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# Integrated diagnostics

Verena Haselmann<sup>1</sup> · Stefan O. Schoenberg<sup>2</sup> · Michael Neumaier<sup>1</sup> · Matthias F. Froelich<sup>2</sup>

<sup>1</sup>Institute of Clinical Chemistry, Medical Faculty Mannheim of the University of Heidelberg, University Hospital Mannheim, Mannheim, Germany

<sup>2</sup>Department of Radiology and Nuclear Medicine, University Medical Center Mannheim, Medical Faculty Mannheim of Heidelberg University, Mannheim, Germany

## Abstract

**Background:** Integrated diagnostics is increasingly gaining scientific traction as it promises to address several challenges currently facing diagnostic medicine. These challenges range from the need for improved diagnostic accuracy to optimized timing of diagnostic procedures, to the variety of diagnostic markers and thus the complexity of their interpretation, and finally to economic pressure.

**Methodical innovations:** While many of these challenges may be difficult to solve with a monomodal approach, the integration of laboratory markers and imaging procedures promises to allow both disciplines to achieve their actual clinical potential. Combining complementary diagnostic approaches can help to improve the interpretation of measurements, provide a better cost-effectiveness particularly when cutting-edge techniques are used for specific indications, and facilitate optimized timing and rational choice of appropriate diagnostic approaches for disease surveillance. Furthermore, close interdisciplinary assessment of diagnostic results will increase diagnostic accuracy and will enable selection of specific patient cohorts at increased risk for certain diseases who are suitable for further testing.

**Conclusion:** The potential of an integrated diagnostic approach represents a strategic goal for diagnostic disciplines as it achieves better visibility and greater clinical impact. In addition to close collaboration among relevant diagnostic experts, an appropriate structure for integrated data evaluation needs to be established to provide actionable health guidance so that integrated diagnostics can be implemented in standard care.

### Keywords

Diagnostic techniques and procedures · Quality assurance · Cost-effectiveness · Diagnostician · Integrative diagnostics

## Background

The vast majority of clinical diagnoses rely on confirmation by multimodal diagnostic procedures [1, 2]. As a result of the increased pace of translation of new diagnostic techniques into clinical care, the value and utilization, but also the complexity of interpreting diagnostic results, have increased significantly. Combined with increasing economic pressures, this development has led to several challenges facing diagnostic disciplines today. These challenges have been recognized by various diagnostic disciplines including radiology and laboratory medicine [3]. They may be addressed by a better and in-

terdisciplinary coordination of diagnostic efforts in the form of integrated diagnostics. In contrast to the current workflow and interpretation of diagnostic results by clinicians, with a combined diagnostic interpretation in the clinical context after completion of all diagnostic procedures, integrated diagnostics consists of an early joint interpretation of test results by interdisciplinary diagnostic experts in real time. In this way, integrated diagnostics can be defined as a holistic interpretation of results within the diagnostic process that will be used by diagnostic experts to adjust diagnostic procedures to individual patient needs. The aim is to directly adjust the diagnostic workflow by continuous in-



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**Fig. 1** ◀ Current challenges for diagnostic disciplines that may be addressed by integrated diagnostics

erations and subsequent refinements and to process it for the clinician in the form of *clinical decision support*. This directly leads to adjustment of the required diagnostic procedures and thus an individualization not only of diagnostic strategies, but also of the need and timing of follow-up. As a result, integrated diagnostics offers the potential to generate unprecedented added value for clinical decision-making and for the patient's journey.

### Current challenges in diagnostic medicine

The reliability of diagnostic results depends on multiple dimensions, including quality-assured and validated standard operating procedures, adequate training and skills of staff, the choice of appropriate diagnostic techniques, equipment functionality, and experienced diagnostic experts. Hence, high time pressure and work overload of clinical staff can significantly affect the quality of diagnostic results, as can the shortage of staff. This may be fur-

ther enhanced by economic pressures that can affect reimbursement options for certain diagnostic procedures. On the other hand, the development of cutting-edge technologies has led to increasingly rapid identification of new diagnostic targets and their translation into clinical care, resulting in the availability of a huge variety of diagnostic markers. However, each of these markers is associated with certain diagnostic limitations: for example, high diagnostic sensitivity may be achieved at the expense of low diagnostic specificity; superior image quality may be realized at the expense of higher radiation dose or costs; high analytical sensitivity may lack the information on organ specificity. In addition to the aforementioned diagnostic challenges, another obstacle that diagnostic disciplines have to face is the appropriate and cost-effective timing of the use of these diagnostic procedures during patient follow-up. Particularly, in the context of screening and early detection of recurrence or relapse, the choice and timing of diagnostic tests are critical. These challenges, summarized in **Fig. 1**, could be overcome by an integrated diagnostic approach.

In this manuscript, the value proposition of integrated diagnostics to address these challenges is evaluated and illustrative clinical use cases are presented to highlight the benefits of integrating imaging and laboratory expertise.

### Integrated diagnostics— a potential solution?

Integrated diagnostics promises to solve major diagnostic challenges by combining complementary diagnostic strategies, complementing the benefits of each method, and balancing their respective limitations. The most striking benefits of an integrated diagnostic approach and how they can help solve the aforementioned challenges are depicted in **Fig. 2** and discussed in more detail below.

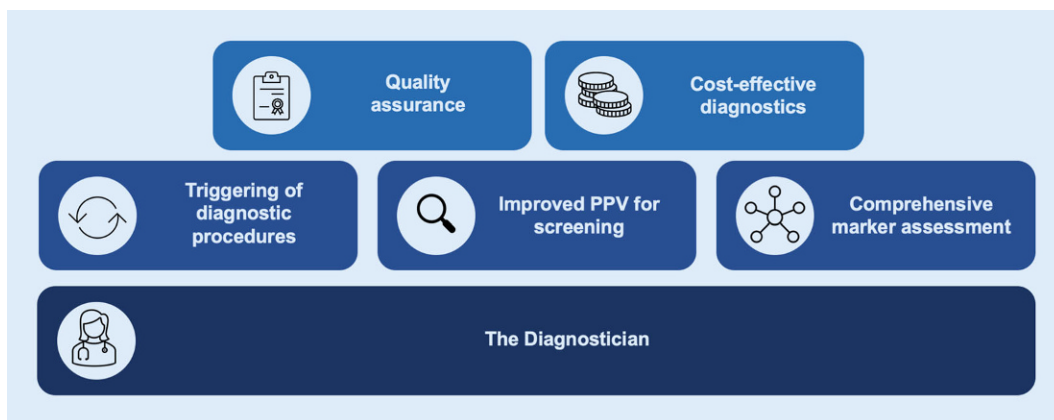
### Cost-effective diagnostics

Demographic change, the adoption of cutting-edge technologies and new treatment options into standard care, and administrative burdens are leading to continuously increasing healthcare costs, e.g., an increase in healthcare costs of more than 200-fold over the past 50 years [4] has been noted. This inevitably results in an enormous increase in cost pressures in medicine. As a consequence, cost-intensive diagnostic approaches are partly not reimbursed and not integrated into clinical workflows or guidelines despite their proven clinical utility and high accuracy. For example, the reimbursement options for liquid profiling are limited to specific tumor subtypes or medications or the use of a certain technique in Europe. Comparably, positron emission tomography (PET)/magnetic resonance imaging (MRI), which is more sensitive for M staging of colorectal cancer, is not reimbursed for all patients in Germany. Thus, from an economic point of view, rational, evidence-based use of diagnostic procedures for specific indications is essential. In this context, the combined use of imaging and laboratory tests can help define patient subgroups that will benefit from sophisticated or cutting-edge methods and thus accelerate translation into clinical practice.

One example of such an approach, already recognized in German S3 guidelines, is the diagnostic workflow for prostate cancer follow-up. Here, the use of prostate-specific membrane antigen (PSMA) PET/computed tomography (CT) is recommended for patients with biochemical recurrence assessed on the basis of

#### Abbreviations

CCT	Cranial computed tomography
DDIM	D-dimer
IRT	Immunoreactive trypsinogen
PE	Pulmonary embolism
PSMA	Prostate-specific membrane antigen
S100B	S100 calcium-binding protein B
TBI	Traumatic brain injury



**Fig. 2** ▲ Value proposition of integrated diagnostics. Complementary diagnostic approaches and orthogonal testing are a tool for quality assurance; the elimination of redundant testing and cross-triggering of diagnostic methods can increase cost efficiency; diagnostic sensitivity can be increased through comprehensive marker evaluation, leading to earlier detection of disease. To realize these potential benefits of integrated diagnostics, appropriately trained diagnostic experts are needed. The diagnostician as such will be the foundation for integrated diagnostics. *PPV* Positive Predictive Value

a prostate-specific antigen (PSA) value of  $>0.2 \mu\text{g/L}$  after radical prostatectomy or of  $>2 \mu\text{g/L}$  after radiotherapy following postinterventional PSA nadir on two separate occasions [5]. The cost-effectiveness of this combined diagnostic approach has been confirmed in initial studies [6].

### Quality assurance and improved clinical outcome

Quality assurance is a cornerstone to ensure the reliability and clinical value of diagnostic results. Therefore, several clinical guidelines recommend multimodal diagnostic algorithms, e.g., for pulmonary embolism [7], myocardial infarction [8], and pneumonia [9]. Noncompliance with such recommendations poses significant risks to patients and imposes an enormous economic burden. According to an estimate by the US National Committee of Quality Assurance, nonadherence to these recommendations in the United States is associated with more than 50,000 adverse health events, more than 30,000 deaths, and nearly \$ 1 billion in additional costs per year—with these numbers applying to only three common disease entities [10]. This finding is supported by the estimate that medical errors are the third leading cause of death in the United States [11]—a problem that may be addressed by a reduction of diagnostic misinterpretations. Misinterpretations represent the post-analytical part that should be quality controlled in addition to the pre-analytical

and analytical phase. Of note, some external quality assessment schemes address this issue.

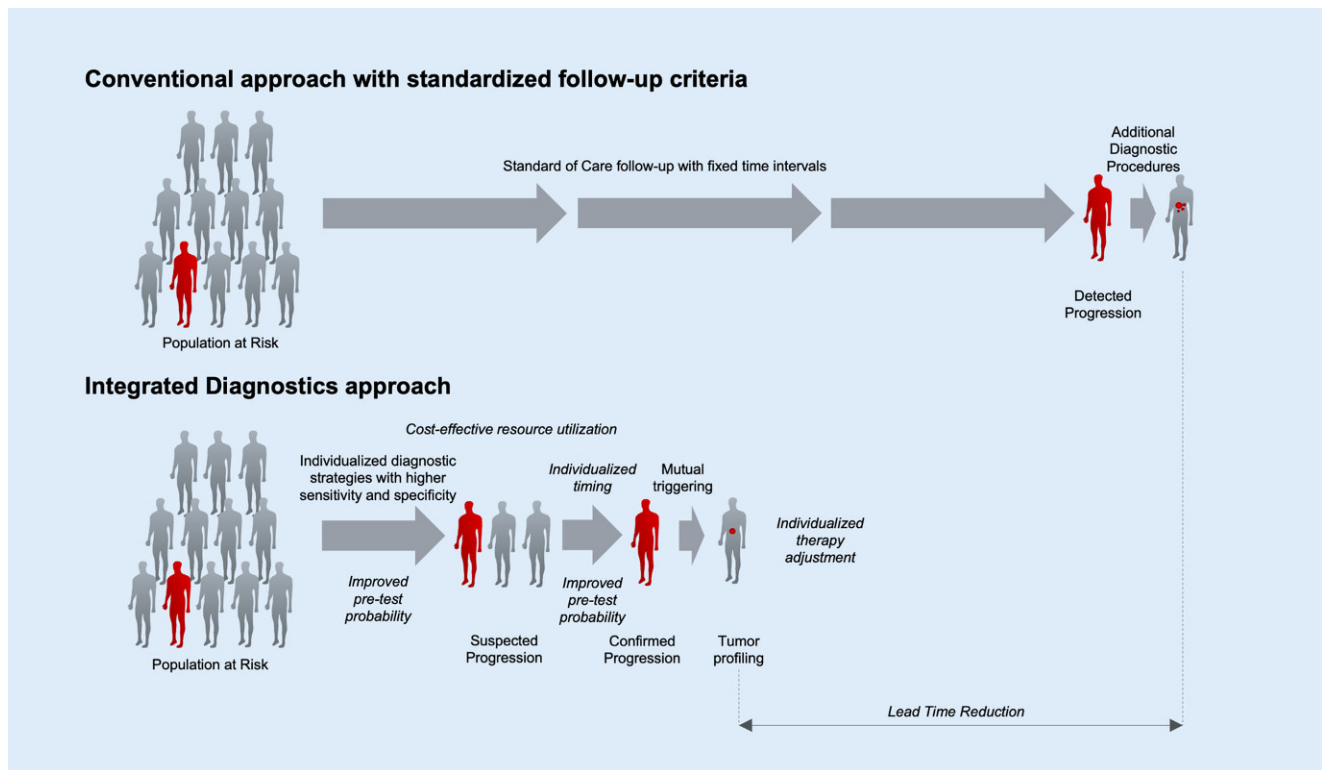
An integrated diagnostic approach as a cross-validation tool represents one way to optimize diagnostic quality. This interplay of laboratory and imaging methodology can be illustrated at several levels in the context of traumatic brain injury (TBI): The use of S100 calcium-binding protein B (S100B) is currently recommended as a precranial CT (CCT) test in the case of mild TBI due to its high negative predictive value of 99% [12]. Recently, however, it has been suggested that S100B should be used as an indicator of potentially false-negative CCT in all cases of TBI, regardless of severity [13], because false-negative CT readings may occur in up to 24% of cases and may be corrected by re-evaluation in up to 85% of cases [14, 15]. Here, the use of a simple laboratory test identifies the cases that require reassessment, thus providing a viable quality control measure, especially in the case of inexperienced readers on night shifts. Based on this integrated approach, patient outcomes may be improved and healthcare savings of up to 30% may be achieved [16, 17].

### Mutual triggering of diagnostic procedures

In chronic diseases, follow-up using clinical and multimodal diagnostics is regularly performed to predict and/or detect disease progression or relapse as early as

possible. In this situation, the appropriate selection of diagnostic modalities and timing poses a serious challenge to clinicians and diagnosticians. Currently, this uncertainty is addressed by disease-specific guidelines that provide standardized decision trees for patient monitoring, including recommendations for diagnostic procedures. However, it is recommended that follow-up tests are performed on a regular basis without specifying individual risk-adjusted time intervals. Here, mutual triggering of diagnostic procedures could help personalize diagnostic workflows, enabling earlier and more stratified detection of relapse.

This is most evident in cancer follow-up, where a balance between missed recurrence and overuse of diagnostic procedures must be carefully considered. The use of two highly sensitive, complementary diagnostic tests may further increase sensitivity, but also carries the risk of increased healthcare costs and false-positive results. For example, the use of protein tumor markers in combination with liquid profiling for surveillance may enable the detection of disease recurrence up to several months earlier than standard-of-care imaging, e.g., a lead time reduction of 10 months has been demonstrated for colorectal cancer [18–20]. However, this gap between the two diagnostic techniques might be reduced by an integrated approach. In this case, the positivity of liquid profiling should trigger a more sensitive imaging strategy—e.g., PET/MRI—for



**Fig. 3** ▲ Visualization of advantages of integrated diagnostics in monitoring of cancer recurrence. The conventional approach relies on standardized follow-up in accordance with guidelines. An integrated diagnostics approach would consist of diagnostic strategies adopted to individual patient needs. Thus, timepoints and choice of appropriate diagnostic strategies will rely on current diagnostic findings. Therefore, this represents the prerequisite to achieve precision diagnostics

confirmation and localization of the tumor site. Prospectively, quantitative image parameters may contribute to the understanding of tumoral heterogeneity [21] and, in combination with genetic tumor evolution assessed by liquid profiling, may be used to guide further follow-up and treatment strategies. For example, blood-based detection of upcoming resistance mechanisms could be directly assigned to specific metastatic sites by radiomics enabling a locoregional, targeted therapy.

### Comprehensive marker assessment

In many clinical situations, the diagnosis cannot be achieved with a single diagnostic modality. In this setting, imaging and laboratory experts can achieve a better diagnosis and better clinical decisions through a comprehensive marker assessment. While imaging can provide topological information about disease manifestations with high sensitivity, laboratory results provide additional information about organ function with high specificity and

detect pathophysiological conditions with high sensitivity. Also, an integrated approach facilitates the selection of the most appropriate further diagnostic procedures.

A well-recognized example of this is the use of D-dimer (DDIM) for moderate-to low-risk patients to rule out pulmonary embolism (PE). With a negative predictive value of up to 100% [22], non-elevated DDIM virtually rules out PE and venous thromboembolism thrombosis in general. Because DDIM positivity is the result of an activation of coagulation and fibrinolysis, which can be associated with several clinical conditions, such as malignancy, trauma, or systemic disease [23], a dedicated CT scan is required to confirm positive test results and provide additional information on location and severity.

### Improved positive predictive value for screening

Screening of a general population is often deemed to fail due to the low prevalence of disease, causing a very low positive-pre-

dictive value, even in cases of very high test sensitivity. Thus, screening programs increase stepwise the pre-test probability. For example, a specific sweat test for cystic fibrosis is performed only if the newborn screening for immunoreactive trypsinogen (IRT), pancreatitis-associated protein, and DNA test results were positive [24]. Similarly, in cancer screening, an initial increase in pretest probability can be achieved by patient selection based on demographic risk: In the case of breast cancer, screening is focused on patients in a vulnerable age group, with genetic risk factors and with a hereditary family predisposition [25]. In the case of lung cancer screening, the use of low-dose thoracic CT should focus on patient collectives with a history of smoking to increase pretest probability. These clinical approaches can be extended to further tumor entities by using an integrated diagnostic approach to patient selection, as proposed by Cohen et al. [26], as pan-cancer screening using a combination of protein and molecular tumor markers. This approach was further developed by

Lennon et al. [27], who reported a step-wise combined laboratory and imaging approach for cancer screening.

### Next steps to leverage the potential of integrated diagnostics

The benefits of an integrated diagnostic approach were recognized by the European Federation of Laboratory Medicine (EFLM) and the European Society of Radiology (ESR) at a strategic conference in 2019 in Mannheim, which eventually led to a cooperation contract between the two societies. As a result, an EFLM taskforce for integrated diagnostics was formed to evaluate the value proposition of integrated diagnostics in cancer [3]. The added value of integrated diagnostics particularly in cancer patient care has been highlighted by the examples provided in this manuscript and depicted in **Fig. 3** with special regard to cancer diagnostics. Moreover, at the organizational level, the establishment of clinical cooperation units between diagnostic disciplines can evaluate, validate, and ultimately implement an integrated approach to specific clinical scenarios to establish close interdisciplinary collaboration, an integrative platform for data evaluation, and the development of shared clinical decision support systems that rely on machine learning and artificial intelligence (AI) may help to increase diagnostic accuracy even further. By AI-based analysis of huge amounts of integrated data, diagnostic marker combinations that are not yet recognized may become visible. Beside an increased diagnostic accuracy, AI can be used to standardize diagnostic interpretation and to trigger reflex testing. Yet, interpretation of these complex interdisciplinary data will require an evolution toward a diagnostician who specializes in either of the diagnostic disciplines and has additional expertise and experience in complementary diagnostic fields. For example, diagnostic rotations and their acceptance for specialization as well as combined diagnostic meetings and symposia represent opportunities to prepare future specialists for integrated diagnostics. Finally, these structural prerequisites will be needed for a broader implementation of integrated diagnostics. Providing clinical decision support for clinicians or

general practitioners will result in a comprehensive interpretation of even complex diagnostic procedures in the individual patient context and thus allow for a stratified therapeutic decision. Cloud-based diagnostic dashboards specifically for referring physicians may offer the necessary technical backbone for successful clinical translation. This will foster joint visibility of diagnostic disciplines to the clinician. Taking the complexity of diagnostic procedures into consideration and their interpretation of the clinical context, clinicians will most likely benefit from such clinical decision support. Accordingly, the interpretation of the clinical findings in this context still remains in the hands of the clinicians and, therefore, may not be interpreted as an interference with their very own work. As a result, a successful implementation of integrated diagnostics will rely on a close collaboration with clinicians during the whole implementation process.

#### Corresponding address



#### PD Dr. med. Matthias F. Froelich, MHBA

Department of Radiology and Nuclear Medicine, University Medical Center Mannheim, Medical Faculty Mannheim of Heidelberg University  
Theodor-Kutzer-Ufer 1–3, 68167 Mannheim, Germany  
matthias.froelich@medma.uni-heidelberg.de

#### Declarations

**Conflict of interest.** V. Haselmann, S.O. Schoenberg, M. Neumaier and M.F. Froelich declare that they have no competing interests.

For this article no studies with human participants or animals were performed by any of the authors. All studies mentioned were in accordance with the ethical standards indicated in each case.

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## Integrierte Diagnostik

**Hintergrund:** Die integrierte Diagnostik gewinnt zunehmend an wissenschaftlicher Dynamik, da sie ein vielversprechender Ansatz ist, um mehrere aktuelle Herausforderungen der diagnostischen Medizin anzugehen. Diese Herausforderungen reichen von einer erforderlichen Verbesserung der diagnostischen Genauigkeit über eine Optimierung des Zeitpunkts für diagnostische Verfahren sowie die vielfältigen diagnostischen Marker und die daraus erwachsende Komplexität ihrer Interpretation bis hin zum ökonomischen Druck.

**Methodische Neuerungen:** Während viele dieser Probleme und Aufgaben mit einem monomodalen Ansatz wohl schwer zu lösen sind, verspricht die Integration von Labormarkern und Bildgebungsverfahren, dass das tatsächliche klinische Potenzial beider Disziplinen ausgeschöpft werden kann. Die Kombination komplementärer diagnostischer Ansätze kann helfen, die Interpretation von Messungen zu verbessern. Weiterhin kann sie eine bessere Kosteneffektivität ermöglichen, insbesondere bei Anwendung modernster Technik in spezifischen Indikationen, und eine optimierte zeitliche Planung sowie rationale Wahl geeigneter diagnostischer Verfahren für die Überwachung von Erkrankungen erleichtern. Darüber hinaus erhöht eine enge interdisziplinäre Beurteilung diagnostischer Ergebnisse die diagnostische Genauigkeit und ermöglicht die Selektion bestimmter Patientenkohorten, die ein erhöhtes Risiko für gewisse Erkrankungen haben und sich für weiterführende Untersuchungen eignen.

**Schlussfolgerung:** Das Potenzial eines integrierten diagnostischen Ansatzes stellt ein strategisches Ziel für diagnostische Disziplinen dar, weil sich damit bessere Sichtbarkeit und größerer klinischer Einfluss erreichen lässt. Neben der engen Zusammenarbeit einschlägiger Experten für Diagnostik müssen geeignete Strukturen für eine integrierte Datenauswertung geschaffen werden, um praktikable gesundheitsbezogene Orientierung zu bieten, sodass die integrierte Diagnostik in der Regelversorgung implementiert werden kann.

### Schlüsselwörter

Diagnostische Techniken und Verfahren · Qualitätssicherung · Kosteneffektivität · Diagnostiker · Integrative Diagnostik