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Krlin R[1], Latsis M[2], Winters J C[1]
1. *Louisiana State University/Ochsner Clinic Foundation,* ***2.*** *Ochsner Clinic Foundation*

EVALUATING OUTCOMES OF ANTI-INCONTINENCE PROCEDURES: DEVELOPMENT OF A MAIL-BASED PAD KIT

Hypothesis / aims of study

Outcome evaluation for the various treatments of stress urinary incontinence (SUI) is often subjective and a standard definition is lacking. Validated questionnaires exist, but an objective measure is usually difficult to obtain as it involves patient time and ancillary procedures. We developed a mail-based kit which combines a 24 hour pad test and validated questionnaires in an attempt to assess the objective and subjective endpoints as part of an overall outcome assessment. The outpatient kit could be applicable to most practitioners of female pelvic medicine.

Study design, materials and methods

The mail-out pad kit was designed through collaboration with the institutional biosafety committee and the U.S. Postal Service (USPS) and ultimately approved by these agencies prior to achieving Institutional Review Board (IRB) approval. The common mandate was to develop a leak-proof system that met federal and institutional requirements in four specific areas: [1]Specimen Category, [2]Hazard Class, [3]Risk Group, and [4]Shipping Class. [1]*Specimen Category*: As designed, the pad kit is categorized as a diagnostic specimen. As such, no one is liable for transporting an infected specimen unless aware that the patient has a confirmed diagnosis. [2]*Hazard Class*: The pad kid was designated as Class 6: Toxic Substance, Infectious Substance or Diagnostic Specimen. [3]*Risk Group*: The risk in sending this kit via the mail was evaluated by the above parties and placed in Group 1, which includes microorganisms unlikely to cause human or animal disease. The pad kit is not regulated as a hazardous material but is subject to the packing requirements of USPS code 601.10.17.10. [4]*Shipping Class:* The USPS requires a biohazard symbol along with a three-step packing procedure to ship Class 6 specimens as either First-Class, Priority, or Express Mail.

Results

To meet federal requirements, multistep packaging was required: First, the incontinence pad was to be placed in a leak-proof primary receptacle (zip-top bag). Then that receptacle would be placed in a leak-proof secondary vessel (biohazard bag). It had to be able to withstand an internal pressure differential of no less than 95 kPa without leaking as well as to hold an absorbent sheet able take in all of the contained liquids in the event of a spill. Third, the sealed secondary vessel was placed into a strong container (corrugated 11 1/8" x 8 3/4" x 2" box), which was then placed in an orange, moisture-proof, biohazard shipping envelope provided by the USPS. Numerous regulatory guidelines were met to ensure handling safety. The cost of each kit was under $2, and the cost for sending the kit with prepaid return First Class postage was $9.60. The above measures gained approval from the USPS, the institutional biosafety committee, and the IRB.

Interpretation of results

A mail-based pad test kit is feasible and can be administered with approval through a local IRB by using the above guidelines. Costs are reasonable and less than other objective measures of incontinence—i.e., repeat urodynamics. Validation with prospective trials is currently lacking.

Concluding message

A mail-based pad kit to be used in conjunction with a validated questionnaire is feasible and relatively inexpensive and meets the requirements of our institutional biosafety committee and IRB as well as USPS regulations. The kits can be used to combine subjective and objective criteria as part of an overall outcome assessment of the various treatments for SUI.

Specify source of funding or grant	**Institutional Funding**
Is this a clinical trial?	**No**
What were the subjects in the study?	**NONE**