EXPERT OPINION AND POSITION STATEMENT

Telemedicine solutions in cardiology

A joint expert opinion by the Information Technology and Telemedicine Committee of the Polish Cardiac Society, the Section of Noninvasive Electrocardiology and Telemedicine of the Polish Cardiac Society, and the Clinical Research Committee of the Polish Academy of Sciences (short version, 2021)

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ABSTRACT

Telemedicine involves diagnostic, therapeutic and educational services being offered remotely by healthcare professionals to exchange crucial clinical information. It is a rapidly developing form of medical activity and part of medical industry, with advanced technologies already available in Poland. Cardiology is one of the fields in which telemedicine methods were pioneered and introduced into everyday practice. Some of these methods have already become standard procedures for diagnosis and treatment in some Polish centers, with other soon to follow. Clinical study results not only demonstrate reliability and usefulness of telemedicine technologies but also show that their use in clinical practice improves the patients' prognoses and quality of life. Moreover, study results in highly developed countries show a potential cost-effectiveness of telemedicine from the perspective of healthcare systems. There is an unquestionable need to establish clear rules for telemedicine use in Poland, which would ensure their high quality and adequate clinical application. This paper is a summary of the current status of telemedicine solutions used in cardiology, with a particular focus on the Polish healthcare system, and presents both the commonly available solutions and those that are expected to develop rapidly in the near future.

Introduction Telemedicine involves diagnostic, therapeutic, prophylaxis-oriented, didactic, and educational services offered remotely by healthcare professionals with the use of information

technology to exchange crucial information.¹ The scope of telemedicine in Poland is regulated by law,^{2,3} with selected services found on the list of state-reimbursed telemedicine procedures. This

TABLE 1 Summary of indications for the use of telecare and tele-education

Recommendations	Level
The use of telecare to some extent and in those selected cases where it would be an important adjunct to standard healthcare, eg, in a subset of patients with heart failure, in patients scheduled to undergo a therapeutic intervention (to optimize preparedness for the elective procedure)	I
Remote modifications to the medication regimen if specific safety conditions are met: ie, the medication was already used before and caused no side-effects at the recommended dose or the risk of such side-effects is low, it is possible to convey the recommendation to the patient in an unambiguous way that can be easily understood, and the effects of the change in treatment can be assessed, eg, via vital signs monitoring	IIb
Tele-education as one of the forms of education for any cardiovascular patients	I
A telecare system that is comprehensive and consistent with the general healthcare model in the given country	I

paper is a summary of the current status of telemedicine solutions used in cardiology, with a particular focus on the Polish healthcare system.

The authors of this paper established a set of guidelines for individual telemedicine procedures based on the European Society of Cardiology (ESC) Recommendations for Guidelines Production. The resulting guidelines have been classified into the following categories: "is recommended/indicated" (I), "should be considered" (IIa), "may be considered" (IIb), and "is not recommended" (III).

Telecare Telecare involves the application of various forms of patient care with the use of telemedicine tools at the patient's place of residence. Telecare complements direct (in-person) healthcare services. Its main goal is to improve patient compliance, to detect possible exacerbations early, and to detect any conditions that may aggravate the course of the patients' current disease. The broad term "telecare" encompasses the use of any diagnostic methods and tools described below.

Telecare, with its fundamental components of teleconsultations and remote treatment monitoring, is generally used to complement in--person healthcare. Observational studies in a group of over 4000 patients with a history of acute coronary syndrome showed that the possibility of contacting a medical call center in case of concerning symptoms significantly lowered the annual mortality rate in comparison with that in the control group.4 Studies evaluating the impact of telemedical solutions on improving care of patients with heart failure have yielded inconclusive results. A number of prospective clinical studies showed no significant effect of teleconsultations or telecare on the rehospitalization rate or prognosis in patients with heart failure.5 However, the TIM-HF2 (Efficacy of Telemedical Interventional Management in patients with Heart Failure) study has been a breakthrough. 6 The study employed monitoring of blood pressure, electrographic parameters, body weight, and clinical symptoms in a group of 1571 patients with heart failure and revealed that this form of care reduced

the number of days lost due to hospital admissions or death and lowered all-cause mortality. As a result, European experts in their 2019 consensus agreed for the first time that at-home telemonitoring may be considered in patients with heart failure. Another report emphasized the benefits of telemedical solutions in certain patient subgroups: such as nondepressive patients with left ventricular ejection fraction of 25% or greater and a history of decompensated heart failure.

Telecare may improve treatment outcomes in cardiovascular patients, both in terms of prognosis and prevention of treatment-related complications. The available telemedicine tools help assess patient adherence to prescribed medication and recommended lifestyle changes. This is achieved by both monitoring the amount of remaining medication and assessing treatment efficacy based on vital signs, such as blood pressure and heart rate, or body weight. The level of physical activity (for example during cardiovascular rehabilitation) can also be monitored (TABLE 1).

Some currently available applications help not only to passively monitor the use of medications but also have additional functions, such as alerts and reminders, if a medication has not been taken. The option of constant supervision over the patients' drug regimen with the use of telemedicine may play a key role in maximizing primary and secondary prevention in major groups of cardiovascular patients: those with heart failure, history of acute coronary event, atrial fibrillation, and history of coronary intervention.

Tele-education Tele-education is an attempt to address the needs of cardiovascular patients that remain unmet in the current healthcare system. For instance, patients may want to know more about and understand the causes and clinical manifestations of certain diseases, indications for individual classes of drugs, cardiac implantable electronic device implantation, and invasive procedures. Thus, tele-education increases the odds of the patients' active participation in prevention, rehabilitation, diagnostic procedures, and treatment. The importance of

TABLE 2 Summary of indications for the use of teleconsultations

Recommendations	Level
Teleconsultations (text consultations, video consultations, video consultations with medical data transmission) between healthcare professionals in cases raising therapeutic or diagnostic questions	I
Teleconsultations between healthcare professionals and patients to optimize patient care in situations where this form of consultation helps reduce the risk to the patient's health resulting from limited access to in-person consultations and if the procedure meets the commonly accepted principles of good clinical practice	IIa
Teleconsultations as one of the available options to provide specialist care in patients in a stable condition who continue their care at a given specialist outpatient clinic, and the procedure is performed in accordance with the principles of good clinical practice	IIa

tele-education in therapy (for example for patients with heart failure) is due to the crucial role of self-care for long-term prognosis. Moreover, studies showed that a significantly higher proportion of patients after myocardial infarction, educated via repeated telephone calls after their hospital discharge, exhibit healthy behaviors, such as increased physical activity and smoking cessation. 9,10 The fact that tele-education tools can be used repeatedly gives the patient an opportunity to learn from experts at his or her own pace. The Polish Cardiac Society offers patients tele-education through the following websites: www.slabeserce.pl, www.copozawale.pl, www.arytmiagroziudarem.pl, and www.copozatorze.pl.

Comprehensive patient tele-education can be also achieved via mobile phone applications, which offer several forms of educational support. These applications may include multimedia presentations about the underlying disease that causes the patient's symptoms and the treatment methods (including visualization of medical procedures). These applications remind patients to take their medications and record the fact of taking each medication; some offer individual behavioral education; and some allow the patient to ask a question of a medical team via text communication or a videoconference. They also remind the patients to follow nonmedication--related recommendations and offer automatic assessment whether they are followed or not (eg, an increase in physical activity) (TABLE 1).

Teleconsultations Teleconsultations are a form of remote medical consultations between healthcare professionals or between a healthcare professional and a patient who are at different locations. Teleconsultations are held with the use of modern technologies of text, verbal, and imaging data transmission for diagnostic, therapeutic, rehabilitation, educational, and effectiveness assessment purposes.

Teleconsultations in the form of text, verbal, or image communications may be achieved via a cellular phone network or internet-based communications system. The key indication for the use of this healthcare service is lack of

an in-person contact between the parties at the time when the medical service is necessary or would help reduce the risk to the patient's health. Specialist consultations may have the form of:

- teleconsultations in an outpatient setting;
- urgent specialist consultations, for example, with the use of telemedicine systems installed at emergency facilities (electrocardiographic [ECG] data transmission);
- scheduled specialist consultations via telemedicine tools, for example, between specialists from tertiary reference centers and primary care physicians, cardiologists from secondary reference centers or specialist outpatient facilities, and specialists from other fields of medicine (text, teleconsultations, audio teleconsultations, and video teleconsultations);
- scheduled teleconsultations on the results of imaging studies (electrocardiography, echocardiography, ultrasonography, radiography, computed tomography, magnetic resonance imaging, coronary angiography, histological examinations, etc);
- teleconsultations as part of medical personnel education programs (TABLE 2).

Key benefits of teleconsultations with specialists are:

- increased accessibility of consultations and an optimal utilization of medical personnel resources;
- rapid diagnosis and help in cases of emergency;
- time and cost savings and increased operational efficiency;
- · epidemiological safety;
- the possibility of including any number of persons, who are at different locations, in the consultation.

Key limitations of teleconsultations:

- teleconsultation participants have to have medical equipment that ensures high-quality recording of biological signals, adequate computer parameters, software, and tools for high-quality transmission of data;
- healthcare personnel have to be qualified, also in terms of using telemedicine technologies;
- ensuring personal data protection and legal personal data processing is necessary;

 there is no in-person contact with the patient, along with its associated consequences, including the necessity to reliably confirm patient identity and having the patient confirm his or her understanding of remotely issued recommendations.

Another important aspect to consider is the fact that some patients may consider a remote contact with a physician to be inferior to a direct examination. The doctor's body language is an important nonverbal aspect of communication, building trust, and establishing rapport. Thus, a preferred form of teleconsultations between healthcare professionals and patients are video teleconsultations.

The coronavirus disease 2019 (COVID-19) pandemic required rapid and widespread introduction of teleconsultations in outpatient settings. As early as on March 12, 2020, the Polish National Health Fund approved conducting medical appointments via teleinformation systems (or other communications systems) in patients continuing their care at a given specialist outpatient clinic. 11 This solution helped, to a large extent, avoid interruptions in specialist medical services and offered care continuity for chronically ill patients, while ensuring the epidemiological safety of both the patients and medical personnel. A number of guidelines and procedures for conducting teleconsultations were developed and implemented; this includes the manuals issued by the Telemedicine Task Force Foundation.¹²

Remote electrocardiographic monitoring

Technical parameters, operational principles Remote ECG monitoring via external recording devices is the basic telediagnostic tool used in cardiology, especially in the area of arrhythmia. Remote ECG monitoring involves analysis of electrocardiograms obtained remotely and transferred to the monitoring center. Remote ECG monitoring helps detect, document, and assess abnormal electrical activity of the heart during daily activities and increases the chances of establishing an accurate diagnosis. Some remote ECG monitoring devices can additionally monitor the respiratory rate, physical activity, and blood pressure. 4

Patient-initiated transmission of short, eventbased ECG (event recording of a single-lead ECG of at least 30 seconds in duration) may be used in the following circumstances:

- at the time when the patient develops symptoms suggesting arrhythmia, a conduction block, or ischemia;
- in circumstances that could trigger an arrhythmia, conduction block, or ischemia;
- in other circumstances selected by the patient and/or at specific fixed time points defined by the doctor.

In event-based Holter devices, the recording function is activated by the patient by pressing

the appropriate event button. 15-17 The preferred tool are external event recorders, which are placed on the patient's chest along with the electrodes and leads, and operate as external loop recorders (ELRs), 14-16,18,19 which makes it possible to obtain ECG recording including a pre--specified period preceding the pressing of the event button. In other cases that may also be considered, the symptoms have to last long enough for the device to be attached and activated. State-of-the-art options include systems that are based on ECG recording modules integrated into smartphones. Event-based ECG recording and immediate data transmission to the monitoring center via a cellular network are possible due to electrodes integrated into the device, which is then placed against the surface of the patient's body. 14 There are also external devices that can record a 30-second to 3-minute electrical activity of the heart and operate when the recording device—which transfers the data to a mobile phone application—is held against the chest wall. These data may be converted into a file and sent via an email. Such devices may be used by patients or by physicians, for example during a home visit.20

One particular form of remote ECG monitoring is the use of implantable loop recorders (ILRs).¹⁴ These devices are intended for patients whose symptoms occur very rarely, and for whom carrying an external device for so long would be impossible. Implantable loop recorders may operate in an automatic mode or react to the patient's command. They also include a retrospective memory function (and retain data for the length of time, or loop length, specified by the doctor), and transmit data to the consultation center. One recent form of remote ECG monitoring are external devices in the form of patch ECG monitors (or PEMs, involving adhesive electrodes), which can continuously record the electrical activity of the heart for up to 14 days. The obtained recording is subsequently analyzed by an automatic abnormality detection algorithm. 13,16 Schultz et al²¹ demonstrated that prolonged monitoring via a PEM doubles the chances of detecting arrhythmia in comparison with a 48-hour recording. Early PEMs were only capable of recording single-lead ECG; however, continued research into this technology may soon allow multi-lead recordings, which should help improve recording quality and its diagnostic value.

The most recent ESC atrial fibrillation (AF) guidelines set at 30 seconds the minimum duration of an ECG recording sufficient for an expert skilled in the ECG interpretation to diagnose AF.²² However, what remains problematic is differentiating AF with other arrhythmias (eg, supraventricular ectopic beats) or conduction blocks, which may be impossible in the case of a single ECG tracing. In light of the possible

complications of AF treatment (including medications increasing the risk of bleeding) it is advisable to be cautious when interpreting recordings from a single-lead ECG.

Mobile device-based technologies (smartphones and smartwatches) are also increasingly popular. They help assess the heart rate and, in selected cases, ECG tracings. Some of these functions require active initiation by the patient, with some capable of monitoring the pulse and if any irregularities are detected—automatically transmitting an ECG recording. 13,22 The paucity of scientific data showing the effectiveness of these methods in detecting AF has been emphasized, and further studies are required to assess the clinical usefulness of these technologies. Moreover, the risk of overdiagnosis and the associated unnecessary decisions to introduce treatment should be taken into consideration. It is also important to consider the psychological aspect of long-term monitoring via devices prone to generating large numbers of false--positive alarms and thus inducing the feelings of fear and uncertainty in patients. 13,22

Transmission of short event-based ECG recordings by medical personnel is a typical part of teleconsultation, which may be also used in emergency medical services and as part of cooperation between higher-level specialist facilities and both primary care and lower-level referral facilities. 16,23

The transfer of continuous ECG recording with the option of online analysis is an advanced method that makes it possible to analyze the complete uninterrupted ECG recording. Such a recording may be sent online to a monitoring center in real time or at a later time. The development of intelligent recording and analysis systems has been a breakthrough in that these systems can classify QRS complexes as normal, supraventricular, or ventricular depending on arrhythmic complexity. Automatic detection of important ST-segment changes is also possible. Transmission of any detected abnormalities to the monitoring center is automatic (auto--triggered recording), with an additional possibility of alerting the given patient and/or physician (via a sound signal or text message). 11,24-26 The diagnostic effectiveness of these automated systems is undoubtedly going to improve with the use of more and more advanced data analysis methods, including machine learning.²⁷

Wristband optical heart-rate monitors are a user-friendly solution; however, only adequately validated devices should be used this way. Another promising solution are smartphone-integrated devices, which can record single-lead ECG. However, they have only been used as purely preliminary diagnostic tools, with the recommended course of action involving confirmation of the diagnosis with an at least 2-lead ECG recording.²⁸

Indications for remote electrocardiographic monitoring The indications for remote ECG monitoring in the diagnostic workup of cardiac patients are directly related to the benefits of this technique over standard ECG monitoring (TABLE 3). 18,22-34 We would like to emphasize that in the case of frequent symptoms (occurring daily or several times a week), conventional ambulatory ECG monitoring (Holter), which in practice can be used for continuous monitoring for up to 72 hours, should be the diagnostic method of choice.34 In the case of indications for an ECG assessment over a period longer than 14 days, the preferred diagnostic method should be remote ECG monitoring. One of its types, event--based remote monitoring, is intended particularly for patients with sporadic symptoms (occurring less than once a month) or those who require ECG monitoring in highly specific situations, and the transmission of ECG data may be scheduled according to a predetermined timetable (eg, cardiac rehabilitation, selected clinical situations, or circumstances associated with the patient's physical activity). The decision to initiate remote ECG monitoring has to be made based on the patient's condition, socioeconomic conditions, and the results of earlier diagnostic evaluations. Remote ECG monitoring is not recommended in patients with typical symptoms (eg, angina pectoris, frequent palpitations), who had not undergone first-line diagnostic investigations (eg, cardiac stress test/coronary angiography, 24-hour Holter ECG monitoring).35

Remote ECG monitoring is used primarily in the diagnostic workup of arrhythmia, both in symptomatic and asymptomatic patients. One specific group are patients with a history of transient ischemic attack (TIA) due to (an often previously undetected) arrhythmia. Cardiac embolism is one of the most common mechanisms of ischemic stroke, with a 10% to 20% risk of TIA recurrence within 90 days. 17,36,37 Therefore, demonstrating that a given embolic event was arrhythmia induced is crucial for secondary prevention (ie, anticoagulant treatment initiation).^{17,38} Remote ECG monitoring improves the chances of detecting arrhythmia and at the same time reduces time to diagnosis.24,34 Detecting AF is of particular importance in patients with high CHA2DS2-VASc scores, since they are at high risk of developing thromboembolic complications.39 A systematic review and meta-analysis by Sposato et al40 demonstrated that remote ECG monitoring in patents after a stroke or TIA helps to diagnose new-onset AF in 16.9% of patients in comparison with 10.9% of patients diagnosed via conventional Holter monitoring. A meta-analysis by Dussault et al34 showed that longer ECG monitoring in post-TIA patients is associated with significantly higher chances of AF detection. Monitoring for up to 72 hours helped detect arrhythmias in 5.1% of

TABLE 3 Summary of the indications for remote electrocardiographic monitoring

Recommendations	Level
Continuous (or event-based) remote ECG monitoring in patients with suspected clinically relevant paroxysmal arrhythmia undocumented in earlier assessments (resting ECG, 24–72h Holter ECG), with a preference towards event-based remote ECG monitoring in sporadic (less than once per month) symptoms	I
Continuous (or event-based) remote ECG monitoring in patients after ischemic stroke, with negative history of arrhythmia and no confirmation of arrhythmia in previous assessments (resting ECG, 24–72 h Holter ECG)	IIa
Continuous (or event-based) remote ECG monitoring in patients with multifocal vascular lesions of the central nervous system, likely to be a result of embolism, with a negative history of arrhythmia, and with no arrhythmia shown in earlier assessments (resting ECG, Holter ECG)	IIb
Continuous remote ECG monitoring after ablation procedures for arrhythmias (mainly atrial fibrillation / flutter) to assess procedure effectiveness (including quantitative, ie, AF burden, assessment)	IIa
Continuous (or event-based) remote ECG monitoring in patients at high risk of life-threatening (especially ventricular) arrhythmias, eg, those at the early post-myocardial infarction period and those with heart failure	IIb
Remote ECG monitoring in patients with paroxysmal atrial fibrillation / flutter that is documented for the first time but likely to be secondary or sporadic.	IIb
Continuous (or event-based) remote ECG monitoring in patients diagnosed with atrial fibrillation / flutter to assess heart rate control in case of discrepancies between the results of earlier assessments (resting ECG, Holter ECG) and the reported symptoms, which suggest inadequate heart rate control in certain circumstances in patients with persistent AF or during episodes of paroxysmal AF	IIb
Continuous (or event-based) remote ECG monitoring to assess the sinus rhythm in case of discrepancies between the results of earlier assessments (resting ECG, Holter ECG) and the reported symptoms, which suggest inadequate heart rate control	IIb
Continuous (or event-based) remote ECG monitoring during the physical training that is part of early cardiac telerehabilitation	Ι
An ILR in patients with recurrent syncope of unknown origin if there is a chance of recurrence within the device's battery life	I
An ILR in patients with recurrent syncope of unknown origin at high risk of adverse clinical events, whose earlier diagnostic assessments failed to provide a diagnosis and who have no indications for an implantable cardioverter-defibrillator and/or pacemaker as part of primary prevention	I
Continuous (or event-based) remote ECG monitoring in patients with syncope of unknown origin (eg, suspected cardiodepressive syncope, paroxysmal arrhythmias / conduction blocks, suspected or diagnosed treatment-refractory epilepsy), whose earlier assessments (resting ECG, Holter ECG) failed to show any association between clinical symptoms and ECG patterns	IIa
Continuous (or event-based) remote ECG monitoring and / or an ELR or ILR in patients with nonspecific paroxysmal symptoms (vertigo, tinnitus, poor exercise tolerance) of unknown origin, whose earlier assessments (resting ECG, Holter ECG) were negative for arrythmia.	IIa
Continuous (or event-based) remote ECG monitoring in patients with suspected atypical, nonatherosclerotic ischemic heart disease (eg, caused by vasospasm)	IIa
Continuous (or event-based) remote ECG monitoring in patients after transcatheter aortic valve implantation considered for early hospital discharge but at a higher risk of developing a conduction block	IIb
Continuous (or event-based) remote ECG monitoring to assess antiarrhythmic treatment effectiveness in case of discrepancies between the results of earlier assessments (resting ECG, Holter ECG) and the reported symptoms, which indicate inadequate treatment effectiveness	IIb
Continuous (or event-based) remote ECG monitoring to assess the safety of potentially proarrhythmic drugs (eg, antipsychotics, antidepressants, antineoplastic drugs, and some antibiotics)	IIb

Abbreviations: AF, atrial fibrillation; ECG, electrocardiography; ELR, external loop recorder; ILR, implantable loop recorder

patients, whereas 3-month remote ECG monitoring yielded this diagnosis in nearly one-third of the study population. Based on these results, the optimal duration of monitoring should be 30 days or longer, which is consistent with the American Heart Association/American College of Cardiology/Heart Rhythm Society (AHA/ACC/HRS) recommendations.⁴¹ However, it is important to note that in most cases, the diagnosis can be established after only a week of monitoring.^{10,42}

Technological advances in the field of mobile devices are associated with new functions of smartwatch-/smartphone-type devices. Their use helps identify patients with suspected AF. The Apple Heart study conducted in nearly 420 000 smartwatch users identified irregular pulse in 0.5% of the study population, and 34% of those were diagnosed with AF via a week-long continuous monitoring with PEMs.⁴³ However, the optimal duration of monitoring with smartphones/smartwatches has not been established,

and the prognostic significance of silent atrial fibrillation remains unknown. 13,22

Remote ECG monitoring is also the most effective tool for assessing whether ablation treatment for arrhythmia has been successful. 5.9.10,14-17,44,45 Although the optimal moment of recording initiation and its duration in such cases should be determined on an individual basis, the authors of the relevant recommendations suggest using remote ECG monitoring not earlier than 3 months following ablation and for anywhere from 1 to 4 weeks.

Remote ECG monitoring may be considered for identifying patients at risk of complex ventricular arrhythmia,³³ particularly those in the early post-myocardial infarction period, those with heart failure, hypertrophic cardiomyopathy, and arrhythmogenic right ventricular dysplasia.^{15,17,46} In those patients, remote ECG monitoring may provide decisive arguments for making the final therapeutic decision. The optimal monitoring duration in these patients should be at least 30 days, or shorter if arrhythmia is detected.

Remote ECG monitoring is also an effective diagnostic tool for syncope of unknown origin (eg, suspected cardiodepressive syncope, suspected paroxysmal arrhythmias/conduction blocks, suspected or diagnosed treatment-refractory epilepsy). ^{17,18} The optimal solution in patients with symptoms occurring less than once a month is ILR. ¹⁸ A meta-analysis of 5 randomized studies conducted in patients with syncope of unknown origin indicated ILR superiority over conventional diagnostic strategies with the use of external recorders, tilt testing, and electrophysiology studies. The use of ILRs increased the relative likelihood of establishing a diagnosis and was cost-effective. ^{47,48}

Remote ECG monitoring may be also considered in the assessment of patients with nonspecific symptoms, which could be caused by undiagnosed arrhythmias, conduction blocks, or ischemia. 17,31,49 The method is a useful tool for monitoring patients after structural heart procedures (eg, transaortic transcatheter aortic valve implantation), 50 for monitoring the effectiveness of antiarrhythmic treatments and the safety of proarrhythmic drugs (eg, selected anti-infectives, antidepressants, psychotropic agents, and antihistamines) and antiarrhythmic drugs of potential proarrhythmic effects, with a particular focus on bradycardia and tachycardia and QT interval assessment. 15,18,51

Key limitations of remote electrocardiographic mon-

itoring The most important limitation of remote ECG monitoring are ECG tracing artefacts, which are most commonly associated with body movements, poor electrode adhesion, conducting wire dysfunction, action potentials in skeletal muscles, and electromagnetic interference from

the environment. These artifacts may mimic arrhythmias, that is, produce pseudo-tachycardia, pseudo-bradycardia, or pseudo-pauses. These, in turn, lead to overdiagnosing (errors of commission) but also to underdiagnosing clinically relevant arrhythmias (errors of omission). Hence the warranted preference for at least 2-lead recordings, patient education, and selecting the remote ECG monitoring devices best suited to the particular patient's abilities and skill in using them.

It is important to remember that ECG recordings obtained via remote ECG monitoring do not have all 12 leads of the standard ECG, which is responsible for certain limitations of these methods in definitive diagnosis of the origin of some arrhythmias, such as wide QRS complex arrhythmias. Although long-term ECG recording is of limited use in the diagnostic workup of myocardial ischemia, the co-occurrence of documented signs of ischemia and characteristic clinical symptoms may call for invasive diagnostic procedures for myocardial ischemia.

Organizational aspects of remote electrocardiography monitoring The optimal solution is a 24/7 surveillance of recordings obtained via remote ECG monitoring. The head of the facility offering remote ECG monitoring should be a specialist in cardiology and have experience in analyzing long-term ECG recordings. Each facility offering such services should have protocols (approved by the head of the clinic/department/facility) for dealing with situations when a patient is at risk and a medical center has to be contacted immediately. These protocols should clearly define the scope of responsibility of the persons conducting ECG surveillance and be adapted to each specific ECG monitoring method.

Patient preparation for remote ECG monitoring should involve detailed training in the use of the recording device, proper adhesive electrode placement, and a preset ECG recording schedule. The forms of communication between the patient and the monitoring center as well as the management of health-related emergencies have to also be established. In life-threatening situations, the supervising personnel has to have the means of immediately notifying the patient and/or the patient's family and/or emergency medical services.

Remote cardiac implantable electronic device monitoring Remote cardiac implantable electronic device (CIED) monitoring involves a cardiac pacemaker or implantable cardioverter-defibrillator (ICD) whose functions allow for remote transmission of acquired data. These systems operate thanks to a transmitter (provided to the patient) that transfers data from the implanted device memory to the monitoring center via a telecommunications network. Moreover,

TABLE 4 Summary of the indications for cardiac implantable electronic device telemonitoring

Recommendations	Level
Regular reading of data from CIED memory to detect AHREs and, once detected, further ECG monitoring to document atrial fibrillation	I
Remote CIED monitoring in conjunction with conventional in-person visits at least once a year, suggested to patients (in particular, to those with heart failure and left ventricular ejection fraction ≤35% to improve prognosis) as an alternative to the traditional healthcare model	I
Remote CIED monitoring in all patients with an implanted CIED with at least one component under recall, where this component's malfunction may be directly life-threatening or cause a loss of an important functionality of the CIED	I

Abbreviations: AHRE, atrial high-rate episode; CIED, cardiac implantable electronic device

recent months saw an introduction of this functionality in mobile phones that can use Bluetooth technology to connect with the implanted device. In those cases, the patient does not need an additional transmitter for data transmission.

Current cardiac pacemakers and ICDs store data on battery status, electrode parameters, pacing effectiveness, detected arrhythmias, and selected parameters of the patient's condition, including the cardiovascular status. Depending on the system type, it may be possible to obtain periodic reports transmitted at predetermined time points (the transmission may be automatic or patient-initiated) or continually monitor the device, which involves automatic parameter assessment and alerting the monitoring center of any irregularities (eg, electrode failure, battery depletion, arrhythmia, ineffective pacing) (TABLE 4).

The frequency of transmissions and minimum scope of transferred data should be set individually, considering the clinical situation (stability of the patient's condition, frequency of treatment modifications, type of arrhythmias, rate of ICD interventions), CIED indications (primary or secondary prevention, pacemaker dependency), and CIED type (pacemaker, ICD, cardiac resynchronization therapy [CRT]). Data transmission should take place every 3 months (immediately in case of an alert), which is more often than direct follow-up visits at the monitoring center recommended by experts⁵² (every 3–12 months for cardiac pacemakers and every 3–6 months for ICDs). Additionally, annual in-person examinations at the specialist clinic are recommended to confirm correct device function, to check if the automatically measured pacing parameters are consistent with the measurements conducted by a physician, to update device settings, and to answer any patient questions.

The transmission should include basic information on the device's function, such as battery status, device settings, lead pacing and impedance parameters, as well as any detected arrhythmia episodes. The scope of transferred data may be subject to certain limitations due to structural constrains of the individual devices (which vary between manufacturers) and the technical

conditions of transmission. One very useful functionality that became available recently allows for transmission of intracardiac signal recording acquired via an ICD; this data transmission is initiated by the monitoring center. Once a connection is initiated, the transmission occurs nearly in real time (with a 2–3-minute delay, depending on the speed of transmission).

According to an HRS expert consensus⁵² supplementing patient care with remote CIED monitoring is superior to the model of care based solely on standard prescheduled in-person examinations. Remote CIED monitoring should be offered to every patient as part of routine care. An in-person visit at a specialist clinic where these devices can be assessed is recommended (depending on the clinical situation) within 2 to 12 weeks after device implantation, and once a year thereafter. The HRS consensus also emphasized the importance of remote CIED monitoring if any of the components of the CIED becomes subject to recall. In such situations, remote monitoring allows for early detection of any malfunction of the recalled component.

ESC recommendations stipulate that remote monitoring of CIEDs with an atrial electrode may help record atrial high-rate episodes (AHREs), some of which may be AF (TABLE 4). Detection of AHRE alone is insufficient to diagnose AF but may prompt active diagnostic efforts. According to guidelines, definitive diagnosis requires AF to be recorded in 12-lead surface ECG or an at least 30-second single-lead recording.²² The question whether AHRE detection in the device's memory is an indication for anticoagulant treatment in stroke prevention remains unanswered,53 therefore each case should be considered individually with respect to AHRE duration and thromboembolic risk. An estimated risk of stroke in patients with AHREs is lower than in those diagnosed with AF, and the co-occurrence of stroke and AHRE/silent AF is uncertain. 13,22 There are ongoing studies that assess the rationale of oral anticoagulant use in patients with an AHRE of 6 minutes or longer.54

In accordance with the IN-TIME (Implant-based Multiparameter Telemonitoring of Patients with Heart Failure) trial methods and

results (level IIb), ESC guidelines for the diagnosis and treatment of heart failure recommend the use of multiparameter telemonitoring of symptomatic patients via implanted ICD or CRT devices (TABLE 4). Remote monitoring has been also useful in heart failure patients with an implanted ICD or CRT device undergoing comprehensive cardiac rehabilitation, in order to assess the effects of rehabilitation. Second Seco

Remote CIED monitoring significantly reduces the time to medical intervention, both in the case of abnormal device function and in other emergency situations. 56,57 This practice showed benefits in the form of improved patient quality of life and reduced frequency of medical appointments due to heart failure exacerbation, arrhythmias, or ICD interventions.^{58,59} The ALTI-TUDE study⁶⁰ conducted in a group of remotely monitored patients with an implanted pacemaker, ICD, or CRT system showed the relative risk of death declined by 50% in comparison with that in nonmonitored patients. However, the randomized IN-TIME trial, conducted in patients with heart failure and an ICD or CRT device, the monitored group showed significantly reduced all-cause mortality and cardiovascular mortality.⁶¹ Similar results were shown in the EF-FECT (Remote Monitoring Improves Outcome after ICD Implantation: the Clinical Efficacy in the Management of Heart Failure) study. 62 These data indicate that remote CIED monitoring considerably contributes towards improving prognosis in patients with heart failure. Another benefit of remote monitoring is the significant reduction in the time needed to assess one patient at a specialist clinic. The mean duration of data transmission analysis is at least 2-fold shorter than that of a conventional device interrogation.63 However, importantly, the effectiveness of telemonitoring requires patients' rigorous adherence to the transmission schedule, a highly qualified monitoring team, and the use of advanced change-tracking algorithms. Inadequate control of these factors could have been the reason for the poor results of the study REM-HF (Remote Management of Heart Failure Using Implantable Electronic Devices), in which the advantage of CIED over standard care was not demonstrated in terms of total mortality and unplanned hospitalization due to heart failure.64

Introducing a system of remote CIED monitoring in Poland would require establishing telemonitoring centers staffed with suitably qualified personnel. The person assessing remotely acquired data should be experienced in managing patients with ICD and CRT devices, including being skilled at evaluating intracardiac electrograms. Remote CIED monitoring in Poland is currently at a pilot stage and is conducted at isolated university centers. The organizational aspects of remote CIED monitoring, requirements that have to be met by remote CIED monitoring

centers, or state-reimbursement criteria for this health service have not yet been conclusively established. Nonetheless, there are ongoing efforts to establish these parameters, which is likely to make remote CIED monitoring available in Poland as a service reimbursed from public funds. Currently, due to the COVID-19 pandemic, rapid introduction of remote CIED monitoring is especially important. It would help limit in-person contact between patients and healthcare professionals, and thus could significantly reduce the risk of infection.

Hybrid cardiac telerehabilitation Hybrid cardiac telerehabilitation is a form of rehabilitation that uses state-of-the-art data transmission technologies, which helps monitor and direct the patient's physical training at any location (within a mobile phone network range and/or internet access). Stage I of hybrid telerehabilitation is conducted in hospital or outpatient settings and typically lasts 1 to 2 weeks. Stage II (telerehabilitation) is conducted at the patient's residence at any location (within the range of a mobile phone network) and typically lasts 8 to 12 weeks.

The center conducting hybrid telerehabilitation should be equipped with a computer system (platform) that offers verbal contact with the patient; acquisition, analysis, and storage of data transmitted from peripheral devices; remote monitoring of peripheral device function, and remote correction of device function. The mobile peripheral device carried by the patient should allow for remote monitoring of appropriate parameters, verbal communication, and directing of the training session.

The monitoring mode (on-demand, automatic-sequential, or continuous) and the scope of monitored parameters depend on the type of rehabilitation and the patient condition (low, moderate, and high risk). 65 Verbal contact should be ensured with any mode and at any moment of telerehabilitation.

The minimum requirements for heart rate and/or ECG monitoring are:

- sequential recording, including the beginning and end of the defined training phase (warm--up, exercise, and cool-down; and the periods of exercise and rest in interval training),
- on-demand recording triggered by the patient or trainer (in case of concerning symptoms or specific circumstances).

On-demand recording should allow for loop recording. The monitored ECG recording should include at least 2 leads. Ideally, the following parameters can also be monitored: oxygen saturation, respiratory rate, body temperature, blood glucose levels (from a glucose meter), and physical activity (accelerometer, pedometer). Apart from the monitoring function, telerehabilitation requires a possibility to direct

Recommendations Level

Comprehensive hybrid cardiac telerehabilitation as a procedure equivalent to the conventional inpatient and / or an outpatient rehabilitation

the training sessions to help the patient complete the assigned individualized training program. The functionalities required for this purpose are:

- sound and/or light signaling of the beginning and end of the exercise phase and the beginning and end of the rest phase (for interval training) and
- sound and/or light signaling of failure to reach the desired heart rate acceleration or of exceeding the individually set maximum heart rate.

Hybrid telerehabilitation may be used as part of remotely monitored at-home rehabilitation programs, in low-, moderate-, and high-risk patients (eg, with heart failure, after heart transplantation). 66-68

The preferred form of physical exercise is continuous/interval walking training, optimally, Nordic walking, including a warm-up, exercise, and cool-down phases (TABLES). 65,69,70

Clinical indications and contraindications for telerehabilitation are the same as for conventional cardiac rehabilitation. However, essential qualifying criteria for telerehabilitation are the patient's consent and her or his ability to exercise alone and to cooperate remotely with the monitoring team. The condition required to initiate telerehabilitation is stable clinical condition (for at least 1 week in low- and moderate-risk patients, and at least 3 weeks in high-risk patients). 65

Telerehabilitation has not been shown to be dangerous. There were no reported deaths or noteworthy complications resulting from remotely monitored physical exercise. 65,70-73 The safety of at-home-based cardiac telerehabilitation depends on following the qualification requirements for such rehabilitation, observing contraindications to physical training, individualized planning of exercise sessions, patient education, and—every time prior to a training session—completing a special procedure to qualify the patient as fit for rehabilitation (based on assessing the patient's condition). 65

The COVID-19 pandemic made telerehabilitation the only possible intervention in many cases. Therefore, the European Association of Preventive Cardiology identified cardiac telerehabilitation as the optimal method of secondary prevention in the COVID-19 era. ⁷⁴

Mobile applications Mobile applications are the software installed in mobile devices (smartphones, tablets) or in external servers made accessible via mobile devices.

Applications for patients Mobile applications may serve as patient education tools or a way to store information on the patients' condition. Some devices may also facilitate contact with healthcare professionals, for example, in the form of videoconferences. Recent years saw the development of applications for patients, which help monitor their pulse with the use of the phone's LED and camera acting as an optical sensor. Some of these applications also have algorithms for detecting irregular heart rate, which may facilitate diagnosis of arrhythmias, including atrial fibrillation. Moreover, some smartwatches currently available on the market can record (single-lead) ECG and provide its automatic analysis, which may also contribute towards detecting arrhythmias.²² Nonetheless, further studies are required to determine the clinical usefulness of these solutions.

Ι

Applications for physicians One of the key types of applications for physicians are educational applications, which allow access to systematized sources of medical knowledge (eg, medical information sources, such as the established guidelines or summaries of product characteristics) and facilitate everyday practice (eg, medical calculators). There are also applications that record biological signals, such as motion (accelerometer), pulse, or electrical activity of the heart (ECG tracings).

Applications as medical devices If an application is used for diagnosis, treatment, or patient monitoring, or for disease prevention, it should be considered a medical device, and as such has to meet the requirements specified in the May 20, 2010, Medical Device Act. 75 Applications that serve as the basis for diagnostic and therapeutic decisions have to be obligatorily reported to the Polish Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products. This includes applications that use mobile devices for storing data acquired from sensors (ECG recording, electroencephalograms, eye movements, blood pressure, oxygen saturation), with the exception of educational applications, medical calculators, and devices used solely as a magnifying glass or sound amplifier, etc.

Other telemedicine solutions used in cardiology An online patient management system with the use of a wearable cardioverter-defibrillator Wearable cardioverter-defibrillators (WCDs), which are more and more accessible in Poland and worldwide, are capable of identifying

TABLE 6 Summary of indications for the use of tele-echocardiography and telemonitoring of hemodynamic and other clinical parameters

Recommendations	Level
A wireless hemodynamic monitoring system (CardioMems) in symptomatic patients with heart failure, previously hospitalized for this reason, in order to lower the risk of rehospitalization	IIb
State-of-the-art methods of invasive hemodynamic monitoring, such as measuring right ventricular pressure, left atrial pressure, and / or thoracic fluid content via transthoracic impedance (as a mobile device functionality) in individual cases of heart failure if the potential benefits of using these methods outweigh the risks associated with their use, and the outcomes of this form of telemonitoring are clinically verified.	IIb
Telemonitoring of the basic parameters of cardiovascular function (heart rate, blood pressure, body weight) and markers of treatment effectiveness in other chronic conditions (eg, capillary blood glucose in diabetes, respiratory function parameters) in patients in whom such telemonitoring may help improve these parameters.	IIb
Tele-echocardiographic examination in technically difficult cases (poor visualization, complex myocardial pathology) as part of scheduled teleconsultations if a remote assessment by a specialist may significantly affect further diagnostic and therapeutic decisions.	IIb
Tele-echocardiography as part of urgent teleconsultations in patients with a life-threatening condition (eg, acute coronary syndrome, acute aortic syndrome, cardiac tamponade) if a remote assessment by a specialist may significantly affect further diagnostic and therapeutic decisions.	IIb

life-threatening ventricular arrhythmias, such as ventricular tachycardia or ventricular fibrillation, and performing life-saving external defibrillation. 5,33,76 The use of WCDs may be indicated in several clinical situations involving patients after recent (<40 days) myocardial infarction and revascularization, with left ventricular ejection fraction of 35% or less, with myocarditis, with de novo heart failure, and potentially reversible causes of cardiomyopathy (peripartum, Takotsubo, heart failure in patients undergoing cancer therapy).⁷⁷

Telemonitoring with the use of a WCD involves a patient data management system (Life-Vest Network) that includes clinical and device function data, such as arrhythmia events leading to an intervention or those resolving spontaneously. The system allows for monitoring many WCD function parameters, such as WCD technical parameters, WCD malfunctions, and the number of hours the patient wore the WCD in compliance with the recommendations.

Tele-echocardiography Tele-echocardiography may involve recording echocardiography images and videos, their transmission to the monitoring facility in real time or at a later time, data analysis by teleconsultants, and transmission of their comments. This method may be useful for both elective and emergency assessments, ensuring specialist support in interpreting the echocardiography images of technically difficult patients (TABLE 6). Tele-echocardiography can be performed with the use of portable devices (point-of-care echocardiography). Also available are miniaturized pocket-sized echocardiography devices and smartphone-compatible echocardiography probes that can be connect with a smartphone via a micro-USB.

Hemodynamic monitoring Hemodynamic monitoring is particularly important in patients with advanced heart failure at high risk of

decompensation. Current ESC guidelines recommend ambulatory pulmonary artery pressure (PAP) monitoring with a special sensor (CardioMEMS heart failure sensor, Abbott Vascular) in symptomatic patients with heart failure previously hospitalized due to heart failure exacerbations (IIb) (TABLE 6). The CardioMEMS device is implanted into the pulmonary circulation, with a Swan-Ganz intravascular catheter used for its calibration. The device communicates with an external system, which allows for remote transmission of PAP measurements. The CHAMPION (CardioMEMS Heart Sensor Allows Monitoring of Pressure to Improve Outcomes in NYHA Class III Heart Failure Patients) study demonstrated the safety of this procedure, with PAP monitoring-based treatment helping reduce the rate of hospitalizations for heart failure exacerbations. 78,79 The MEMS-HF (the CardioMEMS European Monitoring Study for Heart Failure) study confirmed these observations, additionally noting the benefits of CardioMEMS PAP monitoring in terms of quality of life and symptoms of depression.80 Another invasive method-right ventricular pressure monitoring (Chronicle 9520, Medtronic Inc.)—to assess systolic and diastolic right ventricular pressure, the first derivative of right ventricular pressure (dP/dt), and an estimated diastolic PAP, which corresponds to the left ventricular filling pressure.81 Moreover, left atrial pressure monitoring (HeartPOD, St. Jude Medical, currently Abbott Laboratories) is considered a potential indicator of left ventricular volume overload and pulmonary congestion.81

Hemodynamic parameters may be also monitored with bioimpedance methods. Intrathoracic impedance (ITI) is one of the parameters that may be monitored via implantable devices—the lower the value of impedance between the electrode and device case, the higher the fluid

content of the evaluated tissue. 82 After over a decade of inconclusive studies on the prognostic usefulness of the parameters calculated based on ITI, there have recently been some encouraging reports. The PARTNERS HF (Program to Access and Review Trending Information and Evaluate Correlation to Symptoms in Patients With Heart Failure) study83 evaluating tissue fluid content monitoring with OptiVol/Care-Link (Medtronic, Inc., Minneapolis, Minnesota, United States) used a complex prognostic algorithm (based on ITI, heart rate, heart rate variability, AF burden, CRT pacing, ICD shocks, and patient activity), which helped predict the risk of hospitalization due to fluid overload within a 30-day follow-up. Similarly encouraging results were also reported by other authors.^{84,85} There have been also promising reports on the use of mobile devices in monitoring fluid status via noninvasive bioimpedance-based solutions.86-88

Monitoring of other clinical parameters Telemonitoring is also used to remotely monitor a number of parameters (typically measured automatically) associated with chronic diseases co-occurring with cardiovascular disease (blood glucose levels in diabetes, lung function parameters in chronic obstructive pulmonary disease or asthma, etc).⁸⁹⁻⁹⁰ These methods are usually well tolerated by patients, help achieve therapeutic goals, and increase patient health awareness and involvement in the treatment process^{89,91,92} (TABLE 6).

Legal aspects of healthcare services with the use of telemedicine tools The hallmark of telemedicine are situations where a healthcare service is being provided by healthcare professionals who, at that moment, are not at the same location as its recipients. 93-95

Currently, the legal basis for providing healthcare services with the use of teleinformation technologies in Poland is the Medical Activities Act (UoDzL), 96 article 3 item 1 of which reads "Medical activities involve providing healthcare services. These services may be provided via teleinformation or communications systems". Teleinformation tools or communications systems may be also used to promote healthy behaviors, achieve didactic goals, and foster research, including introduction of new medical technologies and treatment methods (UoDzL, article 3 section 2 items 1-2).96 Currently, the law permits providing health services with the use of teleinformation tools, not only in hospital settings but also in outpatient settings (UoDzL, article 24 section 2a).96

An amendment to Medical and Dental Practitioners Act has permitted the use of teleinformation means of transmission for the diagnosis, treatment, and rehabilitation purposes. According to Medical and Dental Practitioners

Act of December 5, 1996 (article 42 section 1) 3 "A medical practitioner provides an opinion on the health condition of the given individual after examining that individual in person or via teleinformation or communications systems." The use of teleinformation tools over the course of treatment is also mentioned in the Medical Code of Ethics, 97 article 9 of which reads "[a] medical practitioner may undertake treatment only after examining the patient. This does not apply to circumstances where medical advice can be only provided remotely," and the decision on whether the service may be provided remotely is always at the discretion of the medical practitioner and cannot be influenced by subjective opinions of other parties. Nonetheless, telehealth services has to involve patient assessment in the form of obtaining a medical history.

The option of providing healthcare services with the use of teleinformation means of transmission may also help minimize health risks in the period of epidemiological threat or an epidemic, such as the COVID-19 pandemic. The decision to provide a healthcare service with the use of teleinformation technologies or other communications systems is always at the discretion of the medical practitioner, who makes the initial assessment of the patient's condition, current needs, and other parameters that are significant to ensure appropriate treatment. In the case of patients who receive treatment remotely, the medical practitioner is obligated to inform the patient of the necessity to visit a doctor or emergency room if their condition worsens or in situations requiring direct (in--person) doctor-patient contact.

Offering remote healthcare services is associated with transmission of patients' personal data, including data on patients' health status. Article 4 section 15 of the 2016/679 Regulation of the European Parliament and Council on the protection of natural persons with regard to the processing of personal data and the free movement of such data (further referred to as GDPR [General Data Protection Regulation]) from April 27, 2016, reads: "data concerning health' means personal data related to the physical or mental health of a natural person, including the provision of health care services, which reveal information about his or her health status." The GDPR requires data encryption or pseudonymization and implementing appropriate measures to ensure ongoing confidentiality, integrity, availability, and resilience of processing systems and services, as well as regular testing, assessing, and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing. Healthcare professionals are allowed to use for their remote work tools and materials that were not provided by the employer; however, this is conditioned on respecting and protecting confidential information and other legally protected secrets.

Summary Telemedicine is a rapidly developing form of medical activity and part of medical industry, with advanced technologies already available in Poland, notably, along with substantial involvement of domestic capital and engineering ideas.

Cardiology is one of the fields where telemedicine methods were pioneered and introduced into everyday practice. Some of these methods have already become standard procedures for diagnosis and treatment in some Polish centers, with other ones soon to follow. Clinical study results not only demonstrate reliability and usefulness of telemedicine technologies, but also show that their use in clinical practice improves the patients' prognoses and quality of life, including improved patient survival (in the case of telemonitoring in patients with an implanted CRT device). Moreover, study results in highly developed countries show a potential cost-effectiveness of telemedicine from the perspective of healthcare systems. 98,99 Such cost-effectiveness is due in part to the provision of specialist care to multiple persons simultaneously, optimizing the use of time by the personnel of high-level referral centers, and effective coordination of the diagnostic/therapeutic process.

Currently, the most important limitation to the use of telemedicine in Poland is the lack of state reimbursement for most telemedicine procedures and no coherent, standardized system for providing remote medical services, with the only exceptions being teleconsultations and hybrid telerehabilitation. There is an unquestionable need to establish clear rules for telemedicine use in Poland, which would ensure their high-quality and adequate funding.

The variety of uses for modern telemedicine technologies presented in this paper shows the validity of the phrase "disease telemanagement," which refers to a commonly accessible, well-coordinated, comprehensive healthcare system, that integrates all levels of healthcare. ¹⁰⁰

This paper includes both the commonly available solutions and those that are expected to develop rapidly in the near future. The indications for the use of telemedicine are expected to progressively expand in scope. However, we would like to emphasize that the development of this aspect of cardiology requires specialist supervision and documenting clinical usefulness of telemedicine solutions in robust research studies.

SUPPLEMENTARY MATERIAL

The Polish version as well as the extended Polish version of the paper are available at www.mp.pl/kardiologiapolska.

ARTICLE INFORMATION

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