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Creating a continuum of care : smart technology in patients with cardiovascular disease

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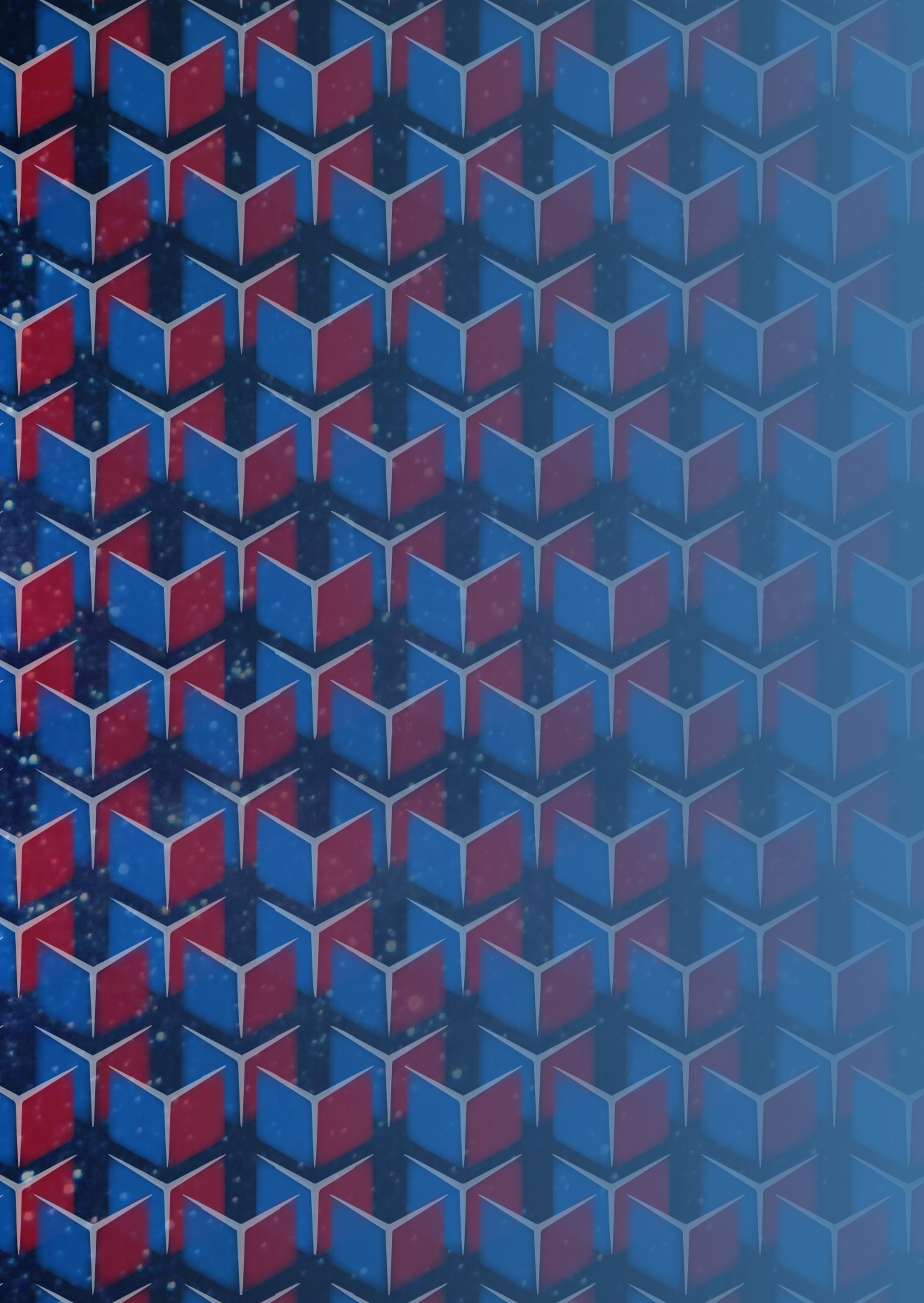

CHAPTER 11

Summary and conclusions

The aim of this thesis was to investigate the use of smart technology in patients with cardiovascular disease. This thesis focuses on the various applications of telemonitoring. It does not only concentrate on clinical effectiveness, but also on patient satisfaction and cost-effectiveness. As e-Health is a relatively new concept, there is not much data available. The research described in this thesis is therefore mostly exploratory.

In the general introduction, **chapter 1,** it is explained that e-Health and smart technology are two poorly defined concepts. For the purpose of this thesis, two definitions are given to indicate the scope of this thesis. Furthermore, the scope of telemedicine is explained and an outline of the thesis is given.

Chapter 2 elaborates on the introduction and gives an overview of already existing technologies. Telemonitoring of implantable cardioverter defibrillators (ICDs) and telemonitoring with smart technology is described. Telemonitoring of ICDs in heart failure patients has been shown to decrease all-cause mortality and hospitalizations. Furthermore, lead fractures were sooner recognized. Lastly, total healthcare consumption was shown to decrease. There are however some safety concerns regarding the data of the ICD. In laboratory circumstances, a group from the University of Washington was able to hack an ICD and to adjust its settings. The data safety of the ICD should therefore be followed with concern. The second part of this review focused on the usage of smart technology. In contrast with ICDs, the clinical benefit of smart technology for telemonitoring has not been demonstrated. There are various applications available to measure ECG, blood pressure, weight and steps. However, these applications are poorly regulated, partly because they are often not considered to be medical devices. Research has shown that multiple apps lack a privacy policy, sell collected data to third parties and do not use encryption to protect data. In order for smart technology to succeed, these concerns need immediate attention.

The role of electronic medical records (EMRs) in the patient's journey is discussed in **chapter 3**. Current existing commonly used EMR systems suffer from a couple of shortcomings: first, they are very expensive. A cost calculation returned an astonishing €2.2 billion spending on EMRs in The Netherlands in 2016 alone. Second, these systems are very generic, which inhibits the input of accurate specialty specific information. Instead, the information should be made in the specific MAS-PAS system. This system is tailored to a patient's journey. Every specialty has its own, tailored, EMR. In case a patient is referred to a certain specialty, the EMR of that specialty (MAS) is opened. Simultaneously, a patient's part is opened (PAS). In

this part, all medical terms are represented as lay terms. In such a way, the patient is better informed and therefore empowered.

The rationale and design of a randomized controlled trial (RCT) in which smart technology is used in the follow-up of acute myocardial infarction (AMI) is described in **chapter 4.** Guidelines recommend a series of pharmaceutical and life style interventions to lower risk of major adverse cardiac events such as revascularization, recurrent AMI, stroke and cardiovascular mortality. Smart technology may be a low cost and clinically effective tool to help patients measure their own vital signs. By sending these data to the hospital, both doctor and patient have more insight in the patient's health. By better informing patients and doctors, shared decision making can be improved. This RCT includes patients that have been admitted for AMI (either with or without ST elevation) at the Cardiology Department of the Leiden University Medical Center. These patients are 1:1 randomized between The Box and regular follow-up. In regular follow-up, patients are followed up with four outpatient clinic visits and no monitoring in between. In The Box group, two outpatient clinic visits are replaced by an e-visit. Furthermore, patients use smart technology to send a single lead electrocardiogram (ECG), their blood pressure, their weight scale and their step count every day. These data are checked by a project dedicated PhD student. In case of possible abnormalities, the patient is contacted and therapeutic regimen can be adjusted if necessary. The sample size of this RCT is 200.

Chapter 5 gives the rationale and design of the MOBILE-AF trial. This RCT includes patients who have been admitted with cryptogenic stroke or TIA. Previous research showed that in approximately 30% of all stroke patients, no aetiology can be determined. These strokes are called cryptogenic. In approximately 1-2% of these patients, atrial fibrillation (AF) is found in the work-up, currently consisting of a 12-lead ECG and a 24-hour Holter monitor. Recent research of prolonged AF monitoring indicated that the AF burden may in fact be higher in this patient population. In the CRYSTAL-AF trial, in 12.4% of patients with prolonged monitoring, AF was detected. However, the device used in this trial is relatively expensive and brings in the risk of pocket infection. Therefore, there is a need for a less expensive and less invasive alternative. One device that is a good alternative may be the AliveCor. This device enables the patient to record a single lead ECG on their smartphone for 30-seconds. Via internet, this single lead ECG is sent to the hospital. In this trial, patients are randomized in a 1:1 fashion to either the single lead ECG device (intervention group) or to a 7-day Holter monitor (control group). When randomized to the intervention group, patients record a single lead ECG 2 times a day for one year. When randomized to the control group, patients wear one additional Holter

monitor for 7 days consecutively. Primary endpoint is the percentage of patients in which AF is detected after one year. The sample size of this RCT is 200.

In **chapter 6**, a study that compares four smartphone compatible blood pressure (BP) monitors is described. Several smartphone compatible BP monitors are validated and available for over-the-counter sale. So far, no study compared these four BP monitors. Therefore, in this study, 43 patients underwent 6 consecutive measurements with four smartphone compatible BP monitors, one oscillometric device and one handheld sphygmomanometer. Primary outcome was the difference in systolic BP between the handheld sphygmomanometer and the other 5 devices. All devices differed significantly, but were well within the accepted range of 5 mmHg, except for one monitor. This chapter showed that smartphone compatible BP monitors are generally well within the accepted range of 5 mmHg and can therefore be used for serial measurements.

In **chapter 7** tools that are used to improve medication adherence in patients with cardiovascular disease are summarized in a narrative review. Medication adherence is of crucial importance in the treatment of cardiovascular disease. Previous research has shown that cardiovascular mortality is significantly higher in patients who are non-adherent. It is the purpose of this review to give an overview of various technologies that are available to address medication adherence. PubMed was searched. The 74 articles that were included were divided into one of the following categories: mobile apps, smart pill boxes, short message service (SMS), telephone calls or web-based interventions. SMS was shown to be a good choice for short, simple reminders. Web-based interventions were shown to be effective for educational purposes. Moreover, their low cost makes them an appealing choice in addressing non-adherence. The evidence for smart pill boxes in the literature is limited and further research is needed there.

Chapter 8 focuses on the clinical value of serial ECG analysis to detect acute ischemia in patients with chest pain. So far, serial ECG analysis has been difficult to implement in practice, because it requires a baseline ECG of every patient. However, with smart technology, this might be possible in the nearby future. In this chapter, the sensitivity and specificity of serial analysis of the ST-segment and ventricular gradient was investigated. To determine sensitivity, a cohort of 84 patients with long balloon inflation times during elective percutaneous coronary intervention (PCI) was used. To determine specificity, a cohort of 398 clinically stable patients without acute myocardial ischemia was used. A ROC curve was drawn. Using a specificity of 89.1% (current STEMI specificity), STEMI criteria showed a sensitivity of 70.2%, ΔST showed a sensitivity of 78.6% and ΔVG showed a sensitivity of 71.4%. The

article therefore concluded that serial ECG analysis of ST-segments can significantly improve diagnosis of acute myocardial ischemia.

To select patients for future e-Health studies, clinical characteristics and emergency care utilization in grown-ups with congenital heart disease (GUCH) with proven interest in e-Health are described in **chapter 9**. Consecutive patients who visited the outpatient clinic were given an e-Health questionnaire. Afterwards, their clinical characteristics and number of visits to the emergency care department were noted. A frequency of three or more visits in 5 years was defined as high care utilization. Of all patients, 8% had a high emergency care utilization. These were predominantly symptomatic patients on anti-arrhythmic therapy or diuretics. In total, 75% of these patients were willing to start using e-Health.

Finally, **chapter 10** describes a screening study in stable heart failure (HF) patients. Previous research in large cohorts has shown that central sleep apnea (CSA) is prevalent (30-50%) in stable HF patients. CSA is associated with higher cardiovascular mortality in this population. Currently, CSA is diagnosed by a polygraph (PG). However, a PG is a burden to the patient and time consuming to analyse. It is therefore unsuitable as screenings method. There is a need for a more patient friendly alternative that is less time consuming. One alternative might be overnight oximetry using a smartphone compatible app. The results of overnight oximetry are sent to the hospital and can be analysed by a MATLAB algorithm. It was the purpose of this study to investigate if overnight oximetry could predict CSA in stable HF patients. A total of 26 patients underwent a PG and overnight oximetry simultaneously in one night. The oxygen desaturation index (the number of dips per hour) was compared to the result of the PG. Results confirmed that sleep apnea is prevalent in stable HF patients (33% CSA, 58% sleep apnea of any aetiology). The ODI, measured by the app, was a weak predictor of both CSA and sleep apnea. However, the ODI, when measured by the PG, was a strong predictor of CSA. This chapter indicates that more research is necessary to make screening in stable HF patients possible.

Conclusions and future perspectives

E-Health is a relatively new concept in the medical field. In theory, e-Health could improve clinical effectiveness, improve patient satisfaction, lower costs of healthcare. Very importantly, it could contribute to the delivery of healthcare in areas where doctors are scarce (remote areas and low-income countries). However, so far, scientific evidence for e-Health is limited.

In this thesis, the rationale and design for two randomized controlled trials were described. The Box investigates the use of smart technology in patients who are followed-up after acute myocardial infarction (AMI). The last patient was included on November 9th, 2017. Therefore, final results will be available in November 2018. It is the hypothesis of the authors that patient satisfaction will increase. It is furthermore expected that by actively involving patients in their own rehabilitation, adherence to therapeutic regimen will improve.

The other trial of which the rationale and design is described is the MOBILE-AF trial. It is the hypothesis of the authors that the AliveCor will be a more effective and more patient friendly alternative to the Holter monitor. It is acknowledged that the AliveCor has not been compared with the Reveal LINQ. However, the Reveal LINQ is not recommended as standard by clinical guidelines. In case it becomes so, the Reveal LINQ could be compared to the AliveCor in a future trial. The authors also acknowledge that cumulative evidence contradicts the causal relationship between AF and cryptogenic stroke. The ATTICUS trial, in which patients are randomized to a NOAC or regular treatment, regardless of AF detection, is recognized by the authors and its results are followed with caution.

One might argue that the future of e-Health is even more interesting than its past or present.
The invention of the iPhone has hugely influenced the field of e-Health and was indispensable in generating the field of mobile health. In the past 10 years, mobile technology has been rapidly adopted. Mobile phones have become faster, percentage of the Dutch population that uses internet has increased and companies have started to use social media as an important way of communicating with their customers. In the upcoming years, it is expected that existing technologies (smartphones, internet) will be improved. Secondly, it is expected that new ICT (such as the internet of things and block chain) will have a major influence on e-Health.
The implementation of these technologies will also be one of the challenges of implementing e-Health. There is a huge discrepancy between the implementation time in information and communication technology (ICT) and the implementation time in medicine. Technologies in ICT that were invented 5 years ago are generally considered old. In medicine, it takes on average more than 10 years to bring a drug to the market. This is mostly because of the rigorous evidence that needs to be generated for a drug to be approved. Therefore, the authors believe that future research should not depend on a single technology. Instead, research should focus on a clinical problem for which a smartphone compatible technology changes the way that problem is approached. That way, the results of a trial will still be valid if the technology is further improved.

Another challenge that needs to be addressed is the digital literacy of the current population with cardiovascular disease. In chapter 9, it was shown that 50% of all patients was not able to perform (a very simple) task on the smartphone. This is a very specific form of non-adherence that should be addressed if smart technology becomes part of clinical practice. First, e-Health innovations should be made simple. Second, it should be taken into account that most e-Health applications will be used by an elderly population. Therefore, concordant visual and audial adjustments (larger buttons, louder instructions) should be made in the applications.

E-Health is a promising concept that may improve the way healthcare is delivered. In 15 years, the current state of e-Health could be known as the first stone of the bridge that was built to connect home and healthcare.