

**Navigating a Complex Policy Landscape:
A Case Study of IVF Policy in Malta**

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Abstract

This dissertation explores the development of In Vitro Fertilisation (IVF) regulation in Malta, as a case study of policymaking on morality politics. This research explores the key policy developments and different stakeholder positions to identify which theories of policymaking can best capture the complex dynamics involved in developing morally contentious policies in Malta.

Using a multi-method qualitative case study approach, this study combines document analysis, which outlines the key policy developments on IVF between 1991 and 2022, and the prevailing stakeholder positions, with an abductive thematic analysis of nine semi-structured elite interviews on this policymaking process. Data triangulation was employed to assess which of the identified theories best capture the dynamics of the policymaking process.

The findings show that the regulation of IVF in Malta has been a long and gradual process, characterised by disagreements between actors with competing interests and political hesitancy to regulate. The theories underscored political will, institutional structures and stakeholder beliefs as key dynamics that influence policymaking on morality politics. Although the theories of Punctuated Equilibrium, Historical Institutionalism and Discursive Institutionalism capture most of these dynamics, other theories of policymaking provide insights into the role of policy entrepreneurs, subsystem coalitions and narrative development.

While this research is limited to the Maltese context, it addresses a notable gap on morality politics and policymaking in Malta. It also contributes to wider research on the IVF policymaking by applying the analysis to a small state context.

Keywords: IVF; Malta; Morality and Public Policy; Morality Politics; Policymaking

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List of Acronyms

ACF	Advocacy Coalition Framework
ART	Assisted Reproductive Technology
BCC	Bioethics Consultative Committee
CRPD	Commission for the Rights of Persons with Disability
DOI	Department of Information
EPA	Embryo Protection Authority
EU	European Union
IVF	In-Vitro-Fertilisation
LGBTIQ	Lesbian, gay, bisexual, trans and gender diverse, intersex and queer
MAP	Medically Assisted Procreation
MGRM	Malta Gay Rights Movement
MP	Member of Parliament
MSF	Multiple Streams Framework
NCW	National Council of Women
NPF	Narrative Policy Framework
PAEF	Professionals Against Embryo Freezing
PBB	Polar Body Biopsy
PET	Punctuated Equilibrium Theory
PGD	Pre-implantation Genetic Diagnosis
PGT	Pre-implantation Genetic Testing
PGT-M	Pre-implantation Genetic Testing for Monogenic diseases
PGT-SR	Pre-implantation Genetic Testing for Structural Rearrangements
PL	Partit Laburista

PN	Partit Nazzjonalista
SAC	Social Affairs Committee
UK	United Kingdom
WAW	Wanting and Waiting

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Chapter 1: Introduction

1.1 Background context

With historical and cultural ties to the Catholic Church woven into the fabric of Maltese society (Aquilina 2018, Bettetini 2010, Pace 2012), it is not surprising that religious values and morals play an important role in Malta's policymaking processes. This is especially pronounced on policy issues that raise significant moral and ethical considerations, referred to as 'morality politics' (Engeli, et al. 2012, Haider-Markel, Meier 1996, Mooney 1999, Smith, Taltovich 2003). This includes policy issues such as abortion, same-sex marriage, and biomedical technologies such as In Vitro Fertilisation (IVF).

Since the 2011 divorce referendum, Malta has seen significant debate on various morally contentious issues (Harwood 2022). These include the regulation of IVF in 2012 and the subsequent amendments that were highly debated, the introduction of the Civil Unions Act in 2014 (Civil Unions Act 2014) and further amendments such as the legalisation of same-sex marriage in 2017 and the legalisation of recreational cannabis in 2021 (Authority on the Responsible Use of Cannabis Act 2021). Other controversial issues discussed at the political level were the introduction of the morning after pill in 2016 (Farrugia 2016), the discussion on decriminalisation of prostitution (Magri 2020) and the first amendment to legalise abortion in exceptional cases in 2023 (Zammit 2023).

From these controversial issues, the regulation of IVF stands out as one of the most longstanding and divisive issues, having dominated the political sphere since the late 1980s. Mallia (2014) explained that despite the various developments in biomedical technology and bioethics, the regulation of IVF remained a central issue for policymakers, "with the government at times feeling paralyzed to move forward" (p. 1290). In fact, the introduction of IVF regulation in 2012 was preceded by nine years of political debate within Parliament (Asciak 2013). The parliamentary discussions were characterised by significant disagreements on key issues such as the status of the embryo, embryo freezing, and who can benefit from IVF (Mallia 2010). The

subsequent amendments in the legislation between 2018 and 2022, which led to the introduction of freezing and genetic testing on embryos, among other changes, gave way to significant controversy (Vella 2022). This was mainly due to “deeply held and diverging convictions about the moral status of an embryo at its various stages of development” which were to be expected in a “country with strong religious roots” (Vella 2022, p.2).

1.2 Research Problem

While a few studies have examined aspects of the policy process on issues such as divorce, abortion and same-sex marriage (Harwood 2015, 2022, Pace 2012, Sammut 2024), there is a lack of research on the policymaking process of morality politics in Malta. In the case of IVF regulation, despite having been on the political agenda for more than 20 years, most literature focuses on the ethical and moral implications of this practice (Agius 1991, Felice 2002, Bianchi 2011). Having said this, there has been some research which explored the policy process on IVF up to the introduction of the first legislation in 2012, mainly focusing on the role of the Church and other stakeholders to influence the debate (Mallia 2010, 2014, 2013). Thus, underscoring a significant gap in the literature on how the policymaking process on IVF evolved over time, and how different stakeholder positions influenced the different policy outcomes. Furthermore, there is a lack of research on the dynamics and processes behind the policymaking process, particularly on agenda setting and policy formulation. Therefore, as a mature policy issue that has been characterised by significant debate at different levels, the regulation of the practice of IVF presents itself as an ideal case to investigate the complex policy landscape that morality politics operate in.

1.3 Research Aim

The main objective of this study is to understand the policymaking process on morality politics in Malta, by taking the development of legislation regulating the practice of IVF as a case study.

To address this objective, this research aims to establish the main policy developments related to policymaking on IVF in Malta between 1991 and 2022. Building on this, this study will explore how different stakeholder positions have influenced the policy process and eventual policy outcomes. Finally, this study aims to establish which theories of policymaking best explain the policymaking process, particularly the agenda setting and policy formulation process, within the local context that can be applied to similarly contentious topics.

These research aims will be addressed by answering the following research questions:

1. How did Malta's legislation regulating the practice of IVF develop between 1991 and 2022?
2. How did the positions held by various policy actors involved influence the policymaking process and eventual policy outcomes?
3. Which theories of policymaking best capture the dynamics and processes involved in developing morally and ethically contentious policies locally?

1.4 Dissertation Outline

This dissertation is divided into five main chapters. This first chapter grounds the context and overall aims of this study. The second chapter reviews the prevailing literature on morality politics, theories of policymaking and their application to morality politics, with a focus on IVF regulation in different Western European countries, and the local context. The third chapter outlines the methodology employed in this research. The fourth chapter presents the findings from

the document analysis and the thematic analysis of interviews undertaken. The fifth and final chapter discusses the main findings to address the research questions and highlight the contribution of this research to the growing literature on policymaking in morality politics.

Chapter 2: Literature Review

This chapter is divided into four main sections. The first section explores morality politics and how these policy issues raise significant moral and ethical concerns during the policymaking process. The second section presents different policymaking theories and how these are applied to different morality politics to explain the policy process. The third section focuses on IVF, first by underscoring the main ethical concerns and then by presenting the prevailing literature that applies policymaking theories to IVF. The final section focuses on the Maltese context, highlighting the local factors that influence policymaking on morality politics.

2.1 Morality and Public Policy

2.1.1 Morality Politics

Although not all policy issues are heavily influenced by moral considerations, certain policies share recognisable characteristics and trigger similar political responses and policymaking processes (Mourão Permoser 2019). Various academics have often categorised historically controversial policy issues such as abortion, same-sex marriage, capital punishment, euthanasia, stem-cell research and assisted reproductive technology (ART), under the umbrella of ‘morality politics’ (Engeli, et al. 2012, Haider-Markel, Meier 1996, Mooney 1999, Smith, Taltovich 2003).

Morality politics was initially defined as policies where “at least one advocacy coalition ... portray(s) the issue as one of morality or sin and use(s) moral arguments in its policy advocacy” (Haider-Markel, Meier 1996, p. 333). However, this definition is too narrow. By focusing on sin, it emphasises religious morality and wrongdoing, while ignoring secular perspectives on civil rights and individual freedoms (Mucciaroni 2011). A broader definition of morality politics is provided by Mooney (2001) emphasising that such policies involve public conflicts over privately held values (Mourão Permoser 2019). As morality policies include matters concerning core values or “first principles”, at least one side of the argument frames the matter as threatening to its

foundational beliefs (Mooney 2001). While moral principles are the basis for many laws, morality politics address contentious issues that are not widely accepted (Mourão Permoser 2019). Mucciaroni (2011) expands on this by defining morality policy as disputes framed by deontological reasoning, where respect for fundamental moral values takes precedence over practical considerations. Consequently, policies are assessed on what is fundamentally good or bad, rather than on possible policy results. Thus, compromise is often difficult due to strong focus on moral principles, as seen in debates on issues such as abortion and same-sex marriage (Mucciaroni 2011).

Mourão Permoser (2019) argues that not enough consideration has been given to the way religion affects morality policies. The author contends that morality policies often involve private, non-negotiable values due to their complex relationship with religion. Several moral issues, such as those on gender, sexuality and human life may clash with core religious beliefs, making it difficult for religious individuals, particularly political actors, to compromise (Rachels, Rachels 2011). This leads to conflicts in secular states where religious beliefs, although private, must be respected and balanced with public policy (Mourão Permoser 2019).

James Hunter's (1991) concept of 'Culture Wars' builds on the challenges identified by Mucciaroni (2011) and Mourão Permoser (2019). Hunter used the term "culture wars" to explain how conflicts on morality politics arise from differing interpretations of 'moral authority'. This reflects two opposing moral philosophies: progress and liberation versus tradition and continuity. Hunter and Wolfe (2006) argue that although policy issues may be the focus of surface debates, the real conflict stems from the fundamental differences between the two sides' conceptions of reality, truth, and goodness. These ideas are based on opposing sources of authority, namely human experience versus transcendent religious values, as presented by Henricson (2016). This ties into Cochran et al.'s (2012) broader conflict between the idea of an 'open society' and the aim to establishing a specific set of moral values through public policy. The concept of an

open society assumes that no group has a “monopoly on truth or wisdom” (p. 481) and emphasises tolerance of the different perspective, including opposing moral and religious beliefs. However, both sides of the culture war – described by the authors as the populist right-wing conservatives and the left-wing liberals – seek to use policy as means of enshrining their moral perspectives, ultimately, undermining the pluralistic and tolerant nature of an open society.

2.2 Theories of Policymaking

Policymaking is a complex process that involves various actors and is heavily influenced by external factors such as culture, norms, and the economic environment (Cairney 2019, Cochran et al. 2012, Hill, Varone 2019). Over the last thirty years, various theories, frameworks and models of policymaking have been developed to simplify and explain this process (Birkland 2020, Cairney 2019, Cochran et al. 2012, Peters 2015). However, neither of these can fully explain the complex of nature of policymaking across all policy areas (Birkland 2020, Cairney 2019, Cochran et al. 2012).

This section examines some the most widely recognised policymaking theories, presented by leading academics in the field, namely Cairney (2019), Knill and Tosun (2020), Weible and Sabatier (2018), and Birkland (2020). The theories have been selected due to their focus on agenda setting and policy change (Heikkila, Cairney 2018), two areas of policymaking that are central to this study. Furthermore, this section is organised thematically rather than chronologically, to allow for more nuanced understanding of different concepts and ideas presented in these theories.

2.2.1 Incrementalism

First articulated by Charles Lindblom (1959), incrementalism posits that the policymaking process is characterised by incremental, non-radical change that rarely deviates from existing policies (Cairney 2019, Hayes 2013). Incrementalism acknowledges the pluralistic nature of

policy process, involving various actors with differing perspective and objectives about the same policy problem (Hayes 2013, Peters 2015). This results in social fragmentation analysis (Baybrooke Lindblom 1963), where no actor is fully informed about a given issue and, instead, different actors provide pieces of information needed to analyse the problem. Due to incomplete information, time constraints, and financial limitations, policymakers are unable to explore all policy options, leading to new policies that differ only incrementally from existing ones (Hayes 2013, Lester, Stewart 2000).

Thus, incrementalism challenges the idea that policies are the result of rational decisions (Hayes 2013). Rather, policymaking is conceived as the result of compromise between various actors with differing information, values, and interests (Lindblom 1965). Ainsworth and Hall (2010) observed this in their study on strategic incrementalism in the context of abortion, which underscored how incremental measures successfully advanced pro-life legislation in the United States since the *Roe v Wade* (1973) judgement. Thus, highlighting the effectiveness of gradual policy change in a highly contentious area to allow for agreement between diverse actors (ibid).

A fundamental aspect of incrementalism is that decision making is ‘remedial’ (Lester, Stewart 2000, p.93). Policymakers focus on addressing current, tangible issues rather than achieving idealistic, abstract policy goals. By “making incremental changes rather than aiming for a perfect solution” (Hayes 2013, p. 288), policymakers can address contentious issues through compromise (Hayes 2013; Lester, Stewart 2000). Building on this, Kees Waaldijk adapted incrementalism into the small-change theory to explain same-sex marriage legislation in Europe as a gradual process with prescriptive steps (Aloni 2020, Hamilton, Sperti 2023). Waaldijk argues that incremental change paves the way for the eventual recognition of same-sex unions while allowing for social change by increasing the acceptance of subsequent developments at a social and political level (Aloni 2020, Hamilton, Sperti 2023).

2.2.2 Institutionalism

Whereas incrementalism focuses on the individual policymaker, institutionalism emphasise the role of institutions in influencing the policymaking process and policy outcomes (Knill, Tosun 2020, Peters 2019, Peters 2022). This theory is divided into classical institutionalism and new institutionalism. Classical institutionalism focuses on official institutions, which are formal, legal structures such as the legislature and cabinets that provide policymakers with formal rules for policymaking. New institutionalism provides a broader definition of institutions that recognises the relevance of formal rules, while emphasising the importance of informal, unwritten rules such as norms, practices, and relationships that guide policymakers and, ultimately, influence the policy outcomes (Cairney 2019, Knill, Tosun 2020, Peters 2022).

According to Peters (2019) new institutionalism is an umbrella term that brings together at least six different approaches: normative institutionalism, rational choice institutionalism, historical institutionalism, empirical institutionalism, discursive institutionalism and sociological institutionalism. Historical institutionalism describes institutions “sets of regularised practices with rule-like qualities” (Schmidt 2010, p. 10) that “structure and shape behaviour and outcomes” (Steinmo 2008, p. 188). A fundamental idea is path dependency, the ideas that shaped an institution in its formation continue to shape policies in the future, leading to a resistance to change as the costs for implementing change increase over time (Cairney 2019, Peters 2019; 2022). Similar to incrementalism, historical institutionalism recognises gradual and adaptive policy change, while also acknowledging that significant policy change happens at critical junctures due to external forces such as political pressure and conflict (Kickert, van der Meer 2011). Therefore, this approach underscores policy continuity, with major policy changes occurring when one idea replaces the initially established idea (Peters 2019, Schmidt 2010).

Discursive institutionalism builds on the role of ideas, by emphasising how ideas and discourse lead to institutional changes and influence policymaking (Knill, Tosun 2020, Peters 2019; 2022,

Schmidt 2010). According to Schmidt (2008, 2010) institutions are “simultaneously constraining structures and enabling constructs of meaning, which are internal to ‘sentient’ (thinking and speaking) agents whose ‘background ideational abilities’ explain how they create and maintain institutions while their ‘foreground discursive abilities’ enable them to communicate critically” (2010, p. 4). Therefore, institutions are shaped by both the ideas that people hold and how they discuss and challenges those ideas in practice. Discursive institutionalism also examines “communicative discourse” which focuses on how political actors communicate ideas to the public for “deliberation and legitimation” (Schmidt 2010, p. 3-4).

Smith (2018) presented the complementarity between historical institutionalism and discursive institutionalism in a comparative analysis of same-sex marriage rights in the USA and Canada. Smith (2018) compared how the formal institutional structures have shaped the political landscape of LGBT movement in both countries and how ideational power, was used by political actors to influence other actors and advance their views on same-sex marriage (Smith 2018, Carstensen, Schmidt 2016). Smith (2018) contends that together historical and discursive institutionalisms provide a “superior approach” for understanding policy development in morality politics, by showing how historical precedents, institutional structures and social movements shape policy beyond simple moral debates.

2.2.3 Punctuated Equilibrium Theory

Building on the assumption of stability presented in theory of institutionalism, is the theory of Punctuated Equilibrium (PET) – developed by Baumgartner and Jones (1993) to explain how “long periods of stability and incremental change are ‘punctuated’ by outbursts of policy activity and radical change” (Princen 2013, p. 844). Overtime, PET evolved into a broad theory analysing how institutions process information disproportionately, leading to overall incremental policy change and occasional large-scale policy shifts (Baumgartner et al. 2018, Cairney 2019, Princen

2013). Morality politics tend to follow this pattern as they are often characterised by long periods of stability and incrementalism; however, when reform occurs it leads to fundamental, large-scale policy shifts (Hurka et al. 2016).

Similar to incrementalism, PET assumes that decisionmakers are rationally bounded with limited attention spans, only able to deal with several issues at a time (Baumgartner et al. 2018, Baumgartner, Jones 2009). However, PET extends this reasoning also to the policy system, positing that policy issues are dealt with in parallel, through different policy monopolies – closed venues of policymaking composed of key actors (Baumgartner et al. 2018, Birkland 2020). Policy monopolies produce negative feedback cycles, as actors seek to preserve the prevailing policy image, leading to incremental policy change and stability (Baumgartner et al. 2018, Cairney 2019). Both historical institutionalism and PET highlight long periods of stability followed by sudden policy departures, however, PET assumes that such changes are not only the result of external events but can also be due to the buildup of unresolved institutional or policy (Zehavi 2011). Such disruptions allow issues to move to macropolitical agenda, where they are characterised by a positive feedback cycle amplifying the need and opportunity for change (Baumgartner et al. 2018, Cairney 2019). Furthermore, for ‘punctuated’ change to occur, the dominant policy image needs to be re-framed with new information, and new actors called policy entrepreneurs become involved in the debate and different venues address the same issue (Baumgartner et al. 2018, Birkland 2020).

This dynamic is observed in New Zealand’s reframing of the Psychoactive Substances (Rychert, Wilkins 2018). Actors in the policy monopoly reframed the long-standing policy image of drug control to market regulation. This led the issue to enter the macropolitical arena, attracting new policy entrepreneurs, namely interest groups and civil society, and the media, forcing policymakers to shift their attention to previously ignored aspects of the policy such as social issues. This led to an urgent amendment of the legislation prior to the national election,

underscoring how policymakers process information disproportionately, by focusing on new information and problems as they arise (Baumgartner et al. 2018).

2.2.4 Multiple Streams Framework

Similar to PET, the Multiple Streams Framework (MSF) seeks to explain both policy stability and change, by focusing on “the role of ideas and agenda setting within a broader setting of policymaking” (Cairney 2019, p. 340). According to Kingdon (1984; 2014), policy change can only occur through three distinct streams – the problem stream, the policy stream and the politics stream – converge during a policy window.

Both PET and MSF assume that policymakers are rationally bounded and have limited attention spans, therefore, they seek to explain how attention shifts between competing policy issues (Heikkila, Cairney 2018). In the MSF, the problem stream highlights how policy issues capture policymakers’ attention, through changes in systematic indicators, focusing events, or experiences and feedback from existing policies (Cairney, 2019, Herweg et al. 2018, Kingdon 1984; 2014). In Germany, organ transplantation reform was pushed at the forefront of the agenda due to high mortality rates among transplant patients that were amplified by the media, and the public kidney donation by a key politician, which drew significant public and political attention, (Wainwright, Hanser 2014).

The policy stream refers to a closed policy community where various policy alternatives are generated creating a ‘policy primeval soup’ (Kingdon 1984; 2014) and policy entrepreneurs push their ‘pet projects’ to gain support and establish them as viable policy alternatives (Herweg et al. 2018). In contrast to PET which focuses on the role of institutional arrangements (Spano 2023), the MSF highlights the role of policy entrepreneurs to couple pet projects with the other two streams, thus creating a window for opportunity (Herweg et al. 2018). This was evident in Germany, where presumed consent system was one of the policy alternatives that circulated the

policy community, however, it gained momentum when an established policy actor championed it, therefore, linking it to the political stream and advancing it on the political agenda (Wainwright, Hanser 2014).

Building on the idea of disproportionate information processing within the political system in PET, the political stream refers to how the political system perceives issues and assesses the urgency for solutions based on the national mood, interest groups and government (Cairney 2019, Kingdon, 1984; 2014). In Germany, while presumed consent was initially favoured, this was scrapped due to coalition disagreements and public opposition (Wainwright, Hanser 2014). Furthermore, in Australia's methamphetamine crisis, "the combination of national mood and elections is a more potent agenda setter" (Kingdon 2014, p. 199), as the winning party during different election campaigns framed their narrative according to the prevailing national mood (Lancaster et al. 2014).

As illustrated in Figure 2.1, all three streams operate independently until a policy window appears, allowing for these streams to merge, creating an impetus for policy change (Birkland 2020, Herweg et al. 2018). In Germany, the EU's deadline for organ transplantation reform created a 'clear policy window' allowing the problem and policy stream to converge (Wainwright, Hanser 2014). In Australia, the problem stream framed by the media as an "ice epidemic" aligned with the political stream, when an election campaign allowed for the conservative party to advocate for a "Tough on Drugs" policy (Lancaster et al. 2014). However, these windows are fleeting, and do not always guarantee policy change (Birkland 2020, Kingdon 2014). Therefore, in comparison to PET, the MSF underscores the ambiguity under which policymaking takes place (Heikkila, Cairney 2018).

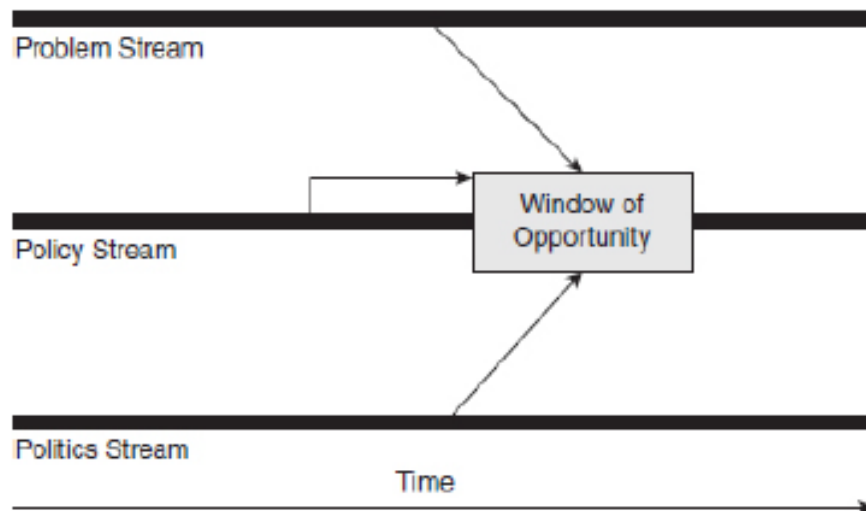


Figure 2.1: Kingdon's Streams Metaphor (Birkland 2020, p. 597)

2.2.5 Advocacy Coalition Framework

The Advocacy Coalition Framework (ACF), developed by Sabatier and Jenkins-Smith (1993; 1999), differs from the previously discussed theories by underscoring the importance of 'cognitive biases' to explain how policy actors engage in coalitions to turn their shared beliefs into policy (Cairney 2019, Heikkila, Cairney 2018; Jenkins-Smith et al. 2018). ACF assumes that policymaking happens within a policy subsystem composed of diverse actors, including non-traditional actors such as media representatives, academics, and scientists, that seek to influence a specific policy issue (Jenkins-Smith et al. 2018, Sabatier, Wiebel 2007). Similar to PET, MSF and incrementalism, the ACF assumes that policy actors are rationally bounded individuals that understand complex issues through belief systems and thus, form coalitions with others who share a similar belief system. According to Jenkins-Smith et al. (2018) Sabatier and Wiebel (2007) belief systems are divided into three levels:

1. *Deep core beliefs* – which consists of core values and perspectives;

2. *Policy core beliefs* – that represent specific policy objectives, priorities and strategies;
and
3. *Secondary beliefs* – which focus on practical considerations such as funding and policy implementation.

To advance policies that are in line with their deep core beliefs through different institutional venues, policy actors from different political levels that share policy core beliefs seek to establish advocacy coalitions (Jenkins-Smith et al. 2018, Sabatier, Wiebel 2007). According to Crawford and Weible (2024) coalitions on morality policies are highly motivated by both policy goals and deep core beliefs.

Policy subsystems are the central focus of analysis for the ACF, setting it apart from other theories such as PET that takes a system-level approach and the MSF that does not clearly define the boundaries of policy subsystems (Heikkila, Cairney 2018). The ACF outlines the wider political framework within which policy subsystems operate, as seen in Figure 2.2, emphasising how coalitions are influenced by “relatively stable parameters” and “dynamic external events”. Stable parameters such as cultural norms and social values, and institutional structures remain consistent over decades, providing “long-term coalition opportunities”. In contrast, external events such as changes in public opinion and governing coalition create “short-term opportunities” that coalitions can take advantage of to strengthen their position or advocate for policy change. (Jenkins-Smith et al., 2018)

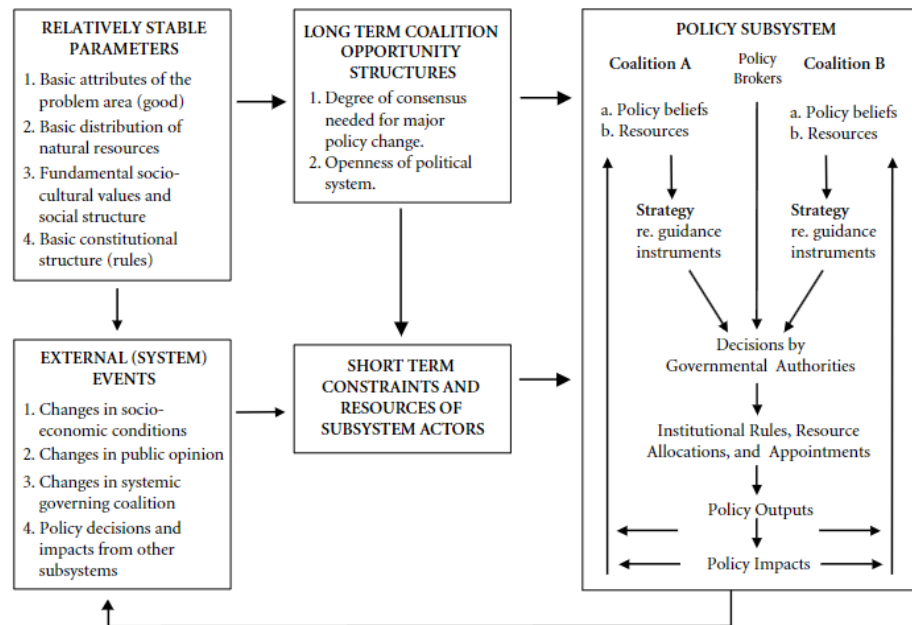


Figure 2.2: Diagram of the Advocacy Coalition Framework (Sabatier, Wiebel 2007, p. 202)

The ACF posits that policy change occurs due to a shift in the prevailing belief system within a subsystem, driven by policy-oriented learning, external shocks, internal subsystem shocks or negotiated agreements (Sabatier, Wiebel 2007). In morality politics, policy-oriented learning and external shocks are the key drivers to policy change (Griessler, Hadolt 2006, Kübler 2001). Policy-oriented learning refers to the “relatively enduring alternations of thought or behavioural intentions that result from experience and/or new information and that are concerned with the attainment or revision of policy objectives”, primarily through influence on secondary beliefs (Sabatier, Jenkins-Smith 1999, p. 123).

Shocks outside of the policy system often lead to “the redistribution of resources or opening and closing venues within a policy subsystem, which can lead to the replacement of the previously dominant coalition by a minority coalition” (Sabatier, Wiebel 2007, p. 199). Furthermore, external shocks can also lead to changes in the core belief of the dominant coalition, leading to policy change (Sabatier, Wiebel 2007). Griessler and Hadolt (2006) observed that in Austria

external factors were essential catalysts for change in issues such as abortion and ART, however, policy-oriented learning was critical in shaping the respective policy outcomes. Kübler (2001) also observed that in the case of Swiss drug regulation, effective change did not occur until the dominant coalition that favoured prohibition was replaced with a minority coalition in favour of harm reduction.

2.2.6 Narrative Policy Framework

Expanding on the importance of cognitive bias presented in the ACF, is the Narrative Policy Framework (NPF), which emphasises the importance of narratives in policy formulation and change (Heikkila, Cairney 2018). The NPF posits that policy actors create narratives that follow a generalisable and observable structure which can be assessed to understand how narratives influence policy across different areas, by either reinforcing or challenging specific policy measures (Cairney 2019, Heikkila, Cairney 2018, Shanahan et al. 2018). All narratives must have two key features: form and content. Form refers to the structural elements of a narrative like setting, characters, plot and moral of the story. Content refers to the strategies used to ensure a narrative's success such as expanding or containing the scope of the conflict to influence public perception and assigning responsibility and blame for the policy problem.

Another strategy recognised by ACF but further developed by the NPF (Shanahan et al. 2011), is the 'Devil-Angel shift', where actors frame themselves as heroes while demonising their opponents (Shanahan et al. 2018). For example, Jung and Huang (2024) observed the evolution of advocacy groups narrative strategies in Taiwan, as same-sex marriage was legalised. They noted that the opposing groups expressed their dissatisfaction with the State's policies by initially employing a devil-shift strategy. Furthermore, the conflict strategy adopted by coalition groups depended on the ongoing policy issues, relevant political events and the preferences of the target

audience. This led to varied and inconsistent conflict expansion and containment strategies across both sides of the debate.

The NPF also assumes that successful narratives are those that build audience's trust, inspire admiration or empathy for important characters, and use the audience's core belief to exploit more flexible ones (Cairney 2019, Heikkila, Cairney 2018). Additionally, effective narratives must ensure that "micro level" strategies, targeting individuals, and "meso level" strategies, targeting coalitions, relate to "macro level", meaning grand policy narratives, that capture core societal beliefs (Shanahan et al. 2018). The NPF goes beyond the ACF's level of analysis, by highlighting and analysing the use of narratives at several levels, not only at the policy subsystem level (Heikkila, Cairney 2018).

The NPF also builds further on the idea put forward by MSF that policy problems are socially constructed, by positing that social constructs can be influenced or manipulated by the narratives told by policy actors (Heikkila, Cairney 2018). However, Kirkpatrick (2017) argues that the NPF lacks in understanding "how long-standing cultural and public narratives shape political behaviour, especially in the absence of a strong policy entrepreneur serving as a narrator" (p. 120). In the case of ART policies, dominant moral narratives within society on motherhood and family shape legislation, which may negatively or positively impact those who rely on ART, such as same-sex couples (Kirkpatrick 2017).

2.3 The Policymaking Process in IVF

2.3.1 IVF as a novel biomedical procedure

As medical research developed and medical procedures become more sophisticated due to growing technology during the second half of the 20th century, new moral and ethical questions

that had never considered started to arise (Galston, Shurr 2003, Jonsen 2003). These new technologies challenged society's traditional moral standards, leading to debates on how existing moral and ethical frameworks need to be adjusted (Swierstra, Rip 2007). The birth of the first 'test-tube baby' IVF in 1978 in the United Kingdom (UK) gave way to new legal and ethical issues that policymakers and the public had never considered before (Galston, Shurr 2003, Jonsen 2003).

As a novel breakthrough for female infertility treatment, IVF challenged the traditional concept of reproduction by making conception possible without sexual intercourse (Beers 2019, Engeli 2009, Jonsen 2003, Wymelenberg 1990). Through IVF, fertilisation takes place in a controlled lab environment where multiple eggs are first retrieved from a female to be then fertilised in vitro (Beers 2019). After fertilisation, the embryos are cultured in an incubator and a selection of the healthiest embryos is made before being transferred to the womb, where they can then develop into a foetus (Niederberger et al. 2018, Beers 2019).

2.3.2 The Ethics of IVF

Over the past 40 years, IVF has raised significant ethical concerns among different actors with competing goals including policymakers, doctors, theologians, and the public, influencing how this practice is regulated (Banchoff 2011, Beauchamp, Childress 2019, Ferber et al. 2020, Galston, Shurr 2003, Jonsen 2003). Early ethical discussions were based on the fear of "playing God", eugenics, and the practice's safety (Banchoff 2011, Jonsen 2003, Wymelenberg 1990). The moral status of the embryo eventually became the focus of the debate, characterised by opposing views on whether life beings at conception or at implantation (Banchoff 2011). The religious world believes that life begins at conception and therefore, the embryo is "a human individual at the earliest stage of existence" (p. 7). While the secular world views the embryo as "an early form of human life, but not a human individual or person" (p. 7). These opposing moral views have

polarised the debate on the regulation of the practice of IVF, such as embryo research and embryo freezing (Banchoff 2011).

As IVF extended beyond its initial scope of curing infertility, it continued to “evoke additional questions and dilemmas” (Asplund 2020, p. 194). This includes the regulation of Pre-implantation Genetic Testing (PGT) and access to IVF for single women and same-sex couples (Asplund 2020, Beers 2019), surrogacy and egg donation (Mackenzie et al. 2020), social egg freezing (Ferber et al. 2020), the donation or adaption of frozen embryos (Clark 2014), and the ownership and use of gametes in cases of separation of the couple or death of one of the partners (Ferber et al. 2020), among other issues.

2.3.3 Key Themes on Policymaking in IVF

Due to distinct institutional, cultural and political settings, the policymaking process for regulating IVF varies greatly between countries. Nevertheless, recurring patterns within the policymaking process have been identified by various academics within the field (Bleiklie et al. 2004, Engeli et al. 2012). Bleiklie et al (2004) presented the first comparative study aimed at understanding the “how and why” behind the design of ART policies across ten countries in Western Europe and Northern America. They propose that ART policy design can be analysed through two key dimensions: the degree of autonomy granted to medical professionals and researchers, and who may have access to these technologies and to what extent (Goggin et al. 2004). Consequently, they posit that in public policy these dimensions can be assessed using a “permissive-restrictive continuum”, where greater autonomy and wider access reflect permissive policies, while strict controls and limited access reflect restrictive policies.

To effectively assess and compare existing policies on ART, a comparative framework was adopted (Goggin et al. 2004) seen in Figure 2.3, which draws on the theory of institutionalism,

ACF, and policy design theory, positing that policy choices in ART are the result of actor characteristics, institutional dynamics that influence the policy design process, the inherent characteristics of the policy designing process and the influence of external factors as identified by Jenkins and Sabatier (1999).

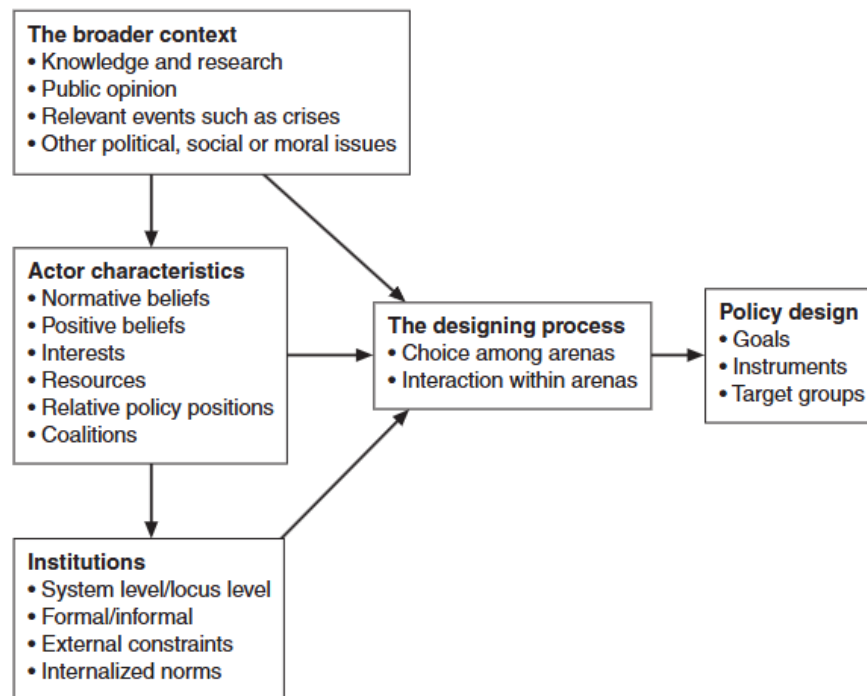


Figure 2.1: Comparative Policy Design Framework by Goggins et al. (2004)

Bleiklie et al. (2004) highlight the importance of actor constellations, which includes political parties, medical associations and interest groups, to influence the policy design, either by directly determining the policy outcome or indirectly, by affecting the process. When actors were aligned on the type of policy envisaged, even if for different reasons, substantial policy change is possible, as seen in the UK and Switzerland. However, significant actor fragmentation leads to policy stagnation, as seen in Italy and Belgium.

Bleiklie et al. (2004) continue that the institutional structure of countries also has significant impact, especially the role of veto players and policy entrepreneurs. Belgium, a federal country with many arenas, gave way to veto players that interrupted the policy design process due to deadlocks within the government. Other federal European countries, such as Germany and

Switzerland, the large number of arenas enabled policy entrepreneurs to push forward their preferred policy design. A similar contrast is noted in countries with few venues as in Italy this led to a process failure while in Spain it paved the way for policy design success. Consequently, it can be concluded that actor dynamics and institutional contexts are the primary drivers of policy outcomes. Past experiences with morality issues, as seen in Belgium, France and Netherlands, also influence the strategies taken by key actors to avoid debate or political crises. Finally, competing policy issues on the macro agenda also affect the policy design process, for instance, to avoid dealing with ART and euthanasia at the same time, the Belgian government delayed ART decisions, while in Spain, at the time, democracy and European integration were salient issues allowing for an expert approach to the policy design process in ART.

Various academics have drawn on PET to explain the policymaking process in ART in different countries. Timmermans and Scholten (2006) explore the role of scientific institutions in The Netherlands to shape the policy image and the agenda setting on ART policy. They noted how a closed policy monopoly where scientific venues, particularly the Dutch Health Council, played an important role in maintaining a strong 'medical' policy image to ensure self-regulation in ART practices, and limited the influence of interest groups in agenda-setting, thus, maintaining a negative feedback process. However, they maintain that shifts in the political coalition and focusing events such as the cloning of Dolly the Sheep altered public opinion thus, challenging the dominant policy image and expanding the debate to include ethical and moral considerations. This created a positive feedback process that helped in reshaping ART policy.

Kettell and Cairney (2010), also employed PET to undertake an in-depth analysis of the role of ideas and political power in shaping the policymaking process in the UK's 2008 Human Fertilisation and Embryology Bill. They argue that the framing of ART issues played a central role in influencing both actor behaviour and institutional outcomes. As a secular framing of ART

within the dominant medical-scientific policy image was instrumental in garnering support for a permissive regulatory framework (Kettell, Cairney 2010).

Schiffino et al. (2009) seek to understand the policymaking process in ART in Italy and Belgium by applying and expanding the PET, focusing on the role of political parties and including concepts such as “conflict expansion, issues framing, values and beliefs” (p. 561). The analysis highlights two key elements that explain the difference in policy outcomes between Belgium and Italy. The first is the role of the Catholic Church, where in Italy, the Church was a key policy entrepreneur that used its influence to frame ART practices in line with religious moral beliefs and values, leading to a restrictive regulation. Meanwhile in Belgium, the role of the Church was less pronounced allowing for a more secular framing of ART policies. Secondly, the role of the political parties in driving policy change. In Belgium, a secular coalition government brought a significant shift in allowing for a reframing of ART values and new institutional venues facilitating change. While in Italy the centre-right party coalition aligned itself closely with the Church, thus, reinforcing a restrictive policy image (Schiffino et al. 2009).

Engeli et al. (2012) build on the work of Schiffino et al. (2009) by examining how morality issues, including IVF, are treated across various countries, focusing on the role of political parties and the framing of these issues. Engeli et al. (2012) also draw on PET by focusing on how the attention from political actors, the actors involved, how these issues are framed and the institutional venue where these issues are discussed, affected the policymaking process. This study makes an interesting distinction between the religious world, where a country’s political system includes religiously based parties, implying an inherent religious-secular conflict and the secular world, where political parties do not have significant religious ties, and a church-state conflict is less prominent. Interestingly, even between countries belonging to the religious world, the policymaking process on IVF varies, as seen in the case of Switzerland and Spain.

In Spain, IVF was not on the parties' political agenda until it gained political attention due to the technological developments (Chaqués Bonafant, Palau Roque 2012). Medical professionals played a dominant role in framing ART in secular terms, primarily as a treatment for infertility, while the political parties supported this secular framing, and involved medical professionals directly in the decision-making process, thus expanding venues for secular policymaking. A change in government to the conservative people's party, which aligned itself with Catholic Church, led to a restrictive IVF policymaking. However, this policy was short lived, as once in government a left-wing party eventually changed the policy to be more permissive, in line with the public support (Chaqués Bonafant, Palau Roque 2012). In contrast, in Switzerland, IVF became politicised through the initiative of non-party actors, namely religious groups, environment and anti-nuclear groups, and feminist groups who collectively argued for restrictive regulation of ART for different policy objectives (Engeli, Varone 2012). Due to the unique Swiss political set-up requiring popular vote for such legislation, the Swiss government created an ambiguous agreement that respected the unusual coalition of actors calling for heavy regulation and the medical professionals who advocated for autonomy (Engeli, Varone 2012).

2.4 Mapping out the Maltese context

2.4.1 Church – State Relations

The relationship between religion and the State is a complex one that dates back centuries (Bettetini 2010, Aquilina 2018). Although Malta is a secular state, the Maltese Constitution establishes the Roman Catholic Apostolic Religion as the official religion of the Maltese Islands. Thus, making Malta a confessional state, recognising the authority of the Roman Catholic Church and granting it the duty and right to teach the principles of right or wrong (Bettetini 2010, Aquilina 2018). According to Bettetini (2010), this provides the Roman Catholic Church (hereinafter

referred to as ‘the Church’) with constitutional authority to define moral and ethical principles, ultimately, allowing Catholic values to influence different legislative matters such as divorce law.

Throughout history, Malta’s political context has been influenced by the role of the Church, which has at times left a negative impact on church-state relations (Harwood 2023). Religion has heavily influenced Malta’s two-party system, as the Nationalist Party (PN), a Christian democratic party, has a close relationship with the Church, while the Labour Party (PL), a socialist democratic party seeks to maintain a secular position (Cini 2002, Harwood 202). The Church has also been an influential figure in the Maltese society, as religious morality has historically shaped Malta’s national identity, and influenced the guiding principles, morals and values within society, particularly those concerning the family (Vella, Cassar 2022). As a result, these religious values have heavily influenced various social policy issues such as divorce and same-sex marriage, which up until recently were aligned with the Church’s morality, underscoring the Church’s political influence (Deguara 2019, Vella, Cassar 2022). Furthermore, although the influence of the Church within the Maltese society seems to be weakening, Catholic values and beliefs still hold relevant ground (Vella, Cassar 2022).

2.4.2 Morality Politics in Malta

Tying into the broader topic of policymaking in morality politics, when observing how morality politics were discussed within the local context, such as the legalisation divorce and same-sex marriage, the eventual policy outcomes were heavily influenced by religious values (Mourão Permoser 2019). Legalising divorce in Malta has been lengthy and tumultuous process, marked by significant church-state conflict. Morally and ethically contentious topics such as divorce had been largely avoided by political parties, as they excluded such topics from their electoral manifesto. In fact, the issue of divorce reached the political agenda unexpectedly, following a Private Member’s bills by a Member of Parliament (MP), which eventually led to a consultative referendum where the majority voted in favour of divorce. This result reflects a shift among public

values, shifting away from the moral standards set by the Church towards secular values and beliefs. Ultimately, this allowed for other morally contentious issues such as LGBTIQ rights to reach the political agenda and the adoption of more liberal legislation reflecting the changing values in society (Deguara 2019, Fenech 2012, Harwood 2022, Pace 2012).

Harwood (2022) observed the development of LGBTIQ rights and the ban on abortion through issues networks, framing and timing. It was noted that the weakened position of the Church following the divorce referendum allowed the LGBTIQ movement to mobilise its professional network among the political class, and framing “the issue as one of civil rights and equality”. Although this narrative was adopted by the PL government, this was not the same for reproductive rights. As lobbies were ineffective in challenging the dominant narrative of political parties and the public, which is deeply rooted in Catholic tradition, particularly on issues such as the amendments to the Embryo Protection Act in 2018.

2.5 Concluding Remarks

The chapter outlined the prevailing literature on policymaking on morality politics, with a specific focus on IVF. The first section explored how the debate on morality politics is shaped by personal values, reflecting a deeper conflict between religious and secular perspectives on morality. The second section identified six prevailing theories of policymaking and literature where the theories were applied to different cases of morality politics. Subsequently, the third section focused on the ethics of IVF, and explored key literature on policymaking in IVF across different countries, providing into how different theories of policymaking can be applied to explain different aspects of the process. The final section focused on the local context, reviewing literature on other morality politics to understand how these issues are dealt with locally.

Chapter 3: Research Methodology

This chapter outlines the methodological framework of this study, starting with the selected research approach and strategy, then continuing by describing the chosen data collection methods and analytical strategy employed, and concluding with the ethical considerations and limitations of the study. The aim of this research is to answer the following research questions:

1. How did Malta's legislation regulating the practice of IVF develop between 1991 and 2022?
2. How did the positions held by various policy actors involved influence the policymaking process and eventual policy outcomes?
3. Which theories of policymaking best captures the dynamics and processes involved in developing morally and ethically contentious policies locally?

3.1 Research Approach

3.1.1 Research Philosophy

A crucial step when selecting the appropriate research strategy is for the researcher to determine their assumptions on how knowledge is produced (epistemological stance) and how they view the nature of the world (ontological stance) (Clark et al. 2021, Saunders et al. 2019). These philosophical views and assumptions determine the researcher's interpretation of the research questions, the data collection methods chosen, and the interpretation of the findings (Clark et al. 2021, Saunders et al. 2019).

This study takes a constructivist view of the world and an interpretivist approach to knowledge. Constructivism emphasises the dynamic nature of social phenomena by arguing that "social phenomena and their meanings are continually being created by social actors" (Saunders et al. 2019, p. 127). Building on this, interpretivism, as a subjective philosophy, focuses on the lived experiences of individuals and their understanding of these experiences to create "new, rich understandings of organisational realities" (Clark et al. 2021, p. 162). This approach allows for

an in-depth understanding of the different policy developments in IVF policy, as a social phenomenon shaped by different actors.

3.1.2 Approach to Theory Development

This research takes on an abductive approach to theory development. This approach combines different elements of the deductive and inductive reasonings, by continuously moving between data and theory (Suddaby 2006). Clark et al. (2021) likens this process to a puzzle: starting with an observation of phenomenon – policymaking in IVF in Malta, identifying different themes and patterns – such as policy actors’ behaviour and influence and periods of slow or significant progress, and then developing “a plausible theory of how this could have occurred” by using existing theories of policymaking (Saunders et al. 2019, p. 158). Thus, abduction was used to identify the best theories of public policy that explain the policymaking process in similarly morally contentious policy issues.

3.1.3 Methodological Approach

Saunders et al. (2019) identify three methodological approaches: quantitative research, qualitative research and mixed methods research. Quantitative research “emphasises quantification in the collection and analysis of data”; in contrast, qualitative research focuses on “words rather than quantification” (Clark et al. 2021, p. 137). Furthermore, quantitative research underscores objectivism and is primarily geared towards theory testing, while qualitative research instead highlights a constructivist reality by focusing on actors’ interpretation of social phenomena (Saunders et al. 2019). Consequently, Hennink et al. (2020) argue that a qualitative approach is more suited to understand decision-making processes, explore complex issues, and identify the social and cultural context in which a social phenomenon takes place. Since this research focuses on the policymaking process on morally complex issues within the Maltese context, a qualitative approach was deemed the most appropriate.

3.2 Research Design

Denzin et al. (2023) describe the research design as “a flexible set of guidelines that connect theoretical paradigms, first, to strategies of inquiry and, second, to methods for collecting empirical material” (p. 23-24). Consequently, the research design provides the necessary framework within which the researcher collects and analyses data based on the research questions and priorities (Burnham et al. 2009, Clark et al. 2021). Academics identify five major research designs: experimental design, longitudinal design, cross-sectional design, case study design and comparative design (Burnham et al. 2009, Clark et al. 2021).

3.2.1 Case Study Design

Yin (2018) describes a case study as “an empirical method that investigates a contemporary phenomenon (the “case”) in depth and within its real-world context” (p. 45). Furthermore, a case study approach allows for a “detailed and intensive analysis of a single case” (Clark et al. 2021, p. 222) while acknowledging the significant external factors related to it (Yin 2018). Therefore, a case study design was deemed to be the most appropriate since this study seeks to understand policymaking in morally complex issues, by analysing the policymaking process of IVF Malta, while taking into consideration the political and cultural context influencing this process.

Yin (2018) identifies four case study approaches: explanatory, descriptive, evaluative, and exploratory. This study can be classified as descriptive, as it seeks to describe the policy process on IVF in Malta and the real-world context it occurred in. The study is also an exploratory case study as, by exploring, firstly, how stakeholders influenced the policymaking process and secondly, by exploring a suitable theory of policymaking to explain the phenomenon, it seeks to explore a phenomenon which “has no clear, single set of outcomes” (Yin 2018, p. 50).

Another distinction made by Yin (2018) is whether the case study will analyse single or multiple cases. A single case study may be selected to illustrate a critical case, a unique case, or in contrast, as a representative case (Clark et al. 2021, Saunders et al. 2019, Yin 2018). Alternatively, a single case may be selected because it is revelatory or has a longitudinal aspect (Clark et al. 2021, Saunders et al. 2019, Yin 2018). The case is both revelatory, due to the lack of research on IVF policy locally, and longitudinal since it explores policy development between 1991 and 2022. This period was selected as the focus of this study, as 1991 marks the birth of the first baby through IVF in Malta (Agius 2012), and 2022 marks the last significant legislative amendment related the regulation of the practice of IVF. Between these years there were significant policy developments that are explored in detail.

3.3 Data Collection Methods

In qualitative research, different sources can be used to collect data. To strengthen the reliability, credibility, and validity of the study, a multi-method qualitative approach incorporating more than one data collection method is encouraged (Clark et al. 2021, Saunders et al. 2019, Yin 2018). This allows for data triangulation whereby the “findings from one method mutually corroborate the findings from the other method” (Saunders et al. 2019, p. 836). From the literature review conducted, it resulted that various scholars employ this approach, relying mainly on data collected from documentary sources and interviews with key actors (Bleiklie et al. 2004, Engeli et al. 2012, Kettell, Cairney 2010). This study adopts a similar approach using various documents to map out the historical policy developments, and conducting elite interviews, for a more nuanced and in-depth analysis of the policymaking process behind the scenes.

3.3.1 Documentary Research

Documentary research refers to the use of official and/or personal documents such as letters, newspapers, and official government documents as data sources (Clark et al. 2021, Saunders et al. 2019, Scott 1990). Documents serve as a valuable tool allowing the researcher to “uncover meaning, develop understanding, and discover insights relevant to the research problem” (Merriam 1988, p. 118). Furthermore, documents are essential to gather information on historical facts and the context of specific phenomena (Bowen 2009). Therefore, this study draws on various documentary sources to uncover the historical developments related to IVF regulation in Malta, and the prevailing national context influencing the final policy outcomes.

According to Clark et al. (2021), Scott (1990) provides the most reliable framework for identifying the nature and quality of the documents to be assessed. When following this framework, the researcher must start by differentiating between personal and official documents. For this research, official documents produced by both the state and private sources were considered. Official documents by the state include legislative acts regulating IVF, parliamentary debates on IVF, relevant meeting minutes and reports published the Social Affairs Committee and the Select Committee on Medically Assisted Procreation on IVF. Official documents from private sources such as political party manifestos referring to IVF, statements and position papers published by various stakeholders, and documents issued by the Bioethics Consultative Committee (BCC) referring to IVF. Moreover, this study makes use of mass media documents, namely newspaper articles and opinion pieces (see Appendix 1).

In view of the large dataset involved, it was imperative that the selected documents are then verified against Scott’s (1990) quality criteria and the recommendations of Clark et al. (2021) based on four pillars: *authenticity* – to confirm that the documents are of genuine and unquestionable origin, *credibility* – to ensure that the documents were not distorted, *representativeness* – to confirm that the document follows similar documents, *meaning* – to verify

that the evidence is clear and comprehensible. The authenticity and credibility of official documents published by the state and private sources were easily confirmed. All documents were acquired from official sources either via official government or stakeholder websites and online archives or directly from the responsible institution following a Freedom of Information request. All documents were clear and comprehensible. With respect to representativeness, the documents selected followed a standard similar to other official documents published. For mass media documents, attention was paid to the authenticity and credibility of the newspaper articles selected, particularly to confirm the authorship and objectivity of the articles. The representativeness of the mass media documents, was easily identifiable especially for newspaper articles.

3.3.2 Semi-Structured Interviews

Interviews are a valuable tool for collecting primary data, providing insights into the interviewee's perspective, while engaging in an in-depth, dynamic discussion. Thus "rich, detailed answers" (p. 1322) are gathered, allowing for a deeper understanding of the participants' views and the phenomena being researched (Clark et al. 2021). For this study, semi-structured interviews were conducted, due to the afforded flexibility and adaptability (Clark et al. 2021, Saunders et al. 2019). By using an interview guide with open questions, the questions were tailored according to the interviewee's replies and even including unplanned questions, enabling the interviewer to probe further into the interviewee's replies (Clark et al. 2021, Hennink et al. 2020, Saunders et al. 2019). The interview guide used for this study covered three broad themes: the policymaking process, the influences and dynamics and the policy outcomes (See Appendix 5).

3.3.2.1 Sampling techniques and recruitment

To select the interviewees, this study employed purposive sampling which allows for "strategically selecting information-rich cases to study, cases that by their nature and substance

will illuminate the inquiry question being investigated” (Patton 2015, p. 402). Therefore, the participants were recruited based on their involvement in the IVF policy process over the years. These participants provided first-hand accounts and not publicly documented insights into the complexities that shaped this policymaking process. Given the flexibility afforded through purposive sampling, a small sample of interviewees was initially selected that evolved as the study progressed (Hennink et al. 2020). Similar to a snowball sampling approach, key participants were identified through initial research, and contacted for an interview, where they provided recommendations on other relevant individuals (Bowen 2009, Clark et al. 2021).

The selected participants for this research were mainly elites, meaning “individuals who are the top ‘top’ of a system, whether this is in politics, in an industry, or in terms of their social status” (Clark et al. 2021, p.1579). As seen in Table 3.1, this included the CEO of the Embryo Protection Authority, politicians, leading local academics in bioethics that held seats or even chaired the BCC, chairpersons from various civil society organisations and thematic political party committees. Interestingly, various interviewees held positions throughout the years in different committees or organisations relevant to the policy process allowing them to provide additional insights from different perspectives.

Public Sector	Politicians	Civil Society	Academics
CEO of the Embryo Protection Authority	Chairperson of the Social Affairs Committee between 2003 and 2008	Chairperson of the Life Network Foundation Malta	Chairperson of the Bioethics Committee between 2003 and 2013
	Chairperson of the Social Affairs Committee between 2008 and 2012	President of Nisa Laburisti	Current Chairperson of the Bioethics Committee
	Minister of Health 2016 - 2024		Former Dean of Theology

Table 3.1 List of Participants

While elite interviewing is the “most effective way to obtain information about decision makers and decision-making processes” (Bowen 2009, p. 231), gaining access and contacting such interviewees can be challenging (Goldstein 2002). Bowen (2009) argues that this is mainly attributed to the individual’s busy schedules and lack of motivation to participate in such studies. For this research, all participants were recruited through a formal request via email. The main challenge, however, was in capturing the participants’ attention, often having to chase numerous times via email to schedule an interview. Despite this initial hurdle, all participants were open to discussion, with some even continuing the discussion informally off-record. All interviews undertaken were recorded and lasted for around one hour.

3.4 Data Analysis

3.4.1 Document Analysis

Document analysis “involves skimming (superficial examination), reading (thorough examination), and interpretation”, combining “elements of content analysis and thematic analysis” (Bowen 2009, p. 32). In line with this framework, after having selected the most relevant documents, the researcher started by organising the information in these documents into three broad categories:

- 1) **The policymaking process** – to collect information on the most relevant policy developments by reviewing official documents from government sources;
- 2) **Stakeholder positions** – to examine the positions of the various stakeholders involved by reviewing official documents from both government and private sources; and
- 3) **The national context** – to better understand on how the debate was framed in the local context by reviewing mass media documents.

After the first review, the most “meaningful and relevant” (Bowen 2009, p. 32) text was reviewed in detail to map out the key developments related to policymaking on IVF regulation between

1991 and 2022. This analysis also revealed relevant themes related to the policy process and the local context, complimenting the data analysed in the subsequent chapter.

3.4.2 Thematic Analysis

One of the most widely used methods for analysing qualitative data is thematic analysis (Clark et al. 2021), which was described by Clarke and Braun (2017), the pioneers of this system of analysis, as the “method for identifying, analysing, and interpreting patterns of meaning (‘themes’)” (p. 296). This approach provides flexibility to researchers as it can be used for both inductive and deductive research designs (Braun, Clarke 2006). This study follows the 8-step abductive thematic analysis approach developed by Jamie Thompson (2022), as seen in Table 3.2. This approach allowed the researcher to move between theory and data, allowing for refinement of gaps in theory by using empirical findings to adapt or expand knowledge in existing literature (Thompson 2022).

Thompson's 8-Step Approach to Abductive Thematic Analysis	
<i>Step 1</i>	Transcription and Familiarisation
<i>Step 2</i>	Coding
<i>Step 3</i>	Codebook
<i>Step 4</i>	Development of Themes
<i>Step 5</i>	Theorising
<i>Step 6</i>	Comparisons of datasets
<i>Step 7</i>	Data display
<i>Step 8</i>	Writing Up

Table 3.2. Thompson's 8-Step Approach to Abductive Thematic Analysis (2022) p. 1412 - 1418

The researcher started by transcribing and familiarising themselves with the content of the data. A hybrid content coding process was then used, that combined inductive coding – by generating codes from the data itself, with deductive coding – by using the policymaking theories identified in the literature review to guide the codes. These were then grouped into overarching themes that explain patterns in the data. These themes were then refined and adapted by comparing them against the core tenets of the policymaking theories and the data itself. Next, a comparative analysis was undertaken to understand how these different themes were expressed by the different participants and assess whether there are significant divergences or similarities, allowing for a better understanding of the different factors influencing the policy process. The data gathered was then presented in a table, organising all the themes and codes identified. Finally, the different findings from the different themes were interpreted and presented to show how the different policy actors shaped the policy process and the impact they had on the final policy outcome. (Thompson 2022)

3.5 Ethical Considerations

This research was guided by Burnham et al.'s (2008) five ethical principles (p. 286): avoiding harm to participants, endeavouring for veracity, respecting the privacy and confidentiality of participants and ensuring informed consent.

In addition to these principles, the researcher ensures that the study follows the University of Malta's Research Ethics Review Procedures and Code of Practice. At recruitment stage, all research participants were sent an information letter with the purpose of the study and the reasons for their participation and reminded before the start of the interview (See Appendix 2). Participants were informed that they may withdraw from this study at any point. Due to the participants' elite status and being publicly involved in the field of IVF, they were requested to sign a consent form where they explicitly consented to disclose their identity in the final published work, to which all participants agreed (see Appendices 3 and 4). Although none of the participants were at risk of harm, precautions were taken to ensure that there are no reputational risks such as only transcribing the data relevant to the research, removing additional remarks, and allowing participants to review all quotes from the interviews to avoid potential misinterpretation.

3.6 Limitations

While every effort was made to overcome any possible limitations, certain limitations were inevitable due to the chosen research design. One of the main challenges was to ensure the generalisability, validity, and reliability of the study, which are crucial for social research, especially when taking a case study approach (Clark et al. 2021, Yin 2018). On generalisability, the main concern is whether the "the results of a study can be generalized beyond the specific research context" (Clark et al. 2021, p. 165). This study is specific to IVF policymaking in Malta, therefore, while the findings may be applicable to other morality policies locally, they may not

be applicable to the same contentious issues in other countries. However, Yin (2018) argues that case studies seek to “expand and generalise theories (analytic generalizations) and not to extrapolate probabilities (statistical generalizations)” (p. 53). Although these findings may not be directly transferrable, they may provide valuable insights into policymaking on morality issues in countries with a similar context to Malta. To strengthen the study’s reliability, the data collection methods employed were based on studies already conducted in the field, ensuring that the study’s replicability to examine other morality policies in Malta such as euthanasia and abortion (Clark et al. 2021, Yin 2018).

Another challenge was the researcher’s novice and outsider status. As argued by Patton (2015) “researcher is the instrument in qualitative inquiry” (p. 1011), therefore, the researcher’s limited experience and training might have affected the data collection. Albeit creating an initial barrier to contact the elites, the researcher’s outsider status did not affect the interviews as elites were forthcoming with providing detailed information on their experience in the field (Berger 2015). Additionally, this research required significant reflexivity and maintaining a neutral stance throughout, especially during the interviews, to ensure that personal biases do not influence the findings of the study (Berger 2015). To this effect, this study sought to represent all stakeholders within civil society to ensure a representation of both liberal and conservative views on the topic, however, the liberal coalition did not reply to the interview request.

3.7 Concluding Remarks

This chapter provided a thorough explanation of the methods employed by the researcher to successfully conduct this study. The following chapter will be dedicated to presenting the data collected and providing an in-depth analysis to address the research questions set out in this study.

Chapter 4: Findings and Analysis

This chapter is divided into four main sections. The first part presents the key policy developments on the regulation of IVF in Malta between 1991 and 2022. Followed by an analysis of the positions held by the different stakeholders involved in the policy process. Complementing this section is a thematic analysis of the perspectives and experiences of policy actors that have been involved in the policymaking process throughout the years. The final part brings together the results of the three sections, to assess which theories of policymaking identified in the literature review best capture the dynamics and processes involved in developing the policy regulating IVF.

4.1 IVF Policy Development in Malta

4.1.1 Early debates (1991- 2000)

Although practiced since the 1980s, IVF remained largely unregulated in Malta. The birth of the first Maltese “test tube baby” on December 16, 1991 (In-Nazzjon Tagħna 1991) led to calls on the Health Ethics Committee to issue guidelines on IVF for private practices, noting that “not all that was scientifically possible was ethically acceptable” (The Times 1991).

In 1992, the National Bioethics Committee presented its first report on IVF titled “Reproductive Technology: Ethical and Legal Considerations” to the Department of Health (BCC 2012). Despite this initial effort, the situation remained unchanged throughout the 1990s and early 2000s. The Bioethics Consultative Committee (BCC), which replaced the Health Ethics Consultative Committee in 1993, continued on the works of its predecessor by providing guidance to the Government on the “ethical aspects and implications” of biomedical technologies (BCC 1993, p. 1). However, with no regulation or guidelines in sight, concerns were raised that regulation was overdue and necessary, especially in view of technological advancements in cloning and genetics testing (Importance of ethics in bio-ethics 1997, National Council of Women 1997).

In 2000, the BCC presented its second report on IVF titled “Ethical Considerations relating to Human Reproductive Technology” (Cauchi 2000). The recommendations addressed various issues, including: the use of IVF by couples in a stable relationship as a cure to infertility; or in the case of grave hereditary diseases, the establishment of a designated authority to regulate IVF, the transfer of a limited number of ova, and the restricted donation and storage of third-party gametes in extreme cases. It was also recommended to ban surrogacy, and embryo experimentation, freezing and donation. These recommendations laid the foundations of the debate on IVF going forward.

4.1.2 First Discussion in Parliament (2004 – 2005)

The debate on the regulation of IVF reached Parliament in 2004 when Nationalist MP Dr Michael Ascjak, then Chairperson of the BCC (2003 to 2013), requested the European and Foreign Affairs Committee to discuss the Council of Europe’s Convention on Bioethics – the first legally binding convention regulating biomedical technologies, including IVF, which Malta had not signed (Council of Europe, 1998). The discussion was then shifted to the Social Affairs Committee (SAC) – the home for the discussion on the regulation of IVF going forward (Foreign and European Affairs Committee¹ 2004).

The Chairperson of the SAC, MP Clyde Puli, proposed for the Committee to prepare a set of recommendations to Parliament, focusing on genetic technology and ART. Between November 2004 and June 2005, the SAC held 21 meetings to consult with medical and scientific experts, bioethicists, civil society, national commissions and persons who used ART. The findings and recommendations were presented to Parliament in September 2005 by the Chairperson in the report “L-Użu tal- Bioteknoloġija – Teknoloġija Ġenetika u Prokreazzjoni Assissitita”, commonly referred to as the ‘Puli Report’ (Puli 2005).

¹ All parliamentary committees are referred to by their official English titles

The Puli Report builds on to the recommendations put forward by the BCC. Both reports acknowledge that life starts at conception, however, the Puli Report proposes that this is enshrined in the Maltese law to protect the moral and legal status of the embryo. On genetic testing, the Puli Report goes a step further by calling for a ban on Pre-implantation Genetic Diagnosis (PGD) and allowing Polar Body Biopsy (PBB) on ova in cases of serious diseases. (Cauchi 2000, Puli 2005). However, in its final recommendations the SAC presents three major dilemmas, reflecting internal disagreement within the Committee. On eligibility, there was no agreement on whether this should be limited to only married couples or include those in stable relationships. On embryo freezing, the report proposes two options: banning it except for exceptional circumstances or allowing it given that embryos are implanted in the woman within a reasonable time. Furthermore, on third party gamete donation, it was recommended that this is either banned or allowed under specific conditions (Puli, 2005).

The Puli Report was eventually overshadowed by the political and religious context. In June 2005, the Opposition opposed the tabling of the Report in the House due to a lack of consensus on the final recommendations between the SAC members, leading to a public clash between the Chairperson and the PL representatives (Malta Independent 2005). Moreover, a week before the document was again tabled in September 2005, Archbishop Joseph Mercieca used his sermon during the Independence Day Mass to denounce IVF “as an ‘illicit’ method of procreation” signalling a strong message to the MPs gathered in attendance (Zammit 2005).

During the same time, the Government was working on a draft legislation labelled “Embryo Protection Act” and the BCC were invited to provide feedback (BCC 2012). Two draft versions of the Bill were presented to the BCC, the draft presented in July 2005 (after the Puli Report was finalised) was in line with the discussions being held in the SAC, such as extending eligibility to couples in a stable relationship, allowing cryopreservation in exceptional circumstance, and

banning practices such as genetic testing, surrogacy, and third-party gamete donation (Embryo Protection Draft Bill 2005). However, there were two main divergences. The first was on the definition of an embryo, as despite the recommendations of the BCC (2005) and SAC (2005), the draft bill stated that “there is an embryo from the moment of fertilization of a human egg cell”. The second issue was the lack of reference to a regulatory authority, and instead inferring the regulatory power to the Minister of Health and Justice.

4.1.3 Renewed Discussion and Eventual Legislation (2009 – 2012)

Discussions between the BCC and the Parliamentary Secretary for Health on the draft legislation resumed in March 2009 (BCC 2009). This draft featured a broader definition of the embryo encompassing the whole process of fertilisation and suggested the establishment of an independent regulatory body (BCC 2009, Embryo Protection Draft Bill 2009). Around the same time, the SAC, chaired by PN MP Edwin Vassallo, prepared a report on the latest ethical and moral teachings on ART based on the recommendations of leading bioethicist, Rev. Prof. Emmanuel Agius. This report, presented in September 2009, tackled the three regulatory dilemmas presented in the Puli Report, that is, eligibility for IVF, embryo freezing, and donation of gametes, recommending that these are discussed further by policymakers both from a legal and medical perspective (SAC 2009).

In October 2009, the Deputy Prime Minister and Minister for Foreign Affairs Tonio Borg tabled a Motion in Parliament to establish a Select Committee on Medically Assisted Procreation (MAP) with the aim of tackling the unresolved issues from the Puli report and providing guidance for future legislation (Motion 113 2009). In the report presented in October 2010, the Select Committee provided recommendations on four main issues: eligibility for IVF, embryo freezing, donation of gametes, and establishing a regulatory authority. On eligibility, the bill echoed the BCC’s 2000 report, recommending that this is open to couples in a stable relationship. In line

with the Puli report it recommended the establishment of an independent regulatory authority which issues licences to clinics, gathers data and certifies the eligibility of couples requesting IVF. Following the advice of medical experts, the Select Committee recommended to allow embryo freezing with clear guidelines on how many embryos are to be created and implanted. It also recommended allowing embryo adoption by sterile couples when embryos cannot be used by the original couple, while prohibiting gamete donation should (Select Committee on MAP, 2010d). However, due to controversy on the introduction of embryo freezing (Schembri 2011, BCC 2012), the SAC re-opened the discussion, and eventually recommended that future legislation allows for ova vitrification while embryo freezing should be allowed only in exceptional cases (SAC 2011a, 2011b).

These reports culminated in the Embryo Protection Bill, tabled in Parliament by on July 9, 2012, by the Minister for Justice, Dialogue and the Family. This came after the Opposition made legislating IVF an electoral promise (Borg 2012), effectively pushing the Government to push for legislation by the end of 2012 (Mallia 2013). As emphasised by the Minister, the Bill aimed at protecting human life and the status of embryo while providing infertile couples the possibility to become parents (Department of Information (DOI) 2012).

The proposals in the Bill reflected the various recommendations discussed over the years, extending eligibility to couples in stable relationships and establishing an Embryo Protection Authority (EPA) that among other functions certifies eligible couples and provides counselling. Furthermore, it also banned third-party gamete donation, surrogacy, and genetic testing on embryos, among other practices. A controversial proposal was to limit ova fertilisation to two per cycle and permitting only ova vitrification, while allowing embryo freezing only in exceptional circumstances (Bill 118 2012).

The Opposition welcomed the Bill but described as “half-baked”, proposing several amendments at Consideration of Bills Committee (House of Representatives 2012b). These included: the possibility for surrogacy when a mother cannot carry a frozen embryo, removing EPA certification for couples and removing the limit on ova vitrification with a protocol based on best practices (House of Representatives 2012a, 2012c, 2012d). However, the Opposition was inclined to find a compromise to ensure that this Bill is passed in a timely manner given the existing legal vacuum (House of Representatives 2012d). Ultimately, the Bill passed on November 26, 2012, retaining most of its original features, with key amendments being the possibility to fertilise three ova in exceptional circumstances and the removal of the consent and counselling from EPA (Embryo Protection Act 2012).

4.1.4 Amending the Embryo Protection Act (2015 – 2022)

With a change in Government in 2013, the debate on IVF shifted significantly. In July 2015, an Inter-Ministerial IVF Review Working Committee was established to review the current legislation, alongside a public consultation. This review was necessary due to the Civil Unions Act and rulings of the European Court on Human Rights. (DOI 2015)

This process led to the 2018 Amendments to the Embryo Protection Act, tabled in Parliament by the Minister for Health Chris Fearne on April 11, 2018, under Bill No. 37. This was the PL delivering on its electoral promise to reform the IVF legislation (PL 2017). These amendments reflected the more liberal proposals put forward in 2015 by the aditus foundation, Malta Gay Rights Movement (MGRM) (2015) and Nisa Laburisti (Malta Independent 2015b) namely: the revision of the definition of “prospective parents” to include single women and lesbian couples, increasing the number of fertilised ova to five, introducing embryo freezing, allowing embryo adoption and anonymous third-party gamete donation, introducing sperm and oocyte banks, and decriminalising altruistic surrogacy (Bill No. 37 2018).

These amendments drew significant backlash from the Opposition, the Church and various pro-life organisations, which joined forces during a national protest (Azzopardi 2018). During the Committee discussions, the Opposition proposed various changes to maintain the ban on embryo freezing, embryo and gamete donation and limit the definition of prospective parents. Simultaneously, the Government decided to remove altruistic surrogacy and allow partial anonymity on gamete donation. (Consideration of Bills Committee, 2018a,2018b,2018c). On June 19, 2018, Parliament passed Act No. XXIV of 2018 – Embryo Protection (Amendment) Act with slight changes to the original Bill. The Prime Minister described this legislation as progressive, non-discriminatory and based on scientific evidence, ensuring the success of IVF in Malta (The Malta Independent 2018b).

The most recent amendment to the IVF legislation was in 2022. This followed an electoral promise made by PL to expand the IVF legislation within the first 100 days in Government (PL 2022). On May 9, 2022 the Minister for Health Chris Fearne tabled Bill No. 5 in Parliament which presented a number of amendments, including improving the framework for gamete donation and embryo donation, allowing the EPA to decide the maximum number of eggs to be fertilised, and allowing pre-implantation genetic testing for monogenetic diseases (PGT-M) on embryos (Xuereb 2022, Bill No. 5 2022, EPA 2022).

The introduction of PGT-M was a controversial yet significant shift in IVF policy. Initially the Opposition opposed the proposal (Sansone 2022a), however, following discussions at the Committee stage it was agreed that the Bill is amended to include PBB, provide parents with guidance on available genetic tests and for a legal notice to be published when there are changes to the protocol (Consideration of Bills Committee 2022a,2022b). Ultimately, the Amendment passed on July 6, 2022, with a quasi-unanimous vote, with only three PN MPs voting against the

Bill who cited the importance of respecting and safeguarding human life from conception (Diacono 2022, Sansone 2022b).

4.2 Stakeholder Positions on IVF

This section explores how stakeholder positions have influenced the different policy outcomes over the years. Following the Googin et al. (2004) model, these positions are grouped and assessed against a permissive-restrictive continuum, focusing on their stance on the most contentious issues that have shaped the debate on IVF in Malta. These include the definition of the embryo, eligible persons for IVF, embryo freezing, PGT, surrogacy, embryo donation and adoption, and gamete donation.

4.2.1 Permissive Position

4.2.1.1 Medical and Scientific Community

Medical experts who pioneered IVF in Malta, namely Dr Josie Muscat, Prof. Mark Brincat, and Mr Mark Formosa, have consistently advocated for permissive policies (SAC 2005a, 2005b, Select Committee on MAP 2010a, Sansone 2012a, 2012c, Vella 2012). They argued that potential legislation should not limit the autonomy of practitioners in the field of IVF, while regulating potential abuse and providing the necessary ethical guidelines on how the service is offered. This group has been consistently in favour of embryo freezing arguing that it is essential to ensure the success of IVF, avoid multiple pregnancies and respect the medical needs of the prospective parents (Agius 2018, Dalli 2015b, Sansone 2012a, 2012c, Select Committee on MAP 2010a, 2010b, 2010d, Xuereb 2018).

However, this group was largely divided on genetic testing and surrogacy, due to ethical concerns. Although there was consensus on legislating in favour of genetic testing, there were divergences on whether this should be limited to specific cases or used on all embryos being before being implanted (TVM 2019, Diacono 2019, Calleja 2022b). On the issue of surrogacy, while some

agree with its introduction (Calleja 2022b, TVM 2019), others opposed it, arguing that this would create an ethical and moral conundrum that Maltese society was not ready to handle (Dalli 2015a, 2015b).

4.2.1.2 National Commissions and Civil Society

In contrast to the medical and scientific community, the involvement of civil society and national commission in favour of a permissive legislation has evolved gradually. In 2010, il-Kummissarju għat-Tfal and Kunsill Nazzjonali tat-Tfal, was the only national commission contributing to the discussion. They agreed with extending eligibility for couples in a stable relationship and embryo freezing, to safeguard the best interests of the child, but opposed third-party gamete donation (Select Committee on MAP 2010d). Although in 2015 the Office of the Commissioner argued against embryo freezing and surrogacy (Office of the Commissioner for Children 2015), in 2018 the Commissioner re-iterated its initial permissive stance, and supported same-sex couples to benefit from IVF and embryo adoption (Micallef 2018). In 2022, the Commission for the Rights of Persons with Disability (CRPD) supported the Government's proposal to introduce PGT-M, arguing that prospective parents carrying genetic disorders should have access to such testing (The Malta Independent 2022). However, 11 council members distanced themselves from this statement, arguing that embryos should not be discarded due to a disability (Zammit 2022b).

From 2015 onwards, MGRM, aditus foundation, and Nisa Laburisti were the leading stakeholders advocating for a more permissive legislation. They consistently lobbied for the inclusion of single mothers and same sex couples, removing age restrictions, introducing embryo freezing, and legalising altruistic surrogacy and gamete donation (aditus foundation and MGRM 2015, The Malta Independent 2015a, Agius, Calleja 2018). In 2022, the pro-choice group Doctors for Choice joined these groups, welcoming the introduction of PGT-M, stating that this will allow couples suffering with genetic disorders to benefit from IVF (Zammit 2022).

The Green Party (formerly known Alternattiva Demokratika and now as ADPD), was consistently in favour of a permissive legislation. They advocated in favour of embryo freezing, allowing “different family forms” to benefit, known gamete donation, PBB, and PGT-M (Briguglio 2012, Vella 2012b, Vella 2011a, Caruana 2012, ADPD 2018a, Sansone 2022a, TVM 2022). However, they maintained a cautious stance on surrogacy and embryo adoption (ADPD 2018b). Volt Malta, as a progressive and liberal party, advocated for even more liberal policies such as increasing the number of frozen embryos to six, introducing PGT-SR which detects chromosomal abnormalities and legalising altruistic surrogacy (Volt Malta n.d, Times of Malta 2022).

Various individuals who had undergone IVF treatment largely argued in favour of a permissive legislation that prioritises the welfare of the couple, and supported the permissive amendments. Others shared their stories to explain why amendments such as the introduction of embryo freezing and PGT-M are necessary from a personal perspective. (Puli 2005, Times of Malta 2012b, Agius 2017, Farrugia 2022, Calleja 2022).

4.2.2 Moderately Permissive

Fr Peter Serracino Inglott, effectively challenged the position of the Church, by calling for a law that limits abuse in IVF without limiting the practice (SAC, 2005a). He supported embryo freezing and argued against enshrining the protection of the embryo. However, he argued against third-party gamete donation and believed that only married couples should be eligible.

The BCC maintained a relatively moderate position on IVF regulation throughout the years, having consistently advocated for extended eligibility to couples in stable relationship while opposing embryo freezing and adoption, genetic testing, and surrogacy (Cauchi 2000, Select Committee on MAP 2010, Times of Malta 2010). As for gamete donation, while initially in favour, the Committee later changed its position against this practice. Dr Pierre Mallia, a leading

bioethicist and current Chairperson of the BCC, and Dr Michael Ascjak, former Chairperson of the BCC between 2003 and 2013, although members of the same committee, have held differing views. Mallia has consistently advocated for extended eligibility to couples in a stable relationship while Ascjak initially advocated for only married couples to benefit, eventually changing his position. On the protection of the embryo, Ascjak called for a restrictive legislation that prioritises the protection of the embryo, while Mallia advocated for flexibility. However, both were against embryo freezing underscoring the moral implications related to the storing and future of such embryos. (Ascjak 2012, 2015, 2022, SAC 2004a, 2005d, 2011b, Select Committee on MAP 2010d).

Three disability advocacy groups: Kummissjoni Nazzjonali Persuni b'Dizabilità, Għaqda Nazzjonali Ġenituri b'Persuni b'Dizabilità, and Kunsill Malti Persuni b'Dizabilità, advocated for a moderately permissive legislation (SAC 2005e, 2005f, Select Committee on MAP 2010d). They underscored the need for a balanced legislation that respects the dignity of the embryo and the parents right for an informed choice on issues such as genetic therapy and engineering. However, in 2022, L-Għaqda Nazzjonali Ġenituri b'Persuni b'Dizabilità, adopted a more restrictive stance on PGT-M, emphasising the potential negative impact on persons with disability within society (Mangiafico, 2022).

4.2.3 Restrictive Position

The Church, affiliated stakeholders, conservative civil society organisations, academics and certain members of the medical and scientific community played a crucial role in shaping the restrictive position on IVF.

4.2.3.1 The Church and Affiliated Stakeholders

Although not formally involved in the discussions, the Church played an important role influencing public opinion and framing IVF as morally problematic. The Church reaffirmed its opposition towards IVF, describing it as an illicit and immoral practice, while maintaining that life starts at the moment of conception (Uffiċju Stampa 2005b, 2005c). Consequently, it advocated for restrictive legislation allowing only married couples to benefit as a cure for infertility (Uffiċju Stampa 2005a, Cremona, Grech 2012). It also opposed the introduction of embryo freezing, gamete donation, and surrogacy, arguing that such practices make the “child a commodity” and PGT, equating it to eugenics (Uffiċju Stamp 2005a, Archdiocese of Malta 2018, Balzan 2022).

Rev. Prof. Agius, who was extensively consulted throughout the years, aligned himself with the Church’s position, consistently advocating for a restrictive legislation that limits eligibility to only married couples and protects the human embryo from conception (Agius 2010, 2012, 2019, SAC 2004b, 2009). He opposed embryo freezing and donation, gamete donation to avoid making orphans by choice, and PGT.

4.2.3.2 Civil Society

The National Council of Women (NCW) and Wanting and Waiting (WAW) – Infertility Support Group, were both included in early discussions and argued for limiting access to married couples and banning embryo freezing, third-party gamete donation, and surrogacy (SAC 2005e, 2005f, Select Committee on MAP 2010d, Kunitat Permanenti Għall-Kunsiderazzjoni ta’ Abbozzi ta’ Liġi 2018a, 2018b). The Gift of Life has also consistently highlighted the importance of safeguarding the embryo from the moment of conception and not treating it as a “disposable commodity” (Vincenti 2005).

In response to the Select Committee's recommendation for embryo freezing, the Professionals Against Embryo Freezing (PEAF), a lobby of more than 100 professionals was established to oppose embryo freezing. They argued that human life beings at fertilisation and raised concerns on embryo adoption, the surplus of frozen embryos and embryo destruction (SAC 2011a, The Malta Independent 2011a). Together with the Gift of Life, the Cana movement and the NCW, they called for a restrictive legislation that bans embryo freezing and enshrines the protection of human life from conception (Attard 2012, SAC 2011a, 2011b, 2011c, Cana Movement 2012, The Malta Independent 2011b).

With the subsequent amendments to the legislation, the same groups, the Life Network Foundation and 100 academics from the University of Malta and experts in various fields came forward in opposition. They argued against embryo freezing, embryo adoption, anonymous gamete donation and surrogacy arguing that this leads to the embryo becoming a “commodity” (Agius et al. 2018, Archdiocese of Malta 2015, Times of Malta 2015, The Malta Independent 2015a, Sansone 2015, Vella 2015a, 2015b, Grech 2018, Abela, Sammut Scerri 2018, Cana Movement 2018, Consideration of Bills Committee 2018a, 2018b, Micallef 2018)

In 2022, the proposal to introduce PGT was equally met with significant opposition. Pro-life groups, organisations working with vulnerable people, Malta Federation of Organisations Persons with Disability and a group of multidisciplinary experts described this legislation as a discriminatory practice that amounted to eugenics. These stakeholders advocated for PBB, to balance the needs of couples suffering from rare genetic diseases, and the ethical and moral complexities related to PGT (Archdiocese of Malta 2022, Cana Movement 2022, Consideration of Bills Committee 2022a)

4.2.3.3 Medical and Scientific Community

Throughout the years there was a number of actors from the medical and scientific community that advocated for a restrictive legislation. Prof. Pierre Schembri Wismayer, a cell biologist and member of PAEF, along with other scientists and the Malta College of Pathologists (2018) recognised the beginning of human life at fertilisation (SAC 2011, The Malta Independent 2018a). A group of more than 500 doctors, known as Doctors for Life, also argued that human life starts at fertilisation and therefore, argued against introducing embryo freezing as a “routine part” of IVF (De Pontbriand 2018). This group maintained a similar stance on PGT, arguing against the introduction of PGT, describing it as “eliminating the ill” and instead favouring PBB (Agius 2022).

4.3 Insights into the Policy Process from Interviews with Policy Actors

This section presents a thematic analysis of the perspectives and experiences of nine policy actors that formed part of the policymaking process of IVF regulation in Malta throughout the years. During the interviews, these actors shared their respective beliefs and values that shaped their role throughout the process. This section primarily focuses on the actors’ lived experiences and personal perception of the policymaking process. Using Thompson’s (2022) approach to abductive thematic analysis, Table 4.1, captures the major themes identified, and the respective codes attributed to the data gathered. The themes identified are: ‘Institutional Design and Formal Structures’, ‘Political Parties and Agenda Setting’, ‘Policy Influence and Stakeholder dynamics’ and ‘Contextual Factors’.

Thematic Analysis	
Theme	Codes
<i>Institutional Design & Formal Structures</i>	BCC Set up and Role
	Parliamentary Committee Dynamics
	Parliament Dynamics
	Policy Entrepreneurs
<i>Political Parties and Agenda Setting</i>	Political Parties
	Political Values and Ideologies
	Political Agenda
	Incremental Change
<i>Policy Influence and Stakeholder Dynamics</i>	Civil Society
	Coalition Dynamics
	Elite Networks
	Influence of scientific community
	Consultation
	Stakeholder Engagement
	Compromise
	Negotiation
<i>Contextual Factors</i>	External Events
	Media
	Public Opinion
	Informal Channels
	Religious Values

Table 4.1: Thematic Analysis

4.3.1 Institutional Design and Formal Structures

As noted in the historical analysis, the BCC and the SAC were two formal structures that were instrumental to the development of the regulation on IVF throughout the years. The former Chairperson of the BCC (2003 and 2013) recalled that the committee:

“Had been harping on the need for IVF (regulation) ... the Health Minister then asked me to start thinking about a law and we set to work.”²

Showing how as a consultative committee, the BCC is dependent on the political will of the Minister. However, the same Chairperson used his position in Parliament to push the discussion on IVF and urge the Government to be proactive. This highlights the important role of policy entrepreneurs to push morally complex issues on the macropolitical agenda, particularly when formal institutional structures lack the power or autonomy to do so.

The importance of policy entrepreneurs is also identified in the SAC between 2003 and 2012, where the respective Chairpersons pushed the discussion and recommendations on IVF regulation at the political level. As explained by the Chairperson of the SAC between 2003 and 2008:

“This is the first report (Puli Report) made by a parliamentary committee to Parliament. Before the Government used to give you a report and you might consider it and discuss it, scrutinising, but this was an own initiative.”

Similarly, the Chairperson of the SAC (2008 and 2012) stated that the report produced during this period was his responsibility:

“It was on my initiative to see that we are carrying out our duties properly and in Parliament.”

² All quotations have been translated by the researcher from Maltese to English

Between 2004 and 2005, the SAC was an important venue to bring together different actors and stakeholders to discuss and provide their recommendations. As stated by the Chairperson:

“This was relatively new, where you are invited to have your say ... the stakeholders, I genuinely got them there to talk and gave them the opportunity to influence the policy. Now it was a slow process but if you tell me, they did influence the policy because that set the ball rolling.”

Despite these efforts, this exercise had a limited impact on the political agenda of the Parliament. As although the Puli Report was presented in Parliament, there was no obligation for the Government to act on its recommendations. This was also the case for the other reports presented in Parliament. Thus, underscoring the limited possibility of a policy issue to move from the policy subsystem and onto the macropolitical level without the necessary political support.

4.3.2 Political Parties and Agenda Setting

As the leading political parties, the PN and PL were responsible for advancing the regulation of IVF onto the Government's agenda. Interviewees noted how the distinct party values and longstanding ideologies influenced the approach taken by the respective PN and PL Governments when legislating on IVF. Various interviewees highlighted the PN's explicit pro-life stance, that influenced the restrictive approach taken for the first legislation. Building on this, the former Chairperson of the BCC argued that this is also linked to the PN's more continental approach, primarily guided by the German and Italian legislation on IVF which is focused on the protection of the embryo.

In contrast, the interviewees noted that following the change in Government from PN to PL in 2013, there was a significant shift in values. As explained by, the former Chairperson of the BCC, the PL have a neo-colonial mentality, therefore, they look at English speaking countries such as

the UK, which as identified in the Literature Review took a more secular and permissive approach to IVF legislation. Consequently, this led to a change in the priority of values, as expressed by the Former Dean of Theology:

“Whereas in 2012, what is the best interest of the embryo ...in 2018 is different, is not what is the best interest of the embryo, but how could we assist the couple.”

This shift towards a more secular view on IVF under the PL, was echoed by the former Minister of Health (2017 – 2024):

“We wanted to improve services and give more opportunity to people who cannot have children in a natural way ... that our doctors can give a better medical service, because at the end of the day IVF is a medical service, ...we give what is ethically available in other countries, we do it in our country as well.”

Despite these ideological differences, both parties undertook a cautious and incremental approach to legislating on IVF. Although the PN was presented with various opportunities to legislate, it took into consideration public opinion and readiness before legislating. As noted by the Chairperson of the SAC (2003 – 2008), the fact that the Government did not act on the Puli Report might have been because the Government did not perceive the need for such a legislation among the public. In contrast, the former Chairperson of the BCC attributed the Government’s decision to legislate mainly due to public demand, emphasising public opinion as key to pushing IVF onto the macropolitical agenda. Similarly, the PL also favoured an incremental approach. The former Minister for Health argued that although they knew that more amendments are necessary, given the moral and ethical complexities surrounding IVF they opted for a “stepwise” approach reflecting a strategic approach to agenda setting, where reforms are gradually introduced to counter controversy and allow the public mentality to adapt.

4.3.3 Policy Influence and Stakeholder Dynamics

4.3.3.1 The Influence of Civil society and the Scientific Community

When analysing the positions of the different stakeholders, a key theme noted was that actors within the permissive coalition were fragmented, while the restrictive coalition was more cohesive. The Chairperson of the Life Network Foundation, who was also a founding member of PAEF, emphasised the importance of networking and strategic coalition building to have a stronger voice. She noted how from 2015 onwards the Life Network Foundation sought to bring together different specialised actors;

“It was definitely not Life Network alone ... all that it does is networking. But the stakeholders who were really specialised people on the subject were rather ignored. I mean, we had psychiatrists, psychologists, ... we had gynaecologists. We even brought people who were living this reality, where it had already entered their country.”

In contrast, the President of Nisa Labursiti reflected that despite sharing the same goals, like-minded organisations fail to coordinate their efforts:

“There are sometimes ... for example (other organisations) they do not approach us, even if they know that we are on the same side.”

She added that this fragmentation weakens the impact of their position, ultimately, limiting the possibility of influencing public opinion in their favour.

Another interesting aspect noted was also the indirect yet strategic involvement of the medical and scientific community, mainly through elite networks and informal access to decision-makers. As explained by the former Chairperson and the current Chairperson of the BCC, who are both medical professionals, they could use their positions to directly access policymakers, therefore, influencing the policy process beyond the formal institutional structures. The former Chairperson of the BCC explained that back in 2012:

“I wrote a lot of the scientific part... I named it Embryo Protection Act for the reason also that I wanted to give in the law a definition of what an embryo is, when human life begins.”

Similarly, the current Chairperson of the BCC noted how the former Minister of Health sought advice from him regarding surrogacy and the number of frozen embryos, which ultimately, the Minister took on board and were reflected in the legislation. Therefore, underscoring the importance of elite networks to indirectly influence the political direction.

However, it could be noted that after 2013, more permissive members of the medical and scientific community influenced the position of the Government. As explained by the Minister of Health, the legislative amendments introduced by the Government were mainly pushed by IVF practitioners, citing concerns such as the low success rather due to the restrictions on embryo freezing and the unfair treatment of certain couples who were not able to access tests such as PGT that were readily available abroad. Thus, highlighting the role of the medical community to influence the secular approach of the Government.

4.3.3.2 Stakeholder Engagement and Negotiation

An interesting aspect noted was how different actors were consulted by the respective Governments over the years. For instance, The Life Network Foundation noted that before the shift in Government in 2013, they were respected and included in the discussions at the highest levels:

“We were part of the law... we were part of the discussion, and they paid great attention to our points.”

The Former Dean of Theology also noted his participation in a “small group” to discuss the 2012 legislation, thus, showing the involvement of a handful of carefully selected actors in drafting the legislation.

However, after 2013, the Chairperson of the Life Network noted that although they were invited to discuss with the former Health Minister; “We were consulted as a courtesy but there weren't really those who consider the matters that we were putting forward”. This underscores the perception that conservative actors felt ignored by the more progressive PL Government.

Other actors such as the CEO of the EPA who was part of the Inter-Ministerial IVF Review Working Committee, challenged this position, arguing that:

“The consultation took its time, that is, it was not a tick of the box, we gave it time, everyone who wanted to come and talk to us, came and met us.”

Additionally, the former Minister of Health also noted that various actors were included in the discussions. However, he argued that:

“We were not doing this exercise to keep everyone happy; we wanted to improve the services ... Now, whoever for his moral reasons does not agree, will not necessarily agree with us, in the end, whoever is in Government, is in Government to make the agenda he was elected on.”

This statement underscores that while consultation was an important aspect for the PL Government, it was determined to proceed with the legislative amendments irrespectively.

Nevertheless, interviewees noted that there was space for negotiation and compromise on some of the most controversial issues like embryo freezing, namely the number of frozen embryos to be allowed, and surrogacy. The CEO of the EPA recalled how the Government took advantage of the division between the Opposition MPs when discussing embryo freezing and took the proposed number of five embryos rather than seven. However, the former Minister of Health highlighted

the removal of surrogacy from the proposed amendments in 2018, as the main compromise made by the Government. This was also echoed by the Chairperson of the Life Network Foundation and the former Dean of Theology, who cited this decision as a tangible achievement of their lobby.

4.3.4 Contextual Factors

4.3.4.1 Informal Channels

A key insight noted is the role of informal channels in influencing the policymaking process. The current Chairperson of the BCC recalled how in 2000, after the presentation of the committee's recommendations on IVF, the Church promptly used informal channels to voice its opposition to the Minister which led to the recommendations being shelved. In contrast, informal channels can also be a venue for developments. The Chairperson of the Life Network Foundation recalled how she had established PAEF following an informal discussion with the Chairperson of the SAC (2008 and 2012) who advised her that to be able to re-open the discussion on embryo freezing there needs to be an official request by an organisation. Furthermore, various interviewees highlighted the importance of direct access to stakeholders, noting that closed-door meetings were instrumental in fostering discussion and shaping the decisions made.

4.3.4.2 Opportunities for Policy Change

Interviewees also referred to different external events that took place over the years, that shaped the development of IVF policy. Malta's accession into the European Union (EU) was described as a distraction that diverted policymakers' attention away from IVF regulation. On the other hand, the divorce referendum was recognised as a catalyst for future progressive legislation. Elections were also cited as crucial in determining policy progress, as there was an opportunity for political parties to acquire a political mandate to legislate on IVF. This was noted by the former Minister of Health who explained that due to the controversy surrounding the 2015 consultation,

the 2017 General Election was an opportunity for the PL to include reference to IVF amendments in the manifesto, similar to what it had done back in 2012 and what it would do again in 2022.

4.3.4.3 Religious Authority, Cultural Norms and Shifting Public Opinion

Religious values were also cited as influential factors, with interviewees noting that Malta is ultimately a Catholic country, therefore, the legislation had to be drafted in a manner that reflects this. Furthermore, public opinion changed significantly over the years. As noted by the CEO of EPA:

“In 2012, the picture was much different, I think the media and society at large, at first they were against legislating IVF... it was shown like we are going to ... introduce something that is immoral.”

Eventually public mentality shifted in favour as they could see the tangible results of the legislation. Public opinion was also heavily swayed by emotional arguments. The former Minister of Health noted that during the discussion on PGT-M when parents and couples shared their story and personal struggles, public opinion changed greatly, prompting the Nationalist Party to vote in favour of the amendment.

4.3.4.4 Media

The role of the media in the debate on IVF was criticised by most interviewees. Although there was significant coverage, interviewees noted that the reporting by the news outlets was political partisan and agenda driven. The Chairperson of the SAC between 2008 and 2012 noted that:

“journalists take a snippet ... they find something that they disagree with, and they amplify it ... to put us in an awkward, negative position.”

Others noted that certain outlets were clearly biased, favouring certain arguments and consequently, leading to unnecessary polarisation of the public opinion.

4.4 Theories of Policymaking

This section brings together the data from the document analysis and the thematic analysis of the interviews, by applying the theories of policymaking to explore which theory best explains the dynamics and processes that were involved in the development of the IVF policy in Malta.

4.4.1 Incrementalism

The gradual, non-radical development of IVF regulation throughout the years can be largely explained by theory of Incrementalism. The Embryo Protection Act in 2012, although a landmark policy outcome, it was not the result of radical reform but rather, years of negotiation and compromise between different actors with competing interests (Lindblom 1965). As noted in this historical analysis, although there were discussions to introduce embryo freezing and embryo adoption, the legislation in 2012 did not include these provisions and instead remained largely similar to the first iterations of the legislation drafted back in 2005, underscoring how policy changed only incrementally over time.

The subsequent legislative amendments introduced by the PL government between 2018 and 2022 were also incremental changes based on remedial decision making (Lester, Stewart 2000). The Government favoured a “stepwise” approach that sought to tackle pressing, tangible issues such as embryo freezing, wider access to IVF and PGT. Although these reforms were introduced in response to the increasing pressures from civil society and the scientific community, they were framed as necessary to ensure the success of IVF and to provide more opportunities to couples. This approach allowed the Government to introduced limited changed with limited backlash.

This incremental introduction of a more permissive legislation can also be explained Waaldijk’s small-change theory (Aloni 2020, Hamilton, Sperti 2023). Every gradual reform introduced,

including the introduction of divorce in 2011, the Embryo Protection Act in 2012 and LGBTIQ rights in 2014, played a crucial role in slowly shifting public opinion and values. By adopting a gradual approach to reforms, it was possible to increase acceptance for more liberal reforms both at the social and political level. This can be noted in how the different reforms were received at different times. When the Government tried to introduce surrogacy 2018, there was widespread backlash. In contrast, the introduction of PGT-M in 2022 was met with less resistance, especially at the political level, thus, signalling that public opinion had gradually adapted over time.

4.4.2 Institutionalism

The development of IVF policy in Malta shows how both formal and informal rules have significantly influenced the policymaking process throughout the years (Cairney 2019, Knill, Tosun 2020, Peters 2022). Parliament, as a formal institution, was an essential avenue to advance the regulation of IVF on the political agenda, highlighting how the institutional structure of a country enables entrepreneurs to influence the agenda (Bleiklie et al. 2004). The procedural rules of the Parliamentary Committees made it possible for policy entrepreneurs such as Ascjak and the Chairperson of the SAC between 2003 and 2008 to elevate a contentious policy issue onto the Parliament's agenda. However, due to the limited institutional powers of Parliamentary Committees, their impact was limited. As seen in the case of the Puli Report in 2005 and the Report of the Select Committee on MAP in 2010, although various policy recommendations informed by expert discussions were put forward, these had no immediate impact until the Government decided to legislate in 2012. This can also be noted in the case of the subsequent amendments, as IVF only resurfaced on the political agenda when the PL Government tabled a motion in Parliament.

Informal rules, norms and practices have also played an important role. Informal channels and long-standing Church-State relations have enabled the Church to act as veto player, limiting the

progress of potential legislation (Bleiklie et al. 2004). In 2000, the recommendations by the BCC on IVF regulation were shelved following informal discussions between the Minister and the Archbishop. Similarly, in 2005, the Archbishop used his sermon during a mass where MPs were gathered to send a strong message against IVF.

When applying Smith's model, which applies historical and discursive institutionalism to morality politics (2018), certain elements are evident in the local context. Taking institutional structures and historical precedents, prior to 2012 the development of IVF policy was characterised by path dependency as the PN government, the executive at the time, resisted change (Cairney 2019, Peters 2019). However, the upcoming elections of 2013 and the pressure from PL by making IVF legislation an electoral promise created a critical juncture that led to a major policy change (Peters 2019, Schmidt 2010). Furthermore, discourse and concepts have significantly influenced how the different Governments framed IVF, ultimately, influencing the policy outcomes (Schmidt 2010, Smith 2018). The PN Government framed the IVF from a moral frame, highlighting the protection and dignity of the human embryo, as ultimately enshrined in the legislation. In contrast, the PL Government employed a secular frame, highlighting reforms as necessary to ensure the success of IVF and for more couples to potentially benefit. These competing discourses reflect the contrasting party values and ideologies identified by interviewees.

4.4.3 Punctuated Equilibrium Theory

The historical analysis conducted has shown that the regulation of IVF in Malta has followed the punctuated equilibrium pattern observed by Hurka et al. (2016) in their study on morality policies across 19 European countries. Overall, IVF policy in Malta has been characterised by significant conflict about "first principles and core values" mainly concerning the protection of the embryo and related IVF practices that challenge this principle. This led to more than 20 years of policy

stagnation that preserved the status quo of no government intervention. However, this stability was disrupted in 2012, with the introduction of the Embryo Protection which was restrictive regulation this signalled a large-scale policy shift.

This period was characterised by a strong policy monopoly, where several actors sought to influence regulation of IVF through closed policy venues, mainly parliamentary committees and the BCC. Due to disproportionate information processing at the system level, the issue of IVF did not reach the macropolitical agenda until there was a re-framing within the policy monopoly. In 2010, the recommendations by the Select Committee on MAP reflected a departure from previous reports, with the Committee seeking to reframe the issue to a secular perspective based on scientific advice. Similar to the case of New Zealand's reframing of the Psychoactive Substances (Rychert, Wilkins 2018), this attracted new policy entrepreneurs, mainly the lobby PAEF which pushed for policymakers to reconsider these recommendations, particularly on embryo freezing. This internal disruption within the policy monopoly pushed IVF regulation onto the macropolitical agenda and captured the attention of political parties which sought to use the upcoming national election to push for regulation. Therefore, policy change in this case was the product of external events (an election) and disproportionate attention by policymakers (Baumgartner et al. 2018) combined with unresolved policy issues that extended beyond the policy monopoly and into the public domain (Zehavi 2011).

The subsequent policy change in 2018 follows the dynamics observed by Engeli et al. (2012) in relation to PET and the role of political parties to influence policy change on morality politics. As noted by Schiffino et al. (2009) political parties play an important role in driving policy change. Until 2013, Malta followed a similar pattern to Italy, with the PN closely aligning its values to the Church, an important policy entrepreneur that framed IVF in line with its religious values and morals, leading to a restrictive regulation. The change in Government in 2013 marked a turning point, with the PL framing IVF from a secular stance which led to subsequent permissive

amendments to the legislation, signalling a new policy equilibrium. A similar pattern was noted in Spain where the election of left-wing party led to a more permissive policy on IVF (Engeli et al. 2012). This shift in Government influenced the policy monopoly on IVF, creating an opportunity for a positive feedback process. As new actors namely civil society groups and medical practitioners entered the monopoly and reframed the dominant policy image, ultimately influencing the political agenda for a more permissive legislation (Timmermans, Scholten 2006).

4.4.4 Multiple Streams Framework

Policy entrepreneurs have been instrumental to push the regulation of IVF onto the policy agenda and influence the policy outcome. Consequently, the MSF provides a useful framework to assess how policy entrepreneurs brought together the three streams together to create opportunities for policy change (Kingdon 1984, 2014).

Between the 1990s and early 2000s, the discussion on IVF was sidelined for various reasons. As argued by the former Chairperson of the BCC, public knowledge and discussion on IVF was very limited and the attention of policymakers was focused on Malta's EU accession. During this time, the BCC, a closed policy venue where policy alternatives on IVF were being generated, had tried to push for a set of recommendations on potential IVF regulation, however, this was shelved by the political stream. The former Chairperson of the BCC used his position as an MP and a member of the PN, to push IVF onto the agenda. Therefore, bringing the three streams together to create a window of opportunity, as seen in the case of organ donation in Germany (Wainright, Hanser 2016). While this did not immediately materialise into policy change (Kingdon 2014) this was the first step in elevating the discussion on IVF regulation to the political level.

Furthermore, the connection between the former Chairperson and the Government, proved to be instrumental to push for the BCC's 'pet project' (Kingdon 2014). As between 2005 and 2012 the

BCC was consistently consulted by the Government on the legislation, allowing the BCC to advance their position on key issues such as embryo freezing, the definition of the embryo, and gamete donation. Along with other actors, they shaped the policy in a restrictive direction as introduced in 2012 (Birkland 2020, Herweg et al. 2018, Kingdon 1984, 2014).

After 2013, another window of opportunity presented itself. The legalisation of divorce, the election to a more liberal Government and the introduction civil rights, had signalled a significant shift in the national mood in favour of a more permissive IVF legislation. This prompted new policy entrepreneurs to enter the policy stream, namely IVF practitioners and civil society. The 2015 consultation on IVF presented an opportunity for these policy entrepreneurs to highlight different issues within the problem stream, such as the low IVF success rate and the inequalities faced by those seeking IVF, especially same-sex couples, to the attention of policymakers. While policy change was not immediate this prompted the subsequent gradual permissive amendments presented by the Government between 2018 and 2022.

4.4.5 Advocacy Coalition Framework

Since coalitions have been instrumental in shaping IVF regulation in Malta, the ACF provides the necessary tools to better understand the coalition dynamics within this policy subsystem. As seen from the stakeholder position analyses, this subsystem is dominated by two coalitions: the restrictive coalition and the permissive coalition. Despite their competing views, both coalitions were highly motivated by deep core beliefs and overarching policy objectives, as is seen with other morality issues (Crawford, Weible 2024).

As emerged from the historical and stakeholder analysis, between 1991 and 2012 the restrictive coalition held a dominant position in the subsystem. Actors from different areas including, theological experts, civil society groups and professional lobby group, were brought together by

their deep core beliefs on the protection of the embryo, as human from conception, and preserving the traditional family values. Driven by these beliefs, they formed a coalition that sought to achieve a restrictive IVF legislation. These actors sought to push their agenda through different institutional venues, mainly the SAC and the BCC. However, certain actors were also directly involved in a small group responsible for the drafting of the legislation in 2012, therefore, signalling the coalition's extended influence even at the executive level. Beyond the influence of elite networks and back channels, this coalition was notably unified on its policy objectives, which is essential for driving policy change (Bleiklie et al. 2004). In contrast, the permissive coalition was a minority coalition mainly represented by members of the scientific community that were not motivated on deep core beliefs but rather secondary beliefs as they focused their efforts on how potential regulation can limit the practice of IVF (Jenkins-Smith et al. 2018, Sabatier, Wiebel 2007).

A turning point came in 2011 with the legalisation of divorce, which weakened the position of the Church within society and reflected a shift in the prevailing public values and beliefs (Harwood 2022, Pace 2012). Adding to this was the change in government in 2013. Together, these external shocks affected the stable parameters within which the policy subsystem had operated for almost 10 years, creating an opportunity for the minority coalition to strengthen its position (Jenkins-Smith et al. 2018, Sabatier, Wiebel 2007). Although the permissive coalition continued to be fragmented, this coalition managed to push for policy change in favour of more permissive legislation, underscoring how effective policy change can only happen when there is a shift in coalitions (Kubler 2001). IVF practitioners were instrumental in guiding the decisions taken by the Government for a more permissive legislation, as seen in between 2018 and 2022 with the introduction of embryo freezing and PGT-M. Civil society, political parties, and different national commissions shared secondary policy beliefs which led them to collectively advocate for more permissive policies that allow for greater access to IVF, this includes gamete donation, surrogacy, embryo adoption and PGT-M.

4.4.6 Narrative Policy Framework

Throughout the debate on IVF regulation and the subsequent amendments, the framing and narratives employed by the various actors involved were crucial in determining the development of the policy. Thus, the NPF can be applied to explain the positions of the different stakeholders through different narrative strategies.

During the early debates, the Church employed a strong narrative framing IVF from a religious moral perspective. Through various statements the Church framed IVF as an immoral and illicit practice, influencing the public perception. This reflected a 'Devil-Angel shift' (Shanahan et al. 2011) whereby the Church positioned itself as preserving the dignity of the embryo and the sanctity of marriage, while those against were challenging traditional core values of society. This narrative was also employed by others within the restrictive coalition, including the PN, civil society, and various experts, who re-iterated their commitment to protecting human life from conception. This was ultimately reflected in the wording of the first legislation where the emphasis on protecting human life is reflected in the name of the legislation 'Embryo Protection Act'.

In contrast, the permissive coalition and the PL government, opted for less polarising narratives, framing their argument in secular terms, based on scientific evidence and empathy for those struggling to benefit from IVF. This coalition relied heavily on micro level strategies, that appeal to the individual. The emotive stories in the media of parents who suffered from genetic diseases were instrumental to influence public opinion in favour of PGT-M. In contrast, the framing of the restrictive coalition on eugenics and discrimination, a narrative that aligns with macro-level concerns of societal beliefs, did not have a lasting impact aligning with Shanahan et al.'s (2018) perspectives.

4.4.7 Summary of Theoretical Insights

While all theories provide distinctive insights that are relevant into the policymaking process, from this assessment it can be conclude that PET and new institutionalism, specifically historical intuitionism and discursive institutionalism provide the most comprehensive insights into the IVF policymaking process. As a theory, punctuated equilibrium can explain both periods of incrementalism and stability, because of negative policy feedback from closed policy monopolies, as well as sudden punctuated change, due to external events or positive policy feedback due to change in the policy monopoly. Historical institutionalism compliments this analysis by explaining incrementalism due to the constraints created by formal and informal rules, while discursive institutionalism provides a deeper understanding into the role of institutions in framing the policy image.

With respect to the other theories, it can be noted that these can be used to further compliments the insights uncovered by these three theories. The theory of incrementalism can provide the insights into how policy developed gradual, remedial policy change across all three theories. The MSF can be used to compliment the PET to explore role of policy entrepreneurs to create opportunities for change. Similarly, the ACF and NPF can be applied to better understand the role of the coalitions within the policy subsystem and the narratives they use to push issues onto the political agenda.

Chapter 5: Conclusion

5.1 The Development of IVF Legislation between 1991 and 2022

Although practiced locally for almost 40 years, the practice of IVF in Malta has been regulated for only 13 years. The debate on IVF regulation was largely stagnant between 1991 and 2000, despite the efforts by the BCC to push the discussion. This stagnation can be largely attributed to the tumultuous political context that required the full attention of policymakers. In 2004, the discussion on IVF reached Parliament, and the first recommendations for future legislation were presented in 2005. At the same time, the Government was drafting the first iterations of the Embryo Protection Act. However, these developments did not materialise in concrete policy change. Between 2009 and 2010, Parliament re-initiated the discussions, and the Select Committee on MAP, appointed by Parliament in 2009 to provide recommendations for future legislation, presented a comprehensive report in 2010. These recommendations were met with significant opposition due to their permissive nature, leading the discussion on IVF to be sidelined until 2012.

In 2012, the PN Government introduced the Embryo Protection Act, which marked a drastic policy change, introducing highly restrictive policies limiting both the autonomy of practitioners and access to those wanting to use IVF (Goggin et. al 2004). The change in government in 2013 marked a turning point. Between 2018 and 2022 gradual amendments were introduced to make the existing regulation more permissive, allowing more flexibility to practitioners and widening access to IVF to more beneficiaries beyond the cure of infertility (Goggin et. al 2004).

The lack of policy progress between 2000 and 2012 can be attributed to ethical concerns that were recurring across the different policy recommendations and draft legislation. These concerns revolved around the moral status of the embryo, embryo freezing, eligibility for unmarried couples and third-party gamete donation (Mallia 2013, 2014). Although the 2012 Embryo Protection Act sought to resolve these conflicts by adopting restrictive policies, there was no consensus. Consequently, this unresolved conflict led to continued debate between 2015 and 2022

on the donation and adoption of frozen embryos (Clark 2014), PGT, access to IVF for single women and same-sex couples (Asplund 2020, Beers 2019), and surrogacy (Mackenzie et al. 2020). Therefore, this highlights how unresolved moral conflicts have largely hampered the development of IVF regulation in Malta, impacting all levels of the policy process, especially at the political level.

5.2 Stakeholder Positions and Influence

The debate on IVF regulation in Malta saw different actors with opposing moral perspectives seeking to influence the policy process and the eventual policy outcomes. As explained by Mucciaroni (2011) morality politics is usually characterised by debate on fundamental moral principles that take precedence over practical policy outcomes. In Malta, the debate on IVF regulation was primarily a disagreement between actors on “first principles” as they publicly clashed over privately held secular and religious values (Mooney 2001, Henricson 2016). Malta’s strong “catholic normative values” (Mallia 2009, p 14) meant that religious beliefs, although private held, deeply influenced the debate, making compromise difficult (Mourão Permoser 2019, Rachels, Rachels 2011).

The actors that called for more restrictive policies, such as Prof. Agius, Dr Ascjak, PAEF, Cana Movement, the NCW, Doctors for life, the Life Network Foundation and the Gift of Life were strongly motivated by core religious beliefs on the moral status of the embryo, as a human from conception, and the preservation of the family (Mallia, 2013, 2014). This led them to adopt a restrictive stance on the eligibility of IVF to married couples or those in stable relationship, and banning practices such as embryo freezing, PGT, surrogacy, embryo donation and adoption, and gamete donation. Between 2004 and 2012, this coalition was largely successful in pushing its agenda through the SAC and at the executive level, through various policy entrepreneurs and informal channels. This was mainly possible as the governing party, the PN, closely aligned itself

with the values of the Church and consistently maintained the protection of the embryo. Ultimately, this coalition came out victorious in 2012 with the restrictive Embryo Protection Act that largely followed the proposals advanced by this group, emphasising the importance a cohesive coalition to achieve its policy objectives, while taking advantage of the existing institutional structures and norms to influence policy (Bleiklie et al. 2004).

The actors that called for permissive policies such as the leading practitioners of IVF, various national commissions, Nisa Laburisti, MGRM, aditus foundation, Doctors for Choice, the Green Party, Volt and various individuals who had undergone IVF, were guided by secular beliefs and human experience (Henricson 2016). This group framed IVF from a scientific perspective, describing it as a medical service and focusing instead on the importance of delivering the best service possible to all those who require it, as explained by the former Minister of Health. They argued for a more flexible definition of the embryo, wide access to IVF to include single women and same-sex couples, and allow practices such as embryo freezing, embryo adoption, anonymous donation of gametes, surrogacy and PGT. This coalition has been largely fragmented, limiting its impact especially between 2004 and 2012. However, the change in Government brought a shift in values in 2013, as the PL also viewed IVF from a secular perspective and framed its arguments for the subsequent amendments in a technical manner tackling tangible issues (Harwood 2022, Hayes, 2013). This led to a shift in the policy subsystem as the permissive coalition lead mainly by the medical community, was able to push its agenda and shift the dominant policy image on IVF (Sabatier, Wiebel 2007, Jenkins-Smith et al. 2018).

The debate on IVF regulation in Malta represents a deeper ideological conflict within society over moral authority, with one side pushing for tradition and continuity grounded in religious beliefs, while the other pushes for progress and liberation based on secular beliefs (Hunter 2011, Henricson 2016). Throughout this process, both sides tried to push for their respective moral perspectives to be upheld in the ultimate policy outcome (Cochran et al 2012).

5.3 Policymaking Theories and Morality Politics in Malta

When assessing which theory of policymaking best captures the dynamics and processes that have shaped the regulation of IVF in Malta, it could be noted that no one theory captures all aspects involved. PET, Historical Institutionalism and Discursive Institutionalism were identified as the prevailing theories that explain the IVF policymaking process. These theories capture both the incremental policy change and sudden large-scale policy shifts, due to external events and institutional dynamics. However, other theories of policymaking also contribute to this analysis as they provide insights into the role of policy entrepreneurs, subsystem coalitions and narrative development. Figure 5.1 presents the different contributions of the respective theories, which may be applied to explore the policymaking process of other morality politics in Malta.

Theory	Keywords
Incrementalism	Gradual, remedial policy change
Institutionalism	Formal institutions; informal rules and practices; critical juncture; path dependency
Punctuated Equilibrium Theory	Long periods of stability; punctuated radical reform; policy monopoly; positive feedback cycles
Multiple Streams Framework	Policy Entrepreneurs; Policy Windows
Advocacy Coalition Framework	Policy subsystem; dominant coalition versus minority coalition; external shocks
Narrative Policy Framework	Devil-Angel Shift; micro & meso level strategies

Table 5.1. Elements of Theories of the Policymaking Process relevant to morality politics

5.4 Scholarly Contribution

This study is the first research undertaken to provide a comprehensive overview of the development of IVF policy in Malta by establishing the key developments on IVF regulation between 1991 and 2022, and presenting the different positions of the stakeholders involved throughout this process. This included political parties, the medical and scientific community, civil society organisations that presented a wide range of positions in the debate, key experts and various national commissions. Furthermore, through the semi-structured interviews undertaken with elites who were directly involved in the policymaking process, this study was able to present insights that were previously not publicly available. Therefore, this study provides a distinct empirical contribution by identifying the specific policy developments and the underlying political and cultural context within which these developments occurred to explain the overall policymaking process of IVF Malta.

Building on this, this study addresses a notable gap identified in the literature review with respect to literature on morality politics and policymaking in Malta. In the local context, most literature has not focused on the overall policymaking process. As for international literature, despite the growing body of literature on the policy design process for IVF regulation across different countries in Western Europe and Northern America, there is a lack of literature available on policymaking on morality politics within small states, and more specifically, in Malta. Furthermore, most studies apply theories of policymaking or parts of, to assess specific cases. By taking an abductive approach, this study is not restricted to one theory but rather shows how different theories provide specific insights into the policymaking process, ultimately, enriching the findings.

5.5 Future Research

Since this study was focused on IVF regulation as a case study policymaking on morality politics in Malta, future studies may apply the different elements of the theories of policymaking identified to similarly contentious policy issues such as abortion, LGBTQ rights, euthanasia, cannabis decriminalisation and divorce. By applying this framework, future research can determine if certain elements identified in this study such as gradual policy change followed by radical policy change, the role of formal institutions and informal rules to influence the policy development and the role of political parties and policy entrepreneurs to advance morality politics on the political agenda, are also observable in other contentious policy issues locally.

Future research may also narrow the focus of this research by applying one specific model of policymaking to a specific contentious policy issue in Malta. While this research employed a rich dataset and explored multiple frameworks, it lacked in-depth analysis into aspects such as policy framing, narrative building and discourse analysis. These are areas that may be explored by future research on IVF regulation in Malta.

5.6 Concluding remarks

This study aimed to explain the policymaking process on morality politics in Malta by taking the development of IVF legislation as a case study. Overall, the regulation of IVF in Malta has been a long and gradual process characterised by disagreements between actors with competing interests and political hesitancy to regulate, especially in the early years. The analysis demonstrated that the institutional structures and informal rules in Malta's political system have largely hindered this issue from reaching the macro-political agenda, often requiring policy entrepreneurs within elite circles to motivate political consideration. Having said this, real policy changes only emerged when there was sufficient political will to do so. Thus, this highlights the

important role of political party values and beliefs in determining the political agenda and the final policy outcome.

Overall, this study underscores the complex policy landscape within which morality politics operate influenced by political will, institutional structures and stakeholder beliefs. The pattern of policymaking identified in this study may be used to explain other morality politics, such as the legalisation of divorce which was absent from the political agenda until a policy entrepreneur raised it in Parliament, and the introduction of LGBTQ rights in Malta that were advanced onto the political agenda following an electoral promise by the PL (Deguara 2019, Fenech 2012, Harwood 2022). Therefore, future research may further explore the dynamics observed in this study to other contentious policy issues and assess whether the same patterns can be identified.

Appendices

Appendix 1 – List of Documents Analysed

Official Documents from Government Sources

Parliamentary Documents

Social Affairs Committee			
<i>Legislature</i>	<i>Document Type</i>	<i>Date</i>	<i>Title</i>
2003 - 2008	Meeting Transcript	15/11/2004	Laqgħa Nru. 16
	Meeting Transcript	29/11/2004	Laqgħa Nru. 17
	Meeting Transcript	10/01/2005	Laqgħa Nru. 18
	Meeting Transcript	24/01/2005	Laqgħa Nru. 20
	Meeting Transcript	21/01/2005	Laqgħa Nru. 21
	Meeting Transcript	07/02/2005	Laqgħa Nru. 23
	Meeting Transcript	28/02/2005	Laqgħa Nru. 26
	Meeting Transcript	09/05/2005	Laqgħa Nru.35
	Meeting Transcript	10/05/2005	Laqgħa Nru. 36
	Report	26/09/2005	L-Użu tal- Bioteknoloġija – Teknoloġija Ġenetika u Prokreazzjoni Assissitita
2008 - 2013	Report	0/09/2005	Aġġornament tal-Aħħar tagħlim etiku u morali fuq il-Prokreazzjoni Assista - Evalwazzjoni tar-Rapport tal-10 Leġislatura
	Meeting Transcript	22/02/2011	Laqgħa Nru. 98
	Meeting Transcript	05/04/2011	Laqgħa Nru. 101

Social Affairs Committee			
<i>Legislature</i>	<i>Document Type</i>	<i>Date</i>	<i>Title</i>
	Meeting Transcript	11/05/2011	Laqgħa Nru. 102
	Meeting Transcript	08/06/2011	Laqgħa Nru. 105

Select Committee on Medically Assisted Procreation			
<i>Legislature</i>	<i>Document Type</i>	<i>Date</i>	<i>Title</i>
2008 - 2013	Meeting Transcript	17/03/2010	Laqgħa Nru. 4
		23/03/2010	Laqgħa Nru. 5
		06/04/2010	Laqgħa Nru. 6
	Reports	19/10/2010	Rapport tal-Kumitat Magħżul dwar il-Prokreazzjoni Medikament Assistita

Consideration of Bills Committee			
<i>Legislature</i>	<i>Document Type</i>	<i>Date</i>	<i>Title</i>
2017 - 2022	Meeting Transcript	06/06/2015	Laqgħa Nru. 32
	Meeting Transcript	13/06/2018	Laqgħa Nru. 33
	Meeting Transcript	14/06/2018	Laqgħa Nru. 34
2022 -	Meeting Transcript	27/06/2022	Laqgħa Nru. 2
	Meeting Transcript	04/07/2022	Laqgħa Nru. 3

House of Representatives			
<i>Legislature</i>	<i>Document Type</i>	<i>Date</i>	<i>Title</i>
2008 - 2013	Motion	21/10/2009	Mozzjoni Nru. 13 - Ħatra ta' Kumitat Magħżul tal-Kamra biex jikkonsidra r-Regolamentazzjoni tal-Prokreazzjoni Medikament Assistita
	Bill	06/11/2012	Motion No.118- Embryo Protection Bill
	Parliamentary Debate Transcript	06/11/2012	Dibattiti tal-Kamra tad-Deputati - Seduta Nru. 518
	Parliamentary Debate Transcript	14/11/2012	Dibattiti tal-Kamra tad-Deputati - Seduta Nru. 522
	Parliamentary Debate Transcript	23/11/2012	Dibattiti tal-Kamra tad-Deputati - Seduta Nru. 526
	Parliamentary Debate Transcript	26/11/2012	Dibattiti tal-Kamra tad-Deputati - Seduta Nru. 527
2017 - 2022	Bill	24/04/2018	Bill No. 37 Embryo Protection (Amendment) Bill
2022 -	Bill	09/05/2022	Bill No. 5 Various Laws relating to Assisted Procreation (Amendment) Bill

Official Documents from Private Sources

Bioethics Consultative Committee		
<i>Document Type</i>	<i>Year</i>	<i>Title</i>
Terms of Reference	1993	Bioethics Consultative Committee - Terms of Reference
Recommendations	2000	Ethical considerations relating to Human Reproductive Technology
Minutes	2005	‘Item 2: Questionnaire requested by Minister Tonio Borg’,
Brief	2009	Brief prepared for the meeting with the Council of Health’
Letter	2009	Letter to the Minister of Health; The Parliamentary Secretary for Health,
Report	2012	Medically Assisted Procreation - The Contribution of the Bioethics Consultative Committee

Political Party Manifestos & Online Statements		
<i>Political Party</i>	<i>Year</i>	<i>Title</i>
Partit Laburista	2017	L-Aqwa Zmien ta' Pajjizna - Manifest Elettorali 2017
	2022	Malta Flimkien - Manifest Elettorali 2022
ADPD	2018	F'soċjetà li tħaddan il-pluraliżmu etiku m'hemm post għall-ebda tip ta' fundamentaliżmu
	2018	Pass meqjus ifisser pass 'l quddiem
Volt	n.d	Surrogacy & IVF

Statements Published by Stakeholders		
<i>Stakeholder</i>	<i>Year</i>	<i>Title</i>
Curia	2005	Stqarrija ta' l -Isfqijiet Maltin - Il-Probemi etiċi tat-teknika għal riproduzzjoni assistita.
		Stqarrija ta' l-Isfqijiet Maltin - Il-ħarsien tal-ħajja tal-bniedem mill-bidu nett tagħha
		Jum l-Indipendenza 2005 – Messaġġ ta' Mons. Arcisqof Ġużeppi Mercieċ – Id-dinjità u l-integrità tal-ħajja umana
	2012	Pastoral Letter – Celebrating Human Life, 2012
	2018	Statement by the Maltese Bishops on the Bill that amends the Embryo Protection Act, 2018
Cana Movement	2012	Statement by the Cana Movement
	2015	A Statement by Cana Movement about embryo freezing
	2018	The proposed amendments to the Embryo Protection Act attempt to cancel out differences endowed by nature itself
	2022	Stqarrija għall-istampa

Position Papers by Stakeholders		
<i>Stakeholder</i>	<i>Year</i>	<i>Title</i>
Curia	2015	Legislation Regulating Human Assisted Procreation - A Position Paper
	2022	Embryo selection is discriminatory and undermines dignity of human life - Position paper on the amendments to the Law on IVF
aditus Foundation and MGRM	2015	Consultation on IVF Legislation - Joint Submission by aditus foundation and MGRM
Academics	2018	Child and family scholars and practitioners offer their reflections to The Embryo Protection (Amendment) Bill, Bill no 38 (2018), University of Malta, Department of Child & Family Studies
	2018	Embryo Protection (Amendment) Bill: Bill no. 38 (2018): Matters of concern - Reflections by Academics, 2018, Various Academics
	2018	Molecular Biologists, Geneticists and Cell Biologists - Letter on Embryo Freezing
Malta College of Pathologists	2018	Position Statement of the Malta College of Pathologists on the proposed Bill to Amend the Embryo Protection Act of 2012

Position Papers by Stakeholders		
<i>Stakeholder</i>	<i>Year</i>	<i>Title</i>
The Commissioner for Children	2015	The ethics of using artificial means to facilitate or inhibit procreation – the perspective of the rights of the child - Position Paper by the Office of the Commissioner for Children

Mass Media Documents

Newspaper Articles

Times of Malta		
<i>Year</i>	<i>Author</i>	<i>Title</i>
1991	N/A	Ethical guidelines for in-vitro fertilisation urged
1997	N/A	Importance of ethics in bio-ethics
2005	Rosanne Zammit	Archbishop insists on commitment to life.
2010	N/A	Bioethics committee against regular freezing of embryos
2011	David Schembri	Lobby against embryo freezing
2012	Monique Attard	Alternatives to IVF treatment
2012	Bertrand Borg	IVF law is top priority for Labour
2012	Ivan Camilleri	Bishops' IVF letter snubbed by priests
2012	Kurt Sansone	Egg freezing is a 'political solution bad for patients'
2012	Kurt Sansone	IVF Bill has a name but no substance yet
2012	Kurt Sansone	IVF Bill may need some 'technical clarifications'
2012	N/A	IVF bill humiliating but can be salvaged - Muscat
2012	N/A	Praise, reservations on controversial Bill
2012	N/A	We did not act against God's will
2015	Kim Dalli	Experts stand united in surrogacy reservations

Times of Malta		
<i>Year</i>	<i>Author</i>	<i>Title</i>
2015	Kim Dalli	Let's base embryo freezing debate on facts, says doctor
2015	Keith Micallef	Discrimination among the unborn - NGO
2015	Kurt Sansone	'Don't expect Christians not to react if insulted'
2015	N/A	Pro-lifers issue IVF legislation statement.
2018	Sarah Carabott	Pro-life groups to discuss IVF law concerns in Sunday meeting with President
2018	Denise Grech	Ludicrous' new IVF Bill slammed by pro-life lobby group
2018	Keith Micallef	Pro-IVF amendment stance by Children's Commission prompts pro-life ire
2018	N/A	Academics and scientists say life starts at moment of fertilisation.
2022	Claudi Calleja	Embryo testing: 'My child was born with a death sentence'
2022	Claire Farrugia	I can now consider having children': writer Lara Calleja on embryo testing
2022	N/A	Tempers flare as House committee discusses IVF law amendments.
2022	N/A	Volt: IVF changes are good, but not ambitious enough
2022	Matthew Xuereb	Embryo freezing is 'a must', couples suffering in silence - lab director

Times of Malta		
<i>Year</i>	<i>Author</i>	<i>Title</i>
2022	Matthew Xuereb	Pre-implantation genetic testing to be allowed in IVF procedures
2022	Mark Laurence Zammit	All you need to know about the new IVF law that MPs will start debating today.
2022	Mark Laurence Zammit	Disability commission and its council members cannot agree on embryo testing.

MaltaToday		
<i>Year</i>	<i>Author</i>	<i>Title</i>
2011	Matthew Vella	AD warns against restricting IVF to appease PM's 'ultra-conservative core'
2012	Bianca Caruana	AD condemns government's delay in ethical IVF regulation.
2012	Matthew Vella	IVF law will send couples abroad' – Josie Muscat
2012	Matthew Vella	Alternattiva Demokratika 'disappointed' at Labour's failure to contrast IVF legislation
2012	Matthew Vella	IVF law 'inherently homophobic' – gay rights movement

MaltaToday		
<i>Year</i>	<i>Author</i>	<i>Title</i>
2012	Matthew Vella	No access to IVF for gay couples – national women’s council.
2015	N/A	Let’s not make IVF a political football
2015	Matthew Vella	Opening IVF to surrogates and sperm donors, ‘egoistic’ says Women’s Council
2015	Matthew Vella	Pro-life movements launch petition against embryo freezing.
2015	Matthew Vella	Pro-lifers on the warpath over embryo freezing plans
2018	Karl Azzopardi	[WATCH] Hundreds protest proposed amendments to IVF laws, Azzopardi, 2018
2018	Massimo Costa	Parliament to discuss bill amending ‘outdated, restrictive’ Embryo Act after Easter.
2018	Kurt Sansone	Pro-life group tears into proposed changes to IVF law
2018	Raphael Vassallo	This is about medicine, not theology - Interview with Mark Sant
2022	Laura Calleja	IVF: what reform are Maltese specialists expecting?
2022	Kurt Sansone	Embryo genetic testing to be allowed for nine conditions as MPs debate IVF changes
2022	Kurt Sansone	Parliament approves embryo genetic testing with cross-party support apart from three PN MPs.

MaltaToday		
<i>Year</i>	<i>Author</i>	<i>Title</i>
2022	Kurt Sansone	ADPD supports embryo genetic testing: ‘It reduces suffering in a tangible manner’

The Malta Independent		
<i>Year</i>	<i>Author</i>	<i>Title</i>
2005	N/A	MPs Squabble over attendance at committee meetings
2011	N/A	Gift Of Life wants ethical IVF .
2011	N/A	Interview: Embryo Freezing ‘tantamount to freezing human life’
2012	N/A	PAEF says IVF authority ‘crucial’
2015	N/A	Gift of Life expresses alarm, disappointment over PM’s ‘foregone’ conclusion on embryo freezing
2015	N/A	Labour women submit 10 recommendations on IVF legislation, Archbishop reacts with a Tweet
2018	N/A	Embryos are human, letter signed by local scientists reads
2018	N/A	Updated: Embryo Protection Act amendments pass through Parliament
2022	N/A	Commission for the Rights of Persons with Disability comes out in favour of IVF legal changes

TVM News		
<i>Year</i>	<i>Author</i>	<i>Title</i>
2015	Owen Galea	Online petition against changes to the Embryo Protection Act
2017	Ritianne Agius	Woman recounts experience of freezing 4 embryos in attempt to have children.
2018	Ritianne Agius	WATCH: Who is in favour and those against amendments to IVF legislation
2019	N/A	States it is time for further Amendments in IVF Law.
2022	N/A	ADPD says PGD is ethically acceptable

Newsbook		
<i>Year</i>	<i>Author</i>	<i>Title</i>
2022	Jurgen Balzan	‘What will become of embryos with genetic disorders?’ Archbishop Scicluna asks.
2022	Monique Agius	Doctors for Life propose Polar Body Testing over PGD

Opinion Pieces

Opinion Pieces			
<i>Author</i>	<i>Newspaper</i>	<i>Year</i>	<i>Title</i>
Paul Vincenti	Times of Malta	2005	Gift of Life and IVF
Rev. Prof. Emmanuel Agius	Times of Malta	2010	IVF, morality and public policy
	Times of Malta	2012	Public policy in IVF issues
	Newsbook	2018	We need a consistent ethics of life in Parliamentary debates
	Newsbook	2019	We need a consistent ethics of life in Parliamentary debates
Dr Michael Asciak	Times of Malta	2012	Innocent human life must be protected
	The Malta Independent	2015	Nisa Laburisti and wombs for hire
	Times of Malta	2022	IVF and the dignity of life
Silvan Agius and Gabi Calleja	Times of Malta	2018	IVF and human rights
Michael Birguglio	Times of Malta	2012	The real politics of IVF
Marchita Mangiafico	Times of Malta	2022	The right to life and PGD
Mark Sant	Times of Malta	2018	Eight cells in the lab
National Council of Women	The Times	1997	This law is taking too long a-coming

Appendix 2 – Information Letter

Information letter

xx/xx/xxxx

Dear _____,

My name is Faith Spearing, and I am a student at the University of Malta, presently reading for a Master of Arts in Public Policy Leadership. I am conducting a research study for my dissertation titled *'Navigating a Complex Policy Landscape: A Case Study of IVF Policy in Malta'*, supervised by Dr Kurt Borg. This letter is an invitation to participate in this study. Below you will find information about the study and about what your involvement would entail, should you decide to take part.

The aim of my study is to explore how policymaking in the field of IVF has developed over the years in Malta and, consequently, identify the best theoretical framework of public policy that can be applied to the local context when analysing morally contentious policy issues. Your participation in this study would provide valuable insights into the complexities of policymaking on IVF over the past three decades, contributing to a deeper understanding of how policymaking in morally contentious policy issues happens in Malta. Any data collected from this research will be used solely for purposes of this study.

Should you choose to participate, you will be asked to sit for an interview that includes 14 questions concerning your involvement in the policymaking process and your views on the policy design process, with a focus on the influences and dynamics that shaped the discussions and the final policy outcomes. The interview will take approximately 60 minutes to complete.

Data collected will be treated confidentially and anonymised to protect participants' identity. Raw identifiable data will be encrypted and stored offline on an external hard drive. Any material in hard copy form will be placed in a locked cupboard. Only my supervisor and myself (and in exceptional cases, examiners) will have access to this data.

The findings which emerge from this research may be published (e.g., in a dissertation, academic journals) and/or presented (e.g., during conferences, meetings). Your name (or any other identifying information) will not appear when the findings are reported. Identities will only be revealed in publications if participants explicitly consent to this; otherwise, a pseudonym will be used when quoting from interviews.

Participation in this study is entirely voluntary; in other words, you are free to accept or refuse to participate, without needing to give a reason. You are also free to withdraw from the study at any time, without needing to provide any explanation and without any negative repercussions for you. Should you choose to withdraw, any data collected from your interview will be erased as long as this is technically possible (for example, before it is anonymised or published), unless erasure of data would render impossible or

seriously impair achievement of the research objectives, in which case it shall be retained in an anonymised form.

If you choose to participate, please note that there are no direct benefits to you. Your participation does not entail any known or anticipated risks.

Please note also that, as a participant, you have the right under the General Data Protection Regulation (GDPR) and national legislation to access, rectify and where applicable ask for the data concerning you to be erased.

All data collected will be stored in an anonymised form on completion of the study and erased within 5 years of completion of the study.

A copy of this information sheet is being provided for you to keep and for future reference.

Thank you for your time and consideration. Should you have any questions or concerns, you may contact myself or my supervisor on the details provided below.

Yours Sincerely,

Faith Spearing

faith.spearing.17@um.edu.mt

79976727

Dr Kurt Borg

kurt.borg@um.edu.mt

2340 3203

Rev. Ivan Attard

iatta03@um.edu.mt

Appendix 3 – Consent Form for in-person interviews

Participant's Consent Form

Navigating a Complex Policy Landscape: A Case Study of IVF Policy in Malta

I, the undersigned, give my consent to take part in the study conducted by Faith Spearing This consent form specifies the terms of my participation in this research study.

1. I have been given written and/or verbal information about the purpose of the study; I have had the opportunity to ask questions and any questions that I had were answered fully and to my satisfaction.
2. I also understand that I am free to accept to participate, or to refuse or stop participation at any time without giving any reason and without any penalty. Should I choose to participate, I may choose to decline to answer any questions asked. In the event that I choose to withdraw from the study, any data collected from me will be erased as long as this is technically possible (for example, before it is anonymised or published), unless erasure of data would render impossible or seriously impair achievement of the research objectives, in which case it shall be retained in an anonymised form.
3. I understand that I have been invited to participate in an interview in which the researcher will ask a series of questions to explore how policymaking, particularly the policy design process, in IVF policy has developed over the years locally. I am aware that the interview takes approximately one hour. I understand that the interview is to be conducted in a place and at a time that is convenient for me.

4. I understand that my participation does not entail any known or anticipated risks.
5. I understand that there are no direct benefits to me from participating in this study.
6. I understand that, under the General Data Protection Regulation (GDPR) and national legislation, I have the right to access, rectify, and where applicable, ask for the data concerning me to be erased.
7. I understand that all data collected will be stored in an anonymised form on completion of the study and erased within 5 years of completion of the study.
8. I have been provided with a copy of the information letter and understand that I will also be given a copy of this consent form.
9. I am aware that, by marking the first-tick box below, I am giving my consent for this interview to be audio recorded and converted to text as it has been recorded (transcribed).

MARK ONLY IF AND AS APPLICABLE

- I agree to this interview being audio recorded.
- I do not agree to this interview being audio recorded.

10. I am aware that, by marking the first tick-box below, I am asking to review extracts from my interview transcript that the researcher would like to publish (e.g., in a dissertation, academic journals) and/or present (e.g., during conferences, meetings), before these are published or presented. I am also aware that I may ask for changes to be made, if I consider these to be necessary.

MARK ONLY IF AND AS APPLICABLE

- I would like to review extracts of my interview transcript that the researcher would like to publish and/or present, before these are published/presented.
- I would not like to review extracts of my interview transcript that the researcher would like to publish and/or present, before these are published/presented.

11. I am aware that, by marking the first tick-box below, I am giving my consent for my identity/the identity of the organisation I represent to be revealed in publications (e.g., in a dissertation, academic journals), reports or presentations (e.g., during conferences, meetings), arising from this research, and responses I provide may be quoted directly or indirectly. Identities will only be revealed in publications if participants explicitly consent to this; otherwise, a pseudonym will be used when quoting from interviews

MARK ONLY IF AND AS APPLICABLE

- I agree that my identity/the identity of the organisation I represent may be disclosed in publications/presentations.

- I do not agree that my identity/the identity of the organisations I represent may be disclosed in publications/presentations.

I have read and understood the above statements and agree to participate in this study.

Name of participant: _____

Signature: _____

Date: _____

Faith Spearing

faith.spearing.17@um.edu.mt

79976727

Rev. Ivan Attard

iatta03@um.edu.mt

Dr Kurt Borg

kurt.borg@um.edu.mt

2340 3203

Appendix 4 – Consent Form for online interviews

Participant's Consent Form

Navigating a Complex Policy Landscape: A Case Study of IVF Policy in Malta

I, the undersigned, give my consent to take part in the study conducted by Faith Spearing This consent form specifies the terms of my participation in this research study.

1. I have been given written and/or verbal information about the purpose of the study; I have had the opportunity to ask questions and any questions that I had were answered fully and to my satisfaction.
2. I also understand that I am free to accept to participate, or to refuse or stop participation at any time without giving any reason and without any penalty. Should I choose to participate, I may choose to decline to answer any questions asked. In the event that I choose to withdraw from the study, any data collected from me will be erased as long as this is technically possible (for example, before it is anonymised or published), unless erasure of data would render impossible or seriously impair achievement of the research objectives, in which case it shall be retained in an anonymised form.
3. I understand that I have been invited to participate in an interview in which the researcher will ask a series of questions to explore how policymaking, particularly the policy design process, in IVF policy has developed over the years locally. I am aware that the interview takes approximately one hour. I understand that the interview is to be conducted in a place and at a time that is convenient for me.

4. I understand that my participation does not entail any known or anticipated risks.
5. I understand that there are no direct benefits to me from participating in this study.
6. I understand that, under the General Data Protection Regulation (GDPR) and national legislation, I have the right to access, rectify, and where applicable, ask for the data concerning me to be erased.
7. I understand that all data collected will be stored in an anonymised form on completion of the study and erased within 5 years of completion of the study.
8. I have been provided with a copy of the information letter and understand that I will also be given a copy of this consent form.
9. I am aware that, by marking the first-tick box below, I am giving my consent for this interview to be audio recorded and converted to text as it has been recorded (transcribed).

MARK ONLY IF AND AS APPLICABLE

- I agree to this interview being audio recorded.
- I do not agree to this interview being audio recorded.

10. I am aware that, by marking the first tick-box below, I am asking to review extracts from my interview transcript that the researcher would like to publish (e.g., in a dissertation, academic journals) and/or present (e.g., during conferences, meetings), before these are published or presented. I am also aware that I may ask for changes to be made, if I consider these to be necessary.

MARK ONLY IF AND AS APPLICABLE

- I would like to review extracts of my interview transcript that the researcher would like to publish and/or present, before these are published/presented.
- I would not like to review extracts of my interview transcript that the researcher would like to publish and/or present, before these are published/presented.

11. I am aware that, by marking the first tick-box below, I am giving my consent for my identity/the identity of the organisation I represent to be revealed in publications (e.g., in a dissertation, academic journals), reports or presentations (e.g., during conferences, meetings), arising from this research, and responses I provide may be quoted directly or indirectly. Identities will only be revealed in publications if participants explicitly consent to this; otherwise, a pseudonym will be used when quoting from interviews

MARK ONLY IF AND AS APPLICABLE

- I agree that my identity/the identity of the organisation I represent may be disclosed in publications/presentations.

- I do not agree that my identity/the identity of the organisations I represent may be disclosed in publications/presentations.

12. I am aware that if the interview is held online, the researcher will use Zoom and will activate *the Require Encryption for 3rd party endpoints SIP/H-323* function. The researcher will *only audio record* the session.

I have read and understood the above statements and agree to participate in this study.

Name of participant: _____

Signature: _____

Date: _____

Faith Spearing

faith.spearing.17@um.edu.mt

79976727

Rev. Ivan Attard

iatta03@um.edu.mt

Dr Kurt Borg

kurt.borg@um.edu.mt

2340 3203

Appendix 5 – Interview Guide

Interview Guide for Semi-structured interviews with Stakeholders

Dissertation: *Navigating a Complex Policy Landscape: A Case Study of IVF Policy in Malta*

Student: Faith Spearing (0121399M)

Course Details: Master of Arts in Public Policy Leadership (PPL5009)

Introduction

1. Can you indicate your professional background and explain how it relates to IVF?
2. If part of an organisation, can you please indicate your role within the organisation and explain the organisation's role in IVF or ART services and/or policy locally?
3. Can you indicate during which of the following periods you were involved in the policymaking process on IVF?
 - a. Pre-2012 legislation
 - b. 2018 Legislative Amendment
 - c. 2022 Legislative Amendment

Policy Process

4. Who were the main stakeholders involved?
5. What measures were taken to ensure that process is inclusive and representative of the different views within society?
6. In your opinion, were these efforts successful?

Influences and Dynamics

7. Were there any particular tensions or challenges which stood out at the time?
8. How did the different stakeholder positions shape the debates or the policy outcome?

9. Were there times when compromises were made to balance the conflicting values and interests? What effect did this have on the final policy outcome?
10. In your opinion, how did the media and public discussion influence the policymaking process? Can you recall specific instances where media coverage significantly impacted the discussions?
11. In your opinion, how did political parties and politicians impact the policymaking process?

Policy Outcomes

12. What best practices, if any, emerged from the overall process?
13. What were/are the main shortcomings of the resulting legislation and/or legislative amendment?

Conclusion

14. Are there any remarks or comments you would like to add?

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