

Prevention of hepatitis B and C among patients with sickle cell disease in Kinshasa: prevalence and the role of PCR in the biological qualification of blood for transfusion, A systematic review

Prévention des hépatites B et C chez les patients atteints de drépanocytose à Kinshasa : prévalence et rôle de la PCR dans la qualification biologique du sang pour la transfusion, une revue systématique

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ABSTRACT :

Blood transfusions play an essential role in the treatment of severe sickle cell disease. However, they carry a cumulative risk of transmitting blood-borne viral infections, especially hepatitis B virus (HBV) and hepatitis C virus (HCV), in patients receiving multiple transfusions. The prevention of these infections largely depends on the biological assessment of blood donations, which in the Democratic Republic of the Congo (DRC) primarily relies on serological tests. In Kinshasa, the particular impact of PCR on this preventive strategy is not well documented. This study seeks to gather and analyze existing data regarding the prevalence of HBV and HCV among sickle cell disease patients who have received transfusions in Kinshasa and assess the specific contribution of PCR, in conjunction with serology, to the biological qualification of blood for transfusions aimed at preventing these infections. A systematic review was conducted in accordance with the PRISMA 2020 guidelines. We explored biomedical databases and Congolese grey literature published between 2010 and 2025, with one notable exception for a publication from January 2026. The search strategy included keywords related to sickle cell disease, hepatitis B/C, blood transfusion, and Kinshasa/DRC. After a two-phase screening process, 20 studies were selected for inclusion. In Kinshasa, among sickle cell disease patients who received transfusions, the prevalence of hepatitis B surface antigen (HBsAg) ranged from 1.6% to 6%. The prevalence of anti-HCV antibodies varied from 4% to 13.5%, depending on the screening method used, with molecular detection via RT-PCR reaching 11.1%. HCV was consistently the most frequently occurring infection associated with transfusions. The only Congolese study providing a temporal reference indicated that all identified HCV cases were present in patients who had been transfused prior to the implementation of systematic screening in 2004. Local data on the biological screening of blood donations suggest that the rapid diagnostic tests commonly utilized have lower sensitivity compared to ELISA, and PCR has not yet been systematically incorporated into the Congolese transfusion framework. However, its documented sporadic contribution among patients with multiple transfusions in Kinshasa indicates specific preventive potential. While there has been a general enhancement in national safety measures for blood transfusions, the findings from Kinshasa, which are still limited and heterogeneous, should be interpreted cautiously. Strengthening prevention through the biological qualification of blood donations, particularly by strategically integrating PCR for patients receiving multiple transfusions, presents a promising area for further evaluation rather than a definitive recommendation based on the results of this review.

Keywords: sickle cell disease; hepatitis B; hepatitis C; blood transfusion; PCR; blood donation biological screening; prevention; Kinshasa; Democratic Republic of the Congo; systematic review.

RESUME :

Les transfusions sanguines jouent un rôle essentiel dans le traitement de la drépanocytose sévère. Cependant, elles comportent un risque cumulatif de transmission d'infections virales véhiculées par le sang, notamment par le virus de l'hépatite B (VHB) et le virus de l'hépatite C (VHC), chez les patients recevant des transfusions multiples. La prévention de ces infections repose en grande partie sur l'évaluation biologique des dons de sang, qui, en République démocratique du Congo (RDC), repose principalement sur des tests sérologiques. À Kinshasa, l'impact spécifique de la PCR sur cette stratégie de prévention est peu documenté. Cette étude vise à rassembler et analyser les données existantes concernant la prévalence des hépatites B et C chez les patients drépanocytaires ayant reçu des transfusions sanguines à Kinshasa, et à évaluer la contribution spécifique de la PCR, associée à la sérologie, à la qualification biologique du sang pour les transfusions destinées à prévenir ces infections. Une revue systématique a été menée conformément aux recommandations PRISMA 2020. Nous avons exploré les bases de données biomédicales et la littérature grise congolaise publiées entre 2010 et 2025, à l'exception notable d'une publication de janvier 2026. La stratégie de recherche comprenait des mots-clés liés à la drépanocytose, aux hépatites B et C, à la transfusion sanguine et à Kinshasa (RDC). Après un processus de sélection en deux phases, 20 études ont été retenues. À Kinshasa, chez les patients drépanocytaires ayant reçu des transfusions, la prévalence de l'antigène de surface de l'hépatite B (AgHBs) variait de 1,6 % à 6 %. La prévalence des anticorps anti-VHC variait de 4 % à 13,5 %, selon la méthode de dépistage utilisée, la détection moléculaire par RT-PCR atteignant 11,1 %. L'infection par le VHC était systématiquement l'infection la plus fréquemment associée aux transfusions. La seule étude congolaise fournissant un repère temporel indique que tous les cas d'hépatite C identifiés concernaient des patients transfusés avant la mise en place du dépistage systématique en 2004. Les données locales sur le dépistage biologique des dons de sang suggèrent que les tests de diagnostic rapide couramment utilisés ont une sensibilité inférieure à celle du test ELISA, et que la PCR n'a pas encore été systématiquement intégrée au système de transfusion congolais. Cependant, sa contribution sporadique documentée chez les patients ayant reçu de multiples transfusions à Kinshasa indique un potentiel préventif spécifique. Bien qu'il y ait eu une amélioration générale des mesures nationales de sécurité pour les transfusions sanguines, les résultats de Kinshasa, qui sont encore limités et hétérogènes, doivent être interprétés avec prudence. Le renforcement de la prévention par la qualification biologique des dons de sang, notamment par l'intégration stratégique de la PCR pour les patients recevant des transfusions multiples, constitue un domaine prometteur qui mérite une évaluation plus approfondie plutôt qu'une recommandation définitive fondée sur les résultats de cette étude.

Mots clés : drépanocytose ; hépatite B ; hépatite C ; transfusion sanguine ; PCR ; dépistage biologique du don de sang ; prévention ; Kinshasa ; République démocratique du Congo ; revue systématique.

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I. INTRODUCTION

Sickle cell disease is one of the most common genetic disorders in sub-Saharan Africa, and the Democratic Republic of the Congo (DRC) records one of the highest prevalences in the world, estimated between 2 and 3% of the general population, according to data from the National Blood Transfusion Policy [1]. This disease exposes patients, from a young age, to recurrent acute complications such as vaso-occlusive crises, acute chest syndromes, and strokes, whose treatment often relies on transfusions of packed red blood cells, whether simple transfusions or frequent exchange transfusions in the most severe cases.

However, each transfusion carries a residual risk of transmitting infectious agents, particularly hepatitis B and C viruses. In the DRC, a significant portion of the population is affected by hepatitis B, with an estimated national HBs antigen prevalence of about 4.9% [2], and similar or even higher rates among blood donors [3,4]. Hepatitis C, although less widespread in the general population (with a prevalence of about 2.9%; [5]), presents particular challenges for patients who have received multiple transfusions, since repeated exposure to blood products is a well-documented risk factor in public health literature in Africa [6,7,8].

To address this risk, biological qualification of blood donations (QBD), which includes all screening tests performed on each unit of blood before it is made available for clinical use, constitutes the main preventive measure. The National Blood Transfusion Centre (CNTS), established in 1999, oversees this system at the national level. Available data indicate a gradual improvement in transfusion safety over the past twenty years [9], while highlighting persistent technical limitations: screening relies mostly on rapid diagnostic tests (RDTs) whose sensitivity, as revealed by several local studies, remains lower than that of immunoenzymatic methods (ELISA) [10]. Moreover, to date, none of the transfusion centers in the DRC routinely uses a nucleic acid testing (NAT) system for viral screening, in contrast to protocols in place in high-resource countries.

Two key concepts structure this review and must be defined according to World Health Organization (WHO) standards. The “serological window” refers to the period between infection of an individual by an infectious agent and the moment when serological markers of this infection (antigens or antibodies) become detectable by conventional screening tests; during this phase, a recently infected blood donor may be falsely classified as negative, while the infectious agent is already present and transmissible. This underlines the need to use nucleic acid detection techniques (NAT/PCR), which can significantly reduce this window. The “residual risk” associated with transfusions is defined, according to WHO

and transfusion safety authorities, as the probability that a labile blood product will transmit an infectious agent, even with the full implementation of biological qualification measures. This risk can never be reduced to zero, but can be minimized, notably through the use of multiple complementary screening techniques. These two concepts form the guiding thread of this review, which aims to assess the extent of this residual risk among transfused sickle cell patients in Kinshasa and to analyze its determinants.

The terms NAT, PCR, and RT-PCR are not synonymous and are used with precise distinctions in this study. NAT (“Nucleic Acid Testing”) refers to a category of validated genomic screening tests for systematic blood donation qualification, generally automated and standardized (such as Cobas platforms). In contrast, PCR and RT-PCR refer to specific molecular biology techniques that may be used for diagnostic research purposes in patients, without necessarily corresponding to a validated NAT platform for systematic donor screening. Thus, a PCR performed in the context of a clinical study, such as that conducted by Ilunga, Kamangu et al. [11], should not be confused with a NAT screening performed routinely for transfusions. Although these three elements the burden of sickle cell disease, repeated exposure to transfusions, and the limitations of blood biological qualification are crucial, the scientific literature does not seem to offer, according to the sources examined for this review, a synthesis that clearly combines these three aspects in the specific context of Kinshasa. Existing research addresses individually the prevalence of hepatitis among donors, transfused sickle cell patients, or the effectiveness of screening tools, without establishing links in an integrated prevention approach.

This systematic review aims to address this gap by investigating the following research question, formulated according to the PICO model: what is the prevalence of hepatitis B and C viral infections among transfused sickle cell patients in Kinshasa, and what role does PCR play, in addition to serology, in the biological qualification of blood intended for transfusion to prevent these post-transfusion infections? More specifically, this study aims (i) to document the prevalence of hepatitis B and C viruses in transfused sickle cell patients in Kinshasa, taking into account available data from the Democratic Republic of the Congo and from similar countries in Central and West Africa, (ii) to analyze the relationship between transfusion exposure and the risk of infection, and (iii) to assess, based on existing data, the specific contribution of PCR compared to serology alone in the prevention of these infections within the system of biological qualification of donations.

II. MATERIAL AND METHODS

II.1. Study design

Regarding the methodology, this review was conducted according to the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA 2020). Given the expected diversity of screening methods and analyzed populations, a structured narrative synthesis was chosen rather than a quantitative meta-analysis. The protocol for this study was registered in advance on the PROSPERO and OSF platforms. Registration was completed on PROSPERO under the number: [CRD420261428743] and it was archived on the Open Science Framework (OSF, DOI: 10.17605/OSF.IO/3QZR9).

Table I. Eligibility criteria, following the PICOS framework.

Population	Sickle cell patients (SS, SC, S β -thalassemia) receiving blood transfusions, in Kinshasa/DRC and in comparable sub-Saharan African settings
Intervention/exposure	Biological qualification of blood (screening for HBsAg, anti-HCV, $\pm$ PCR/viral DNA-RNA quantification) prior to transfusion
Comparator	No systematic screening, incomplete screening, or non-transfused populations
Outcome criteria	Prevalence of hepatitis B and C; effectiveness of biological qualification in reducing transfusion-related risk
Type of studies	Cross-sectional studies, cohorts, case series; systematic reviews and meta-analyses for contextualization
Period	Publications from 2010 to 2025, with a justified exception for a study published online in January 2026 due to its direct relevance to the Kinshasa context
Language	French, English

The PICO framework previously mentioned, which originates from controlled trials, is only partially adapted to a review mainly composed of observational studies. It is thus supplemented by a more relevant PECO framework: Population = sickle cell patients who have received transfusions (main corpus: Kinshasa/DRC); Exposure = exposure to transfusions and modalities of biological qualification of donations; Comparator = absence of transfusion, reduced transfusional exposure, or different screening strategies (serology alone versus serology + PCR); Outcome = presence of HBV markers (HBsAg) and HCV (anti-HCV antibodies and/or HCV RNA depending on the study). It is important to emphasize that a prevalence study measures only the frequency of infections at a given time and is not sufficient to assess the effectiveness of a screening device; thus, the concepts of infection prevalence and effectiveness of biological qualification of donations will be

addressed separately in this review, rather than as a composite outcome.

The body of evidence is divided into three levels: the title of this review focuses specifically on transfused sickle cell patients in Kinshasa, while the eligibility criteria (mentioned above) allow for the inclusion of a broader corpus. To clarify the levels of evidence, the twenty selected sources are now classified into three distinct corpora, the composition of which is specified in Table I: (i) the main corpus, centered on transfused sickle cell patients from Kinshasa/DRC (studies nos. 1, 2, 9, and 10 in Table I); (ii) a corpus for regional contextualization, concerning sickle cell patients or transfused populations from other sub-Saharan African countries (Cameroon, CAR, Senegal, Angola, Nigeria, Congo-Brazzaville); (iii) a corpus relating to the biological qualification of donations and the general blood donor population in DRC, without direct link to the sickle cell population. The conclusions specific to Kinshasa, presented in the Discussion and Conclusion, are henceforth limited to the main corpus (i); corpora (ii) and (iii) are used only for regional comparisons and to provide context, and not as direct evidence concerning the situation in Kinshasa.

The inclusion period mentioned (2010–2025) includes an exception for a study published in January 2026 [11], retained because of its relevance for the Kinshasa context. Excluded were: studies that did not provide quantitative data on the prevalence of HBV or HCV, those focused on populations outside the PICOS framework (neither sickle cell patients nor blood donors/recipients), as well as duplicate publications and secondary reports of studies already counted.

The term comparable context was used in the above PICO table to refer to sub-Saharan African countries sharing with DRC (i) a baseline HBV and/or HCV prevalence deemed intermediate to high by WHO, (ii) similar reliance on rapid serology as the main tool for biological qualification of donations (no routine NAT), and (iii) transfusion management of sickle cell disease based on comparable public hospital facilities. On this basis, Cameroon, the Central African Republic, Senegal, Angola, Nigeria, and Congo-Brazzaville were selected for the regional contextualization corpus; studies from contexts with universal NAT screening would not have met this criterion and were not systematically sought.

The implementation of the outcome “effectiveness of biological qualification of the donation” had not been sufficiently specified at the outset. Given that none of the included studies provide a clear comparative measure, such as the sensitivity or specificity of a complete screening algorithm, the evolution of incidence before and after the

introduction of a new tool, or the proportion of false negatives in real-world large-scale conditions, this review cannot provide a formal conclusion regarding the “effectiveness” of biological qualification of the donation in the strict sense. The available data, however, allow the observation—and are now reformulated in the Results and Discussion—of two main elements: (i) the sensitivity of the rapid test compared with ELISA on a verified subsample [10] and (ii) the evolution of the prevalence of infectious markers among blood donors at the national level [9], without it being possible to prove a direct causal link between this evolution and a specific screening device based on the available data.

Concerning the sources of information and the search strategy, the literature review was conducted in generalist biomedical databases, supplemented by a manual search in French-speaking African scientific journals that publish a significant portion of Congolese literature not indexed in the main international databases, such as Pan African Medical Journal, Health Sciences and Disease, and Orapuh Journal. In addition, documents from institutional grey literature, such as those related to the national blood transfusion policy and CNTS manuals, were examined. The search equation combined, in French and English, terms such as drépanocytose/sickle cell, hepatitis B/C, HBV/HCV, transfusion, biological qualification of donation, Kinshasa, RD Congo/DRC, using the Boolean operators AND/OR.

The study selection process was carried out in two phases: first, screening based on the title and abstract, followed by a full-text evaluation of articles deemed potentially relevant. The details of this process, including the number of records identified, deduplicated, excluded, and finally retained, are presented in the PRISMA flow diagram. For each selected study, standardized information was extracted, including authors, year of publication, country and city, study design, sample size, target population, virological screening method used, as well as prevalence results for HBV and/or HCV.

Risk of bias assessment was conducted qualitatively to appraise the methodological quality of the included cross-sectional studies. This appraisal considered sample representativeness, clarity of diagnostic criteria, and rigor in reporting results, following the principles of the Joanna Briggs Institute critical appraisal checklist for prevalence studies. This process did not lead to a formal composite score, a methodological limitation discussed in section 4.

To meet the PRISMA 2020 requirement for a formalized risk of bias assessment, the table below summarizes the qualitative appraisal of the risk of bias in the twenty selected studies, based on the domains of the Joanna Briggs Institute critical appraisal checklist for prevalence studies (representativeness of the sample, validity of exposure and

outcome measurement methods, adequacy of statistical analysis). This evaluation was based on the characteristics extracted from the studies rather than on a full review by two independent assessors. Although this constitutes progress compared to the previous version, it does not replace a composite score obtained through double blinded assessment, a limitation that remains under discussion in the section “Strengths and limitations of the review.”

Table II. Qualitative assessment of risk of bias in included studies (JBI checklist)

No.	Study	Qualitative assessment (JBI checklist)	Summary justification
1	Bushabu et al. [13]	Moderate risk	Limited sample (n = 100), single-center; clearly described prospective cross-sectional design.
2	Ilunga, Kamangu et al. [11]	Moderate risk	Limited sample (n = 90); study currently distributed as a preprint (bioRxiv/Research Square), not yet peer-reviewed at the time of this review.
3	Batina et al. [1]	Moderate risk	Modest sample (n = 140) but precise time frame and clearly reported design.
4	Katabuka et al. [14]	Low risk	Larger sample (n = 371), described multicenter recruitment.
5	Mwanaut et al. [15]	Moderate risk	Sample size reported only approximately in available sources; sampling method poorly detailed.
6	Kabinda et al. [4]	Low risk	Large sample (n = 1,079), standardized screening method.
7	Muzembo et al. [5]	Low risk	Meta-analysis conducted according to explicit systematic methodology.
8	Shindano et al. [2]	Low risk	Systematic review based on JBI tools, large pooled sample (154,926 subjects).
9	Moloko Maindo et al. [16]	Moderate risk	Adequate sample size (n = 582) but released as a preprint (bioRxiv), not yet published in a peer-reviewed journal with confirmed identification.
10	Kabinda et al. [9]	Low risk	National trend analysis covering multiple years of CNTS data.
11	Kashosi et al. [10]	Low risk	Rigorous comparative design (RDT vs ELISA), sample of 312 bags with systematic retesting.
12	Ngo Sack et al. [6]	Moderate risk	Limited sample (n = 108), single-center.
13	Gody et al. [7]	Moderate risk	Small sample (n = 98) but robust prospective pre/post-transfusion design.
14	Seck et al. [17]	Low risk	Large sample (n = 1,078), well-documented cohort.
15	Seck et al. [18]	Moderate risk	Moderate sample (n = 253), case-control design.
16	Peliganga et al. [19]	Low risk	Very large sample (n = 57,979) over 15 years of follow-up.
17	Akpa et al. [8]	Low risk	Large sample (n = 2,034), multicenter case-control design.
18	Bakarey et al. [20]	Moderate risk	Limited sample (n = 112), single-center.
19	Atipo-Ibara et al. [21]	Low risk	Very large sample (n = 17,351 donors).
20	Atipo-Ibara et al. [22]	Low risk	Large sample (n = 1,363).

II.2. Data synthesis

Due to the variety of screening methods, such as rapid serology, ELISA, and PCR, as well as the limited sample sizes in several studies—including those focused on sickle cell patients in Kinshasa—a meta-analysis was not deemed appropriate. The results are presented as a narrative synthesis, organized by theme, and supplemented by a summary table of study characteristics and comparative graphs.

The heterogeneity that led to preferring a narrative over a quantitative synthesis is not limited to screening methods. It also extends to the populations studied (transfused sickle cell patients, general blood donors, transfused children without specific sickle cell status), to the locations (Kinshasa, other cities in the DRC, and seven countries in sub-Saharan Africa), to recruitment periods (studies conducted between 2010 and 2026), to transfusion exposure (number of transfusions often not reported or categorized differently depending on the study), to biological markers measured (HBsAg, anti-HCV, HCV-RNA as applicable), to diagnostic methods (rapid test, ELISA, PCR/RT-PCR), and to study types (cross-sectional, cohort, case-control, systematic reviews). No subgroup of studies demonstrated sufficient homogeneity across all these aspects to justify a pooled effect calculation, even among the corpus focused on Kinshasa, which includes two studies with partially different designs and populations.

Regarding the narrative synthesis method, studies were grouped by theme (HBV prevalence, HCV prevalence, quality of biological screening of donations, link between transfusion frequency and infection risk), ensuring a clear distinction between the main Kinshasa corpus, regional corpora, and studies on biological qualification of donations (see Methodology section). For each theme, studies are presented in descending order of relevance to the target population (transfused sickle cell patients in Kinshasa first), and reported effects were compared qualitatively, without pooled effect calculation. The risk of bias assessment (Table III) was integrated to adjust the weight given to each study in the discussed interpretation, recognizing that studies presenting a high risk of bias (limited, single-center samples) are to be considered as indicators to be validated rather than robust evidence.

The certainty level of the main conclusions was not formally evaluated according to the GRADE approach. Given the limited number of studies directly relevant to Kinshasa, the predominantly observational nature of research, partial indirectness (a significant portion of studies pertains to blood donors or to other countries rather than sickle cell patients in Kinshasa), and the aforementioned heterogeneity, the certainty of conclusions specifically concerning transfused sickle cell patients in Kinshasa should be considered low to very low.

III. RESULTATS

III.1. Results of the literature search and study selection

The search strategy identified 320 potentially relevant references through the databases consulted and the grey literature (exact figure, basis for the PRISMA flow diagram).

Thirty-five articles were evaluated in full text according to the PICOS criteria. Fifteen of these were excluded for various reasons: lack of quantitative data on the prevalence of HBV or HCV ($n = 6$), population not meeting inclusion criteria ($n = 5$), or duplicate publication ($n = 4$).

In the end, 20 studies were selected for qualitative synthesis (Figure 1). Two of them focus specifically on transfused sickle cell patients in Kinshasa, while the other eighteen provide contextual information on the prevalence of viral hepatitis among blood donors in the DRC and among transfused sickle cell patients in comparable countries of Central and West Africa. Among these twenty sources, eighteen are primary studies, and two are previous systematic reviews [2,5], used only for contextualization and to verify the comprehensiveness of the search, without being counted as independent primary evidence in order to avoid double counting with the primary studies they contain.

III.2. Characteristics of included studies

The twenty selected studies were conducted between 2010 and 2025 in eight sub-Saharan African countries. An additional study, conducted in 2026, was included due to its significance in the Democratic Republic of the Congo. Sample sizes vary widely, ranging from 90 patients with sickle cell disease who had received multiple blood transfusions, to 57,979 blood donors followed over a fifteen-year period. Table III provides a summary of the study design, setting, cohort size, target population, and screening method for each included study.

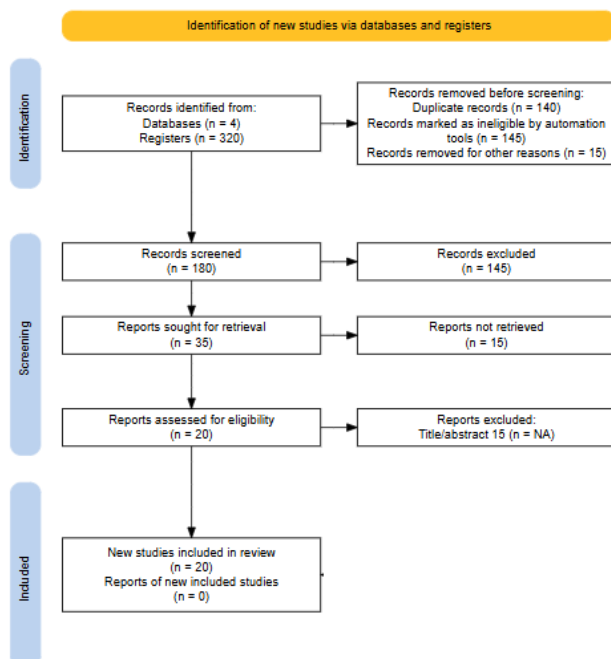


Figure 1. PRISMA 2020 flow diagram[12].

Table III. Characteristics of studies included in the synthesis (n = 20)

No	Study	Country / City	Study design	n	Population	Screening method
1	Bushabu et al. [13]	Kinshasa, DRC	Prospective cross-sectional	100 (50 T / 50 NT)	Sickle cell patients	RDT + ECLIA (Cobas 8000)
2	Ilunga, Kamangu et al. [11]	Kinshasa, DRC	Descriptive cross-sectional	90	Multi-transfused sickle cell patients	Conventional RT-PCR
3	Batina et al. [1]	Kisangani, DRC	Cross-sectional	140 (127 T)	Sickle cell patients	HBsAg/anti-HCV serology
4	Katabuka et al. [14]	Kinshasa, DRC	Multicenter cross-sectional	371	Transfused children	HBsAg/anti-HCV/anti-HIV serology
5	Mwanaut et al. [15]	Kinshasa, DRC	Cross-sectional	≈180	Multi-transfused adult sickle cell patients	Serology
6	Kabinda et al. [4]	Bukavu, DRC	Cross-sectional	1.079	Blood donors	Serology
7	Muzembo et al. [5]	DRC (review)	Systematic review / meta-analysis	16 studies / 13.799	Donors, pregnant women, sickle cell patients	Various
8	Shindano et al. [2]	DRC (review)	Systematic review	28 studies / 154.926	Mostly donors	Various
9	Moloko Maindo et al. [16]	Kinshasa, DRC	Cross-sectional + sequencing	582	Voluntary donors	ELISA + S-gene PCR
10	Kabinda et al. [9]	DRC (national)	Trend analysis	National	Blood donors	RDT/ELISA
11	Kashosi et al. [10]	Bukavu, DRC	Comparative cross-sectional	312	Transfused blood units	RDT vs ELISA
12	Ngo Sack et al. [6]	Yaoundé, Cameroon	Cross-sectional	108	Homozygous sickle cell patients	HBsAg/anti-HCV serology
13	Gody et al. [7]	Bangui, CAR	Prospective cohort	98	Transfused sickle cell children	Pre-/post-transfusion serology
14	Seck et al. [17]	Dakar, Senegal	Retrospective cohort	1.078	Sickle cell patients (SS/SC/Sβ)	Chart review
15	Seck et al. [18]	Dakar, Senegal	Case-control	253 (153 T / 100 NT)	Sickle cell patients	Serology
16	Peliganga et al. [19]	Bié, Angola	Retrospective (15 years)	57.979	Blood donors	Serology + OBI screening
17	Akpa et al. [8]	Southwest Nigeria	Case-control	2.034	Sickle cell patients + controls	ELISA
18	Bakarey et al. [20]	Ibadan, Nigeria	Cross-sectional	112	Sickle cell patients	ELISA/serology
19	Atipo-Ibara et al. [21]	Brazzaville/Pointe-Noire	Cross-sectional	17.351	Blood donors	Serology + NS5B sequencing
20	Atipo-Ibara et al. [22]	Southern Congo	Cross-sectional	1.363	Blood donors	HBsAg + DNA amplification

T = transfused; NT = non-transfused.

III.4. Prevalence of hepatitis B in sickle cell patients and blood donors

In Kinshasa, the seroprevalence of HBs antigen among sickle cell patients who received transfusions ranges from 1.6% to 6%. According to the work of Bushabu et al. [13], the rate among transfused patients rises to 6%, compared to 3% in those who were not transfused. This difference is not statistically significant, as indicated by Fisher's exact test results ($p > 0.05$), due to the small sample size. These results are consistent with previous findings by Katabuka et al. [14] among transfused children in Kinshasa (1.6%) and by Batina et al. [1] in Kisangani (1.6%, i.e., 2 out of 127 transfused).

For blood donors in the Democratic Republic of the Congo, a systematic review conducted in 2018 estimates the HBsAg prevalence at 4.9% (95%CI: 4.2–5.0%), reaching 5.0% (95%CI: 4.9–5.1%) specifically among donors. These data are corroborated by a molecular study carried out at the CNTS in Kinshasa, which showed a rate of 6.9% among 582 volunteer donors, as well as by figures obtained in Bukavu (4.2% out of 1,079 donors; [4]). National trend analysis by Kabinda et al. [9] indicates a notable decrease in HBsAg prevalence among donors between 2001 and 2012, falling from 7.1% to 3.5%, in parallel with the strengthening of biological qualification measures for donations. In Kinshasa, Baleka et al. [3] also report an HBsAg prevalence of about 5% among blood donors, including cases of HIV-HBV-HCV co-infection, which reinforces the coherence of Kinshasa data with those at both the national and Bukavu levels.

Regionally, HBsAg prevalence among transfused sickle cell patients increases with the number of transfusions received in Cameroon [6] and was documented at 14.3% among

transfused children in Bangui [7], while remaining lower in Dakar (2%; [18]). Blood donors in Angola present a prevalence of 8.5% [19] and those in southern Congo-Brazzaville, 9.9% [22], which exceeds the rates observed in the DRC.

III.5. The prevalence of hepatitis C among sickle cell patients and blood donors

Hepatitis C stands out in studies conducted in Kinshasa as the virus most frequently transmitted by transfusion. Katabuka et al. [14] found a prevalence of anti-HCV antibodies of 13.5% among transfused children, far higher than that observed for HBV (1.6%) and HIV (1.3%) in the same study. This trend is confirmed by Ilunga, Kamangu et al. [11], who used RT-PCR on a sample of 90 polytransfused sickle cell patients in Kinshasa, revealing a prevalence of 11.1%, significantly higher than that measured by serology in the study by Bushabu et al. [13] at the same center (CMMASS), which found rates of 4% among transfused patients and 2% among non-transfused patients.

The difference between serological prevalence (4%) and molecular prevalence (11.1%) within the same facility highlights a significant methodological limitation: traditional serology may not accurately reflect the actual circulation of the virus, due to the serological window and the limited sensitivity of commonly used rapid tests.

In Kisangani, Batina et al. [1] report a prevalence of 7.9% (10/127) among transfused sickle cell patients, which is a key point for the conclusions of this review. All positive cases involved patients who had received transfusions before systematic HCV screening was introduced in the DRC in 2004 ($p = 0.043$), while no cases were observed among the thirteen non-transfused patients. This observation, historical and observational in nature, suggests a benefit associated with improved screening and constitutes, to date, the most direct indicator in favor of improved transfusion safety since screening was established. However, it does not allow isolation of the impact of screening from other changes that have occurred over time (donor selection, evolution in overall prevalence, reagent quality, transfusion practices), and thus should not be interpreted as direct evidence of causality.

At the national level, the meta-analysis conducted by Muzembo et al. [5] indicates an overall prevalence of anti-HCV antibodies of 2.9% (95% CI: 1.5–4.3%), all populations combined, and 2.7% (95% CI: 1.1–4.4%) among blood donors. These figures are significantly lower than those observed among transfused sickle cell patients in Kinshasa, suggesting that cumulative exposure related to repeated transfusions is responsible, rather than a simple background prevalence in the general population. In Cameroon,

anti-HCV seroprevalence reaches 42.86% among sickle cell patients who have received more than ten transfusions, compared to 12.77% among those who received fewer than ten transfusions [6] ($p < 0.01$), demonstrating a significant dose-dependent association within the studied cohort.

Regarding the link between transfusion frequency and infection risk, three studies highlight a direct statistical correlation. In Kinshasa, Katabuka et al. [14] found that transfusion frequency is significantly associated with HCV positivity ($p < 0.001$) and HIV ($p < 0.05$), but not with HBV. Furthermore, in Cameroon, Ngo Sack et al. [6] establish a clearly dose-dependent relationship between the number of transfusions and HCV seroprevalence. In Bangui, Gody et al. [7] confirm that a threshold of three or more transfusions is significantly associated with viral seroconversion among children with sickle cell disease.

The study by [1] highlights a complementary aspect, more political than clinical: the association is not limited to the number of transfusions, but also encompasses the period of transfusion in relation to the introduction of screening. This point is fundamental in justifying the ongoing need to improve the biological qualification of blood, rather than merely reducing transfusions, which remain essential in the management of severe sickle cell disease.

In terms of the quality of blood biological qualification in the Democratic Republic of Congo, the available data present a nuanced picture: although there is a trend toward improvement at the national level, technical limitations have been observed locally. It is particularly important to note a critical finding from Kashosi et al. [10]: retesting by ELISA of 307 samples initially deemed negative by the rapid diagnostic test (TDR) revealed very insufficient sensitivity of the latter, with only 25% sensitivity for HBV and 50% for HCV. This implies that one in two HCV-positive samples, and three out of four for HBV, would have been falsely identified as negative by TDR alone, which is used in several Congolese transfusion facilities.

At the national level, Kabinda et al. [9] report a trend of continuous decline in the prevalence of infectious markers among blood donors between 2001 and 2012: HIV prevalence decreased from 4.7% to 2.1%, HBV from 7.1% to 3.5%, and HCV from 11.8% to 2.3%. In 2012, among 375,308 bags tested for four markers (HIV, HBsAg, anti-HCV, syphilis), rapid tests accounted for approximately 77% of all screenings performed.

At the local level, the research conducted by [10] in Bukavu highlights a fundamental aspect of this issue: among 312 samples, 307 that had tested negative using a rapid diagnostic test (RDT) were re-evaluated using the ELISA method.

Fifteen of these samples turned out to be false negatives on the RDT, including three for HIV, three for HCV, and nine for HBV. This demonstrates an RDT sensitivity that is considerably insufficient compared to that of ELISA (approximately 57% for HIV, 50% for HCV, and 25% for HBV), with a Cohen's kappa coefficient of 0.33 for HBV). According to the information compiled in this review, it appears that no transfusion center in the Democratic Republic of the Congo systematically performs genomic viral screening. However, this assertion, which pertains to institutional aspects and sensitive current events, could not be corroborated by any recent and precise official source. Consequently, it should be regarded as unverified information, based on the manuscript and accessible sources rather than as an established fact.

The coexistence of these two findings : a national trend toward the improvement of screening methods based on RDT and ELISA, and the insufficient sensitivity of these same tools at the local level is the central point linking the three aspects of this review. The high prevalence observed in sickle cell patients who have received multiple transfusions in Kinshasa, notably the discrepancy between serological and molecular detection, is consistent with a residual risk of transmission by transfusion that the methods currently used in the Congolese transfusion system fail to eliminate completely.

It is important to note that the data from [10] come from a context specific to Bukavu and constitute significant evidence of a potential vulnerability in the system, without constituting a broadly generalizable estimate of the performance of rapid tests across all transfusion facilities in the country.

III.6. Regional comparative analysis

Figure 2 presents a summary evaluation of the prevalence of hepatitis B (HBV) and C (HCV) viruses as reported in the principal studies examined, both in Kinshasa and in other countries of Central and West Africa. This representation highlights two observations that are consistent with the preceding narrative analysis: (i) in several selected studies, HCV prevalence estimates among sickle cell patients who have received multiple blood transfusions exceeded those of HBV, with a particularly marked gap in Kinshasa and Yaoundé among individuals most exposed to transfusions; (ii) while prevalence among blood donors is decreasing in the Democratic Republic of the Congo, it remains a limited indicator of the actual risk incurred by polytransfused patients, whose cumulative exposure increases the risk beyond the figures provided by general prevalence alone.

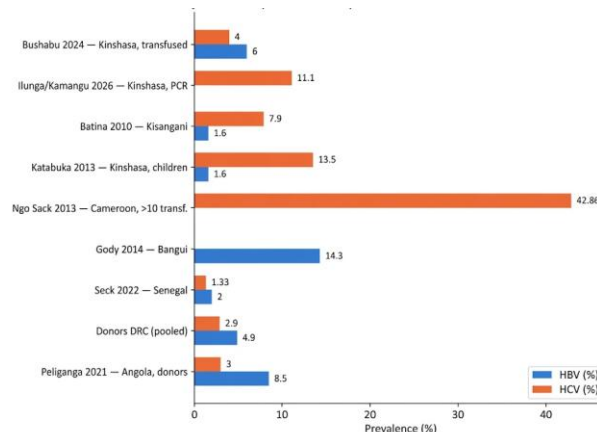


Figure 2. Comparison of the prevalence of hepatitis B (HBV) and C (HCV) viruses according to different studies, focusing on Kinshasa in the Democratic Republic of the Congo as well as similar countries.

This illustration compares estimates drawn from various populations, such as patients with sickle cell disease who have received blood transfusions and blood donors. The data come from different countries and were collected using various methods and biological markers, namely the HBs antigen (HBsAg) for HBV, and anti-HCV antibodies or HCV RNA, depending on the study, for HCV.

IV. DISCUSSION

IV.1. Main results

This systematic review highlights three major conclusions. First, hepatitis C emerges as the most significant transfusion risk for sickle cell patients in Kinshasa, with prevalence rates ranging from 4% to 13.5% depending on the screening method used, which is considerably higher than the baseline prevalence observed among Congolese blood donors (2.7–2.9%; [5]). Second, the only Congolese study offering a precise temporal benchmark, conducted by Batina et al. [1], shows that all identified HCV cases involved patients who received transfusions prior to the implementation of systematic screening in 2004. This provides convincing empirical evidence of the effectiveness, at least partial, of biological qualification of blood donations. Third, the available information on the effectiveness of the screening methods currently applied in routine practice, notably rapid tests, highlights sensitivity limitations that maintain a residual risk of transmission, even in a context where the general prevalence among donors is decreasing.

IV.2. Interpretation in light of the existing literature

The gap noted between the serological prevalence (4%) and the molecular prevalence (11.1%) of HCV within the same reference center in Kinshasa (CMMAS) deserves particular

attention. This gap should not be seen as a contradiction between two studies, but rather as an illustration of a well-documented phenomenon in the virology literature: the serological window period, during which an infected person may remain seronegative while viral load is already detectable by genetic amplification. In a population subjected to multiple transfusions, where exposures are frequent and closely spaced, this diagnostic window becomes particularly significant, as each new exposure decreases the likelihood of detecting a recently infected donor using serology alone. However, this interpretation requires methodological caution: the studies by Bushabu et al. [13] (n = 100) and Ilunga, Kamangu [11] (n = 90) are two distinct cross-sectional cohorts, constituted at different times and according to recruitment criteria that could differ within the same center (CMMASS); consequently, the 4% to 11.1% gap cannot be attributed solely to the serological window, as some of this difference may also result from sampling variability between the two studied populations. A direct and prospective comparison, using the same cohort tested simultaneously by serology and by PCR, would be necessary to confirm the true magnitude of this gap.

This observation echoes the results of [10] in Bukavu, where about 5% of samples initially judged negative by rapid test turned out positive after ELISA retesting. The comparison of these two studies, although conducted in different contexts but within the same national transfusion system, leads to a similar conclusion: the current blood qualification system in the DRC, which relies mainly on rapid tests, does not succeed in reducing the residual risk of viral transmission to a negligible level, especially for a population as vulnerable as polytransfused sickle cell patients.

Regional comparison enriches this analysis. The particularly marked dose-dependent relationship observed in Cameroon between the number of transfusions received and HCV seroprevalence [6] suggests that the risk of infection among sickle cell patients depends not only on the general country-wide prevalence, but also, and perhaps above all, on each patient's cumulative exposure frequency. This finding invites us to consider virological surveillance of polytransfused sickle cell patients not simply as a reflection of national transfusion safety, but as a standalone indicator, potentially more sensitive to the residual shortcomings of the system.

IV.3. Contribution and originality of the review

To our knowledge, there is no synthesis that simultaneously links the prevalence of viral hepatitis in people with sickle cell disease, exposure to blood transfusions, and the quality of biological blood qualification within the specific context of Kinshasa. The two relevant studies identified [11,13] are

based on limited samples and focus solely on measuring prevalence, without detailed analysis of the effectiveness of upstream screening systems. This review seeks to partially fill this gap by relating prevalence data to those concerning the quality of biological blood qualification, thus offering a more comprehensive view of the transfusion risk faced by this vulnerable population.

IV.4. Practical implications

Taking into account the methodological limitations that we will examine later, the results of this review support the need for targeted strengthening of prevention through biological qualification of blood in the Democratic Republic of the Congo. This reinforcement should be structured around three areas to be evaluated, rather than directly formulating recommendations based on the available data. In particular, this review does not propose any comparative efficacy study at the local level, nor economic or feasibility analysis, nor comparison between individual PCR and PCR in mini-pools, which are essential elements before establishing definitive operational recommendations. The first area concerns the gradual integration of PCR as a preventive tool, at least for blood products intended for high-risk polytransfused patients, such as those with sickle cell disease, in order to reduce the diagnostic window period when relying on serology alone. The data presented in this review, particularly the gap observed between serological prevalence and that detected by PCR in Kinshasa, highlight the importance of considering PCR not only as a diagnostic confirmation tool, but as a genuine preventive element within the framework of biological qualification of blood for this population. The second area addresses the safeguarding of the ELISA reagent supply, recognized as a recurrent limiting factor in national data, in order to broaden the verification of negative results from rapid tests, pending wider implementation of PCR. The third area points to the need to establish longitudinal virological surveillance for polytransfused sickle cell patients, combining serology and PCR. This would allow for better documentation of the preventive benefits of PCR over the course of successive transfusions, regardless of trends observed in donors.

IV.5. Strengths and limitations of the review

This review offers several notable strengths, notably broad geographical coverage that allows the data from Kinshasa to be placed into a relevant regional context. Furthermore, it establishes a clear link between prevalence data and those concerning diagnostic performance, while relying on a methodology inspired by PRISMA 2020 standards.

However, certain limitations must be transparently mentioned. Firstly, the number of studies specifically

devoted to transfused sickle cell patients in Kinshasa remains very limited ($n = 2$), with small sample sizes (90 and 100 patients per study) and cross-sectional designs that do not allow for direct causal relationships to be established between transfusion and infection. In addition, the diversity of screening methods used from one study to another (such as rapid serology, ELISA, and PCR) restricts the ability to directly compare reported prevalences, justifying the choice of a narrative synthesis rather than a quantitative meta-analysis. Moreover, the figures in the PRISMA flow diagram are based on a documentary research strategy that, although comprehensive, does not guarantee exhaustive and reproducible extraction from all multidisciplinary databases such as Scopus, Embase, and CINAHL.

It is important to detail these additional methodological limitations. Firstly, the diversity of screening methods and the small sample sizes in Kinshasa led to the preference for a narrative synthesis rather than a quantitative meta-analysis. Thus, it was not possible to calculate a relative risk or an overall odds ratio to assess the association between transfusion and viral infection, which limits the scope of the comparisons presented. Next, the cross-sectional design of the two main studies conducted in Kinshasa [11,13] does not allow for a strict causal relationship between transfusion and infection, as the simultaneous measurement of exposure and outcome makes it impossible to formally rule out other routes of transmission (such as unsafe injections, scarification, and dental or surgical care), which represent potential uncontrolled confounding factors. Finally, the absence of complementary molecular characterization (such as sequencing or phylogenetic genotyping) in the studies conducted in Kinshasa prevents determination of a direct genetic relationship between the strain identified in a donor and that found in the recipient, thus leaving open the possibility of contamination by means other than transfusion itself. These three limitations, along with those already mentioned, invite us to consider the estimates of residual risk presented in this review as plausible indications rather than rigorously established causal measures.

IV.6. Research perspectives

Multicenter research based on prospective cohorts, combining serological and molecular screening in transfused sickle cell patients in Kinshasa, could clarify the actual extent of the residual risk. Furthermore, this would make it possible to evaluate the clinical and economic impacts of targeted introduction of NAT (nucleic acid testing) for this high-risk group. A cost-effectiveness analysis of this improvement, taking into account the constraints specific to the Congolese health system, would be a natural and particularly relevant extension of this synthesis.

V. CONCLUSION

The information currently available for Kinshasa remains limited, with only two primary studies directly relevant, both presenting a low to moderate level of certainty. These data indicate that sickle cell patients who have received transfusions continue to be exposed to a significant risk of infection with hepatitis B and C viruses. The estimates concerning hepatitis C virus (HCV) are generally higher than those for hepatitis B virus (HBV) in the studies examined, and there is a significant difference between the prevalence detected by serology and that identified by PCR. These results are also compatible with a positive preventive effect from the implementation of systematic HCV screening in the Democratic Republic of the Congo, although they do not conclusively demonstrate it due to the observational and uncontrolled nature of the comparisons. Moreover, these data highlight certain limitations—at least at the local level of the tools currently used in routine practice, notably rapid tests whose insufficient sensitivity leaves a residual risk window that serology alone cannot fill. It would therefore be prudent to evaluate more rigorously the strengthening of prevention through biological qualification of blood, notably by extending ELISA re-screening and, especially, by targeted integration of PCR for the most vulnerable populations. This represents an avenue to explore for improving transfusion safety in the context of managing sickle cell disease in Kinshasa and for preventing transmission of HBV and HCV.

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