CHAPTER 5 DISCUSSION OF RESULTS

5.1 DATA ANALYSIS

The data collected in the study was transferred to an electronic database. Data entry was verified and validated. Responses in the different response categories of a question were counted and converted to percentages. Confidence intervals for percentages were calculated where meaningful. All statistical procedures were conducted on SAS® and StatPac® run under Windows® XP on a personal computer, and Microsoft Excel was used in the graphing. A two-sample t-test between proportions was used to determine whether significant variance existed between samples. This was used in preference to the Chi-squared test due to being more accurate in these circumstances.

5.2 **DISCUSSION**

The subjects of the research were patients of Bellevue Pharmacy wishing to purchase laxatives, of which 229 were asked to complete the questionnaire and 197 were willing to take part.

Question 1: Gender

There appears to be a far greater use of laxatives by the female population than by the males in the pharmacy where the questionnaires were completed i.e. 61% female and 39% male. The more prevalent use of laxatives in the female population does corroborate with other studies.³¹

It is generally accepted that the incidence of eating disorders and therefore laxative abuse has increased over the past three to four decades. It is further agreed that at any given time, 10% or more of all adolescent and young women report symptoms of eating disorders while using laxatives.³² Only 5-15% of patients with eating disorders are male, the remaining 85-95% being female.³³ An estimated 0,5- 3.7% of females suffer from

anorexia and 1.1- 4.2% from bulimia in their lifetimes, a great number with associated laxative abuse.³³ One study found that only one in ten patients with eating disorders (and abusing laxatives) are currently in treatment.³⁵

| Gender | O La | smotic axatives | Bulk-forming Agents | | GIT Stimulant Laxatives | | Faecal Softeners | | Total No of Products |
|----------|---------|--------------------|------------------------|-------|-------------------------------|--------|---------------------|-------|----------------------------|
| Male | 9 | (11%) | 2 | (2%) | 68 | (83%) | 3 | (4%) | 82 |
| wide | | (11/0) | 2 | (270) | 00 | (03/0) | 5 | (+/0) | 02 |
| Female | 12 | (9%) | 5 | (4%) | 106 | (82%) | 6 | (5%) | 129 |
| Products | 21 | (10%) | 7 | (3%) | 174 | (82%) | 9 | (4%) | 211(100%) |

 Table 1: Laxative-type used by male and female patients

The confidence intervals on the proportion of patients selecting stimulant laxatives in preference to the other laxative types showed:

Standard error of the proportion = 0,027

Degrees of Freedom = 210

95% confidence interval = $82,0\% \pm 5,229$

Confidence interval range =76,771% to 87,229

This shows that therefore, our best estimate of the population proportion with 5% error is between 76,771% - 87,229% of patients taking laxatives will select the stimulant-type products.

A one-sample t-test between proportions was performed to determine whether there was a significant difference between the number of males and females seeking laxatives.

t-statistic = 3.276

Degrees of Freedom = 210

Two-tailed probability = 0,0012

The t-statistic was significant at the 0,05 critical alpha level, t(210) = 3,276; p = 0,0012. We therefore conclude that the difference between the number of males and females seeking laxative products is significant.

Question 2: Race Group

Of the sample, 155 (79%) were black, 22 (11%) white whilst only 10 (5%) each were from an Indian or coloured population. This is approximately the ratio of clientele in the suburb investigated. This would not be the case for a pharmacy based further away from the city centre or in the urban areas of South Africa.

The confidence intervals of the different race groups interviewed showed: For black respondents: Standard error of proportion = 0,029

> Degrees of freedom = 196 95% confidence interval = 79 ± 5.74 Confidence interval range = 73,26% - 84,74%

For white respondents: Standard error of proportion = 0,022Degrees of freedom = 19695% confidence interval = 11 ± 4.41 Confidence interval range = 6,59% - 15,41%

For coloured and Indian respondents:

Standard error of proportion = 0,016Degrees of freedom = 19695% confidence interval = $5,0 \pm 3.073$ Confidence interval range = 1,927% - 8,073%

The Department of Statistics official estimate dated July 2005 showed that the population in South Africa was made up of 75% black, 14% white, 9% coloured and 3% Indian racial categories.

| Race Group | I | Faecal | 0 | smotic | | GIT |] | Bulk- | | Total | |
|------------|-----------|--------|-----------|--------|------|------------|----|---------|-----|----------|--|
| | Softeners | | Laxatives | | Stir | Stimulants | | forming | | oducts | |
| | | | | | | | La | axtives | | | |
| White | 4 | (16%) | 8 | (32%) | 9 | (36%) | 4 | (16%) | 25 | (100%) | |
| Coloured | 0 | (0%) | 0 | (0%) | 10 | (100%) | 0 | (0%) | 10 | (100%) | |
| Indian | 1 | (10%) | 0 | (0%) | 9 | (90%) | 0 | (0%) | 10 | (100%) | |
| Black | 4 | (2%) | 13 | (8%) | 146 | (88%) | 3 | (2%) | 166 | (100%) | |
| Products | 9 | (4%) | 21 | (10%) | 174 | (83%) | 7 | (3%) | 211 | products | |

 Table 2:
 Laxative type sought by each race group

This shows that irrespective of race group, the stimulant-type laxatives are the most popular, but this is less-so for the white respondents than for the other race groups. On discussing with patients the laxative type chosen, most cited the onset of action, the "apparent" efficacy of the product and the cost as being their primary concerns when selecting a product.

Question 3: Age Group

The age groups of patients using these products were fairly evenly distributed, with the majority i.e. 55 respondents (28%) belonging to the 31-40 year age group, followed by the 22-30 year age group being 50 (25%). One must bear in mind that the age range of the latter group is over a nine year age period. This extrapolated over a ten year period equates to 28% (as calculated in the former age group).

A response of 35 patients (18%) fell into the 10 year category 41-50 years, whereas the largest group being the 50 years plus group accounted for 29 patients interviewed (15%). In the age group 18-21, 28 (14%) of total patients interviewed were found. In a study on aging conducted in Boston, USA, it was found that a decline in frequency of bowel movement is not necessarily a part of the aging process. In the elderly who report being constipated, it is essential to take a careful physical, psychological and bowel history rather than to automatically assume the need for use of laxatives.³⁰ The age group of

respondents under 30 years, showed 78 (40%) were laxative users. Instead of the younger population being more educated and better informed, 17 (61%) of the 18-21 age group and 33 (66%) of the 21-30 age group have a minimum of a standard ten school leavers certificate, they appear to be using these products more than the older less educated interviewees 16 (46%) of the 41-50 age group and 11 (38%) of the over 50's have completed their schooling until standard 10).

| Age Range |] | Faecal | | Osmotic | | GIT | | Bulk- | | Total |
|-------------|----|----------|---|---------|-----|-----------|---------|-----------|----------|--------|
| | Se | ofteners | | Agents | Sti | mulant | forming | | Products | |
| | | | | | La | Laxatives | | Laxatives | | |
| 18-21 years | 1 | (4%) | 2 | (7%) | 25 | (89%) | 0 | (0%) | 28 | (100%) |
| 22-30 years | 1 | (2%) | 4 | (8%) | 44 | (86%) | 2 | (4%) | 51 | (100%) |
| 31-40 years | 3 | (5%) | 5 | (8%) | 54 | (82%) | 3 | (5%) | 65 | (100%) |
| 41-50 years | 2 | (5%) | 2 | (5%) | 32 | (87%) | 1 | (3%) | 37 | (100%) |
| Above 50 | 2 | (7%) | 8 | (27%) | 19 | (63%) | 1 | (3%) | 30 | (100%) |
| years | | | | | | | | | | |
| No of | | 9 | | 21 | | 174 | | 7 | | 211 |
| Products | | | | | | | | | | |

 Table 3
 Laxative types selected by the different age groups

The decrease in usage of stimulant laxatives in the eldest age group could be attributed to the fact that in the more mature patient, the osmotic laxatives are far less potent and gentler on the system with fewer side-effects.

This shows that across all age groups investigated, a similar pattern of laxative-types appears to emerge. It should also be remembered that the area under investigation is an urban area, and hence there would tend to be more patients in the younger age ranges.

Question 4: Monthly Income

The monthly income of patients interviewed shows that 155 (82%) respondents earn below R6000 per month, with the majority 70 (37%) earning between R1500 and R3000 per month and 41 (22%) below R1500 per month. This is probably due to the fact that the Yeoville-Berea- Bellevue area is mainly a middle to lower-income urban area, which has a number of pensioners and students living in the suburbs. Also, the Joubert Park, Hillbrow and Berea areas also have state-subsidized apartments for a number of pensioners (15% of total respondents were above 50 years old). Only 33 (18%) of patients interviewed earn in excess of R6000 per month.

A few patients interviewed (nine) were not willing to disclose their incomes.

| Income | F | Faecal | 0 | smotic | | GIT | | Bulk- | | Total |
|-------------------|----|---------|----|--------|------|---------|----|----------|----------|----------|
| Group | So | fteners | A | Agents | Stir | nulants | f | orming | of | Laxative |
| | | | | | | | La | axatives | Products | |
| | | | | | | | | | Pu | irchased |
| Below | 0 | (0%) | 3 | (7%) | 37 | (90%) | 1 | (3%) | 41 | (100%) |
| R1500pm | | | | | | | | | | |
| R1500- | 4 | (5%) | 6 | (8%) | 65 | (83%) | 3 | (4%) | 78 | (100%) |
| R3000pm | | | | | | | | | | |
| R3000- | 2 | (4%) | 7 | (15%) | 37 | (79%) | 1 | (2%) | 47 | (100%) |
| R6000pm | | | | | | | | | | |
| R6000- | 2 | (10%) | 3 | (14%) | 15 | (71%) | 1 | (5%) | 21 | (100%) |
| R10 000pm | | | | | | | | | | |
| Above | 1 | (7%) | 2 | (14%) | 9 | (65%) | 2 | (14%) | 14 | (100%) |
| R10 000pm | | | | | | | | | | |
| No of Products | 9 | (4%) | 21 | (10%) | 163 | (81%) | 8 | (4%) | | 201 |

 Table 4:
 Laxative-type used by patients in the various income groups

This showed that irrespective of their income group, the most popular laxatives are the gastrointestinal stimulant products.

Question 5: Education Level

The education levels of the respondents shows that 42 (21%) have tertiary qualifications, 74 (38%) have a Standard 10 certificate, 58 (29%) have a high school certificate and 23 (12%) have only a primary school education. This shows that 116 (59%) of those questioned had a minimum of at least having completed matric.

| Level of | F | Faecal | (| Osmotic | | GIT | | Bulk- | | Total |
|-------------|-----------|--------|--------|---------|------------|-------|---------|--------|----------|--------|
| Education | softeners | | Agents | | Stimulants | | Forming | | Products | |
| | | | | | | | A | Agents | | |
| Primary | 1 | (4%) | 2 | (9%) | 20 | (87%) | 0 | (0%) | 23 | (100%) |
| School | | | | | | | | | | |
| High School | 5 | (8%) | 5 | (8%) | 48 | (82%) | 1 | (2%) | 59 | (100%) |
| Matric | 0 | (0%) | 8 | (10%) | 68 | (85%) | 4 | (5%) | 80 | (100%) |
| Tertiary | 3 | (6%) | 6 | (12%) | 38 | (78%) | 2 | (4%) | 49 | (100%) |
| Education | | | | | | | | | | |
| Products | 9 | | 21 | | 174 | | 7 | | 211 | |

 Table 5:
 Laxative-type used by patients with various levels of education

This shows that irrespective of level of education, the GIT stimulants are the most popular group of laxatives purchased.

The confidence interval of patients who requested GIT stimulants showed:

Standard error of proportion = 0.026

Degrees of freedom = 210

95% confidence interval = 83.0 ± 5.112

Confidence interval range = 77,888% to 88,112%

This shows that therefore, our best estimate of the population proportion with 5% error is between 77,888% and 88,112% of products sought will be of the GIT stimulant-type.

Question 6: Laxatives of Choice

The choice of product shows that 82% chose the gastro-intestinal stimulants, with the osmotic laxatives being 10%, the faecal softeners 4% and the bulk forming agents only 3%.

The majority of laxative products purchased during the period of research (174 of the total 211) were gastro-intestinal stimulants, which could possibly be attributed to the financial aspect, as the gastro-intestinal stimulants are generally more affordable. These range from just R5.95 per small container of 10 doses of Supertabs® (Phenolphthalein)-(around 60c to R1,20 per dose), up to around R80.00 per container of 200 tablets of Senekot® (Senna)- (around 80c to R1,60 per dose), and these products are more widely available at supermarkets, café's and roadside vendors.

The bulk-forming agents which are generally recommended for chronic use, range from around R4.50 per dose of Fybogel® (Ispaghula) (except bran which is not widely marketed, and is still relatively cheap), but due to their longer onset of action, do not produce the immediate results that many patients seek and these products are often required on a chronic basis to achieve their effect.

The faecal softeners are not widely recommended any longer due to malabsorption syndrome. In a pharmacy setting where counseling can be conducted, faecal softeners are only recommended as stool softeners for very short-term use. They are also relatively affordable eg. 50ml of liquid paraffin costs under R7.00.

The osmotic laxatives having a lower incidence of adverse effects are commonly recommended, with the generic brands reducing the prices of those of the originator. Products, like lactulose retail for around R22.00 per 150ml bottle which equates to around R4,40 per dose. Generally they have a relatively slow onset of action, thus not providing gratification within a few hours, but are still effective as stool softeners as well as effective in aiding bowel movement.

Many patients cited that the stimulant products worked most effectively as a quick solution to their problem. Although the adverse effects were marked, at least patients could feel that their problems were being resolved quickly.

| Laxative | Most popular | Second most | Others | Total |
|--------------|--------------|--------------------|-------------------|----------|
| Group | | popular | | Products |
| GIT | Bisacodyl 57 | Senna 54 | Total of others 9 | 174 |
| Stimulants | (33%) | (31%) | (5%) | (100%) |
| | | Phenolphthalein 54 | | |
| | | (31%) | | |
| Osmotic | Lactulose 11 | Magnesium Salts 10 | Total of others 0 | 21 |
| Laxatives | (52%) | (48%) | (0%) | (100%) |
| Bulk-Forming | Ispaghula 4 | Bran 2 | Total of others 1 | 7 |
| laxatives | (57%) | (29%) | (14%) | (100%) |
| Faecal | Glycerine 4 | Liquid paraffin 3 | Total of others 2 | 9 |
| Softeners | (44%) | (33%) | (23%) | (100%) |

 Table 6: Laxative-types used showing the popularity of specific active ingredients

It must be noted that phenolphthalein which comprised 31% of all the GIT stimulants sought and 26% of the total number of laxative products sought by these patients is still a highly popular laxative among the patients interviewed, although this product was banned in February 2002, with its final withdrawal from the market in August 2006.

The most popular laxatives in the USA in each group as per the Pharmacy Times 2006 shows:

GIT Stimulants: Senna 46%, Bisacodyl 39%.

Bulk-forming: Psyllium 40%, Methyl cellulose 24%, Polycarbophil 18%.

Faecal Softeners: Docusate 50%, Sodium picosulphate 18%.

There are no available statistics regarding Osmotic Laxatives used in the USA.

Question 7: Time Period using Laxatives

The duration of time that patients have been using laxatives suggest that 87 (44%) have been ingesting these products for four years or more, 31 (16%) between two and four years, 40 (20%) from one to two years and 39 (20%) for under a year. Of the group using them for under a year, only 2 (1%) had never used laxatives before and a further 2 (1%) were purchasing them for just the second time.

It was noted that 126 (64%) of respondents ingest laxatives once a month or more frequently, but on a regular long-term basis and not only for acute constipation.

| Gender | Le | ss than | 1. | 13 - 24 | | 4 years | 4 y | ears and | Total No of | |
|----------|----|---------|--------|---------|----|---------|-----|----------|-------------|--------|
| | 12 | months | Months | | | | а | above | Patients | |
| Male | 12 | (16%) | 12 | (16%) | 10 | (13%) | 42 | (55%) | 76 | (100%) |
| Female | 27 | (22%) | 28 | (23%) | 21 | (18%) | 45 | (37%) | 121 | (100%) |
| Total | | 39 | | 40 | | 31 | | 87 | | 197 |
| Patients | | | | | | | | | | |

 Table 7: Duration of laxative use classified by gender

A two-sample t-test between proportions was performed to determine if there was a significant difference between male and female respondents who have been ingesting laxatives for 4 years or more. The t-statistic was significant at the 0,05 critical alpha level t(195) = 2,478, p = 0,0141. This showed that the male respondents appear to use laxatives for extended time periods significantly more than do the female respondents.

The confidence interval of patients who have been using laxatives for 4 years or more showed:

Standard error of the proportion = 0.035

Degrees of freedom = 196

95% confidence interval = $44.0 \pm 6,995$

Confidence interval range = 37,005% to 50,995%

This shows that therefore, our best estimate of the population proportion with 5% error is between 37,005% - 50.995% of patients taking laxatives will use them long term (4 years or more)

| Race | Less than | 12-24 | 2-4 | For 4 | Total |
|-----------|-----------|----------|----------|----------|------------|
| Group | 12 months | months | years | years or | |
| | | | | more | |
| Whites | 2 (10%) | 6 (26%) | 3 (14%) | 11 (50%) | 22 (100%) |
| Coloureds | 3 (30%) | 0 (0%) | 0 (0%) | 7 (70%) | 10 (100%) |
| Indians | 2 (20%) | 2 (20%) | 2 (20%) | 4 (40%) | 10 (100%) |
| Blacks | 32 (20%) | 32 (21%) | 26 (17%) | 65 (42%) | 155 (100%) |
| Total | 39 (20%) | 40 (20%) | 31 (16%) | 87 (44%) | 197 |

 Table 8: Duration of Laxative use by Race Group

This showed that at least 40% of all respondents have been taking laxatives for 4 years or more, irrespective of race group.

Question 8: Medical Condition being Treated

The conditions for which respondents were ingesting laxatives varied greatly, with a number using these for more than one purpose:

- 19% for treatment of constipation;
- 20% for treatment of bile (or commonly called gal/inyongo);
- 7% for dyspepsia and indigestion;
- 4% for various dermatological conditions e.g. eczema, acne;
- 5% for treatment or prophylaxis of colds & influenza;
- 11% as an appetite stimulant;
- 9% to treat fatigue;
- 3% to treat infertility;
- 4% as an aid in weight loss;
- 4% for gastrointestinal discomfort;
- 5% for detoxification and cleansing of GIT system;
- 2% as a blood cleanser;
- 1% as a kidney cleanser;
- 1% as a libido stimulant;
- 1% as a faecal softener in treatment of haemorrhoids;

- The other conditions for which laxatives were purchased were at a lesser percentage for treatment of headache, dysmennorhoea, depression, diabetes, gout, fever, hypertension, liver pains, lack of immunity, premenstrual tension, diarrhoea, IBS and peptic ulceration.

It should be born in mind that the study population is mainly lower-to-middle income group

| Race Group | Most common | 2 nd most | 3 rd most | Others |
|------------|----------------|----------------------|----------------------|------------------|
| | | common | common | |
| Whites | Constipation | Heartburn | Weight Loss | Others in lesser |
| | 60% | 16% | 6% | amounts |
| Indians | Constipation | Lack of | Fatigue | Others in lesser |
| | 23% | Appetite | 14% | amounts |
| | | 18% | | |
| Coloureds | Lack of | Heartburn/Bile | Fatigue | Others in lesser |
| | Appetite 25% | 17% | 16% | amounts |
| Blacks | Heartburn/Bile | Constipation | Lack of | Others in lesser |
| | 45% | 32% | Appetite | amounts |
| | | | 19% | |

 Table 9: Race groups and medical condition treated by laxatives

It should be noted that only one coloured patient was using the laxative purchased to treat constipation. Among the black respondents, treatment of heartburn or bile was a more common reason for purchasing laxatives than was treatment for constipation.

Question 9: How often are laxatives required

The frequency of ingestion of laxatives showed only 70 (36%) of respondents appear to use these products on a "when necessary" basis i.e. less than once a year to a few times per year, whereas 32% took them regularly once a month, 15% every week and 17% regularly every day.

| Gender | I | Daily | W | Veekly | Monthly | | Consumed | | Consumed | | Total | |
|--------|------|----------|------|----------|-------------|-------|-------------|-------|-----------|------|-------|---------|
| | cons | sumption | cons | sumption | Consumption | | few times | | less than | | resp | ondents |
| | | | | | per year | | once a year | | | | | |
| Male | 7 | (9%) | 12 | (16%) | 26 | (35%) | 25 | (33%) | 5 | (7%) | 75 | (100%) |
| Female | 27 | (22%) | 18 | (15%) | 36 | (30%) | 30 | (25%) | 10 | (8%) | 121 | (100%) |
| Total | | 34 | 30 | | 62 | | 55 | | 15 | | 196 | |

 Table 10:
 Gender in relation to frequency of laxative consumption

A two-sample t-test between proportions was performed to determine whether there was a significant difference between the number of males and females who took laxatives on a regular daily basis. The t-statistic was significant at the 0,05 critical alpha level, t(194)=2,354, p=0,0196. This showed that the female respondents generally used these products on a daily basis significantly more so than the male respondents.

Question 10: Products recommended by

In general, the majority of recipients i.e. 115 (56%), have been recommended to use a product by a family member, friend or self-selected on shopping at the retailer. A further 35 (17%) patients had the product recommended by their pharmacist, 13 (6%) by a medical practitioner and 11 (5%) by their clinic/nursing sisters. A further 16 (8%) began using the product due to an advertising campaign.

Only 59 (29%) of laxative users were taking them (or were previously advised to take them) by a medical professional. The balance were on the recommendation of a traditional healer 15 (7%) or the media 16 (8%).

Of concern is that certain laxative products are marketed as "treatment for kidney and associated complaints", "blood cleansers", "tonics", "detoxifiers", thus indicating to the general public that these products have a wide spectrum of activity and are "healthy" for one to consume.

| Laxative-type | Medical | Nursing/ Clinic | Pharmacist |
|-------------------|--------------|-----------------|------------|
| | Practitioner | Sister | |
| Osmotic Laxatives | 15% | 9% | 23% |
| Bulk Forming | 8% | 0% | 14% |
| Laxatives | | | |
| GIT Stimulants | 69% | 82% | 54% |
| Faecal Softeners | 8% | 9% | 9% |

Table 11. Laxative-types recommended by Medical Professionals

This shows that the GIT stimulant products are the most popularly prescribed laxative products amongst the patients investigated.

Question 11: Satisfaction with Results

The majority of patients interviewed i.e. 162 (82%) feel that the medication treats the condition for which they have taken this drug, 28 (14%) feel that it does not alleviate their problem and 7 (4%) say it is only effective on occasion.

 Table 12:
 Gender assessment of patient's perception of drug effectiveness

| Gender | Drug is | | D | Drug is | | g effective | Total |
|--------|---------|---------|-------------|---------|-----|-------------|------------|
| | ef | fective | ineffective | | Occ | casionally | |
| Male | 67 | (88%) | 4 | (5%) | 5 | (7%) | 76 (100%) |
| Female | 95 | (78%) | 24 | (20%) | 2 | (2%) | 121 (100%) |
| Total | | 162 | | 28 | | 7 | 197 |

A two-sample t-test between proportions was performed to determine whether there was a significant difference between male and female respondents with respect to the percentage that found the product to be effective. The t-statistic was not significant at the 0,05 critical alpha level, t(195)=1,773, p=0,078 showing that a significant difference does not exist between the percentage of male and female patients who perceived the laxative product to be effective. A two-sample t-test between proportions was performed to determine whether there was a significant difference between male and female respondents with respect to the percentage that found the product to be ineffective. The t-statistic was significant at the 0,05 critical alpha level, t(195)=2,935, p=0,037 showing that a significant difference does exist between male and female patients who find laxative products to be ineffective.

| Race | D | Drug is | I | Drug is | Dru | ig effective | r | Total |
|-----------|-----|---------|-----|-----------|-----|--------------|------|---------|
| Group | ef | fective | ine | effective | oc | casionally | resp | ondents |
| Whites | 22 | (100%) | 0 | (0%) | 0 | (0%) | 22 | (100%) |
| Coloureds | 8 | (80%) | 2 | (20%) | 0 | (0%) | 10 | (100%) |
| Indians | 8 | (80%) | 2 | (20%) | 0 | (0%) | 10 | (100%) |
| Blacks | 124 | (80%) | 24 | (15%) | 7 | (5%) | 155 | (100%) |
| Total | 162 | (83%) | 28 | (14%) | 7 | (3%) | 197 | (100%) |

Table 13: Race groups and patient's perception of drug efficacy

This showed that all the race groups found the product they selected to be effective in at least 80% of cases, whereas only 14% on average found the product ineffective and 3% only found the product effective at times.

Question 12: Purchased from

The majority of respondents (63%) appear to purchase these products from their pharmacy, 27% from the supermarket, 7% from cafes and to a lesser extent from their dispensing doctor (1%), street vendors or other sources.

As the respondents were invited to participate in the study only on requesting laxatives when entering the pharmacy, this would not be an accurate indication of the actual ratio of purchases in the market place as many people could purchase from other stores or dispensing doctors without any contact with a pharmacy.

Question 13: Counselling

As regards discussion of the use of these drugs with a medical professional, 73% of interviewees have not discussed the use or misuse of these drugs with a medical practitioner, pharmacist or registered nurse.

| Gender | Have sought advice | | Have <u>not</u> sought | | Total | |
|--------|--------------------|-------|------------------------|-------|-------------|--|
| | | | advice | | Respondents | |
| Male | 22 | (29%) | 53 | (71%) | 75 (100%) | |
| Female | 31 | (26%) | 89 | (74%) | 120 (100%) | |
| Total | 53 | (27%) | 142 | (73%) | 195 | |

 Table 14:
 Analysis of the gender of patients seeking counselling

A two-sample t-test between proportions was performed to determine whether there was a significant difference between male and female patients with respect to the percent who had not previously sought advice on the product they were purchasing or their medical condition. The t-statistic was not significant at the 0,05 critical alpha level, t(193)=0,458, p=0,647. This showed that both male and females were equally unlikely to

seek counselling on the laxative products sought.

| Race Group | Have s | sought advice | Have <u>not</u> sought | | Total | |
|------------|--------|---------------|------------------------|--------|---------|--------|
| | | advice Res | | Resp | ondents | |
| Whites | 16 | (73%) | 6 | (27%) | 22 | (100%) |
| Coloureds | 0 | (0%) | 10 | (100%) | 10 | (100%) |
| Indians | 2 | (20%) | 8 | (80%) | 10 | (100%) |
| Blacks | 35 | (23%) | 118 | (77%) | 153 | (100%) |
| Total | 53 | (27%) | 142 | (73%) | | 195 |

 Table 15:
 Analysis of race groups seeking medical advice on use of laxatives

The confidence interval of patients who have sought medical advice on the use of laxatives showed:

Standard error of the proportion = 0,032

Degrees of freedom = 194

95% confidence interval = $27,0 \pm 6,29$

Confidence interval range = 20,71 - 33,29

This shows that therefore, our best estimate of the population proportion with 5% error is between 20,71% - 33,29% of patients taking laxatives will seek advice on use of laxatives.

 Table 16:
 Analysis of age range of patients seeking medical advice on laxative use.

| Age Range of Patient | Have sought advice | Have <u>not</u> sought advice |
|----------------------|--------------------|-------------------------------|
| 18-21 years | 6 (21%) | 22 (79%) |
| 22-30 years | 13 (26%) | 37 (74%) |
| 31-40 years | 13 (30%) | 40 (70%) |
| 41-50 years | 9 (26%) | 26 (84%) |
| 50 years and above | 12 (41%) | 17 (59%) |

This appears to indicate that with increasing age, patients generally appear to be seeking advice from a medical professional more so than the younger respondents.

A two-sample t-test between proportions was performed to determine whether there was a significant difference between the 18- 21 year age group and the 50 years and above group of respondents who have sought advice from medical personnel regarding their laxative usage. The t-statistic was not significant at the 0,05 critical alpha level, t(55)=1,63, p=0,1089. This showed that there was no significant difference between the patients who sought medical advice from a doctor, pharmacist or nursing sister.

Question 14: Adverse Effects

Noticeable adverse effects were not experienced by 70 (36%) of the total number of respondents, whilst 17 (8%) of the remaining maintained that they experienced more than one adverse effect. Of the patients that did perceive side-effects, 48 (24%) complained of abdominal discomfort, 47 (24%) of thirst, 27 (14%) of fatigue and weakness, 11 (6%) of nausea and vomiting, and the balance to a lesser extent complained of anal pain, bloatedness, headache, pruritis and diarrhoea.

Most patients interviewed, 126 (64%) perceived experiencing adverse affects with 74 (38%) experiencing signs of dehydration (thirst, weakness) and 48 (24%) experiencing abdominal pains. Once these adverse effects were explained to the patients, many were willing to purchase an alternative product with fewer adverse effects.

Question 15: Frequency of Bowel Movements

Of the patients interviewed, 49 (25%) consider their bowel movements to be normal if they defaecated more than once daily, 91 (47%) once daily, 35 (18%) were satisfied with once in two days, 17 (9%) expected a bowel movement once or twice a week and 1 (1%) less than once a week. The 9% who expect bowel movements once or twice weekly appears greater that that in a study on Aging conducted at Harvard Medical School. This showed between 3,8 and 6,3% of patients have bowel movement stwice or less per week. Findings suggested a decline in frequency of bowel movement is not associated with aging.³¹ It was noted that 175 (91%) of patients expect their bowels to work on alternate days to a few times daily whereas only 17 (9%) felt it normal for a bowel movement only once or twice weekly.

| Gender | More than once per day | Once Daily | On alternate days | Once or twice weekly | Less than once per week | Total No of respondents |
|--------|------------------------------|---------------|-------------------------|----------------------------|-------------------------------|-------------------------------|
| Male | 22 (29%) | 31 (41%) | 12 (16%) | 10 (13%) | 1 (1%) | 76 (100%) |
| Female | 27 (23%) | 60 (51%) | 23 (20%) | 7 (6%) | 0 (0%) | 117 (100%) |
| Total | 49 (25%) | 91 (47%) | 35 (18%) | 17 (9%) | 1 (1%) | 193 |

Table 17: Analysis of "normal Bowel habits" as perceived by gender

A two-sample t-test between proportions was performed to determine whether there was a significant difference between male and female respondents who perceive "normal bowel habit" of once or more daily. The t-statistic was not significant at the 0,05 critical alpha level, t(191)= 0.608, p=0,5442. This showed that there was no significant difference between the perception of males and females who felt it to be normal to have a bowel movement of at least once daily.

Question 16: Dosage

Only 105 (53%) of patients interviewed use the dosage recommended on the package insert, 41 (21%) normally use a lower dose than this i.e. sufficient dose to achieve effect, whilst 51 (26%) of patients find it necessary to take in excess of the recommended dose.

| Table 18: | Analysis of dos | age of laxatives r | normally ingested | in relation to g | gender |
|-----------|-----------------|--------------------|-------------------|------------------|--------|
| | | | | | , |

| Gender | L | owest | Dosage as per | | Dosage higher | | Total No of |
|--------|----------------|-------|----------------|-------|---------------|-------------|-------------|
| | effective dose | | package insert | | than in | idicated on | respondents |
| | | | | | package | | |
| Male | 16 | (21%) | 38 | (50%) | 22 | (29%) | 76 (100%) |
| Female | 25 | (21%) | 67 | (55%) | 29 | (24%) | 121 (100%) |
| Total | 41 | (21%) | 105 | (53%) | 51 | (26%) | 197 |

A two-sample t-test between proportions was performed to determine whether there was a significant difference between male and female respondents who took laxatives at higher doses than those recommended on the package insert. The t-statistic was not significant at the 0,05 critical alpha level, t(195)=0,780, p=0,4366. This showed that there was no significant difference between male and female patients who took doses in excess of the recommended dosages stated.

| Level of Education | Lowest effective dose | Dosage as per package insert | Dosage higher than indicated on package |
|--------------------|--------------------------|---------------------------------|---|
| Primary School | 2 (9%) | 14 (61%) | 7 (30%) |
| High School | 6 (10%) | 33 (57%) | 19 (33%) |
| Matric/ Grade 12 | 17 (23%) | 37 (50%) | 20 (27%) |
| Tertiary Education | 16 (38%) | 21 (50%) | 5 (12%) |

 Table 19: Analysis of dosage of laxatives normally ingested in relation to education level

This shows that possibly, the respondents that the patients that are more educated appear to be using lower doses to achieve relief from their symptoms more so than the lesser educated patients.

A two-sample t-test between proportions was performed to determine whether there was a significant difference between the least educated and the most educated groups above who used the lowest effective dose of laxative to alleviate their symptoms. The t-statistic was significant at the 0,05 critical alpha level, t(63)=2,497, p=0,0151. This showed that there was a significant difference between patients with a primary school education as compared with those with a tertiary qualification.

Question 17: Self-assessment of Constipation

Of the number of patients purchasing laxatives, 131 (66%) do not feel that they are suffering from constipation and are taking laxatives to produce bowel emptying for other reasons. The remaining 66 (34%) are purchasing these products for the correct indication for which these products are manufactured.

Of this, 54 (71%) of male respondents and 77 (64%) of female are using these formulations for purposes other than those for which they are indicated.

| Gender | I <u>do</u> suffer from | | I do not | suffer from | Total No of | | | |
|--------|-------------------------|-------|--------------|-------------|--------------|--------|-------------|--|
| | Constipation | | Constipation | | Constipation | | respondents | |
| Male | 22 | (30%) | 54 | (71%) | 76 | (100%) | | |
| Female | 44 | (36%) | 77 | (64%) | 121 | (100%) | | |
| Total | 66 | (34%) | 131 | (66%) | | 197 | | |

 Table 20:
 Comparison of gender and self –assessment of constipation

A two-sample t-test between proportions was performed to determine if there was a significant difference between male and female patients who were purchasing laxatives but felt they did not suffer from constipation. The t-statistic was not significant at the 0,05 critical alpha level, t(195)=0.867, p=0,387. This indicates that there is no significant difference between male and female respondents who took laxatives for purposes other than for treatment of constipation.

However, in another study, it was found that a greater proportion of women report the symptom of constipation more often than do men across all age groups.³¹

| Race Group | I <u>do</u> suffer from | | I do not suffer from | | Total No of |
|------------|-------------------------|-------|----------------------|--------|-------------|
| | Constip | ation | Constip | ation | Respondents |
| Whites | 19 | (85%) | 3 | (15%) | 22 (100%) |
| Coloureds | 0 | (0%) | 10 | (100%) | 10 (100%) |
| Indians | 2 | (20%) | 8 | (80%) | 10 (100%) |
| Blacks | 45 | (29%) | 110 | (71%) | 155 (100%) |
| Total | 66 | (34%) | 131 | (66%) | 197 |

 Table 21: Analysis of Race Group and self-assessment of Constipation

This showed that besides the white members of the population, the majority of respondents did not believe that they were suffering from constipation, yet were purchasing laxative products.

| Level of Education | I <u>do</u> suffer from | | I do not suffer from | | Total No of | |
|--------------------|-------------------------|-------|----------------------|-------|-------------|----------|
| | Constipation | | constipation | | Res | pondents |
| Primary school | 5 | (22%) | 18 | (78%) | 23 | (100%) |
| High School | 12 | (21%) | 46 | (79%) | 58 | (100%) |
| Matric/ Grade 12 | 33 | (45%) | 41 | (55%) | 74 | (100%) |
| Tertiary Education | 16 | (38%) | 26 | (62%) | 42 | (100%) |
| Total | 66 | (34%) | 131 | (66%) | | 197 |

 Table 22: Analysis of the level of Education and self-assessment of Constipation

The confidence interval of patients who were using laxatives although they did not suffer from constipation showed:

Standard error of proportion= 0,034

Degrees of Freedom = 196

95% confidence interval = $66,0\% \pm 6,68$

Confidence interval range = 59,32 - 72,68

This shows that therefore, our best estimate of the population proportion with 5% error is between 59,32% - 72,68% of patients taking laxatives who felt that they were not constipated.

| Age Group | I <u>do</u> suffer from Constination | I <u>do not</u> suffer from |
|----------------|---|-----------------------------|
| | Constipution | conscipution |
| 18 – 21 years | 8 (29%) | 20 (71%) |
| 22 – 30 years | 16 (32%) | 34 (68%) |
| 31 – 40 years | 20 (36%) | 35 (64%) |
| 41 – 50 years | 10 (29%) | 25 (71%) |
| Above 50 years | 12 (41%) | 17 (59%) |

Table 23: Analysis of age-group and self assessment of constipation

The increase in the number of patients above 50 years suffering from constipation appears to be a worldwide problem in perception that as one gets older, bowel movement appears to decrease, but this was proven to be incorrect.³⁰

5.3 <u>COUNSELLING OF PATIENTS</u>

Advice to stop regular use/misuse of laxatives:

- 1. Stop taking laxatives immediately.
- 2. Drink 6- 10 cups of fluid per day to promote hydration (not caffeinated beverages due to their diuretic effect).
- 3. Gradually introduce some daily physical activity and gradually increase this. (In excess, this can have an effect on your metabolism and fluid balance)
- Eat regularly to maintain you body's metabolism- spread out meal plan to at least 3 meals per day at regular intervals.
- 5. Eat more foods to provide normal bowel movements like whole-grain breads, cereals, fruits and vegetables.
- 6. Keep a note of bowel movements. If this is more than 3 days apart, consult your healthcare professional.³⁷
- 7. Be aware that on withdrawal long-term laxative use, it will probably take time for regular bowel habits to resume.

Patients need to be educated that ingestion of laxatives does not prevent absorption of food and is not a remedy for weight gain. Laxatives cause hydration of faeces after the nutrients have already been absorbed in the small intestine.

What was of relevance is that 77 patients interviewed (39%) were willing to try an alternative formulation once medically motivated, e.g. an antacid, H₂ antagonist or low dose PPI for heartburn or bile, a product specifically indicated as such for treatment of colds and influenza, an antispasmodic for treatment of abdominal discomfort, etc. This showed that once properly educated by a medical professional, a large portion of the population are willing to be educated and to try alternative means e.g. increasing roughage in one's diet, increasing fluid intake, etc. The remaining 61% of respondents were unwilling to try an alternative product.

It is significant that in South Africa laxatives are available for purchase at supermarkets and cafés, where there is no medical supervision. Advertisements on buses, taxis, in the print media, on radio and television tend to make inaccurate statements. Being a schedule zero (or unscheduled) drug in our country, allows anybody to trade, advise or purchase these potentially dangerous products.

Although this does not appear to be important in the population under investigation, it must be remembered that compared with non-abusers, laxative abusing patients with eating disorders exhibited the most pathological scores on the scales measuring drive for thinness, body dissatisfaction, ineffectiveness, lack of interceptive awareness, and passive-aggressive and borderline personality features. Anorexic patients who had abused laxatives had the highest scores on the histrionic scale.³⁸

The combination of vomiting and laxative misuse in young women with eating disorders is often indicative of a particularly severe psychiatric disturbance.³⁹ It is also vitally important to advise the patient that although a large number of these products advertise a number of uses of these formulations, their use is registered as a laxative which is used to treat constipation. These products should be used on a "when necessary" basis only, and for short-term use at the lowest effective dose.

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