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National Medical Director

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17 June 2024

Dear Coroner,

Re: Regulation 28 Report to Prevent Future Deaths – Alexander Lee Reid who died on 29 June 2021.

Thank you for your Report to Prevent Future Deaths (hereafter "Report") dated 18 April 2024 concerning the death of Aleander Lee Reid on 29 June 2021. In advance of responding to the specific concerns raised in your Report, I would like to express my deep condolences to Alex's family and loved ones. NHS England are keen to assure the family and the coroner that the concerns raised about Alex's care have been listened to and reflected upon.

I list below the concerns raised within your Report that NHS England can respond to:

- Operation of the COVID-19 Vaccination Programme, including the inclusion criteria for the Shielded Patient List and COVID-19 Population Risk Assessment
- Information provided to patients who were on the Shielded Patient List and subsequently prioritised for vaccination
- Requirements and statutory Clinical Safety duties for GP IT systems suppliers, and our responsibilities for their assurance.

These reflect areas of NHS England's responsibilities which incorporate some activities formerly operated by NHS Digital, which formally merged with NHS England in February 2023. I address these concerns below.

Shielded Patient List

In February 2021, on the instruction of the Department of Health and Social Care (DHSC), a COVID-19 Population Risk Assessment took place. This risk assessment used data routinely extracted from GP IT records systems – obtained under the General Practice Extraction Service (GPES) – and hospital record systems including Hospital Episode Statistics (HES). These data were used to update identification of the cohort of people to whom infection with Covid-19 could pose a greater risk, and so to whom an invitation for vaccination would be prioritised. The risk assessment used the original – and at that time, latest - version of the QCovid® algorithm. This cohort was identified as "clinically extremely vulnerable", and for inclusion on the Shielded Patient List (SPL). They would receive further information on shielding and be prioritised for invitation for vaccination.

Patients identified as Clinically Extremely Vulnerable were managed on an ongoing basis within the SPL, alongside those other patients routinely identified as high risk through:

- the existing clinical methodology
- locally by GPs, or
- by hospital specialists.

As and when patients were no longer considered at high risk by GPs and / or clinicians, their risk status could be updated in the SPL.

Due to the speed and scale of the vaccine rollout, at the time safeguards were introduced into the system to enable curation of the SPL. This included:

- A writeback of the reason for inclusion into the GP records
- A tool to look up the patient's inclusion for prioritisation
- An enquiry page and email to support patients seeking to understand their inclusion.

Issues surrounding this topic were the subject of considerable media interest and discussion at the time of using QCovid®.To support the safety of the process, safeguards were built into the centrally cohorting systems. Regarding the specific issues raised in your Report, these included:

- Use of the most recently recorded patient BMI **within the last 5 years**
- Minimum BMI of 15.0 and maximum of 47.0 – data outside this range amended to either 15.0 or 47.0 and marked as data corrected in processing file.
- Default value of 31 used when no BMI data is available.

These safety steps were made publicly available at COVID-19 Population Risk Assessment - NHS England Digital:

- If a person's BMI was not available, a BMI of 31 was used by default. This was the midpoint BMI in the population data. This would have been utilised in Alex's case, where the recording of the BMI was more than five years previously.
- If BMI was more than 47, then a BMI of 47 was used to generate the results.
- If BMI was less than 15, then a BMI of 15 was used to generate the results. This was because almost all (99.9%) BMIs in the UK are between 15 and 47. BMIs calculated as being lower than 15 or higher than 47 were likely to be a mistake which would affect the accuracy of the result.

It is therefore unlikely that the BMI of 69.87 incorrectly recorded on the GP record in 2004 caused Alex to be identified as Clinically Extremely Vulnerable by the National COVID-19 Population Risk Assessment.

Local areas were also able to create their own lists of Clinically Extremely Vulnerable patients for shielding. NHS England cannot comment on the processes that were operated at a local level as this would be subject to local governance and controls.

More information can be found about SPL [here](#) and details of how the list was created are [here](#). A [transparency notice](#) following the closure of SPL provides further information.

Information to Shielded Patients and their GPs

Patients on the SPL were issued with a letter outlining that they had been identified as Clinically Extremely Vulnerable, that they would be invited for vaccination, and were provided additional advice, guidance, and the support available for clinically extremely vulnerable patients at that time. They were informed that their GP would be made aware of their inclusion in the SPL (via updates to the risk flag indicator in the GP record for each patient), and the letter stated that, where patients were unaware why they would be - or did not believe they were - at high risk from COVID-19, they could contact their GP or hospital clinician who could update their records accordingly (as described above). To support this, the details of their registered GP were included in this correspondence.

Clinical Safety of Structured Data Entry into GP IT Systems

Core GP IT records systems are developed - and centrally assured - against standards set out in the GP IT Futures Framework. More information about this can be found [here](#).

Over and above this, all Health IT systems used in the NHS must comply with statutory duties set out in section 250 of the Health and Social Care Act 2012. These duties are described by two Clinical Safety Standards, [DCB 0129](#) and [DCB 0160](#). These standards require that consideration be given to all potential hazards or harms to patients (and users) through use of the product or system. This includes the entry and transmission of patient data.

Depending on the system, a GP IT system can allow height, weight, or BMI to be entered manually. Most systems will offer to calculate BMI when both height and weight are entered/available.

Where there is an automated calculation using other data items (such as is the case for BMI), there is no currently implementable means to apply validation – or define normal – across domains. It should also be noted that the ranges of values that may be possible (or probable) for height, weight and BMI vary by age, gender, and may vary by ethnicity.

We recognise the value in data validation for factors such as BMI. This currently does not exist and the implementation of such tools should be balanced against the sizable implementation challenges, and subsequent clinical risks and hazards that would arise. Such risks and hazards would be considered within the Clinical Safety Case for the product, and a balanced risk assessment would be required to support implementation.

Central Data Extracts, Validation and Future Cohorting

Cohorting of patients drives many systems within the NHS – from vaccinations through to screening. Ensuring accurate and appropriate cohorting ensures the safety and effectiveness of health protection activities.

As described above, in this case, data was extracted from the GP records system via the General Practice Extraction Service (GPES). Safeguards are developed alongside data use for cohorting of patients. This is clinically assured and includes aspects such as:

- exclusion of data that may not be reliable due to time interval since recording
- normalisation/limitation of effect of extremes of recording.

Patient and Digital Clinical Safety in General Practice

NHS England takes Patient Safety extremely seriously. As such we published our Patient Safety Strategy in July 2019 and have developed the Patient Safety Syllabus, which is accessible to all staff, including those working in General Practice and Primary Care. More information on our Patient Safety Strategy is available here.

With the increasing use of digital systems in the NHS, we subsequently published the Digital Clinical Safety Strategy in September 2021. NHS England has developed materials for training on this subject, which includes the safe, effective use of health IT systems, and made this available to all staff. More information on the Digital Clinical Safety Strategy is available here.

All staff should be trained in the safe use of health IT systems that they use routinely to perform their clinical duties. This is a matter for local employers and the development of policies and procedures to support this are monitored by the relevant regulatory bodies – in the case of health care service providers, this is the Care Quality Commission.
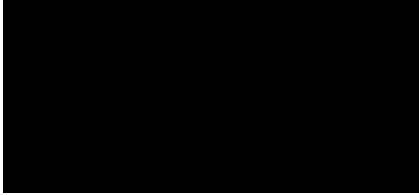
Further actions for NHS England

We note the risks that arise from the inaccurate inclusion of data values in cohorting activities and will continue to operate a clinically assured data extraction and validation service to drive future health promotion activities. We will work towards surfacing inclusion data to patients via their NHS App, so that they may discuss their inclusion in health promotions with their care providers.

To support the work of the Primary Care Patient Safety Team, we will promote the Digital Clinical Safety Strategy, and all training modules that are available for staff via these channels.

I would also like to provide further assurances on national NHS England work taking place around the Reports to Prevent Future Deaths. All reports received are discussed by the Regulation 28 Working Group, comprising Regional Medical Directors, and other clinical and quality colleagues from across the regions. This ensures that key learnings and insights around preventable deaths are shared across the NHS at both a national and regional level and helps us pay close attention to any emerging trends that may require further review and action.

Thank you for bringing these important patient safety issues to my attention and please do not hesitate to contact me should you need any further information.

Yours sincerely,

National Medical Director