



Agenda Item No:

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Report to:	Integrated Care Board
Date of Meeting:	13 September 2023
Subject:	ICB response to the letter from NHS England to the NHS following verdict in the trial of Lucy Letby
Director Sponsor:	Stephen Eames, Chief Executive
Author:	Abigail Combes, Deputy Director of Legal and Regulatory Dr Nigel Wells, Executive Director Clinical and Professional Karina Ellis, Executive Director Corporate Affairs Teresa Fenech, Executive Director Nursing and Quality

STATUS OF THE REPORT:

Approve Discuss Assurance Information A Regulatory Requirement

SUMMARY OF REPORT:

Colleagues across health and care and the nation have been shocked and saddened by the appalling crimes that have been reported through the trial of Lucy Letby and our thoughts are with all the families and colleagues affected by these events.

It is, therefore, incumbent on us to commit to do everything we can to prevent anything like this happening again. A letter received from NHS England on 18th August 2023 (appendix 1) asked NHS Leaders to undertake a number of urgent actions and this report provides the Board with an overview of the:

- Current Freedom to Speak Up (FTSU) processes in place within the ICB
- Role of the ICB Freedom to Speak Up Guardian within the wider system
- Actions / Measures the ICB have started to identify and implement to strengthen the arrangements which go beyond the letter and include:
 - Fit and Proper Person Test
 - Data and Intelligence
 - Work with Coroners and Medical Examiners
 - Bringing the Chairs of Child Death Overview Panels across Humber and North Yorkshire together

The Board are asked to note that this is in addition to the work that our Partner organisations are also undertaking and the response to Lucy Letby has been discussed at their Boards and other actions they are taking include:

- Reviewing registers of the workforce and the requirements for DBS checks
- Reviewing their whistleblowing concerns over the last 2 years to ensure they have been appropriately overseen and if there are any lessons to be learned.

RECOMMENDATIONS:

Members are asked to:

- i) Approve the current ICB FTSU arrangements (approved by this Board on 1 July 2022)
- ii) Discuss the further actions and measures set out in the report and whether there are any further actions the Board would seek to be considered.

ICB STRATEGIC OBJECTIVE *(please click on the boxes of the relevant strategic objective(s))*

Managing Today	<input checked="" type="checkbox"/>
Managing Tomorrow	<input checked="" type="checkbox"/>
Enabling the Effective Operation of the Organisation	<input checked="" type="checkbox"/>

IMPLICATIONS *(Please state N/A against any domain where none are identified)*

Finance	There are no financial implications arising directly from this report.
Quality	There are clear links between closed cultures and patient harm. Where open cultures are supported there is often more learning and candour from events leading to better outcomes for patients.
HR	There are clear links between Freedom to Speak Up and HR processes with a risk that there is a disproportionate focus on utilising pure HR processes when concerns are raised.
Legal / Regulatory	There are specific legal and regulatory provisions relating to Freedom to Speak Up and particularly around the nature of 'Protected Disclosures'
Data Protection / IG	There are specific legal and regulatory provisions particularly around Data Protection and Information Governance linked with Freedom to Speak Up and other areas highlighted in this report
Health inequality / equality	There are clear links between Freedom to Speak up and ensuring equitable approach for all those who wish to raise concerns.
Conflict of Interest Aspects	There have been no conflicts of interest identified specifically for this report.
Sustainability	There are no sustainability implications arising directly from this report.

ASSESSED RISK:

There is a risk that ICB Staff and Staff members working the wider system are not aware of the processes through which they can raise confidentially concerns or issues about the care and support of patients to assure ourselves of the quality of the services our providers deliver or that these concerns and issues are listened to. This paper sets out the arrangements that are already in place and some of the additional actions that will be taken to mitigate this risk.

MONITORING AND ASSURANCE:

Regular updates on Freedom to Speak Up will be presented to the Board. There will be ongoing monitoring and assurance of other actions through Clinical and Professional Executive Committee and the Quality Committee.

ENGAGEMENT:

The Clinical and Professional Executive Committee and the Quality Committee have had a conversation on the issues arising from the Lucy Letby Trial including many of the points made in this report.

REPORT EXEMPT FROM PUBLIC DISCLOSURE

No Yes

If yes, please detail the specific grounds for exemption.

ICB RESPONSE TO THE LETTER FROM NHS ENGLAND TO THE NHS FOLLOWING VERDICT IN THE TRIAL OF LUCY LETBY

1. INTRODUCTION

Colleagues across health and care and the nation have been shocked and saddened by the appalling crimes that have been reported through the trial of Lucy Letby and our thoughts are with all the families and colleagues affected by these events.

It is, therefore, incumbent on us to commit to do everything we can to prevent anything like this happening again. A letter received from NHS England on 18th August 2023 (appendix 1) asked NHS Leaders to undertake a number of urgent actions and this report provides the Board with an overview of the:

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The Board are asked to note that this is in addition to the work that our Partner organisations are also undertaking and the response to Lucy Letby has been discussed at their Boards and other actions they are taking include:

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2. BACKGROUND

Freedom to Speak Up

Freedom to Speak Up processes were introduced into the NHS in 2016. This was as a result of a number of investigations and concerns raised relating to culture, particularly in NHS Trusts and the way in which those raising concerns were supported and listened to during proceeding inquiries.

CCGs were required to appoint a Freedom to Speak Up Guardian which must be someone at Board Level of an organisation and there was also a requirement for there to be a Non-Executive sponsor for the Freedom to Speak Up process. NHS Trusts were required to implement similar processes.

When the ICB was established on 1 July 2022 there was a requirement for the ICB to appoint a Freedom to Speak Up Guardian and implement a policy and process for managing concerns which were raised. NHS Humber and North Yorkshire ICB adopted a Freedom to Speak Up Policy on 1 July 2022 board meeting and since that time have had established arrangements in place for the raising of concerns.

NHSE have now mandated the adoption of the National Freedom to Speak Up policy by January 2024 and the ICB Regulatory team are in the process of producing the Policy and associated Standard operating procedures for consideration by the Board at the end of 2023.

The role of the ICB in the system Freedom to Speak Up arrangements is primarily ensuring that there are appropriate arrangements in place within those organisations and to support in cases where there are significant concerns about the care and support of patients to assure ourselves of the quality of the services our providers deliver.

3. ASSESSMENT

The ICB implemented a Freedom to Speak Up process on 1 July 2022 following approval but the Board of the policy which utilised the existing CCG policies and amalgamating them into one policy.

The Board also approved the Board Level Member Freedom to Speak Up Guardian would be Dr Nigel Wells. It is an NHSE requirement that this Freedom to Speak Up Guardian is a Board level member of staff to ensure that concerns can be taken directly to the Board if required and so that the individual has sufficient autonomy to enable them to take actions to immediately mitigate any harm.

In NHS Humber and North Yorkshire ICB the Freedom to Speak Up Guardian is supported by the Regulatory Function in the Corporate Affairs Directorate. This function is responsible for amendments to the policy and the operating arrangements. This function also supports with triage and assessment of concerns that come in. Where concerns relate to HR and line management matters (the vast majority of internal ICB concerns) then the Regulatory function supports the individual with making contact with HR and will continue to liaise with the individual should they wish to maintain contact for a period of time. The ICB Freedom to Speak Up process has been used in this way for two cases since 1 July 2022.

The ICB has also received Freedom to Speak Up queries relating to provider organisations and commences a process of assessment and triage of those concerns. The Regulatory Function is often the first point of contact for individuals raising concerns although they are welcome to speak directly with Dr Wells should they wish to do so. Those raising concerns are offered anonymity.

We have received some queries from provider organisations which are being managed in accordance with the policy since the establishment of the ICB. However, as they are current investigations details are not provided in this paper due to the nature of the enquiries.

There is a generic inbox which is overseen by the Deputy Director of Legal and Regulatory Functions where concerns can be raised.

The ICB is also required to have a non-executive sponsor for Freedom to Speak Up and this is Mark Chamberlain.

The Board is updated in private on current Freedom to Speak Up matters when this is appropriate or when support is required.

Protected Disclosures

It is important to recognise that although the ICB has a role in supporting Whistleblowing and Freedom to Speak Up; it is not an organisation which can automatically offer 'protected disclosure' status to concerns raised.

A protected disclosure simply means that where someone raises a disclosure about concerns around working practices which fall into a specific category (criminality, harm etc) they are protected from adverse employment outcomes as a result of this disclosure.

The two relevant organisations for the purposes of Freedom to Speak Up in NHS terms are CQC and NHSE (although the HSE may be a possibility in some cases). When a disclosure is made to these organisations and recorded by them the disclosure is automatically a 'protected disclosure' provided it meets the requirements of a protected disclosure (broadly speaking that means that the disclosure is in the public interest and has been made to the relevant person who can do something about it). This means that in the event that there are employment proceedings instituted against the individual, they can refer to this in any subsequent employment tribunal and this will support their case about the nature and quality of the disclosure being protected and support constructive dismissal claims.

If a protected disclosure is made to another organisation such as a Trust or the ICB the whistleblower can still claim the disclosure is a protected disclosure however they must prove this to the Employment Tribunal in any subsequent action. This will require the employee to provide evidence that they specifically set out their case to the employer that the disclosure was in the public interest and the reasons for that. Employment Tribunals have historically found against former employees where they have made disclosures and not used the words 'public interest' within them.

Where a Protected Disclosure is made to NHSE or CQC, this does not mean that the investigation is subsequently run by CQC or NHSE; although of course as Regulators may wish to pick these matters up. The investigation into the concerns raised will still remain the responsibility of the Organisation the concerns relate to.

NHSE also have a number of mechanisms of supporting individuals who have raised concerns completely separately from the organisation which they work for including counselling services and advice. This is a finite resource and therefore is variable in its application.

Log of FTSU Cases

The ICB holds a log of cases which have been referred to it. The log is anonymous and does not contain details of the whistleblower however there is a unique reference number provided on the log and the Deputy Director of Legal and Regulatory Functions holds the reference number and will provide the details of the whistleblower only with the whistleblowers consent (or in other circumstances such as in the event of criminal investigation or with a Court Order). In the event that the Deputy Director of Legal and Regulatory Functions is unavailable there is a process whereby the Executive Director of Corporate Affairs or the Freedom To Speak Up Guardian can access the name of the whistleblower from the unique reference number.

Since the establishment of the ICB there have been 6 matters raised through the Freedom to Speak Up process. Two of these were internal ICB matters and related to HR processes. In both cases the staff raising concerns were supported by the Freedom To Speak Up team to navigate the relevant HR process.

The remaining matters are either being investigated or are awaiting information and decisions from the whistleblowers. In these cases the ICB have been contacted and asked about the process involved in raising concerns but without sufficient detail about the concerns to allow an investigation to commence. In the event that someone contacts the ICB with information but then withdraws support to the investigation this would be raised with the Freedom To Speak Up Guardian and an initial investigation would be commenced to assure ourselves of whether there are any immediate concerns which ought to be mitigated.

It is of note that the medics raising concerns in the Lucy Letby case have expressly stated they did not consider themselves whistleblowers and therefore would not necessarily have made disclosures in accordance with the policy or understanding what a 'protected disclosure' is. It is imperative therefore that the triage and assessment process for Freedom to Speak Up in the ICB supports staff to understand what support and advice they need when making the disclosures.

Nominated individuals

As explained above, it is an NHSE requirement that a Board Level employee and a Non-Executive sponsor are appointed as the Freedom to Speak Up individuals within the ICB. NHS Humber and North Yorkshire ICB appointed Dr Nigel Wells as the Guardian and part of the justification for this appointment over and above the NHSE requirements were that Nigel is a registered medical professional and therefore has a professional obligation to ensure the process is thorough and appropriate. Nigel also Chairs the Clinical and Professionals Group in the ICB and therefore is likely to have contact with the clinical services where the concerns are raised from.

The Deputy Director of Regulatory Functions is also a regulated individual regulated through the Solicitors Regulatory Authority. Importantly the reason that this individual was nominated to be the lead for the Freedom to Speak Up Function is that professional obligations dictate that the postholders duty is to act in the best interests of the Organisation they are employed by. In this case that is the ICB. It was felt therefore that if there was any challenge to pursuing cases where concerns had been raised by any individual, the Deputy Director of Regulatory Functions would be professionally required to raise these with the Board (or directly to the Chair) or be in breach of professional obligations. This is likely to be a key matter examined in the statutory Public Inquiry into the handling of the complaints about Lucy Letby and what the Board were aware of when making decisions.

4. ACTIONS / MEASURES PLANNED OR IMPLEMENTED

Since the Lucy Letby verdict was made public, NHS Humber and North Yorkshire ICB have started to reflect, not only on the Freedom to Speak Up processes but also on wider learning for the organisations. The following are the further actions and measures planned or being implemented across Humber and North Yorkshire.

Freedom to Speak Up

As mentioned earlier in the report, the ICB is currently reviewing the FTSU policy and processes to align with the guidance issued by NHS England and this will be brought back to the Board before the end of 2023.

The responsibility of the ICB is to oversee the effectiveness of the FTSU arrangements within organisations across the ICB, both from a culture and quality perspective. A need to identify emerging issues and to respond to them along with dissemination of learning from one provider to another are also requirements. The ICB intend to meet with FTSU Guardian's from across the system

and understand the processes and policies in place. As a system leader the Executive Director of Clinical and Care Professional will also be keen to understand what has been found within providers in relation to the handling of Freedom to Speak Up matters over the last two years. We will be looking to offer support to the system of Guardian's in respect of training and documentation.

There will be an update and full review of the current ICB Policy and standard operating arrangements to ensure that staff know how to raise concerns, what to expect when they are raised, and reporting arrangements are clear and regular so that Board is sighted on any matters raised.

The ICB will also establish a network of trained members of staff who can act as points of contact through which ICB members of staff can raise their concerns and issues confidentially and receive the appropriate guidance and support.

Fit and Proper Person Framework

The letter from NHS England also makes reference to the recently revised and published Fit and Proper Person Framework ([link to framework](#)). The framework is a response to the recommendations made by Tom Kark KC in his 2019 review of the Fit and Proper Person Test (the Kark Review) and also takes account of the requirements of the CQC in relation to directors being fit and proper for their roles.

The revised framework strengthens and reinforces individual accountability and transparency for board members but particularly for the Chair of the Board in relation to the enacting of the framework. It sets out the additional background checks, including a board member reference template, which will also apply to board members taking on a non-board role. There is a requirement for an annual refresh and for the first time for this to be recorded on Electronic Staff Records so that it is transferable to other NHS Organisation as per of their recruitment processes.

The full assessment focuses on three core elements when considering whether board members are a fit and proper person to perform a role on the Board. There are

- Good character
- Possessing the qualifications, competence, skills and experience required
- Financial Soundness.

The framework is effective from the 30 September 2023 all boards are required to implement it. The Executive Director of Corporate Affairs with the Chair has agreed to establish a small task and finish group to ensure we have all the elements in place and can complete the assessments required.

There will be at least an annual report to a public Board to provide assurance that we have satisfied the requirements of the framework.

Data and Intelligence

The ICB currently has an identified gap in data and intelligence relating to specialised commissioned services. This is in part as a consequence of the hiatus in reporting of data in these services over Covid period but also these smaller services tend not to get adequate focus.

For example, Neonatal services are a Specialised Commissioned Service and for any organisation a relatively low volume service. There is a risk that data and intelligence for small volume and non-locally commissioned services can be missed – especially by boards who often will be looking at

aggregated performance and quality data. The Executive Director of Nursing and Quality has asked providers to review the data and intelligence that is presented to boards in respect of such low volume services and additionally has escalated to region the lack of quality data from specialised commissioned services – the absence of which is as a consequence of the pause during covid.

Work with Coroners and Medical Examiners

The Deputy Director for Legal and Regulatory Functions has written to all the Senior Coroners covering the ICB footprint to remind them of the Freedom to Speak Up arrangements and to ask that they notify the ICB of concerns they have about providers. This is already happening in a number of our Places. The ICB is also providing some training and guidance to Coroners about the move to Patient Safety and Incident Report Framework.

The ICB will be writing to all Medical Examiners (with the support of NHSE) to remind them of their obligations to be transparent and independent and raise concerns with both NHSE and the ICB. The ICB is also working towards data reporting from the Medical Examiners to identify trends and concerns.

Medical examiners are employed by trusts but in conducting their ME responsibilities for non-coronial investigation of deaths – they are independent and their accountability is to NHSE and the ICB along with the Coroner, and not the organisation that employ them. The ICB is responsible for ensuring that learning and improvement from their work is shared at a system level.

With the agreement of NHSE the ICB will be leading on the development of a programme of continuing professional development for MEs in our system.

The Deputy Director for Legal and Regulatory Functions has registered with a Regulation 28 report tracker which provides up to date data on Coroners reports where concerns and actions to prevent future deaths have been identified.

Child Death Overview Panels

One of the areas we anticipate may be something considered by the Letby Inquiry will be the role of Child Death Overview Panels. These can span geographical boundaries which are not the same as those for the Trust or in our case the ICB. The oversight is also determined by the home address of the child and not the place of death and therefore this can lead to a missed opportunity to identify trends. The Executive Director of Nursing and Quality has already taken action to bring the Chairs of Child Death Overview Panels across Humber and North Yorkshire together to identify opportunities to share information and learning.

Implementation of Patient Safety Incident Reporting Framework (PSIRF) – the replacement arrangements for Serious Incident reporting.

We are just in the implementation phase of this – and a presentation will be coming to the board. There is growing understanding that effective implementation and utilisation of these new arrangements is predicated on an open and transparent approach to reporting harm or potential harm. In the absence of this organisational context – a growing concern is that sufficient detail will not be surfaced as part of PSIRF to identify harm appropriately. This is something that has been raised nationally and has been discussed with the regional team – we are however actively considering how to mitigate this risk as the implementation of PSIRF is achieved.

Other actions

The Deputy Director for Legal and Regulatory Functions is working with the Executive Director for Clinical and Care Professionals, the Executive Director for Corporate Affairs, the Executive Director for Nursing and Quality and the Executive Director for People to prepare and produce a training programme to support the ability to raise concerns and the ability to undertake evidence based assessments and decision making in cases where concerns have been raised.

The Deputy Director for Legal and Regulatory Functions has committed to reviewing Employment Tribunal decisions for our provider organisations (all publicly available since 2017) to ascertain whether there are themes and trends which the ICB ought to have regard to. There is for example, one decision from 2021 which refers to the 'toxic culture' in one provider organisation.

5. RECOMMENDATIONS

5.1. Members are asked to:

- iii) Approve the current ICB FTSU arrangements (approved by this Board on 1 July 2022)
- iv) Discuss the further actions and measures set out in the report and whether there are any further actions the Board would seek to be considered.