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Perspectives on the impact of point-of-care testing for cardiac markers on healthcare professional working relationships

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Applications of point-of-care testing (POCT) for diagnostic biomarker measurement in healthcare have increased significantly in recent years in a wide range of clinical scenarios. These include infectious disease, critical care, cardiology and other areas of emergency medicine.

Traditionally, routine clinical pathology investigations were performed by dedicated clinical biochemists and pathologists within a hospital-based central laboratory provision. As an alternative, POCT aims to improve key clinical outcomes by providing for a faster test turnaround time (TAT) facilitated by being deployed in the vicinity of the patient.

In addition, it has been suggested that POCT can contribute to delivering health economic benefits by reducing admissions and hospital length-of-stay costs. Despite these potential benefits, however, POCT poses a considerable challenge in its operation outside the central laboratory.

In particular, it can have a direct impact on healthcare professional working relationships; for example, clinical and nursing staff are commonly responsible for performing diagnostic tests rather than laboratory staff.

At the same time, the widespread deployment of POCT will also generate new support roles for clinical biochemists and pathology staff in the regulation and quality assurance of POCT outside the central laboratory.

In this article, perspectives on the likely future impact of cardiac-marker POCT on working relationships are discussed based on opinions provided in a survey of healthcare professionals.

Introduction

Emergency medicine is a field where the taken time to diagnose a patient's condition in respect to a whole spectrum of diseases and conditions is critical [1-3].

Emergency departments (EDs) are commonly overcrowded due to an increase in patient volume with the situation compounded by delays in accessing resources such as radiology, laboratory and ancillary services, and in waiting for available beds in wards to admit patients [4-5].

The overall impact on service provision within the ED is therefore an increase in patient wait times and delays in time to treatment.

It has been reported that chest pain accounts for 6 % of all attendances to the ED and 27 % of all admissions [4-7]. Patients presenting at the ED with chest pain often undergo extensive diagnostic testing and risk stratification to diagnose acute coronary syndrome (ACS) and determine the likelihood of future adverse cardiac events [4-10].

Chest pain is a time-consuming diagnostic dilemma for the physician and can be either cardiac or non-cardiac in etiology with a range of risk from benign to life-threatening illness requiring rapid diagnosis and treatment [8, 11].

To better identify which patients need extensive diagnostic investigation, several different clinical protocols have been described recently, many of which use point-of-care testing (POCT) for the measurement of acute cardiac markers as diagnostic indicators [4-7, 10, 12].

The process of clinical decision making (CDM) can be described via a patient pathway, which maps the episodes of care provided to the patient [1]. It can be considered as a timeline on which every event relating to treatment can be entered [1, 13-16].

These pathway events include consultation, diagnosis, assessment, treatment, medication and preparation for discharge from hospital all of which can then be mapped on this timeline.

In a time-based management approach the process is divided into a number of patient episodes [1] that describe what actually happens to a patient in the sequence of pathway events from first contact to closing of the case [1, 13-16].

This article provides a perspective on how relationships between various healthcare professionals, (clinicians, nurses and central pathology laboratory staff), can be altered through the introduction of a new and emerging technology within the patient CDM pathway.

Specifically, the application of cardiac-marker POCT in emergency medicine is presented as a case study. The information provided is based on the opinions of the POCT method garnered from a survey of various healthcare professionals in Northern Ireland [4].

Health technology assessment of the impact of cardiac-marker POCT

It is argued that a contributor to increasing costs in the provision of healthcare for organizations such as the UK National Healthcare System (NHS) is the emergence of new and expensive technologies. Estimates suggest that technological advances cause NHS costs to rise by an average of 0.5-1 % per year [17].

Evidence of the clinical and cost effectiveness of such technologies, together with systematic evaluation of actual health outcomes, has therefore become a key part of the policy for delivery of clinical services, which is increasingly being driven by such evidence-based approaches [2, 17].

In this regard, a form of Health Technology Assessment (HTA) has been adopted by many countries with the aim of influencing health policy decision making by the introduction of evidence-based clinical studies.

The objective of HTA is to determine the value and benefits of new health technologies and medical devices

in terms of improving clinical and health economic outcomes [2 ,4, 17-18]. Before a new medical device or healthcare technology is introduced into the UK NHS, a HTA appraisal is carried out in order to formulate an early-stage evidence-based business case to clearly demonstrate its value and benefits.

This appraisal will involve inter alia a combination of health economics, cost effective analysis, human factors engineering, user perspective and patient pathways analysis [2, 4, 13, 15, 17-18].

The MATCH Innovative Manufacturing Research Centre (www.match.ac.uk) is a university-based research collaboration working in the area of HTA and has recently carried out a patient pathway assessment of the impact of introducing POCT in the ED for cardiac-marker measurement in patients presenting with chest pain [4, 6].

The outcomes from this study have highlighted a number of interesting perspectives for the introduction of new technologies and in particular on how they can affect working relationships between healthcare professionals.

POCT organisation - regulators and users

The impact of POCT on working relationships between healthcare professionals is seen by two main groups: POCT regulators and POCT users [4, 20]. Since POCT devices are intended to be used outside the central pathology laboratory (Lab) as decentralized solutions, POCT device users are essentially clinicians and nurses with the latter often making up the most significant element of the user group [4].

Staff in the Lab is normally responsible for maintaining and recording all data and ensuring compliance with regulation and Quality Assurance relating to diagnostic testing in clinical setting. This includes both internal and external QA validation and audits [20].

However, in the case of POCT this may not always be the case since the devices are deployed more generally.

The increased level of hospital testing therefore necessitates a more formal architecture for POCT organization within a typical NHS Health Trust as shown in Fig. 1. In this regard, it is suggested that the Lab Director must play a key role in POCT management.

This can be facilitated via a POCT coordinator and POCT committee and the POCT team comprises an administrative group, which manages POCT processes to meet the needs of both patients and clinicians.

Indeed, there is a clear indication from our previous study [4] that there is willingness from the Lab staff to undertake this type of role. Importantly, this will add real value to the validity of the POCT data recorded and ensure that it fits within the required QA systems.

The POCT coordinator can then manage the routine use of the POCT devices with the CLP director ensuring that there is adequate control over the entire POCT program through regular reviewing of policies and compliance with procedures and CPA regulations in the case of multiple-site usage.

In this way, the laboratory director will assist in the full clinical interpretation and governance of POCT results [20].

This approach is not without its challenges since, unlike the Lab in which most diagnostic testing is carried out on a few high-throughput clinical analyzers by a small number of trained technical staff, POCT is performed by a wide variety of clinical and nursing staff on multiple POCT devices in several different locations, as indicated in Table 1.

The focus of these users is on patient care delivery, not on the routine standard operating procedures of instrument calibration and quality control and they are not generally trained in good laboratory practice and quality control procedures.

Hence ensuring that all staff performs POCT in a consistent manner each time a test is carried out represents a logistical challenge [6-7, 11, 13, 20].

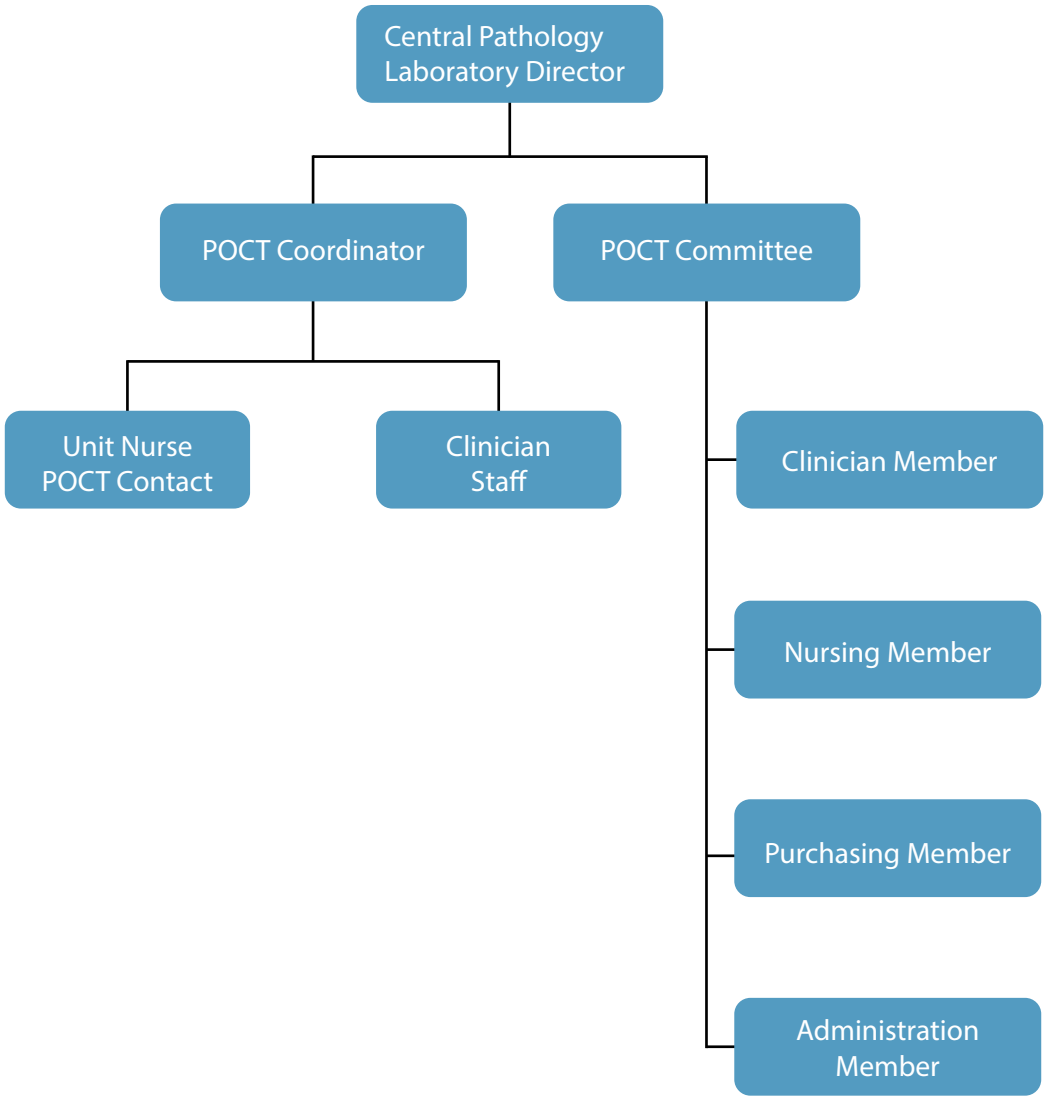

FIGURE 1: Organizational architecture of POCT management in an NHS hospital trust

In addition, the day-to-day documentation management for POCT training, test results, quality control and other data logging can rapidly become overwhelming without POCT coordination included in its initial implementation [2, 4, 10, 20].

Impact of point of care on diagnosis and clinical decision-making process

Although the majority of acute patient episodes can be classified under a small number of clinical conditions and specialist area as outlined in Table 2, there can be several different approaches to the initial management of these patients.

In particular, the use of POCT for diagnostic testing can be inconsistent. This may lead to confusion amongst nursing staff, allied health professionals and patients. The development of simple clinical algorithms for the assessment of such common conditions in order to assist in providing consistent and high-quality care for admitted patients has been recommended [19].

Such tools are designed to provide guidance on the early assessment and management of patients with these common conditions especially in the first 48 hours of a patient's hospital stay [14-16, 19].

Field of medicine	Clinical condition
Cardiology	ST elevation/New LBBB cardiac chest pain
	NSTEMI
	Acute left ventricular failure
	Tachycardia
Gastroenterology	Acute gastrointestinal hemorrhage
	Acute gastroenteritis/colitis
	Jaundice
Renal	Acute renal failure
	Severe UTI
Dermatology	Severe cellulitis
	Acute bullous disease
Diabetes/Metabolic	Hyperglycemic crises
	Hypoglycemia
	Hypercalcemia
Infectious disease	Severe sepsis with shock and unknown source of infection
Respiratory	Acute exacerbation of COPD
	Acute asthma
	Community-acquired pnemonia
	Suspected thromboembolic disease
Geriatrics	Suspected stroke
	Delerium
	Falls/Immobility
Rheumatology	Acutely painful joint
Neurology	Acute meningism
	Unconscious patient
	Epileptic seizure
Toxicology	Drug overdose
	Mushroom poisoning
	Food allergy reactions

TABLE 1: Clinical conditions which can be covered by algorithms

Diagnostic test operational features	
Central Pathology Laboratory	POCT
One site	Multiple sites
Limited instruments perform the bulk of analysis	Multiple devices
Limited staff with focus on sample analysis	Multiple staff with focus on patient care
Staff with laboratory training and experience	Staff with clinical and nursing training, not laboratory education

TABLE 2: Comparison of diagnostic testing performed by the Central Pathology Laboratory and POCT

To be effective, these clinical algorithms should be developed within the context of patient-pathway time frames by identifying the assessments required on arrival within 1, 2 and 4 hours.

A provision for review is a critical component so as to ensure that the patient is on the most appropriate clinical algorithm. This should include the identification of key markers that report on clinical improvement as well as for deterioration.

The algorithms that have been developed generally provide guidance as to the frequency of clinical observations and investigational monitoring as well as confirming the patient status at which an appropriate and safe discharge can occur [19-20].

On this basis, it is vital that the nursing staff who carry out the majority of POCT are involved in this process of clinical algorithm development [1, 3, 4, 6, 13-16, 19-20]. Moreover, the algorithms need to include key diagnostic markers and clinical status indicators, which directly support decisions for hospital admission and at the same time avoidance of inappropriate discharge.

It should be noted that this type of clinical algorithm is not an integrated care pathway since these can only be effectively developed after the algorithms of care are firmly established [19]. It is worth noting that both patient pathways and integrated care pathways are becoming increasingly popular within the UK healthcare system and hence they must be central to any coordinated POCT application strategy [1, 13-15].

Within the UK NHS, patient-pathway analysis, user-centered studies and simulation modeling are often used in HTA appraisals [4, 6-7, 19].

These studies allow for the prediction of the likely impact and outcome of introducing new health technologies, medical devices and clinical protocols into the NHS [1, 2, 4, 6-7, 13-15, 18-19]. An awareness of these requirements provides useful guidance for the integration of POCT in that the analytical data can be directly linked to the procedural aspects of HTA processes.

Moreover, the potential to link key parts of the patient pathway is attractive. Patient episode time can be conveniently classified into three categories: administrative time, diagnostic and care time and waiting time [1].

A significant concern with regard to waiting time is an indication that the patient's status is likely to worsen and may require additional procedures [1, 13-15]. The effective use of POCT may well then provide real benefits in delivering timely clinical diagnosis.

Impact on working relationships between clinicians, nurses and central-laboratory scientists

In order to better understand how the use of POCT will alter working relationships between Lab staff and the nurses and clinicians who actually carry out the tests, it is important to consider the different functions that the three healthcare professional groups (nursing, clinician and laboratory) perform during chest-pain diagnosis within the clinical decision-making (CDM) process.

1. Diagnostic testing by Lab

In the established Lab situation, all diagnostic and pathology testing, quality assurance and clinical data management are carried out by Lab staff and POCT is generally not used at all [4].

Clinicians generally raise patient diagnostic test requests and nursing staff commonly perform specimen collection, including phlebotomy, and arrange for barcoded labeled samples to be sent to the Lab accompanied by patient and test request documentation.

Lab staff then receives these patient samples and test requests, log these on arrival and arrange for patient samples to be pretreated as necessary prior to analysis. Samples are then analyzed in parallel with internal and external controls and reference standard materials on high-throughput clinical analyzers.

Test results are subsequently QA checked by Lab staff and approved by the Lab director before being logged in the laboratory information management system (LIMS). Clinical and/or nursing staff is then alerted either by telephone or e-mail when patient test results may be accessed on LIMS.

Generally, laboratory test turnaround times (TATs) range between 45 minutes to 3 hours [4, 20].

Nursing staff update patient test records as appropriate and consult with clinical colleagues, who make decisions regarding changes to patient-treatment regimes, decide on patient admission, discharge or referral for additional tests and treatment.

2. Emergency department diagnostic testing

Rapid patient diagnosis is of special value in critical care and emergency medicine, such as in the case of a suspected acute myocardial infarction in patients presenting at the ED with chest pain [9]. The standard approach of chest-pain assessment carried out within NHS emergency departments is shown in Fig. 2.

The diagnostic regime involves patient observation and monitoring up to at least 12 hours in duration. The Lab carries out cardiac-marker measurement, at two time intervals from symptom onset in ED, at 6 and 12 hours.

Patients are then subsequently risk stratified into three categories: low, intermediate or high risk and either referred for further treatment and tests, admitted to a coronary care unit (CCU) or discharged home under General Practitioner (GP) supervision [7-9, 11].

Since POCT is not deployed in this scenario, day-to-day healthcare professional working relationships and CDM are unaffected. The typical length of patient stay in the ED under this regime ranges between 12-24 hours [8-9].

Patients being diagnosed under this protocol therefore make a considerable demand on clinician and nursing time and resources [8-11, 13].

An approach that uses rule-out protocols by POCT for chest-pain diagnosis was developed in US emergency departments [12, 20].

This has subsequently been applied in the UK as part of the NHS plan for service improvement, [5-7, 12, 20].

The general algorithm that has been developed in the UK for incorporating POCT for cardiac-marker measurement is shown in Fig. 3. For example, the Royal Victoria Hospital, Belfast uses POCT in a 120-minute rule-out protocol based on the ED acting effectively as a satellite laboratory for this type of diagnostics [6-7].

This type of rule-out method enables either the nurse or clinician to take the blood sample and run the cardiac-marker test in situ in the vicinity of the patient and obtain a result within a shorter TAT of between 15-20 minutes [4-5].

The POCT rule-out protocol involves taking two cardiac-marker measurements 120 minutes apart. If there is a 25 % elevation of any of the three markers on the test panel, the patient is then risk stratified according to the ECG/marker results into three risk categories: low, medium and high.

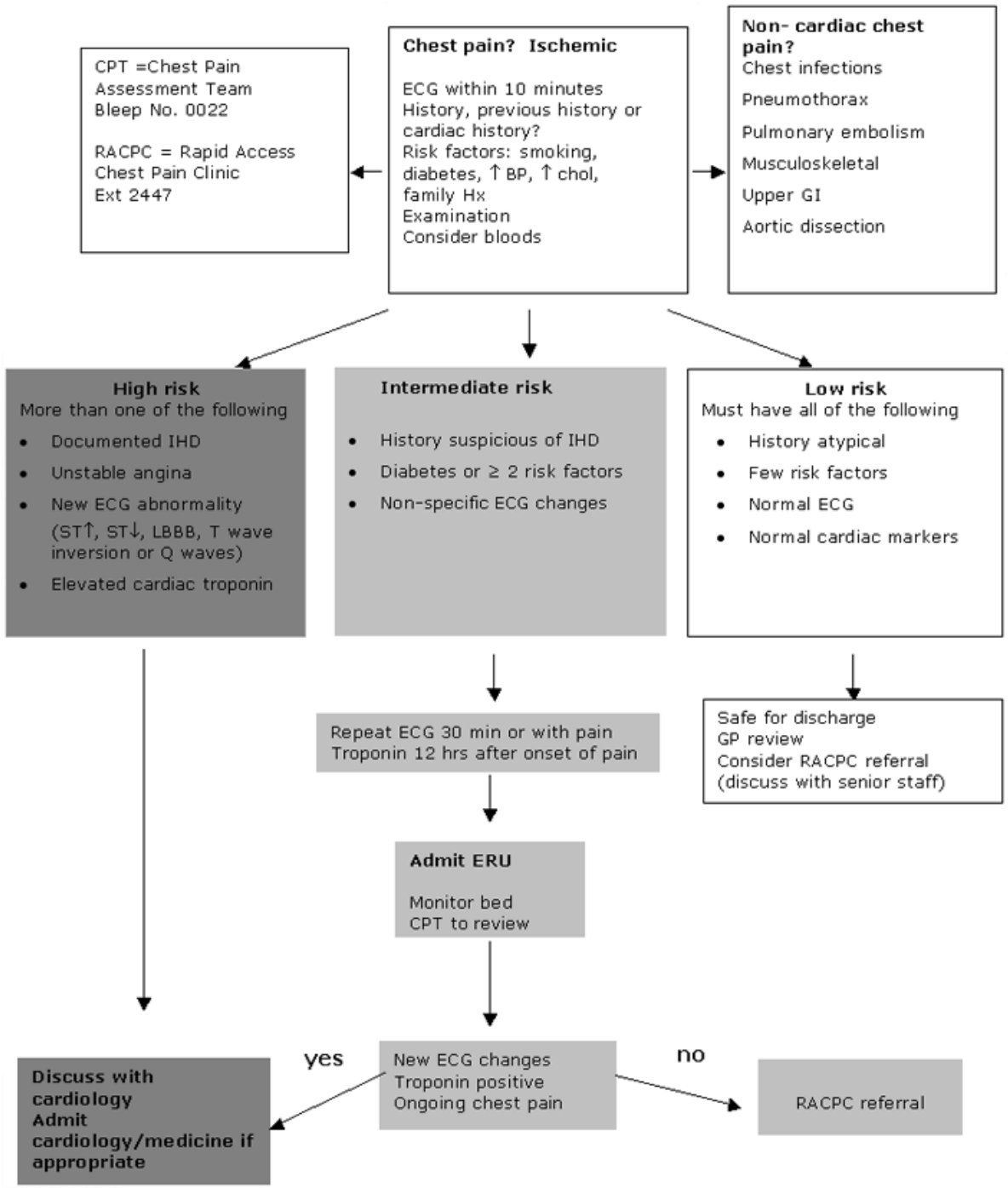

FIGURE 2: Chest Pain Management, Accident & Emergency Department, Belfast City Hospital Trust

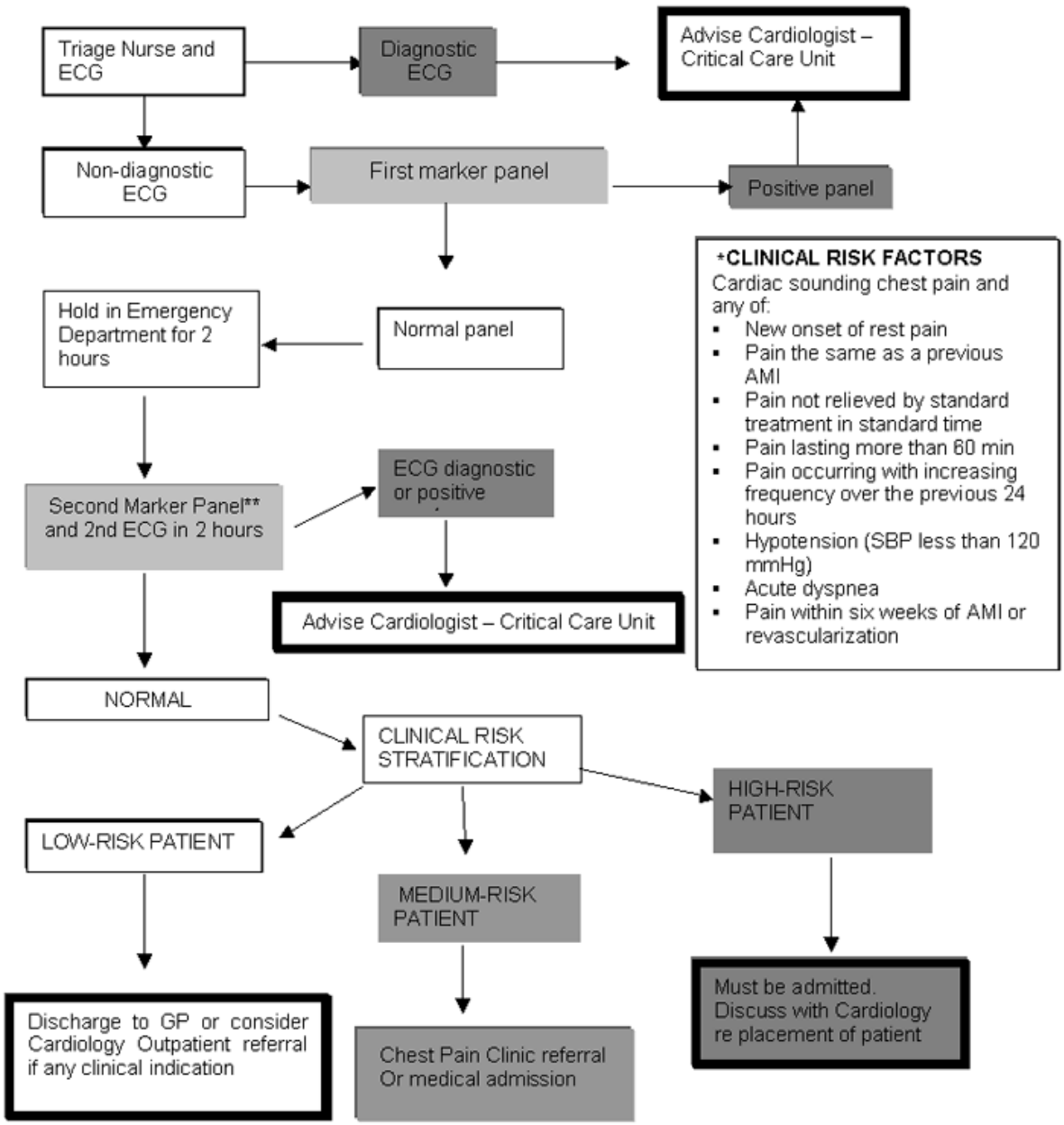

FIGURE 3: Chest-pain algorithm using POCT in the emergency department, Royal Victoria Hospital Belfast

Low-risk patients may be either discharged or referred to their GP or the Cardiology Outpatients department. Medium-risk patients could either be admitted or referred on to the chest-pain clinic while high-risk patients are admitted to the coronary care unit or cardiology department [4, 7].

A recent study has shown that the main impact of such satellite laboratories is that routine diagnostic tests such as cardiac-marker measurement can be performed and completed within the same department originating them in a shorter TAT [3].

This, in turn, should have improved the CDM process by reducing the decision time to discharge or refer by the ED clinician. However, it was also found that the decision time to admit a patient from ED was unaffected by the operation of a satellite laboratory.

Compared to the other scenarios in ED, this produces the shortest TAT for results and CDM times. Hence clinicians will be able to make decisions and treat patients earlier. Patients will therefore spend a shorter period in ED [3, 5, 7].

The use of POCT in this context obviously changes health professional working relationships by facilitating earlier decisions from clinicians in chest-pain diagnosis, resulting in reduced time to referral, admission or discharge, Fig. 3.

However, there are concerns about the changed working relationships between Lab staff and the clinicians/nurses when POCT is introduced in ED. These concerns are mostly about removal of the vital role of QA and test-result verification when not performed in the Lab environment.

Whereas the clinicians and nurses performing these tests might be well trained, there is still the possibility of measurement errors due to the POCT device not being correctly maintained or calibrated, thereby leading to erroneous results and incorrect clinical decisions which could have serious consequences for patients.

Hence, as indicated earlier, there is an important role for the Lab in overseeing the implementation and day-to-day regulation of POCT [2, 4-5, 20]. This should not present major difficulties in implementation, as Lab accreditation in the UK NHS is carried out by Clinical Pathology Accreditation Ltd (CPA) which can handle all laboratory-supervised POCT as well as any POCT carried out without laboratory supervision.

Moreover, the UK Department of Health and the Medicines and Healthcare Products Regulatory Agency have issued guidance for the laboratory supervision and management of POCT, including its implementation, training and QA monitoring.

Hence, the procedural aspects are mostly in place and what is needed is the initiative and collective will to integrate POCT within existing structures in the appropriate manner.

Conclusions

The introduction of POCT modifies the existing algorithms of making clinical decisions and ultimately impacts on integrated care pathways for patients. Conventional procedures are based on a series of diagnostic tests usually carried out in the Lab using high-throughput clinical analyzers.

The potential benefits that POCT offers in providing for earlier diagnosis and subsequent treatment have generally been the main consideration in assessing its value. However, the deployment of POCT more widely with a hospital environment clearly changes this situation and impacts on health professional working relationships.

Currently, Lab provides a centralized but remote supporting role to clinicians in all aspects of biochemical testing. The more pervasive implementation of POCT offers the potential to bring the working relationship of Lab staff closer to that of clinicians and nurses in improving overall patient care delivery.

A central tenant of this development will be the need to have QA and verification at the forefront of POCT use in order to validate the resultant test data.

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