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The problem is obtaining knowledge: a qualitative analysis of provider barriers and accelerators to rapid adoption of new treatment in a public health emergency

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Abstract

Granted by the U.S. Food and Drug Administration, an Emergency Use Authorization (EUA) can only be utilized upon declaration that a specialized set of circumstances exist which justify the authorization. In 2020, the COVID-19 pandemic demanded rapid communication strategies to promote treatment options available through EUA. Despite the authorizations of available monoclonal antibody (mAb) treatments in November 2020, their rate of adoption among health care providers in the U.S. remained low well into 2021. This study examines the accelerators and barriers to provider adoption of COVID-19 treatment so that future adoption of treatments in emerging public health emergencies may be better communicated and hastened. We established a framework informed by adoption accelerators and barriers identified by Diffusion of Innovations (DoI) Theory and conducted a study during the rapidly evolving COVID-19 public health emergency. Most Dol public health research focuses on chronic health issues and has yet to be applied to provider adoption of new treatment under EUA. Through a series of guided interviews with health care providers, primarily physicians or nurse practitioners that were responsible for referring COVID-19 patients, we extracted tools, processes, or other mechanisms (accelerators) and barriers to validate against our Dol framework and fill the gap regarding emergency situations. Our research found that providers supported by large health systems were more inclined to adoption, due to many contributing factors such as the availability of collaborative support and availability of information. Further, communicating evidence-based summaries of treatment options and related processes was also critical to adoption.

Keywords EUA, Emergency Use Authorization, Monoclonal antibodies, Diffusion of innovation, Public health emergency, COVID-19, Provider adoption

Background

In November 2020, COVID-19 monoclonal antibodies (mAbs) became a newly authorized treatment for individuals with mild-to-moderate COVID-19 symptoms who were at high risk for progression to severe disease. Given the evidence that mAbs could reduce the relative risk of progression to serious illness and hospitalization by up to 70% in these patients, [1] their introduction gave healthcare providers an essential tool at a time when



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COVID-19 vaccines were not yet available and COVID-19 cases and hospitalizations were high [2, 3].

The introduction of mAbs amid a public health emergency provided the opportunity for this study to examine the behavior and perceptions of providers in adopting a new emergency treatment. Many providers did not begin prescribing mAbs to their eligible patients in the weeks and months after the U.S. Food and Drug Administration's (FDA) Emergency Use Authorizations (EUAs) in November 2020. Due to the slow provider uptake as evidenced by Edwards [4], the U.S. Department of Health and Human Services (HHS) began a provider education campaign in early 2021 to speed adoption of mAbs through disseminating potential implementation models and informing providers about the scientific evidence. The qualitative research for this study was conducted as part of that campaign. Diffusion of Innovation (DoI) theory provided the grounding framework for our study, and our findings are also relevant to the growing literature on Crisis and Emergency Risk Communications (CERC), specifically related to the actions of health care providers and health systems as they prepare for future emergencies.

Along with the EUA, the U.S. government purchased a large supply of mAbs so that treatment could be available at no cost to eligible patients. From the time of the issuance of the EUA until August 2021, only 5–20% of the initial supply was administered because many providers declined to take their allotment [4]. Edwards [4] reported in December 2020 that many doctors were reluctant to use mAbs for many reasons, including knowledge and logistics.

A lack of uptake can reflect low general knowledge of a treatment among providers. This was the case with previous novel FDA-approved treatments, such as pre-exposure prophylaxis (PrEP) treatments for human immunodeficiency virus (HIV) antiviral medications. In that case, a lack of provider knowledge meant that the medication was not being prescribed, even when patients inquired about it [5]. Uptake of a new treatment authorized during a pandemic could be limited by this problem, because providers must stay up to date with evolving clinical knowledge while also treating surges of patients.

Among providers aware of the treatment, a factor influencing adoption was the EUA status of mAbs. At the time of our study in June 2021, REGEN-COV (Casirivimab and Imdevimab) and the Bamlanivimab/Etesevimab combination were the only two mAb products covered under the EUA, which were authorized in March 2021. For some, it was perceived there were not enough data at the time the EUA was issued to show efficacy [6]. Some providers stated that they were not willing to carve out

resources to manage the logistics for an "experimental" treatment [4].

The practical logistical challenges of providing mAb infusions contributed to provider hesitancy and reluctance [7]. Many outpatient providers "have a general lack of familiarity around utilizing outpatient infusion centers," and, consequently, they are more reluctant to prescribe because of the additional knowledge needed when they are already overcommitted [6]. Prior to the EUA update on June 3, 2021, that authorized subcutaneous injection for one of the already authorized mAbs, administering mAbs required the use of infusion centers, necessitating providers to navigate treating contagious COVID-19 patients in facilities with existing vulnerable populations like cancer patients, [4] or setting up separate sites specifically designed for COVID-19 infusion treatment. While the required logistics and planning overwhelmed some providers who were already short-staffed due to inpatient staffing needs, others, even in rural and remote areas, were able to arrange to refer patients to larger medical facilities instead of providing mAbs themselves [4, 6].

Response to the COVID-19 pandemic required a strategy for the rapid turnaround of information about evolving treatments during a public health emergency on a scale not needed since EUAs were initially authorized in 2004 [8]. Prior to the COVID-19 outbreak, the issuance of EUAs was comparatively rare and thus challenges providers' expectations of "administrative norms" related to therapeutic communication and acceptance [9]. This study of accelerators and barriers to provider adoption of COVID-19 mAbs identifies factors that may help speed provider adoption of authorized treatments in future public health emergency communication.

Implementing innovations in healthcare settings

MAbs have been used in healthcare for decades [10]. Yet, in terms of therapeutic treatments for COVID-19, they can be considered an innovation—what Rogers defines as "an idea, practice, or object that is perceived as new" [11]. This perception can be particularly true for providers who are not accustomed to ordering and prescribing mAbs.

Diffusion of innovations theory

To help understand why COVID-19 mAbs were adopted at different rates with different providers, it is helpful to apply Rogers'[11] DoI theory. DoI helps in understanding how, why, and the speed at which new innovations spread, or are "diffused." In this theory, "diffusion" is a social process that includes multidimensional and intersecting components: an innovation that is communicated

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through channels over time among members of a social system [11–14]. It is used frequently to inform changes in clinics and hospitals, as well as other aspects of public health—e.g., health communication research, prevention campaigns, and behavior change interventions [12, 13, 15, 16]. It provides a grounding framework for understanding barriers and accelerators to the diffusion of an innovation, and the factors that might influence its adoption or rejection.

Rogers distinguished between groups of adopters, based on how quickly they accepted an innovation, calling them innovators, early adopters, early majority adopters, late majority adopters, and laggers. Identifying different types of adopters helps identify the related accelerators and barriers that can influence the speed of an innovation's diffusion.

The DoI concepts most pertinent to understanding the barriers and accelerators in implementing a new EUA treatment include knowledge, communication channels, and social systems. Knowledge is the first step and basic requirement for diffusion in that a lack of knowledge can be a barrier to adoption, whereas the presence of knowledge can accelerate it [13]. Communication channels are key in accelerating diffusion because they are how knowledge gets from one person or group to another. Rogers [11] emphasized that "the nature of the information exchange relationship" between people or groups ultimately determines whether communication about the innovation will occur and argued that interpersonal communications channels tend to be the most persuasive for adoption. In fact, peer-to-peer communication resulting from an educational campaign may have even more impact than viewing the campaign messaging itself [17, 18]. Evidence also suggests that interpersonal communication may be an effective means of combatting health misand disinformation [19]. Although many might assume that the science and data are often the most persuasive aspects when considering innovations, Rogers argues that diffusion is a social process that relies heavily on interpersonal relationships and social systems.

Rogers [11] defines a social system as "a set of interrelated units that are engaged in joint problem solving to accomplish a common goal" (p. 23). Weiner, et al., [20] argue that complex innovations "entail collective, coordinated action by many interdependent individuals"—that success of innovation implementation is essentially a team effort, not an individual effort, and individuals need larger systems in place to help implement the innovations they decide to adopt.(p. 425) Among physicians, evidence further suggests that without the influence of a top opinion leader to champion an innovation to their physician peers, adoption is unlikely [21].

We acknowledge that there are other frameworks that could also be applied in this study—such as the capability—opportunity—motivation—behavior (COM-B) model [22] and the Theoretical Domains Framework (TDF), [23] among others. These frameworks are helpful for understanding individual behaviors and motivations. DoI was chosen for this study because it can assess diffusion among individuals, as well as organizations, or larger systems, [24] giving insights into the systems and structures in place that might be facilitating or hindering the adoption of an innovation.

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Emergency situations

Most DoI public health research focuses on chronic problems and diseases and is rarely applied to emergency and fast-moving situations. For example, previous research has focused on large health campaigns (e.g., smoking cessation, seatbelt use, prevention of opioid overdose, reducing HIV rates, or the introduction of technology infrastructure) that have the luxury of months or years of pre-planning [15, 16, 20, 25] Rogers [11] emphasized this point, explaining, "Many innovations require a lengthy period of many years from the time they become available to the time when they are widely adopted," some of which attempt to speed up this process.(p. 1) A frequently cited study found that it takes approximately 17 years for an innovation to reach 50% adoption [26, 27].

In contrast, the COVID-19 pandemic required that decisions be made quickly, especially in terms of health-care delivery; waiting years, or even months in most cases, was not an option. For example, Sklar et al. [28] studied how mental health providers had to move to telehealth services due to stay-at-home orders during COVID-19 in a matter of weeks instead of what would normally be closer to a three-year transition.

Rapidly changing emergency situations can complicate the DoI process because constant changes can create additional communication and knowledge barriers, as Wensing, et al., [29] aptly summarized:

The amount of immediate information on Covid-19 is very high: there is an ongoing flow of research evidence (much of it not yet peer reviewed, or minimally reviewed), clinical guidance, regulations by authorities and messages in the media. In many countries, the numbers of hospital admissions and deaths due to Covid-19 are reported daily in the general media. Much of this information is uncertain, inconsistent, and quickly replaced or complemented by new insights and guidance. (p. 2)

In emergency situations, "efficiency in intervention" is even more critical [30]. CERC principles anticipate the need for this efficiency by encouraging the development Williams et al. BMC Public Health (2023) 23:183 Page 4 of 12

of relationships of trust before a crisis occurs [31]. This principle is consistent with DoI theory and practice, which has found that individuals with preexisting networks and relationships are more likely to hear about innovations and adopt them [29].

Yet there has been limited attention to how CERC is being performed in public health and health care settings [32] and few studies of DoI amongst providers in emergencies. The few existing studies examine enhancing communication (such as the Ow Yong, et al., [32] study from Singapore), shortening of the adoption curve for less complex interventions than mAbs, [33] and using DoI principles to facilitate the adoption of new guidelines, [34] but do not involve qualitative, in-depth study of barriers and accelerators. Our study addresses this gap by examining accelerators and barriers to provider adoption of a new medical treatment under EUA during the COVID-19 public health emergency. Specifically, our research aims to answer the following research questions:

RQ1: What barriers and accelerators did providers experience in adopting COVID-19 mAbs as an EUA treatment?

RQ2: What do these barriers and accelerators reveal about speeding diffusion of innovation during a public health emergency?

Methods

We employed a qualitative method of inquiry [35] to explore themes associated with diffusion of mAbs treatments among providers as part of an HHS campaign.

Participants and procedures

Participant selection followed three primary inclusion criteria that were defined by the campaign and provided to a third-party recruitment firm to identify candidates. First, participants were healthcare providers, chiefly physicians or nurse practitioners involved in referring and prescribing available treatment to COVID-19 outpatients. Second, participants were selected to represent a range of provider types, including primary care providers, infectious disease specialists, rheumatologists, and cardiologists, and a mixture of healthcare practice settings including large health systems and smaller group practices.

Third, participants came from states with the highest COVID-19 infection rates at the time of the study and from higher social vulnerability index counties, in accordance with the goals of the U.S. government campaign described earlier. Counties of higher social vulnerability were identified based on the Centers for Disease Control and Prevention (CDC) Social Vulnerability

Index [36]. To ensure geographic representation, states were in separate ASPR-coordinated regions [37]. States with active statewide mAbs initiatives (including provider education) were excluded, as these initiatives would potentially bias participant answers.

As soon as potential participants were screened and deemed eligible, they were scheduled for interviews. When 5 participants were screened and scheduled for interviews in a state, no further interviews were scheduled in that state. No scheduled participants cancelled their participation or were removed from the study.

Given the inclusion criteria, we conducted a total of 20 interviews, each from one of the four stratified states: Florida, Minnesota, Nebraska, and Pennsylvania. As indicated by Bowles and Lankenau, [15] small sample sizes used in qualitative research, like this, can "uncover [a] comprehensive understanding of complex issues, such as diffusion," and are "appropriate for uncovering programmatic diffusion and impediments." (p. 346).

Once interviewees acknowledged their informed consent, the interview protocol followed a semi-structured, funnel-shaped interview question format which began with general questions about each participant's environmental context, including their familiarity with mAbs. Gradually, more structured, in-depth questions led to more specific inquiries around enablers and barriers to COVID-19 treatment referral for mAbs, including influences from collaborative partnerships such as peer networks if applicable.

In addition, we classified our 20 participants into groups, following Rogers' DoI: early adopters, middle adopters, and late adopters. This classification was based on the timing of mAbs adoption and level of knowledge about mAbs and their implementation. For example, early adopters—what Rogers refers to as innovators and early adopters—began referring patients to mAbs within two months of the mAbs EUA announcement in November 2020. Middle adopters-what Rogers refers to as early and late majority adopters—began utilizing mAbs between February-June 2021. Late adopters—what Rogers refers to as laggers—were: (1) not referring patients to mAbs at the time of our interviews in July 2021, or (2) referring patients that did not meet eligibility criteria because the provider was not familiar with the criteria, or (3) were giving inaccurate information to patients. July 2021 was late to implement, given that the Infectious Disease Society of America (IDSA) and the National Institutes of Health (NIH) recommended use of mAbs in March and April 2021, respectively [38, 39]. Three providers mentioned that the NIH recommendation would have influenced their adoption had they known about it; given that three months passed between the NIH recommendation and our interviews in July 2021, late adopters Williams et al. BMC Public Health (2023) 23:183 Page 5 of 12

Table 1 Participant demographics

	N (%)
State	
Florida	5 (25%)
Minnesota	5 (25%)
Nebraska	5 (25%)
Pennsylvania	5 (25%)
Gender	
Female	10 (50%)
Male	10 (50%)
Job Position	
Physician	12 (60%)
Nurse Practitioner	4 (20%)
Registered Nurse	3 (15%)
Director of Nursing	1 (5%)
Medical Specialty	
Internal Medicine	3 (15%)
Cardiology	2 (10%)
Rheumatology	2 (10%)
Nephrology	1 (5%)
Primary Care/Family Practice	4 (20%)
Nursing	2 (10%)
Emergency Medicine	3 (15%)
OB/GYN	1 (5%)
Unassigned	2 (10%)
Adoption of mAbs	
Innovators	6 (30%)
Early	2 (10%)
Middle	6 (30%)
Late	6 (30%)
Healthcare Setting	
Health System	4 (20%)
Hospital/Emergency room	8 (40%)
Private Practice	6 (30%)
Solo Practice	1 (5%)
Other/Nontraditional	1 (5%)

experienced a significant barrier to knowledge transfer in an emergency, a topic discussed later in this paper. Based on the DoI definitions, we classified our interview participants as such: eight (n=8) early adopters, six (n=6) middle adopters, and six (n=6) late adopters (see Table 1 for more details and demographic information). Of the eight early adopters, six were classified specifically as innovators because they led adoption in the practice setting.

Data collection and analysis

Upon Institutional Review Board (IRB) approval, the one-hour interviews were conducted via Zoom and

transcribed, producing 670 single-spaced pages. Personal identifiers, recordings, digital files, and any other material used in the study were held in an access restricted location. Names of the study's participants are not directly attributable and named individuals in the interview output are strictly suppressed. However, for purposes of analysis, title, role, and demographic information of the participant may have been used for data comparison, if voluntarily provided.

Transcripts were uploaded to NVivo 12 and NVivo R. The literature review informed a baseline codebook of anticipated themes against which emerging and divergent themes could be identified. Interviews were coded by two of the authors, using the constant comparative method [40]. Additional themes were added if they continually reappeared in the data, and the investigators met with the first author to discuss the new themes, reach consensus, and create hierarchal codes that grouped related codes under hierarchal categories to make sense conceptually [41]. During this time, these three authors also made observations of each interviewee's stated working environment to discover other influences on their perceptions of mAbs as COVID-19 therapeutics. The convergence of the interviewee's explicit comments, derived alignment to anticipated categories, and environmental influences helped to formulate a narrative around provider perceptions of available treatments under EUA.

Results

In our results, we discuss the accelerators that participants identified—tools, processes, or other mechanisms that increase the likelihood of mAbs adoption. We also discuss the identified barriers, or the obstacles participants discussed that made mAbs adoption difficult or less likely to happen. Our focus on how EUA information and knowledge were consumed provided additional insights on rapid adoption of innovations in context of DoI by exploring the differences between early, middle, and late adopters of mAbs under EUA. Table 2 summarizes the accelerators and barriers to mAbs adoption discovered through our study.

Accelerators to mAbs adoption

Accelerators to adoption were mentioned by the majority (70%) of participants. Among the 20 participants, the most mentioned accelerator was *collaboration* (n=12), followed by *communication* (n=10) and then a *proactive approach* (n=7), for example, the proactive establishment of a pathway for providers to refer patients. While there were only two participants who mentioned the EUA itself as an accelerator, those responses were notable given that EUA status created skepticism for others (see barrier section below).

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Table 2 Accelerators and Barriers to provider adoption

Accelerators to Provider Adoption

<u>Collaboration</u>: Peer influence, prevalent in larger health systems, improves early adoption

<u>Communication</u>: More frequent, interpersonal communication from experts and other providers played a more influential role than online communication

<u>Proactive Approach</u>: Providers within systems with established referral pathways at the time of assessment were faster to adopt treatment

<u>EUA as an Accelerator</u>. Treatment authorization, particularly when accompanied by clinical evidence, was seen as an accelerator for some providers

Barriers to Provider Adoption

<u>Lack of Knowledge</u>: Confusion regarding treatment eligibility, evidence, and authorization was augmented by access to rapid changes in treatment information

<u>Complex Logistics</u>: While referral pathways and processes could be resolved quickly, staffing, infusion center capacity, and other logistical complications limited adoption

<u>Skepticism</u>: Treatment efficacy supporting emergency use authorization (versus approval) hindered treatment adoption

<u>Cost</u>: Confusion regarding treatment cost and concerns regarding administration costs limited treatment adoption

<u>Silos</u>: Providers, particularly those outside of large health systems, felt isolated from treatment information which led to late adoption

Collaboration

Participants who worked in health systems and hospitals commented on the high level of collaboration and interdependence with other experts that accelerated their adoption of mAbs, strengthening prior DOI evidence regarding the importance of peer influence on early adoption [21]. One nephrologist from a large health system said, "everybody in the system that we're in was working together...collaborating for the best interest of the patient." Other early adopters described multidisciplinary teams and peer-to-peer collaboration on mAbs, including collaboration with pharmacists that played a key role in their understanding and adoption of mAbs. One illustrative physician comment was: "If I'm going to be putting medication in your arm, I want to know that other colleagues, obviously far smarter than me, have said it's okay to do this."

Notably, no participant in a private practice mentioned that collaboration with others accelerated their adoption of mAbs. An emergency room physician provided a possible explanation: "I think that a lot of my primary care peers don't have a lot of experience with monoclonal antibodies and aren't as well versed in the literature because they don't have an embedded pharmacist spoon feeding them information about it."

A few participants mentioned the importance of collaboration beyond an individual health system or hospital. For example, a hospital in a rural area had a pre-existing relationship with other small hospitals and collaborated with them to speed mAbs access, and a health system in a major city worked with other health systems in the region to coordinate availability of mAbs for populations negatively affected by social determinants of health.

Communication

Several participants described the importance of "real time" or "instant" communication that they received from their health system, hospital, or pharmacist about changes related to mAbs, in addition to weekly calls with infectious disease specialists and other providers. Several participants said that ongoing, regular calls with the state or local health department held for providers helped them stay current and learn how to handle different patient situations and unique circumstances.

While online sources and professional publications played a role for providers, organizational/institutional communication or interpersonal communication with other providers and experts appeared to be the most robust accelerants to adoption, confirming DoI literature cited earlier that this type of communication often has the most impact [11, 17, 18].

Proactive approach

Provider adoption was accelerated by health systems and hospitals that took a proactive approach to providing mAbs by setting up systems and referral pathways that reduced the burden on individual providers for assessment. For example, some systems had a staff member reviewing positive test results (including from urgent care) to proactively identify and cold call patients who met the mAbs eligibility criteria. Others made it easy for providers to refer appropriate patients, with centralized staff managing contact with the patient, answering questions, and scheduling treatment.

EUA as an accelerator

A few participants mentioned the EUA itself was an accelerator. These may be examples of the rapid adoption of treatment due to a crisis, a topic discussed by Wensing, et al., [29] and covered in our discussion. One innovator said: "When the FDA approved [sic.] it, I had confidence that this is what we should be doing and trying. . I never really was of the opinion that it was pushed through too

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quickly. . if they got emergency authorization, they had enough data to say [it] could work."

Additionally, in almost all cases, participants (from early adopters to more skeptical participants) felt more confident after reviewing the information sheets with the clinical evidence from the HHS campaign and the EUAs at the end of the interviews, suggesting that exposure to credible information in summary form might help accelerate adoption by filling in EUA information gaps and reducing the need for providers to dig into primary sources themselves.

Barriers to mAbs adoption

As there were several noted themes related to accelerated use of mAbs among providers, there, likewise, were common themes seen in barriers to mAbs adoption among study participants. Barriers were mentioned by all but one of the participants (n=19). Of the 20 interviewed providers, the most cited barrier for lack of mAbs utilization was general *lack of knowledge* (n=15) about mAbs, followed equally by complex *logistics* (n=8), *skepticism* (n=8) of mAbs as an effective and safe treatment option for their patients, and perceived *costs* (n=8) associated with treatment, and then feeling *siloed* (n=7) to learn about mAbs.

Lack of knowledge

Most participants (n = 15) identified lack of knowledge as a barrier to utilizing mAbs as a treatment, and this sentiment was evenly distributed across innovators, middle adopters, and late adopters. Providers commented about not being aware of availability of mAbs, who was eligible for them, or how to get them. One stated problem was simply knowing where to get information about mAbs. One late adopter said: "The problem has been obtaining knowledge. It's so fast, and it's so changing, and so it's really difficult because at the same time, you're working your full schedule. And so, trying to figure out where to obtain information [is a challenge]." In addition to obtaining information, many who had some information, still felt like they did not know enough. For example, an early adopter physician in a health system said that providers struggle with "knowledge about who should get it and knowledge about how to get it." Similarly, a middle adopter who is an ER nurse practitioner felt very unprepared to talk to patients about mAbs, explaining, "I felt like when I would go into a patient room, I could have been more well versed in providing information to them. But [I] really just didn't have it."

Another physician in a health system explained that many providers are not educated on the eligibility details of the treatment. A physician at a private practice cited a case where her colleague was misunderstanding the EUA eligibility criteria and not offering treatment to eligible patients, but she was able to intervene and correct the situation. Five participants revealed their own misunderstanding or lack of knowledge in their interviews. For example, a physician in a solo practice read the EUA eligibility requirements during the interview and realized for the first time that the treatment must be given before patients are hospitalized (they had been referring the wrong patients). A physician in a health system and a registered nurse each commented that one of the biggest barriers for referring patients was their complete lack of knowledge about mAbs-no one had even talked to them about the treatment and how it is safe and available for patients. A nurse practitioner in an emergency department explained his difficulty in talking to patients about mAbs because of his own lack of knowledge, saying, "I could only share what I know, which isn't very much." Another physician in a private practice explained that he told patients he was unsure if the mAbs that treat COVID-19 are the same as those used to treat other diseases. He also did not understand the eligibility and had referred patients who had "lingering symptoms" (and therefore likely past the 10-day eligibility window) who were ultimately rejected for treatment.

Complex logistics to deliver treatment

Another key barrier was logistics—what is referred to in the DoI literature as "informational assessment"—including staff capacity, infusion center capacity, and the lack of a referral system [12]. While some of these logistical issues are difficult to remediate quickly, others, such as the lack of a referral system or knowledge about how it works, were rapidly addressed by health systems and hospitals in our study.

Nurses administer mAbs treatment, and the U.S. has simultaneously been experiencing an ongoing nursing shortage and a pandemic, stressing staff capacity to its limit [42]. Participants explicitly noted nursing staff time to administer infusions as a barrier, especially during a surge when they were already "super busy." One nurse practitioner explained that her rural hospital had to limit mAbs administration to weekdays due to nursing capacity, "We as a hospital said we're not giving these infusions on weekends because we just don't have enough. nursing staff to do the one-on-one monitoring that's required." Another explained that limited infusion center hours caused people to come to the ER for infusions after hours, which frustrated ER nurses who were already spread thin.

Because of the emergency nature of the situation, logistics were oftentimes planned in real time. As one physician working in a health system in Florida explained, "but this again, was not something we had five years to

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prepare for." A nurse practitioner at a private practice in Minnesota expressed a desire to have more training on how to order infusions, especially because of the discrepancies between CDC, state, and organizational protocols. She also explained that her hesitation and frustration with mAbs was not the treatment itself, but the "red tape" and "that it's not necessarily the science that's rushed" but the logistics. Similarly, a private practice physician in Pennsylvania expressed frustration that she could not find someone who knew the process of referring patients for mAbs, explaining that in a typical situation with treatment, "either you call a pharmacy to send in a prescription, or you can call a department," but she called the infectious disease department and the pharmacy and neither knew who she could contact to get mAbs for her patients. Some providers received incorrect information about how and where to refer patients or had to spend significant time determining how to refer. One provider mentioned the frustration of spending time to decipher the referral process only to discover that their patient could not receive treatment: "when they launched [mAbs], there was such a short supply of it, that when we went into the lottery system, that actually put a lot of distaste in providers mouths. And I don't know that you can make up that first impression, like. I made it this far and then [my patient didn't receive it]."

Time was cited by others as a logistical barrier, as well. A nurse practitioner at a rural hospital and clinic in Nebraska explained that "just being able to break away from clinic or the emergency room just to consent people" was difficult, especially because it also meant refamiliarizing with the consents. She was also concerned that patients might continue to get sicker while waiting for treatment. This concern also was shared by a registered nurse at a health system in Pennsylvania who attributed logistical challenges to the amount of time it took to get a patient to treatment, "But the multitude of steps in between with the short timeframe to be able to administer it, is a challenge, especially when people get the results, they've already waited three or four days."

Skepticism

Almost half of participants (n=8) questioned the efficacy and/or safety of mAbs treatment because it was new and not fully approved. Several mentioned that providers did not have conviction about mAbs efficacy, which affected their representation of the treatment to patients. A few participants specifically mentioned the EUA status of mAbs as a barrier. One physician in private practice, a middle adopter, commented that the EUA made him less confident about referring patients for treatment because "EUA implies that this may not be totally studied or even

totally effective, but we're giving permission to use it regardless because it may help." Several participants commented that they did not have enough time to become familiar with the mAbs clinical evidence themselves, contributing to their hesitancy. Many participants stated that their initial skepticism was addressed by knowledge exchange with expert colleagues. While expert communication and collaboration may not eliminate skepticism, our findings suggest that it plays an important role in reducing it. Seven of the nine participants who expressed skepticism worked in a hospital or private practice rather than in a health system.

Cost

Cost of the treatment was mentioned as a barrier by almost half of participants (n=8), even though the federal government provided the mAbs product itself at no cost to the patient. Some participants mentioned patient costs as a barrier, because they were unaware that the product was provided at no cost and that administration costs were covered as well for most patients. As a result, these providers were unable to confidently reply to patient concerns about cost as a barrier.

Several providers raised broader cost concerns about mAbs treatment, including costs to the health care systems, the financial hit to hospitals, including costs related to providing treatment-related resources (i.e., staff to administer infusions and clean infusion center rooms), and costs of provider time to determine how to refer patients to treatment in locations where a clear referral pathway did not already exist. Cost was more often a barrier for participants in private practice (5 of 8 total) than it was for participants who worked in healthcare systems or hospitals.

Silos

Several participants (n=7) said they were "left on their own" to decipher how to use mAbs and find treatment locations for their patients. None of these participants were part of a health system, and they were most commonly late adopters rather than early or middle adopters. One late adopter in a large private practice said, "if you're trying to get providers to start really utilizing something, [it needs to be] hammered into us. . handheld and walk us through, and that has not happened with this at all." Others commented that they were not part of a network that communicated about mAbs or did not have access to a pharmacist as a source of information. A few providers highlighted the isolation of smaller hospitals, some of whom heard about mAbs by happenstance from informal networks with other hospitals.

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Discussion

Our study on mAbs provider adoption revealed the stark consequences of practice variation during the COVID-19 pandemic. Some of our participants (n=8)worked in settings that adopted mAbs soon after the EUA was issued while other health systems, hospitals, and practices were not as quick to act. The providers in late adopter settings sometimes neglected to refer appropriate patients to mAbs or provided inaccurate information to patients months after the IDSA mAbs recommendation in March 2021 [43] and the NIH mAbs "A" rating and recommendation in April 2021 [43–45]. Given the evidence that mAbs reduced the relative risk of COVID-19 hospitalization and death by 70% or more, [1] continued late adoption that extended into the July 2021 time period of our study likely contributed to unnecessary patient hospitalizations and even death [46].

Our results reveal strategies that could help speed diffusion of new treatments during a public health emergency. By understanding the barriers that slow behavior change by mid and late adopters, and by identifying the accelerants that contributed to early adoption, we can distill lessons for accelerating patient access to potentially life-saving EUA treatments in the future. The three major conclusions of our study are summarized below.

Peer-to-peer communication of evidence

Perception of the scientific and clinical evidence is fundamental to provider adoption under an EUA and can be encouraged by active peer-to-peer communication. The major barriers of skepticism and knowledge were grounded in provider (mis)perceptions of mAbs scientific and clinical evidence as well as their misunderstanding about the standards that must be met for a treatment to receive EUA. Implications for future emergencies include rapid sharing of expert opinion, clinical evidence, and EUA standards through widely available educational opportunities. While it may be tempting to assume that web-based resources and education will be enough to disseminate new information, evidence revealed in the literature and corroborated by our study suggests that these activities will be more effective if they stimulate active peer-to-peer communication, for example, through the opportunity to have conversation with experts about the evidence. In our study, providers in large health systems were more likely to have these peer-to-peer conversations, and, confirming previous research, tended "to be more exposed to innovations and. . more inclined to adopt these." [29] In other words, providers in large health systems were more likely to be innovators and early adopters. Our study revealed that peer-to-peer communication strengthened the knowledge and conviction of providers about the mAbs clinical evidence and made them more likely to prescribe mAbs to their eligible patients.

Participants in private and solo practice, which lacked the institutional peer networks of larger systems, presented the most skepticism and misperception of cost. Evidence suggests that tailoring communication to include "collegial support of the peers" could help provide a "coping mechanism" to these more isolated providers and address cost and skepticism barriers [47].

Implementation processes for siloed providers

Due to the complexity of eligibility factors and logistics to administer mAbs, development of implementation processes by early adopters was vital, and the challenge was to disseminate implementation models rapidly to more siloed providers. Our analysis demonstrated that those who were late adopters of mAbs treatment were often siloed and in settings with no processes in place to refer patients. Consistent with CERC principles discussed earlier, social networks and relationships of trust can and should be established with more siloed providers before another emergency occurs. The referral systems and other processes developed by early adopters could be deliberately shared through these networks, so that providers who are more typically middle and late adopters are in a better position to make emergency treatment available rapidly.

Systematic communication from health departments and associations

Our study revealed the importance of ongoing communication from health departments and professional associations in an emergency. Many providers emphasized this source of communication and access to experts (about treatment, eligibility, processes, etc.) as vital in their early adoption of mAbs treatment, and these organizations can play a central role in the needed outreach to more siloed providers.

During the HHS campaign to increase provider adoption of mAbs, promising practices used by state health departments, health systems, and professional associations were identified and shared widely. The elements of those promising practices were consistent with the findings of this study, in that peer-to-peer networks, interpersonal communication, and interdependence with other experts were key factors in these successful initiatives.

However, improving communication consistency from health departments and associations during a health emergency should be explored. Notably, the IDSA and NIH were slow to recommend the use of mAbs at Williams et al. BMC Public Health (2023) 23:183 Page 10 of 12

the time of the initial EUA in November 2020, [38, 39] although the demonstrated benefit of mAbs became evident by the time of this study in 2021 [48]. Whereas constructive disagreement is encouraged among academics, it likely contributed to the confusion among providers. Further work to assess, document, and align state health department, health system, and professional association communications is called for, as is strengthening public health infrastructure so health departments can continue to play a vital role in information dissemination and coordination for new emergency treatments in future health crises.

Limitations

Many limitations were reflective of this study being conducted in part to inform a public health campaign during a public health emergency. Therefore, the participant recruitment window was very short, limiting the time to potentially expand recruitment and further explore less common provider environment demographics, such as providers in concierge practices or those in mobile practices. Additionally, due to the nature of the research, we limited our study to four states and excluded providers in states with proactive health department mAbs initiatives. Furthermore, given that COVID-19 patients were overwhelming healthcare facilities at the time, recruitment of providers may have resulted in a bias toward providers who were early adopters and had more manageable systems in place, and the most overwhelmed, and potentially uninformed, providers may not have had the time to respond.

Our theoretical framework of DoI also has some limitations when applied in this situation. As noted previously, DoI is rarely used in emergency or fast-moving situations, instead often being applied to the diffusion of innovations over decades. In pandemics and similar emergency situations, this type of time is not available. Another potential limitation is that the framework does not explicitly address capabilities and capacity to deliver programs. Despite these limitations, the focus of DoI on individuals as well as systems sets it apart from other theories that address only individual behavior. DoI was helpful in understanding the larger context in which mAbs adoption was (or was not) occurring, highlighting the different barriers that must be addressed in similar situations. Furthermore, the logistical challenges in program delivery emerged in the interviews and were addressed above when discussing the complex logistical barriers (such as staffing and available treatment space). For these reasons, and others cited previously, applying the DoI framework to this study has revealed important insights for future situations and adds to existing DoI literature.

Conclusion

Our study found that the primary challenge providers faced in an emergency was rapid access to knowledge via evidence-based, expert-backed, trusted information. This is especially important in a situation like the COVID-19 pandemic in which the virus continued to evolve and evade treatment, and clinical guidelines evolved in response. Consistent with DoI literature, lack of knowledge was a fundamental barrier to provider adoption and intersected with the other barriers revealed in our study. For example, lack of knowledge fueled skepticism of treatment, slowed down already complex logistics, and resulted in misunderstandings regarding treatment cost.

Access to and adoption of knowledge is improved through existing trusted provider information systems and networks. Establishing those trusted networks before an emergency occurs is a fundamental CERC principle, and DoI research underscores that providers who have preexisting networks and relationships are more likely to hear about innovations and adopt them. Mere passive access to information is not sufficient, however. This study revealed that peer-to-peer communication of evidence, rapid sharing of implementation processes with siloed providers, and systematic dissemination of evidence accelerated provider adoption of mAbs. Our study highlights the need for further documentation of initiatives by health systems, state health departments, and professional associations to establish active, systematic, and equitable patient access to life-saving treatment by expanding access to knowledge through provider networks. These trusted networks should be established before the next emergency occurs.

Abbreviations

HHS

ASPR Administration for Strategic Preparedness and Response

U.S. Department of Health and Human Services

CDC Centers for Disease Control and Prevention

COVID-19 Coronavirus disease 2019

CERC Crisis and Emergency Risk Communications

Dol Diffusion of Innovations FR Emergency Room EUA **Emergency Use Authorization** FDA U.S. Food and Drug Administration

HIV Human Immunodeficiency Virus

IDSA Infectious Disease Society of America

IRR Institutional Review Board

mAb/mAbs monoclonal antibody/monoclonal antibodies

NIH National Institutes of Health PrEP Pre-Exposure Prophylaxis

The authors would like to acknowledge the contributions of Risa Danan. Denise Scannell, and Linda Desens for their contributions to this research.

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Authors' contribution

SW and MG conceived and designed the research protocol. MM led the collection and analysis of the data by SW, MG, and JO. SW ensured appropriate ethics and consent were attained. MG and JO supervised data collection. SW, MM, and MG made substantial contributions to drafting this research manuscript and addressing subsequent revisions. JO provided substantial contributions for revisions as well as liaised with the U.S. Department of Health and Human Services to determine the manuscript scope and public release. The author(s) read and approved the final manuscript.

Funding

This study was supported wholly or in part with U.S. federal funds from the Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority, under Task Order Number 75A5012F80041.

Availability of data and materials

The datasets generated and analyzed for this study are not publicly available but are available from the corresponding author upon request.

Declarations

Ethics approval and consent to participate

The protocol used in this research was reviewed and approved on June 1, 2021, by the MITRE Institutional Review Board, approval number A080-M21-165. In alignment with the Declaration of Helsinki, all methods were carried out in accordance with relevant guidelines and regulations. Informed consent was obtained from all participants.

Consent for publication

Not applicable.

Competing Interests

The authors' affiliation with The MITRE Corporation is provided for identification purposes only and is not intended to convey or imply MITRE's concurrence with, or support for, the positions, opinions or viewpoints expressed by the authors. The views expressed are solely those of the authors and do not necessarily represent those of the U.S. Department of Health and Human Services.

Received: 31 August 2022 Accepted: 19 December 2022 Published online: 27 January 2023

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