Coronary heart disease (CHD) remains a leading cause of mortality and disability for both men and women in Europe, accounting for 1.92 million deaths each year.1 One in five women (22%) and one in five men (21%) die from the disease. 1 This significant burden necessitates ongoing improvements in patient management and treatment, to minimise the impact of cardiovascular conditions on both patients and healthcare systems.1–3 In 2003, implementation of primary percutaneous coronary intervention (PPCI) accelerated in Europe as the preferred treatment for patients with acute ST-segment elevation myocardial infarction (STEMI). This trend resulted mainly from the publication of two large randomised clinical trials showing better clinical outcomes with PPCI, mainly because of a lower number of reinfarctions.4–7 Since then, a growing body of scientific knowledge favouring PPCI over fibrinolytic therapy has accumulated and meta-analyses show reduction in mortality with PPCI.3,5,8–13

Guidelines from the European Society of Cardiology (ESC) and from the American College of Cardiology (ACC)/American Heart Association (AHA) recommend PPCI as the preferred reperfusion strategy for patients with STEMI, if:

- first medical contact-to-balloon time or door-to-balloon time is less than 90–120 minutes;
- the interventionist is experienced (performs >75 PCI cases per year); and
- the patient is treated in a high-volume centre (one that performs >36 PCI cases per year).3,5,6,9,10,14

Despite these recommendations, only 40–45% of European STEMI patients are currently treated with PPCI and large variations in treatment availability between countries have been reported.15

Knowledge about the challenges of introducing new technologies into clinical practice is substantial.17–28 It is known to be a complex mix of medical, organisational, patient-related, regulatory and economic factors. Although many studies have sought factors to explain international and national variations in access to treatment,17–28 few have succeeded in translating gained knowledge into practice.

The emergence of the evidence of PPCI as life-saving therapy without its effective dissemination into clinical practice represents an urgent public health problem. This article describes the current situation of PPCI implementation and provides an overview of possible barriers to implementation of PPCI in Europe.

Variation in Access to Primary Percutaneous Coronary Intervention in Europe Today

In 2009, Widimsky et al.15 published a study on the use of different reperfusion therapies in 30 different European countries circa 2008. The study revealed large variation in the distribution across countries, with a fairly well developed PPCI service in Northern, Western and Central Europe, whereas medical fibrinolysis was still the predominant treatment in Southern European countries and in the Balkan states. Additionally, a substantial proportion of STEMI patients received no reperfusion treatment. This paper was the first large-scale study to
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Register access to reperfusion therapy in Europe. Since very few comprehensive data registries exist, the study data were often based on expert estimations, causing a potential over- or underestimation of the distribution of reperfusion therapy in Europe. Based on other international and national studies of the use of PCI, it remains evident that variation in PCI access is a substantial problem both within and across countries in Europe. Unfortunately, there is little evidence to suggest that these differences will diminish in the near future.

The explanation for the lack of complete PCI implementation in Europe therefore requires more research. However, some barriers identified in the literature on implementation of healthcare technology in general might provide preliminary indications to guide this research. A literature review from 2005, on the studies of health technology diffusion in the 30 countries within the Organisation for Economic Co-operation and Development (OECD), showed interplay between multiple factors as the explanation for cross-country variation in the diffusion of various markers of healthcare quality. The strongest correlation was found between technology diffusion and economic variables, such as the total health expenditures per capita and economic incentives to hospitals. The diffusion model was based on a theory used in health promotion planning that was found to be very useful in explaining the interplay of factors influencing the diffusion. Figure 1 shows a similar model giving an overview of some of the significant factors and structures considered to play a part in the introduction of new technology. Implementation of new technology usually calls for multidisciplinary action across departmental and organisational boundaries. This strategy is supported by existing literature, in which main categories such as timely delivery, sufficient organisation and economic schemes are dominant.

Barriers to Implementation of Primary Percutaneous Coronary Intervention

Timely Delivery

The success of PCI depends highly on timely access, and system delays have shown to be independently associated with case fatality rates. Across Europe the majority of STEMI patients present to community hospitals without PCI facilities, so the need for well-functioning regional pre-hospital systems for early diagnosis and immediate transport to a PCI centre is crucial. Patients diagnosed by pre-hospital electrocardiogram (ECG) and transferred directly to a PCI centre have a lower mortality. The difficulty of providing timely access to appropriate facilities within the recommended timeframe (90–120 minutes or less from first medical contact to initiation of reperfusion) is one of the major barriers to PCI delivery. Studies have shown that widespread adoption of PCI was potentially limited by anticipated transport delays and practicalities associated with the transfer of patients from non-invasive hospitals to PCI centre. However, meta-analyses suggest that PCI is superior to fibrinolysis even when it requires inter-hospital transfer, and that the advantages of PCI over fibrinolysis are limited to hospitals with a high or intermediate volume of cases. These findings have prompted some European countries to establish PCI networks in which patients bypass or are transferred immediately from local hospitals to specialist centres to reduce system delay. These networks have shown impressive reductions in case fatality rates. This approach requires centralised and co-ordinated communication and transfer organisation between local hospitals, PCI centres and the emergency medical system (EMS). Networks require the availability of ambulances with 12-lead ECG capability and appropriately trained paramedics, which is not the case in many European countries today.

The influence of EMS organisation in Europe on the implementation of PCI has not yet been estimated, but is probably important. Because of these access and infrastructure issues, and the critical importance of time to treatment, fibrinolysis may be generally preferred in hospital systems that cannot meet the time goal for PCI. However, even in patients for whom fibrinolysis is successful, the guidelines now recommend angiography and in many cases percutaneous coronary intervention (PCI) within 24 hours, which further underlines the need to establish PCI networks.

Infrastructure and Organisation

The delivery of PCI requires appropriate cardiac catheterisation laboratories with specialised and experienced staff. Lack of cardiac nurses, technicians and other trained staff may threaten the sustainability of PCI. Outcomes from STEMI are related to appropriate staff education and specialisation, as well as a sufficient volume of procedures. An extensive survey in Canada identified the lack of catheterisation laboratories and experienced staff as primary barriers to complete implementation.

In 2008, the UK National Health Service (NHS) published a comprehensive report on PCI implementation. Based on qualitative interviews, the report highlighted some important barriers towards implementation of PCI among employees. They expressed concerns about the availability of sufficient equipment, training and hospital beds for unplanned admissions. They also worried about disruption to the planned working day programme delaying elective cases, and some staff were not happy to work across role boundaries. Another principal barrier was the 24-hour requirement for specialist staff to be available to respond in an emergency and resistance towards a change in working hours.

In Europe, the optimal rate of use of PCI in STEMI remains unknown, so there are no standards for organisation of systems or training of clinicians and other health personnel. Appropriate staffing is essential to achieve anticipated outcomes, and the requirement for additional resources might be a major barrier to achieving the staff requirements in some countries.
Table 1: Identified Barriers to Implementation of Primary Percutaneous Coronary Intervention

<table>
<thead>
<tr>
<th>Specific Barriers</th>
<th>Patient delay</th>
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<tbody>
<tr>
<td>Time to treatment</td>
<td>Long transport times</td>
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<tr>
<td></td>
<td>Inter-hospital transfer</td>
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<td></td>
<td>Limited access to emergency medical system</td>
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<td></td>
<td>Limited access to out-of-hospital electrocardiograms</td>
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<tr>
<td>Structure and organisation</td>
<td>Educated personnel</td>
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<tr>
<td></td>
<td>Existing catheterisation laboratories</td>
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<tr>
<td></td>
<td>Motivation and inertia</td>
</tr>
<tr>
<td>Economics</td>
<td>Insufficient salary for staff</td>
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<tr>
<td></td>
<td>Insufficient reimbursement for hospitals</td>
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<tr>
<td></td>
<td>Limited healthcare budgets</td>
</tr>
<tr>
<td>Registry data</td>
<td>Lack of reliable national and regional data</td>
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<tr>
<td></td>
<td>Lack of systematic data collection across countries</td>
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<tr>
<td></td>
<td>Lack of patient-level data</td>
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<tr>
<td></td>
<td>Lack of ST-segment elevation myocardial infarction incidence data</td>
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</table>

networks with specialist PPCI centres might again be the best solution to overcome this barrier. 10,36,52,53

Modern healthcare systems are complex and often specialised into many branches that correspond to several broad disease categories. Launching a successful programme for PPCI requires the commitment and collaboration of all members of the healthcare team. Unfortunately, few investigations of the potential organisational barriers to providing PPCI have been performed. 20,28,42 One can envision, though, that regional networks could shift patient load between different hospitals. This change would require reorganisation of hospital structures, formation of new organisational networks and formal partnership agreements across municipalities, all of which may encounter political resistance. 20

Economics

Healthcare costs have increased over the past decades, in part because of the introduction of new technology or the expanded use of existing technology. Efforts to maintain unaltered costs can promote an underuse of new, expensive, but effective (even cost-effective) medical technology. 20 It is widely assumed that financial factors such as the wealth of a country and payment methods have an important influence on technology diffusion; in other words countries that can afford it will tend to adopt expensive new technologies faster. 10

Recent studies emphasise that PPCI is socioeconomically cost-effective, regardless of the high costs to establish the technology. 20-22 This cost-effectiveness is due to a reduction in hospital duration, fewer readmissions, a reduction in subsequent coronary angiography and patients returning to the labour market faster. 20-22 Even if these elements do not offset the higher initial implementation cost, the net effect on costs may be justifiable if PPCI can result in improvement in health outcomes. 20-22 However, PPCI is closely linked to timely delivery of the treatment and unlikely to be cost-effective if significant time delays are present. 20 More studies are required to explore this conceivable important barrier to implementation.

In some European countries, current funding systems could create structural barriers and disincentives to implementation. In US-conducted studies, concerns have been emphasised about resistance to PPCI from non-PCI-capable hospitals. Non-PCI-capable hospitals anticipate the loss of revenue sources and desirable patients with the implementation of PPCI, mainly because the demographics of STEMI patients favour older and better-insured patients. 20-22,43 Losses for the individual hospital would need to be weighed against the benefits in terms of reduced mortality and morbidity and the potential cost savings for the global healthcare system.

Several studies have acknowledged the important influence of payment methods on technology diffusion. 20-22 The reimbursement schemes both for physicians and hospitals can be a strong incentive for technology use. Since PPCI delivery should be available 24 hours a day, national agreements on payment for out-of-hours work can play a tremendous role in distribution. The direct influence has not yet been explored in newer studies, but Ayanian et al. conducted a study using a large sample of community-based physicians who evaluated the necessity of cardiac catheterisation after an acute myocardial infarction. 20 For this group of patients, physicians employed by managed-care organisations were far less likely than physicians in the fee-for-service sector to believe that angiography was necessary, and invasive cardiologists were more likely than non-invasive cardiologists to believe that the procedure was necessary. 20

In the face of cost-containment activities, considerably more information is needed about the kinds of financial arrangements and incentives that influence physicians’ approaches to providing care. Empirical research will be particularly valuable in this respect. 20

Limitations of the Existing Literature

In the field of PPCI delivery, a number of barriers to complete implementation have been identified and strategies have been suggested to overcome these barriers. Table 1 provides an overview of some of the identified barriers. However, both the barriers and solutions identified are based more on intuition rather than empirical data, and might be difficult to transfer from one healthcare system to another. 20,38,52,53 Studies have mainly examined variations across smaller areas, and few studies have taken into account the interaction between the different barriers, as well as the national context in which they arise. 20,38,52,53 Each healthcare system is adjusting its activities to a specific social, historical and cultural setting, in which many different factors may influence the performance and fundamental objectives of the healthcare system. Classic approaches to implementing new technology often fail because little attention is given to the variety of barriers that need to be changed in a certain context. 20 In a systematic literature review from 1999, Cabana et al. found that only 58% of the 120 surveys examined more than one barrier. 20 In addition, many such health service studies are carried out in the US and Canada, so the results may have limited applicability to a European setting.

While a substantial amount of attention has been paid to studies comparing the effect of economic and governmental regulations on implementations across countries, rather less attention has been devoted to examine in detail the factors that influence clinical decision-making in everyday clinical practice. 20-22 The major barrier to this type of research is the lack of good nationwide registries that allow inter- and cross-country comparisons at the patient level. Population-based rates for particular medical procedures may be based on many thousands of decisions taken on many thousands of
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Patients and do not provide insight into any clinical decisions. Aggregated data do not uncover differences between patients treated at each type of hospital and setting that might affect the rate of use.\(^\text{41,42}\) Moreover, studies are often based on selected trial populations of patients with STEMI admitted to hospital led by enthusiasts and those who are keen on inducing changes. This selection tendency may result in an overestimation of the use of reperfusion therapy, since one might expect patients in clinical trials to receive more attention and better care than non-trial patients.\(^\text{41,42}\) A clearer understanding of factors in the clinical setting is likely to refine the decision on quality improvement initiatives and to maximise the technology uptake and guidelines adherence.

Several studies have sought after factors to explain patterns of practice variation, but few have succeeded, particularly in international comparisons. Most detailed studies evaluating adherence to practice guidelines have been conducted at a regional or a national level, mainly due to logistic reasons but also simply due to lack of data availability. Much could be learned by a more detailed examination of broad international practice patterns.\(^\text{41,42}\)

Opportunities for Improvement in Use of Primary Percutaneous Coronary Intervention

The Need for Good Cardiac Registry Data in Europe

One significant obstacle to uncovering barriers to implementation of PPCI is the availability of and access to data. Since the mid-1980s a series of international studies have been published on the differences and similarities between European countries and regions. Cross-national comparisons are now gaining footing, but are still far from perfect. Many comparisons are made on routinely collected data that are often based on what is available rather than what is important, and can lead to misinterpretation of important predictors of implementation. The general aggregated indicators cannot capture the more specific variations in access to healthcare, and still remain extremely scanty in terms of outcome registration. Therefore, awareness of causes of variation remains limited.\(^\text{26,65–67}\)

To our knowledge, no comprehensive overview of existing cardiac registries in Europe has been made. Some national and regional registries and initiatives have been established to register PPCI activities, such as the Berlin Heart registry, Hellenic PCI registry in Greece, II GISE in Italy (registry undertaken by the national cardiology society), Myocardial Ischaemia National Audit Project (MINAP) in the UK and in Portugal, where the National Department of Health is responsible for collecting national indicators of cardiovascular diseases. Moreover, in recent years the ESC has focused on the need for comprehensive registries for cardiology. Through the years, various registries have existed, but they are often voluntary and often die because of the lack of time and funding (e.g. Monitoring of Trends and Determinants in Cardiovascular Disease (MONICA), European Network for Acute Coronary Treatment (ENACT) registry). At the same time, participation from countries and hospitals is often voluntary and frequently lacks sufficient coverage, so is poorly representative of the population-wide medical system targeting cardiac disease. Use of data from existing registries is further hampered by the variety of data collection methods, as well as absence of consensus on data definition for collected variables. National and international collaborations with the establishment of minimum aggregated data sets are needed. Examples of such successful collaborations have been seen in other medical settings.\(^\text{41,42}\)

Systematic documentation and surveillance of health status, treatment schemes and treatment outcomes of heart patients are needed in all European countries.\(^\text{41,42}\) Databases are important to address the full diversity of access to treatment between regions and countries, to target initiatives including implementation strategies; and to compare healthcare systems against each other. Remarkably few sources exist on incidence data on ischaemic heart disease (IHD).\(^\text{41,42}\) The incidence serves as an approximation of the underlying demand for IHD healthcare services – in other words as a source for organising a PPCI strategy to meet actual future need. Obtaining adequate data to conduct precise quantitative comparisons of the impact of technological change on changes in expenditures and outcomes across countries will help to redirect resources to other parts of the healthcare system.\(^\text{41,42}\)

Pan-European Project

In an attempt to reduce differences in treatment access across countries, the European Association for Percutaneous Coronary Intervention (EAPCI) and the ESC have established a pan-European project called “Stent 4 Life”.\(^\text{41,42}\) The project is intended to help countries establish local organisational infrastructures to overcome implementation problems. A survey for 2011 has been planned to document changes in treatment access in Europe following the strategy.

Conclusion and Future Directions

Variation across geographic areas in the use of PPCI is common among patients with acute myocardial infarction, and even though many studies have sought barriers to explain this variation, few have succeeded in translating this knowledge into practice. The implementation of PPCI has multiple barriers, and to provide PPCI in an effective, high-quality and timely manner is a great challenge. Streamlining the processes of care involves patients, physicians and support staff.

An understanding of the potential factors or characteristics that explain the diffusion of PPCI will suggest policy mechanisms and instruments to control and regulate the adoption of PPCI. Such knowledge will be necessary to increase the effectiveness and efficiency of the diffusion, and will be the first step in ensuring equal access to PPCI treatment for STEMI patients in Europe. Better monitoring of STEMI incidence and prospective registration of PPCI in all countries is required to document improvements in healthcare and to identify areas where further effort is required. This type of data collection will require multidisciplinary co-operation.\(^\text{41,42}\)

5. Busk M, Maeng M, Rasmussen K, et al., The Danish multicentre randomized study of fibrinolytic therapy vs. primary angioplasty in acute myocardial infarction (the
Intervention