SUMMARY (Clinical) 4/23/25 ciT1zen science

Establishing the Performance and Acceptability of Dried Blood Spot Sampling for Islet-Specific Autoantibody Screening ciT1zen science summary

Source: Excerpts from "Establishing the performance and acceptability of dried blood spot sampling to screen for islet-specific autoantibodies - Faustini - Diabetic Medicine - Wiley Online Library"
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Purpose: This briefing document summarizes the key findings from the provided source regarding the validation and acceptability of using Dried Blood Spot (DBS) sampling with the 3-screen ELISA assay for type 1 diabetes (T1D) autoantibody screening.
Key Themes:

- **Validation of DBS for Autoantibody Detection:** The study aimed to verify the performance of DBS sampling compared to traditional venous serum sampling for detecting islet-specific autoantibodies (IA-2A, GADA, and ZnT8A) using the ElisaRSR (3-screen) multiplex assay.
- **Acceptability of DBS Sampling:** The study explored the perceived acceptability of DBS sampling for T1D screening among parents and professional stakeholders, including preferences for testing location (home vs. community).
- **Advantages of DBS Sampling:** The research highlights several potential benefits of using DBS for population screening, including reduced blood volume, ease of collection, sample stability, and potential for cost-effectiveness and high-throughput testing.

Most Important Ideas and Facts:

- **Islet-specific autoantibodies predate and predict T1D:** The presence of these autoantibodies is a strong indicator of future T1D development, making them a valuable target for screening programs. The source states, "Islet-specific autoantibodies (Aab) predict and predate clinical onset of type 1 diabetes (T1D)." The presence of multiple Aabs (2 or more) is particularly predictive of a near 100% lifetime risk.
- **Traditional venous blood draw has limitations for pediatric screening:** Venous collection can be distressing for children, requires trained personnel, and has a high failure rate. The source notes that

venous blood draw "can be distressing for children, requires trained phlebotomists and carries a high failure rate (18%)."

- **DBS offers a convenient and reliable alternative:** DBS sampling is less invasive, requires a lower blood volume, is stable for weeks to months at room temperature, and can be collected at home or in community settings. The source highlights that DBS "offers an attractive alternative, as this technique is relatively simple, inexpensive, samples are stable once dry for weeks-months, can easily be collected at home or in community settings and posted back to testing laboratories."
- **The 3-screen ELISA assay is suitable for DBS:** The study found that the performance characteristics of the 3-screen assay were similar for both serum and DBS samples.
- **Sensitivity:** Serum 86%, DBS 89%.
- **Specificity:** Serum 97%, DBS 100%.
- **Concordance:** There was 97% overall concordance between paired serum and DBS samples using the 3-screen assay.
- **Correlation:** A strong significant correlation was observed between DBS and serum sample values ($r = 0.719$, $p < 0.0001$).
- **Note:** While quantitative values for DBS were consistently lower than serum, qualitative concordance was high. Intra- and inter-assay CV were higher for DBS than serum, suggesting potential for further optimization in processing.
- **DBS sampling is acceptable to parents and stakeholders:** Qualitative interviews revealed that both parents and professional stakeholders viewed DBS testing as a "minimally invasive, convenient screening test."
- **Home-testing is perceived as most convenient:** Parents emphasized the "choice of screening location, including home and community settings." The primary benefit of home testing highlighted by parents was its flexibility: "the main benefit of the home test is that you can do it whenever you want, you don't have to take time off to have an appointment."
- **Finger-prick experience impacts parental confidence:** Parents familiar with finger-prick testing from previous experience (e.g., with a child with diabetes) felt more confident in performing DBS testing at home.
- **Anxiety associated with home screening:** Parents unfamiliar with finger-prick testing expressed anxiety about incorrect test completion, obtaining insufficient blood, causing pain to the child, and potential safeguarding concerns. Clear instructions and video guides were suggested to mitigate these concerns.
- **Community testing is an acceptable alternative and improves accessibility:** Screening in community settings, such as schools or

alongside childhood immunizations, was seen as a way to increase awareness, accessibility, and uptake, especially for those hesitant about home testing. A General Practitioner stated, "other places where they're more likely to be receptive to it, so community centres, or what are the settings where they may attempt to go regularly, nurseries and schools obviously."

- **Preference for HCP testing in community settings:** Parents, particularly those of younger children, preferred having a healthcare professional (HCP) perform the DBS test in a community setting to address challenges like distress and the need for "restraint."
- **Potential issues with community testing:** Concerns were raised about parents not being present to comfort children during school-based testing and the potential for added distress if combined with childhood immunizations.

Implications of the Study:

- DBS sampling with the 3-screen assay is a viable and acceptable alternative to serum sampling for general population T1D autoantibody screening.
- The method offers significant advantages for large-scale screening programs due to its lower blood volume requirement, accessibility, lower cost, and amenability to high-throughput testing.
- Offering both home and community-based DBS sampling options is likely to improve screening uptake and accessibility, addressing parental preferences and concerns.
- Further research on optimizing DBS processing for individual autoantibody assessment and the cost-effectiveness of different sampling approaches (home vs. community HCP testing) is warranted.

Overall Conclusion:

The study successfully validates the use of DBS sampling with the 3-screen ELISA for T1D autoantibody screening, demonstrating comparable performance to serum. Furthermore, the findings highlight the strong acceptability of DBS sampling among parents and stakeholders, emphasizing the convenience of home testing and the value of community-based options, particularly when performed by HCPs. These results strongly support the implementation of DBS sampling in future mass screening programs for T1D.