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Use of Tracking and Reminder Systems for Colorectal Cancer Screening in Indian Health Service and Tribal Facilities

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Abstract

Background. Colorectal cancer (CRC) is a significant cause of morbidity and mortality among American Indian/Alaska Native (AI/AN) people. Screening at recommended intervals can detect CRC in its early, most treatable stages, or prevent CRC through removal of precancerous polyps. However, CRC screening percentages remain low among AI/AN people. Reminder and tracking systems can be used to improve CRC screening percentages.

Purpose. In this study we assessed the prevalence of CRC screening reminder and tracking systems in Indian Health Service (IHS), Tribal, or Urban (I/T/U) health facilities.

Methods. A telephone survey of randomly selected small, medium and large I/T/U health facilities nationwide was conducted. Three health facilities from each of the 12 IHS areas nationwide were selected from a list of I/T/U healthcare facilities that provide CRC screening or refer patients to another facility for screening, with the goal of having one small, one medium, and one large I/T/U health facility from each IHS area.

Results. Thirty-four facilities (94%) participated in the telephone survey between April 1 and September 24, 2010. All facilities used the IHS Resource and Patient Management System to manage their patient care, and 82% used the Electronic Health Record (EHR) version. Over half of these facilities (55%) performed in-office fecal occult blood tests (FOBT) collected during a digital rectal exam, all of which reported that they also sent FOBT cards home with patients. Fifty-three percent of facilities used an opportunistic, visit-based approach to CRC screening. Nearly a third (32%) of facilities reported using a reminder system to notify patients that they were due for CRC screening. Almost two-thirds (65%) of facilities used a reminder system to notify health care providers that patients were due for CRC screening. While 73% of facilities used a system to track whether patients were due for CRC screening, only 61% used a system to track patient results for CRC screening, and 42% used a system to track patients with a personal history of polyps or CRC.

In this Issue...

- 10 Use of Tracking and Reminder Systems for Colorectal Cancer Screening in Indian Health Service and Tribal Facilities
- 18 NPTC Formulary Brief: Alcohol Use Disorders
- 20 NPTC Formulary Brief: Alcohol Withdrawal
- 23 Electronic Subscriptions Available

Conclusions. A majority of facilities performed in-office FOBT tests using a digital rectal exam, which is a practice that is contrary to national CRC screening recommendations. Additionally, the majority of facilities reported not using an organized system for CRC screening. Use of patient reminders was suboptimal. However, facilities did report use of provider reminders, tracking when patients were due for CRC screening, and tracking CRC screening results. As the EHR system becomes more widely used and established, I/T/U facilities could be encouraged to

increase their use of the EHR tools available to aid in systematically increasing CRC screening percentages.

Background

Colorectal cancer (CRC) is a significant cause of morbidity and mortality in the United States (US).^{1, 2} In certain geographic regions, rates are higher among American Indian/Alaska Native (AI/AN) people compared with non-Hispanic whites.³ While CRC incidence and death rates have significantly decreased for many racial/ethnic groups over the past 10 years, they have not changed

Table 1. Electronic health system tools available for CRC screening promotion among Indian Health Service (IHS), Tribal, or Urban (I/T/U) health facilities.

System/Tool	Description	EHR/Non-EHR RPMS
CRS forecasts	Linked to the scheduling package; produces a list of patients, and identifies GPRA measures that the patient has not yet met. ²⁸	EHR or Non-EHR RPMS
EHR Consults	Allows one provider to refer to another provider to complete the screening. (Kimiko Gosney, Clinical Applications Coordinator, personal communication, April 20, 2011)	EHR RPMS
EHR Reminders	Responds to data cues in the patient record. Allows for additional management customization improvements such as clinicians being able to "resolve" reminders through the Notes and Consults tabs. ²⁹	EHR RPMS
Health Maintenance Reminders	Assists providers by monitoring and documenting due date to ensure patients receive proper screening at recommended intervals. This is found on the Health Summary. ¹⁷	Non-EHR and EHR RPMS
Health Summaries	Assists providers deliver comprehensive care to patients by highlighting patient problems and preventive healthcare needs. ¹⁷	Non-EHR and EHR RPMS
iCare	Helps to manage the care of patients by allowing patients to be viewed in panels with common characteristics, for example all patients with a history of polyps. ³⁰	EHR RPMS

CRS, Clinical Reporting System; GPRA, Government Performance and Results Act; EHR, electronic health record; RPMS, Resource Patient Management System.

significantly among AI/AN people.^{1,4} CRC can be prevented or detected through recommended screenings. Despite this, CRC screening percentages among AI/AN people remain lower than breast and cervical cancer screening percentages. According to Government Performance and Results Act (GPRA) data, only about 37% of the Indian Health Services (IHS) eligible active user population were up-to- date with CRC screenings in 2010, which was up from about 22% in 2006.⁵

The US Preventive Services Task Force recommends the following CRC screening tests for adults at average risk and aged 50 to 75 years: high-sensitivity guaiac-based fecal occult blood test (FOBT) or fecal immunochemical test (FIT) every year, flexible sigmoidoscopy every five years with high-sensitivity FOBT or FIT every three years, or colonoscopy every 10 years.⁶ People at increased risk, such as those with hereditary syndromes or a family history of CRC, or personal history of polyps or CRC should be screened more frequently and beginning at younger ages.^{6,7}

Healthcare provider recommendation is a strong predictor of increased CRC screening percentages.⁸⁻¹⁰ Reminder and tracking systems are effective at prompting healthcare providers to recommend CRC screening to patients.^{8, 11-14} However, in 2006, a national survey of 229

IHS and Tribal health care providers found that only 56% of respondents reported having an effective reminder system that notified them when a patient was due for CRC screening, and only about 41% stated they actually used the system.¹⁵

Most Indian Health Service, Tribal. or Urban (I/T/U) health facilities currently use the IHS Resource and Patient Management System (RPMS), integrates which clinical, business, and administrative information to manage patient care. The RPMS Electronic Health Record (EHR) is a modification of the traditional RPMS system, and many facilities have switched over to the EHR system.¹⁶ The IHS **RPMS** Patient Care Component Health Summaries Suite

Figure 1. Indian Health Service Area Map. Data Source: www.ihs.gov/PublicAffairs/IHSBrochure/map.asp



provides various tools to generate health care provider reminders, and track screening results to improve patient care.¹⁷ Some specific systems and tools available to monitor CRC screening include: Clinical Reporting System (CRS) forecasts, EHR Consults, EHR Reminders, Health Maintenance Reminders, Health Summaries, and iCare (Table 1).

Little is known about whether I/T/U facilities are using the reminders and tracking systems available in RPMS, or whether they are using other systems to improve CRC screening percentages. This study aimed to identify the types of system(s) that I/T/U facilities use to estimate CRC screening rates, types of reminder and tracking systems being used, and program(s) available to increase CRC screening rates.

Methods

A telephone survey was conducted with randomly selected I/T/U facilities from each of the 12 IHS areas, using facility representatives who were knowledgeable about CRC screening, reminder, and tracking systems at their facility (Figure 1). First, a facility list containing I/T/U healthcare facilities was compiled, selecting for facilities that had evidence of any CRC screening-related visit. This was based on Current Procedural Terminology (CPT) codes for CRC screening from October 1, 2006 to September 30, 2008. Facilities were then organized alphabetically by IHS area and size. They were categorized as small (those with an active user population less than 1,000), medium (those with an active user population of 1,000 to less than 5,000), and large (those with an active user population of 5,000 or greater) facilities. Next, an online random number generator (www.random.org) was used to randomly select the

facilities to contact to participate in the survey. A total of 36 key informant interviews (one small, one medium, and one large I/T/U healthcare facility from each IHS area) were planned. The IHS National Institutional Review Board (IRB) reviewed the protocol and determined the project to be a quality assurance activity in support of public health practice and disease prevention.

An initial email describing the project, with a signed letter attached, was mailed to each of the IHS Area Chief Medical the Clinical Officers and Applications Coordinators for each area. The letter requested contact information for appropriate personnel to interview. Once a contact knowledgeable about CRC screening reminder and tracking

systems for a facility was identified, an email was sent to that person to invite their participation. If a contact did not respond to the email or follow-up emails, a phone call was made. At least three attempts with the identified contact were made to complete the survey. If there was no response from a contact at one facility, another randomly selected facility of the same size from the same IHS area was identified to participate. When it was not possible to obtain an interview with a contact from a facility of the same size from an IHS area (this happened for small and large facilities, in five of the IHS areas), a facility of another size was selected for survey inclusion.

The survey contained both open-ended and close-ended questions regarding the facility's approaches to CRC screening and referral; types of CRC screening offered; health record systems; CRC screening reminders; CRC screening, tracking, and potential tools for patient management, and efforts to improve CRC screening reminder or results tracking. Survey administration took approximately 15 to 25 minutes. Descriptive analysis was conducted using Microsoft Excel, with each facility as the unit of analysis.

Results

A total of 34 (94%) facilities completed interviews for this project between April 1 and September 24, 2010. This included 15% small facilities, 38% medium facilities, 41% large facilities, and 6% mixed (where the respondent represented both a large facility and a small facility or where they answered for many facilities within a system of clinics that included small, medium, and large facilities). Although the initial goal was to obtain interviews for one small, one medium, and one large I/T/U facility from each IHS area, this was achieved only for four IHS areas (33%). Half of the completed interviews (17) were from IHS facilities, half (17) were from tribal facilities. Perhaps because of the small number of urban facilities around the country, no interviews ended up being conducted at urban facilities.

At least one staff member who was knowledgeable about CRC screening at their facility was interviewed for each facility; however, four facilities had two staff members participate in the interview. Of the 38 survey participants, 45% were information technology staff, 26% were nurses, 18% were medical or clinical directors or clinical division managers, 5% were administrative assistants/clerks, and 5% were staff physicians.

All of the facilities provided some form of CRC screening or referrals to another facility for CRC screening. Two facilities (one medium and one large) solely referred patients for CRC screening to other facilities. Of those facilities providing CRC screening procedures, 24% performed colonoscopies and 21% performed flexible sigmoidoscopies. Almost all facilities (94%) stated that they provided FOBT at their facility, with over half (55%) stating that patients completed the first card in-office with the stool specimen collected during a digital rectal exam, and took the other two home or the facility mailed cards to patients to complete at home. Eighteen percent of facilities provided double contrast barium enemas (DCBEs).

A majority of facilities (90%) reported having a system in place to produce their CRC screening percentages. However, three facilities (9%) stated that the reports weren't regularly run or were not available to providers. The majority (93%) reported using GPRA reports or GPRA reports in combination with another software tool (e.g., iCare) to obtain CRC screening percentages. Of the 32 GPRA data-reporting facilities, 72% used GPRA reports to obtain their CRC screening percentages, while the remainder were unaware of GPRA results or unsure how to obtain CRC screening percentages for their facility.

Participants were asked whether they considered their facility approach to CRC screening to be organized or opportunistic. An organized approach to CRC screening was defined as a facility that had a system in place to notify providers whether patients were due for CRC screening, along with a method to notify patients that they were due. An opportunistic approach to CRC screening was defined as relying on provider-patient interaction during clinic visits and not having a system to remind providers or patients about CRC screening. About one third (32%) of facilities reported some aspects of an organized approach and some aspects of an opportunistic approach to CRC screening, while 15% reported an organized approach, and the majority (53%) reported an opportunistic approach to CRC screening.

Key activities of organized systems included empanelment of patients, reminders, notifications, audits and chart reviews, use of iCare and other RPMS tools, reminder letters to patients, and community outreach. Facilities that had an opportunistic approach to CRC screening stated that they noted if patients were due when a patient came in for another medical appointment; relied on the primary care physician to notify the patient if he/she was due for screening; relied on the patient to request screening; or waited for referrals.

Less than a third of the facilities (32%) used some type of reminder system to notify patients due for CRC screening. When asked to specify what types of patient reminders were used, responses included: having educational booths at health fairs and picnics; placing literature in waiting rooms; recommendations provided by health care providers; followup letters; and phone calls. Only 26% of the facilities had a system in place that was set up to notify patients due for CRC screening and did not rely on the patient to come into the facility for a visit.

About two-thirds of the facilities (65%) used some sort of reminder system to notify health care providers about patients due for CRC screening. These reminders included: identifying all eligible patients once a year based on information from the patient history; use of software such as CRS forecasts or FileMan; nurses and case managers notifying primary care providers based on data from the patient's chart; use of health maintenance reminders; and EHR reminders. In addition, some facilities stated that they had newly acquired the EHR system and would be implementing reminders in the future.

Over half (53%) of the facilities used RPMS Health Maintenance Reminders to notify providers if patients were due for CRC screening. Challenges reported for Health Maintenance Reminders included: unreliability; inaccuracy; inconsistency with provider reporting; and difficulty with interpretation by providers. Several facilities that have switched to the RPMS EHR system reported not needing to use Health Maintenance Reminders as much because of other tools available in the EHR system.

Seventy-three percent of the facilities used a system to track whether patients were due for CRC screening. Among the noted tracking systems were: patient histories; reminders; Health Maintenance Reports; EHR clinical dialogs, iCare and other RPMS tools; and the Health Summary in EHR. Sixty-one percent of the facilities used a system to track CRC screening results. Tracking systems noted included: iCare and other RPMS tools; periodic EHR and non-EHR lab report examinations; periodic review of documentation in patient charts; care coordinators and case managers; and relying on surgeons and physicians to follow up on patients. Forty-two percent of the facilities used a system to track patients who had a personal history of polyps or CRC. Tracking systems noted included: problem lists; chart documentation; using the family history tab in EHR; using a polyp registry; and using case management, iCare, and other RPMS tools.

All facilities interviewed used the IHS RPMS system to manage patient care. The majority (82%) used the RPMS EHR versus the traditional RPMS system. Facilities that used the RPMS EHR system were asked if they used software tools available in the EHR system, and specifically whether they used those tools to improve CRC screening percentages. Seventy-four percent of the RPMS EHR facilities interviewed used EHR Consults, a software tool that allows providers to send referrals to other providers at their facility, and 56% used EHR Consults to improve CRC screening percentages. They reported using the consults within clinics and to refer patients for procedures such as colonoscopies. Challenges for EHR Consults included a steep learning curve and lack of time for training on the tool.

Sixty-five percent of the RPMS EHR facilities interviewed used EHR Reminders at their facility, and 54% used EHR Reminders to improve CRC screening percentages. Challenges reported for EHR Reminders included difficulty to set up and use; lack of training, and needing to go through the IHS area office to set them up. These factors contributed to delays, unreliability, and inability to differentiate between procedures (i.e., colonoscopy versus FOBT).

Among the RPMS EHR facilities interviewed, 61% used iCare at their facility and 36% used iCare to improve CRC screening rates. They reported use of iCare by case managers, nursing staff, and medical records personnel to notify health care providers of patients due for CRC screening. Challenges for iCare included lack of training and that iCare was not "user-friendly".

Discussion

This study showed that a number of areas for improvement in CRC screening tracking and reminders systems existed at I/T/U health facilities. The results of this survey demonstrate that I/T/U facilities often take an opportunistic approach towards CRC screening. However, an organized approach, with specific procedures and policies in place to inform providers when their patients are due for CRC screening, can help ensure that all eligible patients get a recommendation for screening.⁸ The facility's policies and procedures need to state that a single in-office FOBT test obtained from a stool sample following a digital rectal exam is not recommended for CRC screening, and that patients are given the appropriate at-home FOBT/FIT test to complete per the manufacturer's guidelines.

Provider assessment and provider feedback have been shown to be effective interventions to improve CRC screening rates.^{8, 12, 13, 18} Most of the I/T/U facilities in the current survey stated that they had a system in place that could be used to notify providers at their facility of CRC screening rates. Most of the participants reported that GPRA or GPRA in combination with a tool, such as iCare, was the primary source of data for reporting CRC screening rates. An area of concern, however, was that several participants stated that reports were neither consistently run nor provided to health care providers. Facilities could be encouraged to use available systems to produce CRC screening rates for the entire eligible patient population, and to produce screening percentages for each provider's panel of patients to encourage providers to recommend CRC screening.

The Community Preventive Services Task Force recommends provider reminder and recall systems as effective interventions to improve CRC screening rates.¹⁹ A majority of the I/T/U facilities that participated in the current survey reported using provider reminders. Health care provider teams need to be able to easily generate a list of patients who are due for CRC screening or who missed their referral appointments, and to generate reminder letters.^{8, 13} Paper and electronic reminders at the front of a patient's chart or EHR are effective methods of increasing CRC screening rates, and combining electronic plus manual reminders is even more effective.^{8, 11, 14, 20} Problem lists or health summaries that include preventive services such as CRC screening could be easily located in the patient chart and can also serve as a "cue to action".8 This study indicated that although available EHR reminders and iCare were being used by facilities, they were not necessarily being used for CRC screening. Facilities could make efforts to use tools that are available to them within RPMS, to help improve CRC screening participation.

A successful strategy to increase patient follow-up for CRC screening is to send out patient reminders, which is recommended by the Community Preventive Services Task Force as an evidence-based intervention to improve CRC screening using FOBTs.¹³ These could be in the form of letters, postcards, phone calls, or any combination of the three; the use of more than one option leads to better results.^{21, 22} Since a small proportion of the I/T/U facilities stated that they used patient reminders when patients were due for CRC screening, implementing patient reminders is an area of opportunity to increase CRC screening in the tribal health system.

Tracking systems help ensure that patients at average and increased risk receive proper recommendations, that patients have followed through with screening recommendations and referrals, and abnormal results receive appropriate followup and treatment.^{4, 8, 20} Electronic or paper-based tickler files, which allow facilities to file documents (e.g., followup reminders) based on the dates that they need action, can be used to track patient follow-through on CRC screening.⁸, ²⁰ Tracking can ensure reminders are sent; ensure patients receive screening results; track provider follow-up on lab results; and ensure that results from referrals are obtained.8, ²⁰ Based on the survey results in our report, a high proportion of I/T/U facilities reported having systems to track whether patients were due for CRC screening, but a lower percentage used their tracking system to track results of CRC screening, which is also critical. To ensure quality of care for patients, physician recommendations of complete diagnostic evaluation following a positive finding on FOBT are essential.²³ Less than half of facilities had a system to track and manage follow-up care for those with a personal history of adenomatous polyps. These individuals are at increased risk of developing CRC, and need to have testing at more frequent intervals than average-risked persons.²⁴

User-friendly software could make it easier for health care providers to query patients and track whether they are due or overdue for CRC screening.^{8,20} One barrier that was identified is that some software tools, such as iCare, are only available to RPMS EHR system users. Within iCare there is a Care Management Event Tracking (CMET) tool that aims to help providers track and manage patient care and minimize loss to follow-up.²⁵ In RPMS EHR facilities, a relatively high percentage used iCare in some capacity at their facility, but not as all facilities reported using iCare for CRC screening purposes. Additional training and support opportunities are needed to increase use of iCare and other EHR tools by IHS and tribal health facilities.

Many I/T/U facilities reported that the lack of Clinical Applications Coordinators was why they did not have reminder or tracking systems. Many facilities, however, stated that they were moving toward hiring a Clinical Applications Coordinator at their facility.

An incidental finding of this survey was that over half of the facilities that use FOBT completed the first card in the office, with a stool specimen collected during a digital rectal exam. This is consistent with a national survey ²⁶ that showed that a majority of primary care physicians used both in-office and home tests and one-quarter used in-office tests alone. National recommendations do not include in-office FOBTs, since in-office tests alone have been shown to miss up to 95% of advanced neoplasia.²⁷ Facilities need to ensure that patients are sent the appropriate at-home test cards and that the patient follows the manufacturer's instructions.

There are some limitations of this survey. Due to the small sample size (34 facilities), testing for significant differences by IHS area or facility size was not conducted. Many facilities reported having recently obtained the IHS EHR system, thus it was difficult to determine if differences in reminder and tracking systems were due to lack of use, or newness of the EHR system. In addition, many facilities indicated that there was a grace period upon receiving the RPMS EHR system where facilities were not permitted to use reminders or other tools available, which may have been why use of these tools was low. By better utilizing tracking and reminders, healthcare providers serving AI/AN may have be able to increase CRC screening percentages among their patient population. If facilities use more patient-centered care models, such as empanelment of patients, and staff members receive training and support on using RPMS EHR, RPMS non-EHR, and other systems, along with using their tracking and reminder tools more efficiently, CRC screening percentages could be improved markedly, eventually leading to reduced CRC morbidity and mortality among the AI/AN population.

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Indian Health Service National Pharmacy and Therapeutics Committee <u>Treatment of Alcohol Use Disorders</u> NPTC Formulary Brief February 2015



Background:

The Indian Health Service (IHS) National Pharmacy and Therapeutics Committee (NPTC) reviewed alcohol use disorders at the February 2015 NPTC Meeting, defining the disease, describing the pathogenesis, prevalence and clinical manifestations of AUDs and summarizing the medications used for treatment. The committee reviewed the Food and Drug Administration (FDA) approved medications for this indication: disulfiram, naltrexone, extended release naltrexone, and acamprosate. Topiramate, gabapentin, baclofen, selective serotonin receptor inhibitors (SSRIs) and ondansetron were also briefly reviewed.

Discussion:

Alcohol use disorders (AUDs) are prevalent in the United States (US) with the highest frequency in American Indians or Alaskan Natives. They are caused by a complicated interplay of genetics (responsible for ~50% of vulnerabilities to AUDs), psychosocial and environmental factors and result in significant morbidity and mortality. Despite the severe health consequences of AUDs, only 13.5% of people with alcohol use disorders received any type of treatment, most of which were in self-help groups. Less than 10% of patients reported treatment in a hospital or clinic based setting.

Referrals to social services or behavioral counseling are an important part of treatment, but these are often insufficient to treat moderate to severe alcohol use disorders. Medication-assisted treatment is an important component of management. Compared to either alone, the addition of pharmacotherapy to psychosocial treatment improves outcomes. Medications can help relieve cravings and symptoms of protracted withdrawal and allow neurons to readapt to a nonalcoholic state. This helps patients increase motivational readiness for change, leading to longer periods of abstinence.

The FDA has approved four medications for the treatment of alcohol dependence: two forms of naltrexone (oral and extendedrelease injectable), acamprosate, and disulfiram. There are data to support the safety and efficacy of all of these medications. In particular, many experts consider naltrexone first-line therapy given its proven efficacy and safety profile, both during supervised withdrawal and in the primary care setting. Despite availability, these medications are extremely underutilized. In a US Department of Veterans Affairs healthcare system, only 1.9 % of patients with alcohol dependence were prescribed naltrexone. A national survey of US physicians who treat addictions showed that only 3–13 % use pharmacotherapy for the treatment of alcohol dependence. Although physicians demonstrate low prescribing patterns, a majority of patients with alcohol dependence report an interest in medication-assisted treatment.

Findings:

<u>Naltrexone</u>: A multicenter randomized, controlled trial (RCT) in 2006 showed efficacy in decreasing heavy drinking and improving clinical outcomes in the primary care setting. A Cochrane Review in 2008 concluded that short term (16 week) treatment of naltrexone decreased the chance of alcohol relapses by 36% (NNT = 7) and lowered the risk of withdrawal in alcohol dependent patients by 28% (NNT = 13). Treatment up to 1 year gave no benefit for relapse prevention, but decreased overall alcohol consumption and diminished cravings

<u>Acamprosate:</u> Of 17 RCTs in 12 countries with 5000 patients measuring 3 months to over a year, 14 of 17 showed increased abstinence, time to first drink and decreased LFT levels. Combined abstinence rate at the end of treatment was 35% in acamprosate versus 21% in placebo groups. Of 3 studies that failed, only a 2 month treatment period was used suggesting that longer periods of treatment are required.

<u>Disulfiram</u>: On review of all 18 RCTs with administering disulfiram under direct supervision, 17 of 18 showed improved abstinence, treatment retention and/or proportion of days of alcohol consumption. The most comprehensive review of literature covering 1937-2005 concluded that supervised disulfiram is an effective treatment for alcohol dependence but disulfiram is similar to placebo when not under close supervision.

There is some promising data for the use of topiramate, gabapentin, baclofen, SSRIs and ondansetron for the treatment of alcohol use disorders but more data is needed.

Guidelines:

The NICE 2011 Guidelines for AUDs states that after a successful withdrawal for people with moderate and severe alcohol dependence, patients should be offered acamprosate or oral naltrexone in combination with an individual psychological intervention (cognitive behavioral therapies, behavioral therapies or social network and environment-based therapies) focused specifically on alcohol misuse.

The Treatment Improvement Protocol published by the US Department of HHS, SAMHSA and CSAT in 2009 stated that the medications were an important part of managing patients with AUDs and physicians should become familiar with these medications as AUDs are treatable medical conditions and treatment can improve health outcomes.

Conclusions:

Naltrexone should be used as first line therapy for those with moderate to severe AUDs unless there is severe liver disease or concomitant opioid use. Acamprosate should be considered first line if there is a contraindication to naltrexone. It can be used as second line if there is partial or no response to other medications. Disulfiram should be used in motivated patients with close supervision. It can also be used as an adjunct to other medications or to support abstinence if attending events that involve alcohol.

Given the increased prevalence, high morbidity and mortality of alcohol use disorders in the American Indian/Alaskan Native population, and given the recommendation for all these patients to have access to medications for the treatment of AUDs, the NPTC **added naltrexone** to the IHS National Core Formulary.

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Indian Health Service National Pharmacy and Therapeutics Committee <u>Alcohol Withdrawal</u> NPTC Formulary Brief February 2015



Background:

Benzodiazepines have been first line therapy in the management of alcohol withdrawal syndromes (AWS), including delirium tremens (DT), since they were first discovered in the 1950s. The National Pharmacy and Therapeutics Committee recently reviewed the role of benzodiazepines and other pharmacologic agents with potential utility in the management of AWS.

Discussion:

Alcoholism affects an estimated 8 million Americans, with approximately 500,000 episodes of patients requiring pharmacological management of alcohol withdrawal annually¹. The symptoms of alcohol withdrawal occur due to the central nervous system depressant effects of alcohol. It both enhances inhibitory tone by modulating gamma-aminobutyric acid (GABA) activity and inhibits excitatory tone by modulating excitatory amino acid activity (such as glutamate). The constant presence of alcohol maintains this balance. The sudden cessation of alcohol unmasks these adaptive responses leading to central nervous system over activity.

Benzodiazepines have served as the "gold standard" in treatment of AWS. Mild withdrawal can be safely managed in an outpatient setting with oral benzodiazepines. Moderate or severe alcohol withdrawal is best managed in an inpatient setting. This often begins with oral benzodiazepines, but many times may require the use of parenteral agents. Prior to the discovery of benzodiazepines, alcohol withdrawal was managed with alcohol infusions, antipsychotics (such as chlorpromazine) or paraldehyde². These therapies are no longer considered safe for use in patients. In more recent times, other alternatives have been evaluated, including anticonvulsants, atypical antipsychotics, centrally acting alpha-2 agonists, beta-blockers, nitrous oxide, propofol and baclofen.

Literature review:

Pharmacotherapy

A Cochrane review assessing the effectiveness and safety of pharmacologic interventions in treatment of alcohol withdrawal was published in March 2011. Five reviews, 114 studies, and 7333 participants were included in the review. The treatments reviewed included benzodiazepines, anticonvulsants, baclofen, gamma hydrobutyrate (GHB), and psychotropic analgesic nitrous oxide (PAN). Among these agents, benzodiazepines showed a protective benefit against seizures compared to placebo and potentially protective benefit compared to antipsychotics. However, no definite conclusions could be drawn about efficacy or safety due to the heterogeneous nature of the studies. There was not sufficient evidence in favor of the use of anticonvulsants, baclofen or GHB^{3,4}. A 2010 Cochrane review of 48 RCTs involving anticonvulsants in the management of AWS suggested that carbamazepine may be more effective than benzodiazepines in treating some aspects of alcohol withdrawal⁵.

In 2006, Addolorato, et al. randomized 37 patients with AWS to either receive baclofen 10 mg three times a day for 10 days or diazepam 0.5-0.75 mg/kg/day for 6 days, then tapering the dose by 25% daily from day 7 to day 10. This was conducted in an outpatient setting with daily assessment. The Clinical Institute Withdrawal Assessment of Alcohol Scale, Revised (CIWA-Ar) was used to evaluate physical symptoms of withdrawal. Both treatment arms experienced significant decreases in CIWA-Ar scores without differences between the two arms⁶.

Lyon, et al. studied baclofen in a randomized, double-blind, placebo-controlled trial involving 31 patients with AWS symptoms who completed 72 hours of assessment either as inpatients or with outpatient follow-up. The patients received symptom-triggered treatment (utilizing the CIWA-Ar score) with lorazepam and were randomized to receive either baclofen 10 mg or placebo three times a day, orally. The cumulative dose of lorazepam administered in this 72 hour period ranged from 1 to 1035 mg in the placebo group and 0 to 39 mg in the baclofen group. Eight of the subjects required 20mg or more of lorazepam during the assessment. This included 1 of the 18 subjects in the baclofen arm and 7 of the 13 subjects in the

placebo arm (P= 0.0004). Only 4 subjects required more than 50 mg of lorazepam, all of which were from the placebo arm $(P=0.023)^7$.

A NICE Clinical Guideline (2010) on diagnosis and clinical management of alcohol-related physical complications recommends offering either a benzodiazepine or carbamazepine following a symptom-triggered regimen for inpatient treatment of acute alcohol withdrawal. For patients with DT not controlled with oral lorazepam, they recommend parenteral lorazepam, haloperidol or olanzapine⁸.

Symptom-triggered therapy

In 1994, Saitz, et al. performed a randomized, double-blind, controlled trial of 101 patients admitted for inpatient treatment of alcohol withdrawal. The patients were randomized to either receive chlordiazepoxide four times a day (fixed-schedule therapy) or treatment with chlordiazepoxide in response to CIWA-Ar scores. The median duration of treatment in the symptom-triggered group was 9 hours, compared with 68 hours in the fixed-schedule group (P<0.001) The symptom-triggered group received 100 mg of chlordiazepoxide compared to 425 mg in the fixed-schedule arm (P<0.001)⁹.

Jaeger, et al. published a retrospective analysis of 216 admissions at Saint Mary's Hospital in Rochester, MN who experienced AWS during the admission. Patients were compared before and after the implementation of symptom-triggered therapy. No significant differences were seen in duration of treatment, benzodiazepine use, total dose of benzodiazepine, or total complication rate. However, there was a significantly lower rate of DT development post-implementation, particularly for those patients with no prior history of DT (P=0.04)¹⁰.

The *Archives of Internal Medicine* published a Swiss prospective, randomized, double-blind, controlled trial of 117 patients with alcohol dependence entering an alcohol treatment program. Fifty-six were treated with oxazepam in a symptom-triggered arm and 61 were treated with oxazepam every 6 hours in a fixed-schedule arm. Thirty-nine percent of the patients in the symptom-triggered group received oxazepam vs. 100% in the fixed-treatment arm (P<0.001). The mean oxazepam dose was 37.5 mg for the first group vs. 231.4 mg in the fixed-schedule group (P<0.001). The symptom-triggered group had a mean duration of treatment of 20.0 hours vs. 62.7 hours (P<0.001). There were no differences in measures of comfort between the two groups¹¹.

Clinical guidance:

Recommendations regarding the clinical management of alcohol withdrawal include:

- 1. Utilize oral benzodiazepines for AWS whenever possible.
- 2. The use of a symptom-triggered rather than a fixed-schedule management plan has been shown to significantly reduce the cumulative dose of benzodiazepines utilized, reducing the duration of therapy, progression to delirium tremens, and with similar measures of patient comfort.
- 3. Several classes of medications could be considered to either augment therapy with parenteral benzodiazepines or as alternative to their use.
 - a. <u>Anticonvulsants</u>- Carbamazepine has been shown to be comparable to oxazepam and lorazepam for the suppression of moderate alcohol withdrawal. It may have advantages to benzodiazepines, as it appears to ameliorate comorbid psychological symptoms and does not interact with alcohol¹². Phenobarbital has been used in the management of AWS, but due to risk of sedation should only be administered in the inpatient setting. Sodium valproate and gabapentin may have a role, especially as adjuncts, but data on their use is limited.
 - b. <u>Baclofen</u>- Growing evidence supports a role for baclofen in the acute management of AWS. It has been shown to decrease the amount of benzodiazepines utilized in inpatient and outpatient settings.
 - c. <u>Antipsychotics</u>- Some guidelines support the use of antipsychotics in the management of AWS. These should be used with caution. Phenothiazines and butyrophenones lower the seizure threshold. These agents also make it more difficult to shed excess body heat, complicating management of DT. If utilized, an ECG to screen for prolonged QT and correction of electrolyte abnormalities should precede use.

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