DEVELOPMENT OF A BIOINFORMATICS SYSTEM FOR INDIVIDUALIZED PRIORITIZATION OF CLINICAL PRACTICE GUIDELINE

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INTRODUCTION

This project directly addresses development, validation, and timing of promising interventions to address consequences of spinal cord injury (SCI), specifically the primary and secondary prevention of pressure ulcers and deep tissue injury, collectively known as pressure injuries (PrI). These chronic wounds are a major negative consequence of SCI. The Spinal Cord Injury Pressure Ulcer and Deep tissue injury (SCIPUD+) healthcare tool enables personalized PrI care planning, supporting identification and validation of best practices in SCI care for musculoskeletal health and rehabilitation interventions.

Over 200 risk factors for PrI development have been reported for individuals with SCI [1], spanning multiple domains [2]. The Center for Medicare and Medicaid Services (CMS) has determined that severe (Grade III and IV) hospital-acquired PrI are completely preventable ‘never-events’ and have discontinued reimbursement [3]. The clinical reality is that many persons living with SCI continue to develop significant PrI, both in the community and in hospital. Patients in acute care hospitals have 33% PrI incidence rates, with prevalence rates up to 69% [4,5]. On admission to skilled nursing facilities, PrI prevalence ranges between 10% and 26% [6,7]. Veterans with chronic SCI have incidence rates as high as 62-80% [8,9] and over their lifetime 34% will require at least three PrI related hospitalizations for treatment [10]. PrIs may lead to other serious medical complications, such as osteomyelitis, sepsis and even death. In addition to the personal distress and negative impact on quality of life (QoL) for the individual, PrI place a major cost burden on healthcare systems. PrI prevention is approximately 2.5 times more economical than treatment [11], with direct treatment costs for one Stage 4 PrI exceeding $100,000 over 6 years ago [12,13,14,15].

Primary PrI prevention is encouraged as the first line of defense [16]. Clinical practice guidelines (CPGs) developed to aid clinicians in this goal combine a balance of evidence based practice and expert opinion. There are multiple CPGs for PrI prevention [17,18,19,20,21], each containing similar recommendations regarding risk assessment, prevention, PrI assessment, measurement, treatment and documentation; however they also contain significant differences. The major challenge with all CPGs is that there are many factors to consider. For example, the CPG from the Consortium for Spinal Cord Medicine released in September 2014 contains a summary of over 25 recommendations to be followed by care providers [16]. However, there is limited guidance on how to prioritize the recommendations for individual cases. It is very challenging and even unrealistic to expect every recommendation to be implemented concurrently, which can be overwhelming [2]. The relative importance of risk factors has not yet been investigated, limiting care planning and prioritization of interventions. Unfortunately, as Thomason et al. found [22], although SCI physicians and nurses generally agree with the written CPG recommendations, they do not believe that these recommendations were fully implemented in their respective clinical settings. Furthermore, an European Pressure Ulcer Advisory Panel survey of PrI prevalence in 5000 hospitalized patients throughout Europe, indicated that clinical expertise and standard treatment guidelines are not in themselves sufficient [23]. The International Pressure Ulcer Prevalence Study from 2006 to 2009 demonstrated an uptick in PrI prevalence in the U.S. While overall PrI prevalence decreased slightly, the prevalence of suspected deep tissue injury increased during the same period [24]. The continued high incidence of chronic PrI, including recurrent wounds, highlights the need to develop new approaches to primary and secondary prevention.

As the problems to be addressed become more complex and investigative tools become more sophisticated, the future of scientific research and evidence-based personalized practice will increasingly require multidisciplinary teams. A multidisciplinary wound management team was initiated by the Wound Healing Research Unit at Cardiff University, Wales over 20 years ago [25]. This approach can optimize effective translation and validation of best practices for standard clinical practice. In 2013, the Veterans Health Administration (VHA) launched a five year strategic plan with the goal of moving the healthcare system for Veterans towards Personalized, Proactive, Patient-driven Health care, delivered across the life continuum from prevention through tertiary care and end of life [26]. To achieve this goal for successful PrI management the patient-centered multidisciplinary team typically includes physicians, nurses, physical therapists, occupational therapists, dieticians, psychologists and biomedical engineers [27,28].

Current PrI screening tools include a variety of risk assessment scales [9,29,30]. It is important that these scales be validated as reliable for use within each specific patient population [31]. Sensitivity and specificity vary
widely between scales, with the Braden scale having the best balance for use in the general population (57.1%/67.5%) [32]. However, in a review of the seven most widely used scales, it was found that evidence of validity for use in the SCI population was limited [31] and that there was no evidence related to reliability or responsiveness for individuals with SCI. A comparative effectiveness review on PrI risk assessment by the Agency for Healthcare Research and Quality found no difference between clinical judgment and the use of any scale [33]. Tescher et al [40] commented that all at-risk patients are not created equal and concluded that the Braden scale does not assist the clinician to develop individualized prevention plans. As noted by Pancorbo-Hidalog et al and others [32, 34, 35], there is no evidence that use of risk assessment scales prevents PrI. Thus it appears that the evidence regarding the effectiveness of risk-assessment tools for actually preventing PrI is very limited.

Reducing PrI incidence and recurrence (primary and secondary prevention, respectively) depends on reliably identifying the risk factors that contribute to PrI formation. A multidisciplinary expert panel found that while it is well recognized that PrI development involves multiple factors, and many risk factors have been identified, many key questions remain unanswered and are in need of further research [2]. Much of the published research on PrI risk focuses on either nursing home residents or on the population with acute SCI. However, the degree to which these risk factors apply to other populations has not been established. PrI environmental risk factors may vary between rural and urban populations due to factors such as ease of access to transportation, access to specialized clinical care and air quality. For example, the VA SCI population includes a high proportion of individuals who receive life-long care in both urban and rural areas, who may have different rates of primary PrI development [36, 37].

The continued high PrI incidence for significant numbers of individuals at-risk in the hospital and community indicates that CPG, standardized pressure relief regimes and risk assessment scales alone are insufficient. PrI management remains complex and multidimensional. Motivational interviewing has been shown help individuals to adhere to personal care plans [38, 39]. However, it has also been shown that focusing primarily on individual motivation using a standardized approach for individuals with SCI is ineffective for secondary prevention [40], highlighting the continued need for a personalized approach.

All persons with SCI are at increased risk of PrI development. However, susceptibility for this devastating consequence of SCI appears to be unique for each individual. A regime of regular postural alteration and pressure relief is generally considered essential to minimize the risk of PrI development. Yet, some individuals remain PrI free even though they do not perform regular pressure relief, while others perform regular pressure relief and repeatedly develop tissue breakdown. The transition from the inpatient hospital or living in a nursing home to the community following rehabilitation may impact environmental risk factors. Likewise, living alone or with a partner can impact social risk factors. CPG consider all these factors but do not provide relative prioritization.

The correction of all PrI risk factors for an individual with SCI can be both overwhelming and impractical to implement in clinical practice. The need to develop effective clinical tools to prioritize the multiple recommendations of CPG has been identified by experts in the field. In preliminary work, our development and application of the preliminary SCIPUD resource has shown that risk factors for primary prevention may not be the same as those for secondary prevention, i.e. PrI recurrence [41].

The application of bioinformatics platforms enables data extraction, storage, and analysis to support clinical decision support and user-interface development for complex clinical challenges such as PrI prevention care planning. A systems approach is being used to develop and validate the SCIPUD+ Resource, a multivariate structural model including all core NINDS Common Data Elements (CDE) [42] expanded with contributions from the many risk factor domains associated with PrI risk (see Figure 1), ranging from the individual’s environment to local tissue health. The SCIPUD+ Resource will provide a personalized healthcare tool to address a major consequence of SCI, specifically PrI prevention care planning. Personalized interactive programs can enhance best practices in SCI care by decreasing both initial PrI formation and readmission rates due to PrI recurrence for high-risk individuals, especially the Veteran with SCI.
The overall study objective is to develop a structural model of environmental, social and clinical factors in order to provide weighted systemic insight to PrI risk in persons with SCI to support personalized care plans for primary and secondary PrI prevention. The SCIPUD+ Resource will be developed using data sets extracted from the VA Informatics and Computing Infrastructure (VINCI) database together with a cross-sectional study of tissue health profiles and validated using an observational cohort study. The central hypothesis of the study is that the individual’s risk factor profile can provide the basis for adaptive personalized care planning for PrI prevention based on CPG prioritization.

METHODS
The study is employing a retrospective electronic health record (EHR) chart review of over 75 factors known to be relevant for PrI risk in individuals with SCI and routinely recorded in the EHR. We also perform tissue health assessments of a selected sub-group. By applying advanced bioinformatics, we will leverage the power of the rich data resource provided by the VINCI and the detailed personal characteristic database of tissue health to provide the weighted, adaptive personalized SCIPUD+ Resource for primary and secondary PrI prevention.

The integrated SCIPUD+ Resource is being assembled from two databases, one using data extracted from the EHR by informatics and text mining, another using tissue health data. PrI risk factor data collected at multiple retrospective time points include modifiable and non-modifiable factors identified in cross-sectional and observational studies. Multi-scale data extraction includes numerical, categorical and text data mining. A Spinal Cord Injury Pressure Ulcer and Deep tissue injury ontology, SCIPUDO, will be developed to ensure robust and

Figure 1: Multiple risk factor domains contribute to pressure ulcer (PU/DTI) risk.
extensive information extraction from the free text clinical note. We will also carry out a cross-sectional study of tissue health profiles in a representative cohort of 60 individuals with SCI.

The Multi-Modality, Multi-Resource Information Integration Environment for Multi-center Physiological and Clinical Research Studies (Physio-MIMI) cloud-based multi-modal data storage and access platform [43] creates a common web-based user interface for data queries and enables development of compatible analytical tools and easier sharing of complex data from multiple domains to support collaborative clinical and translational research using diverse data types. Another tool, OnWARD (Ontology-driven Web-based Research Data Capture) provides robust flexibility of input data storage in a relational database for detailed analysis and can be quickly deployed and customized for any clinical study. OnWARD has demonstrably eased the data entry burden in multiple clinical trials [44].

Structural modeling of factors from multiple domains and their co-impact on developing PrI will be used to provide weighted systemic insight in to initial and recurrent PrI risk in persons with SCI. A comprehensive model will be used to relate the primary outcome of interest (PrI development) with covariates including environmental, social, clinical, personal and tissue health profiles and possible interactions among some of these covariates. The SCIPUD+ Resource is being developed using a detailed chart review of VINCI data using ICD-9-CM codes for paraplegia and tetraplegia with a secondary filter using an SCI-specific Stop Code. The search timeframe is pre-conversion date (Sept 2010 – Sept 2015) because ICD-10 codes do not currently provide accurate delineation of SCI factors. The initial query returned approximately 36,000 different individuals and 120,000 encounters during the search timeframe across the VHA nationally. It was clarified that some individuals coded for SCI actually have a primary diagnosis of multiple sclerosis or amyotrophic lateral sclerosis (ALS). We therefore revised the code to develop a secondary filter to exclude individuals with MS and ALS since risk factors vary considerably in these neurodegenerative diseases compared to SCI. This secondary query revealed a study cohort of over 20,000 individuals with SCI, equivalent to about 8% of the total United States population with SCI. Within this cohort detailed review found that the cohort includes more than 109,000 encounters. Furthermore, we have learnt that each encounter actually encompasses an episode of care and may include multiple different appointments stemming from the same visit, or a long period of hospitalization. Thus we have estimated the cohort includes in the region of 500,000 different events and over 40 million data points.

(a) Clinical and Tissue Health domains predominate. (b) Personal and Clinical domains predominate.

**Figure 2:** SCIPUD+ PU/DTI care plan model. Domain size indicates the relative importance for that individual

Our research strategy builds on our existing methodologies to create the SCIPUD+ Resource to enable personalized care planning for PrI prevention based on the individual’s holistic characteristics [41]. Analysis of multiple PrI risk factors requires a robust and scalable informatics approach to cope with challenges in volume
and complexity. Clinical and demographic data of interest is collected using systems with a variety of sampling rates and formats. Even when checklists and coding are required, data may be missing or only found in the free-form note. During preliminary work we found that ICD-9-CM codes markedly under-reported the number of PrI treated. In a population of 399 eligible patients, only 93 were coded for PrI. We have developed a pathway for construction of disease-specific ontologies for data extraction using Natural Language Processing (NLP) for complex specialized clinical notes. We will create the dedicated domain ontology SCIPUDO by reusing terminology from existing systems ranging from anatomy (SNOMED CT), disease classification (ICD-9 and 10), medication (RxNorm), and NINDS CDE. Because of Physio-MIMI’s highly adaptable system architecture with domain ontology as a plug-and-play component, the proposed SCIPUD+ Resource can be developed by reusing much of the existing open-source tools that we have already developed. Figure 2 shows two theoretical examples. In the first scenario, clinical profile and tissue health response are the most critical domains. Potentially modifiable factors in these domains include spasticity and applied loads. Thus the SCIPUD+ care plan for (a) would prioritize spasticity management and equipment provided. In the second scenario, the critical domains are personal and clinical factors. In addition to the potentially modifiable factors in the clinical domain, potentially modifiable factors on the personal domain for (b) include smoking and BMI.

Sample Size Calculation. Based on our prior data, we defined expected PrI incidence as 30% and a clinically significant difference as reducing the incidence by 50%. The basic PrI status extracted from the EHR is PrI or not PrI, leading to a dichotomous outcome. However, the severity of PrI differs. We will use text mining to further classify wound status as severe PrI (Stage 3 or 4), minor PrI (Stage 1 or 2), deep tissue injury, absent or unclassified, leading to a polytomous outcome. A first-line analysis model for dichotomous outcome uses logistic regression, while the first-line analysis model for a polytomous outcome uses multinomial logistic regression. Considering all variables and their possible interactions would lead to ~3082 covariates to be studied in each model. In practice it is reasonable to expect that only a small portion of these covariates, such as ~25, be sufficient to predict PrI outcomes. Only clinically meaningful interactions need to be considered at the start of our modeling. In order to achieve a fairly rich SCIPUD+ database that allows for a balanced cohort selection of the personal, environmental, social and clinical factors and also for an extensive study of impact of these factors we can and will oversample. Data will therefore be extracted from a retrospective chart review of 5000 individuals selected from the study cohort of over 20,000 individuals with SCI. We will retain 500 representative cases for further validation/testing. Hence this sampling will leave more than 1418 (=5000-3082-500) degrees of freedom, which is more than sufficient to determine the top 25 predictors, validate and test these predictors with at least 80% power under a standard significance level of 0.05, assuming an average difference of PrI incidence of at least 0.15 and a moderately balanced number of cases [45, 46, 47]. The validation and testing of these top 25 predictors will be based on standard tests and bootstrap procedures.

Data Extraction and Processing: Raw data is extracted from VINCI using a stratified ICD-9 code search, de-identified and stored as a csv file. Data formats include categorical, numerical and free-form text in clinical notes. Data to be collected includes factors identified as being possibly related to PrI development or healing either in cross-sectional or other observational studies. Annual evaluations for the complete study cohort to be reviewed will be included. Any patient admission will also be reviewed, together with weekly in-patient and discharge encounters. We are particularly interested in possible differences in PrI risk based on level and extent of spinal injury and motor and sensory impairment. Thus, we will examine quadriplegia motor-complete (QMC), quadriplegia motor-incomplete (QMI), paraplegia motor-complete (PMC), and paraplegia motor–incomplete (PMI).

We are developing SCIPUDO as the knowledge resource for processing specialized terms related to SCI, PrI and deep tissue injuries. Parsing and analyzing clinical narratives present a unique set of challenges that distinguish it from the broader biomedical NLP approaches. There has been extensive work in creating clinical NLP systems focused on information extraction from free text in specific disease domains, such as cancer [48] and tuberculosis [49], however to date there is no community gold standard for SCI or PrI named entities. We will thus build our own gold standard using manual annotations created by team clinical members who will review a random sample of records from the over 20,000 clinical notes for this cohort extracted from VINCI. Each record will be reviewed by one-three clinicians. The SCIPUDO will enable: (1) term disambiguation, i.e. between commonly used synonyms and acronyms of a term such as quadriplegia/tetraplegia, (2) term
normalization, i.e. syntactic variations of a term, such as singular/plural and acronyms will be normalized using classes and customized rules such as PU/PrU/pressure ulcer, and (3) subsumption reasoning using class hierarchy to allow terms to be classified according to their broader semantic type.

Validated extracted data will then be collated using our established standard data collection forms and uploaded to the Physio-MIMI based integrated PrI risk assessment SCIPUD+ Resource. The Physio-MIMI backbone will provide extensible, scalable, and high performance data management for storing and accessing rapidly large volumes of data. Reliable data storage through automated data replication and data integrity verification will ensure consistent data availability and effective disaster recovery with off-site data backup. Data quality assurance and metadata version control will be managed using a combination of GitHub, JSON, and the open-source NSR data management environment [50]. A visual query interface will be adapted from OnWARD to allow all clinicians to directly query the SCIPUD+ Resource via a set of easily usable visual widgets that will be directly populated with the SCIPUDO classes to allow clinicians to flexibly construct queries, specific to the patient. All patient data will be stored in a firewall protected secure environment with role-based access control and audit-trail logging.

**Creation of the SCIPUD+ environmental, social and clinical domain database:** Input data for the SCIPUD+ database will be provided by synthesizing available EHR clinical data from VINCI, using a protocol based on our preliminary work. VINCI provides EHR data storage for all healthcare encounters within the VHA, updated on a daily basis. A preliminary query on 06/10/14, found that during the timeframe 2009-2014 there were 16,076 individuals seen by the VHA with an ICD-9-CM code of 344.00 (quadriplegia) and 24,052 individuals with an ICD-9-CM code of 344.1 (paraplegia). Of these 16% in both groups were also coded for a PrI (ICD-9-CM code 707.00). Within the local area, there were 1,021 encounters with individuals with quadriplegia and 1,443 with paraplegia. The reported rate of PrI incidence was 14%. Extraction of clinical details will entail text mining of the free-form clinical text notes. We are developing a SCI PrI Ontology (SCIPUDO) to enable robust text-mining for data extraction from free form notes in addition to using ICD codes to retrieve data of interest.

**Development and validation of the SCIPUD+ environmental, social and clinical structural model:** We will develop the SCIPUD+ environmental, social and clinical PrI risk factor user interface which will provide a single point of web-based access to well-annotated and de-identified data generated from multiple domains. Modifiable and non-modifiable factors will be considered (see Figure 1). In order to develop the SCIPUD+ environmental, social and clinical PrI risk structural model we will consider PrI status as the response variable. We will employ general logistic and multinomial logistic models with linear mixed effects (transformed if necessary) and interaction terms to fit the data. Tree-based models such as CART (classification and regression tree) and Random Forest will be also used to examine the relationship of the factors to the PrI status. Model and variable selection will be implemented to define the SCIPUD+ environmental, social and clinical model. Final models will be validated using cross-validation. Both models, especially the tree-based models are useful to rank-order factors in order to identify specific critical variables for an individual, with a particular interest in modifiable factors (see Figure 2).

**Development of integrated SCIPUD+ model:** General logistic and multinomial logistic models with linear (mixed) effects and their possible interaction terms will next be fit to the data or their natural groups and the significance of PrI development will be assessed. Natural groupings will be obtained by a cluster analysis of 5000 medical records and 60 detailed tissue health profiles to examine the association of these natural grouping with PrI frequency. Using statistical software R and Splus, tree-based models such as CART (classification and regression tree) and Random Forest, will be also used to examine the relationship of all factors with PrI status. Model and variable selection based on both logistic and tree-based models will be implemented to define the integrated SCIPUD+ model. Final models will be validated using 10-fold cross-validation and some hold-out cases using predictive measures. Both models, especially the tree-based models are useful to rank-order factors in order to identify specific critical variables for an individual. We shall pay particular attention to modifiable factors. The comprehensive model proposed will allow us to borrow the degrees of freedom from all data points to develop the fully integrated SCIPUD+ Resource. We will determine structural models based on both data sources using standard statistical models, and directly using large-p small-n modern techniques for all factors. Special interest models, such as those focused on modifiable factors, will be also developed. We expect that at
most 25 top-ranked factors/indices will be sufficient for modeling PrI risk as either a dichotomous or polytomous outcome and will allow development of the SCIPUD+ care planning algorithm.

RESULTS

As a preliminary high level review we ran a query using the Elixhauser Comorbidity index, which is a tool applied to analysis outcomes of interest to hospital administrators, such as predicting hospital resource use. The 30 variables included are all dichotomous, that is they are either present or absent, which makes categorization much more straightforward than a continuous variable such as some of those we will be looking further, for example level of injury or even living status. The first outcome is that only 6% of the cohort have no comorbidities. We also know that many individuals in the cohort actually have more than one comorbidity. Looking at the 5 most commonly coded comorbidities, it was found that while paralysis was the most common at 14% this is remarkably low for a cohort of Veterans who all have SCI. This finding provides an indicator that much valuable clinical information is not coded and must be extracted from the clinical notes. The second most common comorbidity is Depression. This has also been found in our relational analysis to occur concurrently with many other risk factors. Although we cannot determine which is cause and which is effect at this point, we can clearly see it is a major psychological risk factor which will impact many aspects of personalized PrI prevention planning.

In order to determine the incidence of comorbidities of interest in our cohort we have identified 226 ICD9 codes of interest. We ran an SQL query across all tables and created a summary table of all comorbidity ICD9 codes. This table contains 1,681,050 records for 32,398 individuals (this total number of individuals varies from the overall cohort total because not all individuals have a recorded comorbidity). The current data represent raw counts which have not been corrected for repeated reports, which may be either a chronic condition such as diabetes, or repeated occurrences such as PrIs (Table 1). These extracted data were imported into the query interface adapted from the Physio-MIMI and OnWARD, which enables interactive CDE query and cohort identifications.

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<th>Paralysis</th>
<th>6,408</th>
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<table>
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<tr>
<td>Gastric disease</td>
<td>230</td>
<td>0.5%</td>
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</tbody>
</table>

(a) 5 most commonly coded comorbidities (b) 5 least commonly coded comorbidities

DISCUSSION

The project uses established EHR data to build a comprehensive structured model of environmental, social and clinical PrI risk factors. A concurrent cross-sectional study will develop a structured model of tissue health PrI risk factors. Data from multiple domains will be integrated to provide personalized PrI care planning based on an individual’s risk factor characteristics. The comprehensive SCIPUD+ healthcare tool will be used to relate the primary outcome of interest (PrI development) with covariates including environmental, social, clinical, personal and tissue health profiles as well as possible interactions among some of these covariates. The SCIPUD+ Resource will provide an extremely valuable PrI prevention care planning resource for nurses and other clinical care providers.

The study will result in a validated tool for personalized implementation of CPG recommendations. Maintenance of tissue health provides a foundation for all active duty military and Veterans with SCI to maximize their quality of active life. Recognizing that every person with SCI is an individual; the SCIPUD+ Resource will contribute to Personalized, Proactive, Patient-driven Health care for all. PrI risk characteristics will be used for development of personalized CPG-priority based care plans for primary and secondary PrI
prevention. The use of SCIPUD+ care planning will impact individual health and QoL. Recognizing that healthcare resources are not unlimited, the SCIPUD+ Resource will also support optimization of resource allocation.

The SCIPUD+ Resource has great potential to change the standard of care for PrI clinical practice by enabling clinicians to provide personalized application of CPG priorities tailored to the needs of each at-risk individual with SCI. Use of our tool will allow clinicians to develop effective personalized care plans for primary and secondary PrI prevention for the patients in their care. In the longer term this research also has great potential to directly impact on standard of care by targeting interventions that will most effectively decrease PrI development for each individual. The population as a whole will benefit from a lower PrI incidence, more effective use of resources and reduced healthcare costs for long-term management.

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