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**PULMONARY MEDICINE, INFECTIOUS DISEASE  
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December 6, 2016

Physician-Focused Payment Model Technical Advisory Committee  
C/o U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy  
200 Independence Avenue S.W.  
Washington, D.C. 20201  
PTAC@hhs.gov

Re: The COPD and Asthma Monitoring Project (CAMP)

To The Physician-Focused Payment Model Technical Advisory Committee

Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group Inc of Sacramento, California (PMA) is requesting a review and approval of a innovative project for the acute and chronic management of Medicare beneficiaries with COPD and other chronic lung diseases. The title of the proposal is " The COPD and Asthma Monitoring Project" (CAMP)".

We believe implementation of this proposal will result in improved safety, improved quality, reduced mortality and produce significant cost savings to CMS as is intended by MACRA.

The project leader and primary point of contact for PMA is:

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# **The COPD and Asthma Monitoring Project (CAMP)**

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2013

State of California Department of Health and Human Services  
California Medical Association  
Sierra Sacramento Medical Society  
River City Medical Group

2016

Sutter Independent Physicians Medical Group  
Mercy General Hospital, Sacramento, CA  
Mercy San Juan Hospital, Carmichael, CA  
Sutter Medical Center, Sacramento, CA  
Sutter Roseville Hospital, Roseville, CA

(Note: The 4 hospitals above are on present and/or past "Top 100 Hospitals" lists)

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## Abstract

The COPD and Asthma Monitoring Project (CAMP) is a proposed payment model designed to treat a population of high risk Medicare beneficiaries with COPD and other chronic lung conditions. Care of this high risk population is provided through remote interactive monitoring that brings all the resources to leverage the expertise of a large telemedicine, pulmonary and allergy practice in the acute and chronic management of large populations of patients with COPD, asthma and other chronic lung diseases. Novel data presentation formats, computerized decision support, and smart alarms are used to enhance patient safety, patient education, patient compliance, increase effectiveness, and standardize clinical and operating processes. In addition, the technology infrastructure facilitates performance improvement by providing an automated means to measure outcomes, track performance, and monitor resource utilization. The program is designed to support an integrated healthcare delivery system as well as the independent practicing physician. If approved, CAMP will improved quality, decreased mortality while producing large cost savings for CMS.

## I. Background and Model Overview

The COPD and Asthma Monitoring Project (CAMP) is a proposed care model to address expensive inefficiencies in the care of patients with COPD, Asthma and other chronic lung diseases. A population-based solution; CAMP will improve patient safety, improve patient care quality and will reduce the cost of care to CMS for this high risk population. We propose to build a sustainable continuous quality improvement infrastructure centered on improved monitoring and management of patients with COPD and Asthma.

We propose to do this by expanding the expertise of a telemedicine, clinic and hospital-based intensive care, pulmonary and allergy practice, Pulmonary Medicine Associates (PMA). PMA will employ smart phone application(s), referred to as an “app,” and will operate a remote monitoring center supported by specially-trained providers who will track member input into the app and engage the program participants via voice phone, secure text messaging, email and video conferencing. Our goal is to achieve measurable and sustained improvements in asthma and COPD management and better health outcomes for these people. Enrollment in this service will be offered to all Medicare beneficiaries with asthma and COPD irrespective of healthcare affiliation.

Continuous, interactive remote monitoring of Medicare patients with COPD and Asthma provides unique opportunities of early detection and preemptive intervention before exacerbation of condition as well as early infection detection. Typically, patients with COPD and Asthma will endure days of symptoms while denying the severity of their condition or illness. They then reach a point where they call their physician in a panic. When physicians are called by patients who cannot breathe, the most frequent patient instruction is to go to the nearest hospital emergency room for evaluation and treatment. As we know, this is the most costly intervention, in terms of real dollars as well as in the risk to the patient’s overall health.

Recent findings support remote management, often referred to as telemonitoring, of COPD. Three unrelated studies<sup>1,2,3</sup>, from three different countries, demonstrated statistically significant reductions in ED visits and hospitalizations in the population of COPD patients participating in telemonitoring. The Study by Achelrod, et al<sup>3</sup> has the largest cohort and showed a statistically significant mortality benefit leading to the following conclusion;

***"During the 12-month evaluation period, a lower percentage of individuals died in the intervention group than in the control group (3.23 vs 6.22 %,  $p < 0.0001$ ), translating into a mortality hazards ratio (HR) of 0.51 (95 % CI 0.30–0.86). Since cost savings were achieved, on average, the telemonitoring programme can be considered a dominant technology (i.e. ICER: not applicable)."***<sup>3</sup>

## Model Overview

Patients with a diagnosis of asthma and COPD will be enrolled into a program where they will be provided with daily prompts and tools via their smartphone app in order to monitor their disease state from home. We will provide digital peak flow meters and software that can easily be understood and used, as well as provide a training period to ensure their confidence and accuracy in using these tools. Patients will then transmit data from the Peak Flow Meter device as well as perform manual entry of the diary data points (Appendix A). For individuals without smart phones, electronic “dongles” can be entered into a wall socket and be used to transmit data. Once entered, this data is transmitted to our central server for tracking.

The smart phone software app may also include:

- **Color-coded alerts:** These alerts are prompted when a downward change in lung function occurs, using the American Lung Association Asthma Action Plan Color Coded Template (Green, Yellow, Red).
- **Alarm clock:** Settings are for both AM and PM to remind individuals to complete their questionnaire and perform their twice daily test.
- **"Panic" Button:** A popup button allowing the user to call the telemonitoring center when certain triggers are activated.

As mentioned, each participant will receive training and written instructions on peak flow meter use, phone app use. However, they will also participate in a web-based, classroom-style, individualized COPD/asthma education course, and smoking cessation courses, as indicated. Understanding that support from home is essential to program success, families will be encouraged to participate with the patient in this educational and surveillance process.

Instruction on appropriate use of the peak flow meter and software will be given and a one-week trial data collection period will be performed. Once this baseline data is collected, a review of all trended data elements is performed with the patient. Each individual's disease control will be documented and grouped to three separate risk groups: Low, medium and high. Patient groupings, based on the number of individual chronic conditions will also be monitored.

Based upon this review, any recommendations for medication change will be sent to the primary care provider (PCP) or, alternatively, if the PCP allows, the pulmonary specialist at CAMP will make these changes and they will be recorded in the patient's Electronic Medical Record (EMR). PCPs will receive notification of any changes and any interventions taken by the monitoring center. Following any initial medication change all patients will be prospectively monitored through their data submission. Transmitted data will be sent to a central server. Clinical data points will be trended graphically on a computerized dashboard. Alerts will be embedded into the software both in the phone app and at the monitor center.

## **Compliance initiative**

To facilitate compliance, the "coaching" initiative of the program will be based on multiple prompts. In addition to the tools available on the mobile device, a daily reverse automated phone tree will go out as reminders to perform the peak flow task. A lack of timely data submission will also trigger an alert at the remote monitoring center that will generate a live phone call from a call center representative to the delinquent program participant to "check in" and remedy the problem. All text messaging will be performed using a secure messaging phone app (Section XII. Supplemental Information). Financial incentives for compliant patients enrolled in CAMP is requested as a key element of this payment model.

## **Early Intervention Initiative**

As mentioned, peak flow values and survey questions will be recorded via the mobile app. This data generates a colored alert on the phone that will be seen by the patient as data is sent to the CAMP central server. Patient-specific alerts at the remote monitoring center will be generated by this process. The secure messaging phone app will enable the patient to text or call the center quickly and easily. Patients will have immediate access to the monitor center at any time. Once identified at the command center, all Red Zone alerts will initiate a phone call from a representative at the center to the patient if the patient has not taken the initiative to call the command center.

All Yellow and Red Zone alerts will be screened by health care providers located at the remote monitoring center. All patients requiring intervention by the command center will be placed on a 72-96 hour enhanced monitoring window and flagged for personal follow-up.

A separate and unique database of interventions will be documented for these program participants, in real time on the Athena EMR with reports transmitted to the patient's PCP in real time. Monthly, quarterly, and annual reports will be made available to each participant and their PCP. All individual data will be consolidated for population-based review and reporting from the server housing individual files.

## **II. Scope of Proposed PFPM**

In 2014 there were 3,757,478 Medicare beneficiaries with COPD and 1,715,074 Medicare Beneficiaries with Asthma. Due to the fact that patients with COPD have multiple co-morbid chronic conditions, the average per capita cost of care to CMS was \$35,396.57 in 97% of patients (2 or more chronic conditions) with COPD.

During this same year there were 15,864 Medicare beneficiaries with a diagnosis of COPD and 9,152 beneficiaries with a diagnosis of Asthma in the five county area surrounding Sacramento (Sacramento, El Dorado, Yolo, Placer and Amador).



With these numbers in mind, we are proposing an ambitious initial target pilot enrollment of 2000 patients, with the intention of scaling the service locally once the pilot is validated.

CAMP is a proposed model of care that has only been tested in Europe and Asia. The most detailed result comparable to CAMP is the study by Achelrod, et al<sup>3</sup>.

***"Over the 12-month period, the proportion of patients hospitalised due to all causes (-15.16 %, p\0.0001), due to COPD (-20.27 %, p\0.0001) and COPD-related ED (-17.00 %, p\0.0001) was consistently lower in telemonitoring patients, leading to fewer all-cause (-0.21, p\0.0001), COPD-related (-0.18, p\0.0001) and COPD-related ED admissions (-0.14, p\0.0001). "***

Cost savings in the form of reduced emergency room visits and hospitalizations represented a significant savings to the German Healthcare system. These savings reflected achievement of a statistically significant reduction in mortality in patients enrolled in remote monitoring.

At its inception, CAMP will be designed as a new service offer by our physician practice. The payment mode proposed for CAMP is initially restricted to physicians, board certified in the practice of Pulmonary Medicine. We will recruit and enroll patients from local network of providers within the Sacramento, CA Region.

There is wide spread local interest in CAMP. This project was initially designed to compete in the Innovation Challenge Round 2 in 2013. The target population for the grant was the Medicaid and CHIPs beneficiaries. We were unable to submit the proposal by the deadline. We did, however present the project locally and received endorsements to support its acceptance in the challenge. These endorsements are provided in Appendix A-V. As a result of our efforts to build awareness, we anticipate a wide referral base that will allow us to manage, remotely, patients with COPD and other chronic lung diseases belonging to individual practitioners as well as large group practices within this geographic region.

If proven successful, we would like to see CAMP scaled to meet a greater demand. As previously mentioned, CAMP is designed as a "value-added" or *adjuvant* service designed to ensure that patients of referring physicians with COPD will be managed using best practices. Importantly, referring physicians will receive information to aid in their quality reporting for MIPS. With the prospect of improved care, safety and quality for their patient at risk, we have been encouraged by large group providers who would like to see this proposal be successful. We expect widespread acceptance from the physician community.

Once the payment model is proven, our solution is for regional centers to be built on our existing platform. These regional centers would be managed by regional providers, with CAMP providing contracted remote monitoring services. Providers would receive the benefits of the

AAPM-designation for their practices, with both CAMP and the regional provider sharing the risk in a two-tailed risk sharing agreement.

For ensure the success of this business model, CMS would extend/apply the AAPM designation with regional providers contracted with CAMP. A Safe Harbor exemption from Stark laws would remove potential legal barriers for these regional providers to participate. Stark was put into legislation to prevent abuses and fraud to the Medicare system. The solution we propose will reduce costs to Medicare, improve quality and promote patient safety.

Once proven, this model can then be replicated and scaled to meet demands in different regions of the country, quickly and effectively. We foresee partnerships with major health systems to both improve quality and accelerate scaling. In addition, CAMP will have the flexibility to partner with rural provider networks to provide service to rural beneficiaries of Medicare.

Potential benefits to the patient are unprecedented. Continuous monitoring, with intermittent, interactive intervention when needed, offers numerous educational opportunities and a safety net for the patient with COPD. By partnering with patients in this manner we will be in a position to detect the early onset of preventable diseases. CAMP will protect these patents from harm by giving them tools provided by CAMP. CAMP will facilitate a patient's understanding of their disease state and with this knowledge, high-risk patients become moderate-risk patients. Since most patients with COPD have multiple co-morbid chronic diseases there will be potential future opportunities to establish strategies to care for other co-morbid diseases remotely, thus adding another layer of improved health and safety.

When CAMP was initially designed to compete in the Innovation Challenge Round 2 in 2013 our target population was the Medicaid and CHIPs population. It is our hope to revisit a payment model that will support the remote monitoring and care of this population once the program is validated.

### **III. Quality and Cost**

The value proposition for CAMP is that it will provide both better care and better outcomes at a lower cost. Unlike other chronic conditions, acute illness in COPD is predicable both in seasonality and in its progression to severe illness over short periods of time. CAMP takes advantage of these unique characteristics by identifying critical points in time where early intervention prevents or reduces severity of COPD exacerbation, respiratory infections and further medical complications.

#### **Better Disease Management**

In addition to CAMP's safety net program, the ongoing conversation with this patient population, through the Smart Phone, creates unique opportunities to add new tools and education designed to empower patients to become more self-aware managers of their own disease state. We intend

to create a partnership with each patient through this process. Together, we will use the tools of education, proactive monitoring, ongoing communication, early recognition, and intervention to "move the needle" in the chronic management of COPD.

Our ultimate goal is to shift the population of high risk patients to a moderate risk group and moderate risk patients to a low risk group. This population skewing of the curve can only be accomplished with a population based strategy and payment model.

In order to accomplish our goals and to address Key Drivers (benefits and barriers), an operational template has been created and is located in Section XII. Supplemental Information.

. The 5 major objectives of our Implementation Process are listed below:

- Implementation Objective #1: Confirm CAMP is feasible and aligns with community's health transformation goals
- Implementation Objective #2: Establish Project Scope, Design and Implementation Plan
- Implementation Objective #3: Evaluate the Ongoing Performance and Impact of CAMP-based Alert System
- Implementation Objective #4: Obtain CAMP Information and Transform into a Clinically Meaningful Alerts
- Implementation Objective #5: Integrate CAMP-Based Alerts into Care Provider Workflows

Specific Aims for patients enrolled in CAMP:

1. From January, 2018 to January, 2020, we will achieve measurable improvements in COPD and asthma outcomes by implementing the NHLBI Guidelines Expert Panel Report 3 - Guidelines for the Diagnosis and Management of Asthma (<http://www.nhlbi.nih.gov/files/docs/guidelines/asthgdln.pdf>) as well as strategy recommendations from the Global Initiative for Chronic Obstructive Lung Disease (GOLD, <http://www.goldcopd.org>) in partnership with patients, families, primary healthcare providers and payers of healthcare systems.

2. We will exceed Healthy People 2010/2020: Asthma Related Goals

3. Develop a sustainability model that reduces unnecessary emergency room and hospital admissions.

Healthy People 2010/2020: Asthma Related Goals

- 1.9 Reduce pediatric asthma hospitalization rates.
- 14.29 Increase the proportion of high-risk adults who are vaccinated annually against influenza
- 24.1 Reduce asthma deaths.
- 24.2 Reduce hospitalizations for asthma.
- 24.3 Reduce hospital ED visits for asthma.
- 24.4 Reduce activity limitations among persons with asthma.
- 24.6 Increase proportion of persons with asthma who receive formal patient education including information about community and self-help resources, as an essential part of the management of their condition.

- 24.7 Increase proportion of persons with asthma receiving appropriate asthma care according to NAEPP Guidelines.
- 24.7a. Persons with asthma who receive written asthma action plans from their health care provider.
- 24.7b. Persons with asthma with prescribed inhalers who receive instruction on how to use them properly.
- 24.7c. Persons with asthma who receive education about recognizing early signs and symptoms of asthma episodes and how to respond appropriately, including instruction on peak flow monitoring for those who use daily therapy.
- 24.7d. Persons with asthma who receive medication regimens that prevent the need for more than one canister of short-acting inhaled beta-agonists per month for relief of symptoms
- 24.7e. Persons with asthma who receive follow-up medical care for long-term management of asthma after any hospitalization due to asthma.

### **Measures/Goals**

Outcome goals for patients enrolled in CAMP:

- 90% of patient conditions are well-controlled by 2020.
- Decrease ED visits by 30% in 2018, 50% by 2019 and 70% by 2020.
- Decrease hospital admissions in patients enrolled in CAMP by 10% in 2018, 15% by 2019 and 20% by 2020.
- Decrease total Medicare costs by 10% in 2018, 20% by 2019 and 30% by 2020 in the population of patients enrolled in CAMP using a risk adjusted national chronic condition based benchmark.
- A statistically significant decrease in mortality when compared to an unmonitored cohort.

### **Process Measures:**

100% of patients have “optimal” COPD and asthma care (all of the following):

- assessment and classification of COPD and asthma control using a validated instrument,
- stepwise approach to identify treatment options and adjust medication and other therapies,
- written patient self-management asthma action plan customized to take advantage of real time monitoring and early detection/intervention protocols,
- stepwise approach to identify treatment options and adjust medication and other therapies,
- patients >4 yrs of age with flu shot (or flu shot recommendation,)
- smoking cessation and advise where appropriate,

Key Organizational Drivers for Large Physician Groups, Integrated Health Delivery Systems, ACOs, Payers, etc.:

- MACRA
- Sustainable and Accountable Leadership focused on Health Outcomes
- Partnership creation to promote Healthy People 2010 Asthma Related Goals
- Attractive Motivators and Incentives
- Participation in an Organized Quality Improvement Effort.
- Cost, Personal and Time commitment to develop the program internally

- Creation of a Patient Registry to be able to measure the relationship between process and outcomes
- Creation of a focused Team of Champions
- IT support capabilities
- Risk of failure - Time delay to outcome improvement
- Community Sponsorship at inception and throughout the term of the project

Key Drivers for individual Practitioner, Physician Groups, Hospitals and Payers at the practice level:

- MACRA
- Integration of Quality Improvement into individual practice
- Using a Registry to manage chronic disease states
- Using an evidence-based planned care approach to ensure reliable asthma and COPD control at home
- Integrating primary providers with hospitals, specialist and patients to provide a cohesive care management program with the patient at the center
- Providing consistent educational and self-management support for patients and families
- Safe Harbor exemption from Stark law violations

Key Drivers for Self-Management by Patients and Families:

- Basic education and knowledge of Asthma and COPD
- Basic understanding of an Asthma Action Plan
- Sense of control over their health status and lives
- How controlled is my COPD?
- Understanding the role of Asthma medications
- Use of tools, such as a Peak Flow Meter and/or a daily diary to self-monitor lung status
- Environmental Triggers for Asthma Attacks (Smoking and air pollution exposure, allergies, etc.)
- Seasonality of Asthma and COPD
- When am I in trouble?
- The current gap in the published action plan between the "Yellow" and "Red" zones.

### **Cost Savings for Medicare**

Early recognition of a developing problem by CAMP will lead to intervention that will reduce the current high frequency of Emergency Room visits and subsequent Hospitalizations. Each avoided emergency room visit leading to a hospitalization is equivalent to an estimated \$5,000-\$46,000 savings in Part A Medicare costs, dependent upon the MS-DRG diagnosis for a given admission. Part B savings associated with each aborted hospitalization are estimated to be 25% of the MS-DRG Part A cost savings.

Table 1: Hospital Admissions: The Likely MS-DRG diagnosis used for COPD and Asthma related Chronic Conditions		
Hospital Reference Value*:	\$ 8,000.00	
MS-DRG Title	Weights	Part A Cost/Hospitalization
Chronic obstructive pulmonary disease w MCC	1.1138	\$ 8,910.76
Chronic obstructive pulmonary disease w CC	0.9405	\$ 7,524.16
Chronic obstructive pulmonary disease w/o CC/MCC	0.8145	\$ 6,515.85
Simple pneumonia & pleurisy w MCC	1.2505	\$ 10,004.09
Simple pneumonia & pleurisy w CC	1.0235	\$ 8,187.61
Simple pneumonia & pleurisy w/o CC/MCC	0.8398	\$ 6,718.13
Bronchitis & asthma w CC/MCC	0.7841	\$ 6,272.92
Bronchitis & asthma w/o CC/MCC	0.6252	\$ 5,001.31
Respiratory signs & symptoms	0.6658	\$ 5,326.46
Other respiratory system diagnoses w MCC	1.0636	\$ 8,508.91
Other respiratory system diagnoses w/o MCC	0.7848	\$ 6,278.02
Respiratory system diagnosis w ventilator support 96+ hours	5.1231	\$ 40,984.78
Respiratory system diagnosis w ventilator support <96 hours	2.2463	\$ 17,970.47
Septicemia w MV 96+ hours	5.7579	\$ 46,063.44
Septicemia w/o MV 96+ hours w MCC	1.7484	\$ 13,987.03
Septicemia w/o MV 96+ hours w/o MCC	1.3783	\$ 11,026.12

\*Hospital Reference Value: Each hospital has a reference cost value based on the Hospital's average cost of caring for a Medicare patient. This value is typically between \$7000 and \$9000. Part A costs are determined by multiplying the MS-DRG weight and the Hospital Reference Number.

Medicare patients with COPD and Asthma are among the most expensive subgroups of patients for CMS. We used data from the following sources to create a pricing model for CAMP to determine an appropriate monitoring fee and a process to establish a risk adjusted Medicare payment target that is easily understood and publically available:

- Public Use Files (PUF) obtained from the CMS Chronic conditions Web Site. [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/MCC\\_Main.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/MCC_Main.html)

- Medicare Payments: How Much Do Chronic Conditions Matter?  
*Erkan Erdem, Sergio I. Prada, Samuel C. Haffer*  
Medicare & Medicaid Research Review, 2013: Volume 3, Number 2,  
[https://www.cms.gov/mmrr/Downloads/MMRR2013\\_003\\_02\\_b02.pdf](https://www.cms.gov/mmrr/Downloads/MMRR2013_003_02_b02.pdf)
- Specialty Payment Model Opportunities and Assessment - Oncology Simulation Report.  
Chapin White, Chris Chan, et al.  
[http://www.rand.org/pubs/research\\_reports/RR799.html](http://www.rand.org/pubs/research_reports/RR799.html)

CMS has compiled utilization and cost data for patients with 1 or more chronic conditions as defined by the following list:

Alzheimer’s Disease and Related Dementia	Heart Failure
Arthritis (Osteoarthritis and Rheumatoid)	Hepatitis (Chronic Viral B & C)
<b>Asthma</b>	HIV/AIDS
Atrial Fibrillation	Hyperlipidemia (High cholesterol)
Autism Spectrum Disorders	Hypertension (High blood pressure)
Cancer (Breast, Colorectal, Lung, and Prostate)	Ischemic Heart Disease
Chronic Kidney Disease	Osteoporosis
<b>Chronic Obstructive Pulmonary Disease</b>	Schizophrenia and Other Psychotic Disorders
Depression	Stroke
Diabetes	

Data from PUF obtained from the CMS Chronic Conditions web site provided COPD specific % distribution data as well as *all cause* ED visits per 1000 beneficiaries per chronic condition grouping. The PUF, however, did not provide separate Part A costs and Part B cost data. We were interested in sources with more exact average cost per capita data as defined by each numbered individual chronic conditions category.

Specific costs data for average cost per capita as defined by each number of chronic conditions category was found in the cited article by Erdem, E. et al.<sup>4</sup> This paper compares 2008 data with 2010 Medicare data. This source also provided Part A and Part B specific cost data. Table 2 represents a composite of three sources and requires an explanation. On the Left side of the Table 2008 and 2010 data from Erdem, E. et al. are depicted. The Right side of the table contains data obtained from PUF for 2014 obtained from the CMS chronic conditions web site. Because PUF data was not available per individual number of chronic conditions, the Table rows are color coded; overlaying PUF defined chronic condition groupings, 0-1 condition (white), 2-3 conditions (blue), 4-5 conditions (green) and 6+ conditions (orange) onto the more granular data categories from Erdem, E. et al. The 2014 data come from 2 PUF sources.

Table 2: Cost comparison of 2008 and 2010 per capita Medicare spending based upon the number of chronic conditions combined with 2014 data on per capita ED visits filtered by # chronic conditions and data on %distribution of COPD patients with multiple chronic conditions

Number of Chronic Conditions	2008		2010		2014	
	Average Per capita Part A + Part B cost per beneficiary	% Part A	Average Per capita Part A + Part B cost per beneficiary	% Part A	ED Visits per 1,000 Beneficiaries	% Distribution of Chronic Conditions in patients with COPD
0	\$1,404	17.66%	\$1,511	16.21%		
1	\$4,036	32.56%	\$4,306	31.03%	<b>194.3887</b>	<b>3.00%</b>
2	\$7,256	41.32%	\$7,657	39.52%	<b>439.3492</b>	<b>17.00%</b>
3	\$12,097	49.34%	\$12,700	47.60%		
4	\$19,261	56.01%	\$20,178	54.46%	<b>786.9341</b>	<b>28.00%</b>
5	\$28,519	61.52%	\$29,818	60.07%		
6	\$39,750	65.79%	\$41,584	64.58%		
7	\$52,526	69.00%	\$55,584	68.03%	<b>1985.5931</b>	<b>52.00%</b>
8	\$65,495	71.40%	\$68,800	70.12%		
9	\$76,652	73.08%	\$80,210	72.07%		
10	\$90,700	75.34%	\$94,212	72.70%		

1. Erdem, et al, Medicare & Medicaid Research Review, 2013: Volume 3, Number 2

2. Datatables\_for\_chronic\_conditions\_charts\_2014.xlf, figure 15, [https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Chartbook\\_Charts.html](https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Chartbook_Charts.html)

3. County\_Dashboard\_Data\_Table\_2014.xlf, Spending and Utilization, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CCDashboard.html>

**This table contains a number of critical observations.**

The first observation is the dramatic increase in Medicare costs for beneficiaries with an increasing number of chronic diseases, meaning those with co-morbidities like those identified for this demonstration program. The effect of chronic conditions on Medicare payments is eye-opening. Average Medicare payments increase significantly with the number of chronic conditions.

The second observation is the stability in that cost-relationship as the number of chronic conditions increase, in particular between comparison years 2008 and 2010. PUF from 2007-



2014 also demonstrates this stable relationship. This stable relationship provides a framework for projecting benchmark costs in a risk pool of patients with COPD.

The third observation is the rising actual and proportionate contribution of Part A spending to total Medicare spending as the number of chronic diseases increase. Of particular note is the >50% proportionate Part A costs attributed to patients with 4+ chronic conditions (80% of the distribution).

The fourth observation is near doubling of ED visits with each PUF defined chronic condition grouping (Color coded rows), as well as the average two ED visits/patient with 6+ chronic conditions.

The fifth observation is the population distribution skew of chronic conditions toward multiple co-morbidities in patients with COPD (color-coded rows). The % distribution of lower # condition groupings appear to have Gaussian characteristics.

The projected savings to CMS is predicated on the premise that CAMP will detect symptoms of respiratory infection and worsening shortness of breath at an early onset of illness, allowing for preemptive intervention, which we propose will result in reduced ED visits and hospital admissions. To the extent that shortness of breath and/or infection are primary drivers of ED visits in patients with multiple additional co-morbid chronic conditions will determine how much cost savings are possible with CAMP. The Achelrod study suggests this premise will be valid.

Additional COPD specific data corroborates the high cost of care for patients with COPD.

Chronic Condition Dyads: All Fee-for-Service Beneficiaries with at Least Two Chronic Conditions by Age, Sex, and Medicare-Medicaid Enrollment (Dual Eligibility), 2014	
The average Per capita Medicare spending (\$) for COPD was	\$35,396.57
Chronic Condition Triads: All Fee-for-Service Beneficiaries with at Least Three Chronic Conditions by Age, Sex, and Medicare-Medicaid Enrollment (Dual Eligibility), 2014	
The average Per capita Medicare spending (\$) for COPD was	\$47,392.93

\* Source: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Co-morbidity.html>

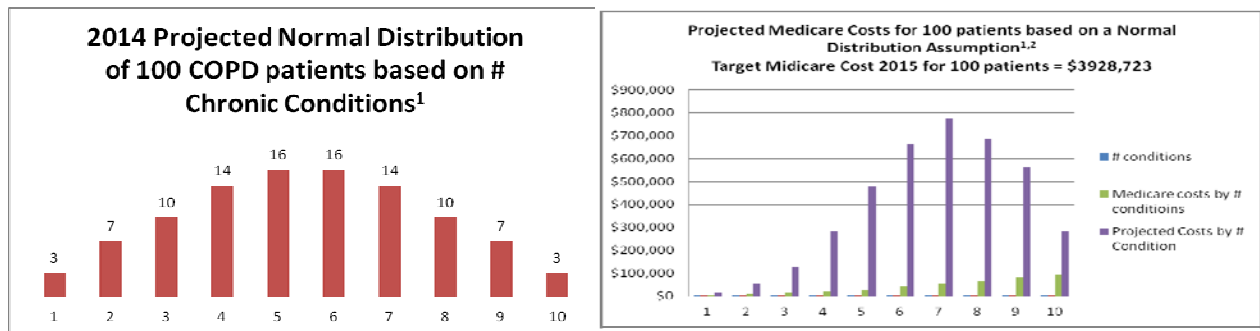
With a projected 97% of Medicare patients with COPD living with two or more chronic conditions, and 80% of patient with COPD managing four or more chronic conditions, the potential for significant savings is high, especially since Part A costs increase dramatically in actual and proportionate costs to the Part B costs as the number of chronic conditions rise.

**Financial impact of the annual cost of monitoring:** (Calculations and assumptions are made as if CAMP were to start on January 1, 2014 and used 2014 data to establish the 2014 Medicare target for risk sharing.)

To calculate the estimated cost of treating 100 Medicare patients with COPD, in 2014 we made the following assumptions:

- Average Per capita Part A + Part B cost per beneficiary for each chronic condition number would be equal to the 2010 costs/chronic condition published by Erdem, et al.<sup>4</sup>
- Observing the Gaussian-like COPD % distribution from the COPD Dashboard statistics for 2014, we arbitrarily assigned a Gaussian distribution for the number of beneficiaries/conditions categories;
  - Group 1 and 10 were assigned 3 patients each
  - Groups 2 and 9, 7 patients each
  - Groups 3 and 8, 10 patients each (17% assignment for combined groups 2-3 and 8-9)
  - Groups 4 and 7, 14 patients each
  - Groups 5 and 6, 16 patients each (30% assignment for combined groups 4-5 and 6-7)
- Individual group Medicare costs were calculated by the product of the 2010 chronic condition number specific average cost and the number of patients assigned to that group.

We took some liberties with the actual patient assignment but maintained the observed 2014 COPD % distribution reported (slightly favoring a higher Group 4- 5 number). By this calculation the cost of treating 100 Medicare patients with COPD in 2014 was \$3,928,723.00, representing a 2014 Average Per capita Medicare spending target of \$39,287.23 using our assumptions (Figure 1, 2).



**Figure 1,2: Projected 2014 Cost distribution Curve**

1. County\_Dashboard\_Data\_Table\_2014.xlf, Spending and Utilization, <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/CCDashboard.html>
2. Erdem, et al., Medicare & Medicaid Research Review, 2013: Volume 3, Number 2

If known, we would have used actual 2014 Average Per capita Part A + Part B cost per beneficiary/chronic condition to accurately calculate the per capita cost and Medicare target for risk sharing. Also, by calculating costs and targets for each category of chronic conditions we can adjust the target for a non-Gaussian distribution of patients enrolled in CAMP.

We then looked at the literature (Appendix B) to see what other centers have accomplished in the form of all cause ED visit reduction and all cause hospitalization reduction to project potential savings to Medicare:

- In the study by Ho, et al.<sup>1</sup> 106 (52 in each group) patients were monitored for 17 months. All cause ED visits reduced 60% and all cause hospital admissions were reduced 66%.

- In the Study by Calvo et al<sup>2</sup> 60 patients were studied (30 in each group) for 7 months. ED visits were reduced 65% and hospital admission reduced 64%.
- In the study by Achelrod, et al<sup>3</sup> 651 patients were monitored for 12 months with a control population of 7047. All cause ED visits were reduced 21% and all cause hospitalizations were reduced 15%.

Assuming our results will be in line with the literature a 15% reduction in all cause hospital admissions and a 21% reduction in all cause ED visits would be achievable. Assuming a 60% Part A - 40% Part B distribution, savings equate to a 17.4% reduction in per capita spending to Medicare (.6\*.15 +.4\*.21). We believe actual savings will be higher as the relative impact of Part B savings will be even greater as ED costs and Hospital admission associated Part B costs have a disproportionate effect on total Part B per capita Medicare spending.

In 2014, a 10% reduction in per capita Medicare spending for the management of COPD patients was worth \$3928.72, based upon our methodology. The savings for 1000 patients would equal 3.9 million. In 2014 there were 3,757,478 Medicare beneficiaries with COPD. The potential savings to Medicare would then have been \$14.76 billion for the entire population of COPD patients. Each addition % savings would equal \$1.47 billion in additional savings to Medicare.

#### **IV. Payment Methodology**

- We are seeking approval to participate in MACRA using the Oncology Model AAPM as a benchmark.
- We are seeking a fee of \$200.00 for (1) Bluetooth Peak Flow Meter per participant, a monthly remote monitoring management fee per patient of \$175/month (inflation adjusted) and wish to participate in a two-tailed risk sharing model of reimbursement.
- We wish to qualify CAMP for AAPM designation for medical providers of this service.
- This service will not replace exiting payment methods under MACRA but will be an added new service.
- We are seeking an agreement that does not require a co-payment from Medicare participants of this proposed payment model.
- We seek an exemption for Pharmaceutical and Devise Companies that would allow them to provide discount pricing or dispense coupons for Medicare recipients who are participants of this program.
- Finally, we seek a Safe Harbor designation from state and federal Stark laws.

Under current law there exists no payment model by which CMS will pay for remote monitoring of patients with chronic conditions.

As this care concept has never existed we will need to invest in new facilities to house the remote monitoring unit, and hire and train healthcare, supportive and IT staff to operate the facility. Personnel costs, hardware costs, software development costs and fees to EMR providers will need to be factored in to the cost of starting CAMP. Software development, including computer algorithms, interconnect ability, vendor relationships etc. have not yet been initiated. If

approved, funding for this project will come from cash flow generated by the monthly fees with the help of outside investment.

IN the RAND white paper “Specialty Payment Model Opportunities and Assessment – Oncology Simulation Report” a suggested monthly management fee of \$160 was used as a benchmark for a two-tailed shared risk analysis. We looked at comparative CMS cost data from the following spreadsheets.

Chronic Condition Dyads: All Fee-for-Service Beneficiaries with at Least Two Chronic Conditions by Age, Sex, and Medicare-Medicaid Enrollment (Dual Eligibility), 2014	
The average Per capita Medicare spending (\$) for COPD was	\$35,396.57
The average Per capita Medicare spending (\$) for Cancer was	\$30,060.19
Chronic Condition Triads: All Fee-for-Service Beneficiaries with at Least Three Chronic Conditions by Age, Sex, and Medicare-Medicaid Enrollment (Dual Eligibility), 2014	
The average Per capita Medicare spending (\$) for COPD was	\$47,392.93
The average Per capita Medicare spending (\$) for Cancer was	\$42,413.39

\* Source: <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Chronic-Conditions/Comorbidity.html>

As average per capita CMS costs for COPD was greater by 11.7-17% when compared to a similar cohort of Cancer patients we determined the proposed monthly monitoring fee of \$175 (9% increase) appropriate.

### **Risk-Sharing**

For 2018, we propose using 2018 National combined non-Dual and Dual Eligibility average per capita cost data, categorized by the number of chronic conditions, 1 through 10, as defined by CMS, as the 2018 benchmark to establish the risk-adjusted cost multiplier for each enrolled patient. Documentation of the number of chronic conditions each patient will occur at enrollment and updated annually. As patients will be enrolled continuously throughout the year we will establish a prorated fractional multiplier for each individual patient based upon an agreed date after their enrollment into CAMP. We will submit our pro-rated population list categorized by the number of chronic conditions. 2018 costs attributed to each chronic condition number will be multiplied to our compiled prorated population of patients for each chronic condition number grouping. The product of each chronic condition number calculation will then be summed up to create a 2018 cost total that will be used as the 2018 risk pool target to establish the null point in a two-tailed risk sharing agreement. This methodology will be used for subsequent annual calculations.

In the 2014 example, the 12 month CAMP cost to Medicare for 100 new beneficiaries would have been \$230,000 (\$200/device + \$2100 per patient monitoring fee), representing 5.8543% additional cost to Medicare (based on a 2014 projected per capita average cost of \$39,287.23)

In a risk sharing agreement, CAMP would have to reduce actual spending by about 6% before it would avoid liability and start making a profit under the risk sharing portion of the agreement.

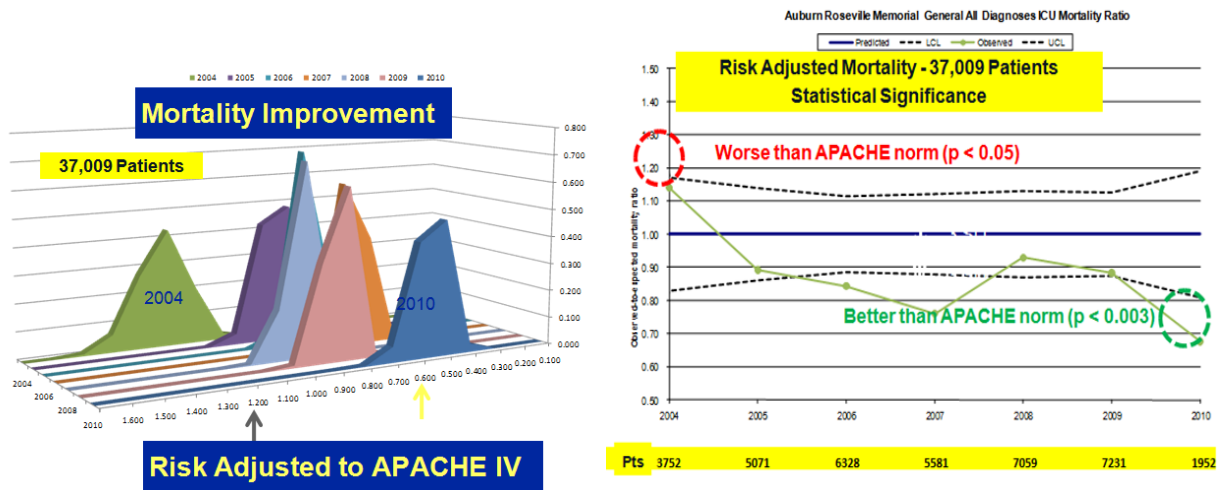
For the purpose of calculating anticipated tail risk, a 1% cost savings (or loss) is projected at \$39,287.23 for every 100 patients covered in a risk pool. The maximum liability or profit to CAMP would be  $\pm$ \$785,744.60, assuming a 20% cap on a risk pool, for every 100 enrolled patients in 2014.

We propose that the start day used for the purpose of calculating actual prorated individual costs attributed to patients enrolled in CAMP begin on the 1st calendar day at least 60 days following actual enrollment into CAMP.

This 60 day waiting period is designed to eliminate enrollment risk and more accurately measure the impact of CAMP. It is anticipated that many patients enrolled in this program will be patients who are hospitalized for their respiratory illness. This is the population of patients we want to target for CAMP, but with a high 28-day readmission rate of around 18-24%, CAMP is not budgeted to specifically reduce the 28-day readmission rate at the point of patient enrollment. We do have an expectation that if enrolled into CAMP for at least 60 days, we will achieve a significant reduction in the admission and readmission rate for patients moving forward.

We are proposing this payment model as an umbrella or add-on service to existing forms of patient management. CAMP is not designed to disrupt current relationships that exist between the patient and their providing physicians, but represents an opportunity in population based chronic disease management. We intend CAMP to work synergistically as an adjuvant to existing treatment models. CAMP's initial primary AIM is to provide an early warning system and safety net for patients at high risk of severe illness and death. In this role CAMP would be an active healthcare provider. We do not intend CAMP to replace the patient's relationship with their current providers.

At PMA we have been fortunate to have a 13 year experience in telemedicine through our partnership with Sutter Healthcare and operator of the Phillips VISICU eICU system. Over the past 13 years we have mastered the use of this technology to be more than a remote safety net for local providers of ICU care. We used the tools of the eICU to provide statistically significant, risk adjusted mortality reduction in a sample size of 37,000 patients (Figure 3,4). Using technology to leverage our expertise allowed us to monitor more patients than we could physically handle. In the role of an early warning system and data repository, the power of remote monitoring with the ability to intervene became apparent to us.



**Figure 3.4: Moving the needle. Impact of remote monitoring of ICU patients in 4 hospitals on mortality at hospital discharge, 2004-2010, risk adjusted, using APACHE IV benchmarks.**

Based upon our knowledge and experience, COPD and Asthma represent an ideal target for population based quality improvement efforts using a centralized, technology driven strategy of patient interaction and education. As an umbrella system, CAMP provides life saving, value-added service to all provider networks that treat patients with COPD and Asthma, without the fear of competition.

#### Patient Incentives

We are requesting that no Co-payment be required of Medicare recipients in this CAMP as well as a Pharmaceutical and Device manufacturer waiver to allow Medicare recipients to be on appropriate COPD and Asthma controller agents and devices without financial worry. We strongly believe that the success of this proposed program will be determined by our success in behavior modification. Price incentives go a long way to changing behavior. The device and Smart phone gives us a unique link to each patient and allows for continuous educational opportunities as well as continuous behavior modification. The pharmaceutical waiver will allow us to partner with industry to provide special pricing for expensive controller medications for this expensive and high risk population where the cost of these agents to the Medicare recipient can be \$200/month or more. Too often we have seen patients admitted to our hospitals because the patient has attempted to save money by reducing the use of their controller medications or stopping altogether due to an inability to afford the treatment. This was particularly apparent when patients were in the "donut hole" of Medicare Part D. Without these incentives, we are unlikely to maximize the Program's acceptance and success.

#### V. Value over Volume

As a population based model of care CAMP is not designed as an episodic care model.

## **VI. Flexibility**

CAMP is a leading edge technology solution for the health and well being of patients with COPD and Asthma. As such, we are likely to introduce change as opposed to adapting to change. We will encourage partnerships with providers, pharmaceutical companies as well as device providers as allowed by CMS.

Base upon our experience operating the VISICU eICU command center for Sutter Heath we expect our center to require a staff of physicians and specialty nurse practitioners that will interact with Medicare Beneficiaries in the program. Support staff will include a command center manager with ancillary personnel that may include medical assistants and secretarial personnel. IT personnel and software engineer will be needed to develop algorithms and needed connectivity between the beneficiary and the command center. Statisticians and data analysts are envisioned to create and measure outcomes. A person trained in psychology will be hired to create tools to evaluate and suggest ways to increase beneficiary ownership in their disease state.

By design, CAMP will be able to accommodate the breadth and depth of differences in clinical settings and patient subgroups. CAMP is designed to work with all provider groups without adversely impacting their current payment model.

## **VII. Ability to be evaluated**

As a data rich model of care, ongoing statistical analysis will be performed. Metrics used are in part discussed in the narrative and in the Implementation Template located in section XII. Regular reporting both to referring providers and to CMS are planned. Detailed information about outcomes, practice patterns, resource utilization, and clinical operations are integrated into Smart Reports for distribution.

## **VIII. Integration and Care Coordination**

The CAMP program will use a suite of information technology tools to support the remote team and the PCP. The core information system collects data from mobile devices and reconfigures it to optimize data presentation and facilitate physician work flow. The goal is to organize data in a format that makes the information easily accessible so clinicians can see temporal and other associative relationships. As part of this application, we provide note-writing and order-writing applications that allow the remote specialist to initiate therapies and document their actions. We also provide real-time decision support designed for succinct data presentation and real-time use in guiding patient care decisions. Computer-based algorithms can provide patient-specific assistance. These decision trees solicit key clinical information and, based on the data entered, provide clinicians with concrete recommendations suited to the situation. Another major focus has been on the creation of an early warning system that provides timely alerts designed to ensure that appropriate actions are initiated as soon as problems begin to develop. The goal is to

move away from a system that encourages emergent evaluation and treatment as the standard of care.

Four key applications will be used to achieve these goals. The first, Athena EMR, is a cloud-based electronic medical record and tool set for executing routine tasks (e.g., note and order writing, care planning, provider communication, etc.). Data display screens will be organized by Peak flow values, rescue inhaler use and symptom frequency reporting to provide context. Data are formatted to show changes in key parameters over time. The data density is high to highlight important relationships. Other screens show more detailed information (e.g., laboratory results, medications, etc.) with icons that announce the presence of new information. The overall acuity of the patient is prominently displayed, and this is tied to specific care processes. For example, the most uncontrolled patients are reviewed comprehensively at least daily by the CAMP team. Another screen contains all details of the care plan.

A second important feature will be the development of clinical algorithms that help physicians deal with a specific patient. Based on physician-provided, patient-specific answers to key questions, the user is directed to appropriate recommendations for medication adjustments to improve control of the uncontrolled chronic lung condition.

The third major application, Smart Alerts, functions as an early warning system. Remember that all relevant clinical data (e.g., Peak Flow values, Rescue Inhaler use, the presence of fever and/or sputum production, etc.) are being stored in a relational database. Whenever new data are entered, they are run against a complex set of rules to determine whether the CAMP team should be notified of an impending problem. These rules can identify values that are out of range or parameters that have changed by a predetermined amount over a fixed period of time.

The fourth application, Smart Reports, also capitalizes on the robust information stored in the database. Smart Reports provides detailed information about outcomes, practice patterns, resource utilization, and clinical operations. For example, a report on the use of oral corticosteroids for acute decline in measured lung function identifies the population at risk of ED visitation and hospitalization, shows when preventative treatments were begun during the CAMP interventions (if at all), and shows which agents were used. These reports, which can detail individual physician practice patterns, become an effective tool for managing change

## **IX. Patient Choice**

By design, CAMP provides an innovative solution to address all models of patient choice as it will not be limited by its geographic location. As a population based solution, CAMP will be able to address racial, ethnic, gender, disabled, and geographic disparities among Medicare beneficiaries using remote technology as the tool to bridge these disparities. Since CAMP is designed as an umbrella service, CAMP will not disrupt the relationship a patient has with their current provider.



## **X. Patient Safety**

Continuous interactive monitoring with early detection of illness will allow for preemptive action by CAMP. Savings to the system will take the form of decreased resource utilization of emergency rooms and hospital admissions. Built within the design of CAMP are a series of checks and balances to ensure patients are not missed or neglected.

There will be patients that do not respond to preemptive action. For those individuals, access to emergency room or to local providers will be facilitated. CAMP provides a specific process designed to improve the health and well being of patients with COPD and Asthma. CAMP is a population based solution. Given the prospects of improved patient safety, quality, and anticipated Medicare cost savings, we can think of no other innovation that will produce measurable results in a timelier manner

## **XI. Health Information Technology**

There is no intention to allow new providers or caregivers to the raw data. Reports will be provided to referring providers of the CAMP in the form of Smart Reports, as well as Medical information that will be transmitted via the EMR. Interactive messaging between patients and CAMP will be performed through a secure messaging phone app or via computer.

CAMP is cutting edge technology and as new innovations become available it is highly likely that we will be on the cutting edge of testing and incorporating new technology into CAMP.

## **XII. Supplemental Information**

Available in Appendix A.

References (Appendix B):

1. Ho, T.-W. *et al.* Effectiveness of Telemonitoring in Patients with Chronic Obstructive Pulmonary Disease in Taiwan-A Randomized Controlled Trial. *Sci. Rep.* 6, 23797; doi: 10.1038/srep23797 (2016)
2. Segrelles Calvo G, Gómez-Suárez C, Soriano JB, Zamora E, González-Gamarra A, et al. A home telehealth program for patients with severe COPD: The PROMETE study. *Respir Med* 108: 453-462 (2014).
3. Achelrod D, Schreyogg J, Stargardt T Health-economic evaluation of home telemonitoring for COPD in Germany: evidence from a large population-based cohort. *Eur J Health Econ.* 2016, Oct 3.
4. Erdem, E, Pada, S, Haffer, S. Medicare Payment: How Much Do Chronic Conditions Matter? *Medicare & Medicaid Research Review*, 2013: Vol 3, Number 2,

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**The COPD and Asthma Monitoring Project (CAMP)  
 Appendix A  
 Supplemental Information**

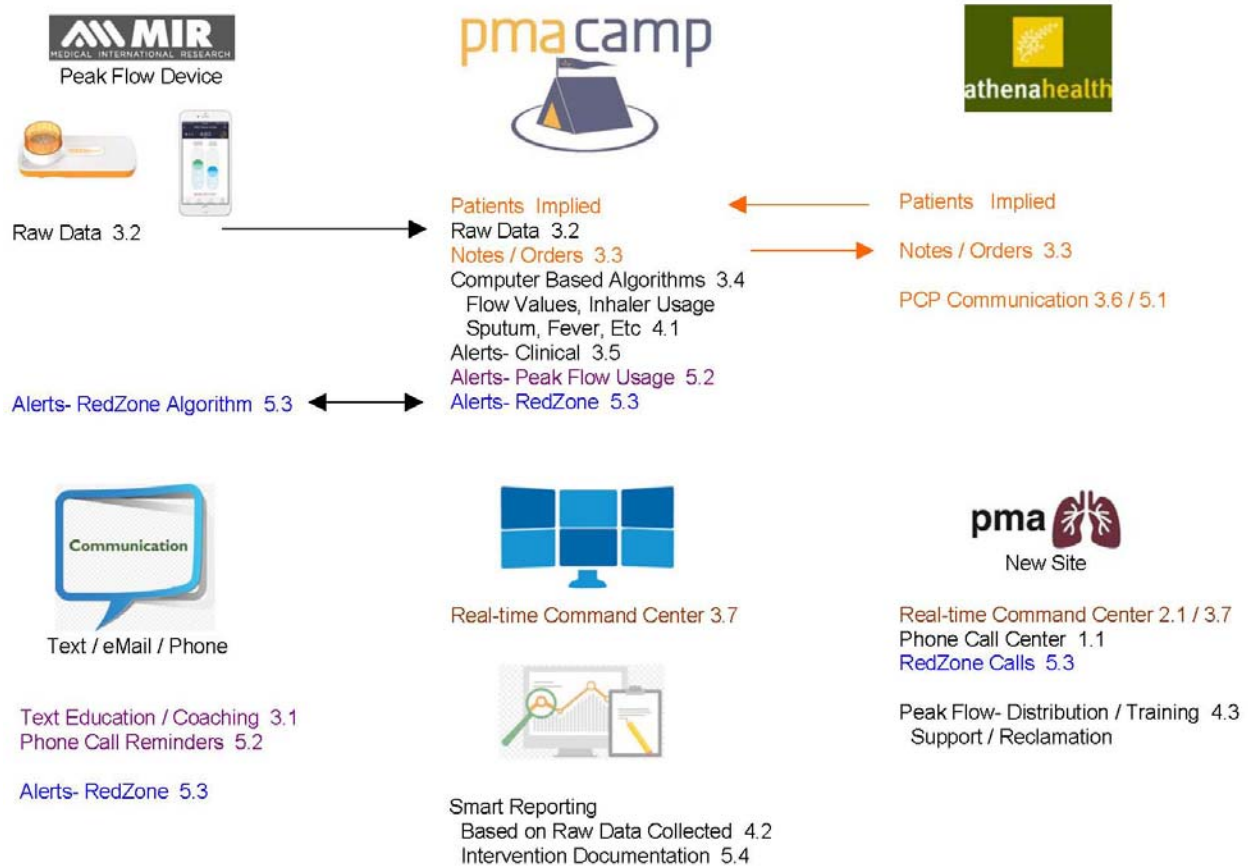
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Appendix A-VII	Letters of Endorsement 2013 State of California Department of Health and Human Services California Medical Association Sierra Sacramento Medical Society River City Medical Group 2016 Sutter Independent Physicians Medical Group Mercy General Hospital, Sacramento, CA Mercy San Juan Hospital, Carmichael, CA Sutter Medical Center, Sacramento, CA Sutter Roseville Hospital, Roseville, CA (Note: The 4 hospitals above are on present and/or past "Top 100 Hospitals" lists)	Page 33



Appendix A for the COPD and Asthma Monitoring Project (CAMP)

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Appendix A-1  
Operational Template for Implementation of CAMP



**Implementation Objective #1: Confirm CAMP is feasible and aligns with community’s health transformation goals**

The first implementation objective is to confirm that an CAMP-based alert system supports the community’s health transformation goals and is feasible within the technology and financial landscape. This begins with engaging partners and stakeholders, understanding the implementation costs and value proposition, assessing the existing technology landscape to inform the development of a project implementation plan, associated goals and selection of technology. This section describes the steps needed, including:

1. Engage support of appropriate partners and stakeholders
2. Clarify and articulate the local value proposition and funding requirements for CAMP-based alerts
3. Assess the technology landscape for feasibility and develop a preliminary systems overview



## Appendix A for the COPD and Asthma Monitoring Project (CAMP)

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4. Establish goals of the CAMP-based alert system in driving clinical transformation

### **1.1 Engage support of appropriate partners and stakeholders**

A strategic plan to engage community-level stakeholders is essential when making key decisions about the feasibility, long-term sustainability, goals, and implementation of an CAMP-based alert system. While the composition of this body of stakeholders will vary across communities, Community consultation, will include both clinical and administrative key stakeholders from hospitals, physician practices and other ambulatory care providers, care managers, and health insurance payers. While not discussed in detail in this document, a vital aspect of the work is the process for coming to agreement on goals and evaluating the feasibility of implementing CAMP-based alerts. This is a significant task even in communities with existing governance infrastructure and a history of collaboration. Each stakeholder group will have important considerations in deciding whether to support and whether to participate in the project.

### **1.2 Clarify and articulate the local value proposition and funding requirements for CAMP-based alerts**

Clearly articulating the value proposition to the various stakeholder groups will assist with obtaining buy-in and commitment from all levels of participating organizations. A strong value proposition for an alert system project explains how it aligns with other quality and performance improvement initiatives, how it will accelerate achievement of local goals, how the financial benefits outweigh the cost of start-up and ongoing operation, and potential funding and revenue sources. Understanding alignments, costs and benefits is necessary to develop a strong value proposition.

#### **Align with existing quality and performance improvement initiatives.**

At the community level, practices, payers, and hospitals, may be involved in several concurrent Quality and performance improvement activities. In order to align existing efforts, an important first step is to develop an inventory of community and practice-based quality and performance improvement initiatives. This activity will help articulate the value proposition and benefits of implementing CAMP-based alerts, building on existing efforts, and strategically aligning with community-wide goals to improve health and care at lower costs. Physician and hospital providers will require an upfront description of how the alert system aligns with other national and local projects in which the practice may be engaged. For example, many practices are attesting for Meaningful Use projects, seeking Patient Centered Medical Home (PCMH) certification, or preparing for future changes brought on by implementation of the ACA or MACRA. Understanding how these programs align with the CAMP-based alert system and articulating this message to participating practices will result in stronger buy-in at all levels within the practice, which will be critical for their participation.

#### **Calculate and consider start-up costs, ongoing operational costs, and potential funding sources and revenue opportunities.**

Costs can fall into several general technical and non-technical categories:



## Appendix A for the COPD and Asthma Monitoring Project (CAMP)

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### Technical

- \_ Sending data from the Peek Flow Meter to the Mobile device
- \_ Inputting data into a daily diary app located in a mobile phone
- \_ Extracting data from the mobile device
- \_ Sending data to repository
- \_ Developing interface to receive data
- \_ Translating data into a format designed to provide graphic interfaces and trigger alerts.

### Non-technical

- \_ Revising workflow to support usability of alerts
- \_ Training alert recipients on appropriate routing and follow-up
- \_ Evaluating and reporting results for real time improvement

### **Understand total cost of care and identify potential savings resulting from achieving quality and performance improvement goals.**

Discussing the shared cost and expected savings from improving care transitions and chronic care patient management with each stakeholder group engaged in the project will also assist with gaining buy-in and support across the community. In recent years, more incentives are becoming available to better coordinate patient care, particularly when patients are discharged from the hospital, such as through hospital readmission penalties and accountable care organization (ACO) shared savings programs. CAMP Interventions enable providers, case managers and care coordinators to reach out to patients transitioning from inpatient hospital care to community based care and provide the care and services needed to reduce the likelihood of a readmission, and the costs associated with readmission.

### **Consider potential impact in revenue resulting from payment reform.**

Existing payment reform models, such as the Pioneer ACO Program, Advanced Payment ACO Program, and the Medicare Shared Savings Program, as well as other payment reform programs such as the Hospital Readmission Payment Adjustments and the Bundled Payments for Care Improvement Initiative, are all structured to reward the value of health care rather than volume of services delivered. Each of these programs has financial rewards or penalties that can affect hospital or provider revenue and bottom line. Hospitals, practices, and communities participating in these programs have strong incentives to consider alert systems to improve care transitions and manage care, thereby maximizing potential revenue from Medicare or commercial payers. The passage of MACRA has now made available another option in payment reform modeling through its APM and AAPM pathways. We seek to implement CAMP employing opportunities presented by these new options. If successful, CAMP will change the Part A landscape. This potential reality creates interesting opportunist to partner with hospitals and Healthcare organizations to scale CAMP to provide sustained cost reduction for CMS and improved quality and safety for the Medicare beneficiary.

### **1.3 Assess the technology landscape for feasibility and develop a preliminary systems overview**



## Appendix A for the COPD and Asthma Monitoring Project (CAMP)

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The following are recommended steps for creating a comprehensive assessment of the technology landscape:

\_ **Determine System Types.** Identify the systems needed to send CAMP messages and the systems that providers and care managers would use to receive them. This supports the design of the HIE system in a manner that supports delivery to the provider recipient.

\_ **Identify Deployment Constraints.** Identify if the capability already exists in the community to receive CAMP -based messages. If the capability exists, the implementation and systems scope can focus on alert creation and delivery. Also gather business requirements, policies, or procedures related to communicating with participating hospitals. Develop an implementation package that describes the system architecture to share with hospital IT departments, along with emphasizing the necessity to test and validate CAMP-based messages before sending.

\_ **Identify System Guidelines and Define Architectures.** Document the performance guidelines and structure of the system. For example, if the health information exchange system currently has a service-oriented architecture (SOA).

\_ **Determine Technologies.** Finally, identify a set of technology options based on system guidelines and using selection factors such as:

- *Potential for Reuse:* Consider systems already used by the community or other partners to avoid unnecessary rework and duplication. Most communities begin by working with existing HIE systems and infrastructure. Their goals may include replacing or augmenting some of those systems.

- *Organizational Policies:* Keep in mind technologies previously approved according to community policy.

- *Resource Skills:* Consider knowledge and experience with previously implemented technologies.

- *Deployment Constraints:* Keep in mind the community's deployment constraints and limitations of existing systems needed to perform required functions. After the systems overview has been documented the community is ready to set goals and move forward towards the design, development, configuration, and testing of an CAMP-based alert system.

### 1.4 Establish goals for the CAMP-based alert systems in driving clinical transformation

Specific Aims for patients enrolled in CAMP:

1. From January, 2018 to January, 2020, we will achieve measurable improvements in COPD and asthma outcomes by implementing the NHLBI Guidelines Expert Panel Report 3 - Guidelines for the Diagnosis and Management of Asthma

(<http://www.nhlbi.nih.gov/files/docs/guidelines/asthgdln.pdf>) as well as strategy recommendations from the Global Initiative for Chronic Obstructive Lung Disease (GOLD, <http://www.goldcopd.org>) in partnership with patients, families, primary healthcare providers and payers of healthcare systems. .

2. We will exceed Healthy People 2010/2020: Asthma Related Goals

3. Develop a sustainability model that reduces unnecessary emergency room and hospital admissions.



## Appendix A for the COPD and Asthma Monitoring Project (CAMP)

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Outcome goals for patients enrolled in CAMP:

- 90% of patients are well controlled by 2020
- Decrease ED visits by 30% in 2018, 50% by 2019 and 70% by 2020
- Decrease hospital admissions in patients enrolled in CAMP by 10% in 2018, 15% by 2019 and 20% by 2020
- Decrease total Medicare costs by 10% in 2018, 20% by 2019 and 30% by 2020 in the population of patients enrolled in CAMP using a risk adjusted national chronic condition based benchmark.
- A statistically significant decrease in mortality when compared to an unmonitored cohort.

Process Measures:

100% of patients have “optimal” COPD and asthma care (all of the following):

- assessment and classification of COPD and asthma control using a validated instrument
- stepwise approach to identify treatment options and adjust medication and other therapies
- written patient self-management asthma action plan customized to take advantage of real time monitoring and early detection/intervention protocols
- stepwise approach to identify treatment options and adjust medication and other therapies
- patients >4 yrs of age with flu shot (or flu shot recommendation)
- smoking cessation and advise where appropriate

### Implementation Objective #2: Establish Project Scope, Design and Implementation Plan

To transition from community goals to an actionable plan, communities should consider the following steps:

1. Determine how the CAMP alert project fits into the technical landscape
2. Enact or amend data use agreements to support CAMP-based alerts
3. Select vendors to support the technical strategy
4. Develop an execution plan and begin with a pilot

With the value proposition, technology landscape, and program goals in mind, the community should scope the project and develop execution plans that minimize the amount of time required in each phase of the system implementation.

#### 2.1 Determine how the CAMP alert project fits into the technical landscape

Community-specific scenarios or use cases of CAMP-based alerts will drive systems development.

Identify use cases, or interactions between users and systems, to select and configure systems appropriately and effectively. Use cases help all stakeholders understand how information flows and helps identify the required system functionality, data elements, and needs for new systems or technology. Use cases also provide a framework for testing, privacy and security assessment, user acceptance, and evaluation of the alert system. Establishing use cases helps providers, technologists, administrators, and other support staff to explore scenarios for how CAMP feeds



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can be developed and used. Providers receiving CAMP-based messages should be involved in identifying the information most useful to them, informing the development of CAMP-based messages to create meaningful alerts, and selecting the candidate system that will provide access to this information. Providers should also be involved in defining shared data elements and alert functionality that support their workflow. Considerations for developing use cases may include:

\_ **How should CAMP feeds be filtered?** A goal is that only clinically meaningful CAMP feeds become events so distracting information is minimized.

\_ **Will Clinical Data be Sent?**

### 2.2 Enact or amend data use agreements to support CAMP-based alerts

Similar to the magnitude of the investment required in convening a representative governance body to facilitate community-level decisions, developing, executing, and maintaining data use agreements (DUAs) is a significant component of implementing CAMP-based alerts. Of note, DUAs and amendments preserve compliance with Health Insurance Portability and Accountability Act (HIPAA), as well as state laws. Stakeholders must first determine what information will be contained in the alert, such as: patient demographic information, specific information about the ED/inpatient visit the recipient requested, and any additional information to append or send as a follow-on document. After the data needed in the CAMP-based alert message is identified, the parties sharing the data determined, and the intended use of the data have been agreed to, a legal team reviews existing DUAs and determines whether amendments are required. If an amendment is required, the governance body creates, reviews, and accepts changes in language to the DUA, followed by obtaining signatures from all participating organizations.

### 2.3 Select vendors to support the technical strategy

A small pilot or prototype will allow for exploring specific design choices by testing various system models and validate new concepts. This enables the community to continuously improve the system design as new business requirements are gathered or as the piloted systems inform the clinical transformation process. If using a rapid prototyping design and development process, ensure that each iteration include design, architecture, and integration activities. The following are typical steps that would accompany system selection:

- \_ Verify business and functional requirements are complete with key stakeholders
- \_ Define and prioritize system selection criteria. Some factors to consider include:
  - Ease of implementation
  - Usability, interoperability, cost, benefits, and maintainability
- \_ Develop a functional prototype to answer any key questions or to further define system requirements
- \_ Review and rank candidate systems against criteria
- \_ Develop a systems selection recommendation
- \_ Use existing system governance structures and processes to make a decision

### 2.4 Develop an execution plan and begin with a pilot

When implementing CAMP-based alerting initiatives, start small and then expand.





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\_ **Counting clicks.** Providers will be more satisfied with a solution that is easy to access and review.

\_ **Amount of information.** Providers can be overwhelmed if receiving too much information, particularly during the initial pilot. While complete clinical information is valuable, communities may decide to gradually increase the amount of information to avoid overloading users.

\_ **Alert frequency.** Providers can be overwhelmed by receiving too many alerts, as well. For example, CAMP-based alerts may be one of many types of alerts that the users receive in a clinical system. CAMP-based alerts should be on an appropriate delivery schedule and take into account other alerting workflows.

\_ **Format and display.** In addition to being accurate, the alerts should be cleanly formatted for display in the source system. Examples of poor formatting can include confusing line breaks, unaligned columns, and excessive use of underline, italics, and bold.

\_ **Usability labs.** Testing alerts in the source system with users provides ample feedback on ways to make the alerts easier to interpret.

\_ **Performance.** Technical problems also impact usability, for example, a button that does not work, not having a way to delete or resolve an old alert so that the alert queue continues to grow, or system slowness. These small technical glitches annoy users or incentivize them to create workarounds that complicate the original workflow.

\_ **Costs and budget.** How much support can the community afford to provide?

\_ **Number of providers.** How many care providers should the pilot include?

\_ **Amount of functionality.** How many new tools and workflows will be incorporated?

\_ **Expansion schedule.** How many phases will the pilot cover, and how long will the delay be between phases?

### Implementation Objective #3 Evaluate the Ongoing Performance and Impact of CAMP-based Alert System

Evaluation is an essential aspect of any quality improvement activity, including an CAMP-based alert system program. Initial conversations around program goals and design should include a discussion of how the program will be evaluated. This section describes several areas in which measurement may be valuable, notes particular measures that may be used for monitoring and evaluating, and highlights the importance of ongoing monitoring and reporting. Communities designing an CAMP-base alert program should consider the following steps:

1. Understand potential measure types
2. Develop reporting mechanisms and ongoing monitoring and review processes While it is important to discuss and determine an evaluation strategy early in the planning stages of implementing CAMP-based alerting, as the system expands and more is learned, the approach will likely evolve.

#### 3.1 Understand potential measure types

A comprehensive evaluation includes measures that describe the characteristics of the system, monitor the quality of information being transmitted, monitor the usage of alerts, and track progress on clinical outcomes as they relate to CAMP alert system goals. Measures used to evaluate performance of CAMP-based alerts capture performance in four distinct areas:

\_ **System Characteristics:** Who is participating in the program?



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\_ **Data Quality:** How well is the system functioning?

\_ **Usage of Alerts:** How many providers and patients are using the alerts?

\_ **Patient Outcomes:** What is the impact on clinical outcomes?

To track and monitor system characteristics, CAMP will consider. Data quality measures of CAMP alert systems address the quality of information being transmitted by the CAMP-based alerting system. Understanding and maintaining high-quality data enables participating clinicians to use appropriate, patient-specific information to enhance patient care. Key questions for assessing data quality may include: Is the information in the alert accurate? Do the data fields contain the expected data (e.g., name field does not include contact birth date)? Are all fields complete? What percent of patients are accurately attributed to the correct practice? It is also important to capture the usage of alerts, or the degree to which CAMP personal act upon the information that they've received. Potential measures here might include the percent of daily alerts reviewed and acted upon. Data monitoring and feedback that shows clinically-valuable alerts are not being used could be an important finding that leads to reexamining key aspects of program design. Finally, the overall goal of implementing CAMP-based alerts is to improve clinical outcomes. Clinical outcome measures for consideration include:

- \_ Emergency department utilization rate
- \_ Hospital inpatient utilization rate
- \_ Hospital readmission rate
- \_ Ambulatory care sensitive readmissions

### 3.2 Develop reporting mechanisms and ongoing monitoring and review processes

Tracking, monitoring, and evaluating key aspects of the CAMP-based alerting program is essential for improving care coordination and chronic disease management and reducing the likelihood of unnecessary ED use and hospital utilization. To the degree possible, providing real-time

information to key stakeholders, participating providers, and program administrators regarding the characteristics of the system, quality of information being transmitted, the usage of alerts, and progress on clinical outcomes will enable appropriate and important adjustments that will contribute to the successful implementation of the CAMP-based alerting system.

### Implementation Objective #4: Obtain CAMP Information and Transform into a Clinically Meaningful Alerts

This section provides an overview of the process for developing clinically meaningful CAMP-based alerts, while preserving security and data quality, accuracy, and utility. This section describes the steps needed, including:

1. Consider security in data transport mechanisms
2. Execute a 5-step transformation process

#### 4.1 Consider security in data transport mechanisms

A critical issue to address when planning an CAMP-based system (CAMP-BS) Is the security of the information being transmitted. Specifically, the technology should:

- \_ Confirm that the data is going to the correct systems, per the intended data use agreement
- \_ Ensure that the appropriate information is sent



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\_ Send the data to the appropriate recipients

### 4.2 Execute 5-step process to transform CAMP message into an alert

The process of triggering an alert is shown in Exhibit 6. While there may be differences across communities with regard to the size and scope of the CAMP-BS, the specific data transmitted and the format of the alerts will always follow this five step process.

1. **Source Systems Create CAMP Message.** Entry of information into a mobile device will trigger an alert both on the mobile device and be transmitted to the central data repository where a duplicate alert will be generated.
2. **CAMP-BS Receives Source Message.** CAMP-BS fields Source messages sent from the parents device so that the alert can be redirected to the appropriate CAMP care provider
3. **CAMP-BS Processes Source Message.** The CAMP-BS's patient matching and device matching functions identify the correct recipient for the alert
4. **CAMP-BS Creates Alert.** Having matched the patient and device, the CAMP-BS compiles the content for the alert into the appropriate format
5. **CAMP-BS Sends Alert to Destination System.** The CAMP-BS sends an alert to the appropriate CAMP care provider system for follow-up.

The following sections will walk through the alert generation process and identify key technical considerations for configuration and testing.

#### Step 1. Source Systems Create CAMP Messages

The most important technical component for automated CAMP alerts involves mapping out the specific data elements required by clinicians to make informed decisions about a patient's treatment needs. . Considerations to explore during system design that impact data quality, accuracy, and utility include:

\_ **Differences in Vendor Capabilities.** Device vendor strengths and weaknesses vary. The specific capabilities of existing vendors will affect the level of effort and cost required to implement CAMP based alerts. The implementation plan will need to account for the differences in vendor capabilities

\_ **Data Format.** Alignment between partners will likely requires formal agreement, in advance, about the format in which the CAMP alerts are provided. It is important for the data to be in a format that can be successfully loaded and stored in a system for future retrieval or analytics, such as an HIE.

\_ **Quality Assurance (QA) and Quality Control (QC).** Quality assurance and quality control processes provide structured mechanisms for the community to test the hospital messages for both message and semantic accuracy. Decisions about specific clinical data elements to include in an CAMP alert can be complicated by the electronic format in which the data are stored and transmitted. For instance, a continuity of care document (CCD) for a patient may contain important information, but the data are only useful to the provider practice if the practice has the capacity to receive, read, and store it. In addition, there may be limits to the amount and consistency of patient information collected by each source system. CAMP may regularly send a complete data set for each patient alert while others systems do not capture as much or even the same information.



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A final, but critical consideration about clinical data in a community is the challenge posed by frequent changes in technology and its use across the community. This is a predictable part of the process and accommodation for these changes should be included in the plan. Expectations and standards about data volume, format, and quality provided by source systems must be spelled out clearly from the outset to avoid confusion or disappointment by users.

### **Step 2. CAMP-BS Receives Source Message**

Before beginning implementation of an community CAMP-BS, it is important to validate the quality of CAMP messages that come from the device. The quality of the data refers not only to the accuracy of the information, but also to the ability of CAMP providers to interpret and understand it. It is vital for the recipients of the alerts to be able to make informed decisions and take appropriate action based on the alert information. Create a process flow map in order to understand the complex interactions resulting from receiving multiple data elements from multiple sources.

### **Step 3. CAMP-BS Processes Source Message**

When processing the Source message, the CAMP-BS will match the incoming information on two dimensions: the patient and the relationship of the patient with the device, also known as patient attribution. Appropriate design of the patient attribution methodology is vital to ensure that the correct practices and clinical staff receive alerts for their patients. To accomplish this, the HIE will:

- \_ Match a patient to a common ID through the master patient index (MPI)
- \_ Determine what to do if a patient does not exist in the MPI (e.g., create a new patient)
- \_ Capture the relationship from the device into CAMP-BS

### **Step 4. CAMP-BS Creates Alert**

After processing the CAMP message, the CAMP-BS will evaluate the message against algorithms to determine whether an alert should be generated. Message triggers and alert evaluation logic must withstand frequent changes without affecting the other parts of the CAMP-BS system.

### **Step 5. CAMP-BS Sends Alert to Destination System**

The best alert transmission method for a particular CAMP Monitoring Station is depends on the recipient of the message. Regardless of the method used, it is important to test usability and consider long-term sustainability:

## **Implementation Objective #5: Integrate CAMP-Based Alerts into Care Provider Workflows**

Ultimately, the goal of CAMP-based alerts are to provide timely, accurate, and comprehensive demographic and clinical information to a clinician who can act upon it. Revising workflows to incorporate and respond to this new information will be necessary to achieve the results desired in quality improvement and efficiency in patient care, especially to high risk chronic disease patients with high utilization of health care resources. Establishing a successful CAMP-based



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alert program requires careful workflow planning to ensure that alerts are used appropriately and effectively to improve care.

This section provides guidance on specific planning activities required to successfully integrate CAMP-based alerts into care provider workflows, with particular emphasis on cost considerations, identifying roles and responsibilities for the alert triage process, providing training and coaching to clinical and support staff, and integrating the alert process into the care provider workflow.

1. Identify roles and responsibilities for the alert triage process
2. Provide training and coaching to clinical and support staff
3. Tailor workflow to support clinically meaningful alerts

### 5.1 Identify Roles and Responsibilities for the Alert Triage Process

A clear understanding and definition of roles, expectations, and accountability of person(s) involved in triaging CAMP-based alerts is fundamental to the integration of alerts into a care provider workflow. To accomplish this, provider practices can identify individual(s) or “Alert Process Owners” who are accountable for managing daily alerts, completing patient follow-up, and initiating quality improvement (QI) activities. These may be administrative or support staff or a designated care

manager. The roles and responsibilities of the Alert Process Owners need to be clearly and formally established and understood ahead of time, along with decisions about appropriate delegation of responsibilities, including a timeframe for follow through on alerts during the triage process based on practice guidelines.

### 5.2 Provide Training and Coaching to Clinical and Support Staff

Adequate training and education of clinical and support staff is critical to the integration of alerts into a care provider workflow, and engaging and empowering providers and staff. The benefits of training and coaching include:

- \_ Well-defined and understood user roles and responsibilities
- \_ Improved workflow incorporating provider or administrative staff input
- \_ Increased use of best practices for follow-up care
- \_ Reduced instances of incorrect matches between patient and device
- \_ Increased patient engagement with regard to care planning and follow-up

Effective training is comprehensive and role-specific focused on the new processes and program.

It is designed for and delivered to care providers and staff, including technical staff.

Collaboration among staff, some of whom may not usually work together (such as technologists, system design teams, and the clinical care team), is important to maximize the benefit of CAMP based alerts. Staff need to coordinate across functions and fully understand how the alerts affect other staff (clinical, administrative, and technical) to provide high-quality care to targeted patients. Training for technical staff includes performance monitoring, triaging issues, and addressing errors during system implementation and for system maintenance. Team members manning a dedicated help desk or team responsible for taking calls from patients or care providers, these team members also require training about the new workflow and how to triage issues.



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### *Exhibit 1: Training Recommendations for Technical Staff*

#### **System Administrators Training**

- \_ Performance monitoring
- \_ System reliability (CAMP message interfaces with source systems)
- \_ Methods to tune key elements (e.g., patient matching, data flow) and change control process
- \_ Plans to scale the system and integrate additional IT systems and content

#### **System Operators Training**

- \_ Use and configuration of additional systems or message formats
- \_ Monitor interfaces and addressing changes in the source systems
- \_ Procedures to request additional information from the source systems
- \_ Processes to contact clinics or other alert recipients
- \_ Review and correct data validation errors on specific messages
- \_ Review and address patient and provider matching errors
- \_ Sequencing the go-live, documentation, and back-out processes

#### **Clinical Care Team Training**

- \_ Standard processes to document alert, actions, and alert resolution in the system
- \_ Role- and facility-specific workflow considerations (e.g., review of clinical information, procedures for patient contact)
  - \_ Accessing, reviewing, and verifying accuracy of alert content
- \_ Standard processes to document alert, actions, and patient contact
- \_ Reporting errors and problems (e.g., logging in, alerts received in error, data inaccuracies, missing alerts)
- \_ Frequently asked questions, known issues, and plans for future scope

### **5.3 Tailor workflow to support clinically meaningful alerts**

Clinical staff training should be focused on identifying and implementing a process workflow to use the CAMP-based alerts. To the degree possible, this process should be aligned with other practice workflows. Exhibit provides a high-level summary of a sample CAMP-based alert process workflow, beginning with the point at which an alert is generated through the completion of activities based on the clinical diagnosis and care needs of patients. See Appendix E for an example of how an CAMP-based alert impacts the workflow and care management process.

### *Exhibit 2: CAMP-based Alert Process Workflow*

- \_ **Review alerts:** The Alert Process Owner reviews alerts based on established protocols and verify the accuracy of the patient and provider information.
- \_ **Review clinical information:** Appropriate staff reviews the clinical information to understand the clinical characteristics that resulted in the alert generation.
- \_ **Contact patient:** Appropriate care team members contact the patient in a timely manner (eg. text messaging, phone call, Skype).
- \_ **Ensure appropriate documentation:** Document all required information about the patient to help ensure that the right course of treatment is provided safely and effectively
- \_ **Document call:** Document patient outreach, if appropriate, to provide confirmation and information about timing of outreach to the practice and the care management team.



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**\_ Complete care coordination or other appropriate patient management activities:** Initiate care coordination and care management once information necessary to determine what actions should be taken is known. Standardize workflows acting on CAMP-based alert workflow include:

- \_ Number of people who interact with the alerts
- \_ Number of patients staff will respond to (e.g., all patients, some patients)
- \_ Responsibilities of responding staff after receiving an alert (e.g., make a follow-up call, complete an assessment)
- \_ Level of integration with an electronic health record.
- \_ Integration with other new or existing care management or quality improvement processes

### Reporting - Potential Performance Metrics for CAMP-Based Alert Programs

#### Considerations Data Source(s)

##### 1 Data Quality

Number and percent of all alerts with a data quality trigger

A measure of CAMP alert data quality.

- Does the alert contain accurate information in data fields?
- Do the fields contain expected values?
- A robust and comprehensive data quality assurance and control process should be in place to ensure that every feed goes through. Ideally, this process would occur at the device source so that the feed can be triaged before submission to CAMP-BS.

##### 2 Data Quality

- Number and percent of all alerts with one or more missing key fields
- A measure of alert data completion.
- Are all the necessary data fields complete, with no key fields having an omission of data?
- Data completeness testing should be in place to ensure that every feed goes through. Ideally, this process would occur at the source so that the feed can be triaged before submission to CAMP-BS.

##### 4 Alert Utilization

Percent of Daily Alerts Triage The percent of all feeds received within a day that the accountable individuals review and triage Need to identify accountable individuals and establish parameters for the timing of alert review and triage

##### 5 Alert Utilization

- Number of Alerts per 1,000 Patients
- The number of alerts received over a specified time period per 1,000 patients enrolled in CAMP.
- The number of clinical interventions generated by the alerts per ,000 patients enrolled in CAMP per day.



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**6 Alert Utilization**

Percent of Hospital Discharges Represented by Participants

**7 Clinical Outcomes**

Emergency Department Utilization Rate The number of ED visit per 1,000 population

**8 Clinical Outcomes**

Hospital Inpatient Utilization Rate

The overall hospital utilization, number of hospital admissions per 1,000 population.

**9 Clinical Outcomes**

Percent of Patients Discharged from Hospital Readmitted within 30-days The percent of patients who experienced unplanned readmission to a hospital after a hospital stay.

**10 Clinical Outcomes**

Ambulatory- Care Sensitive Readmissions





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### Appendix A-II CirrusMD Inc

CirrusMD Inc. is a healthcare communications company that designs virtual care solutions for healthcare organizations developing and implementing new value-based models. It was founded in 2012 and currently has offices in Denver, Dallas, Sacramento, and Washington, D.C. The originating co-founder, Blake McKinney, MD, is a former Captain in the U.S. Marine Corps and is currently a practicing emergency physician in Northern California. Dr. McKinney developed the idea for CirrusMD after seeing patients wait for hours in his ER for issues their primary and specialty care doctors could easily manage if accessible. He set out to create a service that provides patients easier access to healthcare services, regardless of insurance status. CirrusMD's platform is designed to streamline physician productivity and transform industry business models, while substantially reducing costs.

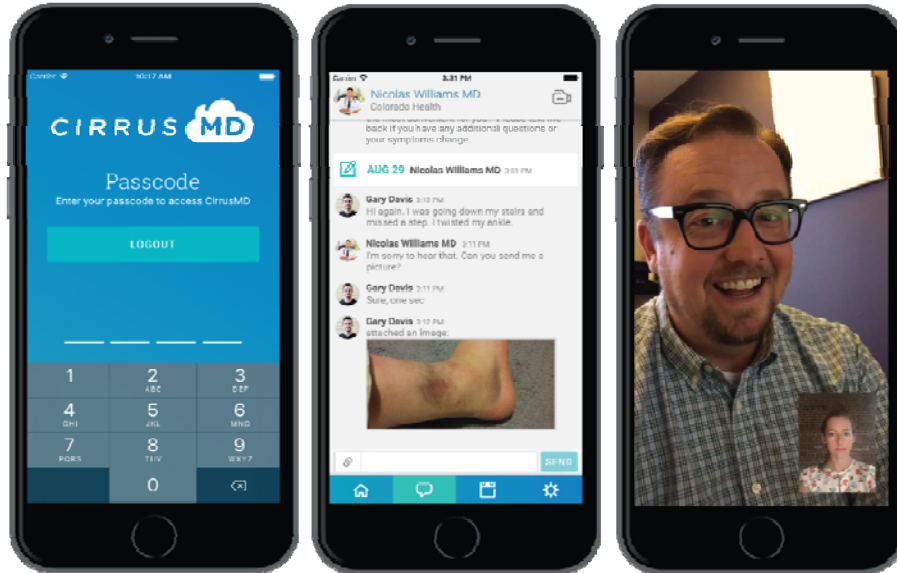
#### The CirrusMD Solution

CirrusMD offers the first telemedicine model designed specifically to meet the needs of risk-bearing healthcare organizations that enables the right "front door" for patients to access on-demand, local medical care through a secure text-message-first based workflow that incorporates live video chat and picture messaging as needed. CirrusMD's asynchronous communications model and clinical workflows are novel and proprietary. CirrusMD's HIPAA-compliant communications platform is accessed via mobile iOS/Android Apps and computer-based web browsers, and it has both an enterprise grade architecture and patient-friendly design with a familiar user interface patients already know how to use. The company has a proven track record of improving patient outcomes while reducing cost across various customer implementations.

The CirrusMD platform fully integrates with electronic medical records (EMRs) and patient portals to enable continuity of care with in-clinic primary care providers and specialists. Combining data integration with a dedicated staffing model using only local providers creates a care experience that optimizes patient outcomes and patient satisfaction.

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**Programs of Virtual Care**

CirrusMD designs and implements programs of virtual care for many forms of medical treatment that patients often struggle to access, including:

- **Virtual Acute Care:** 24/7 on-demand care for common medical conditions such as respiratory illnesses, infections, minor illness and injuries. Programs are staffed by dedicated local physicians integrated into patients' care delivery networks. Average response times are about one minute.
- **Post-acute Follow-up:** access to physicians post-discharge from the ER or a hospital stay to prevent readmissions.
- **Chronic Disease Management:** ongoing access to care coordinators to better manage chronic conditions through regular communication with patients.
- **Primary Care:** virtual extension of a PCP's in-office practice.
- **Behavioral Health:** either as a stand-alone service or integrated with primary care.
- **Specialists:** virtual consults with specialists in coordination with other members of a patient's care team.

Today, the CirrusMD has implemented multiple large scale Virtual Acute Care programs. It is also operating a major Post-acute Follow-up program in the Dallas-Fort Worth metroplex that will soon provide access to approximately 50% of the area's population through local hospital systems. The company has launched Chronic Disease Management and Primary Care programs and is developing Behavioral Health pilots in partnership with a leading nationwide network of therapists and psychiatrists.



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To enable individuals to access all programs of virtual care to which they have access, CirrusMD is has also developed a “many-to-many” patient-to-provider experience. A patient is able to manage and communicate with many, if not all, of his or her providers using CirrusMD’s platform. This latest version of CirrusMD’s platform creates a “front door” for patients to access care while also enabling effective cooperation among the patient’s care team.

### **Superior Outcomes**

CirrusMD is seeing tremendous outcomes from all of its programs. Its Post-acute Follow-up program, for example, is demonstrating 27% ER diversion rates.<sup>1</sup> In other populations, combined ER and Urgent Care diversion rates are greater than 40%. CirrusMD utilization rates are 10 times higher than its competition. About 85% of medical issues addressed are fully resolved via the platform, with no referral to a bricks and mortar provider needed.

CirrusMD also enjoys superior qualitative results. It has achieved a 97% satisfaction rate with physician care and an 84% Net Promoter Score, and it has received almost universally positive patient testimonials (see case study below for some examples). This tremendous reception among patients explains why CirrusMD has the highest repeat user rate in the industry. About 22% of patients have used the CirrusMD platform more than once, using it an average 2.6 times each.

### **Patient-friendly User Experience and Design**

CirrusMD’s user interface is innovative in the simplicity of its design, which looks and feels like familiar, best-in-class messaging applications such as Facebook Messenger, WhatsApp, or iMessage. Simplicity is important to driving both utilization by patients and acceptance by providers. Since its founding, CirrusMD has prioritized creating a user experience that people are already familiar with before they log in for the first time. Over time, CirrusMD has incorporated feedback from both patients and providers on user experience to make its platform even easier and more intuitive to use. Many items on its product roadmap have come directly from user feedback.

### **Sample Patient Journey – Receiving Virtual Acute Care**

This section outlines a step-by-step description of how a patient/end user would use the patient-facing version of the CirrusMD platform to receive medical treatment in a Virtual Acute Care program.

- Patient is made aware of the Virtual Acute Care program from the entity providing the program via email campaigns, direct mail, placement of links on member portals, etc. CirrusMD provides significant support to our clients for this member marketing to ensure high utilization rates.
- Patient accesses platform for first time via email registration or single sign-on.<sup>2</sup>
- Patient has an Encounter and receives treatment

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<sup>1</sup> ER diversion refers to people that were treated virtually via the CirrusMD platform who otherwise would have gone to the ER.

<sup>2</sup> Single sign-on here means the patient logs into one platform such as a patient portal and therefore is automatically logged into the CirrusMD platform as well.



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- After logging in, the patient is immediately presented with a secure chat message stream workflow where the patient may chat directly with the provider on duty to receive medical advice, treatment, and/or a prescription.
- The chat conversation can last as long as the patient and provider deem necessary. Message conversations may be conversational in nature or may be spread over long periods of time, similar to text messaging. When the provider or patient sends a new message, the other party receives an in-app or browser notification.
- During the chat, the patient or provider may upload images directly into the messaging thread.
- The doctor may initiate a video chat during the conversation or may call the patient on the phone if either is medically necessary or advantageous in the opinion of either the provider or patient.
- At the end of the chat, the provider will file a Progress Note that summarizes what was discussed and what care plan was designed for the patient. The Progress Note will appear in the messaging thread (which is persistent) for the patient and provider for future reference.
- Filing a Progress Note signifies the end of one discrete CirrusMD interaction (an “Encounter”). However, providers staffing the platform encourage patients to “stay in touch” during the course of a medical issue. Therefore, either the doctor or the patient may reinitiate a conversation during the course of addressing the medical issue. The messaging functionality alerts the other party to log in and pick up the conversation about the medical issue.
- At the end of each Encounter, the patient receives a survey to ask about the experience and collect some key metrics about the Encounter.
- Patient desires treatment again
  - The patient may seek treatment for acute issues as many times as he or she wishes.
  - The patient can scroll through his or her entire messaging thread with providers to review prior treatment and can update CirrusMD’s “mini-EMR” fields for medical history, medications and allergies.
  - Providers may also follow up with patients proactively to see how they are doing during treatment of a medical issue.

### **Conclusion**

With significant clinical utilization at scale, CirrusMD is the first enterprise class asynchronous messaging platform to achieve physician workforce scalability while leading the market in patient utilization and re-utilization. In clinical medicine, as in much of life, it’s all about communication. By making an expert physician immediately available and enabling that physician to provide effective on-going care that is well-integrated into the local healthcare “ecosystem”, CirrusMD helps patients to be healthier and enjoy real peace of mind. CirrusMD is the right solution to improve doctor-patient communication and therefore significantly increase access to healthcare for large populations that currently struggle to obtain the care they need in a timely manner.

### **Case Study – Successful Virtual Acute Care Program for Major Health Plan Situation**



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In 2014, a large not-for-profit health insurance provider was seeking a solution to help their policy holders access the right care, at the right time, from the right provider. With about 200,000 covered lives, including about 140,000 Medicaid beneficiaries, the insurer found thousands of its members were unnecessarily accessing high-cost points of care such as emergency departments and urgent care centers. These choices were often based on lack of immediate access to primary care, and resulted in claims for unscheduled care that could have been handled remotely with the right kind of physician access. In its highly competitive health insurance marketplace, the insurer needed a solution to help keep costs in check to keep premiums competitive while also meeting its mission as a not-for-profit health insurance provider.

### Challenges

Industry data shows that about 70% of all emergency room and urgent care visits are unnecessary, leading to an enormous waste of resources. The insurer estimated that within its commercial population, each visit to the ER costs it nearly \$2,700, urgent care \$125, and office visit \$75. Diverting these unnecessary bricks and mortar visits to a virtual care program would increase the insurer's cash flow significantly, enabling it to better meet its mandate as a not-for-profit. Doing so would also provide a superior, unique experience for its members, improving member satisfaction and member retention and serving as an attractive added benefit to sign up new members during open enrollment periods.

### Solution

The insurer launched a CirrusMD Virtual Acute Care program in January 2015, white labeled under its brand. Members can access a local ER physician via the platform for a wide range of general medical questions, disease specific treatment, and mental health conditions via secure messaging, phone and video chat. A dedicated doctor on duty is paid an hourly rate by the health plan and responds to members in less than one minute on average. Members ask questions about their symptoms, receive prescriptions and follow-up treatment, and even clarify if they need to go to the emergency room or urgent care or can stay at home.

The CirrusMD platform enables easy documentation of each patient Encounter, and a summary of this treatment is automatically imported to the patient's regular EMR records via a data integration with the local health information exchange. The patient's primary care physician receives electronic notification after each Encounter on the CirrusMD platform so that he or she can stay abreast of the virtual treatment the patient has received and can follow up as needed.

### Results

The insurer views the implementation of CirrusMD's Virtual Acute Care program as a huge success, far greater than had originally been anticipated, from both financial and member satisfaction perspectives.

Key success metrics include:

- Only 2% of patients went to the ER after using CirrusMD and another 2% went to urgent care. All such bricks and mortar visits were appropriate and recommended by the physician who treated the



## Appendix A for the COPD and Asthma Monitoring Project (CAMP)

Page 21

patient virtually, meaning that there were no unnecessary ER or urgent care visits by members that first used CirrusMD.

- Approximately 13% of total visits were diverted from the ER, 30% from urgent care, and 32% from an office visit with their primary care physician, generating a weighted average savings of about \$435 per Encounter.
- 85% of Encounters were handled entirely via messaging.
- Physicians only referred patients for in-person treatment about 15% of the time. As a result of using local physicians who work closely with the insurer, these referrals were made to in-network providers, further increasing the cost savings realized by the insurer.
- Physicians prescribed medications in 34% of Encounters. As with referrals, the doctors write prescriptions on formulary/on protocol for the insurer, optimizing resource utilization within the mandate of the plan and further generating savings.

Members have reported a satisfaction rating of 98% with the program to date, and member testimonials have been overwhelming positive, as these representative samples demonstrate:

- *“This service has restored my faith in insurance. This is the best thing a health insurance company has ever done for its patients.”*
- *“...this has single-handedly restored my faith in health insurance”*
- *“Hi! This service is the best idea EVER! It saves you [health insurer] soooooo much money because you wouldn't have to pay a claim to an urgent care facility for something like what I needed.. a Medral pack! Plus, I don't have pay a co-pay or coinsurance either! Whoo Hoo! ;)”*
- *"I will definitely use and recommend this service to anyone who needs to seek care for a minor illness. I was able to get treatment without having to leave home. The physician was very thorough and I cannot say enough about the care she gave me.”*



Appendix A for the COPD and Asthma Monitoring Project (CAMP)  
Page 22

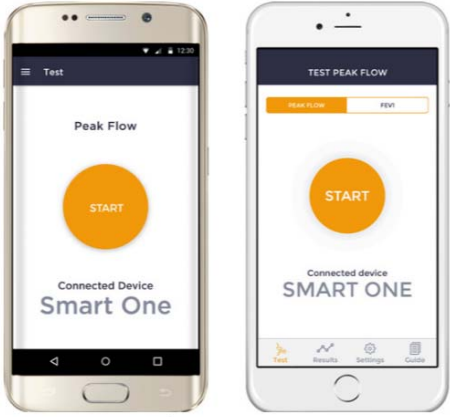
**Appendix A-III**  
**Example of a commercial Bluetooth enabled Peak Flow Meter.**  
Smart One by MIR.

View the Vidio demonstration:  
<http://www.spirometry.com/eng/products/smartone.asp>  
Currently liscensed in Europe and awiating FDA approval in the United States. The MIR Smart One has the capability of meeting technical requirement for CAMP-BS.

Screenshots on smart phones  
Available for iOS and Android



Real Time free FEV1 and Peak Flow on your smart phone



Screenshots on smart phones  
Available for iOS and Android



Insert subject data in order to calculate target values, and generate the traffic light health indicator





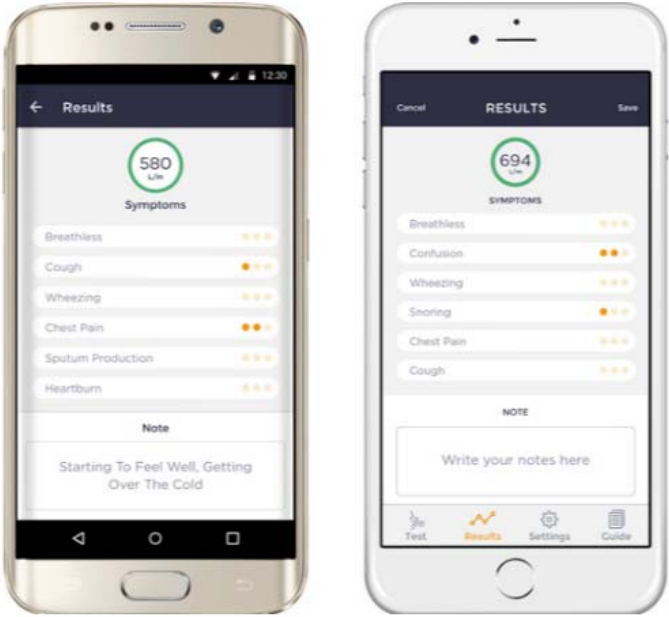
**Appendix A for the COPD and Asthma Monitoring Project (CAMP)**

Page 23

**Screenshots on smart phones**  
Available for iOS and Android



Symptoms selection and easy scoring system with the option of multiple tapping to identify the intensity







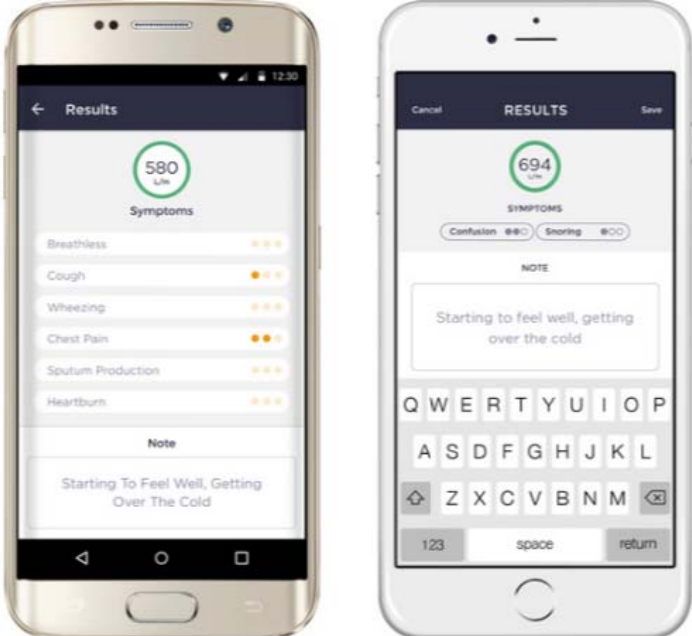
Appendix A for the COPD and Asthma Monitoring Project (CAMP)

Page 24

Screenshots on smart phones  
Available for iOS and Android



Easily tap on the graph to flag any test results and add notes to each single session





**Appendix A for the COPD and Asthma Monitoring Project (CAMP)**  
Page 25

**Screenshots on smart phones**  
Available for iOS and Android



Test results history with FEV1, traffic light health indicator, symptoms scoring and notes



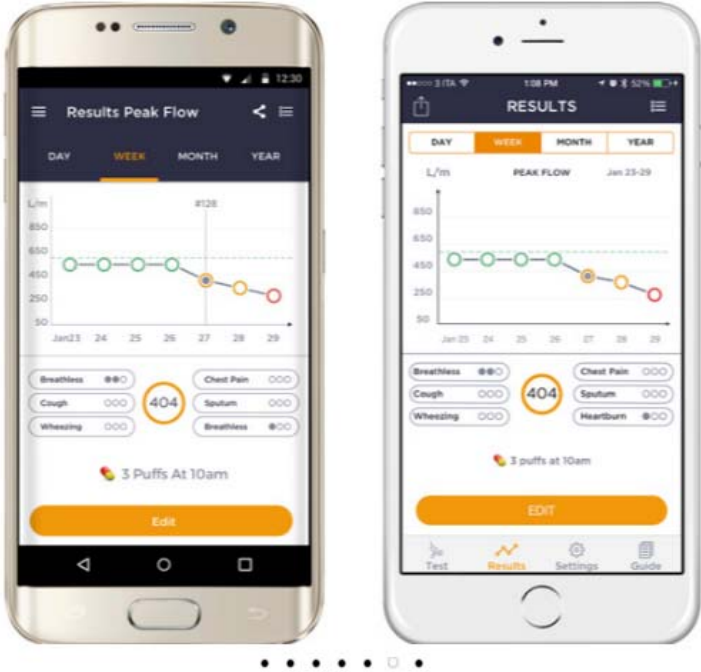


Appendix A for the COPD and Asthma Monitoring Project (CAMP)  
Page 26

Screenshots on smart phones  
Available for iOS and Android



Graphic trend of Peak Flow or FEV1 measurements including option to flag any test session





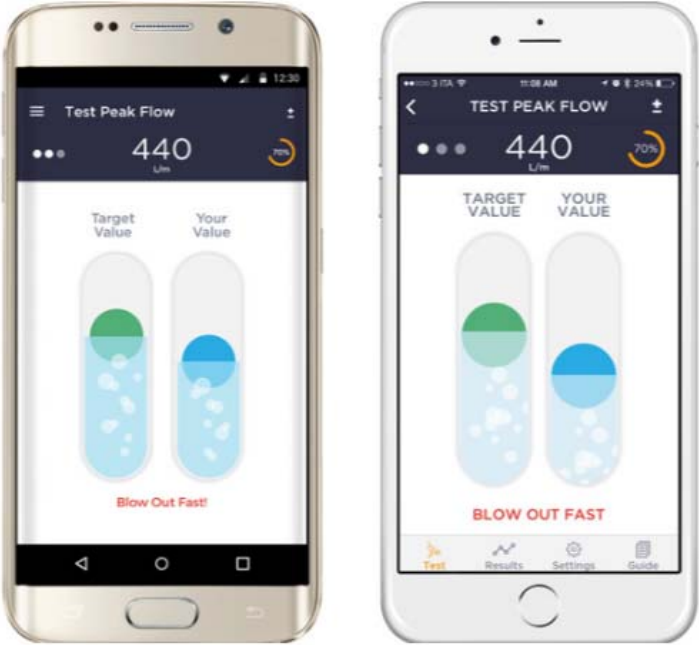
Appendix A for the COPD and Asthma Monitoring Project (CAMP)

Page 27

Screenshots on smart phones  
Available for iOS and Android



Innovative Incentive for test compliance





## **Appendix A for the COPD and Asthma Monitoring Project (CAMP)**

Page 28

### **Appendix A-IV**

#### **About PMA**

Pulmonary Medicine, Infectious Diseases, and Critical Care Consultants Medical Group Inc. is incorporated in the state of California as an S corporation. PMA will serve as the recipient of this proposal.

Following completion of the pilot, PMA may review opportunities to scale the project through a more open organizational structure with other partners.

PMA has a staff of Board Certified physicians in the following specialties:

- Pulmonary Medicine
- Allergy and Immunology
- Infectious Diseases
- Sleep Medicine
- Critical Care Medicine
- Hospice Care

Daniel Ikeda, MD, FCCP is a partner at PMA. Board certified in Internal Medicine, Infectious Disease, Pulmonary Medicine and Critical Care Medicine, Dr Ikeda was the 1<sup>st</sup> Medical Director of the Sutter eICU and oversaw the original implementation of the eICU's integration into multiple hospital ICUs. Through his leadership, ICU best practices were incorporated into multiple ICUs. Through the eICU, in cooperation with local ICU providers, Dr Ikeda initiated multiple, in network studies testing ICU concepts. Taking advantage of the data rich environment of the eICU, mortality benefits from the early identification of Severe Sepsis in early 2004 were discovered on data analysis. These findings led to swift and dramatic process change in multiple hospital ICUs. Sutter Healthcare became an early adopter of the Surviving Sepsis campaign. ICU mortality improvement cited in Section IV was largely due to our ability to use the eICU as a tool to collect data and measure outcomes. With this information we initiated change process and acted, resulting in statistically significant reductions in actual and risk adjusted mortality.

More information on PMA is available on our web site at <http://www.pmamed.com>.




**Appendix A for the COPD and Asthma Monitoring Project (CAMP)**  
Page 29


**Appendix A-v:**

**Healthgrades Quality Awards to Hospitals where Pulmonary Medicine Associates directs care in Pulmonary and Critical Services.**

Mercy San Juan Hospital




2016, 2015, 2014  
**America's 100 Best Hospitals for Critical Care Award™**




2016, 2015  
**Pulmonary Care Excellence Award™**

Sutter Roseville Hospital




2016, 2015, 2014  
**America's 100 Best Hospitals for Critical Care Award™**





2016, 2015, 2014  
**Pulmonary Care Excellence Award™**


Sutter Medical Center, Sacramento



Critical Care Excellence Award™  
2012



2015, 2014  
**Pulmonary Care Excellence Award™**



2014  
**Critical Care Excellence Award™**



Appendix A for the COPD and Asthma Monitoring Project (CAMP)

Page 30

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**Daniel Phillip Ikeda, M.D.**

1485 River Park Drive, Sacramento, 95825  
(916) 325-1040, dikeda@pmamed.com

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**Appendix A-VI:**

**CURRICULUM VITAE**

**EXPERIENCE**

Medical Director, 2006 to 2014

*Coronary Intensive Care Unit, Sutter Medical Center*  
Sacramento California

Medical Director, 2002 to 2006

*Electronic ICU, Sutter Health Systems*  
Sacramento California

Chief, Department of Medicine, 1987 to 1989

*Methodist Hospital*  
Sacramento California

**EDUCATION/TRAINING**

**Internship** - University of Hawaii Integrated Medical Residency, July 1978 - June 1979.

**Residency** - University of Hawaii Integrated Medical Residency, July 1979 - June 1981

**Fellowship – Infectious Disease, July 1981 – July 1983**

University of California, Davis Medical School, Davis California

**Instructor – Internal Medicine, July 1983 – June 1984**

University of California, Davis Medical School, Davis California

**Fellowship – Pulmonary Diseases, July 1983 – June 1985**

University of California, Davis Medical School, Davis California

**M.D., 1978**

University of Washington, Seattle Washington

**Bachelors of Science with Honors – Chemistry, 1974**

University of Washington, Seattle Washington

**HONOR AND AWARDS**

Alpha Omega Alpha, University of Washington, 1978

Silver Hammer Award, University of Hawaii, 1979

Resident of the Year Award, University of Hawaii, 1980



**Appendix A for the COPD and Asthma Monitoring Project (CAMP)**

Page 31

**PROFESSIONAL MEMBERSHIPS**

American College of Chest Physicians, Fellow 1989  
 Alpha Omega Alpha, Member  
 California Medical Association, Member  
 American Society of Microbiology, Member  
 Infectious Disease Society of America  
 Outpatient Intravenous Infusion Therapy Association  
     Board of Directors 1987-1991  
 National Health Lawyers Association

**LICENSURE/CERTIFICATION**

American Board of Internal Medicine, 1981  
 Sub-specialty in Infectious Diseases, 1984  
 Sub-specialty in Pulmonary Medicine, 1986  
 Sub-specialty in Critical Care Medicine, 1990

**CLINICAL TRIAL PROJECTS**

Glaxo Wellcome	Chronic Bronchitis	GFX A4003	1998
Glaxo Wellcome	Flu/COPD/Asthma	NAI30006	1999
SmithKline Beecham	Community Acquired Pneumonia		1999
Genentech-Alto	Asthma	Q2195g	2001
Genentech-Alto	Extension Asthma	Q2195g	2001
Glaxo Wellcome	COPD	SM40315	2001
Inspire	Lung Cancer	12-312	2001
Aventis	AECB	HMR3647A/3013	2001
SmithKline Beecham	COPD	SKB 156	2000
Bristol Myers Squibb	Community Acquired Pneumonia	A1464-029	2000
Octave		CV137-120	2001

**PUBLICATIONS**

Ikeda, D.P. and Goldstein, E.: Pleural Effusions and Empyema. Chapter in CURRENT THERAPY IN INFECTIOUS DISEASES, Edited by E. H. Kass and R. Platt, B. C. Decker, publisher, Trenton, New Jersey, 1983:82-83

Ikeda, D.P. and Goldstein, E.: The Third Generation Cephalosporins, Western Journal of Medicine, 138:712-713, May 1983.

Ikeda, D.P., Barry, A.L., and Andersen, S.G.: Emergence of Streptococcus Faecalis Isolates with High-Level Resistance to Multiple Aminocyclitol Aminoglycosides, Diagn Microbiol Infec Dis 1984;2:171-177



**Appendix A for the COPD and Asthma Monitoring Project (CAMP)**

Page 32

**ABSTRACTS**

Ikeda, D.P., Andersen, S.G., and Barry, A.L.: Multiple Resistance to Aminoglycosides Among Streptococcus Faecalis Isolates. Twenty-second Interscience Conference on Antimicrobial Agents and Chemotherapy. October 4-8, 1982, Miami Beach, Florida, Page 23 (Abstract).

Ikeda, D.P., Steffe, E., and Flynn, N.M.: Clinical Epidemiology of an Aminocylitol-Resistant Enterococcus. Twenty-third Interscience Conference on Antimicrobial Agents and Chemotherapy, October 24-26, 1983, Las Vegas, Nevada, Page 230 (Abstract).

Flynn, N.M., Cohen, S.H., Ikeda, D.P., Harrison, J., Bouvier, B.M., Morita, M.M., and Berlin R.D.: Comparative Utility of Six Methods of Nosocomial Infection Detection. Twenty-third Interscience Conference on Antimicrobial Agents and Chemotherapy, October 24-26, 1983, Las Vegas, Nevada, Page 234 (Abstract).

*The impact of a non physician multi-disciplinary team on an open format adult ICU Critical Care Medicine*, December 2005, volume 33, issue 12. Presented as a poster presentation at the national conference in January 2006.

*Impact of a Protocol Treating Severe Sepsis on Renal Function and Survival of Septic Shock Patients in an open adult ICU*. Abstract accepted to the national conference for SCCM as an oral presentation and published in the December 2006 supplement of Critical Care Medicine.

*Implementation of a standard protocol for the Surviving Sepsis 6 and 24 hr Bundles in patients with an APACHE III admission diagnosis of sepsis decreases mortality in an open adult ICU*. Abstract accepted to the national conference for SCCM as an oral presentation and published in December 2006 supplement of Critical Care Medicine.

*The impact of using a standard protocol for the Surviving Sepsis 6 and 24 hr Bundles in septic patients on total ICU risk adjusted mortality*. Abstract accepted to the national conference for SCCM as a poster presentation and published in December 2006 supplement of Critical Care Medicine.

*Impact Of A Surviving Sepsis Protocol Employing A Vasopressor Restrictive Strategy On The Survival Of The Sepsis Subgroups When Compared To Predicted APACHE III Risk Adjusted Outcomes*. Abstract accepted to the national conference for SCCM as a poster presentation and published in the December 2007 supplement of Critical Care Medicine

*Effect Of The Implementation Of A Protocol Utilizing The 6hr and 24hr Bundles On The Survival Of The Sepsis Sub Groups As Defined by APACHE II Scoring*. Abstract accepted to the national conference for SCCM as a poster presentation and published in the December 2007 supplement of Critical Care Medicine.

**PATENT**

Ikeda, D.P.: Unit Dose Preparation System. Patent Issued February 19, 1991, Letters Patent numbered 4,994,056



**Appendix A for the COPD and Asthma Monitoring Project (CAMP)**

Page 33

**Appendix A-VII: :  
Letters of Endorsement**

2013

State of California Department of Health and Human Services  
California Medical Association  
Sierra Sacramento Medical Society  
River City Medical Group

2016

Sutter Independent Physicians Medical Group  
Mercy General Hospital, Sacramento CA  
Mercy San Juan Hospital, Carmichael, CA  
Sutter Medical Center, Sacramento, CA  
Sutter Roseville Hospital, Roseville, CA  
Methodist Hospital, Sacramento, CA



State of California—Health and Human Services Agency  
Department of Health Care Services



EDMUND G. BROWN JR.  
GOVERNOR

August 8, 2013

Office of Acquisition and Grants Management  
Centers for Medicare and Medicaid Services  
Re: The COPD and Asthma Monitoring Project  
**Competition ID:** CMS-1C1-14-001-017996  
**CFDA:** 93.610

Proposal Reviewers:

I am writing to convey my enthusiastic support for "The COPD and Asthma Monitoring Project (CAMP)" that Daniel Ikeda, MD of Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group (PMA) is submitting to the CMS Innovation Challenge Round 2 competition. Should the grant be awarded, we would be very interested in partnering with PMA to test this novel concept of population-based chronic disease management.

In 2008, a Strategic Plan for Asthma in California was published and designed to help state agencies, health care organizations, and members of the community develop work plans for addressing asthma. CAMP provides for a unique management strategy, that if successful, will help us meet our Healthy People 2020 asthma-related objectives.

This concept of an integrated technology approach to the implementation of a quality improvement strategy for the management of asthma and COPD is timely, appropriate and exciting. We believe this concept has great potential to lower the cost of care, improve patient outcomes, reduce hospital admissions and readmissions, and provides a critical transition of care that is sorely lacking in the current health care environment.

Sincerely,

Neal D. Kohatsu, MD, MPH  
Medical Director



**California Medical Association**  
*Physicians dedicated to the health of Californians*

---

August 12, 2013

Office of Acquisition and Grants Management  
Centers for Medicare and Medicaid Services  
Re: The COPD and Asthma Monitoring Project  
**Competition ID:** CMS-1C1-14-001-017996  
**CFDA:** 93.610

To Whom It May Concern:

This letter is to indicate California Medical Association (CMA) support for the proposal submitted by Dr. Daniel Ikeda of Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group. "The COPD and Asthma Monitoring Project (CAMP)" is very worthy of consideration in the CMS Innovation Challenge Round 2 competition.

CMA is a professional organization that represents more than 37,000 California physicians dedicated to the health of all Californians. CMA is active in the legal, legislative, reimbursement and regulatory areas on behalf of California physicians and their patients. We have worked for many years in tandem with the health care community to address issues related to lung health and chronic disease.

CMA strongly supports the goals of CAMP, and believes that the project has the ability to improve asthma and COPD control. Further, it has great potential to reduce the cost of health care.

Sincerely,

A handwritten signature in black ink, appearing to read 'Scott D. Clark', with a horizontal line extending to the right.

Scott D. Clark  
Associate Director, Medical & Regulatory Policy  
California Medical Association



July 30, 2013

Centers of Medicare & Medicaid Services

To Whom It May Concern:

The Sierra Sacramento Valley Medical Society (SSVMS) is pleased to provide this letter of endorsement for Pulmonary Medicine Associates – Sacramento’s grant proposal to CMS’ Health Care Innovation Awards Round Two.

SSVMS represents nearly 3,000 physicians, medical students, residents and fellows in El Dorado, Sacramento, and Yolo counties. In continuous operation since 1860, SSVMS’ mission is to promote the science and art of medicine, protection of public health, and the betterment of the medical profession.

The physician specialists at Pulmonary Medicine Associates (PMA) have been members of our medical society for many years. PMA is a reputable medical group both locally and at the national level. SSVMS has reviewed PMA’s grant proposal, entitled “The COPD and Asthma Monitoring Project,” and we believe it to be a worthy endeavor and encourage CMS to select this project as a Health Care Innovation Award recipient.

Respectfully Yours,

A handwritten signature in black ink that reads 'David Herbert'. The signature is written in a cursive, flowing style.

David Herbert, MD  
President

Cc: Aileen E. Wetzel, Executive Director  
Daniel Ikeda, MD, FCCP  
SSVMS Board of Directors



August 10, 2013

Office of Acquisition and Grants Management  
Centers for Medicare and Medicaid Services

Re: CAMP

**Competition ID:** CMS-1C1-14-001-017996

**CFDA:** 93.610

To Whom It May Concern:

It is my pleasure to write this letter in support of the grant application being submitted by Dr. Daniel Ikeda of Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group to implement COPD and Asthma Monitoring Program (CAMP) – a computerized decision support model designed to leverage the expertise of pulmonary clinicians and to reduce ED visits and hospitalizations related to chronic obstructive airway diseases. It is my belief that the big dollars to be saved in health care are in better managing those with chronic disease.

Pulmonary Medicine Associates (PMA) physicians have served our community for more than 40 years. With more than 30 physicians and non-physician providers, it is the largest group of its kind in California. PMA providers care for some of the most complicated and critically ill patients in the greater Sacramento area, both in the hospital and in the outpatient office setting. Under this grant, PMA providers would be leveraged, delivering daily evidence-based patient care management strategies to people with chronic obstructive airway diseases all over the state. Using an electronic infrastructure in collaboration with patients, they would be able to deliver a level of care not currently available to most patients with respiratory disease.

As the Medical Director for River City Medical Group, a Medi-Cal Managed Care participant, I strongly support the goals of CAMP. I am confident in Dr. Ikeda and PMA's ability to deliver the results they promise; that the project will result in learnings that will be beneficial for improving asthma and COPD control and lives for patients across the country; and that total cost of health care for this population will be reduced.

A handwritten signature in black ink, appearing to read "Jose Abad".

Jose Abad, MD

Medical Director, River City Medical Group



November 3, 2016

Physician-Focused Payment Model Technical Advisory Committee  
C/o U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy  
200 Independence Avenue S.W.  
Washington, D.C. 20201  
PTAC@hhs.gov

Re: The COPD and Asthma Monitoring Project

To Whom It May Concern:

It is my pleasure to write this letter in support of the payment model application being submitted by Dr. Daniel Ikeda of Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group to implement COPD and Asthma Monitoring Program (CAMP) – a computerized decision support model designed to leverage the expertise of pulmonary clinicians and to reduce ED visits and hospitalizations related to chronic obstructive airway diseases.

Pulmonary Medicine Associates (PMA) physicians have served our community for more than 40 years. With more than 30 physicians and non-physician providers, it is the largest group of its kind in California. PMA providers care for some of the most complicated and critically ill patients in the greater Sacramento area, both in the hospital and in the outpatient office setting. Under this proposal, PMA providers would be leveraged, delivering daily evidence-based patient care management strategies to people with chronic obstructive airway diseases all over the state. Using an electronic infrastructure in collaboration with patients, they would be able to deliver a level of care not currently available to most patients with respiratory disease.

My background as an intensivist and infectious disease specialist plus my administrative experience convinces me that earlier interventions in patients with chronic lung diseases has the potential to greatly reduce hospital admissions and expenses in this population, and Dr. Ikeda's program is an innovative way to accomplish this important goal. I support his project and have confidence in Dr. Ikeda's and PMA's ability to deliver the results they promise: that the project will result in new information that will improve asthma and COPD control and result in improved quality of life for patients across the country while also reducing the cost of health care for this population.

Sincerely,



David Herbert, MD  
President and CEO  
Sutter Independent Physicians



**Mercy General  
Hospital.**  
A Dignity Health Member

4001 J Street  
Sacramento, CA 95819  
direct 916.453.4545  
mercygeneral.org

November 16, 2016

Physician-Focused Payment Model Technical Advisory Committee  
C/oU.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy  
200 Independence Avenue S.W.  
Washington, D.C. 20201  
PTAC@hhs.gov

Re: The COPD and Asthma Monitoring Project

To Whom It May Concern:

It is my pleasure to write this letter in support of the payment model application being submitted by Dr. Daniel Ikeda of Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group to implement COPD and Asthma Monitoring Program (CAMP) – a computerized decision support model designed to leverage the expertise of pulmonary clinicians and to reduce ED visits and hospitalizations related to chronic obstructive airway diseases. It is my belief that the big dollars to be saved in health care are in better managing those with chronic disease.

Pulmonary Medicine Associates (PMA) physicians have served our community for more than 40 years. With more than 30 physicians and non-physician providers, it is the largest group of its kind in California. PMA providers care for some of the most complicated and critically ill patients in the greater Sacramento area, both in the hospital and in the outpatient office setting. Under this proposal, PMA providers would be leveraged, delivering daily evidence-based patient care management strategies to people with chronic obstructive airway diseases all over the state. Using an electronic infrastructure in collaboration with patients, they would be able to deliver a level of care not currently available to most patients with respiratory disease.

As president of Mercy General Hospital, a member of Dignity Health, I strongly support the goals of CAMP. I am confident in Dr. Ikeda and PMA's ability to deliver the results they promise; that the project will result in new information that will be beneficial for improving asthma and COPD control and lives for patients across the country; and that total cost of health care for this population will be reduced.

Sincerely,



Edmundo Castañeda  
President



November 18, 2016

Physician-Focused Payment Model Technical Advisory Committee  
C/o U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy  
200 Independence Avenue S.W.  
Washington, D.C. 20201  
PTAC@hhs.gov

Re: The COPD and Asthma Monitoring Project

To Whom It May Concern:

It is my pleasure to write this letter in support of the payment model application being submitted by Dr. Amit Karmakar of Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group to implement COPD and Asthma Monitoring Program (CAMP) – a computerized decision support model designed to leverage the expertise of pulmonary clinicians and to reduce ED visits and hospitalizations related to chronic obstructive airway diseases. It is my belief that the big dollars to be saved in health care are in better managing those with chronic disease.

Pulmonary Medicine Associates (PMA) physicians have served our community for more than 40 years. With more than 30 physicians and non-physician providers, it is the largest group of its kind in California. PMA providers care for some of the most complicated and critically ill patients in the greater Sacramento area, both in the hospital and in the outpatient office setting. Under this proposal, PMA providers would be leveraged, delivering daily evidence-based patient care management strategies to people with chronic obstructive airway diseases all over the state. Using an electronic infrastructure in collaboration with patients, they would be able to deliver a level of care not currently available to most patients with respiratory disease.

As the president and CEO of Dignity Health Mercy San Juan Medical Center, I strongly support the goals of CAMP. I am confident in Dr. Karmakar and PMA's ability to deliver the results they promise; that the project will result in new information that will be beneficial for improving asthma and COPD control and lives for patients across the country; and that total cost of health care for this population will be reduced.

Sincerely,



Brian K. Ivie  
President and CEO

December 5, 2016

Physician-Focused Payment Model Technical Advisory Committee  
C/oU.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy  
200 Independence Avenue S.W.  
Washington, D.C. 20201

Re: The COPD and Asthma Monitoring Project

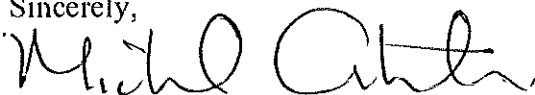
To Whom It May Concern:

It is my pleasure to write this letter in support of the payment model application being submitted by Dr. Daniel Ikeda of Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group to implement the COPD and Asthma Monitoring Program (CAMP) – a computerized decision support model designed to leverage the expertise of pulmonary clinicians and to reduce ED visits and hospitalizations related to chronic obstructive airway diseases. It is my belief that the big dollars to be saved in health care are in better managing those with chronic disease.

Pulmonary Medicine Associates (PMA) physicians have served our community for more than 40 years. With more than 30 physicians and non-physician providers, it is the largest group of its kind in California. PMA providers care for some of the most complicated and critically ill patients in the greater Sacramento area, both in the hospital and in the outpatient office setting. Under this proposal, PMA providers would be leveraged, delivering daily evidence-based patient care management strategies to people with chronic obstructive airway diseases all over the state. Using an electronic infrastructure in collaboration with patients, they would be able to deliver a level of care not currently available to most patients with respiratory disease.

As Chief Medical Executive of Sutter Medical Center, Sacramento, I strongly support the goals of CAMP. I am confident in Dr. Ikeda and PMA's ability to deliver the results they promise; that the project will result in new information that will be beneficial for improving asthma and COPD control and lives for patients across the country; and that total cost of health care for this population will be reduced.

Sincerely,



Michael Abate, MD  
Chief Medical Executive  
Sutter Medical Center, Sacramento  
2801 L St., Suite 700  
Sacramento, CA 95816  
(916) 832-0161

December 1, 2016

Physician-Focused Payment Model Technical Advisory Committee  
C/O U.S. DHHS Asst. Secretary of Planning and Evaluation Office of Health Policy  
200 Independence Avenue S.W.  
Washington, D.C. 20201  
PTAC@hhs.gov

Re: The COPD and Asthma Monitoring Project

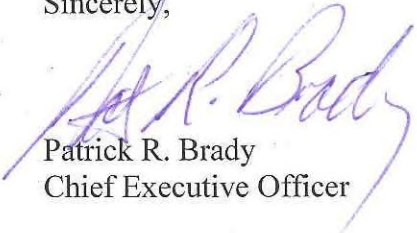
To Whom It May Concern:

It is my pleasure to write this letter in support of the payment model application being submitted by Dr. Daniel Ikeda of Pulmonary Medicine, Infectious Disease and Critical Care Consultants Medical Group to implement COPD and Asthma Monitoring Program (CAMP) – a computerized decision support model designed to leverage the expertise of pulmonary clinicians and to reduce ED visits and hospitalizations related to chronic obstructive airway diseases. It is my belief that the big dollars to be saved in health care are in better managing those with chronic disease.

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I strongly support the goals of CAMP. I am confident in Dr. Ikeda and PMA's ability to deliver the results they promise; that the project will result in new information that will be beneficial for improving asthma and COPD control and lives for patients across the country; and that total cost of health care for this population will be reduced.

Sincerely,

  
Patrick R. Brady  
Chief Executive Officer

Mark W. Lischner, M.D.  
Peter J. Murphy, M.D.  
Alan P. Cubre, M.D.  
G. H. Hayat, M.D.  
Richard DeFelice, M.D.  
Daniel P. Ikeda, M.D.  
Alan R. Yee, M.D.  
W. Randy Martin, M.D.  
Shawn Aghili, M.D.  
Amit Karmakar, M.D.  
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**The COPD and Asthma Monitoring Project (CAMP)  
Appendix B**

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# Medicare Payments: How Much Do Chronic Conditions Matter?

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**Objective:** Analyze differences in Medicare Fee-for-Service utilization (i.e., program payments) by beneficiary characteristics, such as gender, age, and prevalence of chronic conditions.

**Methods:** Using the 2008 and 2010 Chronic Conditions Public Use Files, we conduct a descriptive analysis of enrollment and program payments by gender, age categories, and eleven chronic conditions.

**Results:** We find that the effect of chronic conditions on Medicare payments is dramatic. Average Medicare payments increase significantly with the number of chronic conditions. Finally, we quantify the effect of individual conditions and find that “Stroke / Transient Ischemic Attack” and “Chronic Kidney Disease” are the costliest chronic conditions for Part A, and “Cancer” and “Chronic Kidney Disease” are the costliest for Part B.

**Keywords:** Medicare, Chronic Disease, Gender/Sex Differences in Health and Health Care, Health Care Costs, Health Promotion / Prevention / Screening, Chronic Conditions, Dual-Eligibility, Public Use Files, Medicare Part A, Medicare Part B

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## Introduction

There has been a growing interest in understanding the utilization patterns of patients with chronic conditions (DHHS, 2010). Even though there is a lack of standard definition and identification of a chronic condition (Gorina & Kramarow, 2011), these conditions, such as heart disease, cancer, obesity, and diabetes, are long-lasting and persistent health problems that require continuous care. Recent research has emphasized the disproportionate share of beneficiaries with chronic conditions in healthcare expenditures (Anderson, 2010). For example, patients with multiple chronic conditions can cost up to seven times as much as patients with only one chronic condition (AHRQ, 2006). According to Centers for Disease Control and Prevention (CDC), chronic diseases are responsible for more than 75 percent of the \$2.5 trillion spent annually on health care (CDC, 2009). Examples of efforts to estimate the spending or costs by individual conditions are shown in Exhibit 1.

**Exhibit 1. Summary of Studies on Chronic Conditions**

Chronic Condition	Estimate	Year of Estimate	Organization/Author
Cardiovascular diseases	\$442 billion	2011	American Heart Association/ Heidenreich et al., 2011
Diabetes	\$245 billion	2012	American Diabetes Association, 2011
Lung disease	\$174 billion	2010	National Heart, Lung, and Blood Institute (NHLBI), 2009
Obesity	\$147 billion	2008	Finkelstein, Trogdon, Cohen, & Dietz, 2009
Arthritis/rheumatic cond.	\$128 billion	2003	Yelin et al., 2007
Alzheimer's	\$183 billion	2011	Alzheimer's Association, 2011
All/General	\$2.5 trillion	2005	Centers for Disease Control and Prevention (CDC)

SOURCE: Authors' analysis.

Chronic conditions affect the elderly disproportionately. Lehnert et al. (2011) summarizes the empirical evidence on health care utilization and costs of elderly persons with multiple chronic conditions in the last two decades. The evidence suggests that elders with more chronic conditions had significantly more physician visits, hospital admissions or days/nights spent at a hospital, and more use and/or cost of prescription medications. Studies cited in Lehnert et al. (2011) also suggest that healthcare costs and out-of-pocket payments increase significantly with chronic conditions and that each additional chronic condition almost double healthcare costs.

Medicare is the biggest health insurance program covering the elderly (65 years of age and older) in the U.S.; the prevalence of chronic conditions has been identified as a critical driver of total Medicare spending (Schneider, O'Donnell, & Dean, 2009). Thorpe, Ogden, and Galactionova (2010) argue that much of the recent growth in Medicare spending (1987–2006) is attributable to chronic conditions, such as diabetes, arthritis, hypertension, and kidney disease, and that this represents a shift of spending from inpatient to outpatient services combined with prescription drug use.

This data brief summarizes differences in Medicare Part A and B payments by chronic conditions and estimates the effect of chronic conditions on average Medicare payments by age and gender on both programs. Our analyses take advantage of the newly released 2008 and 2010 Chronic Conditions Public Use Files (PUFs; CMS, 2013). These PUFs are based on claims collected for all Fee-for-Service (FFS) Medicare beneficiaries, thus overcoming some of the limitations in figures available elsewhere, in particular the accuracy due to sampling error, survey design, and/or recollection of past events by interviewees. An equally important goal of this data brief is to describe advantages and limitations of these datasets for analysts who would like to use them for future work.

### **Advantages of CMS Chronic Conditions PUFs**

In this section we describe our data source and highlight its main advantages and disadvantages by comparing it with other sources. The first and most evident advantage is that these PUFs offer a multidimensional view (by all combinations of age categories, gender, Medicaid eligibility, and eleven chronic conditions) of several payment and utilization variables for Medicare beneficiaries by program, previously unavailable to analysts. It is well known that access to Medicare claims data besides these PUFs is restricted to the public due to privacy and confidentiality concerns.

Second, the CMS Chronic Conditions PUF represents 100% of the Medicare beneficiaries provided in the 100% Beneficiary Summary File for each reference year. The 100% Beneficiary Summary File is created annually and contains demographic, entitlement, and enrollment data for beneficiaries who were documented as being alive for some part of the reference year of the Beneficiary Summary File, are entitled to Medicare benefits during the reference year, and enrolled in Medicare Part A and/or Part B for at least one month in the reference year.

Third, the CMS Chronic Conditions PUF provides various measures of utilization as averages for different groups of Medicare beneficiaries, or profiles separated by program and enrollment type. Beneficiaries with 12 months of enrollment in FFS Part A or Part B are separated from beneficiaries with less than 12 months of enrollment. Such figures were not available to the public in a PUF before.

Fourth, chronic conditions included in these PUFs are taken directly from CMS Chronic Condition Data Warehouse Condition Categories, which in turn, are identified using peer reviewed clinical algorithms that look for valid ICD-9/CPT4/HCCPS codes in claims files for chronic-disease-specific reference time periods.

Other PUFs, for instance, the National Health Interview Survey (NHIS) includes over 30 chronic condition indicators, but respondents are asked about their conditions (and information is later processed at NCHS) only if certain limitations (e.g., difficulties walking, eating, bathing, etcetera) are present (CDC, 2011). Similarly, while the CDC's Behavioral Risk Factor Surveillance System (BRFSS) includes questions related to chronic conditions (e.g., "Ever told

you had a stroke?”), these are for a limited number of conditions (e.g., asthma, diabetes, arthritis, cardiovascular disease, diabetes) and are subject to accuracy bias due to self-reporting.

Fifth, the CMS Chronic Conditions PUFs include payments and utilization for each profile. Neither NHIS nor BRFSS include such information. While the Medical Expenditure Panel Survey (MEPS) collects information on expenditures by source of payment (i.e. Private, Medicaid, and Medicare) on a handful of medical conditions, these conditions are self-reported and rely on accurate recollection by respondents (AHRQ, 2011). Another drawback in MEPS is that priority conditions are included in the file only if the condition is current. Even though MEPS collects information directly from providers, such information is not used to supplement or verify reported conditions by respondents.

Although these CMS PUFs contain valuable information on FFS Medicare beneficiaries, they have a few shortcomings. For example, they do not allow for analyzing different types of Medicare enrollees, such as the people with disabilities or End Stage Renal Disease who are also eligible for free Medicare hospital (Part A) insurance (SSA, 2012). Second, the dual-eligibility indicator groups all Medicare beneficiaries who are eligible for any form of Medicaid benefit in any month in 2008/2010, and does not allow for investigation of different types of dual-eligibles (CMS, 2012). Third, the data only contains Medicare payments and does not allow for analysis of other healthcare expenses or payments (e.g., Medicaid costs for dual-eligibles, out-of-pocket expenses). Finally, the data is restricted to a total of eleven chronic conditions. Hence, analyses based on these data might be underestimating the condition of the beneficiaries who may have other conditions that are not included in the data source.

### **The effect of chronic conditions on Medicare payments**

We start by looking at changes between 2008 and 2010 for beneficiaries enrolled in Part A and B (Exhibit 2 and Exhibit 3) for the entire year who were not eligible for Medicaid.<sup>1</sup> We restrict our analyses to this subpopulation of a relatively homogeneous group of beneficiaries for two reasons: (1) by excluding those who were not enrolled for the full year, we control for changes due to deaths and for those just aging into the program; and (2) by excluding those eligible for Medicaid we focus on determinants of cost only for Medicare beneficiaries whose characteristics (e.g., health, socioeconomic status) might differ from dual eligible beneficiaries. Exhibit 2 summarizes enrollment and Medicare spending for Medicare Part A by number of chronic conditions in 2008 and 2010.

The findings in Exhibit 2 can be summarized in the following bullet points:

- Beneficiaries with chronic conditions account for a disproportionate share of program payments for Part A. While 36% of Part A beneficiaries have two or

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<sup>1</sup>Note that these are not two disjoint populations. Most traditional Medicare (Part A) beneficiaries also have Part B coverage (about 90 percent). Medicare beneficiaries who also qualify for Medicaid benefits are known as dual-eligibles.



- more chronic conditions, these beneficiaries account for 86% of total Part A payments in both years.
- Total Medicare payments for Part A benefits increased by 5.2% between 2008 and 2010. 98% of the increase (about \$4.1 billion) was for the care of those with 2 or more chronic conditions.
  - The average Part A payment per beneficiary was higher by a factor of 5.3 in 2008 and 5.4 in 2010 for beneficiaries with exactly one chronic condition compared to beneficiaries without any chronic conditions.
  - Overall, the increase in total payments (5.2%) is explained mainly by the increase in average payment (4.3%), which increases from \$2,945 per enrollee in 2008 to \$3,070 in 2010. The rest of the increase in total Medicare Part A payments is due to the increase in enrollment (0.9%).

Exhibit 3 summarizes enrollment and Medicare spending for Medicare Part B by the number of chronic conditions in 2008 and 2010.

The findings in Exhibit 3 can be summarized in the following bullet points:

- Beneficiaries with chronic conditions account for a disproportionate share of program payments for Part B. However, their share in Part B is lower than their share in Part A. About 41% of Part B beneficiaries have two or more chronic conditions and these beneficiaries account for approximately 70% of total Part B payments in both years.
- Total Medicare payments for Part B benefits increased by 10.7% between 2008 and 2010. 76% of the increase (\$9.2 billion) was for the care of those with 2 or more chronic conditions.
- The average Part B payment per beneficiary was higher by a factor of approximately 2.35 in both years for beneficiaries with exactly one chronic condition compared to beneficiaries without any chronic conditions.
- Overall, the increase in total payments (10.7%) is explained mainly by the increase in average payment (10.3%), which increases from \$3,640 per enrollee in 2008 to \$4,015 in 2010. The rest of the increase in total Medicare Part B payments is due to the increase in enrollment (0.4%). Interestingly, the increase in average Part B payments between 2008 and 2010 is consistently high—in the 8.3% to 9.8% range—even for those without any chronic conditions.

Next, we quantify the effect of each chronic condition *individually* on average Medicare payments.<sup>2</sup> Exhibits 4 (Part A) and 5 (Part B) show these effects by gender and age categories for the same population depicted in Exhibit 2 and Exhibit 3. The values in the tables provide the

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<sup>2</sup>The PUFs are also useful to analyze the effect of multiple chronic conditions, which we do not consider in this study.

ratio of average payment with exactly one chronic condition and average payment without any chronic conditions. For example, having “Alzheimer’s/Senile Dementia” increases the average Medicare payment for Part A by a factor of 7.3 for male enrollees who are in the under 65 age category in 2008.

The findings in Exhibit 4 and Exhibit 5 can be summarized in the following bullet points:

- Exhibit 4 shows that “Stroke / Transient Ischemic Attack” is the costliest chronic condition for Part A payments for every combination of gender and age category both in 2008 and 2010, except for a few gender and age category combinations where “Chronic Kidney Disease” has a larger factor. For example, male enrollees in the 65–69 age category with “Stroke/Transient Ischemic Attack” had average Part A payments 21.5 times higher in 2008 and 24 times higher in 2010 than enrollees without this chronic condition. Average Part A payments for enrollees with “Stroke/Transient Ischemic Attack” were about 12 times higher than enrollees without this chronic condition in 2008 and 12.8 times for 2010.
- The chronic condition with the lowest factor for Part A payments, on average, is “Diabetes” with a range of 1.6–3.3 in 2008 and 1.6–3.2 in 2010 (depending on the gender and age category combination). Also, “Cancer” and “Osteoporosis” were two other chronic conditions with relatively smaller effects on average Medicare Part A payments in both years.
- The factors were higher for males compared to females in the same age category for most chronic conditions (except for a few age categories with “Alzheimer’s Disease” and “Cancer” and one age category with “Congestive Heart Failure”) in 2008. The findings were similar in 2010.
- The effect of each chronic condition in both years is considerably lower for average Part B payments (Exhibit 5) compared to Part A payments. “Cancer” is the costliest condition in both years, with factors of 4.9 for males and 5.5 for females in 2008, and 4.7 and 5.3 in 2010, respectively. Similar to the finding in the analysis of Part A payments, “Chronic Kidney Disease” ranks second in both years. The factors for this condition for beneficiaries under 65 years of age were significantly higher than other age categories: 13.7 and 9.8 in 2008 for males and females, respectively, and 12.0 and 8.3 in 2010.
- Note that average Part B payments for enrollees with “Cancer” are approximately 3–9 times higher than enrollees without any chronic conditions in both years. Also, “Alzheimer’s,” “Diabetes,” and “Osteoporosis” turn out to be the chronic conditions with the smallest effect on average Medicare Part A payments in both years.

**Exhibit 2. Changes in Enrollment, Total Payments and Average Payment per Enrollee for Medicare Part A full year beneficiaries by number of chronic conditions**

Number of Chronic Conditions	Number of Enrollees Part A				Total Payment Part A (Millions)				Average Payment per beneficiary		
	2008	2010	Difference	% Change	2008	2010	Difference	% Change	2008	2010	% Change
0	10,138,926	10,245,731	106,805	1.1%	\$2,511	2,512	1	0.0%	\$248	\$245	-1.0%
1	6,663,517	6,609,818	(53,699)	-0.8%	\$8,754	8,833	79	0.9%	\$1,314	\$1,336	1.7%
2	4,583,587	4,605,347	21,760	0.5%	\$13,740	13,936	196	1.4%	\$2,998	\$3,026	0.9%
3	2,632,736	2,680,459	47,723	1.8%	\$15,714	16,203	489	3.1%	\$5,969	\$6,045	1.3%
4	1,399,364	1,445,912	46,548	3.3%	\$15,097	15,890	792	5.2%	\$10,789	\$10,989	1.9%
5	649,251	686,250	36,999	5.7%	\$11,391	12,292	901	7.9%	\$17,545	\$17,912	2.1%
6	251,404	276,226	24,822	9.9%	\$6,575	7,418	843	12.8%	\$26,153	\$26,854	2.7%
7	80,674	91,023	10,349	12.8%	\$2,924	3,442	518	17.7%	\$36,243	\$37,813	4.3%
8	19,532	23,089	3,557	18.2%	\$913	1,114	200	21.9%	\$46,766	\$48,243	3.2%
9	2,991	3,910	919	30.7%	\$168	226	58	34.9%	\$56,014	\$57,806	3.2%
10	225	269	44	19.6%	\$15	18	3	19.8%	\$68,333	\$68,495	0.2%
<b>Total</b>	<b>26,422,207</b>	<b>26,668,034</b>	<b>245,827</b>	<b>0.9%</b>	<b>\$77,803</b>	<b>\$81,884</b>	<b>\$4,081</b>	<b>5.2%</b>	<b>\$2,945</b>	<b>\$3,070</b>	<b>4.3%</b>

NOTE. Excludes 384 profiles that do not have information on all chronic conditions.

SOURCE: Chronic Conditions Public Use Files, 2008 and 2010

**Exhibit 3. Changes in Enrollment, Total Payments and Average Payment per Enrollee for Medicare Part B full year beneficiaries by number of chronic conditions**

Number of Chronic Conditions	Number of Enrollees Part B				Total Payment Part B (Millions)				Average Payment per beneficiary		
	2008	2010	Difference	% Change	2008	2010	Difference	% Change	2008	2010	% Change
0	7,497,739	7,468,750	(28,989)	-0.4%	\$8,665	9,455	790	9.1%	\$1,156	\$1,266	9.5%
1	6,498,765	6,434,014	(64,751)	-1.0%	\$17,690	19,108	1,419	8.0%	\$2,722	\$2,970	9.1%
2	4,514,823	4,529,488	14,665	0.3%	\$19,222	20,975	1,753	9.1%	\$4,258	\$4,631	8.8%
3	2,606,318	2,651,090	44,772	1.7%	\$15,972	17,643	1,671	10.5%	\$6,128	\$6,655	8.6%
4	1,389,361	1,434,539	45,178	3.3%	\$11,770	13,181	1,411	12.0%	\$8,472	\$9,189	8.5%
5	646,544	682,883	36,339	5.6%	\$7,095	8,131	1,035	14.6%	\$10,974	\$11,906	8.5%
6	250,820	275,493	24,673	9.8%	\$3,410	4,058	648	19.0%	\$13,597	\$14,730	8.3%
7	80,613	90,968	10,355	12.8%	\$1,313	1,617	304	23.2%	\$16,283	\$17,771	9.1%
8	19,543	23,093	3,550	18.2%	\$366	475	109	29.7%	\$18,729	\$20,557	9.8%
9	2,996	3,944	948	31.6%	\$62	88	27	42.9%	\$20,638	\$22,404	8.6%
10	225	269	44	19.6%	\$5	7	2	37.5%	\$22,367	\$25,717	15.0%
<b>Total</b>	<b>23,507,747</b>	<b>23,594,531</b>	<b>86,784</b>	<b>0.4%</b>	<b>\$85,571</b>	<b>\$94,739</b>	<b>\$9,168</b>	<b>10.7%</b>	<b>\$3,640</b>	<b>\$4,015</b>	<b>10.3%</b>

NOTE. Excludes 384 profiles that do not have information on all chronic conditions.

SOURCE: Chronic Conditions Public Use Files, 2008 and 2010

**Exhibit 4. Effect of Chronic Conditions on Average Medicare Part A Payment per Enrollee for FY Enrollee Non Dual Eligibles**

			ALZ	CANCER	CHF	CHRKID	COPD	DEPR	DIAB	ISCHE	OSTEO	RA/OA	STRK
2008	All Male		9.1	5.2	7.5	11.7	8.7	7.8	2.4	5.9	4.7	7.9	15.2
	Male	Under 65	7.3	8.6	6.9	14.4	10.2	7.6	3.3	5.4	6.9	5.0	13.1
		65-69	9.7	9.1	9.9	16.2	10.9	7.8	2.8	8.4	5.1	11.4	21.5
		70-74	7.5	5.4	7.2	10.8	8.6	6.8	2.2	6.4	3.9	8.9	15.8
		75-79	6.7	3.9	6.0	9.0	7.3	6.1	2.1	5.3	3.5	7.5	12.8
		80-84	6.7	3.2	5.2	6.9	6.4	5.2	1.8	4.2	3.4	5.9	11.1
		85 & Older	7.4	3.4	5.9	7.1	6.6	6.2	2.1	3.6	4.7	4.9	11.1
	All Female		10.1	5.8	7.3	9.1	6.7	5.2	2.0	4.8	2.5	6.4	12.8
	Female	Under 65	8.3	6.5	7.7	14.0	7.9	6.0	3.0	4.8	3.7	4.4	10.0
		65-69	8.8	7.3	9.5	12.9	8.4	5.7	2.5	6.3	2.3	9.1	18.0
		70-74	6.6	6.0	7.1	8.9	6.6	4.7	2.0	5.1	2.1	7.3	13.1
		75-79	7.1	5.3	5.7	7.0	5.9	4.3	1.8	4.5	2.1	6.4	11.4
		80-84	6.8	4.7	5.2	5.8	5.6	4.1	1.6	3.8	2.3	5.1	10.0
		85 & Older	7.7	5.0	5.2	5.6	5.6	4.3	1.7	3.2	2.9	3.8	9.3
2010	All Male		10.0	5.1	8.0	12.1	9.0	8.0	2.4	5.4	4.6	8.7	16.5
	Male	Under 65	9.0	7.7	7.2	14.7	10.3	7.6	3.2	5.0	6.7	5.1	12.2
		65-69	11.6	8.5	11.3	17.2	11.6	8.7	2.8	7.8	5.3	12.8	24.0
		70-74	8.7	5.4	7.6	11.7	8.8	6.6	2.2	5.8	4.0	9.9	18.0
		75-79	7.3	3.7	6.5	8.5	7.4	6.6	1.9	4.9	3.4	8.4	13.9
		80-84	6.9	3.2	5.9	7.2	6.2	5.6	1.9	3.8	3.3	6.4	12.0
		85 & Older	8.0	3.2	5.7	7.5	6.8	5.7	2.1	3.4	4.3	4.8	11.7
	All Female		11.4	5.5	7.9	8.8	6.7	5.3	2.0	4.6	2.5	7.1	13.4
	Female	Under 65	8.6	6.7	7.3	14.2	8.2	6.2	2.8	5.0	3.4	4.7	10.4
		65-69	9.7	7.1	10.1	13.2	8.2	5.8	2.6	5.9	2.5	10.4	18.2
		70-74	7.6	5.5	7.1	8.3	6.8	4.9	1.9	4.6	2.1	8.1	13.9
		75-79	7.5	5.0	6.4	6.8	5.7	4.4	1.8	4.2	2.2	7.1	11.7
		80-84	7.3	4.4	5.4	5.4	5.5	4.0	1.6	3.5	2.3	5.5	10.3
		85 & Older	8.5	4.6	5.6	5.1	5.3	4.1	1.6	3.1	2.8	3.8	9.4

NOTE. Excludes 384 profiles that do not have information on all chronic conditions. ALZ: Alzheimer's Disease and Related Disorders or Senile Dementia; CANCER: Cancer; CHF: Chronic Heart Failure; CHRKID: Chronic Kidney Disease; COPD: Chronic Obstructive Pulmonary Disease; DEPR: Depression; DIAB: Diabetes; ISCHE: Ischemic Heart Disease; OSTEO: Osteoporosis; RA/OA: Rheumatoid Arthritis/Osteoarthritis Arthritis; STRK: Stroke / Transient Ischemic Attack

SOURCE: Chronic Conditions Public Use Files, 2008 and 2010

**Exhibit 5. Effect of Chronic Conditions on Average Medicare Part B Payment per Enrollee for FY Enrollees**

			ALZ	CANCER	CHF	CHRKID	COPD	DEPR	DIAB	ISCHE	OSTEO	RA/OA	STRK
2008	All Male		2.1	4.9	2.6	4.9	2.9	2.5	1.8	2.5	2.7	2.7	3.1
	Male	Under 65	2.6	8.9	3.2	13.7	3.7	3.0	2.6	2.7	5.0	3.4	3.4
		65-69	2.3	6.1	2.8	4.5	3.1	2.8	1.9	2.6	2.8	3.0	3.5
		70-74	1.9	4.8	2.4	3.5	2.7	2.5	1.7	2.3	2.4	2.5	2.9
		75-79	1.8	4.1	2.3	3.1	2.6	2.4	1.6	2.2	2.2	2.3	2.6
		80-84	1.6	3.4	2.1	3.0	2.5	2.2	1.6	2.1	2.2	2.2	2.6
		85 & Older	1.7	3.1	2.1	2.8	2.6	2.4	1.7	2.1	2.3	2.2	2.6
		All Female		1.5	5.5	2.2	3.7	2.5	2.1	1.6	2.2	1.7	2.3
	Female	Under 65	2.3	9.4	3.3	9.8	2.8	2.4	2.0	2.4	2.7	2.8	2.9
		65-69	1.8	6.7	2.5	3.9	2.6	2.2	1.7	2.3	1.7	2.6	3.0
		70-74	1.5	5.6	2.3	3.1	2.4	2.0	1.6	2.1	1.6	2.3	2.6
		75-79	1.4	4.7	2.1	2.7	2.3	1.9	1.5	2.0	1.5	2.1	2.4
		80-84	1.3	4.1	1.9	2.5	2.3	1.9	1.5	1.9	1.6	1.9	2.4
		85 & Older	1.5	3.7	2.0	2.5	2.6	2.2	1.6	2.0	1.8	2.1	2.5
2010		All Male		2.1	4.7	2.7	4.4	2.8	2.5	1.8	2.5	2.8	2.8
	Male	Under 65	2.5	8.1	3.4	12.0	3.5	3.1	2.6	2.7	4.8	3.5	3.4
		65-69	2.4	6.0	3.0	4.4	3.0	2.9	2.0	2.7	3.1	3.2	3.7
		70-74	1.9	4.4	2.5	3.3	2.6	2.4	1.6	2.3	2.3	2.5	2.9
		75-79	1.7	3.8	2.4	2.9	2.4	2.3	1.6	2.2	2.2	2.3	2.6
		80-84	1.6	3.2	2.2	2.8	2.3	2.3	1.6	2.1	2.2	2.2	2.5
		85 & Older	1.7	2.9	2.1	2.7	2.4	2.4	1.7	2.1	2.2	2.2	2.5
		All Female		1.5	5.3	2.3	3.2	2.4	2.1	1.6	2.1	1.7	2.3
	Female	Under 65	2.3	8.5	3.5	8.3	2.7	2.4	1.9	2.4	2.8	2.8	3.0
		65-69	1.8	6.7	2.7	3.5	2.5	2.2	1.7	2.3	1.7	2.7	3.1
		70-74	1.5	5.2	2.2	2.8	2.3	2.0	1.5	2.1	1.6	2.2	2.7
		75-79	1.3	4.5	2.1	2.5	2.2	1.9	1.5	2.0	1.5	2.1	2.4
		80-84	1.3	3.8	1.9	2.2	2.1	1.8	1.4	1.9	1.6	1.9	2.3
		85 & Older	1.4	3.5	2.0	2.3	2.4	2.1	1.6	1.9	1.8	2.1	2.4

NOTE. Excludes 384 profiles that do not have information on all chronic conditions. ALZ: Alzheimer's Disease and Related Disorders or Senile Dementia; CANCER: Cancer; CHF: Chronic Heart Failure; CHRKID: Chronic Kidney Disease; COPD: Chronic Obstructive Pulmonary Disease; DEPR: Depression; DIAB: Diabetes; ISCHE: Ischemic Heart Disease; OSTEO: Osteoporosis; RA/OA: Rheumatoid Arthritis/Osteoarthritis Arthritis; STRK: Stroke / Transient Ischemic Attack

SOURCE: Chronic Conditions Public Use Files, 2008 and 2010

## Conclusion

The influence of chronic conditions on healthcare costs has been widely discussed in the literature. In this brief, we provided detailed analysis of changes in Medicare Part A and B payments, enrollment, and average payment per beneficiary stratifying the data by prevalence of chronic conditions. In addition, we estimated the effect of each chronic condition on average Medicare Part A and B payments, individually controlling for age and gender. Our analyses were restricted to beneficiaries who were enrolled for the entire year and who were not eligible for Medicaid.

To conclude, we show that people with chronic conditions account for a disproportionate share of program payments for both Part A and B in both years. Likewise, we show that average payments increase significantly with the number of chronic conditions. For example, the existence of one chronic condition increased average Part A payments by a factor of 5.3 and 5.4 in 2008 and 2010, respectively. We also show that the number of chronic conditions has a larger effect on average payments for Part A than on Part B for both years. Furthermore, our results show that the overall increase in both Medicare Part A and Part B payments is due to rising average payments rather than growth in enrollment.

Lastly, we show that (1) “Stroke / Transient Ischemic Attack” and “Chronic Kidney Disease” are the costliest chronic conditions for Part A program payments in both years; (2) “Cancer” and “Chronic Kidney Disease” are the costliest chronic conditions for Part B program payments in both years; (3) the effect of each chronic condition on average payments is lower for Part B than for Part A in both years; and (4) the effect of a chronic condition on the average Part A and Part B payments is generally larger for male beneficiaries compared to female beneficiaries.

The impact of chronic conditions in the growth of health care costs has been widely recognized. This study does not offer a solution to the problem, but it quantifies how much each of the eleven chronic conditions (available in our source data) increase average Medicare payments. It draws attention to conditions that have the largest effect on costs in Medicare Part A and Part B (e.g., Stroke / Transient Ischemic Attack, Chronic Kidney Disease, Depression), which may be targeted by policy makers. These findings can help policymakers prioritize the efforts to reduce health care costs by focusing on the health conditions that matter the most.

**Disclaimers**

The views expressed in this article are those of the authors and do not necessarily reflect the views of the U.S. Department of Health and Human Services, the Centers for Medicare & Medicaid Services, or IMPAQ International.

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# SCIENTIFIC REPORTS



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## Effectiveness of Telemonitoring in Patients with Chronic Obstructive Pulmonary Disease in Taiwan-A Randomized Controlled Trial

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Chronic obstructive pulmonary disease (COPD) is the leading cause of death worldwide, and poses a substantial economic and social burden. Telemonitoring has been proposed as a solution to this growing problem, but its impact on patient outcome is equivocal. This randomized controlled trial aimed to investigate effectiveness of telemonitoring in improving COPD patient outcome. In total, 106 subjects were randomly assigned to the telemonitoring (n = 53) or usual care (n = 53) group. During the two months following discharge, telemonitoring group patients had to report their symptoms daily using an electronic diary. The primary outcome measure was time to first re-admission for COPD exacerbation within six months of discharge. During the follow-up period, time to first re-admission for COPD exacerbation was significantly increased in the telemonitoring group than in the usual care group (p = 0.026). Telemonitoring was also associated with a reduced number of all-cause re-admissions (0.23 vs. 0.68/patient; p = 0.002) and emergency room visits (0.36 vs. 0.91/patient; p = 0.006). In conclusion, telemonitoring intervention was associated with improved outcomes among COPD patients admitted for exacerbation in a country characterized by a small territory and high accessibility to medical services. The findings are encouraging and add further support to implementation of telemonitoring as part of COPD care.

Chronic obstructive pulmonary disease (COPD) is a leading cause of morbidity and mortality worldwide, and its prevalence and burden of COPD are projected to increase over the next decades<sup>1</sup>. In Taiwan, COPD ranks seventh among the common causes of death in 2010 and is estimated to cost approximately four billion New Taiwan dollars each year<sup>2</sup>. Despite advancements in pharmacologic therapy, patients with COPD often have debilitating symptoms that limit normal daily activities and impair quality of life<sup>3</sup>. Exacerbation of COPD, especially when hospitalization is required, is a major problem because of the negative effect on quality of life, prognosis, and medical costs<sup>4</sup>. There is an urgent need to reduce this burden, which has prompted the development of new COPD management strategies<sup>5</sup>.

Telehealth has shown promise in the management of chronic disease<sup>6–8</sup>. For patients with COPD, implementation of telehealth reduced re-admission, emergency room (ER) visits and disease exacerbation, and was shown to be cost-effective<sup>9</sup>. Telehealth, as a method of delivering healthcare to remote, resource-deprived areas, is not lacking in terms of evidence of benefit<sup>10</sup>; however, the value of its widespread use for monitoring purposes is much less clear. To date, most of the studies dealing with telemonitoring of patients with COPD have been performed

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Item	Scoring
Weight	Score 1 if weight gain $\geq 1$ kg in one day Score 2 if weight gain $\geq 2$ kg in three days
SpO <sub>2</sub>	Score 1 if $< 92\%$ Score 2 if $< 90\%$
Temperature	Score 1 if $\geq 37.5^\circ\text{C}$ Score 2 if $\geq 38^\circ\text{C}$
Heart rate	Score 1 if $> 100$ beats/min Score 2 if $> 120$ beats/min
Blood pressure	Score 1 if systolic pressure $> 160$ or $< 100$ mmHg Score 2 if systolic pressure $> 180$ or $< 90$ mmHg
Breathlessness	Score 1 if daily increase in mMRC Dyspnea Scale of 1 grade Score 2 if daily increase in mMRC Dyspnea Scale of $\geq 2$ grade
Sputum quantity	Score 1 if increase in frequency of expectoration of $\geq 50\%$
Sputum character	Score 1 if purulent
<b>Algorithm</b>	<b>If the sum of the scores is <math>\geq 2</math>, an alert will be issued.</b>

**Table 1. Electronic diary scoring.** SpO<sub>2</sub>, measurement of oxygen saturation via pulse oximeter; mMRC, Modified Medical Research Council.

in large countries<sup>11</sup>. Therefore, it should be investigated whether telemonitoring conveys similar advantages for patients with COPD in a small country.

The primary aim of the present study was to evaluate the effectiveness of a telemonitoring program to reduce COPD-related re-admission in Taiwan.

## Methods

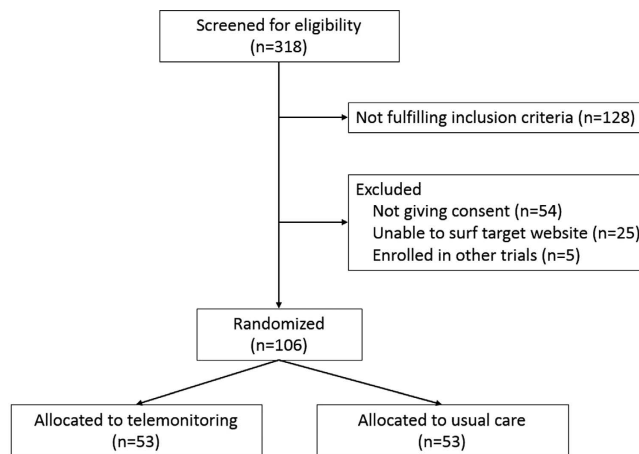
**Study setting.** This randomized controlled trial was conducted in the National Taiwan University Hospital, a tertiary-care referral center in Northern Taiwan, and participants were recruited between December 2011 and July 2013. Taiwan, an island of East Asia in the western Pacific Ocean with a total land area of about 36,000 square kilometers, established a universal National Health Insurance (NHI) program in 1995, and, by 2011, 99.9% of the 23 million individuals had been enrolled in the program<sup>12</sup>. This study was approved by the Research Ethics Committee of the National Taiwan University Hospital (201106097RB) and registered in the ClinicalTrials.gov (NCT01724684) in January 2012. Written informed consent was obtained from all study participants and all procedures were performed in accordance with relevant guidelines and regulations.

**Participants.** All patients aged 20 years or older and admitted to the multidisciplinary combined care wards with a diagnosis of COPD were screened for eligibility. The wards accommodated patients primarily referred from the emergency service. Inclusion criteria included COPD exacerbation as the main diagnosis, current or former smokers, spirometry-confirmed airflow limitation (a value of forced expiratory volume in one second divided by forced vital capacity less than 0.7<sup>1</sup>), discharge to home, and accessibility to the internet and phone. Patients were excluded if they did not provide consent, were unable to access the study website, or had been enrolled in other trials.

**Study protocol.** Patients were randomized to either the telemonitoring group or the usual care group using a computer-generated randomization scheme. Throughout the study, patients in both groups continued to receive usual care from their primary care physicians. For all study patients, a dedicated phone line was available for medical counseling provided by study nurses from 8 am to 8 pm on a daily basis.

A pulse oximeter, thermometer and sphygmomanometer were available for the telemonitoring group patients, and they were trained in the use of the equipment and an online diary by the study nurses prior to hospital discharge. The patients were instructed to report their symptoms using the electronic diary on the website each day for two months after discharge. The diary consisted of eight questions involving disease-related symptoms, vital signs and weight, and took about two min to complete. The submitted data were processed according to the pre-defined algorithm (Table 1), which was established by the study team in a round table conference. The indicators chosen and the scores assigned to each criterion were determined taking into account COPD symptomatology and common physiological responses to illness and by consensus. Once a warning was generated, the study nurses and attending pulmonologists received a notification to respond to the situation. The study pulmonologist would assess the patient's data in light of the patient history, with the option of contacting and evaluating the patient by phone as clinically indicated. Based on the best clinical judgment, the patient could be referred to the clinic or ER.

**Data collection.** Patient characteristics (age, gender, smoking status and pack-years of smoking, and body mass index), medical records (comorbidities, COPD medications and exacerbation history, and spirometry data) and outcomes were retrieved by a registered nurse blinded to the patient grouping. The comorbidities of interest included diabetes mellitus, hypertension, coronary artery disease and heart failure<sup>1</sup>. Major COPD medications were categorized as short-acting  $\beta_2$  agonists, long-acting  $\beta_2$  agonists, long-acting anticholinergics and inhaled corticosteroids. Data on COPD exacerbation were accessed in the previous year prior to enrollment of subjects, and hospitalization and ER visits due to exacerbation were documented.



**Figure 1. Study flow diagram.**

**Outcome measures.** The primary aim of the intervention was to reduce the frequency of re-admission. Accordingly, the primary outcome measure was the time to first hospital re-admission with a primary diagnosis of COPD exacerbation. Exacerbation was considered the primary diagnosis if the presenting symptoms were consistent with and the patients were treated for COPD exacerbation, and no other disease was managed as a priority. The secondary end points included (1) the time to first ER visit for COPD exacerbation, (2) the number of all-cause hospital re-admissions, and (3) the number of all-cause ER visits. All patients were followed up for six months after discharge and the endpoints were assessed at the end of the study period.

**Sample size estimation.** It was assumed that the probability of re-admission was 50% for the usual care group at six months following hospital discharge, and the hazard ratio (HR) was 0.5 for the telemonitoring group<sup>13,14</sup>. To detect a statistically significant difference at the 0.05 level with a power of 0.8, it was calculated that a total of 116 patients should be included for randomization.

**Statistical analysis.** Continuous variables were presented as means with standard deviations and categorical variables as frequencies with associated percentages. For intergroup comparisons, the independent sample t test and Fisher's exact test were used for continuous and categorical variables, respectively. The Kaplan–Meier curves were plotted for time to first re-admission or ER visit due to COPD exacerbation, and the log-rank test was applied to test differences between two groups. Cox proportional hazard regression analysis was used to determine the effects of telemonitoring intervention on risks of re-admission and ER visit due to COPD exacerbation, as shown by an HR with 95% confidence interval (CI). All statistical analyses were two-sided and a p value of <0.05 was deemed statistically significant. The SPSS software (Version 15.0, SPSS Inc., Chicago, IL) was used for all data analyses.

## Results

**Patients.** During the study period, 318 hospitalized patients with a diagnosis of COPD were screened for eligibility (Fig. 1). A total of 106 patients were randomly assigned, 53 each to the telemonitoring and usual care groups. No participant withdrew consent during the course of the trial. The mean age of the study population was  $80.2 \pm 8.8$  years at the time of enrollment and 76% of patients were men. About one-third of the patients were classified as having severe-to-very severe COPD according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) classification<sup>1</sup>. Demographics, pack-years of smoking, presence of comorbidities and disease severity markers were similar in both groups (Table 2).

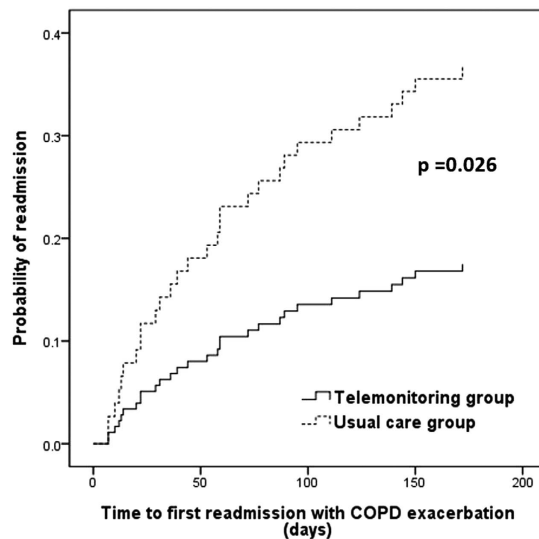
**Time to first COPD-related re-admission and ER visit.** As shown in Fig. 2, the time to first re-admission for COPD exacerbation was increased in the telemonitoring group as compared with the usual care group ( $p = 0.026$  by log-rank test). At six months, the probability of COPD-related re-admission was significantly lower in the telemonitoring group (HR = 0.42; 95% CI = 0.19–0.92). In addition, telemonitoring intervention was associated with increased time to first COPD-related ER visit (Fig. 3), with an HR of 0.50 (95% CI = 0.24–1.04) over the six months of follow-up.

**Re-admission and ER visit.** Telemonitoring intervention was associated with a significant reduction in the number of all-cause re-admissions from 0.68 to 0.23 per patient ( $p = 0.002$ ) over a period of six months (Table 3). Similarly, patients in the telemonitoring intervention group had fewer ER visits for all causes than those in the usual care group (0.36 vs. 0.91 per patient;  $p = 0.006$ ). Moreover, the telemonitoring group patients tended to have fewer episodes of COPD-related re-admissions (0.19 vs. 0.49;  $p = 0.11$ ) or ER visits (0.23 vs. 0.55;  $p = 0.16$ ) per capita than did usual care group patients.

**Medical counseling and responses to alerts.** Twenty-one (40%) patients in the telemonitoring group made a total of 57 phone calls to the study team. Of those, 15 calls (five COPD related) were made to report new

	Telemonitoring (n = 53)	Usual care (n = 53)	p value
Age, years	81.4 ± 7.8	79.0 ± 9.6	0.165
Male sex	43 (81)	38 (72)	0.253
Smoking, pack-years	58 ± 43	47 ± 31	0.143
Body mass index, kg/m <sup>2</sup>	20.2 ± 4.3	20.2 ± 4.1	0.930
Comorbidities			
Coronary artery disease	12 (23)	9 (17)	0.465
Heart failure	14 (26)	13 (25)	0.824
Hypertension	28 (53)	33 (62)	0.326
Diabetes mellitus	11 (21)	10 (19)	0.807
Exacerbation history in the previous year			
Admission	16 (30)	19 (36)	0.536
Emergency room visit	19 (36)	17 (32)	0.682
Spirometry			
FEV <sub>1</sub> (%)	62 ± 23	62 ± 21	0.996
FEV <sub>1</sub> /FVC	0.53 ± 0.11	0.55 ± 0.09	0.314
GOLD classification of airflow limitation			
Mild/moderate	35 (66)	34 (64)	0.839
Severe/very severe	18 (34)	19 (36)	
Medications prior to admission			
Short-acting β <sub>2</sub> agonist	47 (89)	45 (85)	0.566
Long-acting β <sub>2</sub> agonist	32 (60)	35 (66)	0.546
Long-acting anticholinergic	36 (68)	34 (64)	0.682
Inhaled corticosteroid	33 (62)	37 (70)	0.412

**Table 2. Baseline characteristics of the study population.** Data were presented as mean ± standard deviation or number (%) as appropriate. FEV<sub>1</sub>, forced expiratory volume in 1 second; FVC, forced vital capacity; GOLD, Global Initiative for Chronic Obstructive Lung Disease.

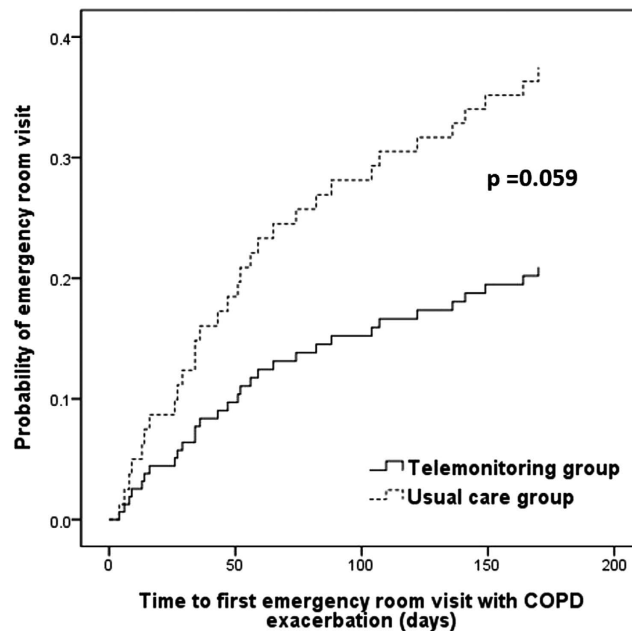


**Figure 2. Kaplan-Meier curves showing the probability of readmission with COPD exacerbation.** COPD, chronic obstructive pulmonary disease.

or altered symptoms. Ten patients (four COPD related) were referred to the ER; subsequently, four (two COPD related) of these were re-admitted. In the usual care group, 68 phone calls were made by 23 (43%) patients. Among these, 18 calls (five COPD related) were associated with new or altered symptoms, and 12 patients (four COPD related) required an ER visit. After initial assessment and management, seven patients (three COPD related) were later re-admitted. Between the two study groups, there were no significant differences in the number of patients making phone calls (21 vs. 23;  $p = 0.693$ ) or the average number of calls per patient (1.1 vs. 1.3;  $p = 0.578$ ).

A total of 192 alerts from 40 patients in the telemonitoring group were issued, 109 (57%) of which were judged to require a phone consultation from the study team. After the contacts, six alerts necessitated an ER referral and





**Figure 3.** Kaplan-Meier curves showing the probability of emergency room visit with COPD exacerbation. COPD, chronic obstructive pulmonary disease.

	Telemonitoring (n = 53)	Usual care (n = 53)	p value
Hospital readmission			
COPD exacerbation			
Total No. of episodes	10 (0–2)	26 (0–3)	
Episodes per patient	0.19 ± 0.44	0.49 ± 0.72	0.11
All causes			
Total No. of episodes	12 (0–2)	36 (0–3)	
Episodes per patient	0.23 ± 0.47	0.68 ± 0.94	0.002
Emergency room visit			
COPD exacerbation			
Total No. of episodes	12 (0–2)	29 (0–3)	
Episodes per patient	0.23 ± 0.47	0.55 ± 0.82	0.16
All causes			
Total No. of episodes	19 (0–2)	48 (0–7)	
Episodes per patient	0.36 ± 0.56	0.91 ± 1.29	0.006

**Table 3.** Outcome measures at six months after discharge. Data were presented as mean ± standard deviation or number (range). COPD, chronic obstructive pulmonary disease.

another six needed a referral to the clinic for further assessment. The remaining alerts were dealt with by health education, providing advice or guidance, observation, or reassurance. The remaining 83 (43%) alerts were considered innocent in that they were present while the patients were recovering from a worse situation.

Throughout the study period, there were no reports of serious adverse events related to the study procedures.

## Discussion

Among a set of patients discharged after hospitalization for COPD exacerbation, our results showed that telemonitoring intervention significantly postponed the time to first re-admission for exacerbation of COPD during a six-month follow-up. The telemonitoring group patients also, on average, had significantly fewer all-cause re-admissions or ER visits than the usual care group patients. In addition, a favorable effect of telemonitoring intervention on time to first ER visit for COPD exacerbation and on average number of re-admissions or ER visits due to exacerbation of COPD was observed. The main implication of this study was that in a country with a small territory and high accessibility to medical services, telemonitoring intervention remained associated with improved outcomes among patients discharged from hospital after COPD exacerbation.

Patients hospitalized for COPD exacerbation are at higher risk of re-admission in the following year<sup>15</sup>; thus, an important goal in patient care is to reduce these adverse events. A number of modalities, such as risk factor

identification and intervention, self-management educational programs, and predischARGE care bundles, have been utilized to achieve such a goal, but with diverse results<sup>16–18</sup>. The past decade has seen the growing use of telehealth as a possible approach to dealing with the increasing population with chronic diseases. In certain studies, telemonitoring has been shown to be beneficial in terms of exacerbation frequency, quality of life, ER visits, hospitalization and death among patients with COPD<sup>19,20</sup>. However, the diversity with regard to study populations, technology employed and components of the telehealth services has been high across the studies. Undoubtedly, there is an urgent need for further investigations to clarify the specific role of telemonitoring in the management of patients with COPD. The distinguishing features of the present study included the fact that it was conducted in a small, isolated island country, the study subjects were enrolled during admission for COPD exacerbation, and they were provided with easily accessible and affordable healthcare under the Taiwan NHI program. Therefore, our findings add to the existing knowledge by showing the effectiveness of telemonitoring intervention in terms of improving COPD patient outcomes in this specific setting.

Telehealth is a complex intervention and may include a variety of components, such as education, counseling, emotional support, remote monitoring and assisted planning<sup>19</sup>. Accordingly, when telehealth intervention is beneficial for the patients, it is difficult to pinpoint its active component. In this study, patients in both groups were provided with medical counseling via a phone call given that it was not only part of our routine practice but might help ease the patients' anxiety and feeling of unsafety when they were randomly assigned to the usual care group. In this way, the only difference between the two study groups was the remote monitoring and response to changing signs and symptoms of patients with COPD. Early recognition and treatment of COPD exacerbations improves recovery, reduces risk of admission, and is associated with better quality of life<sup>21</sup>. Telemonitoring enables that early recognition and access to more timely treatment, thereby improving patient outcomes.

A key factor affecting the effectiveness of telemonitoring in COPD is the items monitored and corresponding algorithm. Prior studies have shown that there is a paucity of reliable early predictors of COPD exacerbation<sup>22</sup>. The parameters that we chose to monitor in this study were easily available and associated with COPD symptomatology, and the algorithm was determined somewhat empirically. Although no severe adverse events related to the study design were reported, a significant proportion of alerts were judged meaningless, with no action being required. Certainly, establishing ideal items for monitoring and algorithms with satisfactory sensitivity and specificity is a priority in the development of remote monitoring for COPD in telehealth. In this regard, combining advanced technologies for data processing and analysis with regularly updated clinical guidelines for COPD management is crucial<sup>23</sup>. Our design herein, at least a safe one, necessitates refinement in future work.

Although a recent review concludes that telemonitoring appears to have a positive effect in reducing COPD exacerbation and hospitalization, there are still few studies in this field and reported data are inconsistent in terms of methodology and conclusions<sup>24</sup>. Moreover, the largest trial to date demonstrated that telemonitoring had no significant clinical benefits but posed a substantial impact on workload for healthcare providers<sup>25</sup>. This trial, along with others using telemonitoring<sup>26,27</sup>, suggested that integration of this technology into existing best or comprehensive usual care does not improve COPD outcomes. Nonetheless, some may argue that the so-called best or comprehensive usual care is hardly a real-world practice and is probably not practical with respect to the large and growing COPD population. It remains to be determined what the best model of healthcare for COPD patients is in the coming studies<sup>28</sup>.

A number of limitations pertaining to this study should be mentioned. First, our sample size of this study did not allow for a subgroup analysis to define the most appropriate population for telemonitoring intervention, an important issue that is worth exploring in further studies. However, the sample size estimation was based on the primary outcome measure, and the predetermined significance level has been achieved in this study, except for the fact that the study included 106 patients as opposed to 116. Second, cost-effectiveness was not assessed in this study, because the study team was engaged in both study work and clinical service, and it was difficult to accurately calculate the direct and indirect personnel expense. In this regard, we are planning on an economic study to answer this question. Third, it was not possible to blind the study subjects and study personnel to treatment allocation given the interactive nature of the intervention. However, the outcome assessor was blinded to group allocation.

In summary, telemonitoring used to care for patients discharged for COPD exacerbation improves outcomes in terms of time to COPD-related re-admission, and average number of all-cause re-admissions and ER visits in the six-month follow-up. The findings are encouraging and promising, and add further support to the concept that telemonitoring is worth implementation as part of COPD care. Nevertheless, the favorable experience needs to be replicated in a large population under healthcare settings similar to those of Taiwan prior to widespread application of this modality.

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## Author Contributions

T.W.H. contributed to the study design, data interpretation and analysis, and drafting and approval of the manuscript. H.C.C., S.Y.R., Y.J.T., C.J.Y. and F.L. contributed to the study design, data collection and analysis, and approval of the manuscript. The HINT Study Group Consortia contributed to the study design, data collection and approval of the manuscript. C.T.H. had full access to all of the data in the study, took responsibility for the integrity of the data and the accuracy of the data analysis, critically reviewed and revised the manuscript, and approved the submission of the manuscript.

## Additional Information

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# A home telehealth program for patients with severe COPD: The PROMETE study



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## KEYWORDS

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## Summary

**Background:** Acute exacerbations of chronic obstructive pulmonary disease (AECOPD) are key events in the natural history of the disease. Patients with more AECOPD have worse prognosis. There is a need of innovative models of care for patients with severe COPD and frequent AECOPD, and Telehealth (TH) is part of these programs.

**Methods:** In a cluster assignment, controlled trial study design, we recruited 60 patients, 30 in home telehealth (HT) and 30 in conventional care (CC). All participants had a prior diagnosis of COPD with a post-bronchodilator forced expiratory volume (FEV<sub>1</sub>)% predicted <50%, age ≥50 years, were on long-term home oxygen therapy, and non-smokers. Patients in the HT group measured their vital signs on a daily bases, and data were transmitted automatically to a Clinical Monitoring Center for followed-up, and who escalated clinical alerts to a Pneumologist.

**Results:** After 7-month of monitoring and follow-up, there was a significant reduction in ER visits (20 in HT vs. 57 in CC), hospitalizations (12 vs. 33), length of hospital stay in (105 vs. 276 days), and even need for non-invasive mechanical ventilation (0 vs. 8), all  $p < 0.05$ . Time to the first severe AECOPD increased from 77 days in CC to 141 days in HT (K-M  $p < 0.05$ ).

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There was no study withdrawals associated with technology. All patients showed a high level of satisfaction with the HT program.

*Conclusions:* We conclude that HT in elderly, severe COPD patients with multiple comorbidities is safe and efficacious in reducing healthcare resources utilization.

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### Abbreviations list

#### AECOPD

acute exacerbations of chronic obstructive pulmonary disease

CAT COPD Assessment Test

COPD chronic obstructive pulmonary disease

CC conventional care

ER emergency room

FEV<sub>1</sub> forced expiratory volume in the first second

HT home telehealth

HULP Hospital Universitario La Princesa

ICS inhaled cortico-steroids

IPC informal primary carer

LABA long-acting beta-adrenergic agonists

LAMA long-acting muscarinic antagonist

NIV non-invasive ventilation

PEF Peak expiratory flow

PDE4i phosphodiesterase 4 inhibitor

PCC primary care center

PROMETE Madrilian Telehealth PROject for COPD

SD standard deviation

SGRQ Saint George Respiratory Questionnaire

TH Telehealth

CMC Clinical Monitoring Center

## Introduction

Chronic obstructive pulmonary disease (COPD) is a leading but under-recognized cause of morbidity and mortality worldwide. No other disease that is responsible for comparable burden worldwide is neglected by healthcare providers as much as COPD [1,2]. COPD is projected to move from the currently fourth to third position in terms of morbidity by 2020 [3,4]. A key aspect in the natural history of the disease are episodes of acute exacerbations (AECOPD). AECOPD are more frequent in patients with larger airflow obstruction and a history of more episodes in the previous year [5]. Moreover patients who suffer the highest numbers of AECOPD are considered to have a faster disease progression, presence of comorbidities, and worse functional prognosis [6].

Research is therefore needed on innovative models of care for patients with severe COPD and frequent AECOPD, in order to detect and manage the occurrence of exacerbations of AECOPD at an early stage, and hence reduce their negative effect on the disease progression. The importance of these programs has been highlighted in the National Strategy for COPD of the Spanish National Health System [7]. Telehealth (TH) is part of these programs, as it allows patients to be monitored in their home, gathering useful information that can be used for an early intervention should an AECOPD occur [8].

Current evidence shows that Home Telehealth (HT) programs can reduce the number and length of stay in hospital admissions and emergency visits [9]. And Sicotte et al. demonstrated that TH increases empowerment and

patient's satisfaction, specially in the older and more severe patients [10].

Although TH programs have been developed for COPD patients, none has been specifically geared to people who experience severe airflow obstruction, multiple comorbidities, and limitations in daily life. We hypothesized that HT can be a useful strategy for monitoring these patients at the home in a follow-up program that coordinates Primary and Secondary Care services.

The purpose of our study (the PROMETE study, "Madrilian Telehealth PROject for COPD) was to assess the efficacy and effectiveness of a home telehealth program for COPD patients with severe airflow obstruction by measuring the number of emergency room visits, hospitalizations, length of hospital stay, and mortality.

## Material and methods

### Study population

We conducted an open-label, controlled, non-blind clinical trial, coordinated at the Pneumology Service of the Hospital Universitario La Princesa (HULP) with the Primary Care Centres (PCC) in its area of influence.

Initially we randomized the PCC customers that belonged to HULP into two groups: HT or Conventional Care (CC). Patients were randomized following a two-color code. All PCC customers were assigned to one or another color using an envelope system dividing into two groups by chance. According to PCC membership patients were

**Table 1** Sociodemographic and clinical characteristics of participants, by randomization to conventional care (CC) or telemedicine (TM).

Parameters		CC (n = 30)	TM (n = 29)	p-Value
Male, n (%)		22 (73.3)	22 (75.9)	1.00
Age (years), mean ± SD		72.7 ± 9.3	75.0 ± 9.7	0.357
Education level, n (%)	Illiterate	1 (3.3)	1 (3.4)	0.998
	Primary	10 (33.3)	10 (34.5)	
	Secondary	10 (33.3)	10 (34.5)	
	University	9 (30.0)	8 (27.6)	
Employment status, n (%)	Active	2 (6.7)	1 (3.4)	0.443
	Retired	25 (83.3)	23 (79.3)	
	Disabled/unable	3 (10.0)	5 (17.2)	
With caretaker, n (%)		19 (63.3%)	18 (62.1%)	1.00
Dyspnea mMRC, n (%)	II	8 (26.7)	3 (10.3)	0.183
	III	17 (56.7)	17 (58.6)	
	IV	5 (16.7)	9 (31.0)	
COPD hospitalizations in the last year, mean ± SD		1.9 ± 1.4	1.7 ± 1.0	0.663
COPD hospitalizations in the last year, n (%)	1 or none	16 (55.2)	16 (53.3)	0.548
	2 or more	13 (44.8)	14 (46.7)	
Mobility, n (%)	Bed-armchair	3 (10)	0 (0.0)	0.201
	Within home	8 (26.7)	10 (4.5)	
	Leaves home	19 (63.3)	19 (65.5)	
Home status, n (%)	Alone	5 (16.7)	4 (13.8)	0.836
	With partner	18 (60.0)	19 (65.5)	
	With other relatives	6 (20.0)	4 (13.8)	
	With caretaker	1 (3.3)	2 (6.9)	
Barthel, mean ± SD		84.5 ± 15.1	89.3 ± 13.7	0.239
Charlson, mean ± SD		3.4 ± 2.1	3.7 ± 1.4	0.555
Drugs per day, mean ± SD		8.3 ± 2.8	8.3 ± 3.7	0.980
Respiratory medications, n	LAMA + LABA + ICCI	23	26	0.95
	PDE4 inhibitors	6	2	0.103
	Mucolythics	12	11	1.000
	Theophyllines	3	2	1.000
	Oral steroids	4	1	0.353
Lung function, mean ± SD	FEV <sub>1</sub> post-BD	37.1 ± 10.8	38.3 ± 11.9	0.525
	BODEX	5.7 ± 1.2	5.2 ± 1.0	0.125
	Home oxygen, hours/day	20.2 ± 4.7	18.6 ± 3.8	0.198
	Home oxygen flow in L/minute	2.06 ± 0.5	2.04 ± 0.4	0.851
Quality of life and other assessments	CAT	21.2 ± 6.6	18.2 ± 7.3	0.771
	euroQOL	4.50 ± 1.8	5.10 ± 2.2	0.396
	Goldberg anxiety	3.0 ± 2.4	3.70 ± 2.9	0.203
	Goldberg depression	3.5 ± 2.7	3.80 ± 2.9	0.468
Parameters measured by home <sup>a</sup> telehealth, mean ± SD	Blood pressure (systolic/diastolic; mmHg)	123 ± 14.1/ 69 ± 12.4	130 ± 13/ 80 ± 12.1	0.52
	Pulsioximetry (%)	92 ± 3.1	94 ± 1.6	0.17
	Heart rate (beat per minute, bpm)	80 ± 14.8	76 ± 15.2	0.71
	Peak-flow (litre/second)		132 ± 57.5	

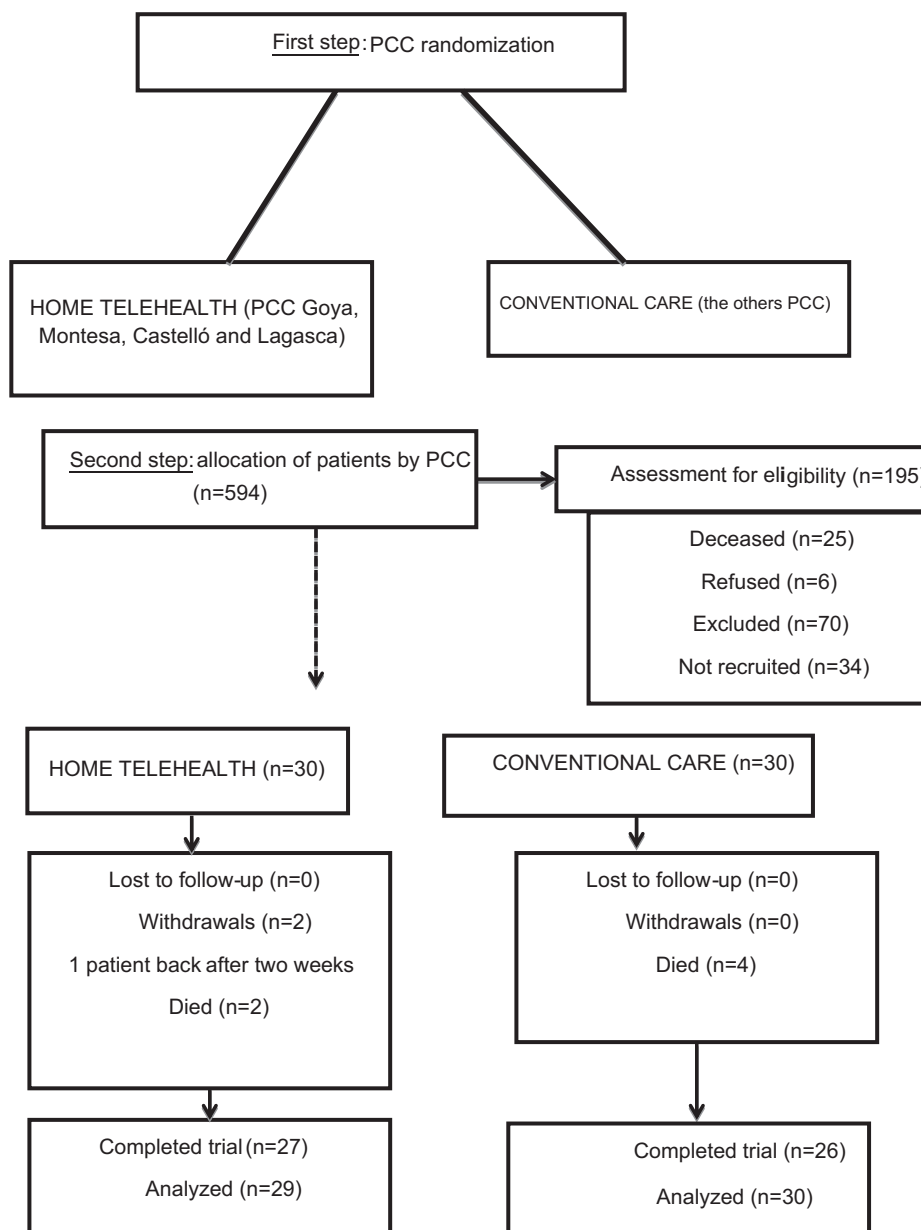
LAMA: Long action muscarinic antagonist; LABA: long action beta-adrenergics agonist; ICCI: inhaled cortico-steroids; PDE4 inhibitor: phosphodiesterasa 4 inhibitor.

<sup>a</sup> These parameters were collected in the first clinical visit at home in the CC group and by telemonitoring (first day) in the TM group.

assigned to each study group (group allocation). Patients referred from the Goya, Montesa, Lagasca and Castello PCC were assigned to HT, and the rest were cluster assignment to the CC group. We performed group treatment allocation by center, one case to one control. All PCC customers shared the same geographic localization (District of Salamanca in Madrid), population characteristic, cultural and

economic levels (Table 1), and hence it is fair to state that all determinants were equally balanced by study group.

In addition, all patients were followed up at the pneumology clinic in our hospital, which also unifies the criteria for monitoring and treatment of respiratory disease. Whenever patients from either group came to the emergency room (ER), they were evaluated by the Pneumologist in charge,



**Figure 1** CONSORT flow chart of trial participation.

ergo maintaining a similar approach in the assessment of ERs and deciding whether the patient should be admitted or discharged, independently of their group assignment.

Eligible patients were identified if they had been admitted to any of the following units in our hospital: Pneumology, Internal Medicine and Infectious Diseases services, with a clinical diagnosis of "COPD exacerbation" during the period from January 1, 2010 to July 31, 2011. We identified a total of 594 patients in the HULP database system (Fig. 1).

Consecutively we selected patients who met the following inclusion criteria: 1) prior diagnosis of COPD according to GOLD criteria [11]; 2) severe or very severe obstruction to airflow (post-bronchodilator forced expiratory volume (FEV<sub>1</sub>)/forced vital capacity (FVC) < 0.70 and FEV<sub>1</sub> %predicted < 50%); 3) age older than or equal to 50

years; 4) on long-term home oxygen therapy; 5) no current smoker, at least for the past 6 months, determined by measuring carboxyhemoglobin levels in arterial blood gas  $\leq 2\%$ . Patients were excluded if: 1) did not meet at least one of the above criteria; 2) were enrolled in a palliative care program for lung or another disease; 3) were institutionalized or at risk of social exclusion; 4) were deemed unable to understand all procedures.

Both study groups continued with their scheduled medical visits during the entire study period within the standard universal, free healthcare for all of the Spanish public system, and therefore we did not change the regular office visits and home calls either by the Pneumologist or the Primary Care doctors.

Patients in the control group had no intervention apart from this standard, conventional care, and no other pro-



active interventions during the entire study. All information during the study was collected by visit at the patient's home except for the satisfaction questionnaire that was obtained through telephone calls in a blinded fashion in both groups.

The study was approved by the Ethics Committee of the HULP, and the study number was 1819. All patients signed an informed consent form prior to inclusion.

## Study procedures

The PROMETE telehealth program was based on the daily follow-up of patients with severe COPD at the home by monitoring the following parameters: blood pressure, oxygen saturation and heart rate on a daily basis, and peak expiratory flow (PEF) three times a week.

Other TH programs have used similar parameters to monitor the patients as: pulseoximetry, blood pressure, temperature, PEF and spirometry [12–14].

We chose to use PEF according to Jódar-Sánchez et al. as PEF as it showed more acceptable to being carried out by the patient [15], and since van de Berge et al. [16] have linked the fall of percentage of peak-flow with the risk of COPD exacerbations.

Measurements were made once a day in the morning, and given the following set of conditions: 20 min after medication had been taken, at rest and while on oxygen therapy. The patients took their measurements on a daily bases (Monday through Sunday). Monday through Friday the data were monitored and assessed by the Clinical Monitoring Center (CMC) from 9:00 to 17:00. And during weekends, the data were directly analyzed by a Pneumologist.

During the recruitment period all patients who were presumed to satisfy the inclusion criteria were consecutively contacted by telephone, until there were 30 patients in each group. The purpose of the study was explained to them, and if they agreed to participate an appointment was made for a home visit with the Pneumologist.

At the first clinical visit the informed consent form was signed, and data were collected including: gender, age, level of education, household composition, limitations of activities of daily living, presence or absence of carer, medication, relevant medical history (Charlson index) [17], basic physical examination, quality of life questionnaires (generic like SF-12, and EuroQol, and disease-specific like SGRQ, and COPD Assessment Test, CAT) [18–20], the Barthel Index [21], and finally the Goldberg questionnaire for anxiety and depression [22].

Throughout the duration of the study we collected the number of ER visits, hospitalizations, length of hospital stay, need for non-invasive ventilation (NIV), and need for admission to ICU for both groups.

## Patient monitoring and follow-up

On the first day of the HT programme, monitoring devices were delivered and installed at the patient's home by nursing staff. Patients were trained in their operation and it was verified that they were able to take all measurements properly. Written information was as well given on how to handle/use the monitoring devices, and how to correctly

transmit the measurements. A contact phone number from the CMC was left to the patients for any technical problems.

The parameters were collected using the following devices: a spirometer, a pulse-oximeter and heart rate monitor (Spirotel<sup>®</sup>, MIR), and blood pressure monitor (A&D, model UA-767 BT). Each day after taking these measurements, data were sent automatically via a modem (Tele-Modem<sup>™</sup>, Aerotel Medical Systems) over the patients' telephone lines. Further details can be found in the [online supplement](#).

Patients entered the study in a stable situation, being exacerbation-free for at least 15 days. Entry into the study of patients in the exacerbation phase was postponed until it was over.

The information was received, monitored, assessed and followed-up by the CMC through an application that acted as a traffic light system:

- Green: meant that measurements had been taken and were within the predefined limits, and no further action was required.
- Yellow: "technical alert". This means that the measurements had not been taken or had not been received. This alert could lead to a "clinical alert" due to a lack of adherence or discouragement. When the parameters were not received the nurse at the CMC called the patient to find the reason behind the alert, and either ruled out medical causes or, if one, notified the Pneumologist leading the study.
- Red: "clinical alert". Meant that a measurement exceeded the limits that were previously pre-established for each patient (further details can be found in the [online supplement](#)).

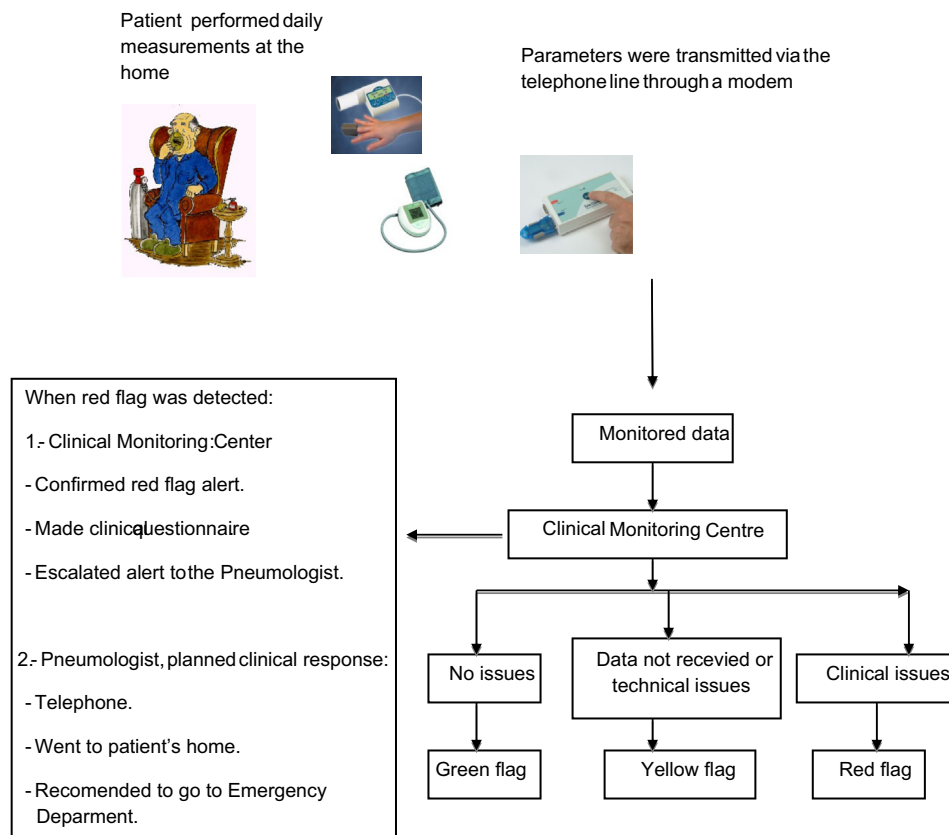
After verification of a Red Flag -Clinical Alert by the CMC, a protocolized escalation and clinical response procedure commenced.

## Clinical support

Clinical support occurs as a result of the coordination between the CMC, the Pneumology specialist and the Primary Care physician.

Whenever a Red Flag (clinical alert) was triggered the nurse at the CMC contacted the patient to verify the alert (further details can be found in the [online supplement](#)). When a Red Flag was confirmed, the nurse escalated the clinical alert to the Pneumologist who then classified the exacerbation as moderate, severe or very severe. For moderate exacerbations, advice to start medical treatment was given over the telephone; in severe cases, visits were made to the patient's home, and in the very severe cases the patient was advised to come to the emergency room department (Figs. 2 and 3).

As we worked in coordination with each Primary Care Center, the head of the PCC was alerted when a Red Flag was detected and, in accordance with our protocol, patients with moderate exacerbations who did not improve with the prescribed treatment were referred to their corresponding PCC for further follow-up.



**Figure 2** Telemonitoring protocol and Clinical Monitoring Center follow-up.

## Exacerbation

In our study COPD exacerbation was defined as: “an acute event” characterized by a worsening of patient’s respiratory symptoms (increased dyspnea, expectoration, purulent sputum, or any combination of these three symptoms) that is beyond normal day-to-day variations and leads to change in medication [11].

## Control group

The control group received Conventional Care. There was a first clinical visit at the home during which baseline data were collected for the study and quality of life questionnaires were completed, and also a visit at the end. Data relating to clinical activity were obtained from the HULP information system and through monthly telephone calls to the patients.

For these patients we collected data related to blood pressure, pulse oximetry and heart rate in the first clinical visit at home. The baseline of these parameters at the beginning of the study compared with the HT group is show in Table 1.

## Statistical analysis

For the descriptive analysis we used mean, range, and standard deviation for quantitative variables, while qualitative variables were expressed in terms of frequencies and

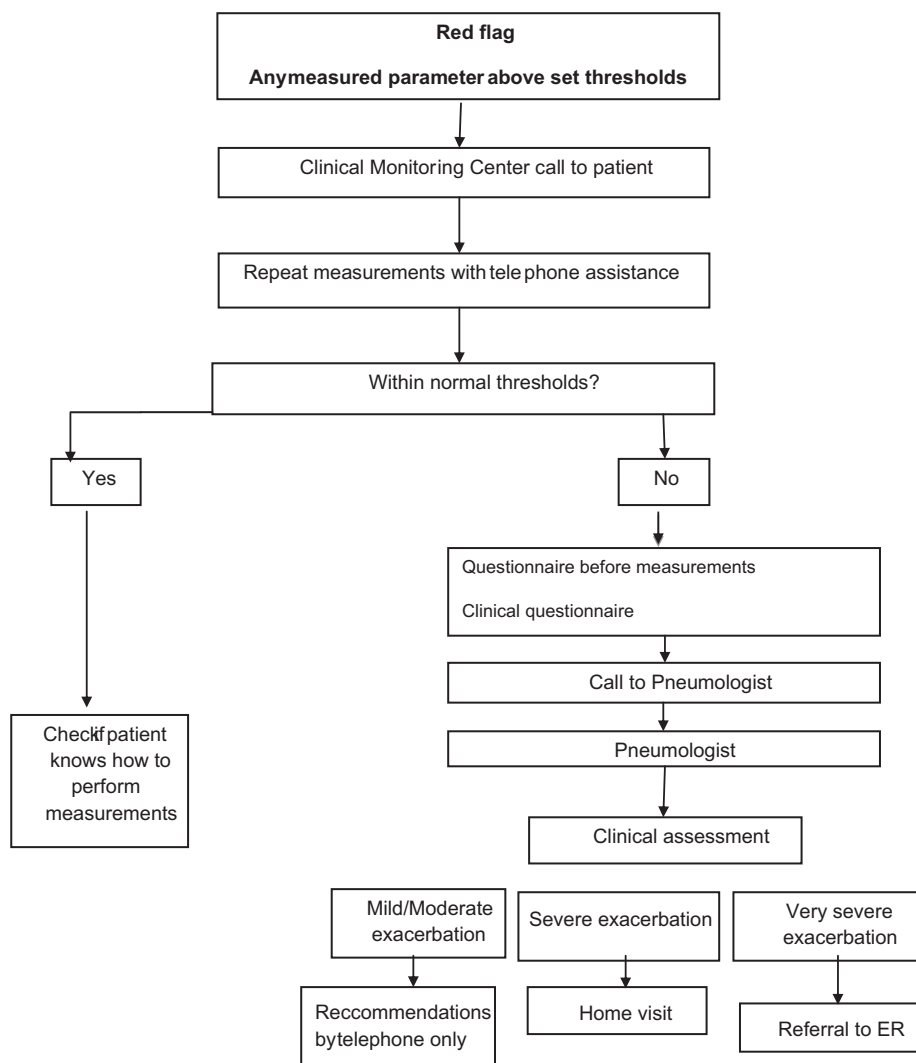
percentages. To measure the relationship between independent quantitative variables Student’s *t*-test was used, and for qualitative variables the Chi<sup>2</sup> test was used. The relationship between two qualitative variables and relative risk was obtained through use of contingency tables. Clinical follow-up and monitoring of both groups was measured using Kaplan–Meier curves to indicate the time to the first contact with the hospital (emergency room visit or hospitalization) analysis. Statistical significance was considered at  $p < 0.05$ .

Given the nature of this pilot study, no formal sample size was estimated a priori. For convenience and availability, we piloted 30 patients per group, which is reasonable number of patients with severe COPD and multiple comorbidities considered to be a representative sample. The study duration was based upon covering the peak months of maximum stability and number of exacerbations (December to February) followed by another period of stability until May. A posteriori, given the differences obtained in all primary and secondary outcomes, they should be considered not only statistically significant but also clinically relevant.

## Results

A total of 594 patients were considered for recruitment. Of these, 195 initially met our inclusion criteria and made up the pool of candidates who were contacted and invited to participate in the study until 60 patients. The 60





**Figure 3** Step-by-step process after identification of a “Red flag”, classification of a COPD exacerbation and response.

participants were recruited and assigned to the two groups: 30 patients to the CC group and 30 patients to the HT group (Fig. 1).

Their socio-demographic and clinical characteristics are shown in Table 1. The mean age was 73.8 years (standard deviation  $\pm 9.5$ ) and 44 patients (74.6%) were men. 62.7% of patients reported having an informal primary carer (IPC); in 60.5% of the cases this was the spouse, followed by the patients’ children (15.7%).

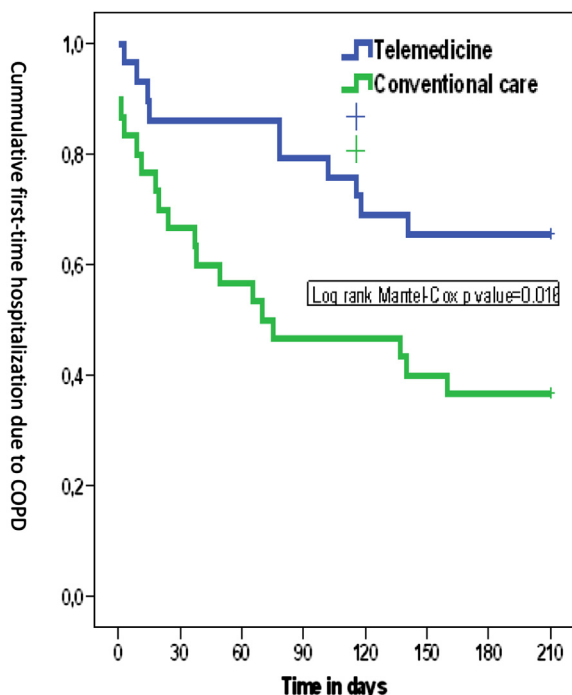
The mean Charlson index score was 3.5 (SD  $\pm 1.9$ ) and the average number of drugs taken by the patients per day was 8.3 (SD  $\pm 2.5$ ). Regarding specific treatments for COPD, the most commonly used bronchodilators were a combination of an inhaled corticosteroid and a long-acting beta-adrenergic agonist together with a long-acting muscarinic receptors antagonist (Table 1).

All patients in the study could be classified into group D as defined by the revised 2011 GOLD classification (patients at high risk and with many comorbidities); mean post-bronchodilator FEV<sub>1</sub> was 39.1%, mean BODE index was 5.5, and CAT questionnaire was 19.3 (moderate impact on stable disease). All patients were long-term home oxygen therapy

users, although seven of them used it erratically. At the study onset, the mean number of days of clinical stability per year (defined as days with no COPD exacerbation) was 166 days, and the mean number of hospitalizations was 1.8 per exacerbation in the previous year.

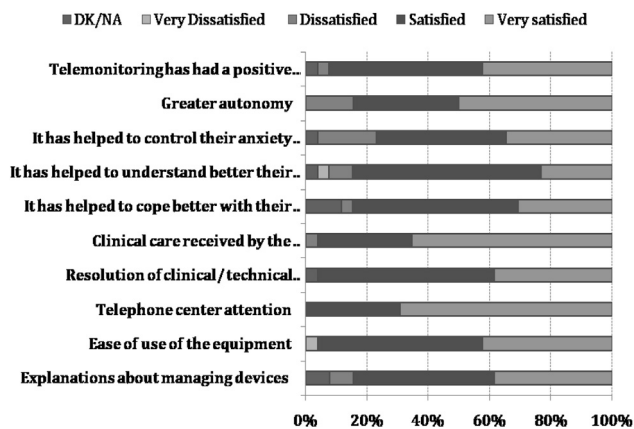
During the 7-months study period, we observed decrease in the number of emergency room visits in the HT group (20 visits) vs. the CC group (57 visits) ( $p = 0.001$ ); number of hospitalizations: HT 12 hospitalizations vs. CC 33 hospitalizations ( $p = 0.015$ ); length of hospital stay: HT 105 days vs. CC 276 days ( $p = 0.018$ ) and need for NIV: HT 0 patients vs. CC 8 patients ( $p < 0.0001$ ). We also found that the average number of days to first exacerbation requiring hospitalization was 77.28 days in the CC group and 141.07 days in the HT group ( $p = 0.003$ ) (Fig. 4). Four patients in the CC group died (3 of causes related to COPD and 1 secondary to a retroperitoneal hematoma) vs. two patients in the HT group (1 of causes related to COPD and another secondary to an intestinal obstruction).

We identified a total of 50 Red Flags (clinical alerts), from which following our classification system: 39 (78%) were classified as moderate, 8 (16%) as severe, and 3 (6%) as



**Figure 4** K–M survival curves of time to the first ER visit/observation/hospitalization, by group.

very severe. Clinical interventions were conducted primarily over the telephone (in 37 occasions) or in the patient's home (in 8 occasions). The main parameters that triggered Red Flags were oxygen saturation (in 30 occasions), followed by peak-flow (in 7 occasions). In 7% (4 occasions) of raised "red flag" were due to blood pressure alteration, though in our study blood pressure had a low predictive capacity to a COPD exacerbation. Importantly, in 12 cases a Red Flag was not raised although the patient had a COPD exacerbation. In the majority of these cases the exacerbation occurred out of office hours or during weekends (5 cases), the parameters received were correct (3 cases), the patient went to the emergency room department without being previously monitored and advised (4 cases).



**Figure 5** Patient satisfaction with the Home Telehealth program at the end of trial.

Overall, 78% of AECOPD in the HT group were classified as of a milder severity. In the CC we did not attend the patient's home or perform any other planned intervention, and for this reason we are unable to establish the severity of the AECOPD in this group.

We did not observe any withdrawals as a result of difficulties in using the devices and the technology, although in one case the data received were those of the carer and not from the patient. The overall patient satisfaction rate was high (median of telemonitoring time was 72.5%), with the HT programme being awarded a score of 9 out of 10 (Fig. 5). The average of telemonitoring days was 152,2 days (72.5% of the total study time). We defined adherence as the percentage of the total days the patient used the devices to monitor parameters during the study period. To improve the adherence each patient was provided with a user manual for each device and a "trial run" was performed to ensure the patient understood the proper functioning of the system. Additionally the CMC nurse called the patients who did not take their measurements on a daily bases.

## Discussion

The PROMETE study is a novel and innovative home telehealth program that improved the care of severe COPD patients. It is the first study conducted in this population and demonstrated an improvement in many clinical outcomes.

The study combines telehealth resources with conventional care and early interventions after a detection of an AECOPD to improve the care of patients with severe COPD. The main results of this trial revealed a significant reduction in emergency room visits, hospitalizations and length of hospital stay of COPD patients enrolled in HT, with equivalent safety and high acceptance for patients receiving CC.

Our study population was made by COPD patients with severe airflow obstruction (mean FEV<sub>1</sub> 38.9%), on long-term home oxygen therapy, with multiple comorbidities (Charlson index score of 3.57), limitations in activities of daily living (Barthel index 89.3 and 64% in need of a carer), using multiple medications (average of 8.30 drugs per day) and 46.7% of the HT group reported hospitalizations due to AECOPD in the previous year. Using HT for daily monitoring and follow-up allowed us to detect and treat exacerbations in their early stages. Overall, 78% of AECOPD were classified as moderate and interventions were conducted mainly over the telephone (74%), or as home visits (5%). We focused on care at the patient's home, initiating treatment for AECOPD from the home in 80% of the cases. We demonstrated that HT allows detecting early changes in measurable parameters and therefore identify an AECOPD prematurely. In fact, we detected more milder exacerbations with HT since we were able to monitor daily changes in the patient's condition.

In December 2011 the UK Department of Health published the results of the "Whole System Demonstrator" (WSD) program, a randomized clinical trial which involved 6191 patients, 3030 of whom had chronic diseases such as COPD, diabetes mellitus or heart failure, across 3 distant geographic areas [23]. Health parameters (blood pressure,

oxygen saturation and temperature) were telemonitored with a device installed at the patients' home. Early results showed a reduction of hospitalizations (20%), length of stay (14%) and time spent in emergency room (14%). The implementation of this program was planned to last about seven years and the potential maximum benefits were expected to be achieved in phase III (in about 3–4 years from start).

In a review published in 2010, HT was shown to reduce the number of hospitalizations and emergency room visits in comparison to CC, although the clinical characteristics of the studies reviewed were very heterogeneous [24]. Similar results were published in a Cochrane review in 2011 [25], which also found improvement in the quality of life of patients. No differences were found in mortality rates; possible explanations being that both study groups were composed of patients in the worst functional class, which in itself is associated with a poorer prognosis, and the short period of follow-up (total of 7 months). All these reports concluded that better-designed studies on specific populations are needed. To the date, studies in groups of patients with more severe disease are limited to Vitacca's work [26] in a population of 240 patients with severe respiratory failure, with a mean FEV<sub>1</sub> of 40%.

With respect to the utility of the telemonitoring parameters, there are few studies exploring the utility of PEF in COPD patients, especially in these patients without bronchial hyperactivity. Hurst [12] and van de Berge [16] linked the fall in the PEF with the probably to detect early COPD exacerbation. In our study, in 7 occasions PEF triggered clinical while oxygen saturation did in 30 occasions, and blood pressure only in 7% of the times (4 occasions).

To sum up the authors concluded that HT programs coordinated by primary and secondary care groups can improve the efficient delivery of the health services to chronic patients due to an easier and more effective follow-up of chronic patients.

## Advantages and limitations

Adherence to the HT program in our trial was good, and there were no withdrawals due to complications of use, although one of the patients had difficulties taking the measurements, and in the end it was identified that data received were those of the carer. This reinforces the importance of selecting patients who may best benefit from a TH program [25]. An important aspect for patient adherence to a HT is the use of devices that are not difficult to use; Finkelstein and Friedman showed that with a short training, elderly patients were capable of using a home monitoring system via videoconference [27].

Our study did not vary the schedule of the patients' appointments to visit the Pneumologist or PCCs, intervening only if there was some change in the monitored parameters that were recorded daily, and thereby ensuring patients did not lose their relationship with their regular doctors. Coordination with the PCC was essential to maintain continuity of care and to avoid duplicating clinical interventions and treatments. We dealt with a large amount of data and information, clinical and non-clinical; and in this case the

CMC nurse played a key role in filtering the alerts. In this way in clinical alert, AECOPD were differentiated from other causes, and were able to detect false positives; And in technical alerts, false negatives were managed by the CMC nurses, all this reducing the burden of interventions by the, as the Pneumologist was only alerted when clinical alerts were confirmed by the CMC nurses.

We must emphasize that any integrated program for COPD care, with or without TH, requires the cooperation and coordination between primary and specialist care within the community and the hospital.

Finally, the main limitations of our study were: 1) the small sample size, albeit given the severity of the disease, it was sufficient to obtain significant clinically relevant and statistically significant differences between the two groups; 2) given the poor functional prognosis (COPD GOLD stage IV with multiple comorbidities) and only 7 months of monitoring period, we were unable to obtain significant differences in mortality between the two groups; 3) the study follow-up was less than one year; and hence we were unable to take into account seasonality of AECOPD 3) the patient selection could be better; although there were no withdrawals because of difficulties in using the devices and the overall satisfaction rate was high; 4) the lack of individual randomization, as mentioned above.

## Future

Real-life effectiveness and economic feasibility studies are needed to implement HT programmes. In addition, larger, multicenter studies and the development of integrated care programs within the healthcare system are needed and no more repetitive "pilot projects". We must improve the selection process to better identify patients that are most likely to benefit from TH programs, define the roles of the staff involved, and assess the impact of these programs on the patient's carer.

In conclusion, the PROMETE study has shown clinical efficacy in monitoring COPD patients in GOLD group D [11] (severe airflow obstruction, respiratory symptoms, and at-risk of AECOPD), who also have multiple comorbidities, by reducing the number of hospital visits through early detection and proactive intervention in the patient home before the AECOPD occur. This was possible with the coordination of Primary Care, Pneumologist, and nursing staff. However, we must carefully evaluate the population who meet inclusion criteria for HT programmes, as the majority of patients are elderly, some of them with cognitive, hearing, or visual defects that may hinder the continuity of TH on a daily basis [28]. Hence, HT programs in severe COPD patients are safe and efficacious in reducing healthcare resources utilization in elderly patients with multiple comorbidities.

## Conflict of interest statement

All the authors have read the manuscript and have approved this submission. Cristina Gómez-Suárez, Ana Jordán and Elena Tadeo work at Linde Healthcare. The remaining authors have no conflict of interest.

The study was approved by the Ethics Committee of the HULP, study number was 1819. All patients signed an informed consent form prior to inclusion.

## Acknowledgments

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## Appendix A. Supplementary data

Supplementary data related to this article can be found at <http://dx.doi.org/10.1016/j.jrmed.2013.12.003>

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# Health-economic evaluation of home telemonitoring for COPD in Germany: evidence from a large population-based cohort

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## Abstract

**Introduction** Telemonitoring for COPD has gained much attention thanks to its potential of reducing morbidity and mortality, healthcare utilisation and costs. However, its benefit with regard to clinical and economic outcomes remains to be clearly demonstrated.

**Objective** To analyse the effect of Europe's largest COPD telemonitoring pilot project on direct medical costs, health resource utilisation and mortality at 12 months.

**Methods** We evaluated a population-based cohort using administrative data. Difference-in-difference estimators were calculated to account for time-invariant unobservable heterogeneity after removing dissimilarities in observable characteristics between the telemonitoring and control group with a reweighting algorithm.

**Results** The analysis comprised 651 telemonitoring participants and 7047 individuals in the standard care group. The mortality hazards ratio was lower in the intervention arm (HR 0.51, 95 % CI 0.30–0.86). Telemonitoring cut total costs by 895 € ( $p < 0.05$ ) compared to COPD standard care, mainly driven by savings in COPD-related hospitalisations in (very) severe COPD patients (−1056 €,  $p < 0.0001$ ). Telemonitoring enrollees used healthcare (all-cause and COPD-related) less intensely with shorter hospital stays, fewer inpatient stays and smaller proportions of people with

emergency department visits and hospitalisations (all  $p < 0.0001$ ). Reductions in mortality, costs and healthcare utilisation were greater for (very) severe COPD cases.

**Conclusion** This is the first German study to demonstrate that telemonitoring for COPD is a viable strategy to reduce mortality, healthcare costs and utilisation at 12 months. Contrary to widespread fear, reducing the intensity of care does not seem to impact unfavourably on health outcomes. The evidence offers strong support for introducing telemonitoring as a component of case management.

**Keywords** Telemonitoring · COPD · Cost-effectiveness · Administrative data

**JEL Classification** I18 · H51

## Introduction

Chronic obstructive pulmonary disease (COPD) is an inflammatory disease of the respiratory system and is aggravated by acute respiratory exacerbations and systemic comorbidities. COPD causes elevated mortality and morbidity as well as soaring healthcare expenditure and utilisation [1, 2]. The number of individuals with COPD in Germany will grow from 5.9 [3] to 8.0 [4] million by 2050 while COPD is expected to become the world's fourth most common cause of death within the next decade [5]. In search of cost-effective concepts of chronic care management, researchers and policy-makers have increasingly recognised the potential of telemedicine in reducing morbidity and mortality, as well as healthcare utilisation and its associated costs [6]. In particular, home telemonitoring (TM)—a technology measuring patients' clinical parameters/symptoms [e.g. forced expiratory volume in one

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second (FEV<sub>1</sub>), oxygen saturation, sputum] at home and allowing communication between healthcare professionals and patients over distance—has gained much attention. Practitioners expect that telemonitoring can anticipate unscheduled, COPD-related physician/emergency department (ED) visits and hospitalisations by detecting anomalies in patients' vital signs sufficiently early.

However, despite a growing body of evidence for TM in the management of COPD and other chronic diseases, such as congestive heart failure (CHF), the benefit of telemonitoring with regard to clinical and economic outcomes remains to be clearly demonstrated [6, 7]. Meta-analyses indicate that telemonitoring reduces the odds ratio of all-cause hospitalisation and ED visits by up to 54 % [8–10] and 73 % [8, 10], respectively, but has no impact on hospital length of stay, disease-specific quality of life (QoL) or mortality [8–11]. Most studies did not differentiate between COPD-related and all-cause healthcare use, leaving space for speculation about the effect on respiratory-related resource utilisation. Similarly, the evidence on cost-effectiveness is very meagre and inconclusive [9]. Recent cost-utility analyses from the UK found that telemonitoring was very unlikely to be cost-effective, with an incremental cost-effectiveness ratio (ICER) ranging between ~120,000 € [12] and ~178,000 € per quality-adjusted life year (QALY) gained [13]. In contrast, a modelling study in the German context found telemonitoring to be cost-effective (ICER 15,400 €) [14].

These findings need to be interpreted with caution though, and their applicability to the German context cannot be warranted because of the complete absence of German studies. The few telemonitoring interventions evaluated were highly heterogeneous, employing manifold technologies that ranged between simplistic telephone calls, patient education, virtual video-consultations, semi-automated transmission of vital parameters or a combination thereof [8]. The breadth and frequency of parameter measurements as well as availability and qualification of support staff diverged across studies. Short follow-up periods (range 2–12 months, mode 6 months) precluded statements about long-term effectiveness [9] and studies were typically under-powered [7] due to small sample sizes (range 18 [10] to 256 [11], median 70 [11]). Moreover, most studies were controlled trials and thus conducted in a well-ordered clinical environment that might lack comparability to routine care settings.

Given the dearth of much-needed evidence, the aim of this study is to analyse the effect of Germany's largest COPD telemonitoring pilot project on direct medical costs, health resource utilisation and mortality. The intervention consisted of a telemonitoring set for transmitting vital parameters, clinical support and patient education. We estimate incremental costs and effectiveness by comparing a COPD

telemonitoring and a COPD standard care cohort over a period of 1 year. In doing so, we address the limitations of existing studies in numerous ways. First, to the best knowledge of the authors, this is so far the largest evaluation of COPD telemonitoring in Europe. A follow-up period of 1 year in conjunction with a sample size that exceeds the mean sample size of conducted RCTs by a factor of ten enables measuring mid-term outcomes reliably. Second, we investigate the incremental causal effect of telemonitoring in pragmatic, routine clinical settings by using a combination of entropy balancing and difference-in-difference estimators. By isolating COPD-related from all-cause outcomes, we can make precise judgements about the effectiveness of telemonitoring on respiratory-related outcomes. Finally, we consider incremental costs in addition to effectiveness of the intervention, and we are the first to conduct an evaluation of telemonitoring for COPD in Germany.

## Methods

### Study design and study sample

Costs from the sickness fund perspective and effectiveness of telemonitoring were evaluated in an observational, retrospective, population-based cohort study design. We compared outcomes of patients receiving telemonitoring in addition to standard care with those of a cohort only receiving standard care over a period of 12 months. The analysis was based on administrative data from AOK Bayern (4.4 million insurances in 2014) which is Germany's fourth largest sickness fund. The dataset contained longitudinal patient-level information on socio-demographic status, medical diagnoses, direct medical costs, as well as on healthcare utilisation between 2009 and 2014.

Patients (>18 years of age) with COPD were required (a) to have had an in- or outpatient ICD-GM-10 (J44) diagnosis in the dataset of the sickness fund and (b) to having been hospitalised with a COPD or COPD-related diagnosis (ICD J41–J44) within 24 months before the index date (variable date for telemonitoring group; 1 January 2013 for control group). The patient cohort was subsequently divided into an intervention group, i.e. patients that voluntarily enrolled in the telemonitoring programme for the first time between November 2012 and December 2013, and a control group, i.e. patients that had never been members of the telemonitoring programme at any point in time between 2009 and 2014. For telemonitoring enrollees, outcomes were measured for 12 months starting from their individual telemonitoring enrolment (index date between November 2012 and December 2013), while for the control group, outcomes were assessed in the 12-month period starting from their common index date (1 January 2013).

In order to allow for risk adjustment, we stipulated a period of 2 years prior to the index date (variable date for telemonitoring group; 1 January 2013 for control group) as the basis for determining patient-level risk profiles. Applying equally to the telemonitoring and control group, individuals were excluded from this study if they (1) switched between the telemonitoring and control group, (2) had not been constantly enrolled at the sickness fund during the 2-year risk adjustment, or (3) the 1-year observation period. Patients who died during the observation period were not excluded. Individuals were excluded if they were suffering from predefined diseases [malignant neoplasms (ICD C00–C97), moderate/severe intellectual disabilities (ICD F71–F74, F78), Parkinson's (ICD G20–G23) and Alzheimer's disease (ICD G30–G32)] or currently undergoing certain therapies (chemo/radiation therapy, dialysis, long-term ventilation) that could impede an active participation in the telemonitoring service and substantially undermine the programme's effect. Likewise, individuals were disqualified if they were taking part in any other telemonitoring/integrated care programme [except for the COPD disease management programme (DMP)] or were not deemed suitable by the telemonitoring provider SHL Telemedizin (e.g. due to difficulties in dealing with technology or language barriers).

### Telemonitoring intervention

Patients received up to two monitoring devices [spirometer for mild to severe ( $FEV_1 \geq 35\%$ ) patients and spirometer + pulse oximeter for very severe ( $FEV_1 < 35\%$ ) patients] that measured vital parameters at least twice a week. Patients were free to choose the time and day of vital parameter measurement, but were called by the surveillance centre if they transferred fewer than two measurements per week. In addition, a telemonitoring console was used to answer a disease-specific [COPD assessment test (CAT)] and general well-being questionnaire (three questions) at least twice a week. Vital parameters and questionnaire data was automatically transmitted to an electronic patient record that was operated by the 24-h-available SHL surveillance centre. Moreover, users received phone calls at jointly agreed frequencies (usually every 2–3 weeks) to receive education on improved diet, exercise and lifestyle as well as support for smoking cessation. Patients were invited to contact the surveillance centre at any time should further questions occur. Based on the transmitted questionnaires and on the spirometer/pulse oximeter data, an algorithm calculated the probability of exacerbation. At enrolment, the SHL surveillance team defined measures to be taken in case of worsening health on the basis of the patient's physician data. In the case of a high exacerbation probability, the medical staff called the

patient in order to adjust emergency medication or take any other measures predefined by the physician.

### Study outcomes

The selection of the study outcomes was based on the most commonly used outcomes in the literature [8] and can be subdivided into (1) direct medical costs, (2) mortality and (3) healthcare resource utilisation. All outcomes represent the average values over the 12-month follow-up period and 24-month baseline period, respectively. COPD-related costs and healthcare utilisation were identified through the J44 diagnosis.

#### *Direct medical costs*

Direct medical costs for inpatient and outpatient treatment, pharmaceuticals, as well as rehabilitation, were calculated from the sickness fund's perspective. Hospital admissions were truncated at 50,000 € per episode (first percentile) in order to limit a potential distortion by extreme outliers. From the sickness fund's perspective, telemonitoring costs were irrelevant since programme costs were reimbursed in a profit-sharing agreement. All costs were reported in 2013 Euros.

#### *Mortality*

All-cause mortality was reported as the average yearly proportion of deceased individuals and hazards ratio (HR). Years of life lost (YLL) due to premature mortality were calculated by subtracting the age of death from the age- and gender-adjusted individual life expectancy [15]. We also calculated an incremental cost-effectiveness ratio (ICER) for avoiding one YLL through the use of telemonitoring. In addition, we extrapolated our mortality rates and total number of YLL to the German COPD population that would be eligible for telemonitoring (based on AOK's eligibility criteria) in order to estimate national cost implications.

#### *Healthcare resource utilisation*

We compared the number of hospitalisations and outpatient physician visits (COPD-related, all-cause, ED), the (average) length of stay (COPD-related, all-cause), the proportion of hospitalised patients (all-cause, due to COPD, emergency department) and the number of pharmaceutical prescriptions between the two groups.

### Statistical analysis

In order to reduce confounding due to unbalanced baseline characteristics between the telemonitoring and control group, a two-step risk-adjustment was applied: (1) entropy

balancing and (2) difference-in-difference (DiD) estimation. In a first step, we ran a reweighting algorithm (entropy balancing) in order to remove imbalances in the mean and variance of a set of pre-specified, observed covariates (e.g. age, sex, comorbidity; see “[Risk adjustment](#)” section). Entropy balancing directly recalibrates the weight of each control individual to maximise comparability to the treatment group, but at the same time it keeps the newly computed weights as close as possible to the base weights to reduce loss of information and model dependency [16]. In comparison to propensity score matching, entropy balancing achieves significantly higher covariate balance, does not discard individuals and obviates the need for manual propensity score model specification and balance checking [16]. Although balance diagnostics is not common after entropy balancing, significance tests [16] and standardised mean differences [17] were used to compare the balance of baseline characteristics before and after weighting.

In a second step, differences in outcomes between the telemonitoring and control group due to unobserved factors (e.g. undiagnosed health conditions) were minimised with the DiD estimation. The gist of DiD is to compare the difference in outcomes after (follow-up period) and before (baseline period) the intervention (telemonitoring) in the intervention group to the same difference for the control group. Outcomes in the baseline period were measured 2 years prior to the respective index date. In order to avoid biased standard errors due to serial correlation, the time series dimension of the 2-year baseline period was removed by averaging the values over 2 years and hence creating one single value per outcome measure for the baseline period [18]. The parallel trend assumption was checked by plotting relevant outcomes over time. Outcomes were calculated monthly (quarterly in the case of outpatient data, due to German reporting standards) for 2 years (baseline period) in order to verify the parallel trend over 24 data points. Finally, using the entropy weights computed in the first step, a weighted OLS regression (DiD estimator) was run with the change in costs/health outcomes as the dependent variable. In addition, the set of conditioning variables selected in the first weighting step (see “[Risk adjustment](#)” section) were used as independent variables in the weighted OLS regression in order to reduce the standard error of the treatment estimate. Because those independent variables have already been used in the entropy balancing, they have no further effect on the DiD estimator.

### Risk-adjustment

We used a set of variables that are considered to possess a high prognostic potential for the outcomes (cost, mortality

and healthcare utilisation). Evidence suggests that gender, age [2, 19], comorbidities [2, 20] and pharmacy-based metrics (PBM) [21] are robust predictors of healthcare costs, mortality and resource utilisation in COPD [22]. Since comorbidities might not always be recorded through the ICD catalogue but are still treated with drugs, prescription claims data (PBM) [21] provide valuable information on the patient’s health status. Consequently, in the entropy weighting procedure, the covariates were socio-demographic variables (sex, age, and insurance status as a proxy for socio-economic status), generic comorbidity measurement instruments (29 of the total 31 Elixhauser comorbidity groups [20, 23] and 32 of the total 32 PBM groups [21]), as well as COPD-specific comorbidity measurement variables. Redundant Elixhauser and PBM groups (e.g. COPD) or those that fulfilled our exclusion criteria (e.g. metastatic cancer) were discarded. The COPD-specific group comprises indicators for COPD severity (lung function) as measured by forced expiratory volume ( $FEV_1$ ) [ICD10 GM diagnoses of J44.x0 ( $=FEV_1 < 35\% \approx$  very severe), J44.x1 ( $=50\% > FEV_1 \geq 35\% \approx$  severe), J44.x2 ( $=70\% > FEV_1 \geq 50\% \approx$  moderate) or J44.x3 ( $=FEV_1 \geq 70\% \approx$  mild)], reported tobacco addiction (ICD F17, yes/no) and membership in a COPD disease management programme (yes/no). For each patient, an ICD diagnosis was included in their risk adjustment profile if it was determined at least once in inpatient settings or at least twice within 180 consecutive days in outpatient settings. All abovementioned covariates were determined in the 2-year risk-adjustment period (variable date for telemonitoring members and 1 January 2013 for control individuals).

### Subgroup analysis

In order to detect differential treatment effects of telemonitoring for different COPD severities, we performed a separate subgroup analysis on mild to moderate COPD ( $FEV_1 \geq 50\%$ ) and on severe to very severe COPD ( $FEV_1 < 50\%$ ), respectively. If COPD stages of different severity existed, we chose the most severe diagnosis for the respective patient. Moreover, to analyse the effect of enrolment in a disease management programme (DMP) whilst using telemonitoring, we conducted a further subgroup analysis by DMP membership status. Because the sample composition changes in subgroup analysis, we computed new entropy weights for each subgroup.

### Sensitivity analysis

We analysed how results changed in response to (1) exclusion of deceased individuals, (2) to truncation of high-cost cases and (3) to an intention-to-treat (ITT) analysis.



Owing to the fact that the last months of life often incur exceptionally high costs and healthcare utilisation, we excluded individuals who died during the intervention period and thus could have potentially distorted the effect of telemonitoring (1). In a further sensitivity analysis, we mitigated the effect of high-cost individuals by truncating the total annual costs at 50,000 € (2). Costs above this threshold are usually extreme outliers that are not representative of the entire population and might undermine true treatment effects. Finally, instead of applying an as-treated methodology, we used an intention-to-treat framework that entails the analysis of all participants regardless of their non-adherence to the assigned telemonitoring treatment protocol (3). ITT is useful in estimating the effectiveness of administering a technology in the wider community in light of inevitable treatment non-adherence [24]. Hence, we still measured outcomes at 12 months starting from telemonitoring enrolment, but we did not exclude individuals that dropped out from the telemonitoring programme during the 12-month intervention period.

## Results

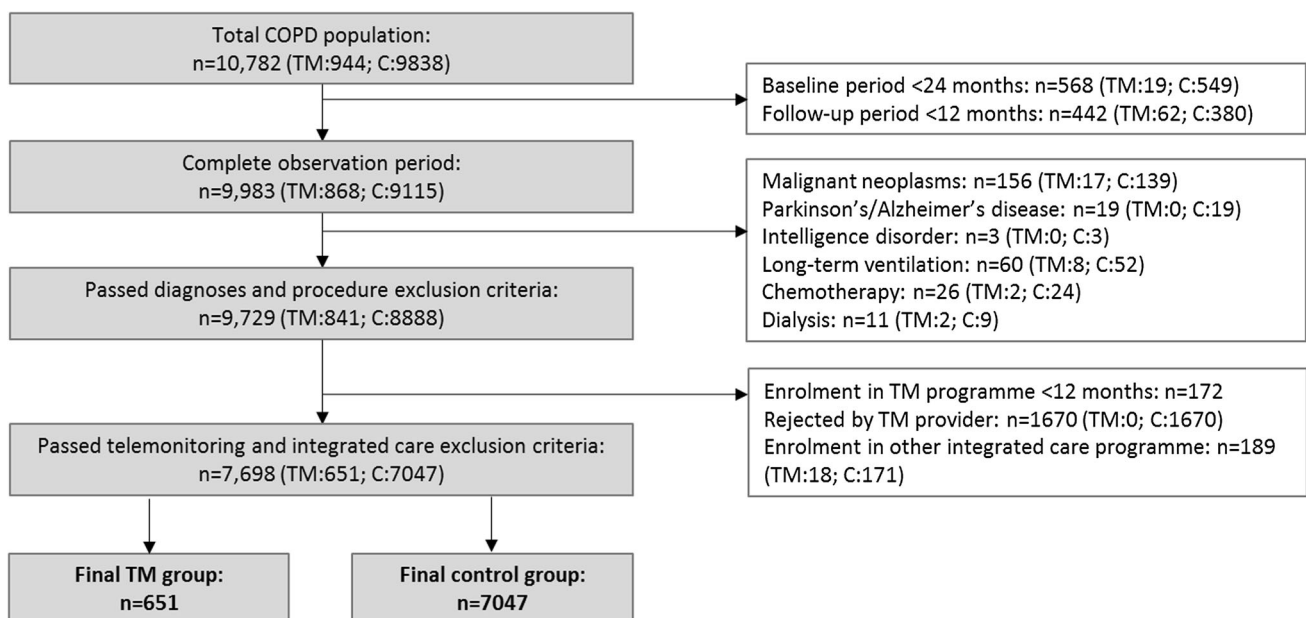
Of the initial 944 telemonitoring (TM) and 9838 control individuals in the dataset, 651 and 7047 remained for the main analysis, respectively (see Fig. 1). The mean age and percentage of female participants of the telemonitoring and the control groups were 64.2 and 69.5 years and 43.9 and 49.2 %, respectively. While the proportion of patients with mild and moderate COPD was equally distributed, the

intervention group had more severe (24.7 vs 17.8 %) and very severe (39.6 vs 25.2 %) cases as well as more patients with tobacco addiction (39.6 vs 23.6 %) before weighting. The average number of total Elixhauser comorbidity groups (5.2 vs 5.2) and PBM groups (6.3 vs 6.0) did not diverge importantly between the telemonitoring and control populations, respectively.

The application of entropy weighting achieved a highly balanced distribution of all observed baseline characteristics (see Table 1). While, prior to weighting, 8 out of 31 Elixhauser comorbidity groups and 10 out of 32 PBM groups differed significantly between the telemonitoring and the control groups, post weighting none of those variables showed any significant differences (see Table 5 in Appendix). Moreover, the differences in age (5.2 years,  $p < 0.001$ ), gender (5.2 %,  $p < 0.001$ ), tobacco addiction (16.0 %,  $p < 0.001$ ) and COPD severity before weighting were removed to non-significant levels (all  $p = 0.999$ ) after weighting.

## Direct medical costs

Total direct medical costs were significantly lower in the telemonitoring group (−895.11 €,  $p = 0.04$ ). The main driver for the total cost difference was the reduction of hospitalisation costs by −1056.04 € ( $i = 0.01$ ), including decreased expenses for COPD-related hospital admissions (−642.28 €,  $p < 0.001$ ). At the same time, costs for outpatient visits slightly increased by 69.54 € ( $p = 0.05$ ) while costs for pharmaceuticals and rehabilitation did not change significantly (Table 2).



**Fig. 1** Flow-chart showing algorithm for selection of study population

**Table 1** Baseline characteristics of the telemonitoring (TM) and control group prior to and post entropy balancing (EB)

Variables	TM	Control		D-statistic <sup>a</sup>		<i>p</i> value <sup>b</sup>	
		Before EB	After EB	Before EB	After EB	Before EB	After EB
Sample size ( <i>N</i> )	651	7047		–	–	–	–
Mean age (years)	64.24	69.47	64.24	48.55	0.00	<0.05	1
Female	43.93	49.17	43.93	10.51	0.00	<0.001	1
FEV <sub>1</sub> values							
FEV <sub>1</sub> ≥ 70 %	6.91	7.25	6.91	1.32	0.00	0.81	1
70 % > FEV <sub>1</sub> ≥ 50 %	17.20	17.28	17.20	0.21	0.00	1	1
50 % > FEV <sub>1</sub> ≥ 35 %	24.73	17.75	24.73	17.12	0.00	<0.001	1
FEV <sub>1</sub> < 35 %	39.63	25.20	39.63	31.19	0.00	<0.001	1
FEV unknown	11.52	32.51	11.52	52.35	0.00	<0.001	1
Tobacco addiction	39.63	23.64	39.63	34.90	0.00	<0.001	1
Insurance status				0.00	0.00		
Mandatory	29.03	21.77	29.03	16.74	0.00	<0.001	1
Pensionary	64.98	71.69	64.98	14.46	0.00	<0.001	1
Voluntary	5.99	6.54	5.99	2.27	0.00	0,68	1
DMP COPD enrolment	62.21	37.16	62.21	51.74	0.00	<0.001	1
Elixhauser comorbidities (see <a href="#">Appendix</a> )							
Before EB	8 of 31 significantly different at <i>p</i> < 0.05						
After EB	0 of 31 significantly different at <i>p</i> < 0.05						
Pharmacy-based classes (see <a href="#">Appendix</a> )							
Before EB	10 of 32 significantly different at <i>p</i> < 0.05						
After EB	0 of 32 significantly different at <i>p</i> < 0.05						

All values in % unless indicated otherwise

EB entropy balancing

<sup>a</sup> D-statistic represents the standardised mean difference

<sup>b</sup> *p* value: Fisher's exact test for dichotomous and t-test for continuous variables

## Mortality and ICER

During the 12-month evaluation period, a lower percentage of individuals died in the intervention group than in the control group (3.23 vs 6.22 %, *p* < 0.0001), translating into a mortality hazards ratio (HR) of 0.51 (95 % CI 0.30–0.86). Since cost savings were achieved, on average, the telemonitoring programme can be considered a dominant technology (i.e. ICER: not applicable).

Although this calculation represents a rough, probably upwards-biased approximation because the morbidity profile of those insured by AOK Bayern may not be representative for Germany, given that AOK Bayern considered 0.25 % of those it insured eligible for telemonitoring, 198,500 COPD individuals nationwide could be considered suitable for telemonitoring (0.245 % of 81.0 million). Thus, a national rollout of telemonitoring would avoid approximately 5941 deaths and 108,689 YLL per year. Given that telemonitoring reduces costs at the same time (−895.11 € per patient), cost savings of 177.7 € million could be achieved.

## Healthcare utilisation

Generally, healthcare utilisation in the telemonitoring group decreased in the inpatient sector and increased in the outpatient sector. Over the 12-month period, the proportion of patients hospitalised due to all causes (−15.16 %, *p* < 0.0001), due to COPD (−20.27 %, *p* < 0.0001) and COPD-related ED (−17.00 %, *p* < 0.0001) was consistently lower in telemonitoring patients, leading to fewer all-cause (−0.21, *p* < 0.0001), COPD-related (−0.18, *p* < 0.0001) and COPD-related ED admissions (−0.14, *p* < 0.0001). On average, people in the intervention group spent 3.1 (*p* < 0.0001) and 2.07 (*p* < 0.001) fewer days in hospital due to all causes and COPD, respectively, than the control group. The average length of stay (ALOS) declined, too. The decrease in inpatient care seems to have been compensated by more frequent outpatient visits (all-cause: 1.27, *p* < 0.0001; COPD-related: 0.86, *p* < 0.0001) and a more intense prescription of pharmaceuticals (1.67, *p* < 0.01).

**Table 2** Outcomes for the telemonitoring (TM) and control group in the baseline (2 years) and follow-up period (1 year) with the respective difference-in-difference estimator and its standard error (SE)

	TM (651)		Control (7047)		DiD estimation	
	Baseline	Follow-up	Baseline	Follow-up	ATT <sup>a</sup>	SE
Total costs (in €)	6799	8314	6961	9371	-895*	445
Inpatient treatment	3393	4296	3768	5727	-1056**	410
Thereof due to COPD	1431	1298	1478	1987	-642***	191
Outpatient treatment	1114	1288	994	1098	70*	35
Pharmaceuticals	2120	2496	2044	2328	92	94
Rehabilitation	171	234	155	218	0	42
Indicators for healthcare utilisation						
Average length of hospital stay	6.05	4.89	5.87	6.14	-1.44***	0.34
Thereof due to COPD	4.77	2.75	4.41	4.14	-1.76***	0.29
Inpatient bed days	9.87	9.97	11.28	14.47	-3.10***	0.82
Thereof due to COPD	4.74	3.39	4.77	5.48	-2.07***	0.40
Inpatient stays	1.09	1.06	1.15	1.34	-0.21***	0.06
Thereof due to COPD	0.51	0.36	0.49	0.52	-0.18***	0.04
Thereof ED visits due to COPD	0.31	0.21	0.28	0.33	-0.14***	0.03
Proportion hospitalized (in %)	93.86	50.23	87.32	58.85	-15.16***	2.36
Thereof due to COPD	74.81	22.27	64.40	32.13	-20.27***	2.53
Thereof in ED due to COPD	49.16	14.29	40.47	22.60	-17.00***	2.47
Physician visits	15.17	16.98	13.38	13.91	1.27***	0.26
Thereof due to COPD	6.09	8.08	5.29	6.42	0.86***	0.13
Prescriptions	36.72	41.49	34.93	38.04	1.67**	0.61
Indicators for mortality						
All-cause mortality (in %)	n.a. <sup>b</sup>	3.23	n.a. <sup>b</sup>	6.22	-2.99***	n.a.

\* &lt; 0.05; \*\* &lt; 0.01; \*\*\* &lt; 0.0001

<sup>a</sup> Average treatment effect for the treated represents excess resource utilisation attributable to DMP<sup>b</sup> Baseline values are not applicable because individuals were only eligible if alive at index date

### Subgroup analysis

Dividing the cohort into mild/moderate COPD ( $FEV_1 \geq 50\%$ ) and into severe/very severe COPD ( $FEV_1 < 50\%$ ) shows that total cost savings were larger in the less sick subgroup (mild/moderate: -1205.13 €,  $p = 0.110$ ; severe/very severe: -518.51 €,  $p = 0.410$ ) but differences from the control groups were not significant in both cases due to smaller sample size (see Table 3). While the biggest savings in the mild/moderate subgroup were achieved in all-cause hospitalisation costs (-1467.91 €,  $p = 0.035$ ) through fewer all-cause hospital days (-4.3,  $p < 0.01$ ), costs and days for COPD-related hospitalisations did not change (-23.16 €,  $p = 0.937$ ; -0.34,  $p = 0.576$ ). In contrast, in the severe subgroup, telemonitoring reduced COPD-related inpatient costs (-635.74,  $p = 0.018$ ), days (-2.2,  $p < 0.0001$ ) and ALOS (-1.81,  $p < 0.0001$ ) but did not affect all-cause admission costs (-607.03 €,  $p = 0.290$ ) and days (-2.0,  $p = 0.065$ ). In both subgroups, the number of all-cause and COPD-related physician contacts significantly increased (see Table 3). Differences in

mortality with a HR of 0.50 (95 % CI 0.27–0.91) were stronger in the sicker subgroup [-3.65 % (3.82 vs 7.47 %),  $p < 0.0001$ ] than in the milder COPD group [-2.81 % (1.91 vs 4.72 %),  $p = 0.021$ ]. The HR did not reach statistical significance in the mild/moderate population (HR 0.40, 95 % CI 0.11–1.54).

The second subgroup analysis revealed that DMP membership did not prominently affect the magnitude or direction of the effect of telemonitoring on costs and other outcomes. Cost-savings for all-cause (DMP: -1051 €; non-DMP: -913 €) and COPD-related hospital admissions (DMP: -649 €; non-DMP: -652 €) was similar in both groups, although statistical significance for all-cause admissions was only reached in the DMP group. No clinically important differences were observed for indicators of healthcare utilisation between the DMP and non-DMP populations. Mortality HRs were still in favour of the telemonitoring interventions in both DMP groups (DMP: HR 0.40, 95 % CI 0.18–0.86; non-DMP: HR 0.67, 95 % CI 0.32–1.40) but was not significant in the non-DMP arm.

**Table 3** Difference-in-difference estimators (ATT) and their respective standard errors (SE) for two subgroup analyses: (1) COPD severity [mild to moderate ( $FEV_1 \geq 50\%$ ) and severe to very severe ( $FEV_1 < 50\%$ )], and (2) DMP COPD enrolment status

	(1) Analysis by COPD severity				(2) Analysis by DMP enrolment			
	Mild to moderate ( $FEV_1 \geq 50\%$ ) ( $n$ : TM = 157, C = 1729)		Severe to very severe ( $FEV_1 < 50\%$ ) ( $n$ : TM = 419, C = 3027)		DMP enrolment ( $n$ : TM = 405, C = 2619)		No DMP enrolment ( $n$ : TM = 246, C = 4428)	
	ATT <sup>a</sup>	SE	ATT <sup>a</sup>	SE	ATT <sup>a</sup>	SE	ATT <sup>a</sup>	SE
Total costs	-1205	748	-519	625	-886	552	-662	726
Inpatient treatment	-1468*	698	-607	573	-1051*	527	-913	643
Thereof due to COPD	-23	292	-636*	269	-649*	266	-652**	226
Outpatient treatment	160*	69	37	47	64	38	83	68
Pharmaceuticals	24	78	84	161	141	112	98	131
Rehabilitation	79	99	-32	50	-40	48	69	79
Indicators for healthcare utilisation								
Average length of hospital stay	-1.59*	0.68	-1.23**	0.46	-1.79***	0.45	-1.09*	0.55
Thereof due to COPD	-0.71	0.56	-1.81***	0.36	-2.03***	0.38	-1.44**	0.45
Inpatient bed days	-4.30**	1.44	-2.03	1.10	-3.00**	1.09	-2.90*	1.28
Thereof due to COPD	-0.34	0.60	-2.22***	0.55	-2.40***	0.53	-1.65**	0.58
Inpatient stays	-0.30**	0.11	-0.11	0.09	-0.19*	0.09	-0.26**	0.10
Thereof due to COPD	-0.06	0.06	-0.17**	0.05	-0.20***	0.05	-0.17**	0.05
Thereof ED visits due to COPD	-0.09*	0.04	-0.13**	0.04	-0.14***	0.04	-0.17***	0.04
Proportion hospitalised (in %)	-9.58*	4.83	-12.84***	3.00	-16.65***	3.13	-14.99***	3.62
Thereof due to COPD	-11.81*	5.29	-19.80***	3.25	-21.51***	3.38	-20.18***	3.86
Thereof in ED due to COPD	-10.71*	4.87	-17.40***	3.22	-17.57***	3.35	-18.08***	3.62
Physician visits	1.55**	0.55	1.10***	0.32	1.21***	0.34	1.35***	0.41
Thereof due to COPD	0.82***	0.25	0.89***	0.17	0.78***	0.18	0.85***	0.19
Prescriptions	2.67*	1.14	1.31	0.79	1.03	0.78	2.75**	0.97
Indicators for mortality								
All-cause mortality (in %)	-2.81*	n.a.	-3.65***	n.a.	-3.26***	n.a.	-2.31	n.a.

### Sensitivity analysis

In all three sensitivity analysis scenarios [(1) excluding dead individuals, (2) truncation, (3) ITT], telemonitoring was 13.28–38.15 % less effective in reducing total costs than in the baseline scenario (see Table 4) and the differences lost statistical significance [(1) -776.26 €,  $p = 0.074$ ; (2) -553.62 €,  $p = 0.132$ ; (3) -706.30 €,  $p = 0.089$ ]. However, the reductions in all-cause [(1: excluding dead): -936.43 €,  $p = 0.019$ ; (2: truncation): -826.14 €,  $p = 0.020$ ; (3: ITT): -919.54 €,  $p = 0.014$ ] and COPD-related inpatient costs [(1: excluding dead): -624.71 €,  $p = 0.001$ ; (2: truncation): -597.94 €,  $p = 0.001$ ; (3: ITT): -554.96 €,  $p = 0.003$ ] remained significant and stable in all scenarios. Relative changes to baseline in all-cause and COPD-related costs ranged from 11.33 to 21.77 % and from 2.74 to 13.60 %, respectively. For scenarios (1: excluding dead) and (3: ITT), direction, magnitude and significance of differences in healthcare utilisation continued to be very similar to the baseline scenario. The mortality hazards ratio further declined in

favour of telemonitoring in the (3) ITT analysis (HR 0.40, 95 % CI 0.24–0.67).

### Discussion

We demonstrated in this observational, population-based cohort study that our 12-month telemonitoring intervention for COPD entails a strong reduction in mortality (HR 0.51, 95 % CI 0.30–0.86), in total yearly costs by -895.11 €, driven by substantial savings in hospitalisation costs (-1056.04 €), and in inpatient healthcare utilisation. Costs (69.54 €) and number of outpatient visits (1.27) slightly increased, though. In terms of ICER, telemonitoring is a dominant technology compared to standard care.

The most striking finding in this study is the marked positive impact telemonitoring had on mortality at 12 months (3.23 vs 6.22 %,  $p < 0.0001$ ; HR 0.51, 95 % CI 0.30–0.86). The largest RCT in telemonitoring, the Whole System Demonstrator (WSD) project, found a very similar mortality HR of 0.59 (95 % CI 0.43–0.80) with somewhat

**Table 4** Sensitivity analysis: three scenarios (1: excluding dead, 2: cost truncation, 3: intention-to-treat) with difference-in-difference estimators (ATT) and their relative change compared to the baseline scenario

	Excluding dead (1) ( <i>n</i> : TM = 630, C = 6607)		Cost truncation (2) ( <i>n</i> : TM = 651, C = 7047)		ITT (3) ( <i>n</i> : TM = 815, C = 7047)		Baseline
	ATT <sup>a</sup>	Δ %	ATT <sup>a</sup>	Δ %	ATT <sup>a</sup>	Δ %	ATT <sup>a</sup>
Total costs	-776.26	13.28	-553.62	38.15	-706.30	21.09	-895.11*
Inpatient treatment	-936.43*	11.33	-826.14*	21.77	-919.54*	12.93	-1056.04**
Thereof due to COPD	-624.71***	2.74	-597.94**	6.90	-554.96**	13.60	-642.28***
Outpatient treatment	63.98	7.99	68.82*	1.03	65.11*	6.36	69.54*
Pharmaceuticals	101.71	-10.79	130.19	-41.82	145.13	-58.09	91.80
Medical appliances/rehabilitation	-5.51	-1266	-0.40	0.00	2.99	-642	-0.40
Indicators for healthcare utilisation							
Average length of hospital stay	-1.48***	-2.91	n.a.	n.a.	-1.24***	13.64	-1.44***
Thereof due to COPD	-1.72***	2.18	n.a.	n.a.	-1.68***	4.673	-1.76***
Inpatient bed days	-3.01***	2.72	n.a.	n.a.	-2.82***	9.05	-3.10***
Thereof due to COPD	-2.07***	-0.21	n.a.	n.a.	-1.86***	10.03	-2.07***
Inpatient stays	-0.21**	4.12	n.a.	n.a.	-0.16**	26.04	-0.21***
Thereof due to COPD	-0.19***	-4.95	n.a.	n.a.	-0.15***	14.03	-0.18***
Thereof ED visits due to COPD	-0.15***	-3.75	n.a.	n.a.	-0.13***	10.50	-0.14***
Proportion hospitalised (in %)	-14.95***	1.38	n.a.	n.a.	-11.77***	22.36	-15.16***
Thereof due to COPD	-19.98***	1.42	n.a.	n.a.	-18.86***	6.95	-20.27***
Thereof in ED due to COPD	-16.72***	1.64	n.a.	n.a.	-15.12***	11.06	-17.00***
Physician visits	1.09***	14.82	n.a.	n.a.	1.21***	5.10	1.27***
Thereof due to COPD	0.77***	10.03	n.a.	n.a.	0.76***	11.85	0.86***
Prescriptions	0.91	45.35	n.a.	n.a.	1.48**	11.31	1.67**
Indicators for mortality							
All-cause mortality (in %)	n.a.	n.a.	n.a.	n.a.	-3.73***	-24.58	-2.99***

Δ %: deviation (in %) of respective sensitivity analysis value from baseline scenario value

\* < 0.05; \*\* < 0.01; \*\*\* < 0.0001

<sup>a</sup> Average treatment effect for the treated represents excess resource utilisation attributable to DMP

higher mortality figures (4.6 vs 8.3 %) [25]. Direct comparisons must be treated with caution, though, because the WSD recruited diabetes and heart failure patients in addition to COPD patients. None of the meta-analyses [8–10] and systematic reviews [11] found any overall statistically significant effect on mortality, potentially because most of the included studies were underpowered (total median sample size: 70) to specifically detect a mortality difference. Meta-analytic evidence from better studied diseases, in particular CHF, indicates similar reductions in mortality risk, ranging between 34 and 20 % [6].

Moreover, the clear decline in hospitalisations found in our study is corroborated in the literature. Two meta-analyses [8, 9] and two systematic reviews [10, 11] concluded that telemonitoring reduced the risk of hospital admission, with pooled odds ratios (OR) and risk ratios (RR) ranging between OR 0.46 [8] and RR 0.72 [9]. The reduction in the proportion of people hospitalised due to COPD (-20.27 %) and admitted to ED due to COPD (-17.00 %) indicates that the telemonitoring intervention

might reduce the number of severe exacerbations and, hence, the need for emergency hospital care. Other studies reported similar, absolute reductions in proportions of individuals with ED visits of 19 % [26] and 23 % [27]. Indeed, the literature suggests that telemonitoring can decrease the number of exacerbations [28], which are most commonly associated with a worsening of peripheral oxygen saturation [9].

Although the exact mechanisms of reducing hospitalisations is not completely clear in our study, we suspect two possible pathways: first, it is possible that the monitoring of patients' oxygen saturation and weight can predict a worsening of the health state to some extent. However, the correlation between daily variation in spirometry and other physiological measures and exacerbations is still poorly understood, leading to a high rate of false-positive warnings [29]. Machine-learning algorithms—taking into account a wider array of variables, such as physiological signs, symptoms, disease severity, prior hospitalisations, medication intake, demographic characteristics as well as



indicators for depression, anxiety or social isolation—could boost telemonitoring's predictive power in detecting exacerbations [29]. Second, patients in our programme received support and education on correct disease management, potentially allowing them to spot a COPD-related worsening of their health in a more timely manner. It is possible that patients learned to better adhere to their medication regimen and, if they perceived the need, to initiate pharmacological therapy with  $\beta_2$ -adrenergic agonists or corticosteroids. A tendency for increased spending on medication (+92 €) as well as evidence on the positive effect of self-management on medication intake in COPD [30] support our hypothesis. Early patient recognition of exacerbations and prompt treatment initiation are associated with reduced risk of hospitalisation and faster exacerbation recovery [31]. Both reduced risk of hospitalisation and faster exacerbation recovery were also found in our study, manifesting themselves in a reduced proportion of patients with hospitalisations (−15.16 %) and a shorter length of hospital stay (−1.44 days) in the intervention group. This finding might suggest that individuals using telemonitoring are hospitalised with less severe exacerbations, potentially because they were recognised and treated earlier.

Given the reductions in frequency and duration of hospitalisations, which constituted 51 and 61 % of the total costs in the follow-up period of intervention and control group, respectively, overall costs were considerably lower in the telemonitoring arm (−895.11 €). Savings in all-cause and COPD-related hospital costs were insensitive to model specifications and analysis methodologies. The decrement in inpatient care seems to have been compensated by higher use of outpatient services (69.54 €). Direct comparisons with other cost studies can hardly be drawn as the telemonitoring technology itself as well as health system-specific reimbursement may largely vary. Still, most studies with a cost-assessment reported savings between 12 and 17 % in the telemonitoring group [32], which is similar to the reduction of 11 % in the follow-up period of our cohort.

Although irrelevant in this specific profit-sharing agreement between the sickness fund and telemonitoring provider, we underestimated the true costs of telemonitoring because we did not possess any information on the costs of the programme (including investments and operating costs for software, hardware, personnel, administration). Consequently, it might take a few years until cost-savings from less intense healthcare use compensate for the technology investment. Given yearly telemonitoring fees of 677 € found in a Danish study [33], the sickness fund would still save 218 € (=895−677) while still reducing mortality. Even at a yearly telemonitoring service cost of 1000 € and a resulting increase in expenditure of 105 €

(=895−1000), the ICER would be highly cost-effective with 191 € per life-year gained.

The subgroup analysis revealed that patients with (very) severe COPD experienced greater reductions in mortality as well as in cost, number and duration of COPD-related hospitalisations than individuals with mild/moderate COPD. This indicates, again, that telemonitoring may effectively decrease the number of exacerbations that require inpatient treatment. Because high-risk patients are usually hospitalised more frequently, they have a greater baseline potential for cutting hospitalisations and costs. A high-quality RCT corroborated our findings, showing that telemonitoring was less effective in curbing hospitalisation rates for mild cases than for severe ones [34]. Similarly, a study on telemonitoring in asthma found no improvements in health outcomes in individuals with mild disease, but showed a reduced risk of admission to hospital for high-risk patients [35]. While savings in all-cause hospitalisations were considerable in the mild/moderate group (−1468 €,  $p < 0.05$ ), the cost reduction in COPD-related cost was not significant. Potential reasons for a lack of statistically and clinically significant changes could be the small sample size (TM;  $n = 157$ ) as well as the fact that COPD-related hospital costs constitute only roughly 28 % of total inpatient costs in our mild/moderate sample. In line with our data, the literature indicates that comorbidities, such as ischemic heart failure or diabetes, are more important drivers of hospitalisation costs in these patients [36]. A positive spill-over effect of TM on the management of concurrent diseases might be possible.

Another important finding of the subgroup analysis is that telemonitoring continues to be cost-saving for COPD-related hospitalisations, reduces healthcare utilisation and still displays a trend for reduced mortality, even when isolating its effect from additional interventions in usual care, such as disease management programmes (DMPs). The lack of statistical significance in some outcomes is most likely due to decreased sample size, as controlling for DMP participation in the baseline scenario still delivered significant results. In most published studies, it was impossible to disentangle the effect of telemonitoring from usual care because the intervention group received enhanced clinical care that could affect outcomes on its own. For instance, care enhanced through the German DMPs for COPD have been found to improve clinical outcomes [37]. A recent randomised controlled trial (RCT) in the UK, however, disentangled the effects of telemonitoring from the effect of the remaining elements of healthcare service and concluded that telemonitoring was not effective in reducing rates of/time to admission, neither QoL [34]. The reasons for these diverging findings could be rooted in differences in telemonitoring interventions employed, as well as in the provision of standard care.

## Limitations

Our results should be interpreted in light of certain data-related and methodological limitations. First, our administrative data provide only limited information on the clinical progression of disease and on smoking status, which are both predictors of health and cost outcomes [1, 2]. Although COPD severity can be approximated in our data by the fourth and fifth digits of the ICD code (J44.XX), clinicians often do not precisely specify these digits in everyday practice. Nor does our data indicate whether telemonitoring simply shifts the burden and costs of care away from the inpatient sector towards the patients themselves or towards their family members and caregivers. Moreover, we had no information on causes of death which would have allowed disentangling the effect of DMP on all-cause and COPD-specific mortality. Similarly, we did not possess life-tables for COPD populations to calculate the number of life-years gained. By using life-tables from the general population, we might overestimate the number of life-years gained for the telemonitoring group. Overestimation is also a potential issue in the budget impact analysis, because the AOK Bayern insured population might be sicker than the average German population, hence inflating the percentage of patients eligible for the TM. In addition, we might have underestimated the number of outpatient physician visits in both groups due to German medical coding modalities and reporting standards. The last data-related limitation is the fact that we had no data to adjust for potentially diverging treatment intensity in the TM group. Despite regularly scheduled remote health examinations, some patients might have participated with a higher adherence to the programme than others. Second, the inferences from the entropy balancing in this non-randomised study rely on the assumption that all relevant patient-related covariates have been included and that no unobserved confounders exist ('unconfoundedness assumption') [38]. This assumption is not empirically testable because it is impossible to measure hidden confounders. For instance, COPD patients participating in the telemonitoring programme might be more motivated to address their disease, have a healthier lifestyle or more social support than those who did not enrol. In particular, the final inclusion of the patients into the TM programme was within the discretion of the TM provider, introducing a potential source of selection bias. However, we minimised the impact of potential hidden confounders by constructing a DiD estimation framework, which even accounts for unobserved differences. Moreover, we conducted an

extensive sensitivity analysis to verify the robustness of our results.

## Conclusion

This is the first German study to demonstrate that telemonitoring for COPD is a viable technology that reduces mortality, healthcare costs and utilisation at 12 months. Contrary to widespread fear, lowering the intensity of care does not seem to impact unfavourably on health outcomes. Subgroups with severe COPD benefit more from the technology than patients with lighter forms of the disease. It remains to be seen, however, whether these positive results are constant over a longer observation period. Future improvements in predicting exacerbations through more powerful algorithms and the use of wearable and mobile devices will underpin the case for a system-wide implementation of telemonitoring for COPD. It should be stressed, however, that telemonitoring alone will not suffice in providing high-quality treatment for COPD patients. Instead, telemonitoring should be introduced as a supporting component of integrated case management, which approaches COPD and its comorbidities holistically.

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## Compliance with ethical standards

**Funding** TS and JS have received funding from AOK Bayern, a sickness fund, and SHL Telemedizin, a provider of telemonitoring services. The sponsors had no role in study design, analyses or interpretation of results.

**Conflict of interest** JS and TS have received funding for conducting the formal programme evaluation that this manuscript is based upon from AOK Bayern, a sickness fund, and SHL Telemedizin, a company offering telemonitoring services.

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## Appendix

See Table 5.

**Table 5** Elixhauser comorbidity groups, pharmacy-based metrics and other (disease-specific) variables before and after entropy balancing with balance statistics

	TM (in %)	Control (in %)		<i>p</i> value <sup>a</sup>		D-statistic <sup>b</sup>	
		Pre	Post	Pre	Post	Pre	Post
<b>Elixhauser comorbidity groups</b>							
(1) Congestive heart failure	31.49	36.17	31.49	<0.05	1	0.10	0.00
(2) Cardiac arrhythmias	19.97	25.43	19.97	<0.01	1	0.13	0.00
(3) Valvular disease	9.83	11.18	9.83	0.3272	1	0.04	0.00
(4) Pulmonary circulation disorders	9.22	10.00	9.22	0.5837	1	0.03	0.00
(5) Peripheral vascular disorders	22.43	21.58	22.43	0.6191	1	0.02	0.00
(6) Hypertension uncomplicated	72.20	74.37	72.20	0.2239	1	0.05	0.00
(7) Hypertension complicated	17.97	22.08	17.97	<0.05	1	0.10	0.00
(8) Paralysis	2.76	2.95	2.76	0.9034	1	0.01	0.00
(9) Other neurological disorders	3.99	3.89	3.99	0.833	1	0.01	0.00
(10) Chronic pulmonary disease	99.69	92.17	99.69	<0.001	1	0.39	0.00
(11) Diabetes uncomplicated	31.18	33.09	31.18	0.3377	1	0.04	0.00
(12) Diabetes complicated	13.21	14.52	13.21	0.382	1	0.04	0.00
(13) Hypothyroidism	18.43	17.17	18.43	0.4165	1	0.03	0.00
(14) Renal failure	13.06	19.74	13.06	<0.001	1	0.18	0.00
(15) Liver disease	21.51	18.93	21.51	0.1182	1	0.06	0.00
(16) Peptic ulcer disease excluding bleeding	2.46	2.26	2.46	0.6811	1	0.01	0.00
(17) AIDS/HIV	0.15	0.06	0.15	0.3572	1	0.03	0.00
(18) Lymphoma	0.00	0.00	0.00	–	1	–	–
(19) Metastatic cancer	0.00	0.00	0.00	–	–	–	–
(20) Solid tumor without metastasis	0.15	0.06	0.15	0.3572	1	0.03	0.00
(21) Rheumatoid arthritis	7.83	6.87	7.83	0.3347	1	0.04	0.00
(22) Coagulopathy	1.69	1.43	1.69	0.6059	1	0.02	0.00
(23) Obesity	31.80	24.98	31.80	<0.001	1	0.15	0.00
(24) Weight loss	4.76	4.19	4.76	0.4762	1	0.03	0.00
(25) Fluid and electrolyte disorders	27.80	30.41	27.80	0.1807	1	0.06	0.00
(26) Blood loss anemia	0.77	0.68	0.77	0.8021	1	0.01	0.00
(27) Deficiency anemias	4.45	5.12	4.45	0.5135	1	0.03	0.00
(28) Alcohol abuse	11.67	7.92	11.67	<0.01	1	0.13	0.00
(29) Drug abuse	3.38	2.27	3.38	0.0794	1	0.07	0.00
(30) Psychoses	2.30	2.23	2.30	0.8895	1	0.01	0.00
(31) Depression	34.41	28.93	34.41	<0.01	1	0.12	0.00
<b>Pharmacy-based groups</b>							
(1) Antiplatelet	7.83	8.36	7.83	0.7106	1	0.02	0.00
(2) Anticoagulant	10.91	14.69	10.91	<0.01	1	0.11	0.00
(3) Epilepsy	10.29	9.21	10.29	0.3593	1	0.04	0.00
(4) Hypertension	18.59	19.74	18.59	0.5029	1	0.03	0.00
(5) HIV	0.15	0.10	0.15	0.507	1	0.02	0.00
(6) Tuberculosis	0.31	0.30	0.31	1	1	0.00	0.00
(7) Rheumatic conditions	64.06	46.20	64.06	<0.001	1	0.36	0.00
(8) Hyperlipidemia	34.56	32.60	34.56	0.3156	1	0.04	0.00
(9) Malignancies	0.31	0.27	0.31	0.6965	1	0.01	0.00
(10) Parkinson's disease	2.00	2.51	2.00	0.5088	1	0.03	0.00
(11) Renal disease	0.61	0.92	0.61	0.6609	1	0.04	0.00
(12) End stage renal disease (ESRD)	0.31	0.44	0.31	1	1	0.02	0.00
(13) Anti-arrhythmic	2.00	6.29	2.00	<0.001	1	0.22	0.00



Table 5 continued

	TM (in %)	Control (in %)		<i>p</i> value <sup>a</sup>		D-statistic <sup>b</sup>	
		Pre	Post	Pre	Post	Pre	Post
(14) Ischemic heart disease/angina	7.07	9.47	7.07	<0.05	1	0.09	0.00
(15) Congestive heart failure	66.67	70.71	66.67	<0.05	1	0.09	0.00
(16) Diabetes	20.74	21.14	20.74	0.841	1	0.01	0.00
(17) Glaucoma	3.53	4.56	3.53	0.2746	1	0.05	0.00
(18) Liver failure	0.31	0.71	0.31	0.3184	1	0.06	0.00
(19) Acid peptic disease	62.67	56.62	62.67	<0.01	1	0.12	0.00
(20) Transplantation	0.92	0.75	0.92	0.635	1	0.02	0.00
(21) Respiratory illness, asthma	98.62	83.77	98.62	<0.001	1	0.54	0.00
(22) Thyroid disorders	22.12	19.98	22.12	0.2017	1	0.05	0.00
(23) Gout	15.51	16.62	15.51	0.5081	1	0.03	0.00
(24) Inflammatory bowel disease, chronic	1.23	0.70	1.23	0.1453	1	0.05	0.00
(25) Pain and inflammation	61.14	55.54	61.14	<0.01	1	0.11	0.00
(26) Pain	19.66	17.95	19.66	0.2872	1	0.04	0.00
(27) Depression	30.72	24.66	30.72	<0.001	1	0.14	0.00
(28) Psychotic illness	6.61	5.35	6.61	0.1762	1	0.05	0.00
(29) Bipolar disorders	0.31	0.21	0.31	0.6501	1	0.02	0.00
(30) Anxiety and tension	11.67	11.31	11.67	0.796	1	0.01	0.00
(31) Hepatitis	0.00	0.09	0.00	1	1	0.04	0.00
(32) Ischemic heart disease	51.15	54.99	51.15	0.0641	1	0.08	0.00
Other matching variables							
Female (in %)	43.93	49.17	43.93	<0.05	1	0.11	0.00
Age	64.24	69.47	64.24	<0.001	1	0.49	0.00
Tobacco addiction	39.63	23.64	39.63	<0.001	1	0.35	0.00
FEV <sub>1</sub> values							
FEV <sub>1</sub> ≥ 70 %	6.91	7.25	6.91	0.8125	1	0.01	0.00
70 % > FEV <sub>1</sub> ≥ 50 %	17.20	17.28	17.20	1	1	0.00	0.00
50 % > FEV <sub>1</sub> ≥ 35 %	24.73	17.75	24.73	<0.001	1	0.17	0.00
FEV <sub>1</sub> < 35 %	39.63	25.20	39.63	<0.001	1	0.31	0.00
FEV unknown	11.52	32.51	11.52	<0.001	1	0.52	0.00
DMP enrolment	62.21	37.16	62.21	<0.001	1	0.52	0.00
Insurance status							
Mandatory	29.03	21.77	29.03	<0.001	1	0.17	0.00
Pensionary	64.98	71.69	64.98	<0.001	1	0.14	0.00
Voluntary	5.99	6.54	5.99	0.6774	1	0.02	0.00

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