Tele- and Digital Health for Mental Health and Substance Use Disorders: The US Experience

Alisa B. Busch, MD, MS

Associate Professor of Psychiatry & Health Care Policy, McLean Hospital & Harvard Medical School

Chief Medical Information Officer for McLean and Behavioral and Mental Health, Mass General Brigham Healthcare System

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• Neither my spouse nor I have a financial or other relationships with a commercial interest producing, marketing, re-selling, or distributing health care goods or services consumed by, or used on patients.

#### Collaborators:

- Haiden Huskamp, PhD
- Ateev Mehrotra, PhD
- Michael Barnett, MD
- Ben Cook, PhD
- Constance Horgan, PhD
- Sharon-Lise T. Normand, PhD
- Pushpa Raja, MD, MSHPM
- Sherri Rose, PhD
- Jessica Sousa, MSW,
- Lori Uscher-Pines, PhD

# The U.S. Context

# U.S. Health Care

U.S. healthcare insurance market—patchwork of public and private insurance markets; not universal health care

- **Commercial/Private**: employer-sponsored health plans, individuals can also purchase
- Medicare: federal government program, elderly (age 65+) and disabled individuals
- **Medicaid:** federal-state joint funded; low-income adults, pregnant women, children
- VA: federal government program, veterans and their family members



Uninsured Private Insurance Medicare Medicaid VA

(U.S. Census Bureau, 2023)

# Prevalence of MH/SUD in the US

- 32% adults in US have a SUD or a MH condition
  - 5.9% (15.4 million) have SMI
- Co-occurring SUD & MH is common
  - 46.2% with SUD have co-MH
  - 33.2% with a MH have co-SUD
    - **48.0%** with severe mental illness have co-SUD

#### 2022 NSDUH



84.2 Million Adults Had Either SUD or AMI (with or without SMI)



#### Worsening Rates of Distress, Suicide & Drug Overdose



(CDC Youth Behavior Risk Survey)

Suicide rates increased 37% between 2000-2018 and decreased 5% between 2018-2020. However, rates nearly returned to their peak in 2021.



Figure 1. National Drug-Involved Overdose Deaths\*, Number Among All Ages, by Gender, 1999-2021



#### Many Who Need Treatment Do Not Receive It

2022 NSDUH







# Mental Health Workforce Shortages

Mental Health Care Health Professional Shortage Areas (HPSAs)



Darker = more areas with shortage of MH professionals

NH

RI





### Telemedicine

# Pre-COVID Studies Telemedicine Efficacy in MH/SUD Care

•Robust evidence for telemedicine similar in efficacy to in-person care for: •Assessments, depression, anxiety, PTSD, collaborative care models

•Less studied in:

•Schizophrenia, psychotic disorders, SUD, group therapy

•Some evidence it may be inferior for working alliance in psychotherapy, compared to in-person care (*Norwood et al, Clin Psychol Psychother, 2018*)

#### Pre-COVID, Telehealth in MH/SUD Care Was Low But Growing

#### Figure 1. Trends in Quarterly Telemedicine Visits for Rural Medicare Beneficiaries, 2010 to 2019 18 Visits Per 1,000 Individuals A Total visits quarterly B Per capita visits quarterly Tele-SUD Visits per 1,000 80000 Individuals with an SUD 1000 quarterly Telemental health Diagnosis terly 8 60000 Nonmental health telemedicine quart Tele-MH Visits per 1,000 sits Individuals with a MH Diagnosis ē 40 0 0 0 visits elemedicine tel 20000 fotal 2 0 2010 2012 2014 2016 2018 2020 2010 2012 2014 2016 2018 2020 2010 2011 2012 2013 2014 2015 2016 2017 Year Year

(Barnett et al, JAMA Health Forum, 2021)

(Huskamp, et al. Health Affairs, 2018)

Note: the scale is visits per 1,000 individuals

### Telemedicine During COVID



# Changes in Telemedicine Health Policy During COVID PHE

Coverage/reimbursement (for Medicare and most other payers)

•Payment for phone & video visits

•Expanded sets of services and providers eligible for telemedicine

•Patients can be at home in any geographical area (not just rural)

•For many, co-pays waived initially

#### Regulatory changes

•Licensure laws temporarily waived

•Federal privacy (HIPAA) rules relaxed

•Federal Ryan Haight Act requirement for in-person visit to prescribe controlled substances waived

#### OUD Medication Fills March-May 2019 & 2020

People on Recent OUD Medication Treatment (n=16,128 (2019), 18,068 (2020))





Percentage Receiving Prescription Fill for Medication to Treat OUD In A Given Week (commercial health plan population)

(Huskamp et al. JAMA, 2020)

#### Telemedicine OUD & MOUD Care Quality

- National commercial insurance data set
  - Observation periods: March 2019-2020 vs. March 2020-2021
  - N=1,768 providers who treat with MOUD & characterized them as low, medium, or high use telemedicine providers
  - N=11,081 patients with OUD
  - Patients attributed to providers (plurality of their OUD care)
  - Observed 1<sup>st</sup> 90 days of OUD care
- Outcomes
  - OUD visits
  - MOUD initiation
  - MOUD continuation
  - OUD clinical events (overdose, injection drug use related infections, detox/rehabilitation treatment)
  - Overall low rates of MOUD initiation, continuation, OUD clinical events
  - Provider proclivity to use telemedicine not associated with differences



#### Telemedicine & Outpatient Visits Among Medicare Beneficiaries with SMI

Figure 2. Differences in Outpatient Mental Health Utilization, 2019 vs 2020



• Outpatient use quickly rebounds.

•But fewer patients have any visits, even after six months (i.e., weeks 12-39)

(Busch et al. JAMA Network Open, 2022)

# Digital Divide

- In MH/SUD care: evidence of continued disparities in telemedicine use
  - Telemedicine (any type) less common among
    - Individuals living in lower income counties
    - Older age groups
    - Rural areas (in commercial insurance population)
  - Evidence mixed among racial and ethnic minorities

#### • Not limited to MH/SUD care:

- Videoconferencing lower among
  - Older age and elderly
  - Racial and ethnic minorities
  - Lower SES & education groups

### Telemedicine and Quality of MH Care

- •Medicare, SMI beneficiaries
- 2 cohorts, March-Feb (2018-2020, 2019-2021)
- •Attributed to specialty MH practice that delivered majority of the MH care
  - Practices characterized: lowest use (0-49%), middle use (50%-89%), highest use (90%-100%) in 1<sup>st</sup> year of pandemic

#### • Outcomes

- MH visits
- Hospital/ED visits
- All cause mortality
- Quality outcomes
  - Antipsychotic/mood stabilizer adherence
  - 7- & 30-day outpatient follow-up after hospital discharge
- Results—among patients seen in middle/highest TM use:
  - MH visits increased (~1 & 2 visits per year--~7% & 13% increase)
  - No change in med adherence, hosp/ED visits, quality outcomes
- How should we interpret these findings?

#### JAMA Health Forum.

#### Original Investigation

Use of Telemedicine and Quality of Care Among Medicare Enrollees With Serious Mental Illness

Andrew D. Wilcock, PhD; Haiden A. Huskamp, PhD; Alisa B. Busch, MD, MS; Sharon-Lise T. Normand, PhD; Lori Uscher-Pines, PhD; Pushpa V. Raja, MD, MSHPM; Jose R. Zubizarreta, PhD; Michael L. Barnett, MD, MS; Ateev Mehrotra, MD, MPH

#### (Wilcock et al, JAMA Health Forum 2023)

#### Figure 1. Two-Year Trends in the Mean Number of Mental Health Visits per Patient According to Practices' Use of Telemedicine



#### Is Telemedicine Leading to Increased MH Visits?

- Data from employersponsored healthcare
- 7 million beneficiaries, adults
- Jan 1, 2019-Dec 31, 2022
- Regression models adjusted for month, sex, state
- Telemedicine use remains robust through May 2022
- Net increase in MH visits (i.e., in-person + telemedicine)
- Is this a good thing or bad thing?



#### Rapidly Changing World Post-PHE

• Medicare has made some expansion permanent for MH/SUD, others TBD

•Permanent: rural not required, patient can be at home, expanded providers who are eligible to deliver services, audio-only (telephone) ok for SUD

•Clinicians will need to see patients in-person within 6 mo following PHE, and every year thereafter to continue with tele visits (delayed implementation).

•To Be Decided: parity for tele vs. in-person services (Dec 2024)

•Other insurers ?

• DEA proposed new rules around prescribing controlled substances via telemedicine after PHE

# Is Telemedicine Leading to Increased Prescribing of Controlled Substances?

- National, commercially insured population, Jan 2019-April 2022
  - Children 2-17 (N=535,629)
  - Adults 18-64 (N=2.1 million)
- Mean monthly adjusted stimulant initiations/100,000 enrollees, pre-vs. during COVID
  - Children: similar (57 vs. 56 initiations)
  - Adults: increased (27 vs. 33 initiations)
- Initiations via telemedicine were common
  - Peaked April 2020 (53%-57%); dropped to 14% (children) and 28% (adults) in April 2022
  - More common among psychiatrists vs. other prescribers
- Follow-up care within 30 days  $\uparrow$  among those with telemedicine initiation vs. in-person care
  - Children OR[95%CI: 1.09[1.00-1.19]; adults: 1.61[1.53-1.69]



Trends in Use of Telemedicine for Stimulant Initiation Among Children and Adults (Huskamp et al, Psychiatric Services, 2024)

## Prescribing Trends for MH Medications

- National dataset of prescription fills, 2018-2022
  - 94% of US prescription fill activity
  - Commercial, Medicare, Medicaid, self-pay
  - 105.5 million prescription fills
- 5 classes of medications
  - Antidepressants, benzodiazepines, ADHD meds (stimulants, non-stimulants), buprenorphine (MOUD)
- Incident fills (51.5 million prescription fills)



# Summarizing What We've Learned

- Telemedicine preserved access to MH/SUD care rapidly and early in the pandemic
- Some inequities in access to telemedicine—digital divide remains a concern
- Early, limited evidence during COVID suggest quality & outcomes at least comparable to in-person care
- Mixed evidence as to whether there are more visits with telemedicine
- Stimulants commonly prescribed via telemedicine and disproportionate increase in stimulant prescribing since COVID compared to other MH/SUD medications—does this reflect better, appropriate access or overuse?

### To Be Learned in the Future

• How will changes in Medicare/other insurers telemedicine rules change the future role of telemedicine in MH/SUD care?

• What effect will the DEA rules (when finalized) have on telemedicine care for controlled substances in MH/SUD care?

•What will be the effect on telehealth companies?

•What models of care (tele-only, hybrid, in-person) are associated with better outcomes, and for which patients?

• How best to improve equity in access to telemedicine

•Is audio-only an important tool to improve equity? Or, is it inferior care?

# **Digital Mental Health**

## Forms of Digital Mental Health

- Diagnostics (including wearables)
- Therapeutics (Software as a Medical Device (SaMD))

Apps (software for self-management/wellness tools)
 Often direct-to-consumer

•Companies that aim to expand access to care (medication, psychotherapy), venture capital/private equity funded, commonly use apps as part of care

- •Direct-to-Consumer (D2C)
- •Business-to-Business (B2B)

•Contract with health plans, businesses to expand access to care for an enrollee/employee population

•Some can include in-person services

# **Digital Therapeutics**

- •FDA approved, SaMD
- SUD, ADHD, VR for exposure therapy

•Payment approaches unclear (formulary/benefit design, NDC codes)

#### •RESET/RESET-O

- •1<sup>st</sup> FDA approved SaMD (2018)
- Adjunct treatment (not stand alone)
- 12 weeks

•Contingency management

•Clinician tools/dashboard

•Unable to secure insurance contracts to be on formulary by insurers

•Parent company (Pear) filed for bankruptcy April 7, 2023.



(K Jennings, Forbes, March 17, 2023)

#### Apps

#### Wellness Apps (unregulated)

- •Hundreds on the market; most unevaluated
- •Focus on wellness, not illness (otherwise get regulated by FDA)
  - •Depression, anxiety management, meditation, wellness management most common
- •Among those evaluated, inefficacious or small effects
- •Some with safety concerns (e.g., incorrect suicide hotline numbers, harmful content from conversation agents using Large Language Models—e.g., Chat-GPT)
- Commonly not transparent (or outright lie) re data gathering or sharing
   Collect personal information (e.g., contacts, details of MH/SUD, diary information)
   Don't need to adhere to HIPAA
   Often share data with 3<sup>rd</sup> parties

Huckvale et al JAMA Netw Open, 2019. doi: 10.1001/jamanetworkopen.2019.2542

Ma et al. arxiv 7/28/2023 DOI: https://doi.org/10.48550/arXiv.2307.15810

#### Digital MH/SUD Companies: Quality of Care

#### • Limited evidence of impact on clinical outcomes

- •Most research (that exists) has weaker experimental designs (i.e., pre-post), no RCTs
- •Lot of early drop off (similar to in-person care)
- •Show patients who continue with services improve in symptoms
- •Concerns about "regression to the mean" (no comparison group)

#### •Some evidence of potential for incentivizing prescribing by clinicians

- •Clinicians who prescribe medication get higher
- scores/ratings by patients
- •Patients who receive prescriptions come back for more frequent visits

#### Use of Direct-to-Consumer Telemedicine to Access Mental Health Services

Jessica A. Hohman, MD, MSc, MSc<sup>1,2</sup>, Kathryn A. Martinez, PhD, MPH<sup>1</sup>, Amit Anand, MD<sup>3</sup>, Mark Rood, MD<sup>2</sup>, Trejeeve Martyn, MD<sup>4</sup>, Susannah Rose, PhD<sup>5</sup>, and Michael B. Rothberg, MD, MPH<sup>1,2</sup> J Gen Intem Med 37(11):2759–67 (2022)

#### **Cautionary Tales**

- **Cerebral**—online MH company, focused on depression and anxiety
  - With relaxation of Ryan Haight Act during pandemic, began to prescribe stimulants for ADHD
  - Accusations of inappropriate stimulant prescribing (and other quality concerns) as per news accounts
  - May 2022, Cerebral announces their clinicians will not longer prescribe stimulants
  - Justice Department opens investigation—possible violation of Controlled Substances Act

تهد New York Times Why Are Ketamine Ads Following Me



# **Digital Health Companies & Privacy**

- GoodRx
  - Online telehealth and pharmaceutical company
  - FTC fines \$1.5 million
  - FTC alleges shared personal health information with advertisers (Facebook, Google, Criteo) since 2017



#### • Cerebral

- Shared sensitive patient information with Google, Facebook, TikTok since 2019
- Names, addresses, IP addresses, appointment dates/times, MH assessments and related data
- 3.1 million individuals affected



#### Future

- Inadequate regulatory oversight
  Establish safety/efficacy of products
  Establish privacy standards
- Are digital health companies addressing the needs of individuals across the spectrum of severity and from traditionally underserved populations?
- •More focus on establishing outcomes of the care delivered by digital health

#### FIRST OPINION

#### We need a way to tell useful mental health tech from digital snake oil

By Thomas R. Insel April 12, 2023

STAT



(STAT, April 12, 2023)

#### A Future of Opportunity....And Challenges

- Digital health & data science offer new opportunities to
  - •Develop new models of care
  - •Improve access to care
  - •Help us monitor our patient outcomes, and population health
- But, still have a lot to learn/work on....
- Ensure these new tools are evaluated and implemented with an equity lens
- **Telemedicine:** How will post-PHE regulatory/health insurance policy changes impact telemedicine care (parity, in-person visit requirements, DEA & controlled substances)
- **Digital therapeutics:** What does the financial path forward look like?
- **Digital health companies:** Will there be a regulatory approach to ensuring a minimum standard of privacy, quality and safety? How will DEA controlled substances rules impact these companies' ability to provide care ("good actors" and "bad actors")?

Thank you

### **Additional Slides**

### Perceived Effect of COVID on Mental Health

2021 NSDUH



Not at all



A little or some

Quite a bit or a lot


#### **COVID** Perceived Effect on Substance Use

Started or increased substance use to cope with stress or emotions related to COVID-19		
	OR [95%CI]	
Received treatment for		
Anxiety vs. not	2.3 [1.9-2.7]	
Depression vs. not	2.1 [1.8-2.5]	
PTSD vs. not	3.8 [3.2-4.4]	



• Individuals with MH conditions more likely to use or increase substance use due to stress/emotions related to pandemic

### Prevalence of MH/SUD in the US





# Exacerbated by nearly half of psychiatrists do not take insurance

Percentages of office-based physicians who accept given insurance in a year



(Bishop, JAMA Psychiatry, 2014)

#### MH Advanced Practice Nurse Supply

By Arno Cai, Ateev Mehrotra, Hayley D. Germack, Alisa B. Busch, Haiden A. Huskamp, and Michael L. Barnett

Trends In Mental Health Care Delivery By Psychiatrists And Nurse Practitioners In Medicare, 2011–19 (Health Affairs, 2022)

Psychiatrist and psychiatric mental health nurse practitioner (PMHNP) supply in US states with full scope of practice, by urban or rural location, 2011–19



#### Changes in the Organization & Financing of Care

#### Alternative Payment and Delivery Models

- •Accountable Care Organizations
- •Pay-for-Performance

#### • New treatment models

- •Collaborative care
- •Hub and spoke
- •No "wrong door"

•Digital "First-Door" Options/Apps

#### **COVID Perceived Effect on Substance Use**

2021 NSDUH



■ A little less or much less ■ About the same ■ A little more or much more



#### Telemedicine plays large role in maintaining healthcare access, particularly for behavioral health

#### Telemedicine visits as a percentage of baseline



Mehrotra et al, Commonwealth Fund, Feb. 2021, <u>https://doi.org/10.26099/bvhf-e411</u>

#### OUD Visits in March-May of 2019 & 2020 Percentage receiving visit in given week



Weeks in March/April/May, Starting March 1st

Weeks in March/April/May, Starting March 1st

Note: This study uses 2019 and 2020 claims data from the OptumLabs<sup>®</sup> Data Warehouse. The panels include individuals who were continuously enrolled in medical, behavioral health, and pharmacy benefits for January through May of the year in question. The vertical line corresponds to the date of Medicare's announced expanded telehealth coverage for the COVID-19 pandemic on March 17, 2020 (week 3). Recent OUD medication treatment is defined as at least one OUD medication fill in January or February of a given year. Among those on recent OUD medication treatment in 2020, OUD visits delivered via telemedicine increased from 0.48% in week 1 to 23.53% in week 13. Among those not on recent OUD medication treatment, OUD visits delivered via telemedicine increased from 0.60% in week 1 of 2020 to 31.82% in week 13.

(Huskamp et al. JAMA, 2020)

OUD Urine Tests in March-May of 2019 & 2020 Percentage receiving test in given week

People on Recent OUD Medication Treatment (n=16,128 (2019), 18,068 (2020)) People Not on Recent OUD Medication Treatment (n=6,127,513 (2019), 5,970,239 (2020))



Note: This study uses 2019 and 2020 claims data from the OptumLabs<sup>®</sup> Data Warehouse. The panels include individuals who were continuously enrolled in medical, behavioral health, and pharmacy benefits for January through May of the year in question. The vertical line corresponds to the date of Medicare's announced expanded telehealth coverage for the COVID-19 pandemic on March 17, 2020 (week 3). Recent OUD medication treatment is defined as at least one OUD medication fill in January or February of a given year. Among those on recent OUD medication treatment in 2020, OUD visits delivered via telemedicine increased from 0.48% in week 1 to 23.53% in week 13. Among those not on recent OUD medication treatment, OUD visits delivered via telemedicine increased from 0.60% in week 1 of 2020 to 31.82% in week 13.

(Huskamp et al. JAMA, 2020)

### Digital Divide

- CDC Pulse
- National Survey of US households
- •Not limited to MH/SUD care
- •Weekly household surveys
- April Oct 2021: any telehealth
- July 2021– Oct 2022: type of tele
- ~808,000 respondents

		Any tele	Video enabled tele
		OR (95%CI)	OR (95%CI)
Age	18-24	1.06 (.96, 1.16)	1.67 (1.31, 2.13)
	25-39	1.19 (1.12, 1.26)	1.51 (1.38, 1.66)
	40-50	1.35 (1.28, 1.43)	ref
	55-64	1.39 (1.32, 1.46)	.70 (.64, .77)
	≥ 65	ref	.37 (.33, .41)
Race and Ethnicity	Latino/a	1.27 (1.22,1.33)	.74 (.66, .83)
	Black	1.36 (1.30, 1.42)	.85 (.76 <i>,</i> .96)
	Asian	1.02 (1.20, 1.35)	.55 (.47 <i>,</i> .64)
	Multiracial/other	1.27 (1.20, 1.35)	.98 (.84, 1.14)
	White	ref	ref
Education	< high school	.91 (.78, 1.05)	.50 (.35, .71)
	high school or GED	.77 (.74, .80)	.60 (.54 <i>,</i> .66)
	some college	.95 (.92, .97)	.81 (.75 <i>,</i> .86)
	Bachelor's or higher	ref	ref
Household Income	< \$25,000	1.41 (1.34, 1.48)	.61 (.54 <i>,</i> .69)
	\$25,000-\$34,999	1.27 (1.21, 1.34)	.61 (.54, .70)
	\$35,000-\$49,999	1.15 (1.10, 1.21)	.69 (.61, .79)
	\$50,000-\$74,999	1.06 (1.03, 1.10)	.76 (.69 <i>,</i> .84)
	\$75,000-\$99,999	1.03 (.99, 1.07)	.82 (.74, .91)
	≥\$100,000	ref	ref
Insurance	Medicare	1.70 (1.62, 1.79)	1.23 (1.09, 1.38)
	Medicaid	1.36 (1.30, 1.44)	.99 (.87, 1.13)
	Other	1.24 (1.13, 1.35)	.97 (.78, 1.22)
	Uninsured	.35 (.32, .38)	.73 (.57, .94)
	Private insurance	ref	ref

(Karimi et al, US ASPE, 2022)

# Telemedicine Preserves MH/SUD Visit Capacity During COVID Surge

- Large integrated healthcare organization, Boston area
- 53,000-73,000 patients seen per year
- During surge
- Non-MH/SUD visits decline
- MH/SUD visit increase
- Largely due to increases in primary care MH/SUD visits



(Yang et al, Gen Hosp Psychiatry, 2020)

### In FQHCs in California, in-person BH visits way down through summer 2020 and very high use of telephone only



Figure. Primary Care and Behavioral Health Visits per 1000 Patients by Visit Type From February 2019 Through August 2020

The rate of visits per 1000 patients was calculated by summing all visits each month across health centers and dividing by 1731326, which is the sum of all unique patients seen across all health centers in 2019. Primary care visits were defined as visits delivered by primary care clinicians including physicians (internal medicine, pediatrics, and family practice), nurse practitioners, and

physician assistants. Behavioral health visits were defined as visits delivered by specialty behavioral health clinicians credentialed by the health center. For 2 participating health centers, in-person visit volume was imputed for February through April 2019; these data were missing due to changes in electronic health records.

### Digital Divide—Rural Population

#### Despite growth, rural Americans have consistently lower levels of technology ownership than urbanites and lower broadband adoption than suburbanites

% of U.S. adults who say they have or own the following



Source: Survey conducted Jan. 25-Feb. 8, 2021.

PEW RESEARCH CENTER

Some digital divides between rural, urban, suburban America persist | Pew Research Center

## Telehealth & Provider Shortages

- Telehealth can improve access to care when geography imposes challenges, but critical shortages remain.
- Licensure laws are further impediment because they are state-based.



### Do Patients Have Choice?

- Mixed methods study
  - National survey of adults who received psychotherapy/med visits (N=571)
  - Qualitative interview participants (21 bipolar disorder; 5 depression)
- Among survey respondents receiving psychotherapy or medication visits
  - ~1/3 reported clinicians offered only one choice (tele vs in-person)
    - Psychotherapy: ~2/3 telemedicine only, ~1/3 in-person only
    - Medications: ~1/3 telemedicine only, ~2/3 in-person only
  - Among respondents with providers who used both telemedicine & in-person care
    - ~1/4 reported clinicians decided psychotherapy visit modality
    - ~1/3 reported clinicians decided medication visit modality
- Interview participants
  - Majority preferred in-person for psychotherapy; tele for medications
  - Many reported there was no explicit conversation about which modality was used
  - Lack of choice affected their engagement in care and therapeutic alliance.

#### TELEHEALTH

By Jessica Sousa, Andrew Smith, Jessica Richard, Maya Rabinowitz, Pushpa Raja, Ateev Mehrotra, Alisa B. Busch, Haiden A. Huskamp, and Lori Uscher-Pines

Choosing Or Losing In Behavioral Health: A Study Of Patients' Experiences Selecting Telehealth Versus In-Person Care

(Sousa et al. Health Affairs 2023)

#### Weekly Outpatient AUD Treatment Use, Unadjusted Analyses



## Weekly Percent of Outpatient AUD Therapy Visits, 2020, Unadjusted Analyses

