Fellows Introduction to Research Training (FIRsT) Course
November 2, 2017

Framing the Research Question

Ravi Mangal Patel, MD MSc
Associate Professor of Pediatrics
Division of Neonatology
rmpatel@emory.edu
@ravimpatelmd

Children's Healthcare of Atlanta | EMORY UNIVERSITY

Overview

- Finding a knowledge gap to address
  - How to know and keep up with the literature
- Asking the right question
  - Making your question a SMART question
- Putting your question onto paper
  - Developing specific aim(s)
- Getting funding
  - Fellow research fund (max of $ 5,000)

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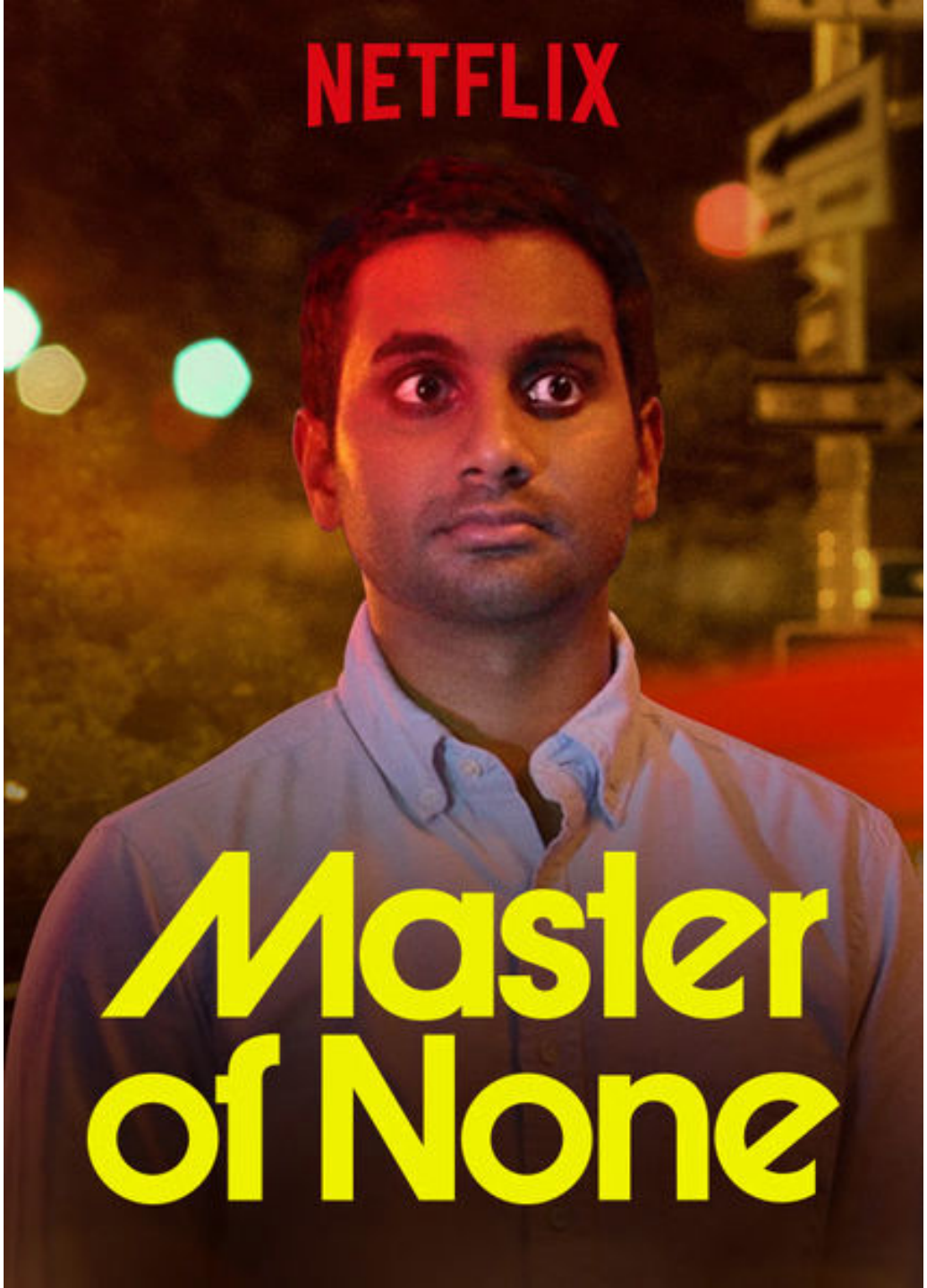
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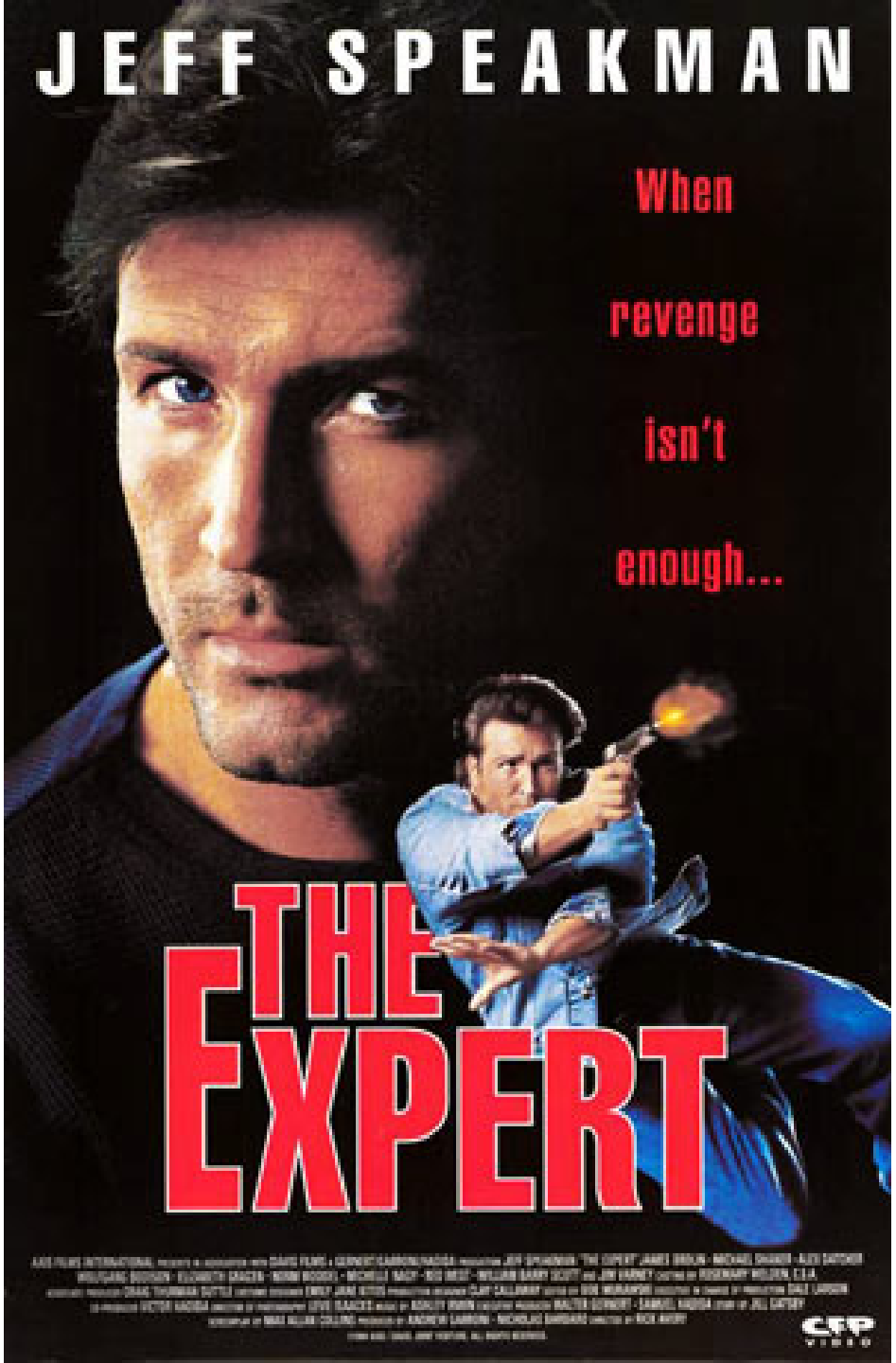
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isn't
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MIND THE GAP


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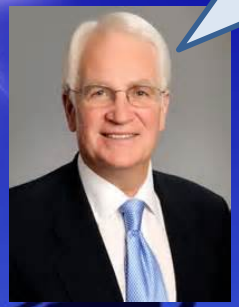
“I wonder if the reason this infant developed NEC was that I advanced feedings too quickly”

I am okay with however fast you want to feed the baby



In my work with fetal lambs, rapid feeding …

I like to advance feedings slowly, I worry about NEC

"Ravi,
I've been practicing for 40 years … I'm confident we don't know what to do when it comes to advancing feeds"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Search results

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1. Systematic Review of the Effect of Enteral **Feeding** on Gut Microbiota in Preterm Infants.
   Xu W, Judge M, Maas K, Hussain N, McGrath JM, Henderson WA, Cong X.
   J Obstet Gynecol Neonatal Nurs. 2017 Oct 14. pii: S0884-2175(17)30407-0. doi: 10.1016/j.jogn.2017.08.009. [Epub ahead of print]
   PMID: 29040820
   Similar articles

2. Impact of nutrition interventions on pediatric mortality and nutrition outcomes in humanitarian emergencies.
   Balhara KS, Silvestri DM, Winders WT, Selvam A, Kivlehan SM, Becker TK, Levine AC; Global Emergency Medicine Literature Review Group (GEMLR).
   Trop Med Int Health. 2017 Oct 9. doi: 10.1111/tmi.12986. [Epub ahead of print] Review.
   PMID: 28992388
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3. Slow advancement of enteral feed volumes to prevent necrotising enterocolitis in very low birth weight infants.
   Oddie SJ, Young L, McGuire W.
   Cochrane Database Syst Rev. 2017 Aug 30;8:CD001241. doi: 10.1002/14651858.CD001241.pub7. Review.
   PMID: 28854319
   Similar articles

3. Slow advancement of enteral feed volumes to prevent necrotising enterocolitis in very low birth weight infants.

Oddie SJ, Young L, McGuire W.

Cochrane Database Syst Rev. 2017 Aug 30;8:CD001241. doi: 10.1002/14651858.CD001241.pub7. Review.

PMID: 28854319

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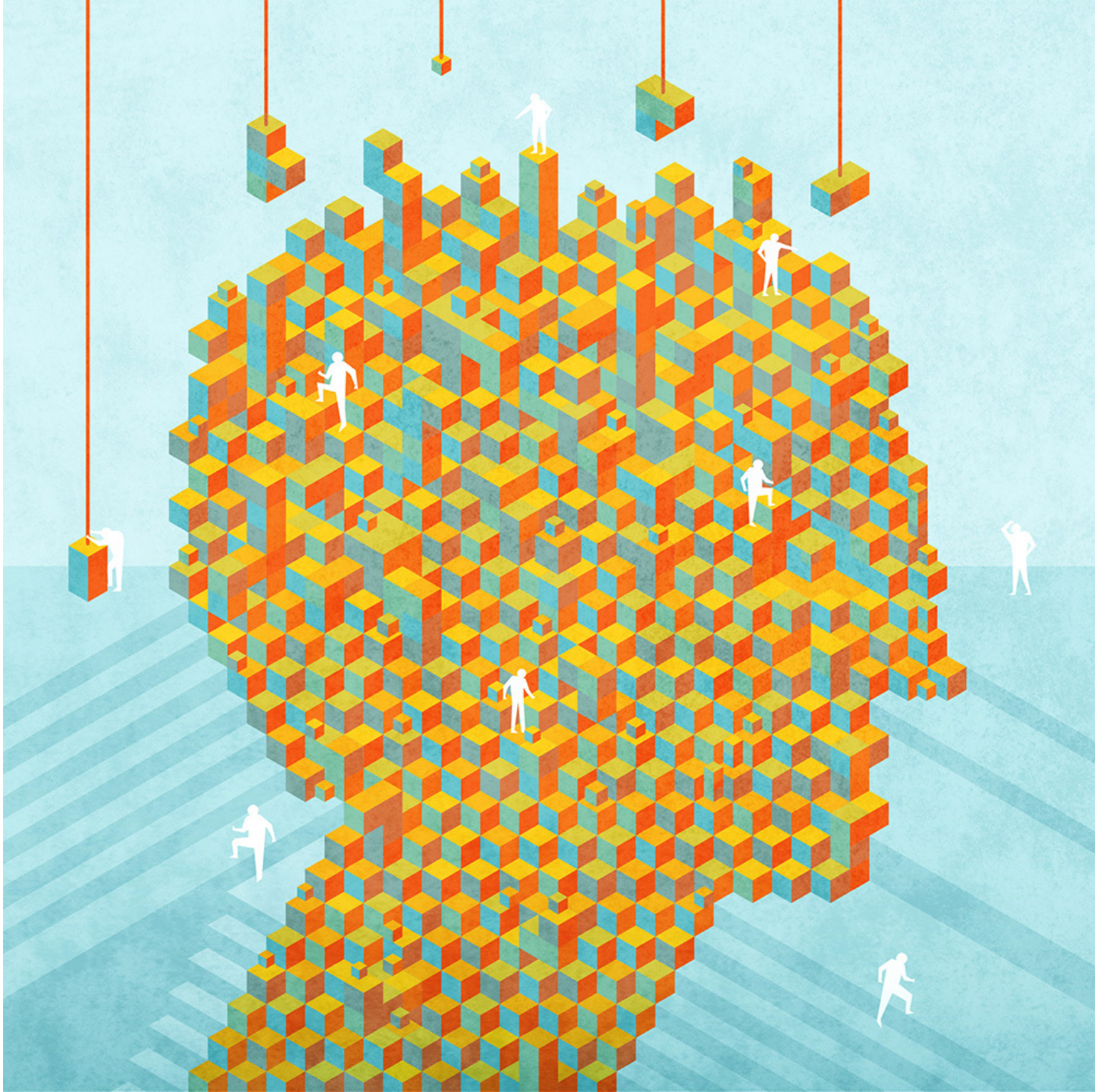
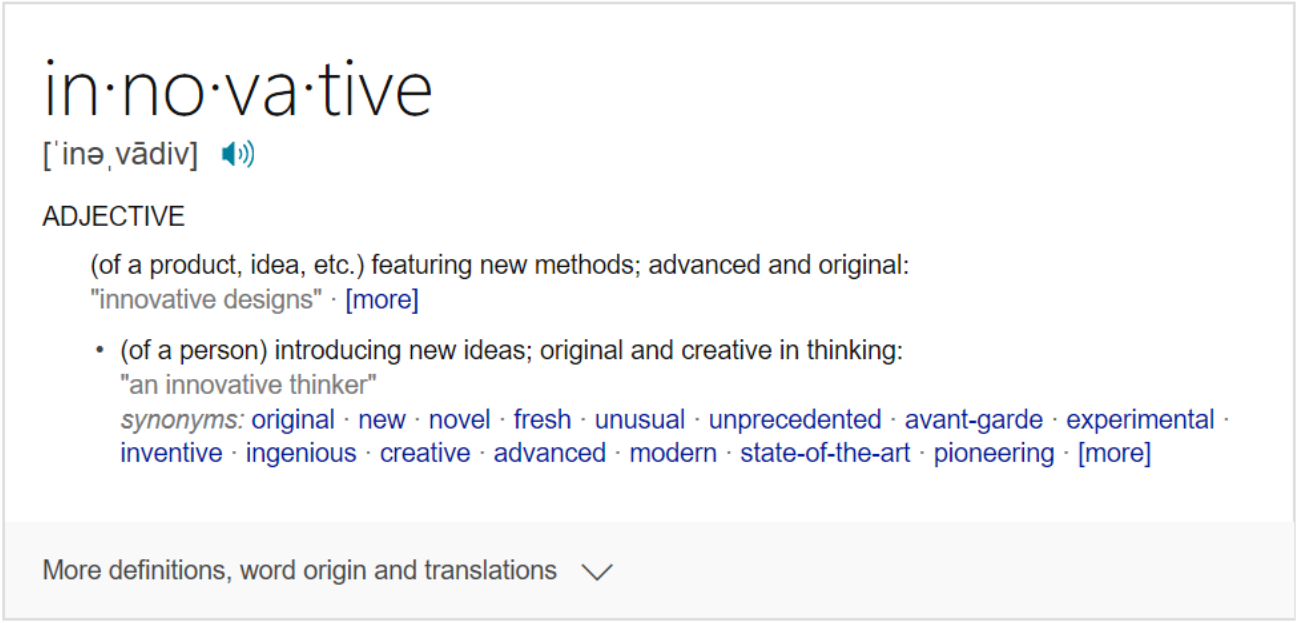
AUTHORS' CONCLUSIONS: Available trial data do not provide evidence that advancing enteral feed volumes at daily increments of 15 to 20 mL/kg (compared with 30 to 40 mL/kg) reduces the risk of NEC or death in very preterm or VLBW infants, extremely preterm or ELBW infants, SGA or growth-restricted infants, or infants with antenatal AREDFV. Advancing the volume of enteral feeds at a slow rate results in several days of delay in establishing full enteral feeds and may increase the risk of invasive infection.



How to know the literature

- As you build knowledge, think about what sparks your interests
- Once you find an area of interest, consider doing a systematic-review of the literature



in·no·va·tive

[ˈinəˌvādiv]

ADJECTIVE

(of a product, idea, etc.) featuring new methods; advanced and original:
"innovative designs" · [more]

- (of a person) introducing new ideas; original and creative in thinking:
  "an innovative thinker"
  synonyms: original · new · novel · fresh · unusual · unprecedented · avant-garde · experimental · inventive · ingenious · creative · advanced · modern · state-of-the-art · pioneering · [more]

More definitions, word origin and translations

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NOVEMBER 2017

	Date	Time	Event	Location
☐	**Nov 9**	11:30am	EndNote for Public Health Sign Up	Health Sciences Center Library, 1462 Clifton Rd, NE, Room B_65 (E-Classroom)
☐	**Nov 14**	9am	Accessing Library Resources for Nurses Sign Up	To be rescheduled
☐	**Nov 15**	12pm	PubMed for Public Health Sign Up	Health Sciences Center Library, 1462 Clifton Rd, NE, Room B_65 (E-Classroom)
☐	**Nov 16**	2pm	Planning for a Systematic Review Sign Up	Health Sciences Center Library, 1462 Clifton Rd, NE, Room B_63 (Collaboration Classroom)
☐	**Nov 29**	3pm	SPSS Basic Sign Up	Health Sciences Center Library, 1462 Clifton Rd, NE, Room B_65 (E-Classroom)

DECEMBER 2017

	Date	Time	Event	Location
☐	**Dec 7**	12pm	Planning for a Systematic Review Sign Up	Health Sciences Center Library, 1462 Clifton Rd, NE, Room B_63 (Collaboration Classroom)

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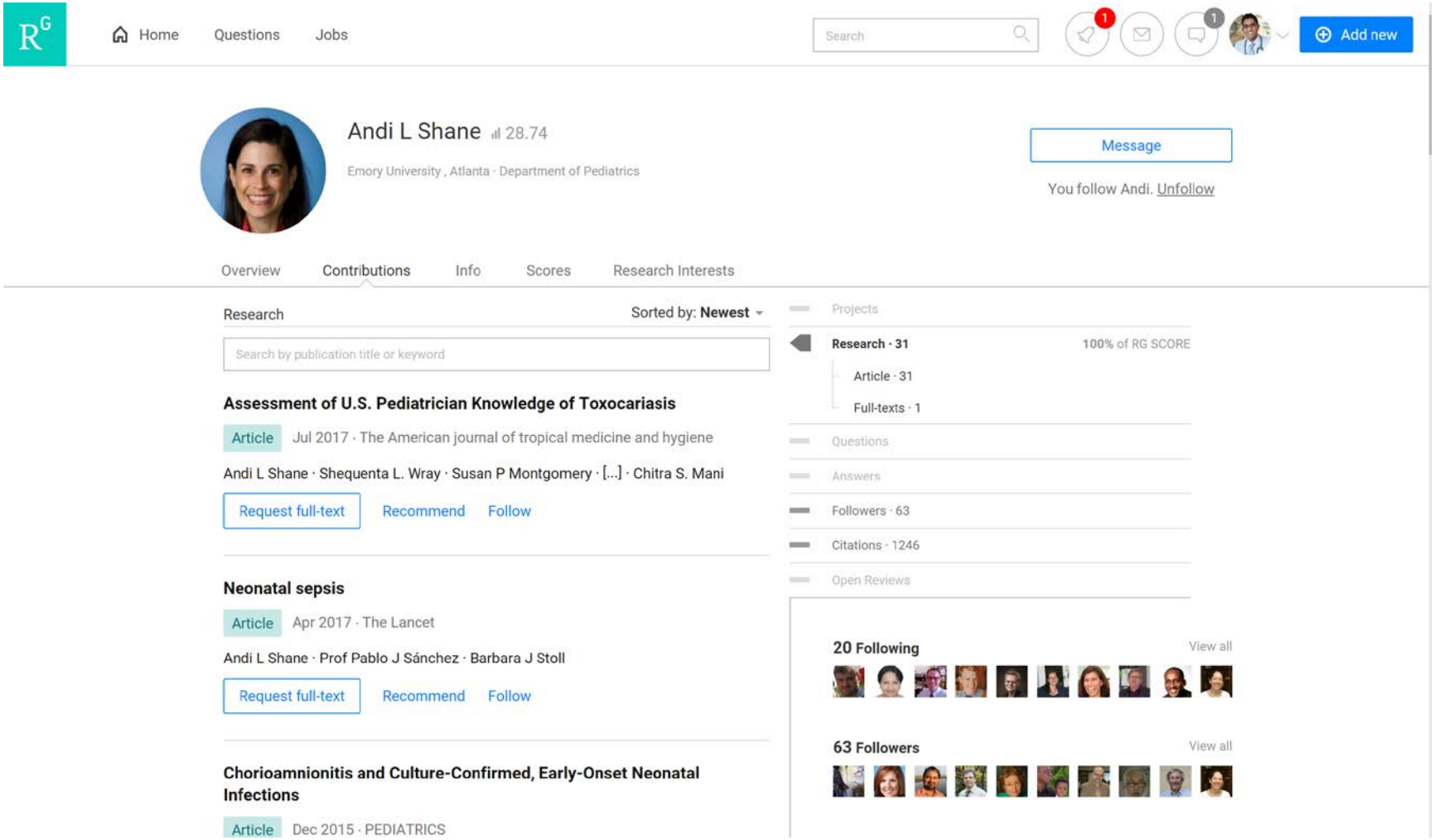
How to know your mentor

- Know the work of your mentor (or potential mentor)
- Ways to do this:
  - Meet with their lab or group members
  - Ask for their CV
  - Check out pedsresearch.org
  - Search for profile on Google Scholar or researchgate.net
  - Do a PubMed search or Web of Science author search

Researchgate.net



Keeping knowledge up to date

Where does this go?

Keeping your knowledge up to date: strategies for efficiency

- Twitter
- Journal alerts
- Data curators
  - Google scholar
  - Mendeley
  - Organizations
  - Amadeo
  - SmartBrief
- Schedule time to review the literature

Twitter

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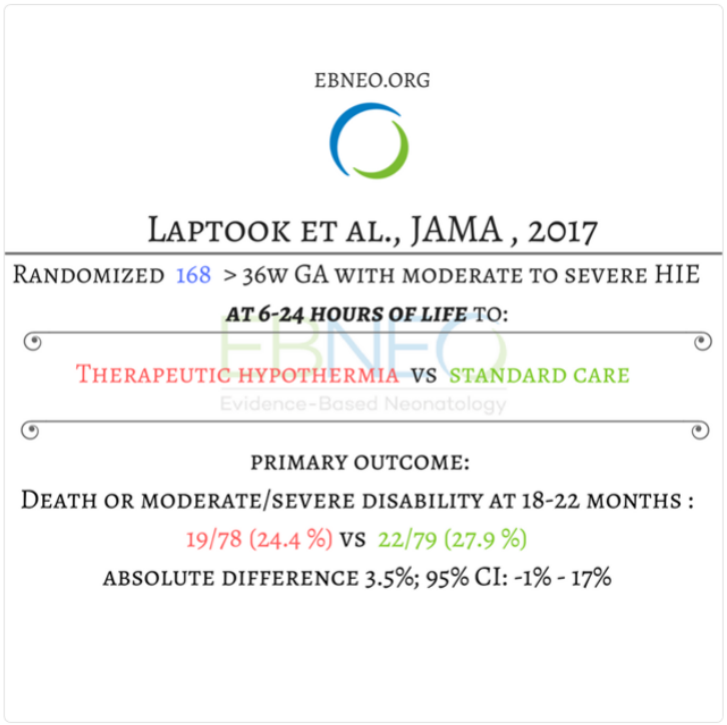
Evidence-Based Neo @EBNEO · Oct 30
Big week in evidence based neonatology: results of the NRN Late Hypothermia RCT in JAMA: ow.ly/sMcO30geakJ #ebneoalerts @JAMA_current



2 25 21

Journal alerts

Mon 10/30/2017 6:30 PM

JAMA Pediatrics <updates@jamanetwork.org>

Online First

To Patel, Ravi Mangal

Online First | OCTOBER 30, 2017

EDITORIAL

Macrolides and Pediatric Community-Acquired Pneumonia—Time for a Paradigm Shift?

Michael J. Smith, MD, MSCE

ORIGINAL INVESTIGATION

Dose, Content, and Mediators of Family-Based Treatment for Childhood Obesity: A Multisite Randomized Clinical Trial

Denise E. Wilfley, PhD; Brian E. Saelens, PhD; Richard I. Stein, PhD; et al

Association Between Early Life Adversity and Risk for Poor Emotional and Physical Health in Adolescence: A Putative Mechanistic Neurodevelopmental Pathway

Joan L. Luby, MD; Deanna Barch, PhD; Diana Whalen, PhD; et al

Effectiveness of β-Lactam Monotherapy vs Macrolide Combination Therapy for Children Hospitalized With Pneumonia

Derek J. Williams, MD, MPH; Kathryn M. Edwards, MD; Wesley H. Self, MD, MPH; et al

This Week at NEJM.org | November 2, 2017

Listen to the Weekly Audio Summary

PERSPECTIVE

Understanding the Planned Parenthood Divide — Albert Lasker and Women's Health ONLINE FIRST

L. Rosenbaum | November 1, 2017 | DOI: 10.1056/NEJMp1713518

Cholera in Yemen — An Old Foe Rearing Its Ugly Head ONLINE FIRST

F. Qadri, T. Islam, and J.D. Clemens | November 1, 2017 | DOI: 10.1056/NEJMp1712099

A Renewed Focus on Maternal Health in the United States

R.L. Molina and L.E. Pace | N Engl J Med 2017;377:1705-1707

Free Full Text Audio Comments

Dreams Deferred — The Public Health Consequences of Rescinding DACA

A.S. Venkataramani and A.C. Tsai | N Engl J Med 2017;377:1707-1709 | Published Online September 13, 2017

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Primary Care Spending Rate — A Lever for Encouraging Investment in Primary Care

C.F. Koller and D. Khullar | N Engl J Med 2017;377:1709-1711

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ORIGINAL ARTICLES

Single-Dose Gene-Replacement Therapy for Spinal Muscular Atrophy

J.R. Mendell and Others | N Engl J Med 2017;377:1713-1722

Quick Take Comments

Journal alerts (or table of contents)

- Pediatrics
- JAMA Pediatrics
- NEJM
- JAMA

- Check journals in your specialty or area of research


KEEP
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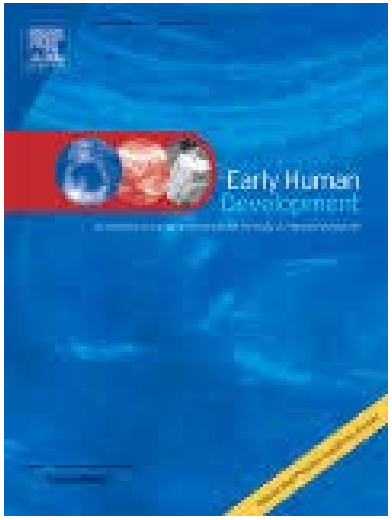
The NEW ENGLAND
JOURNAL of MEDICINE


JAMA Pediatrics


Journal of
Perinatology


Early Human
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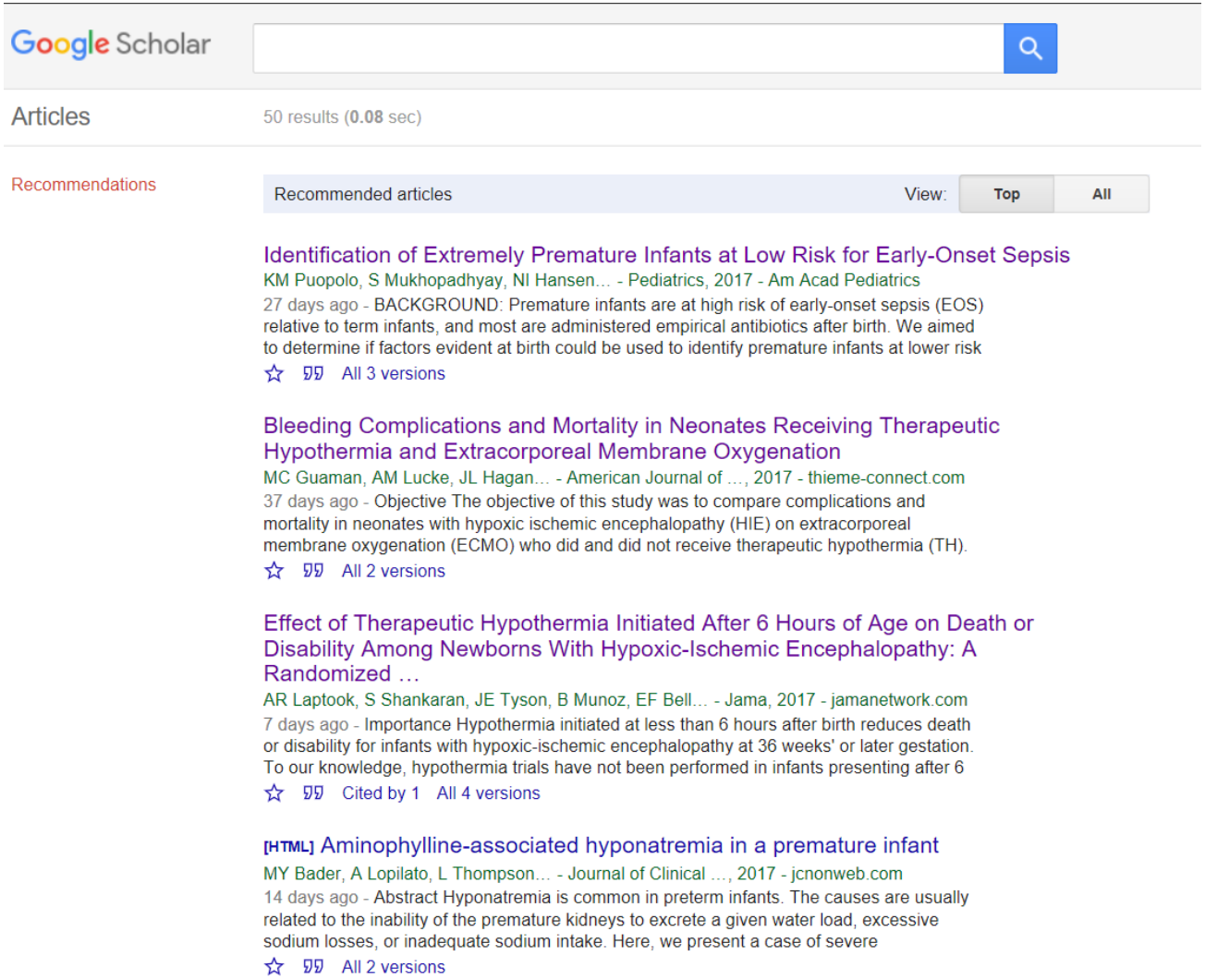
Google Scholar



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Google Scholar Blog

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Friday, October 13, 2017

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James D. Fortenberry MD, MCCM, FAAP

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Professor of Pediatric Critical Care, Emory University School of Medicine
Verified email at choa.org

ECMO and extracorporeal t… sepsis respiratory failure acute kidney injury ICU quality

TITLE	CITED BY	YEAR
Fluid overload before continuous hemofiltration and survival in critically ill children: a retrospective analysis JA Foland, JD Fortenberry, BL Warshaw, R Pettignano, RK Merritt, ... Critical care medicine 32 (8), 1771-1776	391	2004
Pediatric patients with multi-organ dysfunction syndrome receiving continuous renal replacement therapy SL Goldstein, MJG Somers, MA Baum, JM Symons, PD Brophy, D Blowey, ... Kidney international 67 (2), 653-658	373	2005
Fluid overload and mortality in children receiving continuous renal replacement therapy: the prospective pediatric continuous renal replacement therapy registry SM Sutherland, M Zappitelli, SR Alexander, AN Chua, PD Brophy, ... American journal of kidney diseases 55 (2), 316-325	337	2010
Management of pediatric acute hypoxemic respiratory insufficiency with bilevel positive pressure (BiPAP) nasal mask ventilation JD Fortenberry, J Del Toro, LS Jefferson, L Evey, D Haase Chest 108 (4), 1059-1064	208	1995
Modifying risk for extracorporeal circulation: trial of four antiinflammatory strategies JP Gott, WA Cooper, FE Schmidt, WM Brown, CE Wright, JD Merlino, ... The Annals of thoracic surgery 66 (3), 747-753	205	1998
Multi-centre evaluation of anticoagulation in patients receiving continuous renal replacement therapy (CRRT) PD Brophy, MJG Somers, MA Baum, JM Symons, N McAfee, ... Nephrology Dialysis Transplantation 20 (7), 1416-1421	191	2005
Demographic characteristics of pediatric continuous renal replacement therapy: a report of the prospective pediatric continuous renal replacement therapy registry JM Symons, AN Chua, MJG Somers, MA Baum, TE Bunchman, ... Clinical Journal of The American Society of Nephrology 2 (4), 732-738	168	2007

Cited by	VIEW ALL	
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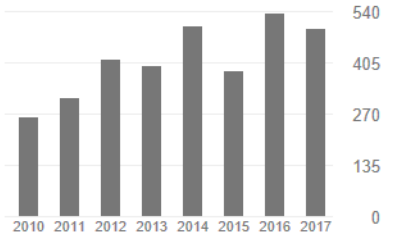
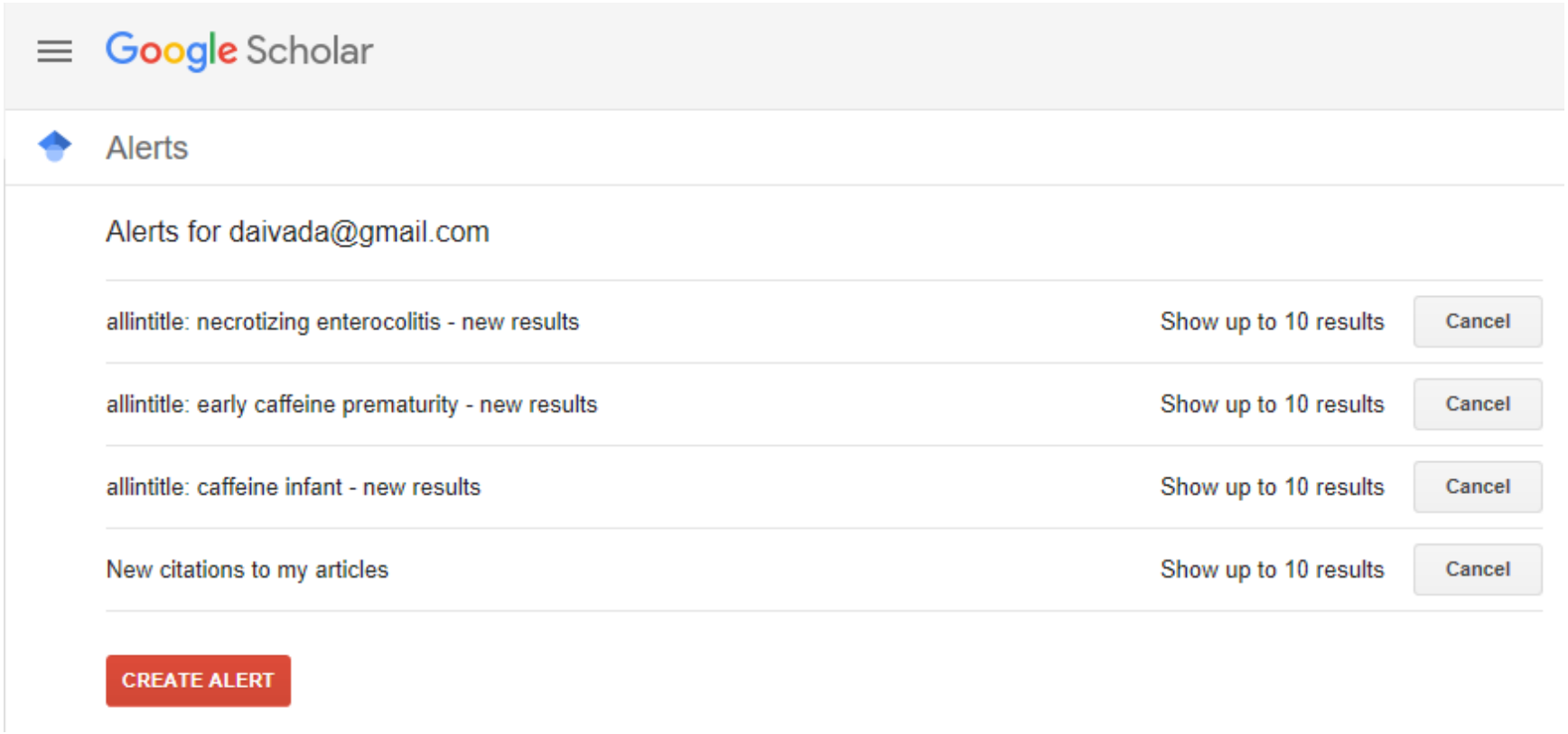


Google Scholar Alerts



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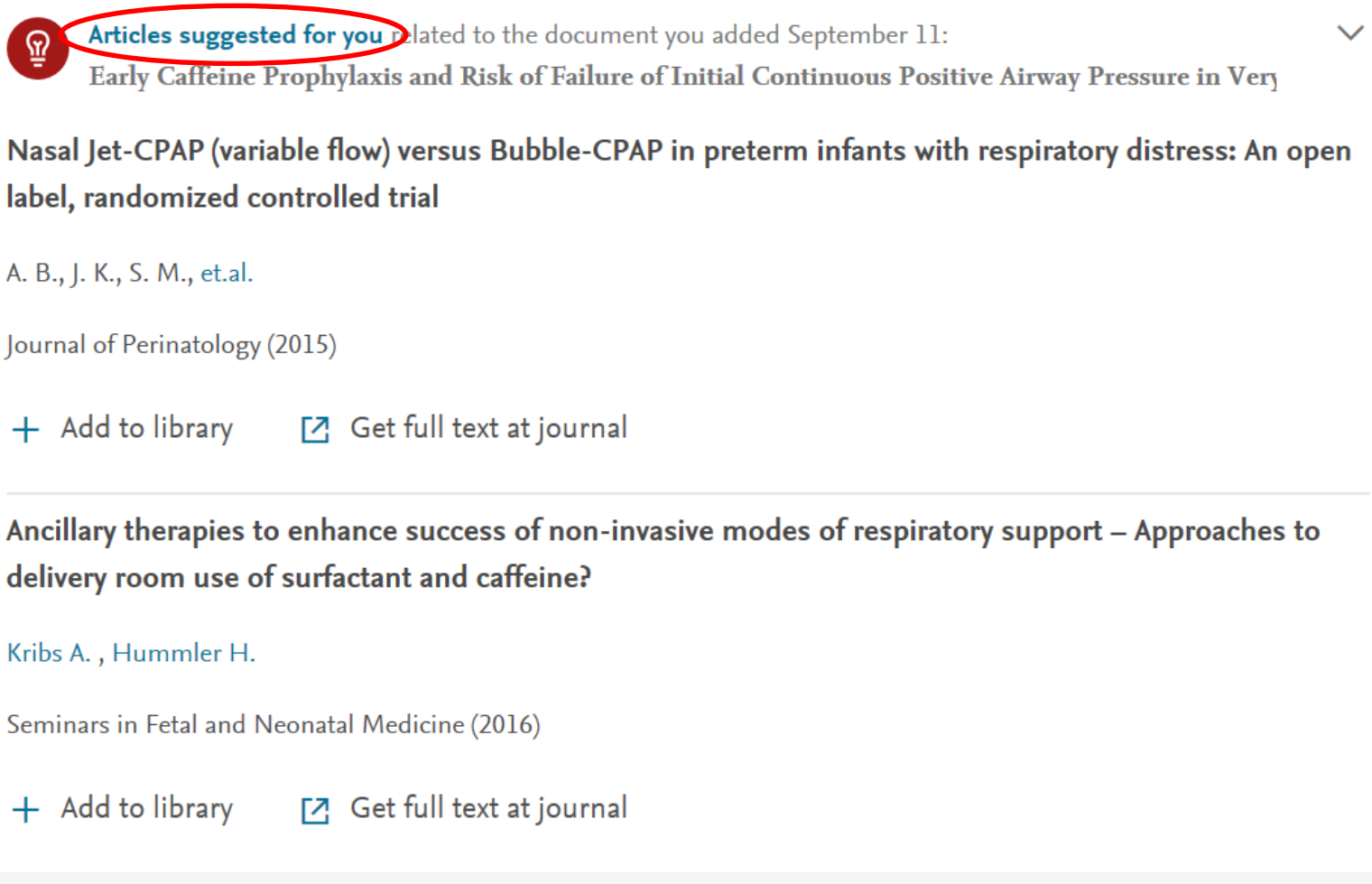

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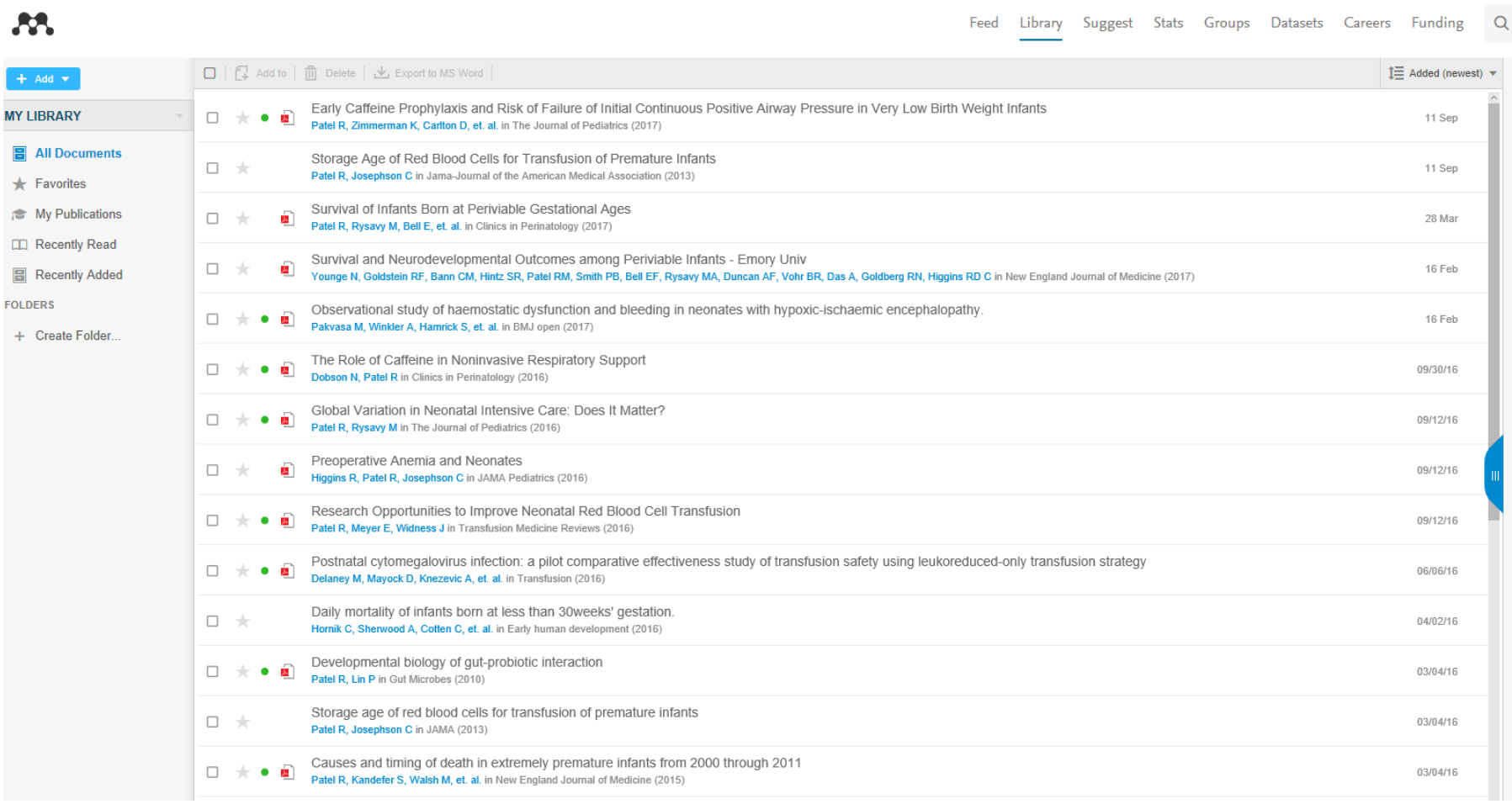

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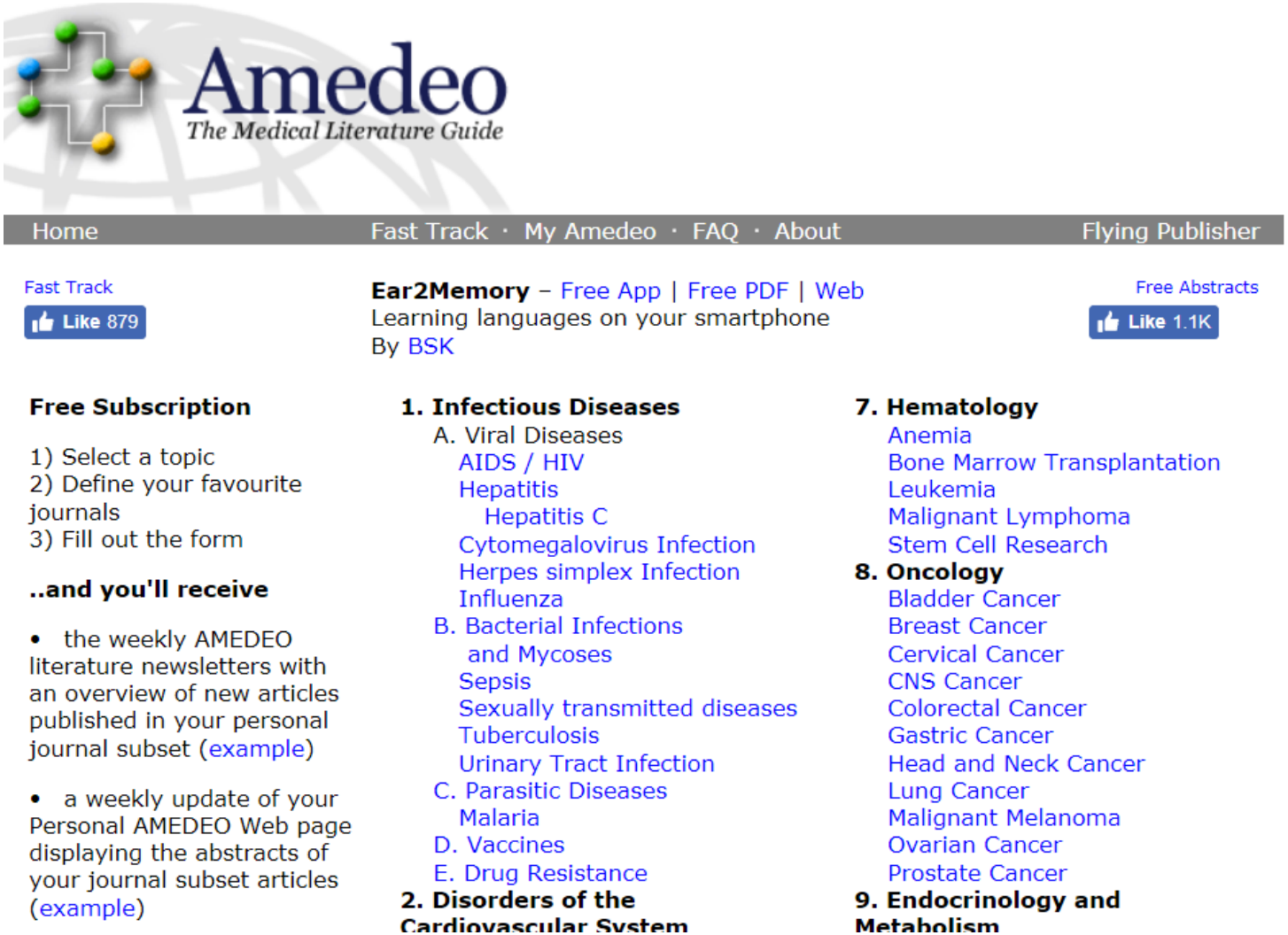
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Hepatitis C
Cytomegalovirus Infection
Herpes simplex Infection
Influenza
B. Bacterial Infections and Mycoses
Sepsis
Sexually transmitted diseases
Tuberculosis
Urinary Tract Infection
C. Parasitic Diseases
Malaria
D. Vaccines
E. Drug Resistance
2. Disorders of the Cardiovascular System
7. Hematology
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Bone Marrow Transplantation
Leukemia
Malignant Lymphoma
Stem Cell Research
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Bladder Cancer
Breast Cancer
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- Articles of Interest
- Journal Club
- Presentations
- MidCaN
- Guidelines and Protocols
- Coding Corner
- Klaus Awards

Section on Neonatal Perinatal Medicine
Neonatologists

Articles of Interest

The Section on Neonatal Perinatal Medicine Website Working Group has posted all new monthly Articles of Interest to neonatologists from the top journals. Access this website first to find the most recent clinical trials, review articles and research related to neonatology.

Selections from September 2017
Click here »

See previous articles:
August 2017

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AAP Section on Neonatal-Perinatal Medicine – Articles of Interest

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Section on Neonatal-Perinatal Medicine

ARTICLES OF INTEREST – September, 2017

Supraglottic atomization of surfactant in spontaneously breathing lambs receiving continuous positive airway pressure
Milesi I, Tingay DG, Lavizzari A, et al. *Pediatr Crit Care Med*.

To determine the short-term tolerance, efficacy, and lung deposition of supraglottic atomized surfactant (surf) the investigators administered surf to 22 preterm lambs receiving CPAP via binasal prongs at 8 cm H2O. They found a significant improvement in arterial alveolar ratio after surf delivery compared to controls (CPAP only) but no difference in PaCO2. Atomization distributed surf evenly between right and left lungs with a net deposition of 32%. The authors show that supraglottic atomization is safe, improves oxygenation and ventilation homogeneity compared with CPAP only.

Residual brain injury after early discontinuation of cooling therapy in mild neonatal encephalopathy
Lally PJ, Montaldo P, Oliveira V, et al. *Arch Dis Child Fetal Neonatal Ed*.

The authors examined brain injury and neurodevelopmental outcomes in 10 babies with mild encephalopathy who had early cessation of cooling therapy at a median age of 9 hours due to rapid clinical improvement. Five infants had injury on MRI or spectroscopy at 2 weeks and two (20%) had an abnormal neurodevelopmental outcome at 2 years. The authors conclude that premature cessation of cooling therapy in babies with mild neonatal encephalopathy does not exclude residual brain injury and adverse long-term neurodevelopmental outcomes.

Caffeine ameliorates hyperoxia-induced lung injury by protecting GCH1 function in neonatal rat pups
Jing X, Huang YW, Jarzembowski J, et al. *Pediatr Res*.

Early caffeine treatment is associated with a decreased risk of bronchouplmonary dysplasia, although the mechanisms of this potential benefit are not clear. In a pre-clinical study, caffeine started at 2 days of age was compared to placebo in a hyperoxia rodent model. Rat pups treated with caffeine had increased cyclic AMP and phosphorylated endothelial nitric oxide synthase levels, suggesting caffeine may protect hyperoxia-mediated lung injury through improvements in eNOS activity.

Neurodevelopmental outcomes of extremely low birthweight infants randomised to different PCO2 targets: the PHELBI follow-up study (PDF)
Thome UH, Genzel-Boroviczeny O, Bohnhorst B, et al. *Arch Dis Child Fetal Neonatal Ed*.

Permissive hypercarbia is increasingly accepted to reduce ventilator induced lung injury. However, there have been concerns about adverse cerebral effects of hypercarbia during the first few days of age, when

Delayed umbilical cord clamping at <32 weeks' gestation: implementation and outcomes
Rhoades JS, Bierut T, Conner SN, et al. *Am J Perinatol*.

This retrospective cohort study sought to evaluate the implementation of a delayed umbilical cord clamping (DCC) protocol for neonates <32 weeks and to evaluate the impact of DCC on maternal outcomes and on the ability to obtain umbilical cord blood gases. Implementation of a DCC protocol for preterm neonates was feasible and successful. No increase in maternal risk or a decrease in the ability to obtain umbilical cord blood gases following DCC was noted.

Procalcitonin-guided decision making for duration of antibiotic therapy in neonates with suspected early-onset sepsis: a multicentre, randomised controlled trial (Neopins)
Stocker M, van Herk W, El Helou S, et al. *Lancet*.

In a randomized controlled intervention trial, neonates of gestational age 34 weeks and older, with suspected early onset sepsis and requiring antibiotics were stratified into 2 groups – procalcitonin guided decision-making or standard care-based antibiotic treatment. For the procalcitonin group, the duration of antibiotic therapy was reduced (55.1 h vs 65 h). Non–inferiority for re-infection could not be shown due to the low occurrence of re-infections hence concluding that procalcitonin-guided decision-making was superior to standard care in reducing antibiotic therapy in neonates with suspected early-onset sepsis.

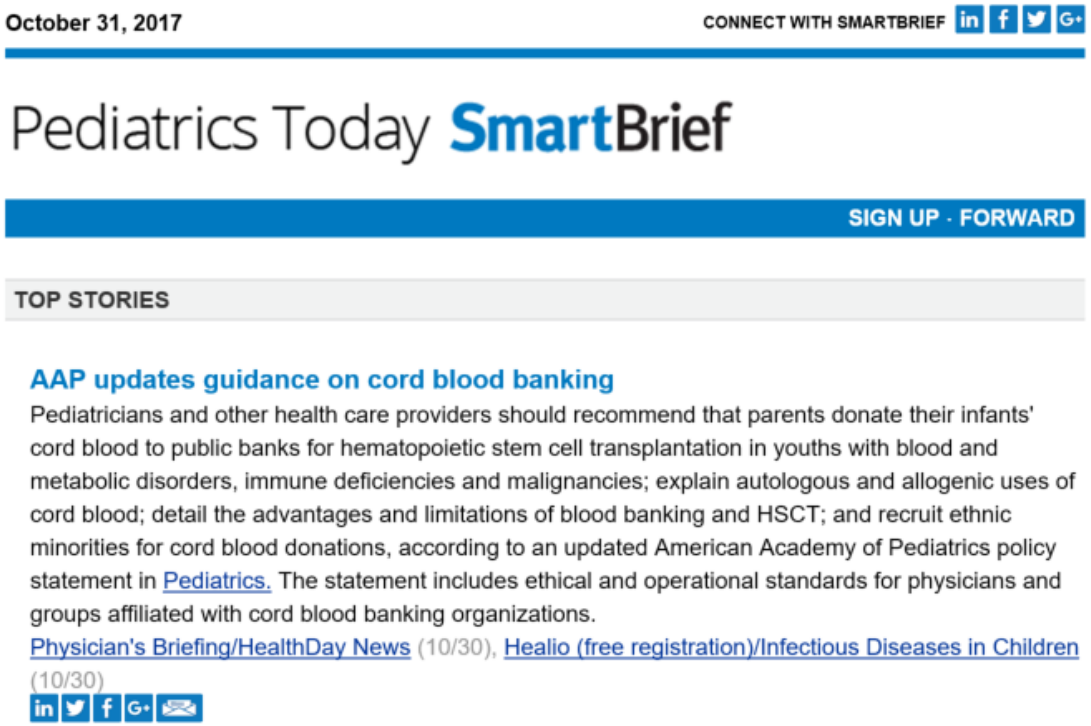
Safety of moderate hypothermia for perinatal hypoxic-ischemic encephalopathy: a meta-analysis
Zhang W, Ma J, Danzeng Q, et al. *Pediatr Neurol*.

The authors investigated the safety of therapeutic hypothermia during intervention in infants with hypoxic-ischemic encephalopathy (HIE). Thirteen trials, including 1806 infants with HIE, containing information on safety and efficacy variables, were included in this meta-analysis. The authors conclude that in infants with HIE, the application of therapeutic hypothermia increases the risk of thrombocytopenia and cardiac arrhythmia during intervention.

OTHER NOTEWORTHY PUBLICATIONS – September, 2017

Pediatrics
Vaccine education during pregnancy and timeliness of infant immunization
https://www.ncbi.nlm.nih.gov/pubmed/28821625
Racial/ethnic disparity in NICU quality of care delivery
https://www.ncbi.nlm.nih.gov/pubmed/28847984
Executive function and academic outcomes in children who were extremely preterm
https://www.ncbi.nlm.nih.gov/pubmed/28853418
Very preterm birth and parents' quality of life 27 years later
https://www.ncbi.nlm.nih.gov/pubmed/28798147
Age at intervention for permanent hearing loss and 5-year language outcomes
https://www.ncbi.nlm.nih.gov/pubmed/28864712
Factors associated with choice of infant sleep position
https://www.ncbi.nlm.nih.gov/pubmed/28827382
Elimination of perinatal hepatitis B: Providing the first vaccine dose within 24 hours of birth (PDF)
http://pediatrics.aappublications.org/content/pediatrics/140/3/e20171870.full.pdf

SmartBrief



October 31, 2017

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Pediatrics Today SmartBrief

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TOP STORIES

AAP updates guidance on cord blood banking

Pediatricians and other health care providers should recommend that parents donate their infants' cord blood to public banks for hematopoietic stem cell transplantation in youths with blood and metabolic disorders, immune deficiencies and malignancies; explain autologous and allogenic uses of cord blood; detail the advantages and limitations of blood banking and HSCT; and recruit ethnic minorities for cord blood donations, according to an updated American Academy of Pediatrics policy statement in Pediatrics. The statement includes ethical and operational standards for physicians and groups affiliated with cord blood banking organizations.

Physician's Briefing/HealthDay News (10/30), Healio (free registration)/Infectious Diseases in Children (10/30)

AAP, ACC issue joint recommendations on managing children with CHD

The American Academy of Pediatrics and the American College of Cardiology released a joint policy statement in Pediatrics with guidelines to help primary care providers and medical homes better manage youths with congenital heart disease. "Care and support provided by the PCP/MH, as outlined in the recommendations, are invaluable for improved outcomes throughout the patient's life span," according to the statement.

Physician's Briefing/HealthDay News (10/30)

Schedule time to review the literature

Overview

- Finding a knowledge gap to address
  - How to know and keep up with the literature
- **Asking the right question**
  - **Making your question a SMART question**
- Putting your question onto paper
  - Developing specific aim(s)
- Getting funding
  - Fellow research fund (max of $ 5,000)

Asking the right question

- Strong background knowledge of field is critical
- Will provide awareness of key gaps
  - Your mentor and faculty can help with this

Transfusion Medicine Reviews 30 (2016) 165–173

Contents lists available at ScienceDirect

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Research Opportunities to Improve Neonatal Red Blood Cell Transfusion☆,☆☆

Ravi Mangal Patel [a,*], Erin K. Meyer [b], John A. Widness [c]

[a] Department of Pediatrics, Emory University School of Medicine and Children's Healthcare of Atlanta, Atlanta, GA
[b] Departments of Pathology and Pediatrics, The Ohio State University College of Medicine and Nationwide Children's Hospital, Columbus, OH
[c] Department of Pediatrics, Roy J. and Lucille A. Carver College of Medicine and University of Iowa Children's Hospital, Iowa City, IA

SMART question

Specific

Measurable

Attainable / Achievable

Realistic / Relevant

Timely

Specific question

Population

Intervention/exposure

Comparison/control

Outcome

Time of assessment

Measurable question

Population

Intervention/exposure

Comparison/control

Outcome

Time of assessment

Attainable / Achievable, Realistic

Population

Intervention/exposure

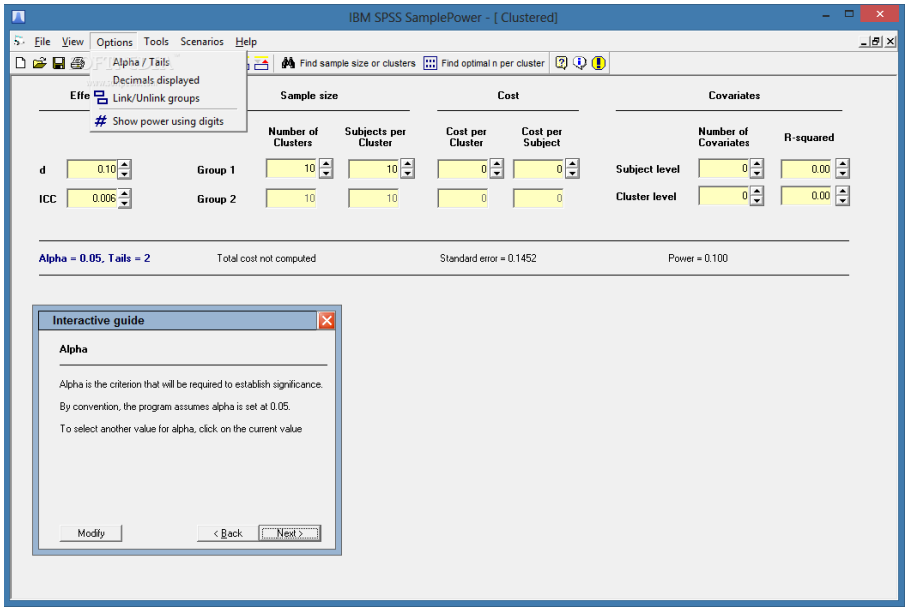
Comparison/control

Outcome

Time of assessment

Attainable / Achievable, Realistic

- Power analysis can be very helpful
  - SPSS Sample Power available at software.emory.edu
- Prospective studies challenging, unless nested within an ongoing study or planned in advance



Relevant question

Will your research help:

- researchers advance the field, guide new studies
- Improve clinical care
- Inform patients regarding prognosis or outcomes

Timely

- Can you finish this during your fellowship
- Is this a relevant question to ask now

- Create a timeline for your study
  - Developing a concept
  - Submitting to IRB(s)
  - Collecting data (or enrolling patients, obtaining samples)
  - Analysis
  - Abstract submission deadline

Overview

- Finding a knowledge gap to address
  - How to know and keep up with the literature
- Asking the right question
  - Making your question a SMART question
- **Putting your question onto paper**
  - **Developing specific aim(s)**
- Getting funding
  - Fellow research fund (max of $ 5,000)

Specific Aims Page

- Write what you want to do on one page
- Revise
- Refine
- Revise
- Share with others

- **Most important part of a grant application**

Anatomy of a Specific Aims page

- Introductory Paragraph
- Second Paragraph
- The Aims
- Final Summary Paragraph

http://www.biosciencewriters.com/NIH-Grant-Applications-The-Anatomy-of-a-Specific-Aims-Page.aspx

Anatomy of a Specific Aims page

- Introductory Paragraph
  - First sentence/hook (disease focused)
  - What is known
  - Gap in knowledge
  - The critical need

Viruses are thought to be involved in 15% to 20% of human cancers worldwide, thus providing critical tools to reveal common mechanisms involved in human malignancies. As the etiologic agent of adult T cell leukemia/lymphoma (ATLL), human T cell leukemia virus type I (HTLV-1) is just such a virus. HTLV-1 encodes a potent oncoprotein, Tax, which regulates important cellular pathways including gene expression, proliferation, apoptosis, and polarity. Over the years, Tax has proven to be a valuable model system in which to interrogate cellular processes, revealing pathways and mechanisms that play important roles in cellular transformation. Although the Tax oncoprotein has been shown to transform cells in culture and to induce tumors in a variety of transgenic mouse models, the *mechanism by which Tax transforms cells is not well understood*. A large number of Tax mutants have been generated and their biological activities have been thoroughly characterized, primarily in cell culture systems. *Currently, a major obstacle in the field* is that the transforming activity of Tax mutants cannot be compared using available transgenic models due to random transgene integration sites, variable transgene copy number, and inconsistent transgene expression levels, making it difficult to link the biological activities of Tax mutants with their transforming potential.

Color Key: Hook | Known Information | Gap in Knowledge | Critical Need

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Anatomy of a Specific Aims page

- Second paragraph
  - Long-term goal
  - Objective
  - Rationale
  - Central hypothesis
  - Qualifications / Pay-off

To solve this problem we will develop an innovative mouse model system in which to study Tax tumorigenesis using targeting vectors containing wild-type or mutant Tax genes that are silenced by a preceding floxed stop cassette. These vectors will be knocked in to the *Rosa26* locus of recipient mice by recombination. After crossing these mice with Lck-CRE mice, the stop cassette will be specifically excised in developing thymocytes where the Lck promoter is active, allowing conditional expression of wild-type or mutant Tax proteins in T cells, the natural target of HTLV-1 infection. The feasibility of our proposed mouse model is supported by the fact that Lck-Tax transgenic mice have been developed and produce a leukemia that closely resembles ATLL. Thus, targeting of Tax expression in cells in which the Lck promoter is active is expected to produce a similar disease in our model. In our improved model system, insertion into the *Rosa26* locus will eliminate random integration sites and standardize gene copy number resulting in consistent levels of wild-type and mutant Tax protein expression.

Color Key: Long-term Goal | Proposal Objective | Rationale | Hypothesis | Pay-off

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Anatomy of a Specific Aims page

- The Aims
  - Specific statements about how you will test your hypothesis
  - Ideally not dependent on one-another
  - Number of aims depends on scope of project
  - Should tie into you larger hypothesis

Aim 1 will establish an innovative mouse model for HTLV-1 Tax tumorigenesis. Targeting vectors containing silenced wild-type or mutant Tax genes will be knocked in to the Rosa26 locus of C57BL/6 mice. These mice will then be crossed with homozygous Lck-CRE mice, thereby excising the stop cassette and generating mice that express wild-type or mutant Tax proteins specifically in T cells.

Aim 2 will examine the effect of mutations that disable specific biological functions of Tax on Tax-mediated tumorigenesis. Tax can bind to and regulate the activity of members of the SRF, CREB, NF-kB and PBM protein families, each of which has been implicated in oncogenesis. Mice established in Aim 1 will allow us to compare for the first time the tumorigenic potential of wild-type and mutant Tax proteins in an effort to identify pathways that are required for Tax tumorigenesis.

Color Key: Aim Title | Experimental Strategy | Outcome or Impact

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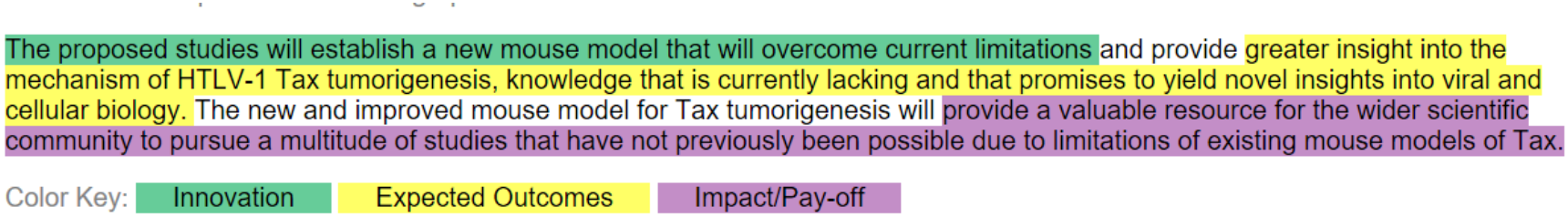
Anatomy of a Specific Aims page

- Final Summary Paragraph
  - Highlight innovation
  - Expected outcomes
  - Impact



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Example – Specific Aims page

SPECIFIC AIMS

Necrotizing enterocolitis (NEC) is the most common serious gastrointestinal complication in very low birth weight (VLBW) infants and case-fatality rates range from 20-30%. We recently found a 35% increase in NEC-related mortality from 2000-2003 to 2008-2011 in a multicenter US cohort of extremely preterm infants, highlighting the urgent need for new prevention strategies. A meta-analysis of observational studies has determined that red blood cell (RBC) transfusion is a potential etiologic factor for NEC, although the underlying mechanisms are unclear. *In a separate preliminary analysis of 598 VLBW infants, we reported that severe anemia (Hgb ≤8g/dL, HR 6.0; 95% CI 2.0-18.0) is an independent risk factor for NEC.* Further, our group has shown that infants who develop NEC following RBC transfusion have paradoxical decreases in gut oxygenation (Gut-rSO_2) measured by near-infrared spectroscopy (NIRS). Our preliminary data suggest that those infants with severe anemia prior to RBC transfusion have a marked, unexpected, paradoxical decline in gut oxygenation. As changes in Gut-rSO_2 occur prior to the onset of NEC symptoms and low Gut-rSO_2 is also seen in infants with severe anemia, measuring Gut-rSO_2 offers a method to potentially identify those infants at high risk of developing NEC. This, in turn, offers a novel risk stratification approach for the evaluation of potential risk factors for NEC and for the testing of novel preventative therapies. The most widely studied and promising treatment to prevent NEC is probiotic therapy, which is thought to induce mesenteric vascular relaxation through production of dietary amines. In addition, probiotic therapy increases intestinal blood flow velocity in preterm infants. This compelling evidence is the rationale for our proposed study to test the effect of probiotic therapy on gut oxygenation and transfusion-related NEC in VLBW infants.

The overarching hypothesis is that probiotic therapy prevents NEC by reducing aberrant declines in gut oxygenation from RBC transfusion given to infants with severe anemia. This observational study will also allow us to test in an exploratory fashion the impact of repeated donor exposure from single RBC units, which may be an important and potentially modifiable risk factor for NEC. *The specific goals are to create new knowledge of the physiological effects of probiotic therapy on gut oxygenation* ***(Aim 1)*** *and identify donor RBC risk factors that are associated with NEC* ***(Aim 2)****.*

Specific Aim 1. To determine the effect of treatment with the probiotic *Lactobacillus rhamnosus* GG (*LGG*) on intestinal oxygenation in transfused VLBW infants.

Rationale: A meta-analysis of 24 trials found that probiotics reduce the incidence of NEC. We've shown that infants with NEC have abnormal declines in Gut-rSO_2 prior to onset of disease. To determine if these abnormal declines in Gut-rSO_2 can be prevented by *LGG* treatment, we will prospectively enroll and monitor VLBW infants receiving *LGG* (n=26) and compare them to a historical cohort of *LGG*-untreated infants (n=24). This study will leverage the resources of a recently initiated, NHLBI-funded prospective study (P01; PI John Roback), which will use NIRS to understand the effects of metabolomics profiles of donor RBCs. This aim will:

a) Quantify the association between *LGG* treatment and mean difference in Gut-rSO_2 after RBC transfusion (primary endpoint) to determine if probiotics can prevent paradoxical changes in gut-rSO_2.
b) Explore subgroup differences in Gut-rSO_2 change between repeat single vs. new donor transfusions.
c) Compare pre-transfusion baseline Gut-rSO_2 between *LGG* treated and untreated infants with anemia to test the hypothesis that *LGG* treatment is associated with higher pre-transfusion Gut-rSO_2.

Specific Aim 2. To determine if repeated single donor RBC transfusion is a risk factor for NEC.

Rationale: Giving multiple transfusions from a single donor minimizes blood donor exposure and reduces the risk of transfusion-transmitted infections. However, there may be adverse effects of this common blood banking practice, such as exposure to aged blood, which may increase the risk of NEC. To test the hypothesis that the risk of NEC is increased with repeat donor exposure, we will use a recently completed NHLBI P01-funded cohort study led by Cassandra Josephson, MD (primary mentor) that enrolled 598 VLBW infants to conduct secondary epidemiological analyses to:

a) Investigate 1,642 RBC transfusion events, with a range of 0 to 12 repeat donor exposures per infant, to estimate the adjusted relative risk of NEC per each additional RBC transfusion from the same donor.
b) Determine if VLBW infants with fewer total RBC donor exposures receive donor RBCs that have been stored for longer durations.
c) Explore the risk of repeated single donor RBC transfusion on neonatal morbidity, including bronchopulmonary dysplasia and retinopathy of prematurity.

Completion of the study aims will allow me to develop needed expertise in transfusion medicine and skills in advanced biostatistics, clinical trial design and execution, and study team management. This will prepare me for an independent R01/U01-funded clinical research career focused on developing therapies to prevent NEC.

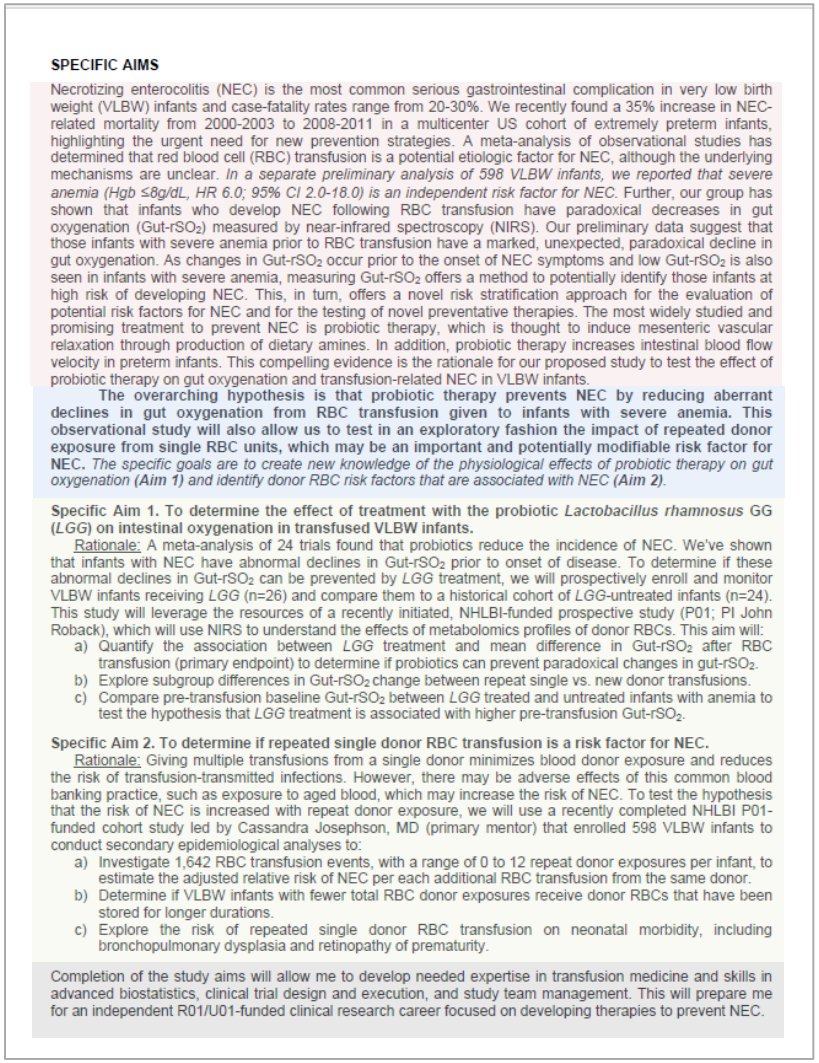
Example – Specific Aims page

Paragraph 1
- Hook/first sentence
- What is known
- Gap in knowledge

Paragraph 2
- Overarching hypothesis

Specific Aims
- Including rationale

Final paragraph
- Expected outcomes
- Pay-off



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- Hook/first sentence
- What is known
- Gap in knowledge

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Example – Specific Aims page

Paragraph 2

- Overarching hypothesis

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Example – Specific Aims page

Specific Aims

- Including rationale

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Another example

Final paragraph

- Expected outcomes
- Pay-off

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Overview

- Finding a knowledge gap to address
  - How to know and keep up with the literature
- Asking the right question
  - Making your question a SMART question
- Putting your question onto paper
  - Developing specific aim(s)
- **Getting funding**
  - **Fellow research fund (max of $ 5,000)**

Fellow & Resident Research Funds

Fellow & Resident Research Funds

1. Fellow Research Fund
    - For MD and MD/PhD fellows within the Department of Pediatrics or in an academic department within The Pediatric Center, Inc.* Typical applicants are late 1st year and early 2nd year fellows, but any stage MD and MD/PhD fellow may apply.
    - Budget:
        - Maximum of $5,000 for one year may be requested, but smaller budget requests are encouraged
        - Dollars requested must be well justified
        - Possibility for second year of funding based on demonstrated progress
2. Resident Research Fund
    - For medical residents within the Department of Pediatrics. Typical applicants are 2nd and 3rd year residents, but any pediatric resident may apply.
    - Budget:
        - Maximum of $2,500 for one year may be requested, but smaller budget requests are encouraged
        - Dollars requested must be well justified
        - Possibility for second year of funding based on demonstrated progress

Application Deadline: Friday, November 17, 2017 at 6:00 PM

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Application Deadline: Friday, November 17, 2017 at 6:00 PM

Application

http://www.pedsresearch.org/research/resources/funding/pilot-grant-programs/fellow-resident-research-awards

Deadline to Apply: Friday, November 17, 2017 at 6:00 PM

Applications must include:

- NIH-style biosketches for the principal investigator and mentor(s)
- Specific aims/research goals (max. 1 page)
- Methods/experimental design (max. 2 pages plus references)
- Impact and relevance to child health (2-4 sentences)
- Brief explanation for how the funds will facilitate your research objectives
- Project time period, detailed line item budget in required template, and detailed budget justification
- The end product that will communicate the results of the project. This could be presenting an abstract at a regional or national meeting in your field, a manuscript or even a resulting grant application to further the research project.

Application questions

General application questions

- Jennifer Villasenor, RN, Lead Program Coordinator
- jkenny2@emory.edu

Grant writing questions

- Stacy Heilman, PhD, Director, Pediatric Research Operations
- stacy.heilman@emory.edu

Overview

- Finding a knowledge gap to address
  - How to know and keep up with the literature
- Asking the right question
  - Making your question a SMART question
- Putting your question onto paper
  - Developing specific aim(s)
- Getting funding
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Thank you.

@ravimpatelmd
rmpatel@emory.edu

Children's Healthcare of Atlanta

EMORY UNIVERSITY