“Health Hazards and Health System Integration (HSI) Considerations for Joint Capabilities Integration and Development System (JCIDS) Process”
Barbara A. Smith
Occupational Medicine Program Manager
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1. Who has heard of HSI and HHA Program?
2. Does everyone know what capability documents are - ICD / CDD / CPD?
3. How familiar are you with the acquisition life cycle?
Mr. Kevin Purcell is an Ergonomist with the US Army Public Health Center. He holds a Masters degree in Human Factors and Ergonomics from San Jose State University, completing his thesis work at NASA Ames Research Center on human-machine interfaces. He is also currently a member of ASTM's standards committee F48.02 Committee on Exoskeletons and Exosuits, as well as F48.02 Technical Subcommittee on Exoskeleton Human Factors and Ergonomics.
What I will cover in this talk:

- Define exoskeletons
- Some background on current exosystems
- Introduce 3 domains for exoskeleton use.
- Exoskeleton in Occupational Health – real and potential
• All the definitions I gave are true, and all at the same time. None is wrong (except for the Iron Man suit)

• Photo: Getty image, Licensed to Army Public Health Center
57224304-612x612 Humans becoming more technologically advanced
Let me give you some background on exoskeletons first, why they exist and where they come from, and you’ll see why I subtitled this talk “blurred lines.”
• This definition of Orthosis might as well be describing anything from a Dr. Scholl’s footpad to an exoskeleton.

• For centuries, people have been faced with the challenge of caring for the injured, maimed, and those with musculoskeletal and neuromuscular injuries and/or missing limbs (Georgia Tech, 2018). Yet only within the past 100 years has scientific research into human locomotion, biomechanics, and the development of new materials been applied towards creating improved solutions like:
  • Prosthetics, used for persons who are missing limbs
  • Orthosis, used to assist persons with a limb pathology
  • and now exoskeletons, used on both those suffering an injury and an able-bodied person, to increase safety, reduce fatigue, and augment their performance.

• This last point, on Human Performance enhancement, is where a lot of the problem comes from. The pursuit of solutions to bodily injury and enhanced healing has long paralleled the desire to augment or increase the healthy body’s strength and endurance. (Herr, 2009, p.1). This has blurred the lines between traditional medical prosthetics, medical orthosis, and bionic exoskeletons.

Top photo: www.dividshub.net,, Photo by Airman 1st Class Anania Tekurio, Cleared for
Public Release
Middle Photo: www.dividshub.net, Video by Airman 1st Class Ryan Mancuso, Cleared for Public Release
Bottom Photo: www.dividshub.net, Photo by Staff Sargent Michael Ellis, Cleared for Public Release
• Exoskeletons to enhance human performance is not a new idea: Nicholas Yagn of St. Petersburg, Russia, patented earliest known exoskeleton in 1890 for a device he called an “Apparatus for facilitating walking” (Yagn, 1890) (Figure 1). This was designed to be used by the Russian Army, as evidenced by the drawing of the guy with a goatee.

• One of the biggest differences between orthotics and exoskeletons is that exoskeletons use a power source to compliment the human’s power source. The design on the left utilized a giant bow spring as an energy source to facilitate leg movement: Passive designs use the tensile and/or elastic strength of the material that it’s made of. All modern exoskeletons have to have an external power source to operate in conjunction with the human body’s power.
• The earliest engine powered, or active, exoskeleton was in 1919 (Kelley, 1919). Called the Pedomotor, this design also was to facilitate walking and running. As an external power source, this device utilized a small steam engine worn on the user’s back.

• Note the cables/lines running in parallel with major muscle groups of the upper and lower leg. These cables contract and expand using the power from the motor. This same basic concept is being used in active exoskeletons today.

Figures: U.S. Patent Office
• Although neither device was actually completed, an unpowered design similar to yagn’s was improved and built by the MIT biomechanics group in 2006.
  • The improvements focused on reducing the metabolic power needed by the user, succeeding by an average of 24% in performing the task of hopping (the biomechanics of hopping are similar to running). (Herr, 2009, p.3).

• The major goal of an exoskeleton is to reduce the human operator’s metabolic cost in performing their task.

• Left figure: U.S. Patent office
• Photo on right: MIT biomechanics group, 2006, used with permission
• Just like the historical examples I just gave, we still divide exoskeletons by Passive or Active systems, but also in a number of other ways.

• Passive systems are less expensive, and can therefore be fielded in larger numbers. Active systems are more expensive, but stronger.

• Active systems, while more expensive, can do heavier work. The example on the right can lift 200 lbs.
  • Note: I am showing this image for 2 reasons – 1) this image is THE state-of-the-art in active exoskeletons, and 2) this shows how quickly things in this field are changing. I downloaded an image of this exoskeleton off the internet, asked the company for permission to use it, and was told it was out of date. They gave me access to their latest photos of their latest design.

• This points out a key point of exoskeletons: their designs are very sensitive to the environmental context in which they are being used, much like Assistive Technology for the physically or mentally challenged.

• Photo on left: Kinetic Edge, used with permission
• Photo on Right: Sarcos Corp., used with permission
• [(Skip talking too much about these – you go over the upper-body design in a couple of slides.)]


• Photo on Right: Several key organizations recently came together to advance exoskeleton technology for the Soldier during an intensive three-day Operations and Maneuver and Technology Interchange meeting. Soldier feedback played a key role in the event. (Photo Credit: U.S. Army)
• Exoskeletons use a ridged frame

• Exosuits are what I think are the answer/wave of the future – soft and can fit underneath clothing. Again, notice the cables basically paralleling the legs muscle groups.

• Photos from left:
  • Sarcos Corp., used with permission
  • Levitate Technologies, Inc., used with permission
  • nbcnews.com, used with permission
  • Harvard Biodesign Lab., used with permission
Why do we have exoskeletons at all? Can’t we just make a Robot do what’s needed?

- Robots work only in a very controlled environments. A good example is a car factory.

- Cobots use the creativity and adaptability of the human.

- Photo: Getty Image, Licensed to Army Public Health Center.
  #1147811550 - heavy automation robot arm machine in smart factory industrial
Exoskeleton designs are very context-sensitive. Those of you familiar with Assistive Technologies for use by the disabled for returning to work might also be familiar with the Human Activity Assistive Model (HAAT) model, which is a method for assessing a patient’s workspace which accounts for the use environment.

Some exoskeleton designs overlap domains, some don’t. If the design can’t be sold to users in multiple domains it increases cost.

Let’s look at some exoskeletons for different domains.

Domains using Exoskeletons:

- Industrial
- Military
- Medical / Rehabilitation
• These are examples of industrial exoskeletons.
• The photo on the top right is an upper-body exoskeleton that you saw a couple of slides ago. It is worn like a backpack and you put your arms into the cups or straps, and is powered by springs and pulleys. Notice the added load experienced by the arms, shoulders and back is being transferred down towards the hips just like a rucksack.
  • This device reduces the workers metabolic cost by about 17%.
  Whereas this might not be a huge amount, it is enough to reduce his fatigue during his workday, reduce his injury risk, and keep his cognitive abilities sharp enough throughout the day to lower his accident risk.
• The photo on the bottom is a worker using a tool-holding exoskeleton – in this case a sander or a grinder. While her exoskeleton is similar, notice hers is designed to transfer the additional load from holding up the tool from her arms, back and shoulders via a belt on her hips and into the ground by way of part of the exoskeleton paralleling her leg. The reduction to her metabolic cost is similar.

Photo Upper left: Fortis, Inc., used with permission
Photo Upper Right Levitate Technologies, Inc., used with permission
Photo bottom: www.dividshub.net, U.S. Air Force Staff Sgt. Christian Watson, an aircraft electrical environmental technician with the 461st Air Control Wing, demonstrates the use of an exoskeleton vest for maintenance on an E-8C Joint STARS at Robins Air Force Base, Ga., Feb. 26, 2019. ,

Cleared for Public Release
• The photo in the top-center is the same concept of a tool-holding exoskeleton, just here the exoskeleton is a different design being used in a different, military task environment.

• The photo on the left is of Lockheed’s Human Universal Load Carrier, or HULC. The HULC was a promising but ultimately unsuccessful design that Lockheed has since upgraded to a more successful one on the right.

  • The HULC was to increase the distance a warfighter could carry a larger load without becoming as fatigued. It removed load from the user’s back, shoulders and legs and putting it into the ground (notice the straps around his boots). At this single task the HULC accomplished it’s goal - for a short time. It couldn’t generate enough power for it’s load carrying goal. As it was battery powered the designers would put on bigger batteries, but that increased the weight the soldier had to carry, so they would put on bigger batteries again, which would increase the weight again, and so on in an endless cycle.

  • The photo on the right is the heir to the HULC, called the ONYX. It is only a lower-body exoskeleton designed for decreasing soldier fatigue and improving performance, only is half the size and weight of the HULC. It is currently being field tested.
Rehabilitation exoskeletons are used for patients recovering from neuromuscular injuries or disease, such as stroke or Traumatic Brain Injuries, and are usually active, lower-body systems.

This photo is of the Lokomat Lower Body Rehabilitation exoskeleton. The FDA classifies this as a “isokinetic testing and evaluation system”, which the patient in a sling using and exoskeleton to move their legs on a treadmill and a clinician standing by to assist.

The FDA describes an exoskeleton used for these patients as a “motorized orthotic”. This description is probably the most accurate description of an exoskeleton out there. These devices get patients up and walking....
## Domain: Medical / Rehabilitation

### Physiological impact on:
- Body composition
- Bone density
- Bowel function
- Cardiovascular fitness
- Metabolic demand
- Pain
- Spasticity
- Fewer urinary tract infections
- Quality of Life

### Psychological impacts:
- Level of assistance/ independence
- Neurologic improvement
- Perceived exertion

### Commercially Available Active Exoskeletons:
FDA Premarket Notification (510(k)) Submissions (i.e., cleared for marketing):


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- ... leading to these advantages for the patient. Hopefully the next step for a patient in the recovery process is to use a mobile exoskeleton. In case they need assistance, they are usually accompanied with a clinician, friend, or the owner’s dog.

- As of this moment, the FDA has certified at least 9 models.

- Currently requires an assistant: “in the way”

Photo: www.dividshub.net, MARSOC Marine Retires, Receives Bronze Star Medal, Story by Cpl. Ricardo Hurtado, Cleared for Public Release
Dr. Zelik asked people from the medical field what were the difficulties regarding the potential adoption of exoskeletons in the medical domain. Here is a partial list that he came up with. Most of these factors are problematic for exoskeleton use across ALL industries and domains.

• One I want to point out is the last one listed here, they are too costly. Currently an exoskeleton designed for home use by a patient similar to the one in this photo costs between $40,000 and $85,000. These prices are coming down all the time, and just like the computer industry, once companies can apply the economies of scale, home use medical exoskeletons will become cheaper.

Photo: www.dividshub.net, VA’s Exoskeletal Program Changing Lives, Photo by Staff
These are some of the more pertinent questions about exoskeletons regarding **occupational health use of exoskeletons** that I’ll try and answer for you before you all get a chance to ask them.
Are exoskeletons PPE or Tools?
Are exoskeletons PPE or Tools?

YES.

PPE is defined as “…any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.”

Tool defined as “a device or implement, especially one held in the hand, used to carry out a particular function.”

- An exoskeleton protects one against musculoskeletal injuries.

- Also increases human performance and is used to carry out a particular function or task. The word particular causes difficulties/arguments/nightmares, as I’ll demonstrate in a couple of slides.
Can I use an exoskeleton in a ‘return to work’ scenario?
Can I use an exoskeleton in a ‘return to work’ scenario?

Potentially, yes (for example, an Assistive Technology).

BUT...
What are the legal ramifications?
What are the legal ramifications?

Currently Unknown.

• No one’s quite sure, but there’s a heck of an argument (I mean discussion) going on!

• Similar to the question/argument of “Is an exoskeleton PPE or a tool?” no one’s quite sure of all the ramifications there are to an exoskeleton.

• The next question is one of the major things they’re arguing about.
Is an exoskeleton a medical device?
This is the definition by the FDA of a medical device. As I mentioned previously exoskeletons can be very sensitive to the environmental context in which you are using them. There is a list of approved lower body exoskeletons for home use by paraplegics, and those are used to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals.

So those are medical devices.

But, a similar type of lower-body exoskeleton can be used to assist a soldier carrying out their mission. Both of these exoskeletons increase the user’s performance, both meet the definition of a medical device but the context in which it is being used is non-medical. So what is it?

Photo left: www.dividshub.net, SUPPORTING THE SOLDIER, LITERALLY, Courtesy Photo U.S. Army Acquisition Support Center, Cleared for Public
Release, U.S. Army

- Photo right: www.dividshub.net, VA’s Exoskeletal Program Changing Lives, 
  Photo by Staff Sgt. David Overson, Cleared for Public Release
Nurses are injuring themselves, having to move patients who can weight twice as much as they do.

a. Stop it.
b. Shows how dedicated you are.
c. You’d think exoskeletons would be perfect for this.
My colleague Dr. Zelik did an informal assessment, asking nurses if they would use an exoskeleton to lift patients. They all said they are currently reluctant to use an exoskeleton to lift a patient as they are “too conspicuous.” As you can see from the photo, exoskeletons used for lifting currently make you look like a Transformer. If I were a patient and a nurse tried to lift me wearing one of those I would be hesitant. Currently developers across the world are trying to design “wearable” exoskeletons that a person can wear underneath clothing, which would help with over-conspicuousness.

Chart: BLS - # of nonfatal Injuries & illnesses involving musculoskeletal disorders with days away from work

Photo: Sarcos, Inc., used with permission
Can everyone physically use an exoskeleton?

SEEMS like a simple, easy to answer question…

Photo: Kinetic Edge, used with permission
• Doing an assessment of a passive exoskeleton, Dr. Zelik used 6 sEMG sensors recording back muscle activations for the left and right LLT, LIL, and LLM.

• Found Inter-subject and inter muscle variability. Different people use different back muscles to lift and object when using an exoskeleton.

• IF, you are brave enough to use an exoskeleton at work, right now the only way to tell if it is going to be of use to you as far as alleviating back pain is for you to try it an see it does any good.

Photo and figures from:
Dr. Karl Zelik
Vanderbilt Center for Rehabilitation Engineering and Assistive Technology
- used with permission
Is there a learning curve to being productive using an exoskeleton?
Is there is a learning curve to being productive using an exoskeleton?

YES.

“...automation (and semi-automation) does not merely supplant, but changes human activity and can impose new coordination demands on the human operator.”

Your body needs to re-learn how to move even with the most “intuitive” exoskeleton.

Even the most basic passive exoskeleton can be labeled as a semi-automated system.

Ergonomic/human factor measurements, such as usability, workload, situational awareness and trust in automation all change as one becomes re-familiarized with their job when learning an exoskeleton.
You would think that after giving you the background I did and discussing some of the problematic current realities of exoskeletons I might be a little pessimistic on their use in occupational health. Just the opposite, I’m an optimist. This photo illustrates why: this is Dr. Hugh Herr, head of the MIT Biomechanics Group. If you want to find out more about him, his biography is on the web and he has a fantastic TED talk on YouTube. Dr. Herr is a double amputee, having lost both of his legs below the knee in a mountain climbing accident. What I want to mention here are the intelligent prosthetic legs he developed for himself. Because they are controlled by microprocessors they can automatically adjust his gait, something that a lot of earlier exoskeleton designs have lacked in the past.

Some of the technology he and others have developed has trickled down into some of those rehab exoskeletons that are listed by the FDA as available for use by patients.

This is NOT the future. It is our PRESENT.
1. Described and defined exoskeletons, which are blurred with Orthoses and Prosthetics due to technological advancement.

2. Exoskeletons are designed to increase the strength/endurance of the user by adding an external power source to major muscle groups to lower metabolic costs.

3. Introduced the 3 major domains for exoskeleton use: industrial, military, and medical/rehabilitation including some specific patient & clinical applications.

4. Given you some of the latest if fuzzy, News regarding Occupational Health and Exoskeletons.
Photo: Bryce Vickmark, used with permission
As far as exoskeletons in regards to occupational health:

1. Things are moving fast in this industry; technology that is 6 months old is in danger of becoming obsolete.

2. The legal and insurance ramifications are holding up the ability to use exoskeletons as a ‘return to work’ assistive device.

3. Not every body type will be able to take advantage of an exoskeleton.

4. There is a learning curve to becoming productive using an exoskeleton.

5. Safe patient handling is a possibility using an exoskeleton, but doing so might upset patients (right now).
Photo: Bryce Vickmark, used with permission
Thank You!

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https://phc.amedd.army.mil/topics/workplacehealth/ergo/Pages/default.aspx

Photo: Bryce Vickmark, used with permission