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RESEARCH ARTICLE

4R COVID-19 Toolkit for Patient Self-Management of Mild or Moderate COVID-19 symptoms

Christine B. Weldon, MBA The Center for Business Models in Healthcare

Brittani James, MD University of Illinois at Chicago, UI Health Mile Square Health Center

Kimberly Jinnett, PhD, MSPH Genentech*

Caroline Solon, MSc Genentech

Claire Thesing, MD University of Illinois at Chicago, UI Health Mile Square Health Center

Judes Fleurimont, UI Health Mile Square Health Centers

Karriem S. Watson, DHS, MS, MPH University of Illinois at Chicago, UI Health Mile Square Health Center

Julia R. Trosman, PhD, MBA The Center for Business Models in Healthcare

* jinnett.kimberly@gene.com

ABSTRACT

There is an under-addressed need to help patients who experience mild-to-moderate COVID-19 symptoms or are asymptomatic, to manage their disease at home. While no approved COVID-19 medical treatments exist for these patients, home-based self-management is crucial because it has the potential to relieve patients' symptom burden and provide concrete actions that help mitigate anxiety, isolation and loss of personal control associated with the disease. Existing resources often provide a deluge of information, which may not be readily actionable by patients. Additionally, existing resources focus primarily on managing severe symptoms. A 4R COVID-19 toolkit was developed to address the unmet need for patients with mild or moderate COVID-19 symptoms based on expert discussions and a literature review. The toolkit applies the principles of the previously developed 4R Oncology Model of providing patients with a project plan for the course of their COVID-19 care, information on self-management of mild to moderate symptoms, and criteria for contacting their medical provider. The toolkit was developed with support from Genentech; it is not intended to substitute for the medical advice of a healthcare provider. The 4R COVID-19 toolkit continues to be improved as updated information is available via patient and clinician feedback, literature, and expert guidance. A copy of the current toolkit is attached to this paper for use and adaptation by care providers, practices, and institutions.

Introduction:

While COVID-19 vaccines are rolling out, the pandemic is expected to continue for the next 6-8 months and potentially beyond. Based on data from China, approximately 80% of patients infected with COVID have mild to moderate symptoms¹. There is an under-addressed need to help patients who are asymptomatic or experience mild to moderate COVID-19 symptoms, to manage their disease at home. While no approved COVID-19 medical treatments exist for these patients, home-based self-management is crucial because it has the potential to relieve their symptom burden and provide concrete actions that help mitigate anxiety, isolation and loss of perceived personal control associated with the disease. Existing resources often provide a deluge of information, which may not be readily actionable by patients. Additionally, existing resources focus primarily on managing severe symptoms.

To fulfill this need, we developed the 4R COVID-19 toolkit, intended for use by patients with mild or moderate COVID-19 to support their self-management. . The toolkit is based on a previously developed and tested 4R Oncology Model – an innovative approach to patient self-management and cancer care delivery²), developed by the Center for Business Models in Healthcare³. 4R means Right Information and Right Care for the Right Patient at the Right Time. The 4R Model has shown to be effective in facilitating patient self-management in cancer care⁴. The 4R COVID-19 toolkit structure, format and approach were adapted from and informed by the 4R Oncology model, while providing COVID-19-specific, literature-supported content. The toolkit guides patients on how to self-manage symptoms at home, when to call their primary care team and when to go to the Emergency Room or call 911. The 4R COVID-19 toolkit will continue to be updated as updated information is available via literature and new data is available through patient and clinician feedback.

This paper describes how the 4R COVID-19 toolkit was developed and provides access to the toolkit with patient materials in English and Spanish.

Methods for 4R COVID-19 toolkit development

The 4R COVID-19 toolkit development was focused on adults, aged 18 to 64 years without significant co-morbidities with confirmed or suspected COVID-19 who are asymptomatic, or with mild or moderate symptoms, and who have not been hospitalized with COVID-19. The 4R COVID-19 toolkit is intended for use in primary care settings for in-person visits, telehealth visits (with screen sharing) and/or phone visits with no video. The toolkit was developed in conjunction with Genentech. It is not intended to substitute for the medical advice of a healthcare provider

The first step of the 4R COVID-19 toolkit development was a targeted literature review conducted in June 2020 to identify content on managing moderate or mild COVID-19. Targeted literature review sources included: government websites and online resources, including the Centers for Disease Control (CDC) and Public Health Departments; non-government organization websites and online resources including large US health systems and academic centers; peer-reviewed publications identified via PubMed and similar databases; and pre-print publications identified via MedRxiv and similar sources. We continue to iteratively review literature for additional information to inform updates to the 4R COVID-19 toolkit.

Most recommendations identified via literature review were consistent, anchoring primarily to CDC guidelines, but varied in the level and amount of detail provided. The recommendations often assumed that a patient is in contact with a health care professional. Some recommendations did not reflect the reality of low-income individuals for whom home care may be especially challenging. For example, recommendations referred to availability of separate rooms within the family home, avoiding public transport and having access to digital technology and internet. In general, there was a limited amount of published literature specifically on COVID-19 outpatient management; only 2 peer-reviewed articles were identified, and both focused on internet / phone application solutions.

To augment the literature review, we conducted discussions with 13 experts in relevant clinical areas starting in June of 2020. Their areas of expertise included: infectious disease management; primary

care and internal medicine; pulmonary medicine; community health work, and psychology. The team used qualitative research methods to analyze literature and interviews, and identified categories,

themes and sub-themes related to patient self-management of mild or moderate symptoms of COVID-19. (Table 1).

Table 1: Managing COVID-19 at Home with Mild or Moderate Symptoms: Themes from Literature review and Expert Discussions

Theme Category	Theme / Subtheme
Clinical Care	<ul style="list-style-type: none"> • Emergency symptoms – when to go to Emergency Room⁵ • When to call the doctor⁶⁻⁸ • Health Maintenance⁹ <ul style="list-style-type: none"> • Sleep¹⁰⁻¹² • Physical Activity • Nutrition¹³⁻¹⁶ • Fluid Intake • Healthy behaviors (smoking, vaping, alcohol, other substances) • When patient starts feeling better⁶ • Symptom Management^{5,17-20} <ul style="list-style-type: none"> • Breathing / Respiration • Body aches, muscle aches, headache • Cough, Sore throat, Congestion • Managing Fevers • Stomach and Diarrhea²¹⁻²³ • Memory and Confusion • Distress / Anxiety (calming activities) • Blood clots (added in Summer 2020)^{24,25}
Protecting Family and Others	<ul style="list-style-type: none"> • Wearing Masks⁵ • Protecting those around you • Living with Others
Social Care	<ul style="list-style-type: none"> • Patient’s ability for self-care at home • Food Access • Missing Work • Activities for patients while being homebound

Using the themes and the structure of the 4R Oncology Model, the team created the 4R COVID-19 toolkit (Table 2). The 4R COVID-19 toolkit used the principles of the 4R Oncology Model[®] Care Sequences[®] for the entire care episode, as patient care project plans, with timing and sequencing of care, information about the care and explicit responsibilities for the patient²⁶. The emphasis was put on patient-centric description of timing and sequencing of care within an actionable and feasible personal care plan, taking into account disparities in social determinants of health and health literacy.

The team conducted multiple revisions of the toolkit to adapt the content to plain language standards

using University of Michigan Plain Language Medical Dictionary²⁷ and align with clinical practice. Special attention was paid to ensuring that the content and tools were appropriate for individuals with lower health literacy, and the tools were accessible and usable by individuals with lower socioeconomic status, including lack of digital access. Subsequently, the team conducted feasibility pilots of the 4R COVID-19 toolkit at the Mile Square South Shore Clinic in Chicago, Illinois. Iterative improvements were made to the 4R COVID-19 toolkit based on pilot feedback (Table 3). After 4 weeks of piloting the 4R COVID-19 toolkit, the toolkit content was translated into Spanish.

Table 2: 4R COVID-19 Toolkit

<p>English Toolkit</p> <ul style="list-style-type: none"> • Individual PDF versions of each document <ul style="list-style-type: none"> ○ “What is COVID-19” one pager that links to the content <p>COVID-19 Patient Self-Management Tools:</p> <ul style="list-style-type: none"> ○ Overall Care Sequence® based on weeks ○ Daily Care Sequence® for COVID-19 based on time of day ○ Symptom Tracker ○ Control Your Symptoms ○ Help Your Body Fight COVID-19 ○ Protect Yourself and Others ○ 5 Things to Do When Better ○ Breathing <ul style="list-style-type: none"> • Individual PowerPoint versions of each document (for editing by clinics and practices, if desired) • Booklet of patient handouts with page numbers • Administration steps for use of COVID-19 booklet • COVID-Phone Script • Smart Phrase for medical records documentation: <ul style="list-style-type: none"> ○ For symptomatic COVID-19 patient ○ For asymptomatic COVID-19 patient <p>Spanish Toolkit</p> <ul style="list-style-type: none"> • Individual PDF versions of each document (same as list above) • Individual PowerPoint versions of each document (for editing by clinics and practices, if desired) • Booklet of patient handouts with page numbers
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Mile Square Health Center and the 4R COVID-19 toolkit

The Mile Square Health Center (MSHC) - part of the University of Illinois Hospital & Health Sciences System - is a Federally Qualified Health Center based in Chicago Illinois that serves nearly 40,000 people each year. Racial and ethnic composition varies throughout the Mile Square service area. Overall, 35% of the population identifies as Black/African American, and another 35% identify as Hispanic. White Non-Hispanics account for 24% of the overall service area population, followed by Asian Non-Hispanic and All Other races (non-Hispanic) at 4.2% and 1.5%, respectively. The overall percentage of the service area population that speaks a language other than English at home is 37%, but the rate is as high as 72% at specific clinics. Nearly a quarter of the population (23%) is living in poverty, defined as individuals living at or below 100 percent of the Federal Poverty Level (FPL). Another near quarter of the population (24%) is living between 101 percent and 200 percent of the FPL, which is considered low-income. In total, 47% of the service area population is considered low-income or in poverty. The Mile Square

participants in our team were Dr. Karriem Watson, Dr. Brittani James, Judes Fleurimont, and Dr. Claire Thesing.

The Mile Square Health Center Research Committee and board have reviewed and approved the team’s request to conduct a feasibility pilot of the 4R COVID-19 toolkit. Dr. Brittani James and Judes Fleurimont actively participated in multiple revisions and improvements to the 4R COVID-19 toolkit prior and during the pilot (August and September 2020). Dr. Brittani James and Dr. Claire Thesing rolled out the 4R COVID-19 toolkit to the MSHC South Shore Clinic staff and clinicians in September 2020. Since then, the 4R COVID-19 toolkit has been provided to over 400 patients at the MSHC South Shore Clinic. The patient handouts are offered to patients who are tested for COVID-19 and patients who ask for information about COVID-19. The handouts are pre-printed into stapled 9-page booklets. After the initial pilot at the South Shore Clinic, Dr. Brittani James presented the 4R COVID-19 Toolkit to the MSHC all-staff meeting in October 2020, and to the Site Medical Directors for each MSHC clinic in November 2020. Subsequently, the 4R COVID-19 toolkit was rolled out to all MSHC clinics

with site specific contact information on the first page of each booklet. This toolkit is intended for patients with a COVID-19 confirmed or suspected

diagnosis and can be used in a similar manner to an after-visit summary with patients who have an in person, phone or telehealth visit.

Table 3: 4R COVID-19 Toolkit Pilot Feedback and Resulting Adjustments to Toolkit

#	Feedback from clinicians	Action
1.	When provided the option of a web line or paper version, Patients preferred paper versions of information. During feasibility pilot the patients were being seen in person.	Provided printed “sets of the tool” to have on hand in clinic.
2.	The first two pages are too boxy and no visual enough for clinicians and patients	Changed format to simpler look for first page.
3.	Consider a cover sheet/table of contents page to help with navigation.	Added page numbers to link to the rest of the content (links for web and pdf versions).
4.	For the paper version do not want web links to references, only link to an electronic version of the document.	Removed references/weblinks from paper version, kept on pdf and web version.
5.	Patients, clinicians and staff “love” the informational handout pages on symptoms, taking care of yourself, protecting others, what to do when feeling better. “Take care” title was not clear	Changed take care to “help your body fight COVID-19” to better describe content.
6.	Due to several factors: move to new EMR, staffing shortage, busy clinics hard to get paper into folder.	Updated set of tools printed and bound so ready to use when arrived at clinic.
7.	Feedback on several words that needed simplification.	This is an ongoing effort to simplify language used but not lose meaning.
8.	Patients feel anxious and want something simple they can do.	Kept timeframe on first page of symptomatic version to set expectations. Added feeling anxious info, and info sheet on breathing with link to 4-7-8 breathing technique.
9.	Need two pages for writing down symptoms, one page wasn’t enough for some patients because they started mid-week.	For printed packet added two pages of “Write down your symptoms each day”.
10.	Need to distinguish symptomatic from asymptomatic materials where relevant. Need a label for clinicians / staff to make the distinction obvious	Made heading different and made the two pages different colors.
11.	Need the toolkit in Spanish for adoption at other clinics as part of MSHC expansion of use	Translated all content into Spanish.
12.	Need talking points for clinicians to help describe the toolkit to patients	Provided content for smart phrase for the electronic medical record.

Implications and Conclusion

There continues to be an under-addressed need to help patients who are asymptomatic or experience mild to moderate COVID-19 symptoms, to manage their disease at home. Home-based self-management is crucial as it has the potential to relieve their symptom burden and provide concrete actions that help mitigate anxiety, isolation and loss of personal control associated with the disease.

Patients benefit by receiving and using a clear plan of actions to care for themselves when they have a suspected or confirmed COVID-19 diagnosis and do not have co-morbidities of concern with COVID-19 and while their symptoms remain mild or moderate. The 4R COVID-19 patient information provides specific information (informed by CDC guidelines) of when to call primary care provider, when to go to ER or call 911.

During the COVID-19 pandemic, it is important to reduce the number of unnecessary in-person visits to the clinic. Patient self-management of mild-to-moderate symptoms and clear direction when a symptom is an emergency, and when to contact the care team for other symptoms, will improve appropriateness of these encounters. The 4R COVID-19 tool kit provides detail on how to manage mild to moderate symptoms beyond information available from CDC's patient guidelines for COVID. These details are supported by literature that may evolve.

As a quality improvement project, the toolkit evolves based on new information in literature and based on feedback from the clinicians and their patients. The team is collecting specific data and feedback from patients who are using the tool and will share that in a future paper.

The toolkit is available to download and adapt to your practice setting through the attached documents to this paper. For additional information or to provide suggestions / feedback, please contact Christine Weldon, weldon@centerforbusinessmodels.com.

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