The Enemy of My Enemy:
Bacteriophage Therapy to Treat Multi-drug Resistant Bacterial Infections

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Associate Dean of Global Health Sciences,
Harold Simon Distinguished Professor,
Co-director, IPATH

Robert Schooley, MD
Senior Director, International Initiatives, UC San Diego
Distinguished Professor,
Co-Director, IPATH

UC San Diego
SCHOOL OF MEDICINE

Disclosures

- Steffanie Strathdee holds stock in Adaptive Phage Therapeutics.

- All patient photos shown are used with permission.


Optima
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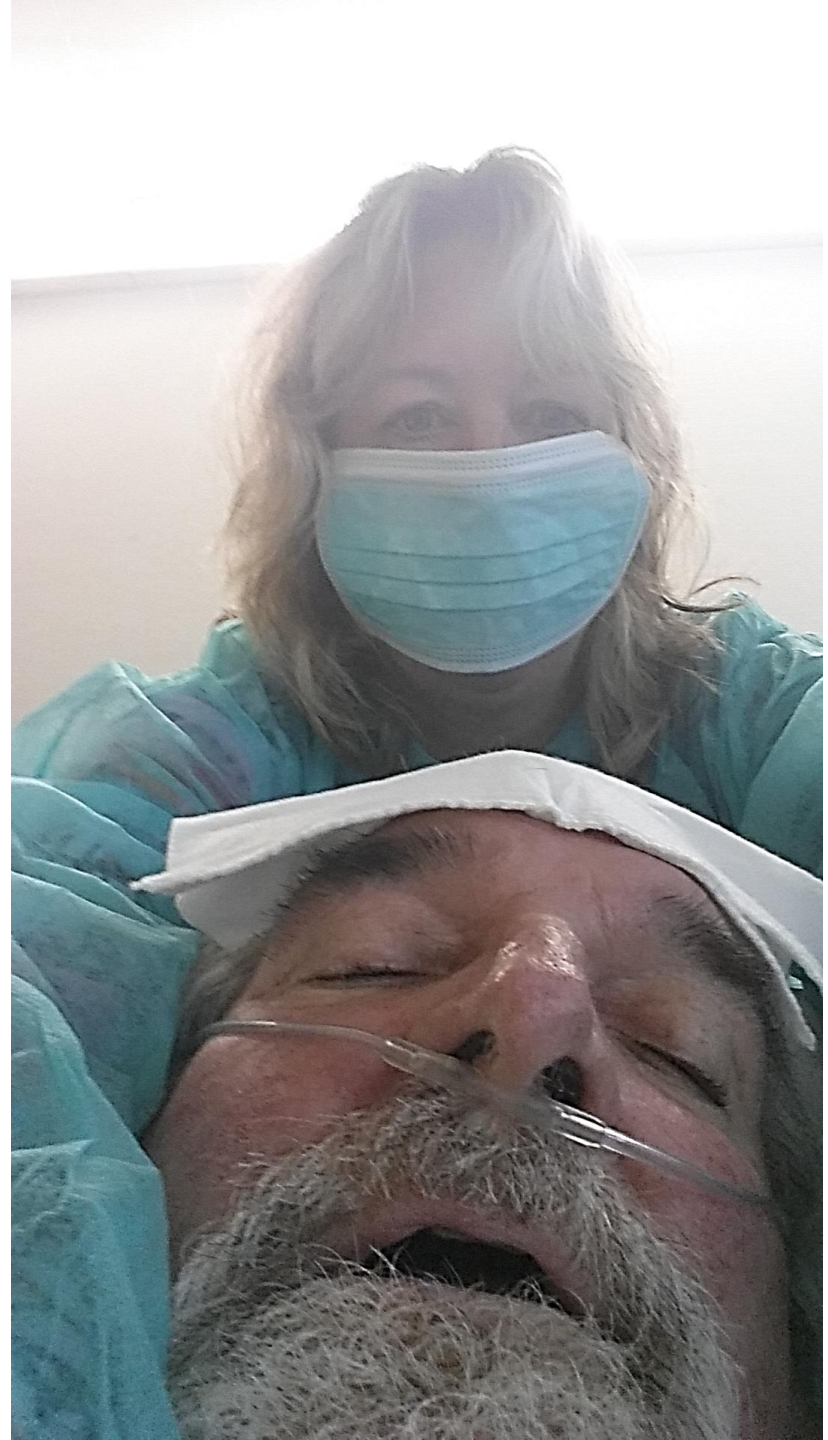



Centers for Disease Control and Prevention

Uniklinick Antibiogram

Name: **Patterson**
Vorname: **Thomas Leroy (M)**
Geb. Datum: *** 18.02.1947**

Untersuchungsmaterial: **Abszesspunktat**
Abnahmeort: **transgastrales Punktat**

Anforderung:
Mikrobiologische Untersuchung

Befund:

1: Acinetobacter baumannii (4MRGN) ***vereinzelt***
*Keine Spezies-spezifischen Grenzwerte vorhanden.

2: Candida albicans ***reichlich***

3: Candida glabrata ***reichlich***
Das Antimykogramm siehe Befund 51569953.

Bemerkung/Bewertung
Die anaeroben Kulturen werden weiterbebrütet. Nur im positiven Falle erhalten Sie einen erneuten Befund.
Telefonische Befunddurchsage erfolgte am 10.12.2015 um 10:03 Uhr
Faxmitteilung erfolgte am 10.12.2015 um 10:17 Uhr
4MRGN: Multiresistentes gramnegatives Stäbchenbakterium mit Resistenz in 4 Antibiotikagruppen (KRINKO-Definition).
Aufgrund der Meldepflicht nach Hessischer Verordnung für besondere Antibiotikaresistenz ist dieser Befund an das Amt für Gesundheit gemeldet worden.

Antibiogramm

Keim	1	*MHK*
Piperacillin	R	
Cefotaxim	R	
Ceftazidim	R	
Meropenem	R	>=32
Gentamicin	R	
Tobramycin	R	
Amikacin	R	>=256
Co-Trimoxazol	R	4
Fosfomycin i.v.	R	
Levofloxacin	R	
Ciprofloxacin	R	
Minocyclin	S	4
Rifampicin	*	8
Colistin	S	1
Ampicillin/Sulbactam	R	>=256

Erläuterung: S = sensibel, I = intermediär, R = resistent

Antimykogramm

Keim	3	*MHK*
Caspofungin	S	0.125

Erläuterung: S = sensibel, I = intermediär, R = resistent
Nummerische Angaben sind MHK in µg/ml


By 2050,
Superbugs Could Kill
10 Million
People a Year
Will cost $100 trillion to the global economy through loss of productivity
Source: Review On Antimicrobial Resistance

Credit: Scott Brundage, Scientific American

Review

Emerging therapies for multidrug resistant *Acinetobacter baumannii*

Meritxell García-Quintanilla*, Marina R. Pulido*, Rafael López-Rojas, Jerónimo Pachón, and Michael J. McConnell

Unit of Infectious Disease, Microbiology, and Preventive Medicine, Institute of Biomedicine of Sevilla (IBiS), University Hospital Virgen del Rocío/CSIC/University of Sevilla, 41013, Sevilla, Spain

The global emergence of multidrug resistant *Acinetobacter baumannii* has reduced the number of clinically available antibiotics that retain activity against this pathogen. For this reason, the development of novel prevention and treatment strategies for infections caused by *A. baumannii* is necessary. Several studies have begun to characterize nonantibiotic approaches that utilize novel mechanisms of action to achieve antibacterial activity. Recent advances in phage therapy, iron chelation therapy, antimicrobial peptides, prophylactic vaccination, photodynamic therapy, and nitric oxide (NO)-based therapies have all been shown to have activity against *A. baumannii*. However, before these approaches can be used clinically there are still limitations and remaining questions that must be addressed.

these infections. In this review, recent advances in nonantibiotic approaches that are currently being explored for prevention and treatment of *A. baumannii* infections are described.

Phage therapy

Bacteriophages, or phages, are viruses that infect, and in some cases lyse, bacterial cells. The potential use of bacteriophages as antibacterial agents was recognized at almost the same time as their discovery nearly a century ago [9]. However, the dawn of the antibiotic era slowed interest in this area in western countries. In the present context of infections caused by multidrug-resistant bacteria for which there are a decreasing number of active antimicrobials, research exploring the use of phage therapy as an alternative treatment has been renewed. In 2010

Trends in Microbiology, 2013

Early Pioneers

Charles Hankin

Frederick Twort

Felix d'Herelle

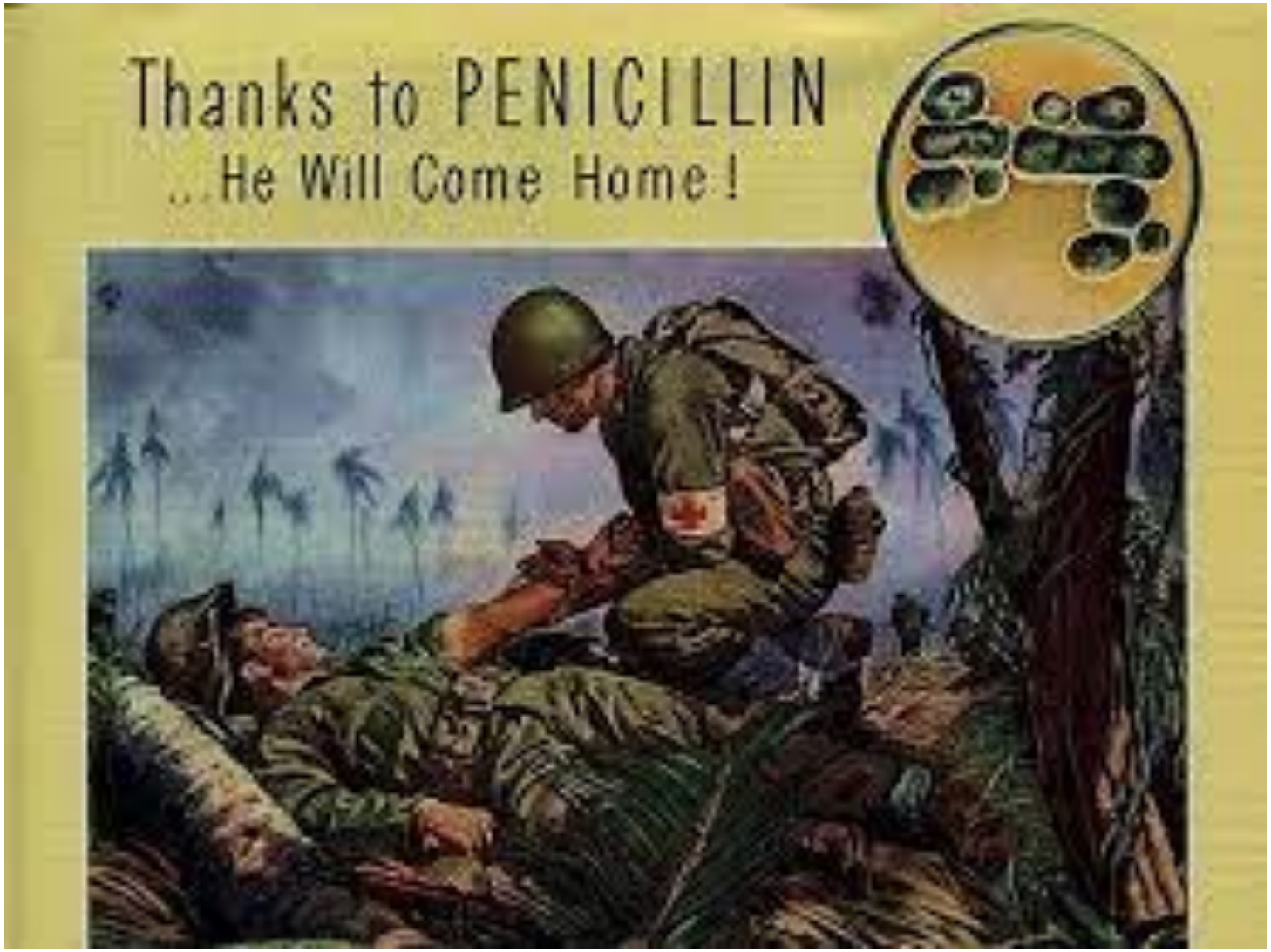
Nicolai Gamaleya

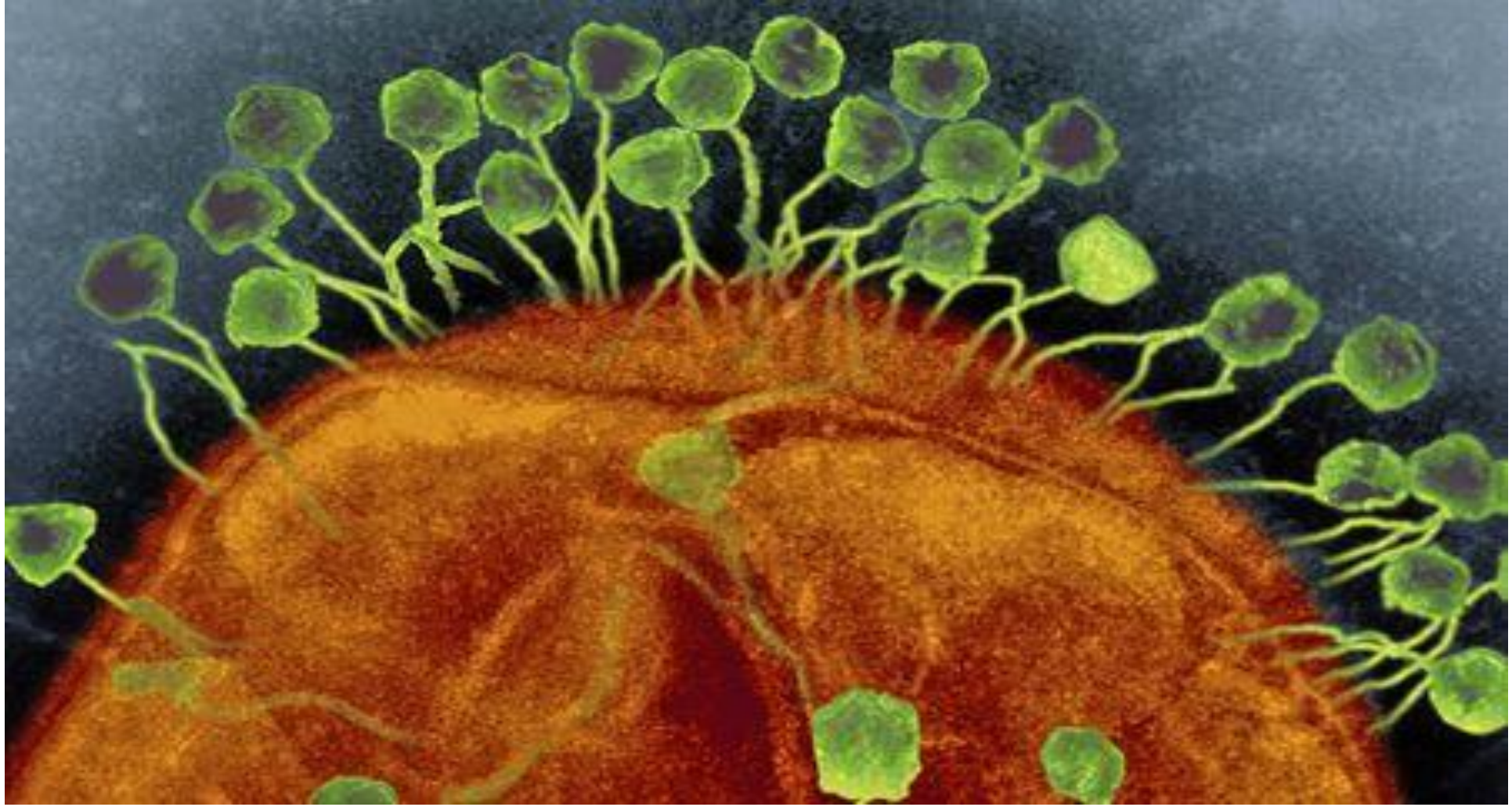
Bronislaw Fejgen

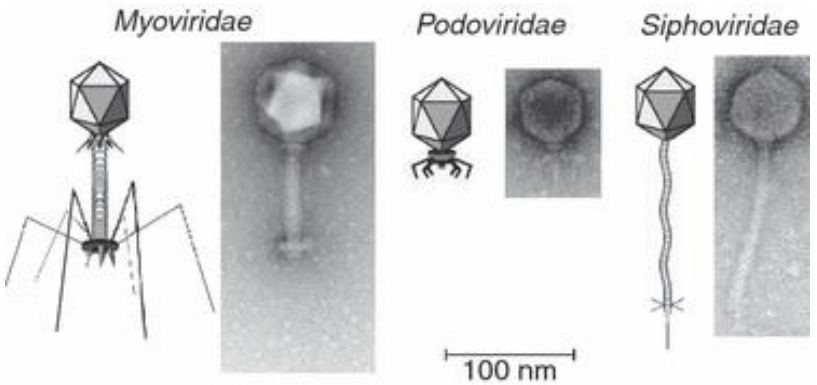
Giorgi Eliava

Phage Therapy Unit
Wrocław, Poland

Foundation ELIAVA


Thanks to PENICILLIN
...He Will Come Home!




Myoviridae
Podoviridae
Siphoviridae
100 nm

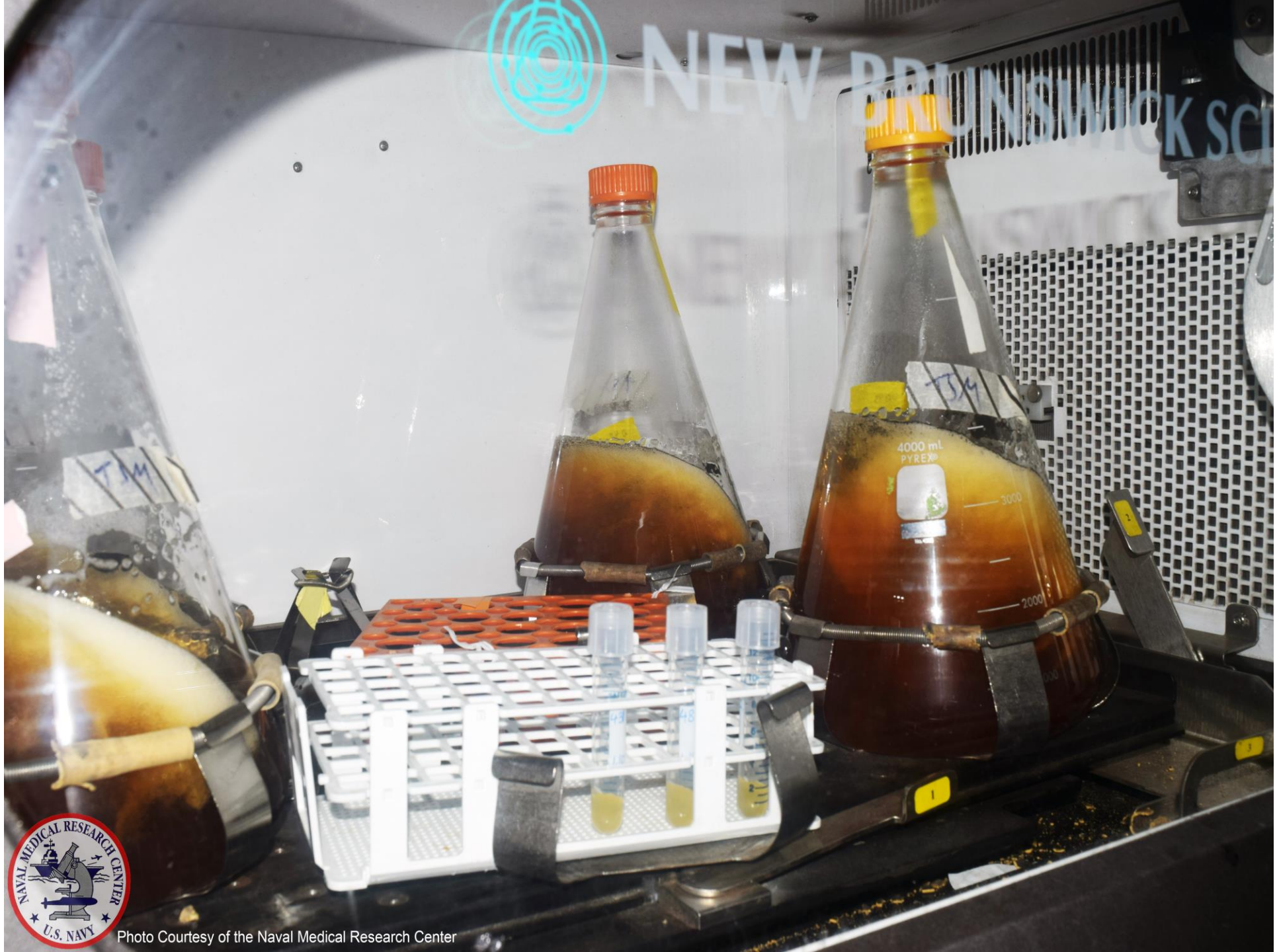
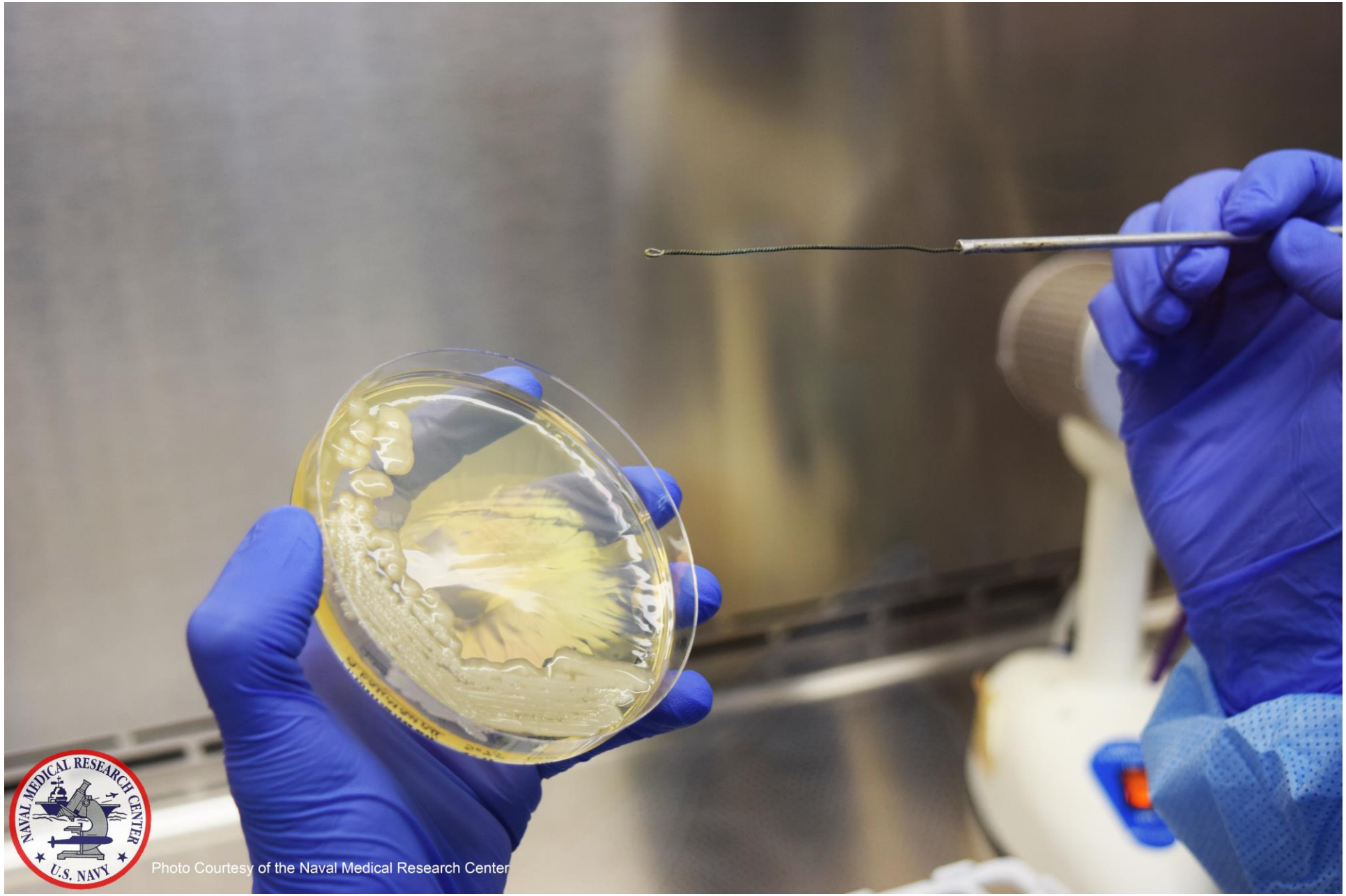


Photo Courtesy of the Naval Medical Research Center


NAVAL MEDICAL RESEARCH CENTER
U.S. NAVY
Photo Courtesy of the Naval Medical Research Center

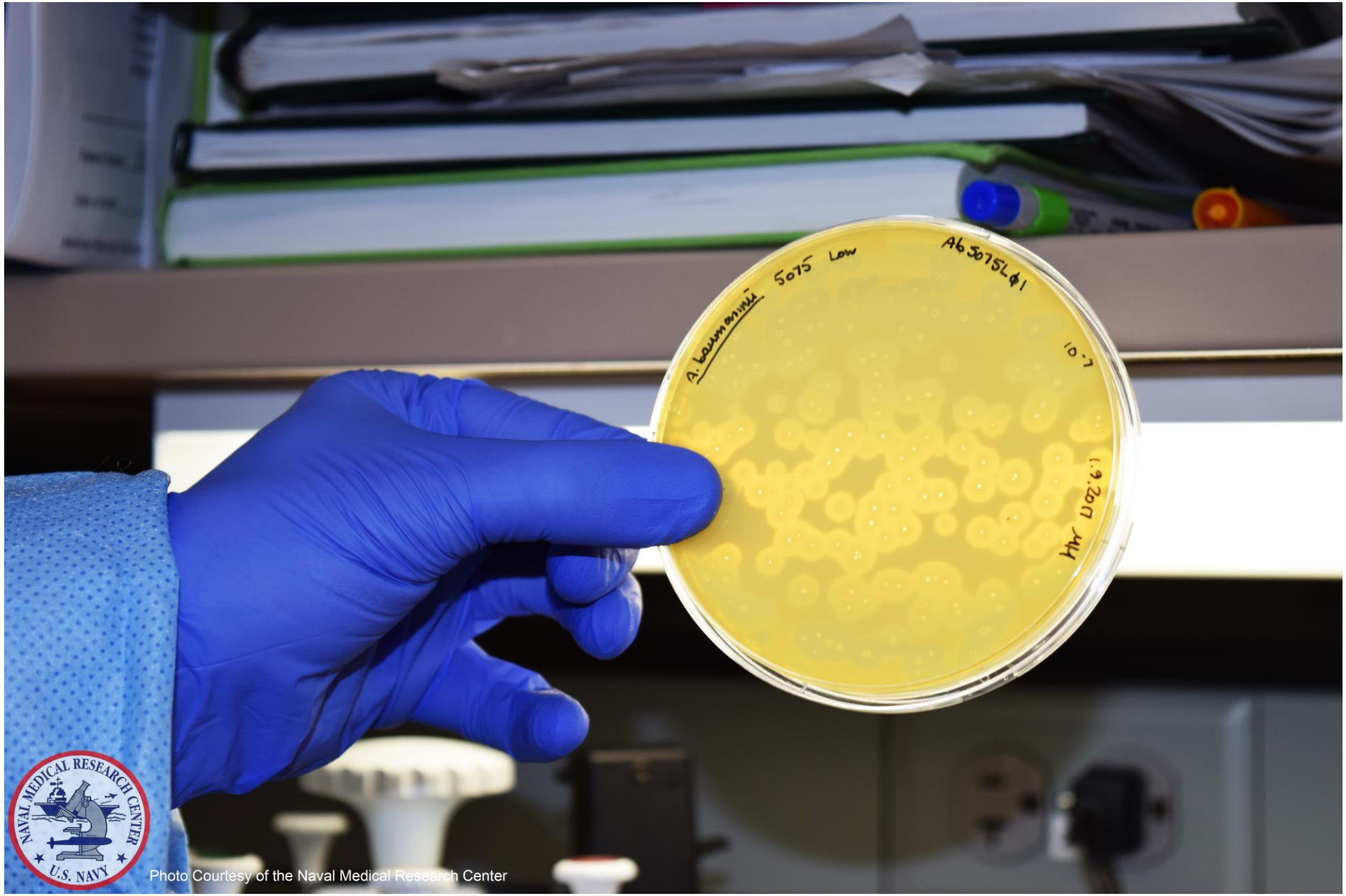


Photo Courtesy of the Naval Medical Research Center


I SURVIVED
IRAQIBACTER

The Phage Hunt Begins…

Dr Ry Young

Texas A&M- Center for Phage Technology

Contacting the FDA….

Dr Robert (Chip) Schooley, UCSD

Dr Cara Fiore, FDA

US Navy Biological Defense Research Directorate

Photo Courtesy of the Naval Medical Research Center

The Endotoxin Issue:

San Diego State University to the Rescue

Anca Segall, PhD

Forest Rohwer, PhD

Jeremy Barr, PhD

The Dosing Dilemma

Maia Merabishvilli, PhD

Carl Merril, MD

Phage Therapy ELIAVA

How much phage to administer?

What routes?

How often?

How long?


PROTECT FROM LIGHT
Investigational Study Medication
Patterson Thomas Leroy
Age:69 yrs [2/18/1947]
MRN#1590?264
Unit:2-TICU-IIC11
Ord#118683420
Bacteriophage cocktail (AB1, AB4, AB71, AB97 phages) 5 x 10^9 in 5 mL lactated ringers, IV solution
Dose:
Frequency: Q12H
Route: IntraVENOUS
Due Time:3/18/16 0900
Investigational Drug eIND# 16907 Bacteriophage cocktail (AB1, AB4, AB71, AB97 phages) 5 x 10^9 in 5 mL lactated ringers, IV solution for bolus per MD discretion. Handle as biohazardous agent - dispose of properly. Investigational drug cosignature required. Protect from light. Discard 24 hours after preparation time.
Pharmacy instruction: Obtain 0.5 mL of 1x 10^11 PFU/mL stock and add to 4.5 mL LR to make working solution #1 (5mL, 1x 10^10 PFU/mL). Obtain 0.5 mL of working solution #1 and add to 4.5 mL LR to make final solution of 5 mL, 1x 10^9 PFU/mL, total dose= 5x 10^9 PFU.
Printed: 3/17/16 1856 [FD]
Tech:_____
RPh:
REFRIGERATE


WARNING:


Happy Birthday!
HAPPY BIRTHDAY!

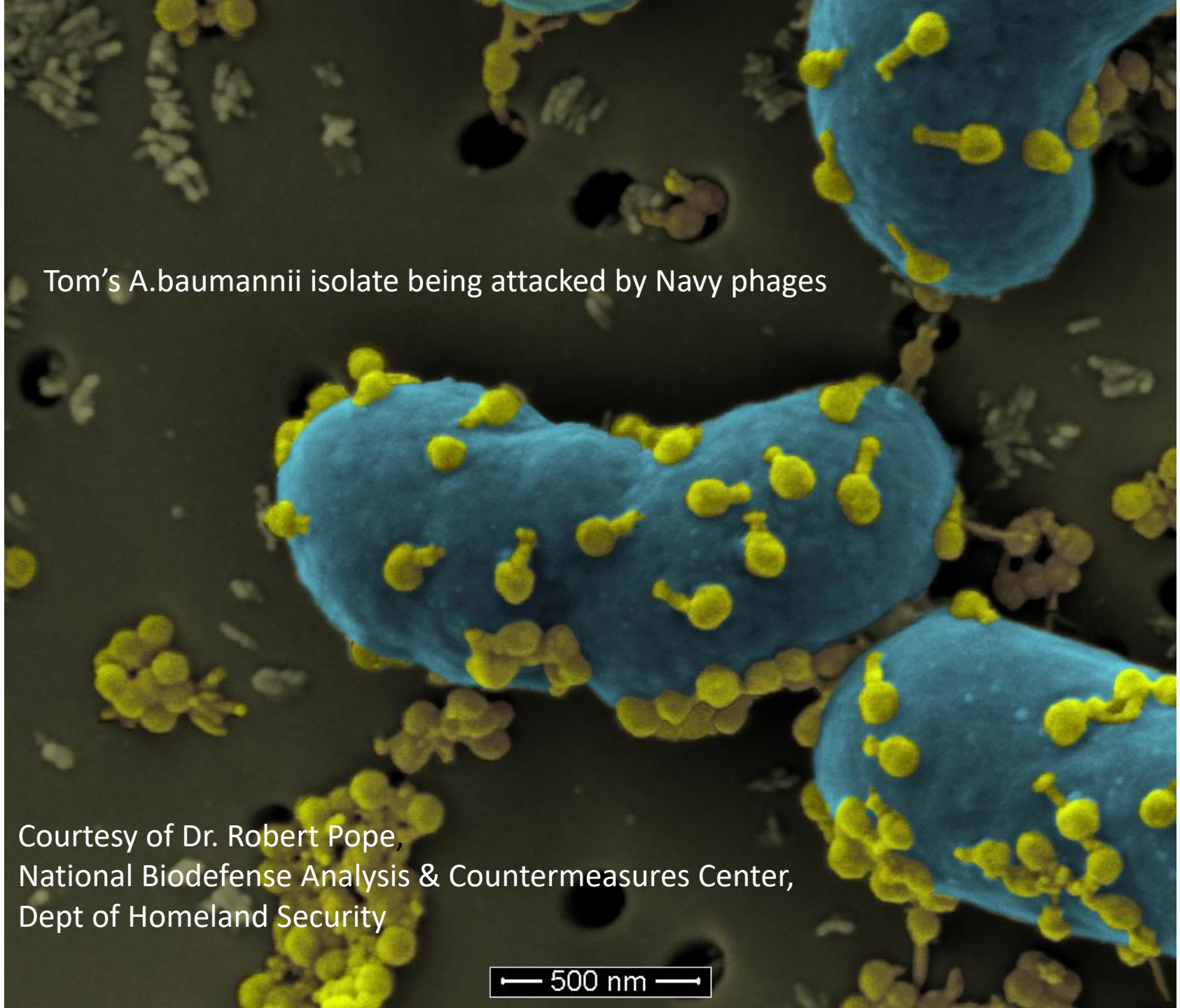

220

Thomas Patterson and Lt Commander Theron Hamilton

AMERICAN SOCIETY FOR MICROBIOLOGY | Antimicrobial Agents and Chemotherapy®

Development and Use of Personalized Bacteriophage-Based Therapeutic Cocktails To Treat a Patient with a Disseminated Resistant *Acinetobacter baumannii* Infection

Schooley et al, AAC, 2017


Tom’s A.baumannii isolate being attacked by Navy phages
Courtesy of Dr. Robert Pope,
National Biodefense Analysis & Countermeasures Center,
Dept of Homeland Security
500 nm

BuzzFeed NEWS / REPORTING TO YOU

Her Husband Was Dying From A Superbug. She Turned To Sewer Viruses Collected By The Navy.

Scientists have long dismissed "phage therapy" as a fringe idea pushed by eccentrics who enjoy fishing in sewage. But now the Navy is betting on it.

WELLNESS

Sewage Saved This Man's Life. Someday It Could Save Yours.

Bacteriophages — viruses found in soil, water and human waste — may be the cure in a post-antibiotic world.

By Lauren Weber

HUFFPOST

Daily Mail .com

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Latest Headlines | Health | Health Directory | Coupons

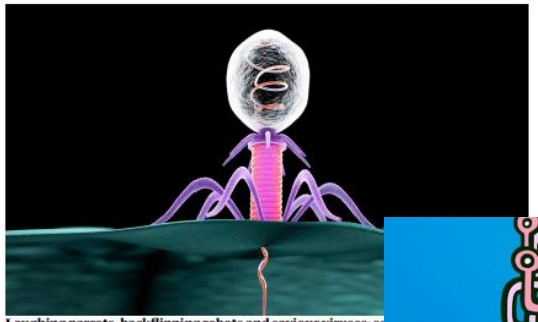
Could gargling a virus that eats bacteria solve the SUPERBUG CRISIS? As overused antibiotics become less and less effective, a tantalising discovery may revolutionise healthcare

- Steffanie Strathdee feared the worst when husband Tom Patterson comatosed
- Husband of 13 years lay in a deep coma, the victim of an aggressive superbug
- His heart, lungs and major organs were all shutting down with little hope left
- Apparently miraculous recovery is result of natural phenomenon that could combat growth of antibiotic-resistant infections and also treat sore throats

JAMA®

The Journal of the American Medical Association

theguardian



Laughing parrots, backflipping robots and saviour viruses: sc

Medical News & Perspectives

Phage Therapy's Role in Combating Antibiotic-Resistant Pathogens

Jeff Lyon

Sometimes, what's old is new again— even in the ever-advancing world of

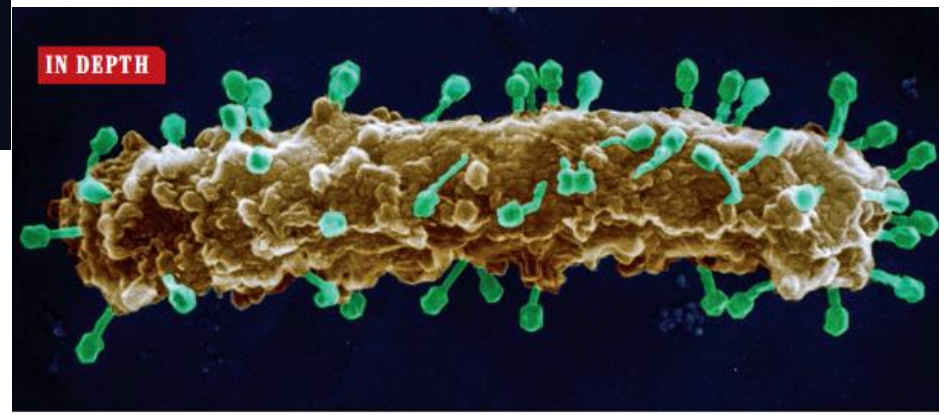
istered under Schooley's direction after applying for and receiving Emergency

THE LANCET

Phage therapy: revival of the bygone antimicrobial

The idea of using bacteriophages as vectors for antimicrobial therapy has existed for decades, but development towards clinical application still lags behind. Geoff Watts reports.

Science
AAAS



BIOMEDICINE

U.S. center will fight infections with viruses

Proving ground for phage therapy will organize full clinical trials of the approach

Phage Therapy Patients treated at IPATH

Patient	Age	Underlying Condition	Organism	Start Date	Outcome
1	67	Disseminated infection	A. Baumannii	May 2016	Treatment success
2	67	Bilateral lung transplant	P. Aeruginosa	May 2017	Treatment success
3	74	Open head trauma	A. Baumannii	June 2017	Treatment success
4	23	CF; pre lung transplant	P. Aeruginosa	September 2017	Treatment success
5	65	Infected LVAD	P. aeruginosa +	December 2017	Failure
6	63	Infected LVAD	S. Aureus	April 2018	Treatment success
7	61	Infected left knee prosthesis	S. Aureus	March 2019 September 2019	First treatment failed, second treatment success
8	83	Infected LVAD	P. aeruginosa	August 2019	Treatment failure, patient passed away
9	56	Recurrent UTI	ESBL E. coli	February 2020	Partial success
10	64	Recurrent bacteremia, aortic graft infection	P. Aeruginosa	March 2020	Treatment success
11	65	Bacteremia	ESBL E. Coli	July 2020	Outcome pending
12	77	Lung infection	P. aeruginosa	September 2020	Outcome pending

Mayo Clinic Experience –Knee Replacement Surgery

After surgery #19 (Jan 2019)

Before phage therapy (June 2019)

After Two Infusions (July 2019)

Clinical Infectious Diseases

MAJOR ARTICLE

IDSA Infectious Diseases Society of America

hivma hiv medicine association

OXFORD

Phage Therapy for Limb-threatening Prosthetic Knee *Klebsiella pneumoniae* Infection: Case Report and In Vitro Characterization of Anti-biofilm Activity

Edison J. Cano,[1,2] Katherine M. Caflisch,[2,3] Paul L. Bollyky,[4] Jonas D. Van Belleghem,[4] Robin Patel,[1,2,5] Joseph Fackler,[6] Michael J. Brownstein,[6] Bri'Anna Horne,[6] Biswajit Biswas,[7] Matthew Henry,[7,8] Francisco Malagon,[7] David G. Lewallen,[9] and Gina A. Suh[1]

Clinical Infectious Diseases
BRIEF REPORT

Successful Treatment of Antibiotic-resistant, Poly-microbial Bone Infection With Bacteriophages and Antibiotics Combination

Ran Nir-Paz,[1] Daniel Gelman,[2,3] Ayman Khouri,[4] Brittany M. Sisson,[5] Joseph Fackler,[5] Sivan Alkalay-Oren,[2] Leron Khalifa,[2] Amit Rimon,[2,3] Ortal Yerushalmy,[2] Reem Bader,[1] Sharon Amit,[1] Shunit Coppenhagen-Glazer,[2] Matthew Henry,[6] Javier Quinones,[6] Francisco Malagon,[6] Biswajit Biswas,[6] Allen E. Moses,[1] Greg Merril,[5] Robert T. Schooley,[7] Michael J. Brownstein,[5] Yoram A. Weil,[4] and Ronen Hazan[2]

[1]Department of Clinical Microbiology and Infectious Diseases, Hadassah-Hebrew University Medical Center, [2]Institute of Dental Sciences, Faculty of Dental Medicine, The Hebrew University, [3]Tzameret, The Military Track of Medicine, The Hebrew University-Hadassah Medical School, and [4]Orthopedic Surgery Department, Hadassah-Hebrew University Medical Center, Jerusalem, Israel; and [5]Adaptive Phage Therapeutics, Gaithersburg, and [6]The Geneva Foundation and Biological Defense Research Directorate Naval Medical Research Center, Frederick, Maryland; and [7]Department of Medicine, Division of Infectious Diseases, University of California San Diego, La Jolla, California

(*Ab*) and multidrug-resistant (MDR) *Klebsiella pneumoniae* (*Kp*) infections. These were successfully treated with a combination of bacteriophages and antibiotics. A phage-resistant *Ab* mutant developed in vitro, but fortunately, not in the patient, and we quickly isolated a new lytic phage to combat it. This shows the potential flexibility of phage treatments.

Received: 14 February 2019 | Revised: 27 May 2019 | Accepted: 27 May 2019
DOI: 10.1111/ajt.15503
BRIEF COMMUNICATION
AJT

Early clinical experience of bacteriophage therapy in 3 lung transplant recipients

Saima Aslam[1] | Andrew M. Courtwright[2] | Christine Koval[3] | Susan M. Lehman[4] | Sandra Morales[4] | Carrie-Lynn Langlais Furr[4] | Francisco Rosas[4] | Michael J. Bruemmer[5] | Joseph R. Fackler[5] | Brittany M. Sisson[5] | Biswajit Biswas[6] | Brittany N. Bivens[6] | Theron Hamilton[6] | Cathy Logan[1] | Nancy Law[1] | Gordon Yung[7] | Steffanie A. Strathdee[1] | Robert T. Schooley[1]

University of California San Diego, La Jolla, California
iversity of Pennsylvania, Philadelphia, Pennsylvania
dation, Cleveland, Ohio

60

CASE STUDY

EVOLUTION, MEDICINE, & PUBLIC HEALTH

Evolution, Medicine, and Public Health [2018] pp. 60–66
doi:10.1093/emph/eoy005

Phage treatment of an aortic graft infected with *Pseudomonas aeruginosa*

Benjamin K. Chan,[1] Paul E. Turner,[*,1,2] Samuel Kim,[3] Hamid R. Mojibian,[4] John A. Elefteriades[5] and Deepak Narayan[3]

rch Directorate, Fort Detrick, Maryland
iversity of California San Diego, La Jolla, California
ndation, Cleveland, Ohio
a, Philadelphia, Pennsylvania

Case Report
iMedPub Journals
http://www.imedpub.com
Journal of Intensive and Critical Care
ISSN 2471-8505
2019
Vol.5 No.2:11

A Case Series of Emergency Investigational New Drug Applications for Bacteriophages Treating Recalcitrant Multi-drug Resistant Bacterial Infections: Confirmed Safety and a Signal of Efficacy

Christopher A Duplessis[1], Michael Stockelman[1], Theron Hamilton[1], Greg Merril[2], Michael Brownstein[2], Kimberly Bishop-lilly[1], Robert Schooley[3], Matthew Henry[1], Bri'Anna Horne[2], Brittany M. Sisson[2], Javier Quinones[1], Saima Aslam[3], S Lavergne[3], Ran Nir-Paz[4], and Biswajit Biswas[1]

Abstract

The advent and increasing prevalence of antimicrobial resistance commensurate with the absence of novel antibiotics on the horizon raises the spectre of untreatable infections. We must now grapple with infections stemming from extensively multi- and pan-drug resistant bacterial strains. Potential non-antibiotic

https://doi.org/10.1007/s15010-019-01319-0

CASE REPORT

Successful adjunctive use of bacteriophage therapy for treatment of multidrug-resistant *Pseudomonas aeruginosa* infection in a cystic fibrosis patient

Nancy Law[1] · Cathy Logan[1] · Gordon Yung[2] · Carrie-Lynn Langlais Furr[3] · Susan M. Lehman[3] · Sandra Morales[3] · Francisco Rosas[3] · Alexander Gaidamaka[3] · Igor Bilinsky[3] · Paul Grint[3] · Robert T. Schooley[1,4] · Saima Aslam[1,4]

Received: 29 January 2019 / Accepted: 9 May 2019 / Published online: 17 May 2019

viruses
MDPI

Article

Bacteriophage Application for Difficult-To-Treat Musculoskeletal Infections: Development of a Standardized Multidisciplinary Treatment Protocol

Jolien Onsea [1,2,*], Patrick Soentjens [3,4], Sarah Djebara [3], Maia Merabishvili [5], Melissa Depypere [6], Isabel Spriet [7], Paul De Munter [8,9], Yves Debaveye [10], Stefaan Nijs [1,2], Paul Vanderschot [1,2], Jeroen Wagemans [11], Jean-Paul Pirnay [5], Rob Lavigne [11] and Willem-Jan Metsemakers [1,2]

ELSEVIER
The Journal of Heart and Lung Transplantation
http://www.jhltonline.org

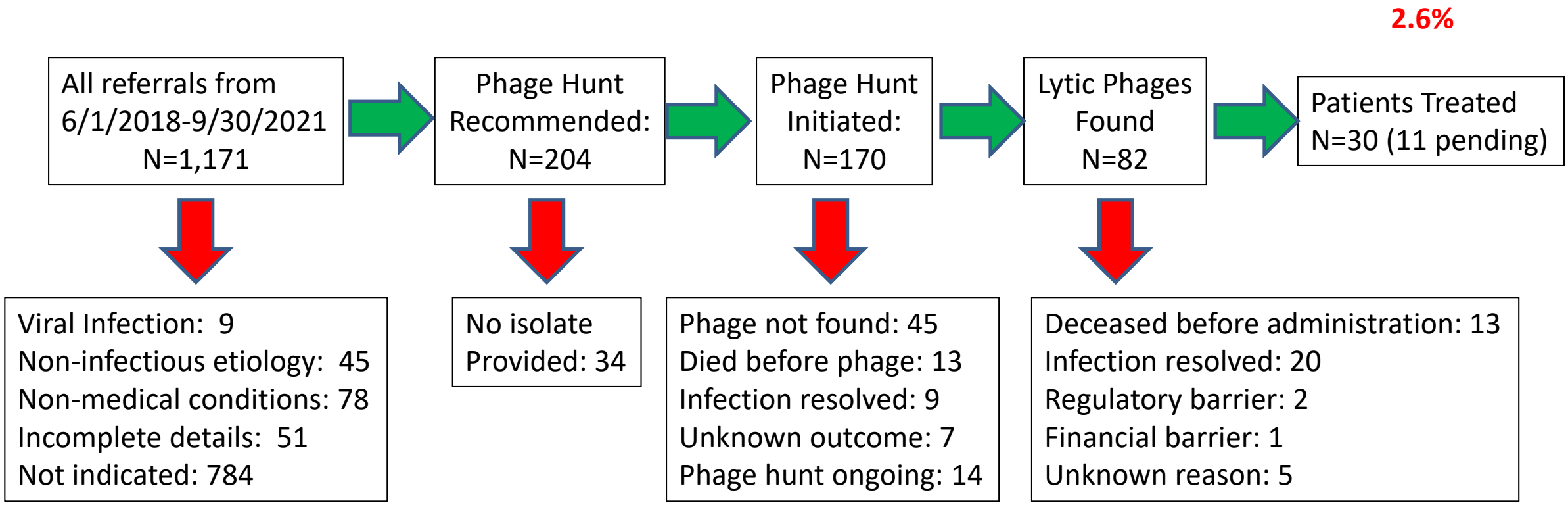
CASE ANECDOTES, COMMENTS AND OPINIONS

Novel bacteriophage therapy for treatment of left ventricular assist device infection

Saima Aslam, MD,[a] Victor Pretorius, MD,[b] Susan M. Lehman, PhD,[c] Sandra Morales, PhD,[c] and Robert T. Schooley, MD[a]

BT was administered without adverse clinical or laboratory events. By Week 1, and thereafter, the patient noted continued improvements in his energy level. Hemoglobin rose from 10.5 to 12.3 g/dl. Calculated panel-reactive antibody levels remained unchanged. Sternal cultures became negative for MSSA at Weeks 1, 2, and 4 (end of therapy, EOT); Week 3 culture grew MSSA and *S epidermidis*. At

Phage Referrals to IPATH



Selected Organisms in Play

Data from 06/01/18 – 9/30/21)

Organism	#Requests	Phage Hunt Initiated	Lytic Phage Found
P. aeruginosa	145	43	30
E. coli	50	7	4
K. pneumoniae	47	9	4
A. baumannii	34	6	1
Achromobacter species	12	10	3
E. cloacae	6	2	2
E. aerogenes	2	1	1
E. species	6	2	2
S. marcessens	5	2	1
M. abscessus	68	29	13
M. chimera	10	8	4
M. avium	35	2	0
B. burgdorferi	55	0	0

Building a Phage Library

nature microbiology

May 2020

news & views

CLINICAL MICROBIOLOGY

Treat phage like living antibiotics

Bacteriophage therapeutics has emerged as one of the few potential beacons that represent possible solutions to the growing global crisis of antimicrobial resistance. Bringing science to the bedside (and vice versa) will maximize the potential of this compelling opportunity.

Robert T. Schooley and Steffanie Strathdee

Robert Redfield, Director of the US Center for Disease Control and Prevention, stated in 2019 that we should "stop referring to a coming post-antibiotic era. It's already here". Bacteriophages (phages) have been parasitizing and shaping evolution of their bacterial prey for 300,000,000 years[1,2]. The primary battlefield for the estimated 10^{31} unique phages and 10^{12} microbial species has been the natural environment, but skirmishes occur continuously within and on surfaces of all animal and plant species[3,4]. In the century during which these 'eaters of bacteria' became known to science, enthusiasm about phages as bona fide antimicrobial therapeutics has fluctuated widely[5]. Phages have been administered for decades in the former Soviet Union and Eastern Europe — generally as crude lysates but rarely parenterally. In this issue of *Nature Microbiology*, Jonathan Iredell's Westmeade Hospital group contributes to a growing consensus that it is time to rigorously evaluate phages in the urgent effort to develop novel approaches to the global crisis of multidrug-resistant bacterial infections[6].

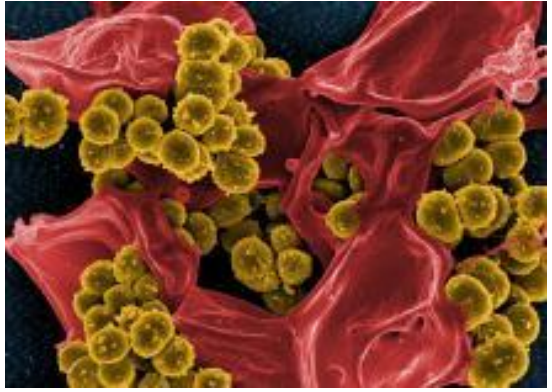
The manuscript reports their experience using adjunctive phage therapy to treat 13 patients with persistent *Staphylococcus aureus* sepsis. As they note, the study design precluded any serious assessment of efficacy. However, it is one of the first efforts to parenterally administer a well-characterized fixed combination of phages to a prospectively defined patient population with a serious bacterial infection. This represents an important step forward from the growing number of isolated case reports of parenterally administered phage therapy in western literature over the past three years. With all of the caveats of missing signal in a severely ill patient population, the investigators add to the knowledge base about the safety of parenterally administering phages prepared under rigorous GMP-like conditions and meticulously scrubbed of bacterial endotoxin. Furthermore, efforts to systematically collect useful information about pharmacokinetics, pharmacodynamics and resistance kinetics were an important addition and illustrate the best in investigator-initiated research.

So, what's next?

It is time to reframe the discussion about phage therapeutics from being fringe to a novel antimicrobial approach that should follow the same clinical development pathways we've successfully applied to traditional antimicrobials for over 70 years. The most important caveat is that phages are living antimicrobials that evolve with their bacterial targets. The guiding conceptual framework of clinical development thus requires working at the interface between bacteriology and virology — developing the clinical and translational research agenda with both disciplines in mind.

The process for developing an understanding of absorption, distribution, metabolism and excretion characteristics of antibiotics is well established and relies heavily on preclinical animal studies in uninfected animals[7]. Many antibiotics have failed simply because they cannot be delivered to their sites of infection or because rapid metabolism and excretion make clinical administration impractical. One of the major advantages of phage therapeutics may well be that replication within their bacterial hosts at the site of infection will make them much more forgiving than antibiotics in terms of delivery. However, phage therapeutics will require the introduction of new considerations, such as multiplicity of infection, physical contiguity and size of the bacterial target population, and the rate of bacterial evolution in the setting of selective pressure by one (or likely more than one) phages during treatment. These investigations should be aided by the

National Institutes of Health



NIH Funds First Phase Therapy Trial ($12 M) through the Antibacterial Resistance Leadership Group

December 13th, 2019

Design: Adaptive Phase 2 Trial

Enrollment to start in 2022

PI: Robert T. Schooley

Next Steps

- Translational studies:
  - PK/PD, Valency, Dose, Routes of administration
  - Potential synergy with antibiotics
- Clinical trials needed to determine efficacy:
  - Fixed vs. personalized cocktails
- Develop a phage library to enable phage to be matched to superbugs within 2 days.
- Genetic engineering to optimize natural phage or develop synthetic phage

nature medicine

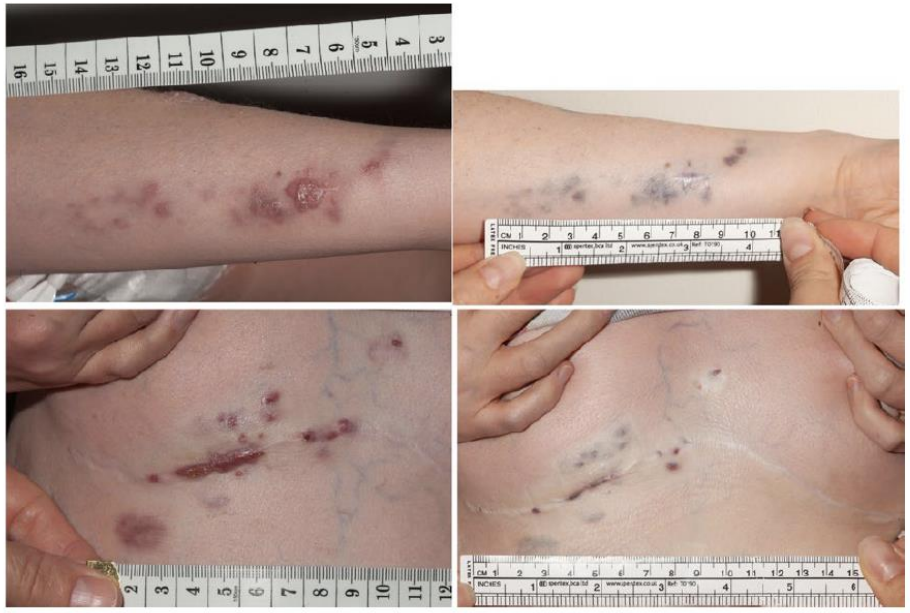
BRIEF COMMUNICATION

https://doi.org/10.1038/s41591-019-0437-z

May 2019

Engineered bacteriophages for treatment of a patient with a disseminated drug-resistant *Mycobacterium abscessus*

Rebekah M. Dedrick[1,4], Carlos A. Guerrero-Bustamante[1,4], Rebecca A. Garlena[1], Daniel A. Russell[1], Katrina Ford[2], Kathryn Harris[2], Kimberly C. Gilmour[2], James Soothill[2], Deborah Jacobs-Sera[1], Robert T. Schooley[3], Graham F. Hatfull[1*] and Helen Spencer[2*]



Before treatment Post treatment

Infection Control & Hospital Epidemiology (2021), 1–14
doi:10.1017/ice.2021.362

SHEA
The Society for Healthcare Epidemiology of America

Original Article

The impact of coronavirus disease 2019 (COVID-19) on healthcare-associated infections in 2020: A summary of data reported to the National Healthcare Safety Network

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Significant increase in standardized incidence rates for:

- Central line associated bloodstream infections
- Catheter-associated UTIs
- Ventilator associated events
- MRSA bacteremia

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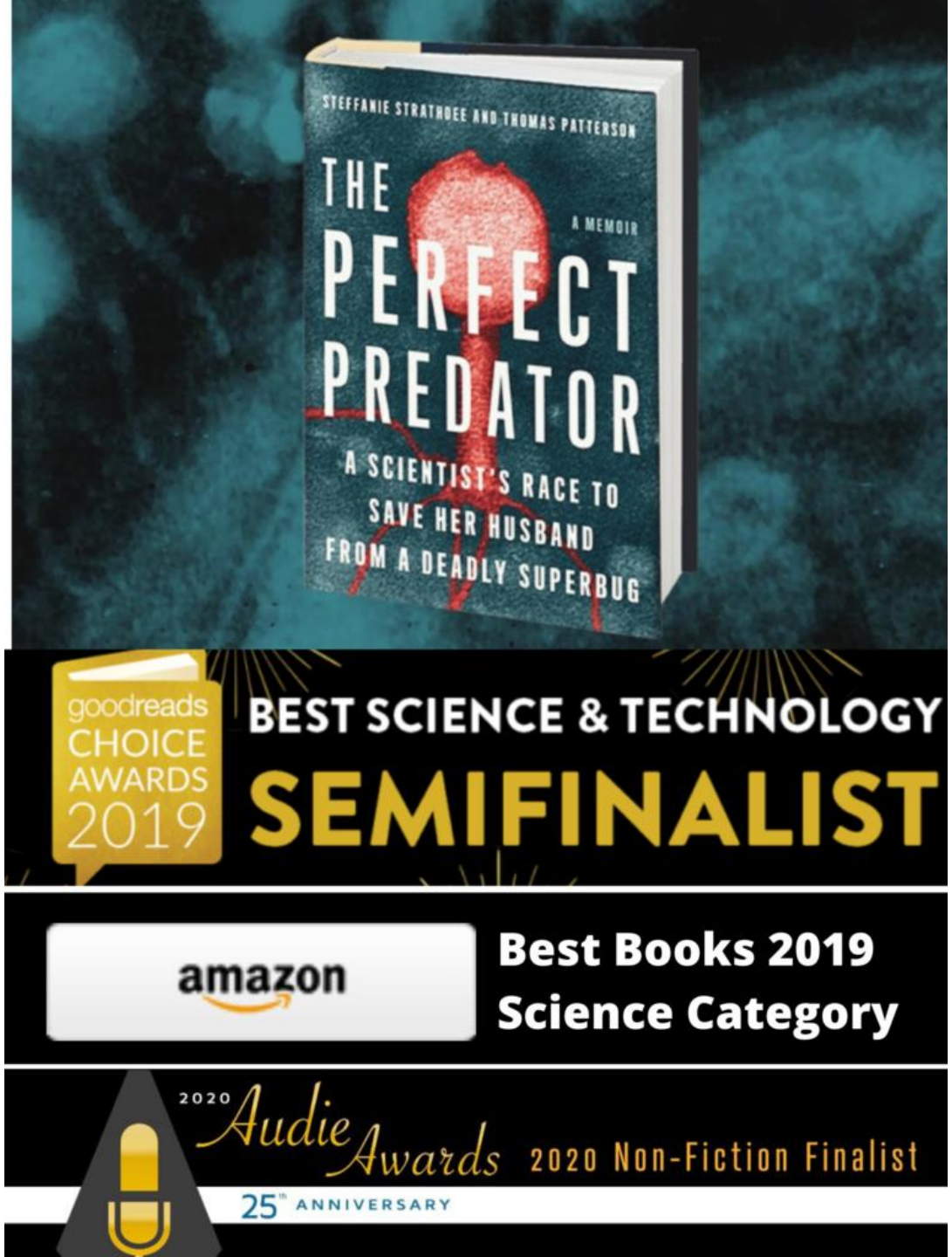

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