Developing a Mobile Electronic D2B Checklist for Treatment of ST Elevation Myocardial Infarction Patients Who Need a Primary Coronary Intervention

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Abstract

ST elevation myocardial infarction (STEMI), one main type of acute myocardial infarction with high mortality, requires percutaneous coronary intervention (PCI) with balloon inflation. Current guidelines recommend a door-to-balloon (D2B) interval (i.e., starts with the patient's arrival in the emergency department and ends when PCI with a catheter guidewire and balloon inflation crosses the culprit lesion) of no more than 90 min. However, promptly implementing PCI requires coordinating various medical teams. Checklists can be used to ensure consistency and operating sequences when executing complex tasks in a clinical routine. Developing an effective D2B checklist would enhance the care of STEMI patients who need PCI. Mobile information and communication technologies have the potential to greatly improve communication, facilitate access to information, and eliminate duplicated documentation without the limitations of space and time. In a research project by the Chi Mei Medical Center, "Developing a Mobile Electronic D2B Checklist for Managing the Treatment of STEMI Patients Who Need Primary

Coronary Intervention," a prototype version of a mobile checklist was developed. This study describes the research project and the four phases of the system development life cycle, comprising system planning and selection, analysis, design, and implementation and operation. Face-to-face interviews with 16 potential users were conducted and revealed highly positive user perception and use intention toward the prototype. Discussion and directions for future research are also presented.

Key words: mobile information and communication technologies, checklist, ST elevation myocardial infarction, door-to-balloon, system development life cycle

Introduction

Acute myocardial infarction (AMI) is the result of myocardial necrosis in response to myocardial ischemia, which is caused by imbalanced supply and demand of blood perfusion.¹ The World Health Organization estimated that in 2004, 12.2% of worldwide deaths were from myocardial infarction, with it being the leading cause of death in high- or middle-income countries.² Worldwide, more than 7 million people a year have AMIs.³ The classic symptom associated with AMI is chest discomfort, but symptoms may also include discomfort in other areas of the upper body, shortness of breath, sweating, nausea, vomiting, and dizziness.⁴⁻⁶ A cardiac troponin rise accompanied by either typical symptoms, ST elevation or depression on electrocardiography (ECG), or coronary intervention is diagnostic of myocardial infarction.⁷

There are two main types of AMI based on the ECG finding: ST elevation myocardial infarction (STEMI) and non-STEMI.¹ STEMI usually requires more aggressive treatment and is by restoring circulation to the heart, called reperfusion therapy, and typical methods are percutaneous coronary intervention (PCI) with balloon inflation.⁸ Non-STEMI may be managed with medication, although PCI may be required if the person is considered to be at high risk.¹

Door-to-balloon (D2B) is the interval that starts with the patient's arrival in the emergency department (ED) and ends when PCI with a catheter guidewire and balloon inflation crosses the culprit lesion in the cardiac catheterization laboratory.⁹ Because of the adage that "time is muscle," meaning that delays in treating an AMI increase the likelihood and amount of cardiac muscle damage due to localized hypoxia,⁹ American College of Cardiology/American Heart Association guidelines recommend a D2B interval of no more than

90 min.¹⁰ Immediately identifying, assessing, and providing prompt PCI for patients with STEMI can enhance care quality and reduce the occurrence of complications.¹ Promptly implementing PCI requires coordinating various medical teams (e.g., emergency physicians, cardiology physicians, emergency triage personnel, nurses, cardiac catheterization room technologists, examination room technologists, radiology technologists, and lab personnel).¹ Therefore, developing an effective D2B checklist would enhance the care of STEMI patients who need PCI.¹¹

The promptness and integrity of disease treatment are crucial to the treatment efficacy and prognosis of patients, especially for acute conditions; however, incomplete task operation or unreliable operating sequences continue to occur in practice. This negatively influences healthcare quality (e.g., causing delayed or missed examinations). The primary reason is the continually evolving division of healthcare work, generating numerous complex items that must be addressed. Healthcare workers might neither memorize all relevant items nor flawlessly complete these tasks in order; thus, slight negligence could immediately cause adverse events, influencing the healthcare quality and increasing healthcare costs (failure cost). In the medical field, checklists can be used to ensure consistency and comprehensiveness when executing complex tasks. The World Health Organization has developed various checklists to serve as references to medical professionals such as surgical safety, safe childbirth, trauma care, and pandemic H1N1 checklists.¹² Additional checklists have been proposed such as the checklist for identifying inpatient suicide hazards¹³ and the KIDS SAFE checklist for use in pediatric intensive care units.¹⁴ These checklists have been proven valuable in enhancing patient safety and the quality of medical care.

In the healthcare field, current checklists primarily remain in written form. Traditional written checklists are flawed in that data entry is overseen and the checklists are not easily recycled, complicating further statistical analyses; however, digitalizing records can amend this flaw. Scholars have reported on various electronic checklist tools,¹⁵ but these tools are primarily used on desktop PCs or other fixed-point customized exclusive systems. When patients must be transported to undergo multiple examinations or treatments (e.g., in the ED), desktop electronic checklists (i.e., checklist systems) are inconvenient. Therefore, mobile checklists (m-checklists) must be developed, but few studies have addressed this need. The major benefits of wireless and mobile computing in healthcare are as follows: (1) enabling information to be captured at the point of care; (2) enabling practitioners to access patient information away from the point of care and provide remote care; (3) ensuring a high degree of timeliness, accuracy, and interoperability; and (4) facilitating multifunctional capabilities such as alerting practitioners about emergencies or providing scheduling information.¹⁶ Thus, wireless and mobile computing is increasingly attractive in healthcare environments.¹⁷ Because mobilization must be both spatially and temporally convenient, m-checklists for D2B are a feasible solution for STEMI patients who need PCI.

Methods and Results

THE PROJECT OF “DEVELOPING A MOBILE ELECTRONIC D2B CHECKLIST FOR MANAGING THE TREATMENT OF STEMI PATIENTS WHO NEED PRIMARY CORONARY INTERVENTION”

The Chi Mei Medical Center (CMMC) is a successfully digitalized large-scale general hospital in Taiwan,¹⁸ featuring 1,200 beds and 470 physicians and annually treating 350–430 acute coronary heart disease patients (approximately 85–105 STEMI patients) who are transferred from the ED. Acknowledging the importance of standardizing a D2B checklist, the Patient Safety and Quality Assurance Committee approved a STEMI D2B checklist development project in early 2009. The expert panel method was used to group senior medical professionals and systematically develop a suitable STEMI D2B checklist, namely, the CMMC STEMI Patient Quality of Care Checklist. Referring to previous literature,¹¹ the first edition was proposed by the Committee in March 2009, and a second edition was revised in November 2010. Despite the need for such methods, no effective and standardized methodology has been proposed or validated to facilitate developing and designing medical checklists¹⁹; however, the STEMI D2B checklist proposed by the expert panel is considered a valuable reference.

In 2011, a project developing a mobile, digital STEMI D2B checklist (hereafter abbreviated as the m-checklist) was initiated at CMMC. The m-checklist was developed to enhance the comprehensiveness, task sequence, promptness, and care quality when executing items critical to treating STEMI patients who need PCI in a time-constrained situation. In mid-2012, an m-checklist prototype was implemented in a pilot ED group.

SYSTEM DEVELOPMENT AND RESULTS

The m-checklist system development was guided using a modified system development life cycle (SDLC) approach,²⁰ which is a well-known methodology for developing information systems (ISs) and is used in healthcare as well (e.g., the work of Lee and Bakken²¹). The primary output in this study was a prototype m-checklist used to manage the D2B process among STEMI patients; healthcare professionals can test this m-checklist in practice. *Figure 1* shows the four phases of the SDLC, comprising system planning and selection, analysis, design, and implementation and operation.

Phase 1. System planning and selection. The first phase of the SDLC involves two primary activities²⁰: (1) identifying the requirements of the desired system and conducting a feasibility analysis and (2) determining the system scope. After the information requirements of the hospital are examined, a project is identified that can meet these requirements. In this study, the system requirements resulted from the following:

- The need to address problems in the current process used to manage the care of STEMI patients who need PCI
- The desire to perform additional tasks
- The realization that mobile technologies can be used to capitalize on an existing opportunity

Fig. 1. System development life cycle.

A standardized checklist was available for managing the D2B process among STEMI patients; however, written checklists remain insufficient for managing time (reminders), sorting records, and completing control, and this could threaten patient safety in emergency conditions. In addition, written records make conducting statistical analyses inconvenient. This is a limiting factor when analyses of such previously accumulated written checklists are used as a basis for improvement. Mobilization technology has continued to advance, and screen sizes and operating interfaces have substantially improved regardless of its application in smartphones or tablet devices. In addition, the operating platforms used in these hand-held devices feature mature development tools that can be used to self-develop applications (apps). Thus, developing an m-checklist for use on hand-held devices was feasible. Although the cost of purchasing equipment must be considered, the quality of patient care cannot be measured using money. After conducting various assessments, the Patient Safety and Quality Assurance Committee at CMMC decided to formally promote this development project.

Phase 2. System analysis. System analysis is the second phase of the SDLC, in which the current system is studied and alternative replacement systems are proposed. The output of this phase is a solution summarized by the analysis team.²⁰ At CMMC, the Patient Safety and Quality Assurance Committee appointed the acute coronary heart disease improvement team and senior system analyst of the Information Management Office to an analytical team. This team reviewed the current STEMI D2B process and checklist, interviewing the primary parties involved in ED STEMI D2B management (i.e., the director, two physicians, and two nurses). After approximately 4 weeks, the team summarized an m-checklist, providing in sequence the assessment records of the five major examination steps.

The ideal and actual times required to complete each step and the accumulated time required to complete all five steps must be displayed in real time to provide a reference and alert to users. These steps are described as follows (Fig. 2):

1. *Step 1. ECG examination (ideally finished within 10 min).* Before each assessment, the Step 1 user (typically an ED triage nurse) must log into the m-checklist. After logging in, patient photographs are uploaded to identify the patient. Thus, the m-checklist must provide real-time photography (for photographing patients or others) and file-upload functions. These patient photographs remain on display as identification. When beginning this step, the user must record the starting time of the ECG examination. The system then provides automatic or manual recording. The physician(s) must be recorded in this step.
2. *Step 2. STEMI operations (ideally finished within 20 min).* This step is distinguished into three stages (working desktop accommodating three full screens is provided). In the first stage, the user reviews the examination results from Step 1 to determine and record whether STEMI is present; if so, cardiologists can be immediately contacted using phone or multimedia messaging services. In addition, the presence of a widened mediastinum in the patient's chest x-ray and the activation time (automatic or manual) of emergency cardiac catheterization must be recorded in this part. In the second stage, the intent of family members to provide consent is recorded as well as the time. Preparation time before completing the cardiac catheterization surgery, detailed notes (e.g., skin preparation, drug administration, cardiac enzyme test, intravenous line, vital signs, and other preparations), and the time of the subsequent notification to send patients to the cardiac catheterization room are recorded. The name of the leading ED nurse must be recorded in this step.
3. *Step 3. Patient transport (ideally finished within 5 min).* During this step, the time that the patient departs the ED must be recorded in addition to any relevant treatment items such as out-of-hospital cardiac arrest, cardiopulmonary resuscitation, on endotracheal intubation, electric shock, computed tomography, and on extracorporeal membrane oxygenation. The name of the leading ED nurse must be recorded in this step.
4. *Step 4. At the cardiac catheterization room, arrival to undergo PCI with balloon inflation (ideally finished within 30 min).* The times recorded in this step comprise the time of patient arrival to the cardiac catheterization room, time at which the cardiac catheterization technician arrives, the time of ED patient departure notification, and the times at which the cardiac catheterization treatment and balloon inflation begin. The name of the cardiac catheterization technician must be recorded in this step.
5. *Step 5. Assessment items (ideally finished within 5 min).* The following factors must be recorded: (1) whether cardiopulmonary resuscitation, on endotracheal intubation, electric

Fig. 2. Snapshots of the mobile checklist involving five major examination steps. ECG, electrocardiography; ED, emergency department; PCI, percutaneous coronary intervention; QR, quick response; STEMI, ST elevation myocardial infarction.

shock, or on extracorporeal membrane oxygenation was performed during cardiac catheterization and (2) the reason that the physician used cardiac catheterization (STEMI or others). The name of the checklist operator must be recorded in this step (typically the operating physician).

The analytical team brainstormed and proposed principal demands of the D2B indicator system:

- Scanning user (operator) identification cards and automatically displaying and recording the relevant staff member as the *operator*
- Noting the sequence and time for each step
- Recording the operating times (using time stamps) for each step
- Providing real-time feedback regarding the operating time

- Displaying an hourglass as a countdown of the time remaining in the relevant step
- Reducing the amount of manual data entry required in subsequent statistical analyses
- Trying to keep data entry to pointer selections
- Preventing repeated entries

Phase 3. System design. System design is the third phase of the SDLC in which the system chosen for development is formulated independently of a technology platform (i.e., logical design) and technology-specific details are subsequently used (i.e., physical design).²⁰ According to the system analysis output, two critical activities should be accomplished in the system design phase: (1) designing the human interface and (2) designing the data storage system (database).²⁰ When designing a human-machine interface, the interface designs used for traditional desktop or notebook computers are not suitable for use with hand-held devices, which have small displays. Regarding the input method, using a keyboard or handwriting entries is inconvenient in an emergency situation; by contrast, sliding data entry interfaces are conveniently suitable.

In addition, large selection buttons facilitate checking records (e.g., checking the times). Virtual keyboards or handwritten entries are only required when necessary (i.e., recording symptoms). A timer function is used to notify users regarding the remaining amount of time per step or other alerts (i.e., providing countdowns for each treatment step, warnings regarding incomplete ECG exams, deactivated emergency cardiac catheterization mechanisms, or the treatment process). Completing data storage is a focus of the system design step

(e.g., should the storage media be file or database for temporary or permanent data? Which format [pure text or a specific format such as Microsoft (Redmond, WA) Excel™] should be adopted for exchanging data with other systems or external institutions?). The suitability of the examination operation and availability of equipment must be considered when assessing software and hardware adoption. Tablet computers (7-inch display) were adopted in this study rather than notebook computers (too large to be mobile) or smartphones (displays too small to operate).

Phase 4. System implementation and operation. During this final phase of the SDLC, developers use the system specifications to develop a working system that is tested and put into practical use.²⁰ In

this project, a cooperative outsourced development model was adopted; thus, the hospital should be in charge to determine requirements and analyze the interfaces, whereas the outsourced IS provider to design and implement the system. The IS provider in this project was highly experienced in the development of medical ISs and mobile apps. Speed was the primary reason for adopting this model because the current hospital IS (HIS) department lacked mature technology and experience in developing mobile apps (i.e., programming mobile apps and Web services). In fact, alliance with an outsourced information technology provider can be the best way to develop mobile healthcare applications.²²

In addition, information security and privacy in the healthcare sector is an issue of growing importance. Various patient-related data are recorded in hospitals to facilitate correct diagnosis and treatment and to avoid adverse drug interactions. However, data (electronic medical records) from mobile devices (i.e., the Apple [Cupertino, CA] iPad® in this study) and core database of the HIS will be communicated electronically via the wireless transmissions. This increases the danger of compromising the security and privacy of patients. For example, a given patient's disease data may be accidentally or maliciously collected or exposed by Trojan or virus programs embedded in someone's mobile device elsewhere in the hospital. Therefore, concerning information security and privacy, the middleware for exchanging patient-related information between the HIS database and the m-checklist pad was provided by the HIS department rather than by the outsourced IS provider.

The prototype was constructed using the development tools of the Apple iOS® platform. In addition to the integrated testing conducted by the IS provider, the prototype was finalized after implemented repeated corrections based on the rigorous assessments and simulations of the physicians on the project team. *Figure 2* shows the primary displays involved in each step (Steps 1–5) of the m-checklist.

EVALUATION FOR USER PERCEPTIONS OF THE PROTOTYPE SYSTEM

For the further understanding of users' perceptions and intention to use the m-checklist, a face-to-face interview was undertaken with 16 potential users (five physicians, five ECG technologists, and six nurses) who are in charge of caring for the D2B interval of ED STEMI patients who need PCI; these interviewees were never consulted during the development phases. A semistructured questionnaire was undertaken during the interview and included eight items, each scored on a 5-point Likert scale, from 1 (strongly disagree) to 5 (strongly agree), and a blank area for free-typing other comments. The Likert-scale items were derived from the Technology Acceptance Model, a well-known theory proposed by Davis et al.²³ for assessing a technology's perceived usefulness and ease of use as well as the users' intentions toward the technology. A researcher (C.-C.H.) first demonstrated the m-checklist prototype to the interviewees and then interviewed them with the questionnaire. *Table 1* summarizes the result of the items and reveals that the users all have high perceptions and intentions toward the m-checklist (means ≥ 4.0).

Table 1. Description Statistics for Perception Items

	PHYSICIANS (N= 5)		ECG TECHNOLOGISTS (N= 5)		NURSES (N= 6)	
	MEAN	SD	MEAN	SD	MEAN	SD
Perceived usefulness	4.73	0.53	4.00	0.67	4.78	0.37
Perceived ease of use	4.87	0.27	4.07	0.77	4.89	0.25
Behavioral intention	4.80	0.40	4.40	0.58	4.92	0.19

ECG, electrocardiography; SD, standard deviation.

Additionally, the interviewees pointed out that the main advantages of using the m-checklist are to make the process significantly smoother, reduce human negligence, increase patient safety, and enhance statistics. The main disadvantages are that it is too expensive, too heavy and/or too large, easily lost, and inconvenient to carry. Finally, legality and information security are two critical concerns pointed out by the interviewees. They mentioned that the m-checklist should implement an electronic signature to realize a legal paperless recording mode (i.e., should comply with Taiwan's Electronic Signatures Act). They were also worried whether the data being transmitted are restricted under Taiwan's Personal Information Protection Act.

Discussion

This study detailed the process of developing a mobile STEMI D2B checklist for use at a medical center in Taiwan, discussing each developmental stage. The experiences described in this study presented values being reference to mobile health (m-health) development, addressing the research gap in m-checklist design. Various potential benefits, the widespread availability of mobile technology, and the relatively low levels of literacy use have prompted the increasing prevalence of m-health.²⁴ The proposed m-checklist corresponded to this statement. The staff members who manage STEMI D2B examinations assessed the proposed system, providing a collective positive appraisal and expressing its perceived usefulness and perceived ease of use.²³

Cross-platform mobile apps should be developed that are compatible with common commercially available mobile platforms and devices such as iOS, Android™ (Google, Mountainview, CA), and Microsoft Windows 8. HTML 5 is recognized as a feasible cross-platform app development language that should facilitate future developments. Based on the current findings, other m-checklist applications, such as preoperative timeout checklists, warrant further investigation. This system requires formal clinical trials to exemplify its feasibility. The possible patient safety and privacy concerns of using mobile and wireless communication must be carefully considered.

Checklists are increasingly developed for and used in the healthcare field²⁵; however, the effectiveness of a checklist depends on its quality and comprehensiveness, the acceptance and compliance of staff members, and a strong culture of safety in the organization.²⁶

Thus, in addition to the adoption of innovative technologies, organizational change presents another challenge.

When using technology in the medical field, user-oriented development is essential. STEMI patients undergo numerous medical procedures between their hospitalization and discharge, and the STEMI check is only one of numerous examinations. This made it difficult to determine the project scope. Based on their individual perspectives, the committee members proposed which activities should or could be recorded using mobile devices. Because of the hospital's lack of experience in developing hand-held mobile technology and the complexity of integrating the opinions of numerous users from extensive operation coverage, the project scope was narrowed to focus on developing an m-checklist for managing the STEMI check processes.

Confirming the system requirements is the key task during the system analysis phase. The examination contents must account for the sufficiency of diagnostic reference, remaining sufficiently simple to maintain the promptness and accuracy of the recording process. To confirm the system requirements, the project team interviewed representative users, namely, physicians, nurses, and examiners. In addition to gathering the currently used written checklists, practical experiences and recommendations were collected from the interviewers. The team members organized the collected data, conducted a rational analysis of the cross-flow operations to propose possible demands of the m-checklist, continually discussed, corrected, and confirmed with user units, and finalized a five-step system process.

The type of mobile computing device adopted is determined in the system design phase. After evaluating various devices concerning the processor power, screen resolution and size, operating features, and ability to support business applications, the project team decided to adopt tablets PCs as the development platform.¹⁷ In addition, extensive time was invested in designing the interface to ensure the convenience of the resulting system. The features of tablets vary from those of traditional computers (e.g., touch screens, virtual keyboards), making traditional menus and pull-down layouts inconvenient. Thus, the system was designed to reduce the amount of text and numerical entries, adopting a unique system of sliding and zooming hand touch gestures to facilitate the rapid, convenient, and accurate use of the m-checklist. Considering its popularity, the Apple iPad 2 was used as the development platform for the m-checklist prototype. However, this does not preclude future developments using other mobile tablets (e.g., Google Android or Microsoft Windows 8). Regarding user identification, quick response (QR) code technology was adopted in addition to traditional account and password entries; when the QR code on a user identification badge is scanned, the system can immediately identify the user and retrieve relevant user identity information.

Regarding data storage, the traditional relational database format was adopted to temporarily store data in the mobile device. XML, which is often used in cross-platform data exchange, was used to design the data import/export model, ensuring the expandability and compatibility of the system. The m-checklist was designed to import general patient information from the HIS, using the offline method to

export the results of examinations from the m-checklist to the HIS. If the security of patient information is verified, the system can be updated to conduct real-time online data exchanges.

Regarding system implementation and operation, outsourced cooperation was adopted; thus, the IS provider was responsible for programming the mobile app. To ensure the free development of future apps, the CMMC IS department must be able to self-maintain and expand the system. Thus, the project team asked the IS provider to adopt object-oriented programming and unified modeling language techniques to develop the system and to prepare complete analysis and design documents that were also provided to the IS department when the source code was delivered. The original documents provided by the IS provider were vague. The project team expressed this concern to the IS provider, specifying the areas of the document that required correction and continuing communications; thereafter, the project team provided satisfactory deliverables. After completing the prototype, the project team conducted simulations and additional interviews with relevant staff members.

Finally, the result of the interviews with the potential users indicates that the m-checklist has high perceived usefulness and ease of use, and the interviewees have high intention to use it. However, specific disadvantages, such as cost, weight, and size, still have to be considered. Furthermore, when introducing the m-checklist in Taiwan, some specific efforts remain to be made such as developing the function of a legal electronic signature and assessing whether the system complies with the new Personal Information Protection Act and other related regulations.

Conclusions

This study describes the process of developing a prototype of m-checklist for treatment of STEMI patients who need PCI. The four phases of the SDLC, comprising system planning and selection, analysis, design, and implementation and operation, as well as discussing the results, were presented in depth. The m-checklist is believed to have the potential to ensure the completeness and sequence of treatment following a patient's arrival in the ED and to improve his or her adherence to the step control by reminding healthcare staff members to perform necessary assessments and document necessary data through the hand-held mobile pad at the point of care.

The m-checklist is still in an early stage with uncertain factors and issues to be clarified, investigated, and overcome. Further randomized controlled trials have to be planned to perform in the future for ensuring its feasibility. If the trial result demonstrates the effectiveness for the treatment of STEMI patients, other influencing factors such as software/hardware costs, process redesign, and staff resistance or acceptance should be overcome for practical use.

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No competing financial interests exist.

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