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Institutional Frictions and Optimization Pathways of Class III AI-Powered Medical Devices in China: An Analysis Based on the Multiple Streams Framework

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Abstract. Currently, the article discusses the reasons why the clinical implementation of Class III artificial intelligence (AI) medical devices in China is limited, regardless of the accelerating technology and robust policy endorsement via programs such as the Healthy China 2030. Beyond technology and risk-based studies, the paper utilizes Kingdon's Multiple Streams Framework (MSF) to determine how the lack of alignment across these three streams of the problem, policy, and political core has resulted in institutional wrangles that have remained. Using regulatory documents, secondary data, and policy evidence, the analysis can pinpoint three linked causes of friction: lengthy and mismatched regulatory approval processes, hospital system mismatch of capacity and responsibility, and the unresolved reimbursement/trust gap at the patient level. Such obstacles are reflections of institutional stalemateness, and not outdated technology, where current regulatory and payment strategies are ill-equipped to respond flexibly and data-driven AI applications. To resolve this misalignment, the paper compares two policy courses, including a market-led adaptive model and a model of rule-based governance, and suggests a step-by-step reform agenda involving the use of regulatory sandboxes, nationally standardized reimbursement, centralized data and reporting, etc. This strategy aims at compensating the innovation incentive, equity, and system persistence by balancing short-term experimentation with long-term institutional coordination. The research paper can add to the literature as it generalizes on the use of MSF and its use in technology governance and provides practical policy recommendations to enhance regulatory consistency and promote the seamless introduction of AI-driven medical devices in China.

Keywords: Artificial Intelligence, Medical Device Regulation, Institutional Frictions, Multiple Streams Framework, Health Policy Reform.

1. Introduction

The incorporation of AI in medical equipment is a game-changer in the medical field across the world, having significant benefits in the precision of diagnosis, workflow speed, and clinical results [1,2]. The given transformation in China is more closely tied to the pillars of national development, like Healthy China 2030 and Digital China, which introduce AI-enabled medical technologies, as

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one of the pillars of future modernization of the health system [3]. The current studies on medical devices based on AI have been mainly centered on technical empowerment, such as the work of the algorithm, the safety analysis, and clinical testing. The focus on the risk-oriented regulatory practices, based on quality management and ethical protection, is also presented in these studies [2,4]. Although such views are fundamental, they tend to favor too little the influential role policy institutions play in the processes of relocating AI innovations between laboratory development and routine clinical use. As practice reveals, institutional elements (such as the disjointed regulation processes, missing administrative capacities, and the ambiguous nature of reimbursement mechanisms) have been identified as the key bottlenecks that inhibit the AI-based Class III medical devices development [3,5]. The existence of this gap in the literature preconditions the necessity of a policy-based analysis. To fulfill this requirement, this paper analyses institutional friction using Kingdon MSF, which is a policy model that best fits the analysis of the converging process of problems, policy solutions, and political conditions to facilitate or obstruct regulatory reform [6].

To find out why these obstacles exist and how they should be addressed, a technical analysis of policy alternatives is not enough. Current research on AI-driven medical devices still focuses on technological advancement, clinical trials, or risk assessment instrumentation, and comparatively lower attention to the institutional opposition within the Chinese policy process [7,8]. These frictions, which cut across regulatory processes, administrative capabilities, and reimbursement systems, cannot be wholly attributed to a technical or clinical point of view [5]. This gap is what inspires the main research question of the paper, that is, how policy institutions are shaping the development course of AI-based Class III medical devices, and why are there still regulatory and adoption barriers in place even in the mature technologies? In answering this question, this paper will carry out an analysis of the dynamics at play using MSF by John Kingdon [6].

The MSF can be a reasonable analytical tool since it is a framework that describes the interaction of problem recognition, policy options, as well as political circumstances to either open or limit the possibility of policy change [6]. It emphasizes the capacity in which alignment of the problem, policy, and political streams may create a policy window, which makes institutional reform possible. The paradigm assumes that huge policy change happens when these three independent streams intersect: the problem stream, where the conditions are framed as urgent problems; the policy stream, where the expertise communities make visible feasible solutions; and the political stream, where the national mood, administration priorities, and stakeholder interests make the country open to change. This paper holds that AI medical device reform in China is beginning to create its window of opportunity. It is also the case that the issue line is escalating, according to the lack of timely regulation and impediments to adoption [7,9]. A workable policy stream has emerged, and it provides rival but more and more specified options on how to incorporate AI into clinical practice [2,8]. In the meantime, the political stream is exceedingly amenable because it is conditioned by the strategic mandates with the emphasis on digital health and AI [3]. The difficult part of the policymaker task lies in being effective policy entrepreneurs, putting these streams together strategically to promote sustainable institutional change. Using the MSF, the analysis below initially diagnoses the main institutional issues, then evaluates the available policy options, and lastly offers a staged coupling approach to use the current policy window and develop a plausible, fair, and sustainable AI medical ecosystem in China.

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2. Problem identification: institutional frictions in China's AI-powered class III medical devices

2.1. Regulatory approval: long timelines and inconsistent standards

Delays in regulatory approvals have become a key institutional bottleneck preventing the development and clinical adoption of AI-based Class III medical devices in China. There is a great level of uncertainty in timetables of approval, because firms wanting to enter the market are uncertain about their entry, as it may take a long time, be unpredictable, and not entirely applied in every region [9].

One of the fundamental roots of such delays could be related to the fact that the existing system of medical device scrutiny is still used to assess AI-enabled technologies. Current data regulation practices focus on archived documentation and comprehensive clinical trial data, whereas dataset updates and post-market learning are fundamental to the AI-based products. This process mismatch constrains regulatory flexibility and makes approval procedures of high-risk AI medical devices slow [2]. Even though in 2014 the National Medical Products Administration (NMPA) began to propose a special review pathway to innovative medical devices, the national level data indicate that the mechanism has not always provided a reduction in turnaround times of the process of the AI-enabled products approval system [9]. The differences in administrative capacities, practices in review, and policy interpretations across local authorities further enhance the regulatory friction effects and create dissimilar results on approvals [3].

The data on national registration depict how this structural bottleneck has been maintained. The average Class III medical device approval time refers to 2024 Annual Report on Medical Device Registration published by the Center of Medical Device Evaluation showed that the average increasing period of the Class III medical device approval was 9.4 months in 2015, then slightly decreased to 32.4 months in 2022, and further reduced to 30.2 months in 2024 [9]. These patterns suggest that approval conclusions of high-risk medical technologies are still being determined by institutional limitations and not by changeable administrative backlogs.

These inconsistencies in regulation impede national policy coordination and demoralize innovation. Whereas AI medicalism has been officially acknowledged as one of the strategic development fields, the absence of coherent duties, ineffective regulatory interfaces, and inconsistent documentation requirements deters companies from engaging in innovative AI products, especially in non-insular and less-developed areas [3]. Subsequently, regulatory uncertainty impedes investment incentives, restricting the national proliferation of AI-driven medical equipment, even as the level of technological maturity increases.

2.2. Hospital adoption: capacity mismatches and unclear responsibilities

Although AI-powered medical devices have already passed the regulatory assessment, their adoption is still low in Chinese hospitals due to the absence of clinical willingness and institutional capacity. Despite this, despite the growing significance of AI-aided tools among medical workers, most of them, especially primary care hospitals, do not have the technical infrastructure and organisational preparedness to implement AI systems into the daily clinical workflow [7,8].

One of the main sources of tension is the lack of underlying digital infrastructure. Many healthcare organizations do not have standardized electronic medical records (EMRs), organized imaging repositories, and non-interoperable information systems, which are the conditions for the implementation of AI-assisted diagnostics on a large scale. Such infrastructural issues indicate the

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capacity limits of execution on the informational management of hospitals and restrict the feasibility of AI tools [8]. Challenges to the adoption are further augmented due to human capital constraints. Evidence gathered through surveys reveals that although most general practitioners demonstrate the readiness to embrace AI technologies, an impressive number of them confirm that they do not have the appropriate skills and knowledge to work with such systems on their own [10]. On the same note, an in-depth review of physicians and medical students reveals that there is a consistent debate about reliability, interpretability, and ethical ambiguity, and that there is an imbalance between technological complexity and clinical competence at the frontline [1].

Hospital uptake is also limited by structural-level barriers. There is no well-presented national framework that outlines liability in the process of AI-assisted clinical decision-making, which leaves a gap of uncertainty in terms of the possible allocation of responsibility in a scenario of diagnostic error. This institutional uncertainty promotes risk-averse behaviour and makes clinicians less inclined to use AI tools in their practices [2,4]. Institutional hesitation is compounded further through financial mechanisms. Even though Diagnosis-Related Group (DRG) and Diagnosis-Intervention Payment (DIP) reforms have been introduced on the national level, current payment systems have not yet created stable reimbursement models of AI-assisted diagnostic services, which restrict the possibility of hospitals to reimburse deployment and operational costs [5,11,12].

These are the operational implications of these institutional frictions. Lack of foreseeable reimbursement and constant needs to maintain and update a system also add to the financial uncertainty of hospital administrators, which will deter investing in expensive AI technologies with unknown returns [5]. In this scenario, the frontline adoption is limited and reduces the potential of AI-based medical devices to enhance diagnostic efficiency and patient outcomes, even in cases where they are shown to have clinical potential [7,8].

2.3. Patient payment and trust: gaps in reimbursement and understanding

At the patient level, insufficient insurance coverage and lack of confidence in AI-assisted care are one of the worst challenges to the dissemination of AI-powered medical devices. Currently, the services of AI-enabled diagnostics are not widely covered by the lists of reimbursement provided by the National Healthcare Security Administration (NHSA), meaning that hospitals have to use out-of-pocket pharmacological care payments made by the patient [12]. This model of payment is especially relevant to the case of AI diagnostics based on imaging, as the patient in question has to spend more money, yet the benefits of this type of clinical intervention are not that obvious. It consequently leads to the unequal provision of services based on AI assistance, which undercuts equity and impedes its rapid adoption [5].

This lack of trust is caused by many factors that are interrelated. To begin with, the lack of insurance cover will have a direct deterrent effect on the uptake rates of patients: it will add to the financial burden and predispose feelings about the perceived exposure to risk when using new technologies [11]. Second, there are legal and institutional uncertainties regarding who needs to be responsible for AI-led clinical decisions, which undermines trust in them. The survey data show that despite most physicians being willing to use AIs in clinical practice, significant percentages assert an ethical issue and perplexity about legal responsibility in case of diagnostic error [1,10]. This type of ambivalence among clinicians is most likely to be transferred to patients in the course of the consultation and justify a distrust of AI-generated results.

Moreover, people do not fully understand AI medical technologies. Most patients already view AI systems as black boxes, and until the mechanisms explaining why AI aids but does not substitute professional judgment are explicitly provided, people cannot be convinced. This is especially acute

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in the primary and community healthcare environment, where institutional control tools and digital literacy are relatively less developed [4].

The combination of these two dynamics creates a two-way structural friction between providers and patients. Reduced patient trust will also stifle utilization, whereas hesitant adoption by physicians will also indicate doubt, making interactions more bureaucratic and arduous, and understanding the informed consent and responsibility assignment. The lack of precise reimbursement procedures and organizational tools to promote transparency and accountability will curtail patient acceptance and the fair and sustainable implementation of AI-driven medical equipment in China [4,5].

3. Policy alternatives: how to optimise policies for AI-powered class III medical devices in China

3.1. Alternative 1: market-led adaptive pathway

The intention of this route is to lessen existing institutional obstacles to enable local markets to become the first to roll out AI-driven medical devices, although a limited supervisory role of the central authority remains to oversee the systemic risk. The basic rationale is to make innovation take place in actual clinical settings first, and then to stockpile countrywide standards of regulation by experience on a pilot-town basis. This is especially the benefit of such a course where the technological capability is surpassed by the clinical requirement, and jointly approved rules are not yet developed [6].

Governance-wise, such a model enables areas that have greater administrative capacity and digital infrastructure to test in conditional regulatory settings. Elaborated localities can allow partial clinical application of AI medical devices, providing approved safety profiles with continued post-market data reporting and control. The developers would be obliged to provide periodical real-world performance and safety information to the assigned regulatory platforms, thus allowing the regulators to monitor the functionality of such technologies in practice and refine the mechanisms of oversight. In the research on international health governance, adaptive and data-driven technologies like medical AI are highlighted as a vital part of regulation only through learning-oriented post-deployment monitoring [2,8].

In an attempt to deal with uncertainty in approval processes, the given route focuses on procedural clarity as opposed to regulatory slackness. The release of short, publicly available approval guidance that clarifies the required documentation, estimated timeframes, and consultation options can easily lower barriers to entry of small firms and provide incentives to comply without raising the risk that this area will be more heavily regulated [3]. Moreover, another mechanism of differentiated oversight of algorithm updates can be implemented. Minor changes, like changes of interface, can be the object of record keeping only; intermediate alterations, like retraining on local datasets, may be expedited in their revision, and large-scale model redesign still will have to undergo a thorough reassessment. These forms of algorithm governance on a tiered basis have been widely discussed as a perceived requirement of dealing with the iterative quality of AI systems in the medical field [2].

This adaptive pathway might also include payment experimentation. Early-stage gaps in reimbursement can be countered by temporary recognition of service using AI-assisted clinical work, the situations where eventual final decision-making still lies under the jurisdiction of physicians. The current literature on AI financing points to the observation that transitional payment

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schemes and outcome-based contracts can minimize the level of financial risk to hospitals, as well as stop the over-exploitation of immature technologies [4,11].

The acceptance of the clinicians is one of the key aspects of success. The literature invariably demonstrates that the issues of explainability, responsibility, and professional accountability have a close connection with resistance to AI tools [1]. The need to have AI systems generate interpretable products, and the foreseeable requirement of assessing the clinical application by physicians explicitly, can create a clear audit trail and enforce the idea that AI is a decision support and not a decision maker. Simplified standard operating procedures and supplementary training at deployment can also be used to minimize perceived risk without creating too much administrative burden [4].

This market-based pathway of adaptation is not meant to substitute national regulation. Instead, it is a bridging process of evidence creation and institutional learning. When a sufficient amount of data and working experience is gathered, standardized national rules, documentation templates, and centralized governance of data can be easily created by policymakers. Politically, this decentralized experimentation model correlates with China traditionally operating with pilot reforms being centrally directed, which makes it a viable policy to follow in moving AI medical devices governance to established institutional settings [3,6].

3.2. Alternative 2: public-good-centered pathway

The other policy alternative theory would be to imagine AI-enabled medical services as a common good and approach it as a similar mechanism to managing other types of critical health infrastructure. AI diagnostic tools have the same data as they are characterized by non-rivalry and increasing returns to scale, as they can be defined when many institutions share access to and data. These characteristics render AI medical services especially appropriate to be publicly invested in, be centrally coordinated, and plan over large periods of time [4].

Under this route, the central consideration of AI in health care would be a central body of control, instead of the divided approach to evaluation in regions, a national system. The requirements of such a body can include the standardization of requirements on updates to algorithms, the minimum requirement levels on explainability, and a clear range of categories involving risk associated with clinical use. This type of centralized governance is often proposed for variants of operating complex, adaptive technologies because it promotes more uniformity, legal orientation, and responsibility across jurisdictions [2].

The second pillar of this strategy is payment reform. Instead of the temporary or local reimbursement arrangements being used, the specific AI-supported clinical services may be allocated nationally recognized reimbursement codes. Current academic literature on AI funds points to stable, publicly determined payment models as a key to sustaining its use and avoiding injustices associated with the capacity of hospitals to pay out of pocket [4,11]. When terms of reimbursement have been standardized, centralized purchasing or pooled contracting arrangements can lead to lower average costs and encourage more equal access across regions.

Another fundamental element of the channel, based on the idea of the public good, is a national data-sharing platform. Such a platform would fill the current fragmentation in the collection of usage, safety, and outcome data by combining national data on hospitals to facilitate continuous monitoring of performance. Notably, centralized data governance has the potential to minimize algorithmic bias through the training and testing of AI systems on representative patient groups, instead of the use of small or sourced data [2]. Equitywise, smaller and rural hospitals should be allowed to use AI software and essential digital devices by the government so they experience the

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same level of diagnostic opportunities as big cities and reduce inequalities in the quality of care they provide [4].

Initial implementation can be restricted to a few national demonstration hospitals to deal with Implementation risks. These locations will be able to pilot training procedures, explain legal obligations, and evaluate how to reconcile workflows under conditions of real-world conditions. Health system research evidence indicates that such learning hubs are important in helping to transform the centralized policy designs into operationally viable models that can subsequently be applied system-wide [8].

This centralized approach to governance is a political approach that represents the logic of governance that places priority on long-term capacity building, coordination, and stability. It will need more initial investment and increased administrative congruence, but has higher prospects of equity, institutional integrity, and public confidence in the long term. In the context of Kingdon, this choice is one of the possible policy choices whose purpose is explicitly an integrate a system-wide wide, and it stands the best chances of spreading when there is a high political goodwill towards equity and national homogeneity [6].

3.3. Practical conditions and evaluation framework for the regulatory reform of AI medical devices

The prevailing Chinese political climate offers an excellent background to the promotion of regulatory change with regard to AI-powered medical equipment. On the national level, AI and digital healthcare have been established as strategic priorities as part of larger state-driven modernization strategies, increasing the political credibility of projects to revise the policy of controlling medical devices. Top-down signaling is an important element of the political stream because it makes administration actors more receptive to an institutional change, and it makes them less resistant to experimentation [6].

The stakeholder level is tending to become more mutually focused on important groups. Medical AI is perceived as an addition to the local governments in economically developed areas, as an increase in the quality of local services, as well as a trend in the upgrading of industries and the development of incentives to underpin regulatory pilots and bits of implementation programs. The medical AI companies that are experiencing longer approval periods with no guarantee of reimbursement have solid reasons to implement more transparent and foreseeable regulatory frameworks. As of now, large public hospitals, though slowly adopting the AI tools, have begun to appreciate the opportunities that can be presented by the AI tools in terms of reducing workforce shortages, enhancing efficiency in diagnosis, and aiding system-wide learning. This convergence of regulators, providers, and firms is proposed to be a necessary condition to achieve successful policy reforms in technologically sophisticated areas based on prior studies about the medical device industry in China [3,8].

The perceptions of AI by the public in health care are mixed. Although AI technologies are traditionally linked to the availability increase and the possibility of decreasing the inequality in diagnostic potential, the issues of data protection, algorithm error, and accountability remain. Perception research has shown that the lack of trust in AI-based care may be caused by uncertainty regarding responsibility and transparency [1,4]. This conflict underlines the argument for government action because there is a need to have more institutional protection to carefully reconcile innovation and societal trust.

Combined, these political situations indicate that a window on policy is open at present. The MSF also suggests that policy change is feasible when there is congruence between problem recognition,

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feasible policy options, and political receptivity [6]. The current situation is one of institutional frictions of approval, adoption, and payment process, clearly documented, as well as two policy alternatives and a favorable political environment. It is in this context that the section below compares the adaptive pathway that is market-led and the one that focuses on the public good, bearing in mind that they contribute to the feasibility, equity, and long-term sustainability that can be applied to lead a balanced reformative approach to the management of AI medical devices in China.

3.3.1. Establishing evaluation criteria and weights

In order to rank the viability and attractiveness of the two policy options that have been proposed, five evaluation criteria have been picked, i.e., regulatory feasibility, implementation costs, innovation effects, equity in access, and long-term sustainability. Such criteria are widely applied when analyzing the issue of health technology governance and indicate basic issues related to the regulation and implementation of AI-controlled systems in medicine [2,8].

Previously existing studies about healthcare regulation, innovation management, and ethical regulation were used to weight the criteria of this research instead of a specific policy document. Literature on the topic of innovation in the public sector underscores that the condition of regulatory feasibility is a major factor influencing the success of a policy in technologically demanding areas because overambitious designs tend to collapse on the implementation stage [3,6]. It was also found that equity in access was valued since the use of digital health technologies has been associated with widespread worries that, over the long term, these applications may contribute to the widening of disparities in case the primary impetus behind their diffusion is market-oriented [4].

The iterative and adaptive characteristics of AI systems gave massive importance to long-term sustainability. The study of AI governance continually emphasizes the significance of lifecycle management, ongoing performance evaluation, and institutional ability to adjust regulatory regulations as time passes [2,8]. Impact on innovation was added because it is necessary to capture the incentives of developers and the necessity to have technological dynamism, especially in the emerging sectors where regulatory inflexibility can discourage investment and experimentation [3].

The lowest criterion of weight was on the implementation cost. The current literature indicates that financial aspects can play a crucial role but usually cannot dominate political viability and institutional fit at an initial stage of implementing public-interest technologies into healthcare systems [4,11].

Collectively, this weighting plan represents a tradeoff between normative priorities (that include equity and accountability) and pragmatic limitations like governance capacity and dynamics of innovation. The resulting multi-criteria model also gives a structured platform on which the two policy pathways can be compared in consistency with the theoretical understanding as well as the empirical evidence, as given in AI healthcare literature.

3.3.2. Coupling the streams: projecting outcomes and confronting trade-offs

The difference between these two models is not just on the grounds of strategy, but what each is losing in the process of attaining its objectives (as represented in Table 1). The fundamental trade-off is the speed versus structure, flexibility versus equity, and short versus long-term functionality.

Market-Oriented approach supports hasty roll-out utilizing sandbox pilot and localized approvals. It is targeted at companies and urban hospitals that are interested in quick deployment and a pay-off. However, there is a price to this speed, which is the lack of uniform implementation and compliance inconsistencies between regulations. Standards may vary between the provinces, and the rural

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hospitals may remain trailing, further supporting the status quo of imbalance. Conversely, the Public-Good model provides structural consistency in the form of centralizing reimbursement, regulatory control, and data control. It focuses on equity and sustainability, especially in under-resourced regions. However, it takes a long setup, necessitates high administrative coordination, and might slow down innovation. In the case of new entrants or small providers, such delays might translate to loss of competitive advantage.

These tensions are manifested in the stakeholder preferences. The Market model is also oriented towards enterprises and advanced hospitals because of its clarity of operations. The Public-Good tendency is more oriented towards central regulators and the regional governments, which are interested in equity and national integration. Appearing timeline is also important: the Market model provides observable benefits within 1-2 years, yet has the risk of fragmentation in the future, whereas the Public-Good model offers systemic capacity within 3-5 years, but may not deliver as well in the area of uptake and momentum of innovations.

Table 1. Pathway choice: the trade-off between innovation velocity and system stability

Evaluation Criteria	Market-Led Pathway (Couples with Speed)	Public-Good Pathway (Couples with Stability)
Regulatory feasibility	Materials high on innovation centers; materials low on underdeveloped economies because of local disparities in capacity.	Assured, but on average, country-wide; requiring coordination ability in the centre.
Equity	Low. Advantages are enjoyed by the hospitals and provinces that are better-resourced.	High. The system was created to minimize the differences by merging procurement and national planning.
Extensive sustainability	Moderate. Relies on local implementation; can have a divided approach to it.	High. Establishes centralized infrastructure and governance ability of lifecycle.
Impact on innovation	High. Promotes effective trial and error and learning on the job.	Moderate. The slower feedback loops can dishearten such a quick iteration.
Cost to implement	Less costs to central government in the short term but variable cost to the localities.	Increased initially cost to the public, but increased long-term cost discipline.

3.3.3. Project the outcomes

Comparing the two policy options, the analysis first concentrates on the effectiveness and equity dimensions, where it is possible to observe the most quantitative outcomes, and policy relevance is at its maximum.

The Market-Oriented model will probably bring in quicker and more noticeable advantages in the segmentation of regulatory delays and enhance clinical adoption. In this case, pilot regions would be allowed to make sandbox approvals, graded update mechanisms, and simplified registration pathways. Based on what has been witnessed in Shanghai, where some of the most risky medical device applications are now done within less than 6 months, it is projected that AI Class III device applications in pilot provinces will shorten the national average of 30.2 months to about 7 to 8 months in two years [9].

Regulatory acceleration of this kind is likely to aid in the significant growth in the actual implementation of the device within urban hospitals, especially in the application of imaging and clinical decision support. This estimate is in line with the high demand among general practitioners toward AI-aided diagnostic imaging and decision support capabilities [10], and the agglomeration of medical device innovative capacity in industrial regions like Guangdong and Zhejiang [3]. Earlier deployment also allows the hospitals to compile actual usage statistics, which can in turn be used in negotiating reimbursement and augmenting the development of adoption incentives [11].

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Under an approach where the market is the primary consideration, however, equity is a big issue. Available evidence indicates that most AI-based diagnostic applications take place in huge urban hospitals, and are not widely spread to county-level and rural institutions. Devoid of a national requirement to expand infrastructure, the dissemination of AI devices using a decentralized framework would probably go through the same route, with little enhancement to county or rural hospitals. In comparison, the Public-Good model focuses on a centralized procurement, nationwide reimbursement coding, and joint digital infrastructure that can help reduce institutional barriers to entering those hospitals still under-resourced and enhance long-term accessibility [11,12].

The rest four criteria: the feasibility, risk governance, strategic alignment, and stakeholder incentives are not so quantifiable but worthy of mentioning. The Market-Oriented course is more allowed in the short term, since it is based on existing local authority and they do not need new institutions. It fits the existing operations capacity of the firms and hospitals quite well; however, it offers fewer capabilities for clinical risk and data quality management. The Public-Good model is more complex in terms of its time and institutionalization requirements, yet more in tandem with the national objectives and long-term digital health regulation. It is also most probably to incorporate safety measures and more equitable sharing of risks, and these advantages would only be realised once the backbone infrastructure has been established.

Altogether, addressing the issue of institutional friction within AI-enabled medical equipment would need not merely the dualistic perspective between the market and centralized control but a gradual institutional approach (as represented in Table 2) to the combination. This is a brief map that demystifies responsibilities of execution, controlling mechanisms, coordination, and mobilization of resources. The approaches to this staged plan will result in capitalization of the existing critical policy window by integrating market-oriented flexibility and systematicity targeted at the benefit of the public. It follows pilot projects of initial regulatory sandboxes in developed states to swiftly gain the hands-on experience, a period of customizing a cohesive national regulatory framework, and finally results in a nationwide fair distribution. The final objective is to build a plausible, unbiased, and sustainable AI health system that improves efficiency and equity.

Table 2. Staged development strategy of AI-powered class III medical devices

	Phase 1 (2025–2026)	Phase 2 (2026–2027)	Phase 3 (2028–2030)
Command	NMPA, together with provincial regulatory authorities in Shanghai, Shenzhen, and Guangzhou, ought to approve regulatory sandboxes to high-risk AI diagnostic devices.	Pilot findings will be collected at a new central coordination unit managed by the NMPA or a larger Digital Health Commission (should one be established).	The NMPA and NHSA will share the control systems of reimbursement and access and control the risks.
Control	Conditional approvals, staged algorithm update models (e.g., minor/mediocre/major changes) will be tested.	One single regulatory framework will be provided with specifications on update thresholds, safety standards, and approvals standards.	AI services will receive national coverage codes on billing, and there will be predefined conditions of the coverage. Long term impacts will be monitored utilizing a centralized data clearinghouse.
Communication	Provincial platforms require developers to provide quarterly RWE. Central regulators will be provided with the results via a national learning network.	To gather the usage, safety and performance data on an AI Medical Device in the country, an AI Medical Device Registry will be established.	White papers will report to them every year with updates on progress, risk update and areas of improvement.

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Table 2. (continued)

Consensus	Local hospital, AI companies and medical insurance agencies will create regional consortia to co-design protocols.	Academic hospitals and industry stakeholders will be engaged in the co-authoring of guidelines to make them technically relevant and acceptable to the clinical sphere.	There will be institutionalization of stakeholder forums, which will include doctors, patients, payers and technologists to discuss the impact of policies.
Financing	Start-up pilots may be co-financed by means of provincial innovation grants and strategic emerging industry funds, optional tax credits may be used by participating companies.	The Ministry of Finance can implement a central AI-enabled Health Infrastructure Fund (AI-HIF) to replicate validated technologies to rural or under-resourced locations.	Contracts of volume based procurement and risk sharing payments (like drug models) will save on costs and will make it viable over long run.

4. Conclusion

This paper focuses on policy-based policy implications of AI-based Class III medical devices in China and specifically discusses the policy formulations that have created resistance in the process of scaling up the innovation of technology to the large-scale adoption of the technology in clinical practice. The MSF indicates three office-caused constraints that are connected with each other, namely, long and uneven processes of regulatory approvals, broken capacity-responsibility mismatches in hospitals, and unresolved gaps in patient payment systems and trust. The presence of these barriers does not suggest that AI technologies are not ready yet, but rather that the current regulatory and institutional mechanisms fail to adjust to the adaptive and data-intensive features of AI-enabled medical devices.

In reaction, the research suggests a gradual stream of optimization, which will efficiently integrate market-based flexibility and the public-good-based coordination. The regulatory sandboxes at the early stages in developed areas can hasten the production of evidence and learning by experience, whereas the later introduction of a single national regulatory system and uniform reimbursement systems is the key to ensuring equity in the long run, sustainability, and proper risk management in the future. Collectively, these phases can describe a consistent institutional approach that balances motivational incentives of innovation with regulatory predictability, which allows policy-makers to use the given policy window of systemic reform. This study is relevant to theory and practice. In theory, it can be expanded to the use of MSF in technology governance and regulatory implementation, showing it to be useful in examining the instantiations of institutional enmity with respect to emerging technology. In practice, the research offers practitioners to improve the regulation system, hospitals, and innovators with clear answers on how the design of regulation, organizational capacity, and payment structure combine to influence the outcomes of the adoption of AI-based medical devices. Simultaneously, the analysis is mostly qualitative and policy-based and is conducted based on institutional evidence and representative cases, instead of major empirical tests.

An element of future studies can be based on this study in various ways. Quantitative research can determine the impact of adjustments in regulatory processes or the inclusion of reimbursement on the rate of adoption in different geographical regions. Additional comparative studies about China and other healthcare systems could further clarify how various institutional models have a role in diffusing AI medical devices. Moreover, micro-level studies of the HRM within hospitals, such as how they make decisions or how they accept patients, would be a possible addition to the macro-level policy study that is available here. Collectively, these actions would enhance knowledge about how AI technologies can be regulated in a manner that is effective and just in the complicated healthcare systems.

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