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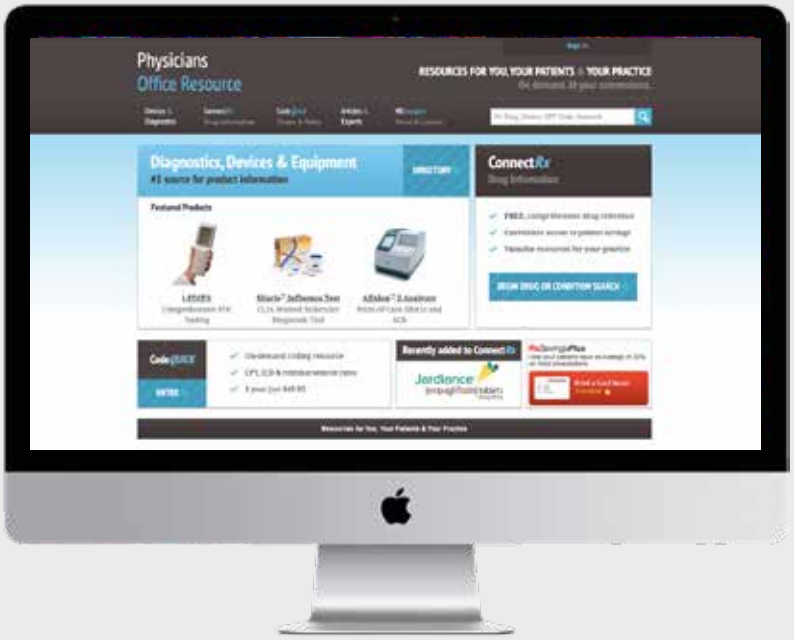
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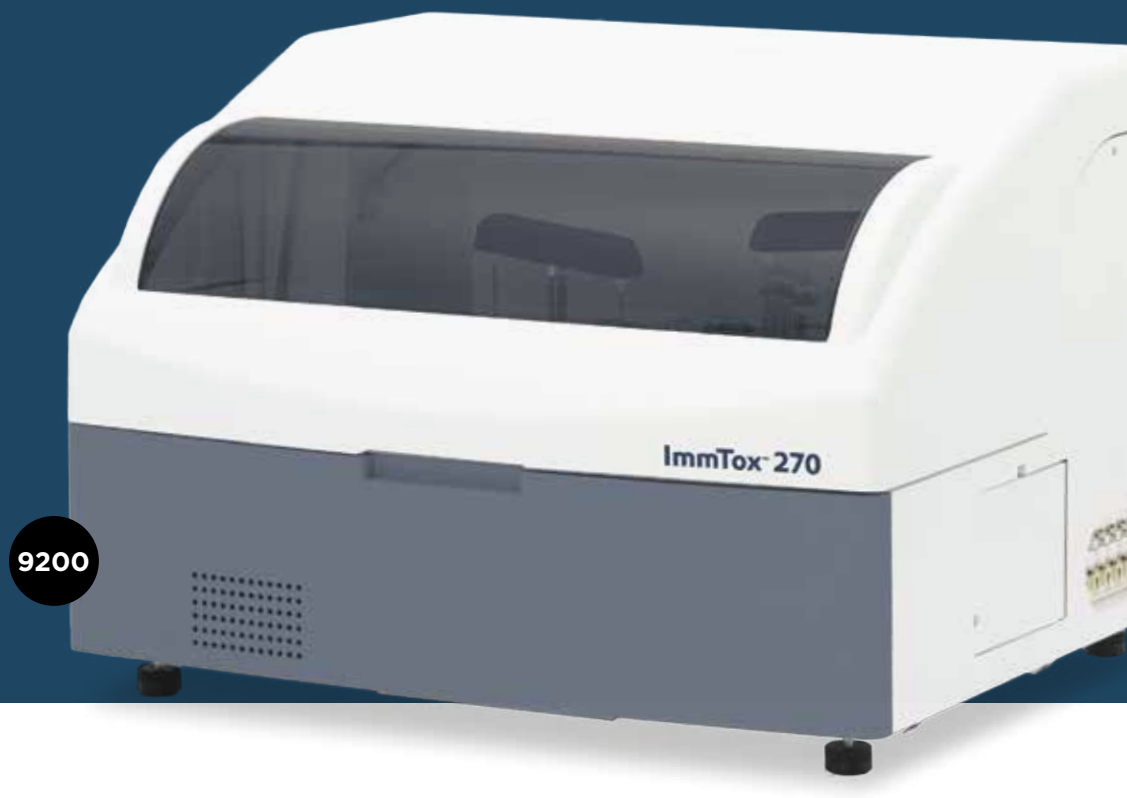
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PSA: TO SCREEN OR NOT TO SCREEN? THAT IS THE QUESTION...

—

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28

DIRECT CONNECTION BETWEEN INEFFICIENCY AND BURNOUT

—

Mark Linzer's research identified workplace chaos as one of the key predictors of physician stress, burnout, and intention to leave. A recent analysis of the data showed that physicians in clinics with chaotic work environments had significantly more stress and burnout and a higher likelihood of leaving the practice within two years.

36

PATIENT ANXIETY: CREATING A BETTER ENVIRONMENT TO HEAL

—

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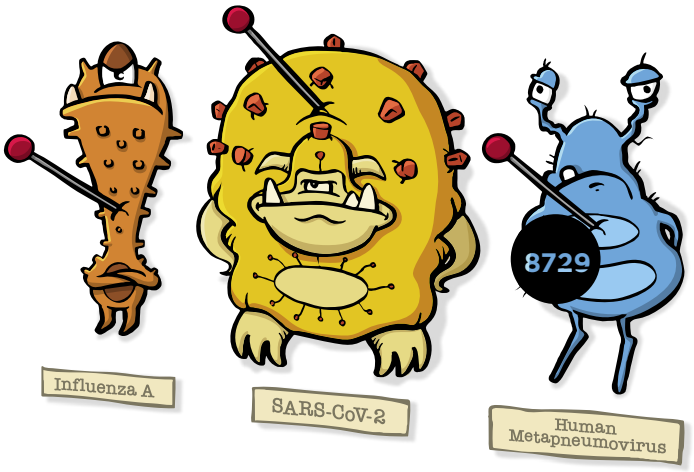
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PSA: To Screen or Not to Screen?

THAT IS THE QUESTION...

BY SEKISUI DIAGNOSTICS

There are certain milestones in life that no one looks forward to—having your wisdom teeth pulled. That first mammogram! At the top of the list for men is likely that first rectal exam at 40 or 50 as an initial screening for prostate cancer. But, like those pesky wisdom teeth and the oh-so-important mammogram, screening for prostate cancer is important and necessary.



A policy paper produced by the European Association of Urology1 states that there were approximately 450,000 cases of prostate cancer in Europe in 2018 and 107,000 deaths expected. In 2019, the American Cancer Society estimates2 that there will be about 174,650 new cases of prostate cancer in the U.S. Globally prostate cancer3 is the second most commonly occurring cancer in men and the fourth most commonly occurring cancer overall.

That being said, prostate cancer often can be treated successfully. In fact, the localized and regional five-year survival rates4 for this type of cancer are near 100%! As with all cancers, early diagnosis is important. Most prostate cancers are first found5 during screening with a prostate-specific antigen (PSA) blood test or a digital rectal exam (DRE). While prostate cancers usually don't cause symptoms in the early stages, more advanced cancers are sometimes first found because of symptoms they cause.

So why are there ongoing controversial discussions about PSA screening? Why do the United States and Europe hold different positions regarding some aspects of screening?

So What's the Deal?

How can one argue that it's better not to screen for a cancer? The medical community is divided due to the risk of overdiagnosis and overtreatment. Cancer overdiagnosis6 is the detection of cancer that would not develop any symptoms during a man's lifetime if not identified by early detection or not result in cancer-related death. Overtreatment refers to unnecessary medical interventions, including extensive treatment for a condition that requires only limited treatment.

According to the European Association of Urology1, the risk of overdiagnosis has been estimated to be as high as 40% in screen-detected prostate cancer, leading to unnecessary biopsies and

detection of insignificant cancers, which could lead to over-treatment. In 2012, the U.S. Preventive Services Task Force (USPSTF) actually recommended against7 screening for prostate cancer in all men! However in 2017, the USPSTF released a new draft recommendation for prostate cancer screening encouraging providers7 to inform men ages 55 to 69 about the benefits and harms of prostate cancer screening.

Worrying Statistics

Practitioners in both the UK and the U.S.1 were advised not to perform PSA for early detection. Two independent studies performed in 2017 and 2018 found that a lack of prostate cancer screening may be reversing1 the trend of declining death rates—meaning mortality from these type of cancer could be on the rise. This year, the European Association of Urology made a call to action8, stating, "Urgent action is required to ensure the new Commission is mandated to support EU Member States in prostate cancer screening in their national cancer plans."

EAU Policy Coordinator Michelle Battye wants the 2003 Council Recommendations on population-based screening to be "urgently reviewed," with prostate cancer added to the list of cancers to be addressed, and wants member states to bring good practice on prostate cancer screening to the Steering Group on Health Promotion, Disease Prevention and Management of non-communicable diseases.

How the U.S. Responded

As we briefly mentioned above, in 2017 the USPSTF released new recommendation for prostate cancer screening encouraging providers7 to inform men ages 55 to 69 about the benefits and harms of prostate cancer screening. The American Cancer Society recommends9 that men learn as much as they can about prostate cancer screening risks and benefits and discuss the information with their doctor before deciding whether to be tested. Men at average risk of prostate cancer should have this discussion at age 50. Men at higher than average risk should have the discussion starting at age 40 or 45.

The consequences of decreased PSA screening10 are numerous:

Increased mortality

The effects of non-curative intervention
Psychological complications of recurrent prostate cancer

So do the risks of prostate cancer screening outweigh the benefits? That's not a question any man should answer alone—he should discuss the pros and cons of screening with his doctor to make an informed decision. However, physicians should bring this topic to the table at the appropriate time for all affected patients.

In the end, prostate cancer screening is important, as it is with all types of available cancer screenings. A little bit of research can inundate you with statistics, recommendations, and lots of other frightening material. What matters is that physicians are aware of recommended guidelines and available screening and treatment options, and that patients are given the information they need to make informed decisions regarding their health.

Sekisui Diagnostics offers two tests (please note that only one is currently available in the U.S.). The FastPack® IP Total PSA immunoassay11 is a chemiluminescent immunoassay for the in-vitro quantitative determination of PSA in human serum and plasma as an aid in the management of patients with prostate cancer. It offers results in 12 minutes.

The FastPack® IP Free PSA Immunoassay12, not currently available in the U.S., is a chemiluminescent immunoassay for the in-vitro quantitative determination of free prostate-specific antigen (free PSA) in human serum. It is designed for use in conjunction with the FastPack IP System for calculating the ratio of free/total PSA, expressed as a percentage (percent free PSA). A free PSA test13 can be used instead of a biopsy if PSA levels are slightly elevated, and may be used to determine how aggressive a recurring cancer is.

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IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Few cases (0.36%) of adverse reactions of cystitis, pyelonephritis and other upper urinary tract infection (UTI) have been reported in Phexxi® clinical studies. Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of Phexxi® in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

Most common adverse reactions were vulvovaginal burning sensation, vulvovaginal pruritus, vulvovaginal mycotic infection, urinary tract infection, vulvovaginal discomfort, bacterial vaginosis, vaginal discharge, genital discomfort, dysuria, and vulvovaginal pain. 9.8% of male partners reported local discomfort.

Patients should be counseled on the following:

- **To contact and consult with their healthcare provider for severe or prolonged genital irritation or if experiencing urinary tract symptoms.**
- **To discontinue Phexxi® if they develop a local hypersensitivity reaction.**
- **That Phexxi® does not protect against HIV infection or other sexually transmitted infections.**
- **To avoid Phexxi® use with vaginal rings.**

phexxi®
(lactic acid, citric acid, and potassium bitartrate) Vaginal Gel 1.8%, 1%, 0.4%

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A non-hormonal prescription contraceptive vaginal gel that's used in the moment

For the women in your practice who...

- Prefer non-hormonal contraception because of unwanted side effects experienced with hormones
- Currently use condoms or withdrawal method
- Want an easily reversible method
- Are likely to research contraceptive options and prefer methods that fit their healthy lifestyles

How to prescribe Phexxi®

PHEXXI® VAGINAL GEL (5 g per applicator)

Sig: Administer 1 applicator intravaginally immediately **before** or up to 1 hour before EACH act of vaginal intercourse as needed.

Rx

Dispense: # 12 applicators

NDC: 69751-100-12

Refill: 11

Discover all Phexxi® has to offer in an immersive experience

To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

INDICATIONS AND USAGE

Phexxi® (lactic acid, citric acid, and potassium bitartrate) vaginal gel 1.8%, 1%, 0.4% is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE

Phexxi® is not effective for the prevention of pregnancy when administered after intercourse.

Please see full Prescribing Information for Phexxi®.
Please see Brief Summary on the following page.

EVOFEM BIOSCIENCES®

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phexxi®

(lactic acid, citric acid, and potassium bitartrate) Vaginal Gel 1.8%, 1%, 0.4%

BRIEF SUMMARY: Consult the Package Insert for complete Prescribing Information

INDICATIONS AND USAGE

PHEXXI® is indicated for the prevention of pregnancy in females of reproductive potential for use as an on-demand method of contraception.

LIMITATIONS OF USE

PHEXXI is not effective for the prevention of pregnancy when administered after intercourse.

WARNINGS AND PRECAUTIONS

Cystitis and Pyelonephritis

Among 2804 subjects who received PHEXXI in Studies 1 and 2, 0.36% (n=10) reported adverse reactions of cystitis, pyelonephritis, or other upper urinary tract infection (UTI). Of these, one case of pyelonephritis was considered serious and required hospitalization. Avoid use of PHEXXI in females of reproductive potential with a history of recurrent urinary tract infection or urinary tract abnormalities.

ADVERSE REACTIONS

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The safety of PHEXXI (pre-filled applicator with 5-gram dose) has been evaluated in two clinical trials (Study 1 and Study 2) in 2804 subjects (over 19,000 cycles of exposure). The racial/ethnic distribution was 66% White, 27% Black or African American, 2% Asian, 1% American Indian or Alaska Native, 0.3% Native Hawaiian or Pacific Islander, and 5% other; 32% of the study population was Hispanic. Study 1 included a one-year extension phase where 342 U.S. subjects were exposed to PHEXXI for 13 cycles.

Hypersensitivity Reaction:

Of the 2804 PHEXXI-treated subjects in Studies 1 and 2, one subject reported a suspected drug hypersensitivity. Avoid PHEXXI use in females of reproductive potential with suspected hypersensitivity to the ingredients in PHEXXI.

The most common adverse reactions (≥10%) in the U.S. population in Studies 1 and 2 (n = 2480) were: vulvovaginal burning sensation (18.0%) and vulvovaginal pruritus (14.5%). The majority of these adverse reactions were mild and few led to discontinuation. Table 1 summarizes the most common adverse reactions (≥ 2%) reported by subjects using PHEXXI in the U.S.

Table 1. Adverse Reactions that Occurred in ≥ 2% of Subjects Who Used PHEXXI to Prevent Pregnancy (Studies 1 and 2 – U.S. population only)

Adverse Reaction	PHEXXI (N=2480) (%)
Vulvovaginal Burning Sensation	18.0
Vulvovaginal Pruritus	14.5
Vulvovaginal Mycotic Infection*	9.1
Urinary Tract Infection†,‡	9.0
Vulvovaginal Discomfort	9.0
Bacterial Vaginosis	8.4
Vaginal Discharge	5.5
Genital Discomfort	4.1
Dysuria	3.1
Vulvovaginal pain	2.1

*Includes preferred terms (PT) vulvovaginal mycotic infection and vulvovaginal candidiasis.
†Includes PTs urinary tract infection, streptococcal urinary tract infection, Escherichia urinary tract infection, and urinary tract infection bacterial.
‡Does not include PTs cystitis, kidney infection, and pyelonephritis [see *Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].

Among subjects who used PHEXXI in Studies 1 and 2, 1.6% discontinued from the clinical trials due to an adverse reaction. The most common adverse reactions leading to study discontinuation were vulvovaginal burning sensation (0.7%); and vulvovaginal pruritus and vulvovaginal discomfort (0.1% each).

Adverse Reactions in Male Partners:

Among male partners of subjects who used PHEXXI for contraception in Study 2, 9.8% (131 of 1330) reported symptoms of local discomfort (burning, itching, pain, and "other"). Of these local discomfort symptoms, 74.7% were mild, 21.4% were moderate, and 3.9% were severe. Two subjects discontinued participation in the study due to male partner symptoms.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

There is no use for PHEXXI in pregnancy; therefore, discontinue PHEXXI during pregnancy. There are no data with the use of PHEXXI in pregnant women or animals. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4 percent and 15 to 20 percent, respectively.

Lactation

Risk Summary

There are no data on the presence of lactic acid, citric acid, and potassium bitartrate or their metabolites in human milk, the effects on the breastfed infant, or the effects on milk production.

Pediatric Use

The safety and effectiveness of PHEXXI have been established in females of reproductive potential.

Efficacy is expected to be the same for post-menarchal females under the age of 17 as for users 17 years and older. The use of PHEXXI before menarche is not indicated.

PATIENT COUNSELING INFORMATION

See FDA-approved patient labeling.

Advise the patient to read the Patient Information and FDA-approved patient labeling (Instructions for Use).

Advise the patient:

- To intravaginally administer the contents of one pre-filled single-dose applicator of PHEXXI before **each** episode of vaginal intercourse and to administer an additional dose if intercourse does not occur within one hour of administration [*see Dosage and Administration (2.1) of PHEXXI Full Prescribing Information*].
- To consult their healthcare provider for severe or prolonged genital irritation [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To discontinue PHEXXI if they develop a local hypersensitivity reaction [*see Adverse Reactions (6.1) of PHEXXI Full Prescribing Information*].
- To contact their health care provider if experiencing urinary tract symptoms [*see Warnings and Precautions (5.1) of PHEXXI Full Prescribing Information*].
- That PHEXXI does not protect against HIV infection and other sexually transmitted infections.

Manufactured for Evofem, Inc.,
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12400 High Bluff Drive, Suite 600, San Diego, CA 92130

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U.S. Patent 6,706,276

REFDOC-001013

To report SUSPECTED ADVERSE REACTIONS, contact Evofem at toll-free phone 1-833-EVFMBIO or you may contact FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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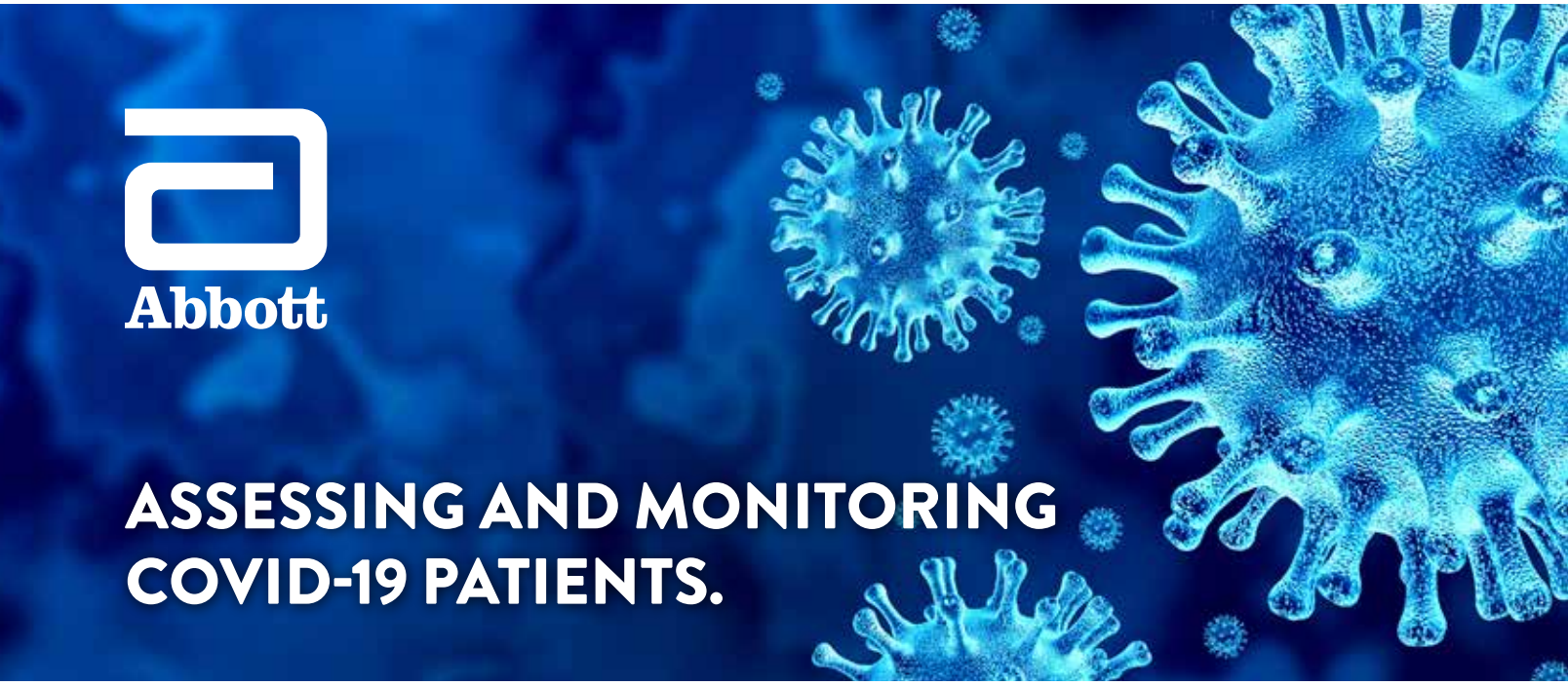
- Takes 3 minutes to analyze a patients' hands and feet
- Provides a 1 page summary report
- Assesses peripheral nerve health (c-fiber function) and asymmetry between each hand and foot
- **Reimburses $130/test (national average)**

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ASSESSING AND MONITORING COVID-19 PATIENTS.

Urgent care facilities, primary care practices, and other outpatient settings at the front lines of the COVID-19 pandemic need on-site testing solutions to support patient assessment and monitoring. With-patient testing can lead to better healthcare performance by facilitating decisions that can optimize patient outcomes in real time, improving the quality of patient care.

For facilities treating COVID-19 patients, having rapid, accurate diagnostic test results may be useful when assessing or monitoring patients for:

- **C-Reactive Protein (CRP)**
  Levels may be elevated in COVID-19 cases, especially severe cases.[2-15]
- **Liver, Kidney and Cardiac function**
  Elevated levels of the following biomarkers may be indicators of COVID-19 severity:[16-27]
  - Alanine Aminotransferase (ALT)[16,17,20-27]
  - Albumin (ALB)[16,19-22,25-27]
  - Aspartate Aminotransferase (AST)[16,17,19-21,23-26]
  - Creatine Kinase (CK)[16,18,20,22-24]
  - Creatinine (CREAT)[16,22,23,25,27]
  - Total Bilirubin (TBILI)[16,20,25,27]



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The Piccolo Xpress does not directly diagnose COVID-19.

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KEY PICCOLO XPRESS PANELS.

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Comprehensive Metabolic Panel
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MetLyte 8
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Liver Panel Plus
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*Calculated

MODERATELY COMPLEX PANELS



BioChemistry Panel Plus
ALB, ALP, ALT, AMY, AST, BUN, Ca, Crea, Glu, GGT, TP, UA, CRP, eGFR*



MetLyte Plus CRP
Na+, K+, Cl-, tCO_2, BUN, Crea, Glu, CK, CRP, eGFR*



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ALB, ALP, ALT, AST, tBIL, dBIL, TP

To learn how the Piccolo Xpress portable diagnostic analyzer can help transform your patient care, contact your Abbott Point of Care Representative or visit www.pointofcare.abbott

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FEATURE

THE DIRECT CONNECTION BETWEEN

INEFFICIENCY AND BURNOUT

BY PAUL DECHANT, MD, MBA AND DIANE W. SHANNON, MD





An excerpt from Preventing Physician Burnout: Curing the Chaos and Returning Joy to the Practice of Medicine.

Mark Linzer's research identified workplace chaos as one of the key predictors of physician stress, burnout, and intention to leave. A recent analysis of the data showed that physicians in clinics with chaotic work environments had significantly more stress and burnout and a higher likelihood of leaving the practice within two years. These clinics also had significantly more missed opportunities to provide preventative services and had significantly higher rates of medical errors.

Our experience and that of many of the physicians we interviewed confirmed the importance of workplace chaos in the development of burnout. Diane identified workplace chaos as the most important factor in the burnout that led her to leave clinical practice. Craig Albanese, MD, MBA, senior vice president and chief operating officer at New York-Presbyterian/Morgan Stanley Children's Hospital and Sloane Hospital for Women, pointed to the chaos and unstable work environment as the driver of his increasing interest in taking on administrative roles. He sensed that "there's got to be a better way." According to John Toussaint, MD, CEO of the ThedaCare Center for Healthcare Value, the workplace prior to implementing a Lean transformation at ThedaCare was replete with inefficiencies. "Physicians, nurses, and administrators and everybody else were all running around like chickens with their heads cut off because all the processes were chaos. There was no standard work. You did it one way on Monday, another way on Tuesday, and a third way on Wednesday. There was no predictability."

Toussaint told us that he and other leaders hypothesized that if they created predictability through standard work, the organization could focus on defect identification and problem-solving at the source. This approach, they believed, would lead to a more stable environment for caregivers and for patients. He described an informal study he did early in the organization's Lean journey. He shadowed a nurse for a week with a stopwatch. The results? Three and a half hours of an eight-hour shift were spent searching for supplies. "It was the same for physicians in the office. What they needed was not in the room when they needed it. They didn't have the information they needed to make decisions. Process after process was so fundamentally broken; it's understandable why people were very stressed out."

In an interview, James P. Womack, PhD, founder and senior advisor to the Lean Enterprise Institute, described a conversation he had with several residents after delivering a presentation at a prestigious academic hospital. He asked the trainees, "What have you learned about medicine?" One said, "Nothing works, so I've learned how to do work-arounds." The fundamental flaw with work-arounds is that they don't fix the underlying error-prone and inefficient processes. These work-arounds can make practice feel a bit like a revolving door. As Gene Lindsey, formerly at Atrius Health, put it, "It became obvious to me that some things were beyond our ability to change as individual

"If you step back and look at [burnout symptoms] and get beyond feeling like it is happening because you're a deficient human being, you realize that these things are happening because you're functioning in a system that is inhumane and not designed for anyone's psychological or emotional survival."

providers. We saw the same problems every day, and just because you solved them one day didn't mean they wouldn't come back, because the solutions were work-arounds. They didn't solve the real problems."

Lindsey told us that at one institution in which he practiced for many years, two awards were given annually to recognize clinicians for stellar patient care. "It occurred to me that they should have been called 'Band-Aid awards,' because the system was so dysfunctional it required heroic efforts to provide care." He noted that such efforts cost the physicians in "personal time and a cascade of other losses." The physicians were willing to make the effort, but the dysfunctional system was the root cause of these sacrifices. He said, "It's perverse not to recognize that a lot of their effort was wasted human effort."

Why are practice environments so chaotic and inefficient? In a setting in which errors can have devastating consequences that can be fatal, why are so many workflows inconsistent and unreliable? The simple answer is that the current practice environments were not consciously designed to be efficient and reliable. They developed over time, as multiple improvement initiatives (or external mandates or the personal preference of individual clinicians) changed workflows. The cumulative changes occurred without a careful assessment of the collective impact. The result is the chaos in which most physicians practice every day in both the hospital and office settings. As Robert Wachter of University of California, San Francisco, described it to us, "We have created jobs that are undoable. We have not given a moment's thought to rethinking the world in which physicians provide care."

A common source of chaos in the clinical workplace is the inefficiency of both administrative and care processes. Physicians perform highly technical work that involves significant quality and safety risks. When physicians express fear that they will inadvertently harm a patient, this anxiety is often reflective of a chaotic workplace. Physicians know what to do, but the disorganized, dysfunctional, unpredictable practice environment in which they work makes it difficult, if not impossible, to do the right thing consistently. Attempting to predict and avoid medical errors in such an environment requires a high degree of vigilance, which is unsustainable in the long term.

According to James Hereford, COO of Stanford University Medical Center, this level of vigilance increases the risk of burnout. "The primary contributing factor to burnout is lack of thoughtful processes and support that avoids hero-level work." We asked Hereford to explain what these processes and support would look like. He told us, "Every ambulatory clinic should have a well-codified prepare-for-visit process. But walk into almost any ambulatory clinic and look for that process, and it is non-existent. Instead, the physician shows up at the appointed time and tries to do his or her best with the summary information in the medical record while trying to engage with the patient. Little wonder it's a stressful encounter. At the end of the visit, there's no well-codified process for the patient exit, follow-up, documentation, or coding. We just expect physicians to function well anyway. It's ridiculous when you say it out loud." Wayne Sotile has seen a direct connection between inefficiency and burnout. He told us that the primary complaint of the physicians and nurses he's worked with is inefficiencies in the work setting.

Lindsey described it this way: "If you step back and look at [burnout symptoms] and get beyond feeling like it is happening because you're a deficient human being, you realize that these things are happening because you're functioning in a system that is inhumane and not designed for anyone's psychological or emotional survival."

Paul DeChant and Diane W. Shannon are authors of Preventing Physician Burnout: Curing the Chaos and Returning Joy to the Practice of Medicine.

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For adults with intermediate- or high-risk myelofibrosis (MF)[1]

INTERVENE

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JAKAFI® (RUXOLITINIB) AT DIAGNOSIS

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Ruxolitinib (Jakafi) is a Category 2A* treatment option for both symptomatic lower-risk† and higher-risk MF – in patients with platelets ≥50 x 10^9/L.[2‡]

*Category 2A: Based upon lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.[2]

†Lower-risk MF is defined as low or intermediate-1 risk based on DIPSS, DIPSS-Plus, and MYSEC-PM, low or intermediate risk based on MIPSS-70 (threshold of ≤3 prognostic variable points), and very low, low, or intermediate risk based on MIPSS-70+ (version 2.0; threshold of ≤3 prognostic variable points).[2]

‡In patients who are not transplant candidates.

SIGNIFICANTLY MORE PATIENTS RECEIVING JAKAFI EXPERIENCED IMPROVEMENT IN MF-RELATED SPLENOMEGALY[1,3,5]

COMFORT-I PRIMARY ENDPOINT[1,3‡]

42% of patients receiving **Jakafi** achieved a ≥35% reduction in spleen volume at week 24 **vs** **0.7%** of patients receiving **placebo** ($P < 0.0001$)

- 4.4 years median duration of spleen response among primary responders (n = 65)[4§]

COMFORT-II PRIMARY ENDPOINT[1,5‖]

29% of patients receiving **Jakafi** achieved a ≥35% reduction in spleen volume at week 48 **vs** **0%** of patients receiving **best available therapy**[¶] ($P < 0.0001$)

Indications and Usage

Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post–polycythemia vera MF and post–essential thrombocythemia MF in adults.

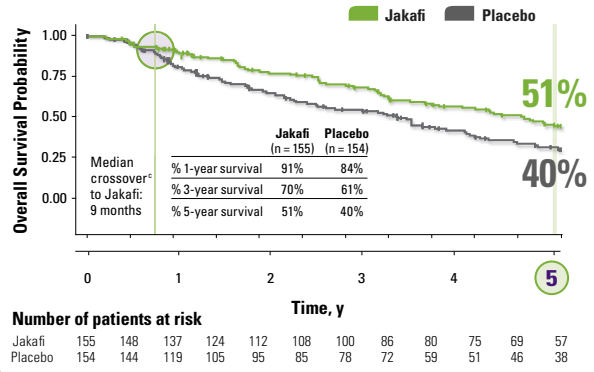
Important Safety Information

- Treatment with Jakafi® (ruxolitinib) can cause thrombocytopenia, anemia and neutropenia, which are each dose-related effects. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated
- Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary
- Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi
- Severe neutropenia (ANC <0.5 × 10^9/L) was generally reversible by withholding Jakafi until recovery
- Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines
- Tuberculosis (TB) infection has been reported. Observe patients taking Jakafi for signs and symptoms of active TB and manage promptly. Prior to initiating Jakafi, evaluate patients for TB risk factors and test those at higher risk for latent infection. Consult a physician with expertise in the treatment of TB before starting Jakafi in patients with evidence of active or latent TB. Continuation of Jakafi during treatment of active TB should be based on the overall risk-benefit determination
- Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate
- Advise patients about early signs and symptoms of herpes zoster and to seek early treatment
- Increases in hepatitis B viral load with or without associated elevations in alanine aminotransferase and aspartate aminotransferase have been reported in patients with chronic hepatitis B virus (HBV) infections. Monitor and treat patients with chronic HBV infection according to clinical guidelines
- When discontinuing Jakafi, myeloproliferative neoplasm-related symptoms may return within one week. After discontinuation, some patients with myelofibrosis have experienced fever, respiratory distress, hypotension, DIC, or multi-organ failure. If any of these occur after discontinuation or while tapering Jakafi, evaluate and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt

JAKAFI 3-YEAR AND 5-YEAR OVERALL SURVIVAL ANALYSES

Jakafi® ruxolitinib (tablets)

Overall Survival Kaplan-Meier Curves by Treatment Group in COMFORT-I[1,4,6,a,b]



Number of patients at risk

Jakafi	155	148	137	124	112	108	100	86	80	75	69	57
Placebo	154	144	119	105	95	85	78	72	59	51	46	38

Adapted with permission from the *Journal of Hematology & Oncology*.[6]

COMFORT-I: 5-YEAR ANALYSIS OF JAKAFI AND PLACEBO[6]

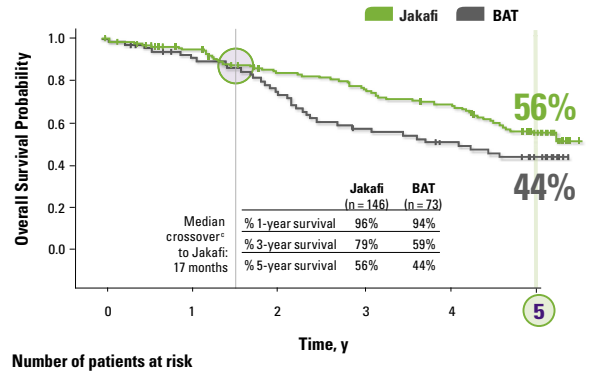
- At 3 years, survival probability was 70% for patients originally randomized to Jakafi and 61% for those originally randomized to placebo[1]
- Overall survival was a prespecified secondary endpoint in COMFORT-I[1]

JAKAFI 5-YEAR OVERALL SURVIVAL PROBABILITY WAS 51%[4]

- All patients in the placebo group either crossed over to Jakafi at a median of 9 months or discontinued[1]

[a] The 5-year overall survival analysis is not included in the Full Prescribing Information for Jakafi. Although the 3-year overall survival analysis is presented in the Full Prescribing Information, *P* values and hazard ratios are omitted from the overall survival Kaplan-Meier curves.[4]
[b] COMFORT-I was not designed to compare survival probabilities between Jakafi and placebo at 3 or 5 years.[4]
[c] Patients randomized to placebo were eligible to cross over to receive Jakafi because of progression-driven events or at the physician's discretion; however, these patients continued to be grouped within their original randomized assignment for analysis purposes.[4]
[‡] COMFORT-I (COntrolled MyeloFibrosis study with ORal JAK inhibitor Treatment-I) was a randomized, double-blind, placebo-controlled phase 3 study with 309 patients with intermediate-2–risk or high-risk MF. The primary endpoint was the proportion of patients achieving a ≥35% reduction in spleen volume from baseline to week 24 as measured by CT or MRI.[1,3]
[§] Duration of spleen response was defined as the interval between the first spleen response measurement that was a ≥35% reduction from baseline and the date of the first measurement that was no longer a ≥35% reduction from baseline that was also a >25% increase from nadir.[4]

Overall Survival Kaplan-Meier Curves by Treatment Group in COMFORT-II[1,7,a,b]



Number of patients at risk

Jakafi	146	130	109	100	88	61
BAT	73	58	48	35	30	22

Adapted with permission from *Leukemia*.[7]

COMFORT-II: 5-YEAR ANALYSIS OF JAKAFI AND BEST AVAILABLE THERAPY[7]

- At 3 years, survival probability was 79% for patients originally randomized to Jakafi and 59% for those originally randomized to best available therapy[1]
- Overall survival was a prespecified secondary endpoint in COMFORT-II[1]

JAKAFI 5-YEAR OVERALL SURVIVAL PROBABILITY WAS 56%[7]

- All patients in the best available therapy group either crossed over to Jakafi at a median of 17 months or discontinued[1]

BAT, best available therapy.

[a] The 5-year overall survival analysis is not included in the Full Prescribing Information for Jakafi. Although the 3-year overall survival analysis is presented in the Full Prescribing Information, *P* values and hazard ratios are omitted from the overall survival Kaplan-Meier curves.[4]
[b] COMFORT-II was not designed to compare survival probabilities between Jakafi and best available therapy at 3 or 5 years.[4]
[c] Patients randomized to best available therapy were eligible to cross over to receive Jakafi because of progression-driven events or at the physician's discretion; however, these patients continued to be grouped within their original randomized assignment for analysis purposes.[4]
[‖] COMFORT-II (COntrolled MyeloFibrosis study with ORal JAK inhibitor Treatment-II) was a randomized, open-label phase 3 study with 219 patients with intermediate-2–risk or high-risk MF. The primary endpoint was the proportion of patients achieving a ≥35% reduction in spleen volume from baseline at week 48 as measured by CT or MRI.[1,5]
[¶] Best available therapy in COMFORT-II included hydroxyurea (46.6%) and glucocorticoids (16.4%), as well as no medication, anagrelide, epoetin alfa, thalidomide, lenalidomide, mercaptopurine, thioguanine, danazol, peginterferon alfa-2a, interferon-α, melphalan, acetylsalicylic acid, cytarabine, and colchicine.[4]

For more data on long-term results with Jakafi, visit JakafiResults.com

or discontinue Jakafi without consulting their physician. When discontinuing or interrupting Jakafi for reasons other than thrombocytopenia or neutropenia, consider gradual tapering rather than abrupt discontinuation

- Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred. Perform periodic skin examinations
- Treatment with Jakafi has been associated with increases in total cholesterol, low-density lipoprotein cholesterol, and triglycerides. Assess lipid parameters 8-12 weeks after initiating Jakafi. Monitor and treat according to clinical guidelines for the management of hyperlipidemia
- In myelofibrosis and polycythemia vera, the most common nonhematologic adverse reactions (incidence ≥15%) were bruising, dizziness, headache, and diarrhea. In acute graft-versus-host disease, the most common nonhematologic adverse reactions (incidence >50%) were infections and edema
- Dose modifications may be required when administering Jakafi with strong CYP3A4 inhibitors or fluconazole or in patients with renal or hepatic impairment. Patients should be closely monitored and the dose titrated based on safety and efficacy
- Use of Jakafi during pregnancy is not recommended and should only be used if the potential benefit justifies the potential risk to the fetus. Women taking Jakafi should not breastfeed during treatment and for 2 weeks after the final dose

Please see Brief Summary of Full Prescribing Information for Jakafi on the following pages.

To learn more about Jakafi, visit **HCP.Jakafi.com**.

References: 1. Jakafi [package insert]. Wilmington, DE: Incyte Corporation. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Myeloproliferative Neoplasms V.1.2020. © National Comprehensive Cancer Network, Inc. 2020. All rights reserved. Accessed May 21, 2020. To view the most recent and complete version of the guideline, go online to NCCN.org. NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. **3.** Verstovsek S, Mesa RA, Gotlib J, et al. A double-blind, placebo-controlled trial of ruxolitinib for myelofibrosis. *N Engl J Med*. 2012;366(9):799-807. **4.** Data on file. Incyte Corporation. Wilmington, DE. **5.** Harrison C, Kiladjian J-J, Al-Ali HK, et al. JAK inhibition with ruxolitinib versus best available therapy for myelofibrosis. *N Engl J Med*. 2012;366(9):787-798. **6.** Verstovsek S, Mesa RA, Gotlib J, et al; for COMFORT-I Investigators. Long-term treatment with ruxolitinib for patients with myelofibrosis: 5-year update from the randomized, double-blind, placebo-controlled, phase 3 COMFORT-I trial. *J Hematol Oncol*. 2017;10(1):55. **7.** Harrison CN, Vannucchi AM, Kiladjian J-J, et al; on behalf of COMFORT-II Investigators. Long-term findings from COMFORT-II, a phase 3 study of ruxolitinib vs best available therapy for myelofibrosis. *Leukemia*. 2016;30(8):1701-1707.

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Incyte

Jakafi®
ruxolitinib (tablets)

BRIEF SUMMARY: For Full Prescribing Information, see package insert.

INDICATIONS AND USAGE Myelofibrosis Jakafi is indicated for treatment of intermediate or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF and post-essential thrombocythemia MF in adults. **Polycythemia Vera** Jakafi is indicated for treatment of polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea. **Acute Graft-Versus-Host Disease** Jakafi is indicated for treatment of steroid-refractory acute graft-versus-host disease (GVHD) in adult and pediatric patients 12 years and older.

CONTRAINDICATIONS None.

WARNINGS AND PRECAUTIONS Thrombocytopenia, Anemia and Neutropenia Treatment with Jakafi can cause thrombocytopenia, anemia and neutropenia. [*see Dosage and Administration (2.1) in Full Prescribing Information*]. Manage thrombocytopenia by reducing the dose or temporarily interrupting Jakafi. Platelet transfusions may be necessary [*see Dosage and Administration (2), and Adverse Reactions (6.1) in Full Prescribing Information*]. Patients developing anemia may require blood transfusions and/or dose modifications of Jakafi. Severe neutropenia (ANC less than 0.5×10^9/L) was generally reversible by withholding Jakafi until recovery [*see Adverse Reactions (6.1) in Full Prescribing Information*]. Perform a pre-treatment complete blood count (CBC) and monitor CBCs every 2 to 4 weeks until doses are stabilized, and then as clinically indicated [*see Dosage and Administration (2), and Adverse Reactions (6.1) in Full Prescribing Information*]. **Risk of Infection** Serious bacterial, mycobacterial, fungal and viral infections have occurred. Delay starting therapy with Jakafi until active serious infections have resolved. Observe patients receiving Jakafi for signs and symptoms of infection and manage promptly. Use active surveillance and prophylactic antibiotics according to clinical guidelines. *Tuberculosis* Tuberculosis infection has been reported in patients receiving Jakafi. Observe patients receiving Jakafi for signs and symptoms of active tuberculosis and manage promptly. Prior to initiating Jakafi, patients should be evaluated for tuberculosis risk factors, and those at higher risk should be tested for latent infection. Risk factors include, but are not limited to, prior residence in or travel to countries with a high prevalence of tuberculosis, close contact with a person with active tuberculosis, and a history of active or latent tuberculosis where an adequate course of treatment cannot be confirmed. For patients with evidence of active or latent tuberculosis, consult a physician with expertise in the treatment of tuberculosis before starting Jakafi. The decision to continue Jakafi during treatment of active tuberculosis should be based on the overall risk-benefit determination. *Progressive Multifocal Leukoencephalopathy* Progressive multifocal leukoencephalopathy (PML) has occurred with Jakafi treatment. If PML is suspected, stop Jakafi and evaluate. *Herpes Zoster* Advise patients about early signs and symptoms of herpes zoster and to seek treatment as early as possible if suspected [*see Adverse Reactions (6.1) in Full Prescribing Information*]. *Hepatitis B* Hepatitis B viral load (HBV-DNA titer) increases, with or without associated elevations in alanine aminotransferase and aspartate aminotransferase, have been reported in patients with chronic HBV infections taking Jakafi. The effect of Jakafi on viral replication in patients with chronic HBV infection is unknown. Patients with chronic HBV infection should be treated and monitored according to clinical guidelines. **Symptom Exacerbation Following Interruption or Discontinuation of Treatment with Jakafi** Following discontinuation of Jakafi, symptoms from myeloproliferative neoplasms may return to pretreatment levels over a period of approximately one week. Some patients with MF have experienced one or more of the following adverse events after discontinuing Jakafi: fever, respiratory distress, hypotension, DIC, or multi-organ failure. If one or more of these occur after discontinuation of, or while tapering the dose of Jakafi, evaluate for and treat any intercurrent illness and consider restarting or increasing the dose of Jakafi. Instruct patients not to interrupt or discontinue Jakafi therapy without consulting their physician. When discontinuing or interrupting therapy with Jakafi for reasons other than thrombocytopenia or neutropenia [*see Dosage and Administration (2.6) in Full Prescribing Information*], consider tapering the dose of Jakafi gradually rather than discontinuing abruptly. **Non-Melanoma Skin Cancer** Non-melanoma skin cancers including basal cell, squamous cell, and Merkel cell carcinoma have occurred in patients treated with Jakafi. Perform periodic skin examinations. **Lipid Elevations** Treatment with Jakafi has been associated with increases in lipid parameters including total cholesterol, low-density lipoprotein (LDL) cholesterol, and triglycerides. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined in patients treated with Jakafi. Assess lipid parameters approximately 8-12 weeks following initiation of Jakafi therapy. Monitor and treat according to clinical guidelines for the management of hyperlipidemia. **ADVERSE REACTIONS** The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling: • Thrombocytopenia, Anemia and Neutropenia [*see Warnings and Precautions (5.1) in Full Prescribing Information*] • Risk of Infection [*see Warnings and Precautions (5.2) in Full Prescribing Information*] • Symptom Exacerbation Following Interruption or Discontinuation of Treatment with Jakafi [*see Warnings and Precautions (5.3) in Full Prescribing Information*] • Non-Melanoma Skin Cancer [*see Warnings and Precautions (5.4) in Full Prescribing Information*]. **Clinical Trials Experience in Myelofibrosis** Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The safety of Jakafi was assessed in 617 patients in six clinical studies with a median duration of follow-up of 10.9 months, including 301 patients with MF in two Phase 3 studies. In these two Phase 3 studies, patients had a median duration of exposure to Jakafi of 9.5 months (range 0.5 to 17 months), with 89% of patients treated for more than 6 months and 25% treated for more than 12 months. One hundred and eleven (111) patients started treatment at 15 mg twice daily and 190 patients started at 20 mg twice daily. In patients starting treatment with 15 mg twice daily (pretreatment platelet counts of 100 to 200×10^9/L) and 20 mg twice daily (pretreatment platelet counts greater than 200×10^9/L), 65% and 25% of patients, respectively, required a dose reduction below the starting dose within the first 8 weeks of therapy. In a double-blind, randomized, placebo-controlled study of Jakafi, among the 155 patients treated with Jakafi, the most frequent adverse reactions were thrombocytopenia and anemia [*see Table 2*]. Thrombocytopenia, anemia and neutropenia are dose-related effects. The three most frequent nonhematologic adverse reactions were bruising, dizziness and headache [*see Table 1*]. Discontinuation for adverse events, regardless of causality, was observed in 11% of patients treated with Jakafi and 11% of patients treated with placebo. Table 1 presents the most common nonhematologic adverse reactions occurring in patients who received Jakafi in the double-blind, placebo-controlled study during randomized treatment.

Table 1: Myelofibrosis: Nonhematologic Adverse Reactions Occurring in Patients on Jakafi in the Double-blind, Placebo-controlled Study During Randomized Treatment

	Jakafi (N=155)			Placebo (N=151)		
Adverse Reactions	**All Grades[a] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Bruising[b]	23	<1	0	15	0	0
Dizziness[c]	18	<1	0	7	0	0
Headache	15	0	0	5	0	0
Urinary Tract Infections[d]	9	0	0	5	<1	<1
Weight Gain[e]	7	<1	0	1	<1	0
Flatulence	5	0	0	<1	0	0
Herpes Zoster[f]	2	0	0	<1	0	0

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0
[b] includes contusion, ecchymosis, hematoma, injection site hematoma, periorbital hematoma, vessel puncture site hematoma, increased tendency to bruise, petechiae, purpura
[c] includes dizziness, postural dizziness, vertigo, balance disorder, Meniere's Disease, labyrinthitis
[d] includes urinary tract infection, cystitis, urosepsis, urinary tract infection bacterial, kidney infection, pyuria, bacteria urine, bacteria urine identified, nitrite urine present
[e] includes weight increased, abnormal weight gain
[f] includes herpes zoster and post-herpetic neuralgia

Description of Selected Adverse Reactions: Anemia In the two Phase 3 clinical studies, median time to onset of first CTCAE Grade 2 or higher anemia was approximately 6 weeks. One patient (<1%) discontinued treatment because of anemia. In patients receiving Jakafi, mean decreases in hemoglobin reached a nadir of approximately 1.5 to 2.0 g/dL below baseline after 8 to 12 weeks of therapy and then gradually recovered to reach a new steady state that was approximately 1.0 g/dL below baseline. This pattern was observed in patients regardless of whether they had received transfusions during therapy. In the randomized, placebo-controlled study, 60% of patients treated with Jakafi and 38% of patients receiving placebo received red blood cell transfusions during randomized treatment. Among transfused patients, the median number of units transfused per month was 1.2 in patients treated with Jakafi and 1.7 in placebo treated patients. **Thrombocytopenia** In the two Phase 3 clinical studies, in patients who developed Grade 3 or 4 thrombocytopenia, the median time to onset was approximately 8 weeks. Thrombocytopenia was generally reversible with dose reduction or dose interruption. The median time to recovery of platelet counts above 50×10^9/L was 14 days. Platelet transfusions were administered to 5% of patients receiving Jakafi and to 4% of patients receiving control regimens. Discontinuation of treatment because of thrombocytopenia occurred in <1% of patients receiving Jakafi and <1% of patients receiving control regimens. Patients with a platelet count of 100×10^9/L to 200×10^9/L before starting Jakafi had a higher frequency of Grade 3 or 4 thrombocytopenia compared to patients with a platelet count greater than 200×10^9/L (17% versus 7%). **Neutropenia** In the two Phase 3 clinical studies, 1% of patients reduced or stopped Jakafi because of neutropenia. Table 2 provides the frequency and severity of clinical hematology abnormalities reported for patients receiving treatment with Jakafi or placebo in the placebo-controlled study.

Table 2: Myelofibrosis: Worst Hematology Laboratory Abnormalities in the Placebo-Controlled Study[a]

	Jakafi (N=155)			Placebo (N=151)		
Laboratory Parameter	**All Grades[b] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Thrombocytopenia	70	9	4	31	1	0
Anemia	96	34	11	87	16	3
Neutropenia	19	5	2	4	<1	1

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0

Additional Data from the Placebo-Controlled Study • 25% of patients treated with Jakafi and 7% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in alanine transaminase (ALT). The incidence of greater than or equal to Grade 2 elevations was 2% for Jakafi with 1% Grade 3 and no Grade 4 ALT elevations. • 17% of patients treated with Jakafi and 6% of patients treated with placebo developed newly occurring or worsening Grade 1 abnormalities in aspartate transaminase (AST). The incidence of Grade 2 AST elevations was <1% for Jakafi with no Grade 3 or 4 AST elevations. • 17% of patients treated with Jakafi and <1% of patients treated with placebo developed newly occurring or worsening Grade 1 elevations in cholesterol. The incidence of Grade 2 cholesterol elevations was <1% for Jakafi with no Grade 3 or 4 cholesterol elevations. **Clinical Trial Experience in Polycythemia Vera** In a randomized, open-label, active-controlled study, 110 patients with PV resistant to or intolerant of hydroxyurea received Jakafi and 111 patients received best available therapy [*see Clinical Studies (14.2) in Full Prescribing Information*]. The most frequent adverse reaction was anemia. Discontinuation for adverse events, regardless of causality, was observed in 4% of patients treated with Jakafi. Table 3 presents the most frequent nonhematologic adverse reactions occurring up to Week 32.

Table 3: Polycythemia Vera: Nonhematologic Adverse Reactions Occurring in ≥ 5% of Patients on Jakafi in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment

	Jakafi (N=110)		Best Available Therapy (N=111)	
Adverse Reactions	**All Grades[a] (%)**	**Grade 3-4 (%)**	**All Grades (%)**	**Grade 3-4 (%)**
Diarrhea	15	0	7	<1
Dizziness[b]	15	0	13	0
Dyspnea[c]	13	3	4	0
Muscle Spasms	12	<1	5	0
Constipation	8	0	3	0
Herpes Zoster[d]	6	<1	0	0

Table 3 continued above.

Table 3 continued.

	Jakafi (N=110)		Best Available Therapy (N=111)	
Adverse Reactions	**All Grades[a] (%)**	**Grade 3-4 (%)**	**All Grades (%)**	**Grade 3-4 (%)**
Nausea	6	0	4	0
Weight Gain[e]	6	0	<1	0
Urinary Tract Infections[f]	6	0	3	0
Hypertension	5	<1	3	<1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 3.0
[b] includes dizziness and vertigo
[c] includes dyspnea and dyspnea exertional
[d] includes herpes zoster and post-herpetic neuralgia
[e] includes weight increased and abnormal weight gain
[f] includes urinary tract infection and cystitis

Clinically relevant laboratory abnormalities are shown in Table 4.

Table 4: Polycythemia Vera: Selected Laboratory Abnormalities in the Open-Label, Active-controlled Study up to Week 32 of Randomized Treatment[a]

	Jakafi (N=110)			Best Available Therapy (N=111)		
Laboratory Parameter	**All Grades[b] (%)**	**Grade 3 (%)**	**Grade 4 (%)**	**All Grades (%)**	**Grade 3 (%)**	**Grade 4 (%)**
Hematology						
Anemia	72	<1	<1	58	0	0
Thrombocytopenia	27	5	<1	24	3	<1
Neutropenia	3	0	<1	10	<1	0
Chemistry						
Hypercholesterolemia	35	0	0	8	0	0
Elevated ALT	25	<1	0	16	0	0
Elevated AST	23	0	0	23	<1	0
Hypertriglyceridemia	15	0	0	13	0	0

[a] Presented values are worst Grade values regardless of baseline
[b] National Cancer Institute Common Terminology Criteria for Adverse Events, version 3.0

Clinical Trial Experience in Acute Graft-Versus-Host Disease In a single-arm, open-label study, 71 adults (ages 18-73 years) were treated with Jakafi for acute GVHD failing treatment with steroids with or without other immunosuppressive drugs [see *Clinical Studies (14.3) in Full Prescribing Information*]. The median duration of treatment with Jakafi was 46 days (range, 4-382 days). There were no fatal adverse reactions to Jakafi. An adverse reaction resulting in treatment discontinuation occurred in 31% of patients. The most common adverse reaction leading to treatment discontinuation was infection (10%). Table 5 shows the adverse reactions other than laboratory abnormalities.

Table 5: Acute Graft-Versus-Host Disease: Nonhematologic Adverse Reactions Occurring in ≥ 15% of Patients in the Open-Label, Single-Cohort Study

	Jakafi (N=71)	
Adverse Reactions[a]	**All Grades[b] (%)**	**Grade 3-4 (%)**
Infections	55	41
Edema	51	13
Hemorrhage	49	20
Fatigue	37	14
Bacterial infections	32	28
Dyspnea	32	7
Viral infections	31	14
Thrombosis	25	11
Diarrhea	24	7
Rash	23	3
Headache	21	4
Hypertension	20	13
Dizziness	16	0

[a] Selected laboratory abnormalities are listed in Table 6 below
[b] National Cancer Institute Common Terminology Criteria for Adverse Events (CTCAE), version 4.03

Selected laboratory abnormalities during treatment with Jakafi are shown in Table 6.

Table 6: Acute Graft-Versus-Host Disease: Selected Laboratory Abnormalities Worsening from Baseline in the Open-Label, Single Cohort Study

	Jakafi (N=71)	
	Worst grade during treatment	
Laboratory Parameter	**All Grades[a] (%)**	**Grade 3-4 (%)**
Hematology		
Anemia	75	45
Thrombocytopenia	75	61
Neutropenia	58	40
Chemistry		
Elevated ALT	48	8
Elevated AST	48	6
Hypertriglyceridemia	11	1

[a] National Cancer Institute Common Terminology Criteria for Adverse Events, version 4.03

DRUG INTERACTIONS Fluconazole Concomitant administration of Jakafi with fluconazole doses greater than 200 mg daily may increase ruxolitinib exposure due to inhibition of both the CYP3A4 and CYP2C9 metabolic pathways [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. Increased exposure may increase the risk of exposure-related adverse reactions. Avoid the concomitant use of Jakafi with fluconazole doses of greater than 200 mg daily except in patients with acute GVHD [*see Dosage and Administration (2.4) in Full Prescribing Information*]. **Strong CYP3A4 inhibitors** Concomitant administration of Jakafi with strong CYP3A4 inhibitors increases ruxolitinib exposure [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. Increased exposure may increase the risk of exposure-related adverse reactions. Consider dose reduction when administering Jakafi with strong CYP3A4 inhibitors [*see Dosage and Administration (2.4) in Full Prescribing Information*]. In patients with acute GVHD, reduce Jakafi dose as recommended only when coadministered with ketoconazole, and monitor blood counts more frequently for toxicity and adjust the dose if necessary when coadministered with itraconazole. [*see Dosage and Administration (2.4) in Full Prescribing Information*]. **Strong CYP3A4 inducers** Concomitant administration of Jakafi with strong CYP3A4 inducers may decrease ruxolitinib exposure [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. No dose adjustment is recommended; however, monitor patients frequently and adjust the Jakafi dose based on safety and efficacy [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. **USE IN SPECIFIC POPULATIONS** **Pregnancy: Risk Summary** When pregnant rats and rabbits were administered ruxolitinib during the period of organogenesis adverse developmental outcomes occurred at doses associated with maternal toxicity (*see Data*). There are no studies with the use of Jakafi in pregnant women to inform drug-associated risks. The background risk of major birth defects and miscarriage for the indicated populations is unknown. Adverse outcomes in pregnancy occur regardless of the health of the mother or the use of medications. The background risk in the U.S. general population of major birth defects is 2% to 4% and miscarriage is 15% to 20% of clinically recognized pregnancies. **Data:** *Animal Data* Ruxolitinib was administered orally to pregnant rats or rabbits during the period of organogenesis, at doses of 15, 30 or 60 mg/kg/day in rats and 10, 30 or 60 mg/kg/day in rabbits. There were no treatment-related malformations. Adverse developmental outcomes, such as decreases of approximately 9% in fetal weights were noted in rats at the highest and maternally toxic dose of 60 mg/kg/day. This dose results in an exposure (AUC) that is approximately 2 times the clinical exposure at the maximum recommended dose of 25 mg twice daily. In rabbits, lower fetal weights of approximately 8% and increased late resorptions were noted at the highest and maternally toxic dose of 60 mg/kg/day. This dose is approximately 7% the clinical exposure at the maximum recommended dose. In a pre- and post-natal development study in rats, pregnant animals were dosed with ruxolitinib from implantation through lactation at doses up to 30 mg/kg/day. There were no drug-related adverse findings in pups for fertility indices or for maternal or embryofetal survival, growth and development parameters at the highest dose evaluated (34% the clinical exposure at the maximum recommended dose of 25 mg twice daily). **Lactation: Risk Summary** No data are available regarding the presence of ruxolitinib in human milk, the effects on the breast fed child, or the effects on milk production. Ruxolitinib and/or its metabolites were present in the milk of lactating rats (*see Data*). Because many drugs are present in human milk and because of the potential for thrombocytopenia and anemia shown for Jakafi in human studies, discontinue breastfeeding during treatment with Jakafi and for two weeks after the final dose. **Data:** *Animal Data* Lactating rats were administered a single dose of [^{14}C]-labeled ruxolitinib (30 mg/kg) on postnatal Day 10, after which plasma and milk samples were collected for up to 24 hours. The AUC for total radioactivity in milk was approximately 13-fold the maternal plasma AUC. Additional analysis showed the presence of ruxolitinib and several of its metabolites in milk, all at levels higher than those in maternal plasma. **Pediatric Use** The safety and effectiveness of Jakafi for treatment of myelofibrosis or polycythemia vera in pediatric patients have not been established. The safety and effectiveness of Jakafi for treatment of steroid-refractory acute graft-versus-host disease (GVHD) have been established for treatment of children 12 years and older. Use of Jakafi in pediatric patients with steroid-refractory acute GVHD is supported by evidence from an adequate and well-controlled trial of Jakafi in adults [*see Clinical Studies (14.3) in Full Prescribing Information*] and additional pharmacokinetic and safety data in pediatric patients. Jakafi was evaluated in a single-arm, dose-escalation study (NCT01164163) in 27 pediatric patients with relapsed or refractory solid tumors (Cohort A) and 20 with leukemias or myeloproliferative neoplasms (Cohort B). The patients had a median age of 14 years (range, 2 to 21 years) and included 18 children (age 2 to <12 years), and 14 adolescents (age 12 to <17 years). The dose levels tested were 15, 21, 29, 39, or 50 mg/m^2 twice daily in 28-day cycles with up to 6 patients per dose group. Overall, 38 (81%) patients were treated with no more than a single cycle of Jakafi, while 3, 1, 2, and 3 patients received 2, 3, 4, and 5 or more cycles, respectively. A protocol-defined maximal tolerated dose was not observed, but since few patients were treated for multiple cycles, tolerability with continued use was not assessed adequately to establish a recommended Phase 2 dose higher than the recommended dose for adults. The safety profile in children was similar to that seen in adults. *Juvenile Animal Toxicity Data* Administration of ruxolitinib to juvenile rats resulted in effects on growth and bone measures. When administered starting at postnatal day 7 (the equivalent of a human newborn) at doses of 1.5 to 75 mg/kg/day, evidence of fractures occurred at doses ≥ 30 mg/kg/day, and effects on body weight and other bone measures [e.g., bone mineral content, peripheral quantitative computed tomography, and x-ray analysis] occurred at doses ≥ 5 mg/kg/day. When administered starting at postnatal day 21 (the equivalent of a human 2-3 years of age) at doses of 5 to 60 mg/kg/day, effects on body weight and bone occurred at doses ≥ 15 mg/kg/day, which were considered adverse at 60 mg/kg/day. Males were more severely affected than females in all age groups, and effects were generally more severe when administration was initiated earlier in the postnatal period. These findings were observed at exposures that are at least 27% the clinical exposure at the maximum recommended dose of 25 mg twice daily. **Geriatric Use** Of the total number of patients with MF in clinical studies with Jakafi, 52% were 65 years and older, while 15% were 75 years and older. No overall differences in safety or effectiveness of Jakafi were observed between these patients and younger patients. Clinical studies of Jakafi in patients with acute GVHD did not include sufficient numbers of subjects age 65 and over to determine whether they respond differently from younger subjects. **Renal Impairment** Total exposure of ruxolitinib and its active metabolites increased with moderate (CLcr 30 mL/min to 59 mL/min) and severe (CLcr 15 mL/min to 29 mL/min) renal impairment, and ESRD on dialysis [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. Reduce Jakafi dose as recommended [*see Dosage and Administration (2.5) in Full Prescribing Information*]. **Hepatic Impairment** Exposure of ruxolitinib increased with mild (Child-Pugh A), moderate (Child-Pugh B) and severe (Child-Pugh C) hepatic impairment [*see Clinical Pharmacology (12.3) in Full Prescribing Information*]. Reduce Jakafi dose as recommended in patients with MF or PV and any hepatic impairment [*see Dosage and Administration (2.5) in Full Prescribing Information*]. Monitor blood counts more frequently for toxicity and consider 5 mg once daily for patients with Stage 3 or 4 liver GVHD [*see Dosage and Administration (2.5) and Clinical Pharmacology (12.3) in Full Prescribing Information*]. **OVERDOSAGE** There is no known antidote for overdoses with Jakafi. Single doses up to 200 mg have been given with acceptable acute tolerability. Higher than recommended repeat doses are associated with increased myelosuppression including leukopenia, anemia and thrombocytopenia. Appropriate supportive treatment should be given. Hemodialysis is not expected to enhance the elimination of Jakafi.

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Patient Anxiety:

CREATING A BETTER ENVIRONMENT TO HEAL

BY DYLAN CHADWICK

When asked to describe anxiety, I often defer to the description I'd give my college therapist. Anxiety fits somewhere between "simple worry" and "full-blown panic." I'd compare it to the dull, but consistent bellowing of a gaggle of monkeys let loose to tromp around the recesses of my brain. Everyone experiences anxiety in some fashion, whether responding to an overwhelming work schedule, an impending deadline or even as a generalized disorder. Physicians certainly aren't strangers to anxiety-provoking work either, especially those who work in emergency capacities.

But while the individual and observable symptoms of anxiety vary from person to person, the overall obstacles it presents are quite uniform. Anxiety and stress are animal instincts, ones which protect us in dangerous situations and motivate us to seek equilibrium and control when we are losing it. However, anxiety can also be an impediment to relationships, an all-encompassing, slippery paralysis that crowds out our ability to think rationally, to make positive judgments and to hear what we most need to hear while in its throes: sound counsel.

When a patient visits their physician, they're prone to feeling a little anxious. Diagnoses and treatment plans, loaded with obtuse medical jargon, can put ones mind in a tailspin and set one's heart a-flutter. Not exactly prime condition to take medical advice. Wary physicians should consider the implications of a patient's anxiety when dispensing information, in order to ensure they're communicating clearly and effectively, and in a way that will benefit the patient long after they've left the exam room. Here's some tips on how physicians can key into those feelings, work within them, and help patients feel less anxious in the process.

Open the Floor

Effective physicians will work to create an atmosphere in which patients can verbalize their concerns, questions and anxieties, and will work to address those before even moving into a treatment discussion. In an office visit, a patient has many more thoughts going through their minds than what's on the surface. In these experiences, physicians should open the floor to patients, ensuring them that their questions and concerns are



not only valid, but an integral part of treatment. Some patients may not feel comfortable articulating their inner concerns, and in these circumstances, a warm invitation to do so will carry much weight. A willing and listening ear can also calm the nerves of an argumentative patient. Ultimately, when a patient comes to a physician's office, they're bombarded with information that can be both frightening and confusing. Creating a scenario in which they're given clearance to air out their fears not only helps them manage and regulate their emotions, but also helps the physician tailor treatment specific to their needs in the long run.

It also goes without saying that there truly is no patient concern that is "wrong" or unimportant. Uncertainty is an unpleasant feature of many medical experiences, but a physician who will set the tone with warmth and an open mind will help alleviate anxiety's burden.

A Room of One's Own

A medical practice can be stressful environment, especially when dealing with a pandemic. Patients are surrounded by foreign looking equipment, strange sterile smells, and often the intermittent bustle of physicians, nurses and other specialists conducting serious and time-sensitive work. Environmental distractions can exacerbate a patient's anxiety, leaving them feeling cagey and alone and in a strange environment outside of their normal comfort zone and preference. It's beneficial for physicians to help control that environment, and create the most quiet, and private place possible so as to dispense medical information in as clear a manner as possible. Besides ensuring that information isn't misconstrued, it helps quell the rampant anxiety provoking factors present in a high-energy workplace, putting fretting patients at ease.

Words Unspoken

Often it's not just the words one uses, but the body language that accompanies the delivery of those words. It's important for physicians to remember how their nonverbal body cues will affect a patient's understanding and emotional processing of the information. Simple things like smiling and maintaining a

"Creating a scenario in which they're given clearance to air out their fears not only helps them manage and regulate their emotions, but also helps the physician tailor treatment specific to their needs in the long run."

calm and collected voice and speaking in soft, yet audible tones, can quell the alarming feelings potentially welling up inside a patient's mind. There's really no deep and nuggety magical formula for it. Physician's should simply be nice and relaxed with patients, clear and controlled in their delivery. It lends an air of stability to the proceedings and will help manage the expectations of the room.

Silence Isn't Always a Bad Thing

We all hate uncomfortable silences and will often seek to avoid them at all costs. They don't always indicate that a conversation is going poorly though. In fact, when given such high levels of sensitive information, many patients need some time to process and digest the lofty information they've just been given. A well-placed section of "breathing time" is often an indication that new and useful information is being processed. When a physician is hasty to "force" conversation in these instances, they can come off as rude and insensitive. Furthermore, patients may not want to speak at all. While it's important to always open the floor, physicians must also respect an anxious patient's desire to simply listen and absorb information.

Choices Empower Patients

Anxiety makes people feel powerless to their emotions or the circumstance at hand. When confronted with a serious health issue, many patients resort to dread and anxiety because they don't feel equipped to deal with the problem. Physicians should be sure to outline multiple choices (where applicable) for treatment options. When a patient knows they have choices and options for their treatment, they feel empowered and capable to deal with the problem, and also feel that their physicians are on their "team." It's also important to remember that even though a physician knows all the nuances and options of a treatment regimen, a patient may not, or may have a significantly limited understanding of it. Let them know that they have options in how they choose to be treated, and aren't being forced into something without having an opportunity to weigh out the pros and cons.

Enlist the Aid of Family or Trusted Friends

There are those circumstances when patient anxiety is extreme and a patient needs someone there to help them on a more intimate emotional level. It's not uncommon for patients to enlist the aid of a spouse or trusted family member to help them receive their treatment options and have said family member accompany them on their visit. In these circumstances, a level-head and an extra set of ears can ensure they the patient gets the most out of their treatment. Healthcare is a joint effort with patients and their families, and some family members need only to be taught how they can participate. In all circumstances, especially ones which involve rigorous or disruptive treatment, it's crucial to get family members on board because when patients feel that they have a team of supporters backing them, they no longer feel alone in their problem. Furthermore, family members can help the patient with alternative perspectives or simply just comforting words that a physician simply cannot.

Physicians are trained to diagnose and treat every level of medical problem and ailment in the known universe. However, beyond medical diagnoses, an understanding of patient anxiety, and the emotional/logical stranglehold it can wreak on its victims, will improve a physician's ability to dispense information clearly and concisely, as well as tending to the emotional healing of a patient.

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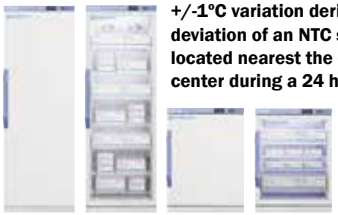
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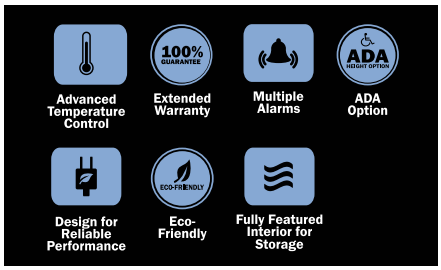


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