

TAKEheart Hybrid Cardiac Rehabilitation (CR) Implementation Guide - Module 10

Using Hybrid Cardiac Rehabilitation to Expand System Capacity and Patient-Centeredness

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Successfully supporting the maximum number of eligible CR patients may require options beyond the traditional facility-based CR program option. Implementing automatic referral (AR) should reduce the number of patients that are unaware that CR would help them. Coupling AR with improved care coordination should increase the number of these patients that enroll in, attend, and successfully complete CR. But there are still likely to be patients that do not enroll in your CR program because onsite CR isn't possible or appealing to them. Reaching these patients may require introduction of an alternative to facility-based CR. At present, the most viable such option is referred to as hybrid CR. Hybrid CR combines some initial onsite CR visits, during which patients can be oriented and assessed, with subsequent CR sessions provided using supervised, real-time (synchronous) two-way audio-visual communication for exercises sessions and synchronous or asynchronous methods to provide all other CR elements. Sometimes hybrid CR continues to blend these two types of CR throughout the entire 12 weeks.

This implementation guide is designed to help you to think through the need for, and feasibility of, offering a hybrid CR option for your patients. It also provides some guidance for the initial steps you should take if you determine that hybrid CR is worth seriously considering. Both facility-based and hybrid CR must be safe and must encompass the same set of required CR components. Done well, hybrid CR may allow you to provide the benefits of CR to patients that otherwise would not participate. Done poorly, hybrid CR can be unsafe, unproductive, and may undermine efforts to promote hybrid CR to payers as a worthwhile activity that they should reimburse programs for providing.

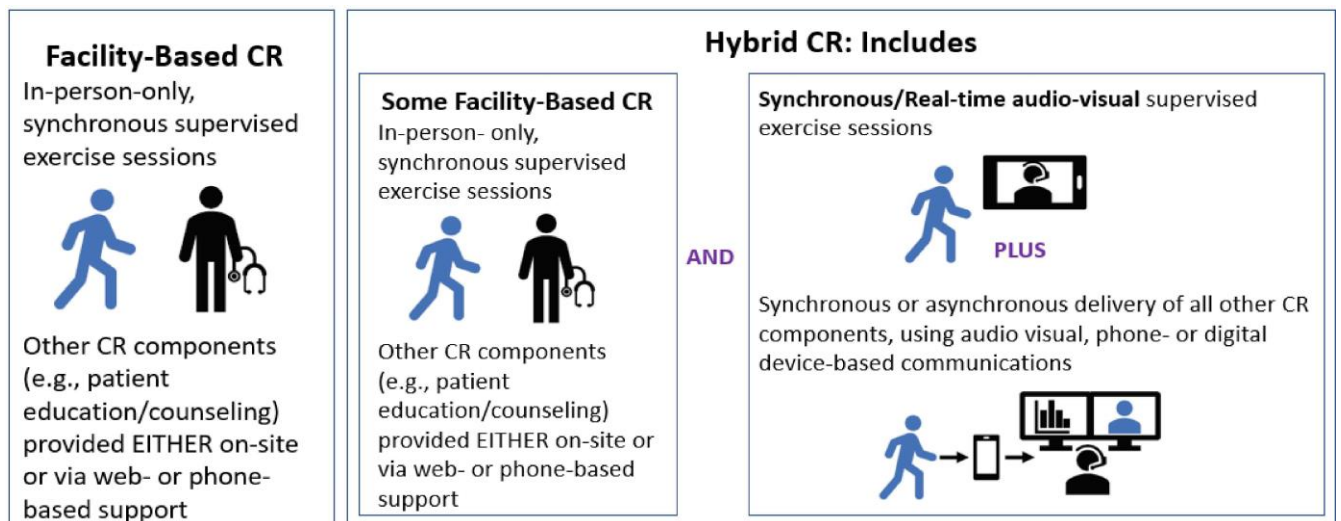
This Implementation Guide is divided into three roughly sequential steps your team can follow. The three steps are:

- 1) Assessing the need to offer a hybrid CR option
- 2) Assessing the feasibility of offering a hybrid option
- 3) Begin planning to implement a hybrid option

Actually implementing a hybrid option will require substantial effort and require that you make some important decisions before you proceed. While this Implementation Guide does not provide detailed instructions for introducing a hybrid option, it should enable you to begin the process and understand the key factors you will need to account for during the implementation phase.

Terms and Definitions

- **Synchronous/real-time audio-visual CR:** CR patients and clinicians are in different locations and engaging in real-time, two-way audio-visual communication. CR clinicians observe patient exercise in real-time over video.
- **Asynchronous, offsite CR activities:** These can include exercise performed offsite that is not directly supervised by a CR clinician or other activities such as independently watching videos about nutrition or wellness or having a telehealth visit to discuss CR-specific material or review patient reported or uploaded data.
- **Facility-based cardiac rehabilitation (FBCR):** Traditional, early outpatient Phase II CR, provided onsite at a defined location that includes the equipment, staff, resources and procedures necessary to offer all expected components of CR. Exercise sessions are directly observed in real time (synchronous) by clinicians.
- **Hybrid cardiac rehabilitation (HYCR):** A combination of facility-based CR PLUS synchronous/real-time audiovisual CR exercise sessions and all other required components of CR provided either synchronously or asynchronously. Key distinctions between FBCR and hybrid CR are illustrated below:



See Keteyian et al. *J Cardiovasc Pulm Rehab Prev.* 2021 Aug 24. doi: 10.1097/HCR.0000000000000634 and [Million Hearts Cardiac Rehabilitation Think Tank: Accelerating New Care Models](#) for additional discussion.

- **Remote, virtual, and home-based CR:** These terms have been defined in different ways and sometimes used interchangeably. Due to definitional confusion, we are avoiding the use of these terms in the training. If you are reading materials that use these terms you should determine how the material is defining these terms. In some contexts, these terms may be describing CR that includes all required elements, including supervised exercise. In other contexts, these terms may mean something different.

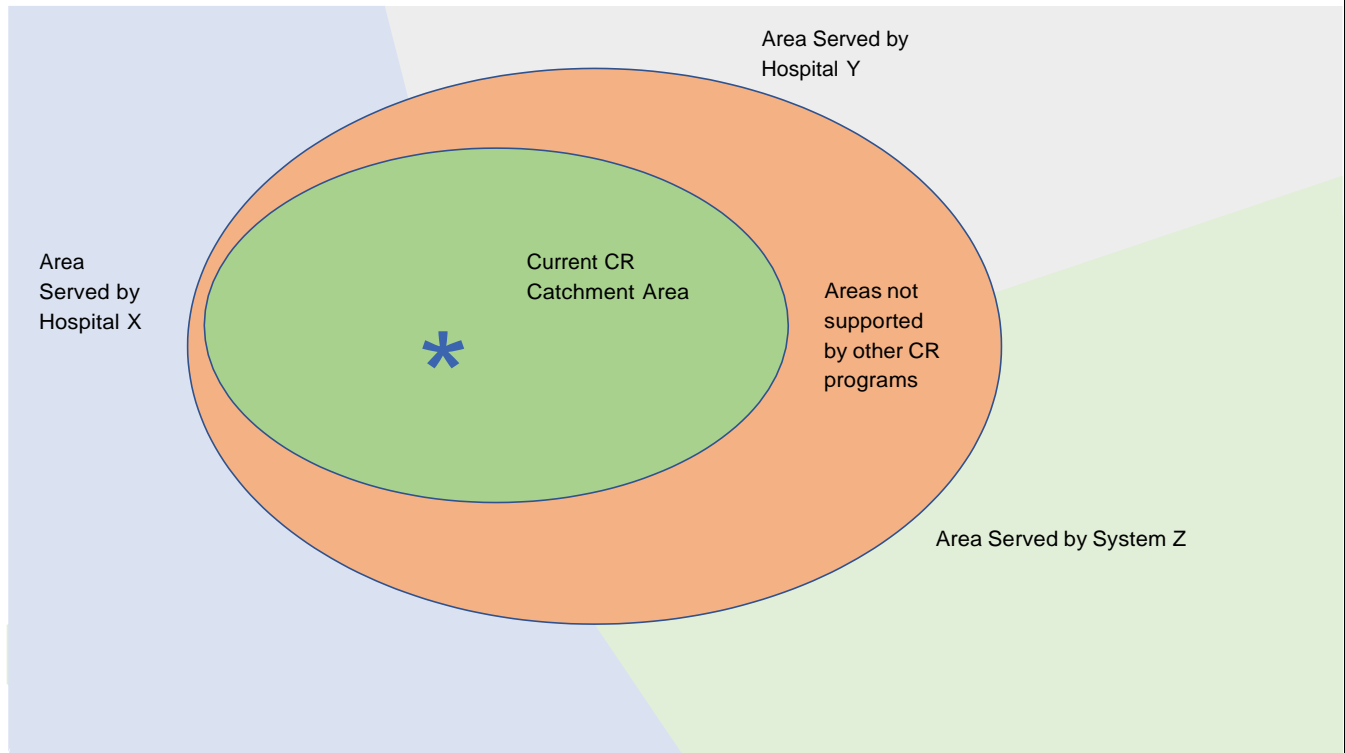
STEP ONE: Assess Your Need for a Hybrid CR Option

Many hospitals and health systems regularly engage in strategic planning activities to make decisions about adding new services or locations. If such a group is available to you, working with them to obtain the information described below may be more efficient than trying to compile this information on your own. Data from this group may also be viewed as more credible by senior decision makers that may need to approve plans to introduce a hybrid model.

Consider at least the following five issues as you assess your community's need for a hybrid CR option.

1) What is your CR program's potential catchment area for a hybrid option?

Your catchment area should encompass both the current areas from which your onsite CR program attracts patients AND other areas that include CR-eligible patients with no viable onsite CR program to attend.



This expanded catchment area may include hospitals without CR programs and health care practices (general practice or cardiology) that do not make referrals to your program because their patients are too far away to participate in twelve weeks of onsite CR.

It may be useful to create a map that shows the location of your CR program, the surrounding area from which you currently attract onsite CR patients, and areas further away that have no other available options for onsite CR. CDC developed maps to document CR deserts that can be accessed at:

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7529047/pdf/nihms-1611589.pdf>.

You can also develop your own maps to document the locations of CR facilities in your region by following the instructions outlined at:

<https://www.aacvpr.org/Portals/0/Million%20Heart%20Change%20Package/4.11.2018%20Files/R-6-CRCP-How%20to%20Find%20CR%20Programs%20in%20US.pdf?timestamp=1523550949639>.

2) What trends affect the population of eligible CR patients your program may need to support?

Trends you should consider include:

- How the total population in your area is changing
- How the demographics of your area are changing. Some areas are experiencing gradual population declines but the number of persons at higher risk of cardiac conditions is increasing .
- How the health care landscape is changing. Are hospitals or CR programs near you at risk of closure? Are any nearby hospitals discussing adding new CR programs or additional locations for CR services?

3) How many patients in your current and potential catchment areas are eligible for CR in a given year or other time period?

These numbers are bound to be imprecise because not all eligible patients are identified or referred to your program. But you should be able to use heart condition estimates provided by CDC

(<https://www.cdc.gov/heartdisease/statistics/maps.htm>) or other sources, information on the number of hospitalizations for relevant heart conditions available online on the CMS website

(<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInitiatives/HospitalCompare>), and information available within your hospital or health system to make reasonable estimates. You also should be able to use the information you gain as you implement automatic referral and track the number of eligible patients identified in your own hospital or health system.

4) How many referred patients decline to participate in your onsite CR program and why?

With automatic referral and improved data collection you should have better data on how many eligible patients fail to participate in onsite CR. If you aren't already, you may want to begin capturing information on WHY some patients choose not to enroll. Possible reasons for non-participation and their implications are captured in the table below.

Non-Participation Reasons	Implications
I don't think it's needed, I can exercise and lose weight by myself, I'm not going to change how I live.	More education and cardiologist recommendations may help increase CR participation. But sometimes there may be more substantive reasons that staff should attempt to uncover. This exploration may reveal other reasons for nonparticipation that a hybrid option can address.
Transportation challenges, distance, conflicts with work, care of children or other family members, reluctance to exercise in group settings or to risk disease exposure	While adjustments to your onsite program can make CR more accessible, many may be better served by a hybrid CR option.
Insurance copays or lacking insurance	Some programs have negotiated with insurers to eliminate copays. Others have provided financial support or reduced session numbers to assist such patients.

If you find that most of your eligible patients are enrolling in CR or that the causes of nonparticipation cannot be solved with hybrid CR, then introducing such a program may not be a priority. On the other hand, you may realize that many CR nonparticipants would be open to an option requiring less travel and a more flexible schedule. In this case, hybrid CR may be worth consideration. As you make this assessment, make sure you account for providers that may choose not to refer patients to CR because they think the patient is too far away, too busy, or reluctant to participate in group activities.

5) What is the capacity of your onsite CR program?

If you have a long waiting list to begin CR, some of your patients are likely to change their minds about participating before they begin. If your waiting list is long and you cannot expand your onsite capacity, a hybrid option may allow you to support more patients. On the other hand, if your waiting list is long because of staffing shortages, adding a hybrid option may not be a solution.

STEP TWO: Assess the Feasibility of Introducing a Hybrid CR Option

While doing what's best for your patients is a top priority, we understand that introducing a hybrid CR option is an investment of time and resources you may not be able to afford. Offering hybrid CR without the planning, equipment, and staff to do it well isn't in anyone's best interest. The following questions can help you assess whether it may be financially feasible to develop a hybrid CR model to support some of your patients.

1) How many CR patients would be likely to participate in a hybrid CR option if you created one?

There's no well-established minimum size for a viable hybrid CR program. But if you suspect that only a handful of patients would be interested in participating, the investment required to create such a program may not be warranted. While you might be able to work with other hospitals in your system or geographic area to create a hybrid option that would support multiple CR programs, attempting to set up your own hybrid program is probably not a good idea.

How can you gauge possible participation numbers?

- When you contact referred patients that choose not to enroll in your onsite program, ask them about whether they would participate if they could do it from their homes? Capture and analyze these results.
- When patients stop attending your onsite program, ask them whether they would continue to participate if they could do it from their home? Capture and analyze these results.
- Compare participation rates for referred patients that enroll and that do not in areas further away or with less access to public transportation. For example, if 40% of eligible patients nearby or in easy transportation areas enroll but only 10% of the 100 eligible patients far away or in a difficult transportation area enroll, then a hybrid option might attract an additional 30 patients from those areas (assuming other demographics are comparable).

2) Are you incurring avoidable costs because patients eligible for CR aren't participating and are being re-hospitalized?

Hospitals with excess readmissions for cardiac conditions incur penalties from Medicare and sometimes also from other insurers. If your hospital is being penalized and a review of re-hospitalized patients indicates that many would have been good candidates for a hybrid CR program, then you may have a stronger financial case for developing a hybrid option.

Hospitals or group practices that participate in an accountable care organization (ACO) may also have stronger financial incentives to offer a hybrid CR option to patients unlikely to attend onsite CR. If the net costs of offering hybrid CR are less than the other medical costs eligible CR patients that do not attend incur, hybrid CR may be a very good investment.

How can you assess these costs?

- The CMS Hospital Compare website will allow you to see your hospital's readmission rates for heart failure and AMI. If those rates are high then you may be incurring penalties (<https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalCompare>)
- Your hospital or system's finance department should be able to tell you if you are receiving either penalties or losing out on potential bonuses due to excess hospitalizations or readmissions and how much money is involved.
- Your ACO contact or hospital or system's finance department should be able to quantify the financial impact that excess hospitalizations or readmissions are having on your finances.

3) Will key payers reimburse you for CR you provide through synchronous audio/visual technologies?

During the federally-declared public health emergency, Medicare reimburses hospitals that bill for CR sessions using synchronous audio/visual communication. At present, these payments will not continue

when the public health emergency expires . Unless extended, the public health emergency will expire on April 16, 2022. While many patients eligible for CR are in fee for service Medicare, others are covered through private insurance or a Medicare Advantage Plan. Some of these insurers cover both synchronous and asynchronous delivery of CR because they believe this coverage pays for itself through avoiding other costs . If your main payment sources will reimburse you for CR provided through a hybrid option, then creating this option may be more financially viable.

If the private insurers and Medicare Advantage plans you work with do not currently reimburse you for synchronous CR sessions then you may be able to make the case for why they should. Because these payers cover patients from many hospitals, working with other hospitals in your system or geographic area to make the case for covering all CR sessions provided in a hybrid option may be more efficient and effective than attempting to do this on your own. We also recommend checking in with your insurers periodically to see if their coverage criteria have changed. As more evidence accumulates that hybrid CR can achieve comparable outcomes to onsite CR, more insurers are reimbursing providers that offer these programs.

How can you find out about coverage policies of key payers?

- Medicare fee for service coverage policies are posted publicly. Changes are typically reported by AACVPR and other associations you may participate in.

How Michigan's Blue Cross Blue Shield Approved Reimbursement for the Telehealth, Synchronized Audio-Visual Component of Hybrid Cardiac Rehabilitation

Henry Ford Health System (Henry Ford) wanted to begin offering hybrid cardiac rehabilitation (CR), but the telehealth or synchronized audio-visual component it includes was not covered by Michigan's largest commercial third-party payer (Blue Cross Blue Shield of Michigan [BCBSM]).

In the Fall of 2016, Steven Keteyian, PhD, the Director of the Cardiac Rehabilitation/Preventive Cardiology Unit at Henry Ford arranged a meeting with senior medical and administrative leaders at BCBSM, during which he (a) reviewed data on the effectiveness of CR as an evidence-based therapy for patients with cardiovascular disease and (b) explained that many patients otherwise eligible to participate in CR did not do so due to travel distance and transportation challenges, conflicting work schedules, dependent care responsibilities, and concerns about exercising in a group setting with others. He then explained how a hybrid CR option would be operationalized and how Henry Ford would offer supervised, synchronous exercise sessions to selected, eligible patients. Dr. Keteyian also discussed the plan for physician supervision, and the current data addressing patient safety and the procedures that Henry Ford planned to help ensure such .

BCBSM appreciated how hybrid CR, a model that involved real-time audio-visual supervised exercise conducted by the patient at home or in the community, could extend the benefits of CR to more patients, leading to fewer hospitalizations and other complications that would otherwise incur costs for BCBSM . Based on this presentation, BCBSM agreed to reimburse health care providers in Michigan for the synchronous/real-time audio-visual CR sessions they provided to patients as part of hybrid CR.

- Medicare managed care or private insurance reimbursement options may be identified by your billing department. Check with them periodically because coverage policies can change.
- If other CR programs in your state offer CR outside of facilities, you should be able to ask them which payers are covering these visits and how to submit bills that they will reimburse.

4) **Can you offer a quality hybrid option to your patients?**

Hybrid CR may require that you invest in needed technologies, ensure secure communication technologies for CR sessions provided with real-time audio-visual support, train staff to support patients remotely, and adjust your workflow processes to support patients you will see in person much less frequently. Even more importantly, you'll need to determine if your organization has the culture and capacity to introduce a new CR option. AHRQ's [Will it Work Here](#) guide can help you think through these issues. If you doubt your ability to invest the time and resources needed to create and operate a hybrid CR program then the timing may not be right to attempt to do so. Even if you decide to contract with a vendor you still should be prepared to invest time to change your work flows so that referrals and care transitions are handled smoothly.

How can you know whether you can offer a quality hybrid option?

- Assess Your organization's culture and willingness to make a change such as introducing a new hybrid option. AHRQ's [Will it Work Here](#) guide can assist with this task.
- Know the right questions that should be asked. The paragraph above identifies key questions that your program will need to consider to ensure that what you do keeps patients (and your interactions with them) safe and that your standard of CR care is not compromised.
- Get the right people involved. No one person can correctly assess all the issues that implementing a hybrid option raise. If you don't involve people that understand the technologies a hybrid program will need, people familiar with the data security practices you'll need to address, staff that will need to train peers to support patients outside your facility, and people from finance and facilities, you probably won't produce a full and accurate answer to this question.
- Talk to other programs that are further along. Getting advice from peers can help you avoid pitfalls that may keep your hybrid program from ever getting started or from thriving once it does.
- Determine what measures you might use to assess whether your hybrid program is working. If you can't get data to compare how your hybrid CR patients are doing with those you support in your facility, then moving ahead may be premature.

STEP THREE: Begin Planning to Introduce a Hybrid CR Option

If you believe that offering a hybrid CR option will benefit your patients and program there are some preliminary planning steps we strongly encourage you to take. These include:

1) Learn more.

There is an emerging body of research about hybrid CR that we encourage you to review. Million Hearts is also introducing resources related to hybrid CR (for useful case studies see table 3 of the Cardiac Rehabilitation Change package on p. 12 available at: [Million Hearts Cardiac Rehabilitation Change Package \(hhs.gov\)](https://www.hhs.gov/million-hearts-cardiac-rehabilitation-change-package) . And people that have introduced hybrid programs or studied their use periodically speak at conferences or offer webinars to share their experiences. These sources can help you compile a list of key things you should do as well as flag common mistakes you should work to avoid. Importantly, learning more will allow you to set realistic expectations for your hybrid option. It will not help you enroll ALL of your eligible patients. It will not work well for everyone. It will require new work and resources to implement and sustain. Setting realistic expectations and then achieving them are key to long term success. Learning more will help you do this.

2) Lay relevant groundwork within your organization.

Like automatic referral and care coordination, adding a hybrid option will require working with a team with the knowledge and perspectives needed to make the case for hybrid and to successfully implement it. The value of forming a team as well as key perspectives that should be included was addressed in the implementation guides for modules 1-2 and module 5. We encourage you to review those guides and to leverage your existing team as much as you can.

Each organization has its own processes for making decisions about adding new programming options such as hybrid CR. It will be very important for your team to understand and follow these processes. As noted above, you may want to include one or more team members that can help you analyze your market to assess the probable demand for a hybrid CR program. You are also likely to benefit from involving one or two key decision-makers early on who can advise you about timing, process, and key decision-making factors you will need to address to other organizational leaders.

We also strongly recommend you engage with physicians and administrators who support the use of CR. If they do not embrace the creation of a hybrid option it may be difficult to convince patients to enroll in it or to obtain resources to develop it. On the other hand, if these groups see the benefits of expanding patient participation in CR through introducing a hybrid option, their support may be key to gaining organizational approval.

Finally, if you are part of a healthcare system or ACO, coordinating with other CR programs within those organizations may be beneficial. If multiple CR programs can use the same virtual communication platform, share the same online educational resources, and develop materials for training CR program staff, you should gain efficiencies that will make implementing hybrid CR more feasible.

3) Work through the appropriate channels.

Every organization has different processes for introducing new programs or care methods. If your focus is direct patient care, you may not even know what these are. Even if you lead your CR program,

you're going to need advice, buy-in and active help from your superiors and other affected departments. If you know enough to help explain what a hybrid option is and what its potential benefits are for your patients and program, you're ready to make the case to your supervisor for why adding this option should be considered. If you can convince them of its potential value, they can work with you to begin engaging with others' whose support will also be needed. In some organizations this process may be fairly simple and short; in others it may take much more time and effort. And you may need to decide when the timing is right (or wrong) to push this forward. That can depend on overall finances, other organizational priorities, where you are in the fiscal year cycle, or how the pandemic or other factors are impacting staff and resource availability.

4) Carefully evaluate your implementation options.

While some hospitals choose to develop an independent hybrid CR option, others may partner with CR programs in their system, ACO or geographic area to create a hybrid option accessible to all of their patients. Such an approach allows each program to provide initial onsite CR sessions for their individual patients and subsequent supervised, synchronous audio-visual CR sessions can be supported jointly. Other programs may contract with a vendor to support their ability to offer hybrid CR either to their organization or to their system or ACO.

The future may even include specialty CR programs that offer hybrid CR specifically tailored to meet the languages, preferences, or cultural expectations of eligible patients with similar backgrounds. While there is no one preferred approach to implementing a successful hybrid CR program, there are benefits and drawbacks to each approach that should be carefully considered before moving forward. Common pros and cons of implementation options are reflected in the table below.

What Can Vendors Do?

Vendors may be able to help you offer hybrid CR to patients by:

- Working with insurers to obtain reimbursement for CR offered offsite
- Providing remote monitoring equipment and support for hybrid CR patients
- Providing secure communication channels to facilitate supervised synchronous exercise sessions
- Offering online educational content to support CR patients

If you are exploring vendors, make sure that your patients will continue to receive **ALL** the expected components of onsite CR. Some vendors do not. Also be sure that systems are in place to ensure that the referring physicians will continue to receive updates on the progress of their patients.

Alternative	Potential Advantages	Potential Drawbacks
Creating Your Own Hybrid Option	Total control over its design and implementation	Set-up costs may be too high for smaller programs
	Tailored to needs of your community and patients	Inefficient to "reinvent the wheel" independently
		Implementation errors may compromise patient care or security
Partnering with Other CR Programs in Your System or Area	Gain efficiencies and economies of scale	Requires system- or area-level support
	Promote better coordination of patient care	Potential implementation delays
	Greater available resources for implementation	Failure to adapt to needs of specific CR programs
	More leverage working with payers on reimbursement	
Using a Vendor	Experience operating hybrid CR	Variability in vendor cost and quality
	Tested and patient-friendly technologies	Lost connections with patients and care providers
	Ability to negotiate reimbursement and copay issues with payers	Lost revenue for onsite CR sessions
	Experience enrolling and supporting CR patients	Loss of control over patient care and experience

5) Collect and use relevant data.

Public and commercial insurers that reimburse for supervised, synchronous/real-time audiovisual CR sessions will want evidence that this investment is worthwhile. Those that do not are unlikely to begin providing this coverage without evidence that hybrid CR programs are safe, efficient, and effective. Each program that implements a hybrid CR option has an obligation to collect and evaluate data related to each of these concerns. These data are also critical to maintaining internal support for your hybrid program and to your efforts to continuously improve it. Ensuring that your hybrid CR option is as successful as your onsite CR program is essential for your patients and your overall CR program.

6) Keep your patients' needs first in everything you do.

Hybrid CR programs will attract patients with backgrounds that are often different from those you support in person. Their needs, preferences, and concerns may also be somewhat different. You also may not develop connections with hybrid CR patients that are as close as those developed with onsite CR patients. All these factors will require you to listen, observe, and actively elicit feedback from your hybrid CR patients to ensure that their needs are being met. Some staff may connect more effectively in online sessions than others so you may need to adjust staff assignments to accommodate their

strengths. The success of your hybrid CR program will depend on how well you learn and tailor your hybrid offering to support the needs of the patients that enroll in it.

Key Resources

- CDC Disease Prevalence Statistics: https://www.cdc.gov/heartdisease/statistics_maps.htm
- Hospitalization data for cardiac and other conditions: <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalCompare>
- Online educational resources used in the Henry Ford Health System: www.henryford.com/education
- Online educational resources developed by Cardiac College at the University Health Network: <https://www.healthuniversity.ca/EN/CardiacCollege/Pages/learn-online.aspx>
- AHRQ Guidance document on how to determine if innovations will work in your health system or facility: <https://www.ahrq.gov/innovations/will-work/index.html>
- Million Hearts Cardiac Rehabilitation Change Package (p.12, table 3 has case studies): https://millionhearts.hhs.gov/files/Cardiac_Rehab_Change_Pkg.pdf

Relevant Publications about Hybrid CR

Anderson et al. (2017). Home-based versus centre-based cardiac rehabilitation. *Cochrane Database Systematic Review*. Full citation and abstract available at: <https://pubmed.ncbi.nlm.nih.gov/28665511/>

Balady et al. (2011). Referral, Enrollment, and Delivery of Cardiac Rehabilitation/Secondary Prevention Programs at Clinical Centers and Beyond. *Circulation*. Full citation and article available at: <https://www.ahajournals.org/doi/full/10.1161/CIR.0b013e31823b21e2>

Heindl et al. (2022). Hybrid cardiac rehabilitation - The state of the science and the way forward. *Progress in Cardiovascular Diseases*. Abstract available online at: <https://www.sciencedirect.com/science/article/pii/S0033062021001365?via%3Dihub>

Keteyian et al. (2021). A Comparison of Exercise Intensity in Hybrid Versus Standard Phase Two Cardiac Rehabilitation. *Journal of Cardiopulmonary Rehabilitation and Prevention*. Full citation and abstract available at: <https://pubmed.ncbi.nlm.nih.gov/33351540/>

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Pack et al. (2014). The Current and Potential Capacity for Cardiac Rehabilitation Utilization in the United States. *Journal of Cardiopulmonary Rehabilitation and Prevention*. Full citation and article available at : http://www.arena-design.com/emc2/resources/Pack_2014_The%20current%20and%20potential%20capacity%20for%20cardiac%20rehabilitation%20utilization%20in%20the%20United%20States.%20-%20Journal%20of%20cardiopulmonary%20rehabilitation.pdf

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Sun et al. (2017). Disparities in Cardiac Rehabilitation Participation in the United States: A systematic review and meta-analysis. *Journal of Cardiopulmonary Rehabilitation and Prevention*. Full citation and article available at: https://journals.lww.com/jcrjournal/Fulltext/2017/01000/Disparities_in_Cardiac_Rehabilitation.2.aspx

Thomas et al. (2019). Home-Based Cardiac Rehabilitation: A Scientific Statement from the American Association of Cardiovascular and Pulmonary Rehabilitation, the American Heart Association, and the American College of Cardiology. *Circulation*. Full citation and article available at: <https://www.ahajournals.org/doi/10.1161/CIR.0000000000000663>

Patel et al. (2021) . Optimizing the Potential for Telehealth in Cardiovascular Care (in the Era of COVID -19): Time Will Tell. *American Journal of Medicine*. Full citation and article available at : [https://www.amjmed.com/article/S0002-9343\(21\)00218-7/fulltext](https://www.amjmed.com/article/S0002-9343(21)00218-7/fulltext)