Errata

The reference list has been revised into a common format according to the recommended style of Monash University (Harvard style) with the journal names have been fully spelt out.

Duplicate references have been removed e.g. Abrahams et al, Altman et al, Maclennan et al and Milsom.

The reference Botlero et al (2011) has been omitted as it was a duplicate.

Amendments

p 15: Add at the end of para 1:

Information provided about test-retest reliability in the QUID validation paper (Bradley et al. 2010) suggests that the test-retest reliability of the final version of the QUID (used in our study) is "very good". The authors quote a statistic (the kappa statistic) for the final version of 0.91 for stress UI and 0.83 for urge UI. However, this information does not allow us to determine what proportion of women would be classified as having or not having UI on repeated testing. For this we would need to know what proportion of women would score <4 or ≥ 4 for stress and <6 or ≥ 6 for urge UI on repeated occasions. This information is not available.

p 108: Add at the end of para 5(last para):

Our prevalence estimate of 44.6% for any UI at follow-up did lie within the 95% CI of the proportion at baseline i.e. 37.0 to 46.2%. This was also true for each of the prevalence estimates for stress, urge and mixed UI. So we accept that, on face value, each result could be seen as consistent with no change. However, as each estimate of prevalence increased over the course of the study we consider it unlikely that the changes were due to chance. The overall picture of a small increase in prevalence of each type of UI is consistent with the change that has been observed with age in other studies. A definite picture would be achieved by a larger group studied for a considerably longer period of time.

Copyright Notices

Notice 1

Notice 2

A LONGITUDINAL STUDY OF URINARY INCONTINENCE IN COMMUNITY-BASED WOMEN: PREVALENCE, INCIDENCE, RESOLUTION, AND ASSOCIATED FACTORS, AND IMPACT ON WELL-BEING AND QUALITY OF LIFE

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Thesis submission for Doctorate of Philosophy

May 2011

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and

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- **Bristol Female Lower Urinary Tract Symptoms (BFLUTS)**
- **Pelvic Floor Distress Inventory (PFDI)**
- **Psychological General Well-being Index (PGWBI)**

List of Abbreviations:

UI	urinary incontinence
FI	fecal incontinence
QoL	quality of life
BMI	body mass index
QUID	Questionnaire for Urinary Incontinence Diagnosis
BFLUTS	Bristol Female Lower Urinary Tract Symptoms
PFDI	Pelvic Floor Distress Inventory
PGWBI	Psychological General Well-being Index
IPAQ	International Physical Activity Questionnaire
HRT	hormone replacement therapy
BL	baseline
FU	follow up
CI	confidence interval
OR	odds ratio
RR	relative risk
HT	hormone therapy
P/H	past history
PFMT	pelvic floor muscle training
LUTS	Lower Urinary Tract Symptoms
SCERH	Standing Committee on Ethics in Research involving Humans
Yrs	years

ABSTRACT

Background

Available data indicate that urinary incontinence (UI) is a condition in women, which adversely impacts on quality of life and daily activities. It affects women of all ages, but is particularly common in older women. It has been associated with significant physical morbidities, lowered well-being, loss of independence as well as sexual difficulties. It also causes a considerable financial burden on both individuals and the healthcare system. A detailed understanding of UI in terms of its prevalence, incidence and risk factors in women is an essential step in reducing the impact of this condition. However, the reported prevalence of UI among women varies widely between studies, with most studies reporting a prevalence of any UI in the range of 25 to 50%. This range is a result of the different definitions used for UI, the heterogeneity of study populations and the different data collection procedures applied for this sensitive health issue. UI is commonly viewed as a permanent condition once it develops. However, few studies have examined the progression and resolution of UI in community-based women with or without treatment. To date no study of the prevalence and incidence of UI in Australian women has been undertaken using a validated instrument. Also, little is known about the natural history of UI and its association with fecal incontinence.

The aetiology of UI is widely recognised to be multifactorial and various risk factors have been identified in different studies. However, the estimated magnitude of risks varies widely in these studies and there is inconsistent evidence with regard to certain factors including mode of delivery, hysterectomy and hormone therapy use.

Aims

The aims of this doctoral thesis are to comprehensively examine UI in community-dwelling women in Australia in terms of its age-specific prevalence, risk factors, impact on quality of life, natural history (incidence and resolution) and its relationship with fecal incontinence (FI).

Methods

The project involved 542 community-based women aged 24 to 80 years in 2006 who were originally recruited from a previous cross-sectional study of 1423 women who participated in the Study of Androgens in Women (SAW). The SAW women were recruited from a database established from the Victorian Electoral Roll. Of the 1423 women who participated in the SAW, 754 agreed to be re-contacted regarding further research and of those, 542 women expressed interest in participating in the study of UI. A detailed self-administered questionnaire was mailed to the participants of this research at baseline in 2006 and again at follow-up in 2008. UI was assessed using a validated questionnaire, the Questionnaire for Urinary Incontinence Diagnosis (QUID) and FI by the Pelvic Floor Distress Inventory (PFDI). The PFDI was included in the follow-up study only. Definitions of stress and urge UI that conform to the standards recommended by the International Continence Society were used. The Bristol Female Lower Urinary Tract Symptoms Questionnaire (BFLUTS) was used to assess the impact of UI on condition-specific quality of life. The impact of UI on well-being was assessed using the Psychological General Well-being Index (PGWBI).

Results

Five hundred and six women provided data for the baseline analysis and 442 women for the follow-up data analysis.

Prevalence: The overall point prevalence of any UI was 41.7% [95% confidence interval (CI): 37.2-45.8%] at baseline and increased to 44.6% [95%CI: 40.0-49.2%] by the end of the follow-up period. Of the 210 women reporting UI at baseline, 16% [95%CI: 12.9-19.3%] reported stress UI; 7.5% [95%CI: 5.2-9.8%] reported urge UI and 18% [95%CI: 14.7-21.5%] reported a mixed pattern. Stress UI was found to be the most common type among middle-aged women (25.3% of women aged 35-44 years), while urge UI was the most common type in women over the age of 75 years (24.2%).

Risk factors: In logistic regression analyses, obesity (P<0.001) and parity (P=0.019) were found to be associated significantly with stress UI. Greater age (P=0.002) was associated significantly with urge UI, and higher body mass index (BMI) (P=0.035) and hysterectomy (P=0.021) were associated significantly with mixed UI.

Impact on well-being and quality of life: Incontinent women had a lower total PGWBI score (76.9 ± 16.5), indicating lower well-being than women with no UI (81.6 ± 15.3) (p=0.001). The total PGWBI mean score was significantly lower in women suffering from stress UI (77.8 ± 16.2, p=0.05) and mixed UI (74.2 ± 17.8, p<0.001) compared with women with no UI. All types of UI were associated with impaired quality of life (p<0.001) and adversely impacted on daily activities, as determined by BFLUTS.

Change over time: Over the 2-year follow-up period the incidence of any UI was 17% [95%CI: 12.4-21.6%] among the unaffected women and the resolution was 16.8 % [95%CI: 11.4-22.2%] among the incontinent women including women who had no treatment for UI.

There was also movement of women between diagnoses of stress UI, urge UI and mixed type during the follow-up period. Only 34 women reported specific treatment for their UI during the follow-up period, and of them, 5 experienced resolution of their condition. Relationship with FI: The overall prevalence of any FI at follow-up was 20.7% (95% CI: 16.9%–24.5%). The prevalence for loose FI was 20.7% (95% CI: 16.9%–24.5%) and well-formed FI, 4.5% (95% CI: 2.6%–6.4%). All of the women with well-formed FI also reported loose FI. About two-thirds of the women with any FI reported co-existing UI. Loose FI was associated significantly with any UI [OR, 2.8(95% CI: 1.7-4.8)] after adjusting for age and BMI ($p<0.001$).

Conclusions

Stress, urge and mixed incontinence have different age distributions and risk factors. Stress UI is the most common type in women at midlife and urge UI at older ages. UI is a dynamic clinical condition, with movement between diagnostic subtypes of stress, urge and mixed UI and periods of resolution. Having any UI negatively impacts on well-being and is significantly associated with impaired quality of life. The relatively low proportion of women who have treatment for their UI suggests there are barriers to treatment that merit further investigation. Loose FI is also a common condition, affecting one in five adult women in our study. Women with loose FI were more likely to have UI, independent of their age and BMI. It is therefore important that clinicians are aware that this is not an uncommon problem and consider the possibility of FI when assessing patients, especially women with UI.

General Declaration

Monash University
Monash Research Graduate School

Declaration for thesis based on conjointly published work

In accordance with Monash University Doctorate Regulation 17/ Doctor of Philosophy regulations the following declarations are made:

I hereby declare that this thesis contains no material which has been accepted for the award of any other degree or diploma at any university or equivalent institution and that, to the best of my knowledge and belief, this thesis contains no material previously published or written by another person, except where due reference is made in the text of the thesis.

This thesis includes four original papers and one review paper published in peer reviewed journals. The core theme of the thesis is urinary incontinence in women. The ideas, development and writing up of all the papers in the thesis were the principal responsibility of me, the candidate, working within the Department of Medicine under the supervision of Professor Susan Davis, Associated Professor Robin Bell and Dr. Donna Urquhart.

Thesis chapter	Publication title	Publication status	Nature and extent of candidate's contribution
1	**Botlero R**, Urquhart DM, Davis SR, Bell RJ. Prevalence and incidence of urinary incontinence in women: Review of the literature and investigation of methodological issues. **International Journal of Urology** (2008) 15, 230–234.	published	
3	**Botlero R**, Davis SR, Urquhart DM, Shortreed S, Bell RJ. Age-specific prevalence of, and factors associated with, different types of urinary incontinence in community-dwelling Australian women assessed with a validated questionnaire **Maturitas.** 2009 Feb 20; 62(2):134-9.	published	
4	**Botlero R**, Bell RJ, Urquhart DM, Davis SR. Associations between different types of urinary incontinence and physical and psychological well-being of women in Australia. **Menopause.** 2010 March; 17(2):332-7.	published	
5	**Botlero R**, Davis SR, Urquhart DM, Bell RJ. Incidence and remission rates of different types of urinary incontinence among women: findings from a cohort study. **Journal of Urology 2011** April; 185(4):1331-37.	published	
6	**Botlero R**, Bell RJ, Urquhart DM, Davis SR. Prevalence of fecal incontinence and its relationship with urinary incontinence in women living in the community (in press **Menopause** September 2010).	in press	

I have renumbered sections of submitted or published papers in order to generate a consistent presentation within the thesis.

Signed: ……

Date: ……

Communications arising during PhD candidature:

Publications

1. Botlero R, Urquhart D, Davis SR, Bell R Prevalence and Incidence of Urinary Incontinence in Women: Review of the literature and investigation of methodological issues. **International Journal of Urology.** 2008 Mar; 15(3):230-4.
2. Botlero R, Davis SR, Urquhart DM, Shortreed S, Bell RJ. Age-specific prevalence of, and factors associated with, different types of urinary incontinence in community-dwelling Australian women assessed with a validated questionnaire **Maturitas.** 2009 Feb 20; 62(2):134-9.
3. Botlero R, Bell R Urquhart D, Davis SR. Urinary incontinence is associated with lower psychological general well-being in community-dwelling women. **Menopause.** 2010 Mar; 17(2):332-7.
4. Botlero R, Bell R Urquhart D, Davis SR. Prevalence of fecal incontinence and its relationship with urinary incontinence in women living in the community (in press **Menopause** September 2010).
5. Botlero R, Urquhart D, Davis SR, Bell R. Incidence and remission rates of different types of urinary incontinence among women: findings from a cohort study. **Journal of Urology 2011** April; 185(4):1331-37.

Published Abstracts

Botlero R, Davis S, Urquhart D, Shortreed S, Bell R. Prevalence and Factors Associated with Urinary Incontinence: Findings from a Cross-Sectional Study of Community-Dwelling Women Australasian Menopause Society Meeting, Melbourne, October 2008.
Botlero R, Bell R, Urquhart D, Davis S Prevalence of Urinary Incontinence and its Impact on General and Psychological Wellbeing of Women in Australia. Australasian Menopause Society meeting, Canberra, 2009.
Botlero R, Davis S, Urquhart D, Bell R. Incidence and resolution rates of different types of urinary incontinence: findings from a cohort study of Victorian women. Early Career Researchers Retreat, Monash University, Melbourne, 2010.

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Finally, my thanks go to all the study participants who gave their valuable time and effort to complete a very long questionnaire on two occasions.

Outline of thesis

Chapter 1 includes a published review of Australian studies pertaining to the incidence and prevalence of UI which was published in 2008 in the International Journal of Urology journal and an update of the literature review, including international studies. Chapter 1 also covers the definition and types of UI, the research tools used to assess UI, known risk factors and the consequences of UI for women, current treatments and a review of the prevalence of FI and its relationship with UI. The study aims and methods are described in detail in Chapter 2. The main study findings are presented in Chapters 3 to 6. Discussion and conclusions of this research, along with future directions and implications, are presented in Chapter 7.

Chapter 1

1.1 INTRODUCTION

Urinary incontinence (UI) is a common, troublesome and under-reported problem in women. It is not limited to the elderly, but can affect women of all ages. It may manifest as incontinence that occurs with increased physical pressure (stress UI), a sudden or uncomfortable urge to urinate (urge UI) or a combination of both (mixed UI). The community costs of incontinence are large. The economic impact of UI in developed countries is indicated by the estimate that the total annual cost of UI in Australia in 1998 was $710.44 million, or $387 per woman with this condition (Doran et al. 2001). Up to 90% of the total annual costs were incurred by women aged over 40 years. Given Australia's ageing population, assuming the same age-specific prevalence and taking inflation into account, the total cost of UI for community-based women is projected to be $1.27 billion by the year 2018 (Doran et al. 2001). Apart from its physical and economic consequences, UI results in considerable embarrassment, social isolation and loss of employment and causes symptoms that can significantly affect a woman's daily activities and quality of life. It has been consistently identified as a major factor influencing placement of elderly women in residential care (Ekelund and Rundgren 1987; Thom et al. 1997).

There remains a need for high quality descriptive epidemiological data quantifying various aspects of UI. The majority of published studies have not employed validated methodology to measure the burden of this condition, or have expressed results in a manner (e.g. reporting overall prevalence rather than age-specific prevalence of types of UI) that is

difficult for policy making and health resource allocation. Little is known about the natural history of UI in terms of its incidence and resolution amongst community-based Australian women. Most of the large, community-based studies of female UI have not reported the natural history, as they have been cross-sectional or retrospective and mainly focused on prevalence and risk factors.

Reported prevalence estimates for UI have shown considerable variation in population-based studies, ranging from 25 to 50% for women of various ages (Sandvik 1996). It is likely that this variation is the result of differences in the definitions used for UI, data collection methods [face-to-face interview (Brown et al. 1996; MacLennan et al. 2000; MacLennan et al. 2000) versus telephone interview (Holst and Wilson 1988) or postal self-administered questionnaire (Seim et al. 1995)], participants' response rates and/or the population studied (Thom 1998). With the substantial differences in the reported prevalences of UI, there is a need for more research to determine the extent of the problem and ultimately, optimise the management and prevention of this condition. Also, a small number of studies have examined the relationships between the different forms of UI and well-being in community- dwelling women (Grimby et al. 1993; Fultz and Herzog 2001; Lasserre et al. 2009; Abdel-Fattah et al. 2007; Andersson et al. 2004). Most of these studies have reported an adverse effect of UI on quality of life using surrogate measures such as 'restriction of activities' (Lasserre et al. 2009) or 'desire for treatment' (Andersson et al. 2004) without the use of validated instruments (Fultz and Herzog 2001; Abdel-Fattah et al. 2007). Moreover, even though it is well recognised that there are different types of UI, no study has examined whether there are differences in the relationships between stress, urge and mixed UI and well-being or condition-specific quality of life.

Similar to prevalence studies, the existing studies on the natural history of UI have yielded varying results, with an incidence rate of UI in women ranging from 2 to 11% per year (Burgio et al. 1991; Nygaard and Lemke 1996; Holtedahl and Hunskaar 1998; Samuelsson et al. 2000). There is also very little information about spontaneous resolution rates of UI. Studies that evaluate treatment for UI generally begin with the premise that incontinence is a static state, and, therefore, if any change is seen in a person's continence status, this is attributable to the treatment or to a placebo effect (Nygaard and Lemke 1996). For prevention and treatment strategies, it is essential to have more knowledge about the natural history of UI as well as the proportion of UI that resolves spontaneously.

Fecal incontinence (FI) is another embarrassing, yet under-researched problem that may affect women of various ages. Validated assessment of the age-specific prevalence of different types of FI (loose and well-formed) has not been carried out in Australia. Furthermore, given the close anatomical relationship between the rectum and the bladder, along with their shared nerve supply and pelvic floor support, a possible association between FI and UI merits consideration. To my knowledge, no study has been undertaken to examine the relationship between UI and FI using validated instruments for both conditions and appropriate analytical methods, taking into account both age and body mass index (BMI).

1.2 LITERATURE REVIEW

This review of the literature covers the current definitions of UI and its major subtypes recommended by the International Continence Society in 2002(Abrams et al. 2002), and reviews of various instruments/questionnaires to diagnose UI and its sub-types. This thesis explores known and proposed risk factors for UI, including age, BMI, parity, gynecological operations including hysterectomy and hormone replacement therapy.

No reviews of the prevalence and incidence studies of UI conducted in Australian women were undertaken prior to the published review by the author up to 2006. However, a review of 13 studies undertaken in Europe and the United States identified considerable variation in estimates of prevalence and incidence of UI (Sandvik 1996). This chapter incorporates a published manuscript covering the prevalence and incidence studies of UI in Australian women up to 2006, the methodological issues associated with these studies and recommendations for future research in this field.

Botlero R, Urquhart DM, Davis SR, Bell RJ. Prevalence and incidence of urinary incontinence in women: Review of the literature and investigation of methodological issues. International Journal of Urology (2008) 15, 230–234.

1.2.1 DEFINITION AND TYPES OF UI

UI has been defined by the International Continence Society as a symptom: 'the complaint of any involuntary leakage of urine' or by observation as: 'urine leakage seen during examination' (Abrams et al. 2002). There are three main types, depending on the symptoms of the patient: stress, urge and mixed UI. Stress UI is defined as involuntary leakage on effort or exertion, or on sneezing or coughing. Urge incontinence is involuntary leakage accompanied by or immediately preceded by urgency. Urgency is the complaint of a sudden, compelling desire to pass urine which is difficult to defer. Mixed UI is the combination of the above two types, which can be defined as involuntary leakage associated with urgency and also with exertion, effort, sneezing or coughing.

1.2.2 KNOWN RISK FACTORS

There are various risk factors suggested by epidemiological studies to have roles in the aetiology of UI in women. These are age, obesity, parity, mode of delivery, menopause, hysterectomy, systemic hormone therapy use and chronic medical conditions, which may increase intra-abdominal pressure, impair cognition status or be associated with poor physical mobility. Female gender itself is a risk factor for UI as the prevalence of UI is significantly higher in women than in men (MacLennan et al. 2000).

i. Age:

The prevalence of most types of UI increases with age. The normal ageing process is associated with a number of structural and functional changes in the urinary tract. These changes include a decrease in bladder elasticity, decrease in the strength of the detrusor muscle, an increase in spontaneous detrusor muscle contractions, a decrease in the ability to postpone urination and a decrease in urethral closing pressure (Menezes et al. 2010). A number of studies have shown an association between UI and increasing age (Chiarelli et al. 1999; Milsom et al. 1993; MacLennan et al. 2000; Bortolotti et al. 2000; Lasserre et al. 2009) with a change in the nature of incontinence from stress to urge type among older women (Parazzini et al. 2000).

ii. Obesity

The association between increasing BMI and UI of all types is well documented. It is believed that the added weight causes chronic strain, stretching and weakening of the pelvic floor (Buckley and Lapitan 2010). Subak et al. (Subak et al. 2009) conducted a systematic literature review up to June 2009 on obesity and UI. They reported that epidemiological

studies showed obesity as a strong independent risk factor for both prevalent and incident UI. There was a clear dose-response effect of weight on UI, with each 5-unit increase in BMI associated with a 20 to 70% increase in the UI risk. The review also reported that the maximum effect of BMI rarely exceeded an odds ratio (OR) of greater than 4 to 5 in well-controlled analyses.

iii. Childbirth

Pregnancy, parity and childbirth have been regarded as major risk factors for UI. Although the precise nature of the relationship between UI and pregnancy or childbirth is not clear, it has been hypothesised to be caused by either hormonal or mechanical changes (Menezes et al. 2010). As the uterus expands during pregnancy, the bladder and urethra are pushed out of their normal positions. This may also affect bladder control, especially when the growing uterus presses on the bladder. Pregnancy itself causes hormonal changes that can lead to UI (Menezes et al. 2010). Pregnancy complications and birth trauma may damage the nerves responsible for bladder control in women. Medical interventions such as episiotomy and forceps delivery can also damage a woman's bladder or urethra, causing UI (Thom and Brown 1998; Chiarelli et al. 1999; Hunskaar et al. 2000). A study by Brown et al. reported that the prevalence of UI increased from 10.8% in the 12 months before being pregnant to 55.9% in the third trimester of pregnancy in nulliparous women. Stress UI (36.9%) and mixed UI (13.1%) were more common during pregnancy than urge UI alone (5.9%) (Brown et al. 2010). Weidner et al. found that urethral sphincter neuromuscular function changes significantly during pregnancy and these changes persist postpartum. They have proposed that lack of recovery by 6 months' postpartum suggests a physiologic impact of pregnancy itself on the future risk of UI (Weidner et al. 2009). Incontinence was more

prevalent 6 months after delivery among women who experienced incontinence during pregnancy (adjusted RR: 2.3, 95% CI: 2.2-2.4) compared with women who were continent during pregnancy (Wesnes et al. 2009).

There is growing evidence for the impact of mode of delivery on UI postpartum. A number of studies have suggested that vaginal delivery is a contributing factor for postpartum UI, possibly because of damage to important muscle tissues or nerves(Boyles et al. 2009; Rortveit et al. 2003; Peyrat et al. 2002). A recent study by Boyles et al. (Boyles et al. 2009) found that women who had spontaneous vaginal deliveries were more likely to have UI than women who had Caesarean deliveries (OR: 4.96, 95% CI: 3.82-6.44, P<.001). This risk increased with instrumental vaginal delivery, for example forceps delivery, and perineal laceration. The Norwegian EPINCONT study also reported similar findings (Rortveit et al. 2003). They found that, compared with nulliparous women, women who had Caesarean sections had an adjusted odds ratio for any incontinence of 1.5 (95% CI: 1.2-1.9) and an adjusted OR for moderate or severe incontinence of 1.4 (95% CI: 1.0-2.1). Only stress and mixed-type incontinence were significantly associated with Caesarean section. The adjusted odds ratio for any incontinence associated with vaginal delivery as compared with Caesarean section was 1.7 (95% CI: 1.3-2.1), and the adjusted odds ratio for moderate or severe incontinence was 2.2 (95% CI: 1.5-3.1) (Rortveit et al. 2003). The study also found that there was no difference in the risk of incontinence between women who underwent elective Caesarean section and those who underwent non-elective Caesarean section suggesting that labour and pushing are not associated with a major increase in the risk of UI (Rortveit et al. 2003). Altman et al. in their study concluded that Caesarean section is not associated with a major reduction in the risk of UI compared with

spontaneous vaginal delivery (Altman et al. 2007). However, it is uncertain whether observed associations between a history of Caesarean section and incontinence actually represent an effect of pregnancy itself. Findings from the South Australian Health Omnibus Survey also suggested that it is pregnancy rather than parturition that contributes most to pelvic floor dysfunction including UI in later life (MacLennan et al. 2000). However, there is a consistent trend that instrumental vaginal delivery increases the risk of nearly all types of pelvic floor morbidity including UI (MacLennan et al. 2000).

A number of studies have reported that the prevalence of UI increases with the number of children delivered (Lasserre et al. 2009) (MacLennan et al. 2000) (Bortolotti et al. 2000) (Danforth et al. 2006). Wesnes et al. showed that parity was a strong risk factor for UI among both nonpregnant and pregnant women, with an adjusted OR of 2.5 (95% CI: 2.4-2.7) for primiparous and 3.3 (95% CI: 3.1-3.5) for multiparous nonpregnant women and during pregnancy an OR of 2.0 (95% CI: 1.9-2.1) for primiparous and 2.1 (95% CI: 2.0-2.2) multiparous women. Some studies reported a threshold for the number of deliveries as a risk factor for UI (Faúndes et al. 2001; Rortveit et al. 2001). Wesnes et al. found that the first delivery has the strongest effect on the risk of UI before a subsequent pregnancy, but subsequent deliveries also add to the risk for incontinence. However, the association with parity was less strong among pregnant women, indicating that pregnancy itself is a risk factor for UI (Wesnes et al. 2007).

In summary, pregnancy and mode of delivery are associated with an increased risk of UI. The risk of UI is higher among women who have had spontaneous vaginal deliveries than among women who have only delivered by Caesarean section and is even higher among

women who have had instrumental vaginal deliveries. Being parous is a major risk factor and the risk increases with the number of pregnancies.

iv. Hysterectomy

Whether hysterectomy, the second major abdominal surgery in women after Caesarean section, is a risk factor for UI is controversial. Despite continued controversy over the relationship between hysterectomy and UI, few long-term, prospective studies that investigate this relationship have been carried out.

Several studies suggest that UI symptoms are more prevalent following hysterectomy (Milsom et al. 1993);(Parys et al. 1989); (Altman et al. 2007). The development of UI could be explained by damage to the local nerves of the urethra and supportive tissues of the pelvis occurring during surgery (Prior et al. 1992; DeLancey 1997; Altman et al. 2007), although the mechanisms by which bladder function are affected are still not clear (Parys et al. 1990). An early study of urodynamic outcomes in women who have had a hysterectomy showed that 47% women had detrusor instability, 37% had urethral obstruction and 25% had stress UI (McPherson et al. 2005).

In contrast, other studies report that total hysterectomy, independent of route (vaginal or abdominal), was not associated with an increase in stress or urge UI symptoms (Gustafsson et al. 2006; Engh et al. 2006). Women who had a hysterectomy for pelvic organ prolapse were more likely to have associated pre-existing UI and as a consequence, may experience improvement of UI following surgery. On the other hand, a woman who had hysterectomy for prolapse or other indications may have pre-existing UI independent of the condition that prompted her hysterectomy. Therefore, it is very difficult to ascertain the cause and effect

relationship between hysterectomy and post surgical UI. These issues should be carefully considered when evaluating the association of hysterectomy with UI.

The conflicting evidence could also be attributed to methodological shortcomings including inadequate statistical precision owing to small sample sizes, scarcity of controls who have not had hysterectomy, short durations of follow up, and systematic errors, such as ascertainment, selection, or recall bias (Thakar and Sultan 2005). These issues can only be clarified when long-term follow-up of recently completed randomised trials are performed (Thakar and Sultan 2005).

v. Hormone therapy

The impact of postmenopausal hormone use on UI also remains contentious. Hormone therapy (HT) for the treatment of UI was based on assumptions about biological mechanisms, associations of various symptoms with menopause, and small, uncontrolled trials (Kim and Chancellor 2006). The lower urinary tract shares a common embryologic origin with the genital tract and the urogenital sinus, and oestrogen and progesterone receptors are present in the vaginal epithelium, urethra, and bladder trigone (Kim and Chancellor 2006). Reduction of oestrogen after menopause leads to significant atrophic changes in the genital tract, which might lead to urinary symptoms including UI. Because HT has a beneficial effect on vaginal mucosa, in particular in improving symptoms of atrophic vaginitis, it was suggested that HT might also improve UI (Kim and Chancellor 2006). However, oral oestrogen replacement therapy, long used to treat UI, has been identified in large trials as a risk factor for the development of stress UI (Grady et al. 2001;

Hendrix et al. 2005). The Women's Health Initiative multicenter double-blind, placebo-controlled, randomised trial (WHI study) which included 23 296 postmenopausal women, reported that conjugated equine oestrogen with or without progestin increased the risk of UI among continent women and worsened the characteristics of UI among symptomatic women after 1 year (Hendrix et al. 2005).

The Nurses' Health Study also reported increased risk of UI in women taking postmenopausal hormones compared with women who had never taken hormones (oral oestrogen: RR 1.54, 95% CI 1.44 - 1.65; transdermal oestrogen: RR 1.68, 95% CI 1.41 - 2.00; oral oestrogen with progestin: RR 1.34, 95% CI 1.24 - 1.44; transdermal oestrogen with progestin: RR 1.46, 95% CI 1.16 - 1.84). There was little risk after the cessation of hormones (RR 1.14, 95% CI 1.06 - 1.23) and a decreasing risk of UI with increasing time since last hormone use; 10 years after stopping hormones, the risk was identical in women who had and had never taken hormone therapy (RR 1.02, 95% CI 0.91, 1.14) (Grodstein et al. 2004).

A recent Cochrane review concluded that systemic hormone therapy, using conjugated equine oestrogen from oral tablets, skin patches or subcutaneous implants, may make incontinence worse (RR: 1.32, 95% CI: 1.17-1.48). The result was similar with the addition of a progestogen to oestrogen therapy (RR: 1.11, 95%CI: 1.04-1.18) (Cody et al. 2009). There is some evidence that oestrogens used locally by means of a vaginal cream, tablet, vaginal ring or other device may improve incontinence (RR: 0.74, 95% CI: 0.64-0.86) (Cody et al. 2009). In clinical practice, vaginal oestrogen is commonly prescribed for postmenopausal women for symptoms of UI and this is supported by the statement in the

Cochrane review : “local oestrogen treatment for UI may improve or cure it” (Cody et al. 2009).

There are too few data to reliably address other aspects of oestrogen therapy, such as oestrogen type and dose, and less is known about the effect of the newer selective oestrogen receptor modulators on UI (Buckley and Lapitan 2010).

vi. Impaired cognitive state or physical mobility

Almost invariably, individuals with dementia will develop incontinence as the disease progresses (Skelly and Flint 1995). However, the primary reason for UI in this setting is often not pathology in the urinary tract, rather, it is due to factors outside the urinary system. Maintenance of continence requires mobility, manual dexterity, mental capacity and motivation. Clearly, an individual with dementia is vulnerable to developing problems in these domains (Yap and Tan 2006). Poor mobility and the presence of nocturia increase the risk of UI in these patients (Miu et al. 2010) as does the occurrence of urinary tract infection.

1.2.3 ASSESSMENT OF UI

A wide range of instruments is available for assessing UI and determining its impact on quality of life. The selection of an appropriate questionnaire for research depends on the psychometric properties (reliability, validity, responsiveness) of the instrument as well as a number of practical considerations. Assessment of UI symptoms and its impact on patients' lives should be assessed by high quality, validated questionnaires and more consistent use of these instruments in epidemiological studies would facilitate comparison of results between studies.

The Symptom and Quality of Life Committee of the International Consultation on Incontinence performed a systematic review of questionnaires related to UI and FI, searching MEDLINE, The Cochrane Library® and other electronic databases between 2001 and 2004 (Avery et al. 2007). The committee developed and recommended a standardised grading system for questionnaires based on the Oxford Centre for Evidence-Based Medicine, Levels of Evidence (Evidence-based Medicine Levels of Evidence 2004). The system was applied to evaluate and categorise questionnaires concerned with UI (Donovan et al. 2002). Two grades of recommendation were established, including Grade A-highly recommended, which is reserved for established measures with documented, rigorous validity, reliability and responsiveness in several clinical studies and Grade B-recommended, which is the grade recommended for measures with some validity, reliability and responsiveness indicated or for which only validity and reliability but not responsiveness have been established with rigor in several clinical studies (Avery et al. 2007).

The Questionnaire for Urinary Incontinence Diagnosis (QUID) is easy to understand and a valid and reliable instrument for diagnosing different types of UI. Bradley et al. (Bradley et al. 2005) developed and validated this questionnaire with incontinence specialists' clinical evaluations as the gold standard. As it was developed after the systematic review of questionnaires related to UI by the Symptom and Quality of Life Committee of the International Consultation on Incontinence, it was not categorised as either Grade A or Grade B category. It has defined cut-off scores and can classify women into groups of stress and/or urge UI with a known level of accuracy (Bradley et al. 2005).The QUID has acceptable psychometric characteristics and may be used as a UI outcome measure in clinical trials(Bradley et al. 2010). Information provided about test-retest reliability in the QUID validation paper (Bradley et al. 2010) suggests that the test-retest reliability of the final version of the QUID (used in our study) is "very good". The authors quote a statistic (the kappa statistic) for the final version of 0.91 for stress UI and 0.83 for urge UI. However, this information does not allow us to determine what proportion of women would be classified as having or not having UI on repeated testing. For this we would need to know what proportion of women would score <4 or ≥4 for stress and <6 or ≥6 for urge UI on repeated occasions. This information is not available.

Measures are now available for UI and its impact on quality of life (condition-specific instruments) and researchers and clinicians are encouraged to use the 18 measures achieving the highest level of rigor and their validated translations. Most questionnaires are gender-specific. Of these, the questionnaires that are suitable for use in women to diagnose UI and its impact on quality of life are: the Bristol Female Lower Urinary Tract Symptoms

Questionnaire (BFLUTS), the International Consultation on Incontinence Questionnaire (ICIQ), the Stress and Urge Incontinence and Quality of Life Questionnaire (SUIQQ), the Urogenital Distress Inventory (UDI), the Incontinence Impact Questionnaire and the Incontinence Severity Index. Many of these questionnaires were not developed primarily to distinguish different types of UI and their diagnostic abilities for classifying subjects' stress and urge incontinence have not been well tested (Bradley et al. 2005). For the present research the BFLUTS was employed as a condition-specific 'quality of life' questionnaire as it is a validated and gender-specific instrument for assessing the impact of different types of UI on quality of life. A more detailed description of the BFLUTS questionnaire is provided in Chapter 2 in the 'Study instruments' section.

1.2.4 PREVALENCE AND INCIDENCE OF UI

The sections below summarise what is known of the prevalence and incidence of UI in Australian women.

Section 1.2.4.1 is a published review of the literature with respect to the prevalence and incidence of UI in Australian women and the methodological issues identified in these studies up to 2006.

Botlero R, Urquhart DM, Davis SR, Bell RJ. Prevalence and incidence of urinary incontinence in women: Review of the literature and investigation of methodological issues. International Journal of Urology (2008) 15, 230–234.

Monash University

Specific Declaration 1

Declaration for Thesis Chapter 1.2.4.1: Review paper (Publication 1)

Declaration by candidate

In the case of Chapter 1.2.4.1(Review paper), the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Critically appraised the existing literature and drafted submitted manuscript, revised manuscript	

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	**Nature of contribution**
Donna M Urquhart	Critical revision of the submitted manuscript
Susan R Davis	Critical revision of the submitted manuscript
Robin J Bell	Critical revision of the submitted manuscript

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

(1) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
(2) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
(3) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
(4) there are no other authors of the publication according to these criteria;
(5) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
(6) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Women's Health Program, Department of Medicine, Level 6, The Alfred Centre, Monash University**

Signature 1	[redacted]	**Date 11.05.11**
Signature 2		
Signature 3		

International Journal of Urology (2008) 15, 230–234 doi: 10.1111/j.1442-2042.2007.01976.x,

Original Article: Clinical Investigation

Prevalence and incidence of urinary incontinence in women: Review of the literature and investigation of methodological issues

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Objectives: Urinary incontinence in women is common and has a significant impact on the physical, psychological and socio-economic aspects of life. The aims of this study were to review the published reports on the prevalence and incidence of urinary incontinence in Australian women and to examine the methodological issues associated with these studies.

Methods: Electronic searches of Medline, EMBASE and the Current Index to Nursing and Allied Health Literature databases were undertaken using 'Medical Subject Heading' terms and 'free text' words. We retrieved papers that investigated the prevalence and/or incidence of urinary incontinence in Australian women and were published in English after 1980. Methodological data from each study were tabulated.

Results: Seven studies were identified which examined the prevalence of urinary incontinence and two studies that reported its incidence. The prevalence of urinary incontinence varied between 12.8% and 46.0%. Study heterogeneity was a consequence of response rates, the inclusion of women in institutional care, the method of data collection, the questions used to identify different types of urinary incontinence and the way these questions were reported, the period over which the urinary incontinence had occurred and the severity of the incontinence. Two studies which examined incidence provided evidence that urinary incontinence can be a transient phenomenon.

Conclusions: Research into the incidence and prevalence of urinary incontinence in Australian women exhibits significant heterogeneity in the findings due to methodological limitations. There is a need for future studies to employ validated instruments and give careful attention to the selection of participants and the reporting of age-specific data.

Key words: incidence, prevalence, stress incontinence, urge incontinence, urinary incontinence.

Introduction

Urinary incontinence (UI) has been defined by the International Continence Society as a symptom: 'the complaint of any involuntary leakage of urine' or by observation as: 'urine leakage seen during examination'.[1] Although not experienced exclusively by women, UI is substantially more common amongst women than men.[2] UI not only affects a woman's physical wellbeing, but also has a significant impact on the psychological and socio-economic aspects of a woman's life. Apart from women leading restricted lives because of their bladder dysfunction, UI is associated with urinary tract infections, falls and fall-related injuries, occurring as a result of rushing to the toilet, as well as admissions to nursing homes and prolonged hospital stays. Thus, in its severe form, UI results in a high financial burden to the individual and their family, as well as to the health care system.

A detailed understanding of the prevalence and incidence of UI in women is an essential step in reducing the huge impact of this condition. To our knowledge no reviews of the prevalence and incidence of UI in Australian women have been undertaken. However, a review of 13 studies that were undertaken in Europe and the United States identified considerable variation in estimates of prevalence and incidence of UI.[3] The aims of our study were to document what is known about the prevalence and incidence of UI in Australian women, to investigate the methodological issues associated with these studies and provide recommendations for future research in this field.

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Methods

Electronic searches of Medline, EMBASE and CINAHL, were undertaken using the following MESH terms: urinary incontinence, urge incontinence, stress incontinence, epidemiology, prevalence, incidence and 'free text' words; bladder control, lower urinary symptoms. Other searches were also undertaken using Google Scholar and specific journal websites including Neurourology and Urodynamics, Australian New Zealand Journal of Public Health, International Journal of Urology, Urology, American Journal of Obstetrics and Gynecology, Medical Journal of Australia and Australian and New Zealand Continence Journal. The reference lists of identified articles were also searched. Studies that examined the prevalence and/or incidence of UI in women in Australia and were published in English after 1980 were selected. Data on the number of subjects, study design, definition and measurement of UI, and the study results were extracted from the papers and tabulated.

Results

Studies reporting the prevalence of urinary incontinence

We identified seven studies that investigated the prevalence of UI (Table 1). These reported the prevalence to range between 12.8% for any UI within the last 12 months in young women[5] to 46% of women aged in their 50's and 60's reporting either stress or urge incontinence within the last month.[7] The numbers of women included in these studies

Table 1 Studies investigating the prevalence of urinary incontinence (UI) in women

Report	Study design	Definition of UI	Measurement of UI	Results	Methodological limitations
Millard (1998)[4]	• Cross-sectional • 651 women • Randomly selected households in Sydney	• Time: 'ever' and 'at present' • Type: any UI	• Self-report survey • 'Symptoms' questionnaire	• Ever: 53% • At present: 34%	• Limited definition of UI • No validated instrument used • Lower participation by people ≥≥60 years • Reported separately on those in institutional care
Chiarelli *et al.* (1999)[5]	• Cross-sectional • 41 724 women • Randomly selected from Medicare database	• Time: 'last 12 months' • Type: any UI	• Self-report • 'Symptoms' questionnaire	• Young: 12.8% (95% CI: 12.2, 13.3) • Middle age: 36.1% (95% CI: 35.2, 37.0) • Older: 35% (95% CI: 34.1, 35.9)	• No validated instrument used • Response rates ~50%
MacLennan *et al.* (2000)[6]	• Cross-sectional • 1546 women • Randomly selected households in South Australia	• Time: 'last 12 months' • Type: specified (stress, urge, mixed)	• Self-report • 'Symptoms' questionnaire	• Overall: 35.3% • Stress: 20.8% • Urge: 2.9% • Mixed: 11.6%	• No validated instrument used • Exclusion of people inside the institutional care • Response rate 73.3% • Households only
Muscatello *et al.* (2001)[7]	• Cross-sectional • 262 women • Randomly selected households in central Sydney	• Time: 'last month' • Type: specified (stress, urge, mixed)	• Self-report • 'Symptoms' questionnaire (selected and adapted from Bristol Female Lower Urinary Tract Symptoms Questionnaire)	• Urge: 29% (95% CI: 23–34%) • Stress: 35% (95% CI: 29–41%) • Stress or Urge: 46% (95% CI: 39–52%) • Mixed: 18% (95% CI: 13–23%)	• A complete validated instrument was not used • Response rate 68%
Sherburn *et al.* (2001)[8]	• Cross-sectional • 1897 women • Randomly selected using telephone number data in Melbourne	• Time: 'last 2 weeks' • Type: any UI	• Self-report • 'Symptoms' questionnaire	• Overall: 15.3% (95% CI: 13–17%)	• No validated instrument used • Limited age range 45–55 years • Response rate 56% at baseline
Liu and Andrews (2002)[9]	• Cross-sectional • 2087 men and women • Randomly selected using State Electoral database in South Australia	• Time: 'last year' • Type: specified (stress and urge)	• Computer-assisted telephone interview	• Stress (often): 4.4% • Stress (occasional): 24.6% • Urge (often): 10.2% • Urge (occasional) 31.2%	• No validated instrument used • Restricted to people aged 65 years and over • Response rate: 53.4%
Avery *et al.* (2004)[10]	• Cross-sectional • 1546 women • Randomly selected households in South Australia	• Time: 'ever' • Type: specified (stress and urge)	• Self-report • 'Symptoms' questionnaire	• Any Stress: 32.4% • Any Urge: 14.5%	• No validated instrument used • Exclusion of people inside the institutional care • Response rate 73.3% • Households only

UI, urinary incontinence; CI, confidence interval

Table 2 Questions asked in different studies to measure urinary incontinence and its types

References (Author/year of publication)	Method of data collection	Recall time	Questions asked
Millard 1998[4]	Questionnaire	Ever/throughout life	• Not stated
Chiarelli *et al.* 1999[5]	Questionnaire	Last 12months	• In the last 12 months have you experienced leaking urine?
MacLennan *et al.* 2000[6]	Questionnaire	Last 12months	• Have you lost urine when you coughed, laughed or sneezed? (Stress UI) • Have you suddenly felt the urge to go to the toilet but had accidentally wet yourself before reaching the toilet? (Urge UI)
Muscatello *et al.* 2001[7]	Questionnaire	Last month	Questions were selected and adapted from the Bristol Female Lower Urinary Tract Symptoms questionnaire • In the last month, how often did urine leak before you could get to the toilet, during the day or night? (Urge UI) • In the last month, how often did urine leak when you were physically active, exerted yourself, coughed or sneezed, during the day or night? (Stress UI)
Sherburn *et al.* 2001[8]	Questionnaire	Past 2 weeks	• Have you been bothered by problems with urine control in the past 2 weeks
Liu and Andrews (2002)[9]	Two questions were asked to measure the 2 kinds of UI	Not mentioned	• Do you have any difficulty holding your urine until you get to the toilet? (Urge UI) • Do you accidentally pass urine? (Stress UI)
Avery J *et al.* 2004[10]	Two questions were asked to determine the 2 types of UI	Ever/throughout life	• Have you ever lost any urine when you did not mean to, when you cough, sneeze or laugh? (Stress UI) • Have you ever suddenly felt the urge to go to the toilet, but have accidentally wet yourself before reaching the toilet? (Urge UI)

UI, urinary incontinence.

Table 3 Age groups with the highest and lowest prevalence rates by different studies

Author (year)	Age range(years) Study population	Age group (years) with highest prevalence (%)	Age group (years) with lowest prevalence (%)
Millard 1998[4]	10–75 + (5 categories)	45–59 (50%)	10–29 (19%)
Chiarelli *et al.* 1999[5]	18–75 (3 categories)	45–50 (36.1%)	18–23 (12.8%)
MacLennan *et al.* 2000[6]	15–97 (7 categories)	70–74 (51.9%)	15–24 (not stated)
Muscatello *et al.* 2001[7]	41–70 + (4 categories)	60–69 (38% for urge UI and 46% stress UI)	41–49 (18% for urge UI) 70+ (27%stress UI)

UI, urinary incontinence.
Avery *et al.*[10] reported the same age groups for the highest and lowest prevalence rates as MacLennan *et al.*[6] using the same dataset and therefore is not repeated in this table.

ranged from 262 to 41 724. All studies randomly selected participants from community-based populations. The populations studied ranged from the Women's Health Australia project which recruited women from the Medicare database and includes all women resident in Australia[5] to studies which recruited from a state electoral roll[9] and studies based on more restricted populations such as women residing in Melbourne,[8] South Australia[6] or Sydney.[4,7] UI was reported across different age groups, with four studies including individuals over a broad age range[4–6,10] and three studies examining specific age groups.[7–9] Four studies reported the prevalence of different types of UI, including stress, urge and mixed incontinence,[6,7,9,10] while three studies reported the overall prevalence of UI without specifying the type.[4,5,8] None of the studies used a validated questionnaire to assess UI, although one study used questions selected from validated questionnaires.[7] Two of the studies were reporting on the same data set (the South Australian Health Omnibus Survey from 1998),[6,10] although the data was analyzed differently. MacLennan *et al.*[6] reported on 'urge only', 'stress only' and 'mixed' incontinence within the last 12 months and Avery *et al.*[10] reported on 'ever UI' in relation to 'any stress' and 'any urge' incontinence.

Differences between studies

There were many aspects of the identified studies that were dissimilar. These included the age groups studied and whether women in institutional care were included; the response rate to the survey; whether the type of UI was specified as stress, urge or mixed incontinence; the actual question(s) administered; whether data collection was by questionnaire, face-to-face interview or computer-assisted telephone interview; the time frame at which UI was reported ('ever', 'in the last 12 months', 'over the last month or 2 weeks' and 'now'); and whether UI was reported as 'occasional' or 'often'. Table 2 documents the different questions used across the studies to establish the prevalence of UI.

Differences in the questionnaires employed

None of the studies reviewed used a validated questionnaire identifying UI. Some questions grouped all types of 'loss of control' together,[4,5,8] while others separately identified urge and stress incontinence.[6,7,9,10] Amongst those that identified stress and urge incontinence, some reported prevalence as 'only stress' or 'only urge';[6,7] while others reported 'all stress' and 'all urge'.[9,10] Other issues related to the time the questions referred to ('ever' versus 'now') and the severity of the problem ('occasional' versus 'often').

Age-specific prevalence of UI

In the 4 studies that compared the prevalence of UI across different age groups,[4–7] the prevalence was reported to be lowest among the younger groups. However, the age group in which the prevalence was reported to be highest varied between studies (Table 3), although the difference between the prevalence estimates for the age groups beyond middle age were not tested statistically. None of these studies used a complete validated instrument for identifying UI.

Relationship between the prevalence of UI and menopausal status

Only one study investigated an association between UI and menopausal status.[8] This study concluded that, although on univariate analysis perimenopausal and surgically postmenopausal women were more likely to have UI than were premenopausal women; on multivariate analysis, which took into account factors such as body mass index and previous gynecological surgery, menopause status did not make an independent contribution to the risk of UI. This study used a single non-validated question to identify incontinent cases.[8]

Studies reporting the incidence of urinary incontinence

We identified two studies that examined the incidence of UI (Table 4). Neither of these studies used a validated instrument to investigate UI. Sherburn *et al.*[8] studied 373 women aged between 45 and 55 with annual interviews for seven years. They asked about 'any UI within the last two weeks' and reported that the prevalence of UI at the start of the longitudinal study was 17% (95% CI 13–21) and at the final year of the study was 19% (95% CI 15–23). However, examining the data from each year during the follow-up period of seven years, 46% of women reported some UI in at least one of the annual interviews. Liu *et al.*[9] studied an elderly population over two years. They reported that there were new cases of incontinence detected amongst those who were

Table 4 Incidence of urinary incontinence in Australia by different studies

Author/year	Study design	Definition of UI	Instruments used	Results	Comments on methodology
Sherburn *et al.* (2001)[8]	• Prospective cohort study for 7 years • Face to face interviews • 373 subjects	• Time: any incontinence over past 2 weeks • Type: not specified	Symptoms questionnaire	Over 7 years • Any UI- 35%	• The study didn't provide annual incidence rate • Validated instrument was not used
Liu and Andrews (2002)[9]	• Prospective cohort study for 2 years • Face to face interviews • 4187 subjects	• Time: 'last one year' • Type: specified (stress and urge)	Symptoms questionnaire (not a validated instrument)	Annual incidence • Stress(at least occasional)- 16.5% • Urge (at least occasional)- 22.6% • Stress (often)- 1.6% • Urge (often)- 2.1%	• Case definition for incidence rate, i.e. whether the analysis included both the transient and more chronic cases was not clear from the methodology • Validated instrument was not used

UI, urinary incontinence.

continent at the start of the study. However, of those reporting some incontinence at the commencement of the study, there were some who improved, some who got worse and others who fluctuated within the course of the study. This study reported that the incidence rates of 'at least occasional' urge incontinence and stress incontinence over a 12 month follow-up period were 22.6% (with 2.1% often) and 16.5% (with 1.6% often), respectively.

Discussion

Despite limiting our review to studies of Australian women published since 1980, we have found a substantial variation in the estimates of the prevalence of UI. Our findings of the inconsistencies in the published reports for Australian women is consistent with what has been reported in studies conducted in Europe and North America.[3]

Although recruitment to all of the studies was population-based, some studies reported response rates below 55%,[5,9] thus limiting the representativeness of the data. Furthermore, those studies that limited recruitment to households are likely to have suffered from a selective under-representation of elderly women, as elderly women are more likely than younger women to be in institutional care. Although none of the studies formally tested whether the estimates of prevalence in women of different ages were different from each other statistically, the implication was that the highest rates of prevalence may be at midlife rather than in the elderly. The inclusion of women in institutional care might provide a different picture. For instance, the study by Millard *et al.*[4] which separately studied people in nursing homes, reported a prevalence of 37%.[4] As prevalence is clearly lower amongst younger women, reporting of UI prevalence must either be age-specific or age standardized.

The methods used to collect the data, specifically the way in which UI was identified, also contributed to differences in findings. Women may be more embarrassed to report UI in a face-to-face interview[8] or a computer-assisted telephone interview[9] compared with a written questionnaire.[4]

Studies of incidence highlighted that there was an apparent small increase in prevalence with age; however, the most useful finding was that UI may be transient. This may be partially a function of successful treatment which shifts women from the symptomatic to the asymptomatic group or it may be that factors related to the symptoms of UI (such as cough) may also be transient.

In conclusion, and consistent with previous data reported by Sandvik 1996,[3] our findings support the need for further research to establish the age-specific prevalence and incidence of UI in women in different countries using validated questionnaires in population-based samples in which the issues of selection bias and response rate are carefully considered. We believe that, ideally, a future study would be of a cohort design and include multiple assessments of UI over 12–24 months to address the transitory nature of the condition. The study should include older women living in institutionalized care, as these women have been under-represented in previous studies. The study should employ a validated instrument to assess UI and be administered in such a way that embarrassment of the women is minimized and the response rate is optimal (self-completed questionnaire). A different method of data collection may be needed for elderly women in institutional care. An accurate understanding of the extent of this problem is essential to planning the provision of intervention strategies and the development of preventive programs.

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As our review paper incorporated Australian studies only on the incidence and prevalence of UI up to 2006, refer to Chapter 3 (Botlero et al. 2009) for a concise review of the international prevalence studies and Chapter 5 (Botlero et al. 2011) for the international incidence studies including studies prior to 2006.

1.2.4.2: Update on my published review

This section provides an update since 2007 on Australian data and international studies subsequent to the publication of the above review paper and describes how the prevalence and incidence reported in Australian studies compare with those reported in international studies.

Prevalence

The reported prevalence of UI varies widely between studies (Table 1). The 3rd (2004) International Consultation on Incontinence (ICI) review of 36 general population studies in 17 countries found prevalence estimates for "any" UI of all types ("ever," "any," "at least once in the last 12 months") ranging from 5 to 69%, with most studies within the range of 25 to 45% (Buckley and Lapitan 2010). This variation is a result of differences in the definitions used, duration of the reference period, method of data collection, the design of the questionnaires and the characteristics of the study population (Thom 1998).

In a recent study by Herschorn et al. (the Canadian Urinary Bladder Survey), UI was assessed by a non-validated questionnaire and the data were collected through a computer-assisted telephone interview (Herschorn et al. 2008). They reported an overall point prevalence of UI of 28.8%, with 68% of affected women having stress UI, followed by

mixed UI in 21% and urge UI in 11% of women (Table 1). The prevalence was lower than for studies that have used a mailed questionnaire, as women are less likely to disclose their UI symptoms during a personal interview (Thom 1998).

The prevalence of and associated risk factors for UI in 19,024 Chinese women aged 20 years or more have been reported using the modified BFLUTS questionnaire (Zhu et al. 2009). The overall prevalence was 30.9% and estimates of stress, urge and mixed UI prevalence were 18.9%, 2.6%, and 9.4% respectively (Table 1.). As face-to-face interviews for data collection were used, the reported prevalence estimate was again lower than for studies which used a self-administered mailed questionnaire (Wallner et al. 2009; Hannestad et al. 2000; Hunskaar et al. 2004; Jennifer et al. 2005).

Wallner et al. quantified the prevalence of UI in a special population group, previously undiagnosed women in a managed care population (Wallner et al. 2009). The prevalence of any UI in the preceding year was 53% and in the preceding week, 39%. They reported the prevalence of previously undiagnosed stress, mixed and urge incontinence to be 18.7%, 12.0% and 6.8% respectively (Wallner et al. 2009).

A recent study by Lasserre et al. in France (Lasserre et al. 2009) reported that UI symptoms were found in almost one in four women attending General Practice clinics with a prevalence of 26.8% (Table 1). Among women with UI, stress UI (45.2%) was found to be the most common, followed by mixed (42.1%) and then urge UI (10.9%), while 2% of women had UI of indeterminate type.

Incidence and resolution

Since my review of the literature (Botlero et al. 2008; Botlero et al. 2011) other reports of the incidence of UI have been published. As my review included Australian studies only, an update on Australian and international studies since 2007 is provided below (Table 2).

There has been one incidence study conducted in Australia as part of the Australian Longitudinal Study on Women's Health (Byles et al. 2009). This study investigated changes in continence status in a large cohort of women aged 70 to 75 years in 1996, who completed four health surveys over a 9 year period. Over this time, 14.6% (95% CI:13.9-15.3%) of the women who had previously reported leaking urine 'rarely' or 'never' at Survey 1 subsequently reported leaking urine 'sometimes' or 'often' at Survey 2, 3 or 4. Strength of this study was the use of a large, national sample of community-dwelling women. However, a limitation was the use of a single question to assess UI.

Four American studies reporting the incidence of UI have been published since 2008, three of which reported on data from the Nurses Health Study (NHS). The incidence of UI amongst participants in the NHS aged 54 to 79 years was reported as 9.2% over 2 years of follow-up (Lifford et al. 2008). Improvement of UI symptoms from frequent to monthly leakage was documented in 8.9% of this sample, with a complete remission rate of 2.0% over the 2-year period. For women in the NHS aged 36 to 55 years, a two year incidence of 13.7% for any UI was reported, with complete remission of symptoms in 13.9% of women with incontinence at baseline (Townsend et al. 2007).

In another paper from the NHS cohort Townsend et al. (Townsend et al. 2010) reported the incidence rates of UI by frequency and type in Asian, black, and white women aged 37 to 79 years. They found that the 4-year incidence rate of any UI was higher in white women (7.3/100 person-years), compared with Asian (5.7/100 person-years; $p = 0.003$) and black women (4.8/100 person-years; $p < 0.001$). The incidence of at least weekly stress UI was significantly lower in black compared with white women (0.1 vs. 0.8 per 100 person-years; $p < 0.001$). The difference in the incidence of any UI and stress UI between black and white women remained significant after adjusting for known risk factors such as age and BMI.

Amongst women in the Study of Women's Health Across the Nation (SWAN study), the average incidence rate for any UI was 11.1% per year for women aged 40 to 55 years. This study involved racially and ethnically diverse, community-based women, who were followed up for 5 years (Waetjen et al. 2007).

None of the above-mentioned studies used a validated instrument to assess UI and in each the age range in the sample was limited.

The prevalence and incidence data from the international studies are consistent with those reported from population-based Australian studies. All these studies have shown that stress and mixed UI are the most common varieties in women. The prevalence of different types of UI differs across the life span, with stress and urge UI more prevalent in women at midlife and older women respectively. UI has a dynamic time-course with relatively high incidence and resolution rates with an overall trend of increasing prevalence with age.

Table 1: Studies investigating the prevalence of urinary incontinence (UI) in women since 2007

Author/year	Definition of UI	Types of UI(stress, urge and mixed)	Methods	Age Mean(SD) /range (years)	Results
Herschorn et al. (2008)(Herschorn et al. 2008)	Time: 'current urinary or bladder control problem'	Specified	• Computer-assisted telephone interview • Non-validated instrument	44.53±16.01	• Overall:28.8% • Stress UI:19.5% • Urge UI: 3.3% • Mixed UI: 6%
Zhu et al. (2009)(Zhu et al. 2009)	Time: 'not specified'	Specified	• Interview • Modified BFLUTS questionnaire	20 or over	• Overall:30.9% • Stress UI:18.9% • Urge UI: 2.6% • Mixed UI: 9.4%
Wallner et al. (2009)(Wallner et al. 2009)	Time(2 ways): leakage of any amount of urine during the past 12 months, and over past 7 days	Specified	• Self-reported mailed questionnaire • Non-validated instrument for UI • Included undiagnosed UI only	25 to 80	• Overall:38% in the preceding week • Stress UI:18.7% • Urge UI:6.8% • Mixed UI:12.0%
Lasserre et al. (2009)(Lasserre et al. 2009)	Time: 'any urine leakage at least once during the past four weeks?'	Not specified	• Partly interviewed by GP and partly by self-reported questionnaire • Validated instrument used for UI	18 or over	• Overall:26.8%

Table 2: Studies reporting the incidence of urinary incontinence in women since 2007

Author /year	Definition of UI	Types of UI(stress, urge and mixed)	Methods	Age-group (years)	Results
Townsend et al. (2010)(Townsend et al. 2010)	leakage of any amount of urine during the past 12 months	Specified	• Self-reported mailed questionnaire • Several questions on UI • Non validated instrument	37 to 79	At least monthly UI: 7.3% in white women, 5.7% in Asian and 4.8% in black women over 4 years Or 1.8%/year in white women, 1.4%/year in Asian and 1.2%/year in black women
Byles et al. (2009)(Byles et al. 2009)	leakage of any amount of urine during the past 12 months	Not specified	• Self-reported mailed questionnaire • Single question for UI • Non validated instrument	70 to 75	Over 9 years: 'sometimes' or 'often'UI: 14.6% Or 1.8%/year
Lifford et al. (2008)(Lifford et al. 2008)	leakage of any amount of urine during the past 12 months	Specified	• Self-reported mailed questionnaire • Non validated instrument • Limited age cohort	54 to 79	At least monthly UI of 9.2% over 2 years Or 4.6%/year
Townsend et al. (2007)(Townsend et al. 2007)	leakage of any amount of urine during the past 12 months	Specified	• Self-reported mailed questionnaire • Non validated instrument • Limited age cohort	36 to 55	13.7% over 2 years Or 6.9%/year
Waetjen et al. (2007) (Waetjen et al. 2007)	leakage of any amount of urine during the past 12 months	Specified	• Self-administered questionnaire • Non validated instrument • Limited age cohort	42 to 52	At least monthly UI: 11.1% / year

1.2.5 IMPACT OF UI ON QUALITY OF LIFE, WELL-BEING AND SEXUAL FUNCTION

Although UI is not a life-threatening health problem, it has been shown to have detrimental effects on quality of life (QoL) in terms of physical, psychological, social and sexual difficulties (Barber et al. 2002). Hunt and McKenna (Hunt and McKenna 1992) defined QoL as the extent to which individuals are able to satisfy their needs. This needs-based model states that an illness or condition will have a detrimental effect on QoL if it prevents the fulfilment of needs. QoL is considered an important outcome for UI interventions because of the condition's potential psychosocial consequences and because interventions may not result in complete cure (Grimby et al. 1993).

Most studies have investigated the impact of UI on QoL using questionnaires that evaluate symptoms, bothersomeness, the impact on general health, the specific impact of symptoms and the impact on sexual function (Donovan et al. 2002). These are "condition-specific questionnaires". Condition-specific questionnaires [such as the Incontinence Impact Questionnaire (Ragins et al. 2008)] assess the impact of UI comprehensively as they measure the symptoms in an individual and the extent to which they impair QoL. They can also be used to evaluate QoL changes in women over time and are useful for the assessment of treatment efficacy. These condition-specific questionnaires include questions about physical and social limitations, along with specific questions about UI (Barber et al. 2005); (Okamura et al. 2009). A recent large community-based study in France reported that UI had a negative impact on QoL (Lasserre et al. 2009). In this, as in other studies, restriction of activities was used as a

surrogate measure of QoL (DuBeau et al. 2006). The main activity reported to be affected was "excursions outside the home" (Lasserre et al. 2009). Similarly, other investigators have not specifically assessed QoL, but asked participants to indicate the degree to which their UI impacted on their daily life, rate the "bothersomeness" of their symptoms (Abdel-Fattah et al. 2007) and report on how UI affected "their feelings about themselves" (Fultz and Herzog 2001). Desire for treatment has also been used as a surrogate for the impact of UI on QoL (Andersson et al. 2004). These studies have consistently reported an adverse effect of UI on the outcome measure chosen.

Few studies have evaluated the relationships between various forms of UI and well-being in community-dwelling women (Grimby et al. 1993) (Fultz and Herzog 2001). Although some studies have found that UI is associated with a reduction in well-being (Grimby et al. 1993; Coyne et al. 2008; Irwin et al. 2006), others using condition-specific questionnaires have concluded that any effect of UI is modest (Aslan et al. 2008; Wyman 1994). However, the use of condition-specific instruments does not allow for the comparison of well-being in women with UI with that of unaffected individuals. Moreover, even though it is recognized that there are different types of UI, no study has examined whether there are differences in the relationship between stress, urge and mixed UI and QoL.

Generic well-being questionnaires [such as the Psychological General Well-being Index (Dupuy 1984)] enable a direct comparison between women with UI and unaffected women in the community. In contrast to the condition-specific questionnaires which quantify the impact of UI on activities of daily living, a generic well-being

questionnaire can be used to evaluate the impact in terms of mood, vitality, anxiety, positive well-being, self-control and general health. Hence, a generic questionnaire enables comparison with women without UI and also with women with other health problems such as diabetes.

In the present research a condition-specific questionnaire (BFLUTS) was used to assess the impact of UI on QoL, and a generic instrument (PGWBI) to assess the impact of UI on well-being of women. The PGWBI was developed to measure the affective states reflecting subjective well-being (Dupuy 1984). It also provides a total score that is a measure of intra-psychic well-being that is not dominated by physical limitations.

Sexual function is one of the most important, but least-investigated domains of QoL that can be affected by UI. QoL questionnaires, such as the BFLUTS, the King's Health Questionnaire and the Incontinence Impact Questionnaire, include questions addressing sexual function but deal with the overall impact of incontinence on the patient's QOL or well-being and do not focus on sexual function (Kammerer-Doak 2009). General questionnaires such as the Female Sexual Function Index (FSFI) (Rosen et al. 2000) focus on sexual function but may not be sufficiently sensitive to detect the specific impact of UI on sexual function. The FSFI is a 19-item questionnaire with 6 domains of female sexual function, namely, desire, arousal, lubrication, pain, orgasm, and satisfaction during sexual activity or intercourse, over the previous month. Each domain consists of 2 to 3 questions and has its own specific coefficient (0.6 for desire, 0.3 for arousal and lubrication, and 0.4 for orgasm, satisfaction, and pain) that is used to calculate the final domain score. Individual domain scores are added up to obtain a total

score; scores higher than this final domain score imply better sexual function. In the study by Sen et al. investigators explored the effects of different types of UI on female sexual function with the FSFI. In this study FSFI scores were compared between the incontinent (women with any UI as well as women with different types of UI) and control groups (Sen et al. 2006). A multivariate linear regression model was used to explore the effects of patient characteristics on total FSFI domain score. The incontinence term had a significant impact on all domain scores of FSFI except lubrication and pain, indicating impaired sexual function in the incontinence group (for total domain mean (SD) score, 20.48±6.20, P=0.005) compared with control group (22.97±6.95). The study concluded that UI adversely affects female sexual function and mixed UI has the greatest impact on sexual function when compared with other types of incontinence (Sen et al. 2006).

The Pelvic Organ Prolapse Urinary Incontinence Sexual Questionnaire (PISQ-12) is a validated, condition-specific questionnaire developed to assess the impact of UI on sexual function (Rogers et al. 2003). It has 12 items with 3 major domains: behavioural, physical and partner-related factors. Using the PISQ-12 questionnaire, a significant inverse relationship between severity of UI and sexual function has been demonstrated with women with more severe urinary symptoms having lower levels of sexual function (Lowenstein and Bitzer 2010; Murphy et al. 2008).

Although the impact of UI on sexual well-being is an important aspect of understanding and managing UI, it was beyond the scope of the present study.

1.2.6 CURRENT TREATMENT FOR UI

UI may require a variety of treatments, depending on the diagnosis, severity and impact on quality of life. It can be managed, and sometimes cured, through lifestyle changes, physiotherapy, pharmacological therapy, pudendal nerve stimulation or a combination of these. Once conservative measures have been exhausted, the management of stress UI is largely surgical, while that of urge UI may be pharmacological or surgical. In some instances 'cure' may be a consequence of natural resolution.

Treatment options are listed below from least to most invasive:

1.2.6.1 Life-style Adjustments

Although evidence supporting lifestyle modifications is, as yet, relatively limited, there is widespread clinical experience and international expert opinion that support the use of lifestyle modifications for the treatment of UI. The initial treatment for stress UI and urge UI should include life-style changes such as weight reduction, smoking cessation, reducing caffeine and alcohol consumption and modifying food and fluid intake as discussed below (Dwyer 2004).

The association between obesity and UI is well-documented. However, there are limited data as to the effectiveness of weight reduction for improving UI symptoms. A small randomised controlled trial by Subak et al. reported that loss of 5 to 10% of total body weight among overweight and obese women experiencing at least 4 UI episodes per week resulted in a 54% reduction in UI episodes, and that the improvement was maintained at the six-month follow-up (Subak et al. 2005).

Some studies have reported an association between smoking and UI (Nuotio et al. 2001; Danforth et al. 2006). Postulated mechanisms include the direct effect of nicotine on the cholinergic detrusor pathways (urge UI) and increased intra-abdominal pressure as a result of coughing (stress UI)(Christofi and Hextall 2007). Women who smoke experience over a two-fold increase in stress UI and it is estimated that the proportion of risk for UI in women smokers attributable to smoking is 28%. The risk increases, both with the number of cigarettes smoked and the duration of smoking (Bump and McClish 1992). There is a lack of evidence to support the notion that stopping smoking helps to reduce the risk of UI in smokers.

Various observational studies have shown a positive association between high caffeine intake and detrusor instability (Tomlinson et al. 1999); (Arya et al. 2000). In their case-control study, Arya et al. reported a statistically-significant association between high caffeine intake and detrusor instability which persisted after controlling for age and smoking (OR: 2.4, 95% CI: 1.1- 6.5%, P =.018) (Arya et al. 2000). Evidence that reduction in caffeine intake lowers the risk of UI is lacking.

Song et al. reported a positive association between alcohol consumption and UI (Song et al. 2005), but studies reporting that reducing alcohol intake leads to a reduction in UI are lacking.

Evidence regarding an association between dietary composition and UI is limited. A large cohort study of middle-aged women followed up for one year suggested that chicken,

vegetables and bread reduced the risk of developing an overactive bladder, and bread reduced the risk of onset of stress UI. Carbonated drinks increased the risk of developing overactive bladder symptoms and a diet high in fat and cholesterol predisposed women to stress UI (Dallosso et al. 2003). Protective functions of the diet containing vegetables and bread could be due to its high fibre content. A low fibre diet is one of the causes of chronic constipation and bowel straining, and can affect pelvic floor neurological function (Snooks et al. 1985). In population studies constipation is found to be associated with UI (Moller et al. 2000). Vegetables are also important sources of many vitamins and minerals, and bread is a valuable source of the B vitamins. The reduced risks noted in this study(Dallosso et al. 2003) could be related to one of the essential biochemical functions that these micronutrients have in the body (Dallosso et al. 2003). Koskimaki et al. reported an increased risk of lower urinary tract symptoms (LUTS) in men with a lower vegetable intake, and suggested that 'vegetables may contain natural ingredients with preventative or curative effects on diseases which cause LUTS' (Koskimaki et al. 2000). Many of the obscured effects of healthy diet may simply reflect healthy behaviour, overall better health, reduced weight and a lower risk of UI.

Maserejian et al. examined intakes of total energy, carbohydrate, protein, and fats in relation to UI in a cross-sectional sample of 2,060 women in the population-based Boston Area Community Health Survey (2002-2005). They did not find any associations between the risk of UI and intake of carbohydrates, protein or total fat. However, the ratio of saturated fat intake to polyunsaturated fat intake was positively associated with UI (highest quintile vs. lowest: adjusted OR: 2.48, 95% CI: 1.22-5.06) and was strongly associated with severity of UI (P for trend < 0.0001). Results suggest that dietary changes, particularly

decreasing saturated fat relative to polyunsaturated fat and decreasing total calories, could independently account for some of the benefits of weight loss in women with UI (Maserejian et al. 2010). Specific pathophysiologic mechanisms that may underlie an association between relative intake of saturated and polyunsaturated fats and UI plausibly involve inflammation or vascular changes that result in endothelial dysfunction relevant to the etiology of urologic symptoms(Steers 2002; Andersson 2003).

Behavioral and lifestyle changes, including weight loss, are often the preferred first line of treatment for most UI patients, yet the evidence for efficacy is limited. There is a clear need for longitudinal studies to evaluate the effects of various life-style interventions on UI. The strongest data, in terms of life-style changes, are for weight loss. Reducing alcohol and caffeine consumption are good health messages and may be worthwhile, and smoking cessation should always be encouraged.

1.2.6.2 Physiotherapy

Pelvic floor muscle training

Pelvic floor muscle training (PFMT) is the most commonly-used physical treatment for women with stress UI. It is also recommended for mixed UI and less commonly, for urge UI. It is especially helpful in motivated, compliant patients and can be delivered as Kegel exercises, pelvic floor physiotherapy or with endovaginal cones. Named after Dr. Arnold Kegel, these exercises consist of contracting and relaxing the muscles that form part of the pelvic floor, especially the pubococcygeus muscles (Brubaker 2010). The aim of Kegel exercises is to improve muscle tone by strengthening the pubococcygeus muscles of the pelvic floor. These should be offered to patients with the assistance of an allied health

professional such as a physiotherapist or nurse practitioner. Pelvic floor exercises are thought to inhibit spontaneous bladder contractions and also increase bladder outlet resistance and so result in reduced leakage and increased voiding intervals. A meta-analysis of randomised controlled trials concluded that PFMT should be included in first-line conservative management programs for women with stress, urge or mixed UI (Dumoulin and Hay-Smith 2010). Women with stress incontinence who do the PFMT for three months or more benefit most (Dumoulin and Hay-Smith 2010).

Bladder training and biofeedback

Bladder training is a first-line therapy for mild symptoms of urge UI. It involves patient education, scheduled voiding and positive reinforcement. Biofeedback can be used to notify the patient when certain physiologic events are occurring (e.g. unstable bladder contraction or proper pelvic floor muscle contraction). The use of biofeedback is a well-known method used to manage UI; through the use of visual, auditory, and/or tactile signals, biofeedback teaches women to recognize and then change or influence unconscious physiological processes (Vasconcelos et al. 2006).

Minardi et al. (Minardi et al. 2010) conducted a randomised controlled study to evaluate the efficacy of a training program with uroflowimetry biofeedback and pelvic floor relaxation biofeedback on urodynamic and voiding parameters in women with dysfunctional voiding. In this study, 86 women with dysfunctional voiding were randomly assigned to receive a treatment schedule as follows: uroflowimetry biofeedback (Group 1), biofeedback training of the pelvic floor muscles (Group 2), uroflowimetry biofeedback combined with biofeedback training of the pelvic floor muscles (Group 3) or no treatment

(Group 4). Patients were regularly evaluated by the American Urological Association Symptom Index (AUASI) and urodynamics for one year. A further evaluation was done at month 24 by the AUASI and free uroflowimetry with measurement of residual urine. The study found that the prevalence of storage and emptying symptoms decreased significantly by 3 months in Groups 1, 2, and 3, and remained stable during the study period (12 months). Therapy continued during the whole observation period (12 months) and when the therapy was stopped, a relapse of symptoms occurred, as observed at month 24. This suggests that the beneficial effect is only maintained while therapy is active (Minardi et al. 2010).

1.2.6.3 Pharmacological

Current pharmacological treatments focus primarily on urge UI, anticholinergics being the mainstay of therapy. Anticholinergics act by inhibiting the involuntary contractions of the bladder, by increasing the capacity of the bladder and by delaying the initial urge to void (Reeves et al. 2007). Six anticholinergics drugs are currently marketed worldwide for the treatment of overactive bladder and urge UI: oxybutynin, tolterodine, propiverine, trospium, darifenacin, and solifenacin (Abrams and Andersson 2007). Each product has demonstrated efficacy compared with placebo in treating UI symptoms but common side-effects include dry mouth, constipation, headache and blurred vision. Extended-release versions of oxybutynin and tolterodine are available. They improve continence and have fewer adverse effects than short-acting forms. A skin patch form of oxybutynin is another option.

Patients with stress UI may benefit from a therapeutic trial of pharmacological therapy. Duloxetine, a serotonin and noradrenaline re-uptake inhibitor was the first licensed drug for the treatment of stress UI, approved in 2004. A series of placebo-controlled randomised trials of duloxetine were conducted internationally (Dmochowski et al. 2003; Millard et al. 2004; Norton et al. 2002). Pooled results showed that duloxetine was more effective than placebo in treating stress UI (Drutz 2006). A Cochrane review concluded that duloxetine reduced the frequency of incontinence episodes and improved QoL scores (Mariappan et al. 2007). Duloxetine has been incorporated into the treatment algorithm for stress UI adopted by the International Continence Society (Andersson et al. 2005). Alpha-adrenergic agonists, such as clonidine, are used to strengthen the smooth muscle that opens and closes the internal sphincter for stress UI. However, they can also have significant side effects, including agitation, insomnia and anxiety. These drugs are currently not approved for treating stress UI (Dwyer 2004).

Postmenopausal oestrogen treatment was previously believed to decrease the symptoms of stress UI. However, data from the Heart and Oestrogen/Progestin Replacement Study showed a significantly higher risk of stress and urge incontinence among women randomly assigned to receive oestrogen alone or oestrogen and progestin than among those assigned to receive placebo (Grady et al. 2001). The Women's Health Initiative (WHI study) trial and the Nurses' Health Study reported similar findings that postmenopausal hormone therapy appears to increase the risk of developing UI and the risk diminishes upon cessation of use (Grodstein et al. 2004; Hendrix et al. 2005). Given these results, the initiation of hormone therapy for treatment of UI is not indicated.

However, in clinical practice vaginal oestrogen is commonly prescribed for postmenopausal women for symptoms of UI, as local oestrogen therapy may improve urethral and bladder functions if it is associated with urogenital atrophy (Cody et al. 2009).

1.2.6.4 Devices

Devices that treat stress UI associated with prolapse include tampons and pessaries. Pessaries are intravaginal devices that support the pelvic organs. Incontinence pessaries have knobs that sit under the urethra to increase urethral support. Pessaries require upkeep and need to be removed and cleaned regularly; the risks associated with use are minimal but include erosion of vaginal tissue and vaginal discharge (Rogers 2008). A randomised, controlled trial comparing the use of super tampons and the use of pessaries with the use of no device in women who were incontinent while exercising found that the tampons and pessaries were similarly effective in reducing the frequency of stress incontinence (Nygaard 1995).

1.2.6.5 Minimally invasive options/Newer therapies

Women with urge UI, refractory to the newer anticholinergic agents, can be treated with minimally-invasive options such as bladder injections of botulinum toxin (Rickey and Kenton 2008) and sacral nerve stimulation (SNS, InterStim^{TM})(Schmidt et al. 1999), as well as more invasive major urinary tract surgery such as detrusor myomectomy and augmentation cystoplasty (McKertich 2008).

InterStim therapy is a reversible treatment for women with urge UI who do not respond to behavioural treatments or medications. InterStim^{TM} is an implanted neurostimulation system that sends mild electrical pulses to the sacral nerve. Stimulation of this nerve may relieve the symptoms related to urge incontinence. As a minimally invasive procedure, SNS provides a promising intermediate option for patients with detrusor overactivity refractory to standard treatment or where these options are medically contraindicated (Siegel et al. 2000). SNS induces neuromodulation through using mild electrical pulses to continuously stimulate sacral nerves that innervate the lower urinary tract (Yamanishi et al. 2008) . The mechanism underlying the action of SNS on the overactive bladder is thought to arise from stimulation of the A delta afferent fibres of the sacral dorsal root, which simultaneously excite central micturition inhibitory pathways as well as blocking the procontractile effect of neuropeptide release from C fibres. SNS may also stimulate urethral sphincter activity, the contraction of which inhibits detrusor contraction (Malossi and Chai 2002). After two decades of experimentation with sacral root stimulation, SNS for the treatment of refractory urge UI was approved by the Food and Drug Administration in the United States in October 1997. The recent approval by the Australian Therapeutic Goods Administration of SNS for the treatment of refractory urge incontinence will now allow physicians to offer this therapy to patients who have failed conservative measures (Chen 2010).

Electrical stimulation of the transcutaneous tibial nerve is another therapeutic option being increasingly used with success in women for UI. The therapy is peripheral, non-invasive and low-cost, and gives good results in the treatment of urge UI. Several studies have shown positive results of this therapy in the treatment of urinary symptoms, including

improvement in the quality of life and urodynamic findings of patients (Cooperberg and Stoller 2005; Skeil and Thorpe 2001; van Balken et al. 2001; Amarenco et al. 2003).

Schreiner et al. conducted a randomised clinical trial to examine the efficacy of transcutaneous electrical tibial nerve stimulation (TTNS) to treat urge UI in women aged over 60 years. The women were treated with 12 weeks of bladder retraining and pelvic floor muscle exercises and half were randomly selected to receive TTNS in addition to the standard therapy. Of the patients, 68.0% in the TTNS group reported cure or improvement vs. 34.6% in the control group (P=0.017). Women in the TTNS group showed significant improvement in most areas of QoL and in urge UI parameters when compared with the control group (Schreiner et al. 2010).

1.2.6.6 Surgery

Surgery is indicated when the degree of incontinence is sufficiently troublesome to the patient, the incontinence has been observed by the examiner, its causes are adequately evaluated and conservative therapies have been exhausted. Primary stress UI in women is effectively treated by a retro-pubic suspension or Burch colposuspension (Takacs and Kobashi 2007), or a pubo-vaginal sling procedure . Minimally invasive sling procedures, in particular mid-urethral synthetic slings, are now the most common operations performed, with a range of slings showing similar levels of efficacy (Novara et al. 2007). The female artificial urinary sphincter is generally an operation of last resort in women who have failed multiple procedures with severe intrinsic sphincter deficiency refractory to fascial pubo-vaginal sling surgery (Duncan et al. 1992). Bio-injectables/urethral bulking agents (e.g. bovine collagen, silicone polymer) are generally reserved for patients at increased operative

risk. They are injected cystoscopically to add bulk to urethral tissue and are unlikely to cause obstruction or bladder dysfunction (McKertich 2008). Future developments in the treatment of stress UI include refining the indications for specific procedures and defining which procedures (various sling procedures or bio-injectables) are best suited to which patients (McKertich 2008).

1.2.7 FECAL INCONTINENCE AND ITS RELATIONSHIP WITH UI

Fecal incontinence (FI), the involuntary passage of gas, liquid or solid stool, is similarly a very distressing condition with great social and economic impact. The symptoms of FI can significantly affect a woman's daily activities and quality of life (Crowell et al. 1998) (Bartlett et al. 2009). Little is known about the prevalence of FI among women in the general community. Reported point prevalence estimates vary from 2.0 to 17.0% for adults of various ages in population-based studies (Giebel et al. 1998; Goode et al. 2005; Kalantar et al. 2002; Lam et al. 1999; Lynch et al. 2001; MacLennan et al. 2000). The variation in the estimates is the result of differences in the definitions used for FI, data collection methods (face-to-face interview versus telephone interview or postal self-administered questionnaire), participants' response rates and/or the populations studied (Macmillan et al. 2004; Kalantar et al. 2002). With substantial differences in reported prevalence of FI, there is a need for more research to determine the extent of the problem.

FI and UI can co-exist in women. Given the close anatomical relationship between the rectum and the bladder, along with their shared nerve supply and pelvic floor support, a possible association between FI and UI merits consideration.

1.3 SUMMARY OF INTRODUCTION

The focus of this thesis is on the gaps in knowledge of UI in relation to its prevalence, incidence, resolution and change in subtypes over time in a sample of Australian women living in the community. The thesis also deals with investigating the factors associated with UI and the aim of this work is to identify the potential risk factors with the view to eventually identifying the potential avenues for the prevention of UI. This thesis will address the impact of different types of UI on well-being and quality of life and the relationship of UI with FI using validated instruments. The publications arising from this thesis are intended to raise awareness amongst clinicians of the high prevalence of UI and FI, and the impact they have on women.

Chapter 2

2.1 Study Aims:

This study aims to investigate

- Age-specific prevalence of different types of UI in a community-based sample of women
- Natural history of UI in terms of its incidence and resolution
- Factors associated with prevalent UI
- Impact of prevalent UI and its subtypes on the well-being of women
- Impact of prevalent and incident UI on condition-specific quality of life
- Prevalence of FI and its relationship with UI

2.2. Methods

2.2.1 Study design:

The research described in this thesis was conducted in 2 stages:

Stage one (baseline questionnaire study)

This involved: (1) recruitment of women who had agreed to be recontacted after the SAW study; and (2) completion of a baseline questionnaire on women's health issues, including UI in July 2006.This baseline study enabled the estimation of the prevalence of UI in different age groups with the use of a validated instrument, as well as the determination of the factors associated with different types of UI in a sample of community-dwelling Australian women. It also allowed an examination of the impact of different types of UI on the well-being of women using a generic validated instrument.

Stage two (follow-up questionnaire study)

This consisted of a 2-year follow-up study and involved recruitment of women who completed the baseline questionnaire in 2006 to complete a follow-up questionnaire in July 2008.This longitudinal study component enabled the determination of the incidence and resolution rates of different types of UI, as well as the examination of its course with and without treatment. In addition, the impact of UI on the condition-specific quality of life of women was examined in the follow-up period. The prevalence of FI and its relationship with UI were also assessed in the follow-up study.

The research also involved investigation of back pain and foot pain in the same study women in both the stages (baseline and follow-up) for the research interest of another

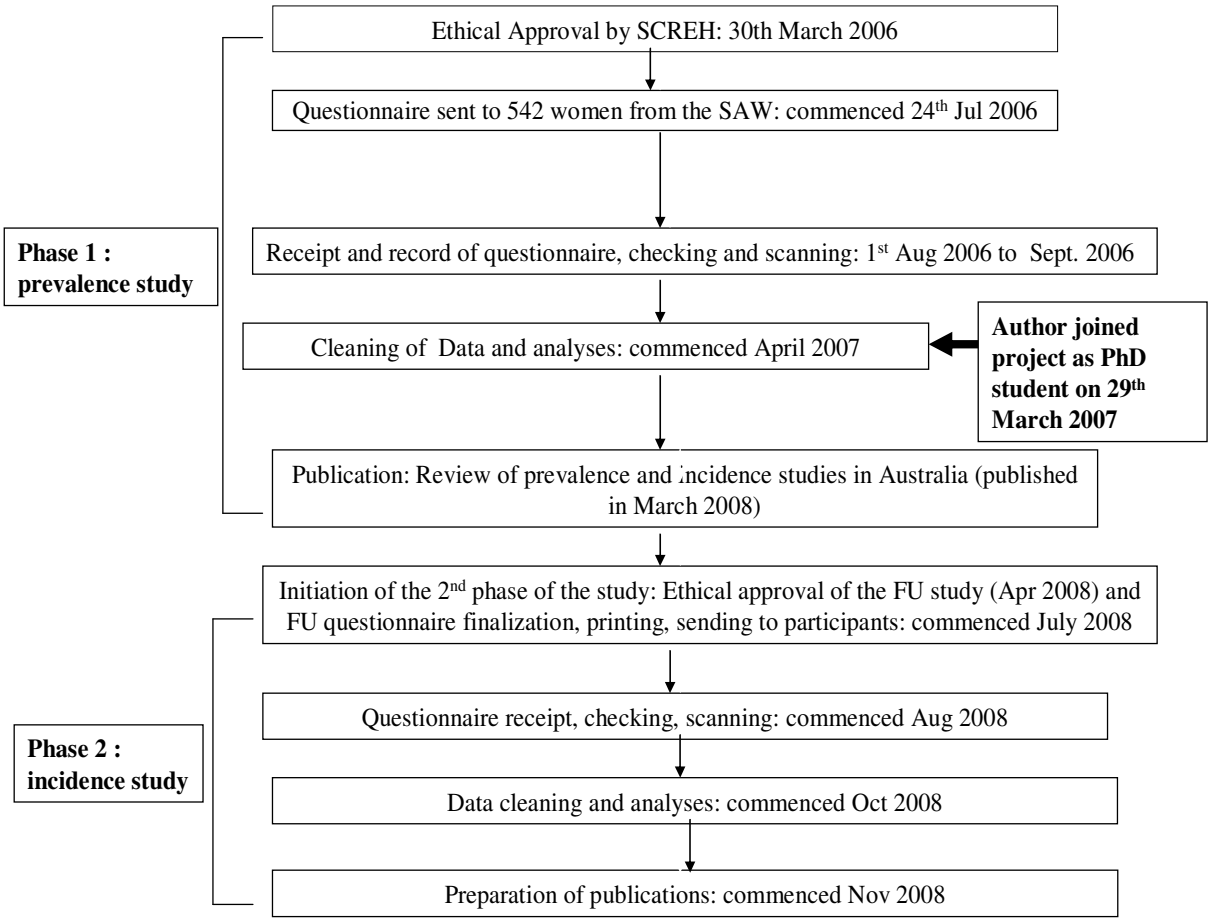
investigator, Dr. Donna Urquhart. These data have been analysed by Dr. Urquhart and are not part of this thesis.

2.2.2 My role in this research project:

The study received ethical approval to commence on 30th March 2006 and the baseline questionnaire was sent to the participants on 24th July 2006. The author commenced her PhD on the 29th March 2007, starting with the literature review of the prevalence and the incidence studies of UI conducted in Australia and the cleaning and analysis of the data from the baseline questionnaire (Figure 1). The author was then responsible for conducting phase 2 (follow-up) of the study that commenced in April 2008, including modifications to the baseline questionnaire. Figure 1 shows the different stages of the project.

The baseline questionnaire was reviewed and expanded for the FU questionnaire by the addition of questions about constipation, treatment approaches for UI, hysterectomy, types of anaesthesia used during childbirth and the Pelvic Floor Distress Inventory questionnaire to assess FI. The author arranged the printing and mailing of the follow-up questionnaire to the study participants and followed up the non-responders by telephone if they had not returned the questionnaire after four weeks. Three attempts were made to contact the participant by phone before a telephone message was left if an answering machine was available. Of the 457 FU questionnaires which were posted in July and August 2008, 349 were returned by the 25th of September 2008 and the other 127 needed follow-up by telephone to prompt return of the questionnaire.

Figure 1. Time flow chart of different stages of the project



2.2.3 Ethical approval:

The initial application for the UI study was approved by the Standing Committee on Ethics in Research involving Humans (SCERH) on 30th March 2006. The project involved the mailing of a BL questionnaire about UI to 542 women in the Victorian community who had previously agreed to participate. A total of 506 completed questionnaires were returned.

A 2-year follow-up (FU) study was planned for the participants (506) who took part in the initial BL questionnaire in 2006. The questionnaire was similar to that previously approved by the SCERH, with some minor modifications. The modified questionnaire along with an amendment application form for the FU study was submitted to the Ethics Committee and was approved in 2008. All participants gave written informed consent for both parts of the study.

2.2.4 Study population and recruitment methods:

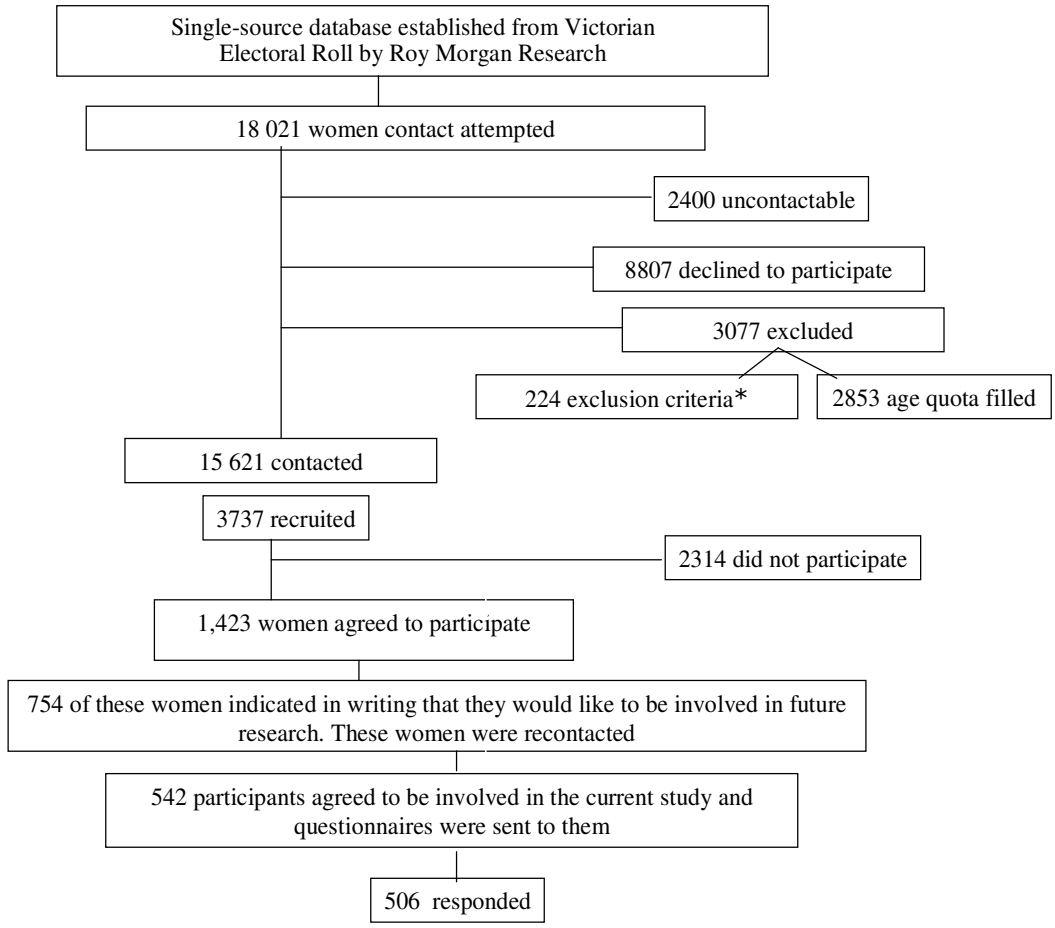
The participants in this study were recruited from a previous cross-sectional study examining the role of androgens in women [the Study of Androgens in Women (SAW)] using a database, the Roy Morgan Single Source Database (RMR). The women in the SAW were recruited from the RMR database between April 2002 and August 2003. In order to describe the normal physiological relationship between androgen levels and age, from the reproductive years to many years postmenopause, healthy women between the ages of 18 and 75 years were included in the SAW study. This age range was further divided into groups: 18-24 years, 25-34 years, 35-44 years, 45-54 years, 55-64 years and 65-75 years, in order that the relationship between androgens and age could be reported and compared between the groups. The SAW study recruited 1423 community-based women from both rural and urban areas of Victoria, forming a representative sample of Australian women. For recruitment purposes to the RMR database, 8 interviews took place each weekend between the hours of 9am and 4pm in every 'sampling point' of each electorate. Sampling points comprise approximately 25,000 people in each electorate. At the time of recruitment for this study, metropolitan Melbourne had 105 sampling points, and rural Victoria had 43 sampling points. Starting addresses in each sampling point were selected at random, with door-knocking by interviewers continuing until a total of 8 interviews were obtained. One person per household only was interviewed for the database; this person remained on the database for a period of 2 years, unless they actively requested prior removal from the database.

For the SAW study, a total of 18,021 eligible women were identified from the database (Figure 2). 2400 women could not be contacted and the remaining 15,621 women

underwent screening for the SAW study by telephone. Recruitment occurred in waves, at approximately monthly intervals, as age quotas and participation rates were assessed. Due to difficulty in recruiting younger women to the study, recruitment of women aged 18-35 years was the main focus in the later stages of the study.

The SAW study involved the completion of self-administered questionnaire by the participants and the collection of a fasting blood sample at a pathology laboratory. After telephone screening, 8807 women declined to participate and a total 3077 women were excluded from participating in the study; 224 women were excluded due to exclusion criteria, whilst a further 2853 women were excluded due to age quotas being filled. The remaining women numbered 3737. Of these, 2314 did not participate in the study, although they had initially agreed to participate, with the remaining 1423 women comprising the participants for the SAW study.

Figure 2. Flow chart of recruitment of subjects to UI study (Davison et al. 2005)



***Exclusion criteria:**

Women were excluded from the SAW study if they reported any of the following:

- Current pregnancy or childbirth within the previous 6 weeks
- Gynaecological surgery
- Active malignancy or cancer treatment (excluding non-melanotic skin cancer)
- Any acute liver, renal, cardiovascular disease or
- Other major physical or psychiatric illness within the preceding 3 months

2.2.5 Stages of recruitment for the present study:

For the baseline questionnaire study

Of the 1423 women who participated in the SAW study only those who agreed to be contacted about further research were eligible to be contacted about the UI study. 754 of the 1423 women agreed to be recontacted and of them, 542 expressed interest in participating in the study of UI. A baseline (BL) questionnaire along with a consent form and plain language statement were mailed to the participants for self-completion in 2006. A free-call phone line was set up and maintained to allow participants to contact the study investigators if they had any questions for the researchers. Participants, who had agreed to participate in the baseline study but had not returned their questionnaire within a month of mail out, were re-sent the letter and questionnaire. If participants had not returned the questionnaire after a further 2 weeks, phone contact was made. Three attempts were made before a telephone message was left. A message left was considered as a contact. Of the 542 participants, 506 returned the completed questionnaire and their data were analysed (Figure 3).

For the follow-up questionnaire study

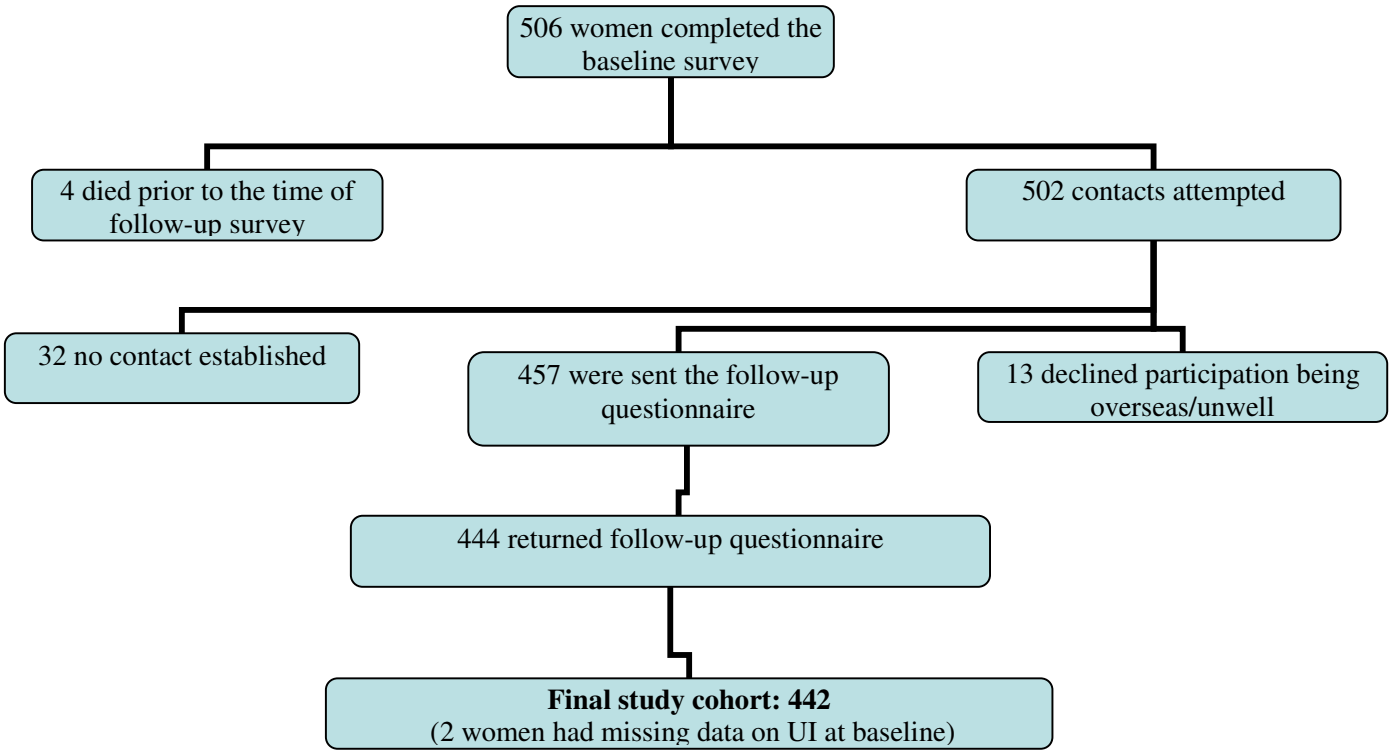
Two years later, the BL questionnaire was modified for the follow-up (FU) study with the addition of some new questions (Refer to section 2.2.5 “Study questionnaires”), whereas in the baseline questionnaire a question would refer to “ in the past”, in the FU questionnaire, the question was changed to “ in the past 2 years”. Only the participants (506 women) who took part in the initial questionnaire in 2006 were contacted for the FU study in 2008, and the FU study used the same procedures as previously approved by the Ethics Committee. The participants were sent a letter advising them that we would be sending a FU questionnaire and expressing appreciation for their continued involvement in the study.

They were asked to notify us, if they did or did not wish to continue. A FU questionnaire was posted to the 457 women who agreed to complete the FU questionnaire and was available to continue in the study (Figure 3). A reminder was given to the non-responders by phone if they had not returned the questionnaire after four weeks. 444 of the 457 women to whom the follow-up questionnaire was sent, responded. The final analysis included 442 women, as 2 of the 444 women did not complete the QUID questionnaire in the baseline survey (Figure 3).

Exclusion criteria for the baseline and follow-up studies:

There were no specific exclusion criteria for women to participate in the baseline and follow-up studies. However, we already knew that all the SAW participants had sufficiently literate in English to complete the study questionnaires. Women who had participated in the SAW were in reasonably good health at their initial recruitment.

Figure 3. Flow chart of participation in the follow-up study of UI(Botlero et al. 2011)



2.2.6 Study questionnaires: (both baseline and follow-up questionnaires are attached in Appendix I and II)

The BL questionnaire collected detailed information on socio-demographic and physical data, including age, height, weight, marital status, occupation, current and past medical history, obstetric history, current prescription and non-prescription medication. It included validated instruments for assessing urinary incontinence [the Questionnaire for Urinary Incontinence Diagnosis (QUID) and the Bristol Female Lower Urinary Tract Symptoms Questionnaire (BFLUTS)], well-being [the Psychological General Well-being Index (PGWBI)], the impact of menopause on quality of life [the Menopause-Specific Quality of Life (MENQOL)] and physical activity [the International Physical Activity Questionnaire (IPAQ)].

Menopausal status was determined on the basis of answers to several questions considered in a hierarchical manner [Figure 4. (Bell et al. 2008)]. Women who had undergone bilateral oophorectomy or were aged 58 years or over were categorised as postmenopausal. Designation of menopause status was then according to responses to questions about use of hormonal contraception, systemic postmenopausal hormone therapy or menstrual cycle regularity and in the case of menstrual irregularity or hysterectomy, presence of vasomotor symptoms (Bell et al. 2008).

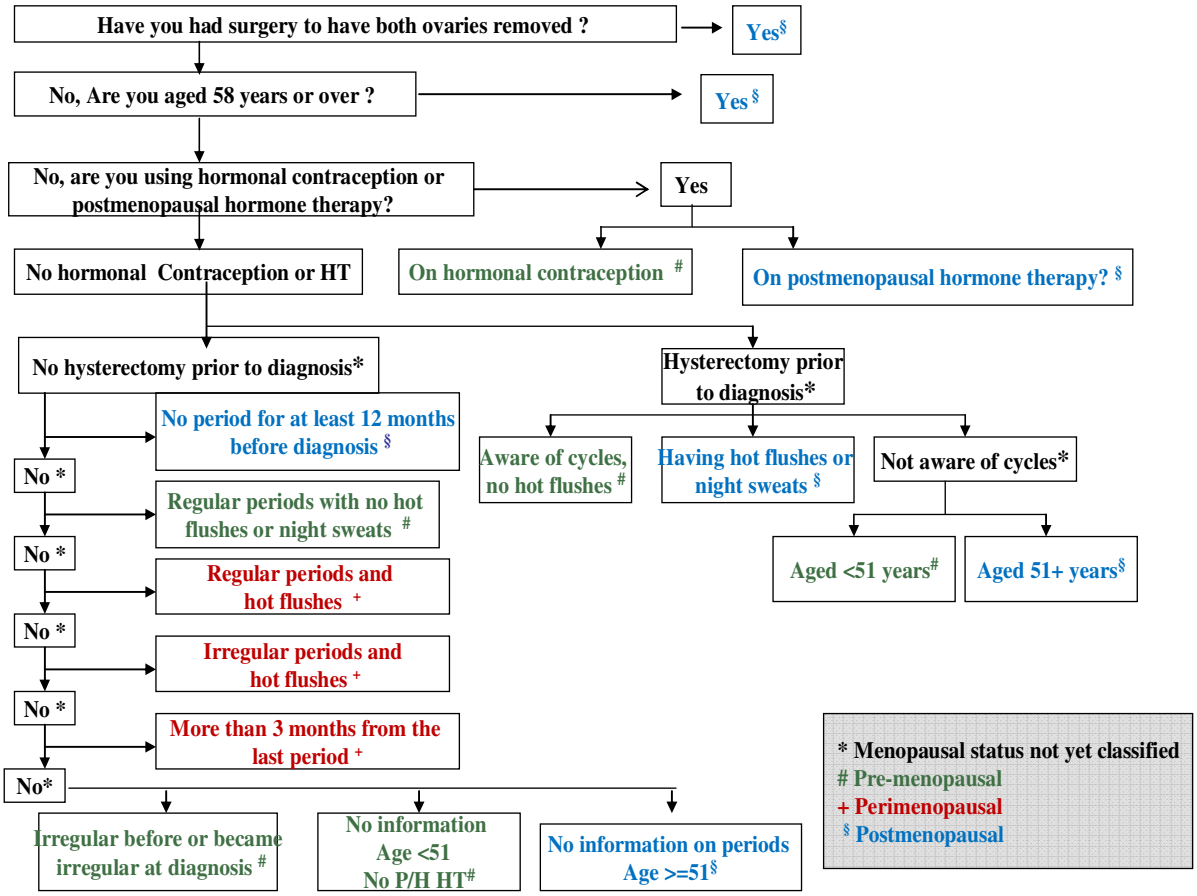
The quantification of exercise using an exercise-specific questionnaire such as the IPAQ is a problematic issue especially in regard to incomplete and contradictory responses and the issue of defining vigorous exercise with which the study investigators have grappled over a number of years, finally resorting to using a dichotomous variable. This was assessed using

the question “Do you participate in any regular exercise/recreational activity?” and the response was categorized as either “yes” or “no”.

The study questionnaires also included validated instruments for back pain, foot pain and some related questions such as treatments used for back pain, back belief questions. The back pain section of the project was for the research interest of another investigator (Dr. Donna Urquhart) and does not form part of the present thesis.

The FU questionnaire was similar to the baseline questionnaire, except for the addition of extra questions about constipation (In the last 3 months have you usually emptied your bowels or passed stools less often than 3 times per week?), treatment approaches for UI, hysterectomy, types of anaesthesia used during childbirth and the Pelvic Floor Distress Inventory (PFDI) to diagnose FI. Regarding treatment approaches for UI, participants were asked if they had ever received treatment for their UI including surgery, medications, physiotherapy or other treatments, and to specify the details of the surgery or medications they received. They were also asked whether they believed their symptoms of UI had improved after having treatment. Improvement of UI symptoms was based on the response to the question “How was your incontinence after treatment?” and the response was categorized as “better”, “same”, “worse” or “unsure”.

Figure 4. Flow chart of classification of menopausal status. HT, hormone therapy; P/H, past history(source:http://www.med.monash.edu.au/medicine/alfred/womenshealth/docs/menopausal-staging-algorithm.pdf) (Bell et al. 2008)



2.2.6.1 Study instruments:

Questionnaire for Urinary Incontinence Diagnosis

In this study, UI was assessed using the Questionnaire for Urinary Incontinence Diagnosis (QUID), a validated questionnaire which contains the following 6 items to assess different types of UI during the previous 30 days:

Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments

1. When you cough or sneeze?
2. When you bend down or lift something up?
3. When you walk quickly, jog, or exercise?
4. While you are undressing to use the toilet?
5. Do you get such a strong and uncomfortable need to urinate that you leak urine (even small drops) or wet yourself before reaching the toilet?
6. Do you have to rush to the bathroom because you get a sudden, strong need to urinate?

The severity of the problem is then assessed by the frequency of the problem within the last 30 days ranging from “rarely” to “all of the time”. Questions 1, 2 and 3 contribute to the stress score and Questions 4, 5 and 6 contribute to the urge score. Each item’s responses range from 0 to 5 based on the frequency of leakage, where a score 0 is given for ‘none of the time’ and a score of 5 is given for ‘all the time’ (score 1= rarely, 2=once in a while, 3=often and 4=most of the time). Scores for each question are added, with a maximum total score of 15 for each of stress and urge UI. A woman with a combined score of ≥ 4 for Questions 1, 2 and 3 is classified as having stress UI and a woman with a combined score

of ≥ 6 for Questions 4, 5 and 6 is classified as having urge UI (Bradley et al. 2005).Women diagnosed with both stress and urge UI by the QUID were identified as having mixed UI (Bradley et al. 2005). The QUID was used to determine the overall prevalence of UI and its different types, namely stress, urge and mixed.

Bristol Female Lower Urinary Tract Symptoms Questionnaire

The Bristol Female Lower Urinary Tract Symptoms (BFLUTS) questionnaire is another validated instrument designed to assess a wide range of urinary symptoms, including incontinence and impact on sexual function and quality of life (Brookes et al. 2004). It contains 12 questions for urinary symptoms including 5 items for UI, 2 questions relating to sexual function and 5 questions for assessing impact on quality of life (QoL) (Brookes et al. 2004).

In this study five condition-specific QoL questions from the BFLUTS questionnaire were used to assess the impact of different types of UI on QoL. Specifically, these questions included frequency of the need to change outer clothing during the day because of urine leakage, frequency of deliberately cutting down fluid intake, the extent to which urinary symptoms affect the ability to perform daily tasks, the frequency of avoiding situations where a toilet is not nearby and the extent to which urinary symptoms interfere with life. The responses to each of these questions were scored from 0 (never) to 4 (all of the time), except daily tasks and overall interference with life, which were scored from 1 (not at all) to 3 (a lot). The BFLUTS-QoL section provides a total score (range 2-18), with a higher score indicating a more adverse impact of UI.

Psychological General Well-being Index

In this research, the impact of different types of UI on well-being of women was assessed by the Psychological General Well-being Index (PGWBI). This generic QoL instrument consists of 22 items with 6 domains, each rated on a 6-point scale and responses to each question score from 0 to 5(Dupuy 1984). The answers to individual questions are added together to assess the domains: anxiety, depressed mood, positive well-being, self-control, general health and vitality. Each domain is defined by a minimum of 3 or a maximum of 5 items. The answers to some questions are reverse scored to ensure that for each domain a high score equates to a "good outcome", thus allowing the scores for all domains to be added to provide a summary score, which reaches a maximum of 110 points, representing the best achievable "well-being".

Pelvic Floor Distress Inventory

The Pelvic Floor Distress Inventory (PFDI) questionnaire was used in this study to assess fecal incontinence (FI). This is a condition-specific, validated questionnaire for women with disorders of the pelvic floor that serves as a symptom inventory for pelvic organ prolapse, FI and UI and also includes questions to measure the degree of bother and distress caused by the symptoms(Barber et al. 2006). The PFDI has 20 items and 3 domains: pelvic organ prolapse distress inventory, colo-rectal-anal distress inventory and urinary distress inventory. The individual domains of the PFDI are created by summing the scores of groups of questions. Respondents were asked if they experienced specific symptoms and the response was categorized as either 'yes' or 'no'. If the response was 'yes', the degree to which the symptom bothered them was measured on a 4-point scale ranged from 'not at all' to 'quite a bit' (Barber et al. 2006).

There are 3 questions on FI (well-formed, loose and flatus) in the colo-rectal-anal distress inventory domain. Leakage of flatus was not included in our definition of FI as it is frequently reported but less bothersome. In this study FI was defined as loss/leakage of well-formed or loose stool beyond control at least once in the preceding 3 months.

2.2.6.2 Rationale for choosing the questionnaires for assessing UI, FI and well-being:

The most valid way of measuring the presence, severity and impact of a symptom or condition on a patient's activities and well-being is through the use of psychometrically robust self-administered questionnaires (Naughton et al. 2004). An increasing number of questionnaires for assessing UI and FI and well-being in women are available. For a questionnaire to be useful in research or in practice it must demonstrate three important psychometric properties: validity, reliability and responsiveness (Bland and Altman 2002; Crosby et al. 2003; Guyatt et al. 1993). The validity of a questionnaire refers to whether the instrument measures what it intends to measure (Bland and Altman 2002; Guyatt et al. 1993). The reliability of a questionnaire refers to its ability to measure in a reproducible fashion (Guyatt et al. 1993; Bland and Altman 2002). Responsiveness refers to a questionnaire's ability to reliably detect the overall effect of treatment and to detect clinically meaningful change (Crosby et al. 2003). Other characteristics that are desirable in a questionnaire include being easy to understand and feasible to implement.

The questionnaire used for assessing UI is the QUID. It is a short, simple and easy-to-understand validated instrument (Bradley et al. 2005). It also provides clear cut-off scores to define stress, urge and mixed UI. The BFLUTS is another validated questionnaire

included in the present study, but as it does not have clear-cut scores to define different types of UI, this questionnaire was not used for diagnostic purposes.

The PGWBI is a validated generic QoL instrument used to assess well-being (Grossi et al. 2006). It has the advantage of allowing comparisons of well-being between women with UI and women without UI, but may lack sensitivity to the unique aspects of UI and how it impacts the life of affected women. Condition-specific QoL instruments are designed to measure the impact of a specific disease on health related QoL (Guyatt et al. 1993). These instruments provide a more in-depth assessment of specific issues and concerns critical to the disease process for which they were designed. However, they are limited in their capacity to allow comparison of a specific group with the community as a whole. In the longitudinal study a subdomain of the BFLUTS was used, a condition-specific QoL instrument, BFLUTS-QoL, to evaluate the impact of different types of UI on QoL. This questionnaire focuses on physical and social limitations due to the symptoms of UI as well as an overall influence on all the activities of daily life.

When choosing an appropriate validated questionnaire for use in the FU study, a web-based search was undertaken for FI questionnaires measuring what we wanted to measure. A brief review of the questionnaire's content and structure was carried out and the reliability, validity, and responsiveness of the questionnaires were assessed by reviewing the related published research works. The use of non-validated questionnaires may provide misleading information or fail to detect important clinical changes (Bland and Altman 2002; Guyatt et al. 1993; Crosby et al. 2003).The PFDI is a validated and reliable questionnaire that is used for women with disorders of the pelvic floor including UI, pelvic organ prolapse and FI

(Barber et al. 2005). This instrument was selected to assess FI as it is validated, assesses what is required for the study and is simple and easy for women to complete.

2.2.6.3 Limitations of the instruments

As the QUID questionnaire does not allow for the grading of severity of UI, it was not possible to examine the relationship between well-being and severity of symptoms within the subcategories of UI.

The PGWBI is not a condition-specific questionnaire.

2.2.6.4 Data Management and cleaning for the FU study

The author and the research nurses checked for missing data on the paper version of the FU questionnaires, and followed up the participants over telephone in an attempt to fill in missing data. The author scanned and verified the questionnaires using the program TeleForm by Cardiff Software, which were then transferred to the database.

TeleForm is a form-processing application that performs three tasks: (1) creates machine-readable data forms, (2) creates databases to contain the data collected using these forms and (3) reads data from the forms created and stores the data in the previously-created databases. Teleform processes forms/questionnaires with an optical technology, called optical character recognition (OCR), which is the mechanical or electronic translation of scanned images of handwritten, typewritten or printed text into machine-encoded text.

The FU questionnaires were scanned by the author using the Teleform Scanner, then were checked for scanning errors and rescanned or manually corrected if required.

The scanned data were then simultaneously verified using Teleform Verifier. There are 2 windows on the computer screen for display. The main window displays the page as it actually appears on the questionnaire. The smaller window below displays the data points, question by question, as been scanned by the Teleform scanner, and allows corrections to be made to the scanned information. Not all the pages of the scanned questionnaire are displayed in the computer screen for review. The optical character recognition (OCR) technology of Teleform makes it possible to edit the text, search for a word or phrase, store it more compactly, display or print a copy free of scanning artifacts. OCR software programs are analytical artificial intelligence systems that consider sequences of characters rather than whole words or phrases. Based on the analysis of sequential lines and curves, OCR makes 'best guesses' at characters using database look-up tables to closely associate or match the strings of characters that form words.

The pages of the questionnaires which were unclear or not scanned properly were detected by the Teleform verifier and displayed on the computer screen for verification. Around 5-10% of all data in each questionnaire which were not written or scanned properly, needed review for corrections and almost 95% of all the questionnaires were verified by the Teleform verifier. Data from around 5% questionnaires did not need verification and were transferred directly to the database.

Cleaning of the data

Data cleaning involved the following steps:

- Completeness check for missing data i.e. whether all the data were entered into the data base from the questionnaires

- Range checks of all variables to check obvious errors
- Consistency checks by running frequency of all variables
- Check baseline data vs. follow-up data for fixed variables such as date of birth, major operations in the past
- Strategies were devised and implemented with the help of supervisors to resolve any data issues such as missing or inconsistent data

If any discrepancy was found the original paper versions of the BL and FU questionnaires were checked. Analysis of the data from the FU questionnaire commenced in October 2008 to evaluate the incidence and resolution of UI and the prevalence of FI and its association with UI.

2.2.7 Calculation of Prevalence, Incidence and Remission Rates for UI:

a. Prevalence: This was reported as the number of women classified as having UI by frequency and type, at baseline and at follow-up divided by the total number of women in each survey.

UI was assessed using the QUID questionnaire which contains the 6 questions to assess different types of UI within the last 30 days.

b. Incidence rate: Incidence included the number of women newly classified as having UI on the basis of the QUID scores in the 2 years of follow-up divided by the number of women free of UI at baseline. For the average annual incidence, this rate was divided by 2.

c. Remission: This was considered to occur when a woman was classified as having no UI according to the QUID scores in the follow-up study, but she had been identified as incontinent at baseline.

2.2.8 Sample size/power calculation:

The sample size was pragmatically determined by the proportion of women from the original SAW (Davison et al. 2005) who agreed to participate in further research. Because of the methods used to recruit women to the SAW study, selection bias had been minimized (Figure 2). The aim with recruitment to this study was therefore to optimize the number of participants, given the original pool of 754 from the SAW who had agreed to be recontacted. We knew that the greater the number of women who could be recruited to and then retained in the study, the more precise would be our estimates of the prevalence of different types of UI. Given that we also wished to model factors related to UI, and the general rule of requiring 10 participants per variable in any model (Kleinbaum et al. 1988) we were confident that we would be able to run such an analysis with over 500 women in the study even for different forms of UI (stress, urge and mixed)

2.2.9 Statistical analysis:

The data were summarized as prevalence and incidence estimates with 95% confidence intervals (95% CI) and socio-demographic data were presented as frequencies, means (± standard deviations, SD), ranges or percentages. Associations between UI and the other health parameters were investigated using Pearson's chi-square tests and logistic regression analyses, adjusting for potential confounders. Linear regression analyses were used to assess the impact of UI on well-being, adjusting for other factors such as age and BMI.

The statistical analyses were performed using SPSS version 14.0 for Windows (SPSS Inc. Chicago Ill. USA) for the baseline prevalence paper (Botlero et al. 2009) and for the well-being paper (Botlero et al. 2009). STATA (version 9) was used for fitting logistic regression models for the prevalence paper (Botlero et al. 2009) and SPSS version 16.0 for Windows (SPSS Inc. Chicago Ill. USA) was used for the analysis of data for the paper on incidence (Botlero et al. 2011) and the FI paper (Botlero et al. 2011).

RESULTS

This section incorporates 4 peer reviewed papers in Chapters 3 to 6:

2 published manuscripts in the journals: “Maturitus” and “Menopause”

2 manuscripts in press in the journals: “Menopause” and “Journal of Urology”

Monash University

Specific Declaration 2

Declaration for Thesis Chapter 3: Publication 2

Declaration by candidate

In the case of Chapter 3 (Publication 2), the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Study design, conduct of the research, data management, analysis of the data, drafted the submitted manuscript, revision of manuscript	

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	**Nature of contribution**
Susan R Davis	Study design, critical revision of submitted manuscript
Donna M Urquhart	Study design, critical revision of submitted manuscript
Shortreed S	Statistical analysis assistance
Robin J Bell	Study design, statistical analysis guidance, critical revision of submitted manuscript

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

(7) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
(8) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
(9) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
(10) there are no other authors of the publication according to these criteria;
(11) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
(12) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Women's Health Program, Department of Medicine, Level 6, The Alfred Centre, Monash University**

Signature 1		**Date**
Signature 2		
Signature 3		

Chapter 3: Publication 2

3.1 Title:

Botlero R, Davis SR, Urquhart DM, Shortreed S, Bell RJ. Age-specific prevalence of, and factors associated with, different types of urinary incontinence in community-dwelling Australian women assessed with a validated questionnaire **Maturitas.** 2009 Feb 20; 62(2):134-9.

3.2 Summary of findings:

UI is a highly prevalent condition in women living in the community, with a prevalence of any UI of 41.7%. Of the women with UI, 16% reported stress only, 7.5% reported urge only and 18% reported a mixed pattern. Stress UI was the most common type amongst middle aged women (25.3% of women aged 35-44 years), while urge UI in women over the age of 75 years (24.2%). In this study obesity ($P<0.001$) and parity ($P=0.019$) were found to be significantly associated with stress UI. Increasing age ($P=0.002$) with urge UI, and being overweight ($P=0.035$) or obese ($P<0.001$) and having had a hysterectomy ($P=0.021$) were positively associated with mixed UI after adjusting for confounders.

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Age-specific prevalence of, and factors associated with, different types of urinary incontinence in community-dwelling Australian women assessed with a validated questionnaire

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ABSTRACT

Objective: The aim of this study was to document the age-specific prevalence of different types of urinary incontinence (UI) in women and to identify the risk factors associated with each type of UI.
Design: A detailed self-administered questionnaire was mailed to 542 community-dwelling women, aged 24–80 years. The questionnaire included a validated instrument, the Questionnaire for Urinary Incontinence Diagnosis (QUID), for the assessment of stress, urge and mixed UI.
Results: Five hundred and six of the 542 women provided data (93.4%). The overall prevalence of any UI was 41.7% [95% confidence interval (CI): 37.2–45.8%]. Of the 210 women reporting UI, 16% [95% CI: 12.9–19.3%] reported stress only; 7.5% [95% CI: 5.2–9.8%] reported urge only and 18% [95% CI: 14.7–21.5%] reported a mixed pattern. Stress incontinence was most common amongst middle-aged women (25.3% of women aged 35–44 years), while urge incontinence was most common in women over the age of 75 years (24.2%). In logistic regression analyses, obesity ($p < 0.001$) and being parous ($p = 0.019$) were found to be significantly associated with stress incontinence, increasing age ($p = 0.002$) with urge incontinence, and being overweight ($p = 0.035$) or obese ($p < 0.001$) and having had a hysterectomy ($p = 0.021$) with mixed incontinence.
Conclusions: UI is a highly prevalent condition in women living in the community. Stress, urge and mixed incontinence have different age distributions and risk factors. These data are important in understanding the etiology, management and possible prevention of these conditions.

1. Introduction

Urinary incontinence (UI) is a common problem in women and has been associated with significant physical morbidity, loss of independence, decreased quality of life and decreased participation in social and domestic activities [1]. The economic impact of UI in developed countries is indicated by the total annual cost of UI in Australia alone, which was estimated to be $710.44 million in 1998, or $387 per woman with this condition [2]. Given the ageing population and assuming the same age-specific prevalences and taking inflation into account, the total cost of UI for community-based women in Australia is projected to be $1.27 billion by the year 2018, with 93% of this cost associated with women aged over 40 years [2].

Previous studies of UI have shown wide variability in prevalence rates in women, with estimates ranging between 25% [3] and 45% [4]. Chiarelli et al. [5] reported the prevalence of UI in women aged 45–50 years to be 36.1%, whereas Millard [6] reported a prevalence estimate of 50% for women aged 45–59 years. Moreover, the peak incidence of stress incontinence has been reported to occur between 25 and 49 years of age [7]. While the prevalence among females over 10 years of age has been estimated at 34% [8], the prevalences of UI in young, mid-age and older women have been estimated to be 12.8%, 36.1%, and 35%, respectively [5]. This variability may be a result of differences in the definitions used, duration of the reference period, the design of the questionnaires and the characteristics of study population [9]. Because of the heterogeneity of published studies, the results are difficult to compare.

Age and obesity are well-established risk factors for UI [10–12]. Parity is another risk factor for moderate and severe stress and any UI [3,10,13]. However, in relation to other risk factors, findings have been inconsistent with some studies showing significant associations between UI and mode of delivery [1], menopausal status [15], postmenopausal hormone use [17,18,22,23] and hys-

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terectomy [12,16,24], with other studies failing to show a significant association of UI with mode of delivery [14], menopausal status [25], postmenopausal hormone use [10] and hysterectomy [26,27]. A recent study has shown that severity is a consideration in whether a risk factor is significant for UI. In the data from the National Health and Nutrition Survey from the United States in 2001–2002, hysterectomy was a significant risk factor for mixed incontinence if it was moderately severe, but not if it was rated as mild [10]. To overcome this problem, the 2nd International Consultation on Incontinence recommended that further studies should be conducted using validated questionnaires to allow the combination of data from prevalence studies with those of cofactors and predictors [28]. Moreover, as different types of UI may reflect different pathologies and involve different risk factors, epidemiological research should also differentiate between the types of UI [29].

The aims of this study were to examine the prevalence and risk factors for different types of UI in a sample of Australian women living in the community.

2. Methods

2.1. Study participants

Women were eligible for the present study if they had been participants in a study of the role of androgens in women (n = 1423) [30]. Recruitment to the androgen study was achieved using a database established from the electoral roll in the Southern Australian state of Victoria between April 2002 and August 2003 [30]. Individuals were recruited from household addresses selected at random on a weekly basis from Australian electoral areas as previously described in detail [30]. Women underwent telephone screening and were excluded if they were pregnant or less than 6 weeks postpartum, or had experienced any of the following in the preceding 3 months: an acute psychiatric illness; acute renal, liver, cardiovascular disease or any other acute major illness; gynecological surgery; active malignancy, or cancer treatment, excluding non-melanotic skin cancer. Women who participated in the androgen study were invited to participate in further questionnaire-based research. Of 754 who agreed to be re-contacted about further research studies, 542 expressed interest in participating in this specific study when they were re-contacted by letter, and these women were sent a study package. This study was approved by the Monash University Human Research and Ethics Committee and all participants gave written informed consent.

2.2. Study questionnaires

Detailed demographic information, including age, height, weight, marital status, medical and obstetric history, current prescription and non-prescription medication, were collected. Menopausal status was determined on the basis of answers to several questions in a hierarchical manner including: history of a bilateral oophorectomy, age (≥60 years), current use of hormonal contraception or systemic postmenopausal hormone therapy, history of hysterectomy, bleeding pattern and the presence of vasomotor symptoms [31].

UI was assessed using the Questionnaire for Urinary Incontinence Diagnosis (QUID), a validated questionnaire which contains the following 6 questions to assess different types of UI:

Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments:

1. When you cough or sneeze?
2. When you bend down or lift something up?
3. When you walk quickly, jog, or exercise?
4. While you are undressing to use the toilet?
5. Do you get such a strong and uncomfortable need to urinate that you leak urine (even small drops) or wet yourself before reaching the toilet?
6. Do you have to rush to the bathroom because you get a sudden, strong need to urinate? All of the questions refer to the "last 30 days". The severity of the problem is then assessed by the frequency of the problem within the last 30 days ranging from "rarely" to "all of the time".

Questions 1, 2, and 3 contribute to the stress score and questions 4, 5, and 6 contribute to the urge score. Each item's responses range from 0 to 5 based on the frequency of leakage, where score 0 is given for 'none of the time' and a score of 5 is given for 'all the time' (score 1 = rarely, 2 = once in a while, 3 = often and 4 = most of the time). Scores for each question are added, with a maximal total score of 15 for each of stress and urge in continence. A woman with a combined score of ≥4 for questions 1, 2 and 3 is classified as having stress incontinence and a woman with a combined score of ≥6 for questions 4, 5 and 6 is classified as having urge incontinence [32]. Women diagnosed with both stress and urge urinary incontinence by the QUID were identified as having mixed urinary incontinence [32]. The prevalence of "any incontinence" was calculated by summing the prevalence of stress only, urge only and mixed UI.

2.3. Data analysis

We used logistic regression to investigate the relationship between potential risk factors and UI. As we were interested in understanding the different risk factors for each of the three types of UI, we compared women with each type of UI (stress, urge and mixed) with the women with no incontinence.

The decision about which variables to include in the logistic regression models involved consideration of results from previous

Table 1
Characteristics of study participants (n = 506).

Participant characteristics	
Age (years), mean (S.D.) range	56.75 (12.5) 24–80
Age category (years), n (%)	
<35	19 (3.8)
35 < 45	75 (14.8)
45 < 55	114 (22.5)
55 < 65	137 (27.1)
65 < 75	128 (25.3)
≥75	33 (6.5)
Body mass index (BMI) (kg/m^2)[a], mean (S.D.)	27.33 (5.6)
Smoking status: yes[b], n (%)	52 (10.3)
Partner status: partnered[c], n (%)	342 (67.7)
Employment status: employed[d], n (%)	260 (53.3)
Menopause status, n (%)	
Premenopausal	178 (35.2)
Perimenopausal	35 (6.9)
Postmenopausal	328 (64.8)
Parity, n (%)	
Nulliparous	87 (17.2)
Parous	419 (82.8)
Systemic estrogen ± progestin use: yes, n (%)	119 (23.5)
Hysterectomy status: yes[e], n (%)	110 (21.9)

Abbreviations: S.D., standard deviation; BMI, body mass index.
[a] BMI: 40 cases missing data.
[b] Smoking status: 1 case missing data.
[c] Partner status: 1 case missing data; Partnered' refers to participants that are married, de facto or single with a partner.
[d] Employment status: 18 cases missing data. Employment excludes voluntary work or unpaid work in the home.
[e] Hysterectomy status: 4 cases missing data.

Table 2
Prevalence of different types of urinary incontinence over the previous month based on 10 year age groups, measured by the "Questionnaire on Urinary Incontinence Diagnosis" ($n = 504$).

Age category (years)	n (%)	No incontinence, n (%)	Any incontinence, n (%)	Types of urinary incontinence		
				Stress only, n (%)	Urge only, n (%)	Mixed, n (%)
<35	18 (3.8)	13 (72.2)	5 (27.8)	3 (16.7)	0	2 (11.1)
35 < 45	75 (14.8)	43 (57.3)	32 (42.7)	19 (25.3)	4 (5.3)	9 (12.0)
45 < 55	114 (22.5)	68 (59.6)	46 (40.4)	20 (17.5)	5 (4.4)	21 (18.4)
55 < 65	136 (27.1)	81 (59.6)	55 (40.4)	20 (14.7)	7 (5.1)	28 (20.6)
65 < 75	128 (25.3)	74 (57.8)	54 (42.2)	15 (11.7)	14 (10.9)	25 (19.5)
≥75	33 (6.5)	15 (45.5)	18 (54.5)	4 (12.1)	8 (24.2)	6 (18.2)
Total	504 (100)	294 (58.3)	210 (41.7)	81 (16.1)	38 (7.5)	91 (18.1)

Data on urinary incontinence missing for 2 cases.

studies, our own univariate analyses, and biological plausibility, as well as taking into account collinearity. The variables used in the logistic regression models were: age (as continuous variable), BMI [categorical with 3 levels: <25, 25 < 30, ≥30 kg/m^2], parity (nulliparous vs. parous), menopausal status (postmenopausal vs. not), use of systemic estrogen (yes/no) and hysterectomy status (yes/no). Due to the small number of women with exclusively urge incontinence, we limited the model for this form of incontinence to one which only included the variables for age and BMI. For each of stress and mixed incontinence, we developed three regression models, model 1 controlling for factors previously recognized as risk factors (age and BMI) with models 2 and 3 used to test the association of UI with more novel factors such as being parous, menopausal status, systemic estrogen use (past or current) and hysterectomy (abdominal or vaginal), although only the full results for model 3 are presented in full (Table 5). Because of the high collinearity between parity and vaginal delivery and a small number of women who were parous but had not had a vaginal delivery, it was only appropriate to include one of these variables and we included parity. Analyses were performed using the SPSS statistical package (version 14) for calculating summary statistics and STATA (version 9) for fitting logistic regression models.

2.4. Sample size

The primary aims of this study were to describe the age-specific prevalence of the different forms of UI and to use logistic regression to model risk factors for the different forms of UI. Clearly the greater the number of participants, the greater the precision in the prevalence estimates. For the logistic regression modeling there is no specific rule concerning sample size, apart from the general rule concerning all regression modeling, that there should be at least 10 participants for every variable included in the model [33]. With our knowledge of the likely prevalence of the different forms of UI in our sample and the intention of including up to 8 variables in the models, we estimated the power of our study would be adequate for the evaluation of stress and mixed incontinence, although power would be limited for modeling of urge incontinence.

3. Results

Of the 1423 women from the previous study from which we recruited for the study of incontinence, 542 women expressed interest in the study and 506 returned the study questionnaire. At the time of the original study, the mean (standard deviation, S.D.) age of the 506 women who subsequently chose to participate in the current UI study was 53.4 (S.D. 12.5) years and their mean BMI was 27.9 (S.D. 6.4) kg/m^2, while the mean age of the 917 women who did not participate in our study of urinary incontinence was 48.1 (S.D. 15.1) years and their mean BMI was 27.8 (S.D. 6.6) kg/m^2. Although the mean difference in age in the previous study (−5.34, 95% CI: −6.80 to −3.87) between women who chose to participate in our study of incontinence compared with non-participators was statistically significant ($p < 0.001$), the mean difference in BMI between the groups (−0.11, 95% CI: −0.82 to 0.60) was not significant ($p = 0.77$).

Over two-thirds of participants were partnered, 82.8% were parous and 76.5% of women reported at least one vaginal delivery. Of all study participants, 64.8% were postmenopausal, 23.5%

Table 3
Summary statistics of potential risk factors for stress, urge, mixed and no urinary incontinence ($n = 504$).

Covariates	Stress only ($n = 81$)	Urge only ($n = 38$)	Mixed ($n = 91$)	No incontinence ($n = 294$)
Age, mean (S.D.)	53.7 (12.3)	63.6 (11.7)	58.1 (11.4)	56.3(12.6)
Body mass index (BMI) (kg/m^2), mean (S.D.)	28.4 (5.1)	28.6 (7.9)	29.5 (5.4)	26.2(5.3)
Parous, n (%)	74(91.4)	31(81.6)	80(87.9)	232(78.9)
Postmenopausal, n (%)	44(54.3)	30(78.9)	62(68.1)	191(65)
Systemic Estrogen ± progestin (yes), n (%)	15(18.5)	10(26.3)	29(31.9)	64(21.8)
Hysterectomy (yes), n (%)	15(18.5)	9(23.7)	32(35.2)	54(18.6)

Table 4
Logistic regression analyses (univariate) for different types of UI.

Covariates	Stress only odds ratio [95% conf. interval] (p-value)	Urge only odds ratio [95% conf. interval] (p-value)	Mixed UI odds ratio [95% conf. interval] (p-value)
Age	0.98 [0.96, 1.00] ($p = 0.10$)	1.05 [1.02, 1.09] ($p < 0.001$)	1.01 [0.99, 1.02] ($p = 0.27$)
BMI: overweight	1.12 [0.59, 2.14] ($p = 0.73$)	0.49 [0.19, 1.30] ($p = 0.15$)	2.13 [1.14, 4.00] ($p = 0.02$)
BMI: obese	3.40 [1.82, 6.35] ($p < 0.001$)	2.09 [0.95, 4.65] ($p = 0.07$)	3.66 [1.99, 6.72] ($p < 0.001$)
Parous	2.8 [1.24, 6.44] ($p = 0.01$)	1.18 [0.49, 2.81] ($p = 0.70$)	1.64 [0.83, 3.22] ($p = 0.15$)
Postmenopause	0.64 [0.39, 1.05] ($p = 0.08$)	2.02 [0.89, 4.57] ($p = 0.09$)	1.19 [0.73, 1.94] ($p = 0.47$)
Systemic estrogen ± progestin	0.82 [0.44, 1.53] ($p = 0.52$)	1.28 [0.59, 2.78] ($p = 0.53$)	1.70 [1.03, 2.80] ($p = 0.04$)
Hysterectomy	1.01 [0.54, 1.91] ($p = 0.97$)	1.36 [0.61, 3.04] ($p = 0.45$)	2.30 [1.40, 3.78] ($p < 0.001$)

In the reference group, participants had a BMI less than 25. CI, confidence interval.

Table 5
Logistic regression analyses (multivariate) for any UI, stress only, mixed UI, and reduced model regression analyses for urge only UI.

Covariates	Stress only odds ratio [95% CI] (*p*-value)	Urge only odds ratio [95% CI] (*p*-value)	Mixed UI odds ratio [95% CI] (*p*-value)
Age	0.99 [0.95, 1.02] ($p = 0.44$)	1.05 [1.02, 1.09] ($P < 0.01$)	1.01 [0.98, 1.04] ($p = 0.59$)
BMI: overweight	1.17 [0.60, 2.28] ($p = 0.64$)	0.47 [0.17, 1.25] ($P = 0.13$)	2.00 [1.05, 3.80] ($p = 0.04$)
BMI: obese	3.26 [1.71, 6.23] ($p < 0.001$)	2.09 [0.92, 4.72] ($p = 0.08$)	3.36 [1.81, 6.25] ($p < 0.001$)
Parous	2.99 [1.19, 7.51] ($p = 0.02$)		1.83 [0.84, 3.97] ($p = 0.13$)
Postmenopause	0.64 [0.25, 1.63] ($p = 0.35$)		0.57 [0.24, 1.39] ($p = 0.22$)
Systemic estrogen ± progestin	0.88 [0.41, 1.88] ($p = 0.74$)		1.57 [0.86, 2.9] ($p = 0.14$)
Hysterectomy	1.15 [0.54, 2.48] ($p = 0.71$)		1.99 [1.11, 3.60] ($p = 0.02$)

In the reference group, participants had a BMI less than 25. CI, confidence interval.

had been on systemic estrogen therapy and 21.9% of participants reported having had a hysterectomy (Table 1).

Overall, 41.7% (95% confidence interval (CI): 37.2–45.8%) of women who participated in this study, reported some form of UI in the preceding month (Table 2). 16.1% reported only stress UI, 7.5% reported only urge and 18.1% reported a mixed pattern. Compared with urge UI, stress UI was more common among younger women, with the highest prevalence of 25.3% found in the age group of 35–44 years. In contrast, urge only incontinence was more common amongst older women and was reported by 24.2% of women over 75 years of age.

Summary statistics of the potential risk factors such as age, BMI, being parous, being postmenopausal, systemic estrogen use and hysterectomy for each type of UI are given in Table 3. The results of the univariate and multiple logistic regression models for stress only, urge only and mixed UI are presented in Tables 4 and 5. The multivariate model for urge incontinence included only age and BMI whereas the full models for stress and mixed incontinence included age, BMI and indicator variables for parity, menopausal status, use of systemic estrogen and hysterectomy status.

For stress only UI, in the univariate analyses, factors found to be statistically significant at the 5% level were obesity and being parous (Table 4). In logistic regression model 1, age [odds ratio (OR) of 0.98 (95% CI: 0.96–1)] and obesity (OR, 3.58; 95% CI: 1.90–6.75) were found to be statistically significant factors for stress only UI. The OR for age indicated that those with stress UI only were younger than those without and that those with stress UI only were more likely to be obese than those with no UI. In model 2, age (OR, 0.97; 95% CI: 0.95–0.99), obesity (OR, 3.44; 95% CI: 1.81–6.50) and being parous (OR, 3.11; 95% CI: 1.25–7.77), were significant and after full adjustment for variables included in model 3, obesity (OR, 3.26; 95% CI: 1.71–6.23), and being parous (OR, 2.99; 95% CI: 1.19–7.51), but not age, remained as statistically significant factors for stress UI (Table 5).

For urge only UI, increasing age, which was found to be statistically significant in the univariate analysis, was also significant in the regression that included BMI (Table 5). Older women were more likely to have urge incontinence with odds of 1.09 (95% CI: 1.03–1.15) for each year of increasing age.

For mixed UI in the univariate analysis, statistically significant factors were being overweight or obese, use of systemic estrogen and having had a hysterectomy (Table 4). In both model 1 and model 2, being overweight or being obese were statistically significant and in model 3, statistically significant factors were being overweight (OR, 2.00; 95% CI: 1.05–3.80), or obese (OR, 3.36; 95% CI: 1.81–6.25), and having had a hysterectomy (OR, 1.99; 95% CI: 1.11–3.60) (Table 5).

4. Discussion

This study highlights that UI is common among women living in the community. We reported that the prevalence of different types of UI differs across the life span, with stress and urge UI more prevalent in women at midlife and older women respectively, although the relationship between stress only incontinence and younger age was lost when age was adjusted for other variables. Our results highlight that being obese and being parous were positively associated with the likelihood of having stress incontinence, whereas for urge UI, only increasing age and for mixed incontinence, higher BMI and hysterectomy, were significantly associated with UI. An independent contribution of menopause status was not seen.

The prevalence of UI among our study sample is consistent with that reported in other population-based studies in Australia [5,6,18]. A number of studies have shown an association between UI and increasing age [5,11,19,20] with a change in nature of incontinence from stress to urge type among older women [34]. We found an effect of increasing age on urge incontinence, but not on stress incontinence. The precise pathogenesis of urge incontinence among elderly women is not understood. It may be involve anomalies of neurological control, an element of obstruction or premature activation of the micturitional reflex [35]. Alternatively, as suggested by Coll-Planas et al., it may be a more global indicator of frailty rather than a specific pathology in its own right [36].

Our study confirms that a high BMI is a risk factor for both stress and mixed UI. For mixed UI, a dose-response effect was seen. The odds of mixed UI were almost three times greater for obese women than for women with a BMI under 25 kg/m^2 and the odds of mixed UI in overweight women was about 2 times that of women with a normal BMI. Although being parous has been reported previously as a risk factor for incontinence [5,9], in our study, the association was limited to stress UI.

Some [11,22,23], but not all [24–26] studies indicate hysterectomy is a risk factor for UI. We found hysterectomy to be a significant factor for mixed UI, but not for stress or urge UI separately. It is biologically plausible that nerve and urethral support structure damage associated with hysterectomy could result in a mixed pattern of symptoms. Alternatively, hysterectomy may be associated with either stress or urge or both but in our study the association may have achieved statistical significance in mixed UI group only because of statistical power, as the mixed UI group had the largest number of women.

We did not find an independent association between menopausal status and UI after adjusting for age, BMI, parity and systemic estrogen use. Studies which have compared the frequency of UI in premenopausal and postmenopausal women suggest that the frequency of UI is higher in postmenopausal women [21,27]. However, these studies did not control for the confounding effect of age. Studies which have taken into account the potential confounding effect of age or analyzed the role of menopause in comparable age groups have not always confirmed an independent relationship between being postmenopausal and having UI [11,28].

The impact of systemic postmenopausal estrogen use on UI remains contentious. A Cochrane review of postmenopausal estrogen use for the treatment of UI concluded that treatment with estrogen alone is associated with perceived improvement or cure compared with placebo [37]. In contrast, a subsequent large, double-blind, placebo-controlled, randomized trial, conducted in

multiple North American centers reported that conjugated equine estrogen alone or in combination with progestin increased the risk of UI among continent women and worsened the UI among symptomatic women [17]. In the longitudinal Nurse's Health Study, Grodstein showed a significant increase in the risk of developing incontinence over 4 years in those taking postmenopausal hormone therapy at baseline. This risk was similar for users of estrogen alone and estrogen combined with progestin, as well as users of transdermal estrogen. The elevated risk was evident for short-term and long-term current users but diminished after cessation of hormone therapy [23]. In the Boston Area Community Health Survey, although it was reported that women taking hormone therapy were more likely to report urinary leakage, the odds ratios were not statistically significant [22]. It is unclear whether these large studies employed a validated questionnaires We found systemic estrogen therapy (past or current) to be positively associated with mixed UI in the univariate analysis, but this association did not persist when systemic estrogen was included in the full model.

Strengths of this study are the use of validated instruments to assess the age-specific prevalence of UI and its different types, use of a community based sample, including women from rural and remote regions of the state as well as the metropolitan region and the application of different regression models in the analyses.

There are some limitations to our study. Because of the cross-sectional study design, where the exposure and the outcome status were measured simultaneously, we cannot establish that various "exposures" examined preceded the "outcome" of UI and so cannot establish a cause and effect relationship. The sample size, although large, may not have been sufficiently large for some factors examined to have achieved statistical significance in the analysis of urge UI. The sample was derived from a larger group of women who expressed interest in participation in further research studies. It is likely that the participants are in better health than non-participants (healthy volunteer bias), so our prevalence estimates may be conservative. The women from our original survey who chose to participate in our study of incontinence were older than the women from the original survey who chose not to participate. We found that younger women were less likely than older women to volunteer for further research studies due to time pressures from work and family responsibilities. The prevalence of UI in older women is also likely to have been underestimated as only women living independently in the community were included, thus excluding elderly women in institutional care. This survey also did not evaluate the severity of urinary incontinence as the classification of different types of UI was based on a yes/no classification only. For those women reporting hysterectomy, we did not obtain information about the surgical route of the procedure.

5. Conclusions

We confirm that UI is a common problem in women across all ages and report that different types of UI are associated with different risk factors. The identification of risk factors associated with different forms of UI is a necessary step along the path of establishing causality and the eventual development of interventions aimed at the prevention of UI.

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Monash University

Specific Declaration 3

Declaration for Thesis Chapter 4: Publication 3

Declaration by candidate

In the case of Chapter 4 (Publication 3), the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Study design, conduct of the research, data management, analysis of the data, drafted the submitted manuscript, revision of manuscript	

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	**Nature of contribution**
Robin J Bell	Study design, statistical analysis guidance, critical revision of submitted manuscript
Donna M Urquhart	Study design, critical revision of submitted manuscript
Susan R Davis	Study design, critical revision of submitted manuscript

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

(13) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
(14) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
(15) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
(16) there are no other authors of the publication according to these criteria;
(17) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
(18) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Women's Health Program, Department of Medicine, Level 6, The Alfred Centre, Monash University**

Signature 1		**Date**
Signature 2	[redacted]	11.05.11
Signature 3		

Chapter 4: Publication 3

4.1 Title:

Botlero R, Bell R Urquhart D, Davis SR. Associations between different types of urinary incontinence and physical and psychological well-being of women in Australia. **Menopause.** 2010 March; 17(2):332-7.

4.2 Summary of findings:

Incontinent women had a lower total PGWBI score (76.9 ± 16.5, p=0.001), indicating worse quality of life than women with no UI (81.6 ± 15.3). The total PGWBI mean score was significantly lower in women suffering from stress-only UI (77.8 ± 16.2, p=0.05) and mixed UI (74.2 ± 17.8, p<0.001) compared with women with no UI. In this study no significant difference in the mean total scores between women with urge UI and women without UI was seen. This may be due to the fact that too few women in our study had urge UI to reach statistical power for examining the relationships between urge UI and well-being. As the women with urge UI tended to be older and have greater well-being, it is also possible that UI does not reduce well-being to the same extent as stress and mixed UI, or that any reduction in well-being in this group is modest. Stress UI was negatively associated with the PGWBI sub-domains of self-control, general health and vitality, whereas those with mixed UI had lower scores for all the PGWBI sub-domains. The associations for UI remained significant after adjustment for age, systemic hormone therapy use, menopausal status, smoking and regular exercise.

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Urinary incontinence is associated with lower psychological general well-being in community-dwelling women

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Abstract

Objective: There are few studies documenting the impact of urinary incontinence (UI) on well-being in women. The aim of this study was to evaluate the relationships between different types of UI and general well-being in women in the community.

Methods: A cross-sectional survey of 542 community-dwelling women, aged 24 to 80 years, was conducted in July 2006. A detailed self-administered questionnaire was mailed to the study participants. UI was assessed using the Questionnaire for Urinary Incontinence Diagnosis, and well-being was assessed using the Psychological General Well-being Index (PGWBI). The relationships between types of UI and PGWBI scores were assessed using multiple regression analyses while adjusting for potential confounders.

Results: A total of 506 (94%) women provided data for analysis. Women with incontinence had a lower total PGWBI score (76.9 ± 16.5) than did women with no UI (81.6 ± 15.3; $P = 0.001$). The total PGWBI mean score was significantly lower in women with stress-only UI (77.8 ± 16.2; $P = 0.05$) and mixed UI (74.2 ± 17.8; $P < 0.001$) compared with women with no UI. There was no significant difference in the mean total scores between women with urge UI and women without UI. Stress-only UI was negatively associated with the PGWBI subdomains of self-control, general health, and vitality, whereas those with mixed UI had lower scores for all the PGWBI subdomains. The associations for UI remained significant after adjustment for age, systemic hormone therapy use, menopause status, smoking status, and regular exercise.

Conclusions: Not only is UI associated with a significant reduction in well-being in community-dwelling women, but also, the relationship between different types of UI and well-being seems to differ.

Key Words: Urinary incontinence – Psychological General Well-being – Stress-only incontinence – Urge incontinence – Mixed incontinence.

Urinary incontinence (UI) affects the quality of life of women at all ages but is particularly prevalent from the late reproductive years on. It is a humiliating condition that may impede interpersonal relationships, decrease sexual function, limit activities, and potentially cause stress and reduced well-being. Ultimately, among the older population, severe UI may precipitate institutionalization.[1]

Much of the published literature pertaining to UI is focused on prevalence, risk factors, treatment, and cost implications.[2-12] Few studies have evaluated the relationships between various forms of UI and well-being in community-dwelling women.[1,13] A recent large community-based study in France reported that UI had a negative impact on quality of life.[14] In this study, as in other studies, restriction of activities was used as a surrogate measure of quality of life.[15] The main activity reported to be affected was excursions outside the home.[14] Similarly, other investigators have not specifically assessed quality of life but have asked participants to indicate the degree to which their UI has affected on their daily life, rate the "bothersomeness" of their symptoms,[16] and report on how UI has affected "their feelings about themselves."[13] Desire for treatment has also been used as a surrogate for the impact of UI on quality of life.[17] Consistently, these studies have reported an adverse effect of UI on quality of life using these surrogate measures and without the use of validated instruments.

Specific instruments have been developed for the evaluation of the impact of UI on well-being (eg, Incontinence Impact Questionnaire[18]). These include questions about physical and social limitations, along with specific questions about UI.[19,20] Although some studies have found that UI is

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TABLE 1. *Characteristics of the study participants (n = 506)*

Participant characteristics	Total sample	No UI	Any UI	Stress-only UI	Urge UI	Mixed UI
No. (%)	506 (100)	294 (58.3)	210 (41.7)	81 (16.1)	38 (7.5)	91 (18.1)
Age, mean (SD), y	56.8 (12.5)	56.4 (12.7)	57.4 (12.3)	53.7 (12.3)	63.6 (11.7)	58.1 (11.4)
Smoking, no. (%)	52 (10.3)	28 (9.5)	24 (11.5)	3 (3.8)	8 (21.1)	13 (14.3)
Menopause status, no. (%)						
Premenopausal	178 (35.2)	103 (35.0)	74 (35.2)	37 (45.7)	8 (21.1)	29 (31.9)
Postmenopausal	328 (64.8)	191 (65.0)	136 (64.8)	44 (54.3)	30 (78.9)	62 (68.1)
Systemic estrogen use, no. (%)	119 (23.5)	64 (21.8)	54 (25.7)	15 (18.5)	10 (26.3)	29 (31.9)
Regular exercise (yes), no. (%)	388 (77.3)	228 (78.1)	158 (76.0)	65 (82.3)	29 (76.3)	64 (70.3)

Missing data: n = 1, smoking status; n = 4, regular exercise; n = 2 UI. UI, urinary incontinence.

associated with a major reduction in well-being or quality of life,[1,21,22] others have concluded that any effect of UI is more modest, as assessed using condition-specific questionnaires.[23,24] However, the use of condition-specific instruments limits the comparison of well-being in women with UI with that of unaffected individuals in the general community. Moreover, even though it is well recognized that there are different types of UI, no study has examined whether there are differences in the relationships between stress-only, urge, and mixed UI and well-being.

The aim of our study was to evaluate well-being in women in whom the presence of UI was determined by their responses to a validated diagnostic questionnaire and to compare their level of general and psychological well-being with that of women unaffected by the condition.

METHODS

The data were collected through a cross-sectional survey of 542 community-dwelling women from the southern Australian state of Victoria in July 2006. The age range of women in the sample was 24 to 80 years, and their recruitment has been reported previously.[25] Briefly, women were eligible for this study if they had been participants in a study of the role of androgens in women (n = 1,423). Recruitment to the androgen study was achieved using a database established from the electoral roll. Women who participated in the androgen study were invited to participate in further research, and 754 women agreed to be recontacted. Of these, 542 agreed to participate in the present study and were mailed a questionnaire including questions about their sociodemographic characteristics, menopause status, hormone therapy use, and medical and obstetric histories and validated questionnaires for the measurement of well-being and UI. The study was approved by the Monash University Human Research and Ethics Committee, and all participants gave written informed consent.

Assessment of UI and well-being

UI was assessed using the Questionnaire for Urinary Incontinence Diagnosis (QUID), a validated questionnaire that contains six questions that assess the primary cause of urine loss, that is, physical pressure (stress-only UI), sudden/uncomfortable urge to urinate (urge UI), or both (mixed UI).[26] The responses were scored accordingly. Respondents were categorized into subgroups based on the QUID composite scores. Methods of scoring and defining incontinence types have been described previously.[25]

Well-being was assessed using the Psychological General Well-being Index (PGWBI), which consists of 22 self-administered items, each rated on a six-point scale.[27] The answers to individual questions are added together to assess six domains: anxiety, depressed mood, positive well-being, self-control, general health, and vitality. Each domain is defined by a minimum of three or a maximum of five items. The answers to some questions are reverse scored to ensure that for each domain, a high score equates to a "good outcome," thus allowing the scores for all domains to be added to provide a summary score, which reaches a maximum of 110 points, representing the best achievable well-being.

TABLE 2. *Total and subdomain mean scores on the PGWBI for the total sample, including women with no UI, any UI, and stress-only, urge, and mixed UI*

PGWBI domains	Sample (n = 506)	No UI (n = 294)	Any UI (n = 210)	Stress-only UI (n = 81)	Urge UI (n = 38)	Mixed UI (n = 91)
Anxiety	18.4 (4.4)	18.7 (4.2)	18.0 (4.7)	18.1 (4.5)	19.4 (4.1)	17.3 (5.1)
Depressed mood[a]	12.7 (2.4)	12.9 (2.2)	12.5 (2.5)	12.6 (2.6)	13.1 (1.9)	12.2 (2.6)
Positive well-being[b]	13.1 (3.6)	13.4 (3.5)	12.8 (3.6)	12.9 (3.8)	13.4 (3.1)	12.4 (3.7)
Self-control[c]	12.3 (2.6)	12.6 (2.3)	11.8 (2.8)	11.9 (2.8)	12.7 (2.0)	11.4 (3.0)
General health	10.5 (2.8)	11.1 (2.7)	9.8 (2.9)	10.1 (2.8)	9.9 (2.8)	9.6 (3.0)
Vitality[d]	12.6 (3.8)	13.1 (3.7)	11.9 (3.8)	12.0 (3.7)	13.0 (3.0)	11.4 (4.1)
Total score[e]	79.6 (16.0)	81.6 (15.3)	76.9 (16.5)	77.8 (16.2)	81.4 (13.3)	74.2 (17.8)

Values are presented as mean (SD). PGWBI, Psychological General Well-being Index; UI, urinary incontinence.
[a] 1 case missing for the depressed mood subdomain.
[b] 3 cases missing for the positive well-being subdomain.
[c] 1 case missing for the self-control subdomain.
[d] 2 cases missing for the vitality subdomain.
[e] 7 cases missing for the PGWBI total score.

TABLE 3. *Regression analysis for total PGWBI*

	Univariate			Multivariate		
Total PGWBI	β	95% CI	P	β	95% CI	P
Stress-only UI	−3.82	−7.66 to 0.02	0.05	−3.95	−7.74 to −0.15	0.04
Age (y)	0.26	0.14 to 0.39	<0.001	0.21	0.01 to 0.41	0.05
Smoking (yes/no)	−6.42	−12.13 to −0.72	0.03	−5.19	−10.80 to 0.41	0.07
Exercise (yes/no)	4.50	0.59 to 8.41	0.03	4.86	1.06 to 8.66	0.01
Postmenopausal (yes/no)	5.98	2.76 to 9.20	<0.001	3.17	−2.19 to 8.53	0.25
Systemic estrogen use (yes/no)	−2.52	−6.40 to 1.37	0.20	−5.58	−9.56 to −1.59	0.006
Mixed UI	−7.38	−11.17 to −3.58	<0.001	−6.96	−10.72 to −3.20	<0.001
Age (y)	0.22	0.09 to 0.35	0.001	0.17	−0.04 to 0.38	0.11
Smoking (yes/no)	−6.55	−11.77 to −1.33	0.01	−4.19	−9.31 to 0.93	0.11
Exercise (yes/no)	4.69	0.87 to 8.52	0.02	4.32	0.59 to 8.04	0.02
Postmenopause (yes/no)	5.58	2.19 to 8.98	0.001	3.11	−2.45 to 8.66	0.27
Systemic estrogen use (yes/no)	−1.69	−5.50 to 2.11	0.38	−3.43	−7.33 to 0.48	0.09
Urge UI[a]	−0.24	−5.35 to 4.87	0.93	−2.08	−7.18 to 3.01	0.42
Age (y)	0.24	0.11 to 0.36	<0.001	0.25	0.12 to 0.38	<0.001

PGWBI, Psychological General Well-being Index; UI, urinary incontinence.
[a]There was no difference between mean total PGWBI scores between women with urge UI and women with no UI, even when the comparison was adjusted for age; thus, no further variables were considered in this analysis.

Statistical analysis

The characteristics of the women are presented as frequencies and percentages. The subgroups of women with different forms of UI are considered separately. The PGWBI total and domain scores are presented as means and SD. Multiple regression analysis was used to evaluate the relationship between each of the PGWBI total and domain scores (each as continuous dependent variables) and UI (each form of UI considered independently with women with that form of UI compared with women with no UI), also including the following as independent variables in the analyses: age (continuous), smoking status (dichotomous), exercise (dichotomous), menopause status (dichotomous), and systemic estrogen use (dichotomous). The variables included in the multivariate analysis were chosen as they have been identified in previous studies as being related to both well-being[28] and UI[25] and could thus potentially confound the relationship between well-being and UI.

RESULTS

Questionnaires were sent to 542 women who expressed interest in the UI study, and 506 participants returned completed questionnaires. Based on responses to the QUID, 210 (41.7%) women had UI, among which 81 (16.1%) had stress-only UI, 38 (7.5%) had urge UI, and 91 (18.1%) had a mixed pattern (Table 1). The women with urge UI tended to be older and were therefore mainly postmenopausal, whereas exclusively stress-only UI tended to be dominated by women at midlife. Women with a mixed picture of UI had characteristics between those of the other two groups.

The mean total PGWBI scores and those of each of the subdomains for women with different forms of UI in comparison with those for continent women are presented in Table 2. The mean (±SD) total PGWBI scores for women with either mixed UI (74.2 ± 17.8) or stress-only UI (77.8 ± 16.2) were lower than the mean score for women with no UI (81.6 ± 15.3), the difference being greater for those with mixed UI (7.4, 95% CI, −11.17 to −3.58; $P < 0.001$) than for those with stress-only UI (3.8, 95% CI, −7.66 to 0.02; $P = 0.05$). Because urge UI is more common in older women and there is a positive association between the overall PGWBI score and age, we age adjusted the analysis of urge UI in relation to overall score. Allowing for age, there was no evidence that urge UI was associated with a lower total PGWBI score (mean difference in total PGWBI score between urge UI and no UI, −2.08; 95% CI, −7.08 to 3.01; $P = 0.42$). The exploration of urge UI in relation to PGWBI score was not taken further because of the small numbers in this category.

The univariate and multivariate regression analyses for the total PGWBI scores for stress-only and mixed UI are presented in Table 3. For both forms of UI, when other variables were taken into account, an independent relationship between UI and lower total PGWBI score remained of a similar order of magnitude to what was seen in the univariate analysis in each case.

For stress-only UI, there was a significant positive association with both age ($P = 0.05$) and exercise ($P = 0.01$) and the total PGWBI score and a negative association with systemic estrogen use ($P = 0.006$). For mixed UI, exercise remained positively associated with the total PGWBI score ($P = 0.02$).

The relationships between both stress-only UI (Table 4) and mixed UI (Table 5) and each of the PGWBI domain scores were explored for the different forms of UI. For stress-only UI, there was a significant negative association between the UI variable and the domain scores for self-control ($P = 0.02$), general health ($P = 0.001$), and vitality ($P = 0.03$). For the analysis of mixed UI, there was a negative association between mixed UI and each of the domains of the PGWBI.

DISCUSSION

We believe this to be the first study to demonstrate that UI in women is associated with reduced general psychological well-being measured with a validated instrument and that mixed UI is associated with a larger reduction in overall well-being than stress-only UI. As previously reported,[29] age and

TABLE 4. *Multiple regression analysis for each of the Psychological General Well-being Index domains for stress-only incontinence*

	Anxiety			Depressed mood			Positive well-being			Self-control			General health			Vitality		
Variable	β	95% CI	P	β	95% CI	P	β	95% CI	P	β	95% CI	P	β	95% CI	P	β	95% CI	P
Stress-only incontinence	−0.46	−1.48 to 0.57	0.38	−0.23	−0.81 to 0.35	0.43	−0.54	−1.43 to 0.35	0.23	−0.73	−1.34 to −0.11	0.02	−1.10	−1.78 to −0.42	0.001	−1.04	−1.94 to −0.14	0.03
Age (y)	0.09	0.04 to 0.15	0.001	0.03	−0.003 to 0.06	0.08	0.04	−0.01 to 0.08	0.12	0.02	−0.01 to 0.05	0.25	−0.02	−0.05 to 0.02	0.38	0.05	0.005 to 0.10	0.03
Smoking (yes/no)	−0.88	−2.39 to 0.64	0.26	−0.78	−1.64 to 0.08	0.08	−1.51	−2.83 to −0.19	0.03	−0.10	−1.93 to −0.11	0.03	−0.37	−1.38 to 0.63	0.47	−0.67	−2.01 to 0.67	0.32
Exercise (yes/no)	0.85	−0.18 to 1.87	0.11	0.50	−0.08 to 1.08	0.09	0.78	−0.11 to 1.68	0.08	0.27	−0.35 to 0.88	0.39	0.70	0.02 to 1.38	0.04	1.72	0.82 to 2.62	<0.001
Postmenopausal (yes/no)	0.49	−0.96 to 1.94	0.51	0.22	−0.60 to 1.04	0.60	0.45	−0.81 to 1.71	0.48	0.33	−0.54 to 1.20	0.46	0.72	−0.24 to 1.67	0.14	0.94	−0.34 to 2.21	0.15
Systemic estrogen use (yes/no)	−1.30	−2.37 to −0.23	0.02	−0.45	−1.06 to 0.16	0.15	−0.61	−1.55 to 0.32	0.20	−0.27	−0.91 to 0.38	0.42	−1.65	−2.36 to −0.94	<0.001	−1.29	−2.23 to −0.35	0.01

All variables are included in all analyses.

exercise were positively associated with well-being, whereas smoking and systemic hormone therapy use were negatively associated with well-being. Our observations about quality of life are made in the context of prevalence estimates for UI consistent with those observed in other studies.[25]

Although it is difficult to translate the observed differences in PGWBI scores between women with either stress-only or mixed UI and those with no UI into what this means for women on a day-to-day basis, the magnitude of the differences we observed for these groups of women was similar to what we have observed in women with low-intensity chronic back pain.[30]

Mixed and stress-only UI were associated with differing patterns in the subdomain scores of the PGWBI. Although both forms of UI were associated with lower scores for self-control, general health, and vitality, only the women with mixed UI had significantly lower scores for anxiety, depressed mood, and positive well-being. This suggests that stress UI is associated primarily with health-related sequelae, whereas mixed UI is more likely to impact on mood and emotional well-being. From a patient care perspective, our findings highlight the need to consider the psychological well-being of individuals diagnosed with UI, particularly mixed UI.

Our study differs from other published studies primarily in the use of a validated instrument that is not condition specific. This approach enabled us to directly compare women with UI with unaffected women. In contrast, condition-specific questionnaires are ideal for longitudinal studies and evaluating the effects of interventions but do not allow for direct comparisons with women without this condition. Moreover, we were also able to examine different types of UI, including stress-only, urge, and mixed UI, and show that there are differences in the relationship between different types of UI and well-being.

Our study has several strengths. The participants were from a community-derived population that included a broad spectrum of women from different social backgrounds, and the diagnosis of UI and subtypes was established using a validated instrument.

One limitation was that few women in our study had urge UI such that the statistical power for examining the relationships between urge UI and the well-being scores was lacking. Hence, we may have missed an association between urge UI and reduced well-being. The women with urge UI tended to be older and have a greater well-being, so it is also possible that UI does not reduce well-being to the same extent as stress-only UI and mixed UI do or that any reduction in well-being in this group is modest. In addition, the QUID does not allow for the grading of severity of UI; thus, we were unable to examine the relationship between well-being and severity of symptoms within the subcategories of UI. Although UI may also have an adverse impact on sexual function[31] and limit social interaction,[22,32] we did not directly evaluate these consequences of UI, which are likely to have contributed to the reduction in the total PGWBI score and its subdomains.

TABLE 5. *Multiple regression analysis for each of the Psychological General Well-being Index domains for mixed incontinence*

	Anxiety			Depressed mood			Positive well-being			Self-control			General health			Vitality		
Variable	β	95% CI	P	β	95% CI	P	β	95% CI	P	β	95% CI	P	β	95% CI	P	β	95% CI	P
Mixed incontinence	−1.41	−2.43 to −0.40	0.01	−0.61	−1.16 to −0.05	0.03	−0.92	−1.76 to −0.08	0.03	−1.21	−1.81 to −0.61	<0.001	−1.25	−1.89 to −0.60	<0.001	−1.57	−2.46 to −0.69	0.001
Age (y)	0.08	0.03 to 0.14	0.001	0.02	−0.01 to 0.05	0.14	0.02	−0.02 to 0.07	0.32	0.01	−0.03 to 0.04	0.62	−0.006	−0.04 to 0.03	0.76	0.06	0.01 to 0.11	0.02
Smoking (yes/no)	−0.70	−2.11 to 0.70	0.33	−0.68	−1.45 to 0.09	0.08	−1.26	−2.42 to −0.10	0.03	−0.70	−1.52 to 0.13	0.10	−0.21	−1.11 to 0.68	0.64	−0.68	−1.89 to 0.53	0.27
Exercise (yes/no)	0.66	−0.36 to 1.67	0.21	0.45	−0.11 to 1.00	0.12	0.69	−0.15 to 1.53	0.11	0.02	−0.58 to 0.62	0.95	0.94	0.29 to 1.59	0.01	1.63	0.75 to 2.50	<0.001
Postmenopausal (yes/no)	0.63	−0.89 to 2.14	0.42	0.02	−0.81 to 0.84	0.97	0.53	−0.72 to 1.77	0.41	0.55	−0.34 to 1.43	0.23	0.22	−0.74 to 1.19	0.65	0.79	−0.52 to 2.10	0.24
Systemic estrogen use (yes/no)	−1.04	−2.11 to 0.02	0.06	−0.14	−0.72 to 0.45	0.64	−0.26	−1.14 to 0.62	0.57	−0.10	−0.72 to 0.53	0.76	−1.26	−1.94 to −0.58	<0.001	−0.64	−1.55 to 0.28	0.17

All variables are included in all analyses.

In our analyses, we used logistic regression modeling to attempt to limit any effects of confounding of the relationship between UI and well-being. We recognize that it is unlikely that we have totally eliminated the issue of confounding not only because we did not include in our models all variables that could possibly act as confounders (for instance, the presence of specific morbidities such as diabetes) but also because the potential confounders we did include, we quantified in a basic format (dichotomous variables for both smoking and exercise).

In more general terms, we need to acknowledge that, within the context of a cross-sectional design where a link has been made between the presence of UI and reduced well-being, it is not possible to prove that the UI is the cause of the reduced well-being.

Although it is most unlikely that the reduced well-being led to the UI, it is not possible to exclude the possibility that other morbidities exist that have contributed to both the development of UI and the reduced well-being, at least in some women.

CONCLUSIONS

UI is a common condition in women. Our study demonstrates not only that UI is associated with bothersome symptoms and restriction of activities but also that women with UI have significantly lower general psychological well-being than do unaffected women. Given the emphasis that is now being given to the concept of healthy aging, the global effects of UI merit greater attention.

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Monash University

Specific Declaration 4

Declaration for Thesis Chapter 5: Publication 4

Declaration by candidate

In the case of Chapter 5 (Publication 4), the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Study design, conduct of the research, data management, analysis of the data, drafted the submitted manuscript, revision of manuscript	

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	**Nature of contribution**
Susan R Davis	Study design, critical revision of submitted manuscript
Donna M Urquhart	Study design, critical revision of submitted manuscript
Robin J Bell	Study design, statistical analysis guidance, critical revision of submitted manuscript

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

(19) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
(20) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
(21) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
(22) there are no other authors of the publication according to these criteria;
(23) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
(24) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Women's Health Program, Department of Medicine, Level 6, The Alfred Centre, Monash University**

Signature 1		**Date**
Signature 2	[redacted]	11.05.11
Signature 3		

Chapter 5: Publication 4

5.1 Title:

Botlero R, Davis SR, Urquhart DM, Bell RJ. Incidence and remission rates of different types of urinary incontinence among women: findings from a cohort study. **Journal of Urology**, 2011; 185 (4): 1331-37.

5.2 Summary of findings:

The incidence of any new UI was 17% [95%CI: 12.4-21.6%] among the unaffected women and the total resolution was 16.8 % [95%CI: 11.4-22.2%] among the women with UI over 2 years irrespective of treatment for UI. There was also movement of women between diagnoses of stress-only, urge-only and mixed UI during the follow-up period. Few women (34/442) reported having treatment for UI, and few (5/34) experienced resolution of their condition. All types of UI were associated with impaired QoL ($p<0.001$) and adversely impacted on daily activities. A negative impact ($p=0.02$) on QoL was also observed in incident cases at follow-up compared with baseline. This study demonstrates that UI is a highly dynamic clinical condition, with movement between diagnostic subtypes of stress-only, urge-only and mixed UI and periods of resolution. Having any UI is significantly associated with impaired QoL.

Incidence and Resolution Rates of Different Types of Urinary Incontinence in Women: Findings From a Cohort Study

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Purpose: We determined the incidence and resolution rates of different types of urinary incontinence in Australian women and examined the course of urinary incontinence with or without treatment.

Materials and Methods: A total of 506 women originally recruited from a community based research database completed a baseline questionnaire in 2006 and a followup questionnaire in 2008. Urinary incontinence incidence and resolution were assessed using the Questionnaire for Urinary Incontinence Diagnosis. The Bristol Female Lower Urinary Tract Symptoms questionnaire was used to assess the impact of urinary incontinence on quality of life.

Results: At baseline and followup 442 women provided data. Mean ± SD age was 59.28 ± 12.1 years at followup. The total incidence of any new urinary incontinence was 17% (95% CI 12.4–21.6) in unaffected women and the total resolution rate was 16.8% (95% CI 11.4–22.2) in women with urinary incontinence during 2 years regardless of receiving treatment for urinary incontinence. There was also movement of women among the diagnoses of stress only, urge only and mixed urinary incontinence during followup. A total of 34 women reported having received treatment for urinary incontinence and 5 experienced resolution of the condition. All types of urinary incontinence were associated with impaired quality of life ($p < 0.001$) and adversely impacted daily activity. A negative impact on quality of life ($p = 0.02$) was also observed in incident cases at followup compared with baseline.

Conclusions: Our study shows that urinary incontinence is a highly dynamic clinical condition with movement among diagnostic subtypes of stress only, urge only and mixed urinary incontinence, and periods of resolution. Any urinary incontinence is significantly associated with impaired quality of life.

Key Words: urinary bladder, urinary incontinence, quality of life, questionnaires, female

Abbreviations and Acronyms

BFLUTS = Bristol Female Lower Urinary Tract Symptoms Questionnaire

BMI = body mass index

QOL = quality of life

QUID = Questionnaire for Urinary Incontinence Diagnosis

UI = urinary incontinence

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Study received Monash University human research and ethics committee approval.

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Supplementary material for this article can be obtained at http://womenshealth.med.monash.edu.au.

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URINARY incontinence is a common condition in women living in the community. It may manifest as incontinence that occurs with increased physical pressure (stress only UI), a sudden/uncomfortable urge to urinate (urge only UI) or a combination of the 2 types (mixed UI). The prevalence of different UI subtypes differs across the life span with stress only and urge only UI more prevalent in middle-aged and older women, respectively.[1] UI is associated with lower psychological general well-being,[2] decreased participation in social and domestic activities,[3] significant physical morbidity,[4] loss of independence[5] and sexual difficulty.[6] Despite its substantial adverse impact the natural history of UI in terms of incidence and resolution remains uncertain.

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Prior studies of the natural history of UI in community dwelling women indicate an average 2% to 11% annual cumulative incidence rate.[7–18] This range reflects variation in UI definitions, limited age ranges of the cohorts in some studies and low response rates, which may increase the risk of bias.[13,16]

We determined the incidence and resolution of different types of UI in a cohort of community dwelling Australian women and examined the course of UI with or without treatment during 2 years.

METHODS

Study participants were recruited from a previous cross-sectional study of 1,423 women that examined the role of androgens in women.[19] For the cross-sectional parent study women were recruited from a database established from the Victoria electoral roll. Detailed information on recruitment of women from this database between April 2002 and August 2003 to the parent study was reported previously.[19] Briefly, 754 of the 1,423 women who participated in the androgen study agreed to be recontacted regarding further research, of whom 542 expressed interest in participating in the UI study. In July 2006 the questionnaire, consent form and information sheet were sent to 542 women. A total of 506 women returned the completed questionnaire and their data were analyzed. Two years later a followup questionnaire was mailed to the 457 women who agreed to continue in the study. Nonresponders were prompted by telephone after 4 weeks.

The followup questionnaire was the same as the baseline questionnaire[1] except some questions referred to "the past 2 years" rather than "in the past." Also, questions on UI duration and treatment approaches, constipation, hysterectomy and types of anesthesia used during childbirth were added as well as a pelvic floor distress inventory questionnaire. The study was approved by the Monash University human research and ethics committee, and all participants provided written informed consent.

Data collected in the questionnaire included age, height, weight, marital status, medical and obstetric history, and current prescription and nonprescription drug use. We asked participants whether they had undergone hysterectomy, whether they had ever received treatment specific to UI, including surgery, medication or physiotherapy, and whether they believed that symptoms had or had not improved. Improvement in UI symptoms was based on the response to the question, "How was your incontinence after treatment?" The response was categorized as better, same, worse or unsure. Menopausal status was based on answers to several questions considered in a hierarchical manner.[20] Women who had undergone bilateral oophorectomy or older than 58 years were categorized as postmenopausal. Menopause status was then designated according to responses to questions on menstrual cycle regularity, use of hormonal contraception or systemic postmenopausal hormone therapy and, in those with menstrual irregularity or hysterectomy, the presence of vasomotor symptoms.[20]

Definition of UI Types

UI diagnosis and subtyping (stress only, urge only or mixed) were based on QUID responses.[21] QUID is a validated questionnaire that contains 6 questions to assess the primary cause of urine loss, including physical pressure (stress only UI) and a sudden/uncomfortable urge to urinate (urge only UI).[21] Each question is scored from 0—none of the time to 5—all the time based on the frequency of leakage, providing a maximal total score of 15 for each of stress and urge UI. A composite score of 4 or greater on questions 1 to 3 classified a woman as having stress only UI and a score of 6 or greater on questions 4 to 6 classified a woman as having urge only UI. We used definitions of stress incontinence and urge UI that conformed to the standards recommended by the International Continence Society and were consistent with a QUID stress score of 4 or greater and a QUID urge score of 6 or greater.[21] Women diagnosed with stress plus urge UI by QUID were classified as having mixed UI.[21]

Condition Specific QOL

Five condition specific QOL questions from the validated BFLUTS questionnaire were used to assess the impact of different types of UI on QOL.[22] These questions included the frequency of the need to change outer clothing during the day due to urine leakage, the frequency of deliberately decreasing fluid intake, the extent to which urinary symptoms affect the ability to perform daily tasks, the frequency of avoiding situations in which a toilet is not nearby and the extent to which urinary symptoms interfere with life. Responses were scored from 0—never to 4—all the time except for daily tasks and interference with life, which were scored from 1—not at all to 3—a lot. The BFLUTS QOL section provides a total score (range 2 to 18) with a higher score indicating a more adverse impact of UI.

Prevalence, Incidence and Resolution Rates

Prevalence is reported as the number of women classified with UI by frequency and type at baseline and at followup divided by the total number in each survey. Total incidence and resolution was calculated for the entire cohort of 442 women. Total incidence included the number of women reporting new onset UI in the 2 years of followup divided by the number free of UI at baseline. Total resolution was considered to occur when women reported no UI at followup but had been identified as incontinent at baseline. Spontaneous incidence and resolution were also calculated, excluding the 402 women who reported treatment for UI during followup.

Six of the 7 women who underwent hysterectomy during followup were excluded from the natural history analysis and the effect of intervention analysis. One woman who underwent hysterectomy also reported being treated with medication for UI during followup. She was retained in the effect of intervention analysis.

Statistical Analysis

Data are shown as the incidence, mean ± SD, median, range and/or percent (95% CI). The nonparametric Mann-Whitney and Wilcoxon signed rank tests were used to compare total QOL scores between women with and without UI, and women with incident or resolved UI

Table 1. *Characteristics of 442 study participants at followup who completed baseline and followup questionnaires*

	No. Pts (%)
Age:	
Less than 45	56 (12.7)
45-Less than 55	95 (21.5)
55-Less than 65	128 (29.0)
65-Less than 75	112 (25.3)
75 or Greater	51 (11.5)
BMI (kg/m^2).*	
Less than 25	165 (38.2)
25-Less than 30	142 (32.9)
30 or Greater	125 (28.9)
Smoker	38 (8.6)
Menopause status:	
Premenopausal	92 (20.8)
Perimenopausal	28 (6.3)
Postmenopausal	322 (72.9)
Parity:	
Nulliparous	70 (15.8)
Parous	372 (84.2)
Systemic estrogen with/without progestin	76 (17.2)
Hysterectomy†	106 (24.3)
Regular exercise‡	343 (78.5)

* Data missing on 10 women.
† Data missing on 5 women.
‡ Data missing on 5 women.

between the baseline and followup questionnaires. Comparisons were considered significant at $p < 0.05$. Statistical analysis was done using SPSS® 16.0 for Windows®.

RESULTS

Table 1 lists participant characteristics at followup. Of the 457 women to whom a followup questionnaire was sent 444 responded. Final analysis included 442 women since 2 of the 444 did not complete the QUID questionnaire in the baseline survey (fig. 1). Mean age was 59.28 ± 12.1 years (range 26 to 82). Mean BMI was 27.38 ± 5.8 kg/m^2 at followup. The 62 women who did not complete the followup questionnaire were not significantly different in mean age or BMI, as assessed at baseline. Mean followup was 2.1 years (95% CI 1.99–2.24). Of the participants 84.2% were parous and 72.9% were postmenopausal at followup. Since the followup survey was done after 2 years, some patient characteristics changed, eg age, parity and menopausal status. Mean age increased by 2.1 years and 4 women changed from being nulliparous to parous. During followup 30 women (6.8%) became postmenopausal.

The overall prevalence of UI was 41.6% (95% CI 37.0–46.2) at baseline, which increased to 44.6% (95% CI 40.0-49.2) by the end of followup (table 2).

Incidence and Resolution in Total Population

The total incidence of any new UI was 17% (95% CI 12.4–21.6) (44 of 258 women) during 2 years or 8.5% yearly among women classified as being free of UI at baseline (table 3). The UI incidence rate was lowest (13.5%, 95% CI 9.3–17.7) in women younger than 45 years and highest (20.7%, 95% CI 15.8–25.6) in those 75 years old or older (table 3). Of the incident cases stress only UI, urge only UI and mixed UI developed in 19, 16 and 9, respectively. Concurrently we observed a total resolution rate of 16.8% (95% CI 11.4–22.2) (31 of 184 women) during 2 years or 8.4% yearly in affected women (table 3).

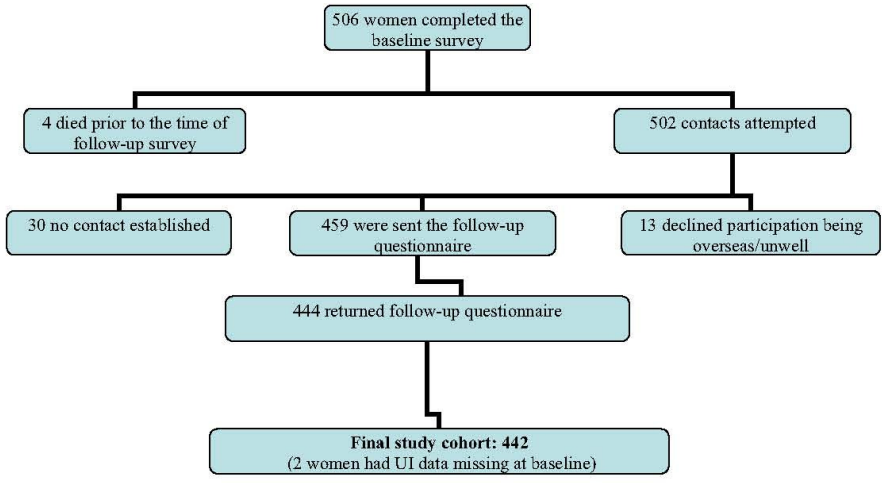

Figure 1. Participation in followup study

Table 2. *Prevalence of different UI types in all 442 women at baseline and followup*

	Baseline	Followup
No. UI:		
No	258	245
Yes	184	197
% UI (95% CI)	41.6 (37.0–46.2)	44.6 (40.0–49.2)
No. UI type:		
Stress only	70	71
Urge only	33	34
Mixed	81	92

Course With No UI Treatment

During followup 402 women did not report any intervention specific for UI during followup. When restricting our analysis to these 402 women, we observed a spontaneous incidence rate of 15.5% (95% CI 11–20) (38 of 245) during 2 years or 7.8% yearly. The spontaneous resolution rate was 15.9% (95% CI 10.2–21.6) (25 of 157 women) during 2 years or 8.0% yearly in affected women. The rate of spontaneous resolution of stress only, urge only and mixed UI was 18.0% (95% CI 8.4–27.6) (11 of 61 women), 33.3% (95% CI 15.5–51.1) (9 of 27) and 7.2% (95% CI 1.1–13.3) (5 of 69), respectively (fig. 2).

Some women moved between different diagnostic categories of UI during followup (fig. 2). Of the 61 women with stress only UI at baseline 14 (23.0%) were classified with mixed UI and 11 had UI resolution at followup. Seven cases (25.9%) of urge only UI were reclassified as mixed UI, 2 (7.4%) were reclassified as stress only UI and UI resolved in 9. Eight mixed UI cases (11.6%) were reclassified as stress only UI, 6 (8.7%) were reclassified as urge only and UI resolved in 5.

Specific UI Treatment During Followup

A total of 34 women reported undergoing a specific intervention (surgery/medication/physiotherapy) that may have modified UI during followup, including surgery (mid urethral sling procedure) in 4, medication (vaginal estrogen, oxybutynin, dothiepin hydrochloride and imipramine) in 5 and physiotherapy (pelvic floor muscle exercise) as the only therapy for the condition in 25 during followup. Notably 11 of these women had not been classified with UI according to their responses to the baseline questionnaire, although 5 of the 11 women had a score only 1 less than the score required to meet QUID criteria for UI. Figure 3 shows interventions in and classification of these 34 women at followup.

QOL Impact

Having any UI was associated with a significant impact (each comparison Mann-Whitney test $p < 0.001$) on symptom specific QOL (fig. 4). Similarly UI incident cases had higher BFLUTS QOL scores at followup than at baseline (Wilcoxon signed rank test $p = 0.02$). Resolved cases failed to show significant improvement on the followup survey (Wilcoxon signed rank test $p = 0.83$, fig. 5).

DISCUSSION

This longitudinal study documents an 8.5% annual incidence rate of UI and an 8.4% annual resolution rate in Australian women recruited from the community. We observed significant movement of women among the stress only, urge only and mixed UI diagnoses.

To our knowledge a new finding in our study is that while most de novo UI cases were stress only or urge only UI, a new diagnosis of mixed UI was made mainly in women who had previously reported stress only or urge only UI. Since the characteristics of our cohort changed during followup, including age and menopausal status, an increase in prevalence is not surprising. It is striking that a third of the women with urge only UI had spontaneous resolution of the condition at followup. Women with mixed UI were less likely to experience resolution than women with urge only or stress only UI.

Few women reported receiving treatment for UI. Of those who did few experienced complete resolution. However, not all women who reported intervention during the study period had been classified with UI at baseline, although half who reported treatment but did not have UI at baseline were just below the QUID cutoff for UI. It is also possible that

Table 3. *Age specific incidence and resolution of different UI types at 2 years in 442 women*

		No. Baseline + Followup UI		No. UI (%)	
Age at Followup	No. Pts	None	Any	Incident	Total Resolution
Less than 45	56	32	15	5 (13.5)	4 (21.1)
45-Less than 55	95	44	39	7 (13.7)	5 (11.4)
55-Less than 65	128	66	40	15 (18.5)	7 (14.9)
65-Less than 75	112	49	43	11 (18.3)	9 (17.3)
75 or Greater	51	23	16	6(20.7)	6(27.3)
Totals	442	214	153	44 (17.1)	31 (16.8)

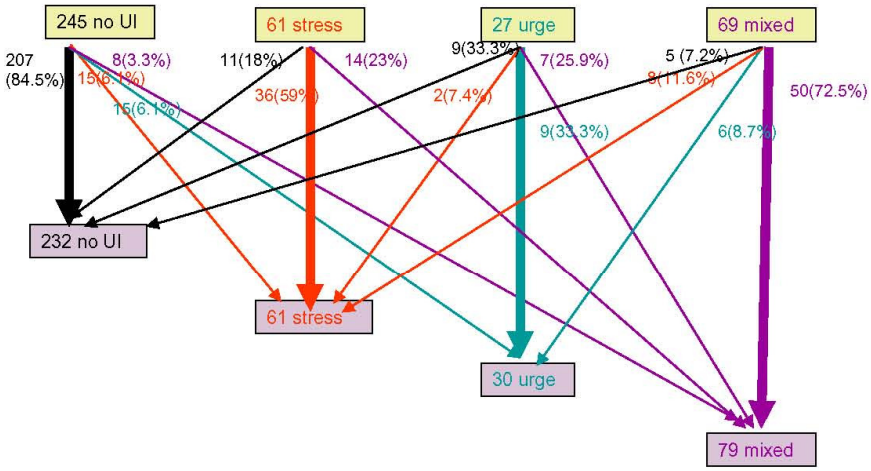

Figure 2. Spontaneous incidence, resolution and movement in 402 women in different UI categories during followup (purple boxes). Yellow boxes represent baseline.

by participating in the study women with infrequent symptoms were prompted to pursue therapy. Age, and symptom duration and severity were associated with a greater likelihood of medical consultation for UI.[23] Nonetheless, greater understanding is needed of the impediments to pursuing UI treatment.

Few longitudinal studies have examined changes in QOL using UI incidence and resolution.[11,24,25] We found that BFLUTS QOL scores were significantly higher (more adverse) in women with all types of UI than in women with no UI while the highest median BFLUTS QOL was reported in those with mixed UI, followed by urge only and then stress only UI. These findings are consistent with evidence in previous studies.[2,26–30]

We also found an increase in the BFLUTS QOL score for incident UI cases. However, resolve cases failed to show a significant improvement in the BFLUTS QOL score. Perhaps the lack of improved QOL in women with UI resolution was caused by the fact that even the infrequent experience of symptoms in those with resolution may remain distressing or it may also have been a function of remaining coexisting morbidity. Our relatively short followup may also be a limitation to examining a significant change in the BFLUTS QOL score in resolved cases.

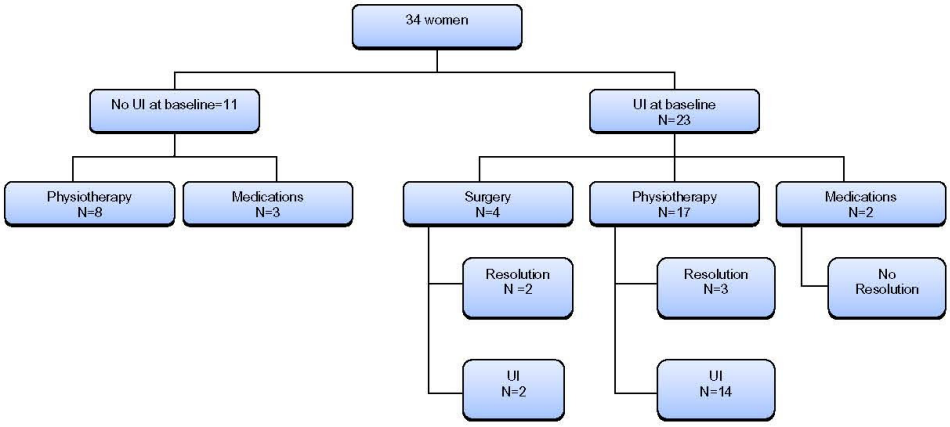

Figure 3. Intervention and classification in 34 women at followup

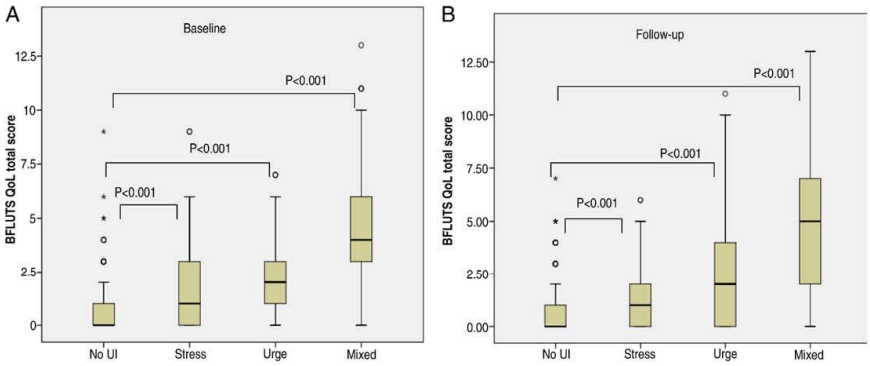

Figure 4. Median and IQR (boxes) of total BFLUTS QOL scores in women with no UI and different types of UI at baseline (*A*) and followup (*B*). Horizontal lines in boxes indicates median. Upper whiskers indicate largest data points, defined as less than 75th percentile + 1.5 × IQR. Lower whiskers indicate smallest data points, defined as greater than 25th percentile − 1.5 × IQR. Circles represent outliers extending more than 1.5 box lengths from box edge. Asterisks indicate outliers extending more than 3 box lengths from box edge.

Our study has several strengths. Validated instruments were used to assess the incidence, resolution and different types of UI, and condition specific QOL. Our study population was community based, including women from rural and remote regions. The longitudinal design allowed us to examine the natural course of different types of UI.

Our study also has some limitations. Since the sample was derived from a larger group of women who had expressed interest in participating in further research studies, and since women with major medical or psychiatric illness within the previous 3 months were excluded from participation in the parent study, participants in the current study were more likely to be in better health than nonparticipants.

We also believe that the incidence and prevalence in older women were likely to have been underestimated since we did not include institutionalized women, who are more likely to experience incontinence. Also, QUID does not allow the grading of UI severity. Thus, we could not examine the relationship between symptom severity in UI subtypes and QOL. We also could not look at the relationship between symptom severity and the type of treatment that a woman received.

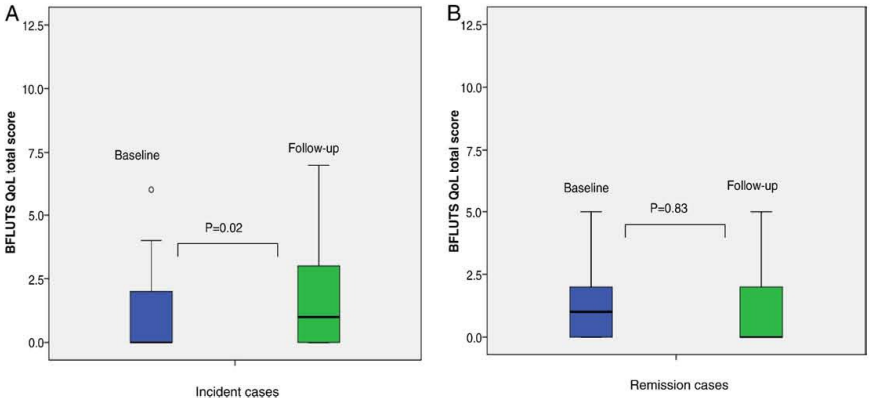

Figure 5. Median and IQR (boxes) of total BFLUTS QOL scores in for incidence (*A*) and resolution (*B*) cases at baseline and followup. Horizontal lines in boxes indicates median. Upper whiskers indicate largest data points, defined as less than 75th percentile + 1.5 × IQR. Lower whiskers indicate smallest data points, defined as greater than 25th percentile − 1.5 × IQR. Circle represents outlier extending more than 1.5 box lengths from box edge.

CONCLUSIONS

This longitudinal study shows that UI has a dynamic time course with relatively high incidence and resolution rates but an overall trend toward increasing prevalence with age. The relatively low proportion of women with UI who receive treatment with proven efficacy suggests that there are barriers to treatment that are worth investigating.

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Monash University

Specific Declaration 5

Declaration for Thesis Chapter 6: Publication 5

Declaration by candidate

In the case of Chapter 6 (Publication 5), the nature and extent of my contribution to the work was the following:

Nature of contribution	**Extent of contribution (%)**
Study design, conduct of the research, data management, analysis of the data, drafted the submitted manuscript, revision of manuscript	

The following co-authors contributed to the work. Co-authors who are students at Monash University must also indicate the extent of their contribution in percentage terms:

Name	**Nature of contribution**
Robin J Bell	Study design, statistical analysis guidance, critical revision of submitted manuscript
Donna M Urquhart	Study design, critical revision of submitted manuscript
Susan R Davis	Study design, critical revision of submitted manuscript

Candidate's Signature		**Date**

Declaration by co-authors

The undersigned hereby certify that:

(25) the above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
(26) they meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
(27) they take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
(28) there are no other authors of the publication according to these criteria;
(29) potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
(30) the original data are stored at the following location(s) and will be held for at least five years from the date indicated below:

Location(s)	**Women's Health Program, Department of Medicine, Level 6, The Alfred Centre, Monash University**

Signature 1		**Date**
Signature 2	[redacted]	11.05.11
Signature 3		

Chapter 6: Publication 5

6.1 Title:

Botlero R, Bell R Urquhart D, Davis SR. Prevalence of fecal incontinence and its relationship with urinary incontinence in women living in the community (in press Menopause September 2010).

6.2 Summary of findings:

The overall prevalence of any FI was 20.7% (95% CI, 16.9%–24.5%). Loose FI was reported by 91 of 442 women, yielding a prevalence of 20.7% (95% CI, 16.9%–24.5%). Well-formed FI was reported by 20 of 442 women, yielding a prevalence of 4.5% (95% CI, 2.6%–6.4%). All the women with well-formed FI also reported problems of loose FI. The prevalence of FI increased with age up to 75 years for both types of FI. FI was not related to parity (p=0.9). The highest proportion of any FI (24.4%) occurred in women with a parity of 4 or greater however, with 20.3% of nulliparous women reporting FI. Within parous women there was no significant association found between FI and past history of self-reported instrumental delivery (p=0.4). About two-thirds of the women with loose and well-formed FI also reported co-existing UI. Loose FI was significantly associated with any UI [OR, 2.8(95% CI: 1.7-4.8)] after adjusting for age and BMI (p<0.001). Well-formed FI was not significantly associated with any UI after adjusting for age and BMI. Being parous was not associated with an increased risk of any FI.

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Prevalence of fecal incontinence and its relationship with urinary incontinence in women living in the community

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Abstract

Objective: The aim of this study was to document the age-specific prevalence of fecal incontinence (FI), as well as its relationship to childbirth and urinary incontinence (UI), in a community-based sample of Australian women.

Methods: A total of 444 women aged 26 to 82 years, originally recruited from a community-based research database, completed a self-administered study questionnaire. Prevalence of FI was assessed using the Pelvic Floor Distress Inventory, and UI and its subtypes were determined using the Questionnaire for Urinary Incontinence Diagnosis. Univariate (Pearson's χ^2 tests) and multivariate logistic regression analyses were used to assess the relationship between FI type and UI adjusting for age and body mass index (BMI).

Results: Data were analyzed for 442 women. The overall prevalence of any FI was 20.7% (95% CI, 16.9%-24.5%). Loose FI was reported by 91 of 442 women, yielding a prevalence of 20.7% (95% CI, 16.9%-24.5%). Well-formed FI was reported by 20 of 442 women, yielding a prevalence of 4.5% (95% CI, 2.6%-6.4%). All the women with well-formed FI also reported problems of loose FI. The prevalence of FI increased with age up to 75 years for both types of FI. FI was not related to parity ($P = 0.9$). The highest proportion of any FI (24.4%) occurred in women with a parity of four or greater; however, 20.3% of nulliparous women reported FI. Within parous women, there was no significant association found between FI and history of self-reported instrumental delivery ($P = 0.4$). About two thirds of the women with loose and well-formed FI also reported coexisting UI. Loose FI was significantly associated with any UI (odds ratio, 2.8; 95% CI, 1.7-4.8) after adjusting for age and BMI ($P < 0.001$). Well-formed FI was not significantly associated with any UI after adjusting for age and BMI.

Conclusions: FI is a common condition affecting one in five adult women in the community. In our study, women with loose FI, but not well-formed FI, were more likely to have UI independent of their age and BMI. Being parous was not associated with an increased risk of any FI.

Key Words: Fecal incontinence – Urinary incontinence – Childbirth – Prevalence.

Fecal incontinence (FI) is a socially debilitating condition, resulting in considerable embarrassment, social isolation, and loss of employment[1,2] and causing symptoms that can significantly affect a woman's daily activities and quality of life.[3,4] Little is known about the prevalence of FI among women in the general community. Reported prevalence estimates for FI have shown significant variability in population-based studies, ranging from 2.0% to 17.0% for adults of various ages.[5-14] It is probable that this variability is the result of differences in the definitions used for FI, the data collection methods (face-to-face interview vs telephone interview or postal self-administered questionnaire), the participants' response rates, and/or the populations studied.[10,15] With the substantial differences in the reported prevalence of FI, there is a need for more research to determine the extent of the problem. Furthermore, given the close anatomical relationship between the rectum and the bladder, along with their shared nerve supply and pelvic floor support, a possible association between FI and urinary incontinence (UI) merits consideration.

Prior studies have evaluated the relationship between FI and UI in women,[16-24] but only one of these used a validated instrument to diagnose FI.[19] We have previously reported that both increased age and being overweight are significantly associated with UI[25]; however, studies of the relationship between FI and UI have not taken into account age or body mass index (BMI)[16-18,23] or adjusted for age only.[19,20,22,24] Only the study by Chen et al[21] undertook multivariate analysis to investigate the relationship between FI and UI, taking into account both age and BMI.

The aims of this study were to document the age-specific prevalence of FI in community-dwelling women using a validated questionnaire and to determine its relationships with

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childbirth (parity and instrumental delivery) and UI, adjusting for age and BMI.

METHODS

This study reports on the findings from a follow-up questionnaire completed in 2008 that represents the follow-up of a previous questionnaire (baseline) that investigated the prevalence of UI. Participants in this study were originally recruited from a research database that was established from the Victorian Electoral Roll in the period between April 2002 and August 2003. Detailed information on the recruitment process from this database to a large cross-sectional study of androgens in women has been described previously.[26] Of the 1,423 participants in the androgen study, 754 agreed to be recontacted regarding further research, and of those, 542 women expressed interest in participating in the study of UI. The 542 women were mailed the baseline questionnaire of the UI study, with 506 women returning the completed questionnaire. Two years later, a follow-up questionnaire was posted to the 457 women who agreed to continue in the study. A reminder was given to the nonresponders by telephone if they had not returned the questionnaire after 4 weeks.

The baseline questionnaire included a validated assessment of UI and questions on sociodemographic data, medical and obstetric history, and current prescription and nonprescription drug use. Menopause status was determined on the basis of answers to several questions considered in a hierarchical manner, including history of a bilateral oophorectomy, age (≥58 y), current use of hormonal contraception or systemic postmenopausal hormone therapy, history of hysterectomy, bleeding pattern, and the presence of vasomotor symptoms.[27] Exercise was assessed by using the question "Do you participate in any regular exercise/recreational activity?" and the response was categorized as either yes or no.

The follow-up questionnaire was the same as the baseline questionnaire with the addition of questions about constipation, treatment approaches for UI, hysterectomy, types of anesthesia used during childbirth, and the Pelvic Floor Distress Inventory (PFDI).[28] This study was approved by the Monash University Human Research and Ethics Committee and all participants gave written informed consent forms.

Assessment of FI

The PFDI questionnaire was used to estimate the prevalence of FI. This is a condition-specific, validated questionnaire for women with disorders of the pelvic floor that serves the role of both a symptom inventory for pelvic organ prolapse, fecal, and UI and a measure of the degree of bother and distress caused by the symptoms.[29] The PFDI has 20 items and three scales (pelvic organ prolapse distress inventory, colorectal-anal distress inventory, and urinary distress inventory). Respondents are asked if they experienced specific symptoms, and the response was categorized as either yes or no. If the response was yes, the degree to which the symptom bothered the participant was measured on a 4-point scale ranging from "not at all" to "quite a bit."[29]

There are three questions on FI (well formed, loose, or flatus) in the colorectal-anal distress inventory scale. FI was defined as loss/leakage of well-formed or loose stool beyond control at least once in the preceding 3 months and was expressed as a dichotomous outcome variable (yes/no). Leakage of flatus was not included in our definition of FI because it is frequently reported but less bothersome.

Assessment of UI

The Questionnaire for Urinary Incontinence Diagnosis (QUID) was used to assess different types of UI (stress, urge, or mixed UI) at baseline and again 2 years later. This is a validated questionnaire that contains six questions to assess the primary cause of urine loss: physical pressure (stress-only UI), sudden/uncomfortable urge to urinate (urge UI), or both (mixed UI).[30] Each question is scored from 0 ("none of the time") to 5 ("all the time") based on the frequency of leakage, providing a maximal total score of 15 for each of stress and urge UI. Composite scores of 4 or higher for questions 1, 2, and 3 classifies a woman as having stress UI and 6 or higher for questions 4, 5, and 6 classifies a woman as having urge UI.[30] Women diagnosed with both stress and urge UI by the QUID were classified as having mixed UI.[30]

Prevalence of FI

Prevalence was calculated as the number of women classified as having different types of FI (well-formed/loose) by the PFDI divided by the total number of women in the survey.

Data analysis

Data were summarized as prevalence estimates with 95% CIs, and sociodemographic data were presented as frequencies, means (SDs), ranges, or percentages. Univariate (Pearson's χ^2 tests) and multivariate logistic regression analyses were used to assess the relationship between FI type and UI adjusting for other risk factors such as age (continuous) and BMI (continuous). Statistical analyses were performed using SPSS 16.0 for Windows (SPSS Inc., Chicago, IL).

RESULTS

Of the 457 women to whom the follow-up questionnaire was sent, 444 responded. The final analysis included 442 women, as 2 women did not complete the baseline QUID. The characteristics of the study participants are shown in Table 1. The mean (SD) age of the women was 59.28 (12.1) years (range, 26-82 y), and the mean (SD) BMI was 27.38 (5.8) kg/m^2; 84.2% of the study participants were parous, 72.9% were postmenopausal, and 17.2% women were on systemic hormone therapy.

Loose FI was reported by 91 of 442 women, yielding a prevalence of 20.7% (95% CI, 16.9%-24.5%). Well-formed FI was reported by 20 of 442 women, yielding a prevalence of 4.5% (95% CI, 2.6%-6.4%). All the women with well-formed FI also reported problems of loose FI (Table 2).

The prevalence of FI increased with age up to the age of 75 years for both types of FI. For loose FI, it increased from 13.8% in participants 45 to 54 years old up to 31.5% in participants aged 65 to 74 years, and for well-formed FI, it increased

TABLE 1. *Characteristics of the study participants (n = 442)*

Age, y	
Mean (SD)	59.3 (12.1)
Range	26-82
Age category (y), n (%)	
<45	56 (12.7)
45<55	95 (21.5)
55<65	128 (29.0)
65<75	112 (25.3)
≥75	51 (11.5)
BMI, kg/m^2[a]	27.4 (5.8)
BMI category (kg/m^2), n (%)	
<25	165 (38.2)
25<30	142 (32.9)
≥30	125 (28.9)
Smoking status, n (%)	
Yes	38 (8.6)
Menopause status, n (%)	
Premenopausal	92 (20.8)
Perimenopausal	28 (6.3)
Postmenopausal	322 (72.9)
Parity, n (%)	
Nulliparous	70 (15.8)
Parous	372 (84.2)
Systemic estrogen ± progestin use, n (%)	
Yes	76 (17.2)
Hysterectomy status, n (%)[b]	
Yes	106 (24.3)
Participation in regular exercise, n (%)[c]	
Yes	343 (78.5)

BMI, body mass index.
[a]10 missing cases.
[b]5 missing cases.
[c]5 missing cases.

from 2.1% in women 45 to 54 years old up to 7.1% in women 65 to 74 years old (Table 2).

FI was not strongly related to parity ($P = 0.9$), and 20.3% of nulliparous women reported FI. The highest proportion of any FI (24.4%) was found to be for women with a parity of four or greater (Table 3). Within parous women, there was no significant association found between FI and history of self-reported instrumental delivery (Table 4).

Nearly two thirds of the women with loose and well-formed FI reported coexisting UI. Mixed UI was the predominant form, followed by stress-only and then urge-only UI associated with both types of FI (Table 5).

Loose FI was significantly associated with any UI, as measured by the QUID, in both the univariate (odds ratio [OR], 3.4; 95% CI, 2.1-5.5) and the multivariate (OR, 2.9; 95% CI, 1.7-4.8) logistic regression analyses after adjusting for age and BMI ($P < 0.001$; Table 6). Well-formed FI was not significantly associated with any UI after adjusting for age and BMI (OR, 1.9; 95% CI, 0.7-5.1).

TABLE 2. *Age-specific prevalence of FI over the previous 3 months using the Pelvic Floor Distress Inventory questionnaire in women according to 10-year age groups (n = 442)*

Age category, y	Sample size, n (%)	Loose FI		Well-formed FI	
		n (%)	95% CI	n (%)	95% CI
<35	12 (2.7)	0	0	0	0
35<45	44 (10.0)	8 (18.2)	6.8 to 29.6	1 (2.3)	−2.1 to 6.7
45<55	95 (21.5)	13 (13.8)	6.9 to 20.7	2 (2.1)	−0.8 to 5.0
55<65	128 (29.0)	20 (15.6)	9.3 to 21.9	7 (5.5)	1.6 to 9.4
65<75	112 (25.3)	35 (31.5)	22.9 to 40.1	8 (7.1)	2.3 to 11.9
≥75	51 (11.5)	15 (29.4)	16.9 to 41.9	2 (3.9)	−1.4 to 9.2
Total	442 (100)	91 (20.7)	16.9 to 24.5	20 (4.5)	2.6 to 6.4

Two women with loose FI have missing data.
FI, fecal incontinence.

TABLE 3. *Proportion of women with any FI (well formed or loose) according to different parity categories*

	Any FI		No FI		
Parity category	n (%)	95% CI	n (%)	95% CI	Total, n
0 (nulliparous)	14 (20.3)	16.5-24.1	55 (79.7)	75.9-83.5	69
1	6 (18.2)	14.6-21.8	27 (81.8)	78.2-85.4	33
2	32 (21.3)	17.5-25.1	118 (78.7)	74.9-82.5	150
3	20 (18.2)	14.6-21.8	90 (81.8)	78.2-85.4	110
≥4	19 (24.4)	20.4-28.4	59 (75.6)	71.6-79.6	78
Total	91 (20.7)	16.9-24.5	349 (79.3)	75.5-83.1	440

χ^2 test, P value = 0.9.
FI, fecal incontinence.

DISCUSSION

We report that FI is common, affecting as many as one in five noninstitutionalized adult women, with loose FI being more common than well-formed FI and both types being more prevalent in older women up to the age of 75 years. Loose FI was significantly associated with any UI independent of age and BMI, whereas well-formed FI was not significantly associated with UI.

The prevalence of FI in our study sample is higher than that reported in other population-based studies.[5,6] In comparison with the studies of Lawrence et al[5] and Nygaard et al,[6] who reported prevalences of 16% and 9%, respectively, we had a lower proportion of younger women, with only 12.7% of the women in our study being younger than 45 years. In the study of Nygaard et al, 32% of the total sample were younger than 39 years, and for Lawrence et al, the mean age of the sample was 56.5 (15.8) years, which is lower than the mean age of 59.3 (12.1) years in our study. There were also differences in time frame for reporting FI, with Nygaard et al reporting involuntary fecal loss in the previous 1 month whereas we asked about FI in the previous 3 months. The use of interviews by other researchers,[6] as opposed to the use of a mailed questionnaire, may have also resulted in a lower estimate of prevalence, as face-to-face or telephone interview techniques are more likely to underestimate the true burden of this condition, which is not easy to disclose. In addition, because our sample was derived from a larger group of women who expressed interest

TABLE 4. *Proportion of women with or without any FI (well formed or loose) according to instrumental delivery (n = 371, excluding nulliparous women)*

	Any FI, n (%)		
Any instrumental delivery	No	Yes	Total
No	249 (80.1)	62 (19.9)	311 (100)
Yes	45 (75.0)	15 (25.0)	60 (100)
Total	294 (79.2)	77 (20.8)	371 (100)

χ^2 test, P value = 0.4.
FI, fecal incontinence.

TABLE 5. *Frequency of different types of UI in women with any FI, loose FI, or well-formed FI (n = 442)*[a]

	No UI, n (%)	Stress only, n (%)	Urge only, n (%)	Mixed, n (%)	Total, n (%)
Any FI (loose or well formed; $P < 0.001$)					
No	214 (61.3)	57 (16.3)	25 (7.2)	53 (15.2)	349 (100.0)
Yes	29 (31.9)	14 (15.4)	9 (9.9)	39 (42.9)	91 (100.0)
Total	243 (55.2)	71 (16.1)	34 (7.7)	92 (20.9)	440 (100.0)
Loose FI ($P < 0.001$)					
No	214 (61.3)	57 (16.3)	25 (7.2)	53 (15.2)	349 (100.0)
Yes	29 (31.9)	14 (15.4)	9 (9.9)	39 (42.9)	91 (100.0)
Total	243 (55.2)	71 (16.1)	34 (7.7)	92 (20.9)	440 (100.0)
Well-formed FI (χ^2 test, $P = 0.05$)[b]					
No	238 (56.4)	68 (16.1)	33 (7.8)	83 (19.7)	422 (100.0)
Yes	7 (35.0)	3 (15.0)	1 (5.0)	9 (45.0)	20 (100.0)
Total	245 (55.4)	71 (16.1)	34 (7.7)	92 (20.8)	442 (100.0)

Data are missing for two women with loose FI.
FI, fecal incontinence; UI, urinary incontinence; QUID, Questionnaire for Urinary Incontinence Diagnosis.
[a]Determined by QUID score.
[b]All women with well-formed FI also had loose FI.

in participating in a study of UI and because FI is often associated with UI, this could have resulted in selection bias and the prevalence of FI may have been overestimated.

Prevalence may have also been greater than that in other studies because we did not exclude women with known bowel diseases such as Crohn disease, ulcerative colitis, irritable bowel syndrome, or other bowel conditions, as we wanted our prevalence estimate to reflect the community as a whole. However, the studies of Lawrence et al[5] and Nygaard et al[6] did not exclude individuals with known bowel disease. We believe that our finding of a lower prevalence in women 75 years or older compared with the women aged 65 to 74 years is likely to be due to incontinent women 75 years or older no longer living in the community but living in residential care.

Nulliparous women were affected by FI to the same extent as parous women in our study. The association between FI and parity is inconsistent in the literature. A study by Boreham et al[31] also did not find any significant association between FI and parity after adjusting for confounders. Increasing age alone seems to have the most substantial effect on anal sphincter function.[32] The internal anal sphincter thickness increases with age, as does the internal anal sphincter diameter, whereas the maximum anal resting pressure decreases with age.[33] These changes will each contribute to an increased risk of FI with age, as in our study. Furthermore, a recent Cochrane review did not find a benefit of cesarean delivery over vaginal delivery in subsequent FI.[34]

We have previously reported an overall prevalence of any UI of 41.7% in this population sample.[25] In the current study, we have found a significant association between loose FI and UI after adjusting for age and BMI, whereas a significant relationship was not seen between well-formed FI and UI. A trend toward a positive association between well-formed FI and UI was apparent such that with a higher power, our study may have revealed a statistically significant association. Alternatively, we saw a relationship between UI and loose FI, but not well-formed FI, which might suggest either that the pathophysiology of loose and well-formed FI differ or that the development of well-formed FI reflects more substantial pathology.

There are several strengths of our study. It is a community-derived study, and we used validated instruments (PFDI and QUID) for the assessments of FI and UI.

The main limitation to our study is that the sample size may not have been sufficiently large to detect a statistically significant relationship between well-formed FI and UI.

TABLE 6. *Logistic regression analysis for loose fecal incontinence (n = 442)*

Covariates	Univariate analysis, odds ratio (95% CI)	Multivariate analysis, odds ratio (95%CI)
Any UI (categorical: yes/no)	3.4 (2.1-5.5)[a]	2.9 (1.7-4.8)[a]
Age (continuous)	1.0 (1.0-1.1)[a]	1.0 (1.0-1.1)[a]
BMI (continuous)	1.1 (1.0-1.1)[a]	1.0 (1.0-1.1)
Parity (nulliparous vs multiparous)	1.0 (0.5-1.9)	

UI, urinary incontinence; BMI, body mass index.
[a]$P < 0.05$.

CONCLUSIONS

This study confirms that FI is a common condition, affecting about 20% of adult women in the community and shows that the prevalence increases with age. Whereas being parous was not associated with an increased risk of any FI, women with loose FI, but not well-formed FI, were more likely to have UI independent of their age and BMI. Therefore, it is important that clinicians consider the possibility of FI, especially in women with UI.

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Chapter 7

7.1 DISCUSSION AND CONCLUSIONS

DISCUSSION

Limited epidemiological data on the age-specific prevalence, incidence and resolution of UI among community-dwelling women led to the conduct of this research. This is the first prospective project to evaluate the prevalence, incidence and resolution of different types of UI using validated questionnaires in a sample of Australian women. In addition, this study attempted to address several risk factors for UI for which data are lacking or inconsistent. Identification of the risk factors for UI may lead to preventative approaches to avoid or slow the development of the condition. The study also investigated FI and its association with UI. This research also evaluated the impact of UI on well-being and condition-specific QoL.

Main findings of this thesis

This research shows that UI is a highly prevalent condition, affecting about 41.7% Australian women in the general community. The prevalence of different types of UI differs across the life span, with stress and urge UI more common in women at midlife and older women respectively. Moreover, our results show that obesity and parity are positively associated with the likelihood of having stress incontinence. In contrast, for urge UI, increasing age was found to be the only significant factor, and higher BMI and hysterectomy were significantly associated with mixed UI. An independent contribution of menopause was not seen in this study.

Although UI is not life-threatening, it is a condition that affects women of all ages and has a considerable impact on QoL. Many aspects are affected including well-being, social interactions and activities, and sexual function and interpersonal relationships (Kelleher et al. 1995). In this study incontinent women, particularly those with mixed and stress-only incontinence, had significantly lower psychological general well-being than unaffected women. Mixed and stress UI were associated with differing patterns in terms of well-being as seen by the subdomain scores of the PGWBI. Both forms of UI were associated with poor self-control, low general health and reduced vitality. However, only the women with mixed UI had significantly more anxiety, depressed mood and lower levels of well-being. This suggests that stress UI is primarily associated with health-related sequelae, whereas mixed UI is more likely to impact on mood and emotional well-being.

The longitudinal study shows that UI has a dynamic time course with relatively high incidence and resolution rates. An incidence rate of UI of 8.5% per year with a resolution rate of 8.4% per year with an absolute 1.5% per year (3% over 2 years) increase in the proportion of women with UI. There is an overall trend toward increasing prevalence with age as it was increased from 41.6% at baseline to 44.6% at FU study as this cohort aged. Furthermore, significant movements of women between diagnoses of stress-only, urge-only and mixed UI were observed which suggest that UI is a highly dynamic clinical condition with changing types and resolution over time.

A new finding from our study is that whereas most of the de novo cases of UI were either stress-only or urge-only UI, a new diagnosis of mixed UI occurred mainly in women who previously had reported either stress-only or urge-only UI. Although our numbers are small,

it is striking that one third of the women with urge-only UI had spontaneous resolution of their condition at follow up. A trend was seen towards women with mixed UI who were less likely to undergo resolution than women with urge-only or stress-only UI.

This research has confirmed that many women do not seek treatment for their incontinence. They may find ways of coping with their symptoms, but many are bothered by their symptoms and could benefit from treatment. Others have also reported that women with UI are generally reluctant to seek medical treatment (Simeonova et al. 1999; Van Der Vaart et al. 2002). Women with UI may not express the desire for treatment unless they are asked; most are unaware that there are effective treatments for UI(Viktrup 2002). Many women are also reluctant to consult a doctor about this condition because of embarrassment. The most important treatment modalities for UI are available and feasible in general practice and the results of treatment have a sound evidence base (Dumoulin and Hay-Smith 2010). It is a challenge to provide information about different treatment options and to select the appropriate one(s) for a woman with UI, so that she can actively decide whether to seek treatment or to cope with her problems some other way, and not simply give up because she thinks there is no help available (EPICONT study, 2002). There should be a plan of providing information on UI as well as different treatment options to the women suffering from this condition, such as patient information sheet on UI at heath care services (source: http://womenshealth.med.monash.edu.au).

The first thing for women with symptoms of UI is to raise the issue with their doctor. Some tests may be needed to eliminate the possibility of a specific cause for the UI. Assessment should include a full medical history including all the medications you are taking and a

clinical examination including a pelvic examination. There are a range of treatment options which may be appropriate and should be discussed with doctor, including pelvic floor exercises, bladder retraining often taught by a physiotherapist, weight loss, avoiding irritants such caffeine containing drinks which increase the urge to pass urine (such as tea and coffee), use of low dose vaginal oestrogen cream/pessaries if postmenopausal. Urinary tract infections could be prevented by drinking plenty of fluid, cranberry juice or taking cranberry tablets. In some women the combination of pelvic floor exercises/bladder retraining and weight loss will be enough to significantly reduce UI. There are a variety of therapies for different forms of UI in the form of medications, surgery and nonsurgical interventions with good outcomes (source: http://womenshealth.med.monash.edu.au).

In the longitudinal study, a condition-specific quality of life instrument was used to evaluate the impact of different types of UI(Brookes et al. 2004). This questionnaire focuses on physical and social limitations due to the symptoms of UI as well as the overall influence on all the activities of daily living and a high result represents poorer QoL. We found that BFLUTS-QoL scores were significantly higher (more adverse) in women with all types of UI than in women with no UI. The highest median BFLUTS-QoL was reported for women with mixed UI, followed by urge and stress UI. These findings are consistent with evidence from previous studies (Chiaffarino et al. 2003; Irwin et al. 2006; Grimby et al. 1993; Fultz and Herzog 2001; DuBeau et al. 2006). An increase in the BFLUTS-QoL score was also found for the incident UI cases compared with women with no UI at both baseline and follow-up. However, women whose UI resolved failed to show a significant improvement in the BFLUTS-QoL score compared with continent women at base line and at follow-up. It may be that even the infrequent experience of symptoms in “resolution

cases" at unexpected times or places may be just as distressing as more frequent symptoms. It is also possible that lack of improvement in quality of life in women whose UI had apparently resolved may be a function of remaining co-existing morbidity.

This thesis also reports that FI is common, affecting as many as one in five non-institutionalised adult women, with loose FI being more common than well-formed FI, and both types being more prevalent in older women. Loose FI was significantly associated with any UI independent of age and BMI, while well-formed FI was not associated significantly with UI, although the number of women with well-formed FI limited the power of this part of the analysis.

Strengths of this work

The entire work in this thesis was based on the reports of participants from the community and the recruitment was from a database which itself was established using population-based methods. Furthermore, the diagnosis of UI, FI and subtypes was established using validated instruments. A further strength is the use of longitudinal data which allowed the incidence and resolution of UI to be determined and the course of the complaint to be identified in women who were not treated for UI. Retention of participants in the follow-up study was high. This study differs from other published studies primarily because it documented both incidence and resolution of UI and in the use of a generic validated instrument (PGWBI) for the assessment of the impact of UI on well-being. This approach enabled the comparison of the psychological well-being of women with UI with that of unaffected women. Moreover, it enabled the examination of psychological well-being in relation to types of UI, including stress, urge and mixed UI.

In the longitudinal study the use of a condition-specific validated questionnaire (BFLUTS) facilitated the evaluation of the quality of life in women with different types of UI, as well as changes in QoL with the onset and resolution of UI.

Potential limitations of this work

The sample size, although large, may not have been sufficiently large for the study to be adequately powerful to assess some risk factors or to assess relationships between urge UI and well-being and between well-formed FI and UI. Moreover, the study had relatively few young women as recruitment of young women, busy with work and young children, proved difficult.

As the sample was derived from a larger group of women who had expressed interest in participation in further research studies, the participants in the UI study were likely to be healthier than non-participants (healthy volunteer bias). So our estimates of prevalence and incidence of UI (and FI) are, if anything, likely to be under-estimates.

The baseline survey which we used to examine risk factors for prevalent UI was cross-sectional. Therefore it is not possible to demonstrate that a risk factor examined preceded the outcome of UI, a necessary step to demonstrate causality (e.g. hysterectomy).

In addition, the QUID questionnaire does not allow for the grading of severity of UI, and thus it was not possible to examine the relationship between severity of symptoms within the subtypes of UI and quality of life.

Our prevalence estimate of 44.6% for any UI at follow-up did lie within the 95% CI of the proportion at baseline i.e. 37.0 to 46.2%. This was also true for each of the prevalence estimates for stress, urge and mixed UI. So we accept that, on face value, each result could be seen as consistent with no change. However, as each estimate of prevalence increased over the course of the study we consider it unlikely that the changes were due to chance. The overall picture of a small increase in prevalence of each type of UI is consistent with the change that has been observed with age in other studies. A definite picture would be achieved by a larger group studied for a considerably longer period of time.

CONCLUSIONS

This study confirms that both UI and FI are common conditions in women living in the community and that prevalences increase with age. Women with loose FI are more likely to have UI, independent of their age and BMI. Therefore it is important that clinicians ask women about the problems of UI and FI, irrespective of their age. UI can have a major impact on women's well-being and quality of life. Women may have to make major adjustments to their everyday lives to accommodate their UI such as planning their activities around access to a toilet, wearing incontinence pads or avoiding activities they know will result in urinary leakage. Women should not accept that UI is a permanent condition, as spontaneous resolution does occur. Only a small proportion of those affected appear to seek medical help and this may reflect both reluctance to discuss the condition and a low expectation of benefit from treatment. There is a need to improve awareness about incontinence and its treatment in women. It is important for women with UI to discuss this issue with their doctors. Effective treatments exist and there is a need for further research to evaluate the barriers to existing treatments in clinical practice.

7.2 FUTURE DIRECTIONS AND IMPLICATIONS

UI and FI can affect women of all ages. Prevalence and incidence data for UI and FI, using validated instruments and free of “healthy volunteer bias”, are currently lacking for younger women.

The relationships between some risk factors such as mode of delivery, hysterectomy, systemic hormone therapy and UI are not well-established and require future research in order to clarify the areas of controversy that exist.

The findings in relation to the spontaneous resolution of UI in some women and the movement of women between different types are likely to stimulate further research to identify the factors responsible for spontaneous resolution and movement from one type of UI to another. This may help to target women with priority for appropriate treatment.

Obesity is such an important risk factor for UI that weight loss as an intervention needs to be further researched and implemented. Although evidence for pelvic floor exercises (PFEs) improving symptoms exists, evidence that PFEs are useful for prevention of UI is lacking. Understanding UI prior to pregnancy is also an important area for future study.

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Appendices

Baseline study questionnaire

A Study of Women's Health

Patient Self-administered Questionnaire

Please PRINT your details below.

This page will be removed from the questionnaire after coding.

Given Names:

Surname:

Address:

Street No. and Name

Suburb | State | Postcode

Phone: ( ) - ( ) -

Home | Work

Mobile

We would appreciate it if you could provide the contact details of a relative or friend that you would be happy for us to communicate with if we cannot contact you in the future (e.g. if you unexpectedly move) Please note this is optional.

Alternative contact (optional):

Given Name:

Surname:

Relationship:

Phone: ( ) - ( ) -

Home | Work

Mobile

Office use only

Date of receipt: / /

Day | Month | Year

A Study of Women's Health

Patient Self-administered Questionnaire

Thank you for taking part in this study.

This study aims to explore key issues that affect the health of adult women. It is essential for us to understand these issues if we are to improve the quality of life and wellbeing of Australian women.

We would be grateful if you could find the time to complete and return this questionnaire in the enclosed reply-paid envelope. It may take you up to 40-60 minutes to complete the questionnaire.

Some of the questions may not apply to you. If this is the case, please mark the 'No' answer. Please DO NOT leave any questions unanswered/blank.

Please note that you do not have to complete the questionnaire in one sitting and all the information that you provide is kept completely confidential.

Please try to finish the questionnaire if you can.

If you have any queries about the study or would like some help in completing this questionnaire, you can contact one of the investigators, Dr Donna Urquhart, on (03) 9903 0590.

If this questionnaire raises concerns for you, please contact your medical practitioner or 'LifeLine', a 24-hour telephone counselling service avaliable on 13 11 14 (for the cost of a local call).

How to complete this form:

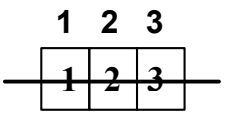
Please complete this form carefully using black ballpoint pen (not felt). Alternatively use blue pen.

Most questions only require you to answer by marking the appropriate box or boxes with a cross like this: ☒

Please do not mark any areas outside the box.

Other questions will require a numeric answer and can be filled in like this: | 1 | 2 | 3 |

If you make a mistake when writing, cross it out with one thick line and write your correct answer above the box.



If you make a mistake, place a diagonal line through the incorrect answer like this: ☒ and then put a cross in the appropriate box of your preferred response. ☒

Yes No

Please do not cross the number 7 (eg. 7). Please make sure to write only one number in each space provided, as demonstrated in the example above.

A Study of Women's Health

General Health

1. Please enter the postcode of your home address: ☐☐☐☐ Postcode

2. Please enter your date of birth: ☐☐ / ☐☐ / ☐☐☐☐ Day / Month / Year

3. Please enter the date that you started this questionnaire: ☐☐ / ☐☐ / ☐☐☐☐ Day / Month / Year

GENERAL HEALTH

We are interested in knowing about your general health, including medical conditions that you may have been diagnosed with.

1. Please enter your current weight (by rounding off to the nearest whole number and not using decimal points):

☐☐☐ kg OR ☐☐☐ pounds OR ☐ Don't Know

2. Please enter your current height (by rounding off to the nearest whole number and not using decimal points):

☐☐☐ cm OR ☐☐ feet ☐☐ inches OR ☐ Don't Know

GENERAL MEDICAL CONDITIONS

3. A. Have you been hospitalized within the past 5 years? Please note to be 'hospitalized' you must have been admitted to hospital for greater than 24 hours. Presentations to the emergency department for less than 24 hours are not included.

Yes ☐ (go to Q3, Part B) No ☐ (go to Q4)

B. Please specify the exact reason(s) for your hospitalization:

YEAR	REASON
☐☐☐☐	
☐☐☐☐	
☐☐☐☐	
☐☐☐☐	
☐☐☐☐	

A Study of Women's Health

General Health

4. Have you been diagnosed with any of the following conditions?

A. Cancer (current or previous) ☐ Yes ☐ No

If yes, please indicate the type of cancer (e.g. breast cancer, ovarian cancer)

(specify)

B. Stroke (includes transient ischaemic attack (TIA), mini stroke) ☐ Yes ☐ No

C. Diabetes ☐ Yes ☐ No

If yes, please indicate whether it is controlled by:

☐ Diet ☐ Tablets ☐ Insulin

☐ Other

(specify)

D. Neurological (nervous system) condition ☐ Yes ☐ No

If yes, please specify:

☐ Multiple Sclerosis

☐ Motor Neurone Disease

☐ Parkinson's Disease

☐ Other

(specify)

E. Respiratory condition ☐ Yes ☐ No

If yes, please specify:

☐ Asthma ☐ Bronchitis ☐ Emphysema

☐ Other

(specify)

F. Trauma to spine and/or pelvis ☐ Yes ☐ No

This <u>includes</u> fractures sustained after a motor car accident, serious fall or other accident.

If yes, please specify:

☐ Neck

☐ Middle Back

☐ Lower Back

☐ Pelvis

☐ Other

(specify)

A Study of Women's Health

General Health

G. Rheumatic condition

☐ Yes
☐ No

If yes, please specify:

☐ Rheumatoid arthritis
☐ Ankylosing spondylitis
☐ Gout
☐ Osteoarthritis - Location(s) (e.g. hands):

(please indicate where)

☐ Other (specify)

H. Kidney Disease

☐ Yes
☐ No

I. Osteoporosis

☐ Yes
☐ No

If yes, was this diagnosed with a bone density test (DEXA)?

☐ Yes
☐ No

J. Fracture after 'minimal trauma'

☐ Yes
☐ No

By 'minimal trauma' we mean a very mild accident or no accident at all. For example, some women have fractured a rib after a coughing spasm, or a wrist after a very mild fall. This <u>does not include</u> fractures sustained after a motor car accident, serious fall or other accident.

If yes, please specify:

☐ Spine
☐ Pelvis
☐ Arm
☐ Leg
☐ Other (specify)

K. Mental illness

☐ Yes
☐ No

If yes, please specify:

☐ Depression ☐ Bipolar Disorder ☐ Schizophrenia

☐ Other (specify)

L. Urinary tract infection in the past 5 years

☐ Yes
☐ No

A Study of Women's Health

General Health

M. Chronic cough
- ☐ Yes
- ☐ No

N. Physical impairment that affects mobility
- ☐ Yes
- ☐ No

SMOKING

5. A. Do you smoke?
- ☐ Yes (Go to Q 5B)
- ☐ No (Go to Q 6)

B. If you smoke, how many cigarettes do you smoke each day:
- ☐ More than 40
- ☐ 21 - 39
- ☐ 10-20
- ☐ 9 or less

A Study of Women's Health

General Health

ALCOHOL

6. A. Do you drink alcohol?

- ☐ Yes (Go to Q 6B)
- ☐ No (Go to Q 7)

If you drink alcohol, please answer the following 3 questions:

B. Which of the following best describes how often you would have an alcoholic drink:

- ☐ Every day
- ☐ 5 - 6 days a week
- ☐ 3 - 4 days a week
- ☐ 1 - 2 days a week
- ☐ 2 - 3 days a month
- ☐ Less often

The following are all equal to approximately one standard drink:

Low alcohol beer (3.5%)	1 can or 1.5 'pots'; (volume 375mls)
Regular beer (4.9%)	1 'pot' or ¾ 'stubby'; (volume 285mls)
Wine (12%)	one small glass; (volume 100mls)
Spirits / liqueurs	one shot/nip; (volume 30mls)
Mixed drinks	1 glass; (volume 30mls of spirits + mixer)
Alcoholic soda (5.5%)	¾ of a 330ml bottle; (volume 250mls)

C. On a day that you would have an alcoholic drink, how many standard drinks would you usually have:

- ☐ 13 or more standard drinks
- ☐ 11 - 12 standard drinks
- ☐ 7 - 10 standard drinks
- ☐ 5 - 6 standard drinks
- ☐ 3 - 4 standard drinks
- ☐ 1 - 2 standard drinks

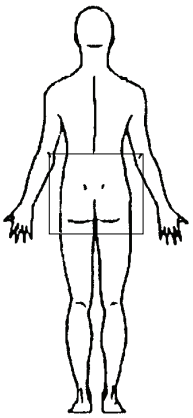
D. How often would you have had more than **4 standard drinks** in a day:

- ☐ Every day
- ☐ 4 - 6 days a week
- ☐ 2 - 3 days a week
- ☐ About 1 day a week
- ☐ 2 - 3 days a month
- ☐ About 1 day a month
- ☐ Less often
- ☐ Never

A Study of Women's Health

Low Back Pain

We are interested in learning about the health of your lower back/spine.



We have defined low back pain as discomfort or pain occurring in the boxed area shown on the body diagram below.
Please refer to this when answering each of the following questions.

Please put a cross in one box for each question ☒

---

7. Have you ever experienced low back pain? ☐ Yes ☐ No

8. Have you had back pain (please complete each of the following (a to f)):

	Yes	No
a) in the past 24 hours?	☐	☐
b) in the past 2 weeks?	☐	☐
c) in the past month?	☐	☐
d) in the past 6 months?	☐	☐
e) in the past 12 months?	☐	☐
f) during your lifetime?	☐	☐

9. Do you have low back pain now? ☐ Yes ☐ No

10. Please indicate your age when you experienced low back pain for the first time? ☐☐ Years OR ☐ Don't Know

11. Did your first attack occur in the past 12 months? ☐ Yes ☐ No

12. How often do you experience low back pain? ☐ Daily ☐ Monthly ☐ Weekly ☐ Yearly ☐ Other _____ (specify)

A Study of Women's Health

Low Back Pain: Pain Intensity

We are interested to know more about the intensity of your back pain.

The following questionnaire is the Chronic Back Pain Grade Questionnaire which assesses pain intensity.

For the following questions with a scale of 0-10, please place a cross in **ONE** box only

Please complete this questionnaire even if you do NOT experience back pain.

Question 13.

A. How would you rate your back pain on a 0-10 scale at the present time, that is right now, where 0 is 'no pain' and 10 is 'pain as bad as could be'?

No Pain — Pain as bad as could be

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

B. In the past 6 months, how intense was your worst pain rated on a 0-10 scale where 0 is 'no pain' and 10 is 'pain as bad as could be'?

No Pain — Pain as bad as could be

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

C. In the past 6 months, on the average, how intense was your pain rated on a 0-10 scale where 0 is 'no pain' and 10 is 'pain as bad as could be'? (That is, your usual pain at times you were experiencing pain.)

No Pain. — Pain as bad as could be

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

D. About how many days in the last 6 months have you been kept from your usual activities (work, school or housework) because of back pain?

☐☐☐ Disability Days

E. In the past 6 months, how much has back pain interfered with your daily activities rated on a 0-10 scale where 0 is 'no interference' and 10 is 'unable to carry on any activities'?

Interference — Unable to carry on any activities

☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

A Study of Women's Health

Low Back Pain: Pain Intensity

F. In the past 6 months, how much has back pain changed your ability to take part in recreational, social and family activities where 0 is 'no change' and 10 is 'extreme change'?

No Change										Extreme change
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

G. In the past 6 months, how much has back pain changed your ability to work (including housework) where 0 is 'no change' and 10 is 'extreme change'?

No Change										Extreme change
☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

A Study of Women's Health

Low Back Pain: Disability

Question 14:

This is the Oswestry Modified Disability Questionnaire. Please complete this questionnaire (even if you do NOT experience back pain). It is designed to give us information as to how your back (or leg) trouble has affected your ability to manage in everyday life. Please answer **every section**. Mark **one box only** in each section that most closely describes you **today**.

Section 1: Pain Intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- ☐ The pain is very severe at the moment
- ☐ The pain is the worst imaginable at the moment

Section 2: Personal Care (Washing, Dressing, etc.)

- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it causes extra pain
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but can manage most of my personal care
- ☐ I need help every day in most aspects of self care
- ☐ I do not get dressed, wash with difficulty and stay in bed

Section 3: Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives me extra pain
- ☐ Pain prevents me lifting heavy weights off the floor but I can manage if they are conveniently placed e.g. on a table
- ☐ Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- ☐ I can only lift very light weights
- ☐ I cannot lift or carry anything

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Low Back Pain: Disability

Section 4: Walking

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me from walking more than 2 kilometres
- ☐ Pain prevents me from walking more than 1 kilometre
- ☐ Pain prevents me from walking more than 500 metres
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time

Section 5: Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favourite chair as long as I like
- ☐ Pain prevents me sitting more than one hour
- ☐ Pain prevents me from sitting more than 30 minutes
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6: Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than 1 hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7: Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

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Low Back Pain: Disability

Section 8: Sex Life (if applicable)

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9: Social Life

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

Section 10: Travelling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from travelling except to receive treatment

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Low Back Pain: Beliefs

Question 15:

This is the Back Beliefs Questionnaire. We are interested in finding out what people think about back trouble. Please indicate your general view towards back trouble, even if you have never had any. Please read each of the following statements and indicate whether you agree or disagree with each statement on a scale of 1 to 5, where 1 is completely disagree and 5 is completely agree.

	Completely disagree				Completely agree
A. There is no real treatment for back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
B. Back trouble will eventually stop you from working	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
C. Back trouble means periods of pain for the rest of one's life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D. Doctors cannot do anything for back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E. A bad back should be exercised	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
F. Back trouble makes everything in life worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
G. Surgery is the most effective way to treat back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
H. Back trouble may mean you end up in a wheelchair	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I. Alternative treatments are the answer to back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
J. Back trouble means long periods of time off from work	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
K. Medication is the only way of relieving back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
L. Once you have had back trouble there is always a weakness	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
M. Back trouble must be rested	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
N. Later in life back trouble gets progressively worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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Low Back Pain: Treatment

We are interested to know about treatment(s) you may have had for your back pain (or may still be undergoing).

16 A. Have you required treatment for your back pain?
- ☐ Yes (Go to Q 16B)
- ☐ No (Go to Q 17A)

B. Was this within the last 5 years?
- ☐ Yes
- ☐ No

---

17 A. Have you been hospitalized because of your back pain?
- ☐ Yes (Go to Q 17B)
- ☐ No (Go to Q 18A)

B. Was this within the last 5 years?
- ☐ Yes
- ☐ No

---

18 A. Have you required surgery for your back pain?
- ☐ Yes (Go to Q 18B)
- ☐ No (Go to Q 19)

B. Was this within the last 5 years?
- ☐ Yes
- ☐ No

---

19. We are interested to know who you <u>have seen regarding your back pain</u>

Mark <u>all the boxes</u> that apply to you:

- ☐ Acupuncturist
- ☐ Chiropractor
- ☐ General Practitioner
- ☐ Massage Therapist
- ☐ Osteopath
- ☐ Physiotherapist
- ☐ Sports Medicine Physician
- ☐ Surgeon/ Consultant
- ☐ Other ☐ (specify)

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Low Back Pain: Treatment

COMPLEMENTARY THERAPIES

Many people consult therapists for complementary (or alternative) therapies during their treatment for back pain.

20. A. Have you consulted a therapist for alternative treatment(s)? ☐ Yes (Go to Q 20B)
☐ No (Go to Q 21)

B. Please indicate, from the following list, which therapists you have consulted.

Mark all the boxes that apply to you:

- ☐ Aromatherapist
- ☐ Ayurveda Therapist
- ☐ Chinese medicine practitioner
- ☐ Herbalist
- ☐ Homeopath
- ☐ Hypnotherapist
- ☐ Iridologist
- ☐ Kinesiologist
- ☐ Naturopath
- ☐ Spiritual healer
- ☐ Other ☐ (specify)

---

21. Please indicate if you are **currently taking** any of the following anti-inflammatory medications, for your back pain

Mark all boxes that apply:

Current use (at least 3 days per week)**:**

- ☐ Aspirin
- ☐ Arthrotec 50
- ☐ Brufen
- ☐ Celebrex
- ☐ Clinoril
- ☐ Cortisone acetate
- ☐ Feldene
- ☐ Indocid
- ☐ Mobic
- ☐ Naprosyn
- ☐ Nurofen
- ☐ Orudis
- ☐ Prednislone
- ☐ Surgam
- ☐ Voltaren
- ☐ Other ☐ (specify)

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Financial and Social Issues

Please complete the following table, which was adapted (with permission) from the Lance Armstrong Foundation 'LIVESTRONG' Poll.

22. Have you had to deal with any of the following issues as a result of your back pain?
If Yes, please rate how difficult a problem this has been for you to deal with (by marking one box) according to the following scale:

Not at all bothered — 0 1 2 3 4 5 6 7 8 9 10 — Extremely bothered

	If you have had this problem during the last 12 months, how bothered were you? 0 1 2 3 4 5 6 7 8 9 10	Did not have to deal with issue	Does not apply to my situation
A. Problems in your relationship with your spouse or significant other	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
B. Lack of advancement, demotion or loss of job	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
C. Divorce, separation or break-up with a significant other	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
D. Made a change in your career direction or switched careers	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
E. Decreased income	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
F. Problems in relationships with friends and family	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
G. Emotional distance growing between you and significant people in your life	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
H. Problems with health insurance coverage	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
I. Problems with travel insurance coverage	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
J. Needing to rely on others for help with everyday tasks	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐

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Urinary Continence: Symptoms

Question 23.1

This is the Bristol Female Lower Urinary Tract Symptoms Questionnaire. We would like to find out about your urinary symptoms and we are very grateful that you can help us by filling in this questionnaire. Please answer each question, thinking about the symptoms you have experienced in the last month. You will see that some questions ask how often you have a symptom:

Occasionally = less than one third of the time
Sometimes = between one and two thirds of the time
Most of the time = more than two thirds of the time

Please put a cross in ONE box for each question ☒

A. During the night, how many times do you have to get up to urinate, on average?

- ☐ None
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4 or more

B. Do you have to rush to the toilet to urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

C. Do you have pain in your bladder?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

D. How often do you pass urine during the day?

- ☐ Every 4 hours or more
- ☐ Every 3 hours
- ☐ Every 2 hours
- ☐ Hourly

E. Is there a delay before you can start to urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

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Urinary Continence: Symptoms

F. Do you have to strain to urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

G. Do you stop and start more than once while you urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

H. Does urine leak before you can get to the toilet?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

I. How often do you leak urine?

- ☐ Never
- ☐ Once or less a week
- ☐ 2-3 times a week
- ☐ Once per day
- ☐ Several times a day

J. Does urine leak when you are physically active, exert yourself, cough, or sneeze?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

K. Do you ever leak for no obvious reason and without feeling that you want to go?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

L. Do you leak urine when you are asleep?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

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Urinary Continence: Symptoms

M. To what extent do you feel that your sex life has been spoiled by your urinary symptoms?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

N. Do you leak urine when you have sexual intercourse?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

O. Do you need to change your outer clothing during the day because of urine leakage?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

P. Do you cut down on the amount of fluid you drink so that your urinary symptoms improve, and you can do the things that you want to do?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

Q. To what extent have your urinary symptoms affected your ability to perform daily tasks (eg, cleaning, DIY, lifting objects)?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

R. Do you avoid places and situations where you know a toilet is not nearby (eg, shopping, traveling, theater, church)?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

S. Overall, how much do your urinary symptoms interfere with your life?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

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Urinary Continence: Diagnosis

Question 23.2.

This is the 'Questionnaire for Urinary Incontinence Diagnosis' (QUID). This questionnaire assists in finding out more about the type of urinary incontinence women experience. Please put a cross in ONE box for each question

Question	None of the time	Rarely	Once in a while	Often	Most of the time	All of the time
Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments….						
A. When you cough or sneeze?	☐	☐	☐	☐	☐	☐
B. When you bend down or lift something up?	☐	☐	☐	☐	☐	☐
C. When you walk quickly, jog, or exercise?	☐	☐	☐	☐	☐	☐
D. While you are undressing to use the toilet?	☐	☐	☐	☐	☐	☐
E. Do you get such a strong and uncomfortable need to urinate that you leak urine (even small drops) or wet yourself before reaching the toilet?	☐	☐	☐	☐	☐	☐
F. Do you have to rush to the bathroom because you get a sudden, strong need to urinate?	☐	☐	☐	☐	☐	☐

A Study of Women's Health

Reproductive Health

We are interested in knowing about your reproductive health. We understand that some of the questions may touch on areas that you may find quite sensitive, however all the information that you provide is kept completely confidential.

Many of the questions may not apply to you. If this is the case, please mark the 'No' answer.

PREGNANCY

24 A. Are you currently pregnant? ☐ Yes (Go to Q24B)
☐ No (Go to Q25A)

B. If yes, how many weeks pregnant are you? ☐☐

CHILDBIRTH

25 A. Have you previously given birth? ☐ Yes (Go to Q25B)
☐ No (Go to Q26)

B. Please complete the table below indicating the year you gave birth and type of delivery.

Child	Year of Birth (eg 2000)	Type of Delivery	
		Vaginal	Caesarian section
First	☐☐☐☐	☐	☐
Second	☐☐☐☐	☐	☐
Third	☐☐☐☐	☐	☐
Fouth	☐☐☐☐	☐	☐
Fifth	☐☐☐☐	☐	☐
Sixth	☐☐☐☐	☐	☐
Seventh	☐☐☐☐	☐	☐

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Menopause Status

The following series of statements are to help us establish whether you have become menopausal.

PART 1

It is important that you respond to each statement even if you feel that it does not apply to you.

26. I am aged 60 years or over ☐ Yes ☐ No

27. I have had BOTH of my ovaries removed surgically ☐ Yes ☐ No

28. I have had a hysterectomy ☐ Yes ☐ No

29. I am using either hormonal contraception or hormone replacement therapy (HRT) ☐ Yes ☐ No

30. I have had a tubal ligation ('tubes' tied) ☐ Yes ☐ No

A Study of Women's Health

Menopause Status

Question 31: PART 2

Please read the 5 separate sections (sections A, B, C, D and E) below and complete the ONE section that best describes you. Place a cross in **ONE** box only.

Section A
I have NOT had a hysterectomy and I am NOT using hormonal contraception or hormone replacement therapy (HRT)

Place a cross in ONLY one box in the following table

(i) I am still having regular periods	☐
(ii) My periods stopped at least 12 months ago. I have had some hot flushes or night sweats	☐
(iii) My periods have become irregular or have stopped but my last period was within the last 12 months. I may have also had some hot flushes or night sweats	☐

Section B
I have NOT had a hysterectomy and I AM TAKING hormonal contraception ☐

Section C
I have NOT had a hysterectomy and I AM USING hormone replacement therapy for menopausal symptoms ☐

Section D
I HAVE HAD a hysterectomy and I AM USING hormone replacement therapy (HRT) for menopausal symptoms ☐

Section E
I HAVE HAD a hysterectomy and I am NOT using hormonal contraception or hormone replacement therapy (HRT) and

Place a cross in ONLY one box in the following table

(i) I have not had any hot flushes or night sweats and believe I have not become menopausal	☐
(ii) I have had hot flushes/night sweats starting more than a year ago and believe that I have passed through menopause. My symptoms may have already stopped.	☐
(iii) I have had some hot flushes/night sweats but only within the last 12 months	☐

A Study of Women's Health

Menopausal Symptoms

The following questions are related to the assessment of menopausal symptoms that you may (or may not) be experiencing now. Please complete these questions whether you think you are menopausal or not.

These questions are from the Menopause-Specific Quality of Life ('MENQOL') questionnaire (permission to use this questionnaire was obtained).

There are no 'right' or 'wrong' answers. Please take the time to complete all of the questions in this section of the questionnaire, if you can.

32. For each of the following items, please indicate whether or not you have experienced the problem in the LAST MONTH.

- If you **have NOT** experienced the problem, mark the '**No**' box and **go to the next item.**
- If you **have** experienced the problem, mark the '**Yes**' box and **then mark the box that indicates how bothered you were by the problem.**
- Please note: 0 indicates you were 'not at all bothered' by the problem,
  6 indicates that you were 'extremely bothered' by the problem.
- Please then go to the next item.

If for any reason you do not wish to complete any item, please leave it and go onto the next one.

Please complete the table below.

	Have you experienced the problem in the last month?	***If you have had the problem during the last month, how bothered were you?*** Not at all bothered 0 1 2 3 4 5 6 Extremely bothered
A. Hot Flushes	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
B. Night Sweats	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
C. Sweating	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
D. Being dissatisfied with my personal life	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

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Menopausal Symptoms

	Have you experienced the problem in the last month?	***If you have had the problem during the last month, how bothered were you?*** (Not at all bothered 0 1 2 3 4 5 6 Extremely bothered)
E. Feeling anxious or nervous	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
F. Experiencing poor memory	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
G. Accomplishing less than I used to	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
H. Feeling depressed, down or blue	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
I. Being impatient with other people	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
J. Feelings of wanting to be alone	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
K. Flatulence (wind) or gas pain	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
L. Aching in muscles and joints	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
M. Feeling tired or worn out	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
N. Difficulty sleeping	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
O. Aches in back of neck or head	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
P. Decrease in physical strength	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
Q. Decrease in stamina	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

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Menopausal Symptoms

	Have you experienced the problem in the last month?	***If you have had the problem during the last month, how bothered were you?*** (Not at all bothered 0 1 2 3 4 5 6 Extremely bothered)
R. Feeling a lack of energy	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
S. Drying skin	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
T. Weight gain	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
U. Increased facial hair	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
V. Changes in appearance, texture or tone of your skin	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
W. Feeling bloated	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
X. Low backache	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
Y. Frequent urination	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
Z. Involuntary urination when laughing or coughing	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
AA. Change in your sexual desire	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
AB. Vaginal dryness during intercourse	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
AC. Avoiding intimacy	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

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Medications

CONTRACEPTION

33 A. Are you currently using any form of hormonal contraception, including hormone injections or a hormonal IUD?

☐ Yes (Go to Q33B)

☐ No (Go to Q34)

B. Please indicate the medication you are using from the following lists:

(i). Combined oestrogen and progesterone tablet:

☐ Biphasil 28
☐ Brenda 35 ED
☐ Brevinor 21 / 28
☐ Diane 35 ED
☐ Femoden ED
☐ Improvil 28 Day
☐ Juliet 35 ED
☐ Levlen ED
☐ Loette
☐ Logynon ED
☐ Marvelon 28
☐ Microgynon 20 ED
☐ Microgynon 30 ED / 21
☐ Microgynon 50 ED / 21
☐ Microlevlen ED
☐ Minulet 28
☐ Monofeme 28
☐ Nordette 21 / 28
☐ Nordette 50
☐ Nordiol 21 / 28
☐ Norimin 21 / 28
☐ Norimin-1 21 / 28
☐ Norinyl-1 21 / 28
☐ Sequilar ED
☐ Synphasic 28 Day
☐ Trifeme 28
☐ Tri-minulet 28
☐ Trioden ED
☐ Triphasil 21 / 28
☐ Triquilar 21 / Triquilar ED
☐ Yasmin
☐ Other (please specify):

(specify)

(ii). The progesterone-only pill ('mini-pill'):

☐ Locilan 28 day
☐ Microlut
☐ Micronor
☐ Microval
☐ Noriday 28
☐ Other

(specify)

(iii). Other hormonal contraceptives:

☐ Progesterone injection ('Depo Provera' or 'Depo Ralovera')
☐ 'Implanon' hormonal implant
☐ 'Mirena' hormonal uterine device
☐ Other

(specify)

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Hormone Therapy for Menopausal Symptoms

The following questions refer to hormone therapy for which a medical prescription is required.

34. Have you taken or used this form of hormone therapy? ☐ Yes (Go to Q35A)
☐ No (Go to Q36)

If you have used hormone therapy, we are interested to know what you have taken and why.

35. A. Please indicate which of the following statements best describe the reason why you have been using hormone therapy.

Mark all boxes that apply to you.

☐ For hot flushes and night sweats
☐ To prevent bone loss
☐ Because my wellbeing is better when I am taking hormone therapy
☐ Other ____ (specify)

B. Please indicate which medication(s) you are **using or have used** from the following list. You may mark more than one box.

(i) Combined oestrogen / progesterone tablet:

☐ Angelique
☐ Climen
☐ Divina
☐ Femoston
☐ Kliogest
☐ Kliovance
☐ Menoprem
☐ Menoprem continuous
☐ Premia 5
☐ Premia 2.5 continuous
☐ Premia 5 continuous
☐ Premia 10
☐ Provelle-14
☐ Provelle-28
☐ Trisequens
☐ Trisequens forte
☐ Other ____ (specify)

(ii) Oestrogen tablet

☐ Estrofem
☐ Genoral
☐ Ogen
☐ Ovestin
☐ Premarin
☐ Progynova
☐ Zumenon
☐ Other ____ (specify)

PLEASE NOTE: MORE OPTIONS ARE DETAILED ON THE NEXT PAGE

A Study of Women's Health

Hormone Therapy for Menopausal Symptoms

(iii) Oestrogen / progesterone patch

- ☐ Climara
- ☐ Dermestril
- ☐ Estalis continuous
- ☐ Estalis sequi
- ☐ Other _____ (specify)
- ☐ Estraderm / Estraderm MX
- ☐ Estracombi
- ☐ Femtran
- ☐ Menorest

(iv) Oestrogen implant ☐

_____ dose of implant

_____ Frequency of Implant

(v) Oestrogen gel ('Sandrena') ☐

(vi) Oestrogen trocheor lozenge ('Triest') ☐

(vii) Oestrogen nasal spray ('Aerodiol' or 'Octdiol') ☐

(viii) Vaginal oestrogen:

- ☐ Ovestin cream
- ☐ Ovestin ovula pessaries
- ☐ Premarin cream
- ☐ Vagifem

(ix) Livial ('Tibilone') ☐

(x) Progesterone cream ☐

A Study of Women's Health

Hormone Therapy for Menopausal Symptoms

(xi) Progesterone tablet:

- ☐ Duphaston
- ☐ Primolut-N
- ☐ Provera
- ☐ Ralovera
- ☐ Androcur
- ☐ Other _____ (specify)

(xii) Androgen Therapy:

- ☐ Andriol tablets
- ☐ DHEA tablets
- ☐ Testosterone cream
- ☐ Testosterone injection
- ☐ Testosterone lozenge / troche
- ☐ Testosterone implant
- ☐ Other _____ (specify)

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Natural Therapies

36. There are other types of hormone therapy which are often described as "natural" forms of hormone therapy.

- These may be recommended by a doctor, other therapists (such as naturopaths or herbalists) or by friends. They may have been purchased over the counter from a pharmacy or health food shop, or naturopaths and herbalists may have made up specific preparations for you.
- Also, some women take custom-prepared medications which a doctor has prescribed and a pharmacist has specially formulated for them.
  - *There are many reasons why pharmacists prepare special formulations of prescription medications (this process is known as compounding).*
  - *Compounded medications are prepared to address specific needs. Some patients may be allergic to preservatives or dyes typically found in standard drug preparations or are sensitive to standard drug strengths. With a doctor's prescription, a compounding pharmacist can change the strength, form or flavour of a medication so as to avoid unwanted medication-related side effects.*

A. Have you taken any "natural" forms of hormone therapy? ☐ Yes (Go to Q36B)
☐ No (Go to Q37)

We are interested to know if any of the medications you have taken as part of natural therapy include specially-formulated medications (also known as a 'compounded medications').

B. Have you taken any compounded medications? ☐ Yes ☐ No

C. Please mark any natural therapy medications that you have taken from the following list.

You may mark more than one box:

☐ American ginseng
☐ Black cohosh
☐ DHEA
☐ Dong quai
☐ Evening primrose oil
☐ False unicorn root
☐ Grape Seed extract
☐ Hops (humulus lupulus) as tablet
☐ Indole-3-carbinol
☐ Korean ginseng
☐ Licorice extract, often as tea
☐ Macca
☐ Meno-eze
☐ Phytolife
☐ Promensil
☐ Remifemin
☐ Sage
☐ Selenium
☐ Soy compounds
☐ St Mary's Thistle
☐ Tribulus
☐ Vitamin A
☐ Vitamin C
☐ Vitamin E
☐ Unknown compound
☐ Other

(specify)

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Physical Activity

We are also interested in knowing about the physical activity that you undertake.

37 A. Do you participate in any regular exercise / recreational activity? ☐ Yes ☐ No

B. If yes, please list the total duration in hours per week: ☐☐ Hours

C. In addition, please place a cross in the appropriate box(es) below which correspond to the number of sessions of exercise you would perform in an average week.

	0 sessions	1-2 sessions	3-4 sessions	5 or more sessions
Walking	☐	☐	☐	☐
Moderate intensity exercise (eg. gentle swimming, social tennis)	☐	☐	☐	☐
Vigorous intensity exercise (eg. jogging, cycling, aerobics, competitive tennis)	☐	☐	☐	☐
Vigorous intensity gardening / yardwork	☐	☐	☐	☐

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Physical Activity

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives.

The following is the International Physical Activity Questionnaire (IPAQ). The questions will ask you about the time you spent being physically active in the **last 7 days**.

Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

QUESTION 38

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

A. Do you currently have a job or do any unpaid work outside your home?

☐ Yes

☐ No → ***Skip to PART 2: TRANSPORTATION***

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

B. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

☐☐ **days per week**

☐ No Vigorous job-related physical activity → ***Skip to question D***

C. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

☐☐ **hours per day**

☐☐ **minutes per day**

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Physical Activity

D. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

☐☐ **days per week**

☐ No Moderate job-related physical ativity → ***Skip to question F***

E. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

☐☐ **hours per day**

☐☐ **minutes per day**

F. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

☐☐ **days per week**

☐ No Job-related walking → ***Skip to PART 2: TRANSPORTATION***

G. How much time did you usually spend on one of those days **walking** as part of your work?

☐☐ **hours per day**

☐☐ **minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

H. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

☐☐ **days per week**

☐ No traveling in a motor vehicle → ***Skip to question J***

I. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

☐☐ **hours per day**

☐☐ **minutes per day**

A Study of Women's Health

Physical Activity

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

J. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

☐☐ **days per week**

☐ No bicycling from place to place → ***Skip to question L***

K. How much time did you usually spend on one of those days to **bicycle** from place to place?

☐☐ **hours per day**

☐☐ **minutes per day**

L. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place?**

☐☐ **days per week**

☐ No walking from place to place → ***Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY***

M. How much time did you usually spend on one of those days **walking** from place to place?

☐☐ **hours per day**

☐☐ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

N. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

☐☐ **days per week**

☐ No vigorous activity in garden or yard → ***Skip to question P***

O. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

☐☐ **hours per day**

☐☐ **minutes per day**

A Study of Women's Health

Physical Activity

P. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

☐☐ **days per week**

☐ No moderate activity in garden or yard → ***Skip to question R***

Q. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

☐☐ **hours per day**

☐☐ **minutes per day**

R. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

☐☐ **days per week**

☐ No moderate activity inside home → ***Skip to PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY***

S. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

☐☐ **hours per day**

☐☐ **minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

T. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

☐☐ **days per week**

☐ No walking in leisure time → ***Skip to question W***

U. How much time did you usually spend on one of those days **walking** in your leisure time?

☐☐ **hours per day**

☐☐ **minutes per day**

A Study of Women's Health

Physical Activity

W. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

☐☐ **days per week**

☐ No vigorous activity in leisure time → ***Skip to question Y***

X. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

☐☐ **hours per day**

☐☐ **minutes per day**

Y. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

☐☐ **days per week**

☐ No moderate activity in leisure time → ***Skip to PART 5: TIME SPENT SITTING***

Z. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?

☐☐ **hours per day**

☐☐ **minutes per day**

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

AA. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

☐☐ **hours per day**

☐☐ **minutes per day**

AB. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

☐☐ **hours per day**

☐☐ **minutes per day**

A Study of Women's Health

Marital Status and Social History

39. What is your current marital status:

- ☐ Married
- ☐ De Facto
- ☐ Single, with a partner
- ☐ Single, with no partner
- ☐ Separated
- ☐ Divorced
- ☐ Widowed

40. What is your current occupation? (e.g. lawyer, nurse, teacher, housewife, student, volunteer, etc.)

41. If you are employed outside the home, please indicate whether you:

- ☐ Work full time
- ☐ Work part time
- ☐ Study full time
- ☐ Study part time
- ☐ Work part time and study part time
- ☐ Not applicable
- ☐ Other (specify)

A Study of Women's Health

Emotional and Psychological Wellbeing

42. We are interested in knowing about your feelings about your health, your outlook on life and changes in your emotional and psychological wellbeing. The following set of questions concern these issues.

These questions are from the Psychological General Well-being ('PGWB') Index (permission to use this index was obtained).

Listed below are a number of statements concerning how you feel and how things have been going with you during the **past month**(s).

Please read each statement carefully and indicate the answer which best applies to you by marking it with an X.

A. How have you been feeling in general during the past month?

- ☐ In excellent spirits
- ☐ In very good spirits
- ☐ In good spirits mostly
- ☐ I have been up and down in spirits a lot
- ☐ In low spirits mostly
- ☐ In very low spirits

B. How often were you bothered by any illness, bodily disorder, aches or pains during the past month?

- ☐ Every day
- ☐ Almost every day
- ☐ About half of the time
- ☐ Now and then, but less than half of the time
- ☐ Rarely
- ☐ None of the time

C. Did you feel depressed during the past month?

- ☐ Yes - to the point that I felt like taking my life
- ☐ Yes – to the point that I did not care about anything
- ☐ Yes very depressed almost every day
- ☐ Yes quite depressed several times
- ☐ Yes a little depressed now and then
- ☐ No never felt depressed at all

A Study of Women's Health

Emotional and Psychological Wellbeing

D. Have you been in firm control of your behaviour, thoughts, emotions, or feelings during the past month?

- ☐ Yes, definitely so
- ☐ Yes, for the most part
- ☐ Generally so
- ☐ Not too well
- ☐ No, and am somewhat disturbed
- ☐ No, and am very disturbed

E. Have you been bothered by nervousness or your "nerves" during the past month?

- ☐ Extremely so – to the point where I could not work or take care of things
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some – enough to bother me
- ☐ A little
- ☐ Not at all

F. How much energy, pep, or vitality did you have or feel during the past month?

- ☐ Very full of energy – lots of pep
- ☐ Fairly energetic most of the time
- ☐ My energy level varied quite a bit
- ☐ Generally low in energy or pep
- ☐ Very low in energy or pep most of the time
- ☐ No energy or pep at all – I felt drained, sapped

G. I felt downhearted and blue during the past month.

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

H. Were you generally tense or did you feel any tension during the past month?

- ☐ Yes – extremely tense, most or all of the time
- ☐ Yes – very tense most of the time
- ☐ Not generally tense, but did feel fairly tense several times
- ☐ I felt a little tense a few times
- ☐ My general tension level was quite low
- ☐ I never felt tense or any tensions at all

A Study of Women's Health

Emotional and Psychological Wellbeing

I. How happy, satisfied, or pleased have you been with your personal life during the past month?

- ☐ Extremely happy – could not have been more satisfied or pleased
- ☐ Very happy most of the time
- ☐ Generally satisfied – pleased
- ☐ Sometimes fairly happy, sometimes fairly unhappy
- ☐ Generally dissatisfied, unhappy
- ☐ Very dissatisfied or unhappy most of the time

J. Did you feel healthy enough to carry out the things you like to do or had to during the past month?

- ☐ Yes – definitely so
- ☐ For the most part
- ☐ Health problems limited me in some important ways
- ☐ I was only healthy enough to take care of myself
- ☐ I needed some help in taking care of myself
- ☐ I needed someone to help me with most or all of the things I had to do

K. Have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile during the past month?

- ☐ Extremely so – to the point I have just about given up
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some – enough to bother me
- ☐ A little bit
- ☐ Not at all

L. I woke up feeling fresh and rested during the past month

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

M. Have you been concerned, worried or had any fears about your health during the past month?

- ☐ Extremely so
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some, but not a lot
- ☐ Practically never
- ☐ Not at all

A Study of Women's Health

Emotional and Psychological Wellbeing

N. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, feel or of your memory during the past month?

- ☐ Not at all
- ☐ Only a bit
- ☐ Some – but not enough to be concerned or worried about
- ☐ Some and I have been a little concerned
- ☐ Some and I am quite concerned
- ☐ Yes, very much so and I am very concerned

O. My daily life was full of things that were interesting to me during the past month.

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

P. Did you feel active, vigorous, or dull, sluggish during the past month?

- ☐ Very active, vigorous every day
- ☐ Mostly active, vigorous – never really dull, sluggish
- ☐ Fairly active, vigorous – seldom dull, sluggish
- ☐ Fairly dull, sluggish – seldom active, vigorous
- ☐ Mostly dull, sluggish – never really active, vigorous
- ☐ Very dull, sluggish every day

Q. Have you been anxious, worried or upset during the past month?

- ☐ Extremely so – to the point of being sick or almost sick
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some – enough to bother me
- ☐ A little bit
- ☐ Not at all

R. I was emotionally stable and sure of myself during the past month.

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

A Study of Women's Health

Emotional and Psychological Wellbeing

S. Did you feel relaxed, at ease or high strung, tight or keyed-up during the past month?

- ☐ Felt relaxed and at ease the whole month
- ☐ Felt relaxed and at ease most of the time
- ☐ Generally felt relaxed but at times felt fairly high strung
- ☐ Generally felt high strung but at times felt fairly relaxed
- ☐ Felt high strung, tight, or keyed-up most of the time
- ☐ Felt high strung, tight, or keyed-up the whole time

T. I felt cheerful, light hearted during the past month

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

U. I felt tired, worn out, used up, or exhausted during the past month.

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

V. Have you been under or felt you were under any strain, stress or pressure during the past month?

- ☐ Yes almost more than I could bear or stand
- ☐ Yes quite a bit of pressure
- ☐ Yes some – more than usual
- ☐ Yes some – but about usual
- ☐ Yes a little
- ☐ Not at all

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Other Medications

Medications not listed previously:

43. Please list **any** other prescription or non-prescription medications that have **not been listed previously** which you are **currently taking**:

44. Please enter the date that you completed this questionnaire:

Day / Month / Year

Please check that you have provided an answer to all questions even if you think they don't apply to you (eg menopause status).

END OF QUESTIONNAIRE

The research team involved with this study would like to thank you for your time and effort in completing this questionnaire.

It is much appreciated.

Dr Donna Urquhart
Prof Susan Davis
A/Prof Robin Bell
Prof Flavia Cicuttini

Follow-up study questionnaire

Draft

Study ID ☐☐☐

A Study of Women's Health

Patient Self-administered Questionnaire

Please PRINT your details below.

This page will be removed from the questionnaire after coding.

Given Names: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Surname: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Address: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Street No. and Name

☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ☐☐☐ ☐☐☐☐

Suburb State Postcode

Phone: (☐☐) ☐☐☐☐ - ☐☐☐☐ (☐☐) ☐☐☐☐ - ☐☐☐☐

Home Work

☐☐☐☐ ☐☐☐ ☐☐☐

Mobile

We would appreciate it if you could provide the contact details of a relative or friend that you would be happy for us to communicate with if we cannot contact you in the future (e.g. if you unexpectedly move) Please note this is optional.

Alternative contact (optional):

Given Name: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Surname: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Relationship: ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Phone: (☐☐) ☐☐☐☐ - ☐☐☐☐ (☐☐) ☐☐☐☐ - ☐☐☐☐

Home Work

☐☐☐☐ ☐☐☐ ☐☐☐

Mobile

Office use only

Date of receipt: ☐☐ / ☐☐ / ☐☐☐☐

Day Month Year

A Study of Women's Health

Patient Self-administered Questionnaire

Thank you for taking part in this 2 year follow-up study.

This study aims to explore key issues that affect the health of adult women. It is essential for us to understand these issues if we are to improve the quality of life and wellbeing of Australian women.

The current follow-up study focuses on investigating FACTORS that lead to the onset of low back pain and incontinence. This information is essential if we are to identify women at risk of these conditions and develop effective strategies.

We would be grateful if you could find the time to complete and return this questionnaire in the enclosed reply-paid envelope. It may take you up to 40-60 minutes to complete the questionnaire.

This questionnaire is almost identical to the previous one. This will allow us to look at our previous data in conjunction with data from the current questionnaire. However, there have been a few minor changes. We have added new questions on incontinence and some questions, which initially look the same, may have been changed to ask about "the PAST 2 years" (rather than "in the past").
Please make a careful note of which time period each question is asking about.

Some of the questions may not apply to you. If this is the case, please mark the 'No' answer. Please DO NOT leave any questions unanswered/blank.

Please note that you do not have to complete the questionnaire in one sitting and all the information that you provide is kept completely confidential.

Please try to finish the questionnaire if you can.

Even though some of the questions in this questionnaire may appear to be repetitive, we would like you to answer all questions. Please don't leave any question unanswered.

If you have any queries about the study or would like some help in completing this questionnaire, please contact Women's Health Program, Monash University, on (03) 9903 0827.

Please also call this number if this questionnaire raises concerns for you.

Or perhaps you may feel more comfortable approaching your GP to discuss your feelings, as they may already know a bit about your experience.

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How to complete this form:

Please complete this form carefully using black ballpoint pen (not felt). Alternatively use blue pen.

Most questions only require you to answer by marking the appropriate box or boxes with a cross like this:

☒

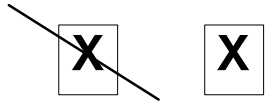
Please do not mark any areas outside the box.

Other questions will require a numeric answer and can be filled in like this:

1	2	3

If you make a mistakewhen writing, cross it out with one thick line like this: ~~1 2 3~~

If you make a mistake, place a diagonal line through the incorrect answer like this: and put a cross in the appropriate box of your preferred response.



Please do not cross the number 7 . Please make sure to write only one number in each space provided, as demonstrated in the example above.

---

1. Please enter the postcode of your home address:

Postcode

2. Please enter your date of birth:

Day / **Month** / **Year**

3. Please enter the date that you started this questionnaire:

Day / **Month** / **Year**

4. Which of the following option best describes your racial background?

- ☐ Caucasian
- ☐ Mongoloid (e.g. Chinese)
- ☐ Negroid
- ☐ Mixed / Other (specify)

A Study of Women's Health

General Health

We are interested in knowing about your general health, including medical conditions that you may have been diagnosed with in the past 2 years.

GENERAL HEALTH

1. Please enter your current weight (by rounding off to the nearest whole number and NOT using decimal points):

☐☐☐ kg OR ☐☐☐ pounds OR ☐ Don't Know

2. Please enter your current height (by rounding off to the nearest whole number and NOT using decimal points):

☐☐☐ cm OR ☐☐ feet ☐☐ inches OR ☐ Don't Know

GENERAL MEDICAL CONDITIONS

3. A. Have you been hospitalized within the past 2 years? Please note to be 'hospitalized' you must have been admitted to hospital for greater than 24 hours. Presentations to the emergency department for less than 24 hours are not included.

Yes ☐ (go to Q3, Part B)

No ☐ (go to Q4)

B. Please specify the exact reason(s) for your hospitalization:

Date (mm/yyyy) (e.g.05/2007)	REASON
☐☐/☐☐☐☐	
☐☐/☐☐☐☐	
☐☐/☐☐☐☐	
☐☐/☐☐☐☐	
☐☐/☐☐☐☐	

4. Have you been diagnosed with any of the following conditions in the past 2 years?

A. Cancer (current or previous) ☐ Yes ☐ No

If yes, please indicate the type of cancer (e.g. breast cancer, ovarian cancer)

☐ (specify)

A Study of Women's Health

General Health

B. Stroke (includes transient ischaemic attack (TIA), mini stroke)

☐ Yes
☐ No

C. Diabetes

☐ Yes
☐ No

If yes, please indicate whether it is controlled by:

☐ Diet ☐ Tablets ☐ Insulin

☐ Other _____
(specify)

D. Neurological (nervous system) condition

☐ Yes
☐ No

If yes, please specify:

☐ Multiple Sclerosis
☐ Motor Neurone Disease
☐ Parkinson's Disease
☐ Other _____
(specify)

E. Respiratory condition

☐ Yes
☐ No

If yes, please specify:

☐ Asthma ☐ Bronchitis ☐ Emphysema
☐ Other _____
(specify)

F. Trauma to spine and/or pelvis

This <u>includes</u> fractures sustained after a motor car accident, serious fall or other accident.

☐ Yes
☐ No

If yes, please specify:

☐ Neck
☐ Middle Back
☐ Lower Back
☐ Pelvis
☐ Other _____
(specify)

G. Rheumatic condition

☐ Yes
☐ No

If yes, please specify:

☐ Rheumatoid arthritis
☐ Ankylosing spondylitis
☐ Gout
☐ Osteoarthritis - Location(s) (e.g. hands):
_____
(please indicate where)
☐ Other (please specify) _____

A Study of Women's Health

General Health

H. Kidney Disease
- ☐ Yes
- ☐ No

I. Osteoporosis
- ☐ Yes
- ☐ No

If yes, was this diagnosed with a bone density test (DEXA)?
- ☐ Yes
- ☐ No

J. Fracture after 'minimal trauma'
- ☐ Yes
- ☐ No

By 'minimal trauma' we mean a very mild accident or no accident at all. For example, some women have fractured a rib after a coughing spasm, or a wrist after a very mild fall. This <u>does not include</u> fractures sustained after a motor car accident, serious fall or other accident.

If yes, please specify:
- ☐ Spine
- ☐ Pelvis
- ☐ Arm
- ☐ Leg
- ☐ Other _____ (specify)

K. Mental illness
- ☐ Yes
- ☐ No

If yes, please specify:
- ☐ Depression ☐ Bipolar Disorder ☐ Schizophrenia
- ☐ Other _____ (specify)

L. Urinary tract infection in the past 2 years
- ☐ Yes
- ☐ No

M. Chronic cough
- ☐ Yes
- ☐ No

N. Physical impairment that affects mobility
- ☐ Yes
- ☐ No

SMOKING

5. A. Do you smoke?
- ☐ Yes (Go to Q 5B)
- ☐ No (Go to Q 6)

A Study of Women's Health

General Health

B. If you smoke, how many cigarettes do you smoke each day:

- ☐ More than 40
- ☐ 21 - 39
- ☐ 10-20
- ☐ 9 or less

ALCOHOL

6. A. Do you drink alcohol? ☐ Yes (Go to Q 6B)

☐ No (Go to Q 7)

If you drink alcohol, please answer the following 3 questions:

B. Which of the following best describes how often you would have an alcoholic drink:

- ☐ Every day
- ☐ 1 - 2 days a week
- ☐ 5 - 6 days a week
- ☐ 2 - 3 days a month
- ☐ 3 - 4 days a week
- ☐ Less often

The following are all equal to approximately one standard drink:

Low alcohol beer (3.5%)	1 can or 1.5 'pots'; (volume 375mls)
Regular beer (4.9%)	1 'pot' or ¾ 'stubby'; (volume 285mls)
Wine (12%)	one small glass; (volume 100mls)
Spirits / liqueurs	one shot/nip; (volume 30mls)
Mixed drinks	1 glass; (volume 30mls of spirits + mixer)
Alcoholic soda (5.5%)	¾ of a 330ml bottle; (volume 250mls)

C. On a day that you would have an alcoholic drink, how many standard drinks would you usually have:

- ☐ 13 or more standard drinks
- ☐ 11 - 12 standard drinks
- ☐ 7 - 10 standard drinks
- ☐ 5 - 6 standard drinks
- ☐ 3 - 4 standard drinks
- ☐ 1 - 2 standard drinks

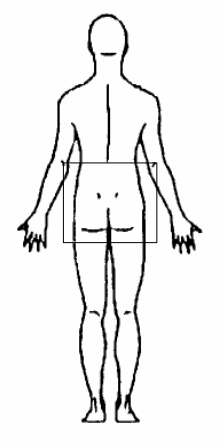
D. How often would you have had more than **4 standard drinks** in a day:

- ☐ Every day
- ☐ 4 - 6 days a week
- ☐ 2 - 3 days a week
- ☐ About 1 day a week
- ☐ 2 - 3 days a month
- ☐ About 1 day a month
- ☐ Less often
- ☐ Never

A Study of Women's Health

Low Back Pain

We are interested in learning about the health of your lower back/spine.



We have defined low back pain as discomfort or pain occurring in the boxed area shown on the body diagram below.
Please refer to this when answering each of the following questions.

Please put a cross in one box for each question ☒

---

7. Have you ever experienced low back pain? ☐ Yes ☐ No

8. Have you had back pain (please complete each of the following (a to g)):

	Yes	No
a) in the past 24 hours?	☐	☐
b) in the past 2 weeks?	☐	☐
c) in the past month?	☐	☐
d) in the past 6 months?	☐	☐
e) in the past 12 months?	☐	☐
f) in the past 2 years?	☐	☐
g) during your lifetime?	☐	☐

9. Do you have low back pain now? ☐ Yes ☐ No

10. Did your first attack occur in the past 2 years? ☐ Yes ☐ No

11. How often do you experience low back pain? ☐ Daily ☐ Monthly ☐ Weekly ☐ Yearly ☐ Other _____ (specify)

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Low Back Pain: Pain Intensity

We are interested to know more about the intensity of your back pain.

The following questionnaire is the Chronic Back Pain Grade Questionnaire which assesses pain intensity.

For the following questions with a scale of 0-10, please place a cross in **ONE** box only

Please complete this questionnaire even if you do NOT experience back pain.

Question 12.

A. How would you rate your back pain on a 0-10 scale at the present time, that is right now, where 0 is 'no pain' and 10 is 'pain as bad as could be'?

No Pain — Pain as bad as could be

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

B. In the past 6 months, how intense was your worst pain rated on a 0-10 scale where 0 is 'no pain' and 10 is 'pain as bad as could be'?

No Pain — Pain as bad as could be

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

C. In the past 6 months, on the average, how intense was your pain rated on a 0-10 scale where 0 is 'no pain' and 10 is 'pain as bad as could be'? (That is, your usual pain at times you were experiencing pain.)

No Pain. — Pain as bad as could be

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

D. About how many days in the last 6 months have you been kept from your usual activities (work, school or housework) because of back pain?

☐☐☐ Disability Days

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Low Back Pain: Pain Intensity

E. In the past 6 months, how much has back pain interfered with your daily activities rated on a 0-10 scale where 0 is 'no interference' and 10 is 'unable to carry on any activities'?

Interference — Unable to carry on any activities

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

F. In the past 6 months, how much has back pain changed your ability to take part in recreational, social and family activities where 0 is 'no change' and 10 is 'extreme change'?

No Change — Extreme change

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

G. In the past 6 months, how much has back pain changed your ability to work (including housework) where 0 is 'no change' and 10 is 'extreme change'?

No Change — Extreme change

☐	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
0	1	2	3	4	5	6	7	8	9	10

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Low Back Pain: Disability

Question 13:

This is the Oswestry Modified Disability Questionnaire. Please complete this questionnaire (even if you do NOT experience back pain). It is designed to give us information as to how your back (or leg) trouble has affected your ability to manage in everyday life. Please answer **every section**. Mark **one box only** in each section that most closely describes you **today**.

Section 1: Pain Intensity

- ☐ I have no pain at the moment
- ☐ The pain is very mild at the moment
- ☐ The pain is moderate at the moment
- ☐ The pain is fairly severe at the moment
- ☐ The pain is very severe at the moment
- ☐ The pain is the worst imaginable at the moment

Section 2: Personal Care (Washing, Dressing, etc.)

- ☐ I can look after myself normally without causing extra pain
- ☐ I can look after myself normally but it causes extra pain
- ☐ It is painful to look after myself and I am slow and careful
- ☐ I need some help but can manage most of my personal care
- ☐ I need help every day in most aspects of self care
- ☐ I do not get dressed, wash with difficulty and stay in bed

Section 3: Lifting

- ☐ I can lift heavy weights without extra pain
- ☐ I can lift heavy weights but it gives me extra pain
- ☐ Pain prevents me lifting heavy weights off the floor but I can manage if they are conveniently placed e.g. on a table
- ☐ Pain prevents me lifting heavy weights but I can manage light to medium weights if they are conveniently positioned
- ☐ I can only lift very light weights
- ☐ I cannot lift or carry anything

A Study of Women's Health

Low Back Pain: Disability

Section 4: Walking

- ☐ Pain does not prevent me walking any distance
- ☐ Pain prevents me from walking more than 2 kilometres
- ☐ Pain prevents me from walking more than 1 kilometre
- ☐ Pain prevents me from walking more than 500 metres
- ☐ I can only walk using a stick or crutches
- ☐ I am in bed most of the time

Section 5: Sitting

- ☐ I can sit in any chair as long as I like
- ☐ I can only sit in my favourite chair as long as I like
- ☐ Pain prevents me sitting more than one hour
- ☐ Pain prevents me from sitting more than 30 minutes
- ☐ Pain prevents me from sitting more than 10 minutes
- ☐ Pain prevents me from sitting at all

Section 6: Standing

- ☐ I can stand as long as I want without extra pain
- ☐ I can stand as long as I want but it gives me extra pain
- ☐ Pain prevents me from standing for more than 1 hour
- ☐ Pain prevents me from standing for more than 30 minutes
- ☐ Pain prevents me from standing for more than 10 minutes
- ☐ Pain prevents me from standing at all

Section 7: Sleeping

- ☐ My sleep is never disturbed by pain
- ☐ My sleep is occasionally disturbed by pain
- ☐ Because of pain I have less than 6 hours sleep
- ☐ Because of pain I have less than 4 hours sleep
- ☐ Because of pain I have less than 2 hours sleep
- ☐ Pain prevents me from sleeping at all

A Study of Women's Health

Low Back Pain: Disability

Section 8: Sex Life (if applicable)

- ☐ My sex life is normal and causes no extra pain
- ☐ My sex life is normal but causes some extra pain
- ☐ My sex life is nearly normal but is very painful
- ☐ My sex life is severely restricted by pain
- ☐ My sex life is nearly absent because of pain
- ☐ Pain prevents any sex life at all

Section 9: Social Life

- ☐ My social life is normal and gives me no extra pain
- ☐ My social life is normal but increases the degree of pain
- ☐ Pain has no significant effect on my social life apart from limiting my more energetic interests e.g. sport
- ☐ Pain has restricted my social life and I do not go out as often
- ☐ Pain has restricted my social life to my home
- ☐ I have no social life because of pain

Section 10: Travelling

- ☐ I can travel anywhere without pain
- ☐ I can travel anywhere but it gives me extra pain
- ☐ Pain is bad but I manage journeys over two hours
- ☐ Pain restricts me to journeys of less than one hour
- ☐ Pain restricts me to short necessary journeys under 30 minutes
- ☐ Pain prevents me from travelling except to receive treatment

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Low Back Pain: Beliefs

Question 14:

This is the Back Beliefs Questionnaire. We are interested in finding out what people think about back trouble. Please indicate your general view towards back trouble, even if you have never had any. Please read each of the following statements and indicate whether you agree or disagree with each statement on a scale of 1 to 5, where 1 is completely disagree and 5 is completely agree.

	Completely disagree				Completely agree
A. There is no real treatment for back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
B. Back trouble will eventually stop you from working	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
C. Back trouble means periods of pain for the rest of one's life	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
D. Doctors cannot do anything for back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
E. A bad back should be exercised	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
F. Back trouble makes everything in life worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
G. Surgery is the most effective way to treat back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
H. Back trouble may mean you end up in a wheelchair	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
I. Alternative treatments are the answer to back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
J. Back trouble means long periods of time off from work	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
K. Medication is the only way of relieving back trouble	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
L. Once you have had back trouble there is always a weakness	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
M. Back trouble must be rested	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
N. Later in life back trouble gets progressively worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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Low Back Pain: Treatment

We are interested to know about treatment(s) you may have had for your back pain (or may still be undergoing) in the past 2 years.

15 A. Have you required treatment for your back pain in the past 2 years?

- ☐ Yes (Go to Q 15B)
- ☐ No (Go to Q 16A)

B. We are interested to know who you have seen regarding your back pain in the past 2 years. Mark all boxes that apply to you:

- ☐ Acupuncturist
- ☐ Chiropractor
- ☐ General Practitioner
- ☐ Massage Therapist
- ☐ Osteopath
- ☐ Physiotherapist
- ☐ Sports Medicine Physician
- ☐ Surgeon/ Consultant
- ☐ Other (specify)

16 A. Have you been hospitalized because of your back pain in the past 2 years?

- ☐ Yes
- ☐ No

17. Have you required surgery for your back pain in the past 2 years?

- ☐ Yes
- ☐ No

COMPLEMENTARY THERAPIES

Many people consult therapists for complementary (or alternative) therapies for various reasons. Alternative therapies are used to complement, or add to, mainstream treatments.

18. Have you consulted a therapist for alternative treatment(s) for any reason in the past 2 years?

- ☐ Yes
- ☐ No

19. Have you consulted a therapist for alternative treatment(s) especially for back pain in the past 2 years?

- ☐ Yes
- ☐ No

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Low Back Pain: Treatment

20. Please indicate, from the following list, which therapists you have consulted in the past 2 years.
Mark all the boxes that apply to you:

	For my back	For OTHER reasons
Aromatherapy	○	○
Ayurveda Therapist	○	○
Chinese medicine practioner	○	○
Iridologist	○	○
Herbalist	○	○
Homeopath	○	○
Hypnotherapist	○	○
Kinesiologist	○	○
Naturopath	○	○
Spiritual	○	○
Other (please specify)	○	○

---

21. **A.** Please indicate if you are **currently taking** any of the following **anti-inflammatory** medications, for your back pain.

Mark all the boxes that apply to you:

Current use (at least 3 days per week)**:**

- ☐ Aspirin
- ☐ Arthrotec 50
- ☐ Brufen
- ☐ Celebrex
- ☐ Clinoril
- ☐ Cortisone acetate
- ☐ Feldene
- ☐ Indocid
- ☐ Mobic
- ☐ Naprosyn
- ☐ Nurofen
- ☐ Orudis
- ☐ Prednislone
- ☐ Surgam
- ☐ Voltaren
- ☐ Other _____ (specify)

B. Please indicate if you are **currently taking** any of the following **pain-killers (analgesics)** medications, for your back pain.

Mark all the boxes that apply to you:

Current use (at least 3 days per week)**:**

- ☐ Panadol
- ☐ Febridol
- ☐ Herron
- ☐ Panadeine Forte
- ☐ Mersyndol
- ☐ Digesic
- ☐ Panadol Osteo
- ☐ Panamax
- ☐ Panadeine
- ☐ Other _____ (specify)

A Study of Women's Health

Financial and Social Issues

Please complete the following table, which was adapted (with permission) from the Lance Armstrong Foundation 'LIVESTRONG' Poll.

22. Have you had to deal with any of the following issues as a result of your back pain?
If Yes, please rate how difficult a problem this has been for you to deal with (by marking one box) according to the following scale:

Not at all bothered — 0 1 2 3 4 5 6 7 8 9 10 — Extremely bothered

	If you have had this problem during the last 12 months, how bothered were you? 0 1 2 3 4 5 6 7 8 9 10	Did not have to deal with issue	Does not apply to my situation
A. Problems in your relationship with your spouse or significant other	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
B. Lack of advancement, demotion or loss of job	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
C. Divorce, separation or break-up with a significant other	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
D. Made a change in your career direction or switched careers	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
E. Decreased income	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
F. Problems in relationships with friends and family	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
G. Emotional distance growing between you and significant people in your life	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
H. Problems with health insurance coverage	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
I. Problems with travel insurance coverage	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐
J. Needing to rely on others for help with everyday tasks	☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐ ☐	☐	☐

A Study of Women's Health

Urinary Continence: Symptoms

Question 23

This is the Bristol Female Lower Urinary Tract Symptoms Questionnaire. We would like to find out about your urinary symptoms and we are very grateful that you can help us by filling in this questionnaire. Please answer each question, thinking about the symptoms you have experienced in the last month. You will see that some questions ask how often you have a symptom:

Occasionally = less than one third of the time
Sometimes = between one and two thirds of the time
Most of the time = more than two thirds of the time

Please put a cross in ONE box for each question ☒

A. During the night, how many times do you have to get up to urinate, on average?

- ☐ None
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4 or more

B. Do you have to rush to the toilet to urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

C. Do you have pain in your bladder?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

D. How often do you pass urine during the day?

- ☐ Every 4 hours or more
- ☐ Every 3 hours
- ☐ Every 2 hours
- ☐ Hourly

E. Is there a delay before you can start to urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

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Urinary Continence: Symptoms

F. Do you have to strain to urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

G. Do you stop and start more than once while you urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

H. Does urine leak before you can get to the toilet?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

I. How often do you leak urine?

- ☐ Never
- ☐ Once or less a week
- ☐ 2-3 times a week
- ☐ Once per day
- ☐ Several times a day

J. Does urine leak when you are physically active, exert yourself, cough, or sneeze?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

K. Do you ever leak for no obvious reason and without feeling that you want to go?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

L. Do you leak urine when you are asleep?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

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Urinary Continence: Symptoms

M. To what extent do you feel that your sex life has been spoiled by your urinary symptoms?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

N. Do you leak urine when you have sexual intercourse?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

O. Do you need to change your outer clothing during the day because of urine leakage?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

P. Do you cut down on the amount of fluid you drink so that your urinary symptoms improve, and you can do the things that you want to do?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

Q. To what extent have your urinary symptoms affected your ability to perform daily tasks (eg, cleaning, DIY, lifting objects)?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

R. Do you avoid places and situations where you know a toilet is not nearby (eg, shopping, traveling, theater, church)?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

S. Overall, how much do your urinary symptoms interfere with your life?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

A Study of Women's Health

Urinary Continence: Diagnosis

Question 24

We are interested in knowing about your urinary incontinence. We understand that some of the questions may touch on areas that you may find quite sensitive, however all the information that you provide is kept completely confidential.Many of the questions may not apply to you. If this is the case, please mark the 'No' answer.

This is the 'Questionnaire for Urinary Incontinence Diagnosis' (QUID). This questionnaire assists in finding out more about the type of urinary incontinence women experience. Please put a cross in ONE box for each question

Question	None of the time	Rarely	Once in a while	Often	Most of the time	All of the time
Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments….						
A. When you cough or sneeze?	☐	☐	☐	☐	☐	☐
B. When you bend down or lift something up?	☐	☐	☐	☐	☐	☐
C. When you walk quickly, jog, or exercise?	☐	☐	☐	☐	☐	☐
D. While you are undressing to use the toilet?	☐	☐	☐	☐	☐	☐
E. Do you get such a strong and uncomfortable need to urinate that you leak urine (even small drops) or wet yourself before reaching the toilet?	☐	☐	☐	☐	☐	☐
F. Do you have to rush to the bathroom because you get a sudden, strong need to urinate?	☐	☐	☐	☐	☐	☐

25. If you reported urinary incontinence 2 years ago or you currently have this problem, how long have you experienced this problem for?

(Best estimate): ☐☐ year(s) ☐☐ month(s)

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26. If you had/have incontinence, have you used specific measures or treatment to control or cure this problem?

☐ Yes (Go to Q28)
☐ No (Go to Q30)

---

27. If yes what type of treatment/measures have you received? (Check as many boxes as appropriate)

A):Medical (with medications) ☐ Yes ☐ No

B):Surgical ☐ Yes ☐ No

If yes, please indicate the name of the surgery (if possible) and year of surgery (best estimate).

Type/Name of surgery ☐ Year ☐☐☐☐

C):Physiotherapy (pelvic floor exercise, bladder training)

☐ Yes
☐ No

Duration of physiotherapy ☐☐ day(s) ☐☐ month(s)

D):Complementary treatments (e.g. herbal medicine, traditional Chinese medicine, homeopathy).

☐ Yes → (If yes please specify) ☐
☐ No

E):Other measures (e.g. pad use, acupuncture, electrical stimulation).

☐ Yes → (If yes please specify) ☐
☐ No

---

28. How was your incontinence after treatment?

☐ Better
☐ Same
☐ Worse
☐ Unsure

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The following question is related to the assessment of transient/intermittent urinary incontinence in the last 2 years.

29. If you did not report urinary incontinence 2 years ago and you do not currently have this problem, have you leaked/lost urine involuntarily at some time within the last 2 years?

☐ Yes
☐ No

We are interested in understanding **bowel problems and pelvic floor disorders** that are experienced by women. Please answer these questions even if you have not experienced these problems in the past.

Please place a cross in one box for each question.

30. In the last 3 months have you usually emptied your bowels (passed stools) less often than 3 times per week (chronic constipation)?

☐ Yes
☐ No

Question 31.
This is the **Pelvic Floor Distress Inventory (PFDI)** Questionnaire.
Please answer these questions by putting an **X** in the appropriate box. If you are unsure about how to answer a question, give the best answer you can. While answering these questions, please consider your symptoms over the **last 3 months.**

A. Do you usually experience pressure in the lower abdomen?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

B. Do you usually experience heaviness or dullness in the pelvic area?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

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C. Do you usually have a bulge or something falling out that you can see or feel in the vaginal area?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

D. Do you ever have to push on the vaginal area or around the rectum to have or complete a bowel movement?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

E. Do you usually experience a feeling of incomplete bladder emptying?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

F. Do you ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

G. Do you feel you need to strain too hard to have a bowel movement?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

H. Do you feel you have not completely emptied your bowels at the end of a bowel movement?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

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I. Do you usually lose stool beyond your control if your stool is well formed?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

J. Do you usually lose stool beyond your control if your stool is loose?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

K. Do you usually lose gas from the rectum beyond your control?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

L. Do you usually have pain when you pass your stool?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

M. Do you usually feel strong urgency and have to rush to the bathroom to have a bowel movement?

☐ Yes
☐ No

If other than never, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

N.Does a part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

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O. Do you usually experience frequent urination?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

P. Do you usually experience urine leakage associated with a feeling of urgency that is a strong sensation of needing to go to the bathroom?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

Q. Do you usually experience urine leakage related to coughing, sneezing or laughing?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

R. Do you usually experience small amounts of urine leakage (that is, drops)?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

S. Do you usually experience difficulty emptying your bladder?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

T. Do you usually experience pain or discomfort in the lower abdomen or genital area?

☐ Yes
☐ No

If yes, how much does this bother you?

☐ not at all ☐ sometimes ☐ moderately ☐ quite a bit

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Reproductive Health

We are interested in knowing about your reproductive health. We understand that some of the questions may touch on areas that you may find quite sensitive, however all the information that you provide is kept completely confidential.

Many of the questions may not apply to you. If this is the case, please mark the 'No' answer.

PREGNANCY

32 A. Are you currently pregnant? ☐ Yes
☐ No

B. If yes, how many weeks pregnant are you? ☐☐ weeks

CHILDBIRTH

33 A. Have you given birth in the past 2 years? ☐ Yes
☐ No

B. Please complete the table below indicating the year you gave birth and type of delivery and type of anesthesia (loss of sensations) used. Mark all the boxes that apply to you.

Year of birth (e.g. 2000)	Type of Delivery	Type of Anesthesia (if used)
First ☐☐☐☐	☐ Spontaneous vaginal/normal ☐ Caesarian section ☐ Forceps ☐ Vacuum	☐ General anesthesia ☐ Spinal ☐ Epidural ☐ No anesthesia/pain killers only
Second ☐☐☐☐	☐ Spontaneous vaginal/normal ☐ Caesarian section ☐ Forceps ☐ Vacuum	☐ General anesthesia ☐ Spinal ☐ Epidural ☐ No anesthesia/pain killers only
Third ☐☐☐☐	☐ Spontaneous vaginal/normal ☐ Caesarian section ☐ Forceps ☐ Vacuum	☐ General anesthesia ☐ Spinal ☐ Epidural ☐ No anesthesia/pain killers only

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Year of birth (e.g. 2000)	Type of Delivery	Type of Anesthesia (if used)
Fouth	☐ Spontaneous vaginal/normal ☐ Caesarian section ☐ Forceps ☐ Vacuum	☐ General anesthesia ☐ Spinal ☐ Epidural ☐ No anesthesia/pain killers only
Fifth	☐ Spontaneous vaginal/normal ☐ Caesarian section ☐ Forceps ☐ Vacuum	☐ General anesthesia ☐ Spinal ☐ Epidural ☐ No anesthesia/pain killers only
Sixth	☐ Spontaneous vaginal/normal ☐ Caesarian section ☐ Forceps ☐ Vacuum	☐ General anesthesia ☐ Spinal ☐ Epidural ☐ No anesthesia/pain killers only
Seventh	☐ Spontaneous vaginal/normal ☐ Caesarian section ☐ Forceps ☐ Vacuum	☐ General anesthesia ☐ Spinal ☐ Epidural ☐ No anesthesia/pain killers only

MENOPAUSE STATUS

The following series of statements are to help us establish whether you have become menopausal.

PART 1
It is important that you respond to each statement even if you feel that it does not apply to you.

34. I am aged 60 years or over ☐ Yes ☐ No

35. I have had BOTH of my ovaries removed surgically ☐ Yes ☐ No

36. A I have had a hysterectomy ☐ Yes (Go to Q36B) ☐ No (Go to Q37)

B If yes, was the surgery (hysterectomy) done through the abdominal or vaginal route?

☐ Abdominal ☐ Vaginal

37. I am using either hormonal contraception or hormone replacement therapy (HRT) ☐ Yes ☐ No

38. I have had a tubal ligation ('tubes' tied) ☐ Yes ☐ No

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Menopause Status

Question 39: PART 2

Please read the 5 separate sections (sections A, B, C, D and E) below and **complete the ONE section** that best describes you. Place a cross in **ONE** box only.

Section A
I have NOT had a hysterectomy and I am NOT using hormonal contraception or hormone replacement therapy (HRT)

Place a cross in ONLY one box in the following table

(i) I am still having regular periods	☐
(ii) My periods stopped at least 12 months ago. I have had some hot flushes or night sweats	☐
(iii) My periods have become irregular or have stopped but my last period was within the last 12 months. I may have also had some hot flushes or night sweats	☐

Section B
I have NOT had a hysterectomy and I AM TAKING hormonal contraception ☐

Section C
I have NOT had a hysterectomy and I AM USING hormone replacement therapy for menopausal symptoms ☐

Section D
I HAVE HAD a hysterectomy and I AM USING hormone replacement therapy (HRT) for menopausal symptoms ☐

Section E
I HAVE HAD a hysterectomy and I am NOT using hormonal contraception or hormone replacement therapy (HRT) and

Place a cross in ONLY one box in the following table

(i) I have not had any hot flushes or night sweats and believe I have not become menopausal	☐
(ii) I have had hot flushes/night sweats starting more than a year ago and believe that I have passed through menopause. My symptoms may have already stopped.	☐
(iii) I have had some hot flushes/night sweats but only within the last 12 months	☐

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Menopausal Symptoms

The following questions are related to the assessment of menopausal symptoms that you may (or may not) be experiencing now. Please complete these questions whether you think you are menopausal or not.

These questions are from the Menopause-Specific Quality of Life ('MENQOL') questionnaire (permission to use this questionnaire was obtained).

There are no 'right' or 'wrong' answers. Please take the time to complete all of the questions in this section of the questionnaire, if you can.

40. For each of the following items listed, please indicate whether or not you have experienced the problem in the LAST MONTH.

- If you **have NOT** experienced the problem, mark the '**No**' box and **go to the next item.**
- If you **have** experienced the problem, mark the '**Yes**' box and **then mark the box that indicates how bothered you were by the problem.**
- Please note: 0 indicates you were 'not at all bothered' by the problem,
  6 indicates that you were 'extremely bothered' by the problem.
- Please then go to the next item.

If for any reason you do not wish to complete any item, please leave it and go onto the next one.

Please complete the table below.

	Have you experienced the problem in the last month?	***If you have had the problem during the last month, how bothered were you?*** (Not at all bothered 0 1 2 3 4 5 6 Extremely bothered)
A. Hot Flushes	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
B. Night Sweats	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
C. Sweating	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
D. Being dissatisfied with my personal life	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

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Menopausal Symptoms

	Have you experienced the problem in the last month?	***If you have had the problem during the last month, how bothered were you?*** (Not at all bothered 0 1 2 3 4 5 6 Extremely bothered)
E. Feeling anxious or nervous	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
F. Experiencing poor memory	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
G. Accomplishing less than I used to	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
H. Feeling depressed, down or blue	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
I. Being impatient with other people	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
J. Feelings of wanting to be alone	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
K. Flatulence (wind) or gas pain	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
L. Aching in muscles and joints	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
M. Feeling tired or worn out	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
N. Difficulty sleeping	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
O. Aches in back of neck or head	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
P. Decrease in physical strength	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
Q. Decrease in stamina	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

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Menopausal Symptoms

	Have you experienced the problem in the last month?	***If you have had the problem during the last month, how bothered were you?*** (Not at all bothered 0 1 2 3 4 5 6 Extremely bothered)
R. Feeling a lack of energy	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
S. Drying skin	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
T. Weight gain	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
U. Increased facial hair	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
V. Changes in appearance, texture or tone of your skin	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
W. Feeling bloated	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
X. Low backache	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
Y. Frequent urination	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
Z. Involuntary urination when laughing or coughing	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
AA. Change in your sexual desire	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
AB. Vaginal dryness during intercourse	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6
AC. Avoiding intimacy	☐ Yes ☐ No	☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

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Medications

CONTRACEPTION

41 A. Are you currently using <u>any</u> form of hormonal contraception, including hormone injections or a hormonal IUD?

☐ Yes (Go to Q41B)

☐ No (Go to Q42)

Please indicate the medication you are using from the following lists:

B. Combined oestrogen and progesterone tablet:

☐ Biphasil 28
☐ Brenda 35 ED
☐ Brevinor 21 / 28
☐ Diane 35 ED
☐ Femoden ED
☐ Improvil 28 Day
☐ Juliet 35 ED
☐ Levlen ED
☐ Loette
☐ Logynon ED
☐ Marvelon 28
☐ Estelle
☐ Microgynon 20 ED
☐ Microgynon 30 ED / 21
☐ Microgynon 50 ED / 21
☐ Microlevlen ED
☐ Minulet 28
☐ Monofeme 28
☐ Nordette 21 / 28
☐ Nordette 50
☐ Nordiol 21 / 28
☐ Norimin 21 / 28
☐ Norimin-1 21 / 28
☐ Norinyl-1 21 / 28
☐ Sequilar ED
☐ Synphasic 28 Day
☐ Trifeme 28
☐ Tri-minulet 28
☐ Trioden ED
☐ Triphasil 21 / 28
☐ Triquilar 21 / Triquilar ED
☐ Yasmin
☐ Valette
☐ Other (please specify):

(specify)

C. The progesterone-only pill ('mini-pill'):

☐ Locilan 28 day
☐ Microlut
☐ Micronor
☐ Postinor
☐ Norlevo
☐ Levonelle-2
☐ Microval
☐ Noriday 28
☐ Other

(specify)

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D. Other hormonal contraceptives:

- ☐ Progesterone injection ('Depo Provera' or 'Depo Ralovera')
- ☐ 'Implanon' hormonal implant
- ☐ 'Mirena' hormonal uterine device
- ☐ Nuva ring
- ☐ Multiload
- ☐ Other _____ (specify)

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Hormone Therapy for Menopausal Symptoms

The following questions refer to hormone therapy for which a medical prescription is required.

42. **A** Have you taken or used this form of hormone therapy in the past 2 years?

☐ Yes

☐ No

B. Are you taking hormone therapy now?

☐ Yes

☐ No

C. Have you taken hormone therapy prior to the last 2 years (before completing the last questionnaire)?

☐ Yes

☐ No

If you have used hormone therapy, we are interested to know what you have taken and why.

43. A. Please indicate which of the following statements best describe the reason why you have been using hormone therapy in the past 2 years.

Mark all boxes that apply to you.

☐ For hot flushes and night sweats

☐ To prevent bone loss

☐ Because my wellbeing is better when I am taking hormone therapy

☐ Other _____ (specify)

B. Please indicate which medication(s) you are **using or have used** from the following list. You may mark more than one box.

(i) Combined oestrogen / progesterone tablet:

☐ Angelique
☐ Climen
☐ Divina
☐ Femoston
☐ Kliogest
☐ Kliovance
☐ Menoprem
☐ Menoprem continuous
☐ Premia 5
☐ Premia 2.5 continuous
☐ Premia 5 continuous
☐ Premia 10
☐ Provelle-14
☐ Provelle-28
☐ Trisequens
☐ Trisequens forte
☐ Other _____ (specify)

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Hormone Therapy for Menopausal Symptoms

(ii) Oestrogen tablet

- ☐ Estrofem
- ☐ Genoral
- ☐ Ogen
- ☐ Ovestin
- ☐ Premarin
- ☐ Progynova
- ☐ Zumenon
- ☐ Other _____ (specify)

(iii) Oestrogen / progesterone patch

- ☐ Climara
- ☐ Dermestril
- ☐ Estalis continuous
- ☐ Estalis sequi
- ☐ Estraderm / Estraderm MX
- ☐ Estracombi
- ☐ Femtran
- ☐ Estradot
- ☐ Other _____ (specify)

(iv) Oestrogen implant ☐

_____ dose of implant

_____ Frequency of Implant

(v) Oestrogen gel ('Sandrena') ☐

(vi) Oestrogen trocheor lozenge ('Triest') ☐

(vii) Compounded estrogen cream ☐

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Hormone Therapy for Menopausal Symptoms

(viii) Vaginal oestrogen:

- ☐ Ovestin cream
- ☐ Ovestin ovula pessaries
- ☐ Premarin cream
- ☐ Vagifem

(ix) Livial ('Tibilone') ☐

Xyvion ☐

(x) Progesterone cream ☐

(xi) Progesterone tablet:

- ☐ Duphaston
- ☐ Primolut-N
- ☐ Provera
- ☐ Ralovera
- ☐ Androcur
- ☐ Other _____ (specify)

(xii) Androgen Therapy:

- ☐ Andriol tablets
- ☐ DHEA tablets
- ☐ Testosterone cream
- ☐ Testosterone injection
- ☐ Testosterone lozenge / troche
- ☐ Testosterone implant
- ☐ Other _____ (specify)

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Complementary Therapies

44. There are other types of therapy which are often described as "complementary therapy".

- These may be recommended by a doctor, other therapists (such as naturopaths or herbalists) or by friends. They may have been purchased over the counter from a pharmacy or health food shop, or naturopaths and herbalists may have made up specific preparations for you.
- Also, some women take custom-prepared medications which a doctor has prescribed and a pharmacist has specially formulated for them.
  - *There are many reasons why pharmacists prepare special formulations of prescription medications (this process is known as compounding).*
  - *Compounded medications are prepared to address specific needs. Some patients may be allergic to preservatives or dyes typically found in standard drug preparations or are sensitive to standard drug strengths. With a doctor's prescription, a compounding pharmacist can change the strength, form or flavour of a medication so as to avoid unwanted medication-related side effects.*

A. Have you taken any complementary therapy in the past 2 years?

☐ Yes

☐ No

We are interested to know if any of the medications you have taken as part of complementary therapy include specially-formulated medications (also known as a 'compounded medications').

B. Have you taken any compounded medications in the past 2 years?

☐ Yes

☐ No

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C. Please mark any complementary therapy medications that you have taken in the past 2 years from the following list.

You may mark more than one box:

- ☐ American ginseng
- ☐ Black cohosh
- ☐ Vitus Agnus Castis (Chaste Berry)
- ☐ Dong quai
- ☐ Evening primrose oil
- ☐ False unicorn root
- ☐ Grape Seed extract
- ☐ Hops (humulus lupulus) as tablet
- ☐ Indole-3-carbinol
- ☐ St. John's wort
- ☐ DHEA
- ☐ Magnesium
- ☐ Fish oil
- ☐ Korean ginseng
- ☐ Licorice extract, often as tea
- ☐ Macca
- ☐ Meno-eze
- ☐ Phytolife
- ☐ Promensil
- ☐ Remifemin
- ☐ Sage
- ☐ Selenium
- ☐ Zinc
- ☐ Glucosamine
- ☐ Chondrotin
- ☐ Other _____ (specify)
- ☐ Soy compounds
- ☐ St Mary's Thistle
- ☐ Tribulus
- ☐ Vitamin A
- ☐ Vitamin C
- ☐ Vitamin E
- ☐ Unknown compound
- ☐ Vitamin D
- ☐ Vitamin B
- ☐ Lavendula

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Physical Activity

We are also interested in knowing about the physical activity that you undertake.

45 A. Do you participate in any regular exercise / recreational activity? ☐ Yes ☐ No

B. If yes, please list the total duration in hours per week: ☐☐ Hours

C. In addition, please place a cross in the appropriate box(es) below which correspond to the number of sessions of exercise you would perform in an average week.

	0 sessions	1-2 sessions	3-4 sessions	5 or more sessions
Walking	☐	☐	☐	☐
Moderate intensity exercise (eg. gentle swimming, social tennis)	☐	☐	☐	☐
Vigorous intensity exercise (eg. jogging, cycling, aerobics, competitive tennis)	☐	☐	☐	☐
Vigorous intensity gardening / yardwork	☐	☐	☐	☐

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Physical Activity

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives.

The following is the International Physical Activity Questionnaire (IPAQ). The questions will ask you about the time you spent being physically active in the **last 7 days**.

Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

QUESTION 46

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

A. Do you currently have a job or do any unpaid work outside your home?

☐ Yes

☐ No → ***Skip to PART 2: TRANSPORTATION***

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

B. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

☐☐ **days per week**

☐ No Vigorous job-related physical activity → ***Skip to question D***

C. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

☐☐ **hours per day**

☐☐ **minutes per day**

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Physical Activity

D. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

☐☐ **days per week**

☐ No Moderate job-related physical ativity → ***Skip to question F***

E. How much time did you usually spend on one of those days doing **moderate** physical activities as part of your work?

☐☐ **hours per day**

☐☐ **minutes per day**

F. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **as part of your work**? Please do not count any walking you did to travel to or from work.

☐☐ **days per week**

☐ No Job-related walking → ***Skip to PART 2: TRANSPORTATION***

G. How much time did you usually spend on one of those days **walking** as part of your work?

☐☐ **hours per day**

☐☐ **minutes per day**

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

H. During the **last 7 days**, on how many days did you **travel in a motor vehicle** like a train, bus, car, or tram?

☐☐ **days per week**

☐ No traveling in a motor vehicle → ***Skip to question J***

I. How much time did you usually spend on one of those days **traveling** in a train, bus, car, tram, or other kind of motor vehicle?

☐☐ **hours per day**

☐☐ **minutes per day**

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Physical Activity

Now think only about the **bicycling** and **walking** you might have done to travel to and from work, to do errands, or to go from place to place.

J. During the **last 7 days**, on how many days did you **bicycle** for at least 10 minutes at a time to go **from place to place**?

☐☐ **days per week**

☐ No bicycling from place to place → ***Skip to question L***

K. How much time did you usually spend on one of those days to **bicycle** from place to place?

☐☐ **hours per day**

☐☐ **minutes per day**

L. During the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time to go **from place to place?**

☐☐ **days per week**

☐ No walking from place to place → ***Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY***

M. How much time did you usually spend on one of those days **walking** from place to place?

☐☐ **hours per day**

☐☐ **minutes per day**

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the **last 7 days** in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

N. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, chopping wood, shoveling snow, or digging **in the garden or yard**?

☐☐ **days per week**

☐ No vigorous activity in garden or yard → ***Skip to question P***

O. How much time did you usually spend on one of those days doing **vigorous** physical activities in the garden or yard?

☐☐ **hours per day**

☐☐ **minutes per day**

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Physical Activity

P. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, sweeping, washing windows, and raking **in the garden or yard**?

☐☐ **days per week**

☐ No moderate activity in garden or yard → ***Skip to question R***

Q. How much time did you usually spend on one of those days doing **moderate** physical activities in the garden or yard?

☐☐ **hours per day**

☐☐ **minutes per day**

R. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** activities like carrying light loads, washing windows, scrubbing floors and sweeping **inside your home**?

☐☐ **days per week**

☐ No moderate activity inside home → ***Skip to PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY***

S. How much time did you usually spend on one of those days doing **moderate** physical activities inside your home?

☐☐ **hours per day**

☐☐ **minutes per day**

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the **last 7 days** solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

T. Not counting any walking you have already mentioned, during the **last 7 days**, on how many days did you **walk** for at least 10 minutes at a time **in your leisure time**?

☐☐ **days per week**

☐ No walking in leisure time → ***Skip to question W***

U. How much time did you usually spend on one of those days **walking** in your leisure time?

☐☐ **hours per day**

☐☐ **minutes per day**

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Physical Activity

W. Think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **vigorous** physical activities like aerobics, running, fast bicycling, or fast swimming **in your leisure time**?

☐☐ **days per week**

☐ No vigorous activity in leisure time → ***Skip to question Y***

X. How much time did you usually spend on one of those days doing **vigorous** physical activities in your leisure time?

☐☐ **hours per day**

☐☐ **minutes per day**

Y. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis **in your leisure time**?

☐☐ **days per week**

☐ No moderate activity in leisure time → ***Skip to PART 5: TIME SPENT SITTING***

Z. How much time did you usually spend on one of those days doing **moderate** physical activities in your leisure time?

☐☐ **hours per day**

☐☐ **minutes per day**

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

AA. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekday**?

☐☐ **hours per day**

☐☐ **minutes per day**

AB. During the **last 7 days**, how much time did you usually spend **sitting** on a **weekend day**?

☐☐ **hours per day**

☐☐ **minutes per day**

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Marital Status and Social History

47. What is your current marital status:

- ☐ Married
- ☐ De Facto
- ☐ Single, with a partner
- ☐ Single, with no partner
- ☐ Separated
- ☐ Divorced
- ☐ Widowed

48. What is your current occupation? (e.g. lawyer, nurse, teacher, housewife, student, volunteer, etc.)

49. If you are employed outside the home, please indicate whether you:

- ☐ Work full time
- ☐ Work part time
- ☐ Study full time
- ☐ Study part time
- ☐ Work part time and study part time
- ☐ Not applicable
- ☐ Other (specify)

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Emotional and Psychological Wellbeing

50. We are interested in knowing about your feelings about your health, your outlook on life and changes in your emotional and psychological wellbeing. The following set of questions concern these issues.

These questions are from the Psychological General Well-being ('PGWB') Index (permission to use this index was obtained).

Listed below are a number of statements concerning how you feel and how things have been going with you during the **past month**(s).

Please read each statement carefully and indicate the answer which best applies to you by marking it with an X.

A. How have you been feeling in general during the past month?

- ☐ In excellent spirits
- ☐ In very good spirits
- ☐ In good spirits mostly
- ☐ I have been up and down in spirits a lot
- ☐ In low spirits mostly
- ☐ In very low spirits

B. How often were you bothered by any illness, bodily disorder, aches or pains during the past month?

- ☐ Every day
- ☐ Almost every day
- ☐ About half of the time
- ☐ Now and then, but less than half of the time
- ☐ Rarely
- ☐ None of the time

C. Did you feel depressed during the past month?

- ☐ Yes - to the point that I felt like taking my life
- ☐ Yes – to the point that I did not care about anything
- ☐ Yes very depressed almost every day
- ☐ Yes quite depressed several times
- ☐ Yes a little depressed now and then
- ☐ No never felt depressed at all

A Study of Women's Health

Emotional and Psychological Wellbeing

D. Have you been in firm control of your behaviour, thoughts, emotions, or feelings during the past month?

- ☐ Yes, definitely so
- ☐ Yes, for the most part
- ☐ Generally so
- ☐ Not too well
- ☐ No, and am somewhat disturbed
- ☐ No, and am very disturbed

E. Have you been bothered by nervousness or your "nerves" during the past month?

- ☐ Extremely so – to the point where I could not work or take care of things
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some – enough to bother me
- ☐ A little
- ☐ Not at all

F. How much energy, pep, or vitality did you have or feel during the past month?

- ☐ Very full of energy – lots of pep
- ☐ Fairly energetic most of the time
- ☐ My energy level varied quite a bit
- ☐ Generally low in energy or pep
- ☐ Very low in energy or pep most of the time
- ☐ No energy or pep at all – I felt drained, sapped

G. I felt downhearted and blue during the past month.

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

H. Were you generally tense or did you feel any tension during the past month?

- ☐ Yes – extremely tense, most or all of the time
- ☐ Yes – very tense most of the time
- ☐ Not generally tense, but did feel fairly tense several times
- ☐ I felt a little tense a few times
- ☐ My general tension level was quite low
- ☐ I never felt tense or any tensions at all

A Study of Women's Health

Emotional and Psychological Wellbeing

I. How happy, satisfied, or pleased have you been with your personal life during the past month?

- ☐ Extremely happy – could not have been more satisfied or pleased
- ☐ Very happy most of the time
- ☐ Generally satisfied – pleased
- ☐ Sometimes fairly happy, sometimes fairly unhappy
- ☐ Generally dissatisfied, unhappy
- ☐ Very dissatisfied or unhappy most of the time

J. Did you feel healthy enough to carry out the things you like to do or had to during the past month?

- ☐ Yes – definitely so
- ☐ For the most part
- ☐ Health problems limited me in some important ways
- ☐ I was only healthy enough to take care of myself
- ☐ I needed some help in taking care of myself
- ☐ I needed someone to help me with most or all of the things I had to do

K. Have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile during the past month?

- ☐ Extremely so – to the point I have just about given up
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some – enough to bother me
- ☐ A little bit
- ☐ Not at all

L. I woke up feeling fresh and rested during the past month

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

M. Have you been concerned, worried or had any fears about your health during the past month?

- ☐ Extremely so
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some, but not a lot
- ☐ Practically never
- ☐ Not at all

A Study of Women's Health

Emotional and Psychological Wellbeing

N. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, feel or of your memory during the past month?

- ☐ Not at all
- ☐ Only a bit
- ☐ Some – but not enough to be concerned or worried about
- ☐ Some and I have been a little concerned
- ☐ Some and I am quite concerned
- ☐ Yes, very much so and I am very concerned

O. My daily life was full of things that were interesting to me during the past month.

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

P. Did you feel active, vigorous, or dull, sluggish during the past month?

- ☐ Very active, vigorous every day
- ☐ Mostly active, vigorous – never really dull, sluggish
- ☐ Fairly active, vigorous – seldom dull, sluggish
- ☐ Fairly dull, sluggish – seldom active, vigorous
- ☐ Mostly dull, sluggish – never really active, vigorous
- ☐ Very dull, sluggish every day

Q. Have you been anxious, worried or upset during the past month?

- ☐ Extremely so – to the point of being sick or almost sick
- ☐ Very much so
- ☐ Quite a bit
- ☐ Some – enough to bother me
- ☐ A little bit
- ☐ Not at all

R. I was emotionally stable and sure of myself during the past month.

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

A Study of Women's Health

Emotional and Psychological Wellbeing

S. Did you feel relaxed, at ease or high strung, tight or keyed-up during the past month?

- ☐ Felt relaxed and at ease the whole month
- ☐ Felt relaxed and at ease most of the time
- ☐ Generally felt relaxed but at times felt fairly high strung
- ☐ Generally felt high strung but at times felt fairly relaxed
- ☐ Felt high strung, tight, or keyed-up most of the time
- ☐ Felt high strung, tight, or keyed-up the whole time

T. I felt cheerful, light hearted during the past month

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

U. I felt tired, worn out, used up, or exhausted during the past month.

- ☐ None of the time
- ☐ A little of the time
- ☐ Some of the time
- ☐ A good bit of the time
- ☐ Most of the time
- ☐ All of the time

V. Have you been under or felt you were under any strain, stress or pressure during the past month?

- ☐ Yes almost more than I could bear or stand
- ☐ Yes quite a bit of pressure
- ☐ Yes some – more than usual
- ☐ Yes some – but about usual
- ☐ Yes a little
- ☐ Not at all

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OTHER MEDICATIONS

Medications not listed previously:

51. Please list **any** other prescription or non-prescription medications that have **not been listed previously** which you are **currently taking**:

52. Please enter the date that you completed this questionnaire:

☐☐ / ☐☐ / ☐☐☐☐

Day Month Year

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Please check that you provide an answer to all questions even if you think they don't apply to you (eg. menopause status).

END OF QUESTIONNAIRE

The research team involved with this study would like to thank you for your time and effort in completing this questionnaire.

It is much appreciated.

Dr Roslin Botlero
Dr Donna Urquhart
A/Prof Robin Bell
Prof Flavia Cicuttini
Prof Susan Davis

Questionnaire for Urinary Incontinence Diagnosis (QUID)

URINARY CONTINENCE: DIAGNOSIS

Question 24. This is the 'Questionnaire for Urinary Incontinence Diagnosis' (QUID). This questionnaire assists in finding our more about the type of urinary incontinence women experience. Please put a tick in ONE box for each question☑.

Question	None of the time	Rarely	Once in a while	Often	Most of the time	All of the time
Do you leak urine (even small drops), wet yourself, or wet your pads or undergarments….						
A. When you cough or sneeze?	☐	☐	☐	☐	☐	☐
B. When you bend down or lift something up?	☐	☐	☐	☐	☐	☐
C. When you walk quickly, jog, or exercise?	☐	☐	☐	☐	☐	☐
D. While you are undressing to use the toilet?	☐	☐	☐	☐	☐	☐
E. Do you get such a strong and uncomfortable need to urinate that you leak urine (even small drops) or wet yourself before reaching the toilet?	☐	☐	☐	☐	☐	☐
F. Do you have to rush to the bathroom because you get a sudden, strong need to urinate?	☐	☐	☐	☐	☐	☐

Bristol Female Lower Urinary Tract Symptoms (BFLUTS)

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Urinary Continence: Symptoms

Question 23

This is the Bristol Female Lower Urinary Tract Symptoms Questionnaire. We would like to find out about your urinary symptoms and we are very grateful that you can help us by filling in this questionnaire. Please answer each question, thinking about the symptoms you have experienced in the last month. You will see that some questions ask how often you have a symptom:

Occasionally = less than one third of the time
Sometimes = between one and two thirds of the time
Most of the time = more than two thirds of the time

Please put a cross in ONE box for each question ☒

A. During the night, how many times do you have to get up to urinate, on average?

- ☐ None
- ☐ 1
- ☐ 2
- ☐ 3
- ☐ 4 or more

B. Do you have to rush to the toilet to urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

C. Do you have pain in your bladder?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

D. How often do you pass urine during the day?

- ☐ Every 4 hours or more
- ☐ Every 3 hours
- ☐ Every 2 hours
- ☐ Hourly

E. Is there a delay before you can start to urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

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Urinary Continence: Symptoms

M. To what extent do you feel that your sex life has been spoiled by your urinary symptoms?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

N. Do you leak urine when you have sexual intercourse?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

O. Do you need to change your outer clothing during the day because of urine leakage?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

P. Do you cut down on the amount of fluid you drink so that your urinary symptoms improve, and you can do the things that you want to do?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

Q. To what extent have your urinary symptoms affected your ability to perform daily tasks (eg, cleaning, DIY, lifting objects)?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

R. Do you avoid places and situations where you know a toilet is not nearby (eg, shopping, traveling, theater, church)?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

S. Overall, how much do your urinary symptoms interfere with your life?

- ☐ Not at all
- ☐ A little
- ☐ Somewhat
- ☐ A lot

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Urinary Continence: Symptoms

F. Do you have to strain to urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

G. Do you stop and start more than once while you urinate?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

H. Does urine leak before you can get to the toilet?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

I. How often do you leak urine?

- ☐ Never
- ☐ Once or less a week
- ☐ 2-3 times a week
- ☐ Once per day
- ☐ Several times a day

J. Does urine leak when you are physically active, exert yourself, cough, or sneeze?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

K. Do you ever leak for no obvious reason and without feeling that you want to go?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

L. Do you leak urine when you are asleep?

- ☐ Never
- ☐ Occasionally
- ☐ Sometimes
- ☐ Most of the time
- ☐ All of the time

Pelvic Floor Distress Inventory (PFDI)

Pelvic Floor Distress Inventory–short form 20

Instructions: Please answer all of the questions in the following survey. These questions will ask you if you have certain bowel, bladder, or pelvic symptoms and, if you do, how much they bother you. Answer these by putting an **X** in the appropriate box or boxes. While answering these questions, please consider your symptoms over the **last 3 months.**

The PFDI-20 has 20 items and 3 scales.
All items use the following format with a response scale from 0 to 4.

Do you _____?

☐ No; ☐ Yes
0

If yes, how much does it bother you?
☐ 1 ☐ 2 ☐ 3 ☐ 4
Not at all Somewhat Moderately Quite a bit

Scales
Pelvic Organ Prolapse Distress Inventory 6 (POPDI-6):

1. Usually experience *pressure* in the lower abdomen?
2. Usually experience *heaviness or dullness* in the pelvic area?
3. Usually have a bulge or something falling out that you can see or feel in your vaginal area?
4. Ever have to push on the vagina or around the rectum to have or complete a bowel movement?
5. Usually experience a feeling of incomplete bladder emptying?
6. Ever have to push up on a bulge in the vaginal area with your fingers to start or complete urination?

Colorectal-Anal Distress Inventory 8 (CRADI-8):

7. Feel you need to strain too hard to have a bowel movement?
8. Feel you have not completely emptied your bowels at the end of a bowel movement?
9. Usually lose stool beyond your control if your stool is well formed?
10. Usually lose stool beyond your control if your stool is loose?
11. Usually lose gas from the rectum beyond your control?
12. Usually have pain when you pass your stool?
13. Experience a strong sense of urgency and have to rush to the bathroom to have a bowel movement?
14. Does part of your bowel ever pass through the rectum and bulge outside during or after a bowel movement?

Urinary Distress Inventory 6 (UDI-6):

15. Usually experience frequent urination?
16. Usually experience urine leakage associated with a feeling of urgency, that is, a strong sensation of needing to go to the bathroom?
17. Usually experience urine leakage related to coughing, sneezing, or laughing?
18. Usually experience small amounts of urine leakage (that is, drops)?
19. Usually experience difficulty emptying your bladder?
20. Usually experience *pain* or *discomfort* in the lower abdomen or genital region?

Scale scores: Obtain the mean value of all of the answered items within the corresponding scale (possible value 0 to 4) and then multiply by 25 to obtain the scale score (range 0 to 100). Missing items are dealt with by using the mean from answered items only.

PFDI –20 Summary Score: Add the scores from the 3 scales together to obtain the summary score (range 0 to 300).

Psychological General Well-being Index (PGWBI)

Psycological General Well Being Index

1. How have you been feeling in general during the past month?

In excellent spirits……	☐ 5
In very good spirits……..	☐ 4
In good spirits mostly……..	☐ 3
I have been up and down in spirits a lot……..	☐ 2
In low spirits mostly……	☐ 1
In very low spirits……	☐ 0

2. How often were you bothered by any illness, bodily disorder, aches or pains during the past month?

Every day……	☐ 0
Almost every day……	☐ 1
About half of the time…….	☐ 2
Now and then, but less than half the time……...	☐ 3
Rarely……..	☐ 4
None of the time……..	☐ 5

3. Did you feel depressed during the past month?

Yes – to the point that I felt like taking my life……..	☐ 0
Yes – to the point that I did not care about anything……..	☐ 1
Yes – very depressed almost every day……..	☐ 2
Yes – quite depressed several times…….……...	☐ 3
Yes – a little depressed now and then…….	☐ 4
No – never felt depressed at all……	☐ 5

4. Have you been in firm control of your behaviour, thoughts, emotions or feelings during the past month?

Yes, definitely so……	☐ 5
Yes, for the most part…….	☐ 4
Generally so……	☐ 3
Not too well……..……...	☐ 2
No, and I am somewhat disturbed……..	☐ 1
No, and I am very disturbed……	☐ 0

5. Have you been bothered by nervousness or your "nerves" during the past month?

Extremely so – to the point where I could not work or take care of things……	☐ 0
Very much so……..	☐ 1
Quite a bit……	☐ 2
Some – enough to bother me……..…….	☐ 3
A little…….	☐ 4
Not at all……..	☐ 5

6. How much energy, pep, or vitality did you have or feel during the past month?

Very full of energy – lots of pep…….	☐ 5
Fairly energetic most of the time……..…	☐ 4

My energy level varied quite a bit……... ☐ 3
Generally low in energy or pep…….…. ☐ 2
Very low in energy or pep most of the time…… ☐ 1
No energy or pep at all – I fell drained, sapped……... ☐ 0

7. I felt downhearted and blue during the past month.

None of this time…… ☐ 5
A little of the time……..…….. ☐ 4
Some of the time…….…… ☐ 3
A good bit of the time…….…….……... ☐ 2
Most of the time…….. ☐ 1
All of the time……..…… ☐ 0

8. Were you generally tense or did you feel any tension during the past month?

Yes – extremely tens, most or all of the time……. ☐ 0
Yes – very tense most of the time…….. ☐ 1
Not generally tense, but did feel fairly tense several times…….. ☐ 2
I felt a little tense a few times…….…… ☐ 3
My general tension level was quite low……. ☐ 4
I never felt tense or any tension at all…….. ☐ 5

9. How happy, satisfied, or pleased have you been with your personal life during the past month?

Extremely happy – could not have been more satisfied or pleased…… ☐ 5
Very happy most of the time…….. ☐ 4
Generally satisfied, pleased…… ☐ 3
Sometimes fairly happy, sometimes fairly unhappy…….. ☐ 2
Generally dissatisfied or unhappy…….…… ☐ 1
Very dissatisfied or unhappy most or all the time…….. ☐ 0

10. Did you feel healthy enough to carry out the things you like to do or had to do during the past month?

Yes – definitely so……..…… ☐ 5
For the most part……..…….…….. ☐ 4
Health problems limited me in some important ways…… ☐ 3
I was only healthy enough to take care of myself …….. ☐ 2
I needed some help in taking care of myself.……. ☐ 1
I needed someone to help me with most or all of the things I had to do..…….. ☐ 0

11. Have you felt so sad, discouraged, hopeless, or had so many problems that you wondered if anything was worthwhile during the past month?

Extremely so – to the point that I have just about given up..……..…… ☐ 0
Very much so….……..…….…….. ☐ 1
Quite a bit…… ☐ 2
Some – enough to bother me…….. ☐ 3
A little bit……..……..……. ☐ 4
Not at all……....…….. ☐ 5

12. I woke up feeling fresh and rested during the past month.

None of the time……....……..…… ☐ 0

A little of the time..…….…….…….. ☐ 1
Some of the time..…… ☐ 2
A good bit of the time…….. ☐ 3
Most of the time…...……..…….…… ☐ 4
All of the time……....…….. ☐ 5

13. Have you been concerned, worried, or had any fears about your health during the past month?

Extremely so…..……....……..…… ☐ 0
Very much so……...……..…….…… ☐ 1
Quite a bit……....…… ☐ 2
Some, but not a lot…. ☐ 3
Practically never.....……..…….…… ☐ 4
Not at all……....…….. ☐ 5

14. Have you had any reason to wonder if you were losing your mind, or losing control over the way you act, talk, think, feel or of your memory during the past month?

Not at all…..……....……..……. ☐ 5
Only a little……..……..…….…….... ☐ 4
Some – but not enough to be concerned or worried about…… ☐ 3
Some and I have been a little concerned…… ☐ 2
Some and I am quite concerned..……..…….……. ☐ 1
Yes, very much so and I am very concerned……....…….. ☐ 0

15. My daily life was full of things that were interesting to me during the past month.

None of the time……....……..……... ☐ 0
A little of the time……..…….……..... ☐ 1
Some of the time……. ☐ 2
A good bit of the time…….…… ☐ 3
Most of the time……..……..…….……. ☐ 4
All of the time……....……. ☐ 5

16. Did you feel active, vigorous, or dull, sluggish during the past month?

Very active, vigorous every day……..……....……..……. ☐ 5
Mostly active, vigorous – never really dull, sluggish…….……..... ☐ 4
Fairly active, vigorous – seldom dull, sluggish……..……. ☐ 3
Fairly dull, sluggish – seldom active, vigorous..…… ☐ 2
Most dull, sluggish – never really active, vigorous...……. ☐ 1
Very dull, sluggish every day……....……. ☐ 0

17. Have you been anxious, worried, or upset during the past month?

Extremely so – to the point of being sick or almost sick……..…….. ☐ 0
Very much so…...……..…….…….... ☐ 1
Quite a bit……...……. ☐ 2
Some – enough to bother me..…….……. ☐ 3
A little bit……..……..……..……. ☐ 4
Not at all…….……....……. ☐ 5

18. I was emotionally stable and sure of myself during the past month.

None of the time……...……..……... ☐ 0
A little of the time……..…….……..... ☐ 1
Some of the time……. ☐ 2
A good bit of the time…….…… ☐ 3
Most of the time……..……..……. ☐ 4
All of the time……...……. ☐ 5

19. Did you feel relaxed, at ease or high strung, tight, or keyed-up during the past month?

Felt relaxed and at ease the whole month……..…….. ☐ 5
Felt relaxed and at ease most of the time…….……..... ☐ 4
Generally felt relaxed but at times felt fairly high strung...……. ☐ 3
Generally felt high strung but at times felt fairly relaxed…… ☐ 2
Felt high strung, tight, or keyed-up most of the time..……. ☐ 1
Felt high strung, tight, or keyed-up the whole month.……...……. ☐ 0

20. I felt cheerful, lighthearted during the past month.

None of the time……...……..……... ☐ 0
A little of the time……..…….……..... ☐ 1
Some of the time……. ☐ 2
A good bit of the time…….…… ☐ 3
Most of the time……..……..……. ☐ 4
All of the time……...……. ☐ 5

21. I felt tired, worn out, used up, or exhausted during the past month.

None of the time……...……..……... ☐ 5
A little of the time……..…….……..... ☐ 4
Some of the time……. ☐ 3
A good bit of the time…….…… ☐ 2
Most of the time……..……..……. ☐ 1
All of the time……...……. ☐ 0

22. Have you been under or felt you were under any strain, stress, or pressure during the past month?

Yes – almost more than I could bear or stand……..…….. ☐ 0
Yes – quite a bit of pressure……..……..……..... ☐ 1
Yes, some – more than usual……..…….……. ☐ 2
Yes, some – but about usual……... ☐ 3
Yes – a little……...……. ☐ 4
Not at all…….……...……. ☐ 5