



Prediction & Prevention of Pelvic Floor Disorders in the Developed World – UR-CHOICE!

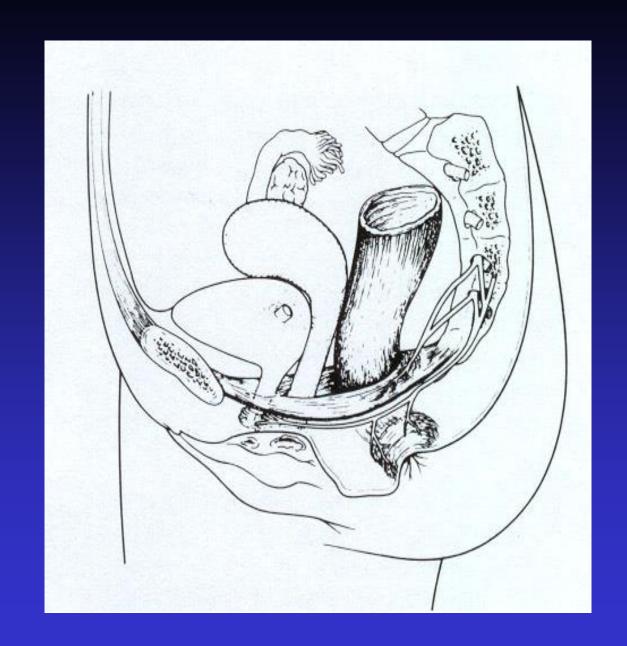
Don Wilson, on behalf of the UR-CHOICE Study Group Emeritus Professor of Obstetrics & Gynaecology Associate Dean (Nelson/Marlborough) University of Otago, New Zealand, Aotearoa "Just about the worst thing that can happen to a woman in this world is to develop an obstetric fistula that leaves her trickling bodily wastes and shunned by everyone around her."

> Nicholas D. Kristof Pulitzer Prize Winner, *New York Times* Columnist

Obstetric Fistula

- 2,000,000 women living with a fistula
- 50,000-100,000 new cases per year
- Approximately 15,000 cases being repaired each year

Shane Duffy (Personal Communication)



Pelvic Floor Disorders

- Urinary Incontinence
- Faecal Incontinence
- Pelvic Organ Prolapse

Pelvic Floor Dysfunction

- Significant effect on quality of life for a large number of women
 - "Epidemic proportions in later life"

(MacLennan et al 2000)

- Significant cost implications for Health Services
- Great importance to identify possible aetiological factors with a view to subsequent prevention/reduction of its impact

Prevalence of Urinary Incontinence and Distribution by Parity



? Pregnancy or? Parturition



Obstetric demographics in developed world changed over past 40 years

- Women older when have first baby
- Women's BMI's are greater
- Babies are heavier

All risk factors for PFD!

Women are having fewer babies

Pelvic Floor Dysfunction

- Prevention of PFD major priority in women's health in the developed world
- Identification of women "at risk" is a key element in current prevention strategies.
- One of the major barriers to effective prevention is our inability to effectively identify "at risk" women.

Current Main Prevention Strategies

- Caesarean Section and other delivery modes
- Pelvic floor muscle training
- Modifiable risk factors/lifestyle interventions

"I would definitely consider paying to have one [Caesarean Section]. I don't think natural childbirth is a great system. I'm worried about stitches, long-term incontinence and a ruined sex life afterwards. I'd rather not take any risks."

(36 year old journalist, Cosmopolitan)

Birth by Design: Are Celebs Too Posh to push?

NEW YORK — Celebs - as usual on the leading edge — are rumored to be at the forefront of a growing movement among new moms: pre-scheduled, elective Caesarean Sections.









By Jennifer D'Angelo
www.foxnews.com

Unintended benefits?



Dr Sylvia Lin BHB, MBCHB, MRANZCOG Research Fellow University of Otago



Prof Don Wilson MBChB, MD, FRCS, FRCOG, FRANZCOG, CU

Can pelvic floor dysfunction be prevented by caesarean section? Findings from the ProLong and other epidemiological studies.

Pelvic floor dysfunction (PFD) in women results in the combination of some or all of the following conditions: urinary incontinence (UI), faecal incontinence (FI) and pelvic organ prolapse (POP). It also influences sexual function.

It is a very common problem, with over 46 per cent of women having some form of major pelvic floor dysfunction and is of epidemic proportions in later life. Approximately 11 per cent of women undergo surgery for this condition during their lifetime, seven per cent for prolapse alone.² In the USA, POP is thought to lead to over 200 000 surgical operations a year, resulting in an annual expenditure of US\$1billion.3 Pelvic floor dysfunction surgery numbers are likely to increase substantially as the population

longitudinal study ProLong (PROlapse and incontinence LONG-term research study). This commenced in 1993–94 and involved the Universities of Otago, Birmingham and Aberdeen in the UK. This is the largest ongoing prospective study in this field and involves a cohort of nearly 8000 women of whom just under 50 per cent returned questionnaires at three months, six and 12 years after delivery. By Women were also examined at the 12-year follow up. 10 It is planned to carry out the 20-year follow up in 2014. In this article the 12-year results of the ProLong study will be presented and compared with other epidemiological studies, with particular emphasis on whether caesarean section is protective for subsequent PFD.

Urinary incontinence

At 12 years after delivery, urinary incontinence is very common, with just over 50 per cent of women having this complaint. Women who delivered exclusively by caesarean section were less likely to have UI in comparison to women who delivered vaginally, (vaginal delivery 55 per cent versus caesarean 40 per cent, OR 0.46:95 per cent CI 0.37–0.58), but not if they had a combination of caesarean and spontaneous vaginal births.¹⁰

A similar reduction is seen at 20 years after delivery in the Swedish National Survey of pelvic floor dysfunction, the SWEdish Pregnancy Obesity Pelvic floor (SWEPOP) study. This involved just over 5000 priminarous women who delivered in 1985–88 with no further births.

ProLong: Longitudinal Study of Pelvic Floor Dysfunction and Childbirth



Universities of Otago, Aberdeen. and Birmingham Funded by: WellBeing of Women and University of Otago









- All deliveries within 12 months (1993-94)
- 7883 participated 3 months after index birth
- 3638 followed up 12 years after delivery

The prevalance of urinary incontinence 20 years after childbirth: a national cohort study in singleton primiparae after vaginal or Caesarean delivery

- Swedish Pregnancy, Obesity and Pelvic Floor (SWEPOP) Study linked Medical Birth Register data to a questionnaire about UI sent in 2008
- 5236 Singleton Primiparae who delivered in the period 1985-1988 with no further births

Gyhagen et al BOG 2012

Role of Caesarean Section on Prevention of PFD – Summary of Evidence

Urinary Incontinence

Partial protection but prevalence still high:

- ProLong 12 years after delivery
 VD 55% CS 40% (OR 0.46, 95%, CI 0.37-0.58)
- SwePOP 20 years after delivery Primipara
 VD 40% CS 29% (OR 1.67, 95% CI 1.45-1.91)
- No difference between elective and emergency Caesars

Role of Caesarean Section on Prevention of PFD – Summary of Evidence

Faecal Incontinence

- No evidence of reduced likelihood of FI in ProLong Study with Caesar at 12 years after delivery
- Similar findings of lack of longterm effect on FI was noted in updated Cochrane Review with Caesar

Forceps/Vacuum

 Risk of long term faecal incontinence is significantly higher after having had one or more forceps deliveries (OR 2.08 95% CI 1.53-2.85)

Role of Caesarean Section on Prevention of PFD – Summary of Evidence

POP:

- Reduced risk of POP symptoms VD 14.8% CS 6.3% (OR 2.55, 95% CI 1.98-3.28)
- Reduced risk of objectively measured signs of prolapse
 VD 29% CS 5% (OR 0.11, 95%, CI 0.03-0.38)
- Reduced risk of POP surgery
 VD vs CS Hazard Ratio 9.2 (95%, Cl 7-12)
 Forceps vs CS Hazard Ratio 20.9 (95%, Cl 20.9, 95%, Cl 5.5-79.9)

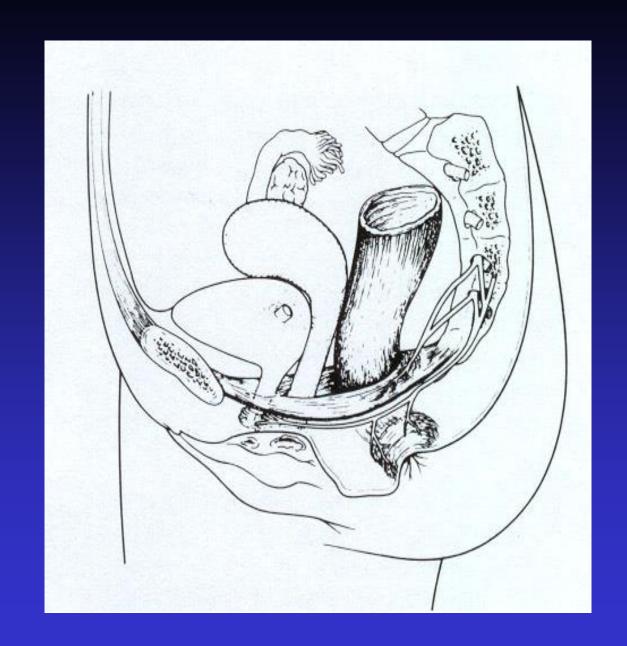
Partial protection for POP and to a lesser degree UI

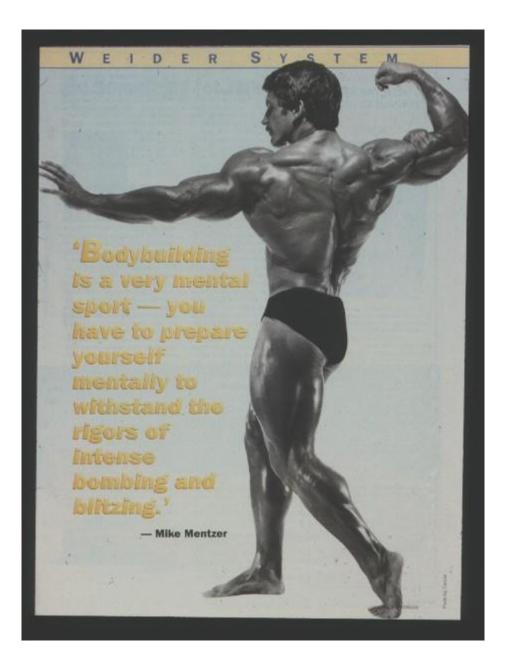
Role of Elective Caesarean Section on Prevention of Pelvic Floor Dysfunction – Conclusion

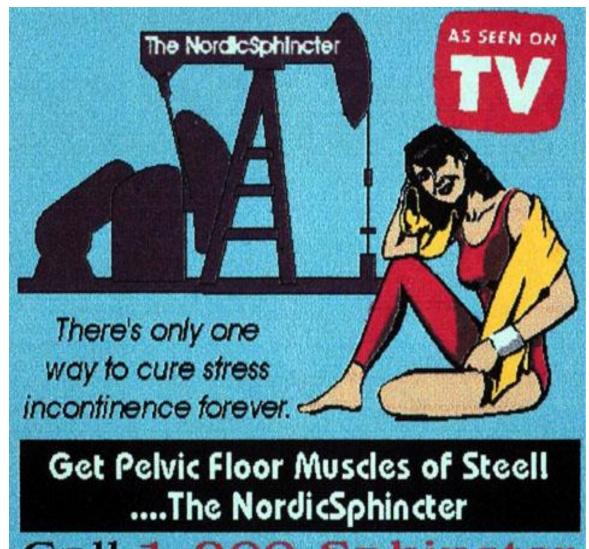
- Controversial!
- Given the associated risks (especially multiple repeat Caesarean deliveries) it is unlikely that elective Caesarean Sections is an effective prevention strategy for most women
- A strategy of offering elective Caesarean Section to women who are at substantially higher than average risk of PFD may be a more appropriate and effective prevention strategy
- ?What risk threshold

Current Main Prevention Strategies

- Caesarean Section and other delivery modes
- Pelvic floor muscle training
- Modifiable risk factors/lifestyle interventions







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(no salesman will call)

Cochrane Review Antenatal PFMT in Continent Women

- 38 trials of 9892 women
- 62% less likely to have UI in late pregnancy
- 29% less likely to have UI at 3-6 months postpartum
- Insufficient evidence for effect greater than 6-12 months postpartum

Cochrane Review Antenatal PFMT in Continent Women - Conclusions

"Targetting continent antenatal women early in pregnancy and offering a structured PFMT programme may prevent the onset of urinary incontinence in late pregnancy and postpartum."



A multicentre randomised controlled trial of a pelvic floor muscle training intervention for the prevention of pelvic organ prolapse

Hagen S, Glazener C, McClurg D, Macarthur C, Herbison P, Wilson D, Toozs-Hobson P, Bain C, Hay-Smith J, Collins M, Elders A

NMAHP Research Unit, Glasgow; Health Services Research Unit, Aberdeen; University of Birmingham; Dunedin School of Medicine, University of Otago; Birmingham Women's Hospital; Aberdeen Royal Infirmary; Yunus Centre, Glasgow Caledonian University



Funded by Wellbeing of Women

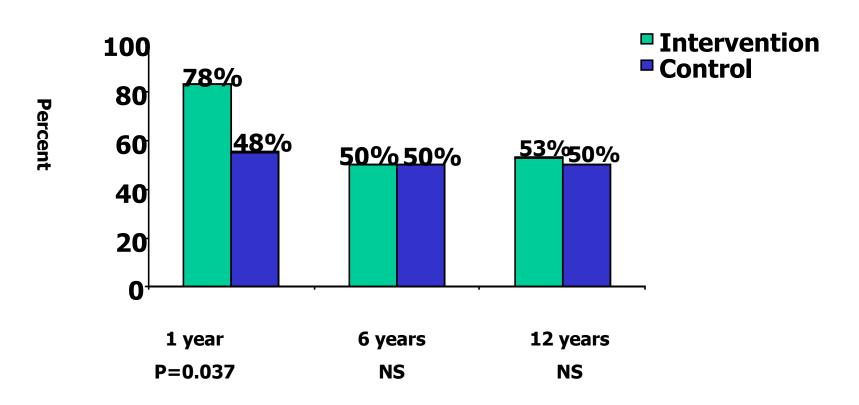
The Lancet. doi.org/10.1016/S0140-6736(16)32109-2 (2016)

PREVPROL – 2 Year Follow Up - Conclusions

- Women in the Intervention group more likely to report doing PFM exercises (77% v 53% P <0.001) and to say they felt a health-related benefit (44.2% v 9.8% P <0.001) compared to Controls.
- ☐ Significantly lower POP-SS score at 2 years in the Intervention Group compared to Control P = 0.004
- ☐ Further treatment for prolapse symptoms was less common in the Intervention Group (5.9% v 14.4% P = 0.007)
- □ Rate of GP consultations related to prolapse symptom was lower in the Intervention Group (2.9% v 12.2% P = 0.01).

Women should be recommended to undertake PFMT even before they have bothersome symptoms

PINT RCT. Results – woman performing pelvic floor muscle training



Pelvic floor muscle training to prevent pelvic floor dysfunction

- It works!
- Challenge How do we increase motivation, and adherence to PFMT?

Current Main Prevention Strategies

- Caesarean Section and other delivery modes
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- Modifiable risk factors/lifestyle interventions

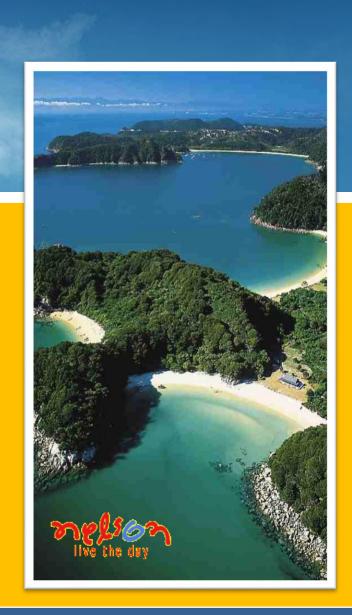
Modifiable Risk Factors/Lifestyle Interventions Preventing Urinary Incontinence

- Women should aim at normal weight before pregnancy (Grade A)
- Aim at regaining pre-pregnancy weight postpartum (Grade B)
- Constipation should be avoided during pregnancy and postpartum (Grade C)

Current Main Prevention Strategies

- Caesarean Section and other delivery modes
- Pelvic floor muscle training
- Modifiable risk factors/lifestyle interventions

Influenced by UR-CHOICE "Score" giving personalised "Risk"/ likelihood of developing PFD (UI, FI & POP)





IUGA Debate

"This house believes that instrumental delivery should be abandoned in favour of Caesarean section"

Te Whare Wänanga o Otägo NEW ZEALAND

Profs Don Wilson & Jim Dornan

CLINICAL OPINION

UR-CHOICE: can we provide mothers-to-be with information about the risk of future pelvic floor dysfunction?

Don Wilson • James Dornan • Ian Milsom • Robert Freeman

Received: 13 January 2014 / Accepted: 13 March 2014 © The International Urogynecological Association 2014

Abstract Vaginal childbirth is probably the most important factor in the aetiology of pelvic floor dysfunction (PFD) and results in the combination of some or all of the following conditions: urinary (UI) and faecal (FI) incontinence and pelvic organ prolapse (POP). Up until now, it has been difficult to counsel women antenatally regarding risk factors for subsequent PFD, as there has been little good-quality, long-

Keywords Pelvic floor dysfunction · Urinary incontinence · Faecal incontinence · Pelvic organ prolapse · Vaginal delivery · Caesarean section · Prediction

Introduction

Moderately robust epidemiological data 12 & 20 years after delivery & pathophysiological data using risk factors

1

Major risk factors for subsequent PFD:

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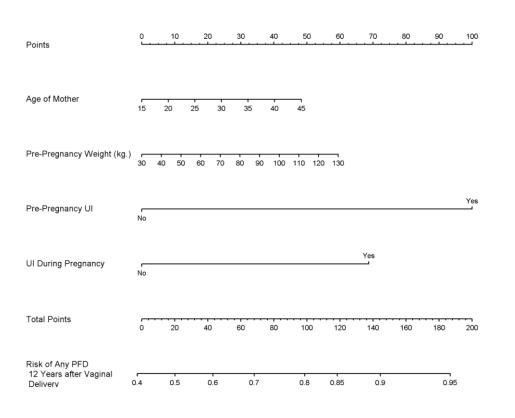
U	UI before pregnancy
R	Race/Ethnicity
С	Childbearing started at what age
Н	Height of mother
0	Overweight (weight, BMI of mother)
ı	Inheritance (family history)
С	Children (number of children desired) or Caesar/delivery mode for postpartum "score"
E	Estimated fetal weight

Wilson, D, Dornan, J, Milsom, I, Freeman, R, (International UrogynaecologyJournal, April 2014)

Prediction Models for Postpartum Urinary and Fecal Incontinence in Primiparous women

Jelovsek JE, Piccorelli A, Barber MD, Tunitsky-Bitton, Kattan MW Female Pelvic Med Reconstr Surg 2013;19:110-118

Vaginal Delivery – Risk of Any Pelvic Floor Disorder (AnyPFD)



Aim:

To Produce normograms that accurately generate individualized prognostic estimates of postpartum UI and FI

Predictive Modelling Co-operation

SwePOP Study Group Sahlgrenska Academy, Gothenburg

Maria Gyhagen, Jwan Othman, Björn Areskoug, Ian Milsom

PROLONG Study Group

Aberdeen, Glasgow and Otago

Don Wilson, Charis Glazener, Suzanne Hagen, Andrew Elders

CLEVELAND CLINIC Group

Cleveland

Matt Barber, Eric Jelovsek, Michael Kattan, Kevin Chagin

Study Population

Data from 2 longitudinal, prospective cohorts

1. Swedish Pregnancy, Obesity and Pelvic Floor Study (SwePOP)

- Only Primiparous women delivered 1985-1988 (n = 9423)
- Swedish Medical Birth Register data
- 4991 linked to Postal Questionnaire 20 years after delivery

2. ProLong study from UK/New Zealand

- All deliveries w/n 12 months (1993-94)
- 7883 participated 3 months after index birth
- Aberdeen (UK), Birmingham (UK), Dunedin (New Zealand)
- 3638 followed up to 12 years after delivery

Study Cohort: 8624

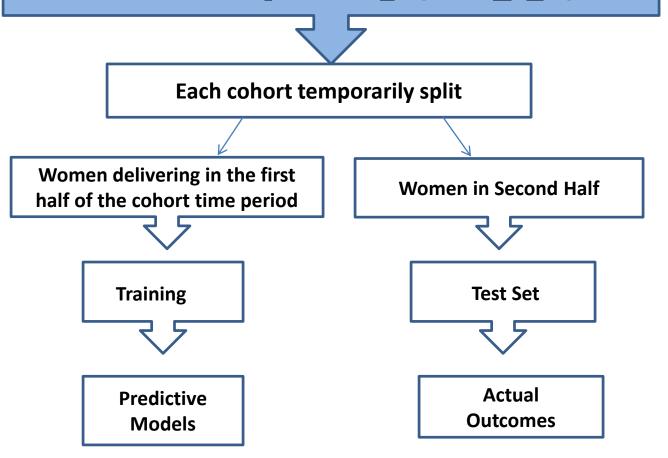
Hypotheses

- Multiple regression models can be developed to predict the likelihood of developing PFDs 12-20 years after delivery that:
 - ☐ Discriminate better than chance women who are at high risk from women who are at low risk

Concordance Index 1 = perfect discrimination 0.5 = no better than chance

☐ Reasonable calibration and are internally and externally validated.

TRIPOD - <u>Transparent Reporting of a Multivariable</u> Prediction Model for <u>Individual Prognosis Or Diagnosis</u>



METHODS

- Training Set
- Multiple logistic models
- Harrell's "Model Approximation" process of backwards elimination
- Best parsimonious model
- Model accuracy was measured as discrimination using a concordance index and calibration using visual plots were created.
- Online calculators

Results

Model Discrimination

Overall all models were able to discriminate better than chance and able to discriminate risk 51-75% of the time for each temporal validation set.

Before delivery, 12 & 20 year concordance indices for bothersome or receiving treatment were:

- POP (0.570, 0.627)
- UI (0.653, 0.689)
- FI (0.618, 0.676)

Other Predictive Models currently used in Clinical Practice

- National Cancer Institute Gail Model for Prediction of Breast Cancer Risk – Concordance Index 0.59
- Framingham Cardiovascular risk model Concordance Index 0.72



UR-CHOICE Pelvic Floor Disorders Risk Calculator

Online Calculator - http://riskcalc.org/UR_CHOICE/

Risk Factors Maternal age at delivery	Outcomes	Route of Delivery	Bothersome/ Treatment	Average risk of bothersome/ treatment
Number of previous births	Pelvic organ prolapse	Vaginal		9%
Maternal pre-pregnancy		C-Section		7%
weight Maternal height	Urinary Incontinence	Vaginal		28%
Estimated birthweight		C-Section		24%
Family History of UI/POP	Fecal Incontinence Any pelvic floor disorder	Vaginal		5%
Urinary Incontinence PRE		C-Section		5%
or DURING Pregnancy		Vaginal		37%
		C-Section		32%

How can we counsel patients?

Case 1: lower risk primigravida

- 28 year old
- Primigravid woman
- 150 pounds, 5 feet 4 inches tall
- EFW = 7 pounds 2 ounces
- Fetal HC = 35 cm
- No history of UI before or during pregnancy
- No family history of POP, UI or FI

Online Calculator http://riskcalc.org/UR_CHOICE/ UR-CHOICE Pelvic Floor Disorders Risk Calculator

Lower Risk Primigravida						
Outcomes	Route of delivery	Bothersome /treatment	Average risk of bothersome/ treatment			
Pelvic organ prolapse	Vaginal	4%	9%			
	C-Section	1%	3%			
Urinary Incontinence	Vaginal	15%	20%			
	C-Section	10%	15%			
Faecal Incontinence	Vaginal	2%	3%			
	C-Section	2%	3%			
Any pelvic floor disorder	Vaginal	20%	27%			
	C-Section	12%	18%			

"C-Section reduces your risk of any bothersome/treatment PFD 20 years after delivery by 8%"

How can we counsel patients?

Case 2: higher risk primigravida

- 28 year old
- Primigravid woman
- 150 pounds, 5 feet 4 inches tall
- EFW = 7 pounds 2 ounces
- Fetal HC = 35 cm
- UI before pregnancy
- Positive family history of POP and UI

Online Calculator http://riskcalc.org/UR_CHOICE/ UR-CHOICE Pelvic Floor Disorders Risk Calculator

Higher Risk Primigravida						
Outcomes	Route of delivery	Bothersome /treatment	Average risk of bothersome/ treatment			
Pelvic organ prolapse	Vaginal	20%	9%			
	C-Section	5%	3%			
Urinary Incontinence	Vaginal	>30%	20%			
	C-Section	27%	15%			
Faecal Incontinence	Vaginal	4%	3%			
	C-Section	4%	3%			
Any pelvic floor disorder	Vaginal	48%	27%			
	C-Section	33%	18%			

"C-Section reduces your risk of any bothersome/treatment PFD 20 years after delivery by 15%"

UR-CHOICE – More Questions than answers!

Pregnant women

- Views about receiving personalised PFD risk information antenatally and postnatally?
- The likelihood that this information would influence motivation and adherence to PFMT and dietary advice?
- What risk reduction would they wish before considering a Caesar?

UR-CHOICE – More Questions than answers!

Midwives/Obstetricians/Service Managers/ Clinical Directors

- Views about delivering personalised PFD risk information antenatally and postnatally?
- What are their views if a woman was higher than average risk?
- What are the implications for services? (Physio, Dietician referrals, ?elective Caesars)

Conclusions of UR-CHOICE "Score"

- Models provide valid individualised risk estimates for the development of PFD 12-20 years after delivery (and the objective effect of Caesar)
- Models are not perfect (C-Stat=1)
- Online risk calculator is available at http://riskcalc.org/UR_CHOICE/
- Predicting risk is major step in prevention
- It supports a woman's autonomy and her right to informed choice regarding her care in pregnancy and childbirth
- Using UR-CHOICE risk calculator increases awareness of prevention of PFD

"In a century that has witnessed the unravelling of the genetic code, it is surprising how little we know about functional changes in women after vaginal childbirth, how to prevent damage to the pelvic floor and how to treat it"

Prevention of Pelvic Floor Dysfunction

