

Position Statement

April 2019



Royal College
of Surgeons

ADVANCING SURGICAL CARE

Recommendations for assuring standards in the independent sector

Introduction

The deeply concerning case of Ian Paterson, the surgeon who was convicted of intentionally wounding patients by carrying out unnecessary breast surgery operations, highlighted the need for an urgent review of how we assure safety standards in healthcare. Despite concerns raised about his professional competence and conduct, he was allowed to continue working for over a decade across the NHS and independent sector. There is no doubt that Ian Paterson was a rogue surgeon. The vast majority of doctors perform their work to a high standard with the utmost care for their patients, and surgical treatment in the UK is among the best in the world. However, the entire healthcare sector must do everything it can to prevent someone like Ian Paterson from ever causing harm again.

Over the last decade there have been a number of initiatives to prioritise patient safety in the NHS. While the Care Quality Commission (CQC) continues to rate most independent providers as good on safety, this drive has not happened consistently across the sector, although there is now a growing focus on better assuring standards of care, including initiatives detailed in this paper. This is important as privately self-funded care is growing for many providers and the NHS is increasingly looking to independent providers to relieve capacity as it faces growing demand for services. In 2017-18, the independent sector undertook almost a third of all NHS-funded knee and hip

replacements and carried out over half a million planned NHS surgical procedures.

Following Ian Paterson's conviction, the Government launched an independent inquiry and announced the scope of its investigation would include the independent sector. The Royal College of Surgeons' (RCS) President, Professor Derek Alderson, gave oral evidence to the Paterson inquiry in September 2018. Separately, the RCS has been working with stakeholders including the Healthcare Quality Improvement Partnership (HQIP) and the Independent Healthcare Providers Network (IHPN) - which had already begun a programme of work - to identify what changes are necessary to improve standards in the independent sector and prevent the circumstances that enabled Paterson to continue practising happening again.

The CQC published *The State of Care in independent acute hospitals* in April 2018 that found the majority of independent hospitals in England are providing high quality care to patients with effective leadership and close oversight of service provision.¹ However the report also revealed variation in quality and showed that two-fifths of independent hospitals required an improvement in safety standards, while "a lack of effective oversight" of consultants with practising privileges was a "major concern". The CQC report led to the Health Secretary writing to the chief executives of independent hospitals, advising them to take urgent steps to improve patient

safety, or face tough sanctions imposed by the Government.²

Ultimately we would like to see equivalent and consistent high standards of care in both the NHS and the independent sector. In particular, alongside IHPN, we are calling for independent hospitals to be enabled to collect and publish equivalent data to that which the NHS routinely provides on patient safety and clinical audits, and to record data on the use of innovative treatments. The RCS and IHPN would also like to see more robust clinical governance procedures to cover the monitoring of consultants' practising privileges and scope of practice, and better sharing of information about consultants' performance between the NHS and independent sectors, particularly for the purposes of appraisal and revalidation. Finally, we would like to see opportunities more consistently available for surgical trainees to work in the NHS-funded independent sector.

The RCS has also received endorsement from the Academy of Medical Royal Colleges (the representative body for the UK and Ireland's 24 medical Royal Colleges and Faculties) for the recommendations in this position paper. The Academy's Council has recognised that these standards would and should be applicable across different medical specialties operating in the independent sector.

Areas where change is needed

Data collection and publication

The RCS welcomes the initiatives to improve data transparency in the independent sector following the Competition and Markets Authority (CMA) report in 2014 that recommended independent hospitals publish more information about the quality of their services to enhance patient choice.³ This led to the creation of the Private Healthcare Information Network (PHIN) with a legal mandate to collect data for independent hospitals across key safety and quality indicators, including admissions rates, average lengths of stay

for each procedure, mortality rates and frequency of adverse events, although much of this information is yet to be published. PHIN produced initial performance measures for over 1,000 consultants working across independent healthcare in the UK in September 2018 and another 4,000 are working towards publication. This year, PHIN and NHS Digital also launched the Acute Data Alignment Programme (ADAPt) with the aim to ensure independent healthcare data is recorded in the same way as NHS data in England. The programme will accelerate the publication of the mandated information collected by PHIN and transfer data on 750,000 privately funded hospital episodes each year from PHIN to NHS Digital.

Undoubtedly progress has been made. A key remaining issue is that there is no regulatory alignment between NHS and independent hospitals' reporting requirements for patient safety and outcomes data.

Patient safety data

Although the independent sector has a duty to report data around unexpected deaths, never events, and serious injuries directly to the CQC, these data are not routinely published by the CQC. This needs to change. Neither does the independent sector yet have a dataset equivalent to Hospital Episode Statistics – the dataset that publishes how many and what procedures have happened in the NHS – although discussions are occurring between PHIN and NHS Digital to enable independent sector data to be included in these statistics.

National clinical audits

The independent sector has to date not been enabled to contribute to the majority of national clinical audits that collect data on care outcomes, including cancer audits, despite the fact that many independent providers regularly offer cancer treatment. The National Joint Registry (NJR) is a notable exception as it is funded by subscriptions paid by both NHS hospital trusts and private hospitals and clinics implanting prostheses, as well as by implant manufacturers. This may

provide a model for other procedures where an implant is used.

The RCS has been working with HQIP and IHPN to review which existing national clinical audits the independent sector can contribute to and the barriers that need to be overcome. HQIP and IHPN would like to explore how the NJR is working in the independent sector and pilot independent sector involvement with cataracts, breast cancer and possibly the prostate cancer audits, and initial discussions are underway with relevant organisations. The independent sector is keen to gain access to the national clinical audit programme and it is hoped that these two pilots will allow any obstacles to be identified and overcome. Once this happens, the RCS suggests this could become a condition of registration for both independent and NHS hospitals' registration with the CQC to ensure participation across all hospitals.

Innovation data

More broadly, we are aware that patients often turn to the independent sector to access new surgical procedures or treatments that are not routinely available in the NHS. However in contrast to medicines, many surgical innovations are currently introduced without clinical trial data or long-term follow-up data, making it difficult to objectively assess benefits and risking patient safety. The RCS is calling for all new surgical procedures and devices to be registered, with related data collected in appropriate national audits before they are routinely offered to patients. This would cover the use of innovative treatments in both the independent and NHS sectors. It would also require Government funding and support, and potentially national guidelines on the introduction of new procedures and technologies. When adverse incidents do occur, it is imperative that they are reported by staff and thoroughly investigated by the Medicines and Healthcare products Regulatory Agency (MHRA).

Clinical governance arrangements

The RCS is concerned that the lack of robust clinical governance procedures in

some independent hospitals makes it more difficult for them to effectively monitor consultants' work and ensure patients are treated safely. Indeed, the CQC's report in April 2018⁴ found wide variation in the quality and effectiveness of governance arrangements in the independent sector, with some relying on informal arrangements based on longstanding relationships.

We welcome the IHPN's initiative to develop a Consultant Oversight Framework for independent hospitals in England and are grateful for the opportunity to contribute through our representation on the reference group. The framework will help to introduce consistent standards for clinical governance and we hope it will address the issues outlined below.

Practising privileges and Medical Advisory Committees

In contrast to the NHS, surgeons are not technically employed by independent hospitals and are instead granted "practising privileges" to work in them. Although not employees of the hospital, regulations set out that consultants working under practising privileges are considered to be in "employment" so the provider has the same regulatory accountability for both.⁵

When a patient undergoes private treatment, the surgeon holds a contract directly with them, while there is a separate contract between the patient and the independent provider to cover the hospital's facilities and services such as nursing. The Medical Advisory Committee in an independent hospital advises the Registered Manager on the granting and monitoring of consultants' practising privileges. These committees are a voluntary structure and not a regulatory requirement, and consist of consultant representatives working in the hospital, the nursing director/clinical services director and frequently the HR director.

The CQC found that poor clinical governance procedures in some independent hospitals were often compounded by the ineffectiveness and

informality of certain Medical Advisory Committees that were not assessing whether a consultant was only undertaking procedures they were experienced to do, and not undertaking new or innovative procedures without effective risk assessment and monitoring. In addition, the CQC was concerned about the informality they sometimes found within the operating theatre – for example, some theatre teams were not following the World Health Organization five-step surgical safety checklist, and this was not always sufficiently challenged by staff. Therefore the RCS recommends that the remit of Medical Advisory Committees in independent hospitals should be more clearly defined to ensure they are better able to advise the Registered Manager on patient safety standards and consultants' practising privileges. It would also be valuable for these committees to include co-opted Board members from the NHS so they can draw on their expertise.

Revalidation and appraisal

Improvements should be made to the wider clinical governance processes that cover both the NHS and independent sectors. For example, as part of the revalidation process overseen by Responsible Officers (ROs) where doctors demonstrate fitness to practise to the GMC, doctors are subject to annual whole practice appraisal. The GMC states that appraisals must cover all the settings where a doctor works and be based on supporting information, including quality improvement activity, significant events, feedback from colleagues and complaints, and contribution to relevant national clinical and audits.⁶ Although this requires the sharing of information about a consultant's performance between the NHS and the independent sector, we are aware of concerns that this is variable as information is not routinely provided to appraisers and vice versa. The GMC recently updated its revalidation guidance to, among other things, "reinforce the importance for doctors who have multiple roles of gathering information that covers the whole of their practice". However the RCS recommends the GMC should improve the appraisal system further by establishing explicit arrangements for

raising concerns in relation to clinical or professional behaviour between the two sectors outside of the appraisal window. Given the vast majority of doctors practising in the independent sector will have a RO in the NHS, there needs to be a more robust process for directly sharing concerns between the RO and independent hospitals.

We also strongly support the IHPN's call for a single dataset or repository about a consultant's whole clinical practice to be available to the independent or NHS hospitals where they work. This could include information about a consultant's practising privileges, indemnity cover, scope of practice, identity of Responsible Officer and appraisal status. Access to such information would help to ensure that concerns about a doctors' conduct or performance are quickly identified and shared with the relevant bodies so that appropriate action can be taken promptly.

Multi-disciplinary team (MDT) working

The RCS believes that independent hospitals should review multi-disciplinary team (MDT) working to ensure a joined-up approach with the NHS where necessary. The MDT system is used to support patients with complex care needs to ensure they receive appropriate treatment based on the views of professionals from multiple clinical disciplines. In particular, independent providers should be required to hold MDT meetings for all cancer patients and to cover the cost if cases are discussed in the NHS. There should also be mandatory arrangements for the transfer of relevant clinical data (e.g. histopathology and imaging) so that it is reported back to MDTs irrespective of whether the pathology was completed in the NHS or by independent pathologists.

Critical care

As the majority of independent hospitals do not have critical care facilities, they usually transfer critically ill patients to local NHS hospitals or to independent sector hospitals with intensive care or high dependency units. However the RCS was concerned by the CQC's findings that some independent hospitals depend on 999 NHS emergency services if an

inpatient deteriorates and do not have formal arrangements in place with local NHS hospitals for the safe transfer of patients. This is despite NICE guidelines that all providers should have standardised systems of care when transferring critically ill patients within or between hospitals. The RCS supports IHPN calls for this issue to be addressed by introducing appropriate service level agreements for critical care support between independent hospitals and local NHS trusts. There should also be robust on-call and emergency cover arrangements for surgeons and anaesthetists within independent hospitals to ensure continuity of care if patients experience post-operative complications.

Surgical training opportunities

The recent RCS position paper, *Surgical training in the independent sector*, outlined our concerns that the transfer of a substantial volume of NHS work to the independent sector has negatively impacted surgical trainees through the loss of training opportunities and a subsequent decrease in morale. The RCS understands that independent providers undertake a pre-assessment risk screening process before treating patients to ensure they can care for them safely, although there is some debate about whether it is fair the NHS will primarily treat more complex patients. This generally means independent hospitals treat patients who are fitter, without major comorbidities, or who require relatively low-risk operations (such as planned hip and knee replacements). As these are ideal training opportunities, this can diminish the access that surgical trainees have to these patients. This means they will have less opportunity to develop the technical and operative skills required for their Annual Review of Competence Progression (ARCP) as their contracts generally do not permit them to work in the independent sector. We are also aware that obstetrics and gynaecology trainees are experiencing similar issues with the loss of training opportunities as benign gynaecology procedures, such as treatment for fibroids and endometriosis,

are increasingly taking place in the independent sector.

Although some local arrangements already exist to support surgical training in the independent sector, the RCS believes that a national framework should be established to give all providers of NHS services across the country the opportunity to invest in the future surgical workforce. To ensure standards of training are consistent, independent providers should adhere to GMC criteria in demonstrating how they identify, train and appraise trainers. We would also like to see reciprocal arrangements for training between independent providers and NHS hospitals, instead of honorary contracts, to ensure that training takes place within NHS contracted hours and trainees are covered by NHS indemnity through the Clinical Negligence Scheme for Trusts.

In order to encourage the independent sector to deliver more training, the RCS understands it would be important that the process is properly funded. This could take place under a tariff based system where the funding follows the patient, instead of hospitals receiving a block grant.

Summary

The RCS is keen to work with the Government, independent providers and the NHS to accelerate improvements in standards of care in the independent sector and ensure the same focus on patient safety as the NHS. Our key recommendations are below:

- Independent hospitals should be subject to equivalent reporting requirements as NHS hospitals for safety and outcomes data. Once the barriers and obstacles to the independent sector participating in clinical audits are overcome, this could be a condition of registration for both independent and NHS hospitals' registration with the CQC to ensure participation across all hospitals.
- All new surgical procedures and devices used in either the independent or NHS sectors should be registered,

with related data collected in the appropriate national audits, before they are routinely offered to patients. This could be supported by national guidelines on the introduction of new procedures and technologies.

- Robust clinical governance procedures should be streamlined across the independent sector to enable consistently effective monitoring of consultants' practising privileges. This should be supported by a clearer remit for Medical Advisory Committees to ensure they are better able to advise on patient safety standards.
- The appraisal process underpinning the medical revalidation system should be reviewed to improve the sharing of information about a doctor's performance between the independent and NHS sectors.
- A single dataset or repository about a consultant's practising privileges, indemnity cover, scope of practice, identity of Responsible Officer and appraisal status should be accessible to all independent and NHS hospitals

where they work to enable prompt action in response to concerns about a doctor's performance.

- Multi-disciplinary team (MDT) working in the independent sector should be reviewed to ensure it includes arrangements for information sharing between the independent and NHS sectors.
- There should be appropriate service level agreements between independent hospitals and local NHS trusts for critical care support, along with robust on-call and emergency cover arrangements for surgeons and anaesthetists within independent hospitals to ensure continuity of care if patients experience post-operative complications.
- In order to improve surgical training opportunities in the NHS-funded independent sector, a national framework should be established to ensure consistent standards of training, streamlined funding and indemnity arrangements, and compliant hospital rotas.

¹ Care Quality Commission, *The state of care in independent acute hospitals: Findings from CQC's programme of comprehensive independent acute inspections*, April 2018

² Letter from Jeremy Hunt, Secretary of State for Health to independent healthcare providers, *Patient safety and acute care in the independent sector*, 8 May 2018

⁴ Care Quality Commission, *The state of care in independent acute hospitals: Findings from CQC's programme of comprehensive independent acute inspections*, April 2018

⁵ Health and Social Care Act 2008 (Regulated Activities) Regulations 2014

⁶ General Medical Council, *Guidance on supporting information for appraisal and revalidation*, May 2018