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# Evidence-based guidelines for the selection and use of continence management products

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University College London, England

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Continence Foundation of Australia, Melbourne, 16-19 Nov 2011

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Based on...

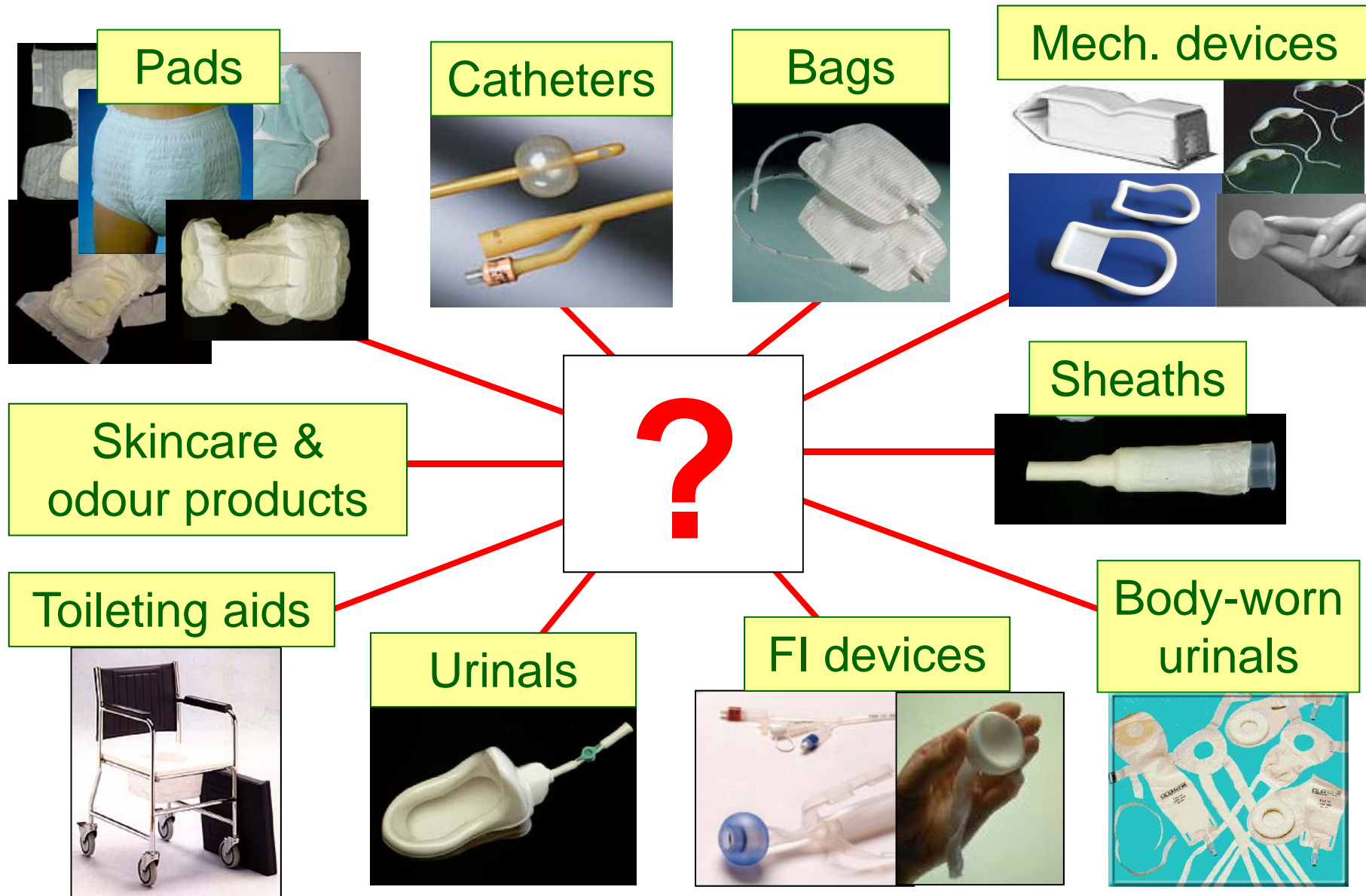


## **4<sup>th</sup> International Consultation on Incontinence 2009**

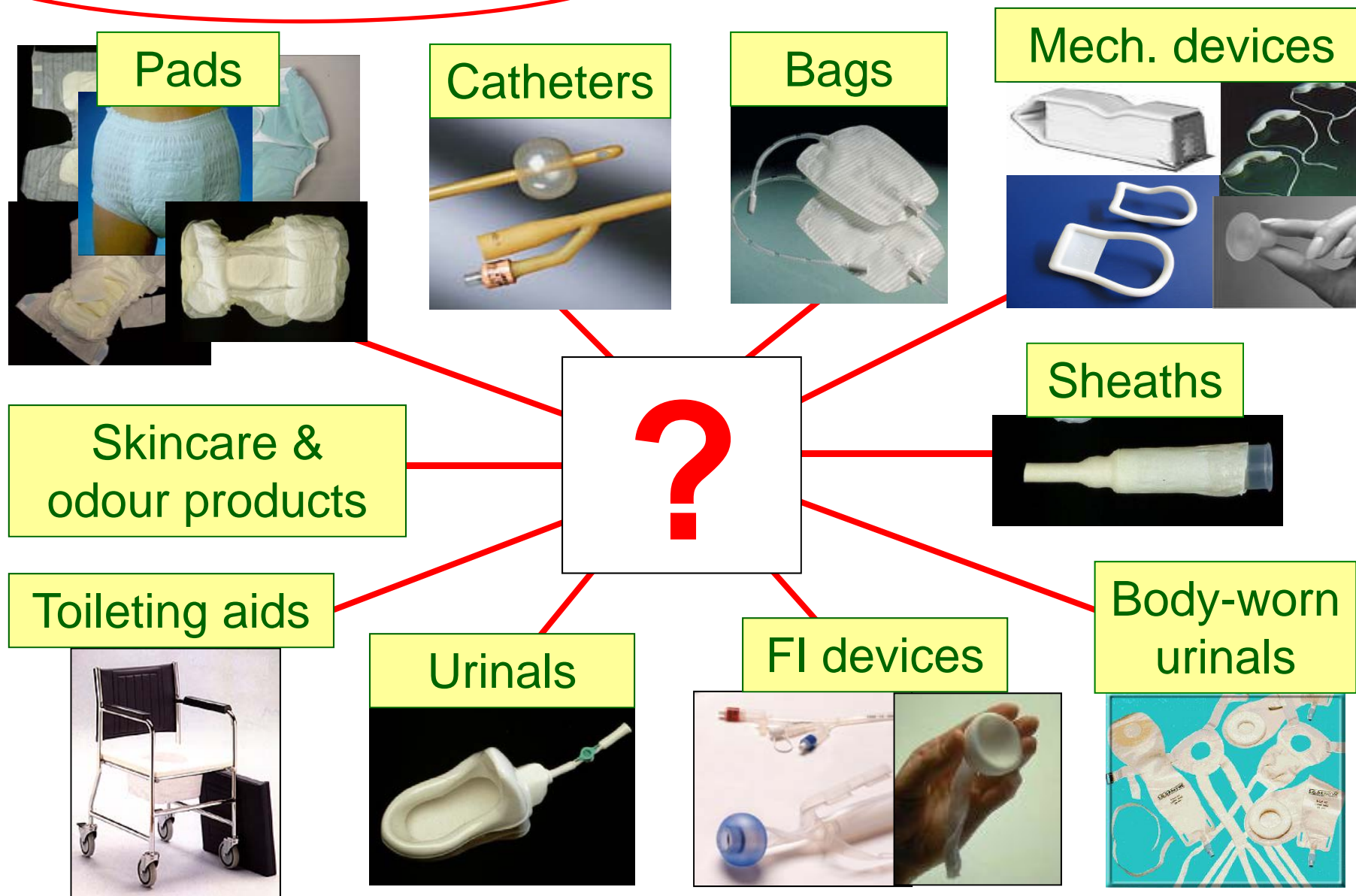
**Committee 20 (Management using continence products):**  
Donna Bliss (USA), Brian Buckley (Ireland), Alan Cottenden (UK),  
Mandy Fader (UK), Kathy Getliffe (UK), Jan Paterson (Australia),  
Ronny Pieters (Belgium) and Mary Wilde (USA)

**5<sup>th</sup> International Consultation on Incontinence  
Paris: February 2012**

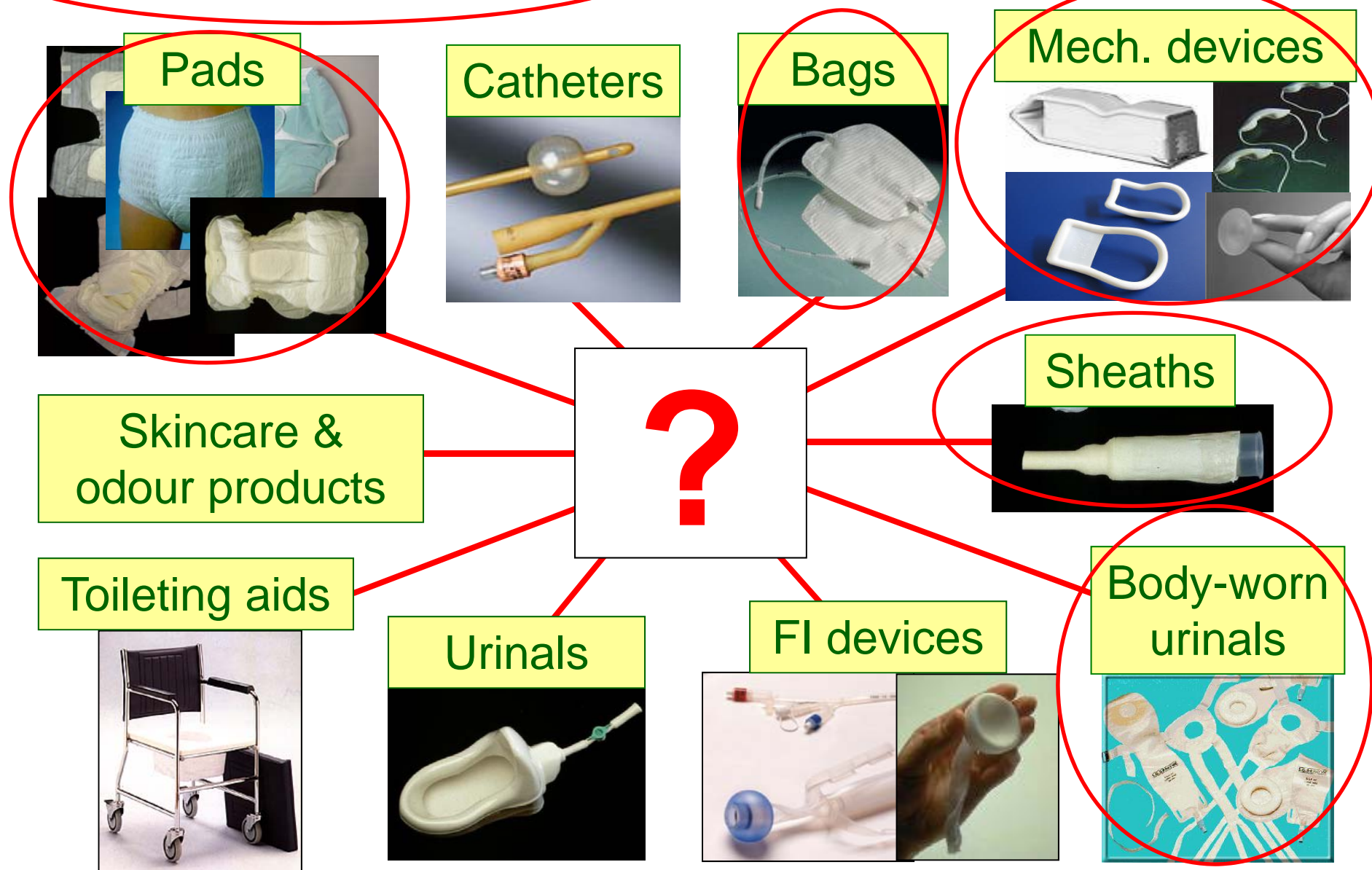
# Products for toileting, urinary retention, urinary incontinence and faecal incontinence



# Products for toileting, urinary retention, urinary incontinence and faecal incontinence



# Products for toileting, urinary retention, urinary incontinence and faecal incontinence



# Background

Continence products find an essential role in enhancing the quality of life of those who:

- Are unable to be (fully) cured.
- Are awaiting treatment.
- Treatment is unavailable.
- Are waiting for treatment to take effect.
- Elect not to pursue cure options.





# Why is evidence-based product selection important?

- Good product selection can radically affect the QoL of people with incontinence.
- Many of those least amenable to treatment have the most severe incontinence and are most dependent on good products.
- Increasing demand for evidence-based, cost-effective product selection to justify choice (frequent product updates).
- Some products (eg catheters) can have significant adverse effects.

# Product user groups

- Females with light UI.
- Males with light UI.
- Females with moderate / heavy UI.
- Males with moderate / heavy UI.





## Levels of evidence

From: **Level 1** (Meta-analysis of RCTs).

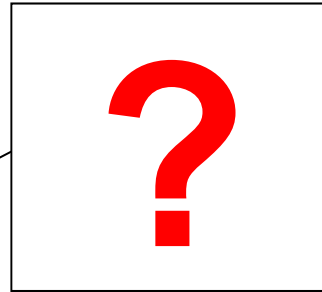
To: **Level 4**: (Expert opinion).

## Grades of recommendation

From: **Grade A**: (Based on consistent Level 1 evidence or lots of Level 2).

To: **Grade D**: (Expert opinion).

# Women, light UI, main product categories



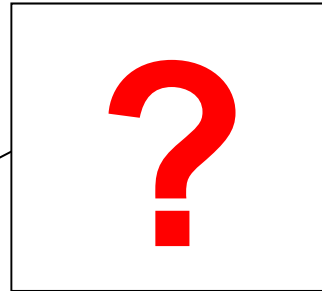
Pads



Mechanical devices



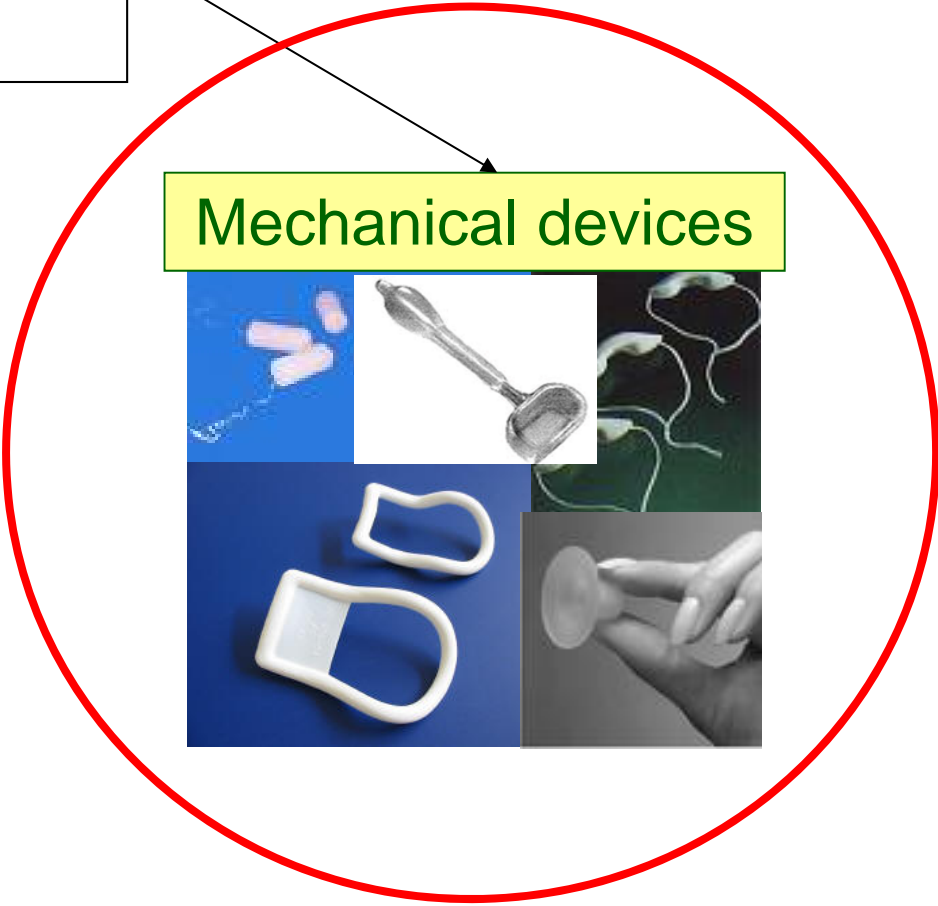
# Women, light UI, Main product categories



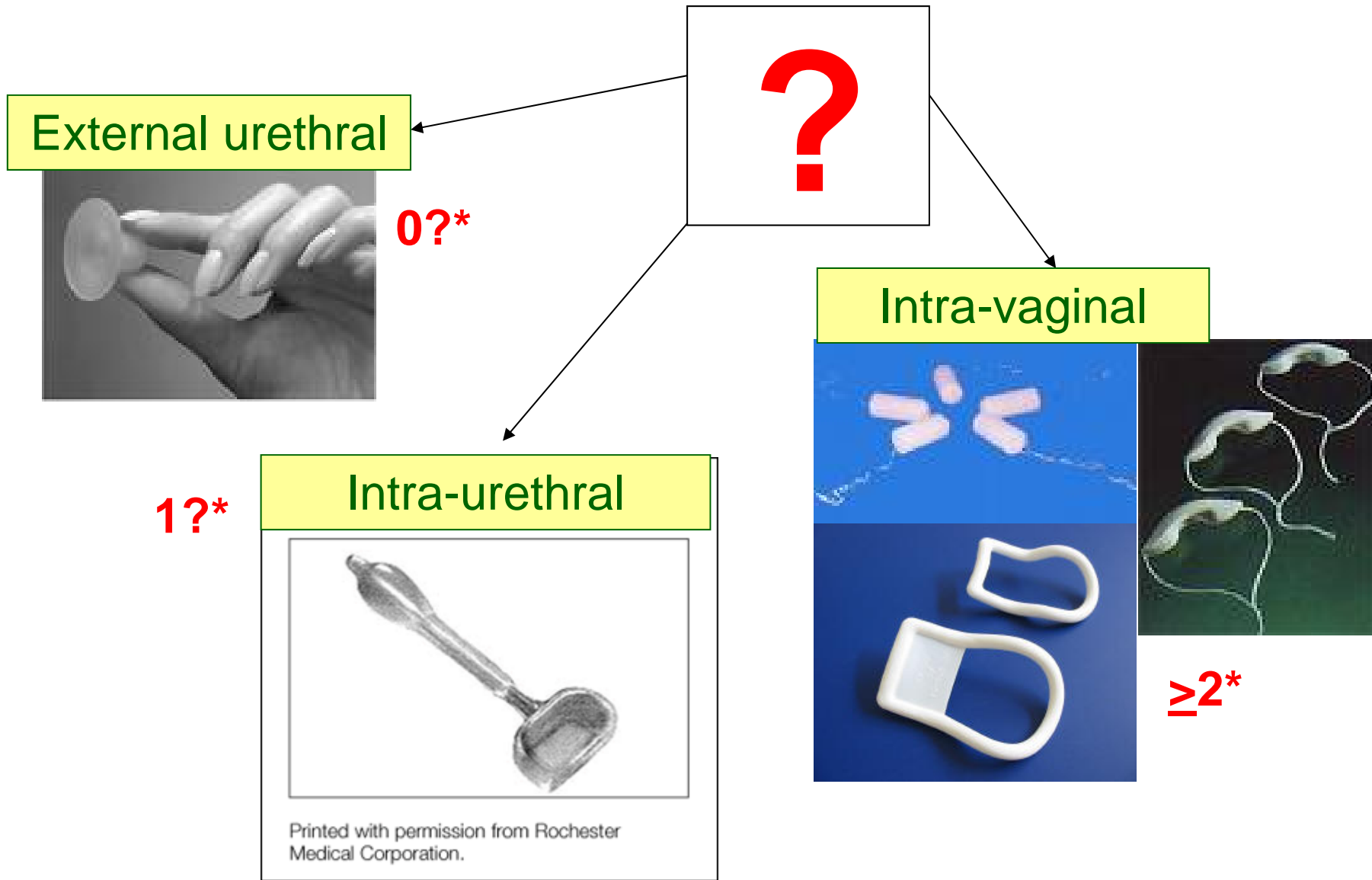
Pads



Mechanical devices



# Women, light UI: mechanical devices



\* Currently commercially available

# Women, light UI: mechanical devices



## Evidence:

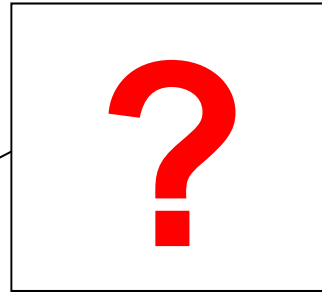
>20 trials, mostly pre/post (most devices no longer available) (Level 2/3)

New Cochrane (Shaikh, 2007).

## Recommendations

Characteristics / priorities / contexts that:	
Favour use	Discourage use
<ul style="list-style-type: none"> <li>• Incontinence is predominantly stress (C)</li> <li>• Manual dexterity is good (C)</li> <li>• Sound cognition (C)</li> <li>• Device concept is acceptable / preferred (C)</li> <li>• Preventing leakage rather than containing it is attractive (C)</li> </ul>	<ul style="list-style-type: none"> <li>• Incontinence has a significant urgency component (C)</li> <li>• Concerns over risks of UTI are high (intra-urethral devices) (C)</li> </ul>

# Women, light UI, main product categories



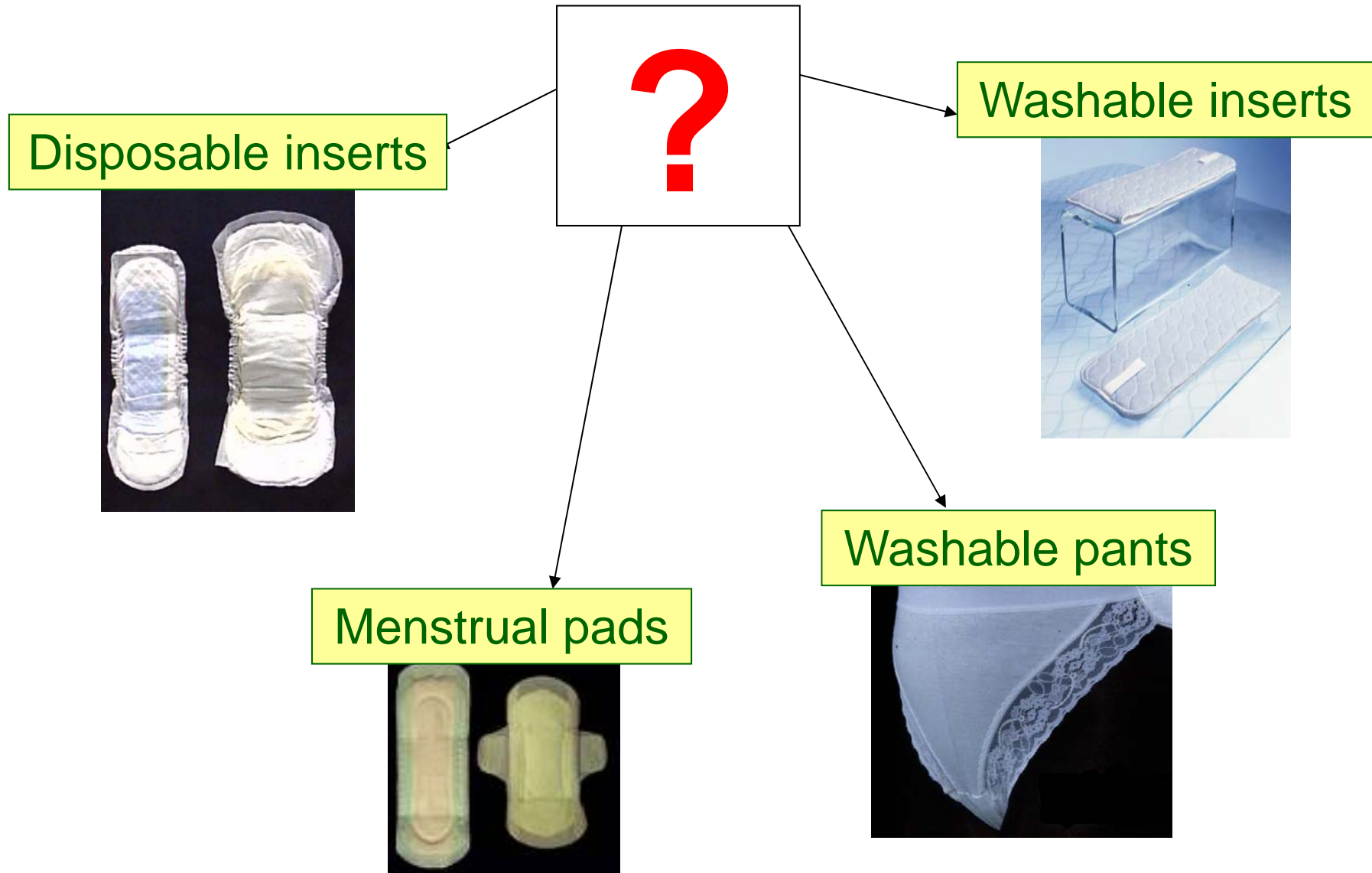
Pads



Mechanical devices



# Women, light UI, pad categories



# Women, light UI: pads

## Evidence:

One published trial (Baker 1996) compared different designs but products were more than 10 years old.

Studies of single designs (Clarke-O'Neill 2004; 2002), engineered pads (Thornburn 1997).

New clinical trial compared the four main designs of absorbents (Fader, 2008)

Fader M, Cottenden AM, Getliffe K. Absorbent products for light urinary incontinence in women. *Cochrane Database of Systematic Reviews* 2007, Issue 2.

Level 2/3

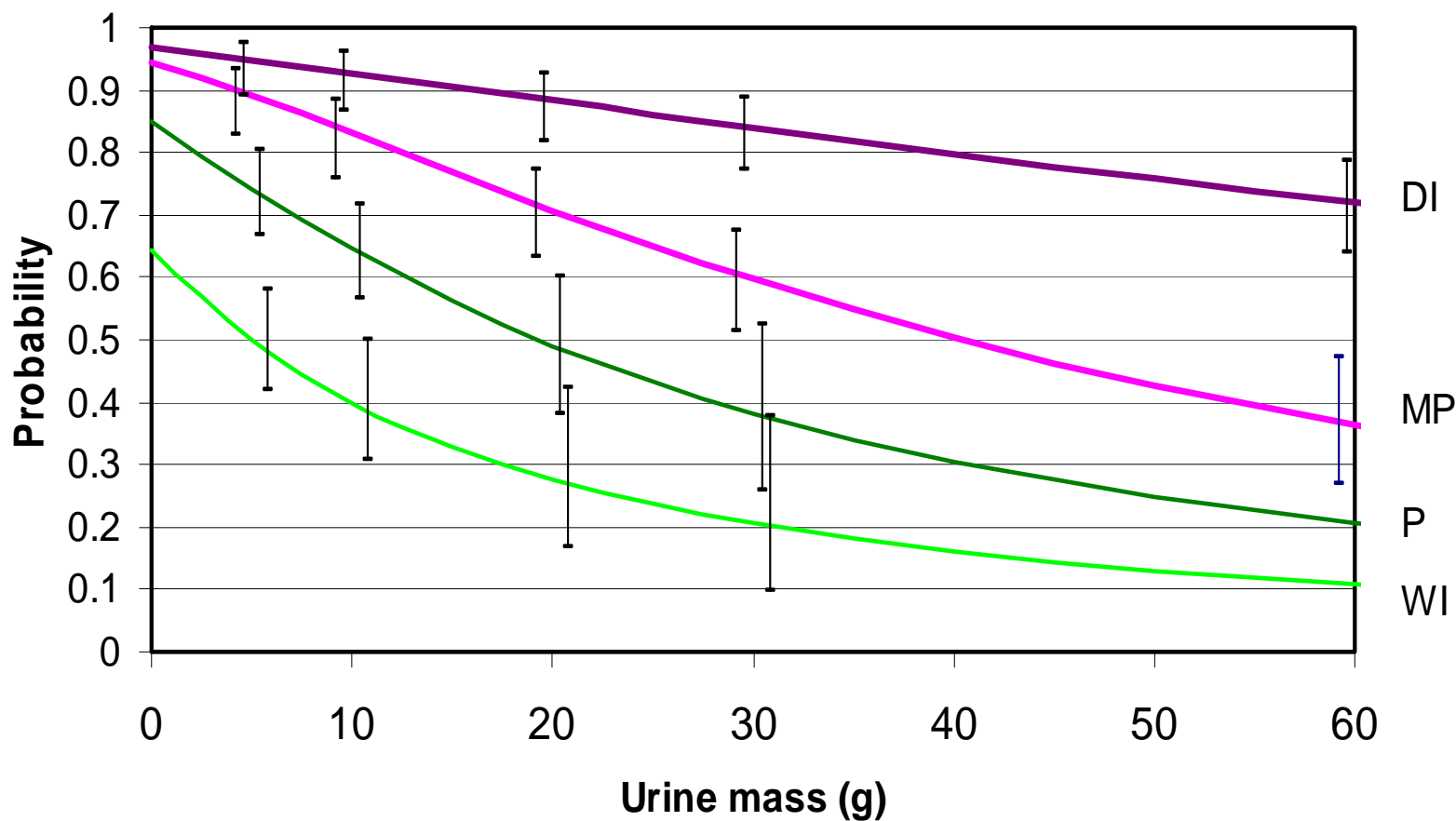
## Top 5 pad characteristics for lightly incontinent women

<b>Top 5 characteristics (day)</b>	<b>% of women (N=99)</b>	<b>Top 5 characteristics (night)</b>	<b>% of women (N=81)</b>
To hold urine without leakage	84	To hold urine without leakage	94
To contain smell	76	To stay in place	78
To stay in place	54	To contain smell	54
To be discrete	41	To be comfortable when wet	54
To be comfortable when wet	40	To keep skin dry	48

# Leakage performance of designs

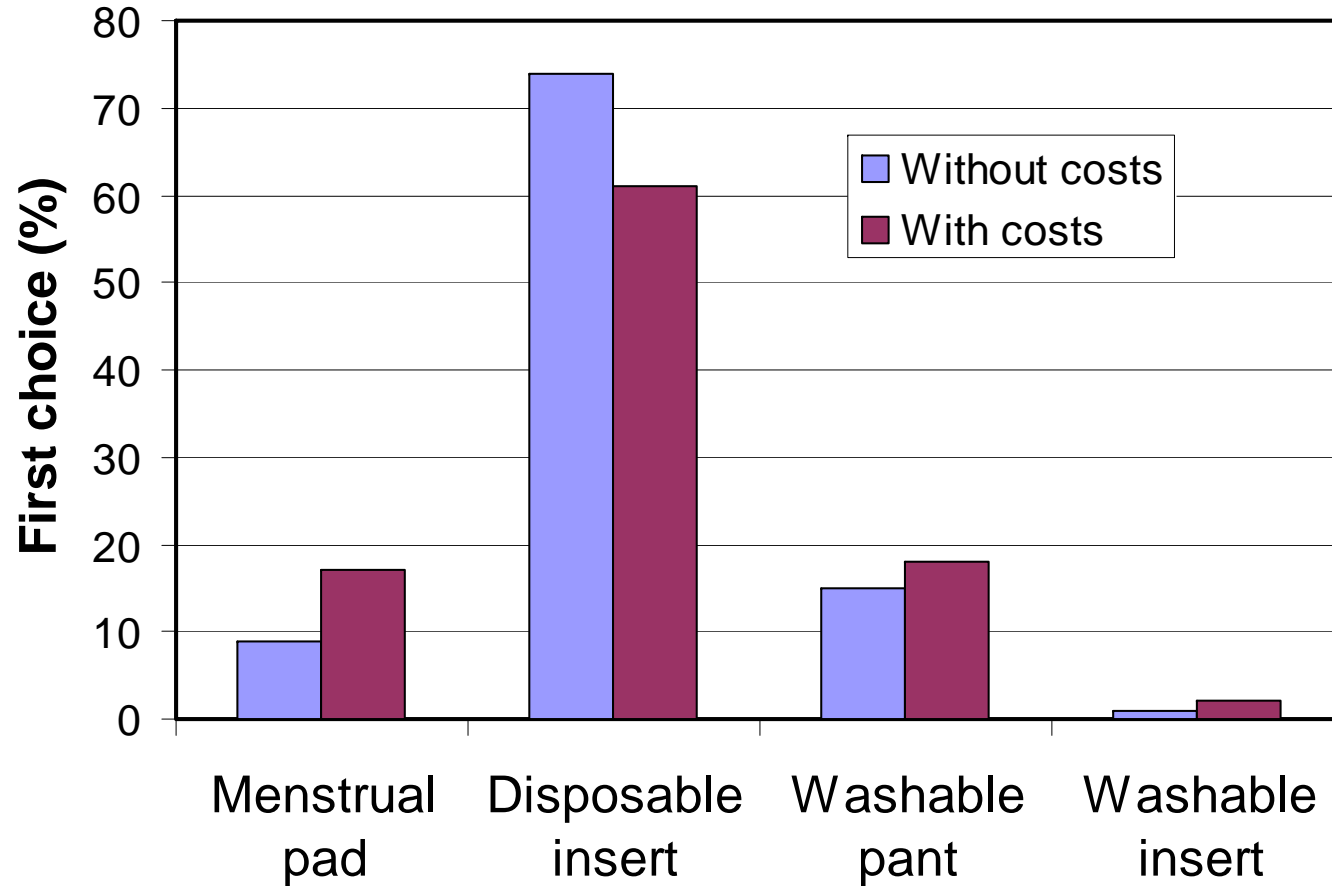
MP = Menstrual Pad    DI = Disposable Insert  
P = Washable pants    WI = Washable Insert

not leaking at all



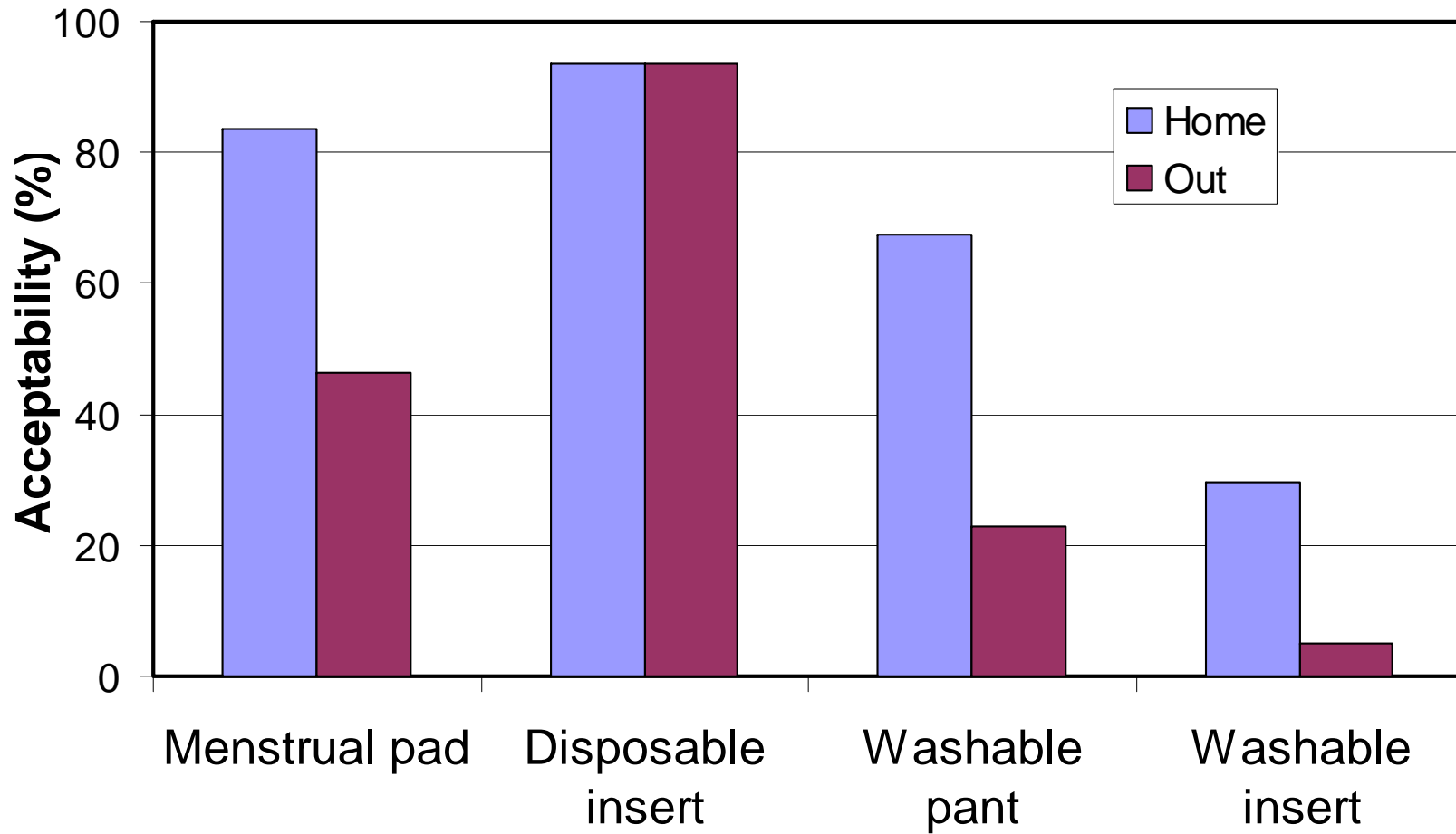
# Women, light UI: pads

Evidence



# Women, light UI: pads

Evidence



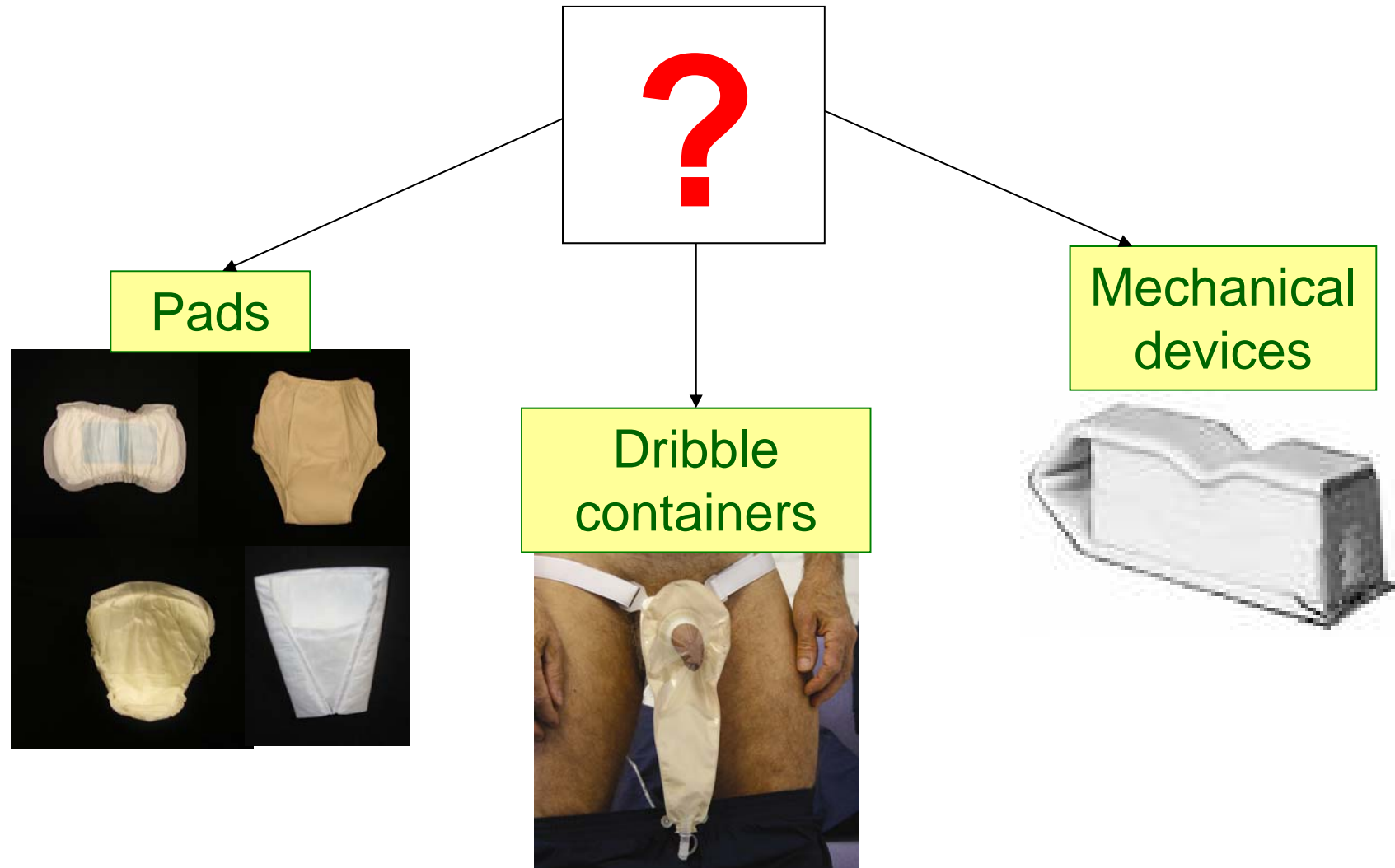
Potential for mix and match

# Women, light UI:pads

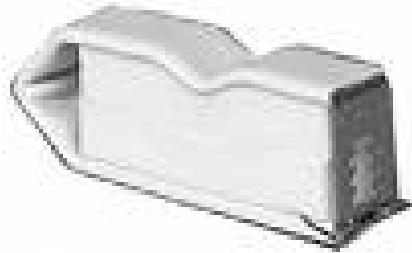
## Recommendations

Characteristics / priorities / contexts that:		
	Favour use	Discourage use
Disposable Inserts	<ul style="list-style-type: none"> <li>• Reliable leakage prevention is a priority (B)</li> </ul>	<ul style="list-style-type: none"> <li>• Low cost is a priority (B)</li> <li>• Discretion is a priority (B)</li> </ul>
Disposable menstrual / sanitary pads	<ul style="list-style-type: none"> <li>• Low cost is a priority (B)</li> </ul>	<ul style="list-style-type: none"> <li>• Incontinence is heavy LIGHT (B)</li> </ul>
Washable Pants	<ul style="list-style-type: none"> <li>• Low cost is a priority (B)</li> <li>• The design concept is acceptable / preferred (B)</li> <li>• Incontinence is light LIGHT (B/C)</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate laundry facilities are not available (C)</li> <li>• The design concept is unacceptable (C)</li> <li>• Carrying used pads when out is an issue (C)</li> <li>• Incontinence is heavy LIGHT (B/C)</li> </ul>
Washable Inserts	<ul style="list-style-type: none"> <li>• As for washable pants, but prefer separate pad (B/C)</li> </ul>	<ul style="list-style-type: none"> <li>• As for washable pants (B/C)</li> </ul>

# Men: light UI, main product categories



# Men, light (and heavy) UI: mechanical devices



Evidence: Moore 2004 (Level 3)

## Recommendations

Characteristics / priorities / contexts that:	
Favour use	Discourage use
<ul style="list-style-type: none"><li>• Highly motivated (C)</li><li>• Periodic / intermittent use (C)</li><li>• Incontinence is predominantly stress (C)</li><li>• Device concept is acceptable / preferred (C)</li><li>• Preventing leakage rather than containing it is attractive (C)</li></ul>	<ul style="list-style-type: none"><li>• Incontinence has a significant urgency element (C)</li><li>• Doubtful level of cognition (C)</li><li>• Risk of skin / tissue damage (C)</li><li>• Bladder sensation poor (C)</li><li>• Poor dexterity (C)</li></ul>

Skilled fitting by a professional is needed.

# Men, light UI: dribble containers

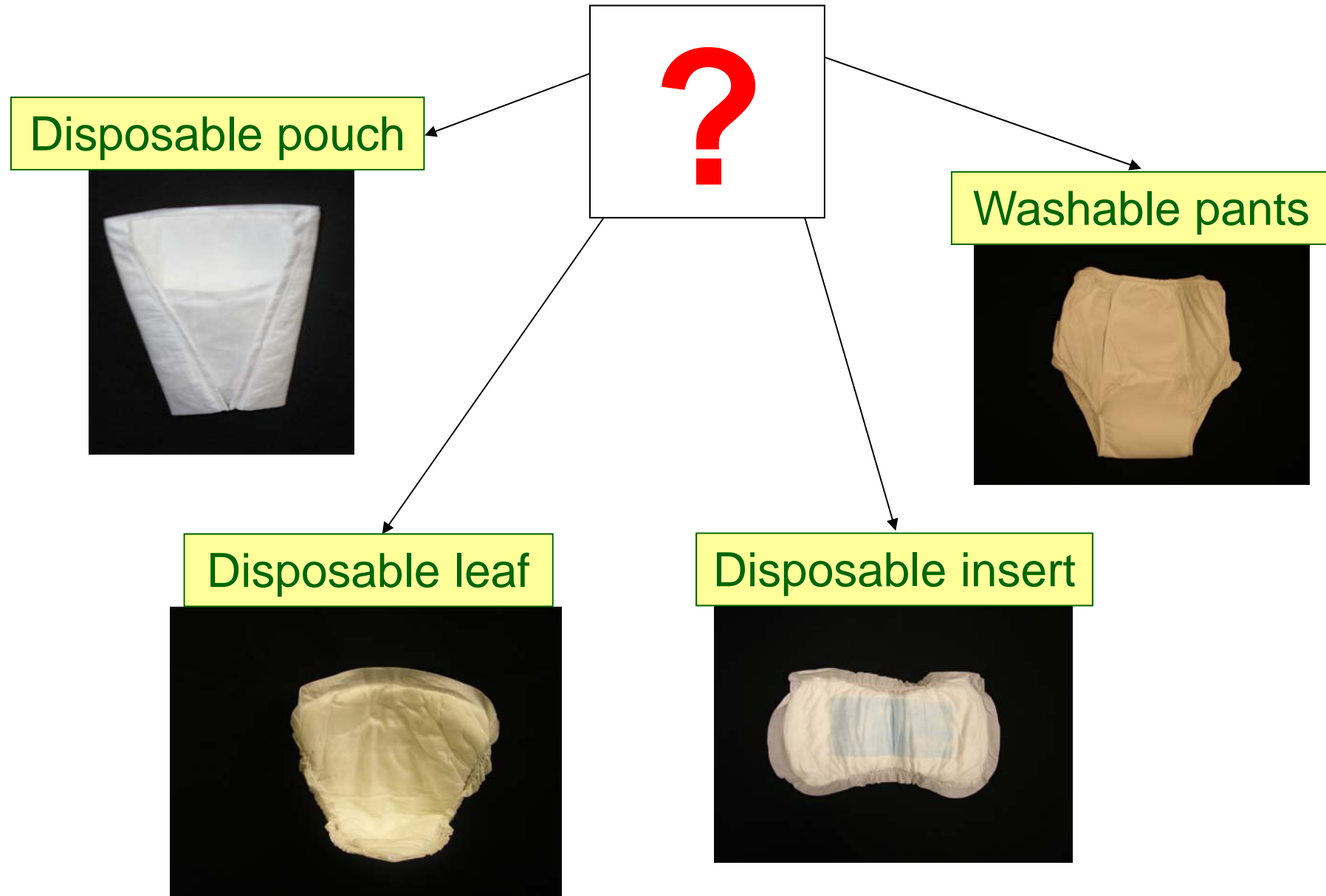


Evidence: No trials (Level 4)

## Recommendations

Characteristics / priorities / contexts that:	
Favour use	Discourage use
<ul style="list-style-type: none"><li>• Device concept is acceptable / preferred (C)</li></ul>	<ul style="list-style-type: none"><li>• Unknown</li></ul>

# Men, light UI, pad categories



# Men, light UI: pads

## Evidence:

One published trial compared the four main designs of absorbents (Fader et al. 2006). (Level 2)

## Overall design performance:

	Good / very good (%)	OK (%)	Poor / very poor (%)
Disposable Leafs	58	25	17
Disposable Pouches	27	21	52
Washable pants	49	9	42
Disposable inserts	48	29	23

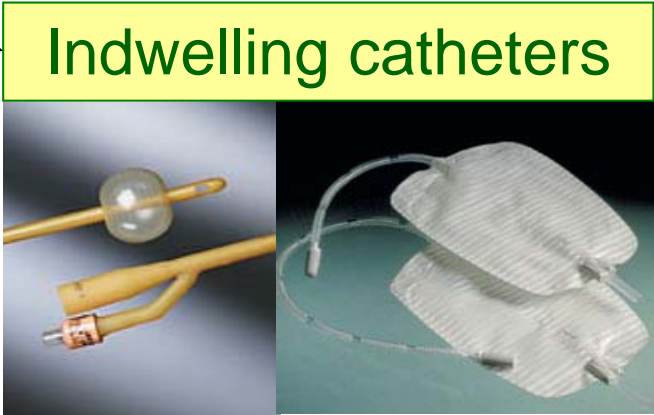
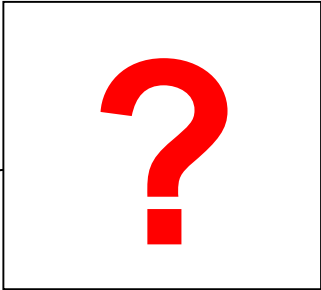
# Men, light UI: pads

## Recommendations

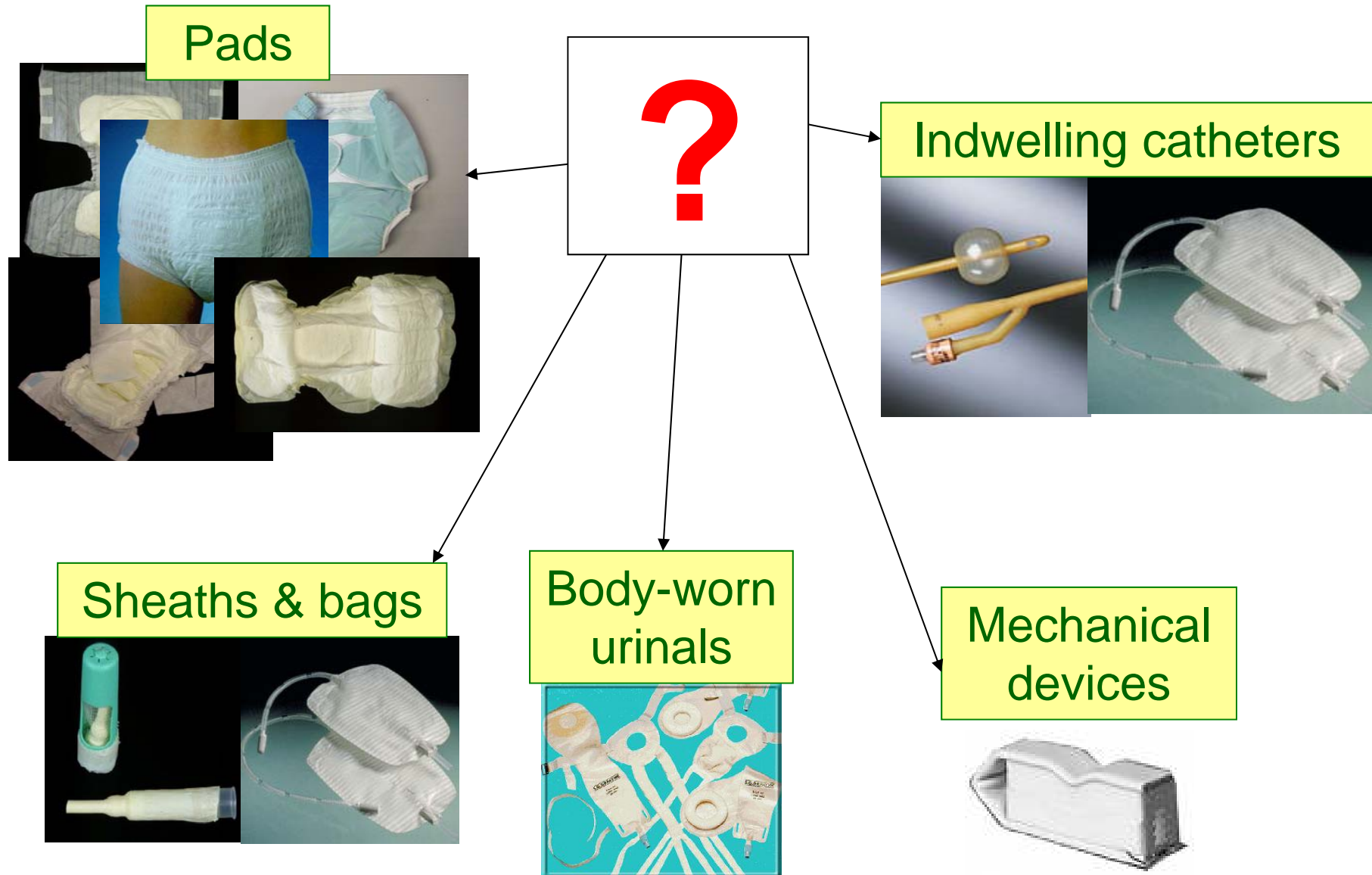
Characteristics / priorities / contexts that:		
	Favour use	Discourage use
Disposable pouches	<ul style="list-style-type: none"> <li>• Discretion is a priority (B/C)</li> <li>• Using a specifically male product is important (C)</li> </ul>	<ul style="list-style-type: none"> <li>• Penis is retracted (C)</li> <li>• Incontinence is heavy LIGHT (B/C)</li> </ul>
Disposable leafs *	<ul style="list-style-type: none"> <li>• In general (B/C)</li> </ul>	
Disposable inserts *	<ul style="list-style-type: none"> <li>• Low cost is a priority (B/C)</li> <li>• Male-specific product unimportant (C)</li> </ul>	
Washables *	<ul style="list-style-type: none"> <li>• Incontinence is light LIGHT (B/C)</li> <li>• Low cost is a priority (B/C)</li> <li>• Design concept is acceptable / preferred (C)</li> <li>• User is mobile &amp; active (B/C)</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate laundry facilities are not available (B/C)</li> <li>• Design concept is unacceptable (B/C)</li> <li>• Carrying used pads when out is an issue (B/C)</li> <li>• Incontinence is heavy LIGHT (B/C)</li> </ul>

\* Appropriate whether or not penis is retracted.

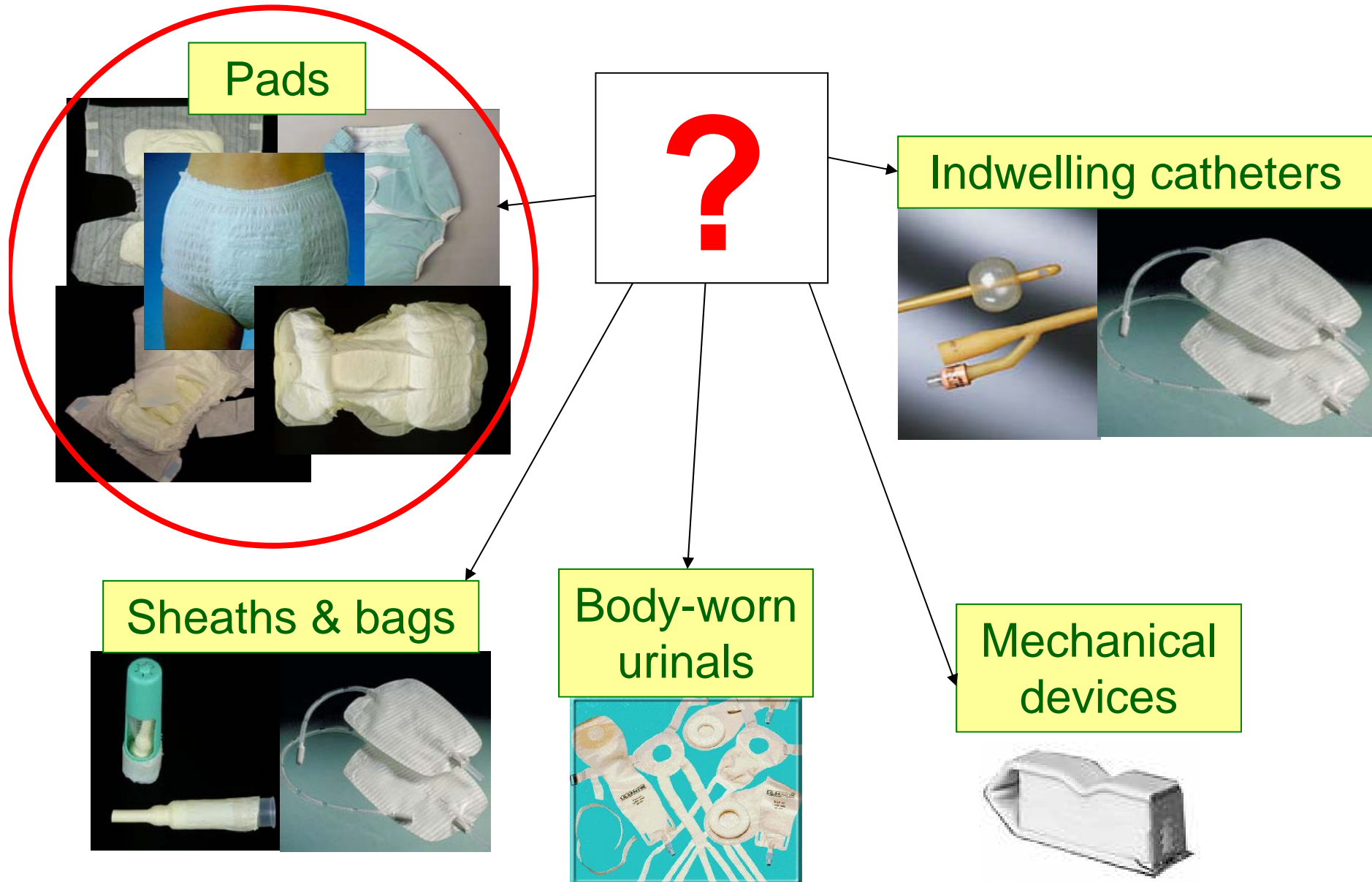
# Women, heavy UI, main product categories



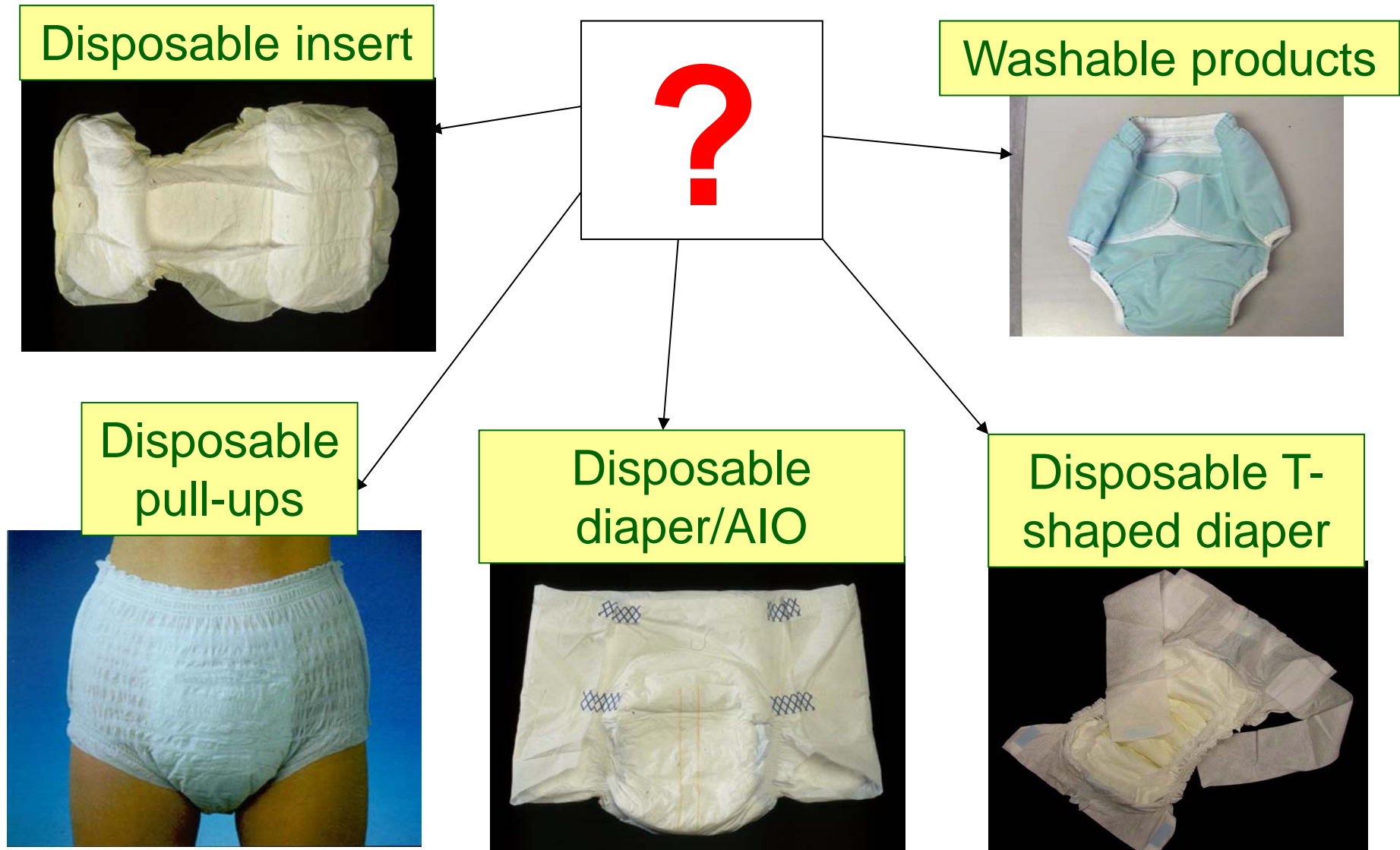
# Men, heavy UI, main product categories



# Men, heavy UI, main product categories



# Men & women, heavy UI, pad categories



# Men & women, heavy UI: pads

## Evidence

Disposable bodyworn designs; since 1990 few trials:

- Specially engineered products (Clancy 1994)
- Single design group (Fader 1997, Pettersson 1998)
- Validation of laboratory study (Cottenden 1993)

Washable bodyworn designs:

- Small pilot study (Macaulay 2004)

Washable versus disposable bodyworn designs

- 7 trials from 1980-1994

Comparisons of different designs, disposables & washables:

- Fader et al., 2008

Level 2-3

# Men & women, heavy UI: pads

Evidence

Top 5 characteristics stated by carers of nursing home residents with moderate / heavy incontinence

Top 5 characteristics	% of care staff (N=68)
To hold urine without leaking	75
To keep skin dry	53
To be comfortable	50
To be easy to put on	37
To contain smell	31

Fader et al. 2008

# Men & Women, heavy UI: pads

Evidence

## Preferences for different designs (Nursing home residents N=99)

	All-in-one style	Pant style
Able to stand	29%	71%
Not able to stand	55%	45%

All-in-one style = All-in-ones or T-shaped all-in-ones;  
Pant style = insert or pull-up

Fader et al. 2008

# Men & women, heavy UI: pads

Evidence

Top 5 pad characteristics for moderate / heavily inco. men & women in the community

Top 5 characteristics (day)	% of men & women (N=77)	Top 5 characteristics (night)	% of men & woments (N=77)
To hold urine without leakage	93	To hold urine without leakage	96
To contain smell	57	To stay in place	69
To stay in place	51	To be comfortable when wet	54
To be discrete	46	Fit of the pad	43
Fit of the pad	43	To keep skin dry	37

Fader et al. 2008

# Men & women, heavy UI: pads

Evidence

## Preferences for different designs (community)

Men: 49 Women: 36		All-in-one (%)	T-shape (%)	Wash-able (%)	Pull-up (%)	Insert (%)
Day	Men	43	24	6	20	6
	Women	11	11	0	61	16
Night	Men	24	10	53	8	4
	Women	8	8	11	53	22

Fader et al. 2008

# Men & women, heavy UI: pads

Evidence

## Preferences for different designs (community)

Men: 49 Women: 36		All-in-one (%)	T-shape (%)	Wash-able (%)	Pull-up (%)	Insert (%)
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Fader et al. 2008

# Men & women, heavy UI: pads

## Recommendations

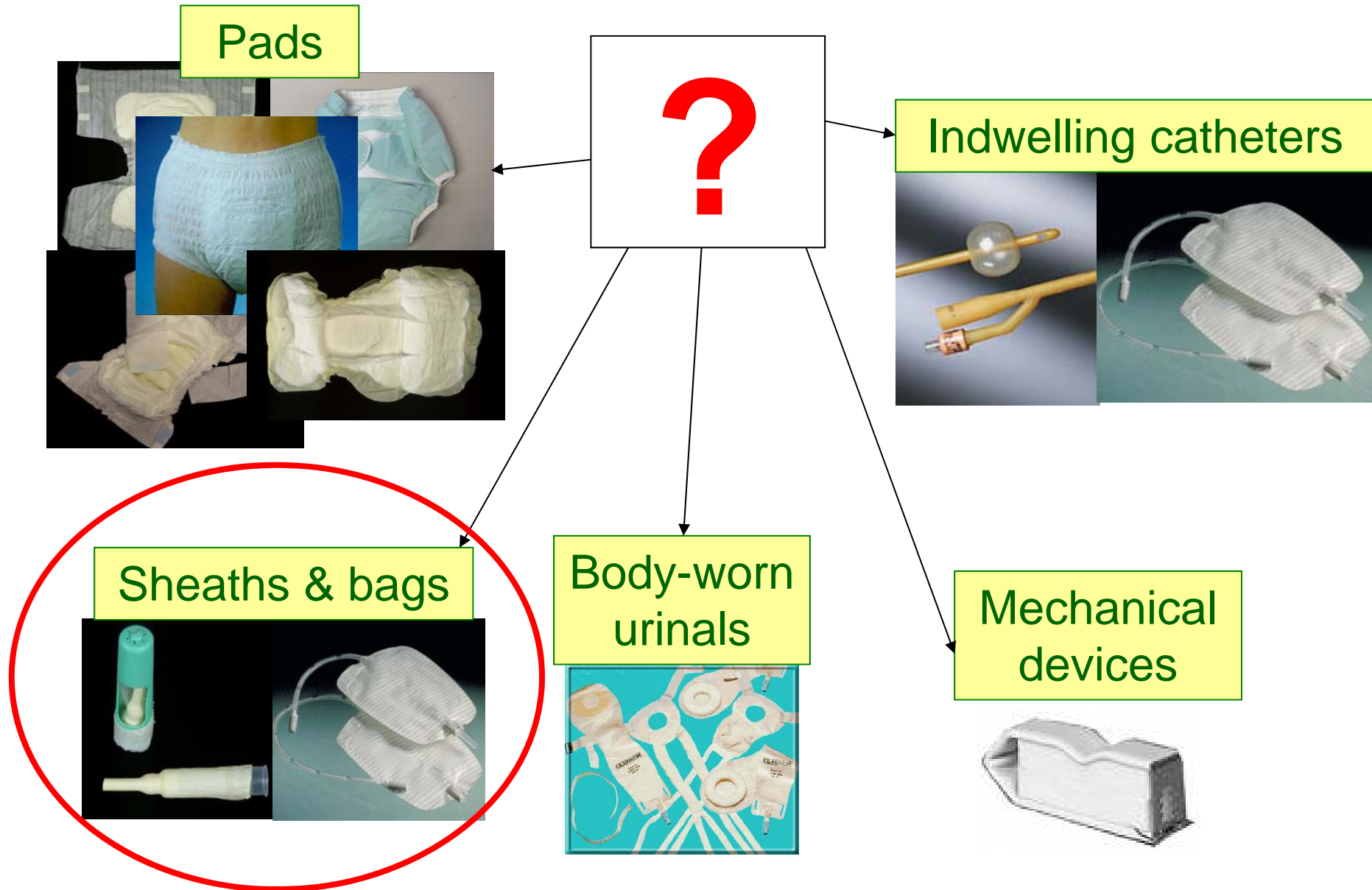
Characteristics / priorities / contexts that:		
	Favour use	Discourage use
Disposable inserts	<ul style="list-style-type: none"> <li>• Carer is needed for pad change and user can stand (B/C)</li> <li>• Discretion is a priority (B/C)</li> <li>• Ease of putting on is a priority (B/C)</li> <li>• Female (B/C)</li> </ul>	<ul style="list-style-type: none"> <li>• Incontinence is heavy HEAVY (B/C)</li> <li>• Mobile and active (C)</li> </ul>
Disposable pull-ups	<ul style="list-style-type: none"> <li>• Carer is needed for pad change and user can stand (B/C)</li> <li>• Reliable containment of leakage is a priority (B/C)</li> <li>• Ease of putting on is a priority (B/C)</li> <li>• Discretion is a priority (B/C)</li> <li>• Female (B/C)</li> </ul>	<ul style="list-style-type: none"> <li>• Removal of clothing for pad changing is an issue (B/C)</li> <li>• Low cost is a priority (B/C)</li> <li>• Night time user, with a carer (B/C)</li> </ul>

# Men & women, heavy UI: pads

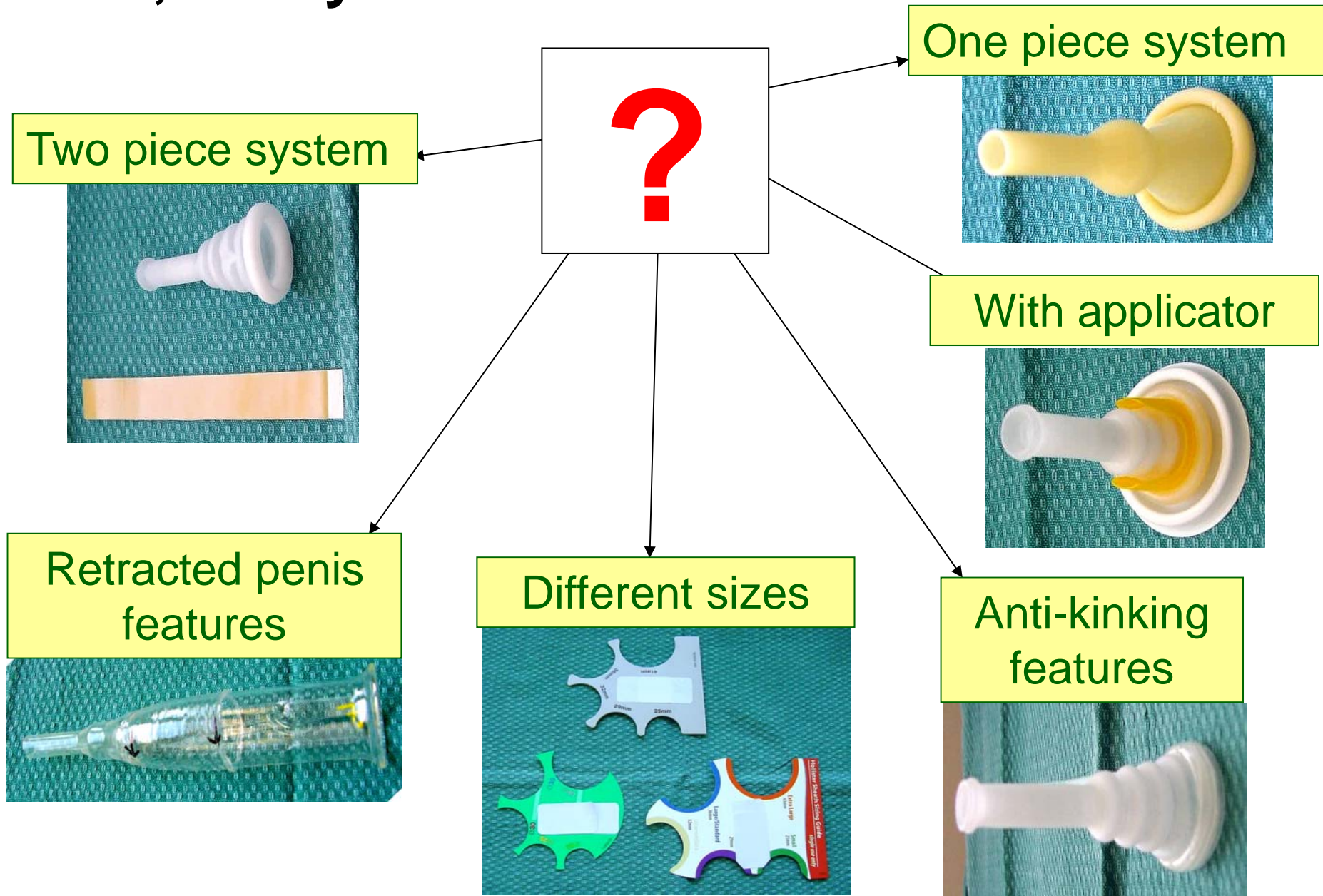
## Recommendations

Characteristics / priorities / contexts that:		
	Favour use	Discourage use
Disposable all-in-ones	<ul style="list-style-type: none"> <li>• Incontinence is heavy HEAVY (B/C)</li> <li>• User can not stand for a pad change (B/C)</li> <li>• Male (B/C)</li> </ul>	<ul style="list-style-type: none"> <li>• Discretion is a priority (B/C)</li> </ul>
Disposable T-shaped pads	<ul style="list-style-type: none"> <li>• Reliable containment of leakage is a priority (B/C)</li> <li>• Male (B/C)</li> </ul>	
Washable bodyworn	<ul style="list-style-type: none"> <li>• At night, if incontinence is heavy HEAVY (B/C)</li> <li>• Male (B/C)</li> </ul>	<ul style="list-style-type: none"> <li>• Adequate laundry facilities are not available (B/C)</li> <li>• The concept is unacceptable (B/C)</li> <li>• Discretion and appearance are a priority (B/C)</li> </ul>

# Men, heavy UI, main product categories



# Men, heavy UI: sheaths



# Men, heavy UI: sheaths

## Evidence:

3 controlled evaluations (Goldyn et al. 1992, Medical Devices Agency 1995, Fader et al. 2001), and a market survey (Nichols and Balis 2000)

A multi-centre crossover study (n=36) compared a previous market leader adhesive integral sheath with a new adhesive integral sheath (Pemberton et al. 2006)

A prospective randomised unblinded controlled trial compared sheaths and indwelling catheters in terms of infections, patient satisfaction and beneficence (Saint et al 2006)

(Level 2-3)



## **Key sheath issues for men and their caregivers**

International survey of 216 men who had used sheaths for at least; 19 sheath brands, questionnaire with Lickert scale (Nichols and Balis, 2000)

- Security (staying in place / freedom from leakage).
- Comfort.
- Ease of application and removal.

# Men, heavy UI: sheaths (and drainage bags)

## Recommendations

Characteristics / priorities / contexts that:	
Favour use	Discourage use
<ul style="list-style-type: none"><li>• Acceptable / preferred to pads (C)</li><li>• Minimal physical intervention is a priority (C)</li><li>• Good dexterity (C)</li><li>• Sound cognition (C)</li></ul>	<ul style="list-style-type: none"><li>• Local skin breakdown (C)</li><li>• Bacteruria, UTI (C)</li><li>• Carer / user unable / reluctant to apply (C)</li></ul>

NB Less risk of bacteruria, recurrent UTIs or death than indwelling catheters (C)

NB More comfortable than indwelling catheters (C)

Sheaths with integral adhesive are more popular than sheaths with separate adhesive.

Sheath applicators are often ineffective and unpopular.

# Men and women, heavy UI: drainage bags



# Men and women: drainage bags



## Evidence:

4 comparative evaluations (>1990)

EPIC (infection control) guidelines 2007

Level 2-3

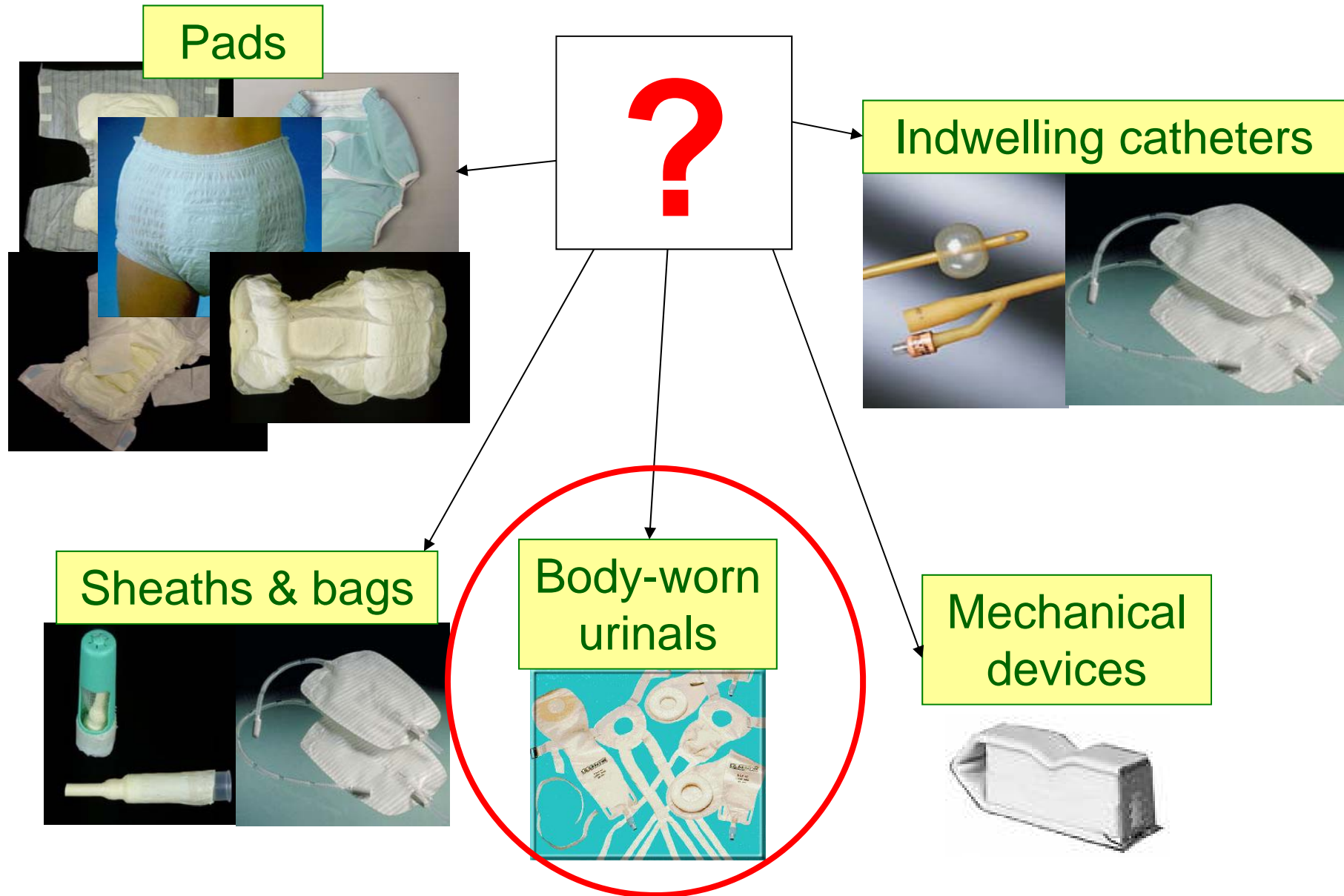
## Recommendations

Pay attention to taps (discretion versus ease of use) and straps.

## Issues

- Bag sterility requirement for acute care settings - ? Requirement for community settings
- Research to provide evidence to underpin practice (bag change frequency, use of antiseptic agents, bag position,...)

# Men, heavy UI, main product categories



# Men, heavy UI: bodyworn urinals



Evidence: No trials (Level 4)

## Recommendations

Characteristics / priorities / contexts that:	
Favour use	Discourage use
<ul style="list-style-type: none"><li>• Desire to avoid pads (C)</li><li>• Concept acceptable / preferred (C)</li><li>• Mobile (not wheelchair user) (C)</li></ul>	<ul style="list-style-type: none"><li>• Latex / materials allergy (C)</li></ul>

# Products for toileting, urinary retention, urinary incontinence and faecal incontinence

Pads



Catheters



Bags



Mechanical

**Coming early 2012....  
International continence product advisor  
hosted on the ICS website**

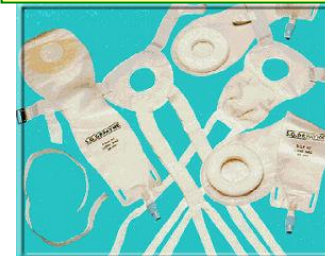
Urinals



FI devices



Body-worn  
urinals





UCL

# Evidence-based guidelines for the selection and use of continence management products

Alan Cottenden  
University College London, England

Continence Foundation of Australia, Melbourne, 16-19 Nov 2011