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# Polymers In Low-Resource Biomedical Innovation: Maker Labs, DIY Devices and Ethics

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***Abstract***

*The low-cost biomedical devices have been prototyped and sometimes put into practice by maker laboratories and community "DIY" (Do-It-Yourself maker) innovators due to the fast-growing availability of polymer-based fabrication (desktop 3D printing, laser cutting, and simple molding). Nowadays, polymers such as PLA, PETG, TPU, and PEEK are used in a wide range of applications, including surgical guides and anatomical models, as well as assistive technology and diagnostic housings. Such innovations based on makers can be used to save money, localize supply chains, and accelerate iteration, especially in limited-resource settings. The transition to clinical utilization raises critical technical, safety, legal, and ethical issues, such as the material biocompatibility and sterilization limits, mechanical dependability, quality control and traceability, patient safety, informed consent, equity and potential legal loopholes. The paper provides an overview of the technical properties of regular polymers in maker spaces, charts the terrain of self-managed biomedical practice, outlines regulatory models relevant to additive manufacturing, and offers a series of effective and ethical advice for makers, clinicians, and policymakers on responsibly applying polymer-based technologies to low-resource healthcare. Setting up minimal material/testing checklists, between makers and clinics relations, local ethical reviews of deployments by do-it-yourself makers, and pathway templates resembling outputs of makers resembling existing regulatory standards are among the key suggestions. (PMC)*

**Keywords:** Bio-medical innovation, DIY, ethics, mechanical dependability, PLA, polymer

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## INTRODUCTION

Biomedical innovation has also evolved due to the increased accessibility and affordability of digital fabrication technologies, particularly in low-resource settings. Consumer versions of fused-filament fabrication (FFF/FDM) 3D printers, desktop stereolithography (SLA) systems, laser cutters and low-cost computer numerical control (CNC) machines are some of the tools that have been relocated out of industrial workshops into community labs, public libraries, and educational makerspaces. The democratization of fabrication has simplified the processes of individuals who have less formal engineering education to experiment with the production of practical biomedical equipment through reduced barriers to access to small-scale production and prototype creation. These tools allow users to rapidly search through the design ideas, to create the prototypes, and to create usable portions without the reliance on

 

centralized manufacturing facilities (they are inexpensive, easy to operate and are compatible with the most popular polymer materials) [1–5].

This technical transition has been accompanied by increased innovation, which is amplified by the appearance of open hardware and online collaboration platforms. Through virtual communities on such sites as GitHub, Thingiverse, and specialized biomedical fabrication forums, users are now able to publish, edit, and exchange design files of various medical adjacent devices. These include orthotic splints, points of the stethoscope, surgical guides, housing of diagnostic devices, prosthetic limbs, and teaching anatomical models. The collaboration between engineers, physicians, patients, and enthusiasts around the world has led to a form of disseminated, social, and community-based biomedical engineering through the refinement of many of these concepts. In other cases, such as the development of cheaply made artificial hands, the communal innovation that these platforms bring about has not only kept pace with business solutions but also improved them and remained free of charge to marginalized individuals [7,16].

This change has significant implications in terms of the effects it has on the environments that have few resources. The traditional biomedical manufacturing often requires specialized equipment, sterile production environments, costly materials and extensive supply chains. Many rural hospitals, community clinics, or missions to the humanitarian field have such infrastructure that is not always available. In such a case, the available polymer fabrication equipment, which is locally available, will offer an alternative channel of producing the required devices [1,3,7]. As an illustration, a community health center that has an FDM printer will have less dependence on external suppliers because it will be able to print a custom splint or a replacement part of the damaged equipment. Maker communities worldwide demonstrated that they were able to fill necessary gaps in supply-chain failures, such as the COVID–19 pandemic by using desktop printing technology to develop face shields, ventilator components, and nasopharyngeal swabs on a large scale.

Despite these benefits, makers of biomedical devices face a variety of challenging technological, legal, and moral concerns in healthcare. Of concern are safety and material excellence. Not all of PLA, PETG, ABS, TPU, and standard resin, which are commonly utilized in consumer fabrication, are medically produced. Mechanical strength, longevity, sterility, and biocompatibility of a device can be significantly affected by a change in print parameters, composition of filaments, or post-processing. To give an example, since FDM prints are built in layers, the pores created during the process are very small and may be a habitat to bacteria, and thus, sterilization becomes harder [1,3,7,16].

Surface roughness, residual monomers in SLA prints or even uneven curing may also pose a risk to devices that are expected to touch skin or mucosal tissue. Another factor is the effectiveness and reliability of the do-it-yourself gadgets. Reproduction is also an issue because the fabrication process of hobbyists is often not as controlled as the fabrication process of industries. A slight alteration in temperature, humidity or quality of the filament could result in two prints produced on the same machine having varied strengths or dimensional accuracy. This discrepancy is a problem when gadgets are to be used in a clinical environment where even minor malfunctions may endanger patient health. More so, even though lots of so-called good groups have open-source ideas, it is not that they are always examined in detail and checked using clinical trials. Without systematic testing, users may accidentally use products that fail to perform or have failed in crucial situations.

Irrespective of their manufacturing, medical equipment is prone to legal regulations aimed at ensuring its effectiveness and safety. The process of desktop fabrication threatens the existing methods of regulations by blurring the line between professional manufacturing and informal production. Organizations such as the U.S. Food and Drug Administration have recognized additive manufacturing as a valid production method, but devices have to follow rigorous specifications in risk classification, documentation, testing, and quality control. The type of traceability, process validation and quality assurance to meet the requirements of regulatory compliance is often lacking in maker-produced products, especially those assembled in non-industrial environments [6,7].

 

These technical and legal challenges are mixed up with ethical issues. The use of biomedical devices produced by makers has raised concerns of informed consent, responsibility, and equity. The patients should be made aware of the risks and limitations when a device is produced outside of the traditional channels of supply. The issue of liability is due to the fact that the clinicians who approve or use them assume responsibilities similar to those of commercial producers. Moreover, although democratized manufacturing can promote fair access, there exists the possibility of the provision of a two-tiered standard, which, in fact, means that poorer groups will receive low-quality equipment simply because it is cheaper or easier to produce [8–16]. Thus, the materials used in maker biomedical scenarios, the structure and objectives of do-it-yourself medical teams, the law concerning additive manufacturing, and the ethical challenges necessary to make innovation responsible are all discussed in the present paper. In this paper, the author tries to offer comprehensive knowledge of the possibilities and constraints of polymer-based biomedical production in low-resource environments through the analysis of these aspects as a whole [8–16].

## BACKGROUND AND LITERATURE REVIEW

### Polymers Commonly Used in Maker Biomedical Fabrication

- *Polylactic acid, or PLA*: is a widely accessible biodegradable filament. For models and non-implantable devices, it is simple to print and has minimal warping. Studies on biocompatibility reveal that surface finish and print parameters affect cell adhesion behavior. PLA is constrained by its limited sterilizability and low glass transition temperature (~60°C). (PMC)
- *PETG (modified polyethylene terephthalate glycol)*: Stronger, more resilient, and more thermally stable than PLA; widely utilized for devices and housings that require vapor or alcohol sterilization. In laboratory studies, PETG exhibits promising mechanical and biocompatibility properties. (ScienceDirect)
- *Thermoplastic Polyurethane, or TPU*: is a flexible filament used for wearable devices, including splints, gaskets, and soft seals. provides flexibility; however, concerns for sterilization are raised by printability and surface porosity. (Online, Taylor & Francis)
- *PEEK, Medical-grade resins, and special polymers*: When greater mechanical/thermal performance and biocompatibility are needed, high-performance engineering polymers (PEEK) and certified biocompatible resins are employed; however, they require industrial printers and regulated processing. (Frontiers)

### What Maker Labs and DIY Medicine Look Like

An empirical mapping of DIY medicine demonstrates that the ecosystem is diverse, encompassing online collaborative design teams, maker laboratories at hospitals to assist in research and surgery planning, hobbyist projects, and community initiatives to meet local concerns. The makerspaces are administered, trained, and handled differently regarding safety. Medical use should be differentiated, and therefore, it goes beyond teaching models and ad hoc equipment in emergencies [8–16].

**Figure 1.** Resin-based 3d printers arranged on a laboratory workstation.
*Source: Phrozen Technology. Resin-based LCD 3D printers in professional laboratory environments. Taipei: Phrozen; c2024 [cited 2026 Jan 8]*

 

### Regulatory Landscape for 3D Printed and Maker-Produced Medical Devices

FDA and regulators treat the 3D printed devices as existing medical devices, and this is regulated by the intended use of the item, the risk level, and the production controls. The FDA has published technical considerations and recommendations on additive manufacturing (AM) with a special emphasis on design control, material characterization, verification of the process, and post-market surveillance. Community-based production, which is decentralized, remains unclear, however, and it takes more specific frameworks that policy observers would insist matchmaker innovators with safety requirements. (U.S. Food and Drug Administration). Figure 1 depicts multiple resin-based (SLA/DLP) 3D printers arranged on a laboratory workstation used for high-precision additive manufacturing, prototyping.

## TECHNICAL CONSIDERATIONS IN LOW-RESOURCE SETTINGS

### Material Selection and Properties

Material selection is one of the most vital concerns in biomedical production based on polymer, more so in low-resource contexts, where the availability of industrial-grade printers, certified medical materials, and specialist polymers is limited. Each of the polymers used in additive manufacturing is reported to offer a unique balance of printability, mechanical behavior, chemical, and thermal resistance, biocompatibility, and environmental resilience. One should understand these traits to ensure the functionality and safety of the final biomedical gadgets [8–16].

The most common polymers used in low-cost maker settings due to their availability, low cost and compatibility with consumer-grade FDM printers are polylactic acid (PLA) and polyethylene terephthalate glycol-modified (PETG). PLA is chosen as it is easy to print, does not warp much, and has a low melting point, thus suitable for prototyping and can be done by a novice. It is, however, not appropriate in high-temperature sterilizing methods such as autoclaving because of the low glass transition temperature (55–60 °C). Also, PLA is brittle with long-term mechanical stress, and even though it is more advantageous to the environment due to its biodegradability, it creates long-term instability when subjected to body heat or moisture [8–16].

PETG, in its turn, offers greater chemical stability, durability, and impact resistance. It is not as easily deformed at comparatively high temperatures, and can resist certain methods of sterilizing better than PLA. However, engineering-grade materials such as PEEK, ABS-M30i, or medical-grade resin are stronger in terms of mechanical and thermal strength compared to PETG. Process validation might also be required before establishing its therapeutic suitability, such as mechanical testing, cytotoxicity testing, and sterilization compatibility testing of devices that are expected to contact skin, withstand physical forces, or operate in hostile environmental conditions.

The surface roughness and porosity of the layer-by-layer deposition method used are significant issues with PLA and PETG, and FDM printing overall. Even fine layer heights can pinpoint microscopic grooves, holes, and imperfect bonding of layers that serve as the site of microbial harborage. Such imperfections complicate hygiene and sterilization in the long term, especially when dealing with those devices that are in physical contact with the skin, mucosa, or open wounds [1,3,7,16]. Due to it, many biomedical applications are based on SLA or industrial processes that produce more isotropic and smooth surfaces, although these technologies are often prohibitively expensive in low-resource settings.

The material choice of maker contexts must thus be a balance between the performance requirement and cost. The most suitable material should be evaluated based on the target clinical performance, expected exposure to the environment, mechanical demands and sterilization constraints instead of being the easiest one to print or the cheapest.

### Sterilization and Infection Control

One of the main obstacles to using polymer-based devices in biomedical practice is sterilization. The sterilization technique must be carefully tailored to the substance because each polymer has unique

 

chemical and thermal tolerances. Steam autoclaving, ethylene oxide (EO) gas treatment, gamma irradiation, and plasma sterilization are examples of conventional medical sterilization techniques that work in environments that can cause certain polymers to deform, deteriorate, or become unstable due to temperature, humidity, radiation, and chemical exposure.

One of the most popular sterilization techniques in clinical settings is autoclaving, which involves subjecting equipment to high-pressure saturated steam at temperatures between 121–134 °C. This heat is too much for many consumer-grade polymers to handle. While PETG softens or warps in an autoclave, PLA undergoes substantial deformation. The only materials that can consistently withstand autoclaving without experiencing mechanical compromise are high-performance materials like PEEK, PEI/Ultem, or specific medical SLA resins. Alternatives include EO gas and gamma irradiation, but they need specialist equipment that is rarely found in rural clinics or community makerspaces [17].

Sterilization choices in the majority of maker environments are restricted to UV-C light exposure or chemical disinfectants (such as alcohol or bleach solutions). For non-critical devices like exterior prosthetic shells, diagnostic housings, or instructional anatomical models, these techniques might be sufficient. They are insufficient, though, for devices that come into contact with sterile tissues, mucosal surfaces, or broken skin. These restrictions make the categorization of device criticality crucial. The commonly used classification system for medical devices is as follows:

- Low-level disinfection is usually sufficient for non-critical equipment that comes into contact with intact skin
- High-level disinfection is necessary for semi-critical equipment that comes into contact with mucosal membranes
- Complete sterilization is necessary for critical devices that enter sterile regions
- Only non-critical devices may be made consistently and safely in low-resource maker environments without extra testing infrastructure or hospital-based sterilizing.
- Therefore, manufacturers, and doctors must evaluate and classify the risk level of any device before it is put into clinical use, taking into account the limitations of the polymer as well as the available sterilization solutions.

**Quality Control and Reproducibility**

Continuous problems in additive manufacturing include reproducibility and quality control (QC), especially in decentralized, low-resource contexts, in which the tools used to fabricate objects, as well as the surrounding environment, vary widely. Consumer-grade technologies, such as FDM (and other types) provide variability in a number of stages of the production process, which, by contrast, is largely homogenized in the case of industrial production, such as in injection molding.

A variety of parameters that are specific to a printer, such as build orientation, layer height, extrusion temperature, nozzle diameter, print speed, and infill density, directly affect the final mechanical properties of a device. An example of that is that the tensile strength and surface nature of a device printed at 0.1 mm layer height will be different from that of a device printed at 0.3 mm. Just to illustrate, an increase or decrease in nozzle diameter changes the nature of surface finish and wall thickness, which in turn affects the durability and sterilization. Other factors that bring unpredictability include printer calibration, moisture absorption, and unbalanced filament batches [25].

These problems can be dealt with by fabrication, reproduction through test prints, documentation of process parameters, and standardized testing (where feasible). Examples of validation in the industrial or research setting include tensile strength testing, flexural testing, cytotoxicity tests and bioburden evaluations. However, such tests are seldom found in low-resource settings.

Simplified QC techniques must therefore be used. These could consist of:

- Calipers are used in dimensional audits to verify printed part correctness
- Leak or pressure checks for parts that handle fluids

 

- Simple mechanical stress testing includes applying known loads to assess failure thresholds or deformation
- Visual examination for under-extrusion, fractures, or layer delamination

By guaranteeing consistency between batches and connecting particular print parameters to device performance, a structured QC checklist can dramatically lower risk. The U.S. Food and Drug Administration's regulatory requirements, which highlight the significance of traceability, process validation, and quality assurance for additively made medical devices, also require this kind of documentation if products are to comply [1].

In the end, repeatability in maker environments depends not just on machine accuracy but also on implementing methodical procedures that transform unofficial fabrication into more dependable biomedical production. Figure 2 depicts a collection of 3D-printed anatomical models, including the brain, skull, heart, spine, and sensory structures, used for medical education, training, and biomedical research.

## CASE EXAMPLES (REPRESENTATIVE)

### Applications of Maker-Based Polymer Fabrication in Biomedical Contexts

Due to the potential to offer affordable, fast, and tailored solutions, polymer-based additive manufacturing has increased in significance in the healthcare sector. There are three critical domains of how makerspaces and community-based fabrication have contributed to modern biomedical practice, which include anatomical modeling and surgical planning, assistive devices and prosthetics, and ad hoc emergency equipment. Each area of implementation has its benefits, limitations, and ethical or legal concerns.

### Anatomical Models and Surgical Planning

The most popular and least risky form of 3D printing in healthcare is the development of anatomical models and surgical planning devices. These models are non-implantable and exterior devices that are developed based on imaging information about the patients, including CT or MRI scans [13] (PMC). They are used to help the surgeons practice the procedures, visualize the complex anatomy, and provide information about the treatment plans to surgical personnel and the patients. Most of the sterility and biocompatibility limits associated with implanted materials are avoided by these devices, as they are never introduced in the body. Therefore, they can be secured using ordinary polymers such as PLA or resin.

**Figure 2.** 3D-Printed anatomical models.
*Source: Mitsouras D, Liacouras P, Imanzadeh A, Giannopoulos AA, Cai T, Kumamaru KK, et al. Medical 3D printing for the radiologist. Radiographics. 2015;35(7):1965–88.*

 

These models have been proven to reduce the operating room time, enhance surgical accuracy and enable better decisions to be made in the operating room. The availability of such models as a result of neighborhood makerspaces could significantly improve preoperative planning in low-resource hospitals without necessarily involving expensive industrial production. They rank as some of the most ethically and clinically feasible uses of polymer-based manufacturing with their low clinical and high operational and instructional utility.

**Assistive Devices and Prosthetics**

Another important field of innovation is community and humanitarian maker projects, which focus on prosthetics and assistive technology. The open-source orthotic braces, mobility aids, finger splints and prosthetic hands have attracted a great deal of attention due to their affordability and customization opportunities. Research in PMC demonstrates that organizations such as e-NABLE have been successful in providing thousands of prosthetic hands, most of them under $50 in materials, compared to thousands in commercial devices, worldwide [3,7].

Most of the external assistive devices are classified as Class I or Class II, depending on their medical claims and mechanical load, as stipulated. Even though the less risky alternative to implanted devices, biomechanical testing, durability, and suitability to the individual are quite essential to successful adoption. The user education must also be considered essential; the recipients should know about limitations, maintenance requirements and precautionary measures of using it. Such devices may be ground-breaking in low-resource regions, particularly with children who grow out of commercial prostheses rather fast, yet they must abide by precautionary measures to avoid injuries or complications [1,16].

**Ad-Hoc Clinical Devices in Emergencies**

The last group is made up of emergency-response devices, which are developed during crises, in this case, the COVID–19 pandemic. According to the Pew Charitable Trusts, it was common to find community-based face mask manufacturing, mask parts, ventilator valves, and diagnostic equipment protective case-making. These quick and improvised attempts showed how powerful decentralization of manufacturing can be in times of supply chain breakdowns. As an illustration, within days, 3D-printed face masks were implemented in healthcare facilities all over the globe, providing the much-needed level of protection to the healthcare staff.

Nevertheless, although these ad-hoc devices will save lives during a crisis, their implementation over a long period needs retrospective validation, regulatory assessment and monitoring. Numerous emergency apparatuses were created under time constraints, and not even fully mechanically tested, sterilized, or clinically tested. With the normalization of supply chains, regulatory bodies increased awareness about the necessity to review these designs based on durability, safety of the material used, as well as medical standards, to ensure its continued use [1,3]. Figure 3 The image depicts a resin-based 3D printer producing a transparent, high-precision prosthetic hand model, highlighting applications in medical prototyping and healthcare manufacturing.

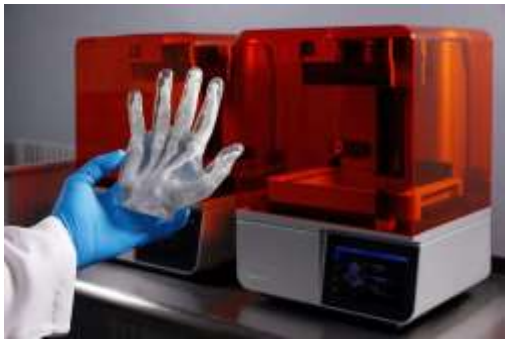

**Figure 3.** 3D printer producing a transparent hand model.
*Source: Rengier F, Mehndiratta A, von Tengg-Kobligk H, Zechmann CM, Unterhinninghofen R, Kauczor HU, et al. 3D printing based on imaging data: review of medical applications. Int J Comput Assist Radiol Surg. 2010;5(4):335–41.*

 

## ENVIRONMENTAL INFERENCES AND SUSTAINABILITY DELIBERATIONS

Though polymer-based biomedical inventions are available and reasonably priced, they also raise noteworthy environmental matters that are often overlooked in low-resource manufacturing ecosystems. While biodegradable resources like PLA are promoted as environmentally friendly, discarding conditions have a significant impact on how well they perform. While discarded PLA may continue in landfills for extended periods of time, adding to long-term polymer waste, industrial composting environments are essential for full degradation.

Noteworthy offcuts, failed prints, support structures, and post-processing remains are shaped by 3D printing processes, conforming to lifecycle analyses. The total environmental impact of additive manufacturing is augmented by these types of waste. Additionally, microplastic shedding can result from frequent motorized wear of printed biomedical devices, particularly those made of PLA, PETG, and TPU. Examples of these devices include splints, prosthetics, and diagnostic housings, etc. When used in healthcare settings, microplastics pose risks of human contact and environmental contamination [17–25].

An additional significant influence is energy consumption. In contrast to the small mass of printed components, additive engineering systems, particularly SLA and engineering-grade FDM printers, have high energy concentrations. This calls into interrogation the notion that low-resource makerspaces are naturally bearable or not. Furthermore, some resins and polymer mixtures need solvents, photoinitiators, and biochemical post-curing, all of which generate dangerous waste that is infrequently handled in informal settings through official biomedical waste trails [17–25].

Sterilization procedures aggravate environmental difficulties. Alcohols, ethylene oxide, and disinfectants based on chlorine are examples of chemical sterilants that crop waste streams that may be improperly inclined in situations with limited resources. Increased disposal rates for single-use or hard-to-sterilize polymer devices upsurge waste production and jeopardize sustainability.

Bio-based polymers, recyclable thermoplastics, and temporary or biodegradable resources that melt after use are some of the potential solutions proposed by emerging research. Plummeting support material, optimizing print orientation, and reprocessing thermoplastic waste are examples of maintainable design philosophies that can further decrease environmental impact [1,3,7,16]. However, there is still a lack of experiential research on the amalgamation of sustainability frameworks into low-resource biomedical fabrication.

## ETHICAL ISSUES

### Patient Safety and Non-Maleficence

The foremost ethical responsibility is to avoid harm. Maker-produced devices must be assessed for foreseeable risks; deploying a device without adequate testing violates professional norms and may harm patients.

### Informed Consent and Transparency

Patients and clinicians using or receiving maker-produced devices must be informed about device provenance, testing status, and potential risks. In low-resource contexts, power imbalances and desperation can complicate consent – heightening ethical obligations to full disclosure.

### Equity and Access

Makerspaces can advance equitable access but may also create two-tier systems: uncertified, rapidly produced local solutions vs. regulated commercial devices. Ethical practice must ensure that lower-cost options are not deployed simply because they are cheap – efficacy and safety must still be demonstrated.

### Accountability and Traceability

Who is accountable if a DIY device fails – the maker, the clinicians who used it, or the institution that hosted the fabrication? Clear documentation, version control of designs, and traceable production logs are essential for assigning responsibility and enabling corrective actions.

 

### Intellectual Property and Open Hardware

Open designs accelerate innovation, but improper use of proprietary designs or a lack of appropriate licensing can raise legal/ethical concerns. Ethical open hardware practices include clear licensing, attribution, and community governance.

## PRACTICAL GOVERNANCE AND IMPLEMENTATION RECOMMENDATIONS

### For Makerspaces and Community Labs

1. *Device classification checklist*: Adopt a simple triage: educational/visual models (low risk), external assistive devices (medium risk), and devices contacting sterile tissue (high risk). Only produce according to the lab's capability and governance
2. *Minimum material and process disclosure*: All prints must include a QR tag or label noting material (brand/batch), print settings (layer height, nozzle), post-processing and sterilization method. This improves traceability
3. *Local testing protocols*: Implement affordable QC checks: dimensional measurement, basic mechanical testing (e.g., load until deformation using weights), and microbial swabbing for devices with skin contact. Use partner labs for cytotoxicity testing when required. (U.S. Food and Drug Administration)

### For Clinicians and Hospitals Partnering with Makers

1. *Formal partnership agreements*: Define roles, responsibilities, and liability. Ensure clinical oversight and informed consent when devices are used on patients.
2. *Clinical risk review board*: A rapid-response review process (akin to hospital IRBs but streamlined) to vet emergent maker-developed devices before clinical use. (PMC)

### For Policymakers and Regulators

1. *Regulatory clarity for decentralized production*: Regulators should publish accessible guidance tailored to hospital and community labs, clarifying when existing device rules apply and what minimal data are needed for low-risk devices. The FDA's technical considerations are a useful template. (U.S. Food and Drug Administration)
2. *Support capacity building*: Fund regional test centers that community makers can use for material characterization and basic biocompatibility testing.

## ETHICS-CENTERED CHECKLIST FOR RESPONSIBLE DEPLOYMENT

The creation of biomedical devices produced by makers should be safely developed through a structured workflow, particularly in low-resource settings. The initial one is defining what the intended use and risk class will be, as the level of scrutiny will depend on the level of device functionality. A non-critical external aid only requires significantly less validation as opposed to a semi-critical or critical device, which has contact with mucosal surfaces or sterile tissues [7,16]. After defining risk, makers are then expected to choose polymer materials whose mechanical, thermal, and biocompatibility characteristics are well documented, and to explicitly highlight sterilization contraindications – such as PLA distending when subjected to autoclave heat or resin prints being sensitive to particular solvents.

Production traceability is essential to hold individuals accountable and make all their decisions reproducible. This involves the creation of version numbers of the design files, filament or resin batch numbers, printer settings and environmental conditions. In addition to documentation, makers are expected to carry out baseline mechanical and microbial tests that are based on the risk profile of the device. Preliminary failures can be detected by simple load tests, dimensional tests, and surface cleanliness tests.

Any device that is meant to interact with a patient should be clinically supervised and informed consent taken, such that the users are aware of the experimental nature of the device as well as its restrictions. Last but not least, a transparency culture is essential: the makers are expected to document the performance, share negative experiences, and communicate discoveries publicly, thus contributing to the overall knowledge base and improving safety levels among the world maker-health community.

 

## LIMITATIONS AND RESEARCH NEEDS

There is limited empirical evidence on the long-term performance, sterilizability, and biocompatibility of consumer-grade polymer prints printed out of the industrial context; however, this has been noted as the key to the safe deployment of maker-based biomedical devices. The majority of the literature deals with simple mechanical characteristics of typical materials like PLA, PETG, and TPU, but such studies do not reflect the entire variation that is posed by different, decentralized printing conditions. Low-resource maker labs may not be climate-controlled, lack standardized calibration equipment, or certified post-processing equipment, such that the adhesion of layers, porosity, chemical residues or microstructural defects may vary dramatically between prints printed on the same machine. The direct impact of these inconsistencies is durability, load-bearing capability and microcrack vulnerability, which is of particular concern to the prosthetic parts, splints, and repeated-use assistive devices [3,7,16].

Another yet to be discovered empirical area is sterilizability. Some initial evidence indicates that a significant part of consumer-grade FDM prints have not been decontaminated of microorganisms despite being subjected to standard disinfectants, in large part because of the roughness of the surface and internal porosity that is hallmark with layered deposition. Autoclaving is also an extremely efficient method, but it cannot be used in low-melting polymers like PLA; high-frequency cycles in the autoclave may lead to warping, softening of mechanical strength or degradation. Research on other technologies, such as UV irradiation, chemical disinfectants, and low-temperature plasma, suggests a possible viable option in non-critical equipment, but also shows that penetration is unreliable into micro-surfaces [1,3,7,16]. There is a severe lack of comparative studies between different brands of filaments, but maximum needs: additives to color, strength, or flexibility can have an effect on heat toleration and compatibility with other chemicals, changing sterilization results. Moreover, biocompatibility assays have not been adequate beyond industrial manufacturing. There is a necessity of cytotoxicity tests, leachate tests, and skin compatibility tests to determine whether household-grade filaments have residual monomers, plasticizers or pigments that are dangerous when applied to human tissue or adjacent to it [16].

In addition to technical inquiries, policy research is required to explore the wider regulatory issues and ethical issues of decentralized biomedical manufacturing. The conventional medical device management approach presupposes centralized manufacturing, supply chains, and approved procedures; maker-based settings challenge this presupposition [17–25]. In the case of production by volunteer makers, open-source designs, or distributed fabrication networks, liability models in terms of injuries or machine failure are not clear. Is it the designer, the print operator, the health institution that granted usage, or the patient who decided to use the device, that is to blame? These questions are further complicated by the low-resource contexts where improvisation may be a necessity and not a choice [1,3]. The policymakers should thus take into consideration adaptable but secure models, which would enable innovation but create minimum standards in documentation, testing, and disclosure of risk. The creation of community-friendly standards, such as lightweight QC guidelines, reduced labeling conditions, and joint liability, can be used to ease the transition between grassroots manufacturing and patient safety [1,3,7,16].

## CONCLUSION

Maker labs have introduced polymer-based production as a strong facilitator of low-resource biomedical innovation. These community spaces enable clinicians and engineers to collaborate on quick and inexpensive prototyping and making of solutions specific to a particular context, such as anatomical models to train on, assistive technologies to benefit patients, or emergency equipment when stocked out. Extremely fast iteration allows designs to be developed through real clinical feedback, bypassing slow traditional manufacturing processes and the reliance on centralized supply chains.

Nevertheless, the potential of polymers has to be anchored on the scientific and ethical limitations of the polymers. The choice of materials directly influences the safety of the device, its durability and possibility of sterilization; cheap polymers such as PLA and PETG exist but are not necessarily

 

clinically resilient [6,7]. In like manner, inconsistency in the 3D printing operations may jeopardize reproducibility, which cannot be afforded in healthcare. Devices containing minimal quality controls can fail under load, wear during usage or can contain microbial contamination.

In order to overcome the gap, maker communities require governance systems that focus on patient safety without stifling grassroots innovation. An ethical ecosystem can be developed with alliances between maker laboratories and medical organizations, standard documents, context-sensitive testing, and more well-defined regulatory routes, particularly for low-risk devices. Under these measures, the textile cropping made out of polymer can grow, responsible for increasing opportunities to reach biomedical devices in places where they are required [16,17].

## REFERENCES

1. Ornaghi HL Jr, Monticeli FM, Agnol LD. A review on polymers for biomedical applications on hard and soft tissues and prosthetic limbs. Polymers (Basel). 2023;15(19):4034.
2. Bhise MG, Patel L, Patel K. 3D printed medical devices: regulatory standards and technological advancements in the USA, Canada and Singapore—a cross-national study. Int J Pharm Investig. 2024;14(3):e-pub.
3. Wexler A. Mapping the landscape of do-it-yourself medicine. Citizen Sci Theory Pract**.** 2022;7(1):38.
4. Shilov SY, Rozhkova YA, Markova LN, Tashkinov MA, Vindokurov IV, Silberschmidt VV. Biocompatibility of 3D-printed PLA, PEEK and PETG: adhesion of bone marrow and peritoneal lavage cells. Polymers (Basel)**.** 2022;14(19):3958.
5. U.S. Food and Drug Administration. *Technical considerations for additive manufactured medical devices: guidance for industry and Food and Drug Administration staff* [Internet]. Silver Spring (MD): U.S. Food and Drug Administration; 2018 [cited 2026 Jan 3]. Available from: FDA website.
6. Kurowiak J, Klekiel T, Będziński R. Biodegradable polymers in biomedical applications: a review—developments, perspectives and future challenges. Int J Mol Sci**.** 2023;24(23):16952.
7. Rimmer M. Open prosthetics: intellectual property, 3D printing, medical innovation, and sustainable development. In: Dinwoodie GB, editor. *The Elgar companion to intellectual property and the Sustainable Development Goals*. Cheltenham: Edward Elgar Publishing; 2024. p. 323–349.
8. Lantada AD, De Maria C. Sustainable open-source medical devices manufactured with green biomaterials and accessible resources. Curr Opin Biomed Eng. 2023;28:100500.
9. Deman AL, Guijt RM, Odhiambo CO, Ndlovu Z, Kersaudy-Kerhoas M. Part of the problem or part of the solution? An interdisciplinary action call for more research on the environmental sustainability of lab-on-a-chip and point-of-care devices. Front Lab Chip Technol**.** 2024;3:1530449.
10. Batet D, Gabriel G. Green electrochemical point-of-care devices: transient materials and sustainable fabrication methods. ChemSusChem**.** 2025;18(7):e202401101.
11. Sengupta J. Natural biodegradable polymers transforming lab-on-a-chip technology: a mini review. Green Anal Chem. 2024;10:100119.
12. Zhu Y, Guo S, Ravichandran D, Ramanathan A, Sobczak MT, Sacco AF, et al. 3D-printed polymeric biomaterials for health applications. Adv Health Mater. 2025;14(1):2402571.
13. Yang CY, Kuan CM, Yeh JA, Cheng CM. Fabricating millimeter-scale polymeric structures for biomedical applications via a combination of UV-activated materials and daily-use tools. RSC Adv**.** 2014;4(24):12538–12544.
14. Mohd Asri MA, Nordin AN, Ramli N. Low-cost and cleanroom-free prototyping of microfluidic and electrochemical biosensors: techniques in fabrication and bioconjugation. Biomicrofluidics**.** 2021;15(6):e-pub.
15. Shin JH, Choi S. Open-source and do-it-yourself microfluidics. Sens Actuators B Chem. 2021;347:130624.
16. Garciamendez-Mijares CE, Agrawal P, García Martínez G, Cervantes Juarez E, Zhang YS. State-of-the-art affordable bioprinters: a guide for the DIY community. Appl Phys Rev**.** 2021;8(3):031403.

 

17. Knapper J, Whiteford F, Rosen D, Wadsworth W, Stirling J, Mkindi C, et al. Developing the OpenFlexure Microscope towards medical use: technical and social challenges of developing globally accessible hardware for healthcare. Philos Trans A Math Phys Eng Sci**.** 2024;382(2274):20230257.
18. Brewster RC, Wu A, Carroll RW. Open source approaches for pediatric global health technologies. J Med Eng Technol**.** 2023;47(8):371–375.
19. Bow JK, Gallup N, Sadat SA, Pearce JM. Open source surgical fracture table for digitally distributed manufacturing. PLoS One**.** 2022;17(7):e0270328.
20. Ibrahim YS, et al. Biodegradable polymers and their biomedical applications. Molecules**.** 2020;25(23):5579. doi:10.3390/molecules25235579
21. Hany A, et al. Advances in polymer-based additive manufacturing for medical devices. Ain Shams Eng J**.** 2024;102759. doi:10.1016/j.asej.2024.102759
22. Smith J, et al. Biomedical polymers for low-cost medical devices. J Biomater Appl. 2024;Epub ahead of print. doi:10.1177/07316844241238507
23. Zhang L, et al. Sustainable polymer systems for medical innovations. BioResources**.** 2024;19(2):2353–2370. doi:10.15376/biores.19.2.2353-2370
24. Chen H, et al. Eco-friendly biopolymers for biomedical prototyping. BioResources**.** 2025;20(2):698–724. doi:10.15376/biores.20.2.698-724
25. Rao A, et al. Performance of medical-grade vinyl polymers in additive manufacturing. J Vinyl Addit Technol. 2024;Epub ahead of print. doi:10.1002/vnl.22167

 