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Table of Contents

Dismantling Our Society's Shame Machines

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This issue of *JLGH* contains a number of timely reports, including a fine review about medicine's great imitator, syphilis; an update on the use of buprenorphine with questions about many of the "edicts" we encounter when prescribing medical assisted therapy (MAT); and an overview of efforts to detoxify Lancaster housing. I am also excited to introduce two new columns, a health care innovation series by PC Nguyen and a book review series by Dr. Cherise Hamblin, who in her inaugural review offers a compelling commentary on *Medical Apartheid.*

I encourage you to spend time with each of these articles. In several of them, the authors ask us to engage an aspect of our history in which shame played a key role in policy, and within each is an opportunity to ask ourselves hard questions about where we've been and where we're headed as a society.

Challenging health-related questions are everywhere we turn. Decisions by our elected and appointed leaders suddenly have a direct bearing on our public health. Shame is increasingly used to influence others. I am struck by the level of vitriol and spite that has permeated the conversation within public forums. From political discourse in the wake of Supreme Court Justice Clarence Thomas's recent opinions, to social media posts about masking and vaccinations, there seems to be an ever-escalating degree of overt vilification. Yet, if there is anything positive that can be said about the rising temperature within the public space, it's this: such discourse has made possible an open conversation about shame itself.

In her new book, *The Shame Machine,* Cathy O'Neil begins by exploring the personal assault she has faced from doctors and others regarding her weight, then quickly moves to the broader medical system and our culture as a whole. She puts forth a cogent argument, that attempts at shaming represent an evolution in relationship dynamics that does more harm than good, missing the intended target and instead inhibiting the kind of change we might hope to facilitate.[1]

Shame can be a valuable tool when used appropriately, such as when we subtly instruct small children not to pee in the reservoir or teens not to steal candy from toddlers. In the same way that pain can protect our bodies, shame can protect our society, especially when transgressors can move smoothly through the stages of shame, from feeling hurt to denial, from acceptance to transcendence. If an individual can reach the last, O'Neil argues, they may experience peace and relief, and shift focus toward their community.

But lately shame as a tool is more than a covert means to correct. We do more than insinuate, we adjudicate and eviscerate, even ridicule. Sadly, those who lack choice and the power to change may become stuck in a cycle of pain and withdrawal.

Shame assaults are everywhere. We shame those who have not been vaccinated, whose weight is outside the "normal" range, who may have ended their pregnancy or require treatment for chronic disease. And while it may sometimes be intended as protective, O'Neil argues, the literature suggests that inflicting shame is no more productive than inflicting corporal punishment.

In a series of elegant trials, shame was determined to be associated with adaptive mechanisms consistent with withdrawal, self-neglect, and self-harm.[2] In opposition, patients less inclined toward feelings of shame were more likely to engage in self-reflection and actions that help move them toward self-correction. Thus, the intentional use of shame as a motivational tool may have unintentional and inappropriate effects.

There is a suggestion, born perhaps of our land-of-opportunity mythos, that we all have limitless resources and therefore opportunities at our disposal, the proposition that all problems are the consequences of poor choices. Yet, few of us have as much agency as we would like, and it becomes too easy to get stuck within any stage of the shame cycle.

Many of our medical policies perpetuate shame-cycling. We endlessly drug test those on MAT, we limit access to emergency contraception and other means to empowerment, and we needlessly delay access to life-sustaining treatments through an out-of-control

prior-authorizations process. Further, we use stigma, one of shame's close cousins, as a way of communicating these strategies to other transgressors, thus keeping those who have been shamed trapped within their cycles of limited autonomy ... and this can lead to a perpetual state.

Chronic shame can consume us with doubt about our own worth, leaving us — leaving our patients — with no energy to overcome the odds. A 2001 study of women in Alcoholics Anonymous found that people struggling with addiction who had higher levels of shame were more likely to relapse.[3]

Once shame-cycling begins, it may continue with only a look, an off-handed phrase, a tone. Patricia DeYoung, in her book *Understanding and Treating Chronic Shame,* describes "the experience of one's sense-of-self disintegrating in relation to a dysregulating other," where the dysregulating other is "a person who fails to provide the emotional connection, responsiveness, and understanding that another person needs in order to be well and whole."[4] Thus, shame can be perpetrated — and perpetuated — without intent.

It's no wonder current victims are disproportionally poor and powerless. Yet we in the medical community may be well positioned to consider shame's power because we have proximity and are not triggered by it. Having committed ourselves to becoming agents of assistance, we can be available to suggest steps to better a patient's situation without judgment.

Shame, in O'Neil's epic, is the tool of the oppressor. Thus, we can honor our mission to shelter those patients who are most vulnerable by asking ourselves if those we see through the lens of shame have a viable choice, and more importantly, the power to make a difference.

Once we realize that shame occurs when we stigmatize, perhaps without meaning to — when we associate any patient's disease with a behavioral characteristic, such as when we inform patients with arthritis they would feel better if they just lost weight — we can then make efforts to *not stigmatize.* Instead, we can look through the lens of shame at each encounter, asking ourselves if those in our presence are being inappropriately compared, made to conflate, made to conform. O'Neil concludes this argument with the suggestion that we reserve judgment and approach every patient encounter by showing empathy.

As far as I know, there is as yet no readily available clinical calculator for discerning a person's risk for shame. The PTSD risk calculator may come close, but it subsumes that one can point to a time and space during which a transgression or trauma was endured. Shame, as O'Neil suggests, is often the result of an insidious series of insults and microaggressions, any one of which is merely a strand of straw within the proverbial camel's burden.

O'Neil thus posits a "dignity roadmap": look for shame and, when we recognize it, analyze its origin and extend respect. Giving people the benefit of the doubt, O'Neil suggests, gives them the opportunity to be trustworthy. Absolution frees us all; by offering forgiveness, Nelson Mandela said, we "liberate the soul and remove fear."

On an individual level, if we can recognize when we may be perpetuating shame in those we treat, we can instead reserve judgment and allow patients safety and space. More importantly, though, we might consider that *everyone* we encounter in our clinics and health care settings is at some risk for feeling shame, and thus it seems most prudent to continue to demonstrate empathy, extend trust, and build pride within them.

When we recognize that all patients have needs and desires, we can make efforts to limit the shame we impose. Why shouldn't we give one another the benefit of the doubt and offer trust?

On the wider level, O'Neil suggests, we can work to give every member of our community a voice, a choice, and the power to make the changes that can better their lives. Within our own system, we can re-examine policy, and recognize that guidelines that punish patients have limited or no utility and should be eliminated. For example, patients miss appointments for all kinds of reasons; dismissing individuals from care probably does not fix a patient-centered problem.

We may further ask ourselves: Why isn't every primary care provider credentialed to prescribe MAT? Why do we limit the capacity to prescribe buprenorphine at all when its availability makes patients safer? Why do we have policies in place that limit access to hepatitis C therapy? Why do we prescribe dieting as a means to weight reduction when studies are underwhelming that such strategies result in sustained weight change at all?[5]

After you have read the pages within, please engage. Think about how we can use what these authors offer as an opportunity to confer dignity, to extend the benefit of the doubt. Let's further develop the awareness we all know intuitively, that people do not suffer of their own volition. Finally, let's take steps toward dismantling our society's shame machines.

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JLGH Summer 2022 Recap

Q&A for Extended Learning

The last issue of The Journal of Lancaster General Hospital *offered scientific reports and columns covering a range of topics – from emergency contraceptives, to fetal demise due to SARS-CoV-2 infection, to simplified rules for pneumococcal vaccination. Review the questions and answers below to see how much you remember from the Summer issue. Need a refresher? All issues of* JLGH *are available online at JLGH.org.*

Q
A

What is the over-the-counter agent used for emergency contraception, and how soon after unprotected intercourse does it need to be taken to be effective?

Levonorgestrel should be taken as soon as possible within 72 hours of unprotected sex since its efficacy decreases with time. Note that it is ineffective if the patient has already ovulated.

Q
A

What method of complement 4d (C4d) staining is most conclusive in confirming the presence of SARS-CoV-2 viral antigens in the placenta of a SARS-CoV-2 positive pregnant patient?

In situ hybridization (ISH) staining proved to be more conclusive than C4d immunostaining in the Lancaster General Health Pathology report looking at two cases presented to Women & Babies Hospital triage. Not only did ISH staining confirm the presence of antigens, but it added evidence to the possibility of vertical transmission of the infection.

Q
A

What are the first three steps in treating hypertriglyceridemia in patients, and what is the most effective lifestyle modification to help these patients reduce their triglyceride levels?

The first steps are to rule out secondary causes, optimize blood sugar control, and optimize therapeutic lifestyle changes. Weight loss has been shown to be the most effective lifestyle change, with up to a 70% reduction in triglycerides in some patients, although dietary modifications and physical activity can also help.

Q
A

What is pneumomediastinum?
What is its main presenting symptom?

Pneumomediastinum in a rare condition in which air is present in the mediastinum; it is most common in young patients. Its main presenting symptom is typically chest pain that often radiates into the neck or back.

Q
A

How long after receiving a 13-valent pneumococcal conjugate vaccine (PCV13) should a 68-year-old patient receive PPSV23? Will any additional shots be necessary?

A 68-year-old patient should receive PPSV23 at least one year after PCV13. No additional shots are then necessary, as the PPSV23 completes the vaccination series.

Syphilis: A Review


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Sir William Osler's aphorism "to know syphilis is to know medicine" still holds true in the year 2022 as the syphilis epidemic continues. As sexual practices and behaviors change, syphilis cases in Pennsylvania are at the highest they have been in the last 30 years.[1] In light of the recent increase in cases, this article aims to review the diagnosis, treatment, and screening guidelines for syphilis, with a particular focus on two key groups: men who have sex with men, and women of reproductive age.

EPIDEMIOLOGY

In 1999, the Centers for Disease Control and Prevention (CDC) initiated a campaign to eradicate syphilis when rates were at an all-time low. Unfortunately, this was unsuccessful: rates began to increase after 2000 and have escalated further in the recent past.[2] Per CDC Sexually Transmitted Disease (STD) Surveillance 2019 data, 41% of the cases of primary and secondary syphilis occur among men who have sex with men (MSM), followed by men who have sex with women (MSW) (18%) or unknown sexual partners (17%), women (16%), and finally, men who have sex with men and women (5%).[3]

Updated data demonstrate a dramatic increase in incident cases of primary and secondary syphilis among women (see Fig. 1).[4] A primary driver of this increase is methamphetamine use and an associated sexual disinhibition (referred to as "ChemSex") and needle sharing (see Fig. 2). Unfortunately, with the increased incidence of syphilis comes the rise of syphilis in the pregnant population and subsequently increased cases of congenital disease.[3]

Over the last year in Pennsylvania, syphilis cases increased 28% with the highest number of early syphilis cases seen in the past 30 years, prompting changes in screening recommendations detailed below.[1] Data from the Sexually Transmitted Diseases Clinic at Lancaster General Health Physicians Comprehensive Care document high rates of syphilis infection in our own community (see Fig. 3 on page 38).[5] Between November 2020 and November 2021, the clinic saw 54 cases of syphilis, which compares to only 35 cases in all of Lancaster County in 2019.

NATURAL HISTORY

Treponema pallidum (T. pallidum) is the infectious agent that causes syphilis.[6] Known as the great imitator, syphilis can be difficult to diagnose as it takes different forms throughout the course of the disease. This is complicated by the fact that while the early stages of the disease are symptomatic, later stages of the disease are primarily asymptomatic.

Syphilis is spread via sexual or vertical transmission. Untreated, it progresses through primary, secondary, latent, and tertiary phases (see Fig. 4 on page 39).[6] These phases can overlap, especially in persons living with HIV/AIDS (PLWHA). Of note, neurosyphilis, otosyphilis, and ocular syphilis can be present during any phase.

In the context of sexual transmission, the chancre of primary syphilis occurs at the site of inoculation and is the manifestation of local spirochete infection. Classical teaching suggests that chancres associated with syphilis are single, sharply demarcated, painless ulcers; however, at least 30% of the time patients have multiple, painful ulcers (see Fig. 5a on page 40).[6] This is more common among PLWHA.

Chancres may be hidden in places such as the cervix or rectum, or there may be no chancre at all. The latter is more common with reinfection. The chancre appears within the first 90 days of exposure, with median appearance at day 21. Chancres heal spontaneously within one to six weeks even without treatment, which often delays presentation to care.

Untreated individuals experience symptoms of secondary syphilis four to eight weeks after resolution of primary symptoms. While primary syphilis is a product of local infection, secondary syphilis is a product of systemic dissemination. Although symptoms are delayed, systemic dissemination begins within hours to days of inoculation, demonstrated by the fact that spirochetes can be found in the central nervous system by that time.

A wide variety of symptoms occur in secondary syphilis. Symptoms may be nondescript and generalized such as fever, headache, anorexia, myalgias, and adenopathy. Rashes are common and can take on almost any character, including being macular, papular, annular, psoriasiform, and rarely necrotic (see Fig. 5b on page 40). Rashes on palms and soles of the feet always warrant syphilis testing (see Fig. 5c on page 40).[6] Other skin/mucous membrane complications include mucous patches in the mouth, condyloma lata, and "moth eaten" alopecia.

Syphilis can further cause gastritis, transaminitis (with alkaline phosphatase elevation out of proportion to alanine aminotransferase/aspartate aminotransferase), proctitis (similar in appearance to

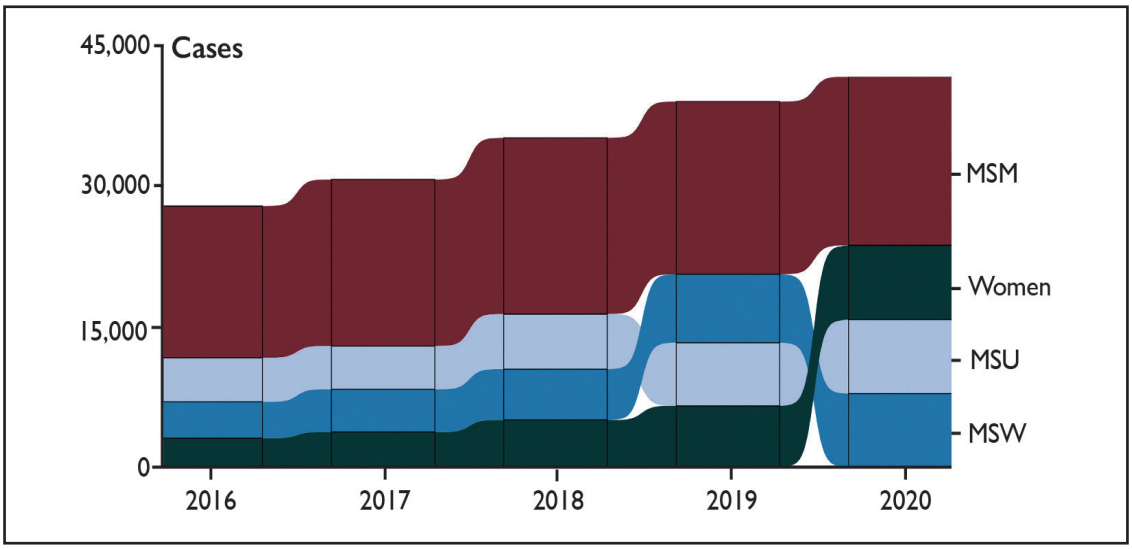

Fig. 1. Primary and secondary syphilis, reported cases by sex and sex of sex partners, United States, 2016-2020 (includes men having sex with unknown sex of sex partners, MSU).[4]

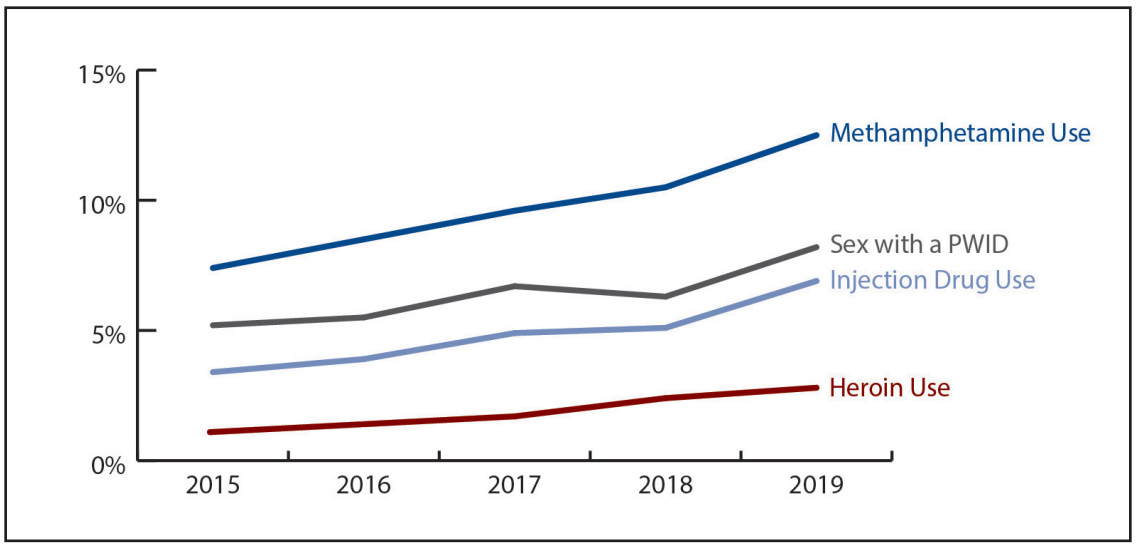

Fig. 2. Reported* injection drug use, methamphetamine use, heroin use, and sex with a person who injects drugs (PWID) among primary and secondary syphilis cases, United States, 2015-2019.[4]

**Proportion reporting each factor with the last 12 months calculated among cases with known data (cases with missing or unknown responses excluded from denominator).*

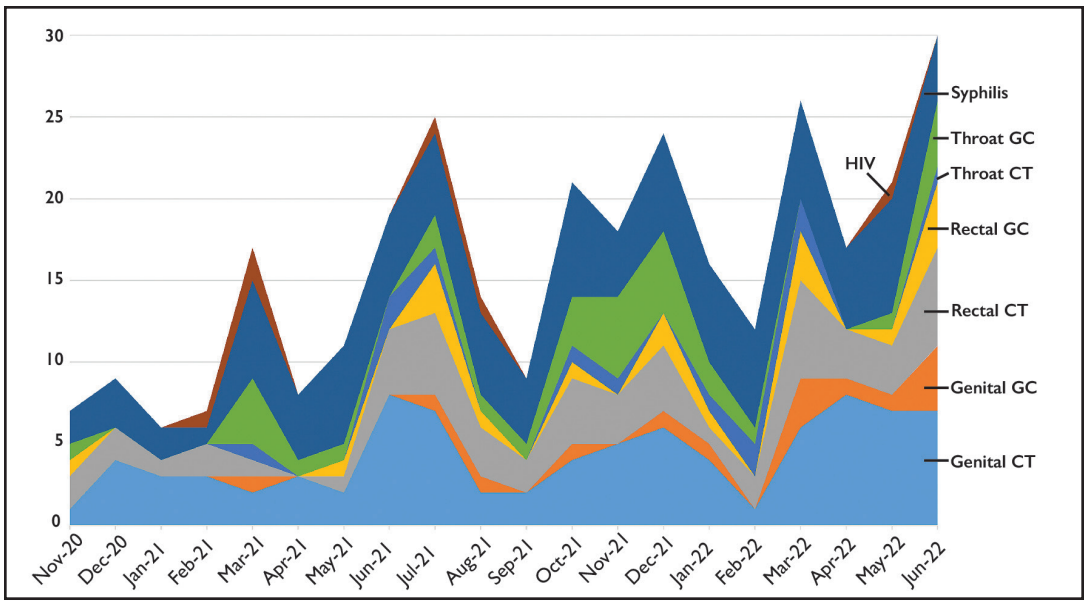

Fig. 3. STDs found over time at LGHP Comprehensive Care Sexually Transmitted Diseases Clinic using chlamydia (CT) and gonorrhea (GC) lab testing.[5]

inflammatory bowel disease on biopsy), glomerulonephritis, nephrotic syndrome, and arthritis.

Without treatment, symptoms of secondary syphilis will also self-resolve. At this point in time, the infection is asymptomatic or "latent." Latent syphilis is divided into early latent and late latent, the latter term describing infection that has lasted more than one year and is rarely transmissible.

Tertiary syphilis occurs years to decades after initial infection and can produce a variety of morbidities, including: cardiovascular disease such as aortic aneurysms, aortic valve insufficiency, and myocarditis; neurological complications including ataxia from Tabes dorsalis; and gumma of skin, bone, viscera, and soft tissues. Although frequently noted in the pre-antibiotic era, these presentations are not commonly seen since the discovery of antibiotics.

Neurosyphilis is further classified into early or late forms, which are distinguished by whether the disease has affected the meninges and vasculature (early) or has disseminated into the spinal cord parenchyma. Symptoms of acute syphilitic meningitis may include headache, confusion, or cranial nerve abnormalities, while meningo-vascular syphilis may present as a stroke-like syndrome and potentially progress to stroke due to inflammatory occlusion of vessels.

Late neurosyphilis is a presentation of tertiary syphilis. Ocular syphilis most commonly causes uveitis, and patients will often report diminished visual acuity. Otosyphilis affects hearing and balance.

DIAGNOSIS

The key to diagnosis of syphilis is a low threshold to include syphilis in the differential diagnosis and a thorough clinical history, including a sexual history. A good sexual history can be guided by the CDC's five Ps: *P*artners, *P*regnancy, *P*rotection from sexually transmitted infections (STIs), sexual *P*ractices, and *P*ast history of STIs.

Two general categories of serological testing are treponemal and nontreponemal. Treponemal tests include EIA, CIA, TP-PA, and FTA-ABS, which all refer to assays that detect *T. pallidum* antibodies. Nontreponemal tests, such as rapid plasma reagin (RPR) and venereal disease research laboratory (VDRL), detect anti-cardiolipin antibodies present in individuals with syphilis.

Treponemal testing is increasingly being performed as the initial screening test for syphilis, followed by nontreponemal testing for confirmation. This method of testing is the "reverse sequence" algorithm and is more cost effective than the "traditional sequence algorithm," which uses nontreponemal immunoassay as the screening test and treponemal assay as the confirmatory test (see Fig. 6 on page 41).[6]

In many cases, once an individual is exposed to syphilis, treponemal assays will remain positive regardless of treatment status. Nontreponemal assays are utilized to document treatment success and identify reinfection. The most common nontreponemal assays are RPR and VDRL. It is important to note that these

are not interchangeable when assessing treatment success or reinfection; an RPR titer can only be compared to an RPR titer.

Treatment success is assured by at least a fourfold decrease in the nontreponemal titer (see Fig. 7 on page 41).[6] This may take months or even up to two years to occur, so it is important in non-pregnant patients to delay repeat testing for at least three to six months to avoid unnecessary re-treatment or patient distress regarding reinfection. If the initial treponemal test is positive and the nontreponemal test is non-reactive, a second treponemal test is completed to establish the diagnosis.

Already complicated laboratory interpretation is further complicated by the fact that FTA-ABS testing will be negative in up to 30% of individuals with primary syphilis, leading to missed diagnosis. Alternatives for diagnosis of primary syphilis include dark field microscopy and PCR of a sample collected from the lesion in question. Additionally, even without treatment, nontreponemal titers will decline over time.[6]

False positives of both treponemal and nontreponemal tests do occur. False positive tests can occur for many reasons, including pregnancy, advanced age, distant previously treated syphilis infections, connective tissue or autoimmune disorders, other infections, cirrhosis, malignancy, intravenous drug use, some vaccinations, and other endemic treponematosis. In individuals who have previously been treated for syphilis, reinfection is defined by a fourfold increase in a nontreponemal titer.

Cerebrospinal fluid (CSF) analysis is needed for anyone with concerns for neurosyphilis or tertiary syphilis of any kind. CSF analysis should be considered for individuals without neurological symptoms who do not have a fourfold decrease in titers when given an appropriate amount of time, assuming they received stage-appropriate treatment and have not been reinfected.

Repeat lumbar puncture (LP) to confirm successful treatment is not needed if symptoms resolve and serum RPR titer is responding appropriately. The exception is individuals living with AIDS or poorly controlled HIV who need a repeat LP to confirm treatment success even if symptoms resolve. Individuals with ocular syphilis will have a normal CSF analysis 30% to 40% of the time, and those with otosyphilis will have a normal CSF analysis 90% of the time, so confirmatory LP is not necessary.

TREATMENT

Individuals with primary, secondary, and early latent syphilis (infection confirmed less than one year ago) should receive intramuscular penicillin G benzathine 2.4 million units once.[8] Individuals with late latent infection, syphilis of unknown duration, or non-neurologic complications of tertiary syphilis should receive three doses of 2.4 million units of intramuscular penicillin G benzathine at one-week intervals. For non-pregnant patients, intervals can likely be extended up to 10 days without sacrificing efficacy. For non-pregnant, penicillin-allergic patients, doxycycline can be used as an alternative.

Individuals with neuro, ocular, or otosyphilis should be treated with a 10- to 14-day course of continuous intravenous infusion of aqueous crystalline penicillin G for a total of 18-24 million units per day. Alternatives include penicillin G procaine 2.4 million

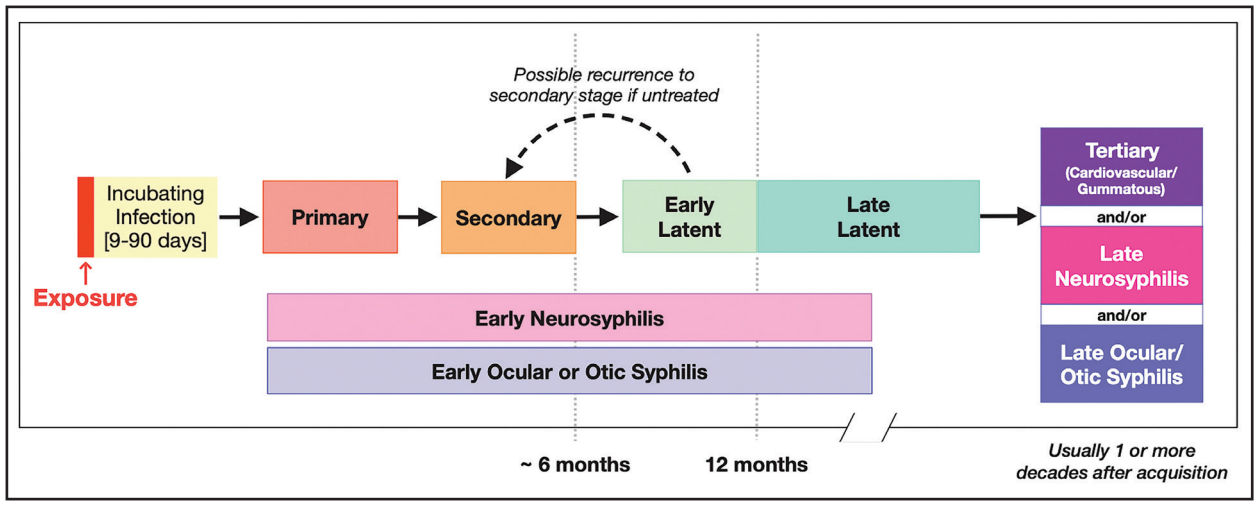

Fig. 4. The natural history of untreated syphilis.
Source: New York City Department of Health and Mental Hygiene, and New York City STD Prevention Training Center. Used with permission.

units intramuscularly once daily plus probenecid 500 mg orally four times a day for 10-14 days or daily ceftriaxone infusions.

Pregnant patients must receive penicillin G benzathine. If they need three doses, they must be administered exactly seven days apart or the regimen must be restarted. Penicillin-allergic pregnant patients with syphilis must be admitted to the hospital for desensitization to proceed with proper treatment.

HIGH-RISK GROUPS

Men Who Have Sex with Men

In the 21st century, patients have available to them the proper treatment and diagnostic tools to stop the spread of this disease, but the most vulnerable of patients continue to suffer from syphilis. In 2015, the rates of syphilis in MSM were 167 times higher than in women and 106 times higher than in heterosexual men.[9] The rates of syphilis are highest in PLWHA.

Multiple contributing factors lead to increased syphilis rates among MSM.[8] Anal sex, which is a more common practice among MSM, has a higher likelihood of transmitting sexually transmitted diseases compared to vaginal sex due to increased likelihood for epithelial abrasions and the highly vascular nature of the anus. The practice of serosorting (choosing partners with the same HIV status), which evolved to decrease the rates of transmission of HIV through unprotected sex, has unfortunately increased the rates of syphilis.

Effective treatment for HIV has allowed for the transition of HIV from a deadly disease to a chronic disease, yet has also decreased condom use. Similarly, access to pre-exposure prophylaxis against HIV has increased unprotected sex and STD infections.[8,10,11] HIV infection itself is a risk factor for syphilis.

Having more dense sexual networks, seeking sexual partners through the internet or apps such as Grindr, and increasing drug use with sex are all risk factors for obtaining syphilis which overlap with practices that are more common among MSM.[12] HIV prophylaxis continues to provide an important role in significantly decreasing HIV transmission; it simultaneously provides an opportunity for regular STD testing and treatment.

Pregnant Persons

Unfortunately, with the increased incidence of syphilis comes the rise of syphilis in the pregnant population. A recent study from the National Institutes of Health (NIH) reported a 61% increase in syphilis cases among pregnant women nationally from 2012 to 2016 across all demographics and ethnicities.[13]

Pennsylvania is not immune to these statistics. In a recent 2022 Pennsylvania Department of Health advisory, a 36% increase in early syphilis cases in females, of whom 90% were child-bearing age, was reported in the past year.[1] The rise of syphilis in the pregnant population is especially concerning given the high probability for transmission of congenital syphilis to the fetus if left untreated.[14]

While the greatest risk of vertical transmission occurs during early syphilis, when disease titers are greatest, syphilis can be transmitted from mother to child at any stage of disease (including latent phases) and during any trimester of pregnancy.[15] Vertical transmission most frequently occurs transplacentally but can also rarely occur during delivery from neonatal contact with a genital lesion.

Congenital syphilis carries significant risks for adverse outcomes, with the World Health Organization estimating that 50% to 80% of pregnancies affected by syphilis end in stillbirth, spontaneous abortion, or other adverse pregnancy outcomes.[14] The fetuses with congenital syphilis that do survive may suffer anemia, blindness, deafness, and hepatosplenomegaly and skeletal abnormalities.

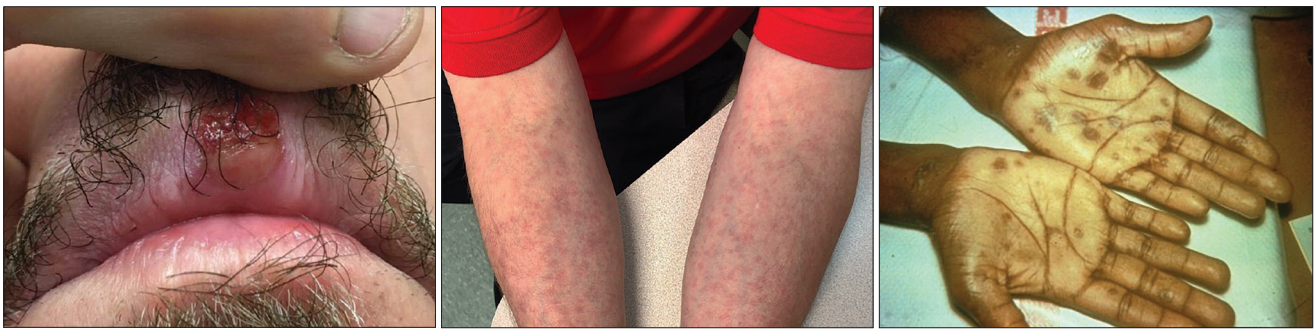

Fig. 5a (left). Ulceration on the upper lip of a patient with primary syphilis.[7] Fig. 5b (center). Rash on the arms of a patient with secondary syphilis. Fig. 5c (right). Lesions on the palms of a patient with secondary syphilis *(photo from https://www.cdc.gov/std/training/clinicalslides/slides-dl.htm).*

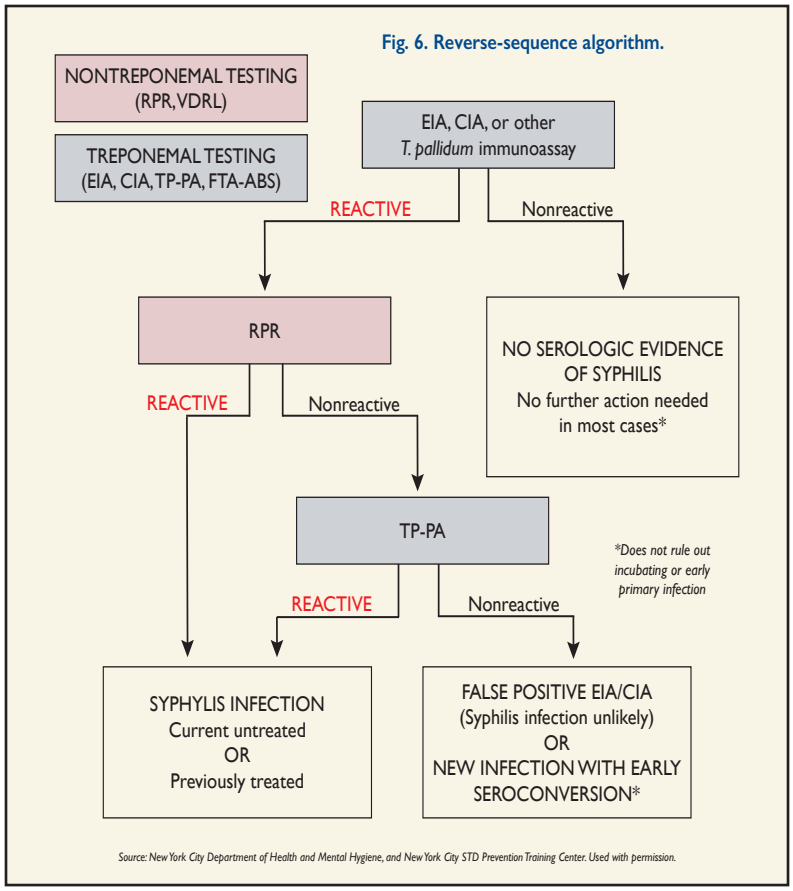

Fig. 6. Reverse-sequence algorithm.

Source: New York City Department of Health and Mental Hygiene, and New York City STD Prevention Training Center. Used with permission.

Importantly, the NIH study reporting the rise in syphilis among pregnant women also demonstrated that medical professionals cannot rely on high-risk behaviors to identify women for repeat screening in pregnancy.[13] In the study of 15 suspected risk factors — including high-risk sexual behaviors and drug use — 49% of pregnant women with syphilis did not report any risk factors.

This data and similar reports support the recent Pennsylvania Department of Health advisory that all pregnant patients should be tested for syphilis at the first prenatal visit, the third trimester of pregnancy, and at delivery, regardless of risk factors, ethnicity, age, or socioeconomic status.[1]

As up to 80% of pregnant women with untreated syphilis transmit syphilis to their fetus, treatment is of utmost importance in this population. As stated above, intravenous penicillin G benzathine is the only therapy with confirmed efficacy for syphilis during pregnancy.

PREVENTION

The keys to syphilis prevention are condom use, early diagnosis of infection, and partner treatment. The U.S. Preventive Services Task Force has given a grade A recommendation to screening for syphilis among asymptomatic, non-pregnant adults and adolescents who are at increased risk for syphilis infection.

Doxycycline prophylaxis is an active area of research for syphilis prevention. In a pilot study, 30 MSM living with HIV with prior syphilis infections were randomized to receive either daily doxycycline as pre-exposure prophylaxis (PrEP) for 48 weeks versus a financial incentive-based behavioral intervention.[16] Individuals in the doxy PrEP arm were significantly less likely to test positive for a bacterial STD during the study period compared to individuals in the control arm.

Further, the use of doxycycline post-exposure prophylaxis (PEP) — that is, the use of 200 mg doxycycline within 24-72 hours of unprotected sex among MSM and transgender women — in a 232-participant subgroup analysis in the French IPERGAY cohort resulted in a 70% reduction in chlamydia and a 70-73% relative reduction in chlamydia and syphilis cases.[17]

The major and thus far unanswered questions regarding use of doxycycline for PEP and/or PrEP are antimicrobial resistance and microbiome alterations. At this point in time, we recommend rare, and carefully considered, use of doxy PrEP.

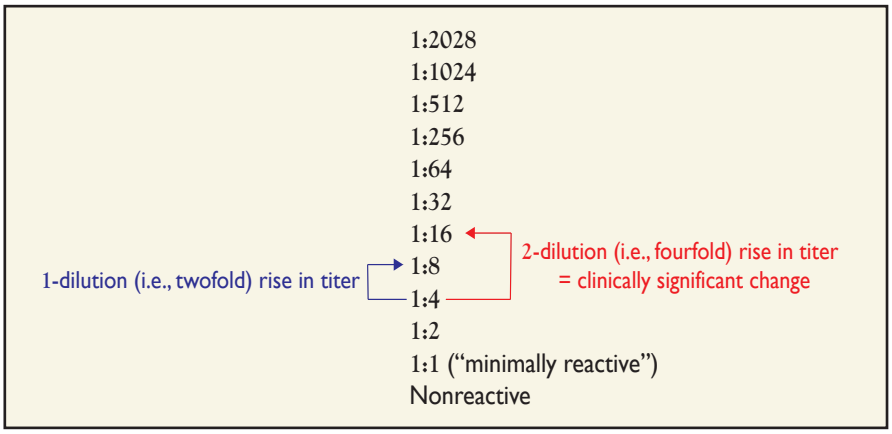

Fig. 7. Example of quantitative nontreponemal titers that indicated clinically significant change. *Source: New York City Department of Health and Mental Hygiene, and New York City STD Prevention Training Center. Used with permission.*

CONCLUSION

Syphilis has been present for much, if not all, of recorded history. It is present in Greek mythology, in the tale of the shepherd Syphilus, who angered Apollo.[18] According to the Columbian hypothesis of the origin of syphilis, it was carried from the Old World to the New in the Columbus fleet. It has been a constant companion of war and displacement.

The advent of penicillin in 1928 allowed for treatment of this ever-present but sometimes diagnostically elusive disease. Despite this, syphilis rates are again on the rise nationally and in Pennsylvania, increasing rates of adult morbidity and congenital syphilis. To combat this disease as clinicians, we must screen frequently, take regular and thorough sexual histories, and have a low threshold to include syphilis in our differential diagnoses.

RESOURCES

The National Network of STD Clinical Prevention Training Centers offers an STD Clinical Consultation Network. Consultations can be submitted through https://www.stdccn.org.

Locally, LGHP Comprehensive Care provides a free walk-in Sexually Transmitted Disease Clinic on Mondays from 4:30-8:00 p.m. where patients can be tested and receive treatment for syphilis.

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Aligning Buprenorphine Treatment for Opioid Use Disorder with Updated National Practice Guidelines

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Earlier this year, the Centers for Disease Control and Prevention (CDC) reported that deaths from unintentional drug poisonings in the United States exceeded 100,000 in 2021.[1] This is the largest number of overdose deaths ever recorded in a one-year period in this country. Further analysis of the data reveals that more than 75% of these overdose deaths were due to opioids.

Lancaster County has not been shielded from this national epidemic of opioid-related overdose deaths. During the 2020 calendar year, our county saw 143 deaths from unintentional drug poisonings, and opioids were implicated in 89% of those deaths.[2] The broad consensus is that untreated, or inadequately treated, opioid use disorder (OUD) is a major factor underlying this crisis.

Our colleague Tara Tawil, MD, described the evolution of this epidemic over the past 30 years in the pages of this journal in 2019.[3] In that article, which serves as useful background for this manuscript, Tawil also described treatment options for OUD, the emergence of buprenorphine in 2002, and efforts to increase prescribing of buprenorphine within the Penn Medicine Lancaster General Health network of primary care practices. Buprenorphine is a medication approved by the Food and Drug Administration (FDA) to treat OUD; the provision of the medication is associated with substantial reductions in all-cause mortality and opioid overdose deaths.[4,5]

In 2020, the American Society of Addiction Medicine (ASAM) released a focused update to their National Practice Guideline (NPG) for the treatment of OUD.[6] The release of this document was overshadowed by the COVID-19 pandemic and likely escaped the attention of many providers of buprenorphine treatment. These guidelines contain new recommendations and substantial revisions pertaining to buprenorphine initiation and medication management. The goal of this article is to highlight specific changes outlined in the ASAM NPG pertaining to buprenorphine treatment and how these may help improve the robust OUD treatment norms that already exist in our community.

THE ROLE OF PSYCHOSOCIAL ASSESSMENTS AND TREATMENT

> Comprehensive assessment of the patient is critical for treatment planning. However, completion of all assessments should not delay or preclude initiating pharmacotherapy for opioid use disorder. If not completed before initiating treatment, assessments should be completed soon thereafter.[7]

> Patients' psychosocial needs should be assessed, and patients should be offered or referred to psychosocial treatment based on their individual needs. However, a patient's decision to decline psychosocial treatment or the absence of available psychosocial treatment should not preclude or delay pharmacotherapy, with appropriate medication management.[7]

These two statements stand in stark contrast to prior guidance, which recommended a comprehensive assessment at the first visit followed by assimilation of this data to determine whether pharmacotherapy is appropriate.[8] Components of this initial assessment consisted of:

- comprehensive medical history with laboratory assessment including screening for infectious diseases,
- assessment for psychiatric disorders,
- evaluation of past and current use of all substances, and
- identification of social and environmental factors that could pose barriers to participation in treatment.[8]

Adherence to such guidance precluded prompt initiation of buprenorphine and implied justification for withholding medication from some individuals seeking treatment. The erstwhile guidelines described addiction as a "bio-psycho-social-spiritual illness"[8] and

clearly undervalued the merit of medication relative to psychosocial interventions. In the face of that background, some buprenorphine prescribers still require patients to have an intake assessment and ongoing involvement with a detached counseling provider or recovery support organization as a condition to receiving an initial and ongoing prescription for buprenorphine. This process risks gatekeeping a medication that, if expedited, may save lives.

The ASAM NPG focused update clearly recognizes the merits of affording treatment-seeking individuals prompt and ongoing access to medication like buprenorphine. That approach recognizes the lifesaving qualities associated with providing opioid-agonist treatment for OUD[4] and the superiority of these medications over other treatment pathways.[9] Psychosocial interventions can have a role in successful treatment, but there is no counseling modality that works for every patient.[10] Medication is now recognized as an effective standalone treatment for OUD.[11]

Physicians and advanced practice providers can offer buprenorphine to patients with OUD who desire treatment and provide informed consent,[7] a process that can occur in the first interaction without jeopardizing treatment retention.[12] Comprehensive assessments can take place at follow-up visits, and the treatment plan can be adjusted accordingly. All patients should be offered psychosocial treatment to give them the best chance to succeed, but buprenorphine should not be delayed, withheld, or removed from individuals who do not participate in psychosocial treatments.

PRESCRIBING NALOXONE TO ALL PATIENTS WITH OPIOID USE DISORDER

> Naloxone, for the reversal of opioid overdose, should be provided to patients being treated for, or with a history of, opioid use disorder. Patients and family members/significant others should be trained in the use of naloxone in overdose.[7]

Naloxone is a medication that rapidly reverses the effects of opioids and has long been a tool of health care providers and first responders to revive an individual on the cusp of death from opioid overdose. Although traditionally a parenteral drug, naloxone can be prescribed as an intranasal formulation, which lends itself to administration by a layperson.[13]

Prompt administration of naloxone in the face of respiratory depression and apnea due to opioid overdose can prevent irreversible brain injury or death, and it should be administered without hesitation when an opioid overdose is suspected.[14]

The nidus for the updated ASAM NPG in 2020 is the recent unprecedented rise in deaths due to unintentional opioid overdose. The new recommendation to prescribe naloxone to all patients with OUD exemplifies the focus on prevention of death as the foremost goal of treatment.

Nearly half of all opioid overdose deaths involve the presence of bystanders,[15] and this recommendation recognizes that naloxone possession and administration should not be confined solely to first responders who encounter the scene of overdose after critical time has passed. Widespread dissemination of naloxone to the public is likely to be the most effective public health intervention to reduce opioid-related deaths over the next decade.[16]

Fig. 1. A combination of buprenorphine and naloxone can be administered sublingually via tablet (8 mg, both sides shown, top) or film (8 mg shown, bottom). *Photos via Wikimedia Commons, CC BY-SA 4.0: tablet by Supertheman, film by Sintegral.*

Regarding the concern that dissemination of naloxone may make use of riskier opioids more appealing by reducing the potential for negative consequences,[17] recent history suggests otherwise. From 2016 to 2019, naloxone dispensing in the United States increased more than six-fold.[18] Yet, rates of opioid misuse declined substantially in all age categories — most dramatically among people under the age of 25 — over the same timeframe.[19] Intranasal naloxone should be prescribed alongside buprenorphine liberally and without compunction.

MEDICATION MANAGEMENT WITH BUPRENORPHINE

> Following initiation, buprenorphine dose should be titrated to alleviate symptoms. To be effective, buprenorphine dose should be sufficient to enable patients to discontinue illicit opioid use. Evidence suggests that 16 mg per day or more may be more effective than lower doses.[7]

The more senior author of this paper has consistently observed that many clinicians consider transmucosal buprenorphine doses of 16 mg per day to be a maximum dose, a rationale based in part on results of "receptor saturation studies." These studies purportedly show that a 16 mg buprenorphine dose provides nearly complete blockade of mu-opioid receptors. Several neuroimaging studies utilize positron emission tomography paired with radiolabeled tracers to describe correlations between serum buprenorphine levels and receptor availability,[20-22] but none corroborate that doses above 16 mg lack additional benefit.[23]

A full narrative of buprenorphine activity at all opioid receptors (mu, kappa, delta, and ORL-1) is beyond the scope of this article, but basic neurobiology informs us that receptor occupancy is a dynamic process wherein ligand binding exists in a state of flux between association and dissociation from the receptor. This introduces tremendous potential for heterogeneity in responses outside of the controlled setting of a research lab.

Further, there is no standard operational definition for mu-opioid blockade and there is no defined threshold of opioid receptor occupancy that correlates with clinically meaningful effects such as withdrawal suppression and attenuation of effects of illicit opioid use.[23] Neuroimaging studies serve as an important foundation for further research, but studies that describe clinically meaningful outcomes in real-world settings are far more valuable.

An appraisal of the history of methadone maintenance in the United States informs us that a similar wariness to escalate dosage above an arbitrary and suboptimal dosage cap was commonplace for its first 20 years post-FDA approval[24] despite evidence that higher doses are more effective.[25,26] The practice of capping buprenorphine dose at a fixed limit of 16 mg per day for all patients may be a sociologic phenomenon reflecting prescriber hesitation that is common to other forms of opioid substitution treatment, but it is not rooted in traditional application of principles of evidence-based medicine.

The ASAM NPG now validates that transmucosal buprenorphine doses above 16 mg per day are associated with clinically meaningful patient-oriented outcomes when compared to lower doses. Daily buprenorphine doses of 16 mg or greater are often necessary to effectively suppress illicit opioid use based on placebo-controlled trials,[27] and higher buprenorphine doses are clearly associated with better treatment retention.[28,29]

BUPRENORPHINE AND PREGNANCY

> A medical examination and psychosocial assessment are recommended when evaluating pregnant women for opioid use disorder. However, completion of all assessments should not delay or preclude initiating pharmacotherapy for opioid use disorder. If not completed before initiating treatment, assessments should be completed as soon as possible thereafter.[7]

Pregnant females are as affected by OUD as non-pregnant individuals,[30] and there is broad consensus that the life-saving benefits of buprenorphine for treating OUD extend to pregnant females and the unborn child. Clinicians should work to decrease barriers to care for this highly vulnerable subset of the population. For example, residential treatment programs may reconsider policies that delay admission to pregnant patients until completion of an ultrasound to assess gestational age.

Buprenorphine induction in the pregnant patient is essentially the same as buprenorphine induction for non-pregnant individuals. Care is taken to avoid precipitated withdrawal, and thorough instructions for starting the medication must be reviewed and understood by the patient. Home induction is feasible and does not appear to be inferior to medically supervised induction,[31,32] and this finding likely extends to pregnant females.[33]

A prevalent practice pattern that demands pregnant females complete an ultrasound before receiving pharmacotherapy and withholds the opportunity to undertake a home buprenorphine induction with informed consent is unwarranted.

> Naloxone should be used in the case of maternal overdose to save the woman's life and can be used in the combination buprenorphine/naloxone product for opioid use disorder treatment as the naloxone is minimally absorbed when taken as prescribed.[7]

Buprenorphine for the treatment of OUD became widely available in Europe in the mid-1990s.[34] When the medication became available in the United States for the treatment of OUD, buprenorphine was combined with naloxone in a 4:1 ratio to deter misuse of the product (see Fig. 1).[35] This combination of buprenorphine/naloxone became the dominant formulation for treatment of OUD in the United States.[36]

Owing to the existence of more robust experience with buprenorphine mono-product during pregnancy in Europe, a common practice pattern emerged wherein patients stabilized on buprenorphine/naloxone combination product were reflexively switched to buprenorphine upon learning of a pregnancy.

Sufficient data has emerged over the course of the past 20 years to reasonably ascertain that maternal and neonatal outcomes with buprenorphine/naloxone are not significantly different from other forms of opioid agonist treatment, including buprenorphine monotherapy.[37] Switching a pregnant female to a buprenorphine formulation that may be more prone to misuse appears to be unwarranted, thus patients who are stable on buprenorphine/naloxone treatment may continue the medication if they become pregnant.

BUPRENORPHINE AND PAIN MANAGEMENT

The addition of a short-acting full agonist opioid to the patient's regular dose of buprenorphine can be effective for the management of severe acute pain in supervised settings, such as during hospitalization. The dose of additional full agonist opioid analgesic is anticipated to be higher than the typical dose necessary to achieve adequate analgesia in opioid-naive individuals.[7]

Buprenorphine is a partial opioid agonist with a strong affinity for the mu-opioid receptor and long duration of action (see Fig. 2). These characteristics, which make it an attractive treatment option for helping a person reduce or eliminate unsafe opioid use, raise concern that the medication could block the effects of other opioid agonists that are administered to treat severe pain.

In 2004, just two years after FDA approval of buprenorphine for treatment of opioid use disorder, the U.S. Center for Substance Abuse Treatment (CSAT) provided guidance that recommended discontinuation of buprenorphine well in advance of anticipated surgery.[38,39] These CSAT guidelines, based on very limited experience, exerted long-lasting influence on practice norms, and we continue to witness inappropriate buprenorphine discontinuation in hospitalized patients and prior to surgery.

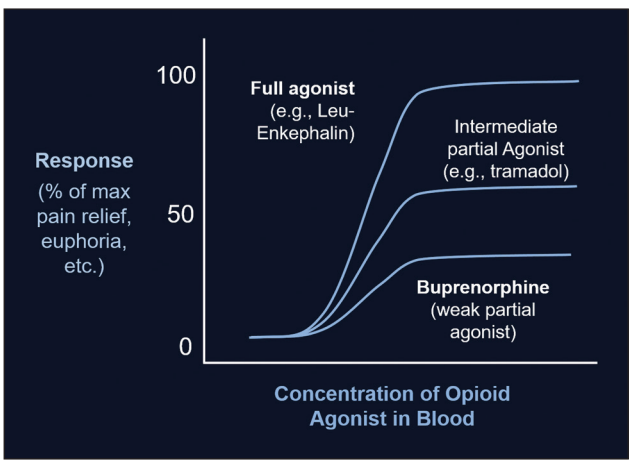

Fig. 2. This graph demonstrates how buprenorphine is a partial agonist of the mu-opioid receptor. This means that when the dose is escalated (moving to the right on the x-axis), there will be a ceiling effect for all the responses related to activation of the mu-opioid receptor. This includes euphoria, analgesia (pain relief), and respiratory depression.

Graph by Vanwa71, via Wikimedia Commons, CC BY-SA 4.0.

Buprenorphine should be continued during the perioperative period of surgery, whether planned or otherwise, and during virtually all episodes of acute pain during hospitalization. Buprenorphine discontinuation is associated with increased all-cause mortality[4] and high rates of adverse events requiring acute care.[40]

Patients are particularly at risk for drug-related overdose deaths after hospital discharge,[41] and an episode of hospitalization for any reason is a very inopportune time to discontinue buprenorphine treatment. Furthermore, post-operative pain management is likely to be more challenging when buprenorphine is discontinued because patients will require significantly more opioid analgesics after surgery.[42]

Multi-modal analgesia and non-opioid pain management interventions should still be utilized first line, although a full discussion of pain management for patients taking buprenorphine is beyond the scope of this article. Yet, we support and encourage the principle that buprenorphine should almost always be continued during hospitalization at a dose that suppresses opioid withdrawal symptoms and preserves treatment retention. For persistent moderate to severe pain in the face of conservative modalities, additional opioid analgesics can be administered and the dose adjusted to achieve the desired effect in hospital-based settings.

BUPRENORPHINE IN JAILS AND PRISONS

All FDA-approved medications for the treatment of opioid use disorder should be available to individuals receiving health care within the criminal justice system.[7]

As of 2017, fewer than 1% of jails and prisons in the United States offered access to buprenorphine treatment,[43] although we have known for at least 15 years that nearly 20% of individuals who enter the correctional system report regular use of opioids.[44] Release from these institutions is associated with 129-fold increased risk of death from drug overdose.[45]

Negative attitudes among correctional staff toward buprenorphine treatment[46,47] likely play a role in restrictions, but the relatively large number of individuals with problematic opioid use within these institutions may pose a more taxing barrier to implementation of this recommendation. National estimates indicate that fewer than 5% of people in the

community misuse opioids and less than 1% have an opioid use disorder.[19] However, most of these individuals report involvement with the criminal justice system,[48] and periods of incarceration are common.[49] Jails and prisons often become repositories which house a high concentration of individuals with opioid use disorder. During the final six months of 2021, more than 20% of all individuals entering Lancaster County Prison required treatment for opioid withdrawal.[50] This disparity in disease burden highlights a need to direct more resources toward treatment of opioid use disorder in correctional settings.

In a recent survey of 23 state prison systems most heavily impacted by opioid overdose deaths (Pennsylvania among them), lack of funds for medication provision was the most frequently cited barrier to providing medication for opioid use disorder.[51] The Social Security Amendments of 1965 prohibit states and counties from using federal Medicaid funds to provide health care to incarcerated individuals. Local governments bear the cost of providing medical care to incarcerated individuals in non-federal prisons. Legislative reform of this decades-old provision could substantially improve the health of incarcerated people[52] and allow for more strategic allocation of federal health care dollars to fund buprenorphine treatment in jails and prisons.

We agree that all medications for opioid use disorder should be available in correctional institutions. Such measures clearly have potential to produce a sizable reduction in fatal overdose associated with community reentry.[53,54] Practical implementation of this recommendation requires increasing subsidies for medication treatment in carceral settings and offering alternatives to incarceration for individuals with opioid use disorder.

CONCLUSION

The 2020 focused update of the ASAM NPG for the treatment of OUD reflects a shift toward prioritization of access to treatment and recognition that medication can be an effective standalone intervention. We should eliminate fragmented and cumbersome intake processes for treatment-seeking individuals to avoid delays in implementation of potentially life-saving medication. Further, psychosocial interventions and recovery support services should not be compulsory nor a condition for receiving medication.

Once initiated, medical management of buprenorphine should be guided by studies that describe clinically meaningful patient-oriented outcomes, and providers should recognize that some patients will do better with higher doses of buprenorphine. Take-home naloxone should be co-prescribed liberally and without hesitation or fear that it will cultivate further opioid misuse. These principles extend to special populations such as pregnant patients, people with acute pain, and those involved in the criminal justice system.

We have an excellent foundation of primary care practices in our community providing buprenorphine treatment to combat our current epidemic of opioid-related overdose deaths. The next stage to winning that fight involves changing prevalent practice norms in the face of new information and aligning buprenorphine treatment of opioid use disorder with these updated national practice guidelines.

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The 2019 Lancaster County Community Health Needs Assessment identified that safe and affordable housing is one of the basic conditions needed to support health in Lancaster County; the risk of lead poisoning in residential properties is a particular concern. In response to this need, Penn Medicine Lancaster General Health's Board of Trustees committed $50 million over 10 years to the Lead-Free Families program to reduce childhood lead poisoning by removing lead hazards from Lancaster County homes.

BACKGROUND

Lancaster County has a lead problem. It is a tainted legacy from much of what we enjoy about this area. Historic buildings in a county incorporated in 1729[1] mean we also have a disproportionate number of structures built prior to 1978, when lead paint was banned by the U.S. Consumer Product Safety Commission.

Lancaster now has the fourth highest rate of lead poisoning among Pennsylvania counties.[2] The fact that we also have the highest percentage of children under age 7 per capita in the state[3] and the second lowest percentage of children in the state screened for lead poisoning[2] adds to the concern that we are underestimating the problem.

PHYSIOLOGIC AND SOCIOECONOMIC EFFECTS OF LEAD POISONING

As has been well known for millennia, lead causes a variety of hematologic and neuropsychiatric effects when it enters the human body. It is only recently, however, that studies have correlated even "sub-clinical" lead exposure in children with future learning problems in school, increased rates of aggressive behavior, ADHD, and lower IQ points.[4] Regarding a loss of IQ points, no detectable threshold level of lead poisoning is considered safe.

Lead poisoning has been implicated in juvenile delinquency, as the result of both prenatal and postnatal exposures.[5] In adults, low-level exposure to lead can accelerate renal insufficiency in patients who already have chronic renal disease.[6] Lead poisoning has also been associated with increased crime rates, rates of incarceration, and lost years of occupational economic advantage.

The associated costs of lead poisoning — including health care, lifetime earning losses, increased need for special education and behavioral services, and crime-related costs — was estimated to be $1.2 trillion in 2008 for a birth cohort of all U.S. children ages 0-6 years and projected for 65 years.[7] A Pew Charitable Trusts issue brief in 2010 suggested that costs to abate lead in homes ranged between $1.2 billion and $11 billion, but would save $192 billion to $270 billion, meaning a return on investment of at least $17 for every $1 spent on corrective action.[8]

LEAD POISONING TREATMENT

As the damaging effects of lead poisoning have become more apparent and overt lead poisoning has decreased, the Centers for Disease Control and Prevention (CDC) has lowered the blood lead reference value (BLRV), representing the top 2.5% of all measured blood lead levels, from 60 mcg/dl in the 1970s to 3.5 mcg/dl in 2021.[9] The reduction in the BLRV does imply some success in the fight against lead poisoning, but significant numbers of children are still being poisoned, even at these lower levels.

Chelation, once a mainstay in treatment for children with elevated blood lead levels, has not been shown to reverse the damage in children with lower lead levels and is now reserved for children who present with levels above 45 mcg/dl. In fact, medical intervention does not reverse the loss of IQ points, nor help deter other neuropsychiatric effects of lead poisoning. The lack of treatment options forces the medical community to focus on primary prevention such as reducing or removing lead hazards before the child is exposed.[10]

UNIVERSAL LEAD SCREENING

Screening for lead poisoning has been a mainstay of routine care within the realm of Family Medicine and Pediatrics for many years. This has taken many forms, from questionnaires given to parents, to targeted screening for Medicaid patients. The U.S. Preventative Services Task Force concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for elevated blood lead levels in asymptomatic children and pregnant women. This screening recommendation reflects the lack of treatment available.

However, other national medical groups and public health organizations, like the American Academy of Pediatrics and the CDC, state that screening should be based on the inherent risks of lead poisoning in the child's community. Screening may limit the effects of further exposure and help local governmental and health care organizations target areas of high lead burden for abatement. It is for these reasons that we advocate for universal screening (two lead tests by age 3 years, one at 12 months, and another around 24 months of age) for all children who live in Lancaster County.

LEAD POISONING DISPARITY

Lead poisoning does not affect all in our community equally. According to Michael Horst, PhD, LG Health epidemiologist, internal modeling of elevated lead tests reported to the Pennsylvania Department of Health for Lancaster County show that communities overburdened by socioeconomic issues — such as higher poverty rates, low rates of high school graduation, and higher unemployment rates, among others — are up to three times more likely to have children who are lead poisoned.

Further, elevated blood lead levels are up to three times more common among Black and brown persons than white persons.[11] Thus, vulnerability to lead poisoning is related to a child's zip code, census tract, race, and socioeconomic status.

Fig. 1. Lead-Free Families Logic Model

Program Statement: Lead dust hazards can occur when lead paint deteriorates or is disrupted during home renovation or remodeling activities. Lead exposure can cause a range of health problems, from behavior disorders and learning disabilities to injuries and death, putting young children at greatest risk because their nervous systems are still developing. Lead paint exposure disproportionately impacts low-income communities and communities of color.

Project Goal: Align key stakeholders and funding to elimiate residential lead exposure in Lancaster County by 2031.

Impact Goal: Eliminate the prevalence of children with elevated blood lead levels in Lancaster County by 2031.

	Resources	Actions	Outputs	Long-Term Outcomes (2031)
Project	Stakeholder participation Aligned funding	Regularly schedule stakeholder meetings Identify and apply for additional funding sources Host education meetings with government officials	# of stakeholders involved Stakeholder attendance Dollars raised # of meetings with government	Reduced incidences of lead poisoning among children and pregnant women in Lancaster County Increased lead-free housing stock in Lancaster County Increased economic mobility for residents in Lancaster County
Outreach and Awareness	Outreach and intake staff Trained and certified lead dust wipe technicians and inspectors	Review data to target outreach efforts Provide education and outreach in community Educate community and program participants	# of outreach events # of people reached # of marketing materials distributed # of social media posts # of impressions	**Intermediate-Term Outcomes (2025)** Lowered EBLL among program participants Increased # of certified firms Increased # MBG, DBE, WBE doing lead remediation and inspection in Lancaster County Increased lead screening rates
WFD	Trained staff to support, educate, and guide families through the program	Engage local contractors Build workforce development program Assess homes for lead Remediate lead hazards in home	# of new jobs created # of contractors trained # of contractors hired # of homes assessed # of homes treated for lead hazards # of lead-free dust wipes	
Family Advocacy	Coordination of lead screening tests	Family advocacy (case management) Education	# of program participants # of home visits # of pre-/post-education assessments	**Short-Term Outcomes (2021-2022)** Increased community awareness of lead hazards Increased lead-free homes 100% client program satisfaction Increased awareness of lead hazards among participants Strengthened lead ordinances
Lead Testing		Referral and coordination to lead testing	# of referrals to lead testing # of lead screening tests	

WFD = workforce development; EBLL = elevated blood lead level; MBG = minority-owned businesses; DBE = businesses owned by economically disadvantaged individuals; WBE = women-owned businesses

ABATEMENT AS TREATMENT

With the knowledge that even low levels of lead in an individual can cause significant health risks, and that the health care community can do very little in the way of treating lead poisoning, abatement (or removal of the lead hazard) in the community is the essential tool in combating this epidemic. As noted above, abatement is cost effective when modeling out the sequalae over decades, and when it comes to lead poisoning, abatement is health care and the primary reason that LG Health has committed significant capital to this effort.

THE LEAD-FREE FAMILIES PROGRAM

Lead-Free Families, launched in August 2021, aims to remove lead hazards from at least 2,800 Lancaster County housing units over 10 years. Lead-Free Families is a direct-service lead poisoning prevention program that includes the following: client outreach, education throughout the community, home visits, lead inspection/risk assessment, lead hazard remediation, clearance and follow-up education, lead-certified contractor training, and capacity building. The required resources, activities, outputs, and short- to intermediate-term outcomes for the program are outlined in the Lead-Free Families Logic Model (see Fig. 1).

The program prioritizes households with young children diagnosed with elevated blood lead levels countywide for lead hazard remediation and lead poisoning prevention education services.

Lead-Free Families aims to increase the overall understanding of childhood lead poisoning among all residents of Lancaster County and will provide lead remediation services for families who meet the eligibility criteria (see Table 1).

Table 1. Program Eligibility Criteria

Property located in Lancaster County
Property constructed prior to 1978
A pregnant woman or child under the age of 6 resides in the property or a child under age 6 spends a significant amount of time visiting
Homeowner or tenant occupant meets the program's income eligibility requirements (household income is less than 400% Federal Poverty Level, i.e., family of four making $111,000 or less)
Property contains at least one bedroom
Property contains lead-based paint hazards as verified by the lead risk assessment

LEAD RISK ASSESSMENT

When a client is enrolled in the program, the team will forward the property to a certified lead inspection company contracted to conduct a lead risk assessment to determine if lead-based paint hazards exist in the property. The lead risk assessor will conduct a lead risk assessment by performing a visual inspection, sampling for lead dust, sampling soil as appropriate, and conducting surface-by-surface inspections to verify the presence of any lead-based paint and lead hazards.

Testing methods will follow all federal, state, and local regulations, and will use the current standards of 1.0 mg/cm^2 or 0.5% by weight as the criteria for lead-based paint. The lead risk assessor will follow state regulations and the federal Guidelines for the Evaluation and Control of Lead-Based Paint Hazards in Housing. The assessor will create a risk assessment report based on testing data and the site visit visual inspection, and forward the report to the program.

If the risk assessment reveals that lead-based paint and lead hazards are present, a scope of work will be developed describing the lead hazard reduction work necessary to meet state and program clearance standards.

TEMPORARY RELOCATION

Abatement can take up to 10 days. Before remediation begins, the team will conduct a home visit and will make arrangements to temporarily relocate the property's occupants. The occupants might stay temporarily with family or friends, or the Lead-Free Families program will utilize hotels in target communities as temporary relocation sites for families displaced by the lead hazard reduction activities. At all times, children and pregnant women will be out of the property during the intervention.

LEAD HAZARD REMEDIATION INTERVENTION (LEAD SAFE PLUS STANDARD)

Lead hazard remediation will be managed by the Green and Health Homes Initiative (GHHI), an organization that addresses the social determinants of health and advances racial and health equity through the creation of healthy, safe, and energy-efficient homes. GHHI's lead hazard control strategy for identified leaded surfaces includes:

- Window replacement with lead-free energy-efficient windows

- Door and baseboard replacement
- Paint stabilization of deteriorated leaded surfaces
- Treatment or abatement of other friction and impact surfaces
- Repair of minor structural defects that are causing paint to chip, flake, or peel
- Lead-specific cleaning, including HEPA vacuuming and wet cleaning of all interior horizontal surfaces sufficient to achieve lead dust clearance

Where the program is providing lead remediation to a household with a child with an elevated blood lead level, the scope of work will meet or exceed local, state, or federal regulations. With the exception of window, door, and baseboard replacement as warranted, the program will employ paint stabilization intervention measures on painted surfaces rather than full lead abatement strategies.

QUALITY STANDARDS AND CLEARANCE INSPECTION

A lead visual inspection and lead dust clearance by a third-party lead inspector will be conducted to confirm that the property is safe for re-occupancy by the clients and to check the quality and completeness of the lead remediation work. All properties receiving lead hazard reduction treatments will pass the lead dust clearance standards.

Services will be subsidized based on property type (rental or owner occupied). Low-income, owner-occupied households will be offered remediation services via Lead-Free Families. Rental property owners with low-income tenants will be offered remediation services via Lead-Free Families with a requirement to pay 10% of the remediation and to maintain rents no higher than fair market for Lancaster County for up to three years.

EVALUATION

Evaluation is essential for monitoring the program, supporting continuous quality improvement, and ensuring that the investment of time and resources is achieving the intended outcomes. The overall goal of the initiative is to prevent lead poisoning in Lancaster County. Thus, the program evaluation aims to answer the following broad questions:

1. Has the program effectively eliminated lead hazards in residential properties?
2. Has the initiative improved policies and systems to identify and prevent lead poisoning?
3. Has the initiative reduced lead poisoning among children under 6 years of age?

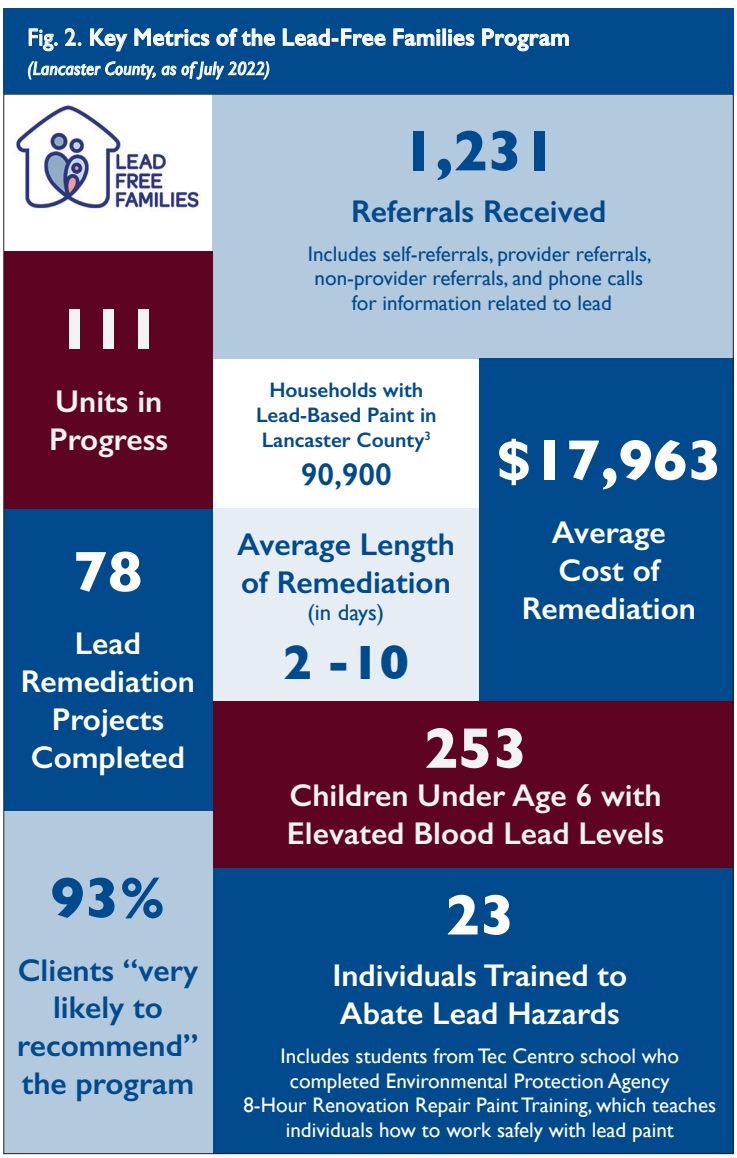
See Fig. 2 for a status report of key metrics tracked and used to evaluate the program.

SUSTAINABILITY

To enhance and sustain efforts, it is essential to increase enforcement of local housing codes, federal lead-related laws (such as Title X and the Environmental Protection Agency Lead Renovation, Repair, and Painting Rule), and lead-safe work practices.

The Lead-Free Families team will advocate for increased inspection and enforcement of housing codes. Enforcing housing codes and citing property owners for chipping and peeling paint violations in pre-1978

Fig. 2. Key Metrics of the Lead-Free Families Program
(Lancaster County, as of July 2022)



properties is a critical component of a lead poisoning prevention strategy. Training existing housing code office personnel and encouraging government agencies to hire additional housing code inspectors will be important priorities for the program staff.

While Lancaster City and Columbia Borough currently have lead ordinances, the Lead-Free Families program is also offering resources to other municipalities to help them create ordinances that work for their communities. This program will thus also aim to increase the number of municipalities in Lancaster County that require lead inspection, hazard remediation, and lead-safe certification of rental units or properties at the point of sale.

Certification of lead-safe rental properties can incentivize property maintenance over time, and revenues from annual certification fees and fines for violations could sustain program operations in the long term.

PROGRAM ENHANCEMENT

LG Health was excited to receive a nearly $2 million grant from the Department of Housing and Urban Development (HUD) in January 2022 to support and enhance the services provided by the Lead-Free Families program. This funding will enable the program to address additional health and safety hazards that are found in homes during home remediation. These include mold and radon issues, risks for falls, and risks for fire and burn injuries.

It is through collaboration with many community partners, municipal leaders, and medical providers that Lead-Free Families will make the goal of eliminating lead poisoning in Lancaster County a reality. The initiative will change the trajectory of the lives of thousands of children and their families.

For information on Lead-Free Families or to refer a patient, providers can type "Amb ref lead" into the Epic order search or call 717-544-LEAD (5323). Individuals may self-refer by calling the same number or emailing info@leadfreefamilies.org.

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Reimagining Health Care Delivery in the Communities We Serve

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Editor's note: This issue, we welcome a new column from the Center for Health Care Innovation at Penn Medicine Lancaster General Health. The center opened four years ago with the mission to develop, test, and implement new strategies to reimagine health care delivery. This article offers an introduction to the program; subsequent columns will provide more detail and share lessons learned and updates regarding project progress.

INTRODUCTION

At its most basic, human-centered design means creating a product or service by prioritizing the user's needs and experiences, and keeping this mindset every step of the way. Design thinking may be a strategic approach or a philosophy, but for those at the Center for Health Care Innovation (CHCI) at Penn Medicine Lancaster General Health, it means being able to use creativity to better solve health care problems, particularly from the patient perspective.

CHCI holds as its edict that health and health care delivery can be reimagined within the communities being served. No matter the issue, this includes a commitment to study problems intimately and approach them through principles of human-centered design while caring deeply about the implementation of solutions that work.

This introduction to CHCI at LG Health will outline the methodology used at the center and the integration of design thinking, including how this model is employed in the signature Innovation Accelerator Program.

APPROACH AND TOOLS: THE DOUBLE DIAMOND

As an eight-member department, CHCI at LG Health is four years old and modeled after the successful Penn Medicine Center for Health Care Innovation in Philadelphia. Both groups approach innovative problem-solving using the same foundational perspective: significant improvements to patient health, clinician experience, and care delivery require experimentation to be developed quickly and at low cost. Only when high-impact solutions are discovered and demonstrated should they be scaled or more broadly integrated.

The human-centered-design framework applies an iterative and agile approach to care delivery called the Double Diamond (see Fig. 1). Through this framework, solutions are continually refined and improved. The Double Diamond comprises four parts that alternate between *divergent* thinking or actions and *convergent* thinking or actions. The former involves intentionally broadening one's perspective to include as many ideas as possible, while the latter entails synthesizing information and making decisions to narrow down those ideas.

The first stage of the initial process phase involves focusing on problem definition in an attempt to understand which solutions might work. "Discovery" is an attempt to learn as much as possible about the problem space and includes a contextual inquiry — an ethnographic method involving the observation and analysis of patients, providers, and care teams in action within the working environment. This phase may include having the innovator experience the process firsthand, which among other things will help the team develop a sense of empathy to uncover patient and care team needs.

The second stage of the initial phase, called "Define," is an opportunity to hone in on the problem and its causes. Journey maps help connect the dots between discoveries from the first stage; fictional users — called *personas* — which are created from the data gathered on their needs, behavior, and preferences, give innovators a locus around which solutions can be designed.

The Discovery and Define stages culminate in defining the needle — or metric — that needs to move. This is an important activity in the process because it allows the innovation team to identify what they are trying to change, as well as to further define metrics, the measure of which will determine whether solutions are safe and effective, and ultimately, worthwhile.

The second phase includes the opportunity to experiment with ideas and pilot the solutions with the hope that solutions may demonstrate a potentially viable business model. This begins with "Ideation," during which brainstorming takes place, and subsequently leads to "Validation," during which ideas become action in a quick, low-cost, and low-barrier way. Experimentation cycles follow, the goal being to test and validate whether

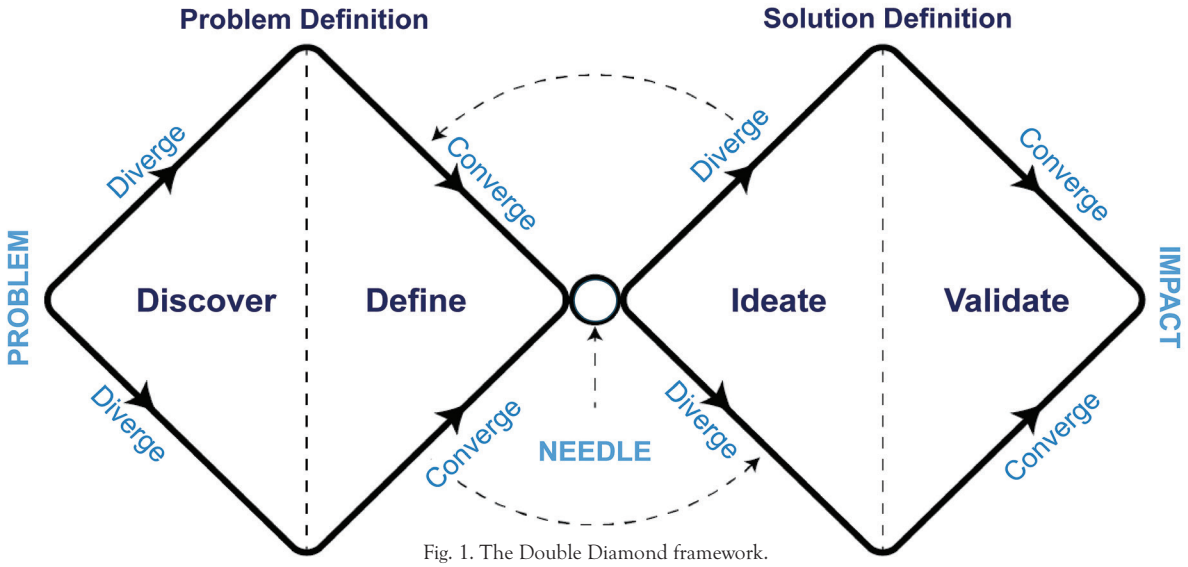


Fig. 1. The Double Diamond framework.

solutions work. Simulation of a product or service allows the innovation team to observe how a persona might encounter the solution in context. The context of each problem determines whether the team must revisit and utilize available tools and opportunities.

INNOVATION ACCELERATOR PROGRAM

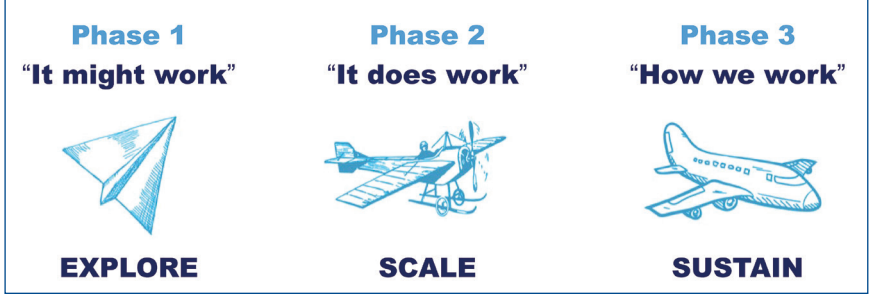
CHCI at LG Health's signature Innovation Accelerator Program (IAP) supports staff from across LG Health in their efforts to develop, test, and implement new approaches to improve health care delivery and patient outcomes. Working closely with mentors from the Innovation Center, teams progress through three phases of work (see Fig. 2) with the goal of bringing successful innovations to scale. This is a year-and-a-half-plus-long program, beginning with an invitation to clinicians and nonclinicians that they submit a Request for Problem (RFP) application. Ideally problems will not come with ready-made solutions, but will have passionate champions who are deeply embedded in the problem space or engaged subject-matter experts. If accepted into the program, the CHCI team at LG Health will work as facilitators and mentors to help fast-track, or accelerate, solutions.

During Phase 1 of the IAP, the team focuses efforts on exploring the problem and its potential solutions. For about six months, they embark on activities that take them through all parts of the Double Diamond framework to help understand the problem space, rapidly test solutions, and gather evidence to move the needle. When they can show a solution that might work, they present it to the health system's leadership for the opportunity to receive additional investment to help take the idea to scale.

Once graduated to Phase 2, teams move from conducting small experiments to testing on a larger scale. Teams are challenged in Phase 2 to demonstrate sustained impact and secure the resources and stakeholder support necessary to move solutions toward implementation. This phase usually takes about a year.

An example of an IAP project currently in Phase 2 is BP Pal, during which the CHCI team at LG Health will embark on a larger-scale pilot with two family practices and test certain escalation pathways. Champions Zachary Bricker, MSN, RN, manager of clinical quality; Michael Bredin, PA, Urgent Care; and Haley Fuller, patient education specialist, had already observed that 30% of LG Health's hypertensive patients were uncontrolled. That meant 21,000 patients were at increased risk of dying from heart attack or stroke. The CHCI team at LG Health helped determine a text-based monitoring solution to allow home blood pressure reporting and offer a high-impact opportunity to improve patient compliance and facilitate faster and better blood pressure management by providers.

Fig. 2. The Innovation Accelerator Program's three phases and foci of work.



BP Pal is based on Penn Medicine Philadelphia's employee hypertension program, which demonstrated 90% of participants became controlled within three months. The LG Health project's executive sponsor is Dr. John Wood, executive medical director of LG Health's Community Care Collaborative and LG Health Physicians.

In Phase 3, leveraging knowledge and momentum from previous phases, teams work with stakeholders to secure the permanent infrastructure necessary for their intervention. Teams "graduate" when they achieve sustainable implementation at scale for their solution. An example of a project in this phase is Screen on Time, championed by Dr. Brian Young, medical director of transformation, and Paige V. Bagwell, manager of diagnostics outreach. The executive sponsor is Tara Casher, administrative director of GI and general surgery service lines.

These project champions had identified that the current colorectal cancer screening approach left thousands of patients unscreened for the third leading cause of cancer-related deaths. During the eight-month initial pilot of a text-based program, patients were prompted to make an active decision about scheduling colorectal cancer screening. Initial results showed the number of screenings increased from 72.8% to over 75%, surpassing the annual goal of 74.1%.

CHCI at LG Health will kick off its third cohort of IAP projects in early 2023 and will accept applications between September 6 and October 21, 2022. More details, including dates of information sessions and how applicants can get help defining their problem, are available at https://innovation.lghealth.org/iap-application.

SCALING EXISTING PROJECTS

CHCI at LG Health also scales projects that its innovation sibling in Philadelphia has already moved through the three IAP phases. BreatheBetterTogether (BBT) is one example.

In 2017, more than 3,000 patients with COPD were admitted to downtown Philadelphia Penn Medicine hospitals over 5,000 times, and 20% were readmitted within 30 days. The Philadelphia Innovation team created a hospital-to-home transition program for patients with COPD to implement personalized home-based interventions. In the pilot phase — in which more than 150 high-risk COPD patients participated — the introduction of BBT led to a 32% reduction in 30-day readmissions, and Penn Cavalry prevented 82% of readmissions. Together, these programs resulted in cost savings to the health system of approximately $10,000 per patient.

The CHCI team at LG Health is working to scale this program in Lancaster, implementing both English- and Spanish-language versions of the programs as well as an over-the-phone option for non-texting patients.

AD-HOC PROJECTS

CHCI at LG Health is approached throughout the year by different practice areas, teams, or Champions for innovation help and insight. For example, one project explored the missed opportunity around monitoring certain diabetes patient groups.

To better understand why continuous glucose monitor patients using Abbott's FreeStyle Libre mobile app were not sharing their glucose readings with their provider — often not even scanning the sensor inserted into their skin — the LG Health innovation team dove deep into the patient perspective and experience of the diabetes management process. Through patient observations, interviews, and studying quantitative data and market research, the team discovered that patients have challenges with the digital setup process, as well as sharing data with their provider's practice. Additionally, many patients do not scan because they do not remember to install a new sensor for various end-user reasons.

EXTERNAL STRATEGIC PARTNERSHIPS

Finally, CHCI at LG Health is involved in strategic partnerships with startups. Through existing relationships with companies that provide capital investment to startups in the health care space, CHCI at LG Health can help run pilot programs and implement companies' ready-to-go offerings. After thorough vetting, startups may be introduced to other LG Health stakeholders who may be interested in implementing their solutions.

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BOOK REVIEW

Medical Apartheid

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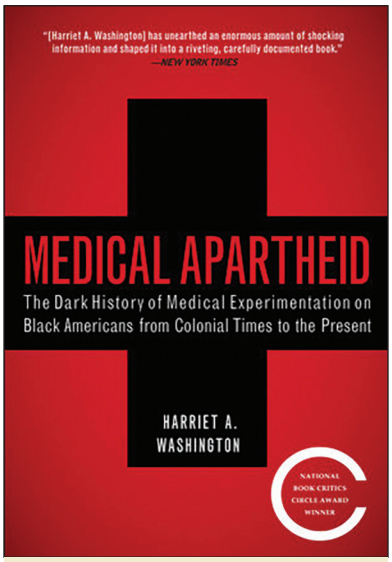
Hamblin


Hill

Editor's note: We also welcome this column from Dr. Cherise Hamblin, who works with the LG Health Family Medicine Residency Program and leads a health equity book club through Patients R Waiting. For more information, visit PatientsRWaiting.com.

Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present by Harriet A. Washington is a journey through the history of medicine that should be required reading for every health professional, from students to seasoned clinicians. Professor Washington takes readers through the history of the medical profession and its advancements, accounting for the inextricable links between the profession and Black people in America from the time of enslavement to the present day.



By Harriet A. Washington, New York, Anchor Books, 2006, 412 p, 11.99 paperback

As we look back on our own premedical and medical education, we both realize that we have had no formal course regarding the history of medicine, although context has occasionally been interwoven into didactic lectures. We came to read this work in early 2021 through a community book club and felt like we had stumbled onto a secret.

Professor Washington takes a methodical and unemotional approach to chronicling the long history of medical experimentation and misadventure of Black people in America from before the Tuskegee syphilis study to the present day. She begins in the 1700s in colonial America and asserts early on, on page 26, that "enslavement could not have existed and ... persisted without medical science." Physicians were dependent upon slavery, both for economic security and for the enslaved "clinical material" that fed American medical research; enslaved Africans bolstered physicians' professional advancement.

Further, in the antebellum South, physicians were complicit during their evaluation of enslaved people, deeming them fit for duty or too sick to work. Washington describes the ethical dilemma of the patient — the enslaved African — who was the legal property of the owner; the physician-client relationship was not with the patient but rather between the doctor and the slave owner. Owners and physicians blurred the therapeutic line by referring to whipping as medicine for malingering slaves; physicians actually prescribed "essence of rawhide" as treatment.

The origins of several medical advancements are depicted through the text, and as the history of medicine is not routinely taught in medical school, this is indeed a highlight. In the early 18th century, an enslaved African named Onesimus saved the city of Boston from a smallpox epidemic by teaching his owner, Cotton Mather — puritan preacher and amateur scientist — about the preventive measure of inoculation. This was a procedure Onesimus had undergone while still in Africa. Mather managed to convince one area physician to embrace and test the concept, ultimately subjecting 250 slaves and his own six-year-old son to the procedure.

When a smallpox epidemic revisited Boston in the summer of 1721, approximately 8,000 Bostonians became ill and 844 died. Remarkably, while one in nine untreated patients succumbed to their illness, only one in 48 of those who were inoculated died.[1] Mather made a scientific report to the Royal Society in 1722, and by 1750, inoculation, long practiced in Africa, had become a standard of care in America and Europe as well.

Today, vaccination is a hallmark of disease prevention, and while the COVID-19 pandemic has seen vaccination again become a hot-button topic, doubtless it can be said we owe untold millions of lives saved to the insight of Onesimus and Mather. This bit of history and context, as well as a litany that followed, are part of what made this reading so rich and compelling.

We took particular interest in the accounting of the work of James Marion Sims, frequently referred to as the Father of Gynecology. Dr. Sims developed surgical instruments and techniques for the repair of vesicovaginal fistulas and is world renowned for his contributions to the field. Yet in recent years, opinion of him has soured as the circumstances of his discoveries have become clear. Sims attended South Carolina Medical College and then Jefferson Medical College in Philadelphia, at a time when medical education consisted of a year and a half of instruction. He then embarked on a career as a plantation doctor in Alabama; the experimentation on the enslaved patients he "treated" has been described in his autobiography and other medical journals and accounts. What is now apparent is that to acquire subjects for his experimentation, he offered the owners of infirm slaves "trial and error" treatments, housing and feeding the subjects under his care.

The best known of these captive subjects were Anarcha, Betsy, and Lucy, three enslaved girls who suffered birth trauma that resulted in fistulas. Anarcha, 17, was attended by Sims, who conducted a forceps delivery that resulted in the death of her child and the formation of chronic unhealed tracts between her bladder, vagina, and rectum. For years, these girls, among others, were housed, drugged, and the subjects of experimentation without anesthesia. After the surgeries and instruments were developed and perfected, Sims toured the world with his discoveries, gaining acclaim and fortune, not conveying the torture he'd inflicted and the debt he owed to these three young women.

In our own time, the confluence of the murder of George Floyd in 2020, the COVID-19 pandemic's exacerbation of racial health disparities, and the widespread recognition that racism is an affront to our population's health has left many of us in emotional turmoil and searching for insight. Like others, we have turned to reading as a way to process feelings and understand where we can be most effective in practice and in our community.

Whether you are a history buff, a medical professional, an activist, or a learner of any sort, this text is a must-read. It is available as an audiobook, but having a physical copy is preferable, in our opinion. With our growing understanding of how racism is baked into our medical decision-making — through race-based calculations, through algorithms, and even in race-based cutoffs — it is imperative that we search for sufficient context to understand our own history. Reading *Medical Apartheid* is a fine first step; it brought us feelings of grief and anger, but ultimately left us feeling informed and renewed. Through over 800 citations, Professor Washington's account of American medical history is one to be read, re-read, and referenced by medical professionals, lest we forget from whence we came.

> *"A closer look at the troubling numbers reveals that Blacks are dying not of exotic, incurable, poorly understood illnesses nor of genetic diseases that target only them, but rather from common ailments that are more often prevented and treated among whites than among Blacks."*

While reading Medical Apartheid, *the quote above jumped out at me; I immediately shut the book. In that moment I was no longer reading for pleasure, but was having vivid flashbacks to my childhood.*

I was born and raised in New York City, in the Bronx and Spanish Harlem — two historically underserved communities stricken by economic, educational, and medical disadvantages. Crime rates are high in both areas, often deemed unsafe, but I have always found a sense of safety in my community. As a little girl, I remember coming together during cookouts and block parties filled with loud music, dancing, and delicious food. My neighborhood taught me how love and unity can bring about tangible change when we work together and uplift one another. Unfortunately, I also remember how members of my community had limited access to health care, and how both my grandmothers suffered from diabetes and hypertension.

Professor Washington sheds light on experiences that many Americans face, and couples their stories with facts and history. I truly believe that any individual pursuing health should read this book — to better understand, connect, and relate. Knowledge is power, and I believe that literature like this helps create better students, better physicians, and better human beings. — Khyla Hill

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Handoffs in Critical Care, Imaging for Blunt Injuries, Trauma Surgery

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Editor's note: This is the 12th in a series of articles from the Penn Medicine Lancaster General Health Research Institute that describes ongoing research studies. Other active studies have been described in previous issues of this journal.

The Lancaster General Health Research Institute welcomes guest authors Dr. Lindsey Perea and Dr. Eric Bradburn for this special spotlight on trauma research. The authors overview top studies below; several additional active studies are listed on the next page. Physicians who wish to refer patients for any of the studies mentioned are encouraged to contact the Research Institute at 717-544-1777.

Other members of the Lancaster General Health staff who are conducting research and wish to have their studies described here are encouraged to contact the offices of JLGH *at 717-544-8004.*

SPONSORED STUDY

Handoffs and Transitions in Critical Care: Understanding Scalability

Sponsor: National Institutes of Health R01
Lead Project Investigator: Meghan Lane-Fall, MD
Site (LGH) Co-Investigator: Lindsey Perea, DO

This is a prospective, observational multicenter study among 12 ICUs across the country. Penn Medicine in Philadelphia is the lead site. This five-year study funded by the National Institutes of Health (NIH) takes a hybrid approach, looking at effectiveness and implementation. The study participants are the providers.

The goal of the study is to standardize and streamline handoff communication from operating room (OR) to intensive care unit (ICU) using protocols tailored to meet the needs of each site. Standardizing handoffs should achieve decreased provider workload, fewer information errors, more efficient communication, avoidance of preventable harm, and improved provider satisfaction.

The study first aims to determine what influences implementation of an OR-to-ICU handoff protocol through interviews, focus groups, and surveys. The next aim of the study is to create a standardized OR-to-ICU handoff protocol tailored to each intensive care unit. Each ICU in the study will subsequently implement the handoff protocol in a staggered fashion. Finally, a handoff protocol kit will be designed for wide dissemination.

This study is being performed in the Trauma Neuro Unit at Lancaster General Hospital. Participation began a year ago, and implementation in the unit is expected in early Winter 2023.

INVESTIGATOR-INITIATED STUDY

REDSOC: Radiographic Evaluation of Delayed Solid Organ Complications

Sponsor (Unfunded): Eastern Association for the Surgery of Trauma (EAST)
Principal Investigator: Lindsey Perea, DO

This prospective, observational multicenter study is looking at blunt injuries to the spleen and liver. Currently, no clear guidelines exist regarding the necessity of repeat imaging or frequency of intervention in these injuries. After performing a dual institution pilot study that was underpowered, the investigators sought to answer these questions on a large scale.

The study aims to define which blunt hepatic and splenic injuries are at risk of delayed complications, which patients warrant repeat imaging, and when the imaging should be performed. Additionally, this study seeks to identify the incidence of interventions performed for delayed complications found on imaging.

To date, over 30 sites worldwide are enrolling patients, with more than 1,000 patients entered into the study database. The overall enrollment goal is 5,000-plus patients of all ages; LG Health has enrolled more than 100 of these patients.

Additional Active Studies in the Division of Trauma and Acute Care Surgery

Dr. Lindsey Perea is the principal investigator on all studies, unless otherwise noted.

INVESTIGATOR-INITIATED STUDIES

- Delirium in the Elderly: Factors in Trauma
- Social Determinants of Health in Trauma Patients — with Eric Bradburn, DO
- COVID-19 and Alcohol in the Setting of Trauma — with Eric Bradburn, DO
- Comparison of Immediate vs. Delayed Operative Outcomes in Patients with Symptomatic Cholelithiasis
- Application of Bundled Procedure in the Critically Ill Trauma Patient
- An Analysis of Patient Follow-up after Implementation of an Incidental Findings Protocol

MULTICENTER STUDIES

- Effects of Age, Anticoagulants, and Antiplatelet Agents on Motorcycle-Related Injuries in Pennsylvania
- CLOTT 3 — Principal Investigator: Eric Bradburn, DO
- Prospective Study of Mean Arterial Blood Pressure Augmentation in the Treatment of Spinal Cord Injuries*
- Outcomes Among Trauma Patients with Duodenal Leak Following Primary vs. Complex Repair of Duodenal Injuries*
- Early vs. Delayed Fasciotomy Following Extremity Trauma**
- Outcomes of Early Initiation of Venous Thromboembolism Prophylaxis in Isolated Traumatic Brain Injuries*
- A Comprehensive and Collaborative Review of the Use of Whole Blood at Trauma Centers in the United States*

NOTES:
** Eastern Association for the Surgery of Trauma (EAST) Sponsored*
*** American Association for the Surgery of Trauma (AAST) Sponsored*

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A complete list of active clinical studies at Lancaster General Health is available online. To access the most current list, scan the QR code at right, or find the link on the JLGH.org Resources/Links page.

Recommendations from the Commission on Cancer and the Critical Care Societies Collaborative

Alan S. Peterson, MD
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This is my 38th article on Choosing Wisely from the American Board of Internal Medicine (ABIM) Foundation. As noted in previous issues of *JLGH*, each specialty group is developing "Five or More Things That Physicians and Patients Should Question."

All items are developed to encourage discussion between physicians and their patients about which tests and procedures are best in each case. Additional resources are available online at ChoosingWisely.org.

I. RECOMMENDATIONS FROM THE COMMISSION ON CANCER

1. Removal of a breast lump for a suspicious finding should not be performed by surgery unless needle biopsy cannot be done. Needle biopsy may be directed by breast imaging (ultrasound, mammographic, magnetic resonance imaging) or by direct palpation. Studies show that confirmation of breast cancer diagnosis prior to any surgery allows for complete multidisciplinary treatment counseling, reduces the overall number of surgical procedures needed for treatment, improves the cosmetic results of surgery, and avoids mastectomy resulting from multiple surgical procedures.[1]

2. **Initiation of surveillance testing after cancer treatment should not be done without providing the patient a survivorship care plan.** The Institute of Medicine identified the need for a survivorship care plan as a key factor to help cancer patients transition to long-term surveillance care, avoid unnecessary services, and seek appropriate rehabilitative care and emotional support.

This plan includes a summary of the type and stage of the cancer, treatment received, the plan for type and frequency of surveillance testing, and information on resources for rehabilitative and supportive care. Templates for survivorship care plans are available from organizations including Livestrong Foundation, the National Coalition for Cancer Survivorship, and the American Society of Clinical Oncology.

3. Initial treatment should not use surgery without considering presurgical (neoadjuvant) systemic chemotherapy and/or radiation for cancer types and stage where it is effective at improving local cancer control, quality of life, or survival.[2] In many cancer types, presurgical chemotherapy, hormone/endocrine therapy, and/or radiation therapy followed by surgery is better than surgery as the first treatment. This often shrinks the cancer, allowing more limited surgery that maintains organ function, reduces the chances of cancer recurrence and spread, and improves the quality of life.

Disease sites where this should be considered should include:

- Clinical stage IIB and IIIA non-small cell lung cancer
- Clinical T2-4a; any N-positive esophageal cancer
- Clinical T3 and T4 rectal cancer
- Clinical T2, T3, or stage III breast cancer
- Head and neck cancer
- Resectable pancreatic cancer
- Extremity soft tissue sarcomas where resection may affect functional outcomes

4. Major abdominal surgery or thoracic surgery should not be performed without a pathway or standard protocol for postoperative pain control and pneumonia prevention. Coordinated care efforts and established care pathways to control pain and prevent pneumonia reduce the frequency of complications and the length of hospital stay, and should be in place.

5. **Cancer treatment should not be initiated without defining the extent of the cancer (through clinical staging) and discussing with the patient the intent of treatment.** Treatment intent may be diagnostic, curative, maintenance, or palliative. Clinical staging should be performed and documented using information from history and physical examination, relevant biopsy, and appropriate imaging based on the type and stage (extent) of the cancer.

Many patients, especially those with advanced or metastatic cancer, do not have a full understanding of the intent of cancer treatment — they identify that treatment may be curative when in fact it is given

only with palliative intent. They often do not understand the costs, risks, and potential side effects of the treatment.[3]

II. RECOMMENDATIONS FROM THE CRITICAL CARE SOCIETIES COLLABORATIVE

This collaborative comprises the American Association of Critical-Care Nurses, the American College of Chest Physicians, the American Thoracic Society, and the Society of Critical Care Medicine.

1. Diagnostic tests should not be ordered at regular intervals (such as every day), but rather in response to specific clinical questions. Compared with a practice of ordering tests only to help answer clinical questions, or when doing so will affect management, the routine ordering of tests increases health care costs, does not benefit patients, and may in fact harm them. Potential harms include anemia due to unnecessary phlebotomy, which may necessitate risky and costly transfusion, and the aggressive workup of incidental and nonpathological results found on routine studies.[4]

2. Transfusion of red blood cells in hemodynamically stable, non-bleeding ICU patients with a hemoglobin concentration greater than 7 g/dl should not be performed. Most red blood cell transfusions in the ICU are for benign anemia rather than acute bleeding that causes hemodynamic compromise. It is possible that different thresholds may be appropriate in patients with acute coronary syndromes, although most observational studies suggest harms of aggressive transfusion even among such patients.[5]

3. Parenteral nutrition should not be used in adequately nourished critically ill patients within the first seven days of an ICU stay. For patients who are adequately nourished prior to ICU admission, parenteral nutrition initiated within the first seven days of an ICU stay has been associated with harm, or at best no benefit, in terms of survival and length of stay in the ICU. Evidence is mixed regarding the effects of early parenteral nutrition on nosocomial infections.

4. Mechanically ventilated patients without a specific indication and without daily attempts to lighten sedation should not be deeply sedated. Several protocol-based approaches can safely limit deep sedation, including the explicit titration of sedation to the lightest effective level, the preferential administration of analgesic medications prior to initiating anxiolytics, and the performance of daily interruption of sedation in appropriately selected patients receiving continuous sedative infusions.

5. Life support for patients who are at high risk for death or severely impaired functional recovery should not be continued without offering patients and their families the alternative of care focused entirely on comfort. Routinely engaging high-risk patients and their surrogate decision-makers in discussions about the options of foregoing life-sustaining therapies may promote patients' and families' values, improve the quality of dying, and reduce family distress and bereavement.

Even among patients pursuing life-sustaining therapy, initiating palliative care simultaneously with ongoing disease-focused therapy may be beneficial.

Top Tips

HOW TO TALK TO BELIEVERS OF COVID-19 CONSPIRACY THEORIES

Experts on misinformation and psychology interviewed by the Associated Press offer several tips for individuals wondering how to talk to friends or family who believe conspiracy theories about COVID-19. Here is what they suggest:

- *Listen, Don't Preach:* Instead of lecturing, listen and ask questions about how they became interested in the conspiracy theory, where they got their information, and whether they have considered other explanations.
- *Stay Calm:* Remember that some people won't change their minds no matter what you say, and arguing over the proven benefits of mask wearing or vaccines isn't likely to convince them. Some folks will listen to health care providers, but not all.
- *Change the Subject:* Bring up shared experiences and interests to help the person focus on personal connections. If someone dwells on the conspiracy theory, politely say that you would rather talk about something else.

As for increasing your own defenses against conspiracy theories and misinformation about the virus (or any other topic), experts suggest the following:

- *Expand Your Media Diet:* Checking a variety of news sources — including some mainstream local, national, and international outlets — is the best way of staying informed and avoiding rabbit holes of misinformation and conspiracy theories.

- *Check Sources:* Look to see who wrote the content and who is quoted. Are they named? Do they have a position, or experience, that lends credibility to their claims? Are other viewpoints expressed in the article? Also, check the dates: misinformation peddlers often post old photos or news stories and claim they are new.
- *Be Wary of Content That Plays on Emotions:* Misinformation and conspiracy theories often exploit anger, fear, or other emotions. Be cautious of content that features strongly emotional language or seems intended to outrage readers.
- *Verify Extraordinary Claims:* If you read something that makes an incredible claim — one that seems too good, too awful, or too weird to be true — check to see if it is being reported elsewhere.
- *Get Offline:* Experts say healthy habits like exercise, meditation, positive relationships, volunteering, and even hobbies can ease some of the dread and make us more resistant to misinformation and conspiracy theories that exploit our fear or anger.

MONITOR YOUNG CHILDREN FOR THYROID DYSFUNCTION AFTER EXPOSURE TO IODINATED CONTRAST MEDIA

The Food and Drug Administration (FDA) has updated a safety communication regarding the risk of thyroid dysfunction in infants following the use of contrast media containing iodine for x-rays and other medical imaging procedures.

The update was based on the agency's recent review of six newly published studies evaluating this risk, along with five earlier studies of 10 to 2,320 children, ages birth through 3 years, who were exposed to iodine contrast media (ICM) injections. The reported rate of underactive thyroid cases ranges from 1% to 15%. Neonates, particularly those who were preterm, were at high risk; patients with cardiac conditions were at greatest risk. Most reported cases were temporary and did not require treatment.

The FDA concluded, "There is compelling evidence of a significant risk of underactive thyroid or a temporary decrease in thyroid levels in newborns and children through 3 years after exposure to ICM."

Considering the review, the agency approved a new warning to be added to prescribing information for the entire class of ICM injections. The warning describes the risk of underactive thyroid or a temporary decrease in thyroid levels.

Museum Showcases LGH Artifacts Online

The Lancaster Medical Heritage Museum at 410 N. Lime Street is closed for renovation, but its virtual museum continues to grow. More than 20 online exhibits showcase artifacts to help tell the story of medicine throughout history. Alan Peterson, MD, a member of the JLGH *Advisory Editorial Board, also serves on the museum's board. He explains that the new Lime Street location is the former home of Lancaster General Hospital's School of Nursing. The space was "graciously provided" by LGH, according to Dr. Peterson, after the school's move to the Pennsylvania College of Health Sciences. The virtual museum can be found online at LancasterMedicalHeritageMuseum.org. A speaker's bureau and online library of publications are also available.*

Health care professions should consider evaluating function within three weeks, especially in term and preterm neonates and children with cardiac or other conditions. If thyroid dysfunction is detected, treat and monitor thyroid function as clinically needed.

VON WILLEBRAND DISEASE MANAGEMENT GUIDELINE[6]

Von Willebrand disease (VWD) is a common inherited bleeding tendency often characterized by easy bruising, epistaxis, heavy menstrual bleeding, and bleeding after dental and other procedures and surgeries. Given the variability in management of the disease, a multidisciplinary panel developed evidence-based guidelines that offer practical recommendations for this difficult-to-manage disease. Key recommendations of the guidelines include:

- When desmopressin is considered as a future treatment option (typically for type 1 VWD), a baseline trial is suggested to confirm efficacy, especially in patients with Von Willebrand factor (VWF) levels <0.30 IU/mL. The panel highlights that desmopressin is usually ineffective in type 2 VWD, is contraindicated in patients with active cardiovascular disease, and is associated with risk for hyponatremia.

- The panel suggests that VWD does not always present an absolute contraindication to antiplatelet or anticoagulant therapy in patients with cardiovascular disease.
- After major surgery, the suggested goal for factor VIII and VWF activity levels is ≥0.50 IU/mL for at least three days.
- Use of hormonal therapy (combined hormonal contraception or an intrauterine device) or tranexamic acid is suggested over desmopressin in women with heavy menstrual bleeding.
- When neuraxial anesthesia is acceptable during labor, the panel suggests targeting a VWF activity level of 0.5 to 1.5 IU/mL, rather than >1.5 IU/mL, during anesthesia for at least five hours after.

The above recommendations are conditional based on low certainty of evidence, but they do provide helpful recommendations consistent with good clinical practice.

It is important to know that VWD does not always present contraindications to the treatment of major comorbid illnesses, such as cardiovascular disease, and that tranexamic acid can be a useful therapy for patients with minor mucocutaneous bleeding. Guidelines on the diagnosis of VWD were published concurrently.[7]

RECENT RESEARCH STUDIES FOR PRIMARY CARE PHYSICIANS[8]

Editor's note: Of the 20 research studies identified as POEMs (patient-oriented evidence that matters), Dr. Peterson picked his top five to share in this column. He does, however, suggest that readers look at the full article, published in the July 2021 issue of American Family Physician.

1. COVID-19: How common is the presymptomatic transmission of the virus that causes COVID-19? Nearly half of COVID-19 transmissions occur during the presymptomatic phase. This analysis of the temporal pattern of viral shedding found that 44% of secondary cases were infected when the index case was presymptomatic.

2. Does aspirin still provide a net benefit as primary prevention? The balance of benefits and harms is equally weighted, so we should no longer recommend aspirin for primary prevention of cancer or cardiovascular disease. The European Society of Cardiology, the American College of Cardiology, and the American Heart Association agree and no longer recommend aspirin for primary prevention of cardiovascular disease.

3. Is physical therapy or a single glucocorticoid injection more effective for the treatment of osteoarthritis of the knee? The bottom line is that physical therapy is somewhat better than glucocorticoid injection for osteoarthritis of the knee. Studies showing this result are limited by the open-label design. Also, regression to the mean may have contributed to the observed improvements.

A Cochrane review concluded that glucocorticoid injections were effective although primarily in the two to four weeks following an injection, and recent American College of Rheumatology guidelines make strong recommendations in favor of both physical therapy and glucocorticoid injections.

4. Which treatments are effective for patients with an exacerbation of COPD? Short-term antibiotic treatment and short-term systemic corticosteroids are both associated with a faster resolution of COPD symptoms and fewer treatment failures. Other treatment approaches do not help.

5. Is continuity of care associated with decreased mortality? Most studies in this systematic review found that greater primary care continuity was associated with lower all-cause mortality.

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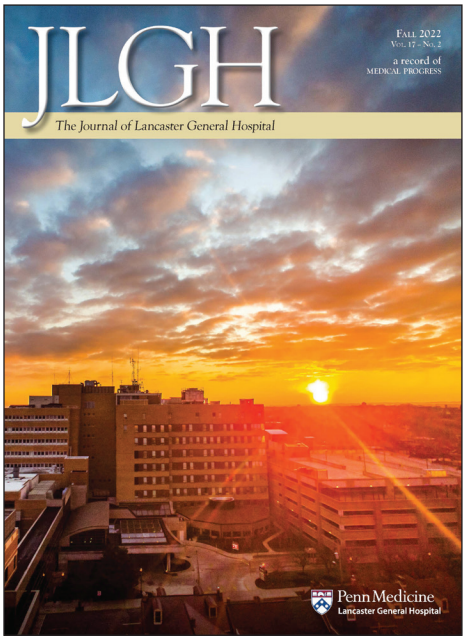

Cover photo by Michael K. Robinson, MD, a family physician at Penn Medicine Lancaster General Health Physicians Family Medicine Oxford.

Dr. Robinson took this photo of the sun rising over LGH from the employee parking garage early one morning while still a resident at the hospital and before renovations began for the new Emergency Department on Duke Street.

HAVE AN IDEA FOR A STORY? WE WANT TO HEAR FROM YOU.

The Journal of Lancaster General Hospital is looking for human interest stories including, but not limited to, staff experiences, patient experiences, and anything else that might be educational for our readers — the medical staff of Lancaster General Health. If you have an idea for a story, scan the QR code at left or log onto our website at JLGH.org to share your idea.

INTERESTED IN WRITING FOR *JLGH*?

The following is a summary of the general guidelines for submitting an article to *The Journal of Lancaster General Hospital*. Details are located on the web at JLGH.org.

Scientific manuscripts are typically between 2,500-4,500 words. Perspective articles are usually shorter, and photo quizzes average about 725 words plus illustrations. Medical articles should report research, introduce new diagnostic or therapeutic modalities, describe innovations in health care delivery, or review complex or controversial clinical issues in patient care. Reports of research involving human subjects must include a statement that the subjects gave informed consent to participate in the study and that the study has been approved by the institutional review board (IRB). Patient confidentiality must be protected according to the U.S. Health Insurance Portability and Accountability Act (HIPAA).

Please contact the Managing Editor, Maria M. Boyer (717-544-8004), Maria.Boyer@pennmedicine.upenn.edu, to discuss submitting an article or for further information.

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EARN CME FOR READING THIS ISSUE OF *JLGH*

DID YOU KNOW, PHYSICIANS CAN EARN CATEGORY 2 CREDIT FOR READING *JLGH*?

American Medical Association Category 2 activities consist of self-directed learning or courses that have not been through a formal approval process. According to the Pennsylvania State Board of Medicine, this includes "learning experiences that have improved the care [physicians] provide their patients." Reading authoritative medical literature — like *JLGH* — is one such activity. More information and the Pennsylvania Board of Medicine CME Reporting Form are available at LGHealth.org/CME. Physicians can also log credit through their eeds account online.

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Department of Medicine Grand Rounds
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Hospitalist Interprofessional Case-Based Conference Series
October 12 & 19, November 16, December 14, 12:30-1:00 p.m.
November 9, 7:30-8:00 a.m.

Pediatric Hospitalist Case Conference & Literature Review
October 11, November 8, December 13, 7:00-8:00 a.m.

Family Medicine Grand Rounds
October 18, November 15, December 20, 7:00-8:00 a.m.

Pediatric Grand Rounds
October 20, 7:00-8:00 a.m.

Special Symposia — Registration Required

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September 22, 6:00-8:00 p.m.

Advanced Medicine at ABBCI
October 6, 6:00-7:30 p.m.

Overcoming Obstacles to Care for the Plain Community
October 22, 8:00 a.m.-12:30 p.m.

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