Report of the State Comptroller of Israel | November 2024

The Ministry of Health

In Vitro Fertilization in Israel – Regulatory and Supervisory Aspects

In Vitro Fertilization in Israel – Regulatory and Supervisory Aspects

Background

The longing for children is a fundamental aspect of humanity and is often regarded as a crucial element of personal fulfillment. However, some couples or individuals encounter challenges in conceiving due to fertility issues (infertility). In vitro fertilization (IVF) is a widely used treatment for those unable to conceive naturally. In recent years, there has been a notable increase in the number of IVF procedures conducted in Israel. The regulatory authority overseeing IVF treatments in Israel is the Ministry of Health, which has recognized 26 IVF units over the years: 22 in public hospitals[1] and four in private hospitals[2].

IVF gained significant public attention in Israel in September 2022 when the Ministry of Health revealed that during an examination of an embryo following IVF treatment performed in one of the units, it was found that the embryo was mistakenly returned not to the biological mother's uterus. In response, the Medical Professions Ombudsman instructed the formation of an inspection committee on behalf of the Ministry of Health, under Section 21(a)(3) of the Patient's Rights Law, 1996, to investigate the circumstances of the case. The committee presented its findings to the Ombudsman in March 2023[3] (the March 2023 Inspection Committee). Subsequently, in May 2023, the Ministry of Health reported additional irregularities involving another unit: a case where a child born through IVF lacked a genetic connection to the father, as well as two instances of the dehydration of fertilized eggs. As of May 2024, the above-mentioned inspection committee has not yet concluded its efforts. These events instigated considerable public concern and among couples and women who had previously undergone IVF treatments, prompting fears that their child may not be their biological offspring and that another family might raise their biological child. In September 2023, the biological parents of

1 Units in government-owned, public, or Clalit Health Services-owned hospitals.

2 Units in privately owned hospitals.

3 The Ministry of Health outlines that the inspection committee's role involves presenting a comprehensive and accurate factual background of incidents to the competent authority, on the basis of which the competent authority will take the necessary actions, including drawing conclusions and making personal, organizational, and organization-wide recommendations. From the personal perspective, the inspection committee's report represents merely one phase in the decision-making process, which may also entail a decision to initiate disciplinary proceedings. The systemic conclusions drawn in the committee's report require immediate attention from the management of the reporting institutions and the relevant authorities within the Ministry of Health. Consequently, according to the Ministry of Health, inspection committees are positioned as risk management tools, highlighting the causes of identified treatment failures and proposing preventive measures to avert recurrence of similar incidents. See the Ministry of Health, Summaries of Reports of 100 Inspection Committees – Drawing Lessons from Irregular Events, Medical Professions Ombudsman, Service Division, Quality and Safety Administration, 2016.

the infant born following the embryo transfer error were identified. This situation remains distressing for those involved, including numerous patients who have feared the possibility of being the child's biological parents. One woman, whom a hospital committee formed to evaluate the circumstances surrounding the incident believed that the fetus may indeed be her biological child, expressed her concerns[4]:

> "The doubt we have been struggling with over the last months can make a person go insane. The thought that we must live with this doubt for the rest of our lives is inhumane and insufferable. This is not a doubt as to the whereabouts of a lost object that cannot be found, but rather a doubt concerning life – a baby, a wish, heart's desire."

The Ministry of Health has indicated that the excess burden in the units where the irregular incidents occurred contributed to their occurrence.[5]

Given the expanding scope of IVF treatments in Israel and the irregular incidents that have transpired in this domain, the State Comptroller has examined various aspects regarding the increase in the IVF treatments scope in Israel and the implications and aspects of regulation and supervision by the Ministry of Health in this area.

4 Submitted to the Supreme Court in Leave to Appeal 23/856 Anonymous v. Anonymous, judgment dated March 6, 2023.

5 Ministry of Health spokesperson's statement dated February 22, 2023 on the main conclusions of the inspection committee's report regarding the circumstances that caused an error during in vitro fertilization in a patient; Ministry of Health spokesperson's statement dated July 20, 2023.

Key Figures

61,000

the number of IVF cycles performed in Israel in 2021. An increase of about 60% since 2011

1st place

Israel tops the list of countries examined in the number of treatment cycles per 1,000 women of reproductive age, with 27 treatment cycles compared to 6 cycles in the UK

about NIS 450 million

total expenses for IVF treatments in 2023: NIS 323 million paid by the four HMOs from the Health Basket and about NIS 128 million from the Additional Health Services programs[6]

4

private units performed 60% of IVF procedures[7] in 2021. Only 40% of IVF procedures were performed in 2021 in public units (21 units operating at the time)

8-fold

the ratio between the average number of procedures performed in a private unit and the average number of procedures performed in a public unit in 2021 (15,250 versus 1,900, respectively)

45%

the shortage rate of embryologists in all units (111 embryologists) compared to the required in the Ministry of Health's benchmarks draft from 2017

14 of 26 units

whose volume of treatment cycles performed in them was about 60%, did not report to the national database via an automated interface as of October 2023. This affected the volume and quality of the units' reports

6 It should be noted that there are additional costs that were not included, such as the cost of medications, which are partly borne by the patients. In addition, there are treatments that are not performed specifically within the framework of IVF treatments, such as insemination, and therefore they were also not included in the calculation of costs. It should also be noted that there are couples and individuals who finance the treatments themselves directly or through their private insurance.

7 It should be noted that the number of procedures does not coincide with the number of treatment cycles, as several procedures are performed in some treatment cycles. As part of the analysis, data on the codes of the main procedures related to the field of in vitro fertilization were analyzed. These procedures account for approximately 99.5% of all procedures performed in in vitro fertilization units. Below is a list of codes: L8970 – In vitro fertilization, IVF stage A, including hormonal tests; L8971 – In vitro fertilization, IVF stage A, without hormonal tests; L8972 – In vitro fertilization, IVF stage B, excluding hospitalization days; L8977 – Egg retrieval and freezing, such as by the vitrification method; 58974 – Return of frozen embryos to the uterine cavity; 89280 – Micromanipulation in IVF, using various methods; 89290 – Genetic diagnosis before transferring an embryo to the uterus, by taking a sample and testing it, PGD.

Audit Actions

From March 2023 to January 2024, the State Comptroller's office audited various aspects of Israel's in vitro fertilization (IVF) policy. The audit examined the Ministry of Health's inspections of IVF units, reports of special (irregular) incidents within these units, the shortage of embryologists[8], and the management of frozen embryos and eggs left unclaimed. The audit focused on assessing the information available at the national level9. The audit was conducted at the Ministry of Health and the Gertner Institute for Epidemiology and Health Policy Research, which supervises the national database for IVF treatments. Additional examinations were conducted from April to July 2024. Moreover, the audit conducted site visits at eight IVF units nationwide, and data was collected from 18 units.

As of the audit end date, some public and private units are not audited bodies under the State Comptroller Law, 1958 [consolidated version]. This report primarily addresses the activities of the Ministry of Health as the regulatory authority for in vitro fertilization.

Key Findings

The Need to Asses the IVF Treatment Policy – the public funding policy in Israel deviates from that of the examined countries – in the maximum age for women eligible for funding, which is set at 45 years[10], one of the primary factors influencing treatment success rates, and in the number of treatment cycles for which women are entitled to receive funding – which in Israel is nearly unlimited. In the countries examined[11], the age limit for public financing ranges from 35 to 43 years, lower than in Israel, and the number of funded cycles is restricted compared to their number in Israel[12]. Concerns have been raised regarding the Ministry of Health's lack of data on the number of IVF

8 IVF laboratory workers.

9 See a previous report on the subject: State Comptroller, Annual Report 63C for the year 2012 and the accounts for the fiscal year 2011 (published in 2012), "In Vitro Fertilization – IVF".

10 It should be noted that the age restriction applies to performing additional egg retrievals. Frozen fertilized eggs can be returned even after this age.

11 Canada – Ontario; Belgium; France; Slovenia; Canada – Quebec; Croatia; Lithuania; England; Ireland; Austria; Finland; Germany; Portugal; Serbia; Spain; Sweden; Czech Republic; Ukraine; Albania; Georgia; Latvia; Switzerland.

12 The number of publicly funded treatment cycles ranges from one to six cycles. It should be noted that there are countries where there is no public funding for these treatments at all.

treatment cycles undertaken by each woman, specifically concerning public funding (as opposed to the total number of cycles).

Over the years, various professional entities have advocated updating the eligibility policy for publicly funded IVF treatment, raising concerns that the current policy may lead to treatments with exceedingly low success rates (based on patient age and their previous failed attempts), a situation incurring both physical and psychological costs for patients and leading to a misallocation of resources, including public funds. Experts have also noted that the continuation of such treatments may prevent patients from exploring alternatives, such as egg donation, ultimately resulting in considerable delays in achieving parenthood, and recommended that changes in egg donation financing mechanisms be considered. As of January 2024, the eligibility policy for IVF treatments has not changed.

- **Lack of National Preparedness for the Significant Increase in the IVF Treatments Volume in Israel –** in recent years, there has been a substantial rise in the annual number of IVF cycles, with about 61,000 performed in 2021 – an increase of about 23,000 cycles, or roughly 60%, over the decade from 2011 to 2021. Despite the Ministry of Health's awareness of these trends, and although significant gaps were raised in some of the units in infrastructure and human resources in the laboratories, which required preparation at the national level, until the occurrence of the irregular incidents in the two units, no proactive measures were taken by the Ministry of Health to address the consequences of the significant increase in the volume of IVF treatments and to ensure the quality of treatment in parallel with this increase. The State Comptroller's Office noted to the Ministry of Health that its past actions have failed to address the increasing volume of IVF cycles adequately, the resultant pressures on some units, and the necessary rectification of the deficiencies identified in the Ministry of Health audits regarding some of the units. The absence of comprehensive measures to address the substantial rise in treatments within specific units has led to an operational environment with a disparity between the demands imposed and the available workforce and infrastructure.

- **A Fundamental Shift in the Service Provider Identity Following the Reallocation of Activities Financed by the Additional Health Services Plans to Public Financing (the Health Basket) –** in late 2017, a plan was initiated to shift activities from private to public financing to reduce waiting times. This plan permitted patients to receive IVF treatments under the Health Basket framework at private hospital units, and not only in the public hospitals' units, as before its implementation. Data analysis indicates that this plan resulted in a notable increase in public-funded IVF activities while concurrently decreasing those financed by the Additional Health Services plans. In 2015–2021, the volume of procedures funded by the Health Basket tripled (from about 22,000 to 67,000), while those financed by the Additional Health Services plans declined by about 17% (from about 40,000 to 33,000). According to the Ministry

of Health data, Additional Health Services plans expenditures on IVF treatments[13] decreased by about NIS 51.5 million in 2021 compared to 2015. This holds financial implications for patients, as treatments conducted under the Health Basket funding do not require patient co-payments, unlike those financed by the Additional Health Services plans.

However, over time, public committees investigating the issue have highlighted disparities between the public and private health systems. They have noted that private system activities are profit-driven, focusing on profitable areas and less severe cases; They engage less in promoting research, education, and personnel training than the public system; And exhibit inferior quality control. Furthermore, these committees expressed concern that the private system's activities could detrimentally affect public system operations, potentially diverting activities and personnel. The plan's implementation has fundamentally altered the identity of service providers in health basket financing, with a significant portion (46%) of IVF activities financed by the Health Basket now being carried out in private hospitals rather than public hospitals.

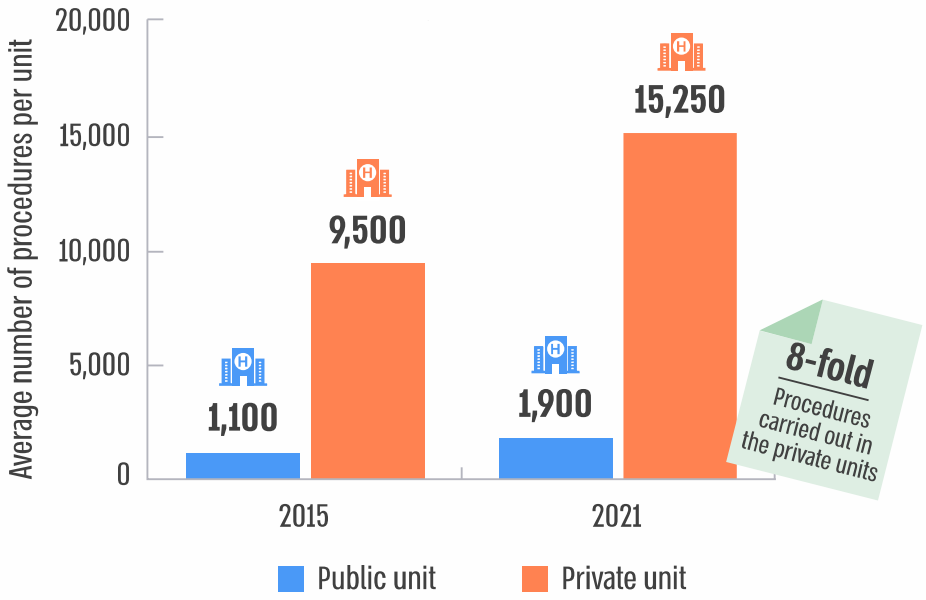
The Implications of Increased Procedures in the Private Units – the March 2023 Inspection Committee concluded that reducing waiting times caused patients to shift from health basket treatments to private hospital IVF units. State Comptroller's Office Analysis indicated that as of 2021:

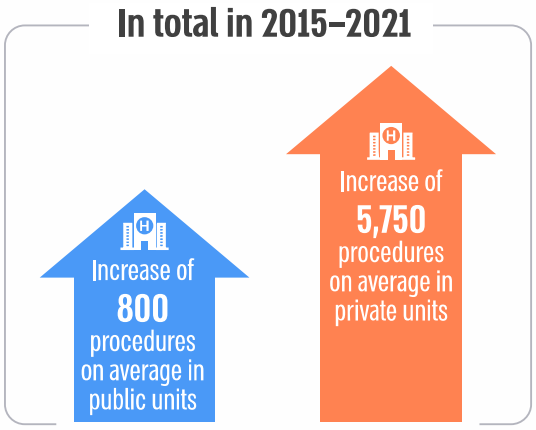
- 60% of IVF procedures were concentrated in four private units, while 40% were distributed among 21 public units.
- The average number of procedures in a private unit was 15,250, eight times that of a public unit, which averaged 1,900 procedures.
- In 2015–2021, there was an increased average of 800 procedures in each public unit, whereas in private units, there was an increased average of 5,750 procedures per unit.

The substantial rise in procedures conducted in private units has exposed patients to considerable risks. Such increases could lead to overburdening and compromised treatment quality if inadequate personnel, infrastructure, and supervision mechanisms are not supported. The March 2023 Inspection Committee report indicated that unit workload was a primary factor in the occurrence of the incident. In July 2023, the Ministry of Health acknowledged that other irregular incidents in a different unit were similarly linked to excessive workloads. As of May 2024, the investigation into these additional irregular incidents has yet to conclude.

13 It should be noted that the calculation was made based on the Ministry of Health price list for 2021, and not on the price actually paid by the HMOs.

The Average Increase in the Number of IVF Procedures in Public and Private Units, 2015 and 2021





According to HMOs data as forwarded by the Ministry of Health to the Office of the State Comptroller (data rounded), analyzed and processed by the Office of the State Comptroller.

The Ministry of Health's Shortage of IVF Work Procedures – it has been noted that although a benchmarks draft was formulated in 2017 addressing all activities of the IVF unit, including the associated laboratory, the Ministry of Health's inspections based on these benchmarks in 2018–2019 have not resulted in the completion of mandatory

benchmarks as of January 2024. Consequently, the status of these benchmarks remains in draft form nearly six years after their initial formulation.

Currently, the valid procedure is the Ministry of Health's 2014 procedure, which predates the audit end date by almost a decade. This procedure pertains exclusively to laboratories and was already identified in 2017 as incomplete in regulating the unit's full spectrum of operations, including the clinic, laboratory, operating room, and recovery room. Moreover, the 2014 procedure lacks specificity regarding laboratory staffing, failing to establish a binding standard for the number of embryologists in laboratories with treatment cycles exceeding 1,200, thereby leaving this determination to the discretion of the unit.

- **Deficiencies and Gaps Raised in the Ministry of Health's Audits of IVF Units About Three Years Before the Irregular Incident in September 2022, and No Follow-up on the Rectification –** the Ministry of Health's dedicated audits in 2018–2019 across all IVF units raised significant gaps regarding the quality and safety of treatments. These deficiencies included laboratory and laboratory director licensing, staffing inadequacies, patient identification failures, insufficient information in patient files medical records, and shortcomings in equipment and infrastructure. It should be noted that not all units exhibited significant deficiencies; Some were found, in said audits, to adhere to high professional standards.

Examples of Deficiencies and Gaps Raised by the Ministry of Health's Audits in Some IVF Units, 2018– 2019

Deficiencies in the licensing of the laboratory and the laboratory director	Lack of a licensing certificate for the laboratory; Lack of a senior embryologist* certificate for the laboratory director; Lack of approval for the laboratory director to manage it.
Deficiencies in personnel aspects	There is a significant shortage of embryologists and deficiencies in the staffing of doctors, nurses, psychosocial staff, and secretary positions. Regarding one of the units, it was noted that "there is a significant deviation concerning staffing, which is insufficient. It should be noted that this is not a matter of convenience but of risk to treatment and the creation of tension and pressure".
Deficiencies in patient identification	There is no patient identification tag; Proper identification of the patient is not carried out during the "time-out" stage** Lack of recording of patients' ID numbers on the plates; Lack of embryologist's signature on the "time-out" form; "The return of embryos is done without a time-out form, the woman has no patient identification tag and there is no documentation or signatures from the team"; Not every shift has two embryologists – there is not always a double signature as required; The shortage of staff does not allow for sufficient presence of staff members for double identification as required; The lack of double identification by embryologists on Fridays and Saturdays.
Deficiencies in patient files and the medical record	A large part of the essential information is not in the files; The absence of a "time-out" form in the patient file; The absence of consent forms in the patient files; "A problematic documentation method in the laboratory that may result in the loss of essential information regarding the eggs and pre-embryos"; "The laboratory is not computerized. The registration of the straws in the canisters is not computerized. Manual registration is cumbersome. This may lead to errors".
Deficiencies in equipment and infrastructure	"The laboratory infrastructure is poor and does not meet any accepted standards," the operating room and the laboratory do not comply with the standards for operating an IVF unit, and do not comply with the Public Health Regulations; "During busy times, there are several patients' plates in one chamber, which is a safety hazard. There is a shortage of incubators that can be critical and jeopardize the safety of the patients." There is a shortage of fume hoods. The existing fume hoods are outdated and do not allow for a clear demarcation between patients; The laboratory structure is very crowded, the laboratory is relatively tiny for the treatment cycle incubator, and the number of staffs - "risk of work accidents"; Deficiencies related to air quality, a medical gas system that does not comply with the standard.
General deficiencies	The laboratory treats active carriers of viral diseases, contrary to instructions requiring their referral to a designated laboratory, and even in the absence of appropriate equipment; There is no monitoring of the quality of work. Quality control is problematic and is not carried out as required; there is a Lack of restriction of entry to the laboratory to authorized persons only.

According to data from the Ministry of Health, processed by the Office of the State Comptroller.

* In vitro fertilization laboratory employees – see below.

** Identifying the patient before performing a procedure in the operating room and ensuring that completed and signed consent forms are available; Reading the patient's name aloud in the presence and signature of the surgeon, anesthesiologist (if present), nurse and embryologist; Identification tag – a wristband with the patient's details such as an ID number.

The audit raised the following:

- The Ministry of Health failed to conduct repeated audits before the error in embryo return that occurred in September 2022, except for two (public) units that exhibited severe deficiencies, and it did not ensure that other units addressed the identified deficiencies, many of which were classified as severe and required immediate rectification.

  Particularly concerning are the serious deficiencies related to patient identification and medical record management that were not re-examined. These are deficiencies related to the incident of 2022.

- The audit raised that certain deficiencies, including personnel shortages noted in audits from 2018–2019, recurred in audits from 2022–2023 conducted in the private units. Additionally, severe related to workload and patient identification, identified in past audits, were again found in the 2022–2023 audits and the investigation committee's findings regarding the embryo return error.

The Ministry of Health is responsible for safeguarding the nation's health and supervising the health system, including IVF units. It should ensure responses are given to serious deficiencies identified in its audits that pose a risk to patients. Consequently, the Ministry should have conducted follow-up audits to confirm that severe deficiencies were addressed. At the same time, the primary accountability for rectifying deficiencies rests with the hospitals housing the units. The failure to rectify serious deficiencies has exposed patients to potential risks. This situation, along with recent events, underscores the critical responsibility of these hospitals to address issues raised in Ministry audits and the Ministry's duty to verify that such serious deficiencies are addressed.

Concerns Regarding the Failure to Report "Special Incidents" (irregular incidents) in IVF – the State Comptroller's Office raised that only four reports of special incidents were submitted to the Ministry of Health from IVF units over six years from 2017 until publication in the media of the error in the return of embryos in September 2022, averaging less than one report per year. However, in the year and eight months following said date (October 2022 – May 2024), 17 reports were submitted, averaging about ten reports per year.

The significant increase in the reporting rate of special incidents post-September 2022 – tenfold compared to prior periods – raises concerns that similar events may have occurred previously but went unreported. For instance, there is concern that incidents of test tubes with eggs or embryos falling or cases of egg or embryo loss were not reported as required:

- In the six years preceding September 2022, only one report of the falling of a test tube with eggs was recorded, whereas the same event was reported five times in the subsequent year and eight months, from October 2022 to May 2024. Such incidents can lead to damage to eggs or embryos, necessitating additional egg retrievals, on all the physical and psychological impacts on patients this entails, and might, in rare instances, jeopardize their chances of conception.

- After September 2022, two additional instances of egg or embryo loss were reported. The severity of these cases extends beyond potential further egg retrievals; They also raise concerns among patients about the misuse of lost eggs or embryos for fertilization with other patients.

The Ministry of Health's efficacy in identifying repeated incidents, failures, and systemic issues and mitigating the risk of recurrence is hindered by the lack of assurance that units or hospitals have provided reports as mandated. Moreover, this uncertainty compromises the Ministry's ability to ensure proper handling of incidents for patients, alongside guaranteeing full transparency regarding the circumstances and implications of such incidents.

Shortage of Embryologists and Its Implications

Embryologists constitute a fundamental component in managing IVF units, carrying out critical procedures related to all stages of fertilization, including identifying eggs and embryos at requisite stages.

- As of 2018–2019[14], IVF units had a significant shortage of 111 embryologists, representing 45% fewer professionals than required based on the benchmark draft, which indicated a need for 244 embryologists. Although these benchmarks remain in draft form, they were designed to establish appropriate benchmarks for the field, and units were directed to align their operations accordingly.

- In 10 of the 25 units assessed, the shortage of embryologists reached or exceeded 50% of the benchmark draft requirements. In 13 units, the shortage ranged from about 30% to 49%, while one reported a 20% shortage. Only one unit met the required number of embryologists per the benchmarks draft.

- Despite the Ministry of Health's audits in 2018–2019 indicating a significant lack of embryologists in IVF laboratories, no national-level measures were taken by it to address this situation.

14 The data is based on Ministry of Health audits of units in these years.

- As of December 2023, the Ministry of Health lacks current data on the number of embryologists employed within these units and does not know the extent of the shortage.

The severe deficiency of embryologists across most units places an undue burden on the existing staff and compromises the capacity to provide optimal, high-quality care within the diverse IVF units.

Preserving of Unclaimed Eggs and Embryos – as of December 2023, despite the Ministry of Health's acknowledgment 15 years prior regarding the accumulation of substantial reserves of unclaimed eggs and embryos, no definitive guidelines have been established concerning their thawing, consequently resulting in their thawing being left unregulated. This has resulted in the significant accumulation of eggs and embryos in various units nationwide, some dating back to the 1980s, while many patients have surpassed the age at which these eggs and embryos are viable or have passed away. Individual data presented by seven IVF units to the State Comptroller's Office indicates that 10% to 25% of stored embryos have remained in these facilities for over 20 years, while additional units reported they did not possess detailed data.

The audit raised that the accumulation of egg and embryo reserves significantly impacts the management of storage containers, heightening risks associated with preserving many eggs and embryos and related costs. Specifically, containment rooms are reaching capacity, necessitating renovations in several units to accommodate additional storage space. The units are also compelled to procure extra containers, incurring considerable expenses for ongoing maintenance. Additionally, some embryos are situated in outdated containers that lack automatic nitrogen filling, resulting in diminished monitoring capabilities. Overcrowding complicates the locating and extracting embryos and eggs from freezing containers, exacerbates challenges related to nitrogen refilling, and raises the risk of cryogenic burns.

The Completeness and Reliability of the National Database for IVF Treatment Cycles – the IVF treatments database in Israel was established to enhance the safety and quality of treatment, facilitating informed decision-making and policy development. However, the audit found that as of October 2023, the national database for IVF treatments in Israel is incomplete and unreliable:

- Fourteen out of the twenty-six units responsible for about 60% of all treatment cycles in Israel did not report to the database through an automated interface. This significantly impacted the scope and quality of the reports generated. Among these, five units, with around 35% of all treatment cycles, submitted reports deemed inadequate, leading to their exclusion from the database analyses.

- Concerns were raised regarding gaps in the units' reports that may bias the database. For instance, specific reports failed to indicate whether pregnancies were the result of egg donation, which is vital for understanding treatment success rates, particularly among older patients. Additionally, in treatment cycles using frozen embryos, reference was made to the woman's age rather than the egg's age, thereby affecting the evaluation of success probabilities, particularly among older patients.

Consequently, the ability to fulfill all of the objectives of the national database – namely, enhancing treatment safety and quality and enabling informed decision-making and policy formulation – is severely lacking and constrained.

Egg Donation from Abroad – in 2022, the Ministry of Health reported receiving donations from 547 egg donors located abroad; However, it lacks data about the number of women who received donations from each donor. This gap arises from the practice where eggs extracted from a single donor may be allocated to multiple recipients, and donors may donate eggs on several occasions. As a result, the Ministry of Health cannot ascertain the number of women seeking assistance in Israel via foreign egg donation. Moreover, the national database does not encompass comprehensive information on this matter. Following the audit's conclusion in March 2024, the Ministry of Health and the Israel Police started an ongoing investigation into allegations that fertilized eggs with genetic diseases were imported from abroad for IVF treatments on Israeli women. This incident underscores the urgent need to improve the data available to the Ministry of Health, particularly concerning the number of women receiving donations from individual egg donors.

In December 2023, new regulations were enacted to allocate an additional funding of NIS 75 million to public units over the three years of 2023–2025. This enhances the scope of activities and facilitates patients' choice of treating physicians. The budget distribution includes NIS 12 million for 2023, NIS 38 million for 2024, and NIS 25 million for 2025. The provision of this additional funding is contingent upon the unit increasing its activities by at least 3% in 2023 and by 5% in each of the subsequent two years. This initiative represents a significant response to the rising volume of IVF cycles and the associated workloads faced by some units. However, it is essential to recognize that this is a long-term initiative, and its results will be evaluated in the future. Furthermore, it should be noted that no solutions have been implemented to address the salary disparities between doctors and medical staff in public units compared to their private units.

The Gertner Institute has worked over the years to establish the national database for IVF treatments, investing efforts to increase the number of units reporting to it and to enhance the quality of data submitted by these units and the interfaces for data transmission. Nevertheless, additional measures are necessary to ensure the completeness and reliability of the database.

Key Recommendations

- The Ministry of Health should ensure that the deficiencies noted in its audits have been adequately addressed. In the absence of the rectifying of severe deficiencies, errors might occur.
- The Ministry of Health should regularly monitor treatment scopes in public and private units to ensure alignment between treatment capacities in every unit and the available workforce and infrastructure, thereby maintaining their quality and safety.
- The Ministry of Health should promptly set the benchmarks for the operation of IVF units due to the increasing volume of procedures performed in them, the existing workload in some facilities, and the need for compliance monitoring.
- The Ministry of Health should have updated data on the number of embryologists within IVF laboratories; Analyze existing and anticipated shortages of embryologists; Evaluate barriers to training, recruitment, and retention; And ensure the staffing levels of embryologists meet the operational demands without compromising training professionalism.
- It is recommended that the Ministry of Health review the recommendations of professional organizations concerning the eligibility policy for publicly funded IVF treatments based on the latest global and domestic data. This review is crucial due to the physical, mental, and economic costs associated with treatments that do not yield favorable results. Concurrently, the Ministry should reassess its policy on egg donation, addressing all relevant ethical and legal aspects to benefit women with significantly low chances of conception from their eggs and pursue appropriate legislative measures.
- It is recommended that the Ministry of Health evaluate the optimal balance in service provision between public and private IVF units, with particular attention to existing workloads and the implications of treatment waiting times.
- It is recommended that the Ministry of Health gather up-to-date data on the workforce and infrastructure of each unit and subsequently formulate a comprehensive overview of the maximum capacity for treatments in Israel. This status assessment will enable the Ministry to identify national gaps between current conditions in the IVF sector and requirements, thus allowing for adequate preparation for the anticipated increase in treatment volumes while ensuring quality and safety.
- The Ministry of Health should regularly monitor the treatment scope in public and private healthcare facilities and assess the impact of regulations implemented from December 2023. Thus, ensuring that the treatment capabilities of each facility are aligned with the available workforce and infrastructure, thereby maintaining the quality and safety of

treatment. Based on the assessment results, the Ministry should consider formulating supplementary measures as necessary, including exploring the potential for increased operational capacity in public hospitals, particularly during afternoon hours, and addressing the salary discrepancies among medical staff.

- Given the emergence of irregular incidents within IVF units, which hospitals have not accurately reported to the Ministry of Health, the Ministry's Director General should exercise his authority under the Public Health Ordinance. This includes obtaining event logs that are kept per the Ministry's procedures within the IVF laboratories, and reports concerning treatment safety and risk management incidents – pre and post September 2022. Furthermore, the Ministry should clarify to these units the obligation to submit reports as required and incorporate this compliance into their periodic controls, instituting necessary measures should non-compliance be identified.

- The Ministry of Health should set guidelines for thawing eggs and embryos frozen for over five years without renewing the storage payments. The urgency of this regulation is amplified by the limited storage capacity in these units, partly attributable to an increase in treatment volume in recent years.

- The national database functions as a tool for national policy formulation and informed decision-making by stakeholders, including patients. Therefore, ensuring that this database is comprehensive and reliable is essential. The Ministry of Health, in collaboration with the Gertner Institute, should engage with IVF units to guarantee that their reporting accurately reflects their activities. This should be facilitated through an automated reporting interface. Additionally, the Ministry should set a binding requirement for these units to transfer their reports to the database (irrespective of the managing entity – the Ministry of Health or the Gertner Institute) to uphold the integrity and reliability of the data. Examining the data types that should be transferred from the database to the Ministry is crucial for effective policy determination and implementation.

- It is recommended that the Ministry of Health enhance its existing data on the number of women benefiting from egg donation from abroad, as this will assist in assessing the current need and inform policy development in this area. Moreover, the incident involving the suspicion of importing fertilized eggs with genetic diseases necessitates reviewing the current control and supervision procedures for egg imports from abroad to ensure their adequacy.

The Volume Increase of IVF Treatments in Israel and its Implications

1
Over the past decade there has been an increase (60%) in the number of IVF treatments in Israel, amongst other things, due to its unusual policy

2
The Ministry of Health has not prepared, on the national level, for the increase scope in the treatments, including in shortage of embryologists – a shortage of 45% compared to the required number of embryologists

3
The Ministry of Health did not follow-up on the rectifying of the key deficiencies it raised in some of the units

4
Workloads in some of the units, that are not commensurate with the conditions therein in manpower and infrastructure, led to the occurrence of irregular incidents

5
In December 2023 the Ministry of Health published regulations addressing the increase number of treatments and the workloads in the private units

6
The Ministry of Health should monitor the implementation of the regulations and ensure the scope of procedures in every unit complies with the manpower and infrastructures therein

Summary

In vitro fertilization (IVF) treatments enable couples and individuals to realize their aspirations of parenthood under circumstances that may have previously precluded such outcomes. Israel distinguishes itself with a progressive policy regarding IVF treatments, as demonstrated by the accessibility of such services, both concerning the maximum age of the female candidate and the number of publicly funded treatment cycles. Over the years, the volume of procedures performed in Israel has significantly increased, with about 61,000 treatment cycles recorded in 2021. Expenditure on IVF treatments, within the frameworks of the Health Basket and Additional Health Services programs, reached about NIS 450 million in 2023[15].

The Ministry of Health plays a crucial role in safeguarding the safety and quality of IVF treatments. This includes setting operational guidelines for treatment units and monitoring their adherence. Recent irregular incidents have raised the issue on the public agenda, underscoring the necessity for thoroughly examining the Ministry's regulatory and supervisory aspects in this domain.

This report raised fundamental deficiencies in the Ministry of Health's approach.

The Ministry has not adequately addressed the rising volume of IVF cycles, which has increased by about 60% from 2011 to 2021, particularly in private units, with an average increase of about 5,750 procedures per unit in 2015–2021. Additionally, the Ministry has failed to respond to the significant shortage of embryologists essential for performing delicate procedures within IVF laboratories. Consequently, the existing infrastructure is unprepared for the annual volume of IVF cycles conducted in Israel.

The absence of comprehensive measures to address the notable increase in treatment volumes at specific units has resulted in a lack of congruence between operational burdens and the available workforce and infrastructure.

Moreover, the Ministry's 2018–2019 audits raised serious deficiencies within some IVF units, particularly regarding patient identification. However, the Ministry did not perform follow-up audits to verify the rectification of these deficiencies.

The Ministry of Health is responsible for safeguarding the population's health and has supervision obligations concerning the health system, including IVF units. Thus, it should follow up on issues identified in previous audits. Hospitals hosting these units also bear primary responsibility for rectifying the noted deficiencies. Failure to address these serious deficiencies has placed patients at risk. This report, alongside recent developments in this

15 About NIS 323 million from the Health Basket and about NIS 128 million from the Additional Health Services programs, not including deductibles. This figure does not include additional costs, such as the cost of medications, which are partly borne by the patients, treatments that are not performed exclusively within the framework of in vitro fertilization treatments, as well as treatments for which payment is made privately or through commercial insurance companies.

area, underscores the essential accountability of hospitals to rectify deficiencies identified in Ministry audits and the Ministry's obligation to ensure that critical issues are adequately addressed.

Additionally, the report raises concerns about specific irregular incidents that have not been reported to the Ministry of Health as required. Without reliable reporting from units and hospitals, the Ministry cannot detect recurring issues and systemic problems, limiting its ability to mitigate risks and enhance treatment safety.

The report highlights an urgent need to bolster the Ministry of Health's supervision and regulatory frameworks concerning IVF. The Ministry should promptly set procedures governing the operation of IVF units, ensure rectifications are implemented following audits, and guarantee the receipt of reports on irregular occurrences.

Moreover, the national database is incomplete and unreliable, hindering the achievement of all its objectives – namely, enhancing treatment safety and quality and informing decision-making and policy formulation. Improvement of this database would assist the Ministry of Health in the formation of policies and in assessing existing strategies.

The regulations issued by the Ministry of Health in December 2023 represent a preliminary effort to address the substantial increase in IVF cycle volumes and the accompanying burden specific units face. The Ministry should ensure that treatment volumes in each unit align with adequate workforce and infrastructure, facilitating a high standard of treatment and safety in this sensitive area.