

9.56 Dr Campbell confirmed that he did not have the kind of discussion he had with Dr Hoeritzauer with any other doctor or consultant, but did emphasise that, in his view, *"everyone (i.e. registrar peers) would have had a fairly uniform sense of Dr Watt's practice"*. In general, he felt colleagues shared concerns about Dr Watt, although Dr Campbell stated that he found it difficult to give precise details about discussions that he had with colleagues. When asked, he would have said that it would not have been in any way surprising for someone in the registrars' room to raise concerns about the management of Dr Watt's patients. Conversations about Dr Watt between registrars, and especially the more senior registrars (which would have at the relevant time period included Dr Hoeritzauer, Dr Carolynne Doherty, Dr John McKinley, Dr Stella Hughes, Dr Aisling Carr and Dr Ferghal McVerry), would have occurred much more frequently with regard to Dr Watt's patients than any other consultant. The discussions would have been case focused and Dr Campbell was clear that there was not a discussion between registrars about what they should or could do as a group.

9.57 Dr Campbell described a general reluctance amongst his peers to become involved with Dr Watt's patients because of the number of perceived uncertainties that existed. Dr Campbell said that it wasn't necessarily the case that the registrars' believed Dr Watt was wrong, merely that he or she didn't understand the treatment proposed for the patient. In summary, he stated:

> So, I think, early on, I was aware that there were some aspects of Dr Watt's practice that I'd reservations about and I would certainly choose not to emulate as a consultant but which did not, in of themselves, constitute significant concerns. However, I think, as time went on and some of those practices became more apparent — some of his methodologies — I did have concerns about those particular practices.

9.58 Dr Campbell went on to say that such concerns were discussed as a group of registrars. He stated:

> **Professor Mascie-Taylor:** Right. So, between you, you talked about this.
>
> **Dr Campbell:** Correct.
>
> **Professor Mascie-Taylor:** I think I need to be really clear about this. Did you talk about the fact that —? Were you saying, "His practice is so unusual: what should we do?"? Was that the nature of the conversation, or was it —? Well, you tell me what it was. I can think of a lot of conversations you might have had.
>
> **Dr Campbell:** Yes. I suppose some of them were, perhaps, inferences, in terms of those discussions regarding handover and so forth. There were specific discussions that, clearly, I recall. I was close to one of the registrars: Ingrid Hoeritzauer was one of the other registrars at that time.

9.59 As Dr Hoeritzauer transferred for a period to Craigavon in February 2014, and Dr Craig took up his post as Clinical Director in or about early 2013, the Inquiry Panel believes that the conversations probably took place in mid-2013. Dr Hoeritzauer believed that subsequent to her conversation with Dr Craig, matters relating to Dr Watt appeared to improve. She indicated to the Inquiry Panel:

> There seemed to be just more care and attention to diagnosis, and there was less of these sort of — less — less — less therapies that seemed to, sort of, come out of nowhere. Dr Watt would then also, sometimes, you know, sort of, say, "Oh, I was listening to the American Academy of Neurology podcast on the way in, and here are the 12 reasons for" whatever. And that's the kind of chat we like to have in neurology, so, you know —. So, there was a lot of that, and I was — I was just really — I was really pleased that I had — I felt I'd raised my concern and action seem to have happened. I did feel like something had happened.

9.60 Dr Hoeritzauer then confirmed that Dr Craig never told her what action, if any, had been taken. Shortly after this, in February 2014, Dr Hoeritzauer went to Craigavon, but on her return in 2015, she again became concerned about Dr Watt. She believed that the behaviour, which she observed on the ward, had a similar pattern to what she had seen previously; namely, minimal or inconclusive investigations giving rise to life altering diagnoses. Although Dr Hoeritzauer did not specify the date of the Grand Round, she remembered Dr Watt presenting patients that had dissections, where imaging was not conclusive. Dr Hoeritzauer recalled that Dr Orla Gray had challenged Dr Watt's conclusions and had said to the medical students who were in attendance, in relation to what Dr Watt had said: *"this is not how we practice neurology"*. She recalls feeling relieved that somebody else was calling the matter out.

9.61 Dr Hoeritzauer's recollection was explained by Dr Gray in her evidence of 4th November 2019:

> But my memory was sitting in the room when Dr Watt was presenting one of the two presentations. I can't remember which. He was doing a PowerPoint presentation and had slides. He showed a slide on the clinical history, and then the next slide that I was aware of was on investigations. There was no slide on the neurological examination.
>
> I actually, to be completely honest, thought I had daydreamed or missed it, so I spoke up and said, "I'm sorry, did I miss the slide on neurological examination?" which I think on retrospect might have come across as sarcastic to the group but wasn't actually intended to be sarcastic. And [Dr Watt] said no that there wasn't a slide and went to move on. And I said, well, neurological examination —. I think he said it wasn't relevant, and I pointed out that the neurological examination is always relevant. And I said for the benefit of the students in the room — so, there's a group of third-year medical students at the back — "I would like to point out the neurological examination is always relevant, even if it's normal, and it's a really important part of what we do". And Dr Watt moved on to the rest of his presentation. At the very end of that meeting, as we were about to leave, I made another statement about that. So, we were about to leave —.
>
> **Mr Lockhart QC:** To the meeting?
>
> **Dr Gray:** To the meeting, to the group. I just said, "Sorry, I would like to just say again, for the benefits of the students, I want to clarify the importance of the neurological examination, and it's really important that you go out there and learn to do it well and —".

9.62 Dr Gray was anxious to explain that it was not at all unusual for consultants to clarify matters for students who were attending. She did not believe that she was questioning Dr Watt's diagnosis.

9.63 The Inquiry Panel sought an explanation from Dr Craig as to what he believed had transpired when Dr Hoeritzauer came to see him. Dr Craig confirmed to the Inquiry Panel, in his evidence of 18th December 2019, that the meeting had taken place in the office that Dr Craig had shared with Dr McDonnell. Dr Craig also confirmed that Dr Hoeritzauer had come to discuss issues with regard to Dr Watt. He recognised immediately that he should have recorded the meeting, irrespective of any outcome. The Inquiry Panel's task would undoubtedly have been easier, and both Dr Hoeritzauer and Dr Craig would have benefitted, had a note of the meeting been taken by Dr Craig. He recognised also that it would have been: *"an incredibly difficult*

thing to do" for Dr Hoeritzauer. He believed that the meeting would have taken place shortly after he had commenced his role as Clinical Director and estimated that this would have been about the middle of 2013. The Inquiry Panel believes that it is important to set out fully Dr Craig's response to Dr Hoeritzauer's evidence:

> **Dr Craig:** In terms of how the meeting was conducted, I'm sure it could have been conducted better on my part. She did mention that she had concerns, as I said — not concerns; it was more she wanted to talk about issues around Dr Watt. I told her that I would have to — anything that she told me, I would have to investigate that formally and fully etc. Again, I didn't make a record of it, but I have a fairly clear recollection that she told me she didn't want that to happen. She didn't want it to be taken forward.
>
> After that, there were very few clinical details given. I do have some memory of being told something about the use of anti— of blood-thinning products in people. But in terms of being offered four names and me refusing, I have no recollection of that happening. Now, I didn't make a record of it, and it's six years ago, but it's so important, it's the sort of thing you're going to immediately remember.
>
> Whenever, obviously, we heard about this [Inquiry] process was going to happen, the fact that I'd had the meeting with Ingrid immediately popped into my mind. I've no recollection of any other, of other registrars coming to me and telling me of any concerns. If they had done, I'm sure that that would have immediately popped into my mind as well.
>
> Ingrid did come, Ingrid did tell me that she wanted to discuss issues with Dr Watt. But in terms of any details being given, and, again, it comes back to a point that you made earlier about, "When do you think you have enough?" I didn't think that I had enough information to take anything forward. As I say, there was the issue about — there was the mention of the blood-thinning products, but that's about as much clinical information as I remember being given. I certainly do not remember being offered four health and care numbers and certainly don't remember declining those.
>
> I note that she'd said that I said that I would take it, I would investigate it, I don't see how I could have done that if I didn't have any details. So I didn't record it; I should have recorded it. I think, looking back at the time, I should really have taken advice, because I was new in the job. I should have gone and should have spoken to somebody and said, "This has happened. What do I do here? Do I go back and insist on a further meeting to try and get details? What do I do here?"
>
> **Mr Lockhart QC:** Do you recall mentioning Jamie Campbell having come to you as well?

Dr Craig: No.

Mr Lockhart QC: No.

Dr Craig: I have a vague recollection in my head that somebody told me that Ingrid was coming to see me. But I can't be certain about that. But Jamie Campbell, I'm not aware that Jamie Campbell had ever brought concerns to me. I've seen testimony from Jamie Campbell from later, a couple of years on, or whatever, but I don't remember Jamie Campbell coming to me.

Mr Lockhart QC: In fairness, Jamie does not refer to the fact that he brought anything to you.

Dr Craig: I don't remember him coming to me.

Mr Lockhart QC: Just to be absolutely clear: you're fairly clear, from your recollection, that you didn't discuss it with anybody else. You didn't say, "By the way, Gavin –".

Dr Craig: No, I didn't. And that was whenever -. Again, this is -. The fact that Ingrid came, that, for me, that, that, you know, concentrate enough on that. The bit about, when Ingrid said she noticed things had changed, I didn't discuss anything. I certainly didn't discuss anything with Dr Watt about this. So if changes took place in what he was doing, I didn't affect those, because I didn't speak to anybody else.

Mr Lockhart QC: Just so that I understand: you're saying that, in your mind, there was insufficient concern to raise investigation.

Dr Craig: Again, I've thought, again, you can imagine, when you read the testimony over and over and over again, and it's kind of hard to remember what you think you knew at the time and what you know now. I did not think that I had anything that I could take forward.

There was a suggestion about, as I say, the blood-thinning products, but I do not remember any conversation about any individual patients, and I do not remember being offered four health and care numbers, but I didn't make a record of the meeting.

Mr Lockhart QC: Was it clear, that she was concerned about his overall practice as a neurologist, as opposed to specific cases? Or, do you recall that?

Dr Craig: I think the only thing, as I say, was mentioned was about the blood-thinning products. And, again, there's no – this is not me in any way trying to make any justification. I mean, that's a clinic, obviously, that was done with shared consultants doing it. None of the other consultants -. You know, it's not like there was somebody else had come to me that would've been overseeing that work a bit more.

> **Mr Lockhart QC:** Whenever you've seen other. I mean, we're going to go through – unfortunately, painstakingly – all these other instances, did you ever think back and say, "Gosh. There's Dr Watt's name again. I wonder what Ingrid's concern was" or, you know, the fact that she came to you was – that you kind of recorded as significant or, you know, that, "Here's a red flag here".
>
> **Dr Craig:** Sorry, in terms of other things?
>
> **Mr Lockhart QC:** Sorry. When other incidents happened, you know -.
>
> **Dr Craig:** Complaints and - ?
>
> **Mr Lockhart QC:** Well, let's look at -. We're going to look at some of the other cases – some of the other complaints that are coming in about [Dr Watt]. In 2013, for instance, there's a number of other complaints, some of which are clinical complaints; some of which are misdiagnosis complaints. And we're going to go through those, and to the extent to which you actually were looking at those in any depth, we'll have to explore because it's not clear that you were. But I'm just wondering, when other incidents occurred, leaving aside the administrative inadequacies, did you ever think back and say, "I wonder is that related to what Ingrid was talking about"? Did it ever occur to you -? Did you ever link other events with what Ingrid had said?
>
> **Dr Craig:** I think the short answer to that is probably no. In terms of the significance of the Ingrid event, nobody had ever come to me before with -. They have since, and when they have, it's been investigated really very promptly …

9.64 In her most recent evidence to the Inquiry Panel, and having been made aware of Dr Craig's recollection of events, Dr Hoeritzauer stated:

> No. The conversation we had was something like, I started off with this thing, 'I don't want to cause trouble. I don't want to get anyone in trouble, but I'm worried about this consultant', and I said Dr Watt. Then he said something like, 'is what he is doing very far outside of the practice of what other people are doing, or is this just he is just doing things in a slightly different, in a sort of personal way, even though it is a bit different?' I said, 'no, this is far outside the remit of what other people are doing, and it is far outside the remit of what I think is normal'. I don't even think I discussed specific cases with him. I just said, 'look, I am worried, and I think this person is doing something that is really different to other people. I might be wrong, I might be absolutely wrong, but I thought I needed to come and talk to you about this. I'm just really worried'. I mean obviously, having read both Dr Craig and Dr McDonnell's statements, it is always hard to say because it's retrospective, but I know how I felt when I left the room. I think he did say, 'leave it with me'. That was definitely my recollection, because if he had said or if we had had a conversation of, 'look, I

> can't do anything unless you want to make a formal complaint', I know that I would have carried that home with me, and I would have thought about that and thought about that and thought about that, and then made a decision based on that. Whereas I walked out of the room and I thought, 'I've left it with him. He's great. He's just such an advocate and somebody I admire so much; you know, really good clinically and just all these great things. I thought I have gone to him and I've said this thing and it's serious, but Jamie said it as well. Great. He knows and that's great, that's really good. You know, this is a weight lifted off my shoulders.

9.65 It is common case between Dr Craig and Dr Hoeritzauer that a meeting took place about Dr Watt and that Dr Hoeritzauer raised concerns probably at the end of 2013. Dr Campbell does recall subsequently discussing concerns about Dr Watt with Dr Hoeritzauer at some point subsequent to Dr Hoeritzauer meeting with Dr Craig. This is likely to have been in 2013, as Dr Campbell went for a period to Brighton in September 2013. As a registrar, Dr Campbell was unsure as to what would happen next. Both he and Dr Hoeritzauer felt that these were difficult and sensitive issues that trainees may not necessarily hear feedback on. He recalls that Dr Hoeritzauer was resolved that if problems persisted, they would need to be addressed in some manner.

9.66 The absence of any notes taken by Dr Craig made it almost impossible to accurately understand with certainty, precisely what transpired. As Clinical Director, Dr Craig was obliged to record the fact that the meeting had taken place and also discuss with either the Associate Medical Director or the Medical Director's Office the general nature of the concern that had been expressed. Dr Craig concluded that he did not have sufficient information to adequately investigate and did not believe that Dr Hoeritzauer wished to take the matter further. While the Inquiry Panel accepts that this was Dr Craig's reasoning, there should have been, at the very least, communication or a further discussion with Dr Hoeritzauer and Dr Craig should have discussed the matter with those who were more senior in medical management.

9.67 Dr Craig's approach was not dissimilar to Dr Donagh MacDonagh, who also concluded that, in the absence of further detailed information, he was constrained. This is not a proper understanding of the role or the responsibility of a Clinical Director. Dr Craig's relative inexperience in the post may have caused him to adopt the approach of a consultant neurologist rather than a Clinical Director. He was used to making diagnoses every day. If information did not permit him to come to a definite conclusion, he ordinarily would not make a diagnosis. As a Clinical Director, however, his role was different. He was required to immediately escalate

to others, concerns raised and allow others to ensure that there was adequate investigation and evaluation. It was not appropriate for him to apply his own filter to the concerns raised.

9.68 The failure of Dr Craig to both record a note of the conversation and escalate the concerns came at the same time as Dr Watt was being investigated by Dr Fullerton and was under the notice of both the Doctors and Dentists Case Review Meeting ("DDCRM') and the Medical Director, Dr Stevens. This was a significant missed opportunity to potentially identify problems with Dr Watt's practice. It also occurred at or about the same time Dr Jim Morrow had indicated that he would speak with Dr Watt regarding concerns relating to the treatment of two pregnant mothers with epileptic medication. Again, no record exists of that conversation, if it did take place. The significance of this period is set out and explained in the 2012-13 Missed Opportunities in chapter. The Inquiry Panel accepts that Dr Craig believed that he did not have sufficient information to investigate further. However, there should have been, at the very least, communication or a further discussion with Dr Hoeritzauer and, as with Dr Jim Morrow, he should have discussed the matter with those who were more senior in medical management.

9.69 The lost opportunity was also compounded by a number of synergistic factors. Dr Hoeritzauer believed that she had noted some subsequent improvement in the situation, which she put down to Dr Craig doing something about the matter. In fact, Dr Craig had not taken any action, nor had he spoken with Dr Watt about Dr Hoeritzauer's concerns. Dr Craig believed that Dr Hoeritzauer was sufficiently reassured and did not wish to progress the matter. That was a significant misreading of Dr Hoeritzauer's position. Dr Hoeritzauer subsequently discussed the matter with Dr Jamie Campbell and was again reassured that a colleague for whom she had enormous respect had similar concerns. Dr Hoeritzauer also perceived that the situation with Dr Watt had improved before she left for Craigavon in February 2014, and she concluded that this was because Dr Craig had addressed the situation. The fact was, however, that the matter was left in abeyance because of the confusion that had emerged. When Dr Hoeritzauer came back from Craigavon in 2015 to the Royal Victoria Hospital, she again noted problems with Dr Watt's practice.

9.70 The Inquiry Panel wish to record how clearly difficult and challenging it was for Dr Hoeritzauer and Dr Jamie Campbell to give their evidence in such a forthcoming and candid manner. For an Inquiry expressly tasked with determining whether there were concerns prior to November 2016, the testimony of these two witnesses was invaluable. There were many occasions during the Inquiry, where the Inquiry Panel

noted evidence of clinicians encountering some of the unusual aspects of Dr Watt's practice. On examination, however, few expressed any concern. The Inquiry Panel was at pains to explore its evidence with all the other registrars (many of whom had gone on to be consultant colleagues of Dr Watt). Ultimately, having heard all of the evidence received by the Inquiry Panel, and with the benefit of hindsight and knowing how categorically damning the Royal College of Physicians ("RCP") report was on Dr Watt, it was surprising that there weren't more neurologists who were more concerned by Dr Watt's practice.

Concerns about Dr Watt's Practice raised by the same Registrar – June 2015:

9.71 On 30th June 2015, Dr Hoeritzauer raised an issue about Dr Watt's practice at a trainees' meeting with Dr Gavin McDonnell, who was the Clinical Programme Director, and for whom Dr Hoeritzauer had the highest regard. Dr Hoeritzauer had returned from Craigavon and her earlier concerns regarding Dr Watt, which she had raised with Dr Craig in 2013, had re-emerged.

9.72 Dr Hoeritzauer indicated, at the end of the meeting in response to an open question about any other matter, that she was concerned about one consultant's practice. She recalls Dr McDonnell asking her whether she would like to talk separately about it. Dr Hoeritzauer cannot recall specifically what she subsequently said but remembers indicating that she was both worried and concerned. She believed that she gave Dr McDonnell the name of one patient. That patient had apparently subsequently made a very good recovery, according to Dr Hoeritzauer and Dr Hoeritzauer believed that there was not much that Dr McDonnell could have gleaned from that particular patient history. Dr Hoeritzauer further stated in relation to Dr McDonnell's response:

> I can't remember anything other than him saying, "Can you give me names? Can you give me the names of the people?" He phoned me and said, "Can you give me the names?", and I said, you know, I just —. By the time I found out that this one name was not helpful, I was already — like, I think I had left everything in Belfast, you know, because I didn't want to take any, you know, any patient stuff with me.

9.73 Dr Hoeritzauer recalled that when she moved to Edinburgh, Dr McDonnell had again contacted her and asked her whether she had any other names for him. Dr Hoeritzauer knew Dr McDonnell to be fair and that he would take anything that a junior had said seriously. Dr Hoeritzauer also remembered, before she left for Edinburgh, speaking on the stairs to Dr Enda Kerr, one of the stroke consultants and that she was worried about Dr Watt and remembered Dr Kerr confirming to her that

he had also spoken to Dr Ivan Wiggam. She believed that Dr Kerr had expressed an unhappiness about the TIA Clinic.

9.74 Dr Kerr gave evidence to the Inquiry Panel on 12th September 2019. He did remember a brief half-minute conversation on the stairs with Dr Hoeritzauer. He believed that they may have spoken about the TIA clinic, where Dr Kerr was keen to improve waiting times. Dr Kerr would have been talking to Dr Wiggam about a new TIA service, but he did not believe that he would have said anything about being concerned about Dr Watt. He could not, however, recall whether Dr Watt was mentioned in the conversation.

9.75 Dr Ivan Wiggam gave a statement to the Inquiry Panel dated 9th June 2021. He had worked alongside Dr Watt in the TIA clinic between January 2000 - January 2004, but not thereafter. He confirmed that, prior to 2017, he had several informal conversations with Dr Kerr about providing a timely TIA assessment service. He did not recall Dr Kerr ever raising concerns regarding Dr Watt's clinical competence.

9.76 Dr McDonnell gave detailed evidence to the Inquiry Panel regarding his recollection of Dr Hoeritzauer's concern, which had been raised in response to an open question at the end of the training programme meeting. Dr McDonnell told the Inquiry Panel on 17th October 2019:

> **Dr McDonnell:** I think she raised —. It's very hard to remember exactly that moment; it is four and a half years ago … It is a long time ago. I know where the meeting was, I know the date, because I have it on my phone and a few of the text messages, which are very helpful, actually, in terms of narrowing it down, which I have put in the statement … My recollection is that she raised concern about one case. And then we resolved —. After the meeting I was going off somewhere else to another meeting, and I indicated to her that we needed to discuss that, obviously. She didn't really get into the specifics of it. I think, at the time, my recollection — I may be wrong — she did say that it was about a patient with motor neurone disease and she thought the diagnosis was wrong … There was a delay, and then, eventually, I did speak to her. You have the sequence of events on the —
>
> **Mr Lockhart QC:** On the statement.
>
> **Dr McDonnell:** — on the statement. And that's my very clear recollection: at the end of that, speaking to her on the phone, she ultimately said, in terms, that she had been overly anxious about it. She didn't want to give me the name, the H&C number, which was what I wanted to be able to investigate further, and that she didn't want to pursue it any further. And that was it. And that was before she went to Edinburgh. She was still in Belfast. She hadn't gone to Edinburgh until the following week, at least the following week …

Mr Lockhart QC: In your recollection, you say that it was about one case, as opposed to a consultant's practice.

Dr McDonnell: Absolutely. Absolutely. Absolutely. And, indeed, the interactions that I had with her … So, this is 16:10 on the 1st of July 2015.

Mr Lockhart QC: That's the meeting with all the registrars?

Dr McDonnell: Yes. So:

"Ingrid, need to talk to you about that issue from yesterday".

So, the implication of that is that it was the 30th of June. And I've checked that. It was a Tuesday, and a Tuesday would make sense because that would be a time that I would sometimes have time with the trainees.

"Are you around week beginning July 20th? I'm busy this Friday, then on leave for two weeks. Gavin".

And she's responded, actually 36 hours later, on the 3rd of July 2015:

"Yes, that would be great".

That's at 9:01 on the 3rd of July 2015. And I've responded:

"Thanks Ingrid".

So, then later on, on 17:17 on 28th of July 2015:

"Ingrid, what about that challenging patient/situation you described a few weeks back? Need to talk to you about it".

Now, that was at 17:17. She responds:

"I'm in the reg. room" –

that would be the registrar room — 17:23 on 28th of July 2015. I was on my way to the Belfast City Hospital, so:

"Heading to BCH. Can I call you in 20 minutes?"

So that was at 17:25. Then she responds:

"I'm on call. Free whenever. I might try to sneak home to see [redacted] before bed" –

That would be her daughter –

"but I can work around you and I may just get bleeped" …

Mr Lockhart QC: Was there ever - ? Did you ever meet with her specifically? Did you ever manage to meet with her about the case?

> Dr McDonnell: About that particular case, no. Because, as I say, following that conversation, she was clear that she didn't want it to be pursued and I didn't get information regarding the patient's name or H&C number to investigate that. And that was it. I didn't hear anything more about it until getting this transcript.

9.77 The Inquiry Panel went through in detail with Dr Hoeritzauer, when she gave evidence on the second occasion on 9th September 2020, the contentions of Dr McDonnell and his strong recollection that only one case had been raised with him by Dr Hoeritzauer. According to Dr McDonnell, this was not pursued because, following the conversation, Dr Hoeritzauer did not wish the matter to be pursued. Dr Hoeritzauer accepted that the case concerning Motor Neurone Disease may have ceased to be problematic. The following interaction took place with the Inquiry Chairman:

> **Mr Lockhart QC:** Just so I understand it, Ingrid, you are clear there was a conversation on 28th July. When you put together Dr McDonnell's text it looks like it was when you were still in Belfast. And you may have said at that time to the best of your recollection Stella sorted that other case?
>
> **Dr Hoeritzauer:** Mm-hmm.
>
> **Mr Lockhart QC:** So, if Dr McDonnell felt like that case in particular was out of the equation, that would be a reasonable assumption?
>
> **Dr Hoeritzauer:** Yes.

9.78 Dr Hoeritzauer was, however, clear that she had broader concerns:

> **Mr Lockhart QC:** But you were also clear that you had broader concerns. Can I just ask you do you recall -- I'm not sure Dr McDonnell recalls this -- a subsequent conversation when you were in Edinburgh?
>
> **Dr Hoeritzauer:** Yes, definitely, because he definitely said to me, 'look, can you give me those health and care numbers? Can you give me any other patient details?' I remember saying to him, 'no, I can't'. You know what I mean?
>
> **Mr Lockhart QC:** Yes.
>
> **Dr Hoeritzauer:** I'm sure he's right and I am sure it just shows that's medicine, doesn't it. I was moving to a different country on the Wednesday and I was on call the Friday night, that's the type of thing. I know I definitely had a conversation with him when I was in Edinburgh and I remember sort of saying to him 'look, I don't have the information'. I remember him saying to me, 'can you get me that? That would be really important. Can you get me that?' I remember thinking, no, I don't think I can. I don't know if I said that out loud,

> but I remember we definitely had a follow up conversation where he asked me, he said do you have other health and care numbers, and I said no.

9.79 The Inquiry Panel found it difficult to come to a definitive conclusion on what exactly transpired whenever Dr Hoeritzauer left Belfast. The text messages disclosed by Dr McDonnell were of assistance in giving context and accuracy to the interaction between Dr McDonnell and Dr Hoeritzauer when the latter was still in Belfast. It does seem likely that Dr Hoeritzauer's concerns regarding a case were ameliorated following discussion with Dr McDonnell. It is also the case, as accepted by Dr Hoeritzauer that she may have started off talking about one patient in the registrar meeting on 30th June 2016. The Inquiry Panel accepts, however, that Dr Hoeritzauer had a broader range of concerns than just one case, although this was not appreciated by Dr McDonnell.

9.80 It is evident that, not only had Dr McDonnell and Dr Hoeritzauer the highest regard for each other, but they approached the matter before the Inquiry Panel with candour and made every effort to piece together the precise sequence of events.

9.81 It is apparent that Dr McDonnell, who throughout his evidence was meticulous and cautious in his approach as a neurologist, made significant efforts to pursue the matter. Unfortunately, however, there is no contemporaneous note apart from the text messages. These messages do not identify the nature of the concern. In any situation where a concern is raised about a colleague, a careful note needs to be taken by the doctor receiving the concern. As with the concerns that had been brought to the attention of Dr Craig and Dr Morrow, this did not happen in this instance. Further, the fact that a concern had been raised should have been discussed, at the very least, with the Clinical Director, even in circumstances where it is genuinely believed that the concern has been addressed or is no longer a concern. In this case, if Dr McDonnell had spoken to Dr Craig, it is likely that Dr Craig's earlier conversation in 2013 with Dr Hoeritzauer would have come to light. At that point, the matter could have been escalated and investigated.

9.82 Dr Hoeritzauer deserves the highest praise. On two occasions she, with great courage, raised concerns first with Dr Craig and then Dr McDonnell. On both occasions, for a wide variety of reasons, the efforts that she made did not result in the issue being properly considered. Dr McDonnell's case is different because he clearly followed up on Dr Hoertizauer's reference to Dr Watt in a trainee meeting. Once again, however, events conspired against those involved. Dr Hoeritzauer went to Edinburgh and, despite attempts by Dr McDonnell they never actually met to discuss matters further. The Inquiry Panel can only reflect with a degree of

frustration that the efforts made by Dr Hoeritzauer ultimately came to nought. If all of these matters had been properly recorded, communicated and escalated, then it seems likely that an earlier investigation would have been instigated.

Prescribing Concerns raised by the Public Health Agency:

9.83 On 15th December 2014, Dr Diane Corrigan from the PHA emailed Dr Craig stating:

> I was running my eye down the IAP monthly request lists and noted quite a lot of requests from one consultant neurologist. About 10 or 11 adult neurologists names were on the list. Of approx. 112 requests for adult neurology between April and September (this may be one or two out as I don't recognise all the names and some might be paeds cases) 40 (35%) were under the name of a single consultant. The next most frequent prescribers had 20 and 17 requests respectively (18% & 15%). Without knowing the subspecialty interest all of the neurologists it is impossible to say whether this would or would not be a surprise to you. I had asked Rhona Fair if perhaps the distribution of new requests by consultant differs from those receiving on going IVIG (and therefore one consultant might simply have a cohort of patients on long term treatment while most other requests were for short term therapy) but until the dedicated pharmacist comes into post in the new year she is not able to analyse the requests in this detail. Is this pattern of use what you would expect knowing colleagues' areas of special interest?

9.84 Dr Craig responded:

> We roughly should have the same. Problem as you have identified is some conditions which are very rare require regular IVIG. If by chance any consultant identifies such patents will significantly skew the numbers. It would be important to link with indications. If approved hard to argue with. Also, consultant activity varies widely. Another topic for discussion.

9.85 The Inquiry Panel accepts that the context of Dr Corrigan's concern is different. She was on an approval panel with Dr Craig. She properly raised a question and, although Dr Craig recognised that the rate of prescription of Human Immunoglobulin ("HIG") should be similar, the matter was not followed up by either Dr Craig or Dr Corrigan.

Concerns about an MS Diagnosis by Dr Watt in 2008:

9.86 The Inquiry Panel became aware that Dr Brendan Lavery, a Consultant in Emergency Medicine, had queried a diagnosis of multiple sclerosis by Dr Watt in or around

2008. The Inquiry wrote to Dr Lavery to ask him about this. His response was as follows:

> I have no access to any notes or the letter which were sent to Dr Watt and can only work from my recollection based on a brief incident which occurred approximately in the year 2008. At this time, I was working as a Consultant in Emergency Medicine in Causeway and we had a female patient of approximately 30 years of age who attended on multiple occasions with unusual collapses. She stated that she had multiple sclerosis as diagnosed by Dr Watt, as this patient was becoming a frequent attender to the Department and her presentations did not easily fit an obvious clinical diagnosis, I reviewed her radiology reports on the NIPAC's system. From memory, the patient had recently been investigated with MRI of brain and spinal cord and these were reported as normal with no evidence of demyelination. Based on this, I dictated a letter to Dr Watt asking him about the certainty of his diagnosis given that the MRI scans were normal. This was addressed directly to Dr Watt and not to any management within the Belfast Trust.
>
> I did not receive a reply to this letter or any communication from Dr Watt regarding my enquiry. Again from memory this patient stopped attending the Emergency Department and I did not follow up on my initial enquiry.

9.87 This correspondence is included in the Concerns section because it revealed that other medical professionals from different sub-specialties had raised concerns about one of Dr Watt's patients as early as 2008. Dr Watt should have responded to this concern. He did not do so, which was not surprising in light of his general reluctance to reply to correspondence. The Inquiry Panel, however, noted this interaction as significant because it was a non-neurologist who was raising an issue about Dr Watt's diagnosis of a patient.

Concerns about the Diagnosis by Dr Watt of MS in a Patient in December 2015:

9.88 The Inquiry Panel received correspondence from Dr Eugene Campbell. He currently works as a consultant in Gastroenterology and General Internal Medicine in the South-West Acute Hospital, Enniskillen. He has worked in Enniskillen since 2008 when he took up a consultant post.

9.89 Prior to coming to Northern Ireland, Dr Campbell mentioned the fact that:

> One post had a profound impact on me at the time, and this has continued throughout my career. Another post has relevance because of more recent events.

Mid Stafford Hospital

I was a specialist registrar during the period that Mid Stafford was in difficulty. I was there when Healthcare Commission members came to inspect the hospital. I learned how to perform safe endoscopy. I learned to undertake the medical take when under pressure. I learned how to see people in outpatient clinics. I learnt to open my eyes and see what can go wrong in an entire hospital institution.

I read the entire Francis Report when it was published. I looked at the lessons. I hope I have become a better doctor from this.

Birmingham Heartlands Hospital

I was a Specialist Registrar during the late 1990s through to 2001 in Birmingham Heartlands Hospital. I was very junior, still essentially a baby in the world of being a Gastroenterology Registrar. The Gastroenterology team were co-located on a surgical ward with the Surgical team. We worked very closely with the surgeons. I knew most of the surgical consultants, some well, some only in a limited fashion.

Mr Ian Paterson was a surgeon in Heartlands Hospital. The Kennedy Review into how Heartlands investigated the events was, for me, an amazing report. These were people I knew and had worked with.

I read the entire Kennedy Review when it was published. I looked at the lessons. I hope I have become a better doctor from this. I hope that I follow the path of openness, candour, honesty that he advocated, to encourage patient safety to be the paramount consideration. The Kennedy Review was critical of doctors and institutional practices; investigations were confidential human resources issues and not treated as a patient safety issue.

I have also read the Vale of Leven Hospital Inquiry Report. I have read the Shipman Inquiry reports. I do not claim that I am a crusader. I am an ordinary doctor, but I do try to be a better doctor and learn lessons from when doctors or NHS institutions have not got it right. I try to learn lessons from when I have not got it right".

9.90 Dr Campbell informed the Inquiry Panel:

I sent a letter to Dr Watt in 2015 querying the diagnosis of Multiple Sclerosis in a patient. I did not receive a reply from Dr Watt.

9.91 The letter which he sent to Dr Watt on 31st December 2015 stated:

I hope you're not insulted if I ask a query about [INI 455]: How strong is the diagnosis of multiple sclerosis? I know, I'll come across as a rude, ignorant Gastroenterologist questioning this diagnosis.

> She has been under BCH for years with pulmonary sarcoid. She has a huge liver stretching over to left upper quadrant with chronic cholestatic LFT. This could easily fit sarcoid liver infiltration as well. She had a liver biopsy back in 2009 which did not show overt sarcoid, but this diagnosis is still possible.
>
> She has had overt hepatic encephalopathy with asterixis and raised serum ammonia levels. She has oesophageal varices on OGD. Clinically she behaves as if has portal hypertension although that 2009 liver biopsy showed no cirrhosis.
>
> Her LP did not show oligoclonal bands. I know these are not found in all MS patients. So I was wondering, could her other pathologies give MRI mimic of MS?
>
> – Could combination neuroscarcoid +/- chronic ischemic changes +/- chronic hepatic encephalopathy give similar MR changes?
>
> – In absence of oligoclonal bands plus possible alternative cause MRI changes, is MS still number 1 diagnosis?
>
> Yes, I admit I am a pain, but always like to question things. Let me know what you think. I am still happy to hear your reply even if you call me an idiot!"

9.92 In his letter to the Inquiry, he was keen to clarify that he had never met or spoken to Dr Watt previously.

9.93 Dr Campbell gave the following details about the specific case:

> I met [INI 455] during outpatient attendances in the South-West Acute Hospital in 2013. She had a previous diagnosis of Sarcoid. Sarcoid is a multi-system disease that can affect any part of the human body. Sarcoid most commonly affects the lungs, but the gut, heart, liver, skin, and brain can all be affected.
>
> I met her again in 2015 during inpatient admissions to the South-West Acute Hospital. By this time, she had features more in keeping with liver cirrhosis and portal hypertension. She suffered from hepatic encephalopathy.
>
> [INI 455] now received a diagnosis of Multiple Sclerosis, sometime circa 2013 or 2014. However Northern Ireland Electronic Care Record [NIECR] could not give me much background as to who or how this diagnosis was made. I am not a Neurology Specialist. I do not claim any expertise here; however, a lumbar puncture examination in 2015 did not reveal any oligoclonal bands in CSF. The presence of oligoclonal bands is one mechanism to help the diagnosis of MS.
>
> Do I have the right diagnosis? If I have the right diagnosis, then hopefully I will give the right treatment. This is a question I ask myself often. Absent oligoclonal bands? Is it MS? Have I got it right? Hence, I wrote my letter to Dr Watt.

> I did not receive a reply. In truth, [INI 455] slipped from my mind. My Gastroenterology colleague in the South-West Acute Hospital was off suddenly with illness in 2016. I was now a single-handed Gastroenterologist trying to do the work of two consultants. I did my best for my patients during this time-period.

9.94 The Inquiry Panels notes that the case referred to Dr Watt by Dr Eugene Campbell followed a similar pattern to that raised by Dr Lavery. The doctors raising the issues were non-neurologists concerned about the diagnosis of multiple sclerosis in patients, who had cause to consult with an emergency physician and a gastroenterologist. Dr Watt did not respond to either doctor, and the matter did not go further. The Inquiry Panel is grateful to Dr Eugene Campbell and Dr Brendan Lavery for their willingness to share their evidence with the Inquiry. The Inquiry Panel notes that a non-specialist was able to raise a significant query about Dr Watt's diagnosis of MS while no similar queries were raised at any time during this period by specialist consultant neurology colleagues of Dr Watt.

Concerns about the Busyness of Dr Watt's TIA Clinic by a Registrar:

9.95 Dr Jamie Campbell is presently a Consultant in the Southern Health Trust, working in Craigavon. He had formerly been a registrar in the Belfast Trust, and it was in this context that he first had concerns about Dr Watt.

9.96 Describing Dr Watt's practice, Dr Campbell gave evidence to the Inquiry Panel on 9th June 2020:

> One of my earliest recollections as a registrar starting was one of the senior registrars — I do not recall who it was — telling me, "Dr Watt does things differently" and that that was something I should be aware of. Over time, I learned quite what that meant and —. I think there was an observation, particularly through outpatients, because that was probably where the greatest turnover was — that Dr Watt would've made a diagnosis quite quickly — at least to me, as a junior registrar. I interpreted that as many years of experience, being able to digest what were quite complex presentations and come upon a diagnosis and a treatment plan. It became apparent as I did other clinics with other consultants that he, perhaps, didn't do as many tests or as many investigations to be certain of that diagnosis. I think that was apparent, and I think we, as a body of registrars, would've recognised that. I think we also recognised that, in general, he didn't particularly believe in psychogenic or psychological presentations for certain conditions.

9.97 Dr Campbell indicated that there were some aspects of Dr Watt's practice that he had reservations about from an early stage, although these would not have been significant. As he became more experienced, problems with the same practices became more apparent to him and he had developed a greater level of concern. He recalled that Dr Watt's practice of neurology was discussed informally among registrars, and he remembered discussing his concerns with Dr Ingrid Hoeritzauer as outlined above at [52] above.

9.98 He told the Inquiry Panel that when he returned from conducting research in September 2015, he was much more aware of patients who were being treated with a blood patch. He stated that he would have occasionally assisted Dr Watt with a number of these procedures. He specifically recalled asking why there was an increase and remembers Dr Watt explaining that he had been in a meeting with the American Academy of Neurology where experts had discussed the spectrum of presentations that can be associated with spontaneous intracranial hypotension ("SIH"). This had caused Dr Watt to look for the condition much more readily and to treat it with epidural blood patches. Dr Campbell indicated that although some patients found the procedure uncomfortable, because it is an invasive procedure, he was not aware of any immediate complications nor, however, was he able to assess the effectiveness of the actual procedure. During his initial evidence to the Inquiry Panel on 2nd May 2019, Dr Campbell disclosed an email that he had drafted to Dr McDonnell, the Clinical Lead for Neurology, on 7th March 2016. The email stated:

> Dr McDonnell
>
> Just wanted to inform you of a potential issue pertinent to training.
>
> There have been increasing demands on the day case registrar as a result of increasing investigations and procedures such as blood patching.
>
> As a result it is almost now routine for an ad hoc day case list (for otherwise routine procedures) to be booked on a Tuesday morning. I appreciate some tests do need to be in the lab before 3pm but this means the day case registrar is frequently unable to attend the neurosciences meeting. As this is our main educational meeting, this inability to attend is potentially detrimental for training.
>
> I am not sure if there is an easy solution to this other than to ring fence additional day case sessions in the longer term but just wanted to let you know in case it creeps up during training surveys etc.
>
> Jamie

9.99 Dr McDonnell, in his evidence, was quite clear that he had not received this email. When the matter was more closely scrutinised, it became apparent that the email may not have been sent or had not been successfully delivered to Dr McDonnell, as there were some subtle differences between this email and others, which had been successfully delivered. This email did not record the time it had been sent, merely the date. In his subsequent evidence of 9th June 2020, Dr Campbell, looking at the printout, noted that it had some different characteristics and accepted that it would not have been received by Dr McDonnell. In all probability it was a draft that was not sent. The Inquiry Panel is also of the view that the email was not received by Dr McDonnell and believe, having regard to his response to Dr Hoeritzauer in June/July 2015 that he would have followed the matter up. Nevertheless, the content of the email does give a sense of Dr Campbell's concern about training at that time and the demands on the day case registrar because of the increasing *"procedures such as blood patching"*. The content of the email does not raise concerns nor is it explicit about Dr Watt's practice.

9.100 Dr Campbell also told the Inquiry Panel, in his evidence of 2nd May 2019, about a registrars' meeting to discuss workplace pressures. Dr Campbell believed that Dr McDonnell was present and possibly Dr John McKinley. Dr Campbell thought this meeting was in or about the autumn of 2016. He stated:

> There was one subsequent meeting towards the end of my training. It was convened primarily because of the pressures that I think the registrars were under. There had been a few people going out of programme, maternity leaves and so forth. And as well as that, I think there had been issues regarding the rota banding, and I think things were very borderline there. So, they were keen to review our workload.
>
> So, it was a meeting convened by the registrar and the then training programme director and, during that meeting, I suggested that trainees be withdrawn from Dr Watt's clinic.

9.101 Dr Campbell, in his evidence, described the meeting as follows:

> **Dr Campbell:** There was no specific agenda for the meeting. Everyone was aware of the issues regarding it, in terms of the workload and so forth. There were various things proposed; for example, one of the major issues we were experiencing was provision of stroke thrombolysis care out of hours. Could we involve the local stroke physicians and so forth?
>
> So, there were various discussions. It was mentioned that the day case waiting list had increased significantly, as we've alluded to in the emails. There were discussions regarding what could be done about that on an administrative basis

and so forth. And then, I think, I volunteered that particular suggestion in the course of that meeting.

Professor Mascie-Taylor: So, you chose to volunteer it at that point. And had you thought about that before you went into the meeting?

Dr Campbell: I don't think I had. I don't think I intended to bring it up as an item in that forum. I don't recall that particularly.

Professor Mascie-Taylor: Right. And can you remember — and clearly this is a long time ago — but what you said, I can envisage the difficulty of all of this, so can you remember what you said to your colleagues and, indeed, to one of the consultants who was there?

Dr Campbell: I suggested —. I think I asked the question: could trainees be withdrawn from Dr Watt's clinic — because I think it's damaging to training?

Professor Mascie-Taylor: And did you give a reason why?

Dr Campbell: No. I'd supposed at that stage it might have led to a discussion regarding that, but it didn't at that time or subsequently. I think the explanation — a response I received was that that would be difficult, and the matter was left there …

Dr Campbell: I don't recall any verbal response. I think there may have been some nodding of heads. I can't say that with absolute certainty.

Dr Campbell: I have to say there wasn't a discussion that followed that may've presented the opportunity for others to maybe remark upon it. And to go back to your first question, about the experience of clinics, they were — I felt they were very difficult clinics to do as a registrar. They were very busy clinics. There were many patients. You had insufficient time with patients to really get at the crux of their initial presentation. And, as alluded to in the [Royal College of Physicians] report, which I received with thanks only last week, a number of issues were highlighted there, in terms of the communication. And, actually, being aware of what was going on in that clinic, it often wasn't clear entirely from the letters, which made getting to grips with the cases quite challenging.

Professor Mascie-Taylor: Sure. So, you thought it was not a good, or even a poor, training opportunity. Were your concerns above and beyond that?

Dr Campbell: By this stage, I had concerns above and beyond that, and I was, in the context of —. Having had that conversation with Ingrid, and I believe, having sent that email about the blood patching[2], there were concerns that there was a lack of investigation; that there was a rush to sometimes make the

2 The Inquiry Panel has already accepted as has Dr Campbell that the email referred to was not sent. In all probability it remained in draft.

> diagnosis, or it was perhaps diagnosed without the same diagnostic rigour as some other consultants may have embarked upon. I felt I was able to say that as a senior trainee by this stage, having seen other clinics and having been away, and I suppose I was concerned about what signal that would send out to maybe more junior trainees —
>
> **Professor Mascie-Taylor:** And the consultant at it, whichever of the two it was —. So, when you said a few moments ago, the response to you raising that was, "That might be difficult" —.
>
> **Dr Campbell:** Yes.
>
> **Professor Mascie-Taylor:** So, who gave that response?
>
> **Dr Campbell:** I'm fairly certain it was Dr Gavin McDonnell at that stage.
>
> **Professor Mascie-Taylor:** And did he enlarge on why it might be difficult?
>
> **Dr Campbell:** No.
>
> **Professor Mascie-Taylor:** Did he ask you any more about why you'd just said what you'd said?
>
> **Dr Campbell:** No, and I'm surprised at that, actually. I thought that was an opportunity, of a senior trainee saying something that's perhaps somewhat unusual in that context.
>
> **Professor Mascie-Taylor:** Did he speak to you after it?
>
> **Dr Campbell:** No.

9.102 Dr Campbell was asked who was at this meeting. He responded:

> There were the registrars — and I can't recall precisely who was there, but I think there was myself, the other registrars at the time, Fiona Kennedy, Martin Harley, Carolynne Doherty.

9.103 Dr Campbell clarified that he thought that Dr Catherine Donaldson, Dr John McKee, Dr Laura Best, Dr Michael Kinney, Dr Rachel Kee, Dr Stephen Barr and Dr John McKinley may also have been present at this meeting. He further stated that there were no minutes taken. Each of the registrars referred to was directly asked whether they recalled Dr Campbell raising the concerns at such a meeting. No one had any recollection of the interaction between Dr Campbell and Dr McDonnell, save for Dr Laura Best, who had a clear recollection of the matter and told the Inquiry Panel on 8th September 2020:

> I don't remember saying very much. I was the most junior there so I don't remember saying very much. I do remember being surprised that Dr Campbell

> had brought up about the TIA clinic. At that stage I hadn't done the TIA clinic, but I had obviously done Dr Watt's other clinics. I could get where he was coming from, that they were so busy that there was probably little opportunity for learning. I remember Dr McDonnell saying that would be very difficult, in response to Jamie suggesting that we shouldn't do it any more … It struck me at the time as an unusual thing to have happened.

9.104 Dr Best agreed with the Inquiry Chairman that: *"It was the sort of thing that would have engendered a fair amount of discussion on the margins"*. She recalled that there had been discussion between registrars after the meeting and confirmed that this was the first time she had ever heard a registrar challenge the ability of a consultant to provide training opportunity. The Inquiry Panel was surprised that none of the other registrars could recollect these events.

9.105 Dr McDonnell was clear that he was unaware of any meeting in which such an issue had been raised:

> **Mr Lockhart QC:** So, you're very clear, anyway: you've no recollection whatsoever of any meeting and —.
>
> **Dr McDonnell:** No, it's — you know, if it was withdrawing trainees because of clinics being busy, I would've thought that was an unusual thing to be — and, specifically, Dr Watt's clinic — would've been, again, odd, because there were others. Like, I've had clinics recently where I've had 36 people at an MS clinic, so should my trainees be taken away?

9.106 Dr McDonnell was again asked about the matter when he gave evidence on 29th April 2021. He considered that the meeting being referred to by Dr Jamie Campbell and Dr Best was in January 2017 and that Dr John McKinley was present. Dr McDonnell was quite clear that no issues were raised in relation to Dr Watt's competence, nor did he remember the term *"damaging to training"*. If that expression had been used, he would have recalled the matter and it would have been minuted by Dr McKinley.

9.107 Dr McKinley, in a written statement to the Inquiry Panel of 17th May 2021, recalled that the meeting was on 10th January 2017. His statement records:

> … My recollection, supported by that note, is that the meeting had been called to address the workload of the Registrars and operational matters with specific reference to Dr Jamie Campbell. He completed his specialist training in early January 2017 so was going to drop of the Registrar rota which meant the workload on the other Registrars was going to increase … One of the issues that was raised related to Dr Watt's Thursday morning clinic. The Neurology Registrar was on the rota to hold the stroke bleep on Thursday morning as well as attending Dr Watt's clinic. The issue was that the stroke bleep would keep

> going off requiring the Registrar to go in and out of Dr Watt's clinic which was disruptive. As a solution, I proposed that we swap the Thursday morning TIA clinic with Dr Watt's Monday afternoon TIA clinic …
>
> The Monday afternoon clinic was also one of Dr Watt's so this wasn't a case of Registrars being removed from Dr Watt' clinics; it was simply a case of swapping one TIA clinic for another. It is also worth noting that Dr Watt had two other clinics with Registrars/junior doctors on Tuesday and Wednesday afternoons and no change was made to either of those. Had there been a discussion about removing Registrars from Dr Watt's clinics generally, it would have to have involved those clinics as well.
>
> My recollection, as supported by my contemporaneous note, is that the discussion about Dr Watt's clinic was not related to Registrars being removed from his clinic due to any issue with him, but simply a scheduling issue. Had the discussion arisen as a consequence of concerns being brought out by the Registrars about Dr Watt that would have been a very memorable event which:
>
> (a) I would expect to recall, and
>
> (b) I would expect to be reflected in my contemporaneous note.
>
> Moreover if a concern was being raised such that we were removing Registrars from Dr Watt's clinics we would have had to remove them from all his clinics, not just the Thursday morning one.

9.108 The Inquiry Panel has not been able to resolve or reconcile the various accounts given as to what actually transpired. It is noted that Dr Best thought the meeting was in the summer of 2016 and Dr Campbell estimated the autumn of 2016. The fact that Dr McKinley was able to use a note, does assist and it may be more likely that the meeting included both Dr McKinley and Dr McDonnell in January 2017. The Inquiry Panel has no doubt that Dr Campbell did have concerns about Dr Watt's practice. That is evidenced by his discussion with Dr Hoeritzauer in 2013. The email, which did not reach Dr McDonnell, also highlights his concern about training. Dr Best had a clear recollection of Dr Campbell raising his concern about one of Dr Watt's clinics. It may be that for most of those attending, and for Dr McKinley and Dr McDonnell, the raising of the issue was too diplomatically put or oblique. Dr Best, however, who was the most junior trainee, had no difficulty in recalling it.

9.109 Perhaps all that can be said with sufficient certainty is that raising concerns about a consultant's practice was so unusual in the context of neurology that regrettably it seems that one needed to be loud and persistent before alarm bells sounded. Dr McKinley makes the point that it would not have made sense to complain about one of Dr Watt's clinics without referring to them all. Dr McDonnell had clearly shown

that he had followed up on a concern by Dr Hoeritzauer in June/July 2015, but unfortunately all of Dr Hoeritzauer's concerns do not appear to have been discussed after Dr Hoeritzauer had left for Edinburgh, partly because she no longer had access to any of the patient numbers.

9.110 Dr Campbell also raised with the Inquiry Panel additional concerns about multiple sclerosis patients. In his evidence of 2nd May 2019, he contrasted the approach of other MS consultants with Dr Watt. He indicated that this was discussed among registrars, and he referred to the Multiple Sclerosis Multi-Disciplinary team meeting, which occurred once per month. Dr Campbell stated:

> It happens once a month, and a very similar case being presented there, one that didn't fulfil current diagnostic criteria. There were very subtle signs on an MRI scan, something we might call radiologically isolated syndrome where there's no — yet — clinical features of it. Dr Watt volunteered that he would treat that patient with Alemtuzumab, or Lemtrada, which is one of the — probably the most potent treatment. That was a group of all the MS consultants, of which there aren't very many, four or five of us — four or five of them; I was a registrar at the time. To which there was a very strong rebuke and actually, no, that that was not the correct thing to do. But to me as a registrar, there was an acceptance that that that was Dr Watt's practice, that he did do that, that that was his approach and that that was conveyed to the group.
>
> **Professor Mascie-Taylor:** So, Dr Watt was straightforward about it.
>
> **Dr Campbell:** He was very open about these treatments.

He believed the meeting would have been late 2015/early 2016. Subsequently the prescriptions of high-end treatment, such as Alemtuzumab and Lemtrada were subject to a specific multidisciplinary review and approval.

In his experience, patients would not have fulfilled the criteria for diagnosis. Dr Campbell noted that some of them were receiving therapies for what one would normally consider highly active MS. Dr Watt, when questioned by the other MS consultants, had explained that he was concerned about grey matter disease, which is not well visualised on conventional MRI sequences. He was also concerned about long-term cognitive outcomes, but, while understanding such concerns, Dr Campbell felt that aggressive early treatment needed to be considered alongside detailed observation and testing. Dr Orla Gray in her evidence of 4th November 2019 indicated that the case in question concerned one of her patients. She explained in some considerable detail the clinical issues that arose and believed the reason for referring the case to the team meeting was whether the threshold had been reached to meet MS. She did not recall a discussion about treatment and stated:

> **Dr Gray:** But to me the questions wasn't "Do we use disease modifying treatments in radiologically isolated syndromes?" In my view we don't. That's not the question. I was asking "Is this MS or not?"

9.111 Dr Campbell summarised his concerns that (1) blood patches were being used too frequently; (2) the speed of diagnosis was inappropriate on certain occasions; (3) the normal tests had often not been carried out before a diagnosis had been given; (4) there was reticence to accept a functional or psychological presentation. Dr Campbell also highlighted the fact that Dr Watt's prescription of HIG varied from his peers.

9.112 The Inquiry Panel asked Dr Campbell whether it was likely that other consultants would have had a good insight into the practice of Dr Watt. In response, Dr Campbell indicated that it was not something that he had ever discussed with any of them. Dr Campbell recognised that some of the consultants would be off-site at other hospitals several days per week and would not have been involved with in-patient services. He accepted that they may not have been aware at all of some of Dr Watt's practices. He did, however, state to the Inquiry Panel that anyone who had been a registrar during his time would have been able to observe the same features of practice that he had observed. In this respect, he believed registrars were uniquely positioned. Many of the registrars before and after Dr Campbell had gone on to become Dr Watt's Neurology Consultant colleagues. Other than the incidents detailed in this chapter, they did not raise any concerns prior to November 2016.

Concerns Raised by a Nurse in 2015/2016:

9.113 Nurse Anne-Marie Hunter worked closely with Dr Watt in the TIA clinic for 21 years. She described how she found it easy to work with Dr Watt and emphasised that patients liked him. In relation to blood patching, Nurse Hunter remembered Dr Watt coming back from a conference and informing her about blood patches, particularly in relation to headache patients. Nurse Hunter would have been present during the initial consultation at outpatients. She recalls Dr Watt going over the entire history with the patient and suggesting the idea of a blood patch to them. He would have asked for the patient's mobile number. Nurse Hunter remembers that at the next review, she would have heard both positive and negative stories about the benefit of the procedure. In her evidence to the Inquiry Panel on 7th March 2019, she assessed that negative and positive experiences were roughly equal at the beginning, but that eventually the reviews began to be overwhelmingly negative. Nurse Hunter's evidence was that she was not present during any of the procedures. She was asked

whether she was aware of the very marked increase in the number of blood patch procedures that were being carried out in the Belfast Trust and she replied:

> Yes. I had my doubts, and I started Googling and asking informal questions and just thought that there were far too many being done with no benefit.

9.114 The following interaction then took place between the Chairman of the Panel and Nurse Hunter:

> **Mr Lockhart QC:** Did you ever speak to him [Dr Watt] about it?
>
> **Nurse Hunter:** Yes. Towards the end he would say to the patients, "Anne-Marie's very sceptical about it", but it would have made me feel very uneasy. That was towards the end, not at the beginning. Again, that was the more I Googled and the more I looked into it —.
>
> **Mr Lockhart QC:** So you would have Googled, Anne-Marie, because you were uneasy and you were feeling —.
>
> **Nurse Hunter:** Initially, I went knowledge finding, and the more knowledge I got, the more it became, "This isn't right".
>
> **Mr Lockhart QC:** When you raised it with him, he would acknowledge before patients that he was seeing that you were a bit sceptical about it.
>
> **Nurse Hunter:** Yes, at the end.
>
> **Mr Lockhart QC:** When you say that it was about 50:50 at the beginning and then it was almost all negative at the end, would you ever have discouraged anyone if you were talking to them by saying, "Look, I'm not sure that you should go through with this"? Do you ever remember doing that?
>
> **Nurse Hunter:** Yes, I did do it.

9.115 Nurse Hunter went on to inform the Inquiry Panel that at one point, she would have been raising concerns with Dr Watt on a weekly basis. While recognising that he was a consultant, she believed that the blood patches were not working and she hoped that by questioning Dr Watt, this would cause him to rethink. Nurse Hunter would have raised more general questions with other nurses and with other registrars, she did not escalate her concerns beyond questioning Dr Watt himself.

9.116 Nurse Hunter indicated to the Inquiry Panel that, in her view, the registrars who were working alongside Dr Watt would have had a similar level of concern to her own, as the practice continued. She did become aware of the restriction placed on Dr Watt in December 2016 when Dr Thomas Peukert was required to supervise the diagnosis and treatment of some patients diagnosed with SIH. When Dr Watt told Nurse Hunter about the restriction, she recalled being pleased.

9.117 Nurse Hunter talked about the difficulties of formally raising concerns, particularly regarding the practice of a consultant. She had experience of one ward sister, who raised concerns about a consultant. The concern was *"pushed under the carpet"*, but 6 months later the consultant went to England. Nurse Hunter believed that even with younger nurses who were better trained about raising concerns, the culture had not fundamentally changed. There was a reticence amongst nurses to raise concerns because of the impact on their own careers and promotion prospects.

9.118 In relation to patients, Nurse Hunter was of the view that she did not believe that the blood patch procedure was significantly harmful to patients, and it was for this reason that she did not formalise the concerns that she had raised with Dr Watt. The Inquiry Panel understood the description of *'formalising'* concerns to mean that the matter was escalated to the Medical Director or some other superior who would have been required to raise the matter with the Medical Director.

9.119 Nurse Hunter did advise a patient to get a second opinion in one case. Nurse Hunter had not been happy with the management plan proposed by Dr Watt. This patient had initially been diagnosed with vasculitis by Dr Magorrian. The patient then attended Dr Watt and was told by him that she was experiencing seizures. He prescribed oral steroids. Nurse Hunter felt instinctively that the amount of medication was contributing to a significant number of side effects. When she raised an issue about the patient, a plausible explanation was given by Dr Watt as to why he wasn't referring the patient on to a different sub-specialty.

9.120 In her own mind, she thought that the patient may be suffering from fibromyalgia and suggested to Dr Watt that she be referred to rheumatology. Dr Watt did not think that this was required. Nurse Hunter decided to discuss the case with another consultant, Dr John McKinley. According to Nurse Hunter, Dr McKinley advised that if the working diagnosis was vasculitis, the family should be advised to get a second opinion. In a statement provided to the Inquiry on 17th May 2021, Dr McKinley did recall a brief corridor conversation with Nurse Hunter. He stated:

> … She told me a patient of Dr Watt's, who was being treated as vasculitis, wanted a second opinion and asked who I would suggest to give that opinion. I knew nothing about the patient and had never seen the patient notes. There was nothing to suggest that there was any issue with Dr Watt's treatment of the patient. In Neurology it is very common for patients to seek second opinions and we would always try and facilitate that. I had no hesitation in recommending Professor Kelly as I have a very high regard for his abilities in the field of vascular Neurology …

9.121 Nurse Hunter subsequently passed this recommendation on to the patient. Subsequently, the patient's parents funded a private appointment in Dublin. After the consultation with Professor Kelly, a substantive letter was sent by Professor Kelly, which the patient then discussed in detail with Dr Watt. According to Nurse Hunter, the letter confirmed a diagnosis of vasculitis. Dr Watt continued to disagree with that diagnosis, but the patient liked him and wished to remain under his care.

9.122 Nurse Hunter then indicated that in her experience of working with Dr Watt, he was reluctant to change his mind. She did recall Dr Paul Conn (see paragraphs [5] above) coming to see Dr Watt. She told the Inquiry Panel that, at that time, she had already been working on what was known as a 'care pathway' to try and avoid inappropriate referrals to the TIA clinic. Dr Conn was in the Royal catchment area and Nurse Hunter and one of the then registrars, Dr Ferghal McVerry, went to see Dr Conn at his Ballygomartin Practice. During the meeting, Dr Conn mentioned a particular concern about a patient's diagnosis and that he would be keen to speak to Dr Watt. Nurse Hunter advised that the best way to "catch him" was to come at the end of a Thursday morning clinic. Nurse Hunter remembered that Dr Conn did meet with Dr Watt at the end of a clinic and that they had 'agreed to disagree' on diagnosis, but a treatment plan was devised that Dr Conn could accept.

9.123 Nurse Hunter, who was a senior nurse, also had concerns about Dr Watt's stroke diagnosis and prescription of medication. Nurse Hunter believed this would have been in 2016. She did talk to most of the registrars regarding her concerns in relation to diagnosis and treatment. The stock response tended to be, according to Nurse Hunter, *"you know what Dr Watt's like"*.

9.124 Nurse Hunter reflected before the Inquiry Panel whether, in light of her concerns, she should have done something more. In response to a question from Professor Mascie-Taylor, Nurse Hunter stated:

> A few years ago, I had said to a girl who's now retired that I had concerns, and she said to me, "Annie-Marie", she says, just, you know, "you've your own registration". This isn't to say that doctors or nurses are any better than each other, but she says, "You've got to look after your nursing registration, because no medical staff will look after your nursing registration". And that's sort of the world that we work in. I suppose that's how I behaved: I looked after my own registration … If I had to do it again, I think I would definitely go to one of the consultants and ask for it to be made formal. But I go back to what I said previously: there only ever was Patient X that, I thought, there was significant harm being done to.

9.125 The Inquiry Panel asked Nurse Hunter if the recall was a surprise to her. She indicated that she was not surprised although she was taken aback by the volume of patients who were involved. She described being devastated and going through all the normal emotions associated with questioning oneself and one's own actions. She described the process as like going through a bereavement.

9.126 Nurse Hunter was an impressive witness who spoke with great courage and candour to the Inquiry. The Inquiry Panel recognised that it would have been easy for her to have downplayed her concerns.

Concerns raised by three Physicians in the Northern Trust about the Diagnosis of a Stroke by Dr Watt – February 2016:

9.127 A question arose as to whether this series of concerns or complaints should have been set out in the Complaints chapter. There was an initial complaint (INI 286) regarding the Antrim Area Hospital by the patient's mother. The response to this complaint involved the Belfast Trust and the Northern Trust. The issues that arose in terms of governance are also highlighted in detail in the 2016 Missed Opportunities chapter.

9.128 On 1st February 2016, following a phone call between Dr Ken Lowry, the Medical Director of the Northern Trust, and Dr Cathy Jack, the then Medical Director of the Belfast Trust, Dr Lowry forwarded a complaint from the mother of INI 286, who had been treated by Dr Watt. In his email, Dr Lowry stated:

> This is the complaint I talked to you about. As I explained in my phone call the patient has significant neurological symptoms but normal CT x6 and MRI x2. All of the clinicians who have seen him in Antrim believe there is no physical explanation for his symptoms and are concerned that he is being harmed by unnecessary treatment and by not having his symptomology challenged.

9.129 Dr Jack sought an independent opinion from Professor Wills of the Department of Neurology at the QMC Campus in Nottingham. Professor Wills was asked if he could advise the Belfast and Northern Trusts *"as to the appropriateness of the diagnosis, care and treatment provided to the patient"*.

9.130 Professor Wills provided a report on 9th June 2016 and concluded that the patient was suffering from a functional neurological syndrome. In the view of the Inquiry Panel, Professor Wills upheld the medical views of the three Northern Trust consultants. His report was not, however, shared with the Northern Trust on the grounds that INI 286 did not apparently want it to be shared and wished to continue being

treated by Dr Watt. This is further explored in the 2016 chapter. The most significant observation for the Inquiry Panel was that the concerns relating to INI 286 made it to the Belfast Trust Medical Director's Office. From there an investigation was commenced. With every other concern prior to November 2016 the ultimate failure for those who were notified of the relevant concern was that the concerns were not recorded and escalated to allow similar investigation.

Concerns raised by a Consultant Neurologist with the Medical Director of Northern Trust – May 2016:

9.131 Shortly before the independent report was received from Professor Wills, Dr Tom Esmonde, who gave evidence to the Inquiry Panel on 8th May 2019, and who sadly passed away in August 2021, again went to the Medical Director of the Northern Trust, Dr Ken Lowry with further concerns about Dr Watt. Dr Esmonde believed that he had found a further example of the misdiagnosis of a stroke patient by Dr Watt.

9.132 This matter was explored with Dr Lowry and is fully set out in the 2016 Missed Opportunities chapter. The Inquiry Panel is quite satisfied that if Dr Lowry had passed on to Dr Jack the additional concerns of Dr Esmonde, this would have been acted upon by Dr Jack. The further information would have lent additional weight to the findings in Professor Wills' report to the extent that a more thorough investigation of Dr Watt's treatment of stroke patients could have been initiated.

Concerns Raised by a General Practitioner in November 2016:

9.133 Some of the earliest evidence to the Inquiry was from General Practitioners ("GPs"). As Primary Care doctors, GPs referred patients to Dr Watt and were in communication with the patients both before and after the consultation, dealing with prescriptions that had been directed. It was, in fact, a GP who first raised a number of index cases[3] with the Medical Director's Office in November 2016, which led to action being taken and ultimately a report being commissioned from the RCP.[4] Further details are set out regarding the precise events that transpired in the November 2016 - May 2018 chapter.

3 Dr Colin Fitzpatrick a Comber GP who was also NCAS representative in Northern Ireland contacted the Medical Director's office in the Belfast Trust about 3 patients in his practice, where he was concerned about the diagnosis given by Dr Watt (Ref).

4 The engagement with the Royal College of Physicians was directed by Dr Cathy Jack, the then Medical Director of the Trust, on 25th April 2017. A copy of the report has been obtained by the Inquiry. A panel of Reviewers was commissioned by the RCP to provide an external independent opinion regarding the clinical management of 48 cases selected from across the range of Dr Watt's practice including 6 index cases earlier identified by Dr Fitzpatrick and Dr Craig. In addition to problems with record keeping and communication Dr Watt was found to have exhibited unsatisfactory care in a large number of MS and blood patching cases in particular.

9.134 As a result of information contained in the patients' questionnaires and the documentation provided to the Inquiry by the Belfast Trust, the Inquiry contacted 9 GP's and who subsequently gave written or oral evidence to the Inquiry Panel. This was merely a sample of those GPs who would have referred patients to Dr Watt, but the exercise proved useful in identifying other concerns and what transpired when they were raised.

9.135 Dr Colin Fitzpatrick was a GP in Comber. He had, for 15 years, worked with the National Clinical Assessment Service ("NCAS") as a Northern Ireland Representative. NCAS[5] looks at ways to identify difficulties, improve performance and provide advice on steps to be taken for doctors and dentists. In his evidence, Dr Fitzpatrick described NCAS as *"facilitators to help Doctors in difficulty get back to safe and effective practice"*. Dr Fitzpatrick dealt with his NCAS caseload part-time alongside his work as a GP. Dr Fitzpatrick stepped back from the role after 2019.

9.136 Dr Watt had examined a new patient from Dr Fitzpatrick's GP Practice who had a complex medical history. Dr Watt had diagnosed the patient with multiple sclerosis at a private consultation. Dr Gavin McDonnell had subsequently disagreed with the diagnosis when the patient attended at Dr McDonnell's NHS clinic. Dr Watt had prescribed a powerful form of steroid. The patient had informed Dr Fitzpatrick that she had not been examined by Dr Watt and that her MRI scan was clear. Dr Fitzpatrick advised that he had knowledge of the tests involved in an MS diagnosis. He informed the Inquiry Panel on 13th May 2019:

> The patient had AF[6], a recognised complication of the strong steroids prescribed and I mentally logged that there must have been other GP's who had concerns about Dr Watt's care.

9.137 A second case concerned a younger patient whom Dr Fitzpatrick saw *"a week or two later"*. The patient had seen Dr Watt privately. Dr Watt had arranged for various tests and prescribed Copaxone for MS, which is a complex drug with a waiting list. The patient decided not to take the drug. Dr Watt reviewed the patient who, at that stage, had developed blurred vision. Once again, there was a complex medical background. Dr Fitzpatrick considered that *"Copaxone was started on little medical evidence"*. He decided to act and contacted Mr Watson in the Medical Director's office on 17th November 2017. Dr Fitzpatrick separately sent the details to Dr Orla Gray on 20th November 2016 for her opinion. Dr Gray phoned him and stated that she did not consider that the two patients had MS. Dr Fitzpatrick informed the

5 Now the Practitioner Performance Advice Service (PPAS).

6 Arterial Fibrillation.

Inquiry Panel that *"This validated my concerns and I advised Dr Gray I would take my concerns forward. I had not provided Dr Gray with personal details of the patients nor the name of the neurologist. I didn't tell her it was Dr Watt"*. Dr Fitzpatrick did not inform the Belfast Trust that he had checked his views first with Dr Gray.

9.138 A third case was brought to Dr Fitzpatrick's attention by his wife[7] who was a partner with him in his Practice in Comber. It concerned a travelling salesman, an epileptic who had been informed by Dr Watt, at a private consultation, that he could continue to drive in 2010. This was shortly prior to the patient having another epileptic episode. It was alleged that Dr Watt had made no arrangements to review the patient. Dr Fitzpatrick's wife became aware of the issue when asked to approve the patient's DVLA form.

9.139 A further 2 cases involving SIH were subsequently identified in the weeks before Christmas 2016 by Dr Fitzpatrick. It was the actions of Dr Fitzpatrick and the investigations that ensued, which brought matters to a head and ultimately led to the RCP report and Patient recall.

Concerns raised November 2016 - May 2018 Examples:

9.140 In addition, there were a further 2 concerns raised by Dr Stephen Hunt and Dr Thomas Peukert with their senior managers during the period covered by Part A of the Terms of Reference between November 2016 and May 2018. The matters are commented upon in detail in the November 2016 - May 2018 chapter. Examples are referred to in this chapter because they indicate that the fundamental problem of ensuring the Medical Director had the appropriate information at the appropriate time, continued.

9.141 Dr Hunt gave evidence on 2nd May 2019 of a conversation with Dr Watt in March 2017. At that time, Dr Watt had been, since December 2016, subject to restrictions relating to the diagnosis of SIH and the related treatment which included blood patch procedures. The precise detail regarding the restriction is set out in the November 2016 - May 2018 Chapter but its outworking was that in all instances, were Dr Watt diagnosed SIH and wanted to perform a blood patch, he needed to get the prior approval of another Consultant Neurologist, Dr Thomas Peukert. Dr Hunt was unaware of the restriction prior to his conversation with Dr Watt.

9.142 Dr Hunt informed the Inquiry Panel that over the next number of weeks, he was asked by Dr Watt to see approximately 5 people and to endorse their diagnosis of

7 Dr Deborah Semple.

SIH. While accepting that neurologists did disagree with each other, he felt that the sequence of exposures was such that he thought to himself, *"this is not normal"*. Dr Hunt was also concerned about obtaining proper consent for blood patch procedures.

9.143 Dr Hunt was concerned at these developments and felt that he needed to take some action. After discussing with his wife, he decided to speak to the Service Manager, Mr Gerry Atkinson. When he could not find Mr Atkinson, he spoke to the Divisional Director, Mr Frank Young[8] and informed him that he had seen cases in the private sector of patients who Dr Watt had diagnosed with the condition of SIH and that he was uncomfortable because he did not agree with Dr Watt's diagnosis. Mr Young indicated that there was a restriction on Dr Watt's practice, following a complaint from a GP. Mr Young's comments on this incident are set out in the November 2016 - May 2018 Chapter, but the key issue was that he did not escalate the concerns to the Medical Director. Clearly, he should have done so especially because of the partial restriction that had been imposed by Dr Jack on Dr Watt's practice.

9.144 On 24th April 2017, Dr Peukert contacted Dr Craig and Dr McDonnell regarding a patient who had been diagnosed with multiple sclerosis by Dr Watt. The MRI scans did not support the diagnosis and Dr Watt's treatment had been questioned by a medical consultant and a neurology registrar. Dr McDonnell decided to arrange for an additional MRI scan, which was carried out on 5th June 2017. Once again, this scan did not show any evidence of demyelination.

9.145 In his evidence to the Inquiry Panel, Dr Peukert was quite clear that he was raising a concern with Dr Craig, Clinical Director for Neurosciences, and Dr McDonnell, Clinical Lead for Neurology. Dr Craig accepted in his evidence that this matter should have been referred by him immediately to the Medical Director.

THE OBSERVATIONS OF CONSULTANTS, REGISTRARS, GENERAL PRACTITIONERS AND NURSES:

9.146 Given that the recall involved neurology, it was critical that the Inquiry received evidence from the neurologists who would have worked with Dr Watt as a consultant colleague. The Inquiry was also able to obtain evidence from each registrar who had worked with Dr Watt. Additionally, nurses who worked alongside Dr Watt in his clinics gave evidence to the Inquiry Panel. The Inquiry Panel was unable to hear evidence from Dr Watt on medical grounds, although it did receive the transcript

8 Co-Director of Unscheduled & Acute Care.

of an interview Dr Watt had with investigators during the Verita investigation as part of the Maintaining High Professional Standards ("MHPS") process. Further, Dr Jim Morrow, former Clinical Lead, was unable to give evidence because of a long-term medical condition. In both these instances, numerous medical reports were provided to the Inquiry, which confirmed that neither Dr Watt nor Dr Morrow would be in a position to give evidence.

Consultant Neurologists:

9.147 A striking feature of the Inquiry, and the evidence obtained, is the apparent lack of knowledge by other consultant neurologists that there were potential problems with Dr Watt's practice. While there were instances of consultants disagreeing about a particular diagnosis, there was a paucity of evidence from neurologists within the Belfast Trust, which revealed that any other consultant neurologist within the Belfast Trust had any specific concern about Dr Watt's practice. While there was a recognition that he was different; that he preferred to work independently; and that he favoured more aggressive treatment and the prescription of more potent medication at an earlier stage in the treatment plan, there was no evidence that this caused serious questions to be raised by any consultant neurologist working within the Belfast Trust.

9.148 The Inquiry Panel notes that the situation amongst consultant neurologists in the Belfast Trust differed from the approach taken by at least one consultant neurologist in another Trust. The late Dr Tom Esmonde trained with Dr Watt and worked alongside him in Belfast before moving on to work at the Northern Trust. He had no animus towards Dr Watt and, in fact, directed his own son to work experience with Dr Watt. Despite this, there was no apparent hesitation in complaining to the Medical Director of the Northern Trust about a number of diagnoses that had been carried out by Dr Watt, which contradicted the views of other clinicians in the Northern Trust. When he identified a further example of what he thought was a potential pattern of misdiagnosis, Dr Esmonde again brought it to the attention of the Medical Director of the Northern Trust. The Inquiry Panel accepts that the initial complaint to the Medical Director arose out of a patient complaint made about Dr Esmonde's colleagues in the Northern Trust. Nevertheless, the contrast remains.

9.149 While the Inquiry Panel accepts that a silo mentality can easily emerge if working practices do not allow for peer review, the strength of the perception of Dr Watt by his colleagues that he was a clinically competent neurologist with administrative difficulties is surprising. There seems to have been little or no reflection on the

fact that Dr Watt was the outlier over several indices and a marked reluctance to believe that Dr Watt's practice was outside the confines of normal practice. Again, the Inquiry Panel accepts that neurology is different to, for example, orthopaedics. Diagnoses often evolve and sometimes can never confidently be made. The margin in neurology for error is legitimately greater. Almost every witness emphasised that in areas such as epilepsy or stroke, a percentage of diagnoses will always be incorrect. Even allowing, however, for an increased differential, and the challenges within neurology itself, there remain a range of objective tests and treatment criteria within neurology, as it has developed, which should provide a solid framework. The failure to carry out tests before confidently giving a diagnosis is, on the face of it, inexcusable. The fact that this was not picked up on and actioned at any time prior to November 2016 is again surprising.

9.150 A besetting problem in neurology and in all probability other specialties is the question of clinical governance by consultant colleagues. There has been a marked change within the professional lifetime of many older neurologists, including Dr Watt. As Trusts have reorganised, and governance has become increasingly important, the role of a consultant has changed. Older consultants would not have been used to being governed by their colleagues and when new practices were introduced, such as the role of a Clinical Lead or a Clinical Director.

9.151 The Inquiry Panel has formed the view that those consultants who took on such positions did so on the implicit understanding between their colleagues that their function was primarily to represent the interests of the relevant area, rather than direct management of their colleagues' practice. The Inquiry Panel has no reason to doubt that this dynamic is common to other sub-specialties. A consistent pattern amongst the Clinical Directors was that they treaded carefully before challenging or imposing a sanction on a consultant colleague. This included the problems with setting up a panel to review the prescription of Alemtuzumab, dealing with late appraisals and believing, in the words of a former Clinical Director, Mr Stephen Cooke, that the role of a Clinical Director was to" explain and persuade".

Registrars:

9.152 Given that registrars work closely alongside consultants in training, it was not surprising to the Inquiry Panel that they gave, in some instances, a much more detailed assessment of the distinctive aspects of Dr Watt's practice and the problems that had emerged.

9.153 A number of registrars identified traits, which in the view of the Inquiry Panel established a clear pattern in Dr Watt's mode of practice. These can be summarised as follows:

(i) Dr Watt did not always carry out the same tests or investigations as other neurologists in making a diagnosis.

(ii) Dr Watt was prepared to make a definitive, and sometimes a life changing, diagnosis when the evidence was uncertain and inconclusive.

(iii) The general sense among registrars was that Dr Watt was reluctant to make a diagnosis of a functional disorder, preferring a clearer diagnosis.

(iv) Dr Watt rarely changed his mind and was comfortable in prescribing drugs such as Alemtuzumab at an early stage, in contrast to his consultant colleagues.

(v) Dr Watt's prescription of HIG was much greater than any other consultant

In addition to the variations in Dr Watt's practice, which were commented upon by the registrars who worked with him over the years, there were instances where registrars raised direct concerns or attempted to raise concerns with consultants.

9.154 The concerns raised especially by Dr Hoeritzauer and Dr Ellen Campbell may have been a critical opportunity lost, particularly if that information had been triangulated with other data that was the emerging.

9.155 The Inquiry Panel agrees with Dr Jamie Campbell that a registrar working alongside Dr Watt during his time would have been able to observe the same features of practice that he had observed. They were uniquely positioned, and it is unsurprising that the most compelling evidence of concerns emerged from the evidence of several registrars. It is however surprising that more registrars did not raise or retain concerns about Dr Watt's practice.

General Practitioners:

9.156 In view of the above, it is not ultimately surprising that problems were identified by doctors who were a step, or several steps, back from the nucleus of neurological work and activity. GPs working in primary care tend to know their patients well. As outlined, it was a GP, who raised a concern in November 2016. The most striking example of other attempts made by GPs to raise concerns prior to November 2016 was the effort made by the late Dr Paul Conn to inform an Associate Medical Director within the Belfast Trust, a series of cases regarding clinical diagnoses made by Dr Watt in 2013.

9.157 It is clear that Dr Conn wanted to have some reassurance that he was raising something that others had noticed, when he first spoke to Dr MacDonagh. This approach is indicative of the prevailing medical culture. When Dr Conn indicated that he did not wish to provide patient numbers to enable records to be scrutinised, Dr MacDonagh erroneously believed that he could not take the matter further. It is correct to say that Dr MacDonagh did give advice that Dr Conn should follow up his concerns directly with Dr Watt.

9.158 The Inquiry Panel accepts that this was at least done in part, insofar as the Ballygomartin Practice sent two letters to Dr Watt, and Dr Conn went to meet him directly. Dr MacDonagh's approach was clearly wrong, and the Inquiry Panel is left to speculate as to what might had happened if the cases raised by Dr Conn had been properly following up on. While Dr MacDonagh should not have let the matter rest and he ought to have brought it to the attention of the Medical Director, Dr Conn also erred in deciding not to give the patient details.

9.159 The Inquiry Panel only had the opportunity to interview a limited number of GPs, who would have referred patients to Dr Watt. It is not possible to state with any degree of assurance that other GPs would not have had specific concerns about Dr Watt. A limited investigation of GP concerns revealed a range of issues that had arisen, which by any standard was troubling.

9.160 The Inquiry Panel sets out below examples of evidence from GPs, which is of relevance:

(i) The fact that 5 cases of concern, which ultimately formed the bedrock of the RCP report were discovered in one small, rural town practice in Comber;

(ii) The fact that one particular GP partnership, namely Ballygomartin Practice, had made a decision not to refer private patients to Dr Watt and that within the same Practice, a senior partner had attempted to discuss concerns directly with Dr Watt and, at a subsequent stage, had brought a series of cases to the Associate Medical Director within the Belfast Trust;

(iii) The actions of Dr Peter MacSorley in raising with his appraiser a number of cases involving Dr Watt, which had given him cause for concern in 2013.

9.161 The actions of GPs reveal both the benefits and limitations of primary care. GPs tend to know their patients better and on occasions, had come to their own conclusions about the approach taken to clinical diagnoses by Dr Watt. Unfortunately, for the most part, their efforts to raise their concerns were inadequate and did not result in

the information getting to the Medical Director of the Belfast Trust prior to November 2016. It is noteworthy that the GP who did ultimately raise concerns with the Medical Director's Office in November 2016, was a doctor who had a separate role as the Northern Ireland representative of the NCAS. Even in this instance, however, Dr Fitzpatrick felt it necessary to privately check with a consultant neurologist friend, Dr Gray, as well as bringing the matter directly to the Medical Director's Office. This is discussed further in the chapter on November 2016 - May 2018.

9.162 The Inquiry Panel did receive evidence from some GPs that they were unsure as to whom exactly they should bring their concerns to if a problem arose. The Inquiry notes and applauds the fact that immediate action was taken by Dr Jack, the then Medical Director, following her initial evidence to the Inquiry Panel, to initiate a reminder to all GPs of how they should escalate and raise a concern about a secondary care medical colleague. On reflection, however, the Inquiry Panel does not accept that the problems identified by some GPs in knowing how to raise a concern are as difficult or obtuse as alleged. All doctors are aware of their commitment and obligations towards patient safety. If they have a concern, then the most basic of research will identify the correct path to take and raise the matter with an appropriate person who can take action. The problem, in the view of the Inquiry Panel, is the medical culture that pertains in a small jurisdiction, where the doctors, for the most part, know each other and have largely gone through the same medical training at the same university. Until the medical culture question is properly addressed, then patient safety in some instances will not be paramount.

Nurses:

9.163 A number of specialist nurses worked more closely with Dr Watt than many of the doctors. Dr Watt was clearly popular and well-liked by many of the nursing staff, some of whom were distressed at how events had transpired. The Inquiry Panel fully accepts that nursing staff are not trained neurologists and that there is a dynamic in place, which makes it extraordinarily difficult for a nurse to challenge a consultant. There is no evidence that any nurse formally raised any concern about Dr Watt's neurology practice; although there was good evidence that some nurses did have concerns.

9.164 Although nurses are not neurologists, it was apparent that many of the specialist nurses within neurology had developed a significant level of expertise. Further, some of the apparent traits of Dr Watt's methods, which involved, for instance, the failure to insist upon tests, would have been conspicuous at times. Despite this, the Inquiry

Panel was surprised at how many nurses who worked with Dr Watt had not noticed anything, which gave rise to comment, even regarding Dr Watt's style of practice, which was clearly different to other neurologists. Many nurses gave evidence in a manner, which suggested that they saw and heard nothing. The consistency of this approach raised a concern amongst the Inquiry Panel that nothing could or should be said, which might give rise to a train of enquiry. The Inquiry Panel does not have sufficient evidence to make any determination on specific individuals, but, nevertheless, has been left with an uneasy sense that out of fear, design or some other reason, some nurses may have decided that the safest course of action was to say nothing.

Conclusions and Findings:

9.165 Part B of the Terms of Reference asks the question as to whether there were concerns prior to November 2016, which should have alerted the Belfast Trust to instigate an earlier and more thorough investigation over and above the extant arrangements. As this chapter demonstrates, there were numerous instances, which, if they had been properly escalated, would have led to a thorough investigation.

9.166 The Inquiry has uncovered a substantial level of concern among other medical professionals, which was not properly formalised to enable a greater degree of scrutiny by the Medical Director's Office. The fact that issues raised were often not acted upon, or taken further, is itself a source of concern and this report deals separately with the question of the prevailing medical culture and its impact on patient safety.

9.167 One cannot but express frustration that highly relevant information was kept in virtual silos, not just in the Belfast Trust, but also in other organisations including another Trust. There was a failure to pass on important data about Dr Watt, which may have made a critical difference. This was especially the case in or about 2013 when other investigations had been directed by the then Medical Director. Although there are clear examples in 2016, this was only a matter of months before the initial restriction was imposed by Dr Jack in respect of Dr Watt's diagnosis of SIH. The critical failing was the fact that information was not communicated to the right person, namely the Medical Director, at the appropriate time.

9.168 The Inquiry can accept that in the absence of adequate peer review, there is every likelihood that consultant neurologists will often not be sighted on the practice of a colleague. It is also acknowledged that neurology, as a specialty, was under

significant pressure and had an extensive waiting list. A neurologist with the seniority of Dr Watt had a reputation for working extremely hard and being willing to take on intractable and difficult cases. One can easily appreciate that once a reputation has been established, it becomes hard to dislodge, even in the face of substantive evidence.

9.169 The Inquiry believes that, for the most part, colleagues did not query Dr Watt's practice and tended instead to characterise his shortcomings as being of an administrative nature. His repeated failure to complete appraisals, provide reports to insurance companies or attend certain meetings was regarded as a consequence of his having one of the largest neurology practices in Northern Ireland, including both NHS and private patients. This perception itself grew over the years and deflected those medical professionals, who looked into complaints or otherwise reviewed his practice. That said, when the matter is independently and intensively scrutinised, there is substantial evidence of clinical concern, which went back many years.

9.170 A further restraint on action was identified by the Inquiry Panel as the evidential threshold for raising a concern. Too often, doctors felt that they had to satisfy themselves to the highest evidential standard before deciding that action was justified. Such an approach tends to contribute to a culture of not escalating the concern and effectively preventing pattern recognition. This restraint also inhibits the development of a culture focused on the paramountcy of patient safety.

9.171 The stark fact is that for a whole number of reasons, concerns about Dr Watt did not reach the Medical Director's Office and numerous opportunities to identify a trend or pattern were lost.

CHAPTER 10 – DDCRM

Inquiry Terms of Reference:

10.1 The Inquiry is required to determine whether there are any *"related concerns or circumstances, which should have alerted the Belfast Trust to instigate an earlier and more thorough investigation over and above the extant arrangements for raising concerns and the existing complaints procedure"*.

10.2 The Inquiry was also asked to identify any learning points and make recommendations in relation to these matters.

10.3 In 2012/2013 and 2016 the Doctors and Dentists Case Review Meeting ("DDCRM") played a role in getting information to the Medical Director's Office regarding issues with Dr Watt's practice and informing the actions taken. The Inquiry notes that when issues of concern were raised in relation to Dr Watt's practice in November 2016, evidence of the involvement of DDCRM is conspicuous by its absence. The Inquiry, therefore, felt it was necessary to examine in detail the constitution, role and functioning of the DDCRM at these key periods of time, namely 2013, 2016 and November 2016 onwards. Further, the Inquiry is specifically asked in Part A of the Terms of Reference to provide "an assessment of the role of the Board of the Belfast Trust." From available evidence it appears that the DDCRM was intended to play a key role in offering assurance to the Board of the Trust.

Background to the DDCRM:

10.4 The DDCRM was an initiative of the then Medical Director, Dr Tony Stevens in 2009. Doctors who would be perceived by the Medical Director or others, such as Associate Medical Directors, as being in some form of difficulty with their medical practice for both clinical and/or administrative reasons would be referred to the DDCRM. The membership comprised the following individuals:

- The Medical Director;
- Representatives of the Medical Director's Office, principally the Senior Manager, Peter Watson;
- Senior HR staff;
- The Trust's solicitor;
- The Service Director of the relevant Directorate; and
- The Associate Medical Director for the relevant Directorate.

10.5 Dr Stevens, in his evidence to the Inquiry Panel on 3rd September 2019, stated that one of the main reasons for establishing the DDCRM was to address issues the Trust was having with the separation of information at that time. He outlined that the first meeting occurred in April 2009 and that it "was an initiative that we had set up bringing human resource, legal, medical professional expertise together in the room to discuss individual cases and try and triangulate information and get expert advice." The Inquiry Panel accepts that this was a serious attempt to address the problems that had emerged.

10.6 Mr Peter Watson was a Senior Manager in the Medical Director's Office at that time. In his evidence of 16th January 2020, that the group *"evolved out of a desire that there be not just everything ending up in the Medical Directors desk, but actually there be expert opinion and advices sought from others"*.

10.7 Dr Stevens, commenting on the function of the group and his role, outlined as follows on 3rd September 2019:

> … it was my committee. I chaired it, unless I was absent and then Cathy [Jack] or, occasionally, I think, Peter [Watson], probably chaired it. I saw it as a means of getting expert advice on how to deal with tricky problems … to navigate the Maintaining High Professional Standards ("MHPS") process … I saw it as a place where we would collate the information. So it was an opportunity for the [relevant] division to bring forward an issue … it was an opportunity for me to hold people to account for the way they were managing people and provide that professional expertise.

10.8 Mr Watson, in his evidence to the Inquiry Panel of 9th October 2019, described the function of the DDCRM as *"a forum for bringing together various advisers in order to agree an action or actions that needed to be taken"*. Mr Watson was clear that the Medical Director was "the key decision maker." While highlighting the role of the Associate Medical Directors in the local management of concerns and the implementation of decisions, Mr Watson believed that the purpose of the Committee was advisory, and that the ultimate decision-maker was the Medical Director.

10.9 Mr Watson told the Inquiry Panel: *"one of my functions was to ensure that things we said were going to happen actually did happen"*. He stated that by 2012, when Dr Watt was first referred to the DDCRM, the meeting was a key forum for reviewing cases and deciding on the next steps to be taken by the Medical Director. He regarded his own role as largely supporting the process and described it as follows:

> My role was principally in terms of capturing the key points in terms of the key position and also capturing the key actions that have been agreed and then, as

> you can see in various files, following through on the actions that have been agreed at various stages, chasing up actions that have been outstanding from previous meetings and so on and so forth. It was principally, at that stage, in providing administrative support to the process, but … I gradually developed an understanding and experience of MHPS which I was able to bring to bear to cases that were being discussion – over time. I think that's probably reflected if you were to look, for example, at my role in the file in 2011 or 2012-13, compared to that which you will, no doubt have seen whenever you've looked at the papers around 2016 … I'd quite an extensive role, working collaboratively and closely with the Medical Director at that time, but the Medical Director always being in the role of decision maker.

10.10 Evidence was also received from the Director of Acute and Unscheduled Services, Mrs Bernie Owens on 3rd February 2020. She regarded the DDCRM as a place to go if you had a concern about a doctor, but fully accepted that there was a disconnect between the description of the forum and the practice. At one point, she told the Inquiry Panel: *"I think they would see because this was a medical matter that they were accounting to the Medical Director in this regard and the Medical Director usually chaired the meeting"*. Mrs Owens saw it very much as a "touch-base" meeting to communicate what was going on. She told the Inquiry Panel:

> I personally took it as it was a forum where we all, all the parties connected with the individual doctor, with HR and with legal there an opportunity just to touch base at a point in time; where are we now with this doctor, what is the ongoing issue and what do we need to do next? Any meeting that took place usually that was outside of the DDCRM would normally have been noted, and Peter Watson kept files on all the doctors who was mainly there.

10.11 The Chief Executive of the Belfast Trust between 2010-2014, Mr Colm Donaghy, was not aware as to why the DDCRM was set up or its Terms of Reference. This would suggest that the assurance role of the DDCRM was not understood by the Trust's Board.

10.12 Dr Cathy Jack became Deputy Medical Director in 2008, but indicated that she had not set up the DDCRM and had not seen its Terms of Reference when she was invited to attend by Dr Stevens. Her view of the function of the DDCRM, as offered in evidence of 11th December 2019, was that it was there:

> To ensure that the investigation is kept on track and any decisions around care and treatment etc. is made, although that would be made in a timely way. So, it's more about keeping the investigation on track. And so, at the moment, the DDCRM meetings are chaired by the Deputy Medical Director. They have Peter Watson in there, who's tracker, chaser upper. And then it is the Co-Director and

> the Chair of Division, and the HR and [legal]. And there's only one of each. If you look at the minutes, it's about tracking the progress of an investigation … because it says actions.

10.13 Dr Ken Fullerton, the former Associate Medical Director from 2013-2016, was *"not 100% sure"* as to the function of the DDCRM, but he believed it was a confidential meeting to discuss and inform those attending as to what needed to be done and what decisions needed to be taken. Describing the structure of the group, Dr Fullerton stated in evidence of 5th November 2019 as follows:

> In terms of the hierarchy of the group, it was chaired by the Medical Director. The next in the hierarchy was the Director of the service group. In the line of things, as Associate Medical Director, I was responsible to the Director; that is Bernie Owens. The executive decision makers, if you like, were those two. That was the common feature of each of the DDCRM meetings in the different service groups – the Medical Director and the Director of that service – and they would then corporately decide what needed to be done.

10.14 Mr Ray Hannon, the previous Associate Medical Director, stated on 19th February 2020, that although it was a team discussion, he believed that the decision-maker would have largely been the Medical Director with the purpose of meeting being *"to try and work out where the problems were and how far you were progressing them"*. He did state to the Inquiry Panel, however, that if the Medical Director was not at the meeting "the team might make a decision".

DDCRM Terms of Reference:

10.15 Both Dr Fullerton and Mr Hannon indicated that they were uncertain as to whether they had ever seen a Terms of Reference or Constitution for the group. The Inquiry was forwarded a copy of the Terms of Reference for the DDCRM dated June 2013, and these are set out below:

> 1. The Board of Directors of the Belfast HSC Trust (The Board) has a responsibility to provide high quality care, which is safe for patients, clients, young people, visitors and staff and which is underpinned by the public service values of accountability, probity and openness. The Trust's existing procedures for the management and support of staff must always be followed and sit alongside the specific support provided through MHPS.
>
> 2. The line management of doctors and dentists is the responsibility of the Service Director (ordinarily delegated to the relevant Co-Director) in whose specialty the doctor or dentist works. Within the Directorate, doctors

and dentists are professionally responsible to their Clinical Director and Associate Medical Director, and through them they are accountable to the Medical Director, who is also the Responsible Officer for the Trust.

3. Concerns about a doctor or dentist may arise from a number of sources e.g. complaints, incident reports, appraisal, audit, morbidity and mortality review, patient/colleague feedback and litigation. Where there is a single significant issue that causes concerns in relation to the performance of a doctor, or where there is an accumulation of issues or concerns, these should be considered, as appropriate, within the directorate and escalated to the Associate Medical Director. The Associate Medical Director (and Co-Director) will be responsible for determining if a threshold of concern has been reached such that the case is brought to the attention of the Medical Director and Service Director.

   The Medical Director will ensure that any case raised, is "logged" for consideration as appropriate at the next Doctor and Dentists Case Review Meeting. This meeting which is attended by representatives of the Medical Director's office, senior HR staff, the Trust's solicitor, and Directorate management staff serves as an advisory body for those with management responsibility for doctors and dentists.

   The DDCR meeting will ensure that where appropriate the informal or formal stages of MHPS are followed.[1]

   Concerns may also be raised directly with the Medical Director's Office through external agencies e.g. the Ombudsman, PSNI, the Deanery, HSCB, PHA, DHSSPS, GMC. These will be logged at the Doctor and Dentists Case Review Meetings.

4. Trust policies, particularly including Complaints Procedures, Incident Reporting and Disciplinary Procedures must be adhered to.

5. Other than in respect of seeking advice from NCAS, actions and communications OUTSIDE of the Trust will be through the office of the Medical Director. For example in the event of communication being required with the DHSSPS, HSCB, PHA, GMC, GDC, PSNI, NIMDTA or other bodies, this will be through the Medical Director's Office, with appropriate liaison with the Service Director and/or Associate Medical Director.

6. Actions and communications WITHIN the Trust will be the responsibility of the manager within the Directorate.

1 DHSSPS, 'Maintaining High Professional Standards in the Modern HPSS; A framework for the handling of concerns about doctors and dentists in the HPSS' (November 2005).

7. The Medical Director's office, and Medical HR will be available to provide advice in relation to these matters outside of the regular Doctor and Dentist Case Review meetings.

8. The Medical Director's office will seek to ensure that due process is complied with in relation to each case, inclusive of review at the Doctor Case Review Meeting.

9. In circumstances where the management of a case involving a doctor or dentist is under ongoing review at the Doctor and Dentist Case Review meeting, the relevant AMD should ensure that the doctor/dentist is aware of this, and also aware of the Terms of Reference of the Meeting. Communication to the doctor/dentist should be considered at the Doctor and Dentist Case Review meeting, and where agreed and completed, should subsequently be logged at the next Doctor and Dentist Case Review meeting.

10.16 The Terms of Reference evolved over time to a limited extent, but the substance remained unchanged during the period covered by the Inquiry's Terms of Reference. The Inquiry Panel concluded that there was a significant disconnect between the Terms and what happened in practice. In particular:

(i) Clarity is lacking from paragraph [2], which seeks to outline who is responsible for the management of doctors. While appreciating that management responsibility sits across different levels within the Trust, there does not appear to be clearly understood lines of accountability. The result being that issues with individual doctors may fall through the gaps created by individuals assuming others have management responsibility.

(ii) There is no definition of what constitutes the threshold of concern in paragraph [3] and the Inquiry Panel has seen no clear guidance or policy produced by the Trust outlining a threshold.

(iii) The DDCRM is referred to in paragraph [3] as an *"advisory body for those with management responsibility for doctors and dentists"*. This is vague and ill-defined and further contrasts with the broader understanding that the DDCRM is there to advise the Medical Director.

(iv) The relationship between the DDCRM meetings and MHPS is unclear. As MHPS is a complex and detailed process, any lack of clarity becomes immediately problematic. The DDCRM is not part of the MHPS procedure and there is an obvious danger that discussing concerns at the DDCRM, which are also being evaluated within the MHPS procedure, could lead to confusion.

(v) Although paragraph [9] refers to doctors being told that they are being discussed at a DDCRM meeting, the Inquiry Panel saw no evidence that Dr Watt was aware that he was the subject of evaluation on numerous occasions.

10.17 In principle, the DDCRM initiative and its Terms of Reference was a positive and innovative step by Dr Stevens to better manage the increasing burden of responsibility on the Medical Director of the Trust. The difficulty, from the evidence relevant to the Inquiry, is that the lack of clarity as to who was responsible and the precise role of DDCRM inevitably led to a situation where everyone was responsible, but no one was responsible, resulting in certain issues falling through the cracks in the management system. An example is the fact that the Terms of Reference cited at [15] above do not make clear whether the DDCRM is an advisory group to the Medical Director or whether it can itself take decisions as happened on a number of occasions with Dr Watt when he was removed from consideration by the DDCRM.

In written evidence submitted by the Belfast Trust on 13th May 2022, the Trust has stated that the Inquiry has mischaracterised the role of the DDCRM:

> '[The Inquiry] has elevated the DDCRM to a status that was beyond its functions as understood by those participating in it. It did not provide direct or fundamental assurance to the Trust Board about patient safety; that was the role of the Medical Director through the Chief Executive. DDCRM, in any of its forms, was and is a management tool to assist the Medical Director with their responsibilities in respect of the management of doctors'

The Inquiry Panel accepts that the above description of the DDCRM is clear about its purpose. It is not however consistent with the wording of the DDCRM Terms of Reference (again see paragraph 15 above). The first paragraph outlines the responsibilities of the Trust Board including reference to high quality care which is safe for patients. Whilst not expressly clear as to the exact relationship between the DDCRM and the Trust Board, there is an implicit link between the DDCRM and the Trust Board and its responsibility for patient safety. Therefore, to suggest that the Inquiry is mischaracterising the DDCRM is not accepted by the Inquiry Panel

Being Referred to the DDCRM:

10.18 The Inquiry considered how a doctor would be referred for review at the DDCRM. Mr Hannon told the Inquiry Panel that *"if somebody somehow raised concerns, whatever that concern was, you would get on it"* (i.e. the DDCRM list). Dr Jack told the Inquiry Panel: *"for me, you get in when there's a concern, and I need to know the specific concern, and*

the individuals needs to know is it health, conduct or performance concern". Dr Fullerton echoed this sentiment stating: *"where a significant concern is raised, even if it has not at this point been confirmed to be accurate, then the doctor will go on a list and that doctor's name will come up at every meeting until such time as it is considered they are no longer of interest, in which case they come off the list again."* The Inquiry considers that it is unclear precisely how a doctor gets referred to the DDCRM and what threshold of concern must be passed for referral.

10.19 Matters were similarly unclear with regards to leaving the DDCRM. Mr Hannon indicated that individuals would be removed *"if somebody said the concern was resolved whatever that mechanism was"*. Dr Jack similarly stated individuals would be removed if a concern was *"resolved or they were on a clear remedial action, but even then they wouldn't get out of it until that's closed and signed off, actually, so it has to be closed"*. The Terms of Reference are silent on the processes governing a doctor leaving the scrutiny of the DDCRM meeting.

10.20 Paragraph 9 of the Terms of Reference indicates that doctors discussed at the DDCRM should be made aware of their inclusion. In terms of doctors being aware that they were either referred to or discussed at the review, Dr Stevens indicated that, at the beginning, doctors would not necessarily have been aware that they were being discussed. The British Medical Association raised this as an issue and the rule was changed so that if a doctor was logged after an initial discussion, they would need to be informed. Mr Hannon described the process as follows:

> We were allowed to discuss a person once but not tell them, but if they were going to be discussed twice - I don't know if it was twice in consecutive months or twice in six months, but there was this kind of rule of don't talk about anybody more than once because if you do that you're going to have to tell them and inform then they are being discussed or they are in MHPS or whatever.

10.21 The Inquiry has seen evidence of Dr Watt being spoken to following discussion at relevant DDCRM meetings, such as by Mr Cooke in 2012 and Dr Fullerton in 2013. It is not clear, however to what extent the process and the fact that he was discussed at the meeting was explained to Dr Watt or whether the Terms of Reference were disclosed to him. Indeed, both Dr Jack and Mrs Owens indicated during the course of their evidence to the Inquiry Panel that they did not know whether Dr Watt was aware of his referral to the DDCRM.

10.22 When Dr Jack took over as Medical Director in 2014, there was some action taken to change the practice. She told the Inquiry Panel on 11th December 2019:

> What we do now is, when a concern arises, they actually get the email of the concern or the summary of the concern or the summary of the discussion or the high-risk complaint or the GMC issue. They would get all that.

While the Inquiry Panel has seen reference to MHPS in letters to Dr Watt summarising and enclosing concerns in relation to the INI 286 case and the concerns subsequently raised in November 2016, there is still no evidence that Dr Watt was aware that he was being discussed at the DDCRM in March 2016.

In written evidence of 13th May 2022 the Belfast Trust submitted that the more significant issue was not whether Dr Watt knew he was being discussed at the DDCRM, but whether Dr Watt was aware of the various issues that related to him and which were discussed at DDCRM. The DDRCM was a means to an end not an end in itself. Having regard to paragraph 9 of the Terms of Reference at 15 above, this is in the view of the Inquiry Panel a further example of a dissonance between the Terms of Reference of the DDCRM and what happened in practice. Whilst clearly, it is important that a doctor is aware of various issues that need addressed there is an inherent value in the doctor knowing that they are being discussed at a meeting attended by senior personnel in the Trust. The very existence of paragraph 9 of the DDCRM Terms of Reference is evidence of this.

10.23 With regards to note-keeping, Dr Stevens indicated that the meeting was sensitive about including too much clinical information. The minutes were kept as an *aide memoire* to assist the process of decision-making, but the focus was on capturing the actions to be taken.

10.24 Mr Hannon indicated that the presence of the solicitor, June Turkington from Directorate of Legal Services, had given him the impression that notes would be privileged, but he accepted that there were no real minutes as such, merely action points and he had no written notes himself.

10.25 Dr Jack accepted that there was a lack of clarity in the minutes, but she again emphasised that the purpose of the minutes was to track the progress of an investigation.

10.26 The Inquiry has seen evidence of typed action points drafted by Mr Watson. The Inquiry made intensive investigations as to whether further notes existed of key meetings, but very few written notes were discovered in relation to the meetings of the DDCRM. On making enquires with the Belfast Trust, it was confirmed that in respect of Dr Watt's involvement with the DDCRM, limited written notes existed as follows:

a. Mr Ray Hannon, Associate Medical Director until 2013, kept no separate written notes.

b. Dr Tony Stevens, Former Medical Director, on reviewing his notebooks found only two references to DDCRMs involving Dr Watt; one dated 25th June 2012 stated *"Michael Watt - ensure action taken"* and the other dated 3rd June 2013 stated *"M Watt – informal stage."* Dr Stevens indicated that it was not his practice to keep detailed notes because he was focused on chairing the meeting.

c. Mrs Bernie Owens, Director for Acute and Unscheduled Care, identified brief handwritten notes from three meetings.

d. June Turkington, DLS, retained brief notes from 4 meetings between 30th March 2012 and 14th October 2013.

e. Interspersed in the papers disclosed by the Trust are regular brief handwritten notes from Mr Peter Watson prepared during the course of a meeting in his role and used to prepare the typed-up action points.

f. The Trust confirmed that all other attendees do not hold any further records.

DDCRM in 2012 / 2013:

10.27 Dr Watt was discussed at the DDCRM on 10 occasions between March 2012 and October 2013. During this time there were a number of concerns raised about Dr Watt's practice and two different Finding of the Facts exercises under the informal stage of MHPS were conducted. A fuller exploration of the issues at that time is set out in the 2012-13 Missed Opportunities chapter.

10.28 What is most readily apparent in an examination of the two Finding of the Facts processes, which had been directed by the then Medical Director, Dr Stevens in 2012 and 2013, was a lack of clarity as to what was required. When asked about this, Dr Stevens in his evidence to the Inquiry Panel of 3rd September 2019, described his expectations of the process as follows:

> Ray Hannon would've been tasked then with that knowledge and with the knowledge that should've been available to him – was available to him – to go and, if you like, start triangulating the data, talk to people. I would've expected him to go and talk to clinicians – at least the Clinical Director, Clinical Lead. I would have expected him and Bernie Owens to think about their own experience and the information they had coming up through complaints; to look at litigation…to look at any serious adverse incidents that might relate to him…

> and also potentially to go and look at things like the national training survey, where the trainees have the opportunity to comment on their experiences.

10.29 Mr Watson, who had the primary responsibility for following upon decisions taken at the DDCRM, also gave his view, about the purpose of a Finding of the Facts investigation under the MHPS procedure:

> The informal stage is supposed to be about establishing the facts – finding the facts or "FTF". "FTF" appears in the notes at some point. That's as much as it was: he was asked to go away and establish the facts, it would've been my understanding, in terms of the concerns.

10.30 Mr Ray Hannon, who had been Associate Medical Director until June 2013, explained to the Inquiry Panel in his evidence of 19th February 2020, his understanding of the direction that had been given by Dr Stevens in the first Finding of the Facts exercise in 2012:

> I take it to mean you clarify the concerns and investigate the factual basis on which the concerns are based, more or less … I thought my role was to go and talk to Steve Cooke to see if there are any more recent concerns or anything worrying Steve, and if nothing else came of it I was to go to Michael Watt and say, 'Michael, get your act together and get this all written down in your appraisal', more or less … it wasn't an investigation. If you look at the flowchart it says finding the facts, but you can't find the facts until you establish the concerns. I was trying to establish where are the concerns, are there recent concerns? ... I didn't think I was asked to go out and trawl around and look for more.

10.31 The first Finding of the Facts exercise carried out by Mr Hannon in 2012 appears to have been influenced by the reservations expressed by the then Clinical Director in Neurosciences, Mr Steve Cooke, and the inability of the extant system to provide Mr Hannon with an up-to-date list of all the relevant complaints. Ultimately, the investigation was downgraded to what Dr Stevens referred to as a *"recorded conversation"*. This did not take place. The final stage in the first Finding of the Facts exercise resulted in a measured letter of 19th July 2012 to Dr Watt from Mr Hannon, which was focused on reflection at the next appraisal and not sanction or threat of sanction.

10.32 In his evidence to the Inquiry Panel, Dr Stevens referred to *"the significant pushback from Ray [Hannon] and Steve [Cooke]"* based on their views. He stated:

> I felt there was a bit of a rising tide. And what had come back to me, from two experienced medical managers, was, "Tony, there's nothing to see here", and they were wriggling on that, and eventually I let them off the hook.

10.33 Dr Ken Fullerton took over as an Associate Medical Director in June 2013. One of his first tasks was to conduct a Finding of the Facts exercise in relation to Dr Watt. It became apparent that Dr Fullerton was not aware of the first exercise that had been carried out and his focus very quickly became on ensuring that Dr Watt had completed his annual appraisal obligations and was able to secure revalidation in accordance with the new statutory requirement. This was, in fact, achieved in September 2013. The 2012-13 Missed Opportunities chapter sets out in greater detail the Finding of the Facts exercises, which were carried out by Mr Hannon and Dr Fullerton respectively.

10.34 In his evidence to the Inquiry Panel on 5th November 2019, Dr Fullerton rejected criticism of his investigation by Dr Stevens and highlighted that, in his view, the focus was on the lack of appraisal and the delay in providing reports:

> At none of those meetings did anyone, including Dr Stevens, raise any concerns about clinical practice. So the context for what I was doing…was investigating concerns about delays in reports, not doing appraisals, those things. So, it's not that my eyes would've been closed to a clinical matter because I'm well aware that an issue in one domain may indicate there's issues in other domains as well, but that wasn't actually the focus of what I was asked to do.

10.35 While it was the DDCRM that had agreed and directed the second Finding of the Facts exercise in June 2013, the meeting itself had limited time to discuss in depth individual cases. The documentation disclosed by the Trust did reveal the intensive efforts of Mr Watson in trying to implement decisions that had been made, but often re-examination or review could only be cursory and the quality of the direction suffered accordingly. This was apparent in 2013 when the focus of Dr Fullerton's investigation changed to making sure that revalidation occurred. Ultimately, no written report was ever provided by Dr Fullerton, as might have been expected, given the level of concern. Dr Fullerton did not believe that there was an expectation that he would produce a written report. In his evidence to the Inquiry Panel on 5th November 2019 he stated:

> It would have been rather different if, as a result of an informal finding-the-facts, I had come to the conclusion that further action did need to be taken. Under those circumstances, I certainly would've produced a written document … from my perspective, I wasn't ever asked, nor did I believe there was an expectation that I would produce a written report.

10.36 Dr Fullerton went on to explain the manner in which he would have communicated with the DDCRM:

> Although the notes from DDCRM meetings are very succinct, and they don't actually outline the conversation, there would have been a conversation on each occasion. So that's the first thing. Secondly, as I've indicated to you, I wasn't just sitting on my hands. Thirdly, the context. Yes, there was a revalidation and there was an appraisal coming up, and there were questions that I wanted to see answered, and I had reason to believe that the answers to those questions would either be contained in the appraisal documentation itself or in the conversation I subsequently had with Dr Watt.

10.37 Dr Stevens believed, in retrospect, that he should have pushed harder for a written report. He told the Inquiry Panel in his evidence of 3rd September 2019:

> It is for Ken [Fullerton] to say how he went about establishing the facts that there were no clinical issues. Rightly or wrongly, I relied on that … maybe we didn't push harder to see a documentary report, but the informal stage for establishing the facts is what it is. It's quite informal …

10.38 Other witnesses who attended the DDCRM were also asked about the two Finding of the Facts exercises carried out by Mr Hannon in 2012 and Dr Fullerton in 2013. Dr Jack indicated that as far as the investigation by Dr Fullerton was concerned, she would have wanted to have had a written report on the Finding of the Facts exercise and not a verbal briefing to the DDCRM. She accepted that Dr Fullerton would have seen himself as a peer expert with regard to some of the complaints being investigated, but she highlighted the fact that the role of a case manager is distinct from that of an investigator.

10.39 It was also apparent in 2013 that the DDCRM failed to triangulate and consider all the relevant information that it received. In June 2013, Mrs Owens referred in the meeting to two recent complaints against Dr Watt (presumed to be INI 334 and INI 347), neither of which were subsequently included in the Medical Director's file. In the view of the Inquiry Panel, both complaints were potentially significant clinical issues, which should have been brought directly to the attention of the Medical Director's Office, included in the relevant file and considered by the Medical Director. Mrs Owens should have brought the complaints to the Medical Director and, having been referred to in the meeting, the Medical Director and / or Mr Watson, should have insisted on seeing copies of same.

10.40 Ultimately, Dr Watt was removed from discussion by the DDCRM at a meeting when the Medical Director was not present, reinforcing the blurred lines of responsibility. On the decision taken to remove Dr Watt from the DDCRM after revalidation in September 2013, Mr Watson stated that it would have been a group decision, but, in contrast, Dr Jack felt that the Medical Director should have been present before

that decision was reached. This is further considered in the 2012-2013 chapter, but the Inquiry Panel notes that when Dr Watt was removed from the DDCRM, an additional complaint against Dr Watt (INI 349) remained extant. Dr Watt was, therefore, removed from the DDCRM without a clear decision from the Medical Director or a proper note of any recommendation or advice from the Associate Medical Director, who had recently completed a Finding of the Facts exercise.

DDCRM in March 2016:

10.41 Dr Watt's next referral to the DDCRM followed the INI 286 case in early 2016. The Inquiry notes that Dr Fullerton, who was at this stage close to retirement, was also concerned that Dr Watt's name had reappeared and advocated his referral back to the DDCRM. At that time, in March 2016, Dr Watt had again not completed his appraisal, there was a concern regarding non-compliance with a request from the coroner and Dr Watt was the subject of a concern regarding INI 286, which had been raised by three consultant colleagues in the Northern Trust. Unfortunately, it is not clear from the notes of the meetings in 2016 what action, if any, was taken as a result of the DDCRM meetings. There appeared to be no follow up meeting at the DDCRM, subsequent to the discussion in March 2016.

10.42 The outcome of the meeting was that Dr Watt was to remain under review at the DDCRM and that *"Mrs Owens would ensure that Dr Craig escalated any other concerns regarding MW"*.

10.43 A specific issue about what happened in March 2016 was considered by the Inquiry. In the March 2016 DDCRM, Mrs Owens was asked to *"ensure that Dr Craig escalated any other concerns regarding MW"*. Mrs Owens did not recall specifically speaking to the Clinical Director, Dr Craig. She had recalled a general meeting with Mr Gerry Atkinson and Mr Frank Young and thinks that she raised various issues on neurosciences, which would have included Dr Watt. Dr Craig, in his evidence as to whether he recalls knowing about Dr Watt being involved in the DDCRM, stated to the Inquiry on 19th December 2019 that:

> I don't know is the honest answer to that. It doesn't stand out that that's something … I saw that in the minutes. I don't remember that happening, her coming specifically to tell me about the DDCRM and any additional concerns I might have. I don't believe that did happen.

10.44 The Inquiry Panel have concluded that it is probable that Mrs Owens did not speak to Dr Craig at that time. As outlined below, Dr Watt was not discussed at any further

meeting of the DDCRM. There is, however, an [2]appended to the notes from 22nd March 2016. This records that notes relating to the INI 286 concern were awaited and that an expert was to be identified, that the Coroner issue was resolved and to be reflected on at appraisal, an anonymous complaint had been received and that Dr Watt had failed to complete his appraisal. The DDRCM did not meet again until November 2016 for reasons which were not adequately explained to the Inquiry Panel.

10.45 Dr Watt was, however, the subject of a meeting outside the DDCRM process, with Mr Young, the Co-Director and Dr Craig, the Clinical Director, in September 2016. This was to address a range of matters including failure to respond to complaints, outstanding appraisal, and a failure to complete necessary forms for the prescription of Human Immunoglobulin ("HIG"). Apart from the appraisal issue, these concerns were not escalated to, or discussed at, the DDCRM. At the same time, there were also concerns with regards to the prescription of Alemtuzumab and the rapid increase of epidural blood patching within the system. Neither of these issues were raised or discussed at the DDCRM, despite coming to the attention of those with management responsibility for Dr Watt. In written evidence submitted to the Inquiry on 13th May the Belfast Trust invited the Inquiry to differentiate the roles of the various levels of management involved. This was a repeated submission in the Belfast Trust's response to warning letters which it had received, but the Inquiry Panel believes that it introduces an artificial dichotomy between senior management and management within the Directorate. Management within the Trust needs to be a unified function.

10.46 The Inquiry sought to understand the role of DDCRM in 2016. Mr Watson was cautious about over-emphasising the significance of the DDCRM at this time and told the Inquiry Panel:

> There is a real danger of elevating that meeting beyond its function, because the reality is, as you can see here, it wasn't the Doctor and Dentist Case Review Meeting, in this context, that ensured that the appropriate stages were followed. They are being followed. The DDCRM is a component part of that management, but the management, as in the case of Dr Watt, takers place, can take place, outside of that meeting.

10.47 Mr Watson, in discussing the INI 286 concern in 2016, did not believe that referring the matter back to DDCRM would have made any difference. He believed that this case was largely managed without getting input or advice from the DDCRM and emphasised to the Inquiry Panel that it was not the case that the DDCRM was the

2 Co-Director of Unscheduled & Acute Care.

sole forum for the consideration of all relevant matters and decision-making in relation to the management of doctors.

10.48 It may well be the case that Mr Watson was correct about referral back to the DDCRM with regards to the INI 286 concern. For further discussion of the management of the INI 286 concerns please see the 2016 Missed Opportunities and the Concerns chapters. That, however, would suggest that the effectiveness of the group was limited and fails to appreciate that there were additional concerns in the system at this time. The Inquiry Panel refers to Dr Watt's meeting with Mr Young and Dr Craig in September 2016, which was convened to address prescribing issues, additional complaints and appraisal. These matters were not escalated to the Medical Director's Office, nor were they considered when Dr Fitzpatrick's concerns were raised, just a few weeks later, in November 2016.

10.49 There was a significant amount of information about Dr Watt within the system in the latter part of 2016 prior to the concerns being raised by Dr Fitzpatrick. While the absence of a DDCRM meeting did not prevent these issues being escalated, it may have allowed them to be synthesised, triangulated and assessed and may have led to an earlier and more thorough investigation.

10.50 When questioned as to why there was no further DDCRM meeting in 2016, Mr Watson stated that the meeting itself *"probably had a greater import historically than it has in more recent time"*. In his evidence of 16th January 2020 Mr Watson indicated that at this time:

> This case [regarding Dr Watt] was largely managed without getting the inputs and advices. And certainly, if DDCRM is about a stopping off point and a tracking, that was all being done very much in real time. And so I don't believe this went back to DDCRM and nor do I think that it would have made any difference if it had gone back to DDCRM.

10.51 There is no record of how Dr Watt was removed from DDCRM or when and how any concerns about his practice were exhausted and addressed. Dr Jack, in her witness statement to the Inquiry dated 2nd September 2021, stated that: *"I do not have any difficulty accepting that Dr Watt should have continued to be considered at any DDCRM relating to Unscheduled and Acute Care that took place from March 2016 onwards"*. The Inquiry Panel recognises that when a serious clinical issue has been identified, and the matter is being actively managed by the Medical Director's Office, there is a need for agility and flexibility in order to ensure that matters are progressed timeously. The Inquiry Panel accepts that relying on the DDCRM during such a procedure is unrealistic, but it does call into question the purpose and utility of the DDCRM.

10.52 The Inquiry Panel noted that the institutional memory of the organisation seems unable to recall that a range of issues had been raised in 2012/2013 and that it would have been important to review that material for common themes and pattern. The evidence suggests that once a matter had been concluded, that was the end of the matter. In written evidence on 13th May 2022 the Belfast Trust submitted that there was nothing found in 2012/2013 (as opposed to what was not found) that would have caused a different approach had matters been reconsidered in November and December 2016 and that a Medical Director must be able to rely on the veracity of what has gone before and not re-open and re-investigate previous matters unless there is a proper basis to do so. The Inquiry Panel disagrees. While a working assumption can be made that a matter has been dealt with there must be room for a retrospective review in light of new evidence. Otherwise, the prospect of pattern recognition becomes almost impossible. Looking for common themes and a pattern of concern is of itself a proper reason to review past instances of concern.

DDCRM from November 2016:

10.53 Significant concerns with regards to the practice of Dr Watt were raised with the Belfast Trust in November 2016. These concerns, which ultimately led to the restriction of his practice and the patient recall, are discussed in detail in the November 2016 - May 2018 chapter.

10.54 Unlike in 2013, and earlier in 2016, the substance, handling and investigation of these concerns was not the subject of review or discussion at a DDCRM. This is despite there being no formal record of Dr Watt leaving the DDCRM process after March 2016, nor was there any note as to how extant concerns were resolved. The Inquiry notes that the Professional Assurance Reports prepared by the Medical Directorate in July 2017 and November 2018 for the Trust Board still refer to the role played by the DDCRM in relation to the handling of concerns and the communication of these to the Trust Board.

10.55 There were attempts to schedule a DDCRM during this period. The Inquiry has seen a copy of an agenda for a DDCRM on 4th September 2017, which recorded that Dr Watt was to be discussed. The Inquiry has not been provided with minutes of the same and it appears that the meeting never took place. Mr Watson, in a written statement to the Inquiry dated 2nd November 2021, indicated that *"while the available agenda indicates an intention to have a meeting on that date, I do not believe the meeting took place. This is evidenced by the fact that I have no notes or communications on any of the doctors that would have inevitably resulted from such a meeting."*

10.56 This evidence is supported by Dr Jack in her written statement to the Inquiry dated 2nd September 2021, which outlines that:

> If there is an open Medical Director's Office file, then the individual would be discussed at the relevant DDCRM. The 4 September 2017 agenda evidences the intention to do that. However, from what I have been able to establish, the meeting did not take place. It appears there had not been an Unscheduled and Acute Care DDCRM between March 2016 and September 2017. There were other DDCRMs but for other areas of the Belfast Trust.

10.57 Both Mr Watson and Dr Jack are clear that had there been a DDCRM for the relevant Division in the period relevant to Part A of the Inquiry's Terms of Reference, Dr Watt would have been discussed. This is attributed to the fact that there was an open file with the Medical Director's Office in his name. While the Inquiry Panel understands that events after 2016 required significant ongoing management, that necessity highlighted the inability of the DDCRM to respond quickly. The difficulty is, however, that in relation to the Trust governance processes, the DDCRM retained in the view of the Inquiry Panel a role with regard to the management of concerns and communication and assurance to the Trust Board on patient safety. There was, therefore, a disconnect between the formal role of the DDCRM and what happened in practice and the Inquiry Panel is concerned as to how assurance was offered to the Trust Board during this period. The Belfast Trust in their written evidence of 13th May submit that the Inquiry has elevated the DDCRM to a status that was beyond its function and that it did not provide direct assurance to the Trust Board and was merely a management tool to assist the Medical Director. This observation is not however consistent with its Terms of Reference for the DDCRM which outline the responsibilities of the Board of Directors of the Trust in paragraph 1 of the Terms of Reference and do not make clear that the DDCRM has merely an advisory role to the Medical Director. To suggest that the DDCRM did not provide assurance to the Board seems to be implicitly at variance with the wording of the Terms of Reference.

10.58 In her written statement dated 2nd September 2021, Dr Jack stated as follows:

> As time progressed, with the bedding down of MHPS, the introduction of the concept of the Responsible Officer etc., and the increase in the volume of concerns escalated to the Medical Director's office (which had to be managed as they arose) the scope for the type of the former DDCRMs reduced. DDCRMs continued to operate, but they performed much more of a tracking function; people would meet as a check to make sure matters were progressed and steps taken. So, while the name of the meeting remained the same, the function of the meeting changed because it was not feasible to operate in the original way.

10.59 The Inquiry notes, however, that the Terms of Reference of the DDCRM remains largely unchanged in the July 2017 and November 2018 Assurance Reports. Any change in function is not, therefore, reflected in the Trust's governance framework and this must be addressed.

10.60 In evidence to the Inquiry Panel, Dr Jack outlined that from November 2016 the approach was different with regards to the handling of concerns, which were "managed in real time". Dr Jack indicated that *"if concerns arise you do not wait for a DDDCRM and that in practice I didn't need the DDCRM … because DDCRM is only for tracking"*.

10.61 The Inquiry Panel agrees with Dr Jack that when a serious issue arises, or has the potential to arise, the Medical Director will have to react quickly, flexibly and cannot wait for the next DDCRM. The fundamental problem, however, is not that the Medical Director's Office needs to manage issues as they arise, but that the DDCRM is relied upon by the Trust Board in seeking to be assured about patient safety. Further, as set out in the chapter in November 2016 - May 2018 there was a need for the type of 'tracking' described, particularly at the outset of acquiring the reports from Dr Gray and Dr McConville. Delays with obtaining patient notes to facilitate the reports is just one example of where this opportunity for tracking was lost.

10.62 In correspondence dated 18th September 2019, responding to a request for information from the Inquiry, the Trust outlined that *"a doctor can only have restrictions placed on him/her under the framework of MHPS. The Belfast Trust's DDCRM ensures that where appropriate the informal or formal stages of MHPS are followed"*.

10.63 The Inquiry notes and agrees that a doctor can only be restricted within the framework of MHPS. However, the Inquiry notes that Dr Watt was not discussed at any DDCRM either in the build up to, or following, the various restrictions imposed on his practice, given the role the group was intended to have, in accordance with paragraph [3] of its Terms of Reference, with regards to ensuring that the stages of MHPS are followed.

DDCRM and Reporting to the Trust Board:

10.64 Mr Colm Donaghy, Chief Executive of the Trust between 2010-2014, indicated in oral evidence on 14th November 2019, that during his time with the Trust:

> The information that I would have had about the number of doctors who would have, at any time, been going through that [MHPS] process would have been

> statistical rather than detail about what it was for. It would only have been if there was a serious patient safety issue that it would have been brought to my attention.

10.65 In an email dated 24th September 2015, Dr Cathy Jack, on sharing a copy of the DDCRM terms of reference with Associate Medical Directors, outlined that she wished *"to take this opportunity to clarify where the Doctor and Dentist Case Review process sits within the Trust Assurance Framework."* Dr Jack then stated as follows: *"A quarterly report is tabled from the Doctor and Dentist Case Review Group to the Safer Recruitment and Employment Group. This group in turn reports to the Trust's Governance Steering Group which is chaired by Shane Devlin"*.

10.66 In a report prepared on the operation of the DDCRM to the Safer Recruitment and Employment Group, Mr Watson of the Medical Director's Office, in relation to 2015/2016, sought to review each of the relevant quarters. In relation to the first quarter, it was noted that DDCRM meetings for Adult Social & Primary Care and Specialist Hospitals, Women & Child Health occurred on 24th August 2015 and 15th September 2015 with a further meeting scheduled on 25th January 2016. In respect of acute and unscheduled care, a meeting took place on 11th July 2015 and a further meeting was scheduled for 25th November 2015. At that point some 58 cases were reviewed, of which 33 were the subject of interest by the General Medical Council ("GMC") and 13 were discussed with the National Clinical Assessment Service ("NCAS" and now known as Practitioner Performance Advice).

10.67 The second quarter report outlined that two DDCRMs were held with regards to Adult Social & Primary Care and Specialist Hospitals, Women & Child Health on 24th August 2015 and 15th September 2016. A meeting was held with regards to Surgery & Specialist Services and Acute and Unscheduled Care on 30th July 2015. During these meetings 57 cases were discussed of which 33 were the subject of interest by the GMC. An unspecified number of cases were also discussed with NCAS during this quarter.

10.68 A report in relation to the third quarter indicated that meetings took place concerning Adult Social and Primary Care on 11th January 2016 and 23rd February 2016. With regard to Surgery and Specialist Services and Acute and Unscheduled Care, meetings took place on 13th October 2015 and 25th November 2015 and a meeting was scheduled for 14th March 2016. In the third quarter, 39 cases were received, of which 15 were the subject of interest by the GMC and 13 involved consultations with NCAS.

10.69 No report was received in respect of the fourth quarter. The Inquiry received evidence from the Belfast Trust that *"there are no DDCR Reports for the period March 2016 (Quarter 4 of 2015/16) until the Safer Recruitment & Employment Group meeting in October 2017. I understand the reason for this was because of other competing priorities in the Medical Director's Office"*.

10.70 The Inquiry has seen evidence that an item concerning "Dr/Dentist Case Review" appeared in the minutes of the Safer Recruitment & Employment Group on 12th October 2017. The minutes of which record that *"Peter Watson was not in attendance no quarterly review has been provided."*

10.71 The DDCRM was further discussed at the Safer Recruitment and Employment Group on 19th April 2018. Under the heading of *"Action Points from previous Meeting"* it is recorded that *"following review of Terms of Reference, it has been decided that Dr / Dentist case review can be removed from the Agenda as a separate group is in place for Drs / Dentist in Difficulty."* It is unclear what the *"separate group"* relates to in practice.

10.72 The Terms of Reference for the DDCRM record that, ultimately, the Trust Board is responsible for providing high quality care and that *"the Trust's existing procedures for the management and support of staff must always be followed."* It is impossible to see how the Board could have been offered assurance based on the information contained within the quarterly reports, which had been reported. Such information was generic and gave no indication of the nature of concerns. It is, therefore, difficult to conceive how this in itself could have offered the Trust Board any degree of assurance on patient safety.

10.73 More significantly, the last such report was provided in December 2015, and it is not clear that any further meaningful update was provided to the Trust Board, through the Safer Recruitment & Employment Group or any other channel, during the time period relevant to Part A of Inquiry's Terms of Reference. The specific communication to the Trust Board relating to Dr Watt and the handling of concerns about his practice from November 2016 onwards is set out in the November 2016 - May 2018 chapter.

DDCRM at Present:

10.74 Dr Jack gave evidence that the present purpose of the DDCRM is *"to ensure that the investigation is kept on track and any decisions around care and treatment etc. is made, although that would be made in a timely way. So it's more about keeping the investigation*

on track." Dr Jack further elaborated as to the present structure of the DDCRM as follows in a witness statement dated 2nd September 2021:

1. The Medical Director and his office continue to deal with concerns, and all his other responsibilities arising as a result, in real time. This may well involve the ongoing engagement with individuals who also attend the regular DDCRM, and indeed others as required in order to properly manage any relevant concern.

2. Every Wednesday morning of each month 3 DDCRMs take place. Each one last 30 mins. This is to allow 12 Division to have one DDCRM each month (one division does not have a DDCRM). Each week, 3 of the 12 Divisions attend for their meeting. The following week it is a different 3 Divisions. The following week 3 different Divisions again, and so on.

3. At the relevant Division's DDCRM there will normally be the Medical Director, the Deputy Medical Director responsible for Workforce, a Senior Manager from the Medical Director's office (Peter Watson) and his PA the PA is the notetaker for the meeting), and a senior representative from HR (normally at Co-Director level). From the relevant Division will be the Chair of Division and the relevant Co-Director.

4. All the ongoing cases within the Medical Director's office, while relate to the While it is clear that there has been some reflection on the role and relevant Division, are on the agenda for the Division's DDCRM.

5. The purpose of the DDCRM is to keep everyone up to date on where a case stands, to act as a means of keeping things on track, and as a check to make sure things are done. For instance, when people are coming to a meeting where they may have to speak to what they have done with an action they had from a previous meeting, it assists in ensuring people deliver what they said they were going to do. While it is not a decision-making body, or an advice-giving body it is the case that discussion of issues does occur and it may be that, with a particular issue someone has to deal with relating to a case, that someone else at the meeting with expertise can assist with some.

6. Given the purpose of the DDCRM is now clearly more of a "keeping things on track" mechanism, the Senior Manager from the office of the Medical Director will generally have a telephone call with the relevant Chair of Division in advance of their DDCRM. That call facilitates a discussion around the ongoing cases affecting that Division and ensures that the DDCRM itself is focused and efficient.

7. One of the questions from the Medical Director's office posed at each DDCRM is whether there are known to be any other concerns in the

Division that the Medical Director should know about. Obviously, concerns can and are brought to the Medical Director on an ongoing basis, but the knowledge that this particular question is posed at the DDCRM means that relevant individuals know they are going to have to answer it and be accountable for the answers they give.

8. The Belfast Trust is currently working on a draft document to do with the management of concerns, which includes the DDCRM mechanism in its present form. The guidance will ensure that there is no room for doubt as to the purpose of the DDCRM mechanism.

10.75 There has undoubtedly been reflection and refinement of the role and purpose of the DDCRM, initiated by Dr Jack, the present Medical Director, Mr Chris Hagan, and the Medical Director's Office. It remains to be seen whether the DDCRM can play the assurance role designated to it by the Trust Board. The Inquiry notes the clarification at sub-paragraph 5 of paragraph 74 above that DDCRM is not an advice giving or a decision-making body. The question that arises is, however, "What exactly is it?" It is to be welcomed that "relevant individuals" know they are going to be accountable for the answers they give about concerns, but it needs to made clearer that all doctors should be accountable and there is no acceptable reason for not bringing concerns to the Medical Director.

Conclusions and Findings:

10.76 As noted by Dr Jack, in her report on the role of the Medical Director dated February 2019: *"the line management of doctors and dentists is the responsibility of the Service Director (ordinarily delegated to the relevant Co-Director and Chair in whose specialty the doctor or dentist works)"*. The report goes on to state that: "within the directorate, doctors are professionally responsible to their Clinical Director and Chair of division and through them to the Medical Director". It is not clear to the Inquiry Panel as to whether the Service Director or the Medical Director is responsible for the management of doctors. The Inquiry Panel fully understands that the Service Director through the Chief Executive has a line management responsibility while the Medical Director has a professional responsibility but because of MHPS it is the Medical Director who is responsible for the discipline of doctors. Insofar as there is a dichotomy, it is a gap, which has led to confusion although the Inquiry recognises that this is not of the making of the Belfast Trust as the MHPS procedure is a national agreement which is imposed on Trusts and which they cannot change or alter.

10.77 The Inquiry Panel accepts that the DDCRM was set up in good faith by the then Medical Director, Dr Stevens, in an initiative which sought to triangulate information

and ensure that those in management were better sighted on ongoing concerns. The extent to which this initiative has succeeded is difficult to assess for the Inquiry Panel within the constraints of the Terms of Reference.

10.78 What is apparent is the manner in which Dr Watt was managed at the DDCRM. In this regard, the Inquiry Panel identified the following salient issues:

(i) The purpose of the group was unclear;

(ii) The manner in which information was to be obtained, shared and disseminated was unclear;

(iii) How people were referred to the group and the criteria used was unclear;

(iv) How Dr Watt was removed from the group was unclear;

(v) The nature of any communication with Dr Watt and discussion about this matter at the DDCRM was unclear.

10.79 The overriding impression was one of a degree of confusion as to the actual role and the responsibility of the DDCRM. The Inquiry Panel does not doubt that a review involving senior managers may be a useful mechanism to track ongoing cases of concern, but, as best illustrated by the events in 2012/2013, and later in 2016, the DDCRM was unable to acquire and disseminate information in a way that really corresponded with its responsibilities.

10.80 The Inquiry Panel did note that Mr Watson was assiduous in following up actions to be taken, but, in general, with the exception of Mr Watson, none of the attendees took a detailed note of what was said, discussed or agreed at any meeting. It was suggested to the Inquiry Panel that the absence of notes was because the meeting focused on actions, but at critical times, it was difficult, if not impossible, to ascertain what actions had, in fact, been taken by Dr Fullerton and Mr Hannon, when they were asked to conduct a Finding of the Facts exercise under the informal stage of MHPS.

10.81 There was some suggestion that if a doctor was discussed twice within a 6-month period, the doctor concerned would be informed. However, it was not clear to the Inquiry Panel if Dr Watt was ever aware he was being considered at the DDCRM, as envisaged by paragraph [9] of the June 2013 Terms of Reference and there was a lack of clarity about what investigatory steps needed to be taken.

10.82 The relationship between the DDCRM and MHPS remains unclear. In oral evidence of Dr Stevens dated 3rd September 2019, he indicated that one of the key purposes of the group was to *"navigate the MHPS process"*. This is supported by paragraph 3 of the June 2013 Terms of Reference, which states that: *"the DDCR meeting will ensure*

that where appropriate the informal or formal stages of MHPS are followed". Dr Fullerton also shared this view in oral evidence of 5th November 2019, stating that *"one of the functions of this meeting would be to make sure that [concerns] were handled appropriately"* within the context of MHPS. The position, however, is far from clear with Dr Stevens also giving evidence that the DDCRM did not have formal status because it was not working inside the MHPS procedure. It is true that there is no reference to a DDCRM type process in MHPS. Further, Dr Watt had restrictions imposed on his practice within the MHPS framework in December 2016, yet there was no monitoring or assurance provided by the DDCRM. The relationship between the DDCRM and the formal and informal procedures under MHPS is another example of how the processes around the group and its aims were unclear.

10.83 Within the periods covering the Terms of Reference of the Inquiry, up to May 2018, Dr Watt was never considered within the formal process of MHPS. Therefore, any consideration of the formal processes under MHPS is outside the Terms of Reference of this Inquiry. Suffice to say for present purposes, that provisions in MHPS relating to informal processes are far from clear and led to confusion in 2012 and 2013.

10.84 The Inquiry has already highlighted several time periods as constituting missed opportunities when the proper triangulation of information and analysis of events could have led to concerns about Dr Watt being addressed. It is a fact that in 2012/2013, Dr Watt was being considered at the DDCRM. The Inquiry has limited notes in respect of 10 meetings of the DDCRM during that period. Despite the fact that two Finding of the Facts exercises were conducted during this period by Associate Medical Directors under the MHPS procedure, and the oversight of the DDCRM, there was great difficulty in understanding what exactly was being investigated. On the first occasion when Mr Hannon was asked by the Medical Director to commence the Finding of the Facts exercise, there appears to have been no written orientation or direction, save for the fact that Dr Stevens wanted Mr Hannon to *"have a look"*.

10.85 The Inquiry Panel agrees that the outcome of the related GMC Inquiry which had just concluded may have given a degree of false reassurance to Mr Hannon, but a combination of factors ensured that the process carried out had a negligible value. These factors included pushback from Dr Watt, the downgrading of a recorded conversation to a letter requiring Dr Watt to reflect on complaints at his next appraisal, the difficulties in collating all of the complaints that were recorded and the general perception that the concerns did not involve Dr Watt's clinical abilities. The letter sent by Mr Hannon to Dr Watt on 19th July 2012, was a mildly worded invitation to reflect. None of these problems were picked up on by the DDCRM.

10.86 The Finding of the Facts exercise conducted by Dr Fullerton between June and September 2013, suffered from similar problems. Relevant complaints were not considered, no detailed written report, which could be considered, was provided and the focus quickly shifted to an emphasis on appraisal and revalidation.

10.87 The Inquiry Panel notes that when Dr Watt was referred back to the DDCRM, shortly prior to the retirement of Dr Fullerton, and at or about the same time as the INI 286 concern was raised in 2016, there were no meetings after the first discussion in March 2016. Prior to the concerns raised by a GP in November 2016, there were a number of other significant issues in addition to the matters raised in the INI 286 concern. These included concerns around the number of blood patches being undertaken by Dr Watt; the fact that Dr Watt was an outlier in relation to the provision of HIG and the prescription of Alemtuzumab for multiple sclerosis; the failure by Dr Watt to respond to additional complaints which had arisen and ongoing issues with appraisal. In addition to the fact that there were no meetings, there is no record of Dr Watt ever coming out of DDCRM prior to the issues being raised in November 2016 and it is unclear whether he was, at November 2016, regarded as a doctor who was the subject of extant concerns.

10.88 Questions arose in the mind of the Inquiry Panel about the effectiveness of the DDCRM and what its role is when serious issues are raised, which need to be focused on by the Medical Director's Office. The primary concern is that the DDCRM continue to be one of the ways in which the Trust Board was assured in relation to patient safety.

10.89 Reports were made to the Safe Recruitment & Employment sub-group within the Board, but these reports are bland and simply record the total number of doctors who are being reviewed. The evidence suggests that there was no meeting of this sub-group between March 2016 and October 2017 and there was no substantive discussion of matters arising from the DDCRM at the October 2017 and April 2018 meetings of the Safer Recruitment & Employment Group, in any event. This raises the significant question as to how the Board can be reassured about safe care if they are not being properly updated or updated at all.

10.90 Reflecting on the operation of DDCRM, Mrs Bernie Owens told the Inquiry Panel on 3rd February 2020:

> It wasn't clear here in the DDCRM exactly what did, what was expected in it, what was the actual concerns. It's now detailed out in terms of in a letter and you know what the concerns are that you're raising with the doctor. Now, that said, there is enough, you know, there is some information in terms of appraisals, in

> terms of, but again because I would say it wasn't clear that to look at the clinical concerns because of the conversation we've had earlier. So I think that would be probably a weakness in that approach at that time. Because of the way the meeting is scheduled or whatever, it isn't expected that you have a detailed conversation about any doctor. It's an hour and a half maybe set up and you might have nearly two dozen people to discuss in that time, so it is usually all verbal reports. If there is something that is of significant nature there's usually another meeting set up to address that and agree actions with probably the same people around the table but it's done differently or done separately.

10.91 Mr Watson felt that the Trust needed to review carefully how concerns about doctors are identified and managed. He was concerned that decisions could not rest with the committee-like structure such as the DDCRM or a Medical Director at the top of an organisation to whom 1800 doctors were accountable. Mr Watson referred to the development of more distributed leadership throughout the organisation.

10.92 In her written statement to the Inquiry dated 2nd September 2021, Dr Jack made it clear that *"there is no statutory or other requirement to have a DDCRM. It is not a concept that is found across all health trusts, either in this jurisdiction or elsewhere"*.

10.93 Dr Jack and Mr Watson have been at pains to point out at various stages to the Inquiry that individuals should raise concerns as and when they arise and should not wait until the convening of a DDCRM. For example, in her written statement dated 2nd September 2021, Dr Jack stated: "someone with concerns that should be brought to the attention of the Medical Director does not need a DDCRM. I accept having an Unscheduled and Acute Care DDCRM would have provided an additional opportunity to raise matters with me, but there are lots of examples of other such opportunities, and which were not taken".

10.94 The Inquiry Panel agrees with Dr Jack's assessment. As the INI 334 and INI 347 cases evidence, it is not acceptable for potentially important clinical complaints to be raised at the DDCRM, without being passed on to the Medical Director for whatever reason.

10.95 The Inquiry Panel formed the view that although initiated in good faith, the volume of review was such that the DDCRM had insufficient time to properly reflect on the issues that were arising. There was both a lack of clarity as to what was required and a failure to rigorously consider the outcomes, which contributed to the failure of the two Finding of the Facts exercises in 2012 and 2013 to adequately address the potential problems with Dr Watt's practice. The first Finding of the Facts in 2012 resulted in what Mr Hannon himself described as a *"tame"* letter to Dr Watt. The

second investigation in 2013, resulted in Dr Watt's revalidation and an oral report to the DDCRM, which ultimately resulted in Dr Watt being revalidated and removed from the DDCRM.

10.96 What is noticeable about November 2016, is that when the first restriction was imposed by Dr Jack in December 2016, following a number of cases being referred to the Trust by a GP, the DDCRM appears to play no role in the ongoing review of Dr Watt's practice and the restrictions that were imposed.

10.97 The Inquiry Panel notes that there is presently work ongoing on the overall management of concerns, which includes a review of the present DDCRM mechanism. The aim is that there would no longer be any room for doubt as to the purpose of the DDCRM procedure. The Inquiry Panel has not seen any proposal but has concluded that the time may have come for the DDCRM to be abolished with a view to setting up a smaller group working within a strengthened Medical Director's Office. This would enable an increased focus on ensuring that the Medical Director is fully sighted on all relevant information and enable a more informed assurance to be given to the Trust Board on patient care.

CHAPTER 11 – APPRAISAL AND REVALIDATION

Introduction

11.1 Part B of the Terms of Reference specifically requires the Inquiry to review the Belfast Trust's participation in processes to maintain standards of professional practice including appraisal.

11.2 The processes to maintain standards of professional practice include clinical audit, job planning, peer review and multi-disciplinary teams. All these matters have been considered in the report, but the system of revalidation introduced and regulated by the General Medical Council ("GMC") and the Trust's requirement for annual appraisal of doctors were topics to which the Inquiry returned on numerous occasions. This chapter seeks to explain these processes, their relationship to each other and comment on the evidence obtained in respect of both.

11.3 The Inquiry assessed the specific issue of appraisal raised in the Terms of Reference by initially examining Dr Watt's involvement with both the process of appraisal and that of revalidation and then considering the role of the Belfast Trust ("the Trust"). Although neither appraisal nor revalidation have been considered by the Inquiry in other medical subspecialties, the Inquiry examined the purpose and scope of appraisal with a range of individuals from different medical backgrounds and with the GMC. The aim was to assist the Inquiry in commenting on the likely effectiveness of appraisal in avoiding the type of safety issues emerging, which led to the recall of neurology patients and the launching of various investigations including this independent public inquiry.

11.4 It is worth noting that most doctors working in NHS hospitals are employees of an NHS Trust, whereas doctors working in the independent sector are not.[1] The Terms of Reference of this Inquiry pertain to the Belfast Trust and the issues which arise from the difficulties that emerged in Neurology. Therefore, the Inquiry has taken evidence and reached conclusions about doctors who are employed in NHS hospitals, and particularly the Belfast Trust, but who may also work in the independent sector. We have not reviewed appraisal and revalidation in other Trusts. The Belfast Trust has stated to the Inquiry that its involvement with these processes is likely to have

1 A small number of consultants in Northern Ireland work exclusively within the independent sector. For those consultants a Responsible Officer is appointed by the independent provider. This contrasts with other consultants engaged in private work, who will also work within the NHS In that situation the Medical Director of the relevant Trust will be the consultant's Responsible Officer .

been comparable and potentially better than other Trusts. It is beyond the remit of the Inquiry to assess the accuracy of this assertion[2].

11.5 Doctors employed in the NHS are contractually required to follow the policies and procedures of their employer as well as the standards set by their regulator, the GMC. The Belfast Trust did have, and currently has, a policy that doctors should have an annual appraisal. Appraisal also underpins the process of revalidation overseen by the GMC.

11.6 A key question for the Inquiry Panel was whether the Trust ensured adherence to their own policies on appraisal. Additionally, even if appraisal had been timeously and sufficiently completed, to what extent would it have identified the problems that arose in Dr Watt's practice? The opening sections of the chapter explain the relevant processes and their role before going on to consider the specifics relating to Dr Watt's involvement with the said processes.

Appraisal:

11.7 The Cambridge Dictionary defines appraisal as *"the act of examining someone or something in order to judge their qualities, success or needs"*.

11.8 Most employees of organisations experience being appraised and may also conduct, in turn, appraisals of others whom they line manage. It is a common component of performance management, and many organisations regard it as essential to hold people to account in discharging the organisation's business efficiently and effectively.

11.9 During an appraisal in an employment setting, the appraisee will typically be held to account by their appraiser for their performance against set goals and objectives. Any difficulties or performance issues are identified and discussed, standards are set, future targets agreed, and the development needs of the individual and organisation aligned. The appraiser is frequently the line manager, but will, in any event, be acting in a managerial role cognisant of the organisation's view of the appraisee's performance and operates on behalf of the employer.

2 In written evidence on 17th May 2022 the Belfast Trust highlighted the January 2017 findings of the RQIA Review of Governance Arrangements in HSC Organisations that support Professional Regulation. The Trust has stated that the statistical information available through the January 2017 report "Taking Revalidation Forward" (the Pearson Review) supports its statement that its involvement with Professional Regulation was comparable and potentially better than other Trusts

Medical Appraisal:

11.10 Appraisal for doctors in the NHS is a fundamentally different process from that described at paragraphs 7-9 above. It is designed to improve performance, but not to manage it.[3] The GMC and other medical organisations have concluded that if doctors reflect on their practice, then their performance will improve. The appraiser can be a doctor from any specialty and, in fact, not all appraisers are doctors. All appraisers must, however, be trained in the medical appraisal process. They need not be the line manager, nor from the same medical specialty as the appraisee. Their role is to help the appraisee reflect and to confirm that the appraisee has completed that obligation. In NHS hospitals where doctors are employed, the job plan (agreed in a separate process) has set objectives and the appraisee may be asked to reflect upon them, but it is not the role of the appraiser, be they the line manager or not, to indicate their view or that of the organisation on the appraisee's performance.

11.11 In addition to appraisal being a developmental formative process, it has also, since 2012, become the bedrock for revalidation of a doctor's practice. The Inquiry has examined the extent to which the Responsible Officer[4] (in Dr Watt's case, the Medical Director of the Belfast Trust) has sufficient detail and confidence to make a positive recommendation to the GMC that an individual doctor has demonstrated that they are up to date and fit to practise.

11.12 Compulsory appraisal for all consultants was introduced following a circular[5] from the Department of Health in 2001. This circular emerged from a national agreement with the British Medical Association. Documentation and advice to support implementation was to be drawn up and Trusts were to consider as to how they were going to implement appraisal. The emphasis was on a standardised format to be applied consistently. The circular further highlighted amendments to the Terms and Conditions of Service for hospital, dental and medical staff.

11.13 The agreement annexed to the Departmental circular set out in detail an explanation of the purpose of appraisal and the process that it would entail. Salient features included the following requirements:

(i) Appraisal for consultants is a professional process of constructive dialogue, in which the doctor being appraised has a formal structured

3 Refer to the GMC Guidance for Supporting Information for Appraisal and Revalidation March 2018 Updated November 2020. See also 'The Good Medical Practice Framework for Appraisal and Revalidation' 2013.

4 The necessary statutory regulations needed to support the system were introduced on 23rd June 2010 and came into operation on 1st October 2010. The Medical Profession (Responsible Officers) Regulations (NI) 2010 established the Responsible Officer role. Guidance on the role is set out by the Department of Health & Social Services and Public Safety ("DHSSPS") and the "Confidence in Care" document is available on the Northern Ireland Department of Health website.

5 Circular HSS (TC8) 3/01.

opportunity to reflect on his/her work and to consider how his/her effectiveness might be improved.

(ii) It is a positive employer-led process to give consultants feedback on their performance, to chart their continuing progress and to identify development needs.

(iii) It is not the primary aim of appraisal to scrutinise doctors to see if they are performing poorly but rather to help them consolidate and improve on good performance, aiming towards excellence. However, it can help to recognise, at an early stage, developing poor performance or ill health, which may be affecting practice.

(iv) Appraisal will be a contractual requirement for all consultant staff.

(v) The relevant Chief Executive is accountable for the appraisal process and must ensure that appraisers are properly trained to carry out this role and are able to undertake appraisal of clinical performance, service delivery and management issues. In most cases, this will be the appropriate Clinical Director.

(vi) The consultant being appraised should prepare for the appraisal by identifying those issues which he/she wishes to raise with the Clinical Director/appraiser and prepare an outline personal development plan.

(vii) The appraiser should prepare a workload summary with the consultant being appraised.

(viii) If, during the appraisal, it becomes apparent that more detailed discussion and examination of any aspect would be helpful and important, either the appraiser or the appraisee should be able to request internal or external peer review.

(ix) The relevant Clinical Director (or the Medical Director, in the case of Clinical Directors) will be responsible for ensuring that any necessary action arising from the appraisal is taken. If the agreed appraiser is not the appraisee's Clinical or Medical Director, the appraiser will be responsible for submitting to the relevant Clinical or Medical Director the details of any action considered to be necessary. The Clinical and Medical Directors will be held accountable to the Chief Executive for the outcome of the appraisal process.

(x) Appraisal will be a contractual requirement and must be carried out annually.

(xi) Refusal by a consultant to participate in the appraisal process will be a disciplinary matter to be dealt with, where necessary, under the

employer's disciplinary procedures. Additionally, the Chief Executive will report the matter to the Discretionary Points and Distinction Award Committees and the consultant will not be considered for an award until he/she has agreed to participate fully in the appraisal process.

(xii) The Chief Executive should ensure the necessary links exist between the appraisal process and other processes concerned with clinical governance, quality and risk management and the achievement of service priorities. In discharging this accountability, the Chief Executive and Medical Director will have confidential access to any documentation used in the appraisal process.

11.14 A further circular[6] providing guidance on appraisal was issued on 29th May 2001. The guidance noted that the appraisal scheme was linked closely with job planning arrangements. The process envisaged in 2001 was, on the face of the guidance, a lot more robust, more closely tied to management and emphasised how concerns should be dealt with by the employer. The Department of Health's direction of travel thereafter appeared to dissipate the initial clarity.

11.15 It is the policy of most NHS Trusts, including the Belfast Trust, that annual appraisal of consultant staff is mandatory. Having noted the differences between appraisal process for NHS doctors and appraisal in other contexts, the Inquiry considered the extent to which, if at all, a consultant's appraisal can assist performance management of the consultant who is the Trust's employee. If the employer is accountable as an organisation, and the Chief Executive the accountable officer for patient safety and the actions of its employees, then the question arises as to how the Trust performance manages its medical staff and the extent to which reliance is placed on appraisal. The Inquiry accepts and acknowledges that the evidence base for any conclusions reached is limited to the events that led to the neurology recall.

11.16 Understanding the difference between medical appraisal and appraisal generally is a key in assessing to what extent the relevant organisations, including the Belfast Trust, the Department of Health, the Health & Social Care Board, the GMC as Regulator, and the public can be assured as to a doctor's fitness to practise.

11.17 The Belfast Trust became operational on 1st April 2007, following the Review of Public Administration ("RPA"). On 23rd April 2008, the Trust issued its Appraisal for Medical Practitioners Policy. This policy noted that: *"an annual appraisal is required for all medical practitioners (directly employed by the Belfast Trust)"*. The policy made clear that appraisal was to be carried out annually by an appraiser in a manner consistent with the guidance.

6 Circular HSS (TC8) 11/01.

11.18 An important facet of appraisal, which is also relevant to the question of revalidation is that appraisal includes the whole of a consultant's practice. An appraisee has an obligation to ensure that all relevant information regarding private practice is with the appraiser, and ultimately the Responsible Officer, prior to revalidation. The Inquiry Panel noted that where a doctor practiced in both the NHS and the independent sector[7], the NHS carried the burden (including cost, resource and administration) for both appraisal and revalidation. The independent sector benefits from this without carrying any similar burden[8]. Indeed, as set out in the Independent Sector chapter, the Inquiry identified key information that was relevant to both processes, and which ought to have been passed on to the Belfast Trust.

Revalidation:

11.19 Every licensed doctor who practices medicine in the UK must revalidate to show they are up to date and fit to practise. According to the GMC,[9] *"Revalidation consists of a process where doctors gather a range of required supporting information across their scope of practice for discussion and reflection at annual appraisal which is then considered alongside other clinical governance information by a Responsible Officer who makes a recommendation to the GMC"*.

11.20 The present system of revalidation for medical practitioners was introduced in December 2012 by the GMC and was implemented by NHS Trusts including the Belfast Trust. The GMC revalidates doctors every 5 years on the recommendation of Responsible Officers.

11.21 Responsible Officers are usually a senior doctor within a healthcare organisation and, as with the case of the Belfast Trust, normally a Medical Director. The role is set out in statute[10] and requires that systems are in place to allow a doctor to reflect on their practice of medicine. This will include making sure doctors are regularly appraised and there are processes to investigate and refer any fitness to practise concerns to the GMC.

11.22 The GMC and the Chief Medical Officers of the four UK countries set out their overall objective for revalidation in a joint Statement of Intent published in October 2010:

7 This is almost invariably the case in Northern Ireland.

8 It is recognised that there are a comparatively small number of doctors who work exclusively in the private sector and whose Responsible Officer will be appointed by the independent sector hospital or clinic.

9 Set out in written evidence of 21st April 2022.

10 The Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010.

> The purpose of revalidation is to assure patients and the public, employers and other healthcare professionals that licensed doctors are up to date and fit to practise.

11.23 In 2016, the GMC asked Sir Keith Pearson[11] to consider how revalidation was working for doctors and whether the public can be reassured that doctors are up to date and fit to practise. In his comprehensive review[12], Sir Keith noted:[13]

> It is a common misconception that revalidation was devised in response to the Shipman inquiry. In fact, revalidation had been proposed by the GMC in 1998, before Shipman was even arrested. Its rationale was not to uncover criminality but to fill a gap in the regulatory framework whereby, barring serious concerns being raised, a doctor could practise from registration to retirement without any check on their performance or competency.

11.24 Sir Keith, however, addressed the critical question of whether revalidation is effective in identifying aberrant practice[14] at paragraph 44:

> Revalidation does not exist solely to identify poor performance. Revalidation does have a vital role to play in helping to identify concerns about a doctor's practice at an early stage, before they escalate. It can and should deal with poor behaviour and performance. However, contrary to a commonly repeated myth, it was never intended to 'catch another Shipman' …

11.25 The Guidance document[15] also comments on the issue of purpose[16]:

> The purpose for revalidation, when it is introduced, will be to assure patients and the public employers and other healthcare professional that licensed doctors are up to date and are practising to the standards defined by *Good Medical Practice*.[17]

11 Formerly the Independent Chair of the Revalidation Advisory Board.

12 Taking Revalidation Forward: Improving the process of relicensing for doctors – January 2017.

13 See Paragraph 14.

14 See Paragraph 44.

15 DHSSPS, Confidence in Care: Guidance on the Role of Responsible Officer for Doctors and Employers, Feb 2011.

16 See Paragraph 12.

17 In written evidence to the Inquiry on 17th May 2022, the Belfast Trust stated as follows: "The purpose [of the revalidation process] is that revalidating a doctor confirms that the doctor is, **at that point**, up to date and practising to the standards defined by *Good Medical Practice*. A subsequent Medical Director must be able to rely, until proof to the contrary, that the assurance system operated properly at the time the revalidation occurred, that the steps leading up to revalidation were appropriate, and that the revalidation decision was correct. This was the approach taken by Dr Jack and Mr Watson, as confirmed in their evidence to the Inquiry. It is why Dr Jack and Mr Watson were entitled to operate on the basis that, post revalidation, there were no outstanding issues of concern in relation to Dr Watt **and that he was practising** in accordance with *Good Medical Practice*." (Inquiry emphasis added in bold and underlined). The Inquiry Panel does not agree with the approach put forward by the Belfast Trust. Such a view conflates a decision made at a point in time based on particular available information with an ongoing assumption about a consultant's practice thereafter and subsequent to the said period of time. It could be interpreted to suggest that as revalidation wipes the slate clean, there is no requirement to look behind it and that a Medical Director can rely on it for the next 5 years to demonstrate that a doctor is practising appropriately. Given that pattern identification is key to identifying aberrant practice, the Inquiry Panel does not agree with the Trust's view.

11.26 The Guidance highlights that the development of the Responsible Officer role will *"ensure that there are fair and effective local systems to identify [issues] and ensure appropriate action to safeguard patients"*[18].

11.27 As noted above, it is usually the case that the Responsible Officer for NHS consultants is the Medical Director of the Trust. Their role is to be both an Executive Director of the Trust, often with responsibility for patient safety and doctors' performance and also as a Responsible Officer, with statutory obligations to make recommendations to the GMC. This presents challenges, which have been considered below.

11.28 Dr Watt was revalidated in 2013 and this is commented upon further in the paragraphs that follow. However, the Inquiry Panel noted that after his revalidation, the perception persisted within the Medical Director's Office that as there were no current concerns, there was, as it were, *"a drawing of a line"*. In his evidence of 29th October 2018, Mr Peter Watson (at that time Senior Manager in the Medical Director's Office) stated:

> I think whether it is characterised as wiping the slate clean, revalidation certainly will have, a revalidation process, you can't be revalidated if there are current concerns. So if I start from that premise that you can't be revalidated if there are current concerns. So by definition then revalidation at a point in time meant there were no unresolved concerns. So that will have been the position prior to the 2016 issues arising [relating to Dr Watt] … So yes, I think there probably is to an extent a drawing of a line because there were no current concerns at that time in relation to that doctor's practice.

Relationship between Appraisal and Revalidation:

11.29 Further advice to the Responsible Officer is contained in NHS England Medical Appraisal Guide v 4. While the document is created for NHS England, it refers to the underpinning guidance which sets out the purpose and context of medical appraisal. The relevant guidance is contained in:

- Medical Appraisal Guide (MAG)
- Good Medical Practice (GMC 2013)
- Good Medical Practice Framework for Appraisal and Revalidation (GMC 2013)
- Supporting information for Appraisal and Revalidation (GMC 2012)

18 See Paragraph 13.

11.30 The Responsible Officer supervises the process of medical appraisal and revalidation and *"where indicated [the Responsible Officer] will inform the GMC of any concerns about a doctor's fitness to practise, or a doctor's refusal to engage in the processes that inform the revalidation process"*.

11.31 The relationship between appraisal and revalidation is set out in Annex A of the Departmental circular HSS (TC8) 3/01:

> The appraisal process is the vehicle through which the GMC's revalidation requirements will be delivered for senior hospital doctors. To this end appraisal discussions and evidence gathering should be sufficiently broad to cover the essential requirements for revalidation.
>
> By this means appraisal will provide a regular structured system for recording progress towards revalidation and identifying development needs (as part of personal development plans) which will support individual consultants in achieving revalidation.

11.32 The minimum requirement for revalidation when the scheme was first introduced was that an appraisal must occur at least once in 5 years. The GMC now stipulate that a doctor should be engaging in annual appraisal.[19] It is also the case that the Belfast Trust, along with many other Trusts, requires all consultants to undertake mandatory annual appraisal as a part of their contract and the quinquennial revalidation process includes a much greater emphasis on peer and patient review and the specific oversight of the Responsible Officer.

11.33 It is the case that the appraisal process is not of itself sufficient to allow the Responsible Officer to recommend to the GMC that a doctor is revalidated. This point was made by Ms Una Lane, Director of Registration & Revalidation, GMC, who told the Inquiry Panel on 13th March 2019:

> I think the second piece around revalidation is an interesting one, because, I think, most doctors think that appraisal equals revalidation equals appraisal. And, of course, revalidation – yes, the doctor's part is they need to participate in appraisal, but the wider clinical governance systems are hugely important to enable the Responsible Officer to satisfy themselves that there are no emerging concerns and to enable them to provide that reassurance to us on a regular basis.

11.34 While revalidation should require a much greater synthesis of information by the Trust above and beyond the information contained in annual appraisal, it remains the case that, in the view of the Belfast Trust witnesses, annual appraisal is the main

19 See for example: Having an annual whole practice appraisal – GMC (gmc-uk.org).

building block for revalidation. This is not the view of the GMC. In written evidence submitted to the Inquiry on 21st April 2022, the GMC stated:

> … We consider that it is important to register the distinction between revalidation and appraisal, noting that Responsible Officers (ROs) should consider appraisal outputs alongside other clinical governance information when making a decision about recommending a doctor for revalidation. We provide guidance to ROs that steers them towards using as broad a range of information to inform this decision as possible, and – at the point of making a recommendation on revalidation – ROs are required to make a declaration to us that there are no outstanding concerns about a doctor's practice …

11.35 The Inquiry Panel accepts that the guidance and statutory framework supports the view outlined by the GMC in its recent evidence. The Inquiry Panel carefully considered both the evidence and the statutory framework. It has concluded that, given the number of doctors that a Responsible Officer will often have to make recommendations on, the actual opportunity for going much beyond annual appraisal is limited in many cases. Consequently, the Inquiry Panel believes that the *de facto* reality is that appraisal is the main building block of revalidation. This issue has been the subject of various recommendations.

11.36 If appraisal is essentially a developmental and not a performance management process, then the danger is that a confusion emerges in relation to the perception of both appraisal and revalidation. Insofar as relevant bodies, and the public, are relying on revalidation as an assurance of patient safety, then there is a significant problem. Recognising accurately what revalidation does, and does not, achieve is a first step to addressing the broader concern as to how an organisation can identify aberrant practice.

Revalidation and the Independent Sector:

11.37 As the Responsible Officer is required to consider the whole practice of a consultant, the information obtained from the independent sector which should be included in the annual appraisal documentation is an essential part of the revalidation process. Obtaining clarity on this was raised during the evidence of Dr Cathy Jack, former Medical Director, Belfast Trust and now Chief Executive of the Trust.

11.38 In her evidence of 28th February 2019, Dr Jack commented on the tension between the role of the Medical Director as a Responsible Officer and the requirements of the GMC. One issue that emerged was the insistence by Dr Jack, when Medical Director,

that letters of good standing were required from independent sector providers where NHS doctors from the Belfast Trust also worked:

> Well, we put all our governance data into it. So, we don't just take the appraisals. We use the governance information systems. And the GMC don't like it, and they've told me that … at the GMC revalidation board, when my previous deputy, Dr Austin, who worked at the British Medical Association at that time, said the Belfast Trust is requiring these letters of good standing and all this, they made it very clear that, actually, there was no need for that; no need at all … And so, it was an individual employer process that was over and above the GMC requirement but, if I'm the Responsible Officer making a recommendation at a point in time, I need to satisfy myself that they are in good standing around all of their practices for good medical practice.

11.39 When the issue of the Medical Director of the Belfast Trust seeking such letters of good standing was considered within the Department of Health, the Deputy Chief Medical Officer, Dr Paddy Woods, was clear. In an email to the Chief Medical Officer on 19th March 2015, Dr Woods stated:

> I understand this is a requirement unique to BHSCT. Has been raised by BMA at most recent revalidation Delivery Board and I am advised, last weeks' GMC UK advisory forum.
>
> At the Delivery Board, I advised (supported by the GMC) that this is not a requirement specified in either the Department's guidance on appraisal or the GMC on revalidation …

11.40 In written evidence of 21st April 2022, the GMC clarified that it did not object to letters of good standing from the independent sector but pointed out that it had no powers to require the independent sector to provide information in any specific form.

11.41 Dr Woods reiterated such a view in a subsequent email to Dr Jack and Mr Watson on 10th July 2015:

> I can be quite categorical on one point, there is no requirement for letters of good standing to be provided to the doctor's designated body for activity conducted outside their employ. However, there is a requirement that appraisal covers the whole of a doctor's practice. The nature of supporting evidence brought to appraisal to cover specific aspects of practice is not specified.

11.42 Dr Woods may well be technically correct, but the situation, in the view of the Inquiry Panel, is unsatisfactory. If the Responsible Officer is required to undertake a whole of practice review, then it is critical that all the necessary information is available. If

the nature of supporting evidence is not specified, as pointed out by Dr Woods, then the situation needs to be reviewed. At present, the lack of clarity simply induces confusion and encourages those with governance responsibility in the independent sector to overly rely on the view of the Responsible Officer without participating actively and fully in the revalidation process. This is highlighted further in the Independent Sector chapter. The Inquiry Panel strongly favours the approach of Dr Jack.

> What did the Inquiry learn about Dr Watt and appraisal and what difficulties in the system were indicated by this history?

11.43 In Dr Watt's case, difficulties emerged when the appraisal requirement was introduced and continued throughout his career. In October 2005, Mr Peter Walby, then Associate Medical Director, replied to an enquiry from the GMC in relation to the investigation of a complaint regarding a failure by Dr Watt to complete medical reports. Amongst other matters, Mr Walby's response included the following:

> There is also concern that Dr Watt failed to complete his first consultant appraisal three years ago and has not been appraised since. He does not give these matters any priority to his clinical work.

11.44 In his response to a GMC enquiry in 2006, Dr Watt commented as follows:

> Mr Walby expressed concern that I have not completed an annual appraisal. I have recently heard that completing an annual appraisal will become a requirement to practice at the Ulster Independent Clinic from 2006 and I have therefore arranged to undergo an appraisal in January 2006.

11.45 The Inquiry Panel noted that this email suggested that in 2006 Dr Watt's motivating factor for being appraised was maintaining his private practice as opposed to fulfilling his employment obligations or seeing a value in appraisal.

11.46 In September 2009, Mr David Adams, Associate Medical Director, whose remit included the Neurology Department, emailed Dr Jim Morrow, Consultant Neurologist and Clinical Lead for Neurology at that time. Mr Adams requested an update on appraisal compliance within neurology.

11.47 In his response, Dr Morrow indicated that five consultants had completed their appraisal, one neurologist had agreed a date for his outstanding appraisal, and one neurologist was newly appointed. In relation to Dr Watt, Dr Morrow noted: *"and as for Michael Watt … well you know the score, he has only ever been appraised once and despite regular reminders does not co-operate"*.

11.48 After 2007, the Trust did not insist that Dr Watt complete a further appraisal until March 2012 for the year ending March 2011.

11.49 When the Inquiry Panel asked Mr Adams about the appraisals not taking place, Mr Adams stated in his evidence of 8th January 2020:

> Consultants must do an annual appraisal; they must absolutely do it and they can't keep on practising without it. So, I don't know why we let [Dr Watt] away with that.

He added that, with the benefit of hindsight, there should have been an investigation into the issue and then that could have been passed on to the Medical Director.

11.50 The Inquiry sought all documentation in respect of Dr Watt's appraisals which should have commenced in 2002. The files provided in respect of his appraisal commenced in 2012 for the period April 2010 to March 2011. Documentation prior to that date was no longer available. The Inquiry reviewed the appraisal forms and made the following observations.

Analysis of Dr Watt's Appraisals 2007-2018:

11.51 Upon request, the Inquiry received written material from Dr Watt's lawyers, comprising of his appraisal forms and supporting documentation for appraisals, which took place in 2013, 2014, 2017 and 2018. The earlier appraisal form for 2010-2011 (conducted in 2012) was provided by the Trust. No other relevant material was available. Dr Watt did undergo appraisal in 2007, but the papers were not retained on file. It is worth noting that as the appraisal always takes place retrospectively it is entirely normal for it to be conducted in the year subsequent to the period to which it relates. The first appraisal which was considered by the Inquiry was carried out for the period in April 2010-March 2011 (meeting 23rd March 2012). The Inquiry noted the following in respect of the appraisal documentation:

> Appraisal 2007. Documentation no longer available
>
> Appraisal 2007-March 2010: No appraisal carried out
>
> Appraisal April 2010-March 2011 (meeting March 2012):
>
> - The appraisal form seeks the outcome of any investigated complaint since the last appraisal. There is no mention made of the GMC investigation and formal 5-year warning effective from February 2007[20].

20 See the GMC chapter and 2006-07 Missed Opportunities for more details on the 5year warning.

- The appraisal does not refer to the GMC investigation into the INI 45 complaint[21].
- In respect of complaints, the appraisal form records that there are *"no issues"*. No reference is made to any of the following complaints – INI 87 (February 2007), INI 430 (June 2007), INI 417 (August 2010), INI 418 (November 2010), INI 419 (December 2010) and INI 5 (December 2010).
- The standard question was asked in the appraisal form: *"Has your registration been called into question since your last appraisal?"* The answer recorded by Dr Watt was "no".
- The form required a comprehensive description of the private work undertaken. The form refers to Hillsborough Private Clinic and the Ulster Independent Clinic, but no detail is provided.

March 2011-December 2011: No appraisal carried out.

- In this period, several important complaints arose which should have formed a central component of the appraisal reflection. Concerns around the number of complaints and correspondence from the GMC in both the INI 45 and INI 346 cases were the primary reasons that Dr Tony Stevens, then Medical Director, initiated a Finding of the Facts exercise in or about February 2012 under Maintaining High Professional Standards ("MHPS"). Dr Watt was also referred for review by the Doctors and Dentists in Difficulty Case Review Meeting ("DDCRM")[22].

Appraisal January 2012-December 2012 (meeting 2nd September 2013):

- A "no complaints" statement is provided by the Trust. Although it is stated that there were issues in previous years discussed, the form declares that there is no issue in 2012.
- The INI 325 complaint received by Ulster Independent Clinic in January 2012 is not referred to in the appraisal. The GMC was advised by UIC on 9th February 2012, following an enquiry regarding INI 45, (only in response to a direct question) that UIC is dealing with *"a complaint by a mother regarding her daughter's consultation with Dr Watt"*. No further details are given to the GMC nor requested by them. The Medical Director

21 See the 2012-13 Missed Opportunities and the GMC chapter for more details on the INI45 complaint.

22 See specific chapter on DDCRM. The Doctor and Dentist Case Review Meeting ("DDCRM") was set up by the then Medical Director, Dr Tony Stevens. The Review meeting deals with doctors who would be perceived by the Medical Director or others such as Associate Medical Directors as being in some form of difficulty with their medical practice for both clinical and or administrative reasons One of the main functions of the DDCRM is to ensure that the formal and informal stages of MHPS are followed. Any complaints about a doctor or dentist, which arise from a whole number of sources, are considered initially within the Directorate in which the doctor works. The Chair of the Division and the relevant Co-Director are responsible for determining if a threshold of concern has been reached; at which stage matters are brought to the attention of the Medical Director as well as the Service Director. When the threshold of concern has been reached, the Medical Director has a duty to ensure that patients and staff are protected and will seek to initiate an investigation around the alleged concern. Further, such a case is logged for consideration at the DDCRM.
This process is explored in detail in the 2012-13 Missed Opportunities chapter.

of the Belfast Trust was never informed, either by the UIC or the GMC in relation to the INI 325 complaint and an opportunity to identify a pattern of complaint was lost.

- There is no reference to the nature of the private work being carried out by Dr Watt at Orthoderm.
- Despite a suggestion from the Medical Director's office that there should be some discussion with Dr Watt as to why he did not refer to issues, particularly with regard to complaints in his previous appraisal, there was no evidence of reflection or discussion about apparent failure to disclose previous issues.
- In the Case Review Section, regarding improvement of professional behaviour, the examples given were all positive and there was no evidence of reflection in respect of improvement of professional behaviour and communication with patients

Appraisal January 2013-December 2013 (meeting 21st November 2014):

- Despite a directive that the next appraisal should discuss Dr Watt's intensive workload, particularly at a job planning meeting, this did not appear to have occurred.
- In respect of complaints, two complaints (INI 350 and INI 349) were omitted. There was no written reflection on any other complaints nor evidence of discussion with his appraiser.
- In terms of case review, only one was completed. No difficulties were identified or areas for improvement noted or learning to be taken.

Appraisal: January 2014-December 2016 No appraisal carried out

Appraisal January 2016-December 2016 (meeting 28th November 2017):

- Email correspondence confirms that this appraisal, which was carried out by Dr John Craig, Clinical Director in November 2017 was also intended to cover 2014 and 2015.
- In addition to the INI 325 and INI 77 complaints,[23] which relate to alleged misdiagnoses, there were 11 other complaints, both written and verbal, recorded by UIC. None of these complaints were forwarded to either the Responsible Officer in the Belfast Trust or the GMC. The letter of good standing from UIC fails to refer to any complaints and states: *"We have no record of any concern relating to Dr Watt's clinical practice at the UIC having been raised in the course of the past 3 years"*.

23 These are set out in detail in the Independent Sector chapter.

- Three structured reflective templates were completed, but others including the INI 286 investigation were not referred to or reflected upon.
- The Inquiry has seen email correspondence from Dr Craig to Dr Watt attempting to arrange an appraisal from 19th September 2016. It would take a further 13 months before an appraisal was completed notwithstanding that his practice was under significant scrutiny by the Trust from December 2016 onwards. By 8th September 2017, Dr Watt was one of only 6 doctors in the Belfast Trust who had appraisals outstanding for the years 2014 and 2015.
- In November 2017, Dr Watt had been subject to a full clinical restriction since July 2017 but remained in employment with the Belfast Trust. According to the appraisal forms, he had acquired two more areas of special interest in addition to those set out in his previous appraisal, namely 'intracranial hypotension' and 'epidural blood patching'. There is no recorded discussion of how he has developed expertise in these subspecialties. The form also states that he is a part of a Multiple Sclerosis disciplinary team, but the form does not highlight the fact that he was working in a single consultant inpatient team without any other neurologists.
- In relation to his private practice, Dr Watt provided a letter of good standing and confirmed that there were no complaints from the private hospitals in which he practiced. Over the period referred to numerous complaints had been made, including INI 325 and INI 77.
- The forms for this appraisal were signed off by Dr Watt, but the appraisal process does not seem to have been completed. The documentation notes: *"Dr Watt currently under investigation and not engaging in clinical work*".
- There was, on this occasion, reference to Dr Watt being under restriction regarding blood patching since December 2016 and having reflected on this. There was no detail about the nature or outcome of this reflection.
- Full restriction from June 2017, following investigation by the RCP and GMC referral is detailed. Reference is made to reflecting on the outcome.

Appraisal: 8th May 2018 (Appraisal for the year January to December 2017):

- The appraisal form records that there are *"No significant concerns identified through Datix*[24] *to Nov 2017"*. This note reflects an email sent to Dr Watt by the Risk & Governance Department of the Belfast Trust. On 12th October 2017, Dr Watt had asked for *"any significant incidents in which my name appears from 08/08/16 and now for the purpose of my appraisal"*. The response

24 Datix is the system utilised by the Belfast Trust to record complaints.

> on 10th November 2017 states: "You would be on the system if there were incidents which you reported, were witness to, were the person affected or otherwise involved/listed with. There were no such records found". The response did not refer to clinical concerns being received, restrictions on clinical practice being imposed, external investigation commenced and/or referral to the GMC. The Inquiry Panel was struck by how extraordinarily inaccurate this response was. The appraisal records that Dr Watt *"has reflected with me regarding his practice with MS, EP lumbar blood patch treatments"*. There is no further information as to the nature or outcome of this reflection, which appeared to be more of a formality in light of the other events including the Royal College of Physician's review that was ongoing at the same time.

11.52 The Inquiry noted several occasions when accurate information could not be obtained or, following a request, incorrect information was forwarded to the person or office making the request:

(i) In 2012, the Medical Director's Office asked the Complaints Department to forward any complaints about Dr Watt, following a request from the GMC.

(ii) In July 2012, in his letter setting out a list of complaints and asking Dr Watt to reflect on these at his next appraisal, Mr Hannon was unable to access the full list of complaints.

(iii) When Dr Watt contacted the Belfast Trust Risk and Governance Department in 2017 regarding any incident, he was informed there were none.

Availability of Information from the Private Sector:

11.53 The Inquiry Panel considered whether information was being appropriately shared between the independent sector and the Responsible Officer (almost invariably the Medical Director) within the Belfast Trust. Mr Charlie Massey, Chief Executive and Registrar of the GMC, who gave evidence to the Inquiry Panel on 13th March 2019, stated:

> The question about how one ensures that there is the appropriate data sharing when doctors are working both in the independent sector and doing NHS work is fundamental to enabling the governance arrangements to work, both in terms of appraisal and in terms of revalidation.

11.54 Despite the completion of appraisal being a pre-requisite to practice and privilege facilities being extended by the independent sector, Dr Watt's failure to carry out

appraisal on numerous occasions, and often for several years at a time, did not prevent him practising in the independent sector. Dr Watt continued to practice at Hillsborough Private Clinic ("HPC") and Ulster Independent Clinic ("UIC") until June 2017, despite having no appraisal completed since 2014. When questioned about this, both providers explained that they placed weight on the fact that a clinician was continuing to practice in the NHS.

11.55 Sister Dianne Shanks, the Nurse Manager at HPC told the Inquiry Panel in her oral evidence of 21st September 2018, that all consultants needed to provide a record of their appraisal to HPC to keep their practising privileges. It was the responsibility of doctors to notify their appraiser as to which other hospitals they worked in, outside the NHS. HPC provided a letter to the doctor to give to their appraiser confirming that they worked in HPC and indicating whether there had been any complaints or incidents. Sister Shanks stated that if a complaint was raised about fitness to practise or poor practice it would have been reported to the doctor's Responsible Officer by HPC. She confirmed that there had been no clinical issues in respect of Dr Watt, which required the Medical Directors to make such a report.

11.56 Sister Shanks indicated that when an appraisal was not received, the doctor was asked for an explanation, but if the doctor was still working in an NHS practice, that was accepted as satisfactory. In her view, there were several reasons for appraisal being delayed and it was not always the doctor's fault that appraisal had not been carried out. When asked about whether appraisals were noticed to be missing from a doctor's file during Regulation & Quality Improvement Authority ("RQIA") inspections, Sister Shanks told the Inquiry Panel that RQIA were content that appraisals were followed up by HPC and were fully aware that some appraisals ran behind.

11.57 In relation to Dr Watt, Sister Shanks stated that his last appraisal was in 2014. On 18th July 2016, Dr Watt informed Sister Shanks that he did not have a more up to date appraisal and, on 23rd May 2017, advised that he would be completing the appraisal shortly. She accepted that the length of time an appraisal was outstanding in Dr Watt's case was unusual and in breach of HPC's own policy, but she emphasised to the Inquiry Panel that other consultants had also not completed their annual appraisals. While this may have been true, it was still not appropriate to rely on the fact that doctors continue to work in the NHS as a means of assuring oneself that a doctor was fit to practise.

11.58 The Inquiry Panel subsequently heard evidence on 11th November 2019 from Mr James Sharkey, a Medical Director at HPC. He explained, when asked about the

ability of HPC to assess the ongoing competence of a doctor in the absence of any appraisal, that to some extent HPC lean on the NHS. He stated:

> Well, we also probably take the view that, if they are perceived as being satisfactory for their NHS work, which is usually their main practice, and if people consider in terms of the much, probably wider and well-established governance structure, if they feel that there is no reason to prevent them from working in what is — to a much larger number of patients —we take the view that, unless there is a compelling reason — that it would be an unreasonable thing to say to somebody, on the basis of a bit of administration, however important, that you have no personal control over and that other parties are preventing you from getting because of the unavailability of it.

11.59 Mr Sharkey's view was confirmed by the other Medical Director at HPC, Dr Gary McKee in his evidence to the Inquiry Panel on 9th January 2019:

> Now within the NHS there's probably always at least 10% of people who haven't done their appraisal on time because they're too busy. They think they are too important or whatever the reason is. You will always get recalcitrant individuals, but we have taken the view that if they're still allowed to work in the NHS, even if they haven't played ball – and we lean on them quite hard for it and they come up with all sorts of excuses as to why they don't do it.

11.60 Dr Stanley Hawkins, who carried out most of the appraisals for Dr Watt during the relevant period, gave evidence to the Inquiry Panel on 9th November 2018. He made the following observation in relation to information emanating from private practice:

> It is minimal and no data on outcomes or procedures.

11.61 Dr Hawkins further indicated that:

> There should be better monitoring of what goes on in private practice and, in particular, in private hospitals in outpatients because there is no monitoring.

11.62 Additionally, the independent sector did not bring to the attention of the Responsible Officer on several occasions clinical complaints, including INI 45, INI 354 and INI 325. These matters are explored in detail in the 2012-13 Missed Opportunities chapter.

11.63 On 3rd February 2016, UIC received a complaint (known to the Inquiry as INI 77) that Dr Watt had missed a diagnosis of Multiple Sclerosis. For the purposes of his appraisal in 2017, in respect of complaints in his private practice, Dr Watt relied on a letter from Dr Colin Russell to Dr Jack of 8th August 2017, which stated that UIC

had no record of any concerns being raised about Dr Watt's clinical practice in the last 3 years.

11.64 It is essential that relevant information as to the entirety of a clinician's practice be made available to the appraiser and the Responsible Officer. Consistent with this, it is not sufficient to simply record that a doctor retains practicing privileges in the private institution. Complaints data and any other related issue should be passed on to the relevant person and, in the first instance, the Responsible Officer, who is ultimately responsible for the oversight of the doctor. If information is retained and not passed on for whatever reason, patient safety is potentially compromised.

11.65 Present arrangements are not imbued with the level of gravity which would require the independent provider to immediately bring to the attention of the Responsible Officer a relevant complaint. Correspondingly, the Medical Director's Office, which is responsible for thousands of appraisals, does not appear to have the resource to interrogate or look behind a brief letter from an independent provider indicating that there have been no complaints. In the view of the Inquiry Panel, the present system needs to be overhauled to ensure that there is a clear obligation on the part of the independent provider to bring clinical complaints and any other relevant information to the attention of the Responsible Officer. Ultimately this may need to be addressed by way of Regulation.

11.66 The independent sector's failure to bring to the attention of the Responsible Officer, on several occasions, that a number of clinical complaints had been made about Dr Watt would have been highly relevant at a critical time. The appraisals that were carried out in respect of Dr Watt were not fully sighted on relevant complaints, thus undermining one of the critical and fundamental aspects of the appraisal/revalidation process.

What are Doctors' views on what should happen when they fail to be Appraised?

11.67 While the evidence to the Inquiry Panel demonstrated that most doctors do not regard appraisal as a means of identifying aberrant practice, the question remains, as to whether consistent non-engagement of itself, should raise questions about a doctor's practice. Dr Craig was clear in his evidence of 20th December 2018:

> I personally think if you don't engage in appraisal, you should … be told within the Trust, "Well, you're not seeing patients anymore. We're stopping your pay". I mean it's an absolute requirement under the GMC to do this …

11.68 On 25th March 2019, Dr Paul McMonagle, Consultant Neurologist, stated to the Inquiry Panel:

> It strikes me that the other thing is that, surely, your licence to practise should be dependent not just on five-yearly revalidation but on an annual commitment to appraisal. And if you don't complete your appraisal, then you don't practise until that has been sorted out.

The Implication of a Failure to be Appraised:

11.69 Mr Charlie Massey, Chief Executive and Registrar of the GMC, indicated in his evidence to the Inquiry Panel of 13th March 2019:

> With every single RO, and one of the questions that we ask them whether there is anybody who is over 15 months without an appraisal? And if there are, name them, and then we will need to follow up and consider whether or not that's consistent with them having a licence to practice on an ongoing basis … The easiest flag of all is that somebody hasn't actually engaged with the appraisal process whatsoever.

11.70 After 2007, the Trust did not insist that Dr Watt completed a further appraisal until March 2012 for the year ending March 2011. His non-engagement with appraisal was tolerated without any disciplinary action being taken.

11.71 His appraiser could not sign off the March 2012 appraisal initially because the paperwork was unsatisfactory. Mr Ray Hannon gave evidence on 16th January 2019 and stated that:

> Michael was an outlier, but I suppose he wasn't the only one. So, there were a few other people who you'd be sort of saying "will you just get this appraisal done so we can get them through the system".

11.72 It is important that the failure of a doctor to complete their appraisal and revalidation obligations is focused on initially as a straightforward breach of contract, as there are effective means at the disposal of the Trust to ensure compliance more effectively than immediate referral to the GMC. Allowing for a short period of adjustment, it should not have been acceptable for a doctor to consistently fail to engage with the appraisal process. In the present environment, where appraisal rates are much higher and effective compliance has now been achieved, the failure of a doctor to complete an appraisal or engage effectively in the revalidation process (without good reason) should, of itself, be a matter of concern to managers. If a doctor believes that it is acceptable to wilfully ignore a contractual obligation, such as appraisal, then there

should not only ultimately be referral to the GMC, but the engagement of a local disciplinary process and the commencement of the Trust's disciplinary process set out in Maintaining High Professional Standards ("MHPS").

11.73 It is appropriate to also point out that if a Responsible Officer informs the GMC of a failure by a doctor to engage with appraisal or the systems underpinning revalidation, the GMC has powers to withdraw the relevant doctor's licence to practise by way of a straightforward administrative process that is outlined in the GMC protocol.[25]

Neurologists' Perception of Appraisal:

11.74 The Inquiry focused on the views of neurologists themselves regarding the appraisal process. Dr Paul McMonagle, Consultant Neurologist, told the Inquiry Panel in his evidence of 25th March 2019 that, while noting that the process of appraisal was helpful in reminding practitioners of their obligations, he felt it was not unduly onerous, particularly in comparison with the appraisal he was required to undertake in the academic sphere:

> The university system was and is looking at performance more. The key to Health Service appraisal is asking people to reflect on their performance … I know that my university appraisal was more precise and exacting than the Health Service.
>
> Initially the appraisal process was entirely self-reporting where the appraisees would report various aspects of their performance to the appraiser and the means of cross-checking what was declared against what might have been undeclared was lacking in some respects.
>
> … It was light touch.
>
> … what I find the most useful thing about appraisal: it reminds you what you're in in the whole thing for. Anything that reminds you about those obligations and duties I don't think we can have any issue with, frankly.

11.75 Dr Orla Gray, Consultant Neurologist at the Ulster Hospital, strongly emphasised the reflective aspect of appraisal when she gave evidence on 4th December 2018:

> To me you need to have shown you are continually educating yourself and continually trying to improve your practice, but it is a time to reflect on how your practice is run and see how you can improve the services that you run and improve your own communication and skills.

25 The GMC protocol for making revalidation recommendations (gmc-uk.org).

11.76 For those who engaged seriously, the process required detailed application by the appraisee. Dr John McKinley, Consultant Neurologist at the Belfast Trust, told the Inquiry Panel on 15th January 2019:

> Then you go through the various domains of appraisal. It's difficult at the time doing it. My last appraisal was two full A4 lever arch files. You put down everything you've done in terms of evidence of, you know, and emails between nurses and stuff supporting the MDT.
>
> At the end of it you go, "Actually, I've done quite a lot". You mightn't think you've done a lot since the last year. So, in a way, I value the ability to sit and reflect on it. My appraisals have always been positive and encouraging.

11.77 Dr McKinley also focused on the theme of reflection and the opportunities presented by appraisal in his evidence:

> But what it does is it forces you to sit, on a 12-monthly basis, and take stock, so that one year just doesn't run into another year. There's a bit at the start of your appraisal where you list your multidisciplinary team; that largely doesn't really change unless there's more resources go in. Then there's an opportunity to write things that are operational challenges: so, for example, not enough beds on the ward, not enough nurses, not enough whatever. So, you reflect on that. Then you move through, obviously, your job plan and you reflect on your job plan with your appraiser, "Are you busy? Are you too busy? Are you not busy enough?" That sort of thing can happen.

11.78 Dr Cathy Jack highlighted the educational dimension of appraisal in her evidence to the Inquiry Panel on 29th October 2018:

> So for me appraisal is a bit about building confidence and a sense check that the doctor is reflecting and keeping up to date. It is very much focused on education and development needs.

What do Doctors Perceive the View of the Public is in Relation to Appraisal?

11.79 Retired Consultant Neurologist, Dr Stanley Hawkins stated in his evidence of 9th January 2018 to the Inquiry Panel, in relation to the public's perception of a doctor's annual appraisal:

> I think it is a performance review in the eyes of the public.

11.80 Dr Lourda Geoghegan, then Medical Director within the RQIA, had a responsibility as the Responsible Officer within the independent sector, until her appointment as the Deputy Chief Medical Officer. When Dr Geoghegan appeared before the Inquiry

Panel on 14th January 2020, she was asked about the difference in perception between the public, medical management and doctors themselves. She stated:

> There is a wide gap in that perception, I think, across the medical fraternity and when I speak to people, it's clear that medical professionals feel it is reflective. Revalidation is based on appraisal and appraisal is a reflective developmental form of process. And when I speak to other people outside the medical fraternity, their sense is very often that appraisal and particularly revalidation is a performance management system. And therefore, if somebody has gotten through their appraisal, and particularly if they've gotten through their revalidation that they are signed, sealed and stamped as their performance is fine. And so, I think there's wide perception there's a wide gap in the perception between the two.

Finding of the Facts Investigations and Referral to the DDCRM:

11.81 Using appraisal as an opportunity to challenge a doctor about leaving complaints out of appraisal is much more a management action than a reflective development. It was, however, on occasion suggested by management as a means of dealing with an issue that had arisen.

11.82 Following the referral of Dr Watt to the DDCRM[26] at the beginning of 2012, Mr Hannon, the Associate Medical Director, was tasked with carrying out an investigation under the MHPS procedure.[27] Following the investigation, the Medical Director stipulated that there was to be a 'recorded conversation'[28] with Dr Watt because of the number of times his name was appearing in complaints and because of the difficulties that had emerged in his attitude towards appraisal.

11.83 The 'recorded conversation' was ultimately changed to a formal letter from Mr Hannon, which was forwarded to Dr Watt on 19th July 2012. The letter highlighted several complaints and asked Dr Watt to:

> … gather these complaints and reflect on them. When your next appraisal becomes due, I would like you to discuss them as a group with your appraiser. This would be an important element of reflection and considering this as a whole may reveal something that requires attention.

26 The Doctor and Dentist Case Review Meeting ("DDCRM") was set up by the then Medical Director, Dr Tony Stevens. The Review meeting deals with doctors who would be perceived by the Medical Director or others such as Associate Medical Directors as being in some form of difficulty with their medical practice for both clinical and or administrative reasons One of the main functions of the DDCRM is to ensure that the formal and informal stages of MHPS are followed. Any complaints about a doctor or dentist, which arise from a whole number of sources, are considered initially within the Directorate in which the doctor works. The Chair of the Division and the relevant Co-Director are responsible for determining if a threshold of concern has been reached; at which stage matters are brought to the attention of the Medical Director as well as the Service Director. When the threshold of concern has been reached, the Medical Director has a duty to ensure that patients and staff are protected and will seek to initiate an investigation around the alleged concern. Further, such a case is logged for consideration at the DDCRM.

27 This process is explored in detail in the 2012-13 Missed Opportunities chapter.

28 A recorded conversation is one that is formally noted for the record.

11.84 Such reflection did not occur, and Dr Watt was referred to the DDCRM at the beginning of 2013.

11.85 Subsequently, Mr Hannon became aware that in Dr Watt's last recorded appraisal completed in March 2012, he had not mentioned any of the outstanding complaints including INI 45, INI 417, INI 418, INI 419 and INI 5. At that time, he emailed Mr Watson at the Medical Director's Office, who responded on 9th January 2013, stating:

> While technically the appraisal (second attachment) was for the year ending March 2011 and the two issues referenced above were during 2011/12 [INI 45], I find it somewhat difficult to understand how Michael made no reference to these issues when appraised in March 2012 … it would also be prudent at this appraisal for their [sic] to be some discussion with Michael as to why he was not explicit in relation to the issues during 2011/12 when engaging in Appraisal in March 2012.

11.86 The evidence that the Inquiry has heard leads it to the conclusion that the confusion between appraisal as a reflective process and appraisal as a performance management tool was prevalent at various times. That confusion led to the appraisal being relied upon inappropriately and in lieu of what should often have been a disciplinary action and/or a recorded conversation with the Medical Director or Associate Medical Director.

11.87 Dr Watt, having been referred to the DDCRM in January 2013, was made the subject of a second Finding of the Facts exercise in June 2013, under the informal stage of the MHPS process. This was carried out by Dr Ken Fullerton in June 2013 to look at issues around appraisal and several new complaints, including INI 334, INI 347 and INI 348.

11.88 Appraisal was carried out by Dr Hawkins in July 2013 for the year January to December 2012. The appraisal file was subsequently reviewed by Dr Fullerton in September 2013 and, as a result of this review, Dr Fullerton was satisfied that Dr Watt should be recommended for revalidation. As part of his Finding of the Facts exercise, Dr Fullerton considered several new complaints.

11.89 The appraiser, Dr Stanley Hawkins, had commented following the appraisal carried out on 18th July 2013 that Dr Watt had *"agreed to consider the intensity of his workload in NHS and private sector"*. There is no reference, however, within the appraisal to any meeting to discuss job planning with the Clinical Director or evidence during the interim period of reflection.

11.90 Three complaints are identified in the folder, namely INI 334, INI 347 and INI 348. There is, however, no reference to INI 349 and/or INI 350 nor any evidence of written reflection on the previous two complaints as directed by Dr Fullerton in September 2013. Further, the information on the INI 347 complaint was out of date and did not include the additional evidence of Dr Fulton, who had disagreed with Dr Watt's diagnosis.

11.91 Notably, the appraisal does not identify any areas for improvement or potential learning.

11.92 Following his review of the file in September 2013, Dr Fullerton identified, in an email of 26th September 2013, outstanding issues including:

(i) Dr Watt's job plan had not been reviewed for several years. It needed to be annually reviewed and a job plan meeting with the Clinical Director was to take place.

(ii) Dr Fullerton recorded *"we agreed that you would immediately reflect in written form on the two complaints mentioned above and include this in your next appraisal"*. It is not clear from the email which two complaints are being referred to as, at that time, several other complaints had been received.

11.93 Dr Watt did not reflect in written form as required nor did the Trust take any action because of this failure. No effective job plan meeting occurred.

Recognition of Aberrant Practice in the Appraisal Process:

11.94 The Inquiry Panel also considered the extent to which appraisal and/or revalidation served as an indicator of aberrant practice. Mr Hannon, the former Associate Medical Director, who had investigated Dr Watt in 2012, told the Inquiry Panel on 16th January 2019 that he had never: *"come across an appraisal turning up a stone, or, you know, a problem that we didn't know about"*.

11.95 Dr John Craig stated to the Inquiry Panel on 20th December 2018:

> [Appraisal] will not pick up poor clinical behaviour or performance or quality or continuous improvement or whatever you want, whatever, how you call it. But, again, it's another potential clue. I mean, what is going on with this person if they fail to engage in something as important as this.

11.96 According to Ms Una Lane, Director of Registration & Revalidation, GMC, any general improvement in overall patient safety and quality of healthcare, which accrues from appraisals being properly completed by all is markedly different

from a system that specifically seeks to focus on identifying poor practice. Ms Lane informed the Inquiry on 13th March 2019:

> For the most part, appraisal is not part — not always, not exclusively — is not part of a local performance management system, and so there is a challenge around appraisal. From our point of view, we say, "Yes, there are significant benefits for the vast majority of doctors", and it is around reflecting on your practice, benchmarking against others where the data is available.

11.97 The evidence which the Inquiry received indicated that, from the point of view of an employer, the appraisal process is often less than satisfactory and adds little to the performance management of the employee. This may be problematic, given that it is the employer who is accountable for the safety of patients within its purview and the actions of its employees. To be clear, an employer, in order to discharge its responsibility for the safety of patients, must be confident that its measure of the outcomes is sufficient to assure itself and others that the organisation is discharging its obligation. The fundamental difficulty with the current model of appraisal is that its focus on the input to safety, whilst entirely laudable, is insufficient to address the question of whether the output is satisfactory.

Confusion as to the Purpose/Utility of the Appraisal Process:

11.98 A difficulty arises if it is perceived that appraisal and revalidation are processes designed to specifically reassure the public as to the competence and safety of doctors, while the actual process adopted utilises a methodology, which does not address or live up to that expectation.

11.99 To additionally confuse matters, despite the consensus among medical practitioners that appraisal was a reflective/developmental process, and was not designed to identify aberrant practice, the Inquiry received evidence that, on occasion, the appraisal process was utilised as a means of managing concerns.

Availability of Information from Other NHS Sources:

11.100 A further problem arises because, in Northern Ireland, many consultant neurologists work in various Trusts not just the Belfast Trust. They often take clinics in different Trusts to ensure that neurological services can be more easily accessed outside Belfast. Each Trust has its own Responsible Officer and Medical Director. Dr Watt did not participate in clinics in a different Trust, but, in one instance, a private patient, whom he had treated, was also a patient in the Northern Trust. Issues arose, which

led to a concern being raised by 3 physicians, including a neurologist, within the Northern Trust about the treatment provided by Dr Watt. This concern was passed on to the Medical Director of the Northern Trust and the Medical Director of the Belfast Trust. This ultimately led to an independent report being obtained and the full details of this case are set out in the 2016 Missed Opportunities chapter.

11.101 Some months after the concern was initially raised, a further case relating to Dr Watt emerged. The concern was identified by Dr Tom Esmonde, Consultant Neurologist, and one of the 3 physicians referred to above. Dr Esmonde had emailed Dr Ken Lowry, the Medical Director of the Northern Trust, with his observations, but for reasons, which the Inquiry Panel believes are inadequate, Dr Lowry did not pass the information on to the Medical Director of the Belfast Trust. Dr Lowry, as the Medical Director of the Northern Trust, would also have been the Responsible Officer for the many of its clinicians. He should have been fully aware of the importance of passing on concerns of this nature. This series of events illustrated that highly relevant medical information cannot be kept inappropriately in 'silos' as this can prevent the identification of a pattern of practice and denies the opportunity for reflection at appraisal.

Availability of Information from the GMC:

11.102 As Regulator, the GMC wishes to reserve to itself the space and discretion necessary for effective decision-making about the practice of a medical practitioner. Consequently, and in accordance with its regulatory functions and the extant statutory framework regarding information sharing and data protection, care needs to be taken with the dissemination of information. At the same time, a Responsible Officer now exercises a statutory role in the revalidation process and the recommendation of the Responsible Officer as to the fitness of a doctor to practise is a critical component in the regulation process.

11.103 Current arrangements require the sharing of information with the GMC, not just by the Responsible Officer, particularly when an issue arises as to the fitness to practise of a particular doctor. At present, the GMC will, as a matter of course, require a Health Trust and other medical bodies to provide information to it as the Regulator on any concerns or problems that have previously arisen with a doctor's practice. The Inquiry Panel understands that this assists pattern recognition and enables the Regulator to have as broad a view as possible of a particular issue.

11.104 Correspondingly, as already stated above, in many instances, a Responsible Officer is also the Medical Director who has a direct responsibility for patient safety. A difficulty may arise if the GMC has significant information about a particular doctor that is not known about by the Medical Director/Responsible Officer of the relevant Trust. At present, there is no requirement or even formal guidance on the sharing of relevant information by the GMC with a Medical Director/Responsible Officer. This is a matter which concerned Dr Cathy Jack. In her evidence to the Inquiry Panel of 29th October 2018, Dr Jack raised a concern about the information being shared with Medical Directors by the GMC:

> **Mr Lockhart QC:** At the moment if I wanted to find out about a particular doctor and a concern was raised about a particular doctor, is there a place that I can go to and find out information which would capture issues with the GMC, issues with the private sector, issues with complaints? Because this is --
>
> **Dr Jack:** The private sector, no.
>
> **Mr Lockhart QC:** Right. What about the GMC?
>
> **Dr Jack:** With the GMC. So it is interesting that you raise that because I am trying to manage the recommendations of the O'Hara Report and some of the concerns that were raised about members of staff in that … That then means I put individual doctors who appear to have been criticised into the same MHPS framework because that is the only framework I can use. I have actually approached the GMC asking if they have anything on file. So they will tell me if they have anything that reaches the threshold. But when I asked them using the Medical Act 1983 I think it's, if there is anything that they have triaged out at a certain level, then they will not disclose that to me. Now I am sitting here as RO with significant concerns that Sir Justice O'Hara raised and yet I am only being told about issues which reach a certain level from the GMC.

11.105 The Inquiry Panel discussed with the GMC representatives, who attended to give evidence on 13th March 2019, the ability of the GMC to disclose relevant information to the Responsible Officer. The exchange, which is set out below, helpfully clarified the fact that the GMC is already disclosing relevant information:

> **Professor Mascie-Taylor:** And then the final point I was just going to make that's arisen is that if we're going to say the first decision maker is the RO, then one of the points we're going to make is that all the organisations, in particular the private sector, have to feed in. But one of the organisations, frankly, that has to feed in is the GMC. So, the GMC can't keep a load of information back from the RO. Do you -?

> **Mr Massey:** …-. Obviously, we need to exercise some judgement about where a leylandii creeps into something. But we will disclose to an RO where there's either a behavioural or a clinical issue which they need to be aware, but which is …a lower level than meets our threshold for investigation.
>
> **Professor Mascie-Taylor:** So you're already doing that.
>
> **Mr Massey:** Yes.

11.106 The Inquiry Panel welcomes Mr Massey's statement above as a positive development. Nevertheless, given the history of interactions regarding Dr Watt as between the GMC and the Belfast Trust and as between other sectors, such as the independent sector and the Belfast Trust, it is important to avoid an ad hoc process with the inherent danger of inconsistency. There is a need to formalise and strengthen the arrangement in the form of clear guidance where the limits of discretion are properly outlined.

11.107 The Inquiry also sought legal advice from David Scoffield QC (now Mr Justice Scoffield) on the ability of the Responsible Officer to collate and retain sensitive personal data in relation to a doctor still practising. This opinion is referred to in the Executive Summary, but the gist of the opinion was that, as a matter of general principle, there was justification for collating and retaining relevant fitness to practise information within the existing statutory framework.

11.108 At present, if a Responsible Officer recommends that a doctor should not be revalidated, and that recommendation is accepted by the GMC, then the doctor is unable to practice. In reality, there is often a delay caused to revalidation by reason of the failure to complete appraisals and gather together the necessary information. It is for this reason that management following up promptly on a failure to complete an annual appraisal is so critical. If delay in completing an appraisal is properly managed, then one avoids the panic around revalidation, as occurred with Dr Watt in September 2013.

The Holding of Information (including DATIX):

11.109 As explained above, appraisal involves a whole of practice reflection by the doctor. A doctor is required to ensure that all relevant material, such as complaints or concerns, is included in the appraisal process. As the evidence above illustrates, in Dr Watt's case, there were often gaps in the appraisal documentation and, in particular, a failure to refer to relevant complaints. The system relied almost exclusively on the doctor being appraised to ensure that all relevant material had been collated. As

already mentioned, there are inherent weaknesses in that approach. An appraisal, which omits relevant complaints, is an inadequate appraisal. In the same vein, if it is only the doctor who stores appraisal information, then errors and omissions will not be known about by the Responsible Officer or indeed the appraiser. It is clear to the Inquiry Panel that information needs to be stored and retained by the Responsible Officer as well as the doctor and that this should be made available to the appraiser (as well as the appraise). The Inquiry notes that the Belfast Trust has already put in place a system (see below) for ensuring that appraisers are provided with information held by the Trust, and this is strongly commended.

11.110 The complaints process is reviewed in detail in the Complaints chapter. Historically, and specifically during the period looked at by the Inquiry, the appraisal exercise relied on information provided by the doctor being appraised to the appraiser, as to whether there have been any complaints about his or her practice. If the doctor did not mention the complaints, as happened on a number of occasions with Dr Watt, then unless the appraiser went directly to the Service Manager within Neurosciences and the Complaints Department, it was unlikely that the complaint will be reflected upon at appraisal. The provision of relevant material by the Belfast Trust to its appraisers should prevent a similar scenario occurring again.

11.111 In 2013, Dr Fullerton was able to pull together most of the complaints after liaising with the Service Manager in neurology. In his letter of 19th July 2012, Mr Hannon asked Dr Watt to obtain some of the complaints himself from the Complaints Department but was not aware of all the complaints. At the beginning of that year, the Complaints Department had not provided an accurate record of the number of complaints against Dr Watt following an enquiry by the Medical Director's Office, who at that time was being required to answer a GMC query about complaints as part of the INI 45 investigation. The Inquiry takes the view that the system of storing and collating complaints data was not fit for purpose.

11.112 As outlined at paragraph 51, following Dr Watt's suspension, the Risk & Governance Department emailed Dr Watt in response to his enquiry of 12th October 2017. Dr Watt had asked for *"any significant incidents in which my name appears from 08/08/16 and now for the purpose of my appraisal"*. The response from Risk & Governance on 10th November 2017 stated:

> You would be on the system if there were incidents which you reported, were witness to, were the person affected or otherwise involved/listed with. There were no such records found' and the email also confirmed that there were 'No significant concerns identified through Datix to Nov 2017.

11.113 In Dr Watt's case, information about complaints was held at a variety of locations, including in the office of the Service Manager, the Complaints Department, which had access to the Datix system and the Medical Director's Office. The inability of the system to hold all relevant complaints information in one central point, which can be easily accessed by the Medical Director, or someone acting on the Medical Director's behalf, was particularly evident. At crucial times, relevant and serious clinical complaints were missed, not disclosed or not adequately reflected upon. The absence of accurate information on complaints clearly undermined the efficacy of the appraisals carried out in relation to Dr Watt, prevented a pattern recognition and allowed a positive recommendation to be made by Dr Fullerton in September 2013.

11.114 Prior to the publication of this report, the Belfast Trust forwarded to the Inquiry details of a live governance system which involved the triangulation of relevant data to provide a means of assurance in the context of revalidation and reflection. This was strongly promoted by Dr Jack in her former role as Medical Director. The availability of real time information would assist those involved with a doctor in the appraisal/revalidation process and also a Medical Director/Responsible Officer in the management of their concerns about doctors. A pilot exercise was approved by the Belfast Trust Executive in May 2018 and, as an IT solution was not immediately available, a manual system that had been utilised in the pilot scheme was commenced. Despite the challenges of the pandemic, the IT solution was completed in December 2021 and the live governance system is now operational for doctors across the Belfast Trust.

> The new system directly accesses for each individual doctor, data which includes complaints, litigation cases and coroner cases relevant to the doctor. Reports generated on demand can be used for appraisal, revalidation and ad hoc governance requests. Although not in a position to evaluate the new system, the Inquiry Panel very much welcomes the initiative and has recommended that the Department assess the system and, if appropriate, make the system a regional wide requirement.

Prescribing Data:

11.115 Evidence was also received in relation to the consideration of a doctor's prescribing practice during the process of appraisal. Dr Hawkins, in his evidence of 9th November 2018, highlighted to the Inquiry Panel a gap in the appraisal process:

> There is another aspect of appraisal where there is a hole and that is in terms of prescribing. There isn't an assessment of a hospital physician's prescribing pattern … During appraisal of general practitioners, particular care is taken of

> the prescribing practises to make sure that they fit within certain norms and standards.

11.116 The Inquiry Panel noted that it was apparent to Dr Watt's colleagues that he was the outlier in respect of the prescription of both Human Immunoglobulin ("HIG") and Alemtuzumab, a second line treatment in multiple sclerosis. The problems of HIG over-prescription were raised by Dr Diane Corrigan, a consultant in public health medicine with the Public Health Agency. Dr Corrigan circulated a letter to all Trust Medical Directors from Mr Dean Sullivan in 2011, which highlighted the rising cost of the use of HIG and the problems of prescribing HIG, where there was a limited evidence base. Neurology was singled out as a problem. Although Mr Sullivan's letter was circulated to all neurology consultants, the issue of over-prescribing was not picked up on or discussed as an issue, at any of Dr Watt's appraisals, nor was it identified as requiring further audit or consideration, having regard to the extant guidance.

11.117 The Inquiry Panel accepts that in the absence of a specific audit which identified Dr Watt individually, it is hard to envisage how an appraiser would be aware of any prescribing problem. Nevertheless, in Dr Watt's case, the issue of prescribing HIG had been raised with Dr Watt in a meeting with Mr Young, the Co-Director, and Dr Craig, the Clinical Director, in August 2016 and audit material did exist which identified Dr Watt's prescribing as different from his peers.

11.118 These matters are discussed in greater detail in the chapter on Prescribing, but the Inquiry Panel concurs with Dr Hawkins' observation that prescribing practice should have been a greater focus in the appraisal of Dr Watt, given the data that existed, the knowledge of his own colleagues, and the fact that prescribing practice in neurology had already been commented upon more generically in Mr Sullivan's letter in 2011.

Patient and Colleague Feedback in Revalidation:

11.119 The requirement of obtaining colleague and patient feedback ensures that revalidation is a more exacting process than annual appraisal. On 9th January 2019, Dr Gary McKee a Consultant Radiologist who was also a Medical Director at HPC, in an exchange with Professor Mascie-Taylor, stated:

> **Gary McKee:** If we start becoming very invasive in terms of, say, regulation, if somebody is qualified to work in the NHS and has gone through the appraisal process, and it's a very time-consuming, hassly process. Revalidation is a reasonably stiff threshold to meet. The annual appraisals, to be frank, are not.

> They are just paperwork, and I'm sure that Harold Shipman would've passed his appraisals quite easily. But the revalidation is a much more thorough process.
>
> **Professor Mascie-Taylor:** So your view of appraisal would be that, in terms of guaranteeing patient safety, it doesn't happen.
>
> **Mr McKee:** Just paperwork. It's not going to stop anything happening.
>
> **Professor Mascie-Taylor:** … But isn't revalidation just the summation of appraisal?
>
> **Mr McKee:** No, you have to get a questionnaire sent out to your colleagues, which is probably the most important thing that you have. I think 20 colleague questionnaires, about 40 patient questionnaires, and they're given out sequentially usually. So you can't just pick all your favourite patients to give the patient questionnaires to. And then you've a detailed, I think, discussion with your lead doctor. I think it's a useful process, and it certainly is the first time the medical profession's been sort of checked.

11.120 On 15th January 2019, Dr Ailsa Fulton indicated to the Inquiry Panel that there were, however, problems with identifying who should give feedback:

> The patient surveys: you know, there are very clear instructions about how it should be performed, and, yet, I saw consultant colleagues having their long-term pet patient, bringing them in, "Oh, we'll get you a wee cup of tea, and we'll sit and go through this piece of paper together". That's not how it's supposed to be done. Likewise, if you nominate who you're asking your 360-degree feedback from: is that going to get you a true idea?

11.121 In the case of Dr Watt, the feedback was overwhelmingly positive, as outlined by Dr Fullerton when he reviewed Dr Watt's appraisal file before revalidation in September 2013.

Missed Opportunities:

11.122 An analysis of the actual appraisal forms submitted by Dr Watt revealed a failure by the Belfast Trust systems, and Dr Watt himself, to disclose complaints that had previously been made. Several of the omissions were identified by management, but too often there was no record of an explanation being sought or a discussion taking place, with an Associate Medical Director, which reminded Dr Watt that the omission of complaints from an appraisal form was not acceptable. Opportunities were, therefore, lost to properly highlight a failure to reflect on complaints or include complaints, thus undermining the value of the appraisal process.

11.123 The Associate Medical Director, Mr Hannon, and Mr Watson from the Medical Director's Office, became aware that complaints had not been reflected upon in the appraisal, which was carried out in 2013 in respect of 2012. No sanction was ultimately imposed, nor action taken by the Belfast Trust. The matter was raised in email correspondence between Mr Hannon and Mr Watson but the Inquiry has been unable to find any evidence that the action discussed was implemented or that there was any consequence to Dr Watt. It is the case that the disclosure of complaints was one of the reasons that Dr Watt remained in the DDCRM in 2013. A further Finding of the Facts exercise under MHPS was also directed by the then Medical Director, Dr Tony Stevens, in June 2013 and was carried out by Dr Ken Fullerton. The result was that Dr Watt was appraised in July 2013 and revalidated in September 2013. However, the issue of whether complaints had been disclosed in an earlier appraisal was not further investigated.

11.124 The decision to recommend Dr Watt for revalidation in September 2013 was a key moment in the chronology of events. The missed opportunities in and around this period are commented upon in a separate chapter[29], but the evidence reveals that the extant complaints in 2011, 2012 and 2013 would have been sufficient to highlight a pattern of professional behaviour, which should have raised greater questions and been an obvious line of enquiry.

11.125 In 2016, Dr Watt had again failed to complete his appraisal for the years 2014 and 2015. The focus of the Medical Director's Office was based on an understanding that the GMC requirement was for at least one year's appraisal in the previous five to qualify for revalidation (see paragraph 32 above). This ignored a consultant's contractual obligation to be annually appraised. As Dr Watt had completed an appraisal in the previous five years, no further action was taken. If the Belfast Trust had simply sought to enforce its own contractual requirements, then the issue of appraisal would have been a greater focus during the period 2013-2017.

11.126 Dr Watt was referred to the DDCRM for the third time in 2016, following the INI 286 complaint to the Northern Trust. At the same time, Dr Fullerton, who was about to retire, rightly recommended that Dr Watt should also be referred to the DDCRM because of previous difficulties including a failure to complete appraisals.

11.127 Further, previous compliance problems with Dr Watt's appraisal were not considered subsequently at the DDCRM[30] in March 2016. It is noted that Dr Fullerton, who, by

29 See the 2012-13 Missed Opportunities chapter.

30 The DDCRM was set up by Dr Tony Stevens, the then Medical Director in 2012 Its membership included the Trust's senior human resource personnel, senior legal advisor, risk and governance staff, the relevant service director and the relevant associate medical director.

that stage, was coming to the end of his tenure as Associate Medical Director, did suggest that one of the reasons Dr Watt should be referred to the DDCRM was because of his previous difficulties: *"I am aware of at least one other current issue, and a series of issues in the past. Given my impending retirement, Dr Watt may need to be discussed at the DDCRM to get a concerted view on what needs to be done"*. Nevertheless, when no appraisal was carried out by Dr Watt in 2015 and 2016, the question of earlier failures was not considered or reviewed, further demonstrating the inadequacy of this process.

11.128 Dr Jack stressed that, in 2016, a failure to carry out an annual appraisal was not of itself evidence of non-engagement within the definition utilised at that time by the GMC. According to Dr Jack, the GMC relied upon the fact that a doctor was revalidated and, although annual appraisal was regarded as good practice, it was not until 2018 that annual appraisal was required by the GMC. The GMC, in its evidence to the Inquiry Panel, did not accept that that was the position[31]. It does appear in more recent correspondence[32] from the GMC that changes made in 2018 by the GMC reinforced the obligations of Responsible Officers, by making it incumbent upon them to inform the GMC if a doctor was not engaging in *"appraisal and local processes that underpin revalidation"*. A circular on how doctors can meet the requirements of revalidation in the first cycle in April 2012, stipulated that doctors must be participating in an annual appraisal process, but also stated: *"The doctor must have completed at least one medical appraisal"*. A degree of confusion is apparent, and it is hoped that recent changes which require the GMC to be informed by the Responsible Officer if an appraisal is missed, will prove effective.

11.129 By November 2017, Dr Watt remained an employee of the Belfast Trust but was not clinically practising. The appraisal documentation records that he had acquired two more areas of special interest, namely intracranial hypotension and epidural blood patching. There is no discussion, however, of how he had developed expertise in these subspecialties. The form also states that he was a part of a Multiple Sclerosis disciplinary team, but the form does not highlight the fact that he was working in an in-patient team without any other neurologists.

11.130 Dr Watt had been required to obtain the approval of Dr Peukert in December 2016 before confirming a diagnosis of spontaneous intracranial hypotension. Within a matter of weeks, Dr Peukert had drawn up a spreadsheet, which highlighted significant concerns about misdiagnoses by Dr Watt. Despite this, Dr Watt's reflection

31 See paragraph 32 above.

32 The GMC position was set out in correspondence of 7th July 2020 from Jane Kennedy Head of GMC Northern Ireland to Geraldine Quinn, Secretary of the Independent Neurology Inquiry.

was that he should stop overbooking clinics and revise his job plan to include more time for epidural blood patching and, in fact, he suggested a secondment to the USA to enable further training. This reflection was 5 months after full clinical restriction in July 2017 and appeared to indicate a complete ambivalence to the serious circumstances in which he had found himself.

Evidence of Availability of Appraisal to the Trust:

11.131 In the process of the Inquiry's investigation, sight of Dr Watt's appraisal folder was requested. The Inquiry was informed by the Belfast Trust that it did not hold a copy of the appraisal folder and, therefore, the Inquiry approached Dr Watt's legal representatives, who subsequently provided the folder, but made reference to the contents being sensitive and confidential. This aspect was commented on by those who had been involved in appraisal. Dr Hawkins, in his evidence of 9th November 2018, stated:

> The Belfast Trust, for good reasons, recycles the appraisers every three years so that the relationship between an appraiser and appraisee is not too cosy. There are good reasons for that, but I agree absolutely if there is a record going back ten years of poor performance or significant complaints that should be made available to the appraiser as well as a deputy medical officer.

11.132 The question of medical management having an overview and access to appraisal documentation was also raised, particularly in relation to job planning. Dr Craig told the Inquiry Panel on 20th December 2018:

> I definitely need to have more oversight [when appraising a colleague]. So, I would not know at the moment if all the people who are — all the neurologists in the Belfast Trust — you know, I wouldn't know specifically have they done their appraisal, where are the deficiencies etc., and I think that would be important. And I think it does need to be aligned with job planning.

11.133 In the view of the Inquiry Panel, it is unsatisfactory for the Trust, and more specifically the Responsible Officer, not to have access to a doctor's appraisal folder. The purpose behind this development was to encourage candour and to help doctors reflect honestly about a range of matters. The difficulty is that an appraiser cannot 'unknow what he or she knows' and there may be issues raised in appraisal, which give rise to more serious concern. In those circumstances, it is not appropriate that the only person who retains the folder is the individual doctor. There must be provision for the Medical Director's Office to have access to all appraisal folders, when necessary, if patient safety is to be of paramount concern.

Further Observations: Compliance Rates in the Trust:

11.134 Compliance rates, which increased from 39% for the year ending March 2007 up to 89% for year ending March 2011, suggested to some doctors that there was a difference between younger, more recently qualified doctors and an older generation. The policy of the Belfast Trust was that consultants should be appraised annually. A failure to complete an appraisal in any given year was, therefore, potentially a performance management issue for the Trust.

11.135 The Inquiry noted that in 2017, Dr Jack, as Medical Director, put in place an escalation process for non-compliance with appraisal. On 6th February 2017, an email was sent by Dr Jack to all medical and dental staff stressing the importance of appraisal and referencing the escalation process. By July 2017, the Trust had still not appraised Dr Watt and his appraisals for 2015 and 2016 remained outstanding. A letter was issued to Dr Watt[33] on 13th July 2017, co-signed by Dr Maria O'Kane, Deputy Medical Director and Ms Cathy McCook, Education, Appraisal and Revalidation Manager:

> Dear Dr Watt
>
> Appraisal for Practice Year Ending December 2016
>
> We hope you have had the opportunity to read the email on 20th June 2017 on behalf of Dr Jack, Medical Director with regards to completing your appraisal. We have attached this again for your convenience.
>
> As you know, the guidance requires that appraisal is completed by the end of June each year. Unfortunately, our records indicate that at this point:
>
> 1. You have not yet finished or submitted your appraisal for the year ending December 2016, or
>
> 2. That we have insufficient information regarding the status of your appraisal, or
>
> 3. That you have been in contact but have not yet finished or submitted your appraisal, or
>
> 4. That you have been on long term absence or leave from your usual work (for example 4. That you have been on long term absence or leave from your usual work (for example sickness, career break, maternity leave, secondment, suspension).

33 As it was issued to all other doctors who had similarly not fulfilled their appraisal obligations.

> We would like to remind you then of the need to submit your completed appraisal as soon as possible please. Please contact the administrator who has sent you this email to provide an update and advise if there are exceptional circumstances causing delay.
>
> Guidance and Contacts for appraisal submission can be accessed on the Trust Hub:
>
> Appraisal Process.
>
> Many thanks

11.136 The Inquiry has been informed that compliance with appraisal requirements within the Belfast Trust from 2013 onwards has been consistently above 95%. Further, intense focus by the Medical Director's Office in 2017 has ensured even better adherence to the obligation[34] and a system is now in place, which escalates, at an early stage, delay and non-compliance.

Conclusions and Findings:

11.137 The current method of appraisal of doctors is an entirely legitimate way of improving performance through a developmental process. The clear consensus of the medical witnesses who gave evidence to the Inquiry Panel was that the appraisal system is essentially a means of assisting doctors to reflect on their practice. The very fact that doctors are formalising and systematising a reflection process may be regarded as positive, especially by comparison with other professions.

11.138 Appraisal requires the doctor to reflect with a trained appraiser on the whole of his or her medical practice in a systematic and structured manner. The benefit of a developmental process is predicated on a recognition that the performance of doctors collectively is a vital input to patient safety, which will improve the overall performance of doctors and, therefore, improve patient safety. The Inquiry Panel agrees that this makes sense and should be recognised and commended. It is, however, something entirely different from performance management or measuring the output of doctors.

11.139 If medical appraisal is to be effective in raising standards, it must be regularly undertaken. The Trust's policy was that all doctors were contractually required to undergo appraisal annually. The Inquiry Panel notes that recent figures of compliance to appraisal obligations have been close to full adherence. The problem, however,

34 The highest figure for compliance is 98.8%. There are still a number of doctors who, for instance, are on maternity leave or absent on grounds of ill health, where appraisal may be delayed.

is how to manage those few doctors, who have shown a persistent reluctance to adhere to their contractual obligations without good reason. If an obligation is not properly enforced, then any value appraisal may have, is correspondingly reduced.

11.140 In the Belfast Trust, the responsibility of recommending the revalidation of a doctor and, therefore, permitting them to continue to practice, falls to the Responsible Officer. Responsible Officers receive training, but they have an onerous task. It is clear from the evidence that they on occasion make their recommendations on the basis of information available to them which may be incomplete in the absence of complete information. Sometimes the information has failed to flow within the organisation, but the Inquiry has seen evidence that, in relation to the Belfast Trust, it also failed to flow from one NHS organisation to another, from the private sector to the Responsible Officer (even though the private sector relies heavily on the revalidation process) and indeed from the GMC itself to the Responsible Officer.

11.141 Further, even in a situation where an appraisal may potentially highlight aberrant practice, the timings of the process are such that the utility of the process is limited, given that the appraisal for any one particular year takes place in the following year.

11.142 Revalidation was introduced by the GMC to *"assure the patients and the public, employers and other healthcare professionals that licensed doctors are up to date and fit to practise"*. The Inquiry Panel fully accepts that revalidation drives improvements in quality and safety by requiring doctors to reflect on their own practice of medicine. The Inquiry Panel does not, however, believe, on the evidence received in this Inquiry, that the revalidation process is well placed to provide the necessary level of assurance on patient safety. The Inquiry Panel takes the view, in line with the overwhelming number of medical witnesses and the Pearson Report, that appraisal is not designed to identify aberrant practice. The use of the term 'appraisal' to describe what is, essentially, a developmental process is, in itself, unhelpful and generates confusion in the minds of the public, professional and medical managers. In every other area, 'appraisal' involves a judgement being made about a person. The appraiser makes the judgement. In medical appraisal it is the appraisee who makes the judgement, which is why it is a useful developmental process.

11.143 It is the case that annual appraisal is the main building block of revalidation every 5 years. Clarity about what is required for revalidation is essential, not just for the Responsible Officer, but also by the GMC, who often has access to information not within the possession of the Responsible Officer and the independent sector. Evidence has shown that the independent sector has been too slow to share information with the Responsible Officer for those many consultants, who also work in the NHS.

11.144 If the GMC had changed its own policy with regard to the Responsible Officer in relation to the disclosure of clinical complaints, which have not, in its view, met a certain threshold, the opportunity for the Responsible Officer to identify patterns of concern would have improved.

11.145 If the independent sector organisations within which Dr Watt worked had understood their obligations, as they are required to do, to ensure that the Responsible Officer was fully aware of clinical complaints then, at key moments, a decision-maker would have been better informed. This is particularly the case in 2013, when Dr Fullerton was involved in carrying out a Finding of the Facts exercise under the MHPS procedure.

11.146 The evidence suggests that managers on occasion sought to deal with ongoing difficulties in relation to Dr Watt by deflecting them to the appraisal process. If managers believe that, what is essentially a reflective process like appraisal can be utilised as a performance management tool, or assure the Trust on patient safety, then there is a weakness in management. Further, if managers act on the basis that what is essentially a reflective process like medical appraisal, can be utilised to address potential disciplinary issues, then that approach will fail, as it did in Dr Watt's case.

11.147 Regarding Dr Watt, appraisals took place, which reflected on complaints, only insofar as they were: (a) disclosed by Dr Watt; (b) disclosed by the Complaints Department; (c) disclosed by the Risk and Governance Department using the Datix system, or (d) referred to by the Clinical Director. Significant complaints at relevant times in both NHS and the private sector were omitted. Dr Watt failed on several occasions to mention complaints, despite being obliged to do so, and certified in the probity statement that all relevant information had been included. The Trust information systems coupled with the absence of information, and information from elsewhere, impeded proper reflection at appraisal.

11.148 Unsurprisingly, the problems in Dr Watt's practice identified by this Inquiry and by other reviews, were not solved by appraisal and, in the view of the Inquiry, never would have been.

11.149 The Inquiry Panel has concluded that if organisations are to be held to account for quality and safety, and a Chief Executive is to be the accountable officer, then some form of robust appraisal in the normal or performance management sense of the word, needs to be introduced.

11.150 The clear danger of the current system of appraisal across the NHS is that many, including NHS general managers and the public, believe that the medical form of appraisal is analogous to other forms of workplace appraisal and provides an assurance that a doctor is practicing safely. Consistent with this perception, these managers tend to see the medical appraisal and the related revalidation process as sufficient to reassure them that all is well. Such confusion is problematic and must be addressed.

11.151 The Trust had a policy in common with most other NHS Trusts which required consultants to undergo annual appraisal. This was a part of the Trust's approach to reassuring the public on patient safety. The Trust did not enforce its own policy and Dr Watt was able to regularly avoid appraisal or complete in a partial manner, which omitted key information such as complaints.

CHAPTER 12 – PRESCRIBING

12.1 In determining whether there were related concerns or circumstances, which should have alerted the Belfast Trust to instigate an earlier and more thorough investigation over and above the extant arrangements, the Inquiry Panel considered whether the prescribing patterns of Dr Watt should have given rise to concern. In particular, the Inquiry received evidence on the utilisation and prescription of human immunoglobulin ("HIG") and the prescription of Alemtuzumab, which is a potent and powerful drug used in the treatment of multiple sclerosis. Both treatments carry potential patient safety risks, are costly and had been subject to intensive monitoring by both the Health and Social Care Board and the Belfast Trust.

12.2 The Inquiry Panel heard evidence that in the prescription of specific treatments, Dr Watt was and had been an outlier for many years. The Inquiry Panel assessed whether, in light of patient safety issues, there was evidence that needed to be further investigated.

12.3 The Inquiry Panel reflected upon the question of prescribing patterns and the extent to which Dr Watt's general approach in neurology was replicated in his specific practice of prescribing drugs or treatments.

The Health and Social Care Board and its Function:

12.4 The Health and Social Care Board ("HSCB") has an important role in the commissioning of services by the Health Trusts and works in conjunction with the Public Health Agency.

12.5 Ms Valerie Watts, the then Chief Executive of the HSCB, attended with other colleagues at the Inquiry on 17th June 2019. She explained the role of the HSCB as follows:

> — the Board was established back in 2009, and it has a range of functions. Basically, they can be summarised under three broad headings as set out in the framework document that was produced by the Department of Health back in 2011. Those three main areas are (1) commissioning; (2) performance management and looking at service improvement; and the third key area is resource management.

12.6 Ms Watts explained that by commissioning, she referred to the HSCB securing the provision of health and social care for the population of Northern Ireland. That included assessing health and social care need and the strategic planning of services to meet those needs. The HSCB would liaise with service providers such as Health Trusts and GPs and agree an annual delivery plan. Once the plan was agreed, the HSCB would monitor the delivery of services to ensure that the identified needs were being met and that services were safe and of high quality. Ms Watts emphasised that evaluation is continual and ongoing. The second area highlighted was that of performance management. The HSCB seek to assist a culture of continuous improvement to ensure the best clinical practice. Performance was monitored against a whole range of targets and standards across the health and social care spectrum. Poor performance was addressed through "appropriate interventions", which can include the withholding of funding. The final area of resource management was about the HSCB trying to ensure the best possible use of the resources available across the entire health and social care system.

12.7 The focus of the Inquiry was on the interaction between the HSCB and the Trusts in respect of both HIG and Alemtuzumab, where costly treatment or drugs had been the subject of review as between representatives of the HSCB and the Trust and the extent to which those reviews made a difference.

Human Immuno-Globulin ("HIG"):

12.8 Human immunoglobulin is a blood product and licensed medicine used to treat patients with a wide range of diseases. The Inquiry Panel heard evidence that there had been a concern over the availability of immunoglobulin to the National Health Service because of a global supply shortage. Difficulties had been compounded by an ever-increasing demand for immunoglobulin, in particular, because of the emergence of new therapeutic indications.

12.9 In 2008 the Department of Health in England drew up guidelines for a Demand Management Plan, a three-part initiative to ensure appropriate use of immunoglobulin products. The document made recommendations on indications for the use of immunoglobulin and the processes to be implemented by Trusts to ensure that it is utilised correctly.

12.10 Until May 2018 the distribution of HIG was controlled and authorised by the Northern Ireland Blood Transfusion Service ("the NIBTS")[1]. The pharmacy department of the Belfast Trust eventually took over responsibility for management of the process in May 2018. Commenting on the previous system, Ms Rhona Fair, Professional Pharmacy Manager, Acute & Regional Services Belfast Trust, stated in her evidence to the Inquiry Panel of 10th September 2019:

> When I looked at the process that there was, it was a very obscure process. So the medical staff phoned the Blood Transfusion Service to request the use of a product and release. They were always told yes; always. And then they had to contact their local blood bank and get a supply from the blood bank having had some sort of communication from NIBTS to blood bank. And then, blood bank sent it to the patient. A bit strange …

12.11 Prior to the setting up of the Immunoglobulin Assessment Panel ("IAP")[2], there were early indications of financial pressures on the existing budget for HIG treatment. At that point, despite an added £1.3m being included within the existing budget, a projected overspend of £600,000 was being estimated. Dr Kieran Morris, the acting Chief Executive with the NIBTS indicated that a regional audit report was being drafted ("the GAIN[3] audit") with a plan for improvement in terms of immunoglobulin use. Dr Morris highlighted the fact that the draft audit report had assessed "a 45% inappropriate use in neurology according to their own professional guidelines".

12.12 In October 2010, the GAIN audit was presented to the Neurosciences Grand Round on HIG by Dr Morris and Dr Gavin McDonnell. The high inappropriate use in neurology[4] was confirmed and the audit made various recommendations, including the importance of prescribing within the guidelines, a rounding down of the dose to the nearest whole vial to conserve drug volumes, a full clinical review of improvement and using a validated scale or method where repeated infusions of immunoglobulin were considered.

12.13 By any standard, the findings of the GAIN audit should have provoked significant management action by the HSCB, the NIBTS and the Belfast Trust. A finding of such a high level of inappropriate use gives rise to an obvious patient safety concern.

1 In written evidence provided to the Inquiry on 23rd May 2022, the Northern Ireland Blood Transfusion Service ("NIBTS") indicated that it would have been extremely difficult for any consultant or scientist in NIBTS to challenge the request for product by a consultant neurologist as they did not have the necessary clinical expertise.

2 See paragraph 23 *infra*.

3 Guidelines and Audit Implementation Network.

4 In her written evidence of 23rd May 2022, Ms Fair pointed out that the GAIN report was also critical of immunology as well as neurology in terms of the use of HIG.

The recommendations made by Dr Morris and Dr McDonnell, sensible as they may well have been, needed to be monitored so that management could assess to what extent the degree of inappropriate use in neurology was being reduced. There is little evidence that fundamental questions were addressed. In particular:

(i) Why was there such a high degree of use outside the guidelines?

(ii) Was this reasonable?

(iii) Was the regular prescription of HIG outside the guidelines confined to one neurologist or was it a widespread occurrence?

12.14 The Inquiry Panel concluded that the answer to (iii) above was obvious from an early stage. In this regard, the Inquiry Panel noted the evidence of Dr Aisling Carr of 11th November 2019. In 2007, Dr Carr was a neurology registrar and collected, in an audit, the human immunoglobulin usage per consultant noting that there was a significantly larger volume of use by Dr Watt. The audit was triggered by Dr Carr's observation of practice as a registrar seeing all the consultants but also her wishing to understand and learn about HIG usage. Her findings were presented at an audit to the Neurosciences Grand Round in 2007[5].

12.15 On 7th June 2011, Mr Dean Sullivan, the Director of Commissioning at the HSCB, following the preliminary findings of the GAIN audit, wrote to the then Chief Executive of the Belfast Trust, Mr Colm Donaghy, about the prescribing of HIG. Salient extracts from this correspondence are set out below:

> … Early indications are that immunoglobulin was being prescribed for a number of conditions where there was a weak or absent evidence-base, dose calculation (amount of drug and frequency of administration) was being carried out in a way which resulted in higher use than necessary for optimal clinical care and patients were continuing on this expensive treatment without review so that they remained on the product event when it was not documented as providing clinical benefit …
>
> Given the financial constraints faced by the HSC, it is incumbent on Trusts to ensure that, in future, this product is used in accordance with recognised guidelines … The area where there is the greatest need to review the indications for use is in the field of neurology …
>
> I am writing to ask that HSC Trusts put in place arrangements to ensure that all relevant clinical staff, especially those working in neurology, are aware that the HSCB does not commission use of immunoglobulin for patients with other neurological conditions outwith these guidelines, other than in exceptional circumstances.

5 Dr Carr commented on this at paragraph 83 *infra*.

> All intravenous immunoglobulin in NI is issued by NIBTS. I have asked the Chief Executive of NIBTS to issue a request form for use by prescribers which must be completed before NIBTS will release the product. If this does not demonstrate that use is for an agreed indication and at an appropriate dose for the patient, it will typically not be issued. NIBTS will also put in place a monthly monitoring system for neurology cases which will list the patient's hospital number, the clinical indications, the appropriateness or inappropriateness score and their compliance with dose determining weight prescribing. This will be reported to the Clinical Director or Lead consultant in Neurology and the Director of Finance in each Trust using the product. Anonymised data will be shared with the HSCB. Trusts may not use their financial allocation for immunoglobulin from the HSCB to pay for use in neurological cases which do not adhere to this guidance, or have not been agreed as exceptions …
>
> Clinicians who wish to use immunoglobulin for patients whose neurological conditions would not be covered by the guidelines must submit an (anonymised) individual patient request to the HSCB, via the agreed Trust system for such exceptional requests. Any request for exceptional use would be expected to include a summary of the strength of the evidence-base for immunoglobulin use in that condition, the clinical circumstances which would support that patient being considered exceptional, the proposed dose and length of treatment and measures that would take [sic] to assess benefit. There may be a small number of very urgent cases where prior approval would delay appropriate treatment. In those cases, senior clinical managers within the Trust would be expected to have considered the request. If they are prepared to support the rationale for use, the Trust may proceed with treatment but submit an exceptional funding request as soon as possible thereafter …

12.16 In an email to Mr Hannon, Dr McDonnell, Dr Hawkins and the other MS specialists (including Dr Watt[6]), Dr John Craig, the Clinical Lead within neurology at the time, noted on 10th June 2011 that:

> We need to be prescribing all treatments, including expensive and not entirely risk-free treatments, such as HIG appropriately … from my perspective the most important thing is that for everyone treated with for example HIG that we should be able to justify our choice to our peers. We absolutely must have objective evidence that it is of benefit to that patient. While it might seem obvious there must therefore be a proper record of how symptoms, examination findings and if appropriate investigation results progress over the time of the treatment. If there is no objective measurable benefit treatment should be stopped.

6 This email from Dr Craig to Mr Hannon was also copied to Bernie Owens, at that time a Co-Director, Dr Stephen Cooke, the then Clinical Director of Neurosciences and Gerry Atkinson, the Service Manager for Neurosciences.

12.17 The email summarised the position as it should have been, and the Inquiry Panel noted the insight that Dr Craig highlighted. The importance of objective justification to peers, evidence of benefit to the patient and a proper record of how symptoms, examination findings and investigation results progress was precisely what was needed to ensure equity and safety.

12.18 In an email to consultants with an interest in multiple sclerosis (but not including Dr Watt[7]) on 23rd June 2011, Dr Craig stated:

> You will be aware that our ability to prescribe IVIG for neurological conditions is likely to become much more regulated and outside of certain defined conditions we will have to apply for exceptional funding by submitting a form to the HSCB, via the Trust that the patient is being treated in.
>
> Since one of the prerequisites will be that we provide a summary of the strength of the evidence base for immunoglobulin use in that condition I would be grateful for your thoughts, as the individuals with an interest in MS, as to whether you think that there is an indication for IVIG in MS. If so, could you provide me with a summary for the evidence base as some of these requests are likely to come my way. Since my sub-specialty interest lies elsewhere and I do not have the time to be reviewing the literature for every neurological indication for IVIG I would be grateful for your combined opinions.

12.19 The approach taken at that time by Dr Craig as Clinical Lead was sensible and proportionate and followed on from his email of 10th June 2011, when he summarised the specific problem.

12.20 The initial focus of consultants was to highlight a number of missing diagnoses on the list. The Inquiry noted that additional indications were timeously included in an amended list drawn up by the HSCB. The prompt response by the Board is to be commended and revealed evidence of good liaison and consultation between the consultants dealing with the patients and the HSCB, who was commissioning the service.

12.21 The Inquiry Panel did take note of the response from Dr Craig on 1st July 2011 to Mr Donaghy. Dr Craig began the letter by reassuring Mr Donaghy that all neurologists across Northern Ireland would work towards appropriate prescription of HIG. It is also important to point out that Dr Craig, however, was concerned that guidelines were never fully up to date and that a number of life-threatening and severely disabling neurological conditions could now be treated by HIG. Dr Craig summarised the problem as follows:

7 There was some evidence that when Dr Watt was appointed a consultant, that there was an issue of his taking on an MS specialism. The Inquiry Panel decided that investigating this in any depth was arguably outside the Terms of Reference, but it does note that Dr Watt was not included at that time in the group of consultants who had an interest in MS.

> … While I fully appreciate that it is important to be able to provide an evidence-base for the use of any medical therapy, the problem here is these conditions are not that common, best treatment is still evolving and there is a serious risk to a bad outcome if treatment is delayed. While I fully accept that an appropriate case needs to be made for exceptional use of immunoglobulin, bearing in mind the complexities of the conditions that we are considering and the rapidly changing field of neuro-immunology I think that it is vital that neurologists are involved in the process of commissioning …

12.22 As part of the response to the concerns about over-prescribing and to the correspondence from Mr Sullivan, an Immunoglobulin Assessment Panel ("IAP") was set up in September 2012 with representation from HSCB, the Public Health Agency and nominees from those sub-specialties within the Trust, including neurology as emphasised by Dr Craig in his correspondence.

12.23 The clinical guidelines for immunoglobulin use were not drawn up by the Department of Health until July 2011. The IAP was set up by Trusts and prescribing indications were colour-coded to reflect clinical guideline recommendations. The IAP was established in line with a model described in the 2008 Immunoglobulin Demand Management Plan.

12.24 If HIG was required in an acute situation, then it would have been colour-coded red. This allowed for ongoing use without approval of the IAP for primary immunodeficiencies only. If, however, it was being required in a chronic situation, it would have been colour-coded blue and if prescription did not fall within the guidelines, or clearly within the guidelines, it would have been colour-coded grey[8]. The IAP was established to consider those cases which involved blue and grey colour-coding. The letter from Mr Sullivan highlighted the rising costs of the use of immunoglobulin and the problems of prescribing where there was a limited evidence base. Mr Sullivan indicated that in addressing the issues identified in the audit, a reduction of 18%, equating to a saving of £700,000, might be achieved in Northern Ireland.

12.25 On 9th June 2011 Dr Diane Corrigan, a Consultant in Public Health Medicine with the Public Health Agency and a member of the Specialist Services Commissioning Team, forwarded the letter dated 7th June 2011 from Mr Sullivan to Mr Colm Donaghy, Chief Executive of the Belfast Trust, which was copied to Trust Associate Medical Directors for Medicine/Specialist Services, in light of the GAIN audit.

8 Initially the colour-coding was confined to red and blue and allowed for a further category of 'exceptional circumstances', where it was proposed to use HIG in an indication not listed in the guidelines. These exceptional cases were redesignated as grey indications in the Clinical Guidelines for Immunoglobulin Use issued by the Department of Health in July 2011.

12.26 The correspondence requested that all HSC Trusts would put in place arrangements to ensure that all clinical staff, especially those working in neurology, were aware that the HSCB did not commission the use of immunoglobulin for patients *"with other neurological conditions outwith these guidelines, other than in exceptional circumstances"*.

12.27 The Inquiry Panel noted that although there was a legitimate focus on budgetary concerns, there was, implicit in Mr Sullivan's correspondence, a concern about prescribing *"where there was a limited evidence base"*. Once again, that is may have been a potential patient safety issue, but this does not seem to have been focused upon at any level at that juncture. Of interest to the Inquiry Panel was that this issue was escalated to the Chief Executive. It was, therefore, directly known about by the Trust at the highest level.

12.28 The NIBTS were also required to put in place a monthly monitoring system for neurology cases, which would list the patient's hospital number, the clinical indications, the appropriateness or inappropriateness score and their compliance with dose determining weight prescribing. This was to be reported to the Clinical Director or Lead Consultant in Neurology and the Director of Finance in each Trust using the product. Anonymous data was then to be shared with the HSCB.

12.29 In relation to cases which were outside the guidelines, clinicians were required to submit an individual funding request to the HSCB via the Trust's agreed system for such exceptional request. The correspondence stressed that there should be a very small number of exceptional cases.

12.30 In his evidence to the Inquiry Panel on 5th November 2019, Mr Sullivan indicated that his correspondence did not analyse the relative performance of individual Trusts or the performance of individual clinicians.

12.31 Mr Sullivan's letter was subsequently emailed to the neurology consultants[9]. In his response to the letter, Mr Ray Hannon, the Associate Medical Director, stated:

> There is increasing evidence, on several fronts, of HSCB requiring Trusts to audit/prove that we are delivering against what has been commissioned/NICE guidelines etc. they are generally looking for evidence of mission creep by us, so we need to be sure of our ground. On the flip side we have to keep an eye on them for mission "shrink".

12.32 Mr Hannon's response highlights the concern first expressed by Dr Craig in his letter of 1st July 2011 about the tension between budgetary efficiency and ensuring that patients obtain appropriate treatment as medical science evolves. The Inquiry

9 Dr Craig's response to this letter is set out in paragraph 16 *supra*.

Panel recognises that this is a continual process and that there is always going to be an inherent tension between budgetary constraint and the evolution of treatment. This possible conflict did not, however, obviate the need for action to be taken.

12.33 By October 2011, issues of compliance with the requirements of Mr Sullivan's letter began to be identified by the HSCB. Dr Corrigan noted that the requisite monthly reporting of data from the NIBTS to the Trusts was not in place. It appears that by November 2011 there were arrangements in place for quarterly reporting of information from NIBTS to the Trusts.

12.34 At a Belfast Trust Neurosciences Clinical Leads meeting on 11th October 2011, it was agreed that a group should be set up to monitor and audit usage in accordance with the requirements of the earlier letter from Mr Sullivan.

12.35 On 28th November 2011, an audit report meeting occurred, attended by Dr Morris, Chief Executive of the NIBTS, Dr McDonnell, Dr Corrigan and others. Dr Morris made it clear that the NIBTS did not have the capability of challenging the prescribing of HIG, NIBTS's role was identified as *"the distributer of the product only and are not the gatekeeper."* Dr Morris further believed that the control of the product would be best managed in a pharmacy setting. It was noted at the time that Northern Ireland had a higher use of HIG than the rest of the UK. Dr Corrigan suggested consideration of the proposal that the product was dispatched from the NIBTS but controlled elsewhere. Additionally, there was further reflection on the establishment of a group to discuss and consider requests from clinicians for HIG, where the clinical indications were regarded as in a grey area. It was felt that this should be a regional group, including the commissioner and clinical experts and that *"individual Trust control of such a group would not work"*.

12.36 Dr Corrigan, in a subsequent email dated 28th November 2011 to Brian Baker, Finance Department within the HSCB, and Ms Teresa Magirr, Assistant Director Specialist Services Commissioning, highlighted concerns that there was no real change in clinical practice in neurology since Mr Sullivan's letter in June. She noted:

> There was some discussion as to how well (or not) Dean's letter had been circulated internally in BHSCT. What is clear is that the financial risk to the Trust does not appear to be taken very seriously and there is minimal clinical engagement … the bottom line is that at a high level there have been neurology issues …
>
> I would like a letter to go to Trusts reminding them of Dean's letter but need to know if this should go from Finance, Dean or even me? I also would suggest a regional neurology review process for all use in that speciality.

12.37 Further issues with reporting and monitoring were then identified. In March 2012 it came to the attention of Dr Corrigan that no Independent Funding Requests had been submitted by the Trusts for grey indications, as required by Mr Sullivan's letter.

12.38 In May 2012, Teresa Magirr emailed Mr Sullivan, copying in Dr Corrigan, and noting as follows:

> The key issue is the identification that Trusts have not adhered to the guidance your previously sent out in June 2011 and are continuing to prescribe inappropriately – this correspondence asks the Trust to undertake engagement with clinicians and carry out an audit … Given the scale of funds potentially able to be released, the robustness of the GAIN audit in determining the protocols it is important that we firmly follow up on this issue.

12.39 Mr Sullivan, in responding to the importance of a firm follow up, was concerned that the HSCB had not been able to introduce a "gatekeeping function". It was highlighted, however, by Dr Corrigan that the technical staff in the NIBTS who issue the product were relatively junior and it was unrealistic to expect them to refuse a consultant neurologist requesting treatment for a very ill patient. Dr Corrigan believed that *"the main lever for change was a managerial one in that Trusts would not be reimbursed". She noted the possibility that HIG might not be issued was "put in as a fairly weak/empty threat*".

12.40 The Inquiry Panel noted that at this time Dr Corrigan had also identified the problem and recognised that a managerial response was needed. Despite much discussion, and many meetings however, the issues were not addressed. If neurology was not adhering to the guidance, then that was a matter which needed to be properly investigated and clear action taken.

12.41 The level of concern within the HSCB reached such levels that follow-up correspondence was drafted in August 2012. This draft correspondence summarised the previous correspondence and the continuing problems and concluded by stating as follows:

> The information also highlights continued use for patients outside the agreed conditions with no corresponding funding requests through the IFR process … It is important that immediate action is taken to put in place the necessary arrangements to reduce the financial risk to the Trust by ensuring that consultant neurologists are reminded of the need to consider [Dose Determining Weight], the clinical conditions that will not be funded by the HSC Board and the need to review the clinical appropriateness of continued treatment in all parties receiving repeat doses. Consultant neurologists still have the opportunity to submit an individual funding request (IFR) for conditions not on the agreed list,

including on a retrospective basis. However, such requests need to clearly set out the grounds for that case to be treated as an exception.

12.42 After this letter was shared by Dr Corrigan with Mr Sullivan, a series of amendments were made to the draft, which included reference to the HSCB's *"serious concern"* that immunoglobulin was being prescribed for grey indications with no corresponding IFR being submitted. This subsequent draft concluded with the HSCB asking each Trust to arrange for prescribing clinicians to undertake a retrospective audit of immunoglobulin prescription, including grey indications, and the use of any internal Trust processes relating to the same. The letter would have required completion of the audit by November 2012.

12.43 Before this updated letter could be issued, Ms Rhona Fair contacted relevant specialties in the Belfast Trust regarding the establishment of the IAP on 24th September 2012. On 25th September 2012 Ms Fair emailed Dr Corrigan regarding the establishment of the IAP and invited her to join the Panel. By way of reply, Dr Corrigan indicated that *"I had just been about to issue a letter to all 5 Trusts on use of IVIg in neurology patients. If BHSCT is setting up a prior approval process and overarching scrutiny of all usage then it may do away with the need for action I had been about to request."* Dr Corrigan shared a draft copy of the letter and indicated, *"if you are confident that the work of the IAP will subsume the sorts of action suggested in my letter in approximately the same timescale, then a retrospective look at practice would not been needed, and I would hold back."* There is no evidence that the letter as outlined above was ever shared formally with the Trusts.

12.44 In September 2012 the Belfast Trust established an IAP, with the intended aim of promoting adherence to the Department of Health's Demand Management Plan. The first meeting of the IAP took place on 5th November 2012 at which the Terms of Reference were settled, and it was agreed that the IAP was to commence reviewing requests from 1st April 2013.

12.45 The policy for immunoglobulin therapy in the Belfast Trust required a request form based on an NHS *pro forma* and adapted for local use to be completed by the relevant consultant. The IAP would then consider the form and reach a decision on approval, dependent upon the colour-coding of the request with regards to local and national guidelines. Red indications would be approved automatically with blue and grey indications requiring approval by the panel member for that specialty.

12.46 The Terms of Reference stipulated that the IAP would include one clinician from each of the main specialties using immunoglobulin (Renal, Dermatology, Oncology, Paediatric Oncology, Neurology and Rheumatology). The panel also included

representation from Belfast Trust pharmacy, Ms Rhona Fair, a Public Health Agency representative, Dr Diane Corrigan, and an Associate Medical Director acting as the independent chair, initially Dr Ken Lowry. The duties of the IAP included interacting with the NIBTS and the HSCB, to provide regular information on immunoglobulin use, to ensure a robust internal review system to monitor use in conjunction with prescribing clinicians, and to undertake regular audit.

12.47 Despite the eminence of the panel that was established, the clarity of what was to be focused upon and the detail of the procedures that were agreed, what became apparent was that the problem was not solved. Neurology continued to be the outlier in respect of the prescription of HIG and Dr Watt continued to be the outlier within neurology.

12.48 Ms Fair, Pharmacy Manager at the Belfast Trust at that time, told the Inquiry Panel in oral evidence on 10th September 2019 that:

> Unlike the rest of the UK, Northern Ireland pharmacy didn't manage them. So, when I became aware of the audit and the fact that they were medicines, I set up the IAP. I devised the – wrote the policy for the use of immunoglobulins. And I based that on practice elsewhere in the UK, such as Leeds … I was looking at reviewing the process, bringing it into pharmacy, and treating it in exactly the same way as other medicines. We eventually achieved that just over a year ago.

12.49 Commenting on the establishment of the IAP, in her oral evidence on 10th February 2020, Dr Corrigan told the Inquiry Panel:

> We were aware there were reports in some places in England there were immunoglobulin assessment panels. Our understanding was that they primarily there to make sure there was a good database of patients on treatment and that they were categorised appropriately so that in the event of a nationwide or worldwide shortage it could be prioritised quickly to those who needed it … it became clear after about six or nine months [after Dean Sullivan's letter] it was not having any impact. We were debating…what to do next, and we were about to ask that a further audit was done but much more focused on neurology. The day after we finally agreed a letter to go out, Belfast Trust informed us that they were about to set up their own immunoglobulin assessment panel, which we thought was a very good idea, and I was invited to be a member of that.

12.50 An email exchange dated 7th December 2012 between Dr Craig and Dr McDonnell highlighted the apparent approach of the neurologists to the IAP. Dr McDonnell had thought the Welsh guidelines as being particularly appropriate, albeit with a provision for rapid approval in grey/emergent areas. Dr Craig responded:

> Thanks Gavin. In essence we will administer grey and then retrospectively seek approval, i.e. it will likely come to me for a decision. I am very unlikely to disagree with a colleague and their decision to administer.

12.51 On 17th January 2013, Dr Craig emailed other consultant neurologists regarding the working of the IAP, explaining:

> If it is a red indication, it will be dispensed automatically, for most blue it will be dispensed as required on an emergency basis, but there will then be a requirement for the indication to be considered by the IAP. For most this will mean a discussion between me, or a deputy and the chair. For other indications, i.e. the grey these will need to have individual HSCB requests put in and for the black case will need to be made as to why they should be considered as grey.

12.52 Immunoglobulin request forms were subsequently utilised from February 2013. In February 2014, Dr Stephen Hunt replaced Dr Craig as the neurology representative on the IAP. At that time, the process was a retrospective process. NIBTS still controlled supply not the Trust pharmacies. Therefore, Immunoglobulin would be issued by the NIBTS and was not dependent on the approval of the IAP.

12.53 On 15th April 2013, Dr Craig emailed all neurologists stating:

> I enclose forms that MUST be completed and forwarded to blood bank … you may get requests from me to provide more information. In addition you may also be instructed to put an IFR for a particular indication (colour coded grey) to justify either retrospective use or a request for ongoing use, for conditions where evidence base is weak.

12.54 There are several examples of consultants being asked to give further information and, in one instance, a request not being approved. By August 2014, Dr Hunt had stepped down from the IAP and was replaced, on an interim basis, by Dr Craig. In October 2014, Dr Lowry, the Associate Medical Director, indicated to the IAP that funding was now in place to allow for a fully prospective process. It does not appear, however, that such a prospective process was put in place at that time.

12.55 The Inquiry Panel believes that this was a significant moment. It is recognised that problems had developed because of the retrospective nature of the process. It was always going to be difficult for an IAP panel to retrospectively review decisions that had already been made. The treatment had been given. The consultant who had sought the treatment had essentially got what they believed the patient needed, and it is hard not to conclude that the panel was seeking 'to close the door after the horse had bolted'. Funding for a fully prospective process would have given the IAP panel the ability to effectively query cases where there was a grey or blue indication. It

would have been both obvious and straightforward to have ascertained that Dr Watt was by some distance the main prescriber of treatment in neurology which did not fit within the guidelines. A panel which was able to consider matters prospectively would have had the ability to act on the problem immediately. This did not happen and was, in the view of the Inquiry Panel, a significant missed opportunity.

12.56 The absence of a panel able to operate prospectively, despite funding being in place, did not, however, prevent the extant panel from identifying Dr Watt as a clear outlier within neurology.

12.57 On 16th October 2014, Dr Diane Corrigan emailed Ms Rhona Fair, Pharmacy Manager at the Belfast Trust as follows:

> I was running my eye down the IAP monthly request lists and noted quite a lot of requests from one of the neurologists (Dr Watt). About 10 or 11 adult neurologist names were on the list. Of approx. 112 requests for adult neurology between April and September (this may be one or two out as I don't recognise all the names, and some might be paeds cases) 40 (36%) were under the name of Dr Watts [sic]. The next most common prescribers had 20 and 17 requests respectively (18% & 15%). Without knowing the subspecialty interest of all of the neurologists it is impossible to say whether this would or would not be a surprise to John Craig. I had thought Dr Watt's special interest was in MS but maybe I am wrong. I had been thinking of asking John for his thoughts on this, but before I do can you tell me whether in the cases where the 'new or on-going' column was not able to be completed initially, this was then updated later on? I think it would be helpful to know if perhaps the distribution of new requests by consultant differs from those receiving on-going IVIG. Any comment on this line of thinking? Has it come up at any of the meetings earlier in the year that I could not attend?"

12.58 Ms Fair responded on 17th October 2014 stating as follows:

> Good point. I am limited in my capacity to chase up gaps in information on the forms. John Craig has agreed to re-join the panel so I think this might be something we should raise with him then. Perhaps this may be a good focus for the pharmacist when appointed. I have attached the most recent collation.

12.59 A meeting of the IAP subsequently took place on 10th November 2014. There was reference at the meeting to the treatment of "functional antibody deficiency" by Dr Watt, and Dr Craig, who by this time had re-joined the committee, was asked to comment. Subsequently, on 15th December 2014, Dr Corrigan emailed Dr Craig at 10:02am as follows:

> I had hoped to catch up with you at an IAP meeting, but I see you won't be there today so I'm emailing instead.

> I was running my eye down he IAP monthly request lists and noted quite a lot of requests from one consultant neurologists [sic]. About 10 or 11 adult neurologist names were on the list. Of approx. 112 requests for adult neurology between April and September (this may be one or two out as I don't recognise all the names, and some might be paeds cases) 40 (36%) were under the name of a single consultant. The next most frequent prescribers had 20 and 17 requests respectively (18% and 15%). Without knowing the subspecialty interest of all of the neurologists it is impossible to say whether this would or would not be a surprise to you. I had asked Rhona Fair if perhaps the distribution of new requests by consultant differs from those receiving on-going IVIG (and therefore one consultant might simply have a cohort of patients on long-term treatment while most other requests were for short-term therapy), but until the dedicated pharmacist comes into post in the new year, she is not able to analyse the requests in this detail. Is this pattern of use what you would expect knowing colleagues' areas of special interest?

12.60 Dr Craig responded within the hour as follows:

> We roughly should have the same. Problem as you have identified is some conditions which are very rare require regular IVIG. If by chance any consultant identifies such patients will significantly skew the numbers. It would be important to link with indications. If approved hard to argue with.
>
> Also, consultant activity varies widely. Another topic for discussion.

12.61 Reflecting on this email before the Inquiry Panel on 10th February 2020, Dr Corrigan felt that Dr Craig's first sentence, when he indicated that consultants should roughly have the same use of HIG, could have been picked up on, but she felt Dr Craig was indicating that there was nothing to be concerned about. On 18th December 2019, in his evidence to the Inquiry Panel on the interaction with Dr Corrigan, Dr Craig pointed to the fact that three of the consultants were using three quarters of the treatment, but one had to recognise that much depended on case mix and case volume. He further stated:

> It's not me trying to be defensive, and I hear exactly what you say, because I suppose the starting point as the clinician is you'll always try and find the clinical or scientific. So, I can talk about the vagaries of neurology and the complexities, and the certain patients that'll skew things or whatever but that's – that may all be assumption. It may turn out to be right, but until you've actually investigated it, you don't know.

12.62 Dr Craig, on reflection, felt that this would have been a reasonable point for someone to dig down deeper into the information, at least for reassurance purposes. He stated:

> Anything that stands out from the crowd, I think should immediately, at least, by somebody, have some level of interrogation, and if there's difficulties or anything that's not clear, you escalate it, you discuss it with somebody else.

12.63 The Inquiry Panel noted that the issue with Dr Watt had been clearly identified and that Dr Craig had recognised that prescription between consultants should roughly be the same. While he caveated this by stating that consultant activity can vary widely, this was quite clearly an opportunity for the matter to be properly investigated. The fact that it was not, either by Dr Craig as Clinical Director or by the IAP, was a missed opportunity.

12.64 At the meeting on 15th December 2014, at which Dr Craig was not present, the minutes noted that there were three requests from Dr Watt for functional antibody deficiency. The minutes recorded that Dr Craig was to provide his comments.

12.65 On 17th January 2015, Dr Corrigan emailed Dr Kieran Morris, Dr Damien Carson, Consultant Anaesthetist at South-Eastern Trust and the Audit & Implementation Lead on the NI Transfusion Committee, and Ms Susan Atkinson, Consultant Anaesthetist at Belfast Trust and the Chair of the NI Transfusion Committee. There was a continuing concern of ongoing increase with the use of HIG. In January 2015, funding was secured for the retention of a Band 8 Pharmacist to assist the future management of HIG prescribing. Describing the current situation at that time, Dr Corrigan noted in her email:

> … After what appeared to be initial success within BHSCT in 2013, things slipped back badly during 2014 and the HSCB has had to provide additional in-year funding to meet the costs of higher use by all Trusts. This level of additional funding would be extremely difficult to find in the coming financial year. Within BHSCT, in part I think this was due to the Panel becoming less active, and the temporary loss of Neurology input. At the most recent meeting I raised the issue that of all use by neurologists, one individual appears to be the main prescriber. Without knowing if that is simply a function of the individual's subspecialty interest it is impossible to comment further. However, I suggested to the Panel (which did not have a neurologist present on the day) that it may be timely to undertake a re-audit of IVIG use in selected specialties. I think the main priority would seem to be neurology …

12.66 On 17th January 2015, Dr Carson responded indicating that following a meeting of the NI Transfusion Committee, assistance would be offered to the newly appoint pharmacist to, *"inform them of the process and findings of the last regional audit and assist them in developing a new retrospective or prospective audit if that is to be considered useful."*

12.67 In February 2015, Mr Ray Hannon, an Associate Medical Director in the Belfast Trust, became the new Chair of the IAP. On 9th February, the IAP discussed the need for the method of monitoring individual funding requests, which had been approved for HIG. Following that meeting, Dr John Craig raised six queries with Dr Watt. Three of the queries were based on requests that were not agreed indications and three further requests needed more information. Subsequent to the email from Dr Craig to Dr Watt on 14th February, Dr Craig followed up with various consultants, including Dr Watt, pointing out that HIG requests were scrutinised closely internally and by the HSCB. Dr Craig suggested that junior staff should be instructed on making sure that they record a diagnosis which tallies with agreed indications.

12.68 At the next meeting of the IAP on 10th March 2015, Dr Craig advised that he had no update from Dr Watt on the queries raised. Mr Hannon asked to be copied in, to any emails and noted that, in his view, an audit should be carried out for all the neurology requests. On the same day as the meeting, Mr Hannon emailed Dr Watt in the following terms:

> I chair the immunoglobulin assessment panel (IAP). This is presently dispensed by Blood bank and NIBTS but will move to Trust pharmacies later in the year. We are presently trying to audit use of various products and will likely move to an agreed list of indications later in the year.
>
> Could you help us by giving us some more information on the patients highlighted by John Craig recently (below)? It may be terminology, but the info given on the prescription request doesn't seem to fit with any of the generally recognised guidelines or give us enough info to justify prescriptions. I would be grateful if you could update us.

12.69 Some further information on the relevant patients was provided by Dr Watt. Subsequently, the use of HIG with three patients was approved retrospectively, while three other patients, who had been treated were not given further treatment by way of HIG. While this development was, in some sense, a step forward, it does not appear to have resulted in a greater curiosity in relation to Dr Watt's prescribing practice or in pressure to implement a prospective system[10].

12.70 On 11th May 2015, there was discussion between Mr Hannon and Dr Corrigan with regards to the need for a re-audit of neurology. Dr Corrigan indicated that a retrospective audit would no longer be necessary as, with Dr Craig having re-joined

10 The Belfast Trust points out in its written submission of 23rd May 2022 that Dr Watt himself indicated that he did not wish to continue with HIG for 3 patients because (1) The IVIG helped when he first had it a few years ago but the two recent courses were ineffective; (2) not clear whether IVIG of any benefit and unlikely to want to repeat; and (3) had appeared to help but things have evolved and her problems are now clearly functional and she will not be getting any more IVIG.

the IAP and providing neurology input and the appointment of the immunoglobulin pharmacist, *"the [IAP] itself is beginning to address the issue."* Dr Corrigan did propose that later in the year an audit could be considered.

12.71 Further queries were raised with Dr Watt regarding HIG requests. In May 2015, two patients had their indications for HIG use challenged and clarification was sought by the IAP. In October 2015, Ms Niamh McMahon, the Pharmacist working with the IAP, indicated that eight of Dr Watt's cases fell within the grey indications and would require individual funding requests to be completed. By January 2016, the list had grown so that eleven grey indications had been identified. These required completed individual funding requests. By May 2016, the number had increased to 14 outstanding neurology requests involving Dr Watt, which required individual funding applications to be made, and the list had further extended to 16 by June.

12.72 The matter was then escalated by the immunoglobulin pharmacist to Mr Hannon, who emailed Dr Watt on 13th June 2016 as follows:

> I am aware that you sometimes struggle with routine paperwork and have a very busy clinical practice. You are, I think, the biggest neurology user of Ig for "grey area" indications in the Trust. You are also by a country mile, the outlier with regard to completion of these forms. We have a process whereby the use of Ig is subject to a degree of audit and the majority of one-off grey area use is approved by the immunoglobulin panel, but we need some feedback on the exact indications for Ig and response to treatment etc.
>
> The Panel have decided that if you aren't up to date with this backlog of requests by September 1st 2016, then any prescriptions or requests for Ig on your behalf will be returned and you will have to make special arrangements for the Ig to be issued if judged appropriate. This could result in delay in issuing Ig for some for some [sic] of your patients, whilst correct clinical justification and prescription is sought.
>
> Methinks it would be better to be up to date and avoid that hassle.

12.73 While the Inquiry Panel noted that Mr Hannon did follow the matter up, it is somewhat unfortunate that the email refers to struggling with paperwork and being an outlier in respect of completion of the forms. The focus was, therefore, on the administrative failing, rather than on the fact that it was Dr Watt who was not just behind with filling in the forms but was consistently the neurologist who was seeking to use HIG outside the recognised guidelines and regularly not complying with the approval process that was in place. While the question of the appropriateness of prescribing is strictly outside the Inquiry Panel's Terms of Reference, it is recognised

that there will be occasions in which it is perfectly appropriate to use HIG outside the guidelines. The key issue is the extent to which, when a pattern was established, there was further inquiry by the IAP as to why Dr Watt was consistently the consultant, who was the outlier in respect of use outside the guidelines and why he was regularly not complying with the process that was in place.

12.74 Although the email exhibits a degree of frustration, the decision of the IAP panel to potentially delay prescriptions to patients because paperwork was not completed, whilst understandable, was not appropriate. One cannot manage a doctor by disadvantaging his patients. The nettle needed to be grasped and the Inquiry Panel reflected on Dr Craig's analysis as far back as 2011:

> … from my perspective the most important thing is that for everyone treated with for example HIG that we should be able to justify our choice to our peers. We absolutely must have objective evidence that it is of benefit to that patient. While it might seem obvious there must therefore be a proper record of how symptoms, examination findings and if appropriate investigation results progress over the time of the treatment. If there is no objective measurable benefit treatment should be stopped.

12.75 The overall sense is of management both in the Belfast Trust and the HSCB, and indeed specifically the IAP, being aware of the problem, but seeking to work around the difficulty and failing to address the obvious issue. Dr Watt was prescribing HIG in cases which did not fit within the guidelines on a scale well beyond any other neurologist and regularly not engaging with the process that was in place.

12.76 The problem continued and by 8th August 2016, 16 neurology requests remained outstanding. At the meeting of the IAP on 8th August 2016, it was noted that the paperwork remained outstanding for the patient requests. Mr Hannon emailed Dr Watt stating that it had been agreed that from 1st September, prescription requests for grey indications would be held until discussed with Ms Niamh Tyrie from the Pharmacy. With an imminent deadline of 1st September 2016, Mr Hannon contacted Dr Watt to inform him of the decision and indicated that it *"would be simpler if everything was regularised well ahead of that."*

12.77 Mr Hannon contacted Dr Craig and Mr Atkinson, Neurosciences Service Manager, to make them aware of the shortfall on completion. Dr Craig indicated that he felt Mr Hannon's approach was "fair." Responding to this, Mr Frank Young[11], Co-Director of Unscheduled & Acute Care, emailed Mr Atkinson and Dr Craig stating:

11 Co-Director of Unscheduled & Acute Care.

> John
>
> Yet again Michael is not doing himself any favours!
>
> Are we getting to a stage where he's at risk of failing to maintain high professional standards to an extent that a more formal approach needs to be brought to bear?
>
> Frank

12.78 Subsequently, on 9th August, Mr Young emailed Dr Craig, indicating that Mrs Owens had requested him and Dr Craig to meet with Dr Watt formally. Mr Atkinson provided a list of outstanding issues regarding Dr Watt as of 9th August 2016. In relation to the immunoglobulin issue, the outstanding matters were set out as follows:

- Query from Immunoglobulin Pharmacist to MW 9 October 2015.
- Request from Immunoglobulin Pharmacist to MW 12 January 2016 to complete IFRs for 11 patients as requested by the Assessment Panel.
- Request from Immunoglobulin Pharmacist to MW 9 May 2016 to complete IFRs for patients (now up to 15) as required by the Assessment Panel.
- Request from Immunoglobulin Pharmacist to MW 13 June 2016 to complete IFRs for patients (now up to 16) as required by the Assessment Panel.
- Request from Ray Hannon to MW 13 June 2016.
- Escalated to John Craig by Ray Hannon 8 August 2016.

12.79 A meeting subsequently took place on 30th August 2016. Dr Watt confirmed at that time that he would complete individual funding requests for all new requests, as agreed. The meeting was attended by Dr Watt, Dr Craig, Mr Young and the Service Manager, Mr Atkinson. Dr Watt's assurance that he would complete individual funding requests suggested that the problem was essentially administrative. Instead of asking Dr Watt to objectively justify the treatment to his peers and, indeed, to management with the benefit of objective evidence, which was properly recorded, the suggestion of a meeting by Mrs Owens, a Director of the Trust, which mandated a discussion about filling in funding requests, failed to analyse the problem. Fundamentally, the issue was not grasped by management at every level and although the HSCB representatives on the IAP identified the clear anomaly, the problem of Dr Watt prescribing outside the guidelines and his failure to consistently engage with the process continued unabated and unchallenged.

12.80 In the case of HIG, the Chief Executive of the Trust was made aware in 2011 of a problem within neurology prescribing outside the guidelines. The fact that such prescribing was largely because of the actions of Dr Watt was identified at an early stage and would have been apparent given the monthly reports available. Yet the problem continued so that by 2016 the response of management within the Belfast Trust was merely to ensure that Dr Watt was spoken to about his failure to fill in the forms properly. The situation was not effectively managed even though there may have been a potential patient safety issue.

12.81 A particular focus of the Inquiry was the extent to which Dr Watt's prescribing practices were observed and/or commented upon by those tasked with overseeing HIG prescription prior to November 2016.

12.82 In a written statement to the Inquiry, dated 14th October 2019, Dr McDonnell indicated that the use of HIG had broadened out over the years and now was utilised for a range of issues, for which there had been no evidence base. He could not recall if Dr Watt had been a heavier user than other consultants but would not have been surprised because of his larger patient cohort. In his written statement Dr McDonnell stated that he was unaware of any conversations in the mid-2000's, such as those reported by Dr Fulton and Sister McConkey (below) in relation to high prescribing rates. It is clear from the preponderance of the other evidence that many other colleagues were aware of the high prescribing rates of Dr Watt.

12.83 In oral evidence on 15th January 2019, Dr Ailsa Fulton indicated that HIG was "difficult to get hold of" and that, while she was a registrar between 2004 and 2006, it had been obvious that Dr Watt was prescribing *"a huge amount more HIG than any of the other consultants"*. In his oral evidence of 1st May 2019, Dr Ferghal McVerry remembered a graph produced as part of the audit presentation that had been compiled in 2007 by Dr Aisling Carr, who was then a registrar. Although he could not remember the precise numbers, he recalled that Dr Watt was *"definitely the highest number for IV immunoglobulin prescription"*. Dr Stephen Hunt also recalled the graph and stated in his evidence to the Inquiry Panel, on 9th September 2019, that Dr Watt was the greatest user of HIG products. Commenting on her audit that had been compiled in 2007, in her oral evidence on 11th November 2019, Dr Carr told the Inquiry Panel:

> Use the example of some of the data that was provided to me before coming here and, also, it is identical to some data I collected in an audit, I think, going back as far as 2007. If you look at the HIG usage per consultant and you look across the spectrum of all of the consultants, there was significantly larger

> volume of use by Dr Watt, and I presented that at an audit to the neurosciences group in 2006-07… I was a very junior registrar – when that was discussed at the neurosciences meeting in 2007-ish, there were a broad range of consultants there, and that data was in front of everyone.
>
> In the context of purely the numbers of patients that Dr Watt saw through his high-turnover public or NHS practice, alongside his high-turnover private practice, the actual numbers of his HIG use was not deemed to be a very worrying outlier.
>
> My naïve suggestion, as a very junior registrar at that time was, "well, if we are using this product or this therapy to help in the diagnostic process – so, if we do a load of tests and we just don't have the answer or they don't tell us for definite – if we use it to see if the patient responds…should we be trying to make measurements of that?" That was my suggestion at the end of the audit. Now, that wasn't taken up.

12.84 The Inquiry Panel noted the evidence of Sister Sharon McConkey in relation to early indications of prescribing trends. Referring to interaction with Dr Watt, in her oral evidence on 26th March 2019, Sister McConkey stated:

> Occasionally, you would've maybe said, "Why are you giving this patient HIG? Do you think it's going to make any difference?" "Well, we have to give it a go. We need to try." And there was always a bit of an undercurrent of – and this sounds so unkind – but we would've -. I've been known to have said, maybe, to my counterpart, "You'd think he had shares in that company, the amount of stuff he uses," you know? That was just the way you said it. That was common talk among other medical staff … other people – medical staff – would've said, "Oh, he's using a lot of HIG" but they – in those days, you just sort of filled the form in and ordered it. Then it started to get tightened up though the Blood Transfusion Service and it's tightened up even more now.
>
> Sister McConkey recalled that there was general discussion about Dr Watt's practice among the registrars because they were the ones, who often completed the forms on behalf of the consultant. However, nobody seemed to take the matter of his prescribing practice any further than discussion between themselves.

12.85 Various other analyses revealed that Dr Watt was an outlier with regard to the prescription of HIG

a. An analysis of figures provided by Ms Fair from the National Database for January 2013 – April 15 shows that MW had a total of 165 requests out of 507 = 32.54% the next highest being Dr Craig with 84 (16.57%).

b. An analysis of figures provided by Ms Fair from the National Database for April 2015 – July 2017 Dr MW had 51 requests out of 139 – 36.69%.

> the next highest was Dr Craig with 16 11.51%. Dr Watt also an outlier with regards to grey indications. With 20/51 and a 39.22%. John Craig again the next highest, 5/16 and a 31.25%.

12.86 The subsequent GAIN audit, in 2010, according to Dr Corrigan, indicated that far more HIG was being used, than should have been used, in Northern Ireland. That audit did not break prescribing down to an individual consultant level and Dr McDonnell explained that, while the audit identified significant issues in relation to the indication to prescribe, number of infusions given, and dosages administered within neurology, the figures may not appear as bad as they first looked. In his written statement of 14th October 2019, he indicated:

> By way of explanation, if 2 patients out of 10 (20%) receive HIG without a clear indication but each of those 2 patients has 5 infusions whilst the other 8 have a single infusion, then the inappropriate use is 56% rather than 20%. However, it is evident that in 2010 significant issues were identified in relation to the prescription and use of HIG within neurology.

12.87 Dr Craig noted that whilst the figures may be alarming, the audit figures can give the wrong impression. Nevertheless, in his oral evidence on 17th September 2019, he told the Inquiry Panel that, on reflection, *"knowing what we know now that [the GAIN audit] would have been a reasonable point to stop and take stock*" and that a starting point might have been *"benchmarking ourselves against what other people were doing"*. Dr Craig also pointed out that the evidence base is generally somewhat behind what neurologists were doing in practice. For some neurological conditions, which were initially regarded as grey, they should have been, and now are, blue or red. In addition, Dr Craig highlighted the fact that in a number of instances, the administration of therapy was time critical, and the bureaucratic process could impede the requirement to act.

12.88 With regard to the IAP, the Associate Medical Director, Mr Hannon, who chaired the IAP, told the Inquiry Panel as follows during his attendance on 19th February 2020:

> So, at every meeting there was a neurologist and if there wasn't a neurologist as soon as the meeting was over, I would email either John Craig or Gavin McDonnell and they almost always sort of said, 'yes, I'm not sure if I would give immunoglobulin but that's a reasonable thing to do once or twice for a patient.' So, there was never any, the clinicians never said: 'stop this.' Nobody at the end of a meeting ever closed the door and said, 'you know, Ray, Michael is out of control with Immunoglobulins' or anything like that … I think the neurologists understood they were passing comment on their colleague's prescription of grey areas, but the other specialities would usually remain silent when a neurology case came up.

12.89 Mr Hannon emphasised that there were rarely grey indications, which came up in other specialties and that the vast majority of them were in neurology.

12.90 Dr Craig, who sat on the IAP, recognised that there was a potential conflict in trying to balance the question of cost with the question of patient care. In his oral evidence on 17th September 2019, he stated:

> There maybe was a conflict, in that, at one level, it seemed very much to be about costs from the people – and rightly so: this is extremely expensive. From the clinicians … there was trying to defend the patch and their patients.

12.91 Commenting further on the limitations of the IAP process, Dr Craig stated:

> Could an immunologist really query me on appropriate use? Could I say to a haematologist, "I don't think you should be giving this?" That would just never happen … in terms of the panel being set up as a means that the individuals who were representing their specialties were really true arbiters of what was actually going on, that was difficulty, and, obviously, what it relied on was, "Dr Craig, patient 64's a query. Here's the form. Go back to the original referral and find out what it was they were really thinking about whenever they put the request in.

12.92 Dr Craig favoured presenting material to his peers. Whilst he accepted that the IAP process was an improvement, he told the Inquiry that it had some way to go and felt that the model of the Disease Modifying Therapy panel for multiple sclerosis was a more effective and accurate vehicle for scrutiny because the arbiters, who were all specialists in multiple sclerosis, were better placed to judge whether a neurologist was straying from the guidelines. Even then, there was a concern that if there was inordinate time spent on deciding by way of a panel that guidelines had been followed, there would be a commensurate reduction in the time given to patients. He told the Inquiry Panel in his evidence of 17th September 2019:

> I think that bit about justifying its choice to your peers: that has to be – especially in the context of the changing evidence base. While the Immunoglobulin Assessment Panel was maybe an improvement on what we had before it's certainly not a comprehensive way of assessing whether or not the right person getting the right treatment at a particular point in time_ So I think I would summarise it as, "First of all this is a really important issue. We need to be addressing it" and I suppose the emphasis there is on "we". We do not want to be denying patients access to something which could help them. We need to be able to monitor it appropriately. We need to be able to justify it to our peers and if this is not working, we need to stop it.

12.93 Dr Corrigan, in her oral evidence of 10th February 2020, observed that *"clinicians who have been nominated to attend might not have been given the appropriate support to make it clear to them that they may have to say no to colleagues that they meet and work with all the time"*.

12.94 In his overall reflections to the Inquiry Panel on the prescription of HIG, Dr Craig expressed his frustration that, in retrospect, there was no synthesis of the information that was available. In his oral evidence of 17th September 2019, he stated:

> Looking back with the results of the GAIN audit, my feeling is that should've been a – the audit wasn't the end in itself. It almost should've been that: "We need to go into this in more detail now, and we need to set up, going forward, prospectively, structures, monitoring etc." What happened, of course, was another process got put in place, but I'm not sure in necessarily, apart from putting a process in place, made that monitoring etc. … any better.

FINDINGS AND ANALYSIS – HIG:

12.95 What is striking about the evidence obtained is the amount of information that was available to all the relevant parties, including members of the IAP, the Clinical Director and Clinical Lead within neurology, and management at all levels – both HSCB and the Belfast Trust. From the internal audit in 2007, to the GAIN audit in 2010, it was apparent that neurology was the outlier in terms of the prescription and use of HIG. Dr Watt was the main user of HIG by some measure. This was known by those within neurology following the audit carried out by Dr Carr in 2007 and by everyone else after the GAIN audit in 2010 and the establishment of the IAP in 2012.

12.96 When one follows the outcome of the queries raised about the prescribing patterns, especially by Dr Corrigan from the Public Health Agency and Ms Rhona Fair the Pharmacy Manager in the Belfast Trust following the setting up of the IAP in 2012, the Inquiry Panel noted the difficulty in following through on obvious questions as to why there was such discrepancies on the prescribing practices of Dr Watt, as opposed to other consultants in neurology.

12.97 It is accepted by the Inquiry panel that as, Dr Craig identified, a patient may require regular treatment of HIG for a very rare condition or, alternatively, that HIG could be a *"function of the individual's sub-speciality interest."* Such nuances might be explored, but the tendency was for those who asked the questions to be deflected by the response given from within neurology. The Inquiry Panel agreed with Dr Craig that anything that stands out from the crowd should have some level of interrogation and that, when matters are not clear, the matter should have been escalated. In the

Inquiry Panel's view, this observation applies with greater force when the consultant who is the outlier is also the one consultant, who is often ignoring the administrative requirements put in place to regulate use. Dr Craig's response in December 2014 was instructive. He recognised that the prescription amongst colleagues should roughly have been the same but highlighted the possibilities of the numbers being distorted for legitimate reasons. Dr Craig further recognised that this was a topic for discussion, but the matter was not advanced or investigated by Dr Craig.

12.98 It is understandable, but ultimately not acceptable that those working within neurology will be apprehensive that those scrutinising or asking questions about budget or guidelines, have a lesser understanding of the complexities of neurology. The primary responsibility to manage, however, resides with the Trusts and the HSCB who have a duty to ask and when indicated, act. In assessing budgetary constraints and putting in place guidelines to be followed, it is the HSCB and individual Trusts who must ensure that matters are followed through, anomalies investigated, and consultants held accountable. In truth, the initiatives taken to regulate were easily circumvented or ignored, particularly when the process was retrospective.

12.99 The HSCB, in addition to its overall responsibility to procure services for the individual Trusts, had a duty also to seek to promote patient safety. The Trusts equally had a responsibility for patient safety. In practice, however, those involved deferred to the expert view of the neurologists. While this may be entirely appropriate in a clinical setting, it does not absolve either the Trust or the HSCB from properly addressing clear variations in practice and anomalies. Dr Watt's prescription of HIG was conspicuous and took place over many years.

12.100 The HSCB and the Trust easily identified emerging problems within the prescription of HIG. It was clear for instance that the budgetary pressures were largely confined to neurology. This was set out in the letter from Mr Dean Sullivan of 9th June 2011 to all Trust Medical Directors. By November 2011, Dr Morris of the NIBTS, had made it clear that his department did not have the capability to challenge the prescribing of HIG. In May 2012, Mr Sullivan was informed that the Trusts had not adhered to the existing Guidance and by the autumn of 2012, Ms Rhona Fair was able to establish the IAP in the Belfast Trust. While individual assessment was a step forward the most significant change was to transfer oversight from NIBTS to pharmacy. This did not take place until May 2018.

12.101 What is apparent from the minutes of the meetings of the IAP was reference to concerns about the failure by Dr Watt to submit the necessary paperwork. 'Paperwork' should not be understood in this sense to be purely administrative. It

was the written clinical justification for treatment, and it, therefore, had a direct link to patient safety. It was this failure, which resulted in the matter being taken up by Mr Hannon and ultimately a meeting took place in August 2016 with Dr Craig, Mr Young, the Co-Director and the Service Manager, Mr Atkinson.

12.102 While the inadequacies surrounding administration should have themselves been of concern, the view of the Inquiry Panel was that administrative failures in relation to HIG contributed to the general perception of Dr Watt as someone who was administratively tardy and dismissive of procedures and guidelines, but otherwise, clinically competent. This was one of the issues raised by Mr Young and Dr Craig when they met with Dr Watt in August 2016. The outcome appears to have been an undertaking from Dr Watt that he would fulfil his administrative obligations. Administrative tardiness might be a factor in raising further questions about a clinician's judgement and overall approach to medical practice and was certainly the responsibility of management. The fact was, however, that the variance had gone on long enough for them to have been questioned with a much greater degree of scrutiny. This was an opportunity missed and the Inquiry Panel has concluded that there was more than sufficient information to initiate a retrospective audit and investigate further why it was that Dr Watt prescribed twice as much HIG as any other neurologist and 36% of the overall total. Mr Hannon was characteristically frank in his evidence to the Inquiry Panel on 3rd February 2020:

> **Mr Hannon:** No, I mean he was an outlier in prescribing and at some point, somebody should have said no.
>
> **Professor Mascie-Taylor:** And somebody is the line manager?
>
> **Mr Hannon:** Yes, you would think.

12.103 Dr Watt had been an outlier in terms of prescription for such a long period of time, going back to the internal audit within neurology in 2007. His prescription of HIG when the indications were grey, was so much more than any other neurologist. The failure to address this question or investigate his practice specifically allowed Dr Watt to continue unchallenged and potentially patient safety to be compromised.

MULTIPLE SCLEROSIS - ALEMTUZUMAB:

12.104 In February 2011, Mr Dean Sullivan, then Director of Commissioning in the Health & Social Care Board, wrote to Mr Colm Donaghy, Chief Executive of the Belfast Trust, in relation to the cost of prescribing drugs for multiple sclerosis. Mr Sullivan was anxious to receive an assurance that the Trust would remain within budget

for high-cost drugs. He noted, in the correspondence, that one of the larger areas of expenditure on a single therapy is the treatment for multiple sclerosis. It was proposed that clinical and managerial representatives would meet with the HSCB and the Public Health Agency to discuss an agreed approach for prescribing drugs for multiple sclerosis.

12.105 The first Multiple Sclerosis Specialist Interest Group ("MSSIG") meeting took place on 27th November 2012. This was a meeting amongst the consultant neurologists with a special interest in MS across Northern Ireland. It was not attended by individuals from HSCB/Public Health Agency etc. The idea behind the formation of this consultant group was to aim for consistency across the service. The meeting was chaired by Dr Orla Gray and met monthly.

12.106 In her evidence to the Inquiry Panel, Dr Gray stated on 4th November 2019:

> I was the one who had suggested that meeting, and at the time, that was because I was the only consultant who specialised in MS who didn't work in the Belfast Trust and, so, I felt that, you know, I would like to have an interaction and to be able to benchmark may own practice against other people and to have a meeting that could actually work on guidelines and pathways.

12.107 At the MSSIG meeting in May 2013, Ms Paula Crawford from the Belfast Trust pharmacy had prepared a pro forma for starting certain Disease Modifying Treatments ("DMT"). The drug Alemtuzumab was first discussed by the MSSIG on 10th June 2014.

12.108 In a written statement of 29th January 2019, Dr McDonnell explained that he had not detected any warning signs from Dr Watt's participation but stressed that meetings tended to be focused on MS service development and organisation, challenges around resources and did not discuss individual cases. In this respect, the Group was very different from a DMT panel.

12.109 In August 2014, Dr Miriam McCarthy from the Public Health Agency wrote to Dr John Craig indicating that the National Institute for Care & Excellence ("NICE") had approved the use of Alemtuzumab for treating adults with relapsing, remitting multiple sclerosis. Initially, Dr McCarthy was asking the Belfast Trust to provide a view on the number of new patients, who would be starting Alemtuzumab and how many of the 1495 patients already receiving DMTs would switch to the drug.

12.110 Dr McCarthy explained to the Inquiry, in her evidence of 10th October 2019, the interest that Public Health Agency and the HSCB had in regulating the prescription of Alemtuzumab:

> Materially, the reason why we were interested in this drug was that, initially, the advice coming from clinicians was that people needed to be admitted as an inpatient: for five days in the first year, they got treatment, and three days in the second. So, given other pressures on neurology and neurosurgery, which shared an inpatient area, we were aware that that was a fairly significant infrastructure, if we were to be in high numbers, and therefore, there was going to be a very real capacity challenge … it wasn't – we weren't trying to limit prescribing because that's an individual clinician decision, but we were aware that we would very easily fall into a position where there would be a waiting list of people to start the drug.

12.111 Dr Craig explained the view of the consultants who had been nominated to participate in the MS Drugs Monitoring Group in his oral evidence of 24th September 2019:

> There's a significant budget for these drugs. It's certainly over £10 million per annum for MS drugs and climbing and was climbing even more whenever the drug came in. so, the HSCB, very much under Miriam's direction, had set up a meeting group where managers, clinicians and people from the HSCB could meet to discuss issues around prescribing from the first-line agents that came around at the start of the 1990s, right through to oral therapies, whenever they came through, round to these bigger hitting drugs. What was never really discussed so much, was actually the practicalities of doing this.

12.112 At a regional meeting with the Belfast Trust Neurology Service on 2nd September 2014, there was discussion regarding what governance measures would need to be in place for the prescription of Alemtuzumab. The minutes record as follows:

> Dr Craig believed that there was a role for a panel decision internally to decide whether a patient receives Tysabri or Alemtuzumab.
>
> The group agreed that it was likely to be a small number of patients who would receive Alemtuzumab, with a small internal group (MDT level decision) making an informed decision as to whether the patients are suitable for treatment. Clinicians agreed that initially the cost per case route was the best method of monitoring usage of Alemtuzumab.

12.113 On 23rd September 2014, Dr Craig emailed the consultants specialising in multiple sclerosis. He pointed out that only two DMT therapies (Dimethyl fumarate and Alemtuzumab) required individual funding requests[12] to be submitted. In those cases, Trust approval was required before being sent to the Health & Social Care Board for consideration. In relation to all other DMTs, Dr Craig pointed out that there

12 An individual funding request is made by the treating clinician, if they believe that because a patient's clinical circumstances are exceptional, they may receive benefit from a treatment or service that isn't routinely offered by the NHS. (From NHS England Guide for Patients on Individual Funding Requests).

was a need for an ongoing audit to ensure appropriate and consistent prescribing. This was probably best organised, in his view, by the regional MS group.

12.114 Efforts were then made in October 2014 to assess the likely demand for Alemtuzumab to complete the draft service notification emailed by Dr McCarthy in August 2014. Initially, in September 2014, Dr McDonnell felt that 5 patients per annum *'might seem reasonable.'* On 14th October 2014, in an email to Dr Craig at 20:15, Dr McDonnell again proposed around 5 new patients and 10 transfers for the remainder of 2014/15, a pro rata rate of about 30 per annum. Dr McDonnell noted that *'there may be a more liberal approach from my colleagues.'*

12.115 Subsequently, however, on 15th October at 07:48, Dr McDonnell emailed Dr Craig saying that his earlier advice was incorrect and *'you had better scrap my previous advice. Looks as if Michael [Watt] is keen on this so the suggested figures are apparently 20% of new starts and 1% for transfers.'*

12.116 Dr Craig emailed the relevant consultants (including Dr Watt) on 15th October at 16:00 seeking estimates and noting there would 'seem to be the possibility for widespread variation in practice.' Dr Craig noted that this was not likely to be acceptable to the HSCB and, in any event, made little sense clinically. Finally, it was noted that, if 5% for new starts was the estimate for other groups of experts, this was the figure that they should be quoting.

12.117 Dr Orla Gray responded the following day saying that while she had proposed a figure of 10%, she had no issue with adopting the 5% figure if this reflected the majority view. Dr Gray noted that *'there will be some variation in practice as with any new medicine.'* Dr Craig replied that while accepting there would always be uncertainties and variability in demand, the estimate of 20% for new patients, as proposed by Dr Watt, would seem hard to justify. In the view of the Inquiry Panel, it was at this critical moment that an audit of prescribing practice would have been appropriate and necessary. There were potential safety, as well as financial, concerns.

12.118 By 20th November 2014, Mr Gerry Atkinson, the Neurology Services Manager, remarked that there were around 12 patients identified to date for prescription of Alemtuzumab. Given that the annual cycle had just begun, this was a significant increase on even adjusted expectations. These figures were discussed at the Regional MS group meeting on 2nd December 2014, at which Dr Craig drew attention to the *'inpatient resource implications associated with the administration of this drug'* and that *'the Belfast Trust would not be able to commence the use of this therapy at this time.'*

12.119 The Neurosciences meeting on 4th December 2014 simply records: *"Lemtrada*[13] *discussed."* It, therefore, seems reasonable to infer that there was, by Christmas 2014, a growing concern with numbers. By January 2015, Dr Watt had 5 cases approved for Alemtuzumab, the amount that Dr McDonnell believed would be required for a whole year.

12.120 On 3rd February 2015 at a meeting of the HSCB Regional Group it was noted that the Trust had previously provided an estimate of 5 patients who were likely to commence Alemtuzumab each year. Five requests were received and approved by the Board the previous week, with one further request going to the Individual Funding Request ("IFR")[14] panel on the week of the meeting.

12.121 Dr McCarthy noted that it had previously been suggested that with the expansion in therapeutic options for MS, the Belfast Trust may develop a peer review system to align the decision-making process on the use of new therapies. Dr Aidan Droogan confirmed that MS consultants may meet monthly to discuss such matters.

12.122 Dr McCarthy told the Inquiry Panel on 10th October 2019 that the expansion of the usage of this drug was more than had been anticipated and that the question had been asked as to whether the Belfast Trust was atypical as compared with other parts of the United Kingdom. This was checked and the data that was received was, according to Dr McCarthy, in line with what would have been expected. Dr McCarthy indicated that the Board had set up the MS Drugs Monitoring Group to ensure that patients were getting their medicines within 13 weeks and secondly to *"keep a watchful eye on the trend of medicine use across Northern Ireland"*. This was to gauge the extent to which the Board would need to invest in subsequent years.

12.123 Dr McCarthy, whilst conducting work as a member of another Health & Social Care group, did notice that there was initially a variation in which consultants were asking for the drug and was aware that Dr Watt was the neurology consultant, who was asking for more than other neurologists. During her appearance on 17th June 2019, she told the Inquiry Panel:

> I suppose the question, then, that we had was, "Why is there a variability in

13 Lemtrada is a brand name for Alemtuzumab.

14 Hospital consultants, on behalf of their patients, are entitled to make an "individual funding request" (IFR) for treatment that is not normally commissioned. The following defined conditions apply:
- The request does not apply to a cohort of patients AND
- The patient is suffering from a medical condition for which the patient's particular clinical circumstances fall outside the criteria set out in an existing commissioning policy for funding the requested treatment OR
- The request is for a new intervention or, for an intervention for a new indication outwith the licensed indication, where no commissioning arrangements exist OR
- The patient has a rare clinical circumstance for whom the hospital consultant wishes to use an existing treatment outwith the licensed clinical indication, with the explicit consent of the patient

> what people are prescribing, and is there something that we should be asking or, indeed, doing about this?" At that time, I was also chairing our regional MS group, so I raised it at the regional MS group, where we would be touch – not touching on; we would actually be talking in detail about all of the new medicines. We did ask the question and say, "Look, we're seeing some variability in the prescribing of this: is there something we should know about?" and a couple of things came forward at that time. The clinicians were saying, "Well, as with any new medicine, there will, of course, be early adopters and there'll be some who will be more conservative, but we'll need to look at this." We subsequently had a meeting with a number of the clinicians who specialise in MS services, and what they suggested they would do is bring their colleagues together – all of the neurologist who specialise in MS, including Dr Watt – and they would look to see whether we needed to have a kind of pathway or a little bit of guidance for prescribing that particular drug in Northern Ireland. They did actually do that, and they subsequently brought back something … a guidance on prescribing in Northern Ireland. In essence what they did was it tightened up the prescribing of alemtuzumab to move it from, potentially, a first-line drug for people with MS to making it a second-line drug.

12.124 In her attendance on 10th October 2019 Dr McCarthy informed the Inquiry Panel that the variation in prescribing had been identified at an early stage and the issue was with Dr Watt. In her evidence, Dr McCarthy explained her view at that time: *"We've seen a variation. Do we need to think about something that will help bring about a greater degree of consistency?"* This had been brought to the attention of the consultant neurologists, who had sat on the MS Drugs Monitoring Group. The response had been for the consultant neurologists to agree specific guidance, which moved prescription from potentially first line to second line treatment, unless there was a very specific reason. The fact that there was, from the information received, a perceived similar prescribing practice of Alemtuzumab in other parts of England was of relevance.

12.125 Reflecting back on the actions of the Health & Social Care Board Cost Per Case Panel, having regard, in particular, to the variation identified at an early stage, Dr McCarthy continued:

> We didn't go back and say, 'We think there's still a variation that has not been addressed.' In retrospect, it would have been helpful to do that, but, I think, if we had done that, we might have actually been asking the Trust to explain the variation – not just tighten up – and say, "what is it is going on that there is such a variation? What is different in either the patient group or the severity of the disease or the individual doctor's practice that explains this?" We didn't do that but the role of the cost per case is to monitor the totality of prescribing. It does,

> though, beg the question of whether, given the information and the intelligence that can be gleaned from that, whether we should be looking at those cost per case applications – not just in this area but potentially on others – to see if there are patterns that we need the trust to explain.

12.126 Subsequent problems with the drug, which became apparent in 2019 were highlighted by Dr McDonnell in his written statement of 14th October 2019, as follows:

> By early 2019 new data had become available on additional risks and safety concerns with Alemtuzumab. In the UK it is now only used in MS that is "highly active" (usually meaning at least 2 relapses in the past 12 months) and only as a third-line DMT or where other DMTs cannot be sued. This follows a change in its licence by the European Medicines Agency.

12.127 Those concerns were not apparent during the relevant period prior to November 2016.

12.128 In his written evidence statement, Dr McDonnell further pointed out that, as with any medication, the approach to prescribing will be dictated by an individual neurologist's overall approach. In his oral evidence to the Inquiry on 17th October 2019, Dr McDonnell accepted that there was a variance between Dr Watt's practice and other neurologists. In that sense, Dr Watt was an outlier, but Dr McDonnell stressed that, even if there is a variance, it may not be problematic, particularly when compared with the whole of the United Kingdom.

12.129 Dr McDonnell was not concerned at that time that Dr Watt was inappropriately giving patients the wrong drug but was focused on the equity of which patients were getting the drug and the overall cost pressures on the system.

12.130 Dr Orla Gray took a similar approach. In her oral evidence on 4th November 2019, she told the Inquiry:

> I knew Dr Watt was prescribing more alemtuzumab, but I thought this was a scientific question about induction versus escalation[15] … I could not have criticised him for taking that approach, when I go to meetings and hear big names in the UK and other places advocating that as an approach.

12.131 Dr Aidan Droogan took a similar view on Dr Watt's prescribing pattern. In his oral evidence on 10th April 2019, he stated:

15 Escalation consists of starting with a first-line medication - intended as a moderate-efficacy high-safety drug - and switching to a second-line treatment (more effective but also with more safety risks) in case of unsatisfactory response to the first line: this is reasonable in most patients seen in the clinical practice who present with mildly or moderately active disease. The induction approach is the initial use of a highly effective second-line treatment in order to obtain the rapid remission of a very active disease, which justifies the risk of serious adverse events. This strategy is intended for MS cases with frequent (i.e., two or more per year) and severe relapses who are at increased risk of rapid accumulation of disability. "Treatment strategies for multiple sclerosis: When to start, when to change, when to stop? Alberto Gajofatto and Maria Donata Benedetti US National Library of Medicine: National Institutes of Health https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4517331.

> What he was doing was not necessarily aberrant practice in prescribing, and the reason is the criteria for alemtuzumab – the prescribing eligibility criteria – are quite liberal compared to some of the other drugs. Some of the other drugs insist that you have to have an active MRI scan to get treatment.
>
> It was within the NICE guidelines and there are colleagues – MS specialists in other parts of the UK – who would favour that drug first. There were other experts with international reputations in MS who would follow the same practice and, certainly, in North America very much so. He was on that more aggressive approach, and there is clear evidence that, if you treat patients with more, stronger drugs earlier in the diseases, they do much better in the long run. However, it's a dangerous drug and its expensive and, therefore, you have to weigh the two factors up. I tend to be more conservative.

12.132 By April 2015, however, it was noted at the Board's Regional MS Monitoring Group[16] that there were several patients waiting to be started on Alemtuzumab. The minutes record:

> It was noted that these numbers were significantly higher than initially anticipated. Dr McDonnell confirmed that each consultant would have a few patients who would meet the criteria for commencing Alemtuzumab … the Trust are to provide information to the Board on the infrastructure requirements.

12.133 By August 2015, the Service Manager, Mr Atkinson, informed multiple sclerosis consultants that a letter was being drafted to the HSCB indicating that the Trust would no longer be able to admit patients for Alemtuzumab until funding had been formally approved. It was also decided that submission of IFRs to the HSCB should cease.

12.134 There was a subsequent meeting in September 2015 with the Trust management and MS consultants, including Dr Watt. An email from Ms Kerry Corey to Mr Paul Cunningham at the HSCB sets out what was discussed. The note records that the potential numbers for Alemtuzumab could be *'significantly higher'* and that it is for the HSCB to carefully consider IFRs before approval. The reasons given for the increase in demand are stated as follows:

- The availability of oral drugs: Those who did not avail of any treatment in the past due to not wanting to avail of treatment by injections or those who tired of treatment by injection, now have the option of oral treatments and are taking this option.
- The starting criteria for these oral drugs are more flexible.

16 This is a different group to the MSSIG which was confined to consultant neurologists.

- Patients are more aware of their options and have higher expectations and so are initiating discussion with their consultant around options.
- ABN stopping criteria (last draft Jun 15) has loosened/made more woolly and less specific the criteria for stopping treatment.

12.135 On 22nd September 2015, Mr Atkinson wrote to Dr McDonnell and Dr Craig referring to an IFR request for Alemtuzumab. Mr Atkinson raised a concern about funding in his email:

> This IFR is for Alemtuzumab. I had sent out an email a few weeks ago suggesting that we needed to put a hold on IFRs for this. While we have since received notification from HSCB confirming funding, Frank [Young] has made it clear that the cessation of IFR submissions for Alemtuzumab remains in place until we have recruited the additional nursing staff. This is being progressed, but it will be several months before we have the staff in place.
>
> I am happy to discuss further with you.

12.136 Dr McDonnell replied on 23rd September 2015 as follows:

> Thanks Gerry. Would it not be better to approve or otherwise and have on waiting list? This is my 2nd request for the drug and the risk is that a patient like this gets bypassed/bumped by a relative flood from elsewhere.

12.137 The pressures on funding continued, although a limited amount of additional funding was found in October 2015. At the regional MS Drugs Group meeting on 3rd November 2015, Mr Baker of the HSCB expressed concern around the number of patients commenced on Alemtuzumab and referred again to the initial projection of 5 per calendar year. He indicated that robust projections in the use of this therapy over the coming years would be important.

12.138 Dr McCarthy from the Public Health Agency asked whether the uptake rate for Alemtuzumab and Dimethyl Fumarate in Northern Ireland were comparable to the rest of the UK. Dr Droogan responded that there were enormous fluctuations across the UK with a higher rate of uptake in Cardiff, Bristol and Cambridge because of clinical trials. Dr McCarthy then referred to the Association of British Neurologists ("ABN") guidance which stated that patients should be on another DMT prior to starting Alemtuzumab. Dr McDonnell indicated that this practice would not make a significant difference in Northern Ireland. It was agreed that clinical colleagues would provide a briefing paper.

12.139 On 7th November 2015, Dr McDonnell contacted Dr Craig and Mr Atkinson about a patient, for whom he had submitted a funding request in September. Dr McDonnell noted in conclusion:

> Understand that 25 patients have received Alemtuzumab to date – leaving 5 spaces within the current funding envelope. Would this patient be filling one of those available 5 slots?

12.140 Dr Craig responded as follows:

> I have signed off four requests for Lemtrada[17] from Michael [Watt] in the last 72 hours!

12.141 On 10th November 2015, the Multiple Sclerosis Special Interest Group convened and discussed potential local guidelines for first/second line treatment for disease modifying treatments in multiple sclerosis.

12.142 This action was initiated because there was a concern that the threshold set by the NICE Guidelines was too low. Dr McDonnell in his evidence to the Panel of 17th October 2019 told the Inquiry Panel:

> Yes, and I think that the reason it was a problem for this drug (alemtuzumab) is that the threshold set by the guidelines and the licence was so low that you ended up with a disparity, whereas this would not have applied, for instance, to natalizumab, which is a drug of equivalent efficacy.

12.143 Subsequently, Dr Aidan Droogan emailed draft guidelines to the MS consultants. While Dr Watt was not present for the discussion on 10th November, he did receive Dr Droogan's draft on 11th November, although he does not appear to have commented on same.

12.144 On 13th November, Dr Droogan forwarded the guidelines to Mr Atkinson as *"the consensus view of our local MS Group on how we will prescribe DMT for MS patients in Northern Ireland". These were referred to as "the Northern Ireland guidelines"*.

12.145 Dr McDonnell, in an email to Mr Atkinson and Dr Craig, stated that the Northern Ireland guidelines *"represent progress"* and are *'tighter on specifics than the ABN (Association of British Neurologists) Guideline.'* Dr McDonnell does go on to state that the new guideline *'does however represent a compromise that ALL of us could live with, rather than what some of us might have preferred. Like anything it will only be as good as its application'*.

17 Lemtrada is a brand name for Alemtuzumab.

12.146 Dr McDonnell informed the Regional MS Commissioning Group on 12th January 2016 that the new Northern Ireland guidelines on prescribing DMTs in MS was being adhered to and was tighter than the guidelines from NICE in respect of Alemtuzumab. In addition, Dr McDonnell indicated that there was a process in place in the Belfast Trust where all applications were being scrutinised.

12.147 On 16th February 2016, Mr Atkinson emailed Dr Craig, the Clinical Director, with a list of Alemtuzumab requests, where 8 out of the 14 requests had been made by Dr Watt. Subsequently, Dr Craig and Mr Atkinson arranged to meet with the MSSIG in light of the *'increasing numbers of referrals for Alemtuzumab'*. A Clinical Leads meeting on 7th April 2016 recorded that: *"[John Craig] and [Gerry Atkinson] to attend next meeting of the MS consultants on 12 April to discuss concerns re the volume of Alemtuzumab referrals."*

12.148 Dr Craig and Mr Atkinson attended a meeting of the MISSIG on 12th April 2016. All the MS consultants were present, apart from Dr Watt. From the agenda, it appeared that Alemtuzumab projections to 31st March 2016, the need for private patients to be referred and seen on the NHS prior to commencing a DMT, and a possible panel to discuss funding requests were considered.

12.149 Subsequently, Mr Atkinson sought to arrange a meeting with Dr Watt to discuss specifically projections from DMTs, particularly Alemtuzumab and also private patient referrals for such therapies. From the minutes of a Clinical Leads meeting dated 5th May 2016, it appears a meeting was held with Dr Watt on 3rd May 2016. The Inquiry Panel has not seen any note or record of this meeting and, with the exception of DMT projections for the financial year 2016/17 being agreed, does not know the outcome of the questions raised.

12.150 In July 2016, a further request for Alemtuzumab from Dr Watt was forwarded by the Service Manager, Mr Atkinson, to Dr McDonnell, the then Clinical Lead. Dr McDonnell sought clarification from Dr Watt, who responded on 9th August 2016 and complained to Mr Atkinson in the following terms:

> Gerry
>
> Virtually all of Gavin's queries regarding Alemtuzumab approvals boil down to whether I can be trusted to diagnose an MS relapse and tell one apart from a pseudo-relapse or the interesting concept of recurrence of symptoms. Relapses were defined in the CARE-MS studies as new or worsening neurological symptoms attributable to multiple sclerosis, lasting at least 48 h, without pyrexia, after at least 30 days of clinical stability with an objective change on neurological examination. As I am not able to see patients and examine to

> document worsening during relapses, I have to believe them when they say their condition decline and look on time off work or treatment with steroids as offering some backing. There was no requirement in the clinical trials for MRI evidence of disease activity and I cannot see why we should arbitrarily introduce this.
>
> Michael

12.151 In response to Dr Watt's concern, Dr McDonnell, in an email dated 21st August 2016 to Dr Watt and the Service Manager, Mr Atkinson and Dr Craig, the Clinical Director, stated:

> Thanks.
>
> This is time consuming hassle and for me it is not a matter of trust. If it is just a rubber-stamping exercise, then I neither need, nor wish to be involved. If there is supposed to be certainty that a guideline is being applied, then it should probably go to a panel rather than a jury of 1.
>
> Gavin

12.152 Dr McDonnell's response was commented upon by the Clinical Director on 22nd August 2016. Dr Craig felt that it was something that should be discussed at a Clinical Leads meeting and noted the requirement for drugs, such as Alemtuzumab, to be signed off at Trust level. Dr McDonnell replied on the same day as follows:

> No problem, John. It's a difficult situation. If a rubberstamp with no responsibility for the clinical decision, then happy to blithely sign. If, however it represents agreement with the clinical decision and confirmation that criteria are being met then that is a different matter. I suspect that for the HSCB the latter is the case but don't know.
>
> I know that I have turned down one application and been told by the applicant that they were pleased I had done so – this makes a rubberstamping exercise a bit awkward.
>
> Regards
>
> Gavin

12.153 Mr Young, the Co-Director for Acute Care, replied on the same date as follows:

> Gavin/John
>
> Given the cost of this drug it is essential that there's a very clear audit trail around the approval process and that the guideline is being consistently applied for every patient – especially as the Board views Michael to be an outlier compared to other Neurologists.

> If we were not to do so and the process were audited (which given the cost could very well happen) the Trust would be very vulnerable and open to criticism.
>
> Definitely need to discuss at the next clinical leads meeting.
>
> Frank

12.154 Dr Watt clearly did not agree with the Northern Ireland Guidelines and the consensus referred to by Dr Droogan at [144] above did not appear to include Dr Watt. Dr McDonnell was asked about the audit carried out in 2018 in respect of prescribing of Alemtuzumab during the period 2015-2016 and he stated to the Inquiry Panel on 17th October 2019:

> **Dr McDonnell:** Yes, like, I think, obviously, there were a number of things that we tried to do. The audit was something that, in that email that you're probably going to come to anyway, I instigated and indicated that we would need to do. It was in that email where — reminding him (Dr Watt) about the obligations around private patients; reminding everybody that they needed to complete the CPC[18], with an indication that the patient met the local guidelines and how they met those local guidelines. And the other thing was to do an audit, which we did, and that audit was all of the cases —
>
> **Mr Lockhart QC:** 39. Yes.
>
> **Dr McDonnell:** — who were not just approved but initiated on treatment, in the 2015-2016 year. And that audit found that — now, that was across all of us. I don't know how many of those patients were his. One would speculate that it was somewhere around the region of 60%, but I don't know that, because that wasn't information that was collected. And the information from that was that all of those patients met the NICE guidelines.

12.155 The difficulty is that if the local consultants had agreed that the NICE Guidelines set the threshold too low, the fact that Dr Watt may have met the NICE Guidelines in an audit carried out in 2018 for the year 2015-2016, did not address the pre-existing problem, which was the reason for the introduction of the local Guidelines in the first place.

12.156 The Inquiry, however, also wanted to examine the reasons behind the failure to establish a panel to consider requests for approval of the use of DMTs, given that it had been suggested by Dr Craig in September 2014. Dr McDonnell had also suggested that a panel should be created, rather than being an individual approval

18 Cost per Case – CPC requests are required from Trusts to secure the funding for specific medicines, where the use of those medicines requires to be monitored. This is normally because the medicine is in the process of being introduced through the Board's managed entry process and the monitoring helps inform an understanding of patient uptake/utilisation. On occasion, ongoing monitoring of a medicine may continue because of specific issues regarding its complexity or specialist nature. CPC requests are for medicines that are commissioned by the Board.

process and, at a European conference on multiple sclerosis in Barcelona between 7th – 10th October 2015, the matter was again discussed. In his written statement of 14th October 2019, Dr McDonnell told the Inquiry Panel:

> There was no support to introduce a panel to consider requests for DMTs at that time with the suggestion being decline by Dr Watt and Dr Droogan as being neither necessary nor desirable. The matter was raised again for further consideration at the MSSIG on 12 April 2016. I felt a panel would provide more transparency in relation to how the patient came into the system, what information was available in relation to patient and discussions as to whether the particular treatment fell within the guidelines … consensus however could not be reached in relation to a panel being created for approval purposes.

12.157 Dr McDonnell reflected that neurology colleagues may have been thinking that they were busy enough and that this would have been extra work. There was, further, no requirement for having a DMT panel in the ABN guidelines nor had the HSCB or the Belfast Trust insisted on same.

12.158 In oral evidence on 4th November 2019, Dr Gray explained that she had recalled tension between Dr Watt and Dr McDonnell in Barcelona with regards to the creation of a panel and scrutiny of the CPC/IFR forms. She stated to the Inquiry Panel:

> So, my understanding was that Dr Watt was getting frustrated that a consultant colleague was looking at forms that he had completed and asking for more information, and that Dr McDonnell felt that this should not be the role of one individual and that there should be a group to look at these forms.

12.159 Dr Droogan explained his own views to the Inquiry Panel in his oral evidence of 10th April 2019:

> There was one main discussion at an MS conference, and I think we had discussed it briefly and certainly informally in groups. I believe that Michael's view was that if he fulfilled the NICE prescribing criteria, he should be allowed to prescribe. We set up a slightly modified form of the criteria for administering these drugs which we were calling the NI guidelines … to get on the more potent drugs, you should have an active MRI scan. That is not one of the NICE criteria, but it was a security feature that meant that the patient was genuinely active.

12.160 The idea of a panel was again discussed at the Clinical Leads meeting on 1st September 2016, at which both Dr McDonnell and Dr Craig were present. The minutes recorded as follows: *"ECR sign-offs. Discussion re responsibilities and accountability. Panel for alemtuzumab requests suggested – [Dr McDonnell] to email relevant colleagues"*.

12.161 Dr McDonnell subsequently emailed neurology colleagues specialising in multiple sclerosis, including Dr Droogan, Dr Hughes, Dr Watt and Dr Gray on 25th September 2016. The full email is set out below:

> Over the last few months CPC requests have been passed on to me for approval, particularly those for MS DMTs. Until now I have been looking at these requests as far as possible before signature as I felt that my signature could be construed as being a guarantor that guidelines are being met.
>
> There are at least a few problems with this, and I don't feel that it is sustainable. Firstly, my requests are not submitted to the same scrutiny by another MS Neurologist. There is therefore an equity issue which could only be addressed by a panel considering all of these requests – there is no consensus among us regarding such an arrangement, however. The second problem is that there is insufficient information provided by the CPC process (and often on ECR) to allow me or anyone else to take a fully informed view on patient treatment. This can really only be done by the individual making the application under the present arrangements. Thirdly the term "Gatekeeper" does not appear anywhere in my job description.
>
> From now on I will approve all CPCs without any scrutiny on the basis that the applicant is fully satisfied that our local guidelines are being met, stating this clearly with supportive evidence. The CPC process is not a method for getting a second opinion. It goes without saying that applications should only be submitted for MS patients who are being managed within the NHS at the time of the application since this is an NHS process for treatment within the NHS.
>
> How we use guidelines is really a matter for an audit process (not a pre-audit which is effectively what I have been attempting to do) and it would probably be sensible for us to audit our use of DMTs against our own guidelines – this could be done on a regular basis by one or more interested trainees.
>
> Regarding alemtuzumab, it is probably just worth noting that there are expected to be □80 approvals for this drug in the current financial year. It is estimated that the current system can cope with 48 patients being treated at most. It shouldn't be this way but this is how it is at present. That will leave 32 patients carried forward to next year, added to whatever approvals are given then. Some of us already have patients waiting 6-7 months for alemtuzumab post approval so it is clearly important that we are deploying our own guidelines appropriately to minimise the risk that some patients get pushed further away from access, by other patients who could perhaps be on a different treatment pathway.

> As a reminder to myself in particular I have attached our local guidelines.
>
> Regards
>
> Gavin

12.162 The Inquiry Panel sought to understand who would have had responsibility for establishing a panel. In his oral evidence on 17th October 2019, Dr McDonnell stated:

> The Trust could have done that. You're right: the Trust could have directed people. They could have changed their job plans, and [HSCB] could have directed the Trust to have DMT panels and change their job plans accordingly … the guidance that comes out in England regarding DMT panels comes from NHS England; it doesn't come from – it isn't left to individual Trusts to make a decision around that. So, it really isn't a local decision. It may be for local implementation but not for a local decision … my perception would be that if the [HSCB] really wanted to have a panel, if they were concerned about the referrals coming through and if they really wanted to have a panel, they simply could have directed that, I would imagine with the stroke of a pen.

12.163 Dr Craig, the Clinical Director, agreed, in his evidence on 18th December 2019, that the establishment of the DMT panel was a matter for the HSCB and the Trust. He stressed the importance of achieving consistency in relation to the more general issue of multidisciplinary team working and peer review albeit in the context of a discussion about the DMT panel:

> I like the model where the edict came from on high: this is what we expect of best practice, and that gets applied across the region. That then allows you to begin to pull in your colleagues, because, as you can imagine, different Trusts have different processes and things, and having that overarching principle: MDT working must be enshrined, it must be built into the system and it must be followed … it's very hard to drive it the other way up.

12.164 The consistent view of both Dr Craig and Dr McDonnell that the establishment of a DMT panel was a matter for both the HSCB and the Trust, highlights a fundamental problem. The Inquiry Panel does not doubt that that was genuinely the view of both the Clinical Director and the Clinical Lead in neurology. At the same time, the Trust had the contractual expectation that those with managerial roles within neurology would manage their colleagues.

12.165 In written evidence to the Inquiry of 2nd March 2022, Dr McDonnell pointed out that his job plan was only amended to reflect the 2 hours per week allocated to the role of clinical lead in April 2016. He also stated that he had not been given training before undertaking the role of clinical lead and had not previously been involved

in medical management. He stated that he brought to the post his observations of how he had been managed over the years and the focus of that had been to reach consensus amongst colleagues. He had not previously come across a situation in his career where a manager imposed a solution in the absence of consensus. In contrast, the Belfast Trust strongly contends that unless a problem was escalated to them, senior management could not act if it was unaware of a particular issue. Therein lay the tension within the management framework and the importance of ensuring that doctors in management are fully aware of their roles and responsibilities and that there is good communication between the first line of medical management and senior management. If the first line of medical management choose to implement a consensus-seeking approach to deal with a particular issue and consensus is achieved then it follows that escalation is not necessary. Where however consensus is not reached then an alternative management approach is required to get resolution. If senior management within the Trust are not aware of an unresolved issue, then obviously it is much harder to manage. The point is, however, that the Trust has a responsibility to ensure that management works. The issue of prescribing is apposite because the problem or potential problem of prescribing variants was known about by different levels of management.

12.166 In her evidence to the Inquiry Panel on 10th October 2019, Dr McCarthy advised that she had not been aware of any of the above dialogue or debate between Trust clinicians and/or managers. She explained:

> We were not aware of any of these conversations. The emails reveal … a quite candid difference of view across the Trust.

12.167 If no one raised an issue or escalated a problem, then more senior management felt they could assume that an issue did not exist. That approach is not sustainable and the disconnect between doctors who were managers, and the senior management structure, has been readily apparent in the evidence to the Inquiry Panel. The artificial requirement for consensus amongst consultant specialists before a panel was established and Northern Ireland guidelines put in place, illustrates the contradiction. It would be well within the ambit of the duties and responsibilities of the Clinical Director and Clinical Lead to issue a work instruction to their colleagues in respect of establishing a panel or working within prescribing guidelines. That is not, however, how things were done, essentially, amongst consultant peers and this is commented further upon in the Medical Culture chapter.

MULTIPLE SCLEROSIS-PRESCRIPTION:

12.168 A table of Alemtuzumab prescription by individual consultants between 2014 and 2018 was provided to the Inquiry by the HSCB and is set out below:

ALEMTUZUMAB		
Count of Date Approved/ Declined Year	Consultant Name	Total
2014/2015	Gray Orla	2
	Watt Michael	9
2014/2015 Total		**11**
2015/2016	Droogan Aidan	2
	Gray Orla	2
	Hughes Stella	8
	McDonnell Gavin	7
	Watt Michael	31
2015/2016 Total		**50**
2016/2017	Droogan Aidan	5
	Gray Orla	2
	Hughes Stella	16
	McDonnell Gavin	12
	McVerry Ferghal	2
	Watt Michael	37
2016/2017 Total		**74**
2017/2018	Droogan Aidan	5
	Gray Orla	2
	Hughes Stella	4
	McDonnell Gavin	12
	Watt Michael	16
	Campbell Jamie	1
2017/18 Total		**40**
Grand Total		**175**

12.169 The evidence in relation to the prescription of DMTs for multiple sclerosis and the prescription of Alemtuzumab, revealed a similar pattern to what transpired with the prescription of HIG. Dr Watt's numbers clearly stood out from those of his consultant colleagues.

12.170 Once again, all the relevant personnel had sufficient evidence of an unexplained variation. As far back as February 2011, Mr Sullivan, the Director of Commissioning in the HSCB, had written to Mr Donaghy, Chief Executive of the Belfast Trust, in relation to the cost of prescribing drugs for multiple sclerosis. At an early stage, therefore, budgetary pressures were identified on the high-cost drugs associated with the treatment of multiple sclerosis. In light of the budgetary pressures, monitoring of trends could have been put in place and discrepancies identified and investigated to understand the reasons for any such discrepancies.

12.171 Early indications suggested that Dr Watt proposed to take a different approach to his colleagues specialising in multiple sclerosis. Dr Watt's estimate of a 20% prescription of new patients was 4 times the estimate for other groups of neurology experts. The Inquiry Panel heard evidence from colleagues of Dr Watt, who stressed that, as with any medication, the approach to prescribing will be dictated by an individual neurologist's overall approach.

12.172 It was accepted by Dr Watt's colleagues that he preferred to adopt a more aggressive approach to first line treatment. Dr McDonnell referred in his evidence to Dr Watt being a more *"enthusiastic"* prescriber of Alemtuzumab. The Inquiry Panel gained the impression from Dr Watt's colleagues that, as far as they were concerned, he was still operating within the margins of acceptable practice. Unfortunately, however, there was no in-depth scrutiny or sufficient investigation of Dr Watt's prescribing practice of Alemtuzumab. As with the case of HIG, the focus of neurologists' frustration is the fact that, within neurology, the Clinical Director and the Clinical Lead were asked to sign off on requests for this drug and this led to Dr McDonnell referring to this internal process as *"a rubber-stamping exercise because he did not have enough clinical information to challenge, for example he didn't have the scans"*.

12.173 The Inquiry Panel noted that when Dr McDonnell queried some of the applications for Alemtuzumab, Dr Watt expressed his own frustration that a colleague was second-guessing his prescribing decision. Without access to the notes, and the ability to properly give a second view, Dr McDonnell was understandably dismissive of the process in place. It was at this point that greater clarity about the management role of both a clinical director and a clinical lead was needed.

12.174 A further problem was the fact that, despite Dr Craig's proposal of setting up a formal review panel within neurology as a means of scrutinising applications and addressing budgetary concerns, which was fully supported by Dr McDonnell, this did not find favour with some other neurologists specialising in multiple sclerosis. The Inquiry Panel understands that Dr Watt, again, was at the forefront of those who

expressed disagreement. The view among some neurologists was that if neurologists were working within the guidelines, further scrutiny was not required and was simply adding to the workload of already pressurised and busy neurologists. The fact that some neurologists were reluctant to set up their own panel was viewed, at that time, by both the Clinical Director and the Clinical Lead as an insuperable impediment.

12.175 In a written submission to the Inquiry of 2nd March 2022 Dr McDonnell though accepting that he was in post as a clinical lead in September 2016[19] was critical of the fact that the concept of a work instruction was not explained to him by other managers. He also pointed out that it was not the norm for a DMT Panel for drugs to be convened in the UK and that it was not until September 2018 that the commissioning body for NHS England made it a requirement for DMT Panels to be established. The Inquiry Panel accepts that Dr McDonnell was proactive in seeking to establish such a Panel as far back as 2015 and that upon receipt of the RCP report in May 2018 successfully took steps to establish an MS DMT Panel.

Further Findings and Analysis:

12.176 The Inquiry Panel gained the impression that neurologists were operating on a consultant-led consensus model, which required a common view before steps could be taken and even then, could be ignored by an individual. There appears to have been little or no challenge to this approach. Once again, however, there is a failure by the Trust and the HSCB to recognise that they had the ability to insist on certain steps being taken. If the Clinical Director felt that he must obtain consensus amongst neurology colleagues, then it is for management within both the Trust and HSCB to give direction. The Inquiry Panel was particularly struck by both the evidence of Dr McDonnell and Dr Craig that the Trust could have established a panel and the Board could have directed the Trust to set up DMT panels, even if that required a change to job plans. Dr Craig stressed that when a direction is given, then that allows him, as a Clinical Director, to pull in his colleagues and require them to implement what has been a direction from a higher level.

12.177 In reality, the situation was very different. There was a very limited understanding of the ability of both the Trust and the HSCB to give such a direction. The impression gained by the Inquiry Panel was that if the neurologists did not want to set up an internal panel, then not much could really be done. Despite the fact that budgetary

19 Dr McDonnell stated in his written evidence of 2nd March 2022 that although interviewed for the Clinical Lead post at the end of May 2015 it was not until 1st April 2016 that his job plan was amended to allow for 2 hours per week allocated to his role as Clinical Lead including attendance at Clinical Leads meetings.

pressures remained, and evidence revealed that Dr Watt was by some distance the outlier, in terms of the prescription of Alemtuzumab, there was nothing to prevent either the HSCB or the Trust from directing that this variance be investigated, that an internal panel be established and that Northern Ireland guidelines were implemented and properly monitored. This power seems to have been ignored and not properly understood.

12.178 Dr Orla Gray emphasised to the Inquiry Panel the importance of the establishment of a DMT panel. In her written statement of 13th February 2020, she told the Inquiry Panel:

> I think most Clinicians would agree that the establishment of the DMT panel is now necessary. This has become clearer over time as further medications have become available and treatment decisions have become more complex. There are various guidelines in relation to the prescribing of MDTs e.g. the ABN Guidelines in 2015, the NICE guidelines on individual DMTs and the Northern Ireland Guidance for use of DMTs in RRMS. The guidelines use differing definitions of highly active or rapidly evolving severe MS, in some cases were very broad (e.g. NICE guidance for alemtuzumab), in some cases very restrictive (e.g. NICE guidance for cladribine need for Gd-enhancing lesions rather than new T2 lesions as evidence for new disease activity) and some have changed over time. The DMTs and their guidelines have therefore become more complex over time and with the complexity, it is clear that the establishment of the group is now required.

12.179 Following the Royal College of Physicians Report ("RCP report"), Dr McDonnell resolved to establish a DMT panel, given the clear recommendations in the report and, in early January 2019, this was successfully initiated. He explained to the Inquiry in his written statement dated 14th October 2019:

> It is multidisciplinary and includes MS neurologists, neuroradiology, MS nursing, pharmacy (when available) and hospital management. MS Clinical Fellows and other interested non-consultant grade doctors also attended. Colleagues with an MS specialist interest in the Southern Trust and South-eastern Trust accepted invitations to attend and so there is equity across N Ireland in how applications for higher level DMTs are considered. It is not a perfect system, but it has transparency and to date has been collegiate, reflected, education and patient-centred. It also enjoys the wholehearted support of all relevant colleagues.

12.180 What is striking is that, when Dr McDonnell established a DMT panel in early 2019, the impact was immediate and appears to have improved the situation considerably. The Inquiry Panel noted that it now enjoys the wholehearted support of all relevant neurologists.

12.181 The Inquiry Panel is not in a position to determine what would have happened if Dr Watt's prescribing practice had been investigated and audited, both in respect of HIG and Alemtuzumab. What the Inquiry Panel can, however, say is that the confusion of roles led to a situation where obvious variances in an environment of significant budgetary pressure were ignored or deflected. At the very least, these variances should have been audited and explanations sought. While the problem was identified, the only efforts made to address same focused on the administrative deficiencies of Dr Watt, which were again obvious and apparent. While these deficiencies were relevant, they failed to properly get at the heart of the problem. This failure to investigate, audit and direct was an opportunity lost for both the HSCB and the Trust to address issues, which may have had a direct impact on patient safety.

12.182 Ultimately, it is the responsibility of the Belfast Trust and the HSCB to ensure that there are processes in place that scrutinise the cost of treatment. In this instance, there were numerous individuals within the HSCB and, to a lesser extent, the Trust who recognised that HIG and Alemtuzumab needed to be allocated carefully to meet inevitable budgetary constraints.

12.183 The Inquiry Panel noted that financial pressures were a major concern for both the HSCB and the Trust and efforts were made to try and properly address the fact that HIG and Alemtuzumab were being prescribed well beyond what had been anticipated.

12.184 It is apparent from the actions that were taken, and the evidence obtained by the Inquiry Panel, that the major focus in these areas was financial. The Inquiry Panel can understand that instinctively neurologists, when faced with a conflict between caring for their patient by prescribing expensive treatment and working within fiscal constraints will want to do right by their patients. The Inquiry Panel agrees with Dr Craig that this was a conflict which was hard to reconcile at times, but it is still critical that variances and outlying practices are investigated properly.

12.185 The fact is, however, that the HSCB and the Trust have, in addition to their financial obligations, an overarching responsibility for patient safety. The Inquiry Panel accepts that it was more difficult for non-neurologists to challenge obvious discrepancies within prescribing and agrees with Dr Craig that the issues are best dealt with by neurologists themselves. That said, the Inquiry Panel noted that attempts by Dr Craig, as Clinical Director and Dr McDonnell, as Clinical Lead to set up an internal panel for the prescription of Alemtuzumab foundered on the question of the consent of other colleagues. It is, of course, preferable that a panel

of peers to review the guidelines is best approached on a voluntary basis but, in a managed system, it should remain the case that a reasonable direction from a line manager or, in this case, a Clinical Director or Clinical Lead should be followed. The misconception that progress could only be by consent was not just a view among neurologists but was accepted by those at other levels of management.

12.186 Given that problems with the utilisation of HIG as a treatment, and the cost of Alemtuzumab, had been identified both by the HSCB and communicated to the Chief Executive of the Trust, it is clear that difficulties were known about and continued over a period of years.

12.187 If Northern Ireland was the outlier in respect of the use of HIG, neurologists were the outlier in respect of the use of HIG within the Trust and Dr Watt was the outlier in respect of neurologists, a fact identified as early as the audit of 2007 by Dr Carr, then these issues need to be both analysed and appropriate steps taken.

12.188 It became apparent, however, that the actions taken did not resolve the issue and the Inquiry Panel has perceived an institutional reticence, both within the HSCB and the Trust to scrutinise prescribing practices of individuals. The fact is that the panels set up to look at both HIG and Alemtuzumab failed to analyse the potential problem of over prescription by Dr Watt.

Conclusions and Findings:

12.189 Although this chapter is focused on two discrete treatments, it has provided an index example of a failure by the Trust to manage a situation effectively. The Inquiry Panel observed that Dr Watt was undoubtedly quicker than his colleagues to move to aggressive therapy, both in terms of prescribing and in terms of interventional procedures. Such an approach is not necessarily incorrect and the adjudication as to whether it was acceptable practice should have been undertaken in the public interest by either his employer or his regulator, the GMC, or preferably both. Unfortunately, this did not occur, and the Inquiry regrets the lack of any clear conclusion which may well have strengthened further the governance recommendations of the Inquiry.

12.190 The actions of management at every level are characterised by a lack of curiosity, a failure to assertively manage and the absence of an effective peer review process. The fact is that initiatives taken by those within the Trust did not adequately address the problem that had been clearly identified. There is a strong flavour in the evidence that, when neurological opinion is sought, that is the end of the matter. Obtaining an expert view is indeed a critical component of decision-making, but that view is not

necessarily definitive, particularly when the problem remains. In prescribing, the right questions were asked but, for various reasons the problems were not properly addressed.

12.191 It is perfectly proper that the HSCB was concerned about the budgetary impact of both HIG and Alemtuzumab prescription. While at times they raised other concerns, often implicitly, the HSCB appears to have been willing to let the Trust deal with any patient safety issue. Given that the HSCB also had a responsibility to ensure patient safety, the method adopted of asking questions and passing on concerns often in an oblique way was not effective.

12.192 The Trust, however, was focused on the administrative obligations that had been stipulated and were often ignored by Dr Watt and at no stage did anyone decide to look further or query Dr Watt, about the patterns emerging which were obvious and should have given rise to an investigation. The capacity of the entire system to work around the problem instead of confronting it, is remarkable.

12.193 The Trust was aware, or ought to have been aware given the high-level correspondence that had been exchanged, that there was a problem within neurology in 2011. Despite several initiatives and queries being raised, especially by Dr Corrigan, nothing was done, and the problem remained in 2016, at which stage it was still being analysed as essentially a failure to complete the paperwork.

12.194 Dr Craig identified what needed to be done in relation to HIG as far back as 2011. Dr McDonnell, in relation to Alemtuzumab, became extremely frustrated with the bureaucratic process in place and felt that he was rubberstamping decisions without the time or opportunity to properly assess the relevant evidence. Greater proactivity from both the Clinical Director and the Clinical Lead could have made a difference. The failure to allow the IAP panel to oversee a prospective process, despite funding being in place, was a missed opportunity, as was the fact that HIG was being initially overseen by the NIBTS and not Pharmacy.

12.195 The entire system including the HSCB and the Trust had a responsibility for patient safety. It is disappointing that, although the HSCB and senior Trust management were aware of the unusual prescribing, they persistently identified this as a financial difficulty and not also as a potential safety issue.

CHAPTER 13 – MEDICAL CULTURE WITHIN THE BELFAST TRUST

13.1 The structure of the chapters in this report has focused on separate and discrete matters, which the Inquiry Panel believes are relevant to the Terms of Reference. There is the potential that the format of the chapters endorses artificial distinctions between areas of governance that should form part of a single coherent system centred on the safety of patients. The question of medical culture within the Belfast Trust and, to some extent, the NHS is an overarching theme, which features in each of the chapters and is arguably the most significant factor that, at times, appeared to undermine the principle that patient safety is paramount.

13.2 By culture, the Inquiry Panel is referring to a way of doing things within the Trust. It is important to note that this chapter does not seek to incorporate the wealth of academic material on the medical and healthcare culture within hospital systems. A more in-depth study would risk stepping beyond the Inquiry Terms of Reference. Culture is being referred to in lay terms and within the understanding of local parlance. It is simply an observation of "how things are done there" but describing the patterns of behaviour repeated over many years is key to an understanding of the reasons that the problems were allowed to continue.

13.3 The Terms of Reference require the Inquiry to comment on the Belfast Trust. The Inquiry Panel considered this largely through the lens of neurology. The Trust is an organisation with a common management system which sits in a much broader system, partly defined by the fact that it is in Northern Ireland and partly because it is a part of the National Health Service. In considering the question of the influence of medical culture the Inquiry has tried to be fair in the extent to which it extrapolates beyond neurology where the bulk of the evidence has been obtained. The Inquiry Panel acknowledges that the further one ventures from neurology the greater the degree of caution in making any finding.

13.4 Northern Ireland is unusual in that circa 85% of all doctors have trained in the same university. For historic reasons, there is a smaller number of medical staff who have trained outside Northern Ireland. The fact that people know one another engenders strong ties and relationships, but it may also make it less likely that concerns are raised about the practice of a colleague, lest that jeopardise social cohesion in a comparatively small community.

13.5 It is further important to establish at the outset, the various models of governance which are relevant within the Belfast Trust and, in fact, throughout the NHS. On the one hand, doctors operate under a professional model where they develop a body of knowledge and competence, which is assessed by the profession itself and monitored through self-regulation enforced by a regulator (the General Medical Council "GMC"). On the other hand, the managerial model, which was introduced into the NHS in the 1980s, develops systems and processes to hold doctors (who are also employees) to account. There is an inevitable tension between the two models and the evidence of this Inquiry is that some doctors are sceptical about the benefits of the managerial model and more comfortable with the autonomy of a self-regulated profession.

13.6 The Inquiry Panel recognises that a chapter about culture is based less on discrete evidence from specific witnesses, but more on the impression gleaned over the course of hearing 230 witnesses and reading thousands of documents. When all the explanations have been provided, the question remains "How did Northern Ireland's largest ever patient recall come about?" The Inquiry Panel must avoid speculation and surmise. One can, however, form a view based on an overall impression after hearing oral evidence over 3 years. Unlike some of the findings contained in other chapters of this report, the conclusions in respect of culture in the Belfast Trust reflect the evidence more by way of an overview as opposed to discrete parts of the evidence. It is important that the reader understands this qualification.

13.7 It is fully acknowledged that doctors and NHS staff regularly go to extraordinary lengths to assist patients and act with the greatest degree of professionalism. It was also apparent that this Inquiry has been a traumatic episode for neurology. One could not help but be impressed by the calibre and industry of the many neurologists and other healthcare professionals who gave evidence to the Inquiry Panel. The commitment to their individual patients was exemplary. To highlight some of the inconsistencies and contradictions that arise in the present system, is not to diminish the respect and esteem in which doctors, nurses and other healthcare workers are held. Nevertheless, many of the themes that have emerged during the taking of evidence, point to a culture, which is, at times, confused and self-protective, to the detriment of the safe care of patients.

13.8 While the evidence has been confined to events within Neurology, the inquisitorial approach of the Inquiry has ensured that a breadth of material has been considered. This spans the Neurology Service in the Belfast Trust, the governance arrangements in the independent sector in Northern Ireland, the role of the GMC, the RQIA and

the Department of Health in Northern Ireland, as well as systems of complaint investigation, handling concerns, appraisal and revalidation in and beyond the Belfast Trust. This is important because the Belfast Trust does not exist in isolation. It is part of a complex system which extends throughout Northern Ireland and the rest of the United Kingdom.

13.9 The influence of the prevailing medical culture within the Belfast Trust arises from a number of factors. The shift away from an administrative model, where hospitals were run by administrators to assist doctors, to a managerial model, where doctors are employed and managed by a Health Trust, was a significant moment in the history of the NHS. It is certainly not the role of this Inquiry to opine on the merits and demerits of a particular model. The reality is that since the 1980s, the NHS has operated a managerial approach to governance and the recommendations of this Inquiry need to be viewed through that lens.

13.10 A core problem considered by the Inquiry Panel was that, in all too many instances, doctors acted as their own filter as an alternative to the ordinary process of escalation. What prevented them from using the processes that were already in place? Did social pressure amongst colleagues have a bearing on whether concerns were raised with management? Were doctors aware of the processes in place and were those processes accessible and clear? Did doctors and other healthcare professionals believe in the processes, and did they properly understand their duty in respect of concerns that arose? Did they introduce a standard of proof when considering a concern, which went well beyond the normal threshold of reasonable suspicion? It was these questions that the Inquiry Panel considered in seeking to analyse the influence of medical culture on the issues that arose out of the Terms of Reference.

The Current Obligation of Doctors:

13.11 All doctors have an existing professional obligation to raise concerns in circumstances where they believe patient safety may be compromised. From the evidence obtained, doctors are fully aware of that obligation. The Good Medical Practice ("GMP") published by the GMC in 2013 states as follows:

> 24. You must promote and encourage a culture that allows all staff to raise concerns openly and safely.
>
> 25. You must take prompt action if you think that patient safety, dignity or comfort is or may be seriously compromised.

> (a) If a patient is not receiving basic care to meet their needs, you must immediately tell someone who is in a position to act straight away.
>
> (b) If patients are at risk because of inadequate premises, equipment or other resources, policies or systems, you should put the matter right if that is possible. You must raise your concern in line with our guidance and your workplace policy. You should also make a record of the steps you have taken.
>
> (c) If you have concerns that a colleague may not be fit to practise and may be putting patients at risk, you must ask for advice from a colleague, your defence body or us. If you are still concerned you must report this, in line with our guidance and your workplace policy, and make a record of the steps you have taken.

13.12 Figures obtained by the Inquiry from the GMC[1] revealed that between 2008 and 2018, there were a total of 56 cases[2] relating to an investigation by the GMC into allegations about doctors failing to report concerns about colleagues. None of those cases involved doctors in Northern Ireland.

13.13 The problem is compounded in the general healthcare system. Nurses have their own separate processes when mistakes happen. The crossover with doctors is, however, trickier. The Inquiry Panel considered that there was an undue deference to the view of the consultant or registrar, which means that legitimate questions can fail to be asked. A specialist nurse will have an informed understanding of problems that may arise in a consultant's practice. To what extent was that apparent in the evidence obtained?

The Case of Dr Watt:

13.14 The Inquiry was tasked by the Department of Health with reviewing governance procedures within the Belfast Trust which led to the recall of neurology patients in May 2018. It was immediately apparent to the Inquiry that the governance systems being reviewed related to the manner in which the Trust had utilised their procedures in respect of the practice of Dr Michael Watt.

13.15 A useful starting point, when considering the number of issues raised about Dr Watt' practice, is to reflect on the conclusions of the Royal College of Physicians ("RCP"),

1 Letter of 2nd September 2019 from Jane Kennedy Head of Northern Ireland Office of GMC to Laura Curran BL of Inquiry Legal team enclosing the relevant data.

2 Of the 56 cases, 1 concluded with an undertaking, 1 received a warning, 3 concluded with advice following investigation, 49 concluded following investigation and 2 cases were closed following a hearing. The figures strongly suggest that doctors will rarely, if ever, find themselves in professional difficulty as a result of failing to raise a concern.

who produced a final report on 26th April 2018[3]. The Inquiry Panel is conscious that it is not required to give its own view as to Dr Watt's clinical competence. Nevertheless, the obtaining of the RCP report and its conclusions are an integral part of the context of this Inquiry, and it would be artificial and unrealistic not to refer to the findings of that report. In particular, to observe the breadth of problems identified and their persistence, which were only noticed by very few medical practitioners, according to the evidence received over many years.

13.16 The RCP was contacted on 25th April 2017, at the behest of the then Medical Director Dr Cathy Jack, with a view to the RCP considering the approximately 75 cases where Dr Watt had diagnosed spontaneous intracranial hypotension ("SIH"), but where Dr Peukert had subsequently considered the patient did not have SIH. Following receipt of the reports from Dr Gray and Dr McConville and further discussion with the RCP, a different course was taken (see the November 2016 - May 2018 chapter for more details). On 11th August 2017 the RCP was commissioned to undertake the review that involved 48 cases spanning Dr Wat's practice.

13.17 The RCP report identified significant concerns that Dr Watt lacked the basic disciplines of careful diagnosis, rational management, and openness to the opinions of others. Highlighted below, are some of the more salient observations:

- There were serious concerns in nearly all the 48 cases reviewed of inadequate record keeping. The report noted: *"a tendency for Dr Watt to document little by way of patient history; this contrasted with the notes that had been made by doctors in training, other consultant specialists and nurses, which often contained a more detailed history"*. Further, the report observed: *"a tendency for Dr Watt not to properly document examinations or investigations in a way that the review team felt would be standard practice"*. Additionally, for many of the cases: *"there was very limited or no recorded physical examination"*. Where an investigation was requested: *"it was sometimes unclear why this particular investigation had been selected and often there was no record of the findings"*.

- Regarding communication with patients, the review team had specific concerns that: *"important discussions that should take place with patients, for example regarding aggressive or high-risk treatments, or with respect to driving or pregnancy for patients having seizures were not documented in the clinical record"*.

- The report concluded that Dr Watt was underperforming in several domains of practice and that this presented a significant risk to patients.

3 The RCP report is included in the appendices to the Inquiry report.

The clinical record review of 48 cases identified a degree of concern in most cases. In total, 21 cases were rated unsatisfactory and 22 were identified as room for improvement, reflecting that clinical or organisational care could have been better. Only 5 cases were deemed to represent good practice.

- In relation to the initial assessment of patients and diagnosis, the review identified a tendency for Dr Watt to make a diagnosis without clear supporting evidence, or where evidence existed that was contrary to the diagnosis he was pursuing. The report stated:

  > Dr Watt tends to persist with a diagnostic theme and to initiate medications or treatments such as epidural blood patches without any reasonable rationale. Treatment is sometimes begun before a diagnosis has been articulated, leaving it unclear what the treatment is seeking to address and whether it is appropriate. Dr Watt does not often document his thinking regarding differential diagnosis, or the investigations required to establish or dismiss a diagnosis. He has a tendency to not be rigorous as to what the diagnosis is and drifts from one treatment to the next.

- The report also highlighted instances of where Dr Watt had been observed making rare diagnoses, which included low CSF pressure due to spontaneous CSF leaks, *"with no obvious appreciation of how unusual these are"*.

- The care of multiple sclerosis patients fell well below a reasonable standard and the management of epilepsy patients fell short of reasonable expectations. Significantly, Dr Watt's approach to blood patching was: *"well outside the acceptable range and raised serious questions about his understanding of the relevant application of this therapeutic technique"*. The report noted:

  > The frequency with which he recommends blood patching is far beyond any practice the clinical reviewers have come across. There must be other doctors who are involved in blood patching, and this may give rise to questions about their approach to the use of this treatment. We have not seen evidence that Dr Watt has reflected on the level of requests he has made for blood patching or that he is far outside the accepted range.

- The report also commented on Dr Watt's communication with colleagues:

  > The evidence with respect to collaboration with other colleagues is mixed. There are occasions when the documentation indicates that Dr Watt works effectively and collaboratively with colleagues. He often seems to work effectively with the multiple sclerosis and the epilepsy

> nurses. However, we have also observed cases where the involvement of colleagues is not evident and there are instances where other clinicians are involved in the case of patients and Dr Watt seems to pay no heed to their observations. Including where they have raised questions regarding his diagnosis. We have not seen evidence of effective multidisciplinary working around key neurological disorders. In fact, Dr Watt seems to work I isolation to his colleagues with little input from other neurologists.

13.18 Many of the consultant neurologists and registrars were given access to the RCP report before they gave evidence to the Inquiry. It is fair to say that the overall reaction to the findings of the report was one of shock and deep concern that the significant problems identified had been happening for years within their specialty in Belfast. The Inquiry is, however, tasked with going somewhat further and asking a more searching question. How was is that no consultant in the Belfast Trust raised an alarm or escalated a concern, when, on the basis of the RCP report, Dr Watt was so 'out of kilter' by comparison to his colleagues and his practice was found to be unsatisfactory in so many instances?

13.19 In Dr Watt's case, reference was often made to him working on the "old contract"[4], as if this in some way permitted him to avoid obligations, which may have been perceived as part of the "new contract". The difference raised between the two contracts was, from the perspective of patient safety and clinical management, a meaningless distinction. Nevertheless, it was apparent that, especially at an earlier stage, reference by Dr Watt to being under the old contract had some degree of weight and bearing on his management by clinical colleagues. The false distinction appears to have been rooted in a desire for individual autonomy. While all consultants do need a degree of autonomy, the problem is when autonomy is out of kilter with the requirement of accountability both to the employer and the regulator.

13.20 An obvious example of this was annual appraisal and job planning. In 2009, the then Clinical Lead, Dr Jim Morrow, emailed the Associate Medical Director, Mr David Adams, to give an overview with compliance in neurology of consultants completing annual appraisals and stated:

> And as for Michael Watt … well you know the score, he has only ever been appraised once and despite regular reminders does not co-operate.

4 The 'old contract' refers to an earlier contract entered into by consultants. Changes were directed by central government unilaterally and some consultants, including Dr Watt, perceived that by not signing up to the new contract they gave themselves greater leeway on obligations on work planning. Annual appraisal remained a contractual obligation under the 'old contract'.

13.21 This written interaction would suggest that the situation was simply not managed and Dr Watt was not confronted to the point where Trust policy was properly enforced. A similar and potentially telling interaction this time relating to job planning took place in the same year, again between Dr Watt and his then Clinical Lead, Dr Morrow. The initial invitation to a meeting with Dr Morrow was forwarded to Dr Watt by Dr Morrow's secretary. Dr Watt responded:

> As I am still on the old contract, I do not need a job planning meeting
>
> Michael Watt

Dr Morrow, appointed to his role by the Trust, responded:

> Michael
>
> I think you do need a job planning meeting-but don't worry we have no control over you (it is a formality).
>
> Jim

13.22 There may well have been a degree of flippancy in Dr Morrow's response, but the interaction revealed to the Inquiry Panel that the then Clinical Lead's view of management was inappropriate and also gave a helpful insight into the approach taken by Dr Watt, who felt on the basis of the written evidence viewed by the Inquiry, that he could ignore contractual obligations and/or the direction of Trust managers It also highlights that the professional model took precedence, even among colleagues who had agreed to take on management roles.

13.23 During the period 2006-2008, the Medical Director, Dr Tony Stevens, was also seeking to ensure that Dr Watt complied with his appraisal obligations.

13.24 While non-compliance with appraisal obligations was a source of continuing irritation to various medical managers, the reality is that nothing meaningful was done to ensure that these were fulfilled. In his evidence to the Inquiry Panel, Mr Adams stated:

> Consultants must do an annual appraisal, they must absolutely do it and they can't keep on practicing without it. So, I don't know why we let him away with that.

He added that, with the benefit of hindsight, there should have been an investigation into the issue and then that could have been passed on to the Medical Director.

13.25 A number of interactions which bookend the problem illustrate the depth of difficulty caused by the introduction of an NHS system in which the medical profession were more assertively managed and regulated. By 2001, annual appraisal had become a

contractual obligation for all medical practitioners and had been agreed nationally by the British Medical Association. By 2011, revalidation every 5 years was a statutory requirement. Problems had arisen because Dr Watt was one of a number of doctors who had not completed their appraisal[5]. This failure had been brought to the attention of Dr Stevens, the then Medical Director, who on 4th October 2006 had stated in an email to colleagues that if: "local resolution is not successful we are close to going down a formal line".

13.26 The then Clinical Director for Neurosciences, Mr Steve Cooke, emailed a reply to the Medical Director and others expressing his frustration:

> … I told him he is going to be in some difficulty if he does not complete the response and get appraised … The difficulty is that I don't think there is an understanding amongst some medical staff of the need to comply with complaints/appraisal/other organisational procedures and they are seen as non-important. There is a need for us to toughen up our approach in such situations, and to be seen as firm, but as [Clinical Director] I really only have explanation/persuasion to use to resolve such problems.

13.27 In fairness to Mr Cooke, even when he acted as a concerned manager, there was significant pushback from colleagues. An interaction in 2008 when Mr Cooke was still the Clinical Director is instructive. In a personal email of 12th January 2008 to a neurosurgery colleague following a neuropathology meeting, Mr Cooke stated:

> … further to the neuropathology meeting on Tuesday, as you know issues were raised at the meeting by colleagues regarding aspects of the management of patient [X]. Given the concerns, the facts stated, and the answers given, I am obliged to pass these issues on, and will be forwarding to Mr Adams Associate Medical Director, for his action as necessary.

13.28 The colleague who was the subject of the concern took issue with the manner in which the matter was raised and copied his response to Mr Cooke to other neurosciences colleagues. This then elicited the following response from Dr Jim Morrow, Clinical Lead, on 25th January 2008[6]:

> Dear [Dr]
>
> I have to say that I am somewhat surprised by Steve's initial email to you which you have copied to myself and others.
>
> Clearly, I cannot comment on an individual case as I was not present at the meeting. However, from a general perspective I find this whole thing very worrying as it seems to set a completely new precedent.

5 In written evidence submitted to the Inquiry the Belfast Trust pointed out that in 2011 the appraisal rate within the Trust was 89%.

6 Email from Dr Morrow to 31 colleagues who normally attended the Neurosciences Grand Round at 13.56pm on 25th January 2008.

> In all the years I have attended our Neurosciences Grand Round, I have witnessed many disagreements arguments etc about patient management, but surely this is what the meeting is all about? It is a learning exercise for presenter and for those in the audience. Medicine is rarely black and white, and people have and will continue to have different management strategies in individual cases – our Grand Round has always been a useful arena in which to discuss the relative merits of these different strategies, but never before have I heard the suggestion that following this meeting a colleague's competence is called into question and that referral be made to the Medical Director.
>
> I am afraid that if this is allowed to continue the Grand Round itself as a format for education will cease to function as we all start to practice defensive medicine. You therefore have my full support in questioning this decision of Steve's.

13.29 The examples cited illustrate the general point. First, that some Clinical Directors viewed themselves as having limited powers of influence and persuasion and secondly, that when serious concerns about competence were raised, a clinical director could expect significant push back from colleagues. The Inquiry was unfortunately unable to ask Dr Morrow about his response, and what should have been done when there was a genuine concern raised about patients, as he was medically unfit to attend and give evidence, but the obvious question is whether he asked Mr Cooke about the nature of the concerns before launching into a robust defence of a colleague. The correspondence would suggest that he did not, and the interaction is an index example of the difficulties doctors in a managerial position faced in identifying and escalating concerns. It is also important to note that Dr Morrow was the Clinical Lead at the time and, therefore, occupied a managerial role, in addition to his duty as a doctor to raise concerns even if they arose in the context of an academic meeting where the focus was on learning.

13.30 Mr Cooke, when he gave evidence to the Inquiry Panel on 4th March 2019, believed that the climate had now changed. Mr Cooke stated:

> I mean I think the junior doctors coming through the system over the last 10 years, they're much more used having a very formal annual appraisal, being more accountable for what they do. But I think and I suppose including myself consultants who were in position the old style, the old type of contract were probably more independently minded and less willing to be directed. And I suppose in terms of the question, if I had concerns about a colleague, which I did have on quite a number of occasions during my tenure, I mean the process was to escalate it up to the associate medical director, then the medical director and the cases were more colleagues were discussed at the doctors' and dentists' review meeting.

13.31 The above illustrative examples took place in the period 2006 to 2009, so one is entitled to ask the question as to whether, in the interim period prior to the Inquiry being launched, the approach to management of doctors by consultants, who are also doctors, has substantially changed. There were clearly significant developments. The importance of appraisal and the introduction of revalidation and the role of the Responsible Officer (who was in Belfast, as often elsewhere, the Medical Director of the employing Trust) and the statutory supervision of the GMC, clearly had an impact. The problem, however, of managing doctors and operating a managed system remained.

13.32 Dr John Craig became the Clinical Director for Neurosciences in 2013. The expectation is that senior consultants taking on the role of Clinical Director are expected to serve for circa 3 years. When the recall was announced, he remained in post and had clearly taken on a huge responsibility with the recall process and leading in a situation when morale, according to the evidence received by the Inquiry, was severely dented. Both he and Dr Gavin McDonnell, the Clinical Lead for Neurology, are to be commended for continuing in their roles during what was the greatest ever challenge to the practice of neurology in Northern Ireland.

13.33 On 17th December 2019, Dr Craig gave evidence to the Inquiry Panel of a meeting in or about June 2018 of Clinical Directors within the Belfast Trust:

> **Mr Lockhart QC:** You get the impression from a lot of the papers that the clinical directors spend a huge number of hours trying to persuade and influence because of the collegial nature of what you are doing. What we have to look at in terms of patient safety is to say. "Well actually there are times when you have an outlier, where ultimately persuasion doesn't work or influence doesn't work" You simply say "This is a reasonable work instruction and I'm asking you to do it with a reasonable period of time. If you don't do it within a reasonable period of time I am going to escalate it to the medical director.
>
> **Dr Craig:** I think all those points are really well made. I don't know if it's the time to bring in an example, but there's a CD[7] forum in the Belfast Trust ... I don't know if it's the time to bring in an example, but there's a CD forum in the Belfast Trust … It stopped for a period of time, and it's been started again. There was a number of new CDs, so there was a kind of an introduction, going round the room. They said, "We'll leave John to the last in terms of giving you his experiences". So, they all went round, and they all seemed very enthusiastic. Some of them gave us the usual answers: "I'm doing this because nobody else would do it"; "People told me I'd been around long enough; I had to give something back". There was a couple of people said that that was the thing that

7 Clinical Director forum.

> they'd always wanted to do. And then, they asked me for my reflections, and I said to them, "I want to ask you a question: 'How many of you truly read your job description before you signed up to this?'", and not a single hand went up. Now, that may be that they just didn't - they were too embarrassed. I didn't, if I'm telling truth. I said, "You know you are in charge now, under the new job description, of clinical governance and safety in your arena". I said very much what you said: "When things are going well, it's fantastic". You get the door; you can go to the big table; you can make your case for your specialism or whatever. But, when it goes bad, you're responsible for it".

13.34 Dr Craig's comment was, in the view of the Inquiry Panel, evidence of the depth of his own reflection, post the neurology patient recall, but it was also a candid and realistic assessment of the reasons people seek to be appointed as Clinical Director and the dearth of understanding of the managerial dimension to the post. Dr Craig's comment suggests that clinical management is not viewed as career progress in the same way as a neurologist may be appointed as a consultant and further develop a subspecialty.

13.35 The Inquiry Panel accepts that the managerial role of a Clinical Director is not grasped by all Clinical Directors. Mr Chris Hagan, who was appointed to replace Dr Cathy Jack as Medical Director when Dr Jack was appointed as the Chief Executive of the Belfast Trust, took a different view. He believed that many Clinical Directors did understand their role and their accountability in management.

13.36 He told the Inquiry Panel about an initiative he had been tasked with by Dr Jack which described a much more proactive approach:

> **Dr Hagan:** I started [the initiative] in children's and maternity in 2017-2018. Then Cathy [Jack] tasked me with spreading that across the organisation. So all the divisions now have a weekly live governance meeting which should include the divisional chair, the co-director and the divisional nurse. Service managers can come to that and they would bring incidents and complaints that they are concerned about. It's a very good way of taking an immediate sense check of your service very much in keeping with Charles Vincent's model of the measurement and modelling of safety, where you are aware of what is going on in your system on a day to day, week by week basis. I think we've been quite proactive about that basis. Then if there is a complaint that mentions a doctor, I would automatically have let Peter [Watson] know about that in the medical director's office.

13.37 It is to be welcomed that such initiatives have already been taken, but the presenting problem as far as medical/healthcare culture is concerned is the dilemma that Clinical Directors face as they seek to play a part in a managerial system. The concern of the

Inquiry Panel was that there appears to be a continuing confusion as to the managerial role among many Clinical Directors themselves and despite all that had happened, such confusion appears to persist. Essentially, while the definitions may be tolerably clear in the job description, the professional model ensures that there is a continuing reluctance by colleagues to be managed, thus making the role difficult to exercise.

13.38 The then Chief Executive, Mr Martin Dillon, described the procedures at Trust Board level. This included the interaction of the executive team with non-executive directors and the various methods by which, through a serious of committees including the Audit Committee, the Trust Board assures itself that targets are met, risks assessed and safety promoted in line with core aims of the Trust. Dealing with his understanding of escalation of concerns, Mr Dillon, in his evidence to the Inquiry Panel on 9th October 2019, stated in answer to various questions specific to appraisal:

> **Professor Mascie-Taylor:** So consultant x doesn't have their appraisal done. Who deals with that? Who would you expect as Chief Executive to be dealing with that?
>
> **Mr Dillon:** The Clinical Lead: The Appraiser
>
> **Professor Mascie-Taylor:** But if the Clinical Lead is not the Appraiser who would it be?
>
> **Mr Dillon:** If the matter of non-compliance or failure to engage I would be expecting, in the first instance the Clinical Director to be dealing with that matter -
>
> **Professor Mascie-Taylor:** Right how would you expect the Clinical Director to deal with it?
>
> **Mr Dillon:** One has to get behind the reasons why the individual was failing to engage, understand it and then send out the instructions that by this date there will be compliance or engagement, and then using the process to say, "What triggers do I have now to move this up to the next level".
>
> **Professor Mascie-Taylor:** But the bottom line is, "This is what the organisation expects you to do", yes?
>
> **Mr Dillon:** Yes.
>
> **Professor Mascie-Taylor:** And do you think the Clinical Director should make a note of that or send a letter or what? How should that be handled? The reason I'm asking that is we're trying to discriminate between undocumented quiet words and a reasonable instruction of a manager, if you like.

Mr Dillon: Yes. Well, everyone will have a different style, and I imagine some people would be more comfortable with the quiet word in the first instance.

Professor Mascie-Taylor: Right.

Mr Dillon: — the cajoling, moving, then, into formal communication and then, if that doesn't produce the desired results, using the appropriate escalation.

Professor Mascie-Taylor: So, what's the escalation route, then? What then happens?

Mr Dillon: Well, then, from Clinical Director, then, to Medical Director.

Professor Mascie-Taylor: Right. So, the Clinical Director should go to the Medical Director and say, "This isn't happening", and the Medical Director in the Trust would deal with that.

Mr Dillon: Indeed.

Professor Mascie-Taylor: Right. And how would you anticipate they would deal with it?

Mr Dillon: They would, I imagine, get the history of it, get some sense of what's going on, hear what the Clinical Director has to say, look at the history of non-compliance or failure to engage.

Professor Mascie-Taylor: Sure.

Mr Dillon: — then look at what are the next triggers or escalation that they, as Medical Director, can use that are set out in the processes, you know.

Professor Mascie-Taylor: Right. And they would be broadly the same, wouldn't they?

Mr Dillon: Yes.

Professor Mascie-Taylor: Get the doctor in, explain to them what was required of them and repeat it in writing to them —

Mr Dillon: Yes.

Professor Mascie-Taylor: — and then, if they fail to do that, the doctor would be into a disciplinary process. Yes?

Mr Dillon: Yes. Always better if we have a very clear escalation process laid down that everybody can see and understand —

13.39 It was apparent that Mr Dillon, who had previously been a Finance Director and interim Chief Executive, was entirely familiar with the workings of the Trust at Board level. However, his understanding of performance management and the relationship between the Board and other managers was less sure-footed.

13.40 The Inquiry Panel accepts that the Board will not often be aware of the specifics of individual cases, given that they are running an organisation with approximately 22,000 employees, but their role is to assure the public that the necessary processes to ensure patient safety are in place. It would be unfair that local managers were held to be responsible without recognising the broader criticism, which should properly be levelled at the body that oversees the various systems.

13.41 The impression given was that the Board of the Trust was confident in the systems that it operated and appeared not to be fully sighted on the substantial difficulties encountered, particularly in the lower tiers of medical management and in the interaction between senior management and the medical tiers of management. The fact is that the systems and processes in place did not address the presenting problems of information getting to the right person at the right time, thus indicating a disconnect between the Board and the lower tiers of management. The responsibility for this sits primarily with the Board.

13.42 In their written evidence of 13th May the Trust stated:

> The Inquiry has clearly identified the failures of local managers in Neurology to escalate concerns they received. It is only fair to broaden that criticism to the Trust Board or higher management if the local managers did not have system in place to operate for the escalation of the concerns they received, or they didn't know they had to operate it. However, they did have a system to operate, and they did know they had to operate it. For whatever reason they did not tell the Medical Director about all the issues the Inquiry has established they knew about Dr Watt. This is a systems faire consequent o the failure of the individuals to do what they knew to be their responsibility (to escalate concerns), but it is not the fault of the systems per se. Consequently, it is unfair to criticise the body that oversees the systems.

13.43 The Inquiry does not agree with the Trust's view. The Inquiry Panel accepted and understood that those who lead organisations cannot know, or be expected to know, of all the detail that sits beneath them. That is why they delegate tasks and responsibilities downwards through the management structure; why they put systems and processes into place to escalate problems when necessary, and importantly to assure themselves that all is well. It is why they appoint, train, and then hold lower-level management to account.

13.44 When their subordinates or their systems and processes fail then they must accept their full share of accountability for that failure and endeavour to learn from it.

13.45 Accountability for patient safety is ultimately the responsibility of the Trust Board, who will, for the most part, seek assurance from the Medical Director. While it may be perfectly reasonable for the Medical Director to have oversight of doctors as regards patient safety, there are impediments, which can cumulatively threaten to undermine a Medical Director, and make their task more difficult. This included:

(i) The inability to access in a compendious and clear manner, information on clinical complaints. The present Datix system receives a vast array of data which is insufficiently distinguished by those inputting into the system, and the volume of information is such that absent proper analysis, it is difficult to discern a pattern of concern except in the most general sense.

(ii) The restricted flow of information between service departments and the Medical Director's Office. An inadequate appreciation of the management role by Clinical Directors encourages a culture, where issues of possible clinical concern are not escalated and the high threshold adopted by clinicians before registering a concern to the Medical Director ensures that a good deal of information is retained within the relevant department and, in this case, neurosciences.

(iii) The intricacies of the Maintaining High Professional High Standards ("MHPS") procedures make dealing with doctors in difficulty a more cumbersome process than should be the case. Good management can and should filter out issues which need not be formalised. Nevertheless, an informal process such as the one which operates within MHPS, must be robust and well documented. The present informal process within MHPS is opaque and often leads to different doctors taking widely different approaches to investigation. Informal processes are sensible and the managerial norm, but they must be coherent. It is recognised that a critique of the MHPS procedure is, of itself, a significant and discrete piece of work, which is beyond the scope of this Inquiry. The Inquiry Panel does wish, however, to place on record its view that reform of the existing procedure is long overdue. The present balance of the procedure is weighted towards the protection of the doctor and in the confidentiality of the process rather than patient safety.

13.46 The Inquiry Panel again emphasises that it is not its role to comment on the merits of various models of NHS governance. The reality is that a managerial system is in place and is unlikely to change in the foreseeable future. Recommendations within this report are, therefore, framed on that basis. The challenge, however, is to recognise the influence of medical culture within the Belfast Trust and attempt to address how the professional model can be positively reconciled with a management model to the

point where overall management is significantly strengthened. This is a challenge faced by many organisations who employ professionals, not just healthcare Trusts.

13.47 If one turns to the various chapters in this report, the cultural question is evidenced, sometimes subtly, in almost every case. The section below comments on the cultural issues that arose in many of the chapters.

Complaints:

13.48 In relation to complaints, the evidence obtained is that these were treated as a bureaucratic exercise where the Complaints Department is assessed on its ability to turn around and resolve complaints quickly reflecting the Trust being performance managed on this measure by the NHS system in which it operates. This may be appropriate when one is dealing with car parking problems or hospital food, but it is singularly inappropriate when the Trust is informed of a clinical complaint. The system did not work. The aspiration expressed by many that the Trust should learn from complaints was not rooted in reality. The focus was on resolving the problem as quickly as possible and in a manner, which prevented the matter from going any further. There was a distinct lack of curiosity on the part of those who were considering the complaints and a lack of independent clinical input. Though it should be acknowledged that a great deal is expected, perhaps unfairly, of those managers who are seeking to handle complaints. The Inquiry Panel also acknowledge that the Departmental Guidance focuses on time scale for reply and resolution as the priority.

13.49 The Complaints chapter outlines numerous instances, where potentially relevant information may have given rise to concerns being identified if the complaint had been adequately investigated. Similarly, a pattern could and should have been identified if the complaints relating to Dr Watt had been properly analysed. An adequate investigation and proper analysis did not take place.

13.50 The system that operated ensured that a complaint was sent to the relevant physician. The Service Manager asked the physician, who was the subject of complaint, for a view and the history of the patient's dealings with the hospital which was then outlined in exacting detail. Almost invariably, Dr Watt would normally disagree with the substance of the complaint and his views would be faithfully recorded in the response without proper analysis by another expert in the field. This process was both accepted and maintained for many years. Although there is now evidence that there is a greater effort to ensure liaison with the Medical Director's Office and

invite independent clinical input much more frequently, the present system needs to be reviewed at every level. The Inquiry has set out in the Complaints chapter the changes that have been made since the advent of the Inquiry in May 2018.

13.51 In relation to clinical matters, it is in no way surprising that non-medical personnel will automatically defer to the view of a consultant when an issue is raised. The Inquiry Panel further accepts that ensuring highly qualified consultants, who are in the role of clinical director, be asked to take on an additional role of assessing the clinical dimensions of complaints, is a significant burden within the time contractually allowed. Nevertheless, a way must be found for clinical complaints to be properly assessed by another suitably qualified consultant who is not party to the complaint (in appropriate circumstances this input may need to be obtained from outside the relevant Trust). The Medical Director's Office must have access to each clinical complaint along with a clearly documented outcome detailing whether there was found to be any substance to the complaint. This will allow an opportunity for pattern recognition. The present system, where information is retained in administrative silos, guarantees that the right information does not get to the right person at the right time. Matters are then left to institutional memory or the assiduousness of an individual.

Why Were Concerns Not Raised Earlier by Consultant Colleagues?

13.52 Throughout the period, which was considered by the Inquiry Panel, there was evidence of some registrars having concerns about individual cases and, the practice of Dr Watt. Prior to the index cases being raised by Dr Colin Fitzpatrick in November 2016, there was no instance of any neurology consultant in the Belfast Trust raising a concern about Dr Watt's clinical practice.[8]

13.53 The Inquiry Panel questioned every consultant[9] and registrar who worked with Dr Watt between 2006 and 2017. All who gave evidence were briefed beforehand with the RCP report. The Inquiry Panel can only record that they were surprised with how few of Dr Watt's colleagues had, during their time working with him, noticed anything that would have pointed to the issues identified in the RCP report.

13.54 The Inquiry Panel can only record that they were surprised at how few of Dr Watt's colleagues noticed anything of concern. The Inquiry Panel accepts that consultants,

8 Dr Tom Esmonde then a consultant neurologist with the Northern Trust was one of 3 consultants from that Trust who raised a concern with the Medical Director.

9 The only exception to this was Dr Watt himself and Dr Jim Morrow, who was unable to attend for medical reasons, which were fully outlined in a medical report to the Inquiry.

particularly in outpatient settings, often work on their own. Further, there is an understanding that there is a spectrum of practice and that neurologists will differ in their approach to both diagnosis and prescribing.

13.55 The question remains as to why the findings in the RCP report, which were stark and alarming, were not previously identified or noticed, especially by consultant colleagues. Was it a case of colleagues not knowing or knowing, but not reporting? The Inquiry Panel notes that there were some registrars who did know and who did seek to escalate appropriately (as set out in detail in the Concerns chapter). Consultant colleagues of Dr Watt in the Belfast Trust did not raise any concern. The evidence in relation to blood patching, prescribing HIG or Alemtuzumab, or adopting a different kind of neurological practice by comparison to his peers was apparent. There was, however, an absence of curiosity or further enquiry. These issues were not escalated to relevant management, and on the occasions when they were escalated, there was an inadequate analysis of available information often coupled with a presumption that there was no underlying problem.

13.56 Some of the most helpful and reflective evidence was provided by Dr Ailsa Fulton, a Consultant Neurologist within the South-Eastern Health & Social Care Trust. Dr Fulton had worked alongside Dr Watt initially as a registrar and later as a consultant colleague. She clearly knew him well. Asked by the Inquiry Chairman whether what had happened came out of a *"clear blue sky"* and whether there was anything, which would have given an early warning, Dr Fulton was quite clear that: *"it did not come out of a clear blue sky"*. She told the Inquiry Panel on 15th January 2019 that there were *"soft pointers"* that did indicate that Dr Watt was practicing differently:

> **Dr Fulton:** There were other things. You said about blood patches. I would've said that really went bananas after I moved to stroke. I was aware of it on the periphery, but I wasn't directly involved. But there were things before that: HIG — human immunoglobulin; I'm sure you've heard. The product we were using and prescribing on the ward was difficult to get hold of, and it was while I was a registrar, so it must have been between 2004 and 2006. As a result, the Trust wanted to change the prescribing practice and, I suppose, make it more robust, and it became ever obvious at that time that Michael was prescribing a huge amount more HIG than any of the other consultants ... So he was standing out above his colleagues at that point.

13.57 The second pointer, according to Dr Fulton was the nature of his practice. She told the Inquiry Panel that: *"Michael was held up as a poster boy, because he was seeing so many more patients than the rest of us"*. This may reflect the broader imperative of the

NHS and in this case the Belfast Trust to manage down waiting lists, which was a reasonable objective.

13.58 Dr Fulton described Dr Watt's TIA Clinic as follows:

> My example would be the TIA clinic on the Thursday. When I started in my first substantive post as a consultant, I did that Thursday morning TIA clinic and I had a separate list from Michael. So, in his clinic with him, he had two consultant geriatricians who became stroke consultants. There was a care of the elderly registrar, a neurology registrar, there was Nurse Hunter, the nurse specialist. So, there were a lot of staff there. But there were 15 to 17 new patients and there were the 35 reviews, and Michael was — the nurses were setting up patients in two or three rooms and he was buzzing in and out of the rooms. He was giving opinions left, right and centre. When he was off on leave and I tried to cover the clinic for him, I couldn't do it. He seemed very comfortable doing it; it was what he was used to. Personally, I couldn't manage it because I didn't feel I was having enough time with each patient to really make the decision that I would want to make, because that's not what I was used to doing.

13.59 The Inquiry Panel asked Dr Fulton whether she had ever queried the number of patients Dr Watt was seeing. Dr Fulton, however, indicated that she thought it was more her problem than his and referenced the fact that Dr Stanley Hawkins, at a time the most senior neurologist, had also traditionally operated a large clinic.

13.60 Dr Fulton also commented on Dr Watt's practice in the private sector. She referred to the fact that other medical subspecialties greatly respected Dr Watt. She also indicated to the Inquiry Panel that amongst patient groups, Dr Watt was known as someone who would have been willing to prescribe a certain drug or give a more definitive diagnosis than other neurologists.

13.61 Dr Fulton mentioned Dr Watt's reticence in relation to the diagnosis of functional neurology. According to Dr Fulton, about 30% of a neurologist's practice would not have a physical basis for the disorders experienced. Although functional neurology was a developing field, she highlighted the fact that older consultants struggled somewhat with it as a distinct category. Her perception was that Dr Watt would have much preferred to have given a physical diagnosis. Reflecting on what had happened, Dr Fulton stated:

> I think, if it had been handled right, he could've been brought on board. Michael is extremely affable. Yes, he's very black and white sometimes about his viewpoints, but talking to him in the right way at the right time —. You know … through my move to stroke, when I was thinking about applying to the Ulster: such a supportive colleague. As a trainee, the learning I had from Michael —

> you know, he's a really hot neurologist in how he makes his clinical diagnoses. You know, you would be sitting in a meeting and it would be something really rare that nobody's ever even read about, let alone seen, and Michael would be on it right away.
>
> So, what changed is how people see Michael. They seem to have forgotten all of that good, and you'll be hearing a huge amount of the anger that has come as a part of the recall. But Michael was a good trainer; he was an excellent colleague. There were system failures; it's not just about Michael. I think, yes, something clearly went very wrong with him towards the end, but, I think, if he'd had the right support in the system at earlier points, that may have been prevented.

13.62 Dr Hawkins retired from practice in 2012, having been a colleague of Dr Watt for many years. In his evidence to the Inquiry Panel on 9th November 2018, Dr Hawkins commented about the consequences of pressing, what he referred to as: *"the red button"*. Having been engaged by the GMC as an expert witness, he knew what was involved and described the consequences of raising concerns about a doctor, or as he put it, *"pressing the red button"* as *"severe, extreme and taking up a lot of time and nervous energy"*. In his perception, it was either the red button or no button and that, on reflection, he felt there should be different levels of response and not just an all or one response.

13.63 Regarding the introduction of a duty of candour, Dr Hawkins accepted that it would change behaviour in a major way but would also undermine collegiality. Dr Hawkins is correct, but the system as presently operated impedes and inhibits the appropriate sharing of information to the point where patient safety is compromised. Patient safety must be the focus of governance and management. Dr Hawkins comments exemplify the inherent tension and potential difficulties which can arise when the professional and managerial models co-exist.

13.64 In relation to Dr Watt, he felt that there were, what he described as, *"flickering amber lights"*. He was asked by the Inquiry Chairman whether there were pointers about Dr Watt:

> **Mr Lockhart QC:** … As you reflect back, you say you were disappointed, you were shocked. Do you think there were pointers along the way which could have identified this at an earlier point?
>
> **Dr Hawkins:** I think, looking at it and thinking about it, I felt there were flickering amber lights, as I talked about this to others, but we have talked about the red light, the panic button. There were reviews which were systematic reviews from patient feedback [as part of the appraisal/revalidation process] and this was the system of anonymised patient feedback. I think 45 people or so who were

> went to be recruited in a systematic way … The feedback that came back on that anonymised system there were no criticisms. If there had been criticisms about a bad attitude or whatever from that system or from colleague feedback, those would have been red lights, given the complaint to the GMC and given the complaint from other sources that came to light.

13.65 The evidence received by the Inquiry further suggests that when concerns were raised, there was a reluctance to properly capture the concern, investigate it and identify whether there was any pattern of behaviour (the detail is set out in the Concerns chapter). The reasons for this are many and varied. In Dr Watt's case, a narrative developed that characterised him as being an extraordinarily hard-working and busy neurologist, probably seeing more patients than anyone else, but who was also administratively tardy and reluctant to co-operate with requirements laid down by the Trust, such as appraisal and job planning. His clinical ability was not, however, questioned by most of his colleagues. On occasion, and more especially in and around 2007 and 2012[10], this narrative seems to have influenced those charged to investigate in a manner, which diverted them from more in-depth scrutiny.

Prescribing:

13.66 As outlined in the Prescribing chapter, the evidence points again to examples of where Dr Watt was the one doctor who was the outlier in terms of prescribing a particular drug or therapy. Patterns were identified, concerns raised, and liaison groups established between clinicians, representatives of the Health & Social Care Board and delegates of the Trust. When a challenge was initiated and there was no pushback or explanation provided, the default reaction was to explain the intricacies of neurology rather than investigate, while those outside the Trust tended to be too easily re-assured. There were instances, with human-immunoglobulin, where audits had been carried out, but such scrutiny tended to be on an ad hoc and irregular basis. Occasionally, more intense budgetary pressure would have caused concerns to be expressed at even Chief Executive level, but the lack of a co-ordinated and systematic response, where roles were understood and action taken, was markedly absent. This was a system failure and an example of weak management by a reluctance to confront and resolve potentially important matters concerning a senior consultant.

10 See the comment of Dr Tony Stevens in the INI 87 case following a meeting with the parents of the Deceased in 2007 that Dr Stevens was not concerned about Dr Watt's clinical ability and his comment in 2012, when Dr Watt was being investigated under the Maintaining High Professional Standards framework, that he did not doubts Dr Watt's clinical abilities.

13.67 An index example of the problem relates to the attempts made by Dr Craig and Dr McDonnell to set up a group of specialist MS consultants to monitor the use of Alemtuzumab, a second line treatment for multiple sclerosis. There was resistance to the setting up of such a group by some of the MS consultants, including Dr Watt. The conclusion of managers seemed to be that, without consensus, the group could not be initiated or take responsibility for monitoring the prescription of this expensive medication.

13.68 Dr McDonnell made the point that not all the consultants who were specialists in multiple sclerosis, worked for the Belfast Trust. In such a scenario, neither Dr Craig nor Dr McDonnell could insist contractually on the group being established. That may be correct in relation to consultants outside the Belfast Trust, but did not apply to those including Dr Watt, who were employed by the Trust. It should not be the case that management initiatives, which are focused on patient safety, are so easily thwarted or circumvented. If the Northern Ireland health system continues to be divided into a number of Trusts, then there must be an appropriate managerial method to ensure that patient safety initiatives can be insisted upon contractually. The method of requiring consensus simply because specialists work for different Trusts, is problematic and ultimately undermines patient safety.

13.69 In any managed organisation an employer is entitled to give a reasonable instruction. If the employee fails to follow that instruction, then ultimately it can become a disciplinary issue. Dr McDonnell, in his response to the Prescribing chapter, stated that as a newly appointed Clinical Lead with no training, he had never heard of a 'reasonable work instruction' so he couldn't possibly have given one. In retrospect, he might have expected other managerial colleagues, such as the Co-Director for Neurosciences or the Service Manager, to have explained the concept to him. Dr McDonnell highlights a critical point. There is a significant disconnect between what is set out in a job description and what is required of clinicians who undertake management responsibilities, by those in the higher echelons of the Trust in comparison with the expectations of clinicians who take on such roles[11].

13.70 Dr McDonnell was not the only clinician who complained that he had not been trained. Dr Fullerton and Dr Mitchelson also made the point. It is hard to avoid the impression that because clinicians are often highly qualified and competent in their specialties, it is assumed that management can be taken on without difficulty. Finding

11 In written evidence submitted on 13th May the Belfast Trust point out that since 2016 90 clinical leaders engaged in King's Fund training, including Dr Mark Mitchelson and Dr John Craig. Mr Frank Young, Co-director of Unscheduled & Acute Care and Dr John Craig had also engaged in the NCAS 2 day case Investigation training in May 2016. It is also pointed out that as senior consultants/ managers working in a teaching hospital directing clinical teams and taking corrective action with trainees is part of day to day work and that the Trust expects them to understand the role of clinical leadership.

consensus was sometimes difficult and, as was the case with Dr Watt, consultants could work in an isolated manner without management intervention. A real problem emerges if clinicians view themselves as independent practitioners working in a shared space. Properly understanding the implications of a management model is essential if change is to be effected.

13.71 The evidence outlined in the Prescribing chapter highlights the autonomy of consultants. The prescribing protocols that were set up were often not followed by Dr Watt and, when challenges were made, they were ignored or left for long periods of time. Under the process that had been initiated regarding the prescription of Alemtuzumab, Dr McDonnell did make efforts to go through the requests made but became frustrated and exasperated when Dr Watt seemed to resent the interference. This led Dr McDonnell in an email to Dr Craig to refer to the process as a *"rubber-stamping exercise"*. Ultimately this was because management was ineffective.

13.72 The process in place made it easier to avoid the issue of an outlier's prescribing practice, as there was little connection between queries raised in the extant prescription and a refusal by the relevant panel to approve the prescription requested by the consultant. The problem that emerges when such processes are put in place is that they become a formality and falsely reassuring. Although it was seen by the neurologists as a "box ticking exercise", this view contrasted with the endorsement that Dr Craig gave to the setting up of the approval panel at its commencement where he highlighted the need for individual neurologists to stand over their prescribing.

Epidural Blood Patches:

13.73 Dr Watt clearly developed a conviction that spontaneous intracranial hypotension ("SIH") was under-diagnosed in many patients, many of whom had proved to be difficult to diagnose previously. Evidence was received from all the other consultants who practiced in the Belfast Trust and, indeed, in neurology in Northern Ireland. While there were some minor variations, all emphasised that SIH was an unusual condition, which they came across only rarely and, in some cases, on just a few instances throughout the course of their medical career. The figures obtained of the number of blood patch procedures carried out in the Belfast Trust prior to 2013 underline this contention. In 2011 there were 2 blood patch procedures. In 2013 there were 6. By 2015 this figure had risen to 115 and the following year to 162.[12] The numbers increased as a result of procedures carried out by Dr Watt in a manner, which was truly extraordinary.

12 See paragraph 37 Blood Patching Chapter.

13.74 The focus of concern for those in Neurosciences management related, however, to the utilisation of Ward 4E (the neurology ward) and the Programmed Treatment Unit ("PTU") by Dr Watt for such procedures. Although there was one meeting of consultants, which did make an attempt to question the number being carried out, there was, for the most part, an indifference to the fact that these procedures had increased so substantially. There was a puzzling lack of curiosity by consultants even though operational managers were complaining loudly of capacity problems for epidural blood patches. The synergy created brings into focus the Swiss Cheese model of system failures.[13]

13.75 The Inquiry Panel accepts that it is easier reflecting back, when the information is all obtained, to see clarity in the patterns that emerged. Nevertheless, it is still remarkable, in the view of the Inquiry Panel, that so few questions were asked, which challenged the diagnosis being made or the efficacy of the treatment being carried out. Despite questions being asked about the reason for the increase in numbers, this was never adequately considered or answered by the Belfast Trust Neurologists. The Inquiry Panel believes that this again relates, in part, to a medical culture issue. At consultant level, there was a marked reluctance to challenge and to question the views of an eminent colleague or to identify that there must be some reason for the fact that the Belfast Trust was carrying out more of these procedures than anywhere else.

13.76 The irony is that the people who noticed were not consultants. Sister Vanessa Boyd asked the critical questions at the right time. No proper answers were ever given to the queries that she raised. Ms Clare Lundy was an Assistant Service Manager, who questioned why the procedures had increased so dramatically in her email in July 2014. Nurse Anne-Marie Hunter worked closely alongside Dr Watt and became so alarmed at the proliferation of the procedure that she quietly advised certain patients to obtain a second opinion. What is conspicuous by its absence, however, is the lack of challenge or query from consultant colleagues. This was despite the fact that Dr Watt had, on 3 separate occasions, presented cases involving SIH to the Neurosciences Grand Round between 2014 and 2017.

Peer Review Teams:

13.77 An acceptance of the status quo and a failure to question the danger of a consultant working in a team of one was also conspicuous in the evidence obtained by the

13 James Reason proposed the image of "Swiss cheese" to explain the occurrence of system failures, such as medical mishaps. According to this metaphor, in a complex system, hazards are prevented from causing human losses by a series of barriers. Each barrier has unintended weaknesses, or holes – hence the similarity with Swiss cheese. These weaknesses are inconstant – i.e., the holes open and close at random. When by chance all holes are aligned, the hazard reaches the patient and causes harm.

Inquiry. When Dr Watt was left on his own in Team A, following the retirement of Dr Hawkins in 2012, there was no query raised as to why the team structure that then emerged was imbalanced. Teams B and C each had 5 consultants and all the neurologists highlighted how well and effective peer review was when working in a consultant team. At no point does it appear that anyone questioned the wisdom of Dr Watt working without meaningful peer review. The Inquiry Panel understands that Dr Watt had perhaps the largest patient load of any neurology consultant and that he was industrious to a fault, but when one stands back, the arrangements between 2012 and 2017, in terms of the in-patient team makeup, were both obvious and apparent.

13.78 It was not until a meeting with Mrs Bernie Owens the Director of Acute Services and Dr Mark Mitchelson on 9th June 2017, that Dr Watt himself raised difficulties with lone working and the problems of becoming isolated. The reality is that the management failed to identify the problem that had been in existence since 2012. This again is indicative of a culture where such fundamental questions are not routinely asked. The absence of questions being raised does not necessarily correlate with knowledge of a problem. When Dr Stephen Hunt was designated to Team A alongside Dr Watt, he asked to be placed in a different team and this was facilitated. Even the setting up of consultant teams required an external facilitator to try and secure agreement as to the personnel. Such a process merely encouraged the perception that consensus was essential.

13.79 It may well be that some consultants work better alongside certain colleagues and others prefer to work on their own. One of the main points of having consultant teams was to have the benefit of an accessible second opinion, as a form of systematised peer review. This also helped avoid aberrant practice. It appears, however, that participation in in-patient consultant teams was optional. This was an issue, which needed to be both identified and acted upon by both medical and general management.

The Independent Sector:

13.80 The culture in the independent sector was deferential to the doctors and the result was that highly relevant information was, to a great extent, inappropriately handled. The information held by the Ulster Independent Clinic regarding patient complaints should have been immediately forwarded to the Medical Director of the Belfast Trust, as Dr Watt's Responsible Officer (see the Independent Sector chapter for details). While this was the responsibility of Dr Watt to disclose during his annual appraisal, the private institution cannot avoid responsibility by simply

relying upon the obligation of the doctor. This issue must be urgently addressed to ensure that patient safety is paramount, and patterns of aberrant behaviour can be identified within the independent sector. The present independent sector culture encourages and facilitates the power and autonomy of the individual consultant.

13.81 In simple terms, people who access private healthcare believe they are attending a hospital with all the protections associated with NHS hospitals. That applies even more forcefully when NHS patients are transferred to private hospitals when Waiting List Initiatives have been sanctioned by government. However, there is already an intense and routine interplay between the private sector and the NHS. The perception has grown that often the only way to obtain a diagnosis or circumvent the impact of a 3-year waiting list is to pay to go to see a consultant privately. For many individuals and families, this will be a significant financial imposition. Patients are, therefore, entitled to expect that the standards within the private sector, in terms of both governance and patient safety, are at least equal to those within the NHS.

13.82 As discussed in the chapter on the Independent Sector, at the heart of the problem is the manner in which the independent sector has viewed itself. The present model overly focuses on providing facilities to a self-employed consultant, albeit with practising privileges. The failure to pass on relevant information to the Responsible Officer, and relying on a consultant to essentially self-monitor, caused significant problems in relation to Dr Watt. The Inquiry Panel is of the view that the approach taken, and the model adopted was a part of medical culture, which, again, does not assist or enhance patient safety.

Appraisal & Revalidation:

13.83 In the aftermath of the Dr Harold Shipman controversy, and the reports by Dame Janet Smith, there was an increased urgency to introduce measures, which would reassure the public about the competence of doctors. In the perception of the public, the system of appraisal and revalidation was the main way in which public concern was to be satisfied. In truth, however, annual appraisal was, and is, a self-reflective process carried out with the assistance of an appraiser, which was entirely dissimilar to the method of appraisal carried out by a manager in a commercial organisation or one operating outside healthcare. While revalidation every 5 years did include the trawling of certain other information, such as complaints and other local governance systems, it is reasonable to refer to revalidation as, in large part, the accumulated reflection of the 5 earlier annual appraisals. Appraisal was the main building block of revalidation.

13.84 Dr Watt was able to avoid appraisal for several years and was only revalidated in 2013 following significant examination and assistance from the then Assistant Medical Director, Dr Ken Fullerton. If one views the matter through the contractual lens, then it was the case that consultants were obliged both to carry out an annual appraisal and to also satisfy their regulator every 5 years in relation to revalidation. A failure, in normal circumstances, to carry out a contractual obligation will lead to disciplinary processes being initiated. This was not done in Dr Watt's case. Instead, there was the unedifying spectacle of others, such as Associate Medical Directors and Clinical Directors reminding and cajoling Dr Watt in a polite manner and then being ignored. Even after concerns were raised in November 2016, it would be another 12 months before Dr Watt would be appraised.

13.85 In the view of the Inquiry Panel, the reason for such courtesy and tolerance towards non-engagement was the medical culture that pertained. It was not the 'done thing' to manage the situation in a contractual way and even though annual appraisal may not have identified aberrant practice because of its emphasis on self-reflection and the time lag in the process, the absence of appraisal of itself should have given much greater cause for concern. The situation with Dr Watt was not managed properly or effectively.

The General Medical Council:

13.86 The evidence is clear that for most doctors, reference to the GMC is taken seriously, and, in fact, there is oftentimes a marked reluctance to escalate matters to a point where the GMC may be involved, as this is perceived to be a 'nuclear option'. It is not surprising that doctors working under intense pressure, are reluctant to see colleagues subjected to investigation and/or sanctions from the regulator, which may ultimately force them out of medical practice. It is perhaps for this reason where everyone knows each other, the temptation is for colleagues to exercise their own filters on information, which is given to them, or on concerns that they come across personally.

13.87 Efforts have been made by the GMC to mitigate against the effects of this problem. In Northern Ireland, an Employment Liaison Officer for the GMC has been appointed and they have an important role to play in ensuring effective lines of communication and common understanding between the regulator and health trusts. Further, Medical Directors also have the assistance of National Clinical Assessment Service, now known as Practitioner Performance Advice, to obtain advice when a problem arises. Despite these mitigations, the fact is that, in Northern Ireland, there is no

record of anyone ever being referred to the GMC for a failure to escalate a concern. The numbers in Great Britain are, for the size of the population, not much different. The culture is such that reference to the GMC is not encouraged and a failure to pass on a concern is also tolerated by the GMC.

13.88 A noticeable facet of this Inquiry was the outcome of a report made by a patient (INI 45) to the GMC in 2012. This has been carefully examined in both the chapter involving the GMC and the 2012/13 Missed Opportunities chapter. The investigation by the GMC of this complaint was inadequate and led to a false degree of reassurance being given to various bodies, including not just the GMC, but the Belfast Trust and Hillsborough Private Clinic. An examination of the investigation reveals a concerning willingness to accept the explanations provided by Dr Watt and to ignore legitimate questions raised by the patient and to wrongly categorise the complaint as relating to communication. The problem was then compounded by the failure to obtain expert neurological evidence on the questions that were being raised. The Inquiry Panel has concluded that the cultural problem of overdue deference to the doctor is also a problem for the regulator. The resultant effect is that lessons are not learned, and patient safety is not paramount.

Missed Opportunities:

13.89 The Inquiry Panel has outlined its concerns in relation to time periods, where it believes that opportunities were missed to identify earlier problems. In 2006/2007, 2012/2013 and 2016, a number of events, when taken together, revealed substantial concerns that should have been more carefully considered. The Inquiry Panel accepts that it is often the case that one incident or issue, taken on its own may not have been sufficient to alert the Belfast Trust to instigate a much more thorough investigation. It is, however, when all the information is properly collated that one can then identify a clear pattern. The normal method of proceeding was to look at matters in an isolated fashion or to place previous incidents within a specific genre, such as an administrative category, rather than looking at the complete picture. This inability to view the evidence as a whole is as a result of a number of factors, including:

(i) The culture, which pertains among senior consultants where the post of Clinical Director is often regarded as an obligation and where the expectation is, despite the terms of appointment, that matters will be kept in-house.

(ii) Doctors applying a filter to issues that are raised with them. The index example of this is when Dr Ingrid Hoeritzauer, then a registrar, raised concerns about the practice of Dr Watt and a number of cases, which called into question, in her mind, his clinical practice. While there may have been confusion as to what precisely was communicated, Dr Craig felt that he could decide not to take the matter any further. Standing back from the incident, it is clear that for any registrar to approach the Clinical Director about the clinical practice of a senior consultant was an unusual and significant event. The fact that Dr Craig did not discuss it with a colleague, or with the Medical Director, was unfortunate. If the matter had been followed up in 2013, then it could have played a role in helping establish a broader pattern of concern. The fundamental problem was that the Clinical Director felt that he did not need to do anything with the information.

Information, which should be forwarded to the Medical Director's Office by other medical institutions outside the Belfast Trust, was also a problem. The Ulster Independent Clinic received a highly relevant complaint from INI 77, which would have contributed to the assessment of initially Dr Fullerton, when he was carrying out the investigation under MHPS at a time when Dr Watt was under scrutiny at the Doctors & Dentists Case Review Meeting ("DDCRM"). Even when diagnosis was independently questioned, as was the case in 2016 when the Medical Director of the Northern Trust passed on the concerns of 3 consultants in his Trust regarding the diagnosis by Dr Watt of a patient, the approach taken was to manage the complaint and try and resolve the situation for the patient. In retrospect, this was a further opportunity to identify a pattern, which was lost.

(iii) Administrative failings were classed together, whether that was the failure to provide a medical report to an insurance company or complete an annual appraisal. The attitude taken was that these were unfortunate side-effects of a consultant with an extraordinarily busy practice, as opposed to an indication of a potential problem, which, when viewed with other complaints and concerns contributed to the perception of a doctor, who was in difficulty, not just administratively, but clinically.

(iv) The failure to record in writing important conversations. This is starkly illustrated by the absence of any documentary evidence relating to concerns about Dr Watt's diagnosis and treatment of pregnant women with epilepsy. The evidence suggests that in 2013 the Clinical Lead for Neurology at the time, Dr Jim Morrow[14], spoke to Dr Watt about this concern but no documentary evidence of that conversation (or the outcome of it) appears to exist.

14 Unfortunately, Dr Morrow was medically unfit to give evidence and, therefore, has not had an opportunity to explain what transpired.

13.90 All the incidents outlined above have been set out in detail in the specific chapters. When viewed against the background of the prevailing medical culture, they suggest a fundamental problem with existing attitudes.

Doctors & Dentists Case Review Meeting:

13.91 The DDCRM was an innovative initiative taken by the then Medical Director, Dr Tony Stevens, to bring together relevant personnel to systematically and regularly review doctors and dentists in difficulty. Throughout the relevant period, Dr Watt was separately referred to the DDCRM on 3 occasions. The Inquiry Panel accepts that time constraints would not permit a detailed review of each doctor at each meeting. A purpose of the group was to try and work through the various professional and other processes in play and try and ensure that the Medical Director was informed of developments. Mr Peter Watson, of the Medical Director's Office, was impressively proactive in following up on agreed actions taken at the meeting. Evidence suggests, however, that while the aims of the DDCRM were laudable, the sharing of information and follow up were missed. On occasion the DDCRM did not meet, or the issue somehow got overlooked. The fact that Dr Watt was not discussed by the DDCRM from May 2016, despite all that was going on, implied to the Inquiry Panel that the group did not function as planned or anticipated.

13.92 A further problem was that in the view of the Inquiry Panel the Board of the Trust relied on the DDCRM as one means by which doctors in difficulty were addressed. In reality, however, the evidence seen by the Inquiry suggests that when a doctor was in real difficulty, the DDCRM tended to fall by the wayside, as happened with Dr Watt from May 2016, when his case was not discussed at the meetings that did occur.

Conclusions and Findings:

13.93 Doctors will often reach different conclusions on diagnosis in neurology and other specialties. A problem may emerge, however, when unexplained difference is accepted as routine and commonplace. When all the instances are pieced together, a clear pattern emerges. How then can any system aid the process of pattern recognition? This remains the challenge if management is to be effective.

13.94 The Inquiry Panel was also struck with the great care that was taken by neurologists before they felt comfortable in expressing a firm opinion on diagnosis and treatment. That, of course, is understandable and laudable. This approach can, however, also

inhibit concerns being raised. The Inquiry Panel has noted that where doctors act as their own filter, significant problems can emerge. The current guidance set out in the Good Medical Practice published by the GMC obliges doctors to ensure that if a patient is not receiving basic care, they immediately tell someone in a position to act. Further, if they have concerns that a colleague may not be fit to practice, they need to ask advice from a colleague or defence body and, ultimately, they may need to formally report the matter.

13.95 While the Guidance is helpful, it leaves a wide margin of appreciation for the doctor. There is a world of difference between satisfying oneself to a standard of 'beyond reasonable doubt' as compared to a threshold for escalation based on 'reasonable suspicion'. The Inquiry Panel has formed the view that within neurology, the standard of proof required before raising a concern was higher than it should have been. It may or may not be reasonable or essential in specific circumstances to insist on seeing all the patient's notes and records. This is, however, not always possible. There are other occasions, when a doctor should be able to recognise that a mode of practice may be problematic.

13.96 Dr Watt's colleagues were all aware that he practised neurology with a different approach to both diagnosis and treatment. This was assumed to be within the range of reasonable practice. The truth is that the perception was never queried or investigated. Given that consultants largely worked with their own patients, and often had little insight into how other patients were being treated, it is to some extent understandable that their view of Dr Watt's practice was limited. Nevertheless, many registrars worked with Dr Watt, and it was there that the most significant observations were made.

13.97 It was striking that those registrars who did make efforts to raise a concern or ask a question found difficulty in doing so. The raising of a concern by a registrar with clinical management should be an obvious sign that the most intense and anxious scrutiny is required. One would hope that in most instances, careful investigation can bring reassurance, but it is at this level that critical steps must occur. Those in clinical management must carefully record the concerns, the steps taken and any conclusions reached, ensuring also that concerns are escalated. If the Medical Director takes the lead role in relation to patient safety, then, even though he or she may rely to a great extent on the expertise of a clinical lead or clinical director, a conversation must take place. There were too many examples where judgements were made prematurely and thus the system failed to operate as devised and intended.

13.98 There is little doubt that social pressure between colleagues is a material factor in a reticence to escalate. Where people work closely together, problems are all the greater. This reality tends to encourage, in the view of the Inquiry Panel, a much higher index of suspicion to be adopted. 'I can only raise this concern if I am personally satisfied beyond all reasonable doubt that my concern is legitimate. I will determine that using my own judgement and coming to my own conclusion'. It is, therefore, counterintuitive at times to have to adopt a different approach when one is deciding to escalate a concern. Once again, the conflict within the managerial model becomes apparent.

13.99 The situation was then compounded because the role of clinical leadership was not well understood, either by other doctors or by other managers. It is a fact that consultants of the same seniority, tended to view the 3-year post of clinical director as something that had to be endured for a season. There are, of course, exceptions, but it is hard to avoid the view that the managerial dimension is misunderstood, not just by clinical leaders themselves, but also by other members of the administrative hierarchy and the clinicians who are to work under the said management. This state of affairs is exacerbated by the limited consultant time[15] allocated to the role of a clinical director or clinical lead and by the fact that as soon as the words "clinical matter" are raised, administrators even at the highest level will tend to defer to the view of the clinician.

13.100 A further issue is that some nursing staff seem to be apprehensive when they perceive that something might be wrong in the practice of a doctor. The current system does not make it easy for someone within the nursing profession to raise a concern. It was striking how few nurses, who had considerable experience of neurology, had no insight into the practice of Dr Watt although the observation can be made even more strongly with consultants and registrars. Some nurses may perceive career disadvantage or a broader detriment if they decide to raise concerns about a doctor. This perception needs addressed so that all healthcare staff can work in an environment where questions can be raised without fear of sanction.

13.101 Medical professionals do know of the processes that exist. The problem is that they perceive that those processes, if enacted, cause significant repercussions and it is a fear of consequences that inhibits a culture of greater openness. The stakes are too high and need to be reduced to the point where raising a concern is not viewed as a nuclear option, but as a strengthening of patient safety and the duty of every doctor. A further problem is that a doctor will often impose their own standard of proof

15 In written evidence submitted on 13th May the Trust stated that 20% of the normal working week was devoted to the post of Clinical Director.

which requires an inappropriately high and often unreasonable threshold being reached before they believe that a concern needs to be raised.

13.102 The outworking of the cultural issue also ensures that those charged with both maintaining standards and assuring safety, are poorly sighted on the workings of the systems that they oversee[16]. The person who is best placed to oversee problems is the Medical Director, but as illustrated, the role can become almost impossible if the preliminary work is not being collated and assessed at every level.

13.103 The Inquiry Panel is fully aware that doctors find this issue not just difficult, but inconvenient and contrary to their normal approach to their own patients. Encouraging a greater culture of openness, identifying mistakes at the earliest stage, and escalating and recording concerns at every level may seem a threat to a long-established model of practice. Unless, however, this change is both embedded and embraced, the problems identified in this report will simply recur from time to time.

13.104 This chapter commenced with an acknowledgement that medical practitioners often go well beyond what is strictly required to assist their patients. Most operate from a vocational perspective and public confidence in the NHS is high, as evidenced by the public reaction to the Covid pandemic. The challenge for the medical profession is in confronting the problems of aberrant practice and ensuring that patient safety is the paramount concern. While such problems may be confined to a small percentage of medical practitioners, the effects of medical malpractice can be significant and long lasting in terms of both patient safety and public confidence.

13.105 There are currently 4 health inquiries in Northern Ireland looking into governance and patient safety concerns. The Independent Neurology Inquiry was set up following the commencement of the most extensive patient recall in Northern Ireland. As demonstrated by the accounts given in the chapter on Patients and the number of responses to the Inquiry questionnaire, the concerns and distress caused to patients because of suspected misdiagnosis or inappropriate treatment was substantial and alarming.

13.106 The same culture that engenders a co-operative collegiality and encourages a vocational approach can, albeit in limited circumstances, be an environment, where aberrant practice is missed, glossed over or even ignored. It is a reality, which presents any Inquiry considering health governance with a fundamental challenge; how does a system address the fact that the prevailing medical culture is resistant to

16 In written evidence submitted on 13th May the Belfast Trust highlighted the time invested by the Trust in strengthening local clinical governance with real time patient feedback, staff feedback and recently trainee feedback. They also state that there are now daily safety huddles in place where staff escalate any issues of concern following the Charles Vincent Model and is similar to that in high performing health institutions.

a managed system? To compound the difficulty, those who are responsible for the managed systems often do not identify the problem, except in the abstract and are often inappropriately reassured by the systems in place.

13.107 A consistent theme of this Inquiry, which runs through almost every chapter, is the prevailing influence of medical culture in determining how issues are addressed. As outlined above, the evidence obtained suggests the following problems, which undermine strong and effective management:

(i) An inappropriate deference to clinicians by those with significant managerial and administrative responsibilities. Of course, clinicians must have the necessary degree of autonomy to make clinical judgments and care for their patients, but the overlap between clinical and administrative is greater than imagined. A dichotomy existed where too many issues were regarded as "clinical" and, therefore, outside the competence of the senior administrator.

(ii) Deference from senior administrators is mirrored in the approach taken by nursing staff. Although nurses often had specialist training in particular neurological disorders, the Inquiry Panel was surprised at how few nurses noted anything amiss or questioned consultant methods. This ensured that the comparison between the few nurses who did have concerns and their colleagues, who saw or knew nothing, was all the more conspicuous. There was a perception among some nurses that raising concerns could lead to more trouble for the person concerned than for the person who is the subject of the complaint.

(iii) Confusion among some clinicians as to the managerial role of Clinical Directors and Clinical Leads. These are often 3-year posts, which are given limited programmed activity hours. The expectation would appear to be that the primary role of the post is to advocate for the particular specialty or division. While set out in the job description, there is insufficient training on the role of a Clinical Director in escalating clinical concerns to the Medical Director. The evidence obtained by the Inquiry Panel suggested that escalation to the Clinical Director of specific clinical concerns happened only rarely.

(iv) Confusion among consultant neurologists in the Belfast Trust as to the role of the Clinical Director and the Clinical Lead. The managerial model within neurology expected a consensus approach to be adopted and, in the absence of agreement, consultants believed that an approach or initiative could not proceed.

(v) The approach taken to the MHPS process, however, when concerns were raised, tended to inappropriately emphasise the critical importance of confidentiality particularly at the early stages of investigation. The emphasis on confidentiality at the initial stage made it much more difficult to obtain a complete picture or identify underlying trends. The opportunities missed concerning Dr Watt are a case in point.

(vi) As the statistics obtained from the GMC attest, rarely, if ever, do doctors face significant sanction for failing to raise clinical concerns about a colleague (see paragraph 11 above). This encourages an overall reticence to take appropriate action and the self-imposed introduction of an inappropriate threshold for concern. Doubts about a colleague can be overcome by carrying out one's own private investigation or positing that such a view was within a range of possible opinions. If one concluded internally that a concern did not reach one's own self-imposed threshold, then nothing further needed to be done.

(vii) The index example of such an approach was the interaction between the late Dr Paul Conn and Dr Donagh MacDonagh in or around 2013. Dr Conn wanted reassurance that there had been other concerns raised before giving details of his own concerns. Dr MacDonagh felt he could not take the matter further unless he was given the specific patient details. Both approaches were flawed and resulted in information not getting to the proper person.

(viii) Information is collated in a generic and indiscriminate fashion in administrative silos so that when an issue arises, significant analysis is required to synthesise relevant data and identify areas of concern. If the information had been properly analysed and available, then the Inquiry Panel believes that both Dr Stevens and Dr Jack would have taken the matter further.

(ix) In the Belfast Trust and NHS culture, patient safety, as the paramount concern, remains in the domain of ideal rather than as a practical reality. When a doctor is dealing with a patient, the vocational approach of the medical profession is to the fore and, as stated above, public regard for doctors remains extremely high. Nevertheless, a comparison with the aviation industry, where safety is clearly paramount and where lessons are learned and applied throughout the whole industry is instructive. In his best-selling book *"Black Box Thinking"*,[17] Matthew Syed states:

Aviation grapples with many safety issues. New challenges arise almost every week: in March 2015, the Germanwings plane crash into the French

17 First published in Great Britain in by John Murray (Publishers) 2015.

> Alps brought pilot mental health into the spotlight. Industry experts accept that unforeseen contingencies may arise at any time that will push the accident rate up, perhaps sharply. But they promise they will always strive to learn from adverse events so that failures are not repeated. After all that is what aviation safety ultimately means.
>
> In healthcare however things are very different. In 1999 the American Institute of Medicine published a landmark investigation. Called 'To Err is Human'[18]. It reported that between 44,000-98,000 Americans die each year as a result of preventable medical errors. In a separate investigation, Lucian Leape, a Harvard University professor, put the overall number higher. In a comprehensive study, he estimated that a million patients are injured by errors during hospital treatment and that 120,000 die each year in America alone[19].

Syed explains the reasons for the number of medical mistakes including complexity. The World Health Organisation lists 12,420 diseases and disorders, each of which requires different protocols. Scarce resources are also a factor with overworked doctors and hospitals at full stretch, as well as doctors being required to make quick decisions in pressurised environments.

The author notes however:

> But there is also something more subtle and deeper at work, something that has little to do with resources and everything to do with culture. It turns out that many of the errors committed in hospitals (and other areas of life) have trajectories, subtle but predictable patterns; what accident investigators call 'signatures'. With open reporting and honest evaluation, these errors could be spotted, and reforms put in place to stop them from happening again as in aviation. But all too often, they aren't.

13.108 Addressing the cultural problem is the most difficult of challenges for any Trust. The Inquiry Panel does not take the view that medical culture problems are likely to be confined to neurology or the Belfast Trust as the extract from *Black Box Thinking* above illustrates. The Inquiry Panel believes that the first step to changing the prevailing culture is recognising the significance of its influence and then seeking to take steps to mitigate the impact of the present dynamic.

13.109 It is recognised that changing medical culture is extremely difficult. The Inquiry Panel understands why many medical and healthcare professionals feel that the proposed introduction of a statutory duty of candour with criminal sanctions is

18 Institute of Medicine (US) Committee on Quality of Health Care in America Linda T. Kohn, Janet M. Corrigan, Molla S. Donaldson, editors. Washington (DC): National Academies Press (US); 2000.

19 Peter L Buerhaus, 'Lucian Leape on the Causes and Prevention of Errors and Adverse Events in Health Care', *Journal of Nursing Scholarship* June 2007.

hard for the profession to accept. Practitioners will point to the welter of existing regulations and policies already in place and argue that, for the vast majority of doctors and other healthcare workers, the introduction of such a punitive step will undermine collegiality and morale. The Inquiry Panel has reflected on this dilemma in some depth. No one wishes to see the development of an unhealthy culture of defensive medicine being practiced. Doctors intensely dislike a culture of blame. They point to the undermining of co-operation and team working if what they perceive as draconian action is taken.

13.110 And yet at the conclusion of all the arguments, the presenting problem remains. No change in policy or procedure alone will alter the prevailing culture unless it is accompanied by a paradigm shift in attitude. The fact is that if the present approach to raising concerns remains unaltered, the health system may resign itself to the periodic emergence of health crises which result in more patient recalls and more public inquiries. There remain too many instances where patient safety is not paramount and where concerns that emerge are not passed on or properly assessed.

13.111 The Inquiry Panel recognises that for some, this will be a painful transition, involving the abandonment of a way of doing things that has provided a degree of certainty and reassurance. Further delay will, however, only increase the extent of the current problem and the ultimate journey that must be undertaken. The airline industry, which is only in some ways comparable, is a good example of 'a no blame' culture, where the emphasis is on learning from mistakes made.

13.112 What is needed, is a substantial and radical culture change, where Health Trusts, independent providers and regulators all understand that they must oversee processes, which work in practice as well as on paper and the doctors understand that they have a duty to pass matters of concern to the relevant person. The ideal situation is for a culture to develop whenever expressions of such concern are routine and commonplace. Early discussion and investigation will often identify an issue, which can be remedied, whilst saying nothing can allow aberrant practice to develop well beyond the ambit of the initial problem.

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