Reducing Risk of Infection with Disposable EEG Electrodes

Making a case for single-patient disposable electrodes
for polysomnography and electroencephalography

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Abstract:

Recent studies and reports continue to shed light on the topic of Reusable EEG Electrodes and justification to transition to single patient Disposable EEG Electrodes. EEG application typically includes preparation of the skin by use of a cotton tip applicator with an agent to prep or abrade the skin to assist with higher quality recordings. By performing this "prepping" action, the surface electrode becomes a **semi-critical item** which mandates a specific process for cleaning and disinfecting the reusable electrode after each use. The definition of a semi-critical item is part of the **Spaulding classification** system, which is used by the CDC and was developed by Earle Spaulding in 1968. Spaulding's classification categorizes medical devices into three categories which can assist the clinician in determining which devices should be cleaned, disinfected and or sterilized prior to use in patient care. The three category classifications are (1) critical (2) semi-critical and (3) non-critical. The Spaulding system encompasses all types of supplies and equipment. Recent reports show electrodes identified as disinfected to the standards of intermittent to high level disinfecting have tested positively for bacterial cultures and thus continues to raise the question of why all electrodes are not single patient disposable. In addition, BeckerHospitalReview.com reports "The hospital reduces the risk of infections associated with medical equipment, devices and supplies" — is cited as "not complaint" 72 percent of the time in 2017.

Supplemental data at www.rhythmlink.com

Keywords: abrade, abrasion, abrasive agent, semi-critical item, non-critical item, critical item, electroencephalograph, polysomnography, long term epilepsy monitoring, single patient disposable electrode, reusable electrode, Healthcare Acquired Infection

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Glossary

Hospital-acquired infection = an infection which is a result of treatment in a hospital or healthcare service unit, but secondary to the patient's original condition
Abrade; abrasion = to scrape or rub off; wear away by scraping or rubbing
Semi-critical item = an item which has contact with mucous membranes or nonintact skin
Non-critical item = an item which has contact with intact skin
Critical item = an item which enters or penetrates sterile tissue, cavity or bloodstream
Spaulding classification = a classification system used by the Center for Disease Control (CDC) which divides instruments and items for patient care into three categories: critical, semi-critical or non-critical items.

Introduction: The use of electroencephalographic (EEG) electrodes has been an acceptable standard for over 50 years. Until recent years, medical specialties that utilized such electrodes had no alternative to the reusable products. The utilization of reusable supplies within healthcare facilities has been transformed with the introduction of disposable products and aggressive technological advances that have produced disposables which outperform their reusable predecessors. In addition to the technological trends, price of disposables has lowered significantly in the past decade. But price point alone has not been enough to bring the disposable transition to the forefront. Reports regarding risk of cross contamination/hospital acquired infection rates are contributing to greater focus on the transfer to disposable technology and its benefits.

Typical Materials and Procedures to Collect EEG: To collect EEG data electrodes must be connected to the patient. Nearly all facilities and services apply surface EEG electrodes in a similar way and the widely accepted application technique incorporates the use of a cotton tip applicator (such as a Q-Tip®) and commercially available abrasive products (such as NuPrep™) to **lightly abrade** or "prep" the patient skin to achieve optimal impedance readings. Proper impedance is critical to achieve acceptable data quality for diagnostic interpretation. The quality of contact between patient's skin and electrode directly affects the recording system's ability to distinguish patient data from environmental artifact. Using a mild abrasive agent on the patient's skin (i.e. prepping the skin) in the location where the electrode will be placed significantly increases the recording systems ability to produce acceptable data enhancing the patient's diagnostic and prognostic process. By performing this "prepping" action, the surface electrode, becomes a **semi-critical item** which mandates a specific process for cleaning and disinfecting the reusable electrode after each use. The definition of a semi-critical item is part of the **Spaulding classification** system, which is used by the CDC and was developed by Earle Spaulding in 1968. Spaulding's classification categorizes medical devices into three categories which can assist the clinician in determining which devices should be cleaned, disinfected and or sterilized prior to use in patient care. The three category classifications are (1) critical (2) semi-critical and (3) non-critical. The Spaulding system encompasses all types of supplies and equipment. Below is an example of the type of products and equipment that fall into these categories: According to Am. J. END Technology 40:73-97,2000 ASET, Iowa

Fig 1: Spaulding Classification table

Category	Level Required	Example of items
Critical	Requires sterilization before/after each use	Subdermal Needle Electrodes, EMG Needles, Sphenoidal Electrodes, Indwelling Electrodes….
Semi-critical	Requires intermediate to high level disinfecting after each use	**Surface Electrodes used with abrasive skin prep/agent or blunt tip syringe**, ERG Electrodes, Nasopharyngeal, Nasal/Oral Thermocouples, cPAP,/BiPAP masks and tubing, any electrode exposed to nonintact skin, blood, or body fluids…
Non-critical	Requires cleaning and/or low level of disinfecting after each use	Tape measures, calipers, oximeter probe, marking pencils, etc….

Contamination of Reusable EEG Electrodes, A Multicenter Study

Excerpt of a full article

The team collected 124 swabs from the electrodes which yielded some fascinating results. Sixty percent of the swabs had epithelial cells and 25% (31 swab samples) were found to have positive bacterial cultures. Eight different bacteria were identified, which were categorized by risk for health care-associated infection (no risk, potential risk, and at risk)…….

……Even more fascinating was that of the 18 antibiotics tested on these positive bacteria cultures, resistant bacteria were found in a median of 1, which is 6.7% in terms of a resistant antibiotic rate. Thankfully, none of the identified bacteria were resistant to all the antibiotics tested against them in the analysis.

…..Overall, although 25% of these reusable electroencephalography cup-electrodes and lead wires were found to have bacteria, only 22.5% were bacteria that were potential or at risk for infection. Unfortunately, this study sheds light on the grim reality of microbial burden in reusable electroencephalography cup-electrodes and lead wires. The investigators focused on those tools that had been cleaned and were ready for patient use, which gives insight into what so many of us already suspected: cleaning of reusable medical equipment is often subpar and contamination is prevalent.

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5 Joint Commission hospital requirements most commonly cited as "not compliant" in 2017

https://www.beckershospitalreview.com/quality/5-joint-commission-hospital-requirements-most-commonly-cited-as-not-compliant-in-2017.html

Here are the top five requirements identified as "not compliant" for hospital accreditation surveys.

Note: The figures represent non-compliance percentage for each standard.

1. The hospital provides and maintains systems for extinguishing fires — 86 percent
2. The hospital manages risks associated with its utility systems — 73 percent
3. The hospital provides and maintains building features to protect individuals from the hazards of fire and smoke — 72 percent
4. **The hospital reduces the risk of infections associated with medical equipment, devices and supplies — 72 percent**
5. The hospital established and maintains a safe, functional environment — 70 percent

CT and MRI Association with Skin Health and Disposables EEG Electrodes: In addition to the data presented above, skin health is also a consideration when using Reusable EEG Electrodes due to the fact no FDA Cleared MR Conditional Reusable EEG Electrodes exist in the market. This means every patient who requires an MRI scan need their Reusable EEG Electrodes removed and then reapplied post the imaging which equals more "prepping" of the skin and the risk of skin breakdown or injury. The removal and reapplication process would be required for every MRI required during a patient stay. FDA Cleared MR Conditional Disposable EEG Electrodes are on the market for used in 1.5T and 3T MRI scanners. With use of an FDA Cleared Disposable EEG Electrode the electrode can remain applied for the imaging session and no removal and reapplication is required.

Price of product and overall budgetary investment: The cost is not simply the price of the product but instead the overall investment. Use the template below to research the overall costs for your department/service. Just like any analysis you will need to gather pieces of information that will help you begin the investigational process.

Fig 2: Cost analysis example:

Investment overview
Project name: Reusable EEG Electrodes vs. Single-Patient Disposable Electrodes Cost Analysis
Generated by: Rhythmlink International, LLC ; Leah Hanson R.EEG/EPT Director of Sales
Date: 9/23/14
General description of benefits: To investigate the cost benefit of transitioning to single patient disposable EEG Electrodes from Rhythmlink versus reusable EEG electrodes. This does not take into account the additional cost associated benefit of eliminating any/all cross contamination risk.

Costs and overview of the services		
Number of EEGs each year		3000
# of electrodes per EEG/test		26
Total # of electrodes used (3000 x 26)		78,000
# of patients being tested at one time(this is to show how many electrodes are in use at one time)		10
How many electrodes being used at one time (10 x 26)		260
Cost for a pouch of reusables (10 / pouch)	$	200.00
Cost per reusable electrode	$	20.00
How often to reorder reusables (estimated at ~ every 2 months which is about 5.5 times a year)		5.5 x per year
Cost estimate for each reorder of reusables? ($20 x 260= $5,200)	$	5,200.00
Annual estimate of reusable electrodes ($5,200 x 5.5)	$	28,600.00
Cost of disinfecting solution for reusables per year	$	360.00
Staff cost per test to disinfect reusables (takes 20 minutes of time so using annual salary plus benefits for 20 minutes of time)	$	7.00
Annual estimate for staff cost to disinfect reusables (3000 x $7)	$	21,000.00
Cost per pouch of single-patient disposable electrode	$	6.00
Cost per single-patient disposable electrode	$	0.60

Initial investment	Reusables	Disposables
Cost estimate to repurchase electrodes each year	$28,600.00	$46,800.00
Unopened electrodes on the shelves waiting to be used if needed (estimates 30 electrodes)	$600.00	$18.00
Disinfecting Solution Cost annually	$360.00	$0.00
Staff cost in time to disinfect electrodes	$21,000.00	$0.00
Sterilization cost of reusables if needed - unknown	$0.00	$0.00
Other costs	$0.00	$0.00
Total estimated costs	*$50,560*	*$46,818*

Summary: Data continues to build supporting the transition away from use of Reusable EEG Electrodes due to the risk of contamination between patients despite attempts to satisfy the requirements of a Semi-Critical Item, the risk of skin integrity due to removal and reapplication of Reusable EEG Electrodes when imaging is required, and the overall budgetary cost savings.

EXPANDED GLOSSARY

Antimicrobial agent: any agent that kills or suppresses the growth of microorganisms.
Antiseptic: substance that prevents or arrests the growth or action of microorganisms by inhibiting their activity or by destroying them. The term is used especially for preparations applied topically to living tissue.
Asepsis: prevention of contact with microorganisms.
Autoclave: device that sterilizes instruments or other objects using steam under pressure. The length of time required for sterilization depends on temperature, vacuum, and pressure.
Bacterial count: method of estimating the number of bacteria per unit sample. The term also refers to the estimated number of bacteria per unit sample, usually expressed as number of colony-forming units.
Bactericide: agent that kills bacteria.
Contact time: time a disinfectant is in direct contact with the surface or item to be disinfected. For surface disinfection, this period is framed by the application to the surface until complete drying has occurred.
Contaminated: state of having actual or potential contact with microorganisms. As used in health care, the term generally refers to the presence of microorganisms that could produce disease or infection
Cleaning: removal, usually with detergent and water or enzyme cleaner and water, of adherent visible soil, blood, protein substances, microorganisms and other debris from the surfaces, crevices, serrations, joints, and lumens of instruments, devices, and equipment by a manual or mechanical process that prepares the items for safe handling and/or further decontamination.
Decontamination: according to OSHA, "the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal" [29 CFR 1910.1030]. In health-care facilities, the term generally refers to all pathogenic organisms.
Decontamination area: area of a health-care facility designated for collection, retention, and cleaning of soiled and/or contaminated items.
Detergent: cleaning agent that makes no antimicrobial claims on the label. They comprise a hydrophilic component and a lipohilic component and can be divided into four types: anionic, cationic, amphoteric, and non-ionic detergents.
Disinfectant: usually a chemical agent (but sometimes a physical agent) that destroys disease-causing pathogens or other harmful microorganisms but might not kill bacterial spores. It refers to substances applied to inanimate objects. EPA groups disinfectants by product label claims of "limited," "general," or "hospital" disinfection.
Disinfection: thermal or chemical destruction of pathogenic and other types of microorganisms. Disinfection is less lethal than sterilization because it destroys most recognized pathogenic microorganisms but not necessarily all microbial forms (e.g., bacterial spores).
Exposure time: period in a sterilization process during which items are exposed to the sterilant at the specified sterilization parameters. For example, in a steam sterilization process, exposure time is the period during which items are exposed to saturated steam at the specified temperature.
Flash sterilization: process designed for the steam sterilization of unwrapped patient-care items for immediate use (or placed in a specially designed, covered, rigid container to allow for rapid penetration of steam).
Fungicide: agent that destroys fungi (including yeasts) and/or fungal spores pathogenic to humans or other animals in the inanimate environment.
General disinfectant: EPA-registered disinfectant labeled for use against both gram-negative and gram-positive bacteria. Efficacy is demonstrated against both *Salmonella choleraesuis* and *Staphylococcus aureus*. Also called *broad-spectrum disinfectant*.

Germicide: agent that destroys microorganisms, especially pathogenic organisms.
High-level disinfectant: agent capable of killing bacterial spores when used in sufficient concentration under suitable conditions. It therefore is expected to kill all other microorganisms.
Hospital disinfectant: disinfectant registered for use in hospitals, clinics, dental offices, and any other medical-related facility. Efficacy is demonstrated against *Salmonella choleraesuis*, *Staphylococcus aureus*, and *Pseudomonas aeruginosa.* EPA has registered approximately 1,200 hospital disinfectants
Intermediate-level disinfectant: agent that destroys all vegetative bacteria, including tubercle bacilli, lipid and some nonlipid viruses, and fungi, but not bacterial spores.
Low-level disinfectant: agent that destroys all vegetative bacteria (except tubercle bacilli), lipid viruses, some nonlipid viruses, and some fungi, but not bacterial spores
One-step disinfection process: simultaneous cleaning and disinfection of a noncritical surface or item.
Pasteurization: process developed by Louis Pasteur of heating milk, wine, or other liquids to 65–77oC (or the equivalent) for approximately 30 minutes to kill or markedly reduce the number of pathogenic and spoilage organisms other than bacterial spores.
Sanitizer: agent that reduces the number of bacterial contaminants to safe levels as judged by public health requirements. Commonly used with substances applied to inanimate objects. According to the protocol for the official sanitizer test, a sanitizer is a chemical that kills 99.999% of the specific test bacteria in 30 seconds under the conditions of the test.
Steam sterilization: sterilization process that uses saturated steam under pressure for a specified exposure time and at a specified temperature, as the sterilizing agent
Sterilization: validated process used to render a product free of all forms of viable microorganisms. In a sterilization process, the presence of microorganisms on any individual item can be expressed in terms of probability. Although this probability can be reduced to a very low number, it can never be reduced to zero.

Conflict of Interest Disclaimer: Author is an employee of Rhythmlink International, LLC. Rhythmlink is a medical device manufacturer.

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