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Artificial intelligence-enabled healthcare access and user experience: comparative institutional analysis and survey evidence from China

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Background: Regulatory entry and public experience describe different aspects of artificial intelligence-enabled healthcare access.
Methods: This health policy study compares institutional arrangements in China, the United States, and the European Union, examines the coverage of equity-related evidence, and analyses an online Chinese survey. Of 480 submissions, 430 passed an attention check, including 32 respondents without reported functional contact and 398 entering the experience models.
Results: The institutional comparison identifies differences in regulatory objects, information recipients, and responsibility allocation. The coverage analysis distinguishes institutional information and hospital governance from measured portal use and service experience. In the survey, lower-capability respondents reported greater entry and operational barriers; 79 of 159 reported reducing or abandoning use because of barriers. Among contacted respondents, functional contact intensity was positively associated with perceived process ease (standardized $\beta = 0.496$), which was associated with perceived health-service responsiveness (standardized $\beta = 0.381$). The contact-by-capability interaction was negative ($B = -0.254$), contrary to the hypothesized direction.
Conclusion: The findings highlight entry and operational barriers alongside differences in experience among existing users, supporting evaluation of both access conditions and service encounters.

KEYWORDS
AI-enabled healthcare, digital health, health information technology, healthcare access, healthcare data governance and health equity, internet-based healthcare

1 Introduction

Research on medical AI spans clinical deployment and human–AI collaboration as well as technical performance (1, 2). WHO's ethics guidance places human rights and public accountability at the centre of health-AI governance (3). Access to healthcare includes identifying needs, reaching services, using them, and having those needs addressed (4). Product authorisation determines whether a regulated technology can enter a service system; knowing where to find a function, operating it, and obtaining an appropriate response concern the public's encounters with that system. A comparison of institutional entry can describe the safeguards

surrounding deployment, while public-experience research can examine difficulties that remain when people encounter the services.

Institutional comparison and public-experience research meet at the relationship between service arrangements and people's ability to obtain care. The patient-centred access framework distinguishes characteristics of services from the abilities involved in perceiving needs, seeking care, reaching services, and engaging with them (4). The Digital Health Equity Framework similarly places individual digital access within wider social conditions and health-system arrangements (5). This distinction makes it important to examine entry conditions as well as experiences among users. Studying users alone leaves people who do not achieve contact outside the experience analysis; comparing regulations alone leaves actual service encounters unobserved.

This study examines institutional entry and public experience as two related aspects of AI-enabled healthcare access. A comparison of China, the United States, and the European Union describes six governance functions. An evidence-coverage analysis then distinguishes institutional provisions, contextual indicators, and directly measured public experiences. The Chinese survey addresses selected public-facing questions through descriptions of access conditions among all eligible respondents and an association model among respondents reporting functional contact. The contribution is a comparison of what institutions regulate alongside a country-specific account of reported barriers and experience.

2 Literature review

2.1 Institutional access and service-system embedding

WHO's regulatory considerations highlight risk–benefit assessment and performance monitoring in the development and use of health AI (6). Its later guidance addresses the governance of large multimodal models (7). Device authorisation, health-information governance, and online clinical-service requirements govern different products, organisations, and users within AI-enabled healthcare. Comparing their regulated objects clarifies how each instrument addresses entry and use.

US device governance distinguishes premarket assessment from the management of subsequent software changes. For AI software regulated as a medical device, the US Food and Drug Administration (FDA) describes pathways such as 510(k) clearance, *De Novo* classification, and premarket approval (8). Its 2024 announcement of guidance on predetermined change control plans (PCCPs) describes planned modifications, the methods for developing, validating and implementing them, and assessment of their impact. The guidance is not itself binding on FDA or the public (9). Separately, the 2024 Health Data, Technology, and Interoperability rule (HTI-1) specifies predictive decision-support information and risk-management requirements within certified health information technology (10).

The European Union (EU) combines AI regulation (11), medical-device requirements (12), data protection (13), and a framework for electronic health-data use (14). These instruments address different objects and obligations, with their respective scope and application dates. The literature discusses both the rights safeguards and the compliance complexity associated with this layered framework (15, 16), as well as professional responsibility for medical AI (17). Algorithmic-fairness research also examines biases across data, model development, and deployment (18).

The Chinese documents distinguish technical review of devices from governance of online clinical services. The 2022 guidance addresses registration submissions for Class II and III AI medical devices and expressly states that it is not enforced as a regulation (19). The 2018 service rules address internet diagnosis and treatment, internet hospitals, and remote medical services, including institutional entry, patient consent, and allocation of responsibility (20). These distinct regulatory objects provide a basis for comparing device review and service governance separately.

The reviewed pathways describe different entry emphases within overlapping governance systems. Comparing the same functional questions across jurisdictions identifies which object is regulated, which subject receives information, and where responsibility is assigned. The FUTURE-AI consensus guideline complements this regulatory perspective with recommendations for end-user involvement, local usability testing, and monitoring (21). Meskó and Topol (22) discuss the regulatory oversight needed for generative AI in healthcare.

> RQ1: How do institutional arrangements in China, the United States, and the European Union address product entry, service embedding, data governance, transparency, accountability, and lifecycle monitoring?

Institutional provisions specify information duties and service requirements. Public-experience evidence addresses users' understanding, trust, and service encounters. RQ2 examines how the reviewed sources cover these questions.

> RQ2: Which access, comprehension, trust, and service-experience questions are directly measured, indirectly informed, or left unmeasured by the reviewed sources?

2.2 Access conditions and service experience

This study draws on complementary healthcare access frameworks. Penchansky and Thomas (23) decompose access into availability, accessibility, affordability, acceptability, and accommodation. Levesque et al. (4) develop a patient-centred process model that moves from perceiving needs and seeking services to reaching services, obtaining services, and having needs met, while distinguishing provider-side characteristics and demand-side capabilities. Saurman (24) adds awareness as a further access dimension. Together, these frameworks allow access to be examined as both a distributional condition and a process involving barriers encountered while obtaining services.

The patient-centred process model treats reaching services and having needs addressed as related but distinct parts of access (4). For AI-related functions, public-experience indicators can describe the effort involved in finding an entry point, the time needed to obtain advice, and the difficulty of interpreting information or deciding how to seek care. These indicators concern the ease of a service encounter.

Health-service responsiveness concerns whether recent care needs are addressed.

2.3 Digital health capability and access differences

Digital health capability is relevant both to entering AI-enabled services and to interpreting the functions encountered during use. Norman and Skinner (25) developed the eHealth Literacy Scale (eHEALS) to assess perceived ability to find, understand, evaluate, and apply electronic health information. Later measurement work includes the multidimensional eHealth Literacy Questionnaire (26) and validation of a Chinese eHEALS version (C-eHEALS) in a rural population (27). Studies examine digital literacy and health behavior among rural residents (28), review digital literacy as an equity concern (29), identify demographic and digital-divide differences in video-visit completion in oncologic care (30), and synthesize digital health literacy research among older adults (31). Griebel et al. (32) review the development of eHealth-literacy research and its conceptual and measurement challenges. Lennon et al. (33) examine the conditions needed to deliver digital health at scale. Research on digital access inequities during the pandemic (34), telehealth implementation across countries (35), and maternal-care telemedicine (36) further situates digital-health use within differing service and population contexts.

Yao et al.'s scoping review distinguishes unequal availability of digital resources from difficulties using digital health services (37). Paulus and Kent (38) examine a different equity concern, how clinical prediction can produce decisions that are differentially harmful or beneficial across groups. Whitehead et al.'s qualitative review of culturally and linguistically diverse populations identifies accessibility, digital literacy, and language as barriers to uptake (39). These findings motivate examining capability alongside the service conditions under which people enter and use digital healthcare. RQ3 examines entry barriers and experience associations in the Chinese sample.

> RQ3: What access-condition differences are reported in the Chinese sample, and how are functional contact intensity, perceived process ease, and perceived health-service responsiveness associated among contacted respondents at different levels of digital health capability?

The access frameworks distinguish reaching and engaging with services from having needs addressed (4, 23). Applied to the survey, more frequent functional contact may accompany greater familiarity with service entry points and advice, motivating the expected positive contact–ease association in H1. Easier navigation and interpretation may also accompany a greater ability to obtain a response to care needs, motivating H2. H3 combines these expectations in an exploratory indirect statistical association. Because the responsiveness items concern general healthcare, this specification examines how the reported experiences covary rather than a sequence within the same service event. Finally, perceived ability to evaluate and apply digital information (25) could complement repeated contact, motivating the original positive interaction predicted in H4. This complementarity is an exploratory expectation, not an interaction established by the cited measurement literature. The four directional hypotheses are retained as follows.

> *H1*: Functional contact intensity is positively associated with perceived process ease.
>
> *H2*: Perceived process ease is positively associated with perceived health-service responsiveness.
>
> *H3*: Functional contact intensity has a positive indirect statistical association with perceived health-service responsiveness through perceived process ease.
>
> *H4*: Higher digital health capability strengthens the positive association between functional contact intensity and perceived process ease.

3 Materials and methods

The design combines comparative institutional analysis with a Chinese public-experience survey. The institutional comparison (P1) identifies governance arrangements and their regulated objects (Table 1). The evidence-coverage analysis (P2) examines which public-facing questions those sources and the reviewed literature address. The survey (P3) measures selected access conditions and experiences within China. Table 2 connects the three components through common access questions and their measurement coverage.

3.1 Structured-focused comparison of institutional entry

P1 adopts the structured-focused comparison method proposed by George and Bennett (40). It applies the same questions to China, the United States, and the European Union across six author-defined governance dimensions: product access, service embedding, data governance, transparency and explanation, accountability, and lifecycle monitoring. Each dimension is examined for the arrangement described in the selected documents, its regulated object, and the subject it directly addresses.

The document is the observation unit. The comparison distinguishes regulations, administrative service rules, nonbinding technical guidance, and official explanatory material. Table 1 identifies the instruments, their directly addressed subjects and the provisions compared; the references provide the source records. General digital-health documents are included where they govern service delivery or data infrastructure relevant to AI-enabled healthcare. The United States and the European Union are policy-level cases, with subnational implementation outside the comparison.

Sources were selected purposively from FDA and ASTP/ONC, EUR-Lex, and Chinese medical-device and health-service repositories to cover product review, health-information governance, and online clinical-service entry. The retained instruments date from 2016 to 2025 and are compared in the versions cited, including the original adopted EU texts. The FDA overview, updated in September

TABLE 1 Six-dimensional comparison of the selected institutional instruments.

Dimension	United States	European Union	China
Product access	Premarket pathways for regulated AI devices (8); authorized PCCPs for specified changes (9).	2024 AI Act Article 6(1) and Annex I, product scope and third-party assessment (11); MDR Article 61, clinical evaluation (12).	2022 nonbinding guidance for registration of Class II/III AI medical devices (19).
Service embedding	HTI-1 predictive decision support within certified health IT, 45 CFR 170.315(b) (13) (10). Clinical-service licensing is not separately examined.	EHDS Chapter II, primary electronic health-data use (14). Member-state clinical-service licensing is not separately examined.	2018 internet-diagnosis measures, Articles 3, 5 and 10; internet-hospital measures, Articles 17–18; telemedicine specification, Sections III–V (20).
Data governance	HTI-1 health-IT certification, interoperability and information-sharing provisions (10).	GDPR Article 9, health-data processing (13); EHDS Chapters II and IV, primary/secondary use (14).	2018 internet-diagnosis measures, Articles 13 and 17, and internet-hospital measures, Articles 21 and 23: information security and electronic records (20).
Transparency and explanation	HTI-1, 45 CFR 170.315(b) (13): source attributes accessible to identified users of developer-supplied predictive interventions (10).	AI Act Article 13 information for deployers (11); GDPR Articles 13–15 and 22 information and safeguards (13).	Internet-hospital measures, Article 15: risk disclosure and consent (20); device guidance, instructions-for-use section: limitations, warnings and decision-support evaluation summaries (19).
Accountability	HTI-1, 45 CFR 170.315(b) (13): developer intervention risk management (10). General clinical and product liability is not examined.	AI Act Article 26, deployer obligations (11); GDPR Articles 77–82, remedies (13).	Internet-hospital measures, Article 32: legal responsibility by organisational form and cooperation agreement (20).
Lifecycle monitoring	2024 PCCP guidance announcement on planned modifications, validation and impact assessment (9).	MDR Article 83, manufacturer post-market surveillance (12); AI Act Article 72, provider monitoring (11).	2022 device guidance, algorithm-update and post-market-generalization sections: major/minor updates and generalization research (19).

Entries describe the cited versions, not a comprehensive inventory of each jurisdiction. Provisions identify the source locations used. The FDA overview was updated on 22 September 2026; its PCCP announcement summarizes nonbinding guidance (Federal Register 89, pp. 96259–96,261). HTI-1 is a health-IT certification rule. EU entries use the original adopted AI Act (2024), MDR (2017), GDPR (2016) and EHDS (2025) texts; application schedules are specified in AI Act Article 113 and EHDS Article 105. China's 2022 device guidance is nonbinding; its 2018 online-service instruments are administrative trial documents.

2026, is used to describe premarket pathways. Application schedules are distinguished from the obligations written into the adopted texts. The resulting comparison concerns this documented corpus, with unexamined dimensions identified in Table 1.

3.2 Evidence coverage and its connection to the survey

P2 is a targeted evidence-coverage analysis organized around entering a service, interpreting information, trust and accountability, and obtaining a service response. These questions draw on the distinction between service characteristics and individual abilities along the care process (4). Focal sources were selected from the institutional corpus, official digital-health reports, and the cited capability, implementation, explainability, trust, and intervention literature to examine the observation level available for each question. Table 2 and Section 4.2 identify the focal sources, their technical objects, observation units and study designs, and the questions they support. Direct evidence measures the stated question in its own population; contextual evidence concerns a related service or institutional practice; normative and conceptual sources specify obligations or arguments without measuring public outcomes. This is a source-specific coverage analysis, not an estimate of the prevalence of gaps across all published research.

Table 2 maps the coverage findings to the constructs measured in the Chinese survey. Entry and operation are described in all 430 eligible respondents; process ease and general health-service responsiveness are analysed among 398 contacted respondents. User trust and the performance of accountability arrangements were not measured.

3.3 Chinese survey of access conditions and experience

The Chinese survey describes access conditions among all 430 attention-check-passing respondents, including 32 without reported functional contact. Experience models use the 398 respondents reporting contact with at least one of six specified functions.

3.3.1 Model structure and variable definitions

The experience model follows a conditional indirect association structure based on Hayes PROCESS Model 7 (41). Functional contact intensity is X, perceived process ease is M, perceived health-service responsiveness is Y, and digital health capability is W on the X-to-M path. Sex, age group, education, and reported health-service need are controls, using the retained binary sex and ordinal age-group, education and need scores. X and W are mean-centred within the contacted sample for each specification. Health-service need is a five-point self-report of recent demand for medical or health services. The additional HC3 regression specifications include access conditions; the conditional model is also examined with that composite added. The principal and additional specifications are reported separately because the access-condition composite overlaps conceptually with operational capability and reported barriers.

TABLE 2 Evidence coverage connecting institutional questions and survey measures.

Access question	Focal evidence and observation level	Chinese survey contribution	Remaining question
Entering and operating a service	2024 US HINTS portal access/use survey, individuals (44); 2018 Chinese service-entry rules, normative institutional duties (20).	Awareness, device/network conditions, operation, assistance need and barrier-related abandonment (n = 430).	Population AI uptake and people unable to participate online.
Interpreting a function	Deployer/user information duties, normative texts (10, 11); older-adult literacy scoping review (31); UK longitudinal qualitative implementation evaluation, 2012–2015 (33); stakeholder explainability, conceptual analysis (47).	Self-assessed interpretive capability; AI-related process ease among contacted respondents (n = 398).	Objective comprehension and effects of specific disclosures.
Trust and accountability	US hospital predictive-model governance survey, 2023–2024 (49); clinician-trust viewpoint, 2020 (50); institutional duties, normative texts (10, 11, 20).	No direct trust or accountability-performance outcome.	Public trust and performance of safeguards in actual encounters.
Obtaining a service response	mHealth intervention review of systematic reviews, 2018, selected care contexts (52).	General health-service responsiveness and contacted-respondent associations (n = 398).	AI-attributable change and comparable US/EU public experiences.

Section 4.2 reports the source-specific findings. Coverage is specific to each source's population and service object; normative obligations and conceptual arguments are distinguished from observed practice and experience.

Functional contact intensity is the mean reported frequency of encountering six AI or intelligent medical functions during the past six months: guidance or triage, pre-consultation or symptom checking, report interpretation, follow-up or medication reminders, health-management advice, and AI health consultation or question answering. Responses range from 1 (never) to 5 (very frequently). Any function rated above 1 defines reported functional contact. The secondary breadth indicator counts functions rated 4 or 5.

Perceived process ease is the mean of four items concerning the time needed to obtain health advice, the effort needed to find departments, physicians or service entry points, the difficulty of deciding the next step in seeking care, and the difficulty of understanding reports or health advice when using AI or intelligent medical functions. Each item is scored from 1 (longer time, greater effort, or greater difficulty) to 5 (shorter time, less effort, or greater ease). Responses indicating non-use (code 6) and missing responses are treated as inapplicable, not assigned zero; the experience analysis requires reported functional contact and complete model scores.

Perceived health-service responsiveness is the mean of five items concerning whether initial consultation needs were addressed, matched professional advice or services were obtained, care transitions were smooth, follow-up support was available, and overall health-service needs received an appropriate response during the past six months. Responses range from 1 (not at all consistent with the respondent's experience) to 5 (fully consistent). Responses indicating no relevant need (code 6) and missing responses are treated as inapplicable, not assigned zero.

The moderator is digital health capability in AI-related contexts. It measures perceived capability to identify, operate, understand, evaluate, and apply relevant functions in AI-enabled medical contexts, including identifying function types, entering health information, distinguishing types of advice, attending to scope of application, judging the need for review, privacy-protection awareness, and cross-platform comparison. The measure uses a five-point Likert scale.

3.3.2 Scale design

Respondents were asked about functions presented as AI or intelligent medical functions, but the survey did not independently verify the underlying software or algorithm. The exposure variable may therefore capture perceived contact with AI-enabled or smart digital-health functions rather than technically verified AI deployment.

The process-ease items form a literature-informed, self-developed composite describing demands within a service encounter. The access frameworks distinguish service characteristics from the abilities involved in obtaining care (4, 23), providing a conceptual basis for examining time, effort and difficulty.

The health-service responsiveness items concern needs being addressed and services being obtained, which are relevant to the patient-centred access process (4). They cover service responses, complementing the process demands measured by M.

The digital health capability scale is adapted from Norman and Skinner's (25) eHEALS and its Chinese version C-eHEALS (27). It retains the core capability dimensions of seeking, understanding, evaluating, and applying information, changes the measurement object from internet health resources to AI-enabled medical functions, and adds AI-specific capability requirements.

The five-item access-condition module measures entry-point awareness, device and network conditions, independent operation, need for assistance, and reduction or abandonment of use because of entry, operational, process, or privacy barriers. All 430 eligible respondents contribute to its description. Assistance need and barrier-related abandonment are reverse-scored as 6 minus the original score before

averaging the five items, so higher composite scores indicate more favorable access conditions. The original directions are retained when reporting individual barrier indicators.

3.3.3 Questionnaire design and data collection

The online questionnaire was administered to adults aged 18 and above on 22–23 May 2026 through a questionnaire link distributed via WeChat. Recruitment was non-probabilistic. Functional-contact, capability, process-ease, and service-responsiveness items were interleaved. An attention-check item was presented in the format of a service-response item, with the designated correct response scored 4; it was excluded from every composite.

The online survey retained 480 submissions. Fifty failed the attention check, leaving 430 for access-condition descriptions. Of these, 32 reported never encountering any of the six functions and 398 reported functional contact and had the required composite and control scores for the experience models. A separate quality sensitivity branch additionally required a recorded duration of at least 120 s, a longest identical-response run below 18, and a response standard deviation above 0.25. It retained 421 respondents, including 391 with contact and 30 without contact (Figure 1).

3.3.4 Overview of analytical methods

Analysis distinguishes access-condition descriptions from contacted-respondent associations. Descriptive statistics include contact status and capability groups, with explicit denominators. Internal-consistency diagnostics describe the sample composites. Heteroskedasticity-consistent type 3 (HC3) robust regressions (42) examine process ease and service responsiveness, and a Model 7-style analysis estimates the contact-by-capability interaction and conditional indirect associations. Indirect-association point estimates are products of fitted full-sample coefficients; percentile confidence intervals use the retained 5,000-resample bootstrap outputs (43). Sensitivity specifications add access conditions, replace intensity with breadth, or use the 391-person quality-restricted contact sample (Section 4.5.3).

3.3.5 Ethics and consent

The study used self-reported questionnaire data from adults and did not involve clinical intervention, biological sample collection, or clinical records. Participants were informed of the study purpose, survey procedures, data use, and voluntary nature of participation and provided written informed consent. Ethics review was considered unnecessary under Article 32(2) of the Measures for the Ethical Review of Life Sciences and Medical Research Involving Human Participants because the study used anonymized questionnaire information. Data were analyzed and reported in aggregate form.

4 Results

4.1 Institutional arrangements and their governance objects

The six-dimensional comparison identifies differences in regulated objects, information recipients, service embedding, and responsibility allocation across China, the United States, and the European Union (Table 1).

The reviewed US documents address device authorisation and information requirements for certified health information technology (IT). FDA describes pathways such as 510(k) clearance, *De Novo* classification, and premarket approval (8). Its 2024 PCCP announcement describes planned modifications, their development, validation and

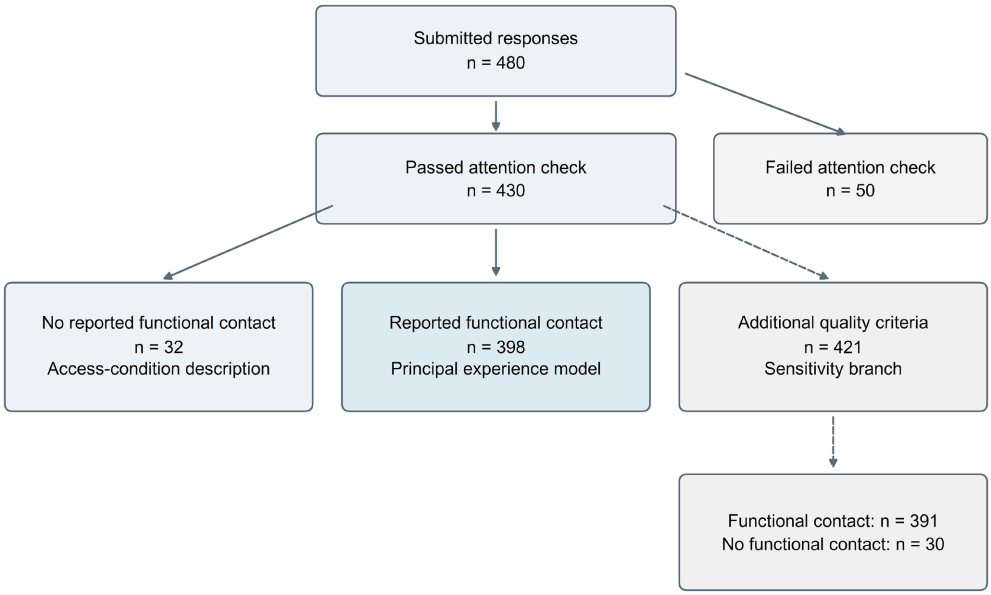


FIGURE 1
Survey sample branches and analytical populations. The principal experience model uses 398 contacted respondents from the 430 who passed the attention check. The additional quality screen is a separate sensitivity branch, retaining 391 contacted and 30 non-contact respondents. Non-contact respondents remain in the access-condition descriptions. Access-condition analyses retain all 430 respondents. Experience models require functional contact and valid item scores. Dashed arrows identify the separate quality sensitivity branch.

implementation methods, and an impact assessment. Changes consistent with an authorized PCCP can be implemented without an additional marketing submission for each described modification (9). HTI-1 requires modules certified to the decision support intervention criterion to enable identified users to access plain-language source-attribute information for predictive interventions supplied by the developer as part of its module (10).

The reviewed EU instruments combine medical-device regulation, data protection and AI governance. Under Article 6(1) of the Artificial Intelligence Act as adopted in 2024, medical-device AI falls within the high-risk category when both the Annex I product-scope condition and the requirement for third-party conformity assessment are met (11). The Medical Device Regulation as adopted in 2017 specifies clinical evaluation and manufacturer post-market surveillance requirements (12). The General Data Protection Regulation (GDPR) regulates the processing of health data and specifies data-subject rights (13). The 2025 European Health Data Space Regulation establishes a framework for primary and secondary use of electronic health data with staged application dates (14).

The Chinese documents address device review and online service governance as distinct regulatory objects. The 2022 technical guidance covers registration submissions for Class II and III AI medical devices, including independent software and devices with AI software components. It expressly states that it is not enforced as a regulation (19). The 2018 rules specify entry requirements for internet diagnosis and treatment provided by licensed medical institutions. They also require internet hospitals to inform patients of risks and obtain informed consent, and identify the responsible legal entity according to the hospital's organisational form (20). The device guidance specifies information on use limitations and warnings, with additional evaluation summaries for decision-support products, and addresses algorithm updates and post-market generalization research (19). These provisions concern different products, services, and information recipients; they do not establish a general patient right to an explanation of an AI-generated decision.

The US materials distinguish device authorisation and planned software modifications from information access within certified health IT. The EU materials layer device, AI, data-protection, and electronic health-data obligations. The Chinese materials distinguish technical device review from requirements for internet clinical services. The comparison identifies the instruments, information recipients, and responsible actors involved in each arrangement.

4.2 Evidence coverage and public-experience questions

The source-level coverage analysis identifies a distinction between information or governance arrangements and observations of public experience. Table 2 maps these coverage findings to the constructs measured in the Chinese survey.

For entry and operation, the 2024 US HINTS patient-portal survey, reported in 2025, directly measures individuals being offered and using online records, but its technical object is a portal rather than AI-enabled healthcare (44). Marwaha et al. (45) discuss organisational and workflow conditions for deploying digital tools, while Carini et al. (46) synthesize patient-portal outcomes, efficiency, and patient attitudes. Studies of rural residents' digital-health behavior (28) and video-visit completion in oncologic care (30) also examine defined populations and services. The digital-equity review (29) and reports on pandemic-era digital access (34), telehealth (35), and maternal-care telemedicine (36) provide additional context. The entry-point awareness, operation and assistance measures in P3 address these questions, including among respondents without functional contact. They do not supply a harmonized AI-use denominator across the three jurisdictions.

For comprehension, the older-adult literacy review examines general digital-health information skills (31), while the 2012–2015 UK longitudinal qualitative implementation evaluation concerns service and organisational readiness (33). The AI Act's Article 13 specifies information for deployers (11), GDPR Articles 13–15 and 22 concern specified data-subject information and safeguards (13), and HTI-1 concerns source attributes accessible to identified health-IT users (10). The explainability analysis distinguishes the needs of different healthcare stakeholders (47). Sendak et al. (48) propose model facts labels to communicate model information to clinical end users. Across these sources, information recipients and study populations differ. P3 contributes users' self-assessed interpretive capability and process ease, rather than an assessment of compliance with a particular disclosure requirement.

For trust and accountability, the 2023–2024 survey of US nonfederal acute care hospitals measures reported local accuracy and bias evaluation, monitoring, and responsibility for predictive models (49). Its unit is the hospital, not the patient, and it includes statistical predictive models beyond machine learning. The clinician-trust viewpoint discusses fairness, transparency and robustness conceptually (50). A US consumer survey examines perceived benefits and risks of AI-based clinical decision-support tools (51). These sources do not measure Chinese public trust; P3 has no trust outcome. Trust therefore remains an open public-experience question within this study.

For service experience, the review of mHealth reviews synthesizes intervention outcomes in selected care contexts (52). Leonardsen et al. (53) instead synthesize patient experiences with technology-enabled care. These reviews inform digital-service evaluation but provide neither a common AI exposure measure nor comparable public outcomes for the three jurisdictions. P3 adds AI-related process-ease ratings and general health-service responsiveness in China. The coverage analysis thus directs attention to the observation unit and service object needed before claims of accessible use or public benefit can be compared.

4.3 Chinese survey samples and measurement diagnostics

4.3.1 Contact status and descriptive statistics

Of the 430 attention-check-passing respondents, 398 reported functional contact and 32 did not. In the 430-person descriptive sample, 43.3% were men, 56.7% were women, 59.1% were aged 26–45, and 76.3% had junior-college education or above. The corresponding figures in the 398-person model sample were 42.2%, 57.8%, 58.8%, and 76.6%. Table 3 reports contact-status descriptions. Respondents without contact reported lower mean capability (3.460 versus 3.859) and lower mean access-condition scores (3.125 versus 3.290) than contacted respondents.

Mean access-condition and capability scores in the 430-person descriptive sample were 3.278 (SD = 0.963) and 3.829 (SD = 0.784). Among the 398 contacted respondents, mean process ease was 3.915

TABLE 3 Survey descriptions by reported functional-contact status.

Characteristic	All eligible (*n* = 430)	No contact (*n* = 32)	Contact (*n* = 398)
Men	186/430 (43.3%)	18/32 (56.2%)	168/398 (42.2%)
Women	244/430 (56.7%)	14/32 (43.8%)	230/398 (57.8%)
Age 18–25	47/430 (10.9%)	5/32 (15.6%)	42/398 (10.6%)
Age 26–35	127/430 (29.5%)	13/32 (40.6%)	114/398 (28.6%)
Age 36–45	127/430 (29.5%)	7/32 (21.9%)	120/398 (30.2%)
Age 46–55	82/430 (19.1%)	5/32 (15.6%)	77/398 (19.3%)
Age 56 or above	47/430 (10.9%)	2/32 (6.2%)	45/398 (11.3%)
Education: Junior secondary or below	31/430 (7.2%)	5/32 (15.6%)	26/398 (6.5%)
Education: Senior secondary/technical secondary	71/430 (16.5%)	4/32 (12.5%)	67/398 (16.8%)
Education: Junior college	108/430 (25.1%)	8/32 (25.0%)	100/398 (25.1%)
Education: Bachelor's degree	139/430 (32.3%)	10/32 (31.2%)	129/398 (32.4%)
Education: Postgraduate or above	81/430 (18.8%)	5/32 (15.6%)	76/398 (19.1%)
Age 26–45 years	254/430 (59.1%)	20/32 (62.5%)	234/398 (58.8%)
Junior college or above	328/430 (76.3%)	23/32 (71.9%)	305/398 (76.6%)
Digital health capability, mean (SD)	3.829 (0.784)	3.460 (0.822)	3.859 (0.775)
Access conditions, mean (SD)	3.278 (0.963)	3.125 (1.179)	3.290 (0.944)

Values are n/denominator (%) or mean (SD).

(SD = 0.836) and mean service responsiveness was 3.937 (SD = 0.942). Table 4 reports the composite distributions.

4.3.2 Internal consistency

The questionnaire includes 27 substantive items across five composites. Cronbach's alpha was 0.847 for access conditions, 0.909 for functional contact, 0.846 for digital health capability, 0.765 for process ease, and 0.884 for service responsiveness (Table 5).

4.4 Access conditions and barriers across capability groups

Lower-capability respondents reported less favorable access conditions and more entry and operational barriers in the 430-person descriptive sample. Capability grouping produced 159 lower-, 146 middle-, and 125 higher-capability respondents; unequal group sizes reflect ties in the discrete composite scores (Table 6).

In the lower-capability group, 58 of 159 (36.5%) reported low entry-point awareness, 73 (45.9%) reported weak independent operation, 59 (37.1%) reported needing assistance, and 79 (49.7%) reported reducing or abandoning use because of barriers. Corresponding proportions in the higher-capability group were 12.0%, 17.6%, 17.6%, and 23.2%.

TABLE 4 Descriptive statistics for the survey composites contact and capability descriptions use all 430 eligible respondents.

Variable	*n*	Mean	SD	Min	Max
Access conditions	430	3.278	0.963	1	5
Functional contact intensity	430	3.879	1.036	1	5
Functional contact breadth	430	4.060	1.916	0	6
Digital health capability	430	3.829	0.784	1.143	5
Perceived process ease	398	3.915	0.836	1	5
Health-service responsiveness	398	3.937	0.942	1	5

Experience scores use the 398 contacted respondents. Inapplicable responses are not assigned zero.

TABLE 5 Internal-consistency diagnostics access, contact, and capability diagnostics use 430 eligible respondents; process-ease and responsiveness diagnostics use 398 contacted respondents.

Composite	Items	Cronbach's alpha
Access conditions (Z)	5	0.847
Functional contact (E)	6	0.909
Digital health capability (D)	7	0.846
Perceived process ease (M)	4	0.765
Health-service responsiveness (Y)	5	0.884

4.5 Associations among contacted respondents

4.5.1 Correlations among contacted respondents

Among the 398 contacted respondents, contact intensity correlated positively with process ease (r = 0.625) and service responsiveness (r = 0.638). Process ease and responsiveness were also correlated (r = 0.734), while capability correlated with both (r = 0.523 and 0.572, respectively). Table 7 reports the contacted-sample matrix.

TABLE 6 Access conditions and barriers by digital health capability. Capability groups use empirical tertiles in the 430-person sample, retaining equal scores together.

Indicator	Lower (n = 159)	Middle (n = 146)	Higher (n = 125)
Access conditions, mean	2.889	3.385	3.646
Entry-point awareness, mean	3.075	3.534	3.904
Independent operation, mean	2.698	3.212	3.552
Assistance need, mean	2.918	2.459	2.256
Barrier-related reduction/ abandonment, mean	3.346	2.753	2.624
Low entry-point awareness (score ≤ 2)	58/159 (36.5%)	29/146 (19.9%)	15/125 (12.0%)
Weak independent operation (score ≤ 2)	73/159 (45.9%)	35/146 (24.0%)	22/125 (17.6%)
High assistance need (score ≥ 4)	59/159 (37.1%)	32/146 (21.9%)	22/125 (17.6%)
Barrier-related reduction/ abandonment (score ≥ 4)	79/159 (49.7%)	40/146 (27.4%)	29/125 (23.2%)

Lower, middle and higher group score ranges are 1.143–3.571, 3.714–4.286 and 4.429–5.000. Higher composite, awareness and operation scores indicate better conditions; higher original assistance and abandonment scores indicate greater barriers. Comparisons are descriptive.

4.5.2 HC3 robust regressions

In the regression of process ease, contact intensity was positively associated with the score (standardized β = 0.496, $p < 0.001$, n = 398). Access conditions (β = 0.187) and capability (β = 0.310) were also positively associated with ease. This direction is consistent with H1 (Table 8).

Process ease was positively associated with health-service responsiveness (standardized β = 0.381, $p < 0.001$), consistent with H2. Contact intensity retained a positive association with responsiveness (β = 0.301).

At mean capability, the fitted conditional indirect association was 0.2835, with a percentile bootstrap 95% confidence interval of [0.2036, 0.3725]. This positive statistical association is consistent with H3.

4.5.3 Conditional associations and sensitivity analyses

The conditional model uses the 398 contacted respondents, with sex, age group, education, and reported health-service need as controls. Table 9 reports fitted coefficients and conditional indirect associations. Figure 2 shows the fitted contact-ease relationship at mean capability and one standard deviation below and above the mean, with HC3 confidence intervals for the predicted mean.

The contact-by-capability coefficient in the process-ease equation was negative (B = −0.2542, $p < 0.001$). The positive-direction prediction in H4 was not supported. Contact intensity had a steeper positive association with ease at lower capability within this contacted sample.

The fitted index of moderated indirect association was −0.1122, with a percentile bootstrap 95% confidence interval of [−0.1736, −0.0594]. Conditional indirect associations were 0.3705 [0.2682, 0.4866] at low capability, 0.2835 [0.2036, 0.3725] at mean capability, and 0.1965 [0.1232, 0.2815] at high capability. Adding access conditions retained the negative interaction (B = −0.2765, HC3 SE = 0.0566, $p < 0.001$). Replacing intensity with breadth also retained a negative interaction, both without access conditions (B = −0.0840, HC3 SE = 0.0220, $p < 0.001$) and with them (B = −0.0906, HC3 SE = 0.0234, $p < 0.001$). The breadth-model index of moderated indirect association was −0.0403 (bootstrap 95% CI [−0.0657, −0.0187]); adding access conditions gave indices of −0.1185 [−0.1787, −0.0666] for intensity and −0.0419 [−0.0671, −0.0230] for breadth. In the 391-person quality-restricted contact sample, the interaction was −0.2504 (HC3 SE = 0.0595, $p < 0.001$).

5 Discussion

5.1 Institutional entry and public experience as distinct access questions

The three components contribute to the same access question at different observation levels. P1 identifies the information recipients and responsible actors specified in the selected instruments. P2 shows that deployer information, hospital governance, portal use and intervention outcomes observe different parts of access. P3 then provides a Chinese account of entry and operational barriers and of experiences after contact. The substantive connection is the distinction between institutional provision and a person's ability to reach and use a service. For example, information addressed to a deployer in the AI Act or to identified health-IT users in HTI-1 leaves a separate empirical question about a member of the public's ability to interpret advice. The Chinese survey addresses perceived interpretive capability and process ease, while trust and accountability performance remain unmeasured.

The patient-centred access framework places service characteristics alongside the abilities needed to reach and engage with care (4). Authorisation and service-embedding indicators describe institutional opportunities. Entry-point knowledge, independent operation, and assistance needs describe the conditions people encounter in reaching services. Process ease and health-service responsiveness describe further aspects of their experience. This organisation connects the observed barriers to the Digital Health Equity Framework's emphasis on individual resources and health-system conditions (5). The health-futures Commission places digital transformation within wider governance and social conditions (54), while van Kessel et al. (55) describe digital health literacy as a determinant of health.

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TABLE 7 Pearson correlations among contacted respondents $n = 398$ for every coefficient.

Variable	Access conditions	Contact intensity	Capability	Process ease	Responsiveness
Access conditions	1.000	0.200	0.362	0.400	0.342
Contact intensity	0.200	1.000	0.285	0.625	0.638
Capability	0.362	0.285	1.000	0.523	0.572
Process ease	0.400	0.625	0.523	1.000	0.734
Responsiveness	0.342	0.638	0.572	0.734	1.000

TABLE 8 HC3 robust regressions among contacted respondents $n = 398$.

Predictor	M3: Ease B	M3 β	M3 p	M4: Response B	M4 β	M4 p
Functional contact intensity	0.6256	0.4959	<0.001	0.4280	0.3011	<0.001
Access conditions	0.1656	0.1871	<0.001	0.0341	0.0342	0.334
Digital health capability	0.3342	0.3099	<0.001	0.3141	0.2585	<0.001
Process ease	—	—	—	0.4287	0.3805	<0.001

M3 and M4 include access conditions, capability, sex, age group, education and health-service need; M4 also includes process ease. These specifications differ from the principal conditional model. B denotes unstandardized coefficients and β standardized coefficients.

TABLE 9 Conditional association model among contacted respondents $n = 398$.

Equation/quantity	Term	Estimate	SE	z or 95% CI	*p* or method
M equation	Functional contact intensity	0.6420	0.0530	12.107	<0.001
M equation	Digital health capability	0.3831	0.0433	8.859	<0.001
M equation	Contact × capability	−0.2542	0.0592	−4.295	<0.001
Y equation	Process ease	0.4416	0.0538	8.207	<0.001
Y equation	Functional contact intensity	0.4250	0.0594	7.161	<0.001
Y equation	Digital health capability	0.3227	0.0459	7.033	<0.001
Index of moderated indirect association	Contact × capability	−0.1122	0.0290	[−0.1736, −0.0594]	5,000 bootstrap resamples
Conditional indirect association	Low capability (−1 SD)	0.3705	0.0560	[0.2682, 0.4866]	5,000 bootstrap resamples
Conditional indirect association	Mean capability	0.2835	0.0431	[0.2036, 0.3725]	5,000 bootstrap resamples
Conditional indirect association	High capability (+1 SD)	0.1965	0.0400	[0.1232, 0.2815]	5,000 bootstrap resamples

X and capability are mean-centred. Both equations control for sex, age group, education and reported health-service need. Coefficient SEs are HC3 robust. Indirect-association point estimates use fitted full-sample coefficient products; their SEs and percentile 95% CIs use the retained 5,000-resample bootstrap outputs. Low and high capability are mean ± 1 SD. Access conditions are added in a separate sensitivity specification.

5.2 Interpreting the negative interaction

The negative contact-by-capability interaction indicates a steeper contact-ease association among lower-capability users, alongside a positive association between capability and ease. Greater reported access barriers can therefore coexist with a steeper association after contact. Possible explanations include less variation in ease among more capable users and assistance supporting some lower-capability users. Neither prior process difficulty nor assistance actually received was measured; these mechanisms require longitudinal or experimental investigation.

Selection into contact may also help explain the pattern. Lower-capability users who reach a function may differ from those who do not in assistance, motivation, service choice, or other resources. Following both groups over time would help distinguish entry conditions from subsequent experience.

5.3 Implications for governance and service evaluation

The differences in Table 1 reflect both the instruments' design and the objects selected for comparison. US device review and

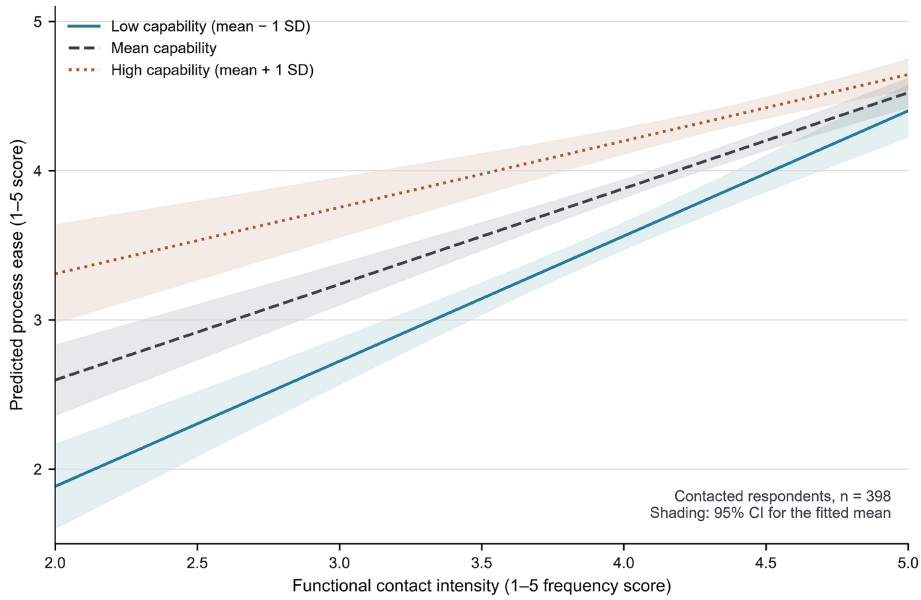


FIGURE 2
Functional contact intensity and perceived process ease at different capability levels. Predicted means from the 398-person principal process-ease equation. Capability is fixed at the sample mean or one *SD* below/above it; sex, age group, education and health-service need are held at sample means. Shading denotes 95% HC3 confidence intervals for fitted means. The *x*-axis covers the observed intensity range of contacted respondents.

planned-change guidance organize information around the product, manufacturer, and specified modifications (8, 9); health-IT certification adds a separate system-level instrument (10). The EU AI Act uses a horizontal risk framework (11), combined with sectoral device rules (12) and data-governance instruments (13, 14). China's 2018 rules organize online clinical services around licensed institutions, practice requirements, consent, and legal responsibility (20), alongside separate device review (19). These institutional design choices explain the emphases visible in the selected texts. Because all three settings have overlapping product, service and data governance, the comparison is better read by governance function than as three exclusive national models. Earlier comparative work on radiology AI likewise distinguished medical-device and data-protection frameworks in Europe and the United States (56).

For China, evaluation of service expansion should include whether users know the entry point, can operate the function, require assistance, or reduce use because of barriers. The institutional comparison identifies explanation, consent, responsibility, and monitoring arrangements as additional areas for evaluation. Chen and Zou (57) argue for embedding patient-centred transparency, participation, and inclusive design in medical AI. Service reach and algorithmic fairness also require distinct evaluation: in a US population-health algorithm, using healthcare costs as a proxy for need produced racial bias in identifying patients for additional care (58).

For service providers and platform operators, the reported barrier pattern supports evaluating navigable entry points, operational support, and routes to human assistance. The FUTURE-AI guideline recommends defining end-user requirements, providing accessible training, and testing usability with users of varied digital proficiency (21). Responsible-AI work on organisational deployment (59) and lifecycle evaluation beyond initial model performance (60) supports studying these arrangements alongside human review, referral, and accountability.

Cross-jurisdiction public-experience comparisons would require harmonized definitions of functions, eligible populations, contact status, process difficulty, and service responsiveness.

5.4 Limitations and further research

The online, non-probability sample has relatively high educational attainment and may underrepresent people with the weakest digital capabilities. Their entry and operational difficulties are likely understated. Including 32 non-contact respondents provides some information about non-use within this sample, but leaves people unable to participate online unobserved. Experience-model findings concern the 398 contacted respondents.

The cross-sectional, common-source self-reports cannot establish temporal order or causal effects and may inflate associations through common-method variance. Item interleaving and the attention check addressed response patterns and quality but cannot eliminate this risk. The process-ease items measure current experience levels, and the responsiveness items concern general healthcare; neither measures AI-attributable improvement. The self-developed and adapted composites have not undergone independent-sample validation. Future studies should assess factor structure, convergent and discriminant validity, prior difficulty, assistance received, and objective outcomes. The Chinese survey does not test differences in public outcomes across the three institutional settings. The purposive institutional corpus and targeted evidence analysis are not exhaustive and lack subnational implementation observations.

6 Conclusion

The study identifies distinct governance arrangements across China, the United States, and the European Union, and

capability-related access barriers within the Chinese survey sample. Among contacted respondents, contact intensity was positively associated with process ease, which was associated with health-service responsiveness. The contact-ease association was steeper at lower capability, alongside greater reported access barriers in that group. Evaluating AI-enabled healthcare therefore requires attention both to reaching services and to the experience of using them.

Data availability statement

The raw data supporting the conclusions of this article will be made available by the authors, without undue reservation.

Ethics statement

Ethical approval was not required for the studies involving humans because the study did not involve clinical diagnosis or treatment, human intervention, drug or medical-device testing, biological sample collection, experimental manipulation, or the use of clinical records. It was based on self-reported questionnaire data from adult participants. Participants were informed of the study purpose, survey procedure, data use, and voluntary nature of participation before completing the questionnaire. In accordance with Article 32(2) of the Measures for the Ethical Review of Life Sciences and Medical Research Involving Human Participants, this study was eligible for exemption from ethics review because it used anonymized questionnaire information data and did not involve identifiable clinical information, biological materials, or intervention-related risks. The data were used for statistical analysis and reported only in aggregate form, following the principles of voluntariness, confidentiality, data minimization, and participant protection. The studies were conducted in accordance with the local legislation and institutional requirements. The participants provided their written informed consent to participate in this study.

Author contributions

HT: Methodology, Formal analysis, Conceptualization, Visualization, Writing – original draft, Investigation. SL: Conceptualization, Supervision, Writing – review & editing, Project administration. QW: Investigation, Writing – review & editing, Data curation, Formal analysis, Validation, Visualization.

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Conflict of interest

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Generative AI statement

The author(s) declared that Generative AI was not used in the creation of this manuscript.

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