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The Use of a Blockchain to Foster the Development of Patient-Reported Outcome Measures

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Introduction to Patient Related Outcome Measures

Patient-related outcome measures (PROMs), which focus on outcomes that are directly related to the patient, have taken on added importance and significance over the past several years. [1] This is due, in part, to the increased attention focused on the patient experience of care and to provide a patient-focused assessment on the burden and impact of disease. PROMs can include symptoms and other aspects of health –related quality of life indicators such as physical or social function, treatment adherence, and satisfaction with treatment. They can also facilitate more accurate patient-physician communication in terms of the burden of treatment-related morbidities by providing a more detailed and complete evaluation of treatments for specific conditions, such as cancer or multiple sclerosis. [2]

PROMs are distinct from traditional clinical efficacy measures (e.g., survival in cancer, smoking cessation) because they directly reflect the impact of disease and its treatment from the patient's perspective. [1] It can examine the balance between the efficiency of the treatment and its burden on the patient. It is also effective in looking at areas such as physical functioning and overall well-being, and highlighting the efficacy and safety of treatments in relation to its overall clinical benefit. Because the measures themselves are developed from the patient's perspective, it can also facilitate greater patient involvement in treatment decision-making as well as providing guidance for health care decisions. [1]

However, there is difficulty in the development, implementation and sustainability of PROMs over the long-term. [3] The success of a well-developed PROM that adequately and accurately reflect that patient's perspective relies on the use of an instrument that is psychometrically tested and validated and can capture the burden of disease or treatment. This means the instrument must be reliable, in that the PROM yields the same metric for evaluation each time it is administered, providing that the construct being measured has not changed. Additionally, the PROM must always measure its intended objective, and not demonstrate significant variation which would obscure the results and provide little value to either the patient or provider. One of the most effective ways of demonstrating reliability and validity of the psychometric properties of an instrument designed to collected patient-reported data is to provide enough evidence to demonstrate it can reliably measure its intended target. [3]

The development and testing of the instrument, in addition to the development and implementation of the PROM, is both time-consuming and expensive. [4] In order to appropriately identify patient experiences, trends and issues that have the most significance, an instrument must be tested through a variety of methods. These may include cognitive interviewing among patient groups, focus groups and behavior coding. To ensure that the results are statistically valid, the appropriate patient population must be included, with the right combination of sociodemographic characteristics, such as race, age, gender, marital status and others. While numerous instruments have been developed successfully to accurately assess patient-based outcomes in areas such as neurology and depression, the process itself can be burdensome, causing the actual development and implementation of a PROM to take two to three years to complete. [5]

The Internet of Things for PROM Development

A potential alternative to the use of standardized instruments to collect data and provide a foundation for the development of a PROM is the use of technologies associated with the Internet of Things (IoT). The US National Intelligence Council defines this term as, "the general idea of things, especially everyday objects, that are readable, recognizable, locatable, addressable and controllable via the Internet – whether through Remote Frequency Identification (RFID), wireless local-area networks (LANs), wide-area networks (WANs) or other means. [6] In a larger context, while the most familiar Internet-connected devices are computer such as laptops, servers, smartphones, and tables, the IoT concept refers to everyday objects that are starting to come online with the use of embedded sensors and microprocessors, communicating with each other and the Internet. In the area of health, this refers to the use of self-tracking devices and personal environment monitoring applications, such as those that provide automate digital health monitoring, ambient behavior management suggestions and other real-time personalized recommendations. [7]

This use of these technologies has rapidly increased as over 80% of all adults use the Internet to search for health information, connect with patients similar to themselves, and share information regarding their condition or the facilities in which they seek treatment. [7] There are currently over 220 million smartphone users in the United States that have downloaded over seven billion applications, of which approximately 22,000 are related to health. [8] In the area of wearable devices and sensors, over 15% of individuals from the ages of 18-55 have devices such as Fitbit and Jawbone UP and 10% of the population from the ages of 65 and over have either wearable sensor technology or sensors integrated into their living environment to manage conditions such as falls, chronic disease and medication management. [9] The utilization of these technologies within the IoT has led to the development of personalized data streams that can identify and manage physical and mental health outcomes.

These outcomes are greatly expanded from the traditional and nearly exclusive focus on cure to branch upwards to a wider set of endpoints, such as establishing baseline and variability levels of phenotypic measure in individuals. Additionally, a greater focus can be placed on improving, normalizing and preventing conditions, while proactively targeting longevity, enhancement and health. This shifting in health outcomes is already starting to be seen in the area of physical health with a new focus on prevention and wellness maintenance. Furthermore, the therapeutic delivery platform of the mobile phone with applications such as *Code Blue* and *Breathe2Relax*, demonstrate that optimization of the technology can affect mental health and mental performance among populations of all ages.

The significant amount of data being generated through these devices, such as electronic medical records (EMRs), quantified self-tracking devices, smartphone applications and personal health records (PHRs) provide an opportunity to gather insight into a patient's health status that was previously only available through the administration of a psychometrically validated instrument. This expanding ecosystem provides a more proactive approach to health as the data streams from these devices can be intermingled with social networks, crowdsourced studies and the Quantified Self community, which collects and shares biophysical assessments. With the increasing interest and need in PROMs, the integrated data streams coming from these tightly coupled software solutions that encompass a large array of patient-based data provide an ability to develop these measures independent of a validated tool.

For example, the emerging quantified data streams could be helpful in elucidating the mental health of both individuals and populations. The US National Institutes of Health estimates that 26.2% of Americans ages 18 and over suffer from a diagnosable mental disorder in any given year. [10] Using PROMs to evaluate a patient's mental status and functioning moves towards understanding their specific condition and helping move towards a more positive position of mental performance optimization, rather than seeking a cure or identifying a pharmacologic solution. Data streams from smartphone applications and patient-based web portals can provide quantified assessments of qualities such as empathy, loneliness, happiness and fulfillment. A measure of these types of qualities that come directly from a IoT device is possibly an early harbinger of what may become in both the development and utilization of a PROM that provides access to a patient's condition. This insight can assist providers and health care administrators determine the most effective treatment protocols to ensure quality care is delivered to a patient that meets those specific parameters. This would also increase the probability that the measure matters directly to the patient as it is taking data from applications and devices that are continuously providing that data.

The Drawbacks of Cloud Storage Solutions

Yet, one of the most significant issues is using data from the IoT to crowdsource PROMs is the security of this individual health data being collected and stored from these devices. The most common mechanism to collect these data streams is through secure cloud storage systems, which give different levels of permissoning access to these data streams. The physical data storage spans multiple servers and is available and accessible through a web-based application programming interface (API), a cloud storage gateway or Web-content management systems. This method of storing and accessing data has become increasingly popular over the last several years, as organizations such as Amazon, Apple and Microsoft rely on this solution to store substantial amounts of consumer-based data. [11] In 2013, the Office of Civil Rights (OCR) redefined a "Business Associate" (BA) and increased protections for the privacy and security of personal health information (PHI) under its "Omnibus Rules." One of the new provisions stated that subcontractors, or organizations/individuals that act on behalf of a BA, become a BA themselves. [11]

This extended to cloud storage providers as covered entities and BAs use them to store health information, often citing that it is more cost effective and there are lower IT management costs. However, as consumers rely on crowd providers to store personal data, they relinquish direct control over that data and, as a result are unaware of who has access and where the data is geographically located. Even if an explicit business associate agreement is developed between the BA and the cloud storage provider, it would only provide the terms of who takes responsibility of the privacy and security of the data in the event a breach occurs. The consumer would potentially have control over access to these data streams, but would rely on the cloud storage provider to enforce those privileges. [11]

Furthermore, although the use of cloud storage is popular, there are still a number of risks that a consumer undertakes when using this mechanism for their personal data. In cloud-based architecture, data is replicated and moved frequently so the risks of unauthorized data use increases. Additionally, multiple individuals with access to the data, such as administrators, network engineers and technical experts that cover a wide area of servers in which the information is stored. [11] This also increases the risk of unauthorized access and use. However, even if the data is secure through strict access controls and is encrypted at its point of origin and while in transit, it still poses a problem for the development of PROMs. The concept of a PROM is to develop a patient-focused measure that relates to an area or focus that is of concern to the patient, and one in which their engagement and feedback is essential for its successful implementation. Accessing large data streams from a variety of devices that are part of the IoT can provide a foundation on which to base a PROM, but it is difficult to ascertain whether that data will produce a measure that will have the intended meaning and relevancy for a patient.

For example, there have been PROMs developed to evaluate common mental health disorders, such as depression, within patients. Using a structured and validated protocol such as the Personal Health Questionnaire (PHQ) can provide input into a measure that may tell a provider about the patient's current status, functioning and quality of life. That knowledge may serve as a predicate to the type of therapy and potential pharmacologic treatment that is needed. An increase in overall quality of life and appropriate management of the underlying mental health condition would benefit the patient and would rely on their direct input to effectively produce a metric from the PROM that would evaluate whether the appropriate care was being delivered. Yet, if there was a reliance on devices through the IoT to produce data for these types of PROMs, it would not be as specific as the input taken from a questionnaire. The data streams within the cloud would contain numerous elements that would have to be mined and stratified to determine their relevancy to the measure. The consumer would have control over access to the data stream, but not to the elements within it. It would be up to the provider to sort through the data itself to populate the measure effectively. This would pose a significant and potentially insurmountable burden to a provider.

Compounding this difficulty is the lack of an interoperable health network system in which disparate data streams from various systems and devices can be integrated together for a singular patient. In evaluating a patient's quality of life, functional status and management of a mental health condition, a number of factors must be considered. The provider should know about potential co-morbid conditions that worsen the mental health status of a patients; the types of medications that the patient is currently on as well as their past medication history; the types of treatments the patient has undertaken to manage their illness; and their family history of mental illness, among other items. This information could be found across smartphone applications, patient web portals and other sensor-based technology, but the data cannot be integrated together. Furthermore, if the data from these personalized technologies needed to be integrated with data from an EMR to provide a more comprehensive health history for a patient, which may be significant in the development of a PROM, that combination of data would be challenging. The way the data in each of these systems is represented is neither similar nor consistent, as tracking data is often represented through web-based languages, such as the Extensible Markup Language (XML), while data from an EMR uses robust and comprehensive clinical vocabularies. Additionally, the lack of a universal patient identifier would also pose burden in aligning the information directly with a patient to ensure their information is correctly represented in a quality measure.

The Use of Blockchain Technology for PROMs

The use of blockchain technology provides an ability to securely protect patient data from all devices, both in transit and at rest; securely provide access privileges to patients on what type of data they would like to exchange; and provide an entryway into interoperability that thus far has been elusive in terms of releasing and using data for a national health network. [12] A blockchain is a data structure that makes it possible to create a digital ledger of transactions and share it among a distributed network of computers. It uses advanced cryptography to allow each user on the network to manipulate the ledger in a secure way without the need for a central authority. [12] Once a block of data is recorded on the blockchain ledger, such as a patient's weekly nutrition log from an application such as MyFitnessPal, it becomes extremely difficult to change or remove. When someone wants to add to it, participants in the network, which may include the patient and others who participate in their overall health care, can run algorithms to evaluate and verify the proposed transaction. If a majority of the network agrees that the transaction is valid, it is approved and a new block is added to the chain. [13]

There are different variations of blockchain networks, but the one most relevant to healthcare has "permissions" in which the network is made up of only known participants. [13] For example, a community health center may receive up to 10 transactions from its patients per second. These transactions may include their current heart rate, blood pressure, current mood, compliance with daily medication protocols, number of calories burned over an hour, number of steps walked within an hour, and others. This information is provided through wearable technologies, smartphone applications, personal web portals and sensor technology that can be directed to the providers. Each of these transactions receive their own digital signature that is associated with a specific patient. Those signatures related to a patient are combined together and given a digital "fingerprint" which uniquely identifies those transactions. The blockchain uses a tree structure that consists of several layers. Once the first fingerprint is given, the transactions move up the tree to the next level, usually to the community health center, which validates the fingerprint and stores the information within the blockchain. Only those with access to the fingerprint can view the data and a copy of this ledger, which consists of the validated data, is sent to the provider to keep locally. These fingerprints are continuously verified to ensure data integrity and to maintain authorized access. Anytime a change is made to the data, a new, unique fingerprint is sent to both the patient and the provider to validate. If the fingerprints do not match, the transaction is regarded as invalid, and the changes are removed. [12]

The use of blockchain technology provides more advantages than cloud storage in that it decentralizes data, which increases the security of sensitive information. A patient can now use their own digital signature and fingerprint, and combine that with a provider's signature to unlock and release data that will be more secure because of the restricted access that can only be leveraged if there is verification from both the patient and the provider. Furthermore, that patient has complete control of their medical information and can determine what is viewed by providers. Placing personal information into the hands of the patient can shift the dynamic between themselves and their provider, as data such as sleep patterns, heart rate, glucose levels and other information gathered on IoT devices can be polled and then stored on a healthcare blockchain. Access to specific elements is authorized by the patient and verified by the providers.

If the data from the patient-based technologies needs to be integrated with information from an EMR, the use of a blockchain can foster interoperability between systems that use disparate data structures. A blockchain can collect information from web-based and mobile applications, as well as sensor technologies and integrate through representational state transfer (REST) application programming interfaces (API). [13] A RESTful API is the default architecture of the Internet, and uses Hypertext Transfer Protocol (HTTP) a common transfer standard of the Internet to exchange data. Information from multiple devices can be placed on a blockchain using common HTTP verbs (such as GET and POST) and Uniform Resource Identifiers (URL), which is the standard address of every web page. Through this standard and platform-independent network, information can be collected through multiple devices.

Furthermore, the use of RESTful APIs is at the foundation of the Fast Healthcare Interoperable Resources (FHIR) data transport standard designed by Health Level Seven (HL7) and backed by the Department of Health and Human Services as a mechanism to foster greater interoperability between EMR systems. As information is collected and given a digital signature that represents a singe patient, information from the EMR can be transported through the FHIR APIs to the blockchain and matched with that same digital signature. The blockchain then becomes the backbone for digital health, incorporating data from patient-based technologies and the EMR to provide a robust and comprehensive pool from which authorized users, such as providers and patients, has access. All of the data is stored in a decentralized manner, with no single entity storing or having singular authority to access. Those parties with interest in the data need an underlying access protocol that designates specific user types and permissions.

This becomes significant in using data from these multiple sources to develop PROMs that would potentially remove some of the barriers that inhibit the development and sustained use of these measures. One of the first barriers is the overall cost and collection of data, which is almost exclusively reliant on standardized and validated questionnaires. While technology has advanced to create web-based patient management systems and surveys that can be answered on smartphones and tablets, the rate of implementation is slow and participation is not always consistent. [14] Secondly, achieving a high rate of patient participation is also difficult, as those individuals who are older, sicker and more deprived tend to be under-represented. [1] Additionally, it is harder to recruit patients with minor conditions or those undergoing minor procedures and those who are outpatients rather than inpatients. Further, designing an instrument that accurately reflect a patient’s feelings must be rigorously psychometrically validated, which is both costly and time-consuming. [3] There is also the issue that the outcomes assed by the PROM can be appropriately attributed to the quality of care provided. This requires meaningful comparisons of providers; assessing an outcome after an intervention has taken place so as to attribute the action of a provider to those outcomes; and understanding how to interpret the output of a PROM to determine if an appropriate threshold of quality has been met. [3]

The IoT cannot be the panacea to all of the barriers to PROM development and use, but the information generated from wearables, smartphone applications and other patient-centered technology, can provide a basis for understanding what types of measures can and should be developed. Combining that data with the patient information found within an EMR is robust enough to populate these measures without the reliance on validated instrument. Studies of wearable technologies for conditions such as osteoarthritis have shown that the generated data provides information on items such as functional activity level, treatment compliance and the development of individualized exercise regimens that has high comparability with reference tools such as surveys. [15] The outcomes in which patient-generated data was used as the basis for the measures were similar to that reported in the literature, with low variance and limited bias between the different types of sensor technologies.

Moreover, this technology is "always-on" and mitigates the barrier to patient participation because information is always being generated. A blockchain gives the patient control over the types of data released and through the unique tree structure of the protocol, the provider would also validate the information as coming from the patient once it is received, and provenance would be established as the digital signature would reflect the origin of the data; the entities that have accessed the data; and what specific data elements were used. Thus, if the provider needed to report on functional status for a particular condition in which sensors or wearable technologies would be effective, the data from the blockchain could populate the specific patient-reported measure and help both the provider and patient evaluate performance, as well as other entities that may be involved in the patient's care.

An Example of Blockchain Use in PROM Development

One of the best examples of how this technology would work in both the development and use of PROMs is in the area of mental health. Particularly with rural adolescents and children, the rate of depression, generalized anxiety disorder and eating disorders is higher than those populations in urban or suburban areas. [16] The scarcity of trained professionals in mental health that is available on a regular basis in these communities is a significant contributor to the problem as is a lack of knowledge about the conditions and the associated co-occurring disorders, such as substance abuse or suicide ideation that can occur. [17] The rate of suicides among rural adolescents is almost three times as high as those in other areas, and substance abuse rates are almost ten times as high. While this population will often seek help through counselors in their school, or licensed social workers when they arrive in their area, the amount of consistent specialized care; development of needed medication protocols and appropriate follow-up is very low. [16]

However, the use of both smartphones and Internet is almost consistent in rural areas as it is amongst other populations. [18] The use of specific mental health applications designed for both adolescents and provide access to this population to alert a specialized and trained mental health professional as to their status and to provider counseling, either directly through an exchange of text messages or video conference, or through a phone conversation with a crisis hot line. [19] While there are currently no peer-reviewed or scientifically valid studies that can directly address the effectiveness of these applications, the overall use of technology to provide mental health services from a distance, or telemental health, has proven to be very effective in assisting rural children and adolescents manage their mental health conditions. [20] Several studies have shown that the use of cognitive behavioral therapy (CBT) is a successful modality to treating mental health disorders in children and adolescents that is successful when used as an adjunct to medication (such as selective serotonin reuptake inhibitors (SSRIs)). [21] With the lack of specialized providers readily available in rural areas to effectively diagnose and treat conditions such as depression and anxiety, the use of these tools may provide access to care and treatment that otherwise would be lacking.

Since it is important to both the patient and their caregivers that their behavioral and functional status is not impaired through the lack of treatment, the use of PROMs would be helpful in ensuring that an accurate diagnosis is made and that the appropriate protocols for treatment are employed. The use of technology from both smartphone applications and the Internet provides a foundation on which a diagnosis can be made. The use of the *Code Blue* application allows children and adolescents with a smartphone reach out to an immediate provider to offer help and assistance when needed. The assistance is provided through text or by phone through a trained provider, who can ask for information and deliver appropriate counseling. If this application is accessed, the provider who responds can ask a series of questions to validate the symptoms as a case of depression, anxiety disorder or an eating disorder and determine what treatment is needed. If the patient reports a mental health condition that is adversely affected their quality of life, then the use of CBT may prove to be beneficial. As such, a PROM could be developed that assesses the effectiveness of CBT on children and adolescents that have a confirmed diagnosis of a serious mental health issue. This can be done through the information gathered and interpreted through a smartphone application, such as *Code Blue* (or others, such as *Talkspace*, *Big White Wall*, or others).

The use of combination of other smartphone applications can be used to administer the CBT through a licensed therapist; receive feedback to assess the effectiveness of the therapy; monitor their medication adherence (if prescribed medications are being used); and evaluate whether other potential co-occurring disorders are present. This can be done through the following applications:

Lantern - An application that develops a customizable CBT plan based on input from the patient and provides coaching and therapy on a daily basis from a licensed provider. The program also provides a feedback component so the patient can measure their progress.

Optimism – A tracking application for a patient to record their daily progress; provide information on triggers that may lead to a compromised mental state; and offers strategies for staying well.

Medisafe – An application that provides patients with a list of the medications they are responsible for taking; the correct dosage and time of administration; and provides alerts as to when it is time to take their medication and alerts providers when the medication is missed.

Each of these applications can collect and process information that can be sent to the provider that is responsible for the patients' care. The licensed therapist contacted through the Code Blue application can also receive data feeds from each of these applications and provide recommendations for a provider to write prescriptions based on their recommendations. Consent would need to be given by their caregivers, given that the patient is under 18, but the treatment and follow-up can be mediated electronically. The data that comes from these applications could be used to populate the PROM measure to ensure that CBT therapy is being utilized and to assess its effectiveness in conjunction with medication therapy.

This is an opportune case study for the development of a blockchain to provide the data from the PROM without the reliance on a standardized instrument and to provide feedback on its effectiveness on a regular basis, rather than evaluating after a prolonged period of time in which information from the instrument would have to be entered and then re-entered after the intervention had taken place. Understanding the effectiveness of care on a more regular basis allows for adjustments to take place to improve the quality of care and to determine if more aggressive strategies that are not reliant on technology are needed. The blockchain allows the patient and their caregivers to determine the types of data they want to share based on the applications being used to assist and monitor their therapy. While many patients feel ashamed of their mental state and feel a stigma associated with conditions such as depression and anxiety, the anonymous nature of these applications may make it more likely for them to seek help. [22] Further, their ability to access and share the data needed to evaluate their treatment gives them control over what is being accessed and used. The caregivers would also have access and would be able to monitor the data input; ensure it is being shared with the providers; and establish an ongoing dialogue with both the patient and provider. The provider would also have access and could verify the data being sent through a digital signature and ensure it is attached to the appropriate patient. The provenance would be established through the origin of the data input and an audit trail is created from each digital signature that is provided.

These types of use cases are the first step in implementing blockchain technology as they help identify the system requirements and looks at the interactions between users and systems. In this case, the focus would be on personal health information that is highly sensitive and coming from mobile applications that require direct interaction between the patient and providers, as well as those involved in the care of the patient. Each scenario that involves a transaction, or data being transferred from the application to those who have "signed" the transaction would be documented so the information flow and usage is understood. In this manner, the appropriate permissions would be granted and provenance could readily be established. It is important to note that the use case would not include software requirements, but would only focus on the transactions and users of the data.

A proof of concept would be the second stage, and could be implemented in a rural area with a Federally Qualified Health Center (FQHC). This would be advantageous in that FQHC's receive funding from the Health Resources and Services Administration (HRSA) and over 50% of them have significant health information technology capabilities, such as the implementation of an EHR; the use of telemedicine for those in extremely remote areas and the sharing and exchange of data between the FQHC and other designated entities. [23] Some examples that may be useful for the implementation of blockchain technology may by the Community Health Centers of West Virginia or the Oregon Community Health Information Network (OCHIN). Data would need to be gathered to determine the prevalence of mental health disorders among children and adolescents in rural areas to determine if the proof of concept is worth implementing, but the underlying infrastructure and capabilities would be present.

Assuming the proof of concept is successful, and the use of information stored on a blockchain allows for both the development and continued use of a PROM that assesses the use and effectiveness of CBT, then a field trial could be the next stage. This would be a limited run using data from the applications applied during the pilot test and more expanded blockchain to accommodate the significant increase in transactions. Perhaps the most applicable environment for a field test are those Health Centered Controlled Networks (HCCNs) that have also been funded by HRSA. An HCCN supports health centers in achieving meaningful use of ONC-certified electronic health records (EHRs), adopting technology-enabled quality improvement strategies, and engaging in health information exchange (HIE) to strengthen the quality of care and improve patient health outcomes. [24] The capabilities would already support the creation of a blockchain and the use of the data coming from mobile applications. Further, since all HCCNs have EHRs, the field test could also include the data coming from the blockchain into an EHR through the RESTful APIs and HTTP protocols. In doing so, the test would ascertain whether greater interoperability is reached through a blockchain and whether an established medical record with information coming from mobile applications can be developed.

To date, there is no full-volume rollout of a blockchain for healthcare, and the scenario presented above represents a hypothetical with a number of contingencies. These would include widespread distribution and sustained use of the applications for rural children and adolescents; intensive care coordination between the licensed therapist and a medical professional that can prescribe treatment, along with other caregivers that may be responsible for the mental health care of the patient; a willingness to allow technology to mediate mental health care in place of an in-person encounter; and either an implementation or a plan to implement appropriate APIs that leverage the common standards of the Internet, either through the HL7 FHIR standard, or other protocols that support the development and use of RESTful APIs. However, the potential for a blockchain to collect this type of data and use it to assess quality of health through PROMs is unlimited. The use of these measures is not limited to mental health, but could be expanded to conditions in which the IoT can provide both useful and needed data. This could include obesity, diabetes, heart disease, arthritis, falls management, medication adherence and others. The unlimited amount of data coming from the numerous devices and technologies available to patients provides a foundation for PROM development, and the use of a blockchain furthers the goals of ONC to provide more patient-centered care and more active patient engagement.

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