



September 12, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, Maryland 21244

Re: CMS-1772-P: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Brooks-LaSure:

The American Association of Cardiovascular and Pulmonary Rehabilitation, the American Association for Respiratory Care, the American Thoracic Society and CHEST/American College of Chest Physicians appreciate the opportunity to provide comments on the CY 2023 update to the hospital outpatient prospective payment and ambulatory surgical center payment rules. Our comments address payment changes to APC 5731, Level I Minor Procedures and direct supervision of cardiac and pulmonary rehabilitation programs by interactive telecommunications technology.

Use of Claims Data for CY 2023 OPPTS and ASC Payment System Ratesetting Due to the PHE (X.D)

CMS provides an overview of the sources of information they use in setting the payment rates under the outpatient prospective payment system (OPPS), taking into consideration the significant impact on cost reports relative to the COVID-19 public health emergency (PHE). For CY2023, CMS proposes to “use CY 2021 claims for the ratesetting process while using the same cost reports from the June 2020 cost report extract to remove the effect of the PHE cost report data on the cost of estimated services.”

An example of the impact of temporary codes created solely in use for the duration of the PHE is HCPCS code C9803, nasal swab testing. This temporary code represents a large volume of services (1,367,531 single claims) available for ratesetting purposes and, according to CMS, would make up 93 percent of the claims used to set the payment rate for APC 5731 – Level I Minor Procedures. This is the APC grouping in which individual pulmonary codes G0237 and G0238 are included.

In the proposed rule, CMS acknowledges in reference to C9803 that “Given that this is a temporary code only in use for the duration of the PHE, that the PHE could conclude before CY 2023, and that the large volume of services for this code in the CY 2021 claims data would dictate the payment rate for APC 5731 if we included this code in ratesetting, we do not believe including the claims data for this code in establishing CY 2023 payment rates would be appropriate.” (87 FR 44681, emphasis added.) Contrary to CMS’ statement, the code was included in APC 5731, Level I Minor Procedures, resulting in a decrease in payment by 45%, from \$25 in CY 2022 to a proposed payment rate of \$14 for CY 2023.

On August 22, 2022, our organizations presented our concerns to the Advisory Panel on Hospital Outpatient Payment. We believe the significant reduction in the payment rate for APC 5731 resulting from the addition of C9803 completely overwhelms and distorts the payment rate for the entire APC 5731. When we look at the cost and weighted averages data of APC 5731 with the publicly available CMS posted files, we calculate that the \$14.00 rate does in fact use that data.

We provided our review of the cost data to the panel members prior to the meeting. A copy is attached to these comments. We are unsure why CMS decided to include the data it clearly states are inappropriate to use in its ratesetting process and believe it could be simply a mismatch of the text of the rule and the CMS files. At the meeting, we presented two options for CMS to consider in addressing the payment distortion caused by the addition of HCPCS C9803 into APC 5731.

Option one, a short-term solution, is to remove the claims data for HCPCS C9803 from the APC payment rate calculation. Per our analysis, that would calculate a weighted average for an APC payment at roughly \$25.88, which is consistent with the payment rate for APC 5731 in past years. Although we recognize our calculation is a very rough back of the envelope estimate, the option does maintain a stable payment rate for hospitals for CY 2023. The panel noted in the meeting that if the language in the proposed rule regarding data used in its ratesetting process was finalized, the C9803 would not be included in its calculations.

One of the weaknesses of excluding C9803 data from APC 5731 calculations is that doing so only solves one problem – establishing a reasonable reimbursement rate for services currently in the APC (excluding C9803). However, removing the C9803 data does not help establish a reasonable reimbursement rate for C9803. In fact, if CMS removes the C9803 data from the APC ratesetting calculation, but continues to use the APC 5731 rate for pay for C9803 services, CMS will be reimbursing significantly above actual costs for nasal swab. This would be an inefficient use of Medicare funds.

A second option we believe as a longer-term solution is to split APC 5731, Level I Minor Procedures, into two APC groups. While CMS maintains C9803 to be a temporary code, we do not see a future in the next three to five years where COVID swab collections are NOT a high-volume service. Even as the COVID strain evolves, we see the need for continued COVID testing and the related costs to continue for some time. We understand, this code was created for the PHE; however, these collections will be in our future for years to come.

Splitting the current APC 5731 into two APCs could better account for the wide range of cost variances within the APC. We looked at options in how to split the APC into groups and determined a natural break in the CMS cost data to be the best solution, which was a break around \$20.00, with one APC including codes costing more than \$20.00 and the second APC including codes costing less than \$20.00. These data and the weighted average are provided in our attached file and resulted in a proposed rate for APC 5731A at 13.xx and APC 5731B at 27.xx. We believe this split is a better representation of the services assigned to this APC and preserves a stable rate for hospitals for these services.

We believe splitting APC 5731 into two APC's is the best option in that it solves two problems. The split will result in reasonable reimbursement rates for all services currently in the 5731 APC and will result in a reasonable reimbursement rate for C9803.

Pulmonary rehabilitation programs have suffered tremendous fluctuations during the PHE, with many programs closing their doors. Two key elements of pulmonary rehabilitation – HCPCS code G0237 and G0238 that are included in APC 5731 – allow individuals who do not meet the COPD or COVID coverage requirements of the full pulmonary rehabilitation benefit to receive individual respiratory therapy services that increase the strength or endurance of the respiratory muscles or improve respiratory function. A payment reduction of 45% as proposed for CY 2023 is unsustainable. One key factor that enabled patients to receive the care they needed to stabilize and maintain their function, symptom control, and quality of life was the ability to receive virtual services through real-time, two-way audio/visual telecommunications technology under the Hospital Without Walls waiver authority granted CMS. We are grateful to CMS for realizing the need to keep patients safe and to allow them to receive services in their homes and are disappointed that the ability of hospitals to continue to provide virtual services in this setting will no longer be available at the end of the PHE. Adding a significant payment reduction on top of the already underutilized program would be a devastating blow to Medicare beneficiaries whose health outcomes are improved by these valuable services.

Recommendations

CMS should put a halt to the proposed 45% reduction in CY 2023 for APC 5731 and remove C9803 from the grouping as a short-term option in the final rule. This will stabilize the payment rate consistent with past years and consistent with the language in the proposed rule in which CMS determined it would be inappropriate to include this temporary code in its ratesetting process.

While a short-term fix is desirable, we strongly recommend CMS consider a long-term option for APC 5731 by splitting the group into two components, using the example we have provided. Hospitals need stable and accurate payments for the services they provide, and we believe the influence of payments related to the PHE will be felt for some time to come.

Direct Supervision of Certain Cardiac and Pulmonary Rehabilitation Services by Interactive Communications Technology (X.C)

Cardiac rehabilitation (CR) and pulmonary rehabilitation (PR) programs are an important part of recovery for those with chronic heart and lung disease and who deal with acute events and exacerbations of their conditions. After hospitalization, it is the standard of care to provide outpatient cardiac or pulmonary rehabilitation services, consisting of exercise and education. These vital programs have been shown to reduce rehospitalization and all-cause mortality, as well as improve physical function, quality of life and lifestyle choices so patients may better self-manage these chronic conditions.

We appreciate the changes that CMS made to 42 CFR 410.2(a)(1)(iv)(D) in previous rulemaking to provide the presence of the physician for purposes of the direct supervision requirement for pulmonary rehabilitation (PR), cardiac rehabilitation (CR), and intensive cardiac rehabilitation (ICR) services to be met through virtual presence via audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. To meet the statutory requirements, this policy has been a lifesaver by keeping Medicare beneficiaries safe during the worst part of the pandemic and enabling them to receive CR and PR services in the home setting under the Hospital Without Walls waivers. Beneficiaries living in rural and underserved areas have particularly benefited from the waiver policy by eliminating the need to travel hundreds of miles in some cases to receive care, resulting in improved adherence to the protocols.

Although CMS confirms in the proposed rule that an individual's home will no longer be a telehealth site when the PHE ends, Medicare beneficiaries can continue to receive services in the hospital outpatient setting as well as other settings deemed "originating sites" in the statute. For that reason, CMS is looking to effectuate a similar policy for hospital outpatient services around direct supervision through virtual presence like the policies in the PFS CY 2023 proposed rule. CMS is seeking comment on whether to continue direct supervision through virtual presence through the end of CY 2023. Other comments sought by CMS include whether there are safety and/or quality of care concerns regarding adopting this policy beyond the PHE and what policies CMS could adopt to address those concerns if the policy were extended post-PHE.

We support continuing direct supervision through virtual presence for PR, CR and ICR programs through the end of CY 2023 at a minimum but have serious concerns about beneficiary access and adherence to these valuable programs if CMS chooses not to extend the policy or make permanent direct supervision through virtual presence via real-time, audio/visual telecommunications technology after the PHE ends. We appreciate the opportunity to provide the comments below in support of our recommendations. These comments and recommendations were also provided by our organizations as part of our response to the proposed CY 2023 update to the physician fee schedule.

Recommendation

We strongly recommend CMS make permanent direct supervision through virtual presence via real-time, audio-visual telecommunications technology in the hospital outpatient setting

so Medicare beneficiaries can continue to receive cardiac and pulmonary rehabilitation services that can improve their lives.

Comments

CMS seeks information to help alleviate concerns over patient safety issues related to direct supervision through virtual presence that can facilitate a decision on whether to extend the policy through CY 2023 or adopt the policy beyond the PHE, consider making the provision permanent or whether it would be a more appropriate option to designate the provision for only a subset of services. From the Medicare perspective, this option to meet direct supervision requirements has only become available during the public health emergency. Thus, it is unlikely there are any peer-reviewed studies that focus on this aspect of virtual care. However, we have attached numerous studies that showcase the effectiveness and safety of virtual CR and PR services that we believe make a compelling case for CMS to make the option of direct supervision through virtual presence permanent. The studies demonstrate virtual and hybrid delivery of CR and PR services provided by staff are safe, improve health outcomes and adherence, and address barriers to access. Based on the importance of these programs in improving patients' lives and their quality of life, we believe the studies speak for themselves in addressing CMS' concerns.

Recommendation

CMS should not restrict direct supervision through virtual presence to a subset of services. The decision on whether to provide direct supervision through virtual presence via real-time, two-way audio/virtual telecommunications should be left up to the practitioner overseeing the patient's care.

Comments

With respect to the current statutory provision that only physicians can provide direct supervision of cardiac and pulmonary programs, our organizations believe they are clearly in the best position to determine whether direct supervision through virtual presence can be provided safely and effectively to their patients based on the individual's medical needs, and they should be given the flexibility to make those decisions on a case-by-case basis. Thus, we do not believe CMS should be making decisions in lieu of clinical judgment as to whether a subset of services is more appropriate than others to receive this important option.

In previous comments, we stated that with more than 97 percent of CR and PR programs in the hospital outpatient setting, it is critical that virtual direct supervision be an option for *both* the outpatient and physician office setting on a permanent basis. This is especially important because emerging data suggests a further benefit of PR: a reduction in mortality. A study by Lindenauer and colleagues¹ found that, in persons hospitalized due to exacerbation of COPD,

¹ Lindenauer PK, Stefan MS, Pekow PS, et al. Association between initiation of pulmonary rehabilitation after hospitalization for COPD and 1-year survival among Medicare beneficiaries. *JAMA*. 2020 May 12;323(18):1813-1823. doi: 10.1001/jama.2020.4437.

PR within 3 months of discharge vs. later or no PR, was associated with a highly significant lower risk of mortality at 1 year (hazard ratio, 0.63; i.e., a 37% lower risk of death over the year following discharge). The study utilized claims data of 197,376 Medicare beneficiaries discharged after hospitalization for COPD.

In persons with fibrotic interstitial lung disease (ILD) including idiopathic pulmonary fibrosis, Guler, et. al.,² demonstrated that those with greater improvement in exercise performance (assessed by six-minute walk distance) following PR had improved survival. Those persons with ILD who participated in at least 80% of planned PR sessions had a 33% lower risk of death. Both studies support PR as a high priority for persons with COPD and fibrotic ILD. Providing permanent virtual direct supervision can significantly improve the ability of physicians to meet their patients' needs to improve their health outcomes and reduce mortality.

Our professional societies and patient advocacy groups believe the attached studies (Attachment B) provide clear evidence that the quality and safety of CR and PR services are not negatively affected when provided via telecommunications technologies and should provide a pathway for CMS to make the option of virtual direct supervision permanent. We intend to make similar comments in the CY 2023 update to the hospital outpatient prospective payment system.

We appreciate the opportunity to provide these comments. If you have further questions, please contact Karen Lui at karen@advocate4action.com.

Sincerely,

American Association for Cardiovascular and Pulmonary Rehabilitation
American Association for Respiratory Care
American Lung Association
American Thoracic Society
CHEST/American College of Chest Physicians
Pulmonary Fibrosis Foundation

Attachment A – Data analysis of APC 5731 (separate file)

Attachment B – Studies on Virtual and Hybrid CR and PR Services

² Guler SA, Hur SA, Stickland MK, et al. Survival after inpatient or outpatient pulmonary rehabilitation in patients with fibrotic interstitial lung disease: a multicentre retrospective cohort study. *Thorax* 2021. doi: 10.1136/thoraxjnl-2021-217361

Attachment A

Summary of Analysis of APC 5731	Single Frequency times geometric mean CY 2023	Total Frequency times geometric mean CY 2023
	<i>Weighted Average</i>	<i>Weighted Average</i>
Option 1 Remove C9803 from APC 5731 and find another APC group for the service	\$25.88	\$27.34
Option 2 Split 5731 into two APC groups based on costs below \$20.00 and above 2000 and keep C9803 in group A		
5731A	\$13.17	\$13.17
5731B	\$27.62	\$29.56

Attachment B

CARDIAC REHABILITATION: Studies involving virtual and hybrid delivery of cardiac rehabilitation services demonstrate safety, improved outcomes over usual care, patient acceptance, and adherence.

- I. Lear, SA, et al., tested the clinical effectiveness of a virtual cardiac rehabilitation program (vCRP) delivered exclusively using Internet-based technology³ in response to a call from American Heart Association Presidential Advisory for more robust research in this area.
 - 72 participants were recruited and randomized to usual care (n=40) or the vCRP (n=38), with age of the participants at 58.4 in the UC group (52.8, 64.7) and 61.7 (51.3, 65.2) in the Intervention Group.

³ Lear, SA, et al., Randomized Trial of a Virtual Cardiac Rehabilitation Program Delivered at a Distance via the Internet. *Circulation: Cardiovascular Quality and Outcomes*. Volume 7, Issue 6, November 2014; Pages 952-959. <https://doi.org/10.1161/CIROUTCOMES.114.001230>.

- Adherence to the vCRP intervention was based on website usage from the 34 completing vCRP participants.
 - A total of 41% of vCRP participants uploaded ≥ 32 exercise reports equating to an average of 2 exercise bouts per week.
 - A total of 26% of vCRP participants uploaded the required 8 blood pressure reports.
 - There were 122 one-to-one private chat sessions between the vCRP participants and the nurse, dietitian, or exercise specialist, which averages to 3.6 sessions per participant.
 - The average participant used 2.4, 2.6, and 2.7 hours of nursing, dietitian, and exercise specialist time, respectively.
- **RESULTS:** The vCRP was safe and superior to usual care in reducing CVD risk and sustaining this reduction delivered exclusively through the Internet to patients in small urban and rural locations.
 - Significant improvements in exercise capacity and dietary quality, with reductions in cholesterol levels was reported. As exercise capacity has a strong association with CVD mortality the authors noted it is a stronger prognostic indicator than other traditional risk factors.
 - After adjustment for the maximal time on the treadmill at baseline, age, sex, type 2 diabetes mellitus, and Internet use for health information, participants in the vCRP had a greater increase in maximal time on the treadmill by 45.7 (95% confidence interval, 1.04–90.48) seconds compared with the usual care group during the 16 months ($P=0.045$).
 - Of importance is that the benefits of the vCRP were sustained for a 12-month period after removal of the 4-month intervention. This is a key finding because recidivism in cardiac rehabilitation is commonplace after completion of a program, and the drop-out rates in these programs are as high as 35%.

- II. Heindl B, et al.,⁴ conducted a review of hybrid cardiac rehabilitation (CR) studies, defined as any combination of supervised center-based and monitored home-based exercise where at least two of the core components are addressed.
- Nine studies were found comparing hybrid CR to 1) traditional center-based CR among coronary artery disease (CAD) patients, (2) usual care among CAD patients, and (3) usual care among heart failure (HF) patients.
 - Each study typically began with a center-based component lasting 2-11 weeks and transitioned to a home-based component lasting 10-22 weeks, with 3-5 exercise sessions per week composed of either walking (usually with a treadmill) or cycling for 25-35 minutes at 60-75% maximal heart rate.
 - Patients recorded data from home exercise sessions, via either a digital heart rate monitor or accelerometer, into logbooks which were reviewed by a therapist at specified intervals (often via telephone).

⁴ Heindl B, Ramirez L, Joseph L, Clarkson S, Thomas R, Bittner V. Hybrid cardiac rehabilitation - The state of the science and the way forward. *Prog Cardiovasc Dis.* 2022 Jan-Feb;70:175-182. doi: 10.1016/j.pcad.2021.12.004. Epub 2021 Dec 24. PMID: 34958846.

- Counseling on risk factor management was predominantly provided during the center-based component.
 - **RESULTS:** Compared with usual care, in patients with CAD, the studies concluded that “hybrid CR reduced cardiovascular events, and improved lipid profiles, exercise capacity, and health-related quality of life (HRQoL).”
 - In patients with HF, compared with usual care, hybrid CR improved physical function, exercise capacity, and HRQoL.”
 - Hybrid CR also led to similar short-term outcomes compared to traditional CR in patients with coronary artery disease (CAD), as well as increased adherence and reduced delivery costs.
- III. A study by Keteyian SJ, et al.,⁵ compared exercise training intensity during standard cardiac rehabilitation (S-CR) versus telehealth cardiac rehabilitation (TH-CR) as part of a Hybrid-CR (combined clinic- and remote home-/community-based) program.
- The over-all mean exercise training intensities during both the S-CR sessions and the TH-CR sessions from Hybrid-CR were not significantly different at 63±12% and 65±10%, respectively (*P* = .29).
 - While the authors acknowledged the model for Hybrid-CR using telehealth may not be feasible for some due to staff preparedness or limited access technology, it was noted that due to the pandemic, most health care systems are now better prepared to equip and assist CR staff with operationalizing a remote CR model that incorporates virtual telehealth.
 - **RESULTS:** There were no serious adverse events or falls that required hospitalization during or within 3 hours after completing a CR session.
- IV. Imran HM, et al.⁶, undertook a systematic review and meta-analysis of randomized controlled trials (RCT) to compare functional capacity and health-related quality of life (hr-QOL) outcomes in heart failure for 1) home-based cardiac rehabilitation (HBCR) and usual care, 2) hybrid-CR and usual care, and 3) HBCR and center-based CR (CBCR).
- 31 randomized controlled trials with a total of 1791 heart failure participants were identified.
 - Among 18 studies that compared HBCR and usual care, participants in HBCR had improvement of peak oxygen uptake (2.39 mL/kg per minute; 95% CI, 0.28–4.49) and hr-QOL (16 studies; standardized mean difference: 0.38; 95% CI, 0.19–0.57).
 - Nine RCTs that compared hybrid CR with usual care showed that hybrid CR had greater improvements in peak oxygen uptake (9.72 mL/kg per minute; 95% CI, 5.12–14.33) but not in hr-QOL (2 studies; standardized mean difference: 0.67; 95% CI, –0.20 to 1.54).

⁵ Keteyian SJ, Grimshaw C, Clinton A, et al. A comparison of exercise intensity in hybrid versus standard phase two cardiac rehabilitation. *JCRP*. 2021;41:19-22.

⁶ Imran HM, et. al., Home-Based Cardiac Rehabilitation Alone and Hybrid With Center-Based Cardiac Rehabilitation in Heart Failure: A Systematic Review and Meta-Analysis. *J Am Heart Assoc*. 2019 Aug 20;8(16):e012779. doi: 10.1161/JAHA.119.012779. Epub 2019 Aug 17. PMID: 31423874; PMCID: PMC6759908

- Five studies comparing HBCR with CBCR showed similar improvements in functional capacity (0.0 mL/kg per minute; 95% CI, -1.93 to 1.92) and hr-QOL (4 studies; standardized mean difference: 0.11; 95% CI, -0.12 to 0.34).
- **RESULTS:** Both HBCR alone and hybrid CR were at least as safe as CBCR and had the potential to improve clinical outcomes over usual care during short-term follow-up.

V. Ganeshan S. et. al.,⁷ compared, in cardiac rehabilitation (CR) patients, the association of in-person, hybrid, and virtual CR with change in performance on the 6-minute walk test (6MWT) between enrollment and completion.

- Patients enrolled between October 2019 and May 2021 were categorized into in-person, hybrid, or virtual groups by number of in-person and virtual visits.
 - All patients received individualized exercise training and health behavior counseling.
 - CR was delivered to patients in the hybrid and virtual cohorts using synchronous video exercise and/or asynchronous telephone visits.
 - Measurement at CR enrollment and completion included the 6MWT, blood pressure (BP), depression, anxiety, waist-to-hip ratio, and cardiac self-efficacy.
- **RESULTS:** Hybrid and virtual CR were associated with similar improvements in functional capacity to in-person and have the potential to expand availability without compromising outcomes.
 - Of 187 CR patients 37/97 (38.1%) were in person patients and 58/90 (64.4) were hybrid/virtual patients ($P=.001$).
 - Compared to in-person (51.5 (51.5 ± 59.4 m) improvement in the 6MWT was similar in hybrid (63.4 ± 55.6; $P = .46$) and virtual (63.2 ± 59.6; $P = .55$) compared with in-person (51.5 ± 59.4).
 - Hybrid and virtual patients experienced similar improvements in BP control and anxiety.
 - While virtual patients experienced less improvement in depression symptoms, they generally had positive perceptions of hybrid and virtual CR.
 - There were no statistically significant changes in waist-to-hip ratio or cardiac self-efficacy.

VI. Jafri SH, et. al.,⁸ compared outcomes of patients (mean age: 72, 98% male) who were referred and attended a home-based cardiac rehabilitation (HBRC) program vs patients

⁷ Ganeshan, S, et. al. , Clinical Outcomes and Qualitative Perceptions of In-person, Hybrid, and Virtual Cardiac Rehabilitation, *Journal of Cardiopulmonary Rehabilitation and Prevention*: April 13, 2022 - Volume - Issue - 10.1097/HCR.0000000000000688. doi: 10.1097/HCR.0000000000000688

⁸ Jafri SH, et. al. Cardiovascular Outcomes of Patients Referred to Home Based Cardiac Rehabilitation. *Heart Lung*. 2022 Mar-Apr;52:1-7. doi: 10.1016/j.hrtlng.2021.11.005. Epub 2021 Nov 18. PMID: 34801771; PMCID: PMC8600943.

referred but did not attend HBCR (Non-HBCR) from 3 to 12 months of the referral date. HBCR consisted of face-to-face entry exam with exercise prescription, weekly phone calls for education and exercise monitoring, with adjustments where applicable, for 12-weeks and an exit exam.

- Primary outcome was composite of all-cause mortality and hospitalizations with all-cause hospitalization; secondary outcomes were all-cause hospitalization, all-cause mortality, and cardiovascular hospitalizations, separately.
 - Primary outcome occurred in 30 patients (19.1%) in the HBCR group and 30 patients (30%) in the non-HBCR group (adjusted HR=0.56, CI 0.33-0.95, P=.03).
 - All-cause mortality occurred in 6.4% of patients in the HBCR group and 13% patients in the non-HBCR group 3 to 12 months after HBCR referral (adjusted HR=0.43, CI 0.18-1.0, P= .05).
 - There was no difference in cardiovascular hospitalizations (HBCR: 5.7% vs non-HBCR: 10%, adjusted HR 0.57, CI 0.22-1.4, P= .23) or all cause hospitalizations at 3 to 12 months between the groups (HBCR: 12.7% vs non-HBCR: 21%, adjusted HR 0.53, CI 0.28-1.01, P= .05).
- **RESULTS:** The study concluded that “HBCR among referred patients was associated with a lower risk of the combined all-cause mortality and all-cause hospitalizations up to 12 months. Based on the outcomes, HBCR is a reasonable option that can improve access to CR for patients who are not candidates of or cannot attend CBCR.”

Studies show that pulmonary rehabilitation programs are safe and yield positive outcomes in a variety of ways.

- I. A 2019 study conducted by Knox et al.⁹, assessed the feasibility, safety, and effectiveness of a virtual pulmonary rehabilitation program in a real-world setting. The study was conducted in Wales as part of a group of hospitals that covers a semi-rural population of 400,000 people living across a large geographical area.
 - The program consisted of a hospital cardiopulmonary center (hub) and a rural village hall and community independent living center (spokes) linked by a real presence video conferencing system with interactive screens.
 - The age of those in the hub (n=24) was 68.6 (12.8); the age in the spoke (n=21) was 70.1 (10.8) with a P-value=0.67 (-8.93-5.79). All participants had moderate to severe COPD, with Medical Research Council (MRC) breathlessness score ≥ 3 , on optimal medications, no exacerbations within 6 weeks, and had varying degrees of airflow obstruction.

⁹ Knox L, Dunning M, Davies CA, Mills-Bennet R, Sion TW, Phipps K, Stevenson V, Hurlin C, Lewis K. Safety, feasibility, and effectiveness of virtual pulmonary rehabilitation in the real world. *Int J Chron Obstruct Pulmon Dis*. 2019 Apr 8;14:775-780. doi: 10.2147/COPD.S193827. PMID: 31040656; PMCID: PMC6459142.

- Mean attendance was 11.0 sessions in the hub and 10.5 sessions in the spoke ($P=0.65$).
 - There was a single (mild) AE (hypoglycemia) in all three hub programs and no AEs in the three spoke programs.
 - Mean COPD Assessment Test scores improved from 25.3 to 21.5 in the hub ($P<0.001$, 95% CI 2.43–5.17) and from 23.4 to 18.8 ($P<0.001$, 2.23–7.02) in the spoke group, with no difference between the groups ($P=0.51$, –3.35–1.70).
 - Mean incremental shuttle walk test scores improved from 142 to 208 m ($P<0.001$, 75–199) in the hub and from 179 to 316 minutes in the spoke ($P<0.001$, 39.3–92.4), with a greater improvement in the spoke ($P=0.025$, 9.31–133).
 - Twenty-one patients saved a total of 8,609.8 miles over the three programs by having the PR in their local spoke, rather than traveling to the usual nearest (hospital) hub.

RESULTS: Video conferencing, which links a local site to a standard PR program is feasible, safe, and demonstrates at least equivalent short-term clinical gains.

- II. A 2021 literature review conducted by Rawal, et. al.,¹⁰ noted that “less than 3% of eligible candidates for PR attend one or more sessions after hospitalization due to many barriers, including the ongoing COVID-19 pandemic.
- Emerging alternative models of PR delivery such as home-based PR, tele-rehabilitation, web-based PR, or hybrid models can help address these barriers.
 - The purpose of the review was to determine if alternative delivery models watered down the effectiveness of PR.
 - Their literature search, using PubMed, CINAHL, and Medline to identify relevant articles through 1 May 2021, identified 26 studies related to pulmonary rehabilitation of which 10 were randomized controlled trials (RCTs), 15 were cohort studies, and 1 was a case series.
 - **RESULTS:** Use of remotely based PR is a feasible and effective option to deliver PR, especially for patients with significant barriers to conventional clinic-based PR. Telerehabilitation was found to be both a feasible and an efficacious option for select patients with lung disease and outcomes across the studies demonstrated similar benefits to traditional PR programs.

NOTE: The studies listed below represent a screen shot of the Tables presented in the Rawal, et. al., study. The reference numbers in brackets relate to those in the study and are not accessible as an active hyperlink in these comments.

¹⁰ Rawal, H.; Cornelison, S.D.; Flynn, S.M.; Ohar, J.A. Will Remotely Based Pulmonary Rehabilitation Water Down Its Effectiveness? *Life* 2021, 11, 1270. <https://doi.org/10.3390/life11111270>.

Table 1. Studies evaluating tele-rehabilitation.

Citation	Study Design/Purpose	Patient Disease/Sample Size	Rehab Site	Intervention	Results	Adverse Events
Tele-Rehabilitation vs. Conventional Pulmonary Rehab						
Layton et al., 2021 [15]	Cohort Study/ Feasibility and efficacy Study	Cystic Fibrosis/ $n = 11$ vs. $n = 8$	Home	Smartphone based application	Increased adherence ($p = 0.03$)	Muscle pain
Hansen et al., 2020 [16]	RCT/ Superiority trial	COPD/ $n = 67$ vs. $n = 67$	Home	Real time broadcast by physiotherapist and nurse	No difference in 6MWT between groups. Higher rate of completion in the tele rehabilitation group ($p < 0.01$)	2 AE's in the Conventional PR group.
Rutkowski et al., 2020 [17]	RCT/ Superiority trial	COPD/ $n = 106$ $n = 34$ Conventional PR $n = 38$ Conventional PR +VR $n = 34$ VR	Inpatient	Virtual game system Conventional PR with physiotherapist	PR+VR group was superior to just PR group in Arm curl ($p < 0.003$), chair stand ($p < 0.008$), Up and Go ($p < 0.000$), and 6MWT ($p < 0.011$)VR group superior to PR in Arm curl ($p < 0.000$), chair stand ($p < 0.001$) and 6MWT ($p < 0.031$)	Not mentioned *
Bernocchi et al., 2018 [18]	RCT/Feasibility and efficacy Study	COPD/ $n = 56$ vs. $n = 56$	Home	Physiotherapist weekly phone call	Improvement in 6MWT ($p < 0.0040$)	None reported **
Horton et al., 2018 [19]	RCT/ Non-inferiority trial	COPD/ $n = 145$ vs. $n = 142$	Home	Physiotherapist weekly phone call	No improvement in CRQ dyspnea ($p = 0.18$)	None reported
Vasilopoulou et al., 2017 [20]	RCT/Efficacy Trial	COPD/ $n = 47$ vs. $n = 50$	Home	Recorded session by physiotherapist, exercise scientist	Home based PR and Conventional PR decreased COPD exacerbation and hospitalization when compared to pharmacotherapy ($p < 0.001$)	Not mentioned
Bourne et al., 2017 [21]	RCT/ Non-inferiority trial	COPD/ $n = 64$ vs. $n = 26$	Home	Pre-recorded session by a physiotherapist	Online PR was non-inferior to Conventional PR in 6MWT ($p = 0.098$) and CAT ($p = 0.373$)	Back pain and muscular pain
Chaplin et al., 2017 [22]	RCT/Feasibility and efficacy trial	COPD/ $n = 51$ vs. $n = 52$	Home	Pre-recorded session physiotherapist	No significant difference in the CRQ dyspnea ($p > 0.05$), ESWT ($p > 0.05$)	Not mentioned
Paneroni et al., 2015 [23]	Cohort Study/ Feasibility and Efficacy Study	COPD/ $n = 18$ vs. $n = 18$	Home	Real time video conferencing with the physiotherapist	Improvement in physical activity (steps per day) ($p < 0.0002$) No statistically significant difference in 6MWT, SGRQ or mMRC	None reported
Tabak et al., 2014 [24]	Cohort Study/ Feasibility and Efficacy Study	COPD/ $n = 15$ vs. $n = 14$	Home	Pre-recorded session by physiotherapist	Improvement in mMRC scale ($p < 0.03$)	Not mentioned
Stickland et al., 2011 [25]	Cohort Study/ Efficacy Study	COPD/ $n = 147$ vs. $n = 262$	Satellite Center under supervision	Real time video conferencing with respiratory therapist	Both telehealth PR and Conventional PR showed improvement in SGRQ ($p < 0.05$)	Not mentioned

Tele-rehabilitation Alone (Pre vs. Post Intervention)						
Lewis et al., 2021 [26]	Cohort Study/ Efficacy and Feasibility Study	COPD/ n = 17	Home	Physiotherapist by real time video conferencing	Improvements in 1 min STS ($p = 0.004$), GAD ($p = 0.023$), PHQ-9 ($p = 0.029$), CRQ dyspnea ($p = 0.001$), CRQ fatigue ($p = 0.004$), CRQ emotion ($p = 0.0002$), CRQ mastery ($p = 0.001$)	None reported
Paneroni et al., 2021 [27]	Cohort Study/ Efficacy and Feasibility Study	COVID-19/ n = 25	Home	Twice a week call by a physiotherapist	Improvement in STS ($p = 0.003$) and 6MWT ($p = 0.0006$)	None Reported
Wootton et al., 2020 [28]	Case Series	COVID-19/ n = 3	Home	Weekly call by physiotherapist	Improvement in 1 min and 5 min STS	Not mentioned
Rassouli et al., 2018 [29]	Cohort Study/Efficacy and Feasibility Study	COPD/n = 34	Home	Smartphone application; pre-recorded videos	Improvement in CAT scores ($p = 0.008$) Improvement in CRQ fatigue ($p < 0.001$), mastery ($p < 0.001$) and emotion ($p < 0.001$).	Not mentioned
Zanaboni et al., 2017 [30]	Cohort Study/ Efficacy and Feasibility study	COPD/ n = 10	Home	Real time video conferencing with Physiotherapist	Improvement in 6MWT, CAT ($p = 0.022$) scores	Not mentioned
Hoas et al., 2016 [31]	Cohort Study/ Efficacy and Feasibility Study	COPD/n = 10	Home	Pre-recorded session by physiotherapist	Decrease in physical activity (Steps per day) 1 year after a 2-year intervention ($p = 0.039$)	Not mentioned
Marquis et al., 2014 [32]	Cohort Study/ Efficacy and Feasibility Study	COPD/ n = 26	Home	Combined Real-time video conferencing by physiotherapists and unsupervised sessions	Improvement in 6MWT ($p < 0.001$), CET ($p = 0.003$) and CRQ ($p < 0.001$) at 8 weeks but not sustained until 24-week follow-up	Not mentioned
Albores et al., 2013 [33]	Cohort Study/ Efficacy and Feasibility Study	COPD/ n = 25	Home	Virtual Game system	Improvement in ESWT ($p = 0.005$), arm-lift ($p = 0.03$), sit to stand repetitions ($p = 0.03$) and CRQ emotion scores ($p = 0.02$)	Not mentioned
Holland et al., 2013 [34]	Cohort Study/ Feasibility Study	COPD/ n = 8	Home	Real-time videoconferenc- ing with physiotherapist	Improvement in 6MWT, CRQ score	Minor adverse events were desaturation < 88% (n=1) & heart rate >150 BPM(n=1)
Wardini et al., 2013 [35]	Cohort Study/ Feasibility Study	COPD/ n = 32	Inpatient con- ven- tional + virtual	Virtual game system	Increased enjoyment using VAS Increased adherence	None reported
Tousignant et al., 2012 [36]	Cohort Study/ Feasibility Study	COPD/n = 3	Home	Real time videoconferenc- ing with physiotherapist	Improvement in 6MWT for 2 out of 3 participants	Not mentioned
Tele-rehabilitation vs. No Rehabilitation						
Gonzalez-Gerez et al., 2021 [37]	RCT/ Feasibility and Efficacy Trial	COVID-19/ n = 19 vs. n = 19	Home	Twice weekly calls by physiotherapist	Improvement in 6MWT ($p < 0.001$) and dyspnea perception using Borg scale ($p < 0.001$)	None Reported
Li et al., 2021 [38]	RCT/ Efficacy Trial	COVID-19/ n = 59 vs. n = 61	Home	Smartphone- based application	Improvement in 6MWT ($p < 0.001$), mMRC ($p < 0.001$), LMS ($p < 0.001$) and SF-12 PCS ($p < 0.001$)	None reported
Bhatt et al., 2019 [39]	Cohort Study/ Feasibility and Efficacy Study	COPD/ n = 80 vs. n = 160	Home	Physiotherapist by real-time video conferencing	Decreased 30-day all-cause mortality ($p = 0.013$) and readmissions due to AECOPD ($p = 0.04$)	None reported
Tsai, 2017 [40]	RCT/ Efficacy Trial	COPD/ n = 37 vs. n = 37	Home	Real-time broadcast by physiotherapist	Improvement in ESWT ($p < 0.001$), self-efficacy ($p < 0.007$) and CRQ ($p = 0.07$)	Not mentioned

AE: Adverse Event; AECOPD: Acute Exacerbation of Chronic Obstructive Pulmonary Disease; CAT: COPD Assessment Test; CET: Constant work rate Exercise Test; COPD: Chronic Obstructive Pulmonary Disease; CRQ: Chronic Respiratory Questionnaire; ESWT: Endurance Shuttle Walk Test; EQ-VAS: EuroQol Visual Analog Scale; GAD: Generalized Anxiety Disorder; MRC: Medical Research Council; mMRC: Modified Medical Research Council; LMS: Lower limb muscle Strength; PCS: Physical Component Score; PHQ-9: Primary Health Questionnaire-9; PR: Pulmonary Rehabilitation; RCT: Randomized Control Trial; SF-12: Short Form Health Survey-12; SGRQ: St George's Respiratory Questionnaire; STS: Sit To Stand; VR: Virtual Reality; 6MWT: 6 Minute Walk Test. * Not mentioned—Studies did not look for adverse events. ** None reported: Studies reported the absence of adverse events.