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Review

Pharmacologic and pharmacokinetic factors in blood donation: A risk-based deferral framework proposal

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ABSTRACT

Objective: The presence of residual medications in blood donors can pose a risk to transfusion recipients, especially when drugs remain in plasma at clinically relevant levels. Current deferral recommendations for medicated donors are often generalized and lack pharmacokinetic rigor. This study aims to propose a pharmacologically and pharmacokinetically informed framework for assessing donor eligibility based on drug characteristics.
Method: A structured literature review was conducted to evaluate key pharmacokinetic variables affecting drug persistence in blood, including half-life ($t_{½}$), time to maximum plasma concentration (t_{max}), maximum plasma concentration (C_{max}), and elimination pathways. Medications were stratified into five risk categories according to their pharmacological profile, systemic exposure, and clinical implications. Corresponding deferral periods were assigned to each category. The framework also considers the type of blood component being donated (e.g., plasma-rich vs. cellular products).
Results: Medications with long half-lives, genotoxic effects, or antiplatelet activity pose higher transfusion risks and require extended deferral periods. Conversely, drugs with minimal systemic absorption, low plasma bioavailability, or that serve as physiological replacements pose minimal risk and may not warrant deferral. The proposed model aligns deferral recommendations with drug clearance data and product-specific plasma exposure.
Conclusions: A pharmacokinetic approach to donor eligibility enhances transfusion safety and supports evidence-based deferral guidelines. Pharmacists and clinicians can collaborate to assess medication risk profiles and optimize donor selection. This model can reduce unnecessary deferrals and maintain blood supply integrity while protecting recipients.
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Consideraciones farmacológicas y farmacocinéticas para la donación de sangre: Propuesta de un marco de aplazamiento basado en el riesgo

Palabras clave:
Donación de sangre
Farmacocinética
Aplazamiento del donante
Medicación
Eliminación de fármacos
Seguridad transfusional
Evaluación del riesgo

RESUMEN

Objetivo: La presencia de medicamentos residuales en donantes de sangre puede representar un riesgo para los receptores, especialmente cuando los fármacos persisten en plasma en niveles clínicamente relevantes. Las guías actuales de aplazamiento para donantes medicados suelen ser generales y carecen de análisis farmacocinético detallado. El objetivo de este estudio fue proponer un modelo de evaluación de elegibilidad basado en características farmacológicas y farmacocinéticas.
Método: Se realizó una revisión estructurada de la literatura sobre parámetros farmacocinéticos que influyen en la depuración de fármacos: vida media ($t_{½}$), tiempo al pico plasmático (t_{max}), concentración máxima (C_{max}) y vías de eliminación. Los medicamentos se clasificaron en cinco categorías de riesgo según su perfil farmacológico, exposición sistémica e implicaciones clínicas. Se propusieron periodos de aplazamiento para cada categoría, considerando también el tipo de componente sanguíneo donado (e.g., productos ricos en plasma vs. celulares).
Resultados: Los medicamentos con vida media prolongada, efectos genotóxicos o actividad antiplaquetaria requieren periodos de aplazamiento más extensos. En cambio, los fármacos con baja absorción sistémica, escasa biodisponibilidad plasmática o que actúan como sustitutos fisiológicos presentan bajo riesgo y podrían no requerir aplazamiento. El modelo integra datos de depuración con el tipo de producto transfundido.

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Conclusiones: Incorporar la evaluación farmacocinética en la selección de donantes mejora la seguridad transfusional y permite establecer recomendaciones de aplazamiento basadas en evidencia. Farmacéuticos y clínicos pueden colaborar en la evaluación del riesgo farmacológico para optimizar la selección sin comprometer el suministro de sangre ni la seguridad del receptor.

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Introduction

Blood donation is a cornerstone of modern medical practice,[1] providing vital supplies of blood products for a variety of treatments, from surgery to cancer therapy. However, the safety of blood donations depends not only on the donor's health but also on the medications they are taking. Medications that affect the donor's blood—such as those that inhibit platelet aggregation, suppress the immune system, or alter blood components—may pose risks to the recipient.[2] Pharmacists play a critical role in evaluating the medications taken by blood donors and in assessing their pharmacokinetic properties to ensure safe blood donations.[3]

Pharmacokinetics—particularly the drug's half-life ($t_{½}$), time to maximum plasma concentration (t_{max}), maximum plasma concentration (C_{max}), and elimination rate—influence the concentration of the drug in the donor's plasma at the time of donation.[4] These parameters help determine whether a drug poses a risk to the recipient. Pharmacists assess whether sufficient time has elapsed for the drug to be cleared from the body, thereby ensuring that the residual concentration is within safe limits. Although blood banks follow strict guidelines regarding medications contraindicated for donation, the pharmacist's role in interpreting these guidelines is critical to making informed decisions about donor eligibility.

Recent European guidelines on blood donation require deferral periods for donors on medication,[1] taking into account both the underlying disease and the pharmacodynamic and pharmacokinetic characteristics of the drugs. However, to date, these guidelines have not been fully translated into specific protocols for donor assessment. To our knowledge, most blood banks do not routinely defer donors solely based on medication use, except in cases involving teratogenic drugs or platelet aggregation inhibitors. Where deferral periods are defined, they often lack a clear pharmacokinetic rationale.

To enhance the safety of blood products, as mandated by official guidelines,[5] and to minimize unnecessary donor exclusions due to medication, it is essential to develop a structured donor evaluation framework. This framework should establish deferral periods based on the pharmacodynamic and pharmacokinetic properties of the drugs administered,[6,7] as well as on the plasma content of the specific blood product and its dilution during transfusion—specifically, considering the concentration that the drug may reach in the recipient's plasma. These considerations constitute the primary objective of this review.

Method

This study was carried out through a comprehensive review of the literature on blood donation eligibility, pharmacokinetic evaluations, and medication-related restrictions. Sources included clinical pharmacology guidelines, blood bank protocols, and recommendations from pharmaceutical regulatory authorities. The aim was to identify the pharmacokinetic factors that influence decisions regarding blood donor eligibility. In addition, key pharmacokinetic parameters—such as half-life ($t_{½}$), time to maximum plasma concentration (t_{max}),[6,7] maximum plasma concentration (C_{max}), and drug clearance—were examined in order to develop a framework for determining the optimal timing of blood donation following medication intake.

The decision to admit or defer a blood donor who is taking medication depends on three main factors: (1) the pharmacological properties of the drug, (2) the drug concentration in the donor's plasma, and (3) the intended type and clinical use of the blood product to be prepared. Based on these criteria, drugs—which vary widely in their chemical structure and pharmacokinetic/pharmacodynamic profiles—can be grouped into distinct categories for the purpose of evaluating donor eligibility.

Results

Medication restrictions based on pharmacokinetics

Concentration of drugs in the donor's plasma

The concentration of drugs in a donor's plasma at the time of donation depends on several factors, including the timing of administration, dosage, route of administration, formulation, and pharmacokinetic properties of the drug. Key parameters such as time to maximum plasma concentration (t_{max}), elimination half-life ($t_{½}$), and maximum plasma concentration (C_{max}) are critical. t_{max} is determined by drug release and absorption, whereas $t_{½}$ is influenced by distribution, metabolism, and excretion. These parameters are drug-specific or formulation-specific (in the case of controlled-release preparations).

If pharmacologically active metabolites are formed, they must also be taken into account. Unbound drug molecules are directly available to interact with biological targets in the recipient and may exert pharmacological effects. However, the protein-bound fraction serves as a reversible reservoir and must be considered in the pharmacokinetic assessment.

Drugs with long half-lives or those that remain in the plasma for extended periods may require longer deferral periods. Although drug concentrations decrease over time, the rate of decline is determined by the drug's half-life and metabolic clearance. For example, a drug with a half-life of 24 h will be reduced to less than 3% of its initial concentration after five half-lives (approximately five days). This residual level is generally considered safe for blood donation.[7]

The framework considers not only the drug properties but also the type of donation, explicitly including plasmapheresis. This procedure, increasingly used as the preferred method for plasma collection, may present specific pharmacokinetic implications compared to whole blood donation, due to the selective extraction of plasma and immediate return of cellular components. In this context, residual plasma drug levels become especially relevant, and the safety threshold for donation should be determined accordingly.

Classification of medications and deferral periods

Basis for calculating deferral periods

- Class 1: Drugs with dose-dependent effects

Following a period equivalent to t_{max} plus five elimination half-lives after administration of a therapeutic dose, approximately 97% of the drug is cleared, leaving only about 3% of the original plasma concentration. At this point, drug elimination is considered complete, and no further dose-dependent effects are expected. Consequently, a

residual concentration of 3% in the recipient's plasma post-transfusion is generally regarded as safe. This concentration is primarily determined by the drug level in the donor's plasma at the time of donation and the extent of dilution in the recipient's bloodstream (see Table 1.1).[8]

In case of teratogenic, fetotoxic, or embryotoxic drugs such as isotretinoin, a deferral period of at least one month after the last dose is required. They are contraindicated in pregnant or potentially pregnant recipients due to the risk of birth defects. These agents act in a dose-dependent manner and exert effects during specific "teratogenic windows" of organ development.

Due to ethical limitations, threshold concentrations for prenatal toxicity have not been clinically tested. However, evidence from case reports and observational data suggests that concentrations below 3% of the therapeutic level are unlikely to cause fetal harm. This is supported by cases where treatment was discontinued a few half-lives before conception (e.g., with isotretinoin, thalidomide, or vitamin K antagonists). After t_{max} plus five half-lives, approximately 97% of the drug is eliminated, making further dose-dependent effects unlikely.[7] Therefore, a residual concentration of 3% is generally considered safe (see Table 1.2).[9–12]

- Class 2: Genotoxic drugs

Genotoxic substances are usually excluded from drug development unless used for serious conditions such as cancer. These agents lack a defined threshold for safety, as even a single molecule interacting with DNA may induce mutations. As a result, dilution during transfusion is not a mitigating factor; the total dose received by the recipient is critical.

According to the European Medicines Agency's guideline on genotoxic impurities,[9] exposure should be avoided or minimized. If not avoidable, a maximum intake of 1.5 µg/day is considered to carry minimal risk (Threshold of Toxicological Concern, TTC).

Due to these properties, chemotherapy agents require extended deferral periods. A conservative recommendation is $t_{max} + 24\ t_{½}$ to ensure sufficient clearance before donation (see Table 2).[13,14]

Table 1.2
Group 1 Medication restrictions.

Medication type	Active ingredient	Time restriction
Psoriasis	Etretinate	Ever
Psoriasis	Acitretin	3 years
HIV treatment		Ever
Experimental Medication or Unlicensed Vaccine		12 months
Isotretinoin		1 month after last dose
Acitretin		3 years after last dose
Thalidomide		2 years after last dose
Lenalidomide		2 years after last dose
Lefludomide		2 years after last dose
Teriflunomide		2 years after last dose
Vitamin A (High doses)		1 month after last dose
Alzheimer/Dementia Medications	Donepezil, rivastigmine, memantine, galantamine	Ever

- Class 3: Drugs with no significant systemic absorption or risk

These drugs generally require no deferral period and include:

- Poorly absorbed drugs: Agents like colestipol, nystatin, or pyrantel that do not achieve significant systemic concentrations.
- Physiological replacements: Substances such as vitamins, enzymes, or hormonal therapies (e.g., contraceptives) that are unlikely to cause adverse effects at transfused concentrations (see Table 3).[15]

- Class 4: Platelet function inhibitors

This class includes drugs such as aspirin and clopidogrel, which inhibit platelet aggregation and may impair the quality of platelet-

Table 1.1
Group 1 Medication restrictions.

Medication	Deferral period	Medication	Deferral period	Medication	Deferral period
Acebutolol	5 $t_{½}$	Hidroxicina	5 $t_{½}$	Rosuvastatina	5 $t_{½}$
Acetaminophen	5 $t_{½}$	Ibuprofeno	5 $t_{½}$	Salbutamol	5 $t_{½}$
Alopurinol	5 $t_{½}$	Indapamida	5 $t_{½}$	Semiglutida	5 $t_{½}$
Amitriptilin	5 $t_{½}$	Indometacina	5 $t_{½}$	Sertralina	5 $t_{½}$
Amlodipin	5 $t_{½}$	Irbesartan	5 $t_{½}$	Sildenafilo	5 $t_{½}$
Aspirina	5 $t_{½}$	Lisdexamfetamina	5 $t_{½}$	Tamsulosina	5 $t_{½}$
Atenolol	5 $t_{½}$	Lansoprazol	5 $t_{½}$	Terazosina	5 $t_{½}$
Atorvastatina	5 $t_{½}$	Levotiroxina	5 $t_{½}$	Trazodona	5 $t_{½}$
Anticoncep. oral	5 $t_{½}$	Lorazepam	5 $t_{½}$	Trifluoperazina	5 $t_{½}$
Bisoprolol	5 $t_{½}$	Meloxicam	5 $t_{½}$	Venlafaxina	5 $t_{½}$
Bupropion	5 $t_{½}$	Metformina	5 $t_{½}$	Verapamil	5 $t_{½}$
Buspirona	5 $t_{½}$	Metilfenidato	5 $t_{½}$	Vortioxetina	5 $t_{½}$
Candesartan	5 $t_{½}$	Metoprolol	5 $t_{½}$	Zopiclone	5 $t_{½}$
Celecoxib	5 $t_{½}$	Mirtazapina	5 $t_{½}$		
Cetirizina	5 $t_{½}$	Mometasona	5 $t_{½}$		
Citalopram	5 $t_{½}$	Nadolol	5 $t_{½}$		
Clomipramina	5 $t_{½}$	Naproxeno	5 $t_{½}$		
Clonidina	5 $t_{½}$	Nifedipino	5 $t_{½}$		
Clopidogrel	5 $t_{½}$	Penbutolol	5 $t_{½}$		
Desipramina	5 $t_{½}$	Perindoprilo	5 $t_{½}$		
Diltiazem	5 $t_{½}$	Fenelzina	5 $t_{½}$		
Doxazosina	5 $t_{½}$	Piroxicam	5 $t_{½}$		
Doxepina	5 $t_{½}$	Prazosin	5 $t_{½}$		
Duloxetina	5 $t_{½}$	Pregabalina	5 $t_{½}$		
Escitalopram	5 $t_{½}$	Proclorperazina	5 $t_{½}$		
Esomeprazol	5 $t_{½}$	Propranolol	5 $t_{½}$		
Felodipino	5 $t_{½}$	Protriptilina	5 $t_{½}$		
Fluoxetina	5 $t_{½}$	Quetiapina	5 $t_{½}$		
Fluvoxamina	5 $t_{½}$	Rabeprazol	5 $t_{½}$		
Hidralazina	5 $t_{½}$	Ramipril	5 $t_{½}$		

Table 2
Group 2 Medication restrictions.

Medication	Deferral period (t_{max} + 24 $t_{½}$)	Reason for deferral
Ifosfamide	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Cyclophosphamide	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Melphalan	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Doxorubicin	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Methotrexate	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Cisplatin	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Carboplatin	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Vincristine	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Docetaxel	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Paclitaxel	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent
Fluorouracil	t_{max} + 24 $t_{½}$	Genotoxic and cytotoxic chemotherapy agent

containing blood products. A typical deferral period of t_{max} + 5 $t_{½}$ is recommended (see Table 4).[16–18]

- Class 5: Biologic drugs

Biologic agents, such as monoclonal antibodies (e.g., adalimumab, etanercept, rituximab), require the longest deferral periods due to their extended half-lives and immunomodulatory effects (see Table 5).[19–21]

Pharmacokinetic calculations for residual drug concentration

Pharmacists can estimate residual drug concentrations in the donor's plasma[7] using the formula:

$$C = C_o \cdot (½)^n$$

where C is the final concentration, C_o is the initial concentration and n is the number of half-lives elapsed.

Table 3
Group 3 Medication restrictions.

Drug name	Deferral period	Rationale
Vitamin C	No deferral period	Minimal systemic effects, no impact on blood donation
Vitamin D	No deferral period	Minimal systemic effects, no impact on blood donation
Thyroid hormones (e.g., Levothyroxine)	No deferral period	Used to replace natural hormones, no adverse effects on blood donation
Insulin	No deferral period	Used to control blood sugar levels, no impact on blood donation
Estrogens (e.g., estradiol)	No deferral period	Minimal impact on blood quality and recipient safety
Progesterone	No deferral period	Minimal impact on blood quality and recipient safety

Table 4
Group 4 Medication restrictions.

Medication	Deferral Period	Reason for Deferral
Aspirin	7 days	Inhibits platelet aggregation
Clopidogrel	5 days	Inhibits platelet aggregation
Ticlopidine	10 days	Irreversible platelet aggregation inhibition
Cilostazol	10 days	Inhibits platelet aggregation
Abciximab	7 days	Inhibits platelet aggregation
Eptifibatide	7 days	Inhibits platelet aggregation
Tirofiban	7 days	Inhibits platelet aggregation

For instance, a drug with a 24-h half-life will reach <3% of its original concentration after five half-lives (i.e., five days). This level is typically regarded as safe for transfusion purposes.

The concept proposed in this review aims to provide blood banks with a practical tool to comply with European blood donation guidelines while minimizing unnecessary donor deferrals. It is intended to support decision-making regarding the eligibility of donors undergoing pharmacological treatment. Based on this approach, individuals taking medication may be allowed to donate blood—particularly for the production of blood components containing less than 50 mL of plasma from a single donor, such as red blood cell concentrates (RBCC)—without requiring deferral periods, except in cases involving genotoxic drugs, retinoids, thalidomide, lenalidomide, dutasteride, or finasteride. Consequently, even long-term drug therapy should not automatically be considered a criterion for general exclusion from blood donation.

Pharmacists play a key role in assessing the pharmacokinetic profiles of medications taken by prospective donors, ensuring both the safety and efficacy of transfused blood products. Through pharmacokinetic calculations to estimate residual drug concentrations and define appropriate deferral periods, pharmacists help reduce the risk of adverse effects in recipients.

Table 5
Group 5 Medication restrictions.

Medication	Condition treated	Deferral period
Adalimumab (Humira)	Autoimmune diseases (Rheumatoid arthritis, Crohn's disease, psoriasis)	Temporary disqualification due to immune suppression
Etanercept (Enbrel)	Autoimmune diseases	Disqualifies while being used, as it suppresses the immune system
Infliximab (Remicade)	Autoimmune diseases	Cannot donate while on medication
Tocilizumab (Actemra)	Autoimmune diseases	Temporary disqualification while under treatment
Ustekinumab (Stelara)	Psoriasis, Crohn's disease	Requires disqualification while under treatment
Secukinumab (Cosentyx)	Psoriasis, ankylosing spondylitis	Temporary disqualification
Rituximab (Rituxan)	Lymphomas, autoimmune diseases (lupus)	Usually implies long-term or permanent disqualification due to immune suppression
Abatacept (Orencia)	Autoimmune diseases	Cannot donate while under treatment
Bevacizumab (Avastin)	Various cancers	Disqualifies while on treatment
Trastuzumab (Herceptin)	Certain breast cancers	Cannot donate until treatment ends and doctor approval is given
Pembrolizumab (Keytruda)	Cancer immunotherapy	Disqualifies temporarily or permanently
Nivolumab (Opdivo)	Cancer immunotherapy	Disqualifies temporarily or permanently
Eculizumab (Soliris)	Rare diseases (e.g., paroxysmal nocturnal hemoglobinuria)	Permanent disqualification due to high impact on immune system
Alemtuzumab (Campath)	Leukemias, multiple sclerosis	Permanent disqualification due to immune suppression
Ocrelizumab (Ocrevus)	Multiple sclerosis	Cannot donate while on treatment
Dupilumab (Dupixent)	Atopic dermatitis	May require a waiting period after administration

Incorporating pharmacokinetic evaluations into the donor screening process is essential for maintaining a safe, effective, and sufficiently available blood supply.

Discussion

The pharmacist's role in evaluating the pharmacokinetics of medications taken by blood donors is fundamental to ensuring the safety and efficacy of transfused blood products. Blood donation safety depends not only on the donor's general health status but also on the potential pharmacological impact of residual medications in their bloodstream. In this context, pharmacists are uniquely positioned to assess whether sufficient time has passed since the last drug intake and to calculate the estimated residual drug concentration in the donor's plasma.[22,23] Through the application of pharmacokinetic principles, they ensure that circulating drug levels are sufficiently low to pose minimal or no risk to the recipient.

Pharmacists must also account for interindividual variability in drug clearance. Key physiological factors—including hepatic and renal function, age, weight, body composition, and metabolic rate—can significantly alter the elimination profile of a drug.[24,25] For example, individuals with hepatic or renal impairment may exhibit slower metabolism and excretion of drugs, potentially leading to prolonged systemic exposure. This is particularly relevant in the context of blood donation, where even small quantities of active drug residues could be transferred to recipients, especially if the blood component contains a substantial volume of plasma.

Furthermore, the nature of the blood product being donated must be considered. Different blood components—such as whole blood, red blood cell concentrates, plasma, and platelets—retain varying amounts of plasma, which can influence the potential concentration of residual drugs in the final product. For instance, red blood cell concentrates generally contain less plasma than platelet-rich plasma or fresh frozen plasma, and thus may carry a lower risk of drug transfer. Plasmapheresis, as a technique specifically designed to collect plasma, results in blood components with maximal plasma content and may require closer pharmacokinetic scrutiny to ensure donor and recipient safety.

This variability highlights the importance of tailoring deferral periods based not only on the drug's pharmacokinetics, but also on the specific characteristics of the blood product.

A major operational challenge for blood banks is establishing robust protocols that guarantee medications have been sufficiently cleared before donation occurs. Determining the appropriate deferral period requires a thorough understanding of pharmacokinetic parameters such as absorption time, time to maximum plasma concentration (t_{max}), elimination half-life ($t_{½}$), and the presence of active metabolites. These calculations must be individualized and evidence-based.

In addition, blood banks must implement reliable systems to accurately track and document the medications reported by potential donors, along with their respective deferral periods.[26] Such systems should be updated regularly to reflect changes in pharmacovigilance recommendations, drug approvals, and clinical guidelines. By doing so, blood banks can safeguard the integrity of the blood supply while avoiding unnecessary deferrals that could impact blood availability. This pharmacist-led, evidence-informed approach ensures that patient safety and blood product quality remain the highest priorities.

Contribution to the literature

This framework links drug pharmacokinetics to donor deferral with a structured, risk-based approach.

It supports pharmacist-led screening to enhance transfusion safety and preserve blood supply efficiency.

Authorship declaration

Roberto Lozano contributed to the conception and design of the work, as well as drafting the manuscript and providing critical revisions with significant intellectual input. María-Esther Franco contributed to the literature review, analysis and classification of medications, and approval of the final version. Carina Bona participated in data interpretation, methodological review, and supervision of the final content.

All authors meet the authorship criteria established by ICMJE: substantial contribution to the design and/or data collection, critical review of intellectual content, and approval of the final version for publication. The corresponding author guarantees that these requirements have been fulfilled and that no qualified individual has been excluded.

CRediT authorship contribution statement

Roberto Lozano: Writing – original draft, Supervision, Investigation, Formal analysis, Data curation, Conceptualization. **María-Esther Franco:** Visualization, Validation, Methodology, Investigation, Data curation, Conceptualization. **Carina Bona:** Writing – original draft, Methodology, Investigation, Conceptualization.

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Conflict of interest

The authors declare that they have no conflicts of interest.

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