2023 | Issue 11

Physicians office Resource

Resources for You, Your Patients, & Your Practice

GAINS FROM LOSSES

WEIGHT LOSS DRUGS AND THE OBESITY EPIDEMIC



MDescapes — WHERE EAST MEETS BEST FOUR SEASONS HOTEL TOKYO AT OTEMACHI
PAGE 32

If you have patients *40+* with diabetes mellitus (DM)* you should consider this FDA cleared test[1]

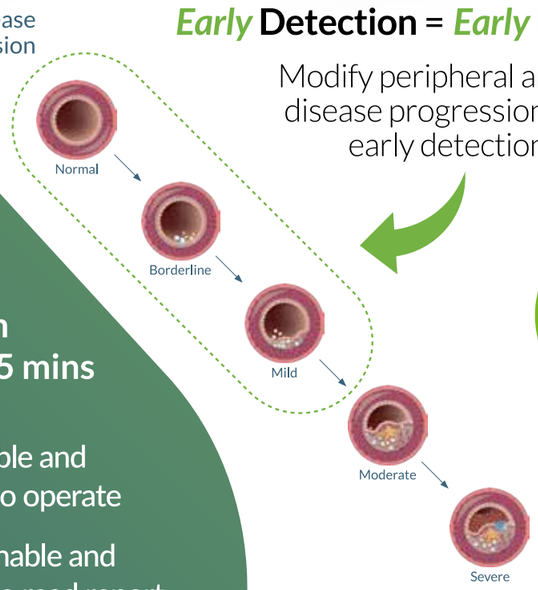
The prevalence of peripheral arterial disease (PAD) in people with DM over the age of 40 is estimated at 20%. For those over 50 with DM it increases to 29%[2].

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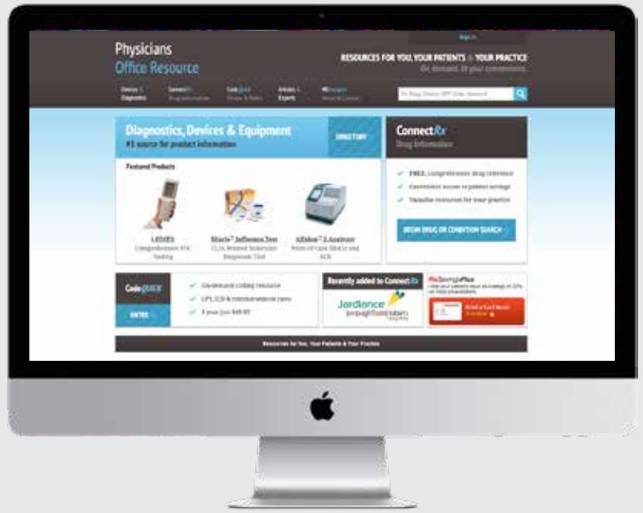
*2016 AHA/ACC Lower Extremity PAD Guidelines: Age ≥ 65y; Age 50-64y, with risk factors for atherosclerosis; Age <50 y, with diabetes mellitus; and one additional risk factor or atherosclerosis[1]

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GAINS FROM LOSSES

Weight Loss Drugs and the Obesity Epidemic

Just one year ago, the outlook on obesity was quite dire. How dire? Look at some of these headlines from news agencies around the world, “Obesity ‘epidemic’ leading to 1.2 million deaths a year in Europe, says WHO,” “Study finds childhood obesity occurring at greater frequency,” and “Number of States with High Rates of Adult Obesity More Than Doubles.” However, there have been some major developments in the treatment of obesity that have changed headlines from bleak and dire to hope and optimism. “FDA Approves Powerful New Drug to Counter Obesity Epidemic,” “New drugs Could Spell an End to the World’s Obesity Epidemic,” “Doctors Grapple with Patients Demand for Weight-loss Drugs.”

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DIAGNOSING AND TREATING RESPIRATORY INFECTIONS IN THE OUTPATIENT SETTING

Antimicrobial resistance (AMR) occurs when microorganisms evolve and adapt, making treatment with antimicrobials (e.g., antibiotics, antiviral, and antifungal medications) ineffective.

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MDescapes — WHERE EAST MEETS BEST FOUR SEASONS HOTEL TOKYO AT OTEMACHI
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FEATURE

GAINS FROM LOSSES

Weight Loss Drugs and the Obesity Epidemic

BY AARON MEDARIS



Obesity has emerged as a pervasive and pressing global health issue, transcending geographic, economic, and cultural boundaries. The World Health Organization (WHO) defines obesity as "abnormal or excessive fat accumulation that may impair health." The prevalence of obesity has reached alarming levels, posing significant challenges to individuals, healthcare systems, and societies worldwide.

The obesity epidemic has grown steadily over the past few decades. According to WHO, global obesity rates have nearly tripled since 1975. In 2016, more than 1.9 billion adults were overweight, with over 650 million classified as obese. Alarmingly, childhood obesity is also on the rise, affecting 38 million children under the age of five.

Obesity is a complex and multifaceted condition with a range of contributing factors. While genetics can play a role, lifestyle choices and environmental influences are primary drivers. Sedentary behaviors, high-calorie diets rich in processed foods, and an increase in portion sizes are major culprits. Additionally, socioeconomic factors, such as limited access to healthy foods and opportunities for physical activity, contribute to the epidemic.

Obesity is not merely a cosmetic concern; it is a major risk factor for a multitude of health problems. Individuals with obesity are at a higher risk of developing chronic conditions, including type 2 diabetes, cardiovascular diseases, certain cancers, and musculoskeletal disorders. The economic burden of obesity on healthcare systems is substantial, with increased healthcare costs and decreased productivity.

According to a 2022 article titled, "The Economic Costs of Obesity," there are currently, "236 diseases that are associated with obesity…[putting] medical care costs of obesity at almost $150 billion per year in the U.S. More specifically, the cost of treating the five most common obesity-related conditions (stroke, coronary artery disease, diabetes, hypertension, and elevated cholesterol) resulted in roughly $9,000 to 17,000 in higher costs compared to normal weight adults."

Just one year ago, the outlook on obesity was quite dire. How dire? Look at some of these headlines from news agencies around the world, "Obesity 'epidemic' leading to 1.2 million deaths a year in Europe, says WHO," "Study finds childhood obesity occurring at greater frequency," and "Number of States with High Rates of Adult Obesity More Than Doubles."

However, there have been some major developments in the treatment of obesity that have changed headlines from bleak and dire to hope and optimism. "FDA Approves Powerful New Drug to Counter Obesity Epidemic," "New drugs Could Spell an End to the World's Obesity Epidemic," "Doctors Grapple with Patients Demand for Weight-loss Drugs."

Drugs such as Mounjaro, Wegovy, and Ozempic are known as incretin medications. Incretins are gut hormones that aid in digestion and blood glucose control. They include glucagon-like peptide-1 (GLP-1) and glucose-dependent insulinotropic polypeptide (GIP). Therefore, incretin medications mimic incretin hormones. They stimulate the release of insulin which helps lower blood sugar as well as slow food passage through the digestive system, making them an effective treatment for those with Type II Diabetes. But how do these medications help people lose weight? Using Ozempic as an example, these drugs often:

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Mimick GLP-1 Activity: GLP-1 is a naturally occurring hormone in the body that plays a crucial role in glucose homeostasis. It is released in response to food intake and stimulates insulin secretion from the pancreas, leading to reduced blood sugar levels. Ozempic acts as a synthetic version of GLP-1, binding to the GLP-1 receptors on pancreatic beta cells. This stimulates the release of insulin in a glucose-dependent manner, meaning that it primarily acts when blood sugar levels are elevated.

Reduce Glucagon Release: Glucagon is another hormone produced by the pancreas, and its primary function is to increase blood glucose levels. In individuals with type 2 diabetes, there is often an imbalance between insulin and glucagon, contributing to elevated blood sugar. Ozempic helps regulate this imbalance by inhibiting the release of glucagon, leading to a decrease in the production of glucose by the liver. This contributes to improved blood sugar control.

Slow Gastric Emptying: Ozempic slows down the emptying of the stomach, which helps reduce post-meal spikes in blood sugar. By delaying the absorption of nutrients from the

digestive tract, it contributes to a more gradual and controlled rise in blood glucose levels after eating.

Appetite Regulation: One of the notable secondary effects of Ozempic is its impact on appetite regulation and weight loss. The medication appears to influence the central nervous system, leading to a reduction in appetite and an increase in feelings of fullness. The mechanisms underlying the weight loss effects are not entirely understood, but they may involve interactions with brain pathways related to food reward and satiety.

Dr. Cecilia Low Wang, a professor at the University of Colorado School of Medicine who also chairs the committee that advises the FDA on drugs related to endocrinology and metabolism, mentioned that those people who used the largest dose of Mounjaro, 15 milligrams, lost as much as 21% of their body weight. "They were able to achieve unprecedented amounts of weight loss. It was dramatic and exciting…We've never had a medication that is so effective for improving diabetes control and weight loss without putting patients at high risk of hypoglycemia," Low Wang said.

Dr. Wang's excitement reflects why these drugs have been changing headlines across the U.S. where an estimated 70% of adults are either obese or overweight. Novo Nordisk, the makers of Wegovy, estimate that if 100,000 people lost 15% of their body weight (which is the average amount lost for their drug), it would cut $85 million from the cost of obesity related conditions over 5 years. Figures like look promising, but how do they compare to the global cost of obesity? In 2020, obesity health issues on a global scale cost over $1.96 trillion or 2.4% of global GDP; and if gone unchecked, is expected to reach $4.32 trillion by 2035. With such a daunting economic and human price ahead of us, can these weight loss drugs really make a difference? I feel the answer is a definite yes. No country has seen a decline in obesity since 1975! What we have with these drugs is an opportunity to use them as a therapeutic option to treat obesity, improve overall health, and slowly cut overall healthcare costs. For instance, in a recent study from Mongan Stanley, "analysts estimate that 24 million people or 7% of the US population will be taking these drugs by 2035." One of the other interesting facts uncovered in the Morgan Stanley analysis, is that over two-thirds of those who took these drugs cut back on their intake of sugary drinks, baked goods, and other foods high in fat and sugar. Not only are these drugs helping people lose weight, but they are helping them change behavior. I feel that it is reasonable to believe that over the next decade that these drugs along healthier habits we could actually see a decline in obesity trends.

Time will tell what impact these therapies will have on the obesity epidemic. But I sure hope that 10 years from now, we're talking about how we've seen the first decline of obesity and obesity related health issues in over a half century.

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What is Mounjaro? And does it work better for weight loss than Ozempic and Wegovy?
https://www.uchealth.org/today/what-is-mounjaro-and-how-does-it-work-for-weight-loss/

Report: Obesity could cost the world over $4 trillion a year by 2035
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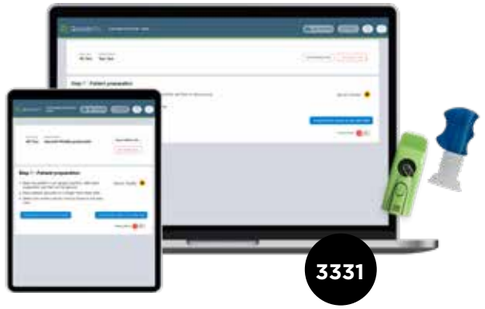
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QuantaFlo® PAD is an easy to use, accurate, point of care, non-invasive solution that aids in the early detection of peripheral arterial disease (PAD). This FDA cleared device can be administered by a medical aide in less than 5 minutes. As published in the Journal of Vascular Surgery and the American Journal of Preventive Medicine, QuantaFlo detected undiagnosed PAD in 31.6% of patients +65.1 QuantaFlo is portable and integrates with other technologies and platforms. It is ideal for both home and clinic environments.

1. Smolderen KG, Ameli O, Chaisson CE, Heath K, Mena-Hurtado C. Peripheral Artery Disease Screening in the Community and 1-Year Mortality, Cardiovascular Events, and Adverse Limb Events, AJPM Focus (2022), https://doi.org/10.1016/j.focus.2022.100016

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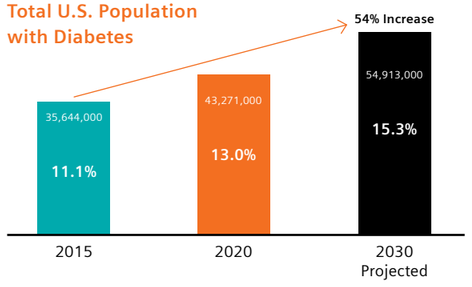


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1. Rowley, William R et al. "Diabetes 2030: Insights from Yesterday, Today, and Future Trends." Population health management vol. 20,1 (2017): 6-12. doi:10.1089/pop.2015.0181.



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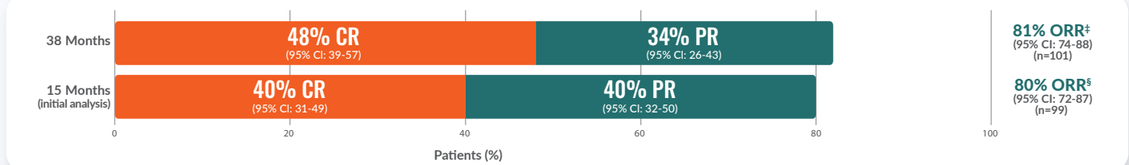
AT 38-MONTH MEDIAN FOLLOW-UP*[1]

8 OUT OF 10 relapsed/refractory mantle cell lymphoma (R/R MCL) patients responded to CALQUENCE[1]

CALQUENCE has continued to show deep responses[1-3]

In LY-004, ORR was 81% (95% CI: 74-88): CR was 48% (95% CI: 39-57) and PR was 34% (95% CI: 26-43) in 124 patients with R/R MCL at a median follow-up of 38.1 months.[†1]

Response rates at median follow-ups over time (N=124)[1-3]



29-MONTH MEDIAN DoR (95% CI: 18-39)[1]

- DoR was measured in the 101 patients who achieved a CR or PR at the 38-month median follow-up[1]
  - Median DoR in patients with Ki-67 index <50% (n=57) was 37 months (95% CI: 21-49) and in patients with Ki-67 index ≥50% (n=20) was 15 months (95% CI: 1.9-34)[1]
  - Median DoR in patients with 1 (n=49), 2 (n=32), and ≥3 (n=20) prior regimens was 26 (95% CI: 15-47), 34 (95% CI: 9-not estimable), and 26 (95% CI: 17-48) months, respectively[1]

The median 38-month follow-up data from LY-004 have not been reviewed by the FDA and are not in the Prescribing Information for CALQUENCE.

*Median follow-up of 38.1 months (range: 0.3-59.5 months).[1] †INV-assessed per 2014 Lugano Classification.[3] ‡38-month median follow-up is INV-assessed.[1] §15-month median follow-up is IRC-assessed per 2014 Lugano Classification. INV-assessed response rates were: ORR, 81% (95% CI: 73-87); CR, 40% (95% CI: 31-49); and PR, 41% (95% CI: 32-50).[2]

CI=confidence interval; CR=complete response; DoR=duration of response; INV=investigator; IRC=independent review committee; ORR=overall response rate; OS=overall survival; PFS=progression-free survival; PR=partial response.

IMPORTANT SAFETY INFORMATION

INDICATION AND USAGE

CALQUENCE is a Bruton tyrosine kinase (BTK) inhibitor indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

IMPORTANT SAFETY INFORMATION ABOUT CALQUENCE® (acalabrutinib) tablets

Serious and Opportunistic Infections

Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia in 6%). These infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients.

Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, *Pneumocystis jirovecii* pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials.

Low rates of atrial fibrillation and hypertension[1,4]

TOTAL EVENTS REPORTED AT MEDIAN 38-MONTH FOLLOW-UP[1]

ATRIAL FIBRILLATION[4]

1.6%	0%
All grades	Grade ≥3

HYPERTENSION[1]

4%	1.6%
All grades	Grade ≥3

- At initial analysis (median follow-up: 15.2 months)[2]
  - Atrial fibrillation was 0% for all grades
  - Hypertension was 2.4% for all grades and 0.8% for Grade ≥3

LEARN MORE ABOUT CALQUENCE MCL DATA

‖Median duration of therapy was 16.6 months (range: 0.1-26.6 months).[3]

AE=adverse event; AR=adverse reaction.

THE 38-MONTH SAFETY PROFILE WAS CONSISTENT WITH INITIAL ANALYSIS

38-MONTH ANALYSIS (N=124)

- **The most common treatment-emergent AEs (≥20%)** were infections (68%), headache (39%), diarrhea (37%), bleeding events (37%), fatigue (30%), cough (23%), myalgia (22%), and nausea (22%)[1,4]
- 2% dose reduction rate and 11% discontinuation rate due to AEs[4]
- **Events of clinical interest (any grade; Grade 3/4)** included infections (68%; 17%), bleeding events (37%; 4%), cardiac events (13%; 5%), and hypertension (4%; 1.6%)[1]

INITIAL ANALYSIS (N=124)‖

- **The most common adverse drug reactions (≥20%)** were anemia (46%), thrombocytopenia (44%), headache (39%), neutropenia (36%), diarrhea (31%), fatigue (28%), myalgia (21%), and bruising (21%)[3]
- 1.6% dose reduction rate and 6.5% discontinuation rate due to ARs[3]
- **Events of clinical interest (any grade; Grade 3/4)** included infections (53%; 13%), hemorrhage (31%; 1%), cardiac events (8%; 2%), and hypertension (2%; 1%)[2]

STUDY DESIGN

LY-004 trial: An international, Phase 2, open-label, single-arm, multicenter trial of 124 patients (≥18 years) with MCL who had received ≥1 prior therapy. Patients received CALQUENCE 100 mg approximately every 12 hours until disease progression or unacceptable toxicity. The primary endpoint was investigator-assessed ORR per 2014 Lugano Classification; secondary endpoints included DoR, PFS, and OS.[2,3]

The initial data analysis was based on efficacy and safety endpoints from March 12, 2015 to January 5, 2016. The median follow-up time was 15.2 months.[2]

The 38-month analysis represents an additional year of follow-up succeeding the 26-month update from March 12, 2015 to February 12, 2018.[1,2,5]

IMPORTANT SAFETY INFORMATION (cont'd)

Hemorrhage (cont'd)

Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3-7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted.

Second Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

Atrial Fibrillation and Flutter

Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (eg, palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

ADVERSE REACTIONS

The most common adverse reactions (≥20%) of any grade in patients with relapsed or refractory MCL were anemia,* thrombocytopenia,* headache (39%), neutropenia,* diarrhea (31%), fatigue (28%), myalgia (21%), and bruising (21%). The most common Grade ≥3 non-hematological adverse reaction (reported in at least 2% of patients) was diarrhea (3.2%).

* Treatment-emergent decreases (all grades) of hemoglobin (46%), platelets (44%), and neutrophils (36%) were based on laboratory measurements and adverse reactions.

Dose reductions or discontinuations due to any adverse reaction were reported in 1.6% and 6.5% of patients, respectively. Increases in creatinine to 1.5 to 3 times the upper limit of normal (ULN) occurred in 4.8% of patients.

DRUG INTERACTIONS

Strong CYP3A Inhibitors: Avoid co-administration of CALQUENCE with a strong CYP3A inhibitor. If these inhibitors will be used short-term, interrupt CALQUENCE. After discontinuation of strong CYP3A inhibitor for at least 24 hours, resume previous dosage of CALQUENCE.

Moderate CYP3A Inhibitors: Reduce the dosage of CALQUENCE to 100 mg once daily when co-administered with a moderate CYP3A inhibitor.

Strong CYP3A Inducers: Avoid co-administration of CALQUENCE with a strong CYP3A inducer. If co-administration is unavoidable, increase the dosage of CALQUENCE to 200 mg approximately every 12 hours.

SPECIFIC POPULATIONS

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. Advise pregnant women of the potential risk to a fetus.

Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy. Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for 1 week following the last dose of CALQUENCE.

It is not known if CALQUENCE is present in human milk. Advise lactating women not to breastfeed while taking CALQUENCE and for 2 weeks after the last dose.

Avoid use of CALQUENCE in patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustment of CALQUENCE is recommended in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment.

Please see Brief Summary of full Prescribing Information on adjacent pages.

You are encouraged to report the negative side effects of prescription drugs to the FDA. Visit www.FDA.gov/medwatch or call 1-800-FDA-1088.

References: 1. Wang M, Rule S, Zinzani PL, et al. Acalabrutinib monotherapy in patients with relapsed/refractory mantle cell lymphoma: long-term efficacy and safety results from a phase 2 study. Poster presented at: American Society of Hematology (ASH) Annual Meeting and Exposition; December 5-8, 2020 (Virtual Meeting). Abstract 2040. **2.** Wang M, Rule S, Zinzani PL, et al. Acalabrutinib in relapsed or refractory mantle cell lymphoma (ACE-LY-004): a single-arm, multicentre, phase 2 trial. *Lancet.* 2018;391(10121):659-667 and supplementary appendix. **3.** CALQUENCE® (acalabrutinib) tablets [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; 2022. **4.** Data on File. REF-103791. AstraZeneca Pharmaceuticals LP. **5.** Wang M, Rule S, Zinzani PL, et al. Durable response with single-agent acalabrutinib in patients with relapsed or refractory mantle cell lymphoma. *Leukemia.* 2019;33(11):2762-2766.

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AstraZeneca

CALQUENCE® (acalabrutinib) tablets, for oral use
Initial U.S. Approval: 2017

Brief Summary of Prescribing Information.
For full Prescribing Information consult official package insert.

INDICATIONS AND USAGE

Mantle Cell Lymphoma

CALQUENCE is indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy.

This indication is approved under accelerated approval based on overall response rate *[see Clinical Studies (14.1) in the full Prescribing Information]*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

DOSAGE AND ADMINISTRATION

Recommended Dosage

CALQUENCE as Monotherapy

For patients with MCL, the recommended dosage of CALQUENCE is 100 mg taken orally approximately every 12 hours until disease progression or unacceptable toxicity.

Advise patients to swallow tablet whole with water. Advise patients not to chew, crush, dissolve, or cut the tablets. CALQUENCE may be taken with or without food. If a dose of CALQUENCE is missed by more than 3 hours, it should be skipped and the next dose should be taken at its regularly scheduled time. Extra tablets of CALQUENCE should not be taken to make up for a missed dose.

Recommended Dosage for Drug Interactions

Dosage Modifications for Use with CYP3A Inhibitors or Inducers

These are described in Table 1 *[see Drug Interactions (7) in the full Prescribing Information]*.

Table 1: Recommended Dosage Modifications for Use with CYP3A Inhibitors or Inducers

CYP3A	Co-administered Drug	Recommended CALQUENCE use
Inhibition	Strong CYP3A inhibitor	Avoid co-administration. If these inhibitors will be used short-term (such as anti-infectives for up to seven days), interrupt CALQUENCE. After discontinuation of strong CYP3A inhibitor for at least 24 hours, resume previous dosage of CALQUENCE.
	Moderate CYP3A inhibitor	Reduce the CALQUENCE 100 mg every 12 hours dosage to 100 mg once daily.
Induction	Strong CYP3A inducer	Avoid co-administration. If co-administration is unavoidable, increase CALQUENCE dosage to 200 mg approximately every 12 hours.

Dosage Modifications for Adverse Reactions

Recommended dosage modifications of CALQUENCE for Grade 3 or greater adverse reactions are provided in Table 2.

Table 2: Recommended Dosage Modifications for Adverse Reactions

Event	Adverse Reaction Occurrence	Dosage Modification (Starting dose = 100 mg approximately every 12 hours)
Grade 3 or greater non-hematologic toxicities, Grade 3 thrombocytopenia with bleeding, Grade 4 thrombocytopenia or Grade 4 neutropenia lasting longer than 7 days	First and Second	Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at 100 mg approximately every 12 hours.
	Third	Interrupt CALQUENCE. Once toxicity has resolved to Grade 1 or baseline level, CALQUENCE may be resumed at a reduced frequency of 100 mg once daily.
	Fourth	Discontinue CALQUENCE.

Adverse reactions graded by the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE).

Refer to the obinutuzumab prescribing information for management of obinutuzumab toxicities.

CONTRAINDICATIONS

None.

WARNINGS AND PRECAUTIONS

Serious and Opportunistic Infections

Fatal and serious infections, including opportunistic infections, have occurred in patients with hematologic malignancies treated with CALQUENCE.

Serious or Grade 3 or higher infections (bacterial, viral, or fungal) occurred in 19% of 1029 patients exposed to CALQUENCE in clinical trials, most often due to respiratory tract infections (11% of all patients, including pneumonia in 6%) *[see Adverse Reactions (6.1) in the full Prescribing Information]*. These infections predominantly occurred in the absence of Grade 3 or 4 neutropenia, with neutropenic infection reported in 1.9% of all patients. Opportunistic infections in recipients of CALQUENCE have included, but are not limited to, hepatitis B virus reactivation, fungal pneumonia, *Pneumocystis jirovecii* pneumonia, Epstein-Barr virus reactivation, cytomegalovirus, and progressive multifocal leukoencephalopathy (PML). Consider prophylaxis in patients who are at increased risk for opportunistic infections. Monitor patients for signs and symptoms of infection and treat promptly.

Hemorrhage

Fatal and serious hemorrhagic events have occurred in patients with hematologic malignancies treated with CALQUENCE. Major hemorrhage (serious or Grade 3 or higher bleeding or any central nervous system bleeding) occurred in 3.0% of patients, with fatal hemorrhage occurring in 0.1% of 1029 patients exposed to CALQUENCE in clinical trials. Bleeding events of any grade, excluding bruising and petechiae, occurred in 22% of patients *[see Adverse Reactions (6.1) in the full Prescribing Information]*.

Use of antithrombotic agents concomitantly with CALQUENCE may further increase the risk of hemorrhage. In clinical trials, major hemorrhage occurred in 2.7% of patients taking CALQUENCE without antithrombotic agents and 3.6% of patients taking CALQUENCE with antithrombotic agents. Consider the risks and benefits of antithrombotic agents when co-administered with CALQUENCE. Monitor patients for signs of bleeding.

Consider the benefit-risk of withholding CALQUENCE for 3 to 7 days pre- and post-surgery depending upon the type of surgery and the risk of bleeding.

Cytopenias

Grade 3 or 4 cytopenias, including neutropenia (23%), anemia (8%), thrombocytopenia (7%), and lymphopenia (7%), developed in patients with hematologic malignancies treated with CALQUENCE. Grade 4 neutropenia developed in 12% of patients *[see Adverse Reactions (6.1) in the full Prescribing Information]*. Monitor complete blood counts regularly during treatment. Interrupt treatment, reduce the dose, or discontinue treatment as warranted *[see Dosage and Administration (2.3) in the full Prescribing Information]*.

Second Primary Malignancies

Second primary malignancies, including skin cancers and other solid tumors, occurred in 12% of 1029 patients exposed to CALQUENCE in clinical trials *[see Adverse Reactions (6.1) in the full Prescribing Information]*. The most frequent second primary malignancy was skin cancer, reported in 6% of patients. Monitor patients for skin cancers and advise protection from sun exposure.

Atrial Fibrillation and Flutter

Grade 3 atrial fibrillation or flutter occurred in 1.1% of 1029 patients treated with CALQUENCE, with all grades of atrial fibrillation or flutter reported in 4.1% of all patients *[see Adverse Reactions (6.1) in the full Prescribing Information]*. The risk may be increased in patients with cardiac risk factors, hypertension, previous arrhythmias, and acute infection. Monitor for symptoms of arrhythmia (e.g., palpitations, dizziness, syncope, dyspnea) and manage as appropriate.

ADVERSE REACTIONS

The following clinically significant adverse reactions are discussed in greater detail in other sections of the labeling:

- Serious and Opportunistic Infections *[see Warnings and Precautions (5.1) in the full Prescribing Information]*
- Hemorrhage *[see Warnings and Precautions (5.2) in the full Prescribing Information]*
- Cytopenias *[see Warnings and Precautions (5.3) in the full Prescribing Information]*
- Second Primary Malignancies *[see Warnings and Precautions (5.4) in the full Prescribing Information]*
- Atrial Fibrillation and Flutter *[see Warnings and Precautions (5.5) in the full Prescribing Information]*

Clinical Trials Experience

As 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 data in the Warnings and Precautions reflect exposure to CALQUENCE 100 mg approximately every 12 hours in 1029 patients with hematologic malignancies. Treatment includes CALQUENCE monotherapy in 820 patients in 6 trials, and CALQUENCE with obinutuzumab in 209 patients in 2 trials. Among these recipients of CALQUENCE, 88% were exposed for at least 6 months and 79% were exposed for at least one year. In this pooled safety population, adverse reactions in ≥ 30% of 1029 patients were anemia, neutropenia, upper respiratory tract infection, thrombocytopenia, headache, diarrhea, and musculoskeletal pain.

Mantle Cell Lymphoma

The safety data described in this section reflect exposure to CALQUENCE (100 mg approximately every 12 hours) in 124 patients with previously treated MCL in Trial LY-004 *[see Clinical Studies (14.1) in the full Prescribing Information]*. The median duration of treatment with CALQUENCE was 16.6 (range: 0.1 to 26.6) months. A total of 91 (73.4%) patients were treated with CALQUENCE for ≥ 6 months and 74 (59.7%) patients were treated for ≥ 1 year.

The most common adverse reactions (≥ 20%) of any grade were anemia, thrombocytopenia, headache, neutropenia, diarrhea, fatigue, myalgia, and bruising. Grade 1 severity for the non-hematologic, most common events were as follows: headache (25%), diarrhea (16%), fatigue (20%), myalgia (15%), and bruising (19%). The most common Grade ≥ 3 non-hematological adverse reaction (reported in at least 2% of patients) was diarrhea.

Dose reductions and discontinuation due to any adverse reaction were reported in 1.6% and 6.5% of patients, respectively.

Tables 3 and 4 present the frequency category of adverse reactions observed in patients with MCL treated with CALQUENCE.

Table 3: Non-Hematologic Adverse Reactions in ≥ 5% (All Grades) of Patients with MCL in Trial LY-004

Body System Adverse Reactions*	CALQUENCE Monotherapy N=124	
	All Grades (%)	Grade ≥ 3 (%)
Nervous system disorders		
Headache	39	1.6
Gastrointestinal disorders		
Diarrhea	31	3.2
Nausea	19	0.8
Abdominal pain	15	1.6
Constipation	15	-
Vomiting	13	1.6
General disorders		
Fatigue	28	0.8
Musculoskeletal and connective tissue disorders		
Myalgia	21	0.8
Skin and subcutaneous tissue disorders		
Bruising[a]	21	-
Rash[b]	18	0.8
Vascular disorders		
Hemorrhage[c]	8	0.8
Respiratory, thoracic and mediastinal disorders		
Epistaxis	6	-

*Per NCI CTCAE version 4.03.
[a] Bruising: Includes all terms containing 'bruise,' 'contusion,' 'petechiae,' or 'ecchymosis'
[b] Rash: Includes all terms containing 'rash'
[c] Hemorrhage: Includes all terms containing 'hemorrhage' or 'hematoma'

Table 4: Hematologic Adverse Reactions Reported in ≥ 20% of Patients with MCL in Trial LY-004

Hematologic Adverse Reactions*	CALQUENCE Monotherapy N=124	
	All Grades (%)	Grade ≥ 3 (%)
Hemoglobin decreased	46	10
Platelets decreased	44	12
Neutrophils decreased	36	15

*Per NCI CTCAE version 4.03; based on laboratory measurements and adverse reactions.

Increases in creatinine to 1.5 to 3 times the upper limit of normal (ULN) occurred in 4.8% of patients.

DRUG INTERACTIONS

Effect of Other Drugs on CALQUENCE

Strong CYP3A Inhibitors	
Clinical Effect	Co-administration of CALQUENCE with a strong CYP3A inhibitor increased acalabrutinib plasma concentrations *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. Increased acalabrutinib concentrations may result in increased toxicity.
Prevention or Management	Avoid co-administration of CALQUENCE with strong CYP3A inhibitors. Alternatively, if the inhibitor will be used short-term, interrupt CALQUENCE *[see Dosage and Administration (2.2) in the full Prescribing Information]*.
Moderate CYP3A Inhibitors	
Clinical Effect	Co-administration of CALQUENCE with a moderate CYP3A inhibitor may increase acalabrutinib plasma concentration *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. Increased acalabrutinib concentrations may result in increased toxicity.
Prevention or Management	Reduce the dosage of CALQUENCE when co-administered with a moderate CYP3A inhibitor *[see Dosage and Administration (2.2) in the full Prescribing Information]*.
Strong CYP3A Inducers	
Clinical Effect	Co-administration of CALQUENCE with a strong CYP3A inducer decreased acalabrutinib plasma concentration *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*. Decreased acalabrutinib concentrations may reduce CALQUENCE activity.
Prevention or Management	Avoid co-administration of CALQUENCE with strong CYP3A inducers. If co-administration is unavoidable, increase the dosage of CALQUENCE *[see Dosage and Administration (2.2) in the full Prescribing Information]*.

USE IN SPECIFIC POPULATIONS

Pregnancy

Risk Summary

Based on findings in animals, CALQUENCE may cause fetal harm and dystocia when administered to a pregnant woman. There are no available data in pregnant women to inform the drug-associated risk. In animal reproduction studies, administration of acalabrutinib to animals during organogenesis resulted in dystocia in rats and reduced fetal growth in rabbits at maternal exposures (AUC) 2 times exposures in patients at the recommended dose of 100 mg approximately every 12 hours (*see Data*). Advise pregnant women of the potential risk to a fetus.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

In a combined fertility and embryo-fetal development study in female rats, acalabrutinib was administered orally at doses up to 200 mg/kg/day starting 14 days prior to mating through gestational day [GD] 17. No effects on embryo-fetal development and survival were observed. The AUC at 200 mg/kg/day in pregnant rats was approximately 9 times the AUC in patients at the recommended dose of 100 mg approximately every 12 hours. The presence of acalabrutinib and its active metabolite were confirmed in fetal rat plasma.

In an embryo-fetal development study in rabbits, pregnant animals were administered acalabrutinib orally at doses up to 200 mg/kg/day during the period of organogenesis (from GD 6-18). Administration of acalabrutinib at doses ≥ 100 mg/kg/day produced maternal toxicity and 100 mg/kg/day resulted in decreased fetal body weights and delayed skeletal ossification. The AUC at 100 mg/kg/day in pregnant rabbits was approximately 2 times the AUC in patients at 100 mg approximately every 12 hours.

In a pre- and postnatal development study in rats, acalabrutinib was administered orally to pregnant animals during organogenesis, parturition and lactation, at doses of 50, 100, and 150 mg/kg/day. Dystocia (prolonged or difficult labor) and mortality of offspring were observed at doses ≥ 100 mg/kg/day. The AUC at 100 mg/kg/day in pregnant rats was approximately 2 times the AUC in patients at 100 mg approximately every 12 hours. Underdeveloped renal papilla was also observed in F1 generation offspring at 150 mg/kg/day with an AUC approximately 5 times the AUC in patients at 100 mg approximately every 12 hours.

Lactation

Risk Summary

No data are available regarding the presence of acalabrutinib or its active metabolite in human milk, its effects on the breastfed child, or on milk production. Acalabrutinib and its active metabolite were present in the milk of lactating rats. Due to the potential for adverse reactions in a breastfed child from CALQUENCE, advise lactating women not to breastfeed while taking CALQUENCE and for 2 weeks after the last dose.

Females and Males of Reproductive Potential

CALQUENCE may cause embryo-fetal harm and dystocia when administered to pregnant women *[see Use in Specific Populations (8.1) in the full Prescribing Information]*.

Pregnancy Testing

Pregnancy testing is recommended for females of reproductive potential prior to initiating CALQUENCE therapy.

Contraception

Females

Advise female patients of reproductive potential to use effective contraception during treatment with CALQUENCE and for 1 week following the last dose of CALQUENCE. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be informed of the potential hazard to a fetus.

Pediatric Use

The safety and efficacy of CALQUENCE in pediatric patients have not been established.

Geriatric Use

Of the 929 patients with CLL or MCL in clinical trials of CALQUENCE, 68% were 65 years of age or older, and 24% were 75 years of age or older. Among patients 65 years of age or older, 59% had Grade 3 or higher adverse reactions and 39% had serious adverse reactions. Among patients younger than age 65, 45% had Grade 3 or higher adverse reactions and 25% had serious adverse reactions. No clinically relevant differences in efficacy were observed between patients ≥ 65 years and younger.

Hepatic Impairment

Avoid use of CALQUENCE in patients with severe hepatic impairment (Child-Pugh class C). No dosage adjustment of CALQUENCE is recommended in patients with mild (Child-Pugh class A) or moderate (Child-Pugh class B) hepatic impairment. The safety of CALQUENCE has not been evaluated in patients with moderate or severe hepatic impairment *[see Clinical Pharmacology (12.3) in the full Prescribing Information]*.

PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

Serious and Opportunistic Infections

Inform patients of the possibility of serious infection and to report signs or symptoms suggestive of infection *[see Warnings and Precautions (5.1) in the full Prescribing Information]*.

Hemorrhage

Inform patients to report signs or symptoms of bleeding. Inform patients that CALQUENCE may need to be interrupted for major surgeries *[see Warnings and Precautions (5.2) in the full Prescribing Information]*.

Cytopenias

Inform patients that they will need periodic blood tests to check blood counts during treatment with CALQUENCE *[see Warnings and Precautions (5.3) in the full Prescribing Information]*.

Second Primary Malignancies

Inform patients that other malignancies have been reported in patients who have been treated with CALQUENCE, including skin cancer and other solid tumors. Advise patients to use sun protection *[see Warnings and Precautions (5.4) in the full Prescribing Information]*.

Atrial Fibrillation and Flutter

Counsel patients to report any signs of palpitations, dizziness, fainting, chest discomfort, and shortness of breath *[see Warnings and Precautions (5.5) in the full Prescribing Information]*.

Pregnancy Complication

CALQUENCE may cause fetal harm and dystocia. Advise women to use effective contraception during treatment and for 1 week after the last dose of CALQUENCE *[see Use in Specific Populations (8.3) in the full Prescribing Information]*.

Lactation

Advise females not to breastfeed during treatment with CALQUENCE and for 2 weeks after the last dose *[see Use in Specific Populations (8.2) in the full Prescribing Information]*.

Dosing Instructions

Instruct patients to take CALQUENCE orally twice daily, about 12 hours apart. CALQUENCE may be taken with or without food. Advise patients that CALQUENCE tablets should be swallowed whole with a glass of water, without chewing, crushing, dissolving, or cutting *[see Dosage and Administration (2.1) in the full Prescribing Information]*.

Missed Dose

Advise patients that if they miss a dose of CALQUENCE, they may still take it up to 3 hours after the time they would normally take it. If more than 3 hours have elapsed, they should be instructed to skip that dose and take their next dose of CALQUENCE at the usual time. Warn patients they should not take extra tablets to make up for the dose that they missed *[see Dosage and Administration (2.1) in the full Prescribing Information]*.

Drug Interactions

Advise patients to inform their healthcare providers of all concomitant medications, including over-the-counter medications, vitamins and herbal products *[see Drug Interactions (7) in the full Prescribing Information]*.

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Diagnosing and treating respiratory infections in the outpatient setting:

Antimicrobial use, infection prevention, and improved patient care.

BY ANDREA PRINZI PHD, MPH, SM(ASCP), MICROBIOLOGY MEDICAL SCIENCE LIAISON, US MEDICAL AFFAIRS AT BIOMÉRIEUX

The Threat of Antimicrobial Resistance

Antimicrobial resistance (AMR) occurs when microorganisms evolve and adapt, making treatment with antimicrobials (e.g., antibiotics, antiviral, and antifungal medications) ineffective. When this occurs, infections caused by drug-resistant organisms may become exceptionally difficult, or even impossible, to treat.[1] The World Health Organization (WHO) has declared AMR one of humanity's top 10 public health threats.[1] It is estimated that in 2019 alone, approximately 1.27 million deaths were directly attributable to infections caused by drug-resistant organisms globally.[2] In the United States, more than 2.8 million antibiotic-resistant infections are reported, and more than 35,000 people die due to AMR each year.[3] Simply relying on the development of new antimicrobials that are effective against drug-resistant organisms is no longer enough. According to the Centers for Disease Control and Prevention (CDC), drug development programs must be coupled with multiple initiatives to combat AMR and keep the public safe. These initiatives include preventing infections, slowing the development of AMR through initiatives encouraging more appropriate antibiotic use, and preventing the spread of antibiotic-resistant organisms when identified.[3]

Antibiotic Use in the Outpatient Setting

Inappropriate antibiotic use is a significant challenge in the outpatient setting (e.g., physician's offices, urgent care clinics). In the U.S., it is estimated that at least 30% of the antibiotics prescribed in the outpatient setting are unnecessary, meaning that an antibiotic is not needed for the patient to improve clinically.[4] Respiratory infections are a major driver of unnecessary and inappropriate antibiotic use in the outpatient setting. For example, rhinosinusitis (commonly referred to as a sinus infection and involving inflammation of the sinuses, nasal cavity, and nasal mucosa)[5] is one of the most commonly diagnosed respiratory conditions in the U.S. and is the fifth most common diagnosis associated with antibiotic therapy.[5] In adults, 90-98% of sinusitis cases are caused by a virus and should not be treated with antibiotics.[6] Additionally, other upper respiratory tract infections (most often referred to as "the common cold") also represent one of the major reasons for physician office visits.[7] There are at least 200 viruses that can cause the common cold, and most of the time, antibiotics are not needed.[6] Unfortunately, upper respiratory tract infections can last for a long time (a week or longer) which may be frustrating for adults and especially worrisome for parents of young children. However, unnecessary antibiotic use is not without complications. In addition to contributing to AMR, antibiotic use has been associated with adverse side effects, including rashes, dizziness, vomiting and diarrhea, and yeast infections.8 In more serious cases, antibiotic use has been associated with severe allergic reactions and infection with Clostridioides difficile (C. difficile), which can cause life-threatening diarrhea.8 In children, inappropriate antibiotic use for treating infections in the ear and sinuses is associated with 3 to 8 times the risk of developing a C. difficile infection.[9]

In addition to the clinical impact of unnecessary antibiotic prescribing for respiratory tract infections, the social and economic impacts can be severe. In adults, antibiotic treatment failure, additional prescriptions, repeat visits, and follow-up testing for acute sinusitis contribute to a health

care expenditure exceeding $3 billion in the U.S. annually.[5] A study published in 2017 demonstrated that in pediatrics, inappropriate antibiotic use for three common infections (ear infections, pharyngitis, and sinus infections) led to excess healthcare costs totaling $53.7 million.[9] Furthermore, antibiotic use in cases of respiratory tract infections caused by viruses increased healthcare costs by approximately $20.7 million.[9]

The Role of Rapid Diagnostic Testing for Respiratory Illness in The Outpatient Setting

Preventing infections before they occur

As seen with the COVID-19 pandemic, prevention of the spread of disease is key. Seasonal surveillance, or the act of collecting data on the viruses in the community causing illness over a defined period of time, is important to identify expected trends but also to catch upticks in disease that may suggest an outbreak or epidemic. Historically, respiratory testing data collected from patient testing in the clinical laboratory have been sent to surveillance programs like the CDC's National Respiratory and Enteric Virus Surveillance System (NREVSS). This system analyzes patterns across time and place of respiratory illnesses to monitor viral seasons and circulation patterns for various common respiratory viruses.[10] Data are submitted to the CDC from participating laboratories on a voluntary weekly basis. Although there are a variety of disease surveillance options available that are web-based, they still require manual entry of data from laboratories which can be time-consuming, associated with delays in reporting, or potentially prone to error.[11]

However, tracking respiratory data in real time is now an option. [11] BIOFIRE® Syndromic Trends (TREND), from bioMérieux, is a software program that collects data from respiratory testing performed on bioMérieux's BIOFIRE respiratory assays and provides insights into pathogen circulation trends.[12] The use of epidemiologic data tools like BIOFIRE TREND provides a high-resolution summary of circulating respiratory pathogens and could potentially aid in detecting new outbreaks by monitoring what is spreading within the community in near-real-time.[11] This is an important step in reducing the burden of respiratory disease and contributing to outbreak responses and vaccine development.[13] The opportunity to have data move directly from a multiplex PCR assay to an accessible cloud may remove the barrier of manual reporting typically performed by a clinical laboratory, making this an appealing option for use in the outpatient setting.

Supporting Appropriate Antimicrobial Use

Many behavioral complexities play into clinical decision-making and antibiotic prescribing practices. Pressure to prescribe an antibiotic, particularly pressure from the parents of pediatric patients, is cited as a major driver of unnecessary antibiotic use in the outpatient setting.[14] Furthermore, diagnostic uncertainty contributes to antibiotic overuse. The symptoms of viral and bacterial respiratory infections are often similar, and it can be difficult to differentiate between them. In the outpatient setting, where it may be challenging or less desirable to perform a procedure to test for this, a clinician may prescribe an antibiotic because it feels like a safer choice.[15] Knowing what is causing a patient's respiratory infection may support clinicians in their conversations with patients and may help patients (or parents of patients) feel more comfortable about not receiving an antibiotic.[15]

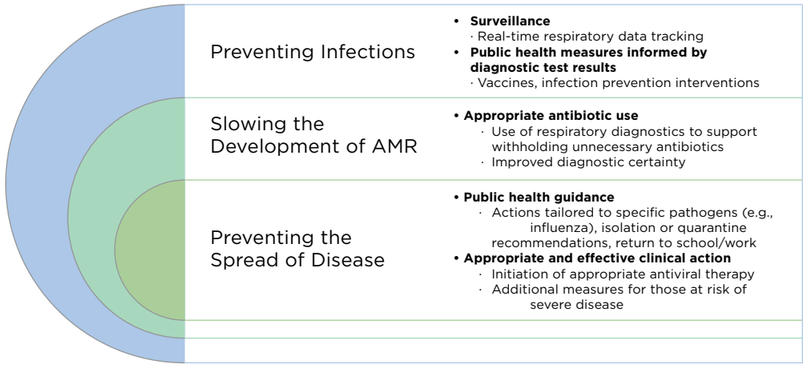
Time constraints are another significant challenge for clinicians in the outpatient setting. Studies that involved interviewing physicians about factors that contribute to antibiotic over-prescription found that workload and time pressures contribute to the problem. Physicians report that as they see more patients repeatedly throughout the day, they are subject to "decision fatigue."[15] Decision fatigue results in declining decision-making abilities after clinicians have to make repeated decisions. This may be more prevalent in the case of acute respiratory infection, where the cause of the disease is often unknown and prescribing an antibiotic feels safe.[15]

Until recently, the primary respiratory tests available to outpatient doctor's offices were rapid antigen detection tests (RADTs). Although relatively cheap and easy to use, RADTs are limited by poor performance, including low sensitivity (the ability of a test to detect a pathogen when it is present) and marginal specificity (the ability of a test to give a negative result when a pathogen is not present). Additionally, the performance of RADTs varies depending on what time of year they are used. For example, when the prevalence of influenza is low within a community, false positive results from an antigen test are more likely. However, negative results are more likely to be true.[16]

Rapid point-of-care multiplex PCR assays are now available in the outpatient setting. These tests are faster, more comprehensive, and perform better than traditional RADTs.[17] For example, the bioMérieux BIOFIRE® SPOTFIRE® Respiratory (R) Panel assay tests for 15 respiratory pathogens and offers a result in about 15 minutes. Paired with education about how antibiotics will not help patients with viral infections, excessive antibiotic use may be reduced by the use of molecular multiplex PCR assays. The Infectious Diseases Society of America (IDSA) states that multiplex PCR testing is indicated when detecting a respiratory virus would influence the decision to withhold unnecessary antibiotics.[18] In addition to potentially preventing the overuse of unnecessary therapy, the knowledge gained from respiratory multiplex PCR testing has been shown to support appropriate antiviral therapy, like those used to treat influenza.[19] The rapid turnaround time for results from a multiplex PCR assay may help support workflow and clinical decision-making in busy outpatient settings and support more effective patient management and care. In a 2020 publication discussing the role of PCR testing for respiratory tract infections, the IDSA stated that respiratory test results (e.g., influenza) must be available



Figure 1. The Role of Respiratory Diagnostics in Supporting AMR Initiatives



during the patient visit to be useful in the outpatient setting.[18] Given this, rapid diagnostic assays for respiratory illness that offer test results quickly (e.g., about 15 minutes) have the potential to provide meaningful clinical results while the patient is still in the office.

Preventing the Spread of Future Infections

The COVID-19 pandemic demonstrated, in real-time, the importance of diagnostic testing and its impact on public health interventions and how people live their lives. The far-reaching effects of the pandemic not only touched individuals' physical health but also led to significant societal disruption and economic loss.[20] Knowledge is power, and accurate diagnostic testing in the outpatient setting may help inform public health actions like social distancing or masking on an individual and population health level.[21] The impact of diagnostic testing on preventing severe disease, hospitalization, and spread is well-demonstrated for influenza. For example, it is estimated that influenza has led to 12,000-52,000 deaths annually between 2010 and 2020 in the U.S. If the diagnosis of influenza is early enough, antiviral drugs can be prescribed, which can shorten the length of illness and make symptoms of the disease milder.[22] Additionally, the CDC recommends that individuals with known influenza stay home for at least 24 hours after their fever is gone to help prevent the spread of the disease.[22] Obtaining information about the causative agent of respiratory disease, paired with appropriate preventative measures, may help protect the most vulnerable individuals in a population.

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FOUR SEASONS HOTEL TOKYO AT OTEMACHI

BY BRANDI BROWER

Japanese proverb: Nido aru koto ha sando aru

Translation: That which happens twice shall happen a third time.

Meaning: Things tend to repeat themselves. In my case, I'm thrilled that I have the pleasure of repeating a luxury stay at the Four Seasons in Japan. All three in the collection offer self-assured service, sleek and sophisticated aesthetics, and the swagger that comes with the Four Seasons brand. Yet, each Hotel is distinct in the experience provided.

They say the third time is the charm, and my third stay in this country at the sky-high sanctuary in the center of Tokyo was so much more than charming. I entered the Otemachi One Tower, located in the heart of Tokyo's most important business district; Four Seasons Hotel Tokyo at Otemachi was completed in 2020. As I walk through the glass doors off the street, it's as if I'm walking through a torii gate, with an archway in the distinct bright original color, not red, not orange, but Japanese torii red. A traditional torii gate symbolizes the transition from the mundane to the sacred—a subliminal design element, signifying that this will be an elevated event. A staff member offers to take my luggage and directs me to the elevator, pressing the 39th-floor button. Up, up, up, ears popping as I'm whisked to the top, doors open, and my eyes pop as well, seeing the impressive floral display in the lobby. Like the famous displays at the Four Seasons Hotel George V in Paris by celebrated artistic director Jeff Leatham, the entryway flowers are welcoming and have a similar wow factor. The beauty of the entrance should come as no surprise, considering Ikebana, translated as 'giving life to flowers,' has been an art form in this country since the 16th century. Ikebana is counted as one of the three classical Japanese arts of refinement, Chado for tea and the tea ceremony, and Kodo for incense appreciation.

The display of floral beauty is equal to the circular dome above it, inspired by the sun, as depicted on the Japanese flag, the dramatic kanji characters free-form calligraphy by Nobuko Kawahara, who spells out "seasons" using the Japanese symbols for spring, summer, autumn, and winter as markings. The impressive welcome of the lobby pours over into the jaw-dropping views of the expansive capital city from the floor-to-ceiling windows surrounding the top floor. The tower's proximity to the extensive Imperial Palace grounds below gives an unobstructed view of the massive metropolis. A bow of reverence to the adjacent sacred land, a 125-foot-long reflective water barrier between the windows and the flooring, is not only symbolic of the moat that protects the Imperial Palace but also a beautiful aesthetic touch. The Lounge is so breathtaking that I put off going to my guest suite to enjoy the afternoon tea service.

The tea ceremony is genuinely an art form, and Hikari is the artist performing the seasonal afternoon tea for me. With exactness and purpose, she makes the preparations for the Matcha. The famous tea is made from Tencha, the first flush tea picked at the beginning of May, carefully stored and aged through summer, and then carefully ground with a stone mill in late autumn. Hikari's rapid movements with the bamboo





chasen (whisk) froth up the Matcha powder in the warm tea cup, guaranteeing a perfectly delicate, nuanced cup of tea. A curated selection of savory and sweet bites complement the service: zucchini flan with melon coulis with ricotta cheese, dill, and mint oil, coconut mouse with melon jelly, and dry coconut and strawberry vacherin with vanilla cream and dry raspberry, to name a few delectables.

After a lovely afternoon in The Lounge, I venture one floor below with an electronic key for my room. I'm about to enter the suite when I realize it's not just a piece of pedestrian plastic that I tap against the door to enter the suite but a thoughtfully designed keycard made of bamboo. The attention to detail is impressive, and I'm even more impressed once I enter the lux accommodations. One of 126 rooms and 28 suites, all are generous with space, starting at more than 500 square feet, equitable with magnificent views of either cityscape or, as my luck would have it, the Imperial Palace grounds. The sleek, ultra-modern style is accented with pinhole recessed lighting and rope accent lights discreetly placed around the base of the bed and around the leather accent wall that holds the sizeable flatscreen TV. The chaise lounge, rug, unique light fixtures, and signature artwork by Namiko Kitaura grace the walls, the nature-inspired paneled mural above the bed evoking a sense of lightness and movement; signed art pieces significantly add to the clean lines and relaxed vibe. A nice nod to Japanese



culture, the room features a beautiful shoji sliding door into the spacious walk-in closet and shoji pocket doors on both ends of the handsome blackstone bathrooms, which feature double sinks, a bidet, a walk-in shower with rain-head, and soaking tub combined. As if the creature comforts, an iPad, Nespresso machine, Bose speakers, and electronic pad by your bedside to control shades and lighting aren't enough, custom cozy pajamas are provided during your visit—a room so comfortable. Frankly, I found it difficult to leave.

The redefinition of what an urban hotel can offer is brought to light by the Belgian-born/based in Malaysia Jean-Michel Gathy. The architectural and interior design firm DENNISTON specializes in top luxury brand hotels and resorts, and Gathy has the innovative vision of creating a new standard for urban accommodations. He is known for his signature room setups, legendary swimming pools, and some of the world's iconic designs. Gathy's innovative vision masterfully aligns modern aesthetics with classical Japanese decorative elements, creating a window into Japan's vibrant artistry.

The 39th floor was impressive by day; by night, the lights turned down, and the energy turned up. The Lounge showcases the sparkling colors of the vast city stretching as far as the eyes can see. A lone saxophone player drives the cool vibe, armed with a beat machine to accompany him; the soloist gives a jazzy version of Ne-Yo's "Because of You." As I make my way over to the Milanese restaurant PIGNETO, with the dining goal of encouraging one to "experience the joy of abbondanza" (a life of plenty.) After indulging in the Salsiccia Tagliatelle pasta dish and Margarita pizza, I have a mid-section of plenty! Maestro Pizzaiolo Alessandro De Leo is the resident specialty pizza chef; he brings his talent up close and personal in the open show kitchen. Raised in Naples, Italy, but sharing his craft in Tokyo at PIGNETO, "Pizza is a way of life in Napoli. We've perfected the art over centuries – it's in our blood. If you start making Pizza in Napoli, it means you want to be the best."

VIRTÙ is an award-winning bar in a glitzy passage just off the lobby if you want the best in spirits. Voted #20 on Asia's 50 Best Bars List 2023, head bartender Keith Motsi oversees the Paris-meets-Tokyo bar, ensuring every guest is having a memorable time, "At the end of the day, we are on stage. And every moment is showtime." It is showtime with the supreme selection of signature drinks surrounded by the gorgeous atmosphere from floor to ceiling, with aesthetic standouts being the kaleidoscope stained glass and checkerboard paneling. Tokyo-based Design Studio Spin receives the creative credit for creating not just the incredible vibe of VIRTÙ but also the distinct designs of PIGNETO and Michelin star 'est.' Whether you stop in for a unique cocktail, mocktail, or a late-night snack off the bar menu, the ambiance alone is worth your time, let alone the memorable mixology.

A bright, beautiful morning greets me, and the clear, cloudless sky brings a surprise gift: A view of snow-capped Mount Fuji. It's going to be a good day. My first stop is breakfast at PIGNETO, where I sit at my table overlooking, once again, a fantastic view of Tokyo. After remembering advice from someone in the States, I ordered a continental set and bakery selection. Before I traveled to Japan, I asked my friend, who was in tune with the culture, what I should be sure to do when I arrived. His answer: "Eat the baked goods. Especially the croissants." He explained that the Japanese take something good and perfect it. "The croissants in Japan are the best!" And that's quite a compliment from someone born/raised in France. The Japanese word Kodawari means the pursuit of perfection. It is persistence, passion, attention to detail, and commitment to perfection. So embedded in the Kodawari meaning is the knowledge that perfection cannot be attained. Yet you pursue it nonetheless. This discipline and drive for excellence is apparent throughout Japan, from its synchronized train system, spotless streets, and ethos to serve others. The country and its people have perfected its attempt at perfectionism (and the croissants are pretty perfect, too.)

The spa facilities at Four Seasons Otemachi are impressive, with 1900 square feet of Fitness Center and a 66-foot indoor heated pool, with a unique industrial design made of riveted steel that looks like an airplane's wings, once again, the unique vision of Jean-Michel Gathy. With abundant natural light from the floor-to-ceiling windows, floating on water is a whole new experience when you can look out and see the floating clouds 39 stories up. Enjoy the invigoration hydro-massage in the vitality pool, or relax in one of several cabanas and chaise lounges surrounding the pool deck. There are many options to disconnect from the busyness of life and explore the art of wellness.

Japanese proverb: Saigetsu hito o matazu

Translation: Time and tide wait for no man

Meaning: Time flows without regard for humans' convenience. There is no morning twice a day. Cherish each moment without wasting time. In other words, make each day count and use time wisely, as it's limited and never returns. As I sit, relaxed in the warm waters of the ofuro bath, alone in my thoughts as I look out the large windows, watching the Shinkansen train below weaving amongst the skyscrapers. At this moment, I reflect on where I am and how I will never pass this way again. How quickly my time in Japan has passed by, and how important it is to cherish each moment.

With a broad, warm smile, my massage therapist, Kazumi, escorts me into the Four Seasons Signature Well-being Ritual Yagusugi Forest Renewal treatment room. Located on the island of Yakushima, Yakusugi are Japanese cedars that have lived for a millennium or more. These long-lived trees, known for their miraculous ability to withstand the passage of time, have occupied a place of honor in Japanese culture for centuries. The Yakusugi inspire the wellness treatment that begins with the ringing of the Orin bell, commencing the positive energy. Yakusugi flour is used to exfoliate, followed by a deeply relaxing massage with Yakusigi oil; aroma and touch come together to create a state of transcendence. The ritual ends, and Kazumi offers my robe and invites me to sit and enjoy the tranquil tea service as my body soaks in a state of soul-deep restfulness. I will never pass this way again.

This travel editorial series, which I entitled "Where East Meets Best," chronicled my lux Four Seasons adventures in Japan.





As my visit ends, it's apropos that I save the best meal for last, which I thoroughly enjoyed at the Michelin-starred 'est.' The contemporary French-influenced, award-winning restaurant is the brainchild of Chef Guillaume Bracaval. Born in a tiny village in northern France, Chef Bracaval learned to respect the origins of ingredients while raised in his family's farm yard and vegetable gardens; also inspired by his deep love for produce from the Japanese terroir, the Chef and his skilled team source 95% of all products used from Japan's natural abundance. A map is presented at the table sharing specific regions and farms throughout the country, highlighting the sourcing partners across Japan that offer the highest quality of ingredients for the menu, even down to where the glassware, dishes, and cutlery were crafted. Reflecting Japan's microseasons, est tasting menus are well curated to accentuate the variety of ingredients used during their peak season. Even the name 'est,' an acronym, announces the three pillars of perfection: E: emotion, S: season, T: terroir. The delicate expression of cuisine, the emotion is from Chef Bracaval's deep respect for Japanese traditions, "...my team and I find endless inspiration in the relationships between people, nature, culture, family, customs, artisans, seasons and produce." He continues, "The link between my roots in France and my journey in Japan is constantly evolving. As I draw on both lands to craft our culinary offerings, my team brings together diverse influences into a harmonious whole."



I'm seated at a table next to a glass wall and a window to view the culinary craftsmanship. It is a show to behold. I'm mesmerized by the skills of the sous chefs, the attention to detail, and the timely orchestration. It is a gastronomy symphony! They bring out the freshly baked bread before it is sliced, explaining where it is sourced. The whole chicken is presented to me, sharing that it was sourced in Nagasaki before being taken back inside the kitchen and served on a plate. Each tasting portion of the Emotion luncheon is paired with a specific tea. To enhance the main course, the tea sommelier brings over a bottle of Irika Royal Blue Tea, bottled exclusively for the Four Seasons Hotel at Otemachi. The tea expert selected the Ruby Imperial to pair with the dessert portion of the sitting. Pastry Chef Michele Abbatemarco's artistic talents were developed in Michelin-star kitchens throughout Europe; he brings his skills to Japan and embraces the change in perspective that the country adds to his craft. "Tastes are like poems that speak to our palate, says Chef Abbatemarco, "Just like with art, we can experience emotions with a dish. If that feeling becomes a lasting memory, then my work is completed." The famous Vincent Van Gogh Sunflower painting inspired his poetry through pastry for my final course. A card with a picture of the painting is displayed just behind the delectable, sweet sunflower confection. A brief history of the post-impressionist painter is also on the card, and an invitation to enjoy the artistic dessert that expresses the "colorfulness and power" of the inspired artwork. Everything was perfect, from the seat assignment so I could view the talented team in action, the explanation of the courses, the fresh and colorful creations, the sophisticated atmosphere, and the sky-high vista; I could not imagine a more memorable note to end my journey on.

Japanese Proverb: Ichi-go Ichi-e

Translation: one opportunity, one encounter

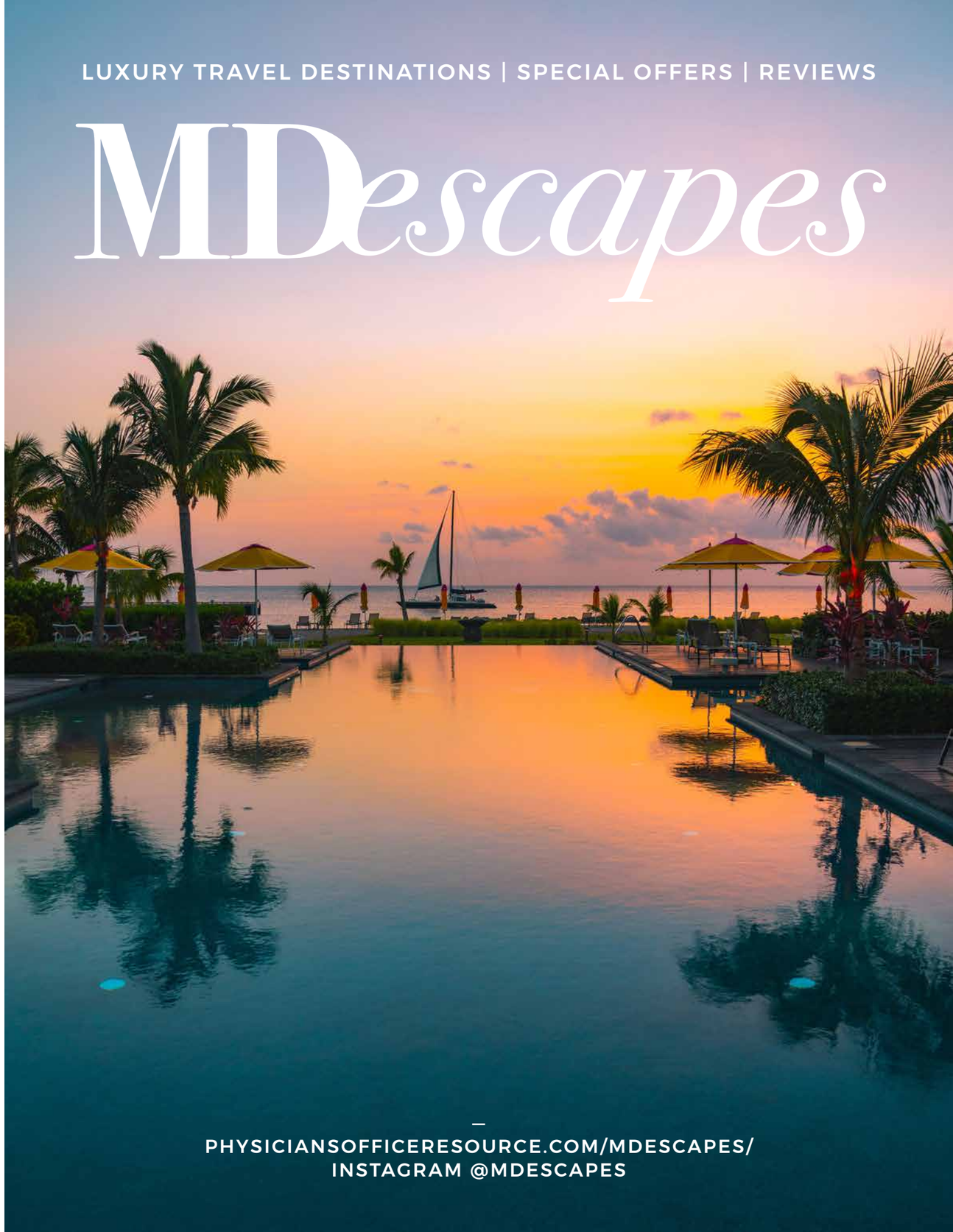
Meaning: treasuring the unrepeatable nature of a moment, for this time only, or once in a lifetime, to remind people to cherish any gathering they may participate in. This journey to Japan has been one opportunity, one encounter, a once-in-a-lifetime adventure I will always treasure.

As I look back on the three distinct visits, my very unique experiences, there is one thing that was a constant: the ethos of the Four Seasons brand and the work ethic of the Japanese culture. The word Isshoukenmei means "I will do this thing with all of my heart and all of my life," or in other words, I'll do my best. The Japanese "isshoukenmei" way of working with utmost effort is not unlike the Four Seasons' legacy of top-tier service. The culture of perfection with the Japanese people, having the attitude always to put forth your best effort, is rarely for individual gain but rather to improve the country. The country, culture, and people continue to amaze me.

As I descend the 39 floors and step off the elevator, walking out to the waiting car to drive me to the airport, I pass through the Torri gate archway, reminding me of the symbolism of this traditional entrance, the transition of the mundane into the sacred. Here I was, leaving the transportive tower and heading back to my reality, my mundane. The sky-high sanctuary of the Four Seasons Hotel Tokyo at Otemachi may be the closest thing to divinity.

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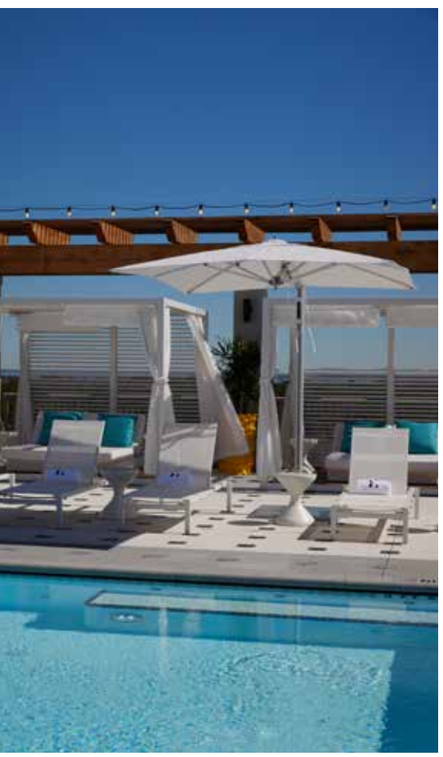
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