Research Article

Advisory and Interpretative Services under ISO 15189:2022: A Prospective Study of Patient-Initiated Laboratory Consultations

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Abstract

Background: ISO 15189:2022 requires accredited medical laboratories to establish advisory and interpretative services to support appropriate test selection, result interpretation, and effective utilization of laboratory examinations. Direct-to-consumer and patient-initiated laboratory testing is reshaping traditional healthcare communication. Patients increasingly seek direct consultation with laboratory physicians for test selection and result interpretation. This study describes the drivers, patterns and perceived value of such interactions in routine laboratory practice.

Methods: A prospective observational study was conducted over 12 months at a high-volume ISO 15189:2022 accredited referral laboratory. All unsolicited, patient-initiated advisory consultations with laboratory physicians were systematically documented using a structured logbook. Consultations were categorized by type (pre-examination advice, post-examination interpretation, clarification of abnormal findings, and resolution of inter-laboratory discrepancies). All abnormal or discordant results discussed during consultation had undergone analytical verification in accordance with internal quality control and validation procedures. Patient satisfaction was assessed using a 5-point Likert scale. Descriptive statistics were applied.

Results: A total of 1,800 advisory consultations were recorded during the study period. The most common categories were post-examination interpretative consultation (35.6%) and clarification of abnormal results (28.3%), followed by pre-examination advice (20.0%) and resolution of inter-laboratory discrepancies (12.2%). Frequently discussed analytes included glucose profiles, lipid parameters, infectious disease serology, and screening tests. Satisfaction data were available for 1,625 consultations, with a mean score of 4.5 ± 0.6; 90% of respondents rated the consultation as satisfactory or very satisfactory.

Conclusions: These findings highlight the growing demand for professional laboratory interpretation in patient-initiated testing environments and support the inclusion of advisory consultations as a measurable quality indicator within laboratory management systems.

Introduction

The expansion of direct-to-consumer (DTC) and patient-initiated laboratory testing has altered the traditional "brain-to-brain" loop of diagnostic medicine [1, 2]. Patients now frequently access laboratory reports without prior clinical interpretation and seek clarification directly from the laboratory [3, 4]. This shift challenges the traditional view of laboratory physicians as background specialists, positioning them as active contributors to patient-centered care. While patient-initiated testing enhances self-empowerment, it raises concerns about unregulated quality, lack of interpretation, and potential risks to patients and public health, including erosion of evidence-based practice standards [5]. An Australian study finds that the majority of DTC tests sold online have low potential clinical utility, often targeting healthy consumers and raising significant concerns about medical overuse, financial harm, and inadequate regulation [6]. The impact of DTC testing may vary depending on context, population, and regulatory environment.

Patient-initiated testing is particularly common in resource-limited settings, where fragmented healthcare, limited access to medical records, and brief consultations lead patients to independently choose tests, thereby increasing the proactive role of laboratory physicians in guiding appropriate test utilization and interpretation. A study in Ghana identifies significant communication gaps between laboratory professionals and patients during pre- and post-sampling interactions, revealing a lack of standardized procedures and patient understanding of laboratory tests despite professionals recognizing the need for better communication [7]. Laboratory physicians, with expertise across pre-analytical, analytical, and post-analytical phases, are uniquely positioned to contextualize results and explain unexpected or discordant findings, particularly when supported by relevant clinical history.

In accordance with ISO 15189:2022, accredited laboratories are required to establish advisory services covering test selection, interpretation of results, and promotion of appropriate test utilization. These responsibilities extend beyond technical validation to include professional consultation. However, limited data exist describing the reasons patients seek consultation with laboratory physicians and how these interactions are perceived. Understanding these interactions is crucial for laboratories to adapt their services, enhance patient care, and navigate the implications of the patient-initiated laboratory testing paradigm. In an author's laboratory, all interpretative consultations are performed by board-certified MD Biochemistry or MD Pathology specialists with competency in clinical interpretation, biological variation, analytical performance characteristics, and harmonization principles. This study aims to categorize the causes and assess the satisfaction associated with patient-driven interactions with laboratory physicians in a clinical laboratory setting. These interactions represent structured advisory services embedded within the laboratory quality management system rather than informal patient encounters.

Materials and Methods

Study Design and Setting

This prospective observational study, evaluating real world demand for laboratory physician consultation, was conducted over a 12-month period (February 2024 to February 2025) at Samyak Diagnostic, a high-volume referral ISO 15189:2022 accredited clinical laboratory in Kathmandu, Nepal. The study was designed to systematically document and analyze real-world, patient-initiated interactions with laboratory physicians occurring during routine service delivery, without altering standard clinical or laboratory workflows or introducing any clinical intervention.

Definition of Patient-Initiated Interaction

A patient-initiated interaction was defined as any direct, unsolicited communication initiated by a patient or accompanying caregiver with a laboratory physician, either before or after testing, for the purpose of test selection, clarification of laboratory results, interpretation of abnormal or unexpected findings, or explanation of inter-laboratory result discrepancies. Interactions initiated by clinicians or internal laboratory quality processes were excluded.

Data Collection Tool and Variables

A structured, purpose designed logbook was developed prior to study initiation and used uniformly by all participating laboratory physicians. For each interaction, the following variables were recorded immediately after consultation:

1. Date of interaction
2. Categorized according to the cause of consultation:

Pre-test consultation

Post-test general consultation Inquiry regarding abnormal results Inquiry regarding disagreement with reports Inquiry regarding discrepant results from other laboratories

3. Other administrative or procedural queries
4. Primary test(s) involved

To enhance consistency, consultation categories were defined a priori and reinforced through internal orientation sessions. The interactions described represent clinical interpretative consultations rather than routine customer-service helpdesk activities. Consultations involved individualized medical reasoning such as interpretation of discordant or paradoxical results, explanation of biological and analytical variation, assessment of test appropriateness, and advice on need for repeat testing or clinical referral. All critical results during consultation were communicated with the clinicians or referred to the hospital. All abnormal or discordant results discussed during consultations had undergone standard internal quality control verification and, where indicated, repeat analysis prior to release, in accordance with ISO 15189:2022 requirements for ensuring analytical validity.

Patient Satisfaction Assessment

Patient satisfaction was assessed immediately following the interaction using a 5-point Likert scale (1 = very dissatisfied; 5 = very satisfied). As only patients who reached physicians were surveyed, the possibility of positive response bias is acknowledged.

Data Quality Assurance

All participating laboratory physicians received standardized training on documentation procedures before study initiation. Logbook entries were reviewed monthly by the study coordinator

to ensure completeness, internal consistency, and appropriate categorization. Ambiguous entries were resolved by consensus discussion among the laboratory physicians involved.

Ethical Considerations

In accordance with institutional policy, the study was considered exempt from formal ethics committee review. The study is a routine advisory service as per ISO 15189:2022 requirement. Data confidentiality and anonymity were maintained throughout the study. This is in compliance with the ethical principles for medical research involving human subjects, in accordance with the Declaration of Helsinki.

Statistical Analysis

Data were entered into a secure database and analyzed using descriptive statistics. Frequencies and proportions were calculated for categories of patient interactions. Satisfactionscores were summarized using means and standard deviations. Qualitative feedback was reviewed thematically to identify recurring patterns and illustrative examples and then categorized to respective heading in the log book.

Results

During the study period, 1,800 patient-initiated interactions were recorded. Post-test general consultations were the most frequent (35.6%), followed by clarification of abnormal results (28.3%). Commonly discussed tests included glucose profiles with paradoxical findings, lipid parameters, equivocal infectious disease serology, and prenatal screening results.

Inter-laboratory discrepancies accounted for 12.2% of interactions, most often involving glucose, triglycerides, and thyroid-stimulating hormone. Explicit disagreement with laboratory reports was uncommon (2.8%). The common examples and distribution of causes of interaction is summarized in Table 1.

Table 1: Causes of Patient-Driven Interactions with Laboratory Doctors (n=1800).

Category	Number	Percentage	Commonest Examples
Post-Test general consultation	640	35.6%	Query on highlighted results outside reference interval, Guidance on test frequency and monitoring, Query on additional test and differential diagnosis based on current reports.
Inquiry about abnormal reports	510	28.3%	Paradoxical glucose results, High triglycerides, Equivocal serology, High risk prenatal screening test
Pre-Test consultation	360	20.0%	VDRL, TB Gold, HLA B27, Apo-lipoproteins, FNAC and Biopsy, Reconfirming tests ordered by clinicians for their symptoms, Test selection based on symptoms
Inquiry about different results from another lab	220	12.2%	Triglycerides, TSH, Glucose, Uric acid
Disagreement with reports	50	2.8%	Vitamin B12 levels, HbA1c, Glucose, Uric acid, Blood Tacrolimus level
Others	20	1.1%	Turnaround time, home collection of samples
Total	1800	100%	

Satisfaction data were available for 1,625 interactions. The mean satisfaction score was 4.5 ± 0.6, with 90% of patients rating the consultation as 4 or 5. Lower satisfaction scores were primarily associated with consultations involving conflicting results from different laboratories.

Discussion

Although ISO 15189:2022 mandates advisory services, the volume and pattern of direct patient engagement observed in thisstudy quantify the operational burden and clinical impact of such services, which has been insufficiently documented in the literature. This study demonstrates a substantial and growing demand for direct access to laboratory expertise in routine practice, driven by patient autonomy and the expansion of DTC and patient-initiated testing. This can be considered as operational characterization of advisory services under ISO 15189. Patients most frequently sought clarification for unexpected, abnormal, or discordant results, areas wherelaboratory physicians provide

distinct interpretative value that cannot be replaced by automated reporting alone. The high frequency of pre-test inquiries in our study, for infectious disease serology and screening tests suggests gaps in patient education that could be addressed through improved pre-test information and standardized interpretative comments. The high volume of inquiries on tests like VDRL and TB Gold, often required for employment or travel, underscores a need for better pre-test patient education. Laboratories could mitigate this by developing targeted informational materials, thereby reducing repetitive consultations [8]. The American Sexually Transmitted Diseases Association states that while patient initiated STI testing including VDRL may improve access and reduce stigma, concerns about test reliability, inappropriate test selection, result interpretation, affordability, and integration into surveillance systems necessitate strict quality standards and clear pathways for clinical follow-up as further highlighted by Martin-García and Santi-Rocca (2024) [9,10].

The substantial burden of consultations related to inter-laboratory discrepancies highlights ongoing challenges in result harmonization and analytical comparability, which directly influence patient trust [11]. This was particularly evident for analytes such as glucose, uric acid, and triglycerides, all of which exhibit high intra-individual biological variation. Incorporating statements on measurement uncertainty in laboratory reports may help align clinician and patient expectations with the inherent variability of these tests [12]. Furthermore, several laboratories worldwide provide Reference Change Value (RCV) calculators on their websites to assist clinicians and patients in determining whether observed differences between consecutive results represent statistically significant physiological change rather than random variation [13]. Many laboratories also integrate RCV-based rules within laboratory information systems as part of auto-verification and delta-check algorithms to flag clinically significant changes.

In our study, discrepancies between patient expectations and laboratory results were occasionally observed, predominantly concerning again with paradoxical glucose results (higher fasting glucose versus post-prandial glucose) and unexpected Vitamin B12 levels. Queries regarding elevated fasting glucose represented the vast majority of these disagreements. Providing a clear physiological explanation for this glucose pattern initially presented a considerable difficulty. In response, we published scientific literature addressing this phenomenon and created self-explanatory videos, which were disseminated via social media to educate patients on the causes [14].

International literature presents divergent perspectives on patient-initiated laboratory testing, balancing concerns regarding safety and regulation with recognition of its potential to improve access and self-management. The EFLM DTCT-Taskforce has proposed reframing DTC testing as “Consumer Initiated Testing,” emphasizing that this model circumvents the traditional “brain-to-brain” testing loop and may introduce significant quality risks, particularly when analyses are performed outside medical laboratories [15]. At the same time, the taskforce acknowledges benefits such as improved accessibility, convenience, and consumer choice, especially for underservedpopulations, and recommends dedicated regulation to ensure tests are appropriate for lay use and direct users toward medical consultation rather than autonomous clinical decisions [15]. Ayala-Lopez and Nichols similarly note that consumer demand is driven by convenience, confidentiality, and empowerment, yet caution that absence of clinical context may lead to misinterpretation, privacy concerns, and unnecessary follow-up from false-positive results [16]. Hinzmann argues that patient-initiated testing can support self-management of chronic disease and rapid decision making, the advantages particularly relevant in resource limited settings while advocating that professionals should focus on public education rather than outright rejection of the model [17]. Conversely, Orth et al. highlight substantial risks arising from regulatory gaps, analytical variability, and lack of oversight, asserting that laboratory specialists have an ethical responsibility to inform the public and promote stricter governance to protect diagnostic integrity [18]. While advisory services support test selection and result interpretation, their scope should remain clearly defined, with direct diagnostic and treatment decisions reserved for the treating clinician to ensure appropriate clinical governance and patient safety.

Our findings suggest that laboratory physicians can partially mitigate these risks by guiding appropriate understanding and follow-up. Importantly, the consistently high satisfaction observed indicates that such interactions are not merely informational but perceived as clinically meaningful by patients. This presents a compelling case for laboratories to formalize such consultation services. Early strategies could include:

1. Interpretative reporting: Short, standardized comments for common abnormal or paradoxical results
2. Patient education: Targeted digital or printed materials addressing frequently queried tests
3. Structured consultations: Brief post-test consultations as part of wellness and screening packages

The increasing demand for advisory and interpretative services highlights the need for enhanced training in clinical communication and interpretation skills for laboratory physicians, as well as appropriate staffing models that allocate dedicated time for consultative laboratory practice. These services should be systematically documented within laboratory information systems or structured records, as this not only ensures traceability and continuity of care but also provides an essential medico-legal safeguard within the framework of ISO 15189:2022-accredited laboratory practice.

Patients seeking consultation in our study were heterogeneous, with varying levels of medical literacy that appeared to influence the nature of queries and expectations. While some required basic explanations, others sought detailed interpretation, underscoring the need for adaptable communication by laboratory professionals; future studies should formally assess the impact of health literacy on advisory service utilization. This single center service evaluation may not capture the full range of practices in smaller, non-accredited, or rural laboratories. However, the observed interaction patterns are likely representative of laboratories experiencing increased patient directed testing and reduced clinician mediated interpretation,particularly in similar

resource limited settings. This also highlight the need for future multi-center studies with inferential or comparative designs to validate these observations.

Conclusions

Advisory and interpretative consultations represent a substantial and measurable operational component of ISO 15189:2022-accredited laboratory practice. Patient-initiated consultations with laboratory physicians reflect a growing need for expert interpretation. While these findings are based on a single-center experience and should be interpreted within this context, the quantification of this activity supports its recognition as a potential quality indicator within laboratory management systems.

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Ethical Approval

The study is a routine advisory service as per ISO 15189:2022 requirement. Data confidentiality and anonymity were maintained throughout the study. This is in compliance with the ethical principles for medical research involving human subjects, in accordance with the Declaration of Helsinki.

Author Contributions

VP: Conceptualization, Formal analysis, Writing original draft. SP, KG, DP, AS and NN: Data curation, Writing-Review and Editing.

Conflict of interest

None.

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Data Availability Statements

The data generated and analyzed in the presented study are available from the corresponding author on request.

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