The Switch Drug Phenomenon

A Phenomenological Inquiry into the Role of Nicotine Replacement Therapy in Smoking Cessation Behaviour

Roger Sherlock, BSc Mgmt.

Presented in Fulfilment of the Degree Master of Business Studies

Dublin City University Business School

Supervisor: Dr Darach Turley

May 1999.
I hereby certify that this material, which I now submit for assessment on the programme of study leading to the award of Masters of Business Studies (MBS) is entirely my own work and has not been taken from the work of others save and to the extent that such work has been cited and acknowledged within the text of my work.

Signed: ___________________________  ID No.: 96970308003
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Abstract
The Switch Drug Phenomenon
A Phenomenological Inquiry into the Role of Nicotine Replacement Therapy in Smoking Cessation Behaviour

Roger Sherlock BSc Mgmt.

This thesis sets out to explore consumers' health behaviour in an era of increased consumer autonomy with the emergence of a new category of drugs; those that have 'switched' from prescription (Rx) control to over-the-counter (OTC) availability. The switching of drugs presents an opportunity for consumer researchers to explore preventive health behaviour and the move to more self-medication practices by consumers.

Nicotine replacement therapy (NRT), to help those who wish to stop smoking, has been one of the most high profile switches in recent years. Smoking is a major health issue worldwide but research remains dominated by the medical community. NRT as an OTC requires researchers to adopt a consumer orientation yet research has been lacking on OTCs generally and consumer behaviour in particular.

This study examines the role that NRT plays in the preventive health behaviour of consumers quitting smoking through in-depth phenomenological interviews. As a paradigm and methodology Existential-phenomenology places the consumer at the centre-stage of the inquiry, recognising the importance of experience as a method to gain understanding of a chosen phenomenon. This paradigm, in line with many others in the field of interpretative research, recognises that the consumer of the nineteen nineties is qualitatively different from our earlier understanding.

The results are presented as themes that emerged from the interpretation of the phenomenological interviews and aim to capture the meanings that consumers hold in relation to NRT, as an OTC. The themes are framed from two case studies; detailed presentations of the consumption stories of two respondents. The themes are reflective of the consumer's meaning categories and uncover many salient aspects, not previously indicated in the literature.

Finally, the conclusions and implications for switch drugs and health care are presented with some recommendations for further research on this emerging area.
Acknowledgements

There are so many individuals that made this study what it is yet the brevity of my acknowledgements to them scarcely does justice to their contributions, either professional or personal.

It is without exaggeration that this study owes everything to my supervisor, Darach Turley. The limiting term ‘supervisor’ fails to capture his many roles as friend, mentor, teacher, enthusiast, and proof reader with saint-like patience. His contribution goes beyond the confines of these pages, unselfishly providing me with his insight and his extensive knowledge, opening windows on so many aspects.

To the staff of the DCU business School, especially Professor Eunan O’Halpin and Dr. Kathy Monks, who provided me with support throughout my time. Even with the fear of neglecting the many members of the staff and the postgraduate students, I must single out a few. Susi Geiger, for her time, efforts and encouragement; Cathal Walsh, a brother-in-arms; all in Room 101, Deirdre, Mary, Eileen, and the one and only Shane; Siobhan McGovern, all at CTYI, and so many others.

All this was only possible with the help of Michele and Paul Mulgrew, not only as professionals but also as friends, who provided so much help. Thanks to the people, to numerous to mention, from the industry and regulatory bodies.

This study came to life with the time and thoughts of the respondents; real people who gave so generously to a total stranger. Only with their co-operation is it possible to make such research a reality; thank you.

Finally, my wife, Ailish, who lived ever moment of this study with me however perplexing, and my children Conor and Orla, who have known nothing else in their lives. Thank you for being there always. It what makes it all worthwhile.
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<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>AMA</td>
<td>American Medical Association</td>
</tr>
<tr>
<td>ASEGP</td>
<td>European Association of the Consumer Healthcare Industry</td>
</tr>
<tr>
<td>BUPA</td>
<td>British United Provident Association</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FTQ</td>
<td>Fagerstrom Tolerance Questionnaire</td>
</tr>
<tr>
<td>GMS</td>
<td>General Medical Scheme</td>
</tr>
<tr>
<td>HC</td>
<td>Hydrocortisone</td>
</tr>
<tr>
<td>HMO</td>
<td>Health Management Organisation</td>
</tr>
<tr>
<td>IMB</td>
<td>Irish Medicines Board</td>
</tr>
<tr>
<td>IPHA</td>
<td>Irish Pharmaceutical Healthcare Association</td>
</tr>
<tr>
<td>MCA</td>
<td>Medicines Control Agency</td>
</tr>
<tr>
<td>NRT</td>
<td>Nicotine Replacement Therapy</td>
</tr>
<tr>
<td>OTC</td>
<td>Over-the-Counter Drug</td>
</tr>
<tr>
<td>PAGB</td>
<td>Proprietary Association of Great Britain</td>
</tr>
<tr>
<td>POM to P</td>
<td>Prescription Medicines Switching to OTC Status, Restricted to Pharmacy Sale</td>
</tr>
<tr>
<td>Rx</td>
<td>Prescription Drug</td>
</tr>
<tr>
<td>VHI</td>
<td>Voluntary Health Insurance</td>
</tr>
</tbody>
</table>
There are many windows through which we can look out into the world, searching for meaning. There are those opened up by science, their panes polished by a succession of brilliant, penetrating minds ... But there are other windows that have been unshuttered by the logic of philosophers; ... Most of us, when we ponder on the mystery of our existence, peer through but one of these windows onto the world. And even that one is often misted over by the breath of our finite humanity. We clear a tiny peephole and stare through. No wonder we are confused by the tiny fraction of a whole that we see. It is, after all, like trying to comprehend the panorama of the desert or the sea through a rolled-up newspaper.

Chapter One.

New Approaches to the Health Care Consumer.

1.1 Introduction.

The objective of this study is to examine consumers' experiences of using Nicotine Replacement Therapies (NRTs) when attempting to quit smoking, with the aim of uncovering the meanings associated with this phenomenon. While the area of smoking has received much attention from many disciplines, smoking cessation research has remained the preserve of the medical specialist. Few consumer researchers have focused on health behaviour generally and smoking cessation in particular.

However, particular imperatives to address such cessation behaviour exist with the advent of a range of products, available without the normal restrictions associated with prescription drugs. Termed switch drugs, because of their status moving from prescription status (Rx) to over-the-counter status (OTC); this category of drugs enhances the autonomy of the consumer in their purchase and use.

As a result there is a need to adopt a new approach to researching the role that such products play in the consumers health behaviour repertoire. In this regard, this study aims to uncover the meanings that consumers associate with the use of NRT in their smoking cessation attempts. Qualitative methods have typically been used to investigate such consumer meanings; the specific qualitative approach to be adopted here will follow the parameters of interpretative inquiry.
methods, reflecting the desire to establish meanings, rather than enhance explanation or aid prediction. In addition, it is felt that utilising consumers’ experience, often a neglected source for research, will provide the best route to uncover the meanings associated with the use of NRT. A further feature to this thesis will be an emphasis on the meanings that consumers ascribe to health behaviours and related products rather than those suggested or imposed by either professional or commercial agencies.

1.2 Overview.

Chapter two attempts to locate a theoretical home for this thesis. Two possible areas are located in the literature. The first establishes NRT as an instance of a broader trend of self-care and self-medication. The second positions NRT usage in the broader domain of preventive health behaviours. In this light it shares common features with dieting, exercise, and check ups. The range of characteristics associated with such health behaviours will be examined with particular reference to NRT. Chapter three is in a more descriptive vein and looks at the wider context of the pharmaceutical market and the emergence of switch drugs. In particular, the evolution of NRT as an OTC and the dynamics of the Irish smoking cessation market are examined.

Following this, chapter four details the methodology used to uncover the meanings associated with the use of NRT by consumers attempting to stop smoking. The focus on consumers’ experience as a source of the meanings entails the use of existential-phenomenology as a paradigm and methodology.
The philosophical tenets of this approach are explored in the context of the broader interpretive paradigm and are followed by an examination of hermeneutics; both the philosophy and the method used to analyse the experiences of the respondents surveyed.

Chapter five presents the findings in terms of themes that emerged through the analysis of the texts of the interviews conducted. Two case studies are presented to illustrate the characteristics of the respondents' experiences and to provide the categories of the themes that emerged. The themes are then examined in respect of the current theoretical knowledge, leading to conclusions on the areas of self-care and preventive health behaviour.

The final chapter assesses the implications for health care, health professionals, and the OTC industry. Also the contribution of this type of research to health care is assessed, with suggestions for further research.

1.3 New approaches to the Health Care Consumer in Consumer Research.

Approaching the end of the century, consumer research, in line with many other disciplines, is grappling with many fundamental issues on the nature, scope and orientation of its endeavours. Much of this soul-searching has been at ontological and epistemological levels, reflecting a deep-felt need to return to basics and perhaps supersede its earlier role as provider of functional market information.

The primary force behind the evolution of the marketing discipline was the focus on the profitability of the commercial enterprise engaged in marketing; in
essence an orientation to explore issues from the viewpoint of the producer. Later, throughout the sixties and seventies, the focus moved to a more psychological or behavioural one; the era of motivational research. While the consumer as an individual received much greater attention as a result of increasing power and vocality, the emphasis remained on sales, profit, and more generally, ‘buying’ behaviour. A persistent trend throughout this era was the emphasis on attaining scientific credibility and the academic legitimacy it confers, with avoidance of the less commercial aspects, loosely termed ‘art’. The heels of the marketing discipline have been firmly dug into a rigid positivistic framework, albeit that the notion of marketing as a science has been shown to be unattainable (Brown, 1996).

For consumer research in particular, the debate over the past two decades has mirrored the broader debate in the marketing discipline. The debate, albeit with varying terminology, has revolved around ways of seeking knowledge and has been polarised as positivistic/neopositivistic versus interpretive, details of which will be explored in chapter four.

Behind this philosophical debate, there has been, at a wider ideological level, a challenging of the concept of what constitutes the consumer. Previously viewed as the passive recipient of marketing effort at the end of the production-consumption span (the ‘end consumer’), current thinking sees the consumer as an active, central player in the consumption game (see Holbrook and Hirschman, 1982; Hirschman and Holbrook, 1982). The use of goods, and for that matter art and entertainment, has become an integral part of the human condition and the
traditional hierarchy between marketing forces and the public has become blurred.

Described as the postmodern condition, this much misunderstood and maligned perspective attempts to capture the meaning of consumers and consumption at the end of the twentieth century. Originating in art and architecture, postmodernism has received attention in a variety of disciplines (psychology, anthropology, sociology, and media studies) but little from mainstream consumer research. An often frustrating aspect of the literature on postmodernity is the lack of clear definitions and boundaries, the use of ambiguity, and the sometimes irreverent treatment of any conventional inquiry making it hard to grasp and difficult to apply. However those at the forefront of consumer research have begun to use the postmodern condition as the canvas to explore consumer behaviour, through a range of paradigms and methodologies, although frequently not overtly alluding to a postmodern dimension.

While postmodernity has received extensive philosophical treatment (see Firat and Venkatesh, 1995), it is best illustrated by the emergence of many postmodern aspects in the marketplace, principally through marketing practice. Marketing and consumption have entered every aspect of western life and culture; advertising campaigns have entered the popular consciousness (Guinness' ‘anticipation’ campaign), and have taken on the role of mini-soap operas (Gold Blend coffee). Others have incorporated the use of parody (Boddington’s ale, Nike-style), and self-referential market research ‘speak’ (Guinness’ ‘didn’t you see a oak tree tossing in a maelstrom in your Guinness?’).
The above examples also demonstrate the pastiche, chronology and fragmented nature associated with postmodernity. Perhaps the clearest manifestation is the existence of hyperreality, where what is now seen as authentic is, in fact, a simulation (real ale and beer, Disney, real Irish bars). Postmodernists revel in the playful, inverted way that the traditional hierarchies and orthodoxies are tackled (low culture, pop art) and a belief that ‘anything goes’. This has led to pluralism in thinking and approach.

These new meanings of the consumer and role that consumption plays in ordinary life require different approaches to the examination of consumption. Firat states that the new postmodern consumer is qualitatively different to the consumer of the past (Firat, 1991), with each ‘act’ of consumption presenting the possibility of representing a different image for the consumer. For example, the consumption of a car can represent an image of charming, efficient, risk-taker, family-orientated, each possible in a different context. As a result, this alternative view of consumption can be viewed as having emancipatory potential (Firat and Venkatesh, 1995).

Consumer researchers have been described as either deliberately or inadvertently addressing the presence of postmodernism (Brown, 1995) and it is undeniable that a type of pluralism exists in the approaches adopted since the mid-eighties. An example of this pluralism, without implicit mention of postmodernism is Murray and Ozanne’s (1991) perceptual map of the different approaches available to seeking knowledge in consumer research. Their map focuses on the two axes of subjective/objective and conflict/order, but does not incorporate or
allude to any postmodern dimension. Another more explicitly postmodern example is the manner in which many researchers are approaching consumption as text or narrative where the meanings of an act of consumption are not fixed by the producer or marketer, but negotiated by the consumer and may be more idiosyncratic.

The implications for consumer health-care research are particularly significant. The move towards the patient becoming a consumer and using products in their health-care reflects the move away from the traditional hierarchy of the doctor/provider-patient relationship, the decrease in the focus on science or drug technology to solve problems, and the fragmentation of markets to more individually tailored treatments. In all, the trend towards self-medication can be viewed as a microcosm of the postmodern condition.

With the exception of Robin Gregg’s (1995) interpretation of women’s paradoxical experiences of pregnancy in a high-tech age, Gould’s exploration of allergy sufferers (Gould, Considine, and Oakes, 1993) and Reimen’s phenomenology of the caring interaction for patients with nursing (Reimen, 1998), health-care research has remained dominated not only by the scientific/medical community, but by positivistic paradigms. Consumer research has been slow to explore health-care generally, but it appears to be increasing in importance, with self-care identified as a ‘mega-trend’ for the coming century. Efforts, such as Moorman and Matulich’s (1993), to examine consumers’ preventive health behaviour, do not fully address the use or consumption of products as a part of self-care nor do they allow for the individual, often...
paradoxical, nature of consumers' health-care. Also, the emphasis remains on the health care system and structures rather than on the personal aspects of the individuals' health regime.

Given that the nature of much of the research reflecting the postmodern condition revolves around the more contemporary, mainstream, even fashionable aspects of consumption (advertising, jeans, the Disney experience), it is not easy to see its usefulness for health-care research. At first sight health care products may seem an unpromising area for postmodern analysis. However OTCs may prove an exception. Marketing for this product class utilises all the features of mainstream marketing activity, for example advertising and branding. So arguably OTCs' 'emancipatory potential' may thus promote consumer autonomy.

Approaching this study of the use of nicotine replacement therapy (NRT) to quit smoking, it is necessary to focus on the consumer's individual experience of using NRT. Giving voice to the consumer, through a phenomenological exploration, recognises a need to focus research away from the hierarchical medical domain to the real producer of meaning, the consumer. It is through the examination of consumers' experience that we can better understand their self-care, preventive health care behaviour, and the associated meanings of NRT.
Chapter Two.
Self Care and Consumers’ Preventive Health Behaviour.

2.1 Introduction.

As outlined in chapter one, this chapter will follow two broad theoretical sections. The first section situates NRT in the wider stream of literature focusing on the move from professional to self-care and increasing self-medication. The second positions NRT consumption in the related literature dealing with preventive health behaviours in general. There is a considerable corpus of research dealing with such behaviours, from dietary care to health check-ups, and their correlates. The components or characteristics of consumer preventive health behaviour are examined with special focus on smoking cessation. It will be argued that there is a need to explore this particular preventive health behaviour with emphasis on the products involved. It is only through the use of such products that a better understanding of the meanings of the behaviour itself can be achieved. Also it is argued that, to achieve such an understanding, it is necessary to adopt a consumer-centred approach.

2.2 The Emergence of Self-Care as a 'Megatrend'.

Consumers are increasingly calling for control over their own health and have more confidence in asking for advice and in deciding on action to be taken outside the traditional health care structures, such as visits to the doctor. What is deemed to be ‘alternative medicine’, by the medical community at least, is becoming the norm in the minds of many consumers who wish to enhance their
health; acupuncture, reflexology, and hypnosis are used to alleviate or treat a range of 'medical' symptoms, including smoking cessation, or to enhance health generally.

The use of medicines, available without prescription, over-the-counter (OTC) in pharmacies or in the supermarket is increasing rapidly. Apart from the more familiar headache or stomach upset remedies, the OTC market now includes a range of more medically sophisticated products such as home cholesterol testing kits, diet aids, vitamins, and heartburn drugs. The move towards self-medication has been identified as a 'megatrend' for the coming century (Nasbitt, 1990). This trend reflects a desire by governments to contain the health care costs associated with prescribing medicines through the deregulation of prescription drugs, and also an acceptance by health care professionals of the rise of a consumer with the ability and desire to look after their health.

2.3 Consumer Research Issues for Switch Drugs.

Given the enormous effort being directed at switching prescription drugs to OTC by the pharmaceutical industry, there is and has been little academic research on the area. Research in the pharmaceutical sector has focused primarily on the prescription drug market with emphasis on topics such as labelling and risk disclosure (Morris and Kanouse, 1981; Morris, Ruffner and Klimberg, 1985), generic drugs (Kendall, Ug, and Schoner, 1991), and direct-to-consumer advertising of prescription drugs (Morris, Mazis and Brinberg, 1989). Some research has addressed switch drugs directly or indirectly (Kotzan, Carroll, Perri,
and Fincham, 1987; Branstad, Kamil, Lilja, and Sjoblom, 1994; Gould et al., 1993) but the majority of research has been on OTCs (Lumpkin, Strutton, Lim, and Lowrey, 1989; Synder, 1995; Kline & Co., 1996). The lack of focus on switch drugs and the rationale for this study is best articulated by Hoy (1994, pp. 94.);

Although a variety of arguments substantiate the opportunity for switch drugs, actual attempts to survey consumer sentiment regarding this issue is lacking ... Further research is needed to examine self-care as a form of consumer behaviour.

Hoy goes on to comprehensively list the research issues for switch drugs generally and this serves as a template for evaluating the research to date and possible future research efforts. The implications of the switch to OTC status depend on the particular type of drug but typically involve four key areas; health and safety, economic, marketing, and consumer behaviour (Hoy, 1994).

Health and safety considerations are twofold. First, increasing OTC availability may encourage greater self-diagnosis, which in turn may be incorrect. Second, the OTC selected may be either inappropriate or improperly administered. The parties most at risk in this regard are children and the elderly.

A key economic consideration is that, while switch drugs and OTCs are typically less expensive, they are not usually covered by either State or private medical schemes. This contrasts with many heavily used prescription drugs where all the associated costs are paid for by state medical schemes. Again the younger and
older members of society are most vulnerable, as they are more likely to be dependent on such state schemes than other groups.

From a marketing viewpoint the control of all promotional activity differentiates prescription drugs from OTC drugs. Direct to consumer advertising for prescription drugs has become a feature in the USA but this has not impacted on Europe. However, OTC drugs benefit from somewhat more relaxed promotional regulations, with the benefit of greater awareness at a consumer level through media advertising. In essence a switch drug will utilise the media and promotional tools associated with OTC drugs, most important of these are the use of labelling, leaflets, in-store point-of-sale and media advertising.

A summary of the consumer behaviour issues across switch, (Rx) and OTC drugs are in Table 2.1, below. Product image is critical when a drug alters status. In the same way as a generic drug can be perceived as inferior and less efficacious than a branded prescription drug, the switch to OTC status may create perceptions that the OTC ‘version’ is somehow diluted. The positioning of a drug as being ‘prescription strength’ can either enhance its view as being more efficacious or conversely be perceived as too high risk to be used without medical supervision. Also it may be perceived as the weaker version of the prescription drug in OTC format or, without exploiting its prescription heritage, it may be viewed as ‘just’ another OTC.

Most importantly from a consumer behaviour viewpoint, the influence on choice of switch drugs is strongly associated with recommendation and word-of-mouth
of family, friends, doctors, and pharmacists. In the case of prescription drugs no such word-of-mouth dynamic operates to any significant degree.

Table 2.1 Consumer Behaviour Considerations For switch Drugs.

<table>
<thead>
<tr>
<th>Similarities of A Switch Drug &amp; Rx</th>
<th>Similarities of A Switch Drug &amp; OTC</th>
</tr>
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<tbody>
<tr>
<td>Awareness of physical symptoms requiring medical attention.</td>
<td>Requires a propensity to engage in self-care behaviour.</td>
</tr>
<tr>
<td></td>
<td>Requires awareness of product availability.</td>
</tr>
<tr>
<td></td>
<td>Consumers have control over which brand they chose.</td>
</tr>
<tr>
<td></td>
<td>Younger consumers more likely to use.</td>
</tr>
<tr>
<td></td>
<td>Others may recommend product/brand usage.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Differences of A Switch Drug &amp; Rx</th>
<th>Differences of A Switch Drug &amp; OTC</th>
</tr>
</thead>
<tbody>
<tr>
<td>May not be used as heavily by older consumers as Rx.</td>
<td>May be perceived as riskier than existing OTC if positioned as ‘prescription strength’.</td>
</tr>
<tr>
<td>May not be perceived as efficacious as Rx.</td>
<td>May be perceived as more efficacious if positioned as ‘prescription strength’.</td>
</tr>
<tr>
<td>May not be perceived as risky as Rx if positioned as now being available OTC.</td>
<td></td>
</tr>
</tbody>
</table>


In addition to the consumer behaviour dimensions above, Hoy sets out a number of research questions associated with switch drugs which clearly place research on this topic within the broader area of preventive health behaviour;

- What would motivate consumers to use switch drugs?
• How might consumer's health care change with the availability of switch drugs?
• What is the domain of self-care as a form of consumer behaviour? What are the implications for public policy?
• How extensive is the consumer demand for switch drugs?
• How does word-of-mouth communication effect the motivation to use OTC products?
• What is the influence of word-of-mouth communication on OTC product or brand choice? What are the ramifications for switch drugs?

While such observations are tantalising to the potential researcher, they give little empirical direction; however they do provide a framework in which to explore the use of switch drugs, particularly in the context of preventive health behaviour research.

2.4 Consumer Research on Switch and OTC Drugs.

This section broadens the discussion by examining switch drugs under the general heading of OTCs of which they are a subset. The justification for so doing is that many of the issues pertaining to OTCs seem applicable to the more specific case of NRTs.

In summary OTC consumers tend to be women, younger, married with children and have high levels of education, income, and 'consumer sophistication' (Hoy, 1994). These demographic indicators are quite in line with the findings on preventive health behaviour. US research on buying decisions reflects a similar
profile of the OTC consumer but includes additional data on the most important factors used in OTC purchasing decisions, detailed in Table 2.2, below. This mail survey of 500 adult consumers asked the respondents to list the factors they considered important when purchasing an OTC. While the pharmacist is clearly the most important factor in the purchase of OTCs, age, income, and education were significant moderating variables mediating the relative importance of the pharmacist and indeed of most of the remaining five influences (Kline & Co., 1996).

Younger consumers (30 or less) were less likely to consult the pharmacist, relying on recommendation by family or friends, and were more likely to read about a product in advance, and purchase it for themselves. Middle aged consumers did not seek recommendation from friends or family but relied on the pharmacist, and were normally purchasing for their family. Both the above groups will seek the doctor’s recommendation, but only half as much as the older (60+) age group. This age group mainly relies on the pharmacist’s recommendation and they do not seek the advice of others to the same degree.
Table 2.2 Factors in OTC Purchasing decisions by Age (%).

<table>
<thead>
<tr>
<th>Factor receiving mention</th>
<th>All respondents</th>
<th>under 30</th>
<th>30 - 59</th>
<th>60+</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ask pharmacist</td>
<td>61</td>
<td>44</td>
<td>60</td>
<td>70</td>
</tr>
<tr>
<td>Read Package</td>
<td>52</td>
<td>63</td>
<td>58</td>
<td>41</td>
</tr>
<tr>
<td>Repeat Purchase</td>
<td>41</td>
<td>53</td>
<td>38</td>
<td>40</td>
</tr>
<tr>
<td>Ask Doctor</td>
<td>33</td>
<td>25</td>
<td>25</td>
<td>50</td>
</tr>
<tr>
<td>Advertised</td>
<td>15</td>
<td>13</td>
<td>15</td>
<td>15</td>
</tr>
<tr>
<td>Family/ Friend</td>
<td>12</td>
<td>29</td>
<td>11</td>
<td>7</td>
</tr>
</tbody>
</table>

Source: Kline & Co., 1996.

The higher the level of education, the greater the propensity to use labelling information, in line with Moorman's finding on preventive health behaviour (Moorman, 1990, see below). Higher levels of education also correlated with greater use of word-of-mouth recommendation from family and friends (Kline & Co., 1996). In contrast, those with a lower level of education showed greater reliance on advertised brands, using coupons or buying the sale brand. In general this end of the educational spectrum utilise the pharmacist and doctor to a greater degree.

Income demonstrated little influence on OTC buying decisions, apart from less reliance on the doctor by higher earners; the opposite for lower earners, with a further lower likelihood of utilising labelling. Again this is reflected in findings on the peripheral role of income in the preventive health behaviour literature, discussed below.
While these findings relate to OTCs in general, not to switch drugs in particular, limited research does suggest that younger, more educated, wealthy consumers also purchased switched OTCs (Kotzan et al., 1987; Leibowitz, 1989). However caution is needed in assuming such data to be indicative of switch drug consumers in general; research of such product switches to OTC status is at an embryonic stage. As a consequence, such switch drugs can be seen to be at the early stages of the product life cycle, and consumers may hail primarily from highly innovative and unrepresentative subsets of the population.

A single, cue-based longitudinal study of the users and their information sources for the switch of topical hydrocortisone (HC) skin ointments in Sweden provides some insights into the evolution of consumer behaviour when a prescription drug moves to OTC status (Branstad et al., 1994). This study examined users at four points in time; the first prior to switching to OTC status from prescription status in 1983, and at three other intervals after its launch over a six year span, through to 1989. Comparisons were made between consumers still receiving HC ointment on prescription (PHC group), and those purchasing it OTC (OTC group) through questionnaires administered in pharmacies. Respondents were asked about their sources of information on the switch to OTC status, as well as their attitudes towards the switch process itself. Results are reproduced in table 2.3 below, highlighting those who purchased the OTC version of the drug in question.

Results for user characteristics illustrated two significant trends. First, the OTC group was younger than the PHC group at all stages and indeed younger than
any other drug user groups in comparative drug studies. The average age of prescription purchasers became older as the study progressed, suggesting a contracting group of loyal customers. Second, those with a university education featured strongly at point two (42%), decreasing to 20% at point three. This reflected the expected profile of innovators who would typically have higher levels of education.

Initially the source of information on the availability of HC ointment OTC came from journal articles, such as health reports, reflecting the type of sophisticated media usage by this group. In regard to the PHC group, the initial source of information was medical journal articles, with 83% aware of the change in status, however over time the doctor became a very important information source, although they did not purchase the OTC product. Again this reflects a strong loyalty to the doctor and the importance of the prescription.
Table 2.3 Information Sources About OTC Preparation Availability - OTC Group (%).

<table>
<thead>
<tr>
<th>Information Source</th>
<th>One Month After the Switch. (Time Point 2)</th>
<th>9 Months After. (Time Point 3)</th>
<th>6 Years After. (Time Point 4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Doctor</td>
<td>14</td>
<td>21</td>
<td>12</td>
</tr>
<tr>
<td>Nurse</td>
<td>5</td>
<td>16</td>
<td>27</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>4</td>
<td>16</td>
<td>35</td>
</tr>
<tr>
<td>Journal article</td>
<td>56</td>
<td>20</td>
<td>5</td>
</tr>
<tr>
<td>Journal adverts</td>
<td>19</td>
<td>11</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>2</td>
<td>16</td>
<td>15</td>
</tr>
<tr>
<td>Total</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
<tr>
<td>Population size</td>
<td>100</td>
<td>104</td>
<td>100</td>
</tr>
</tbody>
</table>

Source: Branstad et al., 1994.

2.5 The Role of the Health Professional.

What appears to be significant for OTCs generally and switch drugs in particular is the role the doctor can play. An important role for the doctor is prescribing medicines, however this role is likely to be altered with the advent of OTC medicines that do not require a prescription from the doctor. Traditionally there has been little focus on the doctor’s role in relation to OTCs, but the imperative to research this area in the light of the increase in switches has been recognised (Snyder, 1995). Two studies have sought to examine this development. In the first, almost ten percent of all drugs ‘prescribed’ were OTCs (Snyder, 1995); in these cases the doctor actually wrote down the recommended OTC in the same
manner as he/she would write a prescription. In the second when doctors recommend as opposed to prescribing an OTC medication, 26% of the time it is in verbal form only, 10% in written form only, and 64% both written and verbal (PAGB, 1996). Therefore in 74% of cases what is virtually the equivalent of a prescription is written. Interestingly not all visits to a doctor’s surgery are as prescription oriented as past literature has suggested. However the proportion still remains high, with 56% of patients expect a prescription prior to their visit, and 24% intend to buy an OTC product after their visit. Of those expecting a prescription but not receiving one, half planned to self-medicate in some form as a result (Rappoport, 1976).

In the case of NRT, research has demonstrated that, while on prescription, only 20 percent of prescriptions were issued on the initiative of the doctor, the remaining 80 percent were on the initiative of the patient, with the patient asking the doctor to prescribe (Urde, 1994). The position in Ireland was quite similar. Niconil, in evaluating the market potential prior to launch, found that little time or attention was spent by doctors counselling their patients about smoking cessation, principally as it wasn’t in any way lucrative and met with resistance from most patients. In all, fewer than 15 percent of doctors recommended formal counselling or drug therapy including NRT (Irish Marketing Surveys, 1993). However, even for the fifteen percent of doctors who did broach smoking cessation with their patients, the actual request to prescribe came from the patients themselves and not from the doctor.
The meaning of a prescription can refer to the written order to the pharmacist from the doctor, the end product itself, or the directions attached to a drug. There are a number of apparent functions the prescription serves such as a method of therapy, a legal document or a means of communication (Smith, 1989). At another level it has been suggested by Pellegrino that there are many latent functions of the prescription, interacting at three levels of symbolism. The three levels are the ingestion of the drug, the legitimisation of illness and therefore the enhancement of the prescription, and the symbolism inherent in the act of prescribing by the doctor (Pellegrino, 1976). A summary by Smith of Pellegrino’s work is contained in Table 2.4 below.

Table 2.4 Latent Functions of the Prescription.

| Visible sign of the doctor’s power to heal. | Fits the concept of modern man that he can control his own destiny. | Means of patient goal attainment. |
| Concrete expression that the doctor has fulfilled his contract. | Symbol of patient control. | Expression of doctor’s control. |


OTCs are often viewed as a great opportunity for pharmacists, with research demonstrating that consumers utilise the pharmacist for information and recommendation, often in place of the doctor (Branstad et al., 1994; Kline & Co.,
1996). It is worth noting that there can be a discrepancy between consumers citing the pharmacist, for example, as an information source but not utilising this source at the time of purchase. Further research in this area has highlighted that 80% + of OTC purchases are stimulated by verbal demand from the consumer. In only six percent of OTC purchases did the consumer ask for and receive information from the pharmacist. Typically it is the pharmacist’s assistant who provides the information when it is asked for (Kotzan et al., 1987).

This trend to take control of one’s health through self-care also reflects an orientation towards prevention rather than cure. It is this shift towards prevention as well as the adoption of the concept of an active, autonomous consumer, rather than a passive patient in health care generally that has begun to impact on health care research. While NRT and its switch to OTC status is an example of self-care, as an ingredient of smoking cessation it can be viewed as one of a range of preventive health behaviours along with taking exercise and dieting. The following section provides an overview of the literature on this emerging area of consumer behaviour.

2.6 The Development of Consumer Health Behaviour Research.

The evolution of consumer health behaviour research has mirrored a pattern in the wider area of management and consumer behaviour research, albeit at a slower pace. In the management context, attention has shifted from the emphasis on efficiencies of the firm, focused on production, to the study of the consumer.
The medical profession has been dominated by a 'technological imperative' (Fuchs, 1968), an emphasis on progress resulting from advances in science and technology, with little regard to the needs for the consumers of health care (Stewart, Hickson, Rathneshwar, Pechmann, and Altemeier, 1982). As a result, the status of the consumer in the health care process has been diminished by the imbalance between patient and provider, identified as 'psychological distance' (Zaltman and Vertinsky, 1971) or 'power imbalance' (Kramer, 1972).

Changes in the increase of supply of health care over demand, coupled with the increasing confidence of the consumer, have resulted in a greater orientation to the consumer by the health care profession. Previously in the 'production' of health care, emphasis was on the creation of better drugs and procedures; the consumer or patient merely at the end of this chain of events.

This change parallels a broader emphasis on consumer empowerment in the consumer behaviour literature. No longer is the consumer at the conclusion of the production process; the consumer is viewed as central to it (McCracken, 1988a). The consumer is not a passive recipient of the goods of production; the consumer can go as far as assuming a range of active roles including that of rebel, victim, activist, or citizen (Gabriel & Lang, 1995). An example of the consumer as activist was the establishment of organisations whose aims were to defend the 'powerless' consumers against corporate giants such as car manufacturers, insurance companies, and the health sector in particular. This trend has been termed Naderism, after the Harvard educated lawyer who formed the Centre for Study of Responsive Law and the Project for Corporate
Responsibility in 1969 (Gabriel & Lang, 1995). While the consumer is being recognised as acting independently, almost subversively, there has been little attention to this aspect from a health research perspective.

It is necessary to note that while much research on health behaviour is viewed as an emerging rather than an established field, some attempts have been made to create a working definition, best articulated by Gochman (1988, p.3);

those personal attributes such as beliefs, expectations, motives, values, perceptions, and other cognitive elements; personality characteristics, including affective and emotional states and traits; and overt behaviour patterns, actions and habits that relate to health maintenance, to health restoration and to health improvement.

More importantly, Gochman expands his argument to state what is not health behaviour; it is distinct from the treatments, structures, and organisation of the health care delivery system but ‘it touches profoundly upon all of these’ (Gochman, 1988, pp. 5). In other words, health behaviour research must focus on the individual’s behaviour, but must also assess how any treatments and/or institutional structures affect this health behaviour. The use of nicotine replacement therapy, as an OTC, is clearly pertinent to health behaviour research.

From the particular perspective of consumer research, four main areas of the health care process have received focus, as identified by Langmeyer and Miaoulis (1981);

1) Consumer participation in the planning and delivery of health care,
2) Consumer satisfaction with delivery systems,
3) Health care decision models,
4) Health promotion.

With the exception of some health care decision models, the research has focused on the traditional areas of health care; inclusion in the planning of health care facilities, doctor/patient relationships, and patient satisfaction with specific types of systems such as health plan coverage and post-operative outcomes (Langmeyer and Miaoulis, 1981). Clearly much of the emphasis has been outside the boundaries of health behaviour research, as defined by Gochman and has neglected the consumers' own actions in particular.

While the 'consumer' is considered, he/she is viewed more as a 'patient' in the context of the powerful health care process. The idea of self-medication or the consumer choosing independently has been addressed by few researchers. More significantly for this study, the use of OTC and/or switch drugs, a clear indication of self-medication, has not been a topic of interest, as highlighted by Kotzan et al. (1987, pp. 44);

Quantitative research investigations of the impact upon consumers of the legend pharmaceutical to OTC switch are limited. A review of the general self-care and self-medication literature does not exactly relate to switched drug products but is certainly pertinent since the process introduces new OTC drugs into the marketplace.

A number of points about the nature of health behaviour research may explain this lack of focus on behaviour and on the use of specific treatments, such as
smoking cessation behaviour and the use of NRT. Consumer researchers in the field of health behaviour have long emphasised that there are a number of unique challenges facing them. As a result of the long time horizons linked with health outcomes, effectiveness is difficult to evaluate (Moorman, 1994). Also the field is an interdisciplinary one, encompassing psychology, health education, sociology, and social marketing (Moorman and Matulich, 1993; Gochman, 1988), thus researchers in this field have been described as 'studying different parts of the elephant' (Gardner and Harris, 1996). There is a clear need to put the consumer at the centre of any inquiry, and this is of particular relevance in the context of self-care and the use of OTC medications.

2.7 Preventive Health Behaviour.

Gochman's earlier definition of health behaviour incorporates three aspects; preventive health behaviour, illness behaviour, and sick-role behaviour. Preventive health behaviour is distinguished by the fact that those undertaking such behaviours believe themselves to be well, have no symptoms of illness, and are doing so to remain well. Such actions can be divided into two areas based on their value to the individual. First, those with primary preventive value; usually, but not exclusively, daily non-medical activities, such as duration of sleep, dietary habits, weight management, exercise, moderating alcohol consumption, and not smoking (Belloc and Breslow, 1972). Second, those behaviours that have a secondary preventive value - activities that facilitate early detection to
minimise the impact of a condition (but do not prevent a condition happening),
such as regular check-ups with doctors, dentists, and cancer screening.

Preventive health behaviour research has encompassed behaviours and activities
outside the traditional health care process, including nutrition information
processing (Russo et al., 1986), exercising (Avis, McKinley, and Smith, 1990;
Howze, Smith, and deGilio, 1989), healthy lifestyle (Muhlenkamp, Brown, and
Sands, 1985; Weitzel, 1989), healthy food use (Saegert and Young, 1983), and
smoking cessation and modification (Avis et al., 1990; Colsher, Wallace,
Pomrehn, LaCroix, Cornoni-Huntley, Blazer, Scherr, Berkman, and Hennekens,
1990; Bernstein, 1970; Best, 1975; Best and Steffy, 1975; Eiser, Eiser,
Gammage, and Morgan, 1989; Hjelle and Clouser, 1970; Keutzer, 1968; Kok,
deVries, Muddle, and Strecher, 1991; Leigh, 1983; and Kviz, Crittenden, Belzer,
and Warnecke, 1991). The scope of what is incorporated in any primary and
secondary preventive health behaviour varies, depending on the particular
behaviour considered, but appears to encompass three areas:

1) Performance of the preventive health behaviour itself and the outcomes.
Central to the performance of any health behaviour is the consumer
characteristics (dealt with below).

2) The acquisition of information regarding preventive health from professional
sources such as doctors, nurses and pharmacists, casual sources, such as family,
friends (termed word-of-mouth in this study), and information from media
sources such as advertising, medical journals/pamphlets, and product labelling (Moorman and Matulich, 1993; Zaltman and Vertinsky, 1971).

3) The interaction with members of the health care profession, health care structures, and the use of treatments and other interventions (Gochman, 1988).

The focus of this study is on the first of the three aspects of preventive health behaviour as it applies to the primary preventive health behaviour of smoking cessation; the actual performance of the health behaviour itself. It goes without saying that this aspect is closely associated with the other two aspects; the acquisition of information on smoking cessation, the interaction with members of the health care profession, and the use of a specific treatment i.e. nicotine replacement therapy.

The bulk of preventive health behaviour research has centred on single independent variables or characteristics such as age, income, education, health locus of control etc., often approached from different fields of interest. A consequence of this orientation is that, frequently, conflicting results are found (Moorman and Matulich, 1993). There are eight consumer characteristics evident in the preventive health behaviour literature, each of which will be examined independently. With input from different disciplines, the consumer characteristics are sometimes conceptualised as either predisposing, enabling, or motivating in nature (Gould, et al., 1993; Moorman and Matulich, 1993). As there are no a priori assumptions in this study, the characteristics will be examined in relation to the part they play in the experiences of the respondents.
2.7.1 Preventive Health Behaviour- Consumer Characteristics.

Preventive health behaviour consumer characteristics can be divided into two groups; specific health characteristics (health motivation, health knowledge, perceived health status, health locus of control, and health behavioural control) and the more general characteristics of age, education, and income. Each of these characteristics will be examined, with particular reference to smoking and smoking cessation.

Health Motivation.

Health motivation can be defined as ‘goal-directed arousal to engage in preventive health behaviours; the willingness to perform or interest in performing health behaviours (MacInnis, Moorman, and Jaworski, 1991). Health motivation has been found to exhibit a positive effect on a range of health behaviours such as regular use of dental services (Gelb and Gilly, 1979), prenatal visits (Zweig, LeFevre, and Kruse, 1988), and breast self-examination (Fletcher, Morgan, O’Malley, Earp, and Pegnan, 1989). It is worth noting that these results relate to behaviours with a secondary preventive value. Only one study attempts to evaluate the effect of health motivation on behaviours with a primary preventive value. Moorman and Matulich’s 1993 study focuses on the role of motivation on a range of five health maintenance behaviours (tobacco non-use, alcohol moderation, negative diet restriction, positive diet addition), and life balancing behaviours (stress reduction) together with health information acquisition.
Moorman's results demonstrate that motivation increases the acquisition of information from media sources and health professionals, but not from casual sources. The nature of much health information is complex, and usually new or innovative such as information on new products, services, or practices. For such information, sufficient difference between the sender and the receiver of such messages is recommended in theory (Rogers, 1983). For this reason information from casual sources, such as friends, may not be sufficiently differentiated to be perceived to be of value (Moorman and Matulich, 1993). Most significantly, health motivation did not demonstrate any effect on either tobacco or alcohol consumption.

Although health motivation has not demonstrated any direct effect on smoking cessation, it appears to manifest itself in relation to other consumer characteristics. The scales used to measure motivation (Moorman, 1990) have more in common with health locus, and health behavioural control. The interaction of motivation with other characteristics is dealt with below.

**Health Knowledge.**

Health knowledge can be defined as 'the extent to which consumers have enduring health-related cognitive structures' (Moorman and Matulich, 1993). Health knowledge has been viewed as an ability that helps consumers engage in health behaviours. Typically health knowledge is measured on the knowledge of the roles of such elements as vitamins, calcium or sodium, amounts of knowledge, rather than its complexity. A small cache of authors has sought to
investigate the relationship between consumers’ health knowledge, and a number of health behaviours. For example, health knowledge has exhibited a positive effect on many health behaviours such as exercising (Avis, McKinlay, and Smith, 1990), improved dietary habits (Boechner, Kohn, and Rockwell, 1990), and personal food selection (Bell, Stewart, Radford, and Cairney, 1981).

But apart from these authors, most of the studies focus on acquisition and retention of health knowledge (Brucks, Mitchell, and Staelin, 1984; Moorman, 1990; Probart, Davis, and Kime, 1989). They looked on health knowledge as starting points in the preventive health care process, rather than as influencers of actual behaviour (Avis et al., 1990). For example the ability required to encode nutrition information was positively related to levels of health knowledge, but the reliance on such knowledge to inform brand beliefs was negatively related to the extent of this health knowledge (Brucks et al., 1984). It appears that knowledge may help the encoding of information and its subsequent acquisition (Brucks, 1985; MacInnis et al., 1991). Conversely, high levels of health knowledge may reduce consumers’ need for more information, as they feel sufficiently knowledgeable (MacInnis and Jaworski, 1989).

Avis et al.’s (1990) study of cardiovascular risk factor knowledge demonstrated that the amount of health knowledge correlated positively with education level and being female. On a further point, the respondents’ knowledge of the risk factors that reduce the risk of a stroke or heart attack tended to centre on those risk factors they felt they had control over, such as exercise and reducing fat
intake rather than on the more serious risk, controlling blood pressure, something most likely seen as under the control of the doctor. In this sense, their health knowledge was biased in favour of factors the consumers themselves controlled.

While knowledge illustrated this bias towards factors under the consumers’ control, there was evidence that such control may have been more perceived than real. The smokers in this study included a list of steps that they could take control of. Not smoking was a key step for this group. In a similar vein, those in the study who were overweight listed weight control as a step they could take. This relationship between what the consumer knows and what he/she feels is under their control, can sometimes prove inconsistent. While health knowledge illustrated this bias towards behaviours under the consumer’s control, those who posses such knowledge can often fail to translate it into actual health behaviour. For example, respondents in this study who smoked registered smoking cessation as the number one step they could take control of. Likewise, those who were overweight reported weight control as the most salient item in their health knowledge.

The inconsistency between health knowledge and behaviour may be a result of the manner in which the former is measured. For example, one study operationalised health knowledge as the number of risk factors the consumer was aware of in relation to the control of blood pressure (Avis et al., 1990). In another it was operationalised as the amount of knowledge about dietary nutrients and their health outcomes (Moorman, 1990). Different definitions will
thus yield different correlations with behaviour. Both of the proceeding examples refer to what is termed objective health knowledge (Brucks, 1985). Matters are further compounded when the consumer’s subjective health knowledge is considered. Where objective health knowledge relates to the amount and complexity of what is known about health matters, subjective knowledge refers to the individual’s confidence in their ability to use this knowledge (Park and Lessig, 1981). To date the role of subjective health knowledge has yet to be examined.

**Health Status.**

Health status, as a consumer characteristic, refers to the perceived physical and mental well-being of an individual (Moorman and Matulich, 1993). The effect of health status has produced mixed results. Positive effects have been reported on cancer detection behaviour (Antonucci, Akiyama, and Adelmann, 1990), dietary improvement behaviour (Contento and Maksymowicz-Murphy, 1990), and health/illness information seeking (Hickey, Rakowski, and Julius, 1988). These are clearly secondary preventive behaviours. In other words, they do not effect actual health in a direct manner but minimise the likely impact of an illness by prompting consumers to monitor or check their health.

In other research, poor perceived health status has been found to be positively related to smoking (Colsher et al., 1990), the use of books and pamphlets, and turning to doctors/health professionals (Feick, Herrmann, and Warland, 1986). The effect of health status on health behaviours can work both ways. Some
consumers who perceive themselves to be healthy may engage in preventive health behaviours to maintain their health status, while others may be complacent in their good perceived health status and fail to maintain it (Moorman and Matulich, 1993). For this latter group, good health status could be viewed as a liability creating an impression of well being. To emphasise this point Taylor and Brown (1988) found that those with an unhealthy status performed more preventive health behaviours than those with higher status. This effect of health status as a liability has been found to operate for both primary and secondary preventive health behaviours.

When health status is viewed as the dependent variable with health behaviours as the independent variable, the relationship between the two shows the same paradoxical features. For example, Colsher et al., (1990) studied the effect of smoking behaviour on the perceived health status of a sample of elderly respondents. Counterintuitively, those who continued to smoke reported a higher perceived health status than those who had quit smoking. One possible explanation for this somewhat bizarre finding is that those who had quit may have been forced to do so in the first place because of illness or disease; hence their lower perceived health status. Whilst respondents who had never smoked did not feature in this study it seems plausible to presume that they would enjoy higher perceived health status than those currently smoking.
Health Locus of Control.

Locus of control has been applied to health behaviour with increasing frequency, following Seeman and Evan’s 1962 seminal article on learning in a hospital setting, as described by Lau (1982). Locus of control can be defined as

the degree to which individuals perceive events in their lives as being a consequence of their own actions, and thereby controllable (internal control), or as being unrelated to their own behaviour, and therefore beyond personal control (external control) (Lefcourt, H.M., in Lau, 1982).

This single bipolar, general locus of control measure reflects the basis of Rotter’s social learning theory, that locus of control beliefs develop from past experience and reinforcement history (Rotter, 1975).

Further work on the development of a locus of control scale from a single to a multiple scale was by Collins (1974). Collins constructed four rating scales of general locus of control; a) beliefs in a ‘just’ world; achievements are as a result of effort, b) beliefs in a ‘difficult’ world; a world full of complications and unsolvable tasks, c) beliefs that the world is governed by luck and chance, and is therefore ‘unpredictable’, and d) beliefs in a ‘politically responsive’ world where all citizens have some control over political affairs (Lau and Ware, 1981).

The application of Collins’ multiple locus of control scale to health behaviour has resulted in a multidimensional health specific locus of control scale (Lau and
Ware, 1981, Lau, 1982, Wallston, Wallston, and deVellis, 1978). Lau and Ware’s multidimensional scale is composed of four subscales; three of which are similar to Wallston, Wallston, and deVellis’ definitions, and one relating to Collins’ difficult world dimension.

1. Self-control over health refers to the individual’s belief in the efficacy of their own self-care; Wallston et al. refer to this as internal health locus of control (IHLOC).

2. Provider-control over health relates to beliefs in the efficacy of doctors; Wallston et al. refer to this as powerful other health locus of control (POHLC).

3. Chance health outcomes reflect the individual’s belief in the role of luck in health.

4. The final scale, modelled on Collin’s difficult world dimension, is general health threat, reflecting the perceived susceptibility to illness by individuals.

Lau and Ware’s exploratory work established that such health specific measures of locus of control predicted health related behaviours more accurately than general locus of control measures. This is reflected in Moorman’s extensive summary of studies of preventive health behaviour and locus of control; of fourteen studies utilising general locus of control, eleven report no effect. Conversely, those researchers incorporating health specific locus of control report an effect in eleven of the fifteen studies (Moorman and Matulich, 1993). IHLOC has been linked with the ability to stop smoking (Best and Steffy, 1975),
and the ability to lose weight (Balch and Ross, 1975). Steffy et al.'s findings suggest that IHLOC has been associated with the ability to stop smoking and, conversely, smokers have been found to demonstrate belief in chance, rather than POHLC or IHLOC (Eiser et al., 1989).

While the health specific locus of control measures are more discriminating than a general measure, there has been little collective correlation among them, suggesting their ability to be independent predictors of behaviour (Lau and Ware, 1981). However a significant result was the positive correlation between self-care or IHLOC and POHLC over health outcomes, contrary to the general view of internal and external control being opposite ends of a spectrum (Lau and Ware, 1981). Not surprisingly, self-control and provider-control were found to correlate negatively with chance health outcomes and general health threat. However, the impact of early family illnesses resulted in a greater belief in chance health outcomes and a negative correlation with provider over health outcomes (Lau, 1982).

Family illness also exercised an effect on self-control over health and in a pronounced fashion. Extreme cases of such illness, such as people dying of lung cancer without ever smoking, had a negative effect on self-control. This may be explained by the fact that good health is the normal state for most people who typically ignore the relationship between their behaviour and its effect on their health. Serious illness prompts these onlookers to examine this relationship and
to do so in a way that minimises the impact of their own efforts on their health and thus creates a bias against internal locus of control (Lau, 1982).

The experience of watching these ailing relatives suffer despite their health behaviour may lead them to conclude that control over health rests outside people’s and/or the health professional’s control and has more to do with chance than human agency. However, apart from this rather exceptional experience of family illness, routine and non-chronic experiences of personal illness appear to have minimal impact on locus of control beliefs. Whatever the impact of family illness on health locus of control beliefs, early health habits (such as regular doctor visits) had a lasting impact on the IHLOC and POHLC.

In this light, Lau’s results are in line with Rotter’s assertion that locus of control beliefs develop from past experience (prior experience with sickness and health and early health habits) and reinforcement history (prior self-care experience). Another important point that can be summarised from research in this area is that internal health locus of control is related positively to an individual’s propensity to take a long term view of their actions, rather than opt for immediate, or short term gratification (see education below). Furthermore health locus of control needs to be viewed as a multidimensional construct rather than a unidimensional one; as illustrated above, it is possible to attribute belief in the efficacy of one’s own efforts while retaining a belief in the efficacy of health professionals.
Health Behavioural Control.

Health behavioural control, while closely aligned with health locus of control, differs in that it relates to an individual’s belief in their ability to perform a specific behaviour in a specific situation (Bandura, 1977). Health behavioural control has also been termed self-efficacy (Kok et al., 1991).

It relates to control over a specific behaviour (i.e. performance of that behaviour), rather than overall control over the outcome. For example, an individual can believe that they can successfully quit smoking, a specific behaviour; this is health behavioural control. On the other hand, locus of control relates to whether that individual believes this cessation is due primarily to their own agency or that of external forces. One’s experience with the specific behaviour, observations and the persuasion of others, and the degree of confidence in performing that behaviour are the determinants of health behavioural control (Kok et al., 1991).

Research on behavioural control almost universally demonstrated a positive effect on preventive health behaviours. The intention to stop smoking and stop-smoking behaviour (Kok et al., 1991; Moorman and Matulich, 1993), and registration in a smoking cessation programme (Kviz et al., 1991) all correlate with positive behavioural control. Other behaviours, such as compliance with prescribed medical treatments (Rosenstock, 1988), and dietary behaviour modification (Davis-Chervin, Rogers, and Clark, 1985) also correlate positively with high behavioural control. The nature of smoking cessation, where the
individual usually makes multiple attempts to quit, makes behavioural control of
great importance to the present study.

**Education.**

Education, in the context of health, can be viewed as an ability which enhances the desire for a healthy lifestyle and improves the efficiency with which the individual consumes health care services (Grossman, 1982). The effect of education has focused on information acquisition and comprehension, and the performance of a range of preventive health behaviours. In relation to information acquisition, use of books and pamphlets, labels, magazine/newspaper articles, and visiting doctors/health professionals (Feick, et al.; 1986; Worsley, 1989), correlate with higher education levels. Also the ability to comprehend nutrition labelling (Moorman, 1990), and provider information seeking (Anderson, Meissner, and Portnoy, 1989) have all reported registered a positive relationship with increasing levels of education.

In terms of health behaviours, education levels have been demonstrated to encourage a range of behaviours such as cancer detection behaviour (Antonucci et al., 1990), compliance with prescribed treatments (Rosenstock, 1988), and a range of healthy eating and health food consumption (Bassler and Newell, 1982; Saegert and Young, 1983; Yung, Contento, and Gussow, 1984). In contrast, continuing to smoke is negatively correlated with education and not smoking demonstrates a positive relationship with education levels (Leigh, 1983). Higher levels of smoking have been found in the less educated strata of the population,
and as a result, registration in smoking cessation programmes has a positive correlation with education (Kviz et al., 1991).

As already highlighted, an important aspect in preventive health behaviour is the time frame involved. Termed 'time preference', it relates to the time horizons individuals utilise when evaluating health; a low time preference means that the individual assesses current actions in terms of how they will impact on their health in ten to twenty years hence. Those with a high time preference do not adopt this long term view. Increasing levels of education have been found to correlate with a lower time preference (Fuchs, in Leigh, 1983).

Age.

In a health context, issues regarding age focus on the individual’s mental and physical ability to engage in health behaviours (Moorman and Matulich, 1993). Increasing age has been found to reduce cognitive skills, resulting in less information acquisition, for example nutrition information (Cole and Gaeth, 1990, Moorman, 1990), and a greater focus on health professionals for information (Probart et al., 1989, Pineault et al., 1989).

In relation to health behaviours, results are, once again, mixed. Increasing age has shown positive effects on good nutrition (Weitzel, 1989), and health food purchases (Yung et al., 1984). However alcohol consumption (Colsher et al., 1990), taking exercise (Weitzel, 1989), and health clinic use (Williams and Dueker, 1985), all correlate negatively with increasing age. Smoking cessation is
positively correlated with age, and associated with the increasing difficulties experienced with health (Colsher et al., 1990, Kviz et al., 1991).

**Income.**

Studies on income level show a positive relationship with a range of health behaviours, both with specific behaviours and with more general attitudes towards health. Examples such as contact with the doctor (Dawson, 1989), use of the doctor (Rosner, Tarler, Namazi, and Wykle, 1988), preventive dental care (Gelb and Gilly, 1979), and oral hygiene behaviours (Laiho, Honkala, and Nyssonen, 1991) reflect this relationship.

While the impact of income is important in the health care system generally and low levels of income in particular militate against full participation in the health care system (Zaltman and Vertinsky, 1971), it remains more peripheral when it comes to individual preventive health behaviours. As demonstrated by Grossman, the effect of income on education is well documented. Income should be viewed in the wider context as impinging on education.

**2.8 The Need To Understand the Interrelationship of Consumer Characteristics.**

Much of the focus on consumer preventive health behaviour has been on single independent variables discussed above such as age, and income, or specific moderating variables such as locus of control or health knowledge. With research spanning different disciplines, little attempt has been made to bring the different variables together, but there are many indications or recommendations
to do so. One comprehensive treatment of preventive health care, by Moorman and Matulich, brings together research in this area. Their 1993 model draws on all prior research in an attempt to develop a complete framework of consumers’ preventive health behaviour. The study focused on the effects of consumer characteristics on health information acquisition and a range of health behaviours. Health behaviours include the three aspects of health information acquisition, and five health maintenance behaviours; tobacco non-use, alcohol moderation, negative diet restriction, positive diet addition, and life balancing behaviours (stress reduction).

The ambiguous results from previous research on variables that affect health behaviours have been attributed to the absence of motivation as a moderating variable. However the hypotheses forwarded by Moorman and Matulich, that health motivation moderates the impact of various health abilities on health behaviours, received little or no support. The whole issue is compounded by the somewhat vague nature of the dependent variable in this case - health behaviours. ‘Health behaviours’ can embrace a wide range of often contradictory behaviours. For example, a consumer may be highly motivated to improve their health by taking exercise while continuing to smoke. A study examining how the full range of consumer variables affects a single preventive health behaviour seems more promising than a study purporting to explain the full gamut of health behaviours.

Moorman and Matulich do recommend a more interactive treatment of consumer characteristics (Moorman and Matulich, 1993). Adopting an interpretive
approach, rather than a cue-based methodology, will facilitate a more comprehensive exploration and understanding of these characteristics. Of equal importance to this comprehensive treatment of consumer characteristics is an understanding of how such characteristics evolve over time and how the use of products impacts on consumers’ health behaviour. For example, as illustrated above, experience of illness can have long term impact on locus of control. Therefore, the use of, or experience with, a medication will also impact on consumers’ preventive health behaviour. The next section draws on research in the field of illness to introduce concepts central to adopting a wider approach to consumer’s preventive health behaviour.

2.10 Consumer Characteristics in Action; the Impact of Experience.

Authors such as Gochman have stated that health behaviour research encompasses the consumer characteristics as well as the use of treatments and the structures of the health care system and therefore it is important to adopt a wider, holistic approach to understanding consumer’s preventive health behaviour. Any one illness could have given rise to a range of remedies and health behaviours and may have involved a variety of interventions on the part of health care agencies and professionals. This process may have taken place over a protracted period of time. The concept of an ‘illness career’, developed by Gould et al. (1993), consists of all consumption and non-consumption events that an individual experiences over the course of an illness. Therefore it is essential to view the consumers’ current health behaviour in terms of a ‘career’ or trajectory.
This movement and change results from the experience gained over time. It must be highlighted that the concept of an illness career encompasses both primary and secondary preventive behaviours, as well as illness-related behaviour.

The illness career approaches the experience of the consumer in a holistic fashion, focusing on the evolution of the consumer’s behaviour over time. Rather than viewing consumer characteristics as static or fixed variables, they are viewed as one part of the evolution of an illness career. Gould et al. used in-depth, unstructured interviews to explore how allergy sufferers coped with their illnesses. The consumers’ characteristics, as well as their interaction with medical professionals, and most importantly, their use and experimentation with treatments contributed to a process described as ‘treatment shopping’ (Gould et al., 1993). The idea of treatment shopping mirrors the traditional consumer behaviour decision making process, with a key factor being the gaining of learning and expertise as a result of experimentation and experience.

Gould et al., in addition to utilising consumer characteristics as predisposing and enabling factors, introduced two response factors, deemed important for allergy suffers. The first response factor related to the idea of self-care and consumers taking responsibility for their health care decisions. The second related to consumers’ health perceptions versus those of health professionals; while the health professional was viewed traditionally as having the expertise, it is the consumer who often develops expertise and self-knowledge of their health far beyond that of the health professional. This accrued from the consumer’s self-medication, experimentation and theorising.
A number of themes to emerge from this interpretive investigation of allergy sufferers are important for this study of consumers using NRT. Consumers trying to quit smoking usually take a number of attempts trying different methods before success and as such the concept of an illness career can be mapped onto a smoking cessation career. Their ‘condition’ requires much experimentation and self-medication, especially for those using NRT.

The central theme uncovered by Gould et al. was that the history of the allergy sufferer followed a path or illness career and reflected increasing consumer expertise, helping account for what appeared to be highly individualistic behaviour among allergy sufferers. There was a constant evaluation and cycling of experience throughout the career as the nature of the consumers’ allergies and their preventive health behaviour seemed to alter over time. The detailed knowledge of their condition and how to alleviate it were very precise and the altered use of medications was an important aspect of their self-medication practices. Such practices gave rise to increased perceived self-efficacy in the consumers’ ability to deal with their allergies.

Overall, Gould et al. demonstrated that a consumer centred approach to exploring health care, while revealing very individualised paths, can be best understood in terms of experience accumulated or as a ‘career’. In viewing this illness career as a whole, it is the consumers’ own understanding that is central, as described by Gould et al., (1993, p. 11);

Moreover, we have demonstrated, at least in the allergy domain, that consumers engage in a process of theorising and empirical self-
observation that seems to be “scientifically” appropriate for their own situations and commensurate with their own illness perspective.

In summary, Gould et al. adopted a holistic approach to their study of allergy sufferers, incorporating the consumer characteristics as well as the use of treatments, many of which were OTCs. Clearly the use of a treatment is central to the performance of any health behaviour as it both shapes and reflects the performance of that health behaviour. Also, approaching the study in an open-ended manner, from the perspective of the respondents themselves allowed the unique careers of different respondents to appear. In this case, unique often paradoxical behaviours of the allergy suffers could be understood with the concept of an illness career. This contrasts to Moorman and Matulich’s study, which attempted to establish uniformity across a range of behaviours and consumer characteristics. Clearly individual health behaviours have particular facets not common across all health behaviours.

For this study of smoking cessation a holistic, open approach should yield unique aspects to this particular behaviour and the role of the characteristics of those performing the behaviour. Certainly the concept of a career appears suitable, given the nature of smoking cessation, as outlined above. The particular consumer characteristics that will be most significant for smoking cessation are difficult to establish in advance, given that the use of a particular treatment, in this case NRT, has not been investigated before. But it is probable that the most important are health knowledge, health status, health locus of control, and health
behavioural control. However, the approach in this study avoids any particular *a priori* assumptions, but attention will focus on these characteristics.

Finally, smoking cessation and its correlates are clearly located in the broader arena of health behaviours. It has been shown already that this arena is increasingly characterised by greater consumer autonomy. Consumers are more likely now than ever to choose, and continence specific health regimes on their own initiative than on the advice or direction of professionals. Increased pharmaceutical deregulation and wider availability of non-prescription drugs both facilitate and support this trend. However the specific constitution of switch drugs to this overall process has yet to be fully investigated. The following chapter charts the emergence and growth of the switch drug phenomenon in a more descriptive vein.
Chapter Three.

The Prescription to Over-The-Counter Switch.

3.1 Introduction.

This chapter outlines the emergence of the OTC market in the context of the wider pharmaceutical market, with particular emphasis on the evolution of nicotine replacement therapy as an OTC, both world-wide and in an Irish context. In addition, the rationale for drugs switching to OTC status and the process of switching drugs is outlined. First, this chapter looks at the range of smoking cessation methods available to those wishing to quit and the process of smoking cessation itself.

3.2 Smoking Cessation Methods.

While smoking cessation has been identified as the single most preventable cause of deaths world-wide, there remains little agreement, even among health professionals, as to the best strategies to employ to encourage and ensure successful cessation (Paul and Sansonfisher, 1996). Ways of quitting smoking include conventional and alternative medical methods, behavioural modification and support strategies, and traditional ‘cold-turkey’ approaches. This section examines the types of methods used, with particular emphasis on nicotine replacement therapy.

Efforts to reduce smoking levels or prevent people starting to smoke in the general population can be broadly divided in two; health education/promotion,
highlighting the dangers and risks associated with smoking, and smoking control, including strictly controlled advertising and sponsorship, no smoking in public buildings, and no smoking zones. The result of both of these reduction strategies has been a gradual decline in smoking, from 43% of the adult population in 1973 (Irish Marketing Surveys, 1982), to 30% in 1996 (Irish Marketing Surveys, 1996). While apparently successful to date, there are two emerging trends that appear to hinder the planned target of reducing the numbers smoking to 20% of the population by 2000.

First, the number of younger children and teenagers, especially females, who are smoking is higher than ever; 18% of girls aged 12 to 18 smoked in 1970; this rose to 26% in 1980 (Irish Marketing Surveys, 1982). Recent indications are that 50% of 10-12 year olds are now smoking (O’Conor, 1997). Second, the number of current smokers who are attempting to or intend to quit is reducing, suggesting that a core of heavy smokers remain who find it increasingly difficult to give up (Irish Marketing Surveys, 1996).

It is in this context that methods of smoking cessation need to be examined. Also it is worth noting that smoking cessation requires substantial effort, and the majority of smokers will try between three and six times before achieving success. As a consequence, most quitters will usually try a variety of methods, often more than once. Research on smoking cessation is mostly of a medical or psychological nature and has tended to utilise ‘captive’ or non-volunteer subjects (Hennrikus, Jeffery, and Lando, 1995). Placing subjects in such an environment predictably produced high success rates as a result of quite detailed and intensive
support for the participants (see Table 3.1, below). Newer methods, such as laser therapy do not have independently verified results and are often prone to exaggeration by proponents.¹

The actual methods available range from individual counselling from doctors, nurses and pharmacists, to telephone counselling, hypnosis, hypnotherapy, acupuncture and laser therapy. Other methods involve behavioural modification encompassing relaxation, rewards and punishment, and avoiding 'trigger' situations. Typically these behaviour modification methods are under the instruction of a psychologist. Many methods involve some combination of the above. However the focus for this study will be on nicotine replacement therapy only.

Smoking cessation treatments are available through a range of channels, including doctors, pharmacies, commercial advertising and, more recently through the workplace as part of a support programme. An example of how such a range of options are made available is the Irish Cancer Society who, under the umbrella of the Department of Health run Health Promotion Unit, provide advice and counselling in workplaces, hospitals, and to individuals with no one method receiving their approval or endorsement.

¹ For example, the author's initial review of cessation methods, through informal interviews, produced a reported 85% success rate for laser therapy.
### Table 3.1 Smoking Cessation Methods and Reported Results

<table>
<thead>
<tr>
<th>Nature of Treatment</th>
<th>Reported Result % not smoking after one year (unless otherwise stated)</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unaided smoking cessation</td>
<td>8.5% - 13.8%</td>
<td>Baillie et al. (1995)</td>
</tr>
<tr>
<td></td>
<td>6.4%</td>
<td>Viswesvaran et al. (1992)</td>
</tr>
<tr>
<td>Self-help booklet</td>
<td>7%</td>
<td>Curry et al. (1995)</td>
</tr>
<tr>
<td>Personalised feedback</td>
<td>9%</td>
<td>Curry et al. (1995)</td>
</tr>
<tr>
<td>Telephone counselling</td>
<td>11%</td>
<td>Curry et al. (1995)</td>
</tr>
<tr>
<td>Nicotine replacement therapy (gum) plus behaviour modification/support</td>
<td>39% for high dependence 49% for low dependence</td>
<td>Herrera, et. al., (1994)</td>
</tr>
<tr>
<td>Nicotine replacement therapy (gum) 2mg</td>
<td>44%</td>
<td>Hall et al. (1982).</td>
</tr>
<tr>
<td></td>
<td>47%</td>
<td>Jarvis et al. (1982).</td>
</tr>
<tr>
<td></td>
<td>38%</td>
<td>Raw et al. (1980).</td>
</tr>
<tr>
<td>Nicotine replacement therapy (gum) 4mg</td>
<td>43%</td>
<td>Blondal, (1989).</td>
</tr>
<tr>
<td></td>
<td>44%</td>
<td>Tonnesen et al. (1988).</td>
</tr>
<tr>
<td></td>
<td>46%</td>
<td>Tonnesen et al. (1988).</td>
</tr>
<tr>
<td>Nicotine patch (Nicotinell)</td>
<td>22% (after six months)</td>
<td>Daughton, (1991).</td>
</tr>
<tr>
<td>Behaviour therapy plus patch</td>
<td>38% (after six months)</td>
<td>Cinciripini et al. (1995).</td>
</tr>
</tbody>
</table>

### 3.3 The Process of Smoking Cessation.

In order to understand smoking cessation it is important to view it as a process rather than a single step. The Stages of Change Model (Prochaska and DiClemente, 1983), also termed the Transtheoretical Model for Intentional
Behaviour Change was developed as a dedicated model to analyse the smoking cessation process and breaks it down into five principal stages;

1) Precontemplation, where the individual has not considered quitting,

2) Contemplation, when the individual is open to evaluating potential options and is receptive to education about the hazards of smoking,

3) Preparation, with a method chosen,

4) Action, the performance or use of the cessation method,

5) Maintenance, the continued adherence to the chosen method.

Using such a structure can help in tailoring any strategy to the individual needs at a particular time. For example, a doctor or pharmacist can help individuals to choose a method and set goals at the contemplation stage or offer support and reinforcement at the action and maintenance stages.

It is also worth noting that two people may possess different levels of nicotine dependence, even though they appear to be at the same stage of the process. In this case, both people may be at the contemplation stage but will have very different requirements for cessation due to their differing nicotine dependence.

The Fagerstrom Tolerance Questionnaire (FTQ) (Fagerstrom, 1978), measures the individual’s level of nicotine dependence using an eight question test, listed in Table 3.2, below. A score of less than or equal to six indicates a low nicotine dependence, with a score of seven or greater indicating a high nicotine dependence, up to a maximum score of eleven. General results suggest that medium to heavy smokers (score of seven or greater) have more success with nicotine replacement therapies than with other available methods.
Table 3.2. The Fagerstrom Tolerance Questionnaire.

<table>
<thead>
<tr>
<th>Points</th>
<th>0</th>
<th>1</th>
<th>2</th>
</tr>
</thead>
<tbody>
<tr>
<td>How soon after you wake do you smoke your first cigarette?</td>
<td>After 30 minutes</td>
<td>Within thirty minutes</td>
<td></td>
</tr>
<tr>
<td>Do you find it difficult to refrain from smoking in places where it is forbidden e.g. library, cinema, church?</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Which cigarette would you be most willing to give up?</td>
<td>Any other</td>
<td>First one in the morning</td>
<td></td>
</tr>
<tr>
<td>How many cigarettes per day do you smoke?</td>
<td>&lt;15</td>
<td>16-25</td>
<td>&gt;26</td>
</tr>
<tr>
<td>Do you smoke more during the morning than during the rest of the day?</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Do you smoke if you are so ill that you are in bed all day?</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>What is the nicotine level of your usual brand of cigarettes?</td>
<td>&lt;0.9mg</td>
<td>1-1.2mg</td>
<td>&gt;1.3mg</td>
</tr>
<tr>
<td>Do you inhale the smoke from your cigarette?</td>
<td>Never</td>
<td>Sometimes</td>
<td>Always</td>
</tr>
</tbody>
</table>


In summary, the literature divides direct cessation strategies into motivational interventions, comprising behavioural interventions and broader media campaigns, and treatment interventions, principally comprising nicotine replacement therapies. The aim of the former is to encourage cessation; the aim of the latter to increase the chance of success. With the concentration of heavy smokers and the saturation of motivational intervention, an intervention that has had little success, it is suggested that the focus should now shift to treatment interventions instead. In particular, it is felt that such treatment interventions,
NRT, holds the greatest promise of success for those seeking to cease smoking. (Foulds, 1996).

3.4 The Emergence of the OTC Market.

While the current focus on patient autonomy, self-medication, and the freedom to purchase medicines without prescription is reflective of a more positive, consumer-orientated era, the origins of OTCs have a less than positive history. The USA of the 1880’s is viewed as the highpoint of the ‘patent medicine era’ \(^2\) by many commentators (Mercill, 1983). At this time a vast array of exaggerated claims linked to mysterious potions challenged the consumer who, in this time of confusion, often opted for a home remedy instead of a visit to the doctor or pharmacist. Some of the OTC brand names are still available today, but bear little resemblance to their origins. Subsequent to this era, greater control by the medical professionals and the health care system generally ensured that most medicines came under their control, principally through the use of prescription status applied to pharmaceuticals.

Today the pharmaceutical market is valued at approximately US $ 206 billion, growing at 3% annually (Polastro, 1995). Two dynamics are shaping this market; the increasing competition from generic drugs and the focus on containing health care costs, both leading to an increase in the number of drugs switching to OTC status.

\(^2\) Patent medicines refer to the patents of royal favour granted by the kings of England to those who served the royal family. The term was adopted by English settlers in the USA who sold such prized medicines
The term generic describes a pharmaceutical preparation based on active ingredients that are no longer patent-protected. Generics are usually marketed by a company other than the originator or its licensees. Generics account for 8% of the European pharmaceutical market, growing at 7% per year, over twice the rate of the total market. In fact US $12 billion worth of drugs will loose their patent protection by the turn of the century (Chapman, 1995). As a result of the loss of patent protection, drugs face direct competition from generic variants. Doctors have the choice of prescribing the original drug or its' generic competitor.

Typically the drugs facing generic competition are the 'wonder-drugs' or 'legend drugs', with US $ one billion-a-year sales and high profit margins. It is forecasted that with twenty-one such drugs in 1993, there will be no drug of this scale in 2000 (Alster, 1995). Also by 2003, 50% of all drugs sold by the top fourteen pharmaceutical companies will face generic competition.

The result of the introduction of a generic product is a 30% to 40% retail price discount on the original branded product in the USA, and approximately a 20% discount in the UK (Marx, 1996). Sales volume on the original branded product can drop by 90%, even in the first months of losing patent protection. This has resulted in the fact that 50% of all prescriptions in the UK are for the generic variants.

The second issue facing the pharmaceutical industry is the attempt by governments to contain health care costs. Drugs account for 7% of government spending on health care in the US and 12% in Europe. OTCs offer a way to shift the cost from the government, who often cover the costs of prescription drugs, to
the consumer by ensuring OTCs are the first option utilised by consumers. This reduces the time and money spent visiting doctors, and results in the consumer paying for the drug.

Allied to both these dynamics shaping the market is the rise of managed health care; Health Management Organisations (HMOs) schemes are taking over the role previously held by government health care programmes. HMOs are essentially private health care schemes and the equivalent in Ireland would be the Voluntary Health Insurance (VHI) or, more recently, BUPA. In 1994, 23% of the American insured population belonged to an HMO. The strength of HMOs is in their ability to purchase, at discount, drugs which they choose to make available to their members, even to the level of agreeing with pharmaceutical suppliers to cover individual patient’s pharmaceutical needs at pre-set prices. The financial attractions of both generics and OTCs to HMOs are clear.

3.5 The Rise of the Switch Drug.

The response from the pharmaceutical companies to both of the trends discussed above has been to prolong the life of the ‘wonder-drugs’ facing patent expiry by two means; enhancing the brand recognition through direct-to-consumer advertising and ‘switching’ the drug to OTC status.

Direct-to-consumer advertising, while banned in Europe since 1992, has become an accepted practice in the USA by the American Medical Association (AMA). Traditionally the doctor has been the focus of pharmaceutical companies marketing efforts. However, with the increasing importance of HMOs and the
rise of a consumer more likely to ask questions, the objective is to use the consumer to ‘pull’ the drug through. In 1989, US $ 10.2 million was spent on direct-to-consumer advertising in the USA, rising to US $ 242.7 million by 1994 (Marx, 1996). Direct-to-consumer advertising reflects the recognition of a powerful autonomous consumer concerned with health care decisions and such advertising attempts to remove the psychological distance between patient and provider and create brand awareness in advance of patent expiration.

While such direct-to-consumer advertising is restricted to the USA, throughout the world the pharmaceutical industry’s main focus has been to switch drugs to OTC status. Until recently the OTC category contained many familiar medicines for coughs and colds, pain killers such as paracetemol, mild stomach remedies, vitamins, and skin care products. Many of these are household brand-names, often available in supermarkets as well as pharmacies.

However today a whole new array of drugs are being switched to OTC status, many of them with a previously strong prescription history and associated with more serious health issues. Identified as the new switch paradigm (Juhl, 1997), these new switches require more than just recognition of the symptoms by consumers; they also require unique patient decision making and more complex product usage.

Therefore the greatest focus is on switched OTC medicines restricted to pharmacy sale only. Such switches are termed POM to P switches (prescription only medicines switched to non-prescription, pharmacy restricted sale). This contrasts to OTCs available in the retail grocery channels, which are termed

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general sale medicines, such as the examples above. The focus of this study will be on OTCs restricted to pharmacy sale only.

The resulting growth of OTCs in revenue terms has been staggering. For example, in 1993, OTCs grew 16.2% to US $ 8.9 billion in the USA, accounting for 26% of all drug sales. A total of US $ 3.7 billion came from switched drugs alone. Estimates are that the OTC market will double by 1999, and the savings in terms of health care, currently US $ 10.5 billion, will rise to US $ 34 billion by the year 2000 (Hoffman, 1995). There are now more than 600 medications containing ingredients or dosages that required prescriptions twenty years ago and the pace of switching is higher than ever. The two dynamics of generic drug growth and cost-control have resulted in the industry and government working together to speed up the introduction of switch drugs.

In Europe the trend has been similar, with large numbers of drugs switching to OTC status. Table 3.3 highlights the strong growth rates for the OTC and self-medication markets throughout Europe. A focus on non-prescription medicines in Europe has only recently emerged, and this is reflected in the nature of the data on the area. There is little consistency in what is included in the categories measured and there is a general lack of historical information. As illustrated in table 3.3, some countries subdivide the non-prescription market to account for the self-medication market, excluding products not used as a medicine, but now available without prescription. An examination of table 3.3 may lead one to conclude that the growth in OTCs as a percentage of the total pharmaceutical market is less than spectacular. For example, OTC market share in Ireland in
1995 was 22% and in 1996, 21.4%. However these percentages must be read in the light of an overall growth in the total pharmaceutical market, both prescription and non-prescription. In other words, a 21.4% market share in 1996 represented an increase of 7% in value terms on the 22% market share for 1995.

Table 3.3 Non-prescription Medicines as a Percentage of Selected European Pharmaceutical Markets (Value)

<table>
<thead>
<tr>
<th>Country; OTC/Self-Medication as a % of Total Pharmaceutical Market/ % Change</th>
<th>1994</th>
<th>1995</th>
<th>1996</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ireland</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Non-Prescription Market</td>
<td>22.4%</td>
<td>22%</td>
<td>21.4%</td>
</tr>
<tr>
<td>Self-Medication Market</td>
<td>19.4%</td>
<td>20.9%</td>
<td>20.6%</td>
</tr>
<tr>
<td>% Change Vs Previous year</td>
<td>+17.9%</td>
<td>+6.99%</td>
<td></td>
</tr>
<tr>
<td>Belgium</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Non-Prescription Market</td>
<td>22.7%</td>
<td>22.3%</td>
<td>21.2%</td>
</tr>
<tr>
<td>Self-Medication Market</td>
<td>18.2%</td>
<td>17.7%</td>
<td>17.2%</td>
</tr>
<tr>
<td>% Change Vs Previous year</td>
<td>+5.4%</td>
<td>+0.6%</td>
<td></td>
</tr>
<tr>
<td>Finland</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Non-Prescription Market</td>
<td>18%</td>
<td>18%</td>
<td>17%</td>
</tr>
<tr>
<td>% Change Vs Previous year</td>
<td>+2.4%</td>
<td>+9.4%</td>
<td>+0.8%</td>
</tr>
<tr>
<td>Hungary</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Non-Prescription Market</td>
<td>10.9%</td>
<td>14.6%</td>
<td>15.5%</td>
</tr>
<tr>
<td>% Change Vs Previous year</td>
<td>+68.6%</td>
<td>+54.9%</td>
<td>+31.2%</td>
</tr>
<tr>
<td>Norway</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Non-Prescription Market</td>
<td>11.1%</td>
<td>11.4%</td>
<td>10.4%</td>
</tr>
<tr>
<td>% Change Vs Previous year</td>
<td>+3.7%</td>
<td>+16%</td>
<td>+2.7%</td>
</tr>
<tr>
<td>Portugal</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Non-Prescription Market</td>
<td>8.2%</td>
<td>10.2%</td>
<td>11.6%</td>
</tr>
<tr>
<td>% Change Vs Previous year</td>
<td>+40.8%</td>
<td>+25.7%</td>
<td></td>
</tr>
<tr>
<td>Spain</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Non-Prescription Market</td>
<td>15%</td>
<td>15%</td>
<td>15.5%</td>
</tr>
<tr>
<td>Self-Medication Market</td>
<td>12%</td>
<td>12%</td>
<td>12.4%</td>
</tr>
<tr>
<td>% Change Vs Previous year</td>
<td>+8.9%</td>
<td>+8.1%</td>
<td></td>
</tr>
<tr>
<td>Sweden</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Non-Prescription Market</td>
<td>11.2%</td>
<td>10.5%</td>
<td>9.3%</td>
</tr>
<tr>
<td>Self-Medication Market</td>
<td>9.2%</td>
<td>8.7%</td>
<td>7.8%</td>
</tr>
<tr>
<td>% Change Vs Previous year</td>
<td>+9.3%</td>
<td>+6.7%</td>
<td>+6%</td>
</tr>
</tbody>
</table>

3.6 The Switch Process

The process for switching drugs varies from country to country but essentially involves a submission by the manufacturer to the drug licensing authority (Food and Drug Administration (FDA) in the USA, Medicines Control Agency (MCA) in the UK, and the Irish Medicines Board (IMB) in Ireland) requesting the switch of a prescription drug to OTC status. The typical requirements of the drug licensing authorities are contained in Table 3.4 below. The decision rests with the authority who in turn stipulates conditions regarding dose sizes, labelling requirements, and advertising restrictions. Central to the switch process is the consumer’s ability to comprehend labelling and directions; the inclusion of a range of educational and support materials have become critical to consumer comprehension as a broader range of drugs are switched.

Table 3.4 FDA Guidelines for OTC Submissions.

- Full knowledge of drug’s scientific base and pharmacology.
- Lack of special toxicities.
- Large safety margin.
- Effects of frequency of dosing on safety.
- Safety profile defined at high doses.
- Minimum three years of prescription use.
- Adequate adverse reaction reporting.
- World-wide marketing experience.
- Data from national prescription audit and national drug disease audit.
- Rigorous risk analysis.
- Literature review on safety and efficacy.
- Possible drug interactions.
The process of switching from prescription only to OTC status can be best viewed in the US context. The USA has been at the forefront of the pharmaceutical industry for many years and the regulatory bodies have pioneered legislation for the move to OTCs for prescription drugs. Prescription drugs were first differentiated from non-prescription drugs by the 1951 Durham-Humphrey Amendment to the Food, Drug, and Cosmetic Act (1938), defining prescription drugs as those that are unsafe for use without professional supervision. Essentially all drugs were OTC by default, and prescription drugs the exceptions. In addition this amendment allowed the Food and Drug Administration (FDA) the authority to ‘switch’ a drug to OTC status.

The FDA, from 1972, developed their OTC strategy in four major steps:

1. The drive to switch drugs came from the formation of advisory review boards who evaluated the safety and efficacy of potential switch drugs based on the product category rather than specific products or brands.

2. From 1976 to 1982 the FDA switched 29 prescription ingredients, including metaproterenol, a drug for asthma sufferers, a switch driven by the FDA themselves. As a result of criticism from medical professionals, its OTC status was revoked by the FDA. The cause of this criticism by medical professionals was as a result of the range of side effects experienced by users. Incorrect usage and combining metaproterenol with other medicines were the major causes of these side effects. Even so, one could summarise that the medical professionals used this opportunity to keep the FDA in check.

Source: Smith, 1983.
3. The increase in switching was evident from 1982 to 1991, with a cumulative total of 40 ingredients receiving OTC status, accounting for more than 200 individual products.

4. Recognising what was termed the OTC revolution, the FDA Commissioner, David Kessler set up the office of OTC Drug Evaluations in 1994 to prepare for the rapid growth expected in both switches and direct to OTC applications (Juhl, 1997). Significantly the OTC drugs Advisory Committee, consisting of five to seven members, included consumers for the first time.

While it can be argued that the USA has developed a clearer policy towards switch drugs, the situation in Europe is somewhat different. The AESGP, the European body representing the interests of the consumer healthcare industry, surveyed all European national associations on their position in relation to switches, the regulatory environment, professional attitudes, and training in relation to OTCs (IPHA, 1997). Excluding France and Spain, European countries have few regulations governing the switch to OTC status. Others have begun to classify OTCs, issue guidelines, and develop regulations, but most switches happen through the 'attitudes' inherent in the countries regulatory bodies and are treated on a case by case basis. Generally the attitudes of doctors and pharmacists towards OTCs are favourable, unless they impinge on the earnings as a result of changes in reimbursement or where they are paid per patient visit. Training health professionals in OTCs is virtually non-existent, reflecting the peripheral nature of OTCs to the healthcare system.
Ireland follows this trend with no formal rules governing switches, outside of the usual efficacy and safety considerations. While pharmacists are receptive to OTCs, there is no training on OTCs currently but discussions are ongoing between the Irish Pharmaceutical Healthcare Association (IPHA) and the pharmacy bodies.

3.7 The History of Nicotine Replacement Therapy.

The principal treatment intervention available to those wishing to stop smoking is nicotine replacement therapy (NRT), developed in 1978. NRT was initially available as Nicorette nicotine gum, developed by AB Leo, who was acquired by the Pharmacia Company in 1990. The emergence of NRT on world-wide markets resulted from a distribution agreement with Marion Merrell Dow and Ciba-Geigy. The original concept was developed in response to a request from the Swedish Royal Navy, who banned smoking amongst submarine crews. The navy wished to find a solution to the withdrawal effects experienced by their sailors. Previously smoking cessation methods relied on psychosocial approaches, with little attention to the physical addiction to nicotine.

The nicotine replacement therapy concept is based on tackling the physical addiction by continuing to supply the body with nicotine, at a lower dosage, to prevent withdrawal symptoms thus allowing the individual to break the habit of smoking. Typically NRT is designed as a twelve week/three month programme, with a gradual reduction of nicotine until it is stopped. While essentially providing the same level of nicotine replacement, the nicotine gum and patch
differ significantly; the gum allows the individual to get the nicotine whenever they feel the need. This is achieved by chewing a piece of gum and resting it between the cheek and gum, where the nicotine is absorbed. In contrast, the patch delivers a regular supply of nicotine, the body absorbing the nicotine into the bloodstream where the patch is worn, usually on the shoulder. Patch programmes are now available for daytime wear only, to counteract difficulties experienced by some users who suffered sleep disturbance as a result of a consistent delivery of nicotine, twenty-four hours a day.

Although clearly effective, there has been resistance from medical professionals aimed at the contradiction of using nicotine to combat nicotine addiction and at the unregulated availability of NRT through its OTC status. Medical ambivalence towards NRT has been further compounded by developments in the tobacco industry. This industry is also regulated by the FDA but in a manner less severe that for the pharmaceutical industry. Tobacco companies are presently developing a range of less harmful product concepts themselves designed to assuage smoker's health concerns.

Medical ambivalence is however waning. The argument that nicotine addiction requires a nicotine-based remedy is gaining currency among the profession. However, for some doctors this support is an unwelcome reminder of their now discredited support for filtered and low tar cigarettes in the 1960’s. The prospect of NRT manufacturers and the tobacco industry acting in concert to address the need of the same smoker segment to minimise the harmful effects of smoking seems quite ironic. This is heightened when one realised that the tobacco
manufacturers can introduce a new brand to the market without impediment from the FDA, while an NRT manufacturer can face a number of years of regulatory obstacles and immense cost in introducing a new flavour NRT gum, through the same regulatory body (Warner, Slade, and Sweanor, 1997). The AMA are presently seeking to correct this regulatory inequality between NRT and tobacco manufacturers and are arguing for more widespread availability of the former claiming that ‘product availability and use will be defined by consumer demand’ (Warner et. al., 1997 p. 1090).

The biggest implication of the switch to OTC status is the transition from drug to brand. This is best described by Christer Wernrud, a director of Pharmacia Nicorette as follows; ‘We have to stop talking about our patients and start talking about our customers instead. After all our customers are no longer the doctors and the chemists but primarily the people who use our products’ (Urde, 1994, p. 25). This shift in focus resulted from three factors; the expiration of the patent on Nicorette in the early 1990’s, the introduction of competition from other branded nicotine patches, and the opportunities afforded by the relaxation of marketing restrictions to develop branded products.

The period up to the nineties was concerned with creating a long-term demand for NRT, rather than for a particular brand. Subsequently the focus was on creating a brand position for Nicorette. Pharmacia realised that positioning rested on the consumer’s perception of the product, not their own view. This shift to the consumer entailed the adoption of a less aggressive and more sympathetic
communication generally, ignoring the temptation to lecture on the health hazards of smoking (Urde, 1994).

The positioning developed rested on the proposition: 'Helps you through the hard times', evolving to the current: 'Enjoy life without cigarettes'. This consumer rather than health professional orientation impacts not only on marketing communication but has also permeated through all facets of Pharmacia, including product development and clinical trials to ensure that all work is in line with the brand vision.

There are a range of brands which are active in the NRT market, many of them sold by different companies in differing markets. For example, Pharmacia & Upjohn distribute Nicorette in Ireland, while SmithKline Beecham hold the rights in the USA and the UK. Key brands in Ireland are Nicorette and Nicotinil (gum), and Nicotinell and Niconil, and recently introduced Nicorette (patches).

The introduction of NRT was in 1982, in the USA, available on prescription only. The introduction of nicotine patches followed in 1991. A more recent development was the introduction of the nicotine nasal spray, in 1995.

The US market is of particular interest for two reasons. First, while the market is primarily restricted to prescription status, direct advertising to consumers is permitted, even though this advertising has not met with American Medical Association approval. This advertising campaign paid a handsome dividend and patches saw an explosion in sales in early 1992 (see Table 3.5, below). Second, the market suffered a downturn in sales from 1992 (Sloan, 1992) as a result of three factors:
1) The two principal companies experienced supply shortages.

2) The FDA expressed concern at the rate of heart attacks among those who continued to smoke while wearing the patch (Warner, 1992).

3) The anticipated drop in sales during the summer resulted in a drop in advertising expenditure and decreased distribution and availability. However the drop in sales demand did not occur so that many potential quitters were unable to acquire the NRT they needed and in the product waned. Subsequent efforts to revive the market failed.

With the success of nicotine gum as an OTC in many other countries, SmithKline Beecham, who took over the marketing of Nicorette, approached the FDA in December 1994 with a view to switching Nicorette to OTC status. This was granted on April 19th, 1996 and was followed by a huge increase in marketing spend of US $50 million, with the intention of realising US $330 million in sales (Mehegan, 1996). Subsequently, Nicoderm and Nicotrol, both patches, were switched to OTC status in the US fuelling even further advertising expenditure.
Table 3.5 US Smoking Cessation Market & Media Expenditure.

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales US $ Million</th>
<th>% Change</th>
<th>Media Expenditure US $ Million</th>
</tr>
</thead>
<tbody>
<tr>
<td>1989</td>
<td>79.5</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>1990</td>
<td>81.5</td>
<td>2.0%</td>
<td>-</td>
</tr>
<tr>
<td>1991</td>
<td>123.5</td>
<td>51.5%</td>
<td>-</td>
</tr>
<tr>
<td>1992</td>
<td>670</td>
<td>531.5%</td>
<td>86.7</td>
</tr>
<tr>
<td>1993</td>
<td>350</td>
<td>(47.8%)</td>
<td>371.1</td>
</tr>
<tr>
<td>1994 (e)</td>
<td>200</td>
<td>(42.8%)</td>
<td>3.4</td>
</tr>
</tbody>
</table>


3.8 Clinical Support and the Benefits of NRT.

The results of clinical trials have been used to support the launch of various versions of NRT (see table 3.3 above). Support has also come from a growing body of literature. For example, the nicotine patch has been found to be more effective for smokers with moderate rather than heavy nicotine dependence, and for younger smokers (Yudkin, Jones, Lancaster, and Fowler, 1996). These findings are further developed by a study of the characteristics of nicotine patch users in the USA. A survey of those refilling prescriptions for the patch showed the influence of media campaigns with 36 percent learning about the patch in this manner, 32 percent from family and friends and 25 percent from doctors. Over half tested with the FTQ were not heavily dependent smokers. Most of the respondents (87 percent) had requested the patch themselves, with only nine percent asked by their doctor to do so (Haxby, Sinclair, Eiff, McQueen, and Toffler, 1994). These findings would seem to support the switch away from
prescription by doctors to OTC status. However a note of caution has been sounded by Fiscella and Franks (1996) who, arguing on a purely cost effective basis, maintain that the costs of prescription and medical advice are more than compensated for by the higher cessation outcomes they produce. In this light they feel that these prescription and medical costs should be covered by health insurance, whether state or private. Unfortunately for them, these views have been overtaken by events.

Nicotine gum has been found to tackle many of the psychological needs satisfied by smoking such as stress modulation, feelings of arousal/pleasure, and hand/mouth activity (Parrott, and Craig, 1995). A major concern when quitting smoking is gaining weight, often as a result of the absence of nicotine and the subsequent increase in appetite; nicotine gum has been demonstrated to suppress weight gain in female users (Leischow et al., 1992).

The Rx versus OTC debate has been conducted in other fora besides the medical world. For example, regulatory bodies in many countries have supported the introduction of NRT, as an OTC, on the basis of its proven efficacy record. In the US it was predicted that, given the current rate of smoking, the switch to OTC status would result in 450,000 additional smokers quitting (Oster, Delea, Huse, Regan, and Colditz, 1996). Indeed the elimination of many of the adverse side-effects of nicotine patches through education and product refinement has lent further support to the switch campaign.
3.9 NRT as an OTC and Smoking Cessation in Ireland.

The core benefit of nicotine replacement therapy is the actual delivery of lower levels of nicotine to tackle the craving; there is little or no pharmacological difference between brands. However all the brands available provide a varied range of support material to aid cessation attempts. In-pack leaflets, audio and video cassettes, free-phone help-lines, and the provision of practical guides to stop or avoid smoking are used. Also heavy advertising on TV and the national press is utilised, focusing on the key quitting times of New Year, Lent, and National No Smoking Day.

Since nicotine gum secured OTC status in 1993, promotion with and within pharmacies has increased. Point-of-sale material and leaflets are prominently displayed alongside packs and the Pharmaceutical Society of Ireland has begun conducting training courses on smoking cessation for pharmacists. This is in addition to NRT manufacturers providing training courses for pharmacists and pharmacy assistants on how to counsel customers on the use of NRT.

Smoking behaviour in Ireland has been tracked annually by Irish Marketing Surveys, on behalf of Pharmacia & Upjohn the distributors of Nicorette. This longitudinal study measures the numbers smoking, attitudes held towards smoking and motivations behind quitting among a representative sample of adults aged 15 and over. Latest results show 30 percent of the population smoke (i.e. 800,000 people), with 17 percent smoking more than 15 a day, and 13 percent smoking less than 15 per day.
In total 21 percent of the population have quit smoking completely. The key issues mentioned as reasons for smokers giving up were 1) to improve health (79% of all smokers), 2) to save money (50%), 3) for my family/partner/children's health (22%), and 4) for social reasons (19%). However the numbers of current smokers who have tried to quit in recent time is diminishing. Table 3.6 illustrates the steady increase in the number of smokers not attempting to quit. Of those smoking in 1993, 48% had not tried to quit in the previous four years; three years later, in 1996, this figure had risen to 54%. Key reasons given by smokers as obstacles to giving up were 1) the craving for a cigarette (26% of all smokers), 2) addiction (19%), 3) irritable/cranky (17%), and 4) can't operate properly without cigarettes (14%).

When pushed for detail regarding the likely time frame within which smokers would consider quitting, 11 percent suggested quitting in the next three months, a further 11 percent in the next six months, 15 percent within the next year, and six percent within two years. Of those actually intending to quit, 37 percent hoped to do so in six months, but a corresponding number saw the time frame extending up to two years or longer, again supporting the view that there is a core group of heavy smokers resisting any persuasion to quit in the short time.

Table 3.6. Attempts to Give Up Smoking - Past Four Years.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Have not tried to stop</td>
<td>48%</td>
<td>48%</td>
<td>50%</td>
<td>54%</td>
</tr>
<tr>
<td>Tried once</td>
<td>17%</td>
<td>20%</td>
<td>15%</td>
<td>16%</td>
</tr>
<tr>
<td>Tried twice</td>
<td>13%</td>
<td>15%</td>
<td>16%</td>
<td>14%</td>
</tr>
<tr>
<td>Tried three or more</td>
<td>22%</td>
<td>17%</td>
<td>19%</td>
<td>16%</td>
</tr>
</tbody>
</table>

Source: Irish Marketing Surveys, 1996.
It is estimated by industry sources\(^3\) that 14 percent of the smoking population would have used or would consider using NRT to quit smoking. The majority of these aged 30 plus in the A, B, C1 social categories. The profile may be due to the relatively high cost of using NRT. This represents a potential market of 112,000 users. While it is difficult to ascertain the impact of the OTC status of nicotine gum and patches on the pattern of smoking cessation, indications are that sales of NRT are rising.

Clearly OTCs are becoming increasingly important in the context of health care yet little research has been conducted on this area. Given the existence of many heavy smokers resisting attempts to quit, it is vital to increase our understanding of the role NRT, as an OTC, can play in smoking cessation. The following chapter details a methodology designed to uncover the meanings consumers hold in relation to their use of NRT, as an OTC.

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\(^3\) Corroborated figures from two senior industry sources.
Chapter Four.

Research Methodology.

4.1 Introduction

The use of NRT as an OTC has been demonstrated to belong to the consumers' domain, rather than to the domain of the health care system. Also, the decision to stop smoking appears to be very individualistic in nature. Therefore the methodology chosen for the study must reflect these two issues, placing the individual at the centre of any inquiry.

This chapter details the approach to, and use of existential-phenomenology as a paradigm and methodology to uncover consumers' experience when using NRT. Existential-phenomenology is presented in the wider context of interpretive approaches to seeking knowledge and proposed as the most suitable for this study. The chapter incorporates two main elements. First, the discussion incorporates many philosophical issues central to understanding existential-phenomenology. Such philosophical issues underpin the paradigm and also closely relate to the hermeneutical techniques used to analyse respondents' experiences. The philosophical issues regarding hermeneutics are dealt with in a later section.

Second, at the methodological level, the precise nature of the phenomenological interview is discussed, incorporating the requirements of correct interviewing techniques from the wider qualitative literature. The generation of the data and
its analysis to uncover themes with the aid of both hermeneutics and the interpretive group is described. Finally, the source of the respondents and the method of recording the respondents' experiences are listed, as are the criteria used to evaluate the chosen methodology.

Central to any methodology is the underlying paradigm; 'the set of beliefs that lead to ways of approaching inquiry' (Erlandson, Harris, Skipper, and Allen, 1993, p, ix). A paradigm incorporates axiological, ontological, and epistemological assumptions about the nature of reality and inquiry, and the knowledge generated. Much time and effort has been expended by consumer researchers demarcating or defending interpretive methods against the traditional positivistic standpoint. Any paradigm, while benefiting from the scrutiny and criticism of others, must stand alone, and therefore it is not necessary to review such literature here. However a brief outline of the interpretivist approach follows more to contextualise the chosen methodology, demonstrating its suitability for this research, than to position it as being superior to any other paradigm (Hudson and Ozanne, 1988).

The choice of a paradigm is principally concerned with the researcher's worldview as outlined above. However it is important in choosing a paradigm to reflect on two other points; the nature of the problem and the audience the research is aimed at (Creswell, 1994). What is evident from the previous review of the literature on health behaviour is a lack of focus on the consumer as the central point of their own health care and on the meanings that consumers hold in relation to their preventive health behaviour. Given the fundamental
importance of health in our lives, it is ironic that the scientific, technological imperative (Fuchs, 1968) has persisted for so long in health research. This may not be surprising given the traditional provider-patient relationships that persist but the current emergence of self-care and a more autonomous consumer highlights the need for research to adopt a greater consumer orientation.

4.2 The Interpretivist Approach To Consumer Research.

In this study, the terms interpretive or interpretivist refer to those paradigms at the opposite end of the spectrum to the traditional positivistic paradigm. As interpretive approaches require a fundamental shift in thinking for most researchers, it is important to highlight a number of issues in relation to the adoption of such an interpretive approach.

1. First, most commentators see an interpretive approach as being ‘incommensurable with the conventional [positivistic] inquiry’ (Erlandson et al., 1993, p. x). Elizabeth Hirschman, supports this view with an analogy of the futility of merging Buddhism with Mohammedanism based on the divergence in their fundamental beliefs (Hirschman, 1986). While this lack of ‘fit’ between the two is generally supported, some commentators wrongly pursue this argument to the level of methodologies employed. For example, Creswell (1994) goes as far as designating quantitative and qualitative methodologies as belonging to separate paradigms. He equates quantitative methodologies with traditional, positivist, experimental, or empiricist studies and qualitative methodologies with constructivist, naturalistic, interpretive, postpositivist, or postmodern studies.
It is important to note that the category of interpretive research incorporates many distinct paradigms, often grouped together under the interpretive banner, or loosely placed alongside each other (see Sherry, Jr., 1991; Hunt, 1989). Peter and Olson (1989), in their criticism of Calder and Tybout's 1987 article 'What Consumer Research is', go as far as separating quantitative, qualitative, and interpretive approaches as distinct methods, again mixing paradigms with methodologies incorrectly.

For this study, interpretive research incorporates naturalistic and humanistic inquiry, phenomenology, hermeneutics, semiotics, and literary criticism (Murray and Ozanne, 1991), and each can be viewed as a distinct way of seeking knowledge. However, as demonstrated later, the use of a paradigm can result in using a combination of various elements of different methodologies. Interpretive research is no exception in this regard. On a further point, it would appear that many studies purporting to espouse one paradigm in fact incorporate facets of other paradigms. The reality is that not every study stands up to the ideals of paradigmatic purity, often combining different facets of other paradigms (Creswell, 1994).

This fluidity over what precisely constitutes a paradigm, what constitutes a methodology and what methodologies properly belong to what paradigm calls for some clarification.

For the purpose of this study;

a) The term interpretive research incorporates a number of individual paradigms, as outlined above, which share some broad axiological and
epistemological assumptions. However, these individual paradigms differ on some finer epistemological assumptions and the role of the researcher in the generation of knowledge.

b) Existential-phenomenology is viewed as one paradigm under the broader interpretive banner. Its application in consumer research, principally by Craig Thompson, has been described as combining the philosophy of existentialism with the methodology of phenomenology. While the particular aspects of existential-phenomenology will be dealt with in the next section, it must be viewed in the wider context of one of the interpretive approaches available.

2. The second consideration when adopting an interpretive approach is that grasping the rationale for interpretive inquiry can be difficult given the ingrained positivistic thinking that most possess as a result of the dominance of positivistic approaches in university teaching. Understanding an interpretive approach requires a substantial shift in thinking, best articulated by Erlandson et al. (1993, pp. 1):

   Most researchers treat their work as a routine exercise, following very specific rules and denying much of the human capacity for flexible thinking, the extension of which, we believe, is the basis for scientific advance and the most satisfying aspect of research.

3. The third and final consideration is that interpretive inquiry differs principally on the inclusion of the researcher as instrument and the concurrent nature of data collection and analysis; this impacts on methodology, which must be viewed as a process rather than a series of discrete steps.
It has been noted that many of the details of interpretive paradigms remain hidden, often due to editorial requirements of journals, and as such are viewed as underdeveloped in contrast with the traditional positivist paradigms. However some authors, most notably Craig J. Thompson, have elaborated on the process of conducting phenomenological research, greatly facilitating researchers who wish to utilise these methods to their fullest extent. Such authors have demystified interpretive paradigms by addressing the core assumptions openly.

The essence of Interpretivism is one of perspective; any researcher must look at the issue from the perspective of the consumers being researched (Ozanne and Hudson, 1989) with a view to enhancing understanding, rather than aiding prediction. While apparently simplistic, this perspective is the very cornerstone of consumer research. An interpretive approach stresses the difference between the humanities and the natural sciences in its quest for understanding rather than explanation or prediction (Holbrook and O’Shaughnessy, 1988).

These differences can be illustrated under three main headings. First, the physical and chemical sciences enhance their knowledge through the continued separation and division of their subject matter into precise, discrete elements. Understanding each element as a separate unit can help the scientist explain and predict the total subject. In contrast, in the humanities, knowledge can only be found when the subject matter is viewed in a holistic manner. Any division or separation of the subject matter loses the contextual aspects.

Second, in the physical and chemical sciences there is understood to be a universal, objective, decidable truth which can be isolated, whereas for
interpreтивists there is no universal truth to be found in the humanities. In fact, there are a multiplicity of truths. As there is no single objective truth or reality 'out there' to be found, this truth or reality is dependent on context, and exists rooted in the individual's view of the world.

Third, the knowledge that is generated in the humanities is co-constituted, based on the interaction between researcher and consumer. As consumer researchers, we generate understanding based on the contextual reality of the consumer in an interactive way; we are part of the generation of this understanding, not separate from or above it. Table 4.1 summarises the interpretivist approach and contrasts it with the traditional positivist approach.
Table 4.1 A Summary of the Positivist and Interpretivist Approaches.

<table>
<thead>
<tr>
<th>Basic Assumptions</th>
<th>Interpretivist</th>
<th>Positivist</th>
</tr>
</thead>
<tbody>
<tr>
<td>Axiological - overriding goal.</td>
<td>Understanding.</td>
<td>Explanation via subsumption</td>
</tr>
<tr>
<td></td>
<td></td>
<td>under general laws, prediction.</td>
</tr>
<tr>
<td>Ontological - nature of reality.</td>
<td>Socially constructed, multiple, holistic, contextual.</td>
<td>Objective, tangible, single, fragmentable, divisible.</td>
</tr>
<tr>
<td>Epistemological - knowledge generated.</td>
<td>Idiographic, time-bound, context dependent.</td>
<td>Nomothetic, time-free, context independent.</td>
</tr>
<tr>
<td>Epistemological - view of causality.</td>
<td>Multiple, simultaneous shaping.</td>
<td>Real causes exist.</td>
</tr>
<tr>
<td>Epistemological - research relationship</td>
<td>Interactive, co-operative, no privileged point of observation.</td>
<td>Dualism, separation, privileged point of observation.</td>
</tr>
</tbody>
</table>

Source: Ozanne and Hudson, 1989, pp. 3.

Interpretation can be defined as 'the critical analysis of a text for the purpose of determining its single or multiple meaning(s)' (Holbrook and O'Shaughnessy, 1988, pp. 400). We live our lives within a social system embedded with shared symbols, signs, and language that create meaning and identity for each of us. As highlighted by Holbrook and O'Shaughnessy, what we strive to gain as knowledge are 'facts-only-as-interpreted, that is data as socially, linguistically, or personally constructed' (Holbrook and O'Shaughnessy, 1988). This means that what can be gained as knowledge comes from the context we live in; whether that is the research culture or the view we have of the world. It is not possible to approach data in some context-free way.
4.3 Existential-Phenomenology as a Paradigm and Methodology.

Existential-phenomenology draws from the philosophy of existentialism and the methodology of phenomenology, incorporating hermeneutical analysis to gain a first-person description of experience in relation to a chosen phenomenon (Thompson, Locander, and Pollio, 1989). Clearly this incorporates a wide scope of philosophical issues and methodological details and each will be examined separately, with a detailed explanation of the role of hermeneutics. The first objective is to 'place' existential-phenomenology in the context of the range of interpretive approaches often utilised by consumer researchers.

A particularly useful map can be seen in Table 4.2, where the range of philosophical positions on the origins of knowledge available to consumer researchers is positioned according to the degree of reliance on either mental or material determinism. One’s position on this epistemological question is contingent upon one’s ontological position on the nature of reality.

This table places both phenomenology and existentialism in the category of subjectivism, recognising that how we understand the world and the knowledge we have resides within the individual. While not exclusively determined by mental or cognitive structures, subjectivism is primarily concerned with the role that mental or cognitive structures rather than social or cultural forces play in how an individual understands the world; essentially a subjective view. These mental structures, such as our perceptions of our experience and the views and attitudes we form as a result, are seen as the source of knowledge on a particular research question. While a number of individuals can have the same experiences,
it is how we understand them mentally, and how we recount or describe these, that differ with each individual. For example, in this study of smoking cessation, two respondents could have the same superficial experience of using NRT. Both respondents could use NRT in an identical manner and achieve the same result. However, it is the experience as they understand it themselves, demonstrated by describing their experience during an interview, which will differ. One respondent may relay their experience of using NRT as a medicinal therapy that helped them quit smoking; another may describe their experience of using NRT as a substitute for cigarettes; the reality of NRT is individually constructed through their respective experiences.

Table 4.2 A Continuum of Philosophical Positions on the Origin of Knowledge

<table>
<thead>
<tr>
<th>Philosophy</th>
<th>View of Reality</th>
<th>Determinism</th>
</tr>
</thead>
<tbody>
<tr>
<td>Empiricism (Common-sense/Logical Empiricism)</td>
<td>Physical Construction of Reality (PCR)</td>
<td>Material Determinism.</td>
</tr>
<tr>
<td>Socio-economic Constructionism (Marxism)</td>
<td>Social Construction of Reality (SCR)</td>
<td></td>
</tr>
<tr>
<td>Interpretivism (Hermeneutics, Semiotics, Structural Criticism)</td>
<td>Linguistic Construction of Reality (LCR)</td>
<td></td>
</tr>
<tr>
<td>Subjectivism (Phenomenology, Existentialism)</td>
<td>Individual Construction of Reality (ICR)</td>
<td></td>
</tr>
<tr>
<td>Rationalism (Ideals, Innate ideas)</td>
<td>Mental Construction of Reality (MCR)</td>
<td>Mental Determinism</td>
</tr>
</tbody>
</table>

Source: Adopted from Hirschman and Holbrook, 1992.
Such a position on the understanding of where knowledge resides contrasts with the empirical position, which takes the view that there is a single, decidable reality to be sought. At the other end of the scale is rationalism, which posits that we understand the world based only on our pre-existing mental categories, which are then used to understand our experience.

Phenomenology began as a movement in contemporary philosophy, originally termed descriptive psychology and was developed by Edmund Husserl. The central aim of phenomenology was to enhance empirical scientific study through viewing the core characteristics of any subject matter for study and target these characteristics through a correctly focused methodology (Churchill and Wertz, 1985). While this appears somewhat self-evident and positivistic in intent, phenomenologists argued that human beings were a different kind of object from physical and animal nature and needed an approach that would reflect this. Dilthey summarised this position as; ‘we explain nature; we understand psychological life’ (Dilthey, in Churchill and Wertz, 1985).

Phenomenology attempts to understand how individuals interact with objects in their environment and the knowledge structures that are created as a result of this interaction. The philosophical basis for this view came from the belief that the only real source of knowledge, for an individual or a researcher, was self-knowledge. The only true source of knowledge was what we could acknowledge ourselves in our own mind; knowledge that we could be certain of. Therefore Husserl put forward the notion of ‘certainty of consciousness’. While this reflects that the source of knowledge resides in an individual’s mind,
phenomenology believed that knowledge was a result of the interaction between our mind and our experiences. For example, what we understand to be a particular tree is made up of our mental understanding (based on memory, image, and meaning to date) as to what a tree is and what we actually experience in reality, the outward appearance. In the case of this study of smoking cessation, the knowledge that will be generated is based on the description of the respondents' experiences of using NRT. Each description will reflect how the experience of the respondent is shaped by the way they view the world and how the experience in turn shapes this view.

One further point on the phenomenological view of knowledge is significant. Husserl believed that the way in which an individual understood the world could be reduced to an essential invariant structure; an 'essence'. It was through the rigorous phenomenological analysis or phenomenological reduction that we could isolate the central underlying meaning of an experience. The detachment that was possible from using such methodological rigour meant that the researcher could determine a single, fixed meaning of an experience.

Existentialism as developed by Heidegger, while an extension of phenomenology, with an understanding that the source of knowledge was essentially the same, differed on its belief regarding the nature of the knowledge generated. Phenomenologists believed experience could be reduced to the essence or essential meaning; understanding could be distilled through the process of interpretation. Heidegger rejected this idea that a privileged essence could be found or isolated. He described knowledge as being situated in our
everyday life; the Dasein (‘being there’). As a result our knowledge or how we understand the world was viewed as ever changing. In the same vein, what we could interpret from the experience of an individual was not fixed or invariant, but dependent on our own changing knowledge. The researcher changes through the experience of researching a phenomenon. Such a highly individualistic, ever-changing view of knowledge may appear impractical and too open-ended for a researcher to grasp but this is clearly rejected by MacQuarrie (1972, p. 78):

The fact that man is unfinished ... does not mean that a description is impossible ... [or] that we are confronted with a formless and indescribable multiplicity, for there are limits or horizons within which all these unique existents fall, and there are structures that can be discerned in all of them.

This point is crucial to understanding the practical issues of such a position on knowledge for research. While knowledge, and experience, is viewed as being individualistic, these individual constructions of reality can be grouped or clustered together to create themes of meaning common to all those respondents in a research study.

The basis for this study revolves around Craig Thompson’s use of existential-phenomenology in the area of consumer research. Thompson and others have argued that consumer experience has been largely ignored in the more behavioural/cognitive orientation of much research and that most methodologies do not facilitate the exploration of experience (Thompson, Locander, and Pollio, 1994; Thompson, et al., 1990). In contrast, existential-phenomenology does
provide a way to explore consumer experience through first-person description of lived experience. To explain how the individual’s experience is embedded in a context or pattern, the core assumption of existential-phenomenology, Thompson uses three analogies of Gestalt psychology. These are the Pattern Analogy, the Figure/Ground Analogy, and the Seeing Analogy.

The pattern refers to the view that the individual and their environment form a totality, rather than being separate. This contextualist view examines experience as it occurs in a context; essentially as it is lived, described as human-being-in-the-world (Thompson et al., 1989), the life-world, or Lebenswelt. It is not possible to view experience in an objective, detached way removed from any context. The meaning of an experience is always situated in the current experiential context and is coherently related to the ongoing project of the life-world (Sartre, in Thompson et al., 1989). This means that the experience reflects how the individual sees themselves, not merely retelling a story of an experience.

The figure/ground metaphor reflects the interplay between individuals and their environment. Each will affect the experience, allowing for differing experiences in different situations. Neither can be separated, or viewed as causing each other; they are co-constituting. The experience is not located inside the person, as a subjective reality, nor located outside, as a subject-free objectivity.

The seeing metaphor differentiates human experience as both reflected and unreflected. Many of our actions, and therefore experiences, are unreflected; we make decisions without pausing to detach ourselves and reflect on our actions. Existential-phenomenology recognises that our unreflected actions can, through
the process of the phenomenological interview, yield meanings or patterns that emerge on reflection. This link between reflected and unreflected experience can be compared to the figure/ground metaphor, with unreflected experience, the ‘ground’, emerging into prominence through the interview to become ‘figure’.

A summary of the existential-phenomenological approach is given in Table 4.3 below, and is compared to Cartesianism or Rationalist philosophy, viewed as a broader set of assumptions that underlies the positivist approach (Thompson et al., 1989).

Table 4.3 Two Approaches to Consumer Research

<table>
<thead>
<tr>
<th>Tenets of paradigm</th>
<th>Existential-phenomenology</th>
<th>Cartesianism</th>
</tr>
</thead>
<tbody>
<tr>
<td>World view</td>
<td>Contextual</td>
<td>Mechanistic</td>
</tr>
<tr>
<td>Nature-of-being</td>
<td>In-the-world</td>
<td>Dualistic</td>
</tr>
<tr>
<td>Research focus</td>
<td>Experience</td>
<td>Theoretical structure</td>
</tr>
<tr>
<td>Research perspective</td>
<td>First-person</td>
<td>Third-person</td>
</tr>
<tr>
<td>Research logic</td>
<td>Apodictic</td>
<td>Predictive</td>
</tr>
<tr>
<td>Research strategy</td>
<td>Holistic</td>
<td>Componential</td>
</tr>
<tr>
<td>Research goal</td>
<td>Thematic description</td>
<td>Causal Reductionism</td>
</tr>
</tbody>
</table>

Source: Thompson et al., 1989, pp. 137.

In summary, the tenets of existential-phenomenology clearly fit with the broad axiological, ontological, and epistemological assumptions of interpretivist inquiry as outlined above but can be differentiated by their focus on the individual and the role that experience plays in generating knowledge. Existential-phenomenology principally, although not exclusively, utilises the phenomenological interview to gain the first-person description of the experience. Such a phenomenological interview goes beyond the typical in-depth interview used in qualitative research. While a phenomenological interview
adopts a similar open-ended, loose approach to ‘data generation’ as an in-depth interview, the phenomenological interview aims to uncover what an experience means to a respondent, rather than attempt to predict or explain the experience. As a result, the nature of questioning is different. The role of the researcher is to provide a context for the respondent to describe their experience. In addition, the principle is avoid asking ‘why’ questions to prevent a respondent rationalising their actions rather than describing their experience.

4.4 Evaluative Criteria for Existential-Phenomenology.

A key question for any researcher, in addition to gaining an understanding of a phenomenon, is assessing whether the study is accurate, right, or conducted to a reasonable standard. While clearly an emerging and complex question (Lincoln, 1995), there has been a range of possible criteria put forward as evaluative standards for qualitative research. Some of these criteria for qualitative research utilise traditional positivistic terminology. It must be noted that there is some division amongst commentators regarding the use of such quantitative or positivistic terminology for qualitative research. Some argue that using quantitative terms suggests that all research is essentially positivistic whatever it may claim for itself (LeCompte and Goetz, 1982). Others, notably Thompson, have confidently adapted such traditional terms to interpretive methods without conceding that their subject matter is compromised in any fashion. Still others have taken this debate further, arguing in a postmodern vein, that such conventional terms as ‘validity’ and ‘reliability’ are unsuitable and out of
hand, not so much because of their positivistic connotation but because their rigid, two dimensional character renders them inherently unsuitable for gauging the quality of multi-faceted consumer research. For example, Richardson’s (1994) metaphor of the crystal makes this point to considerable effect (p. 522);

What we see depends on our angle of repose ... Crystallisation, without losing structure, deconstructs the traditional idea of “validity”; and crystallisation provides us with a deepened, complex, thoroughly partial understanding of the topic. Paradoxically, we know more and doubt what we know.

Lincoln and Guba (1985) have reconceptualised positivistic researchers’ four key criteria - internal and external validity, reliability, and objectivity. These terms have been used as a broad template in the development of evaluative criteria for interpretive research and are now termed credibility, transferability, dependability, and confirmability. While these have been specifically applied to humanistic inquiry (Hirschman, 1986, Erlandson et al., 1993), it can be argued that, in fact, they represent evaluative criteria for all interpretive research.

Naturalistic researchers, like existential-phenomenological researchers, do not aim to remove themselves from the process of inquiry but aim to show that the data ‘can be tracked to their sources, and that the logic used to assemble the interpretations into structurally coherent and corroborating wholes is both explicit and implicit’ (Guba and Lincoln, 1989, pp. 243).

In the particular case of existential-phenomenology, Thompson has argued that many of the concerns of existential-phenomenologists concerning their methods
are shared in common with positivistic researchers concerning their methods. He concludes that the broad evaluative criteria for positivism can be seen as ‘reasonable standards for Existential-phenomenological research’ (Thompson et al., 1989, p. 142). That is, the research should be free of personal bias; others should be able to agree that the conclusions are justified by the data and are empirically based, and that criteria are provided to evaluate competing interpretations.

In summary, while there is some contention over the use of evaluative criteria, it is apparent that such criteria help increase the rigour of a chosen method and should be assessed within rather than across different paradigms and methodologies. The particular evaluative criteria of credibility, transferability, dependability, and confirmability and techniques used to meet these criteria will be discussed in relation to the present study at the conclusion of this chapter.

4.5 The Phenomenological Interview

This section outlines the format, methods, and approaches adopted for the phenomenological interview, and incorporates guidelines for effective interviewing drawn from the wider literature on qualitative interviewing. Specifically it addresses the areas to be ‘covered’ for this study.

Two points need to be highlighted at this stage. While this section deals with data collection and the following section focuses on data analysis, each must be viewed as happening concurrently. As a result, neither one occurs in isolation and the actual design of the study is emergent. Lincoln and Guba (1985, pp. 226)
demonstrate this point in their definition of naturalistic design. It 'means planning for certain broad contingencies without, however, indicating exactly what will be done in relation to each'.

While existential-phenomenology does not rely solely on interviews, it does view them as probably the most powerful method of gaining first-person description of experience (Thompson et al., 1989). Equality between interviewer and respondent is crucial to the success of any interview; the interview should be in the form of a conversation with a structure and purpose (Kvale, 1996), an inter-change of views between two people. The use by Kvale of the gestalt figure/ground drawing of two faces/vase on the cover of his published text is a good metaphor for the interview and perfectly articulates the contextual principle of the phenomenological interview. By definition, the co-construction of the interview by both participants requires a sense of equality, where the researcher avoids adopting a superior stance or a domineering role as instanced in Douglas' (1985) doctor/patient analogy.

Essential steps to be taken throughout the interview can be grouped into three categories. First, before the interview, preparation should include deciding on the level of formality in relation to dress; the general approach recommends underdressing (Douglas, 1985). Also the respondent should know in advance about the general area to be explored and the general purpose of the research. Other key steps are assuring anonymity, explaining what will be done with the data, and confirming the time, date, and place for the interview with the respondent.
Next, beginning the interview, it is necessary to reiterate the purpose of the interview; the objective is to put the respondent at ease. At this point it is recommended that the respondent should be told that the interview will be audiotaped but to refrain from starting to record for five to ten minutes, using general chat to build bridges with the respondent (Douglas, 1985).

As the main aim is to gain a first-person description of the phenomenon or experience, the phenomenological dialogue is in the hands of the respondent. Apart from the initial opening question(s), the interviewer has no *a priori* questions. Such opening questions should be designed to put the respondent at ease and can be termed ‘grand tour’ questions. Grand tour questions also help to demonstrate how the respondent construes the general characteristic of the issue to be explored (Lincoln and Guba, 1985). Douglas (1985) describes this process as the sales pitch, stressing to respondents that they are the experts. The questions themselves are designed to get the respondent to relay their experience, not to explain or think in abstract terms or answer a question per se. Descriptive questions, such as ‘tell me what you were feeling when you bought nicotine gum’ aim to get the respondent to recount the experience, and are described as prompts. Prompts are used by the researcher to ‘nudge’ the respondent and should be free of theoretical language, ideally using the respondent’s type of language, identified during the course of the interview.

The prompts to be used in this study can be grouped into five broad areas:

1. Health information acquisition - ‘Tell me, where did you hear about nicotine gum/patches’. 
2. Preventive health behaviour - 'Tell me about your health, are you doing anything to improve your health at present?'

3. Health professional interaction - 'Tell me about the time you went to the doctor/pharmacist to quit smoking/buy nicotine gum/patches'.

4. The usage of NRT - 'Tell me how it feels to use nicotine gum/patches'.

5. The use of OTCs or other medicines - 'Do you use OTC medicines regularly, what do you think of the idea of them being available without prescription?'

The third and final step, is to bring closure to the interview, allowing the respondent to clarify or add to what has emerged and allow the interviewer to review and summarise what has emerged (Erlandson et al., 1993). At this point it is recommended to keep the dialogue open suggesting that, should the respondent subsequently remember something they feel would be valuable, they can contact the researcher. The researcher should ask if the respondent knows of anyone else they feel would be of value to the particular research. Finally, the respondent should be thanked for their time and thoughts.

4.6 Interpretation of the Phenomenological Interview.

The aim of interpretation is to uncover themes or patterns from the respondents' experience which capture the meanings they associate with the role of NRT. The interpretation of the phenomenological interviews is based on the practice of hermeneutics, the hermeneutical circle, and the use of an interpretive group to be discussed below. The central issue for any phenomenological interpretation is that it remains at the level of first-person experience, and not abstracted to some
higher theoretical level. To achieve this, all interviews are transcribed verbatim, becoming the texts from which the interpretations will be drawn. Three methodological principles are used in existential-phenomenology; an emic approach, the belief in the autonomy of the text, and the principle of bracketing—all aimed at ensuring that abstraction does not occur (Thompson, et al. 1989).

The Emic Approach.

The emic approach involves the researcher using the respondent’s own terms and category systems as they appear in an interview. The primary reason for utilising verbatim transcriptions is to ensure that the experiences of the respondents are relayed as lived, rather than abstracted into conceptual terms. For example, if the respondent states that the benefit of NRT as an OTC was easy availability, a researcher’s tendency may be to explain this in terms of theories of distribution. By remaining at the respondent’s level this tendency to move to abstraction should be reduced. It is essential to take the wider view and uncover what this type of statement means from the respondent’s viewpoint through the entire interview. For example, it may be that the respondent feels that easy availability reflects their desire to avoid contact with health professionals. Therefore it is the respondent’s category system, not the researcher’s, which is vital (Kvale, 1983).

Autonomy of the text.

The text of the interview becomes autonomous in two ways. First, there is no attempt to verify or check that the content of the interview is ‘true’. For example, suppose a respondent reports that ‘deciding to stop smoking was because I only
wanted to save money', and this claim is clearly seen not to be the case. The
seeming lack of veracity should not lead to the statement being dismissed out of
hand. Rather, the lack of correspondence between claim and behaviour is an
integral part of the text. Secondly, autonomy is designed to prevent ‘reading
into’ the interpretation. For example, if a respondent mentions that ‘I quit
smoking for my family’, this does not entitle the researcher to infer that partner
or child pressure was exerted. Only if such evidence exists elsewhere in the text
of the interview can such links be made (further issues regarding autonomy of
the text are discussed in the section on hermeneutics).

Bracketing.

The final principle for existential-phenomenology, bracketing (or
phenomenological reduction), involves holding back any preconceived notions
or pre-understandings about the research topic that the researcher possesses.
Apart from the obvious practical difficulty in trying to set aside or remove the
theoretical understandings, there is some philosophical conflict on this aspect.
Phenomenology, in its earlier form, believed that pre-understandings could be
put aside through methodological rigor, whereas the later existentialists accepted
that knowledge resided in a much wider context, so pre-understandings could not
be bracketed or removed. This polarisation also appeared in hermeneutic
thinking and is detailed below. The concept of bracketing has been taken much
further by other paradigms, such as humanistic inquiry (Hirschman, 1988). Some
humanistic researchers attempt to extract any pre-understandings through a range
of techniques such as member checks and reflexive journals; such measures appear to indicate a move away from the co-construction of data.

In the case of existential-phenomenology, bracketing does not suggest that the rich source of knowledge about the phenomenon held by the researcher is not utilised in interpretation or that some bias-free positivistic stance is being adopted. Existential-phenomenology, in line with hermeneutics, does not advocate a neutral approach to research - the researcher in the interview has some pre-existing perspective on the phenomenon being researched. Bracketing is used to ensure that text is treated from the viewpoint of the first-person description, not abstracted and that room is given for the themes and meanings to emerge in the context (pattern) of the text, rather than being imposed or forced by the researcher (Thompson, 1993). Staying with the respondent’s terms and categories and avoiding the tendency to apply conceptual ideas, however relevant they may seem, are practical applications of bracketing. It should be approached as a paradigmatic aspiration rather than an essential criterion. In general existential-phenomenology is not as stringent as say humanistic research in that it does not require researchers to list and continuously monitor their pre-judgements over the course of the research. The applications of these methodological principles to this study are reviewed in chapter five.
4.7 Hermeneutics, the Hermeneutical Circle, and the Interpretive Group.

Hermeneutics, developed from the practice of studying religious texts to understand their divine meaning, is widely used as a theory of textual interpretation and has been adopted as a general method by the human/social sciences. As such, it is a theory of the interpretation of meaning and understanding. Its most significant aspect is the recognition that individual parts of the text must be interpreted in the context of the whole text (Arnold and Fischer, 1994), described as a part-to-whole method of interpretation (Bleicher, 1980).

The philosophical development of hermeneutics mirrors the progress of much of the thinking by consumer researchers, beginning with hermeneutic theory which held a Cartesian view of the world being objective and rational. Hermeneutic theory held that it was possible to find the objective meaning of a text through rigorous adherence to a series of interpretive steps. Subsequently the move from hermeneutic theory to philosophical hermeneutics, as put forward by Heidegger above, led to a more subjective view the interpretation process. It entailed more than the discovery of the meaning of a text. Interpretations were not a 'decidable' or objective recognition of the author's intended meaning, but rather a process where the interpreter's knowledge resulting from the understanding of a phenomenon goes beyond the phenomenon in question. The researcher is not simply the recipient of further knowledge but is changed; his/her interpretive frameworks are altered.
The next phase in the development of hermeneutics was the development of critical hermeneutics, which sought to purge pre-understandings through the use of various analytical methods. Pre-understandings were seen as perpetuating power interests and therefore as obstacles to be removed. Critical theory, feminist and Marxists theory have utilised critical hermeneutics.

Such wide and varied evolution has led hermeneutics to have ‘all the trappings of a Russian novel’ (Thompson, 1996, p. 391), incorporating Husserlian phenomenology, Gestalt psychology, and structural semiotics. Most recently phenomenological hermeneutics positions itself as incorporating aspects of hermeneutic theory, philosophical hermeneutics, and critical hermeneutics (Bleicher, 1980). Its main proponent is Paul Ricoeur who viewed it as the linking of the hermeneutic problem to the phenomenological method, described as ‘recapturing of an objective sense of the text and an existential appropriation of its meaning into understanding’ (Arnold and Fischer, 1994, pp. 56). This two-stage process, the central feature of phenomenological hermeneutics, recognises that a grasp of the meaning of the text is initially achieved, and is followed by incorporating these meanings into the researcher’s understanding. This has been described as a ‘fusion of horizons’ (Arnold and Fischer, 1994, pp. 63) between the text, representing the understandings of the respondents, and the researcher’s pre-understandings. As a horizon, it is never a fixed point, but is only limited to what we can ‘see’ at any one time. The horizon constantly changes when the researcher fuses their own pre-understanding with the understanding gained from the interpretation.
Thompson also argues that hermeneutics helps to place the voice of the consumer centre-stage, clearly facilitating the use of first-person description of experience to aid understanding. It is important to approach these consumption stories as a narrative form, where the consumer's stories confer a meaningful order onto an experience, through the selective retelling of experience in the interview, as described by Robinson and Hawpe (in Thompson, 1997, p.439):

Experience does not automatically assume a narrative form. Rather, it is reflecting on experience that we construct stories. The stories we make are accounts, attempts to explain and understand experience.

There are five key aspects evident in the hermeneutic view of consumers' experience as consumption stories, (Thompson, 1997):

1) Events and characters are structured by plot lines.

2) Symbolic parallels are found across different events and actions.

3) Consumers' meanings of different consumption stories become integrated in their story of personal history.

4) Conceptions about their own self-identity are negotiated through consumption stories.

5) Their telling of experience reflects shared cultural views and conventions.

**The Hermeneutic Circle.**

The application of hermeneutics to existential-phenomenology involves two steps. First, an understanding of the individual text is sought, relating separate parts to the whole text. Next, the separate texts are related to each other to
identify common patterns or global themes. Termed the hermeneutic circle, it is both a methodological process as well as a philosophy of how the actual process of research works. The objective of the global themes is to capture the patterns across the texts, not to provide an exhaustive description of the phenomenon (Thompson et al., 1989). Evidence for each theme must be available from individual texts, described as ‘seeing as’, in the sense that the situation or experience in one text is experientially the same as another.

While presented as a two-step process, good interpretation requires a continuous back-and-forth process within and across each text to generate a more insightful understanding. Initially a broad sense of understanding is grasped but with continuous re-interpretation, better understanding is achieved.

**The Interpretive Group.**

The use of the interpretive group or dialogic community, like-minded researchers with a willingness to commit their time and effort, plays two roles for the phenomenological researcher. First, it plays a part in managing the huge volume of data, reducing the boredom, helping the researcher ‘see the wood for the trees’ and generating a shared dynamic in the interpretation process. More importantly the interpretative group serves as a check to ensure that no member steps away from the respondent’s experience using pre-conceived theoretical notions and that any theme identified is rooted in the text.

The group also serves an important role in ‘seeing’ other’s interpretations, assessing them, and enhancing understanding. In contrast with critical
hermeneutics, existential-phenomenology aims to describe the respondents' experience thematically, searching for the 'best' interpretation, not a range of equally valid interpretations. So, again, there appears to be conflict at a fundamental level between existential-phenomenology and critical hermeneutics. However, this conflict is, in fact, a small point. Both aim to achieve a good interpretation, with critical hermeneutics believing that no single interpretation is better than another as any interpretation is driven or shaped by pre-understandings.

To this end, the interpretive group acts as a catalyst, bringing the texts into open, lively discussion. At a practical level this requires each member of the group to listen to the audiotapes, read the transcripts of each interview and meet to discuss and establish understandings and global themes. It is important to note that the back-and-forth process entails many readings and discussions of each text, not a single attempt and sufficient time must be allocated to the process. While the themes cannot be established in advance of 'data generation', it is important to establish the potential nature of the themes and the broad terrain to be explored.

These five broad topics, listed above in the section on the phenomenological interview (p.93/4), represent the thematic areas used in this study.

While the themes must be rooted in the respondents’ experience, analysis seeks to go beyond direct reportage of that experience. Cause and effect relationships, so beloved of positivistic research, are not sought, unless found in the text. Any interpretation must be free of internal contradictions, within and across texts. This is one clear example of a methodological 'black hole' in the literature; there
are few pointers as to how such contradictions are to be resolved in practice. In reality contradictions usually exist in the respondents' own experience in addition to contradictions across texts. However, the principle of insight, or achieving a good gestalt, where understanding can suddenly be seen, is suggested in the literature as one such methodological technique, to address such contradictions. In other words, a theme is suddenly seen to capture the essential meaning of the respondent's experiences, a theme that subsumes any smaller apparent contradictions.

In summary, although there are differences between existential-phenomenology and hermeneutics regarding pre-understanding and the principle of self-understanding, much commonality exists such as the link between existential-phenomenology's good gestalt and hermeneutics' fusion of horizons. Also they both rely on the contextual interaction between researcher and respondent, and the language they use to effect this interaction; the linguisticality of understanding. The relevance of hermeneutics for existential-phenomenology is best articulated by Arnold and Fischer, (1994, pp. 66)

As such, it [hermeneutics] leaves the way open for methodological innovation in the pursuit of the fusion of horizons and for paradigmatic pluralism as to what constitutes a legitimate form of expression. The method of hermeneutics is deeply democratic.

Clearly hermeneutics, as a methodological tool of analysis and a way of understanding how we understand, accepts that differing views on the nature of
reality, in the form of different paradigms, can benefit from the application of hermeneutical techniques.

The practical application of these philosophical and methodological techniques will be detailed in the following chapter. Hopefully this will give some insight about the reality of applying a range of theoretical, and sometimes aspirational, techniques gleaned from a variety of sources.

4.8 Sampling Procedure

In the context of existential-phenomenology, and most interpretive methodologies, the rule is that there is no rule for sample size. The principle of purposive sampling is to 'maximise discovery of the heterogeneous patterns' and not to generalise to the broad population (Erlandson et al., 1993). The nature of the simultaneous generation of the data and its analysis creates an emergent design and also impacts on the sampling process. The objective is to 'bottom out' on the phenomenon; continuing to research the topic until each subsequent interview provides no new dimensions on the phenomenon.

The type of respondents sought for this study were those who have used NRT to quit smoking; they included those who have purchased NRT as an OTC and others who had come to NRT via their doctor. It is important to emphasise that it was not successful quitting that was important, but the role that NRT played in the respondents' preventive health behaviour. Therefore failed as well as successful users of NRT were included. Both male and female respondents were
interviewed across a broad social spectrum and users of the nicotine patch and gum were sourced.

The sourcing of the respondents was drawn from four pharmacies in the greater Dublin area: Santry, Ringsend, Lexlip, and Balbriggan. When a potential respondent entered one of the pharmacies to purchase NRT, they were asked to participate in the study. This request was in the form of a leaflet, briefly outlining the topic for research and explaining what was required of them. If they chose to help, all they needed to do was fill in their name and phone number and hand the leaflet to any staff member. All pharmacists and their staff were briefed fully and were able to answer any queries that potential respondents raised. The pharmacists then relayed their names and contact numbers to the researcher who then followed up and interviewed the respondents.

A total of ten respondents make up the sample in this study. While there are no upper or lower limits to sample size for such a study, a sample of ten is typical, with three to ten respondents being utilised by Mick and Buhl (1992), McCracken (1988b), Thompson, (1996), and Thompson et al. (1990). As McCracken describes it ‘qualitative research does not survey the terrain, it mines it. It is, in other words, much more intensive than extensive in its objectives’ (p. 17, 1988b). The nature of the interviews are discussed in detail in chapter five but it must be noted that the interviews appeared to meet the objective of generating extensive descriptions of the respondents’ experiences. More importantly, the interpretation of the interviews ‘bottomed out’ on the topic. No
new aspects appeared in later interviews that suggested that further insights could be achieved from conducting further interviews.

4.9 Evaluative Criteria for this Study.

While the subject of evaluative criteria has been discussed in an earlier section, it is felt necessary to address the specific evaluative criteria for this study following the complete review of the many philosophical and methodological issues concerned with adopting existential-phenomenology. To reiterate, while there is some division concerning evaluative criteria for qualitative research, there is a need for some methods to verify the quality of all research, including qualitative research. Therefore, for this study, the four conventional evaluative criteria utilised in positivistic research - internal and external validity, reliability, and objectivity are adopted using the naturalistic terms of credibility, transferability, dependability, and confirmability (Lincoln and Guba, 1985).

The four evaluative criteria to be used are listed and the methods and techniques used to satisfy the evaluative criteria, drawn from existential-phenomenology and hermeneutics, are discussed.

1. Credibility. Credibility is established by determining if the results of the study reflect reality. It must be noted that what is being sought from the respondents is a reconstruction of their experiences; there is no attempt to check up on them to see if what they say corresponds with the facts. Following Thompson et al. (1989), credibility is operationalised in two ways. First, by ensuring that the themes identified by the group captured key aspects of respondents’ experiences,
in other words, a thick description of these experiences rather than an exhaustive one. Second, credibility rests on anyone viewing the results being able to identify with them and ‘see’ them as believable. This second dimension to credibility is implemented via the interpretive group, who can question any assumptions made by the researcher regarding themes by referring to the transcriptions. Ultimately this criterion is predicated on reaction to the themes in the following chapter on the part of any reader.

2. Transferability. Transferability refers to how the results of this study can be generalised to the wider population. While the sample is not ‘representative’ in the conventional sense, this does not prevent the results from being indicative of the wider population. The themes that emerge should be representative of all the respondents’ experiences and arguably could be themes that are applicable to the wider population. The objective is to understand the phenomenon, ‘to mine the territory rather than survey it’ and therefore the themes should have resonance in the wider population. The techniques used in interpretive research to ensure that themes are representative are the hermeneutic circle, which ensures that any theme generated is reflective of all the respondents’ experiences, and the autonomy of the text, which ensures that any theme can be supported by reference to the verbatim transcriptions.

3. Dependability. The criterion of dependability refers to the ability to replicate the results of the study. Replicating an interpretive inquiry should not necessarily produce a similar interpretation, but rather an improved interpretation. The knowledge and insight gained from one study should enhance any further study,
resulting in refinement and development. In this study, the generation of the data emerged in a particular way, from interview to interview, with the researcher gaining in confidence and gaining new insights into the phenomenon of smoking cessation, as well as receiving perspectives and insights from the interpretive group. If, for example, this researcher were to attempt to replicate this study, even with the same respondents, the outcomes would be different. These differences would not necessarily result in better insights, but would merely reflect new insights as a result of new understandings on the part of the researcher.

4. Confirmability. This refers to how objective a study is. This does not require that the influence of the researcher be removed from the study, but that any personal bias does not influence the generation of the themes. While personal bias on the part of the researcher is to be avoided, it is necessary to highlight the co-constitution of the interviews, where both the researcher and the respondent interplay in the generation of the data. As a result, it would appear impossible to remove the influence of the researcher or bracket pre-understandings. However, it must be noted that the key role for bracketing, or holding back pre-conceived notions about the research topic, is at the stage of interpretation, not during the interviewing stage.

The first technique used to meet the criterion of confirmability is the autonomy of the text, which ensures that any theme is rooted in the transcriptions of the interviews and is not some abstracted notion of the researcher. The second technique used is the interpretive group, who must be able to 'see' any theme.
that is generated both in the literal sense (rooted in the text) and in the figurative sense, where the theme ‘rings true’ and captures a particular aspect of the respondents’ experiences that individual members of the interpretive group may not have seen originally. The final technique used in the interpretive group setting to ensure confirmability is bracketing, where members of the group try to hold each member back from entering into conceptual abstractions on the experiences being reviewed. Although holding back any understandings one can have is difficult when trying to make sense of an interview, the primary role of bracketing is to let meanings emerge rather than impose them on the interview. For example, the tendency of this researcher, in the initial stages of interpreting the interviews, was to search for themes and meanings that conveniently slotted into the theoretical categories identified in the literature. This would have produced a restricted, predetermined analysis of the interviews. The interpretive group recognised this absence of bracketing and convinced the researcher to adopt a more open approach to the generation of the themes.

The following chapter presents the results of this study and evaluates the use of, and challenges associated with the chosen methodology and the process of interpretation using the criteria outlined above.
Chapter Five.

Interpretation of the Phenomenological Interviews: Emergent Themes.

5.1 Introduction.

In this chapter the themes that have emerged from the interpretation of the interviews are presented. The objective is to capture some of the patterns across all interviews of the role NRT, as an OTC, plays in the preventive health behaviour of those attempting to quit smoking. As a first step, a summary of the respondents interviewed is presented outlining their broad demographic characteristics, their chosen method of NRT, and the ‘result’ of using such a method. It must be reiterated that the result, in terms of success or failure, is essentially unimportant; what are critical are the meanings of the experience to the respondents.

Second, there is a review on the nature of conducting and interpreting such phenomenological interviews. The unique challenges of this interview technique are assessed in light of both the literature on this topic and the experience of this researcher. As a result of the emergent design, the evolving nature of the process led to the development of techniques and learnings by the researcher throughout the process. These were applied throughout the course of conducting and interpreting the interviews and are briefly outlined.
In line with the emergent nature of the interviews, the process of interpreting the interviews also develops in a unique manner. Given its centrality to this study, this aspect receives extensive treatment. The ‘result’ of such a process leads to the emergent themes themselves and the rationale for the structure adopted is explained.

The emergent themes are then presented through the use of ‘case examples’, a technique used by Thompson et al. (1990) and Gould et al. (1993). This technique aims to provide an illustration of the phenomenon and, while each respondent’s experiences have many individual facets, the cases presented can be seen as representative of all the respondents’ experiences of using NRT. Finally, the themes uncovered are then presented, capturing the patterns across all interviews, with a view to demonstrating the meanings that consumers hold in relation to their use of NRT as an OTC. These are then evaluated in light of the current literature on self-care and preventive health behaviour.

5.2 Summary of the Respondents Interviewed

A total of ten interviews were conducted from January through to May, allowing time for the transcription of each interview and a review of most of them prior to conducting subsequent interviews. Apart from two of the respondents, all were sourced through the pharmacies, as planned. The exceptions were the first respondent, who was known to the researcher, and one subsequent respondent, who was referred to the researcher by a colleague. While no attempt was made to generate a representative sample, the respondents did reflect a wide spread in
age, social class, education, and occupation. However in terms of sex, there was a firm female bias. The ratio between using nicotine gum and nicotine patches was four-to-one; broadly in line with the market for NRT.

Table 5.1 Summary of the Respondents Interviewed.

<table>
<thead>
<tr>
<th>Name(Sex)</th>
<th>Age (est.)</th>
<th>Social class</th>
<th>Education</th>
<th>Status</th>
<th>Occupation</th>
<th>Gum</th>
<th>Patch</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serge (M)</td>
<td>27</td>
<td>middle</td>
<td>3rd level</td>
<td>Single</td>
<td>Lecturer</td>
<td>gum</td>
<td>fail</td>
<td></td>
</tr>
<tr>
<td>Mariann (F)</td>
<td>mid 20’s</td>
<td>Middle</td>
<td>3rd level</td>
<td>Single</td>
<td>Nurse</td>
<td>gum</td>
<td>success</td>
<td>still on NRT</td>
</tr>
<tr>
<td>Elizabeth (F)</td>
<td>18</td>
<td>Working</td>
<td>currently 2nd level</td>
<td>Single</td>
<td>-</td>
<td>gum</td>
<td>fail</td>
<td></td>
</tr>
<tr>
<td>Anne (F)</td>
<td>mid 50’s</td>
<td>Working</td>
<td>little formal education</td>
<td>married + children</td>
<td>housewife</td>
<td>patch</td>
<td>periodic success</td>
<td></td>
</tr>
<tr>
<td>Ray (M)</td>
<td>30</td>
<td>Middle</td>
<td>2nd level</td>
<td>partner + child</td>
<td>accountant</td>
<td>gum</td>
<td>success</td>
<td></td>
</tr>
<tr>
<td>Lynn (F)</td>
<td>28</td>
<td>Middle</td>
<td>3rd level</td>
<td>Single</td>
<td>garda</td>
<td>patch</td>
<td>fail</td>
<td></td>
</tr>
<tr>
<td>Bob (M)</td>
<td>37</td>
<td>Middle</td>
<td>2nd level</td>
<td>married + children</td>
<td>mkt. research, owns firm</td>
<td>gum</td>
<td>success</td>
<td>current</td>
</tr>
<tr>
<td>Bridget (F)</td>
<td>early 50’s</td>
<td>Lower middle</td>
<td>2nd level</td>
<td>married + kids, empty nest</td>
<td>housewife</td>
<td>gum</td>
<td>success</td>
<td>still on NRT</td>
</tr>
<tr>
<td>Bernadette (F)</td>
<td>mid 30’s</td>
<td>Middle</td>
<td>3rd level</td>
<td>Single</td>
<td>accountant, MBA student</td>
<td>gum</td>
<td>Fail</td>
<td></td>
</tr>
<tr>
<td>Hudie (F)</td>
<td>mid 40’s</td>
<td>Middle</td>
<td>2nd level</td>
<td>married + children</td>
<td>housewife</td>
<td>gum</td>
<td>Success</td>
<td></td>
</tr>
</tbody>
</table>

Four of the respondents were currently using NRT, and three of these could be described as long term users, with the other using NRT at the time of the
interview. The six others had previously used NRT, some with success, some
not. However this simple classification hides the complexity of the experiences
of the respondents, which will be illustrated in greater depth later.

The interviews ranged in time from forty-five minutes to one hour and twenty
minutes, averaging seventy minutes and generated 225 pages of transcribed text.
All respondents were initially contacted by phone and were told about the
objective of the interview, their role to relay their experience, the fact that the
interview would be tape-recorded and transcribed, and that confidentiality would
be assured.

The locations of the interviews varied, with six of them taking place in the
respondents' homes and four in a range of other locations, due to work or other
commitments on the part of the respondents. Two of these were conducted over
lunch in restaurants, another respondent visited the researcher on campus, and
one took place with a postgraduate student in the DCU Business School
restaurant. With the exception of two of these interviews, the locations outside
the respondents' homes did not create the preferred environment necessary for
conducting such in-depth interviews. Ambient background noise interfered with
introspection by the respondents and, in one case, the unfamiliar surroundings
led to the respondent not being at ease. However, all respondents were generous
with their time and thoughts and the topic was sufficiently central to them to
ensure that a rich vein of experiences was uncovered.

All interviews commenced with a period of general conversation, ranging from
the weather to home furnishings, lasting from fifteen to thirty minutes before the
tape recorder was switched on. Apart from the opening question, asking for the respondent to tell of their experience of using NRT, neither the wording nor the sequence of subsequent questions was set. Asking if the respondent had anything further to add and if they knew of any other potential respondents concluded all interviews. Finally the respondents were thanked for their time.

5.3 The Challenges of Conducting Phenomenological Interviews.

There are two central issues worth highlighting regarding the phenomenological interview; the difficulty getting respondents for the interviews and the unpredictable nature of each interview. On a more practical level, it is also worth noting that the process of transcription is lengthy, difficult, and extremely tedious.

The ten interviews did provide informants who were willing to talk in-depth about their use of NRT and their smoking history in general, as demonstrated by the extensive transcriptions generated. In reality, huge effort was necessary to actually get these respondents. Additional effort was spent trying to get a number of other potential respondents, who were contacted on numerous occasions, but were subsequently unable to facilitate this researcher and take part.

It must be noted that all the pharmacies went to great lengths to assist in getting respondents to sign up to take part. As well as the leaflets explaining the purpose of the research, A3 laminated posters were placed in three of the pharmacies and all the pharmacists’ assistants were briefed by the researcher on location. The respondents were sourced, often as a result of the personal efforts by the
pharmacists involved. In tandem with these efforts by the pharmacists, the researcher visited all the locations on a number of occasions to keep momentum behind the search. Without such co-operation, it would have proven a far more difficult task.

Unlike typical phenomenological inquiries, which utilise respondents who are usually known to the researcher, this study only used one respondent known to the researcher. Clearly this presented some difficulties, but also provided diversity in experience, background, and outlook of the respondents.

The main difficulty was the amount of prior knowledge about the respondents. Often, but not always, the pharmacist could provide some information, which proved helpful principally in putting the researcher at ease. This absence of knowledge about the respondents meant that each interview was essentially speculative. The diversity of their backgrounds resulted in each interview developing in a unique manner. While each respondent’s experience was different as expected, the ability to quickly tune into the respondents was exacerbated by the open nature of the interview.

On a positive note, it appears that the topic, which was of great interest and centrality to all the respondents, overcame any apprehensions that the interview would not reveal extensive, detailed experiences. It may have proven more difficult to elicit such responses on other less central and emotive topics. As a result, the need to access ‘super-informants’, as often indicated in the literature, proved unnecessary in this case.
While the process of interviewing was emergent, with new aspects being incorporated with each subsequent interview, the most emergent aspect was the learning process on the part of the interviewer. An essential element was the role of the members of the interpretive group, who highlighted both the positive and negative aspects of this researcher’s interview technique. Also, the opportunity to transcribe each interview prior to conducting each subsequent interview was very beneficial in addressing weaknesses in the researcher’s technique and in identifying new aspects of the phenomenon to tackle in future interviews.

A number of techniques were adopted throughout the course of conducting the interviews, which improved the quality of the material uncovered. Insight came from reviewing both the tape recording and transcription of each interview. The first interview suffered from poor location and a desire by the researcher not to be directive, and, as a result, the interview remained at a surface level. Subsequent interviews focused more on probing the respondent’s experience. An initial concern of the researcher was to uncover the way in which NRT was used by the respondents, but this led to too many flat, descriptive questions that avoided the important experiential aspects. Again this was avoided in later interviews. While a good rapport was developed with all respondents, it became important to balance the friendly, ‘yes I know what you mean!’ type response, with a more serious tone to generate introspection on the part of the respondents. In the initial interviews, the researcher referred to the extensive prompt list to ensure coverage of all the relevant areas. Subsequently, this was not referred to directly but, for particularly important areas, a range of different ways of
exploring the same area was developed to facilitate deliberation. The use of the third person was particularly effective in this regard (E.G. 'Do you think it would make a difference to other people?'). The terms used by the respondents were adopted by the researcher throughout the interviews in order to avoid jargon and to foster rapport.

The final point to be made relates to the practicalities of transcribing the interviews. Regardless of typing proficiency, a typical interview required approximately twelve hours to transcribe, due to the need to review certain passages to capture the respondent's words. While this results in an intimate knowledge of the interview, tedium does occur. The quality of the recording equipment does assist in clarity of the interview and in the transcription. Technical features, such as the ability to slow down the recording, when playing it back, does help this process and it is recommended to invest in a good, unobtrusive tape recorder.

**5.4 The Process of Interpreting the Interviews.**

To understand the process of turning 225 pages of text into thematic findings it is necessary to focus on two elements; firstly the role of the interpretive group, and secondly, the analysis of the researcher.

The process of interpretation involved presenting the two other members of the interpretive group with a transcription of the interview, prefaced by a brief outline of the respondent, the source of the respondent, location of the interview, a summary of the interview, and any relevant notes. The tape recording of the
interview was listened to in its entirety to gain an overall view of the respondents’ experience. Subsequent to this, the transcription was scrutinised and a wide ranging discussion was held, which was tape-recorded to capture all the points and observations made.

These recordings, as well as the notes made, were collated by the researcher and refined and brought back to the group for further discussion. The final themes and their patterns were presented to the group to ensure consensus, remembering that the aim is to capture patterns across the interviews, achieving a ‘good gestalt’, not to provide an exhaustive description of the phenomenon.

While this process does appear logical and in accordance with the literature, a complex and often confusing back and forth process occurred. Both the process and the themes that emerged became more tailored and sophisticated as mistakes made were rectified after the initial efforts became more streamlined. The actual focus on the interpretations adopted, by the researcher in particular, changed throughout the process. For example, after an initial review of the interviews, the first five were presented to the group in the form of summary themes uncovered. However, these were initially shoehorned into the pre-existing categories, as described in the literature and outlined in the prompts developed for the interviews. This proved unsuccessful. Subsequently, each interview was assessed as a single entity, with a description of the respondent’s experience, utilising verbatim transcriptions, translated into key themes. The key to interpreting such a phenomenon is to effectively start with no *a priori* themes or ideas; a blank canvas in a sense.
The real difficulty was to combine all the interviews along common themes. The most important aspect of the development of the themes and the understanding of the respondents' experiences was to allow them to develop, rather than force them. For example, each initial assessment of any transcription left the researcher with a somewhat vague notion of the key issues, but no closer to seeing themes. Through a process of listening to the tape recordings on a number of occasions and rereading the transcriptions, a better understanding developed. This understanding moves from simply being familiar with the content to seeing the underlying patterns. It appears that extensive analysis is the only way to move from reading a description of someone's experience to seeing patterns or themes.

A particular challenge was to highlight what was important to the respondent, in light of the literature on the area, but not to abstract the respondent's experience into some theoretical arena. The development of a separate file, which took the themes apparent in an interview in the form of verbatims of the respondents, helped to distil the voluminous transcriptions and allowed the categories to emerge.

An example of the emergence of a theme helps to demonstrate the process at work. The central theme, that respondents used NRT either to break free from the world of smoking or, alternatively used it to stay in the world of smoking developed over the course of interpreting the interviews. Initially the interpretive group viewed most respondents as successful or unsuccessful quitters. Simply looking at the evidence in any interview confirmed this apparently banal fact.
However, as the interviews were assessed it became apparent that all facets of any respondent’s experience related back to this central point. The way respondents classified NRT as either within the world of smoking or as a way to break free from the world of smoking subsequently provided a fundamental template or framework in which their other meanings for NRT could be located. It can be best described as achieving a deeper understanding of the interviews through the process of interpretation, encompassing reflection, insight, and effort on the part of the interpretive group. It must be noted that such insights appear as comments or observation initially and then develop into more refined themes. The need to retain notes and an open mind is essential so that the themes develop in a loose, fluid, yet progressive fashion.

The composition of the interpretive group obviously results in particular perspectives and thinking, as well as containing different areas of expertise. In this case the group consisted of three members. The researcher’s perspective included being a smoker and a background and understanding of the regulatory environment and OTC industry. Another member, a senior academic, with extensive expertise in the area of interpretation, was a non-smoker. The third member was a post-graduate student, who moved from being a smoker to a non-smoker during the course of the interpretation, although not as a result of the process apparently. It was clear from the process that all members could be described as moving to new horizons of understanding about the phenomenon of smoking cessation. This, it must be stressed, resulted from a huge input in time,
thinking, and effort on the part of the members. A task such as this demands time and effort, and should not be underestimated.

5.5 The Rationale for the Structure of the Findings.

Two elements were at play in the development of the findings, presented below. First, in line with researchers utilising phenomenological interviews, it was felt necessary to present as much as possible of the respondents’ experience in the form of a narrative or description of their experience. Therefore, two case studies are presented in detail. The benefit of using case examples is to ensure that the overall experience of each respondent is rooted in its context and not removed or abstracted in any way. The cases also help to present the respondents’ experiences in terms of a narrative structure, again ensuring that the experience is not abstracted. While not exhaustive, the cases do serve as an illustration of the key aspects of the phenomenon of using NRT to quit smoking. The decision to use two cases resulted from a divergence in one overarching theme that emerged.

The second element refers to the structure of the themes. In a similar way to the analysis of the interviews, the structure was not pre-determined but resulted from a logical progression of the process of interpretation. The structure reflects a hierarchy of the themes in an attempt to highlight the most significant meanings of NRT to the respondents. As a result, there is some overlap of certain aspects of some themes but this is reflective of the nature of such an inquiry. For
example, many of the meanings associated with NRT itself are linked with other aspects such as the meanings associated with health professionals.

A further difficulty was to integrate the themes from all the respondents’ interviews while retaining the individual meanings associated with each interview. There were some themes which occurred in isolation but could not be considered representative of the phenomenon generally. Such single themes have been termed non-linear themes (Gould et al., 1993) and, while not necessarily representative of all the respondents’ experiences, are none the less valid.

5.6 Two Case Studies on the Role of NRT.

Before detailing the case studies, it is worth reiterating the objective of this study. First, the use of NRT was examined in the context of an emerging trend of self-medication and increased consumer autonomy. A key feature of this trend is the switching of drugs from Rx status to OTC status. Second, smoking cessation was examined as one of a range of preventive health behaviours that consumers engage in. The central point to note in this regard is the previous lack of focus on the role that a product, such as NRT, could play in consumers’ preventive health behaviour.

It is worth noting that an overarching theme which emerged across all interviews was not so much the success or failure of the respondents in smoking cessation, but whether they used NRT to break free of the world of smoking or incorporated it into their world of smoking. Therefore two case examples will be
presented reflecting these divergent positions, but bearing in mind that many facets were common to both of these cases as well as across other interviews.

A feature that characterised these cases was a sense of the respondents progressing or learning as a result of using NRT. Those who used NRT to break free of the world of smoking, even if only temporarily successful, demonstrated a sense of progress. The respondents demonstrated a range of learnings and accumulated experiences that led to the development of skills and strategies that were either successful or which they believed could be used in future smoking cessation attempts. This reflected the concept of an illness career, as forwarded by Gould et al. (1993). In contrast, others who used NRT to stay in the world of smoking showed little learning.

The two cases were chosen to demonstrate the two contrasting aspects of the central theme and to incorporate the majority of the themes that emerged. The particular respondents presented as cases both spoke extensively about their experience and were chosen by the researcher for this reason. However it must be noted that all the other interviews could achieve the same objective, each in their own way.

5.6.1 Case One: Non-Smoking Role for NRT: Hudie

Hudie, married with six children, was the 1997 Nicorette Stop Smoking Achievement award winner, a competition for the most inspiring quitter, regardless of the method used. Her story is often of epic or dramatic proportions, with a ‘road to Damascus’ event that contributed to her decision to stop smoking.
Another important aspect to her story was her background as a successfully recovering alcoholic. As a result, much of her language and thinking reflected the importance of this aspect of her life.

Hudie smoked forty to sixty a day, and smoking was obviously a central aspect of her life. Therefore her decision to stop was a difficult one, as described in the following excerpt;

I was crying an awful lot. My God I cried and cried. I just cried all the time, just, whether it was that I had lost my best friend which in a way I had you know. This was my friend who was always there for me when I was happy, when I was sad, when I was nothing, when I was you know. It was like a bereavement. It was. And then I was comparing it to the way I felt when my father died. As I say, I can't say this to my mother because she'd think "Oh my God! comparing my cigarettes with my father". But that's exactly how I felt, I felt that bad as I did when he died and that's the only close death I ever had was my father.

Her decision to quit came after a visit to a friend in hospital, a smoker with throat cancer. At the hospital another friend gave her a piece of Nicorette chewing gum which she took home and tried, almost unconsciously. There were no clear stages in the process, just an hour by hour, day by day approach, symptomatic of Alcoholics Anonymous’ approach to addiction. This style of thinking and use of AA’s techniques was clearly evident in this case.

Her own lack of instrumentality in chancing upon NRT was reflected in the manner in which she drifted away from it;

so I don't ever remember coming off the chewing gum, I don't know, there's no, there's no line there where I came off Nicorette chewing gum it happened so gradually you know I can't remember when I stopped, I can't remember stopping you know, it just happened that God I
haven't had any chewing gum for a couple of days! And prior to that it might have been once or twice a day or you know?

The manner in which she appeared to easily drift away from using NRT would suggest that, for Hudie, her cessation attempt was not challenging. This belies the fact that, for her, this was the most difficult thing she had ever done. While she was completely successful, she was acutely aware of how easy it would be to start smoking again. Her overall experience also shows that NRT, while vital to cessation success, was only a constituent part of it. She often referred to the support of friends and family, as well as walking as part of a holistic approach to her cessation. For Hudie, NRT was a necessary but not a sufficient factor in her successful attempt to quit.

Clearly NRT's role was an instrument in an 'armoury' of different mechanisms used to cope with quitting. Apart from the techniques learnt at AA meetings, the support of family and friends played a big role. As she came out about quitting, she was joined by her husband and other friends who subsequently quit. Walking the local mountain, which she took up on the first day, was described as 'another one of my kind of therapies', and reflects her holistic approach. She did not rely on any single prop in her efforts to quit, preferring to incorporate a range of options into her cessation attempt. It was interesting to note that although Hudie had been the recipient of a holiday from the manufacturers and had completed many press interviews, she rarely mentioned the brand name, Nicorette. There was a clear sense that she had in no way become close to the product. The main
role for NRT was the way it enabled her, on a psychological plain, to believe that it really was possible to quit smoking;

I think it made me see it was possible because once you got through the first few times that you needed a cigarette and didn't have it you realised you didn't die, because that's what I thought, I would actually die. So if it wasn't for the gum I wouldn't have even got to the point of realising I could go a half a day or that fifteen minutes, you know [yeah] Like when she said it to me I really didn't think I could go fifteen minutes, I really didn't, I said no I couldn't. She said, "just try it"

The respondents, when describing Nicorette and NRT generally, uncovered much regarding the role NRT could play. For Hudie, in addition to the psychological benefit above, NRT served a more specific role as a painkiller or medicine to take when she was ‘sick’.

I. okay, yeah, so would you think of it as a medicine or how would you describe it?

R. Yes, Yes, I would consider it as medication when you'd be bad. You know, yeah. And you would only need to take it when you'd be bad, you know you'd never think of picking it up unless you badly wanted a cigarette ... There was a, there was no nice thing about it at all it was definitely purely medicinal just to get you over the attack, the bad attack, and boy did it do that.

Although NRT did work at a psychological level, allowing Hudie to see it was possible to quit, and a more functional level, in reducing the physical cravings, NRT still fell short in addressing the deep desire for a cigarette;

Well it eased the terrible longing, it did, it definitely worked. It didn't ease the goo for one, but the real need for one. You know I would still fancy one and want one but the craving, the terrible pain - it kills the pain. The pain of wanting one.
Aside from the physical and psychological aspects, what was most apparent was the private, almost secretive dimension to Hudie’s experience of using NRT. This was most apparent in her ‘decision’ to quit, but also extended to her family, friends, doctors and pharmacists, and even herself;

I. OK and did you know exactly what you needed or did you go in and have a chat with him [the pharmacist] and ask him about the ins and outs of it?

R. No, I just went in and asked for a box of Nicorette. Again I didn't want to discuss it. You know I didn't want to discuss it with anybody because if I said it I might have to do it. And I still hadn't really decided I was going to do it. I was going along with this thing. It was like there was two parts of me. There was one that was saying nothing and there was one that was actually going through the process of stopping smoking, but I couldn't acknowledge it ... It really was an hour at a time for the first couple of days definitely. So and I wouldn't discuss it with anybody else you see I was into three or four days before it could actually be openly said "Hudie's not smoking you know!" And I said "well I'm trying" you know but eh for the first few days, it was like I'd pressed pause you know, in my feelings, in my attitude, in my talk, and in everything, I just went through the motions and tried, you know but there was no talking about it definitely not with anybody. [okay] I couldn't bring myself to talk about it.

Although articulate, vocal, and even passionate about revealing her experience, the initial stages of her cessation were characterised by secrecy and a reluctance to discuss it that extended to the use of the product itself;

I think I actually had it hidden for the first day or so because again that would advertise that I was giving them up. it was secretive like, I was, rather than being secretive about doing something I was secretive about giving it up which was the opposite, I didn't want anybody to know I was giving them up I suppose because I was sure, I was so sure I was going to fail maybe
so I didn’t want the failure to be seen. If I said nothing then nobody could see me as a failure or whatever, I don’t know.

It is clear that the fear of failure was the primary reason for her secrecy as she began her cessation attempt and it is notable that this extended to NRT itself.

Various aspects of control were themes running throughout this interview. One way in which this control manifested itself was the manner in which she used NRT. Hudie described NRT as a painkiller to be used when necessary, rather than as part of a consistent regime. Her regime of compliance was sporadic, only using one to ‘kill the pain’, and she was unsure about the overall time she used Nicorette. Another facet to this personalised regime was Hudie’s method of chewing the gum. Hudie chose to break up the pieces, giving her control over the dosage;

I. .. did you kind of take over the control of Nicorette in that way? You know being able to take so many a day and split pieces or whatever?

R. Not really in a sense, because I took it when I got the craving, so my cravings were still really dictating with it, the same as it is with the cigarettes. You know, I wouldn’t have really control over the cravings. So in that sense no, the only control I would have was the size of the piece and that was only because I didn’t like it

Her individualistic method reflected a belief in how central her own efforts were, but it was also possible to bolt on something else to her armoury. While remaining in control, she had no difficulty in adopting any remedy or treatment
for her campaign to quit, including NRT. She described this aspect thus ‘everybody is their own architect to their method of giving up’. She was adamant that, at least in the case of NRT, the individual should be in control of their own intake. This control was easier to exercise and was more clearly evidenced in self-medication, where it was possible to develop a personalised regime. This was evident when comparing the gum to the patch;

R. And, like, I went through all my pains in the beginning, there was no pain at the end. Whereas with them {husband and friend using the patch} it was. But there is a weaker patch and in fact they went on to the weaker patch so I would think maybe there should be a weaker again patch. I think there's two levels, maybe there's three but maybe there should be an even weaker again, because with the chewing gum you can reduce it by the day...

Clearly the gum allowed greater personal intake and control especially when it came to reducing dosage.

She also described the role of NRT as a crutch, in a positive sense; something that helped, didn’t take over, and was only temporary. The following excerpt demonstrates that for Hudie, there was no sense that using a crutch was something that showed any weakness. Using NRT as a crutch did not suggest that you lose control. She stressed that there was nothing to apologise for when using a crutch;

I. But you wouldn't think of them as a crutch would you?

R. I would in a way but I mean I don't see any harm in the crutch to help you through to get over something. I mean if you break your leg you'll take a crutch to help you off the leg until it's strong enough. So you know, and I think any crutch, once you don't use it or rely on it for the
rest of your life, but I don't - crutches are there to help you until something gets strong, whether it be you or whether it be a broken leg or whether it be whatever, you know? I don't see anything wrong with a crutch, I don't see it as a sign of weakness you know it's only an enabler to you to keep you going. I mean we all serve as crutches to each other in different times in life. You know? To help each other through things or over things, so I would see it as a crutch, yes, and a very good crutch really you know yeah for temporary use as crutches would be meant to be.

This view of NRT as a successful medicine or even drug contrasted with her more cynical views on other drugs and the pharmaceutical industry. The difference in her views related to the addictive properties of such drugs, which have the potential to become lifelong crutches. In addition she expressed concern at the lack of control of such drugs. She cited examples of doctors over-prescribing medicines and a widely held view that Valium was used as a universal cure for many ailments, resulting in abuse. Her scepticism of drugs did not differentiate between Rx or OTCs, or even alcoholic drink and cigarettes for that matter; all had potential addictive properties. This scepticism applied to both doctors and pharmacists, who were viewed as operating to the same agenda, promoting reliance on such addictive drugs.

Hudie's attitude above is vital to understanding her view of NRT as a switch drug. While aware of NRT’s previous status as an Rx, there was no sense of this switch being in any way important in her estimation of its efficacy. For Hudie, what really mattered was availability. Availability facilitated both privacy and not missing the moment;

1. What happens if that was on prescription, it used to be on prescription?
R. It used to be on prescription, that's right yes. [Would you have?] I probably wouldn't have lasted you see. Until I would have gone to... I mean that would have been going to a doctor and telling him. And I couldn't, I actually couldn't have told anybody I wouldn't have had the nerve because I couldn't tell myself, I myself, like I nearly sneaked down for it, like, like an addict would for a hit.

You know I wouldn't have gone to the doctor no I wouldn't so I would disagree with it being on prescription. I'd say it should be as freely available as possible [okay] I would definitely, no I wouldn't, because that would mean ringing and making an appointment and going down and sitting in a surgery, no way! [you wouldn't make it!] You wouldn't make it! that's for sure! ... I think the easier it is because it's so it is only a minute and it's all gone. It only takes a minute to pick up the cigarette and smoke it. And it's gone you know it's not like you can start again after having one cigarette. It doesn't happen like that. You know you have one and you are gone.

Overall, the involvement of health professionals and prescriptions militated against this desire for privacy. The bureaucracy of getting a prescription further meant that immediate availability was impossible.

Another important theme across the interviews was how the respondents contrasted NRT with smoking; whether they felt it was a direct replacement, similar, or completely different. Two points should perhaps be made in this regard. First, Hudie, like other respondents, saw similarities between smoking and NRT on some features and equally saw dissimilarities on others. Second, these similarities/dissimilarities were often more evident by the respondents' reported behaviour than in any explicit comparison they articulated.
For Hudie, NRT provided some of the oral gratification of smoking but was limited as a direct replacement for cigarettes. The role of NRT was not primarily to mirror cigarettes but rather to ease the pain involved in quitting, as she previously mentioned. Overall, NRT worked in the functional sense of easing the cravings and occupying Hudie to some extent, but did not take the place of cigarettes. It is worth recalling that she described her cigarette brand, Major, as her best friend and the loss of her Major as a bereavement. Hudie never came that close to the Nicorette brand in any manner;

I. And what would you tell people about going, or how would you describe it to them you know?

R. How would I describe. Well taste wise awful, but it functions perfectly on a par with a cigarette in terms of meeting the requirements for a replacement for a cigarette. It would function just like a cigarette in that sense and you do get you know, a certain oral gratification in picking it up and putting it into your mouth. So, but it's still something it doesn't do obviously which is still you know you would be crying for a cigarette, and dying for a cigarette but it does well, it really does well.

Overall, the sense of learning Hudie gained from her experience of using NRT was reflected in her unique outlook on smoking that she formed having successfully quit. Her reflections on her experience of quitting smoking gave her and her family a unique perspective on the danger of smoking. This perspective was based not on the frequently cited health dangers of continuing to smoke, but the difficulty that a smoker would face, at some point in the future, when they had to attempt to quit:
R. I think if they really knew what it was like and I think my son hasn't smoked since, Orla hasn't. I think seeing, and the boys saw it as well, seeing what was involved in giving them up I think that scared them more than seeing people with cancer or seeing ... because they are all maybes whereas if you start smoking you are definitely going to have to give them up and the giving up kind of scared them because they saw what I went through and what Donal went through and they know it's not a pleasant thing.

In summary, Hudie was articulate and richly described her experience of NRT. A key concern was the availability of NRT as a switch drug and that there should be no medical or professional barriers impeding access to it. Hudie placed NRT outside the sphere of medicines, whether Rx or OTC. Availability, privacy and control were the key meanings for her in the role NRT played in her successful smoking cessation attempt.

5.6.2 Case Two: NRT Within the World of Smoking: Bridget.

Bridget, a housewife in her mid-fifties, lived with her husband, also an ex-smoker. In brief, the past eleven years has seen Bridget quit for one year, with Nicorette gum, and then continue to use NRT and smoke for a further year. Subsequently she returned full-time to cigarettes for five years and, most recently, has been using NRT for the past four years.

What was most pronounced in this case was how central NRT was to Bridget; all questions or conversations, regardless of their nature, featured NRT and more particularly, Nicorette the brand. Experiences or aspects which she described were placed in a time context of either when she was smoking (‘Carrolls was my
brand’), years ago (‘when Nicorette was on prescription’), or now (‘when I have my Nicorette’). While quantitative measures are unimportant, it is enlightening to note that she mentioned the brand Nicorette eighty times in the interview, in contrast to Hudie, who mentioned the Nicorette brand eight times.

Not surprisingly, with the benefit of reflection, Bridget expressed some concern about her consumption throughout the interview, but was very reticent to express any real desire to quit nicotine gum. She appeared basically content with her situation and Nicorette had clearly replaced cigarettes, although not as good as ‘the real thing’.

An example of how central Nicorette was to Bridget, and how it was constantly used to frame her experiences, is demonstrated in the following two excerpts. One important facet to these stories was the inherent naughtiness in using NRT. Bridget viewed NRT in the same manner as she viewed cigarettes. The first excerpt is her response following inquiries about her health status;

R. Oh yeah, I am fairly healthy, fairly healthy yeah... And actually I, last year I did have reason to go to the hospital but em, they asked me if I smoked. I said I did but I had given them up and I told them I was on the Nicorette. So, they didn't seem to mind, but one doctor said to me, well try and wean yourself off that as well you know [okay] You’d hear my daughter she was with me the day, but ‘now did you hear him, you’re supposed to give up the Nicorette as well’ you know, but not not for any particular reason because there is nothing wrong with me, thank God

When asked what she thought of what the doctor said to her, she demonstrated the way she would usually reply to such a comment from anyone. She used an example of smoking and cigarettes and immediately followed this with a
reference to Nicorette. In addition to the naughtiness associated with using NRT, this excerpt demonstrated her defiance. Again this would be typical of a smoker, rather than a non-smoker;

I. So what did you think of what he said?

R. I would, but I think that the more people tell you to do things, well with me anyway, I'd be kinda going my own way and maybe that used to be the same with smoking you know if someone said you should give them up or cut them down or whatever, I used to find that that would make me smoke more

It was increasingly apparent that Nicorette, while obviously the topic of our conversation, was much more; it was a central part of Bridget's life. This centrality was evidenced in many unsolicited references to Nicorette even during areas of the interview when smoking cessation was not being discussed;

R. Last year I went, I'd be a bit nervous so I got some tablets for getting up in the aeroplane; drug addict! I asked for them Ah just fear, fear of probably flying, that was the only thing but I got them, got back.... I got the Nicorette over there as well too, much dearer than here too it is, much dearer [is it?] But you can only buy it in bigger packets you see, there's more in them.

In other areas of the interview the centrality took the form of Nicorette as a constant companion. The role of Nicorette as a companion, was demonstrated in the following vignette, in which her reluctance to use the Valium prescribed by her GP for a plane journey was discussed;

R. But I got on all right. I'd do it again now actually And that was the funny thing too, when I was going anywhere, if I was flying on a plane anywhere, I would never go into, I would never
smoke on a plane so I wouldn't. But I had my Nicorette you see going over as well and I was
grand, so I had...

Turning now to the role or function of NRT, especially its function in relation to
cigarettes, rather than being an addition to any armoury of mechanisms designed
to help her quit smoking, Nicorette simply took the place of cigarettes;

R. my son-in-law worked in the Airport and I knew the Airport also has a chemists and I said to
him to get me a package of Nicorette, I said because I forgot to get and the Chemists won't be
open tomorrow. He came home without it and there was holy war, I nearly killed him. But, lucky
enough my sister over here had some and I was having her for dinner on the Sunday and she had
bought me the Nicorette on the Saturday and had it over there for me for the Monday.

She described herself as 'more of a smoker' than most of her friends and
continued this story by demonstrating that only a smoker could understand her
attachment to Nicorette;

I. Because she knew it {the absence of Nicorette} was going to happen?

R. She knew. She didn't know then that I had none and she didn't know that I had asked Matthew
and that Matthew had forgotten to get me any. But she said, "I have them for you", because she
is a smoker as well. So she had it for me and then it was grand.

Nicorette played a central role in Bridget's life, replacing the role previously
held by cigarettes. As a result, there was no attempt to control the amount of
Nicorette she consumed or any effort to reduce it. The role for NRT was to take
the place of cigarettes in the widest sense. Bridget was unable to specify exactly
what NRT did for her, much less differentiate between its impact on physical
cravings and its impact on emotional needs. The role it played was only explained by direct contrast to cigarettes once again;

I. And what is it {Nicorette} like to work, what kind of sensation do you get, what did you feel with it?

R. Well actually none, I don't know about me. I definitely haven't got the longing for the cigarette. Now as I said, when I started on the Nicorette there was always a cigarette in front of me as well, because there's definitely nothing like a cigarette you know ... Now there's the odd time now, but it's growing less I must say. I used to wake up and there used to be a cigarette in front of me you know what I mean, that was all I could see. Now I can get up and I don't - you know what I mean. Well I have my Nicorette there if I want it [okay] you know.

While it appears that she may have struggled to articulate certain points during the interview, it was apparent that, despite her claims to the contrary, there was no clear separate function, sensation, or purpose to NRT, just a direct replacement for cigarettes;

R. The Nicorette..., I, I really can't say that it did anything, you know what I mean, unless it was just my.......the way, I don't know................As I say I really can't........... It doesn't make me feel any different [okay] apart from the fact that I haven't got the longing for a cigarette since I started to take it.

I. How would you describe it. What does it do., what would you call it in that way?

R. Em, I'm trying to think....................Well I have to say, to me, it doesn't do anything now.....it doesn't, I don't feel any different, you know what I mean, it doesn't give me a buzz or anything like that, the Nicorette. It definitely doesn't. Apart from the fact that I'm not smoking .... I suppose the same as when I was smoking. I was smoking and that was it. Now I'm not smoking, now it's Nicorette [yeah]. That's all I can tell you
While NRT was definitely a replacement for cigarettes, it could not be described as being an equal replacement. Bridget’s descriptions often equated NRT with cigarettes however it enjoyed few of the more enjoyable aspects of smoking;

R. I can't see anything good about it, to be honest with you. Only I know that, you see I'd nearly have to prove to myself that if I hadn't got the Nicorette, would I smoke? But I don't think I would now you know, I don't know what it is, maybe it is only mental you know what I mean, the way you're thinking, you might be thinking a bit differently now. But no ... Yeah because I can't see anything, Nicorette is nothing like a cigarette, you know what I mean, to me It's not! It's not like a cigarette [yeah] but I'm delighted now to be, to be off the cigarettes. I am and as I say it's not for financial reasons. But I, I feel more healthier I think, I do now, than when I was smoking.

Even four years later, Bridget continued to have vivid dreams about smoking, and showed her attachment to her brand. So, while NRT echoed the role of cigarettes in many ways and paralleled many of its functions, it could never address the emotional and satisfaction deficit that resulted when a brand of cigarettes was abandoned;

R. Oh but I often used to be nearly, I could actually taste the cigarette and everything else and I'd get up the next morning and say to myself, "was I dreaming, or was I smoking?" I used to love the Carroll’s, I used never smoke anything other, only Carroll’s the No. 1. I had the packets and they were gorgeous and I enjoyed every one of them in my dreams. I loved them. Now that'll tell you how much I loved them. Now I'd never dream of Nicorette.

Leaving aside the role of NRT, a further aspect to this thesis was the meanings associated with NRT’s switch to OTC status. In addition to having a broad fear
of doctors, Bridget also had a strong fear of medicines in general. She often described her tendency to stop taking or even to avoid collecting drugs prescribed for her. This was somewhat similar to Hudie, the first case study. However, Bridget, in contrast, was comfortable using and discussing many OTCs and NRT in particular. In the case of NRT, it was clear that she had no real concerns about her usage or side-effects, typical concerns for anyone using NRT;

R. Well as I say I had seen it and I talked to this girl and actually it does have a few side-effects when you start taking them first. You know you kind of have a raw throat and your head can be a bit dizzy and that, but that kind of, it kinda wears off after a while.

Although Bridget was unclear about what the Nicorette actually did for her, she was aware that it was something with a ‘drug’ in it. She was concerned about this drug aspect to NRT. For Bridget, drugs had dangers such as their addictive potential. However, despite her concerns about this drug in NRT, she remained comfortable about her continued use;

R. Now that kind of worried me [yeah] you know, I know that there’s a drug in it, the Nicorette is in it The nicotine is in it you know.

I. When you say drug, what way would you, do you mean the nicotine itself?

R. Yeah, yeah, because they are coming out now with it, aren't they, that it's the nicotine that is the drug. I know it's not the cancer, what causes the cancer, it's the tar, and carbo- whatever else they have in the cigarette. But still surely that must have some effect on your system as well, the Nicorette, the nicotine in the Nicorette,
Although NRT had drug associations, Bridget did not view NRT in the same manner as other medicines. The reason she was less concerned about the drug aspect to Nicorette was due to her clearly placing NRT outside the medicinal arena altogether;

I. Do you think of it like, you know you get it in the pharmacy, do you think it's like a medicine or anything?
R. No, no I wouldn't class it as a medicine, no [okay] would not, definitely not so I wouldn't. The only thing now I can tell you about the Nicorette, I don't know what it is, but em... all I know is that I am not smoking, but I'm on the Nicorette. I don't even know how they got the name Nicorette, unless from the nicotine [laughs] and the cigarette.

As stated above, there was a strong contrast between Bridget's view of Nicorette as a drug and her approach to the use of medicines generally. In the case of medicines, there were many instances where she articulated her reluctance to use tablets, even those prescribed to her;

R. I don't like taking any kind of tablets actually so I don't, but, em, well I would take a Panadol or whatever for a headache but only... I have tablets there now for arthritis and all, but I don't take them..... There does be murder. First of all I think they don't agree with me and em, but I would take a Panadol or a Nurofen, or anything like that [okay] you know. But I'm kind of wary of what I take. I'm a bit nervous. I'd take an odd Valium now, but actually the doctor prescribed them over at the hospital as well, but only one, but you could become addicted to them as well you see. I'd only take one at night if I couldn't sleep, you see what I mean?

Clearly the dangers of more powerful medicines were the dangers of addiction. To understand her reluctance, especially to prescribed drugs, the following
verbatim illustrates that the drug content of these prescribed drugs was the issue. Her use of the term ‘drug’ captured her fear of the addictive dangers. This was contrasted homeopathic non-prescription remedies;

R. I did be dad, I don't mind trying out anything that is natural. You know what I mean, herbal things, I would try them out. I'd try herbal tea or anything like that [right that’s quite nice actually] ah yeah I would

I. So it's the naturalness that you go for.

R. Ah yeah I do, well there are no drugs in it, is there in the home remedies or whatever you like to call them, there’s no, there’s no drugs in them [yeah] so there’s not.

There was a marked contrast in her nervousness with drugs, especially those prescribed to her, and her confidence when using OTCs. On one hand there seemed to be an understanding that Rx drugs were powerful and had addictive potential. She did her utmost to avoid such drugs. OTCs were completely different in her view. She expressed no reluctance in using OTCs for many ailments and was knowledgeable about the ingredients of the OTCs she used. It was apparent that, in Bridget’s mind, drugs were in one category or the other. It must be noted that it took much effort to get Bridget to understand the concept of a drug switching status, even though she was fully aware of Nicorette’s previous status.

When she did discuss switching, she did so in terms of the doctor’s role in protecting the user from dangerous drugs, by only allowing something safe to move to OTC status. The doctor’s ability to ‘pass’ or legitimise the switch to OTC status was crucial to Bridget;
R. Because would you not think then now if it's readily available without prescription, after it being on prescription you'd kinda feel more safe using it, wouldn't you? [okay, okay] Well I would, you know what I mean That you are not just going to be like a guinea pig, going down and getting something over the counter, and that you really don't know. So that if a doctor kind of could pass it [right], you know, and then you would say to yourself, well they are not going to prescribe something bad for you are they [okay] you know......so?

This safety aspect was explored further and revealed a trust in the doctor, rather than in the product as such. The product still had dangers, such as the dangers of addiction;

R. Yes, it would be more safer than just trying something, you know, what....... willy nilly, whatever you want to say A doctor wouldn't, wouldn't prescribe something, surely, that wouldn't be bad for you you know what I mean ..... 

I. This is true, okay so...........

R. I'd feel more safer taking it, apart from the addiction part, for me, [okay] that I might get hooked on it. It's the same with prescribed tablets too, as they did, Valium or anything else, you can become addicted to them as well.

Her willingness to use Panadol above Nurofen was also described in terms of their safety. Such brands were clearly placed in the OTC arena. For Bridget, what became increasingly evident was that such purchases did not require any involvement with the doctor and any contact with a health professional. The meaning of getting something OTC was that there was no need for any interaction with the chemist. For Bridget, over-the-counter meant that she could
pick up such products with the assurance that they were safe and had been passed by the doctor;

R. I don't like taking them, I'd take the Panadol quicker, I think they are the safest.

I. And what's make them safe, the Panadol?

R. You can get them over the counter as well, you can get Panadol over the counter, so you can.
And you can get the Nurofen over the counter, without a prescription. In most chemists now you can buy over the counter.

This division between the doctor, prescribing drugs, and the safe, easy availability of OTCs in the chemist was reflected in the way she dealt with such health professionals. Her confidence in dealing with the chemist or simply picking up what she wanted contrasted with her general nervousness and avoidance of the doctor;

R. Yes, a little bit yeah, sometimes I do. I'm a little bit afraid of doctors, but if I had to go, I will go. But I will avoid going to him as long as I can. But if I, if he says I have to do something, I do, I do. I'd work up my courage. No I don't go to the doctor that much as I said before [good] unless I feel there's something not all right

Bridget's apparent contradiction between concerns over drugs and her continued use of NRT can be understood by Nicorette's prior history as an Rx drug. Bridget often alluded to 'the time when Nicorette was on prescription', promising safety through the doctor's ability to 'pass it', as she described it above. This gave Bridget the reassurance she needed to continue to use Nicorette despite the addictive associations of nicotine in NRT. This reassurance was
combined with her understanding that NRT was not a medicine in her terms. Medicines, especially powerful prescription medicines, had addictive potential. NRT was more like Panadol or Nurofen, and with the added benefit of a proven track record from the doctor. What was most appealing to Bridget was the ability to access Nicorette without any interaction with a doctor, or a pharmacist, in the knowledge that Nicorette was safe.

In her description of Nicorette she did not refer to any idea of therapy or process. In contrast to Hudie, where Nicorette was a means to an end, Bridget saw Nicorette as an end in itself. Nicorette took the place of cigarettes keeping Bridget in the world of smoking. The meaning of NRT for Bridget was of safety, where a potentially addictive product had received sanction from the doctor. NRT allowed her to remain in the world of smoking, using it in an identical manner to cigarettes despite the fact that NRT did not satisfy all the dimensions previously served by cigarettes.

**5.7 Emergent Themes from the Phenomenological Interviews.**

While the themes are presented as a hierarchical pattern, it is essential to understand the interrelationships and overlaps that exist between many of the themes. As a result, many of the themes can be viewed as forming non-linear patterns, typical of such a study (Gould et al., 1993). It must be noted that the emergent nature of the interviews resulted in uncovering many more diverse aspects to the consumers' meanings of NRT than were originally anticipated. The primary purpose here is to present a coherent picture of the key themes.
Such a thematic picture is the result of common aspects appearing across the experiences of the respondents.

The pattern of the themes is presented in three broad stages. First, a range of wider themes common to all respondents underpinning their particular meanings of NRT is presented. These themes are termed meta-themes. Apart from their own particular relevance, these themes inform and contextualise the role that NRT, as an OTC, played in the experience of the respondents. Second, the central theme, that respondents used NRT to either stay in the world of smoking or break free from smoking, forms the core pattern of eight themes. Finally, a number of non-linear themes are presented that provide further insight into the meanings of NRT to the respondents, although these are essentially peripheral in nature.

5.7.1 Meta-Themes

These meta-themes set the scene for the particular meanings of NRT as an OTC for the respondents and help to make sense of what, in some cases, were apparent contradictions between key themes. It must be reiterated that the primary objective of this study was to explore the role of a drug switching from Rx to OTC status. According to the literature this status change remains within the medical sphere, albeit that the consumer has greater autonomy (Hoy, 1994). However, the two case studies above suggest otherwise, illustrating that there was a marked contrast between the usage of NRT and the usage of any kind of medicine by respondents. For Hudie, using NRT contrasted with her cynicism.
and avoidance of all other medicines. For Bridget, using NRT, as a drug with a recognised prescription history, was also in contrast with her avoidance of prescribed drugs. The same was true for many of the respondents who had no compunction in taking NRT while at the same time protesting that they were 'not really tablet takers'. NRT and medicines were clearly in separate compartments. This difference in outlook towards taking medicines and NRT can be best understood by looking at the actual meanings associated with NRT. Essentially it is outside the medical arena. Smoking cessation is not a curative process. It is not recovering from an illness. It is not strictly speaking a health issue. As a result, it is not the proper concern of doctors or medical professionals.

Two aspects, common to all respondents, illuminated this distinction between medicines and NRT; a) the fact that smoking and smoking cessation were not viewed in any way as an illness or even a health issue, b) the subsequent absence of any role for the doctor or medical professional.

**Smoking Cessation is not to Cure**

a) While smoking cessation is clearly identified more as a preventive health behaviour than a remedy for illness, the respondents rarely made reference to health issues. Occasionally health issues such as the long-term effects of smoking did arise and if a more causative approach had been adopted in the research methodology, health would likely have been the 'factor' most mentioned. However, for all respondents using NRT the absence of any articulated health meanings was very apparent, despite a focus on many of the
elements of preventive health behaviour by this researcher throughout the interview process. Therefore, at this level NRT was seen as being outside the conventional boundaries of medicines as described by Serge;

Eh well that's a different issue... that's a different issue emm because I would consider, any say kind of direct ill-health different to what is proactive health move...[okay]...to give up smoking is proactive health when I'm ill I'm coughing, I know I have an infection.... you know that there are different dosages of different types of antibiotics, and you know that there is a medical judgement that has to be called into play there where as with the nicotine substitutes or replacements you know you can make you're own

b) Following on from this point was the fact that there was no role for any health professional in smoking cessation. If there were no illness connotations to smoking cessation it followed that the doctor had no right to play a role in the individual's cessation attempt. Smoking or quitting was a matter of personal choice for the respondents and also one that required privacy. Furthermore, as smoking cessation was outside the remit of the doctor, any advice or help was seen as irrelevant at best or insulting at worst;

Ray. Ah the doctor, any time you go to the doctor no matter with what they'll ask you how many do you smoke a day, you should really give them up or whatever, but you know....

Bernadette. I just listen to him for the sake of having to go and get a prescription for an inhaler. No, it wouldn't make any difference.

All respondents acknowledged that the doctor constantly gave advice, but this was never heeded, due to its perceived perfunctory nature. At first glance, many respondents highlighted that they had received advice from their doctor, and it
appeared that this represented an 'information source'. Further analysis revealed that this advice was of little relevance to the respondents. While it is widely reported in the literature that doctors do encounter resistance from patients regarding cessation advice, the doctor is nonetheless often cited as a source of information. In this case the doctor's role in providing information was a perfunctory one. His/her views were listened to but not sought out.

Some took the doctor's advice but it formed part of a game with the doctor, where both participants had a tacit understanding of each other's position. For example, Ann, while relying totally on the doctor for all medical issues and even obtaining the doctor's permission to use the patch, saw such advice as part of a game. Again at first sight, Ann appeared to be the quintessential good patient, highly respectful of the doctor and his advice. However, it became clear that this advice was part of a game where Ann continued to smoke despite the doctor's advice and the doctor himself went along with the dissemblence;

He do say to me 'Are you off the cigarettes Ann?' and normally I just say yes, no point in saying no, and 'good for you' he says 'Ann' and he gave me a book and all on it, you know, first, first day your off them, how many did you smoke and all that, so I used to smoke one or two [okay so...] but he does really, he's down on cigarettes

The result of smoking cessation being outside the realm of cures and beyond the remit of the doctor was that NRT was not viewed as a medicine or drug in the conventional sense. The extension of this was that switching from Rx to OTC was essentially meaningless. The switch is 'medical' whereas cessation is not in the medical sphere.
In summary, this first meta-theme focused on how NRT, though available only through medical outlets, was itself seen as essentially being outside the medical domain. As a result of this perception, medical professionals, in particular GPs, were in a sense disenfranchised; it was simply not deemed appropriate for them to be consulted regarding this product.

While all respondents, in their own way, chose to locate NRT outside the medical sphere there was a parting of the ways when it came to the meanings associated with the use of NRT. This leads to the second meta-theme uncovered in the research. This theme was already evidenced in the two case studies discussed earlier (section 5.6). However, it also surfaced in most of the other transcripts and centred on whether NRT was used to either break free or remain in the world of smoking. Each of these two groups will now be examined separately and the range of sub-themes associated with each group will be explored beginning with those who used NRT to break free from the world of smoking.

5.7.2 Core Theme One

**Breaking Free From the World of Smoking**

Respondents, such as Hudie, used NRT to break away from the world of smoking. In Hudie’s case this was clearly successful but for others it proved to be a temporary success. It will be remembered that this ‘break free’ group comprised both those who failed and succeeded in their cessation attempt. For those who lapsed back to smoking it would be plausible to assume that they
returned to the world of smoking and that little had changed. However, what marked these non-succeeders from other non-succeeders was their experience of prescribing their own role for NRT and the learnings that resulted. Such respondents clearly expressed a sense of progress and a better understanding of how they could utilise NRT in the future by approaching certain aspects differently.

For the successful and unsuccessful respondents in this group there were clear, if varied understandings of the function and purpose of NRT. This notion of NRT serving some clear and definite purpose marked out respondents in this 'break free group'. The specific function or purpose of NRT ranged from being a simple, direct replacement for cigarettes, a painkiller for specific moments, an aid as part of a wider battle, or a reward for not smoking. For some NRT addressed the physical aspects only and for others it acted in a more holistic manner, including many emotional aspects.

Regardless of the specific role that NRT played there was a clear understanding of the mechanics of nicotine replacement. This understanding of the mechanics was not necessarily the result of what would be described as health knowledge but the result of the respondents taking an active role in their smoking cessation attempts. Such an active role was primarily related to the individual remaining in control. In fact, control issues were the most salient themes for such respondents.
Taking Control

The central meaning of NRT lay in its ability to allow respondents control many aspects of their cessation attempt. Control related to more than regulating their intake, although this was important. In fact, three control related meanings emerged from this 'break free group'; control of the decision to quit, control of the dosage, and control of access and timing.

Taking Control of the Decision to Quit

Typically in a health context, there is little privacy for individuals engaging in health behaviour. There is a range of health professionals, hospitals, clinics, all usually operating in a very public fashion. Much has been written on this topic and initially the respondents' experiences of cessation appeared to highlight this lack of privacy. However, on closer examination, privacy appeared to be an important requirement in the sense that privacy facilitated control over the decision to quit. There was a desire to remove the cessation process from public scrutiny both medical and non-medical.

Like Hudie's decision to purchase and use NRT secretly, many other respondents cited this aspect. For Lynn, both smoking and quitting were personal issues. The decision to stop was her own choice. This was apparent when the notion of NRT being on prescription was discussed. The decision to quit was not something that required permission;
On prescription. I dunno, because I think, you know, smoking, it's your own personal thing and I mean it should be up to you, not a doctor, whether or not you know, you need to give up as such. Em, You know, it's almost as if you've to sort of ask somebody's permission

While privacy in this sense of personal autonomy and owning the decision, there was an important private dimension to the use of NRT. Like Hudie, who cited the need to conceal her initial efforts when using NRT, many respondents felt that NRT aided secrecy and helped retain control. The concept of control and privacy was also important for those who felt that any disclosure to others of using NRT added unnecessary pressure on them in their attempt to quit. For Bernadette, her privacy minimised the pressure arising from social scrutiny, advice, and rebuke;

Yes. I'd prefer to use the patch. And as well as that if you are sitting in at a meeting you can't really be chewing gum, and you couldn't be smoking either. Because nobody knows you are using a patch. If you are seen chewing on chewing gum people will say oh, you are giving up smoking now? If you are giving up smoking everyone decides to give you a lecture. But because the patch is not visible, yes I'd prefer it. You won't have someone saying, you gave in you're smoking. That's very difficult. You try to give up and people are very, and say you didn't stick it out.

This ability to retain control over the decision to quit and protect the individual in the initial stages of cessation was made possible with NRT. Of equal importance was the need to retain control throughout the cessation attempt. For this reason developing a personalised regime was crucial to these respondents.
Control Through Self-Medication

In contrast to the received wisdom regarding compliance with dosages for medicines generally, many respondents took control over their intake of NRT, ignoring the recommended dosages and instructions. Apart from meeting their individual physical needs for certain levels of nicotine replacement, the personalised regimes meant that the 'break free' respondents stayed in control. This was often illustrated by the contrast between the gum and the patch in the minds of the respondents. Although identical in nicotine delivery and clearly having the same function, the respondents had contrasting opinions on the merits of the gum and the patch. For Ray, altering the amount, frequency, and even the strength of Nicorette gum was vital to staying in control. This was best illustrated when he explained the reluctance to use the patch;

Yeah I....can I give you a good reason for that, em........I don't know what it is, I mean for want of a better way of putting it, I mean you stick a patch on your arm and you, I mean I don't know the full details of the patches to be honest with you, but it's the nicotine coming into the system the whole time is just...with ever thinking about it too deeply, it just never, never appealed to me [it didn't?] at least when you're chewing the gum you have the control yourself to take it off

In a similar vein, Lynn, who had used the patch as an experiment subsequently questioned the manner in which the patch put nicotine 'directly into your system'. On reflection Lynn questioned this loss of control;

That might be better {nicotine gum} because you can control the level that you're actually taking in. You'd feel more in control that way.
Such issues regarding control were often disguised by more banal observations or comments by the respondents. The often-quoted aspect of the gum being associated with the ritual of smoking appears to be more related to the individual retaining control than necessarily being a better replacement. Respondents who referred to the ritual of gum placed emphasis on remaining in control and those who had used the patch often cited the lack of control. Serge emphasised the need to be in control of the ‘hit’ or impact of his nicotine replacement;

eh ... and there was no immediate satisfaction from putting on a patch as there would be with having a packet, which is something tangible, that you can take out and have some kind of ritual associated with it like there is with a cigarette, there’s matches, and there’s a wrapper and there’s is ..I don’t know. ... so my logic was choose the chewing gum because its a direct hit, its a quick immediate satisfaction

**Control of Timing: Quitting and Topping Up**

As highlighted in Hudie’s case, a key role for NRT as an OTC was the ability to ‘seize the moment’ and purchase NRT whenever the need arose. This aspect was also critical in an ongoing way when quitters found themselves without any NRT to hand; all it took was one cigarette to undo the cessation effort if NRT was unavailable. However equally important was the barrier presented to any potential quitter, in terms of access, when NRT was on prescription. The protracted process of visiting the doctor, gaining a prescription, and purchasing
NRT meant that many viewed it in terms of losing control of the timing of their cessation attempt.

This benefit of retaining control over the time to quit was described by Lynn, who had made the decision to try patches only when she saw the packs on the counter in a pharmacy;

I think it's brilliant and it should be like that because, I mean, I'm sure it works for some people. You know, I mean you should be able to just, if you feel, grand, sure I can give them up and there's an item that's going to help you that's sitting there looking at you, why not? I mean, I think it's, I mean it's so much trouble going to give up anyway, why put some one under all the extra pressure of having to go to the doctor, pay the fee and get the prescription, then head off the chemist as well. I mean, like, its, you know, if it's possible to just pick it up over the counter, why not? Maybe think it should be more readily available than just chemists.

The three control centred dimensions just discussed might lead to the conclusion that this ‘break free’ group were exclusively pre-occupied with their own personal ‘internal locus of control’ resources in their battle against smoking. However this was not the case. Examples abounded of these successful and unsuccessful quitters embracing a range of stratagems and supports including NRT. The following section examines how this group availed of a range of such supplementary stratagems and supports but did so in a way that bolstered rather than minimised their perceived internal control. This is the second sub-theme evidenced in the break free group.
Supplemented Control

This theme related to the inclusion of NRT into the armoury of tactics that respondents developed when attempting to quit. Rather than viewing NRT as in some way conflicting with their internal resources, NRT was commonly described as an aid or addition. Aside from any specific role that was demanded of NRT, the respondents held a collective understanding that NRT was a positive, helpful addition, but above all, they were in control of the NRT not vice versa. This was illustrated by Ray;

the hypnotherapist but ...no neither of them would appeal to me really.......okay, you say willpower but, I feel as though if you have something to help you you might as well use it .. Well you do need the willpower ... I mean that, you need that foremost [yeah] em, like anything else that can help you, I know I could have, had I been stronger, I could have given them up but with the aid of Nicorette....

Others described NRT as a crutch in a positive sense or even as a life belt to be used when needed. Bob, for example, extended this meaning of NRT as a positive additional resource by describing it, not simply as a replacement, but as something that could be used as a reward for his own efforts. In this case NRT could supplement and reinforce his own internal resources;

Em and that's another thing, one of the good things about Nicorette is that, say if you use the example of Friday night, that I was more or less able to reward myself for being off cigarettes with still indulging myself with the nicotine on the Friday night. Whereas any other time I tried to give up smoking it was always with a great feeling of deprivation, that I was denying myself something.
Closely related to the meaning of NRT as a supplementary resource to the individual’s efforts was the need to sustain their own willpower. While willpower and motivation typically feature in the literature as pre-requisites for quitting, here it is a case of willpower being expressed throughout the quitting process. Such willpower was not in any sense weakened or debased by incorporating an external agent such as NRT into cessation regimes. Many respondents, who emphasised the need to continue the effort, rather than become complacent, articulated the sense that willpower needed to be sustained. The respondents’ willpower benefited from the experience of using NRT, even if it ended in a failure to quit smoking. Such experience was added to the armoury of learnings and techniques that could be utilised during later attempts and willpower was not lost;

Bob. But it is all to do with the sustainability of your willpower, how long you can sustain the effort for. Because when it reaches the stage where the effort, particularly if you are not suffering any health consequences because of it ...

So the willpower to do it comes from the readiness to give up, just from it being the right time. And the willpower to sustain it comes from a combination of that and also the sense of achievement ... you have that sense of experience then that you can say, well I have done it and I will be able to do it. And also having failed so many times. I know, basically I know there is a complete armoury now.

Clearly, the manner in which NRT was co-opted into the cessation efforts of the respondents suggests that internal and external control forces could work in tandem for this ‘break free’ group. In fact, it is hard to separate these two forces,
the individual’s belief in their own efforts and their belief in the efficacy of a product like NRT. Crucially, it was the autonomous behaviour that was facilitated by NRT’s availability that resulted in such a close alignment of these two forces. NRT was a worthwhile, effective, external agent. At the same time its availability meant that this efficacy could be tailored and managed in a way that represented no threat to the user’s sense of internal control. Indeed, in a further sense, it reinforced user’s sense of control. By virtue of its OTC status, the prescription and expert power, previously vested in the doctor had now been transferred to the lowly NRT purchaser. This leads to the third sub-theme emerging from the break free group, the transfer of expert power from medical professional to lay consumer.

Control switches to the Consumer

As outlined previously, NRT’s unique aspects deemed it to be outside the medical arena. In the case of those who used NRT to break free of the world of smoking its meaning specifically as a switched OTC entailed three aspects. These were the consumer as expert, the subsequent lack of any role for health professionals, in particular pharmacists, and the notion of NRT requiring an even further switch beyond OTC status to even wider availability. These three aspects were characterised by a struggle between the power and control of the doctor or medical profession and the desire of the consumer to gain control. This struggle for control is given added texture by the fact that NRT, unlike other switch drugs, should never have been on prescription in the
first place. Advocates of greater NRT availability can point to its harmlessness and its lack of side-effects as compelling grounds for returning power to its rightful owner, the consumer. Such a sentiment was described by Ray;

Well to be honest I can’t understand why it was on prescription before, again I say again, because to me you’re getting just, it’s a substitute for cigarettes [yeah] so I can’t really understand it, why it was, as well as that it stopped an awful lot of people trying to give up cigarettes like using the Nicorette or [yeah] whatever so I never saw the logic of having them prescription........

Respondents noted the fact that, in cases of illness, doctors retained power through their specialist knowledge. This contrasted with smoking cessation, where the ‘patient’ would understand the diagnosis and the solution, thus negating the power of the doctor. Bob described this aspect in detail;

I can’t think of any other medicine, or any other product that has been advertised to a potential market that then has to go to their doctor to get it all right So, if I go to the doctor, or if somebody goes to the doctor, if they go with a problem and the doctor prescribes a solution and he prescribes a solution based on his specialist knowledge of the problem okay, so your left toe is swollen up and your right ear won’t stop flapping, well that’s such-and-such a disease so I’ll look up my big thick book and I’ll decide what to prescribe for you. Now the reason that I can justify paying the doctor for that is because he went to college for all those years and it’s his experience that enables him to diagnose a solution to my problem.

If I go along to the doctor with the problem and with the solution and really all I’m asking him to do is not even to buy it from him, but for him to enable me to get it, it isn’t the same thing.

Inherent in Bob’s description of the control rightfully residing with the consumer is the concept of the power of the prescription itself (Pellegrino, 1976, detailed in
chapter 2, section 2.5). In circumstances where an illness was the issue he emphasises the doctor prescribing a solution as well as prescribing a remedy. It was this ability to prescribe that gave the doctor the power. Bob emphasises the difference when it came to NRT; the only function of the prescription was to allow him ‘buy’ NRT. In this sense the power of the doctor to prescribe NRT was viewed as self-aggrandising. This was a power that was not rightfully the doctors.

A further aspect to the power of the prescription is the sense of mystery associated with the act of writing a prescription. In the following excerpt Bob extended the meaning of power switching to the consumer. In this instance he refers to any OTC medicine, not just NRT. The removal of prescription status negated the mysterious powers of the doctor, removing the secret communication between doctor and pharmacist. The important point is that the mysterious, almost witch-doctor behaviour was symptomatic of a power that was inherently false and bogus when it came to NRT or other OTCs;

... and it's all, I think, to do with this mystique that doctors have that if it's 'Patang-a-kiprobang' if the doctor has to scrawl it on a piece of paper in a code that nobody else can read, then it's obvious that this is like a secret elixir, or whatever and it's almost like power is given back to the people if it is taken off prescription.

Throughout the interviews respondents demonstrated that they were the expert and knowledgeable regarding their smoking and smoking cessation. They understood what would work or not work for them and which option of NRT or other method would suit their particular circumstances. This expertise extended
to their own tailored prescription regime which could be described as being ‘scientifically appropriate’ to their needs (Gould et al., 1993). Respondents described how NRT worked, what combination of dosage, time and effort was needed to quit successful or the way NRT could be tailored to suit their desire to break free from the world of smoking. This personal expertise was demonstrated when respondents talked about their ideal method of quitting. Often the range of ideas captured the themes uncovered, such as privacy, control, and availability. This also explained why there were so many individualistic, tailored approaches to using NRT.

The most significant aspect of NRT, as either an Rx or OTC was the absence of a role for the pharmacist. As with doctors, so too were pharmacists bypassed for any influence they might have been expected to exercise. At the outset, this role was expected to be central. Initially, the transcripts appeared to make frequent references to the pharmacist. While the respondents related many stories about their experiences, featuring various characters including the doctor, family, and friends there were few that included the pharmacist to any depth, other than stories relating to a basic retailing role for the pharmacists.

It appeared that NRT, switching to OTC status, moved from the doctor’s control to the consumer’s control without involving the pharmacist. When the respondents described the battle for control between the doctor and themselves, the pharmacist was bypassed, as highlighted by Bob above.

The unique nature of smoking cessation and NRT may lead one to conclude that the product in this case would be atypical of OTC medicines. The fact that it
served as a replacement for cigarettes, the very antithesis of a medicine, suggested that the meanings of NRT as an OTC were unique. However, a further dynamic to power switching to the consumer was the marketing and promotion of NRT as an OTC. Such marketing efforts as mainstream television advertising, a common feature of OTCs in general, placed NRT and by association other OTCs further into the consumer domain. Once again, as demonstrated below, the power switched from the doctor to the consumer, bypassing the pharmacist. Most importantly, NRT was described as a consumer product;

Bob. Because it’s back to this thing about the powerful, the witch doctor medicine or whatever. So I think the problem with Nicorette is it’s a consumer product. It’s sold in the same way as washing powder, or sold in the same way as beer, or sold in the same way as anything that I can buy or have access to. So the doctor doesn’t get any brownie points for knowing that that is something I should have.

The logical extension of this point was that the switch of NRT to OTC status was only a point along the road to a further switch to wider availability. NRT was a consumer product; a replacement for cigarettes that did not require any health professional involvement. With control being of paramount importance, NRT required a further switch to facilitate even greater access, at least as broad as that of cigarettes;

Bob. And also, like I mean, the principle of it is wrong because if you can walk into a newsagents and buy cigarettes, then you should be able to walk in to a newsagents or somewhere else and buy a nicotine substitute. Because If you are controlling the replacement you are controlling the wrong substance. If cigarettes were available only on prescription then you could make a sustainable argument.
In summary, those in the break free group, whether successful or unsuccessful in their cessation attempts, were distinctive in the manner in which they used NRT. They had a clear sense of purpose when it came to using NRT, however idiosyncratic the role or purpose was. Specifically, their desire to maintain control of all facets of their cessation was pronounced. Control was crucial in deciding to quit, regulating their usage, and ensuring access to NRT at all times. In spite of this desire for personal control, it was clear that NRT, as an external factor, could be incorporated alongside the respondents' belief in their own personal control. While NRT could supplement their personal efforts, there was a clear sense that these personal efforts were the dominant force.

The need for control was also evidenced when the nature of NRT as a switch drug was explored. Given this group's belief in their expertise, the switch to OTC status meant that power and control, previously vested in the doctor, returned to the consumer. Interestingly, this meaning resulted in the pharmacist being bypassed in the switch to OTC status. Finally, the logical extension of the power switching to the consumer was that NRT required a further switch from being pharmacy restricted to availability in line with that of cigarettes.

5.7.3 Core Theme Two

*Staying in the World of Smoking.*

A number of specific themes emerged for those who used NRT to stay in the world of smoking. The experiences of these respondents were also characterised
by the meta-themes discussed above. To reiterate, these were the fact that
smoking cessation was not an illness and therefore did not require the
intervention of any medical professionals. Also, the unique situation of NRT, as
a replacement for cigarettes, meant that it was not a drug or medicine in the
conventional sense. However, the meanings of NRT differed significantly for
this group remaining in the world of smoking; the 'stay in' group.

What characterised the role of NRT for this 'stay in' group was the absence of
any purpose or function for NRT. Like Bridget, the respondents struggled to
describe what NRT did for them other than simply replace cigarettes. This
replacement role was all embracing, simply mirroring the place held by
cigarettes previously. Ann for example, constantly switched from smoking to
using NRT, depending on her health. While she appeared to be a successful
quitter when she was using NRT, the wider picture demonstrated that, in fact,
NRT was used to remain in the world of smoking. Another example of those
staying in the world of smoking was Mariann, who successfully quit smoking
but was using NRT for the past two years. The manner in which she paralleled
NRT with cigarettes was quite marked. The concerns about long-term usage of
NRT might well have been voiced by a smoker expressing concern over the
negative side-effects of cigarettes;

Yeah, yeah it is a dirty habit, a really dirty habit.....something I have to do....I was going to give
it up this year as my New year's resolution, I was going to give up Nicorette chewing gum, it
just didn't happen, didn't happen ... on New Years Eve this year I eh, coming back from Lexlip
and I eh called into the pharmacy there and I asked for a packet of Nicorette, and your man says,
at the counter, 'Ah yeah oh congratulations you know giving up the cigarettes, I says no actually
I gave them up a year ago, you know [laughs]

The lack of any role for NRT as part of a realistic cessation attempt was reflected
in the respondents’ understanding of the actual mechanics of NRT. Many failed
to grasp the basic function of NRT as a nicotine replacement. At the extreme was
Bernadette who went so far as describing NRT as a gimmick, a form of placebo,
with no actual function. This was in spite of her extensive experience of using
NRT over many years;
I don't think they are a replacement, it's some psychological thing to convince you. I don't know
if they actually do anything physically to you. I just felt it was some sort of psychological
gimmick to make you think that you are getting nicotine into you.

Hand in hand with this ignorance of any physical function went the absence of
any sensation, feeling, or ‘buzz’ when using NRT - a stark contrast with those
who used it to break free from smoking (page 149). It was perplexing to find
such a divergence on this point between the two groups of respondents, both of
whom were using the same product.
The break free group was in control precisely because they had achieved the
necessary ‘psychological distance’ from NRT. They had grasped its various
functions, mastered its dosage, experimented with its effects and understood the
sensation it could confer when cravings needed to be addressed. In the absence
of such psychological distance, the ‘stay in’ group lacked this ability to stand
back from NRT and gain an understanding and appreciation of how it could
function for them personally. In summary, it would appear that control is predicated on achieving some such perspective, some psychological distancing, from the object over which one aspires to exert control. It became apparent that the lack sensation, feeling, and impact from NRT for the ‘stay in’ group was due to their lack of instrumentality in using NRT. In effect this ‘stay in’ group chose to hand over control to NRT.

**Handing Over Control**

The prevailing understanding regarding NRT, and medicines in general, was that control over the cessation attempt was given over to NRT and the individual played little or no part. Two aspects of this loss of control were apparent here; the sense that anything ‘taken’, whether NRT or any other medicine should work on its own in an almost undetectable manner and the role that others, especially the doctor, played in taking control.

The manner in which control was handed over in the first sense above, was demonstrated by the advantage of the patch, which could be put on and forgotten about, knowing it would work away on its own. This contrasted with the gum that required effort on the part of the respondents, something that was not the case with medicines generally. Bernadette described the way in which the patch took control, emphasising that the patch almost intuitively knew when to give you a nicotine boost;
What I'd prefer about the patch is you can put it on and forget about it you can leave it there, you don't have to think about eating it like a piece of chewing gum. It's supposed to release nicotine when you feel like you want some, isn't it?

This contrasted with the excessive personal effort that was required to use the gum. For Lizzie, the gum regime simply required too much effort on her part. Throughout the interview she made constant reference to the problem of 'chewing the chewing gum'. This constant reference to and description of NRT as a mere gum was summed up when she described the occasion when she first got NRT. She was surprised that she had such a large role to play with this product and felt it odd to be in control of the product;

I snuck up to my room with the tape and the booklet and the leaflet and everything...and I read the little instructions like, I mean the amount of instructions that goes with this chewing gum is something else! for one piece of chewing gum, you know ... and like all its basically saying to you is all that's right, 'chew it, stick it in the side of your mouth, and when the taste goes away chew it again, and that's all their really saying, you know

She was emphatic about NRT being in no way like a medicine, again in line with all other respondents. However, her understanding of NRT not being like a medicine extended beyond the non-medical connotations highlighted earlier. NRT was unlike a medicine because of the excessive effort needed when using NRT. In addition, NRT, unlike medicines, would not produce a result. NRT would not 'get you off cigarettes' in the way that antibiotics would cure an infection. The following verbatim, while apparently about the inability of NRT to 'cure' smoking, reflects her understanding that NRT does not solve the
smoking problem on its own. Medicines, on the other hand, do tackle the various illnesses and disorders they are targeted at;

so I wouldn’t think of it as medicine now ... a medicine, if you take a medicine as well it clears something up so if, some people that better, you know if you antibiotics for clear something, by the time you’re finished the antibiotics it’ll be gone you know [yeah] but the nicotine, it’s not, you’re still em, still dying for a cigarette at the end of it, you know, its not making you better if you know what I mean, it’s not getting you off the cigarettes [yeah] no I wouldn’t see it as a medicine

This verbatim encapsulates the feelings of many of the stay in group on handing over control to NRT. Handing over control to NRT was not dissimilar to handing over control to medicines. Both were expected to work independently of any input or effort on the consumer’s part. This expectation was fed in part by the relative ignorance of these respondents. It is easier to acquiesce in some external agent when one has not the critical knowledge to assess its efficacy. So, this group seemed content at the outset to cede control to NRT; just as they did for medicines in the expectation that it would secure smoking cessation on its own. However, as was seen above, this expectation proved to be misplaced. Handing over control to NRT did not deliver the same dividend as handing over control to medicines.

The propensity to hand over control also manifested itself in a second way. Several respondents could still see the value in the former Rx status for NRT. Under the old regime NRT was under the control of the doctor. If the doctor prescribed a course of the product, the patient could cede control, abdicate
responsibility and simply follow the prescribed dosage and instructions. The doctor is in charge, the ‘patient’ simply ‘on a course’. The way prescription status facilitated this desire to hand over control is best summed up by Lizzie; and they go up to the doctor and say look my chest is killing me, my lungs, everything I have is in bits you know, where if you’re able to give me something to help me give try and give up smoking and if he can give them the nicotine patch on prescription, they will be there ‘That’s grand, like I know if I need another packet I can go back up to him, cause you know, you’re on a course then once you start you’re on a course [yeah] and like doctor supplies them with the patches you know

The extension of this issue of handing over control to an external force highlighted a further theme in this vein. In contrast to the respondents in the first group who saw willpower and NRT as complementary parts of the cessation attempt, the respondents who stayed in the world of smoking emphasised a dichotomy of control.

**Dichotomy of Control**

Respondents viewed NRT as almost in conflict with their own efforts to quit smoking. There was no sense that both forces could work together. The choice was to use one’s own resources or seek help from external forces. This fissure between personal and outside resources for control, between willpower and cessation kit is borne out in the following verbatim by Bernadette. However, in her case, expectations in ringing up the Nicorette help-line were coloured by the fact that, in her opinion, the only advice she received was to chew the gum itself.
She believed this advice in no way suggested utilising both willpower and the gum. She had hoped that the alternative to willpower might be something less mundane;

I thought it was just em, it said help giving up smoking, you know, and I thought it was just general help giving up smoking, and yet and withall you have to buy the nicotine chewing gum as well to help, like you it was kinda like he wasn't telling people to kind of give up with their own willpower, he was telling people to chew the chewing gum.....like oh don't bother with willpower, just chew the chewing gum and you'll be away, which I thought was lying, I thought lying you know

This incompatibility between personal willpower and NRT was further evidenced in the way in which the use of one resource was seen to minimise the impact of the other. Some respondents emphasised a loss of their willpower as a result of using NRT. In some way it was blemished or tainted by instance of the fact that it needed to be complimented by some agency in this case, NRT. For example, Lizzie understood that her willpower was used up in her first attempt to quit smoking without NRT. Using NRT on her second attempt meant that she was unable to go back to willpower as its efficacy was in some way weakened as a result of using an outside aid. Her first attempt to quit was successful, using her own resources. However, the next attempt was more problematic. Using NRT had emasculated her willpower, something that she regretted;

Lizzie. I don't know I think if your really kind of, if you really just want to give up the cigarettes you will give them up when, and if you don't give them up you really didn't want to go off them at all....[right]..... your willpower will do it, whereas if it done it for me the first time, just
willpower, and I went off them and I... and now when I think of it I wish I stayed off them, 'cause its a lot harder to go off them a second time then it was the first time.

So for the stay in group personal and external resources were incompatible. There was either an inability or unwillingness to employ one resource in tandem with the other. This failure to explore complimentary possibilities is not at all that surprising given that the tendency of this group to cede control to external agencies examined in the last section.

**Paradox of Control**

The manner in which both groups used NRT reflected different emphases on control, however, in the case of those who used NRT to stay in the world of smoking this control had a paradoxical dimension. Many of the respondents described their initial experience of NRT as a form of conquest. This conquest was over different aspects such as the taste, the side effects or the sensation often experienced when using NRT originally. It must be noted that this awareness of the taste or sensation when using NRT later gave way to the absence of such sensations. Such descriptions were not seen initially as significant or remarkable in the analysis. Adverse comments such as these had been expected. However, subsequently, it became apparent that such descriptions were in fact based on the respondents trying to demonstrate some control. Mariann described her history of using NRT in graphic detail. Time and time again she had battled against the 'horrible' effects of NRT, ultimately conquering such difficulties;
... started on Nicorette chewing gum and the very, very first one I had I thought it was horrible, I nearly got sick, made me vomit, nearly fainted, it was horrible stuff altogether, but then emm when I was eating, my appetite increased an awful lot, then I eh decided well yeah maybe I'll give this Nicorette another go ... when I went out at night and then I went off it and when my tongue swelled up, as I used it for a little while, and then my tongue swelled up and really really bad mouth ulcers, so I said right I have to give these up, so emm, when that all went away I went back on it again,

Such dramatic demonstrations illustrating how the respondents conquered the distasteful or distressing aspects of NRT, actually masked the reality that NRT had in fact taken full control of them. Mariann, in her description illuminated this paradox. In her experience NRT had taken over completely, consuming her; Mariann. Its a distraction, it is, it is a therapy in a sense that..., you know you do em, you do become totally consumed by it and you kinda eh, its counselling and its eh therapeutic in the sense that it does relax you, so yeah, it is a therapy...

So for Mariann her 'control' over NRT consisted primarily in controlling and minimising some of the distasteful side effects of the gum. However it did extend to her being able to control the overall impact of NRT on her life. The NRT managed her, not vice versa. Apart from this paradoxical side to their control, this stay in group can be summarised as follows.

Those who used NRT to stay in the world of smoking were characterised not so much by their failure to quit, but by their inability to see any role for NRT other than as a direct replacement for cigarettes. When it came to control, they understood that control rested with an external agent – in this case either the
product itself or the product as prescribed by a medic - and that it was not possible to combine one’s own resources with such an external agent. Given this overall disposition, this group tended to invest most of their confidence and expectations in such outside agencies and remedies. Control was readily surrendered; something that may well have something to do with the fact that members of this group had never in effect left the world of smoking.

Although these respondents used NRT to stay in the world of smoking and often directly replaced cigarettes with NRT, their cessation attempts must be seen as genuine and equally as valid as the attempts of those who used NRT to break free from smoking. The objective here is not to advance reasons for success or failure in cessation much less to determine the contribution if any that NRT played. It is the meanings of such a product that are important.

While section 5.7.2 and 5.7.3 have highlighted themes that differentiated each group from the other, break free group from stay in group, this contrast between them will conclude by discussing features of NRT that they actually had in common. This commonality was a result of their understanding that smoking cessation was not curing a sickness and therefore NRT can be liberated from the restrictions of medical sanction and this wider availability can in turn facilitate aspects such as privacy and personal choice. Despite this general consensus, the meanings of NRT as an OTC were paradoxical to some extent between the groups. Those who used NRT to stay in the world of smoking emphasised that it was in no way like a medicine. Yet their understanding of the ideal crutch or tool to help them quit was something that was legitimised by medical professionals
and that functioned in a way similar to the way they perceived medicines to function.

In contrast, those who broke free from the world of smoking treated NRT like a medicine which for them meant something they could incorporate into their own personal regimes and self-medicate. Indeed they emphasised the need for greater access and autonomy by moving NRT away from the medical arena into more mainstream distribution and retailing channels.

Before moving on to examine the themes uncovered in this research in relation to the literature in chapter two, two further themes are outlined. Their separation from the main themes is due to their non-linear nature. These themes were viewed as significant but isolated and could not be seen as indicative of the experiences of all respondents. They do not relate to the break free, stay in distinction in any systematic way.

5.7.4 Non-Linear Themes

Medicines are only Rx.

For those respondents at the lower levels of income, OTCs were in no way viewed as being within the medical arena. While this was not surprising for NRT for the reasons outlined above, it became apparent that for other drugs this was a defining issue. All OTCs, including NRT, were simply not medicines. The notion of a switch drug per se was essentially meaningless.

When it was a question of health the doctor was the only route, and the outcome being a prescription for a particular drug. Since OTCs did not involve the doctor
they were not seen as medicines. This meant that OTCs were viewed as a waste of money or irrelevant, as eloquently described by Lizzie:

Well if I have to get vitamin tablets or whatever, I'd just go in and pick it up, but say the likes of em, cough bottles, I just, if I have a cough or a bad flu, I'll just go up to the doctor and say Ah here, got a bad flu, can't breath or whatever, which like I'm always stuffed up or whatever [yeah] and he'll say well get blah blah drugs or write it down on a prescription or whatever, but I wouldn't go into like a chemist and just buy stupid stuff for, just for the sake of it, for having it in the medicine cabinet or whatever like ...

Lizzie was surprised that a product that was ‘only a gum’ without medical associations actually involved a range of side effects and a complex set of usage instructions. While this was in no way unusual for respondents describing NRT, it became apparent that Lizzie’s emphasis on the complexity of a simple chewing gum was symptomatic of her view of anything that could be bought in the pharmacy. OTCs were not viewed as complex, serious, or effective medicines;

I snuck up to my room with the tape and the booklet and the leaflet and everything..and I read the little instructions like, I mean the amount of instructions that goes with this chewing gum is something else! for one piece of chewing gum, you know ...

If Lizzie was surprised by the complexity of OTCs, she was equally surprised by its efficacy. OTCs as seen previously were not medicines and therefore could not be expected to share in any of the benefits or efficacy of medical products. Her experience of using an OTC recommended by the pharmacist, that successfully cured a sore throat, came as a complete surprise. She did not intend to purchase an OTC, but was forced to do so because the doctor’s surgery was closed.
Despite the success of this isolated OTC she still expressed an inherent reluctance to use OTCs;

And she gave me, she’s very good and they, so I started taking it and it is its actually, I actually made, I didn’t believe it myself, its actually good like, but I wouldn’t be mad to go into places you know to like, buy any, stuff there was no need for like [yeah] you know.

Ann mirrored this understanding that true medicines were those prescribed by the doctor when she contrasted going to the chemist as opposed to going to the doctor. Anyone who had a minor complaint was wasting their time going to purchase an OTC on his or her own initiative in the chemists. The only occasion where medicines should come in to play was when the doctor had legitimised the illness;

Ann. Ah there’s people go in to the chemist, go in for this I have a pain in their finger and they want to run to the shagging chemist but, run to the doctor, but you just have to wait to see, takes it’s own course [yeah, yeah] you know it gets better, it gets better, which a lot of things do, and then if it gets worse go to your GP.....

Rx is Free, OTC You Pay.

An extension of the preceding theme, among the same respondents, was that there was an implicit understanding that when the doctor provided a prescription, the recipient would not have to pay. This issue, the reimbursement of prescription charges or State coverage of health care costs, is outside the boundaries of this study. However, the implications for OTC drugs appear crucial; OTC status meant paying for the drug in the minds of these respondents.
In the following simple extract, Ann captures this issue. The inquiry revolved around her experience of asking the doctor to allow her use the patches;

I. Okay, and did he give you a prescription for it {patches} or what you...
Ann. No I have to pay him ... Yeah, if the doctor could, if he could give you the prescription, but he can’t [yeah] you have to pay for them yourself.

This financial burden only compounded the futility of purchasing OTCs. Not only were they ineffectual but, unlike ‘real’ prescription medicines, you had to pay for them.

5.8 Summary of the Emergent Themes.

This section will attempt to give an overview of all the themes to emerge. The most striking aspect of the themes that emerged was a lack of focus on health, albeit that most respondents alluded to health ‘concerns’ as reasons for quitting smoking. This aspect was given further credence when one considered the nature of the interviews, which focused extensively on the respondents’ preventive health behaviour. In reality, most respondents who owned up to a desire to improve their health through smoking cessation rarely articulated this in any great detail. The relationship between respondents’ presents health status and their future health status if they continued to smoke did not arise in most cases. If future health status was not a factor of respondents’ use of NRT, control certainly was.

Indeed the notion of control was arguably the most significant and overarching theme to emerge in this research. Put succinctly, smoking cessation does not
involve curing an illness, it is outside the provenance of professional medical providers, as such it enjoys OTC status and can lend itself to a range of self-controlled regimes and self-medication.

Indeed, this latter theme was the grounds for separating respondents into two groups; those who chose to exert control over their use of NRT and break free from the world of smoking and those, for whatever reasons, chose not to explore these possibilities, and relinquished control to NRT thereby leaving themselves still within the world of smoking. Each of these groups had their related repertoires of meanings. These meanings were seen to relate to the degree of distance the real/potential quitter had created between themselves and the world of smoking. In the case of the break free group this distance permitted them to envision a clear and distinct role for the product, to grasp how it could be used in tandem with other supports, and to assume control over dosage and timing of cessation. On the other hand, those respondents who did not enjoy this distance saw no function for NRT other than that of a cigarette substitute. They readily relinquished control to NRT, as they did to all medicines (even though NRT was not itself seen as a medicine) and trusted that it would produce the desired result without any demands being made on their own internal resources. Control for this group was only understood in a rather reactive sense – the ability to overcome the negative side effects of NRT. There was scant evidence of any proactive ‘managerial’ meanings attaching to their use of the product.

In terms of the significance of switching, almost all of the respondents viewed it as an irrelevance in the case of NRT. The consensus favoured increasing the
availability of NRT even further for a variety of reasons. In the wider context of prescription drugs achieving OTC status, there was a certain understanding that better, stronger drugs came this route. However, over and above the strength or lack of strength of OTCs, the key issue was the removal of certain barriers; barriers, which had denied consumers, access to such drugs previously.

Such sentiments expressing the change of status in terms of barriers removed reflected an understanding that power switched from the doctor to the consumer. The traditional mystique of the doctor and the secret coded nature of a written prescription ensured that the doctor retained power and remained in control. In the case of NRT this power of the doctor was clearly bogus. The switch to OTC status had given power back to the consumer; power that rightfully belonged to the consumer.

The logical progression to the above point was that NRT in particular, and OTCs in general, were clearly established as being within the independent consumer's remit. At no point did the pharmacist appear to be of significance, other than as executor of the doctors' instructions by acting as the retailer for prescriptions written by the doctor.

As the individual was the hub of his or her smoking cessation efforts, the role that NRT played revealed much about each respondent. The distinctive nature of the usage, compliance, length of regime, and 'knowledge' developed about NRT by some respondents demonstrated that there is clearly an autonomous health care consumer, who develops their own 'scientifically appropriate' understanding of the role NRT could play. The paradoxical and idiosyncratic
approach to taking NRT contrasted with the traditional view held by the scientific/medical community regarding prescribing and compliance for drugs generally. However viewed as a learning or accumulation of personal experience by the respondents, the unconventional, non-traditional and personalised usage of the product took on a clear and more coherent aspect.

Overall, no simple picture emerged of the factors that could lead to successful smoking cessation using NRT. It was not the characteristics of the product, as either gum or patch nor the strength or dosage that determined whether NRT would prove successful. Individual respondents adapted NRT to their own needs, based on the meanings NRT held and the role that the product could play. The traditional view of a product having one purpose or function is clearly not relevant for those using NRT.

5.9 Thematic Findings in the Context of the Current Literature.

This section examines the findings in relation to the two theoretical homes identified in chapter two; self care/self-medication, and consumer preventive health behaviour. The themes identified in the previous section are those that emerged from the process of interpretation and no attempt was made to shoehorn the themes into the categories identified in the literature. This creates some difficulties when trying to compare this study to cue-based, primarily quantitative, data in the current literature. An extension of this point is that the methodological approaches between this study and the literature differ to a great extent. For example, what is considered significant in this study of ten
respondents is compared to representative, generalisable data from previous studies. However it is both possible and desirable to examine the findings in this study in the light of the current literature. Such an approach is recommended by Thompson (1990). The findings will be contrasted with the current literature by highlighting any conflicting aspects or any new findings. Elements of the findings that concur with the current literature will be reiterated where necessary. First the findings will be contrasted with those in self-care/self-medication literature. In terms of switch OTCs, this study demonstrated significant differences in relation to the typical user profile of OTC medicines. While there was a large proportion of the respondents who could be described as young, educated, and exhibiting 'consumer sophistication', there were respondents who could be described as being diametrically opposed to this classification. In fact, some of the more independent, strong-willed respondents were older and less educated. This may be due to the extra-medical status of NRT, and in normal circumstances an OTC would be not the preferred option. But then again, Bridget, who was older and less well educated sought OTCs whenever possible and did so whilst remaining reliant on the doctor in the conventional sense. For such respondents, prior prescription history was a positive factor in OTC usage, ensuring safety rather than efficacy. Perhaps switch OTCs need to be examined without the assumption that the older, less educated are more reliant on the health care system generally.

The switch to OTC status impacted solely on respondents’ views of the availability and access it afforded to NRT. It did not impact on their views of its
efficacy. In fact, NRTs’ non-medical aspects negated any efficacy issues completely. When it came to OTCs in general however, there seemed to be a haziness and lack of clarity concerning the links between Rx, switch, and OTC both with regard to grasping the schematic properties of each and their respective efficacies. However, with specific reference to switch OTCs, the properties of safety and reassurance, resulting from their previous prescription status appeared more important that any change in their strength or efficacy. Put simply, all these respondents needed to know about a switch drug was that the medical profession had agreed to its deregulation and that it was safe to use. Indeed it probably had been safe all along.

The literature in chapter two suggested that an OTC such as NRT would not be part of the doctor’s remit and that, as a result, greater influence would accrue to the pharmacist. The results of this research did support the absence of any substantive role for the doctor, however, surprisingly, there was little or no support for any input from pharmacists. Their principal purpose was to function primarily as retailers rather than advisors. The self-care literature also acknowledges the role of the pharmacist’s assistant as an information source in the purchase of OTCs. This role is supported in the current research. However a caveat should be entered as respondents who spoke to such assistants or asked for their advice showed little evidence of implementing or using it subsequently. The literature demonstrated that there was a contrast between consumers citing something as an information source and actually using this information in their purchasing. In this study, the pharmacy was mentioned in the context of its
retailing role rather than as a provider of product information utilised by the respondents in their usage of NRT. The little information sought or received by the respondents was indicative of the peripheral role the pharmacist played, where little contact or dialogue was the norm.

In a wider context, lower income, and perhaps lower education, illustrates a key issue for OTCs. Income has been relegated to a secondary position as a concern in health care, principally because the health care system takes care of those in such circumstances. For these people in society who rely on the medical card system, OTCs and self-care were viewed as an irrelevance, wasteful, and ‘not part of the system’. Any focus on encouraging consumers to adopt a more proactive approach to health care or to self-diagnose, self-medicate, and of course pay for a range of OTC medicines flies in the face of the meanings associated with OTCs for these consumers.

The final issue for self-care and self-medication related to sources of information. The literature indicates two main approaches taken by consumers in sourcing information on OTCs. The first of these sources is the pharmacist and/or the pharmacist’s assistants, which was discussed previously. The second source of information on OTCs identified in the literature can be grouped together under the area of sources other than health professionals; mainly family, friends, or word-of-mouth. This area appeared relevant for respondents in this study, using NRT. Much of the ‘information’ about NRT that the respondents relayed appeared to be a mixture of facts, stories from friends, and the respondents’ own expertise, resulting from their use of NRT.
Overall, what shapes consumers' behaviour or usage appears to be the meanings ascribed to the information rather than the source of the information as such. The profusion of information in health care generally through leaflets and media campaigns and the emphasis on specific sources of information in health research in particular may result in a neglect of the pivotal role played by a variety of interrelated, informal beliefs and meanings. These meanings exert a tangible impact on self-care despite there being neither knowledge nor concern as to where they have come from.

Next, turning to preventive health behaviour, it is worth reiterating its scope as defined by the literature to highlight a number of broad observations. The literature defines preventive health behaviour as being primarily concerned with the performance of the behaviour itself, in this case smoking cessation. In addition, while not central, preventive health behaviour it is also closely related to the treatments and structures of health care. In this study, the treatment, NRT, would appear to be central to the performance of the health behaviour, smoking cessation. NRT appeared to both define the manner in which the behaviour was conducted and reflect the characteristics of the respondents themselves. Both the break free group and the stay in group were defined by the way they used NRT. For example, in the case of the break free group NRT facilitated their need to exercise control over their cessation. In the case of the stay in group their use of NRT was reflective of their belief that it would work on its own and achieve successful cessation.
Another overall aspect of the literature which merits attention is the three areas that have been identified as being the primary concerns of health behaviour researchers; the performance of the behaviour itself, interaction with health professionals, and the acquisition of information (Gochman, 1988). The first two aspects are clearly relevant to this study. Before detailing the performance of the behaviour itself the two other areas will be addressed.

With regard to the second area, interaction with health professionals, the assumed role of such professional was tenuous at best in the majority of cases. In the minority of cases where there was such a role, the health professional’s advice was often adapted and modified to suit personal ends. The final aspect as indicated above, the acquisition of information, requires research to address the meanings associated with the actual information rather than its contents or sources. For example, the focus in the literature revolving around the amount of knowledge held by consumers neglects the manner in which the knowledge is used. Respondents in this study volunteered a range of so called information that they had gathered from a variety of sources, including doctors, friends, family, and the media. What was important was the way this information was distorted and the credence that the respondents gave to this information. Ann, for example, believed that smoking and wearing the patch was ‘allowed’ provided it was only in the morning. In her opinion, this gave her licence to combine the patch with cigarettes. This issue clearly relates to the nature of knowledge in terms of subjective knowledge. It is not the content of the knowledge per se but the
manner in which it is used that is significant. Meanings not amounts of knowledge are crucial to understanding its role in smoking cessation.

Turning to the actual behaviour itself, eight consumer characteristics were identified in the literature as being salient to performing any preventive health behaviour. The findings in this study, in relation to these characteristics, will be discussed by focusing on their apparent differences with those in the current literature. Also, these findings relating to the characteristics will be presented in order of their significance.

Clearly the most important characteristic in this study was locus of control. Most of the findings in the current literature on this topic were supported. The ability for the different types of locus of control, internal and external, to act independently (Lau and Ware, 1982) was clearly evidenced with the break free group exhibiting their belief in the importance of their own efforts while at the same time expressing a belief in the efficacy of NRT. A significant factor was the manner in which self-control was clearly ‘in control’ of the external agent, NRT, despite the belief in NRT's efficacy.

Another notable feature of control in this study was the extent to which a medicine - an OTC in this case - could act as a powerful other health locus of control factor. While powerful other health locus of control includes a belief in the role of the health care system generally, and could arguably include the medicines provided as part of that system, medicines on their own have not featured in the literature to date.
The fact that an OTC can act in such a distinct pronounced fashion might stem from an OTC being a product with an identity, brand name, and even a personality. Also, the more an OTC is removed from the health care system, the greater the propensity for an OTC to develop its own web of meanings in the minds of consumers. Unlike prescription drugs, whose names, origins, and contents are unfamiliar, unpronounceable, and unapproachable due to the control of the doctor/pharmacist, there appears to be a closer relationship between consumers and the OTC products they choose independently. While this is well-documented in consumer behaviour literature, it merits attention in health care research on the use of OTCs.

Other aspects of locus of control did appear, though not central to the meanings generated in the analysis. In Lizzie’s and Ann’s cases there was evidence of the belief in chance health locus of control that resulted from the impact of prior family illness. However, these instances appeared to be of little significance in their usage of NRT. In a similar vein, the impact of prior self-care experience on internal locus of control (Lau, 1982), such as using other OTC medicines, did arise in the break free group but cannot be viewed as central to their usage of NRT.

The second area of control which was significant in the context of the current literature was behavioural control; the individual’s belief in their ability to perform a health behaviour (Bandura, 1977). The significant aspects in this research were the polarisation in the respondents’ views on their ability to perform the behaviour and the manner in which behavioural control could be
modified or controlled. The interesting aspect of this behavioural control, often termed ‘willpower’ by the respondents in the study, was the way in which NRT could influence this behavioural control.

On one hand, the expectation of the stay in group, that medicines work in an independent fashion, meant that they felt the need to disengage and hand over control to NRT. It is reasonable to assume that these respondents believed that they could quit smoking using NRT at the start of their cessation efforts. They probably had a positive compliment of behavioural control at the outset. However, it appeared that by handing over control to NRT, their behavioural control was diminished. Also, there was a dichotomy of control between the individual and NRT in this stay in group. It was impossible to believe in one’s own ability to perform the behaviour if one handed over control to an external agent.

On the other hand, respondents in the break free group took a more pragmatic approach. They viewed NRT as an addition to their armoury and something that could be added to their individual efforts. Behavioural control could be managed, supplemented, or even rewarded, as evidenced in Bob’s case. Rather than viewing behavioural control as a stable characteristic, it appeared important to adopt a more fluid approach to its role. It could be modified, adjusted or even diminished through the use of a product such as NRT.

Behavioural control appears to be of particular importance in smoking cessation, where numerous attempts are made and many different approaches are tried. Prior experience with the behaviour is identified as a determinant of behavioural
control (Kok et al., 1991). For the stay in group, who relinquished control to NRT in the belief that it would work on its own, successive attempts to quit may continuously erode their behavioural control. Two other influences on behavioural control have been identified in the literature. These are the observation of others performing the health behaviour and the persuasion of others when one is performing the behaviour oneself. Given the individualised, personal, and private nature of smoking cessation identified in this study, it is unlikely that behavioural control could be influenced in this manner.

Income was identified as being peripheral to consumers’ preventive health behaviour in this case, in agreement with the literature generally (Grossman, 1982). This is due to the nature of such a characteristic, which, while important to the individual, is not viewed as a core behavioural characteristic. In the case of smoking cessation, the actual cost of NRT in comparison with the cost of cigarettes is not an issue, although some studies report saving money as a reason for quitting.

What was surprising was the meaning of an OTC for the lower income respondents. In such cases, OTCs, as a result of being paid for by the respondents rather than being provided gratis by the doctor through the medical care system (GMS) were not seen as medicines in any sense. Medicines came from the doctor only. The added insult in the case of OTCs was the fact that, in addition to not being medicines, they had to be paid for. This applied in the case of NRT and to OTCs generally. While it can be argued that income is not a
behavioural characteristic, such an assumption is not appropriate in the case of OTCs.

The role of health knowledge also needs attention. As indicated above, in relation to the sources of information used in OTC selection, health knowledge must be more concerned with the nature and meaning of information, rather than the volume, scope, or content of the knowledge. The literature does indicate that health knowledge should focus on what individuals believe is under their control, rather than the actual knowledge pertinent to any behaviour (Park and Lessig, 1981), but this has received little attention. The concept of an illness career (Gould et al., 1993), comprising the accumulated experience and knowledge an individual gains through the course of an illness, is perhaps the correct approach to adopt when exploring health knowledge. Health knowledge, in this context, consists of a range of facts, anecdotal evidence, and personal experience; an evolution of detailed knowledge that increases self-efficacy. The benefit of such an approach to health knowledge is the recognition that highly individualised regimes developed by individuals engaging in health behaviours are the norm. They should not therefore give rise to undue concern on the part of those who lay stress on strict compliance in the consumption of medicines.

One characteristic, age, did appear to be significant, albeit in one case in this study. Age is typically viewed in the same manner as income; less a behavioural characteristic and rather something the health care system makes adjustment for, through a range of controls, for example, through the issuing of a prescription. Young and old are therefore to be totally covered by the health care system for
all their needs. This of course does not include OTCs, which have to be paid for by all age groups. This oversight has meant that health behaviour research to date has failed to address the possibility that younger age groups, in particular teenagers, might attach their own specific meanings to NRT in particular. This seems quite remarkable given that smoking begins in this age group and that cessation campaigns directed at them have proven so unproductive.

The other characteristics identified in the literature, health status, health motivation, and education, did not highlight any significant features in this study. Certainly health status exhibited its double-edged nature (Moorman and Matulich, 1993), operating on one hand as a driving force for those with poor perceived health status, encouraging them to engage in a preventive health behaviour. On the other hand, good health status could operate as an inhibitor to respondents engaging in preventive health behaviour; those in good health status seeing no need to engage in any preventive health behaviour.

Health motivation identified in the literature as playing no role in primary preventive health behaviours (Moorman and Matulich, 1993), especially smoking cessation, was also evident in this study. Health motivation, as an antecedent in health behaviour, appears to be less important over the course of engaging in a health behaviour. What appears to be of greater importance is behavioural control in the manner in which willpower can be altered, enhanced or diminished throughout the performance of a health behaviour.

The final characteristic of the eight preventive health behaviour characteristics, education, was positively linked with the acquisition of information (Feick, et
al., 1986) and the wider desire to improve lifestyle. As such it is not a core behavioural characteristic. Lower education levels are clearly associated with higher levels of smoking in the wider population but this study did not aim to measure such factors. Clearly the role of education in relation to the acquisition of information needs to focus on the meanings and usage of such information, rather than its volume or source as outlined above.

In summary, the findings in the context of the current literature highlight a number of important issues. Most important is the need to combine the two theoretical areas of self-medication and preventive health behaviour in order that a better understanding of such behaviour is achieved. This means incorporating the use of medicines, especially OTCs, into the framework of factors that influence or guide health behaviour. In other words, to see what light if any might be gleaned by looking at how self-medication might impact on the eight independent preventive health behaviour consumer characteristics. In the context of individuals using NRT and other OTCs, such individual, personalised product usage is an integral part of their behaviour.

This would make a new departure in both bodies of literature on self-care and preventive health behaviour. Gochman's definition of preventive health behaviour states what is not health behaviour; it is distinct from the treatments, structures, and organisation of the health care delivery system (Gochman, 1988). This study on the other hand highlights the fact that the treatment, NRT, does appear to be central to the performance of the behaviour and the nature of the characteristics. The performance of the behaviour itself, smoking cessation, was
completely dependent on the manner in which NRT was used. The manner in which respondents started their cessation, continued it, and completed it was a function of the product, NRT. In addition, the respondents' usage of NRT reflected and illuminated their characteristics and, more importantly, shaped them. For example, the stay in group required products and agencies they could hand over control to. NRT was seen by them as such a product; it would perform the 'donkey work' of cessation in lieu of their own efforts. This understanding of how NRT worked had a considerable impact on their sense of behavioural control. So, behavioural control, one of the eight characteristics mentioned previously, far from being an antecedent internal variable affecting behavioural control, was in fact seen to be mediated by the nature of the treatment used in pursuit of that goal. In light of this it should be obvious that health behaviour research should begin to address the broader area of how health-related products or treatments are an integral part of preventive health behaviour. In consumer behaviour terms this reflects the truism that the study of consumer desires and meanings cannot be divorced from the study of the products and services used to achieve them. As a result the boundaries of health behaviour research need to be expanded.

The second core issue is that the switch process, for NRT as least, is not relevant to consumers. Perhaps this is surprising from a health perspective, given the emphasis on 'structures', but it reflects a new understanding of the consumer who is no longer in awe of the health professionals and the health care system. In fact, the autonomous health care consumer has a greater understanding of the
elements of the health care system and less mystery surrounds the doctor in particular. What is important to the consumer, for NRT at least, is access and availability, and the privacy they afforded. The switch is primarily viewed as a process that is the concern of the health care authorities rather than something that affects the product being switched in any intrinsic sense.

Viewed from the consumer’s perspective, a product switching to OTC status moves into a world where the modern day, sophisticated consumer is in control. This is in complete contrast to the health care or pharmaceutical arena, shrouded in mystery where the expert, the doctor, holds power. As a result, it is the meanings as determined by the consumer that dictate the role that a product, such as NRT, plays in the consumer’s behaviour, not the intended meaning of the producer, in this case the manufacturer. In fact, this perspective on the production of meanings can be extended to research on such behaviour. It can be emphasised here that adopting a consumer-centred approach facilitates the uncovering of meanings, meanings not originally anticipated at the outset of this study.
Chapter Six

Conclusions, Implications, and Future Research.

6.1 Introduction.

Health care research has been dominated by a variety of disciplines, such as psychology, pharmacology, and sociology, but has received little attention from the field of consumer behaviour. As a result the 'consumer' of health care has been viewed more as a patient, especially in the scientifically orientated medical community. While there is recognition that consumers are increasingly more powerful, vocal, and autonomous in their health behaviour, research on consumers' health care is limited.

The centrality of the consumer's role in their health care behaviour continues to increase with the advent of self-medication and a more preventive orientation being adopted by consumers. The most apparent manifestation of these changes is in the rise of OTC drugs. Today there is a wider range of OTC drugs, many of which can be described as complex both in terms of their make-up and in terms of the medical conditions they are intended to address.

The switching of prescription drugs to OTC status has been the main reason for the increase in OTC drugs of this nature. Even so, switch drugs have received little focus and attention from the medical profession and health care researchers. Perhaps the medical community views them as being peripheral to the health care system. An imperative rests with consumer behaviour researchers to address this switch drug phenomenon for a number of reasons. First, the nature of switch
OTC consumption, including their purchase and use, together with the nature of switch OTC marketing, places them in the domain of an everyday consumption activity. As an everyday consumer activity OTC usage can now be considered an appropriate area for consumer researchers. It seems reasonable to suppose that, after five decades of study, consumer behaviour will be able to shed some light on this growing phenomenon. Also, as consumer research continues to widen its horizons, examining every facet of everyday life, the horizon should include the consumption of health care. Health is such a central aspect to individuals that a better understanding of such an area could deepen understanding of many other aspects of consumption.

6.2 Towards a New Understanding of Consumers, Consumption, and Health Care.

The consumption of OTCs should be viewed as a consumer behaviour phenomenon and not simply a research topic for the medical community. For this reason, health care research must shift the discourse to one of discussing consumers rather than discussing patients. For example, much of the research on NRT has been in the form of strictly controlled medical clinical trials, far removed from the actual nature of its everyday use. However simply adopting a basic consumer focus is insufficient. Some consumer researcher has developed an altered understanding of the consumer; essentially an interpretive view. This view emphasises the central role that the consumption of products can play and the meanings that ensue and inform such consumption.
The topic of smoking, and smoking cessation in particular, has been dominated by a scientific/medical orientation, with smokers and those attempting to quit smoking often portrayed as helpless addicts to nicotine. However this study has illustrated that many consumers remain in control of their behaviour and develop their own personal methods and regimes in their smoking cessation behaviour. In fact, aspects of personal control were the key themes to emerge in this study.

More importantly, the consumption and ensuing meanings of NRT were not always those intended by the manufacturer but were dictated and shaped by the consumer. Such an understanding of consumption may be far removed from view of the medical community, however, in this study, these meanings were readily volunteered and were not the product of any anti-medical establishment agenda. It is the respondents relaying their experiences that has uncovered these patterns. As a result, future research might benefit from adopting a more consumer orientated holistic focus, examining what the consumer does with the product rather than what the product does with the consumer. In addition, the thrust of this research should be more open-ended and sensitive to the range of personalised meanings and regimes that consumers engage in.

This post-positivistic view is in contrast to the implicit assumptions in much research on smoking cessation and switch OTCs. These assumptions are based on the expectation that OTC usage generally, and NRT in particular, are primarily health behaviours that include doctors and pharmacists as central figures. This study clearly rejects these assumptions. The meanings of NRT to consumers in this study were primarily concerned with the role that the
consumers themselves had generated. This may be due to the product itself, being seen more as a cigarette replacement than a cure for an illness or sickness. Even so, the fact that control and power could switch to the consumer, rather than being mediated by the pharmacist for example, suggests that the meanings of OTC consumption need to be addressed in a wider context than traditional health care alone. The fact that NRT research has been medically sponsored and that the product itself has only being available through what might be termed ‘medical’ channels may have blinkered researchers to the breadth of non-medical meanings that consumers attach to it.

6.3 Implications for Switch Drugs.

Although this study only focused on one switch drug and while there appear to be a variety of unique facets to NRT, there are some important implications for switch drugs generally. Put simply, the switch of a drug from Rx to OTC status was not important for the respondents in this study. Either the respondents struggled to grasp the concept or were primarily concerned with other aspects. For example, the key implication of the meanings that emerged for NRT was the expressed desire to widen availability and reduce the barriers to access; essentially a further switch outside the confines of the pharmacy. Apart from the obvious financial benefits to the manufacturers, there is a clear consumer demand to widen availability beyond the pharmacy channel.

NRT, in the eyes of the users, was outside the medical domain and this aspect should receive more consideration. The expressed desire for privacy in the
respondents' efforts to quit smoking also needs attention. As a result the role of health professionals in the campaigns to either reduce the number of people taking up smoking or help those smoking to quit needs to be reviewed. The impact of this research is that the importance of medical professionals in the smoking cessation process may be less decisive than was thought hitherto.

In the wider context, meanings of safety and security were more important than meanings relating to efficacy for respondents in this study. The switch did not mean that the drug had become any more or less effective but it did mean it was safe to use. Doctors simply would not have agreed to waive the prescription requirement unless it was safe to do so. This security could be described as a halo effect of the doctor's previous ability to prescribe a given drug. This contrasts to the received wisdom that efficacy, the power of the product itself, can be either diluted when switched to OTC, or alternatively it can be enhanced as a result of a drug's prior prescription history. Again it is the consumer perspective that dismisses the assumption that changing product efficacy is a prime concern.

6.4 Implications for Health Care Policy.

There are two areas of consideration in regard to health care policy - OTCs generally and smoking cessation in particular. Probably the most far-reaching implication is the position of OTCs in the health regimes of those at lower levels of income, the medical card holders. While this study does not purport to generalise to the wider population, OTCs, for those at lower income levels, were
viewed as irrelevant and costly. The desire of health care policy makers to reduce the expenditure on drugs through the current medical card system, and the much promoted benefit of OTCs as a first step in health care appears at odds with some consumers relying on the doctor to legitimise illness and provide free prescription medicines only.

Throughout the health care system OTCs receive little focus and attention and can be viewed as being on the periphery. The move to switch prescription drugs is being driven by the pharmaceutical industry with little proactive effort from regulatory authorities. Switch drugs use a range of marketing techniques, such as branding and advertising, and this opens up a new array of meanings in the mind of consumers. Most importantly, OTC consumers are competent and marketing literate as a result of their everyday experiences of many other product categories and that they are likely to absorb, modify, and construct meanings associated with OTCs as they do with any other mass-market goods. For the moment however, OTCs, on foot of health policy restrictions, remain confined to the pharmacy and health policy makers may well assume that these restrictions inoculates OTCs from this meaning-making process. This research suggests that in so doing they are quite mistaken.

Health care policy for NRT in particular needs review, given the findings in this study. Of primary importance is the need to clarify the policy on NRT itself. Given that reducing the levels of smoking in the population is one of the major aims of health care policy, there is ambivalence towards the role NRT can play. It has been demonstrated elsewhere that NRT is probably the best option for the
remaining smokers in the population as they are usually more 'nicotine dependent', yet NRT has received little overt support in health care policy.

This study highlights a number of important points in relation to NRT. First, allowing consumers to describe the role played by NRT in their smoking cessation, it was apparent that NRT was outside the medical domain. NRT was described as a simple, consumer product, and a direct replacement for cigarettes. As a result, the priority was for even greater access to NRT. Second, although evident in only one respondent's case, consideration needs to be given to younger teenage smokers who wish to quit. Again there is a lack of direction on health care policy towards this particular problem, although many commentators have highlighted the growth in teenage smoking, especially among females.

6.5 Implications for Health Professionals.

The switch to OTC status for a drug suggests a decreasing role for the doctor and an increasing role for the pharmacist. While the former was certainly evident, the latter was not. To understand this it is necessary to look at the result of the drug switching to OTC status. From the viewpoint of the medical community, a drug changes status within the medical system. However from the viewpoint of the consumer, a drug moves from the domain of the doctor into the domain of the modern day, marketing literate consumer. Essentially in the consumer's eyes, it is a move from the dispensary to the marketplace. The result is that the doctor looses his/her control of power and knowledge but this control of power and
knowledge bypasses the pharmacist completely, switching entirely to the consumer.

This study suggested a minimal role for the doctor in particular, especially in light of the product chosen for the study, NRT. In this study doctors were heard but not listened to. While they advised respondents to quit smoking this was seen as conversational foreplay before the real purpose of the visit was addressed. Doctors were perceived to advocate cessation simply because this was what they felt they should do. Nonetheless, the doctor did appear to play a role of sorts in the consumer's use of switch and OTC drugs generally. The doctor could, in a tacit way, add a sense of safety and security to the use of an OTC if it had a prior prescription history. One area where the doctor could play a greater role is in the broad promotion of OTCs as a realistic option for their patients, in place of prescription drugs. Doctors are at the front line and are ideally placed to help 'switch' consumers to OTCs.

OTCs are often presented as an opportunity for pharmacists to use their professional knowledge to assist consumers in their product choice. As illustrated previously, the pharmacist is not utilised to the extent cited in the literature. This applies not only to NRT, but also to OTCs in general. Essentially the pharmacist is viewed as an extension of the doctor's power to prescribe medicines, providing a dispensing service for prescriptions. When the aura of the prescription is removed, so too is the power of the pharmacist.

The most important implication for pharmacists is the need to be aware of the existence of a confident, autonomous consumer. As OTCs become more like
consumer products, with advertising, branding and positioning commonplace, pharmacists need to understand the nature of modern consumption patterns.

6.6 Implications for Consumer Health Care Research.

There is an imperative for health care research to adopt a consumer focus, especially in the area of OTC usage. With health care research being rooted in the medical arena for so long it is now perhaps timely for consumer researchers to contribute to the field of health care research. Consumer research can offer a vast body of knowledge on consumer behaviour as well as an array of methodologies ideally suited to exploring consumer health care issues. There has been some notable research by consumer researchers on the area of health but further efforts are needed.

Interpretive research paradigms can provide a platform for health care research with an aim of enhancing understanding, rather than increasing predictive abilities. The benefit of such paradigms are in placing the consumer at the centre of any study and adopting a level of equality between researcher and respondent, rather than placing the researcher above the respondent. In particular, the latest, cutting-edge thinking on the role that products play, the postmodern view of consumption, offers new insight into OTC usage in particular. Adopting such a position does help in clarifying some of the more paradoxical aspects of consumers' behaviour.
Certainly this postmodern position, with its ‘anything goes’ philosophy, urges researchers to explore any aspect of consumption and health care research should benefit from such a pluralist approach.

6.7 The Benefits and Drawbacks of Existential-Phenomenological Research.

The choice of the Existential-phenomenological paradigm for this study was to achieve the objectives of placing the consumer at the centre of the inquiry and uncovering their experience of using NRT in their smoking cessation behaviour. These objectives were achieved resulting in both benefits and drawbacks. In terms of benefits, the topic of smoking cessation proved to be a rich area of experience and was so important to the respondents that they talked openly and extensively on the subject. However, it would appear that not all topics would generate as much discussion. It would be hard to imagine more particular topics, such as brand choice or the use of an OTC for a minor complaint, eliciting such extensive discussion. The greatest benefit to the chosen approach was the scope of what was uncovered. While no a priori assumptions were made in advance of the interviewing, an even greater scope of meanings was uncovered than anticipated.

On the other hand, findings beyond what are expected at the outset can be disconcerting for a researcher, especially when it is their first occasion to use such a methodology. The result of the emergence of findings beyond the expected also makes linking these to findings in the current literature somewhat difficult. This is exacerbated further when the current literature is primarily cue-
based and quantitative in nature. The shadow of the current literature tends to hamper the process of interpretation. The process of interpretation itself is challenging as both skill and patience are required when one is faced with hours of varied, apparently inconsistent transcriptions with few, if any, directions as to how to proceed. It must be reiterated that the benefits of the interpretive group cannot be underestimated. Apart from the obvious benefit of sharing the burden, the interpretive group provides expertise and a range of perspectives essential to developing good interpretations.

Overall, while there are some difficult challenges to using Existential-phenomenology, it does add a new dimension to research on the area. It must be viewed as an alternative way of seeking knowledge; complementing rather than conflicting with other paradigms.

6.8 Future Research.

Given the extent of switch drug activity in the marketplace this study highlighted the need to examine other categories of switch drugs and their meanings to consumers. While NRT was viewed as outside the medical domain, many other products that have recently switched to OTC status could be viewed as more medical in nature. As a result, a different pattern of meanings remains to be uncovered. High profile switches, such as Tagamet, once the largest selling pharmaceutical in the world, have recently moved to OTC status and such drugs merit attention.
The switch to OTC status reduces the power and control of medicines by the doctor, switching this power and control directly to the consumer. Conspicuous by its absence was a role for the pharmacist in this study. Further research on the role and meanings of the pharmacist is vital in the context of OTC consumption.

For NRT in particular, there is a need to research the benefits of widening its availability. This must be approached from a non-medical perspective given the findings in this study. One further issue, albeit that it arose with a single respondent, was the need to address younger smokers and their desire to quit. The recent rise in teenage smoking, despite all the efforts to contain it, presented a unique situation regarding NRT. Although there are clearly safety implications for widening the availability of NRT to younger and possibly 'underage' users, there appears to be a need to consider this delicate point. It clearly comes under the heading of socially 'sensitive' marketing activity but is nonetheless important for consideration.

Ultimately it is the field of consumer research that can lead the way forward to a better understanding of the 'new' health care consumer in the emerging switch drug market. Placing the consumer at the centre of any inquiry, adopting a level of equality between researcher and respondent, and recognising the often paradoxical, individualistic patterns of consumption present a unique opportunity to enhance our understanding of health care consumption.
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