

**The Credential INR (Acute Stroke) sponsored by the Royal College of Radiologists: not as simple as it seemed. What factors are preventing approval of training for non-radiologists to perform MT in the UK (and will further delay the establishment of comprehensive interventional services for acute ischaemic and haemorrhagic stroke)?**

R Lenthall, P White on behalf of the UK Neurointerventional Group (UKNG) 11/03/2022

## **Background**

Mechanical thrombectomy (MT) is a potentially life altering or life-saving procedure for patients with acute ischaemic stroke caused by blockage of a brain blood vessel. The evidence of efficacy is beyond debate and the service has been Nationally-commissioned in England since April 2018.

In the UK, MT is overwhelmingly provided by Interventional Neuroradiologists (INRs) working in regional Neuroscience Centres (RNSC). The only specialty curriculum that includes training to perform MT is Interventional Radiology (IR) and sub-specialty training in INR takes 3 years. Additionally, the Royal College of Radiologists (RCR) recognise that the knowledge, competencies and experience required for safe INR practice can't be acquired comprehensively within these three years and that supported practice after qualification is routinely provided for junior INR consultants in RNSCs<sup>1</sup>.

85% of the population in the UK live within 45 minutes road travel of a RNSC. The statutory requirement to provide equitable services for NHS patients raises particular challenges for dispersed rural populations that live remote from a RNSC. Service modelling indicates that a number of new centres will be required to support larger population but remote (from RNSC) communities in the UK<sup>2</sup>.

Once meta-analysis of the landmark MT trials was published<sup>3</sup>, INRs in the UK identified the need to expand operator numbers for MT immediately and embraced the concept of training other doctors to perform MT<sup>4</sup>. In the following years the INR community worked cooperatively with IRs and the RCR to expand training opportunities and improve patient access to MT. In 2017 an agreement was established to provide focused training for IRs that would enable them to join MT service rotas in RNSCs<sup>5</sup>. This has happened in a small number of RNSCs to-date.

In parallel with this development the RCR agreed to establish a working group to produce a Credential curriculum that would enable doctors from other specialty (non-Radiology) backgrounds to acquire the necessary competencies that would enable them to join established MT services. The multi-disciplinary working group included relevant stakeholders from radiology, neuroscience,

medical, cardiological, educational and regulatory backgrounds as well as patient representation via the Stroke Association.

After confirming proof of concept with the GMC, the RCR working group rigorously evaluated and developed the proposed content of the Credential curriculum, reached consensus across the domains required and outlined by the contemporary GMC guidance and produced and submitted the Credential INR (Acute Stroke) to the GMC Curriculum Oversight Group (GMC-COG) in September 2019.

The content of this inclusive, multi-specialty consensus document was thought to align well with MT training recommendations internationally<sup>6-8</sup>, complied with the requirements of excellence by design and included a requirement for training in both MT and brain aneurysm treatment. Successful implementation of training would enable qualified Credential holders to join established services in RNSCs and help address under-resourced 7/7 services for patients with both ischaemic and haemorrhagic stroke.

### **Justification for Credential training that includes competencies in both mechanical thrombectomy and aneurysm treatment.**

Two clear, strong themes related to training have evolved from the evidence (MT trials and international audits of practice) over the last decade. These are: 'training to participate in an MT service takes time' and 'MT service performance correlates directly with institutional and operator experience and procedural volumes'. These themes have informed remarkably consistent training guidance from the multiple specialist societies involved in INR and MT training around the world<sup>6-11</sup>.

Training opportunities for MT are determined by the workload and service hours of MT services (these were comparatively limited at the time the credential was developed and remain so in current UK practice), so developing the skills to deliver both MT and aneurysm treatment would have the following advantages:

Broaden the theoretical, clinical and practical training experience, accelerate training, enable operators to manage life threatening complications of MT<sup>12</sup>, establish working relationships with INR & neuroscience clinicians and in addition to MT, expand available cover for 7-day aneurysm treatment services in RNSCs (still not provided comprehensively, despite the recommendations of the 2013 NCEPOD report<sup>13</sup>).

The development of advanced clinical, diagnostic and operative abilities beyond the capacity to perform a simple MT procedure was felt particularly important for practitioners that qualify and start work in a new MT centre remote from a RNSC (where Credential holders will practice without immediate support from highly experienced INR colleagues).

It was anticipated that Credential training would develop practitioners capable of contributing to both of the emergency clinical services delivered on a 7-day or 24/7 basis by INRs. This would help meet long standing service needs, would facilitate practical integration with current clinical services and would create a cohort of like-minded clinicians that would also import valuable clinical experience into the INR community.

These concepts were discussed widely amongst INRs and trainees at our 6-monthly UKNG (Specialist Interest Group, SIG) meetings and were supported with understandable reservations about the implications of the Credential for INR training opportunities and potentially for future practice in INR.

### **Progress of the Credential INR (Acute Stroke) from September 2019.**

The scope of training proposed in the Credential INR (Acute Stroke) and the associated time and cost implications, seemed to translate directly into unacceptable messages for the GMC COG. These being 'training would take considerably more time than the COG anticipated' and 'operator numbers will continue to be one of the rate limiting steps that delays the establishment of comprehensive 24/7 MT services across the UK'

The GMC COG rejected the Credential INR (Acute Stroke) with a list of requirements for revision of the document, chief among which were removing aneurysm treatment from the list of required competencies and removing any reference to anticipated training time, or case experience required for acquisition of the necessary competencies. A crucial assumption underpinning COG discussions about training requirements was that other clinical specialists (IRs and cardiologists) already had many of the necessary skills required to participate in a MT service and that training would not take the time suggested by the multidisciplinary group of experts that had worked to produce the Credential (and which aligned with multiple published international guidelines). It is not clear what evidence or experience was used to inform this feedback from GMC-COG, other than the obvious view (shared by all of us) that it was important to expand MT services as soon as possible.

Given the time and effort invested in creating the Credential INR (Acute Stroke), the working group members and RCR officers sought ways to revise the document that would meet COG requirements and could be supported mutually. As revisions progressed, the measures that INRs advised to ensure robust oversight of: credential learner selection, appointment, training and qualification were diluted to a point where working group members and the wider INR community lost confidence in the process.

In late November 2021, RCR officers joined the UKNG meeting in Leeds to encourage and advise the UKNG to accept the revised Mechanical Thrombectomy Credential and to continue to develop its' content with the Curriculum Advisory Group (CAG) after GMC-COG approval. Following a robust discussion, UKNG members voted unanimously against supporting the much revised Credential document. It was clear that there was uncoupling of trust and strategic purpose between the INRs (the coalface MT service providers and trainers) and the institutions responsible for overseeing training in the UK.

#### **Factors that may have confounded GMC-COG evaluation of the Credential INR (Acute Stroke)**

The GMC continued work to revise guidance related to credential development at the same time that the RCR working group was developing the Credential INR (Acute Stroke). Revision of the guidance was required in response to feedback from different Credential development groups, as it became apparent that a one size fits all concept would not be effective for the very different areas of medical practice where Credentials were being developed.

Requirements of employers and service providers to train locally and to manage workload when Consultants take time away from clinical services for training (the mantra to train quickly and therefore to remove potential obstacles to achieving this goal) directly influenced perspectives on how training might be delivered and how long it should take.

The GMC COG's remit proved seemingly inseparable from 4-Nation medical politics. The requirement to ensure that accelerated MT training arrangements would be able to meet the service needs of all 4 Nations (regardless of any Nation's INR establishment, or geographic / demographic advantages, or disadvantages) created expectations that were at odds with current INR training and all reputable international experience and guidelines.

In addition, overt measures were taken to ensure that any standards defined by the Credential would not expose any current or future novel MT training process that developed independently of an INR-supervised training pathway in a RNSC, to medicolegal or political hazard.

**Concerns and consequences that have become apparent during revision of the Credential INR (Acute Stroke).**

The protracted exercise of Credential revision (admittedly exacerbated by the COVID pandemic) has consumed considerable time, effort and resources and is at the point of failure. The unique opportunity to strengthen INR services in the UK now hangs in the balance.

Push back by GMC-COG effectively unpicked the hard fought multispecialty consensus that produced the Credential INR (Acute Stroke), a bespoke cross-specialty training process, supported by the wider neuroscience community, designed to meet the future needs of all stroke patients robustly and sustainably. The removal of aneurysm coiling as a required competency alienated and arguably disenfranchised allied neuroscience specialties, as well as making MT training much more difficult to plan and deliver in practice.

The removal of quality/quantity guidance from the MT Credential is likely to result in different training standards for non-radiologists where the training requirements as outlined in the current MT Credential, are defined appreciably less stringently than in the RCR IR curriculum. The INR trainees have raised specific concerns about both the quality and competition issues that may ensue with the RCR. Dilution and even bypass of robust INR trainer oversight of Credential learner selection, supervision of training and determination of qualification, has led to the INR trainers voting to withdraw their support of the current version of the MT Credential.

In the absence of INR agreement with the changes that the GMC-COG required before supporting the MT Credential, RCR officers have expressed concerns that failure to embrace Credential training may open the door to expedient training solutions that do not have INR or RCR oversight. Such proposals have been made by new start-up centres and other professional groups, with scant regard to advice from the INR community. The National Lead for Stroke in England is also briefing for a rapid response to address the MT capacity gap and considering novel (unproven) solutions to expand training and local MT service delivery (outside RNSCs).

The INR community in the UK agrees there are significant risks this may be attempted and are extremely concerned that novel MT training processes that develop without the support of or input from INRs and RNSCs may undermine training standards, service quality and patient safety in future.

**Risks of focusing on operator numbers as ‘the’ rate limiting step for service expansion and advocating accelerated MT training as a solution.**

The focus on accelerating MT training as a solution to MT service development is understandable but misguided and overlooks the major and arguably much greater system wide challenges that will continue to delay MT service expansion regardless of operator numbers. The NHS remains comprehensively under resourced at Acute Stroke Centre (ASC), Ambulance Trust and Comprehensive Stroke Centre (CSC) levels.

The protagonists for accelerated training do not take sufficient account of the costs and lead-times required for MT service set up and delivery (particularly for newly qualified MT practitioners and for new MT capable CSCs). These include:

Capital - building, imaging equipment, PACS integration, AI tools (and adequate back-up arrangements)

Revenue - consumable equipment, staffing, training

Organisational - establishing new regional cross-Trust integrated systems of care and clinical governance, reputational (service performance)

Personal – moral injury, work-life balance, resilience, burn out

There are also concerns related to sustainability after Credential training, as a fine balance between operator numbers and skill maintenance exists in this field. Given increasing evidence that low centre and individual operator volumes result in greater mortality and poorer outcomes in stroke survivors<sup>10-11</sup>, MT capable CSCs will likely need to sustain unit thrombectomy volumes >125 per annum and >40 interventional procedures per annum per operator to avoid significantly worse outcomes. To sustain 24/7 rotas, at least 6 WTE operators are likely to be required<sup>14</sup>. This will easily be achieved in RNSCs with already large volumes of neurointerventional procedures, but may be unachievable in new MT only CSCs.

While expanding MT service coverage may be achievable by developing new MT-capable CSCs, will it be equitable and cost effective? There is no high quality evidence in the UK to support any such

assertion. Furthermore, service modelling that enables MT-capable CSC to achieve the MT volumes that ensure all operators have sufficient caseload to comfortably maintain skills, results in an optimum number of MT centres in the range 34–40, a total that is only slightly greater than existing number of RNSCs in the UK (n=30). Creation of multiple small volume MT-only CSCs seems likely to prove an extremely expensive route to achieving inequitable services.

Investing in the existing 30 RNSCs to expand train opportunities for doctors from a variety of medical backgrounds that can work with and develop alongside INRs, with their support, is likely to prove a faster, safer and considerably more cost effective solution to expanding MT service delivery. A small number of additional geographically appropriate high volume MT only centres are still likely to be required in addition to RNSCs if (lower) investment in helicopter air ambulance services is not judged an appropriate alternative. The opportunity costs of speculative investment in new services will be reduced available funding for existing established effective services (by diverting funding from RNSC) and reduced funding for whole service development (across referral networks to the RNSC).

The operationally naïve specialists volunteering to train in novel schemes may be substantially under-estimating the time it takes and the local expertise required, to establish new safe multi-institutional patient care pathways in what for them would be a totally new area of medical practice. Investment in novel training processes is proposed to help accelerate training despite unproven clinical efficacy and uncertain longer-term returns.

Predicable, inevitable and avoidable learning curve issues await new inexperienced operators practicing in low volume MT centres (with the consequent risks of individual and or service failure exposing patients to risks of service unavailability as well as increased complications). There is also the risk that once trained, Credential holders will form or join SIGs that are independent of INRs and the RCR, with a consequent divergence of processes to document clinical outcomes, audit procedures, report complications and subsequently to proliferation of SIG specific standards and guidelines, as has happened in other countries. This is not in the best interest of patients or the NHS.

### **Ethical ideals vs. facts of life in NHS MT services**

While equitable service provision is both the ideal and the goal, inequality of access to clinical services is regrettably an established operational reality across NHS services. The clinical effectiveness of MT as a procedure adds an appropriate sense of urgency to all measures that we take to expand MT service delivery. However, the INR community argue that failure to rapidly

expand comprehensive MT services is the result of broadly acknowledged system wide issues in the NHS and that it is not wise, appropriate, or defensible to misuse the slow pace of service development as justification to promote novel unproven training pathways to drive down training times for future practitioners. How does this align with putting patients' first<sup>15</sup>?

The failure to account for current patterns of service provision, medical evidence, specialist expertise, trainer experience and real world constraints to service delivery and development is mind boggling to the INR community that is actually delivering the MT service in the UK. We are extremely concerned by the implications and likely consequences of the GMC-COG supporting novel MT training pathways for future practitioners that develop without INR support or RCR oversight<sup>16</sup>.

That said, despite the absence of support for the MT Credential in its' current form, the UKNG will continue to explore options with the RCR to develop MT training opportunities. We hope pragmatism will prevail and despite our Credential experience to date, the INR community remains open-minded and prepared to train doctors from other backgrounds (mainly IR and neurosurgical so-far) to join practices in RNSC without a formal qualification beyond their CCST.

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