

Ms. Rebecca Sutton,
Assistant Coroner for County Durham and Darlington,
H.M. Coroners Office,
P.O. Box 282,
Bishop Auckland,
Co. Durham.
DL14 4FY

27 March, 2024

Dear Madam,

Re: Response to Regulation 28 Report to Prevent Future Deaths dated 5 February 2024

1. This is Oracle Corporation UK Limited's (formerly Cerner Limited) ("**Oracle Health**") response (the "**Response**") to the Regulation 28 Report to Prevent Future Deaths dated 5 February 2024 (the "**Report**"). The Report was issued by Assistant Coroner Ms. Rebecca Sutton (the "**Assistant Coroner**") following an Inquest opened on 6 January 2023 into the death of the Deceased on 19 December 2022 (the "**Inquest**"). Oracle Health was not invited to participate in the Inquest or given an opportunity to make representations and was not aware of it until receiving the Report.

A. EXECUTIVE SUMMARY

2. Oracle Health deeply regrets and was saddened to learn of the various medical omissions which ultimately caused the death of the Deceased and extends its condolences to the family of the Deceased and others bereaved. Oracle Health assures the Deceased's family that Oracle Health takes the contents of the Report extremely seriously and that in response to it, Oracle Health has conducted a thorough and in-depth review of the Millennium software deployed and in operation at the Emergency Department of the University Hospital of North Durham ("**Durham Emergency Department**").
3. While there is no suggestion that the software was at fault, and many factors contributed to the death of the Deceased, based upon Oracle Health's review and the facts and matters described more fully in this Response, it concludes as follows (key findings in this Response are highlighted in **bold** throughout):
 - 3.1. Oracle Health has not identified any evidence to suggest that the death of the Deceased was preventable by reason of any alleged defect in its software. The Millennium software was working as designed and configured in conjunction with the County Durham and Darlington NHS Foundation Trust ("**CDDFT**").
 - 3.2. Launchpoint's homescreen does provide clinicians with a colour coded 'RAG rated' Acuity Score for individual patients.

- 3.3. Launchpoint's homescreen also provides clinicians with a separate 'Early Warning Score' for individual patients (an aggregate assessment of certain vital signs and physiological measurements). While this *aggregate value* is not colour coded, Launchpoint does display the constituent *individual* vital signs and physiological measurements entered through Millennium in red where classified by healthcare providers as 'critical'. The functionality also exists to colour code any other values by their risk level.
- 3.4. Oracle Health has no record of CDDFT raising any clinical safety issues relating to the display of patient Acuity Scores or Early Warning Scores in Launchpoint during the Millennium training process or additional support period. CDDFT raised no service issue with respect to the display of patient Acuity Scores or Early Warning Scores in Launchpoint as part of the deployment testing process or subsequent to the systems going live in October 2022.
4. Notwithstanding the above conclusion, that the Millennium software at Durham Emergency Department was working as designed, configured and approved by CDDFT, Oracle Health fully acknowledges the importance of the Assistant Coroner's observations. In particular, the Assistant Coroner's desire to ensure that there is a "*quick and clear way of identifying the most critically ill patients*", especially "*in times of extreme pressure*" on Durham Emergency Department, including through the inclusion of a "*RAG rating system*". Oracle Health has engineered a configuration enhancement, namely an additional colour coded column on Launchpoint's homescreen charting individual patient's 'Early Warning Score Risk Level'. This enhancement will be available for deployment to CDDFT and other legacy deployments from around June 2024.

B. ORACLE HEALTH AND MILLENNIUM

5. Oracle Health's Millennium software has been successfully deployed globally, first in the United States in 1984 and since 1986 internationally. Oracle Health has licensed its solution at 28,000 facilities around the world, and has adapted Millennium to various types of facilities, including 3,000 hospitals, 3,500 physician practices, 200 home health facilities and 200 employer sites. Oracle Health's clients include over 39 NHS Trusts.
6. Oracle Health designed Millennium as an electronic patient record solution. The solution automates the care process and workflows by creating an electronic medical record through which physicians can access near real time data. By organising the data around the patient, rather than the patient encounter, Millennium eliminates duplication and encourages best practice by placing data only once in a central repository. Millennium enables information from disparate clinical domains and multiple facilities to be seamlessly integrated.
7. The Millennium solution currently comprises nine solution and service sets with sub-modules. Within Millennium's Emergency Medicine Solution, the relevant sub-modules for the purposes of this Response are as follows:
 - 7.1. **FirstNet:** is a data entry and management solution that supports functionalities including registration, triage and tracking of patients through their Emergency Department encounter and nursing documentation. Features of this solution include the ability to integrate with patient registration, the clinical patient chart, and patient tracking lists that can be customised to check patient status and view test results quickly, providing ED clinicians with the information and tools they need to streamline patient care and patient throughput.

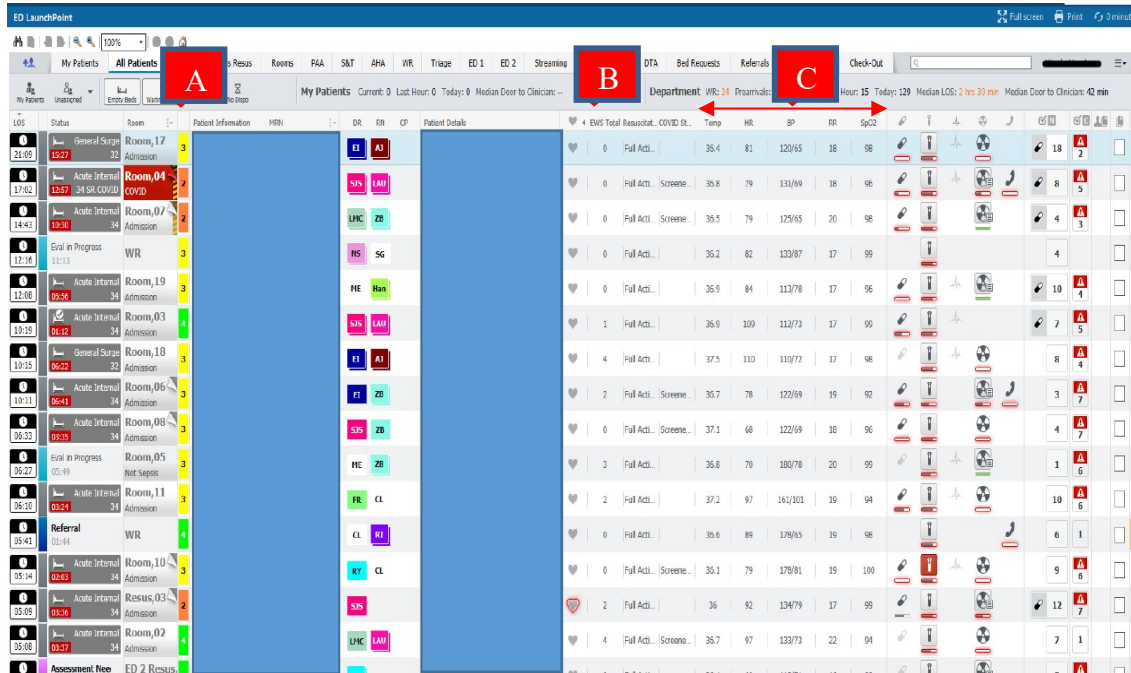
- 7.2. **Launchpoint:** provides a clinician-focused view of the data held in FirstNet. It is a dashboard that is used for managing and monitoring all patients within an Emergency Department. It provides a single location for the Emergency Department clinicians to locate and view the workflow, orders and patient information enabling them to drill down where additional detail is available. It is distinguished from FirstNet on the basis that Launchpoint is the principal interface through which clinicians view clinical data entered through FirstNet.

C. DEPLOYMENT OF MILLENNIUM AT CDDFT

8. In December 2020, CDDFT signed an agreement to implement Oracle Health's Millennium solution. Millennium went live in the Durham Emergency Department in October, 2022.
- (i) Configuration of Launchpoint by CDDFT
9. The initial steps in the deployment of the Millennium solution involves an assessment of a client's existing systems, an evaluation of their objectives and a demonstration of the relevant solutions in default configuration. Following the initial consultation process, Oracle Health hosted a series of design and configuration workshops for CDDFT between around June 2021 and mid-October 2021. Workshops covering FirstNet and Launchpoint were hosted by Oracle Health's Emergency Department and/or Clinical Documentation Teams and were attended by subject matter experts empowered to make design decisions on behalf of CDDFT. It is critical to the success of deployments that appropriate decision-makers attend these sessions and they are required to have a solid understanding of the workflow processes within their areas of expertise.
10. There are no specific Government or NHS regulations, or guidance, governing how patient Acuity Score or 'National Early Warning Score' ("**News2**") information is displayed in electronic healthcare systems. However, as an experienced industry leader in electronic healthcare, Oracle Health has developed content, workflows and decision support to meet the needs of its client base. As part of the design and configuration workshops, CDDFT representatives were given the opportunity to tailor certain aspects of FirstNet and Launchpoint functionality to the specific needs and workflows of CDDFT.
11. Oracle Health understands that the display of patient information was only raised during the course of oral evidence at the Inquest and that the Assistant Coroner may not have had the benefit of a written, or visual, description of Launchpoint. Such evidence also appears to have used the terms patient 'Acuity' and 'Early Warning Score' interchangeably, but they are separate and distinct concepts:
- 11.1. **Acuity** is a measurement of the severity of a patient's condition and the urgency with which they need to be seen by a clinician. FirstNet licences and incorporates the 'Manchester Triage System'. Acuity is generally assessed at the point of admission to the Emergency Department and does not typically change during a patient's journey through the Emergency Department. A patient's Acuity Score assists Emergency Departments in determining onward patient care, including the timing and frequency of further medical intervention and observations. The Acuity Score is to be *contrasted* with a patient's Early Warning Score (described below), which typically will change through the patient journey.
- 11.2. An **Early Warning Score** derives from News2, a system endorsed by the Royal College of Physicians, NHS England and the National Institute of Clinical Excellence (NICE). The system strives to improve detection and response to clinical deterioration, by scoring certain vital signs and physiological measurements that are routinely recorded at a patient's

bedside (e.g., blood pressure, temperature and respiration rate) according to a standardised NHS scale for assessing and responding to acute illness. The scores assigned individual vital statistics and physiological measurements are then aggregated to provide an overall score. As a patient’s relevant vital statistics and physiological measurements change, so too will their Early Warning Score.

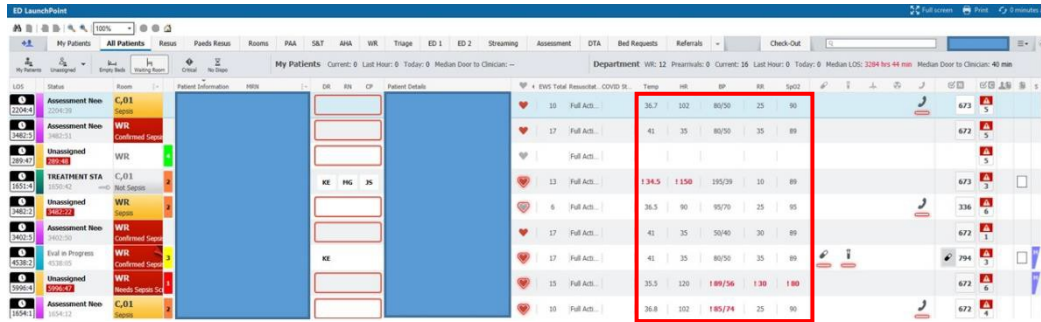
12. The following is a screenshot of Launchpoint as configured in conjunction with CDDFT:



Screen 1: Launchpoint as configured in conjunction with CDDFT.

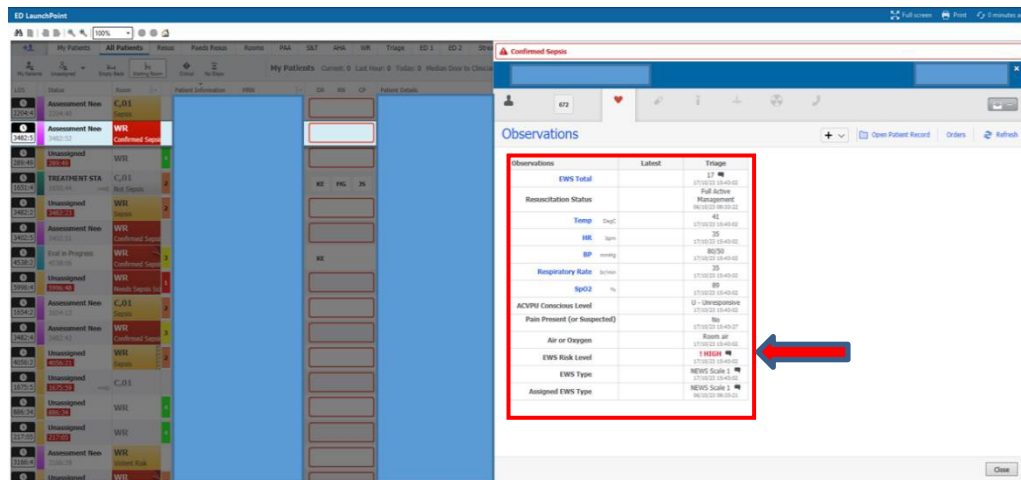
13. By way of further explanation of the above screenshot:

- 13.1. **The column labelled ‘A’ displays a colour coded, ‘RAG rated’ Acuity Score for each patient.** With reference to the Manchester Triage System, clinicians can enter the relevant score into FirstNet, which is then displayed in Launchpoint as above.
- 13.2. **The column labelled ‘B’ displays a patient’s Early Warning Score.** Unlike the patient Acuity Score listed in Column A, the functionality does not currently exist to colour code the Early Warning Score when FirstNet is used in conjunction with Launchpoint. CDDFT representatives did not identify this limitation as a clinical risk, or other impediment to go-live, during the design workshops and were content to proceed.
- 13.3. **The columns labelled ‘C’ display a patient’s individual, vital statistics and physiological measurements,** including certain data from which the overall Early Warning Score is calculated. As demonstrated in the screenshot below, **Launchpoint displays in red any such observation entered through FirstNet classified by the healthcare provider as ‘critical’** and the functionality exists to colour code the other values by reference to their risk level.



Screen 2: Launchpoint as configured in conjunction with CDDFT displaying red colour coding.

14. In addition, Launchpoint as configured in conjunction with CDDFT:
 - 14.1. Generates a separate 'pop up' notification if a clinician clicks through the options to view a specific patient's electronic health record and if their Early Warning Score has started to deteriorate significantly, irrespective of the task currently being performed on the system.
 - 14.2. Contains a separate, colour coded Early Warning Score Risk Level that appears when a clinician clicks on any field in columns B to C as demonstrated in the screenshot below. The Early Warning Score Risk Level is determined by reference to a patient's Early Warning Score, and is split into three categories, each appearing in colour coded capital letters: 'LOW' (black), 'MEDIUM' (orange, with an upwards or downwards arrow to indicate 'medium high' or 'medium low' risk), and 'HIGH' (red with an additional exclamation mark).



Screen 3: Launchpoint Early Warning Score Risk Level shown in the Extra Information Window as configured in conjunction with CDDFT.

15. Millennium is not intended to replace the alarms or alerts generated by the hardware monitoring the individual, vital statistics and physiological measurements e.g., a heart rate monitor, which alarms and alerts remain an important element of patient response.
16. Accordingly, Launchpoint as designed, configured and approved by CDDFT did provide a "a clear indication at first glance" of a patient's: (a) Acuity Score, including through a colour coded, 'RAG rated' column; (b) Early Warning Score; and (c) individual vital signs and physiological measurements, with critical values displayed in red where entered through FirstNet.

(ii) Testing, Training and Ongoing Monitoring of Launchpoint by CDDFT

17. Oracle Health has no record of CDDFT raising any clinical safety issues relating to the display of patient Acuity Scores or Early Warning Scores in Launchpoint during the Millennium training process or additional support period. Further, CDDFT raised no service issue with respect to the display of patient Acuity Scores or Early Warning Scores in Launchpoint as part of the deployment testing process or subsequent to the systems going live in October 2022.

D. POTENTIAL ENHANCEMENTS TO LAUNCHPOINT AS DEPLOYED AT CDDFT

18. Oracle Health continuously engages in ongoing dialogue with its clients with regard to potential software code and configuration enhancements to its Millennium solutions. Such enhancements can arise at the global, or national, level in response to the knowledge and experience gained by Oracle Health from working with its extensive client base. They can also arise in response to specific issues at the level of local deployments. In each case, Oracle Health will discuss with its client the appropriateness of taking a potential upgrade and its impact on existing workflows and the user interface. Ultimately, the decision on whether to take a particular code or configuration enhancement remains with the client and can involve clinical and commercial considerations.
19. Oracle Health is in discussions with CDDFT as to whether there are configuration changes that can be made to further support the Durham Emergency Department. In particular, Oracle Health has offered the following to CDDFT:
- 19.1. **Duplicate the existing Early Warning Score Risk Level in a new colour coded Early Warning Score Risk Level column in the Launchpoint home screen, located adjacent to the existing Early Warning Score. The new column displays in a colour coded, capitalised letter format the risk level of each patient (i.e., 'HIGH', 'MEDIUM' or 'LOW') determined by reference to their Early Warning Score, and includes exclamation marks for those at 'HIGH' risk.** The inclusion of a colour coded Early Warning Score Risk Level is comparable to having a colour coded, 'RAG rated' Early Warning Score, but achieves it through means of a separate column. This additional functionality is an enhancement and is **already available for configuration in new deployments of Oracle Health's Emergency Treatment solution. It is projected to be available to existing clients through Oracle Health's standard upgrade programme from June 2024.** For the avoidance of doubt, the Early Warning Score Risk Level is already available to Durham Emergency Department where a clinician clicks on any field in columns B to C as demonstrated in Screen 3 above.
- 19.2. Any supplemental training packages by Oracle Health of the Durham Emergency Department staff in their use and operation of Launchpoint as may be considered helpful.

Yours faithfully,

 Vice President and General Manager

For and on behalf of Oracle Corporation UK Limited

Copy to:

ORACLE®

- (i) [REDACTED], Executive Medical Director of the County Durham and Darlington NHS Foundation Trust, The University Hospital North Durham, North Rd, Durham DH1 5TW, [REDACTED]
- (ii) The Chief Coroner, Room C09, Royal Courts of Justice, London, WC2A 2LL (chiefcoronersoffice@judiciary.uk).