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Leadless Pacemaker: Report of the First Experience in Hawai‘i

Edward N. Shen MD; Cory H. Ishihara; and Dwayne R. Uehara

Abstract
We had the opportunity to implant the first leadless pacemakers in Hawai‘i. This device represents a major change in pacemaker technology. This is a report of the first five cases and a review of the literature. All these devices were implanted via femoral venous access (versus conventional upper chest axillary/subclavian/cephalic routes), with an unique fixation mechanism allowing direct attachment to the ventricular myocardium (dispensing the usage of long transvenous electrode leads). The miniature generator can is over an order of magnitude smaller and lighter than the currently available ones. This article provides an understanding of the device design, implantation technique, the advantages and limitations, and the potential of this new pacemaker.

Keywords
Leadless pacemaker, Pacemaker, Hawai‘i, Bradycardia

Introduction
Pacemaker implantation in humans began in 1958 with Drs. Elmvist and Senning, needing thoracotomy and epicardial electrode placement. Transvenous pacing (with the electrode wire inserted through a vein on the chest wall thus sparing the thoracotomy) came in 1962, with Drs. Lagergren, Parsonnet, and Weltrt. Since the first implant over half a century ago, there were many innovations, and these included programmability (altering the set pacing and sensing parameters), dual chamber capability (pacing in the right atrium as well as the right ventricle), remote monitoring (allowing radiofrequency interrogation of the device at a distance, from a nearby console), rate adaptiveness (altering the pacing rate according to the patient’s physiological needs), resynchronization therapy (involving pacing a third chamber typically the left ventricle, to allow both the left and right ventricles to contract in synchrony). Yet despite all these advances, the basic device format remained unchanged: an electronic generator housed in a pectoral pocket with one or more electrical conducting leads inserted via an upper chest vein (subclavian, axillary, cephalic) and anchored or screwed into the atrial or ventricular myocardium.

The pectoral pocket transvenous lead configuration is burdened by significant complications. Pocket complications include bleeding (hematoma), erosion, infection, and discomfort. Lead complications involve pneumothorax, dislodgement, perforation, phrenic nerve stimulation, erosion, venous thrombosis/occlusion, lead insulation defect and conductor failure, pericardial effusion (sometimes tamponade), tricuspid valve malfunction, and infection. It is estimated that for each implant, there is at least a 20% chance of a significant complication. Infection generally demands removal of the entire pacing system with its attendant morbidity. Infections often occur at a rate of 1%-2% at one year, 3% over the lifetime of the initial system, and over 10% after generator replacement. A leadless system that eliminates the generator pocket and the leads would avoid most of the above complications.

The concept of the leadless pacemaker started as early as 1970 with Dr. Spickler. A practical device that underwent successful human implantation and clinical testing came into fruition only recently. There are two devices in use: Micra (Medtronic Inc., Dublin, Ireland), and Nanostim (St. Jude Medical Inc., St. Paul, Minnesota). Both systems are available commercially in Europe (as of 2012 and 2013 respectively). In the United States, only the Micra was approved by the US Food and Drug Administration (since April 6, 2016). The current indication is for patients who have symptomatic bradycardia requiring single chamber ventricular pacing, typically with persistent atrial arrhythmia (fibrillation/flutter). It is also appropriate for patients with rare bradycardia (such as infrequent long pauses), when the lack of atrial sensing/pacing is not of major consequence. Symptomatic bradycardia with lack of upper chest venous access may prove to be an indication in selected patients.

This article is a report of the first 5 cases of leadless pacemaker implantation in Hawai‘i. This report also provides a review of the device design, implantation technique, and the advantages and limitations of the new technology.

Device and Implantation
The Medtronic Micra device is a small cylinder weighing 2 gm, with a size of 2.59 x 6.7 mm (height and width) and a total volume of 0.8 mL (Figure 1). It is a self-contained miniaturized titanium cased single chamber rate-responsive pacemaker. It is powered by a lithium carbon monofluoride (Li-CFx) battery, with an estimated battery life of 12 to 14 years (14 years at 50% pacing at 1.5 V at 0.24 msec pulse width at 600 ohms at 60 bpm). The rate-response mechanism is a three-axis accelerometer sensor. The steroid-eluting cathodal tip electrode is made of titanium nitride coated platinum iridium. There is an anodal ring electrode on the generator case. The fixation mechanism is composed of 4 electrically inactive protractible nitinol prongs.

The device delivery is by femoral venous access. After access is achieved, the vein is progressively dilated to accept the 23 French (Fr) introducer sheath over a super-stiff guidewire. The sheath is advanced up the inferior vena cava to the floor of the right atrium. The deflectable delivery catheter is then introduced into the right atrium and then the right ventricle. With a clockwise rotation, the catheter is turned to face the septum. The catheter is then pushed against the endocardium firmly. The position is confirmed by fluoroscopy in the right anterior oblique and left anterior oblique projections and by small injections of contrast through the catheter tip. The pacemaker is housed in a well at the tip, with the tines in a straight configuration, and with the back end connected to the outside of the delivery tool via a tether or rope. The well is gradually retrieved, allowing the
preformed prongs to resume their curved form and dig into the myocardium. The attachment is deemed acceptable when the measured parameters (sensitivity and capture threshold) meet criteria and when at least 2 out of the 4 prongs are attached (as evidenced by the prongs flaring out when the pacemaker is tugged via the tether). When the position is acceptable, one of the two tether ropes is cut and the tether can be pulled out, leaving the can in place (Figures 2 and 3). After the introducer sheath is removed, hemostasis can be achieved by a combination of Perclose Proglide closure device, purse-string (or figure-of-8) subcutaneous stitch, and manual pressure.

While not the focus of this article, the Nanostim is quite similar in shape and size, being slightly longer (2 gm, 42.0 x 6.0 mm, 1.0 mL), with the fixation mechanism being a helix, which requires rotation of the delivery catheter for fixation. The introducer sheath is smaller at 18 Fr. The battery life is similar. The rate responsive mechanism is temperature based.4,6

Figure 1. The size of a Micra generator as compared with the latest generation Medtronic dual chamber pacemaker and a quarter coin.

Figure 2. Implantation of the device, with the delivery catheter pushed up against the right ventricular septum. In left anterior oblique view.

Figure 3. The generator is delivered, and the delivery sheath is pulled back. In right anterior oblique view.
Case Series
Our series comprised of five consecutive patients, with mean age of 73.6 ± 11.0 years (range 64 to 86 years). They all had Micra devices. The implantations were performed between April 19, 2017 and July 31, 2017. They were four males and one female. The indications were atrial fibrillation with high grade AV block in two patients and sick sinus syndrome in three patients (two with lack of upper chest venous access).

The acute implant success rate was 100%. The average duration of the procedure was 47 ± 11 minutes. The duration progressively shortened from a peak of 65 minutes for our second case to 38 minutes for the last case. The mean capture threshold (the least amount of electrical current or energy needed to depolarize the ventricle) was 0.53 ± 0.27 volts (V) at 0.24 msec pulse width (range 0.25 V to 0.88 V). The mean sensitivity (the magnitude of the patient’s own ventricular depolarization detected by the device) was 13 ± 5.8 mV (range 5.2 to 19.1 mV). Two of the five patients had a narrow paced QRS complex. Typically, with conventional right ventricular pacing, the paced complexes were wide, due to dispersion of electrical conduction from the pacing site through both ventricles. A narrow paced complex suggested a more orderly sequence of depolarization, resembling more the spontaneously conducted QRS complexes.

There was no acute dislodgement. There was no major bleeding at the access site. One patient had minor oozing which resolved with manual pressure. Four out of five patients ambulated after 3 hours. The patient with mild oozing ambulated the morning after the procedure. The acute complications common to conventional pacemaker implantation were not present (pneumothorax, pocket hematoma, lead perforation). All patients were alive, with no dislodgement or infection on follow up at 5 months.

Discussion
The commercial availability of leadless pacemakers is a true revolution, a major paradigm shift. For over half a century (since 1962), the format for pacemaker implantation was pectoral generator pocket and transvenous lead insertion. This device eliminated the lead and the need for a pocket.

From the available literature, it is appreciated that the procedure is simple and easy, with few acute and chronic complications. The landmark Micra trial was published in 2016. This was a prospective, nonrandomized, multicenter, single-arm study enrolling 725 patients. The device was successfully implanted in 99% of patients. The primary safety endpoint was freedom from system-related or procedure-related major complications at 6 months. This was achieved in 96% of study patients compared to 83% of historical controls. The primary efficacy end point was the percentage of patients with low and stable capture thresholds at 6 months. This was attained in 98% of study patients versus 80% of historical controls. Both endpoints are significantly better among Micra patients than historical controls. The complications included perforation or pericardial effusion (1.6%), groin complication (0.7%), elevated threshold (0.3%), venous thromboembolism (0.3%), and others (1.7%).

There was no dislodgement or infection. Compared with an unmatched historical control cohort of 2667 patients, the absolute risk reduction was 3.4% at 6 months, resulting in the need to treat 29 patients to benefit one. Compared with cohorts, there was a reduction in subsequent hospitalizations (2.3% vs 3.9%) and device revisions (0.4% vs 3.5%). Longer term follow-up data from the Nanostim study showed an absolute risk reduction of 11.7% at 2 years, suggesting a need to treat 8.5 patients to benefit one. With more prolonged follow-up, the relative risk reduction, and thus the advantage of leadless pacing, is expected to increase.

Compared with conventional pacemakers, there is a 1% to 2% groin complication rate which is unique to leadless devices. This is in large part related to the very large introducer sheath, which may be difficult to significantly improve on. The cardiac perforation rate may be improved with cautious sheath maneuvering and by always implanting the device on the septum.

There are other advantages with leadless pacing. The procedure time is shorter, and should average 37 minutes for the Micra. There was a learning curve, as our first 2 cases took 50 and 65 minutes respectively, and our last case took 38 minutes. For conventional single chamber pacemaker implantation, the authors typically take 50 to 60 minutes. This is also a cosmetic advantage. The immediate shoulder mobility may allow for earlier resumption of normal activities (our first patient had a great round of golf three weeks post implantation), thereby avoiding the “frozen shoulder” and worsening of preexistent arthritis. Both leadless systems were designed to be compatible with magnetic resonance imaging (MRI). The battery life is longer (the average transvenous pacemaker lasts 7 years compared to 12 to 14 years for Micra). Lead related tricuspid regurgitation is fairly common with 10% of patients experiencing new severe regurgitation. This should be minimized as the small leadless generator does not physically interact with the tricuspid valve.

What has not been emphasized in the studies so far is that a high septal implant would allow for a fairly natural sequence of ventricular depolarization (as evidenced by a narrow paced QRS complex in two of our five patients). This may theoretically obviate the long-term ventricular desynchronization and heart failure seen in some patients with conventional right ventricular apical pacing. Without the constant reminder of the bulge in the upper chest, our patients report not being aware of the presence of a pacemaker. The persistent questions of ability to do pushups, lift weights, shoot a rifle, wear a seat-belt, and don a low cut dress have also ceased.

One question often raised is end-of-life of the battery and new generator replacements. The Micra does not have a dedicated retrieval system, unlike the Nanostim. Retrieval up to three years post implant has been done with the Nanostim system without event. About twelve to fifteen years post implant, the generator is likely to be well encapsulated and retrieval may be technically challenging. But retrieval of a used generator may not be necessary. A study using human cadaver hearts have shown feasibility of 3 simultaneous right ventricular Micra implants without physical interaction. Thus simply implanting a new device may be all that is needed.
Limitations of Current Study
The current case series only has 5 patients and no firm conclusion can be drawn from our results. Our cohort has expanded to ten patients at the time of the article review and the experience is unchanged. The statements made in the article mainly reflect the authors’ experiences and the current literature.

Limitations of Micra Device
It is estimated the Micra costs about $10,000 per unit. A regular single chamber pacemaker costs $2,500 to $5,000 with another $800 for a single lead. The higher upfront cost may be balanced by the longer battery life (which is practically double that of a conventional pacemaker). The reduced complication rate should translate to cost savings on a population basis. A cost-efficacy study reported that one complication of a transvenous pacemaker was more expensive than the initial implant itself.\(^{11}\)

One should also take into account the reduction of morbidity and human suffering (for example, the discomfort of a chest tube for pneumothorax, and the risk of severe complications in lead extraction for infection).

Indications for single chamber pacing constitute about 20-30% of all pacemaker implants (which exceed 1 million per year worldwide).\(^{12}\) Patients with intact sinus rhythm will generally benefit from a dual chamber pacemaker with atrial sensing and pacing capabilities, unless the need for pacing is highly infrequent and the pacing duration is short.

Future Directions
Right atrial implants and dual chamber pacing is the next logical step of leadless pacemaker evolution. Active research is underway in this regard and prototypes are being studied.

Further evolution may include an implantable cardioverter-defibrillator (ICD) itself being leadless and implantable endocardially. This is unlikely to happen in the near future, the limitations being that the defibrillator requires a large enough power source and a sizable capacitor to allow for rapid charge and discharge, and thus obliges a certain size which is difficult to miniaturize.

However, the leadless pacemaker may work well with the subcutaneous implantable cardioverter-defibrillator (SICD). This is a defibrillator by which the power source and the leads are all implanted subcutaneously on the chest. This setup provides only defibrillation. The leadless pacemaker may allow for anti-tachycardia as well as backup bradycardia pacing. The combination is currently being studied in a device by Boston Scientific.\(^6\)

Conclusions
Leadless pacing is an effective and safe alternative to standard transvenous pacing, with significant reduction in acute and intermediate term complications. It is a dramatic step forward in the art and science of pacemaker therapy.

Conflict of Interest
None of the authors identify any conflict of interest.

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References
Chuukese Patients, Dual Role Interpreters, and Confidentiality: Exploring Clinic Interpretation Services for Reproductive Health Patients

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Abstract
This exploratory study analyzes limited English proficient (LEP) Chuukese patients’ perspectives on dual-role interpreters in Guam and Chuuk. Methods included ethnographic observations of encounters with healthcare workers (HCWs) and 225 female Chuukese patients seeking reproductive healthcare in community health clinics: 126 women in Guam and 99 women in Chuuk. Ethnographic observations were supplemented by semi-structured interviews with 26 HCWs, and life history interviews with 15 Chuukese transnational migrant women. Notes from interview transcripts and observations were analyzed using critical interpretive and grounded theory. Findings demonstrated that Chuukese LEP patients need and at times want interpreters in order to understand their healthcare visits. In the absence of professional interpreters, ad-hoc interpreters (family interpreters and employees of the clinic) are an important resource. However, social and cultural concerns with community confidentiality influenced patient trust of staff interpreters. This lack of trust can limit access to health care overall, as some patients may avoid seeking care to prevent their confidential health information being disclosed. These complexities in interpretation must be considered in order for clinics to provide optimal care for the communities they serve.

Keywords
Interpreters, migrant health, health care, confidentiality, Micronesia, Guam

Introduction
The ability for patients and providers to communicate is important for the healthcare experience, especially for patients who are limited English proficient (LEP). LEP inhibits people from accessing care in what are already marginalized communities.1 Further, increases in LEP patients in clinics is linked to increased misdiagnoses, inappropriate treatment, misunderstandings, and/or distrust of care received, and lack of follow-up care.2-5 Providing interpretation services has been linked to more positive evaluations of healthcare experiences; improved understanding during visits; and increased visits and prescription filling.6,7 While several studies identify benefits for all interpreter types, the best outcomes are consistently linked to trained medical interpreters.7,8 Unfortunately, health insurance plans rarely cover interpretation, leaving many clinics unable to provide professional interpreters. Moreover, communities with a high volume of diverse migrants may encounter several language groups, making on-site professional interpreters for all languages logistically impossible. Instead, ad-hoc interpreters are used.

Ad-hoc interpreters are untrained interpreters who are family/friends of the patient, or clinic/hospital staff employed in other positions, pulled in to interpret as needed and called “dual role” interpreters.7,10 Scholars deem the use of ad-hoc interpreters unethical, and point to potential problems in disrupting social roles, understanding medical terms, providing accurate interpretation, and preserving confidentiality.6,7,11-13 Despite these risks, budgets and time constraints make them the most common interpreters.6,14 Few studies have examined dual-role staff interpreters separate from family interpreters, particularly regarding LEP patients’ perspectives.

This study analyzes the perspectives of female Chuukese LEP patients and the health care workers (HCWs) serving them at two reproductive health clinics. One clinic is located in Guam, a United States (U.S.) territory characterized by a large and diverse migrant population, and one clinic is in Chuuk, a state of the Federated States of Micronesia. Chuuk is the poorest state in Micronesia, and a lack of health, economic, and educational infrastructure fosters migration to the U.S.15-17 These circumstances, combined with discrimination in host communities leads to a vulnerability in Chuukese communities that is reflected in their disproportionately poor health outcomes.18-23 Previous studies of Chuukese patients in Hawai‘i demonstrate that 75 percent of Chuukese patients need interpretation assistance, and prefer family members or friends for interpreters.24 Why this is the case is largely unexplored. The present study explores the dynamics between patients, dual-role interpreters, and HCWs, and considers concerns with confidential interpretation in Chuukese communities.

Methods
From September 2012 to August 2013, Chuukese women were observed during reproductive healthcare appointments at two clinics: (i) Guam’s Island Community Clinic (pseudonym) and (ii) a reproductive health clinic in Chuuk. Long-term participant observation was followed by semi-structured interviews with HCWs and life history interviews with transnational Chuukese women. Roughly half of the population served by Island Community Clinic was of Chuukese descent, where there were two Chuukese-speaking staff. These individuals were hired in other support positions with the expectation they would serve as dual-role interpreters for this marginalized community. This was part of a larger study that explored both Chuuk and Guam to compare reproductive health care and experiences at home and abroad.25 LEP patient issues were not expected in Chuuk, but health care providers in Chuuk are largely outsourced from other countries, making English the primary language utilized in exam rooms. Thus, interpretation concerns for LEP patients described herein are relevant findings for both sites.
Observation Phase
Chuukese women were approached in the waiting room, assessed for eligibility, and were asked for permission to be observed throughout their healthcare visit. The HCWs serving Chuukese women were also observed, and provided informed consent prior to undertaking any clinical observations. Inclusion criteria were: women who identified as Chuukese, aged 18 years or older, and seeking care in the reproductive health clinic. After a participant gave consent, the researcher accompanied her as she moved from medical records, to vitals and intake, then to the clinician providing care, and finally to the processing nurse. Ethnographic jottings were written in-between conversations and longer field notes were typed immediately upon visit completion.

Interview Phase
For the interview phase with Chuukese women and HCWs, interview guides and final inclusion criteria were edited after analyzing months of observations in an iterative process. Interview participants were recruited after several months of rapport and trust-building in the clinics and communities. All interviews were recorded with the permission of participants and transcribed verbatim; notes were also taken during the interviews.

Reproductive Life History Interviews – Chuukese Women
Life history interview guides for Chuukese women were drafted with guidance from Hirsch, who worked with transnational Mexican women, then edited to reflect particular historical and sociocultural elements shaping Chuukese women’s lives and early observational findings. Hirsch’s approach included a six-part life history interview that began with less sensitive topics, such as childhood and family life, and progressed to more sensitive topics. Inclusion criteria were women of Chuukese descent who: (1) lived in Guam for at least one year; (2) spoke English proficiently; and (3) were at least 35 years old, to capture a longer time span for life histories. Complete interviews lasted an average of four hours with a wide range (1 to 11 hours) over the course of one to four sessions. A $15.00 gift card per session was provided as an incentive, as well as a thank you gift (ie, scented lotion). Interview sessions were limited to 90 minutes, unless the participant insisted continuing upon visit completion.

Semi-Structured Interviews – HCWs
Semi-structured interviews with HCWs asked a range of questions, including: their experiences working in publicly funded clinics serving Chuukese patients, their perspectives on Chuukese migration, and their concerns about Chuukese women as patients: behavioral, environmental, economic, and sociocultural. Inclusion criteria were HCWs (1) aged 18 or older, (2) who identified as serving Chuukese patients seeking reproductive health care. A $25.00 gift card was offered as an incentive for participation. HCW interviews lasted 30 to 90 minutes.

Data Analysis
Data were analyzed in the software program MaxQDA+ using a modified form of grounded theory. It was modified to reflect Lock and Scheper-Hughes’ critical interpretive theoretical framework, which synthesizes structural determinants, social and symbolic meaning, and individual lived experiences. First, field notes and interview transcript sets were analyzed separately, exploring common themes within the data set, creating codebooks and coding according to themes. Overall themes were then assessed for the entirety of data, and all notes and interviews were recoded together. The findings informing this manuscript emerged from analyzing the following codes: patient-health care provider interactions, and the subtheme: language. An additional code: perceptions of others, was analyzed, separated by the role of the participant (eg, Chuukese women’s perceptions of HCW).

Ethical Considerations
Ethics review was approved by both the home and local institutions. All procedures for informed consent (in Chuukese and English) and ethical research were followed. Pseudonyms are used to describe all participants and clinics, and HCWs are not distinguished by profession to protect identities.

Results
Health care observations were completed with Chuukese women seeking reproductive health care and their HCWs in Guam (n=126), and in Chuuk (n=99). Chuukese life history interview participants (n=15) were middle aged (mean = 46 years old, range: 35 to 60 years old), with an average of 3.7 children (range: 1 to 8 children). Most had public (n=7) or no (n=6) health insurance at the time of the interview. HCW interview participants (n=26) consisted of physicians (n=4), nurse practitioners or nurse midwives (n=5), nurses and nurse aids (n=6), medical records clerks (n=6), and non-medical support personnel (medical social workers, health program coordinators and health educators) (n=5). HCW interview participants were primarily female (n=21) and ethnically identified as Chamorro (n=8), Filipino/a (n=8), Chuukese (n=7), and White (n=3).

Findings from all phases are presented together. Three themes emerged across all data sets: 1) the perceived importance of hiring Chuukese interpreters to interpret and advocate for Chuukese migrant women; 2) Chuukese concerns with confidentiality; and 3) the influence of age and gender on confidentiality concerns. Data are presented by theme, and representative quotes from Chuukese women and HCWs are presented together within themes.

Theme 1: Hiring Chuukese staff to interpret met an important need
When Island Community Clinic hired two Chuukese staff to serve as dual-role interpreters, Chuukese women expressed great appreciation for this decision. They stated they felt more respected, safer, and thought it would be easier for Chuukese
patients to receive services now. Jevlyn (All names are pseudonyms), for example, said:

“It’s good if Chuukese working here too. Before, no Chuukese, we treated like, you know nobody wants to help us!”

Jevlyn articulated what many women described: that these dual-role staff interpreters don’t just translate, but advocate for the Chuukese patients:

When they go down to [Island Community Clinic] they say ‘oh I like that’ cause [Chuukese interpreter] really helps them. And I’ve heard that from other people. One woman went to appointment and waited there since early morning, but stay all the way after lunch and they don’t call her! Yeah, so that Chuukese [employee] came out and said ‘oh, why you guys don’t call this lady she been here since early morning.’

It was not only Chuukese patients who expressed appreciation for the hiring decision; HCWs also perceived this as an important step toward improving care for Chuukese patients. A particularly poignant statement reflecting this theme came from Sally, an H CW who described her hope that other clinics would also hire Chuukese interpreters:

I like how [Island Community Clinic] hired a Chuukese interpreter…If’d be neat if [other clinics] could do it, if they have the funds…with most of the women coming from Chuuk. That would really help a lot with the language barriers.

The Chuukese interpreters also saw their role as successfully helping Chuukese patients. One interpreter, Nelly, said:

I see that for me being here is easier for the Chuukese. Yeah they feel more confident especially with the language barrier.

Choosing to hire Chuukese staff in Guam’s Island Community Clinic who could also interpret for patients was perceived as a good decision by all participants.

Theme 2: Chuukese patients were concerned with loss of confidentiality

Although all participants stated that hiring dual-role interpreter staff was a good idea, some Chuukese patients did not trust Chuukese interpreters with their private health information. Jevlyn, who previously celebrated the hiring of these Chuukese staff, was one of many women with this concern:

Jevlyn: For me, right, when, when I saw those Chuukese, I really thought “whoa back up?” right? I don’t feel good when they, translated if I have something. […]

Author: So it is almost better to have doctors and nurses who are not Chuukese?

Jevlyn: Yes!!! […] I don’t care, as long as not Chuukese cause, […] if they know my sickness, right? They go and tell everybody. They make story about it.

While the interpreters explained to each patient that they honored confidentiality, patients did not believe it. Pamela, another Chuukese woman, refused to return to that clinic after learning about the Chuukese staff hires:

Pamela: I want to go to the other clinic. I don’t like Chuukese to know my business.

Author: Oh, well they have to keep it secret. It’s confidential.

Pamela: No secrets with Chuukese. I’ll take the extra bus to go to the other clinic.

Pamela was willing to go out of her way to a clinic 30 minutes further to avoid the Chuukese interpreters. Several women told me that they or their relatives similarly avoided Island Community Clinic since they hired the Chuukese staff. Women who continued to visit this clinic often said they were nervous about sharing their private health information, and requested no interpreters despite clear LEP. On one occasion, a patient asked if she could hide behind the author so that the interpreter didn’t see she was there (and pregnant), because they (the interpreter and the patient) know the same people. Patients also regularly brought family members to translate for them to avoid the use of the Chuukese staff. The researcher noted family interpreters were frequently LEP, but patients consistently requested no staff interpreter when accompanied by a family member who could try to interpret. These concerns and avoidance practices were expressed regularly throughout all phases of data collection.

This issue was based on a general consensus that Chuukese people do not respect the concept of confidentiality. One patient, Lizzy, explained:

Confidentiality doesn’t exist in Chuuk. You know we read and sign this paper, but it doesn’t mean anything.

This concern was discussed at both the Guam and Chuuk clinics, but was a more frequent theme in Chuuk clinics, as there were more Chuukese HCWs. One Chuukese HCW in Chuuk, Bella, explained:

Everything is confidential but you know in Chuuk, paper stays here but the word of mouth doesn’t. You know people talk.

A second Chuukese HCW stated:

Well you know in Chuuk you can’t trust anybody.

The Guam-based Chuukese dual-role interpreters acknowledged this barrier to their work as well; that confidentiality is not a characteristic that is perceived to exist in the Chuukese community and thus, they were not trusted. Rayna, a Chuukese interpreter, explained:

One of our coworkers was telling my supervisor that there are some Chuukese that don’t want me to help them. And I told my supervisor you have to remember that culture is very, very strong in our islands. And they think if I’m Chuukese, they don’t want me to know.
She continued, explaining that it depends on the situation:

But I’ve seen some, they’re very open because they need to understand. But if they don’t want me to help, I’m ok. Because we are from the same place.

Rayna and Nelly, the two staff interpreters in Guam, explained that the closer their island was to the patient’s island of origin, the more likely the patient did not trust them; this was because of fear of knowing the same people and thus their private health information getting disclosed to community members. Yet, many patients with LEP did not have an alternative to utilizing their interpretation assistance.

**Theme 3: Trust was mediated by gender and age**
Trust in staff interpreters was a concern mediated by other factors, such as age and gender. First, Chuukese patients complained about the age of Chuukese interpreters. In Guam, younger patients complained about the older interpreter, and older patients complained about the younger interpreter. In Chuuk, older women like Eryna, told me they didn’t trust Chuukese “girls” working at the Chuuk clinic:

Yeah. I don’t feel like going have check up with those girls. Yeah, they talk even though we sign confidence. Confidentiality doesn’t work in Chuuk. They need older women in there if they want older women to come for care. Then we are equal and we can talk to each other about things.

Similarly, young girls were scared to seek family planning services in Chuuk because of too many “aunties” (ie, older relatives or women close to the family/community) working in the clinics, who could reveal they were sexually active. HCWs of Chuukese descent corroborated these concerns in their patient population.

In regards to gender, Rayna explained that men were uncomfortable with her, and she understood, as she was uncomfortable interpreting for them, too (Rayna and Nelly translated for all sections of the clinic, not just reproductive health). She said:

I hope they are hiring, cause I told them it’s kind of weird me translating to a male [laughs]. They won’t open up to me.

Chuukese patients and Chuukese HCWs stated that clinics should have male and female translators there at all times to accommodate the importance of respecting gender roles.

**Discussion**
Achieving high quality healthcare is important in efforts to improve Chuukese women’s disproportionately poor reproductive health outcomes. A critical component of this care is the ability to communicate effectively with HCWs, which includes utilizing interpreters. In this study, there were two types of interpreters: dual-role staff and family members. Most studies do not differentiate between these two ad-hoc interpreters, but the distinction is important here. While Chuukese women in the present study expressed satisfaction with the Guam clinic’s decision to hire Chuukese staff, Chuukese patients expressed distrust as a major barrier to care. Hattori-Uchima’s study also noted that Chuukese women in Guam did not trust Chuukese interpreters “knowing their problems.” This is also a concern in Chuuk, where there are more Chuukese HCWs working in the clinic. The current study further demonstrates that levels of trust may be mediated by the age and gender of the interpreter.

Family interpreters were preferred by participants in this study, specifically to avoid working with staff-interpreters. This reflects findings by Ramsey and colleagues, who found that in Hawai’i, physicians preferred in-person (staff) interpreters for communicating with Chuukese patients (67%), while Chuukese patients preferred family members or friends (61%). Yet, family members were often LEP as well, and do not always understand the medical terminology. These concerns with utilizing family members, combined with funding issues preventing professional interpreters, means that dual-role staff will likely continue to be the most common type for clinics serving patients from multiple language groups.

The findings from this study reflect the ethnographic literature in Chuukese communities, which report that family privacy is very important, and fear of community gossip is prevalent, especially regarding sickness. Additionally, women’s overall sexuality and thus reproductive health is considered a taboo subject. While socio-cultural ideas are fluid and do not necessarily reflect complex patient worldviews, the present study found that expectations of privacy and concerns with confidentiality remain.

Since this study took place in a small migrant community, findings from this study may similarly reflect other diasporic communities, and concerns with confidentiality of interpreters have been noted elsewhere. Future studies should further examine this concern in LEP populations for both professional and dual-role interpreters. Yet, HCWs must also be mindful of overgeneralizing “cultural attributes” of communities. Anthropologists have long critiqued well-intended efforts toward cultural competency, because they often lead to the development of problematic lists of cultural traits in which people are put into categories that reflect and reinforce stereotypes, leading to differential care. Further, efforts at understanding culture in the context of health care has led to a common practice of blaming patient culture for what are often structural issues such as insurance coverage, access, racism and poverty. More research is needed to examine the best policies to provide appropriate interpretation services for Chuukese LEP patients that respect their sense of privacy, while considering additional structural, social and individual factors simultaneously influencing access to quality health care.

This exploratory study demonstrates the need to examine policies regarding dual-role staff interpreters, and determine what is most appropriate for particular communities and patients. Ethnographic studies like the present study have the advantage of high internal validity from long-term investment into understanding what to ask and how to ask it, and observing practices, interactions, and experiences of people. This study
also has limitations. Observational data must consider observer effects, although these effects are likely diminished given the long-term follow-up and rapport-building. An additional limitation is that the ethnographer was conversational, but not fluent in Chuukese, so in-depth life history interviews were not possible with monolingual Chuukese speakers, who may have different perspectives. Finally, while this study explored concerns with interpreter trust in-depth, it was an exploratory study, so it cannot be generalized. Findings instead contribute to understanding HCW-interpreter-Chuukese patient interactions from a nuanced, theoretical perspective. Findings from such exploratory studies can be used for designing larger systematic studies which can quantify and generalize these findings.

Future research directions include a systematic study quantifying interpreter preferences and confidentiality concerns with staff interpreters who are not trusted by virtue of their insider (Chuukese) and outsider (not close family) status, considering the variables of gender and age. Future studies should also systematically assess the differences between the quality (eg, accuracy, amount of details) of interpretation and the perceived role and practices (eg, as advocate, cultural broker, or language conduit) of interpreters in this context, among both dual-role and family interpreters. Another important future direction is to explore other contexts serving Chuukese patients; namely Hawai‘i, to find patterns across and particularities within each host site. Finally, to improve experiences and outcomes in ways meaningful to communities, findings from this study should be used to form a community-based participatory project that proposes community-driven solutions.

Conflicts of Interest
The author has no conflicts of interest.

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As part of its mission, the John A. Burns School of Medicine (JABSOM) is dedicated to research and translating discoveries into practice. Uniquely located in the mid-Pacific, JABSOM is a leader among community-based medical schools, focusing on improving the health of ethnic groups, and conducting research with those groups in a culturally relevant manner. Advanced medical and biomedical research at JABSOM has received international recognition for pioneering work, which includes areas in human fertility, human heredity, comparative genetics, evolution theory, infectious disease, pharmacology, and cross-cultural psychiatry.

To facilitate investigators with research awards, the JABSOM Grants Development Office (GDO) was established in 2003 to aid in grants preparation and submittal process. The office works closely with the Dean’s Office, the Fiscal Office, and the Office of Research Services (ORS). The ORS is responsible for policy interpretation and institutional signatory authorization on all outgoing proposals. The GDO is responsible for designing and administering effective procedural systems that help increase the probability of award success. The office reviews proposals, collaborative agreements, and financial and personnel requirements. It also assists with budget preparation and grants writing. After a project is funded, the office ensures that all requirements are met for implementation.

In fiscal year 2017 (July 1st 2016 through June 30th 2017), JABSOM placed third in total award dollars for UH Manoa at 20.9% ($61.53 million). Of the total extramural funding, JABSOM was awarded over $35.45 million in research dollars.

The following list of initial research grants and principal investigators were awarded in fiscal year 2017. This list does not include incremental, supplemental, or time and cost extension awards.

**Department of Anatomy, Biochemistry, and Physiology**

**Stefan Moisyadi** – Nanobody Research Fund. Nanobodies are a new candidate class of therapeutics. Therapeutic nanobodies could be manufactured in a patient’s cells by injecting non-integrating, long term expression plasmid vectors into muscle tissue. Long term Nbs expression vectors termed Uroboros were constructed and targeted important inhibitory immune checkpoint receptors including: PD-L1 (the ligand of the PD-1 receptor in T-cells), CTLA-4, CD47, and the T-cell stimulatory molecule Fe OX40L. The goal is to prevent the development of mouse mesothelioma and lung carcinoma tumor xenographs Qy expressing key Nbs from within the tissues of live mice.

**Monika Ward** – The Role of the Y chromosome Encoded Gene Zfy2 in Spermatogenesis will advance understanding of genetic regulation of male reproduction. Considering that Y chromosome deletions are the most common genetic cause of male infertility in humans, this work has potential to guide future infertility treatments.

**William Ward** – The Role of ORC Proteins in Polar Body Extrusion. A remarkable event in reproduction is the sequestration of 3/4 of the meiotic DNA during oocyte development into two polar bodies with minimal cytoplasm. This event provides the future embryo with the large cytoplasmic store and the haploid maternal genome needed for its development. Several laboratories have shown that actin and associated proteins are required to complete these two asymmetric polar body extrusions (PBE) [1-4]. The project team has identified a protein associated with DNA replication, the licensing factor ORC4 that forms a lattice-like shell around the chromosomes that will be eliminated in the polar bodies in both meiotic divisions. The project terms this shell the ORC4 Cage. By specifically targeting the formation of the ORC4, it is demonstrated that it is required for PBE. This is the first chromatin associated protein that is asymmetrically associated with only the extruded set of chromosomes.

**Department of Cell and Molecular Biology**

**Pietro Bertino** – Preclinical Development of TVAX: An Advanced Multi-Antigen Vaccine for Therapy and Prevention of Malignant Mesothelioma aims to generate more specific, and therefore less harmful, immune responses with the use of advanced anti-cancer vaccines.
Olivier Le Saux – Exploring the physiological roles of ABCC6 in vascular biology. The mechanistic hypothesis is that ABCC6 is an upstream regulator of a pathway that modulates PPi production and adenosinergic signaling affecting ectopic calcification, and atherosclerosis. The restoration of ABCC6 plasma membrane localization and function will ameliorate these functions.

Kathryn J Schunke – A Novel Inhibitor of HIF Action in the Heart. The HIF axis is an ancient response to the rise in atmospheric oxygen and controls many aspects of cellular homeostasis. In this study a potent and previously unsuspected regulatory mechanism for HIF that may directly influence the course of myocardial infarction will be investigated. The identification of a new oxygen-dependent regulator of HIF may provide a target for new therapeutic approaches to ischemic heart disease.

Department of Medicine

William Boisvert – Role of CD98 in smooth muscle cell proliferation. This research will test if CD98 is a key player in vascular remodeling in atherosclerosis via its ability to regulate proliferation of vascular smooth muscle cells.

William Boisvert – Treatment of Atherosclerosis with Interleukin-10. The work proposed in this application will reveal if IL-10 expressed via the macrophages in the artery wall will succeed in quelling the vascular information and ultimately slow down the development of atherosclerosis.

Michelle Diane Seidel – Role of Tcf21 in Cardiac Fibroblasts. This proposal hypothesizes that Tcf21 plays a key role in regulating cellular functions of the cardiac fibroblast.

Cecilia Shikuma – Extended Immunologic Analyses for ‘Hepatic Safety of Raltegravir-based and Efavirenz-based Antiretroviral Regimens in Antiretroviral-Naive HIV-infected Subjects Co-Infected with Hepatitis C’. Utilizing banked peripheral blood mononuclear cells from a study conducted in Vietnam entitled “Hepatic Safety of Raltegravir-based and Efavirenz-based Antiretroviral Regimens in Antiretroviral-Naive HIV-infected Subjects Co-Infected with Hepatitis C”, this study will assess levels of monocyte activation markers, and CD4 and CD8 T cell activation and negative checkpoint receptors. These parameters will be correlated with liver fibrotic and neuropsychological changes on study.

Department of Native Hawaiian Health

Claire Townsend Ing – PILI ‘Ohana Dissemination Project will assist in developing the partnering community-based organization’s capacity to sustain the delivery of the PLP and/or PIC and to engage in future health disparities research through various strategies including workshops on grant seeking and writing, research methods and evaluation strategies, and advocacy.

Claire Townsend Ing – Examining hypertension and cardiovascular disease risk in Native Hawaiian communities. This project aims to comprehensively examine multilevel risk factors and assess their contribution to HTN and CVD risk in NH.

Dee-Ann Carpenter - Kukalahale – Learning Project will provide: (1) wrap-around coordination of new and existing services; (2) a more complementary/comprehensive set of existing complementary/comprehensive set of existing and new services and programs to address student gaps in knowledge/skills; (3) school community home visits, Kuder Career Counseling, blue-collar fire-fighter training for entry-level exams; and (4) Native Hawaiian cultural education activities. The University of Hawai‘i will evaluate the project’s process, effort, and effectiveness using qualitative and quantitative methods, as well as assist in the development of health literacy/educational programming.

Marjorie K.L.M. Mau – Diabetes Prevention Program Outcomes Study. The objective is to evaluate the long-term effects of active diabetes prevention program interventions on the prevalence of the composite diabetes-related microangiopathic and neuropathic outcomes.

Department of Obstetrics, Gynecology and Women’s Health

Michael Carney – Evaluation of Metronomic Chemotherapy Regimens in Ovarian Cancer Models. This pilot project goal is to form a research team composed of an oncologist and two basic researchers interested in identifying and evaluating low-dose, orally administered chemotherapy regimens for the treatment of ovarian cancer. Using xenograft models, proof-of-concept data on the impact of metronomic regimens on ovarian cancer will be gathered that can subsequently be used to submit an R21/R01 grant. The long-term ambition of ultimately proposing clinical trials for ovarian cancer patients. The results of this project should help the development of therapeutic ideas, and generate new models of drug resistant ovarian cancer.


Reni Soon – Expanding Reproductive Healthcare Access for Adolescents in Primary Care Settings at a Community Health Center: A CBPR Project. This proposal is a pilot intervention to improve reproductive health services for adolescents and young adults at the Wai‘anae Coast Comprehensive Health Center.
Department of Pediatrics

Marian Melish – Effect of Doxycycline on Developing Coronary Abnormalities in Kawasaki Disease (KD). The project will test the hypothesis that there is a significant elevation in biomarkers related to vascular damage in children with acute KD and coronary artery abnormalities (CAA) compared with children with uncomplicated KD; and that a 3 week course of doxycycline during the critical period of vascular damage will decrease the levels of these biomarkers and prevent the progression of vascular damage.

Department of Surgery

Junji Machi – Detection of Metastases in Lymph Nodes Using Quantitative Ultrasound. The University of Hawai‘i Medical Center and Riverside Research Institute of New York will investigate the use of novel ultrasonic methods for discriminating cancer-containing and cancer-free lymph nodes of cancer patients. Emphasis will be on improving sentinel-node dissection biopsy procedures particularly for breast-cancer patients. Success in this project will benefit lymphnode evaluations of all types, not only for breast cancer, but also for a range of other cancers, including colorectal, stomach, and lymphatic.

Department of Tropical Medicine, Medical Micro and Pharmacology

Michelle Louise D’antoni Brogan – Targeting of Chemokine Receptors to Probe Neurocognitive Impairment in HIV. Samples from a single arm clinical trial at the Hawai‘i Center for AIDS, whereby 24 HIV-infected individuals with HIV-associated neurocognitive disorder on combination antiretroviral therapy received a CVC intensification regimen for 24 weeks, will be studied.

Melissa A Agsalda-Garcia – Optimizing Mitochondrial DNA Measurement to Assess Risk of Relapse in Childhood Lymphoma Including Children in Hawai‘i will measure mtDNA and MRD in blood and bone marrow from children being treated for NHL.

Mukesh Kumar – Defining the function of Schlafen4 in the pathogenesis of flavivirus encephalitis. The objective of this proposal is to define the role of miRNAs in ZIKV replication and pathogenesis.

Axel T Lehrer – Preclinical Development of a Thermostable Trivalent Filovirus Vaccine. The goal is the development of a thermostable (dry) non-replicating, trivalent filovirus vaccine candidate based on recombinant virus subunits that is safe and effective in protecting civilian and military populations against infection by lethal strains of Ebolavirus and Marburgvirus.

Iain S Macpherson – Multiplexed Single-cell Proteomics using Covalent Aptamers, Microfluidics, and High-throughput Sequencing. This research project is to develop methods to better diagnose cancer in Hawai‘i.

Lishomva Chakanga Ndhlouvo – Reversal of Adaptive Immune Dysfunction in Shock and Kill HIV Cure Strategies. This study seeks to facilitate the elimination of HIV infected cells through increased antiviral T cell function. The study will achieve this through a novel immune regulatory pathway that when blocked restores T cell function capable of depleting latently HIV infected T cells. This study will be extended to the SIV infected non-human primate model of AIDS to confirm whether this novel strategy specifically targets and destroy latently infected cells.

Department of Tropical Medicine, Medical Micro and Pharmacology

Bruce Shiramizu – Hawai‘i IDeA Center for Pediatric and Adolescent Clinical Trials (HIPACT). The project will establish the Hawai‘i IDeA Center for Pediatric and Adolescent Clinical Trials (HIPACT) as a partner in the IDeA States Pediatric Clinical Trials Network (ISPCTN). HIPACT will work with ISPCTN to launch and enroll infants, children, and adolescents from Hawai‘i from rural and underserved communities and across IDeA partner institutions in ISPCTN approved trials.

Bruce Shiramizu – JABSOM Raman-Enhanced Screening Protocol Expanding Cancer Testing. To generate preliminary data and show "proof-of-concept".

Saguna Verma – Under Attack: Modulation of the Blood-testes Barrier by Zika Virus. Understanding how ZIKV gains entry into the immune privileged site of the testes and the role of inflammatory mediators in facilitating this process will fill the fundamental gap of the mechanism of testicular infection of ZIKV and facilitate development of strategies to prevent virus-testes entry.
Angel Yanagihara – Pathogenesis of Life Threatening Box Jellyfish Envenomation and Irukandji Syndrome. Box jellyfish stings pose a public health threat in tropical and subtropical coastal areas. Irukandji syndrome is a complex, potentially life-threatening clinical sequelae of box jellyfish envenomation. The research will clarify the role of the jellyfish pore-forming protein (or porin) in Irukandji syndrome. This improved understanding will guide the development of more effective treatments.

Angel Yanagihara – Venom Inhibitor Test Methodology will research, develop, and document appropriate test methodologies, models, and/or protocols for assessing the effectiveness of venom inhibiting substances.

Department – Dean’s Office

Katalin Csizsar – Collaborative Mentoring and Research Support for Project Olona. The proposed collaborative mentoring, research, and research infrastructure support program is designed to advance the educational, scientific, innovative, and social enterprise goals of Project Olona by furthering interest in undergraduate and graduate education, active student research, and career development among underserved and Native Hawaiian students.

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References
Unexploded ordnance (UXO) has been a significant problem in the State of Hawai‘i since the Second World War (WWII) when lands throughout the Hawaiian Islands were used to train soldiers for combat in the Pacific theater. As necessary as it was to prepare US troops, a legacy of explosive items and munition remnants from historic target and maneuver areas, impact areas, bombing ranges, and small arms ranges lie scattered, often out of sight, across the state on hillsides, residential areas, shorelines and public lands. This essay examines the problem, the Department of Health’s (DOH) limited regulatory authority with respect to ordnance, and the Department’s critical role in injury prevention and safe re-use of tens of thousands of acres throughout the Hawaiian Islands.

Extent of Impact of UXO in Hawai‘i
The impact of these historic combat training activities cannot be overstated. In addition to large swathes of land and shorelines entrusted to the Department of Defense (DoD) for training maneuvers, many other coastal and mountain areas were used for target practice from the sea and air, and several off-shore locations were used for dumping waste munitions. Further, these lands represent only a portion of lands impacted by UXO as they do not include combat training areas on current military installations or state and privately owned lands still under military control.

Because of how innocuous and old UXOs look, UXOs in Hawai‘i present an even greater risk to the public than other types of risks such as dermal exposure, ingestion, and inhalation which are commonly associated with chemicals. UXOs can often look like an old rusted pipe or a canned food item, making them easy to misidentify. There is also the misconception that an UXO becomes less dangerous as it ages. The reality, however, is that an UXO becomes more dangerous as it ages. Explosives in an UXO fired during the second world war are just as energetic 80 years later. Secondly, as firing pins become rusted and loose, UXO items become more sensitive to touch and are more likely to detonate if disturbed. At the famous Hapuna Beach on the Big Island, a diver inadvertently dragged an UXO to the shore, creating a significant threat to the highly trafficked beach in 2013. This type of incident highlights the need to inform the residing public as well as visiting tourists of the dangers of UXOs and the steps they need to take, most notably, the 3 Rs – Recognize, Retreat, and Report (Figure 1).

Federal Involvement at UXO sites
There are 120 Formerly Used Defense Sites (FUDS) throughout Hawai‘i used for troop training during WWII and other conflicts that remain impacted by UXO. These lands were returned to the State or to private ownership by the end of the wars. The United States Army Corps of Engineers (USACE) prioritizes and remediates hazards at these sites following guidelines established in the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), under the regulatory oversight of the DOH Hazard Evaluation and Emergency Response Office. The most notable FUDS in Hawai‘i are the former Waikoloa Maneuver Area on the northwest portion Island of Hawai‘i, Kamahena Point Bombing Range (Ahihi Kinau Natural Area Reserve, Maui), Pali Training Camp (Maunawili), Oahu Target Island (Goat Island) and Waikane Training Area on Oahu and Makanalua Bombing Range (Kalaupapa, Moloka‘i). FUDS properties awaiting investigation and remediation pose hazards to the public because DoD does not have legal authority to restrict access or use of properties returned to private ownership. Compounding the problem, the total cost to clear all munitions sites in Hawai‘i is over a billion dollars. USACE is allocated only about $15 million annually to address the highest priority sites in Hawai‘i, American Samoa, Guam, and Saipan. This amount is insufficient as costs for individual sites can range from tens to hundreds of millions of dollars to investigate and remediate. Finally, the CERCLA process is designed to assess potential hazards associated with chronic exposure to chemical contaminants in the environment, and does not specifically address the physical hazard UXOs pose. The potential exposure hazards from chemical contaminants associated with UXO and...
other munitions, referred to as Munition Constituents, tend to be less of a health concern than the acute and lethal explosive hazard of an UXO. On Hawai‘i Island, at least nine people have been killed or injured by UXOs since 1945, including two Parker Ranch employees killed when a mortar exploded in 1954 which prompted a clearing operation that uncovered over 900 additional UXO items. The magnitude of the problem regarding munitions is easily highlighted by the Former Waikoloa Maneuver Area. At over 100,000 plus acres of heterogeneous terrain, it is the largest munitions site in the nation. The extent, complexity and potential hazards in the maneuver area are so severe that the late Senator Daniel Inouye spearheaded a $723 million congressional appropriation providing $10 million/year of dedicated funding for Waikoloa, expected to span 70 years. As the total cost to complete all munitions sites in Hawai‘i is over a billion dollars and the USACE only is allocated roughly $15 million annually to address the sites, one can easily see how (1) costly a single FUDS can be to clean, (2) how disproportionate the substantial existing funding to address munitions sites is to the cost to investigate and remediate, and (3) the current regulatory framework to address hazards was not designed for the physical hazard posed by UXOs.

**State Involvement at UXO Sites**

Addressing UXO contamination is challenging and the risk cannot simply be removed. Unlike other types of contaminants addressed under the Hawai‘i Environmental Response Law (ERL) (HRS 128D) and CERCLA, UXO is more of a physical hazard than a chemical one, which limits the number and kinds of treatment technologies available to address the problem. To complicate matters further, due to limitations of current technologies, the ability to detect metallic items at depth in the soils of the Hawaiian Islands is difficult because of their high ferrous content.

While risks to human health and the environment associated with chemical contamination is generally assessed based on the potential for long-term chronic exposure, the risk of exposure to UXO is a highly acute effect where a single contact can have deadly results. What’s more, the area of effect both on people and property can be extremely large, requiring whole communities to be evacuated when conducting a removal action. When these factors are combined, UXO investigations and clean-ups are both complex and costly.

The Hazard Evaluation and Emergency Response (HEER) Office traditionally addresses sites for chemical contamination and has a vast amount of experience in investigating such sites. As there was little experience regarding UXO sites initially, the USACE was relied upon to address the sites because they had far greater expertise in dealing with munitions related issues. However, as active and skilled as the USACE has been at addressing UXO sites, due to the technical limitations there is no way to achieve 100% clearance and removal of all UXO, therefore some residual contamination remains even in areas cleared by the USACE. The limitations of the technology lie in the fact that the Hawaiian Islands are volcanic in origin, making the soils ferromagnetic by nature and composition. As the current magnetometers cannot discern between hot rocks and munitions, the accuracy and precision of UXO detection in Hawai‘i are hampered, especially at depth.

**Community Involvement and Educational Outreach – Recognize, Retreat, & Report**

The primary mission of the HEER Office is the protection of human health and the environment. To prevent injuries and protect communities during the long UXO remedial process, the HEER Office focuses its injury prevention strategy on three primary components,

1. Building trust and open lines of communication with affected property owners to ensure they understand their rights and responsibilities with respect to federal clearance activities;
2. Recognize, Retreat, Report. Maintaining an active, personal presence educating keiki to kupuna in communities affected by UXO and alerting tourists to safe practices through visitor industries;
3. Helping residents, property owners and developers understand and safely manage potential hazards on their property.

For chemical driven sites, residual contamination can be managed in a variety of ways, and for most sites, the long-term exposure hazard is minimal. This is not the case with UXO. Even following an effective clean-up by the USACE, undetected UXO contamination may persist and can be just as dangerous as if the site was not cleaned at all because the potential exposure hazard from even a single undetected UXO item is still highly acute (severe injury or death). This caused the HEER Office to re-evaluate how to address long-term residual contamination left after UXO clean-ups were performed. The solution the HEER Office came up with was to partner with the USACE and assist them with their public outreach efforts across the state.
Because of the unique nature of UXO hazards, and the fact that even areas “cleared” by the USACE pose potential explosive hazards, a key response action to address UXO contamination has been educational outreach and community involvement. The USACE regularly attends various events across the state to promote its “3Rs: Recognize, Retreat, Report” UXO safety message (Figure 1). The USACE also visits elementary schools in the affected regions to provide children with their safety message. Unfortunately, due to distrust of the military on the part of some residents, the message is not always getting out there. So, the HEER Office decided to collaborate with USACE at its public outreach events.

The HEER Office began to attend these events in 2012 to support the USACE. The joint stance of the USACE with the HEER Office at these events created a positive image for the USACE and made the messages that they were espousing more effective. The public at large became more receptive and welcoming, knowing that the regulatory agency was supportive of the USACE and their efforts. The HEER Office also started to open doors and opportunities for the USACE to spread its message by facilitating meetings with the Hawai‘i Tourism Bureau, the County of Hawai‘i, the United States Department of Housing and Urban Development (HUD), and other public agencies. HEER Office staff participate in neighborhood meetings, elementary school assemblies, and community events. Efforts are also made to work with landowners and the USACE to help with the posting of signage on public and private lands to warn visitors of the potential dangers of UXOs.
Events attended on the Big Island since 2012

3Rs of Explosives Assemblies
- Waikoloa Elementary and Middle School
- Waimea Elementary School
- Waimea Middle Public Conversion Charter School
- Waimea Country School
- Kanu o ka Aina Learning Ohana
- Nawahiokalaniopuu School (Figure 2)
- Waikoloa District Summer Fun
- Waimea District Summer Fun
- Kanu o ka Aina Learning Ohana Summer Fun
- Keonepoko Elementary School
- Pahoa Elementary School
- Pahoa Intermediate and High School
- Pahoa District Summer Fun

Public Events
- Waikoloa Back to School Bash (Figure 3)
- Wiliwili Festival
- Cherry Blossom Festival
- Hawai’i Island Boy Scouts Makahiki
- Healthy Keiki Festival
- Puukohola Festival
- Hawai’i Island Hoolaulea
- Makuu Farmers Market (Figure 4)
- Pahoa Hoolaulea

Town/Public Meetings
- Waimea Community Meeting (Figure 5)
- Waikoloa Community Meeting
- Waikoloa Senior Citizens Meeting
- Kamehameha School 1962 Reunion
- DHHL Contractors Safety Meeting
- Parker Ranch Safety Meeting
- Hawai’i County Safety Meeting

Assisting with Property Access

Another problem faced by the USACE when they wish to conduct a clean-up on privately-owned property is that they require a Right-Of-Entry agreement from the property owner to do the work. Difficulties in obtaining Right-of-Entry agreements from some owners have left some properties unaddressed. In the interest of protecting the public’s health, the HEER Office provides assistance with obtaining Rights of Entry. The biggest issue the USACE was facing prior to the HEER Office’s involvement, was a general distrust by the public at large. The Stryker Brigade conversion project in 2003-2004 as well as the continued active training at Pohakuloa Training Area on Hawai’i Island led to a high level of skepticism and doubt of the USACE’s intentions when they approached residents about Rights of Entry. What the people needed was a voice on their side who represented their interests, and that was something the HEER Office could provide as a State regulator.

Local Area Examples (former Waikoloa Maneuver Area)

The USACE-HEER partnership was first tested in March of 2012 when a large parcel (~8000 acres) owned by the Department of Land and Natural Resources (DLNR), that was a portion of the 123,000-acre former Waikoloa Maneuver Area on Hawai’i Island, was ready for investigation and cleanup but no Right of Entry had been given, due to legal concerns. The HEER Office along with the Deputy Director of Environmental Health helped facilitate the signing of this Right of Entry so that the parcel could be investigated by USACE. Seeing the tangible benefit of the partnership (8,000 acres were investigated and addressed with no federal monies lost or allocated elsewhere), the HEER Office began to partner with the USACE to assist in other areas where Rights of Entry were not granted.

The effectiveness of this approach was highlighted in the Sandalwood residential community near Waimea Town (also part of the former Waikoloa Maneuver area) on Hawai’i Island. When the USACE first approached the residents, only 8 of the 32 owners agreed to sign. After the HEER Office began to partner with USACE, several public meetings were held to inform and educate residents, and after going back out to the same residents, all 32 owners agreed to sign. Thanks to the combined efforts of the HEER Office and the USACE, the Sandalwood area was investigated and cleared. Since then the HEER Office has assisted in several areas where Right of Entry agreements have been problematic, and in regions where investigations may have been halted, they could proceed on schedule.
Conclusions
The by-products of these cooperative efforts are that the public awareness and education of the public has been greatly enhanced and most UXO contaminated areas have been free of incident since. The HEER Office discovered that education and awareness are the best way to combat long term residual risk to UXOs. As with other public safety hazards like traffic and fire safety, the best thing that can be done as health professionals is to heighten awareness by educating people on what not to do. The relationships formed between USACE, the HEER Office, and the public has allowed trust to be built, which in turn has allowed many UXO projects throughout the state to proceed successfully and safely. Only by continuing to foster good relations between all parties and to educate and make aware all affected parties, can the risk be reduced for the public at-large even where undetected UXO contamination remains.

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GET OUT OF THE WAY F.D.A. GIVE THESE PATIENTS ONE MORE SHOT.
American medicine is producing new therapies for everything from macular degeneration to uterine cancer. The problems arising relate to the drug approvals that are not keeping pace. President Trump correctly stated in his state of the union address, “patients with terminal conditions and terminal illness should have access to experimental treatment immediately that could potentially save their lives.” He called on Congress to “give these wonderful, incredible Americans the right to try.” Last year the Senate passed a bill that says: Government will not get in the way of a patient with a life-threatening disease who wants to take a flyer on a treatment not approved by the Food and Drug Administration (FDA). The drug must have cleared a phase of FDA trials for safety but not efficacy. The FDA already runs a “expanded access” to allow investigational drugs when a physician can ask the FDA to sign off on such treatment. The FDA approves 99% of requests, but has only about 1,000 applications annually because the FDA process was a bureaucratic nightmare for patients who don’t have the time or knowledge. FDA Commissioner Scott Gottlieb said the new form now takes about 45 minutes with one attachment, down from eight. Moreover, Gottlieb states that emergency requests can usually be granted immediately over the phone.

BORING? REPETITOUS? DIMMING, BUT STILL POPULAR.
The Super Bowl football game was a nail-biter to the end with the Eagles prevailing over the Patriots 41-33. Yet according to Nielsen it was the least viewed TV audience since 2009. This year’s ratings marked a 7.1% drop from last year’s. Ratings for the play offs were down also. The decline in viewership for the Super Bowl is in line with drops in National Football League (NFL) numbers experienced for the regular season. The average audience for an NFL game in 2017 at 14.9 million viewers was almost a 10% decline from 2016, and it was down 8% compared with 2015. Television executives have blamed the decline in NFL ratings on an oversaturation of product and audience fragmentation. A Wall St. Journal/NBC news poll, painted graphic, socioeconomic, and other factors that warrant explanation. Rate. Whether a patient receives cataract surgery depends on demographic, cognitive, socioeconomic, and other factors that warrant explanation. Covariate-adjusted models showed a link between cataract surgery and the incidence of mortality was 1.52 per 100 person-years in the surgery group and 2.56 per hundred-person years in the cataract diagnosis group. Covariate-adjusted models showed a link between cataract surgery and mortality related to cancer, vascular, accidental, neurologic, pulmonary and infectious diseases. Despite their overall sicker systemic profile, patients who underwent cataract surgery had a much lower mortality rate. Whether a patient receives cataract surgery depends on demographic, socioeconomic, and other factors that warrant explanation.

ADDENDA
- For the first time in history more than half of all members of the U.S. Congress are millionaires.
- After a loss, fans of NFL teams were found to eat 16% more saturated fat and 10% more calories compared with declines of 9% in fat and 5% calories after a win.
- 80% of drug busts at border patrols involve U.S. citizens.

ALOHA AND KEEP THE FAITH rts
(Editorial comment is strictly that of the writer.)
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