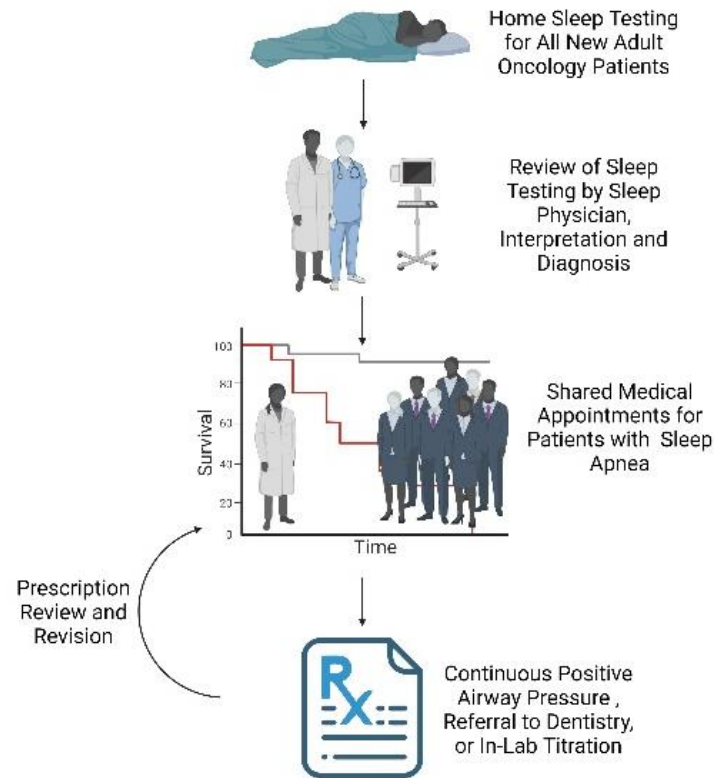


I. Innovation and Executive Summary

Overview of the Executive Summary

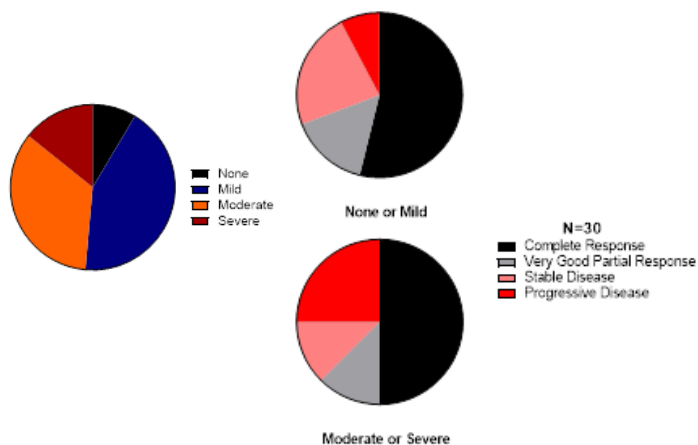
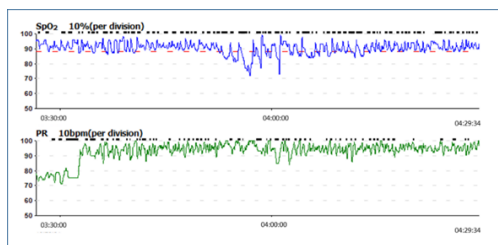
Summary: Good quality sleep is important for the treatment and resolution of most diseases. However, sleep medicine is traditionally tied with neurology, pulmonology, cardiology, or psychiatry, and this tradition has limited the influence of sleep medicine on other medical specialties. Oncologists, in particular, do not often collaborate with sleep specialists, partly because: 1) the sleep medicine clinic may be physically distant from the cancer center; 2) clinical availability of sleep specialists is often limited, and 3) sleep apnea tests have been traditionally difficult to be schedule and reimburse. Here, we illustrate a plan to full integrate sleep medicine into regular cancer care, with several innovations: 1) the creation of a dedicated sleep medicine clinic inside a large tertiary-care cancer center; 2) use shared medical appointments to expand the clinical availability of sleep specialists; and 3) same-day, ultralow-cost disposable home sleep apnea tests. Our plan will significantly improve the quality of cancer care and patient satisfaction and will serve as a role model to expand the reach of sleep medicine to other medical specialties and special patient communities.



Overall schematic of the Oncology Sleep Clinic at the University of Iowa Holden Comprehensive Cancer Center.

Introduction: “Changing Medicine, Changing Lives” are the words we live by at the University of Iowa Hospitals and Clinics. The Holden Comprehensive Cancer Center is a large academic tertiary-care cancer center, serving nearly 1,500 new patients a month, and is among the 71 designated by the National Cancer Institute (NCI) as a Comprehensive Cancer Center. Obstructive sleep apnea (OSA) promotes cancer aggressiveness, resistance to treatment, and increased cancer mortality, but **OSA is not routinely screened for or treated in cancer patients**. Our data in blood cancer patients suggest that a large number of these patients have obstructive sleep apnea that interferes with their quality of life and confers resistance to induction chemotherapy. Large epidemiological datasets support a strong link between overall increased cancer incidence and mortality and moderate-to-severe OSA. We recently performed the largest national survey of oncologists and found that few talk to their patients about sleep, few understand the guidelines, but most agree that sleep is important to cancer patients. Thus there is an underappreciated need for sleep specialists to support oncologists and develop solutions to treat sleep disorders in cancer patients. As an NCI-designated cancer center, the Holden Cancer Center will serve as a representative center to trial these novel approaches that address unmet patient care needs.

What is the solution? We propose that providing home sleep apnea testing (HSAT) will allow us to find and treat oncology patients with OSA, potentially improving their treatment response, quality of life, and overall survival. Several factors have limited our ability to provide comprehensive sleep treatment to oncology patients including limited clinical space, a primarily rural patient population that lives more than 50 miles from our hospital, and a large number of lower-income patients with less ability to travel. These are solved by the novel shared medical appointment model proposed here. The formation of an Oncology Sleep Clinic using HSAT and the Shared Medical Appointment Program model will, at last, provide screening and care for patients with cancer that may have been previously underappreciated by oncologists and are masked by their treatment and other comorbidities.



Data from the University of Iowa Holden Comprehensive Cancer Center Multiple Myeloma Clinic. An example of one hour of home sleep data from a 67-year-old man with multiple myeloma (top) showing 55 desaturation events per hour. 55% of patients have moderate-to-severe OSA (n=50, bottom left), and having moderate-to-severe OSA is associated with a decreased probability of complete response to induction chemotherapy and increased probability of progressive disease (bottom right) (Bates and Tomasson, in preparation).

What is our plan to change the paradigm of treating OSA in oncology patients? Despite the link between OSA and cancer mortality, and our data showing a link between OSA and chemoresistance, there are no universal guidelines to treat OSA in oncology patients. The new Oncology Sleep Clinic at the Holden Comprehensive Cancer Center will establish a protocol that conveniently and efficiently screens for sleep-related breathing disorders and other sleep disorders. Through home sleep apnea testing, shared medical appointments, and vigilant monitoring, a seamless process from the diagnosis of a sleep problem to treatment can be accomplished within 24 hours.

As Dr. Michael Tomasson addresses in our video, cancer patients often ask, ***“What else can I be doing to help with my own treatment?”*** Even in the unexpected scenario that treating OSA did not improve cancer survival directly, treatment improves fatigue, quality of life, and depressive symptoms, which are issues with a high degree of overlap in oncology.

Why is this the right time for this solution? Several recent events at the University of Iowa have created the “perfect storm” to set our program up for success. In 2018, Dr. Mertens and others developed an HSAT and Shared Medical Appointment Program to address a critical threat to our general medicine sleep clinic’s success – the long wait between HSAT and follow-up visits because of limited provider numbers and clinic space. Implementation of the Shared Medical Appointment Program decreased time to follow-up, improved patient satisfaction, and has substantially increased the number of patients that can be diagnosed and treated.

At the same time, Drs. Bates and Tomasson published their first data linking intermittent hypoxia, a feature of OSA, to the aggressiveness of multiple myeloma, an incurable cancer of plasma cells. They began collecting data in patients and found that **91% of multiple myeloma patients have OSA and 55% have moderate-to-severe OSA**. Patients with moderate-to-severe OSA were more likely to have a poor response to induction chemotherapy, which is associated with poor overall survival. Epidemiological evidence supports these findings in cancer patients, in general. This raised the question: How do we provide OSA testing and treatment to a potentially large number of patients?

What is the potential return on investment of a Sleep Oncology Clinic? We performed a rate of accrual analysis using the previous 36 months of data from our medical record to determine the number of patients that would be candidates for the Oncology Sleep Clinic and a “worst-case scenario” revenue analysis, assuming that reimbursements would not be made for patients with no or mild OSA. If only 10% have OSA and only their testing and treatment are reimbursed, our clinical will break even. If, as we see in our multiple myeloma patients, 55% of oncology patients have OSA and only their testing and treatment is reimbursed, our clinic will generate \$2.3M in revenue that can be reinvested to further grow our program. If all patients’ testing and treatment are reimbursed and the prevalence of OSA in all oncology patients is similar to what we found in multiple myeloma, we could generate up to \$3.9M in revenue.

II. Situation Analysis

Our group performed a comprehensive SWOT analysis to inform our plan. In this section, we discuss the key components of our analysis.

Table 1: SWOT Analysis of the Sleep Oncology Clinic at the Holden Comprehensive Cancer Center

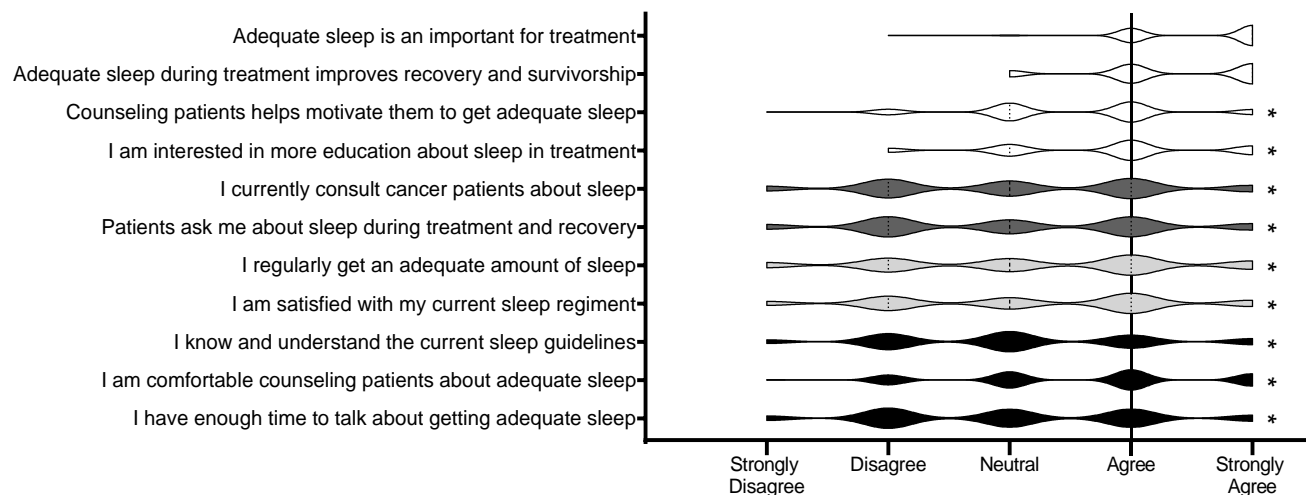
STRENGTHS	WEAKNESSES	OPPORTUNITIES	THREATS
<ul style="list-style-type: none"> • HSAT is inexpensive and can be performed at home. • HSAT is ideal for our rural patients who live >50 mi from our hospital. • World class leaders in oncology, physiology, and sleep with track records of collaboration. • Established shared medical model is ideal to accommodate the large oncology patient volume. • HSATs are disposable, so financial loss is lower if the device isn't returned • Large number of oncology patients support a financially sustainable program • Shared medical appointments can be virtual 	<ul style="list-style-type: none"> • HSAT and shared medical appointments are required for feasibility. • HSAT must be interpreted by board certified sleep physician, not oncologist or APP. • ~50% of patients are lower income and may be less able to travel to UIHC for visits • Current HSAT program is not housed in HCCC • Current HSAT program has only one sleep tech and APP • HSATs can still be uncomfortable and some patients may not tolerate testing • Preliminary data are in blood cancer patients and may under-estimate total oncology prevalence 	<ul style="list-style-type: none"> • Preliminary data supports link between OSA and an incurable cancer (Multiple Myeloma). Treatment may improve survival, QOL and outcomes. • Establishing shared medical appointments and HSAT in large groups would be a paradigm shift that could support implementation in other groups • Rural populations are under-served • The existing Molecular Epidemiological Resource in the HCCC will allow us to generate a large dataset linking OSA to outcome, which we will make freely available • Opportunity to pioneer virtual programming to increase patient education opportunities 	<ul style="list-style-type: none"> • Space is severely limited at HCCC • Insurance may not reimburse for HSAT in patients with a negative test • Risk of “over-treating” patients with mild OSA • Some patients may object to shared medical appointments • Community infection status (eg, COVID-19) may limit feasibility of shared medical appointments • Some patients may still need in-lab titration study following HSAT

Abbreviations: HSAT, home sleep apnea testing; APP, advanced practice practitioners including nurse practitioners and physicians' assistants; UIHC, University of Iowa Hospitals and Clinics; HCCC, Holden Comprehensive Cancer Center; OSA, obstructive sleep apnea; QOL, quality of life.

What is the evidence that OSA is important in cancer outcomes? There is a growing body of literature demonstrating that OSA is a potent driver of cancer, increasing tumor aggressiveness and increasing mortality. Investigators from the University of Wisconsin performed inpatient sleep studies in a cohort of 1,522 state employees and followed these individuals prospectively. Twenty-two years later, 30% of individuals with moderate-to-severe OSA had died of cancer (OR 2.0-4.8 compared to those without OSA), even patients who are not obese or excessively sleepy during the day. We became interested in the link between OSA

and multiple myeloma, an incurable cancer of bone marrow plasma cells. In 2019, we demonstrated that intermittent hypoxia, a feature of OSA, drives the terminal engraftment of malignant cancer cells in mice and promotes tumor aggressiveness (Ali, et al. AJP-Regu). We began screening our patients for OSA (Tomasson, et al. Int J Biol Sci, 2019), followed by home sleep testing, and found an astonishing 91% have OSA and 55% of them had moderate-to-severe OSA, which itself is linked to increased risk of cancer mortality. We evaluated their response to induction chemotherapy and found that patients with moderate-to-severe OSA were more likely to have stable or progressive disease after chemotherapy, which is strongly associated with decreased overall survival (See figure, Page 2). Similar links between OSA and mortality have been made in solid tumors including lung, colon, breast, and melanoma. Taken together, these data provide a strong rationale that OSA is likely under-diagnosed in cancer patients and, because of its tight link to poor survival and chemoresistance, there is a justification to screen and treat patients for OSA.

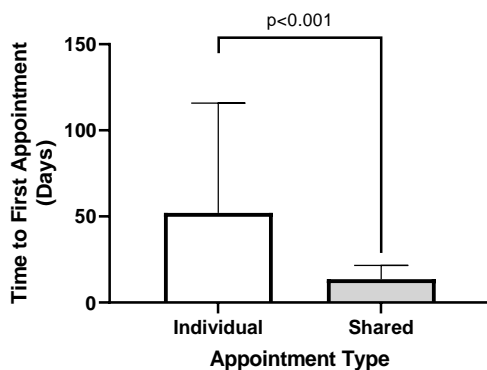
Why do oncologists need sleep provider partnerships to improve OSA treatment for their patients? We recently performed the largest national survey of U.S. oncologists to ask about attitudes toward sleep, diet, and exercise (n=239, Bates, et al. in preparation). Overall, providers agreed that adequate sleep is important for treatment and that it improves recovery and survivorship. They did not agree that they felt comfortable counseling their patients, that they had enough time to also treat their patients' sleep disorders, or that they understood the current guidelines. They also did not agree that they have enough time to discuss sleep with their patients or that they were interested in additional education. Taken together, these data indicate that oncologists would be receptive to partnerships with sleep medicine to treat oncology patients because they see the contribution of good sleep to patient outcomes, but they are not comfortable performing this counseling themselves and do not have time to add this counseling to their current workflow. We propose that partnerships between sleep medicine and oncology could provide a framework toward addressing this need.



Oncology providers' responses to statements about sleep (n=239). * indicates statements with which the providers did not agree (p<0.05).

What are the current challenges to providing treatment to our oncology patients? The Holden Comprehensive Cancer Center is the only comprehensive cancer center in Iowa, and the University of Iowa Hospitals and Clinics has the only academic sleep medicine clinic in Iowa with an ACGME-certified sleep medicine clinical fellowship. Around 47% of our oncology patients have Medicare or Medicaid as their primary insurance, half are lower-income, and many are rural and live more than 50 miles from our hospital. It can be very challenging for this patient population to access sleep medicine and oncology services in the community. Traveling to our hospital for a separate visit with the sleep clinic adds to the already high financial burden they face from their cancer care. Yet, we appreciate the importance of treating OSA in this population. The Shared Medical Appointment Program physically located in our cancer center, together with using low-cost disposable HSAT kits, is an ideal solution because HSAT can be delivered remotely, and shared medical appointments and follow up can be delivered in-person or remotely, depending on a patient's preference. The ability to offer some number of these appointments remotely addresses a potential threat to our program – the limited space currently available in the Holden Comprehensive Cancer Center, some patients' inability to travel, and a large number of patients that will likely be eligible for treatment. Without these progressive changes to our practice, we would simply not be able to treat oncology patients within our current infrastructure.

How do Shared Medical Appointments Provide an Opportunity to Expand Care to Oncology Patients?



Time to first appointment following home sleep apnea testing for patients completing a traditional individual medical appointment (n=221) or a shared medical appointment (n=201). Shared medical appointments decreased the time to first appointment by 38 days.

For both financial and ethical reasons, this was an unacceptable option.

Home sleep apnea testing is an alternative to polysomnography for the diagnosis of OSA and was initiated at the University of Iowa Hospitals and Clinics in 2017. During the first year, the demand for home testing outpaced the sleep clinic's ability to schedule patients for return visits as needed and patient complaints regarding long wait times escalated. Multiple solutions were evaluated to address the problem that patients were waiting a long time. One was to hire another provider. However, the process to recruit and hire a provider is lengthy. The second option was to shorten clinic visits from 30 minutes to 20 minutes to fit more patients into the daily schedule. This option would have compromised the quality of care and was unrealistic for staying on time. The third option was to suspend HSAT temporarily to address the

Shared medical appointments were implemented by Drs. Iannone and Mertens as a solution to address the growing wait time between testing and initiation of treatment. Shared medical appointments are face-to-face visits where multiple patients with the same diagnosis meet with a provider, and are utilized in other clinical settings to manage chronic conditions. The rationale to implement shared appointments as a solution to long wait times was that the educational content, initial treatment (auto-titrating positive airway pressure), and plan for subsequent follow-up visits varied little between patients. Instead of repeating the same content six times per day, it made sense to deliver the information one time per day to six-ten patients. Attending a shared medical appointment significantly reduced the time between testing versus a visit to receive results and start treatment by 38 days (52±64 days vs 14±8 days, $p<0.001$). Negative comments from patients regarding long wait times stopped. Based on our experience in the

general sleep medicine clinic, we realize that a dedicated oncology provider could offer 6 shared medical appointments a day, with 10 patients per appointment, and accommodate all of the patients seen by the Holden Comprehensive Cancer Center.

Can Shared Medical Appointments Improve the Longitudinal Treatment of OSA in Cancer Patients? OSA patients are most commonly treated with continuous positive airway pressure (CPAP) therapy, although a small group of OSA patients may be better treated with an oral appliance or hypoglossal nerve stimulation. Similar to the national average, our experience has been that at one year after starting CPAP, about 50% of patients use CPAP less than full time during sleep. After a follow-up visit with our sleep clinic, most of those patients improve their CPAP use, and patients who are better treated with non-CPAP therapies can be appropriately referred. Thus, our experience and nationwide research support the use of regular follow-up clinic visits to improve the longitudinal adherence to CPAP therapy. We foresee no issue using Shared Medical Appointments for these follow-up visits, similarly to how we use them to efficiently schedule initial clinic visits. Furthermore, because most cancer patients need to follow up at our cancer center at least annually, the follow-up visits will be scheduled to put the patient's Shared Medical Appointment (which is flexible) on the same day as the patient's cancer clinic follow-up visit. This will save the patients time and the cost of additional travel.

How is our team uniquely suited to pioneering OSA treatment for cancer patients? We have identified a unique group of individuals with a strong desire to improve outcomes in oncology patients by treating their sleep. The strong clinical and research track record at the University of Iowa, combined with a culture that encourages cross-disciplinary innovation and collaboration, has led to the formation of a group that already is forming a strong track record of collaboration. Several of the team members have shared grant support and collaborations, clinical collaborations, and Dr. Bates served as Dr. Mertens' mentor for her doctorate degree. This group already meets bi-weekly to discuss issues related to sleep and oncology and has grant funding around these ideas (Bates, et al, American Cancer Society). A core value of this group is a strong commitment to patient-driven, as opposed to patient-centered, care. We believe that empowering patients to participate in their care will improve outcomes.

Our team contains the following members:

- **Lisa Mertens, DNP, RRT**—Director for Patient Education and Shared Medical Appointments and Overall Program Director. Dr. Mertens developed the shared medical appointment model. She will direct the shared medical appointment program
- **Michael Tomasson, MD** – Professor of Internal Medicine (Hematology, Oncology, and Bone Marrow Transplant). Dr. Tomasson is a leading expert in blood cancer, Director of the Myeloma Molecular Epidemiological Resource, and Co-Director of the Cancer Genes and Pathways Program for the Holden Comprehensive Cancer Center. He will be the liaison between the cancer center and sleep medicine program.
- **Alexandra Iannone, DO** – Assistant Professor of Neurology and Interim Director, Neurology Sleep Lab will facilitate the relationship with Neurology.
- **Melissa Bates, PhD** - Associate Professor of Health and Human Physiology, Internal Medicine (Hematology, Oncology, and Bone Marrow Transplant) and Pediatrics (Neonatology), Director of the Leukemia Molecular Epidemiological Resource, is a leading expert in the short- and long-term impacts of sleep apnea, including the impact on cancer outcomes. She performed the initial data analysis for the shared medical appointment program in general sleep medicine will manage data collection and analysis for this new program.
- **Junjie Liu, MD, PhD** – Assistant Professor of Neurology, he will serve as lead interpreting physician for home sleep apnea tests

- **Loreen Curley, DNP, ARNP** – She will assist with shared medical appointments and follow-up
- **Scott Jones, RSPGT**—Lead Sleep Technician, will supervise the processing of home sleep apnea data and collection of treatment adherence reports

III. Solution Framework and Business Plan

What is Special About the University of Iowa Hospitals and Clinics in Iowa City, Iowa?

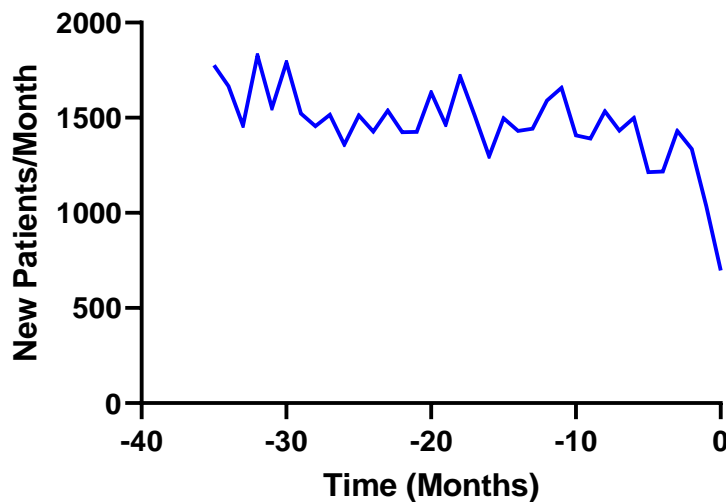
Forbes Magazine named the University of Iowa Health Care (UIHC) as the # 7 employer in the healthcare industry category and in the top 50 in all industries (2018). Forbes also places UI Health Care in the top 25 in the healthcare industry for its Best Employers for Women ranking (2018). UI Hospitals & Clinics was the first hospital in Iowa to be designated a Magnet Hospital (2004) by the American Nurses Credentialing Center (ANCC) and the first hospital in Iowa to be re-designated three times (2008, 2013 and 2018).

How Does Our Current Strategy to Treat OSA Support Increased Revenue?

Currently, home sleep apnea testing is offered only after a referral is made by a UIHC provider, and most referrals come from primary care providers. Home sleep apnea testing at UIHC has generated an additional \$7M in revenue and is a leading revenue source. Unlike a polysomnogram, the interpretation of the results of a home sleep apnea test is generally straightforward and can be done quickly.

We currently offer nine home tests per night and increasing that number will not overburden the

schedule of the interpreting sleep physicians. Given the evidence to support the high prevalence of obstructive sleep apnea in patients with cancer, an Oncology Sleep Clinic will identify patients who are not being treated and falling through the cracks.



Rate of accrual analysis based on 36 months of data. The average number of new patients seen is 1,423 per month (1,827 max and 897 min). Data over the last four months coincide with the COVID-19 pandemic and do not necessarily reflect typical clinic volumes.

We performed a rate of accrual analysis based on the past 36 months of data from our cancer center. On average, we anticipate seeing 1,423 new patients per month. Based on these projections, we will hire a 50% FTE (full-time equivalent) daytime sleep technician to assist Scott Jones, RSPGT, a 50% FTE sleep physician (Liu), and a 150% FTE sleep APP (Mertens and Curley)

Costs and Reimbursements Factored in Revenue Projection Modeling

Costs

- HSAT at \$90/Test
- 50% FTE Sleep Physician (\$125,000 plus fringe)
- 150% FTE APP and 50% FTE Sleep Technician (\$195,615 total)
- 31% Institutional Fringe Rate for clinical salaries
- Annual hospital floor space charges @ \$65/sqft
- Indirect costs of 15% on all revenue

Reimbursements

- \$168 average reimbursement per HSAT
- \$44.24 average reimbursement per shared appointment with 3/year/patient

Abbreviations: HSAT, home sleep apnea testing; FTE, full-time equivalent salary; sqft, square feet

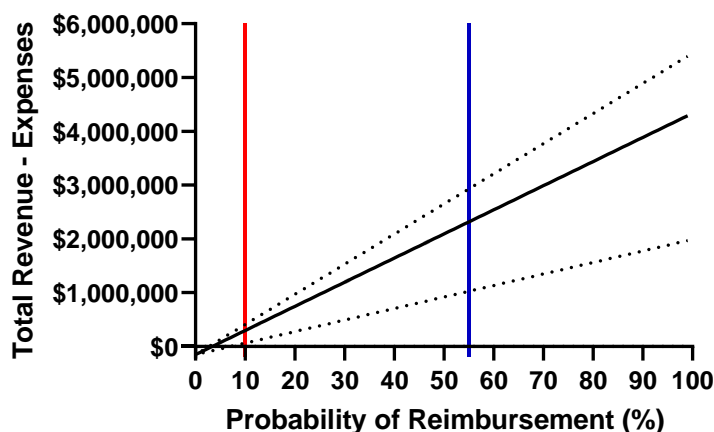
revenue that will be generated by our program. Reinvesting this income in our program could allow us to grow our research, teaching, and clinical missions, offset the important potential cost barriers discussed below, and better serve oncology patients.

By leveraging our own research, we plan to bring awareness to the link between OSA and cancer and the vital importance of an Oncology Sleep Clinic. As we collect data and secure resources for future study, we will establish a model for other disciplines in health care that will demonstrate an efficient strategy to identify and care for patients whose poor sleep is affecting their health.

What are our start-up requirements?

Start-up requirements for our program are \$12,807 to purchase one year's worth of additional home sleep tests, \$163,750 to support 50% time for an additional sleep physician, and \$283,500 to support an 100% FTE (full-time equivalent salary) a full-time oncology APP (Mertens), 50% FTE for a sleep technician and 50% FTE for an additional sleep APP.

We then performed a “worst-case scenario” revenue analysis based projected costs and anticipated revenue, assuming full reimbursement for different percentages of our patients and incorporating the costs of our program (see Table). If 10% of our patients require full treatment and we are reimbursed fully reimbursed, our clinic will break even and be self-sustaining. If we are reimbursed for the number of patients we expect to have moderate-to-severe OSA (55% of our patients, based on the data from our myeloma clinic), we anticipate \$2.3M in revenue and if 91% of our patients require treatment (the total percentage of our myeloma patients with OSA), and we are reimbursed for screening and treatment, we will generate \$3.9M in revenue. These revenue calculations do not include revenue generated from treatment (eg, CPAP, nerve stimulator implantation, etc.) and likely underestimate the true



Revenue analysis based on probability of full reimbursement for HSAT and shared medical appointments. Red line indicates the “break even” point of our program. The blue line indicates the prevalence of moderate-to-severe sleep apnea observed in our multiple myeloma patients. The solid black line represents the average number of all adult oncology patients and black, dotted lines represent the maximum and minimum number of patients seen at the Holden Comprehensive Cancer Center

Who are your most important partners? This is a new partnership between Hematology, Oncology, and Bone Marrow Transplant, The Holden Comprehensive Cancer Center, and Neurology. Buy-in and input from all parties will be critically important to the success of this endeavor. To be successful, we will need the cancer center to provide a physical footprint within the cancer center for shared medical appointments as it is not feasible for our patients to travel to the current sleep clinic. We will need buy-in from oncology providers to promote our program to their patients and from neurology to re-dedicate clinical staff. We will also need the support of marketing, scheduling, and operations to appropriately prepare patients for shared medical appointments

What are the activities you will perform every day to create and deliver your value proposition? Daily, we will screen patients seen in The Holden Comprehensive Cancer Center for OSA and provide a home sleep apnea test unit. For all patients with OSA, we will conduct shared medical appointments during which patients will be educated on the results of their home sleep apnea test, negative health consequences of untreated OSA, and options for treatment. Based on the severity of the OSA and the patient's preferred treatment option (determined during the shared appointment), positive airway pressure, nerve stimulation, or a mandibular advancement device can be prescribed. Some patients may need an in-lab titration study. Patients with mild OSA could be referred to their primary care provider, according to their preference. We appreciate that some patients will want to continue care that is coordinated with their oncologist.

Patients who start PAP therapy will be fully supported. Two weeks after the initiation of PAP, the sleep technician will obtain the report from the patient's device and contact the patient to address questions or concerns. When necessary, the sleep technician will arrange for an appointment with the advanced practice provider. Most of these appointments will be conducted in a shared setting. It will be the discretion of the sleep technician to arrange one-on-one appointments with the provider. Patients with moderate OSA who choose a mandibular advancement device will follow up with their dentist but will have the option of attending a shared medical appointment.

What is the value you deliver to your customer? Which of your customer's problems are you helping to solve? What is the customer need that your value proposition addresses? What is your promise to your customers? What are the products and services you create for your customers? The value to the patient is a better night's sleep and improvement of their OSA, which improves their quality of life and, potentially, their response to cancer treatment. The value to the UI Hospital is furthering the mission to change medicine and change lives by diagnosing and treating patients with cancer who are falling through the cracks. To remain an NCI-Designated Cancer Center, the Holden Comprehensive Cancer Center must show that it treats cancer truly comprehensively. The economic value to the hospital may reach millions of dollars per year. The value to the global medical community is the generation of evidence that supports the need to screen for and treat sleep disorders in patients with cancer.

What relationship does each customer segment expect you to establish and maintain? Patients will expect to be supported by having access to their care team. They will expect high-quality communication between teams in oncology and sleep medicine, which we already do through weekly tumor board programs. The UI Hospital will expect high quality patient care while keeping costs stable. As we discuss in our video, patients often ask what more they can do to participate in their own care. Addressing sleep disruptions requires patient partnerships with their providers and is an ideal arena to both empower patients and possibly improve their responses to chemotherapy.

What are resources do we need to create and deliver our value proposition? We have already created the foundation of the program in our general medicine clinic. To expand our program to oncology, we will need at least one half-time sleep technician, advanced practice provider, and board-certified sleep physician. We will need a meeting space for in-person shared medical appointments and equipment for virtual appointments.

How does our value proposition reach our customers? How will we display/share the economics of our idea to demonstrate feasibility? This plan will be presented to the medical and financial leadership teams of Oncology and Neurology. The evidence generated by Drs. Tomasson and Bates demonstrate the need for a sense of urgency and reason for UI Hospitals to act. Data exist that show shared medical appointments are an effective way to treat patients that are newly diagnosed with obstructive sleep apnea. And we have performed model projections of the feasibility in oncology. Patients will learn about the new partnership between Oncology and Neurology via social media, outreach to community providers, and the UIHC websites for each department, and internal communications done by the UIHC marketing team.

What are the important costs to create and deliver your value proposition? We foresee the cost of diagnostic sleep apnea tests as the most important and modifiable cost in our business plan. The last two decades saw a large expansion of the use of HSAT in clinical sleep medicine. HSAT costs much less than the standard polysomnography (in-laboratory attended sleep study, yet has comparable accuracy in diagnosing OSA, especially when the OSA is moderate or severe (AHI is above 15 per hour). Indeed, because of the attractive cost-saving, many commercial health insurances now require HSAT, and deny polysomnography, as the initial sleep study that is reimbursed. Traditionally, HSAT was designed as a simplified, “stripped-down” version of polysomnography, and included measurements of respiratory airflow and respiratory effort. These measurements often result in a relatively high price of the HSAT device, and can complicate the patient’s self-directed setup (e.g. it may be hard to set up the nasal cannula or the chest belt correctly). HSAT based on measuring the peripheral arterial tone (PAT) has significant advantages over the traditional HSAT. Probably the most studied and validated PAT-based HSAT device is the WatchPAT device (by Itamar Medical), which requires just a probe over one finger, a monitor worn on a wrist, and a probe taped on the anterior chest. This simple arrangement saves the hassles of measuring respiratory airflow or effort, and so is more user-friendly to patients than the traditional HSAT with comparable diagnostic accuracy. Furthermore, because PAT-based HSAT only requires a few probes, the material cost can be very low, to the extent that the entire HSAT device can be disposable after one-time use. For example, Itamar Medical recently introduced the WatchPAT One HSAT device, at a wholesale price (to medical providers) of just \$90 per device. The patient can receive WatchPAT One in the mail, take HSAT with self-directed set up, upload the data with the patient’s own Internet or cellular data connections, and then discard the device. This makes this a perfect solution for patients that are rural with limited resources to travel. While many of our rural patients may not have high speed internet access, most have access to cellular data.

WatchPAT One and other ultralow-cost HSAT devices are clear “disruptors” to the field of OSA diagnostics, and can “threaten” the current roles of health insurances and medical providers. Insurance reimbursement for a sleep study is notoriously cumbersome and stringent, largely as a vestige from decades ago before HSAT was available, and has changed little over time. Even now, when HSAT costs less than what most medications cost in a year, most insurances still require a medical provider to order the HSAT, with a prior authorization process that can take several weeks to approve the HSAT. This requirement has become a major financial and administrative barrier against diagnosing OSA. To circumvent this barrier, WatchPAT One can be purchased in retail pharmacies and even marketplaces on the Internet (e.g. amazon.com) at

an out-of-pocket price of \$250-300. This price often includes a brief consultation with a sleep medicine provider via telemedicine to explain the results of the HSAT. However, this arrangement threatens the patient's safety as well as the general reputation of sleep medicine, because the telemedicine-based sleep medicine provider is out of the patient's usual healthcare system, has no access to the patient's medical chart, and cannot provide quality care with continuity. Thus, the current environment implies new opportunities for sleep medicine providers to leverage the ultralow cost of disposable PAT-based HSAT devices.

To work around the barriers from insurances (third-party payors), and engage with our cancer patients to broaden their access to HSAT, we have made an innovative plan to use our revenue to **offer HSAT to selected patients at no cost** to them or their insurance. As discussed above, we have a large revenue cushion such that if just 10% of cancer patients have OSA, we can break even. Additional potential revenues, not included in this calculation, may come from in-laboratory sleep studies that may be needed for some complicated patients e.g. to optimize CPAP therapy, and may come from referring suitable patients to non-CPAP therapies (e.g. hypoglossal nerve stimulation) provided within our UIHC system. Thus, the projected financial cushion is large enough that we can afford to offer HSAT for free for certain patients who, at the discretion of the sleep medicine providers, have a high pre-test probability of having moderate or severe OSA or would experience additional financial toxicity as a result of participating in our program. The probability can be estimated using well-validated models, such as the STOP-BANG model. This approach to ensuring the engagement of cancer patients with moderate-to-severe OSA is akin to the business approach of maximizing market share with lower revenue per customer, and can result in positive financial gain in the long run. For example, although we may initially lose around \$100 by offering free HSAT to patients who likely have moderate-to-severe OSA, if these patients benefit from CPAP use and improve their quality of life through CPAP, they will follow up longitudinally with us, and such follow-up visits bring clinical revenues that will easily remedy the initial \$100 loss.

IV. Anticipated Impact

We anticipate that our clinic will newly diagnose moderate to severe sleep apnea in 50% of cancer patients. We anticipate that compliance with therapy will be at least 50%, given the motivation often seen in newly diagnosed cancer patients. At the very least, we anticipate that treating OSA will improve fatigue and quality of life. We hypothesize that treatment of previously undiagnosed OSA in our patients will also translate into improved responses to treatment. Although beyond the scope of this proposal due to the long-time frame needed for survival studies, we will integrate our data into the outstanding infrastructure at the Holden Comprehensive Cancer Center to examine the effect of OSA treatment on treatment response and survival in our patients. If we are correct, that sleep apnea contributes significantly to response to treatment, our program will serve as a model for others, changing national practice patterns, contributing to improved quality of life and better outcomes in patients across the US with malignancies.