Digital Healthcare in Germany: An Overview

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Digitalization is also referred to as the "industrial revolution" of the twenty-first century. In many industries, it has been introduced in routine processes, although it is not yet "common practice" in the healthcare sector. Legal and technical prerequisites exist, but what exactly is the current state of digital possibilities in the healthcare sector in Germany?

The term digitalization can be defined in many ways. On the one hand, the term stands for the digital conversion and representation of information. On the other, digitalization is also often associated with the process of digital modification. It is also credited with the major benefit of improving the speed of communication channels (Cf. Deckert 2019, p. 7 f). Digitalization is spreading across various sectors and is also increasingly affecting the provision of healthcare. Due to the diverse interests of various players, this is proving to be a complex process. Challenges include the digitalization of documents and the processing of large volumes of data. The opportunities presented by the expanding process of digitalization can be seen in the context of innovations and new technologies. Important considerations here are adaptations to legal framework conditions, but also reforms. The expansion of digitalization also creates the possibility of designing new healthcare services, for which active co-design by the patient is a fundamental criterion (Cf. Da Cruz et al. 2017, p. V f).

If we now consider the concept of digitalization in healthcare, we can say that digital healthcare encompasses various areas. On the one hand, it creates new diagnostic and treatment options, such as personalized medicine, and on the other,

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Table 1 Areas of digital health and explanations

Digital health area	Explanation
Artificial intelligence (AI)	AI learns from digital health data and can recognize patterns. This can help doctors in diagnostics and decision-making
Big data	As a result of the digitalization of healthcare, the amount of data is rapidly growing. This data can be used to detect the risk of diseases earlier. Personalized healthcare is also based on big data
Telemedicine	Telemedicine uses modern communication solutions for the purposes of remote monitoring, diagnostics, and therapy. It facilitates care in rural areas (for example in the application of video consultations)
E-health	This term covers all applications that use new information and communication technologies in the provision of medical care, for example the electronic health card
Robotics	Robot-assisted procedures can be used in the operating room and in nursing care; they are mainly used as assistance systems

Source: author's own representation based on PricewaterhouseCoopers GmbH (n.d.)

it enables easier communication among the individual players in the healthcare system. In addition, individual patients can take greater control of their health, for example through apps. Digitalization in the healthcare sector creates the opportunity to counteract the shortage of skilled workers and significantly relieve the burden on doctors and nurses in areas such as administrative activities and documentation, diagnostics, and everyday practical activities (Cf. PricewaterhouseCoopers GmbH n.d.). The different areas of digital health are presented in Table 1.

Due to demographic changes in society, the number of elderly and people suffering from chronic diseases and multimorbidity is growing. This is increasingly becoming a challenge in the healthcare sector, because an aging society makes greater use of medical services. Other existing challenges are the shortage of skilled workers in the nursing and medical professions and underuse of medical services in structurally weaker regions.

However, because the German healthcare system is characterized by an innovation-inhibiting structure and financial imbalance, the digital optimization of operational processes and care innovations is consequently also made more difficult. This is also shown by the DIGITAL Economy Index of the German Federal Ministry for Economic Affairs and Energy (BMWi), which measures sector-specific progress in digital transformation. Here, the German healthcare sector performed comparatively poorly in 2018, scoring 37 out of 100 points (Cf. Pfannstiel et al. 2020, p. 254). The Healthcare Information and Management Systems Society (HIMMS) also came to similar conclusions. In its Analytics Electronic Medical Record Adoption Model (EMRAM), which measures the digitalization of institutions on a scale from zero (no digitalization) to seven (paperless hospital), German hospitals scored only 2.3 in 2017. They are thus significantly below average in terms of digitalization compared with other countries (e.g. Denmark 5.4, Turkey 3.8) and the European average (3.6) (Cf. Klauber et al. 2019, p. 17 ff).

Up to now, digital isolated solutions have prevailed in the German health care system, preventing interdepartmental networking. This is set to change with the expansion of the telematics infrastructure. At the end of 2018, a wake-up call went through Germany when the Bertelsmann Foundation's highly regarded Digital Health Index provided evidence of how far Germany lags behind other countries in terms of digitalisation: It ranked 16th out of 17 countries compared, with only Poland scoring lower. Since then, however, a lot has happened in the digitisation of the German healthcare system. The Federal Ministry of Health, health innovation hub, gematik, the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung) and leading health insurance funds have initiated, driven forward and implemented many reform projects in recent years. Since the end of 2017, doctors' and dentists' surgeries have been successively equipped with the necessary technology to guarantee a fast and secure exchange of relevant patient data. The introduction of the "app on prescription" and the associated remuneration of digital health applications (DiGA) will in all likelihood stimulate patient demand for electronic health aids. McKinsey's eHealth App Barometer, which measures app usage based on download figures, shows how dynamically the market for health apps is developing in Germany: At the first peak of the Covid-19 crisis in the first quarter of 2020, health apps and services came to almost two million downloads—a doubling compared to the same period last year.

At first glance, the connection of doctors to the telematics infrastructure seems to be progressing rapidly: According to expert estimates, 85% of all physicians in private practice and 98% of all dentists now have the technical prerequisites. However, the scope of use still leaves much to be desired—the practices currently only transmit patient master data. A broader exchange of information would require the introduction of comprehensive standards across the board, but these have only existed in part so far.

Nevertheless, digitalization is becoming increasingly important in healthcare. This applies in particular to the exchange of data and information among all those involved in a patient's treatment. Communication between doctor and patient is also being transformed by digitalization. For this reason, the term telemedicine is closely linked to digital healthcare. This may refer, for example, to video consultations, which are becoming increasingly common. However, outpatient digital care includes other methods of supporting medical care. For example, the Digital Care Act (DVG), which came into effect on December 19, 2019, explicitly includes the use of health apps, among other things. The term ambulatory digital care thus describes all digital measures that support ambulatory care.

Digital expansion in the healthcare sector is accompanied by high costs and is therefore associated with increasing cost pressure. At the same time, however, it represents an opportunity to create new business models (Cf. Dachtler et al. 2017, p. 241 f). New approaches and solutions must be established above all for immobile and high-risk patients and in rural areas, where there is a lack of (specialist) medical care. The opportunity for better healthcare lies primarily in digital care structures and digitalization. A study conducted by the Bertelsmann Foundation in 2018 analyzed how actively the healthcare policies of different countries are acting on

digitalization. Of the 17 countries surveyed, Germany came in 16th place. An international comparison therefore shows that German healthcare policy has a lot of catching up to do in terms of expanding digitalization.

Furthermore, the problem of the increasing shortage of nursing specialists is already widely known in Germany. As of August 30, 2020, the number of people in need of care was 3,414,378 (Cf. Gesundheitsberichterstattung des Bundes 2020), and this number will continue to rise in the future. According to forecasts by the German Federal Statistical Office (Destatis), up to five million people will be in need of care in 2025. At the same time, there are fewer and fewer caregivers to look after such people. In 2025, there is expected to be a shortfall of around 500,000 care professionals (Cf. Heeser 2020, p. 10). At the same time, increasing digitalization is making itself felt in all areas. Healthcare players—doctors, clinics, practices, and patients—are already having to deal with many digital innovations (Cf. Deutsche Gesellschaft für Orthopädie und Unfallchirurgie n.d.). These digital innovations, as well as assistive technologies, offer great potential benefits for the healthcare sector (Cf. Elmer 2017, p. 23). For example, the shortage of skilled workers described above could be countered by using new solutions that relieve staff of time, physical, and informational burdens. In addition, modern nursing aids can not only support staff but also increase the attractiveness of the nursing profession (Cf. Graf 2019, p. 20).

The latest point at which the "app on prescription" for patients was introduced into healthcare was when the DVG came into force, thus laying an important foundation stone for advancing digital healthcare in Germany. As a result, around 73 million people insured under the statutory health insurance scheme are entitled to the provision of digital health apps. These can be prescribed by doctors and psychotherapists, for example, and are then reimbursed by the health insurer of the patient.

For this reason, German policymakers are striving to expand the digitalization of the healthcare system by, among other things, providing and expanding a secure infrastructure for digital care through the Gesellschaft für Telematik (Society for Telematics), and by strengthening and promoting digital care structures, for example through new legislation. As a result of the DVG, for example, the areas of "electronic patient records," "health apps," and "video consultations" in particular have been strengthened and integrated into everyday care. Digital healthcare structures, which have so far been underutilized in Germany, are therefore currently becoming increasingly important in nationwide healthcare provision.

The following provides an insight into some lighthouse projects in digital care. Because medical care in Germany is divided into outpatient and inpatient care, the following examples are divided accordingly. Outpatient care includes all treatment services that are provided without an overnight stay in a clinical facility. Inpatient care involves staying in a hospital for medical treatment and is provided if the treatment goal cannot be achieved on an outpatient basis.

1 Outpatient Care

Telemedicine is already being used, predominantly in funded pilot projects and individual cases. Legal framework conditions have already been created for this in the DVG. The application areas of telemedicine can support both the physician and non-physician nursing and medical staff in their activities. In addition to the DiGA (digital health applications) process (see chapter "Inpatient Market Access for Digital Health"), there are other options in the outpatient care sector that can be used to introduce digital care solutions, especially if they are not a DiGA, into the German healthcare market.

1.1 The Innovation Fund (IF)

The IF was adopted in 2015 with the Act to Strengthen Care in Statutory Health Insurance (GKV, Versorgungsstärkungsgesetz) and came into force in 2016. The overarching goal of the IF is to further develop the quality of care provided by the statutory health insurance (SHI) system. To achieve this goal, the IF's funding is divided into two areas: forms of care and care research. On the one hand, the funding is intended to support new forms of care in SHI that go beyond standard SHI care and have the potential to be included in care on a permanent basis. On the other hand, financial support is to be given to new research projects aimed at gaining knowledge to improve existing care (Cf. Hecken 2017, p. 462). The funds for the IF come from the liquidity reserve of the Health Fund and the statutory health insurance funds and, accordingly, indirectly from the contributors to SHI (Cf. Pollandt 2017, p. 466 f). From 2016 until 2019 inclusive, 300 million euros was made available annually, 80% of which was for new forms of care and 20% for health services research (Cf. Gemeinsamer Bundesausschuss Innovationsausschuss 2020, p. 1 ff). Because only a few IF projects have been completed so far, it is not yet possible to conclude the extent to which the IF project results will ultimately find their way into standard care.

The decision-making body for the IF's funding decisions is the Innovation Committee (IA, Innovationsausschuss). This is composed of three representatives of the GKV Spitzenverband (National Association of Statutory Health Insurance Funds); one representative each of the Kassenärztliche Bundesvereinigung (National Association of Statutory Health Insurance Physicians), the Kassenzahnärztliche Bundesvereinigung (National Association of Statutory Health Insurance Dentists), and the Deutsche Krankenhausgesellschaft (German Hospital Federation); the impartial chairman of the Federal Joint Committee (G-BA); two representatives of the Federal Ministry of Health; and one representative of the Federal Ministry of Education and Research. In addition, two patient representatives sit on the IA, but they have no voting rights, only the right to submit proposals and to participate in consultations. The IA determines funding priorities and criteria for the allocation of funding from the IF. On this basis, applications for funding can be submitted, and the

IA decides whether the project in question should be funded. A majority of seven votes is required to pass decisions by the IA.

One example of digital care that was supported by the IF and is now to be transferred to standard care is the Telenotarzt (remote emergency doctor service) in Bavaria. The goal of the Telenotarzt Bavaria project was to optimize emergency care in a rural region. Here, the emergency ("Telenot") physician supports the rescue service from a distance during call-outs. The patient's vital signs are measured on site, transmitted from the ambulance to the emergency physician, and immediately analyzed by him or her for diagnosis and initial treatment. This means that the patient's treatment can begin sooner. Because emergency medical services are regulated by state laws, the findings obtained are forwarded to the health ministries of the federal states. These ministries will decide whether the Telenotarzt concept can be usefully established in their federal state and whether existing state laws governing rescue services may have to be reformed for this purpose. The project was approved for transfer to standard care by the Joint Federal Committee on December 18, 2020.

1.2 Selective Contracts

Like collective contracts, selective contracts are independent forms of contract in the healthcare system. However, whereas collective contracts in the outpatient sector are concluded between the associations of health insurers and the associations of SHI-accredited physicians, selective contracts are concluded directly among individual service providers (physician, hospital, pharmaceutical company, etc.) and one or more health insurers. Health insurance funds can conclude selective contracts in the following circumstances:

- model projects (§§ 63 ff. SGB V [German Social Code, Book 5])
- the Disease Management Program (§§ 137 f. SGB V)
- special care (§ 140a SGB V) such as integrated care.

As a result, insured persons have access to treatment options to which they would not be entitled without a selective contract. Thus, contracting between health insurers and service providers promotes innovation in the healthcare system and strengthens competition among health insurers (Cf. Müller 2015).

The following examines the selective contract "Telemedicine Heart," which was concluded between the health insurance fund Techniker Krankenkasse and the Robert Bosch Hospital in Stuttgart and the company Phillips. Within the framework of a telemedical program, insured persons diagnosed with heart failure are individually monitored and looked after for 1 year. This offer is not considered a substitute for personal doctor–patient contact, but as a useful supplement to it. Since July 2017, 333 participants have completed the program, while 281 participants are still in ongoing care.

The patient uses a tablet to carry out daily monitoring of his or her health values and transmits them to the telemedicine team at Robert Bosch Hospital. There, the data is monitored by specialists who are also available as contact persons and who contact the insured person in case of abnormalities. The attending physician can obtain information about the patient's state of health from the Robert Bosch Hospital at any time and optimize the therapy accordingly. In addition, the tablet regularly offers training videos that are adapted to the patient's particular health situation. This provides additional information and support for outpatient treatment.

An evaluation of the selective contract was planned for the end of 2020. This means that there will be a performance audit in which the costs and benefits are analyzed by the health insurer. The Joint Federal Committee also examines the benefit provided by this care by means of a method evaluation. If the cost–benefit assessment is positive, this form of treatment can be included in the standard care provided by the health insurance funds.

Another selectively contracted digital care option is the "TeleArzt-Rucksack" (tele-doctor backpack). The project is described as a supportive, telemedical, and general practitioner (GP) delegation model. In the future, the project is expected to cross sector boundaries between care facilities and outpatient home-based care, leading to an improvement in care. The provision of competent telemedical care as a combination of documentation aids, video technology, and measuring devices creates a care solution that represents a new form of treatment.

The TeleArzt-Rucksack is equipped with six sensors:

- telemedicine pulse oximeter
- telemedicine spirometer
- telemedicine blood-pressure monitor
- telemedicine blood-glucose meter
- telemedical vitaphone 3-channel electrocardiogram
- telemedicine personal scale.

The equipment in the TeleArzt-Rucksack enables the medical assistant (Mfa)—who must undergo additional training—to measure the patient's values directly at home and transfer them to the doctor's systems using a tablet. If necessary, it is also possible to use a tablet included in the rucksack to conduct video consultations with the primary care physician, for example to discuss medication or fill out questionnaires. The aim of the project is to increase capacity by improving efficiency and quality in outpatient primary care.

The TeleArzt-Rucksack is already in use in 12 of 19 Kassenärztliche Vereinigung (KV, Association of Statutory Health Insurance Physicians) districts. Thuringia was the first federal state to make the care model available statewide. The first telemedicine area contract in Germany was signed in April 2018 between the general local health insurance fund AOK PLUS and KV Thuringia. Techniker Krankenkasse in Thuringia is also the first major substitute health insurer to honor the TeleArzt. In Lower Saxony, the TeleArzt has been used in the city of Gifhorn since mid-2019. The pilot phase of the project was completed in November 2018 and received a positive evaluation from GPs, the Lower Saxony KV, politicians, and the AOK. The

contribution made by the TeleArzt-Rucksack convinced the Lower Saxony AOK to include the project in their service catalog. The parties mentioned above decided to continue and expand the project in Lower Saxony. Likewise, the state government of Lower Saxony sought an extension to 2021 if the project continues to prove its worth. The Lower Saxony health regions will provide financing in the region of 80,000 euros until the end of 2020. It is not only family doctors who benefit from using the TeleArzt-Rucksack. The MfA, who provides home visits instead of the doctor, also profits from this project. It facilitates the documentation of service providers, because the transmission takes place automatically. The MfA can also take on additional tasks, such as wound documentation, and, in the event of abnormalities, can be put in touch via teleconsultation with the doctor, who will assess the clinical picture (Cf. Vitagroup AG 2020a).

The state government in Thuringia decided on a funding program and has been supporting physicians in the procurement of TeleArzt rucksacks since April 1, 2019. The TeleArzt is also being used by the state government in Schleswig-Holstein to support telemedical care there (Cf. Vitagroup AG 2020b).

2 Inpatient Care

In general, hospital services are differentiated according to Section 39 of the German Social Code, Book V (SGB V) into full and partial inpatient services, pre- and post-inpatient services, and outpatient operations. The remuneration of elective services is based on a separate contractual agreement between the hospital and the patient (Cf. GKV Spitzenverband 2019). The DRG (Diagnosis-Related Groups) system according to Section 17b of the German Hospital Financing Act (KHG, Krankenhausfinanzierungsgesetz) forms the basis for the financing of full and partial inpatient services. Further legal regulations for individual variants of remuneration can also be found in the Hospital Remuneration Act (KHEntgG) and in the flat rate per case agreement of the self-governing partners (Cf. Bundesministerium für Gesundheit 2020). The DRG system is a patient classification system and forms the core of the payment system for inpatient services.

In hospitals, the principle of "permission with prohibition" applies, i.e. in principle, examination and treatment methods (NUB) can be used as long as they have not been excluded by the G-BA according to § 137c SGB.

The financing of investments in recent years has declined, resulting in an investment backlog of at least 30 billion euros. An investment gap of almost four million euros is created each year. As a result, urgent investments—for example, in buildings, medical technology, and digitalization—cannot be made. Due to the withdrawal of funding by the federal states, hospitals often have to finance the investments themselves. This is done with the help of loans or via internal financing, in which hospitals increase revenues for given operating costs or try to save on personnel and material costs for given revenues.

Various regulatory options are available to fund digital health solutions in the inpatient setting, which are introduced in detail in chapter "Inpatient Market Access for Digital Health". These regulations include the Hospital Futures Act for the digitalization of hospitals, which is an investment program designed to counteract the investment backlog. Additionally, under Section 68a of Book V of the SGB, health insurance funds have been given the opportunity to participate directly in the promotion of digital innovations. Under the Act, they can either:

- participate in a development in cooperation with manufacturers of medical devices, companies from the field of information technology, research institutions, and service providers and communities of service providers, or
- acquire shares in the investment fund.

Thus, health insurers have been given the opportunity to promote and finance new innovations in collaboration with hospitals.

Examples of advancing digital care in inpatient facilities can be found in many processes, including:

- voice recognition systems that patients can use to call a nurse or lower blinds in their rooms
- inpatient wristbands with an embedded chip or a printed code.

In the latter example, if a mobile patient has an appointment for an electroencephalogram (EEG), he or she can "check in" at a terminal using his or her wristband. This automatically notifies the EEG department staff that the patient is in the waiting area. The EEG findings, documents, and doctor's letters are stored digitally for each new patient and are thus available to all parties involved at any time or place (electronic patient file).[9]

According to studies, 5–10% of all hospital patients receive the wrong medication during their stay. The electronic patient record (ePA) and associated systems are therefore intended to make hospital treatment safer for patients. Closed Loop Medication Management (CLMM) refers to a closed loop in which all steps of the medication prescription process are digitized (Cf. Maier 2020, p. 19). The Hamburg-Eppendorf University Medical Center (UKE) is considered a pioneer for introducing this particular medication process. The UKE is one of the most modern university hospitals in Europe and in 2011 was the first European hospital to receive the highest possible score (7.0) in EMRAM for having introduced a completely digital patient record. The project to introduce the ePA also included the conversion of drug supply from traditional ward cabinet logistics to a patient-oriented unit-dose procedure, which is a part of the CLMM. The unit-dose process makes solid drugs available for oral use in individual packages. For this purpose, the previously handwritten medication plans were replaced by digital plans, and a closed medication process, the so-called closed loop process, was established.

Doctors and scientists at Freiburg University Hospital (UKF) have been researching for years how intelligent programs can support the work performed in clinics. One example of their research can be found in the evaluation of microscope images, which are crucial for many diagnoses. In the Department of Ophthalmology

at the UKF, microscopic images of the endothelial layer, a wafer-thin layer of cells in the eye, must be viewed regularly. The endothelial cells keep the cornea in the eye transparent by continuously pumping water out of the cornea. However, when the cells die, the cornea becomes cloudy. For this reason, the endothelial cells must be counted regularly to determine the right time for treatment. For a long time, physicians counted the cells by hand, which was both time-consuming and prone to error. The evaluation is now done by a self-learning piece of software, which was developed by the team at the eye clinic. The software has been trained on hundreds of hand-counted images and can now provide an evaluation of the microscopic images within a few seconds. This frees up physicians' time for other activities and reduces the error rate tremendously. In addition, the software can be used in future studies to examine significantly more images than before, which will make these studies more precise (Cf. Universitätsklinikum Freiburg 2019, p. 18).

Other examples of the advancing digitalization at the UKF can be found in the areas of training and surgery planning. In the urology outpatient clinic, students practice catheter placement on a model during their internship. Augmented reality (AR) glasses support the students' learning. The AR glasses contain a tiny camera that detects what is in the user's field of vision. Helpful tips and information on the next step of catheter placement are then displayed on the semi-transparent lens. Virtual reality is also used in surgery planning. Surgeons can, for example, use a 3D model to practice hand movements before operating on the brain (Cf. Universitätsklinikum Freiburg 2019, p. 27) or "play through how best to work their way between blood vessels and sensitive structures to a tumor" (Universitätsklinikum Freiburg 2019, p. 28). Practicing can make even the most difficult operations safer for the patient (Cf. Universitätsklinikum Freiburg 2019, p. 28).

Financing of digital medicine in the inpatient sector can be realized within the framework of dual hospital financing, provided that the hospital is included in the hospital plan of the state. Further details are included in chapter "Inpatient Market Access for Digital Health".

The financing of digital care in nursing homes requires the involvement of the nursing care insurance funds, e.g. for the purchase of digital aids. The fact that digital aids are financed via individual insurance benefits—i.e. the nursing home can use the devices for only one resident—is seen as an obstacle to the spread of technical aids. To date, the following options exist for refinancing digital care:

- funding under the Nursing Staff Strengthening Act (PpSG, Pflegepersonal-Stärkungsgesetz)
- entitlement within the framework of the catalog of aids
- telecare/telemedicine reimbursement
- robotics reimbursement.

In accordance with Section 82 of the SGB, Book XI, care facilities receive a so-called care allowance, which is used to remunerate general care services as well as a fee for room and board. The care allowance is also known as the care rate. The care allowance is paid by the person in need of care or their cost bearer, while the fee

for room and board must be paid by the person in need of care themselves. The care-rate amount is determined by the care-rate agreement concluded between the facility operator and the cost bearers. Performance-related nursing rates are to be assessed according to uniform principles for all residents of the home. "Performance-related" means that the nursing rates are adjusted according to the respective degree of nursing care (Cf. §82 and 84 SGB XI). In addition, the nursing facility is allowed to charge separately for capital expenditures required for operations or for rent, leases, etc (Cf. Braeske et al. 2019, p. 36 f). The so-called training levy is intended to equalize the costs of training between facilities that train a lot and those that train less. In 2020, the training levy in each full inpatient care facility was €1.25/day (Cf. KVJS (2020, n.d.).

Case conferences in nursing can now also take place via video. Previously, they could already be conducted with nursing homes if a cooperation agreement existed for the insured person (Cf. Kassenärztliche Bundesvereinigung 2020). They can be billed by the attending physician or psychotherapist three times per treatment case in accordance with the standardized assessment scale (EBM). Only the physician or psychotherapist who initiated the video case conference receives a technology surcharge.

To acquire the systems and necessary technical equipment for conducting video case conferences, the care facility can take advantage of funding under the Nursing Staff Strengthening Act. In 2018, the Nursing Employers' Association called for telecare to be included in the standard provision of nursing care and recommended that the legislature include existing telecare projects in the SHI benefits catalog.

The new introduction of Digital Care Applications (DiPA), which are to be financed by the Social Care Insurance, is also planned. The Federal Institute for Drugs and Medical Devices (BfArM) will be given responsibility for a procedure to check the reimbursability of DiPA; it is also to set up a DiPA directory as a web portal. The procedure will be set up on two tracks, in alignment with the DiGA procedure, in order to allow both permanent and provisional inclusion of a DiPA in the directory."

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