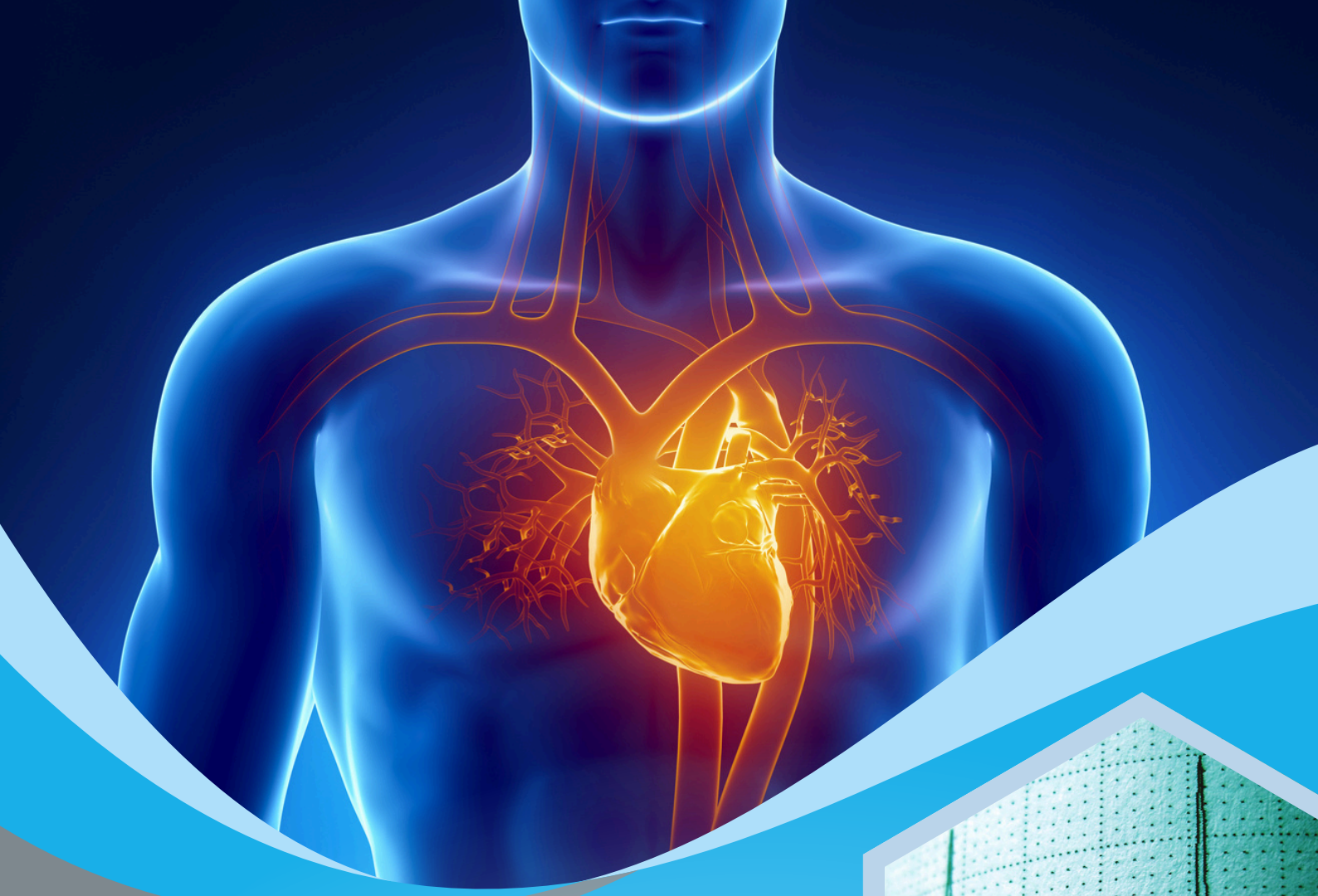

ADVANCING CARDIOGENIC SHOCK PATHWAYS

HealthTech ALLIANCE

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FOREWORD

The Parliament & Health Tech Cardiogenic Shock Roundtable brought together key players in the sector to discuss the current state of play around cardiogenic shock (CS) and solutions for improving the care pathway for CS patients within the NHS.

The central discussion points focused on enhancing patient outcomes for those suffering from cardiogenic shock. Roundtable participants, which primarily consisted of interventional cardiologists and NHS administrators, shared their experiences of treating CS patients, highlighted key challenges in the care pathway, and proposed solutions for improving clinical outcomes for CS patients.

Key themes included:

- The critical need for early recognition and diagnosis
- Ensuring access to echocardiography at the initial point of contact
- Developing robust networked care systems to facilitate timely transfer to specialist centres
- The role of advanced medical devices
- The importance of data collection and analysis to inform policy and demonstrate effectiveness
- The potential for partnerships between the NHS and industry
- The importance of supporting and strengthening cardiac networks, despite NHS financial constraints, to improve patient outcomes

CARDIOGENIC SHOCK

As described in the Johnson & Johnson MedTech Cardiogenic Shock Manifesto, CS is a life-threatening emergency condition characterised by a low cardiac output, which leads to inadequate blood and oxygen supply to vital organs, called hypoperfusion, which can lead to multi-organ failure and potential fatality.

There are various conditions that can lead to CS, with heart failure being the most prevalent. It typically develops in around 10% of individuals who have suffered a heart attack, with other notable causes including inflammation of the heart muscle (myocarditis) and post-cardiotomy. It is estimated that around 10,000 people in the UK suffer from CS per year, although this figure is likely to be an underestimate due to current diagnostic limitations.

It is a challenge to effectively diagnose CS as screening tools are not widely available, and it can only be reliably diagnosed with an echocardiogram (echo). Not all hospitals have the ability or expertise to perform or interpret an echo, particularly in the smaller district general hospitals (DGHs).

Currently, outcomes for CS patients are poor, with one in two people, especially those with acute myocardial infarction (heart attack), not surviving due to lack of rapid diagnosis and treatment. However, recent trials, such as the International RCT - DanGer Shock trial (in which Harefield Hospital was the only UK centre to participate), have shown promising results for reducing mortality. This trial demonstrated a 12.7% reduction in absolute mortality at 6 months in patients who received a microaxial flow pump (the Impella) in addition to standard care. For patients under 77 years old, the absolute mortality reduction observed was 20%.

The biggest burden on the NHS is heart failure, with the recorded total direct costs of CS to the NHS estimated to be up to £3 billion annually (according to the Johnson & Johnson MedTech Cardiogenic Shock Manifesto). Early diagnosis and intervention in CS can not only save lives, but also prevent patients from progressing to chronic heart failure and increasing the burden on NHS resources.

PATIENT CASE STUDIES

CHRISTIAN HOBBS

Christian, a 17-year-old amateur boxer, sadly passed away from cardiogenic shock in 2017. His case highlighted several critical systemic failures.

Despite presenting with severe symptoms, his cardiac problem was not recognised early on. He was thought to have sepsis, and there was no immediate access to echocardiography to confirm a cardiac issue. Crucially, there was no existing pathway to escalate his care to specialists, as he was not having a typical heart attack. The coroner noted that factors which could have prevented his death were not in place, leading to a regulation 28 notice advising on implementing "Shock to Survival" guidelines to prevent future deaths, a report published in 2022 which provides a framework to improve the care and outcomes of people with CS in the UK.

NANA SAO

Nana Sao, a 44-year-old man suffering from COVID-related myocarditis, survived cardiogenic shock in 2020 due to prompt intervention. The key reason for his survival was that a diagnosis was made immediately at the "front door" of Chelsea Westminster Hospital.

This was because the treating doctor happened to be aware of CS and the escalation required, due to prior specialist training. A quick decision was made to escalate his care to a specialist centre, the Royal Brompton Hospital, which had an operational cardiogenic shock service during COVID. Nana received a mechanical circulatory support device, an Impella heart pump, and was also placed on VA ECMO (a form of life support). His survival underscored the importance of early diagnosis and immediate access to a specialist team and functional network.

KEY ROUNDTABLE THEMES

The discussion at the roundtable highlighted several critical areas for improvement:

Executive Summary

- Earlier recognition and diagnosis: There is a critical need for early recognition and diagnosis of CS, especially at the initial point of contact. This includes improving awareness among all frontline staff, from paramedics to A&E doctors.

- Ensuring access to echocardiography (echo): It is vital to ensure access to echo at the initial point of contact for rapid and accurate diagnosis. While basic echo imaging can be taught, expert interpretation is crucial.

- Ensuring clear pathways to specialist care centres: There is a critical need for robust networked care systems to facilitate timely transfer to specialist centres. These networks should connect DGHs to regional cardiac centres and transplant centres, ensuring appropriate support and resources for patient referral. London has made significant strides in this area, creating a functional network where different hospitals collaborate.

- Leveraging medical devices: While advanced medical devices, such as Impella heart pumps and ECMO, can significantly improve outcomes, their effectiveness relies on being used in the right patient and within a comprehensive, well-structured pathway.

- Importance of data collection and analysis: There is a critical need for data collection and analysis to inform policy and demonstrate effectiveness. A lack of comprehensive data on CS incidence and outcomes hinders an understanding of the full scope of the problem.

- Potential for partnerships and collaboration between NHS and industry: The potential for partnerships between the NHS and industry was also discussed, particularly in areas like data collection and innovation.

CHALLENGES & PROPOSED SOLUTIONS

DIFFICULTY IN EARLY DIAGNOSIS

CS is difficult to diagnose, and current screening tools are inadequate. This often leads to delayed recognition, as seen in Christian's case, worsening the prognosis for CS patients.

SOLUTION

Improved training and awareness

There is a fundamental need for early diagnosis of CS, particularly at the initial patient point of contact. There needs to be greater awareness among all frontline staff, from GPs to A&E doctors and acute medicine staff. Education should focus on basic recognition and initial management of early signs of CS, which will not necessarily require significant additional funding.

Automatic alerts can be implemented within existing digital patient record systems based on shock parameters (e.g., lactate, heart rate, blood pressure) to guide clinicians towards a shock pathway. The London Cardiogenic Shock Network is piloting such alerts based on lactate, heart rate, and blood pressure, to prompt clinicians to think along the shock pathway. The goal is to upskill the entire network through discussions and remote management advice for referring hospitals.

LACK OF ECHOCARDIOGRAPHY ACCESS

Many hospitals, especially smaller DGHs, do not have the necessary echo equipment or trained staff for an immediate diagnosis. Even when available, devices might be locked away or staff might lack the expertise for accurate interpretation.

SOLUTION

Better access to diagnostics

It is essential to guarantee the availability of echocardiography at the initial patient contact point for swift and precise diagnosis. Frontline staff should know how to perform point-of-care echo (POCUS), as this is becoming part of the curriculum for acute medicine trainees.

Crucially, there is a need to establish remote interpretation services through expert networks. A system should be developed where echo images can be quickly sent to on-call experts for rapid interpretation, regardless of the hospital's location, as expert interpretation is crucial for diagnosing CS and misinterpretation can be life-threatening. AI holds potential for aiding echo interpretation, particularly for identifying normal versus abnormal findings and for population-level studies, though validation is needed before widespread release.

ABSENCE OF A CS NATIONAL PATHWAY

There is no consistently applied national pathway for managing CS, leading to unwarranted variation in care and outcomes based on geographical location. Large geographic areas remain with no available access to mechanical circulatory support (MCS) services outside of the Transplant centres creating inequitable care across the NHS.

SOLUTION

Ensuring clear pathways to specialist care centres

There is a critical need for robust interconnected care systems to facilitate timely transfer to specialist centres. These networks should link DGHs with regional cardiac centres and transplant centres, to ensure suitable support and resources for patient referrals.

The London Cardiogenic Shock Network is an example of how hospitals can collaborate effectively. This approach, similar to the successful VV ECMO service, aims to establish regionalised networks to ensure no patient needing advanced support is unable to access needed care. Virtual platforms like Microsoft Teams should be leveraged for remote multidisciplinary team (MDT) discussions, enabling experts to discuss patient cases across the country, improving decision-making, and advising on transport logistics. These networks must provide a clear pathway for patients to reach specialist centres for advanced treatment, including mechanical support. The goal is to standardise care across all heart attack centres, ensuring early identification, diagnosis (e.g., echo, blood gas), and timely referral to a specialist centre if needed.

FRAGMENTED DATA COLLECTION

Currently, there is no comprehensive national database for CS, making it challenging to understand the true incidence, outcomes, and effectiveness of interventions. Existing data sets are often separate and difficult to link.

SOLUTION

Make data collection more effective

There is a critical need for data collection and analysis to inform policy and demonstrate effectiveness. A lack of comprehensive data on CS incidence and outcomes hinders understanding the full scope of the problem.

The ability to link various data sets is crucial for a richer understanding of patient journeys and outcomes. Support for ongoing evidence generation for device effectiveness should align with interventional procedure guidance processes. There is an opportunity for collaboration with the industry to aid in data collection initiatives that comply with regulatory requirements. Currently, the absence of an extensive national database impedes a complete grasp of the incidence and outcomes of CS.

FINANCIAL CONSTRAINTS WITHIN THE NHS

The NHS faces significant financial constraints and ongoing restructuring, impacting the stability and funding of cardiac networks. There is also a perception that expensive devices are the primary focus, rather than the entire pathway.

SOLUTION

Maximising existing resources

The consensus from the roundtable was that effective implementation of networks is crucial and can often be achieved without significant extra funding, by leveraging existing expertise and fostering collaboration. While financial constraints are a major problem, especially regarding funding for cardiac networks, the vulnerability of these networks is understood.

The focus should be on getting the basics right, such as education and initial diagnostic capacity, which can be done without large financial investment. Industry partnerships can be explored to offer discounts or support data collection for ongoing assessment, offsetting costs.

CHALLENGES IN DEVICE ADOPTION AND IMPLEMENTATION

While devices like Impella show potential to improve patient outcomes, their effective and safe use requires highly skilled teams and sufficient patient volumes to maintain proficiency, posing a challenge for widespread, equitable rollout across 68 primary PCI centres. Consequently, complication rates are something to be aware of.

SOLUTION

Strategic device commissioning

Although medical devices can enhance patient results, their effectiveness relies on being used in the right patient and within a comprehensive, well-structured pathway.

This policy should define the type of patient who may benefit, how devices are used, and how teams are trained and maintained. The findings of trials like DanGer Shock, which showed a 12.7% reduction in 6-month mortality with the use of a microaxial flow pump in addition to standard care for acute myocardial infarction patients (20% for patients younger than 77 years old), should inform commissioning decisions. It's recognised that the device is part of a spectrum of care, and commissioning should be done once, nationally, to ensure widespread and equitable access, especially if devices gain a second indication in complex PCI to increase volume and safety.

The focus should be on rolling out devices once and well, balancing benefits with complication rates and the need for skilled teams and sufficient patient volumes.

IT SYSTEM FRAGMENTATION

Different hospitals use various digital notes and results systems making it difficult to implement standardised alerts or share patient data seamlessly across the NHS.

SOLUTION

Using technology

Implement automatic alerts within existing digital patient record systems based on shock parameters (e.g., lactate, heart rate, blood pressure) to guide clinicians towards a shock pathway. The NHS is working on making single pathways for main IT centres to build and share across the NHS, starting with the heart failure pathway, to simplify system implementation.

CONCLUSION

CS is a seriously life threatening condition which is all too often missed or poorly managed with tragic consequences.

This report identifies a series of actions:

- Improve early recognition and diagnosis of CS at the first point of contact, increasing awareness among all frontline staff.
- Ensure rapid access to echo and expert interpretation for accurate diagnosis.
- Establish clear, robust pathways and networks for timely transfer to specialist care centres.
- Facilitate collaboration between hospitals, connecting DGHs to regional cardiac and transplant centres.
- Use advanced medical devices, such as Impella and ECMO, within comprehensive and well-structured care pathways.
- Collect and analyse data on CS incidence and outcomes, encouraging NHS-industry partnerships for data collection and innovation.

Collectively, these actions have the potential to transform CS patient outcomes, significantly improving survival rates and quality of care, while reducing the long-term burden on NHS resources.

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