

Question: How many diseases are vaccines for children supposed to prevent? A) 5 B) 10 C) 15 D) 20

Book Review: The War on Informed Consent
By Jeremy R. Hammond

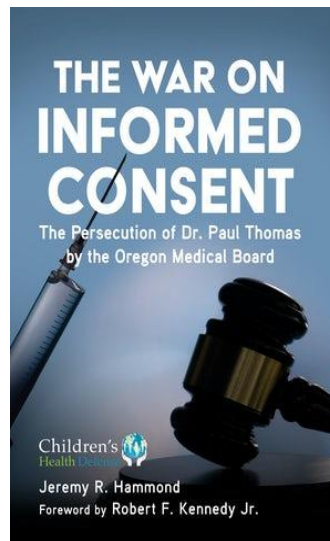
A patient-safety colleague who sits on a medical board was sent a copy of this book and she alerted many of us in the patient safety community. It attracted my attention because I am a proponent of greatly improving informed consent. I have also tried to persuade the CDC to improve information on vaccines for patients, to no avail. The author is described as a journalist seeking to expose state and media propaganda that manufactures consent for harmful government policies. He writes about the ‘persecution’ of pediatrician Paul Thomas, MD by the Oregon Medical Board (OMB) because it has sanctioned Thomas for his practice of informing parents of his ‘soft vaccination’ for children. This is inconsistent with the CDC’s vaccine schedule, so the medical establishment views Thomas’ practice as a violation of ‘standard of care.’

The author rightly accuses the CDC of often using financially biased ‘experts’ to formulate its recommendations, such as those for rotavirus. He describes the potential toxicity of mercury and aluminum compounds in some vaccines. In the end, the story boils down to a paper Dr. Thomas and a colleague published in *The International Journal of Environmental and Public Health Research* on 22 November 2020. Effective 3 December 2020, the OMB ordered an emergency suspension of Dr. Thomas’ license because he was promoting his ‘Dr. Paul approved’ vaccination schedule as superior to the CDC’s. The board cites the testimony of several parents. On 3 June 2021, the OMB withdrew its ‘emergency order of suspension’ and issued an order allowing Dr. Thomas to do only acute care with no discussion of vaccination while further investigation by the OMB is underway. On 22 July 2021 the key paper he published in the journal

was retracted by the journal editors. Their retraction stated that there were methodological issues and ‘confirmed that the conclusions were not supported by strong scientific data.’

My further investigation sought to engage relatively independent sources to assess the validity of the CDC’s vaccination schedule. I found the WHO vaccine schedule¹ and compared it to the one issued by the CDC.² Both are quite complex but are generally compatible. There appears to be more flexibility in the WHO timing, and it has more notes for vaccines in countries where diseases such as TB or yellow fever are common. The CDC version features a ‘catch-up’ schedule. My conclusion as a non-expert is that the CDC vaccination schedule is credible and should be followed with some adaptation for adverse effects when they occur. Apparent vaccine harm should be reported to the CDC by parents and physicians.³ I know of pediatricians who will not accept patients whose parents refuse to follow the CDC schedule and others who allow scheduling flexibility based on the condition of a child and parental insights. Apparently, Dr. Thomas’ schedule fell well beyond ‘standard’ flexibility.

There is some value in this book because it raises questions that need to be answered, such as the long-term effects of vaccines and the toxicity of chemical components. It also properly treats the requirement that patients, or parents in this case, be given sufficient information by the pediatrician to make informed decisions about childhood vaccinations. I give the book 1/5 stars. \$22 at Amazon.



¹https://www.who.int/immunization/policy/Immunization_routine_table1.pdf?ua=1

²<https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-combined-schedule-bw.pdf>

³<https://vaers.hhs.gov/reportevent.html>

Renewed Call for Better Device Regulation

In 2011 the Institute of Medicine recommended to the Food and Drug Administration (FDA) that it trash its existing method of clearing medical devices because it failed to ensure effectiveness and safety and could not be changed to do so. The FDA did not dispose of the 510(k) clearance-process as recommended. The legacy of this decision is that calls regularly appear for reform. The latest comes from several experts who examined the history of the JET 7 reperfusion catheter that was given the most serious of type of recall (Class 1) in January 2021 after 200 reports of patient harm and 14 deaths.⁴ Since the reporting is voluntary, this is probably an under count. The catheter is intended to help break up clots.

The device was cleared on scanty data in July 2019, and the first report of death was in October 2019. It seems that the tip of the catheter often breaks off as attempts are made to remove the offending clot. More than 200 instances of patient harm ensued, and in July 2020 the manufacturer notified clinicians of serious safety concerns. Four months later, the company reported record high sales of the device. The company issued a voluntary recall in December 2020 and the FDA Class 1 recall was issued a month later. This device and most others are cleared by ‘substantial equivalence’ to a device already cleared. This can lead to ‘device creep’ that leads to dangers to patients. The authors noted several changes in the FDA’s 510(k) clearance process that are needed to protect patients from serious harm. In addition, the voluntary reporting system after clearance falls far short of leading to timely recalls of dangerous devices.

As a patient, you must ask about the clearance status of any device planned for insertion into your body. Ask if there has been any manufacturer or FDA recalls of ‘substantially equivalent’ devices. Ask how many times your clinician has used the device, and if he or she has found that it harms some patients. You may want to ask about alternatives. Such questions should be asked during a forthright shared decision-making process. It is your right to decide what is done to your body.

Choosing Wisely – Sort of

The Choosing Wisely campaign began as a collaboration between Consumer Reports and The American Board of Internal Medicine Foundation with a goal of identifying procedures that were of low or no value in specific clinical situations. Many of the procedures may harm patients or set off a cascade of unnecessary procedures. Professional societies were engaged to identify such procedures, producing a list of more than 600 procedures by 2021. Four experts wrote

⁴ <https://pubmed.ncbi.nlm.nih.gov/34842892/>

about the success of the campaign and where it should head in the future.⁵ The annual cost saving by fully applying the campaign would be about \$90 billion.

The authors conclude that ‘progress in reducing low-value care and reducing costs has been modest at best.’ The challenges seem to lie in the inertia associated with ‘deimplementation’ of procedures. Of the 600+ procedures, only about 100 cost more than \$2,000. Most are inexpensive imaging or laboratory studies. The authors note that the ‘list’ will be continuously updated, but that stakeholders must take actions to magnify the impact of the list on cost and harm reduction. This is where patients may play a role. Tell your clinician(s) you are aware of Choosing Wisely and would like to be involved in knowing the value of the procedures that are planned for your medical care. By doing this, you may avoid harm and save the system a few dollars.

Medicare Spending on Cancer Drugs with no Benefit

It should be no surprise to readers that expedited approval of many cancer drugs by the FDA results in patients being exposed to drugs that ultimately show no clinical benefit. The FDA’s rationale is that drugs showing a positive effect on a *surrogate* endpoint *may* prove to be effective against the cancer targeted, but that follow up studies must be performed by the drug’s proponent to demonstrate effectiveness. In the past year, the FDA has reevaluated 10 cancer treatment drugs that had accelerated approval but do not improve overall survival.⁶ Between 2017 and 2019, Medicare spent about \$570 million on treatments using the 10 drugs that have shown no overall survival benefit.

The authors recommend that the FDA insist on timely follow up studies to demonstrate effectiveness and that if this does not happen, then approval should be withdrawn. From my point of view as a patient safety advocate, I would note that oncologists are ethically bound to tell their patients if a cancer drug proposed for use has never shown improvement in survival. Cancer drugs often have unpleasant side effects, so lack of survival benefit would be no more than torturing patients.

Gentler Pain Management

Four investigators in Australia wondered if, after surgical reset of a major bone fracture, pain could be well managed with a weak opioid prescription and acetaminophen when compared to management with a

⁵ <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2786584>

⁶ <https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2785231>

strong opioid (oxycodone).⁷ The study was conducted at a single medical center and involved 120 patients split into comparable groups and given one of the prescriptions for comparison. Pain was rated daily by the patients on a 10-point numerical pain scale.

From day 1 to day 7 after discharge patients took the planned treatment. Those on strong opioid medications had an average pain score of 4.04, whereas those on the weak opioid-acetaminophen combination scored an average 4.54 on the pain scale. The authors report that the difference was not statistically significant even though the opioid dose in the strong group was 6-fold more than the opioid dose in the weak group. The authors suggest that the weak opioid + acetaminophen be prescribed at discharge instead of the stronger opioid.

Patients who are about to be discharged after a surgery that may cause plenty of pain may want to ask their clinician for a ‘gentle’ prescription for managing pain instead of something like oxycodone alone. It strikes me that a pain level of 4 to 4 ½, as measured in the study, is not all that pleasant. A score from 4 to 6 is considered moderate pain.

Breakthrough Benefit of SARS-CoV-2 Infections

In a research letter, seven investigators compared antibody levels in fully vaccinated healthcare workers with a mild breakthrough case of SARS-CoV-2 to antibody levels in comparable subjects that had been fully vaccinated but had no breakthrough infection.⁸ The study was small – only 26 subjects in each group. The immunoglobulin levels in those with a mild breakthrough infection were roughly 3 times higher than in the controls with no breakthrough. The results of this study suggest that people with mild breakthrough infections should not be totally disappointed in that happening. It seems that they may subsequently enjoy a higher level of protection against another SARS-CoV-2 infection. Confirmatory studies are necessary.

Fluoroquinolones and Black Box Warnings

A huge team of investigators undertook the task of assessing the changes in fluoroquinolone prescribing habits of physicians following black box warnings from the FDA in 2013 and 2016.⁹ The FDA issues such warnings when it receives many reports of harm, in this case involving the musculoskeletal system, the peripheral nervous system, and the central nervous system. The

FDA must deem that the risk of serious harm outweighs any benefit. This class of drugs is routinely prescribed for sinusitis, uncomplicated urinary tract infection, and acute exacerbation of chronic bronchitis. The study included 1,238,000 Medicare fee-for-service patient records and 171,000 different physicians. The mean age of patients was 70 years and about 2/3rd were women.

If you chance to look at this study, skip the details and look at the graph. Before the 2013 FDA warning there was a sharp decline in the percentage of patients with bronchitis or sinusitis that received this class of drugs. The authors attribute this to a warning issued in 2008. There was no decline in prescribing to patients with UTIs. Even after the warnings in 2013 and 2016, the percentage of patients receiving this drug for their condition in 2017-2018 was as follows: UTI (20%), sinusitis (2 ½ %), and bronchitis (1 ½ %). While the authors conclude that the FDA warnings have had some effect on prescribing habits, depending on the clinical setting and specialty of the physician, there seems to be room for much improvement.

The message for my readers is to ask if any drug prescribed for you is off label (not indicated for your age or clinical condition) or has a black box warning. The box warning is the most serious the FDA can issue short of taking the drug off the market. Always ask if there is another drug choice that has no such warning.

Missing Pediatric Guidelines

In the December issue of *JAMA Pediatrics*, three pediatricians wrote their opinion, which was entitled ‘The silent crisis of pediatric clinical practice guidelines.’¹⁰ Such guidelines, when written without bias, are evidence-based, and up to date, form the basis of what clinicians should know and follow when treating their patients, in this case children. Following guidelines improves outcomes for patients. The authors provide a list of 7 factors that must be met during guideline development to ensure their quality. Some of these are not being met for pediatric guidelines. Prior to 2018 when it was defunded, the National Guideline Clearing House required that guidelines be updated every 5 years. The authors call for government reinstatement of the clearing house or an equivalent institute. They note that 2/3rd of the current pediatric guidelines are more than 5 years old. They also call for continuous updating of guidelines and international collaboration on guidelines. In the U.S. they call for sustained funding to pay for the preparation and maintenance of guidelines. If you are looking after the care of a child, ask if a guideline exists for treatment of the child’s condition.

⁷<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2786200>

⁸ <https://jamanetwork.com/journals/jama/fullarticle/2787447>

⁹<https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2786698>

¹⁰ <https://pubmed.ncbi.nlm.nih.gov/34424270/>

End Lead Poisoning in the U.S.

As a toxicologist at NASA, I recall the strenuous debates we had over acceptable levels of lead in the drinking water of astronauts. Two experts wrote an editorial in *JAMA Pediatrics* on the need to eliminate lead exposure, especially in children.¹¹ Unfortunately, lead was an ingredient in paint, pipes, and gasoline for many years. It was phased out first in gasoline in 1975, and in subsequent years the average blood level of lead fell from 16 µg/dl to 2 µg/dl.

Over the years, the CDC has lowered its reference level from 25 to 5 µg/dl. The WHO has declared that no level of lead is acceptable in a child's body. As an analytical toxicologist I know that 'undetectable' is silly because detectability of a substance depends on the ability of the analytical method. In 2017 the CDC estimated that ½ million children had unsafe levels of lead in their blood. The editorialists note a recent study showing that almost 2% of U.S. children have blood levels of 5 µg/dl or more and more than half have detectable blood levels. They noted stark disparities by race, income, ethnicity, and zip code.

The article depicts a couple of Dutch Boy paint company adds from the 1920s in which the boy celebrated lead. We have come a long way in a century. Kits are readily available for testing paint for lead. Inexpensive test kits for lead in water are available, but there is a fee for laboratory testing. Sensitivity is at the 1 ppb level, but the EPA seems to be driving to a 'zero' level and provides a graphic for non-experts.¹²

Links to Media

Leapfrog announces top hospital awards:

<https://www.leapfroggroup.org/ratings-reports/top-hospitals>

We need more accurate death certificates: <https://hhri.net/more-accurate-death-certificates-are-necessary/>

US is undercounting COVID deaths:

<https://www.usatoday.com/story/news/nation/2021/12/09/covid-death-count-america-cdc/6435124001/>

CA Medical Board president stalked and confronted by COVID misinformation group: <https://www.msn.com/en-us/news/crime/medical-board-president-says-she-was-stalked-by-covid-misinformation-group/ar-AARCP4Q>

Beware of dialysis in the US: <https://www.ajc.com/news/failing-safety-standards-at-dialysis-centers-put-georgians-at-risk/XAAM54Y75ZASRJE5MM725KD6LU/>

Worst offenses in nursing homes:

<https://www.nytimes.com/2021/12/09/business/nursing-home-abuse-inspection.html>

¹¹ <https://jamanetwork.com/journals/jamapediatrics/article-abstract/2784262>

¹² https://www.epa.gov/sites/default/files/2017-08/documents/epa_lead_in_drinking_water_final_8.21.17.pdf

Dentists are overprescribing opioids (Pharmed Out):

<https://pubmed.ncbi.nlm.nih.gov/34689958/>

Omicron mild symptoms should not lead to underestimating this variant:

<https://www.infectioncontroltoday.com/view/omicron-s-mild-symptoms-can-t-mask-danger-it-poses>

Federation of State Medical Boards opposed laws preventing medical boards from disciplining doctors for medical misinformation:

https://www.medpagetoday.com/special-reports/exclusives/96132?xid=nl_covidupdate_2021-12-13&eun=g403075d0r&utm_source=Sailthru&utm_medium=email&utm_campaign=DailyUpdate_121321&utm_term=NL_Gen_Int_Daily_News_Update_active

National action plan to advance patient safety:

<http://www.ihi.org/Engage/Initiatives/National-Steering-Committee-Patient-Safety/Pages/National-Action-Plan-to-Advance-Patient-Safety.aspx>

CA medical board returns licenses of 59% of sexually abusing doctors:

<https://4patientsafety.org/2021/12/15/these-doctors-sexually-abused-patients-the-medical-board-gave-them-their-licenses-back/>
<https://4patientsafety.org/2021/12/16/bies-are-calling-for-drastic-reforms-in-response-to-revelations-that-the-state-medical-board-gave-licenses-back-to-doctors-who-sexually-abused-patients/>

Many nurses and physicians intend to change jobs in the next 2 years:

<https://www.beckershospitalreview.com/workforce/1-in-5-physicians-2-in-5-nurses-intend-to-leave-practice-within-2-years-ama-led-study-finds.html>

Private-equity firm bought dermatology practice and patient care suffered:

<https://www.nbcnews.com/health/health-care/get-money-dermatologist-says-patient-care-suffered-private-equity-back-rcna9152>

Get this device out of my chest – The FDA in inaction (ProPublica):

<https://www.propublica.org/article/get-this-thing-out-of-my-chest>

Embarrassing how CDC tracks COVID cases (Politico):

<https://www.politico.com/news/2021/12/20/cdc-covid-omicron-delta-tracking-525621?cid=apn>

Hospital gift to you may be Covid: <https://khn.org/news/article/as-patients-fell-ill-with-covid-inside-hospitals-government-oversight-fell-short/>

A very bad day at the CDC: https://erictopol.substack.com/p/the-very-bad-day-at-the-cdc?utm_campaign=post&utm_medium=web

Health Watch USA Newsletter: <http://www.healthwatchusa.org/HWUSA-Publications/Newsletters/20220101-HWUSA-Newsletter.pdf>

Find past newsletters:

<http://patientsafetyamerica.com/e-newsletter/>

Answer to question: Best answer is 'C' (16)

<https://www.cdc.gov/vaccines/schedules/hcp/imz/child-adolescent.html>



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