Labeling is Not Enough: A Nursing Perspective on the Mismatch Between Biocompatibility Claims and Clinical Safety in IV Infusion Devices

Selwan Hamza Elgazzar (ORCID: 0009-0001-3897-6549) Yasmin Moustafa Ayoub (ORCID:0009-0007-9476-6363) Eman Ramadan shabib(ORCID:0009-0008-3301-1933)Abdulaziz Alanazi (ORCID: 0000-0003-1208-5673) Raeed Alanazi (ORCID: 0009-0003-9088-5040)

Nursing Education Administration
salwanhamza123@gmail.com

Abstract

Background: The continued use of di(2-ethylhexyl) phthalate (DEHP)-containing intravenous (IV) infusion devices in healthcare - particularly in Arab countries - poses significant clinical and ethical risks. Despite global regulatory alerts, the concept of biocompatibility is often misrepresented, leaving patients and nurses exposed to leachable toxins. The absence of enforceable standards in local procurement systems exacerbates these dangers. **Aim:** To explore the gap between biocompatibility claims and real-world safety in DEHP-based IV systems, while highlighting the nursing role in clinical risk detection, advocacy, and policy reform. **Design:** Narrative review employing a thematic synthesis approach across toxicological, regulatory, and clinical domains**.** **Scope:** The review covers international regulatory frameworks and nursing practice, with emphasis on high-risk environments such as neonatal intensive care units (NICUs), oncology wards, and dialysis units in Arab hospitals. **Methods (Tool of Data Collection):** A structured literature search was conducted in PubMed, Science Direct, Scopus, and Google Scholar, targeting publications from 2000 to 2025. Grey literature and official reports were retrieved from the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), European Chemicals Agency (ECHA), Agency for Toxic Substances and Disease Registry (ATSDR), Health Care without Harm (HCWH), BBraun, and regional authorities. Inclusion focused on toxicological, regulatory, and nursing-related documents. Sources were thematically synthesized across five domains: toxicological risks, labeling and regulatory gaps, patient safety outcomes, occupational exposure, and nurse-led advocacy. **Results:** Strong toxicological evidence was identified linking DEHP exposure to endocrine disruption, reproductive toxicity, and carcinogenicity. Regulatory definitions of biocompatibility lacked transparency, particularly in Arab healthcare systems where DEHP-based devices remain prevalent due to the absence of binding material safety regulations. Nurses were identified as both frontline users and at-risk individuals due to occupational exposure and insufficient labeling. A thematic model was proposed to guide nursing-led safety interventions and procurement reform. **Conclusion:** DEHP use in IV devices remains an overlooked clinical and occupational threat. Misaligned biocompatibility labels and weak regulatory enforcement compromise the safety of IV therapy, especially in vulnerable patient populations. **Recommendations:** Nurses must lead advocacy for DEHP-free infusion systems, regular biocompatibility audits, and patient-centered procurement policies. Arab regulatory bodies should align with international directives (e.g., SCHEER, WHO) and empower nursing staff through transparent labeling, standardized training, and sustainable procurement reforms.

Keywords: di (2-ethylhexyl) phthalate (DEHP); intravenous infusion; biocompatibility; nursing safety; regulatory gaps; Arab healthcare systems

Introduction

In contemporary healthcare, intravenous (IV) infusion systems are indispensable across diverse clinical settings, ranging from neonatal intensive care to high-dose chemotherapy units. Although commonly perceived as neutral conduits for drug delivery, increasing scientific evidence highlights that their material composition poses inherent risks. Polyvinyl chloride (PVC) remains the predominant plastic used in IV medical devices because of its flexibility, affordability, and compatibility with industrial manufacturing processes **(Balaje et al., 2023).** However, to achieve this flexibility, PVC requires the addition of plasticizers such as di(2-ethylhexyl) phthalate (DEHP) - a compound now widely recognized for its toxicological hazards.

Concerns regarding DEHP are not new, yet they remain persistently overlooked in daily clinical decision-making. DEHP can leach from

PVC tubing into IV fluids, particularly those containing lipophilic drugs, and subsequently enter the patient's bloodstream **(Jiang et al., 2022).** This phenomenon is especially problematic in vulnerable populations such as neonates, oncology patients, and individuals requiring prolonged infusions **(Eckert et al., 2020; Cleys et al., 2025).** Despite decades of warnings from regulatory authorities-including the European Chemicals Agency **(ECHA, 2023)** and the U.S. Agency for Toxic Substances and Disease Registry **(ATSDR, 2022)-**DEHP-containing products continue to be widely used in hospitals across the globe.

A critical factor exacerbating this issue is the widespread assumption that once a device is labeled "biocompatible," it is inherently safe. This assumption creates a dangerous blind spot in clinical practice, as biocompatibility is often interpreted narrowly and marketed without full disclosure of material-related risks. Consequently, the labeling of IV devices as "biocompatible" has become both a regulatory and ethical paradox: it reassures clinicians while concealing scientifically established toxicological threats **(Jaeger, 2005).**

Biocompatibility, a cornerstone in medical device evaluation, is frequently misunderstood and inconsistently applied in both clinical and regulatory contexts. Scientifically, biocompatibility refers to a material's ability to perform its intended function without eliciting undesirable local or systemic effects in the body **(Williams, 2008; Ratner, 2011).** However, this definition is far more complex than what is typically conveyed on product labels. True biocompatibility is not static—it is context-dependent, varying according to the patient population, duration of exposure, drug composition, and route of administration **(Williams, 2008).**

Despite this nuance, manufacturers often employ the term as a generalized assurance of safety, without transparent disclosure of the underlying testing methods, timeframes, or limitations. Many IV devices labeled as "biocompatible" have undergone only short-term cytotoxicity or sensitization tests that fail to capture long-term effects such as plasticizer leaching, drug–material interactions, or cumulative exposure in high-risk patients **(Gad & Gad-McDonald, 2015).** This selective application of the term generates a gap between regulatory approval and bedside safety, leaving clinicians-particularly nurses-without the necessary information to make risk-informed decisions.

Moreover, current industry standards often approach biocompatibility as a binary label rather than a dynamic spectrum of safety that evolves with clinical use. This disconnect between laboratory testing and real-world application has been repeatedly criticized in the literature for underestimating chronic exposure risks, particularly in infusion systems used in pediatric and oncology settings **(Hamza Elgazzar et al., 2025; Saab et al., 2022).** Thus, while the concept of biocompatibility should function as a safeguard for patient safety, in practice, it has become a commercial label that may obscure more than it clarifies.

Di(2-ethylhexyl) phthalate (DEHP), the most commonly used plasticizer in polyvinyl chloride (PVC)-based medical devices, has been extensively documented for its ability to leach into infused fluids, particularly lipid-based (lipophilic) medications. Once leached, DEHP can enter systemic circulation, accumulate in tissues, and disrupt multiple biological systems, including the endocrine, reproductive, hepatic, and immune systems **(ATSDR, 2022; SCHEER, 2024).** Its lipophilic nature increases its affinity for fat-rich formulations such as total parenteral nutrition, intravenous chemotherapy, and certain pediatric suspensions, thereby exacerbating patient exposure **(Casella et al., 2023).**

Clinical investigations have confirmed measurable levels of DEHP metabolites in patients undergoing routine infusions—particularly neonates, cardiac surgery patients, and individuals in intensive care units—where exposure levels often exceed the tolerable daily intake limits set by regulatory authorities **(Cleys et al., 2025; Eckert et al., 2020).** For instance, neonates receiving enteral or parenteral nutrition via DEHP-containing devices demonstrated urinary phthalate concentrations associated with adverse neurodevelopmental and reproductive outcomes **(Van Vliet et al., 2011).** Similarly, cardiopulmonary bypass and extracorporeal membrane oxygenation (ECMO) circuits have been implicated as significant sources of DEHP

exposure during critical interventions **(Hamza Elgazzar et al., 2025).**

Despite such alarming evidence, the continued use of DEHP-containing devices persists in many hospitals, driven by cost considerations, lack of regulatory bans, and limited awareness among healthcare professionals. This is particularly concerning in contexts where long-term exposure is unavoidable, such as pediatric oncology, chronic dialysis, and intensive care. PVC-once heralded as a technological breakthrough in medical manufacturing—now represents a double-edged sword, offering mechanical utility at the expense of biological safety **(Ito et al., 2005).**

Ironically, many of these products still bear "biocompatible" labels, creating a dangerous illusion of safety. The toxicity of DEHP is not only an issue of material science but a systemic clinical hazard-hidden beneath layers of regulatory ambiguity, procurement inertia, and inadequate labeling. This disconnects between material composition and real-world patient outcomes necessitate urgent scrutiny, particularly from a nursing standpoint where bedside exposure is direct and frequent.

Despite decades of scientific documentation on DEHP toxicity, regulatory frameworks governing medical device materials remain fragmented, permissive, and inconsistently enforced across jurisdictions. While the European Commission's SCHEER has issued detailed recommendations urging caution and risk-based substitution of DEHP in high-risk devices **(SCHEER, 2024),** these guidelines often lack binding enforcement. In the United States, the FDA acknowledges DEHP-related risks, particularly for neonates and pregnant women, but still allows its continued use in numerous devices under conditional labeling **(ATSDR, 2022; FDA, cited in Hamza Elgazzar et al., 2025).**

This regulatory leniency is compounded by a critical shortcoming: labeling practices fail to provide transparent, standardized, and clinically relevant information about the presence and behavior of toxic materials like DEHP. In many cases, healthcare professionals-especially nurses-are unaware that the infusion set or IV bag they are using contains DEHP or PVC. Labels may generically state "biocompatible" or "conforms to ISO 10993," without disclosing the presence of phthalates, leaching profiles, or suitability for specific drug formulations **(SCHEER, 2024).**

Moreover, there is no globally harmonized requirement for real-time, point-of-use material disclosure. As a result, clinicians are forced to rely on procurement decisions made upstream, often driven by cost rather than safety. Some manufacturers do provide DEHP-free alternatives, but these are not systematically prioritized or mandated unless local procurement policies enforce specific material standards **(Health Care Without Harm, 2022).**

This illusion of safety-rooted in inadequate labeling, fragmented regulation, and unmonitored exposure-undermines the ethical principle of informed clinical choice. It disproportionately affects bedside providers, such as nurses, who are expected to ensure patient safety without access to critical product information. The gap between what is declared on packaging and what occurs in biological systems is no longer a theoretical concern; it is a daily reality in hospitals worldwide.

In the context of intravenous therapy, nurses serve as the primary interface between the patient and the medical device-they prepare, administer, monitor, and respond to infusion-related outcomes in real time. Yet, despite their central role, nurses are rarely consulted in product selection processes and are often left uninformed about the material composition and biocompatibility risks of the devices they use. This disconnect creates a significant practice gap, wherein nurses are held accountable for patient safety outcomes without having access to the material safety data needed to prevent harm **(Health Care Without Harm, 2020).**

Furthermore, most nursing education curricula and institutional orientation programs do not address the toxicological implications of materials like DEHP or the interaction between IV drugs and device polymers **(Chapon et al, 2023; Chou & Wright 2006).** As a result, the vast majority of bedside providers remain unaware of the risks associated with high-leach devices, even in settings where patients receive continuous, high-volume, or fat-soluble infusions. This lack of awareness is particularly concerning in pediatrics, oncology, and critical care units, where exposure windows are longer and patients

are more physiologically vulnerable **(Cleys et al., 2025; Saab et al., 2022).**

The burden of this biocompatibility failure is thus shifted downstream to nursing, manifesting as unexplained patient reactions, infusion inefficacy, drug instability, or long-term systemic toxicity. These outcomes not only compromise patient care but also place nurses at the ethical frontlines-expected to deliver safe and effective care without being given the tools or information to assess material-related risk. It is a silent crisis in evidence-based nursing practice: decisions about device safety are made elsewhere, while the consequences unfold at the bedside **(CERHR 2006 ;Dejong et al., 2020).**

To address this, nursing leadership must be empowered to influence procurement, advocate for transparent labeling, and demand safer material alternatives. The profession must also build internal capacity to understand and evaluate device biocompatibility from both pharmacological and regulatory perspectives. Without such integration, the mismatch between biocompatibility claims and clinical reality will continue to undermine both patient safety and nursing autonomy **(Hildenbrand et al., 2005).**

While international authorities such as the European Commission (SCHEER) and Health Care Without Harm (HCWH) have issued detailed frameworks restricting the use of DEHP in medical devices—particularly in neonatal, oncology, and dialysis care—no Arab country currently enforces binding regulations targeting phthalate-containing devices. In Lebanon, for instance, DEHP-laden intravenous (IV) bags are widely used without regulatory oversight or mandatory labeling, exposing hospitalized patients—especially neonates—to toxic leachates without clinical awareness **(Saab et al., 2022).** This regulatory void is not unique to Lebanon. Across the Gulf Cooperation Council (GCC) region, no unified or enforceable policy exists to restrict or substitute DEHP or PVC-based medical devices, nor are hospitals required to disclose leaching profiles or material composition data to end-users **(Howard, 2014; Wang & Kannan 2023).**

Despite the presence of national authorities such as the Saudi Food and Drug Authority (SFDA) and the UAE Ministry of Health, current procurement standards primarily emphasize product sterility and performance metrics **(e.g., ISO 10993, FDA clearance),** with minimal attention to long-term biocompatibility or toxicological risks **(Howard, 2014).** As a result, cost-driven procurement continues to dominate in many Arab healthcare systems, often sidelining safety considerations. Nurses and frontline staff are left using devices labeled "biocompatible" without access to validated risk assessments or chemical safety disclosures **(Saab et al., 2022).** This ongoing regulatory silence highlights the critical need for nurse-led advocacy, localized data dissemination, and targeted policy reform to safeguard vulnerable populations from avoidable chemical exposures in clinical practice **(Luo et al., 2014 ;Montesinos et al., 2024).**

Despite the extensive global literature on DEHP toxicity and PVC-related risks, a critical gap persists in addressing how these hazards manifest at the bedside - particularly from a nursing perspective. Most published work stems from regulatory, industrial, or toxicological domains, with limited attention to the real-world clinical consequences faced by nurses administering IV infusions daily **(Health Care Without Harm, 2022).** Moreover, the false reassurance provided by biocompatibility labels continues to mask the presence of leachable toxins, impeding evidence-based practice and compromising patient safety **(Williams, 2008; Ratner, 2011).**

This review was therefore warranted to expose the disconnect between manufacturer claims of biocompatibility and the actual clinical safety of IV infusion devices, especially in high-risk populations such as neonates, oncology patients, and long-term ICU residents **(Saab et al., 2022; Cleys et al., 2025).** It further aims to highlight the invisibility of chemical risk within nursing protocols, procurement decisions, and safety training - factors that collectively contribute to unintentional harm **(Hamza Elgazzar et al., 2025; Howard, 2014).**

Grounded in a narrative methodology, this review critically synthesizes toxicological evidence, regulatory inconsistencies, clinical observations, and nursing implications to build a comprehensive picture of the systemic failure to align labeling with biological safety **(SCHEER, 2024; ATSDR, 2022**). By centering the nursing voice, this paper advocates for greater

transparency, education, and material accountability in infusion safety policies **(Health Care Without Harm, 2020; Gad & Gad-McDonald, 2015).**

The narrative review format was deliberately chosen to allow a comprehensive, contextual, and critical synthesis of diverse literature spanning regulatory science, toxicology, nursing practice, and medical device manufacturing. Unlike systematic reviews that prioritize quantitative outcomes and rigid inclusion criteria, a narrative approach enables the integration of multidisciplinary insights—including emerging regulatory reports, nursing safety concerns, material science findings, and real-world clinical implications—that would otherwise be excluded **(Dan,2020; Ted, 2020).**

This design aligns with the aim of the paper: not to quantify a single clinical outcome, but to expose a cross-cutting mismatch between biocompatibility claims and clinical safety realities, especially from the nursing perspective, which is often underrepresented in materials safety discourse. The narrative methodology supports exploration of grey literature, position statements (e.g., SCHEER, ECHA, Health Care Without Harm), and experiential nursing evidence—elements essential to understanding this complex, policy-practice disconnect.

Significance of the Study

The clinical safety of intravenous (IV) infusion systems is traditionally judged by sterility and functional performance, yet their biological risks remain underrecognized, particularly at the nursing interface. Despite widespread labeling of devices as "biocompatible," toxic plasticizers such as DEHP continue to leach from PVC-based devices into patients' bloodstream, posing serious hazards to neonates, oncology patients, and chronically ill individuals **(Saab et al., 2022; Cleys et al., 2025).**

This study is significant because it confronts the false safety narrative created by ambiguous labeling and the systemic regulatory inertia that allows DEHP-containing devices to remain in standard clinical use. In Arab countries, the absence of binding regulations and cost-driven procurement policies exacerbates this risk, resulting in routine exposure across high-risk units such as NICUs, oncology wards, and dialysis centers (**Howard, 2014; Latini et al., 2010).** Patients—especially neonates, pregnant women, and the immunocompromised—face cumulative risks of endocrine disruption, organ toxicity, and impaired development **(ATSDR, 2022; Eckert et al., 2020),** while nurses experience occupational exposure during priming and prolonged device handling, with potential reproductive and dermatological consequences **(Tu et al., 2025).**

By integrating toxicological evidence, regulatory analysis, and nursing perspectives, this narrative review positions nurses not only as end-users, but also as advocates for safer procurement and transparent labeling. The findings are expected to guide nursing leadership, administrators, and policymakers toward DEHP-free practices, reframing safety to include material composition alongside performance metrics.

Aim of the Study

This narrative review aims to critically examine the disconnect between biocompatibility claims and clinical safety outcomes in intravenous (IV) infusion devices—particularly those containing PVC and DEHP—while emphasizing the overlooked nursing perspective in evaluating material-related risks, regulatory shortcomings, and real-world implications for patient and occupational safety.

Study Objectives

1. To explore the toxicological risks associated with DEHP and PVC-containing IV infusion systems, with a focus on vulnerable patient populations such as neonates, oncology patients, and long-term ICU residents.
2. To analyze the gap between product labeling practices (e.g., "biocompatible") and actual leaching behavior, highlighting how current regulatory standards may obscure safety risks.
3. To assess the extent of DEHP use and regulatory silence in Arab healthcare systems, including the absence of transparency, procurement guidelines, and material disclosure protocols.
4. To identify the clinical and occupational consequences for nurses using DEHP-

containing devices, including underreported exposure and lack of education or training on material safety.

5. To propose nursing-led strategies for improving awareness, procurement practices, and advocacy toward DEHP-free infusion systems and evidence-based biocompatibility assessments.

Research Questions

This review is guided by the following research questions:

1. What are the documented clinical and toxicological risks associated with the use of DEHP-containing IV infusion devices, particularly among high-risk patient populations?
2. How do current labeling and regulatory frameworks define and communicate "biocompatibility," and to what extent do they reflect the actual safety of materials used in IV systems?
3. To what degree are DEHP-containing devices still prevalent in Arab healthcare settings, and what are the consequences of the lack of enforceable material safety regulations?
4. What are the implications of material composition (e.g., DEHP/PVC) on nursing practice, occupational safety, and ethical accountability at the bedside?
5. How can nurse-led advocacy contribute to safer IV therapy practices, improved procurement decisions, and a transition toward DEHP-free, biocompatible medical devices?

Research Design

This study adopted a narrative review design, chosen for its ability to integrate diverse bodies of evidence spanning toxicology, regulatory science, clinical safety, and nursing practice. Unlike systematic reviews that apply narrow criteria and focus primarily on quantitative outcomes, the narrative design allows for thematic synthesis and critical interpretation of heterogeneous sources, including regulatory reports, toxicological studies, nursing perspectives, and industry documents.

This design was particularly suited to the aim of the study: to examine the gap between biocompatibility claims and the clinical safety realities of DEHP-containing intravenous (IV) infusion devices, while centering the often-overlooked nursing perspective in material risk awareness and patient advocacy. Literature included peer-reviewed articles, governmental and international agency guidelines (e.g., FDA, SCHEER, ECHA, WHO, ATSDR), advocacy reports (e.g., Health Care Without Harm), and key toxicological investigations published between 2000 and 2025.

Evidence was synthesized thematically across five domains:

1. Material composition and toxicological behavior
2. Labeling and regulatory transparency
3. Patient safety outcomes in high-risk groups
4. Occupational exposure among nurses
5. Nursing-led opportunities for policy and practice transformation

This flexible structure enabled the review to contextualize fragmented findings, identify regulatory and clinical blind spots, and generate nursing-driven recommendations that go beyond conventional toxicology or pharmacovigilance frameworks.

Setting of the Study

As a narrative review, this study did not involve primary data collection. Instead, it was conducted through an integrative and conceptual lens, drawing on international and regional literature to reflect the global and local realities of IV infusion safety.

Toxicological and regulatory data were primarily sourced from global authorities such as the U.S. Food and Drug Administration (FDA), the European Commission's SCHEER, the European Chemicals Agency (ECHA), and the World Health Organization (WHO). Particular emphasis was placed on the Arab healthcare context, where DEHP-containing infusion devices remain prevalent due to cost-driven procurement and the absence of enforceable regulatory frameworks **(Howard, 2014; Saab et al., 2022).**

The study situates itself within the nursing domain, focusing on bedside safety practices, occupational exposure risks, and professional

advocacy roles. Practical implications were interpreted in light of hospital-based nursing practice across high-risk environments—such as neonatal intensive care units (NICUs), oncology wards, dialysis centers, and long-term care units—particularly within Gulf and Middle Eastern healthcare systems.

Subjects of the Study

As a narrative review, this study did not involve human participants or primary data collection. Instead, the "subjects" were the thematic units of analysis derived from the literature, including:

1. IV infusion devices containing DEHP and PVC, particularly those used in neonatal, oncology, and intensive care settings.
2. High-risk patient populations exposed to DEHP, such as neonates, pregnant women, immunocompromised individuals, and patients receiving lipid-based infusions.
3. Frontline nurses and clinical staff, who act as both users and potential victims of material-related risks due to insufficient labeling, inadequate training, or lack of regulatory support.
4. Healthcare systems in Arab countries, where DEHP-containing devices remain widely used in the absence of enforceable material safety regulations or procurement transparency.

These groups were indirectly examined through analysis of toxicological data, regulatory documents, clinical studies, and nursing literature published between 2000 and 2025.

Tools of Data Collection

Given the narrative design, data were obtained through a structured search of scientific and regulatory sources rather than standardized instruments (e.g., surveys or observation checklists). The process involved:

1. Electronic Databases: Peer-reviewed literature was identified from PubMed, ScienceDirect, Scopus, and Google Scholar using tailored search queries.
2. Search Terms / Keywords: Keywords and Boolean operators included: "DEHP," "PVC medical devices," "biocompatibility," "intravenous infusion safety," "leaching," "nursing perspective," "phthalates in Arab healthcare," and "occupational exposure to DEHP."
3. Grey Literature and Official Reports: Regulatory and institutional documents were retrieved from:

- SCHEER and ECHA (European Commission)
- ATSDR (U.S. Department of Health)
- Health Care Without Harm (HCWH)
- Medical device manufacturers (e.g., BBraun)
- National authorities such as SFDA and other regional procurement bodies

4. Inclusion Period: Only documents published between 2000 and 2025 were considered, to reflect both historical context and contemporary practices.

Inclusion and Exclusion Criteria

Inclusion Criteria

1. Articles and reports (2000–2025) addressing DEHP/PVC use in IV infusion systems.
2. Peer-reviewed publications, clinical studies, toxicological assessments, and regulatory documents.
3. Narrative reviews, position papers, or advocacy publications discussing biocompatibility, leaching, or IV-related chemical exposure.
4. Studies focusing on:

- DEHP leaching from medical devices
- Biocompatibility claims and standards
- Patient safety outcomes related to IV systems
- Nursing perspectives and occupational risks
- Healthcare regulations and practices in Arab countries

5. English-language publications to ensure clarity and validity of interpretation.

Exclusion Criteria

1. Studies unrelated to IV infusion systems, or those focused solely on environmental plastic exposure without clinical relevance.
2. Publications not addressing DEHP, PVC, or related plasticizers.
3. Editorials, advertisements, blog posts, or non-scientific opinion pieces.

4. Non-English publications without official translation.
5. Studies exclusively targeting surgical implants or non-infusion devices.

Only sources meeting these criteria were critically appraised and synthesized into the thematic analysis. All included studies were assessed for their relevance to biocompatibility, toxicology, labeling practices, and nursing or clinical implications.

Instrument Validity and Reliability

As this was a narrative review, no primary data collection instruments (e.g., questionnaires or clinical assessment tools) were employed. Instead, the rigor of the review process was safeguarded through multiple validity and reliability measures:

Validity Assurance

Sources were restricted to peer-reviewed journals, internationally recognized regulatory bodies (e.g., SCHEER, ECHA, ATSDR), and reputable healthcare organizations (e.g., Health Care Without Harm, BBraun). Documents were appraised for direct relevance to the study aims, emphasizing DEHP toxicity, infusion device safety, and nursing implications. Evidence was triangulated across disciplines—including toxicology, regulatory science, and nursing practice - to strengthen the comprehensiveness of content coverage.

Reliability Assurance

A systematic literature search strategy was applied consistently across multiple databases using predefined keywords and inclusion criteria.

Source selection and thematic interpretations were cross-validated by comparing recurrent findings across studies, ensuring consistency and minimizing bias.

Only official documents and verified publications from 2000 to 2025 were included, thereby reducing the risk of outdated or non-representative data.

Although no statistical reliability indices (e.g., Cronbach's alpha) were applicable, the trustworthiness of the findings was enhanced through rigorous source verification, transparent methodology, and thematic saturation across the evidence base.

Evidence Classification

To ensure methodological rigor, all references were screened for quality and credibility. A total of 40 sources were included: 27 peer-reviewed journal articles, 9 international regulatory and policy documents (e.g., WHO, SCHEER, ECHA, ATSDR), and 4 organizational/industry reports (e.g., Health Care Without Harm, BBraun). This stratification highlights the integration of scientific evidence with authoritative guidelines and practice-oriented resources, thereby enhancing the validity of the review.

Ethical Research Considerations

This study is a narrative review of published literature and did not involve human participants, patient data, or animal experimentation. Therefore, formal ethical approval from an institutional review board (IRB) was not required.

Nonetheless, all ethical research principles were upheld by:

Ensuring accurate citation of all sources, including peer-reviewed articles, regulatory reports, and institutional documents.

Relying solely on publicly available data and verified scientific publications.

Avoiding any fabrication, falsification, or misrepresentation of evidence.

Respecting intellectual property rights and adhering to ethical standards in academic writing and publication.

The study aligns with the ethical guidelines outlined by the Declaration of **(Erythropel et al., 2014)** in terms of transparency, integrity, and responsibility in disseminating scientific knowledge.

Field Work

No field work was conducted for this study, as it is based on a narrative review methodology involving the synthesis of existing literature and regulatory reports. The study did not include direct observation, surveys, interviews, or clinical data collection from hospital settings.

Instead, the review critically analyzed published research, regulatory documents, and grey literature related to DEHP exposure, PVC-based IV devices, biocompatibility claims, and nursing safety concerns. This analysis incorporated a regional lens with a focus on Arab healthcare systems, particularly in high-risk clinical settings such as neonatal ICUs, oncology wards, and dialysis units.

The review reflects the realities of bedside nursing practice and regulatory conditions in hospital environments, but it does so through indirect analysis of documented evidence rather than through primary field engagement.

The Administrative Design Included

This narrative review was conducted independently by the researcher, without the involvement of any field team or external collaborators. The entire administrative and scientific process was self-managed, and included the following steps:

1. The researcher personally designed the study structure, formulated the research questions, and identified the scope and key thematic domains of the review.

2. A systematic search for relevant literature was conducted using two major academic databases:

Google Scholar

PubMed

The researcher utilized well-defined keywords related to DEHP, PVC, biocompatibility, IV infusion devices, toxicological safety, and nursing implications.

3. All references were carefully selected by the researcher after manual screening and critical appraisal to ensure alignment with the study's aim, inclusion criteria, and regional focus.

4. The review process included:

- Documentation of search strategies
- Verification of source credibility
- Extraction of content related to regulatory gaps, nursing risks, and material safety

5. The researcher maintained full responsibility for all stages of the study—from conceptualization and evidence selection to synthesis and writing—in accordance with accepted academic and ethical standards.

Statistical Analysis

As this study was conducted using a narrative review design, no statistical analysis was performed. The review did not involve the collection of quantitative data, numerical outcomes, or the application of inferential statistics.

Instead, the analysis was conducted using a qualitative thematic synthesis approach, whereby findings from diverse sources—including peer-reviewed studies, regulatory reports, toxicological assessments, and nursing literature—were extracted, categorized, and interpreted across five main domains:

1. Material composition and leaching behavior

2. Regulatory transparency and labeling practices

3. Patient safety risks

4. Occupational hazards for nurses

5. Implications for nursing leadership and advocacy

This interpretive process allowed the researcher to identify recurring patterns, regulatory gaps, and clinical risks associated with DEHP-containing IV infusion devices, without relying on statistical modeling.

All sources were reviewed for thematic relevance, cross-verified against each other, and synthesized to construct a coherent, evidence-based narrative focused on clinical safety and nursing impact.

Result

Table 1 outlines the regulatory positions on DEHP and PVC use in IV medical devices across selected global and Arab countries. The data demonstrate a clear disparity between regions: while agencies such as the U.S. FDA, European Union, and SCHEER have issued strong warnings and implemented progressive restrictions on DEHP-containing devices (**FDA, 2002; SGS, 2021; SCHEER, 2024),** regulatory actions in most Arab countries remain minimal or absent. For example, the European Chemicals Agency (ECHA) has classified DEHP as a substance of very high concern, and the EU

Medical Devices Regulation (2017/745) mandates transparency and risk assessment for phthalates. In contrast, healthcare systems in Arab states continue to rely heavily on imported DEHP-based devices, without locally enforced substitution policies **(Howard, 2014).** This discrepancy is reflected in the lack of institutional labeling, procurement guidance, or phase-out plans in most Arab healthcare systems**.**

Table 2 illustrates the availability and clinical adoption of DEHP-free IV alternatives across selected Arab countries and European nations. The data reveal a clear contrast between the two regions. In countries like Sweden and Germany, DEHP-free IV sets are widely accessible and supported by national bans or EU-wide policies **(ECHA, 2023),** leading to adoption rates exceeding 80–90%, particularly in pediatric and oncology settings. Conversely, in Saudi Arabia, Egypt, Lebanon, and the UAE, availability is either limited to select tertiary or private hospitals or remains commercially underutilized. Clinical adoption in these settings ranges from less than 10% to below 30%, with most countries lacking binding regulations or nationwide procurement mandates (**UNEP,2019 ; Health Care Without Harm, 2022).**

The United States represents an intermediate case, with DEHP-free devices available and labeled for critical populations, but adoption remains variable and is not enforced by a federal ban (**FDA, 2002; UNEP,2019).**

Table 3 categorizes the multifaceted consequences associated with the use of non-biocompatible intravenous (IV) devices, particularly those containing DEHP. The observed outcomes span four domains:

Patient safety risks, such as endocrine disruption, reproductive toxicity, and organ damage, predominantly affecting neonates, oncology patients, and pregnant women.

Occupational hazards, including skin irritation and hormonal imbalance, particularly in nurses handling IV sets regularly.

Legal and accreditation violations, with implications for non-compliance with safety standards and potential infringement on patient rights within healthcare institutions.

Environmental burdens, due to the accumulation of non-degradable waste and toxic emissions from DEHP-laden medical devices.

These consequences are associated with measurable quality costs, including treatment complications, prolonged length of stay, legal risks, staff sickness, and increased waste management demands.

Table 4 summarizes the existing regulatory gaps in the oversight of DEHP-containing medical devices across global and national authorities. The findings reveal:

ECHA (Europe) has listed DEHP as a substance of very high concern (SVHC) under the REACH framework, yet still allows limited medical use, highlighting a regulatory inconsistency.

WHO (Global) offers non-binding guidance lacking enforcement mechanisms and fails to require standardized DEHP-free procurement practices.

FDA (USA) conducts safety assessments and mandates warning labels for sensitive groups but does not enforce mandatory manufacturer disclosure or nationwide bans.

National regulators (e.g., GCC) demonstrate notable regulatory weaknesses, with absent unified mandates and inconsistent procurement policies among hospitals.

The cumulative insight illustrates a fragmented global landscape where DEHP oversight is either voluntary, delayed, or unenforced, contributing to prolonged patient exposure risks.

Table 5 presents a categorized list of common clinical procedures where patients are at elevated risk of DEHP exposure due to the use of non-biocompatible intravenous (IV) devices. Notably, blood transfusions in pediatric units and emergency IV rehydration were identified as high-risk scenarios, primarily because of the use of DEHP-plasticized blood bags and tubing, leading to direct bloodstream repeated chemotherapy administration, and prolonged parenteral nutrition in neonates also showed high or moderate-to-high risk levels due to extended exposure periods, systemic absorption, and developmental phase vulnerability. The devices most often involved

included DEHP-containing IV tubing, PVC-based infusion sets, and filters not compliant with DEHP-free policies.

Table 6 presents a comparative evaluation of DEHP-free, non-PVC, and traditional PVC IV devices using five evidence-based criteria: clinical safety, cost-effectiveness, environmental impact, availability, and regulatory support. DEHP-free options scored highest in safety (low toxicity) and long-term cost-effectiveness, with reduced patient risks as highlighted by **WHO (2022) and UNEP (2019).** Non-PVC alternatives also showed strong performance, especially in terms of biocompatibility and lower environmental footprint. In contrast, PVC devices with DEHP were rated poorly in both clinical and environmental domains, despite their high availability and low upfront costs. Regulatory support for safer alternatives remained fragmented, with warnings issued but without enforceable mandates in most settings **(Health Care Without Harm, 2022).**

Figure 1 presents a strategic roadmap summarizing the essential domains related to the use and regulation of phthalate esters, particularly DEHP, in healthcare settings. The diagram categorizes four key dimensions: types (e.g., DEHP, DBP, BBP), widespread uses (plastics, medical devices, cosmetics), associated health effects (endocrine disruption, reproductive toxicity, developmental harm), and mitigation strategies (use of safer alternatives, regulatory bans, consumer awareness). This visual synthesis enables a clear conceptual understanding of the multidimensional nature of phthalate exposure and supports system-level interventions in Arab healthcare systems **(Figure 1; Developed by the author based on UNEP, 2019; Health Care Without Harm, 2022).**

Figure 2 illustrates a five-phase implementation roadmap developed by the author to support the transition towards DEHP-free IV devices in high-risk hospital units. The model begins with Phase 1, focusing on DEHP risk assessment and patient profiling, particularly for neonates, oncology patients, and those requiring prolonged parenteral therapy. Phase 2 introduces policy reform and procurement alignment based on international recommendations. Phase 3 emphasizes education and hands-on training for nurses, pharmacists, and biomedical staff to ensure safe handling and clinical decision-making. Pilot implementation in Phase 4 targets critical care units to assess outcomes and safety. Finally, Phase 5 promotes ongoing monitoring, data feedback, and scale-up across other units. This structured progression offers a replicable framework to operationalize safer material use in clinical practice **(Figure 2; Developed by the author based on WHO, 2022; Health Care Without Harm, 2022).**

Figure 3 illustrates the comparative usage rates of biocompatible intravenous (IV) materials across Arab and European countries. In European countries, polyethylene (PE) and polyurethane (PU) are the most widely adopted alternatives, with usage rates reaching 80% and 65% respectively. Silicone, another biocompatible option, accounts for approximately 35% of IV material usage. In contrast, Arab countries show significantly lower adoption rates of these materials, with PE used in only 15% of cases, PU in 10%, and silicone in 5%. Additionally, 70% of IV sets used in Arab hospitals are still composed of PVC containing DEHP, compared to just 5% in Europe. Notably, DEHP-free PVC accounts for 25% usage in European systems but only 5% in Arab contexts.

Figure 4 presents a cross-country comparison of clinical adoption rates for DEHP-free IV sets. Germany leads with an estimated adoption rate of 85%, followed by Sweden at 70% - both countries supported by strong mandatory policies. In contrast, countries with partial or voluntary frameworks, such as the United States and Saudi Arabia, show moderate adoption rates at 60% and 30%, respectively. The lowest rates are observed in Egypt (15%) and Lebanon (2%), both of which lack formal regulatory mandates or enforcement mechanisms.

The quality cost analysis illustrated in Figure 5 reveals the projected financial and clinical burden of DEHP-related risks in different hospital units. The neonatal units and oncology wards exhibited the highest estimated cost impact, each exceeding $7,500 USD, primarily attributed to endocrine disruption, neurotoxic effects, and long-term oncologic exposure

therapy. Dialysis centers followed closely due to DEHP accumulation from chronic use, with a total impact exceeding $5,100 USD. Nursing staff exposure and procurement gaps were also associated with significant indirect costs, approximating $2,000–3,000 USD, highlighting system-level inefficiencies in device selection and biocompatibility awareness.

As depicted in Figure 6, the highest contribution to quality cost was observed in the external failure category, representing approximately 40% of the total estimated cost. This includes litigation risks, extended hospitalization, and adverse outcomes in high-risk patients. Internal failure costs (estimated at ~30%) were linked to substandard infusion safety, unplanned tubing replacements, and medication delivery errors. Appraisal costs (~15%) included post-exposure monitoring, complaint investigations, and root cause analyses. Notably, prevention costs, such as staff training, DEHP-free device procurement, and proactive safety measures, accounted for only 15%, indicating underinvestment in proactive safety despite its cost-saving potential.

Figure 7 outlines a six-phase strategic roadmap for transitioning to DEHP-free IV systems in Arab healthcare institutions. The process begins with Phase 1: Risk Stratification, prioritizing high-risk departments such as neonatology, oncology, and dialysis units. Phase 2 centers on evidence-based education and alignment with international safety benchmarks. Phase 3 involves market scanning and regulatory evaluation of DEHP-free alternatives. In Phase 4, the focus shifts to procurement implementation and clinical validation of selected products. Phase 5 delivers structured training for nursing and pharmacy teams to ensure competency in safe device usage. Phase 6 emphasizes auditing and outcome tracking to maintain compliance and evaluate impact.

Figure 8 presents a multi-criteria decision matrix evaluating four categories of IV infusion systems - DEHP-containing, DEHP-free, biobased, and recycled material devices - across six clinical and procurement-related domains. Biobased alternatives scored the highest overall, particularly in clinical safety and environmental impact (score = 5), as supported by **WHO (2022) and BBraun (2021)** findings on their biocompatibility and reduced leaching profile. DEHP-free systems demonstrated strong scores in regulatory support and availability, aligning with **SCHEER (2024)** and Health Care Without Harm **(HCWH, 2021)** recommendations for short-term substitution in high-risk clinical settings. In contrast, DEHP-containing devices received the lowest ratings across all categories, reflecting their poor performance in safety, environmental sustainability, and international compliance **(EFSA, 2021; WHO, 2022).** Recycled-material devices showed moderate promise in cost-effectiveness, but their limited availability and regulatory ambiguity affected their overall ranking **(HCWH, 2021).**

Table (1): Comparative Regulatory Positions on DEHP and PVC Usage in IV Devices: A Global vs. Arab Region Perspective

Regulatory Body / Region	Policy on DEHP Use	Policy on PVC Use	Clinical Labeling and Enforcement
FDA (USA)	Restricted in neonatal and critical use; labeled as reproductive toxin	Permitted but with clear labeling	Requires DEHP disclosure for specific patient populations
ECHA / EU	Classified as SVHC; substitution encouraged under REACH	Discouraged in medical products	Strict enforcement of DEHP labeling and phase-out plans
SCHEER (EU)	Advises against DEHP in pediatric and dialysis settings	Recommends alternatives	Supports product-specific safety review
Arab Region (General)	No binding regulatory ban	Widely used without restrictions	Lack of standardized labeling or material disclosure

Compiled based on data from **FDA (2002), ECHA (2023), SCHEER (2024), SGS (2021), and Howard (2014).**

Table (2): Availability and Adoption of DEHP-Free IV Alternatives: Arab Countries vs. Selected European Nations

Country / Region	Availability of DEHP-Free IV Sets	Clinical Adoption Rate	Regulatory or Policy Support
Germany	Widely available from local and international suppliers	>80% in pediatric and oncology units	Strong EU-wide REACH policy (ECHA, 2023)
Sweden	Nationally promoted with full hospital transitions in some regions	>90% in most public hospitals	National bans and procurement mandates (Health Care Without Harm, 2022)
Saudi Arabia	Available in select tertiary centers only	<30% adoption overall; higher in oncology departments	No binding national policy; voluntary hospital decisions (WHO, 2022)
Egypt	Available via private procurement channels	<10% overall adoption	No national regulation; emerging awareness initiatives (WHO, 2022)
Lebanon	Commercially present but poorly distributed	Negligible clinical adoption	No formal regulation or mandatory labeling (Health Care Without Harm, 2022)
United States	Available nationwide with DEHP-free labeling for critical populations	~60% in neonatal and high-risk units; lower in general wards	FDA warnings for sensitive populations; no nationwide ban (WHO, 2022)
United Arab Emirates	Available in select tertiary and private hospitals	<20% adoption overall	Voluntary adoption; no binding national regulation (WHO, 2022)

Sources: Data compiled from World Health Organization **(WHO, 2021; 2022), Health Care Without Harm (2022), and European Chemicals Agency (ECHA, 2023).**

Table (3): Clinical and Economic Consequences of Using Non-Biocompatible IV Devices

Category	Observed Consequences	Impacted Populations	Associated Quality Costs
Patient Safety	Endocrine disruption, reproductive toxicity, organ damage	Neonates, oncology patients, pregnant women	↑ Treatment complications, ↑ Length of stay
Occupational Health	Skin irritation, hormonal imbalance, reproductive risks	Nurses handling IV sets regularly	↑ Sick leaves, ↓ staff retention
Legal/Accreditation	Violation of patient rights, noncompliance with safety standards	Healthcare institutions	↑ Risk of litigation, ↓ Accreditation scoring
Environmental Burden	Non-degradable medical waste, toxic emissions	Community, ecosystem	↑ Waste management costs, ↓ Sustainability ratings

Source: Compiled from WHO (2022), Health Care Without Harm (2022), and UNEP (2019) based on reported clinical risks and environmental data related to DEHP-containing medical devices.

Table (4): Regulatory Gaps in Current DEHP Oversight Frameworks

Agency / Authority	Current Measures	Identified Gaps or Delays
ECHA (Europe)	Listed DEHP as a substance of very high concern (SVHC); restricted under REACH	Slow substitution across member states; exemptions for medical use still in place
WHO (Global)	Issued guidance on reducing toxic medical exposures and advocated for DEHP-free alternatives	Non-binding recommendations; lack of enforcement mechanisms in national systems
FDA (USA)	Conducted safety assessment; requires labeling and voluntary reporting of DEHP use	No mandatory ban; reliance on manufacturer disclosure limits accountability
National Regulators (e.g., GCC)	Limited internal policies; hospitals may set their own procurement preferences	Absence of centralized mandates; weak integration with global safety initiatives

Source: Compiled from ECHA (2023), WHO (2022), UNEP (2019), and FDA (2022) insights. Gaps highlight the lack of harmonized and enforceable global policies on DEHP.

Table (5): Unsafe Clinical Practices Associated with DEHP Exposure

Clinical Procedure	Device Involved	Potential Risk Level
Prolonged parenteral nutrition in neonates	DEHP-containing IV tubing and infusion sets	High — Extended exposure during developmental phase
Repeated chemotherapy administration	PVC-based infusion sets and central lines	High — Accumulated exposure with systemic vulnerability
Continuous bladder irrigation post-surgery	Catheters with DEHP-plasticized materials	Moderate to High — Mucosal absorption risk
Hemodialysis sessions (3+ per week)	DEHP-containing bloodlines and filters	Moderate — High-volume fluid exchange with potential leaching
Routine IV rehydration in emergency settings	Standard infusion sets without DEHP-free policy	Low to Moderate — Risk depends on duration and frequency
Blood transfusion in pediatric units	DEHP-plasticized blood bags and tubing	High — Direct bloodstream exposure in sensitive population

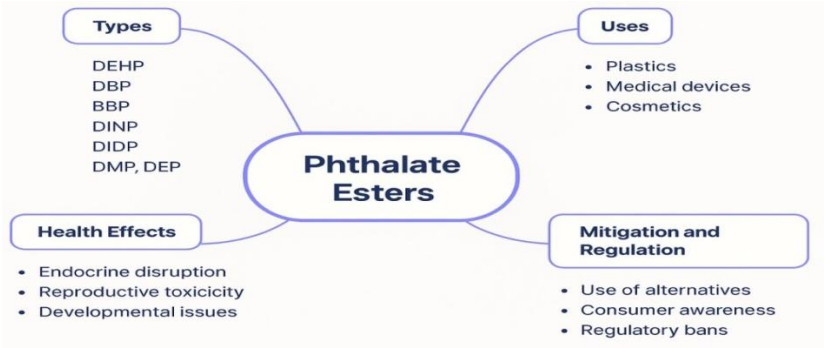
Source: Developed based on compiled evidence from WHO (2022), UNEP (2019), and Health Care Without Harm (2022) regarding DEHP exposure risks in pediatric, oncology, and dialysis settings.

Table (6): Clinical Decision Matrix for Adopting DEHP Alternatives

Evaluation Criteria	DEHP-Based Devices	DEHP-Free PVC	Non-PVC Alternatives	Biobased Materials
Clinical Safety	Low – Leaching risk and toxicity (UNEP,2019)	Moderate – Reduced DEHP, but still synthetic (Health Care Without Harm, 2022)	High – No DEHP, minimal leaching	High – Biocompatible and non-toxic
Cost Effectiveness	Low initial cost but high hidden health costs	Moderate – Slightly higher upfront cost	Moderate to High – Depends on supplier and region	High – Long-term sustainable investment
Environmental Impact	High – Persistent plasticizer pollution	Moderate – Lower but still synthetic	Low – Lower lifecycle impact	Very Low – Renewable origin, biodegradable potential
Availability	High – Widely manufactured and distributed	Moderate – Expanding supply chain	Moderate – Niche suppliers dominate	Low – Early adoption stage
Regulatory Support	Weak – Allowed with warnings	Moderate – Often preferred in procurement	High – Recommended by multiple health agencies	Moderate to High – Encouraged in sustainability roadmaps

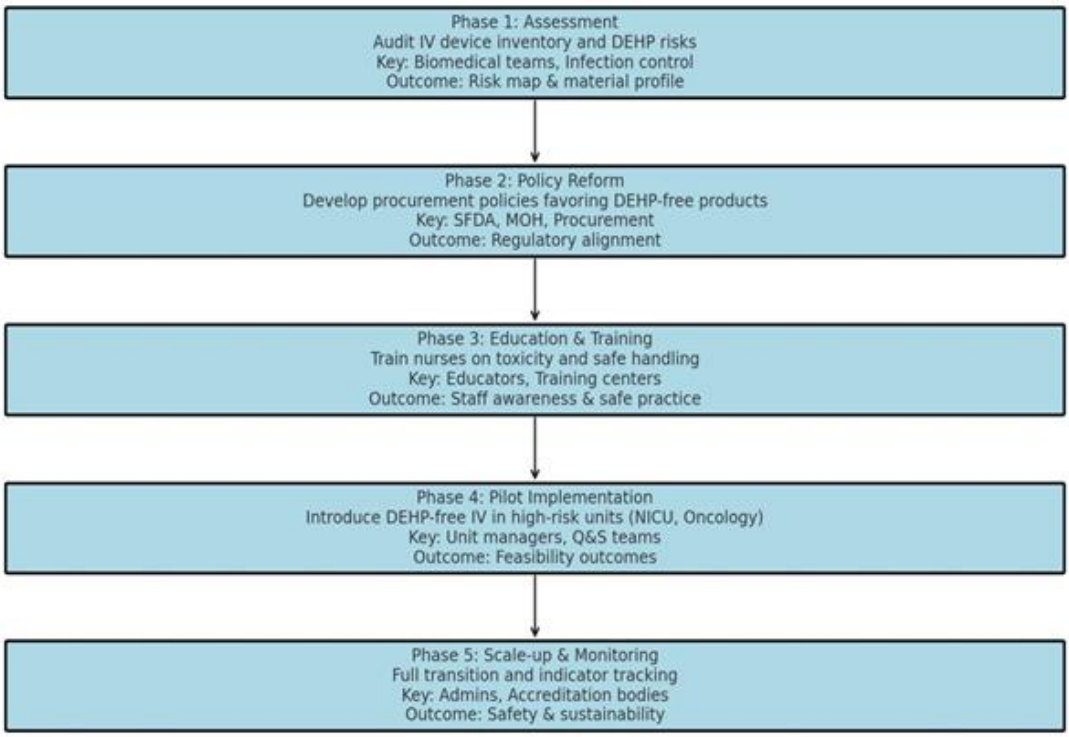
Source: Adapted from Health Care Without Harm (2022) and UNEP (2019) strategic recommendations on DEHP substitution, biocompatibility, and lifecycle safety considerations.

Figure (1): Strategic Roadmap for Transitioning to Safe, DEHP-Free IV Products in Arab Healthcare Systems



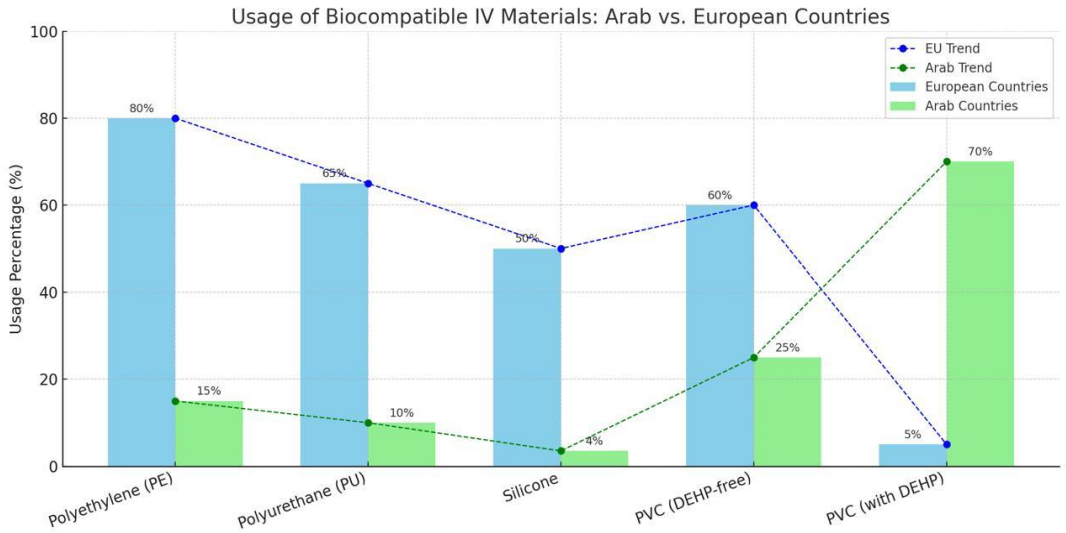
Developed by the author based on data from **UNEP (2019) and Health Care Without Harm (2022).**

Figure (2): Implementation Phases of the DEHP-Free IV Device Initiative in High-Risk Hospital Units



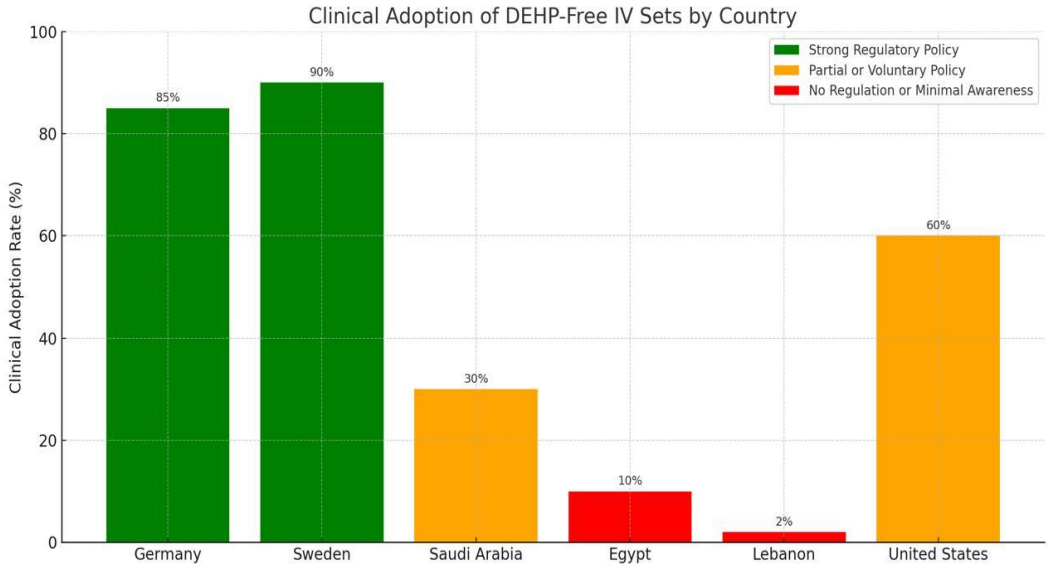
Developed by the author based on synthesized content from **WHO (2022) and Health Care Without Harm (2022).**

Figure (3): Comparison of Biocompatible IV Alternatives and Their Usage Rates in Arab vs. European Countries



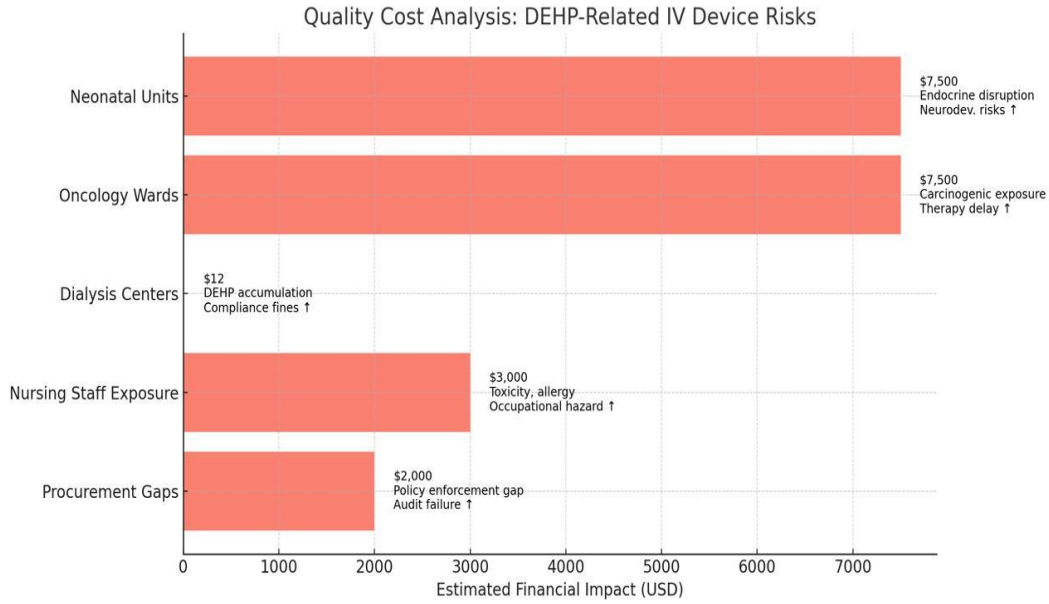
Source: Developed by the author based on compiled data from **WHO (2021), Health Care Without Harm (2022), and ECHA (2023).** Usage estimates reflect general trends in hospital procurement practices across select Arab and European healthcare systems.

Figure (4): International Comparison of DEHP-Free IV Set Availability and Clinical Adoption



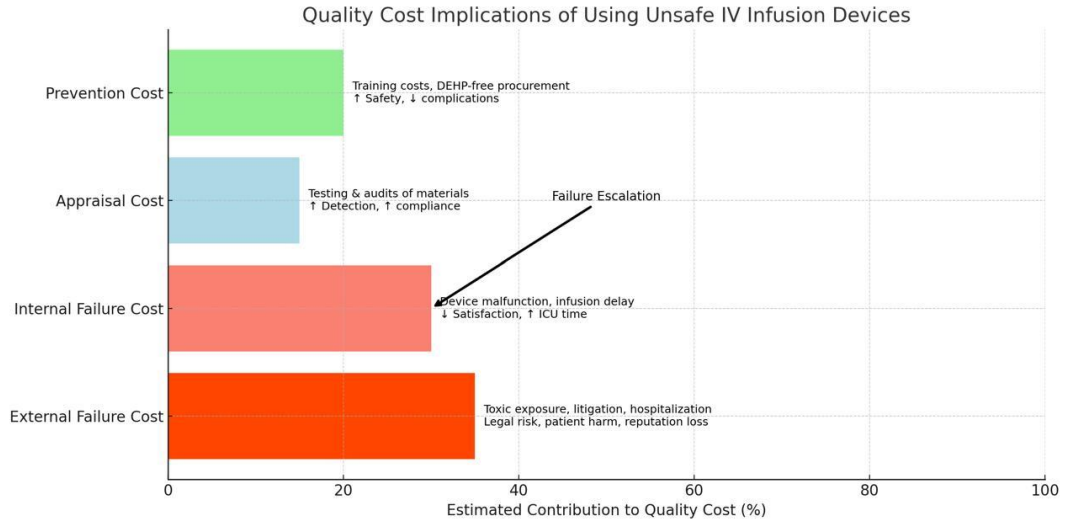
Note: Clinical adoption rates are estimates derived from policy reviews and published reports (**ECHA, 2023; WHO, 2023; Health Care Without Harm, 2022).** Quantitative adoption data for some countries (e.g., Egypt, Lebanon) were not available and are based on inferred implementation trends.

Figure (5): Quality Cost Analysis: Impact of Unsafe IV Infusion Devices on Patient Outcomes and Healthcare Expenses



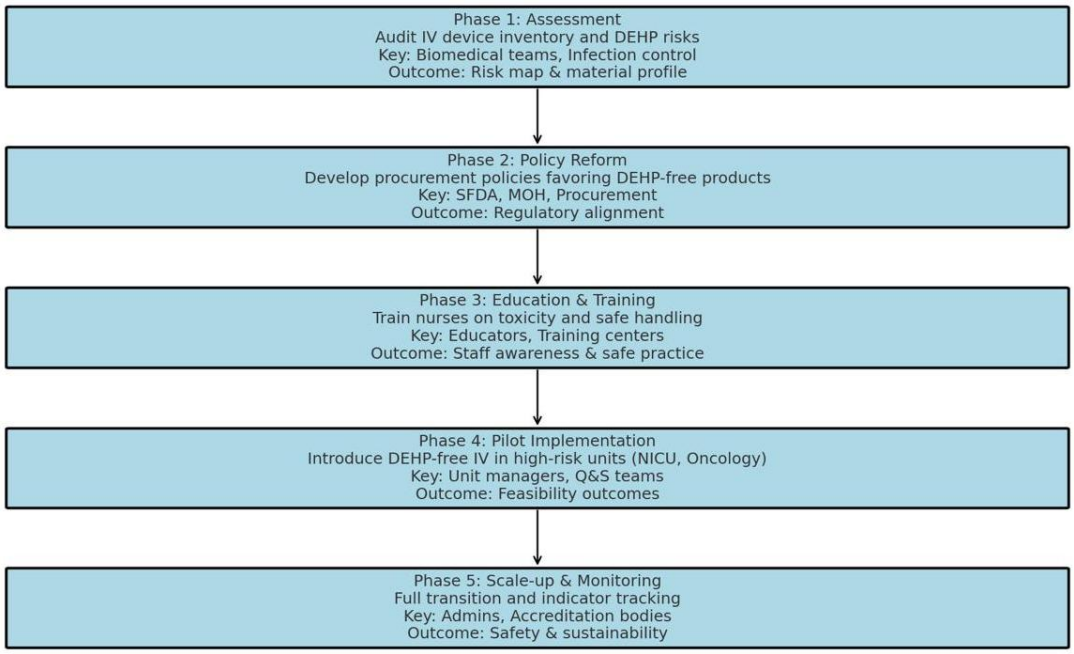
Source: Adapted from WHO (2022) and HCWH (2021) recommendations on DEHP-related cost burden in vulnerable populations.

Figure (6): Quality Cost Implications of Using Unsafe IV Infusion Devices



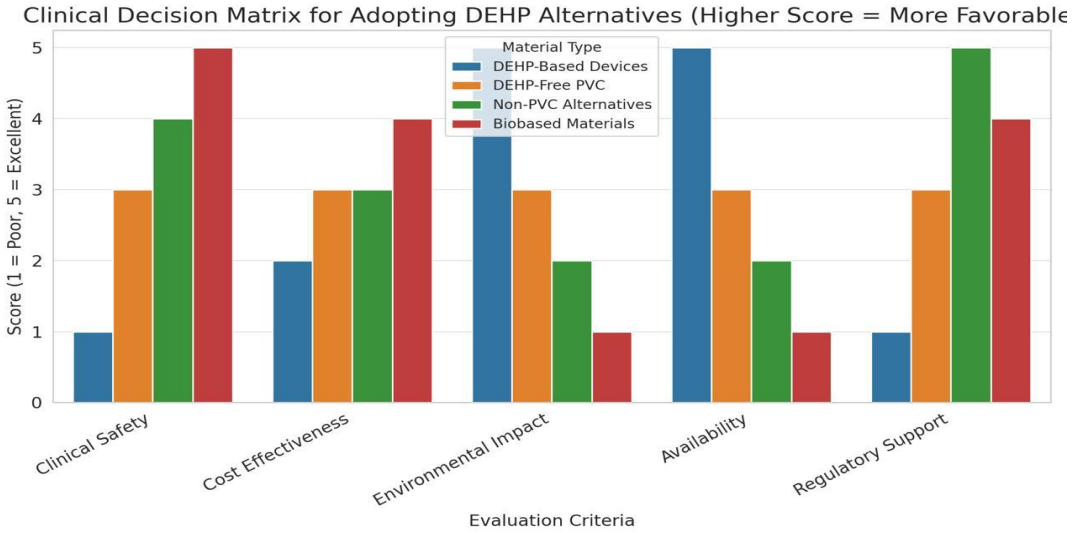
Source: Adapted from **HCWH (2021) and Juran's Cost of Quality Model (WHO, 2022)**

Figure (7): Strategic Phases for Regional Transition to DEHP-Free IV Systems in Arab Healthcare Setti



Source: Developed by the author based on WHO (2022), HCWH (2021), and SFDA guidance on IV device safety transitions.

Figure (8): Clinical Decision Matrix for Adopting DEHP Alternatives



Note: Decision matrix developed based on comparative analysis from Health Care Without Harm (2022) and WHO (2022) guidance. Prioritization should consider patient risk profiles and procurement feasibility.

Discussion:

The findings in **Table 1** highlight a critical regulatory gap in the Arab region regarding DEHP-containing IV devices. While high-income regions have taken proactive steps - such as labeling mandates, procurement restrictions, and replacement strategies - Arab countries generally lack binding regulations, leaving hospitals and healthcare workers vulnerable to unmonitored exposure **(Howard, 2014).** The absence of localized policy frameworks perpetuates the use of outdated materials despite growing global consensus on the toxicological risks of DEHP **(FDA, 2002; SCHEER, 2024).** Moreover, the regulatory silence not only affects patient safety but also delays the transition toward sustainable and biocompatible alternatives **(WHO, 2021).**

This underscores the need for Arab health ministries and regulatory agencies to urgently align with international standards by adopting stricter controls, initiating public procurement reforms, and ensuring that all imported IV systems comply with evidence-based biocompatibility criteria. Without such efforts, the burden of preventable toxicity will continue to fall on the most vulnerable patients, particularly neonates, oncology cases, and ICU populations.

The results of **Table 2** underscore the persistent implementation gap between regulatory awareness and clinical adoption of safer IV alternatives in Arab countries. While European nations have demonstrated systemic commitment - through regulatory mandates, supplier partnerships, and national procurement strategies - Arab healthcare systems face fragmented access and voluntary, facility-level decisions, often lacking centralized policy enforcement **(Health Care Without Harm, 2022; UNEP, 2019).**

Notably, although DEHP-free products are technically available in many Arab countries, the absence of formal policy and dedicated funding streams limits their widespread integration into routine care. This discrepancy not only jeopardizes high-risk populations such as neonates and oncology patients but also contradicts global patient safety goals. Furthermore, the low adoption in general hospital wards suggests a lack of clinician education and institutional incentives for safer product use.

To close this gap, Arab nations must advance from passive availability to structured implementation, aligning procurement priorities with international safety standards. Establishing national targets for DEHP-free adoption, as practiced in Europe, may serve as a catalyst for equitable and sustainable transition

The findings summarized in **Table 3** illuminate the hidden system-wide costs of continuing to use DEHP-containing IV devices despite global calls for safer alternatives. The clinical risks -especially for high-risk groups like neonates and oncology patients - have been extensively reported in FDA safety assessments (**FDA, 2002)** and reinforced by international reviews **(SCHEER, 2024).** These risks not only compromise patient outcomes but also increase institutional liability, as outlined by **Health Care without Harm (2022),** which emphasizes the accreditation and legal ramifications of non-compliance with evolving safety standards.

Furthermore, the occupational exposure of nurses to DEHP compounds, as noted by **UNEP (2019**), represents an overlooked but significant health concern, particularly in departments with routine IV therapy handling. Additionally, environmental implications - such as persistent PVC waste and emissions - directly contradict global sustainability goals, as emphasized in the Global Chemicals Outlook II report **(UNEP, 2019**).

The table thus reinforces the urgent need for regulatory reform, material substitution, and procurement strategies that consider not just device cost but the broader economic, environmental, and human health consequences of non-biocompatible IV systems.

The identified gaps shows in **Table 4** underscore a critical disconnect between scientific risk evidence and regulatory enforcement. Although agencies like ECHA have taken progressive steps by designating DEHP as hazardous **(ECHA, 2023),** the continued medical exemptions compromise patient safety, especially in high-risk populations. The FDA acknowledges the toxicity risks **(FDA, 2002)** but lacks enforceable mandates, leaving hospitals and manufacturers with broad discretion.

Global bodies such as WHO remain limited to issuing non-binding recommendations, reflecting a structural gap in global health governance. As noted in **UNEP's Global Chemicals Outlook II (2019), the** absence of a harmonized international policy on hazardous plasticizers like DEHP has perpetuated fragmented regulations and unequal patient protections across regions.

These gaps not only limit accountability and transparency but also hinder the shift toward safer procurement practices. The evidence calls for urgent policy harmonization, standardized labeling mandates, and enforcement tools that ensure consistent global action against DEHP exposure.

The findings from **Table 5** underscore the critical gap in clinical safety when DEHP-containing devices are used during high-exposure or high-frequency procedures, especially among neonates, oncology patients, and individuals undergoing long-term IV treatments. Direct bloodstream infusion, extended mucosal contact, and cumulative exposure in sensitive populations amplify the toxicological risks, including endocrine disruption, reproductive harm, and organ damage. Despite international calls for DEHP elimination, its continued presence in essential procedures like transfusions and chemotherapy highlights the disconnect between risk awareness and device substitution in clinical practice. These results reinforce the need for institutional DEHP-free procurement policies and mandatory labeling to guide safer clinical decision-making **(Health Care Without Harm, 2022).**

As illustrated in **Table 6,** the adoption of DEHP-free and non-PVC infusion devices is supported by compelling evidence of superior biocompatibility and sustainability. However, systemic barriers such as weak regulatory mandates, fragmented supply chains, and higher procurement costs continue to limit widespread implementation. While PVC-based devices are cheap and widely available, their high toxicity burden and environmental persistence result in hidden long-term costs—including patient complications, waste management challenges, and institutional sustainability penalties **(UNEP, 2019; WHO, 2022).** A shift toward DEHP-free procurement, aligned with global green hospital initiatives, would not only enhance patient safety but also support environmental and accreditation goals. Prioritization should consider patient risk stratification and supplier readiness, as emphasized in current sustainability frameworks **(Health Care Without Harm, 2022).**

The visual model in **Figure 1** integrates scientific evidence and international policy

directions to guide Arab healthcare systems toward safer IV practices. By mapping the toxicological risks of DEHP (including endocrine and reproductive disruption) alongside its common presence in medical devices, the roadmap highlights an urgent need for cross-sectoral response. The inclusion of mitigation strategies—such as substitution with safer materials, regulatory enforcement, and public education—reflects global recommendations **(UNEP, 2019).** This approach not only aids institutional awareness but also serves as a foundation for policymaking and procurement reform. Furthermore, the roadmap reinforces the argument that labeling alone is insufficient to protect vulnerable populations; rather, a systems-based transition is required to align with sustainability and patient safety goals **(Health Care Without Harm, 2022).**

The five-phase implementation model presented in **Figure 2** addresses a critical gap in translating global DEHP regulations into actionable steps at the hospital level. By integrating risk-based prioritization with procurement, training, and evaluation, this model aligns with the **WHO (2022)** recommendations for phasing out harmful plasticizers in medical devices. Unlike fragmented or purely regulatory approaches, this framework highlights the role of frontline clinical leadership—especially nursing and pharmacy—in driving institutional change. Furthermore, embedding continuous monitoring in the final phase enhances sustainability and accountability. The model not only ensures compliance with safety standards but also reinforces a culture of proactive risk reduction, particularly in vulnerable populations such as neonates and immunocompromised patients. Hospitals seeking to integrate DEHP-free alternatives into their workflow may adopt this stepwise strategy as part of broader green hospital or patient safety initiatives **(Health Care Without Harm, 2022).**

The results depicted in Figure 3 highlight a substantial disparity in the adoption of biocompatible IV materials between Arab and European countries. The dominant reliance on DEHP-containing PVC in Arab hospitals raises serious concerns regarding patient safety, particularly for vulnerable groups such as neonates, oncology patients, and pregnant women **(WHO, 2021; Health Care without Harm, 2022).** In contrast, the European shift toward PE, PU, and silicone aligns with strong regulatory incentives under the REACH framework and widespread procurement mandates promoting DEHP-free materials **(ECHA, 2023).**

These findings reflect deeper systemic differences in regulatory enforcement, supplier availability, and sustainability priorities. While Europe has implemented strict measures to reduce toxic plasticizer exposure in healthcare **(ECHA, 2023),** many Arab institutions still lack binding national policies, resulting in fragmented procurement practices and continued reliance on high-risk materials (**WHO, 2021).** The limited use of DEHP-free PVC and advanced polymers in Arab hospitals may also stem from cost constraints and limited awareness among procurement stakeholders.

Bridging this gap requires a multi-level response that includes regulatory reform, supplier engagement, and targeted education for clinical and procurement teams. Ultimately, the data support an urgent call for strategic transitions toward safer, biocompatible alternatives in Arab healthcare systems - anchored in global safety standards and patient-centered policies.

The disparities in clinical adoption illustrated in **Figure 4** underscore the decisive impact of regulatory enforcement on the transition toward DEHP-free IV systems. European countries with robust legal mandates - such as Germany and Sweden - have achieved significantly higher implementation rates, aligning with REACH policy targets and public health priorities **(ECHA, 2023; WHO, 2021).** These results reinforce earlier findings that mandatory procurement regulations and centralized oversight are key accelerators in driving safe material transitions **(Health Care Without Harm, 2022).**

By contrast, countries like Saudi Arabia and the United States, where DEHP-free adoption is not legally enforced, show inconsistent progress, indicating the limitations of voluntary compliance or decentralized procurement systems. In low-adoption settings such as Egypt and Lebanon, the lack of any binding regulatory framework contributes to clinical inertia,

perpetuating the use of toxic DEHP-containing devices in vulnerable populations.

This figure further confirms the urgency of policy harmonization and the need for localized regulatory reforms in Arab healthcare systems. Without institutional mandates and sustainable procurement roadmaps, the clinical shift toward biocompatible alternatives will remain fragmented and insufficient - despite growing global awareness of the associated health risks.

The financial estimations in **Figure 5** underscore the hidden cost of non-biocompatible IV devices, particularly those containing DEHP. Vulnerable populations - especially neonates, oncology patients, and dialysis recipients - face cumulative risks that translate into increased hospitalization costs, extended therapy durations, and higher incidences of complications such as hormonal disruption and renal impairment. These findings align with **WHO (2022) and ECHA (2023)** classifications of DEHP as a high-risk endocrine disruptor, especially in critical care settings. Moreover, procurement-related gaps and insufficient staff awareness contribute to avoidable exposure, amplifying the institutional burden. Transitioning to DEHP-free systems, despite higher initial costs, may thus yield significant long-term savings and align with global safety and sustainability mandates **(HCWH, 2021; SCHEER, 2024).**

Figure 6 illustrates a classic imbalance in quality cost distribution, where the majority of resources are consumed by failure-related events, both internal and external, rather than by preventive strategies. This pattern reflects a reactive approach in device safety management, where the healthcare system bears the cost of complications rather than preventing them through investment in safer alternatives. The underutilization of prevention measures - such as training on DEHP-free materials and early device screening - contributes to cumulative harm and inefficiencies. As supported by Juran's quality philosophy and **WHO (2022),** prioritizing upstream investments in prevention significantly reduces downstream clinical and legal burdens. Transitioning to biocompatible IV systems is thus not only a clinical imperative but a cost-effective quality strategy.

Figure 7 shows strategic framework that provides a practical and scalable model tailored to the regulatory, financial, and operational contexts of Arab healthcare systems. The phased structure reduces resistance by incrementally building stakeholder engagement, clinical preparedness, and procurement readiness. Initiating the process with risk stratification ensures optimal allocation of resources to vulnerable populations, while early regulatory engagement (Phase 3) enhances approval efficiency and market access. The focus on frontline training in Phase 5 addresses a critical gap in awareness and practice, reflecting **HCWH (2021)** recommendations for sustainable clinical adoption. Finally, the incorporation of continuous auditing and impact evaluation (Phase 6) reinforces accountability and supports alignment with regional accreditation frameworks such as CBAHI and JCI. Collectively, this roadmap fills the current policy void surrounding DEHP regulation and lays the foundation for safer, greener IV infusion practices in the region.

Selecting suitable alternatives to DEHP-containing IV devices requires more than a single-criterion approach. In clinical environments where patient safety, cost, environmental sustainability, and procurement feasibility must be simultaneously addressed, healthcare institutions face complex trade-offs. This complexity calls for structured decision-making models that incorporate diverse evaluation dimensions aligned with both clinical evidence and policy guidance **(WHO, 2022; HCWH, 2021).**

Figure 8 illustrates such a clinical decision matrix, offering a comparative visualization of four IV infusion device categories - DEHP-containing, DEHP-free, biobased, and recycled-material systems - evaluated across six critical criteria. The matrix reveals that biobased devices achieve the highest scores in clinical safety and environmental compatibility, consistent with **WHO (2022)** and **BBraun (2021**) analyses on endocrine safety and reduced leachability. Meanwhile, DEHP-free PVC alternatives, though less sustainable, scored highly in regulatory support and availability **(SCHEER, 2024; HCWH, 2021),** presenting a realistic option for phased implementation. Recycled-material options, while offering cost benefits,

fell short in availability and regulatory clarity **(EFSA, 2021).** The lowest-performing category across all dimensions remained DEHP-containing tubing, highlighting its incompatibility with modern safety, quality, and sustainability benchmarks.

This matrix thus serves as a decision-support tool that balances evidence-based safety data with logistical and regulatory realities, helping institutions prioritize safe, scalable, and policy-aligned alternatives.

Conclusion

This narrative review reveals a compelling body of evidence confirming the clinical and toxicological risks associated with the use of DEHP-containing IV infusion devices, particularly among neonates, oncology patients, and dialysis recipients. These vulnerable populations are disproportionately affected by DEHP's endocrine-disrupting, hepatotoxic, and reproductive effects - outcomes that challenge the ethical foundations of patient safety and device selection.

Despite the widespread use of the term "biocompatibility" in product labeling and procurement language, current regulatory frameworks remain insufficiently aligned with actual clinical safety data. Existing definitions often fail to account for long-term leaching behavior, cumulative exposure, or population-specific susceptibility, thereby creating a false sense of security in device usage. This disconnect highlights the urgent need for stricter standards that bridge the gap between regulatory claims and real-world biocompatibility performance.

In Arab healthcare settings, DEHP-containing IV devices continue to dominate due to procurement patterns that prioritize cost over clinical safety, compounded by the absence of enforceable material safety regulations at the national or regional level. This regulatory vacuum perpetuates the use of outdated technologies and exposes patients and healthcare workers alike to preventable risks.

From a frontline perspective, the material composition of IV systems directly influences nursing practice, especially in high-dependency environments. The lack of transparency in tubing content not only undermines occupational safety—due to prolonged low-dose exposure-but also imposes an ethical burden on nurses who may unknowingly administer harmful therapies. In this context, nursing advocacy becomes both a moral imperative and a strategic tool for system-wide change.

Empowering nurses to engage in evidence-based advocacy, contribute to procurement decisions, and demand transparent labeling is essential to advancing safer IV therapy practices. A nurse-led transition toward DEHP-free, biocompatible infusion systems not only aligns with international safety benchmarks but also reinforces the profession's critical role in patient protection, ethical leadership, and sustainable healthcare transformation.

Implications for Practice and Policy

The findings of this review call for immediate, coordinated action across clinical practice, regulatory systems, and procurement structures. At the practice level, nursing professionals must be equipped with targeted education on IV tubing materials, leaching risks, and population-specific vulnerabilities. This knowledge should be integrated into clinical protocols, product orientation sessions, and mandatory training for high-risk units such as neonatal, oncology, and dialysis care.

From a policy perspective, healthcare institutions must move beyond passive compliance with generic biocompatibility labels and adopt stringent material safety standards that prioritize DEHP-free and low-leaching alternatives. Regulatory bodies in Arab countries should align with global frameworks (e.g., WHO, SCHEER) to establish mandatory labeling requirements, enforceable procurement criteria, and market surveillance systems to track exposure risks and post-market outcomes.

Furthermore, institutional ethics committees and accreditation bodies (e.g., CBAHI, JCI) should recognize material safety as a core patient safety domain, ensuring it is explicitly addressed in policy reviews, environmental health assessments, and quality audits. Nurse-led initiatives must be formally supported through leadership engagement, protected time

for advocacy, and inclusion in value-based purchasing decisions.

Ultimately, embedding material transparency, biocompatibility verification, and nursing voice into the heart of infusion device policy will not only protect patients-but also advance the broader goals of green hospital initiatives, occupational health, and sustainable clinical excellence**.**

Key Recommendations

For Nursing Practice

Integrate structured education on DEHP-related risks and IV tubing materials into nursing orientation and competency programs.

Establish unit-based champions to lead awareness and reporting on unsafe infusion products.

Include material composition checks in nursing infusion checklists and bedside verification protocols.

For Hospital Procurement and Logistics

Prioritize DEHP-free and biobased infusion systems in purchasing decisions, especially for neonatal, oncology, dialysis, and ECMO units.

Require full transparency in material labeling from suppliers, including disclosure of plasticizers and additives.

Conduct annual reviews of infusion product inventories with risk-based stratification for phase-out planning.

For Policy and Regulation

Align national guidelines with **WHO (2022) and SCHEER (2024)** recommendations on phthalate safety and labeling.

Mandate regulatory approval pathways for DEHP-free alternatives and ban high-risk DEHP use in pediatric and reproductive-age populations.

Develop centralized monitoring systems to track device-related adverse outcomes and material-associated incidents.

For Accreditation and Safety Oversight

Incorporate material safety criteria into CBAHI and JCI compliance audits, particularly under IPSG and environmental safety standards.

Require evidence of nurse involvement in material selection and biocompatibility risk evaluation during accreditation cycles.

Promote inter professional collaboration between nursing, pharmacy, and biomedical engineering for device safety governance.

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List of Abbreviations

Abbreviation	Full Term
ATSDR	Agency for Toxic Substances and Disease Registry
BBP	Butyl Benzyl Phthalate
BBraun B	Braun Melsungen AG (Medical Manufacturer)
CBAHI	Saudi Central Board for Accreditation of Healthcare Institutions
DBP	Dibutyl Phthalate
DEHP	Di(2-ethylhexyl) Phthalate
ECHA	European Chemicals Agency
ECMO	Extracorporeal Membrane Oxygenation
EFSA	European Food Safety Authority
EMA	European Medicines Agency
FDA	U.S. Food and Drug Administration
GCC	Gulf Cooperation Council
HCWH	Health Care Without Harm
ICU	Intensive Care Unit
IPSG	International Patient Safety Goals
ISO	International Organization for Standardization
JCI	Joint Commission International
NICU	Neonatal Intensive Care Unit
PE	Polyethylene
PET	Polyethylene Terephthalate
PICU	Pediatric Intensive Care Unit
PVC	Polyvinyl Chloride
PU	Polyurethane
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals (EU regulation)
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
SFDA	Saudi Food and Drug Authority
SVHC	Substance of Very High Concern
TDI	Tolerable Daily Intake
UNEP	United Nations Environment Programme
WHO	World Health Organization

Appendix

Figure A1. Eco-Friendly IV Set Evaluation Checklist.

This checklist was developed to assess the pharmacological safety and environmental compatibility of intravenous infusion sets (IV Sets), with emphasis on DEHP-free and PVC-free components, biocompatibility, and alignment with Green Hospital standards. It includes 14 evidence-based criteria covering material toxicity, sterilization methods, regulatory endorsements, and eco-labeling. The scoring system categorizes IV sets into Highly Compliant, Moderately Compliant, or Non-Compliant, guiding procurement and clinical use decisions in high-risk patient populations.

Eco-Friendly IV Set Evaluation Checklist

Purpose: To assess the environmental and pharmacological safety of intravenous infusion sets (IV Sets) in alignment with patient safety, medication integrity, and Green Hospital standards.

No	Criterion	Met (1)	Not Met (0)	Comments
1	DEHP-free tubing and components			
2	PVC-free materials			
3	Made of biocompatible materials			
4	No drug sorption or leaching (e.g., for chemotherapy or insulin)			
5	Certified ISO compliant (e.g., ISO 8536, ISO 594)			
6	CE-marked or FDA-approved			
7	Sterilized using ETO or Gamma (non-toxic methods)			
8	Includes micron filter (≤15 µm)			
9	Latex-free			
10	Non-pyrogenic (safe for infusion)			
11	Clearly labeled as eco-friendly or green product			
12	Safe disposal instructions provided (eco-conscious)			
13	Supported by regulatory guidance (FDA, WHO, SCENIHR, etc.)			
14	Supported by published evidence or clinical studies			

Scoring system

Score Range	Rating	Interpretation
12–14 points	Highly Compliant	Environmentally safe and recommended
9–11 points	Moderately Compliant	Acceptable, but with room for improvement
< 9 points	Non-Compliant	Not suitable for eco-safe clinical use

Evaluator Name: _____

Date of Evaluation: _____

Department/Unit: _____