CMS Reimbursement for Home-based Diagnostics

Bringing Point-of-Care Testing Home

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Overview

The COVID-19 pandemic has brought an unprecedented focus on the critical role of telehealth and at-home testing in healthcare delivery. The term telehealth commonly refers to the use of telecommunications technology to provide healthcare services remotely. The method can include video consultations, remote monitoring of patient health data, and digital messaging for communication with healthcare providers. On the other hand, at-home testing involves patients collecting samples for nearly instant results or sending the samples to a laboratory for analysis. This type of testing can apply to various conditions, including but not limited to COVID-19, sexually transmitted infections (STIs), and genetic predisposition to certain diseases.

The Center for Medicare and Medicaid Services (CMS) has recognized the potential benefits of these services, expanding coverage during the public health emergency to increase access to healthcare, improve patient satisfaction, and reduce risks and costs. This piece aims to delve into the advantages of remote point-of-care testing and its applicability for continued or expanded coverage by CMS for multiple use case scenarios such as infectious wdiseases, drugs of abuse, and sexually transmitted infections.

Furthermore, this paper highlights the need for clear regulatory guidelines and reimbursement policies from CMS to promote these services, ultimately enhancing access to testing, improving public health outcomes, and reducing long-term healthcare costs. Despite a lack of FDA regulations for at-home infectious disease testing, significant commercial interest in creating comprehensive home assays for various viral and bacterial pathogens underscores the pressing need for CMS to adopt these services.[1]

THE ADVANTAGES OF REMOTE POC TESTING

Point-of-care (POC) testing has been implemented in various healthcare settings, including pharmacies and ambulatory care clinics, exempt from complying with the Clinical Laboratory Improvement Amendments (CLIA). As a result, people outside the healthcare industry are using more tests due to the availability of sample-to-result testing that patients can do at home, commonly referred to as "at-home" or "home use" exams.

The advancement of molecular diagnostics has emerged as a critical catalyst for the progression of technology, making it possible to create companion diagnostics for drugs and innovative therapeutic procedures such as non-invasive testing. Molecular diagnostics have made noteworthy strides in both diagnosing illnesses and developing new pharmaceuticals, and they now have a significant role in the current healthcare delivery system.[2, 3]

INCREASED ACCESS

Due to various factors, accessing urgent medical care has become increasingly challenging and avoided in the aftermath of the pandemic. In such circumstances, teleconsultation has gained favor among individuals seeking medical attention, particularly those experiencing upper respiratory tract infections who would prefer to avoid lengthy queues at urgent care facilities. The availability of home testing provides patients with the convenience of being in the comfort of their own homes while receiving virtual supervision from healthcare professionals.[1, 4]

In the case of community-based HIV testing and counseling (HTC), remote testing services offer several anticipated benefits, including building public trust, reducing stigma and discrimination, and protecting human rights. Such services can also help overcome structural, logistical, and social barriers to accessing HTC, especially for those who cannot afford transportation to facility-based services.[5]

EQUITABLE ACCESS

Remote POC testing can increase access to healthcare for patients located in remote or underserved areas. By providing timely and accurate diagnoses, which is crucial for chronic condition management, remote POC testing can help bridge the healthcare access gap and ensure that all patients can have access to necessary care, regardless of their location or socioeconomic status.[4, 6]

REDUCED COSTS

Remote POC testing can be a cost-effective approach to managing healthcare, as it eliminates unnecessary testing, reduces hospital readmissions and emergency department visits, and can significantly reduce healthcare costs. By using remote POC testing, patients can receive accurate and timely diagnoses and treatment plans without the need for in-person appointments, reducing the overall cost of healthcare.[1, 7]

Remote point-of-care testing provides a more convenient alternative, where patients are given a prescription for a home-use test kit. A healthcare provider (HCP) then helps the patient or a family member administer the test and run it with the provided kit. Billing and coding are still implemented from delivery through in-home assay runs. However, the cost for this example is reduced to around $150 due to the streamlined nature of the procedure. Testing is conducted at a distant point-of-care location, with teleconsultation included in the procedure to allow for an HCP to be accessible during the whole procedure via video conference and a supervising HCP to interpret the findings as soon as they are available. The patient or members of the patient's family can conduct the test themselves.8 Remote point-of-care testing provides a more convenient alternative, where patients are given a prescription for a home-use test kit. A healthcare provider (HCP) then helps the patient or a family member administer the test and run it with the provided kit. Billing and coding are still implemented from delivery through in-home assay runs. However, the cost for this example is reduced to around $150 due to the streamlined nature of the procedure. Testing is conducted at a distant point-of-care location, with teleconsultation included

in the procedure to allow for an HCP to be accessible during the whole procedure via video conference and a supervising HCP to interpret the findings as soon as they are available. The patient or members of the patient's family can conduct the test themselves.[8]

To address potential arguments about the costs of specific POC tests possibly exceeding that of normal laboratory tests, there has been a suggestion to evaluate the economic impact of POC testing from a broader health system perspective, taking into account a longer-term view than what is typically considered in standard economic evaluations.[9]

REDUCED STAFFING NEED

There is currently a noticeable shortage of healthcare workers worldwide due to various factors, such as the recent pandemic, increased job demands, insufficient rest, and fear of contracting or spreading coronavirus.[10] These challenges have led to many healthcare workers leaving the industry. However, remote POC testing can help solve this problem as it requires less staff to provide virtual care to patients, accommodating more patients than face-to-face visits, alleviating the burden on healthcare workers, and potentially reducing burnout rates.

BETTER TREATMENT PLANS

POC testing can serve as companion diagnostics, helping healthcare professionals make informed decisions about whether to prescribe antibiotics or not. Combined with a telehealth visit, at-home POC testing can provide a more comprehensive analysis of the patient, resulting in a more effective treatment plan. In the context of European legislation, a companion diagnostic is defined as an essential device for the safe and effective use of a corresponding medicine, identifying patients who are likely to benefit from the medicine or at increased risk of serious adverse reactions due to treatment with the medicine, either before or during treatment. Typically, companion diagnostics have been utilized in precision medicine,[11] although several diagnostics for infectious diseases are being used as companion diagnostics, even if not officially approved as such.[12]

INCREASED PATIENT SATISFACTION AND ENGAGEMENT

By providing accessible and convenient healthcare services, remote POC testing can improve patient outcomes, engagement, and satisfaction. Patients benefit from timely and accurate diagnoses and discreet testing options for sensitive tests, leading to better treatment outcomes and management of chronic conditions. Additionally, remote POC testing enables patients to take an active role in their healthcare, ultimately resulting in higher patient satisfaction.[1]

THE CHALLENGES FACING REMOTE POC TESTING

Telehealth and remote POC testing have the potential to revolutionize healthcare delivery by providing patients with access to convenient and cost-effective care. However, these innovative technologies face several challenges that hinder their widespread adoption and use. These challenges include regulatory barriers, limited access to technology and infrastructure, reimbursement policies, privacy and security concerns, and provider resistance. Each of these challenges requires a comprehensive approach to overcome and fully realize the potential benefits of telehealth and remote POC testing. We will explore these challenges and potential solutions to ensure necessary healthcare access for all.

REIMBURSEMENT

One of the biggest challenges facing telehealth and remote POC testing is reimbursement. While some insurance plans do cover telehealth services, many do not, and the policies around reimbursement can be complex and difficult to navigate.

A study analyzing regulations for POC testing and reimbursement in seventeen European nations found that the reimbursement of POC diagnostics was necessary for the payment of diagnostics for community-acquired acute respiratory tract infections (CA-ARTI). This finding means that general practitioners or other health providers who work with outpatients must be reimbursed for conducting POC testing in their offices. Even in nations with a reimbursement list, funding from such lists was used for CA-ARTI studies more often than product-specific funding.[7]

REGULATORY BARRIERS

Remote POC testing faces significant challenges, such as accuracy and reliability concerns about test results, the requirement for sufficient training and support for healthcare providers and patients, and the possibility of rising healthcare costs if testing is not correctly targeted or unnecessary testing is carried out. Additionally, there is a pressing need for regulatory oversight and standardization to guarantee the safety and efficacy of remote POC testing. This guidance would necessitate proper test validation and approval, provider education and result interpretation, and straightforward test use and timing guidelines.[13]

Additionally, regulatory barriers such as licensing requirements, for example, can make it challenging for healthcare providers to offer services across state lines, while privacy and security concerns can limit the use of certain technologies.[1]

TECHNOLOGICAL INFRASTRUCTURE

Telehealth and remote POC testing require a robust technological infrastructure, including high-speed internet and reliable communication tools. However, these infrastructure components may not be available in many rural and underserved areas.

In California, the Department of Health Care Services' Post-COVID-19 Public Health Emergency Final Telehealth Policy Proposal released in December 2022 highlights the benefits of synchronous video and audio-only visits for Medi-Cal beneficiaries. Numerous studies have shown that telehealth offers particular benefits to patients with ongoing medical issues or behavioral health needs, including enhanced access to treatment, increased patient satisfaction, and reduced costs associated with seeking out-of-office care.[14]

PROVIDER AND PATIENT RESISTANCE

Some healthcare providers and patients may resist telehealth and remote POC testing due to concerns about the quality of care, the accuracy of test results, or the lack of in-person interactions. Overcoming this resistance will require education and outreach efforts to help providers and patients understand the benefits of these technologies.[1]

THE PATH FORWARD FOR REMOTE POC TESTING

Telehealth and remote POC testing have the potential to revolutionize healthcare delivery by providing patients with access to convenient and cost-effective care. However, the widespread adoption of these innovative technologies faces several challenges that CMS must address to ensure access to necessary care, regardless of a patient's location or socioeconomic status.

One of the biggest challenges facing telehealth and remote POC testing is reimbursement. While some insurance plans cover telehealth services, many do not, and the policies around reimbursement can be complex and challenging to navigate. CMS needs to create more straightforward policies for healthcare providers and patients to ensure that reimbursement does not serve as a barrier to the use of telehealth and remote POC testing.

Based on a study published in the National Library of Medicine, remote POC testing has the potential to improve patient outcomes and satisfaction, but this will not be possible if patients cannot afford it.[4]

Given the advantages of remote point-of-care testing, there is a compelling case for CMS reimbursement for these tests due to their significant value. As discussed previously, traditional laboratory testing including in-office visits, on-site sample collection, processing, and billing can be expensive for patients and primary care providers.

CMS coverage therefore can be costly, with estimated costs ranging from $200 to $300 for laboratory testing in conjunction with telehealth. In contrast, CMS reimbursement for at-home testing is estimated to be slightly more than $140. By covering remote point-of-care testing, CMS would be able to allocate its budget to benefit more individuals, as it would only cost half of what conventional testing coverage typically requires.

This approach could benefit more people and allow for greater coverage. It would only require half of the usual cost for conventional testing to cover remote point-of-care testing. Additionally, this would result in the utilization of the budget allocation for coverage, making it a more efficient use of resources.

CMS must address technology infrastructure issues by allowing currently available technologies, such as audio-only telehealth visits, to be utilized or by providing funding to improve and expand the technological infrastructure in these areas. CMS can ensure that all patients, regardless of location, have access to telehealth and remote POC testing.[14]

Regulatory barriers can also present challenges to telehealth and remote POC testing. Licensing requirements, for example, can make it difficult for healthcare providers to offer services across state lines, while privacy and security concerns can limit the use of specific technologies.1 CMS needs to create policies that enable healthcare providers to offer telehealth and remote POC testing services across state lines and establish guidelines for using technologies that address privacy and security concerns.

Overcoming patient and provider resistance will require education and outreach efforts to help providers and patients understand the benefits of these technologies. CMS can play a vital role in this effort by providing information and resources to healthcare providers and patients about the benefits and best practices of telehealth and remote POC testing.[14]

Additionally, CMS should address the issue of over-the-counter (OTC) testing and its applicability to Clinical Laboratory Improvement Amendments (CLIA) regulations. OTC testing provides patients with an accessible and convenient option for testing. However, it may be subject to a different level of regulation than laboratory testing conducted in a healthcare facility. CMS needs to establish clear guidelines for the regulation of OTC testing to ensure that it is safe and effective for patients to use.[4]

Both the CMS and the FDA are instrumental in the process of a solution. The CMS has the authority to regulate and reimburse for remote POC testing services, and its policies can significantly influence the adoption and utilization of these technologies. On the other hand, the FDA ensures the safety and effectiveness of medical devices, including remote POC tests. Its approval process is necessary to ensure these tests are accurate and reliable. Therefore, the collaboration between these two agencies will be essential in developing policies and regulations that promote the appropriate use of remote POC testing while ensuring patient safety and effective healthcare delivery.

CONCLUSION

Telehealth and remote POC testing have the potential to revolutionize healthcare delivery by providing patients with convenient and cost-effective care. However, several challenges must be addressed to ensure widespread adoption and utilization. Most importantly, CMS needs to create clear policies for reimbursement.

Reimbursement is one of the most significant barriers to adopting telehealth and remote POC testing. If patients cannot afford these services or healthcare providers cannot be reimbursed for providing them, the potential benefits of these technologies will not be realized.

It is crucial that CMS takes steps to ensure that healthcare providers are adequately reimbursed for telehealth and remote POC testing services. Successful at-home POC testing can be achieved by creating policies that are more straightforward and clear for healthcare providers and patients, to ensure that reimbursement does not serve as a barrier to the use of telehealth and remote POC testing.

Furthermore, CMS needs to establish reimbursement policies that reflect the cost-effectiveness of telehealth and remote POC testing. As we mentioned earlier, remote POC testing has the potential to improve patient outcomes and satisfaction, and at-home testing is estimated to be less expensive than traditional laboratory testing. By appropriately reimbursing for these services, CMS can help to ensure that patients have access to the care they need, regardless of their location or socioeconomic status. CMS could consider providing incentives for healthcare providers to offer telehealth and remote POC testing services. These incentives could take the form of increased reimbursement rates for these services or other financial incentives to encourage healthcare providers to adopt these technologies. By doing so, CMS can promote the widespread adoption of telehealth and remote POC testing, leading to improved healthcare access and outcomes for all patients.

CMS will also need to address technological infrastructure gaps, overcome regulatory barriers, and provide education and outreach efforts to healthcare providers and patients. However, outreach efforts would need to be much less if CMS has already promoted the services by allowing fair coverage and reimbursement for those services.

Collaboration between the CMS and the FDA is also essential in developing policies and regulations that promote the appropriate use of remote POC testing while ensuring patient safety and effective healthcare delivery.

CMS has a critical role in ensuring that all Americans have access to the care they need, regardless of their location or socioeconomic status. The time to act is now. By expanding the ability for providers to offer all applicable services via telehealth, allowing payment parity between in-person and telehealth services, and allowing most telehealth modalities for new and established patients, CMS can help to bridge the gap between patients and providers.

Additionally, by waiving site limitations and allowing for expanded access to telehealth through non-public technology platforms, CMS can help to ensure that patients in underserved and rural areas have access to the same quality of care as those in more densely populated areas.

CMS can take bold steps to provide this care as patients and healthcare providers advocate for changes in policies and regulations that promote the appropriate use of telehealth and remote POC testing. These services will improve patient outcomes and satisfaction and increase the efficiency and cost-effectiveness of healthcare delivery.

In conclusion, it is up to all stakeholders to work together to overcome the difficulties facing the widespread adoption and utilization of telehealth and remote POC testing. Reimbursement is a significant challenge facing the adoption of telehealth and remote POC testing. To ensure that patients have access to the care they need, regardless of their location or socioeconomic status, CMS must establish reimbursement policies that reflect the cost-effectiveness of telehealth and remote POC testing, and provide incentives for healthcare providers to offer these services. By doing so, CMS can promote the widespread adoption of these innovative technologies and revolutionize healthcare delivery in the United States.

It is time to create a healthcare system that provides convenient, cost-effective, and high-quality care to all patients, regardless of their location or socioeconomic status. Let us take action now to ensure that the future of healthcare delivery is patient-centered, technologically advanced, and accessible to all.

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