Independent Review of Pulmonary Embolism fatalities in England and Wales

Recent trends, excess deaths, their causes and risk management concerns

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1 Dedication and author

My Mum, Jennifer, or, Jenny, as she was known to friends was born in 1947 and raised in Farnham, Surrey. She was 74 when she died, 20 years' younger than her mother and 12 years' younger than her father at their ages of passing.

Jenny was a much admired and loved grandmother, mother and friend to many who had many more years to live.

She attended University College London to read Geography and Economics in the 1960's, a time when women from her background were discouraged from attending University. Having graduated Jenny then worked for British Leyland, moved to Germany with my Father and subsequently taught English during which time she had me. Jenny returned alone with me to England in 1985, and she taught GCSE and A-Level for 27 years at Lewes Old Grammar School. Upon retirement, in 2012, she became an active participant in the U3A, line-dancing and was an avid traveller.

Before her passing on February 27th 2022, she did thankfully get to meet my daughter, her only grandchild, Anaïs Edwards, three times.

I am Jenny's son, Tim Edwards the author of this report. I work in the reinsurance industry and am a Chartered Insurer (ACII) and, part way through my Chartered Financial Analyst (CFA), professional accreditation. I am also a Certified Catastrophe Risk Management Professional (CCRMP).

My experience in the financial services industry of assessing and mitigating catastrophe risk, then putting in place meaningful action plans should, I hope, be useful in reviewing this concern around pulmonary embolism misdiagnosis. I have interacted with financial regulatory authorities and seen how effective risk management and regulation may reduce prudential risk in the financial setting.

2 Executive Summary – Aims, Call for Action, Key Failures

2.1 Aims and objectives

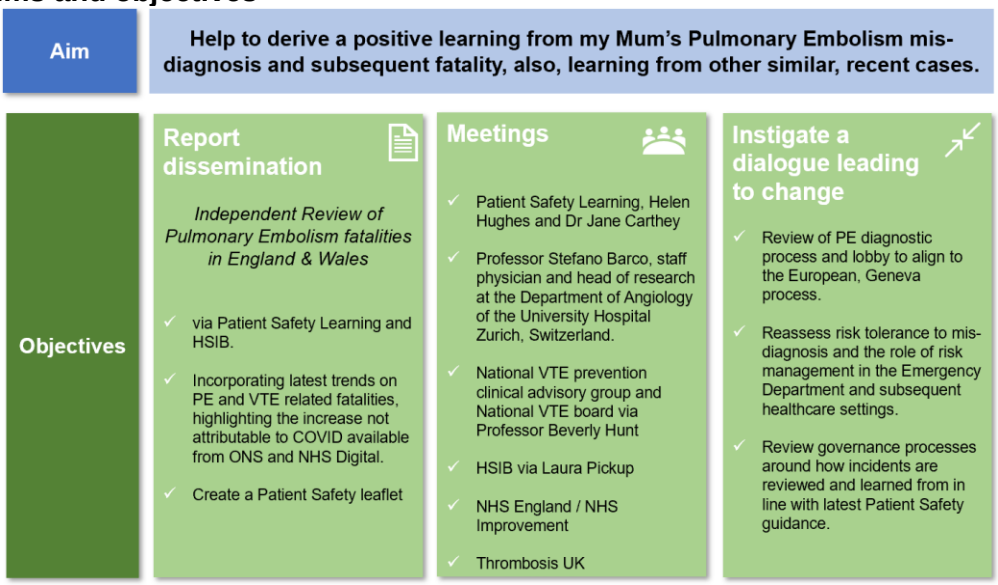


Figure 1: What the dissemination of this report and related objectives seeks to achieve

The need for these aims and objectives is driven by my mother's early passing from a missed pulmonary embolism (PE), see 3.1 and 3.3. At the same time, the high rate across England and Wales of PE fatalities, see 4.1, and the increase, post 2020, in PE and Venous Thromboembolism (VTE) related mortality rates, (see 4.2), are related concerns. That fact that these increases are above the rate of increase in COVID mortality after the second half of 2020 indicates that pulmonary embolism's were increasingly not being diagnosed, leading to an **otherwise avoidable rise in mortality – I estimate 400 from March 2021 to April 2022 in England alone**. This risk in England and Wales remains for reasons outlined in this report. Specifically, much confusion appears to be driven by the diagnostic tools used, whereas the report notes other more refined tools are used across Europe, (considered in 5.3).

2.2 A Call for Action

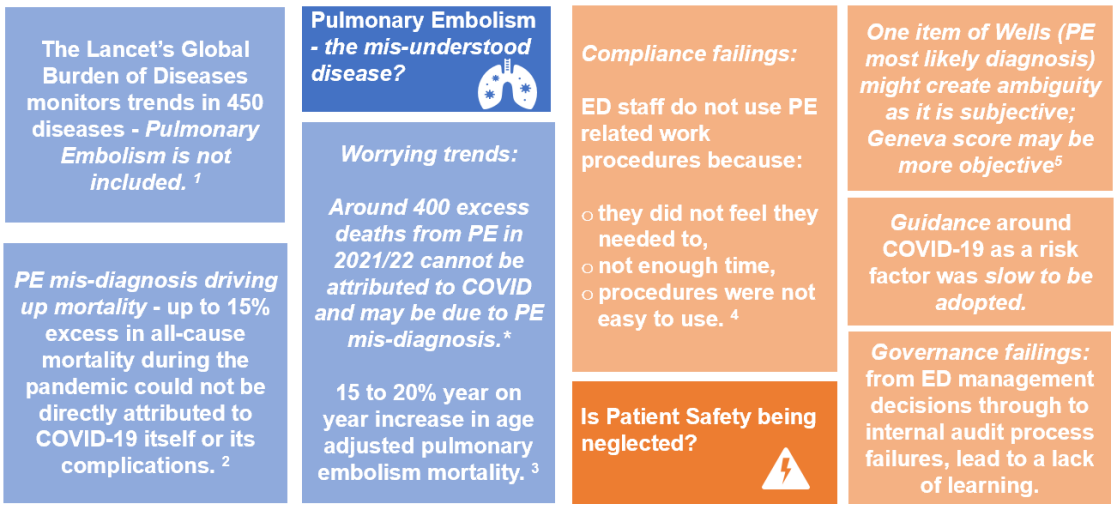


Figure 2: A Call for Action – urgent change required to reduce future mortality from pulmonary embolism and related venous thromboembolism (VTE) conditions.

Sources: Global Burden of Disease [1], Journal of the American College of Cardiology [2], NHS Digital [3], HSIB report [4] and an expert interview [5].

[1] The Lancet, Global Burden of Disease, 2019.
[2] Journal of the American College of Cardiology, 2022
[3] NHS Outcomes Framework indicators – March 2022 release . 5.1 Deaths from VTE related events within 90 days post discharge from hospital. * calculated excess deaths relative to 2019/20 from this data source
[4] Healthcare Safety Investigation Branch I2019/016, 2022
[5] Interview with Dr Stefano Barco

The Patient Safety Incident Response Framework (PSIRF) [6], launched in August 2022, recommends that incident response teams outline areas for improvement based on their investigation findings. The areas for improvement can then be used to frame conversations with relevant stakeholders to engage them in developing specific safety actions that will address the systems gaps identified. The findings of my personal, also nation-wide, investigation show the following areas for improvement:

- *Area 1: Suspicion* – given a surge in PE related deaths, greater awareness amongst frontline emergency department and other clinicians of the importance of considering the possibility of PE during their diagnostic decision-making. More general training alongside specialisms and simulation to support practice and development of decision-making skills.
- *Area 2: Buy-in for clinical guidelines* - easy to use, accessible tools to support diagnosis of pulmonary embolism in Emergency Departments and other clinical settings which clinicians have been empowered to develop and test in real-world settings, and which they have faith will support accurate diagnosis of PE.
- *Area 3: Avoidance of high-risk appetite* - to achieve operating standards and meet financial incentives, risk appetite should not be a variable that can be compromised or amended.
- *Area 4: Compliance and risk management* - oversight approaches/audits, embedded within existing clinical governance systems that effectively identify when best practice for diagnosis and treatment of suspected PE is not embedded in clinical practice with the ability to review and challenge.
- *Area 5: National consistency* - exploration of the underlying causes of regional variation in deaths from PE including why there may be systemic failure in UK healthcare to consistently assess the third most common type of acute cardiovascular syndrome after myocardial infarction and stroke.
- *Area 6: Patient engagement* - meaningful engagement with those affected when carrying out an incident investigation to ensure family members' expertise is harnessed and they are treated as partners in the learning response (where they so wish), not just in setting the terms of reference.
- *Area 7: Independence* - effective regulatory oversight to ensure team members of an incident investigation are independent of the case being reviewed to avoid the introduction of bias.
- *Area 8: Knowledge sharing* – effective, timely dissemination of learning from a serious incident investigation carried out in one organisation across the NHS to other organisations which may experience a similar type of PE misdiagnosis incident in the future. Ensure Clinical Knowledge Summaries providing the latest research and clinical findings are sufficiently disseminated and actioned by frontline emergency department and clinical staff.
- *Area 9: Patient awareness* – extension of existing marketing campaign targeted advising those at risk of the symptoms to look out for and when to seek medical attention.

2.3 Process failures

In attempting to frame the problem of avoidable deaths from pulmonary embolism from a risk management process standpoint - first reviewing the clinical process ('work as prescribed') then, comparing this to the actual result ('work as done') - it is apparent that there are both individual and systemic process failures evident with my mother's diagnosis and subsequent care. I have obtained the information on her diagnosis and care following the raising of a complaint to the relevant trust where I refer to:

- the resultant Serious Incident Report (published 30th June, 2022),
- Coroner's Inquest (5th July, 2022).

Similarly, the Healthcare Safety Investigation Branch (HSIB) I2019/01 report [4] into pulmonary embolism diagnosis and treatment further highlights limitations with the PE diagnosis from their review of 14 other recent Serious Incident Reports.

Contrasting my mother's experience with the published findings from the HSIB's report, along with the following information sources enables a wide-body of insight, a mosaic, to be formed of the individual case in the broader regional and national context. The additional data sources referred to:

- Healthcare Safety Investigation Branch (HSIB) I2019/01 report into pulmonary embolism diagnosis and treatment [4]

[6] Patient Safety Incident Response Framework

- Care Quality Commission – Fundamental Standards [7]
- Care Quality Commission – 2022, Hospital Inspection report for where my mother was admitted [8]
- NHS Outcomes Framework – Domain 5.1 [3]
- NICE Clinical Guideline NG158 – Venous thromboembolic diseases: diagnosis, management and thrombophilia testing [9]

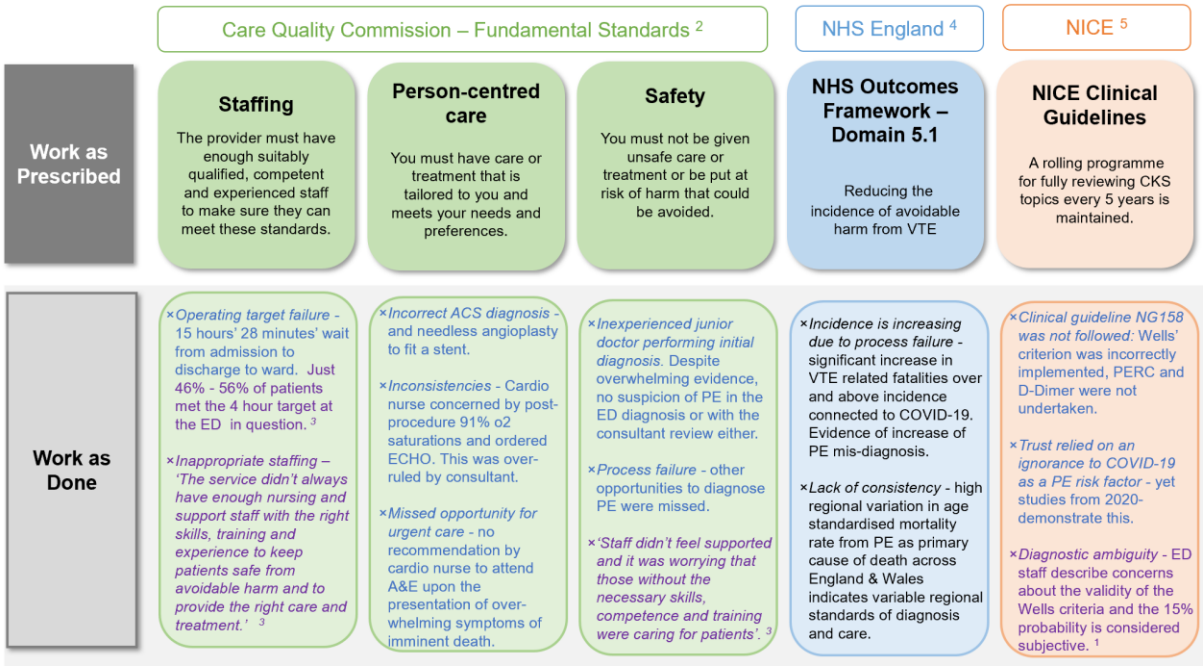


Figure 3: Process failures evidenced by the diagnosis and care of my mother

Sources: Items in blue from Serious Incident Report and Inquest; items in purple from the additional data sources listed above; items in black from analysis of Office for National Statistics (ONS) [10] and NHS Digital data [3]

2.4 Governance failures

From the review of the documentation provided associated with the Serious Incident Report (June 2022) and Coroner's Inquest (July 2022) it is apparent that:

- numerous Governance failings were in operation around the treatment and management of risk in the Emergency Department (ED) concerning my mother's diagnosis and care.
    - the failure to learn from mistakes was an observation from the CQC's July report into the hospital Emergency Department [3].
- this failure to learn was also in evidence from the limited Serious Incident Report (June) findings and actions. Despite NHS England's 2015 Serious Incident Framework [11], in operation at the time, encouraging hospital trusts that members of a Level 2 or Level 3 report should be independent to ensure objectivity this was not the case here. The subject-matter experts were all involved with the original care of my mother and hence objectivity of the report was lost.
- because the Serious Incident Report team concluded that '*the investigation found it would have been very hard to diagnose a co-existing PE'* the subsequent actions were inadequate to address cases comparable with my mother that arose either in the Trust, or across hospitals in other Trusts.
- the Serious Incident Report team relied on an ignorance of COVID-19 being a risk factor to PE when discounting shortness of breath, a key PE symptom, although this link had been known back in 2020, (see 5.4).
- moreover the Serious Incident Report team contradict themselves by discounting right-heart strain when this was clearly in evidence, whilst the pre-supposed 'classical' symptoms for PE are at odds with recent studies into PE risk factors and symptoms, (see 5.2).

[7] Care Quality Commission Fundamental Standards, 2022
[8] Care Quality Commission Hospital Inspection Report, July 2022
[9] National Clinical Excellence Guidelines (NICE) NG 158 published March 2020
[10] Office for National Statistics NOMIS web-service via Freedom of Information request to NHS England
[11] NHS England Serious Incident Report Framework (2015)

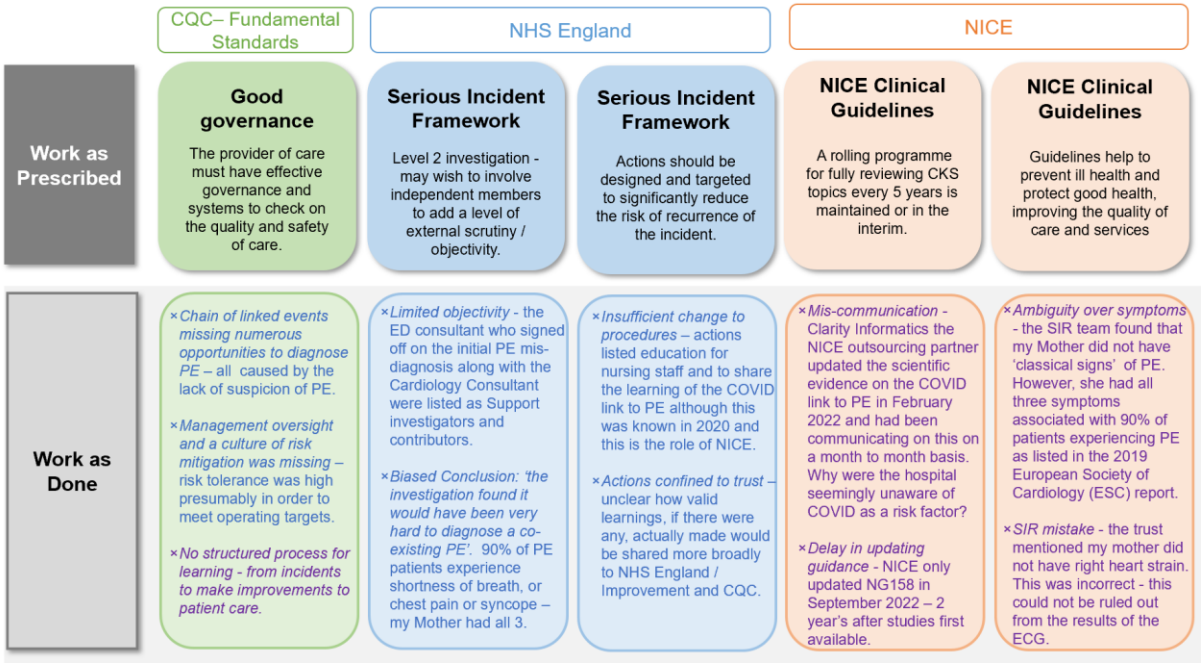


Figure 4: Governance failures evidenced by the diagnosis and care of my mother

Sources: Items in blue from Serious Incident Report and Inquest; items in purple from the additional data sources listed above

As can be seem in section 6.3, there are clear gaps in how the three lines of defence risk management model typically used in financial services firms is applied in the ED setting within an Integrated Care Board setting.

The centralised, top-down approach to ED risk management may work well for homogenous conditions that are easy to diagnose and treat. However, for complex conditions such as PE stronger second line a risk and compliance function that monitors the implementation of clinical guidelines and ensures strong first line management review maybe required to mitigate risk and improve patient safety.

3 Background to the report

3.1 Timeline of events

The relevance of the time-line is to highlight:

- the asymptotic nature of the COVID-19 infection,
- the gap between the infection, where no symptoms were observed, and the acute period of shortness of breath,
- the time spent in hospital and then at home,
- the key junctures of interacting with the hospital emergency and cardiology departments.

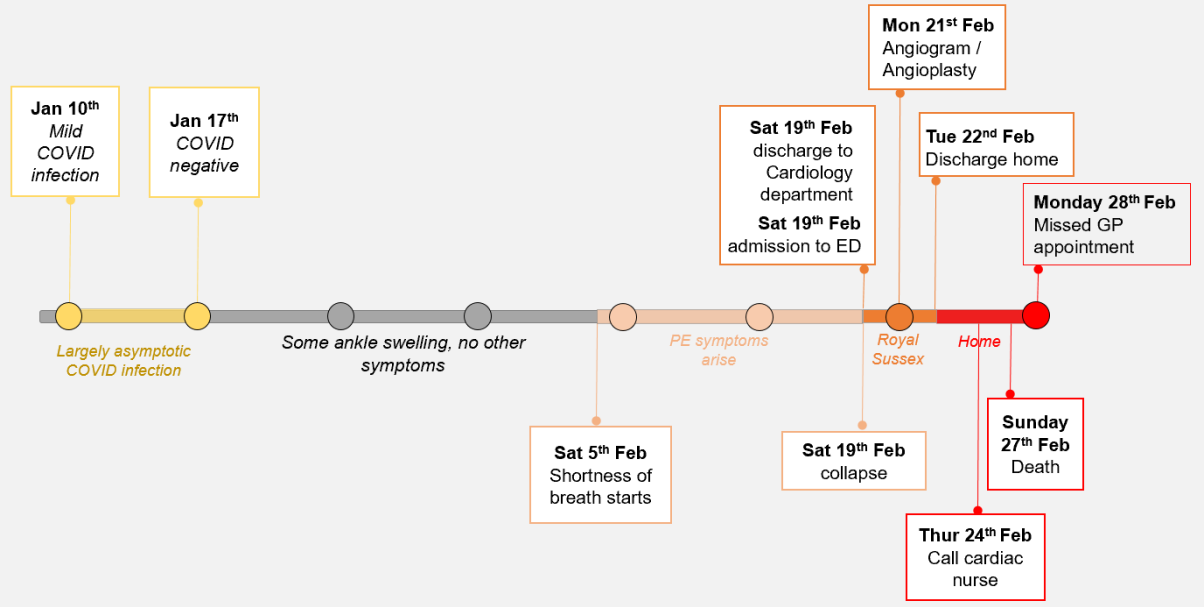


Figure 5: Seven weeks covering the asymptotic COVID-19 infection through to the passing of my mother

3.2 Work as Prescribed - NICE guidelines for PE diagnosis

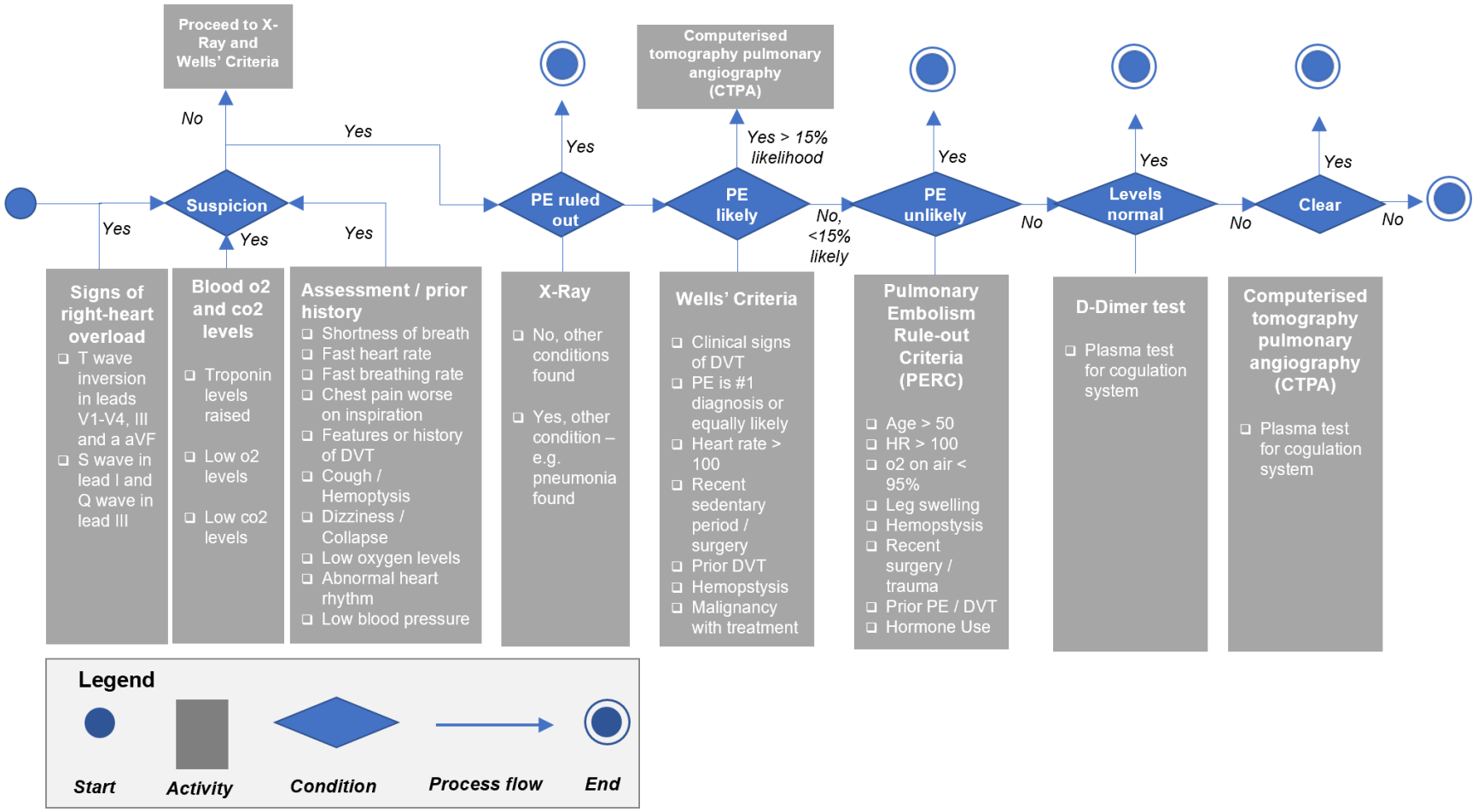


Figure 6: National Institute of Health and Care Excellence guidelines for PE diagnosis [9] and 2020 recommendation to refer to the Pulmonary Embolism Rule-out Criteria (PERC) [9]. The Wells' Criteria for Pulmonary Embolism form a key step in this process [9].

(Note the comments in 3.5 following the interview with Dr Stefano Barco on the use of the Wells' criteria and PERC.)

3.3 Work as Done – PE diagnosis followed in the case of my mother – Saturday, 19th February, 2022

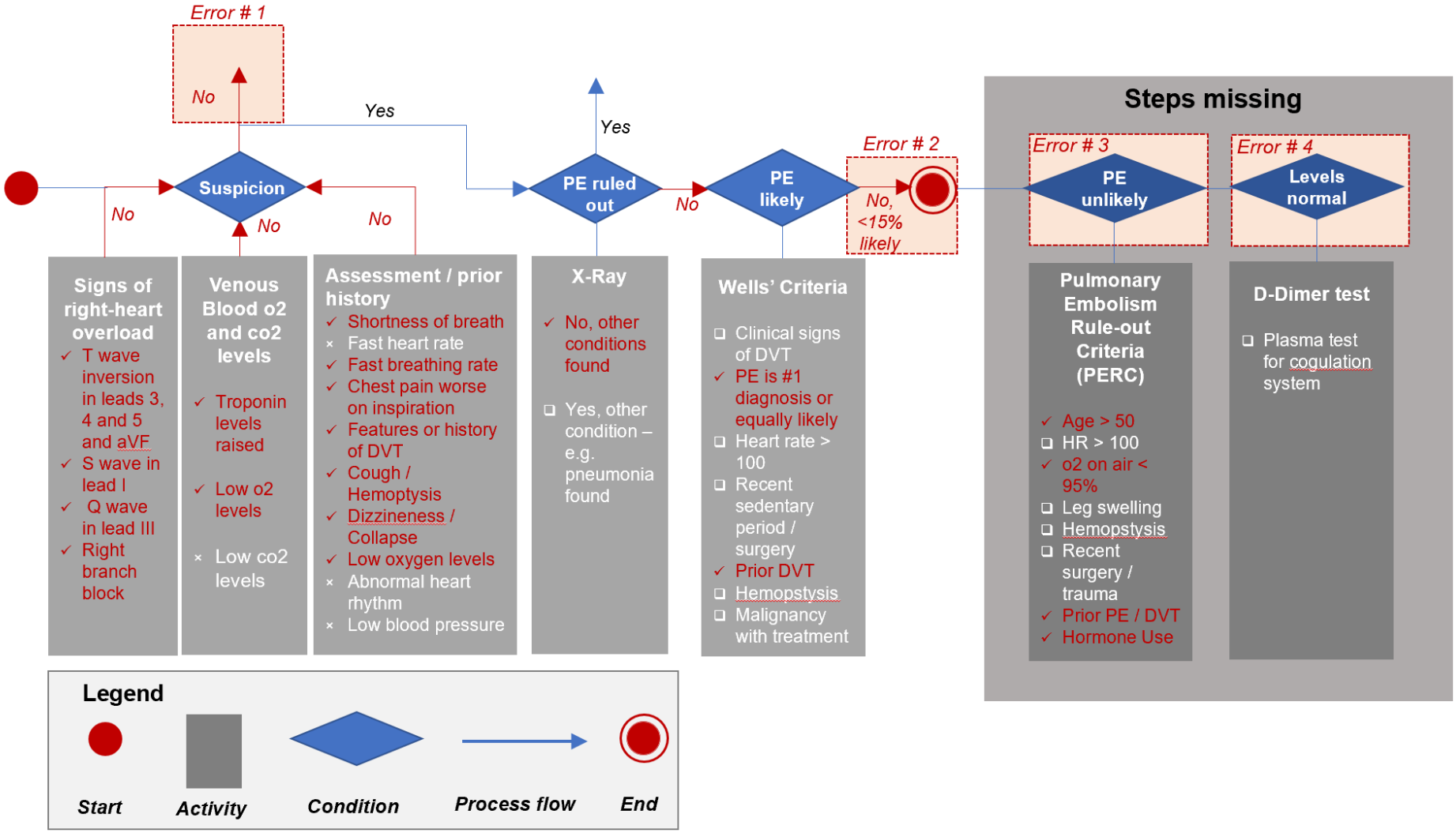


Figure 7: Four key process errors in the clinical decision-making for the case of my mother overlayed on top of the National Institute of Health and Care Excellence guidelines for PE diagnosis in the Emergency Department setting. Text in red indicates the risk factors and symptoms that she exhibited.

Key Process failings:

Error # 1: Saturday 19th February 2022

- despite all the signs of
    - right-heart overload -T wave inversion in leads V3, V4, V5 an aVF S wave in lead I and Q wave in lead III.
    - a right-branch block
    - raised troponin levels – 274 and 216
    - low O2 levels – 92% on 19th February
    - dyspnoea / shortness of breath
    - fast breathing – 22 breaths per minute
    - chest pain worse on inhalation
    - history of DVT – in 2015
    - cough
    - dizziness / collapse – the prior night.

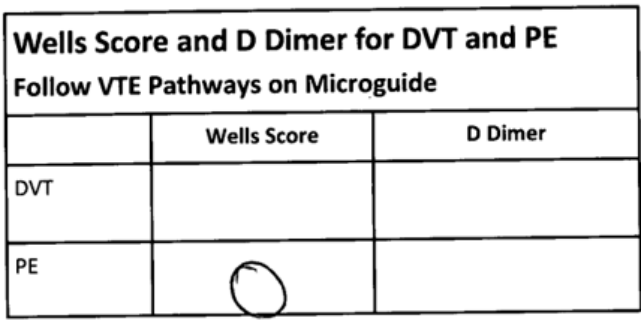
No suspicion of PE was advanced by the junior doctor involved, or by the reviewing ED consultant. This was the critical failing as all subsequent failings can be linked to this. This lack of suspicion is considered further in 5.3.

- The Emergency Department Consultant reviewed and presumably accepted this assessment upon which the Cardiology Department Registrar accepted and prescribed medicines in lieu of an assessment of acute coronary syndrome, heart failure.

Error # 2: Saturday 19th February 2022

The Wells' criteria were incorrectly completed, the two criteria score should have resulted in:

- prior incidence of DVT + 1.5 points
- PE is #1 diagnosis or equally likely + 3 points
- clinical signs and symptoms of DVT (occasional mild leg swelling) + 3 points



Wells Score and D Dimer for DVT and PE Follow VTE Pathways on Microguide		
	Wells Score	D Dimer
DVT		
PE		

Figure 8: Wells' criteria assessment for Jenny Edwards, 19th February 2022

Given a correct assessment of these criteria, my mother would likely have been deemed as 'PE likely' and sent for a CTA, or at least a D-dimer, if considered unlikely.

Error # 3 (due to Error #1), Saturday 19th February 2022

The pulmonary embolism rule-out criteria (PERC) was not considered or actioned, given no suspicion of PE. Of the 8 criteria my mother will have fulfilled 4 of these, i.e. 50%.

Error # 4 (due to Error #1), Saturday 19th February 2022

For patients with a local level of likelihood but a suspicion of PE a D-dimer test is considered appropriate where an age-adjusted D-Dimer level can be used to rule out a PE. This test was not commissioned.

3.4 Work as Done – missed opportunities for PE diagnosis following angiogram and stent fitting on 21st February by Cardiology department

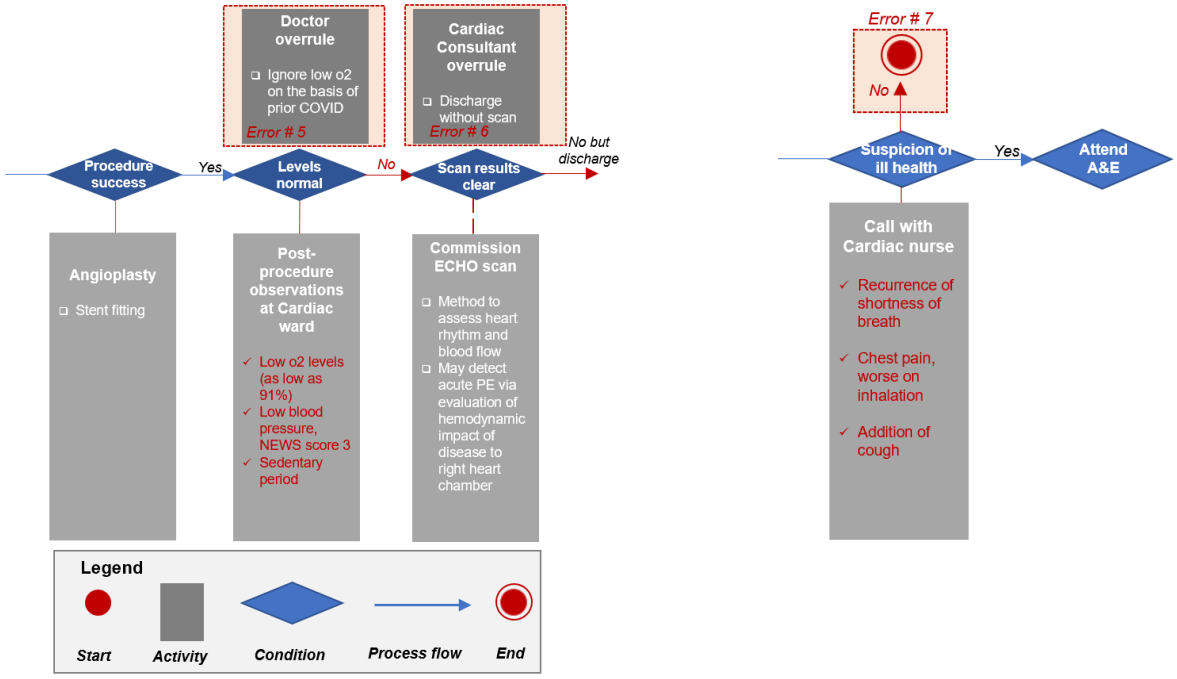


Figure 9: Three further process errors in the clinical decision-making for the case of my mother where an opportunity to diagnose PE was missed, left, February 20th/21st in the Cardiology ward; right, 24th February during a call to a cardiology nurse from her home.

Unfortunately the risk management system in place continued to be contingent on Errors #1 and #2 setting in motion Error #3 and #4. These were compounded by further errors #5 and #6, during the after-care for Jenny Edwards. Both of these may be traced to Errors #1 and #2. The risk management barriers implemented were not independent of one another.

Having been incorrectly assessed as requiring a stent via angioplasty, upon completion of this procedure my mother continued to exhibit Low O2 levels – as low as 91/92%. The nurse subsequently requested an ECHO scan and held back discharge because of this.

Key subsequent Process failings:

Error # 5, Monday 21st February 2022

Low O2 levels were attributed to COVID-19 and were of 'zero concern.'

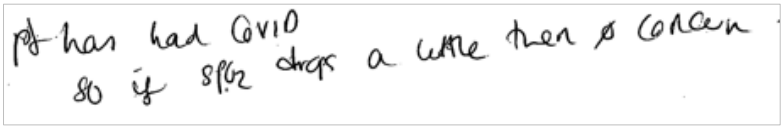


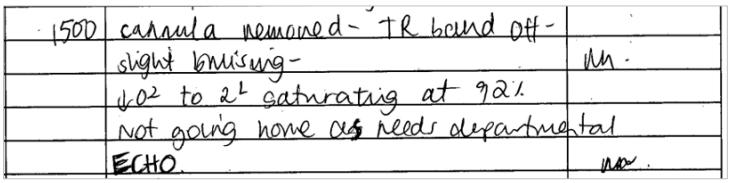
Figure 10: Discounting of low o2 levels on the grounds of prior COVID-19 infection

This clinical assessment failing is discussed in section 5.4. By February 2022, it had been known for at least 18 months that COVID-19 was a risk factor for VTE-related conditions. Per 3.1 the COVID-19 infection was largely asymptotic and the shortness of breath was not chronic after the COVID-19 infection, it was acute 2 weeks' before my mother's passing.

Error # 6, Tuesday 22nd February 2022

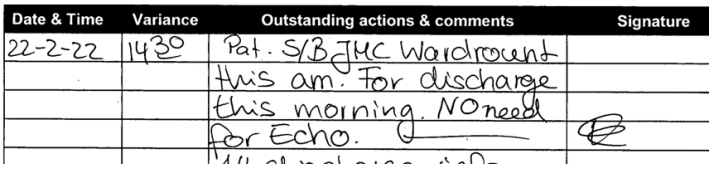
Cardiac consultant over-ruled the need for an ECHO scan.

Despite not considering the prior medical history and case notes the consultant discounted the need for an ECHO scan that may have indicated PE using non-invasive assessment of the hemodynamic status.



1500	cannula removed - TR band off -	
	slight bruising -	MN.
	O_2 to 2L saturating at 92%	
	not going home as needs departmental	
	ECHO.	MN.

Figure 11: Nursing staff concern at low O2 levels and calling for an ECHO scan



Date & Time	Variance	Outstanding actions & comments	Signature
22-2-22	1430	Pat. S/B JHC Wardrounds	
		this am. For discharge	
		this morning. NO need	
		for Echo.	

Figure 12: Consultant cardiologist over-riding concern

Error # 7, Thursday 24th February 2022

Cardiac nurse advised against going to A&E on the grounds that symptoms were likely due to time required to adjust to new medication.

The shortness of breath was assumed to be 'nothing new' that this was a chronic condition. However, the shortness of breath had been acute for a period of 2 weeks prior to death (see 3.1). Again, the shortness of breath, a key symptom of PE, was not being recognised and was over-looked.

In two interviews, one with a practising paramedic and the other with a General Practitioner (GP), it was confirmed that upon hearing of shortness of breath and chest pain, a patient would - under normal circumstances - be advised to attend A&E on an urgent basis, particularly after a major surgery and a period of being sedentary.

3.5 Concluding comments

The Wells' criteria and PERC were not used appropriately in the case of my mother.

Moreover, the Wells' criteria are not used across Europe, as recommended by the European Society of Cardiology (ESC). One limitation with Wells' (PE most likely diagnosis) is that it may create ambiguity as it is subjective; the revised Geneva score may be more objective. This concern of subjectivity was repeatedly raised by ED clinicians in the HSIB report. [4]

In addition, PERC should not be used in European countries, as the prevalence of PE cases is too small for PE to then be safely ruled out. Its use is more appropriate in the US given the larger population and prevalence.

Clearly the current diagnostic process may contribute to misdiagnosis and excess fatalities.

4 Latest national, regional and age adjusted trends in PE driven fatalities

4.1 Total pulmonary embolism deaths (2013 – 2022*) in England and Wales

Venous thromboembolism (VTE), clinically presenting as deep vein thrombosis (DVT) or pulmonary embolism (PE), is globally the third most frequent acute cardiovascular syndrome behind myocardial infarction and stroke[12]. Indeed, many PE's likely go un-diagnosed and attributed to other acute cardiovascular conditions.

Despite reductions in case fatalities, longitudinal studies[13] , [14] have revealed a rising tendency in annual PE incidence rates, given ageing populations. Estimates of annual expenditures for VTE are up to €8.5 billion in the European Union alone.[15]

Data presented in Figures 13 and 14 for England and Wales shows a significant increase in total PE related fatalities (where PE is listed as the primary cause of death), over and above pre–COVID average levels. From 2013-2021 there is a 21% increase in all age fatalities and 7% for the over 70's. The forecast 2022 levels, although reducing from the peak in 2021, remain significantly above pre–COVID levels.

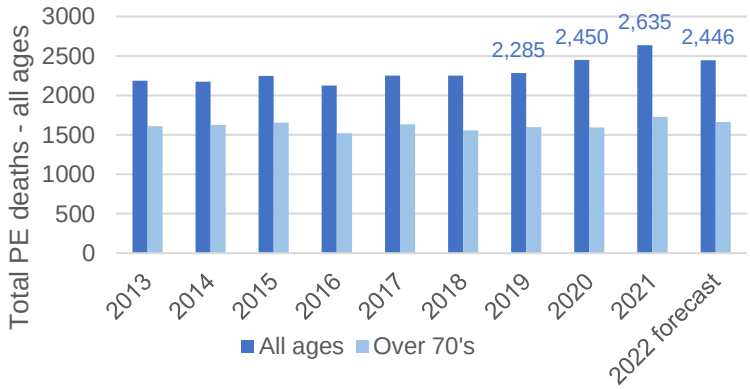


Figure 13: Total pulmonary embolism fatalities in England & Wales, male and female, all ages (dark blue bars) and over 70's (light blue bars)[16]

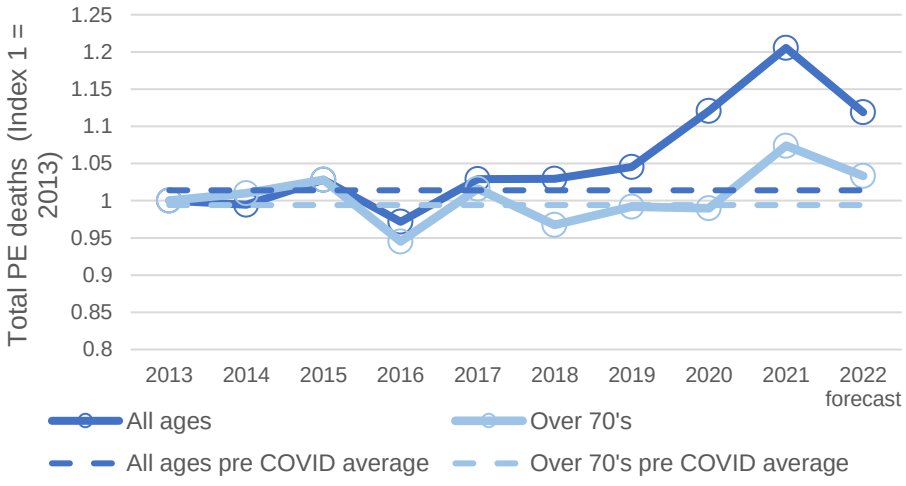


Figure 14: Index of total pulmonary embolism fatalities in England & Wales, male and female, all ages (dark blue bars) and over 70's (light blue bars) with 2013 counts = 1 [16]

[12] Raskob GE et al, 2014
[13] Lehnert P et al 2018
[14] Keller K et al 2020
[15] Barco S 2016
[16] Office for National Statistics NOMIS web-service via Freedom of Information request to NHS England, I26 classification

The increased trend for total PE-related fatalities reflects a change in age distribution, with the proportion of elderly people increasing over this period.[17]

However, the significant increase in total fatalities in recent years is a concern, and this may be due to the association with COVID-19 either directly, or, due to misdiagnosis.

4.2 Total venous thromboembolism (VTE) deaths' index (2007 – 2021*) in adults for England and an estimate of excess PE deaths

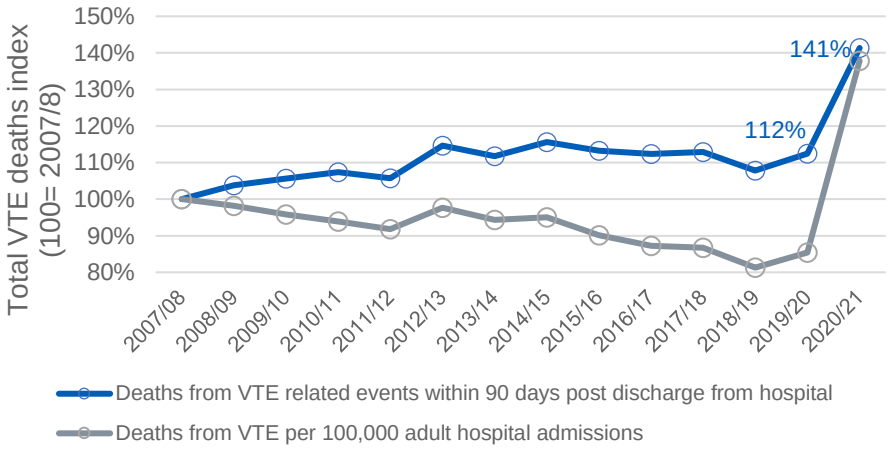


Figure 15: Index of total venous thromboembolism deaths in adults for England and crude rate per 100,000 adult hospital admissions

NHS England publishes its NHS Outcomes Framework [3] to *'monitor the health outcomes of adults and children in England. The framework provides an overview of how the NHS is performing.'* Over the period 1/4/2020 to 31/3/2021, overlapping with the two largest COVID-19 waves of infection we see a 26% year on year increase in VTE fatalities using this measure post hospital discharge. The ICD-10 scheme codes used in the analysis are I80.1, I.80.2, I26.0, I26.9, O22.3 and O88.2. The apparent trend is a similar absolute increase to that indicated in 4.1 for pulmonary embolism.

This metric that NHS England collects concerns fatalities where the cause being measured is listed anywhere on the death certificate, regardless of whether it is assumed to be the primary cause or not. This metric, in absolute terms, is then more complete than the data otherwise published by NOMIS/ONS on the primary cause of death. For instance for 2020/21 there are 4,592 deaths from these VTE-related conditions as the primary cause of death but 15,732 where a VTE-related condition is listed anywhere on the death certificate.

There is an outstanding freedom of information request to assess the relative, monthly change in VTE-related fatalities (split PE and non-PE) relative to the change in COVID-19–related fatalities, post March 2021 (although this data will only be available in March 2023). According to the Journal of the American College of Cardiology (2022), [2], it is anticipated that not all the 2021 and 2022 increase in VTE– and PE–related mortality can be attributable to COVID-19 infection. Therefore, the risk of mis-diagnosis for these conditions has increased.

By my calculations, using data sources that are available from NOMIS:

- there were around 8,550 total PE related fatalities (with a PE condition listed anywhere on the death certificate) in England for the year 2020/21, a 28% increase from the previous, largely, COVID-19 free year, 2019/20 – estimated by splitting out total PE to total VTE as the primary cause of death from NOMIS.
- considering the evolution in the total number of PE's given as the primary cause on the death certificates from 2021 to (forecast) 2022 I would estimate that there were 7,500 total PE–related fatalities - again with a PE condition listed anywhere in the death certificate - for the year 2021/22.

[17] https://www.statista.com/statistics/270370/age-distribution-in-the-united-kingdom/

- as there were ~25% of the number of COVID-19 fatalities in 2021/22 than the prior year we can assume this proportion, 25%, to the increase in total PE related fatalities in 2021/22 relative to the COVID–19 free 2019/20 year. This yields 7,103 fatalities as a 'COVID-19 risk adjusted' estimate for 2021/22, a 7% increase from the COVID–19 free 2019/20 year. The difference between 7,500, the actual estimate, and 7,103 (i.e. 396) may then be attributable to other sources of risk; I'd hypothesis much of this is due to PE mis-diagnosis. Given the effectiveness of vaccines and that only around 50% of VTE-related incidents occur post hospital discharge, this risk adjusted estimate is likely to be an over-estimate and then the difference being attributed to mis-diagnosis is likely to be higher.

Once the freedom of information request (for monthly data to April 2022 on total VTE deaths) is available from NHS Digital in 2023, this estimate may be corroborated. For now, a projection of the VTE fatalities may be inferred from the projection of primary cause PE fatalities provided by the ONS. Indexing the COVID and VTE fatalities to April 2020 levels and adding in an average monthly VTE level of mortality:

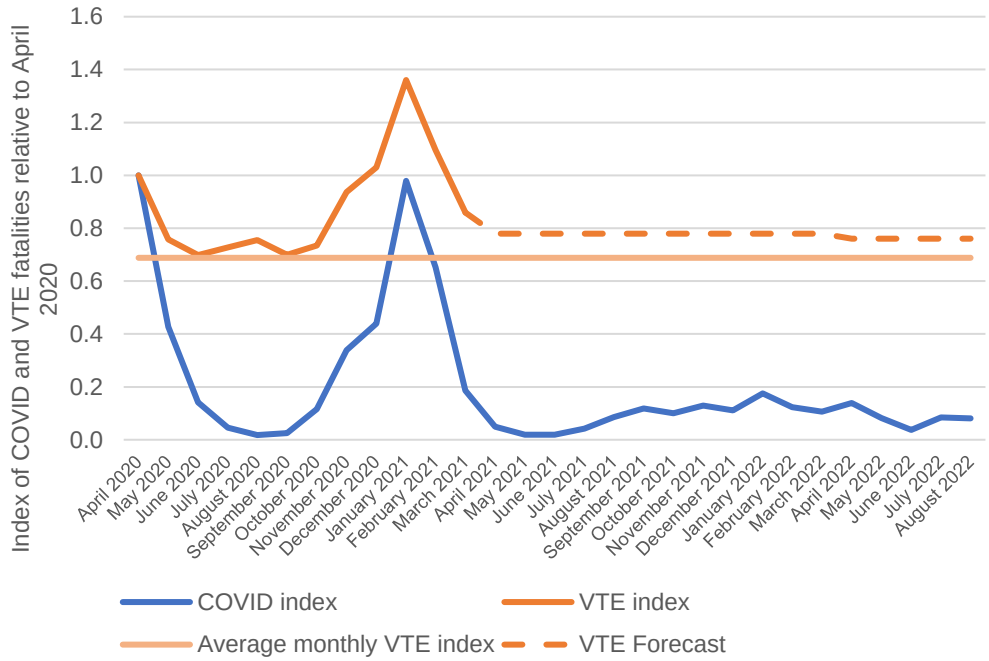


Figure 16: Index of COVID-19 and Total Venous Thromboembolism deaths relative to April 2020 levels and adding the 2007-2020 Average Monthly VTE fatalities relative to April 2020 levels

Figure 16 indicates:

- from the period, June to September 2020 where COVID-19 levels fell back to low levels it's apparent that VTE mortality resembled the long-run average.
- the peaks in April 2020 and January 2021 are clearly explainable by the COVID-19 trend.
- however, forecast VTE mortality remains significantly above long-run average levels despite relatively low COVID-19 levels.

4.3 Pulmonary Embolism to Total Deaths (2013 – 2022*) in England & Wales

Another population adjusted measure to consider the trend in PE–related fatalities is shown below.

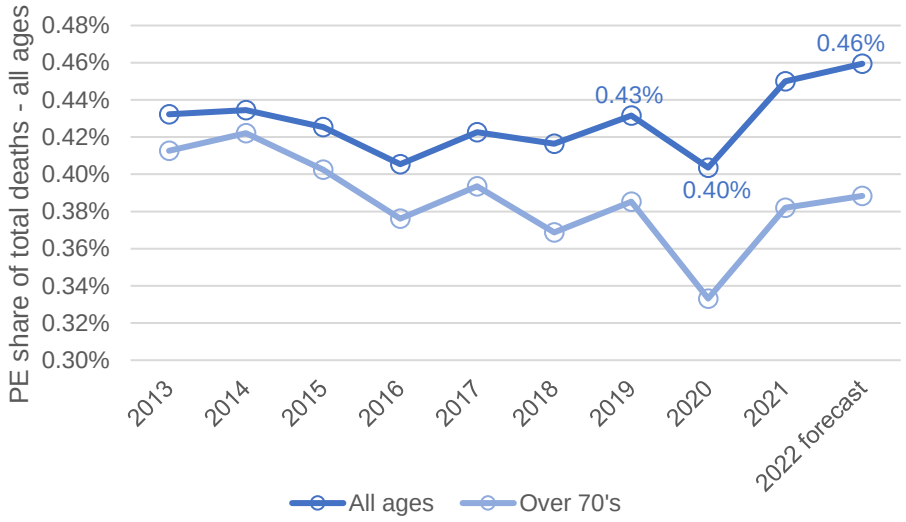


Figure 17: Total pulmonary embolism fatalities in England & Wales, male and female, all ages as a percentage, %, of total all cause fatalities in England & Wales (dark blue bars) and over-70's (light blue) [5].

Two potential trends emerge. First, there is a stable pattern with no significant trend emerging in the all-ages % of total until 2021 and the 2022 forecast, where there is then an increase. The period of no trend is broadly explainable by studies that show that despite the increased annual incidence rates, resulting from an increase in the elderly population, there is an off-setting reduction in case fatality rates.[18]

The second trend that emerges is that over the past two years there is a reversal in the declining trend in the % of PE to total fatalities in the over-70's. That the 2013-2020 period sees a substantial drop off in PE–related fatalities to total deaths may again be explained by the reduction in case fatality rates reported. Thus, it is a concern that there is a significant increase in the % of total fatalities attributable to PE in the 2021 and the 2022 forecast years in the over-70's (17% over two years). Presumably, this is partly linked to a broader association with COVID-19, explored further in 5.4, or a rise in misdiagnosis.

4.4 Age-standardised Mortality Rates (2013-2022*), ASMR, in England & Wales

Age-standardised mortality rates (ASMRs) are computed globally to compare mortality rates between multiple time periods and across geographies, accounting for the time and geographic differences in the age structure of the populations being compared. [19]

Comparing ASMRs across counties and unitary authorities in England & Wales enables an assessment of whether there are parts of the country where the mortality rate is highest and lowest. Such a comparison also highlights how much variability there is. The following algorithm was applied:

- the average was calculated for the total PE fatalities (for code I26 only, where the primary cause of death – 98% of total PE fatalities in 2019) expressed as a % of the total population by age band for 2019, 2020 and 2021. 2022 was not used, given the granularity of data is not yet available and the year is not yet complete.
- weighting each age band according to the 2020 ONS age distribution for England, Wales and Scotland, the latest available year that this data is made available.

[18] Global studies collated by the European Centre of Cardiology – 2019 Guidelines on Task Force for the diagnosis and management of acute pulmonary embolism.
[19] Age-Standardized Rates – Statistics Canada

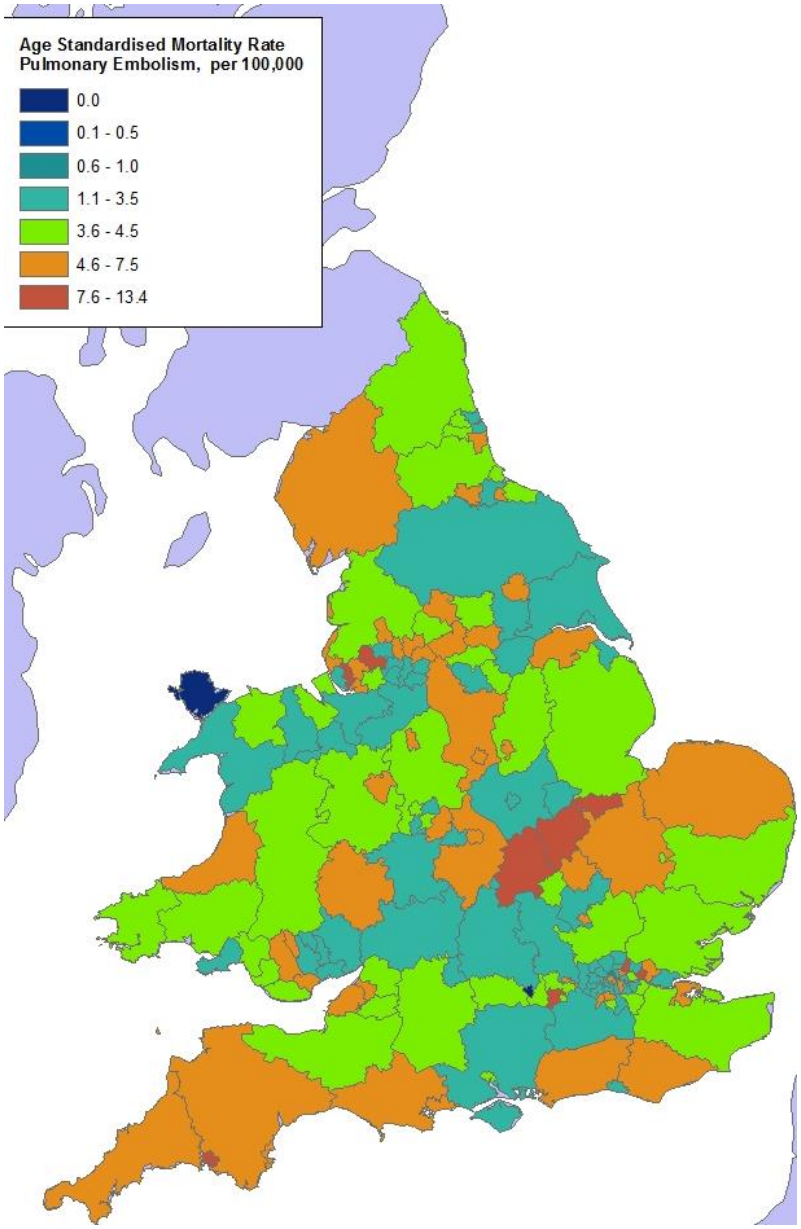


Figure 18: Age-standardised mortality rate from pulmonary embolism fatalities in England and Wales, male and female, all ages, 2019-2021 average, by county / local authority. *(ICD-10 code I26 only, where the primary cause of death). Light green = in-line with national average, dark blue tones = below average, brown tones = above average.*

It is apparent from this NOMIS data on primary cause of death that:

- there is significant variability in the ASMR for pulmonary embolism fatalities across England and Wales [16].
- there are some regions where the age-adjusted mortality rate for pulmonary embolism fatalities is almost three times the national average.

To assess whether this variability in the ASMR is common in other causes of fatality, or whether there is an outlier for pulmonary embolism ASMRs, the ASMR for heart diseases [20] is computed for comparison, given it is a leading source of fatality. [21]

In Figure 19, the three-year average ASMR is computed for each of the 174 counties / local authorities in England and Wales and compared between PE and heart disease. It is apparent that heart disease

[20] Office for National Statistics, NOMIS web-service, LC30 code for heart disease and I26 for PE.
[21] ONS Leading Causes of death, UK: 2001-2018

causes a far greater number of fatalities than PE; in fact, 23 times the national average ASMR between conditions.

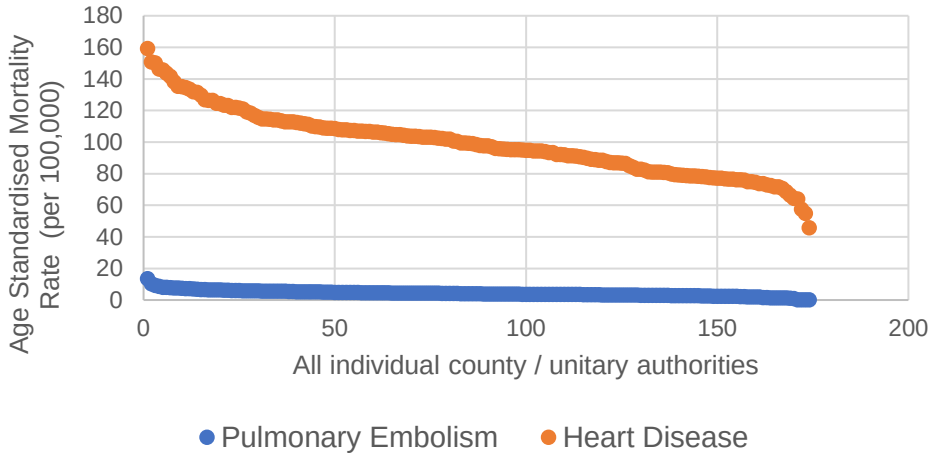


Figure 19: Age-standardised mortality rate for pulmonary embolism (PE) and heart disease in England and Wales, male and female, all ages, 2019 – 2021 average by county / local authority

A comparison of the statistical distributions of the PE and heart disease ASMRs may indicate whether there is greater variability and extreme outcomes in the ASMRs of PE. The ASMR for each county / local authority has been standardised by the following formula so that units of standard deviation can be compared:

Standardised ASMR per county / local authority $_{x}$

= (ASMR x – Mean ASMR $_{\text{England \& Wales}}$) / Standard Deviation ASMR $_{\text{England \& Wales}}$

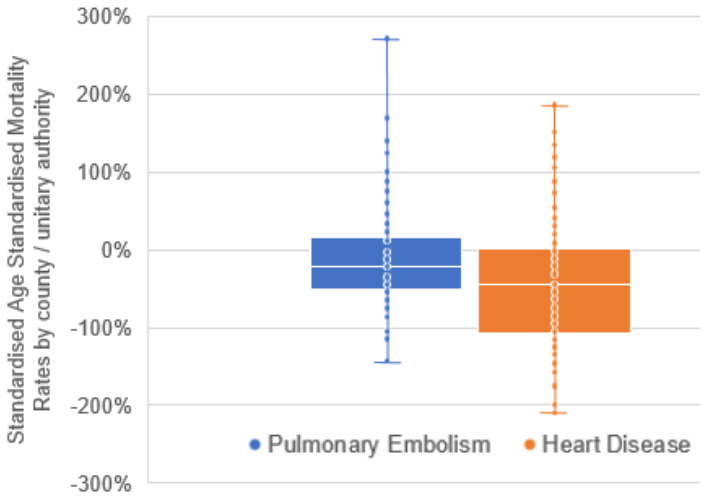


Figure 20: Box and whisker plot indicating max, min, quartiles 1, 2 and 3 values of PE and heart disease ASMRs per county / local authority.

In conclusion:

- there is more variability in the PE ASMRs by county / local authority, the 75th percentile values (Q3) are ~0.2 standard deviations above the mean, average value whereas for heart disease the 75th percentile ASMR value is approximately equal to the mean
- both distributions are skewed right to high ASMR outcomes; both have a mean greater than the median
- however, the ASMR distribution for PE is significantly more skewed, the max county / local authority ASMR value is 2.7 standard deviations greater than the mean whereas for heart disease the equivalent maximum is 1.8 standard deviations higher.

This is potentially an indicator that either reporting and/or diagnosis also care for VTE– and PE–related conditions is more variable across the country than it is for heart disease, and that further work on reporting and defining best practice diagnosis and care may be required.

4.5 A regional comparison of PE fatality rates in England and Wales

As indicated in Figure 18, rates of PE ASMRs are highly variable across the country, whilst the preceding discussion in 4.4 established that there is excess variability of the PE ASMRs in relation to the heart disease ASMRs. Focussing in on the region of interest, Figure 21, below, compares the PE deaths to total all cause deaths.

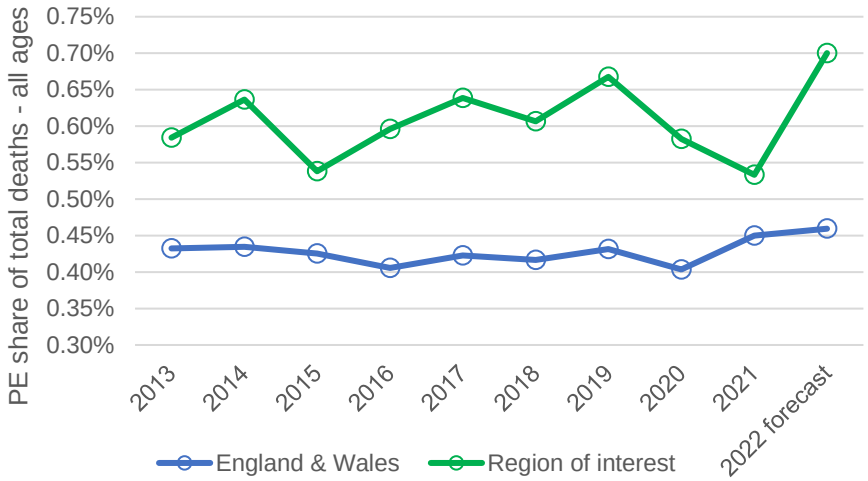


Figure 21: Total pulmonary embolism fatalities in England & Wales, for male and female, all ages as a percentage, %, of total all cause fatalities in England & Wales (dark blue) and compared to the region of interest (green) [9]

Across 2020 to (forecast) 2022 there is a 38% greater incidence of PE to total fatalities than the national average. Even removing the impact of age by focussing just on the over-70's, there is similarly a 42% greater incidence in the region of interest than the national average, (see Figure 22 below).

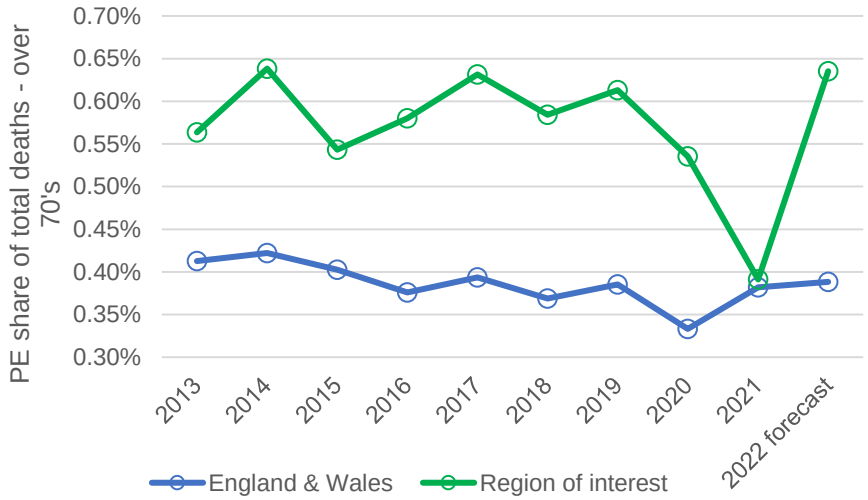


Figure 22: Total pulmonary embolism fatalities in England & Wales, for male and female, over 70s as a percentage, %, of total all cause fatalities in England & Wales (dark blue) and compared to the region of interest (green) [9]

Three potential explanations for regional variations include:

- *variability in the quality of patient care and patient safety* – A&E national care quality indicators, discussed in 6.1, illustrate this variance.

- *variability in the risk appetite of the integrated care boards* – as per 6.3, adoption of NICE guidelines, NHS Outcomes and A&E national care quality indicators varies according to resources and financial constraints.
- *expertise-driven* – heterogeneities in stroke care demonstrate that average length of stay per patient is inversely proportionate to the size of the department [22]. This replicates a study in Japan [23] showing that hospitals with larger stroke volumes are those with more favourable patient outcomes.
- *a weekend effect* – evidence of more adverse outcomes at weekends in the UK, even after accounting for severity of disease. [24]

All these factors may explain the highlighted regional differences, as does the experience of my mother when attending the ED on a Saturday morning.

4.6 A European cross-country comparison of pulmonary embolism age-standardised mortality rates (ASMR)

Using datasets and methods referred to in Barco et al. (2021), [25] data for ten European countries' on age-standardised mortality rates for pulmonary embolism, including that for England and Wales, is compared below – standardisation here follows the 2013 European Standard Population (ESP), and the PE codes assumed are I26, I82, O88.2 for the primary cause of death only.

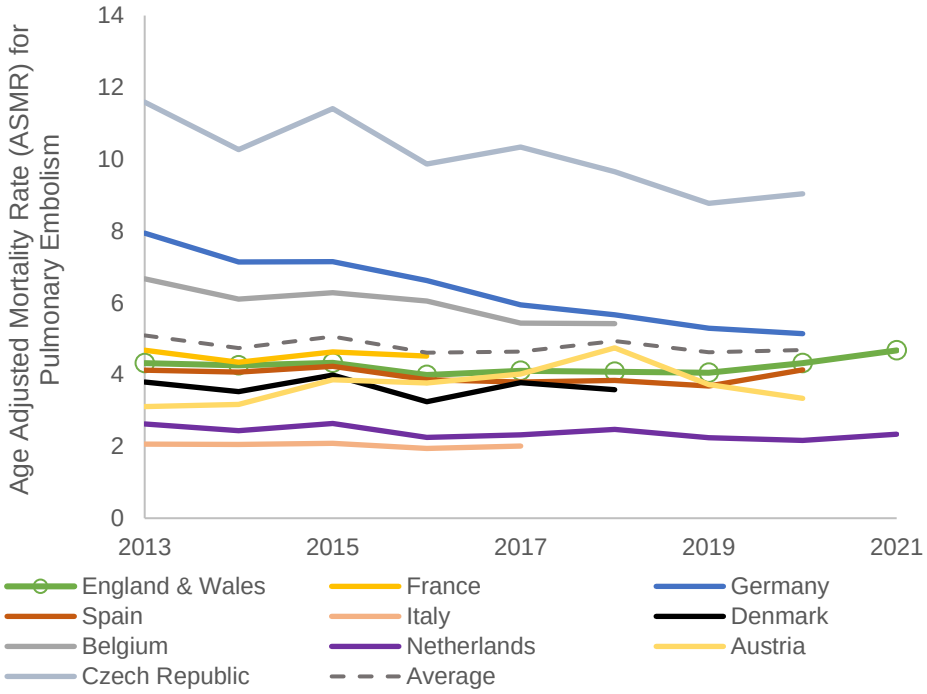


Figure 23: Age-Standardised mortality rate (ASMR) for pulmonary embolism fatalities in England & Wales, for male and female, all ages, 2013-2021 where available. *Source: World Health Organisation Mortality Database and national statistical agencies*

Some observations from this extension of the prior Barco et al analysis:

1. *Pulmonary embolism ASMR fell after 2013* for many countries, and on average across the ten European countries selected, by between 8 and 10% depending on which countries are included within the average. This is consistent with reductions in case fatality rates, pre–COVID-19, as

[22] Michelle Tørnes et al, 2019
[23] Yoshihisa Fujino et al, 2014
[24] Kate Honeyford et al, 2018
[16] Global studies collated by the European Centre of Cardiology – 2019 Guidelines on Task Force for the diagnosis and management of acute pulmonary embolism.
[25] Stefano Barco et al, 2021

reported by the Task Force for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology (ESC; 2019). [16]

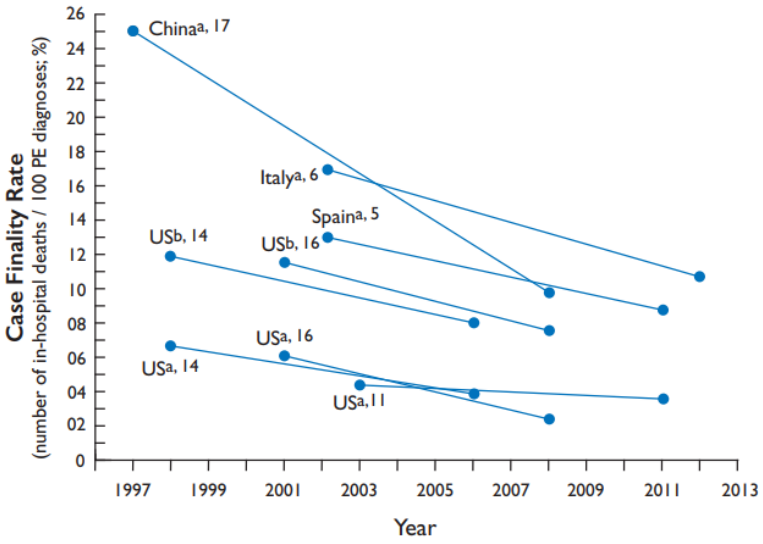


Figure 24: Trends in case fatality rates of pulmonary embolism around the world, based on data retrieved from various references [16]

2. *The variability in levels of ASMR across countries is significant* – in Germany the ASMR for PE is 3–4 times higher than in Italy, and in Czech Republic it is 4–5 times higher. As highlighted in Barco and Sebastian (2020) [26], deaths primarily related to PE maybe misclassified as cardiac or other deaths, rendering cross-country comparison challenging. Some countries' ASMR for pulmonary embolism may be artificially low, the true incidence cannot be reasonably compared without the data for all-cause fatality being reported.

3. *There is a 15% increase in ASMR, in England & Wales from 2019 to 2021 when PE is the primary cause of death* – this reversal in the previous year's reduction in PE ASMR is concerning and potentially attributable to COVID-19 representing an additional risk factor for PE. Over the period to the financial year 2021/22 the increase represents around 400 fatalities over and above levels seen pre-COVID and above the increase attributable to COVID. While across countries the absolute levels may be difficult to compare, year-to-year changes may be more insightful. Additional data for 2021 has been requested across countries and it will be useful to compare to England and Wales data once this is available.

4.7 Mis-diagnosis of PE – causes and impacts

The above discussion raises the potential that there is variability across England and Wales and across countries concerning PE reporting, diagnosis and care. Indeed, increasing PE misdiagnoses may undo much of the benefit from the reduction in case fatalities.

One US study reviewed various cases and established that, in Emergency Department settings, 27.5% of patients with PE are misdiagnosed.[27] The study noted that the commonly diagnosed conditions instead of PE were respiratory infection, heart failure and acute coronary syndrome (ACS). Some specific points raised in this study:

- often the demands on the health service are such that there is a lack of resources to regularly review the care they delivered,
- there may be no interest by healthcare professionals and services to into identifying misdiagnosis as it only potentially raises problems related to care,
- it is underreported in the literature because it raises concerns about the competency of clinicians and this can affect the trust between doctors and patients.

[26] Stefano Barco and Tim Sebastian, 2020.
[27] Chun ShingKwok, 2022

- ideally, there should be mechanisms and efforts to consider misdiagnosis in clinical practice which can take place in the form of health service evaluations (e.g. significant event review, morbidity and mortality meetings) and clinical audits; identification of the problem is key, as once it is identified, then the rationale for clinical-decision making can be reviewed, and it can be determined if any intervention is needed, such as education of clinicians, pathway development or knowledge exchange; this could improve outcomes for future patients.

The 2019 National Confidential Enquiry into Patient Outcome and Death (NCEPOD) identified delays in the processes for treating patients with PE in almost 40% of the 526 cases it reviewed.[28]

A 2017 prospective cohort study [29] of patients admitted to a respiratory department in Madrid, Spain evaluated whether patients with PE had better outcomes if they were acutely managed according to international guidelines, or not. In the study:

- 19% of patients did not receive guideline-adherent PE management
- the risk of death from any cause among patients with non-adherent management was about two-times higher and the risk of PE-specific death was about five-times higher than in patients with adherent management.

Another French / Belgium study [30] established that typical factors that led to patients being mis-diagnosed were:

- age exceeding 75 years'
- known heart failure
- chronic lung disease
- current or recent pregnancy
- currently receiving anticoagulant treatment
- lack of a written diagnostic algorithm and clinical probability scoring in the emergency department.

More recently, COVID-19 led to a rise in PEs. However, Farmakis et al. (2022)*,* [2] demonstrate that the increase in the age-adjusted PE-related mortality rate cannot all be explained by associated COVID infection, particularly after the second half of 2020. A 15% rise may then be attributable to non-COVID factors, such as misdiagnosis.

The consequences of misdiagnosis in PE have been shown to be significant. [31] There is a 4–5 times greater chance of death. The death rate for diagnosed and treated PE is 8%, and hence the risk is significant but manageable, given early diagnosis and appropriate treatment.

4.8 Concluding comments

The first Freedom of Information Request made to ONS has illustrated the following trends in PE-related fatalities:

- +3%, all ages, and +12 % over-70s increase in total PE fatalities from 2013 to 2022 (forecast), +7%, all ages, and +21 % over-70s increase in total PE fatalities from 2013 to 2021
- a 26% year on year increase in VTE fatalities using the all-cause measure in the 60 days post hospital discharge
- an estimate of 400 all-cause PE deaths in England for 2021/22 attributable, in whole or in part to PE misdiagnosis
- A 17% increase in PE related deaths to total all-cause deaths from 2020-2022 (forecast).
- there are some regions where the age-adjusted mortality rate for pulmonary embolism is almost three times the national average; the distribution of county / local authority ASMRs is more positively skewed for PE than it is for heart disease
- across 2020 to 2022 (forecast), there is a 38% greater incidence of PE to total fatalities than the national average in the area of focus. Even removing the impact of age by focussing just on the over 70's, there is similarly a 42% greater incidence in the area of interest than the national average

[28] National Confidential Enquiry into Patient Outcome and Death. (2019) Know the score
[29] David Jiménez et al 2017
[30] Pierre-Marie Roy et al 2006
[31] Jan Bělohlávek, 2013

- in a cross-country study, pulmonary embolism age-adjusted mortality is falling across Europe, since 2013, although there is a 15% increase in ASMR in England and Wales from 2019 to 2021– this represents 400 fatalities.

Following on from the discussion on PE mis-diagnosis in 4.7, it is evident that patient outcomes after the onset of VTE and PE, in particular, vary across England and Wales and that misdiagnosis remains a genuine concern. This is not just a few patients ‘falling through the cracks’, there appears to be a systematic failure to consistently assess the third most frequent acute cardiovascular syndrome after myocardial infarction and stroke. Furthermore, the effects of COVID appear to have caused a reversal of the prior reduction in the case fatality rate.

5 Academic literature review on PE risk factors and symptoms with application to the case of Jenny Edwards

5.1 PE risk factors and symptoms

Various studies attempt to summarise the risk factors and symptoms associated with PE [32] [33]. However these are often not entirely consistent, and the recent addition of COVID-19 as a risk factor complicates the assessment (see 5.4).

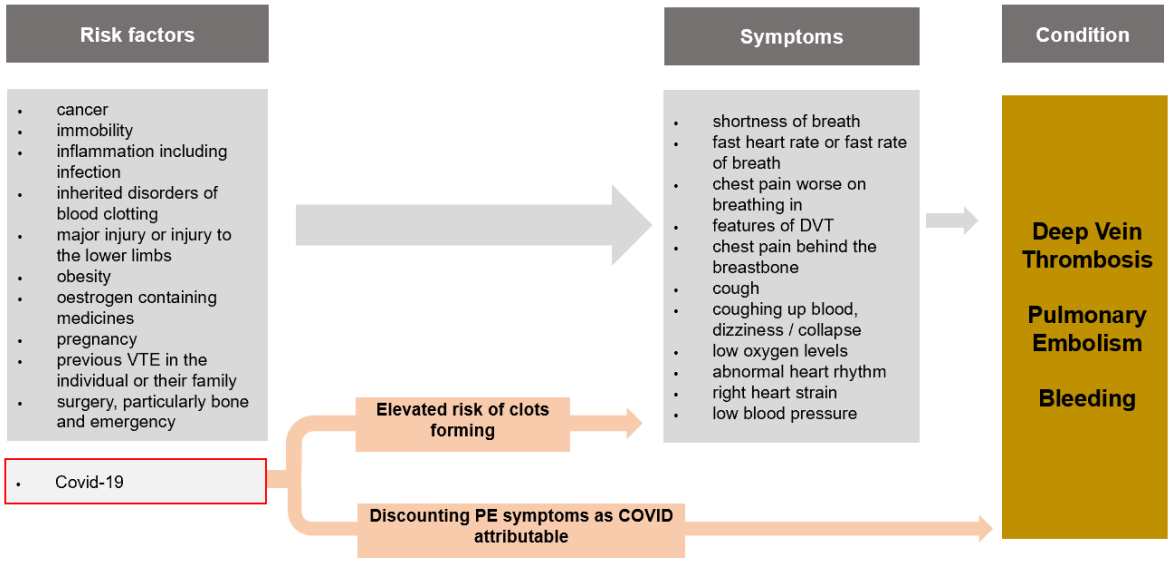


Figure 25: VTE and specifically Pulmonary Embolism risk factors and symptoms

Some guidelines indicate tachycardia (fast heart rate) is a key symptom, whereas other studies indicate tachypnea (fast rate of breathing) as a symptom.

Either way, clinical diagnosis tests (e.g. Wells' criteria, Geneva; see 5.2), typically rely on binary exceed vs within-tolerance criteria. These offer simplicity but discount symptoms altogether below the designated thresholds that, in totality, may clearly indicate PE.

A particular complication with PE diagnosis is the overlap of risk factors and symptoms with other acute coronary conditions. [34]

- chest pain or discomfort, which may involve pressure, tightness or fullness
- pain or discomfort in one or both arms, the jaw, neck, back or stomach
- shortness of breath
- feeling dizzy or lightheaded
- nausea
- sweating

These symptoms, however, are subtly different; chest pain for PE for instance is more in the centre of the chest and worse on inhalation or exercise.

[32] Clarity Informatics Ltd. (2020)
[33] American Thoracic Society, PATIENT EDUCATION | INFORMATION SERIES
[34] Acute Coronary Syndrome, https://www.heart.org/

5.2 Likelihood of PE risk factors

The Task Force for the Diagnosis and Management of Acute Pulmonary Embolism of the European Society of Cardiology (ESC) report [35] that in 90% of cases, suspicion of PE is raised by the clinical symptoms dyspnoea (shortness of breath), chest pain and syncope (loss of consciousness), either singly or in combination. They cite two studies where [36] [37] pleuritic chest pain (upon inhalation), whether or not combined with dyspnoea (shortness of breath), is one of the most frequent presentations of PE.

Symptoms	PE confirmed (n=219)
Dyspnoea / shortness of breath	80%
Chest pain upon inhalation	52%
Chest pain / substernal	12%
Cough	20%
Haemoptysis / coughing blood	11%
Syncope / loss of consciousness	19%

Signs	PE confirmed (n=219)
Tachypnea / fast rate of breathing (>20 p/min)	70%
Tachypnea / fast rate of breathing (>100 p/min)	26%
Signs of DVT	15%
Fever (>38.5%)	7%
Cyanosis / skin discolouration	11%

Figure 26: Prevalence of symptoms and signs in 219 patients with suspected PE according to final diagnosis [19]

Other points noted by the Task Force of the European Society of Cardiology (ESC) [18] study:

- PE is generally associated with hypoxaemia, but up to 20% of patients with PE have a normal arterial oxygen pressure (PaO2) and a normal alveolar-arterial oxygen gradient [D(A-a)O2]
- electrocardiographic (ECG) signs of RV strain, such as inversion of T waves in leads V1–V4, a QR pattern in lead V1, the classic S1Q3T3 type and incomplete or complete right bundle-branch block, may be helpful, particularly when of new onset.
- nevertheless, such changes are generally associated with the more severe forms of PE and may be found in right ventricular strain of any cause.

Clearly, shortness of breath is the key symptom observed in the majority of cases.

5.3 Should there have been a suspicion of PE in this case?

Four methods will be used to assess whether or not Suspicion of PE should have arisen from the 19th February Emergency Department assessment.

5.3.1. Did my mother match Symptoms and Signs associated with 219 Pulmonary Embolism cases? Yes.

Considering the studies cited in the European Society of Cardiology (ESC) report, upon Emergency Department assessment on February 19th my mother exhibited 86% of the total 'area' of the independent probabilities associated with PE from the Miniati et al. study (1999). [36]

[35] The Task Force for the Diagnosis and Management of Acute Pulmonary Embolism of the European Society of Cardiology (ESC), 2008
[36] Miniati M et al 1999
[37] Stein PD 1991

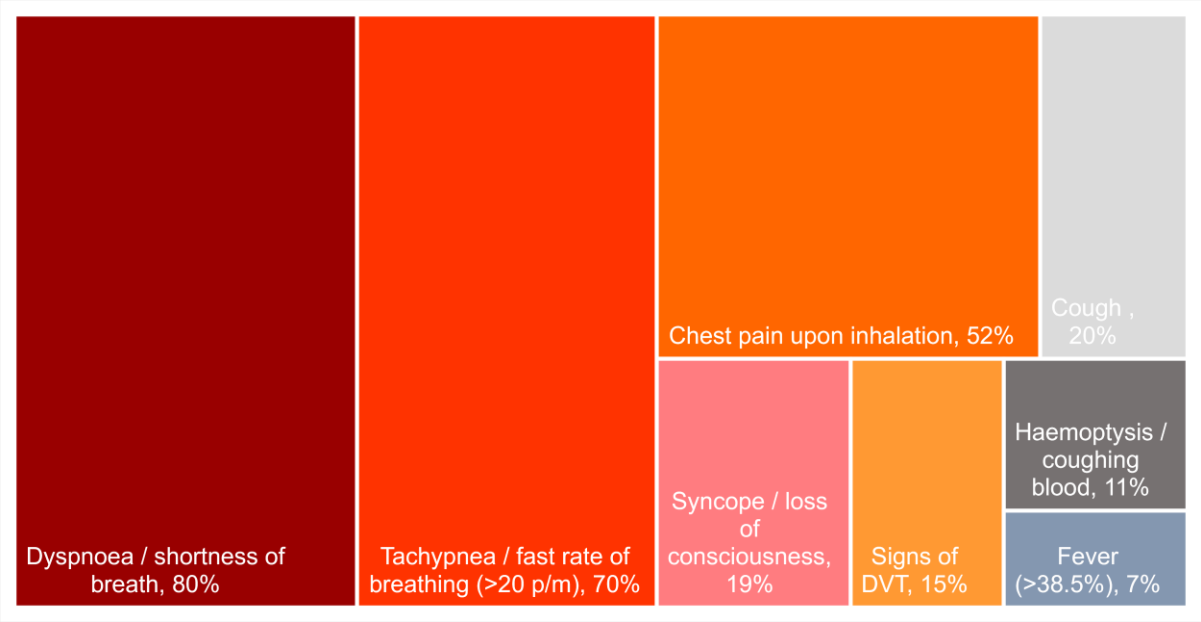


Figure 27: Symptoms and signs associated with 219 pulmonary embolism cases, those in red/orange/pink were those my mother experienced. [36]

5.3.2 Did my mother exhibit clinical signs of a *severe* PE? Yes.
Clinical signs such as sinus tachycardia and right heart strain are considered highly specific to a severe PE.

- My mother's peak heart beat was 95 per minute, at its reported peak on 1st February, just 12% away from the 100 beats per minute and within the safe 60-100 per minute range. This was a near miss but discounted altogether from clinical assessment
    - She did, however, exceed the 20 breaths per minute (22 breaths) associated with tachypnea
- she exhibited an S wave in Lead I, Q waves in Lead III, inverted T wave in Lead III and aVF, also a right bundle branch block, indicating a partial or complete blockage or electrical impulse to the right ventricle.

5.3.3. How did my mother's observations compare to a large sample of PE patients? They should have aroused suspicion.
Another way of expressing the findings in the Miniati et al. study is to average the observations across the patients exhibiting PE. Below is a comparison of my mother's observations to the average (mean) observed recordings from the 1,880 PE patients summarised in Pollack et al. (2011).[38]

Vital signs at presentation in ED	Pollack et al, n = 1,880	My Mother (19/02)
Heart rate, beats/min	95.7	95
Respiratory rate, breaths/min	20.5	22
Systolic blood pressure, mm Hg	132.3	123
Oxygen saturation, %	95.3	94

Figure 28: % of PE patients and their vital signs at presentation in ED, compared to my mother's observations on February 19th, 2022

Three of the four observations from my mother are consistent with the average summarised in Pollack et al, (2011); two of the four were worse than this average. Interestingly, the average of 95.7 beats per

[38] CV Pollack et al (2011)

minute is less than the 100 beats per minute minimum assumed as being 'typical of PE' and adopted in the Wells' criteria. Indeed signs of my mother's PE were discounted partly due to the minimum heart rate threshold not being exceeded in accordance with the Wells' criteria.

5.3.4. How would my mother have scored on the revised Geneva clinical prediction rule for PE? [16] PE likely.

Items	Clinical decision rule points	My Mother (19/02)
Previous PE or DVT	1	1
Heart rate: 75-94 bpm	1	0
Heart rate: >_95 bpm	2	2
Surgery or fracture within the past month	1	0
Haemoptysis	1	0
Active cancer	1	0
Unilateral lower-limb pain	1	1
Pain on lower-limb deep venous palpation and unilateral oedema	1	0
Age >65 years	1	1
Clinical probability		
Two-level score		
PE unlikely	0-2	
PE likely	>_3	5

Figure 29: Revised Geneva clinical prediction rule with highlights for where my mother matched the criteria

Interestingly the criterion in the revised Geneva clinical prediction rule is that the threshold for high heart rate is now 95 beats per minute, in line with Pollack et al. (2011) and lower than the Wells' criteria. The revised Geneva score has been extensively tested and one study of 300 PE patients shows that revised Geneva scoring does not over-diagnose PE relative to the Wells' criterion [39].

To conclude, pulmonary embolism should have been suspected on the basis of all four of these assessments.

5.4 COVID-19 as a risk factor

COVID-19 acts to complicate the diagnosis of PE- and VTE-related conditions given that, firstly, shortness of breath may also be associated with COVID-19. As shown in Figure 23, clinical practitioners may, in some cases, confuse shortness of breath with COVID-19 and discount it from their assessment of PE. Moreover, D-dimers in the blood may be elevated due to associated inflammation, reducing the perceived effectiveness of this test, and again reducing the likelihood of a PE diagnosis.

The second risk factor associated with COVID-19 involves the increased likelihood of blood clotting. Studies dating back to 2020, at the onset of COVID, established the link between critically ill COVID-19 patients and VTE conditions.

A systematic review of 24 of these studies and a meta-analysis [40] across 2,500 patients revealed a high prevalence of VTE in critically ill COVID-19 patients. Pulmonary embolism was shown to have a higher incidence than DVT, which led researchers to consider micro-thrombosis as an additional mechanism of PE in COVID-19 patients.

[39] F.A Klok et al, 2007
[40] Mohamed, M et al 2021

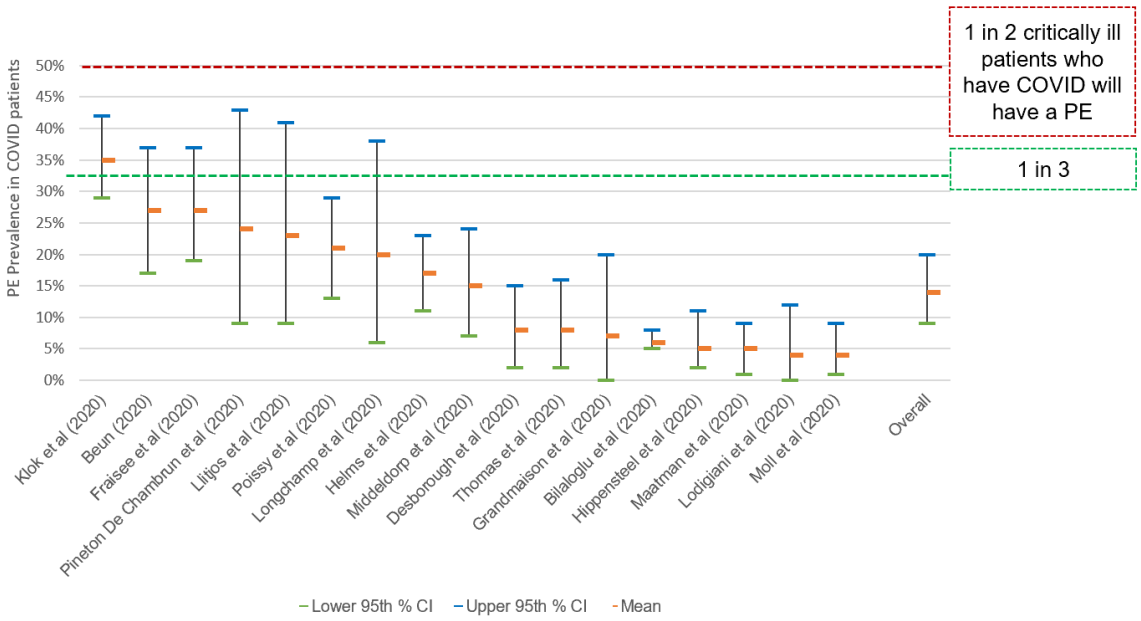


Figure 30: from Prevalence of Pulmonary Embolism in Critically Ill COVID-19 Patients: Systematic Review and Meta-analysis, Mohamed et al. (2020) [21]

Subsequent studies [41, 42, 43, 44, 45] established the incidence of COVID-19 with pulmonary embolism over various lengths of time, and also considered the severity of the initial COVID-19 infection.

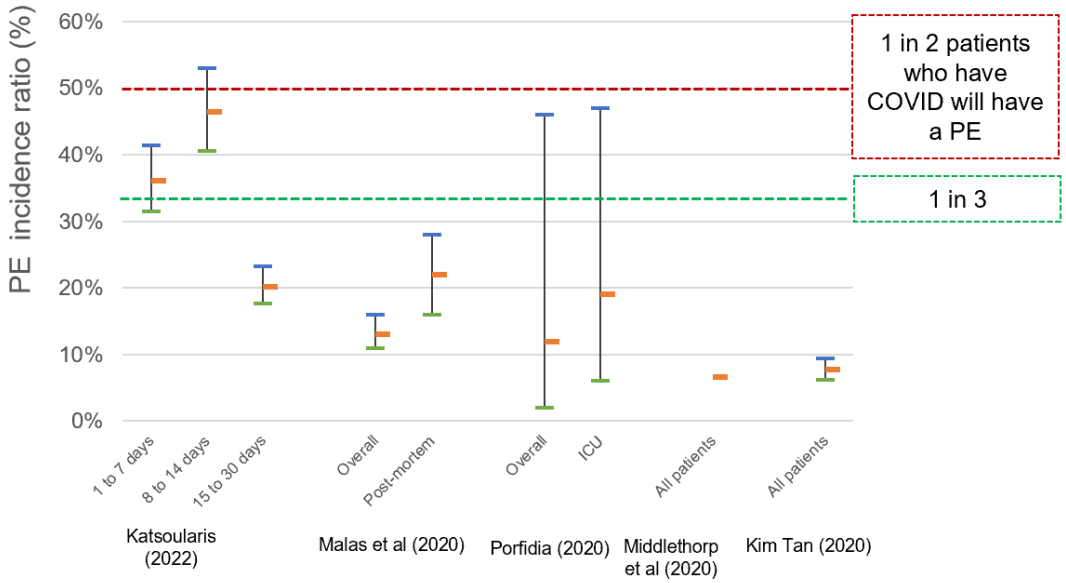


Figure 31: Prevalence of pulmonary embolism in COVID-19 patients, various studies

Key conclusions from these COVID-19 and VTE incidence studies indicate:

- incidence rates differ between DVT and PE
- infections involving intensive care or ventilator treatment lead to a higher incidence of VTE related conditions
- incidence rate ratios were significantly increased after 110 days for pulmonary embolism

[41] Katsoularis et al, 2022
[42] Malas et al (2020)
[43] Porfidia et al (2020)
[44] Middeldorp et al (2020)
[45] Kim Tan et al (2020)

- rate ratios were highest in patients with critical COVID-19 and highest during the first pandemic wave in Sweden compared with the second and third waves, indicating the effectiveness of vaccines at reducing incidence of VTE-related conditions.

5.5 Concluding comments

There are many risk factors and symptoms associated with PE that are, however, complicated by the overlap in these symptoms with other acute coronary conditions; also, COVID-19 is now an additional risk factor.

However, given the results of four separate assessments to gauge suspicion of PE, my mother clearly should have been considered as likely to be experiencing a severe PE. The last of these assessments is the revised Geneva clinical prediction rule for PE, which has been adopted across much of Europe.

From reviewing the findings of Pollack et al. (2011) and the European Society of Cardiology (ESC) 2019 guidelines, it is apparent that the Wells' criteria are not consistent with the latest science. One limitation of Wells (PE most likely diagnosis) is that it may create ambiguity, as it is subjective; the Geneva score may be more objective. Moreover, use of PERC is not considered appropriate to rule out a PE in Europe, given the lower incidence to that experienced in the US.

6 Risk Management and Patient Safety

6.1 Where risk management barriers may fail in acute care settings

From reviewing the hospital in question and other cases summarised in the HSIB report [4], it is concerning that clinicians and managers do not consistently follow clinical best practice and a risk management system with multiple lines of defence. Failure to suspect PE and the incorrect implementation of the diagnostic process should not be able to set in motion a chain of contingent decisions that undermine patient safety. As far as possible, each barrier should be independent of the other, so as to minimise the chance of 'group-think' and cognitive biases. The 2021 NHS National Patient Safety Strategy [46] aims to ensure safety culture is embedded at every level, from senior leadership to the frontline.

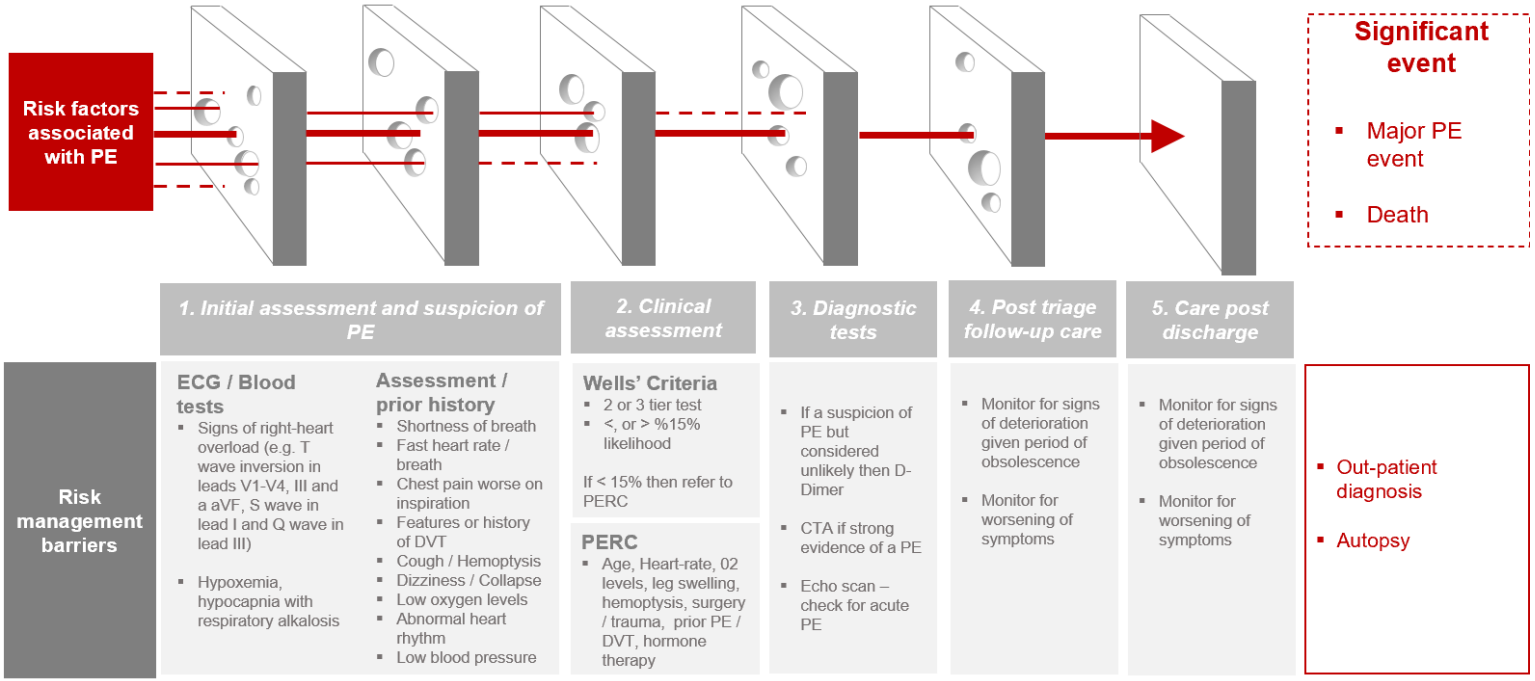


Figure 32: Example of independent risk management barriers acting to reduce the probability of misdiagnosis and adverse PE outcome

[46] NHS Patient Safety Strategy 2021 update

Patient Safety Learning's *Mind the Implementation Gap* report [47] notes that there are around 11,000 avoidable deaths in the UK annually due to safety concerns. A key reason for this is *the implementation gap*, the difference between what we know improves patient safety ('Work as Prescribed') and what is done in practice ('Work as Done'). To highlight one key recommendation to address the implementation gap:

- patient safety inquiries and reviews need system-wide commitment and resources, with effective and transparent performance monitoring to ensure that the accepted recommendations translate into action and improvement.

A&E national care quality indicators [48] from April 2021to March 2022 demonstrate performance monitoring in action whereby the following, for the hospital of interest relative to the national average for England, demonstrates consistent under-performance:

- 48% to 49% average of ED patients meeting the four-hour standard for the hospital of interest, clearly a proxy to over-crowding relative to staffing levels
- 112 minutes from time of arrival to treatment in hospital of interest compared to 84 minutes for England as a whole.

The hospital in question appears to be over-whelmed and does not reliably deliver patient safety. This conclusion is consistent with the Care & Quality Commission (CQC) inspection report released in July 2022 [8]. Indeed these findings follow Enforcement Undertakings undertaken with the hospital in 2017.

Another CQC report [49] on how a leading trust is managing the diagnostic process, in lieu of increased demand to ED's, demonstrated that it ensured patients are be seen by a decision-making clinician (F2 or above) within 60 minutes of arrival. Clearly this highlights the importance of not just being equipped with sufficient resources, but also having diagnoses overseen by a skilled, experienced clinician.

6.2 Generic review around PE diagnosis limitations and associated failings around risk management

Feedback from clinical practioners' in the HSIB report [4] for PE diagnoses and broader ED risk management processes suggests that:

- the national operating standard in England are contentious
- there is evidence that it has benefited patients by reducing long waits and overcrowding, which are known to be associated with harm
- however, the standards have not been consistently met for some and may have led to a focus on performance, rather than quality of care and good outcomes for patients [50]

Feedback across Eds, specifically on the diagnosis process for PE, indicates:

- novice ED nursing staff told the investigation that they sometimes found the initial assessment of patients difficult
- training had not taught them how to assess symptoms and signs to select investigatory tests; rather they were expected to follow published work procedures
- the suspicion of, and decision to pursue, a diagnosis of a PE was influenced by workload, years of experience, expertise in the skill of decision making, ED performance targets, available test results and previous decisions about a patient's potential diagnosis
- ED staff described concerns about the guidance for PERC that limited their use of it to inform their decisions
    - in practice determining a 'less than 15%' likelihood of PE in a patient is challenging. NICE does not provide further guidance on this, but does provide the background to the recommendation
    - the criteria for when PERC can and cannot be used is unclear

[47] Patient Safety Learning, 2022
[48] Provisional Accident & Emergency Quality Indicators, England, April 2021-March 2022
[49] Care Quality Commission, Under Pressure – Safely Managing Increased Demand in Emergency Departments, 2018
[50] Moulton and Mann, 2021

- ED staff described concerns about the validity of the Wells score that limited their use of it; because it is over 20 years old, staff questioned whether it accounted for the types of patients now commonly seen in EDs, such as those with obesity, on the oral contraceptive pill, with suspected but not confirmed cancer, and with reasons for not developing a high heart rate
- ED staff told the investigation that they did not use work procedures because:
    - they did not feel they needed to
    - they could recall from memory what needed to be done
    - there was not enough time at initial assessment to go through them
    - the procedures did not address the reality they were facing
    - the procedures were difficult to find and not easy to use.

That ED staff can state they did not use work procedures, as was evident with my mother, is a red-flag and an area that a second-line compliance function should be picking up, per 6.3, below. This review should not just be an internal audit function or from external regulatory oversight.

6.3 Variations in risk management systems and risk appetite across integrated care boards

Having originated in the financial services sector in the late 1990s and early 2000s, the three-lines of defence risk management model has been widely adopted across all industries, albeit to varying degrees, since the Institute of Internal Auditors (IIA) formally adopted the model in 2013. It involves a shared responsibility to identify, assess and manage risk across an organisation reducing dependencies on any one operational function. It is useful to contrast the different levels of adoption of this risk management model in order to highlight potential deficiencies.

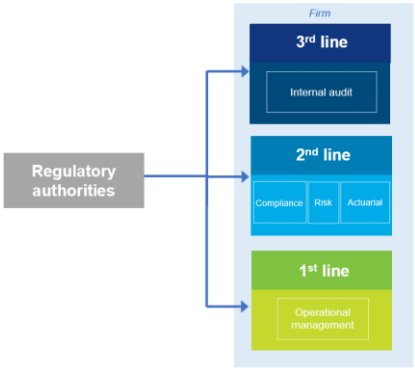


Figure 33: Financial services' adoption of three-lines of defence risk management model – e.g insurance industry

According to Aviva, the UK's largest insurer, their risk governance approach involves their operational managers as their first-line of defence.

- implementing and applying the risk management framework
- monitoring the operation of their system of internal control
- with primary responsibility for risk identification, measurement, management and reporting lies with management.

Their second-line of defence involves the Risk function comprising the Risk Management, Actuarial and Compliance control functions.

Internal Audit acts as Aviva's third-line of defence, independently evaluating the adequacy and effectiveness of the internal control system and system of governance.

According to a 2020 Deloitte report [51] the level of the three-lines of defence model broadly correlates to the strength of regulatory pressure. For large firms, such as Aviva in heavily regulated industries, such

[51] Deloitte 2020, Modernizing the three lines of defense model

as financial services, they have well-established risk management processes and clear lines of defence, see Figure 33.

In less-regulated industries, the Deloitte report notes smaller or emerging organizations typically lack the three defined and distinct lines, with overlapping first- and second-line roles or overlapping second- and third-line functions.

From a 2012 King's Fund review into the now integrated care boards [52] and the 2019 paper on NHS Patient Safety Strategy [53], these indicate that regulatory compliance functions tend to be absorbed into both the risk (second-line) and internal audit (third-line) functions, while top-down sub-regional clinical governance teams oversee the provision of safe care across care as a third-line activity.

While the clinical governance teams aim to create and implement best practice guidelines, monitor systems (quality indicators, patient surveys) and quality assurance systems (clinical governance arrangements and audit processes) there appears to be a void in risk and compliance within a second-line function.

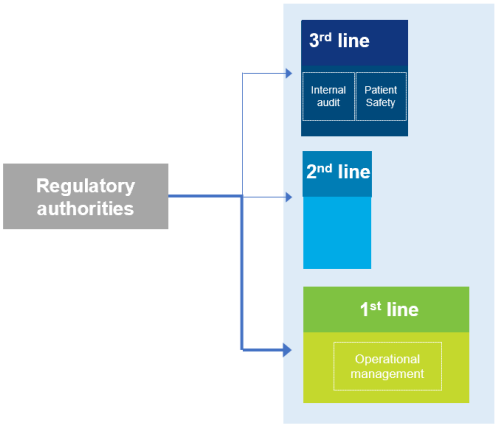


Figure 34: NHS' Emergency Department adoption of three-lines of defence risk management model – weak 2nd line and culture of regulatory review of 1st line performance

The approaches across agencies to quality assurance have been layered on top of each other according to the King's Fund report. [52] The requirements of licensing and the associated powers of inspection and enforcement are used alongside commissioning and incentives. Indeed a 2008 comparative study across European healthcare authorities concluded that England had the most extensive top-down quality assurance system in Europe. [54]

The top-down approach applies operating standards through to integrated care boards involving financial incentives to adhere to these. The various bodies and groups are highlighted in Figure 35, below.

[52] The King's Fund, 2012
[53] The NHS Patient Safety Strategy
[54] Legido-Quigley et al 2008

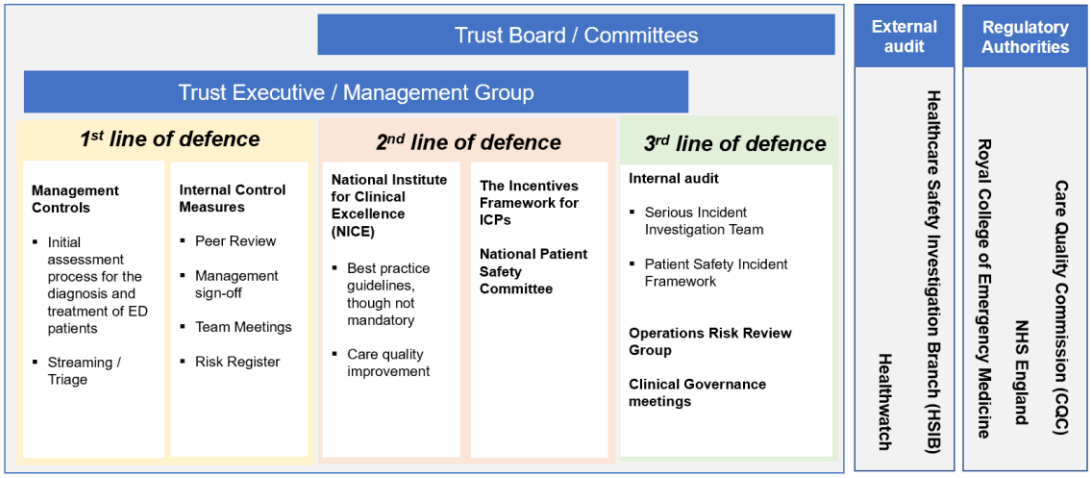


Figure 35: Interpretation of an Integrated Care Board three-line of defence risk management model

Clearly there is a regulatory burden yet also pressure to meet operating standards, which creates a trade-off in order to meet financial incentives. As a result, each integrated care board may adopt varying approaches to risk in order to meet these, sometimes, conflicting objectives. The Good Governance Institute [55] has attempted to define a matrix for assessing risk appetite within the integrated care boards to how they approach these challenges:

Risk levels ▶ / Key elements ▼	0 Avoid – Avoidance of risk and uncertainty is a key objective	1 Minimal – Preference for ultra-safe delivery options	2 Cautious – Preference for safe delivery options	3 Open – Willing to consider all potential delivery options	4 Seek – Eager to be innovative and choose delivery options	5 Mature – Confident in setting high levels of risk appetite
Financial	Avoidance of financial loss is a key objective.	Very limited tolerance of financial loss.	Accept limited financial loss.	Minimise financial loss by manging to acceptable level	Accept possibility of financial loss subject to controls..	Maximise return and accept risk.
Compliance / regulatory	Play safe avoid anything which could be challenged.	Want to be very sure we could win any challenge.	Limited tolerance for sticking neck out.	Challenge would be problematic but will likely win challenge.	High chance of losing challenge and significant consequences.	Constantly pushing back on regulatory burden.
Quality	Tight management controls with limited devolved authority.	Decision making authority held by senior management.	Decision making authority generally held by senior management.	Responsibility for non-critical decisions may be devolved.	High devolved authority – management by trust rather than tight control. .	Complete devolved authority – management by trust rather than tight control.
Reputation	No tolerance for any decisions that could lead to scrutiny.	Tolerance for risk taking limited to events here there is no chance of repercussions.	Tolerance for risk taking limited to events here there is little chance of repercussions.	Appetite to take decisions with potential to expose the organisation to scrutiny.	Willingness to take decisions that bring scrutiny.	Decisions made for the right reasons with benefits outweighing risks.
APPETITE	NONE	LOW	MODERATE	HIGH	SIGNIFICANT	

Figure 36: Risk Appetite for NHS Organisations – a matrix to support better risk sensitivity in decision-making

The evidence of my mother's care, also that from other cases indicated in the HSIB report [4], suggests that there may be high or significant levels of risk appetite. Achieving an element of choice and variance across integrated care boards may only mean varying levels of risk appetite. Is this an acceptable outcome?

[55] Good Governance Institute, 2020

According to the King's Fund report [52], Monitor used to 'require trusts to demonstrate compliance to objectives, health care targets and indicators and to comply with all relevant legislation, also to maintain a programme of internal audit review and independent assurance'. Whilst this responsibility was passed to the CQC the focus then became more on 'the outcomes of care achieved whereas the Commission for Health Improvement (then Healthcare Commission) was more focused on the internal processes for assuring clinical quality.'

Perhaps there needs to be a return to this greater focus on internal processes as a way of ensuring patient safety.

6.4 Concluding comments

Limitations in the risk management culture observed contributes to an *implementation gap* in quality of care. To meet operating standards and financial incentives some integrated care boards may adopt a high-risk appetite. These have been identified in the care of my mother and a recent CQC inspection report. [8] These findings correspond to other findings of PE misdiagnosis as detailed in other Serious Incident Reports. [4]

Consistency in approaches to risk may be achieved by adopting multiple lines of defence, active management review and ownership, clinical governance procedures and a focus on internal processes.

The centralised, top-down approach to ED risk management may work well for homogenous conditions that are easy to diagnose and treat. However, for complex conditions (such as PE) a stronger second-line function incorporating a strong risk and compliance function that monitors the implementation of clinical guidelines and ensures strong first-line management review maybe required to mitigate risk and improve patient safety.

A simplified gap analysis evident from my mother's case as well as that apparent in the HSIB report indicates the following:

Component	Who	Role	Gap
1st line	Clinicians and Managers	Responsible for providing services as well as manage the risks of its processes.	Lack of responsibility and management oversight. Unaware of emerging risk. Lack of real time 'command and control' achieved through a senior medical, nursing, and administrative team.
2nd line	Enterprise and Compliance Risk units	Implementing and monitoring the system of internal control, monitor and assess the first line's processes, risks and controls.	Lack of monitoring and compliance against clinical guidelines. Unclear how effective the Clinical Governance and Operational Risk forums are and how connected they are in sharing issues, learnings and making decisions. Is the frequency of engagement with the 1st and 2nd line sufficient to achieve meaningful influence? Operational targets are shown to undermine quality and safety. Clinical excellence guidelines are not always adhered to.
3rd line	Internal Audit	Independently evaluate the adequacy and effectiveness of governance and risk management.	Lack of independence with Incident Investigation teams.

Figure 37: Assessment of gaps in the three-line of defence risk management model

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