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A:CARE CONGRESS

Improving access to self-management support for patients with chronic conditions: digital solutions

Prof. John Piette

Professor of Health Behavior & Health Education & Director of the Center for Managing Chronic Disease at Ann Arbor Michigan, US

Dr. Bernard Vrijens

Professor of Biostatistics & the University of Liege
CEO of AARDEX
Belgium

Prof. Enrique de Madaria

Associate Professor of Gastroenterology, Miguel Hernández University, Elche; Coordinator of the Biliary-Pancreatic Unit at Alicante's University General Hospital. President of the Spanish Association of Gastroenterology, Spain

Improving Access To Self-management Support For Patients With Chronic Conditions: Digital Solutions

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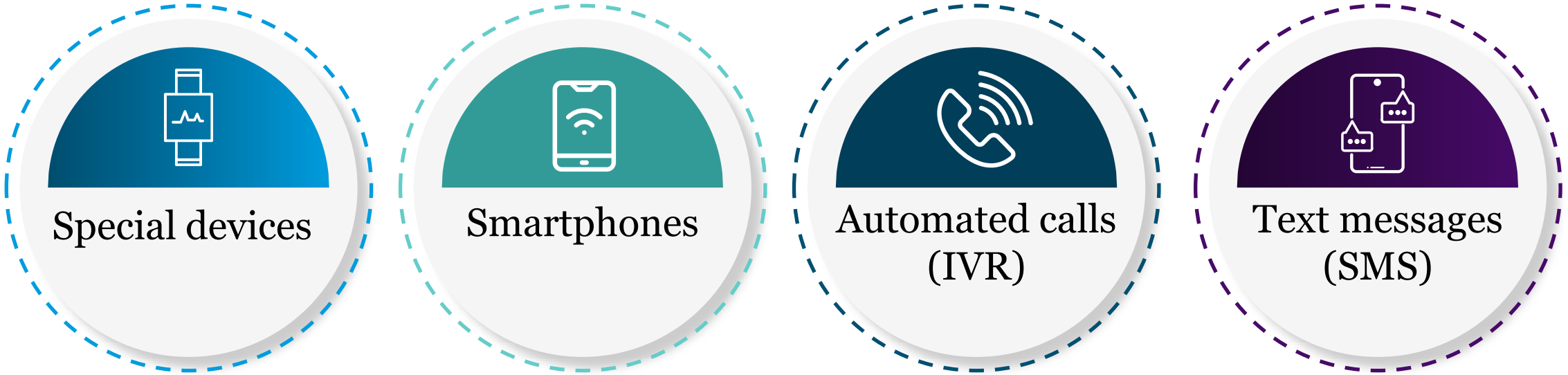
Professor of Health Behavior & Health Education &
Director of the Center for Managing Chronic Disease at Ann Arbor Michigan, US

A digital solutions can be defined along three dimensions

- Sociodemographic population served
- Mobile technologies and communication channels
- Program goals and functions

Mobile technologies for improving self-care support



A digital solutions can be defined along three dimensions

Sociodemographic population served

Mobile technologies and communication channels

Program goals and functions

Treatment Adherence

Monitoring

Text Messaging for Disease Monitoring in Childhood Nephrotic Syndrome

Chia-shi Wang[1], Jonathan P. Troost[2], Larry A. Greenbaum[1], Tarak Srivastava[3], Kimberly Reidy[4], Keisha Gibson[5], Howard Trachtman[6], John D. Piette[7], Christine B. Sethna[8], Kevin Meyers[9], Katherine M. Dell[10], Cheryl L. Tran[11], Suzanne Vento[6], Krishna Kallem[9], Emily Herreshoff[2], Sangeeta Hingorani[12], Kevin Lemley[13], Gia Oh[14], Elizabeth Brown[15], Jen-Jar Lin[16], Frederick Kaskel[4] and Debbie S. Gipson[2]

Introduction: There is limited information on effective disease monitoring for prompt interventions in childhood nephrotic syndrome. We examined the feasibility and effectiveness of a novel text messaging system (SMS) for disease monitoring in a multicenter, prospective study.

1. Department of Pediatrics, Emory University and Children's Healthcare of Atlanta, Atlanta, Georgia, USA; 2. Department of Pediatrics and Communicable Diseases, University of Michigan, Ann Arbor, Michigan, USA; 3. Department of Pediatrics, Children's Mercy Hospital and University of Missouri at Kansas City, Kansas City, Missouri, USA; 4.Department of Pediatrics, Montefiore Medical Center, New York, New York, USA; 5.Department of Medicine and Pediatrics, University of North Carolina, Chapel Hill, North Carolina, USA; 6. Department of Pediatrics, NYU School of Medicine, New York, New York, USA; 7.Department of Health Behavior & Health Education, University of Michigan, Ann Arbor, Michigan, USA; 8.Department of Pediatrics, Cohen Children's Medical Center of New York, New Hyde Park, New York, USA; 9.Department of Pediatrics, Children's Hospital of Philadelphia, Philadelphia, Pennsylvania, USA; 10. Department of Pediatrics, Case Western Reserve University, Cleveland Clinic Children's, Cleveland, Ohio, USA; 11. Department of Pediatrics, Mayo Clinic, Rochester, Minnesota, USA; 12. Department of Pediatrics, Seattle Children's Hospital, Seattle, Washington, USA; 12. Department of Pediatrics, Children's Hospital-LA, Los Angeles, California, USA; 14. Department of Pediatrics, Stanford University, Palo Alto, California, USA; 15. Department of Pediatrics, UT Southwestern Medical Center, Dallas, Texas, USA; and 16. Department of Pediatrics, Wake Forest University, Winston-Salem, North Carolina, USA

Text Messaging for Disease Monitoring in Childhood Nephrotic Syndrome

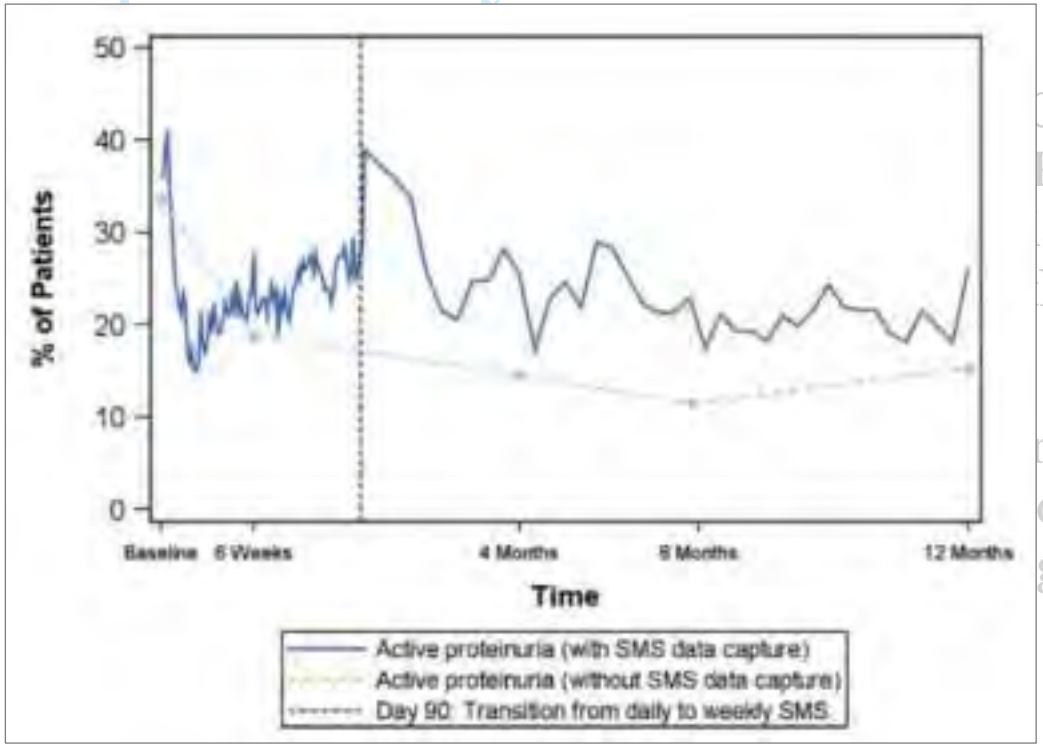


Figure 4: Percentage of patients with nephrotic range proteinuria as captured by short message service (SMS) reporting versus in-person clinic visits

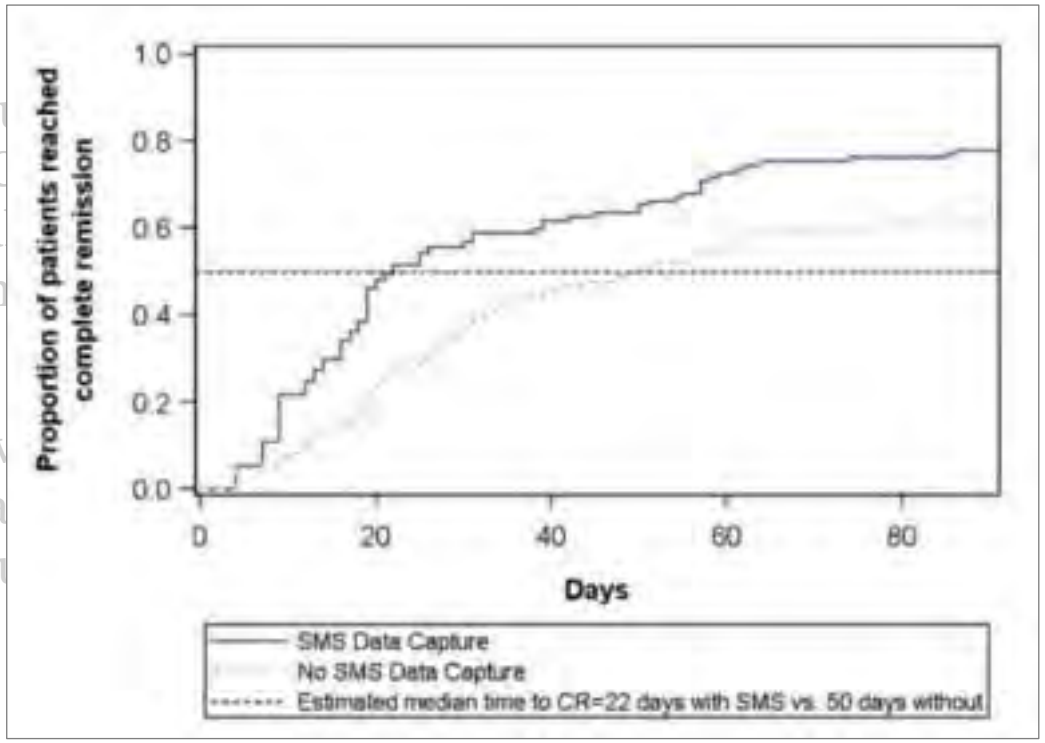


Figure 5: Time to remission after study enrolment by short message service (SMS)- captured urine protein results versus participant reporting during in-person study visits. CR, complete remission

Lifestyle behaviors

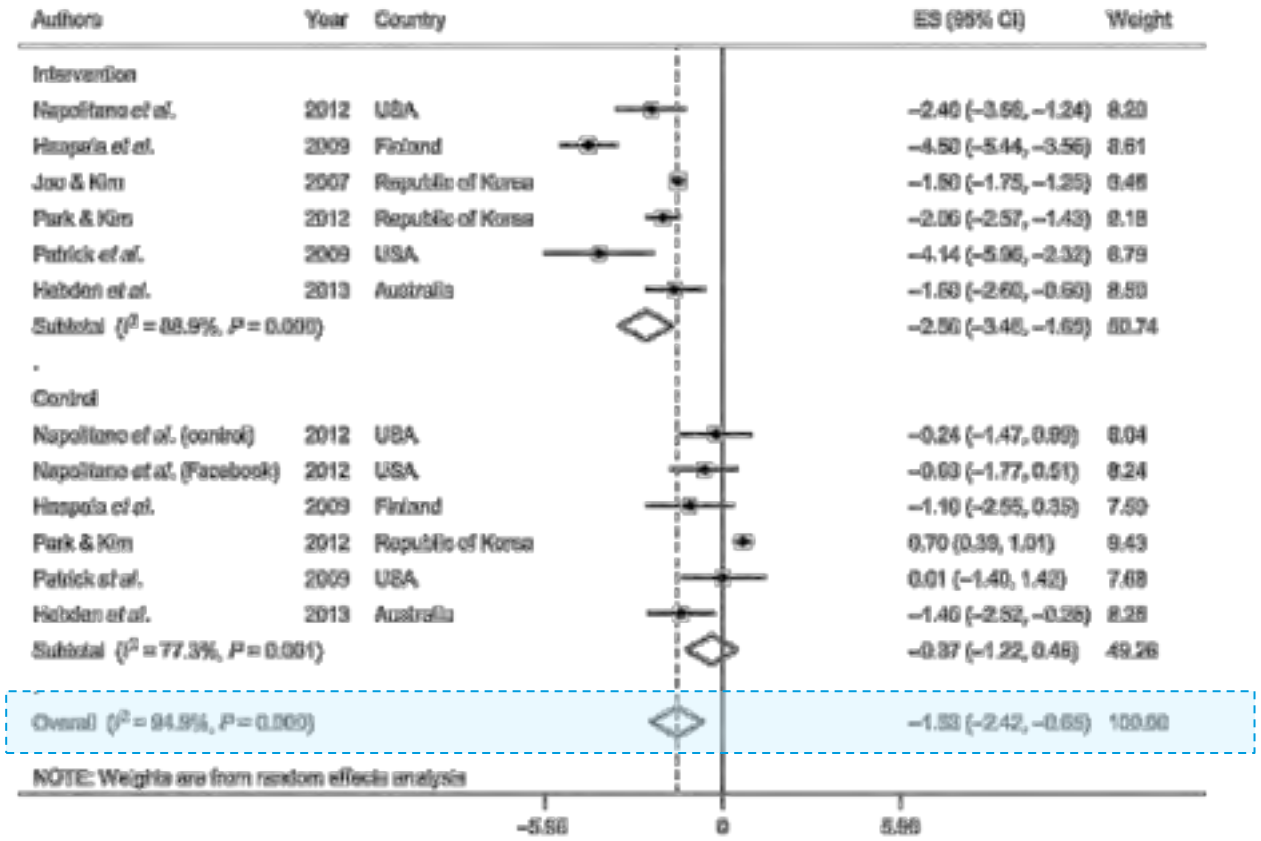
Interventions for weight management using text messaging

BDA The Association of UK Dietitians
THE OFFICIAL JOURNAL OF THE BRITISH DIETETIC ASSOCIATION
Journal of Human Nutrition and Dietetics

Review

A systematic review and meta-analysis of interventions for weight management using text messaging

G. Siopis,[1] T. Chey[2] & M. Allman-Farinelli[1]



Forest plot: mean weight change in body weight of intervention and control participants with the combined meta-regression shown below. Effect size (ES) is indicated by black diamonds; percentage weighting of each study towards the overall effect is indicated by the size of grey squares; 95% confidence interval is indicated by horizontal lines; the overall treatment effect lies at the center of the diamond with left and right endpoints indicating the 95% confidence interval (CI).

1. School of Molecular Bioscience, The University of Sydney, Sydney, NSW, Australia; 2. School of Public Health, The University of Sydney, Sydney, NSW, Australia

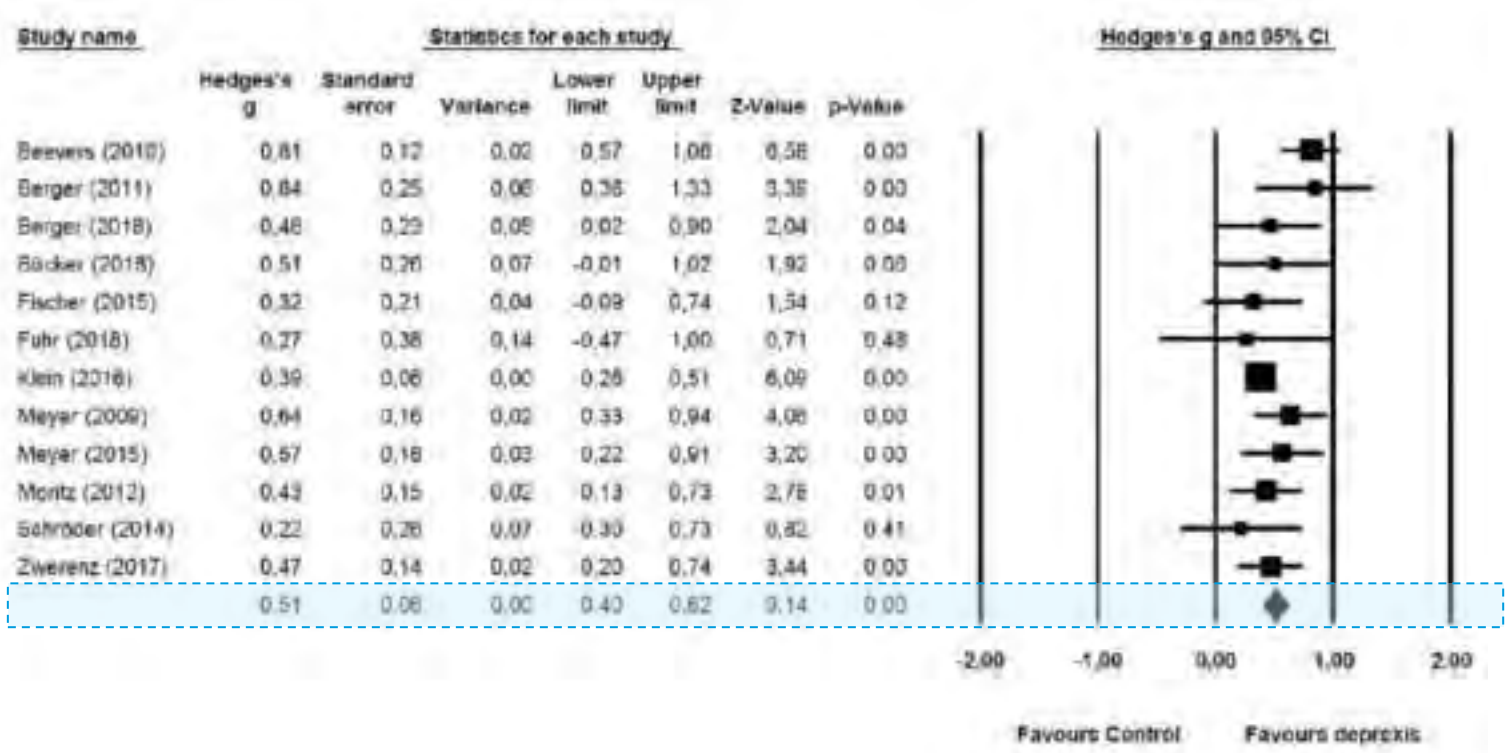
Complex behavioral health challenges

Tailored integrative Internet intervention for depression

Research Article

Effectiveness of a tailored, integrative Internet intervention (deprexis) for depression: Updated meta-analysis

Conal Twomey[1], Gary O'Reilly[1], Oliver Bültmann[2], Björn Meyer [2,3,a]



1. School of Psychology, University College Dublin, Belfield, Dublin, Ireland; 2. Research Department, Gaia, Hamburg, Germany; 3. Department of Psychology, City, University of London, London, England, United Kingdom

Interactive Voice Response-Based Self-management for Chronic Back Pain

THE COPES NONINFERIORITY RANDOMIZED TRIAL

Alicia A. Heapy. PhD; Diana M. Higgins. PhD; Joseph L. Goulet. PhD, Kathryn M. LaChappeIIe, MPH; Mary A. Driscoll. PhD; Rebecca A Czlapinski. MA; Eugenia Buta. PhD; John D. Piette, PhD; Sarah L. Krein, PhD: Robert D. Kerns. PhD

IMPORTANCE Recommendations for chronic pain treatment emphasize multimodal approaches, including nonpharmacologic interventions to enhance self-management. Cognitive behavioral therapy (CBT) is an evidence-based treatment that facilitates management of chronic pain and improves outcomes, but access barriers persist. Cognitive behavioral therapy delivery assisted by health technology can obviate the need for in-person visits, but the effectiveness of this alternative to standard therapy is unknown. The Cooperative Pain Education and Self-management (COPES) trial was a randomized, noninferiority trial comparing IVR-CBT to in-person CBT for patients with chronic back pain.

OBJECTIVE To assess the efficacy of interactive voice response-based CBT (IVR-CBT) relative to in-person CBT for chronic back pain.

DESIGN, SETTING, AND PARTICIPANTS We conducted a noninferiority randomized trial in 1 Department of Veterans Affairs (VA) health care system. A total of 125 patients with chronic back pain were equally allocated to IVR-CBT (n = 62) or in-person CBT (n = 63).

INTERVENTIONS Patients treated with IVR-CBT received a self-help manual and weekly prerecorded therapist feedback based on their IVR-reported activity, coping skill practice, and pain outcomes. In-person CBT included weekly. individual CBT sessions with a therapist. Participants in both conditions received IVR monitoring of pain. sleep, activity levels. and pain coping skill practice during treatment.

MAIN OUTCOMES AND MEASURES The primary outcome was change from baseline to 3 months in unblinded patient report of average pain intensity measured by the Numeric Rating Scale (NRS). Secondary outcomes included changes in pain-related interference, physical and emotional functioning. sleep quality. and quality of life at 3.6. and 9 months. We also examined treatment retention.

Heapy AA, Higgins DM, Goulet JL, LaChappelle KM, Driscoll MA, Czlapinski RA, Buta E, Piette JD, Krein SL, Kerns RD. Interactive Voice Response-Based Self-management for Chronic Back Pain: The COPES Noninferiority Randomized Trial. *JAMA Intern Med*. 2017 Jun 1;177(6):765-773.

Interactive Voice Response-Based Self-management for Chron

THE COPES NC

Alicia A. Heapy. PhD; D
Rebecca A Czlapinski. M

IMPORTANCE Recom
enhance self-manageme
improves outcomes, but
person visits, but the eff
(COPES) trial was a ran

OBJECTIVE To assess

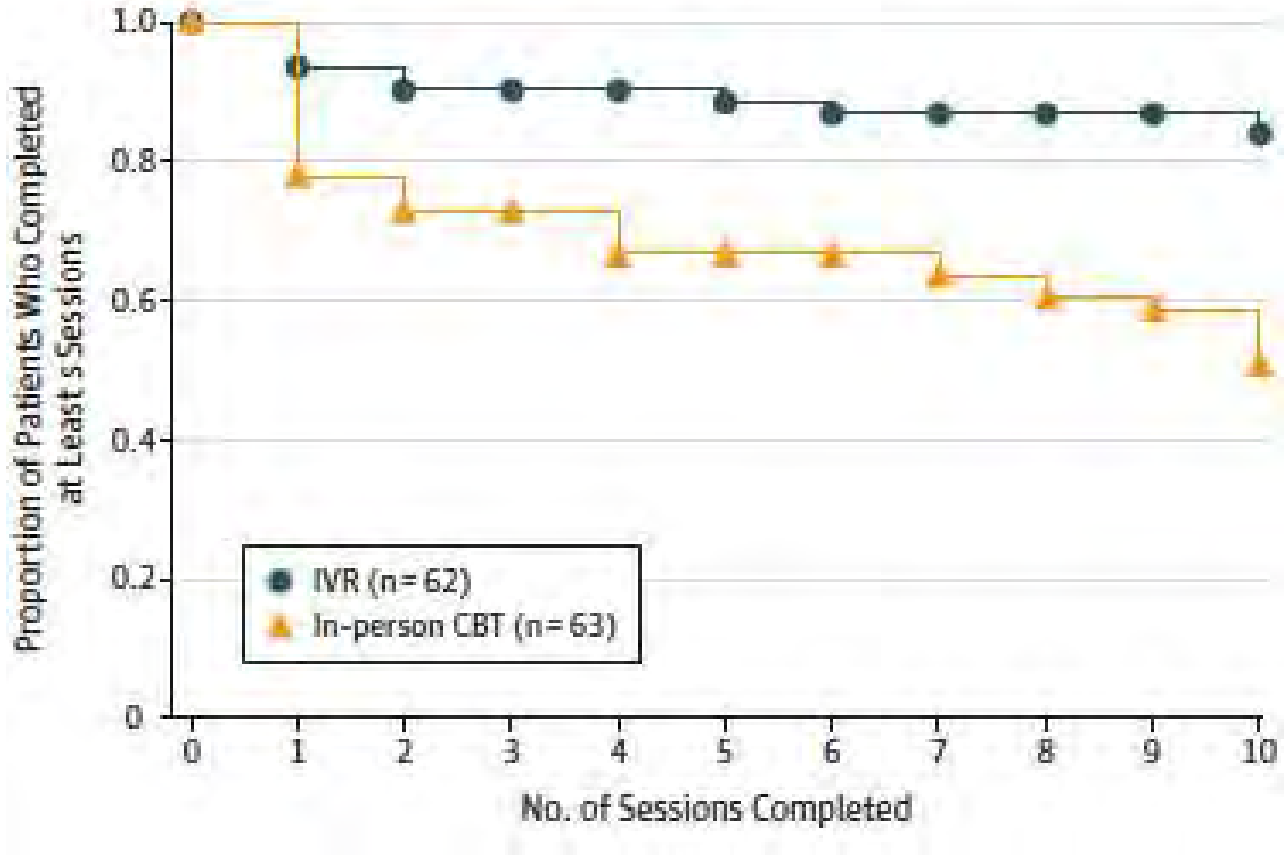
DESIGN, SETTING,
care system. A total of 1

INTERVENTIONS Pa
reported activity, copin
in both conditions recei

MAIN OUTCOMES A
pain intensity measured
emotional functioning.

Heapy AA, Higgins DM, Goul
Chronic Back Pain: The COPE

NUMBER OF TREATMENT WEEKS BY CONDITION



CBT indicates cognitive behavioural therapy; IVR, interactive voice response.

l. PhD;

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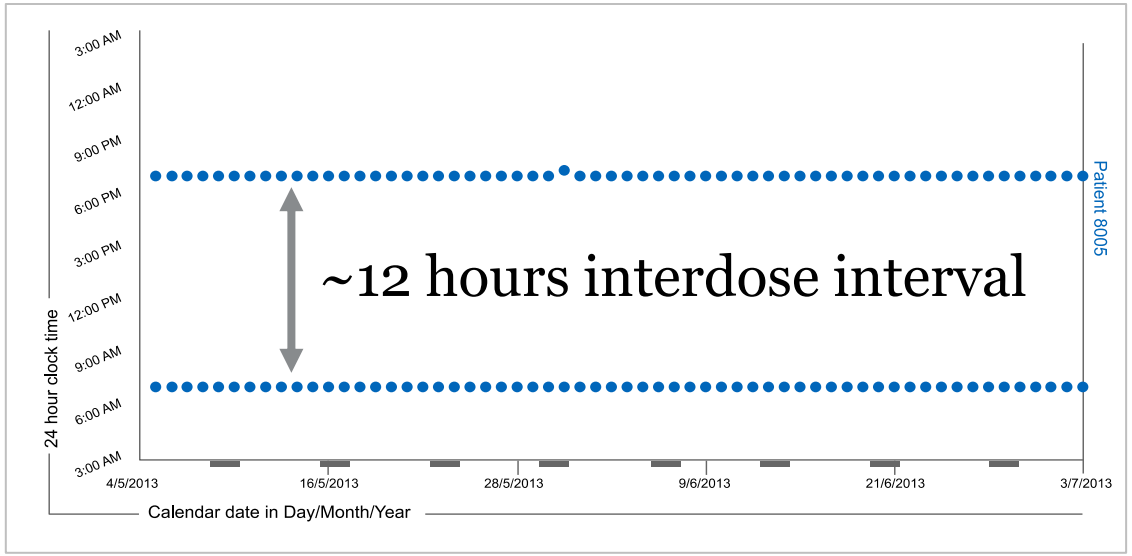
Improving Access To Self-management Support For Patients With Chronic Conditions: Digital Solutions

Dr. Bernard Vrijens, PhD
AARDEX Group
Liège University
Honorary Member, ESPACOMP, Belgium

Medication Intake Behavior



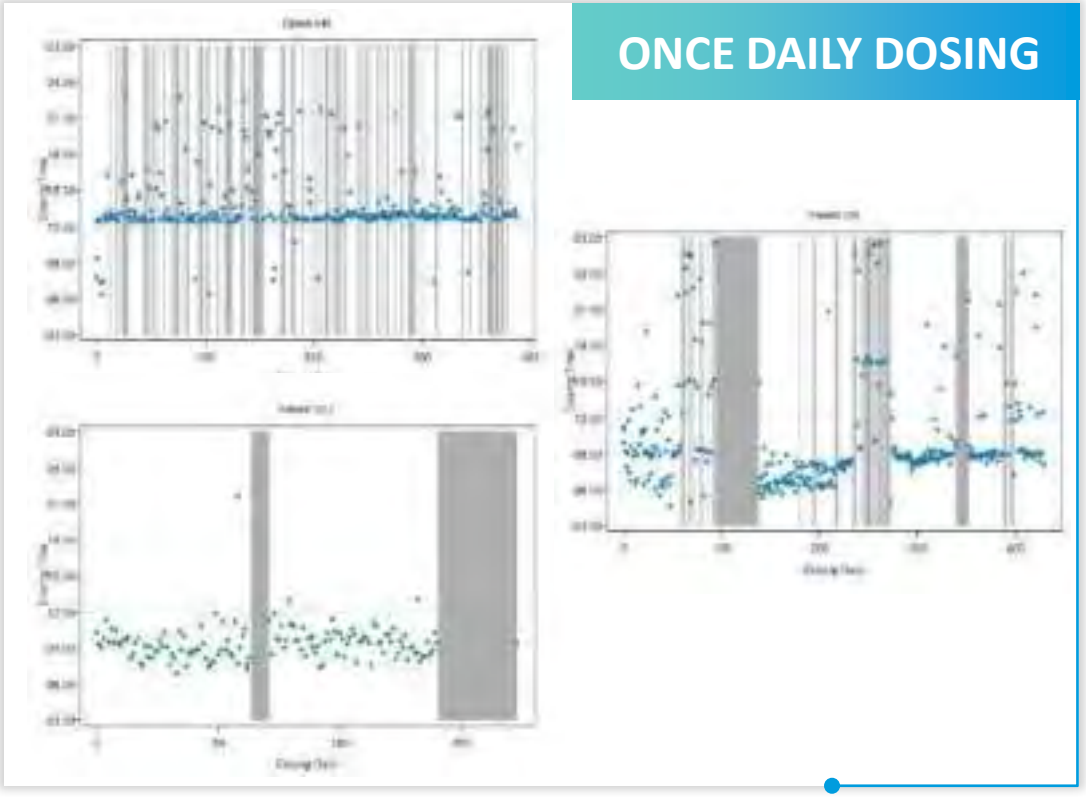
YOU CAN'T MANAGE WHAT YOU DON'T MEASURE

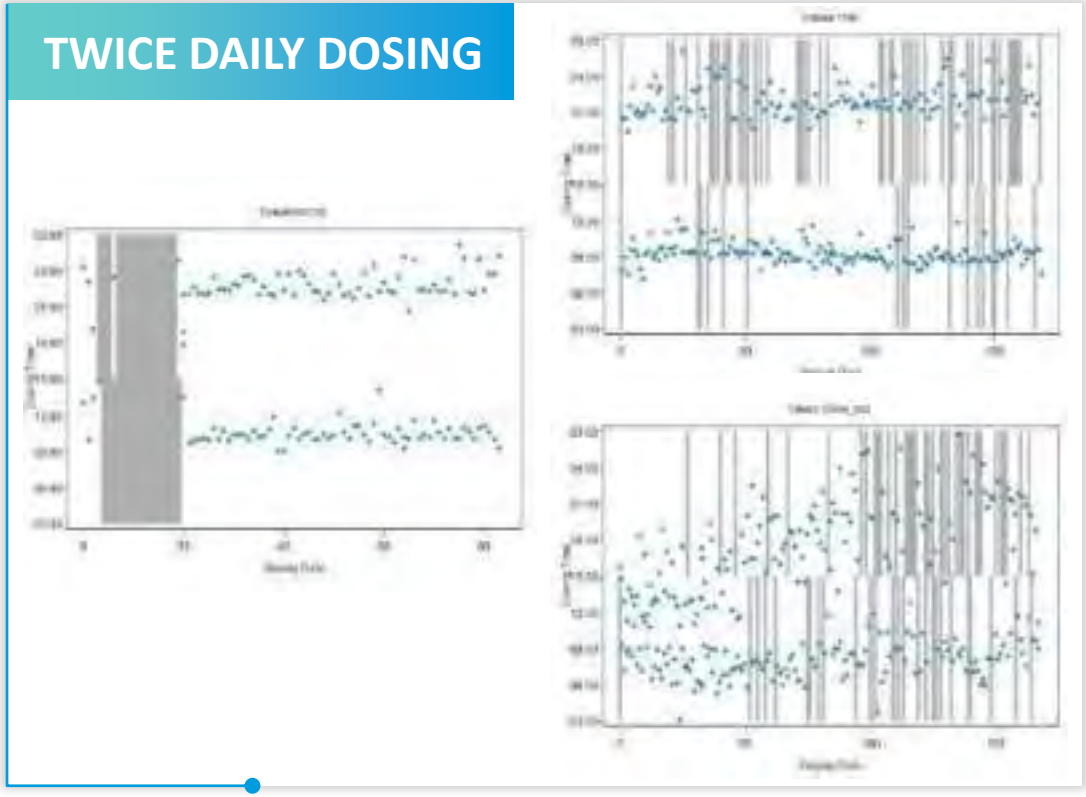
Measure

Manage

The Unfortunate 80% Rule!

EACH OF THESE 6 PATIENTS TOOK THE SAME PERCENTAGE (81%) OF PRESCRIBED DOSES, WHICH SOUNDS GOOD, BUT LOOK



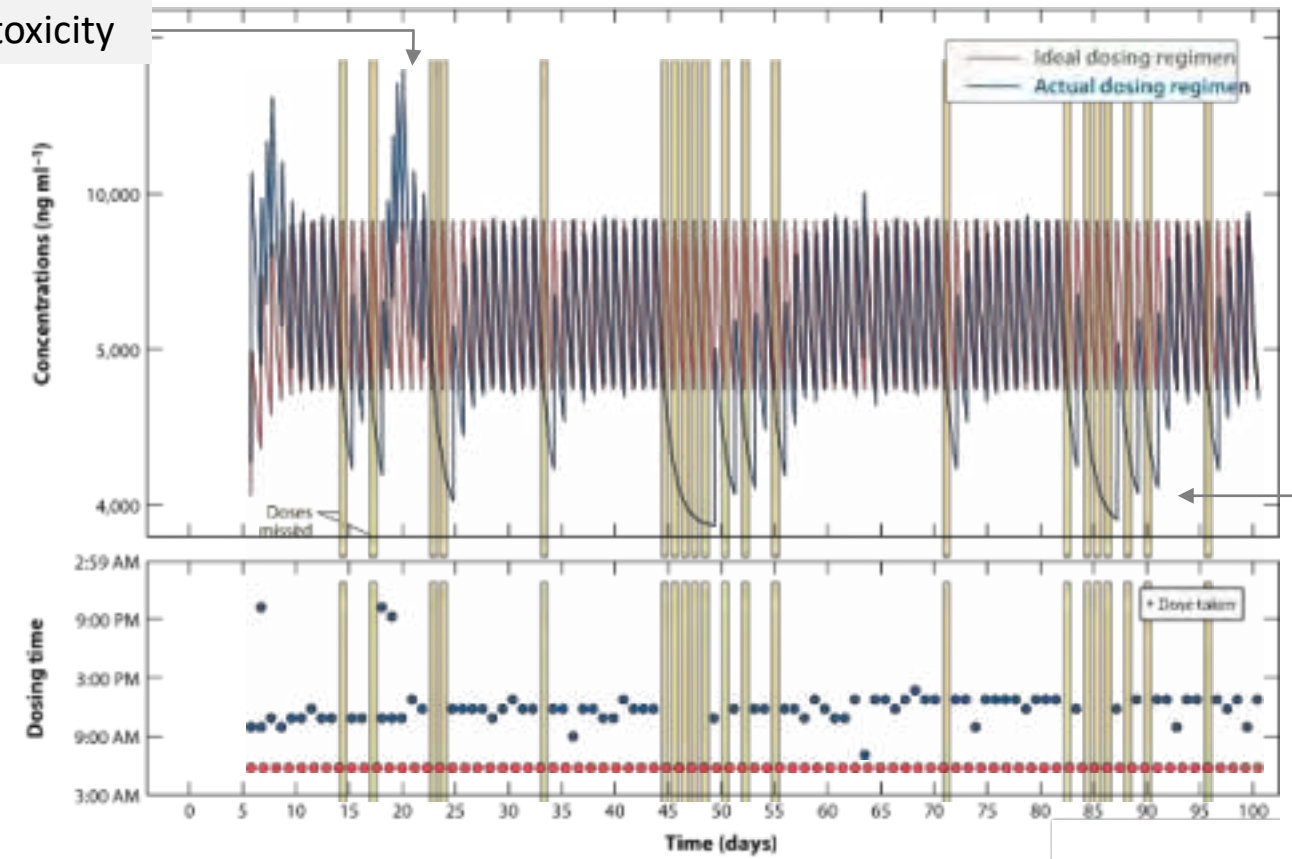


The variability in all these cases poses a significant risk to clinical success

Vrijens B et al., Assessment of medication adherence in field research, First Edition, *John Wiley & Sons*, Ltd., 2016

Variable adherence creates drug-specific issues of efficacy, safety & drug resistance

Occasional toxicity



Periodic loss of effectiveness & emergence of drug resistance

Blaschke TF, Osterberg L, Vrijens B, Urquhart J. Adherence to medications: insights arising from studies on the unreliable link between prescribed and actual drug dosing histories. *Annu Rev Pharmacol Toxicol*. 2012;52:275-301.

Medication Event Monitoring System (MEMS®)

MEASURE

MEMS® Hardware Ecosystem

MANAGE

MEMS® Adherence Software

1 million users

70 countries

35

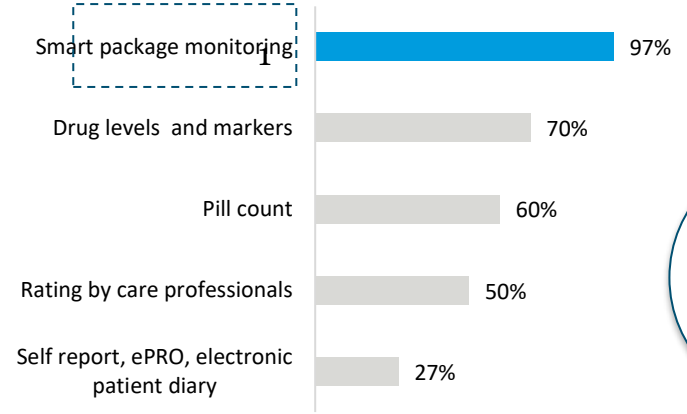
35 years

800+ Publications

The Scientific Evidence

MEASURE

Accuracy of the measurement methods



- Accurate & continuous measure
- No burden for the patients
- Available for all patients included

&

MANAGE

↑20% → Up to ↑ 50%

Data-driven adherence feedback is the most effective means to empower patients and improve adherence

1. El Alili M, Vrijens B, Demonceau J, Evers SM, Hiligsmann M. A scoping review of studies comparing the medication event monitoring system (MEMS) with alternative methods for measuring medication adherence. *Br J Clin Pharmacol*. 2016;82(1):268-279. 2. Demonceau J, et al. Identification and assessment of adherence-enhancing interventions in studies assessing medication adherence through electronically compiled drug dosing histories: a systematic literature review and meta-analysis. *Drugs*. 2013 May;73(6):545-62.

Empower Patients and Providers

- Self-management and patient engagement in care
- Facilitate communication between the patient and providers (e.g. shared decision making)
- Consistency in the message delivered based on individual measures (e.g. multidisciplinary team)
- Individualized care based on data (e.g. rational decision rather than irrational or emotional)
- Risk stratification and prevention (e.g. set priorities and optimize providers' time)

Digitally-Enabled Integrated Person-Centred Care[1]

BENEFITS FOR ALL STAKEHOLDERS – TIME IS RIPE FOR A CHANGE!

Patients

- Improves quality, safety, and effectiveness of medications
- Greater patient awareness and participation in care

Providers

- Better use of time allocation
- Emergence of new forms of collaboration and multidisciplinary approaches

Payers

- Decrease healthcare expenditures on chronic therapies
- Improve return on Rx spend by improving outcomes and reducing wastage

Industry

- Maximise value of the molecule to sustain high growth
- Improve image, retain patients

Bousquet J, Bedbrook A, Czarlewski W, et al. Guidance to 2018 good practice: ARIA digitally-enabled, integrated, person-centred care for rhinitis and asthma, *Clin Transl Allergy*. 2019 Oct 9;9:52.

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a:care

IMPROVING ACCESS TO SELF-MANAGEMENT SUPPORT FOR PATIENTS WITH CHRONIC CONDITIONS: DIGITAL SOLUTIONS

Lock-down: The Impact Of COVID-19 On Patient Adherence

Prof. Enrique de Madaria
Miguel Hernández University, Elche
Alicante's University General Hospital
President of the Spanish Association of Gastroenterology
Spain

Disclosures

HONORARIA FROM TAKEDA PHARMACEUTICAL COMPANY, ABBOTT AND MYLAN.

COVID-19 pandemic

SINCE DEC 2019 TO SEPT 2021

- 226,418,202 cases
- 4,660,390 deaths

KEY FEATURES OF COVID-19

- Direct person-to-person respiratory transmission[1]
- Primary transmission via respiratory particles, hand contamination by secretions[1]
- Early reports: mild 81%, Severe 14%, critical 5%, 2.3% mortality[2]

1 The Lancet Respiratory Medicine. COVID-19 transmission-up in the air. *Lancet Respir Med*. 2020 Dec;8(12):1159. 2 Wu Z, McGoogan JM. Characteristics of and Important Lessons From the Coronavirus Disease 2019 (COVID-19) Outbreak in China: Summary of a Report of 72 314 Cases From the Chinese Center for Disease Control and Prevention. *JAMA*. 2020 Apr 7;323(13):1239-1242.

Image from: Johns Hopkins Coronavirus resource center, Sep 16 2021

COVID-19 And Patients With Non-communicable Chronic Diseases

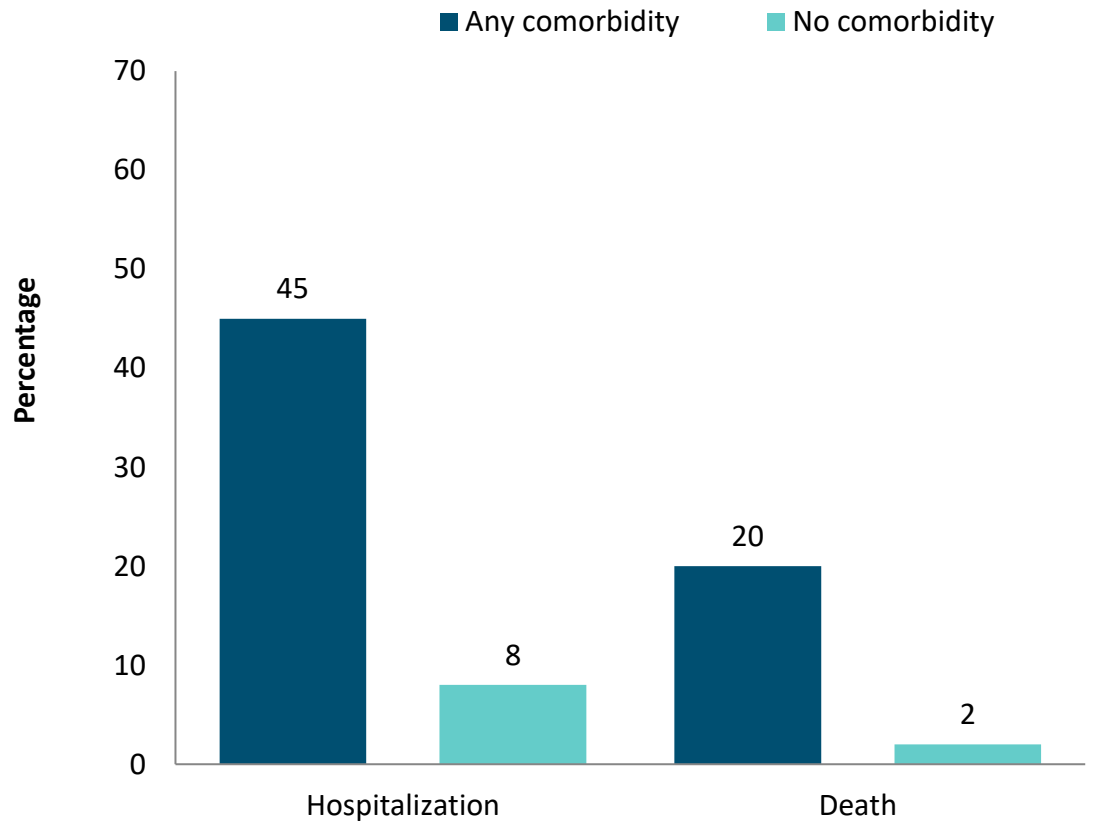
EFFECTS OF THE LOCK DOWN ON RISK FACTORS

- Probable increase in habits like caloric/ salty food intake, tobacco use, alcohol and cannabis use[1]
- After an initial decrease, the number of smokers have risen[2]
- Decrease in the effectivity of smoking cessation programs[3]

1 Rolland B, Haesebaert F, Zante E, Benyamina A, Haesebaert J, Franck N. Global Changes and Factors of Increase in Caloric/Salty Food Intake, Screen Use, and Substance Use During the Early COVID-19 Containment Phase in the General Population in France: Survey Study. *JMIR Public Health Surveill*. 2020 Sep 18;6(3):e19630. 2 The Lancet Respiratory Medicine. COVID-19, smoking, and cancer: a dangerous liaison. *Lancet Respir* Med. 2021 Sep;9(9):937. 3 Veldhuizen S, Selby P, Wong B, Zawertailo L. Effect of COVID-19 on smoking cessation outcomes in a large primary care treatment programme: an observational study. *BMJ Open*. 2021 Aug 26;11(8):e053075.

Comorbidity and COVID-19

COVID-19 CASE SURVEILLANCE, USA



Stokes EK, Zambrano LD, Anderson KN, Marder EP, Raz KM, El Burai Felix S, Tie Y, Fullerton KE. Coronavirus Disease 2019 Case Surveillance - United States, January 22-May 30, 2020. *MMWR Morb Mortal* Wkly Rep. 2020 Jun 19;69(24):759-765.

COVID-19 And Patients Receiving Chronic

DECREASED MEDICAL ADHERENCE?

- Fear of patients with comorbidity to have severe disease/ to die
- Fear of visiting healthcare facilities, decreased availability for general practitioners, collapse of hospitals -> 40% decline in outpatients visits in USA[1]
- COVID-19 is perceived as a major health threat, chronic conditions may seem harmless
- Economic crisis: decreased incomes, loss of medical insurances
- There may be disruption of drug supply chains (8% increase in drug shortages during first quarter of 2020 in USA[2])

1 Ziedan et al, Effects of State COVID-19 Closure Policy on NON-COVID-19 Health Care Utilization, NBER working paper series 2020:1-68 2 Ziedan, J Chem Inf Model 2020

Impact of COVID-19 on noncommunicable disease (NCD) resources and services, WHO survey

75% countries in 2020 with considerable degree of disruption of NCD services

- All regions, all income groups. Higher impact on LMICS

Most countries had disruption in essential services for hypertension, diabetes and cancer

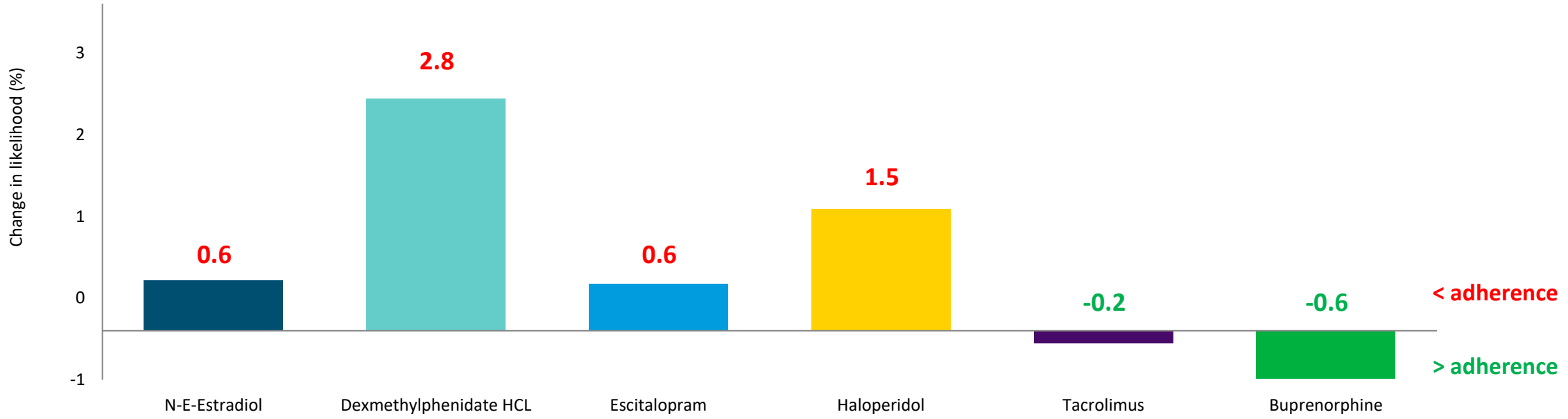
Main reasons:

- Decrease in inpatient volume due to the cancellation of elective care
- Closure of population-level screening programs and outpatient disease-specific clinics
- Lockdowns
- Impacts on staffing
- Insufficient personal protective equipment (PPE)

WHO 2020, The impact of the covid-19 pandemic on noncommunicable disease resources and services: results of a rapid assessment

Retrospective analysis on a dataset of 9.4 billion US prescription drug claims from 252 million patients from May 2019 through August 2020

LIKELIHOOD OF DISCONTINUING DRUG



Clement J, Jacobi M, Greenwood BN. Patient access to chronic medications during the Covid-19 pandemic: Evidence from a comprehensive dataset of US insurance claims. *PLoS One*. 2021 Apr 1;16(4):e0249453.

COVID-19, medical adherence and low-and middle-income countries (LMICS)

High disease burden: chronic infectious and non-communicable diseases[1]

- HIV/AIDS, tuberculosis, hepatitis, diabetes, cardiovascular diseases, cancers, chronic pulmonary diseases and mental illnesses[2]

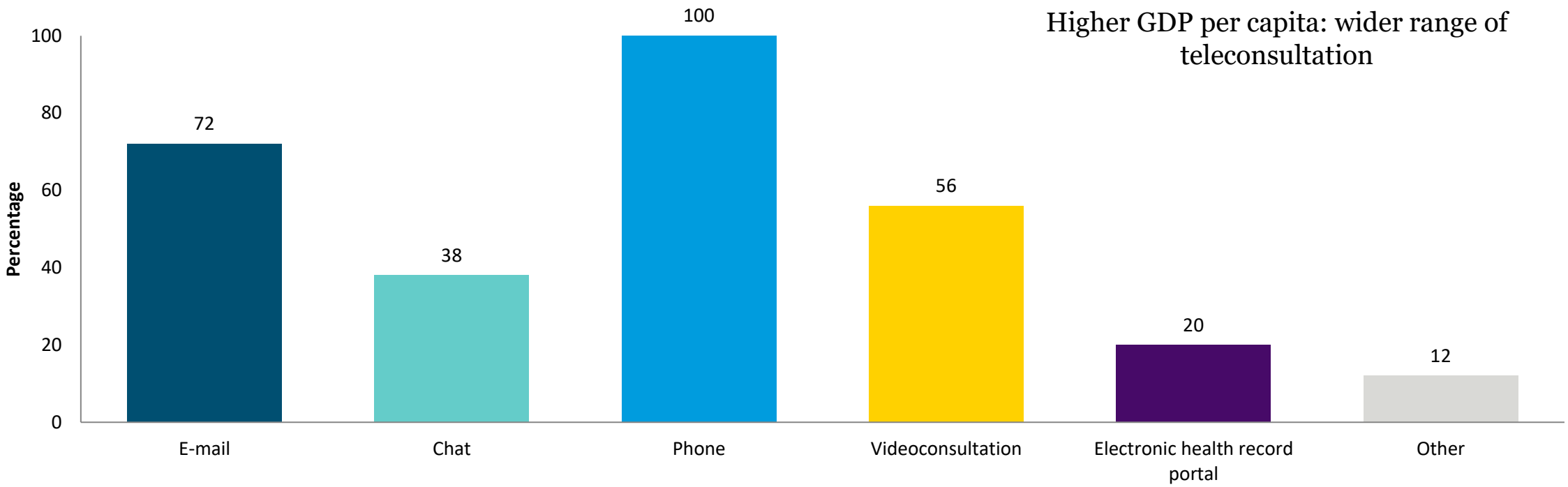
LMICs often rely heavily on drug imports, COVID-19 global shut down

Lower access to technology but 40% LMICS countries used telemedicine during COVID-19 crisis in 2020[3]

1 Kretchy IA, Asiedu-Danso M, Kretchy JP. Medication management and adherence during the COVID-19 pandemic: Perspectives and experiences from low-and middle-income countries. *Res Social Adm Pharm.* 2021 Jan;17(1):2023-2026. 2 Boutayeb A. The double burden of communicable and non-communicable diseases in developing countries. *Trans R Soc Trop Med Hyg*. 2006 Mar;100(3):191-9. 3 WHO 2020, The impact of the covid-19 pandemic on noncommunicable disease resources and services: results of a rapid assessment https://www.who.int/publications/i/item/9789240010291 [Accessed October 2021]

European Network to Advance Best practices & technoLogy on medication adherencE (ENABLE) cross-sectional study

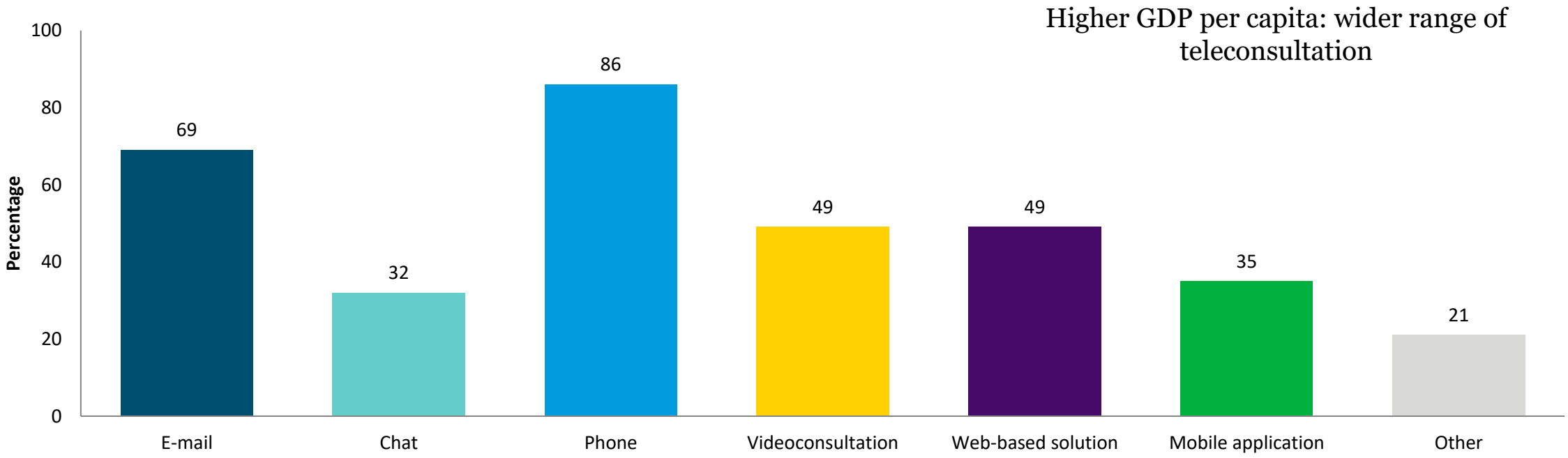
AVAILABILITY OF VARIOUS FORMS OF TELECONSULTATION



Ágh T, van Boven JF, Wettermark B, Menditto E, Pinnock H, Tsiligianni I, Petrova G, Potočnjak I, Kamberi F, Kardas P. A Cross-Sectional Survey on Medication Management Practices for Noncommunicable Diseases in Europe During the Second Wave of the COVID-19 Pandemic. *Front Pharmacol*. 2021 Jun 7;12:685696.

European Network to Advance Best practices & technoLogy on medication adherencE (ENABLE) cross-sectional study

AVAILABILITY OF OPTIONS FOR REQUESTING CHRONIC MEDICATION PRESCRIPTIONS



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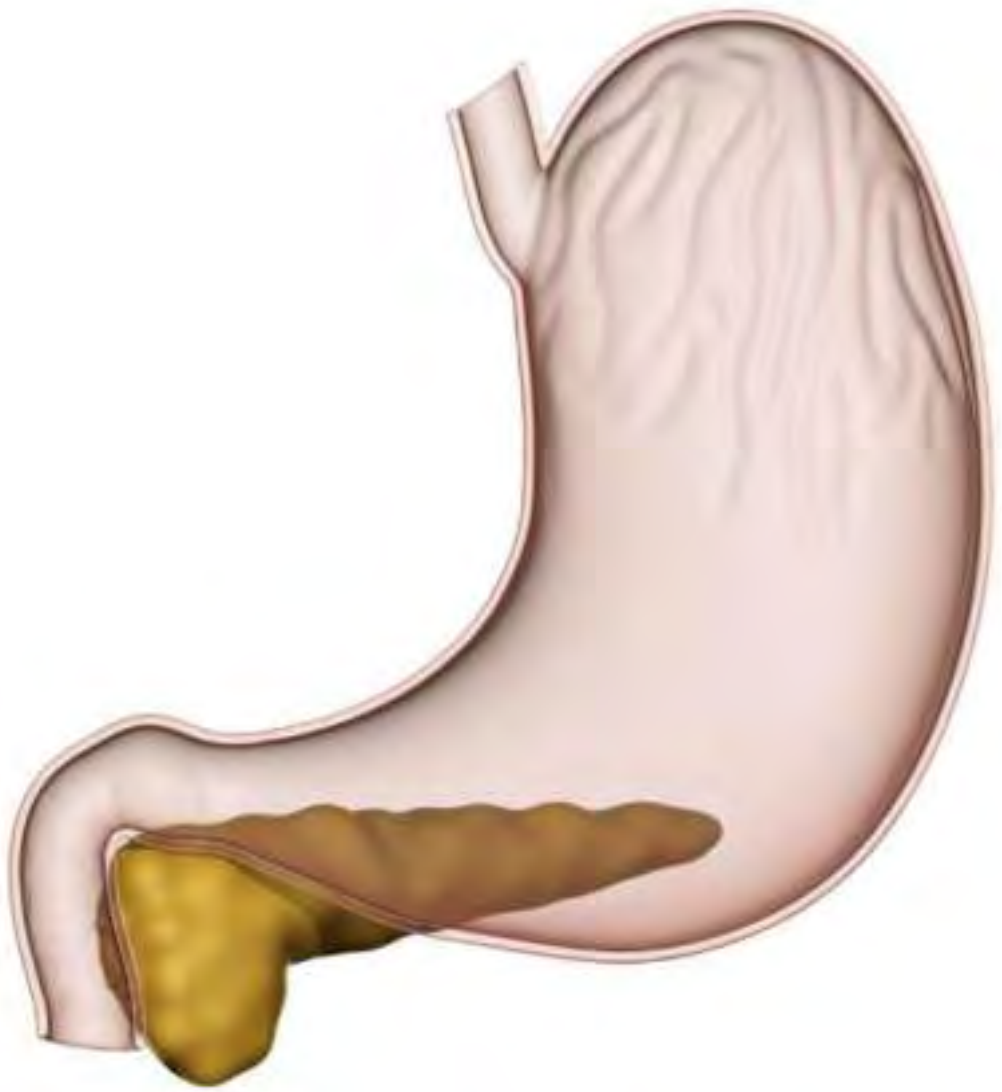


Example: Pancreatic Enzyme Replacement Therapy (PERT)

Pancreatic juice is needed for adequate digestion of food, particularly fats

Many pancreas diseases/ conditions associated to Pancreatic Exocrine Insufficiency

- Chronic pancreatitis
- Acute pancreatitis
- Pancreatic cancer
- Cystic fibrosis
- Pancreatic surgery
- Celiac disease

PEI is managed with oral pancreatic enzymes, a chronic treatment

Low adherence presumably associated to malnutrition and poorer outcomes[2]

1. Brennan GT, Saif MW. Pancreatic Enzyme Replacement Therapy: A Concise Review. JOP. 2019;20(5):121-125. *Epub* 2019 Jul 30. 2. Trapnell BC, Chen S, Khurmi R, Bodhani A, Kapoor M, Haupt M. Hospitalization rates among patients with cystic fibrosis using pancreatic enzyme replacement therapy. *Chron Respir Dis*. 2020 Jan-Dec;17:1479973119900612.

PERTCOVID survey

PERTCOVID SURVEY

Patients with PEI receiving PERT

Impact of COVID-19 on adherence

Gastroenterology Department, Alicante´s Univ. Gen. Hospital & Psychology Department, Miguel Hernandez University, Alicante, Spain

Phases of development

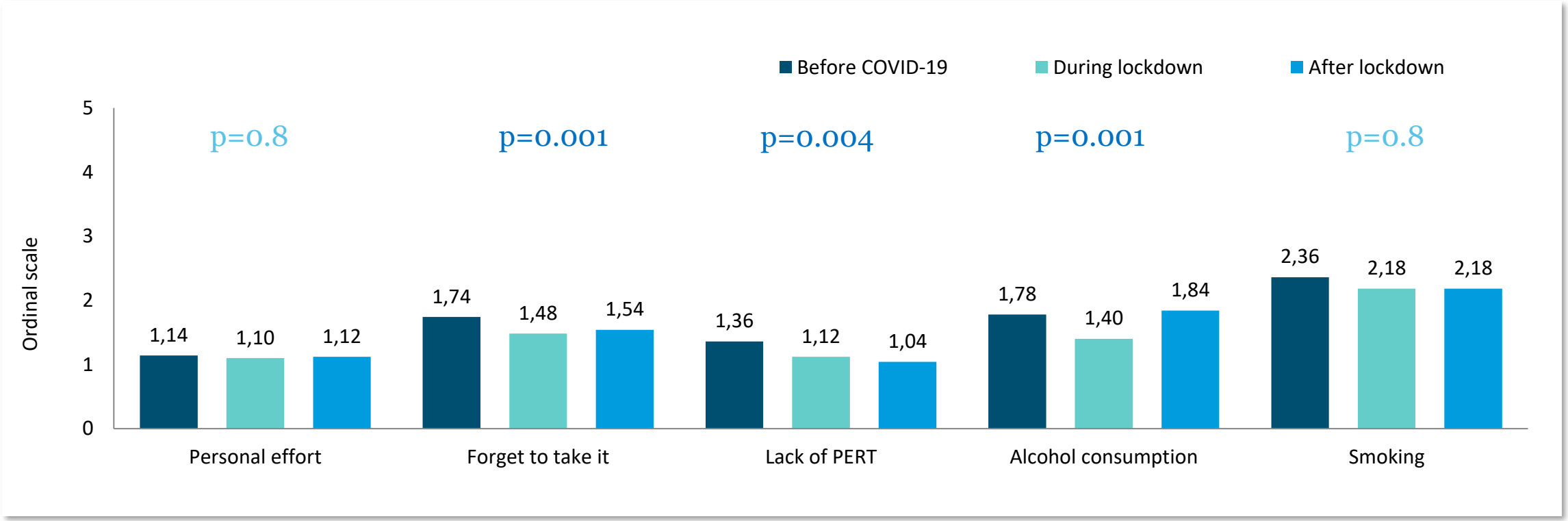
- June 2021: initial interviews of psychologist team with a small sample of patients (5)
- July 2021: first draft of the survey
- August 2021: initial tests with small sample of patients (4) for validation
- September 2021: final data acquisition

PERTCOVID SURVEY – conducted by Alicante's Univ. Gen. Hospital, preliminary results.

PERTCOVID Survey

50 PATIENTS UNDER PERT, 92% CHRONIC PANCREATITIS, 4% ACUTE PANCREATITIS, 2% PANCREATIC CANCER, 2% PANCREATIC SURGERY

0: Never, 1: Seldom, 3: Sometimes, 4: Often, 5: Always



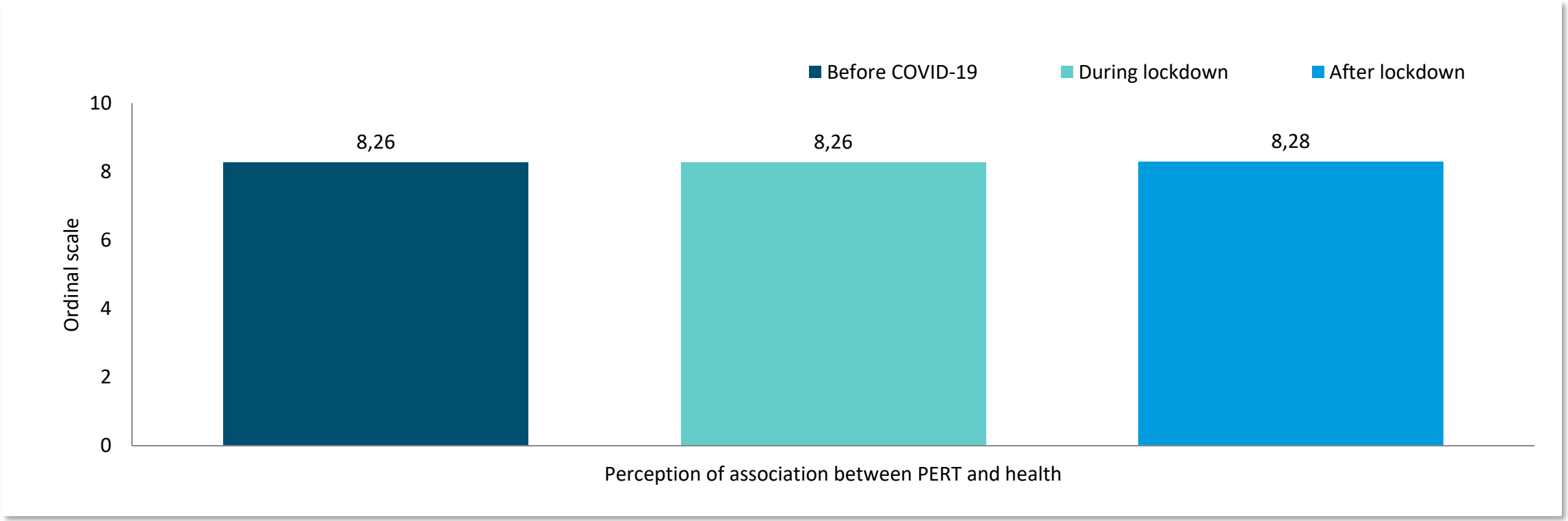
PERTCOVID SURVEY – conducted by Alicante's Univ. Gen. Hospital, preliminary results.

PERTCOVID Survey

50 PATIENTS UNDER PERT, 92% CHRONIC PANCREATITIS, 4% ACUTE PANCREATITIS, 2% PANCREATIC CANCER, 2% PANCREATIC SURGERY

0: no association, 10: absolute association

p=0.8



PERTCOVID SURVEY – conducted by Alicante's Univ. Gen. Hospital, preliminary results.

CONCLUSIONS

- The pandemic seems to be associated **with increase in** unhealthy habits
- Risk factors for decreased medical adherence: fear of visiting healthcare facilities + decreased availability, decreased awareness about the importance of chronic diseases, economic crisis, disruption of drug supply chains
- More important impact of the pandemic in low-and middle-income countries
- Digital tools are important to fight against decreased medical adherence in this scenario