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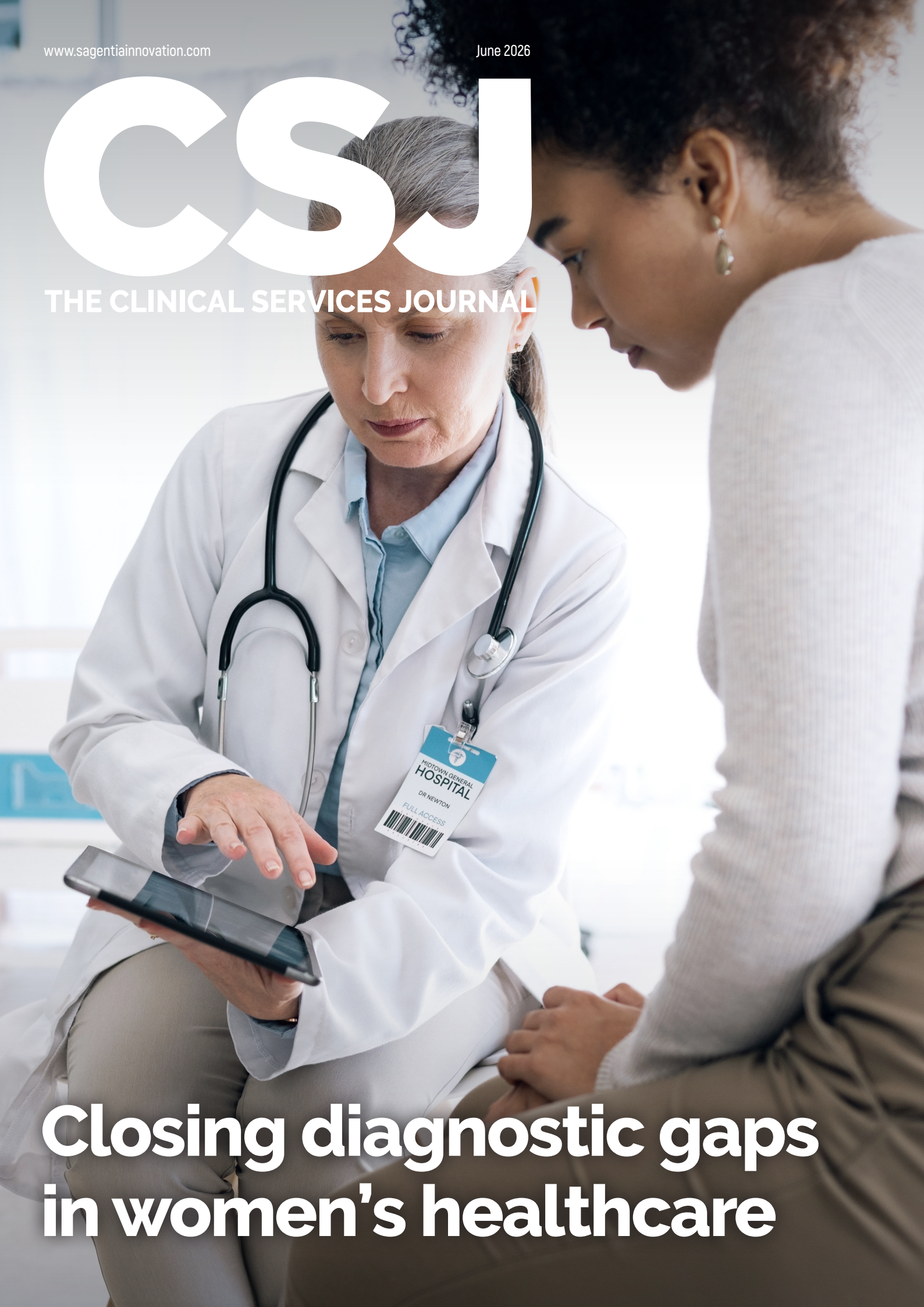

Closing diagnostic gaps in women's healthcare

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Hermione Blakiston and **Erica Kantor** warn that delayed diagnosis is having a negative impact on outcomes for women, while placing an increased strain on healthcare services. They look at the potential of promising biomarkers in closing the 'diagnosis gap'.

Diagnostic delays remain a persistent challenge in women's healthcare. In the UK, endometriosis can take more than nine years to diagnose,[1] leaving women to navigate years of unmanaged symptoms. Similarly, mastitis – which affects one in four lactating women – frequently goes undetected until inflammation becomes severe, even though early self-management can be highly effective for preventing escalation.

Delayed diagnosis has a negative impact on patient outcomes and increases strain on healthcare services, with many women presenting multiple times or undergoing repeated investigations. For example, in the UK, nearly half of women with endometriosis see a GP more than ten times before it is diagnosed.[2]

Scientific understanding is not always the limiting factor. Promising biomarker candidates exist for both endometriosis and mastitis. The real challenge lies in translating these biomarkers into diagnostic tools that are practical, affordable, and robust enough for routine use at the point of need. This is especially important for enabling earlier detection outside specialist settings.

Many women first seek support at home, in community care, or in primary care, creating opportunities to shift elements of diagnosis to an earlier point in the pathway. Simple, reliable tools for use in these settings could help differentiate between conditions, prioritise referrals, and reduce the need for repeated consultations, supporting more efficient use of clinical resources.

However, achieving this vision is not straightforward. Diagnostic tools developed for use in controlled laboratory environments often rely on sample types, preparation steps, or equipment that are difficult to reproduce reliably in real-world settings. In women's health, these technical constraints frequently intersect with other factors such as time pressure, stigma, physical discomfort, and fragmented access to care. All of these can hinder the uptake and effective use of new tools. As a result, usability, simplicity and integration with daily routines are critical factors that determine whether a clinically valid diagnostic solution will be effective in practice.

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Disconnects between scientific understanding and practical implementation reflect broader challenges in how diagnostics are developed and implemented. Women's health has historically suffered from lack of investment, limited research funding, and systemic under-prioritisation. This includes conditions that affect women differently or disproportionately, as well as female-specific health matters. While women comprise half the global population, women's health receives only 6% of private healthcare investment worldwide.[3] Such chronic underfunding reduces the incentive and capacity to build evidence, validate biomarkers in diverse populations, and develop user-centred diagnostic technologies.

Together, these factors help explain why promising biomarkers in women's health, including those for mastitis and endometriosis, have not yet been leveraged in routine care. Improving female diagnostics requires the integration of biological insight with practical design and behavioural considerations, and a new investment mindset that recognises women's health as both a scientific priority and an economic opportunity.

Early detection of mastitis using a biomarker found in breastmilk

Mastitis detection is a prime example of an unmet need in women's healthcare. This common, painful postnatal condition has implications for the physical and emotional wellbeing of mothers and infants. When identified early, interventions such as increasing the frequency of breastmilk expression can reduce inflammation and prevent infection. Supporting women to implement these strategies promptly may reduce the need for clinical intervention and the use of antibiotics.

At present, there is no home-use solution for early detection, and diagnosis typically occurs once breast tissue has already become inflamed or infected. However, a precedent for earlier detection can be found outside human healthcare.

In dairy farming, somatic cell count (SCC) has long been used as a routine indicator of mastitis

in cows. SCC reflects the immune response within the udder and is widely adopted as a proxy for subclinical infection. More recently, diagnostic approaches that combine SCC with additional parameters, such as differential cell counts, have been shown to improve sensitivity and specificity, enabling earlier and more precise detection of mastitis at the individual animal level. This builds on the strengths of SCC, while addressing its known limitations as a non-specific biomarker.[4]

Similar principles are now being explored in women's health. A recent pilot study demonstrated that SCC thresholds established in the dairy industry (more than 2.5 x 10^5 cells/ml) may also be effective in identifying subclinical mastitis in lactating women. Elevated SCC levels were shown to correlate strongly with inflammatory markers such as interleukin-8, indicating that SCC could serve as a meaningful indicator of otherwise asymptomatic breast inflammation.[5]

Successful use of the SCC biomarker in dairy farming highlights how routine, repeatable measurement embedded into everyday scenarios can enable earlier intervention at scale. Translating this principle into human healthcare could help accelerate the adoption of new biomarker-led diagnostics. Doing so requires more than technical insight; it demands a holistic approach to feasibility, usability and implementation. To explore how this could be achieved, we developed a concept – the celleste device – aimed at enabling earlier detection of mastitis in lactating women.

Designing for real-world postnatal care

Our work combined user research, concept development and exploratory microbiological testing to assess how the concept might function in real-world settings. Through interviews and co-creation sessions with mothers, we examined potential care pathways and daily use scenarios, ensuring the design aligned with the practical demands of early parenthood.

In parallel, laboratory testing using representative breastmilk samples evaluated

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whether impedance-based measurements could reliably detect inflammation-related SCC changes. Together, these activities provided early evidence for both the technical feasibility and the practical viability of a home-use diagnostic grounded in SCC.

Insights from user research highlighted the diversity of postnatal experiences and the practical constraints faced by mothers. Feeding methods, daily routines and home environments varied significantly, yet a consistent theme emerged: solutions must fit seamlessly into busy, often unpredictable schedules. The celleste concept was designed to enable simple, intuitive testing at any point during the day, requiring only a few drops of milk to generate a rapid indication of SCC. This supports regular, proactive monitoring of breast health, allowing mothers to spot early signs of inflammation before symptoms develop.

Form factor was another important consideration. To be effective, the device needed to be portable, discreet, and easy to clean, with simple and intuitive sample collection. Immediate, easy to interpret feedback was central to the concept. The device provides a simple indication of whether further action may be needed, while an optional companion app provides more detailed information and tailored guidance on symptom management.

Importantly, our focal point was early, preventative action rather than responding to established symptoms. Where elevated somatic cell levels are detected, users can be guided towards practical, proactive steps to help reduce inflammation, such as adjusting feeding patterns, applying heat, or expressing milk from the affected breast. If symptoms develop or persist, appropriate escalation to clinical care can be prompted. This approach could support structured postnatal care pathways, enabling earlier intervention within community settings. Identifying issues before symptoms escalate may reduce the need for GP consultations and antibiotic prescription through consistent, preventative care.

Overall, the celleste concept illustrates how clinically relevant biomarkers can underpin practical tools that support early detection in everyday settings. By linking biomarker measurement to clear guidance, it has the potential to reduce uncertainty, support self-management, and enable timely intervention within existing care pathways.

Extending the model: opportunities in endometriosis diagnosis

Harnessing known biomarkers in accessible diagnostic devices could also support earlier diagnosis of endometriosis. Current diagnostic pathways rely on imaging techniques, such as transvaginal ultrasound and MRI, both of which have variable sensitivity across different forms of the disease. Laparoscopic surgery remains the current reference standard, but its invasive and resource-intensive nature can contribute to significant delays in diagnosis.

As a result, there is growing interest in a range of non-invasive approaches, with sample types including venous blood, saliva, and menstrual blood being investigated for their diagnostic potential. Among these, menstrual blood has emerged as a particularly promising sample, as it contains endometrial cells, immune components, and inflammatory markers shed directly from the uterus, providing insight into the disease environment.

Studies have reported encouraging

performance from menstrual blood-based biomarkers, with sensitivity of up to 95% and specificity of up to 90% across multiple endometriosis types. These figures compare favourably with many circulating blood biomarkers and highlight the potential of menstrual blood as a diagnostic sample. Further research, including the Research OutSmarts Endometriosis (ROSE) study,[6] demonstrates differences in stromal cell activity using single-cell RNA sequencing of menstrual blood, reinforcing the biological relevance.

Much of the current evidence is derived from small, single-centre studies, and further validation would be needed for menstrual blood-based diagnosis to be integrated into routine clinical practice. There are also practical considerations around sample collection, stabilisation and processing.

This reflects a broader pattern across women's healthcare. While promising biomarkers continue to be identified, translating them into practical diagnostic tools requires more than scientific validity. Progress depends on building the surrounding ecosystem for early detection, including appropriate sampling methods, robust device design, usable workflows, and clear clinical pathways. Aligning biomarker innovation with compelling value propositions for payers, providers, and investors is essential to secure the support needed for these tools to reach routine clinical and home use settings.

Closing diagnostic gaps

As the mastitis and endometriosis examples demonstrate, identifying promising biomarkers is only one step towards improving diagnosis in women's healthcare. For biomarkers to deliver real-world benefit, they must be measurable in ways that are reliable and reproducible, and presented in a form that supports clinical decision-making. The breastmilk and menstrual blood examples show that the practicalities of sample collection and handling can ultimately determine whether a diagnostic approach is viable in routine use.

Closing diagnostic gaps therefore requires more than continued biomarker discovery. Progress depends on the co-ordinated development of the wider diagnostic ecosystem, including practical sampling strategies, manufacturable and usable device formats, clear result outputs, and defined pathways for action within clinical and community care. Early consideration of regulatory pathways, intended use, and reimbursement strategy is essential to ensure new diagnostic tools can progress beyond research and pilot settings.

These challenges are not limited to female-specific conditions. Similar patterns can be seen in conditions that affect women disproportionately or differently to men, such as Alzheimer's disease. In this case, emerging blood-based biomarkers offer the potential for detection years before cognitive symptoms emerge, yet integration into care pathways that support earlier therapeutic intervention, or prevention, remains a significant barrier.

A systems-level approach also includes designing for the environments where women first seek help, whether at home, in primary care, or within community settings. It requires expanding the evidence base to validate biomarkers across diverse female populations, addressing long-standing research biases that have limited the generalisability of many diagnostic tools. In many cases, the core technologies and biological insights already exist. The priority now is to integrate them effectively into diagnostic tools that can deliver impact at the point of need. Doing so will help narrow diagnostic gaps and contribute to a more equitable healthcare landscape for women. **CSJ**

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About the authors

Hermione Blakiston, MSc, CPhys MInstP, R&D Consultant at Sagentia Medical

With an academic background in computational and theoretical physics, Hermione's expertise spans optics and sensor technology, particularly within diagnostic, surgical, and women's health applications. Her projects encompass IP landscaping and technical due diligence, as well as the design and development of demonstrator devices for pre-clinical testing across clinical settings worldwide. Hermione excels at translating innovative technologies into tangible products that enhance patient outcomes.

Erica Kantor, CEng, Commercial Lead for Surgical and Women's Health at Sagentia Medical

As a Chartered Mechanical Engineer with 11+ years' experience in medical device R&D, Erica leads complex development programmes from strategy to manufacture. In women's health, Erica works at the intersection of technology, usability and commercial strategy to help address systemic gaps and accelerate meaningful, equitable outcomes for women.