"*A New Era in Clinical Diagnostics: The Power of Self Sampling*" - Output from the 2026 PCSIG Workshops

Summary

Patient centric sampling approaches have the potential to revolutionize the process of sample collection for clinical diagnostics. This approach can facilitate the collection of samples in places away from clinical facilities, such as at home, or at a pharmacy. Further, these approaches can enable sampling for those that may have difficulty with routine venous sampling, such as children, the elderly, individuals with needle phobia and those with learning difficulties and can enable more regular timed sampling, if required. However, there are hurdles to overcome to enable effective adoption and realise these benefits.

To address this, the PCSIG hosted regional free to attend on-line workshops focussing on Europe and North America, each in two parts:

- Part 1 – Each workshop focussed on identifying challenges to the routine understanding and more widespread adoption of patient centric sampling approaches for clinical diagnostics in the region
- Part 2 – Each regional workshop discussed potential solutions to the key challenges defined in part 1 and set-out an action plan to deliver them.

These live events were recorded for transmission through the PCSIG YouTube channel.

This document summarises the combined output from these events and sets out proposed future activities, deliverables, working groups and partnerships to deliver the proposed solutions.

The Workshops

Europe Focus

Speakers and Panellists

Vincent Molenaar (Greiner Bio-One International), John Fabule (PiCC United (Patient Involvement and Collaboration Community)), Joseph Burt (MHRA), Sharon Geaghan (IFCC and Stanford University School of Medicine), Timothy Woolley (Inuvi) and Rachel Carling (Synnovis).

Moderated by Neil Spooner (PCSIG)

Recordings

- *Part 1: Reviewing technologies and identifying challenges*
- *Part 2: Examining potential solutions to the key challenges and setting-out an action plan to deliver them*

Output

The discussions focussed on:

1. Developing a best practice guideline on how patient instructions and training for PCS should be formulated, including how to capture patient confidence and needs.
2. Building best-practice guidance for integrating PCS samples into laboratory workflows and reducing pre-analytical complexity.
3. Producing documentation that can demonstrate the cost benefits of a PCS approach and highlight the benefits to the patient pathway.

All the above were also outputs from the North American focussed discussion.

The detailed output of the challenges defined, and the solutions proposed for the European events is summarised in Appendix 1.

North America Focus

Speakers and Panellists

Bradley Collier (LabCorp), John Fabule (PiCC United (Patient Involvement and Collaboration Community)), Marianela Perez-Torres (Division of Chemistry and Toxicology Devices, CDRH, FDA), Sharon Geaghan (IFCC and Stanford University School of Medicine) and Bryan Andrus (US Specialty Labs).

Moderated by Neil Spooner (PCSIG)

Recordings

- *Part 1: Reviewing technologies and identifying challenges*
- *Part 2: Examining potential solutions to the key challenges and setting-out an action plan to deliver them*

Output

The discussions focussed on:

1. Convening representatives of industry (instrument & device vendors, laboratories), patient groups, global regulators, payers, healthcare economics, etc in a collaborative community to work through how we can progress patient centric sampling approaches for clinical diagnostics.
2. Developing a best practice guideline on how patient instructions and training for PCS should be formulated, including how to capture patient confidence and needs.
3. Building best-practice guidance for integrating PCS samples into laboratory workflows and reducing pre-analytical complexity.
4. Producing documentation that can demonstrate the cost benefits of a PCS approach and highlight the benefits to the patient pathway.

Points 2-4 were also outputs from the European focussed discussion.

The detailed output of the challenges defined, and the solutions proposed for the North American events is summarised in Appendix 2.

Potential Follow-up Activities & Partners

- Share this outline of workshop output on the PCSIG website and PCSIG LinkedIn Group
- Communicate the findings of the workshops and next steps in a PCSIG webinar – Scheduled for 22 September 2026
- Publish manuscript in the Journal of Patient Centricity, summarising the events and their outputs, along with Q&As
    - Next steps - Request volunteers from the PCSIG LinkedIn Community
- Develop a recommendation or guideline on how patient instructions and training for PCS should be formulated, including how to capture patient confidence and needs.
    - Next steps - Explore partnerships with Project COMFORT, PiCC United and other patient organisations to deliver the solution.
- Building best-practice guidance for integrating PCS samples into laboratory workflows and reducing pre-analytical complexity.
    - Next steps - Explore partnerships with LabMed, IFCC, ASLM, ADLM, CLSI, UKAS, etc to deliver the solution.
- Producing documentation that can support cost-benefit and reimbursement arguments for the adoption of PCS approaches.
    - Next step - Request volunteers from the PCSIG LinkedIn Community and additional experts.
- Convening representatives of industry (instrument & device vendors, laboratories), patient groups, global regulators, payers, healthcare economics, etc in a collaborative community to work through how we can progress patient centric sampling approaches for clinical diagnostics.
    - Next steps - Explore partnerships with; PiCC United and other patient organisations; bodies responsible for national / international clinical laboratory regulatory oversight (FDA, MHRA, EU, etc); organisations providing standards for medical professionals (CLSI, UKAS, etc); organisations representing clinical laboratory professionals (LabMed, IFCC, ASLM, ADLM, etc); representatives of industry and manufacturers (device vendors, analytical platform vendors, automation suppliers, etc); other appropriate bodies (Project COMFORT, American Telemedicine Association, payers, etc).

Appendix 1 - Europe

All the Discussion Topics below came from the 16th April 2026 (Europe) PCSIG Workshop. Those addressed specifically at the 23rd April 2026 PCSIG Workshop for solutions are highlighted in green.

Discussion Topics and Solutions

Patient

- Knowing what the patient wants
    - Patient needs to trust the device / process and therefore the result
        - **Solution – Ask patients in a small working group in your local area for the particular use case.**
        - **Solution – Produce short summaries to look at where the patient voice is most useful for a pathway.**
    - Learnings from user experience taken and incorporated into the product – how device is used, etc. However, this is problematic because the manufacturer's insert is part of the FDA/CE application and for FDA, cannot be changed unless post-market surveillance requires FDA action.
        - **Solution - PCSIG make a recommendation about what instructions should look like and how to include the patient**
        - NOTE – ISO 62366 already out there and covers how device is being used in a lay setting
            - **Solution - Needs to be greater adoption of these standards**
- How to instruct the patient to collect a quality sample
    - **Solution – Provide initial training in the use of the technology in the clinical setting**
    - **Solution - Digital platform with video and / or HCP that can guide the patient**
        - Need to offer different formats, as different patient like to learn in different ways
- Patient Identification
    - Use digital tools already available
- New upcoming publication from LabMed will provide recommendations

Labs

- Integrating current process for samples derived from PCS into current highly automated workflows. Including requirements for different / multiple tube types
    - **Solution - Work with the manufacturers – go through the process**
    - **Solution – LabMed UK meeting in Liverpool (sept 2026)**
    - **Solution - Set up event at IFCC event?**
    - Treat sample as a pediatric sample. Substantial increase in time/labor cost and staffing implications to handle samples as pediatric, requires manual manipulation rather than automation.
    - PCSIG to help to communicate how it can be done, as some labs find it simple – aliquoting is the main problem at the moment.
- Limited analyst experience with these sample types

    - **Solution - Produce best practice documentation – LabMed publication expected this year**
- Compatibility with current reference intervals (see explanation below)
    - **Solution - Perform comparability study, therefore do not change the reference intervals. Often includes stability study**
    - Has been a publication – To Convert or Not to Convert? Official International Association of Therapeutic Drug Monitoring and Clinical Toxicology Guideline: Considerations and Recommendations for Converting Capillary Blood Microsampling Concentrations to Plasma Concentrations
    - Project COMFORT also working on this.
    - One labs study cannot be mapped to another lab, as can be a number of differences in equipment, consumables, etc.? Requirement that each lab performs its validation / qualification locally
    - Need input from clinicians – how comparable does the data need to be?
    - Working collaboratively to get a cross lab validation could be done, but might be difficult – might be important for dried blood samples
- Knowing what assays / devices are qualified by which labs
- Many assays are not CE-marked / cleared for capillary blood; validation burden sits with labs

Economics

- Lack of robust tools to make the cost / benefit analysis and build business case. Reimbursement coverage of microsampling approaches
    - **Solution – invite payers to discussions. What do they need to see to help make decisions? Work with patient groups. How to capture all the factors and make a case. Include Health Economics experts.**

Sample Quality

- Demonstrating long term whole blood stability under conditions encountered by the sample
- Tracking transit time and conditions

Clinical

- Different reference intervals (intervals is current preferred term, since mathematically it is not a true range but a 95th or 99th percentile (see CLSI, Clinical Laboratory Standards Institute and others) might be needed – blood vs plasma / serum; capillary vs venous; difference in analytical approach, i.e. MS vs IA

Logistics

- Getting devices to patients and samples to the lab
- Standardisation of temperature monitoring
- Waste management
- Net zero

Data Management

- How do you know the test was ordered?
- How does the lab know a sample has been sent by patient?

- How does the patient know a sample is received by lab?
- How, where and to who will the results be reported?
- How will critical values requiring immediate action be handled?

Regulatory

- Getting devices and collection tubes with the correct approvals (layuser vs HCP)
- Assay claims for capillary blood

Appendix 2 – North America

All the Discussion Topics below came from the 30th April 2026 (North America) PCSIG Workshop. Those addressed specifically at the 7th May 2026 PCSIG Workshop for solutions are highlighted in green.

Discussion Topics and Solutions

Patient

- Patient and provider need to be confident in using the test and the results
    - Lack of confidence translates into lack of adoption of PCS approaches
    - Sample quality can go down in lay peoples hands
        - **Solution – Develop device independent standards for training, materials, IFUs, videos, on-line interactions, etc? Include good and bad examples. Recommendations on how to return sample, timely manner, etc. Need to involve the patient's voice. Use of plain language essential**

Regulations

- Role of FDA vs lab developed tests & CLIA
    - Would be helpful if community was more transparent to regulators about what they see – warts and all
    - Self policing is important, but oversight is needed.
        - **Solution – Convene industry / regulator group to discuss – potential for "Collaborative Community". Potential to involve global participants and regulators**

Labs

- Treating small sample size like pediatrics
    - Problems with lack of lab automation for these sample types
    - Requires more time and specialist staffing
    - Increases costs.
        - **Solution – Bring together instrument and device manufacturers with labs and regulators – Collaborative Community – needs to be global and include regulators in addition to the FDA**
- Validating a system, not just an assay. More complex than just developing an LDT, as process reaches beyond the lab
    - Return of samples may not be to standard.
        - **Solution - Standardisation of stability testing experiments and acceptance criteria**
- Off label use (lab and pharma) – pediatric and neonatal – devices have not been validated in children.
    - Clinician opinion must be sought and is often missing for performance requirements of a test for clinical decision-making
        - **Solution - Labs need to be clear about what their intentions are – ie not for diagnostic use. This is not clear to the patient**

        - **Solution - Need to have more data bridging the gap between venous and PCS samples, with what device, how handled, what test used.**
- Analytically – what is good enough? Can there be different rules for different patient groups?
    - Context intended use – risk vs benefit
        - **Solution – Publish case studies and share best practice. Define what is good enough. Learn from current best practice , e.g. diabetic self testing and what is working in other labs, countries, etc**

Logistics & Data Management

- Home sampling brings challenges of getting kits to homes and samples to the lab
    - Concerns over stability of samples during transport from home to lab
        - **Solution – Define standards for stability testing and acceptance criteria across devices.**
        - **Solution - Define standards for packaging and logistics. Learn from best practice, i.e. Dutch postal system.**
        - **Solution – Share best practices. More published data**

Economics

- Clinical laboratory bears cost of handling specimens and increased labor of manual (versus automation) specimen analysis, but savings will be realized elsewhere.
    - Cost-benefit arguments are holistic in nature (eg health benefits, preventative care, patient travel costs and lost work time) but costs are borne by a cost center.
    - Need better understanding of cost benefit models
    - No reimbursement codes for home sampling.
        - **Solution - Need to keep working for general acceptance. Will then lower the reimbursement barriers. OTC is part of the discussion**
        - **Solution – Emphasise positive use cases where the benefit is high, i.e. rural / remote communities, homebound individuals, those with learning disabilities, etc**
        - **Solution – Develop cost / benefit models**