

**Descriptive Overview of Proposed Study Titled:  
Timely Digital Reminders Impact on Soldier Dental Readiness**

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School of Medicine

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CERTIFICATE OF APPROVAL

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This is to certify that the Master's Capstone Project of

Kevin B. Parker

**“Descriptive Overview of Proposed Study Titled:  
Timely Digital Reminders Impact on Soldier Dental Readiness”**

Has been approved

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**Abstract**

Dental readiness classification (DRC) is a categorization system used in the Army to determine if a Soldier is dentally ready to deploy. If a Soldier does not have a dental exam within their yearly anniversary they fall into a DRC class 4 category. When a Soldier is categorized as DRC class 4 they are in a non-deployable status. This occurrence is detrimental to the readiness of Army units. This also places a considerable amount of stress on the Soldier as they will be immediately identified and be faced with a considerable amount of attention from their unit until they receive their dental exam and are changed from a DRC class 4 status. It is believed that many Soldiers fall into DRC class 4 because of a lack of awareness that they are coming due for their yearly dental exam. There is a functionality built into the Corporate Dental System (CDS) to identify Soldiers 60 days prior to their annual dental exam due date, and emailing that Soldier with a reminder to schedule an exam. Though this functionality exists it is not automated and is rarely used. A process improvement (PI) project was conducted at the Joint Base Lewis – McChord (JBLM) Dental Activity (JBLM DENTAC) where Soldiers were identified 60 days out from their yearly exams. If the Soldier didn't have a scheduled appointment they received an email reminding them to schedule an appointment at 60 and also at 30 days prior to them converting to DRC class 4. This was completed over a four month period and two months of data was collected prior to and post intervention to act as a control. It is desired to see if the email reminders improve readiness and the variables of age, gender, and rank will be evaluated for significance. Also there will be an email survey sent out to gather patient satisfaction information, contact method preference for oral health communication, and also to evaluate dental appointment availability. This survey will help control for the confounding factor of appointment availability. From the survey we hope to gain insight on trends of how Soldiers prefer to

receive healthcare communication. It is believed that Soldiers don't use email as frequently as they did in the past, and the survey data would help explore this idea in the discussion section of the paper. By analyzing results of an email based communication intervention, combined with the survey results it is desired to gather information that could possibly influence communication plans for the future.

### **Military Relevance**

This study could help address the possibility that strategically timed email reminders could help to improve dental readiness. If this is found to be effective in improving readiness it could be the basis for funding a project to develop the capabilities of automating the reminder emails in CDS. This ability and information could empower commanders to use this tool to increase readiness levels in their units. Currently readiness levels are relatively high ranging from 93-98 % ready. However, that translates to 2-7 out of every 100 soldiers in a unit is not ready to deploy. This readiness level can and needs to be improved to allow for commanders to have a fighting force that is dentally ready to deploy.

### **Background and Significance**

The primary focus of the military health is centered on maintaining a deployable force which is measured by Soldier readiness. The main objective of this study is to assess whether a series of timely email reminders can help improve soldier dental readiness. To assess the effectiveness of the email reminders the control group (record of soldiers that data was recorded for 60 days prior and post intervention). The amount of days at which they schedule appointments will be compared to those in the test groups that receive email reminders. The amount of days in which it takes for the Soldier to schedule an appointment will be compared as well as the amount of the control vs the intervention group that convert to DRC class 4. The intervention group consists of 325 Soldiers and the control group contains approximately 200 Soldiers. There will also be an analysis of descriptive statistics such as rank, age and gender to determine if there are any associated differences. If differences are detected, targeted initiatives could be used to address readiness issues within the identified groups. Other interventions that could be considered would be other contact modalities such as text or social media. The development of a readiness tracker app may be a future option to

allow the Soldier to track their own yearly appointments (dental, PHA, vision, etc.).

## **Research Design**

This will be a retrospective analysis of data collected from a JBLM DENTAC Process Improvement (PI) project to increase dental readiness. It will be a quantitative review of the data collected from the PI Project comparing subjects that received and didn't receive the intervention. It shares design elements with a quasi-experimental design where there are study groups with pre- and post-test data to compare. There will also be an analysis of several descriptive characteristics (age, gender, unit, and rank) to see if there are any significant differences associated with those characteristics. The groups were not randomly selected and this was a retrospective study.

There will be a follow up survey that will be used to address the confounding variable of appointment availability. Because of the survey, this study will be ambi-directional in nature with possessing both a retrospective and prospective aspect. The study will contain no identifiable information so there will be no way to tie the survey data back to the data from the PI project. The survey data will be evaluated using linear regression to evaluate for trends to facilitate further discussion.

## **Target Population**

US ARMY Soldiers stationed at Joint Base Lewis-McChord receiving care at JBLM DENTAC Clinics.

## **Inclusion and Exclusion Criteria**

Inclusion criteria: US ARMY Soldiers that receive treatment at the dental clinics in JBLM DENTAC that are going to become DRC class 4 within 30 and 60 days over a four month period. Subjects must have had a current email address stored in CDS software program. All subjects that received the emails will be invited to take the follow-up survey.

Exclusion criteria: Air Force Personnel that receive treatment at JBLM DENTAC Clinics. If the Soldier, from the selected time period, had a scheduled appointment at a JBLM DENTAC clinic they did not receive the intervention in the PI project.

No Prescreening, screening, or enrollment processes occurred. The process improvement project that is being studied simply enrolled Soldiers coming due for dental exam in the identified time period of four months. The Soldiers that were included in the study because they fell into the four month period will receive the email survey after IRB approval is obtained. The control group will come from data gathered on Soldiers from 30 days prior and post intervention. No email survey will be sent to the control group.

### **Consent Process**

Retrospective look at data gathered during a previous command directed PI project. No consent obtained.

For the follow-up survey an information sheet will precede the survey to obtain consent for the survey.

### **Subject Screening Procedures**

Eligibility was completed by the mere fact that the patients were coming due for a dental exam during the four month time frame chosen for the evaluation.

### **Privacy of the Subject**

No more than minimal risk is anticipated to the subjects of this study. There will be no direct effect on the patient as there will just be an analysis of timelines to action retrospectively evaluated from the email reminders they received from the DENTAC process improvement project. They will be unaware that the retrospective study is occurring. The studied data will be de-identified to protect their personal identifiable information (PII) and personal health information. The survey will gather no PII data and there will be no way to track the data from the surveys back to the patient data gathered from the process improvement project.

### **Data Collection**

<b>Variable</b>	<b>Data Source</b>
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Age	Readiness report pulled from CDS
Rank	Readiness report pulled from CDS
Gender	Readiness report pulled from CDS
Time taken before scheduling appointment in CDS after receiving the email reminder	Readiness report pulled from CDS
If they became DRC class 4	Readiness report pulled from CDS
De-identified Qualitative and Quantitative data collected from Survey(survey attached in Appendix A)	Emailed Survey

**Table 1.** Data collection variables and Data Source

Data was collected by the principle investigator/author that also completed the DENTAC level PI project. This data is stored in a collection of worksheets and will be collated into a single spreadsheet for analysis.

**Confidentiality of the Data**

Data will be collected by the principal investigator on one computer that is accessed using a secure government network. The data will be de-identified. Master key will be used to maintain confidentiality of data. After the data analysis is completed the master key will be destroyed to prevent possible re-identification of the data.

**Sample Size Estimation**

A power analysis was completed to determine the appropriate sample size for this study. 325 Soldiers made up the study population. The control was obtained by

collecting data without the intervention for 30 days pre and post intervention and this totaled 132 Soldiers.

To conduct the power analysis, two groups were hypothesized as group A and group B. It is believed that a 15 day difference would be notable and the mean of group A was set at 30 days that it would take to schedule an appointment after the intervention and group B was set at 45 days. A standard deviation was reasonably estimated at 20 days. With a desired alpha of .05, a power of 80%, it was determined that a sample size of 216 would be needed. The sample size of 325 collected from the JBLM DENTAC PI project would be considered an appropriate amount to support this proposed study.

Estimate Required Sample Size	<b>216</b>
Estimate Participant Drop Out / Withdrawal	<b>10 (anticipated amount of patients becoming DRC class 4)</b>
Total Enrollment Requirement	<b>226</b>

**Table 2.** Required sample size from power analysis with adjustment

<b>Site</b>	<b>Enrollment Number (Sample Size)</b>
JBLM DENTAC	325

**Table 3.** Sample Size JBLM DENTAC

**Primary and secondary endpoints**

Primary outcome variable: Duration (time) within 60 days of scheduling exam.

Secondary endpoints: Age, Gender, Rank, Unit.

**Data analysis**

1. Duration (time) within 60 days of scheduling exam.

2. Age: Age will be compared against time utilizing a t-test to see if there is a relation.
3. Gender: Chi square analysis will be used to determine if there is a significant difference between genders and their responsiveness to the email reminders.
4. Rank: Chi square analysis will be used to determine if there is a significant difference between ranks and their responsiveness to the email reminders. Rank will be broken down into six categories.
5. Unit: Compare units with Chi Square analysis to determine if some units are better at getting their Soldiers in for exams than others.

Confounding variables:

Lack of appointment availability could negatively influence the Soldiers ability to schedule an appointment. This will be evaluated in the follow-up survey. Also reports from DENTAC on appointment availability during those time frames will be solicited.

Another confounder may be if clinic practice managers or front desk had other initiatives to contact and get the same population in for dental exams. This will not be able to be tracked or accounted for. If there is an outlier a survey of those personnel at the noted clinics could be evaluated for best practice interventions to be employed across the whole DENTAC.

Some units may be better at tracking their units DRC status. This could be gathered from historical documentation if available in DENTAC records.

### **Risk/Benefits assessment**

No risks are identified with this study. The largest risk would be the participants being somewhat annoyed by receiving a survey and considering it to be “spam”.

### **Benefits**

It is possible that the results from this study could provide a resource to help remind the Soldiers of upcoming required dental appointments. The benefit to society would be a better understanding of the current effectiveness of emails as a means of contacting patients for healthcare communication. It has been demonstrated in the past that email reminders are an effective means of

communication.<sup>1</sup> However, with our changing demographics and with a reliance on texting and other communication means email may not be as effective as before. By comparing the variables gathered on the subjects it would allow us to determine if there is a difference in age, gender, and rank in responding to email communication. From the survey we would gain insight on how patients like to receive dental care communication.

There is a potentially a big benefit to military commanders if there if there is an increase in readiness from the emails. Even if there is small increase in the readiness percentages of at least one percentage points that could mean an extra 20 to 30 Soldiers are deployable in a brigade.

### **Adverse events, unanticipated problems, and deviations**

No adverse events are anticipated from the review of the retrospective data. There is a rare chance that someone may not like receiving the emailed survey. It is possible that they could complain about the survey as being “spam”. It is very unlikely that this would be viewed as an adverse event. Any such feedback will be recorded and covered in the discussion section of the paper.

### **Time required to complete the research**

104 days total anticipated to complete the research. 15 days to prepare the survey and email out the surveys. Allow 14 days for responses, 50 days to analyze data and complete paper, and 25 days for draft revision and peer editing.

### **Research closure procedures**

Results from study will be documented and submitted to be published in a peer reviewed journal. No HIPAA authorizations or informed consent forms are intended for this study.

### **System used to collect the information**

One of the big focus areas in the Army is on "readiness" and more specifically dental readiness which entail yearly dental exams. This seems like a simple task but it is very difficult to keep Soldiers coming in on a yearly basis. The model employed now is centered on the hope that the Soldier is diligent at checking a secure Army website that tracks their dental readiness and when their next exam is due. When they see that that their dental exam is due they must find the clinic

they are assigned to, get the contact information for the front desk of the clinic, and call to set up their dental exam appointment. This happens most of the time, but if it doesn't then the Soldier's First Sergeant (higher level Soldier Supervisor) will send the delinquent Soldier a rather unpleasant email telling them that their dental is overdue and they need to go in for an exam, ASAP.

The main tool used to record and track dental readiness is the Corporate Dental Application (CDA). CDA was originally developed to function as a scheduler and workload capture software.<sup>1</sup> It was a "home grown" product developed for the use at an enterprise level in the Army dental care system. Due to its modular design CDA has grown into a robust and function in a larger capacity in the US Army Dental Corp.<sup>1</sup> Its expanded abilities were recognized by the Navy and the Air Force and CDA (now renamed CDS) is being used by most of the dental clinics in the Military Health System. CDS has a reporting capability that is very powerful and provides numerous reports to clinic leadership, commanders, and directorate level administrators. The dental readiness report from CDS is a simple tool that is used to identify patients that are coming due for their yearly dental exam, and there is a capability within CDS to send email reminders out to those Soldiers. There have been some efforts to use this functionality to improve readiness at the clinic level. Several Army front desk staff have taken the initiative to email Soldiers manually when their exams were coming due. This took due diligence on their part and constantly needed to be managed. Some were successful in decreasing the amount of Soldiers that fell into DRC class 4. The disadvantage of this type of manual system is that it is difficult to find staff motivated enough to extend this practice into a long-term and sustainable option.

For the future, an automated system developed to email the Soldiers 30-40 days prior to their dental exam due date so they are aware of this upcoming requirement could greatly increase readiness levels in a unit. Within this email would be the due date for their exam and information on how to set up the exam appointment. Another future addition would be a link to a "live" interactive schedule display that refreshes on a frequent basis to inform the Soldiers of open time slots for exam appointments at the Soldiers assigned clinic. Ultimately, it would be ideal to allow the Soldier to link from that email to an online scheduler and set the appointment up at that time. The scheduling aspect would be a future goal and not be a focus for this study. Instead, the patient will be supplied the phone number of the dental clinic they are assigned to, that would facilitate an

easy and prepared way for the patient to set up their dental exam appointment. This would be an effort to assist the patient and remove possible barriers to facilitate timely access to care prior to their past due date.

Soldiers may fail to set up their dental exam appointment for many different reasons, but a common reason is the lack of awareness of the upcoming due date. They may just need a reminder and access to information. With these prompts I believe that it will take stress off of the Soldiers and also improve their dental readiness. In the future, I would like to investigate this quantitatively by identifying a group of Army Dental clinics that have similar readiness numbers, randomly select clinics to implement the intervention, let the automated email system work for several months, and then compare the numbers in the different groups. I hypothesize that there will be an increased level of readiness in the clinic populations of the clinic that received the intervention vs the control clinics. I also think that the patients could be surveyed and qualitative information could be gathered on the acceptance level and perceived usefulness of the email reminder to the patients (Soldiers). This would be a pilot study and depending on its success the email reminders could be extended to other Soldier deadlines (medical, vision, hearing exams, etc...). One fear would be that if too many emails are sent that it could become too cumbersome and the Soldiers may start ignoring these emails. This may be the case and could be investigated as well with future studies.

### **Possible Conflicts**

This study is wholly dependent upon command support. If the local command is not supportive of this initiative then there is a possibility to complete this initiative in a separate DENTAC in a geographically separate area. Support from the Army Dental Directorate is also important if this is to be conducted at an Enterprise level in the future.

From discussion with CDS technical staff it was determined that over 90% of the patients have current email addresses in the database which will be imperative to complete the email survey portion of the study. The CDS database is also believed to contain 50% of current cell phone numbers. A possible texting initiative could be investigated for success compared to an email regiment in future studies. This could be completed at the JBLM DENTAC using a similar study design as this study, but comparing email vs texting.

## **Expected Results**

It is expected that there will be an increased level of readiness in the groups that were part of the PI project. The results will likely not be a large percent as most dental clinics hover around 90-95% readiness. It is also expected there will be an increase in dental wellness. Dental wellness is the measure of patients that don't have any pending dental needs. One of the main dental needs to be addressed is dental cleanings. Usually, this cleaning is also an annual requirement that is currently combined with the dental exam. With the email reminders it is believed that the dental wellness will also increase. It is believed that the increase will be more dramatic in wellness as there is a larger possibility for improvement as most dental clinics. In a CDS DRC report generated in May of 2016 the JBLM DENTAC wellness percentage was at 70.16%. With the prospect of an increase in wellness and readiness it is expected that the leadership will be very interested and supportive of this study.

From the survey it is believed that there will be a trend identified of the communication format preference of Soldiers. It is believed that Email will no longer be Soldiers' preferred method of receiving dental communication. From general observation it appears that texting is becoming the preferred mode of communication of most Soldiers. However, it is believed that Soldiers may not want their personal communication to be intertwined with their professional communication. Each Soldier has an Outlook Email account that is used for professional communication. They are directed to review their email on a regular basis. Due to this functioning requirement there may be an inclination of the Soldiers to keep their professional email communication isolated to one forum. The results of the survey will be included in the discussion section of the study.

## **Lessons Learned**

The lessons learned from this project were vast. One of the main lessons learned was that of respect for the design, development, and approval processes involved in research. The design process was centered on looking at a PI project that was completed at the JBLM DENTAC, and working with the commander to learn of his desires. The DENTAC level commander is charged with overseeing the oral health care for a designated amount of military units in a given area, while providing the highest level of care with a limited budget and time constraints. This must be

balanced with the other commanders of the units that fall under the care of JBLM DENTAC to the highest levels of readiness. Learning about his desires helped focus the study on readiness and a desire to increase the readiness of his patient population. The changes we were hoping to achieve are based on a well-established process and the readiness percentage improvement is expected to be a relatively small number. Gaining permission from the commander to study this data set was the first step in the process.

After gaining the authorization from the commander to analyze the data sets I began discussions with my capstone advisor. She gave pertinent and helpful guidance in developing the study. Her input in reference to the ethical study of the Soldiers and the way to look at the data was very beneficial in the design. I also referenced the chief medical informatics officer at Madigan Army Medical Center. His insight into the military specific nuances was helpful. Part of our discussion was security and the nature of information awareness issues involving the government network where the data resided. This extra level of security is beneficial to decrease the possibility of breaches of the collected data.

One of the more beneficial exercises of this process was taking part in the Madigan Department of Clinical Investigation Protocol Development Workshop (PDW). This workshop consisted of a panel of researchers that designated 45 minutes of their time to review the proposed study with the researcher. Prior to the workshop the panel received a synopsis of the proposed study, study design, power analysis, and a forecast of the statistical analysis that would likely be employed. They reviewed the provided content and came prepared with notes and questions to help improve the study. The panel consisted of the head researcher of the department, bio-statistician, nurse researcher, two fellows of the faculty development fellowship, research assistants, chief of the lab research, and research administrative staff. One of the primary recommendations from this group was the development of a participant survey. The panel deduced that the survey would be very beneficial to help strengthen the discussion section of the paper. One of the desired results from the anonymous survey would be an assessment of the preferred communication method of the Soldiers when they receive communication in reference to their oral care management.

Another key fact that was identified in the PDW was the possible confounding factor of appointment unavailability. To account for this variable the survey would have questions directed at this factor to assess if this was indeed an issue.

After the PDW, per the recommendation of my fellowship director, I researched other surveys that had been validated to help increase the validity of the survey to be used in the proposed study. A comparable survey is the DOD Dental Patient Satisfaction Survey (DOD PSR) that had been used in the Military Health System for over seventeen years.<sup>2</sup> From this survey there was a component that was used to determine appointment availability. The office that managed the survey at the Army Dental Directorate was contacted to receive consent to use a form of their questions in the desired study. It was also important to learn about their validation process. From this survey there were well developed questions to assess the demographics and satisfaction of the participant that was used in the proposed survey questions. The research that was used to develop the DOD PSR and satisfaction has roots in the work completed by Chisick.<sup>3</sup> He found that predictors of satisfaction were centered around availability, convenience, pain control, and interpersonal skills of staff.<sup>4</sup> Mangelsdorff and Finstuen further described factors in a satisfaction prediction model that were centered around attitudes and beliefs.<sup>2</sup> Some of the factors that were evaluated were age and access to gauge waiting time, status of health, and gender.<sup>3</sup> These studies were used to develop the patient satisfaction component in the DOD PSR and hopefully can lead to a validation of a dental question specific model.<sup>3</sup> The DOD patient satisfaction questions from the DOD PSR were used as template and customized to address the customer satisfaction levels of the patients that had received the email reminders and their experience in receiving care at the JBLM DENTAC Clinics.

The questions were developed for this study and submitted to the CMIO at Madigan, capstone advisor for review, and research team at the CDI department. Comments were received and revisions were made. The PDW offered that I could use a use online public survey tool that is commonly used outside of the DOD to conduct the survey for this study. This option was discussed with the information management division security officer and they note that was an option but there were options that were more secure that could be used on the DOD network. Madigan had developed a survey tool as part of larger prior project that has been

authorized to conduct other studies. It is called HERMES and has to be accessed via two factor authentication (using the DOD Common Access Card with user certificates and password). The system administrator of the HERMES product was contacted and a meeting was conducted to discuss the nature and needs of the survey. The survey was submitted for development to the system administrator to be ready for distribution once IRB approval was obtained. A completed survey was required as part of the Madigan IRB submission packet. If changes were requested from the IRB on the survey it was determined that it would take a minimal amount of effort to adjust the developed HERMES survey if it were developed prior to submission. This was done in an effort to expedite the distribution of the survey to receive the responses in an expedited timeframe.

One of the questions that arose with this proposed study was which institution would administer the IRB. This study would be completed solely at the Madigan Army Medical Center with a review of data collected on Soldiers stationed at Joint Base Lewis-McChord from a process improvement project completed by the JBLM DENTAC. This study would also have ties to the Oregon Health & Sciences University due to the fact that I am currently a student in the Department of Medical Informatics and Clinical Epidemiology department in the Master of Biomedical Informatics program. This study would be part of that curriculum meeting the capstone requirement of that Master's program. Discussing this with my capstone advisor and academic advisor it was determined that I would likely need to complete an evaluation by the IRB at Madigan and also the OHSU IRB. The OHSU IRB office was contacted and they confirmed that this study would be primarily evaluated by Madigan. It was determined that OHSU would likely waive oversight to the Madigan IRB as the research was being conducted there. This process was estimated at taking 3-4 weeks by the OHSU IRB representative. The Madigan IRB submission paperwork was completed and submitted. There were revisions to the submission packet that were requested by the Madigan IRB. This process was five weeks into the process and an evaluation was made of the timeline. The Madigan IRB office had lost their online access to their eIRB (IRBNet) system and the paperwork submission process had slowed their ability to expeditiously process the growing number of protocol submissions. There was a concern that began to develop that there would be an insufficient amount of time for the IRB to complete their review at Madigan, receive the approval letter

(required for the waiver by OHSU), submit paperwork to OHSU IRB, receive approval from OHSU IRB, and complete the statistical analysis prior to the capstone submission timelines. Due to the backup the Madigan IRB had been adding extra review sessions on weekends to meet the growing submission list. Once this backup was recognized both, I contacted my fellowship and capstone mentors to share my timeline concerns. My mentors were understanding of the situation and evaluated the situation. After careful review it was assessed that there would be an insufficient amount of time to complete the study if the minimal time projections from the two IRBs were achieved. An amendment to the capstone project was developed and submitted for review to the Master's program administrators. The amendment was approved and this paper is the deliverable from that amendment. It was decided to let the IRBs take their natural course, write an overview of my experience and study, and finally complete the study after both IRB approvals were completed. Note: at completion of this paper the Madigan IRB is still pending approval.

The main lesson learned from this process was that of time management in the process of completing a study of this size. My lack of awareness and experience were showcased in the time projections allotted to complete this capstone project on time. One part of the process that was time consuming and was a primary factor in not completing the study was participating in the PDW. Though completing the PDW paperwork and scheduling were time consuming the lessons learned from this were very beneficial. The opportunity to have my study idea evaluated by a panel of research professionals and then being provided thoughtful and insightful feedback was a huge growing experience. My growth and understanding grew exponentially from this experience and the quality of the study will be much improved from this process. With a retrospective analysis of the study development process I found the PDW to be a central point in my learning and I am very satisfied that I had that opportunity. If I had opted out of the PDW I would have likely made the deadlines but I would have missed out on this valuable part of the process.

### **Ethical concerns of shared research**

Shared research, or research being conducted under the purview of two governing institutions presents some ethical issues that can negatively affect a

study. The main concern about a shared research situation is identifying the jurisdiction of and responsibility of oversight. In this situation, OHSU has responsibility to monitor all research being conducted by its faculty and students. Also the facility where the research is being completed also has the responsibility of oversight as the research is being conducted on its patient population and at its facility. It is in the best interest of both institutions to promote beneficence to the patients to make thorough reviews of the proposed study.

A primary consideration is the time to complete the IRB review process at two institutions. It was noted by Obeid et al, that shared IRB reviews are important but they are hampered by systems that are not interoperable and very time consuming.<sup>5</sup> There is a desire to get the study completed as soon as possible after the completion of the PI project. The patients involved in the JBLM DENTAC PI project and proposed study are being asked to recall things that happened at an increasingly larger time interval between the two events. This will result in a decrease in the quality of the data as their recollection of the event will be clouded by time. It isn't fair, and borderline infringing upon unjust, to demand a survey response in regards to a singular email that was sent to them over a half a year ago during the PI project. This request would challenge the memory of most and would not be beneficent in nature.

Other considerations are the lack of proper understanding between the two organizations on who will be taking responsibility of oversight. It does open the possibility that certain areas of oversight may be waived when in reality they should be addressed by the facility that waived the oversight. If certain items are believed to be covered by one institution but that isn't clearly communicated it opens up possible issues that could jeopardize the patient's anonymity or privacy. This would hopefully never happen but it is a possibility. This would become more of a problem as the amount of sharing increases in conducting the study. If there is data gathered at two or more facilities then there needs to be an increased amount of oversight between all of the involved institutions IRBs to ensure there will not be areas that go overlooked. This is addressed in the Common Rule when it discusses the rule that each site has responsibility for the ensuring protection for the welfare and rights of the human subjects.<sup>6</sup>

Another possible shared research ethical issue could present with the lack of transparency and communication between the two organizations. Under the Common Rule (45 CFR Part 46.114) spells out the relationship of projects that involve more than one institution, but it allows for institutions to create an agreement of reviewing responsibilities.<sup>6</sup> With this collaboration there will be a delineation for workload sharing that leads to the possibility that something may be overlooked. Also, if the conduit of communication between the IRBs is the principal investigator then it generates the possibility that the study may be altered or the communication deliberately crafted to ensure that the study is approved by all of the different IRBs. Studies generally have deadlines or time goals for completion. If the investigator is placed under an undue amount of pressure to meet the time obligations while being met with IRB roadblocks it opens up opportunities for ethical decisions to be made. It is hoped that the investigator would always act ethically but this may not always be the case. An investigator may decide to start the study prior to the approval thinking that “no harm will come from this and then I can meet my deadline”. This would violate the autonomy of the patients as the investigators decision may be made without fully completing the IRB process and subjecting the patient to interventions that have not been cleared for a study. A discussion should be had between the investigator and all of the institutions IRB representatives to discuss realistic timelines and division of responsibilities prior to starting the study design and development. This could help alleviate any unrealistic understandings of timelines and also delineate oversight responsibilities. The communication should continue past this initial meeting to make sure that any nuances or issues are addressed to ensure the proposed timeline can be met.

### **Projected actions after IRB approval**

After the Madigan IRB is completed it is likely that I would have already graduated from the Master’s program at OHSU. A meeting was arranged between an OHSU IRB representative, the OHSU DMICE Education Programs Coordinator, my Capstone advisor, and I to decide on a way forward address the completion of the OHSU IRB after the Madigan IRB was completed. It was determined that if the study is completed after graduation that it would no longer need to be assessed for a waiver of IRB to another hospital due to the fact that I would no longer be a student there. Also since all of the data collection was completed at Madigan, the

data is stored at Madigan, the patient population is at Madigan, and the analysis of the data would be completed at Madigan that IRB at OHSU would not need to review this study. This was agreed upon by all parties in the meeting.

Once the necessary revisions from the Madigan IRB are completed and approval is granted the survey will be sent to the Soldiers that had taken part of the PI project. They will receive two weeks to complete the survey and then the data will be collected from the HERMES survey engine. While the survey is being completed by the participants the PI project data will be accessed, consolidated, de-identified, and analyzed. The Madigan bio-statistic team in the Department of Clinical Investigation will be used as a resource to help analyze the data. After the data analysis is completed the paper will be completed and submitted for publication. It is projected that the information gathered would be the most applicable to be published in the Journal of Military Medicine.

## **Conclusion**

This paper describes the background of the proposed study, the study design, the roadblocks encountered, and once the IRB approval is completed the next steps necessary to accomplish the study. One major roadblock that was encountered was my attendance in Madigan Department of Clinical Investigation's Protocol Development Workshop (PDW). The PDW application process was time consuming and the actual event was scheduled out months in advance. Even though this learning experience delayed the completion of my study it provided a strong foundation for this research project and gave me a better understanding of the research process in general. Another difficulty encountered was the Department of Clinical Investigation losing its ability to accept research projects through their Electronic IRB system. This created a waiting list of IRB submissions that further delayed the approval of my study from the IRB.

From this study it is desired to learn if the intrinsic capability built into CDS to email Soldiers when they are one to two months away from becoming DRC class 4 could be used to increase the readiness of the Soldiers in the JBLM DENTAC. Also from the use of the patient survey we also hope to learn more about the preferred means of medical communication in our military population. With this better understanding of the Soldiers preferred method of communication, this

can be relayed to commanders to allow for them to better manage the dental readiness of their units in the future.

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## Appendix A:

Survey Questions for the study titled: "Timely Digital Reminders Impact on Soldier Dental Readiness" by LTC, Kevin B. Parker, DC

1. What is your Gender? M, F,
2. How old are you? (6 categories- 17 and under, 18-19yrs, 20-29 yrs, 30-39 yrs, 40-49 yrs, 50 yrs and above)
3. What is your rank? (6 categories- a. Enlisted (E-1 to E-4), b. Enlisted (E-5 to E-9), c. Officer (O-1 to O-4), d. Officer (O-5 or Higher), e. Warrant Officer, f. Cadet/ROTC)
4. What is your preferred method of receiving communication:
  - a. Email
  - b. Text
  - c. Phone call
  - d. Letter
  - e. Other \_\_\_\_\_
5. Did you receive the email prompting you to call the dental clinic to make an appointment? (If no skip to question 8)
6. How did you feel about receiving the email from the dental clinic reminding you to schedule an appointment? (a. Very Negative, b. Negative, c. No Opinion, d. It Was Somewhat helpful, e. It was Very Helpful )
7. After you received the email, how many days did it take you to make your appointment?(scroll down menu to enter days)
8. How many days were there between the day of your appointment was made and your dental exam? (a. Unknown, b. Same Day, c. 1 day, d. 2-3 days, e. 4-7 days, f. 8-14 days, g. 15-21 days, h. 22-30 days, i. More Than 30 days for the soonest appointment, j. More Than 30 Days by your choice.
9. How do you rate the number of DAYS you waited for your appointment? (a. Very Poor, b. Poor, c. No Opinion, d. Good, e. Very Good)