Prescription drug safe storage practices in Arizona tribal communities

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ABSTRACT
This paper provides an overview of an opioid poisoning prevention pilot project conducted in several American Indian/Alaskan Native communities using an applied public health approach. The intent of the project was to identify a prescription medication safeguarding option for use in the home environment. The authors engaged the target population to obtain their buy-in to select an intervention that was acceptable and appropriate for their needs. Focus groups and key informant interviews conducted in several tribal communities resulted in the selection of a heavy-duty, lockable storage box as the intervention. Through community-based partnerships, 55 boxes were installed in participating households. Along with the box, participants also received education on safe medication storage and disposal. At baseline, only 1% of the participants reported storing their medication securely. During a 60-day follow-up visit, 95% of the observed boxes were being used to store medications. Also at baseline, 31% of the participants reported a history of lost or stolen medications. There were no reported lost or stolen medications during the 60-day period among the participants. During the follow-up visits, project staff also found the boxes being used to store other items valuable to the participants. Reportedly, having their medication and other valuables securely stored in one location provided a heightened feeling of security. Since the completion of this pilot project, several organisations and entities have replicated it in their communities.

INTRODUCTION
In Arizona, opioid-related deaths have increased by 74% since 2012. In 2018, there were over 1300 suspected opioid deaths and over 9300 suspected opioid overdoses.1 The American Indian and Alaska Native (AI/AN) populations across the USA are similarly affected by the opioid crisis. According to the CDC, AI/AN as a group had the second highest overdose rate from all opioids in 2017 (15.7 deaths/100 000 population) among all racial groups in the USA.2 Phoenix Area Indian Health Service (IHS) surveillance data suggest a 310% increase of opioid-related incidences from 2008 to 2016 among its AI/AN service population in Arizona.3

The increased use of prescription opioid medications has led to patient misuse, addiction and diversion/theft.4 There is limited information on diversion statistics; however, it has been estimated that prescription drug diversion is a $72.5-billion-a-year industry.5 Strategies to curb diversion include educating patients on medication usage and proper storage.6 According to a report published by authors from Johns Hopkins University, one of the recommended strategies identified is to provide clear guidance on safe storage of prescription drugs.7

An additional article sought to demonstrate the value of safe storage of medication where children are present. Their findings recommended that providing lockable storage devices for prescription medications in concurrence with medication safety education was a practical intervention to reduce the poisoning risk among children.7

IHS Division of Environmental Health Services (DEHS) provides direct environmental health services and consultation to Al/AN governments and IHS programmes and includes the Injury Prevention Program, which is tasked with addressing injury disparities among AI/AN communities.8 Injury Prevention Program staff sought an opportunity to address the opioid issue by pilot testing a medication storage intervention for the home environment. Throughout this paper, IHS DEHS staff including Environmental Health specialists and the Injury Prevention Program staff will be referred to collaboratively as project officials.

METHODS
Medication lock box (MLB) devices are widely available for purchase in the public marketplace, commonly described as safes, security cabinets or lock boxes intended to safeguard medication. The MLB project goal was to identify a secure storage intervention to reduce opioid-related poisonings by decreasing unlawful access to medications. The project used various methods including: focus groups, a community-based design to ensure a comprehensive approach, safe medication storage education and placement of MLBs as a protective factor.

Public involvement
This project was designed based on knowledge, attitude and behavioural information collected from members of the target population and key stakeholders. This was done to establish community engagement, to ensure a culturally appropriate approach and to increase acceptability of the proposed intervention.

Focus groups
As described below, focus groups were conducted among AI/AN elders to gather input on acceptability of MLBs as a community-based option to encourage safe medication storage practices in the home environment. Focus groups are planned,
organised events in which participants are invited to share ideas and perspectives that can lead to facilitating public health interventions. In the study, four different MLB models were demonstrated, and all participants had hands-on opportunities to test the usability and functionality of each MLB model. Two heavy-weight boxes at approximately 9 kg each, and two lightweight boxes at approximately 0.9-1.4 kg each were presented. The heavyweight boxes had steel exteriors and were wall mountable. The lightweight boxes were portable and not mountable. All had unique locking mechanisms ranging from a physical key, electronic keypad, biometric touchpad to a combination dial.

From October 2017 to May 2018, 10 focus groups were conducted with a total of 101 participants from seven Arizona Tribal communities. There are 21 federally recognised tribes in Arizona; communities range from urban to rural settings. Elders were selected based on the nationally high polypharmacy rates among adults over 60 years of age. The definition for an elder (ie, age) varies by tribe: the authors selected the age of 50 years and over to be inclusive and maximise participation. They are also known as leaders of change in their community and families. Many elders live in multigenerational homes, which is unique to tribal communities in Arizona. The results strongly indicated that participants preferred the heavy lock box model, which featured an electronic keypad coupled with back-up physical key access. Based on these findings, a wall mountable box featuring two-method accessibility was selected for the project.

Programme design
Pilot sites were selected based on interest and capacity to implement and administer the project. Demonstration of capacity included partnership participation from the Community Health Representatives (CHR) programme to other various programmes such as Public Health Nursing (PHN), housing departments, first responders and local IHS clinic pharmacies. The CHR programme is an IHS-funded, tribally contracted and directed programme of community-based healthcare providers who provide healthcare, health promotion and disease prevention services in their communities. Due to their community-based work, the CHR/PHN programmes enjoy a heightened level of rapport with the target audience. Partners selected 55 elders in the communities based on working relationships and willingness to participate in the pilot project. These 55 elders were followed from start to finish for the entire project. To maintain consistency across all sites, several project tools were developed by the Injury Prevention Program staff that included: (1) recruitment expectation form; (2) participant application form; (3) user guide; (4) installation and observation survey; and the (5) evaluation form for 30-day and 60-day follow-ups.

Recruitment expectation form
The recruitment expectation form was developed to provide a project overview to participants and stakeholders. The form provided inclusion factors for participants, which were: participants must be ages 50 years or older, living within tribal boundaries and currently prescribed at least one chronic pain medication. Using these inclusion factors, a potential participant list was generated either by the IHS clinic pharmacy and/or by the CHR/PHN programme. The partners met the Health Insurance and Accountability Act (HIPAA) requirements as well as coding any patient identifiers to maintain participant privacy. From this list, participants were contacted by their local CHR/PHN programme and asked to participate in the pilot project. All participants that were contacted agreed to participate.

Participant application
The participant application form captured demographic information, ownership status of homes and any history of medication theft/diversion. Participants were required to sign a condition of agreement that authorised: consent for project officials to conduct home visits: to instal MLB units, interview participants and return for 30-day and 60-day follow-up evaluations.

User guide
The user guide provided education on safe medication storage and disposal methods for the home environment based on Food and Drug Administration (FDA) guidelines. In addition, the user guide contained a list of community locations that accept expired, unused or FDA-recalled medications for proper disposal. Finally, the user guide provided instructions on MLB operation and back-up entry options.

Installation and Observation Survey form
The installation and Observation Survey was the baseline data collection tool for the project. It was composed of an initial interview section to identify: ages of individuals living in the home, knowledge of prescribed medications with regard to storage location inside the home, disposal methods used and any history of diversion/theft. The form was also used to record MLB installation inside the home, four-digit personal identification number (PIN) and back-up key location.

Evaluation form
The evaluation form was intended to assess MLB usability and functionality. The form was used during follow-up visits at 30-day and 60-day intervals after initial installation. The evaluation was divided into two parts: a visual observation section and a participant interview section. The visual observations were conducted to document the use of MLBs. To properly assess this, participants were asked to demonstrate opening the box, thus providing information about MLB operational knowledge related to usability and functionality. The interview section was used to gather qualitative data that identified knowledge, attitudes and behaviours regarding prescription medication storage methods and disposal practices before and after MLB installation. The evaluation form also contained questions concerning medication diversion/theft and safety concerns following MLB installations.

Implementation
Project implementation required a comprehensive community-based approach. The Injury Prevention Program is a community-based programme that works in collaboration with many tribal entities. The community partners consist of first responders, housing departments and CHR/PHNs that provide day-to-day community services. The CHR/PHN programmes have a more direct role with the target population that includes in-home health screenings, wellness checks and preventative health education.

Lock box procurement
Based on focus group findings, the decision was made to purchase heavy-duty, mountable MLBs featuring digital keypad access coupled with a backup physical key entry system. This was the focus group consensus preferred model of the four MLBs.
models presented. The dimensions of the purchased MLBs were 35.1×24.9×24.9 cm and weighed 7.3 kg. Estimated cost per MLB was $75 USD. The MLBs were provided to project participants at no cost.

Kick-off meetings
Several kick-off meetings were held between project officials and partners to discuss roles and expectations. These meetings included project planning, information sharing and coordination between community partners and project officials. They also allowed the community partners to become familiar with the selected MLB model, to review the installation process and to distribute data collection forms.

Installation
MLB delivery and installation dates were established with participants and community partners. During installations, each partner had a specific role. Housing programme staff installed MLBs in the participant selected locations inside the homes. Participants were also asked to determine whether they wanted the MLB wall-mounted, anchored with a steel cable to an anchor point or freestanding. While MLBs were being installed, CHR/PHN staff reviewed the user guide with participants and completed Installation and Observation Survey form interviews. Participant options included the second key to remain with them, a trusted family member or a community or project partner. Depending on the community, back-up physical keys could be left with either first responders or pharmacy staff depending on whether the community had those specific programme options in place. Where available, first responders and pharmacy staff offered participants a 24-hour assistance resource. Additionally, a list of keypad access codes were recorded and shared with the CHR/PHN staff in case participants were to need assistance to open MLBs following the installation process. Copies of the user guide as a reference were left with participants at each of the homes. Prior to project staff leaving the home, participants were asked if they had any additional questions and were reminded of the 30-day and 60-day scheduled follow-up visits.

Programme evaluation
The programme evaluation follow-up visits were conducted by the CHR/PHN staff and project officials. The CHR/PHN staff established the scheduled times for the follow-up visits. The follow-up visits were conducted using the 30-day and 60-day evaluation forms that had similar questions to the baseline evaluation questions. Project officials conducted a visual observation to determine MLB status including: containing prescription medications, locked or unlocked access and located at original installed locations inside the homes. Two follow-up attempts were permitted for participants who missed their original scheduled visit in their allotted time range.

RESULTS
Baseline interviews indicated that all participants (n=55) reported taking prescription medications; 75% (n=40) were taking pain medications; and 44% (n=24) reported taking opioids. Since baseline interviews consisted of self-reported information, we were interested in learning if participants were self-aware of medication types, specifically opioids, being prescribed to them. Medication types reported among participants are summarised in figure 1.

At baseline, only 2% (n=1) of participants had medications stored securely. ‘Stored securely’ was defined as medication locked in some manner. Additionally, 31% (n=17) of participants reported a history of lost, stolen or misplaced medications. Interviews revealed 24% (n=13) of participants had children under the age of 14 years living with them. During the interviews, participants were asked where they stored medications (see figure 2). Over half (65%) of participants stored medications in their bedroom; less than a quarter (19%) stored them in the kitchen.

When asked about receiving assistance with their medications at home, 45% (n=25) reported they receive no assistance; 38% (n=21) are assisted by the CHR programme; 15% (n=8) are helped by a family member; and 2% (n=1) reported receiving assistance from the PHN programme.

The majority (41%; n=22) of participants wanted the MLB located in the bedroom. Overwhelmingly, 84% (n=46) of the MLBs were wall-mounted; 15% (n=8) were not mounted or secured to any fixed location in the home; and 2% (n=1) were unmounted and secured with a cable. Forty-five per cent (n=25) of the participants preferred the physical back-up key to be kept by a trusted family member or themselves; 40% (n=22) preferred first responders or pharmacy representatives; and only 15% (n=8) of participants chose to store back-up keys with CHR/PHN staff.

Follow-up visits
Follow-up visits occurred at 30-day and 60-day intervals after MLB installation. Not all follow-up visits were completed due to reasons such as the participant had relocated, was unavailable or language barriers existed. At the 30-day follow-up visit, 48 of the 55 (87%) participants were available. During the 60-day follow-up visit, 40 of the 55 (73%) participants were available.

Medication storage status
During the 30-day visit, 41 of the 48 (85%) MLBs were in use to secure medications. Of the 40 MLBs observed during the 60-day visit, 38 of the 40 (95%) were in use to secure medications (see table 1).

DISCUSSION
The need to address safe medication storage in tribal communities resonates across Arizona. This is evidenced by strong community participation throughout the project. This is further evidenced...
by the increased number of MLBs locked with contents stored inside from 30-day to 60-day follow-up visits. These findings indicate safeguarding access to medications in households where children are present is an important concern for elderly patients who are often caregivers for children and grandchildren.

Baseline
All participants, except one, reported they did not store prescription medications in a secure location. The three most common storage locations were the bedroom, kitchen and bathroom. These locations were initially reported by participants as unsecured and accessible to children living with participants or others who had access to the home. This finding emphasised the need to provide a cost-effective means to securely store prescription medications while raising participant awareness about the risk of diversion/theft. Placement of the MLB interventions coupled with concurrent education delivery served to change behaviour and reduce risk factors regarding unsecured and improperly stored prescription medications. This resulted in improved safe medication storage and disposal practices inside pilot project homes.

Another finding related to diversion/theft reduction was participant selection of community partners to store back-up physical keys. This decision was likely due to participants being concerned they would forget their four-digit access PINs after business hours. Only a few project participants elected to have back-up keys stored with CHR/PHNs. This was a deviation, where it was expected by project officials that CHR/PHNs would be the preferred back-up key holders based on the established relationship many CHR/PHNs have with the patients/participants.

Installation
As part of the installation process, participants were able to choose locations as well as the manner in which the MLBs were installed inside their homes. Participants chose to place them in three different locations: master bedroom, bathroom or kitchen. These rooms were self-reported during baseline interviews as primary medication storage areas and unsecured. The majority of participants selected wall-mounted MLB installations, which provided additional security by anchoring the MLBs in a permanent manner to wall frames inside the homes.

Follow-up visits
The increased observed MLB use rates at follow-up visits were substantial. This may be attributed to CHRs/PHNs providing consistent communication and dialogue with participants during the project period and with the reinforced safe medication storage guidance offered at each visit. In addition, participants mentioned several reasons that may have contributed to high use rates: (1) enjoyed convenience of medications stored in one place; (2) MLB was easy to use and accessible; (3) MLB kept medications out of reach from unauthorised individuals such as grandchildren and other visitors; and (4) could store additional valuables inside the MLB. These responses were similar to earlier responses collected during focus groups.

Limitations
Several limitations of this project warrant acknowledgement. Partnerships for this project proved to be varied. For example, housing departments were not always available in the project communities to provide installation services. In some cases, this led project officials to conduct MLB installations themselves or to use other community partners to assist. In some project communities, pharmacists were not available to assist to identify eligible participants. In those instances, the CHR/PHN programmes identified eligible participants through Electronic Health Record review. Finally, all follow-up visits could not be completed due to reasons including: participant relocation, participant availability or language barriers impeded communication and coordination.

CONCLUSION
The MLB pilot project is a promising community-based complement to clinic-based activities aimed at addressing the opioid epidemic. The project led to improved medication storage practices in participating Arizona and Nevada Tribal communities. MLBs, not unlike similar interventions intended to safeguard access to other lethal means of self-harm (eg, gun safes), represent a protective factor that aligns well with community-based approaches to injury prevention and control. Since project completion, several tribes, other IHS areas, as well as academic institutions have replicated this project; multiple funding opportunities have been made available to and by tribes in addressing opioid poisonings. This serves as a testimony to the power of simple, well-informed, community-based models intended to reduce opioid morbidity and mortality.

Recommendations for future sites to consider include: (1) implement procedures to use observers who had not been part of the study and have a vested interest in its success; (2) correlate observation usage with storage of a secondary key; (3) address disposal of unused or expired medications in the educational portion of the intervention for 30-day and 60-day follow-up visits; and (4) assess outcomes to identify if numbers of thefts, diversions or overdose change.

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