Department of Health

From Dr Dan Poulter MP
Parliamentary Under Secretary of State for Health

Richmond House
79 Whitehall
London
SW1A 2NS

Tel: 020 7210 4850

Mr A Harris
Senior Coroner
The Coroner's Court
1 Tennis Street
London
SE1 1YD

16 OCT 2014

Dear Mr Harris

Thank you for your letter following the inquest into the death of Thomas Warren. I was very sorry to read of Thomas' tragic and avoidable death.

I understand Thomas suffered from cerebral palsy. Your report indicates that on 17 November 2008, Thomas was prescribed a 25mg Fentanyl patch for pain by a doctor in the A&E department of the Queen Elizabeth Hospital Woolwich. He developed symptoms of drowsiness, sickness, drinking a lot and feeling hot and cold. He had a heart attack at home on 19 November 2008 and although advanced life support was provided by ambulance and hospital staff, he did not regain consciousness and died later the same day.

You found that the failure of the prescribing doctor to admit Thomas to hospital and prescribing an opiate drug to a small opiate-naive child, outside the drug's licence, amounted to neglect. Opportunities were missed by the pharmacy to stop the dispensing of the drug and to give Thomas's parents adequate information to monitor the effects of the drug.

The prescribing doctor was recruited as a locum Paediatric Registrar the day before this incident, through a recruitment agency. There appeared to be no requirement by the Trust for the Agency to make checks on registration or fitness to practice.

The Trust did not interview the doctor concerned but had checked there were no restrictions on the doctor's practice by the GMC. It had obtained a reference from an employer in Canada. However, the doctor had been employed in New Zealand in the interim where concerns were raised and an investigation begun. In addition, the doctor had been referred for NCAS assessment from an NHS Trust in Wales in 2007. This had not been completed because the doctor left

NHS employment and went to New Zealand in January 2008. The assessment was subsequently completed in 2009.

At the evidence giving, a former Trust medical director agreed it would be feasible for a consultant to ask each new locum about previous fitness to practice concerns or NCAS referrals and that such an initiative would reduce the risks. He also considered that revalidation would offer more reassurance in future, although not necessarily for prospective employers of locums from abroad or with long gaps between UK jobs, as was the case here.

Evidence also suggested that the problem was a complex national one so that the issues should be considered nationally, not just by the local Trust. I agree with this assessment. Robust recruitment and quality assurance of locum doctors working in secondary care is an important issue, and there are several strands of work aimed at improving the situation.

In December 2012, the General Medical Council (GMC) introduced the system of medical revalidation. The vast majority of doctors practising in England will have undergone revalidation during the next three years. All doctors licensed to practise in the UK are now required to demonstrate every five years that they are up-to-date and fit to practise. This is achieved through regular participation in medical appraisal.

In support of medical revalidation, Responsible Officers (ROs) have a statutory duty to ensure appraisal and clinical governance systems are robust and, once every five years, to use outputs from appraisals and clinical governance information to make a revalidation recommendation to the GMC for each doctor. Thus information about doctors, including locums, should be available at national level (held by the regulator) and at local level (held by the employer).

Medical revalidation is still at a very early stage and we need to allow time for the system to bed down so we can assess how well arrangements are working in practice. In the meantime, we have asked the GMC to monitor issues relating to secondary care locums and ensure these issues are reflected in their annual reports.

In November 2013, I established a high level Secondary Care Locum Doctor Working Group. This made a series of recommendations to Government to strengthen the existing arrangements:

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- to strengthen GMC guidance to doctors on appraisals about the need to report on any locum work undertaken;
- to strengthen guidance to ROs to ensure they check with doctors that locum work has been recorded;
- to strengthen the NHS Employers Pre-Employment Standards to include a seventh standard - covering the need for an employer to be provided with information about an individual's RO, dates of revalidation, appraisal and that the employer should check an individual is both fit for practice and purpose;
- NHS Employers to publish a standard audit guide for pre-employment checks, providing greater confidence in audits and checks;
- to strengthen guidance for Trusts, emphasising the desirability of using framework locum agencies, with a section to include best practice when using non-framework agencies;
- NHS Employers to issue guidance to Trusts suggesting the development of a set of core metrics on locum usage, which will give boards visibility of locum usage and quality assurance processes; and
- to provide guidance to Trusts on best practice with regards to quality assurance controls, which sets out minimum requirements.

It is the responsibility of both the locum agency and the healthcare provider to check a doctor is up to date, fit to practise and suitable for a specific post. Ultimately, the employer is responsible for the staff it employs, but if an agency is involved, the agency should apply the same checks as the Trust itself would if employing directly.

The current regulations, *(The Health and Social Care Act 2008 (Regulated Activities) Regulations 2010),* state that the provider must operate effective recruitment procedures to ensure that no person is employed to provide healthcare unless that person is of good character, has the necessary qualifications, skills and experience, and is physically and mentally fit for their role.

Employers must also ensure that for each person they employ, they have available satisfactory evidence of conduct in previous employment concerned with health or social care, including children or vulnerable adults. Where a person was previously employed in a position that involved work with children,

the provider must have satisfactory evidence, as far as is reasonably practical, of the reason why that employment ended, and a full employment history, with satisfactory written explanations of any gaps in employment.

These regulations apply to the employer and ultimately, if the Care Quality Commission (CQC) judges that they have not been met, CQC can take enforcement action.

In addition, the *Medical Profession (Responsible Officers) Regulations 2010* make it a responsibility of ROs to ensure medical practitioners have qualifications and experience appropriate to the work to be performed and to ensure appropriate references are obtained and checked. ROs are fully registered licensed doctors who are responsible for evaluating other doctors' fitness to practise and ensuring effective systems are in place within organisations for the medical revalidation of doctors.

NHS Employers subsequently published guidance on the appointment and employment of locum doctors in 2012 and updated it in August 2013.

http://www.nhsemployers.org/~/media/Employers/Publications/Guidance-on-the-appointment-and-employment-of-locum-doctors.pdf

Section six of this guidance, concerning 'NHS Employment Check Standards' states:

"NHS providers must give evidence of their compliance with these six standards as part of the Care Quality Commission's annual regulatory framework. When employing or engaging locum doctors via an agency, organisations must provide evidence to the Care Quality Commission that the agency is satisfying the same level of employment check standard for each individual doctor as an NHS organisation would apply. Ultimate responsibility for the competence of locum doctors rests with the employer. If the employment checks are delegated to an agency, there must be a clear understanding between the two parties so that no checks are overlooked for any individual doctor."

The Responsible Officer Regulations and GMC guidance make it clear there is an obligation to share information about a doctor when required to maintain patient safety. The NHS Revalidation Support Team developed the Medical Practice Information Transfer (MPIT) form to support the appropriate transfer of information about a doctor's practice to and from the doctor's RO.

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The RO system should now ensure that there is a record of any locum work doctors have done, including any concerns about performance, thus enabling a better transfer of information between NHS organisations.

In addition, an alert notice system also exists whereby an NHS employer can make other bodies aware that a healthcare professional may pose a threat to patients or staff. This system is now administered by the National Clinical Assessment Service (NCAS), having previously been managed by Strategic Health Authorities. NHS organisations who wish to request the issue of an Alert Notice must notify NCAS. NCAS has developed an *Operational protocol for issue of Health Professional Alert Notices* which can be seen at the following link:

http://www.ncas.nhs.uk/EasySiteWeb/GatewayLink.aspx?alId=133014

The ROs, introduced to support medical revalidation, should also ensure appropriate clinical governance systems are in place to record information about the performance of doctors within their organisation. For short-term locum appointments, it is particularly important to ensure any concerns about a doctor are passed on. An exit report should be completed and sent to the doctor, the locum agency and the Responsible Officer, if the Responsible Officer is not from the agency that supplied the doctor. This will help ensure appropriate remediation is put in place. Where there are serious, immediate, concerns about public safety, the alert notice system would enable an NHS employer to make other bodies aware that a healthcare professional may pose a threat to patients or staff.

Your main concerns in this case rightly focus on the employment of locum doctors and the systems that exist to ensure fitness to practise. However there is an issue concerning the prescribing of an opiate drug, fentanyl, to a small opiate naive child. I have therefore provided the following supplementary information on the use of fentanyl, which you may find of interest.

Officials at NHS England have advised that the risks associated with the unsafe use of fentanyl patches are known by the Medication Safety Team in NHS England. In response to a number of patient safety incident reports concerning fentanyl transdermal patches, the team, working with the CQC, have published

guidance on the risks with fentanyl patches, and additional system safeguards to minimise the overdose of fentanyl patches to opiate naïve patients. This

guidance has been distributed to the Accountable Officers for Controlled Drugs in the NHS and is published on the CQC website at the following address:

http://www.cqc.org.uk/content/use-controlled-drugs

This guidance recommends that healthcare provider organisations consider the following safeguards:

Checklist for safer use of fentanyl and buprenorphine CD transdermal patches

1. CD transdermal fentanyl patches should be restricted to patients that are already receiving regular doses of opioids

i. ***Do not use*** *for acute pain.*
ii. ***Do not use*** *in opiate naïve patients.*

2. Before using a CD transdermal patch, calculate the total daily dose of all the opioid analgesics that the patient has received previously. This is usually in morphine equivalence.

Use locally or nationally approved dose conversion charts to do this. There are dose conversion charts in the 'Prescribing In Palliative Care' Section of the British National Formulary and in CD transdermal manufacturers guidance (SPC).

3. Determine a new dose of analgesia to be delivered by transdermal CD patch in morphine equivalents. For changes in analgesia, as a 'rule of thumb', the total daily dose should not be increased in steps greater than 50% of the previous daily dose.

Use a conversion chart to determine the total daily dose of analgesia by CD transdermal patch(es) and where necessary divide by 24 to equate with the micrograms/hour strength of available products.

To deliver the intended dose more than one CD patch may have to be used.
n/b - Formally double check the calculations and where possible have the patient's dose independently verified.

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Following your letter, the Medication Safety Team at NHS England is planning, once again, to highlight this risk and the recommended safer practice at a future monthly meeting of the National Medication Safety Network.

I hope that this response is helpful and I am grateful to you for bringing the sad circumstances of Thomas Warren's death to my attention.

Yours sincerely,

Dr Daniel Poulter MP