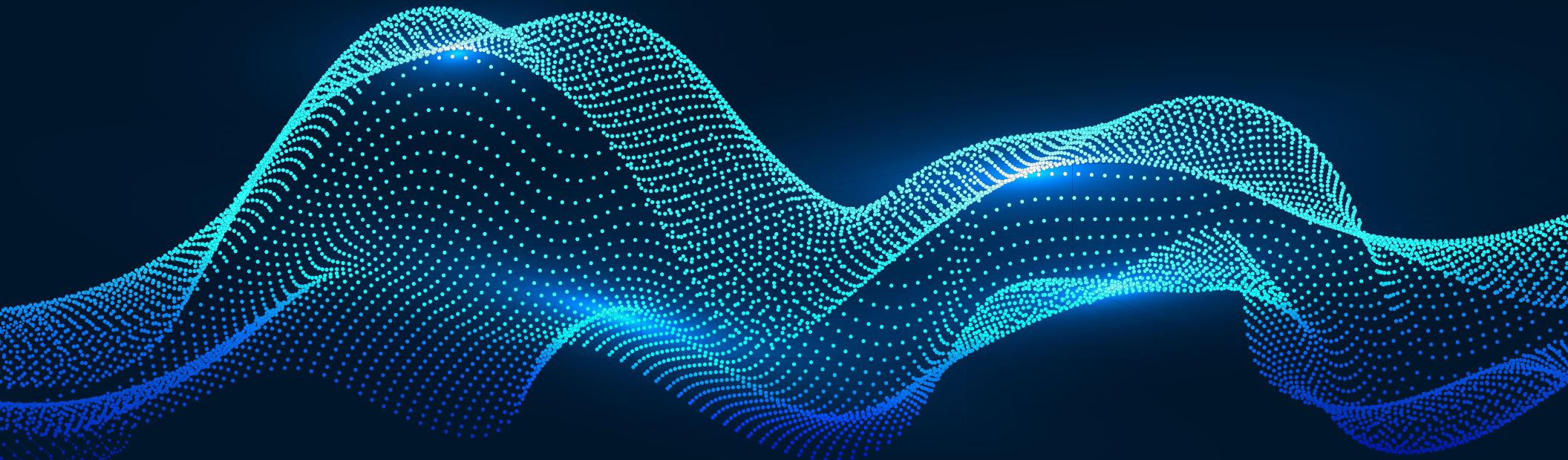
American Academy of SLEEP MEDICINE™

TECHNOLOGY REPORT:

Adapting to a Global Pandemic

April 2022



Introduction

In this report, members of the American Academy of Sleep Medicine's Emerging Technology Committee, in collaboration with the AASM Telemedicine Presidential Committee and Artificial Intelligence in Sleep Medicine Committee, highlight several clinical and consumer sleep technology advancements that increased in importance or came about as a response to the COVID-19 pandemic. Organized into **five themes**, this report dives into key sleep technology concepts and innovations of 2020-2021.

1

Interest in and use of consumer sleep technologies related to remote self-help and tracking increased during the pandemic.

2

With the expansion of telemedicine there is a growing interest in remote diagnostic and data monitoring technologies by both clinicians and patients.

3

Consumers and clinicians have an increased interest in new technologies with therapeutic potential.

4

There has been an expansion of artificial intelligence (AI), machine learning (ML), and deep learning (DL) to process multiple sensor and data sources to provide recognizable sleep data outputs.

5

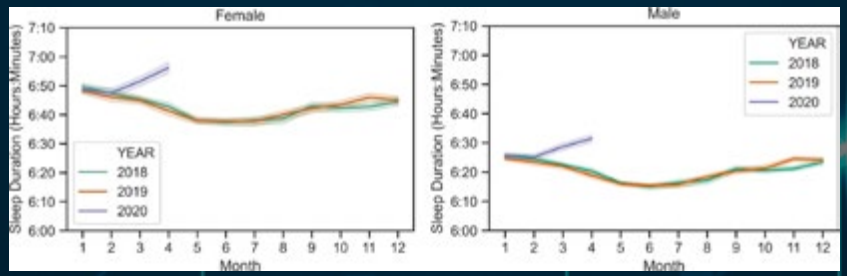
Consumer and clinical sleep devices/apps are big business, and sleep technology innovations continue to rapidly expand, often faster than supportive evidence for the product.

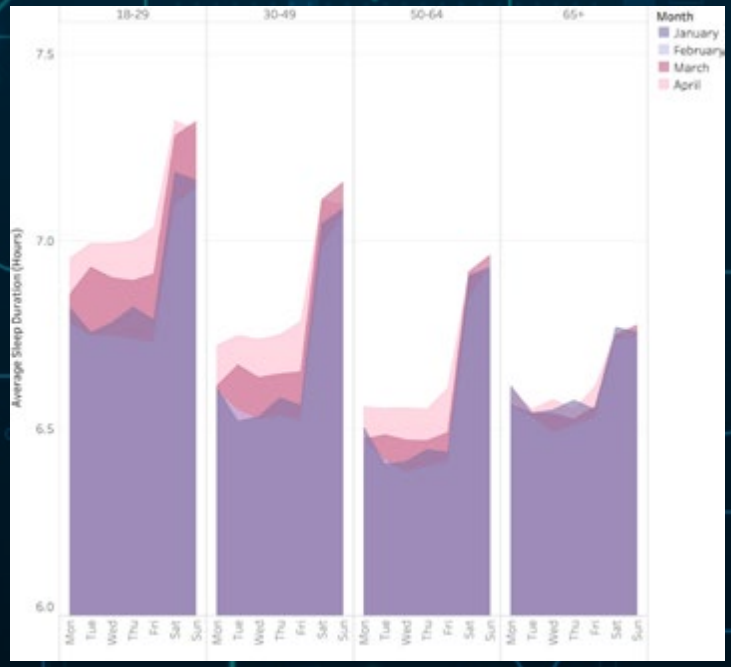
Interest in and use of consumer sleep technologies related to remote self-help and tracking increased during the pandemic.

Consumer sleep technologies (CSTs) have been utilized both personally and as a means of gauging the impact of the pandemic on sleep. CSTs can monitor sleep in individuals over long periods of time as well as provide broad population-based approximations of sleep. CST data have been utilized to examine the impacts of the pandemic on sleep in populations of different ages or occupations, such as health care workers.

A large-scale study using data from active Fitbit users in the U.S. shed light on sleep duration, timing, and variability during the COVID-19 pandemic.

"This study examined changes in sleep duration, sleep timing, and regularity in 163,524 Fitbit users in 6 major US cities: New York, Los Angeles, Chicago, Houston, San Francisco, and Miami from January through April 2020, during the COVID-19 pandemic, with additional analyses in May and June 2020. The overall results of these analyses show that over the course of the pandemic, adults experienced changes in sleep—especially duration and timing."





Source: Rezaei N, Grandner MA. Sleep Health. 2021 Jun;7(3):303-313
https://doi.org/10.1016/j.sleh.2021.02.008

With the expansion of telemedicine, there is a growing interest in remote diagnostic and data monitoring technologies by both clinicians and patients.

Diagnostic considerations include increased use of home sleep apnea testing overall—especially an increased interest in disposable home sleep apnea testing devices in the context of the pandemic.

Remote data monitoring has become increasingly important as a means of facilitating fruitful telemedicine visits, as well as selecting appropriate patients for remote visits compared with those requiring additional support during an in-person visit. Examples of such technologies include both consumer and clinician facing remote data monitoring CPAP applications.

The Telemedicine Presidential Committee highlighted the effects of the COVID-19 pandemic on the use of telemedicine. Their findings include:

1. Use of telemedicine increased during the pandemic.

   Both clinicians and patients gained a better understanding of how telemedicine can be used effectively for sleep care. Synchronous and asynchronous models of care delivery were found to be effective in the management of sleep disorders. Availability of asynchronous modalities such as home sleep apnea tests (HSATs) and remote PAP (positive airway pressure) monitoring increased access to sleep medicine care. Synchronous telemedicine services were expanded to include the out-of-center model of care delivery, in addition to the existing center-to-home and center-to-center models.

2. Regulations surrounding the use of telemedicine were altered temporarily during the pandemic to allow for increased use of telemedicine.

   CMS expanded telemedicine benefits on a temporary and emergent basis under the 1135 waiver authority and Coronavirus Preparedness and Response Supplemental Appropriations Act. This waiver allowed reimbursement for telemedicine services to patients all over the country, regardless of location, and allowed for telemedicine visits to occur while both patients and clinicians remained in their homes. Additionally, states eased restrictions temporarily to allow for cross-border practice by licensed clinicians.

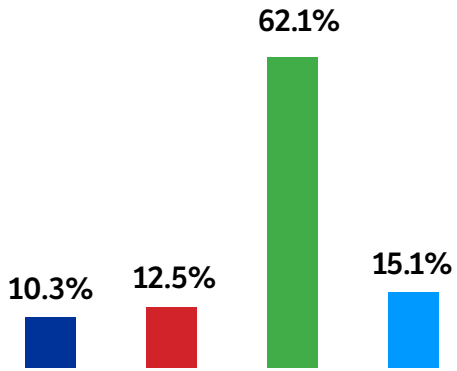
3. Further enhancements are still needed to improve the ease and efficacy of telemedicine visits.

   Easier methods are needed for integrating translation services into telemedicine platforms. A uniform database for uploading consumer sleep data for viewing during telemedicine visits is needed to augment clinical decision-making. Also, development of patient educational materials is needed to enhance efficiency. Finally, greater access to reliable networks of internet/broadband services, increased availability of telemedicine-enabled digital devices, and improved digital health literacy are all needed to overcome the geographic and socio-economic digital divides to make telemedicine accessible to all.

4. The long-term sustainability of telemedicine depends on governmental, regulatory, and payor support.

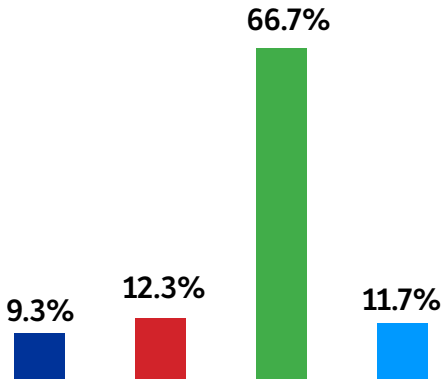
Post-pandemic utilization of telemedicine

(if telemedicine services are adequately reimbursed)



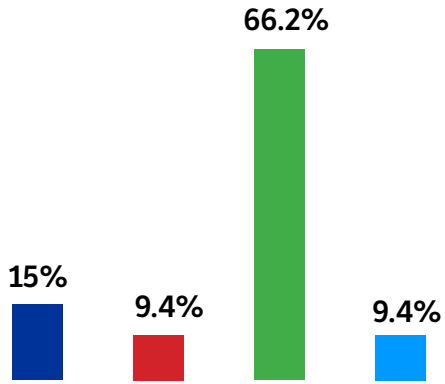
August, 2020:

551 Responses



December, 2020:

495 Responses



April, 2021:

234 Responses

Results from the 2020-2021 AASM COVID-19 pulse surveys

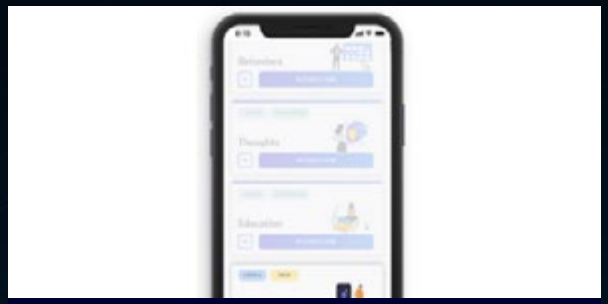
Less than pre-pandemic level | The same as pre-pandemic level | Greater than pre-pandemic level | Unsure

Consumers and clinicians have an increased interest in new technologies with therapeutic potential.

Technological innovation continues to drive development of therapeutic interventions for sleep disorders such as obstructive sleep apnea, central sleep apnea, insomnia, and PTSD-induced nightmares.

The AASM Emerging Technology Committee regularly posts assessments of new consumer and clinical devices in the #SleepTechnology resource. Representative examples of technologies evaluated on #SleepTechnology are listed below. Further details are available on #SleepTechnology.

A ring-like pulse oximeter sensor, the **Belun Ring** is a wearable device that claims to assess sleep apnea, stress, and sleep quality by using pulse oximetry, an accelerometer, and proprietary AI/ML algorithms.



Somryst, a prescription app that delivers cognitive behavioral therapy for insomnia, claims to improve the symptoms of chronic insomnia.

eXciteOSA's neurostimulator therapy is used on the tongue while awake; the induced muscle changes claim to reduce snoring and treat mild obstructive sleep apnea.

Using EEG, pulse oximetry, and an accelerometer, the **Dreem 2** is a wireless headband worn during sleep that claims to analyze physiological data to offer sleep staging and coaching to improve sleep quality.

A prescription app that runs on a watch during sleep, **Nightware** claims to reduce sleep disturbance related to nightmares by arousing but not awakening the user during a dream using vibration.

Using a proprietary valve-based positive airway pressure system, the **Somnera System** claims to treat obstructive sleep apnea by delivering therapeutic breathing pressure to the patient.

There has been an expansion of artificial intelligence (AI), machine learning (ML), and deep learning (DL) to process multiple sensor and data sources to provide recognizable sleep data outputs.

For example, many consumer and clinical technologies use AI (and ML/DL) to process data from integrated triaxial accelerometers, pulse oximeters, and heart rate variability (HRV) photoplethysmography (PPG) sensors. This processed AI/ML/DL data may provide sleep staging, apnea derivations, or interactive outputs.

Artificial intelligence was the driving force behind innovation that allowed for non-contact sleep medicine care and sleep research during the pandemic.

The Artificial Intelligence in Sleep Medicine Committee highlighted several developments relevant to sleep medicine providers.

1. Apnea detection from PPG
    - Photoplethysmography (PPG) sensors optically measure pulse wave signal. PPG inclusion in smart watches and fitness trackers provides pulse data and derived features to algorithms that attempt to predict sleep stages and may also be used to identify obstructive sleep apnea. An AI algorithm called auto-correlated wave detection with adaptive threshold (ACAT) was able to identify individual respiratory events and differentiate patients with AHI>= 15 with 82% sensitivity, 89% specificity, and 85% accuracy.
    - Therefore, the ubiquitous availability of PPG technology may allow for OSA diagnosis at scale.
2. AI to understand sleep and mental health from social media
    - The Valence Aware Dictionary and sEntiment Reasoner (VADER), an AI sentiment analysis tool, allowed for the analysis of tweets in pregnant women and identified anxiety, depressive symptoms, sleeping problems, and distress related to isolation during the COVID-19 pandemic.
    - AI provides powerful tools to extract themes from social media derived big data and reveals how global events impact our sleep.
3. Virtual sleep agent
    - KANOPEE is a smartphone application that uses decision tree architecture and interaction with the user's body motion and voice to act as a virtual agent that screens and provides interventions for insomnia. The virtual agent successfully reduced insomnia through personalized recommendations.
    - KANOPEE is just one example of the potential for AI based mobile apps to augment and extend the expertise of our behavioral sleep medicine providers to patients in need, regardless of location.

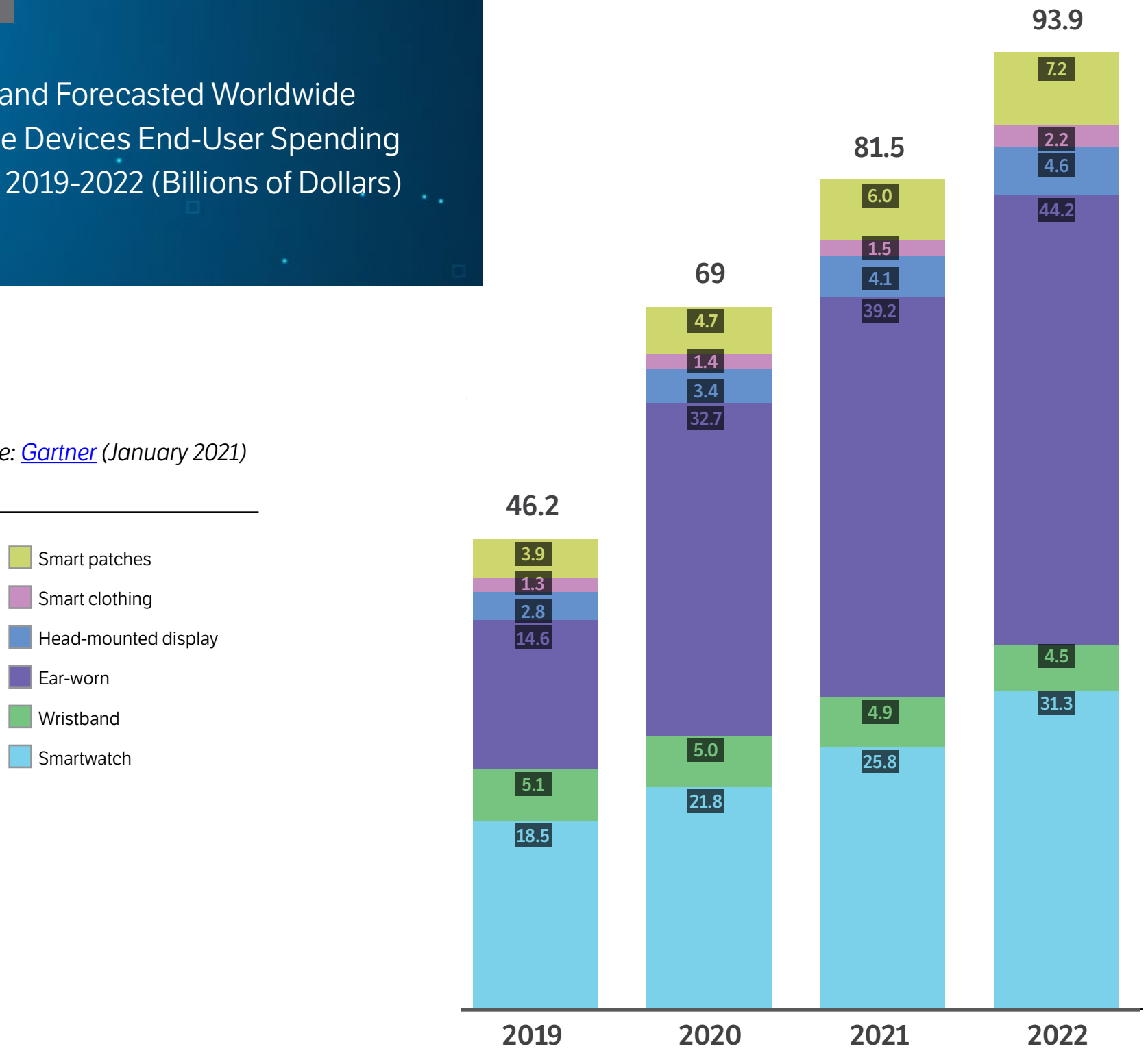
Consumer and clinical sleep devices/ apps are big business, and sleep technology innovations continue to rapidly expand, often faster than supportive evidence for the product.

Both wearable and nearable proprietary sensors and proprietary AI/ML/DL algorithms may be used to provide device/app specific data outputs. As such, a branded sensor or its applications may not be generalizable across devices. Thus, each device/app requires individual assessment.

In particular, clinicians want confidence in the device/app data outputs. While the technological innovations are exciting and promising, and some are FDA cleared or approved, the AASM Emerging Technology Committee has used caution when examining marketing claimed uses for each device/app against available evidence.

Past and Forecasted Worldwide Wearable Devices End-User Spending by Type, 2019-2022 (Billions of Dollars)

Source: Gartner (January 2021)



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