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Requirements for electronic laboratory reports according to the German guideline Rili-BAEK and ISO 15189

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Abstract

Objectives: Legal regulations and guidelines such as the Guidelines of the German Medical Association for the Quality Assurance of Laboratory Medical Examinations (Rili-BAEK) and ISO 15189 apply to electronic laboratory reports. However, many laboratories struggle with practical implementation of these regulations and guidelines.
Methods: Laboratory and legal experts analyse the relevant guidelines and provide checklists and practical recommendations for implementation.
Results: Laboratories have less control over the display of electronic laboratory reports than over paper documents. However, an electronic report alone is legally sufficient and need not be accompanied by a paper copy. Rili-BAEK and ISO 15189 stipulate a set of minimum information in every report. The laboratory must verify that reports are transmitted and displayed correctly. To help laboratories do so, agreements between laboratories and the report recipients can clarify responsibilities.
Conclusions: Electronic laboratory reports can improve patient care, but laboratories need to verify their quality. Towards this end, Rili-BAEK and ISO 15189 set out helpful provisions.

Keywords: electronic laboratory report; electronic patient record; ISO 15189; regulation; Rili-BAEK.

Introduction

Laboratory reports are the main means of communication between laboratories and physicians caring for patients or the patients themselves. Laboratory reports today convey measurement results and interpretive comments [1]. Laboratories often regard the report as a showcase for their overall quality. They have devoted much effort to creating a design that allows the quick absorption of essential information. Paper reports as well as plain PDF files have been

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standard laboratory report formats for years. They have evolved over time, reflecting the quality of the laboratory as well as the needs of its customers. However, these types of print-oriented documents are not optimized for digital transmission, display, or access. The transmission of a paper report usually requires printing, sorting, and mail services, where each step introduces different types of errors, such as bad print quality, sorting errors, delays, or even a total loss of the document. The paper report also requires work for the recipient since it needs to be (correctly) archived. The use of plain PDF reports transmitted electronically has helped to overcome some of these problems, but limitations regarding the display and access of such reports remain. In addition, the depiction of cases over time is only possible using multiple reports and comparing them manually. Several changes in patient treatment require laboratory reports that are readable and interpretable electronically, so-called (structured) electronic reports. Medical pathways have become increasingly fragmented and involve many medical specialists [2]. Thus, laboratory reports must always be available at the place of treatment. Helpfully, electronic laboratory reports allow the fast [3] and reliable transfer of data. The COVID-19 pandemic has highlighted the importance of these processes not only for traditional patient care but also for public health [4]. In a modern clinical environment, reports are presented via digital archives and displayed on various devices. In contrast to structured electronic laboratory reports, a plain PDF report is often nearly unreadable on small screens [5]. In addition, structured information can be transmitted further, e.g., to other medical documents, such as to discharge summaries or to research platforms [6]. Electronic displays offer more options for highlighting important laboratory results and visualizing trends and patterns [7]. This kind of report also offers medical doctors on the ward the ability to customize their views, e.g., filtering for specific parameters of interest. In clinical decision support systems, electronic laboratory reports can be evaluated automatically [8–10]. Since electronic transmission is inexpensive, these reports can lead to cost reductions. Furthermore, patients are increasingly demanding a more active role in their health care and often want to manage their health and view their laboratory reports using more interactive tools, such as mobile health applications.

However, laboratories act in a highly regulated environment. Legally binding regulations and guidelines are in place to guarantee quality standards in medical laboratory procedures. Since both the devices used and the software required are, if they serve a medical purpose, classified as medical devices, the corresponding laws have to be taken into account. With the upcoming revised European legal framework in the form of the *In-vitro* Diagnostic Device Regulation (IVDR) [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0746&from=DE] and the Medical Device Regulation (MDR) [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=DE], modified requirements will need to be met when medical devices are initially placed on the market, made available, or put into service. Furthermore, the Guidelines of the German Medical Association for the Quality Assurance of Laboratory Medical Examinations (Rili-BAEK) [11, 12] sets forth quality standards and is also referenced by section 9 para. 1 of the German Medical Devices Operator Regulation (MPBetreibV) regarding quality assurance systems for medical laboratory examinations. Additionally, many medical laboratories obligate themselves to meet international quality standards, such as ISO 15189 [13]. Adherence to these quality standards is controlled in an accreditation process. In Germany, the German Accreditation Body (DAkkS) is responsible for the accreditation of medical laboratories.

German Rili-BAEK does not differentiate between different forms of laboratory reports. The related ISO 15189 has an additional section on information system management (5.10.3). It is undisputed that both normative documents apply to electronic laboratory reports as well. However, many laboratories struggle with practical implementation. This work examines formal and legal requirements for electronic laboratory reports and provides easy tools for laboratories to check their fulfilment of these requirements.

Materials and methods

Laboratory experts (organized in the German Society for Clinical Chemistry and Laboratory Medicine e.V. (DGKL)) identified disputed questions regarding electronic laboratory reports. After this, legal experts analysed the relevant normative documents to answer these questions. To make the findings easy to use, they were distilled into checklists.

Results

Laboratories have less control over electronic reports than over paper-based or PDF reports

The traditional paper-based or (plain) PDF laboratory report differs distinctly from the (structured) electronic laboratory report (Table 1). Since it cannot be changed after

Table 1: Differences between paper-based and electronic laboratory reports.

Paper-based laboratory report	Electronic (structured) laboratory report
Examples: laboratory report on plain paper, via fax, as plain PDF file	Examples: electronic laboratory report via LDT, CDA (special PDF with electronically readable data), HL7 V2 or V3, FHIR, or other formats
Data (analytical results, interpretative comments, etc.) are immutable	Data (analytical results, interpretative comments, etc.) are immutable
Display of data is immutable	Display of data may change depending on the program used by the report recipient
Cannot be evaluated electronically	Can be evaluated electronically
Cannot easily be further transmitted, usually transmitted with a loss of quality (paper copy)	Can easily be further transmitted, usually without a loss of quality
Retrieval of archived paper reports can be difficult	Easy electronic retrieval of archived reports

Table 2: Required elements of laboratory reports according to Rili-BAEK part A 6.3.2 and ISO 15189 5.8. These elements must also be accessible in an electronic laboratory report.

- Date and, if required, time the report was issued
- Identification of the patient
- Name or other means of identifying the sender of the specimen and, if required, his or her address; the address of the recipient of the report if not the same as that of the sender
- Name of the medical laboratory
- Date and time when the specimen was collected if this information is available and important for interpreting the examination results
- Date and time when the specimen arrived at the medical laboratory
- Type and quality (ISO 15189, 5.8.2) of the specimen
- Name of the laboratory examinations and methods used if the latter is important for interpreting the examination results
- Examination results and corresponding units as necessary
- Biological reference intervals, clinical decision limits, or diagrams/nomograms supporting clinical decision limits, where applicable
- Interpretation of results, interpretive comments, interpretive flags, or warning notices, e.g., due to limited sample quality, where appropriate
- Identification of the person responsible for releasing the report
- Identification of examinations undertaken as part of a research or development programme and for which no specific claims on measurement performance are available
- The clear identification of being a revised report if applicable[a]

[a]Also required by German Hemotherapy Guidelines 4.6.1.

it is released by the laboratory, the laboratory can easily verify that all information is included and displayed as intended. In the electronic laboratory report, data such as analytical results and interpretive comments should remain elementally unchanged as well. However, in many software applications, the display of the laboratory report needs to be adjusted to specific needs (e.g., the screen of a smartphone or tablet). Indeed, many electronic formats for the transmission of a laboratory report, such as Health Level Seven Version 2 and 3 (HL7 V2 and V3) [14], LDT (LDT = Labordatentransfer, a data transfer standard used for the communication of laboratory data in the outpatient sector in Germany) and Fast Healthcare Interoperability Resources (FHIR) [15], do not convey stylistic information. Only the Clinical Document Architecture (CDA) format allows the laboratory to specify how the report should be displayed in a special PDF file [16].

Legally, the electronic laboratory report is equivalent to the paper-based report

Despite the differences between these forms of reports, no normative document specifies that the laboratory report has to be paper based. None of the relevant laws (e.g., German Arzneimittelgesetz (Medicinal Products Act), German Transfusionsgesetz (Transfusion Act)) prohibit the electronic processing of laboratory reports. The electronic laboratory report alone is therefore sufficient. However, electronic laboratory reports must, of course, meet the same legal requirements as conventional paper-based reports. The German Rili-BAEK regulates the postanalytical procedure in part A 6.3. Rili-BAEK part A 6.3.2 and ISO 15189 5.8 specify general requirements and a minimum set of information that must be included in a laboratory report (Table 2). When an electronic laboratory report is displayed, this complete set does not have to appear on every screen. However, all items must always be accessible by the recipient. The laboratory is required to have written rules and adhere to certain specifications regarding the revision of reports and original results must remain available (Rili-BAEK part A 6.3.4, ISO 15189 5.9.3). In the case of electronic reports, the requirements of ISO 15189 for ensuring that the transcription is error-free (5.8.1) must also be complied with. Laboratories must ensure sufficient IT security and must establish contingency plans to maintain services in the event of IT failures (Rili-BAEK part A 7.1.1, ISO 15189 5.10.3).

Rili-BAEK and ISO 15189 are the main sector-specific normative documents for electronic laboratory reports for patient treatment in Germany. Other normative documents, including sector-specific laws, such as the

Medicinal Products Act, the German Transfusion Act, the German Guidelines for the Preparation of Blood and Blood Components and the Use of Blood Components (Hemotherapy Guidelines, see sections 12a, 18 German Transfusion Act) and the German Transplantation Act, do not stipulate any further requirements. However, the general requirements of data protection law must be met, meaning that any form of data processing is prohibited, unless it is expressly allowed by law, or the patient has consented to the processing. Furthermore, the General Data Protection Regulation contains technical and organizational requirements to secure the protection of personal data that might apply (e.g., Article 32, "Security of processing").

Ultimately, both the diagnostics and the transmission software as well as the devices themselves may be subject to product regulation. With the upcoming revised European legal framework, *in vitro* diagnostic and other medical devices are subject to a tighter legal framework.

Checklists help verify correct electronic laboratory reports

ISO 15189, 5.10.3 specifically refers to information system management, stating that the underlying systems in use shall be "validated by the supplier and verified for functioning by the laboratory before introduction, with any changes to the system authorized, documented and verified before implementation". According to ISO 15189, this also explicitly includes the "proper functioning of interfaces between the laboratory information system and other systems such as with laboratory instrumentation, hospital patient administration systems and systems in primary care". Ultimately, ISO 15189 5.10.3 also requires the laboratory to "verify that the results of examinations, associated information and comments are accurately reproduced, electronically and in hard copy where relevant, by the information systems external to the laboratory intended to directly receive the information".

The laboratory must verify that the laboratory report is transmitted (ISO 15189 5.8.1) and displayed correctly in systems that are intended to receive information directly from the laboratory (ISO 15189 5.10.3). The laboratory has no obligations regarding systems that receive information not directly but via a third party (e.g., if a primary care physician sends laboratory reports to an app his or her patients access). The laboratory also has no obligation when parts of an electronic laboratory report are extracted and reintegrated into other documents, such as medical reports.

Verification of the correct transmission and display has to be done not for every laboratory report but in a

Table 3: Checklist with probable pitfalls for proper report presentation in each system.

Comments	– Comments are displayed in their entirety
	– The part of the laboratory report to which the comment refers remains evident
	– Special characters (e.g., German umlauts like 'ä') are displayed and transcribed correctly
Reference interval	– The reference interval (or clinical decision values, etc.) and the unit are displayed as intended in the laboratory report
	– Changes in the reference interval do not affect results prior to that change
Abnormal flags	– The "flags" used to highlight some results (e.g., because they exceed the reference interval +/–) are displayed equivalently
	– Comments on sample quality that might compromise examination results (e.g., haemolysis) must be clearly visible
Results	– Unit conversions must be performed correctly
	– Non-numeric results ("less than", "greater than", "not detected") are displayed correctly
	– Graphical results (e.g., Reiber's diagram [17], nomograms) must be displayed correctly
	– The cumulative presentation of results must be correct
Naming and positioning	– If measurands are renamed (e.g., to group related measurements in one view), the original name must still retrievable (e.g., POCT glucose and central lab glucose)
	– The order of the measured values must not lead to misinterpretation, e.g., in the case of comments that are only linked to the reported value by their position on the next line
Reporting status (ISO 15189 5.9.3)	– The different stages of a report must be clearly indicated – preliminary report – final report – amendment to the final report – corrected report
	– Documentation of prior notifications, e.g., by telephone or fax must be provided
Possible "actions" of a recipient (ISO 15189 5.10.3)	– If an electronic laboratory report is printed, all information must be accurately reproduced

systematic manner, e.g., before the transmission of real-life data and when subsequent changes might influence the display. Towards this aim, a checklist (Table 3) has been generated with probable pitfalls so that laboratories can examine their electronic report reception and display system.

The correct electronic display of reports becomes easier if laboratories organize their software with electronic reports in mind. Interpretive comments should be directly assigned to the relevant analyses. If this reference can only be inferred from the textual description (e.g., "Interferences for all transaminases.") or from a specific order on the paper-based electronic report (e.g., "Results below are consistent with severe hypothyroidism."), electronic displays will struggle to attach the comments correctly. For purely administrative comments (e.g., "Barcode damaged; please label carefully for faster processing."), other forms of communication besides the laboratory report should be used. Some forms of electronic laboratory reports require laboratory analyses to be encoded with a terminology such as the Nomenclature for Properties and Units (NPU) or the Logical Observation Identifiers Names and Codes (LOINC) for semantic interoperability [18]. Units become interpretable electronically if encoded in the Unified Code for Units of Measure (UCUM) [19].

Agreements between laboratory and report recipient clarify responsibilities

Most software has to be regularly updated to ensure its safe operation. However, software updates can always introduce new errors unintentionally. Therefore, laboratories have to re-verify the correct transmission and display of their electronic laboratory reports after each update. The laboratory information system and software updates of the report receiving system should be embedded in a quality and change management system that includes risk management, personal information, documentation, and an evaluation of the process. Because the recipients of laboratory reports will probably use a variety of IT systems and because software updates are frequent, verification of the correct display of electronic laboratory reports can be a time-consuming exercise. A legal agreement between the laboratory and the recipient of its reports should define responsibilities and allows the use of a target-oriented approach. Both the laboratory and the recipient must agree on the transmission format (e.g., FHIR, LDT) and its concrete specifications. The recipient should also notify the laboratory about all changes in the software it uses to display laboratory reports. With this information, the laboratory can, in turn, consider the interface between the systems and limit its efforts to verify the correct display of the laboratory results. Virtual test patients with laboratory measurements covering the pitfalls previously mentioned could be created for an in-depth evaluation of all involved parts of the IT system. Using these test patients, laboratory reports should be electronically exported in the selected format. These exports can be used to verify the correct display in the receiving IT system. If the laboratory information system is updated, the test patient exports can be checked for any changes. If the new exports have changed, the reason for the modification should be investigated to exclude errors in the laboratory information system. If the change was intended (e.g., because of an update of the export format), all IT systems that receive and display laboratory reports must be re-verified. Additionally, when new examinations or comments are implemented that are very distinct from previous procedures (e.g., analysis with graphical results), the test patient exports must be amended and examined on all receiving systems. However, if no change in occurred in the exports, no verification is necessary. When an IT system displaying laboratory reports is updated, it can be quickly re-verified using test patient exports.

If no agreement can be reached and the laboratory is not informed about software updates, the laboratory should re-verify the display of its reports at fixed intervals using the reports of test patients.

Discussion

While the majority of laboratory errors are caused by pre-analytic problems, the post-analytic phase accounts for a rate of 5–47% of all errors [20, 21]. Nevertheless, with the upcoming increase in electronic laboratory reports, post-analytic errors may become more prominent [22]. The correct display of electronic laboratory results becomes more difficult when laboratory reports are released directly to the patient [23] or when reports from multiple laboratories are integrated into one electronic view [24, 25].

Since many laboratory specialists were trained in the era of paper reports, they rely on the electronic equivalent, PDF reports. This explains the common stance of laboratory professionals towards the structured electronic report that "I can't control the whole process of electronic reporting, so I am not responsible for this type of report." Our work clearly counters this view since it is the responsibility of the laboratory to assure the correct transmission and presentation of laboratory reports in clinical information systems according to the German Rili-BAEK

and ISO 15189. Other legal sources have established similar stipulations [25]. The following difficulties for the laboratories are obvious: Structured information of different statuses must be complete even if they are usually transferred in an atomized way (message-based). In clinical settings where this information is meant for different systems (such as report presentation systems, electronic patient archives, and patient data management systems) created by different vendors, the report presentation can vary greatly, especially if medical doctors have the option to customize their view. Another problem is that the complex presentation verification processes necessary for each customer are not reflected in the remuneration of the laboratory, although they cannot be implemented and applied without appropriately qualified personnel. Our checklists should help laboratory professionals verify these various forms of presentation. Since the presentation of results can be affected by software updates, we recommend performing this verification after major updates or releases or even doing so at regularly schedule intervals. The College of American Pathologists Laboratory General Checklist recommends reviewing electronic patient reports at least every 2 years [26]. Having a single agreed-upon IT standard for the transmission of laboratory reports instead of the variety of standards in use in Germany today would simplify the process of verifying the correct display of reports. Some IT systems are certified, e.g., according to "QMS-standard" for LDT in Germany (https://www.qms-standards.de/standards/ldt-schnittstelle/zertifizierung/) or with ring trials in Australia [27]. These standards reduce the amount of testing necessary.

Conclusions

Electronic laboratory reports can be used in new applications such as electronic patient records or clinical decision support systems. Laboratory medicine professionals should embrace these changes because they might drastically improve patient care. However, to ensure patient safety, laboratory medicine professionals should guarantee that the quality of laboratory reports is not compromised. Towards this end, Rili-BAEK and ISO 15189 set out helpful provisions.

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