Pharmacy News

UNIVERSITY HOSPITAL
Newark, New Jersey

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Special Points of Interest:

- P&T Update-Formulary Additions/ Deletions
- Policy and Procedure Update
- CAR-T Cell Therapy
- Artificial Intelligence in Healthcare
- Vitamin D supplementation: Does it help to reduce risk of diabetes?
- The Dangers of Vaping and E-Cigarettes

P&T Update

Formulary Additions

- **Degarelix (Firmagon®) Formulary addition request**
  Degarelix is a gonadotropin-releasing hormone (GnRH) antagonist which reversibly binds to GnRH receptors in the anterior pituitary gland, blocking the receptor and decreasing secretion of luteinizing hormone (LH) and follicle stimulation hormone (FSH), resulting in rapid androgen deprivation by decreasing testosterone production, thereby its level. Testosterone levels do not exhibit an initial surge, or flare, as is typical with GnRH agonists.

  Degarelix is FDA approved for metastatic Prostate Cancer - Degarelix Formulary Addition- Approved with restriction to oncologists only.

- **Brentuximab vedotin (Adcetris®) Formulary addition request**
  Brentuximab is an antibody-drug conjugate directed at CD30 consisting of 3 components. The conjugate binds to cells which express CD30, and forms a complex which is internalized within the cell and releases monomethylaruistatin E (MMAE). MMAE binds to the tubules and disrupts the cellular microtubules network, including cell cycle arrest (G2/M phase) and apoptosis.
  Brentuximab is FDA approved for refractory Hodgkin lymphoma and non-Hodgkin lymphomas. – Formulary Addition- Approved with restriction to hematologist/ oncologist only.

Line Extension:

Del Nido cardioplegia solution
Formulary Addition- Approved.

Formulary Deletions

Gentamicin 120mg/100mL NS

- Request for removal due to low usage; Formulary Deletion-Approved
- Reperfusate and Warm induction cardioplegia solutions Formulary Deletion- Approved

Policies & Procedures/Floorstocks

707-1400-115 Baseline and Ongoing Lab requirements during anticoagulation Therapy – Approved
Functional or Anatomical Asplenic Adult Patient (Greater than 18 years of age
Vaccine guideline – Approved
831-200-668 Warfarin Dosing Guideline for Adults – Approved

(Continued on page 2)

P&T Updates
(Continued from page 1)

HEPARIN INDUCED THROMBOCYTOPENIA (HIT or HITTS) GUIDELINE – Approved
707-600-180 Sentry Data Systems the operation of its 340B – Approved
707-600-180A 340B University Hospital policy – Approved
707-600-180B 340B University Hospital Contract Pharmacy policy – Approved
707-700-150A Intravenous Medication Administration Guideline revision
Revised guideline to update additions and deletions of UH Formulary was presented – Approved
UH Guideline For Treating Systemic Fungal Infections In Adults
Newly created guideline approved by Anti-infective subcommittee was presented for approval – Approved
University Hospital Guideline for Treating Skin and Soft Tissue Infections in Adults
Newly created guideline approved by Anti-infective subcommittee was presented for approval – Approved

Formulary Addition of Medications at University Hospital

1) Any member of the medical, dental, PCS and pharmacy staff may initiate a request to add medications to the hospital formulary by submitting a request to the P&T (Pharmacy and Therapeutics) committee.

2) The P&T committee meetings are held every 3rd Wednesday of the month except in August when there is no meeting.

3) All requests for addition of medications to the formulary must be submitted in writing on the Formulary Addition Request Form. Forms are also available from the hospital pharmacy or http://pharmacy.uh.uhnj.org/.

4) The formulary addition request form must be TYPED and 3 supporting primary articles must be attached. The form must be endorsed by the department or division head, and signed/supported by two professional colleagues/ healthcare providers. The P&T committee will not honor the form which is prepared by the pharmaceutical sales representative.

5) The requestor must submit the formulary addition request 6 weeks prior to the next P&T meeting.

6) The request is reviewed by the Secretary of the P&T Committee or the clinical pharmacy department for completeness prior to being submitted to the P&T committee.

7) The P&T committee only reviews up to 2 full formulary addition requests per meeting. Any additional requests are pended for the subsequent meeting on a first come first serve basis.

8) Once the request is deemed complete, the clinical pharmacy reviewer includes it on the next P&T meeting agenda. The clinical pharmacy reviewer also prepares the medication monograph and submits the information to the committee members in advance for review through the P&T meeting packet. The information may include primary studies evaluation, pharmaco-economic analysis, cost/reimbursement data, medical letter, procurement/storage/dispensation logistics, listserve surveys, miniFMEAs (failure mode and effects analysis) and other pertinent information as applicable.

9) Multiple P&T committee members are also assigned as the comprehensive reviewers for the formulary addition request and present their input to the committee during the meeting.

10) The P&T committee performs a thorough assessment of the clinical data, safety/efficacy, primary literature, procurement/dispensing/restriction logistics, pharmaco-economic impact and patient needs at the meeting. The committee members then vote to reach a final decision to either approve (including approval with restrictions or conditional approval) or deny the formulary addition request.

11) The requestor is communicated of the decision taken by the P&T committee after the meeting. Further information may be requested from the requestor if deemed necessary and the requestor may be asked to be present at the next meeting. Requestors are not permitted to be at the meeting unless specifically notified.

12) If the request is not deemed appropriate for the formulary addition by the committee, the requestor must wait for a minimum of 1 year for the reapplication of the same formulary addition request.

13) If the formulary addition request is approved, the pharmacy IST personnel initiates a request to start the Epic build of the new medication and the pharmacy purchasing supervisor is informed.

14) The formulary addition is formally/finally approved as an action item by the Medical Executive Committee (MEC) usually two months after the P&T meeting and becomes available for ordering by the prescribers.

15) The Pharmacy Department periodically reviews the formulary items and

recommends formulary changes to the P&T committee.

DEFINITIONS:

A) Formulary Item: A therapeutic or diagnostic agent recommended as essential for patient care, one whose place in therapy is well established. Such an item is listed in the Hospital Formulary and stocked in the Hospital Pharmacy. The list of approved formulary items is available from the Hospital Pharmacy. It is also available on the website: http://pharmacy.uh.uhnj.org/

D) Non-Formulary Items: Any commercially available therapeutic or diagnostic agent other than those classified as a formulary item or investigational drug or any brand of a formulary item not in stock at the time requested. Items in this category are not stocked in the Hospital Pharmacy but will be obtained by the Pharmacy upon receipt/review/approval of a completed non formulary medication section in Epic specifically for the patient for whom the item was requested.

Weblinks:
Formulary Addition Request Form-
http://pharmacy.uh.uhnj.org

Hospital Formulary Policy 707-300-101-
https://universityhospital.ellucid.com/documents/view/901

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(Continued on page 4)

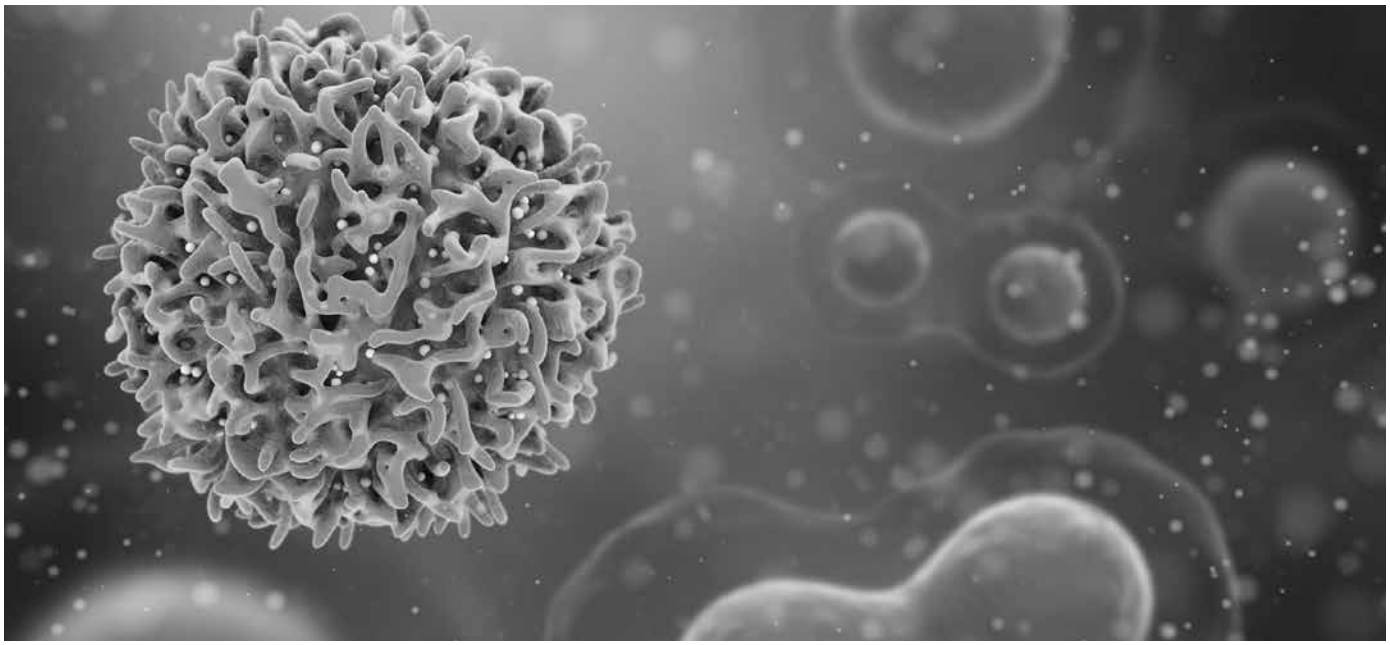
CAR-T Cell Therapy

The landscape of cancer immunotherapy has been rapidly changing in recent years to include new strategies that improve the prognosis and quality of life for cancer patients. One rapidly emerging approach is adoptive cell transfer (ACT), which involves collecting a patient's own immune cells to treat his/her cancer[1]. A major breakthrough in cancer immunotherapy is the recent approval of a targeted approach that involves the genetic modification of a patient's own immune cells that allows the cells to find and attack cancer cells throughout the body[2]. This technique is known as chimeric antigen receptor (CAR) T cell therapy. The process involves collecting a person's T cells via apheresis, a process that withdraws blood from the body and removes blood components such as T cells, and genetic modification of the T cells so they can target cancer cells. A sample of a patient's T cells are collected from the blood and modified to produce special structures called chimeric antigen receptors (CARs) on the surface. These genetically modified CAR-T cells are expanded in the laboratory over a few weeks. While the CAR-T cells are expanding, patients may receive chemotherapy as a conditioning therapy to help create space in the immune system for the infused CAR-T cells to expand and proliferate[3]. The modified T cells are then re-infused back into the patient's bloodstream as a single infusion. When the CAR-T cells are infused into the patient, the new receptors enable them to identify and latch onto a specific antigen on the patient's tumor cells and kill them[3].

CAR-T cell therapy serves as a bridge to connect genetically modified T cells to the surface antigens of targeted tumor cells. This modification intensifies the immune system's natural response to cancer, in which T cells hunt down and destroy abnormal cells, including cancer cells. Since these are living cells, they will continue to multiply in the body and thus, only need to be injected once. In fact, the effectiveness of these CAR-T cells may actually increase with time as the cells proliferate and expand[2].

FDA-Approved Indications

CAR-T cell therapy has demonstrated success in treating cases of childhood acute lymphoblastic leukemia (ALL), Non-Hodgkin lymphoma (NHL), and multiple myeloma (MM). So far, two CAR-T cell drugs, Kymriah (tisagenlecleucel) and Yescarta (axisabtagene ciloleucel), have been approved by the FDA, both of which target CD19, an antigen that is commonly overexpressed in B cell hematologic and other malignancies. CD-



CAR-T Cell Therapy

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19-directed genetically modified autologous T cell immunotherapy identifies human cells that are modified by a lentivirus, and eliminates CD-19 expressing cells via T cell signal transduction.

Risks/Side Effects

This powerful new treatment approach comes with serious risks and side effects. Cytokine release syndrome (CRS) is a potentially life-threatening reaction that is triggered when the CAR-T cells initiate a massive release of inflammatory molecules called cytokines; this results in symptoms that may be flu-like, with high fever and/or chills, low blood pressure, confusion, and difficulty breathing. This can be remedied by the FDA-approved tocilizumab (Actemra)[2]. Neurologic problems may also result from CAR T-cell therapy. These may manifest as stupor, delirium, hallucinations, seizures, and coma. Though these problems are often self-limiting and go away on their own, some patients have died from these adverse drug reactions[2].

The risk/recovery period following CAR T-cell therapy is usually approximately 2-3 months. During this time, the patient must be monitored for side effects and treatment response[3]. The FDA requires patients treated with CAR T-cell therapy to remain near the cancer center for follow-up care during the initial 30-day acute recovery period.

Limitations

The applicability of immunotherapy products is limited by logistic and financial barriers. Due to the highly specialized, highly personalized nature of this treatment, CAR T-cell therapy is available at a limited number of cancer centers with specialized expertise in cellular therapies[3]. The FDA-approved labelling states that currently CAR T-cell therapy is available only through a restricted REMS program at REMS participating sites. The process involved in CAR T-cell therapy typically takes 17 to 22 days. During this time period, the patient may have active cancer and might become too sick to get the CAR T cells while waiting. In addition, the patients may have been heavily treated previously with other anti-cancer agents, which affects the health of their T cells that are the starting material for CAR manufacturing. The cost of this procedure comes at a significant cost for the single dose. Health insurers are currently reviewing coverage on a case-by-case basis as they prepare their coverage policies for the FDA-approved therapies[3]. Currently, these therapies are priced at a 1-time cost of $475,000 for B-ALL and $373,000 for B-NHL[5].

Future Directions

With its demonstrated success in treating hematologic cancers, CAR-T cell therapy is currently being explored in the treatment of solid tumors[3]. A number of clinical trials are in early stages for pancreatic cancer, mesothelioma, lung cancer, and breast cancer, among others. The in-vivo immunologic effects and treatment durability are under continued investigation.

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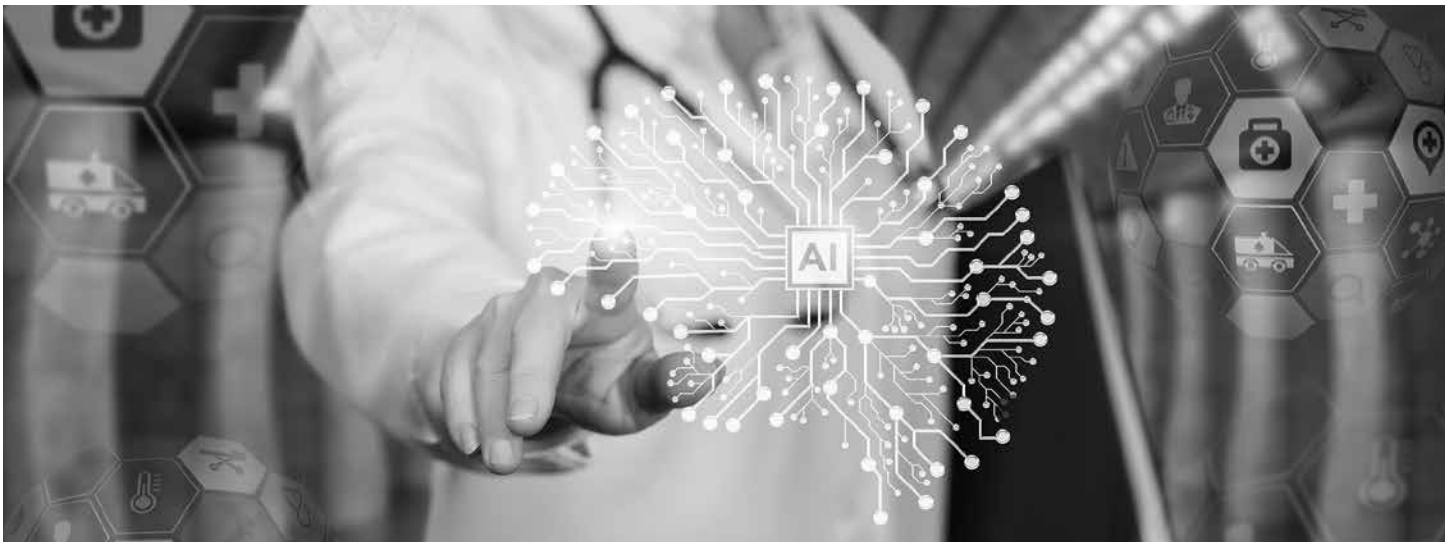
Artificial Intelligence in Healthcare



Due to increasing demands of healthcare and high-costs, artificial intelligence (AI) has gained increasing interest in the healthcare field with promising outcomes. Artificial intelligence merges technology with the human mind, creating algorithms and analytic datasets for rapid medical applications. Robot-assisted surgery, automated image diagnoses, cyber-security, and administrative workflow assistance through AI are becoming prevalent in hospitals to curate efficiency, accessibility, quality and improved patient outcomes.

The current impact of AI commonly seen is electronic health records (EHR's) that have been revolutionized by AI to be extensive, searchable databases. EHR's data consolidate large volumes of patient data that can assist in analyzing health trends, making personalized recommendations, and identifying patients at risk before symptoms arise.

Artificial intelligence systems can be programmed through inputting data that is clinically based such as screening, diagnosis treatment, etc. in order to be able to learn the different groups of subjects and the outcomes. These can make the diagnosis of Artificial Intelligence more accurate. Artificial Intelligence includes two major categories such as machine learning (ML) and natural learning processing (NLP). ML analyzes data such as imaging. It predicts the probability outcome of the disease. The NLP takes information from clinical notes or journals which are used to enhance the structured medical data that is already present. The NLP takes these texts and transforms them into a way in which it can be read by the machine so that it can be analyzed by ML.

ML can be divided into two categories which are unsupervised and supervised learning. Unsupervised is for feature extraction while supervised learning is for predictions based on a relationship between patient traits and the outcome of interest. NLP, on the other hand is more focused on physical examination, clinical lab reports, etc. so that it can be able to help with clinical decision making through these texts. This is very helpful because it alerts treatment arrangements, monitors adverse effects of the medication and more.

To lessen physician burnout impacting patient care, these technologies can decrease time physicians spend on the computer documenting or searching for electronic healthcare records and devote that time towards the patients. Often times, feeling overworked causes physicians to be prone to errors that lead to adverse drug events. AI can potentially decrease such errors by creating a more time-efficient and standardized system that detects errors and prevents mistakes.

According to artificial intelligence in healthcare, there are a few disease types that artificial intelligence is focused on such as cancer, neurology and cardiology. In cancer, Artificial intelligence focuses on diagnosis of cancer through a double-blinded study and it can use clinical images to be able to identify cancer subtypes. Similarly, dermatologic photos can be taken of a patient's skin to predict the diagnosis and potential treatments.

In Neurology, there is an artificial intelligence system that is developed to help restore the ability to control movement for patients with quadriplegia which is a spinal cord injury that can cause partial or complete paralysis of both arms and legs. In cardiology, artificial intelligence can help with diagnosing heart disease through cardiac imaging. In cardiology, softwares are being created that interpret electrocardiograms, detect arrhythmias and screen for heart murmurs in children. Therefore, minimizing errors in diagnosis and properly treating patients

One example of artificial intelligences impact in the hospital setting is for stroke care. For diagnosis, neuroimaging data from MRI and CT scans can be processed by the computer for analysis and diagnosis. For treating stroke patients, another study used support vector machine (SVM) to determine the appropriate stroke treatment with intravenous thrombolysis based on patient characteristics, bleeding risk, and treatment efficacy. SVM's are a type of artificial intelligence that analyzes data inputted by classifying into subgroups and performing a regression analysis. These algorithms predicted stroke mortality at discharge with 70% accuracy.

The cost of health care will be another major driver in the application of AI in medicine. AI applications will be utilized to reduce unnecessary testing, decrease the disparity and discrepancies in care throughout the United States and the rest of the world, and reduce hospital admissions and length of stay. On the other hand, implementing these programs to hospitals while also training staff poses a high initial financial investment for each hospital. The complex algorithms and softwares will require extensive training before being implemented and the new applications may also face reluctance from staff who wish to continue to do things traditionally. It is also important to consider concerns of safety and security of data. As technology and algorithms become more complex, the responsibility of protecting patient data and avoiding security breaches need to be addressed

While artificial intelligence in the hospital setting has many promising avenues, it is crucial to be aware of its disadvantages. Transitioning to electronic medical records and the ease of accessing patient data has increased demands on health care providers for faster and better diagnosis and treatments. Unfortunately, the overload of work has seen to provide greater risk for diagnostic and therapeutic errors. With AI, physicians will have the opportunity to reduce errors and increase efficiency and quality of care. However, it is important to note that artificial intelligence systems shouldn't replace an empathetic, informed physician but complement decision making.

In conclusion, healthcare is rapidly progressing and merging with technology in a variety of ways. It has the ability to empower human intelligence and lead to various breakthroughs in medicine for our future. Many fundamental challenges exist in improving and fine-tuning errors in artificial intelligence system before implementing them into our healthcare community.

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Vitamin D supplementation: Does it help to reduce risk of diabetes?

Diabetes is a highly prevalent illness in the United States and many people are at an increased risk of developing it. Risk factors for diabetes include being overweight or obese, having a high fasting blood glucose level or having glucose intolerance. Although some of these risk factors can be modified, it is quite difficult where many people have already endured too much damage to reverse it. Another potential risk factor for diabetes is low 25-hydroxy vitamin D levels. Over the past 10 years, studies have shown that patients presenting with low 25 hydroxyvitamin D levels may have a possible risk of Type 2 Diabetes Mellitus (T2DM).

This may be because impaired pancreatic beta-cell function and insulin resistance are associated with low blood 25-hydroxyvitamin D levels and the risk of diabetes. In the patients observed over the past 10 years, reports have shown impaired pancreatic beta-cell function and insulin resistance. Using vitamin D supplementation has demonstrated an improvement with pancreatic beta cell function by 40%. Unfortunately, it is unknown whether Vitamin D supplements decrease the risk of T2DM. The trial of Vitamin D supplementation and prevention of Type 2 Diabetes was initiated to evaluate whether Vitamin D supplements reduce the risk of T2DM in adults who are at high risk.

Previous trials in this study area included the Tromsø Vitamin D and T2DM trial in Norway, where pre diabetics were given either 20,000 units of Vitamin D every week or, alternatively, a placebo. The results of this study showed that the occurrence of diabetes in the Vitamin D group was much lower, but, unfortunately, the results were also not significant. Another study in Japan (Diabetes prevention with active Vitamin D) used the same method as the previous study and portrayed the same results but again, the results were insignificant.

In order to further study this area, a double blind, randomized controlled, event driven trial took place where 2,423 pre-diabetic patients were split evenly into placebo and intervention groups. The intervention was to take 4000IU of Vitamin D3 once daily. Patients were separated according to the location, BMI, and race. They were told to avoid taking diabetes-related medications, weight loss supplements, any other form of vitamin D, and limit calcium supplements to 600 mg per day. Patients had at least two out of three glycemic criteria, which included fasting plasma glucose level (100 to 125 mg per deciliter), plasma glucose level 2 hours after a 75-g oral glucose load (140 to 199 mg per deciliter) and glycated hemoglobin level (5.7 to 6.4%). The duration period of this trial was from October 2013 to February 2017. This study was different than those previously performed because it was testing for a specific decrease (25%) in the risk of developing diabetes with the consumption of Vitamin D. Their inclusion criteria also used methods that resemble those that are used to diagnose prediabetes in clinical practice and the participants were continuously enrolled to avoid certain confounding biases i.e. “seasonal variability”.

By the end of the trial, 616 patients had developed diabetes. As mentioned before, the other two trials seemed to show that Vitamin D did make a difference in the development of diabetes in pre-diabetic patients but their results were also shown not to be significant. The effect size that this study used was too high, and the study would have been more applicable if there was a smaller effect size being tested. The study was generalizable because there were various people from different races included, along

with both genders and different locations that participated. One of the baseline characteristics that could have been changed was including people of all BMI indexes so it could be seen if the medication helped at certain BMI levels over others. It was also interesting how they kept a continuous enrollment throughout the years to try and avoid seasonal variability (meaning the chance of developing a certain condition during a particular season at a higher rate as compared to other times of the year). Overall, the conclusion of this study showed that Vitamin D supplementation of 4000IU did not lower the risk of diabetes in comparison to the placebo.

While this specific study did not find beneficial effects to Vitamin D supplementation with diabetes, a study regarding similar topics was researched. A study ran by the Iranian Diabetes Society compared the effects of daily intake of vitamin D in the form of a fortified yogurt drink (vitamin D3 + calcium) on glycemic status in subjects with Type 2 Diabetes. The inclusion criteria was patients ages 30 to 60 years old and a fasting blood glucose concentration >= 126 mg/dL at the first visit. The exclusion criteria were patients who had an inability to participate, intake of vitamin D, calcium or omega 3 supplements within the past 3 months, use of medications that could affect vitamin D metabolism, a disease that could influence vitamin D metabolism such as renal, hepatic, or endocrine disorders, and the use of insulin or any change in the type of hypoglycemic medications during the intervention period.

Ninety diabetic patients were randomly put in 3 different groups. Groups were set in plain yogurt (PY group), vitamin D supplement group (DY group), vitamin D and calcium supplement group (DCY group). Specific dosage of supplements for the PY group contained no vitamin D and 150 mg Ca/250 ml, DY group contained 500 IU vitamin D3 and 150 mg Ca/250 ml, and DCY group with 500 IU vitamin D3 and 250 mg Ca/250 ml. Patients were given yogurt twice a day for 12 weeks. The concentrations of the supplements were determined by the Deputy of Food and Drug of the Iranian Ministry of Health. Parameters that were noted were fasting serum glucose, glycated hemoglobin, homeostasis model assessment of insulin resistance, serum lipid profile, and percentage fat mass.

(Continued on page 10)

ISMP Best Practices for Vincristine (and other vinca alkaloids) Administration

(Continued from page 9)

Both the DY and DCY group had significant results in weight, BMI and waist-to-hip ratio ($P < 0.001$). Fasting serum glucose ($P = 0.024$), insulin ($P < 0.001$), HOMA-IR ($P < 0.001$) and HbA1C ($P < 0.001$) all increase after 12 weeks in the PY group but did not change remarkably in the DCY groups. The DY group had significant decrements in serum glucose and HOMA-IR.

This concluded that there was a significant change in glycemic optimization and weight control. Decreased insulin resistance showed that there was an improvement in insulin response. The findings indicated a direct and indirect glycemic optimizing effect on vitamin D. Having adequate vitamin D may be considered as a treatment with diabetes.

We can surmise that there are different medical reports discussing the effect of vitamin D and diabetes. There needs to be more studies performed to gather further data regarding the relationship between Vitamin D and its use in the treatment or prevention of diabetes mellitus. The current data shows differing results and therefore demonstrates various conclusions that are drawn. In order to streamline and either confirm or deny this supplementation as a prevention or treatment factor, further actions need to be taken. The Iranian study included yogurt with Vitamin D and calcium, which could have played a crucial factor in the different results. In the other studies, particularly the one conducted in the United States, there was a limit for the intake of calcium which may have skewed the results.

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The Dangers of Vaping and E-Cigarettes

Vaping and electronic cigarettes have been prevalent in the news as of late. So far eight states have banned flavored electronic cigarettes and New Jersey is considering the addition of a similar ban.[1] The FDA has been cognizant of the dangers of e-cigarette usage, and has taken action. In 2018, the agency issued over 1,300 fines and warning letters to retailers who illegally sold electronic cigarette products to minors, during a nationwide undercover operation.[2] Recently, as a result of an article published in The Journal of the American Medical Association, Juul has just announced its halting in sales of its mint flavor in an effort to appease the public and collaborate with regulatory agencies. Juul, in the surveys conducted, was indicated as the most popular e-cigarette brand, and the article stated mint as the most popular flavor.[3]

Smoking a cigarette behind the bleachers of the football field is no longer the "cool" activity to participate in. Today's youth have been warned and scared away from typical cigarettes, acknowledging the dangers and risks. However as the usage of typical tobacco products declines, e-cigarette usage continues to increase. According to the CDC, e-cigarettes are the top tobacco product among children and adolescents. E-cigarette usage has been increasing since its introduction. The most recent data from 2019 indicates that over 5 million youth are currently using e-cigarettes. According to the 2019 National Youth Tobacco Survey, 27.5% of high schoolers and 10.5% of middle schoolers are engaging in e-cigarette usage.3 This is a dramatic increase from the usage in high schoolers and middle schoolers in 2018, which was 20.8% and 4.9% respectively.[4] Cigarettes are no longer the new popular tobacco product, and only account for 5.8% of tobacco product usage in high schools.[3] While the percentage is still high, it is a stark difference compared to the electronic cigarette usage. So what are electronic cigarettes, and why are they so dangerous?

Electronic cigarettes (e-cigs) are also known as electronic nicotine-delivery systems. They produce an aerosol by heating a liquid consisting of a solvent (usually vegetable glycerin, propylene glycol, or a mixture of the two), one or more flavorings, and nicotine. In some electronic cigarettes, nicotine is substituted for other substances.

(Continued on page 12)

The Dangers of Vaping and E-Cigarettes
(Continued from page 11)

The combustion of tobacco and aerosol formation are fundamentally different processes. In e-cigs the heating element will evaporate the liquid and cool it to form an aerosol. In cigarettes, the tobacco is lit and the smoke is directly inhaled. Even the aerosol composition and the smoke from the tobacco are completely different. Each e-cig device includes a battery, a reservoir that contains the liquid, and a vaporization chamber which includes the heating element. Current devices allow users to customize a single device with different liquids and heating elements.[5]

The popularity of electronic cigarettes is not without harm. The ability to interchange different flavors or add tetrahydrocannabinoil (THC) provides a tempting choice to adolescents. Unfortunately, electronic cigarettes can cause severe health problems in individuals. The CDC has reported 1,888 cases of e-cigs or vaping associated lung injury (EVALI). These reports have come from 49 different states (every state except Alaska), the District of Columbia, and one U.S. territory as of October 29, 2019. All EVALI patients have admitted to a history of using e-cigs or vaping. Most people reported using THC-containing products, and THC is present in a large majority of samples tested by the FDA. National and state findings suggest THC products, especially those from unverified sources (e.g. illicit dealers), are the most problematic and linked to the recent emerging outbreaks of EVALI.[6]

A total of 35 patients had cases of EVALI reported to the Wisconsin department of health-services since August 27, 2019. An additional 47 cases were reported to the Illinois department of public health equating to a total of 82 cases reported. Of the 82 cases reported, 53 case patients met the definition of a probable case of EVALI (25 total, with 13 in Wisconsin and 12 in Illinois) or a confirmed case (28 total, with 15 in Wisconsin and 13 in Illinois). Pathologists reported patients had findings of mild and nonspecific inflammation, interstitial and peribronchial granulomatous pneumonitis, acute diffuse alveolar damage, and foamy macrophages all associated to electronic cigarette usage. Infectious disease protocols had patients tested for possible viral, bacterial, and fungal pathogens. Almost all infectious laboratory testing for patients in the case reports were found to be negative. Of all of the patients, 91% had an abnormal chest radiograph at presentation, and 100% of the 48 patients who received CT scans showed abnormal presentation, and had opacities in both lungs. The opacities were characteristically described as ground-glass opacities. In total, there were 4 cases of pneumomediastinum, 5 cases of pleural effusions, and 1 case of pneumothorax. One patient had both a pneumomediastinum and pneumothorax. Another patient had both a pneumomediastinum and pleural effusion. Patients were also found to have lipoid pneumonia, a new pneumonia that has been associated with electronic cigarette usage.[6,7]

Lipoid pneumonia is a growing concern in e-cigarette users. In July and August of 2019, five patients aged 18-35 experienced symptoms of dyspnea, nausea, vomiting, abdominal discomfort, and fever. These patients showed tachypnea, increased work of breathing on examination, hypoxemia, and bilateral infiltrates on chest x-rays. All of these patients used marijuana oils or concentrates in e-cigarettes. Additionally, all patients were hospitalized for hypoxemic respiratory failure. Of those five patients, three required intensive care for acute respiratory distress syndrome, and one of those patients required intubation and mechanical ventilation. Luckily all patients survived. When these patients first presented, they were empirically treated with antibiotics on the suspicion of community-acquired or aspiration pneumonia. However patients continued to worsen and eventually experienced respiratory failure within 48 hours. Blood and sputum cultures all came back negative for pathogens. After clinical history, radiography, laboratory and bronchoscopic diagnostics, all patients were given a diagnosis of acute exogenous lipoid pneumonia. Patients were treated with steroid therapy and all improved.[8]

While the exact association between lipoid pneumonia and e-cigarettes is not directly understood, one theory is that aerosolized oils are deposited within the distal airways and alveoli, which then activates a local inflammatory response that causes impaired vital gas exchange. Lipoid pneumonia is difficult to diagnose due to its nonspecific symptoms. Variable chest imaging and vague symptoms can often times lead to delayed or missed diagnosis. Corticosteroids might assist with lipoid pneumonia, but the optimal treatment regimen, duration, and long-term effects of the disease are still to be discovered.[8]

Currently, the FDA and CDC have not yet been able to link EVALI to a specific compound or ingredient. It is suspected that more than one ingredient is at fault. E-cigs or vaping is the only shared characteristic among all cases. Many different substances are still under investigation including the following: glycerol, propylene glycol, nicotine, acetone, acrolein, 1,3-butadiene cyclohexane, diethylene glycol, ethylene glycol, ethanol, and formaldehyde. The CDC currently recommends avoiding the usage of e-cigs that contain THC. The CDC also recommends that people should not buy anything relating to e-cigs or vaping off the street, including parts to modify the device, or any substances used for e-cigs or vaping. The only way to assure no risk of EVALI is to refrain from using e-cigs or vaping because the specific compound or ingredient causing lung injury has not yet been identified. People who continue to use e-cigs or "vape" should carefully monitor themselves and contact a healthcare provider immediately if they develop any signs or symptoms. Youths, young adults, and pregnant women should never use e-cigs or engage in vaping. Adults should not start using e-cigarettes if they have not been using tobacco products due to the possible health risks that all tobacco products. THC use is associated with a wide range of health effects (especially with heavy usage), and the best way to prevent these potentially harmful effects is to not use THC. This includes not smoking THC by means of e-cigs or vaping as well. People who have marijuana use disorder should seek treatment by a health care provider.[9] Overall, the dangers of vaping exist, while scientists are still trying to learn more about the full effects of vaping, the safest option is to refrain from engaging in e-cigarette usage.

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Contributed by:
Amy Tsay, Pharm. D Candidate 2020, Rutgers Ernest Mario School of Pharmacy
Derek Chen, Pharm. D Candidate 2020, Rutgers Ernest Mario School of Pharmacy

Welcome New Pharmacy Technician

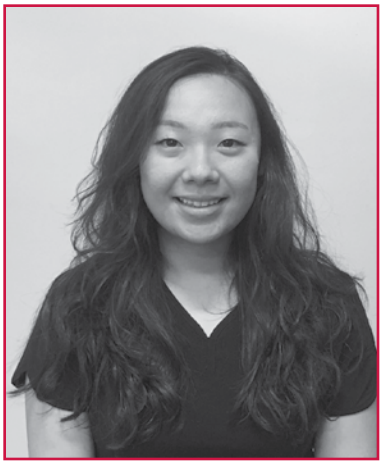
Michael Gerges is from Egypt originally. He cares a lot about his family and friends. Michael is newly hired in University Hospital as a pharmacy technician. His short term goal is to learn well from his job. His long term plan is to be a pharmacist in this hospital where he can help many people.

Welcome New Pharmacists

Dr. Bryan Okwuonu was born in Houston Texas. He has 3 sisters and he is the 3rd child. He graduated from the Ernest Mario school of pharmacy at Rutgers University in 2012. He got his first tattoo after his sophomore year in college and has a total of 4 so far. He is currently working on creating his 5th and biggest one. He has a 2006 Kawasaki ninja 650r motorcycle. He is a huge sports fan, with football being his favorite. His favorite team he lives and dies for is America's team; the Dallas Cowboys (how bout dem cowboys). As a child and growing up he loved professional wrestling (WWE); his favorite wrestler being stone cold Steve Austin and he currently owns a replica championship belt.

Dr. Bruce Sabino, Pharm. D. graduated from The Jefferson College of Pharmacy (Thomas Jefferson University) in 2016. Prior to joining University Hospital, he was a pharmacy manager at several CVS Pharmacy locations and had worked for CVS since graduation. Prior to school, he worked as a pharmacy technician for ~11 years in both retail (CVS) and hospital at Beth Israel Deaconess Medical Center (Boston, MA) and St. Luke's Hospital (New Bedford, MA). He grew up in MA and when he is home he enjoys the amazing seafood, Portuguese food (the city he is from: New Bedford, has a big Portuguese population similar to Newark), going to the beach, and spending time with family, friends, and his two dogs. In his free time, he likes to try new restaurants, travel the world, binge watch anime, and plays tennis! He is excited to begin his career as a hospital pharmacist and looks forward to the challenges ahead!

Dr. Rebecca Kim, Pharm. D. just graduated from Ernest Mario School of Pharmacy in Rutgers University this past May. She enjoys making brunch food and hand drip coffee. She loves to learn about culture, food, and learning new languages. She also loves to travel, with her most recent trip being the islands of Italy. She looks forward to learning about everyone's culture & tradition and hopes to find a new travel buddy!



Dr. Aidan Ziobro. Pharm. D, MBA is a recent graduate from Albany College of Pharmacy and Health Sciences. He has worked in the hospital setting for 6 years now and has enjoyed every minute of it. He likes to do research projects and poster presentations on the impact pharmacy can have on patient care. Outside of work, he enjoys hiking with his dog, cooking, traveling, and trying new foods.

Dr. Marielle Fajardo, Pharm. D. graduated from the Ernest Mario School of Pharmacy at Rutgers in 2017. In the past, she has worked as both a pharmacy technician and as a pharmacist at Hoboken University Medical Center and at Saint Peters University Hospital. On her off time, she tries to travel as much as possible; in 2019 she traveled to the American Southwest (Arizona, Utah, and Nevada), Oregon, Miami, and Puerto Rico and she is excited to plan for more destinations next year. In college, she played club Ultimate Frisbee which traveled to all different states and colleges up and down the east coast, and in post graduate life she continues to play in leagues and pickups (come join her!). She also loves writing and photography, so if you do either, come share your work with Marielle!

T.E.A.M. Award Winner

Norma Rodriguez, Lead Pharmacy Technician CPhT
University Hospital's Quarterly Award Nomination for
T.E.A.M Together Everyone Accomplishes more & Outstanding Service and Support

I am a new pharmacy technician at University Hospital. The work environment of a hospital pharmacy is different than the work environment of an independent pharmacy. When I started working here, I was very overwhelmed. Then, I met Norma, the lead pharmacy technician at University Hospital. Norma is a great trainer, teacher, and leader.

Norma trained to focus on patient safety. She advised me to never rush because that might increase the risk of medication error. However, working safely with speed without error is also important. I learned from Norma to prioritize my tasks so that the most important task gets completed first. Also, she was always keeping her eyes on me while I was on training. Norma did that not to make me feel uncomfortable, but to make sure I understood what I was doing and make sure I do it right. Whenever she passed by me she did not forget to ask me if I am ok or if I have any questions. This communication gave me a sense of teamwork.

Whenever I was falling behind on my tasks, she came and helped me or she makes sure one of the other team members helps me so that the tasks get completed on time. One day, as for our hourly rounds we prepare medications, patient-specific and also for the Pyxis. I was very behind, Norma came with another technician and helped me catch up so the medication gets to our patient on time. This is a great skill of a great leader and a team-player.

My training period went very smooth. I felt welcome to the department and always love to come to the pharmacy department and work with my team to provide outstanding service to our patients.

Nominated By:
Tafazzul Islam, Pharmacy Technician, University Hospital

Outstanding Patient Care Award

Mrs. Dawn Brown, Pharmacy Administrative Coordinator
University Hospital's Quarterly Award Nomination for
Outstanding Patient Care Award

Mrs. Dawn Brown was completing her daily routine when she saw someone experiencing apparent distress and on the verge of falling. She immediately ran and caught the person thinking only for that person's safety, not even for a second considering her own safety. She acted with an innate motherly instinct.

The patient was found to be trembling, shaking, experiencing shortness of breath, and hyperventilating. Dawn Brown held the patient on the floor, hugging her, and continuing to tell the patient to breathe in slowly in order to calm her down. Mrs. Brown went out of her way to help this patient, who was a stranger, and cared for her. She waited until EMS came to the scene and her fast reaction prevented any further injuries.

The fact that somebody such as Dawn Brown is present at University Hospital makes us feel at ease because she is someone who puts the needs of others ahead of her own. That is exactly what we strive for at this hospital. We, the pharmacy management team, would like to state that Mrs. Brown went above and beyond, showing a display of good heart and compassion. Together, we feel that she should be recognized for her selflessness and devotion.

Nominated by:

Michael Chu, PharmD, Clinical Pharmacy Manager
Royston C.C. Irving, Pharm. D., Pharmacy Supervisor
Nermin (Nina) Boles-Attia, Pharm. D. Pharmacy Supervisor

University Hospital Formulary Additions and Deletions for January 2018 – November 2019

Generic Name	Brand Name	P&T Date	Approved	Denied	Deleted	Reason/Comments /Criteria
Niacin 50mg tablets	SLO-Niacin	Jan 2018			X	
L-Cystine HCL Injection	Elcys	Jan 2018			X	
Methocarbamol Injection	Robaxin	Jan 2018			X	
Tenofovir Alafenamide	Vemlidy, TAF	Feb 2018	X			FDA approved for the treatment fo Hepatitis B with compensated liver disease
Epinephrine 0.3mg/0.3ml	Epipen	Feb 2018	X			Restricted to the ED
Epinephrine 0.15mg/0.3ml	Epipen Jr	Feb 2018	X			Restricted to the ED
Oseltamivir 30mg	Tamiflu	Feb 2018	X			
Hepatitis A virus antigen 25 units/0.5ml Vaccine	VAQTA	Feb 2018			X	
Nitroglycerin 0.6mg/hour transdermal patch	Nitro-Dur	Feb 2018			X	
Acetaminophen 500mg Caplet	Tylenol	Feb 2018			X	
Acetaminophen 80mg and 325mg suppository	Tylenol	Feb 2018			X	
Carbamazepine ER 300mg cap	Carbatrol	Feb 2018			X	
Chlorpromazine 50mg and 200mg tab	Thorazine	Feb 2018			X	
Cortisone 25mg tab		Feb 2018			X	
Cyclosporine modified 25mg capsules	Neoral	Feb 2018			X	
Dexamethasone tablets 0.75mg, 1.5mg, 6mg		Feb 2018			X	
Trimethoprim	Proloprim	Feb 2018			X	
Adefovir Dipivoxil	Hepsera	April 2018			X	
Aminosalicylic Acid 4g granules	Paser	April 2018			X	
Amoxicillin 125mg/5mL Suspension	Amoxil	April 2018			X	
Cefuroxime Axetil 250mg	Ceftin	April 2018			X	

tablets						
Cephalexin 125mg/5mL Suspension	Keflex	April 2018			X	
Ciprofloxacin 750mg tablets and 20-5mg IV Solution	Cipro	April 2018			X	
Clindamycin 300mg/50mL IV solution	Cleocin	April 2018			X	
Dicloxacillin 250,500mg tablets	Dynapen	April 2018			X	
Famciclovir 125,500mg tablets	Famvir	April 2018			X	
Griseofulvin Microsize 125mg/5mL suspension	Grivulvin V	April 2018			X	
Isoniazid-Rifampin 150-300mg tablets	Rifamate	April 2018			X	
Itraconazole 250mg IV kit	Sporonax	April 2018			X	
Lopinavir-Ritonavir 200-50mg Tablets	Kaletra	April 2018			X	
Micafungin 50mg IV	Mycamine	April 2018			X	
Nitrofurantoin Macrocystals 50,100mg tablets	Macrodantin	April 2018			X	
Penicillin V Pot 125mg/5mL, Penicillin V Potassium 250mg Capsules	Veetids	April 2018			X	
Phenazopyridine 200mg tablets	Pyridium	April 2018			X	
Quinine Sulfate 200,260,325mg capsules		April 2018			X	
Naphazoline Eye Drops	Naphcon	April 2018			X	
Edrophonium for Injection	Enlon	April 2018			X	
Zoster Vaccine- Recombinant, Adjuvanted	Shingrix	April 2018	X			Restriction to outpatient use
Lidocaine 4% Patch		May 2018	X			
Prismasol and Phoxillum Solutions		May 2018	X			Line Extension. Restriction to Nephrology and Surgical Intensive Care Service
Cyclosporine modified		June 2018	X			Line extension
Levothyroxine 125mcg,150mcg,175mcg tablets	Synthroid	June 2018			X	

(Continued on page 20

Formulary Additions and Deletions

(Continued from page 19)

Mupirocin cream		June 2018			X	
Spironolactone-Hydrochlorothiazide 25mg-25mg		June 2018			X	
Calcium gluconate oral tablet 500mg		June 2018			X	
Fluorescein strip		June 2018	X			Line extension
Intravenous Immune Globulin	Gammagard liquid	June 2018	X			Line extension
Rabies Immuneglobulin	HyperRab 300IU/ml-1ml	July 2018	X			Line extension
Rabies Immuneglobulin	HyperRab 150IU/ml	July 2018			X	
Rabies Immuneglobulin	Imogam 150IU/ml	July 2018			X	
Factor VIII Anti-hemophilic factor recombinant	Xyntha Solofuse	July 2018	X			Line extension
Factor VIII Anti-hemophilic factor recombinant	Helixate	July 2018			X	
Chloramphenicol		July 2018			X	
Cyclophosphamide	Cytoxan	July 2018			X	
Chlorzoxazone 500mg tab	Lorzone	July 2018			X	
Cefuroxime axetil 250mg tablets	Ceftin	July 2018	X			Reinstatement
Cefuroxime axetil 250mg/5ml oral liquid	Ceftin	July 2018			X	
Diclofenac 50mg, 75mg tablet	Voltaren	July 2018			X	
Hydroxyzine pamoate	Vistaril	July 2018			X	
Maraviroc 300mg tab	Selzentry	July 2018			X	
MVI with fluoride 0.25mg, 0.5mg, 1mg tablets	Poly-Vi-Flor	July 2018			X	
Nortriptyline 50mg capsule	Pamelor	July 2018			X	
Timolol 5mg tablet		July 2018			X	
Translingual nitroglycerin spray	Nitrolingual	July 2018			X	Usage to be restricted to the EMS
Apixaban	Eliquis	Sep 2018	X			
Basiliximab	Simulect	Sep 2018	X			

Anidulafungin	Eraxis	Sep 2018	X			
Glucose oral gel formulation		Sep 2018	X			Line extension. Restricted to ambulatory clinic kits use only
Lidocaine topical Jelly	Glydo	Sep 2018	X			Line extension
Nesiritide	Natrecor	Sep 2018			X	
Zinc sulfate and chloride IV		Sep 2018			X	
Andexanet alfa	Andexxa	Oct 2018	X			Prescribing restriction
Hepatitis B vaccine, recombinant, adjuvanted	Heplisav-B	Oct 2018	X			Approved for outpatient use only
Naltrexone	Revia	Oct 2018	X			Restricted to detox certified prescribers and psychiatry department only
IV acetaminophen	Ofirmev	Oct 2018	X			Line extension approved for neonates with PDA for up to 7 days
Intrauteral devices (IUD)	Nexplanon	Oct 2018	X			Approved only for outpatient use
Promethazine 50mg/mL injection		Oct 2018			X	
Theophylline 100mg, 200mg tablets		Oct 2018			X	Discontinued by manufacturer
Acetaminophen 80mg chewable tablets		Oct 2018			X	Discontinued by manufacturer
Morhuate Sodium		Oct 2018			X	Discontinued by manufacturer
Polidocanol	Asclera	Nov 2018	X			
Elvitegravir/cobicistat/emtricitabine/tenofovir alafenamide	Genvoya	Nov 2018	X			
Ticagrelor	Brilinta	Nov 2018	X			Approved to include neurointerventionalist
Phentolamine		Nov 2018	X			
Potassium Iodide		Nov 2018			X	Discontinued by manufacturer
Trichophyton skin test		Nov 2018			X	Discontinued by manufacturer
Mexiletine 150mg and 200mg		Nov 2018			X	
Temazepam 30mg		Nov 2018			X	

(Continued on page 22)

Formulary Additions and Deletions

(Continued from page 21)

Candida albicans skin test		Nov 2018			X	
Bupivacaine Liposome Injectable Suspension	Exparel	Jan 2019		X		
Glimepiride 1mg and 4mg tablets		Jan 2019			X	
Atorvastatin 80mg tablets		Jan 2019			X	
Glipizide ER 5mg and 10mg tablets		Jan 2019			X	
Niacin 500mg tablets		Jan 2019			X	
Paroxetine 30mg tablets		Jan 2019			X	
Nadolol 40mg and 80mg		Jan 2019			X	
Medroxyprogesterone 10mg tablets		Jan 2019			X	
Haloperidol 20 mg tablets		Jan 2019			X	
Premarin 1.25mg tablets		Jan 2019			X	
Rasburicase	Elitek	Feb 2019	X			Restricted to approval by Nephrology/Oncology service
Eribulin	Halaven	Feb 2019	X			Restricted to the oncology service
Pembrolizumab	Keytruda	Feb 2019	X			Restricted to the oncology service
Ado-Trastuzumab Emtansine	Kadcyla	Feb 2019	X			Restricted to the oncology service
Paclitaxel Protein Bound	Abraxane	Mar 2019	X			
Rotavirus RV1	Rotarix	Mar 2019	X			Ambulatory Care clinic outpatient use
Dtap/IPV 0.5ml	Kinrix	Mar 2019	X			Line extension
MMR-V 0.5ml	ProQuad	Mar 2019	X			Line extension
Loperamide 1mg/7.5ml		Mar 2019	X			Line extension
Selzentry 150mg tablets		Mar 2019			X	
Phenol 89% bottle		Mar 2019			X	
Cefotaxime Injection		Mar 2019			X	
Loperamide 1mg/5ml		Mar 2019			X	Discontinued by manufacturer
Epoprostenol	Flolan	April 2019	X			Line extension

Hydrocortisone 0.5% ointment		April 2019			X	Discontinued by manufacturer
Hydrocortisone 1000mg injection		April 2019			X	
Desipramine 50mg		April 2019			X	
Methylprednisolone 2000mg injection		April 2019			X	
Sodium Zirconium Cyclosilicate		May 2019	X			Limited to Nephrology and Cardiology Services
Torsemide		May 2019	X			
Dalbavancin	Dalvance	June 2019	X			Restricted to Hblue Observation unit patients and to approval by infectious disease services
Carfilzomib	Kyprolis	June 2019	X			Restricted to the oncology service
Emtricitabine and Tenofovir alafenamide	Descovy	June 2019	X			
Degarelix	Firmagon	Sep 2019	X			Restriction to oncologists only
Brentuximab	Adcetris	Sep 2019	X			Restriction to hematologist/oncologist only
Del Nido Cardioplegia		Sep 2019	X			Line extension
Gentamicin 120 mg/100 mL NS		Oct 2019			X	
Sodium zirconium		Nov 2019	X			Formulary line extension approved for unrestricted one time dose through order-set, maintenance dose will require cardiology and nephrology approval
Aspirin 325 mg, aspirin EC 81 mg, aspirin EC 325 mg		Nov 2019			X	
Activated charcoal with sorbitol		Nov 2019			X	
Allopurinol IV		Nov 2019			X	

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Fairleigh Dickinson University School of Pharmacy and Health Sciences

Michael Chu, Pharm D, Clinical Pharmacy Manager

Fairleigh Dickinson University (FDU)

2019 Preceptor of The Year Award

Pictured (from left to right): Assistant Dean Dr. Anastasia Rivkin, Dr. Michael Chu, Assistant Dean Mrs. Barbara Rossi, Dean Dr. Michael Avaltroni

Dr. Michael Chu has been the Clinical Pharmacy Manager at University Hospital since 2003. His position involves overseeing and evaluating the different units (i.e. ICU, oncology, etc.) of the hospital. He graduated from the University of Illinois at Chicago with a Doctor of Pharmacy degree in 1990 and proceeded to become the first clinical pharmacist at University Hospital in Newark, NJ. He has been working at University Hospital for a total of 27 years.

Dr. Chu has also served as a preceptor to many pharmacy students over the years from different schools within the tri-state area, including Rutgers University, Fairleigh Dickinson University, and St. John's University. Dr. Chu's time and dedication with students has been recognized and applauded by students and staff at Fairleigh Dickinson University (FDU) with the 2019 Preceptor of the Year award. He greatly appreciates the opportunity to teach future pharmacists as well as the support of the pharmacy department staff in teaching students about hospital pharmacy.

In his free time, Dr. Chu enjoys giving back to his community. He has recently helped build a well-filtration system for purification of drinking water for the residents of his homeland, Burma. Dr. Chu is a family-centered man and enjoys spending time with his wife, Dr. Noreen Tan-Chu, and his children, Conan and Shannon Chu, who are currently juniors at Cornell University in Ithaca, New York.

Submitted by:
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Director of Pharmaceutical Services