· 专家述评 ·

献血者选择与献血适宜性

——献血年龄上限与献血间隔期调整刍议

胡雨薇[1] 李玲[2] 王珏[1] 刘忠[1,3]

[1. 中国医学科学院 北京协和医学院 输血研究所,四川 成都 610052;2. 西南交通大学医学院,成都市第三人民医院(西南交通大学附属医院) 输血科,四川 成都 610031;3. 中国医学科学院 北京协和医学院 群医学及公共卫生学院,北京 100730]

摘要:献血者筛查标准是保障献血者与受血者安全、维护血液供应充足与可及的核心环节。百余年来,随着血库体系建立及经血传播病原体识别,健康征询、体格检查和实验室检测逐步纳入筛查流程,保障了血液服务安全、可靠且有效地运转。而近数十年来随着科学技术不断提升,人类对于人体的认识也不断加深。因此有必要对献血者筛查标准设置的科学性、必要性和合理性系统地进行反思和再认知。本文作为本期全血献血间隔与献血年龄上限系列文章的导论性刍议,围绕献血者筛查标准形成与动态调整逻辑,结合本期相关专家共识及我国多中心真实世界研究概况,探讨献血安全与血液供应之间的平衡,并从政策本土化、循证施策和试点评估三个层面提出我国献血者筛查标准优化的未来方向。

关键词:献血者筛查;献血者选择;献血适宜性;血液安全;血液供应

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Blooddonor selection and suitability for blood donation: a discussion on adjusting the upper age limit and interval for whole blood donation

HU Yuwei[1], *LI Ling*[2], *WANG Jue*[1], *LIU Zhong*[1,3].

1. *Institute of Blood Transfusion, Chinese Academy of Medical Sciences & Peking Union Medical College, Chengdu* 610052, *China*; 2. *Department of Blood Transfusion, The Third People's Hospital of Chengdu (Affiliated Hospital of Southwest Jiaotong University), College of Medicine, Southwest Jiaotong University, Chengdu* 610031, *China*; 3. *School of Public Health, Chinese Academy of Medical Sciences & Peking Union Medical College, Beijing* 100730, *China*.

Corresponding author: LIU Zhong, Email: liuz@ibt.pumc.edu.cn

Abstract: Objective Blood donor selection criteria provide the core framework for assessing whether a prospective donor is suitable to donate blood, with the dual aim of protecting donor health and recipient safety while supporting a sufficient and accessible blood supply. Over the past century, with the establishment of blood banking systems and the progressive identification of transfusion-transmissible pathogens, health questionnaires, physical assessment and laboratory testing have become integral parts of the donor selection process, contributing to the safe, reliable and effective operation of blood services. In recent decades, advances in science and technology, together with a deeper understanding of human physiology, disease risk and transfusion safety, have made it necessary to systematically re-examine the scientific basis, necessity and appropriateness of existing donor selection criteria. As an introductory commentary to this series on whole-blood interdonation intervals and the upper age limit for blood donation, this article discusses the rationale underlying the establishment and dynamic adjustment of donor selection criteria. Drawing on the relevant expert consensus statements in this series and an overview of multicenter real-world studies from China, it explores the balance between donor safety and blood supply sufficiency and proposes future directions for optimizing donor selection criteria in China through local adaptation of policies, evidence-informed decision-making, and pilot evaluation.

Key words: blood donor screening; blood donor selection; donor eligibility; blood safety; blood supply

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第一作者简介:胡雨薇(1999-),女,博士研究生在读,Email:yuweihu007@gmail.com; **通信作者**:刘忠,Email:liuz@ibt.pumc.edu.cn

在人类历史的长河中,自发现输血能够挽救生命以来,如何在保护献血者及受血者安全的前提下维持血液供应的安全、充足与可及,一直是输血医学中的核心问题之一[1]。世界卫生组织(World Health Organization, WHO)与国际输血协会(International Society of Blood Transfusion, ISBT)共同强调:采供血机构的首要责任是提供安全、充足、及时的血液和血液制品。在履行这一职责的同时,必须确保献血行为本身是安全的,不对献血者造成伤害[2-4],并尽量避免对安全、健康献血者的非必要延期[1, 5-7]。在这一理念的指导下,献血者筛查标准应运而生,基于医学原理和风险控制目标所界定的"献血适宜性(suitability for blood donation)评估"这一概念,通过法律、技术指南与规程文件制度化而形成具体操作规范。这些标准在实践中直接决定了献血者群体的构成,同时也延伸了献血者适宜性的定义,并推动了筛查政策的动态修订与完善[1, 8-10]。

当今,随着人口老龄化加剧[11]以及由此带来的医疗需求持续增长和献血者年龄结构变化,多地当前及未来均面临日益严峻的血液供应压力[12-13]。严格的献血健康检查标准与不断变化的人口结构,已成为限制献血者队伍扩大的主要制约因素[14]。在此背景下,如何在优化筛查策略以保障安全的同时,稳定保留有经验的献血者并有效招募新献血者,已成为全世界输血领域亟待解决的关键问题。

本期围绕"献血者选择与献血适宜性"组织系列文章,从循证证据、标准建议及真实世界数据等不同层面,概述全血献血间隔和献血年龄上限两个筛查标准调整的学理。其中,由相关领域专家形成的专家共识系统梳理国内外相关标准及现有证据,并提出相应建议;两项多中心回顾性队列研究则基于海南、江西和深圳大规模献血者数据,分别评估将全血献血间隔下限调整至 3 个月和无偿献血年龄上限放宽至 65 岁对献血者安全及献血行为的影响。

全血献血间隔期的科学学理主要涉及血液储备、红细胞再生与营养平衡(如铁代谢)。人体血液总量约占体重的 7%~8%,其中约四分之一为储备血,可在失血或应激时迅速释放以维持循环稳定。献血后机体可在数小时至数周内恢复血浆和血细胞;同时,红细胞生成依赖铁元素供给,铁储备不足可能增加疲倦、眩晕等不良反应风险[15-17]。因此,WHO 建议男性全血献血最短间隔为 12 周、女性为 16 周,该全血间隔期在保障献血者健康的同时可提升供血潜力[1, 18]。在这一理论基础上,本团队基于深圳市与海南省的大规模献血者真实世界数据,开展了多中心、回顾性非劣效性队列研究,共纳入约 37.5 万名重复全血献血者、累计 129 万余次献血。研究发现,将全血献血间隔下限调整至 3 个月虽略增加不良反应发生率,但绝对风险低于预设非劣效界值;同时,短间隔献血显著提高了年复献率、年献血次数及年全血献血量,显示出对血液供应能力的积极作用。这一工作不仅共同验证了献血间隔的科学学理在中国人群中的适用性[19],也为优化献血间隔政策提供了循证依据。

虽然献血间隔期的设置仍是控制铁缺乏、保障献血者长期健康的重要管理手段[20],但在一些国家或特殊情况下,部分高频献血者可能出现铁缺乏或贫血倾向[21-23]。为预防献血诱导性缺铁(donation-induced iron deficiency, DIID),实践中通常会结合献血前血红蛋白水平评估献血者的造血功能与铁代谢状态[24-28]。近年来,血清铁蛋白作为更敏感的铁储备指标,其监测有助于早期识别铁缺乏风险[29-31]。因此,未来研究可进一步通过国内献血人群的大样本多中心研究探索缩短间隔后献血者铁代谢的动态变化及生理恢复机制,以科学评估不同献血频率下的健康风险,并为优化献血管理提供循证依据。

同时,在献血者适宜性评估中,年龄作为 1 项基础性人口学特征长期被纳入筛查流程[32-34]。传统观念认为随着年龄增长,人体机能下降,老年人献血可能增加献血者及受血者风险。然而,多项研究显示,献血不良反应风险与年龄呈负相关,年龄越大总体不良反应发生率越低,最易发生不良反应的反而是年轻献血者(尤其 18~19 岁)[32, 35-41]。其原因可能与高龄献血者心理状态更稳定、献血经验丰富、流程熟悉度高有关;此外,绝经后女性因月经停止、铁丢失减少,其铁缺乏风险亦相对降低[42-45]。在保障受血者安全方面,多项大规模研究评估了献血者年龄与受血者预后之间的关系,结果均未发现高龄献血者血液对受体生存有不良影响[46-52]。

本团队纳入 118 万余名献血者、累计 202 万余次献血,评估将无偿献血年龄上限放宽至 65 岁后高龄献血者(56~65 岁)的安全性与献血行为。研究发现,高龄献血者在总体不良反应、全身性反应及晕厥风险均显著低于 18~55 岁群体,局部反应差异不显著;同时,该群体的年复献率、人均献血次

数及献血总量均持续增长,显示出稳定的复献能力和血液供应潜力。这一工作为高龄献血者安全性提供了实证依据,也表明适度延长献血年龄上限可有效拓展献血人群,应对人口老龄化背景下血液供需紧平衡的压力。

近年来,ALT 指标的放宽源于检测技术进步与实验室筛查手段的更新,体现了检测能力对筛查策略的优化[53-62];血压与年龄上限的调整,则是在广泛实践和循证研究中逐步确认其与献血不良反应之间并无明确关联,甚至发现高龄献血者的不良反应发生率可能更低[41,63-74];而献血间隔期的设定,近年来研究表明,将全血献血间隔期缩短至 3 个月亦未显著增加不良反应风险[1, 18-19,75]。

献血者筛查标准并非一成不变,而是应随着检测技术、风险证据及实践条件的变化持续接受科学评价与动态调整。这些变化与策略更新,正体现了世界卫生组织在献血者筛查核心任务中所倡导的理念[1]:在每次献血前依照规范流程完成健康征询、体格检查和实验室检测,仅从健康状况良好且输血传播风险较低的个体中采集血液,并准确识别需延缓或永久排除的情形,尽量避免对健康献血者的不必要延期[74-75],以实现献血者和受血者的双重安全并保障血液供应的可及性。

最后,为构建更科学、更合理的献血者筛查体系,在确保安全的基础上保障血液供应的稳定与可持续,未来应着重从以下三个维度系统推进筛查标准的优化:第一,在政策本土化层面,需系统梳理并借鉴国际筛查标准与实践经验,结合我国人口结构、疾病谱系与采供血服务体系特点,推动将符合国情的筛查项目与标准逐步纳入国家法规与技术规范体系,实现筛查策略的持续优化与有效落地。第二,在循证施策层面,应依托国内大规模献血人群监测数据、多中心临床研究及不良反应报告系统,构建本土化的风险评估与证据链,为制定更具针对性、科学性的献血者选择标准提供支撑。同时,在血站增设或调整筛查项目时,应开展系统性的成本与成本效益分析,综合评估新增措施在安全获益、献血者保留与血液供应保障之间的价值,以提升政策决策的客观性与可持续性。第三,在试点分析层面,鼓励有条件地区开展筛查标准调整试点,进行临床研究(前瞻性研究更佳),系统收集并分析献血反应、延期情况、血液质量与供应影响等多维数据,结合血站管理实践与临床用血反馈实践,凝练可复制、可推广的实践经验,最终形成符合中国实际的筛查路径与标准方案。

利益冲突说明/Conflict of Interests

所有作者均声明不存在利益冲突。

伦理批准及知情同意/Ethics Approval and Patient/Donor Consent

本文不涉及伦理批准及知情同意。

作者贡献/Authors' Contribution

胡雨薇:论文初稿撰写;李玲:文章设计,论文修改;王珏:论文修改;刘忠:文章构思设计,论文写作指导与最终版本修订。

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