Independent Neurology Inquiry

Report
June 2022

Volume 5

(Revised – 27th June 2022 at Appendix C)

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CONTENTS

GLOSSARY

Abbreviation	Meaning
ABN	Association of British Neurologists
AF	Arterial Fibrillation
AIHO	Association of Independent Healthcare Organisations
AMD	Associate Medical Director
BBC	British Broadcasting Corporation
BCH	Belfast City Hospital
BHSCT	Belfast Health and Social Care Trust
BP	Blood Patch
CD	Clinical Director
CMO	Chief Medical Officer
CNS	Central Nervous System
CPD	Continuing Professional Development
CRP	C-Reactive Protein
CSF	Cerebrospinal Fluid
CT	Computerized Tomography (Scan)
CV	Curriculum Vitae
DDCR	Doctors & Dentist Case Review
DDCRM	Doctors & Dentist Case Review Meeting
DHSSPS	Department of Health, Social Services & Public Safety
DGH	District General Hospital
DICOM	Digital Imaging and Communications in Medicine
DLS	Directorate of Legal Services
DMD	Duchenne Muscular Dystrophy
DMT	Disease modifying therapy
DOH	Department of Health
DRO	Designated Review Officer
DSU	Day of Surgery Unit

Abbreviation	Meaning
DVLA	The Driver and Vehicle Licensing Agency
EBP	Epidural Blood Patch
ECR	Electronic Care Record
EEG	Electroencephalography (test)
ELA	Employment Liaison Advisor
ENT	Ear, Nose and Throat
EP	Epidural
ER	Expert Report
FTF	Finding the facts (exercise)
FTP	Fitness to Practice
GAIN	Guidelines and Audit Implementation Network
GDC	General Dental Council
GMC	General Medical Council
GMP	The Good Medical Practice
GP	General Practitioner
HIG	Human Immunoglobulin
HPC	Hillsborough Private Clinic
HR	Human Resources
HSC	Health and Social Care
HSCB	Health & Social Care Board
HSS	Health and Social Services
IAP	Immunoglobulin Assessment Panel
ICH	Intracerebral Haemorrhage
ICO	Information Commissioner's Office
ISP	Independent Sector Providers
IT	Intrathecal (Baclofen Pump)
IVIg	Intravenous Immunoglobulin
LFT	Liver Function Test

Abbreviation	Meaning
LP	Lumbar Puncture
MAG	Medical Appraisal Guide
M&M	Morbidity and Mortality
MD	Medical Director
MDO	Medical Directors Office
MDT	Multidisciplinary Team
MDU	Medical Defence Union
MHPS	Maintaining High Professional Standards
MPS	Medical Protection Society
MR	Magnetic Resonance
MRI	Magnetic Resonance Imaging
MS	Multiple Sclerosis
MS MDT	Multiple Sclerosis Multidisciplinary Team
MS SIG	Multiple Sclerosis Special Interest Group
NCAS	National Clinical Assessment Service
NHS	National Health Service
NHSCT	Northern Health and Social Care Trust
NICE	National Institute for Health and Care Excellence
NIECR	Northern Ireland Electronic Care Record
NIMDTA	Northern Ireland Medical & Dental Training Agency
NIPAC	Northern Ireland Picture Archiving and Communication (System)
NMC	Nursing and Midwifery Council
OGD	Oesophago-Gastro-Duodenoscopy
OHS	Occupational Health Service
PA	Personal Assistant
PAS	Patient Administration System
PDP	Personal Development Plan
PHA	Public Health Agency

Abbreviation	Meaning
PTU	Programmed Treatment Unit
QMC	Queen's Medical Centre (Campus)
RANC	Rapid Access Neurology Clinics
RCP	Royal College of Physicians
RO	Responsible Officer
RPA	Review of Public Administration
RQIA	Regulation and Quality Improvement Authority
RRMS	Relapsing-remitting multiple sclerosis
RVH	Royal Victoria Hospital
SAI	Serious Adverse Incident
SEA	Significant Event Audit
SEHSCT	South Eastern Health and Social Care Trust
SHO	Senior House Officer
SIH	Spontaneous Intracranial Hypotension
TIA	Transient Ischemic Attack
UIC	Ulster Independent Clinic
VTE	Venous Thromboembolism

APPENDICES INDEX

APPENDIX A

Terms of Reference for the Independent Neurology Inquiry

Terms of Reference for the statutory Public Inquiry established to review matters related to the Neurology Service provided by the Belfast Trust

This Public Inquiry has been converted from the original non-statutory Independent Neurology Inquiry (INI). The Chairmanship and panel for the inquiry will remain unchanged from the INI.

The work will form part of a series of actions which have been initiated by the Department in response to the recall of patients. This includes work being taken forward by the Regulation and Quality Improvement Authority (RQIA) as follows:

- A review of the governance of outpatient services in the Belfast HSC Trust, with a particular focus on neurology services. This review will then be extended to cover all four remaining HSC Trusts over the subsequent 12-18 months;
- An expert review of the records of all patients or former patients of Dr Michael Watt, who have died over the past ten years; and
- A review of the corporate and clinical governance of health services delivered in the independent sector in Northern Ireland.

The clinical practice of Dr Michael Watt is being investigated by the General Medical Council (GMC) and employer led processes under Departmental Guidance on "Maintaining High Professional Standards in the Modern HPSS", it would, therefore, be inappropriate for the Public Inquiry to encroach on the GMC's remit or employer led processes. However, the Panel will consider the role of the Trust as an employer in terms of professional practice in the context of the Trust's system of Governance during the period covered by the Public Inquiry.

The Terms of Reference of the Public Inquiry remain unchanged and are outlined below:

a) In relation to the circumstances which led to the recall of patients in May 2018 (for the period from November 2016 until May 2018), to evaluate the corporate governance (with particular reference to clinical governance) procedures and arrangements within the Belfast Trust. This specifically includes the

communication and escalation of the reporting of issues related to potential concerns about patient care and safety, within and between the Belfast Trust, the HSC Board and Public Health Agency, the Department and any other areas which directly bear on patient care and safety and the general public, including an assessment of the role of the Board of the Belfast Trust;

b) To review the Belfast Trust's handling of relevant complaints or concerns, identified or received prior to November 2016, and participation in processes to maintain standards of professional practice, including appraisals. The Panel are asked to determine whether there were 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; and
c) To identify any learning points and make recommendations to the Department in relation to points (a) and (b) above. In particular to consider the application of any learning arising from the Inquiry to the framework for clinical social care governance, the current balance between problem sensing and assurance seeking in the extant system and its underpinning processes.

The Public Inquiry Review Panel will be chaired by Mr Brett Lockhart QC working together, and in partnership with Dr Hugo Mascie-Taylor.

The methodology to be used by the Public Inquiry Review Panel is outlined below:

There are 2 main phases envisaged of the Panel's work; to submit a preliminary report as soon as practicable to the Department and at that stage advise the Department as to when the final report and recommendations will be provided to the Department. Should the Panel, as part of their Review, establish any issue of concern, which they believe needs to be brought to the Department's immediate attention, then this will be done.

The Public Inquiry will be an inquisitorial inquiry. The Panel has a legitimate expectation of full cooperation by all parties involved, as affirmed by the Department, reflecting the professional duty of candour and HSC Code of Conduct. The Chair will determine how further they wish to conduct the review.

APPENDIX B

Chairperson statement in relation to Inquiry conversion from a non-statutory public inquiry to a statutory public inquiry (11 January 2021)

CHAIRMAN'S STATEMENT

As the Inquiry has now been converted from a non-statutory public inquiry to an Inquiry under the Inquiries Act 2005, I consider that it is appropriate and opportune to say something about what that means for the workings of the Inquiry and for those affected by our work.

By way of background, the Inquiry was established in May 2018 as a non-statutory public inquiry at a time when there was no Minister for Health in Northern Ireland.

At the outset of our work, I decided with Professor Mascie-Taylor, my Co-panelist, that the Terms of Reference would be fulfilled in a manner, which ensured that the voice of patients was heard. To date, we have interviewed 205 witnesses and anticipate finishing almost all of the oral evidence by the end of January 2021. There are approximately 12 further witnesses who are due to give evidence, of whom only 3 have not given evidence previously to the Inquiry. Evidence to date has been unsworn, but the Inquiry had adopted a rigorous and discursive approach to interviewing witnesses.

On 11th December 2020, the Minster for Health Robin Swann MLA, converted the Independent Neurology Inquiry from a non-statutory public inquiry to a statutory public inquiry. If the conversion had taken place at a much earlier stage of the Inquiry then I might have considered the merits of receiving sworn evidence. Having regard, however, to the advanced stage now reached by the Inquiry, I consider that it would be unreasonable and unfair for the remaining small number of witnesses to be asked to give their testimony in a different manner to those who have previously attended. Nor do I think it would be reasonable or fair to require witnesses who have given their evidence to begin the process again. This would inevitably cause extensive delay to the conclusion of the Inquiry without, in my view, altering the final Report.

It is, therefore, my intention that the Inquiry will continue with its current methodology. The approach to date can be summarised as follows:-

(i) Patients (or their relatives or carers) can provide evidence to the Inquiry in writing by completing the Inquiry questionnaire. Thereafter if any matter referred to requires further explanation or investigation the relevant individual may be invited to give oral evidence.

(ii) All witnesses are invited to attend the Inquiry on specific dates and times as communicated by the Inquiry Secretary.

(iii) All witnesses are provided with relevant documentation touching upon areas which the Inquiry wishes to explore. Witnesses are requested to provide any documentation under their control and likely to relate to the work of the Inquiry.

(iv) Where a specific document is required by the Inquiry this will be requested in writing.

(v) Extracts from the evidence of other witnesses, which is relevant to the testimony of the witness appearing is provided prior to the date for hearing.

(vi) Witnesses are entitled, but not required, to make a written statement in advance of their attendance.

(vii) Witnesses may be legally represented when they attend for hearing should they so wish, however this is not required. If a witness is unable to afford representation and in my view fairness dictates that he should have the benefit of legal advice, I will consider making an award for reasonable costs.

(viii) The questioning of witnesses is to be conducted by myself and Professor Mascie-Taylor.

(ix) A transcript of the evidence given to the Inquiry is provided to the witness at the conclusion of their evidence and opportunity is given to the witnesses for any corrections to be made before the transcript is finalised.

(x) Hearings take place in private.

(xi) Transcripts and documentary evidence will be used by the Inquiry in writing the report. I will restrict, by Order, the publication of any evidence gathered by the Inquiry.

(xii) Individuals named in the report and subject to criticism will be given an opportunity to comment prior to finalisation of the Report.

(xiii) No patient will be named in the report without their prior consent.

As a consequence of the conversion of the Inquiry to a statutory Inquiry, I can now utilise powers contained in the Inquiries Act 2005. Most significantly:

a. If necessary, I now have the power to compel witnesses to attend to give evidence to the Inquiry;

b. I can compel production of relevant documentation.

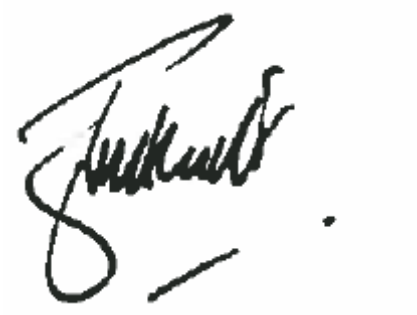
Further to the conversion, I have also decided to allow witnesses the opportunity to provide the Inquiry with a written closing statement.

In reaching my decision with regard to restricting attendance at the Inquiry hearings and not to allow publication of evidence at this late stage of our work, I have had particular regard to the matters set out in Section 19(4) of the Inquiries Act 2005 and concluded that were I not to make such restrictions at this stage of our work, the impact on those who have given their evidence to date; the delay caused to the Inquiry's work and the additional work that a retrospective publication would entail would be entirely disproportionate.

The Terms of Reference refer to a preliminary report and a final report. For the avoidance of doubt, the preliminary report will be the substantive report and will include the Panel recommendations. The reference to a final report in the original Terms of Reference was in the event that other related processes and reviews had not concluded their work by the time the preliminary report by the Panel was completed. It is not anticipated that any of the other reviews, which address matters largely outside the Inquiry's Terms of Reference, will in any way change or alter the Inquiry's preliminary report. Nevertheless, and out of an abundance of caution, the Terms of Reference have reserved to the Inquiry the ability to finally comment on any of the other processes, should they touch upon the Inquiry's Terms of Reference.

This Inquiry will make recommendations, which I believe, when implemented will

improve patient safety. I have taken the decisions above with a view to ensuring the work of the Inquiry is not delayed and those recommendations can be considered promptly by those with the responsibility for healthcare in Northern Ireland.



Brett Lockhart QC
Chairperson
Independent Neurology Inquiry

11 January 2021

APPENDIX C

Revised 27th June 2022

Royal College of Physicians' Report of the Clinical Record Review to BHSCT

Report of the clinical record review to Belfast Health and Social Care Trust

On 6, 15, 22 November and 7 December 2017

Clinical record review: Belfast Health and Social Care Trust
Final report: 26 April 2018

1.0 Introduction and background

Belfast Health and Social Care Trust contacted the Royal College of Physicians of London (RCP) on 25 April 2017 to seek an independent, external opinion regarding the clinical management of 48 neurology patients.

Dr Cathy Jack, medical director, and Mr Peter Watson, senior manager (medical director's office), discussed the background of the request with Dr Peter Belfield, Medical Director of Invited Service Reviews (ISRs) at the RCP.

Concerns were initially raised about the practice of Dr A, a consultant neurologist, with respect to the very high numbers of patients being managed with blood patching. Internal review within the Trust questioned the appropriateness of 84 out of 98 patients on the waiting list for epidural blood patching when there was a diagnosis of headache. Subsequently, several other concerns were raised about wider neurology practice, firstly by a general practitioner, and then by a colleague of Dr A. These concerns were about the care provided to six cases (hereafter called index cases) and two additional cases identified by the Trust during an early part of its review of Dr A's practice.

It was agreed that the RCP, with support from the Association of British Neurologists (ABN), would convene a panel of reviewers to provide an independent, external opinion regarding the clinical management of 48 cases selected from across the range of Dr A's practice. The sample contained the six index cases, the two further cases where concerns had been raised, and 40 cases selected (as described in the methods) from general neurology, multiple sclerosis and headache practice (details of the cases reviewed are given under section 2).

Dr A was restricted from all clinical duties, pending outcome of this review. The Trust has undertaken discussion with the General Medical Council (GMC) Employer Liaison Advisor, however no referral has yet been made to the GMC. The doctor is supported by his defence organisation, the Medical Protection Society (MPS), which was reported to agree with the Trust's decision to seek independent review of his cases. The doctor and the MPS were aware of the scope of the review and that the cases covered the breadth of the clinician's practice. The approach has also been endorsed by the Public Health Agency in Northern Ireland and the National Clinical Assessment Service.

The terms of reference for this clinical record review were:

1. To review the clinical management of the 48 patients and to make an assessment of the overall quality of care. Consideration will be given to:
    - Initial assessment of patient and diagnosis
    - The appropriateness of the patient's treatment plan and implementation of this
    - Arrangements and plans for follow up of patients
    - Communication with the patient and/or their relatives
    - Evidence of communication with colleagues
    - Clinical record keeping and documentation

In reviewing the overall care, to take into account whether this is in line with national good practice and guidelines, and/or what would be considered by the view of a body of clinical professionals in a similar situation.

2. To highlight any concerns and any lessons to be learned and if required, recommend appropriate actions.

2.0 Methodology and documents received and reviewed

The RCP was provided with the following background documentation and these have been listed below:

1. Medical records of 48 of Dr A's patients selected as described below.

The RCP recruited four specialists to act as reviewers; all are fellows of the RCP, of good standing and were proposed by the Association of British Neurologists. Each has relevant specialty background expertise in neurology. One reviewer with specialist expertise in multiple sclerosis, took the lead in reviewing the multiple sclerosis cases. A second reviewer with specialist expertise in headache and intracranial hypertension led the review of these cases. The two other reviewers led the review of the general neurology cases. A lay reviewer contributed to the discussions that took place with respect to the findings but did not review any clinical records.

The breakdown of the 48 cases selected by the Trust was as follows:

Cases reviewed	Index cases	Other cases	Total cases
Multiple sclerosis (cases A1-A12)	2 cases (A1, A2)	10 cases (A3-A12) – five were patients on first line disease modifying treatments (DMTs); five on second line DMTs	12
Headache (cases B1-B13)	3 cases (B11, B12 and B13)	10 blood patching cases (B1-B10), five of which were on a waiting list for blood patching and were deemed inappropriate by a separate review process, and five where patients had received blood patching	13
General neurology (cases C1-C11; D1-D12)	1 case (C1) 2 cases (C2, C3) where concerns had been raised internally	20 cases (C4-C11, and D1-D12) selected (exclusive of intracranial hypotension and multiple sclerosis cases) from the same general neurology clinic Dr A held on 9 May 2017.	23
		Total cases reviewed	**48**

In each case the lead reviewer considered the case notes using used a structured judgement form (adapted from the RCP National Mortality Case Record Review (NMCRR) programme[1]) to independently examine all phases of care that the patient received. These were graded by the reviewer as **1 = very poor care; 2 = poor care; 3 = adequate care; 4 = good care, or 5 = excellent care.**

The reviewers then met at the RCP on 6, 15, 22 November and 7 December 2017 to discuss and agree their findings. During these meetings, the lead reviewer presented the cases that they had considered to the other specialists and a consensus was reached. These sessions were highly participative, had an

[1] https://www.rcplondon.ac.uk/projects/outputs/national-mortality-case-record-review-nmcrr-programme-resources

appropriate degree of supportive challenge and led to the formulation of an agreed view about the case. All these sessions were chaired by the Medical Director for Invited Service Reviews (ISR), who was not one of the neurologist reviewers.

The review team also utilised a grading system originally developed by the National Confidential Enquiry into Patient Outcome and Death (NCEPOD)[2] to give an overall perspective on the quality of care provided. This considers both clinical and organisational care. In making judgements about the overall care provided to the patient, the review team gave consideration to whether this was in line with national good practice and guidelines. The form completed for each case is shown in Appendix 1.

In the context of this report it is important to note that:

- The RCP reviewers in many cases did not receive a totally complete set of patient notes. The reviewers could make observations only on the documentation provided.

- This documentary review has taken place in a vacuum with respect to the context in which Dr A was of practicing. The review team had no insight into the pressures Dr A was working under at the time, in terms of the size of clinics, booking schedules and waiting times. The review team also knew little about any support mechanisms such as a multidisciplinary team (MDT) that Dr A was part of or Dr A's role within it.

Section 3.0 of this report details the review team's key findings arising from review of the 48 cases. An assessment of the overall quality of care provided to the patient is also given. In making judgements about the overall care provided to the patient, the review team considered whether this was in line with national good practice and guidelines. Section 4.0 details the review teams conclusions against the matters outlined in Term of Reference 1.

3.0 Findings of the clinical record review reviewed

The overview of the findings of the 48 cases can be found in Appendix 2, figure 2.1 and 2.2. This section provides detailed findings with references to individual cases, where relevant.

3.1 General

Two findings were relevant to nearly all the 48 cases.

3.1.1 Record keeping

This review raises serious concerns with respect to Dr A's record-keeping. We observed a tendency for Dr A 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 contain a more detailed history. We also observed a tendency for Dr A not to properly document examinations or investigations in a way that the review team felt would be standard practice; for many of the cases, there was very limited or

[2] http://www.ncepod.org.uk/grading.html

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. This again contrasted with the case notes we reviewed which included entries from other consultants, doctors in training, and specialist nurses. This lead the review team to conclude that, there were deficiencies in Dr A's record-keeping (with the caveat that a complete set of notes was not available for every case).

3.1.2 Communication with patients

Written evidence of effective communication with patients by Dr A was lacking. The review team saw no evidence that Dr A copies his GP letters to patients. Whilst the Department of Health and Social Services and Public Safety in Northern Ireland has not made it a requirement to copy letters to patients, many clinicians would consider it to be good practice. This would be particularly so when patients are for example on complex medication regimes.

Further observations about Dr A's communication with patients are difficult, as has been previously stated, these are not well documented. However, 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 and pregnancy for patients having seizures, were not documented in the clinical record. This leads us to question whether these discussions actually took place with patients.

3.2 Multiple sclerosis (cases A1-A12)

3.2.1 **Overview of cases:** Two cases (A1 and A2) were index cases and had attracted concern from neurologists within the Trust. There were 10 selected multiple sclerosis cases, of which five were patients on first line disease modifying treatments (DMTs) and five were on second line DMTs.

3.2.1 **Overall findings:** Only two of the 12 cases were found to demonstrate good practice; three of 12 cases (including the two index cases) were rated unsatisfactory and the remainder were classified as 'room for improvement' (in four cases, there were aspects of clinical care that could have been better, and for three cases, both clinical and organisational care could have been better). The review panel noted that Dr A was prescribing all available multiple sclerosis disease-modifying therapies and therefore felt that his practice should be compared to that of a specialist multiple sclerosis neurologist working in a multiple sclerosis centre. His care of multiple sclerosis patients fell well below a reasonable standard in this comparison and, overall, it was found to be unsatisfactory.

3.2.2 **Areas of good practice:** Cases A4 and A9 were both rated 'good practice', as they were found to reflect a standard that the reviewers would expect from themselves, their trainees and their institution. Dr A demonstrated an attentive and responsive approach to patients where their multiple sclerosis was established, and he made reasonable efforts to alter treatments to improve the patient's symptoms. For example, for case A4, Dr A switched the medication prescribed for a patient in response to their intolerance of side effects. An area of good practice relates to his communication with nursing colleagues (see paragraph 3.2.12).

3.2.3 **Approach to assessment:** In several cases, Dr A demonstrated that he had arranged appropriate tests, such as an MRI scan, lumbar puncture or nerve conduction tests (cases A2, A3, A4, A6, A7). However, we identified two areas of concern with respect to Dr A's assessment of patients. First, for several of the multiple sclerosis cases, it was not evident from the documentation provided whether Dr A had carried out an examination of the patient (cases A1, A4, AS, A10). Neurological examination is important in helping to establish a diagnosis of multiple sclerosis; however, we also observed little evidence of examination of blood pressure or heart rhythm in a patient with atrial fibrillation (case A1). Second, we observed a failure (based upon the documentation provided) by Dr A to assess or document the patient's level of disability (cases A6, A10, A11, A12). There are no disability scores or qualitative assessment of disability contained in the documentation we have seen, which compounds the apparent failure to conduct a physical examination of several patients (or, if it happens, it is not documented). This should be an integral part of a systematic approach to assessing a patient's eligibility for a specific medication (case A11, for example). The assessment of disability in multiple sclerosis must be done by a neurologist, due to the expertise required in some parts of the examination.

The Expanded Disability Status Scale (EDSS) is a method of quantifying disability in multiple sclerosis and monitoring changes in the level of disability over time. It has increasingly been recognised that an annual EDSS is desirable in MS practice. This was introduced in 2002 with the requirement for an annual EDSS in the NHS "Risk sharing scheme" for prescribing beta-interferon. From 2017, annual EDSS has been a mandatory requirement of clinics prescribing any disease-modifying therapy in MS in England (under the NHS England high-cost drugs system called BluTeq). In recent times, all MS prescribing clinics in England perform annual EDSS. In North American prescribing centres, annual EDSS has been a requirement of reimbursement for some years. The review team believe this is the gold standard in MS practice. Importantly, in the absence of an EDSS, it would be desirable to document the progress of disability in other ways; we found no evidence that Dr A used any system to record progression.

3.2.4 **Approach to diagnosis:** There are several cases where we have serious concerns that Dr A has diagnosed multiple sclerosis incorrectly, either in situations where the diagnosis was very unlikely (such as in a 75-year-old person, case A1) or where the diagnosis was not supported by investigations (for instance, a person with normal MRI scans and negative cerebrospinal fluid oligoclonal bands, case A2). These breach NICE clinical guidelines for the diagnosis of multiple sclerosis (CG186).[3] For case A6, Dr A persisted with the diagnosis of multiple sclerosis, despite a consultant colleague advising that the diagnosis was very unlikely (a similar situation arose for case C3, a general neurology case). We acknowledge that the diagnosis of multiple sclerosis may be difficult. But in such cases, where the diagnosis of multiple sclerosis is made in unusual circumstances or without support from tests, we would at least expect to see a careful rationale documented in the notes. However, Dr A does not make such careful notes. Instead, the diagnosis of multiple sclerosis seems to be made casually. As a result, Dr A sometimes fails to consider alternative, more likely, diagnoses and he prescribes inappropriate, expensive and potentially toxic medication to patients.

[3] NICE (2014). *Multiple sclerosis: management of multiple sclerosis in primary and secondary care*. https://www.nice.org.uk/guidance/cg186

3.2.5 The following three cases caused us particular concern with respect to Dr A's approach to diagnosis. Case A1 concerned a patient aged 75 years; Dr A failed to demonstrate that he was open to the possibility of a misdiagnosis of multiple sclerosis as evidence accumulated to the contrary. Consequently, the patient received two doses of steroids inappropriately. Most important, the opportunity was missed to treat the most likely diagnosis of cerebrovascular disease. Case A2 concerned a patient aged 42 years; Dr A's diagnosis of multiple sclerosis cannot be correct, given the normal MRI scans and negative cerebrospinal fluid oligoclonal bands. Therefore, Dr A failed to identify the real diagnosis, which might have been clots from the heart (given the ophthalmic finding of an embolus in a retinal artery); and he also put the patient on an inappropriate, expensive, medication which would not have addressed the underlying condition (Copaxone). Case A6 concerned a patient aged 61 years; Dr A's ability to diagnose multiple sclerosis was hindered by the patient's refusal to have a lumbar puncture, nonetheless the diagnosis of multiple sclerosis is very unlikely. Yet, Dr A prescribes expensive and potentially harmful treatments only suitable for people with a definite diagnosis of multiple sclerosis.

3.2.6 **Approach to prescribing:** We identified several concerns in this area. First, we observed that Dr A often prescribes vitamin B12, without evidence of B12 deficiency, for fatigue in people with multiple sclerosis (cases A2, A5, A7). This directly contravenes instructions in NICE guideline CG186 on multiple sclerosis: 'Do not use vitamin B12 injections to treat fatigue in people with MS.'[4] These 2014 NICE guidelines are a convenient summary of good practice; however, these recommendations or standards were not novel. Vitamin B12 was known to be at normal levels in multiple sclerosis in the 1960s (Basil W, J Clin Pathol. 1965) and as early as 1970, an authoritative review by Archie Cochrane said: 'The number of prescriptions for [vitamin B 12 in] herpes zoster and multiple sclerosis seems difficult to justify' (Cochrane AL, Br J Prev Soc Med. 1971). The 1980s literature is extensive and unequivocal: by the 1990s it was clear that B12 was not deficient in MS and should not be used as a MS therapy.

3.2.7 Dr A often prescribes corticosteroids, in the form of dexamethasone, for persistent symptoms of multiple sclerosis. This is inappropriate because corticosteroids are only used for the treatment of relapses of multiple sclerosis, and as NICE guideline CG186 states: 'Do not routinely diagnose a relapse of MS if symptoms are present for more than 3 months.'[5] Even if the patients are having a relapse, the wrong form of steroids are prescribed. NICE guideline CG186 states 'do not prescribe steroids at lower doses than methylprednisolone 0.5 g daily for 5 days to treat an acute relapse of MS.' As a result of this misuse of corticosteroids, patients were exposed to potentially harmful side-effects without any prospect of benefit. As for Vitamin B12, these 2014 NICE guidelines are a convenient summary of good practice. The fact that steroids should be used only in MS relapses, and have no impact on the long term course of MS, was established by the following trials in the 1980s and 1990s: Milligan, Newcombe et al. JNNP 1987, Beck, Cleary et al. 1992 NEJM; Beck, Cleary et al. 1993 NEJM.

3.2.8 Dr A prescribed multiple sclerosis disease-modifying therapies without clearly establishing the patient's eligibility. These drugs are expensive, costing £30,000-£80,000 per patient annually,

[4] NICE (2014). *Multiple sclerosis: management of multiple sclerosis in primary and secondary care.* https://www.nice.org.uk/guidance/cg186
[5] NICE (2014). *Multiple sclerosis: management of multiple sclerosis in primary and secondary care.* https://www.nice.org.uk/guidance/cg186

and some are potentially toxic, including with life-threatening side effects. As a result, their use is carefully controlled by the licensed indication, NICE technology appraisals and by reimbursement bodies. For each drug, there are eligibility criteria. These range from relatively simple criteria, such as those for interferon-beta (two relapses of multiple sclerosis in the previous two years, and the patient is still able to walk with aids) to very complex criteria, such as those for Tysabri (two disabling relapses in the previous twelve months, and with one or more Gadolinium enhancing lesions on brain MRI or a significant increase in T2 lesion load as compared to a previous recent MRI, and the patient is still able to walk with aids). As a minimum, a multiple sclerosis neurologist is expected to carefully document that the patient has fulfilled the eligibility criteria when using each drug. This means describing the relapse frequency, the appearance of MRI scans, and the level of a patient's disability. It is clear from some of the entries in notes (cases A5 and A9), that Dr A is aware of the prescribing criteria, but he either fails to document eligibility for each patient or, worse, contemplates prescribing drugs when the patient is clearly ineligible. For instance, he considers Tysabri in case A3, simply because the patient was not tolerating her Copaxone injections. Similarly, in case A10, the patient was given Tysabri, and for case A8, the patient was given Lemtrada, in both instances without satisfying the prescribing criteria. As these drugs have serious risks (see below), this approach to prescribing is unacceptable.

3.2.9 It is not evident that the risks of multiple sclerosis disease-modifying therapies are discussed adequately with patients. Tysabri has a risk of Progressive Multifocal Leukoencephalopathy (PML), a rare and usually fatal viral disease, at anywhere between 1/50 to 1/1000 risk. In case A10, there is no documentation that the risk of PML was discussed with the patient. Lemtrada is a powerful and effective therapy, which leaves people open to potentially serious side effects for four years after each infusion; there is no indication that the risks of Lemtrada were discussed in case A8.

3.2.10 Dr A appears to be managing people with multiple sclerosis and prescribing disease-modifying therapies without the support of a multi-disciplinary team, or informal colleague support. This is not a current requirement of multiple sclerosis prescribing, but it is good practice. In England, from 2018, the potent multiple sclerosis therapies may only be prescribed by a multi-disciplinary team consisting of two multiple sclerosis neurologists and a multiple sclerosis specialist nurse.

3.2.11 **Communication with patients and their family:** This is discussed in section 3.1.2.

3.2.12 **Communication with colleagues:** Across these cases there was generally evidence of communication with colleagues, and particularly with multiple sclerosis nurses (cases A3, A4, A5, A7, A10, A12), but also with GPs and other secondary care consultants (for example, A1). There was only one case (A6) where evidence of communication with colleagues was lacking. Whilst case A10 was rated unsatisfactory overall, the review panel identified excellent communication with the multiple sclerosis nurses. Overall, Dr A makes diagnostic and management decisions in isolation, without allowing any challenge from colleagues or the multi-disciplinary team. Having made these decisions by himself, he then communicates them effectively, especially with the multiple sclerosis nurses. Better practice is when several multiple sclerosis specialists and multiple sclerosis nurses meet to discuss a case, review the scans, (then confirm the diagnosis together if needs be) and the appropriate treatment is selected by the group.

3.2.13 **Organisational issues:** We have previously highlighted (section 2) that this review was conducted without a good understanding of the context of practice for D1. However, some of the cases raised issues with respect to how the neurology service is organised. For example, for case A5 (rated room for improvement for both clinical and organisational care), there is a gap of three years when the patient was not seen. The notes do not provide any insight into the reasons why this was the case, but it is relevant to note that NICE guideline CG186 states: 'Ensure all people with MS have a comprehensive review of all aspects of their care at least once a year'.[6] The two other cases rated room for improvement for clinical and organisational care were A3 and A8. For both these cases, Dr A prescribed drugs that are associated with strong eligibility criteria (Tysabri and Lemtrada, respectively) and it was not evident that Dr A was counselling patients effectively, before consenting them, and documenting this, which is an organisational issue, as well as a clinical one.

3.2.14 We identified two further organisational issues that warrant further investigation by the Trust. First, we observed a delay in the dictation of one of Dr A's clinic letters, which occurred two months after the clinic, for case A6. Second, for case A12, we noted that Dr A had seen this patient several times in his private clinic before referring the patient to himself in the NHS. This same practice of self-referral happens several times across the 48 cases. For cases, A2, A5 and A6, the patient was seen by Dr A privately before tests were arranged under the NHS.

3.3 Headache (cases B1-B13)

3.3.1 **Overview of cases:** This sample contained three index cases (B11, B12 and B13); two of spontaneous intracranial hypotension (SIH) and one of migraine. There were also 10 selected blood patching cases, five of which were on a waiting list for blood patching and were deemed inappropriate by a separate review process, and five where patients had received blood patching.

3.3.2 Low Cerebrospinal Fluid Pressure (CSF) pressure due to spontaneous CSF leaks is a fairly rare condition in general neurological practice, with the American literature suggesting an incidence of less than 5 in 100,000 in a specialist USA tertiary headache centre[7].

3.3.3 **Overall findings:** Only 1 of the 13 cases was found to demonstrate 'good practice'; 1 was rated 'room for improvement', as aspects of clinical care could have been better, but 11 cases were rated 'unsatisfactory', including the three index cases. These cases raise concerns about Dr A's headache practice. This review was triggered by concerns regarding the frequency with which Dr A recommends epidural blood patching (EBP), and we have found his practice to be far outside of the range considered acceptable in this regard. Moreover, several of the cases raise other, serious concerns about Dr A's overall neurology practice.

3.3.4 **Areas of good practice:** Case B7 was rated 'good practice'; this was a difficult SIH case and Dr A followed the usual pathway offered to such patients. However, even here, where a correct treatment is offered for this difficult condition, Dr A demonstrated an enthusiasm for

[6] NICE (2014). *Multiple sclerosis: management of multiple sclerosis in primary and secondary care.* https://www.nice.org.uk/guidance/cg186

[7] Schievink WI (2006) JAMA ;295(19):2286-96

interventional treatments without showing consideration of the need for further diagnostic testing or MDT review. He treated this patient with four EBPs, when normally only two would be expected. There was little evidence of involvement of the MDT despite this being a complicated case that ran over many years.

3.3.5 **Approach to assessment:** Dr A demonstrates an inconsistent approach to documenting patient history. In some cases, he recorded a good history (B8, B13), but for case B2 there was little documented history; just two lines for a new patient appointment. This approach sometimes contrasted with the more detailed history documented by other doctors, including doctors in training. Similarly, there is an inconsistent approach to examination. For some cases, a neurological examination was documented well (for example, case B1, B5, B8, B9 and B13), but in other cases there is no documented examination (for example, B11 and B12). B6 was a complex case, and whilst the initial assessment of the patient was of a reasonable standard, this dropped as time went on.

3.3.6 **Approach to diagnosis:** The review team was surprised by some of the diagnoses made by Dr A. He diagnosed several patients with low pressure syndrome and embarked on treatment for Low CSF headache without first seeking any diagnostic testing to support or refute the suggested diagnosis. For example, for case B8, a letter from the Specialist Registrar documents that Dr A still believed the symptoms suggest Low pressure even though it was not postural, and the headache had settled (in other words, the patient did not show classical low pressure symptoms). For case B1, Dr A suggested a diagnosis of intracranial hypotension despite previous work ups and an atypical history of a low pressure syndrome. There is no evidence of investigation undertaken to confirm this potential diagnosis before suggesting treatment. For case B6, Dr A persevered in making changes to medication, whilst others involved in the patient's care were questioning the diagnosis. Dr A appeared to ascribe symptoms to idiopathic intracranial hypertension (IIH) but it is not evident that he conducted any active assessment to explore whether IIH was active or not (there is no record of examination of the fundus or visual function). Despite CSF pressure repeatedly being recorded as normal over several years, the patient was subject to repeat shunt revision or elective lumbar puncture, which increased the potential for post-procedure low pressure headache.

3.3.7 A recurring theme is that Dr A does not clearly articulate the diagnosis, and will often initiate treatment, leaving it unclear what condition he is managing. NICE Clinical Guideline CG150[8] states that doctors should convey to patients 'a positive diagnosis, including an explanation of the diagnosis and reassurance that other pathology has been excluded'.[9] For case B12, Dr A described a clinical syndrome that was not consistent with the symptoms the patient reported. Case B2 concerned a patient referred with Horner's syndrome. Dr A did not articulate in his notes the diagnosis or explain what the patient's symptoms may be due to. He initiated treatment, leaving it unclear as to exactly what he was treating. For case B10, there was little detail in Dr A's notes as to the nature and duration of the attacks, no investigations were detailed, and no diagnosis is mentioned. This left the reviewers unclear what condition Dr A was treating with anti-convulsant medication. For case B13, the notes are vague as to the diagnosis;

[8] NICE (2012). *Headaches in over 12s: diagnosis and management*. https://www.nice.org.uk/guidance/cg150
[9] NICE (2012). *Headaches in over 12s: diagnosis and management*. https://www.nice.org.uk/guidance/cg150/chapter/Recommendations#assessment

it is not clear what symptoms were involved, making it hard to understand why the patient was put on steroid treatment. Again, it was unclear what condition Dr A was managing. For case B11, Dr A reached a surprising conclusion of SIH based on the list of symptoms; we conclude that he pursued one symptom instead of looking at the whole.

3.3.8 There are several cases where Dr A appeared to suddenly decide upon a new diagnosis, the rationale for which is not always clear (cases B2, B4, B5, B9, B10). Again, we observed a tendency for Dr A not to cite the evidence to support the new diagnosis and his decision-making seems to flit from one condition to another. In case B5, Dr A queried whether the patient had vascular disease, but did not document any tests to explore this possibility. He diagnosed a stroke in this 24-year-old patient, despite the history and lack of risk factors, and despite a cardiologist's review. This diagnosis would inevitably impact on the patient's outlook and life choices. Dr A then shifted to a working diagnosis of SIH. For case B4, Dr A went from suggesting the potential of total abdominal hysterectomy for menstrual related headaches, to a new diagnosis of SIH – there was no documentation to explain why this new rare diagnosis was being considered, or to describe the symptoms that were suggestive of SIH. Similarly, a potential diagnosis of SIH comes out of nowhere for case B2, seven years after he began seeing the patient and, again, in the absence of any characteristic history of SIH. Cases B9 and B10 also highlight an unexplained change in working diagnosis to SIH.

3.3.9 **Approach to prescribing:** We were concerned by several instances where Dr A fails to document that the patient had been counselled regarding the impact of the medications he prescribed. For case B2, the patient was exposed to unnecessary risky anticoagulation in addition to anti-platelet therapy (thankfully without mishap). For case B5, Dr A prescribed steroids in the absence of evidence to support use of steroids in that situation, and which caused the patient to feel worse. There is some evidence that Dr A initiated therapies but gave them limited time to work before increasing the dosage or switching. The inappropriately frequent review of patients would appear to contribute to this swift switching of drugs, with Dr A setting out a management strategy, but then not giving it a chance to take effect before changing the strategy. For example, for case B9, the patient had a follow up appointment only one month after the previous appointment and then again at six weeks. The change of medication was premature and does not follow best practice or recommendations on conventional migraine prophylaxis management. For case B13, the initial assessment was reasonable but as the patient's case progressed there were multiple drug changes without a documented diagnosis, and often very rapidly. Case B4 is another example, where there were no new tests to justify the change in prescription, and little evidence that the working diagnosis was communicated to the patient.

3.3.10 **Approach to treatment:** Whilst some of the management of patients seemed appropriate, we have observed that Dr As approach to diagnosis can lead to surprising, and clinically questionable, treatment recommendations. For case B3, he recommended total abdominal hysterectomy in the absence of any data to support this, in a case suggestive of menstrual-related headache/migraine. Subsequently, Dr A listed the patient for EBP without giving any rationale, and recommended anti-coagulation. This surprising approach to treatment is illustrated most effectively by Dr A's use of EBP, as follows.

3.3.11 **Approach to epidural blood patching (EBP):** We found Dr A's approach to referring patients for EBP often lacked clinical justification and is a significant clinical concern. This treatment was pursued in several patients without a good clinical rationale or first undertaking the common

diagnostic tests for CSF suspected SIH due to CSF leak. The EBP procedure can cause harm and is not in itself a reliable diagnostic test when the clinical story is not typical of SIH. The frequent usage of EBP in several cases without rational clinical justification constitutes an unsatisfactory practice. It is common for consultant neurologists to see vague sensory symptoms and not to find anything significant and to counsel the patient appropriately. EBP should be conducted only where the syndrome of SIH has first been established.

3.3.12 For example, for case B2, Dr A listed the patient for EBP before an MRI scan had taken place to establish a suspected diagnosis of SIH; in this case the anaesthetist declined EBP appropriately. For B3, Dr A planned to do an EBP, which would not normally be first line therapy in this scenario; the approach seemed irrational and another doctor stopped the EBP from happening. For case B1, Dr A recommended EBP because the patient had unexplained sensory symptoms and fatigue, without objective signs of investigations. The patient's history alone is not suggestive of low pressure syndrome and appropriate investigation was needed. Similarly, there was no clear rationale for cases B4, B9 and B10, and for case B5, whist the history was reasonable for EBP, we would expect other tests to be conducted first. For case B8, we would have expected more caution over the second EBP, and for Dr A to have undertaken simple investigations first. For case B12, the patient became worse after having two EBPs, suggesting the approach caused iatrogenic harm. For case B6, the patient had what looked like Idiopathic Intracranial Hypertension (IIH), but we saw no evidence of fundal examination to confirm this, and Dr A proceeded to do lumbar punctures. This patient went on to need a lumbar laminectomy. The patient had been referred for invasive treatment when their condition was not necessarily active. Dr A should have involved a neuro-ophthalmologist and in the absence of this, it seemed inappropriate to proceed to lumbar puncture as a treatment.

3.3.13 For case B7, where EBP was an appropriate treatment, the approach taken was outside conventional practice. Dr A arranged for 4 EBPs, when conventional practice would have been for just two.

3.3.14 **Communication with patients and their family:** As set out previously, there was little documentation to evidence Dr A's communication with patients. We have already highlighted concern that evidence is lacking that some patients were counselled as to the impact of the treatment they were being prescribed. For case B12, we could not identify that the patient was properly consented for EBP. Similarly, for case B6, it was not evident that the patient was counselled that there is a 60% complication rate arising from shunts in patients with IIH. Later correspondence shows that this patient felt that the shunts were not doing them much good. The frequent change of management strategy reinforced the need for effective communication with patients about drug regimes, however there is little documented evidence that this happened.

3.3.15 **Communication with colleagues:** We observed that several of Dr A's letters risk leaving GPs unclear as to the comprehensive management plan. For instance, there is a lack of evidence of communication about dose escalation or how the medication should be used (cases B4, B9). The frequent change of management strategy for an individual patient again reinforced the need for effective communication with the patient's GP. There were instances where we believe Dr A should have sought advice from other neurologists on difficult cases or have discussed a case with the wider MDT; however, there was no evidence that this happened. For case B4, whilst there was referral to colleagues for procedural interventions, it is not evident that there was any

engagement of a second opinion to help clarify a unifying primary diagnosis. This was despite Dr A looking after the patient for three years, with multiple reviews, and the lack of benefit seen to any treatment. For case B6, Dr A did not refer the patient to an ophthalmologist or neuro-ophthalmologist for assessment of sight until quite late – around 5% of such patients can go blind, so it was a significant omission not to do so earlier. For case B13, Dr A paid little attention to a second opinion that raised questions about his diagnosis (echoing cases A6 and C3).

3.3.16 **Organisational issues:** We were struck by the frequency, and seemingly unnecessary, review of some patients (for example, cases B2, B9). As with the multiple sclerosis cases, we had some concerns regarding Dr A's approach to self-referral to the NHS having seen a patient privately (B5); for several other cases patients were initially seen privately and the mechanism by which they came to receive NHS care is not clear (cases B3, B10, B11, B12, B13). For case B13, we observed that Dr A's private clinic letters were much more detailed than his NHS clinic letters.

3.4 General neurology (cases C1-C11; D1-D12)

3.4.1 **Overview of cases:** We reviewed 23 general neurology cases. Of these, one was an index case, with a potential diagnosis of epilepsy; concerns had been raised internally regarding two further cases. The remaining 20 cases were selected (exclusive of intracranial hypotension and multiple sclerosis cases) from the same general neurology clinic Dr A held on 9 May 2017.

3.4.2 **Overall findings:** Only two of the 23 cases were found to demonstrate good practice. Nine of the cases were rated 'room for improvement' for clinical reasons; one was rated room for improvement for organisational reasons, and four were rated room for improvement for both clinical and organisational care. Across the sample of 23 cases, seven were rated unsatisfactory, this included one (case C2) of the two cases where concerns had been raised internally.

3.4.3 **Areas of good practice:** Cases C7 and D8 were both rated 'good practice'. For case, C7, we rated the care as good, and identified only minor points for improvement (around blood monitoring and weighing the risk of osteoporosis on a patient of that age). Similarly, for D8, we considered that the patient's headache was treated appropriately. In the section on communication with colleagues, we highlight several examples of collaborative practice.

3.4.4 **Approach to assessment:** Inadequacies in Dr A's record-keeping restricted our ability to understand the diagnosis and management plan for several of the general neurology patients. The brevity of his clinical records has impeded our ability to understand whether Dr A has examined patients (for example, cases C1, C2, C3, C9 and D7), what any examination revealed, what investigations were undertaken, if any, and what the findings of those investigations were. This inadequacy is amplified by the clinical records of other specialists (including other neurologists), doctors in training (case D12) and clinical nurse specialists (cases D1 and D6), where there is often a detailed clinical assessment and a clear management plan.

3.4.5 **Approach to investigation:** Dr A's management does not always follow NICE guidelines. NICE clinical guideline CG137, for the management of epilepsy, states that patients should have appropriate investigations, and certainly in the patients reviewed all should have been referred

for MRI scans, EEG and in some cases also telemetry.[10] For case C4, there is no evidence that an ECG or EEG was conducted, which falls short of best practice. For case C5, the patient should have been referred to a tertiary centre. For case C8, the patient should have had an EEG and maybe telemetry. For case C9, there was no onward referral to a specialist despite Dr A trying many different anti-epileptics with this patient. For case, D1, we were concerned that there is no evidence to show that this patient, who was having partial seizures, was offered a scan or EEG. For case D4, it is most likely that the patient has juvenile myoclonic epilepsy, but this diagnosis is never documented. The patient needed to have an EEG to confirm the diagnosis, which would have definite implications for treatment and prognosis. Case D2 should have been referred for an EEG and for an MRI scan, as the patient was continuing to have frequent attacks. When this patient did not respond to treatment, they were not referred for telemetry to help with the diagnosis. It is quite possible that this patient was having non-epileptic seizures, and this possibility should have been pursued. For case D5, the patient should have had an MRI scan as, clinically, a diagnosis of focal onset seizures has been made. It may be that the test was done but it was not documented in the clinical notes. D10 was having very frequent events that were thought to be seizures, and was eventually referred for telemetry, which would have been very useful, but the patient did not attend. Her non-attendance should have raised suspicion as to the underlying diagnosis.

3.4.6 **Approach to diagnosis:** The review of these records gave rise to several concerns regarding Dr A's approach to diagnosis. First, there are several cases where Dr A fails to demonstrate steps taken to accurately classify the epilepsy a patient is considered to have (see cases C8, D1, D2, D3, D5, D6, D10). Good practice would be to classify, where possible, the type of seizures, the type of epilepsy, whether generalised onset epilepsy (primary generalised epilepsy) or focal onset epilepsy, and then, if possible, the epilepsy syndrome. By taking such an approach, the clinician is better able to advise as to the most appropriate treatment and it also helps with prognostication (NICE CG137, 1.7[11]). For example, for case C9, there is no evidence of a seizure diary or any sense of the frequency of the patient's seizures, and yet five or six anti-epileptic medications are tried.

3.4.7 As for the multiple sclerosis cases, we identified one case (D12) where the approach taken by Dr A appeared to show that he had diagnosed multiple sclerosis in the patient, however this was not documented in the notes and it left the reviewers curious as to whether he had explained to the patient (or their GP) that multiple sclerosis was suspected, or indeed likely. This reflects a wider theme that we observed with the general neurology cases, which is that Dr A does not always articulate the diagnosis, which can leave it unclear what condition is being treated. For example, for case C1, there was some uncertainty over whether Dr A believed the patient suffered from epilepsy and migraine, or migraine alone. For case C10, the diagnosis is not articulated in the records, yet Dr A initiates treatment of Lamotrigine and so the implication is that Dr A thought the patient had seizures. He did not appear to answer the GP's query over whether the patient was having seizures, or address the context of alcohol abuse. The Specialist Registrar raised the possibility that these events were non-epileptic attacks, and the description in the notes suggests that this is most likely to be the correct diagnosis, but Dr A does not seem to consider this and continues to try different anti-epileptic drugs. There is eventually mention

[10] NICE (2012). *Epilepsies: diagnosis and management*. https://www.nice.org.uk/guidance/cg137
[11] NICE (2012). *Epilepsies: diagnosis and management*. https://www.nice.org.uk/guidance/cg137

of referral to telemetry, but the patient does not attend, which itself would suggest the diagnosis needs to be reviewed.

3.4.8 On some occasions, Dr A was observed to make a diagnosis in the absence of clear supporting evidence. For case C2, a diagnosis of multiple sclerosis was made, even though the patient did not meet the criteria for this diagnosis. For case, [redacted], Dr A thought the patient had epilepsy, even though the previous doctor had diagnosed non-epileptic attacks.

3.4.9 A recurring theme for the general neurology cases was a tendency not to refer to known significant co-morbidities in correspondence to the patient's GP. For case C10, there is no documentation as to how much alcohol the patient was drinking, though it was known from first contact that they had an alcohol problem. For case C6, significant issues with alcohol and substance/prescription drug misuse were not explored thoroughly on follow up visits, despite being relevant to the ongoing care of the patient's epilepsy. For other cases, the patient had mental health problems that were not referred to. For case D2, the patient was known to be experiencing mental health issues and the last clinic letter described the patient as 'intoxicated' by the medication, yet the dosage was increased further, despite the drug (Perampanel) having known psychoactive side effects. This patient was also an insulin dependent diabetic, but Dr A did not refer to this or demonstrate consideration of its relevance to their other symptoms. For case D6, the patient was under the care of the mental health team and this team had contacted D1, however there is no reference to this in the neurology notes. For case D7, the patient's significant congenital neurological disorder was often not mentioned in the neurology notes. There was a tendency for third parties, such as occupational health or other specialists, to highlight co-morbidities, which Dr A then made no reference to in his own record-keeping (cases C6, D2, D3). This led the reviewers to conclude that Dr A does not sufficiently consider the relevance and implications of significant comorbidities for the patient's management plan.

3.4.10 Approach to prescribing: We have several concerns regarding Dr A's approach to prescribing. Firstly, our concern is that Dr A has not demonstrated awareness of the NICE guidance for epilepsy with regard to documenting what patients are taking in terms of medications. Dr A's notes tend to be very brief, and with a number of the cases where epilepsy is diagnosed it was not clear what other medication patients were on, nor always the dose of the anti-epileptic drugs there were taking. Secondly, on several occasions, Dr A stopped a medication and replaced it with another, and there is nothing in the documentation to demonstrate that he discussed with the patient (or provided guidance to the GP), on how the first medication should be stopped (for example, cases D2, D3, D10). Sudden withdrawal of certain medications could precipitate continuous seizures and have serious ramifications for patients, so this omission is significant. Thirdly, when a patient was suffering a potential side effect to a medication (Perampanel), the dosage was increased (case D2). Fourth, there are instances where Dr A prescribed medication in the absence of clear indications for treatment (for case C2, Dr A embarked upon treatment for multiple sclerosis in the absence of a diagnosis of multiple sclerosis, then another treatment, which Dr A suggested would help with smoking cessation). Finally, some of the general neurology cases echoed the findings relating to the multiple sclerosis cases, where Dr A started a patient on vitamin B12 in the absence of evidence to demonstrate a vitamin B12 deficiency (cases C2, C3, D12).

3.4.11 Communication with patients and their family: In several cases, Dr A did not demonstrate that he had counselled the patient regarding the implications of medication he was prescribing.

Many of the epilepsy patients were female, of child bearing potential, and women need special consideration when prescribing anti-epileptic medication (NICE CG137, 1.15[12]). They need to be counselled about the effects drugs might have on the unborn child and given advice regarding contraception, as many drugs affect the efficacy of some forms of contraception. Such counselling was not evident in cases D3, D4, D5, D7 and C6. For case C6, there was no reference in the records to the patient being counselled regarding driving, safety and contraception, as per NICE guidance, even though Dr A thought the patient may have epilepsy. In contrast, for case C9, the patient was counselled regarding contraception, which demonstrates that Dr A has awareness of the importance of this, but only considers, or documents it, for certain patients.

3.4.12 **Communication with colleagues:** Some of the letters Dr A wrote to the patient's GP were of a reasonable standard (for example, case C1). However, for case C2, the GP wrote requesting clarification of the diagnosis, and in several letters we observed a lack of detail regarding titration (cases C4, D2) and dosage (cases C9 and D7). These letters left it unclear how the GP could undertake to issue a repeat prescription.

3.4.13 We identified several examples of collaborative practice. For case C7, we rated communication with colleagues as excellent, largely because of the support Dr A provided to the epilepsy nurse. Similarly, for C8, Dr A provided good support to the epilepsy nurse and junior doctors in the clinic when deciding on plans for the patient. Evidence of liaison by Dr A with the epilepsy nurse was also evident in cases D1, C3, C4, C9. For C3, there were multiple case conferences and Dr A worked with the pain clinic in the treatment of the patient. For C4, Dr A appears to have been supportive of the epilepsy support nurse, providing advice where this was sought.

3.4.14 In contrast, there were several cases where we could not identify evidence that Dr A had collaborated with colleagues over a patient's care. For case D6, there is no evidence of communication with the mental health team (who had written to Dr A) or any ongoing involvement with an epilepsy nurse. For case D10, there is no evidence of regular involvement of an epilepsy nurse, and for case D4, there is no mention made of referral to an epilepsy nurse for further advice regarding managing the patient's epilepsy.

3.4.15 **Organisational issues:** As for the other sets of cases, for these general neurology cases we were sometimes surprised at the frequency of patient review. For example, for case C8, the patient was reviewed every three to four months. As for previous case sets, we question the route some patients took to the NHS clinic, having first been seen privately by Dr A (cases D4 and D9). We observed a delay in issuing a letter that Dr A had dictated five days after clinic, which was typed nearly two months later (case C5). A similar typing delay occurred for case C11.

[12] NICE (2012). *Epilepsies: diagnosis and management*. https://www.nice.org.uk/guidance/cg137/chapter/1-guidance#women-and-girls-with-epilepsy

4.0 Conclusions relating to the terms of reference.

4.1 Terms of reference 1: To review the clinical management of the 48 patients and to assess the overall quality of care.

4.1.1 Overall, this review has identified significant concerns that Dr A lacks the basic disciplines of careful diagnosis, rational management, and openness to the opinions of others. Some of his management decisions are unsafe, and we conclude that his practice is unsatisfactory in a number of areas.

4.1.2 Based upon the records provided to us, the clinical reviewers conclude that Dr A is underperforming in several domains of practice and that this presents a significant risk to patients and the Trust's reputation. The clinical record review, of 48 cases, identified a degree of concern in a majority of cases. In total, 21 cases were rated unsatisfactory, which means that, in the opinion of the reviewers, several aspects of the clinical and/or organisational care fell well below the standard that the reviewers would expect from themselves, their trainees and their institutions. Of the remaining cases, 22 were identified as room for improvement, reflecting that clinical and/or organisational care could have been better. Only five cases were deemed to represent good practice; the standard we would all expect.

4.1.3 Some aspects of the unsatisfactory practice we have identified are an immediate concern for patient safety and we draw attention to the following cases: diagnosis of epilepsy in case D10, as well as the multiple sclerosis cases A1, A2 and A6. We suggest these cases are urgently reviewed by the Trust.

4.2 Initial assessment of patient and diagnosis

4.2.1 This review has identified concerns regarding Dr A's approach to diagnosis. We have observed a tendency for Dr A to make a diagnosis without clear supporting evidence, or where evidence exists that is contrary to the diagnosis he is pursuing (for example, a diagnosis of multiple sclerosis in a patient with normal examination, normal imaging and normal spinal fluid). Dr A tends to persist with a diagnostic theme and to initiate medications or treatments such as EBP 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 A often does not 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. We refer in our findings to NICE guidance for headache, namely CG150[13], which expects doctors to make a positive diagnosis once this is achieved (i.e. to communicate the diagnosis to patients).

4.2.2 Dr A has been observed making rare diagnoses (for example, multiple sclerosis in someone over 70 years of age, as well as some diagnoses of low CSF pressure due to spontaneous CSF leaks) with no obvious appreciation of how unusual these are. He has been seen to change diagnosis

[13] https://www.nice.org.uk/guidance/cg150

without apparent reflection or justification, for example, changing headache diagnosis from migraine to CSF hypotension. Often, he does not declare a diagnosis at all, as in the case of attacks for which he prescribed anticonvulsants, but did not say whether the patient has epilepsy. We identified particular concern with respect to Dr A's assessment of patients diagnosed with multiple sclerosis, and specifically regarding the absence of evidence that he had carried out an examination of the patient and a failure to document the patient's level of disability. There are several cases where we had serious concerns that Dr A has diagnosed multiple sclerosis incorrectly, and instances where the diagnosis was not supported by investigations and breached NICE guidelines for the diagnosis of multiple sclerosis.

4.3 Appropriateness of the patient's treatment plan and implementation of this

4.3.1 Dr A has demonstrated that he has a satisfactory technical knowledge of drugs and procedures. For example, his comments on multiple sclerosis drugs suggest he is aware of their side-effects and their place in national prescribing guidelines. Dr A also comes across as responsive to patients and keen to provide them with treatments to alleviate their symptoms. However, this can result in patients being prescribed medications for which the rationale is sometimes unclear and not articulated by Dr A in the clinical records. In many of the cases we have seen, there is no clear rationale for treatment choices. This is clearest in some of the cases referred for blood patching, where there is no good evidence at all to support a diagnosis of a low CSF pressure syndrome or associated CSF leak. Similarly, some of his decisions around multiple sclerosis drugs appear to be irrational.

4.3.2 We have some very serious concerns about certain of the treatments he proposed: hysterectomy for menstrual related headaches; anti-coagulation where the need for this was not established; and some treatments for multiple sclerosis without first establishing that eligibility requirements have been met. Dr A has a range of practice across a number of quite advanced therapies and there are times when referral to a specialist centre is indicated, or where the patient would have benefited from multidisciplinary discussion about their care. Dr A tends to change medication frequently; sometimes drug changes are too rapid for their slow onset of action.

4.3.3 **Multiple sclerosis:** Dr A's care of multiple sclerosis patients falls well below a reasonable standard and, overall, is unsatisfactory. We identified several concerns with his approach to prescribing, including vitamin B12 to treat fatigue; his incorrect use of steroids; and his use of disease-modifying therapies without clearly establishing the patients' eligibility, or demonstrating that the risks of these therapies have been properly discussed with patients. We are particularly concerned that Dr A appears to be managing people with multiple sclerosis and prescribing potent disease-modifying therapies without the support of a multi-disciplinary team, or informal colleague support.

4.3.4 **Blood patching:** Dr A's approach to blood patching is well outside the acceptable range and raises serious questions about his understanding of the relevant application of this therapeutic technique. The frequency with which he recommends blood patching is far beyond any practice the clinical reviewers have come across. There must be other doctors at the Trust who are involved in blood patching and this may give rise to questions about their approaches to the use

of this treatment. We have not seen evidence to suggest that Dr A has reflected on the level of requests he has made for blood patching, or that it is far outside the accepted range.

4.3.5 **Epilepsy:** Based on the records reviewed, Dr A often falls short of reasonable expectations for the management of epilepsy patients. Rarely is the epilepsy syndrome defined, often there is inadequate information as to how drugs are to be introduced or withdrawn, there is no mention of driving advice, and rarely is counselling documented regarding the side effects antiepileptic drugs might pose for women of child bearing potential. These practices fall short of national guidelines. The diagnosis of epilepsy should be reviewed in some patients as it is quite possible they are having non-epileptic seizures.

4.4 Arrangement and plans for follow up of patients

4.4.1 We know little about Dr A's context of practice and how much pressure he is under (for example, how many patients he sees in clinic), and whether there are organisational issues that put pressure on his clinical approach. He appears to see a number of his patients for follow up with an increased frequency that we find surprising. Lastly, if all the general neurology cases provided to us were from a single half-day outpatient clinic, it is our view that this would be an unmanageable clinic load.

4.5 Communication with patients and their family

4.5.1 As highlighted earlier (paragraphs 3.1.2, 3.3.14, 3.4.11), we have not found evidence that Dr A copies his GP letters to patients, which we regard as good practice. It is difficult to make further observations regarding his communication with patients, as little is written about it in the notes. The Trust needs to explore further Dr A's communication with patients. This review raises questions about whether certain patients were counselled adequately, for example regarding aggressive or risky treatments, or with respect to driving and pregnancy for patients having seizures.

4.6 Communication with colleagues

4.6.1 It is not evident that Dr A is corresponding clearly and effectively with GPs. This is particularly important in the context of some of the medications he is prescribing and the frequency with which he changes the management strategy.

4.6.2 The evidence with respect to collaboration with other colleagues is mixed. There are occasions when the documentation indicates that Dr A 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 care of patients and Dr A 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 A seems to work in isolation to his colleagues, with little input from other neurologists.

4.7 Clinical record keeping and documentation

4.7.6 We highlighted in the method section (section 2) that, in many cases, we did not appear to receive a complete set of patient notes. Therefore, we have made observations only on the documentation provided. That said, the review has raised very serious concerns with respect to Dr A's record-keeping. We have observed a tendency for Dr A to document little by way of patient history, examinations or investigations, and diagnosis. His approach often contrasts markedly with that of other clinicians whose notes were included in the documentation.

4.7.7 We have identified in a very small number of cases, delays in typing and issuing dictated letters. These delays were not insignificant, being two months. This may not reflect on Dr A's practice directly, but is an issue that the Trust needs to consider.

4.7.8 We have also highlighted Dr A's practice of self-referral of patients from his private clinic to his NHS clinic, which happens several times across the 48 cases. The reviewers question this arrangement, particularly in light of the perceived deficiencies we have drawn attention to in Dr A's practice, and his record-keeping.

5.0 Recommendations

Term of reference 2: To highlight any concerns and any lessons to be learned and if required, recommend appropriate actions

For immediate action (within six weeks):

a. In light of the very serious concerns we have highlighted, the Trust should further discuss this case with NCAS and/or the GMC Liaison Advisor, which may lead to formal referral. Dr A's full restrictions on clinical practice should remain in place whilst these matters are ongoing.

b. The Trust should communicate with the responsible officers of any private organisation that Dr A works, and they must be made aware of the conclusions arising from this review. This recommendation will help protect patients.

c. We recommend that the Trust undertakes further scrutiny of Dr A's practice in these three specific areas:

   I. The Trust should review Dr A's multiple sclerosis patients (and particularly A1, A2 and A6), to establish whether the diagnosis is correct and in light of this, any implications for their treatment.
   II. The Trust should review case D10, to establish whether the diagnosis of epilepsy is correct and considering this, any implications for this patient's ongoing treatment.
   III. The Trust should review all patients where Dr A has recommended EBP, to establish whether the diagnosis is correct and considering this, any implications for their ongoing treatment.

d. In cases deemed unsatisfactory, the Trust should consider its duty of candour to those patients with respect to the care they received.

e. We recommend that the Trust ensures that Dr A is offered appropriate support in light of this review and the actions that follow.

For short-term action (0-6 months):

f. In addition to c), the Trust should risk stratify the remainder of Dr A's outpatients and systematically ensure their review. The review should consider whether the diagnosis is secure; that a proper management plan is in place; and that prescribing is appropriate. This is in line with our letter of 20 December 2017 (appendix 3).

g. The Trust should establish an MDT meeting at which all recommendations for disease-modifying therapies for MS patients are discussed.

h. The Trust should review the role played by the epilepsy nurse for patients newly diagnosed with epilepsy. There should be a protocol setting out the areas that the epilepsy nurse will counsel every new patient about, including the implications of medications for pregnancy and contraceptive issues and driving issues.

For medium term action (6-12 months):

i. The findings of this clinical record review raise fundamental questions about clinical governance, mechanisms for local scrutiny and Trust oversight. We therefore recommend that a full-service review of the neurology service is carried out on site.

j. The Trust should have a clear protocol for referral for blood patching and there should be scrutiny of other clinicians at the Trust who are involved in providing this treatment.

The RCP requests details of an action plan to check progress on these recommendations at six months.

Appendix 1

Review of patient notes	
Case type:	Neurolo

Brief background summary
[e.g. gender/age/co-morbidities of patient/presenting condition/operation/outcome/any other relevant factual information from the notes. As the report needs to be understood by a lay person it is helpful not to use medical shorthand and to explain any terminology that may need it.]

Initial choice of treatment options/management plan (investigations, prescribing skills etc)

Click here to enter text.

Please rate the care received by the patient during this phase.
1 = very poor care 2 = poor care 3 = adequate care 4 = good care 5 = Excellent care

Ongoing care and treatment plan (investigations, prescribing skills, care during stay, evidence-based treatment, decisions regarding patient's treatment plan and implementation of this)
Click here to enter text.

Please rate the care received by the patient during this phase.
1 = very poor care 2 = poor care 3 = adequate care 4 = good care 5 = Excellent care

Communication with patients and their family (sharing of information, discussion and agreement on management plans etc)
Click here to enter text

Please rate the care received by the patient during this phase.
1 = very poor care 2 = poor care 3 = adequate care 4 = good care 5 = Excellent care

Colleagues – Evidence of communication with colleagues including delegation, including multi-disciplinary working, referrals etc)
Click here to enter text

Please rate the care received by the patient during this phase.
1 = very poor care 2 = poor care 3 = adequate care 4 = good care 5 = Excellent care

Clinical record keeping
Click here to enter text.

Please rate the care received by the patient during this phase.
1 = very poor care 2 = poor care 3 = adequate care 4 = good care 5 = Excellent care

Any other issues identified from clinical record review
Click here to enter text

Please rate the care received by the patient during this phase.
1 = very poor care 2 = poor care 3 = adequate care 4 = good care 5 = Excellent care

Reviewers' comments
We are interested in comments about the quality of care the patient received at each phase of care, and whether it was in accordance with current good practise (for eg, your professional standards or your professional perspective). If there is any other information that you think is important or relevant that you wish to comment on then please do so.

Clinical Reviewer's overall perspective on quality of care (please mark X in the relevant box)

Good practice - a standard you would accept from yourself, your trainees and your institution.
Room for improvement: aspects of clinical care that could have been better.

Room for improvement: aspects of organisational care that could have been better.

Room for improvement: aspects of both clinical and organisational care that could have been better.
Unsatisfactory: several aspects of clinical and/or organisational care that were well below that you would accept from yourself, your trainees and your institution.
Insufficient information available to make an assessment of quality of care.

Appendix 2

Figure 2.1 Summary totals

Summary	
A1-A12	
Good practice	2
Room for improvement - clinical	4
Room for improvement - organisation	0
Room for improvement – both clinical and organisational	3
Unsatisfactory	3
Insufficient information	0
Total	**12**
B1-B13	
Good practice	1
Room for improvement - clinical	1
Room for improvement - organisation	0
Room for improvement – both clinical and organisational	0
Unsatisfactory	11
Insufficient information	0
Total	**13**
C1-C11	
Good practice	1
Room for improvement - clinical	4
Room for improvement - organisation	1
Room for improvement – both clinical and organisational	2
Unsatisfactory	3
Insufficient information	0
Total	**11**
D1-D12	
Good practice	1
Room for improvement - clinical	5
Room for improvement - organisation	0
Room for improvement – both clinical and organisational	2
Unsatisfactory	4
Insufficient information	0
Total	**12**

Figure 2.2 Broken down case by case

RCP no.	Case type	Additional notes	NCEPOD grading
A1	MS	Index case	Unsatisfactory
A2	MS	Index case	Unsatisfactory
A3	MS	1st line DMT	Rfi- both
A4	MS	1st line DMT	Good practice
A5	MS	1st line DMT	Rfi- both
A6	MS	1st line DMT	Rfi - clinical
A7	MS	1st line DMT	Rfi - clinical
A8	MS	2nd line DMT	Rfi- both
A9	MS	2nd line DMT	Good practice
A10	MS	2nd line DMT	Unsatisfactory
A11	MS	2nd line DMT	Rfi - clinical
A12	MS	2nd line DMT	Rfi - clinical
B1	SIH	Blood patching case deemed NOT appropriate by Dr C	Unsatisfactory
B2	SIH	Blood patching case deemed NOT appropriate by Dr C	Unsatisfactory
B3	SIH	Blood patching case deemed NOT appropriate by Dr C	Unsatisfactory
B4	SIH	Blood patching case deemed NOT appropriate by Dr C	Unsatisfactory
B5	SIH	Blood patching case deemed NOT appropriate by Dr C	Unsatisfactory
B6	SIH	Blood patching case completed by Dr A	Unsatisfactory
B7	SIH	Blood patching case completed by Dr A	Good practice
B8	SIH	Blood patching case completed by Dr A	Rfi - clinical
B9	SIH	Blood patching case completed by Dr A	Unsatisfactory
B10	SIH	Blood patching case completed by Dr A	Unsatisfactory
B11	SIH	Index case	Unsatisfactory
B12	SIH	Index case	Unsatisfactory
B13	SIH	Index case	Unsatisfactory
C1	General Neurology	Index case	Rfi - clinical
C2	General Neurology	Issue raised internally re sativex for smoking cessation	Unsatisfactory
C3	General Neurology	Issues raised internally re documentation and patient follow up	Rfi- both
C4	General Neurology	Clinic date selected 9 May 2017	Rfi - clinical
C5	General Neurology	Clinic date selected 9 May 2017	Rfi- both
C6	General Neurology	Clinic date selected 9 May 2017	Unsatisfactory
C7	General Neurology	Clinic date selected 9 May 2017	Good practice

[redacted]

C8	General Neurology	Clinic date selected 9 May 2017	Rfi - clinical
C9	General Neurology	Clinic date selected 9 May 2017	Unsatisfactory
C10	General Neurology	Clinic date selected 9 May 2017	Rfi - clinical
C11	General Neurology	Clinic date selected 9 May 2017	Rfi - organisational
D1	General Neurology	Clinic date selected 9 May 2017	Rfi - clinical
D2	General Neurology	Clinic date selected 9 May 2017	Unsatisfactory
D3	General Neurology	Clinic date selected 9 May 2017	Unsatisfactory
D4	General Neurology	Clinic date selected 9 May 2017	Rfi - clinical
D5	General Neurology	Clinic date selected 9 May 2017	Rfi - clinical
D6	General Neurology	Clinic date selected 9 May 2017	Rfi- both
D7	General Neurology	Clinic date selected 9 May 2017	Unsatisfactory
D8	General Neurology	Clinic date selected 9 May 2017	Good practice
D9	General Neurology	Clinic date selected 9 May 2017	Rfi- both
D10	General Neurology	Clinic date selected 9 May 2017	Unsatisfactory
D11	General Neurology	Clinic date selected 9 May 2017	Rfi - clinical
D12	General Neurology	Clinic date selected 9 May 2017	Rfi - clinical

Appendix 3

Royal College of Physicians

Invited Service Reviews
Royal College of Physicians
11 St Andrews Place
Regent's Park
London NW1 4LE
Tel: +44 (0)20 3075 1237
Email: ISR@rcplondon.ac.uk
www.rcplondon.ac.uk

Dr Cathy Jack
Deputy Chief Executive/Medical Director
Belfast Health and Social Care Trust
BY EMAIL

20 December 2017

PRIVATE AND CONFIDENTIAL

Dear Dr Jack,

I am writing to you to provide you with an update on the review of 48 clinical records for the Belfast Health and Social Care Trust, the medical specialty is neurology.

The clinical reviewers have now completed their review of all the medical records and are in the process of bringing together their findings and conclusions.

This has been a lengthy but rewarding process. The Association of British Neurologists (ABN) and their reviewers have all been excellent in supporting this review.

Once the report is drafted it will go through a quality assurance process and this will involve it being reviewed by senior college officers and a manager, a lay reviewer and a representative of the ABN. With this in mind, we aim to have the report with you for the end of February/March 2018.

In the meantime, based on the preliminary findings we would consider it to be appropriate for the restrictions to remain in place for Dr A's clinical practice, both in the NHS and privately. Dr A's colleagues should continue to review and manage his patients. In addition to this, we feel that there should be a particular focus on patients on disease modifying therapies for multiple sclerosis, similar to that described of those patients on the waiting list for blood patching.

If helpful, we would be happy to discuss progress with you in the New Year. Please contact the ISR team and who can make arrangements for this.

Yours sincerely,

Dr Peter Belfield
Medical Director for Invited Service Reviews

APPENDIX D

Inquiry Questionnaire

INDEPENDENT NEUROLOGY INQUIRY

Questionnaire

Personal Contact Details	**Section 1**
You had a concern and you raised it at the time.	**Section 2**
You had a concern but did not raise it at the time.	**Section 3**
You are responding as an organisation.	**Section 4**
Additional Information	**Section 5**
Sharing Information, Checklist & Signature	**Section 6**

THE CLOSING DATE FOR THE RECEIPT OF QUESTIONNAIRES IS

7 DECEMBER 2018

If you require assistance completing this questionnaire or using the guide to questionnaire, please telephone

0300 200 7829

A guide to the questionnaire is enclosed and you are strongly advised to read the guide. As you complete the questionnaire you will see references to headings contained within the guide. These references provide you with information to assist you in completing the questionnaire. We also have a Frequently Asked Question (FAQ) section of the website https://neurologyinquiry.org.uk/patients-and-family-members.

This questionnaire will be considered by the Inquiry to gain information from you about your experience of Neurology Services. It may look daunting, but it has been broken down into a number of sections. You will only need to answer a small number of questions and most people will only complete one section relevant to their experience.

The work of the Inquiry is independent of all other organisations and that includes healthcare providers, regulators and government departments. The Inquiry will exercise care in protecting any personal information provided to it. We will not be publishing completed questionnaires.

SECTION 1 – PERSONAL CONTACT DETAILS

We encourage you to fill out your personal details in the box below as it will increase your potential input to the Inquiry. If you wish, however, you may complete the questionnaire without providing us with those details. Please read our **Privacy Notice** to understand what we do with the information you provide to us.

If you do provide your personal details, please tick this box to confirm you have read the information section in the Guide entitled '**Personal Details'**. ☐

If you do not provide your personal details, please tick this box to confirm you have read the information section in the Guide entitled '**Choosing not to provide personal details'.** ☐

NAME:	
ADDRESS:	
TELEPHONE NUMBER:	
EMAIL:	

Are you completing this questionnaire as a -

- Patient or former patient ☐
- Relative of a patient or former patient* ☐
- Someone else (please state your role) ☐

*<u>For relatives of patients/ former patients</u>: please tick the following box to confirm that you have the express authority of the patient to engage with the Inquiry and provide information relating to their care and treatment. ☐

<u>For Relatives of Deceased Patients</u>: If the patient is deceased, please tick the following box to confirm that you have discussed providing information concerning the deceased patient with other relatives and that no objection was raised. ☐

Please complete the table below to detail when you accessed neurology services.

From (please insert date)	To (please insert date)	Location (e.g. Royal Victoria Hospital)

Continue on a separate sheet if necessary

Please read the options in the table below and then go to the relevant section. Everyone should complete Section 1 and, if you had a range of concerns that cover more than one section then complete all the sections that apply to you. When you have completed all section(s) please proceed to Section 6 and sign the completed questionnaire.

You had a concern and you raised it at the time.	**Section 2**
You had a concern but did not raise it at the time.	**Section 3**
You are responding as an organisation.	**Section 4**
Additional Information	**Section 5**
Sharing Information, Checklist & Signature	**Section 6**

SECTION 2 – YOU HAD A CONCERN AND YOU RAISED IT AT THE TIME

Note Please refer to Page 8 of the Guide entitled Completing Section 2.

2.1 **Please provide details of your concerns?**

2.2 **When did you raise these concerns or make a complaint?**

2.3 **Who did you raise the concerns with or make a complaint(s) to?**

2.4 **Did you raise your concerns or complaints verbally or in writing?**

Tick all that apply.

Verbal	
Written	
Email	

2.5 **If you made the complaint or raised your concerns in writing, can you provide copies of the correspondence?**

2.6 **Did you receive an acknowledgement or a response to your complaint? If so, can you provide copies?**

2.7 **What was the outcome?**

Additional sheets can be attached

SECTION 3 – YOU HAD A CONCERN BUT DID NOT RAISE IT AT THE TIME

Note Please refer to Page 9 of the Guide entitled Completing Section 3.

3.1 **Please outline what your concerns were?**

3.2 **Please explain why you did not raise your concerns at the time?**

3.3 **Did anything prevent you from raising your concerns?**

Additional sheets can be attached

SECTION 4 - YOU ARE RESPONDING AS AN ORGANISATION ON BEHALF OF A GROUP OF INDIVIDUALS

Note For anyone other than patients or family, with information relevant to this Inquiry. Please refer to Page 9 of the Guide entitled Completing Section 4.

4.1 **Please outline what your concerns were?**

4.2 **Please explain why you did not raise your concerns at the time?**

4.3 **Did anything prevent you from raising your concerns?**

Additional sheets can be attached

SECTION 5 - Additional Information

5.1 Please provide any additional information which you feel will be of relevance to the Inquiry.

Additional sheets can be attached

SECTION 6 – SHARING INFORMATION

The Inquiry may consider that the information you have provided is more relevant to one of the other organisations carrying out a review or investigation as detailed in the guide under the heading “other related reviews”. Would you be content for the Inquiry to pass on this information to the relevant organisation?

Yes, I would be content for the Inquiry to share the contents of my questionnaire with the other relevant organisations referred to above. ☐

Or

No, I would NOT be content for you to share the contents of my questionnaire with the other relevant organisations referred to above. ☐

Please note that in some very limited circumstances it may still be necessary for the Inquiry to share the information you have provided with another organisation. Where this is the case, we will contact you further to discuss this and take all reasonable steps to protect your privacy and personal data.

Completed Questionnaire Checklist & Signature

I have enclosed the following: -

Completed questionnaire. ☐

Supporting information, such as copies (not originals) of correspondence. ☐

Additional sheets, where the space wasn’t sufficient to answer questions. ☐

Signed _____ Date __/___/2018

Intentionally Blank – Use Sheet if required

Intentionally Blank – Use Sheet if required

APPENDIX E

Inquiry Guide to the Questionnaire

Guide to the Neurology Questionnaire

This guide provide an explanation of the Inquiry and its work, and provides guidance as to how you can share relevant information.

The Inquiry is independent from all other organisations including government departments, regulators and healthcare providers. The Inquiry encourages you to assist it by engaging with its work.

The Inquiry invites written contributions to be submitted by 7 December 2018 and details as to how you can respond are set out in the following pages.

If you require this guide in a different format such as large print, braille, or a language other than English please contact 0300 200 7829. If you require help or support in completing the questionnaire please see the section in this guide under the heading “Help and Support”.

Contents

Background

The Independent Neurology Inquiry ("The Inquiry") wishes to receive information from the public to assist with its work. We are particularly keen to hear from patients and their family members regarding concerns or complaints that they may have had in relation to Neurology Services. The Inquiry is interested in Neurology Services provided both by both the NHS and the private sector. Whether or not you acted on any concerns should not prevent you completing the questionnaire.

We also welcome comment from anyone else who may have had concerns regarding Neurology Services, for example, those working in or alongside the health service.

The following content is intended to help you understand the work of the Inquiry and to provide you with information relating to the questionnaire, so that you can make an informed decision as to whether and how you wish to respond. We are also keen that you provide information, which is of use to this Inquiry in fulfilling its remit. For this reason, on the following pages, you will find an explanation of what type of information we are seeking.

Why the Inquiry was established

On 10th May 2018 Richard Pengelly, Permanent Secretary for the Department of Health, announced his decision to establish an Independent Inquiry. This followed concerns being raised relating to the Belfast Health & Social Care Trust's governance procedures in respect of patient care and safety, specifically within Neurology Services. The Terms of Reference are available on the Inquiry website at – https://neurologyinquiry.org.uk/sites/ini/files/terms-of-reference-for-the-independent-neurology-inquiry.pdf

What this Inquiry is investigating

The Inquiry is investigating whether appropriate action was taken in light of the information that was known, or ought to have been known, by those with responsibility for decision making or oversight. At the end of the Inquiry's work it is hoped that recommendations and learning points can be identified.

The Inquiry is independent of all other organisations and is of an inquisitorial nature.

The Inquiry Panel is chaired by Mr Brett Lockhart QC, who is a senior barrister, and Professor Hugo Mascie-Taylor who is a qualified medical doctor with significant expertise in clinical governance.

The work of the Inquiry

The work of the Inquiry is to review the events which led to the Belfast Trust initiating a recall of neurology patients in May 2018 and to consider issues such as:

- whether the Trust's investigations were sufficient;
- whether the steps taken were appropriate;
- whether relevant organisations were adequately performing their function; and
- whether alternative steps could, or ought to, have been taken at an earlier stage.

The Inquiry's investigations will consider the corporate decision making, including the clinical governance procedures and arrangements within the healthcare system and the escalation and reporting of concerns relating to patient care and safety.

It is likely that these investigations will result in the Inquiry reviewing the role and input of various organisations including the other Health and Social Care Trusts, the Health and Social Care Board, the Public Health Agency, the Department of Health, the Regulation Quality and Improvement Authority ("RQIA") and the independent care providers.

What the Inquiry is not doing

To avoid any misunderstanding the Inquiry wishes to make clear what it is **not** doing:

- We are not making decisions on the clinical practice or employment status of Dr Michael Watt, Consultant Neurologist;
- We are not responsible for the recall process;
- We are not involved in any compensation scheme for anyone who may be dissatisfied with the Neurology Services they have received.

Other related reviews

It is also important to explain that there are a number of other reviews and investigations currently ongoing and relating to either Neurology Services or arising out of the same circumstances, which led to the Inquiry being commissioned.

Whilst some of the reviews and investigations may overlap with the work of the Inquiry, and some of their outcomes may be of interest to the work of this Inquiry at a later stage, the work of the Inquiry is distinct from, and independent of, the other reviews.

An overview of the purpose of the other reviews and investigations is set out below together with details of the organisation responsible for each of the review/investigation. In the event that the Inquiry receives information which is relevant to one of the matters listed below it may be necessary to forward the information you provide on to the relevant organisation.

Public Health Agency and the Regional Health and Social Care Board:

- The recall of Dr Watt's neurology patients - This process is being carried out by the Belfast Trust and is being overseen by the Public Health Agency and the Regional Health and Social Care Board. Any concerns or issues in respect of the recall process should be addressed to –

Public Health Agency
12-22 Linenhall Street
Belfast. BT2 8BS
Tel: 0300 555 0114
Web: http://www.publichealth.hscni.net/

Health and Social Care Board
12-22 Linenhall Street
Belfast. BT2 8 BS
Tel: 0300 555 0115
Web: http://www.hscboard.hscni.net/

Belfast Health and Social Care Trust:

- Investigation into the clinical practice of Dr Watt during the course of his employment - This process known as "Maintaining High Professional Standards" is being carried out by the Belfast Trust as the employer of Dr Watt

and any information you wish to provide in respect of this investigation should be addressed to the Belfast Health and Social Care Trust.

Belfast Health and Social Care Trust
Trust Headquarters
A Floor
Belfast City Hospital
Lisburn Road
Belfast. BT9 7AB
Email: info@belfasttrust.hscni.net
Tel: 028 9504 0100
Web: http://www.belfasttrust.hscni.net/

General Medical Council (GMC):

- An investigation into the professional conduct of Dr Watt – This investigation is being conducted by the General Medical Council.
  3 Hardman Street
  Manchester.
  M3 3AW

Regulation and Quality Improvement Authority (RQIA):

- A review of the governance of outpatient services in the Belfast Trust with a particular focus on neurology service - This review is being conducted by the RQIA and any concerns or issues should be addressed to the RQIA.

  The Regulation and Quality Improvement Authority,
  9th Floor Riverside Tower
  5 Lanyon Place
  Belfast. BT1 3BT
  Email: info@rqia.org.uk
  Tel: 028 9536 1111
  Web: https://rqia.org.uk/

- An expert review of the records of all patients or former patients of Dr Watt who have died over the past ten years - This review is also being conducted by the RQIA and any concerns or issues should be addressed to the RQIA.

- A review of the corporate and clinical governance of health services delivered in the independent sector in Northern Ireland - This review is also being conducted by the RQIA and any concerns or issues should be addressed to the RQIA.

Department of Health:

- Regional Review of Neurology Services – The Department of Health announced on the 31 July 2018 that work will commence on the review of neurology services covering all neurology specialities. This Departmental review is unrelated to the Inquiry. Any queries in relation to this Departmental review should be addressed to the Department of Health –

  Department of Health
  Information Office
  C5.20, Castle Buildings
  Stormont
  Belfast. BT4 3SQ
  Tel: 028 9052 0500
  Email: webmaster@health-ni.gov.uk
  Web: https://www.health-ni.gov.uk/contact

Information of relevance from the public

The Inquiry is specifically interested in concerns or complaints raised relating to patient care and safety within Neurology Services and it is in this area that we wish to receive input from the public.

The questionnaire is specifically designed to enable you to provide the Inquiry with details of any such concerns or complaints. The questions posed have been carefully worded to help ensure that the information sought falls within the remit of the Inquiry.

It is clear to the Inquiry that the more information it obtains about concerns or complaints relating to Neurology Services (including in respect of individual Consultant Neurologists), the better placed it will be to fulfil its remit. We are therefore anxious that anyone who had concerns, even if they were not communicated, engages with the work of the Inquiry by completing the questionnaire.

Your input

Your input can make a difference to the work of the Inquiry. You do not have to complete all the questions, but we would encourage you to complete all those that are relevant to you. Section 1 asks you for your personal details and information about where and when you (or your relative) was receiving neurology care.

If you are providing information in relation to a deceased relative you should discuss the position with other relatives and agree in advance that there are no objections to information being shared with the Inquiry. There is a box or boxes to tick to confirm that you have the necessary agreements/permissions.

Completing Section 2

This section of the questionnaire allows you to provide information relating to any concerns you raised in the past relating to Neurology Services. You should complete this section if you raised concerns regardless of whether you did this formally or informally. Please provide as much information as necessary and attach any additional sheets if required.

Where you have documentation relating to the information you have provided (for example if you sent a complaint letter or kept notes of discussions or telephone calls), please attach a copy of that documentation (and not originals) to your questionnaire. Please note that we do **not** require sight of your medical notes and records as part of this public engagement so please do not send these documents to us.

Completing Section 3

This section of the questionnaire allows you to provide information relating to any concerns had in the past relating to Neurology Services but did not raise it at the time. Please provide as much information as necessary and attach any additional sheets if required.

Where you have documentation relating to the concern (for example if you kept notes of discussions or telephone calls or observations), please attach a copy of that documentation (and not originals) to your questionnaire. Please note that we do **not** require sight of your medical notes and records as part of this public engagement so please do not send these documents to us.

Completing Section 4

This section of the questionnaire allows you to provide information if you had concerns about Neurology Services but for some reason did not raise the concerns. If you fall into this category the Inquiry is particularly keen to understand why the concerns were not raised. The Inquiry is interested to understand what led to those concerns not being shared with others. The Inquiry will not judge you for not raising these at the time. Please provide as much information as necessary and attach any additional sheets as required.

Where should completed questionnaires be sent?

Completed questionnaires can be returned by post addressed as follows:

The Independent Neurology Inquiry
106 University Street
Belfast. BT7 1EU

Alternatively, completed questionnaires can be emailed to:
info@neurologyinquiry.org.uk

Personal Details

Please be assured that we will handle your personal information in keeping with the relevant law including the Data Protection Act 2018 and General Data Protection Regulations 2018.

The Inquiry may wish to invite specific individuals to address them in person. By providing your personal information you will enable the Inquiry to do so. Please do not let the possibility of being invited to attend the Inquiry in person prevent you from completing a questionnaire. We will not take steps to compel anyone who completes a questionnaire to attend the Inquiry in person against their wishes. Similarly, the completion of a questionnaire does not automatically result in any entitlement to attend the Inquiry in person, as any such invite will be at the discretion of the Inquiry Panel.

Choosing not to provide your personal details

If you so wish, you can complete the questionnaire anonymously. Please note however that completing the questionnaire anonymously will limit your input to the Inquiry in a number of ways: -

1. if you complete the questionnaire anonymously it will not be possible to invite you to attend before the Inquiry in person;
2. anonymised questionnaires are likely to be of less evidential value to the Inquiry; and
3. if the Inquiry considers the information provided by you is relevant to a review/investigation being carried out by another organisation then we may share this information with the relevant organisation and without your personal details we will be unable to notify you of this.

The Inquiry is committed to openness in its proceedings where possible and for that purpose it has established its own website (www.neurologyinquiry.org.uk).

Please note that in some very limited circumstances it may still be necessary for the Inquiry to share the information you have provided with another organisation. Where

this is the case, we will contact you further to discuss this and take all reasonable steps to protect your privacy and personal data.

Documents you may wish to read

The following documents are available on the Inquiry website:

- Frequently Asked Questions (FAQs) https://neurologyinquiry.org.uk/patients-and-family-members
- Privacy Notice, which provides details on how we handle data https://neurologyinquiry.org.uk/privacy-notice
- Terms of Reference, for background purposes only https://neurologyinquiry.org.uk/sites/ini/files/terms-of-reference-for-the-independent-neurology-inquiry.pdf

Help and Support

We recognise that completing this questionnaire may be difficult, and in some circumstances traumatic. Help and support is available from a number of organisations. These are detailed on the next page.

CHARITY CONTACT DETAILS

NINCA - NI NEUROLOGICAL CHARITIES ALLIANCE

THE NORTHERN IRELAND NEUROLOGICAL CHARITIES ALLIANCE (NINCA) WAS ESTABLISHED IN 2006 TO REPRESENT AND PROVIDE A VOICE ON BEHALF OF PEOPLE LIVING WITH A NEUROLOGICAL CONDITION IN NORTHERN IRELAND.

OUR MISSION:

TO BE THE UNITED VOICE ON BEHALF OF PEOPLE LIVING WITH NEUROLOGICAL CONDITIONS IN NORTHERN IRELAND

CONTACT US:
INFO@NINCA.ORG
WWW.NINCA.ORG.UK

niNCA
Neurological Charities Alliance

BRAINWAVES NI (SUPPORTING THOSE AFFECTED BY A BRAIN TUMOUR)

OFFICE: 02893 353995
EMAIL: K.FERGUSON@BRAINWAVES-NO.ORG

CHILD BRAIN INJURY TRUST

TEL: 02890 817 145
EMAIL: INFO@CBITUK.ORG

THE DYSTONIA SOCIETY

OFFICE: 020 7793 3651
HELPLINE: 020 7793 3650
HELPLINE EMAIL: SUPPORT@DYSTONIA.ORG.UK

EPILEPSY ACTION NORTHERN IRELAND

HELPLINE: 0808 800 5050 – FREE FROM ALL UK LANDLINES AND MOBILES.
HELPLINE EMAIL: HELPLINE@EPILEPSY.ORG.UK
UK TEXT MESSAGES: 0753 741 0044

HEADWAY THE BRAIN INJURY ASSOCIATION

NURSE LED CONFIDENTIAL HELPLINE: 0808 800 2244
HELPLINE EMAIL: HELPLINE@HEADWAY.ORG.UK
CONTACT: 078 2690 9110
CONTACT EMAIL: JOHNY.TURNBULL@HEADWAY.ORG.UK

MND ASSOCIATION

MNDA BRANCH CONTACT SIOBHAN ROONEY
TEL: 07434839842
EMAIL: MNDANI@HOTMAIL.CO.UK
OR MNDA: TEL 0808 802 6262
EMAIL: MNDCONNECT@MNDASSOCIATION.ORG

MS SOCIETY NORTHERN IRELAND

COUNSELLING SERVICE: 02890 802 802
HELPLINE: 0808 800 8000 – FREE FROM ALL UK LANDLINES AND MOBILES.
HELPLINE EMAIL: HELPLINE@MSSOCIETY.ORG.UK

PARKINSON'S UK NORTHERN IRELAND

HELPLINE: 0808 800 0303
EMAIL: HELLO@PARKINSONS.ORG.UK
PARKINSON'S LOCAL ADVISORS COVERING EACH OF THE HEALTH TRUSTS CAN BE CONTACTED VIA OUR SERVICE MANAGER PATRICIA JORDAN ON 0344 225 3682

SYRINGOMYELIA ARNOLD CHIARI ASSOCIATION (SACA)

HELPLINE TEL: 07826 004008
EMAIL: SACA.INFO@YAHOO.CO.UK

APPENDIX F

Letter to Recall Patient Support Group following the MPTS decision in relation to Dr Watt's voluntary erasure (11 October 2021)

INDEPENDENT NEUROLOGY INQUIRY

STRICTLY PRIVATE AND CONFIDENTIAL

[redacted]

Our ref: BL-0013-21

Date: 11 October 2021

Neurology Recall Patient Support Group

By email only: [redacted]

Dear [redacted],

Re: Addendum to the Closing Statement (06/10/21)

[redacted]

In view of the questions raised in the submission and recent events including the BBC Spotlight program and the decision of the Medical Practitioners Tribunal Service, ("MPTS") I believe that it is both appropriate and necessary to explain in greater detail a number of matters, in so far as I am able to do so, given my broader obligations as the Chairman of a statutory Public Inquiry.

I want to first of all express my disappointment at the decision of the MPTS. This disappointment is shared by Professor Mascie-Taylor. My understanding of the legal position is that it would have been open for the Tribunal to have proceeded in any event, even if Dr Watt was not in attendance. While that would not be an ideal situation, it would have enabled evidence to be adduced and findings to be made. The present situation is unsatisfactory, particularly for patients and in this regard I am acutely conscious that you have all been told *"again and again"* that the GMC will be dealing with the regulatory aspects of Dr Watt's practice. We have written to the GMC and have been informed that they have retained senior counsel to advice on the question of whether there are any legal remedies open to them.

I now want to address the issue, which I think has been at the heart of your concern in relation to the Spotlight program. The substance of the allegation made was that in failing to have Dr Watt independently examined, I had conducted what amounted to a mere '*paper exercise*.' That is far from the case, as I seek to explain below. Although I am constrained in various ways in what I can legitimately disclose, I have approached this correspondence in the same manner that I adopted with the BBC in seeking to comprehensively answer their questions prior to broadcast.

Before setting out the legal considerations, I have outlined below the steps that were taken in a chronological format to assist understanding:

On 15th of March 2021 the Inquiry issued a Notice compelling Dr Watt to attend and give oral evidence. On 6th May 2021 Dr Watt's lawyer disclosed expert psychiatric evidence to the Inquiry. On 18th May 2021 the Inquiry sent correspondence to Dr Watt's lawyer identifying a number of misapprehensions about the Inquiry's work and posing a series of questions about options for taking evidence. A further report from the same psychiatric expert was received on 22nd June 2021 addressing these matters and coming to the same conclusion.

On 1st June 2021 a series of incomplete text messages between Dr Watt and a patient, (known as 'Jane' in the BBC Spotlight program) were considered by the Inquiry Panel and its legal advisers. One message dated June 2019 was considered carefully, because one interpretation is the *emoji* implied that Dr Watt may have found it amusing that he had been considered a suicide risk. The conclusion was reached that they did not have sufficient weight as to be relevant to either the Inquiry's Terms of Reference, in particular because the text message focused upon was dated 6-7 months before the first psychiatric examination by the expert psychiatrist retained by Dr Watt's lawyers.

On 25th June 2021 the Inquiry wrote to its own independent expert psychiatrist requesting a report in order to quality assure the expert psychiatrist report received

from Dr Watt's lawyers. A report from the independent expert was received on 30th June 2021.

On 8th September 2021 the Inquiry took the additional precaution of providing copies of the messages to the independent expert psychiatric expert and the expert psychiatrist instructed by Dr Watt in order to judge whether the original consideration on the relevance of texts was valid or whether either of the experts wished to reconsider their opinions.

On 12th September 2021 the expert psychiatrist instructed by Dr Watt provided an addendum report to the Inquiry re-affirming their view that Dr Watt was not fit to give evidence.

On 13th September 2021 the Inquiry's independent expert provided an addendum report to the Inquiry re-affirming their view that Dr Watt was not fit to give evidence. The independent expert psychiatrist commented in their addendum report that trying to draw conclusions about mental state and risk from text messages is *"inappropriate, risky and unhelpful."*

The factors considered in concluding that Dr Watt would not be able to give evidence included:

(i) The fact that the Inquiry had received a detailed psychiatric report, where an examination had initially commenced in December 2019 and continued with further examination in September 2020, February 2021, and April 2021. The most recent examination was nearly 2 years after the text message in June 2019 wherein Dr Watt referenced his own mental health. The Inquiry was satisfied that it had in its possession a contemporaneous and substantive assessment carried out not just by the expert psychiatrist instructed by his lawyers, but with the report being informed by a different psychiatrist as well as a psychologist attached to the community mental health team, both of whom had also examined Dr Watt.

(ii) Even allowing for this, the Inquiry had already raised a series of questions with the expert psychiatrist to explore every possible option. When those answers were subsequently received the Inquiry had more than sufficient evidence to come to a conclusion. Nevertheless I decided as an additional precaution to obtain a further report from an independent expert psychiatrist.

(iii) The reports received from the psychiatrist retained by Dr Watt and the psychiatrist asked to report separately to the Inquiry all exhibit a declaration of truth and a statement indicating that any conflict of interest is disclosed (there were none).

(iv) I was required to apply the legal test[1] as to whether there was sufficient evidence to cast serious doubt on the medical opinions already expressed. It might be helpful to explain that had I concluded that there was serious doubt the matter would ultimately have had to be determined by the High Court and the starting point is to consider whether there has been some fundamental flaw in the assessments carried out. The fact that a witness was or was not independently examined by the body issuing the witness summons is not necessary for a court to come to a conclusion. There must be some obvious and serious failing in the medical evidence, before a court would decide to look behind the assessment of a relevant medical practitioner.

(v) I also was cognisant of the fact that we had received a draft copy of the Verita report, which included a detailed transcript of evidence Dr Watt had provided in May 2019. Recognising that the Independent Neurology Inquiry was not the Dr Watt inquiry it was apparent that as much as Dr Watt's attendance at the Inquiry would have been beneficial, it did not at all prevent a report being completed within the Terms of Reference.

(vi) At each stage, I considered the matter with not just my co-panellist Professor Mascie-Taylor, but with the Inquiry Solicitor and the Senior Counsel appointed to the Inquiry. Meetings to consider these matters were comprehensive and detailed.

[1] See, for instance, the decision of David Richards J in ***Re: Coroin*** [2012] EWHC 2343

(vii) In good faith, the unanimous view of the Panel and its legal advisers was that there was nothing in the reports furnished, which brought into question the veracity of any of the conclusions.

The Inquiry can at any time before it reports give further consideration to the issue of Dr Watt's fitness to give evidence. Any such consideration, however, must be based on appropriate expert evidence and a material change in circumstances. The Inquiry remains ongoing, and will continue to assess and weigh up relevant material until the report is finalised.

Given the limited explanation given in the Spotlight broadcast I can understand how patients may have assumed that the assessment was cursory. As I have sought to explain, the situation implied is entirely different to the reality of how the decision was taken. I also spoke with Dr Gabriel Scally following the program and had a cordial and helpful conversation, which I think explained our position. Dr Scally made it clear that he had not been briefed with the detailed explanations I had provided to the Spotlight program before he commented.

Your addendum raised some other matters, which I can only address partially at this juncture. I do hope that when the report, which is at an advanced stage and close to completion, is published some of the fears you have expressed may be allayed.

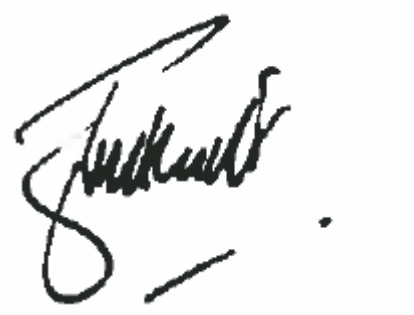
As stated above the decision not to hear the GMC case and allow findings to be made is extremely disappointing. I fear the vacuum created leads to the Independent Neurology Inquiry being shouldered with expectations that cannot be fulfilled, because of the process we are required to follow within the Terms of Reference. While governance procedures and systems may be viewed as rather dry, the reality is that they are inextricably linked to good patient outcomes and an improvement in patient safety. I can state at this stage that our report will consider the relationship between governance and safe clinical practice.

The voice of patients was heard at the beginning and continues to be heard. It has helped to shape the direction of the report and the issues, which need to be focused upon. I remain

determined to produce a meaningful report with clear recommendations based on the premise that patent safety is and remains the paramount consideration.

Thank you again for the submissions.

Yours sincerely,



BRETT LOCKHART QC
Chairman Independent Neurology Inquiry

APPENDIX G

Inquiry Briefing to the NI Assembly Health Committee following MPTS decision in relation to Dr Watt's voluntary erasure (4 November 2021

BRIEFING TO THE HEALTH COMMITTEE

INDEPENDENT NEUROLOGY INQUIRY

21 OCTOBER 2021

In view of recent events and the decision of the Medical Practitioners Tribunal Service, ("MPTS") I believe that it is both appropriate and necessary to explain in greater detail a number of matters, in so far as I am able to do so, given my broader obligations as the Chairman of a statutory Public Inquiry.

I want to first of all express my disappointment at the decision of the MPTS. This disappointment is shared by Professor Mascie-Taylor. My understanding of the legal position is that it would have been open for the Tribunal to have proceeded in any event, even if Dr Watt was not in attendance. The GMC have indicated that there was no appeal against the decision of the MPTS to accede to Dr Watt's application for voluntary erasure. That may well be correct, but, nevertheless, I do note that the possibility of a judicial review of the situation could be investigated. The Inquiry Solicitor has been informed by the Chief Executive of the GMC that this is currently being considered and advice is being taken from leading counsel. If the MPTS had recognised that it was in the public interest to receive the evidence and make findings, even in the absence of Dr Watt, then I believe that this would, in part, have given the GMC the opportunity to properly adduce the evidence of many patients.

The present situation is unsatisfactory, particularly for patients and in this regard I am acutely conscious that patients have been told *"again and again"* that the GMC will be dealing with the regulatory aspects of Dr Watt's practice. I note and welcome the *"extreme disappointment*" of the GMC in their public statement. What concerns me most however is the lack of an explanation from the MPTS on why the public interest test was not satisfied in Dr Watt's case.

I fear the vacuum created leads to the Independent Neurology Inquiry being shouldered with expectations that cannot be fulfilled, because of the process we are required to follow within the Terms of Reference. While governance procedures and systems may be viewed as rather dry, the reality is that they are inextricably linked to good patient outcomes and an improvement in patient safety. I can state at this stage that our report will consider the relationship between governance and safe clinical practice.

I now want to address the issue, which I think has been at the heart of public concern; namely that in failing to have Dr Watt independently examined, I had conducted what amounted to a cursory examination of the issues. That is far from the case, as I seek to explain below. Although I am constrained in various ways in what I can legitimately disclose, I have approached this correspondence in the same manner that I adopted with the BBC in seeking to comprehensively answer their questions prior to broadcast.

Before setting out the legal considerations, I have outlined below the steps that were taken in a chronological format to assist understanding:

> On 15th of March 2021 the Inquiry issued a Notice compelling Dr Watt to attend and give oral evidence. On 6th May 2021 Dr Watt's lawyer disclosed expert psychiatric evidence to the Inquiry. On 18th May 2021 the Inquiry sent correspondence to Dr Watt's lawyer identifying a number of misapprehensions about the Inquiry's work and posing a series of questions about options for taking evidence. A further report from the same psychiatric expert was received on 22nd June 2021 addressing these matters and coming to the same conclusion.
>
> On 1st June 2021 a series of incomplete text messages between Dr Watt and a patient, (known as 'Jane' in the BBC Spotlight program) were considered by the Inquiry Panel and its legal advisers. One message dated June 2019 was considered carefully, because one interpretation is the *emoji* implied that Dr Watt may have found find it amusing that he had been considered a suicide risk. The conclusion was reached that they did not have sufficient weight as to be relevant to either the Inquiry's Terms of Reference, in particular because the text message focused upon was dated 6-7 months before the first psychiatric examination by the expert psychiatrist retained by Dr Watt's lawyers.
>
> On 25th June 2021 the Inquiry wrote to its own independent expert psychiatrist requesting a report in order to quality assure the expert psychiatrist report received from Dr Watt's lawyers. A report from the independent expert was received on 30th June 2021.
>
> On 8th September 2021 the Inquiry took the additional precaution of providing copies of the messages to the independent expert psychiatric expert and the expert psychiatrist instructed by Dr Watt in order to judge whether the original consideration on the

relevance of texts was valid or whether either of the experts wished to reconsider their opinions.

On 12th September 2021 the expert psychiatrist instructed by Dr Watt provided an addendum report to the Inquiry re-affirming their view that Dr Watt was not fit to give evidence.

On 13th September 2021 the Inquiry's independent expert provided an addendum report to the Inquiry re-affirming their view that Dr Watt was not fit to give evidence. The independent expert psychiatrist commented in their addendum report that trying to draw conclusions about mental state and risk from text messages is *"inappropriate, risky and unhelpful."*

The factors considered in concluding that Dr Watt would not be able to give evidence included: -

(i) The fact that the Inquiry had received a detailed psychiatric report, where an examination had initially commenced in December 2019 and continued with further examination in September 2020, February 2021, and April 2021. The most recent examination was nearly 2 years after the text message in June 2019 wherein Dr Watt referenced his own mental health. The Inquiry was satisfied that it had in its possession a contemporaneous and substantive assessment carried out not just by the expert psychiatrist instructed by his lawyers, but with the report being informed by a separate treating psychiatrist as well as a psychologist attached to the community mental health team, both of whom had also examined Dr Watt.

(ii) Even allowing for this, the Inquiry had already raised a series of questions with the expert psychiatrist to explore every possible option. When those answers were subsequently received the Inquiry had more than sufficient evidence to come to a conclusion. Nevertheless I decided as an additional precaution to obtain a further report from an independent expert psychiatrist report.

(iii) The reports received from the psychiatrist retained by Dr Watt and the psychiatrist asked to report separately to the Inquiry all exhibit a declaration of truth and a statement indicating that any conflict of interest is disclosed (there were none).

(iv) I was required to apply the legal test[1] as to whether there was sufficient evidence to cast serious doubt on the medical opinions

already expressed. It might be helpful to explain that had I concluded that there was serious doubt the matter would ultimately have had to be determined by the High Court and the starting point is to consider whether there has been some fundamental flaw in the assessments carried out. The fact that a witness was or was not independently examined by the body issuing the witness summons is not necessary for a court to come to a conclusion. There must be some obvious and serious failing in the medical evidence, before a court would decide to look behind the assessment of a relevant medical practitioner.

(v) I also was cognisant of the fact that we had received a draft copy of the Verita report, which included a detailed transcript of evidence Dr Watt had provided in May 2019. Recognising that the Independent Neurology Inquiry was not the Dr Watt inquiry it was apparent that as much as Dr Watt's attendance at the Inquiry would have been beneficial, it did not at all prevent a report being completed within the Terms of Reference.

(vi) At each stage, I considered the matter with not just my co-panellist Professor Mascie-Taylor, but with the Inquiry Solicitor and the Senior Counsel appointed to the Inquiry. Meetings to consider these matters were comprehensive and detailed.

(vii) In good faith, the unanimous view of the Panel and its legal advisers was that there was nothing in the reports furnished, which brought into question the veracity of any of the conclusions.

The Inquiry can at any time before it reports give further consideration to the issue of Dr Watt's fitness to give evidence. Any such consideration, however, must be based on appropriate expert evidence and a material change in circumstances. The Inquiry remains ongoing, and will continue to assess and weigh up relevant material until the report is finalised.

As I have sought to explain the reality of how the decision was taken differs materially from the perception of how it was made. In particular, I would highlight the following matters which I fear have been misunderstood:-

(1) The initial reports I had received included input from a further treating psychiatrist and a psychologist who was part of a Community Mental

[1] See, for instance, the decision of David Richards J in ***Re: Coroin*** [2012] EWHC 2343

Health team, both of whom had agreed with the views of the psychiatrist who provided the report.

(2) There were four separate examinations over a period of 18 months by the psychiatrist who prepared the report.

(3) In understanding the decision it is critical to apply the requirements of the legal test. Was there any serious reason to doubt the conclusions of the evidence that had been obtained? The case law makes it clear that it is not at all usual for a court to look behind the clear conclusions of a medical report. The fact that the Inquiry decided, as an additional precaution to obtain an independent view on the manner in which the reports had been compiled, was, in truth, acting out of an abundance of caution. There was quite clearly sufficient evidence to make a decision based on the legal test on the evidence already obtained.

(4) Only the Inquiry can be in a position to assess the evidence, which is not in the public domain and cannot be disclosed

I replied at length to a number of patients representing the Independent Neurology Recall Support Group on 11th October and received a helpful and constructive response, which made clear that the Group were appreciative of the explanation provided.

Overall Progress of the Inquiry:

As previously indicated, the oral evidence was effectively completed in June 2021. The issue with regard to Dr Watt has been explained in detail above. I should make clear, however, that as a result of further enquiries, and also aspects of the Spotlight programme, we have followed up with a discrete number of additional witnesses, particularly in relation to medical records. In addition, we have received a significant amount of further documentation from the Trust, which has now been analysed. The Inquiry report is at a very advanced stage. We believe that we can begin what is referred to as the Maxwellisation process in early November 2021. This will, of necessity, take a little time, but I remain anxious to deliver the report as soon as that process is completed.

The voice of patients was heard at the beginning and continues to be heard. It has helped to shape the direction of the report and the issues, which need to

be focused upon. We remain determined to produce a meaningful report with clear recommendations based on the premise that patent safety is and remains the paramount consideration.

Brett Lockhart QC, Chairman
Professor Hugo Mascie-Taylor, Panel Member

Independent Neurology Inquiry

APPENDIX H

Advice on Responsible Officers and data protection – David Scoffield QC and Alistair Fletcher BL (30 October 2020)

BRIEF TO ADVISE

THE INDEPENDENT NEUROLOGY INQUIRY

in relation to the potential for lawful retention of information relevant to patient safety by responsible officers

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COUNSEL'S OPINION

INTRODUCTION

1. In May 2018 the Permanent Secretary of the Department of Health announced the establishment of the Independent Neurology Inquiry ('the Inquiry') to review aspects of the neurology service provided by the Belfast Trust ('the Trust'). In general terms, the Inquiry is tasked with considering the Trust's system of clinical governance during the timeframe which is subject to the Inquiry's assessment.

2. The Inquiry's general evaluation of governance procedures is to include to evaluate the corporate governance (with particular reference to clinical governance) procedures and arrangements in relation the "*communication and escalation of the reporting of issues related to potential concerns about patient care and safety, within and between the Belfast Trust, the HSC Board and Public Health Agency, the Department and any other areas which directly bear on patient care and safety and the general public…*".

3. The Inquiry's Terms of Reference also specifically task it with identifying any learning points relating to "*the framework for clinical social care governance, the current balance between problem sensing and assurance seeking in the extant system and its underpinning processes*".

4. As part of its work the Inquiry wishes to consider the question of information sharing in the context of the professional regulation of clinicians by a health trust's 'responsible officer' (whom we understand generally to be the same person as the Trust's Medical Director). In particular, the Inquiry provisionally considers that the responsible officer is potentially

uniquely placed to act as a repository for a wide range of information relating to clinicians which ought to be retained and assimilated in the interests of patient safety.

5. At the same time, the Inquiry has, in the course of its inquiries, been struck by data protection procedures being raised as an actual, or perceived, impediment to the sharing and retention of information relevant to a practitioner's clinical practice.

6. In this context, we are asked to advise the Inquiry[1] in relation to the legal basis for retention by a responsible officer of certain information pertaining to clinicians and patients. Specific questions have been asked of us, which we detail further below. Broadly, however, in these advices we consider, at a high level, whether information sharing and retention by responsible officers is permissible under the privacy and data protection legal framework in Northern Ireland.

THE RESPONSIBLE OFFICER

7. Before considering how the privacy and data protection regime potentially impact upon information retention and sharing by a responsible officer, it is important to be clear as to what that office entails and under what statutory obligations responsible officers operate. The Medical Profession (Responsible Officers) Regulations (Northern Ireland) 2010 ('the 2010 Regulations') make provision for responsible officers, including the requirement to nominate or appoint them, the conditions for nomination and appointment, and their responsibilities.

8. For responsible officers with a prescribed connection with medical practitioners under regulation 8, the following duties are detailed in regulation 9:

> "*(1) The responsible officer for a designated body has the following responsibilities relating to the evaluation of the fitness to practise of every medical practitioner who has a prescribed connection with that body by virtue of regulation 8.*
>
> *(2) The responsibilities referred to in paragraph (1) are —*

[1] This Opinion has been produced solely for the benefit of the Inquiry. It should not be relied upon by any other person or body.

(a) to ensure that the designated body carries out regular appraisals on medical practitioners in accordance with paragraph (3);

(b) to establish and implement procedures to investigate concerns about a medical practitioner's fitness to practise raised by patients or staff of the designated body or arising from any other source;

(c) where appropriate, to refer concerns about the medical practitioner to the General Council;

(d) where a medical practitioner is subject to conditions imposed by, or undertakings agreed with, the General Council, to monitor compliance with those conditions or undertakings;

(e) to make recommendations to the General Council about medical practitioners' fitness to practice;

(f) to maintain records of medical practitioners' fitness to practise evaluations, including appraisals and any other investigations or assessments.

(3) The responsible officer must ensure that appraisals carried out under paragraph (2)(a) obtain and take into account all available information relating to the medical practitioner's fitness to practise in the work carried out by the medical practitioner for the designated body and for any other body, during the appraisal period."

9. It can immediately be seen from regulation 9(1) that the suite of responsibilities devolved to responsible officers has as its aim the facilitation of "*the evaluation of fitness to practise*" of medical practitioners with the prescribed connection to the responsible officer's body. In addition, the responsibilities suggest that this evaluation should be both proactive (by means of regular appraisal and, as outlined further below, monitoring) and reactive (investigating and dealing with "*concerns*").

10. Significantly in the context of these advices, a responsible officer is responsible for maintaining records of evaluations relating to practitioners' fitness to practice, including appraisals and "*any other investigations or assessments*": see regulation 9(1)(f). Where an appraisal is being

undertaken, it is incumbent on the responsible officer to obtain and taken into account "*all available information*" relating to the medical practitioner's fitness to practise in the work carried out by them for the designated body and any other body during the appraisal period: see regulation 9(3). It may properly be said, in our view, that information collection and retention, so enabling it to be taken into account in assessment of fitness to practice, is an integral part of the role of a responsible officer in discharging their responsibilities.

11. Further responsibilities are imposed by regulation 14, under the heading 'Additional responsibilities of responsible officers: prescribed connection under regulation 8'. Regulation 14(2) provides as follows:

> *"In relation to monitoring medical practitioners' conduct and performance, the responsible officer must —*
>
> *(a) review regularly the general performance information held by the designated body, including clinical indicators relating to patient outcomes;*
>
> *(b) identify any issues arising from this information relating to medical practitioners, such as variations in individual performance; and*
>
> *(c) ensure that the designated body takes steps to address any such issues.*"

12. Put simply, in the course of his or her *monitoring* role, the responsible office can and must keep up to date with general information held by their designated body in order to seek to identify issues relating to particular medical practitioners and ensure that, if there are any such issues, they are addressed. There should not be a narrow focus on the practitioner's own information; but it should be considered, and compared with, wider information relevant to patient safety which is held by the body.

13. Regulation 14(3) is in the following terms:

> *"In relation to ensuring that appropriate action is taken in response to concerns about medical practitioners' conduct or performance, the responsible officer must —*
>
> *(a) initiate investigations with appropriately qualified investigators;*

(b) ensure that procedures are in place to address concerns raised by patients or staff of the designated body or arising from any other source;

(c) ensure that any investigation into the conduct or performance of a medical practitioner takes into account any other relevant matters within the designated body, for example wider concerns about operational or systems issues;

(d) consider the need for further monitoring of the medical practitioner's conduct and performance and ensure that this takes place where appropriate;

(e) ensure that a medical practitioner who is subject to procedures under this paragraph is kept informed about the progress of the investigation;

(f) ensure that procedures under this paragraph include provision for the medical practitioner's comments to be sought and taken into account where appropriate;

(g) where appropriate —

(i) take any steps necessary to protect patients,

(ii) recommend to the medical practitioner's employer that the medical practitioner should be suspended or have conditions or restrictions placed on their practice, and

(h) identify concerns and ensure that appropriate measures are taken to address these, including but not limited to—

(i) requiring the medical practitioner to undergo training or retraining,

(ii) offering rehabilitation services,

(iii) providing opportunities to increase the medical practitioner's work experience,

(iv) addressing any systemic issues within the designated body which may have contributed to the concerns identified,

(i) maintain accurate records of all steps taken in accordance with this paragraph."

14. This provision fleshes out the obligations of a responsible officer where there are "*concerns*" in relation to a medical practitioner's conduct or performance. Addressing "*concerns*" is a feature of the regulations, as with much other policy and guidance in this area. A variety of processes are available in this regard, depending on the nature and severity of the concern and the initial fact-finding in relation to it. The responsibilities set out in regulation 14, however, point again to statutory aims of ensuring that concerns are identified and addressed whatever their source[2]; that there is 'joined up thinking' when a concern is being investigated, appropriately linking it to "*other relevant matters*" within the designated body, which might include other concerns or systems issues[3]; and that a practitioner's conduct and performance is monitored on an ongoing basis where appropriate[4].

15. Again, the importance of maintaining "*accurate records of all steps taken*" in accordance with the identified responsibilities – including the responsibility to identify concerns – is emphasised by being expressly mandated: see regulation 14(2)(i).

16. Slightly different duties are provided for responsible officers prescribed under regulation 10, pursuant to regulations 11 and 15, but for present purposes it sufficient to note that they are materially similar.

17. Regulation 12 is applicable to responsible officers prescribed under both regulation 8 and regulation 10. Regulation 12(1) provides for certain resources to be provided to them in the following terms:

> "*Subject to paragraph (2), each designated body must provide the responsible officer appointed or nominated for that body with sufficient funds and other resources necessary to enable the officer to discharge their responsibilities for that body under regulations 9 and 11.*"[5]

18. Although there is no definition of "*other resources*", and no case law of which we are aware to indicate what this means in the context of the 2010 Regulations, it seems to us plain that

[2] See regulation 14(2)(b) and (h).

[3] See regulation 14(2)(c).

[4] See regulation 14(2)(d).

[5] Paragraph (2), to which regulation 12(1) is subject, is not relevant for present purposes; but it is designed to cater for the circumstances where the designated body does not directly employ its responsible officer.

this will include the facilities necessary to permit the responsible officer to discharge their statutory responsibilities; and that it is at least arguable that this includes the provision of information concerning clinicians and patients in so far as it relates to the monitoring of the former's clinical performance.

19. It can be seen, therefore, that responsible officers play a central, and statutory, role in medical regulation. They are accountable for the local clinical governance processes in their designated organisation, including the oversight of the conduct and performance of doctors.

20. Responsible officers are also required, by virtue of regulation 13 of the 2010 Regulations, to have regard to certain guidance, including guidance given by the General Medical Council (GMC). Guidance from the GMC[6] regarding the function of the responsible officer provides as follows:

> "*Responsible officers must take appropriate action in response to any information of note they receive about the practice of a doctor who is connected to them, bearing in mind the needs of patients and of the doctor concerned. This includes information received from outside the doctor's designated body.*
>
> *Where a responsible officer becomes aware of information about a doctor that could affect the safety or confidence of patients, they should share that information with all places where the doctor is known to be working in a medical capacity.*
>
> *If a responsible officer has concerns about a doctor who is no longer connected to them, they should share these with the doctor's new responsible officer. In situations where the doctor's new employment has yet to be confirmed, it may be appropriate to delay: responsible officers should have reference to the GMC's ethical guidance on writing references and relevant local advice about pre-employment checks.*
>
> *Where the doctor concerned no longer has a connection for the purposes of revalidation, the previous responsible officer should take appropriate steps to protect patients. They should remind the doctor of their responsibility to bring the matter to the attention of their next responsible officer and to practise only within their*

[6]Available at https://www.gmc-uk.org/registration-and-licensing/managing-your-registration/revalidation/the-responsibilities-of-responsible-officers-and-designated-bodies-in-preparing-for-revalidation/responsibilities-for-sharing-information.

competence. Responsible officers should also retain information for transfer to the doctor's future responsible officer.

In line with the GMC's recommendation protocol, at the point of making a revalidation recommendation about a doctor, responsible officers should consider clinical governance information from each of the organisations where the doctor works. This may be obtained via the appraisal process or directly from the organisations concerned."

21. Responsible officers' obligations in relation to information touching upon concerns in respect of a clinician's fitness to practice are therefore two-way in nature: the Regulations (and these advices) focus principally on the collection and consideration of relevant information in the discharge of the responsible officer's functions; but their obligations to *share* information with others in the interests of patient safety is emphasised in the guidance. This appears to us to be harmonious with the primary statutory purpose of ensuring patient safety by the identification, communication and addressing of concerns in relation a clinician's practice.

22. We have not had sight of any Northern Ireland specific guidance on the role of the responsible officer, but that produced by NHS England states the following in relation to the information to be retained by them[7]:

> *"4.35 In order for the responsible officer to fulfil their statutory duties, effective mechanisms for sharing relevant information within and between organisations are necessary. Further guidance on this relevant to responsible officers in England can be found in the document Information Management for Revalidation in England. An electronic template for completion by ROs when there is a need to share information is available via NHS England.*
>
> *4.36 Information about doctors' fitness to practise is one of the foundations of the revalidation process. Responsible officers must assure themselves that the systems and processes in use within their organisation to store personal information about doctors are secure and comply with relevant legislation and good practice guidance. The sharing of information about a doctor should occur in a way which complies with the principles of data protection and is fair*

[7] Available (in draft) at https://www.england.nhs.uk/revalidation/wp-content/uploads/sites/10/2014/06/ro-guidance-draft.pdf.

to the doctor concerned, but in determining the information which should be shared, responsible officers, medical directors and employers should regard patient safety as the overriding priority. They must ensure that appropriate auditable governance arrangements are in place to control access to the data and any transfers of that data."

THE PRIVACY AND DATA PROTECTION REGIME

Overview

23. In the United Kingdom (UK) the regulation of the use of personal data is governed by the General Data Protection Regulation (GDPR) and the Data Protection Act 2018 ('the DPA'). The GDPR became directly effective in the UK on 25 May 2018; and the DPA came into force on the same date. Given that the GDPR is a part of EU law, the impact of Brexit on the regulatory framework for data protection is not clear and will likely only become so in coming months and years. Although the DPA makes express reference to the GDPR and must be read alongside it, this does not necessarily mean that the regulatory landscape will remain the same once the transition period ends, the UK having left the EU. We are therefore only able to give advice as to the position in UK law as it currently stands and, in any event, as appears below, do so only at a high level of principle in light of the nature of the request for advice provided to us.

24. Broadly speaking, the GDPR sets out the general data protection principles that must be followed by controllers of data, whilst the DPA provides for some additional requirements and permits limited derogations from the GDPR. The basic principle of the GDPR is that personal data can only be processed if the individual consents to that processing or the processing is permitted on a specified basis allowed for in the GDPR. It requires controllers that process personal data to establish and publish a basis for lawful processing. Sanctions are applicable if breaches occur, and supervisory and regulatory powers are vested in the Information Commissioner's Office (ICO).

The data controller

25. For the GDPR to be applicable to the responsible officer it is necessary for that person to be a "*controller*" or "*processor*" of "*personal data*". The definitions of these terms are found in article 4 of the GDPR:

> *'personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person;*
>
> *'processing' means any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction;*
>
> *'controller' means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law;*
>
> *'processor' means a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller…*

26. There are different obligations under the GDPR for controllers and processors. In general terms, a controller is the main decision-maker and exercises overall control over the purposes and means of the processing of personal data. A processor (generally a person outwith the controller's organisation) acts only on the instruction of a controller.

27. The responsible officer for most clinicians in Northern Ireland will be a person employed by an NHS Trust. Their position is not a free standing one, with corporate legal personality, but rather they act within their relevant designated body, albeit they have specific statutory obligations to fulfil. As such, the data controller is likely to be the relevant designated body itself (often a Trust), rather than the responsible officer. The justification for the NHS Trust

retaining personal data in this context is, however, directly related to obligations imposed upon the responsible officer in respect of medical practitioners with a prescribed connection to it; and it is therefore appropriate in our view to view the data protection issue through that lens. In other words, we look at justifications for the NHS Trust to retain personal data based on the obligations of its responsible officer. Consequently, in this opinion when we speak of retention of personal data by a responsible officer we are referring ultimately to its retention by the designated body in which he or she acts.

Personal data

28. It is clear to us that the information which responsible officers will retain and share is personal data. The information will likely fall into two categories: (a) information concerning clinicians and (b) information concerning patients.

Use of personal data

29. As the responsible officer is a controller of personal data they are bound by the GDPR. Article 5 of the GDPR sets out certain requirements for use of personal data, namely that:

> *"Personal data shall be:*
>
> *a. processed lawfully, fairly and in a transparent manner in relation to the data subject ('lawfulness, fairness and transparency');*
>
> *b. collected for specified, explicit and legitimate purposes and not further processed in a manner that is incompatible with those purposes; further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes shall, in accordance with Article 89(1), not be considered to be incompatible with the initial purposes ('purpose limitation');*
>
> *c. adequate, relevant and limited to what is necessary in relation to the purposes for which they are processed ('data minimisation');*
>
> *d. accurate and, where necessary, kept up to date; every reasonable step must be taken to ensure that personal data that are inaccurate, having regard to*

the purposes for which they are processed, are erased or rectified without delay ('accuracy');

e. kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed; personal data may be stored for longer periods insofar as the personal data will be processed solely for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes in accordance with Article 89(1) subject to implementation of the appropriate technical and organisational measures required by this Regulation in order to safeguard the rights and freedoms of the data subject ('storage limitation');

f. processed in a manner that ensures appropriate security of the personal data, including protection against unauthorised or unlawful processing and against accidental loss, destruction or damage, using appropriate technical or organisational measures ('integrity and confidentiality')."

30. The principles set out in article 5 of the GDPR are central to understanding how personal data should be processed and retained. It is apparent that personal data are only to be processed to the extent necessary for the purpose they are processed. Only personal data relevant to this purpose should be processed and they should not be retained or stored for any longer than is necessary. This will likely be a key concern for a responsible officer as a value judgment must be made as to how long information realistically needs to be retained in order to monitor a clinician's practice. This is obviously a matter on which views may differ; and it is an issue to which we return below.

Bases for processing personal data

31. The processing of personal data is lawful only if at least one of the justifications in article 6 of the GDPR is applicable. Those justifications are as follows:

"*Processing shall be lawful only if and to the extent that at least one of the following applies:*

a. the data subject has given consent to the processing of his or her personal data for one or more specific purposes;

b. processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering into a contract;

c. processing is necessary for compliance with a legal obligation to which the controller is subject;

d. processing is necessary in order to protect the vital interests of the data subject or of another natural person;

e. processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller;

f. processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child."

32. Section 8 of the DPA provides a gloss to article 6(1)(e) of the GDPR. It provides:

"*In Article 6(1) of the GDPR (lawfulness of processing), the reference in point (e) to processing of personal data that is necessary for the performance of a task carried out in the public interest or in the exercise of the controller's official authority includes processing of personal data that is necessary for —*

(a) the administration of justice,

(b) the exercise of a function of either House of Parliament,

(c) the exercise of a function conferred on a person by an enactment or rule of law,

(d) the exercise of a function of the Crown, a Minister of the Crown or a government department, or

(e) an activity that supports or promotes democratic engagement."

33. Other than consent provided by the data subject, on the basis of legal duties to which a responsible officer is subject pursuant to the 2010 Regulations, it is our view that the justifications provided in article 6(1)(c) and (e) can legitimately be relied upon by an NHS Trust[8]. The responsible officer is under a statutory obligation to both appraise and monitor clinicians and it is obvious that this cannot be done with any effectiveness without, in principle, ready access to appropriate information pertaining to clinicians and patients.

34. As it is envisaged that the responsible officer will require access to information pertaining to patients as well as clinicians, there will need to be retention of data about a patient's health and article 9 of the GDPR, relating to the processing of special categories of personal data, is therefore applicable.

35. Article 9(1) provides that "*processing of… data concerning health or data concerning a natural person's sex life or sexual orientation shall be prohibited*"; but this does not apply if one of the bases in article 9(2) is satisfied. In the present context, our view is that an NHS Trust could rely upon article 9(2)(h) – or possibly, although perhaps less naturally, article 9(2)(i) – which provide as follows:

> *"h. processing is necessary for the purposes of preventive or occupational medicine, for the assessment of the working capacity of the employee, medical diagnosis, the provision of health or social care or treatment or the management of health or social care systems and services on the basis of Union or Member State law or pursuant to contract with a health professional and subject to the conditions and safeguards referred to in paragraph 3;*
>
> *i. processing is necessary for reasons of public interest in the area of public health, such as protecting against serious cross-border threats to health or ensuring high standards of quality and safety of health care and of medicinal products or medical devices, on the basis of Union or Member State law which provides for suitable and specific measures to safeguard the rights and freedoms of the data subject, in particular professional secrecy;*"

[8] We note that the definition of an "*enactment*" for the purposes of the DPA, relevant to section 8 of that Act quoted above, is wide enough to encompass the 2010 Regulations, since it includes "*an enactment comprised in, or in an instrument made under, Northern Ireland legislation*": see section 205(1)(e) of the DPA.

36. That these purposes may justify the processing of the most sensitive data is an indication of their importance. It is worth noting in passing that in the Report of the Independent Inquiry into the Issues raised by Paterson[9] also encountered reliance on data protection as a barrier to information sharing relevant to patient safety but emphasised that Inquiry's view that maintaining patient safety was an important exemption within the GDPR/DPA regime. In particular, that inquiry report stated as follows:

> *"Several witnesses told us that data protection is a barrier to sharing information between organisations and cited particularly the General Data Regulation Protection (GDPR). GDPR was not in place when Paterson was practising. However, we believe this is a misinterpretation of the regulation, and that sharing of information to maintain patient safety is an important exemption within the legislation. Furthermore, failure to share vital information which could promote patient safety is a breach of the Caldicott principles, established in 1997 to protect patient confidentiality within the context of the increasing use of information technology in the NHS:*
>
> *"The duty to share information can be as important as the duty to protect patient confidentiality."*
>
> *…*
> *We have concluded that there is confusion about individual organisations' responsibilities, data protection legislation and commercial confidentiality, and that this stands in the way of the timely sharing of information to protect patients."*[10]

Data subjects' rights

37. The GDPR provides data subjects with certain rights in relation to the personal data possessed by a controller, namely:

i. the right to be informed;
ii. the right of access;

[9] Ordered to be printed by the House of Commons on 4 February 2020: a report into what the Inquiry Chairman (The Rt Rev Graham James) called "*a rogue surgeon*" but also "*a healthcare system which proved itself dysfunctional at almost every level when it came to keeping patients safe, and where those who were the victims of Paterson's malpractice were let down time and time again*" (see the opening statement by the Chair).
[10] Paterson Inquiry Report, Chapter 6, pp 184-185.

iii. the right to rectification;

iv. the right to erasure;

v. the right to restrict processing;

vi. the right to data portability;

vii. the right to object; and

viii. rights in relation to automated decision making and profiling.

38. Given the significant scope and multi-faceted nature of these individual rights on the part of the data subject, it is clearly outside the scope of these advices to deal with them in any particular detail, save to say that designated bodies such as a Trust ought already to have established policies in relation to them. These are equally applicable to the role envisaged by the responsible officer; and data held by such an officer will be subject to the rights of the data subject to which they relate, as adumbrated above. The precise scope and effect of each right in any given case will be a matter for individual consideration of the merits and circumstances on a case-by-case basis.

SPECIFIC QUERIES

39. We have, however, been asked by the Inquiry to advise on a set of specific queries, which we address below. A necessary caveat is that, in each particular scenario, the relevant responsible officer (assisted by the designated body for which they act) will need to make an assessment as to whether to retain data based upon the particular facts before them. The following advices must necessarily address each question posed in principle and at a high level of generality. Each Trust will no doubt have its own GDPR policy and approach to how it processes data, and it may be that there are already established approaches to a number of the questions addressed below. A challenge for readers and recipients of the Inquiry's report will be the extent to which their processes can and should be adjusted in order to maximise patient safety and find the correct balance between that goal and the rights of data subjects, including medical practitioners.

40. In the case of most of the queries posed below, it seems to us that there will *prima facie* be a lawful basis under the 2010 Regulations for recording and retaining the relevant information since, as we have seen, the Regulations place an obligation on responsible officers to investigate and address concerns effectively and then also to "*maintain records*" of the various

investigations and assessments undertaken in relation to a practitioner's fitness to practice, as well as all of the steps taken by the responsible officer himself or herself in response to concerns[11]. The Regulations themselves do not impose any cut-off point for the retention of such data. Accordingly, we address the queries below on the basis of whether a challenge to the retention of data under the GDPR/DPA regime might be sustained.

41. We also note that the questions posed to us are premised on the assumption that there is a "*potential compromise to patient safety*". The justification for data retention in relation to concerns about medical practitioners is largely based on patient safety, so it is important that careful consideration is given to the relevant risk by a responsible officer. Self-evidently, and as a matter of first principle, if the information in question relates to or discloses a high risk to patient safety, the justification for its retention is much easier to make out. The more speculative the link to patient safety, the less likely there is to be a lawful basis to retain the information for a lengthy period. As such, the responsible officer will need to give careful thought to what matters can realistically be said to give rise to potential concerns over patient safety.

42. On the one hand, a substantiated complaint about improper conduct or inadequate professional practice falls at one end of the spectrum. The position is much less clear cut where a complaint has been fully investigated and dismissed, with the clinician being exonerated of any wrongdoing. Even then, however, there may well be a case for retention of the relevant information in case an error was made in the assessment of the proper outcome, for instance by giving the clinician the benefit of any doubt, in circumstances where later concerns or incidents may shed fresh light on the earlier assessment. Addressing the matter principally from the perspective of patient safety[12] would tend towards an expansive approach to information retention. Indeed, the 2010 Regulations discussed above appear to take that approach, which may therefore be thought to represent the Department of Health's, and the Northern Ireland Assembly's judgment as to the correct balance. No doubt the Inquiry itself will have something to say on these issues when it reports.

43. We turn then to the specific queries which have been addressed to us for our view.

[11] See again regulation 9(2)(f) and 14(3)(i).

[12] And treating it as the overriding priority, as the guidance referred to at paragraph 22 above suggests is appropriate in this context.

Q1: Where a colleague flags a concern relating to a clinician's practice and the concern raises a potential compromise to patient safety, under what circumstances can the details regarding this concern be lawfully retained by the Medical Director/ Responsible Officer?

44. It seems to us that, in principle, this information can be lawfully retained by a responsible officer as it concerns a matter that is intimately related to their role under the Regulations. There is a specific obligation to investigate concerns raised by patients or staff; and to record the details of what steps are taken. Our starting point is that any information raising legitimate concerns about patient safety is entitled to be retained for so long as it may be relevant to the protection of patient safety. In general terms, this is likely to be for so long as the relevant clinician remains in practice and treating patients.

45. However, it is unrealistic to suggest that the justification for retaining information cannot and will not be affected by the outcome of any investigation into concerns which have been raised, as foreshadowed by our observations at paragraph 42 above. There is a plain obligation in the Regulations to investigate concerns and take appropriate action. The strength of justification for retention for a lengthy period will be affected to some degree by the outcome of the investigation into the concerns.

46. Where the concern has been fully investigated and no disciplinary or other action has been taken in respect of it, there is an argument that the personal data relating to the concern is not relevant to patient safety (since the concern was ill-founded) and there is therefore no proper basis for retention. For example, if a concern is found to have been entirely without substance and raised maliciously, then there must be a question as to the relevance of the personal data in respect of it, at least in relation to the clinician who was the subject of the initial concerns.

47. That analysis might well, however, be unduly simplistic. It may be that an argument can be made as to the need to retain this information in case it later becomes relevant to the identification of a pattern of concerns. That argument will hold more weight if the case is unresolved; or effectively 'not proven' against the clinician about whom concerns have been raised, but in circumstances where doubt might remain about their conduct or performance. The cogency of the argument for retention will likely be affected by the experience and assessment of those, including the Inquiry, who have considered cases where serious adverse outcomes may have occurred against a background of earlier concerns which were

unsubstantiated but later came to be recognised as missed opportunities for intervention. The more empirical evidence there is that retaining information about past complaints, even if not substantiated, could significantly improve patient safety in the longer term, the more likely retention of such information is to be justified. We simply sound a note of warning that there is an obvious argument to the effect that records of demonstrably unwarranted concerns can be of limited if any utility in this regard.

48. If a concern is investigated and the investigation results in an assessment which produces a negative finding against the practitioner in terms of conduct or performance, then it is of course easier to see how retention can be justified so long as the data is necessary for ongoing monitoring or identification of systemic issues. As noted above, it seems to us that information about any concern that leads to a negative assessment of the clinician could justifiably be retain whilst the clinician is still in practice (or might reasonably resume practice).

49. The approach recommended in Department of Health guidance for the moment plainly seems to envisage comprehensive maintenance of records where concerns have been formally investigated, even where the outcome appears to have been entirely favourable to the clinician concerned. We take this from a number of provisions of *Maintaining High Professional Standards in the Modern HPSS* (MHPS). Consistent with the straightforward approach in the 2010 Regulations, that records must be kept of all steps taken in addressing concerns which have been raised, paragraph 17 of Section IV of MHPS (Procedures for Dealing with Issues of Clinical Performance) states that, where a hearing has been held, "*A record of all findings, decisions and written warnings should be kept on the practitioner's personnel file…*". It seems that this will also include a finding that the allegations are exonerated and the practitioner exonerated, which finding should also be "*placed on the practitioner's record*"[13].

Q2: Where another organisation (for example an independent sector provider for whom a clinician provides services) or an individual (for example, a General Practitioner) raises a concern and the concern raises a potential compromise to patient safety, under what

[13] See paragraph 16 of the same section of MHPS. To similar effect, in paragraph 38 of that section, dealing with appeal hearings, the following is stated: "*Records must be kept, including a report detailing the performance issues, the practitioner's defence or mitigation, the action taken and the reasons for it. These records must be kept confidential and retained in accordance with the clinical performance procedure and the Data Protection Act 1998. These records need to be made available to those with a legitimate call upon them, such as the practitioner, the Regulatory Body, or in response to a Direction from an Industrial Tribunal.*"

circumstances can the details regarding this concern be lawfully retained by the Medical Director/Responsible Officer?

50. The same analysis as discussed above applies equally to this query. The fact that the concern originates from another organisation does not in our view alter how the data can be retained.

Q3: Where a complaint is made relating to an individual clinician and raises a potential compromise to patient safety, under what circumstances can the details regarding this complaint be lawfully retained by the Medical Director/Responsible Officer?

51. A complaint is, we assume, simply a concern that is raised in circumstances where the complainant expects it to be investigated; whereas a concern *simpliciter* may not be something which the person raising it expects to be formally investigated. There may in fact be no material difference between the two terms but, in any event, our analysis of concerns applies equally to complaints.

Q4: Where a coroner's inquest, serious adverse incident or civil litigation case addresses the practice of an individual clinician and raises a potential compromise to patient safety, under what circumstances can the details be lawfully retained by the Medical Director/Responsible Officer?

52. As with complaints, in our view this information can justifiably be retained by a responsible officer as it directly relates to their duties under the 2010 Regulations. The justification for retention may be greater where the process giving rise to the information (the inquest, SAI review or litigation, as the case may be) has independently determined that there were valid concerns about the clinician's conduct or performance. Certainly, this would be information which would be required to be obtained and taken into account in the course of appraisal[14]. Alternatively, the information may simply be such as to trigger a requirement for investigation under the procedures overseen by the responsible officer in the designated body[15].

[14] See regulation 9(3).

[15] Recalling the obligation in regulation 14(3)(b) to ensure that procedures are in place to address concerns raised by patients or staff of the designated body "*or arising from any other source*"; and the obligation to like effect in regulation 9(1).

53. Again, the key question is how long the data can lawfully be retained. During the currency of the inquest or litigation the information is clearly relevant so as to allow the responsible officer to be aware of any issues arising that require independent investigation or action. At the close of those proceedings, as discussed above, the potency of any justification for retention will relate to the outcome of the examination of the clinician's conduct or, alternatively, the need for further investigation by the designated body itself. As already noted, there is a correspondingly weaker justification for retention if no criticism is ultimately made of the clinician, subject to the observations above in relation to (a) a distinction to be drawn between full exoneration and unresolved concerns and (b) the potential for even apparently unsubstantiated concerns to shed light on a practitioner's practice in due course in light of additional information. If criticism is made of the clinician then there is a good argument that information should be capable of retention until the clinician ceases employment, provided the criticism remains relevant or potentially relevant to patient safety.

Q5: Where an independent expert report (for example a report commissioned as a result of the processes in the preceding question or in the investigation of a complaint) comments on the practice of an individual clinician and raises a potential compromise to patient safety, under what circumstances can the details be lawfully retained by the Medical Director/Responsible Officer?

54. The discussion provided above seems to us to be equally applicable to this query. The key focus is the significance of the information, the basis of the concern and its relevance to risks to patient safety. The precise channel through which it is brought to the responsible officer's attention is secondary to those considerations.

Q6: Where an independent expert report (for example a report commissioned as a result if the processes in the preceding question or in the investigation of a complaint) comments on the practice of an individual clinician and raises a potential compromise to patient safety, under what circumstances can the details be lawfully retained by the Medical Director/Responsible Officer?

55. Again, the answer given above seems to us to be equally applicable to this query.

Q7: Where the GMC has issued a sanction against an individual clinician, under what circumstances can the details be lawfully retained by the Medical Director/Responsible Officer?

56. If a sanction has been imposed by the GMC then this data can justifiably be retained by a responsible officer. As discussed above, the Regulations specifically require the responsible officer to "*ensure that appraisals carried out… obtain and take into account all available information relating to the medical practitioner's fitness to practise in the work carried out by the medical practitioner for the designated body and for any other body, during the appraisal period*". The responsible officer also has ongoing responsibility for monitoring, which would include the clinician's response to any sanction and any re-training or re-skilling required as a result of the finding giving rise to the sanction. Where a sanction has been imposed, it appears to us that this is one of the more obvious instances where ongoing retention is likely to be justified based on patient safety.

Q8: Where an individual clinician fails to comply with the reasonable instruction of a line manager can the details be lawfully retained by the Medical Director/Responsible Officer? For example, the failure to provide reports, follow guidelines or complete professional appraisal.

57. It seems to us that the analysis above in relation to concerns raised by other persons is equally applicable here, as presumably the line manager would raise these compliance issues as a concern or complaint, in which case it would be investigated pursuant to the responsible officer's obligations. Some distinction might require to be made between failures which, although perhaps within the clinician's employment obligations, were entirely unrelated to clinical practice and therefore patient safety; and those which did (potentially) engage issues of patient safety. The examples provided in the query, however, seem obviously to fall within the second category.

Q9: Where an individual clinician is investigated under Maintaining High Professional Standards, under what circumstances can the details (to include minutes of meetings) be lawfully retained by the Medical Director/Responsible Officer? Does it make any difference whether the said investigation is "formal" or "informal" within the meaning of MHPS?

58. We are of the view that the approach discussed above in relation to concerns is again applicable to both formal and informal investigations. Where either leads to no remedial action then the same issue arises as with concerns; namely the extent to which there can be a convincing basis for retention of the personal data once the investigation is complete. In our view, however, it is the substance of the concern and the findings of the investigation which are important, rather than the question of form as to whether the formal or informal process within *Maintaining High Professional Standards* is used.

Q10: In respect of the above matters, should the clinician resign, how long should the information be kept by the Medical Director's Office? And should the individual clinician move to another employer, would it be lawful for the information to be shared with the subsequent Responsible Officer?

59. If the clinician retires, in that they cease to be a practising doctor anywhere, then the justification for retaining personal data would be weak (unless perhaps the information was relevant to the identification or prevention of systemic issues relating to patient safety, not particularly related to the practice of the individual retiring clinician). There may yet be instances where a limited period of retention is justified, such as where an investigation into that clinician is ongoing at the time of retirement. As mentioned above, retention may also be justified if the data is needed as part of a general assessment of medical practices generally where systemic issues are examined. However, the data could only be retained as long as that information was necessary to fulfil the limited purpose.

60. The justification for retention is likely to be greater, and made out[16], if a clinician is not retiring but merely resigning from a particular post with a view to transferring, or resuming, their practice elsewhere. If a clinician moves to another employer then a transfer of personal data to that employer (in their capacity as a controller) would be possible and lawful in principle; but the Standard Contractual Clauses for transfers between controllers prescribed by the European Commission should be executed.

CONCLUSION

[16] Provided there was a lawful basis for retention up to the time of resignation.

61. As a matter of general principle there are justifications for collating and retaining the information that the Inquiry envisages should be made available to, and kept by, the responsible officer. It is likely that the great majority of this information will already be held by the relevant Trust, albeit perhaps not in any centralised or organised manner. If the Trust is permitted to retain the data in the first instance, then there should be no issue with the responsible officer collating it under their auspices, on the basis that the Trust is in reality the controller for GDPR purposes. In our view, the obligations under the 2010 Regulations give additional justification for the retention of data by the Trust through the responsible officer in the cases discussed above.

62. The central question is what the appropriate period of retention is. This is a question that avails of no easy answer and will need to be assessed on a case-by-case basis. We are sympathetic to the suggestion that, in broad terms, information relevant or potentially relevant to the identification of risks to patient safety should be retained throughout the period of practice of the clinician to which it relates. We assume for this purpose that such information will, obviously, be held and stored securely, have access to it limited, be used only for the permitted purposes and so on, namely that the basic features of responsible information management and any other specific legislative requirements[17] will be observed. It would also be helpful if, periodically, reviews were undertaken of the continuing need to retain information since its utility, and hence the justification for its retention, may well be seen to recede on later review[18].

63. Since these issues are both intensively fact specific and themselves involve elements of clinical judgment, there will necessarily have to be a careful consideration by the relevant responsible officers and Trusts (or other designated bodies) in Northern Ireland as to what purpose the data can serve, as this will determine the basis for prolonged retention; and as to where in particular the dividing line must fall between information which can and should be retained for long periods and information which should not. If there is a plausible link between the personal data and necessary monitoring of the individual clinician or clinicians at a more global level (*i.e.* 'trend spotting') then that could well point to a basis for retention throughout the course of the clinician's practice.

[17] For instance, compliance with article 9(3) of the GDPR where reliance is placed on article 9(2)(h) as a basis for processing.

[18] An obvious example may be a complaint from a very long time ago where it is clear that there have been many years of practice since without any similar concerns having been raised.

64. Central to this, however, will be the need for Trusts to adhere to the principle of minimisation: only the minimal amount of data that is necessary for the purposes of the responsible officers should be retained. The question of what *is* necessary in that regard is a matter on which the report of the Inquiry itself might well shed some light. Insofar as the balance is struck in the content of the 2010 Regulations themselves, they seem to favour expansive information collection, retention and sharing in the interests of patient safety. That appears to us to be a reasonable starting point out of an abundance of caution; the limits of which may require to be tested on a case-by-case basis in due course.

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