# Pooled Saliva Testing for Newborns Enhances Early Detection of Congenital Cytomegalovirus

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Infection Control Today® Editorial Staff

*News* *Article*

*Hadassah Medical Organization's pooled saliva testing for newborns effectively screens for congenital cytomegalovirus, identifying asymptomatic cases and potentially reducing severe cognitive and auditory problems globally.*



*Destruction of cytomegalovirus*

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In a groundbreaking study, Dana G. Wolf, MD, a senior infectious diseases physician at the Hadassah Medical Organization, and Moran Yassour, PhD, a professor of computer science and computational biology at the Hebrew University-Hadassah Medical School, have demonstrated that pooled saliva testing of newborns is a highly effective method for screening congenital cytomegalovirus (cCMV). This method can detect the virus even in asymptomatic infants, proving to be as accurate as individual testing and more efficient than the current global standard.

Published recently in *Nature Medicine*, the study's results indicate that adopting pooled-saliva screening globally could significantly reduce the number of children developing severe cognitive and auditory issues from cCMV. To learn more about the study, *Infection Control Today*® (*ICT*®) interviewed Wolf, who is also a professor of virology and infectious diseases at the Hebrew University in Jerusalem, where she heads the Clinical Virology Unit and holds the Ted and Frances Chanock Chair in Virology.

***ICT*: Can you explain the significance of the pooled saliva screening method in detecting congenital cytomegalovirus (cCMV), especially in asymptomatic newborns, as revealed by the study at Hadassah Medical Organization?**

**Dana G. Wolf, MD:** Cytomegalovirus (CMV) is the most common infectious cause of [congenital disabilities] in the US, with about one in 200 infants born with congenital CMV (cCMV). One in 5 infants born with cCMV will have life-altering health difficulties, some of them lifelong, such as hearing loss and developmental problems. The disabilities associated with cCMV can manifest at [birth] or develop later during childhood. Importantly, the majority (~90%) of congenitally infected newborns are asymptomatic at birth; however, 10-15% of initially-asymptomatic infants will later develop permanent complications.

*Dana G. Wolf, MD*

*(Credit by Avi Hayun)*

Thus, universal newborn screening of cCMV has been increasingly advocated to facilitate timely diagnosis and management of both symptomatic and initially asymptomatic newborns. In the absence of a high-throughput screening test that can identify all infected neonates, the development of an accurate and efficient testing strategy for universal cCMV screening has remained an ongoing challenge. Addressing this gap, we have developed and implemented the new pooled saliva screening method for cCMV.

***ICT*: What are the key takeaways for infection prevention personnel of this study?**

CMV is most often transmitted from the mother to the fetus via her placenta. While standard universal precautions can generally prevent its transmission in health care, CMV is often acquired at home and in daycares via close contact with young children. Since approximately 40% of the annual pregnancies in the US involve seronegative mothers who lack the virus antibodies in their blood, these women are at risk of developing primary CMV infection during pregnancy. The data derived from the newly implemented universal screening can define the true burden of cCMV and identify high-risk populations for the prevention of cCMV and its complications.

***ICT*: How does the pooled-saliva method compare to the current global standard of care for screening newborns for**

**cCMV? What advantages does this method offer in terms of accuracy and efficiency?**

Currently, targeted screening of cCMV infection by PCR testing of individual saliva samples is employed in many centers, focusing on infants who manifest at birth with failed newborn hearing screenings or clinically suspected cCMV infection. However, targeted screening of high-risk neonates misses the majority of infants with cCMV who are asymptomatic at birth yet are at risk for late-onset complications.

Testing individual saliva samples produces a vast number of negative results in addition to false-positive ones and is not optimal for large-scale universal cCMV screening. Here, we describe a way of minimizing screening costs while reducing the number of false-positive results and demonstrate the efficiency and accuracy of a pooling approach for universal screening. While the loss of sensitivity was minimal, the empirical efficiency was high, which means that 83% of the saliva tests that would have been required if testing each sample individually were no longer necessary.

***ICT*: Could you elaborate on the potential impact of implementing the pooled-saliva screening method as the new global standard of care for cCMV? How might this change affect the number of infants identified with the virus and subsequently receive treatment?**

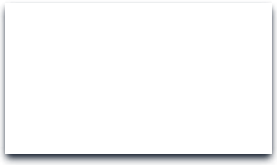
Our findings demonstrate the feasibility and benefits of pooled-saliva testing for universal screening of cCMV and support its global implementation. The pooled-saliva screening method can be easily implemented in any medium-to-large medical laboratory, and parental acceptance of cCMV screening was high, mitigating early concerns. Our finding that in the absence of universal screening, more than half of cCMV cases would have remained undiagnosed underscores the clinical implication of universal screening toward early diagnosis, monitoring, and potential treatment of cCMV.The study highlights the importance of universal screening in defining the true population prevalence of cCMV.

***ICT*: What inspired the decision to explore the use of pooled testing, initially successful in COVID-19 screenings, for detecting congenital cytomegalovirus? How has this method proven effective, particularly in identifying cases that might have been missed under the current screening protocols?**

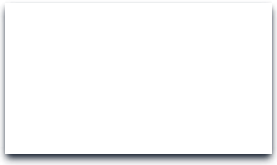
Our study was primarily driven by the unmet clinical need to identify all neonates with cCMV so that early treatment and monitoring could be delivered to a large proportion of infants who are currently missed. This project was facilitated by the newly available pooled diagnostic approach (which we have implemented to cope with the vast number of tests during the COVID-19 pandemic), which made universal screening of cCMV feasible.

Utilizing our preexistent pooling pipeline (including an easy robotic setup and a dedicated software), by which we had tested hundreds of thousands of patients during the pandemic, we were able to rapidly incorporate the new neonatal saliva pooling into routine clinical practice. Finally, an essential component of this study was the close collaboration of experts in virology, data processing, neonatology, and obstetrics. Together, the resulting screening rate of cCMV, approaching ~94% of all neonates at our centers, along with the high real-world efficiency and sensitivity of the pooled saliva tests, represent the most important achievements of the study.

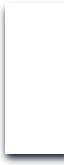
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