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By Email

Mr David Cullum
Clerk to the Health and Sport Committee

healthandsport@parliament.scot

18 December 2017

Dear Mr Cullum

NHS CLINICAL GOVERNANCE

Thank you for your letter of 7 December seeking further information on parts of the evidence that I gave to the Health and Sport Committee on 28 November. I understand that the Committee has also written to my colleague, Robbie Pearson, Chief Executive of Healthcare Improvement Scotland, seeking similar information.

It may be helpful if I first of all explain that in 2012, the Cabinet Secretary for Health, Wellbeing and Cities Strategy instructed Healthcare Improvement Scotland (HIS) to develop a national framework and a programme of reviews for adverse events. [The National Framework](#) was published in September 2013 following extensive consultation. It was then refreshed in April 2015 to reflect changes in best practice and to ensure consistency of approach. We work closely with HIS on a wide range of matters, but as it is the lead organisation for Adverse Events, it will be best placed to respond to a number of the questions in your letter that make reference to Adverse Events, including the implementation of the Framework and the extent to which this has improved consistency of approach across NHS Boards

With regard to your question on a national reporting system for Serious Adverse Events, the Scottish Government's view is that counting what are very rare events at a national level would serve no real purpose other than to provide a false sense of security. Scotland has a very broad and comprehensive approach to patient safety and in the last ten years has seen globally recognised improvements in infections, mortality and harm. We have achieved this by empowering teams in the health system to tackle causes of harm with support and guidance from the SG, HIS and Health Protection Scotland. We have never been convinced that counting so-called 'never events' is a helpful way to drive change.

You have also asked me to provide details on the number of adverse events over the last 3 years. This information is not held centrally but is collected at Board level in order to drive improvement and to identify emerging patterns of incidents and areas of concern, which are then fed into the national learning from adverse events which is overseen by HIS.

The monitoring and management of certain adverse events involving medicines and healthcare products and health and safety (excluding medical matters or quality of care) is complicated by the fact that those areas are also regulated on a UK-wide basis.

The Medicines and Healthcare Products Regulatory Agency (MHRA) is the statutory body that has overall responsibility for the regulation of medicines and healthcare products throughout the UK, and the Health and Safety Executive (HSE) is the statutory body that has overall responsibility for the regulation of health and safety, again, throughout the UK.

The majority of the safety alerts for medicines and medical devices originate from the MHRA or are collaborative outputs from the MHRA and other organisations. The MHRA sends drug alerts, press statements, and important new information to named contacts in the Pharmacy and Medicines Division in Scottish Government. These contacts then send the information to named healthcare professional groups' representatives within the NHS across Scotland with further direction for onward cascade to other identified groups of staff.

Drug Alerts require actions to be undertaken in a directed period. It is the responsibility of the nominated staff group within individual NHS Boards to action and document locally the action record. In the event of a defective product being administered to a patient and it is suspected that the person has been harmed as a result, a report is made to the Scottish Government so that it can decide whether there are any ameliorative steps that need to be taken to prevent further such incidents.

HSE Safety alerts are used to rapidly alert healthcare systems to risks and provide guidance on preventing potential events that may lead to harm. Safety alerts are generated from national and international surveillance of adverse event reporting systems.

You have asked for greater detail on how the performance management infrastructure operates in Scotland. Divisions from across Health and Social Care come together at monthly meetings to consider information on quality, service delivery, finance, and workforce for each NHS Board. Consideration is given to the latest information on the Local Delivery Plan Standards - available through [Scotland Performs](#); the Hospital Scorecard (including Hospital Standardised Mortality Ratio and re-admissions - shared directly with NHS Boards); and other audit or scrutiny information mainly published by ISD or HIS.

Reports are provided to the Health and Social Care Management Board on a quarterly or exceptional basis. Where there are particular concerns about specific NHS Boards, these are escalated. This can involve asking NHS Boards for improvement plans, as well as providing expert clinical or professional advice and support, including support from HIS or dedicated teams.

As the Committee will appreciate, the provision of health and social care services will always be associated with a certain amount of risk and there are unintended or unexpected events that result in harm from time to time. When this happens, people want to be told honestly what happened, what will be done in response, and to know how actions will be taken to stop this happening again to someone else in the future.

It is well established that being candid promotes accountability for safer systems, better engages staff in improvement efforts, and engenders greater trust in patients and service users. That is why we plan to introduce regulations using the powers created under Section 22 of the [Health \(Tobacco, Nicotine, etc. and Care\) \(Scotland\) Act 2016](#), which will introduce a statutory organisational duty of candour procedure to be followed by NHS and social care organisations. The Duty of Candour Scotland Regulations 2018 will come into effect on

1 April 2018. From that date, it will be a legal requirement for NHS boards to publicly report on adverse events where the duty of candour has been applied and on the learning and improvement actions resulting from the review of these adverse events.

However, it is important to stress that duty of candour is not about apportioning blame. In most instances failures in the provision of treatment or care relate to a need for focused attention on quality improvement through the range of improvement and change mechanisms available, supported by strong leadership in a culture of openness and continuous learning. The duty of candour procedure will play a significant role in promoting that agenda.

As regards to building dignity and respect into the healthcare system, The Patient Rights (Scotland) Act 2011 requires Scottish Ministers to publish a Charter of Patient Rights and Responsibilities, which summarises the rights and responsibilities of everyone who uses the NHS in Scotland. The Charter sets out that everyone using NHS services and receiving NHS care has a right to be treated with dignity and respect and to have their individual needs and preferences taken into account.

One of the ways in which we ensure dignity and respect is built into the healthcare system is through our strategic focus on person-centred care. The Scottish Government is taking a proactive approach to involving people and communities in the planning, delivery and continuous improvement of services. The Our Voice framework continues to develop at individual, local and national level, to strengthen public involvement and make sure that listening improves services for everyone. The Our Voice Citizens' Panel is just one example of how people across Scotland are getting involved in shaping and improving health and social care policy and services.

Since 2013, the Scottish Government has supported NHS Boards to engage with the independent website [Care Opinion](#), which enables people to enter into constructive dialogue with service providers about their experience of care. With more than 10,000 experiences shared on the platform and over 1,000 NHS staff reading them, Care Opinion has become a rich source of knowledge about how people in Scotland are feeling about their NHS, what is working well and what could be improved.

For the past two years we have formed a partnership with people who work in healthcare to hold Scotland's 'What Matters To You?' Day. This has proved to be a great way to encourage a collective focus on hearing from the people across Scotland who use health and social care services. This year What Matters To You Day was held on 6 June, when around 700 individuals and teams from across Scotland registered to take part. The aim is for this to become an on-going conversation, taking place every day in health and care settings across Scotland.

The Scottish Government also supports Healthcare Improvement Scotland's Person-Centred Health and Care Improvement Programme, which is bringing people who access support or care together with the people who provide it to co-design improvements to services (using Experience-based Co-Design Methodology). The Programme is also supporting teams working in acute care settings to gather real-time feedback from patients and to use it to inform continuous improvement to services.

Finally, as regards to ensuring that health professionals are able to keep their skills and practice up to date, all healthcare staff who are professionally registered with a statutory body are required to fulfil mandatory hours of continuous professional development (CPD) in order to maintain current registration, provide evidence for revalidation and eligibility to work.

CPD can be undertaken in a range of ways including attendance at educational events, self-directed study and collaborative learning. For nurses and midwives there is a 2% predictable absence allowance for CPD which is built in to the workforce planning tools.

I hope that this information is helpful to the work of the Committee.

A copy of this letter goes to Robbie Pearson, Chief Executive, Healthcare Improvement Scotland.

Yours sincerely

A handwritten signature in black ink, appearing to read 'J. Leitch', with a long horizontal flourish extending to the right.

JASON LEITCH