**Systemness® powered by CarePICS®**

The term “Systemness” refers to the seamless integration of assets and services within a healthcare system to deliver quality care to patients and value to stakeholders. Systematic changes to behavioral and activity-based processes are the typical methods used to produce positive outcomes within organizations. Our approach to population health management with pioneering wound measurement technology and customizable protocol-formulary management based on standard accepted clinical outcomes is unmatched in the industry. Systemness® powered by CarePICS® facilitates “Population Health Management for Wounds” throughout the care continuum utilizing this unique new smartphone based virtual solution that delivers a user-friendly experience and has a uniquely configurable cloud-based architecture.

Watch: CarePICS® Video

Read: CarePICS® Submission for Connected Patient Challenge 2019

Visit: CarePICS.com

See: CLI case study on patient that had leg saved because of CarePICS® early detection

**Wounds, Canary in the Coal Mine**

Wound formation is frequently multifactorial, involving pressure, trauma, nutrition, poor hygiene, venous insufficiency, congestive heart failure, attenuated micro-vasculature, and poor arterial perfusion. The need for a multi-disciplinary team approach has been championed by leading experts to manage the disease that may be the cause of the wound(s). The use of CarePICS® makes this concept a viable reality. Utilization of an accurate means to capture and trend wound surface area over time gives clinician a bellwether of underlying disease states. If a wound does not progress to heal it may mean addition intervention is needed. An EMR agnostic communication tool allows all involved with a patients’ care to share information and starting 2019 get paid for doing so. This coupled with an algorithm based on measurements and defined clinical tests to assess patient progress can significantly reduce the number of amputations and costly readmissions within a hospital system. We will use the Critical Limb Ischemia (CLI) as a disease state to show what CarePICS can do that has not been done before. CLI intervention is an effective treatment but outcomes can be improved and wound readmissions can be reduced (current up to 50%) with oversight once the patient goes back into their community.

**CLI Team Approach (Systemness)**

Background
Effective January 1, 2019 Medicare has approved under the Physician Fee Schedule (PFS) allowing Interprofessional Consultation Services utilizing internet technologies. These CPT codes (99451, 99452, 99446, 99447, 99448, and 99449) financially support effective population health management of chronic wounds and underlying disease states. It has been shown with proper follow up post intervention CLI patients do better and have fewer readmissions than those that do not.

EHR systems serve as a repository for clinical data but are rarely mined for actual care improvements so they fall short of promise of improving clinical effectiveness and efficiencies. CarePICS® facilitates Systemness® through standardizing acquisition and interpretation of imagery measurements, supporting a customizable protocol and formulary management system that optimizes clinical decisions, providing a patient encounter tool that offers clinician formulary suggestions from an enterprise configured protocol for proper wound therapy and treatment of underlying etiologies which is complemented by a machine learning algorithm that alerts users to the success of therapies over time.

Clinical Consultant Model
According to a 2014 report, over 8 million Medicare beneficiaries suffer from chronic wounds and total Medicare spending estimates for all wound types are $28.1 billion (low-range estimate), $31.7 billion (midrange estimate) and $96.8 billion (upper-range estimate). Additionally, diabetes and CLI rates continue to grow in our aging population and CLI intervention patients can have up to 56% readmission rate; 50% are from wound care complications alone. Agency for Healthcare Research and Quality reports that the average costs of one Medicare patient readmission averaged $13,800 in 2013. Value-based reimbursement models from Medicare and Medicaid are compelling care providers to reduce overall costs while standardizing care, monitoring patients throughout the care continuum and evaluating practices to maximize positive outcomes and patient satisfaction. A simple Population Health Management solution is central to enabling clinical collaboration for decision making that impacts quality patient care. Systemness® powered by CarePICS® fulfills this requirement through the following unique criteria for the 2019 PFS requirements that no other technology vendor currently offers:

1. Wound assessment format specific to provider protocol with planimetry and trending module with cross platform formats (iOS, Droid, web based)
2. Billing Interface specific to CMS timed increments billing criteria for consultant provider with tailored reports specific to referral source needs for billing per CMS requirements for inter-professional consult per PFS 2019 schedule
3. Real time, latent real time, store and forward formats for communication with referral source and all clinical personnel in care continuum (VoIP, streaming video, secure SMS and encrypted email)
4. Proprietary protocol and formulary algorithm configurable to specific clinical and economic requirements of enterprise partner creating a standardized format within host IDN or enterprise

1 https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS-1693-F.html
5. Acquisition module for simple image capture by clinical support personnel
6. HL7 ADT Interface to facilitate clinical billing
7. Electronic order module with e-signature with direct interface to fulfillment provider
8. Gratis system to referral source and patient

The current standard for protocol and formulary configurations consists of static programs embedded into EHR systems. The ability for clinical enterprises to make dynamic decisions based on live data is limited. More so, proper adherence to a current and uniform formulary is difficult. Currently, medical staff are provided hardcopy protocol and formulary schemas that are ambiguous and dated. In a typical hospital system there may be multiple protocols and formularies because they have not standardized on one that is most practicable.

A novel concept in this operation is a control system utilizing customizable trending, protocol and formulary to determine treatment and therapy efficacy. The CarePICS® logic tree is a Python-based program that interfaces with a PostgreSQL database in order to support a REST based API. This interface allows for iPhone, Android and Web Application clients to first populate a visual chart for a user to fill out on behalf of a patient, then send the chart data to the server in real-time using the charting API, which finally results in a two-way socket response to update the client’s chart with a proposed treatment solution using the formulary logical operators.

The CarePICS® logic tree algorithm uses n number of customizable clinical chart fields with a series of drop downs in order to formulate a recommended treatment or therapy method for a patient that is specific to that clinical enterprise’s needs. The algorithmic determination compares n number of logical operators to produce a resulting primary and secondary treatment option. Users select treatment options from an assortment of medical products or therapies that exist inside of our database and outside the influence of an individual user’s decisions. This creates a clinical chart input method that may vary between clinical enterprises but produces a medical product outcome that replicates easily within an enterprise.

All of the customizable chart fields exist in a specific database table for a given enterprise and are shared with its users. Each series of formulary combinations resides in the enterprise’s database under a formulary table that contains rows of formulary options. When a mobile application user selects a series of chart values within the application, the server runs a formulary database lookup using the chart fields that user selected in order to find a formulary table-row case that matches the user’s input. The case matching begins with the most specific and works backwards to match off with the least specific.

**Image Capture and Measurement**

CarePICS® supports a wound imagery capture tool that functions on any smart device operating Android or iOS systems. The feature contains a planimetry algorithm utilizing a reference phantom that yields very accurate measurements of wound surface area. Primary or secondary users can trace the edges of wounds on the device screen to define this measurement. The accumulation of images and measurements from successive clinical sessions generate trends to account for change over time. A supplementary web services application administers all relevant clinical data for comparison. “According to the Wound Healing Society’s guidelines, "if ulcer does not reduce by 40% or more after 4 weeks of therapy, re-evaluate and consider other treatments”. Indeed, as described by Sheehan et al., the percentage of wound surface reduction to 4 weeks is a strong predictor of healing at 12 weeks. In a retrospective study by van Rijswijk et al., shows that the reduction of ulcer surface by 40% or more during the first 4 weeks is a positive predictor for healing. It's accepted that a 50% decrease in size after 6 weeks is a sensitive predictor (93% sensitivity) to complete healing at 12 weeks. As the consecutive measurements are compiled in the application and available as a graphic, the mobile solution gives the care provider some critical information about wound healing evolution and prognosis.”

*Baseline wound area – current wound area /baseline wound area = % change over time*
Wound Determinant Protocol

Few clinical enterprises subscribe to a universal protocol based on specific wound determinants. While a single entity considers several key criteria to be instrumental in defining a formulary choice, others may require different solutions. CarePICS® affords a clinical end user a configurable protocol defined by wound determinant categories and available therapies. The wound determinants categories (wound state, wound type, tissue type, drainage and drainage type, pain, odor, ABI, etc.) contribute to building a custom clinical profile specific to any entity. Clinical support personnel highly trained in wound assessment and etiology construct this profile via the user-friendly web services application. After database implementation, the wound determinants within the chart section of the mobile application can prompt lesser-trained clinicians with the proper formulary choices for advanced wound care products or therapy choices.

Formulary Management

Formularies aggregate from primary and secondary therapy categories (wound dressings, debridement, bioengineered tissue, vascular intervention or surgery, NPT, HBOT, etc.), which determine the type of advanced therapy. However, not all clinical enterprises agree on what specific categories are necessary for a certain formulary. CarePICS® formulary choices are configurable for each custom clinical enterprise.

In the graphic above, Enterprise A hosts n custom chart fields and each of these custom chart fields have n number of selectable options. When creating the formulary, Enterprise A can combine some or all of the selectable options to create a logical tree of resulting CareProducts. Resultant CareProducts display universally by the database and remain a static list of selectable treatment options to the users.

The logic tree interfaces with the trend algorithm to determine over time the efficacy of chosen protocol and formulary configuration. Additionally, the trending algorithm alerts users to regressive or stalled wound healing cycles for further clinical overview. This approach allows earlier intervention in treating specific patients with alternative regimens. The analysis of wound care products’ comparative efficacy produces cost savings and better population management. Specific reports are available to profile the value of product selections within the formulary.

Decision models are reliable and effective decision-making techniques that provide high classification accuracy with a simple presentation of gathered knowledge. These structures drive countless different areas of medical decision making. CarePICS® is the first company to utilize an exceptionally accurate algorithmic-based imagery measurement tool coupled with logic-based analytics to provide optimized clinical and economic outcomes. This is truly a disruptive technology offering that lends itself to real time clinical study of the efficacy of the therapy.
Clinical suspicion of critical limb ischemia: Rest pain, tissue loss, or gangrene

- Prompt vascular specialist consult
- Measure ankle-brachial index (ABI) with or without pulse volume recording

Normal ABI

- Tissue loss/gangrene?
  - Y: Search for alternate cause of rest pain
  - N: Continue proper wound care

- Determine toe systolic pressure, toe pressure waveform, toe brachial index, skin perfusion pressure, transcutaneous oxygen saturation
  - Normal
  - Abnormal
    - Are wounds healing?
      - Y: Revascularization if patient is a candidate
      - N: Surveillance
    - Does rest pain persist?
      - Y: Revascularize inflow disease
      - N: Does tissue loss/gangrene persist?
        - Y: Consider invasive angiography or noninvasive imaging
        - N: Tissue loss/gangrene possible: Stiff vessels that are noncompressible
          - Y: Tissue loss/gangrene
          - N: Revascularize inflow disease

Abnormal ABI

- ABI not possible: Stiff vessels that are noncompressible

Nonhealing ulcer

Narrowed arteries

Gangrene