Million Hearts Cardiac Rehabilitation Think Tank: Accelerating New Care Models

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ABSTRACT: This article describes the October 2020 proceedings of the Million Hearts Cardiac Rehabilitation Think Tank: Accelerating New Care Models, convened with representatives from professional organizations, cardiac rehabilitation (CR) programs, academic institutions, federal agencies, payers, and patient representative groups. As CR delivery evolves, terminology is evolving to reflect not where activities occur (eg, center, home) but how CR is delivered: in-person synchronous, synchronous with real-time audiovisual communication (virtual), or asynchronous (remote). Patients and CR staff may interact through ≥1 delivery modes. Though new models may change how CR is delivered and who can access CR, new models should not change what is delivered—a multidisciplinary program addressing CR core components. During the coronavirus disease 2019 (COVID-19) public health emergency, Medicare issued waivers to allow virtual CR; it is unclear whether these waivers will become permanent policy post-public health emergency. Given CR underuse and disparities in delivery, new models must equitably address patient and health system contributors to disparities. Strategies for implementing new CR care models address safety, exercise prescription, monitoring, and education. The available evidence supports the efficacy and safety of new CR care models. Still, additional research should study diverse populations, impact on patient-centered outcomes, effect on long-term outcomes and health care utilization, and implementation in diverse settings. CR is evolving to include in-person synchronous, virtual, and remote modes of delivery; there is significant enthusiasm for implementing new care models and learning how new care models can broaden access to CR, improve patient outcomes, and address health inequities.

Key Words: cardiac rehabilitation • delivery of health care • patient-centered care • patient advocacy • public health

Million Hearts 2022 is a national initiative, co-led by the Centers for Disease Control and Prevention and the Centers for Medicare and Medicaid Services (CMS), with the goal of preventing 1 million heart attacks, strokes, and other acute cardiovascular events in a 5-year period. Included in the strategies supported by the initiative is achieving a target of 70% participation in cardiac rehabilitation (CR) by eligible patients.1 CR is an evidence-based, class I guideline-recommended secondary prevention strategy for many cardiovascular conditions.2–6 Despite strong evidence of its benefits, CR is extremely underutilized; only 24% of Medicare fee-for-service beneficiaries eligible in 2016 participated in CR through 2017.7 In addition, disparities in participation exist related to age, sex, race/ethnicity, qualifying diagnosis, geography, comorbidities, health care system, and socioeconomic status (SES).7–14

Many barriers impede participation in the standard program of 36 center-based sessions, including transportation, parking, financial concerns, limited program hours, and competing responsibilities (eg, work or caregiving).15 Even if these barriers did not exist, studies suggest that if all center-based CR programs were at 110% capacity, existing programs could only accommodate ≈45% of eligible US patients.16 Moreover, many parts of the United States are CR deserts; 14% of adults live in counties where there are no CR centers, and 74% live in counties where there is <1 CR center per 100,000 adults.17

The coronavirus disease 2019 (COVID-19) pandemic added an additional challenge to participation...
in center-based CR. To mitigate viral spread, many center-based CR programs closed or limited in-person services. As a result, to continue providing essential risk-reduction services, many programs pivoted to new delivery methods.

Million Hearts and the American Association of Cardiovascular and Pulmonary Rehabilitation (AACVPR) partnered to hold a think tank to advance new care models for CR. Evidence behind new care models has been growing, but many questions remain about implementation in the United States including standards, terminology, payment/reimbursement, scalability and spread, and approaches to address health equity. In October 2020, the Million Hearts Cardiac Rehabilitation Think Tank: Accelerating New Care Models convened, including representatives from professional organizations, CR programs, academic institutions, federal agencies, payers, and patient representative groups (see the Data Supplement for attendees). In this article, we describe the think tank proceedings and recommendations for accelerating new care models.

MODELS AND TERMINOLOGY

The absence of standardized terminology has contributed to confusion about new CR delivery models. Therefore, we propose the following framework to clarify terminology. Historically, CR delivery models have referred to the location where the patient participates in CR (eg, center, home). Recently, hybrid CR models have emerged, with some activities in the center and some in the home. Many terms were discussed, including center, home, hybrid, hyflex (hybrid and flexible), innovative delivery model, remote, virtual, and patient-centered. Ultimately, it was recognized that terminology for CR delivery is evolving to reflect not where activities occur but how CR is delivered. We propose a new model for describing CR delivery (Figure 1). Virtual CR refers to synchronous CR delivered with real-time audiovisual communication technology to facilitate patient and clinician interaction during an exercise session. Remote CR refers to CR delivered with asynchronous activities without real-time communication between patients and clinicians at the time of an exercise session. An individual program may offer ≥1 modes of delivery; an individual patient may participate through ≥1 modes of delivery.

CR PROGRAM CORE COMPONENTS

There was a strong think tank consensus that regardless of the delivery mode, the multidisciplinary components of CR must be preserved. Although exercise training is a vital component of CR programs, it is not the only component. Programs must consider not only how they will provide exercise training but also how they will deliver the full range of CR services in new care models, including disease management (eg, medication adherence) and behavioral education and counseling (eg, healthy dietary patterns, psychosocial wellness, and tobacco cessation).

The structure of a CR program was defined in the Social Security Act (Table 1). According to this statute, CR programs can be located in a hospital (on or off the primary hospital campus) or in a physician's office. In addition, programs must be supervised by a physician who must be immediately available to provide consultation or handle medical emergencies at all times CR services are being provided. Each patient must have an individualized treatment plan, signed by a physician and updated every 30 days. There are additional requirements for qualifying diagnoses, session duration, and intensive CR programs. These requirements apply specifically to patients with Medicare insurance. Nongovernmental payers tend to mirror Medicare but often have varying requirements for CR programs. Of note, nonphysician clinicians will be allowed to provide supervision for CR sessions in lieu of a physician beginning in 2024.

In addition to program structure, the Social Security Act also defines CR services. Based on these requirements, the AACVPR and the American Heart Association defined the core components of CR and secondary prevention programs (Table 2). CR is a comprehensive, multidisciplinary, secondary prevention program.
program including exercise training, patient education on the core components of CR, nutritional counseling, cardiovascular disease risk factor modification, and psychosocial management. CR programs consist of a multidisciplinary team of clinicians including physicians, nurses, clinical exercise physiologists, behavioral health experts, dietitians, physical and respiratory therapists, and others who collaborate to deliver CR services. Any new delivery models must include the multidisciplinary team and these core components for successful delivery of CR.

In addition to requirements for the structure and components of CR programs, professional societies have published quality and performance measures to promote high-quality care. The American College of Cardiology and American Heart Association performance measures address referral and enrollment of eligible patients from inpatient and outpatient settings, as well as quality measures of time to enrollment, adherence, and communication with referring clinicians. The National Quality Forum endorses referral from the inpatient and outpatient settings as quality measures. Healthcare Effectiveness Data and Information Set includes measures for the percentage of eligible members who attend ≥2, ≥12, ≥24, and ≥36 sessions within various time frames. Among programs that meet guidelines, AACVPR provides a recognition and certification program. Recently, AACVPR published additional performance measures including improving functional capacity, blood pressure control, reducing depressive symptoms, and tobacco cessation interventions. Consideration of evaluation and program certification pathways for new delivery models are needed to provide external validation of the quality of the services provided.

Table 1. Cardiac Rehabilitation Program Requirements

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Details</th>
</tr>
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<tbody>
<tr>
<td>Location</td>
<td>Hospital (on or off campus) or physician office</td>
</tr>
<tr>
<td>Physician supervision</td>
<td>Individualized treatment plan signed by a physician and updated every 30 d</td>
</tr>
<tr>
<td>Qualifying diagnoses</td>
<td>Acute myocardial infarction in the last 12 mo</td>
</tr>
<tr>
<td></td>
<td>Coronary artery bypass graft surgery</td>
</tr>
<tr>
<td></td>
<td>Coronary artery angioplasty or stenting</td>
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<tr>
<td></td>
<td>Heart valve repair or replacement</td>
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<td></td>
<td>Heart or heart-lung transplantation</td>
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<td></td>
<td>Stable angina</td>
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<tr>
<td></td>
<td>Stable chronic heart failure*</td>
</tr>
<tr>
<td>Requirements for session duration</td>
<td></td>
</tr>
<tr>
<td>Additional requirements for intensive cardiac rehabilitation programs</td>
<td></td>
</tr>
<tr>
<td>Required components (Table 2)</td>
<td></td>
</tr>
</tbody>
</table>

*Defined as left ventricular ejection fraction <35% after 6 wk of optimal medical therapy.

Table 2. American Association of Cardiovascular and Pulmonary Rehabilitation/American Heart Association Core Components of Cardiac Rehabilitation and Secondary Prevention Programs

<table>
<thead>
<tr>
<th>Component</th>
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<tbody>
<tr>
<td>Patient assessment</td>
</tr>
<tr>
<td>Nutritional counseling</td>
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<tr>
<td>Weight management</td>
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<tr>
<td>Blood pressure management</td>
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<td>Lipid management</td>
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<td>Diabetes management</td>
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<tr>
<td>Tobacco cessation</td>
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<tr>
<td>Psychosocial management</td>
</tr>
<tr>
<td>Physical activity counseling</td>
</tr>
<tr>
<td>Exercise training</td>
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</tbody>
</table>
POLICY

Before the COVID-19 pandemic, CR was provided almost exclusively in-person. US examples of virtual or remote CR existed in the Henry Ford, Kaiser Permanent, and the Veterans Administration health systems. These delivery models were reimbursed by nongovernmental payers or conducted in a managed-care fashion. Medicare and most nongovernmental payers have historically only reimbursed CR sessions delivered in-person. Thus, in-person synchronous delivery of CR services has overwhelmingly been the most common delivery method in the United States.

As a result of the COVID-19 pandemic, CMS provided waivers to expand the use of audiovisual communications technology to deliver health care services, including CR. Because the overwhelming majority of CR is provided in a hospital outpatient setting, rather than a physician office setting, the remainder of this section focuses on hospital waivers. Similar opportunities, with some caveats, exist for physician office programs. These waivers allow CR delivery in a virtual, synchronous manner using real-time audiovisual communication technology. Hospitals wishing to obtain reimbursement from Medicare for these services must complete a number of administrative tasks such as registering the patient’s home as an outpatient department of the hospital and attaching applicable billing modifiers to indicate virtual delivery.

CR professionals are encouraged to work with the relevant departments at their institutions regarding reimbursement. It is important to note that these waivers allow for the virtual, synchronous delivery of CR services but not remote, asynchronous delivery. Physicians still must be available for supervision and consultation for CR services, but they can use real-time audiovisual communications technology when needed for virtual sessions.

Though these services are being delivered virtually, all requirements and components of a CR program (Tables 1 and 2) must still be met. These waivers change how CR services can be delivered but do not change what must be delivered. Programs must still deliver the same comprehensive, multidisciplinary intervention of CR via any delivery model.

The future of virtual CR delivery after the public health emergency is unknown at this time (June 2021). There is great enthusiasm to make permanent many of the CMS waivers that have expanded the use of audiovisual communications technology for health care services. To what extent CR services will be included in these initiatives is unknown at present. If included, it may be that only virtual, synchronous delivery of CR services using real-time audiovisual communications technology would be reimbursed by CMS. As of June 2021, there is still no mechanism for CMS reimbursement of remote, asynchronous delivery of CR. In addition, whether nongovernmental payers will reimburse for virtual or remote delivery of CR services during or after the COVID-19 pandemic is unknown at present. Regardless, opportunities may exist to pilot reimbursement opportunities for virtual and remote delivery of CR services as part of the Medicare Advantage (MA) Value-Based Insurance Design Model or through model tests from the Centers for Medicare and Medicaid Innovation.

EQUITY

A plethora of studies have documented persistent disparities in CR utilization, with lower rates of participation among women, racially or ethnically underrepresented groups, older adults (≥85 years), rural populations, people living in low SES ZIP codes, and people with limited educational attainment. Individuals of these diverse and underserved populations have a disproportionate burden of cardiovascular disease and worse outcomes, in part, related to untreated risk factors and poor access to care. The disparities in CR utilization begin at referral and continue to manifest in low rates of participation, adherence, and completion of CR. CR attendance is poor in the Medicaid enrolled population. Patients with limited educational attainment are less likely to be referred or participate in CR. There is geographic variation in referral and participation with lower participation in rural areas and low SES ZIP codes.

Both patient and health system factors can contribute to disparities in CR delivery (Table 3). Unfortunately, strategies to combat these factors are less well understood or tested, especially among patient populations with disproportionately low CR participation.

Evolving CR delivery models may help address some of these factors, such as transportation issues or CR deserts. New CR delivery models must also be developed and delivered with attention to avoiding exacerbating disparities due to the digital divide. Technology-facilitated solutions should take into consideration access to technology, digital literacy, usability, and the need for broadband access. Still, the impact new care models have on addressing disparities in CR uptake will not be realized until action is taken to address the larger patient and health system factors at play. It is for this reason that the think tank partnered with the Million Hearts Cardiac Rehabilitation Collaborative—an open forum of >400 individuals committed to achieving the 70% CR participation target, to establish the Cardiac Rehabilitation Collaborative Health Equity Workgroup. This multidisciplinary workgroup is charged to work with the larger Cardiac Rehabilitation Collaborative to develop and implement
sustainable and patient-centric strategies that address both the patient and health system factors that contribute to the disparate uptake of CR in the United States. Patient and community members will be included in all workgroups emerging from the think tank to embrace diversity and inclusion throughout the spectrum of CR delivery models. The need to ensure equitable access to new CR delivery models was echoed throughout the think tank, and the following potential solutions were brought forward.

**Leveraging Community Resources for Delivery of CR to Underserved Populations**

Knowing what potential partners and resources are available in the community is key to ensure patients have what they need to complete their CR program and maintain a healthy lifestyle beyond graduation from a CR program (see the Data Supplement for community resources). Community-based organizations can facilitate access to reliable internet and internet-enabled devices, exercise equipment and healthy lifestyle programs, healthy foods for food insecure patients and their families, translation services, and peer support. Leveraging public programs may also help patients secure health insurance, access the transportation they need to get to medical appointments, and secure housing. Additional physical activity programs and tobacco cessation programs may supplement a patient’s individualized treatment plan or help maintain a heart-healthy lifestyle after CR.

**Medicaid Coverage for New CR Models**

Medicaid coverage of CR is suboptimal. A 2018 review of state laws identified 21 states with state statutes for CR coverage in their fee-for-service Medicaid programs. Of the states that offer coverage, many policies are administratively burdensome with prior authorization requirements, limitations on the number of billable sessions, the duration of coverage, or the qualifying diagnoses and procedures. State Medicaid programs are afforded the flexibility to reimburse for services provided via telehealth without needing a state plan amendment. State Medicaid telehealth policies vary based on the services eligible for delivery via telehealth (all telehealth services versus a select list), the mode of delivery (synchronous versus asynchronous), the location of the patient, and other applicable state policies. Medicaid programs can also explore or test opportunities to cover new CR models by using Medicaid managed-care authorities (including the use of Performance Improvement Projects), applying section 1115 demonstrations, seeking support from a Medicaid Innovation Accelerator Program, using options through the Medicaid state plan, and joining state-based multipayer initiatives.

**Reducing Financial Barriers**

The financial investment to participate in the program is cited as a leading barrier to participation for people with low SES. For CR, out-of-pocket expenses come in the form of copayments, coinsurance payments, deductibles, direct payments, or transportation costs. In addition, CR becomes more costly as the patient progresses through the 36-session program due to the accumulation of copayments, creating a disincentive for them to continue. A recent study demonstrated a clear dose response such that an increase in cost-sharing was associated with lower CR attendance.

To circumvent this issue, payers are encouraged to cover CR, no matter the mode of delivery, with zero cost-sharing. CMS issued a final rule that promoted the opportunity for qualified health plans to offer value-based plans that cover CR and 7 other high-value services with zero cost-sharing in exchange for increasing cost-sharing for low-value services. The MA Value-Based Insurance Design Model offers MA Organizations the opportunity to eliminate cost-sharing for CR, cover alternative CR delivery models, and provide beneficiaries with cash or monetary rebates for their participation in CR. MA plans offered by Blue Cross Blue Shield Michigan have eliminated cost-sharing for CR. Hospitals may also be part of the solution by using a pool of philanthropic funds to...
supplement the cost of CR for their uninsured or underinsured beneficiaries.40

IMPLEMENTATION

The implementation of a CR program with virtual or remote delivery involves numerous considerations, including patient eligibility and safety, exercise regimen and prescription, patient monitoring, and patient education (see the Data Supplement for resources and patient selection considerations).

Patient Eligibility and Safety

Since CR began in the 1970s, patients have been encouraged to exercise on their own on days when not attending CR. Therefore, patients with cardiovascular disease exercising on their own at home is not a new paradigm. What is relatively new is monitoring and progressing these patients outside the center in a manner that targets the core components of CR.

Though exercise at home requires caution for some patients, such as those receiving continuous inotropic support, having recently received a mechanical support device, or who are symptomatic at low workloads (≤2 metabolic equivalents [METs]), most stable patients can exercise on their own at a relatively low risk of complication. For example, the HF-ACTION trial (Heart Failure: a Controlled Trial Investigating Outcomes of Exercise Training) assessed the safety of exercise training (initially center based, then remote) in 2331 patients with chronic systolic heart failure and found no significant difference between the exercise and usual care groups for the risk of hospitalization (1.9% versus 3.2%, respectively) or death (0.4% versus 0.4%, respectively) within 3 hours of exercise and no significant difference in ICD shocks between groups.41,42 Meta-analyses and other controlled trials investigating hybrid, virtual, or remote CR also report favorable safety data.43-48

Strategies to further promote safety include having the patient (1) compete a symptom-limited exercise test before or soon after starting CR to quantify exercise tolerance and screen for significant arrhythmia or ischemia by ECG, (2) attend ≥1 ECG-monitored sessions in center-based CR before transitioning to virtual or remote, and (3) periodically return for an in-person session to observe symptom and blood pressure responses with exercise training. Initial in-person contact can also orient the patient to the program, its staff, and any equipment that may be used. Finally, before a patient starts a virtual or remote CR program, a mutually agreed upon emergency plan should be in place and have the patient explain it back. At the beginning of each virtual CR session, staff should confirm the patient's emergency contact information and location in case emergency services are needed.

Exercise Regimen and Exercise Prescription

Regardless of whether a synchronous, asynchronous, or combined model is used, exercise volume should progress patients to 150 minutes per week of moderate-intensity exercise.49 The type of activity should be whole body and rhythmic such as, but not limited to, stationary cycling, walking, or seated rowing. Resistance training using home equipment or bands is encouraged to minimize sarcopenia and dynapenia.50 All patients should start with continuous exercise and only progress to moderate or higher intensity interval training if desired and tolerated. Initially, exercise intensity should be set at a moderate-vigorous level (ie, rating of perceived exertion of 11–14 on 6–20 scale or 55%–80% of heart rate reserve). For higher intensity interval training, the work interval is typically set between 85% to 95% of heart rate reserve or a rating of perceived exertion of 13 to 16.21,51,62

Patient Monitoring

For virtual delivery, real-time audiovisual communication and monitoring of the patient can occur using a commercial video conferencing system or through video systems linked through a patient portal in the electronic health record.23,43,53 For remote delivery, patient-generated data can be transmitted to clinicians for asynchronous review. Remote data can include data manually logged into an electronic platform by the patient or data that are collected by wearable devices.25,48,54 Remote models with paper and pencil logs reported to CR staff by telephone have also been implemented.26,44,55 Although it is uncommon for ECG monitoring to change patient care, even in center-based CR,56 some studies of new delivery models have included ECG monitoring44 but most have not.29,41,53,54 Many virtual and remote delivery models use a chest strap or wrist-worn tracking device for heart rate and exercise intensity monitoring.25,41,43,53-55

Patient Education

As with center-based CR, virtual and remote CR should also have education addressing CR core components and health behaviors including physical activity, healthy dietary pattern, mental wellness, medication adherence, and tobacco cessation.21 A variety of educational models have been deployed in virtual and remote models21,23,25,26,56; future research is needed to determine the most effective approach.

RESEARCH

Meta-analysis of randomized clinical trials demonstrated that home-based CR has similar safety and efficacy to center-based CR.46 The American College of
Cardiovascular Disease/Scientific Statement concluded “prior randomized trials have generated low- to moderate-strength evidence that home-based CR and center-based CR can achieve similar improvements in 3- to 12-month clinical outcomes. Although home-based CR appears to hold promise in expanding the use of CR to eligible patients, additional research and demonstration projects are needed to clarify, strengthen, and extend the home-based CR evidence base for key subgroups, including older adults, women, underrepresented minority groups, and other higher-risk and understudied groups.

The think tank identified 4 priority research areas for new CR models: (1) use among specific populations including women, racially and ethnically underrepresented groups, and individuals with low SES; (2) impact on patient-centered outcomes, (3) effect on long-term (>1 year) outcomes and health care utilization, and (4) implementation in diverse health care settings, including optimization of delivery models and staffing considerations.

Ongoing Studies
Several ongoing studies will provide evidence about new care models (see PreThink Tank Webinar Recordings in the Data Supplement). Improving ATTENDANCE to Cardiac Rehabilitation Trial is randomizing diverse participants to center-based CR or hybrid CR (using a virtual synchronous model) and examining outcomes including completed CR sessions, improvement in exercise capacity, and patient-centered outcomes (https://www.clinicaltrials.gov; unique identifier: NCT03646760). The MACRO study (Modified Application of Cardiac Rehabilitation for Older Adults) is randomizing older adults to standard care versus flexible delivery of personally tailored CR and examining the impact on physical function and patient-centered outcomes (https://www.clinicaltrials.gov; unique identifier: NCT03922529). The Enhancing Cardiac Rehabilitation Through Behavioral Nudges study is comparing center-based CR to a choice of center-based CR or mobile application-assisted home-based CR with or without behavioral nudges and examining the impact on adherence to CR and patient-centered outcomes, including long-term outcomes and health care utilization (https://www.clinicaltrials.gov; unique identifier: NCT03834155). HeartHome: A Nurse-Driven, Home-Based Cardiac Rehabilitation Program study is combining nurse home visits with telephone and electronic supports for participants in a home-based CR program compared with center-based CR (https://www.clinicaltrials.gov; unique identifier: NCT04131816). Though these studies will provide additional evidence about new care models, gaps will remain; more data will be needed on effectiveness of implementation in diverse patients and health care settings.

Research Network
We propose the development of a research network to address knowledge gaps related to new delivery models. This research network will bring together researchers and stakeholders to identify important patient-centered outcomes, plan cooperative studies to understand the long-term effects of new CR delivery models, and attract funding. Outcomes highlighted as important to study include CR referral, CR enrollment, timeliness of enrollment, CR participation, exercise capacity, blood pressure, obesity, hemoglobin A1c, blood lipids, medication adherence, diet quality, mental health, cognition, physical function, tobacco cessation, quality of life, self-efficacy, patient and clinician satisfaction, cardiovascular events, health care utilization, and disparities reduction. Furthermore, research should address and help mitigate impact of the social determinants of health and be inclusive of diverse populations.

Registries and Surveillance
To better understand use of new care models, existing data systems will need to be modified. For example, the AACVPR quality improvement registry will need to be expanded to include identifying how CR was delivered to enable comparisons among delivery models within and across programs.

Referral to and enrollment in CR have been monitored using data from quality improvement registries, Medicare, and VA. Recently, collaborators from the Million Hearts Cardiac Rehabilitation Collaborative conducted surveillance on CR participation among Medicare fee-for-service part B enrollees. Additional approaches to surveillance with Medicaid, MA, and nongovernmental payer data can complement Medicare fee-for-service data to capture participation among younger adults and others. To monitor use of new delivery models, standard codes and modifiers will need to be used and analyzed. These surveillance efforts should seek to understand the population eligible for CR, CR referral, CR enrollment, CR delivery through traditional and new models, and the impact of CR on outcomes and health care utilization. Finally, these efforts should seek to understand the role of social determinants of health, as well as disparities in CR access, participation, and outcomes to guide interventions to promote health equity.

CONCLUSIONS
CR is evolving to include in-person synchronous, virtual synchronous, and remote asynchronous modes of delivery (Figure 2). Though new models may change how CR is delivered, new models should not change what is delivered—a multidisciplinary program that addresses CR core components. Long-term policy changes will be needed for
broad uptake of new CR care models. Existing evidence supports the efficacy and safety of virtual and remote CR and many programs provide examples of successful implementation, but questions remain about effects on patient-centered and long-term outcomes in diverse populations and settings. There is significant enthusiasm for efforts to implement new CR care models and learn how new care models can broaden access to CR, improve patient outcomes, and address health inequities.


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