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Dear Gillian,

### **Never events framework consultation**

APIL welcomes the opportunity to respond to NHS England about the review of the Never Events framework. We believe that the Never Events framework remains an important mechanism to drive patient safety improvement.

The current definition of a Never Event helps identify and prevent serious medical errors that should never occur in any healthcare setting. Whilst we appreciate the issues surrounding the use of the words 'never' and 'wholly preventable' for NHS culture and acknowledge CQC and HSIB's comments regarding the effectiveness of the current framework, we believe that the current definition remains an important driver of patient safety. We do not believe that incidents that occur despite all known controls being put in place should be removed from the framework altogether. Understanding human factors is a key element of a better patient safety system.

The CQC report itself, referred to in the consultation paper<sup>1</sup> found that only 4% of Never Events are amenable to a wholly systemic and technical approach, whilst the overwhelming majority require human factors-based solutions and controls. The persistence of Never Events despite their classification as 'wholly preventable' incidents poses implications for patients, staff, safety culture and blame culture in the NHS. It is therefore our view that option 4 should be explored further as this is more likely to address those issues whilst ensuring patient safety improvements and learning opportunities.

Subject to further consultation and discussion on the new framework, APIL supports the proposal in the consultation paper for a two-tiered approach based on the hierarchy of control requiring a redefinition of the system, placing emphasis on addressing the human element of controls, enabling patient safety improvement. Staff should also be provided with training about patient safety and the interaction between human and system-focused controls and barriers.

We also agree with the proposed introduction of a mechanism to review the lists every three years, as described in the consultation, by the National Patient Safety Team.

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<sup>1</sup> Care Quality Commission's (CQC) *Opening the door to change* (2018) <https://www.cqc.org.uk/publications/themed-work/opening-door-change>

We are of the view that the 'serious, largely preventable, and harmful clinical events' category proposed could have a positive impact on blame culture in the NHS. However, the 'wholly preventable' definition if not implemented correctly could imply blame and should be kept only for 'strong, systemic, protective' barriers. Option 4 recognises the presence of human factors in safety controls and, alongside whistleblowing management and the Duty of Candor, can mitigate blame culture.

APIL also believes that the framework proposed in option 4 is more aligned with the Government's objectives to reduce the cost of clinical disputes. There are financial benefits of maintaining a properly regulated Never Events framework as this is often referred to as part of the pre-action litigation process. Part of the new process for handling lower damages clinical negligence claims requires a 'never event' for a case to be allocated to the light track. This process is due to come into force soon. There was significant debate as part of the Civil Justice Council working group about ways to reduce cost and enable swift resolution of claims with an early admission of liability.

APIL has several concerns regarding options 2 and 3. Option 2 poses a significant risk of undermining patient safety. Past experiences indicate that allowing the NHS to regulate itself without a structured framework leads to defensive behaviour, lack of transparency and accountability when things go wrong. Defensiveness weakens the opportunities to understand the reasons behind safety issues and frequently results in missed opportunities to focus on the identified learning. We strongly believe that abolishing the framework would be a backward step with dangerous consequences for patient safety and would be contradictory to all the work being developed in that area, including the establishment of the Health Services Safety Investigations Body (HSSIB).

We recognise that option 3 presents a more realistic interpretation of Never Events due to the strength of the barriers available to prevent the occurrence of those incidents. However, this approach essentially disregards people-focused barriers, which represent the majority of available controls. The importance of human behaviour must not be overlooked, and as mentioned above, we believe addressing these issues through training could bring meaningful change in patient safety. We also think that this approach would be detrimental to transparency and openness in the NHS and would not align with the Duty of Candor regulations.

We hope that our comments prove useful. If you would like to discuss our response further, please use the contact details below.

Yours sincerely,



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