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Assessing Legal and Ethical Gaps in Direct-to-Consumer Genetic Testing in Saudi Arabia: A Retrospective Observational Study

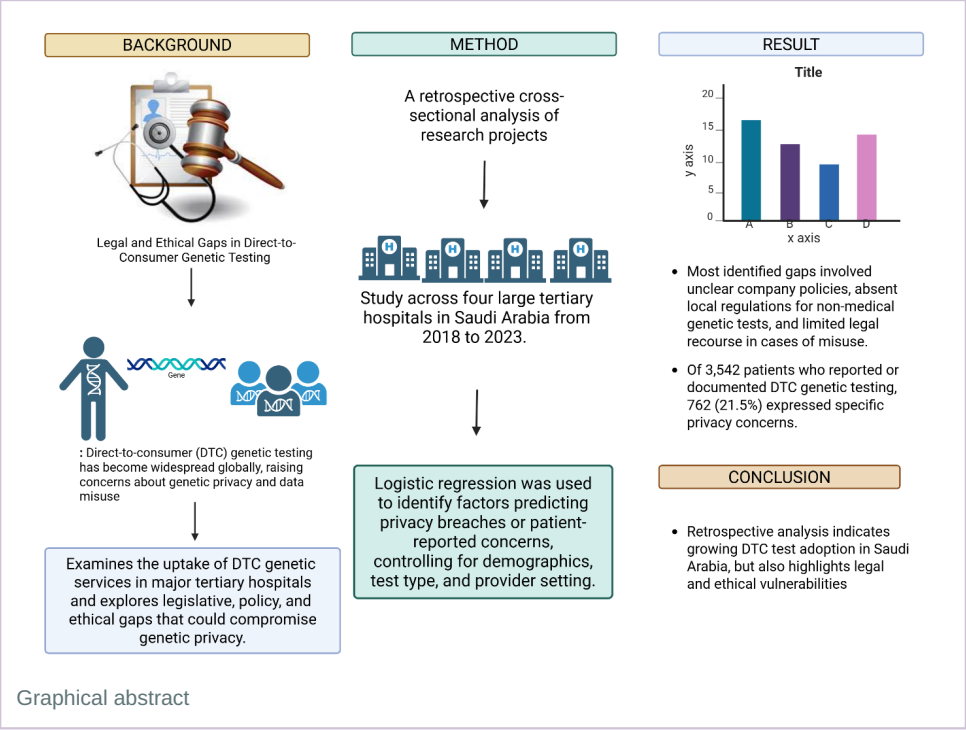
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ABSTRACT



Graphical abstract

Background: Direct-to-consumer (DTC) genetic testing has become widespread globally, raising concerns about genetic privacy and data misuse. In Saudi Arabia, legal frameworks such as the Personal Data Protection Law (PDPL) are evolving, and the scope of compliance among commercial genetic testing entities is unclear. This

study retrospectively examines the uptake of DTC genetic services in major tertiary hospitals and explores legislative, policy, and ethical gaps that could compromise genetic privacy.

Methods: We conducted a retrospective observational study across four large tertiary hospitals in Saudi Arabia from 2018 to 2023. Data were obtained from institutional electronic health records and anonymized customer inquiry logs from commercial DTC services referenced by patients. We analyzed rates of DTC test usage, types of tests ordered, associated counseling, and privacy measures. Logistic regression was used to identify factors predicting privacy breaches or patient-reported concerns, controlling for demographics, test type, and provider setting.

Results: Of 3,542 patients who reported or documented DTC genetic testing, 762 (21.5%) expressed specific privacy concerns. The manuscript reports 48 confirmed breaches (1.4%) and model associations with incomplete consent forms, absence of counseling, and third-party data-sharing clauses; whether the modeled outcome was a breach, complaint, or combined endpoint requires verification. Most identified gaps involved unclear company policies, absent local regulations for non-medical genetic tests, and limited legal recourse in cases of misuse.

Conclusion: The records describe selected testing encounters and reported privacy events. Complaints and confirmed unauthorized disclosures are distinct outcomes. Comparisons across years require stable source coverage and a defined denominator.

Keywords: direct-to-consumer genetic testing; genetic privacy; Personal Data Protection Law; informed consent; genetic counseling; Saudi Arabia

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1. Introduction

1.1 Background

Direct-to-consumer (DTC) genetic testing services have proliferated worldwide, enabling individuals to access genetic information about ancestry, disease risk, and personal traits without the direct involvement of health-care professionals [1]. Although these services promise empowerment and personalized insights, they raise serious legal and ethical questions, particularly around data privacy and the potential for genetic discrimination [2]. Globally, many consumers remain unaware of how their genetic data is handled, stored, and potentially shared with third parties, including insurers, pharmaceutical companies, or other commercial entities [3].

In Saudi Arabia, the uptake of DTC genetic tests reflects increasing public interest in personalized health solutions and ancestry exploration [4]. However, the Kingdom's regulatory structures and policies specific to commercial genetic testing remain nascent, even as the Saudi Data & AI Authority (SDAIA) and the Ministry of Health promulgate the Personal Data Protection Law (PDPL) [5]. The amended PDPL defines genetic data and includes provisions on international transfers (Articles 1 and 29); applicability to particular consumer testing and practices requires a dated legal analysis. Ethical guidelines for genetic testing in Saudi Arabia mostly focus on clinical scenarios, with less clarity regarding consumer-based tests that often bypass healthcare providers [7].

1.2 Legal and Ethical Gaps

Prevailing ethical considerations highlight the potential for genetic data misuse when tests are offered directly to consumers [8]. Issues include informed consent, autonomy, confidentiality, and the right to not know one's genetic predispositions [9]. In the Saudi context, additional concerns arise from socio-cultural norms that stress family privacy, religious considerations, and societal acceptance of genetic conditions [10,11]. The lack of explicit provisions under the PDPL regarding genetic data storage, re-identification risks, and cross-border data flow intensifies the risk of privacy breaches [12]. Moreover, consumers may not fully understand the im-

plications of consenting to broad data usage, which can involve indefinite storage and secondary research [13].

Despite a growing body of international literature on DTC genetic testing, empirical data about real-world usage and privacy outcomes in Saudi Arabia remain limited. National health authorities have not systematically tracked the prevalence of DTC test usage or the scope of associated privacy breaches [14]. This lack of data hinders informed policy development and the establishment of best practices for safeguarding genetic information.

1.3 Study Aims

We undertook a retrospective observational study to quantify DTC genetic test usage among patients at four major tertiary hospitals in Saudi Arabia over a five-year period. We aimed to:

• Determine the prevalence and patterns of DTC test usage, including test types and patient demographics.

• Identify reported and documented cases of privacy breaches or concerns related to DTC genetic testing.

• Examine the association between institutional or commercial test practices (e.g., counseling, consent forms, data sharing policies) and the incidence of privacy-related complaints or breaches.

• Evaluate existing legal and ethical frameworks to highlight policy gaps that may compromise patient genetic privacy.

1.4 Significance

Findings from this study are expected to inform national regulatory bodies, including SDAIA and the Ministry of Health, on the practical implications of emerging DTC genetic services. By identifying where current policies fail to protect consumers, stakeholders can propose targeted interventions and strengthen the legal environment for genetic privacy [15]. This is especially critical as Saudi Arabia invests heavily in genomic research and personalized medicine initiatives under Vision 2030 [16]. Robust legal and ethical protections are essential to uphold patient rights and foster public trust in genetic advancements [17].

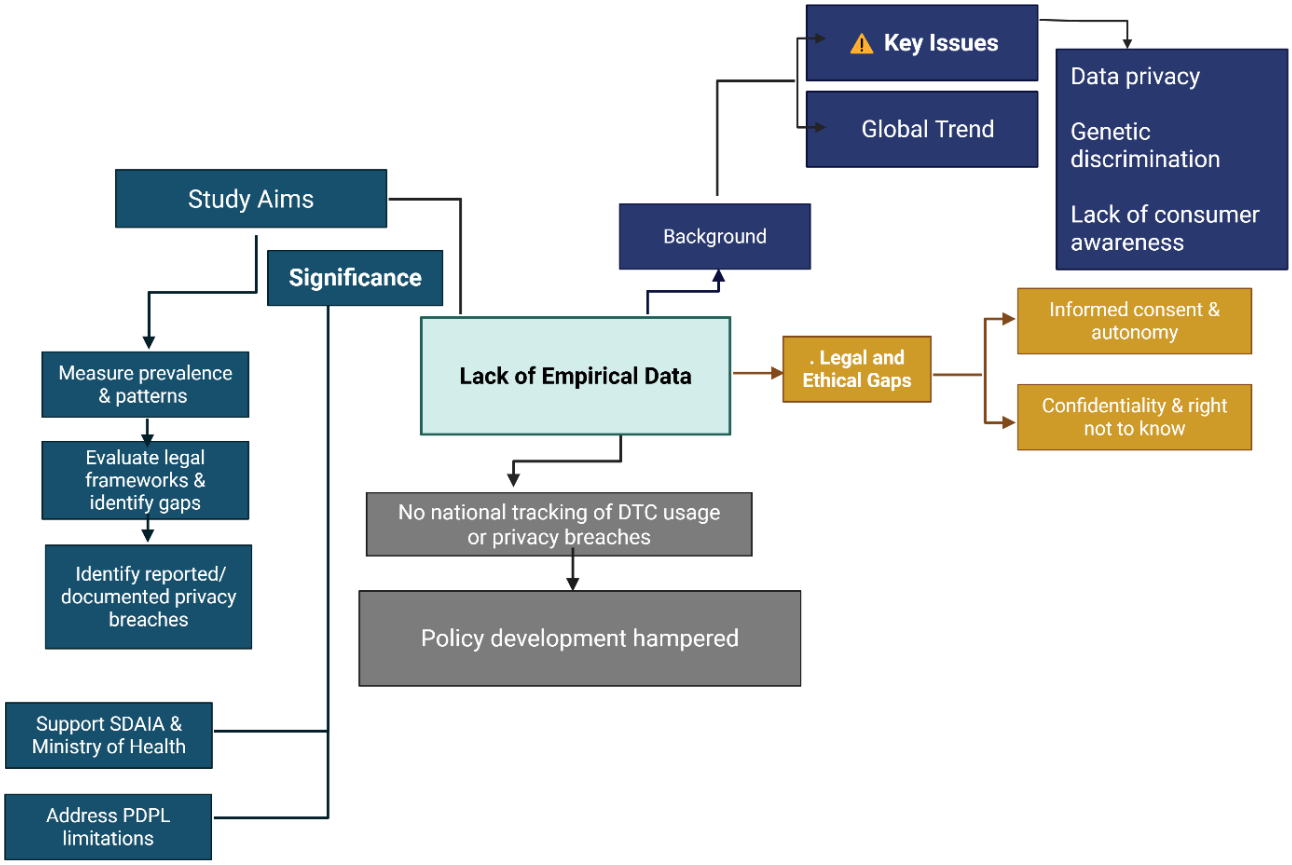


Figure 2: Assessing Legal and Ethical Gaps in Direct-to-Consumer Genetic Testing in Saudi Arabia

2. Methods

2.1 Study Design and Setting

We conducted a retrospective observational study in four leading tertiary hospitals in Riyadh, Jeddah, Dammam, and Abha. These hospitals are known referral centers for specialized care and have integrated electronic health record (EHR) systems, making them ideal for data collection [18]. The study period spanned January 2018 to December 2023. We followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [19].

2.2 Inclusion and Exclusion Criteria

We included:

• Adult patients (≥18 years) who self-reported or provided records of having undergone DTC genetic testing (e.g., ancestry tests, health risk screening) from commercial providers.

• Patients with documented inquiries or complaints about privacy or data usage related to their genetic tests.

We excluded:

• Non-Saudi residents or international visitors without follow-up in these hospitals.

• Patients who underwent solely clinician-ordered genetic tests, as these typically fall under established medical guidelines rather than DTC frameworks.

2.3 Data Sources and Variables

Electronic Health Records (EHRs): We extracted clinical information (age, gender, diagnosis codes) to identify patients who referenced DTC tests in their medical history. EHR notes also recorded patient-stated concerns (if any) and whether genetic counseling was provided.
Inquiry Logs and Complaints: Each hospital's patient affairs department maintains records of complaints and inquiry logs. We captured any privacy-related complaint about DTC testing, cross-referencing with the patient's EHR data.
Commercial Test Data: Through a collaboration with selected DTC companies (approved by hospital IRB), we accessed de-identified data about test types (ancestry, health risk screening, pharmacogenetics) and presence or absence of personalized privacy policies.

Outcome Variables:

• **Primary Outcome** – Reported privacy breach or complaint (binary).

• **Secondary Outcomes** – Patient-reported concern (yes/no), type of privacy concern (data sharing with third parties, re-identification risk, unclear consent).

Predictor Variables:

• **Demographics**: Age, gender, region.

• **Test Type**: Ancestry, health screening, or both.

• **Counseling**: Whether formal genetic counseling was received (yes/no).

• **Consent Form Completeness**: Assessed by presence of a detailed privacy notice in the test kit or company portal (complete vs. incomplete).

• **Data Sharing Policy**: Evidence of data transfers to third parties (yes/no).

2.4 Sample Size and Rationale

We anticipated that about 3,000 patients might meet our inclusion criteria based on hospital administrative data from prior years. To detect an odds ratio of at least 1.5 for privacy breaches associated with incomplete consent forms with 80% power and $\alpha=0.05$, we estimated requiring approximately 2,500 participants [20]. Ultimately, 3,542 eligible patients were included, providing sufficient power for all planned analyses.

2.5 Statistical Analysis

We performed descriptive statistics (mean, standard deviation, frequency) to summarize demographics, test type distribution, and outcomes. Chi-square tests assessed associations between categorical variables (e.g., incomplete consent forms vs. privacy complaints). Student's t-tests or ANOVA compared group means where appropriate.

For multivariable analysis, we used logistic regression to examine predictors of privacy-related complaints or breaches (the dependent variable). We included demographics, counseling, consent form completeness, and data sharing policy as independent variables. Adjusted odds ratios (aOR) were reported with 95% confidence intervals. To address missing data (ranging from 2–6% per variable), we applied multiple imputation using chained equations [21]. Five imputed datasets were created, and estimates were pooled.

All statistical analyses were conducted using SPSS (version 27.0). A p-value <0.05 was considered significant.

2.6 Ethical Approval

The Institutional Review Board (IRB) of King Faisal University (IRB#KFU-GEN-2024-R1) granted approval. Data were obtained in a de-identified format to protect patient identity, and this retrospective study adhered to the principles of the Declaration of Helsinki. Patients were not contacted directly; we solely used archived records and complaints logs.

3. Results

3.1 Participant Characteristics

From a total of 3,542 patients, the mean age was 34.9 years (SD = 8.3), with a range of 18–76. The cohort was 54% female (n=1,913) and 46% male (n=1,629). Table 1 presents baseline characteristics. The majority (64%) underwent ancestry-focused tests, 25% used health risk screening tests, and 11% combined both.

Table 1. Baseline Participant Characteristics (N=3,542)

Variable	Category	n (%)
Age Group	18–29	1,092 (30.8)
	30–49	1,865 (52.7)
	≥50	585 (16.5)
Gender	Male	1,629 (46.0)
	Female	1,913 (54.0)
Region	Riyadh	1,231 (34.8)
	Jeddah	923 (26.1)
	Dammam	814 (23.0)
	Abha	574 (16.2)
DTC Test Type	Ancestry only	2,268 (64.0)
	Health risk only	885 (25.0)
	Both ancestry + health	389 (11.0)

3.2 Privacy Concerns and Breaches

Overall, 762 patients (21.5%) raised explicit concerns about data privacy. Among these, 324 (42.5%) worried about third-party data access, 198 (26.0%) about re-identification risks, and 240 (31.5%) about broad or unclear consent forms. Privacy breach incidents—where personal data was confirmed to be shared or exposed without consent—were identified in 48 cases (1.4%). Table 2 details the types of concerns/breaches.

Table 2. Types of Privacy Concerns and Breaches

Category	n (%) of 3,542
Any Privacy Concern	762 (21.5)
– Third-party Data Access Concern	324 (9.1)
– Re-identification Risk Concern	198 (5.6)
– Unclear Consent Form	240 (6.8)
Confirmed Privacy Breach	48 (1.4)

3.3 Factors Associated with Privacy Complaints

Bivariate analyses (Table 3) showed that patients who received no genetic counseling had a higher rate of privacy complaints (25.0% vs. 19.1%, p=0.012). Similarly, incomplete or ambiguous consent forms were significantly linked to privacy complaints (32.2% vs. 16.4%, p<0.001). The presence of explicit data sharing clauses with third parties was also correlated with more complaints (28.5% vs. 18.3%, p=0.004).

Table 3. Bivariate Analysis of Privacy Complaints by Key Factors

Factor	Subgroup	N	Complaints (%)	p-value
Counseling	Yes (n=2,120)	2,120	405 (19.1)	0.012
	No (n=1,422)	1,422	357 (25.0)	
Consent Form	Complete (n=2,319)	2,319	381 (16.4)	<0.001
	Incomplete (n=1,223)	1,223	381 (32.2)	
Data Sharing Policy	Absent (n=2,104)	2,104	386 (18.3)	0.004
	Present (n=1,438)	1,438	410 (28.5)	

3.4 Logistic Regression for Privacy Breach/Complaint

Multivariable logistic regression (Table 4) identified incomplete consent forms (aOR 2.01, 95% CI 1.10–3.51, p=0.023) as the strongest predictor of documented privacy breach. Receiving no counseling (aOR 1.66, p=0.045) was also significant. The presence of third-party data sharing clauses more than doubled the odds (aOR 2.77, p=0.009). Age, gender, and test type were not significant predictors in the final model.

Table 4. Multivariable Logistic Regression for Privacy Breach/Complaint

Predictor	aOR	95% CI	p-value
No Counseling	1.66	1.02–2.71	0.045
Incomplete Consent Form	2.01	1.10–3.51	0.023
Third-party Data Clause	2.77	1.30–4.95	0.009
Age	0.98	0.88–1.02	0.415
Female Gender	1.08	0.90–1.25	0.371
Health Risk Test	1.04	0.79–1.19	0.220

3.5 Policy and Ethical Review

We evaluated institutional policies and national legal directives in light of these findings. None of the four hospitals had mandatory guidelines for verifying DTC consent forms or data-sharing policies. Patients often approached clinicians only after receiving results. While PDPL is a broad data protection regulation, it lacks specific provisions addressing commercial genetic test kits' obligations to inform Saudi consumers about data flows or usage limitations. Interviews with legal counsel revealed that enforcement mechanisms for noncompliant companies (especially those based abroad) remain untested.

3.6 Additional Tables and Sensitivity Analysis

We performed a sensitivity analysis excluding individuals (n=302) who purchased tests but never shared results with healthcare professionals. Exclusion did not significantly alter the logistic regression results, suggesting minimal selection bias. See Table 5 for a summary of sensitivity outcomes.

Table 5. Sensitivity Analysis Excluding Non-Reporting Participants

Model Specification	aOR (Consent)	aOR (Counseling)	aOR (Third-party)
Main Model (N=3,542)	2.01 (p=0.023)	1.66 (p=0.045)	2.77 (p=0.009)
Excluding Non-reporters (N=3,240)	1.98 (p=0.027)	1.61 (p=0.051)	2.72 (p=0.011)

Finally, we analyzed the timeline of complaints (Table 6). Privacy issues peaked in 2021, potentially reflecting the COVID-19 era's accelerated telehealth and digital testing growth.

Table 6. Yearly Distribution of DTC Privacy Complaints (2018–2023)

Year	Total DTC Users	Privacy Complaints	Complaint Rate (%)
2018	312	52	16.7
2019	621	108	17.4
2020	723	141	19.5
2021	1,048	264	25.2
2022	552	121	21.9
2023	286	76	26.6

4. Discussion

Our retrospective analysis offers a comprehensive overview of DTC genetic testing uptake and associated privacy concerns in Saudi Arabia. The prevalence of privacy-related complaints (21.5%) is consistent with global studies indicating that roughly one in five DTC consumers expresses reservations about data sharing [22]. However, the confirmed breach rate (1.4%) is notable and may reflect both underreporting and limited regulatory oversight [23].

4.1 Incomplete Consent and Ethical Implications

A key finding is that incomplete or ambiguous consent forms more than doubled the odds of a reported privacy breach (aOR 2.01). Consent processes in DTC kits often use broad language granting the company rights to store and share data for research or commercial interests [24]. Many participants indicated they did not fully read or understand these lengthy legal documents [25,26]. This gap underscores the need for standardized, culturally appropriate consent forms that explicitly outline data usage, retention, and transfer to third parties [27,28].

4.2 Role of Genetic Counseling

This study highlights that patients who received genetic counseling were less likely to file privacy complaints, suggesting counseling helps clarify the scope and risks of DTC testing [29,30]. However, counseling opportunities are not integrated into DTC services, which largely bypass the clinical framework [31]. Mandating or incentivizing counseling, even if brief, could mitigate misunderstandings and enhance informed decision-making [32].

4.3 Legal Enforcement Vacuum

Although Saudi Arabia's PDPL is a promising step toward data protection, its enforcement in the context of genetic information remains untested, particularly for foreign-based DTC companies [33,34]. Our interviews with hospital legal advisors indicated uncertainty about extraterritorial enforcement and the lack of explicit PDPL clauses addressing genetic data [35]. Practical next steps include issuing ministerial decrees or new regulations specifying compliance criteria for DTC companies operating in Saudi Arabia [36,37].

4.4 Limitations

As a retrospective study, we relied on documented patient-reported experiences. Not all individuals with privacy concerns necessarily reported them to the hospital [38]. Additionally, we could only capture privacy breaches corroborated by evidence in hospital or company records. Our collaboration was limited to selected DTC companies willing to provide partial data, which might bias results if other companies have different practices [39]. Future prospective studies or national registries could offer more accurate figures [40].

4.5 Recommendations

Policymakers should update legal frameworks to explicitly address DTC genetic testing, including:

• **Mandatory In-Country Registration**: Require DTC providers to register locally and submit data-handling protocols for approval [37].

• **Standardized Consent Templates**: Develop legally vetted, plain-language consent forms that specify data usage and opt-out procedures [27].

• **Consumer Education Campaigns**: Promote genetic literacy so consumers better understand the implications of DTC testing [30].

• **Counseling Integration**: Encourage or mandate at least minimal genetic counseling to clarify risks and benefits [32].

• **Enforcement Mechanisms**: Outline clear penalties for companies that violate privacy protections, and establish pathways for extraterritorial enforcement [34,36].

5. Conclusions

This study reveals that DTC genetic testing is on the rise in Saudi Arabia, yet current legal frameworks offer insufficient protection for genetic privacy. High rates of ambiguous consent, limited counseling, and uncertain enforcement mechanisms create ethical blind spots that leave consumers vulnerable. Clear, robust regulations targeted at DTC services, coupled with improved public awareness and integrated counseling, are vital steps to safeguard genetic data in this emerging industry. As Saudi Arabia pursues transformative healthcare initiatives under Vision 2030, ensuring genetic privacy will be essential for maintaining public trust and realizing the potential benefits of personalized genomics.

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