5 TIWIKLY
5 Things I Wish I Knew Last Year (2017)

Louis Kuritzky, MD
Clinical Assistant Professor Emeritus
Department of Community Health and Family Medicine
University of Florida, Gainesville
(352)-377-3193 Phone/FAX
Lkuritzky@aol.com

Objectives

• Identify a therapeutic role for dopaminergic augmentation treatment in depression
• Employ successful alternative treatments for rosacea
• Recognize a highly successful intervention for Schamberg’s disease
Disclosures

Louis Kuritzky, MD has NOTHING TO DISCLOSE

In reference to the content of this presentation

5 TIWIKLY 2017 Score Card

<table>
<thead>
<tr>
<th>Item #</th>
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ARS: What to do about this facial flushing?

A 36 y.o. has failed multiple treatments to reduce facial flushing attributed to rosacea. She is frustrated that people keep inquiring about excessive alcohol intake, since she does not drink. She has failed multiple “traditional” treatments. What might help?

a) Niacin (nicotinic acid) 2 g daily p.o.
b) Nifedipine 60 mg po
c) She should stop lying about being a non-drinker & sober-up
d) Carvediol
Pronounced facial flushing and persistent erythema of rosacea effectively treated by carvedilol, a nonselective β-adrenergic blocker

Chia-Chi Hsu, MD, Julia Yu-Yun Lee, MD

Journal of the American Academy of Dermatology
Volume 67, Issue 3, Pages 491-493 (September 2012)
DOI: 10.1016/j.jaad.2012.04.017

Erythematotelangiectatic Rosacea
Endorsed Treatments

- Severe Erythematotelangiectatic Rosacea
  - B-Blockers
  - Clonidine
  - Naloxone
  - Ondansetron
  - Endoscopic Thoracic Sympathectomy

ETR: Carvedilol Case Series

Study: ETR Case series (n= 11)
Based upon initial success in 1 case
Previous Failed Rx with ≥1 of
- Doxycycline
- Corticosteroids
- Propranolol
- Clonidine
- Metronidazole

Rx: carvedilol 3.125 mg/d → 31.25 mg/d divided b.i.d.-t.i.d. added to existing Rx x 1 yr

Metrics:
- Photo-based facial erythema
- Cheek temperature
- VAS 0-10 (pt assessment)

Results
“All patients experienced significant clinical improvement within 3 weeks (range 3-21 days, mean 10.5 days).”
ETR: Carvedilol Case Series

Results

<table>
<thead>
<tr>
<th>Carvedilol</th>
<th>Cheek Temperature</th>
<th>VAS: Baseline</th>
<th>VAS End of Rx</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2.2°C</td>
<td>8.4/10</td>
<td>2.1/10</td>
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*all results are MEAN


ETR: Carvedilol Case Series

Discussion

“Carvedilol appears special among β-blockers in its significant antioxidant and anti-inflammatory properties, which may explain its efficacy in treating ETR in the current study.”

ARS: Osteoporosis Risk Stratification: MEN

A 62 y.o. uninsured MAN weighs 180# and does not have COPD. His 72 y.o. brother, who has COPD, 160#, just sustained an osteoporotic hip fracture. He would like to avoid the expense of a DEXA Scan. Based on this information alone, what is the likelihood that a DEXA scan will show osteoporosis?

a) <2%
b) 10%
c) 25%
d) >50%
OSPS in Men: Foundations

- Men uncommonly screened, even on chronic steroids, after fragility Fx
- #3 rank for hospital days in men
- Male mortality > female for in-hospital post-Fx mortality
- 1-yr post-Fx mortality
- USPSTF 2011 Male OSPS Statement: "I"


MORES Score

<table>
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<tr>
<th>Risk Factor</th>
<th>Points</th>
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<tbody>
<tr>
<td>Age (years)</td>
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<tr>
<td>≤55</td>
<td>0</td>
</tr>
<tr>
<td>56-74</td>
<td>1</td>
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<tr>
<td>≥75</td>
<td>2</td>
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<tr>
<td>Weight (kg)</td>
<td></td>
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<tr>
<td>≤70</td>
<td>6</td>
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<tr>
<td>71-80</td>
<td>4</td>
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<tr>
<td>&gt;80</td>
<td>0</td>
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<tr>
<td>COPD</td>
<td>3</td>
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+ Screen: ≥6 points


MORES Score Validation Trial

- Study: Men age ≥ 60 yrs attending Primary Care clinic for ‘usual care’
- Exclusions:
  - Hx of OSPS or bone disease (e.g., Pagets)
  - On any OSPS Rx for any indication
  - Bilateral Hip replacement surgery
  - Weight >300# (DEXA scanner limit)
- Metric: DEXA after MORES Score
- Outcome: MORES Sensitivity & Specificity

**MORIES Score Validation Trial Results**

“Men who screened negative with the MORES had only a 1% chance of having osteoporosis.”


**ARS: A Young Woman with Moderate-Severe Depression**

Tiffany is a 32 year old woman with moderate-severe depression (Hamilton Depression Rating Scale score = 24). She wants to know if there are any non-drug Rx's that are effective for depression. Your evidence-based YES answer includes:

a) Systemic Vitamin D  
b) Exercise  
c) Omega 3 Fatty Acids  
d) Steam-bath therapy

**Exercise & Depression**

“Although numerous treatments are available for MDD, selecting among the options remains the biggest challenge facing clinicians.”

**Exercise & Depression: Premises**

- Exercise ↓ incidence mood/anxiety disorders
- MDD: Efficacy of exercise as
  - monotherapy: YES
  - augmentation Rx: YES
- May also benefit insomnia, cognitive Fx
- Doesn't work for everyone


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**Exercise for Depression:**

Is There an EASY Way to Determine in Which Patients it will Work?

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**Affect Following First Exercise Session as a Predictor of Treatment Response in Depression**

Anisha M. Suterwala, BA, Chad D Rethorst, PhD, Thomas J Carmody PhD, Tracy I Greer, PhD, Bruce D Grannemann, MA, Manish Jha, MD, and Madhukar H Trivedi, MD

Response to 1st Exercise Session Predicts Success in Depression

**Study:** RCT MDD (N=122)

**Inclusion**
- Age 18-70
- Nonpsychotic MDD as per DSM-IV
- ≥ 6 weeks adequate dose SSRI
- Moderate residual Sx (HDR-S ≥ 14)
- Not already engaged in regular exercise


Response to 1st Exercise Session Predicts Success in Depression

**Rx:** Moderate-vigorous exercise X 12 weeks
- 'Public Health' dose: 180 mins/week
- 'Low' dose: 45 mins/wk

**Metric:** PANAS (Positive and Negative Affect Scale) after 1st session

**Outcome:** Relationship between PANAS on Day 1 and end-of-trial depression status


Results

“The PANAS composite affect score predicted change in IDS-C score as well as Rx response and remission for those in the high-dose group but not in the low-dose group.”

**Response to 1st Exercise Session Predicts Success in Depression**

**Conclusions**

“These findings suggest that the composite positive affect following the first exercise session has clinical utility to predict Rx response to exercise in depression and match the ‘right patient’; with the ‘right Rx’.”


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**Gingko Biloba for Cognitive Edge**

A 64 y.o. woman with T2 DM stopped her glimepiride 2 months ago because of her limited income. She takes a variety of supplements, e.g., multivitamins, omega-3 fatty acids, and gingko biloba, which she maintains has been proven to maintain mental sharpness. Your evidence-based response:

a) Gingko is a good investment of her $$; KOKO
b) Omega-3-FA enhance the + effects of gingko

c) A large RCT did not confirm + gingko effects for cognition
d) Favorable cognitive effects have only been seen in persons over age 75

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**Trends in Dietary Supplement Use Among US Adults From 1999-2012**

JAMA | Original Investigation

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Supplements: Majority Rules?
Interviews with NHANES Adults (n = 37,958)

“Overall, the use of supplements remained stable between 1999-2012, with 52% of US adults reporting use of any supplements in 2011-2012.”

Kantor ED et al JAMA 2016;316(14):1464-1474

The Supplement Paradox
Negligible Benefits, Robust Consumption

JAMA 2016;316(14):1453-1454
What Paradox?

“... a steady stream of high-quality studies evaluating dietary supplements has yielded predominantly disappointing results about potential health benefits, whereas evidence of harm has continued to accumulate.”

Cohen PA JAMA 2016;316(14):1453-1454

Are You Prepared?

“Moreover, even after high-quality studies that show no meaningful clinical differences between supplements and placebos are published, the law provides manufacturers latitude to continue advertising their products based on earlier, low quality data.”

*emphasis added*

Cohen PA JAMA 2016;316(14):1453-1454

Are You Prepared?

“For example, Ginkgo biloba continues to be sold ‘to support mental sharpness’ despite a large, high-quality NIH-funded study that found evidence to the contrary.”

*emphasis added*

Cohen PA JAMA 2016;316(14):1453-1454
Risks of Herbal/Dietary Supplements

“Herbal or Dietary supplements are the fourth most common cause of drug-induced acute hepatic necrosis requiring liver transplantation in the U.S.....”

Nogrady B. Frontline Medical News 2017 (March 15): p 5

- Study: urgent liver transplant registry data
- Population: Adults (n = 2,408) mean age 36.8
  - Drug induced = 625
  - mean Herbal or dietary Supplements = 21
- Example agents cited: Lipolyze, Hydrocut, OxyElite Pro

Nogrady B. Family Practice News 2017 (March 15): p 5
**ARS: Starting A Combined Oral Contraceptive**

Your Monday morning patient, Martina is a 19 yo woman who has elected to begin a combined oral. Her last menstrual period ended 10 days ago. **When/how should she start her pills?**

a) This upcoming Sunday  
b) The first Sunday after her next menses begins  
c) Today  
d) On the first day of her next menses

**Immediate vs 'Conventional' OC Initiation**

“The conventional approach to initiating OCs is to start during the menstrual period.”

**Rationale**

- Patient not pregnant
- Ovulation inhibited from 1st cycle
- Minimizes disruption of bleeding pattern


**Risks May Be an Underestimate**

“The authors suggested the true figure for herbal/dietary supplement-induced liver transplantation may be underestimated, pointing to the fact that in this study a further 154 cases were recorded as drug-induced injury, but no drug was listed.”

Nogrady B. Family Practice News 2017 (March 15): p5
Immediate vs ‘Conventional’ OC Initiation Problems

- Up to 25% of recipients do NOT start after waiting till next menses. WHY?
  - Pregnancy
  - Changes in motivation
  - Confusion on when/how to start
  - Forgetting
  - Fear of side effects

“Quick Start” Method for OC Initiation

- Woman takes first pill observed in clinic
- Continues at home
- Condom back-up contraception X 7 days

But does this method result in more irregular bleeding, reportedly the most common reason for OC discontinuation?

“Quick Start” OC Initiation: A Clinical Trial

- RCT: adult women age 18-35 (n=113)
- Inclusion
  - Regular menses X 12 months
  - No recent use of hormonal contraception
  - If previously pregnant, >2 menses post-partum
  - No EC in current menstrual cycle
  - Negative pregnancy test
- Exclusion: unprotected sex in prior 10 days
“Quick Start” OC Initiation: A Clinical Trial

- Method: QS vs CS X 90 days
- Rx: 35 mcg ethinyl estradiol combination OC pill
- Bleeding pattern monitored by diary
- Outcomes:
  - Patient satisfaction
  - Bleeding Patterns


<table>
<thead>
<tr>
<th>All results over a 90-day interval</th>
<th>Quick Start</th>
<th>Conventional Start</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td># spotting days</td>
<td>8.6</td>
<td>10.1</td>
<td>NS</td>
</tr>
<tr>
<td>&gt;4 spotting episodes</td>
<td>20.6%</td>
<td>26.8%</td>
<td>NS</td>
</tr>
<tr>
<td>Prolonged bleeding</td>
<td>22.2%</td>
<td>24.4%</td>
<td>NS</td>
</tr>
<tr>
<td>Amenorrhea</td>
<td>0%</td>
<td>0%</td>
<td>NS</td>
</tr>
<tr>
<td>Bleeding Pattern Acceptable</td>
<td>46%</td>
<td>43.9%</td>
<td>NS</td>
</tr>
<tr>
<td>Same Start Next Time</td>
<td>92.1%</td>
<td>95.1%</td>
<td>NS</td>
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**QS vs CS: Concerns?**

“One concern regarding the QS approach is that if fertilization has [already] occurred... early pregnancy will be exposed to contraceptive hormones. In 40 years’ experience... many women have inadvertently taken OCs during early pregnancy, and substantial evidence exists that this exposure is not associated with adverse pregnancy outcomes.”
QS vs CS: Aside

Drop outs?

“One subject in each group was found to be pregnant during f/u despite a - pregnancy test at enrollment. The CS subject became pregnant while waiting to start OCs; the QS subject was found to be pregnant after she completed taking her first cycle of pills, and then disclosed that she had an episode of unprotected intercourse immediately before enrollment, which she had not previously reported.”


ARS: EARS?

Which of the following is true about this gent?

a) He is probably a better than average listener
b) He is probably a long-term, high-volume Wax Museum donor
c) He has a family history of progeria
d) He has increased probability of CAD

Diagonal ear lobe crease (DELC) is a wrinkle-like line extending diagonally from the tragus across the lobe to the rear edge of the auricle of the ear. This sign was first associated with CAD by Frank in 1973.
“Controversy exists concerning the relation between diagonal ear lobe crease and CAD”

- Study: aSx Adults with no Hx CAD (n=430)
- Metric: Coronary CT Angiography
- Endpoints:
  - Any CAD
  - Significant CAD (≥50% stenosis)
  - Multivessel disease
  - # segments with plaque
Frank’s Sign: Outcome

“After adjusting for confounders, DELC remained a significant predictor of all 4 measurements of CAD (Odds Ratio 1.8-3.3, p 0.002-0.017).”


Frank’s Sign: Conclusion

“In conclusion, in this study of patients imaged with CT angiography, finding DELC was independently and significantly associated with ↑ prevalence, extent, and severity of CAD.”


ARS: Asymptomatic Rust-Colored Spots

A 48 y.o. man seeks advice about asymptomatic spots on both lower legs, present for at least 5 years. No other health problems or medications. This is

a) Uniformly fatal guttate melanosis.
b) Schamberg’s Disease
c) Lamivudine toxicity from adulterated cocaine
d) Venous insufficiency
Schamberg’s Disease

• AKA: Progressive pigmented purpuric dermatosis, Purpura Simplex
• Males > Females
• Cause Unknown
• Characteristic feature: “orange-brown, pinhead-sized ‘cayenne pepper’ spots.”
• “Lesions persist, but 67% eventually clear.”

ARS: Schamberg’s Disease

“But Doc, I am embarrassed to wear shorts, people think I have some weird contagious disease. Isn’t there anything I can do to get rid of it?” You might try
a) Pentoxifylline (Trental)
b) Cryotherapy
c) Imiquimod (Aldara)
d) There is no known treatment
Successful treatment of Schamberg’s disease with pentoxifylline
Yuko Kano, MD, Kaiko Hirose, ME, Masaru Ohba, MD, and Tsuyoshi Shibata, MD
Tokyo, Japan
J Am Acad Dermatol 1997;36:827-830

Schamberg’s Disease: Pentoxifylline

- Study: Schamberg’s disease patients (n=3)
- Rx: pentoxifylline 300 mg t.i.d. x 8 weeks
- Site: Tokyo, Japan
- Outcome: all 3 improved; 1 recurrence responded to re-Rx


Schamberg’s: Pentoxifylline Rx x 8 weeks

Before
After

Schamberg’s Disease: Pentoxifylline

Study: Schamberg’s Disease patients (n=30)
Rx: pentoxifylline 400 mg t.i.d. X 9 weeks

<table>
<thead>
<tr>
<th>Improvement</th>
<th>Mild</th>
<th>Moderate</th>
<th>Marked</th>
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<td></td>
<td>4</td>
<td>5</td>
<td>17</td>
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"We conclude that pentoxifylline should be considered as 1st line therapy in all patients with Schamberg’s disease."

Majid RM, Pakistan Assoc Dermatologists 2008;18:97-99

ARS: What’s Causing the Hypomagnesemia

A 32 y.o. woman who presented to the emergency room with extreme fatigue and weakness. Her plasma magnesium level is 1.2 mg/dL (normal range = 1.7 mg/dL – 2.3 mg/dL). Which agent below could have caused this?

a) Roflumilast (Daliresp)
b) Spironolactone (Aldactone)
c) Omeprazole (Prilosec)
d) Amiloride (Midamor)
FDA Drug Safety Communication: Low magnesium levels can be associated with long-term use of Proton Pump Inhibitor drugs (PPIs)

PPIs and Hypomagnesemia

“...FDA is informing the public that prescription proton pump inhibitor drugs may cause hypomagnesemia if taken for prolonged periods of time (in most cases, longer than one year).”

¼ cases Mg++ repletion did not respond
Had to D-C PPI
Pertains to Rx, not OTC

...consider obtaining serum Mg++ levels prior to initiation of prescription PPI Rx in patients expected to be on these drugs for long periods of time, as well as patients who take PPIs with medications such as digoxin, diuretics, or drugs that may cause hypomagnesemia.”


“The mechanism responsible for hypomagnesemia associated with long term PPI use is unknown.”


PPI/Hypomagnesemia Data Set (n = 61)

- Patients on diuretics excluded UNLESS
  - D-C diuretic → no Δ Mg++
  - PPI D-C → ↑ Mg++
- Duration of PPI Rx to produce ↓ Mg++
  - ≥3 months, typically, > 1 year
- post-PPI Mg++ normalization time = 7 d (mean)
- Re-challenge → hypomag at 14 d (mean)

PPIs and Hypomagnesemia
FDA Example (Real) Cases

- 63 y.o. ♀, 67 y.o. ♂
- PPI Rx duration 6 yrs (♀), 11 years (♂)
- Presentation: Seizures
- IV Mg++ could not normalize Mg++ until PPI was stopped


Drugs Associated with ↓Mg++

- Furosemide
- Bumetanide
- Torsemide
- Ethacrynic Acid
- Chlorothiazide
- Hydrochlorothiazide
- Indapamide
- Metolazone


ARS: Residual Depression Sx Despite Escitalopram

A 42 y.o. man was treated for 8 weeks with escitalopram, but has significant residual symptoms (HDRS-17 score = 5). Which treatment might be effective to reduce residual symptoms?

a) Quinine Sulfate
b) Lisdexamfetamine dimesylate (Vyvanse)
c) Pregabalin (Lyrica)
d) Tiotropium bromide (Spiriva)
“A RCT of the Efficacy and Safety of Lisdexamfetamine Dimesylate as Augmentation Therapy in Adults with Residual Sx of MDD After Rx with Escitalopram”


Lisdexamfetamine for MDD Augmentation Rx

- Study: MDD patients with HDRS-17 score ≥4 after 8 weeks of escitalopram 20mg/d (n=239)
- Rx: lisdexamfetamine titrated 20 mg/d → 50 mg/d X 14 weeks
- Outcome: MADRS ∆ baseline-to-week 14


Premises for Augmentation Rx of MDD

- < 1/3 attain remission with SSRI/SNRI
- < 1/3 non-remitters attain remission when augmented with bupropion or buspirone*
- We need to do better

*STAR-D Trial Citalopram-based
Lisdexamfetamine for MDD Augmentation Rx

Conclusion
"...lisdexamfetamine dimesylate augmentation of escitalopram therapy reduced depressive Sx in individuals with MDD who responded inadequately to escitalopram monotherapy."


ARS: Head Lice

A 6 y.o. child was sent home from school because of head lice. Which of the following topical agents has demonstrated the greatest treatment efficacy?

a) 1% Permethrin Cream Rinse (Elimite, NIX)
b) 1% NaCl (LiceFreee Spray)
c) Mupirocin Cream (Bactroban)
d) Fluticasone Spray (Flonase)


Evaluation of the Efficacy and Safety of 1% Sodium Chloride (LiceFreee Spray) against 1% Permethrin Crème Rinse on Head Lice Infested Individuals

Lilia Serrano¹, Lorraine S. Decurz¹, Luisa Phan¹
Pediculosis capitis 1% NACL vs 1% Permethrin Creme

PREMISES
- Various Rx methods: physical removal, combs, topicals, systemic agents
- Typical topical: day 0 and day 7-10
  - Dose #1 kills nymphs/adults but not ova
  - Dose #2: allows hatched ova to kill
- Resistance problems: permethrin sensitivity
  97-99% (1998) → 10-72% > 1999


Pediculosis capitis 1% NACL vs 1% Permethrin Creme

- Study: patients (age 6-43) with at least 10 live head lice identified (n = 42)
- Family screened: enrolled if +
- Outcome: Presence of live lice day 8, 15

Lice-Free at Day 15

How Come NaCl Works At all?

“...in vitro data have shown that the ovicidal activity of gelled 10% NaCl formulation is > that of permethrin.....the in vivo ovicidal efficacy of NaCl Spray has yet to be determined....”


ARS: A Heart Failure Patient Debating an ICD

Your 68 y.o. patient with recently diagnosed HFrEF has been advised by his cardiologist that he should have an ICD placed. Based upon published data, what is the likelihood that an ICD might be inserted in the ABSENCE of good evidence for its use?

a) Duh: 0%; no reputable cardiologist would suggest it without appropriately selecting patients
b) ±5%
c) 10-15%
d) >20%

WHY

Should I Have to Learn All About This Disorder and Its Treatments?.... the Patient Already Has a Cardiologist...Dermatologist...Gastroenterologist...Otherologist
Just Because There Is a Specialist…

Just Because The Consultant is a CARDIOLOGIST Doesn’t Mean That All The Right Stuff Happens All The Time

Why Should I have to Learn All the Treatments?

New Guidance for ICD Implantation Offers Decision Aids for Physicians and Patients

WHY

A 2011 study found 22.5% of 111,707 patients receiving ICDs from 2006-2009 were similar to those who either were excluded from major clinical trials...or shown in other trials not to benefit from ICD therapy.

WHY?

"A 2011 study found 22.5% of 111,707 patients receiving ICDs from 2006-2009 were similar to those who either were excluded from major clinical trials...or shown in other trials not to benefit from ICD therapy."

Temporal Changes in Non-Evidence-Based Implantable Cardioverter-Defibrillators (ICDs) US National Cardiovascular Data Registry

- Any non-evidence-based ICD implant
- Congestive heart failure of chronic duration
- Coronary artery bypass graft with diabetes

Source: JAMA, 2011;305(18):1819-1825

Mitka M. JAMA 2013;309(16):1671-1672
Dear Colleague

Our CHF patient, Mr. X, has asked my opinion about whether he would benefit from having an ICD implanted. According to my review of the literature (NEJM 201X), which I have shared with him, Mr. X does not fall within the guidelines indicating this procedure. Hence, I have advised against it. In the event that you have at hand evidence that supersedes my own, if you would be so kind as to share that with me, I will be happy to review and consider it.

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<td>12) Why We Always Need a Team</td>
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