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14. ABSTRACT
The goal of this Phase I project is to develop an engineering plan and to create a prototype for a mobile, cloud-based expert system to aid in diagnosis, decision support and predictive analytics to improve clinical outcomes for veterans, soldiers, and their families with traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD). Lifecom, Inc. is a health information technology company with over ten years of experience enhancing the quality and safety of health care through improving the accuracy and timeliness of medical diagnosis and management. Lifecom has developed clinical decision support and predictive analytics technology based on its Adaptive Knowledge Engine (AKE), a novel, general-purpose, platform agnostic, and nonlinear decision engine. The AKE, in conjunction with its modular data ontology and industrialized content development process, uniquely positions Lifecom to successfully meet the requirements of this SBIR Phase I project. While initially focused on TBI and PTSD, Lifecom’s engineering plan, supporting technology, and underlying clinical ontology will be capable of providing a template for the development and implementation of a range of future expert systems with semantic search capabilities that can serve any commercial or Department of Defense requirements, medical or otherwise.

15. SUBJECT TERMS artificial intelligence, clinical ontology, decision support, expert system, mHealth, PTSD, semantic parsing, TBI

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Introduction:

Lifecom Inc. received a Phase I SBIR Award to evaluate the engineering feasibility of using its Adaptive Knowledge Engine (AKE®) (a novel, patented, general-purpose, platform agnostic, and nonlinear decision engine), clinical data ontology, CDSS platform, applied analytics, and content development processes to provide an agile platform for current and future Department of Defense (DoD) requirements for integrated decision support across the full range of potential end users including individual soldiers. While the initial use case targeted decision support on a mobile, cloud-based architecture to aid in diagnosis, provide decision support and predictive analytics, and improve clinical outcomes for veterans, soldiers, and their families with traumatic brain injury (TBI) and posttraumatic stress disorder (PTSD), the goal was to create a general-purpose platform. Working with clinical experts in TBI/PTSD and evaluating relevant technology and existing DoD clinical data structures, Lifecom has determined that a robust and flexible system is feasible using our technology. A basic Web-based demonstration prototype application has been created along with an engineering plan capable of providing a template for the development and implementation of a range of future expert systems with semantic search capabilities serving any commercial or Department of Defense requirements, medical or otherwise. Execution of the engineering plan could provide DoD with a scalable and open decision support architecture that enhances patient safety, introduce greater clinical standardization, promote rapid dissemination of best practices and research, leverage non-physicians as clinical force multipliers, and provide standardized clinical records data optimized for applied analytics.

1. Results of Phase I Work:

Lifecom achieved each of the technical milestones identified in the original statement of work. The following are summaries of Lifecom’s Phase I Technical Objectives Findings:

Objective #1-Clinical Decision Support Software (CDSS) Infrastructure:

Summary: No modifications to either Lifecom’s underlying technology or data dictionary architecture will be required to accomplish stated DoD goals for integrated CDSS beyond the system interfaces described below. Data types unique to PTSD/TBI and associated clinical content for diagnosis, triage, stratification, and management of these conditions fit easily into the existing Lifecom Lexicon structure. Enhancements to existing external data and content management portals will allow approved DoD practitioners/researchers the ability to analyze operational data from the CDSS and author custom DoD clinical content.
Objective #2: Voice Recognition:

Summary: Major revisions to our original approach to incorporation of voice activation into the CDSS workflow resulted from detailed evaluation of the Nuance System Tool Kit (STKs). Figure 2 summarizes the pre-discovery approach Lifecom had proposed to address the goal of integrating voice recognition and (Watson-like) semantic parsing into clinical decision support. Readers are encouraged to review the original response to the SBIR proposal if they have questions.

Two pathways are now envisioned: one that would accommodate limited range open-ended text requests in a manner similar to our original concepts, and one that would support key word navigation of any term within the existing Lexicon. Open-ended text requests would be limited to History of Present Illness (HPI) and Review of Systems (ROS) data categories to minimize technical risk and expense while allowing patients maximum flexibility in response to clinical interview questions.

Revised Strategy: The underlying Lifecom technology suite and associated clinical data ontology (Lexicon) lends itself to integration with current generation voice activation. Fundamental to Lifecom’s approach to data collection and decision support is the iterative nature in which our technology interacts with the user. This approach is designed to improve the quality, precision, and completeness of clinical input data (enhanced clinical interview), and is important to understand in designing the user interface and integrating voice recognition. Figure 3 illustrates the Lifecom approach to iterative clinical assessment designed to support this function.
1) Clinical interview and patient history data is gathered and sent to the AKE for real-time analysis.

2) The AKE assesses the data and returns a set of relevant results or reports.

3) Context specific clinical reports are generated. Contexts include generation of a relevant differential diagnosis for an acute care assessment, selection of an optimal therapy track for a given patient, triage of the patient’s recommended level of service, clinical resource management, disease management, etc.

4) Generated result reports guide the AKE in the selection and prioritization of dynamically generated follow-on questions presented to the user. These questions mitigate cognitive biases, assist in the collection of a more complete data set on the clinical encounter, suggest appropriate pathways to pursue any outlier data that is encountered, and assist in translating patient responses into the appropriate and most precise medical terminology.

The AKE takes key initial observations, analyses the data, and provides the best set of next questions to ask to optimize the clinical encounter. A few open-ended data elements are used to establish an optimized strategy to compile a structured set of data elements that create the medical record of the clinical encounter.

When using non-physicians to provide care, this method is crucial. Non-physician users enter the initial patient responses into the system. The system dynamically establishes a strategy for conducting a complete interview on the patient. The non-physician user is fed an appropriate set of next steps to take with the patient. At this point the machine supplied refinement questions assume a more active role in ensuring the completeness and relevance of the clinical interview data set. This role shift is an obvious break point for voice technology as described by the revised Figure 4 below. The same strategy also works if the patient is using the system for self-care.
To enhance user experience, Lifecom will incorporate voice recognition into the user interface. As part of this Phase I engineering design assessment, Lifecom obtained a 60-day evaluation license for the Nuance voice recognition System Tool Kit. Based on this evaluation the following architecture is proposed. The pathway used depends on whether the user is employing a simplified set of known commands/key phrases or the user wants to input free text by voice.

![DHP 12-005: Post-discovery Approach to Voice Recognition](image)

1. To input free text by voice, the user selects voice activation control and issues voice commands or input data, which is converted into text.

2. The Lifecom Context Parsing Engine (CPE) evaluates the converted text. The CPE is a semantic text reader developed by Lifecom to deconstruct medical literature source documents (e.g. journal articles, book chapters, etc.) into knowledge fragments that can be mapped to Lexicon concepts as part of content development. In this case the CPE would assess the submitted text, identify one or more candidate concepts from the Lexicon that matched the original text and submit the candidate(s) to the user. This concept conversion is required to properly format knowledge concepts into a machine-readable form. This method will only be supported for initial data input of history of present illness (HPI) and review of systems (ROS) data (described later).

3. The user will have to verify that the CPE generated knowledge concept is an accurate representation of the user’s free text statement. If not, alternate selection may be made or the user may elect to revert to manual user interface data entry at any time.
4. Since the CPE presents properly formatted digital concepts, once the user verifies fidelity of the CPE text conversion, this concept triggers an assessment call to the AKE via the extant API (6) requiring no additional modification.

5. Once the AKE assesses the data it will present the user with the most appropriate interface template relevant to the assessment and appropriate refinement questions that can be used to guide the interview form this point forward. Selection of further data inputs will involve straightforward key word mapping of the displayed interface elements without requiring a CPE concept mapping. This same key word command mode can be used initially to select interface concepts from existing menus. For example, the user may say, "HPI; pain complaint; location abdomen" which would trigger the interface to open the HPI interface template to the abdomen location selection list for a pain complaint. From that list the user may say, "RUQ" which would trigger the interface to send a properly formatted concept to the AKE containing the elements of 'HPI: Pain: Location-RUQ' to the knowledge engine.

**HPI, ROS limits for free text assessment:** Limiting free text commands to HPI and ROS categories with key word commands for other areas is the best approach. This approach provides the greatest flexibility where it is needed most – interpreting patient complaints as part of their medical history while limiting development risk. Key word commands should provide ample flexibility for the majority of data input screens and for refinement question selection. This method is also scalable in that additional CPE assessment protocols can be added in the future if required by operational experience.

The obvious goal is to switch to key word command as quickly as possible during the assessments to reduce the possibility of framing errors or misinterpretation of input statements. This architecture supports a reasoned approach to voice recognition using existing technology made possible by the inherent structured nature of the Lifecom CDSS infrastructure.

**Objective #3-EHR integration:**

**Summary:** A phased integration with the EHR is envisioned which leverages existing mappings to the 3M Healthcare Data Dictionary (HDD). Both manual and automated deployment of CDSS within the existing EHR environment is planned in a manner that minimizes the impact on existing software and workflow. Together, 3M and Lifecom have determined that mapping of HDD to the data dictionary we use to configure knowledge files for our Adaptive Knowledge Engine (AKE) is feasible and practical.

Step I integration would exclusively link to existing systems and records through HDD. Manual input CDSS and automated safety assessment options would be supported. The EHR would automatically direct EHR data converted or stored in HDD format to the Lifecom AKE using an internal set of APIs that would also convert any AKE derived data into HDD for record storage.

Step II would support more direct integration of workflow tasks within the EHR that have been identified during Phase I as optimal candidates for real-time CDSS.

**Step I EHR integration**

Lifecom is working directly with 3M Corporation to evaluate mapping of our clinical data ontology (Lexicon) with HDD. Both HDD and the Lexicon express complex medical concepts and entities through fundamental relationships, although the Lifecom Lexicon has the advantage of being more granular at the clinical bedside level, reflecting the system’s focus on clinical assessment. Both ontologies do use alpha numeric IDs rather than objects to represent key concepts.

Lifecom’s Lexicon is a post-production style data dictionary where fundamental relationships are used to construct more complex entities. These complex constructions are utilized to create pre-production style content for use by the AKE. Lifecom already uses ICD, CPT, and LOINC (which are part of HDD) to
define disease states, treatment protocols, care management, etc. This level of integration with HDD is inherent.

Lifecom’s Lexicon already supports multiple identifier fields. Addition of HDD ID fields for concepts not covered by the above standards is simple and straightforward.

The relative simplicity of mapping to HDD provides a natural attachment point for integrated EHR/CDSS that minimizes the impact on existing systems and clinical workflows. Minimizing impact reduces technical risk, costs, and potential resistance from clinicians already used to using a particular EHR system.

As discussed in the section on CDSS infrastructure, the Lifecom system supports modular content. Initially, a limited set of functions and supporting content would be deployed to support PTSD/TBI assessment and management. Later additions could support phased deployment of a progressively more complete set of clinical use cases.

Figure 5 below illustrates key elements of the final engineering plan.

1. **EHR to HDD:** currently, a significant portion of existing data entries from the operational EHRs used by the DoD are mapped to HDD which serves as one format for stored medical data within a format that is supportive of applied analytics. HDD includes the majority data inputs that would be necessary to support CDSS.

2. **HDD to Lexicon:** External to the DoD system, HDD will be mapped to data and classifications within the Lifecom Lexicon.

3. **HDD/Lifecom machine interface:** The Lifecom Knowledge Repository Publisher (KRP) will publish a versioned copy of the integrated data dictionary and associated medical content (Knowledge Repository or KR) for use by the system at runtime. This KR will provide up to date instructions to the HDD/Lifecom machine interface allowing it to handle and create properly formatted calls to the AKE using our existing standard application program interface (API). This machine interface will be a modified version of our existing machine interface designed to prosecute automated calls from medical devices. HDD data will be processed in the same manner as telemetry coming from any medical device.

4. **Automated API calls:** Modified HDD data will be used to trigger an assessment call to the AKE using extant protocols if the data warrant it.

5. **AKE Assessments:** The AKE will assess the HDD supplied data against its current KR content. This process will use an unmodified AKE and associated methods.

6. **Lifecom GUI - AKE Reporting and Iterative Assessment:** In Phase I, AKE assessment reports will be presented to the user via a separate graphical user interface accessible via the existing EHR. This minimizes technical risk and disruption. Clinical users will receive auto-generated CDSS assessments and be asked dynamically generated refinement questions, as is standard practice for an AKE-based system in an iterative manner. Answers to these questions will trigger standard AKE reassessment calls via the existing API. Data generated through these assessments would automatically be stored in HDD format as part of the record.
This model supports alternate workflows. CDSS modules such as PTSD/TBI assessment and management processes could be called up by any level of clinician and accessed via the Lifecom GUI. Again, the resultant data would be stored in the record in HDD format.

**Step II:** Functional expansion is easy with this architecture. Adding additional content increases the range of CDSS support in a step-wise fashion. Modules added to the system over time will reflect evolving clinical priorities. A major attribute of Step II is that it would showcase the power of integrated CDSS to support clinical force multiplication and improved patient safety without major disruptions in existing workflow. Once clinicians were convinced of the utility, additional modules would be integrated into the workflow. Expanding the range of clinical modules available to clinicians is the major focus of Step II. The precise nature of these offerings would be dictated by input from clinicians and analysis of clinical trends from HDD data. The body of CDSS content would eventually reach a critical mass that would argue for direct integration of the EHR to the AKE systems or embedded interfaces within it. By this time, lessons learned from the step-wise integration would provide both the impetus and optimization strategy for successful transition to a record that is optimized for CDSS rather than simple modified to accept limited computerized decision support.

This architecture is flexible, scalable and represents minimal technical risk. The AKE and its KR's can be deployed locally or centrally depending on preference.

**Objective #4-Sensory Device Interface:**

**Summary:** Sensory device input to the CDSS will use proven methods employed by Lifecom customers. Device inputs will involve simple mappings to the Lifecom data dictionary supplied to a general-purpose machine interface developed by Lifecom for this purpose.
Discovery suggested that formal device testing for PTSD/TBI was not currently emphasized in the civilian market however evaluation of the outputs of a neuro-cognitive assessment device, previous work on incorporating EEG data, and a customer who uses our technology as an imbedded CDSS tool for patient bedside monitoring provided models for engineering assessment. Device input data does not create problems for AKE systems. It is simply another class of data and additional classes can be added as needed to support future devices.

Lifecom will employ its proven method for device integration as described in Figure 6 below.

**DHP 12-005 PHASE2: Machine Interface**

1. Approved medical devices will send data to the machine interface that has been configured to accept it. If the device manufacturer has any proprietary analytic algorithms that analyze the data prior to delivery those operations occur on their side of the machine interface.

2. The machine interface properly formats calls to the AKE using the standard API.

3. Any post interface analytics that Lifecom employs with the device data is performed prior to the AKE assessment so that the results of those analytics are available to the AKE.

4. This is a two-way protocol. The AKE can return its reports via the machine interface to be managed by the device or the results can be displayed using the standard GUI, which can display refinement questions, triggered by the machine data input. The refinement questions can be directed to ask for additional data types beyond what the device could provide. In this way, device inputs can be used to trigger a broader context assessment or search for more complex patterns requiring disparate data sources.
Objective #5-Engineering Document and Product Roadmap:

High-Level Engineering Plan

1. Communication with the legacy EHR systems is initially limited to HL-7 elements or the 3M Healthcare Data Dictionary (HDD).

2. Voice recognition will be supported by an interface using Nuance STKs interacting with Lifecom’s Context Parsing Engine (CPE) as an intermediary layer between user and the existing Lifecom API.

3. Two alternate manual user interfaces are planned: a mobile application running on iOS or Android smart phones and tablets as well as web services interface.

4. A separate machine interface and associated API tool kit will be provided for external developers enabling them to map to the Lifecom device interface.

5. The existing Lifecom API will manage calls between these interfaces, external clients, and the Adaptive Knowledge Engine AKE.

6. The existing Lifecom AKE will assess incoming calls against modular content data files containing both Lifecom derived and externally supplied content (KR).

7. The data dictionary supporting content development and AKE operations (Lexicon) will be synchronized with HDD.
8. Content development and maintenance will be ongoing, leveraging the Lifecom CPE as a force multiplier. External editors including DoD approved staff can vet content and make suggestions for additions and/or upgrades to development using a portal called the Collaborative Knowledge Development Environment (CKDE).

9. Data records of assessments are stored in a dynamic format (Case Server) that allows the AKE to access past record information in future assessments.

**Objective #6-PTSD/TBI Prototype:**

As part of this Phase I report, a web services prototype is provided demonstrating the use of appropriate clinical inputs to define the nature of the patient’s condition, help identify appropriate assessment tools and metrics based on patient triage, and the ability to supply appropriate follow-up questions to a clinical interviewer. The appendix includes instructions for accessing the demo website and a PDF tutorial on navigation.

**Future Research**

Most other approaches to clinical decision support concentrate on using natural language processing (NLP) to potentially identify free text data patterns indicative of risk or suggestive of one or more occult diagnoses such as TBI/PTSD or suicidal ideation. The advantage of this approach is that it can be applied to existing unstructured records. The disadvantages are that unstructured records are often incomplete, contain biased or erroneous data, are highly affected by semantics, and frequently result in imprecise recommendations. However, combining natural language processing with Lifecom’s system would preserve the advantages of NLP while mitigating the vulnerabilities.

The power of the combined approach is illustrated in Figure 8 below.

---

**Figure 8**
In this approach, NLP can identify potential patterns within the free text data that trigger the AKE to seek out confirmatory data, activate assessment protocols, or alert clinicians to potential problems.

1. NLP filters mine free text data to identify patterns.

2. Trigger patterns having a reasonable probability of being associated with diagnoses or situations of interest are cataloged.

3. Relevant trigger patterns are mapped to the Lifecom API converting them into structured data calls.

4. Mapped patterns are recorded in structured format for later retrieval and the AKE processes the assessments.

5. NLP patterns trigger a formal clinical interview or assessment by the AKE. The AKE opens a dialogue with the appropriate end user, providing refinement questions geared toward:
   - Resolving semantic ambiguity in the free text data
   - Capturing a more complete set of data relevant to the conditions or diagnoses suggested by the NLP patterns
   - Increasing confidence in the diagnosis suggested by the NLP pattern
   - Triaging risk
   - Activating standardized protocols for specific conditions
   - Supplying alerts to clinicians and care teams

6. All AKE assessment data is captured in structured format providing both Lifecom and 3rd party analytics (including the NLP provider) rich data required to improve or increase the trigger patterns or system responses.

**Key Research Accomplishments:**
1. CDSS Infrastructure plan
2. Voice recognition integration plan
3. Integration plan of Lifecom’s data ontology with 3M HDD and EHR integration exploration
4. Sensory device interface
5. Engineering Document and Product Roadmap
6. PTSD/TBI Prototype

**Reportable Outcomes:**
Demonstration prototype will be hosted at “ake.lifecomhealth.com/akeweb_64”. Call 503-750-6659 for technical or clinical assistance.

**Conclusions:** Figure 9 below illustrates the importance of these findings. Demand for physician care greatly exceeds the capacity of the current health care system. This will become even more acute with the introduction of long-term care for our wounded veterans from the conflicts in Iraq and Afghanistan. Lifecom’s system provides a means to expand health care capacity by enhancing the effectiveness of care teams and elevating the scope of practice of lower level health care providers such as medical assistants, field medics, nurses, and physician assistants (all components of a care team) by augmenting their level of ability with integrated clinical decision support. This greatly expands the pool of health care providers that is currently available. In this way, Lifecom’s CDSS can provide the needed force multiplier to provide the care to our soldiers and veterans without a major clinical manpower expansion.
In the current system, the choke point that limits clinical throughput is physician availability. Non-physician care teams provide minimal offloading because of clinical limitations. This leads to large delays in care and suboptimal access.

CDSS like Lifecom’s AKE system can address the disparity between need and throughput capacity in the following ways:

1. Mobile patient-centered apps using AKE technology can provide immediate access to records, resources, disease management, triage templates, symptom checkers, etc. These functions provide early warning of developing problems to physicians, and care teams, collect actionable data sets that reduce clinician workload, or redirect users to appropriate resources sparing clinician time.

2. Care team applications provide smart templates that increase the clinical utility of the teams by overcoming known limitations. The applications prompt the care team user to collect a complete set of clinical data, follow up on all relevant directions of inquiry suggested by the clinical data, pre-fill data into existing clinical pathway tools, triage patient risk, recognize clinical outliers, create actionable data sets for physician oversight, and provide evidence-based protocols to manage routine problems.

3. Physician CDSS provides safety checks, enhanced care protocols, improved situational awareness of all facets of care including care team oversight, and more time with individual patients by reducing redundant data gathering and off loading of routine management tasks that can now be accomplished by non-physicians.
Acknowledgements: We are grateful to have been allowed to participate in this important concept exploration. We would also like to thank Dr. Andy Ellis and Ms. Kathy DeDomingo of Progressive Rehabilitation for sharing their TBI insights and expertise and to Dr. Jesus Caban and Ms. Sharon Rasamalle for their timely assistance and guidance throughout the project.

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New report forecasts large gains for decision support, Kyle Hardy, Healthcare IT News, June 29, 2010
Web Application Tutorial

Basic Organization of the Application: 1

This is the application interface on login. The interface is divided into three areas with adjustable borders.

NOTE: This software is a simple proof of concept prototype. The functionality is limited and the user interface is simplified for demonstration purposes.

Basic Organization of the Application: 2

Select a Question Context: The upper left of the screen houses controls for Patient ID information, question template categories, and report creation.

Adaptive Knowledge Engine Questions: Once a context has been selected (Pre-op anesthesia assessment, Pre-op PE, etc.) the relevant questions for that category are displayed in this panel.

Adaptive Knowledge Engine Generated Considerations: The interactive feedback from the knowledge engine and the relevant reminders are displayed in the lower half of the screen.
Starting the Assessment

After the patient information has been typed into the entry fields, the user should select 'Pre-op anesthesia assessment' before either PE or ROS categories. This category covers key elements in the patient's history that are required for the software to conduct an assessment of pre-op risk.

Assessment: 1

Once you click on the question context on the left, the right-sided panel displays the questions in that context as part of a tree control to the left and the complete set of questions as a scrollable list on the right.

IMPORTANT NOTE! The Adaptive Knowledge Engine in this prototype system has been configured to recognize only one assessment context - 'TBI/PTSD screening' and ignore all other assessment contexts. If you don't click this choice, no recommendations will be made by the knowledge engine.
Assessment: 2

Prototype idiosyncrasies: The prototype uses an interface configuration that was developed for internal testing. It is not optimized for external users. In order to get utility from the system the user must be aware of these issues which are described in these pages by purple text.

Assessment: 3

All questions need not be answered. Clicking on a question category on the left will take you to the question on the right. Clicking on the 'top' link after any question set will return the user to the top starting position.
Adaptive Knowledge Engine (AKE) Recommendations

Before selecting another context (eg. pre-op PE), click on ‘Submit to AKE’, which fires the knowledge engine.

AKE reports are displayed below.

Adaptive Knowledge Engine (AKE) Recommendations

Click ‘Refine’ to see additional questions to be answered.

Click ‘Why’ to see the data that supports the recommendation.

Red text reflects clinical guideline recommendations.
Starting a new case or clearing an existing one

To preserve patient confidentiality, no digital record of an assessment is stored. Logging out of the system will erase the current assessment. To start a new case or clear the existing one before log out, press the 'New Patient' button. This dialogue window will pop-up asking you to verify that you intend to erase the current assessment. Press 'Cancel' if it was a mistake.

Clinical Report

When the assessment is completed, click 'Generate Report' to have a separate report window opened.
The generated report is the only permanent record of the assessment. The history and exam findings will become part of the patient record. (The AKE recommendations are only for educational purposes and will not be used for clinical decision-making.) To create a permanent record within the institution’s firewall, a PDF document must be created from the generated report.

A PDF is created by selecting the assessment report screen and clicking on the ‘File’ tab on the browser controls.

Then select ‘Print’ from the file menu.

Once your printer dialogue box opens, click on the PDF tab at the bottom and select ‘Save as PDF’. These PDF documents must be handled in accordance with the facility’s confidentiality and security policies prior to their addition to the patient record.