October 22, 2020

Medical Director on Demand Call

Representatives
- Jan Berger, MD
- Faiyaz Bhojani, MD
- Scott Conard, MD
- Andy Crighton, MD
- Mark Cunningham-Hill, MD
- Chuck Cutler, MD
- Ray Fabius, MD
- Ryan Jackson, MD
- Ron Kline, MD
- Ned Kusti, MD
- Justin Moore, MD
- Suresh Mukherji, MD
- Stan Schwartz, MD
- Bruce Sherman, MD
- Christa-Marie Singleton, MD
Agenda

- Welcome – Scott Conard, MD
- Don't Fall Back on "Flu-VID“
  - COVID-19: Around the world update - Mark Cunningham-Hill, MB ChB (MD), FFOM, FACOEM, Medical Director, Northeast Business Group on Health
  - Flu season: Latest updates - Scott Conard, MD, Medical Director, National Alliance of Healthcare Purchaser Coalitions
  - Importance and Effectiveness of Vaccinations: COVID-19, flu and others - Rita Patel, MD, Pediatric Residency Program Director, Payton Manning Children's Hospital
  - COVID-19 Prevention: Masks, immunity, distance, hygiene, data, etc. - Ray Fabius, MD, Co-founder and President, HealthNeXT
- Open Discussion & Wrap Up
Questions

Raise your hand
Why are we talking about Patient-centered Outcomes Research Institute (PCORI)?

• PCORI'S MISSION IS RELEVANT TO EMPLOYERS
  • PCORI helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high-integrity, evidence-based information that comes from research guided by patients, caregivers, and the broader healthcare community.

• EMPLOYERS ARE A KEY STAKEHOLDER AND PRIMARY FUNDING SOURCE TO PCORI
Why are we talking about Patient-centered Outcomes Research Institute (PCORI)?

**NATIONAL ALLIANCE HAS BEEN DISSEMINATING PCORI FINDINGS FOR OVER 4 YEARS TO ITS' COALITION NETWORK:**
- Increase awareness of PCORI
- Increase employer's utilization of evidence in healthcare decision-making
- Educate employers on why incorporating research in their policies is critical, especially now!

**PCORI COVID-ENHANCEMENT FUNDING IS GAME-CHANGER**
- $110 Million approved for COVID Research
- Employers can benefit from this investment
- National Alliance is recipient of PCORI COVID Enhancement Funding for expanded dissemination through March 2021 – MD on Demand will host two official campaigns including interviews of Principal Investigators of Featured Research Projects.
Examples of PCORI Resources:

• COMPARATIVE EFFECTIVENESS RESEARCH (CER) STUDIES + FINDINGS + PEER REVIEWS

• EVIDENCE SYNTHESIS
  • Evidence synthesis evaluates all relevant completed studies on a particular clinical question to clarify what is known and what evidence gaps still exist. It can yield useful information within a year or two, instead of the three to five years typically required for a new research study.

• PCORI HEALTHCARE HORIZON SCANNING SYSTEM (HCHSS): BI-WEEKLY COVID 19 SCANS
  • The HCHSS COVID-19 supplement scans for, identifies, monitors, and reports on emerging and available COVID-19-related treatments, diagnostics, preventive measures, management strategies, and systems changes with potential for high impact to patient outcomes—for individuals and populations—in the United States in the next 12 months.
PCORI Resource Example

- SEPTEMBER HORIZON SCANNING INCLUDED THIS TABLE:
  - Over 45 Sources with the most relevant COVID-19 information related to patient-centered treatments, interventions, drugs, process, testing and more.
  - Link will be sent to attendees.

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### Appendix A. Scanning Resources for COVID-19

#### Table A.1. Selected Scanning Sources Most Relevant to COVID-19

<table>
<thead>
<tr>
<th>Resource Name</th>
<th>Description</th>
<th>Biologics Biotech</th>
<th>Device</th>
<th>Drug</th>
<th>In Vitro Diagnostics</th>
<th>Procedure/Therapy</th>
<th>Process</th>
<th>Off-label Use</th>
</tr>
</thead>
<tbody>
<tr>
<td>BIOX</td>
<td>Emerging economic and technological trends in the clinical diagnostic market; diagnostics market and reports on regulatory, reimbursement, and policy issues</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Advances in Pharmacy ASHP Daily Briefing</td>
<td>Daily email briefing summarizing key medical and health care news from the previous 24 hours; targeted to health system pharmacists</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>AHA Emerging Science Series</td>
<td>Online forum for late-breaking clinical trials, key updates of previously presented trials, late-breaking science; new analyses or substudies, major bench-to-bedside breakthroughs; and more</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>AMIA</td>
<td>Daily download on the development and application of biomedical and health informatics in the support of patient care, teaching, research and health care administration</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>BioPharma Dive</td>
<td>In-depth journalism and insight into the most impactful news and trends shaping biotech and pharma. The newsletter and</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
<td>x</td>
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<td>x</td>
</tr>
</tbody>
</table>
PCORI-funded Research Study Highlight

• Comparing Patient-Reported Impact of COVID-19 Shelter-in-Place Policies and Access to Containment and Mitigation Strategies, Overall and in Vulnerable Populations
  • The question: How restrictive policies are actually impacting the populations they serve?
  • The Project: A Citizen Science Cohort over 20,000 individuals across the US who are self-reporting daily symptoms of COVID-19, comparing effectiveness of:
    • Impact of different shelter-in-place/reopening policies
    • county-level containment and mitigation strategies at achieving timely access to testing, healthcare, information, and contact tracing
    • accuracy of different algorithms designed to predict risk of infection and severe COVID-19 among patients with symptoms.
  • These findings will be critical to Healthcare Professionals in developing policies for their workforce. Link to study will be sent to attendees.
COVID-19: Global Update

Mark Cunningham-Hill, MB ChB (MD), FFOM, FACOEM
Medical Director
Northeast Business Group on Health
Diversity of Global Experience

Daily new confirmed COVID-19 cases per million people
Shown is the rolling 7-day average. The number of confirmed cases is lower than the number of actual cases; the main reason for that is limited testing.

• Initial peak
• Some secondary breakouts
• Overall successful management of the pandemic

Source: European CDC – Situation Update Worldwide – Last updated 20 October, 10:35 (London time)
Outside of S Africa most of Africa has seen little COVID-19 activity. Reasons include:

• Experience with other infectious diseases
• Government response
• Potential limited testing and/or data reporting
Europe:

- Experiencing a true second wave
South America:
- Varied picture
- Ongoing high level of activity
- Mixed government responses

https://ourworldindata.org/
New confirmed cases of Covid-19 in New York, California, Florida, Texas, North Dakota and Utah

Seven-day rolling average of new cases (per million), by number of days since 0.1 average daily cases (per million) first recorded

Number of days since 0.1 average daily cases (per million) first recorded
Influenza

• Influenza activity currently low
• Expected to increase Q4
• COVID protections may reduce influenza this winter
• Still need to support flu vaccination
Questions
Flu season: Latest updates

Scott Conard, MD
Medical Director
National Alliance of Healthcare Purchaser Coalitions
Flu Season – Looking Back

• Pre and Post Holidays
• Southern Hemisphere
• Flu Vaccine
• What we've seen in US so far in 2020

• Sources:
  • https://www.cdc.gov/flu/weekly/index.htm#ILIMap
  • https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7276009/
Flu Season – Looking Forward

• Implications of flu vaccine for COVID-19
• Getting access
• When you have a flare this fall
• Other thoughts
Vaccines: as much as I can tell you about them in less than 10 minutes

Rita Patel, MD MPH
Pediatric Residency Program Director
Peyton Manning Children’s Hospital
Indianapolis
It all started with milkmaids...

- English doctor Edward Jenner observed that milkmaids who had gotten cowpox did not seem to get smallpox.

- Recruited milkmaid Sarah Nelmes and James Phipps, the 9 year-old son of Jenner’s gardener. Dr. Jenner took material from a cowpox sore on Nelmes’ hand and inoculated it into Phipps’ arm.

- Jenner exposed Phipps a number of times to variola virus, but Phipps never developed smallpox.
A True Success Story

• 1796 Jenner – smallpox
• 1885 Pasteur – rabies
• 1952 Salk and Sabin – polio

Since then vaccines have saved millions of lives and eradicated entire diseases (Smallpox eradicated 1977, Polio in 1991 in the US)

Tetanus
Measles
Percentage of 20 year old women diagnosed with CIN 2 / CIN3+ by birth cohort year

https://vk.ovg.ox.ac.uk/vk/hpv-vaccine
Vaccines routinely given today

- DTaP/TdaP/Td
- IPV
- HIB
- PCV
- Hepatitis B
- Hepatitis A
- MMR
- VZV

- HPV
- Meningococcal ACWY
- Influenza
- Meningococcal B
- PPSV23
- Zoster
So vaccines work…why do we have issues getting people to vaccinate?
Myth: Vaccines aren’t tested

FIGURE 1
Vaccine pipeline: prelicensure and postlicensure vaccine development activities. From Hardt K, Schmidt-Ott R, Glismann S, Adegbola RA, Meurice F. Sustaining vaccine confidence in the 21st century. *Vaccines.* 2013;1(3):204–224. Copyright © 2013 by the authors; licensee MDPI, Basel, Switzerland. Reproduced under the terms and conditions of the Creative Commons Attribution license (http://creativecommons.org/licenses/by/3.0/).
Myth: Vaccines cause autism

- Group of families with kids with autism sought to sue the vaccine manufacturer
- The lawyers funded a study done by Andrew Wakefield which was published in The Lancet in 1998
- That study has fueled much of the argument given by vaccine-hesitant parents, particularly with MMR
- 12 years later...
Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and pervasive developmental disorder in children

A J Walker-Smith, S H Murch, A Anthony, J Linnebank, D M Cockett, M Malick, M Benkendorff, A P Delius, M A Thompson, P Harvey, A Valente, S E Dawkins, J A Walker-Smith

Summary

Background We investigated a consecutive series of children with chronic enterocolitis and regressive developmental disorder.

Methods 12 children (mean age 6 years [range 3–10]; 11 boys) were referred to a paediatric gastroenterology unit with a history of normal development followed by loss of acquired skills, including language, together with diarrhoea and ascitic pain. Children underwent gastrointestinal, neurological, and developmental assessment and review of developmental records. Histology and biopsy sampling, magnetic resonance imaging (MRI), electrophoresis polymorphisms (CEP), and hormone profile were done under sedation. Barium follow-through radiography was done where possible. Biochemical, haematological, and immunological profiles were examined.

Findings Most of the children were asymptomatic at birth and did not present with diarrhoea. Onset of symptoms was at 3–9 years of age, but no granulomas. In one child, diarrhoea developed at age 12 years. Histology showed patchy chronic inflammation in the rectum and colon in 11 children and patchy inflammation of the small intestine in seven, but no granulomas. The median duration of symptoms included: diarrhoea (1 year), malnutrition (6 months), weight loss (1 year), and anal fistula (1 year). There were no focal neurological abnormalities, and all ID8 and LD8 tests were normal. Antibody testing was not significantly raised in any patient and compared with age-matched controls, with negative results in four children who were evaluated.

Interpretation Ileal-lymphoid-nodular hyperplasia was associated with regressive developmental disorder, which was generally associated with EIAV infection. This association was further supported by the analysis of the cases.

Introduction We saw several children who, after a period of apparent normality, lost acquired skills, including language, together with diarrhoea and ascitic pain. They all had gastrointestinal symptoms, including abdominal pain, diarrhoea, and vomiting and some growth failure and weight loss. In some cases, food intolerances. We detected physical signs, and gastrointestinal investigations were undertaken.

Patients and methods 11 children, aged 1–10 years, were seen at the department of paediatric gastroenterology at the Hospital for Sick Children, London. A target of 1000 children was planned, but 11 children were included, all of whom were referred to the department.

Clinical presentations included details of duration and severity of symptoms, and assessment of the children. In 11 children in the study, the examination was performed by the senior clinicians (M.A., M.A.T., and M.W.S.). All patients underwent an extensive diagnostic work-up, which included haematological and biochemical investigations.

Dietary management included dietary adjustments to improve symptoms, especially those associated with food intolerance. All patients were treated with a low-residue diet, and the diet was adjusted according to the individual needs.

Laboratory investigations Serological tests were performed to assess the presence of enteric pathogens, including Salmonella, Shigella, and Campylobacter. Stool samples were tested for Clostridium difficile toxin, and indirect immunofluorescence (IF) was used to detect Campylobacter jejuni and Campylobacter coli in stool cultures.

Results Eleven children were included in the study. All children had a history of chronic enterocolitis, and five children had a history of regressive developmental disorder. The onset of symptoms was at 3–9 years of age. The median duration of symptoms was 1 year. The median duration of diarrhoea was 1 year, and the median duration of weight loss was 6 months. No children had a history of prematurity or low birth weight.

Discussion The findings support the hypothesis that childhood enterocolitis and regressive developmental disorder are related to environmental factors. The association between enterocolitis and regressive developmental disorder is further supported by the analysis of the cases.

Conclusions Ileal-lymphoid-nodular hyperplasia, non-specific colitis, and regressive developmental disorder are associated with childhood enterocolitis. The findings support the hypothesis that childhood enterocolitis and regressive developmental disorder are related to environmental factors. The association between enterocolitis and regressive developmental disorder is further supported by the analysis of the cases.

Correspondence to: A J Walker-Smith
Myth: Vaccines cause autism

• Denmark: Retrospective cohort 537,303 children, 838 with autism, 82% received MMR. No association

• United Kingdom: Incidence of autism before and after MMR vaccine introduction in 1988. Identified 498 cases. No causal relationship

• Montreal: 27,749 kids born 1987-1998 - rate of ASD increased as MMR vaccination rates decreased

NEJM 2002;347:1477
Lancet 1999;353:2026
Pediatrics 2006;118:e139
But the damage was done...
1992 to 2019: Measles is eliminated but bounces back

1995-1998: Measles eliminated
- 1998 False link to autism: British doctor Andrew Wakefield publishes false link between MMR vaccine and autism in Lancet.

1999-2000: Measles eliminated

2001-2014: Measles eliminated
- 2014 Disneyland outbreak: Disneyland outbreak begins in California, capping off year of travel-related measles outbreaks.

2015-2019: Measles eliminated
Vaccine Refusals Fueled California’s Whooping Cough Epidemic

September 30, 2013 · 9:57 AM ET

When the whooping cough vaccine was invented in the 1940s, doctors thought they had finally licked the illness, which is especially dangerous for babies. But then it came roaring back.

In 2010, a whooping cough outbreak in California sickened 9,120 people, more than in any year since 1947. Ten infants died; babies are too young to be vaccinated.
Where are we with a SARS-CoV-2 vaccine?

• **Operation Warp Speed (OWS)** – partnership between Department of Health and Human Services, the Department of Defense, and the private sector

• Goal to safely develop and deliver a vaccine by 2021

• **4 platforms**: mRNA, replication-defective live-vector, recombinant-subunit-adjuvanted protein, attenuated replicating live-vector

• **6 candidates**

Slaoui et al, NEJM August 26, 2020 DOI: 10.1056/NEJMp2027405
Where are we with a SARS-CoV-2 vaccine

- **ACT Accelerator**: WHO and other global agencies collaborating to accelerate development, production, and equitable access to COVID-19 tests, treatments, and vaccines

- **169 COVID-19 vaccine candidates** under development, with 26 of these in the human trial phase

Where are we with a SARS-CoV-2 vaccine

- Two most promising vaccines in phase 3 trials
  - Moderna: mRNA-1273
  - Pfizer/BioNTech: BNT162b2

- Other contenders
  - Novavax: NVX-CoV2373
  - Johnson and Johnson: JNJ-78436735
  - AstraZeneca and University of Oxford: ChAdOx1 nCoV-19

McKeever, Amy National Geographic October 2 2020
Flu Vaccine

- Influenza is a bad disease even in the best of times with millions infected and tens of thousands deaths
- With the threat of a “twindemic”, this year is critical to optimize vaccination rates
- Can get either a trivalent or quadrivalent vaccine
- Immunity kicks in about 2 weeks after administration
- 2018-2019 flu vaccination prevented an estimated 58,000 flu-related hospitalizations.
I don’t get the flu vaccine because...

- I always get the flu after I get the vaccine
  - Your body is making antibody to the vaccine
  - You caught the flu before the vaccine kicked in

- The vaccine doesn’t work
  - Efficacy changes each year, but overall pretty effective (last year 47%)
  - You caught another virus - not all viruses are the flu
I don’t get the flu vaccine because...

- I don’t like getting a vaccine every year
  - The flu virus functionally mutates every year. Right now, we don’t have another way to handle that

- I get the flu all the time – it isn’t so bad
  - Most people get pretty sick from the flu so you may have gotten other viruses
  - Every year is a new virus – are you willing to chance it?

- I would rather get the disease naturally
Take home points

• Vaccines are safe and effective AND are the best tool we have against a lot of bad diseases

• A lot of smart people are extremely motivated to get a vaccine for SARS CoV-2 out ASAP BUT the vaccines are still going through all the same trials as other vaccines before them

• Get your flu shot!!!!!
Benjamin Franklin, a prominent early antivaccination campaigner, regretted his skepticism about vaccination after his 4-year-old son died from smallpox, writing:

“I long regretted bitterly, and still regret that I had not given it to him by inoculation. This I mention for the sake of parents who omit that operation, on the supposition that they should never forgive themselves if a child died under it, my example showing that the regret may be the same either way, and that, therefore, the safer should be chosen.”
"I hate the term anti-vax. It's so negative."

"How about pro-disease."
Prevention in the Age of COVID

Ray Fabius, MD
Co-founder and President
HealthNeXT
CDC Recommendation

COVID-19 Prevention

- Clear message to stay home if you are sick
- Avoid contact with people who are sick
- Maintain screening of those entering workplace
- Require masks in worksite and public settings
- Physically distance from others – adjust workplace
  - Create pods to avoid losing whole departments to the virus
- Clean & disinfect commonly touched objects or surfaces
- Frequently wash hands for 20 seconds with soap & water
  - Post signage in rest rooms
  - Avoid touching eyes, nose, mouth with unwashed hands

- Use alcohol based hand sanitizer with at least 60% alcohol if soap & water are not available
  - Distribute throughout workplace
- Cover your cough or sneeze with a tissue and then rapidly dispose of it
Importance Guidance

Relative Risk of Behaviors

Recognize why it is hard
Isolation can be mitigated while still exercising caution

Focus on others
Civic responsibility to not spread this virus
Commit to caregiving others in need of help

Risk is not all or nothing
Opening the mail versus going to a bar
In Lieu of Cures or Vaccines

**Vitality is the Best Medicine**

- 0 tobacco use
- 1 call a loved one daily
- 3 times a day express gratitude
- 5-9 fruits & vegetables daily
- 7-8 hours of sleep
- 10,000 steps
- 25 BMI
- 30 minutes of exercise
- 100% seat belt use
- 100% vaccination especially flu this year
- 100% have a medical home
- 100% wellness screenings –

**Control your:** cholesterol, fasting blood sugar, blood pressure, BMI with your health care provider
The Coronavirus is not an equal opportunity infection

• More commonly infects the elderly
• More commonly infects the poor
• More commonly infects people of color
• More commonly infects people with health risks and pre-existing conditions
• AND These categories experience more serious consequences such as hospitalization and death as well

The Pandemic is Teaching us the Importance of Social Determinants of Health
During the COVID-19 pandemic, we have learned that underlying health conditions and chronic disease impact resistance and resilience.

COVID-19 **obese** patients under 60 are:
- 1.5x more likely to be hospitalized
- 2x more likely to enter the ICU
- 3x more likely to die

COVID-19 **hypertensive** patients are:
- 1.6x more likely to be hospitalized
- 2x more likely to enter the ICU
- 1.4x more likely to die

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**Emphasizes the importance of taking care our ourselves**
More Important than a Mask: Getting the vulnerable members of the DTE family in the best shape possible to mitigate the mortality from COVID-19

People with pre-existing conditions are at the greatest risk of dying.

Emphasizes the importance of taking care of our loved one
Almost one in four adult workers is vulnerable to severe illness from COVID-19

Emphasizes the importance of taking care of our co-workers
COVID-19 Hospitalization and Death by Race / Ethnicity

Race and ethnicity are risk markers for other underlying conditions that impact health — including socioeconomic status, access to health care and increased exposure to the virus due to occupation (e.g., frontline, essential, and critical infrastructure workers).

<table>
<thead>
<tr>
<th>Rate ratios compared to White, Non-Hispanic Persons</th>
<th>American Indian or Alaska Native, Non-Hispanic persons</th>
<th>Asian, Non-Hispanic persons</th>
<th>Black or African American, Non-Hispanic persons</th>
<th>Hispanic or Latino persons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cases¹</td>
<td>2.8x higher</td>
<td>1.1x higher</td>
<td>2.6x higher</td>
<td>2.8x higher</td>
</tr>
<tr>
<td>Hospitalization²</td>
<td>5.3x higher</td>
<td>1.3x higher</td>
<td>4.7x higher</td>
<td>4.6x higher</td>
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<tr>
<td>Death³</td>
<td>1.4x higher</td>
<td>No Increase</td>
<td>2.1x higher</td>
<td>1.1x higher</td>
</tr>
</tbody>
</table>
400% Accountability

- Take care of ourselves
- Take care of our loved ones
- Take care of our co-workers
- Take care of others in our communities
Impact of Covid 19
Across the Continuum

- Mental Health
- Primary Care
- Chronic Illness
- Critical Care
- Covid Infection

National Alliance of Healthcare Purchaser Coalitions
Driving Innovation, Health and Value

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The Bifurcation of Health Care Delivery
Employer Guidance – “It is safe to access care”
Important Guidance

Promote Well Visit, Immunizations, Preventive Screenings, Chronic Care Management

- Appropriate ER use
- Medical Home
- Build relationship with PCP(s)
- Annual Checkup
- Recommended Vaccines
- Recommended Preventive Screenings
- Biometrics
- Manage chronic conditions
- Medication Adherence
Important Guidance

Encourage Support All Avenues of Resiliency & Stress Reduction

Ways to Reduce Stress

- Keep Wake/Sleep Times Consistent
- Engage in Relaxation
- Exercise
- Do Yoga
- Eat Right
- Meditate
- Have a Hobby You Enjoy
- Take Time Off From the Usual
- Seek Support from Friends and Family

TIPS FOR GETTING BY

- Try to see your experiences as strengths. When bad things happen, you can be either positive or negative, depending on your perspective.
- Learn from others. You are not alone. There may be support groups in your area that can help you cope with stress.
- Look for opportunities to take action. Sometimes the best way to feel better is by helping others.
- Do what makes you happy. To help remember how things used to be, start doing something you enjoy.
- Find ways to honor your loss. It may be helpful to celebrate, celebrate with a loved one, or honor the memory of someone who passed away.

National Alliance
of Healthcare Purchaser Coalitions
Driving Innovation, Health and Value
Open Discuss & Wrap Up