

Electromicyn®

WHO Essential Medicines List

Lance Gravatt *PhD*

Founder

Te Arai BioFarma Ltd

40 Years of the Model List
of **Essential Medicines**
1977 - 2017

Finding a Global Partner

- Oculus Innovative Sciences, Petaluma, CA
 - Launched Microdacyn at NZWCS Conference, Blenheim 2015
 - Expanded agreement to include Australia and Pacific Islands
 - Expanded agreement to include WHO:
 - Electromicyn 500 mL Solution spray bottle
 - Electromicyn 250 g Hydrogel spray bottle
 - Less expensive per mL than povidone-iodine to WHO



WHO Essential Medicines List

- WHO EML updated every 2 years since 1977
- The core list is a list of minimum medicines for a basic health-care system, listing the most efficacious, safe and cost-effective medicines for priority conditions.
- Priority conditions are selected on the basis of public health relevance, and potential for safe and cost-effective treatment.

Declaration of Human Responsibilities 1997

“all people, to the best of their knowledge and ability, have a responsibility to foster a better social order, both at home and globally.”

Finding WHO Sponsor

- **Professor Bernadetta Allegranzi**
 - Coordinator Infection Prevention and Control Global Unit, Ebola Response Team
 - Role of hand hygiene in healthcare-associated infection prevention. *J Hosp Infect.* 2009
 - Healthcare-associated-infection in Africa: A systematic review. *Bull World Health Org.* 2011
 - New WHO recommendation on intraoperative and postoperative measures for surgical site infection prevention: an evidence-based global perspective. *Lancet.* 2016

Is There a Public Need?

- September 2016 FDA issued Rule:
“Safety and Effectiveness of Consumer Antiseptics; Topical Antimicrobial Drug Products for Over-the-Counter Human Use”
 - The following products are no longer considered safe and effective:
 - Iodophors
 - Triclosan
 - Methyl benzethonium chloride

2016 International Wound Infection Institute Consensus Guidelines

Solution	Type	Cytotoxicity	Effect on Biofilm	Comments
Super-oxidised solution with hypochlorous acid (HOCl)	Antiseptic	May vary depending on concentration	Penetrates biofilm rapidly, killing formations from within. Does not promote resistant bacterial strains	Purported to provide desloughing and antimicrobial activity. Available in gel and irrigation preparations that can be used together or separately



2017 Review

- Totoraitis K et al., Topical approaches to improve surgical outcomes and wound healing: A review of efficacy and safety. *J Drugs Dermatol*. 2017.
 - *“The overuse of topical antibiotics as prophylaxis for infection has contributed to increased bacterial resistance, and in fact is no longer recommended....in clean postsurgical wounds. Topical antiseptics including chlorhexidine and povidone-iodine, can have a cytotoxic effect on keratinocytes and may actually impede wound healing as a result. Emerging products, such as hypochlorous acid, may be a potential alternative...as it has effective antimicrobial actions and minimal adverse effects.”*

Summary of Evidence

Indication	Comparator	Trials	Participants	Results
DFU	Povidone-iodine	4	363	↑ successfully healed ↓ time to healing ↓ cellulitis ↓ odour ↓ ulcer area
DFU	Saline	3	267	↑ Healing ↑ DFU score reduction ↓ hospital days ↓ Bacterial infection
Acute/chronic wounds	Povidone-iodine	4	400	↓ Wound area ↓ Pus ↓ Days infection ↓ Days hospital
Peritonitis	Saline irrigation	2	180	↓ Purulent discharge ↓ Burst abdomen ↓ Surgical site infections
Peritonitis	Povidone-iodine irrigation	1	178	↓ Infections
Burns	mupiricon chlorhexidine	1	na	↓ MRSA infection rate
VLU	n/a	1	897	100% healed ↑ Periwound tissue oxygenation
Intraperitoneal Dialysis	Povidone-iodine	1	111	↓ Infections ↓ Time to healing

Consultation Responses

- Support from a number of New Zealand submitters – *thank you*



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March 15, 2017

The Secretary
Expert Committee on the Selection and Use of Essential Medicines Innovation, Access and Use (IAU)
Department of Essential Medicines and Health Products
20 Avenue Appia
CH-1211 Geneva 27
Email: emlsecretariat@who.int

Dear Secretary,

The Southern Arizona Limb Salvage Alliance (SALSA) and our collaborators and members from more than two dozen nations support the application for hypochlorous acid solution (HOCL) to be included on both the EML and EMLc.

With antimicrobial resistance rising as fast as its frequent overutilization, inexpensive yet effective solutions such as HOCL are becoming more and more attractive. We have used this technology for decades in various forms and have never been more enthusiastic about it than we are now.

The inclusion of hypochlorous acid solutions in recent international guidelines and recommendations reflects the growing body of scientific and clinical data. We support these benefits being made available to countries utilising the EML.

Should you have any questions, do not hesitate to contact me personally.

Yours very truly,

A handwritten signature in black ink, appearing to be 'D. Armstrong', written over a horizontal line.

David G. Armstrong, DPM, MD, PhD
University Distinguished Outreach Professor of Surgery and Director,
Southern Arizona Limb Salvage Alliance (SALSA)
University of Arizona College of Medicine

WHO Independent Expert Reviews

- **Reviewer 1:**

- *“Electromicyn should be included into the WHO EML, in terms of the facts that Electromicyn is an effective and safe biocidal agent and superior over the existing biocides and some topical antimicrobial agents.”*

- **Reviewer 2:**

- *“It is recommended that the Expert Committee consider hypochlorous acid for inclusion in the Essential Medicines List.”*

- **Reviewer 3:**

- *“Unable to recommend the product under review to EML. There are already 3 (ethanol, chlorhexidine, povidone iodine) antiseptics in the EML”*

Independent Expert Committee Meeting, Geneva, March 2017

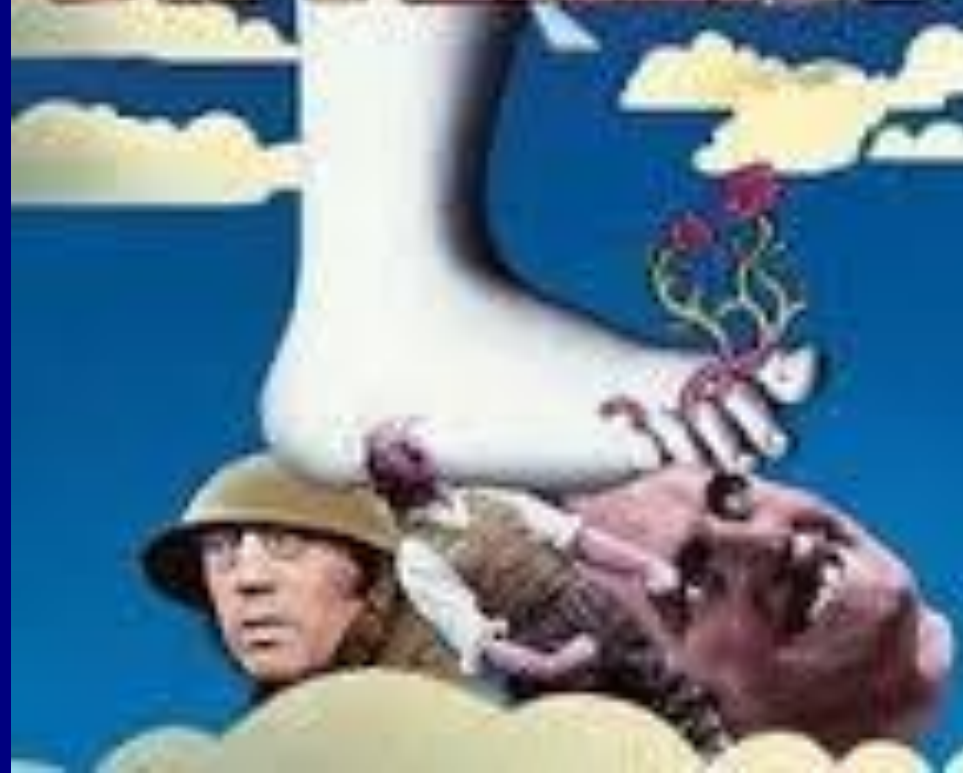
Decision following WHO General Assembly
22-31 May 2017

Whenever an individual
or a business decides
that success has been
attained, progress
stops.

Thomas J. Watson

QuotePixel.com

**MONTY PYTHON'S
AND NOW FOR
SOMETHING
COMPLETELY
DIFFERENT**



Cosmesis Consensus Clean Wounds

- Literature review and consensus statement post-procedure treatment and scar prevention
- Gold M H et al., *J Cosmet Dermatol.* 2017: 1-6.

“A postprocedure regime using this technology, aimed at preventing infection, reducing inflammation, and promoting healing is proposed to have benefits over current regimes as it appears to be effective, safe, and well tolerated.”

