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Review Article

Impact of Screening and Brief Intervention (SBIRT), Urinary Drug Testing, Minimally Invasive Procedures, and Electromyography on Pain Reduction, Functional Improvement, and Continuity of Care in Chronic Pain Patients

Leon Margolin[1*], David Streem[2], Daniel Margolin[1], Sandford Lefkowitz[1]

[1]Comprehensive Pain Management Institute, LLC (www.cpmiohio.com), Columbus, Ohio, USA

[2]Chief of Psychiatry and Medical Director of the Alcohol and Drug Recovery Center (Lutheran Hospital Division), Cleveland Clinic Foundation

Associate Professor of Medicine at the Cleveland Clinic Lerner College of Medicine of Case Western Reserve University

[*]**Corresponding author:** Leon Margolin, Comprehensive Pain Management Institute, LLC, Columbus, Ohio 43213, USA

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Abstract

With the alarming explosion of overdose risk in the opioid epidemic since 1999, Opiate Use Disorder (OUD) has cost in excess of $600 billion, harming the economy and killing tens of thousands nationally. According to research conducted in 2017 on opioid mortality, data showed Ohio to be the second-highest opioid mortality state in the US, representing more than 2.6 times the death rate per 100,000 population compared to the US average (39.2 in OH vs. 14.6 in US, see Figure 1 below).

Although socioeconomic factors play a role, authors suggest that lack of availability or the consistent denial of these services by insurance carriers play a role in this situation. A recent Ohio Department of Health report showed that the population of patients susceptible to the opioid epidemic was in fact at least twice the non-minority risk level for COVID 19 pandemic (Figure 2). The recent AMA brief [26] alarms about great concern over increased opioid mortality during COVID 19 pandemic.

This retrospective chart review study provides a systematic analysis of the Screening and Brief Intervention (SBIRT), urinary drug testing, minimally invasive procedures and electromyography on the pain reduction and functional improvement of moderate to high risk chronic pain patients, with risk level determined by NARX scores.

Key Points

SBIRT protocol is mandatory for the compliant operation of a pain management clinic providing medical management to the population with a significant percent of high-risk patients in the high-risk area like Ohio.

Nerve Conduction Studies (NCS)/ Nerve Conduction Velocity (NCV) with or without needle EMG tests as part of the effort to document organic pathology (both initial tests and follow up tests) are medically necessary tests and cost-effective tests that have a strong statistically significant contribution to the proper choice of medications and procedure for chronic pain patients and strongly associated with functional improvement and pain reduction [18].

Using Pain Assessment and Documentation Tool (Figure 3 – PADT) and other validated assessment tools, we demonstrated a statistically significant impact of these services on pain reduction and functional improvement of moderate to high risk (as defined by NARX score and other factors) chronic pain patients over a 2 year period. Using these services and testing since 2011, our practice has been able to identify patients in need and refers to Addiction medicine evaluation and treatment for more than 2000 high-risk patients (who would otherwise be at significant risk of opioid mortality, morbidity, diversion, and incarceration).

Denial coverage for these services by third-party payers or defining them as "Unallowable costs" puts the practice in noncompliance with the guidelines described above, making the ethical operation of the practice impossible and putting patients and staff at considerable risk.

Objective data (Figure 1) shows that a new approach described in this review by the medico-legal system and third

party payors required to address the opioid crisis and protect the population at the high risk for COVID 19 epidemic (Figure 2).

Background

Opioid epidemic crisis affects the lives of thousands of Americans on a daily basis. Since 1999 hundreds of thousands of Americans have died from overdoses. On an average day in the US close to 5,800 people misuse opioids for the first time, and over 1,000 Americans on an average day are treated in the emergency departments for issues related to opioid misuse. The societal and healthcare cost of the opioid epidemic is at least 600 billion dollars and it continues to rise. Proper screening of pain management program patients (including SBIRT protocol G codes, POC UDS, and NCV/EMG) for narcotic medications is extremely important in the prevention of street drug use. The 2018 National Drug Threat Assessment conducted by the Drug Enforcement Administration, showed that prescription drugs such as "Opioids were responsible for the most overdose deaths of any illicit drugs since 2001" and "heroin-related deaths nearly doubled from 2013 to 2016". Ohio is one of the states most affected by the opioid crisis. Ohio has one of the highest death rates related to the Opioid crisis. Efficient and Ethical pain management program that uses appropriate testing to document organic pathology and screen appropriate candidates for pain medications and refer other patients to Addiction medicine evaluation is extremely important in this challenging environment of the opioid epidemic crisis.

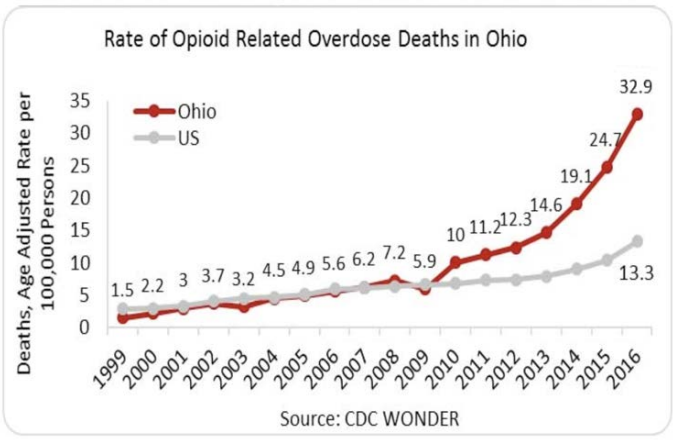


Figure 1: Based on 2017 government Opioid mortality data, Ohio is rated number two in the US with more than 2.6 times death rate per 100,000 population compared to US average rate (39.2 in OH vs. 14.6 average).

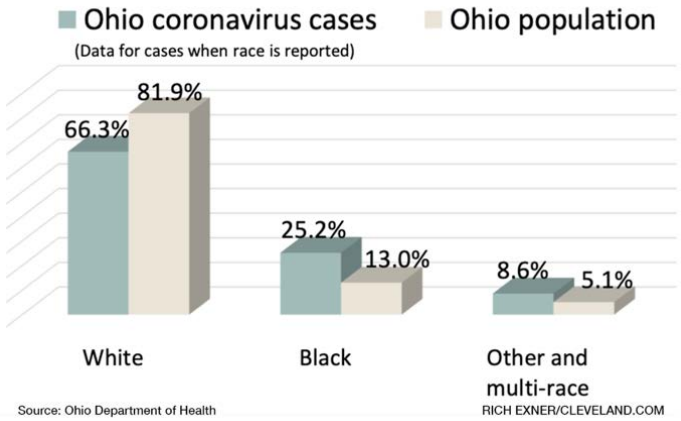


Figure 2: Based on the age, medical comorbidities, socio-economic challenges and possible immunosuppressive effect of Opioids, our patient is at increased risk for the COVID-19 pandemic.

The national and state guidelines require risk stratification and close monitoring of patients on chronic Opioid medication [1]. This study tests the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) functional improvement and continuity of care of chronic pain patients. This is frequency of the SBIRT protocol (G codes such as G0397), POC UDS (80307, 80304) and minimally invasive procedures (76942, 64450, 64418, 20533 and other similar codes are based on the "Pain Management Best Practices Inter-Agency Task Force Report", Medicare MLN and LCD OH L36029, Medicare guidelines for the presumptive and definitive testing [1,10,15].

Our practice is a tertiary referral practice that gets referrals for high-risk patients. This is the reason for conducting this study that tests the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) functional improvement and continuity of care of chronic pain patients for the quality of care documentation and information for the third-party payers.

Consequences of denial labeling as unallowed service for SBIRT and other services.

Unfortunately, on many occasions' providers face denial of the SBIRT and other services by the private and the government insurance plans. When the insurance carriers challenge the

necessity of SBIRT protocol (G codes), it denies coverage for procedures that are required by the Ohio state law (please review Michael Staples attached) and creates a "catch 22 scenario" that puts the patients and the staff at risk. These procedures include face to face time spent by physician and the nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT [2], COMM [3], Flowchart form based on SMBO Administrative Rule 4731-21-02 [4], withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines not only significantly impact pain program ability to function as a business, but also puts an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of our peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality.

At the time of the COVID-19 pandemic additional requirements for SBIRT, withdrawal screening and mental screening suggested by the American Academy of Pain Medicine [17]. Denial of these services exposes staff and patients for additional risks during the pandemic and depletes necessary practice funds required for the personal protection equipment suggested by the American Academy of Pain Medicine [17] during the COVID-19 pandemic.

National and state guidelines require documentation of the organic pathology as part of a comprehensive evaluation in a pain management clinic. NCV, EMG, and Autonomic testing is part of such evaluation.

For example, Mayo Clinic Proceedings [5] that were adopted by the state of Ohio and referenced on each printed copy of the OARRS report, reported that in the area of pain management "The predominant reason for inappropriate care was a failure of the prescribing physician to adequately verify patient's prior medical history". Appropriate testing including NCV and EMG is a step in such verification.

Most of the patients referred to Comprehensive Pain Management Institute, LLC (CPMI) for the evaluation of chronic pain in two or more extremities, or have the diagnosis of peripheral neuropathy, lumbar, or cervical radiculopathy suggested by the referring provider.

The numbers of NCV/EMG tests are based on the OH local coverage determination [6]. All patients had a comprehensive evaluation including initial, follow up evaluation forms, PADT forms enclosed, and extensive review of OARRS reports offered a written consent based on the AANEM guidelines [7] with a detailed explanation of the risk and benefits of the tests. NCV is reviewed and incorporated into the treatment plan.

The most commonly tested nerves in the upper extremities were sensory ulnar, median and radial studies, motor median, ulnar, radial, and in selected cased Axillary studies with Median and Ulnar F waves. For the low extremities the studies included sensory Sural, Superior Peroneal, Motor studies included Common Peroneal, Tibial nerves, and Common Peroneal, and Tibial nerve; F waves and H reflex studies selected based on the comprehensive assessment results. The needle examination typically included (UE) Cervical Paraspinals, Deltoid, Biceps, Extensor Carpi Radialis, Triceps, Flexor Carpi Radialis, APB muscle, (LE) Lumbar Paraspinals, Vastus medialis, Extensor Hallucis Longus, Biceps Femoris, Peroneus Longus, Medial Gastrocnemius, the studies selected based on the comprehensive assessment result.

Between 2011-2015 as a result of regulatory changes in the state of Ohio (including HB 93 law), CPMI received a high number of referral/evaluation requests for high risk challenging patient populations.

Many of these chronic pain patients seen by the CPMI suffer from anxiety and depression, and/or substance use disorders, drug-seeking behavior and had a poor tolerance of the NCV/EMG testing and poor cooperation with the test, especially with the needle part of the test (EMG), (this part performed with inserting EMG needle in 6-12 sites) and frequently refused by the challenging patient population. All the patients signed a written consent based on the AANEM guidelines [6,7].

Cost Efficiency

The cost of the opioid epidemic is more than 600 billion dollars and keeps rising annually. Pain Management programs like our practice that carefully screen and test patients to properly document organic pathology and utilize alternative treatments, careful monitoring, and SBIRT approach not only prevent significant morbidity and mortality but save very significant costs to the healthcare system.

Insufficient testing, monitoring, SBIRT screening and lack of alternatives to opioid medications can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing 5/9 appropriate pain medications to patients who may look for alternatives "On the street" with significant risks or morbidity and mortality.

The host of hospitalization including ER, inpatient care, ICU, detoxification, and maintenance programs is astronomic and can be reduced by patient screening treatment in outpatient programs like our practice (Comprehensive Pain Management Institute). This approach is also supported by the 2017 five-point strategy by the HHS.

When the insurance carriers challenge the necessity of SBIRT protocol (G codes), it denies coverage for procedures that are required by the Ohio state law and creates a "catch 22 scenario" that puts the patients and the staff at risk. These procedures include face to face time spent by physician and the nurse practitioners, more than 30 min of telecommunication video material, structured review of several assessments including patient's history and physical examination, PADT, COMM, Flowchart form based on SMBO Administrative Rule 4731-21-02, withdrawal assessment form, point of care and conformation urine and saliva drug screen reviews, OARRS reviews, and several educational materials. The initial evaluations include additional assessments such as SOAPP-R and ORT and additional educational materials.

Insufficient testing, monitoring, SBIRT screening, can potentially result in either prescribing opioid medications to not appropriate candidates that can potentially overdose or divert medications to other people, or not prescribing appropriate pain medications to patients who may look for alternatives "on the street" with significant risks or morbidity and mortality. The host of hospitalization including ER, inpatient care, ICU, detoxification, and maintenance programs are astronomic and can be reduced by patient screening and testing including NCV/EMG testing and other testing.

Our practice performs the NCV/EMG testing and another testing for a fraction of the cost charged by main hospitals in the area including the Ohio State University clinic.

It is difficult for many patients to find alternative providers. If left untreated, patients may turn to illicit means of obtaining substitute medications which drastically increases the risk of overdose and death (overdose death rate in Ohio is the highest in the nation and is up more than 800% since 2013). The cost of the opioid epidemic is estimated as more than 600 billion nationwide, we run a low-cost program that saves hundreds of thousands of dollars to Medicare by identifying and referring for addiction treatments for hundreds of patients using our SBIRT protocol. We billed much lower rates than comparable hospital-based programs and chose lower-cost codes (i.e. G codes vs. office visit and time codes).

In summary, denial payments for the appropriate testing and screening procedures for drugs and alcohol put in danger about several hundred high-risk patients (just in December of 2019 we had a case of assault by a discharged drug-seeking patient and an attempted assault by another patient at our office).

Denial payments for the appropriate testing and screening procedures for drugs and alcohol required by the state and national guidelines would not only significantly impact pain program (such as CPMI) ability to function as a business, but would also put an extremely vulnerable patient population at risk. Our patient population is unique as compared to many of our peers. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use. However, this allows our patients to achieve an extraordinary level of function relative to managing their pain and prevent morbidity and mortality.

Methodology

Risk Stratification for the patient in sample 1 (please see NARX table below):

NARX Score analysis of the patients in the sample.

Our treatment protocol, including the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) is based on patient risk stratification, NARX risk stratification (validated by the CMS) LCD OH L36029 [27] and state and national guidelines.

NARX score is a nationally validated risk score accepted in the state of Ohio and many other states [9]. There are no frequency guidelines for the G code, however, the NARX score (that shows the risk of overdose and death) seems to be the golden standard accepted by the CMS and Medicare. The clinical recommendations by the CMS and SMBO attached (attachment NARX Manual, NARX clinical application).

Only 6% of the sample 1 patients (3/50 pts) are low risk (NARX below 100)

Only 16% are high risk (NARX 100-189) Odd ratio for overdose increased 10 times (chapter 12 Overdose Risk Score page 63 attached).

The rest are at a very high risk of 34% (NARX above 200) and an extremely high risk of 24% (NARX above 350). The odds ratio for death from overdose is 10-12 times average (see the clinical application of the NARX score attached page 67). The odd ratio for overdose increased 10-12 times or more (chapter 12 Overdose Risk Score page 63 attached).

Undoubtedly the patient with this type of risk would require frequent G code screening and another testing such as EMG.

The vast majority of the "sample 1" patients were on increased risk dose of the opioids (more than 20 MME- increased risk of death as per CDC 2016 guidelines increased adjusted Hazard Ratio (HR) for an overdose and death) [10], many patients obtained opioids

from more than one prescriber, used multiple pharmacies and multiple classes of opioid medications, some also used sedatives or stimulates that greatly increased the risk according to the CDC guidelines and NARX score database (please find original NRAX score reports for each patient attached).

These types of risky patients require a high frequency of SBIRT (G code use) based on the criteria discussed above.

Risk stratification of sample 2 (sent by a separate email) demonstrated similar results.

Use of SBIRT G code vs. use of the E/M office visit codes.

Many of the CPMI patients have multiple medical comorbidities and dependent on transportation (can schedule only a limited number of visits). Therefore on many occasions, we have to schedule the minimally invasive procedure and the office visit for medical management on the same date.

This study shows the advantages of using SBIRT/G codes rather instead of E/M level 3 or 4 codes in these encounters. This approach provides cost-saving to third party insurance payers and emphasizes the screening and brief intervention approach which is crucial in managing high-risk patients on opioid medications.

Cost-saving secondary to use of G code use vs more expensive office visit (E/M) codes:

According to the national standards for Pain Medicine [11] office visit codes, 99213 and 99214 combined constitute almost 100% of the total visit billings (48.8% for 99213 + 44.9% 99214). These codes are more expensive than G codes and can also be combined with time codes.

Our billing data analysis below shows that in our practice these more expensive office visit codes (99213 and 99214) constitute only 16-30 percent of the total annual visits.

Our practice started the appropriate use of G codes since its inception in 2014 (which explains the 91% percent increase in comparison to 2013).

The use of these codes was based on the certified biller and coder review below and saved Medicare tens of thousands of dollars (as proven by the billing and coding data below).

Between 16-30 % of our follow up visits were billed as the more expensive E/M codes 99213, 99214, the rest were billed as G codes instead of more expensive office visit codes.

In other words, analysis of G code and office visit codes E/M codes billed shows significant cost savings in using G codes vs. the use of more expensive E/M codes for the office visits. That is clearly demonstrated in the patient example 1: the 79 times the G code was billed - it was billed for 79 follow up visits instead of more expensive office visit code.

Coding and billing statistics for our office

	Office Visits	G Codes	Total Visits
2014	2330	5104	8239
2015	2056	5622	8157
2016	1146	6621	7885
2017	1373	7294	8491
2018	1160	7907	8111
2019	2317	8838	9494

Implementation of the LCD OH L36029 [27]

Our study also provides a clear proof that frequency of the SBIRT/G code monitoring should depend on the compliance with the prescribed opioid medications and NARX score risk stratification, rather than reliance on the self-reported risk factors like alcohol or drug use in the initial evaluation by the staff or by a pain psychologist.

LCD OH L36029 [27] sets the frequency of monitoring that depends on prescribed opioid medications and other elements and not only on the initial psychological evaluation that used. These are the factors that set the frequency of testing and screening (including the SBIRT/ G codes use).

- Patient history, physical examination, and previous laboratory findings
- Current treatment plan
- Prescribed medication(s)
- Risk assessment plan

The rationale for such screening LCD OH L36029 defines as:

- Identifies the absence of prescribed medication and potential for abuse, misuse, and diversion;
- Identifies undisclosed substances, such as alcohol, unsanctioned prescription medication, or illicit substances;
- Identifies substances that contribute to adverse events or drug-drug interactions;
- Provides objectivity to the treatment plan; e. Reinforces therapeutic compliance with the patient;
- Provides additional documentation demonstrating compliance with patient evaluation and monitoring; g. Provide diagnostic information to help assess individual patient response to medications (e.g., metabolism, side effects, drug-drug interaction, etc.) over time for ongoing management of prescribed medications.

All these elements and factors are documented in our records and evaluated in our study. We would like to illustrate the importance of this approach using the examples below:

Patient examples that show an efficient SBIRT implementation that enables successful patient participation in the program and timely detection of aberrant drug-seeking behavior.

(Patient examples reviewed by the ABPMR without protective health care information disclosure and provide examples of the common cases mistakenly denied overlooked by providers and denied by third party payers).

Example #1: DS. This patient-reported the last drink 26 years ago, however, this patients meet criteria for a high-risk patient with a chronic pain syndrome failed back syndrome after (s/p) 4 back surgeries). This is an example of SBIRT screening directed towards compliance with the prescribed opioid substances and confirmation of the lack of the non prescribed narcotic substances as per SMBO, Ohio Board of Pharmacy and NARX [25], CDC, and LCD OH L36029 We will analyze the necessity and the frequency of the SBIRT and G code screening (SBIRT /G code) code at least 79 SBIRT (G code) performed since 2015) and the impact on patient compliance and participation in the program.

Case Review: This is a patient s/p 4 back surgeries that require chronic pain management.

NARX score analysis/ example 1

Narcotic Score 470 Sedative Score 170 Overdose Risk Score 190 (Odds ratio for overdose and death is about 10 times higher than average please refer to the NARX score review material enclosed (25 In addition, he is currently on 60 MME daily (Three times the dangerous dose threshold per CDC guidelines), he has received more than 150 prescriptions from 5 different prescribers using 2 different pharmacies including high-risk substances like Oxycodone, Morphine Sulphate and Fentanyl (that is responsible for a large number of overdoses and death).

Since this is a high-risk patient on chronic opioid medications, he requires frequent follow-ups and compliance monitoring. Our practice monitored the patient compliance with at least 79 screenings and brief interventions performed over the span of the last 3-4 years. This number is conservative for this type of patient and required by the SMBO, Ohio Board of Pharmacy and NARX, CDC, and LCD OH L36029.

The screenings are related to continuous exposure to different narcotic substances and not to his prior drinking history as described above. Of note, this chart was reviewed by the Board of Pharmacy in 2015 and found fully compliant.

Use of different codes for this patients would have resulted in increased cost for the third party payers.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) use saves significant costs funds for the third party payers and enforces compliance for the high-risk patients.

Also, this patient has been coming to our practice for close to 5 years (despite multiple competing providers just a few miles away) and even volunteered a video testimonial (together with close to 70 other patients).

Example #2: LH, on the initial interview with the pain psychologist – the patient did not report any history of alcohol or drug abuse. The Board of Pharmacy NARX score defines this patient as a very high-risk patient:.

NARX score analysis/example 2

Narcotic Score 451 Sedative Score 290 Overdose Risk Score 370 Stimulant Score 20 (Odds ratio for overdose and death is about at least 12 times higher than average or more please refer to the NARX score review material enclosed [25] Additional risk factor more than 100MME with an average 40 MME daily (please find the original NARX report enclosed). Recently patients are getting 60 MME daily. These are very dangerous doses according to the NARX and CDC guidelines attached that require frequent SBIRT (G code screenings).

The patient received more than 82 prescriptions for several types of medications including Percocet, Oxycodone, Morphine, Hydrocodone, Phentermine, Lyrica, and Gabapentin from 7 prescribers and 5 pharmacies.

44 screenings and brief interventions (SABIRT/G code) performed over the span of the last 3-4 years for such risk patients is a reasonable required number as per SMBO, Ohio Board of Pharmacy, and NARX, CDC, and LCD OH L36029. The screenings are related to continuous exposure to different narcotic substances.

Use of different codes for this patients would have resulted in increased cost for the third party payers.

This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) saves enforcement for the very high-risk patients on multiple controlled substances and saves funds for third-party payers.

Example #3: LH

Case Review: This is a chronic pain patient with a symptomatic spinal stenosis who requires chronic pain management. Besides, the patient reported being a victim of physical domestic abuse (additional risk factor) and required chronic benzodiazepine therapy (alprazolam).

The patient had multiple prescriptions of alprazolam (potent benzodiazepine) combined with opioids [12] which is an additional high-risk factor for overmedication and death that requires SBIRT interventions each time the combination is prescribed according to the CDC guidelines. Please find the list of the prescriptions enclosed.

The patient had an abnormal urine drug screen which positive for non prescribed benzodiazepine (which a very high-risk factor combination of medications as per accepted guidelines) and the follow up pain psychology report that conditioned patient clearance for opioids with closed monitoring (SBIRT protocol/G codes). 26 screenings and brief interventions (SBIRT/ G codes) performed over for such a very high-risk patient is a reasonably required r as per SMBO, Ohio Board of Pharmacy and NARX, CDC, and LCD OH L36029.

The screenings are related to continuous exposure to a combination of benzodiazepines narcotic substances and not to the patient's prior drinking history. Use of different codes for this patients would have resulted in increased cost for the third party payers. This example shows how efficient and cost-effective use of the SBIRT screening (G0397 code) saves enforcement for the high-risk patients on opioids and benzodiazepines and saves funds for the third-party payers.

Cases 1-3 show that despite the initial denial of prior risk factors (i.e drinking history) on the initial psychological interview, NARX score and structured assessment analysis can help to implement proper SBIRT/ G code screening for safety and compliance.

Example #4: JM

Patient chart review shows that the patient was prescribed on October 20, 2016, 30 tablets of OxyCodone 5 /APAP 325 for 15 days as per state prescription monitoring system (OARRS). On 11/2/16 our practice performed a random urine screen that was NEGATIVE for prescribed OxyCodone. The urine screen was reviewed by a Doctor of Pharmacology consultant and discussed with a pain psychologist, both of them requested tight monitoring because of concern for medication diversion (which is considered a felony by the state of Ohio and federal law).

Also, the follow-up note dated 11/02/16 states that the patient did not bring medication bottles for a pill count. The patient claimed she "has a lot of Percocet at home" raising additional concerns about hoarding and medication misuse. Unfortunately, the patient was not compliant with the reasonable monitoring and self-discharged herself.

NARX score analysis/example 4

This patient has a high NARX score (Narcotic score 371, Sedative score 150, Overdose risk score 170), she received opioid medications from 7 prescribers, using 4 pharmacies based on the Board of Pharmacy database.

In summary, our management of the case was appropriate and mandated by the federal and state law, SMBO, Ohio Board of Pharmacy, DEA, and CDC regulations. Patient examples of proper use of informed consent and respect for patient autonomy based on the AANEM policies and guidelines [6,7].

In the previous part of the study dedicated to the EMG/ NCV protocol, we introduced the use of informed consent in our practice. The following examples analyze the use of the informed consent by the patients.

Example # 5

ST This is a high-risk patient (NARX score analysis defines her as a high-risk patient: Narcotic Score 441 Sedative Score 200 Overdose Risk Score 340 (Odds ratio for overdose and death is about 10 times higher than average as per Ohio PMDS (OARRS) manual [25]. The Board of pharmacy summary also mentioned more than 5 opioids or sedative providers from 4 pharmacies. Proper testing such as NCV/EMG testing is necessary for such a patient for documentation of organic pathology.

This patient "First refused the needle EMG, then left the box unchecked and then agreed to the needle EMG test". The patient refused the needle EMG in 2014, later when the patient required prolonged care in 2016, and in 2017 she agreed to the needle testing. In 2016 she gave verbal consent (not marking the checkbox is irrelevant based on the AANEM ethical guidelines enclosed) and 2017 she gave both verbal and written consent which is also consistent with the guidelines. Patient informed consent for and against the testing was respected each time as per AANEM and Medicare consent policy. The 2014 and 2016 tests were both carpal tunnel evaluation exempt by the AANEM policy and provided credible information even without the needle testing.

Example # 6 MS

MS is a high-risk patient. (NARX score analysis defines her as a high-risk patient: Narcotic Score 381 Sedative Score 160 Overdose Risk Score 210 (Odds ratio for overdose and death is about 10 times higher than average please refer to the NARX score review material enclosed [25]. Mark recently had a urine screen positive for use of illicit marijuana (as per consultation with the Doctor of Pharmacology consultant). The Board of pharmacy also mentioned more than 4 opioids or sedative providers from 2 pharmacies (total more than 50 prescriptions). Proper monitoring testing such as NCV/EMG testing and alternative procedures are necessary for this patient.

This patient also has been seen at our practice for several years (despite multiple competing providers just a few miles away) that testifies for the quality of care she has received. Close follow up that included an interview by pain psychologist and psychological assessments helped to address patient anxiety. This patient initially refused the needle EMG testing. Even though the test is called "Needle" EMG, the test is performed using a recording probe (and not a needle) in a conventional sense (nothing is injected through the EMG "needle"). Therefore it's quite natural for a patient to refuse the needle EMG testing that does not directly relieve the pain (and also involves 6-12 probe sticks).

At the same time, the patient agreed to the nerve block injection that involved one small needle stick that provides immediate pain relief through medications injected through the needle. Patient informed consent for and against the testing was respected each time as per AANEM and Medicare consent policy. The 2014 and 2016 tests were both carpal tunnel evaluation exempt by the AANEM policy and provided credible information even without the needle testing.

POC UDS testing

Use of the POC UDS testing performed in compliance with the state and federal guidelines as part of the patient monitoring program using the risk stratification scale discussed above. Data shows a significant impact of the testing on the patient treatment plan and compliance [13-15].

Ultrasound-guided procedures

Ultrasound-guided procedures (peripheral nerve blocks, trigger point injections, and others). The minimally invasive procedures are cost-effective alternatives to the opioid medications required by the guidelines. All the patients received the informed consent and the medical necessity forms. Statistical analysis shows a strong impact of these procedures on the patient treatment plan and compliance.

Analysis of sample 2 – discharged patients

We have reviewed the charts of patients positively screened for non-compliance with the patient contract (illicit substance abuse, failed pill counts, doctor shopping, urine screens negative for prescribed medications, and other issues) using the SBIRT protocol (G codes) that we discussed.

Methods

- A retrospective review of charts of regular and incomplete studies to assess the impact of the test on the treatment decision making (such as choosing non-opioid adjuvant medications and opioid medications, pain reduction and functional improvement as documented by PADT forms and performance of proper clinical assessment that justify study repletion in the selected group of patients.
- The retrospective review studies the impact of the frequency of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) on the treatment decision making (such as choosing non-opioid adjuvant medications and opioid medications), pain reduction and functional improvement as documented by PADT forms and performance of proper clinical assessment as all the compliance and participation in the program (lengths of participation in months).

When pain reduction was 30%-50% we defined it as a "Moderate", above 50% a "Significant" and more than 70% a very significant pain reduction. When functional improvement as documented by PADT included 2 parameters or more, we called it significant, if only one parameter we called it a "moderate" functional improvement. If three or more functional parameters improved we called a very significant improvement. The effect is illustrated with several patient example analyses.

Results

SBIRT and UDS and procedure impact analysis

Sample 1

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis.

The table below how the average NARX scores change with Months in Program:

Table 1:

Months	Average	Max	Number Patients
Short (1 month)	308	450	6
Medium (>1 month, < 2 years)	271	390	13
Long (2 years)	309	770	23

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis results

Enforcing and monitoring patient compliance is a major challenge for pain management programs. The average and the maximum NARX scores reflect the high risk and the very high-risk profile of our patient population. Our SBIRT protocol and other tests and treatment described in the study is effective in monitoring and enforcing the high-risk patient compliance for prolonged periods (more than 23 months).

Functional Improvement Analysis

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Table 2:

	Moderate	Significant	Very	Total
Less than 2 years	16	7	6	29
2 years	5	1	20	26
	21	8	26	55

Table 3:

% of Row Totals for the table above.

	Moderate	Significant	Very
Less than 2 years	55.2%	24.1%	20.7%
2 years	19.2%	3.8%	76.9%

For example, of the 26 patients with 2 years of treatments (for whom we also had data on Functional Improvement), 20 of them or 76.9% showed Very Significant Improvement.

Performing a chi-square test in Table 3 (combining the first 2 columns to enhance the test) shows there is a significant difference in 'months of Treatment ($p<.01$).

Functional Improvement Analysis Results

There is a significant relation (at .05 level) between Months in Program and Functional Improvement. The SBIRT protocol and other treatments in our program showed a strong statistically significant impact on the patient functional improvement – which is the main outcome measure of the pain management program.

Pain Reduction analysis

Table 5:

	Moderate	Significant	Very	Total
Less than 2 years	22	4	2	28
2 years	17	5	4	26
Total	39	9	6	54

Table 6:

% of Row Totals for Table above

	Moderate	Significant	Very
Less than 2 years	78.6%	14.3%	7.1%
2 years	65.4%	19.2%	15.4%

Most patients had only moderate pain reduction (72.2%). Of the patients in the program for 2 years, 15% (4 out of 26) had Very Significant pain reduction while 65% of the 2-year patients had Moderate Pain Reduction.

Performing a chi-square test on Table 5 (combining the last 2 columns to enhance the test) shows there is a significant difference in 'months of Treatment ($p=.02$).

Pain Reduction analysis results

We demonstrated a very significant pain ($p=.02$) reduction over time in our program. As time participation in the program increases (more than 2 years), the pain reduction becomes more significant.

Statistical analysis

Sample 2

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis

The table below how the average NARX scores change with Months in Program

Table 7:

NARX Score vs Months in Program

	Average	Max	Number Patients
< 2 years	317	480	9

NARX Score (risk stratification) and SBIRT protocol screening effectiveness analysis results (sample 2):

Enforcing and monitoring patient compliance is a major challenge for pain management programs. As we have observed in sample 1, in sample 2 the average and the maximum NARX scores reflect the high risk and the very high-risk profile of our patient population. Our SBIRT protocol and other tests and treatment described in the study is effective in monitoring and enforcing the high-risk patient compliance for prolonged periods (more than 23 months).

Functional Improvement Analysis

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Table 8:

Months in Program vs Functional Improvement

	Significant	Very	Total
< 2 years	5	6	11
2 years	8	25	33

Table 9:

% of Row Totals for the table above

	Significant	Very
< 2 years	45.5%	54.5%
2 years	24.2%	75.8%

The table below compares Months in Program vs Functional Improvement (based on the PADT and other tools). Given the low number of patients in the 'less than a 2-year group, these 3 groups are combined.

Functional Improvement Analysis Results

All the patients in the sample stayed in the program for 6 months or longer, most of the patients for 2 years or longer. All the patients achieved functional improvement at 6 months and continue with significant or very significant improvement after that.

Pain Reduction analysis

Table 10:

Months in Program vs Pain Reduction

	Moderate	Significant	Very	Total
< 2 years	4	5	0	9
2 years	0	21	11	32

The difference between the "< 2 years" group and the "2 years" group is statistically significant (binomial test, P<.01)

Table 11:

% of Row Totals for Above Table

	Moderate	Significant	Very
<2 years	44.4%	55.6%	0.0%
2 years	0.0%	65.6%	34.4%

Pain Reduction analysis results

We demonstrated a very significant pain (p=.01) reduction over time in our program. As time participation in the program increases (more than 2 years), the pain reduction becomes more significant.

Sample 3 (discharged patients)

Discharge Reason	Number Patients	% Total Patients	3 months	6 Months	12 Months	2 years	Average NARX Score	Number with NARX Score
COC	14	35.9%	7	2	4	1	367	14
THC	2	5.1%	2	0	0	0	160	1
METH	2	5.1%	2	0	0	0	80	1
ETOH	12	30.8%	2	2	5	3	442	11
FENT	1	2.6%	1	0	0	0	50	1
ADLTERATION OF URINE	3	7.7%	3	0	0	0	236	3
BUP	5	12.8%	4	0	0	1	486	5

Two-thirds of all Discharge reasons were for COC or FPC.

Dividing the patients into 3 groups, COC, FPC, ALL Others, there is no significant difference in Average NARX Score amongst the 3 groups (t-test at .05 level).

Discharged patient analysis results

Data shows the high complexity and the high-risk status of our patients. The most discharged patient tested positive for cocaine (COC) and ETOH (35.9 and 30.8 percent), the highest NARX score was associated with buprenorphine (486).

NCV/EMG study analysis results

All initial and repeated tests were performed after a comprehensive evaluation and proper documentation of medical necessity as required by the AANEM guidelines and Ohio LCD.

All NCV tests with or without EMG testing had a documented impact on the narcotic and non-narcotic medication prescriptions, pain reduction, and functional improvement.

There was a significant association between pain reduction and functional improvement.

	Pain Reduction	Functional Improvement
Moderate	58.3%	20.8%
Significant	16.7%	25.0%
Very Significant	25.0%	54.2%

Applying a chi-square statistic to patient outcomes of functional improvement, we observe: that NCV and NCV+EMG are statistically significant at the .05 level.

Association between the repetition of the test and functional improvement (number of studies and percent of patients):

	Moderate	Significant
No Repeat	5	5
Repeat	0	14

	Moderate	Significant
No Repeat	20.8%	20.8%
Repeat	0.0%	58.3%

Conclusion

SBIRT analysis

The use of the SBIRT protocol (G codes such as G0397), of the POC UDS (80307, 80304) and minimally invasive procedures on the pain reduction (76942, 64450, 64418, 20533 and other similar codes) show a significant documented positive effect on increasing overall patient safety, encouragement of safe controlled substance prescribing for practitioners, maintaining compliance with State and Federal laws and regulations, reduction of patient overdose deaths, early detection and intervention of substance use disorder, and improving overall standards of care.

The vast majority of patients in the sample fit the high-risk profile which requires frequent SBIRT monitoring. CPMI SBIRT protocol is associated with effective long-term monitoring of compliance of the chronic pain patients on opioid medications and effective diagnostics of aberrant drug-seeking behavior and referral to Addiction Medicine evaluation. Our protocol is based on the "Pain Management Best Practices Inter-Agency Task Force Report", Medicare MLN and LCD OH L36029, Medicare guidelines for the presumptive and definitive testing, Medicare CPT code definitions.

This study has important conclusions for third-party payers and clinicians. SBIRT protocol (G codes such as G0397) is mandatory for a compliant pain management practice. Without proper implementation of the SBIRT protocol (G codes such as G0397), a safe and compliant pain management program is hardly possible, and patients and staff are exposed to significant risks.

Alcohol/substance abuse structured assessments and brief interventions of 30 minutes or longer, under code G0397 (SBIRT protocol) performed at Comprehensive Pain Management Institute, LLC are based on the accepted guidelines and "HHS Pain management best practices inter-agency task report" and required for the state and federal guidelines compliance. The SBIRT protocol is documented on all the charts in the study and compliant with the Medicare MLN # and LCD OH L36029.

This study shows a significant positive impact of the SBIRT protocol on pain reduction and function improvement is well documented in this study. SBIRT protocol is mandatory for the compliant operation of a pain management clinic providing medical management to the population with a significant percent of high-risk patients in the high-risk area like Ohio. Denial coverage for these services by third-party payers or defining them as "unallowable costs" puts the practice in noncompliance with the guidelines described above making the ethical operation of the practice impossible and putting patients and staff at considerable risk.

Denial payments for the appropriate testing and screening procedures for drugs and alcohol (such as of the SBIRT protocol (G codes such as G0397) required by the state and national guidelines) would not only significantly impact of a pain program ability to function as a business, but would also put an extremely vulnerable patient population at risk. The chronic pain patient population is unique as compared to many other specialties. Our patients are extremely complex; we take pride in creating individualized treatment plans which do require a significant amount of testing and time for screening for substance and alcohol use and other tests and procedures described in this study. However, this allows our patients to avoid the risk of morbidity and mortality (Ohio has one of the highest rates of opioid mortality per 1000 population in the country) and achieve significant pain relief and improvement in the level of function relative to managing their pain.

NCV/EMG analysis

Using a chi-square test, we can and conclude (with $P<.01$) that repeating the test has a positive association with functional improvement.

The association can be explained by the fact that an additional comprehensive evaluation was performed prior to the test and additional NCV and EMG test results were incorporated in the treatment plan that helped to achieve additional functional improvement.

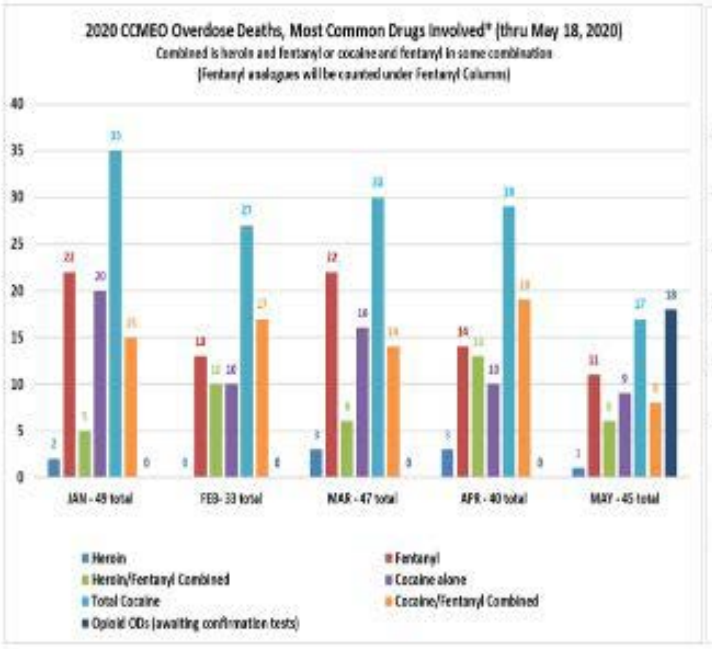
A functional improvement which is the main goal of pain management program (which is more important that pain reduction) has most strong statistically significant improvement with the use

of the NCV and EMG testing (with or without the needle testing). These findings underscore the medical necessity and cost-effectiveness of the NCV and EMG tests based on the sample examined.

NCV with or without needle EMG tests as part of the effort to document organic pathology (both initial tests and follow up tests) are medically necessary tests and cost-effective tests that have a strong statistically significant contribution to the proper choice of medications and procedure for chronic pain patients and strongly associated with functional improvement and pain reduction.

Despite a possible improvement in 2018-2019 data, objective data (Figure 1) shows that a new approach described in this review by the medico-legal system and third party payers required to address the opioid crisis and protect the population at the high risk for COVID 19 epidemic (Figure 2). These trends are confirmed by the Cuyahoga County Medical Examiner's Office (Figure 4 and 5) for 2019 and the beginning of the 2020. Of note, Cuyahoga County is one the most affected counties by COVID-19 as well.

Figure 4,5 and 6 (Cuyahoga County Medical Examiner's Office)



As a small independent office, without a special research budget me have done our best to provide SBIRT care with is compliant with the best standards in the specialty based on the American Board of Physical medicine and Rehabilitation and HHS guidelines discussed above.

We advocate for large prospective studies and provider and third party payor education on these subjects.

Additional risks of SBIRT denials during the COVID-19 pandemic American Academy of Pain Medicine (AAPM)

American Academy of Pain Medicine (AAPM) recently made recommendations for COVID-19 pandemic 20) additional requirements for SBIRT including additional withdrawal screening and mental screening suggested. Denial of the SBIRT and other services exposes staff and patients for additional risks during the pandemic. In addition the AAPM guidelines required using expensive personal protective equipment (such as N-95 masks). Denials of the SBIRT and other services deplete necessary practice funds required for the personal protection equipment and creates additional risks for staff and patients. The recent AMA brief [26] alarms about great concern over increased opioid mortality during COVID 19 pandemic.

Concerns for singling out minority patient populations and practices

There are multiple concerns raised about racial disparity, social injustice in context of the opioid crisis. Specifically concerns related to the fact that minority populations and practices targeted with unjust denials of the SBIRT and other essential services. On many

occasions, these denials are done without a proper review process specified in the Medicare integrity manual, without adequate expert review and with no expert review at al. That is one the reasons for the increased gap between opioid mortality in Ohio and average nation levels (2,6 time higher in Ohio, see Figure 1).

Huge Medicare Medic Aid HMOs silence criticism of these policies and denials by ignoring business integrity and patients safety retaliatory recoupment and forcing providers to resign from the plan. Several concerns were raised about Caresource the billion dollar HMO that controls more then 50% of the Ohio market by more than ten senators (Figure 7) in 2018. In April 2020 Case Western Reserve University, Board of Health of Cuyahoga County organized a conference on the Racial Disparity, Social Justice and the Opioid Crisis Conference at Case Western Reserve University [21] (the conference had to be postponed because of the pandemic). In June 2020, both Columbus and Cleveland proclaimed racism a public health emergency [22,23]. It is important to see these declaration and concerns translated into practical changes to avoid additional risk to the medical personnel and patients.

Concerns of the overregulated environment

As discussed during the Case Western Reserve University meeting [16], regulations, audits and supervision are necessary in middle of the opioid crisis. At the same time excessive regulations that interfere with efficient function of the pain clinics (the first responders in the opioid crisis), manipulation of the regulatory agencies by the retaliatory complaints from patients discharged for non compliance result in a significant worsening of the opioid crisis. (Figure 1).

SBIRT and other services denials and security risks to the staff and patients

The recent survey by the American Academy of Pain Medicine found high rate of finds high rate of violent threats toward pain practitioners [24]. Our practice has suffered from property damage, threats to the staff and recently from an unprovoked assault of the physician and two female medical assistants by a violent patient with aberrant drug seeking behavior.

The Columbus city prosecutor (Case 2020 CR B 001416) mentioned that “Because of the lack of funding secondary to insurance denials of essential services (such as screening and brief intervention for drug and alcohol) (pain practices like ours) do not have appropriate funding for additional security measures”.

This is a real public safe and health crisis that requires urgent attention.

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Ohio Opioid Task Force, Cuyahoga County Board of Health

Case Western Reserve University continuous education program expert panel

This data was reviewed and approved by the American Board of Physical Medicine and Rehabilitation [19].

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