University HOSPITAL
Newark, NJ

Pharmacy News

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Special Points of Interest:

- P&T Update-Formulary Additions/Deletions
- Policy and Procedure Update
- The Role of a Diabetes Stewardship Pharmacist
- Dapagliflozin: The Recent Indication for Heart Failure With Reduced Ejection Fraction
- Duration of Dual Antiplatelet Therapy After Percutaneous Coronary Intervention Past One Year

P&T Update

Formulary Additions

1. ***Remdesivir (Veklury)***
   Discussed: FDA Approved for COVID-19
   - RCTs: ACT 1
     - Patients required supplemental oxygen
     - No mortality benefit
     - Mild-mod potential benefit, waiting for larger RCTs
     - Mixed data on eGFR < 30

   Motion to approve Remdesivir to formulary with Restriction to ID consult or stewardship team for approval no consult required, with 1 month follow up with P&T group – APPROVED

2. ***Cefiderocol (Fetroja)***
   - Discussed: An addition as part of a last line resort for any gram-negative resistant bacteria that may present.
   - Restricted to ID consult and the stewardship team
   - Limit use to gram-negative organism, carbapenem-resistant organism
   - Current hospital formulary for carbapenem-resistant organisms are: ceftazidime/avibactam and ceftolozane/tazobactam
   - Cefiderocol will be a last line option when these options can't be used.

   Motion to approve to formulary addition with restriction to ID and Stewardship team addition – APPROVED

2. ***Dapagliflozin (Farxiga)***
   - Discussed: Use of the SGLT2 class drugs as a potential to be part of hospital formulary due to its FDA approval for DM2 and Heart Failure patients.
   - If a patient is admitted to the hospital that was on a different SGLT2, it would be best to keep that patient on their own prescribed SGLT2 they brought with them from home.

   Motion to approve to hospital formulary addition – APPROVED

3. ***Tretinoin PO***
   - FDA Approved Indications: Acute promyelocytic leukemia (remission induction).

   Request for addition: Approved restricted to oncology services/ home medication. Restricted to second sign

Formulary Deletions

1. ***Benzocaine spray 20%***
   Pharmacy does not carry Benzocaine spray 20% due to unavailability. Request for deletion – APPROVED

2. ***Cardioplegia solution***
   Formulations not being used were recommended for UH Formulary deletion. Request for deletion – APPROVED
   Induction 4:1 High K (60 mEq) 830 mL
   Maintenance 4:1 Low K (36 mEq) Low Tromethamine 10

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P&T Update

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Formulary Line Extensions

Methacholine kit

Used in pulmonary field for the bronchial hyperreactivity testing, the usage is minimal (only 18 vials used last year).
Request for line extension Methacholine ready to use kit – APPROVED

Methacholine 100mg vial - Formulary deletion- Approved

Methylene Blue 0.5%

- 1% on backorder for years
- Recommend to line extend methylene blue 0.5% 10mL. Injection onto UH Formulary – Request for line extension – APPROVED

Policies & Procedures/Floor stocks

1. 707-500-124 (UH Hazardous Drug Management)
   Drugs classified as a hazardous drug under the NIOSH list will be added under the formulary list – APPROVED

2. B-1 Diet Manual Policy
   Food and Nutrition department submitted their policy to be approved by P&T. – APPROVED

3. Standard Concentrations for IV Infusion Medications
   Neonatal infusions were coming in bags instead of syringes, and not in neonatal specific concentrations – APPROVED

4. IV Medication Administration Guideline
   Updated changes are highlighted in red. This includes new formulary additions (i.e. ipilimumab, cefiderocol) as well as updates to previous medications (i.e. allowing ketamine infusions in the ED) – APPROVED

5. Refrigeration Policy
   Updated policy as it pertains to the process of COVID-19 vaccine storage including receiving, inventory, storing and handling, late stage return, and back up thermometer – APPROVED

Medication/Clinical Guidelines:

1. **Infectious Disease Guidelines**
   a. Skin and Soft Tissue Infectious Guideline
   b. Treatment of Systemic Fungal Infection Guideline
   c. Community Acquired Pneumonia and Healthcare-associated Pneumonia Guideline
   d. Hospital Acquired and Ventilator-Associated Pneumonia Guideline
   e. Clostridioides/Clostridium difficile Infection Guideline
   f. Fecal Microbiota Transplantation in Management of Clostridioides/Clostridium difficile Infection Guideline

Annual Review – APPROVED

The Role of a Diabetes Stewardship Pharmacist

Diabetes is classified by the CDC as a pandemic. Based on the 2020 national diabetes statistic report, there are roughly 34.2 million people that have diabetes in the United States which makes roughly 10.5% of the total population[1]. Hyper and hypoglycemia occurrences can adversely impact the outcome of hospitalized patients including increased hospital length of stay, increased healthcare expenditure as well as higher mortality rate[2]. Pharmacist stewardship has been proven to be successful for providing optimal patient care, enhancing medication use safety as well as promoting cost effectiveness. In addition, professional organizations have endorsed pharmacist involvement in the management of glycemic control. The diabetes stewardship pharmacist fosters long term relationships, promotes health, and works across disciplines to safely and effectively manage glycemic control issues.

A diabetes stewardship pharmacist program initiated by the University of Nebraska Medical Center (UNMC) has demonstrated vast improvements in patient safety, cost avoidance and clinical efficacy outcomes. The diabetes stewardship pharmacist then works collaboratively with the interdisciplinary team to improve glycemic control and provides services including but not limited to developing institutional policies, order sets, serving as co-chair on the Glucose Management Team (GMT), monitoring and making timely interventions. During this program, the University of Nebraska Medical Center (UNMC) experienced a roughly 65% reduction in hypoglycemia rate in critical care units and roughly 50% reduction in non-critical care units from January 2015 to June 2020. This translates to an estimated cumulative length of stay of 0.46 days and greater than $690,000 in cost avoidance annually with an additional $150,000 in cost savings from formulary management strategies according to Jon Knezevich, the hospital's diabetes stewardship pharmacist[3].

One of the biggest challenges at the initiation of the program was to quickly and correctly identify and intervene in real time when patients experienced fluctuation in blood sugar. The diabetes stewardship pharmacist worked with the IT department to develop a new system. In particular it stressed the importance of centralized monitoring. The program utilized an electronic, glycemic focused, patient-specific dashboard that serves as a surveillance tool with up to date blood glucose variations[3].

In addition, the diabetes stewardship pharmacist also developed an acute glycemic management credentialing competency which provides review of organizational policies, protocols and workflows, guidance with transition of non formulary agents as well as offering recommendations for dealing with special populations to nurses and inpatient pharmacists. The nursing audits captured a 178% improvement in the percentage of education provided to eligible inpatients after the initiation of the module.

In conclusion, a diabetes stewardship pharmacist can improve institutional policies and protocols, make timely interventions which leads to improvement in patient clinical efficacy outcomes, patient safety and cost savings. Although such a program is not as widely used today, UNMC has demonstrated significant

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The Role of a Diabetes Stewardship Pharmacist

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improvement in patient outcomes as well as cost avoidance. In addition, such a program is easily adoptable by University Hospital with the resources available. With the increasing need to serve the growing diabetic population, a diabetes stewardship pharmacist can serve as a leader to make a difference and improve patient health[3,4].

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Dapagliflozin: The Recent Indication for Heart Failure With Reduced Ejection Fraction

Heart failure is becoming more and more prevalent. It is estimated that 6.2 million Americans over the age of 20 had heart failure from 2013 to 2016. While 5.7 million Americans had heart failure from 2009 to 2012. Approximately half of all hospitalized heart failure is characterized by a reduced (systolic) ejection fraction and half by a preserved (diastolic) ejection fraction.[3] Common heart failure symptoms include shortness of breath during day to day activities, trouble breathing while lying down, and weight gain and swelling in the feet, legs, or ankles.

Dapagliflozin, a sodium-glucose transporter 2 inhibitor that blocks glucose reabsorption in the proximal tubule of the kidney and promotes glucosuria, has historically been used for type II diabetes.[4] Through multiple clinical trials, SGLT2 inhibitors have demonstrated favorable cardiovascular effects, including a reduction in the risk of hospitalization for heart failure. Thus, after the DAPA-HF trial dapagliflozin has been shown to decrease hospitalizations and death from cardiovascular causes in patient with and without type II diabetes. In May 2020, the Food and Drug Administration approved dapagliflozin, based on the finding from the DAPA-HF trial, for the new indication of heart failure with a reduced ejection fraction to reduce the risk of cardiovascular death and hospitalization for patients with heart failure.

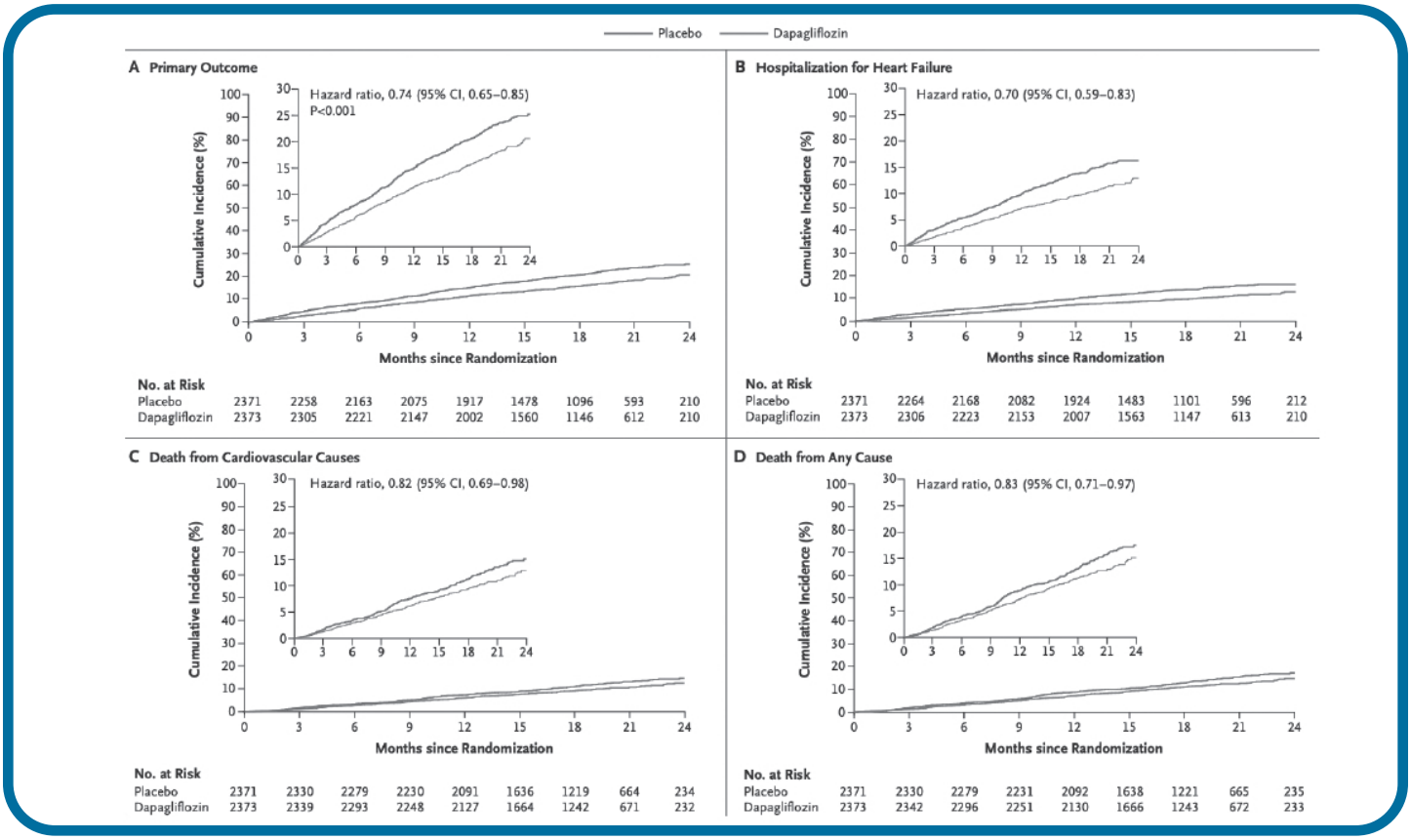
Dapagliflozin in Patients with Heart Failure and Reduced Ejection Fraction Trial[1]

- Placebo-controlled, phase III trial
- Randomly assigned heart failure patients with New York Heart Association class II, III, or IV and a reduced ejection fraction of 40% or less to receive either dapagliflozin (10mg once daily) or placebo, plus the recommended standard of care
- Inclusion Criteria[1]
- Plasma level of N-terminal pro–B-type natriuretic peptide (NT-proBNP) of at least 600 pg per milliliter (or ≥400 pg per milliliter if they had been hospitalized for heart failure within the previous 12 months)
- Patients with atrial fibrillation or atrial flutter on baseline electrocardiogram were required to have an NT-proBNP level of at least 900 pg per milliliter
- Required to receive standard heart failure device therapy (an implantable cardioverter–defibrillator, cardiac resynchronization therapy, or both) and standard drug therapy, including an angiotensin-converting–enzyme inhibitor, an angiotensin-receptor blocker, or sacubitril–valsartan plus a beta-blocker
- Patients with type 2 diabetes continue to take their glucose-lowering therapies, but doses could be adjusted as required

Patients were randomly assigned to receive either dapagliflozin (at a dose of 10 mg once daily) or matching placebo, in accordance with the sequestered, fixed-randomization schedule, with the use of balanced blocks to ensure an approximate 1:1 ratio of the two regimens. Then, the patients were evaluated at 14 days and 60 days post randomization. More evaluations continued at 4 months and at 4-month intervals thereafter.[1]

The primary outcome included worsening heart failure or death from cardiovascular causes. Worsening heart failure would include an unplanned hospitalization or urgent care visit leading to the initiation of IV therapy to treat the heart failure symptoms. The secondary outcomes included total number of hospitalizations for heart failure and cardiovascular deaths, change from baseline to 8 months in the total symptom score on the Kansas City Cardiomyopathy Questionnaire, worsening renal failure defined as an eGFR of 50% or greater, end-stage renal disease, and death from any cause.[1]

The results were obtained from February 2017 to August 2018 with a total of 4744 patients assigned to either arm. When screening, 42% of patients in each arm had type II diabetes and an additional 3% received a new diagnosis of diabetes. The primary outcome of worsening heart failure or death from cardiovascular causes occurred in 386 patients or 16.3% in the dapagliflozin group and 502 patients or 21.2% in the placebo group. In addition, 231 or 9.7% of patients were hospitalized for heart failure in the dapagliflozin arm and 318 or 13.4% of patients in the placebo arm. There were 567 total first and recurrent events (340 hospitalizations for heart failure and 227 deaths from cardiovascular causes in 382 patients) in the dapagliflozin group and 742 total events (469 hospitalizations for heart failure and 273 deaths from cardiovascular causes in 495 patients) in the placebo group. The increase in the total symptom score on the Kansas City Cardiomyopathy Questionnaire (indicating fewer symptoms) was greater in the dapagliflozin group than in the placebo group between baseline and month 8.[1]



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Dapagliflozin: The Recent Indication for Heart Failure With Reduced Ejection Fraction

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The Future

There are many medications in the class of sodium-glucose transport 2 inhibitors that are in ongoing trials for various cardiovascular indications. Empagliflozin is one of the SGLT-2 inhibitors being studied for its positive cardiovascular effects for treatment of heart failure with a reduced ejection fraction less than 40%. The trial evaluated the primary outcome event (a composite of cardiovascular death or hospitalization for worsening heart failure) which occurred in 361 of 1863 patients (19.4%) in the empagliflozin group and in 462 of 1867 patients (24.7%) in the placebo group (hazard ratio for cardiovascular death or hospitalization for heart failure, 0.75; 95% confidence interval [CI], 0.65 to 0.86; P<0.001). The result of the EMPEROR-Reduced trial showed empagliflozin is superior to placebo in improving heart failure with patients on already guideline-directed medical therapy, regardless of a diabetes diagnosis. This trial was recently published in The New England Journal of Medicine in October 2020, thus the future is bright for patients with HFrEF.[2]

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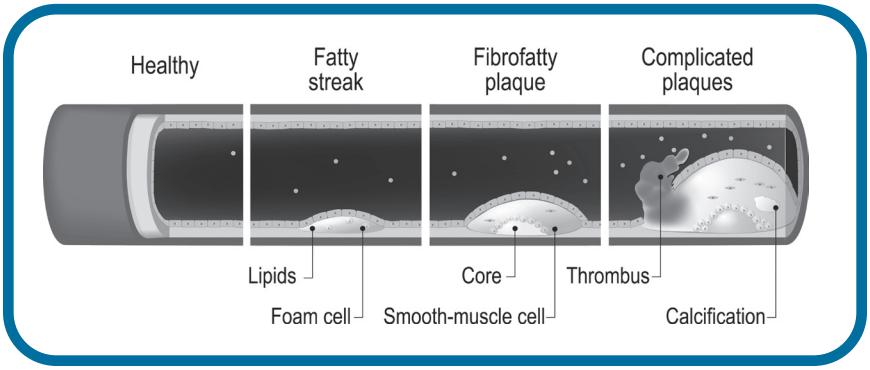
Duration of Dual Antiplatelet Therapy After Percutaneous Coronary Intervention Past One Year

Coronary artery disease (CAD) is the narrowing or blockage of the coronary arteries that carries blood to the heart. This is caused by atherosclerotic plaques building up inside arteries leading to clogging or damage of the arteries, eventually diminishing myocardial blood flow otherwise known as Ischemia.[1] Ischemia is an imbalance of oxygen supply and demand translating to chest pain in patients. When these atherosclerotic plaques rupture, clot forms and is now described as acute coronary syndrome (ACS).[1]

ACS contains three types of CAD that are associated with sudden rupture of plaque inside the coronary arteries known as unstable angina, NSTEMI, and STEMI. An ECG and cardiac biomarkers like troponin and CK-MB are obtained to helps diagnose the different types of ACS.[1] For treatment, thrombolysis in myocardial infarction (TIMI) scores are utilized to calculate the risk of death along with cardiac events and help select the site of care such as the need for Ischemia guided medical management versus invasive strategies such as Percutaneous coronary intervention (PCI) with medical treatment or Coronary artery bypass graft (CABG) with medical treatment.[1]



A PCI is a procedure that uses a catheter to place a stent to open the blood vessels in the heart that have been narrowed as a result of atherosclerosis. There are two types of stents placed, known as bare metal stent (BMS) and drug eluting stent (DES). The treatment used for ischemia guided medical management consists of dual antiplatelet therapy (DAPT), Beta blockers, ACE/ARB, Statins, and parenteral anticoagulants. P2Y12

inhibitors can be used in patients managed with PCI or ischemia-guided strategies and depending on the stent it can be used 30 days for BMS or 12 months for DES.[1] DAPT with aspirin and P2Y12 inhibitors are the standard of care after PCI with DES to mitigate risk of stent-related ischemic events.

Journal of the American College of Cardiology (JACC) guidelines evaluate the use of DAPT > 1 year. The guidelines specifically address the use of DAPT in patients with NSTEMI or STEMI that have received PCI. The guidelines recommend that all ACS patients treated with stent implantation and have tolerated DAPT without any bleeding complications may continue DAPT for longer than 12 months.[1] This recommendation is based on several clinical trials which found a benefit in mortality when continued DAPT versus the initial guideline recommendation for minimum of 1 year.

Wang and colleagues[2] observed benefits and risk when continuing DAPT for more than 1 year. Published in 2020, this study included a total of 4,578 patients who underwent a PCI after (NSTEMI or STEMI) and are going to be placed on DAPT. Patients were split into two groups based on duration of DAPT (Aspirin + Clopidogrel) use, which were DAPT > 1-year and DAPT ≤ 1-year. The trial's primary efficacy endpoints were observation of major adverse cardiac and cerebrovascular events (MACCE) such as all-cause death, MI, or stroke occurred.[2] The primary safety endpoint was clinically relevant bleeding occurrence defined by Bleeding Academic Research Consortium (BARC) classification with prolonged DAPT use.[2] The results demonstrated that the risk of MACCE is significantly lower in the DAPT > 1 year group versus guideline treatment group (1.9% vs. 4.6%; hazard ratio (HR) adj, 0.394; 95% CI, 0.275–0.565; P < 0.001).[2] In terms of safety endpoints, the risk of BARC type 2,3, or 5 bleeding occurred more in the DAPT > 1-year group but was not significantly increased versus guideline therapy group (1.1% vs. 0.9%; HR adj, 1.106; 95% CI, 0.575–2.130; P = 0.763).[2]

The evidence from this trial concluded that prolonged DAPT provides more effective protection against atherothrombotic events, including cardiac death but is counterbalanced by an increased risk of bleed.[2] However, the type of bleeding event did not significantly increase.

The Benefit-Risk Profile of DAPT Continuation Beyond 1 year after PCI according to the Wang and colleagues [2] and JACC guidelines suggest that the use of DAPT may be continued for longer than 12 months if patients have tolerated therapy without any bleeding complications because there may be a benefit of decreasing a MACCE event and all-cause of death.[1,2] In both the trial and the guidelines, they concluded that if a patient is high risk of bleeding or cannot tolerate DAPT due to a bleeding event, it is safer to discontinue DAPT past 12 months.[1,2] If the recommendation is to continue past 12 months, you must weigh the risk versus benefit, and both references have stated that if you can tolerate it, and do not have high risk of bleed, you may continue DAPT past 12 months. Some examples of high risk of bleeding include history of stroke, TIA, on concurrent anticoagulant therapy, history of major surgery, or diabetes.[2]

All ACS patients treated with stent have tolerated DAPT without any bleeding complications, and are not high-risk candidates for bleeding, and therefore may continue DAPT for longer than 12 months. The reason for this is because there is a benefit in reduction of atherothrombotic events, including cardiac death when continuing DAPT for more than 12 months.

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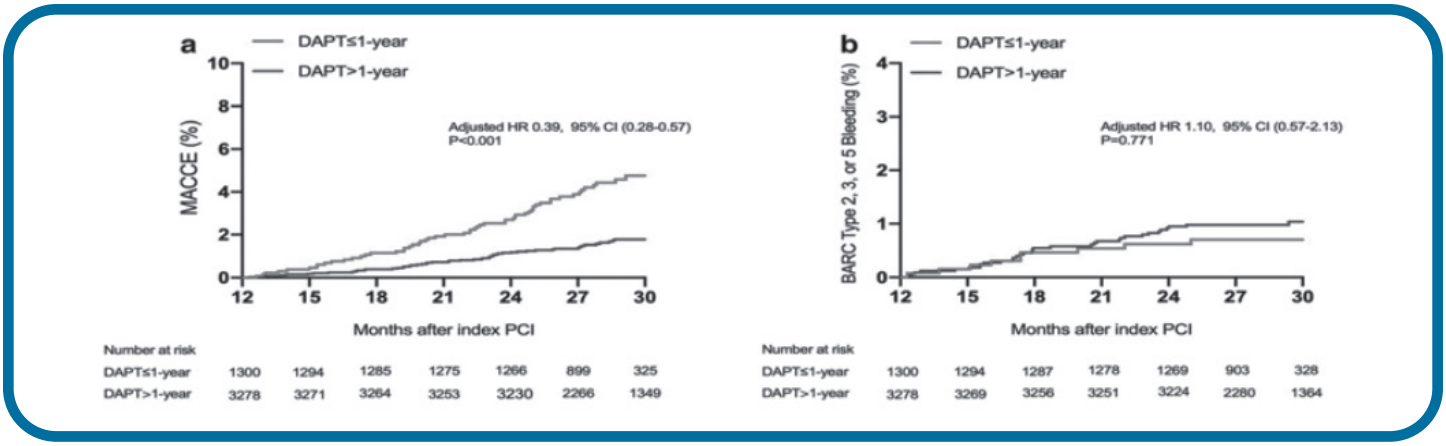

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Covid-19 Vaccines

	Pfizer/BioNTech[4]	Moderna[5]	Johnson & Johnson[6]
Type of Vaccine:	mRNA in lipid nanoparticles	mRNA in lipid nanoparticles	Non-replicating adenovirus vector
Number of doses	Two-dose series	Two-dose series	One-dose Vaccine
2nd dose taken after:	21 days	28 days	N/A
Efficacy:	96%	94.5%	75%
Age qualifications:	16 years or older	18 years or older	18 years or older
Route of Administration:	Intramuscular	Intramuscular	Intramuscular
Dosing Administration:	0.3 ml Injection (**Each**)	0.5 ml Injection (**Each**)	0.5ml Injection (**Once**)
Dosages Per Vial:	6 doses per vial	10 doses per vial	5 doses per vial
Storage Conditions (UNPUNCTURED VIAL):	• Ultra low Temp freezer until expired [-80ºC to -60ºC (-112ºF to -76ºF)] • Freezer Temp for up to 2 weeks max [-25°C to -15°C (-13°F to 5°F)] • Refrigerator Temp for up to 5 days [2ºC to 8ºC (35ºF to 46ºF)]	• Freezer Temp until expired [-25º to -15ºC (-13º to 5ºF)] • Refrigerator Temp for up to 30 days [2° to 8°C (36° to 46°F)] • Room Temp for up to 12 hours [8° to 25°C (46° to 77°F)]	• Refrigerator storage until expired [2°C to 8°C (36°F to 46°F)] • Room Temp for a max of 12 hours [9°C to 25°C (47°F to 77°F)]
Storage Conditions (PUNCTURED VIAL):	• After dilution storage temp [2°C to 25°C (35°F to 77°F)] • Use within 6 hours from time of dilution	• Refrigerator and room tempt you must discard after 6 hours [2° to 25°C (36° to 77°F).]	• Refrigerator for up to 6 hours [2°-8°C (36°-46°F)] • Room Temp for a max of 2 hours [Max 25°C or 77°F]
Clinical Pearls:	• During storage minimize exposure to room light, sunlight, ultraviolet light. • Any vaccine remaining in vials after dilution must be discarded after 6 hours	• Discard vial after 6 hours • Vaccine is a white to off-white suspension • Do not administer if vaccine is discolored or contains other particulate matter	• Vaccine is a colorless to slightly yellow, clear to very opalescent suspension • Discard 6 hours after refrigeration or 2 hours after room temperature

After the World Health Organization declared COVID-19 (SARS-COV-2 virus) a global pandemic on March 11, 2020, life as we knew it changed drastically, and millions went into lockdown[1]. As surges have flared up since then, much of the world has had to deal with masks, distancing, hand hygiene, and lockdown periods. The death toll from COVID-19 infection has been devastating, as have the economic and mental health consequences of the shutdowns. The need for a long-term solution, such as safe and reliable vaccines, has never been greater[1].

Vaccines are among the most efficient tools for promoting individual and public health. Vaccines stimulate your body's natural defenses to create immunity, and lower your risk of contracting the disease. All three vaccines received Emergency Use Authorization (EUA) for use in the USA. EUA is a mechanism to facilitate the availability and use of medical remedies, such as vaccines, during public health emergencies like the pandemic.

COVID-19[7]. The Pfizer and Moderna vaccines are made using messenger RNA (mRNA), a technology that delivers a bit of the genetic code into the cells. This is all in efforts to make surface proteins, known as spike proteins, on the SARS-2 virus. These proteins are then instructed by our bodies to see spike proteins as foreign objects and develop antibodies against it[4,5]. The J&J vaccine uses a different approach called viral vectored vaccines. They store gene coding in a double stranded DNA inside an Adenovirus. This will evidently build spike proteins that will provoke the immune system to react[6].

In the United States, the COVID-19 pandemic death toll has surpassed 500,000 deaths. Without vaccines, masks, social distancing, and hand hygiene, the numbers will continue to rise[4]. In the United States and other countries, a range of vaccines that have shown to be particularly successful in preventing symptomatic COVID-19 in clinical trials are currently being used. Those vaccines are listed in the table above.

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