

Best Practices: An Electronic Drug Alert Program to Improve Safety in an Accountable Care Environment

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ABSTRACT

BACKGROUND: The accountable care organization (ACO), one of the most promising and talked about new models of care, focuses on improving communication and care transitions by tying potential shared savings to specific clinical and financial benchmarks. An important factor in meeting these benchmarks is an ACO's ability to manage medications in an environment where medical and pharmacy care has been integrated. The program described in this article highlights the critical components of Marshfield Clinic's Drug Safety Alert Program (DSAP), which focuses on prioritizing and communicating safety issues related to medications with the goal of reducing potential adverse drug events.

PROGRAM DESCRIPTION: Once the medication safety concern is identified, it is reviewed to evaluate whether an alert warrants sending prescribers a communication that identifies individual patients or a general communication to all physicians describing the safety concern. Instead of basing its decisions regarding clinician notification about drug alerts on subjective criteria, the Marshfield Clinic's DSAP uses an internally developed scoring system. The scoring system includes criteria developed from previous drug alerts, such as level of evidence, size of population affected, severity of adverse event identified or targeted, litigation risk, available alternatives, and potential for duration of medication use. Each of the 6 criteria is assigned a weight and is scored based upon the content and severity of the alert received.

OBSERVATIONS: In its first 12 months, the program targeted 6 medication safety concerns involving the following medications: topiramate, glyburide, simvastatin, citalopram, pioglitazone, and lovastatin. Baseline and follow-up prescribing data were gathered on the targeted medications. Follow-up review of prescribing data demonstrated that the DSAP provided quality up-to-date safety information that led to changes in drug therapy and to decreases in potential adverse drug events. In aggregate, nearly 10,000 total potential adverse drug events were identified with baseline data from the DSAP initiatives, and nearly 8,000 were resolved by changes in prescribing.

IMPLICATIONS: Implications and additional thoughts from The Working Group on Optimizing Medication Therapy in Value-Based Healthcare were provided for the following categories: leveraging electronic health records, importance of data collection and reassessment, preventing alert fatigue utilizing various techniques, relevance to ACO quality measurement, and limitations of a retrospective system.

RECOMMENDATIONS: While health information technologies have been recognized as a cornerstone for an ACO's success, additional research is needed on comparing these types of technological innovations. Future research should focus on reviewing comparable scoring criteria and alert systems utilized in a variety of ACOs. In addition, an examination of different data mining procedures used within different electronic health record platforms would prove useful to ACOs looking to improve the care of not only the subpopulations with specific metrics associated with them, but

their patient population as a whole. The authors also highlight the need for additional research on health information exchanges, including the cost and resource requirements needed to successfully participate in these types of networks.

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What is already known about this subject

- Adverse drug events are a leading cause of morbidity and mortality in the United States and a major concern for accountable care organizations.
- Due to the vast amount of drug safety warnings issued by the FDA, it is challenging for health care providers to effectively and efficiently incorporate these warnings into clinical practice.
- Integrating health information technologies into clinical care allows for health care providers to communicate with one another and ensure continuity of care for patients.

What this study adds

- The program described in this article highlights the critical components of Marshfield Clinic's Drug Safety Alert Program, which focuses on prioritizing and communicating safety issues related to medications with the goal of reducing potential adverse drug events.
- Sending direct communications to providers regarding drug safety concerns for their patients can reduce potential adverse events from occurring.
- Utilizing an electronic health record rather than claims data to conduct a drug utilization review improves data accuracy and provides a platform to conduct quality improvement efforts related to drug safety.

The Patient Protection and Affordable Care Act has ushered in a new era of evolving payment and delivery models that seek to improve care and reduce health care expenditures. The accountable care organization (ACO), one of the most promising and talked about models, focuses on improving communication and care transitions by tying potential shared savings to specific clinical and financial benchmarks.¹ An important factor in meeting these benchmarks is an

TABLE 1 Generic Example of DSAP Scoring System

Alert Criteria	Scoring Levels				Weight (%)
	1	2	3	4	
Severity of adverse event(s) identified by the alert	35	70	105	140	35
Size of the estimated or affected patient population	20	40	60	80	20
Level of evidence	15	30	45	60	15
Potential duration of medication use	12	24	36	48	12
Litigation risk	10	20	30	40	10
Availability of alternative medications	8	16	24	32	8
Total	100	200	300	400	100

Final Score = Points/Total Possible Points (400) × 100

ACO’s ability to manage medications in an environment where medical and pharmacy care has been integrated. Previous research has shown that although medications are a critical component to achieving the lower costs and improved quality in this model, ACOs have yet to fully optimize the utilization of medications to meet these goals.²

Adverse drug events are a leading cause of morbidity and mortality in the United States. The Patient Safety and Clinical Pharmacy Services Collaborative, a national quality improvement effort administered through the Health Resources and Services Administration, defines potential adverse drug events (pADEs) as “medication errors that were identified and stopped with appropriate interventions before harming the patient.”³ Because of the large number of drug safety warnings issued by the U.S. Food and Drug Administration (FDA), it is a challenge for health care providers to effectively and efficiently incorporate these warnings into clinical practice.

While every ACO approaches care delivery in different ways, they are all focused on quality and financial goals and, therefore, have the potential to learn from one another. The program described in this article highlights the critical components of Marshfield Clinic’s Drug Safety Alert Program (DSAP), which focuses on prioritizing and communicating safety issues related to medications with the goal of reducing pADEs. The authors hope that certain aspects of the interventional program described in this article can be utilized by other organizations.

Program Description

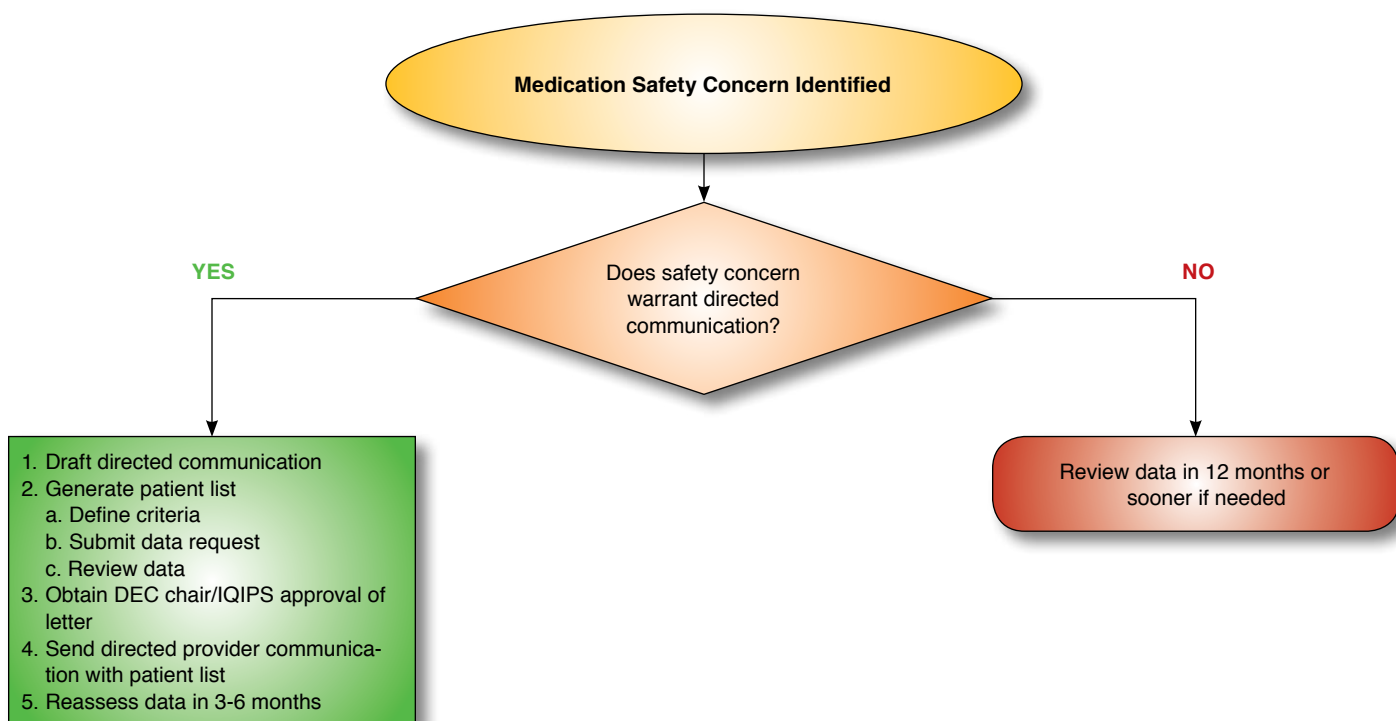
Marshfield Clinic is a multispecialty not-for-profit [501(c)3] physician group practice in Wisconsin. It has 56 regional sites and more than 780 physicians who care for more than 383,000 unique patients annually. Marshfield Clinic is a national model for health care reform and served as 1 of only 10 sites in the United States selected by the Centers for Medicare & Medicaid Services (CMS) to take part in a Physician Group Practice demonstration project.⁴ In 2011, all 34 Marshfield Clinic primary care sites achieved Level 3 Patient Centered Medical Home recognition from the National Committee on Quality Assurance (NCQA).⁵

To improve patient safety, the Clinical Pharmacy Services department at Marshfield Clinic designed the DSAP to improve

clinicians’ awareness of relevant FDA and manufacturers’ drug safety communications. The goal of the DSAP is to provide prescribers throughout the health system with timely and clinically meaningful medication safety information, while also identifying patients who were prescribed medications for which concerns were raised. With an integrated EHR that includes an electronic prescribing platform, the clinic is well positioned to quickly identify unique patients and their respective prescribers when medication safety-related alerts arise. The first step of the DSAP process is to determine if the safety concern warrants an alert. Once the medication safety concern is identified, it is reviewed by the DEC to evaluate whether an alert warrants sending prescribers a communication that identifies individual patients or a general communication to all physicians describing the safety concern.

When the FDA or a manufacturer issues an alert, it is reviewed against the criteria of a scoring system. The particular alert must rise to a certain threshold before the clinic will trigger widespread intervention with its physicians. Instead of basing its decisions regarding clinician notification about drug alerts on subjective criteria, the clinic’s DSAP uses an internally developed scoring system (Table 1). The scoring system includes criteria developed from previous drug alerts, such as level of evidence, size of population affected, severity of adverse event identified or targeted, litigation risk, available alternatives, and potential for duration of medication use. Each of the 6 criteria is assigned a weight for the overall score and scoring levels. Scoring levels are selected based upon evaluation of the alert content and severity. The product of the weight and the scoring level provides an individual score for each criterion, which are combined for the overall score. Scores of 80% or greater result in directed communication and a drug safety alert letter that is sent to the prescriber with a patient list. Scores between 70% and 79% often result in a general communication to prescribers who commonly prescribe the medication. Scores of less than 70% result in no direct intervention at that time, but close evaluation and follow-up. The scoring criteria, weighted score, and intended results are routinely reviewed and updated when necessary.

FIGURE 1 DSAP Workflow



DEC = Drug Evaluation Committee; DSAP = Drug Safety Alert Program; IQIPS = Institute for Quality, Innovation and Patient Safety.

Prior to dissemination, communications in the form of educational letters to clinicians are reviewed and approved by leaders of the DEC and IQIPS. For safety alerts with a score of 80% or greater, letters include a list of patients who have been prescribed a medication of concern, and it remains active in the EHR. Assessment of the prescribing data regarding an individual medication safety concern occurs at baseline prior to communication, 3 to 6 months after the letter was issued, and then every 6 to 12 months to quantify the effect of the letter on providers' prescribing habits. Reminder direct communications may be initiated at any time by DEC or IQIPS. Figure 1 shows the DSAP workflow outline.

Observations

Results are assessed by evaluating prescribing data. To quantify the net impact of the DSAP, the interventions are reviewed individually and in aggregate. The total number of pADEs at baseline was defined as the total number of patients within each medication initiative that met the alert criteria. Examples of alert criteria include, but are not limited to, the following: (a) patient prescribed simvastatin with a contraindicated drug (gemfibrozil); (b) patient prescribed pioglitazone with a diagno-

sis of bladder cancer; (c) patient prescribed citalopram >40 milligrams (mg) per day; or (d) any patient prescribed glyburide.

In its first 12 months, the program targeted 6 medication safety concerns involving the following medications: topiramate, glyburide, simvastatin, citalopram, pioglitazone, and lovastatin. Baseline and follow-up prescribing data were gathered on the targeted medications. Follow-up review of prescribing data demonstrated that the DSAP provided quality up-to-date safety information that led to changes in drug therapy and to decreases in pADEs. In aggregate, 10,337 total pADEs were identified with baseline data from the DSAP initiatives, and 8,007 were resolved by changes in prescribing. The organization determines that a pADE is resolved when it no longer is present for that patient (e.g., citalopram dose decreased). The roughly 2,000 unresolved pADEs were most likely due to (a) the benefits may have outweighed the risks; (b) there may have been a new provider or patient entered into the health system; and (c) the provider may not have responded and would continue to be monitored. While cost savings have not been determined at this point, the cost of developing the DSAP was modest once electronic prescribing data were made available in the data warehouse to generate reports.

TABLE 2 Citalopram Example of DSAP Scoring System^a

Scoring Level	Weighted Score	Alert Criteria
Severity of adverse event(s) identified by the alert		
4	140	Potential for severe harm (e.g., permanent disability or death)
Size of the estimated or affected patient population		
4	80	>10,000 patients
Level of evidence		
4	60	Preponderance of data supporting this treatment issue is derived from high-quality studies with minimal bias (i.e., randomized trials and systematic reviews or meta-analyses).
Potential duration of medication use		
4	48	Medications that are likely intended for long-term use or treatment of an ongoing condition (e.g., antihypertensive or cardiologic medications, antidiabetic medications, or lipid-lowering medications).
Litigation risk		
3	30	Moderate risk (e.g., listed with suggestions to call lawyers if taking medication)
Availability of alternatives		
4	32	>2 medications with similar mechanism, efficacy, and improved safety profile
Total score		
390		390/400 = 98%

^aPlease contact the corresponding author for more information on the scoring tool.

Marshfield’s DSAP in Action

On August 24, 2011, the FDA released a drug safety communication regarding the antidepressant citalopram.⁶ The medication safety concern was a dose-dependent increased risk for QT prolongation. Clinical trials found a clinically significant QT prolongation at the dose of 60 mg once daily (18.5 milliseconds; 95% confidence interval = 16-21). Additional benefit in the treatment of depression has not been shown at doses greater than 40 mg once daily. Therefore, the FDA now encourages doses to be limited to 40 mg once daily and even lower for patients at increased risk of QT prolongation (e.g., congenital long QT syndrome, hypokalemia, hypomagnesemia, recent myocardial infarction).

The Marshfield Clinic DEC reviewed the FDA drug safety communication at the September 2011 meeting, and initial education was distributed systemwide through the Marshfield Clinic Pharmacy Capsule Newsletter in September 2011. The DSAP scorecard for citalopram calculated a score of 98% (see Table 2). Based on the score and the information available, the DEC recommended direct communication to prescribers, including a list of patients for whom they had prescribed citalopram at doses over 40 mg once daily.

After the initial letters were distributed, follow-up data review was performed in May 2012 and identified an approximately 75% reduction in the number of patients taking doses of citalopram over 40 mg once daily. Follow-up letters with patient lists were sent to the clinic’s prescribers in May 2012. Data were evaluated from the clinic’s electronic prescribing platform every 6 to 12 months, and the review identified that, in November 2012, there was an overall 84% reduction in the number of patients taking doses of citalopram over 40 mg once

daily. Upon follow-up review in subsequent months, an overall reduction of 91% was noted.

Implications

There are important lessons learned that may be helpful to other health care organizations as they develop their own drug utilization review (DUR) programs. The authors sought additional feedback from participants of The Working Group on Optimizing Medication Therapy in Value-Based Healthcare to provide insight on how similar programs in their respective ACOs operate and to highlight key implications. The following observations stand out.

Leveraging EHRs

Marshfield Clinic’s DSAP differs from traditional DUR programs used by HMOs.^{7,8} In traditional DUR programs, claims data are used. However, claims data were not designed for this purpose, and mining claims data can lead to inaccurate information.^{9,10} The Marshfield Clinic’s DSAP mines clinical data from the EHR, which provides detailed data directly from the chart. A diagnosis that is inferred from claims data may be inaccurate; identifying a diagnosis directly from the EHR improves accuracy. However, the authors acknowledge that diagnoses are not always available in EHR systems. Given that EHRs and other health information technologies serve as the workflow backbone for ACOs, the workgroup agreed that leveraging EHR data will be a critical element providing further insight into the practices of ACO providers.

The ability to reproduce data collection from baseline data to follow-up data every 6 to 12 months allows for monitoring of changes in prescribing patterns. This type of performance

reporting and quality improvement can help an ACO achieve accreditation from organizations such as URAC and the NCQA, which in turn can assist health systems in attracting commercial accountable care contracts.

The ability to link prescription data from a computerized provider order entry system to patient data from an EHR is essential to identifying a target patient population. The data included in a drug safety alert can be broken down into 4 basic sections: (1) inclusion and exclusion criteria, (2) patient information, (3) prescription information, and (4) prescriber information.

The inclusion and exclusion criteria are used to identify patients on a drug relevant to the drug safety alert. Additional factors or conditions may be considered to narrow the population if specified in the drug alert (e.g., dose, diagnosis, patient gender, interacting medication). Use of a unique patient identifier other than name is preferred to help reduce risk of privacy disclosures and can also be more effective for removing duplicate data entries. Prescriber information is used to generate patient lists that can be distributed and acted upon. Generally, patients are assigned to the provider who last prescribed the medication.

Preventing Alert Fatigue

With EHRs and clinical decision support tools serving as the backbone for ACO workflow, the issue of physician alert fatigue and providers overriding the alert has become a serious concern.¹¹⁻¹⁴ The Marshfield Clinic's DSAP is designed to avoid "alert fatigue or overload," which occurs when so many alerts come through the EHR that clinicians begin to ignore or overlook them. The clinic's physicians do not get DSAP alerts on each patient, and this is a practice utilized by the other ACOs involved in the workgroup. Instead, the alerts are packaged in a report that aggregates all of the patients who have been prescribed a certain medication rather than individual notices. This critical aspect of the clinic's DSAP ensures that providers are only given the information they need and encourages them to integrate the alerts into their care plans.

The clinic utilizes hard stops—preventing providers from continuing their workflow without accepting or acknowledging receipt of an alert—for level one contraindicated drug-drug interactions. Similar to Marshfield Clinic, Fairview Health System in Minnesota utilizes hard stops but only as a last resort—when an alert level is so critical that the organization requires physicians to read and acknowledge the alert before moving on in their EHR workflow system. Geisinger Health System in Pennsylvania utilizes a different approach that allows pharmacists, enabled by their physician-approved collaborative practice agreements, to make changes on behalf of the physician with a notification sent to the physician that a change has been made along with an explanation. Analogous to Marshfield Clinic's approach, other health systems have

utilized a color coded alert system to notify clinicians of the level of importance of an alert. This helps distinguish between an alert that is educational in nature and one that is critical to patient safety. The way in which ACOs approach informing and potentially altering a physician's medications plans is highly dependent on the culture of the organization as seen in the differing approaches to countering alert fatigue.

Relevance to Improving Quality for ACOs

The Marshfield Clinic's DSAP targets some of the quality measures that CMS is highlighting so there is an added benefit for the accountable care population. Traditional DUR programs identify injurious scenarios where the doctor needs to examine the therapy's risk and benefits for a particular patient. The same rule-based system can be used to identify underuse. Most DUR programs look for errors of commission not errors of omission, and the clinic has created a system that combines the 2 approaches. The clinic has also utilized the DSAP model for quality improvement initiatives, a key aspect of the CMS Medicare Shared Savings Program.¹⁵ For example, 1 quality improvement project focused on improving the health of the diabetic patient population through appropriate hypertension management. The percentage of patients who have diabetes and hypertension that are filling a prescription for an angiotensin-converting-enzyme (ACE) inhibitor or an angiotensin receptor blocker (ARB) is 1 of the quality metrics for performance as an ACO. A similar process to the clinic's DSAP was utilized to send targeted letters to prescribers, including a list of patients with diabetes and hypertension who were not on an ACE inhibitor or an ARB and did not have a documented allergy to both classes of medication. The DSAP and similar processes have shown to be an effective tool in addressing this quality metric.

Geisinger uses the EHR to identify patients that meet the ACEI/ARB criteria for diabetic patients, for example. The organization mines the data for patients by clinic and pushes the information to the clinical pharmacists at those locations. The pharmacists in turn ensure that any suggested change is clinically appropriate and not contraindicated, then they work with the physicians in the collaborative practice setting to make the indicated changes. Fairview does something similar by identifying patients that meet the ACE/ARB criteria. The information goes to the provider. Members of the care team ensure that the medications are appropriate and then automatically make the change. Fairview also has similar data mining procedures in place for several different quality metrics.

Limitations

Although the Marshfield Clinic's initiative to reduce pADEs has been shown to be effective, it does have limitations. While the safety alerts from the FDA and manufacturers are received in real time by the clinic, the process by which these alerts are

communicated to physicians is retrospective. This is due to the DSAP “filtering” alerts utilizing the aforementioned scorecard, as well as the clinic’s acknowledgment of physician alert fatigue and not wanting to inundate physicians with safety messages. In contrast, Geisinger has the ability to push alerts to physicians on a real-time basis, which has resulted in improved outcomes. For instance, if a clinician calls in an order for a warfarin or citalopram dose that is above the recommended level, an alert will occur in real time. Before a patient leaves the clinic, a change can be made in the prescription.

Another limitation is that the DSAP does not have access to data for individuals who are not included in the clinic’s EHR system, an issue shared by many ACOs. The data for community physicians who are not connected directly with the clinic are not included in the DSAP and thus may be more susceptible to pADEs related to medication safety. At some point, that information may be available when a health information exchange (HIE) is up and running, but at this time, there are few HIEs able to provide this service. This limitation demonstrates the importance of not only having a systemwide EHR, but also the development of an HIE that would allow for different systems or practices to communicate with one another.

Recommendations

Future research should focus on reviewing comparable scoring criteria and alert systems utilized in other organizations. This will allow for organizations interested in adopting such a system to determine what system not only fits their clinical needs, but also seamlessly works in their health system’s workplace culture. Additional research should also investigate how the number and intensity of alerts affect physician workflow. For ACOs looking to adopt a similar system, this will assist them with determining how frequently and to what degree they push safety alerts to physicians. As with most clinical and technological interventions, it will also be important for organizations to demonstrate the return on investment of utilizing such a system. The costs of installing, staff training, and launching an electronic reporting system such as the DSAP can be expensive, especially for health systems that may require significant investments in health information technologies to allow for this system to work effectively.

As more ACOs move toward effectively using their EHR systems through electronic communication and data mining, it will be critical for these organizations to understand how to best leverage the technology available to them. Future research should focus on how ACOs can utilize clinical data from an EHR system to identify specific subpopulations of importance to ACOs. An examination of different data mining procedures used within a variety of EHR platforms would prove useful to ACOs looking to improve the care of not only the subpopulations with specific metrics associated with them, but their patient population as a whole. Finally, the authors recommend

organizations utilizing HIEs to disseminate this information more broadly to ensure that ACOs looking to participate in these information exchanges understand the importance of financial backing and data contribution. Future research focusing on the benefits of participating in an HIE may convince current and future ACOs to support these data exchanges to improve their population’s clinical outcomes.

In conclusion, Marshfield Clinic’s DSAP showcases an innovative approach to the efficient use of resources by leveraging the available electronic prescribing data to decrease pADEs and improve the care of the patients. The DSAP takes advantage of the existing workflow of the DEC to review drug safety alerts, dramatically decreasing the number of manual chart reviews necessary and providing prescribers more time to spend with their patients. By decreasing pADEs, the DSAP helps to fulfill the tenets of the Triple Aim.¹⁶ The authors hope that the information provided in this article will encourage other organizations to share similar systems, collaborate with one another, and move the accountable care field forward so that all patients receiving care under an ACO can receive the high-quality and safe care they deserve.

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Study concept and design were contributed by Griesbach, Lustig, Westrich, and Dubois. Data collection was conducted by Griesbach, Malsin, and Carley, and analysis was carried out primarily by Griesbach, assisted by the other authors. The manuscript was written by Lustig, Griesbach, Westrich, and Dubois, assisted by Malin and Carley, and was revised primarily by Griesbach, along with Lustig, Malsin, and Carley.

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