Original Research Article

The Compliance and Quality Of Biological Examination Requests At The Douala General Hospital

ABSTRACT

INTRODUCTION:

The prescription of biological examinations is the first step in guaranteeing the quality of the results of the biological analyzes given by the laboratory. Indeed, the irregularity of requests for biological examinations makes it difficult to carry out and interpret the results and also compromises the optimal and rational use of the diagnostic aid tool that is the clinical biology laboratory. The purpose of this study was to assess the compliance and quality of Biological Examinations Requests (BERs) at the Douala General Hospital (DGH)

MATERIAL AND METHODS:

A descriptive cross-sectional study was conducted from January to June 2022 in the clinical biology laboratory department of the DGH. The information provided on each request for examinations was evaluated using a technical sheet containing the evaluation grids of the ISO 15189 standard.

RESULTS:

A total of 1765 BERs from 10 known clinical departments and 5.20% (n = 91) with no details on the department were analyzed. Prescriber qualification was absent in 13.31% (n=235), clinical information was notified in 23.79% (n=420), prescriber contact in 2.89% (n=51). The compliance assessment revealed that 49% (n=867) requests were non-compliant. Furthermore, a correlation was observed between non-compliant BERs and the internal medicine department (OR = 0.52 and P-value = 0.038) and medical specialists (OR = 0.576 and P-value = 0.048) with a significant association.

CONCLUSION:

It was observed that the non-compliant BERs lacked information identifying the patient, the prescriber, as well as the examination/sample. The ISO standard recommends the accuracy of this information. Because their absence would make it impossible to carry out the examinations,

waste of time searching for the service/prescriber for additional information or for the return of the results. These results suggest an improvement in practices in the prescription of medical biology analyzes at the DGH in particular and in Cameroon in general.

***Keywords: Conformity, Request for biological examinations* , Prescriber Information**

1. INTRODUCTION

To guarantee the reliability of results, the clinical biology laboratory must have a system that guarantees the quality of results and covers the pre-analytical, analytical and post-analytical stages of the biological examination [1,2]. The pre-analytical stage chronologically includes the prescription of biological analyses by physicians, i.e. the Biological Examination Request (BER), the preparation of the patient, the collection of the biological sample, the transport to the bench for the analysis [2–4]This stage is the most vulnerable, with a greater proportion of errors than the analytical and post analytical stages, i.e. approximately 68% of errors in the performance of a biological examination[5–7]. Moreover, it has been shown that approximately 41% of non-conformities in the laboratory are related to the prescription of biological examinations, which is therefore a fundamental element in the control of quality during the pre-analytical stage[4,8]. However, numerous studies have shown that poorly written biological examination requests or those that do not contain sufficient information will affect the quality of laboratory tests[8]. This is the case in Nigeria, where a study on the evaluation of biological examination requests (regularity or frequency of errors), showed the dangers of incomplete forms or forms that included an erroneous diagnosis, leading to poor management[9]. This dependence of patient management on this diagnostic and therapeutic monitoring tool underlines the need for prescribers who request a complementary analysis to write the request with the information defined by the rules of good writing practice for this medical prescription[6,10]. The absence of information or the occurrence of errors in a request may affect the quality of the execution of the examinations, lengthen the time required to transmit the results and cause re-takes[11,12]. In Cameroon, the compliance of biological analysis requests is a subject that deserves to be raised, because these medical orders are not always written according to the recommendations of international standards[13].

The purpose of this study was to evaluate the compliance and quality of Biological Examination Requests (BERs) at the Douala General Hospital (DGH).

2. METHODOLOGY

2.1. Type, location and time of study

This was a descriptive cross-sectional study conducted from January to June 2022 (six months) at the Clinical Biology Laboratory of the DGH.

2.2. Study population

The study included all biological test requests received at the laboratory. Requests that were written on insurance forms or HIV 1/2 viral load request forms with Ministry of Health letterhead were excluded.

2.3. Methods and techniques used

The sampling used was collected randomly. The tool used to evaluate the conformity of the biological test requests was a digitalized data sheet, containing the technical regularity elements (information on the patient and on the test/sample, relevant clinical information), as well as the additional information (prescriber, health structure issuing the request), which

must be present in a biological test request (table 1).

The minimum sample size was determined from the formula for the confidence interval C_I= [f - $\frac{1}{\sqrt{n}}$; f + $\frac{1}{\sqrt{n}}$], where f is the frequency and n the sample size.

Wefind the margitude of IC to be$\frac{2}{\sqrt{n}}$. For a margin error (risk of being wrong) set at 0.05 we have $\frac{2}{\sqrt{n}}$< 0.05, after calculation we find n ≥ 1600.

Thus weanalysed at least 1600 requests for examinations to obtain significant results with a risk level of fixed at 5%.

2.4. Criteria for interpreting the results

In order to be considered compliant or regular, the request had to have at least 80% (i.e. at least 16) of the elements sought in the evaluation form[4,10].

Next, a search for factors associated with biological test requestnon-compliance was conducted.

2.5. Statistical tests used

A uni-variate analysis was used to determine requests compliance. A logistic regression test was used to compare the different qualitative variables, in particular to determine any association between request non-compliance and the other study variables (period, services, prescriber qualification, etc.).

Table 1: Information sought on each biological test request [4,10]

	Information
Patient	Identity: Name(s) and surname(s)
	Date of birth
	Gender
	Patient contact
	Relevant clinical information: symptoms, diagnosis, current treatment…
	Residence
	Room or bed number
	Unique identifier (issued to the laboratory or the originating department)
Examination/ sampling	Exact wording of the tests requested
	Type of primary sample, anatomical site of origin
	Date of prescription
	Nature of the sample
	Date of collection
	Identity of the sampler
	Identity of the carrier
	Time of collection
Prescriber	Identity: name or unique identifier
	Qualification

	Signature
	Stamp
	Contact: phone/email/ extension number

3. RESULTS

A total of 1765 requests were included in the study.

3.1. Patients, services, prescriber qualification

The majority of BERs came from hospitalized patients 54.62% (n = 964), from the surgery department 51.90% (n = 916) and were prescribed by specialist doctors 61.08% (n = 1078) (Table 2).

3.2. Frequency of notification of the elements sought on a Biological Examination Request

Regarding patient information, surname, first name and sex were the most reported with 99.77% (n = 1761) and 80% (n = 1412) respectively. Relevant clinical information was provided in only 23.79% of requests.

Regarding the type of primary sample, it was specified in 100% (n = 1765) of the cases and the examinations were correctly labeled in 99.43% of the cases (n = 1755).

The information most represented among prescribers was identity (name or unique identifier), signature, and stamp, with 97.11% (n = 1714), 93.48% (n = 1650), and 85.78% (n = 1514), respectively (Table 3).

3.3. Compliance of Biological Examination Requests

Among the requests for non-compliant biological examinations, 76.24% (n = 661) came from non-hospitalized patients, 63.78% (n = 553) were provided by the internal medicine department, 70.36% (n = 610) were written by medical specialists and in 17.88% of cases (n = 155) the qualifications of the prescribers were not specified (Table 4).

3.4. Identification of factors associated with non-compliance

The BERs received during the day (adjusted OR = 0.094 and P-value = 0.000), the internal medicine department (adjusted OR = 0.52 and P-value = 0.038) and the intensive care unit (adjusted OR = 0.281 and P-value = 0.001) can be potentially associated with statistical significance with a relative risk close to having non-compliant requests (Table 5).

Table 2.Distribution of requests according to patient type, department and prescriber qualification

Variables	Terms and conditions	Frequency	
		N	%
Types of patients	Non-hospitalized interns	964	55
	Hospitalized interns	762	43
	Externals	39	2
Services	Surgery	916	51,90
	Radiotherapy	189	10,71
	Gynecology Obstetrics	181	10,25
	Isolation (COVID Unit)	137	7,76
	Internal Medicine	116	6,57
	Not specified	91	5,16
	Ophthalmology	88	4,99
	Pediatrics	32	1,81
	Radiology	10	0,57
	Intensive Care Unit	3	0,17
	Emergencies	2	0,11
Prescriber Qualification	Medical specialist	1078	61,08
	General practitioner	340	19,26

	Not specified	235	13,31
	Medical Resident	97	5,50
	Medical student	11	0,62
	Nurses of the unit	3	0,17
	Dental surgeon	1	0,06

Table 3. Notification of information required

Information		Frequency	
		N	%
Patient	Last name(s) and first name(s)	1761	99,77
	Gender	1412	80
	Age	1060	60,06
	Date of birth	676	38,3
	Relevant clinical information	420	23,79
	Patient contact	89	5,04
	Residence	71	4,02
	Room/Bed number	34	1,93
Examination/sampling	Type of primary specimen/ anatomical site of origin	1765	100
	Exact wording of the tests requested	1755	99,43
	Date of prescription	1747	98,98
	Nature of the sample	1717	97,28
	Date of collection	1626	92,12
	Collector identity	584	33,09
	Carrier identity	565	32,01
	Reported emergency	332	18,81
	Time of collection	319	18,07
Prescriber	Identity: name or unique identifier	1714	97,11
	Signature	1650	93,48
	Stamp	1514	85,78
	Contact	136	8
	Department extension number	33	1,87

Table 4. Distribution of requests by compliance

Variable		Requests for Biological Examinations N (%)	
		Compliant	**Not in compliance**
Type of patient	External	13 (1,44)	26 (3)
	Inpatient Non-hospitalized	303 (33,74)	661 (76,24)
	Inpatient hospitalized	582 (64,81)	180 (20,76)
Period	Day	731 (81,40)	846 (97,58)
	Guard	70 (7,95)	16 (1,85)
	Weekend	97 (10,80)	5 (0,58)
Service	Radiotherapy	0 (0)	3 (0,35)
	Gynecology Obstetrics	118 (13,14)	71 (8,19)
	Isolation (COVID Unit)	7 (0,78)	3 (0,35)
	Internal Medicine	363 (40,42)	553 (63,78)
	Not specified	47 (5,23)	44 (5,07)
	Ophthalmology	0 (0)	2 (0,23)
	Pediatrics	142 (15,81)	39 (4,50)
	Radiology	4 (0,45)	28 (3,23)
	Intensive Care Unit	41 (4,57)	47 (5,42)
	Emergencies	117 (13,03)	20 (2,31)
	Surgery	59 (6,57)	57 (6,57)
Prescriber Qualification	Dental Surgeon	1 (0,11)	0 (0)
	Medical student	8 (0,89)	2 (0,23)
	General Practitioner	276 (30,73)	64 (7,38)
	Medical Specialist	462 (51,44)	610 (70,36)
	Medical Resident	60 (6,68)	36 (4,15)
	Not specified	91 (10,13)	155 (17,88)

Table 5. Association between variables and non-compliance of test requests

Variable		Compliance		Adjusted OR (IC95%)	P value
		Yes	No		
Period	Day	731	846	0,094 (0,03-0,24)	**0,000**
	Guard	70	16	0,275 (0,09-0,83)	**0,023**
	Weekend	97	5	Ref	Ref
Services	Radiotherapy	0	3	Na	Na
	Gynecology Obstetrics	118	71	0,895 (0,44-1,79)	0,756
	Isolation (COVID Unit)	7	3	0,43 (0,09-1,98)	0,279
	Internal Medicine	363	553	0,52 (0,28-0,96)	**0,038**
	Not specified	47	44	0,412 (0,19-1,87)	0,201
	Ophthalmology	0	2	Na	Na
	Pediatrics	142	39	2,366 (1,14-4,88)	**0,020**
	Radiology	4	28	0,325 (0,09-1,15)	0,081
	Intensive Care Unit	41	47	0,281 (0,13-0,60)	**0,001**
	Emergencies	117	20	0,462 (0,22-0,94)	**0,033**
	Surgery	59	57	Ref	Ref
Prescriber Qualification	Dental surgeon	1	0	Na	Na
	Medical student	8	2	2,603 (0,40-16,88)	0,316
	General practitioner	276	64	1,518 (0,79 - 2,88)	0,203
	Medical specialist	462	610	0,576 (0,33-0,99)	**0,048**
	Medical Resident	60	36	Ref	Ref
Patient	External patient	13	26	0,179 (0,08-0,37)	**0,000**
	Outpatient	303	661	0,246 (0,18-0,32)	**0,000**
	Hospitalized patient	582	180	Ref	Ref
Text boxes	Patient	887	742	5,43 (2,72-10,81)	**0,000**
	Sampling/Examination	511	511	0,538 (0,36-7,19)	0,117
	Prescriber	374	400	1,577 (0,720-2,32)	0,621

*Ref = Reference; *Na = Not applicable

4. DISCUSSION

4.1. Evaluation of the compliance of biological examination requests

4.1.1. Type of patient and period of prescription

The majority, i.e. 76.24% of non-compliant requests came from non-hospitalized in-patients, with outpatients generally more numerous in a health facility with many specialties. It is in this sense that this result joins that obtained by Ateba et al. in 2014, who observed that 63% of non-conformities related to BERs when registering at the reception of clinical

biology laboratories[13].
The higher rate could be explained by the fact that their study determined different types of non-compliance in the pre-analytical phase, whereas we worked only on non-compliances related to the prescription.
Indeed, the ISO 15189 standard recommends specifying the patient's identification information as well as the prescription period. The absence of this information can lead to the impossibility of carrying out the examinations, a loss of time in searching for the patient's identity, a delay in the course of the examination, an inappropriate evaluation of the test results by the biologists and an impossibility of following the chronology of the examinations [4,14,15].

4.1.2. Service

For 5.07% of non-compliant ballots, the service was not specified. Toshniwal et al. in 2017 in a study on non-compliance of test orders for the biochemistry laboratory had 1.10% (n = 84) of cases where patient services were not known[16].Oladeinde et al. in 2012 had observed 20.10% of test requests without specifying the patient's service of origin [9]. This difference could be explained by an improvement in writing practices over the years or the sample size.
The ISO 15189 standard particularly advises traceability in a univocal way, by prescription sheet and labeling of the service of origin of the sample. Incorrect information or the absence of this item leads to a loss of time in searching for the service in the event of the need to transmit an urgent result or for additional information[4,15].

4.1.3. Qualification of prescribers

In 17.88% of cases, the qualification of prescribers is not specified and general practitioners prescribed 7.38% of non-compliant requests. Yacouba et al. had observed that 7.20% of non-compliant examination reports did not include the qualification of the prescriber[17]. Similarly, Nutt et al (2008) found that 19.9% of critical results came from test reports that did not contain information on the prescribers[18].
In fact, the absence of this item does not allow for a recipient of the analysis report, in addition to not allowing the technician to obtain additional information if necessary[15,19].

4.2. Notification of the elements of a biological examination request

4.2.1. Patient Information

The majority of information on the requests for examinations was first and last name (99.77%), sex (80%) and age (60.06%). These results are close to those of Yacouba et al. who show that the majority of the information on the patients was first and last name (99.80%), age (96.70%) and sex (94.30%) [17]. In addition, only 23.79% of requests had the relevant clinical information reported, which is lower than the 33.30% obtained by Onyiaorah et *al.* in 2012[20].
According to the ISO 15189 standard, information on the identity and relevant clinical information of the patient must be indicated, because the consequences of a lack of these items, incomplete identity (or erroneous identity) to a mismatch between the identity on the request for examination and that on the biological sample and non interpretable result for the biologist [4,21]

4.2.2. Examination/sampling

Of all the requests for biological examinations, the type of primary sample was specified, the time of collection was indicated in 18.07% of cases and the date of collection in 92.12% of the reports. Regarding the type of primary sample, our result is superior to that of Kipkulei (2019) et al. in a study of test requests sent to the haematology department, in which it was specified in only 84.40% of cases[22]. For Toshniwal et al. in the observational phase of their study in 2017, the date and time of sampling were notified in 99.11% (n = 7603) and 99.07% (n = 7670) respectively[16].
The standard NF EN ISO 22070 which completes the standard NF EN ISO 15189 gathers as specific requirements the precision of the nature of the primary sample, the time of sampling; the failure to respect them exposes for example to the rendering of an invalid result by the non-respect of the analysis time[18,23,24].

4.2.3. Prescriber Information

The identity (name or unique identifier) was specified in 97.11%, the signature was notified in 93.48% of the cases and the stamp was present in 85.78% of the requests. These results are similar to those obtained by Yacouba et al. who showed that the identity (name and surname) of the prescribers was mentioned in 94.10%, the signature was present in 94.20% and the stamp in 44.10% of cases [17].
ISO 15189 recommends a unique identification of the clinician, health care provider or other person legally authorized to order tests or use medical data, with the recipient of the report and contact data; indeed, the absence of this item does not

allow for a recipient of the test report, nor does it allow the technician to obtain additional information if needed, or [15,19].

5. CONCLUSION

This study on The Compliance and Quality Of Biological Examination Requests (BER) at the DGH according to the recommendations of ISO 15189 revealed that almost half of the BER were non-compliant ; in addition, the search for factors associated with the non-compliance of BER suggests a significant association between their non-compliance and certain variables (internal medicine department for example). It is therefore imperative that prescribers are made aware of the importance of well-written BERs for the proper management of the patient at the laboratory level. This can be done by improving the quality of test requests forms so that they all contain sufficient information to be filled in by the prescribers, by organizing refresher seminars for doctors and other prescribers on the principles of writing BERs. However, it would be preferable to computerize the BERs as this would considerably reduce the frequency of errors when ordering tests.

ETHICAL APPROVAL

Our study is committed to respecting the confidentiality and protection of the dignity of patients and prescribers, as well as the use of data for scientific purposes and publication of results. All this with the agreement of the Ethics and Institutional Committee of the University of Douala (No. 3215CEI-Udo/06/2022/T), with the approval of the heads of the institutions solicited for this study, with a strictly scientific and non-profit purpose, ensuring the confidentiality of the data collected.

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