

# Patient Education for Consumer-Mediated HIE

## A Pilot Randomized Controlled Trial of the Department of Veterans Affairs Blue Button

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### Keywords

HIE, patient portals, consumer-mediated HIE, Blue Button, care coordination

### Summary

**Objectives:** Consumer-mediated health information exchange (HIE) is one of the three types of HIE designated by the Office of the National Coordinator. HIE is intended to improve the quality of care while reducing cost, yet empirical support for this claim is mixed. Future research should identify the contexts whereby HIE is most effective.

**Methods:** This study was conducted as a pilot two-arm randomized controlled trial. In the intervention arm, 27 veterans were taught how to generate a Continuity of Care Document (CCD) within the Blue Button feature of their VA patient portal and were then asked to share it with their community non-VA provider. In the attention control condition, 25 Veterans were taught how to look up health information on the Internet. The impact of this training on the next non-VA medical visit was examined.

**Results:** Nineteen (90%) veterans in the intervention arm shared their CCD with their non-VA provider as compared with 2 (17%) in the attention control arm ( $p < 0.001$ ). Both veterans and non-VA providers indicated high satisfaction with the CCD. Comparison of medical records between the VA and non-VA providers did not indicate improved medication reconciliation ( $p = 0.72$ ). If veterans shared their CCD prior to their non-VA providers ordering laboratory tests, the number of duplicate laboratories was significantly reduced ( $p = 0.02$ ).

**Conclusions:** In this pilot randomized controlled trial, training 52 veterans to share their CCD was feasible and accepted by both patients and providers. Sharing this document appeared to reduce duplicate laboratory draws, but did not have an impact on documented medication list concordance.

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## Introduction

The HITECH act provides individuals with the right to obtain their medical record health information in an electronic format. Providing patients the ability to view, download, and transmit their health information is a requirement for Meaningful Use Stage 2 [1]. The view/download/ and transmit function facilitates patient engagement in consumer-mediated health information exchange (HIE). Though patient portals are promising, it is not yet known if the view/download/transmit function is beneficial and acceptable to patients and providers, or if it improves the quality of health-care services by improving continuity of care between providers.

Early estimates of the cost of poor communication between providers were quite large. Walker et al. [2] examined HIE between outpatient providers and laboratories and estimated a potential savings of 31 billion dollars per year. Jha et al [3] estimated that eliminating preventable adverse events could save the United States healthcare system 16.6 billion dollars. This study found that eliminating redundant tests, identified when providers indicated a test was no longer needed after receiving information about prior laboratory results, could save 8 billion dollars annually.

Since these earlier estimates, the United States healthcare system has undergone an unprecedented implementation of electronic health records (EHRs) designed, in part, to improve the exchange of information to improve the quality and efficiency of care. Although we are still in the early stages of this transformation within our healthcare system, there is ongoing research investigating whether the investment in electronic health records is realizing the anticipated benefits of improved care, improved patient experience, and reduced cost.

The RAND Corporation, in collaboration with the Office of the National Coordinator, conducted systematic reviews of the empirical evidence addressing this question and concluded that the support for the value of EHRs remains mixed [4, 5]. Perhaps, more importantly, the review authors indicated that more in depth analysis of how EHRs yield value is needed before their impact can be fully understood. They state “more studies are needed to identify what does and does not work and in what contexts” suggesting the need for greater granularity in studying the value of EHRs [5].

EHRs promote HIE in multiple ways [6] including: directed exchange, the ability to send and receive secure information electronically between providers; query-based exchange, the ability for providers to find and/or request information on a patient from other providers; and consumer-mediated exchange, where patients aggregate and control the use of their health information among providers.

This pilot aimed to investigate the value of consumer-mediated exchange by training veterans to use the Blue Button feature of their VA patient portal, My HealtheVet, to download and share their Continuity of Care Document (CCD) with their non-VA providers. Recent estimates indicate that 45 to 65% of VA enrollees also receive care outside VA, and this number may increase as VA currently promotes care in the civilian sector through the Veterans Choice Act [7–10]. This pilot allowed for an in-depth analysis of both consumer and provider experience as it relates to health information sharing, continuity of care, and reduction of diagnostic duplication. Therefore, it was designed to answer questions about the value of consumer engagement in health information sharing using an established patient portal, as well as the contextual factors that may impact this value.

## Methods

This study was a two-arm randomized controlled trial conducted in 2014. Veterans in the intervention arm were trained to use the Blue Button feature of their VA patient portal, My HealtheVet [11]. My HealtheVet launched the Blue Button feature in August of 2010. The Blue Button is a registered service mark of the US Department of Health and Human Services and is indicated by a clickable blue circle on the web page [1, 11–14]. It provides patients with easy access to view, download, or print their information to share with trusted others. The VA Health Summary (a standard Continuity of Care Document in C32 format) became available in the VA Blue Button in January 2013. Information in this document includes: allergies, history of encounters, history of procedures, immunizations, laboratory results, medications, problems/conditions, vital signs, and emergency contact information. At the time of this study, the only way patients could transfer the VA Health

Summary to others was by printing the document or downloading a file and providing an electronic file to others.

## Sample

The pilot focused on veterans with chronic medical conditions that require ongoing management (i.e. diabetes, hypertension, chronic lung/ heart disease, etc). Veterans needed to have an appointment with a non-VA provider within the study timeframe, report taking 5 or more medications, and had not previously used the Blue Button feature. Eligible veterans were invited by letter to participate in a study about using the Internet to manage their health information. A total of 1182 veterans indicated interest in participating, 1120 did not meet inclusion criteria for the following reasons: no non-VA provider (n=659), previously printed health information from My HealthVet (n=166), taking less than five medications (n=80), lack of technology access to a computer/internet/ printer (n=73), no upcoming appointment with a non-VA provider (n=60), and other (n=82). The remaining 62 subjects provided written informed consent and were randomized to one of two study arms: Randomization was blocked in groups of six to allow for equal distribution in study arms and stratified by age(< or >= age 60), gender (M/F), and race (white/minority). VA Health Summary training or the attention control.

As this was designed as a pilot study, sample size was determined based on minimal intervention arm size needed to estimate effect size for a larger randomized controlled trial. The target sample size was 60 with 30 veterans randomized to each intervention arm. In total, 62 veterans signed the consent form. We were unable to reach six of these after receiving their consent form and were therefore withdrawn. Another four veterans withdrew shortly after starting the study reporting they did not have time to complete study procedures yielding a total sample size of 52.

All VA patient participants provided written informed consent and all aspects of this study were reviewed and approved by the local Institutional Review Board and the local VA Research and Development committee.

## Randomization and Intervention Arms

Veterans who met the study criteria were then randomized to one of two study arms: VA Health Summary Training arm or the attention control arm. Within VA's patient portal, the continuity of care document (CCD) is referred to as the VA Health Summary because veterans will more readily understand this term. In the VA Health Summary Training arm, veterans received online (via an openly available web link) and paper-based training materials that

1. discussed why sharing health information using the VA Health Summary was important (i.e., improved health management and reduction of duplication);
2. provided them with step-by-step instructions on how to generate a VA Health Summary using the Blue Button feature of My HealthVet; and
3. discussed the importance of maintaining the privacy of this information.

The Attention Control group was provided written materials about how to evaluate the quality of health information found on the Internet. For example, these materials included discussion of how the suffix for a website (i.e. .com, .gov .edu) indicates the type of organization hosting the site and reveals whether or not it has commercial interest in the information it is presenting. It was decided that an active comparator was needed to control for participation factors, such as attention from investigators or general patient activation in response to health information technology training. In addition, an active comparator would be more effective than no intervention in motivating patients and providers randomized to this arm to complete their study assessments. This would thereby promote comparable data quality between study arms.

## Medical Record Review

The primary outcomes for this study were derived from medical record review. Medical records from the non-VA visit were requested with patient authorization and then compared with the VA

medical record current at the time of the visit. Information compared between the two records was medication lists and laboratories drawn.

### Medication List Comparison

A medication discrepancy metric was calculated to determine the degree to which the VA and non-VA providers' medication lists did not agree as described below. The complete medication lists were compiled from both the VA and non-VA medical records and compared in a process informed by Smith et al. [15] and Cornish et al. [16]. Medications were marked as discrepant if the dose or frequency of administration differed between lists or if a VA medication was missing from the non-VA medication list EXCEPT for medications changed during the non-VA medical visit as indicated in the medical note or the provider post-visit assessment. The discrepancy metric was calculated by including the total number of medications that were discrepant as the numerator divided by the total number of unique medications on the combined two medication lists. Medications on the non-VA provider list that were not on the VA medication list were excluded from consideration, and not included in either the numerator or denominator, since this direction of the information exchange in this study was from VA to non-VA provider, not from non-VA provider to the VA. As this metric was a proportion, possible values for the metric ranged from 0 (no discrepancies between the medication lists to 0.50 (approximately half of the medications were discrepant) to 1 (all medications were discrepant) with larger values indicating a larger proportion of total medications were discrepant.

### Laboratory Duplication

The laboratory values included in the VA Health Summary were compared to the laboratories drawn as part of the non-VA provider visit as indicated by the medical record to determine if there was duplication. Duplication of any lab tests was assigned as a dichotomous variable (0=Veteran had no laboratory duplication at the non-VA provider visit; 1=Veteran had one or more laboratory duplications at the non-VA provider visit). For example, if a complete blood count and a hemoglobin a1c laboratory was drawn the day of a non-VA medical visit and the Veteran's VA medical record included both a hemoglobin a1c and a CBC occurring at VA 28 days prior to the non-VA medical visit, that Veteran would receive a "1" indicating a duplicate laboratory occurred.

### Self-report Assessments

Veterans in both conditions completed assessments of their experience of the training. They then indicated the time of their next medical visit with a non-VA provider. One week before this visit, patients in both intervention arms were called by the study research assistant and reminded to use their training experience at their upcoming medical visit.

Patients were also sent a one-page provider assessment form and asked to share it and to request their provider complete the form after the visit and send it back to the research team's mailing address in a pre-addressed postage paid envelope. This provider assessment was used to corroborate comparison of the medical records. The one-page provider assessment included questions about whether VA care was discussed during the visit, and if the Veteran shared a VA Health Summary with the provider. If providers responded "yes" to receiving the VA Health Summary, they were then asked a series of questions about how it may or may not have influenced the visit with specific questions about medication management and laboratory orders.

### Analyses

Veterans in the two study arms were compared on demographic and outcome variables using the Fisher's exact test for categorical variables and two-sample t-test for the two continuous variables, age and the medication reconciliation metric. As a pilot study, the aim was to establish feasibility and estimate effect sizes. The small sample size means only large group differences would reach statistical significance, but all results are provided to indicate potential effect sizes. Similarly, we did not correct for multiple comparisons as the results are intended to inform about effect size more than to draw definitive statistical conclusions. All statistical analyses were conducted using SAS Statistical Software [17]. All p-values provided are for two-tailed tests of significance.

## Results

► Table 1 presents the individual characteristics of Veteran participants by group assignment prior to any training. The sample was predominantly male with the average age of 68 years found in both groups. The majority in both groups rated themselves as intermediate or advanced in self-rated Internet ability, and the VA Health Summary Training arm had slightly higher ratings of fair or poor health. The most common co-insurance was Medicare as evidenced by the high proportion in both the VA Health Summary Training arm (77.8%) and the attention control arm (72%).

► Table 2 presents Veterans' perceptions of how their VA and non-VA providers share information at baseline, prior to receiving any training. Approximately half of the combined sample viewed both VA and non-VA providers as equally responsible for their health care. The remaining half had clearly designated one (VA) or the other (non-VA) as their primary healthcare provider. Approximately two-thirds of veterans (67%) saw themselves as the one primarily responsible for sharing information between VA and non-VA providers. In contrast, 28% indicated that their VA and non-VA providers communicated by mailing or faxing their medical records.

After initial training, 67% of the Veterans in the VA Health Summary Training arm endorsed that using the VA Health Summary helped them to become more involved in their healthcare and 92% endorsed that they will share their health summary with their providers outside the VA regularly.

### Post appointment assessments- Medical Record Review

Based on the medical record reviews, the average number of unique medications prescribed was 11.4 (SD=4.1) in the VA Health Summary Training arm and 11.3 (sd=5.5) in the attention control arm (► Table 3). The proportion of discrepant medications was slightly larger in the VA Health Summary Training arm (0.53 sd=0.26) than in the comparison arm (0.45 sd=0.23), although the difference was not statistically significant ( $p=0.49$ ). In the VA Health Summary Training arm, 52% of the non-VA providers were primary care physicians as compared with 68% in the attention control arm ( $p=0.27$ ). The proportion discrepant between primary care (Mean=0.44; SD=0.23) and specialty non-VA providers (Mean=0.50; SD=0.26) indicated slightly lower, but not significant differences favoring primary care agreement ( $p=0.45$ ). A range of specialty providers participated, including podiatrists, urologists, cardiologists, and endocrinologists.

Four (15%) patients in the VA Health Summary Training arm received duplicate laboratory draws related to the follow-up visit as compared with 9 (38%) in the attention control arm (Fisher's exact=0.15). However, in reviewing the laboratories drawn at the non-VA provider visit, it was revealed that many providers actually ordered the laboratory draws to occur in the week before the non-VA visit and prior to the Veteran sharing his or her VA Health Summary. For example, a provider caring for a patient with diabetes, may see his patient at 6 month intervals and order the lipid panel for the follow-up visit at the initial visit six months prior. All labs occurring in the VA Health Summary Training arm occurred in these pre-visit laboratory draws and should technically not be considered a duplicate, as the provider had yet to see the VA Health Summary. In this study, 7 Veterans in the VA Health Summary Training arm had their labs drawn in the week prior to their medical visit and prior to the time when they shared their VA Health Summary, whereas 3 in the attention control arm had labs drawn prior to their visit. Of the 20 in the VA Health Summary Training arm who had labs drawn at the time when they shared their summary, 0 had duplicate draws, whereas 6 of the 22 in the attention control arm had duplicate draws the day of their medical visit ( $p<0.001$ ).

### Self-report Assessments

The post-appointment provider questionnaires were returned by 20 (74%) of providers seeing veterans in the VA Health Summary Training arm as compared with 13 (52%) of those in the attention control arm (► Table 4). Based on these questionnaires, 19 (90%) of providers in the VA Health Summary condition received the VA Health Summary from their patient, whereas 2 (17%) in the attention control arm received the VA Health Summary (Fisher's exact<0.001). Eighty-one percent in



the VA Health Summary Training arm reported that they discussed the patient's care received at the VA as compared with 58% in the comparison condition (Fisher's exact  $p=0.23$ ).

For providers in the VA Health Summary Training arm, 95% endorsed that they had confidence in the accuracy of the information provided in the VA Health Summary. Ninety percent indicated that information in the summary improved their ability to have an accurate medication list and 32% endorsed that they did not order some laboratory tests because of the information available on the VA Health Summary.

## Discussion

This pilot study found that training veterans about how to download and share their VA Health Summary, a Continuity of Care Document, from their patient portals greatly increased the proportion of VA patients sharing their health summary with community non-VA providers. Both veterans and their non-VA providers reported benefit in sharing the VA Health Summary. Moreover, patients may also have benefited from simply accessing and viewing their VA medical record. With this information, they may have alerted their providers to potential duplication of laboratories. Patients reported feeling more engaged in their healthcare, while providers endorsed that the information helped them to have a more accurate medication list and that they did not order laboratory draws because of the information found in the summary. Although provider satisfaction seemed high, comparison of medical records between VA and non-VA providers did not indicate improved medication list agreement between VA and non-VA providers. Medical record review did confirm that veterans sharing their VA Health Summary had fewer duplicate laboratories. However, when providers request laboratory draws to occur prior to the actual medical visit, often ordered at a prior medical visit occurring months earlier, the sharing of the VA Health Summary did not occur at a time that could prevent the duplicate lab draw.

The discrepancy between 90% of providers reporting positive impact on medication management and no indication of improved reconciliation when comparing medical records warrants further investigation. It is possible that providers were simply endorsing positive benefits as part of a halo effect or social demands to be positive about the study. In contrast, the VA Health Summary may have been helpful, but the provider did not transfer the information from the printed out document to the electronic or paper-based record –which was the record used to quantify medication list concordance (18). More attention to the optimal workflow is needed to ensure sharing of Continuity of Care Documents have their intended impact on the quality of care.

This pilot study occurred before VA developed the ability for patients to send their Continuity of Care Document directly to non-VA providers using Direct exchange. Future exchange of standardized Continuity of Care Documents will allow interoperability and receiving providers will be able to integrate or “harmonize” discrete aspects of the document, such as a new medication, or a recent laboratory result, directly into the providers' electronic medical record. This should improve medication reconciliation and overall continuity between VA and non-VA providers.

The provider endorsement that the VA Health Summary reduced laboratory draws was supported by the medical record review, but only under certain circumstances. If the provider had the VA Health Summary at the time of making orders for a laboratory draw, it appears to have reduced duplication. However, if the draw occurred prior to the visit, as a result of laboratory orders written at the time of a prior medical visit, the VA Health Summary could not have an impact.

Though it is possible that other models for HIE, such as provider-directed or query-based exchange, may prevent this problem, some modification in workflow is required nonetheless. When providers write laboratory orders months in advance for a follow-up visit, *they are setting in motion a duplicate laboratory draw before the draw they are duplicating has even occurred*. When the patient goes for the laboratory draw prior to the follow-up visit, the laboratory technician would have to use a HIE process to learn that similar labs have been drawn recently but even then, some discussion with the ordering provider must occur because only this provider knows the patient's complete medical history and the underlying reason for the draw. Only this provider can then determine if the second draw is medically justifiable. This illustrates how the value of information technology is dependent upon the context and specific clinical workflow in which it is applied.

Though this study offers preliminary insights into consumer use of a patient portal to generate a Continuity of Care Document, it has some limitations which highlight the need for further exploration. First, as this was a pilot study, the sample size was small and overall power to detect differences was limited. Second, the evaluation was for only one medical visit. Optimally, we could test the impact of such training on longer term quality and health outcomes. In retrospect, the attention control condition did not result in equal response rates from the non-VA providers and its content may have engaged participants in their healthcare -though it is unlikely it led any to generate a health summary in their VA patient portal. Sample selection may have been biased towards veterans who are more comfortable using technology and therefore, not representative of the full VA population. Finally, this study focused on a specific group of patients, Veterans, so the generalization to other healthcare settings and patient groups is also unclear.

## Conclusion

Electronic health records and their corresponding patient portals are expected to improve communication between all members of a patient's treatment team. However, this study is an example of how the technology platform promotes continuity, but only under certain contexts and clinical workflows. Though this study focused on consumer-mediated generation and sharing of a standardized Continuity of Care Document, the ordering of laboratory draws months in advance would likely lead to laboratory duplication even in other HIE models. Workflow issues must be addressed to ensure the information is received in time to influence the medical decision-making that drives utilization.

## Clinical Relevance Statement

In this study, training patients to use their patient portal to generate and share their Continuity of Care Document yielded some improvements in the quality and efficiency of their care. However, clinical workflow must be addressed to ensure providers have the information when they are making clinical decisions. Moreover, though the study clinicians indicated they valued the information sharing, this was not evident in their electronic health record documentation. Though this presents results from a pilot study, the focused nature of the evaluation revealed key features that will also be relevant in larger scaled randomized controlled trials or population-based evaluation of the value of HIE.

### Conflict of Interest

There are no conflicts of interest for any of the authors of this study. This work was supported by the Department of Veterans Affairs, Health Services Research & Development (PPO-13-178). The views expressed in this article are those of the authors and do not necessarily represent the views of the Department of Veterans Affairs

### Protection of Human and Animal Subjects

This study was approved by the local Institutional Review Board and the local Veterans Administration Research and Development Committee.

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**Table 1** Participant Characteristics

	VA Health Summary Training N=27	Attention Control N=25	P-Value or Fishers exact value
<b>Age- Mean (SD)</b>	68.4 (6.0)	68.5 (6.4)	0.72
<b>% Male N (%)</b>	25 (92.6%)	21 (84.0%)	0.41
<b>Race</b>			0.61
White	24(88.9%)	24 (96%)	
Black/Asian	3 (11%)	1 (4%)	
<b>Education</b>			1.0
< High School	1 (3.7)	0 (0.0%)	
High School Degree	17 (63.0)	16 (64%)	
College Classes, Degree or Higher	9 (33.3)	9 (36%)	
<b>Marital Status</b>			0.17
Married	24 (89%)	18 (72%)	
Divorced/Widowed/Single	3 (11%)	7 (28%)	
<b>Income</b>			0.28
<\$10,000	1 (3.8%)	3 (12.5)	
\$10,001 – \$50,000	17 (65.4%)	11 (45.8)	
> \$50,001 or higher	8 (30.8%)	10 (41.7)	
<b>Other Health Insurance- Type*</b>			
Medicare	21 (77.8%)	18 (72%)	
Medicaid	2 (7.4%)	3(12%)	
Private Insurance	5 (18.5%)	7 (28%)	
Tricare	1 (3.7%)	4 (16%)	
<b>Self-Rated Health (1–5 Poor-Excellent) % Fair or Poor</b>	11 (42%)	6 (24%)	0.28
<b>Self-rated Internet Ability</b>			0.44
Beginner	4 (15.4%)	1 (4.0%)	
Intermediate	12 (46.1%)	12(48%)	
Advanced	10 (38.5%)	12(48%)	

Note: Proportions add up to greater than 100% because participants could select more than one option. None of the differences between groups on each of these possible responses were significant.

**Table 2** Baseline Patient Health Information Management Characteristics and Perceptions of Coordination of Care between VA and non-VA providers.

	Total Sample	VA Health Summary Training (n=27)	Attention Control (N=25)	P-Value Fisher's Exact
<b>Who do you consider primarily responsible for your health care?</b>				0.76
VA Provider	15 (28.8%)	9 (33%)	6 (24%)	
Provider Outside the VA	10 (19.2%)	5 (18.5%)	5 (20%)	
Both are Equally Responsible	27 (51.9%)	13 (48%)	14 (56%)	
<b>How do your VA providers and providers outside the VA currently learn about health care you receive at the other provider's office? Check all that apply.</b>				
Veteran shares the information between them.	35 (67%)	20 (74%)	15 (60%)	0.38
Doctors Exchange Medical Records via mail or fax.	15 (28%)	7(26%)	8 (32%)	0.76
Veteran does not know how they communicate	8 (15%)	5 (18.5%)	3 (12%)	0.70
They do not communicate	4 (8%)	2 (7%)	2 (8%)	1.0
They speak by phone	0 (0%)	0 (0%)	0 (0%)	-

**Table 3** Medical Record Comparison between VA and non-VA Providers\*

	VA Health Summary Training (N=27)	Attention Control (N=25)	P-value
Average of Total Number of Unique Medications	11.4 (sd=4.1)	11.3 (sd=5.5)	0.16
Proportion of Discrepant Medications	0.49 (sd=0.25)	0.44 (sd=0.23)	0.72
Number (%) Veterans where non-VA labs were drawn.	13 Veterans (48%)	15 Veterans (60%)	
Number (%) Veterans receiving duplicate lab at non-VA visit.	4 Veterans (15%)	9 Veterans (36%)	0.11
Number(%) Veterans receiving duplicate lab when lab was drawn the day of the medical visit (N=42).*	0 Veterans	6 Veterans	0.02

\*Analysis excluded Veterans who had their lab drawn before the non-VA medical visit where they shared their VA Health Summary, n=20 in the VA Health Summary Training arm, n=22 in the Attention Control arm.

**Table 4** Survey Results from Non VA Provider Visit using Provider Self-Report (N=33)

	VA Health Summary Training	Attention Control	p-value
	N=20	N=13	
Patient brought a VA Health Summary to the Appointment	19 (90%)	2 (17%)	0.001
Patient and I discussed care received at the VA	17 (81%)	7 (58%)	0.23
Patient discussed information s/he looked up on the internet.	8 (40%)	3 (23%)	0.45
<b>Questions specifically about the VA Health Summary asked <i>only</i> of those indicating a patient brought a summary in (N=19)</b>			<b>N/ Percent endorsing "yes"</b>
<i>I have confidence in the accuracy of the information provided.</i>			18 (95%)
<i>Information from this health summary improved my ability to have an accurate medication list and make treatment decisions about medications.</i>			17 (89%)
<i>I did not order some laboratory tests because of the information available on the health summary document.</i>			6 (32%)

Note: Smaller sample size is due to 20 (74%) of providers in the VA Health Summary Training arm and 13 (52%) of providers in the attention control returning their self-report surveys.

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