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7 CENTERS FOR MEDICARE AND MEDICAID SERVICES

8 Medicare Evidence Development & Coverage

9 Advisory Committee

10

11 (Meeting Held Via Webex)

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16 July 22, 2020

17

18 Centers for Medicare and Medicaid Services

19 7500 Security Boulevard

20 Baltimore, Maryland

21

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23

24

25

1 Panelists

2

3 Chairperson

4 Peter Bach, MD, MAPP

5

6 Vice-Chair

7 Joseph Ross, MD, MHS

8

9 MEDCAC Members

10 Timothy J. Barreiro, DO, MPH, FCCP, FACOI

11 Anita Fernander, PhD, ABPBC

12 Michael J. Fisch, MD, MPH, FACP, FAAHPM

13 Melissa M. Garrido, PhD, BS

14 Kim Kuebler, DNP, APRN, ANP-BC

15 Greg Manship, DBe, Mdiv, MA

16 Joy Melnikow, MD, MPH

17 Carla Perissinotta, MD, MPH

18 Marcel Salive, MD, MPH

19

20 CMS Liaison

21 Joseph Chin, MD

22

23 Industry Representative

24 Laura Mauri, MD

25

3

1 Panelists (Continued)

2

3 Guest Panel Members

4 Gerard J. Criner, MD, FACP, FACCP

5 Peter C. Gay, MD

6 Neil MacIntyre, MD

7

8 Invited Guest Speakers

9 John M. Coleman III, MD

10 Michael E. Wilson, MD

11

12 MEDCAC Coordinator

13 Tara Hall

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1 PANEL PROCEEDINGS

2 (The meeting was called to order at
3 8:00 a.m., EDT, Wednesday, July 22, 2020.)

4 MS. HALL: I want to welcome the
5 committee chairperson, vice chairperson,
6 members and guests to our first virtual MEDCAC
7 meeting. I am Tara Hall, the Medicare Evidence
8 Development and Coverage Advisory Committee
9 coordinator.

10 The committee is here today to look at
11 the state of evidence on home use of
12 noninvasive positive pressure ventilation in
13 patients with chronic respiratory failure
14 consequent to chronic obstructive pulmonary
15 disease. We are seeking the MEDCAC's
16 recommendations regarding the characteristics
17 that define those patient selections and usage

18 criteria, concomitant services and equipment
19 parameters necessary to best achieve positive
20 patient health outcomes in beneficiaries with
21 CRF consequent to COPD.

22 The following announcement addresses
23 conflict of interest issues associated with
24 this meeting and is made part of the record.
25 The conflict of interest statute prohibits

7

1 government employees from participating in
2 matters that could affect their or their
3 employer's financial interests. Each member
4 will be asked to disclose any financial
5 conflicts of interests during the introduction.
6 We ask in the interest of fairness that all
7 persons making statements or presentations
8 disclose if you or any member of your immediate
9 family owns stock or has another formal
10 financial interest in any company, including
11 any Internet or e-commerce organization, that
12 develops, manufactures, distributes and/or
13 markets consulting, evidence reviews or
14 analysis or other services related to the use
15 of CPAP, BPAP or mechanical ventilators. This
16 includes direct financial investments,

17 consulting fees and significant institutional
18 supports. If you require a financial
19 disclosure statement, please email Leah
20 Cromwell so she can send you the form for
21 completion. Her email is Leah, L-E-A-H, dot
22 Cromwell, C-R-O-M-W-E-L-L, 1@cms.hhs.gov.

23 We ask that all presenters adhere to
24 the time limits. We have numerous presenters
25 to hear from and a tight agenda; therefore, we

8

1 cannot allow for extra time. During each
2 presentation I will let the presenters know
3 when they have hit their halfway mark and when
4 they have a minute remaining to help the
5 presenters stay within their allotted time.
6 Presenters will receive a prompt prior to their
7 speaking time to ensure they are ready to
8 present.

9 During the open public comments,
10 attendees who wish to address the panel will be
11 given that opportunity on a first come basis.
12 Please email Leah Cromwell if you want to
13 address the panel by 9:30 a.m. eastern standard
14 time.

15 For the record, voting members present
16 for today's meeting are Joseph Ross, Timothy
17 Barreiro, Greg Manship, Anita Fernander, Kim
18 Kuebler, Michael Fisch, Melissa Garrido, Joy
19 Melnikow and Marcel Salive. A quorum is
20 present and no one has been excused because of
21 conflicts of interest.

22 The entire panel, including nonvoting
23 members, will participate in the voting
24 process. The voting results will be available
25 on our website following the meeting.

9

1 We ask that all speakers state their
2 name each time they speak, speak slow and
3 precise so everyone can understand, speak
4 directly into your computer mic, and do not use
5 your speaker phone to help achieve best audio
6 quality. Insure your devices are on mute if
7 not speaking and while speaking, please place
8 the ringers on silent. Remove pets from your
9 area and anything else that will minimize
10 distractions and limit background noises.

11 This meeting is being held virtually
12 in addition to the transcriptionist. By your
13 attendance you are giving consent to the use

14 and distribution of your name, likeness and
15 voice during the meeting. You are also giving
16 consent to the use and distribution of any
17 personally identifiable information that you or
18 others may disclose about you during today's
19 meeting. Please do not disclose personal
20 health information.

21 In the spirit of the Federal Advisory
22 Committee Act and the Government in the
23 Sunshine Act we ask that the advisory committee
24 members take heed that their conversations
25 about the topic in hand take place in the open

10

1 forum of the meeting. We are aware that many
2 attendees including the media are anxious to
3 speak with the panel about these proceedings.
4 However, CMS and the committee will refrain
5 from discussing the details of this meeting
6 with the media until its conclusion. Also, the
7 committee is reminded to please refrain from
8 discussing the meeting topics during breaks or
9 lunch.

10 And now I would like to turn the
11 meeting over to Dr. Joseph Chin, CAG deputy

12 director.

13 DR. CHIN: Thank you, Tara, and good
14 morning. Good morning, panelists and
15 participants. I would also like to thank
16 Dr. Peter Bach and Dr. Ross, our chair and vice
17 chair, and the panel members who are really
18 helping us by participating on this MEDCAC.

19 We have an important topic that we're
20 discussing, the chronic pulmonary disease.
21 It's very prevalent in the population and our
22 decisions on these types of devices date back
23 to 2001. So there's been a number of
24 developments and much evidence that has been
25 published since then, so it's helpful to get

11

1 input into what the evidence is showing at this
2 point. We appreciate the input of the MEDCAC
3 to help us fully judge the strength of the
4 evidence to go through a very complex sort of
5 environment with the number of different
6 devices that have come into use since our last
7 decision. So I think we should see fully based
8 on good interaction with patients and your
9 comments, the MEDCAC does not make coverage
10 determinations but your input and your review

11 of the evidence does inform our decisions and
12 our decision-making, so again, appreciate that.

13 And our team Tara, John and Michele
14 and our division are here to support the
15 meeting and if you have any questions or
16 difficulties during the day please email them.
17 Since this is our first virtual meeting I think
18 as glitches occur we will try to work through
19 them as quickly as possible, and ask for some
20 patience during those times, but again, thank
21 you and we look forward to the day, so I'll
22 turn it back over to our chair, Dr. Bach.
23 Thank you.

24 DR. BACH: Good morning, MEDCAC
25 members and speakers. Good morning, CMS staff.

12

1 I am the chair today. I think of myself, this
2 primary role as a ringleader, en emcee or
3 something like that. A lot of my role will be
4 to help the meeting move along to cover the
5 steps that we've all agreed are necessary to
6 have an open decision, to proceed with that
7 discussion and produce useful votes and
8 comments for the purposes of CMS's coverage

9 process. Part of this job for me is being a
10 bit of a pain with regards to speakers and
11 keeping everyone on time. I'll say in advance
12 that I will seek to stop you when your time is
13 up. It's not that you don't have important
14 things to say necessarily, it's not at all
15 that, it's just that we have an agenda and we
16 have other speakers to get to, and things can
17 very quickly fall off the rail. So with that
18 in mind, I will ask everyone if you are able to
19 and if not, let's discuss how to do it, is to
20 please open your chat windows. I've been
21 sending a couple of test chats both to CMS
22 staff and to some of the speakers this morning
23 already and not getting responses, so if you
24 can look in your chat, that will be a useful
25 way for me and probably for CMS people to

13

1 communicate with people individually about only
2 logistical things. A reminder to MEDCAC
3 members and panelists and speakers, panelists,
4 that we are supposed to communicate openly in
5 front of the panel and the public, so please no
6 chatting about anything that isn't logistical,
7 that all needs to be out in the open.

8 With that, I want to thank you again
9 for coming and participating in this process.
10 I think with that I will, we should get -- is
11 it okay, Tara, Joe, if we get started? We are
12 a little bit early. Let's get started with Dr.
13 Katonak's presentation.

14 MS. HALL: Rachel, are you ready?

15 DR. KATONAK: Yes. Good morning. My
16 name is Lieutenant Commander Rachel Katonak,
17 and I just want to reiterate, thank you for
18 everyone coming today and the panel members and
19 invited GOEFTS for taking the time and
20 dedication to participate in this important
21 event. Next slide.

22 The Center for Medicare and Medicaid
23 Services is conducting a Medicare Evidence
24 Development and Coverage Advisory Committee
25 panel to examine the scientific evidence

14

1 pertaining to the various types of noninvasive
2 positive pressure ventilation or NIPPV devices
3 in order to help us assess the characteristics
4 as to selection criteria, the usage parameters,
5 the associated services and equipment

6 parameters that are necessary to best achieve
7 positive patient health outcomes and
8 beneficiaries with chronic respiratory failure
9 that is consequent or related to COPD. Next
10 slide.

11 Chronic obstructive pulmonary disease
12 or COPD is a productive disease that can cause
13 acute and chronic respiratory failure which
14 interferes with the ability to breathe. Its
15 prevalence is heavy in our Medicare population.
16 Respiratory failure is a condition that may be
17 treated with various methods both pharmacologic
18 and non-pharmacologic. In certain individuals
19 NIPPV may be safely provided in the home and
20 improve the beneficiary's clinical condition.

21 For the administration of such
22 treatment, it's possible to choose from a
23 selection of equipment that for the purposes of
24 Medicare may be broadly classified into three
25 categories, from mechanical ventilators,

15

1 bilevel pressure positive airway pressure
2 devices or BPAP, and continuous positive airway
3 pressure devices or CPAP devices. Next slide.

4 CMS's national coverage determination

5 for durable medical equipment reference list
6 indicates that ventilators may be covered for
7 neuromuscular disease, thoracic restrictive
8 disease and chronic respiratory failure
9 consequent to COPD. However, when necessary,
10 each of these diseases may also be treated with
11 other types of respiratory equipment. The
12 choice of the appropriate treatment plan
13 including the determination to use a ventilator
14 versus BPAP versus a CPAP is based upon the
15 specifics of each individual and if it's a
16 serious medical condition. Next slide.

17 Currently there's substantial
18 variability and, you know, regarding the
19 prescribing patterns, guidelines and policies
20 for these types of devices, yet the
21 inappropriate prescription of such devices can
22 lead to clinical deterioration, poor quality of
23 life and ultimately death. We want to note
24 that from 2009 to 2019 the growth and the
25 number of Medicare beneficiaries receiving

16

1 ventilators has risen 1,278 percent, which is
2 of great concern to us. Next slides.

3 In the afternoon session today the
4 panel will vote and provide additional
5 discussion on the following questions which I'm
6 going to read for the record. We want to know
7 that the types of NIPPV devices being referred
8 to in the voting questions are used in the home
9 for chronic respiratory failure consequent to
10 COPD, and as I already mentioned, they're both
11 home mechanical ventilators, BPAP and CPAP
12 devices. Next slide.

13 Voting question number one: How
14 confident are you that the evidence is
15 sufficient to determine the patient selection
16 criteria that will improve health outcomes?
17 For example, laboratory values, comorbidities,
18 frequency of exacerbations requiring ER or
19 hospital admissions, hospital discharge timing,
20 pulmonary function tests, et cetera, when used
21 with any category of home NIPPV devices? Next
22 slide.

23 Voting question number two: How
24 confident are you that the evidence is
25 sufficient to determine the NIPPV equipment

2 patient-related outcomes? For example,
3 decreased mortality, decreased frequency of
4 exacerbations requiring ER or hospital
5 admission, increased time to hospital
6 readmission for respiratory-related disease,
7 and improved physical function and quality of
8 life. Next slide.

9 Voting question number three: How
10 confident are you that any improved
11 patient-related outcomes noted above made with
12 any type of NIPPV device in the home can be
13 attributed to the use of the equipment alone as
14 opposed to the concomitant provision of other
15 support services like home respiratory
16 therapists, home medication reconciliation and
17 repeated elective hospital admissions? Next
18 slide.

19 Voting question number four: How
20 confident are you that the evidence is
21 sufficient to provide the patient usage
22 parameters that are necessary to achieve the
23 successful patient outcomes in question two?

24 Thank you.

25 DR. BACH: Thank you very much for

1 that presentation, and thank you on top of that
2 for ending early.

3 I already have messed up in my role as
4 chair because I was supposed to ask each of the
5 MEDCAC members, panelists to both introduce
6 themselves and state their conflicts. I'm
7 going to call out names, I'll start with
8 myself.

9 I'm Peter Bach, I'm chair of the
10 MEDCAC. I'm a physician at Memorial
11 Sloan-Kettering Cancer Center, and I have no
12 conflicts in relation to this meeting.

13 I call on my vice chair Joe Ross to
14 introduce himself and also describe his
15 conflicts, if any.

16 DR. ROSS: Good morning, everyone. My
17 name is Joe Ross, I'm a general internist and
18 on the faculty at Yale and also the vice chair
19 of MEDCAC, and I have no conflicts as it
20 relates to this meeting.

21 DR. BACH: Peter Bach again. I also
22 remind the panelists please to turn on their
23 cameras as part of doing this in the public.
24 Everybody understands if you have to turn your
25 camera off for a second or so, but please turn

1 them on as part of your participation in this
2 meeting. I'll call next on Dr. Barreiro.

3 DR. BARREIRO: Good morning everybody,
4 my name is Tim Barreiro, I'm a pulmonary
5 critical care physician in Youngstown, Ohio,
6 and I have no conflicts of interest.

7 DR. BACH: Next, I have Dr. Fernandez.

8 DR. FERNANDER: Dr. Fernander. I am
9 on the faculty at the University of Kentucky
10 College of Medicine, I have no conflicts.

11 DR. BACH: Apologies for that. Dr.
12 Fisch?

13 DR. FISCH: Good morning, I'm Michael
14 Fisch, I'm a medical oncologist, internist and
15 palliative care physician. I'm a clinical
16 professor at M.D. Anderson Cancer Center and
17 I'm employed by AIMS Specialty Health. I have
18 no conflicts as pertains to this topic.

19 DR. BACH: Dr. Garrido?

20 DR. GARRIDO: My name is Melissa
21 Garrido, a health economist and on the faculty
22 at Boston University's School of Public Health
23 and the Partnered Evidence-Based Policy
24 Resource Center at the Boston VA Healthcare
25 Center, and I have no conflicts of interest.

1 DR. BACH: Thank you. Dr. Kuebler?

2 DR. KUEBLER: Good morning, I'm
3 Dr. Kim Kuebler. I am the director of the
4 Multiple Chronic Conditions Research Center,
5 I'm a specialty provider in spine and
6 orthopedics, and I have no conflicts of
7 interest.

8 DR. BACH: Thank you. Dr. Manship?
9 Greg Manship? Okay. I know we saw him earlier
10 today but all right, I will go on. Dr.
11 Melnikow? Oh, no.

12 MS. HALL: You're on mute.

13 DR. MELNIKOW: Can you hear me now?

14 DR. BACH: Yes. Hi, Dr. Melnikow, can
15 you hear me?

16 DR. MELNIKOW: Yes, sorry about that.

17 DR. BACH: Something froze. Please go
18 ahead and introduce yourself and state your
19 conflicts.

20 DR. MELNIKOW: I'm Joy Melnikow at the
21 University of California, Davis. I'm a family
22 physician and I direct the Center for Health
23 Care Policy and Research, and I have no

24 conflicts of interest.

25 DR. BACH: Great, thank you. And I

21

1 don't know, I think we sort of got frozen there

2 for a second. Is Dr. Manship on?

3 DR. MANSHIP: Yes. Can you hear me

4 now?

5 DR. BACH: Yes, hi. Good morning.

6 DR. MANSHIP: Hello. Greg Manship, I

7 currently serve as the manager of the Human

8 Subject Protection Program for OSF Healthcare

9 that is headquartered in Peoria, Illinois, and

10 I have no conflicts to disclose for this

11 meeting.

12 DR. BACH: Thank you very much. And

13 Dr. Salive?

14 DR. SALIVE: I am Marcel Salive, I'm a

15 physician at the National Institute on Aging,

16 NIH, and I have no conflicts.

17 DR. BACH: Great, thank you very much.

18 I think, Tara, we might as well introduce the

19 other members. I don't know, Tara, if

20 conflicts need to be disclosed for them, I

21 can't recall.

22 MS. HALL: You said presenters?

23 DR. BACH: It's just Laura Mauri,
24 industry rep, and the guest panel members.
25 MS. HALL: Yes, okay, we can start

22

1 with them.
2 DR. MAURI: So good morning, everyone,
3 I'm Laura Mauri, I'm an interventional
4 cardiologist, I'm employed by Medtronic and I'm
5 the industry representative. And as a
6 disclosure, Medtronic does manufacture
7 ventilators although in the United States not
8 for home use; outside of the U.S. they are
9 occasionally used for home use.
10 DR. BACH: Thank you. Dr. Criner?
11 DR. CRINER: Yes. I'm the chair,
12 thoracic medicine and surgery at Temple
13 University School of Medicine. I have research
14 grants from Fillantrust (phonetic) regarding
15 noninvasive ventilation, and I have about
16 \$1,500 of consulting fees with them in study
17 design over the last five years.
18 DR. BACH: Great, thank you very much.
19 Dr. MacIntyre?
20 Dr MacIntyre: This is Neil MacIntyre, I'm

21 a professor at Duke University in pulmonary and
22 critical care medicine. I do intermittent
23 consulting with VieAir, Pentec and HillRon, all
24 of whom do, are in the noninvasive ventilation
25 field. I primarily advice their engineers, I'm

23

1 not involved in their marketing.

2 DR. BACH: Thank you very much.

3 Dr. Gay?

4 DR. GAY: Pete Gay, I'm a professor at
5 Mayo Clinic Rochester pulmonary and critical
6 care and sleep medicine, and sadly I have no
7 conflicts at this time.

8 DR. BACH: We will see what we can do
9 about that. All right, so I think we can
10 proceed now. The first speaker, invited
11 speaker was Dr. Coleman, who can introduce
12 himself, state his conflicts, and then we can
13 proceed with his presentation. Dr. Coleman,
14 I'll hand it over to you for your review.

15 DR. COLEMAN: Can you hear me?

16 DR. BACH: Yes.

17 DR. COLEMAN: Okay. I thought I was
18 going after Dr. Wilson, I just wanted to
19 clarify.

20 DR. BACH: You know what, you're
21 absolutely right, you are, it's my mistake.
22 I'm having a rough morning. Again, I'm not in
23 my caffeine therapeutic window. I apologize.
24 Thank you for your presentation, Dr. Coleman,
25 we will now go to Dr. Wilson. Again, my

24

1 apologies.
2 DR. WILSON: Good morning. Can you
3 hear me okay?
4 DR. BACH: Yes, Dr. Wilson.
5 DR. WILSON: Okay.
6 DR. BACH: So we will get your slides
7 up here and again, my apologies.
8 DR. WILSON: Excellent, thank you.
9 It's really a delight to be here. My name is
10 Michael Wilson, I am a pulmonary critical care
11 physician at the Mayo Clinic in Rochester,
12 Minnesota, and also an investigator with the
13 Mayo Clinic evidence-based practice center.
14 And the topic is to discuss noninvasive
15 positive pressure ventilation in the home in
16 patients with COPD. This was part of a large
17 systematic review that our evidence-based

18 practice center performed in the past two years
19 or so regarding noninvasive positive pressure
20 ventilation in the home for all disease
21 conditions, and today we will speak on patients
22 with COPD. Next slide.
23 I would like to thank the director and
24 associate director of our evidence-based
25 practice center and all of the colleagues that

25

1 we worked with on this systematic review
2 practice, Dr. Hassan Murad and Dr. Zhen Wang.
3 Next slide.
4 The full report of this systematic
5 review is available through the AHRQ website
6 and of note, a portion of the report regarding
7 patients with COPD was published in JAMA in the
8 past year. Next slide.
9 I have no relevant disclosures in
10 relationship to this project or this meeting.
11 Next slide.
12 I would also like to acknowledge the
13 multiple other people who were involved in this
14 project, so colleagues at AHRQ, Dr. Lionel
15 Banez, Dr. Elise Berliner, and colleagues at
16 CMS, Dr. Susan Miller and James Rollins. And

17 in addition we have several key informants who
18 helped guide this project and several peer
19 reviewers who reviewed the final report and
20 gave significant input, and I would like to
21 thank all of them. Next slide.

22 Okay. So let's start a little bit
23 with the background, and we discussed this just
24 a little bit, but the condition that we are all
25 here to discuss today is chronic respiratory

26

1 failure, usually an inability to maintain
2 normal oxygen or carbon dioxide levels, and
3 this is a condition that goes on for some time
4 and it's not just an acute issue for these
5 patients. As discussed before, there can be
6 many different types of causes of chronic
7 respiratory failure, COPD, thoracic restrictive
8 disorders, neuromuscular diseases, obesity
9 hypoventilation syndrome and additional causes
10 as well, and if chronic respiratory failure is
11 not adequately treated there can be low oxygen
12 levels, there can be high carbon dioxide
13 levels, and there can be potentially
14 significant consequences associated with it,

15 including possible decreased quality of life,
16 sleepiness, hospital admission, intubation,
17 respiratory arrest, even death, and there's a
18 high health care utilization and cost
19 associated with each of these things. Next
20 slide.

21 So one treatment for chronic
22 respiratory failure is noninvasive pressure
23 ventilation. In its most basic form it
24 consists of a machine and a hose and a mask or
25 mouthpiece or some other noninvasive interface.

27

1 And in the home this is typically at least
2 initially delivered usually at nighttime so
3 nocturnal use, although some patients may use
4 it at night, some patients may use it during
5 the day, and some patients may use it nearly
6 continuously during the daytime and the
7 nighttime.

8 As discussed before, there's three
9 general types of machines that can deliver
10 noninvasive positive pressure ventilation. The
11 first is a BPAP machine or a Bi-PAP machine;
12 second is a home mechanical ventilator machine;
13 and the third would be a CPAP machine. Next

14 slide.

15 So there's different settings. Yeah,
16 so previous slide. Thank you. So under BPAP,
17 there can be different settings or different
18 modes for a BPAP machine. Some examples
19 include BPAP S or BPAP spontaneous, which is
20 where you have a positive pressure when you
21 inspire, you have a positive pressure when you
22 expire, and there's no backup rate. You can
23 have BPAP SP where you have a backup rate added
24 on to that. You can have volume assured
25 pressure support which tries to target a

28

1 certain minimum ventilation or a certain tidal
2 volume, and there's other settings for BPAP
3 machines.

4 Home mechanical ventilator machines,
5 some common modes of ventilation in these types
6 of devices include pressure support, pressure
7 control, volume assist control where you can
8 give a preset tidal volume in addition to
9 others. Next slide.

10 So there's quite a bit of variability
11 between these different types of machines, BPAP

12 machine, home mechanical ventilator machine or
13 a CPAP. Some machines are approved to be used
14 through noninvasive or invasive interfaces. An
15 invasive interface in the chronic setting would
16 usually mean a tracheostomy. They can differ
17 in their modes of ventilation, they differ in
18 the respiratory circuits, monitoring
19 capability, safety and alarm systems, internal
20 battery life, form of oversight and servicing,
21 as well as the ability to perform device
22 maneuvers such as long volume recurring. Next
23 slide.

24 So there's several clinical dilemmas
25 including, there's marked variability in usage,

29

1 prescribing patterns, policies and guidelines
2 of these different devices and the questions
3 remain which devices are optimal for which
4 patient population and how do these impact
5 outcomes. Next slide.

6 The objectives of our systematic
7 review were to evaluate noninvasive positive
8 pressure ventilation in adult patients with
9 chronic respiratory failure in terms of
10 initiation criteria, effectiveness, equipment

11 parameters, respiratory services and adverse
12 events. Next slide.
13 The key questions we had for our
14 systematic review are based on those questions,
15 including which characteristic criteria were
16 used when initiating noninvasive positive
17 pressure ventilation, what was the effect of
18 these different devices on patient outcomes,
19 which equipment parameters were used and which
20 home services were provided. Next slide.

21 So now I'll go to the methods of a
22 systematic review and then analysis that we
23 performed. Next slide.

24 So first we defined the study
25 eligibility criteria and this is where we used

30

1 stakeholder and key informant input. We
2 performed a literature review including nine
3 databases. We evaluated studies for possible
4 inclusion. We assessed the risk of bias of
5 individual studies. We abstracted the data and
6 outcomes of those individual studies. We
7 performed a meta-analysis where we looked at
8 where possible the outcomes of all studies

9 combined together. We assessed the strength of
10 evidence based on all of this for the four main
11 outcomes, and then we wrote the report which
12 was then peer reviewed and with input from
13 public commentary as well. Next slide.

14 So here are the inclusion criteria and
15 exclusion criteria that we used. So the
16 population is adults 18 years of age or older.
17 We did not evaluate pediatric patients.
18 Interventions were any studies that used any of
19 these types of machines through a noninvasive
20 mask or mouthpiece interface. We evaluated
21 studies which had a comparative arm, so
22 compared device use to usual care or no device
23 use, or compared one device use to a different
24 type of device use, or one type of mode from
25 one device to another type of mode. Studies

31

1 needed to include one of these following
2 outcomes; the four primary outcomes that we
3 looked at were mortality, hospitalization, need
4 for intubation and quality of life, with a wide
5 variety of secondary outcomes including ICU
6 admission, outpatient visits, ER visits,
7 exacerbations, ADLs, dyspnea, sleep quality,

8 exercise tolerance, and adverse events.
9 Timing, we evaluated studies that enrolled
10 patients where they used the device at least
11 one month in the home setting, and we evaluated
12 patients who used the device in the home or
13 assisted living settings. Study designs, we
14 included randomized controlled trials, we also
15 included nonrandomized comparative studies,
16 prospective and retrospective, as well as
17 looking at relevant systematic reviews and
18 current clinical guidelines. We did not
19 include before and after studies with single
20 arm intervention. We evaluated studies that
21 were published in the medical literature from
22 1995 up until November 6, 2019. Next slide.

23 For the four main study outcomes which
24 were mortality, need for intubation, quality of
25 life and hospital admission, we assessed each

32

1 one of these outcomes as strength of evidence
2 according to published criteria. So for
3 example, high strength of evidence means that
4 we are confident that the estimate of effect
5 lies close to the true effect and that the body

6 of evidence has no deficiencies and was judged
7 to be stable. Moderate, the body of evidence
8 has some deficiencies and is likely to be
9 stable. Low strength of evidence means that we
10 have limited confidence that the estimate of
11 effect lies close to the true effect, or
12 estimate of effect that we found in the
13 systematic review lies close to the true effect
14 of what actually exists. And insufficient
15 evidence means we could not make a conclusion
16 about the strength of evidence. Next slide.

17 So the determinants -- so thank you.

18 So the determinants to come up with the
19 strength of evidence include the study
20 limitations, so each study was individually
21 assessed for risk of bias, the directness of
22 the evidence to the key questions, the
23 consistency of the results, precision, and
24 publication bias. Next slide.

25 Okay. So now I'll go to the results

33

1 of this review that we performed. Next slide.
2 So for all of these categories we looked at
3 about 6,000 abstracts. We looked at a thousand
4 full texts and included 68 studies in our

5 review on all disease categories. Of those,
6 studies evaluated patients with COPD. In
7 addition to that, we did find 13 current
8 guidelines as of 2019 regarding home
9 noninvasive positive pressure ventilation. Of
10 note, among the 68 studies that we included,
11 the majority were published, the majority of
12 the published studies were performed in Europe
13 with a few in the United States and throughout
14 other parts of the world. Next slide.

15 So here's the first key question.
16 What characteristics criteria were considered
17 when initiating noninvasive positive pressure
18 ventilation in patients with COPD? To cut to
19 the chase, they were widely variable amongst
20 all of the different studies. Some studies
21 used one criteria to start home NIPPV, some
22 studies used criteria to start home NIPPV.
23 Common criteria but not exclusive criteria were
24 let's start it in patients with COPD who have
25 hypercapnia. The definition of hypercapnia or

34

1 the cutoff range to enroll patients in this
2 study was quite variable as well, ranging from

3 a 45 to greater than 56 millimeters of mercury.
4 Studies often used pH above normal, or normal
5 or above, to enroll patients. Some studies
6 used hypoxia in addition to those other
7 criteria. And some studies, and studies often
8 used low FEV1 as part of the definition to
9 include patients with COPD. Next slide.

10 Oh, sorry, we'll go back, let's see,
11 oh, disease stability. Okay. So 24 studies
12 enrolled patients with quote-unquote stable
13 COPD which was defined as no recent
14 exacerbation. 11 studies enrolled patients
15 with unstable disease, so after hospitalization
16 for an exacerbation. And a few studies
17 enrolled patients with both stable and unstable
18 COPD, and one study did not. And I'm so sorry,
19 I can't really read the last bottom portion of
20 the slide. Okay, it's the next one.

21 So in addition to the criteria used to
22 start NIPPV, the processes used to titrate
23 NIPPV were also quite variable. Common
24 criteria included reduction of hypercapnia,
25 reduction in hypoxia including nocturnal

2 volumes, and a reduction in patient symptoms.
3 Some of the studies had quite elaborate
4 processes to titrate NIPPV including being
5 admitted to a hospital, and some studies
6 initiated and titrated an NIPPV at home, and
7 some studies just used preset criteria and did
8 not really use any process to titrate NIPPV at
9 all. Next slide.

10 So the next key question is what was
11 the effect of these different devices on
12 patient outcomes. So the first comparison is
13 studies that evaluated BPAP device use compared
14 with no device use and I've lifted the four
15 primary outcomes here, so mortality, hospital
16 admissions, need for intubation and quality of
17 life. So with regards to mortality we found
18 that there was lower mortality in patients who
19 used BPAP compared with no device. This was
20 based on 13 studies enrolling 1,400 patients
21 including eight randomized controlled trials
22 and five observational studies. The odds ratio
23 was .66, and 55 fewer deaths per thousand
24 patients in those who used BPAP compared to no
25 device. And our assessment of the extent of

1 evidence was moderate strength of evidence to
2 support this conclusion.

3 With regards to the number of hospital
4 admissions we found no difference in patients
5 who used BPAP compared with no device. Again,
6 this is based on five studies with low strength
7 of evidence.

8 One study reported the number of
9 patients with hospital admissions and this
10 study showed fewer hospital, fewer patients
11 with hospital admissions, and low strength of
12 evidence, in patients who used BPAP compared to
13 no device.

14 With regards to need for intubation or
15 the number of intubations we found that there
16 were fewer intubations in patients who used
17 BPAP compared to no device. This is based on
18 three studies and about 267 patients, with
19 moderate strength of evidence.

20 Regarding quality of life, we found no
21 difference in quality of life, and this was
22 based on ten studies and about a thousand
23 patients. Next slide.

24 If we look at secondary outcomes, so
25 again, this is in Bi-PAP or BPAP compared to no

1 device, here's all of the secondary outcomes we
2 looked at. So one study showed that the number
3 of emergency department visits was lower in
4 patients who used BPAP. The number of ICU
5 admissions was almost statistically significant
6 lower but not quite the number of patients with
7 ICU admissions -- sorry, there's a lot of
8 beeping on my computer and I'm going to just
9 shut this down. Okay.

10 So the number of patients with ICU
11 admissions based on one observational study was
12 lower. Regarding COPD exacerbations, four
13 studies majored this. There was no difference
14 between BPAP and no device used. Activities of
15 daily living, no difference. Dyspnea based on
16 six randomized controlled trials, there was a
17 statistically significant reduction in dyspnea
18 and, or sorry, improvement in dyspnea
19 associated with device use. No difference in
20 six-minute walk distance tests, and one
21 randomized controlled trial did show an
22 improvement of 72 meters in the shuttle walk
23 test amongst patients who used BPAP. Next
24 slide.

25 Now if we look at studies that

1 enrolled patients using HMV devices compared to
2 no device, there were far fewer studies who
3 reported this, so regarding mortality there was
4 no difference in mortality. This is based on
5 two observational studies. Regarding hospital
6 admissions, there was one study, it was
7 observational and it did show a reduction in
8 hospital admissions amongst patients who used
9 HMV devices compared with no device, and again,
10 this was a low strength of evidence.

11 If you look at studies that compared
12 HMV device use compared with BPAP use, there
13 was one observational study, and this showed
14 fewer patients with hospital admission. If you
15 look at HMV compared to CPAP use it was the
16 same study, a large observational study, and
17 the number of patients who used, I'm sorry, the
18 number of patients who required hospital
19 admission in the BPAP was lower compared to
20 those who used CPAP. Next slide.

21 We performed a subgroup analysis in
22 patients with stable COPD versus patients with
23 unstable COPD and we showed benefits, or there

24 were benefits in both of these groups. In
25 patients with stable COPD there was lower

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1 mortality, higher activities of daily living
2 and reduced dyspnea. In patients with unstable
3 COPD or recent exacerbation there was reduced
4 need for intubation. Next slide.

5 Based on reviewers' comments --

6 MS. HALL: No, you have 25 minutes
7 left.

8 DR. WILSON: Okay, thank you. Based
9 on reviewers' comments we performed a post-hoc
10 analysis to see if different CO2 initiation
11 thresholds had an impact on outcomes and there
12 were no direct comparisons, so no study
13 compared patients with, you know, CO2 of 46 to
14 49 versus higher or anything like that, so we
15 performed an indirect comparison regarding
16 this, and regarding mortality and
17 hospitalizations we found no statistically
18 significant differences regarding the level of
19 hypercapnia used to initiate home NIPPV.
20 Regarding quality of life there was a very
21 modest improvement or higher reduction in
22 quality of life for patients who had higher CO2

23 initiation thresholds. So for example, the
24 initiation threshold of 50 to 51 to 52, there
25 was a larger improvement in quality of life

40

1 compared to those studies where there was a
2 lower initiation threshold such as 45 to 49.
3 Again, this is very few studies and this was a
4 very, it was just very few studies to support
5 this and again, no direct comparisons to
6 evaluate this data. Okay, next slide.

7 So looking at other device comparisons
8 what we've done so far is BPAP compared to no
9 device, HMV compared to no device, and then
10 both of those compared to each other. If we
11 look at BPAP compared to CPAP there was one
12 study, number of patients with exacerbation was
13 mildly reduced but not significantly. If we
14 look at BPAP, volume assured pressure support
15 ventilation versus BPAP ST, there was one
16 randomized controlled trial that evaluated all
17 of these different outcomes, and basically did
18 not show any statistically significant
19 difference in outcomes. If you look at HMC
20 pressure controlled ventilation versus HMV

21 pressure support ventilation, no significant
22 difference in quality of life or six-minute
23 walk. If you look at length of use of patients
24 who were on BPAP on six months versus patients
25 who were on BPAP for less than six months,

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1 there was one randomized controlled trial which
2 showed mild increase in six-minute walk
3 distance that was statistically different, but
4 really no other difference in other outcomes
5 they measured. If you looked at a group of
6 patients that used either HMV or BPAP pressure
7 controlled ventilation high intensity versus
8 low intensity, there was no impact in quality
9 of life. Treatment adherence versus
10 nonadherence, there was one observational study
11 that showed a reduction in all-cause hospital
12 admissions that was statistically significant.
13 There was one randomized controlled trial that
14 looked at BPAP ST started in the home using
15 telemedicine versus BIPAP ST started in the
16 hospital and the outcomes there are listed,
17 with really no statistically significant
18 differences noted. Next slide.
19 So regarding the kind of main

20 outcomes, here are the forest plots from the
21 JAMA article on patients with COPD. So if you
22 can advance, so if you look at BPAP versus no
23 device those are the studies as were listed,
24 some are randomized controlled trials and some
25 are observational, and again, there was a

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1 reduction in mortality in this group.

2 If you look at HMV versus no device
3 there was no statistically significant
4 reduction in mortality and this is just based
5 on those two studies there. And then if you do
6 a pooled analysis, you know, combining all of
7 the studies together, BPAP or HMV versus no
8 device there was a statistically significant
9 reduction in mortality. Next slide.

10 Looking at hospital admissions again,
11 BPAP versus no device, there was no difference
12 in the number of hospital admissions. HMV
13 versus no device, one study, observational,
14 showed fewer hospital admissions with HMV. If
15 you combine all of those results together, it's
16 not statistically significant, the number of
17 hospital admissions. Next slide.

18 Number of intubations, BPAP versus no
19 device, there was a statistically significant
20 reduction and these are the studies that were
21 included in that analysis. Next slide.

22 These are the studies that evaluated
23 quality of life in BPAP versus no device.
24 Regarding HMV, there were no studies that
25 evaluated quality of life that met the

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1 inclusion criteria, and you can see the pooled
2 analysis at the bottom with the light green
3 diamond shape, shows that there might be a
4 slight improvement in quality of life but it is
5 not significant. Next slide.

6 Okay. So in summary for patients with
7 COPD based on this systematic review, our
8 conclusion was that HMV versus no device is
9 associated with fewer hospital admissions, low
10 strength of evidence. HMV compared to BPAP was
11 associated with fewer hospitalization
12 admissions, low strength of evidence. HMV
13 compared to CPAP was associated with fewer
14 hospital admissions, again very low strength of
15 evidence. BPAP compared to no device is
16 associated with lower mortality with a moderate

17 strength of evidence; reduced need for
18 intubation, moderate strength of evidence; and
19 fewer number of patients with hospitalizations,
20 low strength of evidence. Next slide, or
21 advance.

22 And again, there were a number of
23 secondary outcomes which had some improvements
24 and a number of secondary outcomes that had no
25 differences noted. Next slide.

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1 So key question three is which
2 equipment parameters were used in these studies
3 which enrolled patients using home NIPPV for
4 COPD. So the BPAP modes that were used and
5 described in these studies included BPAP S,
6 BPAP ST, BPAP volume assured pressure support,
7 pressure control, and some studies did not
8 specify which mode of BPAP they used. HMV
9 modes used pressure support and pressure
10 control. The prescribed daily usage for the
11 individual studies was quite variable. Studies
12 ranged in suggesting that their patients use
13 the device for greater than five hours,
14 although we have two greater than or equal to

15 eight hours a day in the BPAP studies, and up
16 to 12 hours a day in the HMV studies. And the
17 actual usage was a range; means nightly for
18 these patients included a mean of
19 four-and-a-half to nine hours amongst the
20 different studies. And again, there was
21 significant variability in these modes,
22 prescribed daily usage and actual usage for the
23 studies. Next slide.

24 Regarding home services, so there were
25 38 studies on COPD; only 15 of them talked

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1 about anything related to home services. The
2 home services that they discussed included a
3 telephone hot line staffed by nurses, scheduled
4 phone calls by a respiratory therapist, home
5 visits by respiratory therapists, smoking
6 cessation programs, and one study evaluated a
7 comprehensive home care program with evaluation
8 of physical, occupational and dietary needs in
9 addition to prescribing them the device.

10 At this time we did not find any
11 evidence or any studies that included criteria
12 which assessed the efficacy of, or the impact
13 of these different home services on the

14 outcomes of interests. Next slide.
15 Regarding adverse events, so we
16 categorized adverse events or either serious
17 adverse events or non-serious adverse events.
18 Examples of serious adverse events, so I guess
19 first of all, death, hospitalization need for
20 intubation are serious adverse events but we
21 characterized those as primary outcomes on this
22 study and not as adverse events. So the
23 adverse events were respiratory failure, any
24 life-threatening illness, any disability, any
25 required intervention or congenital anomaly or

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1 birth defect. Non-serious adverse events were
2 skin symptoms, eye symptoms, nose or mouth
3 symptoms, GI symptoms, device or mask
4 intolerance. Next slide.
5 So only 28 studies, and sorry, this is
6 going back to all studies on all disease
7 conditions, I will speak specifically about
8 COPD in just a second but only about a third,
9 and this is about the same for COPD, reported
10 adverse events. So the majority of studies did
11 not report adverse events and among those

12 studies that did report adverse events there
13 really was no consistent approach for
14 evaluating and reporting adverse events. But
15 if you look at all studies, for example in
16 these different device use categories, so for
17 example at the top, HMV, the incidence rate of
18 serious adverse events was quite low in all of
19 the categories, including the no device
20 category at the bottom. Then if you go to
21 non-serious adverse events for all patients who
22 used an at-home NIPPV of any type, or of these
23 different types, it's about 35 percent or
24 31 percent, or 27 percent or 39 percent, so
25 roughly a third of these patients experienced

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1 non-serious adverse events, and then none in
2 the groups of patients which used no device.
3 Next, or you can advance. Advance.
4 And here are the different types of
5 serious adverse events that were reported. So
6 there were several reports of acute respiratory
7 failure in patients, treatment failures, TIA,
8 stroke, arrhythmia, so these are the serious
9 adverse events that were reported in these
10 studies in patients who received these

11 different treatment arms. Again, very few
12 serious adverse events. Next slide.
13 We will go to the middle section, so
14 there was really no difference in adverse
15 events or treatment withdrawals in groups who
16 used the device compared to groups who did not
17 use the device or was amongst different devices
18 in comparisons. In patients with COPD, six
19 studies directly compared adverse events in
20 patients who used home NIPPV versus those who
21 did not use home NIPPV, and there was no
22 difference, statistically significant
23 difference in the total adverse events in those
24 groups. Next slide.
25 So that is the data for the systematic

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1 review that we did in patients with COPD.
2 Taking a step back, we realize that there are
3 significant limitations to the systematic
4 review and analysis that was performed. One of
5 the primary limitations is really the vast
6 variability and heterogeneity amongst all of
7 the different studies that were included,
8 including the devices used, the modes used, the

9 duration of use, the prescribed uses that
10 ancillary respiratory services provided, the
11 definitions of the outcomes, the measurement
12 tools to measure the different outcomes, the
13 follow-up length of time, the amount of time
14 the patients used these devices in the home.
15 In addition to that, the conclusions from this
16 are based really on low to moderate strengths
17 or moderate strength of evidence, suggesting
18 that for moderate strength of evidence the
19 conclusions are, we would estimate would likely
20 estimate a true effect in these different
21 categories, but for low strength of evidence
22 there is some, there's room for higher level or
23 higher quality studies. There's limited
24 evidence on studies that directly compare HMV
25 devices versus BPAP devices. There's limited

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1 evidence to evaluate the impact on clinical
2 outcomes of the initiation criteria, the
3 parameters that the home respiratory services
4 provided. Amongst many studies there's a lack
5 of reporting of the device type or the device
6 mode. Part of this might be that a lot of the
7 studies were done in Europe and there may be

8 less, well, there might be different
9 regulations in comparing different devices in
10 home devices in Europe compared to the United
11 States and other countries around the world.

12 There's a lack of consistent approach
13 to reporting adverse events with, you know,
14 two-thirds of studies not reporting adverse
15 events. We included studies that were
16 published only in English and excluded studies
17 that were not reported in English. Again, the
18 majority of studies were conducted in Europe
19 and the provision of home respiratory services
20 may be different or is different in several
21 European countries compared to the United
22 States, and some of the reporting of the home
23 respiratory services may not have been explicit
24 but rather implicit, and it's unclear.

25 And in addition, all the studies that

50

1 we included only enrolled patients who used
2 nocturnal COPD in the home. We did not find
3 studies that met our inclusion criteria where
4 there were patients in COPD who for hypercapnia
5 required daytime usage for COPD. In addition,

6 we were unable to assess for publication bias
7 because the number of studies was low in each
8 individual direct comparison. Next slide.

9 So there's several areas for future
10 research, I'm sure which many of you on this
11 phone call are well aware of, but there is room
12 to evaluate which devices and which modes are
13 best for which patient population, what is the
14 impact of home respiratory services on
15 outcomes, what are the initiation practices
16 which are optimally associated with improved
17 patient outcomes, and how do all of these
18 things differ or change when considering
19 patients who require daytime NIPPV support.

20 And again, this last one is probably more,
21 there's just fewer patients with COPD who use
22 daytime support but it does exist. Next slide.

23 So in conclusion, in patients with
24 COPD who use BPAP compared to no device, there
25 was lower mortality, lower intubations, fewer

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1 patients with hospital admissions, improved
2 dyspnea, no change in quality of life. In
3 patients who used home mechanical ventilator
4 devices compared individually with BPAP, CPAP

5 or no device, there were fewer hospital
6 admissions. These conclusions are based on low
7 to moderate strength of evidence as we could
8 assess them. Current comparative effectiveness
9 evidence is really not available to the impact
10 of many device capabilities on patient outcome.
11 The criteria to initiate and titrate home NIPPV
12 and home respiratory services are quite
13 variable and not really validated in
14 comparative studies included in this study.
15 And there's significant variability in the
16 devices used and the modes used for each of
17 these different devices. Next slide.

18 So that concludes our presentation, or
19 my presentation. I will turn it back to
20 Dr. Bach. I don't know if we have time for
21 questions now or if we want to save that for a
22 different time in the day. Thank you so much,
23 I really appreciate being here.

24 DR. BACH: Dr. Wilson, thank you very
25 much for that presentation, and it was

1 extraordinarily clear. Thank you also for
2 finishing on time, which I'm of course obsessed

3 about, you're actually early. The process for
4 you and everyone, we are going to hold
5 questions until we have had input from all
6 speakers and then there's a section immediately
7 after lunch where there can be questions to the
8 presenters, which would include Dr. Wilson, who
9 I assume knows he's with us for the entire day
10 or a better part of it.

11 So I'd like to move on now to Dr.
12 Coleman, it's your second time to start
13 presenting. I apologize again for my mess-up
14 earlier. So if we can pull up Dr. Coleman's
15 slides, great. Dr. Coleman, do we have you?

16 DR. COLEMAN: I'm here.

17 DR. BACH: Okay, and I'll ask everyone
18 to please open your chat windows also so that
19 for logistical issues we can be communicating
20 as are needed. So Dr. Coleman, thank you very
21 much for coming, and go ahead with your
22 presentation.

23 DR. COLEMAN: Great, thank you,
24 Dr. Bach. I am John Coleman, I am a professor
25 of pulmonary critical care and sleep medicine

1 at Northwestern University, and today I'm going

2 to talk about noninvasive ventilation in
3 chronic obstructive pulmonary disease. I thank
4 the panel for my time here today. I am a
5 clinician and spend the majority of my time
6 dealing with chronic respiratory failure so
7 it's an issue that's very important to me and
8 very relevant for everyone to hear about this.

9 Next slide.

10 I have no financial disclosure. Next
11 slide.

12 So my role today is to take you on a
13 journey of kind of what Dr. Wilson commented on
14 earlier, and we are going to talk about the
15 role of noninvasive ventilation in chronic
16 obstructive pulmonary disease. So we're going
17 to talk about, a little bit about the
18 epidemiology and pathophysiology of what we're
19 trying to achieve with noninvasive ventilation,
20 and then I'm going to take you through the data
21 that Dr. Wilson just went through and tell it
22 in a story. Chronic respiratory treatment has
23 evolved over time and I think that's very
24 important to an understanding of where we are
25 today and where do we go forward in the future.

1 I'm going to talk about the early stages of
2 noninvasive ventilation and then talk about how
3 the paradigm changed and how we are applying
4 its use in our clinic today. Next slide.

5 So in a pre-COVID world, COPD was the
6 fourth leading cause of death in the United
7 States and the third most common cause of
8 hospital readmission among the Medicare
9 population. It is a disease that has a high
10 burden both in quality of life and financially
11 and this in turn contributes to a strain on the
12 U.S. health system. Because of this strain and
13 the effect on people's quality of life, this
14 has led to an exploration of therapies beyond
15 traditional pharmacotherapies, pulmonary rehab
16 and oxygen, and this is where the role of
17 noninvasive positive pressure ventilation comes
18 into play. For my talk today so I'm clear,
19 when I say noninvasive ventilation I'm
20 referring to noninvasive positive pressure
21 ventilation, so you'll know what I'm referring
22 to. Next slide.

23 So what is the hypothesis, or what are
24 we trying to achieve with noninvasive
25 ventilation? (Unintelligible, static) and

1 improve respiratory mechanics, focusing
2 specifically on hypercapnia, so you'll see this
3 in two elements. We have emphysema starting at
4 the alveoli and we have chronic bronchitis.

5 Emphysema leads to a hyperinflation of
6 the lungs, the hyperinflation of the lungs from
7 emphysema increases the lower airway
8 resistance. This lower airway resistance puts
9 increased pressure on the diaphragm muscle,
10 increases the work of the diaphragm and it can
11 lead to diaphragm muscle atrophy. So as you
12 can see on the bottom of the slide, on the left
13 side you have a normal lung, you have the
14 regular diaphragm curvature, and then on the
15 right side you can see the hyperinflated lung.
16 The diaphragm is pushed down, the muscle fibers
17 are stretched. It is this combination of
18 diaphragm muscle atrophy and the increased area
19 of resistance that leads to an increased muscle
20 load for our patients with emphysema, and this
21 contributes to that (unintelligible). Next
22 slide.

23 So what are the goals of noninvasive
24 ventilation? So the target on NIV is to offset
25 this diaphragm dysfunction and actually achieve

1 a control of breathing with near abolition of
2 diaphragm activity, thus reducing hypercapnia.
3 We know from studies that chronic hypercapnia
4 can induce skeletal muscle dysfunction, it can
5 impact the function of the diaphragm. We also
6 know that chronic hypercapnia can lead to
7 suppress innate immunity, and reduce CO2 levels
8 which may reduce COPD exacerbations.

9 Today I'm going to talk about chronic
10 hypercapnia. It's well established in the
11 literature that noninvasive ventilation in this
12 study, versus COPD reservation, reduces
13 mortality, reduces COPD exacerbation and
14 reduces hospitalizations and length of stay.
15 What I'm going to do today is talk about
16 chronic COPD. Next slide.

17 So what does the data show? So I'm
18 going to talk you through the data that
19 Dr. Wilson kind of put together in his
20 meta-analysis, and kind of pull it out and
21 focus on how it has evolved over time.

22 So the story of COPD started around
23 the turn of the century as Dr. Chin mentioned

24 earlier, it was in 2001. So the first study
25 I'm going to talk about was done by Ciro

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1 Casanova. The purpose of the study was to look
2 at the role of COPD versus, the role of
3 noninvasive ventilation for severe COPD versus
4 long-term oxygen therapy. This was a
5 randomized controlled trial, they looked at 52
6 participants, and what they did in this trial,
7 they randomized noninvasive ventilation
8 spontaneous with no backup rate versus home
9 long-term oxygen therapy, and they included all
10 patients with an FEV1 of less than 45 percent.
11 The outcome of the study looked at the rate of
12 COPD exacerbation, hospitalizations,
13 intubations and mortality. They followed the
14 subjects for one year and what they saw in this
15 study was that after one year there was no
16 difference in mortality, intubations, or any
17 difference between interventions.

18 So this was followed by a study the
19 next year by (unintelligible) and colleagues.
20 This was a study that had 122 patients with
21 chronic hypercapnia, so they had LEV1 greater
22 than 50 percent in the study, and these

23 patients all had levels of hypoxia where they
24 required supplemental oxygen. It was a
25 multicenter prospective trial that looked at

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1 the role of noninvasive ventilation with a
2 backup rate and supplemental oxygen versus
3 long-term oxygen therapy alone, and the outcome
4 was, what was the change in hypercapnia with
5 CO₂ levels and hospitalizations? They followed
6 the patients out for a year and didn't see any
7 change in the hospitalizations, but what they
8 did notice was that the patients who did the
9 therapy longer actually had decreases in their
10 hypercapnia and CO₂ levels, and they actually
11 showed improvement in their dyspnea. Next
12 slide.

13 So this was followed by a large study
14 by Dr. McEvoy, so this was a study where they
15 (unintelligible) ventilation patients with
16 severe COPD for improved lung function,
17 survival and quality of life. It was a large
18 multicenter randomized controlled trial that
19 looked at the role of noninvasive ventilation
20 plus long-term oxygen therapy versus long-term

21 oxygen therapy alone. All these patients were
22 admitted to the hospital and started on
23 noninvasive ventilation over a period of three
24 to four days. They all had evidence of
25 hypercapnia with a baseline CO2 level of 46

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1 with the average being around 53. They were
2 also administered noninvasive ventilation in a
3 spontaneous mode, so BPAP without a backup
4 reading, and their average pressure was
5 somewhere around 13 to 5, and what they do is
6 they monitored CO2 levels.

7 What they saw in this study was that
8 people on the long-term therapy actually had
9 increases in their hypercapnia the next
10 morning. While there was an improvement in the
11 patients that -- while there wasn't as high an
12 increase in the patients using noninvasive
13 ventilation, there was still an increase in the
14 CO2 levels. And so again, there was no benefit
15 in this study that showed noninvasive
16 ventilation had any usefulness. They also
17 found in this study that patients started a
18 decline in the quality of life. Next slide.

19 So this was early around the turn of

20 the century, a lot of trials, randomized
21 controlled trials, not a lot of success, right?
22 These were well conducted randomized controlled
23 trials that showed no clear benefit, showed no
24 change in CO2 levels, it showed that survival
25 did not change. The (unintelligible) therapy

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1 and the readmission rates were not impacted.
2 Next slide.
3 So people with chronic severe COPD,
4 they kept having hospital readmissions.
5 Something, they were out of therapy, so the IPE
6 team guy said well, you know, it works in the
7 acute setting, why is it not working here? So
8 around this time a new paradigm for severe COPD
9 kind of evolved, and the thought process was
10 that if we give patients a larger inspiratory
11 pressure leading to a wider pressure support
12 difference, so if we give a higher IPAP
13 pressure and a low BPAP pressure, it will give
14 them a big pressure support and will increase
15 their tidal volume. If we increase their tidal
16 volume it will improve alveolar ventilation, if
17 you improve alveolar ventilation it will

18 improve gas exchange, if you improve gas
19 exchange it will improve CO2 levels. And so as
20 the CO2 level starts to go down the diaphragm
21 will relax, the muscles will get their strength
22 back, and so this was where the development of
23 what Dr. Wilson kind of led to as high
24 intensity pressure support kind of started.
25 Next slide.

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1 So building the foundation for high
2 intensity noninvasive ventilation, so again,
3 high intensity targets high inspiratory
4 pressure and they also included backup rates.
5 So some of the earlier studies around the turn
6 of the century did not include a backup rate,
7 it was just spontaneous mode, so the whole idea
8 was to control ventilation. So this was a
9 study done in 2009 by Dr. Windisch and it was a
10 retrospective case study of 73 patients with
11 severe stable COPD. All the patients had an
12 FEV1 around 30 percent predicted. In this
13 study they targeted a normal PaCO2 level and
14 improvement in oxygenation. And so they looked
15 at patients and the average inspiratory
16 pressure that they had was somewhere high

17 around 28, the average expiratory pressure they
18 had was low, around four or five, so these were
19 really low pressures. In addition they were
20 given backup rates so the whole idea was to
21 control that.

22 And what they saw in this study was
23 that when they used high intensity pressure
24 support ventilation with a backup rate, you
25 improved PaCO₂ levels and you increased or

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1 improved oxygen levels. Next slide.

2 So this was very different than what
3 we have seen previously, right, so now we're
4 giving high intensity pressure support
5 ventilation which might mean okay, we're on the
6 right track, but there's always the fear that
7 that's a lot of pressure and if we're giving
8 somebody a pressure of 24 or 28 it's like
9 drinking out of a fire hose. So the idea was
10 well, how (unintelligible) which the earlier
11 studies showed? So there were some very small
12 randomized controlled trials done by Dr. Dreher
13 that looked at the role of high intensity
14 versus low intensity pressure support. Again,

15 these were very small randomized controlled
16 trials, kind of a proof of concept, so there
17 was a trial that was just 17 cases in a
18 randomized controlled trial with chronic
19 hypercapnia and they randomized them to a high
20 intensity pressure support, so a pressure as
21 high as 28 with backup rate, versus low
22 intensity pressure, and what they saw in the
23 study was that the high intensity pressure
24 support actually had improvement in the tidal
25 volume. An improvement in their tidal volume

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1 led to improvement in their hypercapnia. In
2 addition, they saw that patients noted
3 improvement in their dyspnea, their FEV1 and
4 their quality of life. Also, they noted that
5 more patients that were treated with the low
6 intensity actually dropped out of that study.
7 So high intensity compared to low intensity
8 seemed to have some benefit, but there was
9 always (unintelligible) distrust, and so they
10 did another very small randomized controlled
11 trial and they put again high intensity versus
12 low intensity, and they did polysomnography in
13 this study, and what they saw was in this

14 study, was that there were actually more
15 patients that dropped out that were on the low
16 intensity model, and that there was no change
17 in SWS with the low rate, and again, they
18 noticed that there was an improvement in
19 hypercapnia. Next slide.

20 So high intensity is gaining momentum,
21 we're seeing a beneficial therapy, and then
22 came the Kohnlein study. And so the Kohnlein
23 study was a randomized controlled trial, a
24 multicenter randomized controlled trial that
25 looked at severe COPD and then looked at high

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1 intensity noninvasive ventilation versus no
2 noninvasive ventilation or long-term oxygen
3 therapy. They looked at 195 patients, 93 were
4 in the control group, 102 were in the
5 intervention group, and they did a one-year
6 followup. And all these patients came in,
7 again, were chronic severe stable COPD, so they
8 had a PCO₂ level greater than 52, and they had
9 GOLD Stage 4 COPD with FEV₁ levels less than
10 30 percent. They looked at patients and they
11 got them high intensity pressure support about

12 22 over four with a backup rate, and the goal
13 was to reduce the PaCO₂ levels. All patients
14 were admitted to the hospital but,
15 (unintelligible) you get the targeted therapy.
16 What they saw in the study was there was an
17 improvement in mortality. This was the first
18 multicenter trial that showed improvement in
19 mortality.

20 So they saw that as a primary
21 endpoint, 31 patients in the control group
22 versus 12 patients in the intervention group
23 actually died after one year, which is huge.
24 So now we're seeing mortality benefits for high
25 intensity, it's the first time we are seeing

65

1 improvement in the mortality level. Next
2 slide.

3 Great, we're cooking with fire now,
4 we're like okay, high intensity is the way to
5 go for COPD treatment. This was followed very
6 shortly by the RESCUE trial, so with the RESCUE
7 trial it was again a multicenter randomized
8 controlled trial and there was 201 patients.
9 All these patients had severe COPD GOLD Stage 3
10 or 4 and evidence of persistent hypercapnia

11 greater than 52. The patients came to the
12 hospital with acute exacerbation and they were
13 treated with noninvasive ventilation and the
14 noninvasive ventilation was stopped and it
15 still had elevated PCO₂ 48 hours after the stop
16 of noninvasive ventilation. They were again
17 restarted, and what they were again started on
18 was high intensity noninvasive ventilation, so
19 high positive pressure with backup rate. And
20 what they saw in this study was just here on
21 the right, so we saw that there was really no
22 mortality difference, there was less decrease
23 in the PCO₂ levels both through arterial blood
24 gas and through tracking TcCO₂ monitoring, we
25 saw there was actually no change in the

66

1 spirometry and that they had no improvement in
2 their quality of life, no improvement in mood,
3 no improvement in dyspnea. Next slide please.

4 Here we have a Kaplan-Meier graph that
5 shows no change in survival, no change in
6 hospital admission. How is this so different
7 from what we just saw in the Kohnlein study?
8 Patients enrolled in the RESCUE trial were

9 enrolled as acute COPD patients. They were all
10 given (unintelligible) bundled care, access to
11 respiratory therapists, nurses, close followup.
12 The question for this was why was it so
13 different, and the hypothesis is that the
14 hypercapnia seen in the acute period may not
15 have represented true chronic hypercapnia and
16 may have been transient, and if the patient had
17 more time to reset after the exacerbation
18 perhaps they would have normalized their CO₂
19 levels and that's why we saw that. In
20 addition, it was noted that the patients didn't
21 have hypoxia. Next slide please.

22 So now I'm confused, right, the data
23 is all over the place. We have one study that
24 says it's great, one study that says there's
25 mortality benefits, and one study that says

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1 nope, wrong. So then came out the HOT-HMV
2 trial, and this was a randomized controlled
3 trial of noninvasive ventilation in hypercapnia
4 post acute exacerbation. So the timing of
5 these studies is very important and plays a
6 role in when we should time therapy. This was
7 a multicenter randomized controlled trial that

8 looked at 116 patients. 59 of them were given
9 HOT therapy or home oxygen therapy, and 57 of
10 them were given home oxygen therapy plus home
11 mechanical ventilation. The patients all had
12 evidence of hypoxia and hypercapnia, with PaCO₂
13 levels of 53. The mean PaCO₂ level was around
14 59. They all had evidence of severe COPD with
15 FEV₁ of 23 percent and they had low BMIs, so
16 there was very little concern that concomitant
17 OSA. The patients were targeted again with
18 high intensity pressure support so they got
19 inspiratory pressure around 22 to 26, low
20 expiratory pressure, and control of breathing
21 with a backup. And what they saw in this study
22 was they looked at a composite endpoint of
23 mortality and admissions; patients with home
24 oxygen therapy and home mechanical ventilation
25 or noninvasive ventilation actually had

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1 improved by 4.3 months compared to those with
2 just home oxygen therapy that died at about
3 1.6 months, so there was a mortality benefit
4 and hospital admissions benefit.
5 This was planned post exacerbation so

6 what was the timing of this study? So the
7 timing of this study was that they looked at
8 patients that had persistent hypercapnia two to
9 four weeks after their acute symptoms, so very
10 different from the RESCUE trial, the RESCUE
11 trial was set at 48 hours. The Kohnlein study
12 looked at just chronic without any timing, but
13 here in the HOT-HMV trial they were looking at
14 post exacerbation and returning back to their
15 levels of chronic hypercapnia. And so we think
16 that this endpoint that saw a benefit resulted
17 from, again, targeting that chronic
18 hypercapnia. Next slide.

19 The HOT-HMV study was done in Europe,
20 and so if we translate the facts that they saw
21 in the HOT-HMV trial to a U.S. model, let's
22 say, we see that the potential cost of
23 noninvasive ventilation in the chronic
24 hypercapnia patient is saving more than \$3,900
25 per patient in the U.S. We know that the home

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1 noninvasive ventilation saves money, improves
2 quality of life and decreases hospitalizations.
3 Next slide.

4 Great. We have some really strong

5 data in the evolution of how treatment has
6 grown. This was all done in Europe. How does
7 this apply to a U.S. model, right?

8 So the next slide we're going to look
9 at two different U.S. studies. So there are no
10 randomized controlled trials that have been
11 done, they are both retrospective trials, and
12 the first trial was done by Dr. Galli. It was
13 a single center retrospective study that looked
14 at 166 patients, 88 of them were not on
15 noninvasive ventilation, 78 of them were and
16 they were diagnosed with chronic hypercapnia
17 but at much a lower level, with an average
18 PaCO₂ level of 45. They were again given high
19 intensity noninvasive ventilation but
20 interestingly these patients were started on
21 noninvasive ventilation in an acute setting and
22 they continued it throughout. And what this
23 study showed was that there was a reduction of
24 hospital admissions and there was improvement
25 in mortality.

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1 Now this is confusing, right, because
2 the last trial showed none of that, and now

3 this retrospective trial showed it, so okay,
4 why is that a factor here? Next slide.
5 So here are the Kaplan-Meier curves
6 for the RESCUE trial and the Galli
7 retrospective study, and they both looked at
8 post COPD exacerbation in treatment. So why is
9 there such a difference? Well, I think if you
10 look at it, I think there's a difference in the
11 model. So there's the role of noninvasive
12 ventilation but then what else is included in
13 that model? So in the RESCUE trial all those
14 patients were started with noninvasive
15 ventilation but they also had access to a home
16 respiratory therapist, in-home care, someone
17 checking on them kind of providing followup.
18 The U.S. study did not have that, so it was
19 just noninvasive ventilation. In addition when
20 you look at this U.S. study, when you look at
21 the characteristics the patients tended to have
22 higher BMIs. The question was, was the
23 noninvasive ventilation used in the
24 retrospective study in the United States really
25 true hypercapnia or are we treating untreated

1 sleep apnea, and that remains unclear. Next

2 slide please.

3 The second retrospective study came
4 out of a VA model out in the west, and so it
5 was 397 patients over 2010 to 2014, and it was
6 on patients that had been hospitalized with two
7 or more hospitalizations for acute COPD
8 exacerbation in the last year. Then they
9 looked at patients with severe COPD so they had
10 GOLD Stage of 2 or more, and they had BODE
11 index of greater than 5, and they either had
12 hypoxia with a PaO2 level less than 60 or a
13 PaCO2 level of 52. These patients were started
14 on a bundled therapy program. They were given
15 access to a pharmacist for medical teaching,
16 understanding how their procedures worked, they
17 were given access to a respiratory therapist.
18 They were started on noninvasive ventilation,
19 they were given home oxygen, and they had
20 in-home care coordination where someone is
21 checking on them.

22 What they saw after four years of
23 watching, that they went from 397 patients with
24 greater than two admissions down to nine. The
25 question was, again, was it the noninvasive

1 ventilation that they were getting or was it

2 the bundled therapy. Next slide please.

3 So I think it's very important to take

4 Dr. Wilson's meta-analysis and actually break

5 it down into the way that the treatments have

6 evolved. So in Europe we had these great

7 strong multicenter randomized controlled trials

8 and prospective trials. These patients had

9 benefits with chronic hypercapnia. The severe

10 stable COPD not in the setting of exacerbation

11 had benefits.

12 The United States only had

13 retrospective studies. We see that there are

14 some improvements in readmissions after acute

15 exacerbation but again, what was the target

16 there? Was the target sleep apnea or was the

17 target actually chronic hypercapnia? And the

18 model that worked in the United States was

19 through the VA and that's a bundled program and

20 they add home care; how much of an impact did

21 that have?

22 The common hurdle that runs with

23 noninvasive ventilation, and especially in high

24 intensity, pressure and power, so if you want

25 to get to the target of high intensive pressure

1 support you've got to deliver a lot of
2 pressure, and how do you get patients
3 acclimated to that? How do you get patients
4 acclimated to a mask who are not used to a mask
5 on their face? The European models provide a
6 prolonged acclimation that showed in increased
7 adherence to noninvasive ventilation, and what
8 they showed was that it effectively chronic
9 stable CO₂. Next slide.

10 So to take the data and kind of break
11 it down from low intensity to high intensity,
12 so we see the early low intensity that showed
13 no benefit, so there was no improvement in the
14 development, no improvement in mortality, no
15 improvement in hospitalization. Then we
16 switched the model, we changed the paradigm and
17 went to high intensity, full control of
18 ventilation. What we saw was that if we treat
19 chronic COPD and hypercapnia, there is an
20 improvement in mortality and hospital
21 readmissions, and the timing is very important.
22 Next slide.

23 So if we look at the evolution of
24 noninvasive ventilation in chronic COPD there
25 is evidence that it was truly beneficial, if we

1 target chronic hypercapnia it is beneficial,
2 but how do you actually apply it to your
3 patients in the United States? Next slide.

4 So I want to take --

5 DR. BACH: Dr. Coleman, you have about
6 three-and-a-half minutes left.

7 DR. COLEMAN: Perfect. So let me step
8 back here and talk about BPAP, so BPAP is
9 essentially a respiratory device, a respiratory
10 device plugged into a wall and it doesn't have
11 any alarms, it provides different modes of
12 therapy. Compared to a home mechanical
13 ventilator that has an internal battery, allows
14 portability, it is a licensing issue. In the
15 United States in order to qualify a patient for
16 a BPAP machine or a respiratory assist device
17 under COPD guidelines, you have to show
18 evidence of hypercapnia and hypoxia, and when
19 you do that, the best you can do is give
20 someone a BPAP machine without a backup rate.
21 Next slide.

22 In order to get them a BPAP machine
23 with a backup you have to show a failed

24 (unintelligible) with therapy with BPAP. You
25 have to repeat all the things happening while

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1 they've been on noninvasive ventilation. Next
2 slide. Skip this slide.

3 So what is the cost of therapy? In
4 the United States a respiratory device or a
5 BPAP machine costs about \$400, a home
6 mechanical ventilator costs about \$1,500. Next
7 slide.

8 Because of this, as Dr. Patel
9 referenced earlier, people want to treat COPD,
10 there's evidence that supports it, but the
11 criteria to get a BPAP or CPAP respiratory
12 device is extremely too stringent, so this has
13 led to an increase in the use of home
14 mechanical ventilators, which is overkill
15 therapy. Next slide.

16 You can see since 2009 to 2015 the
17 number of home mechanical ventilators has
18 increased exponentially to treat COPD, and this
19 could have been resolved if there were easier
20 more applicable therapies to get through
21 noninvasive ventilation. Next slide.

22 Why are we doing this? Because the

23 Affordable Care Act of 2012 actually started to
24 penalize hospitals for hospitalizations so
25 there's an urgency today, how can we prevent

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1 COPD? Next slide.
2 So where do we go from here? Well,
3 while limited to European trials, there are
4 several randomized controlled trials that show
5 benefit with noninvasive ventilation with a
6 backup rate, to reduce hospitalizations and
7 mortality. The target of noninvasive
8 ventilation should be hypercapnia, not hypoxia.
9 And under the current U.S. guidelines it is
10 extremely difficult to qualify a patient for
11 noninvasive ventilation, especially when the
12 backup rate with all the data have proven
13 beneficial. This has led to an increased home
14 mechanical ventilation at a much higher price
15 point and less stringent criteria. Next slide.
16 So there needs to be a revision to the
17 respiratory assist device guidelines to
18 simplify the ability to obtain devices that can
19 provide high intensity pressure support with a
20 backup rate. These revised guidelines should

21 be based on chronic stable hypercapnia and not
22 include hypoxia. If we improve and resolve our
23 respiratory device issues, we can make the
24 criteria more applicable, and we will improve
25 and decrease our home mechanical ventilator

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1 issue. Next slide.

2 That's all I have for you. Thank you
3 for joining me on this journey.

4 DR. BACH: Dr. Coleman, thank you so
5 much for that presentation, again for finishing
6 on time. I'm sorry about the little bit of a
7 crunch on that. That was extremely helpful to
8 us. We are as I mentioned holding questions
9 until a period after lunch so I hope you are
10 prepared to stay with us for the day.

11 To everyone, we are going to take a
12 15-minute break. Like everything else we're
13 going to stay on time here so I have us coming
14 back at 9:53 for the beginning of the scheduled
15 public comments. The first person who I have
16 is Dr. Robert Owen listed, and we will see you
17 at 9:54.

18 (Recess.)

19 DR. BACH: Thank you everyone for

20 rejoining. We are going to go on to the next
21 part of the meeting having completed our break,
22 which are scheduled public comments. Each
23 speaker will have eight minutes. Like all
24 these other things I will add, I will keep you
25 on time, please. Our first presenter is Robert

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1 Owens from the University of California
2 San Diego. I ask you that you do your
3 disclosures or give a disclosure slide, that's
4 terrific. Thank you very much.
5 DR. OWENS: Thank you very much for
6 the opportunity to present today. Can you hear
7 me okay?

8 DR. BACH: Yes, we can, thank you.

9 DR. OWENS: Okay, thank you. So as
10 mentioned, my name is Bob Owens, I'm calling in
11 from California, and I'm in the division of
12 pulmonary and critical care and sleep medicine
13 and I'm speaking today on behalf of the
14 American Thoracic Society. Next slide please.

15 So by way of disclosures, ResMed,
16 which is a maker of PAP devices, did give a
17 donation to our UCSD Sleep Center. I've also

18 received an honorarium and travel reimbursement
19 from ResMed and was site PI on a multisite
20 research study. Next slide please.

21 The reason I'm presenting to you today
22 on behalf of the American Thoracic Society is
23 it's an organization of 16,000 clinicians; this
24 includes doctors, scientists, nurses,
25 respiratory therapists all designed to, or all

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1 trying to improve respiratory disease and sleep
2 disorders. I was most recently the chair of a
3 clinical practice guideline which is coming out
4 next month, long-term noninvasive ventilation
5 in chronic stable hypercapnic COPD.
6 Dr. Coleman, who just spoke, was a member of
7 the panel as well. Next slide please.

8 So in preparing for this meeting there
9 were several voting questions that were posed,
10 and I briefly summarized those questions as
11 what were the patient selection criteria that
12 could improve outcome with any NIPPV device;
13 what are the NIPPV equipment parameters
14 necessary to improve patient-reported outcomes;
15 can the improvement in outcome be attributed to
16 the use of NIPPV equipment; and what are the

17 patient usage parameters that will improve
18 outcomes?
19 I wanted to approach this problem by
20 presenting two use cases or two patient
21 scenarios, and that's patients who have COPD
22 and obstructive sleep apnea, which is common,
23 not quite as sick patients, and then those
24 patients with chronic stable hypercapnic COPD.
25 Next slide please.

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1 So thinking about our COPD and
2 obstructive sleep apnea, this is often termed
3 the overlap syndrome, it's fairly common. And
4 I think in the absence of hypercapnia,
5 continuous positive airway pressure or CPAP can
6 be used. And when CPAP is used in these
7 patients there are associations with improved
8 mortality, reduced ER and hospital admissions,
9 and better quality of life. While more use is
10 better, I'll show you some data that more hours
11 per night is still the magic number, and I
12 don't have it on the slide but when CPAP is
13 provided it's usually little more than the
14 device, so any improvements here are really

15 related to CPAP itself, not to other associated
16 care. Next slide please.
17 So this is the study by Jose Marin
18 about 10 years ago showing that patients with
19 overlap syndrome have high mortality and if you
20 use CPAP the mortality can improve. So the red
21 curve there, patients with COPD and OSA have
22 reduced survival with COPD only. The blue
23 curve is patients who have COPD and OSA who use
24 this. So if we can advance the slide please,
25 and next slide.

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1 Besides mortality, patients who have
2 COPD and use CPAP also have reduced ER visits
3 and admissions, so studies by Konikkara and
4 colleague looked at patients who were in the
5 hospital with COPD. They were rapidly
6 diagnosed with obstructive sleep apnea and were
7 provided with CPAP. On the left panel there
8 you can see the difference between patients who
9 used their CPAP device and those who did not
10 use it, and there was a reduction of about two
11 or three ER and hospital admissions over the
12 next six to 12 months. Next slide please.
13 Now more CPAP use is associated with

14 improved survival. This is a study by
15 Stanchina, Mike Stanchina at Brown, where he
16 showed a nice dose-response with the more CPAP
17 that patients with sleep apnea used, there was
18 a better survival outcome. But what I wanted
19 to point out on this slide is that even using
20 CPAP for just two to four hours per night,
21 there was a pretty robust improvement in
22 survival. Next slide.

23 So those are patients with obstructive
24 sleep apnea and COPD, you can treat them with
25 CPAP and CPAP probably by itself to lead to

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1 improved outcomes without a lot of associated
2 care. This is speaking to patients with COPD
3 and stable hypercapnic failure. This is a
4 smaller group of patients, they have high
5 morbidity and mortality, and we have very few
6 treatments that show improvement such as
7 smoking cessation or oxygen therapy. Part of
8 the problem is that these patients have defects
9 in both oxygenation and ventilation, and we
10 rarely think about ventilation. So the panel
11 on the bottom left is an old trace from David

12 Flenley showing that oxygen drops during, or
13 oxygen saturation drops during the night. But
14 more rarely measured, like in the panel on the
15 bottom right, is the transcutaneous CO2 which
16 is also rising during the night. Next slide
17 please.

18 So we took there are problems with
19 both -- well, I see you skipped one slide here,
20 but because there are problems with both
21 oxygenation and ventilation, it will be best to
22 treat both of these things at the same time.
23 So John Coleman just went through the Kohnlein
24 study, but these are sick patients who have
25 severe COPD. It's notable that they exclude

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1 patients who have high BMIs of more than 35 or
2 who have other heart and other lung disease;
3 perhaps those are the patients that a true home
4 mechanical ventilator might help. But in this
5 study with Kohnlein, again, the intervention
6 was a bilevel PAP with a high backup rate
7 trying to reduce CO2. Next slide please.

8 And again showing how sick this
9 patient is, or the patient group is, 33 percent
10 of controls had died at the end of one year, so

11 this is a higher mortality than some cancers.
12 There was a substantial impact from noninvasive
13 ventilation. You can see the curves separate
14 and again, you'd rather be in the curve that
15 got noninvasive ventilation. Even though we
16 think of these pressures as perhaps being
17 uncomfortable, they improved without
18 noninvasive intervention. Now this
19 intervention did include scheduled
20 hospitalizations and extensive followup and
21 there was a very high rate of adherence, close
22 to six hours a day. Next slide please.

23 Again, this is the Murphy trial, I
24 think these slides were unfortunately out of
25 order, but again, it's testing the hypothesis

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1 that these patients don't only have an
2 oxygenation problem but an oxygen and a
3 ventilation problem, and in the Murphy trial
4 here it is providing both was superior to
5 providing oxygen alone. Next slide.

6 Now one of the criticisms have been
7 that since it required substantial efforts to
8 bring patients into the hospital and to set

9 them up, Peter Wijkstra published this paper
10 last year showing that you don't necessarily
11 have to bring people into the hospital, there
12 are good outcomes, not inferior, with starting
13 people at home with their NIV machines. Next
14 slide please.

15 So in terms of the voting questions,
16 what are the patient selection criteria, I
17 think if you have a patient with COPD and
18 obstructive sleep apnea they can be treated
19 with CPAP. If you have a patient with COPD and
20 chronic stable hypercapnia they probably need
21 bilevel PAP with a backup rate. In terms of
22 improvements attributed to NIPPV equipment
23 alone, I think merely yes with CPAP equipment
24 for COPD and OSA; for those with chronic
25 hypercapnia they need ancillary services as

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1 well. In terms of patient usage parameters,
2 four hours per night is not a magic number,
3 more is better, and in some of these studies it
4 takes people a long time to get adherent and
5 you might need a longer period to get them on
6 therapy. Next slide please.

7 I'd just like to finish with some

8 additional comments. First as was alluded to
9 by Dr. Coleman, bilevel PAP with a backup rate
10 is really what's been studied for improvement
11 on these patients but often it can be easier to
12 satisfy requirements required to get a home
13 mechanical ventilator. So modifying the
14 requirements to obtain bilevel PAP with a
15 backup rate will impact H MV utilization.

16 The last thing I would mention is that
17 particularly with a sticker group, COPD and
18 chronic stable hypercapnia, I think patients
19 would also benefit from ancillary services as
20 well.

21 Thank you very much for the
22 opportunity to present this morning.

23 DR. BACH: Thank you very much,
24 Dr. Owens, for that presentation. Our next
25 presentation will be Dr. Nunez.

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1 DR. NUNEZ: Hi, yes, good morning. My
2 name is Dr. Carlos Nunez, and I want to thank
3 you first and foremost for the opportunity to
4 speak today, and to the panel for their time
5 and consideration of the comments that we

6 submitted. As I mentioned, my name is Carlos
7 Nunez, I am a physician, I am currently the
8 chief medical officer at ResMed, who is one of
9 the leading manufacturers of all the equipment
10 we have been talking about today. Very
11 briefly, I am an anesthesiologist and
12 intensivist, critical care physician by
13 education and training, and as mentioned, I
14 work as the chief medical officer at ResMed.
15 As the chief medical officer obviously I am a
16 full-time employee. I am compensated not only
17 with salary but also with equity in the
18 company.

19 Also just to note, there are a couple
20 of my colleagues on the line from ResMed who
21 are listening in, and if there's a need for
22 them to chime in during th Q&A I may refer to
23 either Larissa D'Andre, our vice president of
24 government affairs and market access, or Amanda
25 Voldeer who's our senior manager of government

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1 affairs. So if you can go to the next slide
2 please, oh, that is my disclosure slide so I
3 just went through that so we don't need to
4 mention that again, so if you'd go to the third

5 slide.

6 I want to just quickly mention the
7 culture of innovation at ResMed. I'll start by
8 saying the slides are a little busy because
9 obviously we wanted to get a lot of comments
10 into the public record, but I'll highlight just
11 the real big takeaways here. As I mentioned,
12 ResMed is one of the leading manufacturers of
13 all the technologies we talked about today,
14 from CPAP devices to bilevel devices to home
15 mechanical ventilators.

16 But I also want to mention something
17 that's really really important that was just
18 mentioned by Dr. Owens actually when he talked
19 about more than four hours is better and
20 ancillary services. You can't talk about these
21 devices in this day and age without talking
22 about the fact that these devices are now much
23 more modern connected and allow the physicians
24 and providers to remotely not just access data
25 about the patient's care on a daily basis but

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1 manage that care, and even to do telemonitoring
2 and use the data as the basis for telemedicine.

3 Now more than ever, especially in the throes of
4 the COVID-19 pandemic, we have seen an
5 explosion of digital health, telemedicine,
6 telemonitoring and virtual visits, and so we
7 need to think about this as we move forward
8 through these discussions.

9 We are talking about taking care of
10 patients in the home with very advanced devices
11 that do require ancillary services and we want
12 to make sure that when you think of ancillary
13 services, part of that is the software, the
14 platforms, the connectivity and the digital
15 health capabilities that make these devices
16 more modern and more suited for the health care
17 system we have today. If you can go to the
18 next slide please.

19 On this slide I will reiterate some of
20 the things you heard from the last two
21 presenters. There is a bit of a discrepancy in
22 the requirements for patients to receive a
23 respiratory assist device versus a home
24 mechanical ventilator. And you see, there is a
25 growing body of evidence, some stronger than

1 others, that shows that this type of care is

2 important for patients. But when you restrict
3 access to an appropriate type of care for a
4 lower, potentially lower acuity of patients,
5 you see an overuse or potential overuse of
6 higher spec devices, I believe it was one of
7 the earlier presenters who said it just like
8 this, that you created an artificial situation
9 where patients who can do just fine with a less
10 expensive device, and I think he used the
11 average of about 400 bucks, that are often
12 being prescribed devices that are over spec and
13 more expensive than what they need. These are
14 not one size fits all options, and I think we
15 have to keep in mind that clinicians need the
16 flexibility to look at these very complicated
17 patients with lots of comorbidities and
18 understand which technology will work the best
19 for them, which settings, the features and the
20 capabilities that the devices have, and can we
21 have payment and reimbursement guidelines,
22 policies, requirements to make it easy for
23 patients to get the therapy they deserve. Next
24 slide please.

25 Again, busy slide but I will hit on

1 the highlights. You've heard a lot of
2 presentations about the current state of the
3 evidence and as you see, there is a lot of
4 evidence and a growing body of evidence that
5 shows that quality of life and other measures
6 are increased with noninvasive positive
7 pressure ventilation. The HOT-HMV study which
8 I talk about here on this slide was mentioned
9 by several of the previous presenters so I
10 won't go into the details there, but again, we
11 see a growing body of evidence that shows
12 treating patients with chronic hypercapnia in a
13 variety of situations outside the hospital
14 helps improve their quality of life, helps
15 improve their clinical outcomes, and the
16 evidence continues to get stronger. So these
17 studies that have happened in recent, in the
18 recent years that have strengthened the body of
19 evidence that led to an update of the GOLD
20 guidelines for 2020 and an update to ERS
21 guidelines, the European Respiratory Society
22 guidelines at the end of 2019, and we just
23 heard from Dr. Owens the ARS is working on
24 similar guidelines themselves. If you can jump
25 to the next slide please.

1 The evidence also showed that there is
2 a cost effectiveness to noninvasive positive
3 pressure ventilation. Going back to the
4 HOT-HMV trial, there was a cost effectiveness
5 study that was done looking at both U.K. and
6 U.S. models of care and the data from the
7 HOT-HMV study looking at home mechanical
8 ventilation in addition to oxygen. And what
9 they found is this therapy, looking at the
10 findings from the HOT-HMV study was not only
11 more effective but it was also less costly when
12 you calculate the incredible cost effectiveness
13 ratio or ICER, and what they found was the cost
14 effectiveness ratio was minus over \$50,000 per
15 quality adjusted life year that was gained. It
16 doesn't mean everybody going on to a mechanical
17 ventilator all of a sudden sees that \$50,000 a
18 year but what it shows is for every quality
19 adjusted life year, a year of quality life adds
20 savings to the health system. And so we now
21 see this therapy is not just more clinically
22 effective but also more cost effective in the
23 long-term. And I've got about a minute left,
24 so if you'd jump to the next slide. I'm still
25 seeing the original slides.

1 DR. BACH: We're looking at the
2 recommendations to MEDCAC.

3 DR. NUNEZ: All right, I will jump to
4 it, for some reason something froze.

5 So the recommendations we have is that
6 MEDCAC should consider the spectrum of
7 technology available, it is not just the
8 bilevel with a backup rate versus home
9 mechanical ventilation. It is those ancillary
10 services, it's the software, the platforms, the
11 connectivity, all of the technology of the
12 modern devices that make it more appropriate
13 for their use as home devices, and make it
14 easier for providers, clinicians, physicians
15 and others to manage that care.

16 Should consider all of those
17 technological innovations especially in light
18 of the pandemic and some of the clinical
19 changes that we're going to see in health care
20 going forward.

21 Should prioritize recent evidence and
22 recent clinical guidelines, I mentioned the
23 2020 GOLD and the 2019 ERS.

24 And then lastly, the patient usage
25 criteria in coverage recommendations, there's

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1 insufficient clinical evidence and this could
2 interfere with clinical decision-making.

3 I hear the timer so I will be quiet.

4 DR. BACH: Thank you very much for
5 your presentation, and we're going to go on to
6 the next speaker. And just so everyone knows,
7 I'm taking the soccer ref approach to this, you
8 get extra time if we have technical problems,
9 but thank you very much for your presentation.

10 I'm going to go on to Dr. Lisa Wolfe.

11 DR. WOLFE: My name is Lisa Wolfe.
12 Can you guys hear me?

13 DR. BACH: Yes, we can.

14 DR. WOLFE: Okay, great. First of
15 all, I am here today representing CHEST, which
16 is the American College of Chest Physicians.
17 And in addition to all the other thank yous
18 from other folks today, I'd like to give a
19 thank you to Tara, who has done an amazing job
20 herself as being an innovator, as this is the
21 first online version of the MEDCAC meeting, and
22 it's been a great experience. I'd like to go

23 to the next slide please.

24 Okay, I'd like to address the four
25 questions before us by taking our patients with

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1 COPD and dividing them into three distinct
2 groups which other speakers have already done,
3 I'd just like to do it more formally and do
4 this in a way in which we can look at these
5 groups together. In terms of patient criteria,
6 we're going to look at those with OSA and COPD.
7 The patients that have normal CO2 and oxygen
8 levels are frequently referred to as the OSA
9 and COPD overlap syndrome. Notably these
10 patients are determined through
11 polysomnography, as compared to patients with
12 COPD who are found to have acute exacerbations
13 requiring hospitalizations with hypercapnia,
14 and their COPD is determined clinically.

15 If we then compare that to the more
16 common group in the U.S. which is least likely
17 to have been studied, this is an overlap of
18 obesity hypoventilation syndrome with COPD.
19 These patients are distinct because they have
20 BMIs greater than 35 and the COPD is associated

21 with more hospitalizations and hypercapnia.
22 Please go to the next slide.
23 If we look at our next issue which is
24 NIPPV equipment parameters, we can look at our
25 three predefined groups and easily determine

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1 how equipment parameters fall into these
2 locations. In our OSA field with COPD overlap
3 syndrome the most commonly used device is CPAP.
4 The difference between our patients with
5 overlap and a standard OSA patient is that
6 frequently these patients require oxygen in
7 addition to CPAP therapy.

8 Whereas, our severe COPD patients
9 usually are treated with Bi-PAP with backup
10 rate as has been described by many of our
11 speakers today in order to provide high
12 intensive pressure support which is far
13 superior, as described in Dr. Coleman's talk.
14 It is important, however, to remember that some
15 of these patients require home mechanical
16 ventilation either due to very high need for
17 oxygen bleed that will require an internal
18 blender, or the need for backup batteries or
19 daytime portability.

23 noninvasive ventilation for all forms of CRF to
24 align with the best evidence, and providing
25 better care for Medicare beneficiaries. Next

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1 slide please.
2 So the pathway would be that we
3 support the multi-society supported expert
4 panel today that has been speaking all morning
5 to provide CMS with the recommendations from
6 clinical experts to provide reasonable and
7 necessary treatments. Data suggests mortality
8 is reduced, hospitalizations, decreased cost of
9 care, and better quality of life. I'd like to
10 thank the MEDCAC panel for the opportunity.
11 Thank you, Dr. Bach.

12 DR. BACH: Thank you very much,
13 Dr. Vohra, for that presentation. I ask
14 everyone who is not speaking to please mute
15 your microphones. We're going to go on now to
16 our last scheduled presenter, who's Dr. Gregory
17 Holt.

18 DR. HOLT: Good morning. Can
19 everybody hear me?

20 DR. BACH: Yes, we can.

21 DR. HOLT: All right. My name's
22 Dr. Greg Holt, representing Respiratory Quality
23 Services, a DME company based out of Texas.
24 Next slide.
25 And I do have nothing to declare.

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1 Next slide.
2 This is the first slide that comes up
3 and Dr. Coleman briefly presented this slide,
4 but this is the reason why we're here. I think
5 everybody understands that there's been a shift
6 in the utilization of the HCPCS Code E0466 to
7 COPD and chronic respiratory failure, away from
8 neuromuscular disease, and this is over a
9 period of six years but this is when things
10 really started to happen. Next slide.

11 So the first thing that came up was a
12 decrease, a 30 percent reduction in the
13 reimbursement rates for the code in 2016, so
14 this was pretty significant all the way around.
15 But then it was added to the competitive
16 bidding process. Along with the OIG reports
17 there was other things that Medicare was
18 looking at, and it was also added to a
19 potential list of codes that didn't require, or

20 that would require preauthorization without any
21 further discussion, so it's on a list right now
22 of a noninvasive code for ventilation that
23 they're going to have like other restrictions
24 placed onto it. So recently, everybody knows
25 that ventilators were removed from the

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1 competitive bidding process because of the
2 pandemic, but there's other things going on
3 that weren't reversed, and what were not
4 reversed is some policy by third-party
5 companies of a rent to own ventilator policy
6 which is never going to happen, it's not a good
7 idea but it's coming around from Blue Cross
8 Blue Shield in Louisiana and Mississippi. Next
9 slide.

10 So when we take a look at what
11 happened, so how did we get here? Well, we are
12 meeting about noninvasive ventilation and COPD,
13 but first there was that OIG report. And then
14 what shifted the utilization of the noninvasive
15 ventilators was this reimbursement of RAD
16 devices requiring frequent substantial
17 servicing. So that was like the ongoing thing

12 tried to like come out with criteria before a
13 few years ago and it sort of fell flat, but you
14 can look at establishing a panel to look at NIV
15 criteria in this new population, specific
16 criteria. That's why a diagnosis of, you know,
17 like having a combination, problems of obesity
18 and obstructive sleep apnea and COPD, things
19 like that, but when you look at that you can
20 compare it to like other national standards.

21 You can also look at initially things
22 like RAD tolerance. You look at RAD tolerance
23 when they're stable as severe COPD patients. I
24 couldn't believe that all of those guys were
25 able to jump on, something like 26 over 4

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1 centimeters of water pressure and everything
2 was fine. Most of the time the chief complaint
3 is shortness of breath and they don't want
4 anything on their face. So you know, maybe
5 trying the RAD early on in the diagnosis and
6 looking at a RAD with recurring exacerbations,
7 and also trying to find out if they're on a
8 RAD, if they have it like to where they can
9 bring their CO2 down during the exacerbations,
10 because you have to look at the transition

11 points of RAD to home mechanical ventilation
12 and you have to decide when to switch and when
13 you need the secondary settings, battery backup
14 power, and that was a good thing about the
15 secondary settings, because it's baseline
16 settings and then it's like an exacerbation of
17 rescue breathing setting, and that's about --

18 DR. BACH: Dr. Holt, you're out of
19 time.

20 DR. HOLT: All right, that's fine. So
21 respiratory failure you need home mechanical
22 ventilation, you need to know the transition
23 points and you need to decide how you're going
24 to reimburse that, should you include a
25 respiratory therapist, or just look at a

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1 schedule that includes some type of support.

2 Thank you.

3 DR. BACH: Dr. Holt, thank you very
4 much. As I mentioned earlier, I had a
5 technical problem on my end that interfered
6 with Dr. Wolfe's presentation and I'd like to,
7 Dr. Wolfe, if you're there and it's possible
8 technically, CMS, if we can go to slide seven

9 of Dr. Wolfe's presentation, I'd like to give
10 her a few minutes to go through that slide, and
11 number eight. Does that work on a technical
12 level?

13 DR. WOLFE: That would be wonderful,
14 yes.

15 DR. BACH: Thank you. I know this has
16 set us to change our schedule. While we are
17 waiting for this slide, a couple of changes.
18 We are ahead of time because of everyone doing
19 a phenomenal job on the presentations staying
20 on time and only a few technical glitches,
21 almost all on my end. So my preference here is
22 unless there are objections, to move part of
23 the agenda up and keep lunch which is scheduled
24 right now at 11:30 eastern at the same time, so
25 we will hear Dr. Wolfe, a couple of slides,

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1 there's someone waiting to give an open public
2 comment, and then we will start the questions
3 to presenters and we will do what we can, then,
4 until we break for lunch. If there are any
5 objections to that plan or logistical problems,
6 please privately chat with me about that so I
7 can fix them. Dr. Wolfe, please go ahead.

8 Thank you very much.

9 DR. WOLFE: Thank you. Can you hear
10 me?

11 DR. BACH: Yes, we can hear you.

12 DR. WOLFE: Okay, great. So just very
13 quickly, I've broken my summary down into the
14 four key questions in front of us.

15 First of all, patient selection
16 criteria. Most important is going to be
17 daytime hypercapnia and it is the only marker
18 that seems to be relevant.

19 Number two, NIPPV equipment
20 parameters. With the COPD phenotype, if you
21 look at them the way I've broken them down,
22 they easily allow us to assign appropriate PAP
23 therapy. And I would emphasize as Dr. Coleman
24 said at the end of his talk, fixing the RAD
25 criteria will allow us to more appropriately

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1 give the right NIPPV to the right patient.

2 Number three, is it important to have
3 concomitant provision and other support
4 services? The presence of daytime hypercapnia
5 is a hallmark that we need to be more

6 aggressive with support in the home and in
7 order to do that, to reduce the frequent and
8 substantial servicing on the HMO has been a
9 benefit; if it can be provided other ways, it
10 should be. The evidence isn't sufficient to
11 provide the patient usage parameter, time
12 cutoffs are not specific, but the greater the
13 use the greater the effect. Next slide.

14 Is that the last one? Oh, there it
15 is. And my final thoughts were summarized
16 before, that we need to modernize how we
17 approach this because we no longer have the old
18 data with low intensity, high intensity should
19 force us to expand how we look at these things,
20 update the RAD criteria, and encourage more
21 research in the U.S. that looks at our patient
22 phenotype, and that's it.

23 DR. BACH: Well, thank you very much.

24 We are going to move on to public comment. We
25 have one registered speaker for public comment.

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1 We give two minutes for each public comment,
2 and that is Kathleen Lester. Dr. Lester, are
3 you on the line?

4 MS. LESTER: Hi, it is Kathy Lester

5 and I wish I were a doctor but I'm only a
6 lawyer, but I appreciate the opportunity for
7 comment today, and I want to give huge kudos to
8 Tara, Leah and Marvelyn for making this virtual
9 meeting so seamless, it is working great from
10 our perspective. I am the executive director
11 of the Council for Quality Respiratory Care and
12 the CQRC is a coalition of the nation's seven
13 leading home oxygen and sleep therapy providers
14 and manufacturing companies, so together they
15 provide in-home patient services and
16 respiratory equipment to more than 1.5 million
17 Medicare patients.

18 As you can tell, our members don't
19 prescribe these devices but they are filling
20 the prescriptions written by the qualified
21 health care professionals and are the subject
22 of the documentation audits that apply in the
23 coverage criteria, and some of the ideas you
24 all are thinking about today.

25 We submitted written comments but

1 wanted to emphasize the importance of making
2 sure that the patients who medically need NIV

3 in the home can access those devices. Thus we
4 need standards that are recommended, especially
5 around clinical criteria. It should be
6 objective and very clear to document. The more
7 subjective the criteria the more likely there
8 will be documentation problems and auditing
9 issues that could result in patients not being
10 able to get access to the equipment.

11 So building off today's great
12 presentations, we support the comprehensive
13 look at coverage not just for NIV but for the
14 RAD policy, to allow for the complete
15 discussion that recognizes the broad spectrum
16 of devices and various patient populations who
17 medically require them. We also believe it is
18 important to avoid the tried and failed method,
19 as others have stated, or standards that would
20 result in time-based criteria which are nearly
21 impossible to document and have created serious
22 access problems in other parts of the Medicare
23 program.

24 Given the importance of understanding
25 the documentation issues as well as the

2 would like to be part of this process, to have
3 a seat at the table as we move forward, and we
4 agree with other commenters who suggested a
5 technical expert panel.

6 So thank you again for considering
7 this very important area and allowing us to
8 provide comments today.

9 DR. BACH: Thank you very much for
10 those comments, and we are going to move now to
11 the questions to presenters section. We have
12 about an hour scheduled for that. In my
13 experience it can go a little shorter sometimes
14 and longer sometimes. We need the time to have
15 an open discussion. This is all new in terms
16 of the technical challenges so let me say what
17 my at least initial plan here is. I have a
18 participant menu in front of me, I have a
19 panelist menu in front of me. You can raise
20 your hand, you can also chat with me privately
21 to say you have a question, this is for the
22 panelists, or I would actually propose being
23 redundant so that I can try and monitor this
24 and do my best. But I do know there were a
25 couple of questions that were already sent to

1 me that they want to address to the panelists.
2 As far as the speakers -- I'm sorry -- as far
3 as the presenters, questions need to go to the
4 people who presented them and the answers have
5 to come from them. We can't have any other
6 input from people who aren't registered to
7 speak at the meeting, that's part of our rule.

8 So anyway, I'm happy to start
9 anywhere. If you would like to raise your hand
10 I'll call on you and if you can address, if you
11 have a person you would like to address with
12 your question, please make that part of the
13 question. I'd also like to remind you when I
14 do call on you or if you would like to just
15 speak if you're having trouble getting called
16 on if there's no one talking, please make sure
17 your camera is on and you identify yourself so
18 we can have a transcription.

19 DR. MACINTYRE: Dr. Bach, this is Neil
20 MacIntyre. I don't see a hand to raise, I sent
21 you a chat. Is it okay just to ask questions
22 like this?

23 DR. BACH: I think that's fine, just
24 please identify yourself and identify who you
25 would like to ask the question of if that's

1 possible.

2 DR. MACINTYRE: My name is Neil
3 MacIntyre, I'm one of the invited panelists.
4 Again, I'm from Duke University, a critical
5 care pulmonary physician. I'm not sure these
6 are questions or comments, they probably focus
7 more on Dr. Coleman's comments, but I would
8 like to point out, I think the distinction
9 between home mechanical ventilation and Bi-PAP
10 or RAD is really quite ordered. Both supply
11 inspiratory pressure to augment tidal volumes
12 and on those muscles, both supply expiratory
13 pressure to assist triggering, both have backup
14 rates, and indeed the terminology, the Bi-PAP
15 ST is in effect pressure assist control
16 ventilation on a ventilator, and Bi-PAP
17 spontaneous is in effect standalone pressure
18 support.

19 Moreover, these devices have very
20 similar pressure capabilities. HMV, home
21 mechanical ventilation devices do offer more
22 alarms and volume assist control loads which, I
23 don't think these are really important in the
24 home. But my point is, because of the very
25 blurred distinctions trying to argue

1 superiority of one device over the other is an
2 exercise in futility.

3 And this leads me to my second point
4 and I would be interested in Dr. Coleman's
5 comments here. I have found over the years
6 that clinicians really opted for HMV, that is
7 home mechanical ventilation, not for superior
8 performance capabilities, not for ease of
9 prescribing, but because of the extremely
10 important link of home mechanical ventilation
11 to the availability of clinical and technical
12 support, and I think this is a critical point
13 here. I think we should be arguing, or not
14 arguing, but addressing this critical component
15 of the home mechanical ventilation provision,
16 and get away from the device performances and
17 rather focus on the clinical and technical
18 support. In theory the, not theory, reality,
19 these devices are lifesaving and are life
20 support devices, and tolerance, adherence and
21 making sure patients are doing what they need
22 to be doing to me is the critical decision
23 driver here, not the actual technical specs of

24 the device.

25 So Dr. Coleman, thoughts on that?

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1 DR. BACH: Dr. Coleman, you are on
2 mute. And before you answer, Dr. Coleman, I
3 have a Ross, Garrido, Barreiro and Fisch queued
4 up for questions right now.

5 DR. COLEMAN: So would you like me to
6 answer now, or wait?

7 DR. BACH: Yes please, go ahead.

8 DR. COLEMAN: This is John Coleman.
9 Thank you very much for your comments. I agree
10 with you that I think, I agree with you a
11 hundred percent in the sense that the servicing
12 of in-home respiratory care support is
13 essential for the activity of noninvasive
14 ventilation. I do think, you know, being in
15 the hospital on a daily basis and seeing
16 patients that are trying to get set up with
17 this, I think that while the benefit of home
18 mechanical ventilation gives the respiratory
19 care and advocates home ventilation, we
20 acknowledge that basis, I think the fact of the
21 matter is that this is being driven by a lot of
22 primary care physicians, being driven by a lot

23 of hospitals, being driven by a lot of internal
24 medicine decisions. We need to understand the
25 differences and when they try to say oh, I want

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1 to order a Bi-PAP machine, they are getting in
2 some ways kind of encouraged to do home
3 mechanical ventilation, it's easier to meet
4 that criteria.

5 So again, while I think it's a twofold
6 problem of getting the benefit of in-home
7 respiratory care support and the frequent
8 services of the home mechanical ventilator, I
9 also think you need, the criteria is less
10 stringent, and if you'd go through all of these
11 things with a Bi-PAP sheet, I think it would be
12 more readily prescribed.

13 DR. BACH: Thank you very much. I'd
14 like to go to Dr. Ross next for his questions.

15 DR. ROSS: Thanks, Peter, this is Joe
16 Ross, and I'd like to thank Dr. MacIntyre for
17 asking that question because as a general
18 internist I was having trouble differentiating
19 Bi-PAP to HMV and was trying to figure out what
20 exactly was the difference between the two,

21 although I've never prescribed them.
22 The question I really had was for
23 Dr. Wilson. I was a bit surprised that some
24 review he presented combined evidence from
25 randomized controlled trials and observational

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1 studies to arrive at your effect estimates, and
2 given my concerns about observational studies
3 and confounding, particularly when you're
4 considering more national health plans and my
5 concerns about socioeconomic status and being
6 able to obtain these devices, I just wonder if
7 you could comment a bit on the effect from
8 randomized controlled trials alone.

9 DR. WILSON: Hi, this is Michael
10 Wilson, can you hear me okay?

11 DR. ROSS: Yes.

12 DR. WILSON: You can hear me, okay.
13 So, agreed that when summarizing the data we
14 looked at randomized controlled trials and we
15 looked at observational studies. So when we
16 did see a JAMA paper we did a subgroup analysis
17 where we looked at the impact based on study
18 design. So for example, what were the effects
19 on outcomes when we just looked at randomized

20 controlled trials, what were the effects on
21 outcomes when we looked at just observational
22 studies? And primarily the effect when we
23 looked just at randomized controlled trials,
24 the effect size went away and was not
25 significantly significant. There were trends

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1 in improvement when we looked at randomized
2 controlled trials but a majority of the effect
3 is coming from observational studies.

4 So we combined the effect size for
5 both types of study interventions for this
6 paper based on what, the results were
7 consistent, they were in the same direction,
8 and I think if more randomized controlled
9 trials would be done, the effect size will
10 agree with that in the observational studies.

11 But agreed, there is a difference there and
12 we're trying to evaluate the data, we're just
13 trying to look at all the studies which are
14 currently available.

15 DR. BACH: Does that answer your
16 question?

17 DR. ROSS: Yes.

18 DR. BACH: Let's go on to Dr. Garrido.
19 DR. GARRIDO: This is Melissa Garrido.
20 My question is for Dr. Wilson. First, thank
21 you for your very clear and comprehensive
22 presentation. You mentioned one post hoc trial
23 with completely different hypercapnia levels.
24 I was wondering if any of the other studies
25 included in your review were powered to assess

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1 any other treatment effects, or in other words,
2 differences in outcomes for patients with
3 different baselines.

4 DR. WILSON: So thank you so much,
5 this is Mike Wilson again. What specific
6 characteristics were you looking at, or do you
7 have any in mind?

8 DR. GARRIDO: I don't have any
9 specific ones in mind, I was just curious if
10 any others came up in your review.

11 DR. WILSON: Yeah, so the only ones
12 that really came up were the ones that I
13 mentioned in my presentation. So there was,
14 when we looked at comparisons of different
15 devices for different disease categories,
16 different modes, so some studies looked at

17 stable versus unstable, so patients with a
18 recent exacerbation versus no recent
19 exacerbation. I don't recall that we found
20 that the studies that enrolled patients with
21 different FEV1s or something like failed to
22 compare or even enroll, you know, patients with
23 severe COPD versus less severe COPD. And
24 again, we didn't find studies that looked at
25 the different levels of hypercapnia, this was

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1 just looking at, you know, if we have 10
2 studies and they all have different levels of
3 CO2 and we sort of indirectly analyze that, is
4 there a signal there somewhere which would have
5 no direct comparisons.

6 DR. GARRIDO: Thank you.

7 DR. BACH: All right, on to

8 Dr. Barreiro.

9 DR. BARREIRO: Thank you, Chair. I
10 have two questions and I hope I can do it that
11 way. Number one is -- both questions are for
12 the complete panel. The first question is why
13 was Europe so much better, meaning why are
14 there so many studies done there, and most of

15 the studies done by pulmonologists like they
16 are here, or are they mainly ordered by
17 intensivists or family practitioners, and
18 that's why they are often so different?

19 My second question goes along with
20 Dr. MacIntyre's. The technology that was
21 mentioned repeatedly and the use of respiratory
22 therapists in an inpatient or outpatient
23 setting in order to help with compliance and
24 adjustment seemed to be mentioned in each one
25 of the presentations. I wanted to know if they

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1 looked at was there a timeframe in which the
2 respiratory therapist was available, was there
3 a number of visits that were important in order
4 to increase compliance? Was there training
5 that also went from the respiratory therapist?
6 In other words, were they all certified or not
7 certified? Because my frustration as a
8 pulmonologist is I rarely can get someone to go
9 out to help these patients when they're in
10 trouble or have questions. So I would like to
11 know the percent of changes that were made with
12 each visit if possibly known.

13 And the other part is the connection,

14 we keep talking about technology, the
15 connection with my office. So we use DMR, but
16 the connection between what the DME companies
17 are doing and getting me the information to
18 make changes doesn't seem to be very unique
19 and/or unified, and is there this task force
20 that keeps being mentioned by all the panel
21 members, is there a way, who would you ask on
22 this task force? Thank you.

23 DR. BACH: Whichever -- go ahead,
24 Dr. Nunez.

25 DR. NUNEZ: Just to follow up on two

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1 of the questions from Dr. Barreiro, and the
2 first one about Europe. So most of the studies
3 that I am familiar with, and I've worked
4 directly with some of the subject matter
5 experts in Europe on some of these studies, are
6 conducted by either intensivists or pulmonary
7 specialists. It seems to be a very specialty
8 driven approach in Europe to this research and
9 so these principal investigators and the
10 majority of these PIs are not just doing this
11 every single day in their clinical practice but

12 researching this quite extensively for many
13 many years. So some of the names you saw
14 mentioned like Dr. Dreyer from Germany, you
15 know, he's a pulmonologist and thinks about
16 this all the time.

17 I would say in terms of the question
18 regarding the connection of information between
19 your EMR or your office, the HME and the
20 patient, based on some of the comments I made
21 earlier, the new generation of devices, the
22 ones that are connected to the Cloud that allow
23 you to see that information directly, we are
24 slowly ushering in a new age where both the
25 DME, HME, providers and patients themselves

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1 will have access to the data, and what we have
2 found is the more access to data from the
3 therapy, the better the adherence. You know,
4 medication adherence in the U.S. is 50 to
5 55 percent at best, which is about the same for
6 CPAP or home mechanical ventilation. But when
7 you add in the connective device or when you
8 add in patient engagement and the ability to
9 connect with them even remotely, the adherence
10 to therapy rises significantly. And so I think

11 we need to work on those connections. It is
12 the entire community here whether, it's not
13 just the vendor, the patients and the
14 providers, we need to work on making sure the
15 data is available so that as we move into an
16 era of remote care, remote monitoring,
17 virtualized care, how we can take advantage of
18 the technology that already exists.

19 DR. BARREIRO: Is there a HIPAA
20 restriction to this as well?

21 DR. NUNEZ: Obviously there are
22 because there's a potential of personal health
23 information being transmitted but again, modern
24 platforms, modern devices have that all built
25 in, security is designed in from the ground,

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1 and so we want to make sure that we don't lose
2 that critical connection so that any provider,
3 any clinician does have the appropriate access
4 to that type of information in a private and
5 secure manner.

6 DR. BACH: Thank you very much,
7 Dr. Nunez. Dr. Lisa Wolfe has an answer about
8 the technical panel which was the previous

9 question, if you'd like to jump in, Dr. Wolfe.

10 DR. WOLFE: Okay, thank you. Can you
11 hear me?

12 DR. BACH: We can.

13 DR. WOLFE: This is Lisa Wolfe. As
14 the representative of CHEST I'd like to give a
15 little bit of background on the technical
16 panel. The original, original technical panel
17 that established the RAD criteria dates back to
18 1998. That was convened by AARC which is now
19 part of CHEST, in which many members who are
20 here today actually helped to contribute
21 information that allowed us to establish the
22 criteria by which different diagnostic
23 criterion are used to say bilevel is
24 appropriate, bilevel with backup is
25 appropriate, et cetera. Since 1998 those

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1 criteria have not been updated. The discussion
2 of things such as high intensity pressure
3 support and the importance of hypercapnia that
4 we now know can cause research was not
5 available at that time. And so although
6 technically not part of our four questions
7 today, we find that there is significant

8 interlacing between our ability to understand
9 how HMV is used and our ability to fix the RAD
10 criteria allowing us to better and more
11 appropriately use high level PAP in the home.
12 And so what we are asking is that for
13 Medicare as an organization as we address the
14 issues of HMV, as we address the issues of
15 chronic respiratory failure and COPD, that we
16 also take a 10,000-foot view, step back and say
17 we'd like to fix the system globally. That
18 includes a new technical panel and an updating
19 of the out of date RAD criterion.

20 DR. BACH: Great, thank you very much,
21 Dr. Wolfe. Dr. Fisch, did you have a question?

22 DR. FISCH: Yes.

23 DR. BACH: So I have Dr. Gay,
24 Dr. Frazier, Dr. Criner and Dr. Kuebler who are
25 queued up, so please take down your hands if

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1 they are still up.

2 DR. FISCH: Thank you, Dr. Bach. So I
3 have a question I would like to address to
4 Doctors Wilson and Wolfe, and it has to do with
5 the fact that we are focusing our questions

6 here on Medicare beneficiaries, but we've heard
7 a lot about how things are different in Europe
8 compared to the United States. One, the
9 different distributions of phenotypes being
10 treated, and different models related to the
11 wraparound services that go with what is
12 actually the intervention of one of these
13 devices plus the settings being used plus the
14 other services like respiratory therapy or
15 pharmacy consultations, et cetera.

16 So the question is, one question is
17 how comfortable should we be in generalizing
18 the data from Europe given that there are no
19 randomized control trials in the United States?
20 And then the other question I have is, it's a
21 bit of a naive one I guess, I'm a medical
22 oncologist, and it seems there are, you know,
23 there is maybe 230,000 lung cancer patients per
24 year in the United States, yet we routinely see
25 randomized trials in the United States

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1 enrolling 500 patients overall, and there's
2 just no trials in this whole field of 200
3 patients or more. I'm just incredulous as to
4 how that could be for such a prevalent and

5 serious condition like COPD.

6 DR. WILSON: So this is Dr. Mike

7 Wilson. Thank you so much for your comment.

8 So with regards to generalization, I agree with

9 you on that, life in Europe is different than

10 life in the United States, both in terms of the

11 devices but like you said, in terms of the

12 services and the whole infrastructure that is

13 set up to deliver this. And so I think for

14 today, if I understand correctly, CMS is able

15 to talk about or provide coverage for the

16 devices but I don't know if CMS is able to

17 provide coverage or who in the United States

18 would provide coverage for the associated

19 respiratory services. And so I think trying to

20 say well, does device use alone with or without

21 respiratory services provide a benefit, and

22 then the second question is in the United

23 States, will the addition of those respiratory

24 services provide benefit and if so how can we

25 achieve that in the United States, but there

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1 are questions with regards to generalization.

2 That being said, the observational studies in

3 the United States do go along, some of them,
4 with the conclusions that are made based on the
5 European studies. And so I do think that even
6 in our population in the United States, there
7 are benefits from device use alone.

8 And to your second question, why are
9 there so few randomized controlled trials, A,
10 in the United States, and B, that have enrolled
11 fewer numbers of patients. I think one in
12 power, so the ones that have been conducted
13 have been adequately powered usually to see
14 this but not to detect all outcomes, and so I
15 agree with what's been said previously. We
16 need more randomized controls in the United
17 States, this would help significantly.

18 DR. BACH: Thank you very much, and
19 we're going to move on to Dr. Gay please.

20 DR. GAY: First I want to address the
21 MEDCAC group and thank them for the opportunity
22 to speak with this fantastic array of people
23 here. Ultimately the historical comments
24 really deserve perspective. I was one of the
25 fossils that was part of the 1998 guideline

2 decades, but it's difficult to understand that
3 insofar as we knew hypercapnia was the key, but
4 we are all short-term focused in a three-month
5 study that showed that CO₂ can be changed, but
6 now we're focusing on much more important
7 things.

8 But in the process of all of this, CMS
9 had to address delivery of equipment and
10 reimbursement issues that completely distorted
11 the criteria from a patient-focused problem to
12 a device-focused problem. There was a huge
13 difference in reimbursement for not only a home
14 mechanical ventilator, which was not part of
15 the RAD criteria, and early on the backup rate
16 was twice the cost of producing something with
17 a spontaneous rate. So these artificial
18 barriers grew out of all this and rather than
19 addressing the specific patient phenotypes we
20 got locked into the devices.

21 The devil's in the details, and I've
22 spent a lot of time reading the pendencies of
23 these randomized controlled trials, and they in
24 fact attempt to address these different
25 phenotypes. They talk about whether they did

1 sleep studies, they talk about the BMI, and
2 ultimately recognizing that it's so hard to do
3 these. The Kohnlein trial took six years to
4 do. All of those require such an immense
5 consideration of how to get these done that now
6 the best evidence narrows this to the point
7 where it's very difficult to get perspective on
8 the clinical issue.

9 So I'm going to move to my question
10 for Dr. Wilson. I know him as a superb
11 researcher, I also know him as a great
12 clinician. And recognizing all this intense
13 evidence pointing to this small subgroup of
14 patients, we've been trying for five years now
15 to get CMS to give us this expert panel, and
16 I'm going to ask Dr. Wilson if we were to
17 empower you and turn you into a policy wonk now
18 instead of the great researcher that you are,
19 with your interest in obviously taking care of
20 patients with hypercapnic respiratory failure,
21 how would you direct this expert panel that we
22 all are asking for to create criteria that
23 would ultimately take this evidence, would
24 deliver a product to the Medicare beneficiary?

25 DR. WILSON: Okay. So thank you,

1 Dr. Gay, for your question. Can you -- you
2 would say how would I direct the expert panel
3 to do what?

4 DR. GAY: To create the focus on
5 chronic respiratory failure as not just so
6 specific to these questions coming out of
7 hypercapnic COPD, but recognizing that the
8 phenotypes in these specific studies are more
9 broad than what you can actually talk about in
10 just a single study. So now, how would you
11 bring all of these phenotypes together and take
12 advantage of the more specific evidence that
13 you addressed in your meta-analysis. Put it
14 all together.

15 DR. WILSON: So I think putting it all
16 together, I think there is, regardless of the
17 device type, we have more evidence for Bi-PAP
18 compared to HMV machines. But if you look at
19 noninvasive positive pressure ventilation as a
20 whole, I think independent of the respiratory
21 services offered, I do think this is
22 significant evidence to support its use in the
23 home. But I think that still specifically, you
24 know, which exactly, who do we put on these
25 devices, so out of all the patients with COPD,

1 who deserves to be on, who needs, or who would
2 benefit from a noninvasive positive pressure
3 ventilation?

4 I think that the criteria for that is
5 quite gray, so what level of hypercapnia do we
6 do? Some studies use a level greater than 45
7 and they enroll and they show a benefit. So
8 used a CO2 level greater than 56, they enrolled
9 and they can show a benefit. And so I think,
10 but I think generally speaking there is support
11 for people with stable COPD, unstable COPD, and
12 some degree of hypercapnia to use these devices
13 in the home. And so then the question begins
14 if you look at that, then how do you make that
15 happen for individual patients, and that's kind
16 of translating the data to a policy.

17 DR. BACH: Thank you very much for
18 that thoughtful answer. A couple of things
19 logistically. I would ask that people turn off
20 their cameras so we can preserve bandwidth if
21 you are not speaking. We are, we have a couple
22 more minutes before the lunch hour, which is
23 11:30 eastern. The next person to ask a

24 question is actually one of the speakers,

25 Dr. Frazier.

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1 DR. FRAZIER: My question's for Dr.
2 Wilson. Dr. Wilson, you're getting all the
3 action this morning. Thanks for your
4 presentation and thanks for the wonderful paper
5 you wrote up. I've got to nitpick with you, I
6 want you to answer for me.

7 There are two studies comparing home
8 mechanical ventilation to no device that you
9 chose for the review, one is the Heinemann
10 paper and the other's the Paone paper. I
11 reviewed those in great detail and in fact the
12 Paone paper didn't use home mechanical
13 ventilation, it used a Respironics Synchrony,
14 which is a RAD device. What's important about
15 that is that's the study that showed a higher
16 mortality in the treated group, not
17 statistically but numerically, 13 deaths versus
18 10 deaths, and with putting that with the
19 Heinemann paper you reached a conclusion that
20 there was no evidence that HMV reduced
21 mortality. But if you remove the Paone paper,
22 which was actually done with a RAD device,

23 there is a statistically significant reduction
24 in mortality, though obviously it's only the
25 one study, the Heinemann study. I think that

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1 makes a difference.

2 DR. WILSON: So thank you for your
3 comment, I really appreciate that. For that
4 specific thing, I guess I will have to go back
5 and look and review it myself. From what I
6 understood, that this was classified as an HMV
7 device, but I will be happy to go back and look
8 at our files to look that up, and if for
9 example that's what you have noted, then the
10 conclusion may be different.

11 Again notwithstanding, I think that
12 even if you combine all the studies,
13 noninvasive positive pressure ventilation
14 versus none, it does support the mortality
15 benefits, so I think there are signals on
16 several levels, where this device used or NIPPV
17 is associated with better mortality, or less
18 mortality for patients with COPD.

19 DR. FRAZIER: Certainly, no question.
20 I just want to make sure because it does say in

21 the paper conclusion that HMTV did not show a
22 mortality benefit when in fact in reclassifying
23 the device, it does. That's my point. You're
24 right, put together it all shows a benefit, but
25 it specifically in this meta-analysis, HMTV does

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1 if we reclassify it. Thank you.

2 DR. WILSON: Yeah, thank you.

3 DR. BACH: Thank you very much for
4 your question, Dr. Frazier. Dr. Criner.

5 DR. CRINER: Yes, Jerry Criner from
6 Temple University in Philadelphia. This is
7 directed to, again, Dr. Wilson, and I want to
8 assimilate a lot of disparate information and
9 make it understandable. So some of the
10 limitations that you mentioned both in your
11 paper and your presentation kind of looks at
12 the ability to take the aggregate body of data
13 and really come up with specifics, although
14 there's a directional improvement with therapy,
15 but who to treat, how to treat, when to treat,
16 and really the specifics of the why we're
17 treating patients. Do you feel that the
18 current information is adequate to show that
19 now, or is there not a need for additional

20 studies, but for a larger multicenter
21 randomized controlled trial where really the
22 technique, the specifics of patient
23 characteristics and the outcomes are better
24 defined in the United States population, not
25 because the United States is different than the

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1 rest of the world but because our patient
2 population in terms of comorbidities, obesity,
3 concomitant medications are different?
4 DR. WILSON: Just sort of -- thank you
5 so much for your comment. Yeah, so I would
6 agree with you. So I think the status of
7 affairs from the best that could be summarized,
8 I think show a directional impact of these
9 devices on outcomes. That being said, the
10 variability, the heterogeneity in all of these
11 studies and sometimes disparate conclusions
12 between one study versus another, we need some
13 better level evidence here. And so even if you
14 look at the European studies, there's still
15 several questions to be answered when applying
16 this to a United States Medicare population.
17 So I completely agree with you that further

18 studies such as the one you suggested would be
19 very beneficial.

20 DR. BACH: Thank you very much. Thank
21 you, Dr. Criner, for your question. We'll take
22 a question from Dr. Kuebler.

23 DR. KUEBLER: Can you hear me?

24 DR. BACH: Yes, we can.

25 DR. KUEBLER: Some of the questions

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1 that I had have already been answered, but it's
2 glaring to me the inconsistencies in the data
3 and the use, Dr. Wilson identified 13 different
4 guidelines, and some of the other studies
5 relied exclusively on the GOLD criteria and the
6 St. George Quality Of Life Questionnaire. But
7 my, I'm shocked at the amount of increase in
8 ordering. I'm wondering who's ordering these
9 devices and what is, you know, if it's
10 pulmonologists, you know, that's one thing; if
11 it's primary care providers or nurse
12 practitioners that's another thing, you know.
13 But from the information or guidelines we rely
14 on, it looks like the last guideline that we
15 had was 1998, and Dr. Owens mentioned that a
16 new guideline was being developed.

17 Are these addressing all providers? I
18 mean, who is ordering these devices in the
19 United States?

20 DR. OWENS: This is Bob Owens from
21 UCSD. I'm not sure that I can answer all of
22 your questions. I do think our guidelines are
23 designed for all people that take care of
24 patients with COPD. I think that a consistent
25 theme through all of these questions really has

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1 to deal with the fragmentary nature of our care
2 for patients. You know, they're coming in with
3 an acute exacerbation, they're being taken care
4 of in an ICU. They go to the floor, they're
5 under the care of our hospitalists. They're
6 discharged, they're under the care of a DME.
7 So in my mind one of the differences between
8 Europe and America is the integration of care
9 and how we practice in different settings. I
10 think that explains differences in outcomes, it
11 explains why we don't have large studies, you
12 know, it's just very hard to do these kinds of
13 things.

14 So again, our guidelines are for all

15 providers. I think perhaps some of the DME
16 companies can speak to this. My sense, and
17 Dr. Coleman, Dr. Wolfe and others, the panel
18 can probably give their opinion, but my sense
19 is often these devices are ordered upon
20 discharge from the hospital and trying to help
21 patients, and it's easier to go the HMV route
22 than to get a patient to a qualified provider
23 very quickly and do Bi-PAP or bilevel PAP with
24 a backup rate.

25 DR. BACH: Thank you very much,

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1 Dr. Owens. Dr. Melnikow?

2 DR. MELNIKOW: Can you hear me now?

3 DR. BACH: Yes, we can. Put your hand
4 down when you have a chance.

5 DR. MELNIKOW: Okay. So I have some
6 kind of basic questions that maybe everyone
7 else on the panel understands, but as a family
8 physician these are not devices that I interact
9 with very often. And I'm still, there's been a
10 lots of discussion about HMV versus Bi-PAP and
11 I'm not really sure what the difference is, and
12 other than differences in what's covered and
13 what's not, why one would order one device

14 versus the other, and the justification for
15 doing separate analyses of these different
16 devices as well. So maybe Dr. Wilson can speak
17 to that or maybe Dr. Coleman could educate me
18 further about this.

19 DR. WILSON: Dr. Coleman, this is
20 Dr. Wilson, so feel free to chime in. Right
21 now there are different criteria in order to
22 qualify someone for use for one of these
23 devices. So if you want to qualify somebody
24 with COPD for a Bi-PAP S then there are certain
25 criteria that you need to fulfill. If you want

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1 to qualify somebody for a Bi-PAP ST device or a
2 device with a backup rate there are different
3 criteria that you need to use to qualify them.
4 If you want to qualify somebody for a home
5 mechanic ventilator or a life support or
6 lifesaving device then there are separate
7 criteria. And so some perceive that the
8 criteria to get a home mechanical ventilator
9 device is easier to qualify an individual
10 patient sometimes for this such device compared
11 to a Bi-PAP S or ST or something like that, so

12 that could be one of the reasons why a lot of
13 people are using this, using home mechanical
14 ventilator devices. But that being said, the
15 reimbursement and costs and everything is much
16 more expensive with the HMV devices compared
17 with the Bi-PAP devices.

18 Dr. Coleman, I don't know if you have
19 any other thoughts on that.

20 DR. COLEMAN: Sure, so thank you very
21 much. Great question, and I would like to, I
22 prefer to keep things simple so if you look at
23 the two big categories. Bi-PAP, when we talk
24 about all these different modes of ventilation
25 we're talking about pressure support, we're

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1 talking about how do we get ventilatory
2 support, right, and I agree with Dr. MacIntyre
3 that all the terminology gets jumbled up.

4 So when we talk about giving bilevel
5 or Bi-PAP support, those devices are what are
6 called respiratory assist devices, so those
7 are, if you think of treating one of your
8 patients at home with sleep apnea, those fall
9 into the categories of respiratory assist
10 device machines. They provide different modes

11 of ventilation, they can provide CPAP, Bi-PAP,
12 Bi-PAP with a backup rate, and they have to be
13 plugged into a wall. They have to, they don't
14 have any alarms, they are not like the seeing
15 devices per se because if the power goes out
16 there will be no support beyond that.

17 Home mechanical ventilators kind of
18 grew as chronic respiratory failure moved out
19 of the ICU and into home usage. It's very
20 common in patients with neuromuscular diseases
21 like ALS or muscular dystrophy. They are a
22 life support machine so they have internal
23 batteries, they have portability. A home
24 mechanical ventilator can be used in different
25 ways. It can be used noninvasively with a mask

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1 or a nasal cannula, or it could be used
2 invasively with a tracheostomy.

3 When we talk about different modes of
4 ventilation, the Bi-PAP or Bi-PAP with a backup
5 rate, they can be used on both machines so
6 that's where it gets confusing. In the United
7 States under the current respiratory guidelines
8 if a patient comes into the hospital with acute

9 COPD exacerbation, and Dr. Owens kind of
10 alluded to this, that patients come into the
11 hospital with acute COPD but this is the third
12 or fourth time they are coming in, and now
13 hospitals are working to prevent hospital
14 admissions. So the thought is they come in,
15 they had acute chronic hypercapnia, we gave
16 them Bi-PAP and they get better, so if they had
17 that Bi-PAP to go home maybe they won't come
18 back as often. And I think that that is where
19 this is being driven for why there's being so
20 much use of noninvasive ventilation.

21 So criteria currently in the United
22 States, giving somebody a Bi-PAP machine or a
23 respiratory assist device is much more, is very
24 challenging, so instead you can just do a blood
25 gas and call someone hypercapnic and get them a

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1 home mechanical ventilator. They are using the
2 same type of respiratory ventilation support,
3 it's just that the device is, again, it's just
4 like a Tesla versus like a Honda, they both get
5 to the same point if you have the same drivers,
6 but you don't need to actually have the Tesla.

7 DR. MACINTYRE: Peter, this is Neil

8 MacIntyre. Can I make a comment here? Peter?

9 DR. BACH: Dr. MacIntyre, you are free
10 to make a comment and then we're going to stop
11 after this question for lunch.

12 DR. MACINTYRE: I will be very brief.
13 I just want to reiterate that the technical
14 differences between a Bi-PAP or a RAD and a
15 home mechanical ventilator are really quite
16 subtle and blurred. And in fact in many parts
17 of the world what we call a Bi-PAP machine is
18 often used in an ICU as a full-fledged
19 ventilator because the technical features are
20 somewhat similar.

21 I will agree with the other speakers
22 that the choice of using a Bi-PAP or using a
23 home mechanical ventilator actually rests on
24 things other than the technical differences.
25 The ease of qualification has been emphasized

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1 by several, and I would also want to reiterate
2 that one of the major drivers, I think, of
3 ordering a home mechanical ventilator as
4 opposed to a Bi-PAP system is that you get the
5 very very important frequent servicing by

6 technical experts.

7 DR. BACH: Thank you very much.

8 Dr. Wolfe, I was going to take a break here.

9 Is this in relation to this question?

10 DR. WOLFE: Yes, 30 seconds.

11 DR. BACH: Absolutely, if it's in
12 relation to this question, everyone should have
13 a chance to speak and then I'm going to take a
14 break.

15 DR. WOLFE: So Dr. Melnikow, just a
16 couple of things that are very hard differences
17 between the two devices. A RAD device maxes
18 its pressure at 25, if you need more than 25 of
19 pressure you've got to go to a bigger device.
20 Since ventilation which is used during the
21 daytime is only available on a home mechanical
22 ventilator, it's not available on a RAD, if you
23 need a set interface with the mouth for daytime
24 you've got to go to the other device. Also in
25 our patients that need portability, the

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1 internal battery on the home mechanical
2 ventilator allows them to have that
3 portability, and if they are so in need of care
4 that if their electricity were to suddenly go

5 out like we see in our tornado and hurricane
6 corridors, the need for that internal battery
7 is essential, so I just wanted to summarize
8 that in short form.

9 DR. FRAZIER: Peter, this is Bill
10 Frazier. I want to make one quick comment on
11 this very same question. Another difference is
12 regulatory. Remember, HMV, home mechanical
13 ventilators are indicated by the FDA to treat
14 chronic respiratory failure, for the most part
15 RAD devices aren't.

16 DR. BACH: Thank you very much. If
17 that is the totality of the answers to
18 Dr. Melnikow's question we are going to break
19 for lunch.

20 Just so you know, I currently have two
21 questions for the panelists, Dr. Fernander and
22 Dr. Salive, which we will do immediately after
23 lunch. If you also want to ask a question and
24 I didn't get to you, please send me a chat. We
25 are going to stop for one hour, it is currently

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1 11:40 eastern or 11:39. We're going to
2 reconvene at 12:40 on the dot. Please, as I

3 said, if there are any issues please feel free
4 to email me. Everyone enjoy your lunch and we
5 will talk soon.

6 (Luncheon recess.)

7 DR. BACH: Good afternoon, everyone.

8 I'd like to get started with the afternoon
9 session. We had a handful of holdover
10 questions to the presenters from the morning,
11 I'd like to start right off with those. First
12 from Dr. Fernander, are you back from lunch
13 yet.

14 MS. HALL: Peter, before you do that,
15 can I do the rollcall to make sure all the
16 panel members are on the line please?

17 DR. BACH: Oh yes, thank you, Tara.
18 Please, Tara, go ahead, we will do the rollcall
19 for the MEDCAC panel.

20 MS. HALL: Okay, thank you. Of course
21 Dr. Bach is on the line. Dr. Ross, are you
22 there?

23 DR. ROSS: Yes, I'm on the line.

24 MS. HALL: Dr. Garrido?

25 DR. GARRIDO: Yes, I'm here.

1 MS. HALL: Dr. Kuebler?

2 DR. KUEBLER: Yes.

3 MS. HALL: Dr. Manship? Dr. Manship?

4 Dr. Barreiro? Dr. Fernander? You might want

5 to wait a couple minutes to make sure everybody

6 gets back on.

7 DR. BACH: We are down a couple of

8 people it sounds like, so we will give this a

9 few minutes here.

10 MS. HALL: Okay.

11 (Recess.)

12 DR. BACH: Tara, whom are we waiting

13 for still?

14 MS. HALL: I thought Dr. Manship, I

15 was going to wait until 12:45 and then ask him

16 again. Dr. Manship, are you on the line?

17 DR. BACH: I don't see him in the

18 attendee list either.

19 MS. HALL: Okay, I'll send an email.

20 Dr. Barreiro?

21 DR. BACH: Also not here.

22 MS. HALL: Dr. Fernander?

23 DR. BACH: Dr. Fernander is on.

24 MS. HALL: I know Dr. Fisch is on.

25 Dr. Melnikow? And I saw Dr. Salive. Dr. Gay,

1 I see you. Dr. MacIntyre.

2 DR. MACINTYRE: I'm here.

3 MS. HALL: And then Dr. Criner? Okay.

4 So I will email those to see what's happening

5 and you can go on with your questioning. Thank

6 you.

7 DR. BACH: Tara, can I proceed.

8 MS. HALL: Oh, yes, I'm sorry. I

9 thought you heard me, I said you can go on with

10 the questions and I'll email them.

11 DR. BACH: All right. I now have

12 Doctors Fernander, Salive and Garrido waiting

13 to ask questions. Can we start with

14 Dr. Fernander please?

15 DR. FERNANDER: Good afternoon,

16 everyone. I just have a question. Given the

17 patient population and what we know about

18 health disparities and health inequities

19 related to respiratory illness, I am curious as

20 to whether any of the presenters can discuss

21 any studies or any data that might exist

22 regarding health inequities related to the use

23 or prescription recommendations regarding the

24 use of any of the devices based on the etiology

25 of the disease or otherwise. We know that

1 there may be various differences in etiology
2 among marginalized populations for a variety of
3 reasons whether it's race, ethnicity,
4 socioeconomic status and so forth, as well as
5 comorbidities that are related to those same
6 issues. So I'm just curious if there's any
7 data that discusses disparities as well as
8 inequities in treatment recommendations and how
9 they may influence outcomes that we are
10 interested in this afternoon.

11 DR. WOLFE: If anyone else doesn't
12 have an answer, I have one.

13 DR. BACH: Please, Dr. Wolfe?

14 DR. WOLFE: One of the things that I
15 spoke to in my slides is the big interplay that
16 we see in obesity on top of COPD. It's a huge
17 confounder in our population that have more
18 complications with access to care. It's
19 something that very unique in terms of what we
20 see in the American population that's not in
21 the European population, probably in large
22 degree to the overlap in the risk of developing
23 obesity and diabetes with it in this group.
24 And so I think that we need to think broadly
25 about assuring that as we make changes to

1 access in COPD that we recognize that these
2 patients may also have obesity hypoventilation
3 and that needs to remain having equal access to
4 care.

5 DR. BACH: Thank you. Would anyone
6 also want to address this question?

7 DR. OWENS: This is Dr. Owens from
8 UCSD. You know, I think we are not (inaudible,
9 static) but when we formulated our upcoming
10 guidelines we also were concerned that
11 providing home mechanical ventilators as an
12 expensive therapy needing specialized input
13 that there was the potential to worsen health
14 disparities. I would emphasize what Lisa said.
15 I think that providing high quality care and
16 providing the right care for patients, kind of
17 one of the themes we've been talking about,
18 providing care around the patients as opposed
19 to around the device, I think will be very
20 important for the panel to consider. Thank
21 you.

22 DR. BACH: Thank you very much. I'm
23 going to move on to Dr. Salive, who has a

24 question.

25 DR. SALIVE: Thank you, Marcel Salive

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1 from NIH. So it's kind of a followup to the
2 last comments. I think, you know, we heard
3 some interesting comments about the comorbid
4 conditions such as obesity, obstructive sleep
5 apnea. I had a question more broad about other
6 potential comorbidities. It seems like
7 congestive heart failure was excluded from the
8 review for some reason, and then some of the
9 comorbidities of obesity can be things like
10 diabetes, goes along quite commonly with that,
11 so it may be really multi-morbidity rather than
12 just pairs of conditions that would link to
13 potential outcome of these studies.

14 So my question is for, I have two
15 questions, one I think is for Dr. Wilson and
16 the other is broader for anybody. But in the
17 systematic review, were you able to look at the
18 comorbid conditions in the meta-analysis,
19 because sometimes that is possible since you
20 had so many small studies, and did you see any,
21 you know, effects from the comorbid conditions
22 linked to the outcomes? Or could that, as I

23 think was suggested by Dr. Wolfe in her
24 comments, would certain comorbidities be
25 relevant for the device selection in this case?

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1 And then my overarching question is
2 since I think this is a big gap, it's commonly
3 seen in guidelines as was mentioned a moment
4 ago, that guidelines need better evidence on
5 groups of people that have the common comorbid
6 conditions, how can we get better evidence with
7 this question here? Thank you.

8 DR. WILSON: Can you hear me okay?
9 This is Mike Wilson. Thank you for your
10 question. So in our systematic review we
11 analyzed patients with COPD and we also
12 analyzed patients with obesity hypoventilation.
13 Now in looking at the COPD, patients with COPD,
14 I would say a majority of the included studies
15 excluded patients with concomitant sleep apnea
16 or suspicion of sleep apnea, I would say maybe
17 two-thirds of them, I don't have the exact
18 number. So it's much, but no, we did not a
19 priori pre-specify should we analyze outcomes
20 based on did they include any patients with

21 sleep apnea or with mild sleep apnea or severe
22 sleep apnea or obesity or these types of
23 things, so we don't have that data available.
24 So that's probably the answer to your question.
25 DR. FRAZIER: This is Bill Frazier;

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1 may I answer that question? In the study that
2 I talked about, our Medicare database
3 retrospective looking at limited data, we
4 pulled the 36,000 patients diagnosed with COPD
5 CRF and in the subgroup, the 410 that were
6 placed on HMO, remember in the limited data set
7 I only get five percent of the data, that's all
8 Medicare offers, and so that 410 is the
9 five percent I got. In that group I can tell
10 you that 86 percent were Caucasian,
11 eight percent were African-American. In that
12 group 14 percent had a stroke, 32 percent had
13 congestive heart failure, four percent were
14 paraplegic, eight percent had a recent
15 myocardial infarction, four percent had chronic
16 liver disease. Their Charlson comorbidity
17 numbers were three and four. So your point is
18 exactly right, these people have a lot of very
19 serious comorbidities that are in the HMO group

20 and they're also in the control group as well.

21 DR. SALIVE: So is your publication in
22 press now or is it, you said it --

23 DR. FRAZIER: Yes, sir, this first one
24 is revised and the revision has been submitted.
25 The second, the manuscript is under

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1 preparation, it will be presented in a slide
2 show presentation to CHEST in October.

3 DR. WOLFE: This is Dr. Wolfe. Can I
4 just say one thing real quick? I'm sorry to
5 interrupt. Specifically to address the issue
6 of heart failure, we know that heart failure
7 patients can present with Cheyne-Stokes
8 respirations which is a different valatory
9 issue. The hallmark of Cheyne-Stokes
10 respirations is actually a low to normal CO₂
11 level so the pathophysiology is very different.
12 We know from the trial that that actually
13 increases mortality, so the reason that heart
14 failure is not discussed with the comorbidities
15 in this set is that if we had a heart failure
16 with low CO₂ they wouldn't qualify for the
17 device and it wouldn't be prescribed given the

18 increase in mortality with the device, so heart
19 failure is off the table.

20 DR. BACH: Thank you very much.

21 DR. OWENS: This is Bob Owens. If I
22 could also just add and put what was just said
23 in slightly different form, from the studies we
24 saw in the Kohnlein study, you know, a third of
25 patients were dead in one year, so this is a

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1 really sick population that you add
2 comorbidities just to go back to what some of
3 the speakers have been saying. It would be
4 great to have more data but, you know, if it
5 takes many years, these patients don't live
6 that long. You know, it's very hard to get a
7 large study in these people.

8 DR. SALIVE: So I would say it needs
9 to be measured, that's kind of my point, not
10 that we needed -- you know, it's just not
11 measured a lot of times. I think the claims
12 data makes it pretty well, if you don't look
13 and say what comorbid conditions people have,
14 you know, what, you just have to make
15 assumptions.

16 DR. BACH: Thank you very much. We

17 will go on to Dr. Garrido with a question.
18 DR. GARRIDO: Thanks, this is Melissa
19 Garrido. This question is for any of the
20 speakers and it's actually closely related to
21 Dr. Salive's question. So we heard today about
22 some of the observational studies that are
23 seeking to understand whether it's just a
24 matter of noninvasive ventilation or associated
25 with improved outcomes in an overall sample of

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1 patients with COPD. And some of them, like
2 Dr. Frazier's studies, are using propensity
3 score matching or waiting to match the treated
4 and comparison patients based on patient care
5 metrics.
6 So one of the, the benefit of some of
7 the observational designs is to the ability to
8 help identify patient subpopulations for whom
9 an intervention is most likely to be effective,
10 so to better target the intervention. And from
11 what I have gathered today, I haven't heard
12 anything about studies having the explicit goal
13 of doing that. I just wanted to double-check
14 if any of the observational studies that any of

15 you have mentioned or are otherwise aware of
16 how an explicit goal of identifying the
17 population of patients with COPD who would be
18 most likely to benefit from any of the types of
19 noninvasive ventilation we've discussed?

20 DR. GAY: This is Peter Gay. If you
21 look at the retrospective study that Coughlin
22 did, that was a clear directive of taking sort
23 of a mixed bag of hypercapnic COPD patients,
24 they had all the comorbidities, but the
25 directive was clearly keep them out of the

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1 hospital, we will pay you immense amounts of
2 money not to have them come back. So the
3 aggressive effort in that way to use HMV
4 whether it needed to be or not, it got this
5 device and with all their comorbidities it
6 immensely reduced the readmission rate.
7 Thanks.

8 DR. GARRIDO: So to clarify, in those
9 analyses, yes, they had a very open inclusion
10 criteria, but the analyses didn't try to
11 identify which subgroup of the included
12 patients were most likely to benefit, correct?

13 DR. BACH: Dr. Gay, you're muted, so

14 we're not hearing your answer.

15 DR. GAY: I'm sorry. They clearly
16 concentrated on the acutely ill hypercapnic
17 COPD by their very nature but you're right, it
18 was not well tabulated, there were a lot of
19 assumptions in there that there were generally
20 many comorbidities in a southern, southwestern
21 population.

22 DR. FRAZIER: This is William Frazier
23 again. I've also started another study that I
24 have tried to carve out of the Medicare
25 database looking at hypercapnia as a predictor

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1 to response, to see if now with including the
2 completed 2019 data I'll have enough ICD data
3 for hypercapnia that we will be able to make
4 some comment if that shows up as an independent
5 predictor of outcome with HMV therapy.

6 DR. CRINER: Dr. Bach, this is Jerry
7 Criner from Temple. I'd like to address
8 Dr. Garrido's question.

9 DR. BACH: Go ahead, please.

10 DR. CRINER: I'm thankful that Joe was
11 the senior author and the purpose of that was

12 trying to define subsets of people that were
13 acutely ill that could benefit from noninvasive
14 ventilation and towards design of an NIH
15 submission for treatment. So what was defined
16 from that study is that patients that were
17 acutely ill and hypercapnic from discharge who
18 were overweight with prior history of
19 respiratory failure within at least two weeks
20 of that admission were the ones more likely to
21 benefit, so that was an observational study
22 that was designed for that purpose.

23 DR. GARRIDO: Thank you.

24 DR. BACH: Thank you. And I will
25 remind everyone to turn on your cameras when

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1 you're speaking just so we can, you know, to
2 improve the interactivity. I'm not seeing any
3 other questions. Is there anyone who wants to
4 ask another question? Otherwise I'll be happy
5 to move on to the open panel discussion.

6 DR. ROSS: Peter, I have one more
7 question, this is Joe Ross, if I could ask.

8 DR. BACH: Sure.

9 DR. ROSS: Sorry, let me turn on the
10 video, sorry about that. Dr. MacIntyre made a

11 passing comment about the difference in the
12 devices that are used in Europe and the United
13 States, and either the similarity or
14 dissimilarity between the RADs and the HMs. I
15 was just wondering if our commenters could just
16 say a bit more about that given that so much of
17 the research that has been discussed came from
18 Europe.

19 DR. MACINTYRE: This is Neil
20 MacIntyre, I can make an introductory comment
21 here. I've been trying to reiterate, I think
22 it's the settings that are used, how the device
23 is used rather than the device per se, because
24 again, the technical features on RADs and home
25 ventilators are very similar. I think the big

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1 difference is how those settings are applied to
2 an individual patient and what kind of support
3 is available to assure compliance adherence and
4 effective therapy. Thank you.

5 DR. COLEMAN: This is John Coleman,
6 I'm going to respond to that as well. So I
7 think just to kind of put it in very broad
8 based terms, when we think of respiratory

9 support or ventilation we have acute and
10 chronic, right? So when we have acute
11 respiratory failure those are our patients that
12 end up in the medical intensive care units,
13 some have influenza, they come up COVID, they
14 get intubated or they end up with a
15 tracheostomy and they get inpatient
16 ventilation.

17 Then we talk about chronic respiratory
18 failure and we talk about noninvasive
19 ventilation, and noninvasive ventilation can be
20 done in many ways, it can be done through
21 various devices, and those devices include home
22 mechanical ventilators and they include
23 respiratory assist devices. Within respiratory
24 assist devices there's multiple modes of
25 ventilation, so Bi-PAP with a backup rate,

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1 Bi-PAP without a backup rate. You can do the
2 same thing with a home mechanical ventilator.
3 They're both forms of noninvasive ventilation.

4 And so I think that is where, you
5 know, like Dr. MacIntyre said, there's a lot of
6 alphabet soup that goes, that makes this issue
7 very complicated, right? You hear things like

8 NIV, NIC, HIV, RAD, BPAP, there's a whole bunch
9 of different anagrams. I think the important
10 things are that when you talk about noninvasive
11 ventilation for chronic respiratory failure you
12 are talking about respiratory muscle support,
13 and that can be done through a variety of
14 different devices. It just so happened that in
15 the European model sometimes they used pressure
16 support devices, sometimes they used home
17 mechanical ventilators. The same thing
18 happened in the United States.

19 Currently to treat chronic respiratory
20 failure in the United States under Medicare
21 guidelines, you give them a respiratory assist
22 device, so a machine like Dr. Wolfe alluded to,
23 that needs to be plugged into the wall, does
24 not offer portability and is not really a
25 machine that has alarms. You have to meet

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1 criteria and that criteria is very stringent to
2 meet, and so that's why we have gone down in
3 America the increase of home mechanical
4 ventilators. Both devices are similar, it
5 comes down to the modes of ventilation. That

6 is the point that I wanted to make in my
7 presentation here.

8 MR. GAY: This is Peter. I think,
9 John, you did a very nice job with your
10 presentation. I think it should be understood
11 that the difference between Europe and the U.S.
12 is that the Europeans do not have the
13 distinction between a backup rate and a
14 spontaneous rate. They expect as a standard of
15 care, for example, obesity hypoventilation, the
16 vast majority of patients are started in the
17 hospital with a backup rate and many of them
18 never even get a polysomnogram. The French
19 study that looked at the use of a high level
20 backup rate in fact pointed out the fact that
21 without that high backup rate it really didn't
22 work very well. So it's the standard of care
23 there, they're not worrying about the backup
24 rate. It made it very simple for them to have
25 a majority of these devices be a BPAP with a

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1 backup rate rather than a mechanic ventilator.

2 It's just the opposite here in this
3 country since the backup rate is immensely
4 difficult to get, dating back to 1998 studies I

5 apologize for, but ultimately that created this
6 artificial barrier. Thanks.

7 DR. FRAZIER: This is Bill Frazier, I
8 want to comment as well. I have a little
9 different perspective. I think the difference
10 in performance characteristics makes a
11 difference between ventilators and RAD. I
12 think the increased IPAP and I think the
13 increased peak flow really does make a
14 difference here. The outcomes data from the
15 U.S. that we generate is all the patients need,
16 and I could see some RAD-generated data in the
17 U.S. Medicare populations that would tell me
18 that those were equivalent outcomes. I'm not
19 sure they're going to be.

20 DR. VOHRA: This is Dr. Vohra, I have
21 a comment, Dr. Bach.

22 DR. BACH: Yes, please.

23 DR. VOHRA: Thanks. Another condition
24 that can lead to a positive differential can be
25 stent or bypass, and I think that's a very

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1 important intervention, but we don't look at
2 the cost of care, especially if that is as

3 common as it is, and the demographic change, so
4 I think that is something that has to be
5 considered.

6 And taking off of Dr. Gay's point
7 about having, alarming patients having the ST
8 mode and the S mode, and having to accommodate
9 for that, it's helping with the issue a lot,
10 and practitioners won't have to exacerbate the
11 same intervention, which is Bi-PAP all the
12 time. Direct comparison studies, yeah, they
13 are hard to do but it would be nice to have a
14 study like that, but those studies are hard to
15 do. That's my only comment. Thank you.

16 DR. BACH: Thank you very much. Would
17 anyone else like to --

18 DR. BARREIRO: This is Tim Barreiro, I
19 had a question and I just want to make sure
20 that I didn't miss anything. We spent a great
21 deal of time with the experts discussing the
22 cause of the hypercapnia. In the big packet
23 which we reviewed prior to the meeting,
24 however, there was a lot of comments and
25 diatribe that talked about the role of FEV1,

1 which I'm not necessarily a huge fan of because

2 I think you could have a very high FEV1 and
3 still be hypercapnic, and some of these studies
4 go as low as severe COPD with FEV1s that were
5 less than 30, and some that are mainly
6 moderate. So I just want to make sure if the
7 panel could be clear to me, are we saying that
8 hypercapnia, which I agree is most likely the
9 driving factor, then we should eliminate the
10 FEV1 role? Any comments to that?

11 DR. GAY: Clearly severe COPD is
12 important here. This goes back to really the
13 Jones study back in 1995 which was the hallmark
14 study that allowed noninvasive use for COPD and
15 hypercapnia. If you look at the only study
16 that really carried Medicare into this arena it
17 was that study, and I think the subtlety there
18 was if you looked at their oxygen run-in, those
19 are the patients that in fact developed more
20 hypercapnia on supplemental oxygen. If you
21 looked at his studies when he did the
22 polysomnogram criteria, his average AHI was 10
23 per hour. These patients in fact had mixed
24 disease, they had mild overlap syndrome, and I
25 think that gives you the perspective in the

1 degree of just, is it FEV1 or is it something
2 else. They have to have that nocturnal
3 hypoventilation component that I think drives
4 this hypercapnia.

5 DR. BARREIRO: Yeah, we may be saying
6 the --

7 DR. GAY: You're muted, Tim.

8 DR. BARREIRO: Thank you, sorry about
9 that.

10 DR. BACH: Dr. Barreiro, let me, let's
11 hold for one second, hang onto your thought. I
12 just want to tell the CMS people, it appears we
13 have naturally segued to the next phase of the
14 agenda so just to be clear, I think we are done
15 with asking questions of the presenters and we
16 are now having an open discussion between the
17 panel. I've gotten a couple of messages as
18 well that people want to ask each other on the
19 panel questions, that is what we are scheduled
20 to do right now. Again, it's scheduled for an
21 hour but we will be, we're going to go with the
22 flow here to some extent. It is not uncommon
23 for presenters to have things they want to
24 point out during this discussion. I'll ask
25 that you not interrupt but just message me, and

1 I will try and work it in even though we are
2 now within the panel discussion, so that we can
3 proceed from there. So Dr. Barreiro, I'm sorry
4 for interrupting you, you were about to respond
5 to Peter Gay on an issue, so go ahead.

6 DR. BARREIRO: No problem whatsoever,
7 Chair. I think we may be saying the same thing
8 and I want to be sure that Dr. Gay and I were
9 saying the same thing. I was struggling with
10 the concept of the heterogeneity of COPD and
11 that you could have, we would all agree that
12 the likelihood is here that advanced lung
13 disease causes more hypercapnia but we still
14 see people with mild disease that might be
15 hypercapnic and as he mentioned, the overlap
16 phenomenon or some other practice would go to
17 this.

18 As I'm thinking about our charge
19 moving forward, I just wanted to get some
20 clarity that maybe the FEV1 may not be included
21 in a criteria that we should be using, and I
22 wanted to make sure I was thinking along the
23 same lines, or maybe I was wrong.

24 DR. WOLFE: This is Lisa. Can I just
25 say one thing real quick? One of the sources

1 of confusion is the use of the standard GOLD
2 criteria to decide what's severe and what
3 isn't. That would still require FEV1
4 measurements. However, for the purposes of
5 home-based ventilation, severity is based on
6 hypercapnia and it really doesn't matter what
7 the spirometry shows. The vast majority of
8 inpatients during an exhibited exacerbation of
9 COPD are diagnosed with COPD, they are treated
10 for COPD, they do not get spirometry because
11 it's typically not available in a medical ICU.
12 And as such I would agree, FEV1 should not be
13 part of the criteria.

14 DR. BACH: And so let me point out
15 again, first of all we can, people can turn
16 their cameras off it it's easier for bandwidth
17 issues, but if you're speaking try and turn
18 your camera on unless it freezes your computer.

19 This is, just to be clear, this is a
20 conversation between the panel. I am asking
21 CMS as a courtesy to leave this open to the
22 presenters. Please respect that courtesy. To
23 the extent that if you feel there's some

- 24 critical factual clarification that is needed
- 25 please do let me know, message me, but please

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- 1 let the panel have their discussion. I hope
- 2 that's okay with everyone.

- 3 DR. VOHRA: So I have a comment on Dr.
- 4 Barreiro's question and Dr. Wolfe's comment.

- 5 DR. BACH: If this is a factual
- 6 clarification, that's great, but otherwise we
- 7 need to move on to our part of the discussion.

- 8 DR. VOHRA: Okay, just for the panel,
- 9 one of the things about the CO₂ versus the
- 10 FEV₁. In the HOT-HMV study they did use CO₂,
- 11 that's one of the parameters that was
- 12 monitored, and actually showed a significant
- 13 decrease in the transient CO₂ at 12 months.

- 14 DR. FRAZIER: This is Bill Frazier,
- 15 again being a contrarian. I'm an either/or guy
- 16 on this issue. Certainly hypercapnia is
- 17 sufficient for NIV but I'm not sure it's
- 18 necessary. All these people that have been
- 19 studied have hypercapnia, so the question
- 20 answers itself, of course it's beneficial. It
- 21 begs the more important question, is there a
- 22 bigger group of patients who might benefit and

23 how do we identify them, and I think FEV1 is
24 one of those tools. I think a clinical
25 characteristic such as a GOLD D, a frequent

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1 exacerbated recurrence is another way to
2 measure that. I don't want us to shut our
3 minds that there may be other patient groups,
4 because we've only studied one patient group.
5 And again, in my data set only 12 percent were
6 said to be hypercapnic, okay, maybe it was 50,
7 maybe it was 60, but it certainly wasn't all of
8 them, and in that all comers group there's real
9 mortality and health care utilization benefit
10 with HMO. Let's keep an open mind.

11 DR. BACH: Thank you. So I think some
12 of the panelists had questions or discussions
13 they wanted to have with the other panelists
14 and this is the time for that. Without putting
15 any pressure on you, Dr. Holt, I think you were
16 one of them.

17 DR. HOLT: Yes. I just wanted to
18 bring everybody back to why we're here at the
19 meeting. We're still trying to figure out what
20 Medicare is asking all of us, is there

21 something else that needs to be done, is there
22 some kind of adjustment, revision to the
23 qualification criteria, and I know
24 Dr. MacIntyre would say, you know, it's not the
25 device but, you know, it's more of like the

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1 right device for the right patient. So it
2 doesn't have to be a progression of CPAP to
3 Bi-PAP to Bi-PAP ST or Bi-PAP S to home
4 mechanical ventilation, it's getting the right
5 device. But there still has to be an answer on
6 how do you get the right device to the patient,
7 because right now Medicare is saying it's not
8 working and something extreme is going to
9 happen to the entire NIPPV code unless we say
10 that this is what we should do. Thank you very
11 much.

12 DR. BACH: Thank you. Panelists,
13 please. So one of the things that can be
14 useful for the panel I think at this point is
15 pretty soon I'm going to ask you to vote on the
16 questions that everyone has. So sometimes it's
17 useful to take a look at those questions at
18 this point and ask yourself if you feel there
19 are questions of clarification, something

20 worthy of discussion that would start off a
21 discussion amongst all of us. If you want to
22 start a discussion, you can feel free, we are
23 waiting, which is fine. I don't want anyone to
24 think the line has gone dead. We will take a
25 few moments here and I'm going to check in with

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1 everyone in two or three minutes.
2 DR. GAY: Well, out of human
3 compassion, Dr. Bach, I'll just mention that
4 ultimately I think we're here about hypercapnia
5 in severe COPD, so in the patient selection
6 criteria you can open with that base. But
7 we've had a lot of discussion about the fact
8 that there are subtle comorbidities, there are
9 subtle mixes of population, whether the BMI
10 went to 35, whether they had specific PSC to
11 rule out all of the sleep disorder, some of
12 them allowed an HI up to 15, so I think a good
13 discussion should talk about that selection
14 criteria. We know it's hypercapnia and severe
15 COPD we're talking about but in those studies
16 there is more of a variation to answer question
17 number one and that discussion needs to take

18 place. Thanks.

19 DR. BACH: Thank you very much,
20 Dr. Gay. Other panelists? For what it's
21 worth, I'm not, I don't participate in the
22 actual discussion as I mentioned, I'm just the
23 emcee if you will. Other panelists who'd like
24 to chip in?

25 DR. MACINTYRE: So this is Neil

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1 MacIntyre. I'd like to sort of clarify point
2 number two or question number two when you talk
3 about NIPPV parameters, where I feel somewhat
4 strongly that the settings, the high settings,
5 the necessary settings, there is a good
6 evidence base for settings, but as I've
7 repeated several times over the course of the
8 day, I'm not convinced there is enough evidence
9 to pick a particular type of device. If the
10 device can supply the necessary pressures,
11 backup rates, et cetera, et cetera, I'm not
12 sure what it really matters what the name of
13 the device is.

14 DR. MELNIKOW: So, Joy Melnikow. It
15 seems like there's maybe some qualifying
16 language around which I don't, being new to

17 this process, I'm not even sure that's
18 possible, but by what is meant by equipment
19 parameters, right? Because that's kind of a
20 vague term and it could be that it means which
21 device or it could be that it means the device
22 setting. And reflecting on this it strikes me
23 that although the evidence is clearly quite
24 imperfect, it's certainly advanced since 1998
25 when the last determinations were made, and it

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1 does seem like there's the need to revise what
2 is covered or how it's covered compared to
3 1998.
4 DR. BACH: Thank you, Dr. Melnikow.
5 So as we go through the voting, just a small
6 preview, we will have the opportunity, or you
7 will have the opportunity not only to vote but
8 then I will poll you and you will also be able
9 to clarify the reason for your vote or if you
10 want to articulate it, and we will also have
11 discussion depending on how the votes work out,
12 we may have more discussion allowing you to
13 clarify these things. And to remind everyone
14 who's attending this meeting today, these votes

15 are to guide CMS and so this input is not
16 binding in any way on the agency, and so I
17 generally think about this voting as a
18 quantitative way of assembling information and
19 then a lot of discussion and presentations from
20 today, and the discussion around the voting,
21 will give them more qualitative information
22 about what's known, what's lacking, what a vote
23 means. I don't know if that helps you.
24 Dr. Fisch, you had a question?
25 DR. FISCH: Yes. I guess I wanted to

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1 just reflect out loud that, you know, in the
2 course of our presentations this morning, the
3 Kohnlein study really had a lot of weight, you
4 know, in Dr. Wilson's paper when we looked at
5 the forest plots that we were shown, it was
6 both the largest study in that meta-analysis,
7 it had a little over 10 percent weight in the
8 meta-analysis, and it had the most significant
9 magnitude of treatment effect with the odds
10 ratio of .27, so it was really an outlier. And
11 that was of course a European study that
12 excluded patients with a BMI greater than 35,
13 and excluded patients with heart failure or

14 other significant lung or cardiac disease, and
15 had relatively high thresholds in terms of the
16 PCO2 being at, you know, around, greater than
17 52, and the GOLD 4 criteria. So I'm just sort
18 of raising that as a point that I noticed in
19 trying to figure out how that affects my level
20 of confidence that this will generalize to the
21 Medicare population in the United States, in
22 sort of how I put all that together.

23 DR. GARRIDO: This is Melissa Garrido.
24 I just want to kind of echo Dr. Fisch's
25 statement. Beyond the generalizability I think

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1 a lot of the study designs that were included
2 in his reviews and the individual studies
3 themselves, they weren't designed to really
4 inform a lot of these questions, so we might
5 know that there were improved outcomes within a
6 specific sample that had X, Y and Z patient
7 characteristics, but we do not know from those
8 studies which of those characteristics are most
9 important in predicting better performance with
10 any of the devices.

11 DR. BARREIRO: This is Tim Barreiro,

12 Mr. Chair, if I may speak. So I would like a
13 little bit of a more robust conversation on
14 question number three, how confident are we
15 that the evidence is sufficient to provide
16 patient usage parameters? There's been
17 multiple discussion that for CPAP, CMS required
18 four hours based on studies X, Y, Z, and then
19 we've seen some of the studies that were
20 presented today that six hours, and then the
21 longer you allow people to try it, the more
22 compliant it may be, and I think that's
23 important.

24 The other point goes back to Melissa,
25 if I may use her first name, is that we are

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1 also in the business of helping patients live
2 better lives, so while mortality is the holy
3 grail, improvements in patients' symptomatic
4 scores may be reasonable enough for us to try
5 multiple devices along the way in order to help
6 them live a better quality of life. Two things
7 that we know, at least I think from what was
8 presented today and my readings, is that
9 hypercapnic patients with the use of this have
10 a reduction in mortality and are reduced in

11 hospitalization, which we know in the COPD
12 patients in and of itself, there's a reduction
13 in mortality and staying out of the hospital,
14 so there's some robust information provided
15 that I feel confident in that.

16 I'm not sure I know how to handle
17 whether or not, I personally would say, and I'm
18 sorry for my long diatribe, is that I've had
19 multiple patients have their equipment removed
20 and I think this was eloquently stated in some
21 of the handouts where people wrote the same
22 thing. If you wear it for three hours and 59
23 minutes we take it away, but if you wear it for
24 four hours and one minute, we keep it, and I'm
25 not sure that's the ideal way to do that,

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1 although again like every policy, we have to
2 have some kind of cutoff. So I'd like some
3 additional discussion if I could from other
4 experts. Thank you.

5 DR. GAY: If you want to know the
6 magic of the four hours, it really came from
7 dichotomized observational data of Krebbs in
8 1994, where he was looking at the use of really

9 just a CPAP device, and ultimately it was just
10 that the patients that wore it more than four
11 hours had a better response than those who wore
12 it less than four hours. And right around that
13 time when there was a flurry of studies, people
14 were just fishing for a cutoff point, and four
15 hours got embedded into the literature.

16 But what's apparent is, I think
17 looking at Struik with less than 50 percent of
18 the patients using it more than five hours a
19 night, Murphy's was better, more is better is
20 the mantra and take home point.

21 DR. BACH: Thank you, Dr. Gay.

22 DR. MAURI: This is Laura Mauri,
23 sorry, if I may?

24 DR. BACH: Please.

25 DR. MAURI: I just wanted to make one

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1 comment looking back replying to one of
2 Dr. Fisch's questions earlier about the impact
3 of heart failure, and I wanted to pick up on
4 that as a cardiologist as well, understanding
5 the presence of heart failure in the study
6 means something quite different than for
7 example excluding patients with the study

8 criteria with heart failure from a prospective
9 randomized trial like the Kohnlein study, is a
10 bit different from the report of heart failure
11 and comorbidities, not to say that that's not
12 an important descriptor of the patient
13 population that was studied under Medicare and
14 is currently being treated. But I think it is
15 appropriate to still view the results from
16 Kohnlein as being important for defining the
17 impact of the therapy on this specific
18 population that has hypercapnia and excluding
19 those patients who might not benefit having a
20 different mechanism for respiratory failure, as
21 Dr. Wolfe was commenting earlier. So I just
22 wanted to comment that that discrepancy between
23 what exists in Medicare and what exists in the
24 Kohnlein paper, I don't see that as a
25 deficiency of the conclusion, but the fact that

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1 it was not studied.

2 DR. BACH: Thank you very much.

3 DR. CRINER: Dr. Bach, this is Jerry

4 Criner, I would like to --

5 DR. BACH: Dr. Criner, just before

6 you, I think Dr. Garrido was going to ask a
7 question, maybe I'm wrong.

8 DR. GARRIDO: Yes, Peter, this is
9 Dr. Garrido. I just wanted to ask kind of a
10 clarifying question to Tim. As one of the
11 non-clinicians on this group, I guess I could
12 use a little bit of clarification from any of
13 you really on how often patients present with
14 chronic respiratory failure but do not have
15 some level of hypercapnia. From what I
16 understood that was present in almost all of
17 the patients, but I want to make sure that I'm
18 understanding the clinical parameters better.

19 DR. BARREIRO: I think the question
20 was directed to me, thank you for the question,
21 Melissa. I will approach this question in
22 multiple different facets. I think first and
23 foremost, what we in the pulmonary literature
24 would support, and other experts on the panel
25 as well, is regardless of your FEV1, everyone

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1 has an exacerbation, but whether we define that
2 exacerbation as being hypercapnic probably
3 could be somewhat argumentative. We do know
4 that it's more likely the worse your symptoms,

5 the more likely you will be hospitalized
6 because of it, but still regardless of that,
7 all patients some way or the other in this
8 mixed heterogeneous disease may end up in the
9 hospital. Clearly the literature supports the
10 more often that you have an exacerbation or are
11 in the hospital, the more likely you'll come
12 back to the hospital, and that carries a
13 significant mortality with it. So for me, this
14 is where patients usually get intervened with
15 trying to start these noninvasive ventilators
16 or whatever we want to call these, at this
17 point that might be subject to argument, but as
18 an adjunct in order to help keep them out of
19 the hospital and improve survival, so I think,
20 hopefully I answered that question in that
21 regard.

22 So I'm not necessarily sure that
23 hypercapnia, it may continue to be argued may
24 not be the only criteria, I think that was what
25 one of the presenters mentioned, that it's

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1 always a fascinating aspect of it, but that all
2 patients with COPD doesn't absolve you from

3 having an exacerbation, whether that's defined
4 by hypercapnia or not. But we do know reducing
5 the concept of hospitalization does reduce
6 mortality, and so this does appear that these
7 devices do do that, and if it does that, that's
8 I think relatively important from my
9 perspective.

10 DR. BACH: Thank you. Dr. Ross, do
11 you have a question?

12 DR. ROSS: Yeah, I had a question,
13 thank you. So this is Joe Ross and I really
14 had a question for Dr. Gay, who seems to know
15 the literature really well, and I'm sure
16 Dr. Coleman covered this, but one of the things
17 that I'm sort of struggling with is not just
18 how good the Kohnlein study looks, but how bad
19 the Struik study looks, it's a bigger study and
20 it's clearly negative. You had kind of made a
21 comment around adherence and is that the
22 general assumption in the pulmonology
23 community, that the reason that trial failed
24 was that people were nonadherent?

25 DR. GAY: Actually if you want it

1 quick and dirty, one of the nicest reviews was

2 Nick Hill's editorial of the Murphy paper where
3 he goes at the Struik dissection that you're
4 asking me for. The big two that were in that
5 was, number one, were these truly the chronic
6 hypercapnic, and to help Melissa too, these
7 patients come in with hypoxia or hypercapnia or
8 both, and the hypoxic are not what we're
9 talking about. So the ones that came in with
10 acute hypercapnia, a couple of days later with
11 antibiotics you take care of their hypoxemia,
12 their hypercapnia is gone. The argument was,
13 you didn't really establish the hypercapnia
14 level when you grabbed them when they came into
15 the throes of the hospital very very ill.

16 Number two was the actual usage
17 criteria was lousy in Struik. They had 43 out
18 of their 101 patients that broke five hours.
19 In most interventional trials where you can't
20 even get half the people to do what you want
21 them to do are highly suspect, so I hope that
22 answers your question.

23 DR. ROSS: That's helpful, that is
24 helpful, thank you.

25 DR. FRAZIER: This is Frazier. I'm

1 old like Peter so I've read some of this
2 literature when it came out as well, you know,
3 you get bored when you get to my age. Here's
4 something else to think about. Kohnlein, they
5 were stable, not in the hospital, right, you
6 found them and then you put them on therapy.
7 Struik, they were in the hospital but you
8 washed them out for two to four weeks before
9 you went back and put them in the study. What
10 we now know is there's a tremendous mortality
11 the first two or three weeks after a COPD
12 exacerbation requiring NIV; that's Lindenauer's
13 work from December of 2017. Then that
14 mortality starts to plateau at about 30 days.
15 So what you've done is not enroll people with a
16 high risk of mortality because they died during
17 that two- to four-week period where you washed
18 them out, and therefore you get a less at risk
19 for death patient, a lower pretest probability
20 as we would say, and it's harder to show
21 mortality benefit because you've lost the
22 chance to save their life earlier. That same
23 kind of thing shows up in my Medicare database,
24 very early reduction in mortality that first 30
25 days.

1 DR. BACH: Actually, so I'm not
2 participating in the discussion, I just want to
3 ask a clarification, Dr. Frazier. Are you
4 saying that the covered period should only be
5 until that plateau then?

6 DR. FRAZIER: No, it doesn't go away
7 for 69 weeks, but the biggest decrease occurs
8 in the first four to five weeks, but you have a
9 mortality benefit in my study until week 69,
10 when the lines cross.

11 DR. BACH: Okay, thank you. And so
12 back to the panelists, I think Dr. Barreiro,
13 and I will emphasize again, this is a
14 discussion in the panel. The speakers, because
15 I have found it useful in the past, if speakers
16 have factual clarifications, and I think
17 everybody knows the difference between facts
18 and conjectures based on facts, if I can draw
19 the line between those two things, I would like
20 to, if you'll indulge me, but I would like to
21 go back to the panel discussion, and so
22 Dr. Barreiro has his hand up.

23 DR. BARREIRO: Thank you, Mr. Chair.
24 I wondered, and maybe I'm doing this wrong
25 after that comment. I wondered if the fourth

1 question that wasn't answered, or maybe should
2 be added, is my frustration with trying to get
3 people the device. And I know there was a very
4 nice discussion and I'm glad we had it about
5 disparities. In the studies published
6 longitudinally we see that 30 to 40 percent of
7 over a million admissions to the hospital every
8 year for COPD exacerbation or chronic
9 respiratory failure happen to have, happen to
10 occur in minorities. And again, we didn't seem
11 to have any information of whether or not there
12 is diversity and/or discrepancies in the
13 gender/race role and ethnicity within this, and
14 I think we'll continue to struggle with that.

15 But I guess my question is since there
16 might be people that are from the DME
17 companies, I can't seem to get them to comply
18 with much of anything, and/or supporting the
19 patients that need it, and I wondered if others
20 were sharing the same aspects. We can talk
21 about the criteria but it doesn't seem to be
22 getting delivered to the patients effectively,
23 and/or being removed inappropriately.

24 DR. BACH: Does anyone have a response
25 to that?

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1 DR. MAURI: I would, this is Laura
2 Mauri again and on that topic, because I think
3 it does tie into the comments of Dr. Ross as
4 well, I think these things are all linked. We
5 worry that the more adherence there is, the
6 more successful the treatment will be, and so
7 as we look across the different studies we see
8 that in the studies or in the patients from an
9 observational standpoint, those that got more
10 treatment did better, so we think more
11 treatment is better. But what we don't have is
12 something that would prescribe a certain amount
13 of treatment as being more effective, because
14 we don't really have a randomization that would
15 show that. And we also know from what has been
16 presented earlier today that the trials that
17 show more services provided, they're the ones
18 that have had more success in terms of showing
19 the effectiveness of the NIPPV. So I think on
20 the topic of whether it makes sense to require
21 a minimum amount of therapy or the
22 administration of therapy that a patient would

23 be compliant with in order to receive high
24 intensity noninvasive ventilation, the problem
25 with prescribing a threshold is that that

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1 adherence pattern depends on the services a
2 patient receives, and we know that those are
3 markers for better outcomes, but they're also
4 things that are strongly influenced by
5 socioeconomic status and access to care, and
6 the services that we can provide for those
7 patient populations.

8 So I think, I would be concerned that
9 if we depend on an arbitrary threshold of
10 amount of usage and don't provide a mechanism
11 to ensure access, that that will potentially
12 increase the potential inequities in terms of
13 the delivery of adequate care, and it's
14 difficult to measure and I think that one of
15 the corrections that, you know, we would like
16 to see going forward, is more data on whether
17 those variations exist. But from what we're
18 hearing from the clinicians presenting today,
19 at least on the level of access to similar
20 modes of ventilation, but using for example the

21 Bi-PAP with backup rate, modes of ventilation,
22 that there are differences that are not
23 directly related to patient needs, and
24 ultimately we want to bring this conversation
25 back to getting the right therapies to the

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1 right patient.

2 DR. BACH: Thank you very much.

3 Dr. Criner, do you have a question?

4 DR. CRINER: No, I wanted to follow up
5 with Dr. Fisch's statement about the Kohnlein
6 study and how generalizable it was, and address
7 a little bit the last speaker as well as

8 Dr. Barreiro. I mean, one of the issues are is
9 the quality of the data that exists right now
10 that we're trying to extrapolate to form for a
11 U.S. policy, or how to improve the U.S. policy
12 that currently exists for placement, there's a
13 problem with the studies that exist that we're
14 basing this on, the three largest most recent
15 randomized controlled trials, none of them are
16 pragmatic trials that tried to mirror clinical
17 practice. Some of them had special features
18 that made it not very acceptable to patients
19 and hard to broaden the conclusions to the

20 general population at large.

21 The Kohnlein paper which, you know, is
22 judged to have the greatest treatment effect on
23 a forest plot, that had 36 centers that
24 recruited 200 patients over seven years. So
25 these patients, these centers overall recruited

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1 in some cases less than one patient per year.
2 And in the Murphy study, the most recent, the
3 HOT-HMV study, that rejected 95 percent of the
4 patients that were screened. So we're really
5 talking about subsets of populations that were
6 enrolled who basically were making conclusions
7 for broadened therapy.

8 When we look at PCO₂ elevation, that's
9 not a monolithic marker to identify all
10 patients who may benefit from the therapy.
11 Hypercapnia can result because you have high
12 dead space, or it can result because you're
13 hypoventilating, or it can be a combination of
14 both. So there's not a good physiological
15 endpoint that you can identify your patient
16 population with reliably.

17 And I think the third point about the

18 adherence and compliance, it's just not because
19 patients can't get the therapy or patients
20 don't want to use the therapy or don't know
21 what the therapy provides. In some cases with
22 COPD compared to other diseases that do cause
23 hypoventilation such as obesity or restrictive
24 neuromuscular disease, these patients have
25 dynamic changes in lung function that can

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1 contribute to hypercapnia and intolerance of
2 using an applied pressure. So I think it's a
3 little bit more complicated than saying we
4 choose a PCO₂ high or low to identify patients
5 reliably that may benefit or not benefit from
6 the therapy. Thanks.

7 DR. BACH: Thank you very much,
8 Dr. Criner.

9 Tara, I think you have a procedural
10 announcement.

11 MS. HALL: Yes. For the presenters,
12 I'm going to switch you out of the panel member
13 group into the attendee member group where you
14 can just listen now to the rest of the meeting
15 so that the panel members could have their
16 discussion. So we thank you for your

17 participation thus far, and please continue to

18 listen in.

19 DR. BACH: Thank you very much, Tara,

20 and thank you again to the presenters for all

21 of the input and insight. I have I think

22 Dr. Manship.

23 DR. MANSHIP: Thank you very very

24 much. I wanted to begin by thanking everybody.

25 I am a non-clinician, philosopher and

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1 theologian by training, and it's been

2 fascinating to listen to all this and to think

3 and to put all of this together. And Dr. Mauri

4 and Dr. Criner and a couple of others just over

5 the course of the day have mentioned compliance

6 and adherence and those are resonating with me,

7 and so my question is probably more on

8 phenomenological or lived experience,

9 philosophical question, and I'm curious to know

10 from the experts, the clinicians, how do

11 patients experience the use of this equipment,

12 how do they experience their own illness, and

13 how does that inform your response to them,

14 your treatment for them, and then how does that

15 inform how we should be thinking about this
16 with regards to answering questions about
17 patient populations? So it may be somewhat of
18 a nebulous question, it's not quantitative,
19 it's certainly more qualitative, but to me that
20 provides context, so I'd like to hear from
21 members, from clinicians, how do patients
22 experience COPD, how do they experience
23 hypercapnia, how do they experience, you know,
24 obstructive apnea and the overlaying obesity
25 comorbidities, and then how should this inform

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1 how we're thinking about our questions for
2 today? Thank you very much.

3 DR. BARREIRO: A question to the chair
4 for clarity. Is this open for all of us to
5 discuss?

6 DR. BACH: Yes, it is, amongst the
7 panel it is open for all of us to discuss,
8 absolutely.

9 DR. BARREIRO: Great. I'd like to try
10 to answer that question from my own personal
11 experience, and that is that I usually would
12 say I break it up into groups. 50 percent of
13 people that get first started on it love it and

14 if they do love it immediately, you usually
15 don't have to worry about them, they're going
16 to remain extremely compliant, usually stay out
17 of the hospital, not all the time, but it's
18 significantly reduced. Of the 50 percent
19 that's left, 25 percent of those patients
20 continue to wear it because I tell them the
21 benefits in the long term, keeping them out of
22 the hospital, reducing the chance of heart
23 failure, irregularity, things of that nature.
24 And then 25 percent just don't want, no matter
25 what we try, interfaces that we use, just don't

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1 seem to get used to it, get on it, or can be
2 adjusted to get it to work well for them.
3 I would say that a fair amount of
4 patients, and this would be a perspective of
5 where my office is, I'm a disparities scholar
6 and so I work in a free clinic in part of the
7 hospital system for Inogen, and so my big
8 complaint is something that you've probably
9 heard me state over and over again, is trying
10 to get the companies to provide my patients the
11 equipment has been frustrating. They would

12 love to have it, loved it when they got it but
13 it was removed or, you know, again, it's a
14 tough patient population with difficult and
15 mobility issues, those things occur and we
16 usually end up having to do multiple restudies
17 to get them back on the equipment, which seems
18 also to be a waste to Medicare if we're talking
19 about cost-effective processes that occur in
20 this discussion, so that's my experience with
21 it.

22 DR. BACH: Thank you very very much.
23 Any other comments or followup to Dr. Manship's
24 question?

25 DR. KUEBLER: I have a comment. In

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1 terms of compliance and adherence, you know, in
2 listening to and reviewing all of the studies,
3 listening to the presenters today, providers
4 are not given standardized information, there's
5 not a lot of data readily available to us right
6 now to determine which device to put a patient
7 on. And without that if we're, you know,
8 practicing in the dark, kind of trying to
9 figure out what it is that we should put a
10 patient on, what device to put a patient on,

11 that interferes with adherence and compliance
12 and if we're not clear, we're not going to be
13 able to educate the patient in order to stay
14 compliant and to utilize it appropriately.

15 DR. MANSHIP: I understand that, and
16 thank you for that.

17 DR. BACH: Dr. Kuebler, did you have
18 another comment you wanted to make or was that
19 it? I have you queued here.

20 DR. KUEBLER: Well, I think it's
21 important to recognize that if we look at
22 comorbidities that three out of four Medicare
23 beneficiaries had two or more chronic
24 conditions at any given time. And if we look
25 at standardized BMI across the country for

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1 adults, women and men 18 and older, the average
2 BMI for women is 29.6 and for men it's 29.2, so
3 we're bordering on obesity as an average in the
4 United States, and those markers have to be
5 considered when we look at our qualitative new
6 studies.

7 DR. BACH: Thank you.

8 DR. GAY: I'd like to make a comment

9 about compliance, since I see this kind of
10 going towards the number four, usage
11 parameters, and it very much parallels the OSA
12 CPAP population as we see very similar to the
13 chronic respiratory failure, that it's really
14 how you come out of the blocks that determines
15 your compliance overall. It's hugely important
16 to get them involved very quickly, empower the
17 patient with paying attention to what's going
18 on. We say how can we get them going if we
19 don't know what kind of box to put them on.
20 Well, it is a bit of a salesmanship prospect,
21 but how well you do almost in the first week,
22 certainly in the OSA literature is strongly
23 supported, so that patients who have a good
24 initial experience with a lot of service
25 attention, physician, whoever is the caregiver

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1 that teaches them right from the get-go that
2 this is important, really determines that
3 outcome more than it does the actual device
4 that you're working on. Thanks.

5 DR. BACH: Thank you, Dr. Gay.

6 Dr. Salive, do you have a question or comment?

7 DR. SALIVE: Thanks, Marcel Salive.

8 So I had a couple comments. I think it's
9 higher than what was stated about the
10 comorbidities for COPD really in the Medicare
11 population, not that that number was low, but
12 it is actually more like four conditions, I
13 think, people have if they have COPD on
14 average, there's a few with only that. So
15 Medicare is a highly comorbid population and
16 this particular group, I think, you know,
17 they're near the end of life, as people stated
18 earlier.

19 I think that, I wanted to reflect on
20 the comments about, that were just made about
21 using this in the home. I think that we were
22 asked about device versus the surrounding
23 services and I think they're inextricably
24 linked, I don't see how we can really
25 disentangle that and in fact we wouldn't want

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1 to really in my opinion. I think the, you
2 know, it's the whole package that was studied
3 in these studies and that's what works to
4 improve the health, so I don't think we can
5 split that out, but that's my opinion.

6 And so I think the home care piece of
7 it needs to be really pretty aggressive. I
8 know that, you know, Medicare has seen a large
9 growth of home care, but this particular part
10 has a lot better evidence than most home care.
11 And you know, the device is not, you know, it's
12 not like your FitBit or anything like that,
13 right, so it's a complicated thing that takes
14 some learning I think by the patients in that
15 home setting, and I don't think folks learn it
16 somewhere else while they're being discharged
17 and dealing with all the hospital situations.

18 One of the gaps I noticed that I think
19 is puzzling to me, I guess it's not a crucial
20 point to me, but the comment was made about
21 adverse events not being studied in these
22 trials at all, like 75 percent of the trials
23 had no adverse events even, they weren't even
24 looking for them. And you know, I guess it's
25 not, you know, we're not that worried at this

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1 point about the devices having safety problems,
2 but it still seems like, you know, a missed
3 opportunity, because I think that the patients
4 do want to know things like that and you really

5 run the risk of being in a situation where the
6 patient might, you know, read something, you
7 know, the classic case, read something in the
8 front page of the New York Times about some
9 adverse event and suddenly feel like their
10 thing is very dangerous. Well, you know, if
11 you're not studying that systematically we
12 don't really know the answers, and maybe we
13 just missed the piece from what the FDA has
14 found, you know, since these devices have been
15 on the market. I don't know, I'm not that
16 concerned, but I would wonder, you know,
17 because these devices are always prone to, you
18 know, generational change as they get two new
19 chips, new prices, and you know, things can
20 happen. But those are my comments.

21 DR. BACH: Thank you, Marcel. Tara
22 has put in a chat box which we can message each
23 other now, because only we on the panel can see
24 those messages. I do not see, maybe I've
25 missed, Dr. Criner, your hand is up?

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1 DR. CRINER: Yeah, I just wanted to
2 make a comment about the discussion with

3 Dr. Kuebler and the last discussion also. One
4 of the things to consider is like was
5 mentioned, these people are frail, people with
6 COPD, 90 percent of them have at least two
7 comorbid conditions, and about 75 percent have
8 four, and they're older. And some of them, as
9 was mentioned by Dr. Barreiro, they're
10 impoverished. And trying to get patients to do
11 additional tests, that need to come back and
12 forth when they've just been discharged from
13 the hospital and they're still fragile and ill,
14 those are important barriers to get therapy.

15 One of the questions that was asked,
16 how do you know what's going to work in an
17 individual patient to promote adherence?
18 Assign the support mechanisms and have someone
19 who's genuinely interested in evaluating the
20 therapy and titrating them. It's also really
21 trying to make the patient understand and
22 having a long-term relationship with them. And
23 when you have a patient that it works and then
24 you put other barriers in front of them, then
25 you have to do this or that. Another thing, to

1 be able to qualify for the therapy that they

2 proved was efficacious for them, those are
3 needless barriers I think in terms of
4 regulations, those can be addressed and make it
5 easier for the patient to get effective therapy
6 or continue effective therapy they've been
7 compliant with and has shown physiologic or
8 some other parameter of clinical benefit.

9 DR. BACH: Thank you. Dr. Fisch?

10 DR. FISCH: Yes, I was just kind of
11 reflecting about that interesting question
12 about the lived experience for the patients. I
13 don't have enough experience with these
14 particular patients in my oncology practice,
15 but I was just thinking about first, the fact
16 that in Dr. Wilson's meta-analysis, the forest
17 plot of the quality of life was pervasively
18 negative, and even the strongest positive study
19 that we mentioned, the Kohnlein study, was
20 negative for, or mostly negative in quality of
21 life. And I found myself like an oncologist,
22 kind of wishing I knew what proportion of
23 people who use these devices get a major
24 response, you know, like we heard, like they
25 get on it, they like it, they're clearly

1 benefitting. There's no doubt in my mind that
2 selecting certain patients with a certain
3 phenotype and parameters give major benefits.
4 So, you know, we want to be able to figure out
5 how to bring that major benefit to the right
6 people.

7 There's a bunch of patients, I can
8 imagine, that are minor responders that have to
9 be kind of coaxed to stay on it and hoping that
10 they get some mortality benefits, and then
11 there are some that are non-responders that
12 don't tolerate it, and I wish I had a sense of
13 the proportion, right, for any given way of
14 selecting the cohort and defining the composite
15 intervention. You know, is it a 15 percent,
16 you know, major response rate, or is it 25
17 percent or 45 percent, you know. That would
18 really, I think it would really help clinicians
19 and patients if we had some idea about that.

20 But again, my major observation is
21 that at least quality of life wise, there
22 doesn't seem to be any study that showed a
23 signal in that realm.

24 DR. BACH: Thank you very much.

25 DR. GAY: I can perhaps give you a

1 perspective on that. As you pointed out, these
2 are people who are very sick, they have the
3 burdens of comorbidities, and here you are
4 adding another thing that they have to do. It
5 doesn't work once a week, it doesn't work twice
6 a week, you've got to use it every night, so
7 you are adding another burden to their life.
8 Now if you ask about what proportion of these,
9 I might give this perspective. I think at
10 least as a clinician and looking at the
11 studies, and Dr. Coleman might chime in at
12 this, when you see a seven- to nine-millimeter
13 change in CO₂, that can be really life changing
14 to a patient, a patient that can ventilate that
15 dramatically different is really going to have
16 a better sense of well-being. So the studies
17 that showed that higher change, and if that's
18 the 50 percentile that changed seven to nine
19 millimeters, that is in fact a ballpark idea,
20 if half of them do that, that's the kind of
21 respond rate that's going to be dramatic.
22 Maybe that gives you some perspective.

23 DR. BARREIRO: If I could add on to
24 Dr. Gay's comments, we also should be careful
25 about clinically significant criteria versus

1 statistically significant, and those can be
2 different depending on how you look at the
3 data, right, even with St. George's Respiratory
4 Questionnaire. So as an oncologist you
5 probably understand that just as well, right,
6 with people that get treatment. And
7 everybody's quality of life may look at
8 different aspects. I mean, we do know with
9 treatment alone, and the amount of depression
10 in patients with COPD and chronic respiratory
11 failure adds to the variable as well. So I do
12 agree with the parameters that we're looking
13 objectively that are so important are the
14 physiologic ones but there's other aspects of
15 it too that may not be statistically
16 significant but clinically significant, and I
17 don't remember him mentioning that in his
18 slide.

19 MS. MAURI: If I may, I would add, you
20 know, I think just to follow on to your
21 comments that patient experience is so
22 important as we think about, you know, what are
23 the next steps here, including that patient

24 experience I think would be really critical,
25 because it's difficult to represent that

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1 uniformly in a quality of life questionnaire.
2 When you look at the really excellent
3 meta-analysis that Dr. Wilson presented
4 earlier, you know, it's quite clear that there
5 were consistent improvements in JCL, which is
6 the most specific thing that one could look at,
7 and although it's not labeled as quality of
8 life, the feeling of shortness of breath
9 certainly would impact the quality of
10 somebody's life.

11 But I think that that, it's so complex
12 in terms of what an individual might select in
13 terms of avoiding hospitalization. You know,
14 we have patients who live in remote locations
15 who may actually find it quite difficult to be
16 able to return to the hospital environment and,
17 you know, particularly in this current setting
18 with the pandemic, that brings even heightened
19 awareness to that. So I agree that at this
20 point to look at the meta-analysis results and
21 not see an overall impression of a positive
22 impact, but then I think you also have to

23 recognize that the heterogeneity of the data
24 and the low standard of evidence that
25 Dr. Wilson observed is a marker of the

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1 uncertainty of that estimation. And on the
2 other hand, there's, you know, moderate
3 certainty around the estimation about the
4 important effects on mortality,
5 hospitalization, dyspnea, that I think are
6 meaningful to a patient's lived experience.
7 DR. BACH: Thank you very much,
8 Dr. Mauri. I am not seeing any further
9 comments but I want to check in with everyone,
10 if you'd like to make a comment or ask a
11 question of fellow panelists. Okay. Barring
12 that, next I propose we take a break now. It
13 is 2:02, we'll take a 15-minute break and at
14 2:17 we'll come back for the next step on the
15 agenda which is the formal remarks and voting
16 questions. Thank you very much, everyone, for
17 sticking with this. I know it's difficult on
18 line but I'm finding the discussion to be
19 productive and engaged, and I very much
20 appreciate everyone's effort on that.

21 (Recess.)
22 DR. BACH: Hi, I'd like to start
23 reassembling for the next stage of the MEDCAC
24 meeting, please. Tara, should we do a rollcall
25 of voting committee members? Tara, are you on?

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1 MS. HALL: Hello.
2 DR. BACH: Hi, okay, great.
3 MS. HALL: Yes, I'm here.
4 DR. BACH: Should we do a rollcall of
5 the voting MEDCAC members so we can go on to
6 the voting section?
7 MS. HALL: Okay, that's fine.
8 Dr. Ross, are you on?
9 DR. ROSS: Yes, I am.
10 MS. HALL: Dr. Garrido.
11 DR. GARRIDO: Hi, I'm here.
12 MS. HALL: Dr. Kuebler?
13 DR. KUEBLER: Yes, I'm here.
14 MS. HALL: Dr. Manship?
15 DR. MANSHIP: Yes, I'm here.
16 MS. HALL: Dr. Barreiro?
17 DR. BARREIRO: Yes, I'm here.
18 MS. HALL: Dr. Fernander?
19 DR. FERNANDER: Yes.

20 MS. HALL: Dr. Melnikow?

21 Dr. Melnikow?

22 DR. MELNIKOW: I'm here.

23 MS. HALL: Dr. Salive?

24 DR. SALIVE: Here.

25 MS. HALL: And Dr. Fisch?

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1 DR. FISCH: Yes, I'm here.

2 MS. HALL: Okay, everyone is present.

3 DR. BACH: I'm sorry, I asked for --

4 there's, the subgroup of people who just did

5 the rollcall are the people whose votes are

6 counted by CMS for the scoring on the

7 questions. There is a number of members of the

8 committee whose votes do not count who have

9 also been participating and we can do a

10 rollcall of them as well if you'd like.

11 It's Dr. Mauri, Dr. Mauri, are you

12 here?

13 DR. MAURI: Yes, I'm here.

14 DR. BACH: Great. Dr. Criner?

15 DR. CRINER: Yes.

16 DR. BACH: Dr. Gay?

17 DR. GAY: Present.

18 DR. BACH: And Dr. MacIntyre?
19 DR. MACINTYRE: Yes, present.
20 DR. BACH: Great. Joe, do you want to
21 say something about the voting or do you want
22 me to make a couple remarks about it, or which
23 do you prefer?
24 DR. ROSS: Peter, this is Joe Ross;
25 you mean Joe Chin, right?

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1 DR. BACH: I mean Joe Chin, yes,
2 although Joe Ross, if you'd like to say some
3 formal comments about the voting first, that's
4 fine.
5 DR. ROSS: No, that's fine.
6 DR. CHIN: Thanks, Peter. I don't
7 have any specific comments about the voting.
8 I think one question that I heard
9 earlier about adding a new question or
10 modifying, I think that will be difficult in
11 this format. I think if there are really, if
12 there is information that you would like to
13 supplement in the discussion part of the answer
14 or your voting, that might be an area that you
15 can mention comment on any particular point so
16 that we would have that on record. I think we

17 will go ahead with the votes that we have.

18 DR. BACH: Okay, thank you, Joe. And
19 to emphasize as I said earlier, I hope I said,
20 I tried to say, CMS takes into account all
21 that's transpired today, not just the votes.
22 And so certainly comments, including many we've
23 already heard, but comments around these
24 questions and your, you know, wholesome
25 description of the answer is warranted, it is

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1 something that they will take into account, but
2 as Joe has already suggested, we can't change
3 the questions per se at this point.

4 In that case, I think I will try and
5 start the voting. If you do not know how to
6 vote at this point, I know we tried a dry run,
7 there was no shame in that because of the
8 technology, please privately message Tara and
9 she will privately message you back how to log
10 on if you are one of the people whose votes
11 counts.

12 We're going to vote. When we have all
13 the votes collected, I'm going to be notified
14 that we can proceed, at which point I'm going

15 to poll each of the MEDCAC members regarding
16 their votes, and then we will have, when you do
17 that, you will state your vote out loud and
18 your name, although I'll just call on you, and
19 if you have anything you want to say about your
20 vote, that's a good time to do that. So why
21 don't we try the first question here. I will
22 pause, just ask Tara if anyone is still waiting
23 to get logon information, in which case I
24 should wait.

25 MS. HALL: I don't have anyone asking

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1 me questions right now, so hopefully everyone
2 knows how to do it.
3 DR. BACH: Thank you. Okay. The
4 first question is: How confident are you that
5 the evidence is sufficient to determine the
6 patient selection criteria that will improve
7 health outcomes, for example laboratory values,
8 comorbidities, frequency of exacerbations
9 requiring ER or hospital admission, hospital
10 discharge timing, pulmonary function tests and
11 the like, when used with any category of home
12 NIPPV device? And we'll get to the discussion
13 maybe depending on how the votes come in. So

14 please vote now.

15 MS. HALL: We're waiting for one more
16 vote. If you're unable to vote or you haven't
17 voted -- okay, everyone has voted.

18 DR. BACH: Okay. Tara, are you going
19 to display the results at this point?

20 MS. HALL: Yes, everyone has voted.

21 DR. BACH: Okay, the mean value is
22 2.89, greater than the intermediate confidence
23 cutoff, I will come back to what that means in
24 a second. I'm going to now poll the panelists,
25 ask your vote, and this is a time to clarify or

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1 explain, that is not required, but that's the
2 opportunity. I'm going to start in the order
3 of the list in front of me. Dr. Barreiro?

4 DR. BARREIRO: Thank you, Mr. Chair.
5 I voted a four, but would have went with a 3.5
6 but we weren't allowed that. My clarification
7 is I feel there's adequate evidence that, if a
8 decrease in mortality and a decrease in
9 hospitalization is enough for me to support the
10 continued utilization of any form of
11 noninvasive ventilation based on those

12 parameters.

13 DR. BACH: Thank you very much,
14 Dr. Barreiro. Could we just, we're all used to
15 doing this in person, just so people, it's not
16 obvious on line, there's four individuals whose
17 votes, if you will, don't count, the industry
18 representative, Dr. Mauri, and the guest panel
19 members. I should be recording their own
20 personal votes, I am going to poll you and ask
21 for your input on them, they're not counted in
22 the tabulation, but what you say and your
23 comments are things that help CMS, so just to
24 know, I will get to you here as I go down the
25 roll.

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1 DR. BARREIRO: Mr. Chair, may I extend
2 my comment, and I apologize, I wrote it on the
3 side. I would also like to add that because
4 there was clear data that there was no serious
5 or non-serious adverse events, I think that
6 those two parameters with the lack of serious
7 adverse events is enough for me to feel more
8 confident there is adequate data.

9 DR. BACH: Thank you very much,
10 Dr. Barreiro. Dr. Fernander?

11 DR. FERNANDER: Four.
12 DR. BACH: Okay. Dr. Fisch?
13 DR. FISCH: Sorry. My answer is a
14 three, and I'll say that I sort of started at a
15 four based on my prereading, but going over the
16 discussion with some of the presenters and the
17 panelists' comments, and understanding how
18 difficult it is to generalize this information,
19 brought it down from a four to a three for me.

20 DR. BACH: Thank you very much,
21 Dr. Fisch. Dr. Garrido?

22 DR. GARRIDO: Thank you. I voted a
23 two. I think we know that it is efficacious in
24 hypercapnic patients but I don't believe that
25 we have enough data on real world

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1 effectiveness, especially compared across
2 different patient populations. All the
3 observational studies that have been created,
4 or conducted rather, have been small and
5 they're not powered to examine heterogeneous
6 treatment effects.

7 DR. BACH: Thank you, Dr. Garrido.
8 Dr. Kuebler?

9 DR. KUEBLER: I voted a one. I'm not
10 comfortable with the data set that supports the
11 exacerbation criteria, FEV1 criteria, it just
12 seems like there's no standardization or
13 specific measures, the data is all over the
14 place for me.

15 DR. BACH: Thank you. Dr. Manship?

16 DR. MANSHIP: I voted three, and the
17 primary reason for that three was as it's been
18 expressed by others, that heterogeneity, the
19 difficulty in taking what data we currently
20 have to make larger generalizations, so a three
21 for me.

22 DR. BACH: Thank you. Dr. Melnikow?

23 DR. MELNIKOW: I voted three, which to
24 me, intermediate confidence is pretty good for
25 the kind and quality of evidence that we have.

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1 This is really a question about patient
2 selection and it seems to me the evidence for
3 selecting hypercapnic patients for these
4 interventions is moderately good. There may be
5 other patients that also benefit or other
6 criteria that could be used, and that was my
7 reason for a three and not going higher.

8 DR. BACH: Thank you very much.

9 Dr. Salive?

10 DR. SALIVE: I voted a three for
11 similar reasons to what Dr. Melnikow just
12 stated. I believe there is some criteria
13 available for patient selection but it could be
14 better, but the ones that exist are, you know,
15 have a pretty decent evidence base.

16 DR. BACH: Great, thank you. I now
17 move on to the other panel members. Dr. Mauri?

18 DR. ROSS: Peter, this is Joe Ross. I
19 wasn't sure if I was part of the --

20 DR. BACH: Oh, I'm sorry, Dr. Ross,
21 you're right.

22 DR. ROSS: I voted a three and like
23 Dr. Melnikow and Dr. Salive, I felt like there
24 was strong evidence for selecting patients on
25 the basis of either a severe COPD or persistent

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1 hypercapnia, but felt like there were limited
2 trials, and observational evidence didn't
3 support selection criteria based on any other
4 patient characteristics, including timing of
5 hospital discharge or other related criteria

6 like that, obesity and other comorbidities.

7 DR. BACH: Thank you. All right, now,

8 I'm sorry, Dr. Mauri, your vote?

9 DR. MAURI: I voted a four. I agree

10 that the data presented is a strong evidence

11 base for some specific areas where there's a

12 clear benefit. I also really think that the

13 input from the experts who presented is quite

14 valuable and gives another level of security

15 that the physician community can identify based

16 on the data available, patients with true

17 benefit with reduction in mortality and

18 dyspnea.

19 DR. BACH: Thank you. Dr. Criner? I

20 will come back to Dr. Criner. Dr. Gay?

21 DR. GAY: I gave the evidence level a

22 four. I think as a person who has been doing

23 this now for about 30 years, I have no

24 difficulty in saying I can select patients that

25 will benefit from this. And I think the fact

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1 that all of the parameters aren't clear,

2 weighing a vote to say that the evidence is

3 poor is why I stay away from a one, two or a

4 three, but to say that a hypercapnic COPD

5 patient that I can recognize to that degree is
6 not going to have a good outcome, I'd have to
7 say that's a four or five, but I'll say a four.

8 DR. BACH: Thank you very much.

9 Dr. Criner, are you with us?

10 DR. CRINER: Yes, I am. I gave it a
11 three, I believe that the evidence suggests
12 that patients with COPD and hypercapnia may
13 benefit, but the specific details to permit me
14 to characterize that patient population to
15 definitely improve their outcome as broad
16 therapy need to be better defined.

17 DR. BACH: Thank you very much. Dr.
18 MacIntyre?

19 DR. MACINTYRE: So I gave it a four,
20 primarily because I think the evidence for
21 hypercapnia and important outcomes, the
22 evidence is just pretty good. Other criteria
23 for selecting treatment I think are less
24 compelling, and some of the other outcomes are
25 less compelling, but CO2 and things like

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1 mortality promote me to a four. Thank you.

2 DR. BACH: Thank you very much. Now

3 the discussion, because we cleared as you can
4 see the two-and-a-half cutoff, we are being
5 asked, I'm going to ask you to provide
6 selection criteria for the specific categories
7 of equipment. This question is to the
8 panelists first.

9 DR. ROSS: Peter, this is Joe Ross.
10 Do you just want us to chime in with what we
11 thought the selection criteria were good, or do
12 you want to go in order?

13 DR. BACH: It makes sense to just
14 chime in. If you have an organizational
15 framework for it, let's start there.

16 DR. ROSS: So for me it was severe
17 COPD based on GOLD criteria or persistent
18 hypercapnia, those are the selection criteria.

19 DR. BARREIRO: A point of order.
20 Isn't this the same thing you're asking in
21 question number two, or am I looking at that
22 wrong?

23 DR. ROSS: This is Joe Ross. I
24 thought question number two was about how the
25 devices, I don't have the wording in front of

2 DR. BARREIRO: Oh, so it says the
3 equipment parameters, not necessarily the
4 parameters to get the equipment.

5 DR. ROSS: Yeah, not the patient
6 selection parameters.

7 DR. BARREIRO: Okay, thank you.

8 DR. BACH: I think CMS wants us to
9 discuss CPAP, HMV, bilevel positive airway
10 pressure, and if we can further articulate
11 selection criteria at this time based on
12 today's discussion.

13 DR. BARREIRO: Yeah, this is Tim
14 Barreiro, I made notes. I would say
15 unfortunately for me, I didn't think there was
16 any clear criteria. However, it would more
17 likely remove some. One, I didn't feel there
18 was any significant evidence that any degree of
19 hypercapnia was ideal, given the fact that I
20 would say that any hypercapnia may be
21 reasonable enough for me, since the mortality
22 benefit was seen with it, to be more
23 appropriate than to have a cutoff of 55 or 58
24 or 60.

25 I also was in favor of eliminating

1 FEV1 as that FEV1 rarely changes over time and
2 in turn seems to put you into a category where
3 only the severest of patients will benefit from
4 this device, when we know that the
5 heterogeneity of FEV1 and COPD is quite vast.

6 I will however add that I would like
7 to have at least a criteria where one
8 additional comorbidity was present since we
9 know that would be easy to meet criteria, and
10 we know that they have at least four based on
11 the comments today, that that should be a
12 reasonable thing to add into the criteria or
13 keep into the criteria, so that we know there's
14 additional benefit to those patients. Thank
15 you.

16 DR. BACH: Great, thank you. Further
17 discussion with regard to the selection
18 criteria for specific categories of equipment?

19 DR. MELNIKOW: Joe, I have a
20 clarification question really, going back a
21 little bit to this discussion point versus
22 question two. Are we talking about selection
23 criteria of patients for NIPPV devices, which
24 we heard this morning seems like other than the
25 distinction between CPAP and the others, there

1 isn't necessarily a lot of difference in how
2 they might be used, or are we talking about
3 selecting patients to be eligible for this
4 intervention at all?

5 DR. BACH: My interpretation of this
6 is it's both, but it's more the former. And I
7 think the comment you just made, feel free to
8 elaborate, is useful information for CMS, that
9 the delineation between the devices is not
10 fully spec'ed out, if you will, I think to
11 summarize what you just said, more so than the
12 general question of eligibility. But I, both
13 CMS can give us feedback but also other
14 panelists, feel free to weigh in.

15 DR. MELNIKOW: Yeah. I mean, this is
16 a learning experience for me about these
17 devices, but my understanding from the
18 discussion this morning is that while, you
19 know, CPAP is the preferred device for
20 obstructive sleep apnea, in terms of chronic
21 respiratory failure really the distinctions
22 between Bi-PAP and home mechanical ventilation
23 are fairly limited, and other that the backup
24 battery, there's not a lot of reason to make a
25 distinction between them. That was my

1 understanding, but maybe others who know more
2 will correct me.

3 DR. GAY: This is Peter, I'm sort of
4 reading this a different way. If you voted,
5 for example, that you believe that the
6 selection criteria tell you that it will have
7 that outcome, it's not a comparator of whether
8 one is better than the other, the question is
9 if I think, like I voted a number four
10 selection criteria, can I do that with an HMV,
11 can I do that with a Bi-PAP, yes, yes. Could I
12 do that with a CPAP, clearly no. So the idea
13 is, I don't think the question's asking whether
14 it's clear you should use a Bi-PAP versus an
15 HMV, that is question two, where it's asking
16 the parameters of the equipment. This question
17 asks if your selection criteria is this, can
18 you get that outcome with an HMV, can you get
19 it with a Bi-PAP, and that is where I would say
20 yes, yes, CPAP no. Is that the way I should
21 interpret that?

22 DR. BACH: I think that input is very
23 helpful. Are there other comments on this?

24 DR. FISCH: Yeah, this is Mike Fisch.

25 I guess, you know, I sort of recognize that the

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1 best master clinicians are going to be able to
2 select patients and get good outcomes, but I'm
3 just a little bit concerned about the idea of
4 really broad inclusion criteria that enhance
5 access, but also, you know, is probably going
6 beyond where the data are. I guess I'm more
7 comfortable choosing access criteria that
8 mostly resemble where the best data were and
9 not getting too broad. You know, we heard one
10 comment, we don't want to wait for the
11 literature to catch up with utilization, but
12 you know, I think using the literature
13 parameters as a guide is a good idea, so you
14 know, stable hypercapnic respiratory failure
15 with parameters that resemble the best evidence
16 is what I would favor.

17 DR. BACH: Okay. Barring any more
18 comments on that part of the question, I would
19 like to move on to question two, please. The
20 question is: How confident -- John, I don't
21 know why there's a one showing there. Has
22 somebody already voted when you cleared out the

23 votes? We seem to be having -- here we go.

24 All right. Can we proceed with voting on

25 number two?

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1 I'll read the question: How confident
2 are you that the evidence is sufficient to
3 determine the NIPPV equipment parameters
4 necessary to promote successful patient-related
5 outcomes, for example decreased mortality,
6 decreased frequency of exacerbations requiring
7 ER or hospital admission, increased time to
8 hospital readmission for respiratory-related
9 disease, and improved physical function and
10 quality of life? Please vote now.

11 MS. HALL: Everyone has voted.

12 DR. BACH: Okay, I'd like to poll,
13 starting with Dr. Ross.

14 DR. ROSS: This is Joe Ross. I voted
15 a one because I didn't really get a sense of
16 differences by equipment parameters, either by
17 low intensity or high intensity, or by
18 different equipment types even.

19 DR. BACH: Thank you. Dr. Barreiro?

20 DR. BARREIRO: Again, thank you,

21 Chair. I voted three but was again in turmoil.
22 I thought there was insufficient data that the
23 parameters are adequate for the use of the
24 equipment alone. However, I struggled with the
25 mere fact that it seems that it did not matter

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1 except for CPAP alone based on the discussion
2 today. But it seems that the patients with
3 chronic respiratory failure secondary to COPD
4 and hypercapnia should receive some type of
5 device other than CPAP alone based on the
6 information that we have. In addition, the
7 criteria of adding increased responsibility to
8 the accepting DME company and providing
9 increased support for education home care, I
10 thought was adequate. I did not feel that
11 there was enough information for the definitive
12 evidence on very few small trials that the high
13 flow changes present, that was presented today,
14 was adequate to suggest that it should be the
15 standard of care, but suggested adjusting the
16 machine in frequent followups seems to be more
17 important. Thank you, Mr. Chair.

18 DR. BACH: Thank you. Dr. Fernander?

19 DR. FERNANDER: Three.

20 DR. BACH: Dr. Fisch?

21 DR. FISCH: Two for me. I would have
22 started pre-meeting at a one, but I think some
23 of the expert commentary has nudged me to a
24 two.

25 DR. BACH: Dr. Garrido.

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1 DR. GARRIDO: I voted a three. I'm
2 viewing the word parameters very loosely
3 similar to Dr. Barreiro. I think we don't have
4 much evidence about the effectiveness of CPAP
5 but we do have better evidence on different
6 outcomes with the other types of equipment.
7 But beyond that I don't think there's any,
8 there's insufficient evidence of other
9 equipment parameters.

10 DR. BACH: Thank you. Dr. Kuebler?

11 DR. KUEBLER: I voted a three. In the
12 technology assessment report the tables showed
13 that patients that were using something versus
14 no equipment at all did reduce hospitalization
15 and exacerbation data.

16 DR. BACH: Thank you. Dr. Manship?

17 DR. MANSHIP: I voted a three. I have

18 no substantive comments to add.

19 DR. BACH: Dr. Melnikow?

20 DR. MELNIKOW: I voted a three also,
21 thinking that the evidence from those studies
22 that were reviewed has equipment parameters in
23 it, and clearly when those equipment parameters
24 are used there are, you know, on balance,
25 improved outcomes.

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1 DR. BACH: Thank you. Dr. Salive?

2 DR. SALIVE: Yeah, I voted a three
3 basically for the same reason. I think the top
4 line conclusion of the technology assessment
5 was, you know, said enough evidence to give me
6 a three on this question, that's about it. I
7 think there was still that mix of observational
8 trials, so it didn't go any higher.

9 DR. ROSS: Peter, this is Joe Ross.
10 I'm sorry to interrupt, can I just make a
11 clarification on my comment?

12 DR. BACH: Of course.

13 DR. ROSS: I just want to make it
14 clear that my, the reason I rated it as a one
15 is I didn't think there was evidence that
16 differentiated either high intensity or low

17 intensity, or home mechanical ventilation
18 versus Bi-PAP, not that the machines
19 themselves, the NIPPV wasn't effective.

20 DR. BACH: Okay, thank you. We're
21 going to go on to the nonvoting panelists.
22 Dr. Mauri?

23 DR. MAURI: Yes, thank you. I voted a
24 four. I think when we look across the
25 different options for treatment, I thought

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1 Dr. Coleman's presentation showing the
2 evolution of care and how that impacted the
3 findings over time was an important one, and
4 each of the studies presented did have fairly
5 clear parameters associated with the outcomes
6 looking at effectiveness. I guess I would also
7 add how important I think it will be to
8 incorporate physician decision-making, expert
9 decision-making in selecting the modes of care,
10 I think Dr. Wolfe outlined that very clearly in
11 her presentation, and so I would actually be
12 supportive of continuing to work with experts
13 and patients in the future to develop some of
14 these pathways.

15 DR. BACH: Dr. Criner?
16 DR. CRINER: Yes, I say it's a two,
17 and I think it's a reflection of the small
18 nature of all the studies that doesn't allow
19 the heterogeneity of setting changes across the
20 patient groups which have different degrees of
21 air trapping and physiology under them, so I
22 think it's the quality of the data that makes
23 my confidence a two.
24 DR. BACH: Thank you. Dr. Gay?
25 DR. GAY: I think it's a four. I

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1 agree very much with Dr. Mauri that HOT, high
2 intensity changed the outcome of COPD patients'
3 mortality, and it was strikingly supported
4 again by the Murphy data. I think to look at
5 this and try to dissect the individualities of
6 should it be a delta ten, should it be a delta
7 12, should it be a range of 12 to 14 is not the
8 question. It's specifically whether or not a
9 high intensity really was well supported by the
10 best studies, that's why I gave it a four, and
11 that's when I think Dr. Coleman really took
12 over the top when he pointed out how things
13 changed.

14 DR. BACH: Thank you. Dr. MacIntyre?

15 DR. MACINTYRE: So this was a
16 multipart question to me. I would give, the
17 summary I guess would be a three. I think
18 four, I have high confidence that things like
19 high level support does improve outcome in
20 hypercapnic COPD, but I have lower confidence
21 about the difference between Bi-PAP and home
22 mechanical ventilation, and I have a higher
23 level of confidence that CPAP is inferior to
24 both those other two devices. So I took into
25 account multiple different things and am going

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1 to, what did I say, a three or a four, I can't
2 remember, I'm sorry, so I think three looking
3 at all things put together.

4 DR. BACH: Thank you very much. There
5 are two discussion questions. Is there any
6 other point anyone wants to make? Okay. There
7 are two discussion questions. First, are there
8 any outcome measures that should be considered
9 other than those noted above, and the next
10 relates to the equipment parameters for
11 specific categories of equipment. A couple of

12 things.

13 One is, I'm going to ask Joe Ross to
14 temporarily take this over because my computer
15 is doing some things very odd and I'm going to
16 try and log back in. But I'll ask that you
17 discuss the outcome measures that should be
18 considered other than those noted, and I'm
19 anticipating with regard to parameters a
20 similar discussion to the earlier one, I want
21 to have it, but understand that if the answers
22 are akin to those we can, to the ones on the
23 prior discussion, that's very helpful as well.
24 I'm going to log off here for a second. Joe,
25 have you got it covered?

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1 DR. ROSS: Yes, no problem, I can
2 steer that conversation. So let's start with
3 that first point, are there any outcome
4 measures that should be considered other than
5 those that have been noted above, which were
6 mortality, frequency of exacerbations requiring
7 emergency room or hospital admission use, time
8 to hospital readmission for respiratory-related
9 disease, physical function or quality of life?
10 And I guess like last time, we can just ask

11 people to chime in.

12 DR. KUEBLER: This is Kim Kuebler.

13 There's nothing here about symptoms, dyspnea,

14 exercise intolerance, things that would be

15 specific to an exacerbation.

16 DR. ROSS: Thank you, Dr. Kuebler.

17 Anybody else?

18 DR. SALIVE: This is Marcel Salive. I

19 think adverse events should be considered as an

20 outcome measure always.

21 DR. ROSS: I agree, Dr. Salive. Is

22 there specific adverse events or serious

23 adverse events that you would be most

24 interested in seeing?

25 DR. SALIVE: Not -- yeah, I would be

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1 interested in serious events. I didn't see

2 much and I'm not that worried, but I think it

3 has to be always included.

4 DR. ROSS: Okay. Any other comments?

5 I will note that at one point during our

6 conversation somebody noted depression and

7 other psychiatric or related disease as a

8 potential outcome.

9 UNIDENTIFIED SPEAKER: I think the
10 symptom scores and the depression was as you
11 mentioned, I included those in the quality of
12 life at the time the question was asked, some
13 aspects to that, but I'm glad the panel agreed
14 to think outside the box just to make sure that
15 they were included, and I agree upon them.

16 DR. GARRIDO: This is Melissa Garrido.
17 I agree with anxiety and dyspnea being
18 important outcomes.

19 DR. ROSS: Thank you, Dr. Garrido.
20 Who else was speaking at the same time?

21 DR. FISCH: This is Mike Fisch.
22 Caregiver, sort of a caregiver satisfaction
23 might be something to consider as well.

24 DR. ROSS: Thank you, Dr. Fisch.
25 Okay.

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1 DR. BARREIRO: Joe, we talked about
2 health care resources so that may be obviously,
3 I think we're including that -- I'm sorry, this
4 is Tim Barreiro -- utility or health care
5 utilization, how many, that may be included
6 under hospital/ER visits but there's also other
7 aspects of that, and obviously that may be

8 something to consider.

9 DR. GAY: One of the things that is
10 not often spoken about is whether they returned
11 to work or a level of productivity. We used to
12 quip, did they file a tax return the next year,
13 just showing the improvement in their ability
14 to function, or whether they were placed in a
15 nursing home, so that kind of outcome.

16 DR. BACH: Peter Bach, I'm back.
17 Further discussions on the question of
18 additional outcomes to consider? Okay.
19 Barring further discussion on that point, I
20 would like to move to the second discussion
21 question, which is triggered by having the
22 intermediate confidence greater than or equal
23 to two-and-a-half. Please provide the
24 equipment parameters for the specific category
25 of equipment. And as I said, I am not trying

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1 to lead the discussion but I'm going to start
2 with a baseline response, which is that the
3 data regarding parameters is presented in
4 various manuscripts and reviews and evidence
5 reviewed that we have discussed today, and I'm

6 wondering if that is a fair summary of the
7 panel's response. Please correct me as you
8 wish.

9 DR. MACINTYRE: So this is Neil
10 MacIntyre. We didn't really discuss this and
11 there aren't much data supporting or addressing
12 it. But one feature of these home devices that
13 I think could make an impact is mobility, the
14 ability of the patient to actually walk with it
15 or move around the house with it. The idea of
16 increased mobility improving outcomes is
17 important in other studies, it's never really
18 been looked at in this, or with these devices,
19 but I would just like to have that comment on
20 the record. Thank you.

21 DR. BACH: Thank you.

22 DR. KUEBLER: This is Kim Kuebler.
23 There was a lot of discussion that this patient
24 population is not really a candidate for
25 randomized controlled trials. I think it would

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1 be important to look at these different devices
2 from a comparative effectiveness research
3 perspective, and maybe CMS could partner with
4 the Patient-Centered Outcomes Research

5 Institute to develop some studies in this area.
6 DR. GAY: I agree with that. I think
7 the difficulty is in the clinical arena, the
8 reason they use an HMV has generally been moved
9 towards the more severe patients without
10 dichotomizing the patient population into the
11 severe, which favors in a lot of cases an HMV
12 versus a bilevel device. For the less severe
13 you're biasing your outcome the minute you go
14 with the selection criteria.

15 With respect to the actual question
16 here, I think again, maybe I'm interpreting
17 this a little differently than others, we
18 talked about number two, the question of the
19 equipment parameters, how do you set the thing,
20 it's pretty clear to me from the data that
21 setting high intensity is pretty overwhelming
22 in terms of the outcomes, it's changed the way
23 we practice. In terms of what devices can do
24 this, the question is not whether it's better
25 or worse, we're not doing a comparative thing

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1 in the discussion in my mind, we're just saying
2 can an HMV do this, can a BiPAP do this, yes,

3 yes. Can a CPAP do this, no. That's the way
4 I'm interpreting that. Thanks.

5 DR. BARREIRO: Yeah, I interpret it as
6 you did, Peter, this is Tim Barreiro, the same
7 exact way as with the equipment. I would like
8 to add to the equipment a way to interface with
9 the physician in order to make changes, and put
10 some responsibility on the DME. I know that
11 may be nearly impossible, but nonetheless in an
12 ideal world I would still request it. The
13 equipment itself I would say is adequate
14 regardless of the type except for CPAP, in the
15 setting of hypercapnic COPD and chronic
16 respiratory failure, CPAP likely could not be
17 ordered.

18 DR. BACH: Thank you. Other comments?

19 Okay, barring other comments I'd like
20 to move on to question three please. The
21 question reads: How confident are you that any
22 improved patient-related outcomes noted above
23 made with any type of NIPPV device in the home
24 can be attributed to the use of the equipment
25 alone, as opposed to the concomitant provision

2 therapists, home medication reconciliation, and
3 repeated elective hospital admissions? Please
4 vote now.

5 MS. HALL: We're still waiting on one
6 person to vote. Everyone has voted.

7 DR. BACH: Okay, I would like to poll
8 the panel. Dr. Ross?

9 DR. ROSS: Yeah, this is Dr. Ross, Joe
10 Ross. I voted a three, intermediate
11 confidence, not that I felt like the trials
12 really disentangled these, it was very
13 difficult to know about how home respiratory
14 therapists play a role, but I just don't have
15 confidence that home medication reconciliation
16 or repeated elective admissions would have the
17 impact that was observed in the trials
18 otherwise.

19 DR. BACH: Dr. Barreiro?

20 DR. BARREIRO: Thank you, Mr. Chair.
21 My vote was a two. I mainly voted for a two
22 because I thought that the question
23 specifically asked the device alone, where I
24 found that there was more evidence to suggest
25 that the equipment necessarily played a factor,

1 NIV use did not, but without the concomitant
2 addition including some of the studies that
3 were presented earlier in our packet, that some
4 patients got respiratory and pulmonary
5 rehabilitation, some people got home medication
6 adjustment, those things seemed to be adjunct
7 and additional parameters that seemed also, I
8 couldn't eliminate from the data, thus I gave
9 it a two.

10 DR. BACH: Thank you. Dr. Fernander?

11 DR. FERNANDER: I gave it a four. I
12 do agree that there was not much data provided
13 or discussion to tease out the adjunctive
14 therapies. However, I just kind of kept
15 falling back on that four-hour minimal exposure
16 and timing. To me that indicated that there
17 was some efficacy with these devices alone, but
18 clearly I'm not sure that we have done the
19 studies necessary to really tease out the
20 adjunctive therapies, so that's just kind of
21 the reason for my score.

22 DR. BACH: Thank you. Dr. Fisch?

23 DR. FISCH: I also voted two, and the
24 recurring theme for me is just this was based
25 on integrating the sense of evidence, which is

1 kind of a one, and my sense of the medical
2 reasoning and expert consensus which was more
3 of a three, so I integrated it to a two.

4 DR. BACH: Thank you very much.

5 Dr. Garrido?

6 DR. GARRIDO: I gave it a one, swayed
7 by the fact that a lot of the studies have been
8 done in Europe where respiratory therapy is
9 part of the intervention and the fact that we
10 can't see that.

11 DR. BACH: Thank you. Dr. Kuebler?

12 DR. KUEBLER: I gave it a two and for
13 the same reasons that have already been voiced,
14 the fact that we only have two retrospective
15 studies here in the United States and that the
16 majority of the studies came from Europe with
17 comprehensive home care support.

18 DR. BACH: Thank you. Dr. Manship?

19 DR. MANSHIP: I also voted a two. The
20 only thing that I would add to the comments
21 that have been made so far is that we had a
22 couple of presenters throughout the day who did
23 make comments about the importance of
24 wraparound services and that resonated with me.
25 So that being said, it was hard for me to have

1 any greater confidence that the device alone
2 would have those outcomes, so I voted a two.

3 DR. BACH: Thank you very much.

4 Dr. Melnikow please?

5 DR. MELNIKOW: I gave it a two as well

6 mostly for reasons that have already been
7 stated, and then in terms of the evidence, I
8 don't think that we really have the evidence to
9 separate out the device by itself, and then
10 also combined with my clinical experience in
11 other areas of trying to get home support
12 services along with equipment rotations and the
13 difficulty of coordinating that, where without
14 the support the equipment is not as effective.

15 DR. BACH: Thank you very much.

16 Dr. Salive?

17 DR. SALIVE: I also gave a two, I
18 think for similar reasons to what has been
19 stated. I think, you know, the device has a
20 great effect but you can't do it alone with the
21 device, and we do need maintenance, training
22 and reassurance in the home, I think many
23 things like that.

24 DR. BACH: Thank you. We will now
25 move to the nonvoting members of the panel.

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1 Dr. Mauri?

2 DR. MAURI: Thank you. I gave it a
3 four. I actually agree with the comments that
4 Dr. Salive just made, which are that the device
5 has an effect but it helps to have the
6 additional home support to make it more
7 effective. The reason I gave it a four is that
8 I read this question as really, is there an
9 independent effect of providing NIPPV over
10 oxygen therapy alone or less intensive therapy,
11 and I think the randomized trials in Europe
12 clearly show that, where in both cases there
13 are provisions of home services, so I gave it a
14 four.

15 DR. BACH: Thank you very much.

16 Dr. Criner?

17 DR. CRINER: Yes, I gave it a three.
18 I do that based on our personal experience and
19 our family reports from our institution, and
20 the patients in both arms received as much
21 intensive care, in fact the ones that were
22 admitted more were the ones that did not

23 receive that NIPPV, and the rest of them got
24 the same outpatient care, so I think this is a
25 three.

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1 DR. BACH: Thank you very much.
2 Dr. Gay?
3 DR. GAY: I give it a four for the
4 reasons being that, first of all, nobody drop
5 ships these devices to the front door. And you
6 also read into the methodology of every single
7 study, nobody even imagined not going through
8 in detail with the device, how it works, what
9 to do with it. It's implicit to me the way
10 they designed the trials that you would not
11 even expect the device alone to do what it
12 needs to do unless you provide the education,
13 the support, the kind of things that make you
14 come out of the hospital or chronically want to
15 use this, so I think it's implicit in the
16 methodology that you have to have the support
17 services.

18 DR. MACINTYRE: So --

19 DR. BACH: Was somebody --

20 DR. MACINTYRE: I was jumping the gun,

21 this is Neil MacIntyre, I was going to be
22 called next. But Peter, if I may, did you
23 really mean, it sounded like you were
24 supporting the, or you were not supporting the
25 idea of the device all by itself, which would

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1 put a low number. You gave it a very high
2 number, that you thought the device could be
3 used alone. Did you vote that correctly?

4 While you're thinking about it I'm
5 going to give it a one, because, and I'm going
6 to -- (inaudible, crosstalk).

7 DR. GAY: I did read that backwards,
8 so it's just the opposite of the spectrum, I
9 agree with you.

10 DR. MACINTYRE: Thank you for
11 clarifying that. Okay, because I was going to
12 use your comments to defend my position of a
13 one. And just to solidify, my position is just
14 personal experience. We've heard multiple
15 talks over the course of the day, these
16 patients are frail, they're depressed, they're
17 anxious, and getting them the support they need
18 to work with these rather complicated devices
19 that require cooperation every night of their

20 life, I don't see how you can do it without, I
21 love the term wraparound service, so I gave it
22 a one.

23 DR. BACH: Thank you, Dr. MacIntyre.
24 Since this is unusual, but Dr. Gay, your votes,
25 as I pointed out before, do not count towards

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1 the tabulation, but you have spoken a vote. If
2 you'd like to add to your comments that you
3 would have voted some other way, you read the
4 question differently, you're free to do so and
5 CMS will be able to use that information, but
6 there's no requirement for you to do so
7 whatsoever.

8 DR. GAY: No, I'm very thankful for
9 Neil. We essentially said the same thing, only
10 I reversed the interpretation of the question.
11 I clearly agree that it should be on the one
12 side, that without the services this does not
13 work alone.

14 DR. KUEBLER: Peter, can I support my
15 clarification about the question?

16 DR. BACH: Okay.

17 DR. KUEBLER: It's a question of

18 clarification. How I interpreted the question
19 was does the device work in and of itself, and
20 then does the device work best when you have
21 adjunct therapy. I did not read the question
22 as does the device work if you have an expert
23 showing you how to use it. Those other
24 therapies or support services are additional
25 therapies, not directed on how to use the

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1 device. Am I misinterpreting it?
2 DR. BACH: I don't think -- I think
3 that's a perfectly reasonable interpretation
4 and the reason we have this discussion after
5 the votes is to add just that kind of clarity
6 so that CMS can consider the input, you know,
7 beyond just the numerical vote. And I
8 certainly understood what you just said, I
9 think CMS will as well from the transcript and
10 from being part of this discussion.
11 And I'm perfectly happy to pause now
12 and if there are any other panelists who would
13 like to clarify the reason for their vote, I
14 can't let counting votes get revoted per se,
15 that's the process, there's this line to the
16 input from others, but you can certainly

17 clarify if you feel it's important, how you
18 interpreted the question.
19 DR. BARREIRO: This is Tim Barreiro.
20 I don't want to change my vote. However, I
21 would also say that idealistically when we look
22 at people that enroll in a clinical trial, it
23 also may not be the general population which we
24 also look at. So if we just look at the
25 previous discussion, which I thought was very

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1 enriching, it's also known that the people that
2 enroll may be highly motivated individuals as
3 well, and all the other things that may come
4 with that such as supported and nonsupport.
5 But generalizable however, I do have issues
6 with the mere fact that we should be cautious
7 about the machine alone and without that, going
8 back to why I voted the way I did, was merely
9 the fact that most people may not have the
10 ideal support that is done in a clinical
11 trial.

12 DR. BACH: Thank you very much,
13 Dr. Barreiro. Any other comments from the
14 members, the voting members at this point?

15 Okay, we are going to go on because discussion
16 is not triggered in this case, we did not cross
17 the greater than or equal to 2.5 mean vote
18 threshold, so we're going to go on to question
19 four now please, John.
20 Question four reads: How confident
21 are you that the evidence is sufficient to
22 provide the patient usage parameters that are
23 necessary to achieve the successful patient
24 outcomes listed in question two? I don't know
25 who has these in front of them so I will just

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1 read to you what those patient outcomes were,
2 I'll remind you that this is related to the
3 discussion we just had about what other
4 outcomes should be considered but are not in
5 that question. The question two outcomes are
6 decreased mortality, decreased frequency of
7 exacerbations requiring ER or hospital
8 admission, increased time to hospital
9 readmission for respiratory-related disease,
10 and improved physical function and quality of
11 life. And so the question is with those
12 outcomes again, how confident are you that the
13 evidence is sufficient to provide the patient

14 usage parameters that are necessary to achieve

15 those outcomes? Please vote.

16 MS. HALL: All members have voted.

17 DR. BACH: Okay, I'm going to poll the

18 committee, starting with Dr. Ross.

19 DR. ROSS: Yeah, I voted a three,

20 intermediate confidence because many people

21 spoke throughout their presentation about the

22 need for patients to use four, five or six

23 hours, or four or five at least, hours of use.

24 DR. BACH: Thank you. Dr. Barreiro?

25 DR. BARREIRO: I too voted a three,

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1 intermediate confidence. I was not exactly

2 extremely excited about the role of using

3 criteria such as an hour time of use based on

4 the information in the packet and what was

5 presented, despite the fact that we know the

6 longer that you use it, the more beneficial it

7 may be. However, I didn't think it was robust

8 enough. I should note, however, patients

9 should not have to necessarily fight for the

10 equipment. Based on the data presented today

11 less than half, 15 of 38 studies showed, which

12 is less than half, showed that they got
13 adequate support from the equipment and/or home
14 care, and I think that is sufficient enough to
15 give me intermediate confidence.

16 DR. BACH: Thanks you. Dr. Fernander?

17 DR. FERNANDER: Three.

18 DR. BACH: Dr. Fisch?

19 DR. FISCH: Three.

20 DR. BACH: Dr. Garrido?

21 DR. GARRIDO: I voted a one. I think
22 there's minimal evidence to suggest that some
23 number of hours is effective for reducing
24 all-cause hospital admissions, at least in the
25 trial evidence. I think we really need more

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1 real world evidence to understand ideal
2 parameters and I wouldn't recommend that any
3 decisions about whether someone should or
4 shouldn't be using these devices be based on
5 the existing evidence of usage parameters.

6 DR. BACH: Thank you. Dr. Kuebler?

7 DR. KUEBLER: I gave it a one. I am a
8 little discouraged that a lot of the criteria
9 is based on the 1998 guidance that's almost 32
10 years old, and I'm hoping that the new

11 guidelines that are being produced through
12 Dr. Owens' presentation that he alluded to will
13 make a difference in some of these outcomes.

14 DR. BACH: Thank you. Dr. Manship?

15 DR. MANSHIP: I voted three, the
16 reason being that there was this consistent
17 reiteration of, again, four hours, even though
18 it was immediately disqualified as the Golden
19 Rule. With that being said, for me there's
20 sufficient evidence that we do have at least
21 the beginning of establishing a firm parameter.
22 More data is definitely necessary but for now,
23 I am comfortable with a three.

24 DR. BACH: Thank you very much.

25 Dr. Melnikow?

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1 DR. MELNIKOW: I voted a three.

2 DR. BACH: Dr. Salive?

3 DR. SALIVE: I voted a two. I think
4 it's actually pretty hard to develop good
5 evidence for patient usage parameters and we
6 did not have that. These were mostly efficacy
7 studies and then some observational studies
8 that were not really measuring that too well,

9 so that's why I gave it a two.

10 DR. BACH: Thank you very much. I'm
11 going to now move to the nonvoting panelists.
12 Dr. Mauri?

13 DR. MAURI: I voted a one. I agree
14 with the comments that we might observe an
15 increased effect with longer duration of
16 treatment, but I think that that's an
17 observation that has to do with how well
18 patients tolerate the treatment. And as you
19 heard from the clinician presenters, it's not
20 always easy immediately to tolerate, especially
21 the more effective higher pressures, but they
22 may be quite effective in reducing mortality,
23 and I'm afraid that if we restrict to those who
24 are able to achieve those parameters in a
25 certain timeframe, then we may be actually

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1 putting limits on the access for some of the
2 sickest patients who may have the most trouble
3 actually adapting to the effective therapy, and
4 also be putting the burden on patients who may
5 not have the support that they need to be able
6 to achieve those successful durations of
7 treatment.

8 DR. BACH: Thank you very much.

9 Dr. Criner?

10 DR. CRINER: I gave this a two,
11 although I believe that you have to use it to
12 get benefit in hours of use, and therefore it
13 should go along with benefits. There's no
14 reason to believe that patients need to use it
15 for the same time each day, they might
16 episodically use it based on their symptoms
17 overall. In most of the studies, the data was
18 reported by hours logged of use; that means the
19 machine might be running but you don't know
20 whether the patient is appropriately applying
21 it or not, so I think the data is poor to show
22 exact parameters of usage correlating with
23 outcome.

24 DR. BACH: Thank you very much.

25 Dr. Gay?

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1 DR. GAY: For more or less the same
2 argument that Dr. Criner offers, I give it a
3 three. I do think more is better with Kohnlein
4 being close to six and Murphy being close to
5 five, and Struik clearly being the least. But

6 I follow Dr. Mauri, in fact advocate the
7 comment that it should be noted to CMS that
8 there are patients that gain benefit from
9 relatively lesser use, and to have these
10 arbitrary 30-year-old criteria saying if you
11 don't meet the 4.0001 hours we're going to take
12 it away can't be supported. Thanks.

13 DR. BACH: Thank you very much.

14 Dr. MacIntyre?

15 DR. MACINTYRE: Yeah, I'm going to go
16 with a three here. Again, I've got sort of two
17 conflicting views here. It's going to seem
18 trivial and trite, but I do think you have to
19 have some documentation that the patient is
20 using it. I've heard many a war story about
21 devices being delivered to patients' homes that
22 never even get plugged in, so I think there
23 needs to be some criteria that the patient is
24 actually using it. Having said that, I would
25 agree with most of the panel members that I

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1 have no idea what the threshold should be, and
2 it's going to be arbitrary, and I would keep it
3 low; I would rather treat as many patients with
4 low levels of effectiveness than not treat

5 people that way.

6 DR. BACH: Thank you very much. We
7 did not meet the threshold once again to go on
8 to the discussion regarding patient usage
9 criteria so we're going to move on to the next
10 section of the agenda having completed the
11 voting session, which is final open panel
12 discussion, that I will lead.

13 As it is sometimes the case that after
14 the course of this day and the voting and the
15 discussion we've just had, there's a feeling,
16 some panelists might have a feeling that
17 there's more to discuss, there's other issues
18 to raise. This is a discussion for CMS. I've
19 already heard a few things mentioned that might
20 really be things that the Agency, you feel the
21 Agency should hear based on this review and the
22 votes and the rest of it. So now is really the
23 time for that.

24 There's just a few of us, please feel
25 free to just speak up, and of course you can

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1 also private chat with me and I will call on
2 you if that's more comfortable for you, but

3 anyone who cares to open this discussion should
4 feel free to do so. It's also okay if people
5 feel that most of the things that should be
6 discussed have already been discussed in this
7 forum, if that's -- and again, everyone
8 probably thought the day would be a long day,
9 but now here's someone who may want to talk, so
10 Dr. Gay?

11 DR. GAY: Yeah, I think that belittles
12 why we spent all this time here if we walk away
13 from this. First of all, I've been delighted
14 to participate in this, I think it's a
15 fascinating way that great minds exchange ideas
16 that brings us forward in Medicare. And I
17 think as tragic, as human as it's been, it's
18 brought us out to understand that we're out
19 here to make things better for our patients and
20 when we are pushed to the limit, we do better,
21 and the people that do better are those who
22 work with the data and really are the experts
23 in the field that share their experience, their
24 ability to analyze data.

25 The reason I assume, at least I'm

1 going to say, just editorializing why we're

2 here to talk about hypercapnic COPD is that it
3 was a life changing event, certainly in Europe,
4 to see the high intensity effect. It's sad to
5 say that this was in 2014 that the Europeans
6 published data that was in their mind for years
7 by the time this went forward, and we're not
8 talking about the things that we feel strongly
9 about in this country, for example the obesity
10 hypoventilation, which may be another topic for
11 us, I'll throw that out to the MEDCAC people
12 who I'm sure have nothing to do right now.

13 But ultimately that really, I think
14 came forward because there is some pretty
15 strong data that now the real outcomes like the
16 hospitalizations, like the mortality are being
17 talked about. When we started this back in the
18 stone age when I was still building the ark,
19 ultimately this was all about gas exchange, we
20 just, boy, if the CO₂ got better that was a
21 touchdown, we started talking a little bit
22 about quality of life. But the way that it
23 first was introduced by Medicare was the fact
24 that the CO₂ went down in the Meacham-Jones
25 trial. Incidentally, that was the only one.

1 My trial was negative, C.C. Lind's trial was
2 negative, Nick Hill's trial was negative. So
3 one trial that said woo, there's something to
4 this, triggered 20 years worth of use.

5 So I think the reason we're here for
6 this hypercapnic COPD is that this data is I
7 believe real, and how we now parse this out to
8 what subset of patients should be, how long we
9 use it, we've still got a long way to go.

10 Please, let's not stop here. Again, we've been
11 talking about it, pleading with CMS for a while
12 about getting more experts together to take
13 this to the next step. The next NCD should not
14 just be about hypercapnic COPD, we've got to
15 talk about what this technology is doing for a
16 host of patients.

17 Where is the HMO? The HMO is out
18 there for a reason, it was built for a reason,
19 the market bought it for a reason, it has its
20 use. We need to define that, not just say it's
21 expensive and it was used in such a superfluous
22 manner that it's a bad thing, we really need to
23 take it to the next step.

24 And again, I thank everybody for the
25 time they gave here and sharing their thoughts

1 with me. Thank you.

2 DR. BACH: Thank you, Dr. Gay. Anyone
3 else?

4 DR. MANSHIP: Yes, Dr. Bach, this is
5 Greg Manship, and again, I've been reflecting
6 on the entire day and with Dr, Gay just spoke
7 and what others have said, I have a question
8 again for the clinicians and subject matter
9 experts, and the question, here's some context
10 and the context is this. That is that in the
11 research portfolio that I'm seeing at OSF,
12 we're seeing more and more clinicians who are
13 using machine learning, so natural language
14 programming, building algorithms, you know,
15 pulling huge data sets, creating these
16 algorithms in an attempt to integrate this into
17 medical devices, and not just for theoretical
18 predictive modeling, but to enhance the
19 interconnectivity between device, provider and
20 patient.

21 And my question is, you know, based on
22 the conversation we've had here today, where
23 this may or may not go in the future. Does
24 anyone have any thoughts or comments about how
25 using machine learning in a situation like this

1 would improve the, not only the effectiveness
2 of this equipment for patients, but would
3 improve our ability to make decisions about
4 which patients would benefit more and how
5 patients would actually be able to interact in
6 real time with those, with that equipment, with
7 providers? And perhaps in some cases there's
8 going to be a user interface that would
9 actually predict based on real time data how
10 that machine would adapt to a particular
11 patient's needs. So it's probably more
12 philosophical, but I'm curious to know if
13 anyone has thought about those things and how
14 that informs where we go from here. Thank you.

15 DR. BACH: Thank you very much.

16 DR. MAURI: I can speak to that a bit
17 just broadly in that, you know, you heard from
18 one of the medical device companies earlier
19 today, ResMed, but I think this is not unique
20 as is true for many other companies who are
21 involved with medical devices, that the level
22 of care and telemedicine are currently possible
23 and are currently, and machine learning to be

24 able to utilize data across different types of
25 sources of data, whether it's from the devices,

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1 from the patients or from their medical
2 records, is a common thing that I think we're
3 all trying to work together with providers and
4 patients to achieve. So I do think that that's
5 the future and that we're already working on
6 that, and COVID, if anything, has highlighted
7 that we can do that and that it can be quite
8 useful and particularly being able to manage
9 patients, connect patients, physicians, their
10 other caregivers in ways that are remote.

11 DR. BARREIRO: This is Tim Barreiro.
12 This may be a little bit different than what
13 you're asking, but the concept of machine
14 learning I think can be really complex,
15 especially some of the information that's out
16 there about how it breaks down data. When we
17 look at, and I'm going to just glance over,
18 when we look at the obstructive sleep apnea
19 equipment and how it can auto titrate and
20 regulate, and the information we get back from
21 those machines to help us adjust patients, I
22 think is a form of machine learning to some

23 degree and it really does help us adjust those
24 machines to a greater compliance and more
25 comfort, which gives in the end likely better

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1 outcomes. So I think we've started doing,
2 started the possibility of doing that in the
3 basic sense of some machine learning.

4 DR. GARRIDO: This is Melissa Garrido.
5 I'd just make a plug for going beyond machine
6 learning which has its uses, but to use
7 administrative data on who's used these
8 devices, what are their outcomes, what are
9 their baseline characteristics, pool data from
10 multiple different sources so we can get a
11 better understanding of who's mostly going to
12 benefit under which circumstances, which extra
13 or supportive circumstances in addition to the
14 ventilators. And so that's more of an entrance
15 framework than the predictive modeling that
16 machine learning is usually using, but more
17 data is usually a good sign.

18 DR. MELNIKOW: This is Joy Melnikow.
19 I think just trying to integrate what's being
20 reviewed and what's being said and thinking

21 about going forward and what are the research
22 needs, it seems to me that definitely in the
23 last 22 years there has been, the field has
24 moved forward in terms of the evidence, and
25 Medicare really needs to respond to that, hence

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1 the technical report and hence this meeting,
2 and hopefully there will be some positive
3 changes in terms of what patients can get
4 access to improve their outcomes. But there's
5 also definitely a need for more research, more
6 U.S. based research, more research that really
7 examines that interface between using, you
8 know, the home ventilation device and what
9 support services can optimize its use to
10 improve outcomes.

11 And then the other thing that really
12 we didn't talk about today but I think maybe is
13 an issue that is at least worth getting expert
14 consideration of is the possibility that the
15 use of these devices in the home may contribute
16 to transmission of COVID-19 in certain
17 circumstances, and whether or not there needs
18 to be any whatever, warning label or such
19 depending on what happens with this pandemic,

20 but it certainly seems to be continuing.

21 DR. SALIVE: This is Marcel Salive, I
22 have a couple comments. I think, you know,
23 this has been an interesting experience for me
24 to see some of the things. I think it's a
25 cautionary tale that this coverage was put in

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1 place, you know, so long ago and let stand for
2 this long, hearing that the evidence was so
3 sketchy back in the late '90s. And so, you
4 know, guidelines do need to be revisited
5 periodically and this, you know, it's very hard
6 to translate a guideline if it's a coverage in
7 my experience. I wonder if this coverage has
8 inhibited trials taking place in the U.S.,
9 because it seems like the evidence we saw, you
10 know, may suggest that, but I'm glad we had a
11 lot of trial evidence and I'm glad that Europe
12 has conducted these trials because it is
13 helpful and I think it will advance coverage.
14 It seems like fairly normal that the
15 reconsideration is based on increased use of
16 this technology that catches the attention of
17 the policy-makers, so I think it's good that at

18 least we are reconsidering things, and I
19 thought it was very good that this technology
20 assessment was able to align observational
21 evidence with trial evidence and still draw
22 some conclusions which were, I thought
23 supported kind of equally by both sets of
24 evidence, so that was very interesting for me.
25 DR. CRINER: This is Jerry Criner. I

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1 just wanted to comment on what was just said
2 about the lack of U.S. based data, and it has
3 been a mixed bag. I think some of it is
4 probably related that it might be more
5 available in the U.S. compared to other
6 countries, but it's not available to all
7 Medicare beneficiaries, it's somewhat uneven in
8 its availability. The problem with these
9 studies is this patient population is set, and
10 the studies that would be well done multicenter
11 prospective shared controlled studies would
12 need to be large and well conducted, and those
13 are going to be populations that are going to
14 be probably a thousand to 1,200 patients to be
15 able to be enrolled across multiple sites to be
16 able to get the endpoints that are needed, the

17 things that we're struggling with today.
18 And just like with lung volume
19 reduction surgery and with long-term oxygen
20 treatment trial, these are the kind of studies
21 that only Medicare would be able to support
22 with scientific guidance from agencies like the
23 AHRQ or the NIH, to be able like we did with
24 BOT (phonetic) and what we did with the NET
25 trial was to be able to come up with what

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1 patients benefit from those patients that might
2 not get any benefit or could be harmed. So I
3 think it's time to really think about how to
4 design the studies that would address these
5 important questions.

6 DR. BACH: Thank you very much. The
7 floor remains open.

8 DR. GAY: If I might, I might pick up
9 on what Professor Melnikow spoke of in the
10 COVID era with respect to what's going to
11 happen when they come home. There's a lot of
12 concern about these things, in fact it's almost
13 a dirty word, they're called aerosol generating
14 procedures, and AGP is a frightening thing to

15 say in the hospital environment, it generates a
16 lot of droplet when mask leak takes place and
17 these things blow around the room, so that is
18 being considered.

19 But the other thing again, about the
20 COVID tragedy is with, now depending on
21 telemedicine, whatnot, and we shouldn't
22 overlook this, and it's not in any of those
23 studies, is the effect it's had on patient
24 empowerment, the patients have to play more of
25 a role, they have to be able to work with their

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1 own mask and engage with their clinicians
2 through telemedicine. I think somehow or other
3 if we incorporate these things into future
4 studies where it's not just the respiratory
5 therapist, it's the respiratory therapist
6 empowering the patient to participate in these
7 chronic therapies that go on for the rest of
8 their lives will make an impact on this.
9 Thanks again, everybody.

10 DR. BACH: Thank you. Okay, we're
11 back. I'm going to draw this portion of the
12 meeting to a close with a few closing remarks.
13 I'll start and then Joe Chin will also make a

14 few remarks.

15 I want to thank everyone, including

16 the presenters, for their unflagging dedication

17 to this day-long meeting. I know even in

18 person how long a day it is, I really

19 appreciate the engagement. I know CMS does as

20 well. I appreciate how much the information in

21 the pre-meeting and information presented and

22 discussed today was integrated by all of you in

23 your thinking. I could see it in the votes and

24 the comments and the discussions, and I think

25 it will be of great utility as everyone is

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1 obviously aware, not only from this discussion

2 but from more general contexts, how critical it

3 is for CMS to have this kind of input. These

4 types of decisions often do get embedded for

5 rather a long period of time, so the best

6 decisions that can be made with the current

7 information is always desirable and has

8 long-term effects.

9 So I just wanted to thank everyone,

10 also for putting up with the technology. I

11 actually thought it went pretty well, we didn't

12 have a lot of glitches, and that's about it.
13 Thank you very much for serving on the MEDCAC
14 today. Joe, I will pass it to you, Joe Chin.

15 DR. CHIN: Thank you, Peter, and also,
16 I wanted to thank the panel, the presenters and
17 the experts today for the discussion and the
18 comments which have been really helpful to our
19 understanding of these complex patients and
20 devices. We greatly benefit from the input of
21 experts such as MEDCAC and the presenters, and
22 our team will really be considering the
23 evidence and the presentations over the next
24 few weeks. We are interested in your special
25 society recommendations and guidelines that

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1 were mentioned so we'll look for those
2 publications, I think they are also important
3 to inform our consideration.

4 I think we have a common goal and
5 we're really trying to provide the best
6 evidence-based treatment and devices to the
7 Medicare populations. So, and also based on
8 that, are committed to having the most
9 appropriate policies in place for potentially
10 lifesaving treatments and devices for those

11 patients.

12 So thank you to everyone that
13 participated today. I would like to
14 acknowledge the efforts of Dr. Susan Miller,
15 our medical expert, and Dr. Rachel Katonak, who
16 have really put a lot of effort into
17 preparation for the meeting today. And of
18 course Tara Hall, our coordinator, for a great
19 running of the meeting, and she has been behind
20 the scenes for what I think has been a very
21 successful first virtual MEDCAC for us. And
22 our chair Dr. Bach, and vice chair Dr. Ross.
23 So, thank you again, and we look forward to
24 really continuing our discussions in this area
25 and look forward to future interactions.

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1 DR. BACH: Thank you, Joe. With that,
2 I will call this meeting to a close, and thank
3 you all for your participation.

4 (Whereupon, the meeting adjourned at
5 3:43 p.m. EDT.)

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