Multiple Bio-behavioral Self-Monitoring in Type 2 Diabetes: Using Connected Technologies to Implement Behavioral Interventions from Clinical Trials to Clinical Practice

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Professor, Vice Dean of Research

UT Health San Antonio
Center on Smart & Connected Health

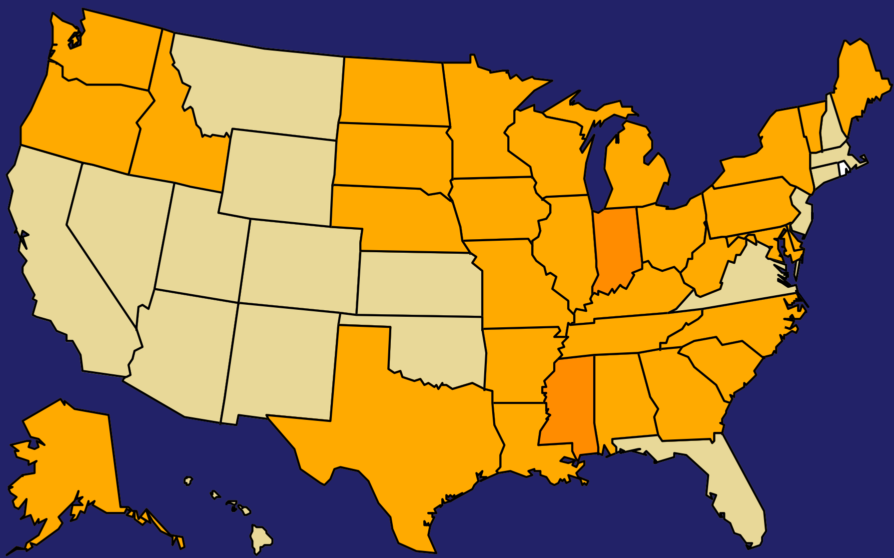
OVERVIEW

- Obesity and Diabetes
- Behavioral Lifestyle Intervention
- Mobile Technology
- Connected Technology
- Future Directions

Age-Adjusted Prevalence of Obesity and Diagnosed Diabetes Among US Adults

1994

Obesity (BMI≥30 kg/m^2)



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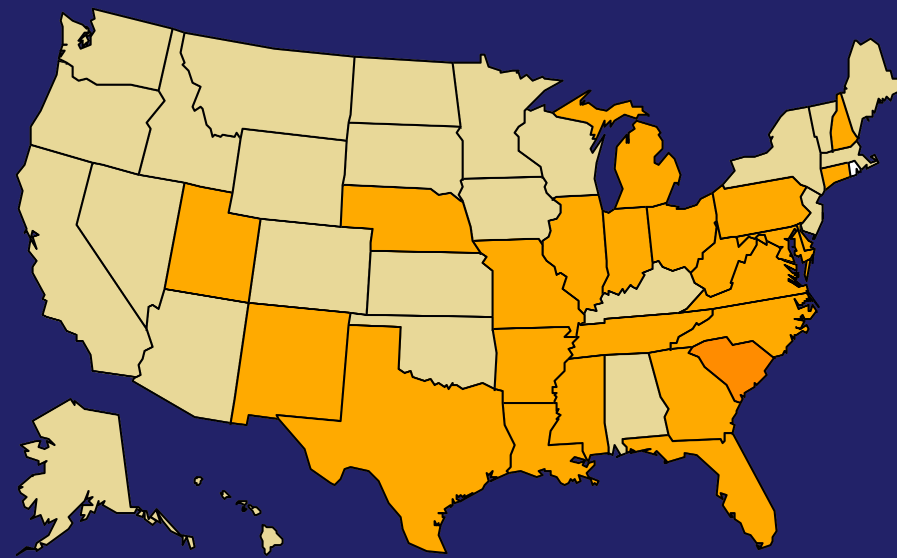

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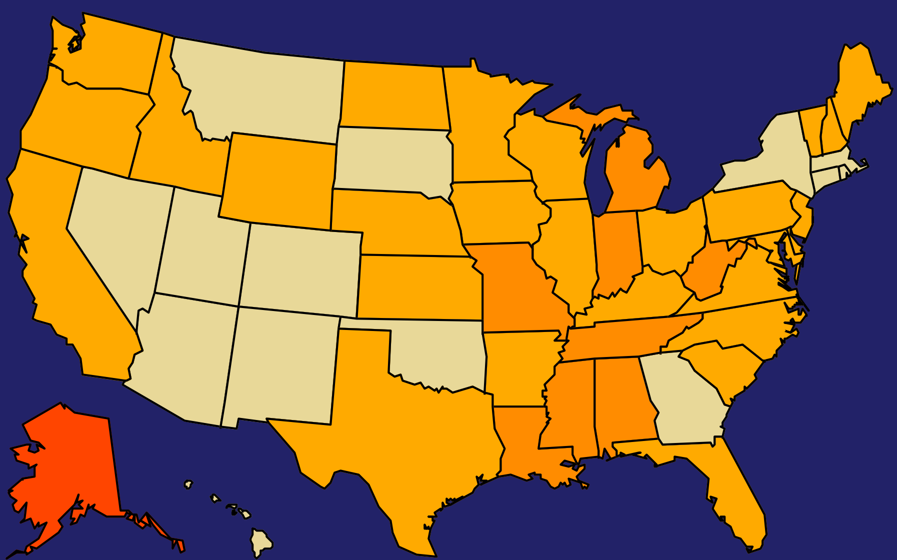

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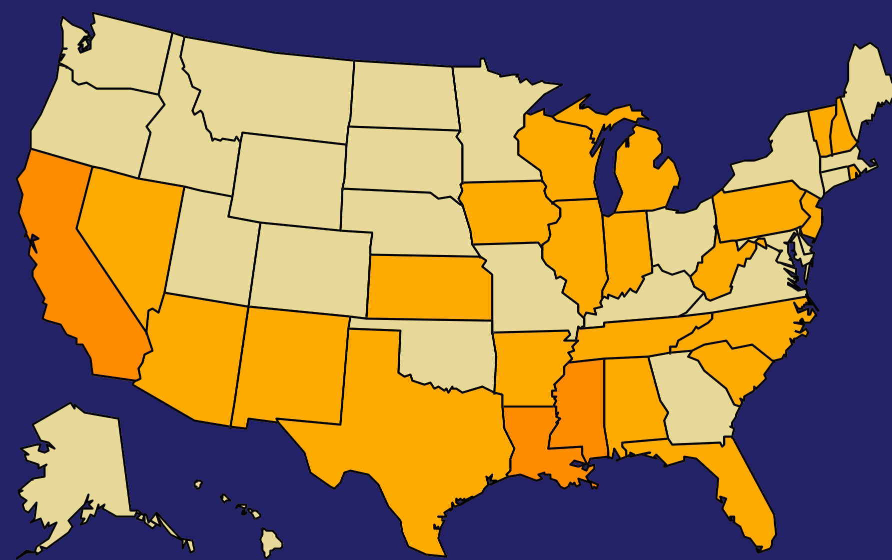

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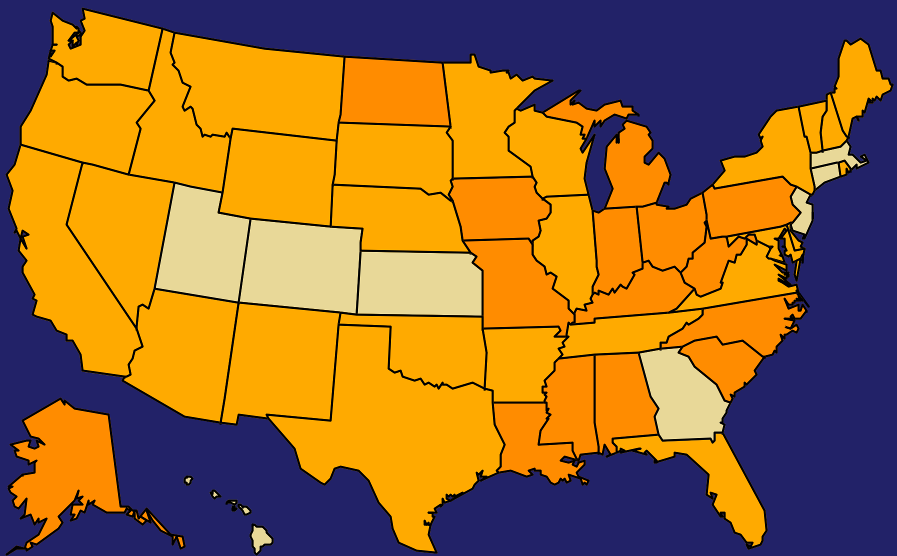

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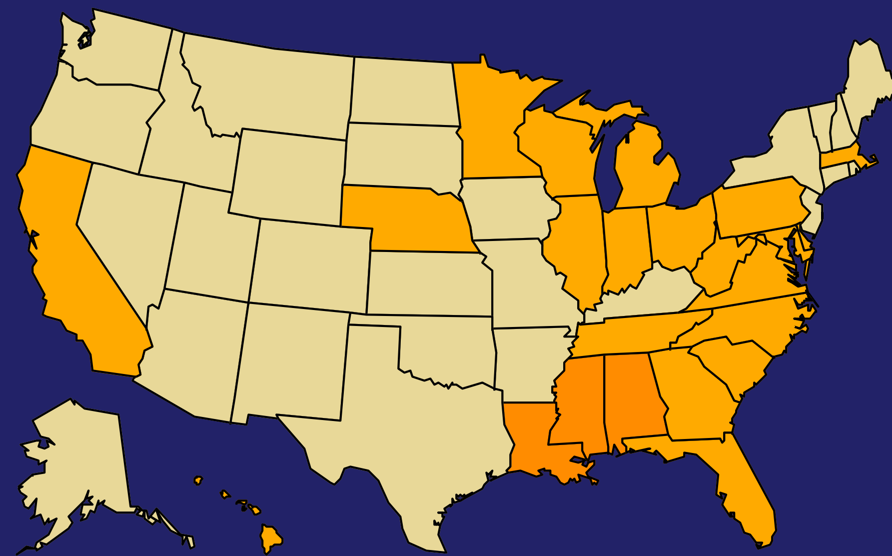

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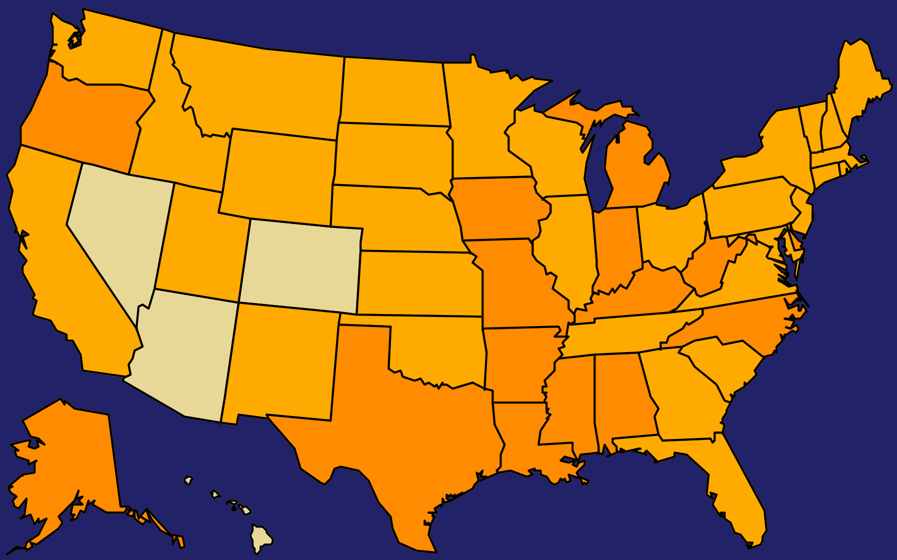

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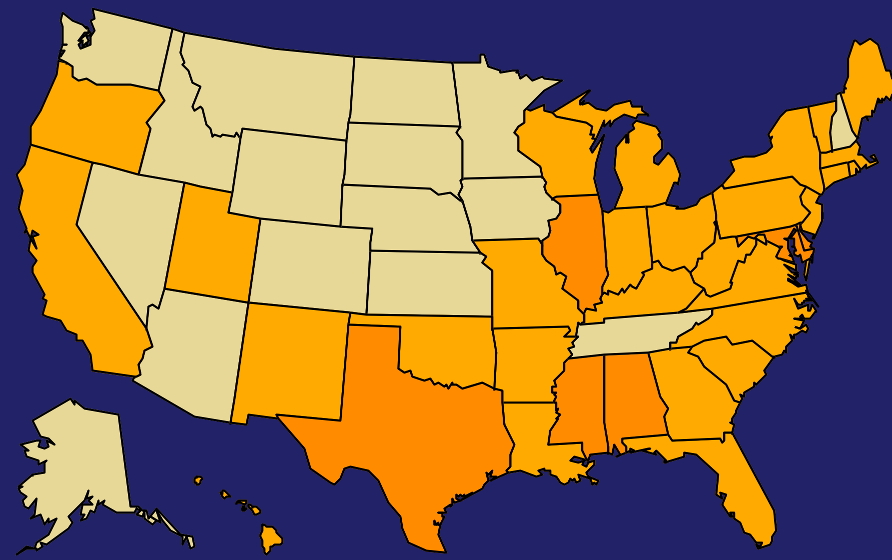

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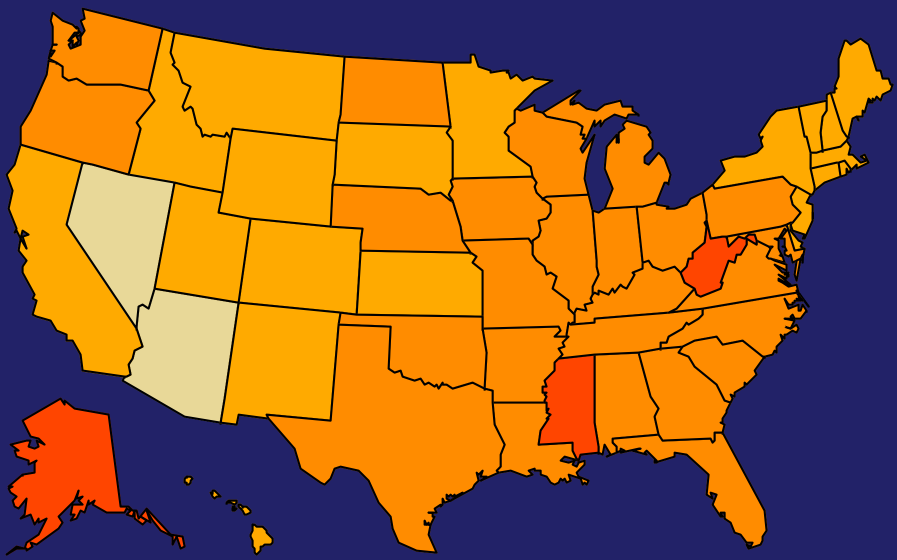

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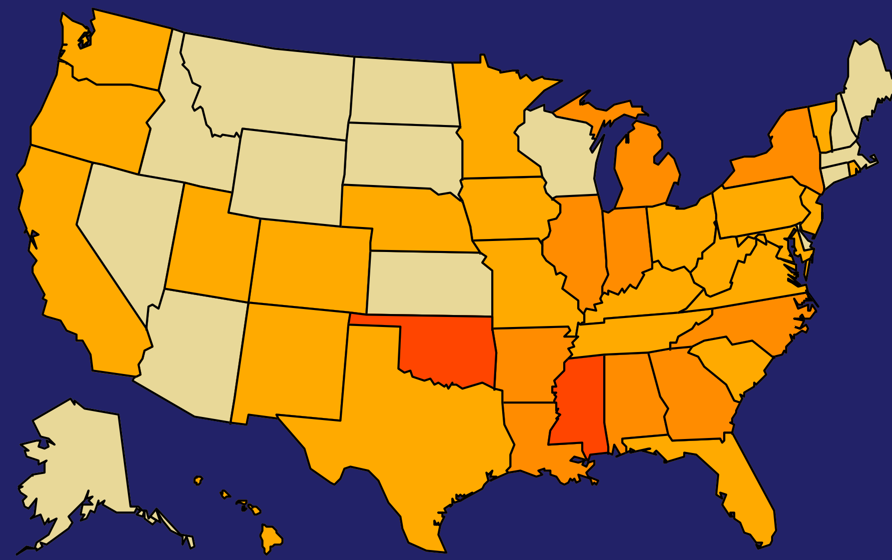

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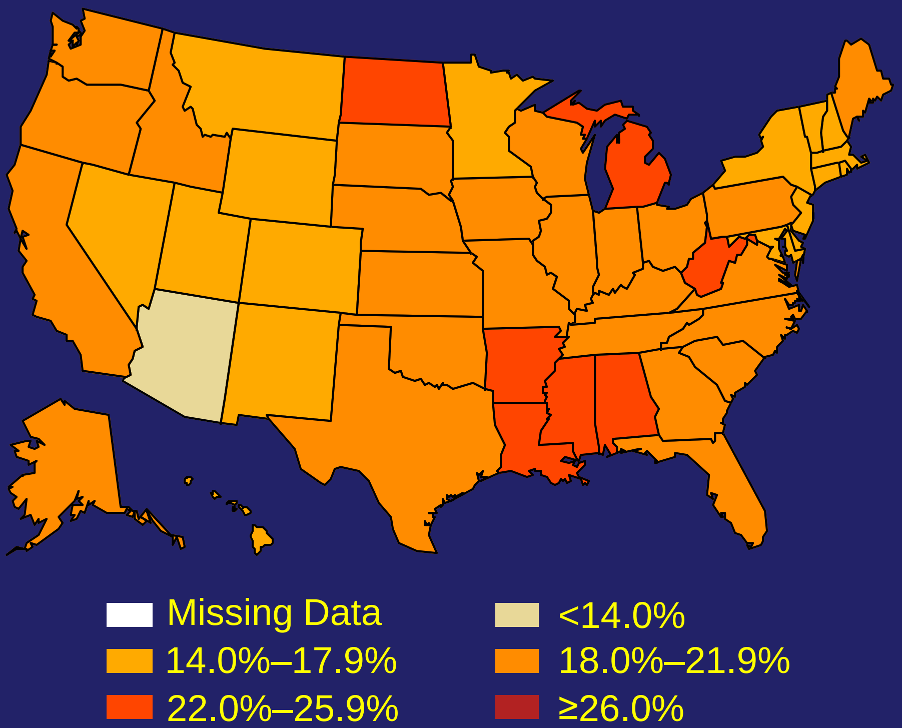

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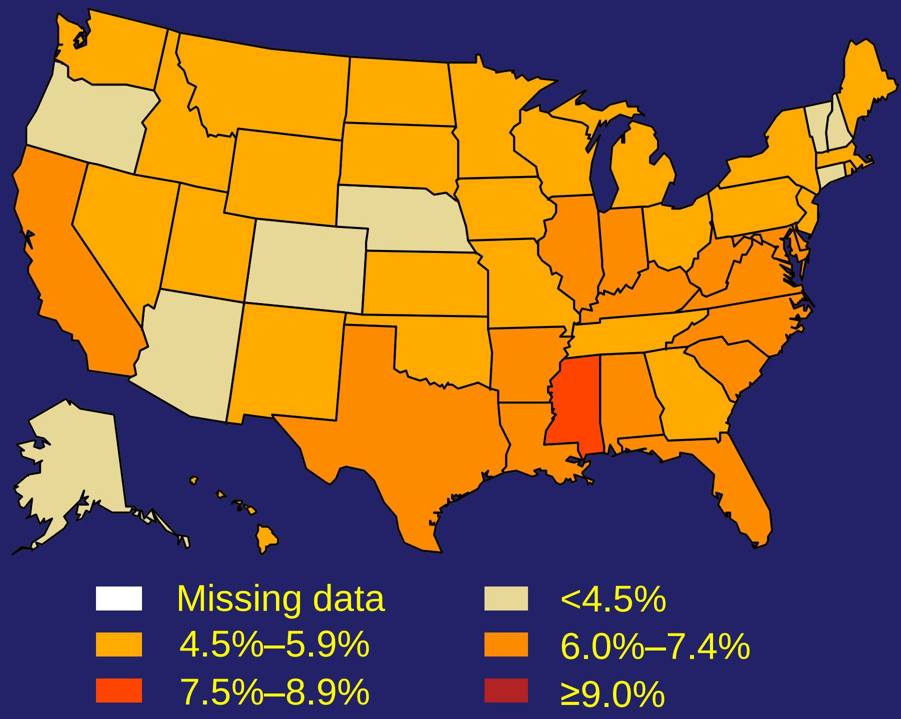

Age-Adjusted Prevalence of Obesity and Diagnosed Diabetes Among US Adults

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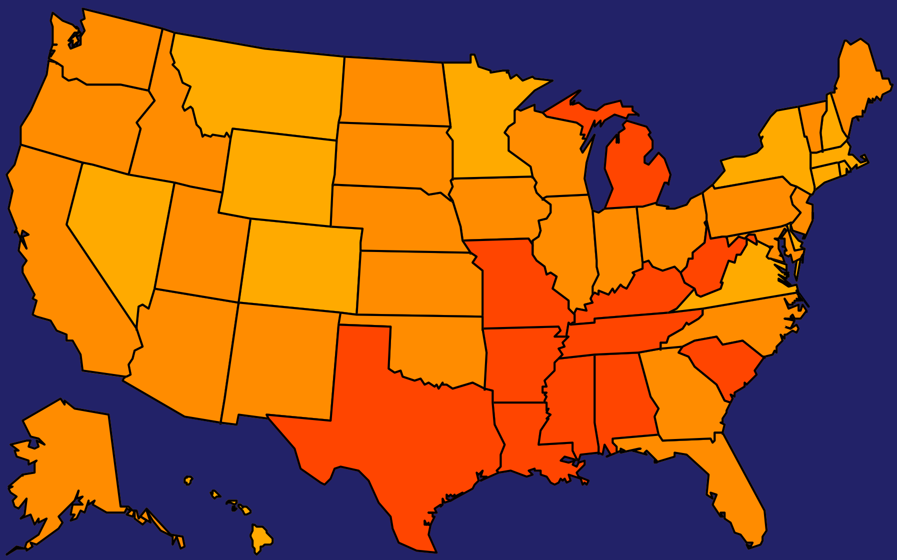

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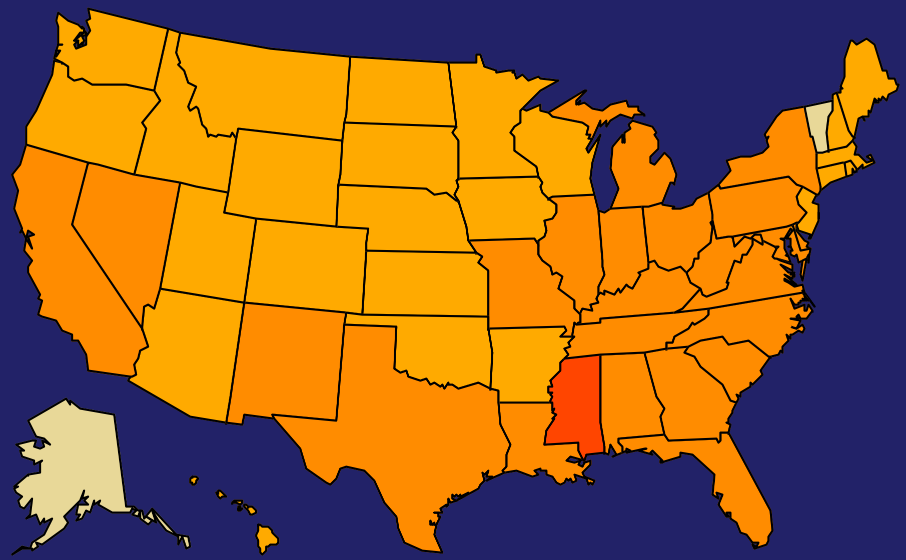

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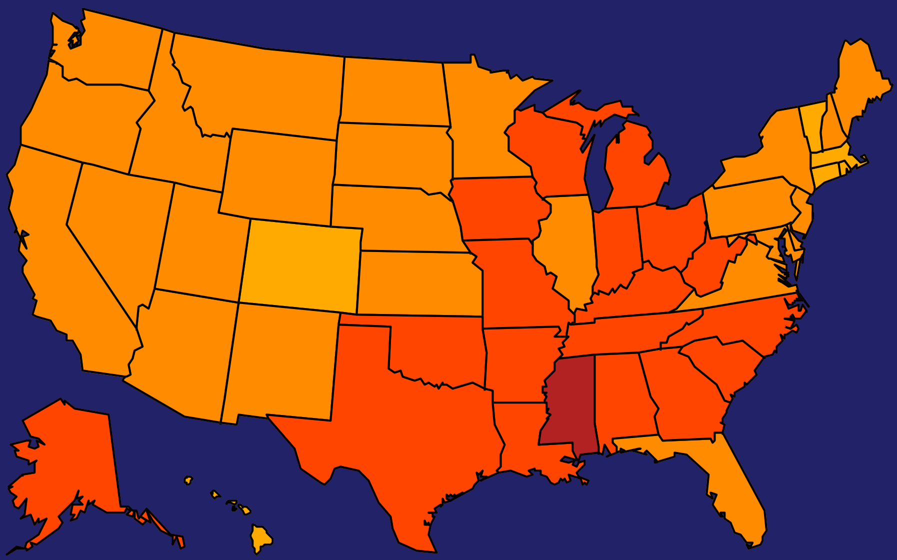

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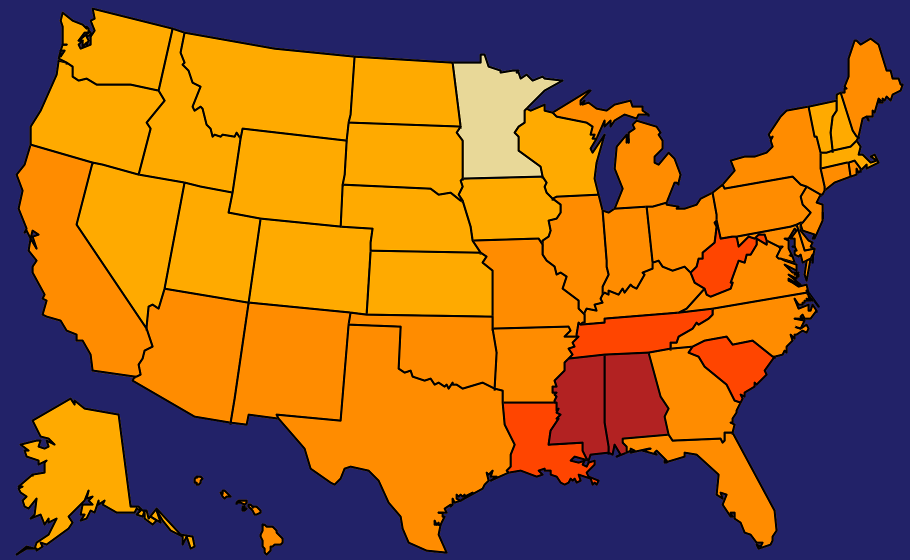

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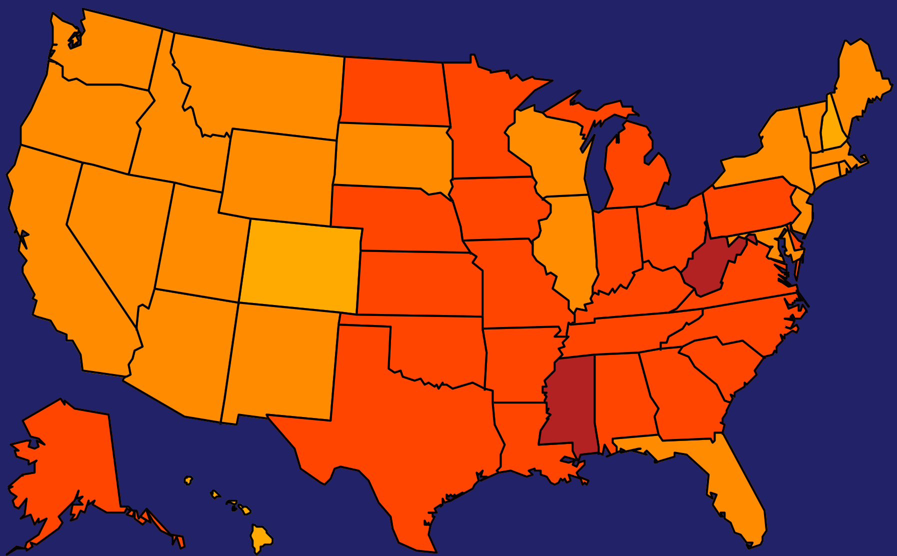

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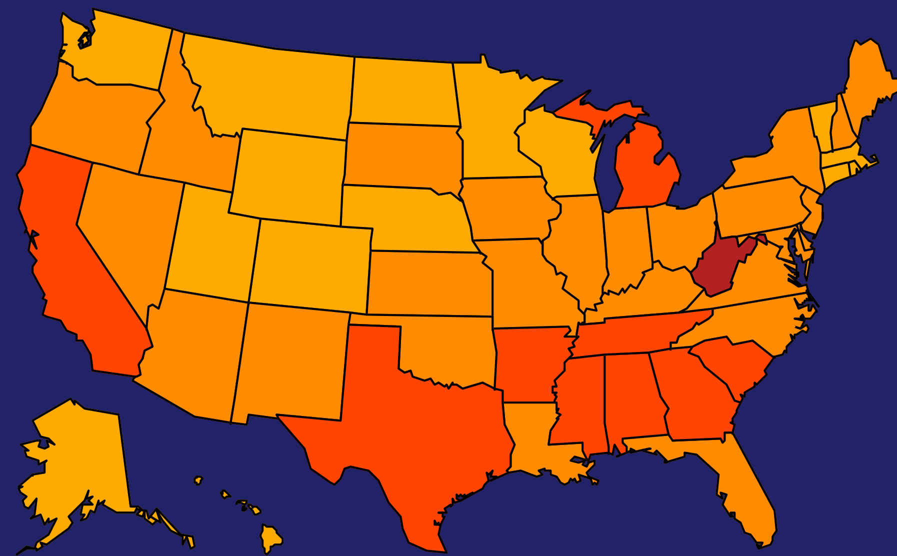

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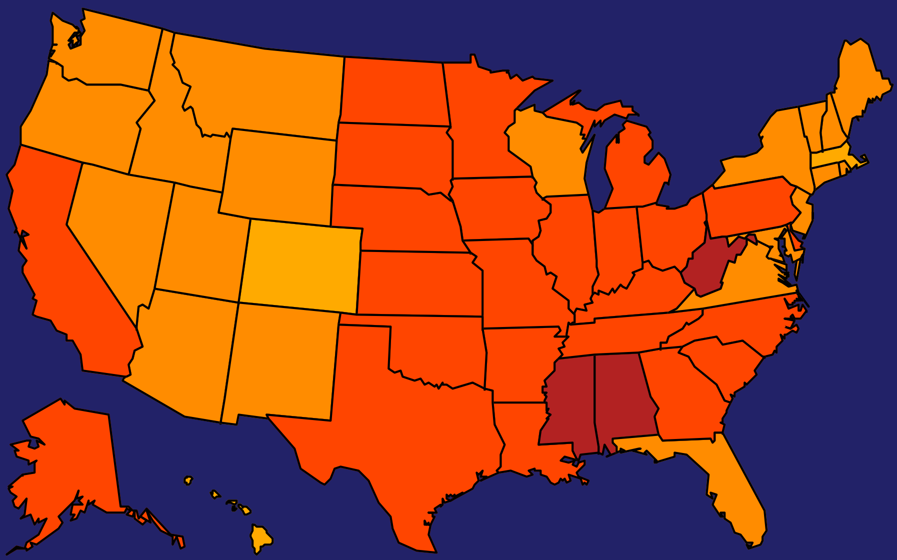

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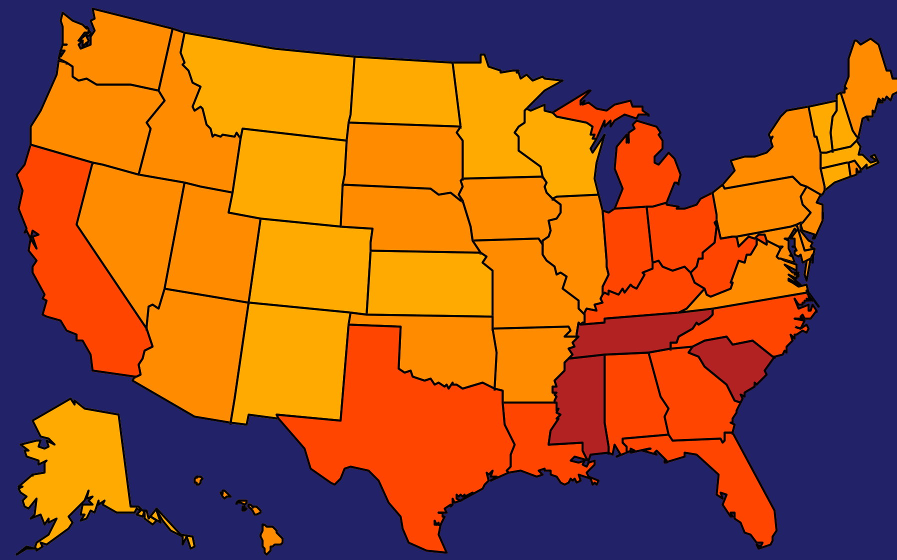

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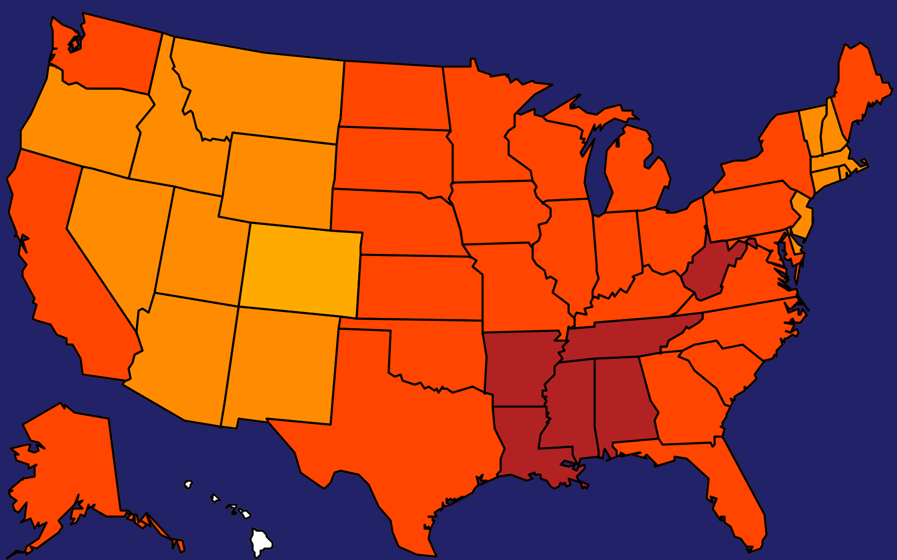

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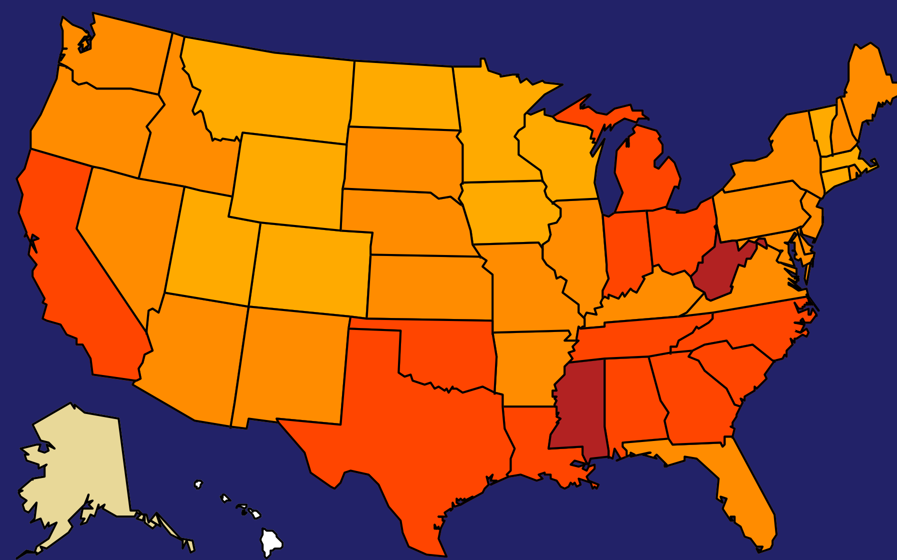

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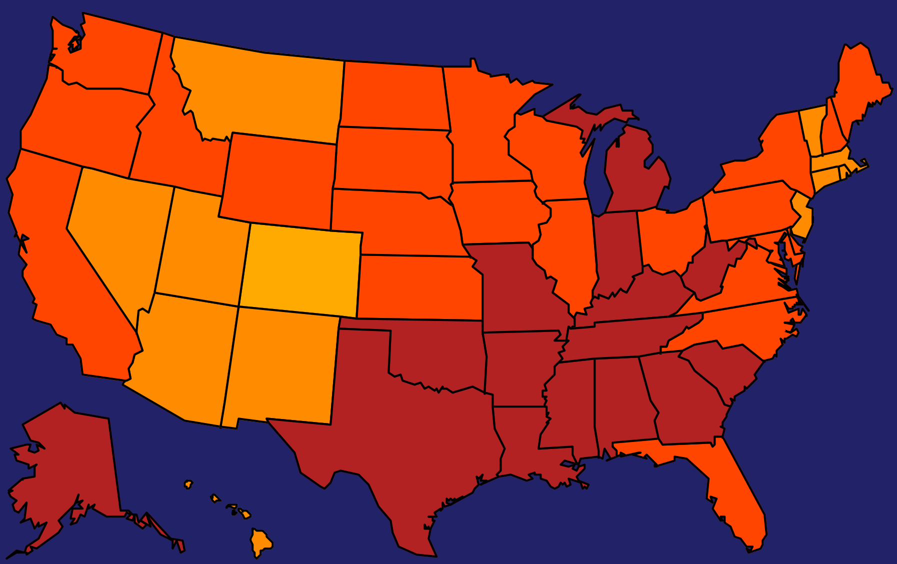

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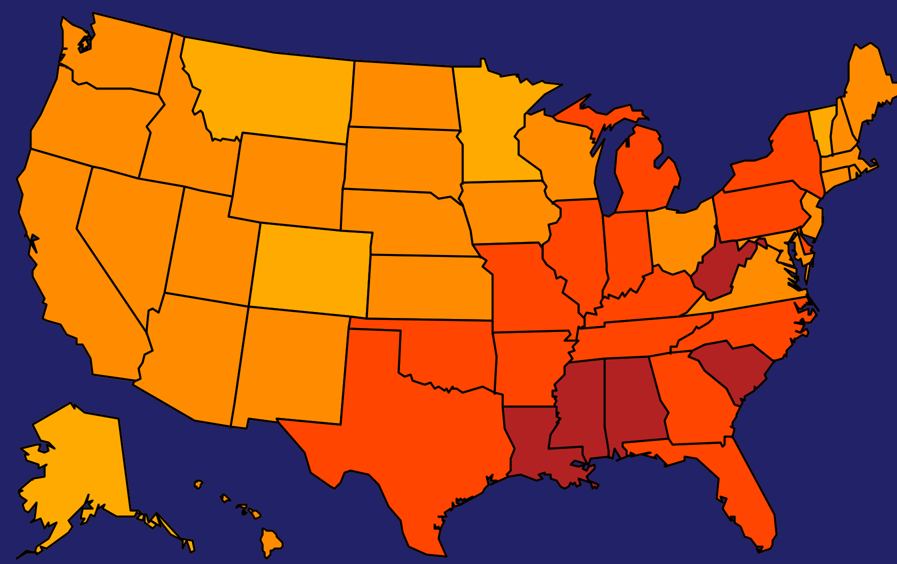

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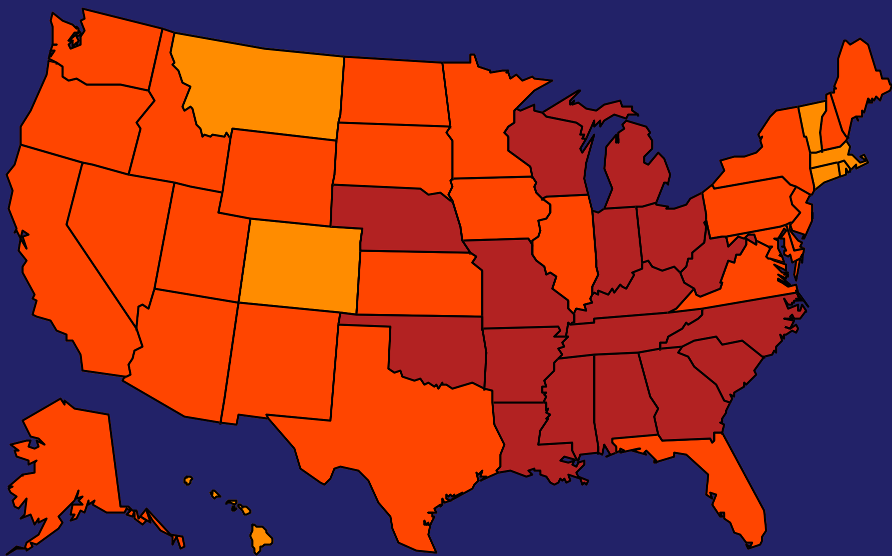

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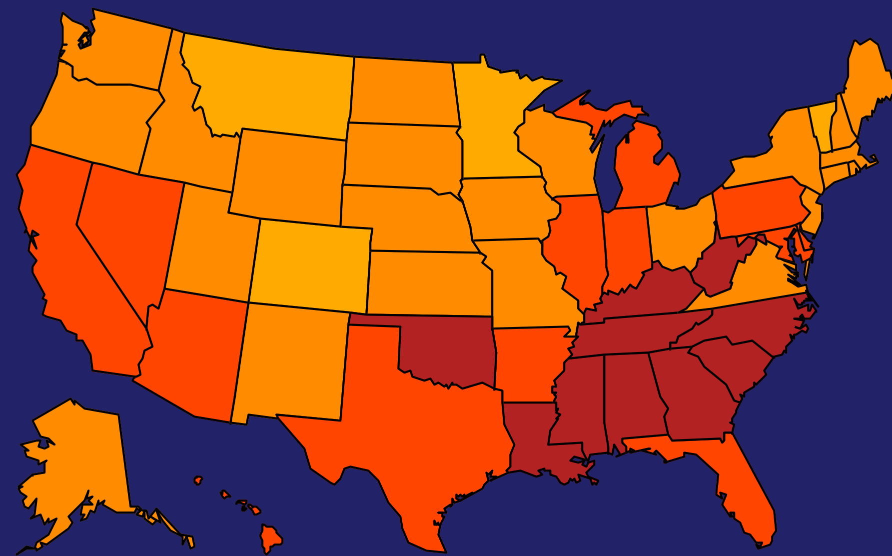

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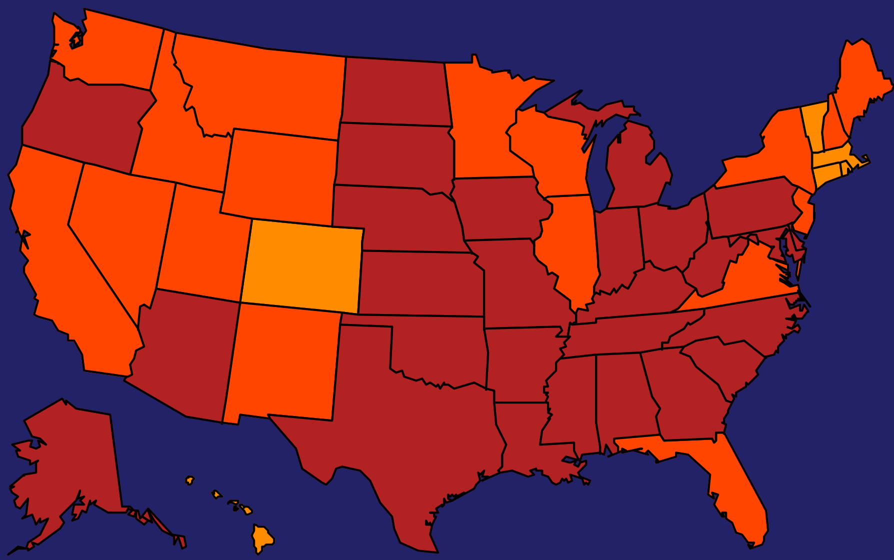

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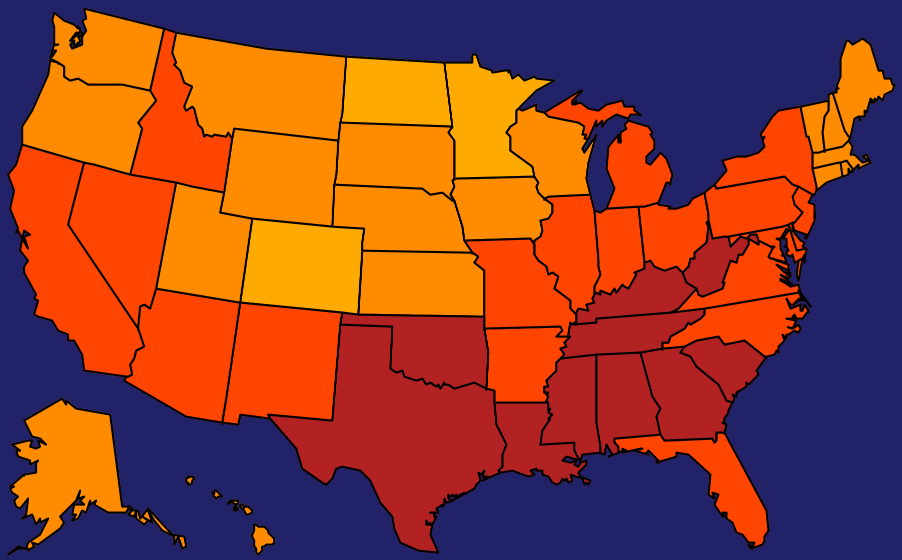

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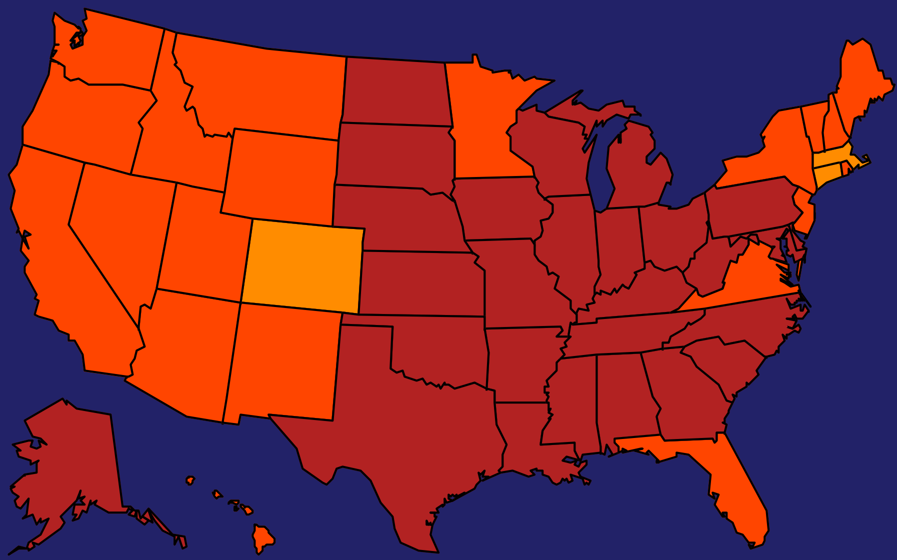

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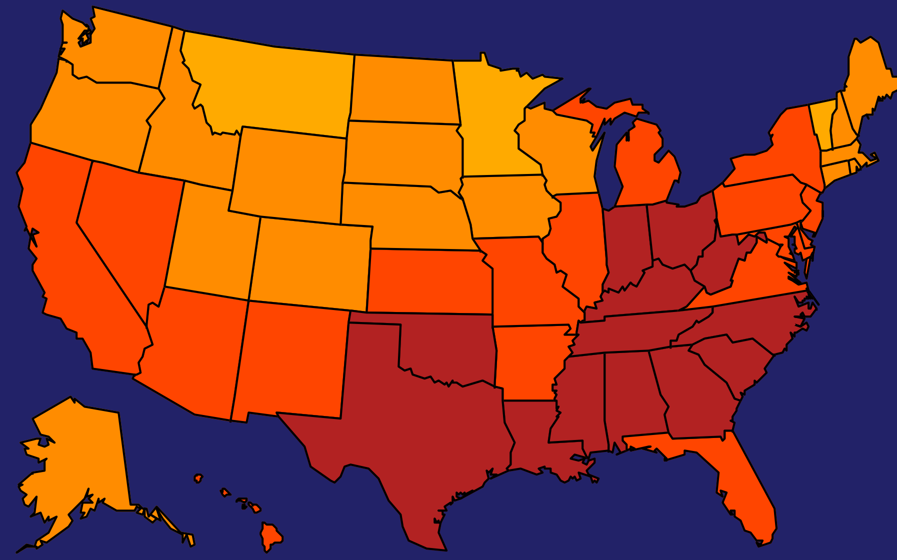

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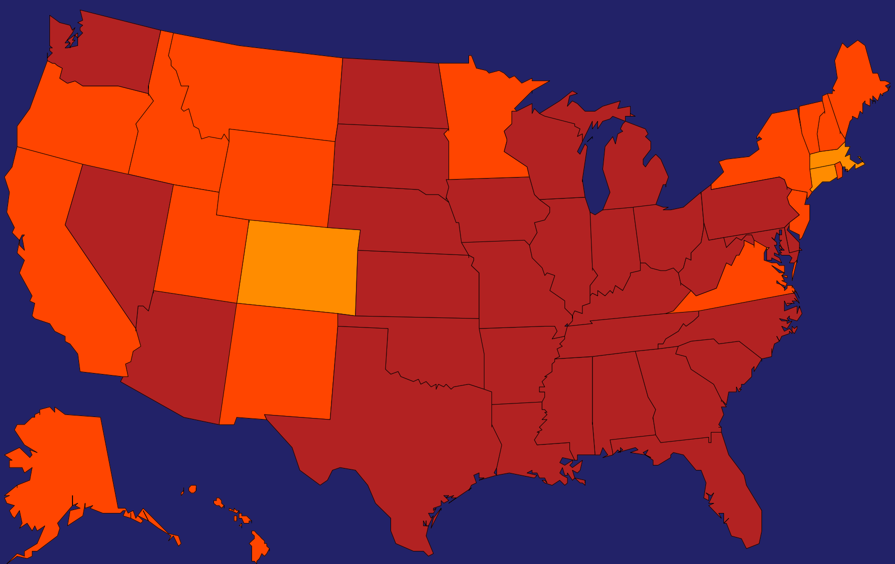

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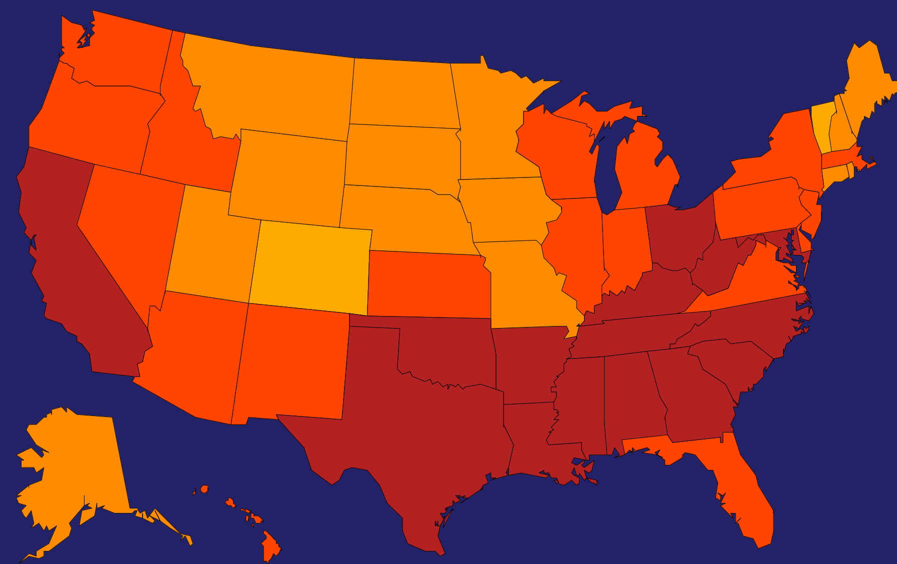

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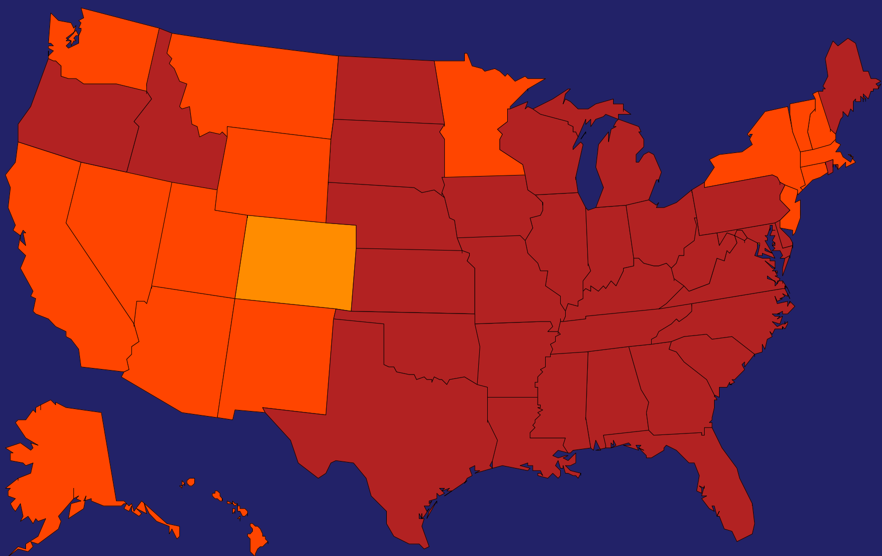

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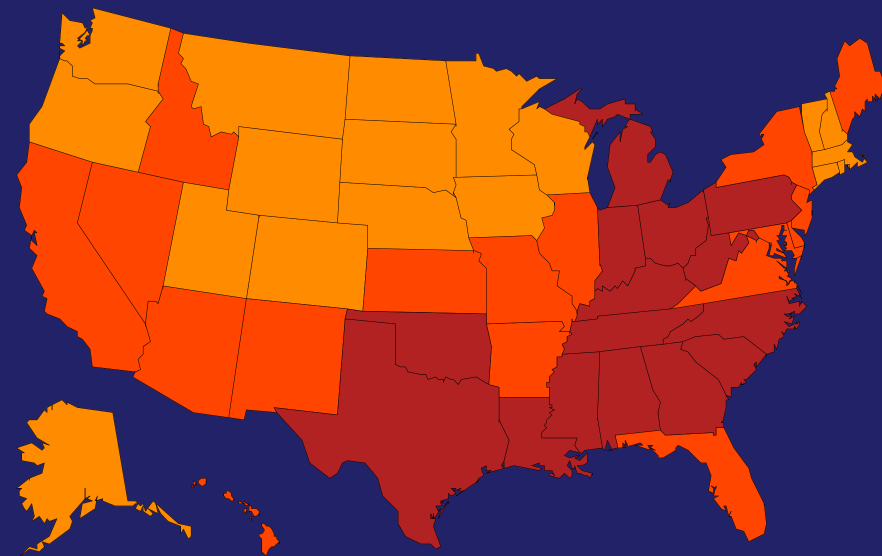

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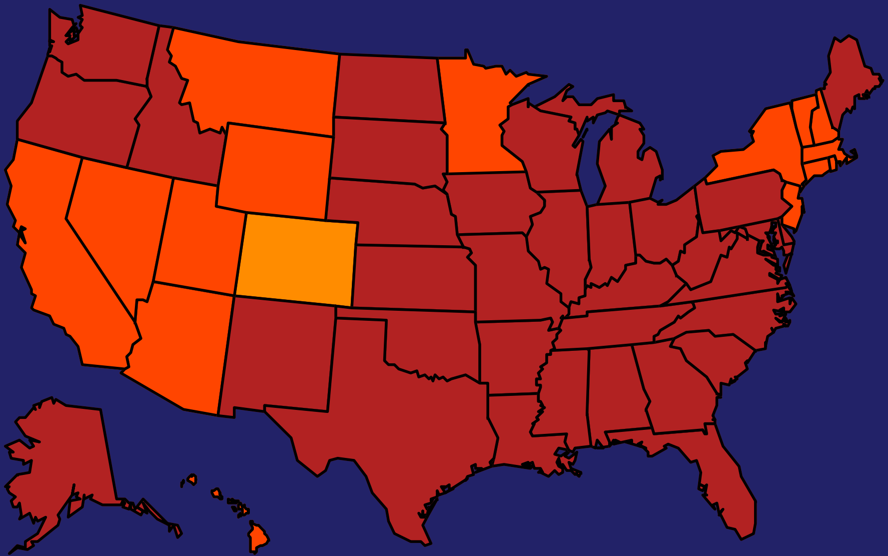

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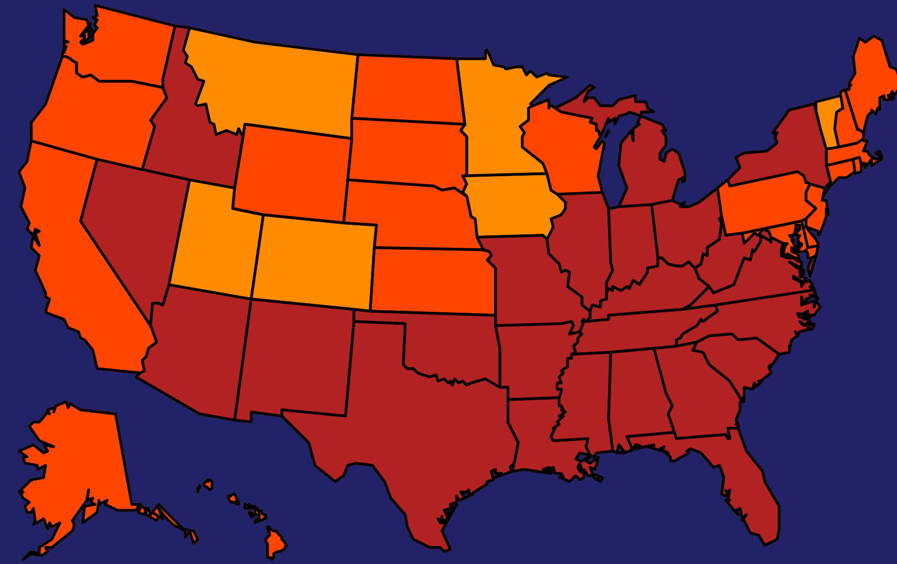

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Age-Adjusted Prevalence of Obesity and Diagnosed Diabetes Among US Adults

2012

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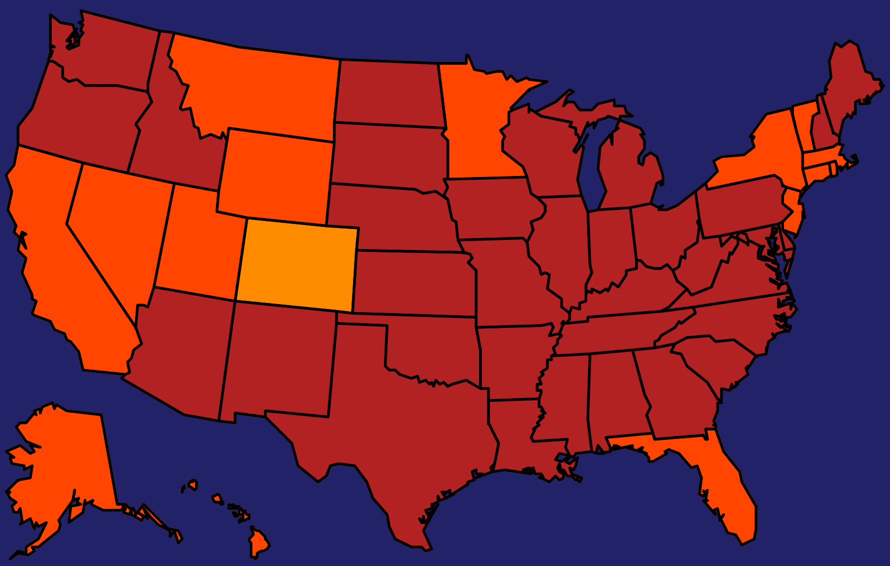

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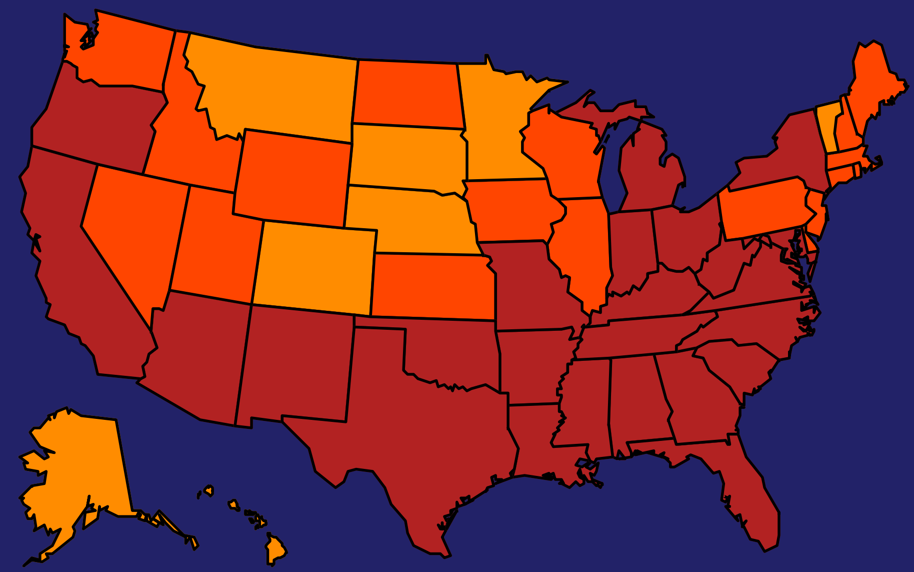

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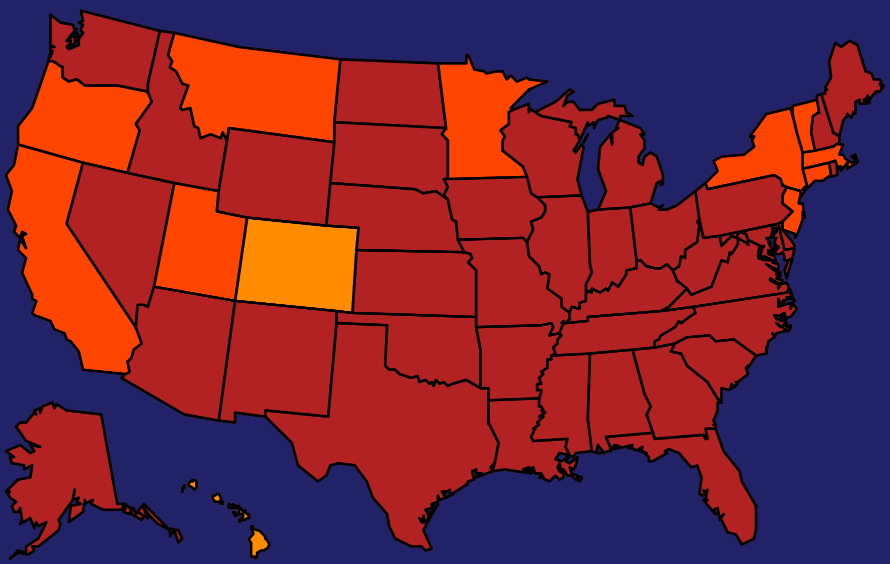

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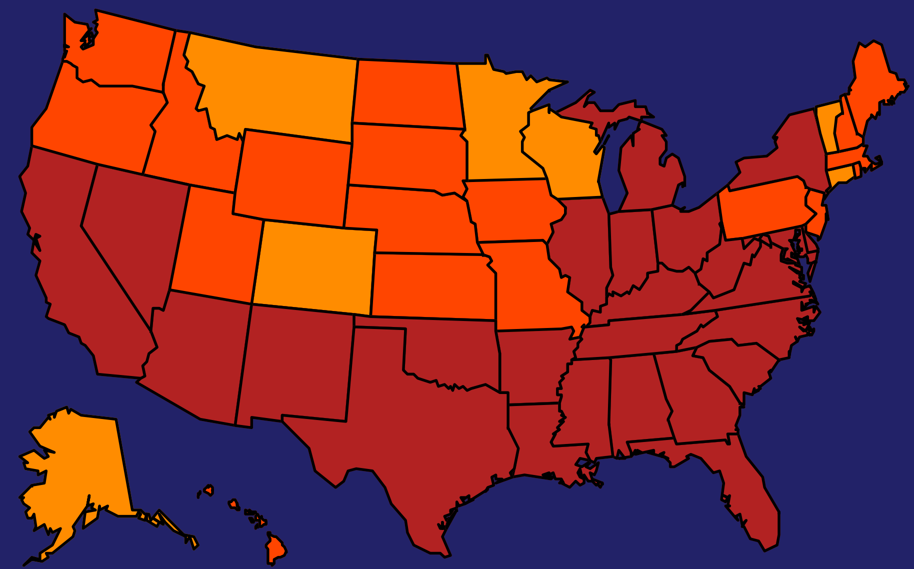

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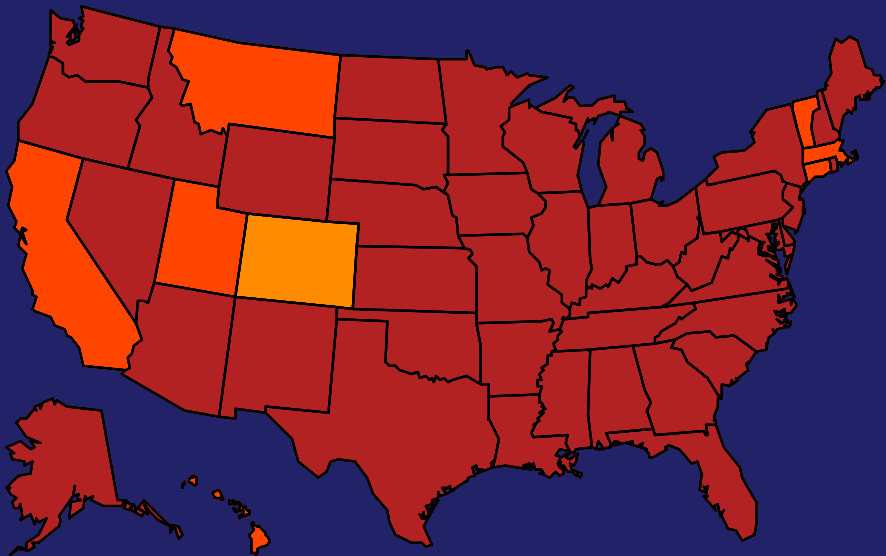

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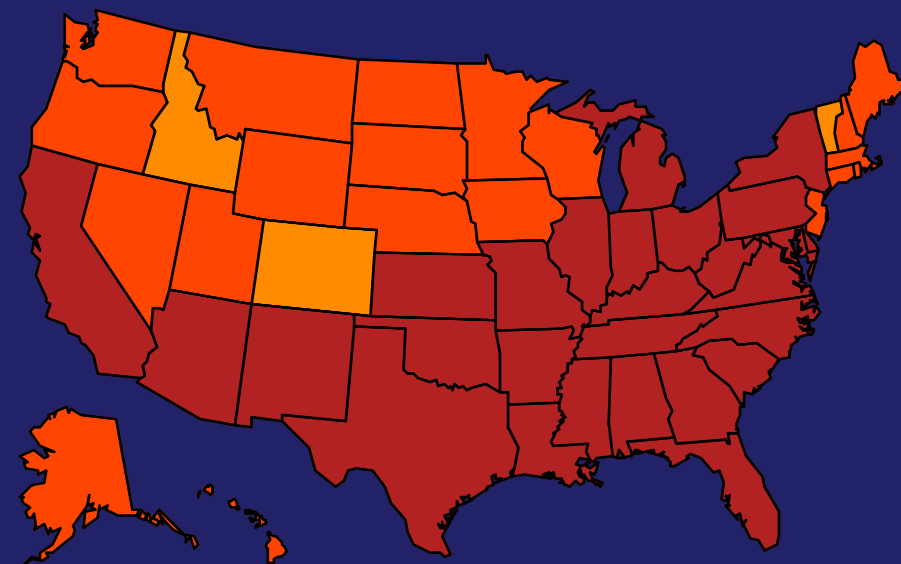

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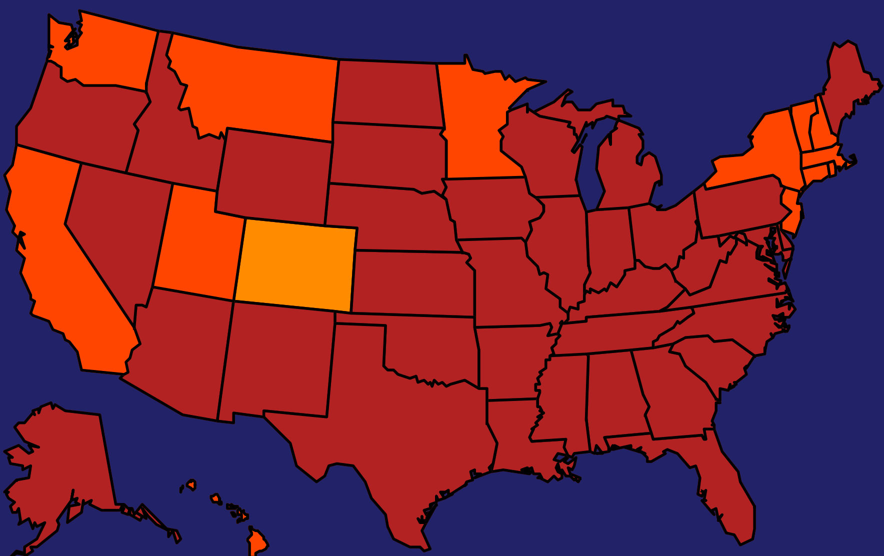
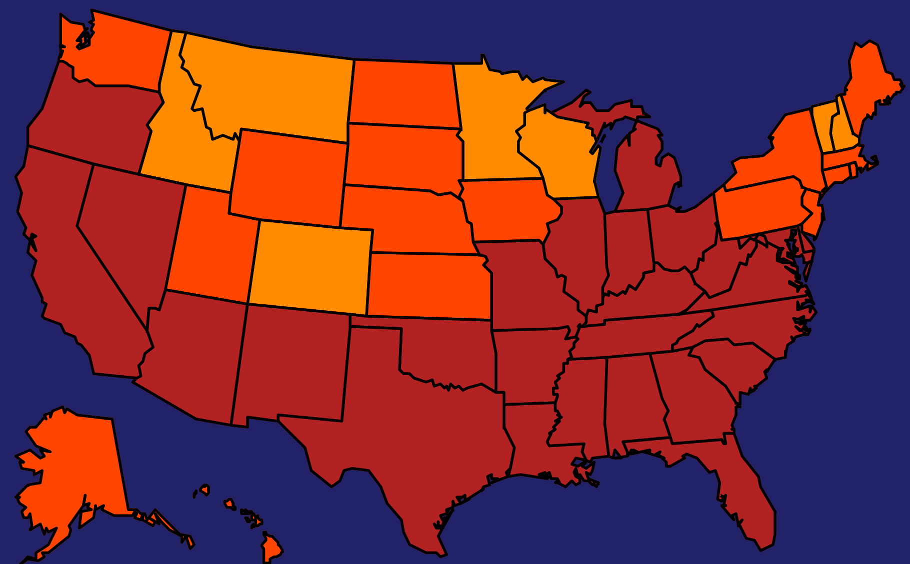
2015

Obesity (BMI≥30 kg/m²)



Missing Data
14.0%–17.9%
22.0%–25.9%
<14.0%
18.0%–21.9%
≥26.0%

Diabetes



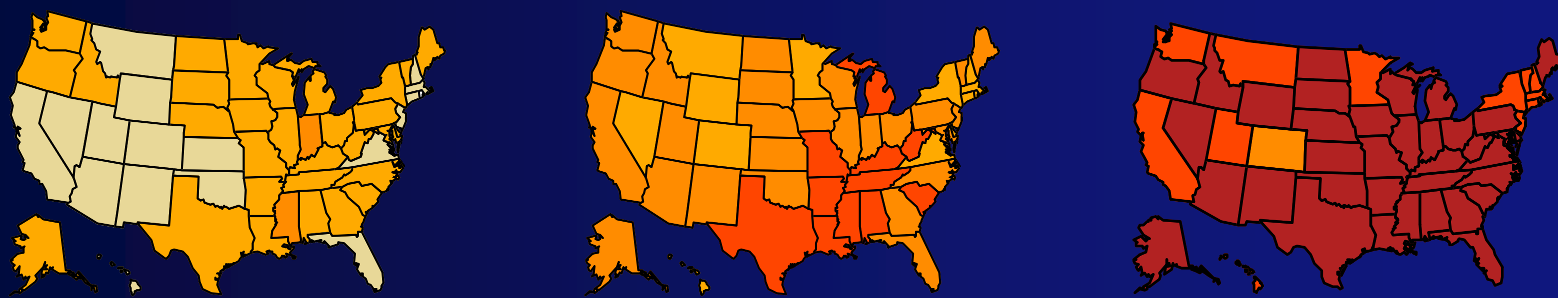
Missing data
4.5%–5.9%
7.5%–8.9%
<4.5%
6.0%–7.4%
≥9.0%

CDC's Division of Diabetes Translation. United States Diabetes Surveillance System available at http://www.cdc.gov/diabetes/data

Age-adjusted Prevalence of Obesity and Diagnosed Diabetes Among US Adults

Obesity (BMI ≥30 kg/m²)

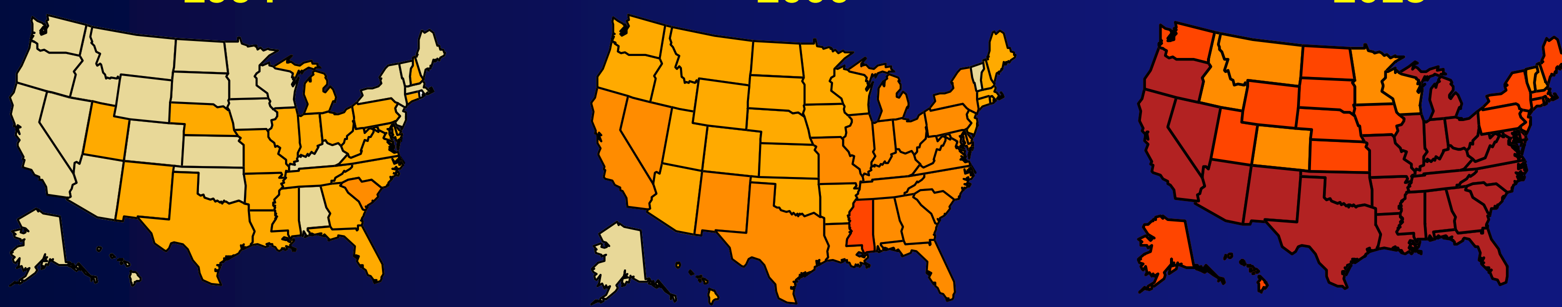
1994 2000 2015



No Data <14.0% 14.0%–17.9% 18.0%–21.9% 22.0%–25.9% ≥26.0%

Diabetes

1994 2000 2015



No Data <4.5% 4.5%–5.9% 6.0%–7.4% 7.5%–8.9% ≥9.0%

CDC's Division of Diabetes Translation. United States Surveillance System available at http://www.cdc.gov/diabetes/data

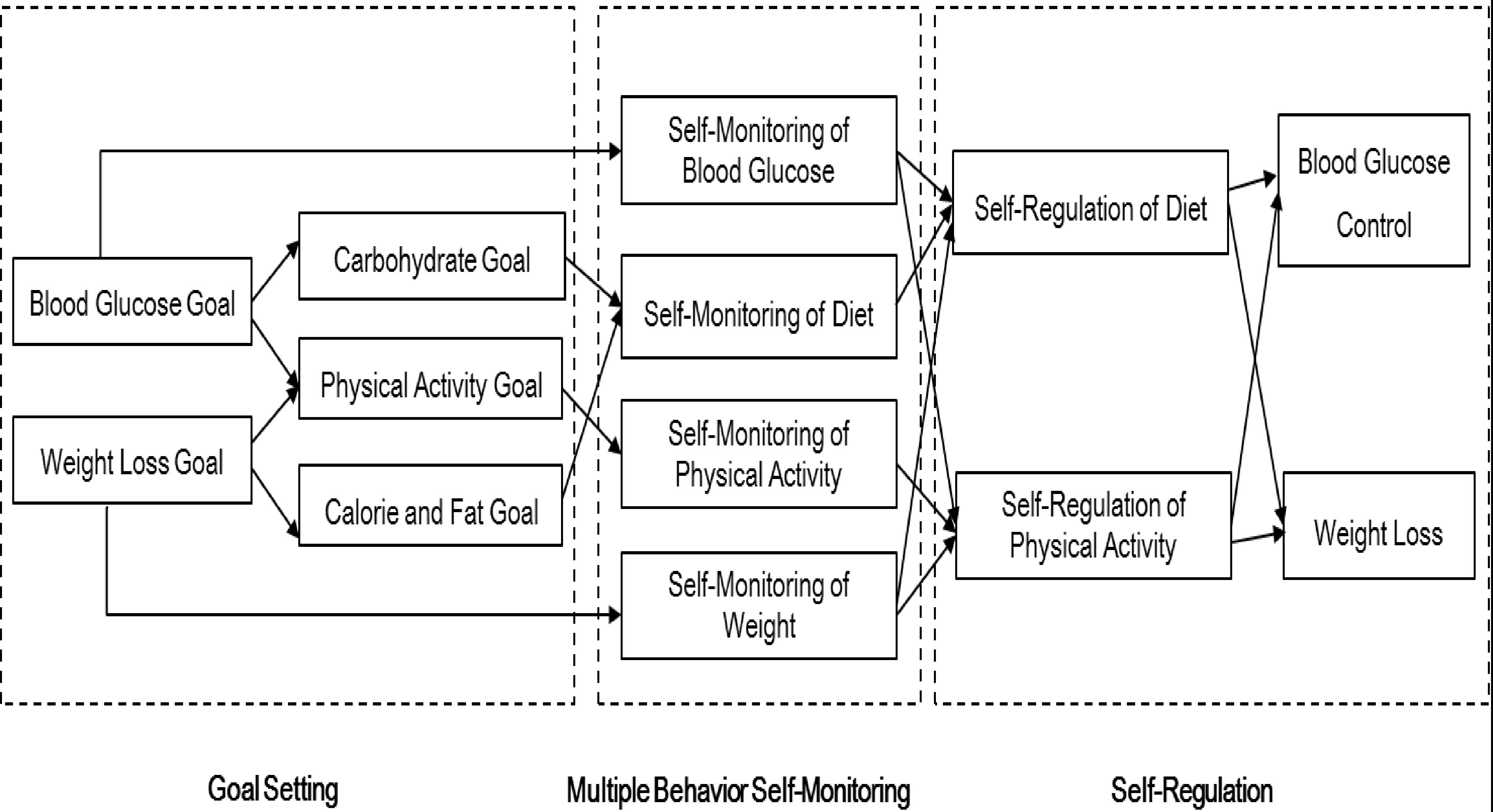
LANDMARK NATIONAL STUDIES ON OBESITY AND DIABETES

- Diabetes Prevention Program
- The Look AHEAD study

BEHAVIORAL LIFESTYLE INTERVENTION

- Social learning theory
- Self-regulation theory

STUDY MODEL



Blood Glucose Goal
Weight Loss Goal
Carbohydrate Goal
Physical Activity Goal
Calorie and Fat Goal
Self-Monitoring of Blood Glucose
Self-Monitoring of Diet
Self-Monitoring of Physical Activity
Self-Monitoring of Weight
Self-Regulation of Diet
Self-Regulation of Physical Activity
Blood Glucose Control
Weight Loss
Goal Setting
Multiple Behavior Self-Monitoring
Self-Regulation

SELF-MONITORING

The Office of the National Coordinator for
Health Information Technology

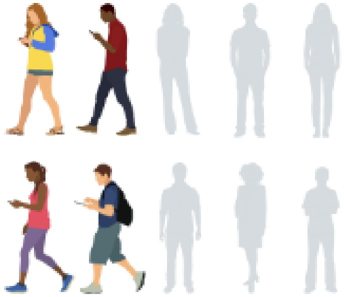
Patient Engagement Playbook

In 2017,

More than

4 in **10**

smartphone or tablet owners used their device to **track progress on a health-related goal.**[60]



The Office of the National Coordinator for
Health Information Technology

Patient Engagement Playbook

Technology has changed how patients monitor their own health.

1 in 5

people use technology to track their health —
from fitness monitors to home medical devices.

PILOT STUDY

Effect of a Behavioral Intervention with Smart Phone Based Self-Monitoring on Weight Loss and Glycemic Control in Adults with Type 2 Diabetes: A Pilot and Feasibility Study

BACKGROUND

- Self-monitoring is a cornerstone of behavioral interventions for obesity and diabetes
- Mobile technology may improve adherence to self-monitoring & patient outcomes
- However, no study has tested the use of a smartphone to facilitate self-monitoring in overweight or obese adults with type 2 diabetes among the underserved

STUDY PURPOSE

- To examine feasibility and preliminary efficacy of a behavioral lifestyle intervention using smart phone based self-monitoring of multiple behaviors on weight loss and glycemic control in a sample of overweight or obese adults with type 2 diabetes living in underserved communities

STUDY DESIGN

- A 6-month pilot randomized controlled clinical trial
- Mixed-method design
    - Quantitative to evaluative feasibility and preliminary efficacy
    - Qualitative focus group and individual interviews to assess acceptability and perceived usefulness

STUDY SETTING

- Participants were recruited from an American Diabetes Association certified diabetes education program, located in a community health center primarily serving uninsured or underinsured individuals living in Harris County, TX

INCLUSION CRITERIA

- Diagnosis of type 2 diabetes for at least 6 months
- Overweight or obese (BMI>25)
- 21-75 years of age
- Be able to read and write in English

EXCLUSION CRITERIA

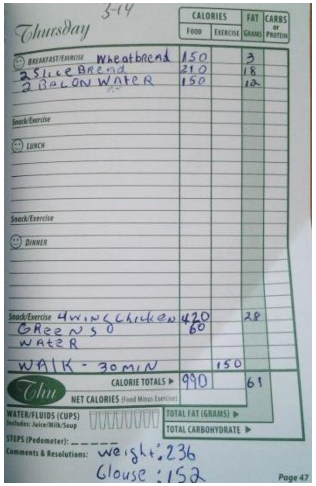
- History of severe psychiatric disorders
- Unable to perform regular activity
- Current or plan to be pregnant or nursing in the next 6 months
- Planned vacation in the next 6 months
- Previously participated in an intensive behavioral lifestyle intervention
- Alcohol or substance abuse in the past year

PATIENT FLOW CHART

34 screened for eligibility

26 randomized

11 assigned	9 assigned	6 assigned



“Phone” group	“Paper” group	Control group
10 at 6 months 1 withdrawal	8 at 6 months 1 loss to follow-up	6 at 6 months

BEHAVIOR INTERVENTION

- Both phone and paper groups received a standard behavioral lifestyle intervention: a total of 11 group sessions, weekly for month 1, biweekly for month 2-3, and monthly for month 4-6, and an individual session after month 3
- The group sessions were held at the recruiting community health center and included a grocery shopping trip, pedometers, weight scales, and food scales were distributed in the sessions

BEHAVIOR INTERVENTION

- An individual intervention was added ad hoc to evaluate individualized goals and behavior change plans
  - Review individual weight loss goal
  - Review current weight and diaries
  - Review how to tip the calories
  - Develop specific diet and physical activity goals to reach weight loss goal

PHONE GROUP

- A FDA approved blue-tooth enabled glucometer
- A smart phone with data plan and two applications downloaded to the phone:
  - *LoseIt!* to track diet, physical activity and weight
  - *Diabetes Connect* to automatically receive blood glucose levels via a blue-tooth enabled glucometer

ELECTRONIC DIARY

PAPER GROUP

- Give Calorie King paper diaries to track diet, physical activity, weight, and blood glucose
- A calculator to add up the numbers
- A Calorie King Calorie Counter to look up calorie, fat, and carbohydrate content

CONTROL GROUP

- Received usual diabetes care and education
- The recruitment site offered standard diabetes self-management education through it diabetes education program
- Received the paper group intervention materials after the final data collection at 6 months

TREATMENT FIDELITY

- A checklist was used for each group and individual session to track the content delivered

OUTCOME MEASURES

- Feasibility
  - % retention at 3 and 6 months
- Preliminary efficacy
  - Primary outcome: weight loss and A1c changes at 6 months
- Acceptability
  - Qualitative data

ANALYSIS

- ANOVA was used to examine group differences on primary outcomes
- Qualitative analysis

RETENTION

- 96% (25/26) at 3 months
- 92.3% (24/26) retention at 6 months

SAMPLE CHARACTERISTICS

- Average Age: 56.4 years
- Average # of years educated: 12.15±1.22 years
- 61.5% (16) female
- 69.2% (18) African Americans

RESULTS

Variables	Phone	Paper	Control	p
Weight at baseline	240.3 (179.8, 295.4)	243.6 (222.2, 321.8)	201.2 (195.8, 213.8)	0.41
Weight at 6 months	-5.1 (-12.2, -0.6)	0.4 (-7.4, 2.0)	3.3 (-8.8, 7.2)	0.21
HbA1c at baseline	8.50±2.46	10.37±2.41	8.95±2.35	0.25
HbA1c at 6 months	6.94±1.00	9.09±1.83	8.90±1.59	0.01

RESULTS

- At 6 months, participants in the Smartphone and Paper Diary groups had a weight loss of 2.73% and .13% respectively, while the control group had an average of .49% weight gain
- In the Smartphone and Paper Diary groups, participants HbA1c changed from 9% to 7% and 10% to 9% respectively, while the control group's HbA1c level remained at 9%

RESULTS

- We did not find statistical significance on % weight loss ($p=.20$) and HbA1c changes ($p=.44$) among the groups with this small sample size
- However, we found a large effect size of .40 for weight loss and a medium effect size of .28 for glycemic control, with effect sizes classified by Cohen (1988)

RESULTS

- Focus group data and individual interview data showed that patients were acceptable to all components of the intervention and found the intervention useful

CONCLUSIONS

- Delivering a behavioral lifestyle intervention using smartphone-based self-monitoring in an underserved community is feasible and acceptable
- A full scale randomized controlled trial is needed to confirm the findings of this pilot study

Patterns of Adherence to Diet and Physical Activity Self-monitoring using Smartphones versus Paper Diaries in a Pilot Intervention Study among Diabetes Patients

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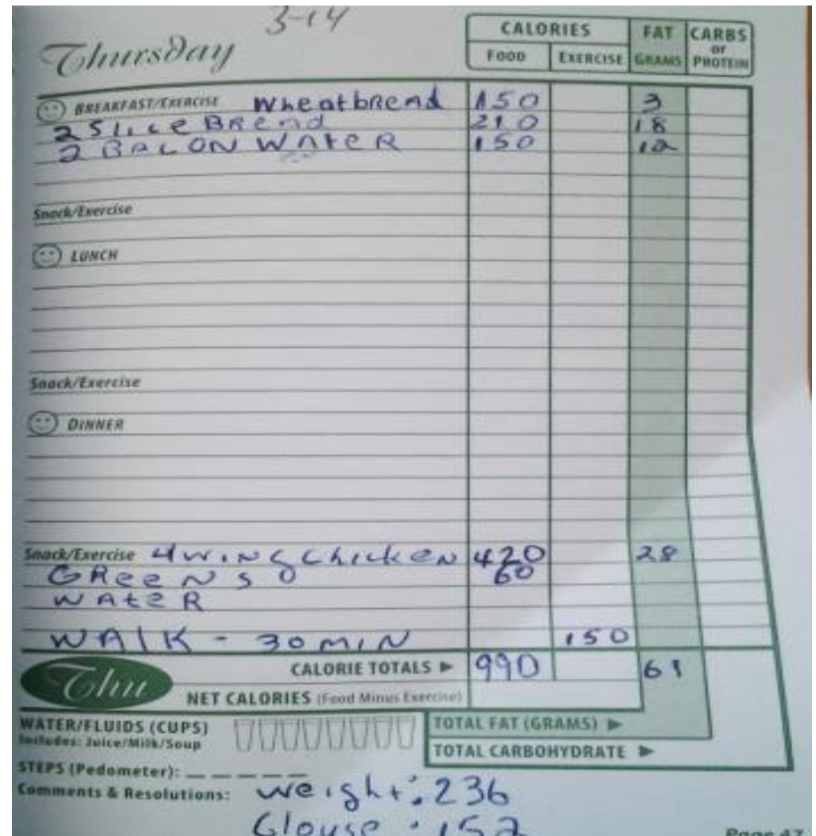
JING WANG, PHD, MPH, RN

THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER
AT HOUSTON

SMARTPHONE AND PAPER DIARY

Smartphone group (n=10)
LostIt! application



Paper diary group (n=6)
Calorie King diary book

DATA USED IN THIS ANALYSIS

We used data from 16 participants that provided self-monitoring records of diet and physical activity

Data collection spanned 161 days, with daily measurements of:

- Meals, calories, fat, carbohydrate intake
    - Converted to dichotomous variable (yes/no)
- Physical activity and calories expended
    - Converted to dichotomous variable (yes/no)
- Not used: glucose and weight monitoring data from parent study

RESULTS – ADHERENCE RATES

SMARTPHONE GROUP

At least one entry for self-monitoring of diet:

- 96.0% of days (median)

At least one entry for self-monitoring of physical activity:

- 37.3% of days (median)

PAPER DIARY GROUP

At least one entry for self-monitoring of diet:

- 10.6% of days (median)

At least one entry for self-monitoring of physical activity

- 1.2% of days (median)

$p < 0.05$

$p < 0.05$

METHOD: PATTERN OF ADHERENCE

How soon do participants resume adherence after a discontinuity?

- Distributions of consecutive missing entries (i.e. length of discontinuity) were compared between the two groups
    - Character strings of adherence were created
        - “1110111” indicates one missing entry on day 4
            - Missed-entry substring of length 1: “0”
        - “1100001” indicates 4 consecutive missing entries (day 3-7)
            - Missed-entry substring of length 4: “0000”
        - Prevalence of all lengths of missed-entry substrings were collected across all participants

DISTRIBUTION OF LENGTHS OF DISCONTINUITIES

N (≥1)	N (≥2)	N (≥3)	N (≥4)	N (≥5)	N (≥6)	N (≥7)	N (≥8)	N (≥9)	N (≥10)
212	168	90	57	34	17	9	6	3	2

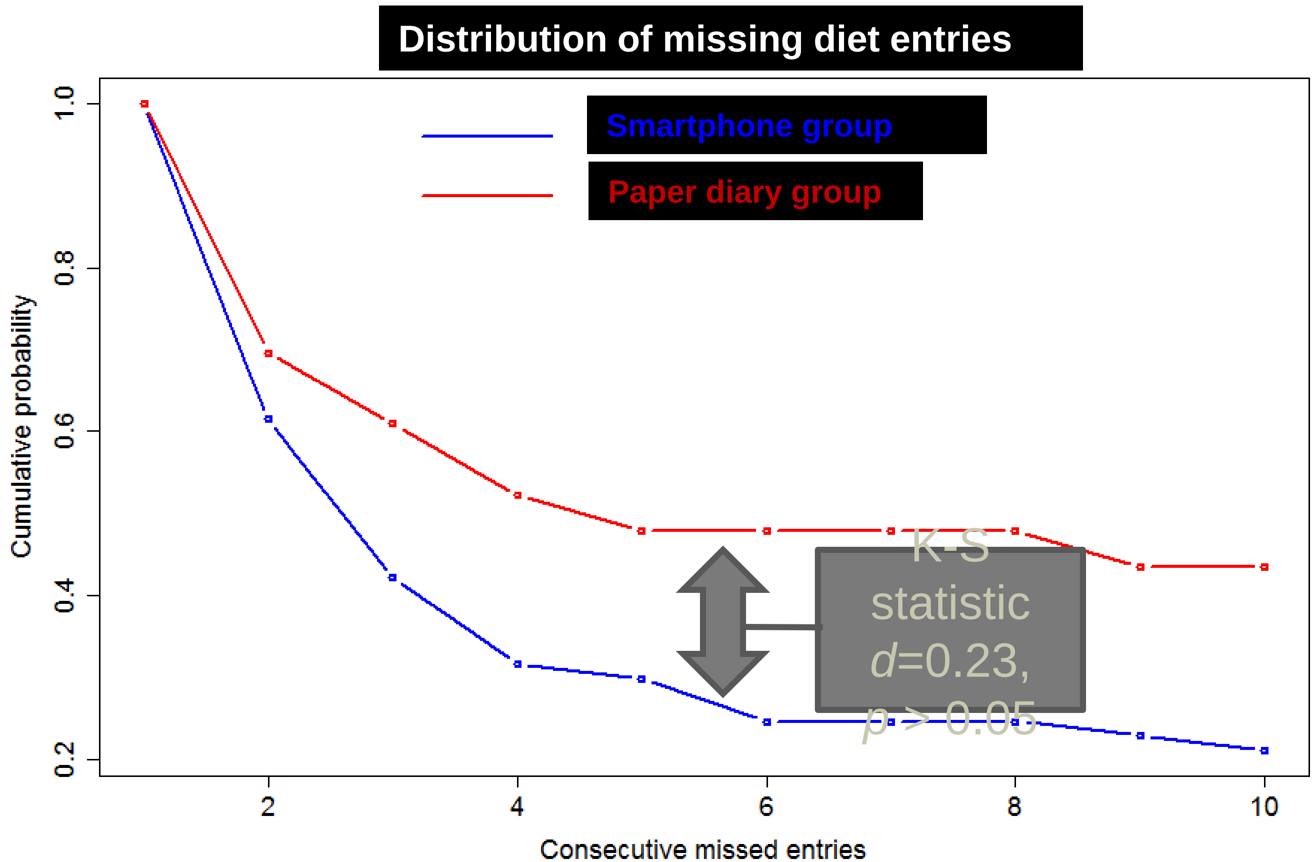
P (≥1)	P (≥2)	P (≥3)	P (≥4)	P (≥5)	P (≥6)	P (≥7)	P (≥8)	P (≥9)	P (≥10)
1	.792	.425	.269	.160	.080	.042	.028	.014	.009

This yields probability distribution of 2 or more consecutive missing entries

- conditional upon existence of at least one missing entry

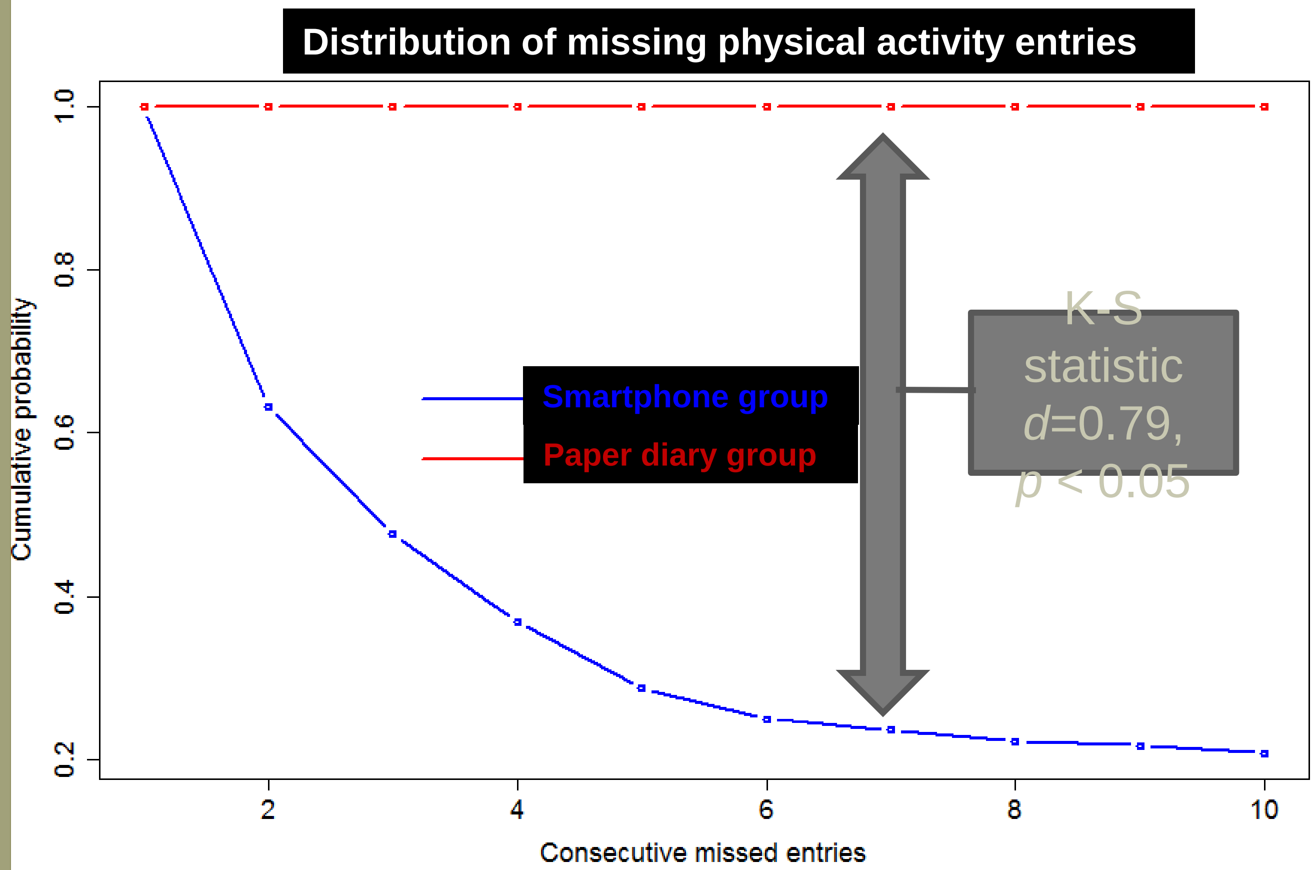
RESULTS: PATTERNS OF DIET ENTRIES

Conditional probability of 2 or more consecutive missing entries is smaller in the smart phone group, but the Kolmogorov-Smirnov statistic was not significant



RESULTS: PATTERNS OF PHYSICAL ACTIVITY ENTRIES

Conditional probability of 2 or more consecutive missing entries is smaller in the smart phone group, and the Kolmogorov-Smirnov statistic was significant

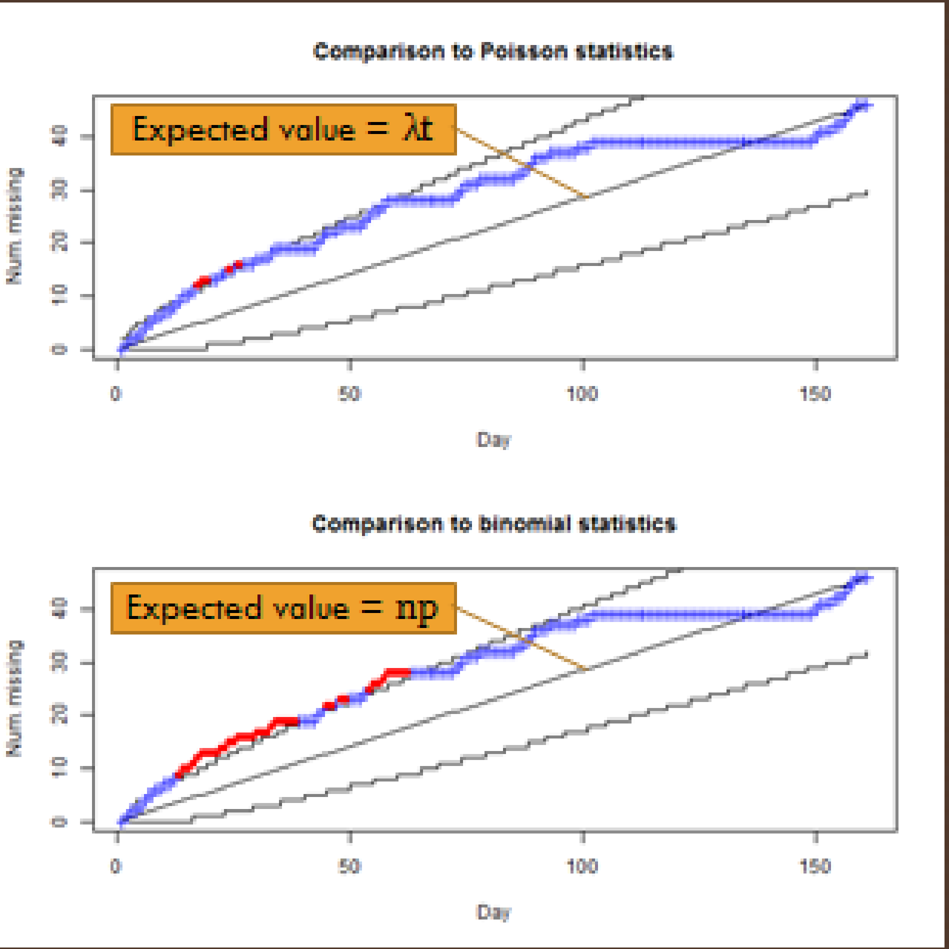


HOW DO MISSING ENTRIES ACCUMULATE?

Comparison of observed accumulation of missing entries to expected number from Poisson and binomial processes

Red data points show violations of 95% confidence intervals

(Representative data set from a participant in the smartphone group)



MISSING ENTRIES ARE MEMORYLESS IN SMARTPHONE GROUP

	Diet			Physical Acitvity		
	Range of λ/p	Violations of Poisson statistics	Violations of binomial statistics	Range of λ/p	Violations of Poisson statistics	Violations of binomial statistics
Smart phone group	0.00 to 0.80	51	167	0.06 to 0.88	54	168
Paper diary group	0.54 to 0.99	147	326	0.99 to 1.00	0	13

Proximity to Poisson distribution in the smartphone group indicates memoryless missing entries

The number of events in any bounded interval of time after time t is independent of the number of events before t

CONCLUSIONS: ADHERENCE & DISCONTINUITY

The smartphone group was more likely to be adherent to self-monitoring of diet and physical activity, as compared to the paper diary group

When a discontinuity appeared, the smartphone group was also less likely to have an extended span of missing entries for physical activity

- Participants were more likely to resume record-keeping after a break
- The same trend for diet, but not significant

CONCLUSIONS: *MEMORYLESSNESS* IN SMARTPHONE GROUP

Incidence of missing entries was close to being a Poisson process for the smartphone group

- The Poisson process has the property of being *memoryless*

Incidence of missing entries in the paper diary group does not appear to be memoryless

- Diet: Many violations of Poisson process
- Physical activity: Once a discontinuity appears, it tends to continue for a long time

TRANSLATING INTO CLINICAL CARE

- Physical activity difficult to estimate
    - Wearable fitness tracker
- Patient and provider needs of connected technology

CONNECT DIABETES STUDY
A MULTI-SITE CLINICAL TRIAL

Jawbone Up

CONNECT +

CHRONICLE DIABETES

- The Chronicle Diabetes Data Management System was developed by and with diabetes educators
- It serves as a national resource for monitoring self-management education programs recognized by the American Diabetes Association (ADA)

American Diabetes Association
Patients
Education
Reports
Alerts
Patient, Deedee
Self Monitoring - Nutrition
June 01 - June 28
Launch Letter Manager

SELF-MONITORING EXERCISE

⇦ Back One Month | September 13, 2015 - October 10, 2015 | Forward One Month ⇨

	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Week Totals (Averages)
	Sep 13	Sep 14	Sep 15	Sep 16	Sep 17	Sep 18	Sep 19	Sep 13 - Sep 19
Calories Burned:	2560	1294	1412	181	1159	194	107	6907 (987)
Steps:	8441	9721	10914	3506	8438	3708	1990	46718 (6674)
Exercise:	108min	50min	57min	-	48min	-	-	263min (37min)

SELF-MONITORING NUTRITION

Back One Month	September 13, 2015 - October 10, 2015					Forward One Month	
	Sunday	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Week Averages
	Sep 13	Sep 14	Sep 15	Sep 16	Sep 17	Sep 18	Sep 19	Sep 13 - Sep 19
Calories:	661	847	756	1188	230	No Data	No Data	736.4
Carbs:	72g	115g	128g	148g	36g	No Data	No Data	99.8g
Saturated Fat:	5g	15g	4g	10g	4g	No Data	No Data	7.6g
Unsaturated Fat:	23g	9g	8g	31g	2g	No Data	No Data	14.6g
Fiber:	12g	7g	17g	10g	0	No Data	No Data	9.2g
Protein:	23g	32g	19g	33g	5g	No Data	No Data	22.4g

STUDY PURPOSE

- To seek educators' insights in developing an interface within Chronicle to transfer smartphone collected self-monitoring (SM) information from patients to diabetes educators to facilitate follow up on behavioral goals

METHODS

- A convenience sample of diabetes educators were recruited
- The focus group and individual interviews were audiotaped and transcribed verbatim
- Two trained professionals coded the transcriptions independently
- Common themes concluded

SAMPLE

- Eight diabetes educators (3RNs, 5 RDs) with an average of 22 years practice, 13 years diabetes education experience and 1.75 years using Chronicle Diabetes system were recruited from Pittsburgh and Houston.

THEME ONE

Enthusiasm of diet and PA data was demonstrated while sleep data was not emphasized as much

- “…so this would be an great opportunity for them to really see that, you know, they’re not as active as they think they are..”
- “The sleep not so much. The nutrition, um, I guess nutrition weekly summaries would work. And, exercise weekly summaries too...”
- “…want to track food logs for sure.”

THEME TWO

Educators value viewing detailed dietary macronutrients and PA data, however, they prefer different details depending on patients' needs and conditions, and in relation to their behavioral goals

- ""I think it depends on the patient. You know, it's all about um, pushing them to go a step further from with they're currently doing.
- "if I was visually looking at it, my number one things would be calories, carbs, protein, and fiber... But I work in the Weight Management Center, and protein and fiber are, like, all we really focus on"

THEME THREE

Different type of educators have different preferences on diet and PA data to be shown at different intervals

- “total burned calories would be important so we know that they’re not—their caloric intake is matching up or negative, if they want to lose weight.”
- “I would like to know what are the food items.”
- “….eventually am I going to be concerned about fiber”

THEME FOUR

All liked integration of smartphone collected data into Chronicle Diabetes and with current electronic health record (EHR) systems

- “then we wouldn’t have to double document it. If we could put it in there and it would automatically go, that would be nice.”
- “Well that’d be great because then I wouldn’t have to chart so dang much. Like, it—all the information would already be in the chart.”

THEME FIVE

A healthcare team and central EHR system need to be formed for educators to share summary of SM data with other providers

- “May not be good for physicians, no time to look at all these independently, but if educators shared with time, they might look at chart briefly/quickly. An educator in team approach… ”

CONCLUSION

- Need for flexibility in tracking details of mobile collected information
- Integration into Chronicle Diabetes and EHR systems is valuable for educators to track patients and share with health care team members
- These perspectives are currently integrated into the development of the actual interface; usability evaluations of this interface was completed, multi-site pilot trial ongoing…

Attitudes Towards Aging in Place Using Wearable and Remote Monitoring Technology among Underserved Homebound Seniors

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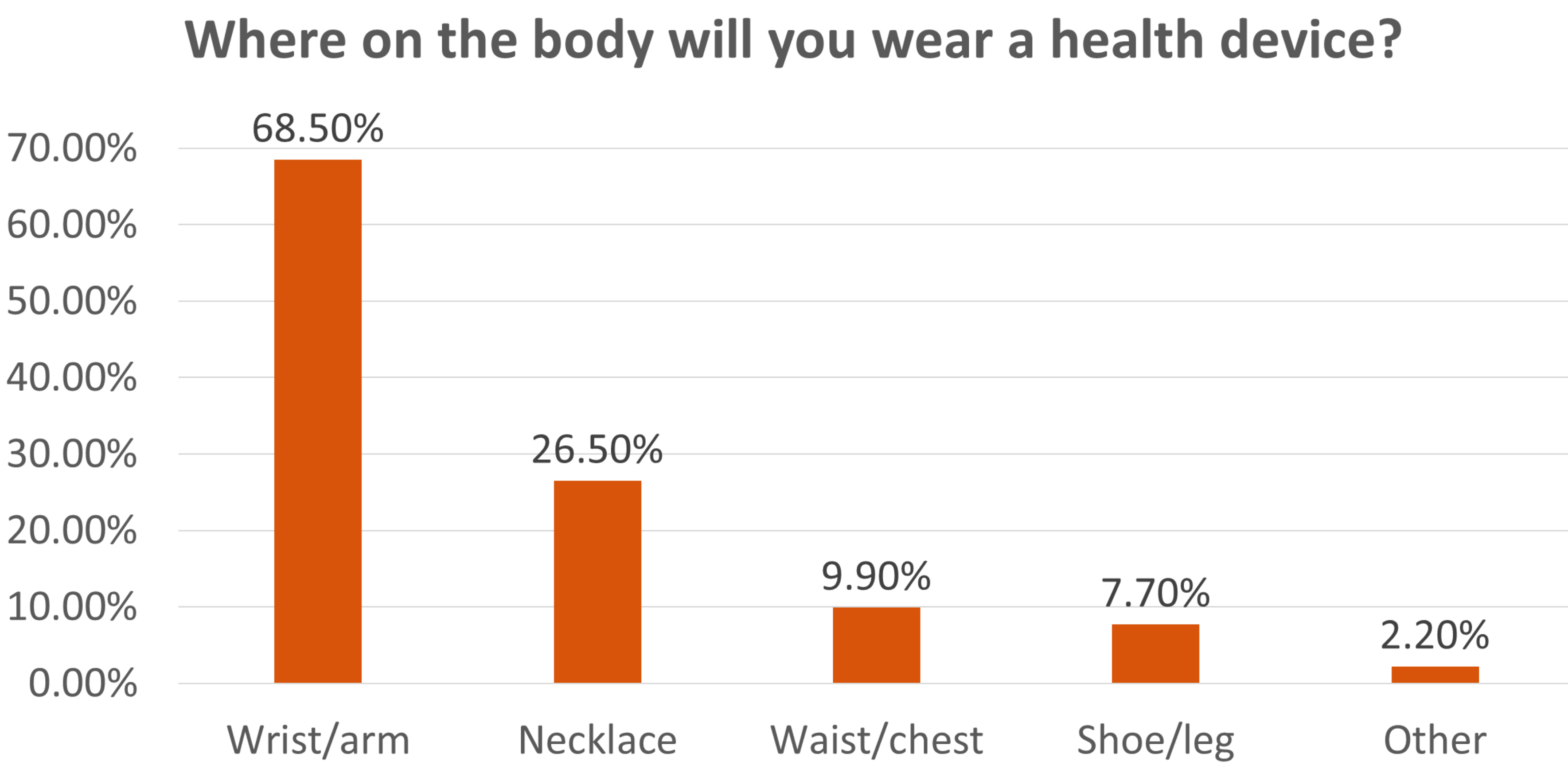
STUDY PURPOSE

To investigate the attitudes of underserved homebound seniors towards wearable and remote monitoring technology including their current use, interests, preferences, and potential concerns of these devices to allow aging in place

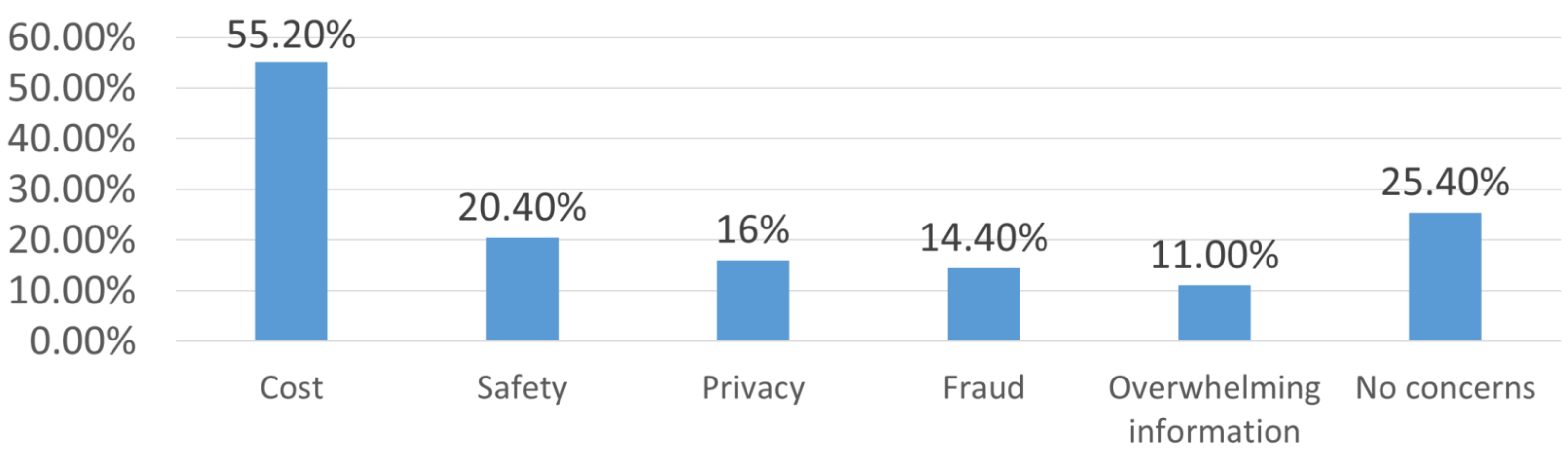
SAMPLE

Sample characteristics (N=181):

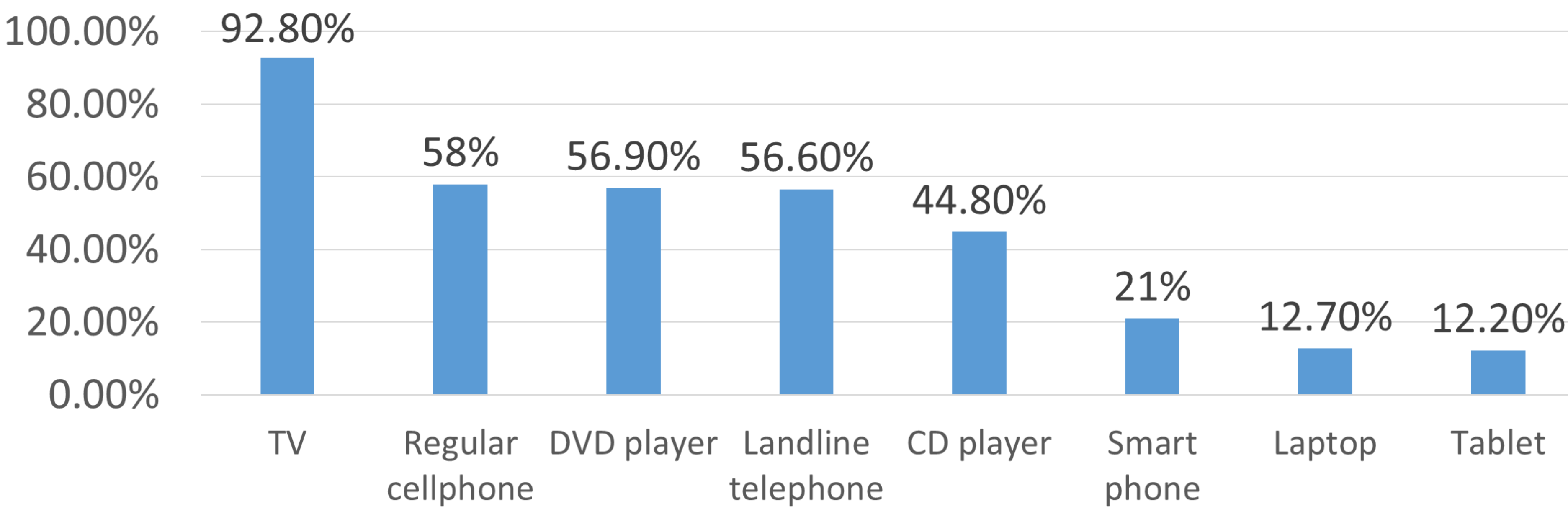
- **Average Age: 77 (±9.42) years**
- **66% (120) female, 49% (88) White, 36% (65) African Americans**
- **Nearly 51% lived alone, 22/7% lived with a spouse, 22.7% lived with at least one family member**


Where on the body will you wear a health device?
70.00%
60.00%
50.00%
40.00%
30.00%
20.00%
10.00%
0.00%
68.50%
26.50%
9.90%
7.70%
2.20%
Wrist/arm
Necklace
Waist/chest
Shoe/leg
Other

CONCERNS ABOUT USING WEARABLE DEVICES



ELECTRONIC DEVICES USED



FUTURE DIRECTION

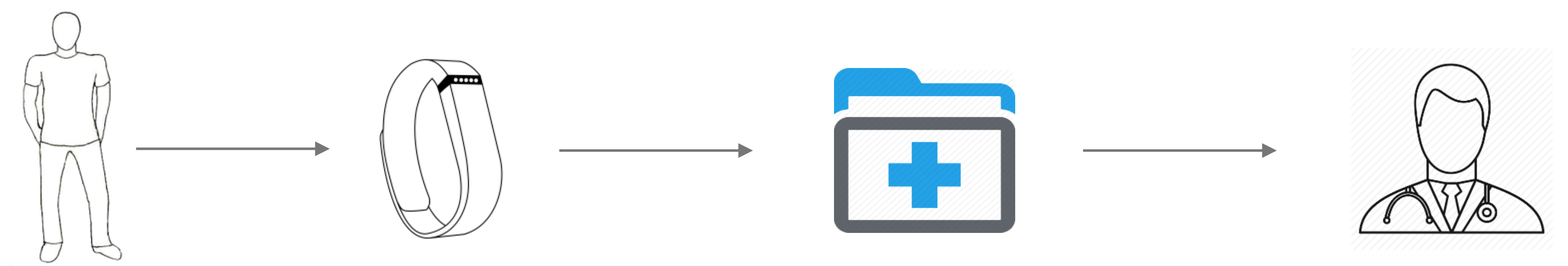
- Connect patients with clinicians
- Connect interprofessional teams
- Clinician workflow and burnout
- Utilize social media to study social determinants of health
- Artificial intelligence and machine learning for tailored feedback
- Patient and consumer engagement
- Population health
- Aging in place sensors
- Diabetes Self-management **Support**

Center on Smart & Connected Health Technologies

UT Health
San Antonio
Center on Smart & Connected Health

PURPOSE

To advance integration of smart and connected clinical care and smart and connected health home



Patient

Mobile device trackers

Data integrated into patient's EHR

Data accessible by Provider

INTIATIVES

Training and Simulation Center

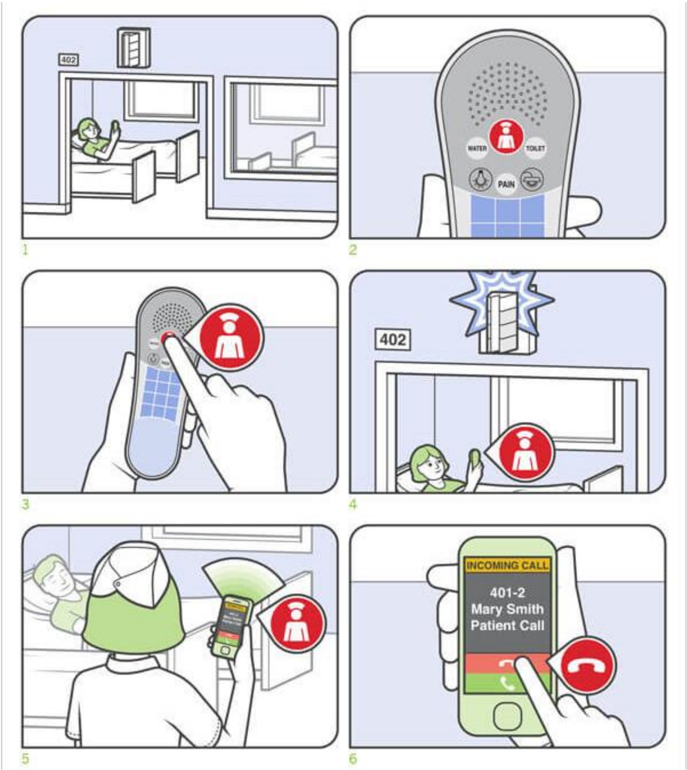
Innovation Lab

South Texas Connected Health Living Lab

Clinical Collaborative

TRAINING AND SIMULATION CENTER

The training and simulation center offers interprofessional education programs for students and clinicians on connected health/telehealth, advancing the skill sets of participants to utilize technology in clinical practice.



UT Health San Antonio
Center on Smart & Connected Health

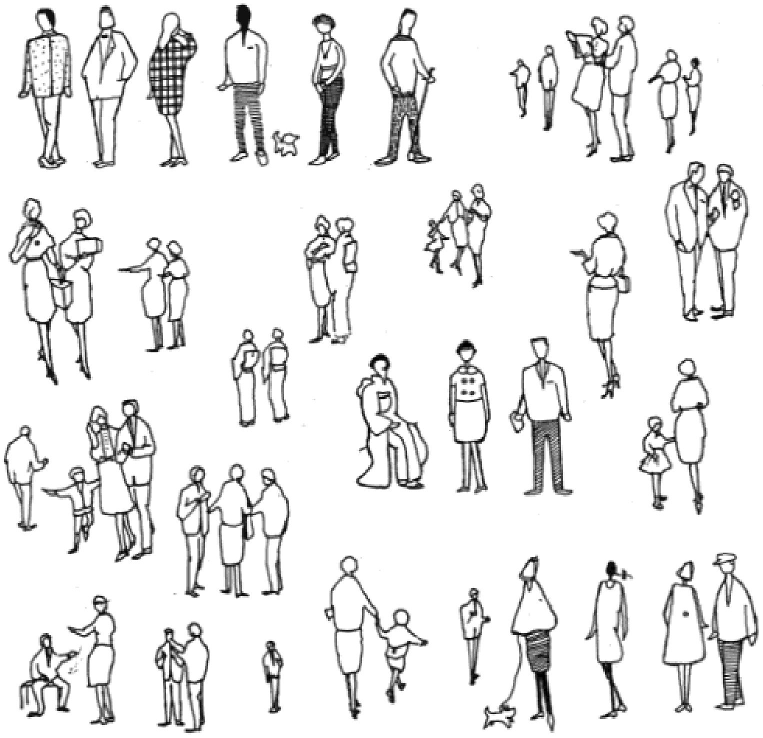
INNOVATION LAB

The innovation lab offers researchers a location to develop and pilot test new connected technology solutions in advance of testing them in clinical or home care settings.

UT Health San Antonio
Center on Smart & Connected Health

SOUTH TEXAS CONNECTED HEALTH LIVING LAB

The living lab uses community engagement efforts to recruit adults, including adults with chronic conditions, seniors, and adults that speak and understand diverse languages to participate in real world testing of innovative connected health solutions.



UT Health
San Antonio
Center on Smart & Connected Health

CLINICAL COLLABORATIVE

The clinical collaborative builds authentic relationships between researchers and clinicians to enable the development and clinical testing of connected health solutions.

ACKNOWLEDGEMENT

- All study participants, diabetes educators
- Research assistants and nursing students
- Collaborators
- Technical Support
    - LoseIt!, Inc
    - PHRQL, Inc
    - Flipside Media, Inc
    - Validic, Inc
    - Jawbone, Inc

THANK YOU