The Regents of the University of California

HEALTH SERVICES COMMITTEE
December 15, 2020

The Health Services Committee met on the above date by teleconference meeting conducted in accordance with Paragraph 3 of Governor Newsom's Executive Order N-29-20.

Members present: Regents Blum, Guber, Lansing, Makarechian, Park, Sherman, and Zettel; Ex officio members Drake and Pérez; Executive Vice President Byington; Chancellors Block, Hawgood, and Khosla; Advisory members Hernandez and Spahlinger

In attendance: Regents Cohen, Elliott, Kieffer, Leib, Mart, Muwwakkil, Reilly, Stegura, and Sures, Regents-designate Torres and Zaragoza, Faculty Representatives Gauvain and Horwitz, Secretary and Chief of Staff Shaw, Deputy General Counsel Nosowsky, Executive Vice President and Chief Financial Officer Brostrom, Vice President Nation, Chancellor Larive, and Recording Secretary Johns

The meeting convened at 11:25 a.m. with Committee Chair Lansing presiding.

1. **APPROVAL OF MINUTES OF PREVIOUS MEETING**

Upon motion duly made and seconded, the minutes of the meetings of October 20 and November 18, 2020 were approved, Regents Drake, Guber, Lansing, Makarechian, Pérez, Sherman, and Zettel voting "aye."[1]

President Drake recognized the heroic efforts of UC Health workers during the COVID-19 pandemic and expressed gratitude to the frontline workers—doctors, nurses, and other healthcare professionals in UC's hospitals, as well as the many critical support workers who kept UC patients safe and hospitals running. These workers faced difficult circumstances every day and risked their lives to care for others. President Drake felt hope about the new year with the development of two vaccines which had received emergency use authorization. He anticipated that the next several weeks would be very challenging, as the virus continued to rage throughout California communities.

This was the last time that the Regents would convene in a year that had been quite turbulent. As he looked forward to a new year, President Drake was very mindful of another generational challenge affecting health and safety around the planet, the challenge of climate change. The proliferating threats of wildfires, drought, heatwaves, and infectious diseases made it clear that climate change was also a health crisis. It was time to take action on climate change. The University's Carbon Neutrality Initiative had served UC well. UC Merced was the first public research university in the U.S. to become entirely carbon

[1] Roll call vote required by the Bagley-Keene Open Meeting Act [Government Code §11123(b)(1)(D)] for all meetings held by teleconference.

neutral. President Drake looked forward to discussions of UC's plans to expand its leadership in the fight against climate change.

2. **UPDATE OF COVID-19 IMPACT ON THE UNIVERSITY OF CALIFORNIA: UC HEALTH ISSUES**

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Executive Vice President Byington commented on the first COVID-19 winter in the U.S. A chart showed that the current third COVID-19 surge far exceeded the first two surges in the spring and summer. There was exponential growth in cases across the nation. Deaths in the U.S. had now exceeded 300,000, and 3,000 deaths per day were being reported. This rate was expected to continue for a number of weeks into the future. In November, about one death from COVID-19 was occurring every minute; now one death was occurring about every 30 seconds. Healthcare workers were dealing with this unprecedented level of mortality each day. The entire United States was now covered with COVID-19 hot spots, and there had been a marked change in California. In November, there were about 4,500 hospitalizations in California. On December 11, the number of hospitalizations in the state was 12,940, and on this day, December 15, the number might be 13,000, a dramatic increase in hospitalizations.

In November, the UC medical centers had 177 patients with COVID-19. Two weeks after Thanksgiving, that number rose to 486, and UC hospitals now had 514 COVID-19 inpatients. This number surpassed both the spring and summer surges. UC facilities were coping well with these high numbers. UC Davis, UC Irvine, and UCLA all had more than 100 of these patients. All the medical centers were seeing increases in test positivity rates and case numbers. The San Francisco Bay Area had lower numbers. UC Health was working as a system to ensure that each hospital had the necessary personal protective equipment, laboratory diagnostic testing, and personnel. At this moment, ensuring sufficient personnel was the most challenging need.

Governor Newsom had recently issued new "stay at home" orders, based on the intensive care unit (ICU) bed capacity in California. When this capacity fell below 15 percent for a given region, additional restriction would be put in place. At this time, the San Joaquin Valley and Southern California had less than five percent capacity. Fifty-four of the 58 counties in California were documenting widespread transmission of COVID-19, an area with 99 percent of the state's population. All counties with UC facilities were experiencing widespread transmission. The adjusted case rates per 100,000 population were of particular concern in Riverside County, which had a rate of 47.8; some other counties were in the 30s or the high 20s. UC campuses had managed to avoid becoming "super spreading" locations in the counties where they were located, and campuses had lower positivity rates than their counties. UC Health continued to perform a high level of testing for its healthcare employees. Positivity rates remained low, and UC Health was monitoring this closely.

The CA Notify application (app), an exposure notification app, had been piloted at UC. The pilot program had been led by Dr. Christopher Longhurst at UC San Diego, expanded to most UC locations, and had been able to enroll about 250,00 UC employees, students, and faculty. The program was so successful that is was launched across the state, and five million people were now enrolled in this app. The app was designed to alert people if they had been in proximity to someone who had tested positive for COVID-19, in order to expedite the isolation, testing, and contact tracing processes.

Dr. Byington reported that UC medical centers were stemming revenue losses compared to losses experienced earlier, in the spring. The volume of emergency department and surgical visits had returned to pre-COVID-19 levels. There had been increases in ambulatory and virtual visits. Average daily census had increased. The number of full-time equivalent employees was higher than it had been previously. The numbers of discharges were similar to the past year.

The extraordinary news was that COVID-19 vaccines had come to fruition. In November, they were on the horizon but had not yet been approved. On December 8, Margaret Keenan, a 90-year-old woman in the United Kingdom, was the first to receive the Pfizer-BioNTech COVID-19 vaccine. Similar joyful events were taking place in the U.S., where the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) needed to approve the vaccines. Dr. Byington noted that UC Health professors participated on the relevant FDA and CDC committees. Dr. Mark Sawyer of UC San Diego was a member of the FDA Vaccines and Related Biological Products Advisory Committee and Dr. Peter Szilagyi of UCLA served on the CDC Advisory Committee on Immunization Practices. On December 10, the FDA met to discuss emergency use authorization for the Pfizer vaccine. Dr. Byington described this as the most important question of the 21st century. The FDA needed to determine whether, based on the totality of scientific evidence available, the benefits of the Pfizer vaccine outweighed its risks for use in individuals 16 years of age and older.

Dr. Byington outlined FDA criteria for an emergency use authorization: the agent referred to in the emergency use authorization declaration must cause a serious or life-threatening disease or condition; the medical product may be effective to prevent, diagnose, or treat the disease or condition; the known and potential benefits of the product must outweigh its risks; and there must be no adequate, approved, or available alternative to the product. On December 10, the only FDA-approved product for COVID-19 was Remdesivir, which was used for treatment but not prevention. In granting emergency use authorization, the FDA had certain expectations. The pharmaceutical company must demonstrate that it can manufacture with high quality and consistency, must present clear and compelling safety and efficacy data for the product, and have plans for further evaluation of the vaccine's safety and effectiveness, including ongoing clinical trials, active and passive safety monitoring during widespread use, and observational studies.

The FDA also discussed the ethics of vaccine approval. It was an unusual situation to distribute a vaccine under emergency use authorization, especially in the case of a vaccine that one wished to deliver to 80 percent of the U.S. population. Dr. Steven Goodman,

Associate Dean of Clinical and Translational Research at Stanford University, discussed the ethics of this situation, which presented a choice not between right and wrong actions, but between different right actions, each justifiable under a different moral framework. For example, there might be a choice between actions that were good for an individual versus actions that produced the greatest good for society. The resolution of this type of situation almost always required compromise. Compromise minimized moral injury (a wrong or harm) from unfairness, violations of autonomy, and personal or societal harm. Dr. Byington stressed that these were important principles for the Health Services Committee to understand and embrace. One dealt with questions like these in health care every day, and one had to make difficult decisions. Actions deemed ethical can vary in different contexts or conditions. The context included the current state of knowledge and uncertainty. As the context changes, the ethical context can change as well.

The safety of the vaccine was judged relative to its efficacy. The Pfizer and Moderna vaccines both reported 95 percent efficacy. In order to be considered for emergency use authorization, the FDA required that vaccines report at least 50 percent efficacy. Both the Pfizer and Moderna vaccines far exceeded the required level of efficacy.

Dr. Byington presented a chart showing the cumulative incidence of COVID-19 after one dose of the Pfizer vaccine. Following the time needed for immunity to develop, 14 days, there were almost no infections among individuals who had taken the vaccine. The FDA found that there was a positive benefit-risk for the vaccine. It was effective for the proposed indication of prevention of coronavirus disease caused by SARS-CoV-2 in individuals 16 years of age and older. There were no significant safety concerns identified in 43,448 subjects and no evidence of enhanced disease severity in vaccine recipients. An overall efficacy rate of 95 percent was observed. The vaccine was efficacious in both younger and older adults and across various demographics, including at-risk individuals, and it was efficacious against severe disease.

The FDA committee's vote to approve emergency use authorization for this vaccine was historic. While 17 of the committee members voted to approve, there were four "no" votes and one abstention. Dr. Byington explained that this was due to concerns about whether 16- and 17-year-olds should be included in the first wave of vaccinations. The UC member of the committee voted in favor of the vaccine, and Dr. Byington stated that she would also have voted "yes," because she saw no difference in physiology between 16- and 17-year-olds on the one hand and 18-year-olds, who were part of the vaccine trial. This vote on December 10 was the beginning of the end of the COVID-19 pandemic in the U.S. On December 12, the CDC Advisory Committee on Immunization Practices voted for an interim recommendation, which was required before the vaccine could be distributed in the U.S. The interim recommendation was immediately publicized and, on December 13, the Western States Scientific Safety Review Workgroup, which included four UC members, met to discuss the safety of the vaccine and the interim recommendation. The Workgroup voted unanimously to move the vaccine forward. Immunization in California could begin.

Dr. Byington reported that the University would be taking a different approach with this vaccine than it had this year with the influenza vaccine. While there were 50 years of safety

data for the influenza vaccine, this was a new vaccine, using a new mRNA technology, and there were only two months of safety data. Certain categories of people were not included in the clinical trials, such as pregnant women and immunocompromised people. For that reason, UC Health had determined that its healthcare workers would have mandatory participation in vaccination education. UC's healthcare workers would be offered the vaccine. They would either receive the vaccine or would choose to sign a declination.

The University had received its first vaccine doses at UC Davis and expected vaccines to be at all UC Health sites later this day. Vaccinations of UC healthcare workers would begin this day. UC Health had identified a large number of staff, almost 70,000, for Phase One vaccinations, and hoped to vaccinate all those in this group who wished to receive the vaccine over the next two to three weeks.

Dr. Byington outlined projections for herd immunity. Following the third COVID-19 surge, the U.S. population might have as much as 20 percent herd immunity from natural infection and about zero percent immunity from the vaccine. Immunizations would now begin, and there was a goal of immunizing more than 100 million people by July 2021. As the U.S. reached 50 to 60 percent immunity, there would be a real change in the trajectory of the pandemic. The goal was to immunize 75 to 80 percent of the U.S. population, which would in effect stop the pandemic. July 2021 was projected to be the first phase in nearing herd immunity, and having a sufficient degree of immunity to change the trajectory of the pandemic. This was beginning today in California. This was a day of awe for those working in the field of infectious diseases, something that many people had not believed could be accomplished so quickly. The vaccine was an astonishing achievement for science.

When the pandemic ended, there would still be a great deal of work to do to rebuild the UC Health system and to build resilience in the UC Health workforce. Dr. Byington asked the Regents to think about the healthcare workers and the sacrifices they were making in these exceptionally dark times. At an upcoming meeting, Dr. Byington would discuss a program to build resilience and invest in the UC Health workforce as UC recovered from the pandemic. The University's motto, Fiat Lux, had never seemed more appropriate.

Committee Chair Lansing referred to CDC recommendations about the order of vaccinations for different groups of people: first for healthcare workers, then nursing home residents, and then others. She asked if the State of California would follow this order. Dr. Byington responded that California would follow this guidance. There might be some overlapping of these categories as some individuals declined the vaccine.

Committee Chair Lansing asked about the differences between the Pfizer and Moderna vaccines. Dr. Byington explained that, at this point, the FDA had found the Moderna vaccine to be safe. It would undergo the same review process as had the Pfizer vaccine. The CDC would review the relevant information on December 19 and 20, and, if it moved forward with the Moderna vaccine, this vaccine would begin to be distributed after December 20. The two vaccines were extraordinarily similar. They were both mRNA vaccines. For Dr. Byington, to see two separate mRNA vaccines produce almost identical

results in different trials, with different people, was very reassuring. The Moderna vaccine was 95 percent efficacious, like the Pfizer vaccine, and a similar side effect profile. The Moderna vaccine was easier to store, which might make it easier to bring this vaccine to outpatient clinics. The Pfizer vaccine must be stored at very cold temperatures.

Regent Makarechian asked about the numbers of ICU beds used in Northern California. Dr. Byington responded that there were differences in the pandemic by region. Although cases were increasing in Northern California, they had not reached the rate seen in Southern California. This was not reassuring, because this could be only a temporary situation.

Regent Makarechian asked about the mRNA technology and the vaccine's effects. Dr. Byington responded that receiving the vaccine was far safer than viral infection. Regent Makarechian asked about organ damage that could be caused by COVID-19, and if receiving the vaccine would prevent such damage. Dr. Byington explained that people who had had COVID-19 infection were at risk of organ damage, including to the lungs, heart, and kidneys. With a vaccine, there was no living virus and only minor side effects, such as fever, fatigue, and muscle ache, generally lasting only 24 hours and not harming the organs.

Regent Makarechian asked if survivors of COVID-19 infection who had not been in the hospital should have checkups. Dr. Byington responded that all COVID-19 patients deserved a good follow-up. The majority would recover and recover well. But in some cases, even with minor symptoms, there had been effects to the heart or kidneys. All UC medical centers had set up clinics for patients feeling effects long after recovering from COVID-19.

Regent Makarechian asked if someone who had been infected should receive the vaccine. Dr. Byington responded that this question had been discussed at length by the CDC. The recommendation was that those who had been infected and had recovered should be vaccinated. The vaccine immunity might be more durable and protect them from future infections. It was recommended that patients who had recently recovered should wait 90 days, because they might have natural immunity, and allow others who had never had COVID-19 to be vaccinated first.

Regent Makarechian asked how one could assert that vaccine immunity would be more durable than natural immunity, given how new the vaccine was. Dr. Byington responded that the final answer to this question was not yet known. But it was known that for most vaccines, vaccine-induced immunity was more specific and long-lasting, specifically for respiratory viruses, and COVID-19 was a respiratory virus. All the individuals who participated in the vaccine trials would be followed for two years. All individuals not in a vaccine trial but then vaccinated would have the opportunity to be followed for one year by the CDC. The immunity of those individuals with natural infections, who were asymptomatic or had mild symptoms, appeared to fade quickly. Those who had experienced more severe COVID-19 disease still had antibodies six to eight months later, but it was not known if this would be permanent.

Committee Chair Lansing asked how long immunity from the vaccine would last. Dr. Byington responded that this was not yet known.

Regent Kieffer asked how work by UC faculty in the last ten to 20 years had contributed to the development of these vaccines. Dr. Byington concurred that the technology had been breathtaking, such as the ability to sequence the virus. This was a far cry from vaccinology of a century earlier. The work of a medical historian would be required to answer Regent Kieffer's question. Dr. Byington credited the work of biochemist Katalin Karikó, recently at the University of Pennsylvania, in developing the mRNA technology and allowing this breakthrough for the COVID-19 vaccine.

Regent Kieffer emphasized the importance of past research carried out at UC, the University of Pennsylvania, and other institutions which led to this breakthrough. The future promise of research being done now could not be known. This lesson about the significance of science and research should not be lost on the University or the public.

Regent Muwwakkil asked about prioritization of the vaccine for faculty, students, or staff. Dr. Byington responded that UC was considering vaccination for faculty, students, and staff outside UC Health. These groups would be evaluated in terms of the tiers recommended by the CDC. UC was working with the California Department of Public Health to determine the definition of essential workers on UC campuses. In the remainder of December and in January healthcare workers would receive the vaccine, and essential workers would begin to be vaccinated in February. Dr. Byington anticipated that, in March, UC would be considering vaccination for all individuals with high-risk medical conditions or over age 65. After that point, vaccination would open up, and UC Health would consult with the chancellors on how this would take place on the campuses.

Regent Muwwakkil asked about community anxieties about the vaccine and how UC was addressing these concerns. Dr. Byington responded that UC was discussing this now with its healthcare workers to identify individuals from specific communities who could be spokespersons for the vaccine. UC Health was being as transparent as possible with data and working to ensure equity in its distribution of the vaccine. Vaccinating essential workers would also protect their households. Regent Muwwakkil concurred with Regent Kieffer's comments and stressed the University's amazing ability to benefit local communities and the world through its research mission.

Regent Stegura commented on the CA Notify app, which allowed a user to know if he or she were within a certain distance of someone who had tested positive for COVID-19. She asked about privacy concerns that might stop people from enabling this technology as part of a voluntary effort that required a great deal of cooperation. Dr. Byington confirmed that privacy was a major concern. The CA Notify app did not include any personal identifying information about an individual, only the location of a cellphone of an individual who had tested positive for COVID-19. There was no exchange of private or personal information. CA Notify was being used at UC. Notifications had come through on UC campuses, and individuals were being tested and isolated and were participating in contact tracing faster than they would have done without this app.

Regent Stegura expressed support for this technology, although she had concerns about privacy. Dr. Byington noted that five million people had already signed up for this program.

Regent-designate Zaragoza asked how UC would identify high-risk individuals. Dr. Byington responded that identification would probably be voluntary, on the part of individuals. The CDC had a list of criteria, such as having diabetes or other serious conditions, or being over the age of 65. UC would publish these criteria widely and ensure that people know where they can receive the vaccine.

Regent-designate Zaragoza asked how UC would care for students with long-terms effects from COVID-19. Dr. Byington responded that dealing with new chronic illnesses would be a challenge, but UC Health was able to manage chronic illnesses, and this would be matter for the individual and the provider. One was still learning about the long-term effects of COVID-19. The aftereffects of the pandemic would be felt for some time, but Dr. Byington expressed confidence in UC Health's ability to address these issues.

Regent Reilly asked about the average length of stay in ICUs at this moment, compared to the previous COVID-19 surges. Dr. Byington responded that the average length of stay in the first surges had been up to 30 days. The average length of stay had become shorter. The number of available patient beds in ICUs was not the only concern at this point, but also insufficient numbers of qualified staff.

Regent Reilly asked if there would be other vaccines, besides the Moderna vaccine, coming on to the market soon, and if this would shorten the timeline for reaching herd immunity. Dr. Byington hoped that other vaccines, including vaccines in other countries, would come to fruition in 2021. The greater number of effective vaccines available, the faster the pandemic would end. Infectious diseases teach one that we are all connected across the globe. Until one ended the pandemic everywhere, it would not be ended.

Committee Chair Lansing asked about rapid testing. One company had received recent approval for home testing. Dr. Byington responded that this one approved test was in short supply. The accuracy was about 95 percent, but the total number of samples that had been reviewed was small. Committee Chair Lansing asked that Dr. Byington send information to Regents about home testing.

Regent Makarechian asked if doses would be the same for everyone, regardless of age, and if there would be need for repeated vaccinations later in life. Dr. Byington responded that all ages would receive the same dose of the Pfizer and Moderna vaccines. She did not know if repeated vaccinations would be necessary. This would be determined by clinical trials which had begun and were under way. COVID-19 and its effects would be discussed for the foreseeable future. The duration of the vaccine's efficacy and the duration of immunity from natural infection were not yet known.

Regent Makarechian asked about reinfections. Dr. Byington responded that there were well-documented cases of repeated infections. Most cases were less severe the second time. A second infection could occur, but one did not know how often this might occur. She

believed that many of these cases were milder infections and therefore not coming to the attention of medical professionals.

Committee Chair Lansing concluded that this discussion had made it clear how science can save lives and the fact that the mission of the University was more important than ever.

3. **SPEAKER SERIES – HONORING THE PATIENT: 3 WISHES PROGRAM AT UCLA HEALTH**

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Thanh Neville, M.D., Assistant Professor in the Division of Pulmonary and Critical Care at UCLA Health, gave a presentation on her work with the 3 Wishes Program, which focused on palliative care interventions to provide patients and their families the means to achieve a dignified and compassionate end of life experience. She began her discussion by showing a photograph of an intensive care unit (ICU) and commenting that this environment, where a patient is surrounded by and connected to medical machines and devices, can be dehumanizing and depersonalizing. Not surprisingly, academic medical studies have shown that there is a great deal of stress for families of patients who die in the ICU. Providing care to terminally ill patients in the ICU also creates stress for healthcare workers, in particular nurses.

The premise of the 3 Wishes Program was that bringing a set of wishes to fulfillment in the final stages of a patient's life would bring peace to patients and their families. Wishes may be those of the patient, their family members, the ICU clinicians, or the 3 Wishes team. The program was designed to be broad enough so that even a comatose patient with no family could receive an act of kindness from a healthcare worker. The goal was to improve the end of life experience for patients and their families and to ease the grieving process. Specific objectives were, for patients, to dignify their death and celebrate their life; for families, to humanize the dying process and create positive memories; and for providers, to foster patient and family-centered care.

The first program of this type was initiated in 2015 by a Canadian physician, Deborah Cook, at St. Joseph's Healthcare in Ontario, and the results of the program were published. Semi-structured interviews with patients and clinicians showed that the program created positive memories, individualized end of life care, and promoted inter-professional care and humanism.

The 3 Wishes Program at UCLA was launched in December 2017. Dr. Neville recounted the efforts of UCLA Medical Center staff to move a terminally ill 36-year-old man who required ventilation out of the ICU space to die on an outside terrace at the Medical Center, with his wife next to him and with a view of the sunset.

Dr. Neville outlined the eligibility of patients for the program. The patient must be a critically ill patient, with 95 percent probability of dying during the ICU stay or a patient

for whom the decision is made to withdraw or withhold advanced life support in anticipation of death. There must be agreement from the primary care team that the patient is an appropriate candidate. The program team, nurses and other staff, take a conversational approach and use this opportunity to get to know the patient and his or her family.

The program had fulfilled many different patient wishes, including wishes for live music, personalized spaces for the patient, special decorations, spiritual recognition, special foods and beverages, time with a beloved pet, time outside in the sunshine, an exhibit of artwork by a patient who was an artist, and wedding celebrations performed in the patient's space. The program also produced keepsakes and mementos for patient families.

Dr. Neville and her colleagues had evaluated the program, reviewing the quantity and categories of wishes, determining costs, and characterizing the enrolled patients. They conducted 50 semi-structured interviews with family members, three focus groups with nurses, two focus groups with ICU attendants, and five semi-structured interviews with hospital leadership.

At this point, almost three years since the program began, it had enrolled 611 patients and fulfilled more than 2,000 wishes. Patients had a range of one to ten wishes, and there was an average number of 3.45 wishes per patient. The average patient age was 61.85 years. The average cost of fulfilling these wishes was modest, only $29.59 per patient. Although the core 3 Wishes team was small, 220 nurses at UCLA had been involved in implementing the program so far. Dr. Neville shared reflections on the program by families and clinicians and briefly outlined how the program had adapted to the situation of the COVID-19 pandemic.

The 3 Wishes Program was an academic project as well as a practical project. Results had been published in the journal *Annals of Internal Medicine*, showing that this program was sustainable, affordable, and transferable. The program was highlighted in numerous other publications as well.

Dr. Neville concluded her presentation by commenting on how this project could change the culture in the ICU. Death was regarded as a failure, but this was a moment and an opportunity to reduce suffering, to honor a patient's wishes and autonomy, and to celebrate the patient's life. At this moment, the end of a patient's life, healthcare workers must stop asking what the matter was with the patient and ask what mattered to the patient.

Committee Chair Lansing asked if this program only existed at UCLA. She would like to recommend that all UC hospitals adopt this program. Dr. Neville responded that she would like to expand the program and bring it to other hospitals. She was in communication with other hospitals in the U.S. who had expressed interest, and she had applied for a National Institutes of Health grant in order to expand the program in Los Angeles County. UCLA Health President Johnese Spisso remarked that the program had begun at UCLA as a pilot program, first at the Medical Center in Westwood, then expanded to the Santa Monica hospital. There was great interest among the UC Health chief nursing officers and chief

medical officers. Information about this program would be shared across the UC system. The program's experience had been very positive.

Regent Zettel asked about organ donations. Dr. Neville responded that organ donations were more likely to come from patients who had died in automobile accidents, and whose organs were still salvageable.

4. **CENTER FOR DATA-DRIVEN INSIGHTS AND INNOVATION AND OTHER STRATEGIC PLAN-RELATED UPDATES FOR AREAS FUNDED BY MEDICAL CENTERS AT UC HEALTH**

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Chief Data Scientist Atul Butte reported that, over the past two years, the Center for Data-Driven Insights and Innovation had made tremendous progress in creating a central database for UC Health patient data for safe and responsible use. The Center's oversight board was composed of representatives with various different roles, including chief information, medical, quality, and operating officers, population health and clinical research leaders, and innovation, non-health campus research, legal, and compliance and ethics leaders. Use of the data set itself as a whole was overseen by Chief Health Data Officer Cora Han, who joined UC Health the prior year. The team of 11 employees at the Center was privileged to work closely with talented campus leaders and information technology professionals on many health system priorities. First and foremost was to improve the quality of care delivered by UC Health and to better document that care, especially for State and federal agencies. Care can be improved when similar care teams across UC Health share their best practices. Data sometimes provide the way for groups to best work together. The Center had also been involved in trying to optimize UC's own self-funded health plan, gathering data and helping to study variations in delivered care charges and to save money on unnecessary medications by, for example, starting employees and their dependents on generic medications instead of more expensive brand name medications.

UC Health was still far from finished with addressing the COVID-19 pandemic. UC hospitals had had a record high of 514 COVID-19 inpatients the previous day, over 4,000 had been admitted to date, and there had been 19,000 positive cases out of nearly 400,000 UC Health patients tested. Over the past seven days, more than one in every ten UC Health patients was COVID-19-positive. The rate was higher than one in five at UC Irvine.

Dr. Butte presented some of the lessons learned from COVID-19. Prior to March 2020, the Center's monthly data feed from each of the UC Health campuses was more than sufficient. The Center had now switched to a daily feed, at least for the COVID-19-tested patients. This feed ran at six a.m. every weekday. The Center team worked with all the UC Health campus teams to achieve a consistent set of data every day, to smoothly stitch the daily data feed on tested patients with the weekly data feed on COVID-19 inpatients and with

the monthly feed on all other patients. This was not always a smooth process, and, on that morning, it had been delayed by 90 minutes. In order to be able to produce these data, UC Health had reached a new level of sharing across the campuses. The Center was able to borrow working software code from UC San Diego and share elements of that software across the campuses' information services teams so that all would have the same level of ability. The Center had learned to harmonize important data elements quickly. Harmonizing meant using the same codes to mean the same thing. There were 49 different ways of ordering a COVID-19 PCR test. All these tests and results had to be harmonized every morning, and the system was still adding newer COVID-19 tests. The Center knew how to harmonize and share data elements such as blood tests, diabetes, blood pressure, and other population health measures; but now, all at once, one had to harmonize new data elements such as inpatient extracorporeal membrane oxygenation (ECMO) settings. ECMO was one of the most invasive ways to support a COVID-19 inpatient. Fortunately, UCLA had already made progress on ECMO data, having mapped these data elements from the electronic health records system into the standard open data model used by the Center. Starting with UCLA's work, the Center connected clinicians, the Epic electronic health record programming team, and UC Biomedical Research Acceleration, Integration, and Development (UC BRAID), the University's coordinated network for clinical and translational science. These elements were now mapped, so that the Center could track ventilator usage, oxygen levels, and ECMO across the UC Health campuses. The Center also learned how many groups need these data, from helping with COVID-19 reporting to the counties, multiple State organizations, and many federal agencies. Nearly 500 people or teams receive the Center's daily email dashboards. The Center was in near constant contact with the U.S. Food and Drug Administration (FDA), providing the FDA with frontline data on diagnostics and therapeutics.

The Center quickly learned to share central clinical data in a safe, respectful way with UC Health researchers. The Center developed a safe way to enable all these researchers to access all COVID-19-related clinical data. The Center regenerated this data set every week, removing patient-identifying data elements and securely transferring the data to each UC Health campus. Hundreds of UC Health campus researchers used the same local secure research system with which they were already familiar. Non-UC Health campus researchers accessed the data by working with the clinical research staff on a UC Health campus.

Education on this database was provided by local campus medical system programs, such as one at UC Irvine which drew over 150 clinicians and researchers. These efforts were carried out to ensure that all UC researchers could use this data resource to work individually or to join national consortia studies of COVID-19. The Center had learned that the public needed to see these data, which manifested the reality of COVID-19. Since the Center had begun in April publicizing data every weekday on Twitter, its postings regularly reached millions of individuals or impressions. The Center had learned a great deal during COVID-19, and these lessons would help UC Health become even stronger.

The Center worked closely with the systemwide population health team. There had been discussions for a long time about the importance of understanding the social determinants

of health. It was now possible to calculate the Area Deprivation Index (ADI), which estimated a patient's socioeconomic status based on income level, housing, education, employment, and other factors at the neighborhood level, using nine-digit zip codes, which could be geocoded from home addresses. An ADI ranking of one indicated living in the most favorable neighborhoods, while an ADI of ten indicated living in the most challenging neighborhoods. Homeless individuals were considered to be in the ADI ten category. A chart with an overview of more than 33,000 diabetes patients tracked by UC's population health team showed that the five UC medical centers treated patients in all ten ADI rankings.

Dr. Butte presented a map of California with ADI rankings. Not every ADI ranking had the same number of people in California. Larger rural areas were considered disadvantaged but also had a smaller population. He then presented four regional maps which covered the six UC Health campuses. One could see that these regions presented the entire ADI range from one to ten. This precise geocoding capability was unique to the Center, which provided these data to the campuses.

When ADI rankings were paired with race, ethnicity, gender, and age, one could more precisely identify health disparities. The hemoglobin A1C test was routinely used for diabetes patients. UC Health and the American Diabetes Association recommended that the A1C level should be below seven percent. Through its statistical epidemiology work, the Center had learned that UC diabetes patients' A1C levels were associated with age, race, ethnicity, and, independently, with ADI. Where a patient lived made a difference. Dr. Butte presented an example of three hypothetical patients, modeled from UC data. The hypothetical "best outcome" patient, a 78-year-old white non-Hispanic female, living in one of the best neighborhoods in California, would have an average A1C level of 6.83. The hypothetical "hardest outcome" patient, an 18-year-old black Latino male, living in one of the more challenging neighborhoods, would have an average A1C level of 8.96. One might think that race, ethnicity, and neighborhood go together. But sometimes these challenges must be addressed individually. If the hypothetical 18-year-old black Latino male lived in a neighborhood with an ADI one ranking, this patient would have an A1C level of 8.56. This was still not a perfect score, but with only a different home location, the A1C level was better by 0.4. It was clear that UC Health would have to care for these three hypothetical patients in different ways. The Center had made these calculations for nearly six million UC patients. The Center was doing this work with the systemwide diabetes and hypertension teams, using ADI, among many other elements, to identify disparities and to design efforts to specifically target those disparities. ADI was one of hundreds of data elements used for new artificial intelligence methods being developed. For example, work done at UCLA and UC Davis predicted which patients would need the most help in preventing worsening disease, complications, and readmissions.

Cancer genetics were now at the cutting edge of precision medicine. The DNA sequences of particularly difficult cancers were measured, and this enabled patients to be treated with or enrolled in clinical trials for novel drugs. Working closely with UC Cancer Consortium teams of oncologists, information technology professionals, and researchers, and with leadership from UC San Diego, Davis, and Irvine, the Center was now receiving cancer

genetics reports into its central data warehouse. The Center had data for over 10,000 cancer genomes and was on track to receive thousands more. Dr. Butte anticipated that the Center would have 15,000 reports from testing over the past five years. These cancer genetic data were now integrated into the same data warehouse with all the other drug and laboratory test data. There was a new prototype data dashboard which allowed one to examine any cancer or gene and to identify the genetic differences between cancers. The National Cancer Institute commonly launched and coordinated major clinical trials for its precision medicine initiative. UCSF was involved in one such trial, testing two new medications. This trial was only enrolling patients with a mutation in their lung cancer, specifically in either the ROS1 or ALK gene. Dr. Butte presented dashboard information identifying patients with ALK mutations and their cancers. The dashboard showed clearly that lung adenocarcinoma was the most frequent cancer observed with this mutation, and that there were 56 such patients at UCSF, 68 at UC Irvine, and 65 at UC Davis. One might not have realized that these patients at UC Irvine and Davis could have qualified for this trial run by UCSF, with potentially life-saving drugs. The dashboard further showed that there were patients with colon adenocarcinoma and this mutation. Although this was colon cancer and not lung cancer, researchers might consider whether these patients might also benefit from these drugs, and could provide this information to the pharmaceutical company to consider a wider trial.

The Center was helping the entire UC system learn to safely and respectfully build this new data-driven future for biomedicine. The Center had helped organize the first UC-wide Artificial Intelligence in Biomedicine Conference. Other than three keynote speakers, all the participants were from UC only. In spite of this limitation, there were 500 scientists, staff, and trainees from all ten campuses and two National Laboratories. Knowledge was being shared across the UC system to enable better collaboration and success. The Center had recently released its second annual report, and Dr. Butte invited the Regents to read and share this report, which contained much more information about the Center's activities.

Dr. Butte outlined some of the next steps for the Center. The Center would continue to help UC Health with its work on COVID-19 and would assist the population health teams working on the value of UC care, especially on rising pharmacy costs and finance and quality measures. There was more to do with research, enabling trainees at all levels and on all campuses to safely and respectfully use data. There was also a need to enable more cross-UC clinical trials, especially trials for underserved patients. There were many technical challenges to address. One issue was how to obtain more data from UC-affiliated health centers to better estimate drug costs and leverage at a larger scale. UC would not receive data from these partners unless UC continued to push forward its data governance model. The Center planned to execute the next stage of systemwide health data governance to achieve a justice-based model for health data use and would convene local governance groups to share best practices. Dr. Butte concluded that the work of the Center showed how much stronger UC is when it works as a system.

Regent Pérez referred to the information on the three hypothetical patients and reflected on the ongoing consequences of growing up in poverty. He asked if this model would be able to track patients over time and inform treatment for patients who might have moved from

one ADI ranking to another. Dr. Butte responded that this information was fascinating and frustrating. UC Health now had eight years of data on many individuals and would be studying this question in order to understand how ADI and patient profiles change as life conditions change for patients from childhood through adulthood.

Regent Pérez praised the Center's work, in particular its efforts to broaden the number of patients engaged in clinical trials.

Regent Park noted that calculating and documenting the value of care had been listed as a next step. She asked how this would be done. Dr. Butte responded that the value of care could be defined mathematically, as the quality of care divided by the cost of care. UC Health was good at documenting the quality of care, but this could be expanded to more elements of care, complex care procedures in cancer, diabetes, hypertension, organ transplantation, and other specialty areas. The cost of care can be variable. UC would study this to ensure that the quality of care improved without increasing the cost of care.

Regent Park asked about quantifying the value that the Center itself created, and if Dr. Butte felt that the Center was the right size. Dr. Butte responded that the Center had only two full-time staff members at UC Health at the Office of the President (UCOP). All others were on other campuses. It was a small team.

Regent Park expressed interested in seeing the Center grow at UCOP in addition to developing relationships. This work was critical to everything that UC Health wished to do. Dr. Byington concurred that this work was foundational. The platform for being able to follow patients through time needed to be established now. Investments made today would benefit research and patient care in the future. The Center's work was an important part of UC Health's strategic plan.

Regent Park commented that, as with the Leveraging Scale for Value initiative, it would be good to quantify the value of the Center's work to make the business case for this investment.

Regent Park referred to information in the annual report. There were two positions on the Center's oversight board that were "to be determined," one for business and innovation and one for patient voice. She asked when these positions would be filled. Dr. Butte responded that the Center intended to fill these positions in the next six months.

5. **ENDORSEMENT OF RECOMMENDATIONS OF THE UC HEALTH WORKING GROUP ON CLINICAL QUALITY, POPULATION HEALTH, AND RISK MANAGEMENT**

The President of the University recommended that the Health Services Committee endorse the recommendations of the UC Health Working Group on Clinical Quality, Population Health, and Risk Management for implementation by University of California Health, as shown in Attachment 1.

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Advisory member Spahlinger recalled that these recommendations were the product of 18 months of deliberations by the Working Group on Clinical Quality, Population Health, and Risk Management. These deliberations were informed by feedback from UC Health chief executive officers, chief medical officers, vice chancellors, and chief nursing officers. The recommendations were an important next step to drive systemwide improvement in quality and safety at all UC medical centers.

UCLA Chief Medical and Quality Officer Robert Cherry observed that the Working Group discussions fell into five categories which could be phrased as questions. The first question was that of overall clinical quality strategy. How are clinical priorities reflected in data and dashboards? Second, how does one leverage and align groups across a complex and distributed organization such as UC Health? UC Health addressed this with performance improvement plans, clinical leadership groups, and task forces. Third, how are data signals and concerns captured within the medical centers and escalated to the Health Services Committee, in order to inform action plans and strategies? Some examples of this real-time data capturing were patient data surveys, adverse event reporting, employee engagement surveys, and culture of safety surveys. Fourth, what is the relationship between the Working Group and the relevant Regents' Committees with respect to risk management? Fifth, how does one launch a collaborative structure for clinical quality that allows for in-depth discussion?

The Working Group recommended two essential goals: first, to drive systemwide improvement work that lifts the performance of all UC academic health centers; second, to provide the Health Services Committee with prioritized and timely information to support its oversight function for clinical quality and safety across UC Health.

The Working Group identified four essential elements of the UC Health quality framework. First, UC Health must be a learning health system with a value-based model of care. Second, UC Health must be aligned with quality domains identified by the Institute of Medicine/National Academy of Medicine. Third, UC Health wishes to be a high reliability organization, with zero harm and an optimal culture of safety. Fourth, UC Health must be mindful of the patient and employee experience.

In order to ensure coordination and oversight, the Working Group recommended the establishment of a UC Health Clinical Quality Committee, which would essentially continue the activities of the Working Group. The Clinical Quality Committee would collaborates with clinical leaders to recommend priorities each year; reviews quality and safety metrics, external benchmarks, trends, and actions taken; reviews each health center's inpatient and ambulatory quality and safety plans; monitors serious adverse events, especially with regard to required reporting to the State; and coordinate with the Regents' Finance and Capital Strategies and Compliance and Audit Committees to review items of shared interest.

The Clinical Quality Committee would recommend standards and expectations for corrective and preventive action plans, including oversight and progress reports, to the Health Services Committee and the Compliance and Audit Committee. The Clinical Quality Committee would work with Office of the President Risk Services and the Chief Risk Officers to share and disseminate lessons learned and best practices. This should be reflected in corrective and preventive action plans across the health systems.

The Executive Vice President – UC Health is strategically accountable for the quality framework. UC Health was currently recruiting for a Chief Clinical Officer. When this position was filled, the Executive Vice President would direct the Chief Clinical Officer to coordinate and oversee a value-based care performance improvement model across various UC Health task forces and teams. The Chief Clinical Officer would serve as the Chair of the Clinical Quality Committee, which would include representatives of all the UC Health campuses. The Clinical Quality Committee members would be chief medical, nursing, quality, and operating officers, chief risk officers, UC legal counsel, chief information officers, and a patient representative. Other expertise might be recommended to this Committee as well.

The Clinical Quality Committee would align UC Health metrics with the quality framework and short- and long-term priorities. The Committee would seek input on the metrics from the clinical and administrative leadership groups, recommend measurements and benchmarks to senior management and the Health Services Committee, use the resources of the Center for Data-Driven Insights and Innovations and the UC Health Data Warehouse to expand upon existing dashboards, and use Vizient as the academic health system collaborative for measurement, benchmarking, and performance improvement opportunities.

The Clinical Quality Committee's quality measurement should be guided by certain priorities and principles. The Committee must be mindful of healthcare disparities, seeking health equity for its patients and workforce, and attentive to patient and employee experience, population health, maintaining accessibility for Californians, quality and safety, and risk management.

Regent Zettel noted that these recommendations were a compilation or wish list of the Regents, goals that would help elevate the standards of UC Health in delivering high-quality care and pioneering the use of new technologies. Ultimately, this would lead to good outcomes for UC patients.

UCSF Dean Talmadge King asked if there would be representatives from the Schools of Medicine on the Clinical Quality Committee. Dr. Cherry responded that the medical centers' work on quality, safety, population health, and performance improvement is done collaboratively with the medical centers.

UC Irvine Dean Michael Stamos commented that, on many campuses, School of Medicine faculty report to the vice dean of clinical affairs. These vice deans or some representatives of UC Health faculty should be on the Clinical Quality Committee. Dr. Cherry responded

that this could be done. Vice President Nation noted that this effort had been intended as an inclusive endeavor, and she and others would take this concern into account.

Upon motion duly made and seconded, the Committee approved the President's recommendation, Regents Drake, Lansing, Makarechian, Pérez, Sherman, and Zettel voting "aye."

6. **REMOTE SERVICES OFFERED AT STUDENT HEALTH AND COUNSELING CENTERS**

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

Chief Medical Officer Brad Buchman reported that the student health and counseling centers had been very busy in caring for students who had decided to go home during the COVID-19 pandemic as well as continuing to care for students still on campus. He recalled that "stay at home" orders had been announced in mid-March. The student health and counseling centers realized that they had to do many things quickly, including establishing telehealth capacity de novo, without infrastructure in place. The centers worked to establish this capacity, to understand how electronic health records would be dealt with and how to maintain compliance with the Health Insurance Portability and Accountability Act (HIPAA), to train staff, and to try to secure waivers and guidance relating to interstate practice for medical and mental telehealth services. On this last point, UC had approached various State agencies with some success to seek change in official language which stated that providing telehealth care to a patient outside California was unprofessional conduct because the provider was not licensed in the state where the patient was residing. At the federal level, passage of the TREAT (Temporary Reciprocity to Ensure Access to Treatment) Act might address this need and remove concerns about discipline or actions by outside medical boards. This Act would apply to mental and medical care providers and be in effect during the duration of the COVID-19 pandemic.

In spite of the challenges of this time, the student health and counseling centers had built the capacity to offer a combined total of over 5,000 visits per week by the first week of April. Dr. Buchman presented a chart showing the numbers of student telehealth visits from July through September. About half of visits were medical visits, about 40 percent for counseling, and slightly less than ten percent for psychiatry. These numbers appeared to have remained constant through the fall. The student health and counseling centers offered a variety of types of telehealth visits; not only individual calls, but also couples therapy, groups, workshops, and drop-in sessions. Dr. Buchman presented another chart with data on telehealth visits by students in the UC Student Health Insurance Plan (UC SHIP), who represented about 45 percent of all UC students. From the beginning of calendar year 2020, about 23,000 students had made telehealth visits under UC SHIP, totaling about 110,000 visits. About three-quarters of the 110,000 visits were for mental health concerns and one-quarter for medical concerns. The average cost per UC SHIP telehealth visit was about $130. Mental healthcare visits were charged at a higher rate. The total paid for all these telehealth visits by the end of the data collection period, the end of September, was

about $14 million. On another chart, Dr. Buchman presented figures for total claims and average cost per visit for UC center visits versus other telehealth provider visits in the year 2020 to date. UC student health and counseling centers had received about 15 percent of the total claim amount and almost 30 percent of the visits. Dr. Buchman stressed again that the UC centers had had to build up telehealth capacity quickly, starting from nothing. The cost per visit with a UC provider was considerably lower than with a commercial telehealth provider, or 53 percent. There were a number of reasons for this. UC centers typically charged less for services and provided a blend of services that resulted in lower cost.

UC San Diego Health Associate Dean Lawrence Friedman noted that he had served as the physician director for the UC Telehealth Collaborative for a number of years. He reflected that COVID-19 had become the golden era of telehealth and telemedicine, which might eventually come to be called "virtual health" or "virtual care." The University's plan for a telehealth platform was called "UC Health Anywhere," and would provide health services to students and others. Because of the significant needs in student health, especially for mental health services, and the gap between supply and demand, UC Health Anywhere would begin in Year One with a focus on student mental health. All UC campuses provided telehealth, but one goal of this program was to have campuses collaborate, so that a student at one campus could be seen by a provider at another campus, if no provider was available at the student's campus. The program would provide new incremental services and not interfere with already existing services. In Year Two, the program would prioritize UC SHIP students and provide telehealth clinical care. The program would continue to grow in Year Three and develop the infrastructure to provide cost-efficient services to patients, hospitals, and payers across California. UC Health Anywhere was beginning with student health, but had a goal of growing beyond that, because there was a significant need for these services.

Dr. Friedman discussed the value proposition, the question of why one would choose UC telehealth services over commercial, for-profit services. UC would provide quality, leveraging providers across the UC system. In mental health, UC had world-class specialty services in the areas of substance abuse and eating disorders, among others. UC would offer convenience and easy-to-use technology. There was discussion ongoing about whether UC could move to a unified system for electronic health records. UC telehealth would expand to more cost-effective and efficient hours of coverage, work to improve coordination and sharing of information, work to provide better continuity of care, build referral networks within the UC system. This effort reflected the core values of the University, such as diversity, equity, and inclusion. The providers in the program should represent the diversity of the State of California and the diversity of the UC student body. Another element of the value proposition was that UC was a non-profit rather than a for-profit organization.

Beginning in April 2019, the program carried out a campus-by-campus student health assessment to determine needs and had begun working with a group of pilot campuses—Irvine, Santa Cruz, Santa Barbara, and San Francisco; the Berkeley campus might also participate. Among the deliverables for Year One, the program had created a governance council. It would recruit and hire staff. Dr. Friedman anticipated that, at the end of the

second year, the program would have hired an additional ten clinical providers. The program would pilot clinical services, including after-hours telehealth triage and, working with the governance council, establish patient satisfaction, provider productivity, and other quality benchmarks.

Future initiatives for the UC Telehealth Collaborative included additional service lines for UC students, a UC-wide tele-stroke collaboration, and eConsult coverage. The Collaborative had communicated with the UC SHIP foundation, and, at the end of October, was notified that it would receive funding over three years to launch its program. Dr. Friedman believed that the program would have achieved a sustainable business model in Year Three. Volume was critical for telemedicine, and there would be sufficient volume by Year Three to achieve this sustainability. The program was very cognizant of the fact that UC SHIP was providing this funding, but its goal would be to expand and provide services to all students, regardless of payer source.

Regent Leib asked how the number of telehealth visits compared to in-person visits the past year. Dr. Buchman responded that this information would be presented at an upcoming meeting as part of an annual update. There had been a decrease in the number of visits by students in spring. The numbers rebounded in summer, and students had higher numbers of visits with their providers. As shown by a number of different measures, student anxiety levels increased in spring and summer. Dr. Buchman noted that these conclusions were based on the students with whom UC counselors interacted. One could not speak for the state of students who were not interacting with counselors.

Regent Leib asked if telehealth was more efficient in providing quick care to patients. Dr. Buchman responded that for urgent issues, 99 percent of students were seen on the same day. For routine counseling appointments, the wait had decreased from about 11 or 12 days to seven days. Wait times for follow-up appointments were in the same range. Wait times for routine psychiatry appointments had decreased somewhat.

Regent Leib asked about offering telehealth services to rural Californians, and if this would be possible in the future. The University could charge for its services, and this would benefit the state. Dr. Friedman responded in the affirmative. This was one of the program's goals.

Regent Stegura asked about student input on the deployment of these services, since they were the target audience. Dr. Friedman responded that there had been focus group meetings with students on the UC SHIP board. There would continue to be discussions with students, and there were seats on the governance council for students.

Regent Reilly asked if UC was able to see any student who reached out to UC counseling centers in a timely manner, or to refer them elsewhere. Dr. Buchman responded that students were seen quickly for urgent issues. The campuses were currently using a short-term therapy model, which allowed access for all students, regardless of their insurance. If there was too large a number of students who needed weekly or frequent therapy, counselors would not be available for many other students. Complex cases requiring a high

level of care would be referred to community providers. Dr. Buchman hoped that, over time, more of these students could use UC telehealth services or receive specialty care at a UC medical center, if the student was at a campus with a medical center.

7. **MEDICINES PATENT POOL – CONSIDERING UNDERSERVED POPULATIONS WHEN LICENSING INTELLECTUAL PROPERTY**

[Background material was provided to the Committee in advance of the meeting, and a copy is on file in the Office of the Secretary and Chief of Staff.]

UCLA Health Sciences Vice Chancellor John Mazziotta explained that this item was a response to comments made during the public comment period at past meetings, to concerns that certain pharmaceutical products licensed by UC were either not available or not affordable in several low- and middle-income countries, and about making these innovations available to underserved populations. As one of the great public research universities in the world, UC had the opportunity and the responsibility to deliver these new discoveries to society. In the biomedical sciences, these were new medications, vaccines, devices, and procedures. Delivering these to the public required the prosecution of the associated intellectual property through licensing agreements with manufacturers. The University cannot produce these products, but gives licenses to commercial operators to produce them. These agreements were complex, highly competitive, and frequent. In the last six years, 14 new cancer drugs developed at UCLA had been approved by the U.S. Food and Drug Administration (FDA). The cost of bringing a new drug to market can exceed $1 billion. For this reason, licensees are loath to have any restrictions or conditions in licensing agreements. UC, as a great public research university, had an obligation to try to find mechanisms by which new life-saving or life-prolonging drugs can be made available to people in low- and middle-income countries. Students, faculty and others had spoken during the public comment period and stated that the University was not fulfilling this public obligation with regard to a prostate cancer drug developed by UCLA scientists and distributed by Pfizer.

After many discussions with students, faculty, and members of the pharmaceutical and biotechnology community, Dr. Mazziotta believed that the University had found one approach to this problem, through a non-profit organization based in Switzerland, the Medicines Patent Pool (MPP). MPP was backed by the World Health Organization and worked to bring medications to low- and middle-income countries. MPP had agreements with many leading pharmaceutical companies, particularly for drugs for the treatment of HIV, hepatitis C, and tuberculosis. Typically, MPP worked with manufacturers through a sublicense to deliver generic versions of a drug in countries where the primary licensee had little intent of making a profit. MPP worked with local governments and the World Health Organization to distribute these drugs.

Once a device or a drug was licensed, UC had limited leverage to influence the manufacturer’s actions with that license. In new licensing agreements from now on, UC would be able to include language to address this. The UCLA Technology Development Group had proposed an approach of including a requirement in new licensing agreements

for an Affordable Access Plan, which might involve the MPP. Once a drug was approved by the FDA or the equivalent body in another country, the licensee would deliver to the patent holder, UC, its plan for making the drug available. This process had been tested in the real world and had been well received.

There were pros and cons to this approach. The University had been concerned that adding restrictions or requirements to a license might drive manufacturers away from UC in commercializing products, but this had not been experienced during a pilot period. This approach provided an actual vehicle in future licensing to allow for this kind of distribution at low cost in low- and middle-income countries. Dr. Mazziotta had received feedback from intellectual property groups at all the campuses. Many campuses had taken approaches to this matter, but a systemwide approach would be preferable. He reflected that comments made during the public comment period were taken seriously by the University and had moved all the way to a solution that could make UC a role model in this area.

Committee Chair Lansing remarked that UC was listening, paying attention, and taking advice.

Regent Makarechian asked if MPP would give UCLA credit for the development of drugs and if the Research and Innovation Office at the Office of the President (UCOP) and its technology transfer group was in support of this approach. Dr. Mazziotta responded that MPP publicized the role of institutions in drug development. This approach had been presented to technology transfer groups on each campus and at UCOP; they viewed this as one of a number of potential tools to address this question.

Regent Park stated that MPP appeared to be a viable option for making drugs affordable in low- and middle-income countries. She referred to background material provided and asked about proposed language to be included in license agreements stipulating the Regents' right to request an Affordable Access Plan from licensees. She asked about the mechanism for ensuring this and if this would become a delegated authority to UCOP. Dr. Mazziotta responded that there was not yet a firm answer to this question. Research and Innovation at UCOP might have suggestions about the governance of this function. The Regents were the ultimate place where UC patents resided. Within that structure, one would have to determine how this delegation would be effected to achieve the goal making drugs affordable.

Regent Park noted that Regent Leib was chairing a working group on innovation and entrepreneurship. Regent Leib, Regent Park, and the working group would be interested in knowing how this would be implemented.

Regent Zettel asked about making drugs affordable in the U.S. Dr. Mazziotta responded that the view of major pharmaceutical and biotechnology companies was that they would not make profits in certain countries in any case. But the question of people who cannot afford a drug in developed countries like the U.S. was much more difficult. There was a global landscape with a dividing line that companies would accept. Dr. Mazziotta also

noted that most patents came from universities, while not many came directly from biotechnology and pharmaceutical companies. If universities were unified in their approach, there might be leverage to move in this direction.

UCSF School of Medicine Dean Talmadge King asked about having pharmaceutical companies dedicate a certain percentage of their profits to make drugs available for those who could not afford them. Dr. Mazziotta responded that pharmaceutical companies would not make such an agreement up front without leverage from universities in general. All possible strategies had been suggested as vehicles to solve this problem, which was a humanitarian issue.

Committee Chair Lansing observed that these questions of health inequity were also an issue for the federal government.

Student observer Medha Vallurupalli addressed student health and counseling concerns. Many students had returned home during the COVID-19 pandemic. For some this was local, while for others home was out of state or in a different country. This made a significant difference for accessing health and counseling services. Since the beginning of the pandemic, the need for mental health services had grown, with increasing rates of anxiety and depression among students. At this moment, students needed more mental health care, not less. Although all the campuses had transitioned to telehealth services, these services were for the most part limited to students residing in California. State licensure laws prevented UC clinicians from providing services to students outside California. The University's efforts to address this were commendable, and UC should continue to advocate for interstate telehealth services for UC students.

Student-to-counselor ratios were far above recommended averages. While hiring more clinicians was necessary in the short term, preventative mental health care could alleviate the burden on clinicians over the long term, reducing wait times for students and allowing for more consistent care. Mental health models across UC took a reactionary approach to mental health care. A heavy emphasis on Tier One support, including counselors and psychiatrists, placed a burden on clinicians to provide individualized support for an unsustainable number of students each year. Students would benefit from investment in additional Tier Two and Tier Three support programs, such as integrated prevention programs, targeted training for faculty, intervention programs, enhanced partnerships between counseling personnel and residential life programs, development of web-based mental health services, and creation of a centralized UC mental health services guide. The development of the UC Telehealth Collaborative would help address the need for additional mental health clinicians and make access easier for students. In this telehealth effort, Ms. Vallurupalli urged the University to be mindful of its core values of diversity and inclusion; its hiring practices should reflect the diversity of California's population. She thanked Executive Vice President Byington for being an excellent role model for women in the fields of science and medicine.

The meeting adjourned at 3:20 p.m.

Attest:

Secretary and Chief of Staff

University of California Health (UCH) Working Group on Quality, Population Health, and Risk Management:

Recommendations for the UC Health Services Committee

Last Revised: November 30, 2020

Introduction

The University of California Health (UCH) is committed to a Learning Health System that embraces a value-based care model for performance improvement (i.e., Value = Quality + Access ÷ Cost) and the development, implementation, and dissemination of evidence-based knowledge. UCH also recognizes the importance of and continuously pursues high reliability (zero harm). By identifying and reviewing *systemwide* metrics and best practices over the entire continuum of care and by comparing these to external benchmarks, UCH's steady aim is to move toward consistent care processes and outcomes; particularly for high volume, high variability care, and the major care delivery drivers of total cost of care.

Goals

The goals of these recommendations are: a) to drive systemwide improvement work that lifts the performance of all UC academic health centers and b) to provide the Health Services Committee (HSC) with prioritized and timely information to support its oversight function for clinical quality and safety across UCH.

Recommendations

1. **UCH should establish a systemwide quality framework** whereby initiatives, measurements and incentives are aligned with the Institute of Medicine's six quality domains: safe, effective, timely, patient-centered, efficient and equitable care.

2. **UCH should establish a Clinical Quality Committee (CQC)** to coordinate and oversee the quality performance of the UC academic health centers and report to the HSC at each of its regular meetings. Responsibilities of the CQC are proposed to include:

    a) Working in partnership with administrative and clinical leaders and individual health system governing bodies to establish and recommended UCH priorities and quality and safety metrics for each year including reviewing

each health center's inpatient and ambulatory quality and safety improvement plans;

b) Reviewing of UCH standardized quality and safety metrics at every HSC meeting, with trends and comparison to institutional and external benchmarks;

c) Reviewing of serious adverse events (by State definition) no less than twice annually;

d) Recommending to the HSC and Compliance and Audit Committee standards and expectations for corrective and preventive action plans, including oversight and progress reports
    - UC Office of the President Risk Services and the Chief Risk Officers should continue to share and disseminate lessons learned and best practices, often reflected in corrective and preventive action plans, across the health systems;

e) Coordinating with the Finance committee to review various items of shared interest.

3. **Management of the UCH quality framework and the CQC**

a) The Executive Vice President (EVP) of UCH should be strategically accountable for the quality framework.

b) The EVP should direct the Chief Clinical Officer (CCO) to coordinate the CQC and oversee a value-based care performance improvement model across various UCH task forces and teams.

c) The CCO should work collaboratively with administrative and clinical leaders across the system. Existing systemwide leadership teams should be leveraged and engaged, including but not limited to: the individual health system governing bodies, the Vice Chancellors and Chief Executive Officers, Chief Medical and Nursing Officers, Population Health Steering Committee, Chief Risk Officers, and Chief Financial Officers.

4. Membership of the CQC

a) UCH Chief Clinical Officer (chair) and representatives from each of the following systemwide health leadership groups: Chief Medical Officers, Chief Nursing Officers, Chief Operating Officers, Chief Risk Officers, Chief Quality Officers, UC legal counsel, Chief Information Officer, Patient Representative, and others as may be recommended by the Executive Vice President of UC Health or the CCO.

5. **Establishment of a UCH set of measures**

   a) The CQC should recommend a UCH standardized set of metrics aligned with the quality framework and tied to UCH short- and long-term priorities.

   b) The CQC should seek input on the UCH metrics from the clinical and administrative leadership groups mentioned above and should recommend measurements and benchmarks to senior management and the HSC.

6. Establishment of outcomes tracking and reporting

   a) The CQC should advise on internal and external dashboards and short and long-term UCH quality and safety objectives to be reviewed by the HSC and escalated to the full Board of Regents as deemed necessary by the HSC.

   b) The UC Health Data Warehouse (UCHDW), functionally owned by the UCH Center for Data Driven Insights & Innovation (CDI2), should be used to expand upon and complement existing internal dashboards.

   c) Specific clinical measures should be chosen in the context of the following overarching principles

      i. Measures will be tied to the UHC systemwide quality framework such as: patient, family, and employee experience, population health, access (geographic, care, price/affordability), health equity, quality, safety, risk management.

      ii. Healthcare disparities are recognized as a major public health concern and addressing them should be a primary strategic priority for UCH; related metrics should be reflected in our clinical measures and include health and health care equity in both *patient and workforce* outcomes.

      iii. The Vizient University Healthcare Consortium (Vizient) is currently UCH's main academic health system collaborative for measurement, benchmarking, and performance improvement opportunities.

   d) One example systemwide effort that reflects these principles is the UC Health FY 2021 Systemwide Clinical Objective and the accompanying UCH Executive Quality Dashboard that utilizes Vizient to report on the quality and safety measures and the quarterly Vizient ranking for UC Health in the aggregate and each UC health center (see appendix).

APPENDIX

The FY 2021 UC Health Systemwide Collaborative Clinical Improvement Objective

The purpose of the UC Health enterprise clinical objective is to develop sustainable, system-wide initiatives resulting in significantly improved clinical quality outcomes. The success of this initiative is important for UC Health to deliver efficient, high-value, and consistent clinical care throughout the entire enterprise. To support this system-wide approach, **the Clinical Improvement Objective for FY21 will be composed of five measures that span each of the six quality domain of the Institute of Medicine: risk adjusted mortality, 30-day all cause readmissions, CABSI SIR, HCAHPS Overall Rating, LOS Index, and Equity Points received.** The UCH Executive Summary of the Quality Dashboard will include these measures and, when available, the quarterly Vizient rankings.

UCH Executive Summary Dashboard: Inpatient (Q2 2020)

Domain	Mortality	Effectiveness	Safety	Patient Centeredness	Efficiency	Equity	Rank
Institution	**Inpatient Mortality**	**% 30 day Readmissions**	**CLABSI SIR**	**HCAHPS: Overall Rating**	**LOS Index**	**Equity Rank*, % Points Received**	**Vizient Rank***
UCD	0.74	13.77%	0.70	73.5%	0.98	1 / 98, 100%	57 / 98
UCI	0.37	12.04%	0.20	79.1%	0.76	1 / 98, 100%	10 / 98
UCLA - RR	0.52	11.25%	1.27	83.9%	1.02	32 / 98, 96.7%	13 / 98
UCLA - SM	0.59	12.17%	2.03	78.6%	0.96	39 / 92, 96.2%	36 / 92
UCSD	0.56	13.38%	0.75	81.9%	0.93	1 / 98, 100%	9 / 98
UCSFa	0.71	11.82%	1.35	81.8%	1.13	NR	65 / 98
UC Health	**0.59**	**12.52%**	**0.93**	**79.6%**	**0.97**	**NA**	**NA**

Median Nat'l Comparator Group	0.83	12.32%	1	72.6%	0.97	1	25