

Review

Ethical, Legal, and Social Implications of Genomics in China: A Scoping Review and Implications for Precision Public Health

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ABSTRACT

We conducted a scoping review of Chinese language studies on the ethical, legal, and social implications of genomics and identified four broad themes: ethical considerations, regulatory framework, perceptions of genomics and precision medicine, and future directions of genomics. Ethical, legal, and social implications of genomics are growing in importance and are highly relevant to public health in China.

China is one of the six countries involved in the Human Genome Project and is a critically important player in human genome research globally. China's regulatory requirements for genomics research and practices are evolving, and after the birth of the world's first genetically edited babies (1), there has been a renewed interest in assessing the ethical, legal, and social implications (ELSI) of genomics in China.

Applications of genomics lead to Precision Medicine, which tailors treatments to individuals (2), with potentially revolutionary changes in three areas: disease classification, clinical research paradigms, and clinical evidence (3–4). A subsequent concept is Precision Public Health, which is described as “an emerging multidisciplinary field that uses genomics, big data, and machine learning/artificial intelligence to predict health risks and outcomes and to improve health at the population level.” (5) Demand for precision medicine and precision public health will continue to grow after the coronavirus disease 2019 (COVID-19) pandemic subsides, and it is therefore critical to examine the ELSI of genomics for public health (6). We conducted a scoping review of the landscape of ELSI of genomics research in the Chinese scientific literature and explored its public health

implications, including for capacity building and policy development.

METHODS

Our intent was to survey the landscape of ELSI of genomics research and practices in China. We identified studies through a systematic literature search in the three major Chinese citation databases: China National Knowledge Infrastructure (CNKI), Wanfang Database, and Beida Fabao (PKULaw). To be included, articles must be in Chinese and published between January 1, 2000, and December 31, 2020. Two groups of keywords (in Chinese characters) were used in our search*. Reflecting our dual foci on genomics and ELSI, we restricted our scoping review to studies described by one or more keywords from group 1 and one or more keywords from group 2.

We excluded studies related to non-human genome research, such as studies of genetically modified organisms; editorials, news, comments, and conference report collections; studies in settings other than the mainland of China; and articles not in Chinese.

Two reviewers (JX and LJ) independently screened titles and abstracts for eligibility. Inconsistent decisions were resolved through discussion and, when unable to be resolved, were reviewed and decided by the Principal Investigator (ZC).

RESULTS

The initial search yielded 657 articles; there were 37 duplicate records that were excluded. Title and abstract review excluded another 134 records because of wrong publication type (n=36), lack of relevance to human genetics (n=88), or non-Chinese language (n=10). Among the remaining 486 full-text articles, 420 were excluded because of lack of relevance to genomics (n=330), lack of relevance to ELSI (n=70), non-

* Group (1) 基因组学=genomics, 基因测序=genetic testing, 遗传学=genetics, 精准医学=precision medicine, 克隆=clone, and 基因图谱=genetic mapping; and Group (2) 经济学=economics, 伦理=ethics, 法律=law/legal, and 社会=society/social.

Chinese study population (n=17), and wrong outcome (n=3). We identified 23 additional articles by reviewing reference lists and conducting a manual search. In all, 89 studies were included for review and narrative synthesis (Figure 1). A complete list of the studies is in the [Supplementary Material](http://weekly.chinacdc.cn) (available in <http://weekly.chinacdc.cn>).

Four themes emerged from our review: ethical considerations, regulatory framework, perceptions of genetic testing and genetic counseling among physicians and the general public, and future directions for genomics.

Ethical Considerations

Qiu and Zhai outlined ELSI issues related to China's precision medicine strategy, including

informed consent, independent ethics review, privacy protection, and equity in the use of precision medicine research (7). Chen et al. summarized ethical issues related to clinical genetics in China in seven settings — diagnosing hereditary genetic conditions, prenatal diagnosis, newborn screening, making prognoses with genetic information, identifying carriers of pathogenic variants, preimplantation genetic diagnosis, and whole-genome sequencing — and advocated for ethical considerations during genetic testing (8). Tao and Wang cautioned against discrimination in employment, marriage, education, and inclusion based on genetic information, and advocated for desensitization and deidentification of biomedical big data (9).

Likely spurred by the 1996 cloning of Dolly the

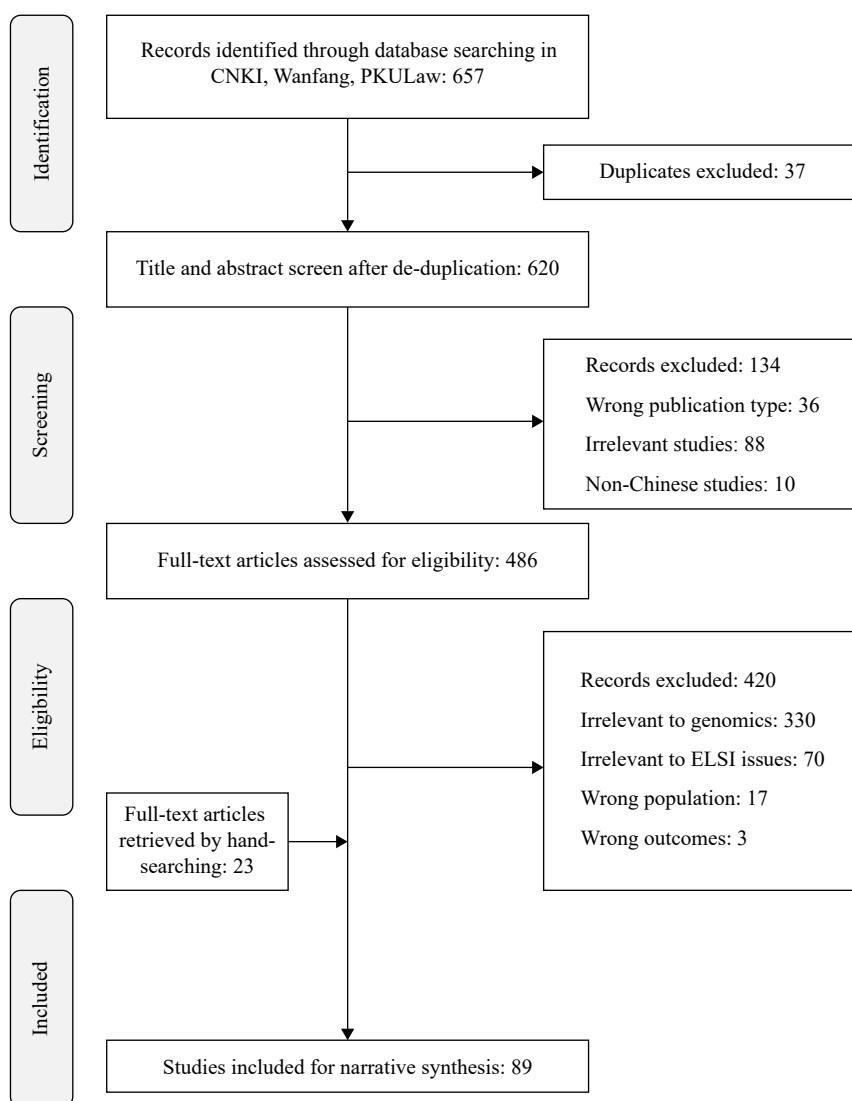


FIGURE 1. Flow chart for literature search of ethical, legal, and social implications of genomics in China. Abbreviation: ELSI=ethical, legal, and social implications; CNKI=China National Knowledge Infrastructure.

sheep, 50 studies had “cloning” in their titles, with additional papers discussing cloning as a component of genomics research. An emerging consensus is a ban on reproductive cloning while allowing the exploration of cloning for research and therapeutics (10).

Regulatory Framework

Research interests in ELSI of genomics in China have grown after the revelation of genetically edited babies (1), with particular attention to informed consent and privacy protection (9,11–12). Other areas of interest include gene patents and over-the-counter genetic testing (GT) (12–14). Recent literature cautions against discrimination based on genetic information (12). Such issues require legal or regulatory oversight and warrant additional discussions.

Wang and colleagues used text analysis to outline key issues on ethical oversight related to GT, including data security and sharing, privacy protection, standard operating procedures, and regulations for clinical use of GT and genetic counseling (GC). Seven regulations require informed consent, and two require informed consent on data reuse. These seven regulations stress protection of patient privacy, but provide limited practical guidance. The article by Wang et al. provides a detailed list of the regulations, and recommends strengthening the existing legal and regulatory framework on ethical issues related to GT, stressing the adaptability, agility, and sensitivity of ethics governance; and providing ethics training for precision medicine practitioners. The “Rule on Human Genetic Resources Management, People’s Republic of China” outlines regulations on collection, preservation, use, provision, services, governance, and legal responsibilities concerning human genetic resources. (9,11)

Perceptions of GT/GC among Physicians and the General Public

A new line of research examines perceptions of GT/GC among physicians and the general public (15–20). Niu and colleagues conducted a stratified random sample survey of Changsha city residents during June–July, 2012 and found positive attitudes toward GT/GC (73.4% of the 399 respondents) but a low level of understanding of GC (19). They found married people and college educated people are more likely to have positive attitudes toward GT. Xu and Zhang assessed public perception and attitude toward GT in Guangzhou City and found limited knowledge

of GT among respondents (20). They predicted higher demand for GT but expressed caution about uncertainties related to wide adoption of GT, given limited familiarity with GT/GC and existing concerns over ethics and privacy protection (20). Cao and colleagues presented quantitative analyses of survey data on the perception of precision medicine and its applications in Shanghai Municipality and Lanzhou City from November 2018 to April 2019 (21). The authors surveyed 2,250 residents and found that residents were attentive to privacy protections, informed consent, and pricing of precision medicine treatment (21). Li et al. found limited knowledge of GT (78.2% of the respondents reported either “never heard of GT” or “just heard about the term GT”) among 1,647 households in Xiacheng District, Hangzhou City (17). Family history, age, and knowledge and attitude toward GT were strongly associated with demand for GT services (17).

Cui and colleagues assessed the perception, attitude, and adoption of precision medicine among 434 clinicians in 48 hospitals across 12 provincial-level administrative divisions (PLADs) (15). Consistent with prior studies, they found limited knowledge of precision medicine among the clinicians. However, 92.6% of the clinicians surveyed believed that precision medicine has clinical utility, and 90.3% would recommend GT to patients who would benefit (15). Bai et al. surveyed 45 physicians in nine public hospitals on knowledge and attitudes toward GT and bioethics (18). They found that young, junior, male physicians tended to have positive views of GT and genetic therapy (18).

Future Directions

The development of ELSI of genomics research can be summarized by the three principles of ethics development for precision medicine that were proposed by Tao and Wang — privacy protection, database development and sharing, and shared responsibility and governance (9). Tao and Wang had four recommendations for future directions: developing ethical principles and rules for precision medicine, providing training on precision medicine ethics, strengthening ethics review for precision medicine research, and developing legal and regulatory framework governing precision medicine.

Guan pointed to a lack of governance on market entry, GC, and licensing and accreditation of genetic counselors in China, as the existing legal requirements and regulations have primarily focused on technology

and laboratory oversight (13). Wu highlighted challenges for clinical guidelines in the era of precision medicine (22).

DISCUSSION AND PUBLIC HEALTH IMPLICATIONS

Our scoping review leads to five critical assessments. First, Chinese researchers have increasingly attended to the key ELSI issues in genomics research and practices, as evidenced by the expanding body of literature on this topic (Figure 2). Second, empirical investigation of ELSI of genomics remains scant. Studies have surveyed attitudes and preferences toward GT/GC among physicians, patients, and the public, with a heavy representation of populations in the south and east of China and in one city (Lanzhou), but no national survey exists. Third, China's regulatory framework over genomics research and precision medicine has been responsive to the growing demand, but with varying pace. Currently, no regulations on over-the-counter GT/GC exist in China (13). Fourth, there has been no research on reimbursement for GT/GC services. Fifth, GC is an emerging field that requires coordinated effort for capacity building and regulatory oversight in China (13).

Conventional wisdom has it that genomics and

precision medicine occur at the individual level, and therefore there is no clearly defined role for public health (23). However, genomics and precision medicine involve multiple levels of interventions, including patient-provider relationships, families, communities, and reimbursement policies (23). Precision public health was a key tool in the COVID-19 response by helping to provide the right interventions for the right populations and by helping to reduce health disparities (24). With predictive analytics, genomics extends its reach from precision medicine to precision public health (25). The Evaluation of Genomic Applications in Practice and Prevention Initiative provides an example of precision public health practice (26). Our review offers important implications for the emerging field of precision public health in China by assessing the landscape of ELSI of genomics in China.

Our review has two important limitations. First, we limited our search to studies published in Chinese. While this was by design to identify studies more relevant to the genomics research and practice in China, we may have missed important literature on ELSI of genomics published in other languages by Chinese authors. Second, we did not assess study quality because most retrieved studies were qualitative in nature. As the literature on ELSI of genomics in China continues to expand, we will revisit this topic

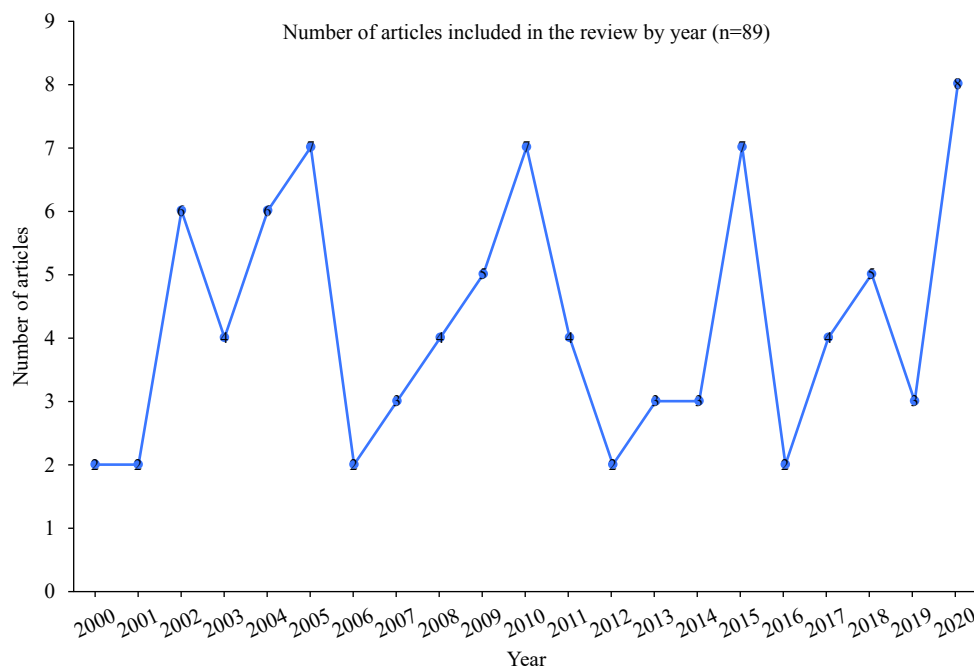


FIGURE 2. Number of publications on ethical, legal, and social implications of genomics in Chinese language included in our review by year of publication.

and update our review.

CONCLUSIONS

We conducted a scoping review of studies on ELSI of genomics in the Chinese language and identified four broad themes of the literature — ethical considerations, regulatory framework, perceptions of genomics and precision medicine, and future directions. We conclude that ELSI of genomics is a growing field and is highly relevant to public health in China.

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SUPPLEMENTARY MATERIALS

LIST OF STUDIES

Ethical Considerations (50)

1. He YJ. The ethical predicament and its countermeasures about therapeutic clone-technology. *Chin J Soc Med* 2007;24(3):196 – 8. <https://kns.cnki.net/kcms/detail/detail.aspx?FileName=GWSY200703020&DbName=CJFQ2007>. (In Chinese).
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