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Policies on Electronic Health Record Implementation in Iran: A Documentary Analysis

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Abstract

Background: Electronic health records play significant roles to increase the effectiveness, and efficiency of health system services by creating transparency, decreasing the use of unnecessary services, decreasing medical errors, helping health research, etc. Throughout the years, several laws and regulations regarding electronic health records have been enacted. This research intended to examine Iran's electronic health record implementation policy.

Methods: This study was conducted within the framework of Walt and Gilson's policy analysis triangle. The researchers reviewed Persian and English articles, reports, and studies on electronic health records in Iran from 2001 to 2022 to collect data. The reports of organizations such as the Majlis Research Center, Iran Health Insurance Organization, Social Security Insurance Organization, and Ministry of Health were also studied within the format and framework of Walt and Gilson's policy analysis triangle.

Results: The examination of upstream documents and articles in "policy content" dimension indicated unrealistic and different schedules, the lack of a clear strategy, and proper planning. Furthermore, the main actors of electronic health records included the Ministry of Health, The Information Technology Executive Council, Supreme Council of Health Insurance, the Iran Health Insurance Organization, medical insurance organizations and funds, the Iran Medical Council, health, diagnostic, therapeutic, and pharmaceutical centers, the information technology service companies, as well as people. The contextual elements impacting policy are in three categories, including cultural-social, economic-financial, and political-executive, which have been identified with several impediments to the deployment of electronic health records. The policy process has also faced many challenges in the implementation and evaluation of the policy in a way that after 17 years of the approval of legal decrees due to the electronic health, the implementation has not been based on the assigned tasks and has not been approved by the supervisor.

Conclusion: The electronic health record was considered by focusing on the priority of starting from the family medicine program and the referral chain in the upstream documents, and it was not fully used in Iran's health service provision system still after 17 years. Designing a roadmap, which is confirmed by key stakeholders, clarifying the task of each stakeholder, allocating proper budgets, and paying attention to the infrastructures are the key strategies for a more successful implementation of the electronic health record program.

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Highlights:

What is current knowledge?
After more than 17 years, Iran's health system still does not have an efficient electronic health record, and this issue needs comprehensive investigation.

What is new here?
Adopting a single policy with the support and participation of various stakeholders in the design and implementation of the electronic health record and the appropriate budget allocation can play an essential role in the success of the electronic health record.

Introduction

The health systems are working with the aim to improve public health, along with the financial protection for people and responding to public expectations and needs all over the world. The World Health Organization (WHO) report in 2000 introduced the service provision system as the main function of health systems and a bridge between society and health system (1). As a requirement, health systems must be able to offer services efficiently and effectively and have prompt access to information (2). An electronic health record is a tool for the electronic collection of information during a person's lifetime, registered by healthcare providers, and it is accessible at all levels of care (3). Electronic health records do not have the inherent limitations of paper records (physical storage, the lack of easy access to information at any place and time, etc.) which can play an important role to fulfill the needs of the health system of any country by processing reliable data into the usable information (4). WHO considered the information system an important requirement to achieve the objectives of universal health coverage in 2016 and emphasized that paying attention to electronic health, including electronic health records, was an essential part of any strategy, and the most important program to create development in the health system in the 21st century (5-6) Even though the electronic health record offers many benefits, there have always been obstacles that have prevented its full deployment. The most significant obstacles are those related to cost, technology, and attitudinal-behavioral restrictions (7). The need for the comprehensive investment in infrastructure, and training and preparing users to participate and accept it are among the requirements for the implementation of electronic health records (8). Creating of a comprehensive health information system for Iranian citizens was considered in Iran since 2004 in Clause (e) of Article 88 of the Fourth National Development Plan, along with the family physician program and referral system (9), and it was formulated in October 2007 with the focus on the creation and use of electronic health records, and the Ministry of Health and Medical Education became responsible for its implementation (10). The formation and implementation of electronic records have been stressed in the fifth and sixth development plans, as well as the budget plan legislation of 2019, 2020, and 2021. Throughout these years, the Iranian health system has often devoted particular attention to electronic health records (11). Policy analysis with a look at the past seeks to determine how a policy enters the agenda, what its content is, how it is implemented, and whether it has achieved its goals (12). A successful policy change needs systematic and continuous polity analysis (13). Therefore, policy analysis and explanation of the roles of contextual factors, content, process, and electronic record policy actors can contribute to a more successful

implementation of plan. Hence, the present study aimed to analyze the electronic health record policies in Iran using the policy analysis triangle method.

Methods

The present study analyzed the electronic health record policies within the framework of Walt and Gilson's policy analysis triangle using a retrospective method and based on studying the content of upstream documents, and studies on the electronic health records. The researchers reviewed Persian and English articles, reports, and studies in the field of electronic health records in Iran from 2001 to 2022 using the keywords "electronic record", "electronic health record", "electronic health", "prescription", "electronic medical records", "electronic health record", and "medical record" in databases such as PubMed, Scopus, Sid, and Google scholar search engine. Furthermore, they studied the reports of organizations such as the Majlis Research Center, the health insurance organization, the social security insurance organization, and the Ministry of Health and Medical Education and included them within the framework and format of Walt and Gilson's policy analysis triangle. The framework was divided into four main categories: content, context, actors, and decision-making. Political objectives, operational guidelines, and other topics were covered. Actors made reference to powerful individuals and corporate bodies. Context referred to social, economic, political, cultural, and other environmental conditions. The decision-making process included four sections: Problem detection, policy formulation, policy implementation, and policy evaluation (12).

Results

Content

Based on upstream documents over the past two decades, the Ministry of Health and Medical Education has to establish a comprehensive health information system for Iranian citizens for continuous improvement of the quality of health services and increase in productivity.

Based on the content of upstream documents, the following goals were set: Suitable information platforms to provide new services to citizens, creating electronic health records for 100% of Iran's population, decreasing the costs of health system by 10% by helping new technologies and knowledge, increasing the capacity of knowledge production, creating comprehensive access for stakeholders, creating integration in information, developing the information security and confidentiality at all levels, designing health information architecture, and providing health insurance services in interaction with electronic health records.

Fair access to health service resources by helping the information and communication technology (ICT), fast, cost-effective, stable, and safe access to 100% of health records of all members of the society, creation, and the development of electronic health system based on Islamic ethics, social security, provision of electronic health services with respect for personal privacy, and the development of basic electronic services in the health system are among the values of electronic health record policy. Electronic health records are essential to provide high-quality, customer-oriented, and cost-effective care services, as well as timely access to complete and correct information (13).

Table 1 presents upstream documents for electronic health records. Different scheduling for policy implementation is another issue which has received insufficient attention. In the resolution of Supreme Council of Health in 2008, a 1-year schedule was considered for developing an operational plan and creating an electronic health record within a 10-year period. In the resolution of Council of Ministers in 2010, a 5-year time frame was considered for the creation of electronic records for 100% of Iran's population. The fifth development plan law in 2011 considered the electronic file system establishment in less than 2 years, and the sixth development plan law in 2017 considered the establishment of the Iranians' electronic health record system and information systems of health centers in the first 2 years of the plan.

Table 1: Upstream documents according to the electronic health record

Policy document	Year	Content of the document
Fourth development plan law	2004	Article 88- Clause E- Ministry of Health and Medical Education has to design and establish a comprehensive health information system for Iranian citizens to continuously improve the quality of health services and increase productivity
Resolution of the Supreme Council of Health and Food Security	2008	In the implementation of Article 88 of the Fourth Development Plan Law, the Ministry of Health and Medical Education in cooperation with the Ministries of Welfare and Social Security, Communications and Information Technology, the Supreme Council of Information Technology, the Supreme Council of Informatics, and Iranian Legal Medicine Organization are obliged to prepare an operational plan and executive regulations for the creation and development of the electronic health record within a year to create appropriate information platforms to provide new services to citizens in ten years.
Resolution of the Council of Ministers	2010	Article 1- Clause (d), the resolution of electronic health development is considered a basic priority in the development of information and communication technology in Iran. Article 7, Clause 3- The electronic health record filing for 100% of Iran's population was set as a quantitative goal for the next five years due to the information technology performance for the Ministry of Health and Medical Education.
Comprehensive scientific map of Iran	2010	National strategy for the development and localization of health sciences and technologies in Iran Measures: the development of information and communication technology in the field of health to establish an electronic health system according to Islamic ethics, social security, and privacy.
Comprehensive scientific map of health	2010	Completing the health innovation cycle, decreasing 10% of health system costs by helping of new knowledge and technologies. Priorities of health science and technology: management of health knowledge and information. Policies: Increasing the capacity for knowledge production, dissemination, and sharing, and facilitating and establishing communication). Defining the organizational structure for health information technology centers in all organizations.
Fifth Development Plan Law	2010	Article 35, to maintain integrity in the management of knowledge and information, the Ministry of Health is obliged to establish an electronic health record system for Iranians, and the information systems of health centers should be based on the Statistical Centre of Iran, and the National Organization for Civil Registration should provide electronic health services by the family physician program and referral system with respect for privacy and priority.
Health system development map	2011	Fifteenth policy: the development of information technology to improve health programs with three components: 1- Development of basic electronic services in the health system; 2- Fair access to health services and resources by helping the information and communication technology; 3- Fast, cost-effective, stable, and safe access to 100% of the health records of all people in society by helping the information and communication technology
General health policies	2014	In general health policies, it was finally removed despite being in the initial draft.
Regulations of the electronic health service workgroup	2014	Main strategies: 1- Creating integrity in information, 2- Creating comprehensive access for stakeholders, 3- Creating smart health information management tools, 4- Developing security and confidentiality of information at all levels, 5- Designing health information architecture, 6- Management of knowledge about health information sharing, 7- The standardization of electronic health services and products, and 8- Continuity of electronic health services
Resolution of the Supreme Council of Cyberspace	2016	Dissolution of the supreme councils of informatics, information, and security of the information exchange space, and transfer of tasks to the supreme council of cyberspace. Changing the name of the Supreme Council of Health Technology to the Executive Council of Health Information Technology
Sixth development plan law	2016	Article 74- Clause A- Ministry of Health has to establish the electronic health record system of Iranians and the information systems of health centers within the first two years of the implementation of development plan law in coordination with the national statistics center and the National Organization for Civil Registration with a priority of starting from the family physician program and the referral system and respecting privacy subject to their permission and data confidentiality. Ministry of Health and Medical Education is obliged to organize health insurance services in an integrated and IT-based way according to the electronic health record system of Iranians within a maximum of 6 months after the full establishment of this system in cooperation with health service organizations and centers and the health insurance organization.
Resolution of the Supreme Council of Health and Food Security	2017	Ministry of Health and Medical Education has to coordinate with the Vice Presidency for Science and Technology and participate with the Ministry of Communications and Technology to establish a technical committee affiliated with the Secretariat of the Supreme Council of Health and Food Security to examine the trends, opportunities, and threats of the entry of digital technology into the health domain and present the results in the next meeting of Supreme Health Council with the president.
Budget bill	2020	Paragraph G, Note 17. The Supreme Council of Insurance must design and issue the electronic version based on the rules in the law.
Budget bill	2021	Ministry of Health should collectively create an electronic health record in the health and treatment sector and make it available to physicians and patients via the electronic website. If the Ministry of Health and Medical Education does not perform it within three months, the basic insurance organizations should provide the patient's health history in the form of electronic health records to physicians and patients.
Budget Bill	2022	Annexed Paragraph 1, Note 17 of the Single Article for implementation of Paragraph (G) of Article (70) of Sixth Development Plan Law on the establishment and completion of the data of the online database of the medical insured and management of consumption and resources. All companies and basic and supplementary medical insurance funds, either public and private, as well as the executive agencies subject to Article (5) of the Civil Service Management Law, including Armed Forces Medical Services Organization, Social Security Organization, and other insurance organizations, are obliged to send the information of their insureds online to Ministry of Health and Medical Education and update the database for free and continuous access within a maximum period of three months from the promulgation of this law. Regarding the completion of the project for the creation and installation of the complete electronic health system and authorized sub-projects, as well as guaranteeing the security and privacy of health information, see Annexed Paragraph 2, Note 17 of the single article. Annexed Paragraph 4, note 17 of the single article about creating of necessary infrastructure and mechanisms for modernizing the cycle of drug prescription to consumption and providing health services on an electronic platform (all health, medical, pharmaceutical, and diagnostic services)

Actors

Based on a review of the upstream documents in Table 1, the actors have not been completely and accurately identified and their duties were not well defined during these years. Article 88 of the Fourth Development Plan obliges only the Ministry of Health and Medical Education to establish a comprehensive health information system for citizens. Paragraph A of Article 35 of the Fifth Development Plan obliges the Ministry of Health and Medical Education in cooperation with Statistical Centre and the National Organization for Civil Registration to establish the electronic health record for Iranians and obliges all health centers, public and private, to cooperate in this field. Paragraph B of article 35 of the fifth development plan discusses the electronicization of insurance services and the roles of the Ministry of Cooperatives, Labor, and Social Welfare and all relevant public and private units. Paragraph 7 of the executive rules of electronic version, which was announced at the beginning of July, introduces the main stakeholders of the establishment of the electronic version, including citizens, prescribers of health services, health service providers, organizations, and institutions that purchase health services (basic and supplementary insurances), and the sub-stakeholders of this plan, including the Ministry of Health, Food and Drug Administration, Blood Transfusion Organization, Iran Medical Council, and other institutions involved in prescribing and providing health services. Various studies mentioned the roles of actors such as the Ministry of Communications, the Ministry of Economy, Tax Organization, Iran Medical Council, the outpatient and hospital healthcare service centers, service-providing labor, the ICT Guild organization, private companies for providing electronic health services, and pharmacies (14-17). The main actors of electronic health records are as follows: The ministry of health and medical education (as the custodian of electronic health records), Information Technology Executive Council (as the supervisor of the electronic health project in the E-government), the Supreme Council of Health Insurance (as the regulatory body of basic medical insurance which is responsible for designing and promulgating the electronic version based on the budget law of 2020), Iran Health Insurance Organization (as the trustee of the establishment of the national medical insurance online database), medical insurance organizations and funds (as health service purchasers), Iran Medical Council (custodian for issuing electronic signatures), health, diagnostic, therapeutic, and pharmaceutical centers (obliged to provide services based on the electronic health records), and information technology service companies (intermediary and infrastructure services) (18).

Contextual factors

The successful contextual elements in this strategy may be categorized into three groups: cultural-social, economic-financial, and political-executive aspects. These components were chosen based on the research that was available.

Socio-cultural factors

The social and cultural factors, which were effective in the implementation of policies for many years, include the insufficient familiarity of health officials with information and communication technology capabilities, the health managers and activists' lack of sufficient knowledge about macro goals and vision, low awareness of people and patients present existing capabilities of the electronic health system, the existence of resistance in the national health system against changes in terms of using information technology, the low experience of the health system in the field of using information technology, and the lack of necessary computer literacy to use the electronic health system services (19-20).

Financial-economic factors

The lack of funds to expand computer networks to various health and treatment centers, the lack of sufficient financial resources to equip the body of Ministry of health with information and communication technology, the high cost of establishing the necessary external systems in the electronic health, the failure to realize a part of financial credits allocated to electronic health, and the lack of tangible financial return for the implementation of e-health projects. (21-22).

Political-executive factors

In contrast to the fifth development plan and health system development map, which were released in 2010 and 2011 respectively, the complete scientific map of health in 2010 solely relates to the creation and expansion of knowledge and information management. This policy is eliminated from general health policies, despite being present in the initial draft, indicating the lack of long-term policy, and strategy and the underestimation of electronic health records. This issue has caused the dependence of programs and policies on individuals, and the lack of managerial stability has prevented the implementation of plan (21).

Process

Within the framework of the policy analysis triangle, the process refers to a set of measures and activities carried out for the implementation of policy, and it comprises the policy-making stages of problem determination, formulation, implementation, and assessment (23).

Identification of the problem

The diversity of diseases in deprived areas, the concentration of facilities in big cities, the necessity for physician's access to patient records, the need for information and statistics of diseases, many limitations of paper records, the lack of sufficient control and supervision of care, and drug consumption, and the necessity to increase the treatment efficiency are among the cases that indicated the need for electronic health records. Electronic health records can serve the health management and policy system, facilitate the provision of health services, and raise the quality of healthcare services by organizing a lot of information that is generated in healthcare institutions (24).

Policy formulation

World Health Organization has introduced e-health as an essential part and an important tool of health development plans (25). An essential element of electronic health is the electronic health record. The analysis of earlier papers over the previous two decades shows that for the creation of policies, electronic health has been taken into account at different times and electronic health records at other times. Electronic prescription was reported in recent years. Electronic health was introduced in the fourth development plan law in 2004 simultaneously with family physician program and referral system. During these years, the lack of success in the implementation of the family physician program and referral system was associated with insufficient attention to electronic health records (26).

The formulation of electronic record policy was carried out in an isolated way without a unique and clear strategy and vision along with the rapid changes in managers, especially in the Ministry of Cooperatives, Labor, and Social Welfare, and the Ministry of Health and Medical Education in different periods of the presidency and Islamic Consultative Assembly during the past two decades. Instead of finishing earlier measures, each group has started again with planning and measurements. When determining policy, the government and Consultative Assembly have been regarded stakeholders, whereas the business sector and civil society have been ignored. Less attention was paid to major requirements, including a roadmap for designing and developing electronic health records, which are agreed upon by all stakeholders, in the formulation of policies. The electronic file should be gradually developed in a balanced way in the evolution of the family physician program, but it was the opposite. The software and hardware infrastructures were weak at the beginning of fourth development plan, leading to serious problems in policy implementation (27).

Policy implementation and evaluation

Based on the upstream documents and studies, the executive policies of electronic health records are performed from up to down. The frontline healthcare employees' lack of preparation and knowledge about electronic health records services in health centers and hospitals, and the lack of proper local technical infrastructures indicate that less attention was paid to local levels in the adoption of executive policies. Hospital and health information systems were also expanded in terms of implementation of rural and urban family physician program ver. 2 in 2012 in addition to the health system development plan in 2014, and then reporting and recording data in different systems were performed electronically in primary care centers. The growth of information systems has led to decentralization, but it has also produced a vast amount of data that is difficult to manage, integrate, and continually evaluate. As a consequence, using information has become more difficult (28). Poor inter-sectoral and intra-sectoral coordination for the development of electronic health records has caused problems when it was accompanied by the growth of private sectors to provide health system services (29). The necessary requirements and prerequisites for the implementation of electronic health record policy have not received enough attention during the last two decades. There are issues such as not appointing the main custodian of program, insufficient attention to the necessary technical and physical infrastructures, the lack of network equipment and infrastructure to connect the centers to each other, lack of sufficient access to high-speed internet in healthcare service centers, the lack of knowledge, lack of expert labor in electronic health, poor computer equipment, lack of a standard health information exchange system, high sensitivity to ensuring the confidentiality and security of patient information, complexity to define the access of different people to patient information, the lack of necessary and sufficient legal rules and regulations for the implementation of electronic record, lack of coordination between universities of medical sciences and the information technology centers of the Ministry of Health and Medical Educations, vast changes and turnovers in the main managers and decision-makers involved in the national health system, and not-specified information technology custodians in the universities (29-30).Formal evaluation is a kind of social science research that often seeks to discover whether a particular form or plan of intervention has achieved its objective(s) (31). Wes reviewed the level of realization of what is mentioned in the upstream documents to evaluate the policies of the electronic health record. Regarding the review of upstream laws and documents, even though Iran's comprehensive scientific health map in 2010 and the health development plan mentioned the creation of a collective database as an important task for the information technology management of the Ministry of Health and Medical Education, there was no success in creating of a single health data system during

the past 10 years, and on the contrary, it has led to diverse and scattered information systems in a way that there is no information exchange between different information systems and levels (28). The fifth development plan recommended establishing the electronic health records of Iranians in the first 2 years of the plan, as well as the interaction of insurance services with the electronic health record system in 1995, but the lack of budget credits in addition to challenges of financing owing to international sanctions on the Iranian economy strongly affected the implementation of electronic health policy. Ministry of Health and Medical Education announced the launch of four electronic health record projects in 2017, and then Minister of Health announced the unveiling of electronic health records in 2019, but it faced the announcement of the project's inability to operate by the project supervisor secretariats (32). Electronic prescription became required and established in basic insurance starting in January 2021 after trial stages, which resulted in a decrease in in-person referrals, crowds, and disorder in the government service offices where insurance organizations provided service. This was due to the elimination of paper notebooks and the trial stages of electronic prescription. Furthermore, it faced many challenges to receive the services from outpatient physicians, pharmacies, services requiring supplementary insurance, electricity and internet outages, and slow computer systems. However, 89% of physicians (out of 111000 physicians registered in the system) prescribed electronic prescriptions in Iran Health Insurance up to April 16, 2022 (32). However, the physicians' digital signatures were not issued yet. The implementation has not been based on the assigned tasks and has not been approved by the supervisor after 17 years since the approval of legal decrees on electronic health (18).

Discussion

The present study aimed to review documents and policies of the electronic health records in Iran and investigated various factors involved in this process based on the policy analysis triangle in four categories, namely the actors, content, context, and process.

Despite the approval of numerous regulations on the establishment of electronic health records in Iran and various measures to implement the legal obligations, there is still a long way to its full implementation. The lack of a macro integrated architecture trusted by the main actors is an important barrier to the implementation of laws which causes scattered, parallel, and isolated measures (as an important barrier to the rapid progress of this project).

Based on this study's results on the upstream document content, the unrealistic and different schedules in the text of documents along with the lack of a clear strategy, correct planning, and necessary financial resources and infrastructure during these years have led to the failure of policy implementation. This issue resulted in financial losses, loss of time and trust of people and stakeholders. It has been presented in the Consultative Assembly report on legal requirements and executive challenges of the electronic health record, different schedules in upstream documents, the lack of a macro integrated map and architecture, and non-proportion of the executive structure with dimensions and scope of the plan are introduced as the challenges of electronic health record in Iran (18).

Regarding the stakeholders of electronic health records, various actors have played roles, and based on the research findings, the key actors have not been identified in a clear and specific process and their tasks were not clarified during the 17 years from the fourth development plan up to now (33). Furthermore, their roles were not clearly mentioned in planning and upstream documents, thereby affecting strategic planning and reducing the level of coordination among key actors in the implementation of the plan (14-17).

The study results revealed several obstacles to the adoption of the electronic health record, with behavioral, infrastructural, and budgetary constraints having the most impact on the formulation of this policy. Various studies mentioned technical problems and weaknesses in hardware and software systems (inconsistency of codes, the lack of forecast of mechanisms for ensuring security and information confidentiality, failure to implement electronic signature, and weakness in infrastructure), and frequent managerial changes as the barriers to the creation of electronic health records (34-36). Moreover, financial issues and the lack of planning in the using the resources have affected the design and implementation of electronic health records (37).

The electronic health record was considered by focusing on the priority of starting the family physician program and the referral chain in upstream documents, which have also affected the electronic health record establishment owing to the failure of family physician program in recent years. Takian et al. indicated that the lack of a clear strategy and macro architecture of electronic health led to the lack of planning, failure in programs, and loss of financial resources (33). Data recording, a lack of data exchange between hospitals, and a lack of inter-sectoral cooperation were also cited by Abbasi et al. as major obstacles to the successful implementation of electronic health records, which caused information to become dispersed and prevented timely information analysis, service monitoring, and evaluation (38). The results of reviewing documents of electronic health record policies indicate that the policy was supported by various stakeholders and sectors, but it has not brought acceptable results after 17 years. Designing a roadmap approved by key stakeholders, clarifying the duties of each stakeholder, allocating the proper budget, and paying attention to infrastructures are among the key strategies for a more successful establishment of the electronic health record program.

Conclusion

The electronic health record was considered by focusing on the priority of starting from the family medicine program and the referral chain in the upstream documents, and it was not fully used in Iran's health service provision system still after 17 years. Designing a roadmap, which is confirmed by key stakeholders, clarifying the task of each stakeholder, allocating proper budgets, and paying attention to the infrastructures are the key strategies for a more successful implementation of the electronic health record program.

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Ethical statement

All ethical considerations have been taken into account based on the Helsinki Declaration and the 26 codes of the country's research ethics, such as obtaining informed written consent and maintaining confidentially of personal information.

Conflict of interest

The authors declare that there is no conflict of interest regarding publication of this article.

Author contributions

SM and AAH, contributed to the conception and design of the study. SM, MV and EK collected the data. SM, MSH, MV, and AAH evaluated and edited the manuscript.

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