Risk of Urinary Retention
Revision A.4

Human System Risk Board (HSRB)

HSRB CR: SA-07566
Approved 2/13/2025

Risk Custodian Team

SD/Richard Cole
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Purpose

- This package includes:
  - Updates the formats of the LxC Risk matrices from the 3x4 to the 5x5 format

Contents

1. Risk Title and Risk Statement

Risk Title:

Risk of Urinary Retention

Risk Statement:

Given that the space flight environment alters the gravity vector involved in terrestrial micturition and causes physiological changes that may require use of predisposing medications, and that mission operational schedules may limit access to voiding, there is a possibility of performance impact during space flight by significant discomfort from urinary retention and associated urinary tract infection.

2. Risk History

Item	Date	Outcome/Status
HSRB Risk Presentation	02/13/2025	**Decisiona**l – CR SA-07566 HSRB DAGtionary Updates and DAG Corrections; CR approved with modifications. Rev A.4
HSRB Risk Presentation	02/23/2023	**Decisional** – CR SA-05752 HSRB Risk Matrix Format LxC Change from 3x4 to 5x5; CR Approved with Mods, Rev A.3
HSRB Risk Presentation	05/12/2022	**Decisional** – CR SA-05096 HSRB Directed Acyclic Graphs Errata Changes; CR Approved out of board, Rev A.2
HSRB Risk Presentation	12/16/2021	**Decisional** – CR SA-04403 Updates to Risk's Directed Acyclic Graphs (DAGs): Behavioral, Electric Shock, Toxic Exposure, Renal Stone, Urinary Retention and Sleep; CR Approved, Rev A.1
HSRB Risk Presentation	09/19/2019	**Decisional –** CR Approved with Mods. Approved Rev A
Risk Evaluated via CR	03/12/2018	CR evaluation period closed 3/26/2018
HSRB Risk Presentation	04/22/2015	**Decisional** – Action Items (AI-HSRB-14-038, 039 & 14-040) Approved for closure
HSRB Risk Presentation	11/12/2014	**Decisional** – CR Approved with Mods. Approved Risk Baseline
Risk Evaluated via CR	10/02/2014	**Decisional** – Provide entire risk information based on new risk process (JSC 66705)
HSRB Risk Presentation	07/02/2014	**Informational** – Evaluate previous content, assess, and disposition risk based on new process. Risk will be evaluated via CR for baseline.
HSRB Risk Presentation	03/09/2011	**Decisional** – Content reviewed and approved by the board. It included LxC assessment. BASELINED
Risk Evaluated via CR	02/28/2011	**Decisional** – CR Released

3. Executive Summary

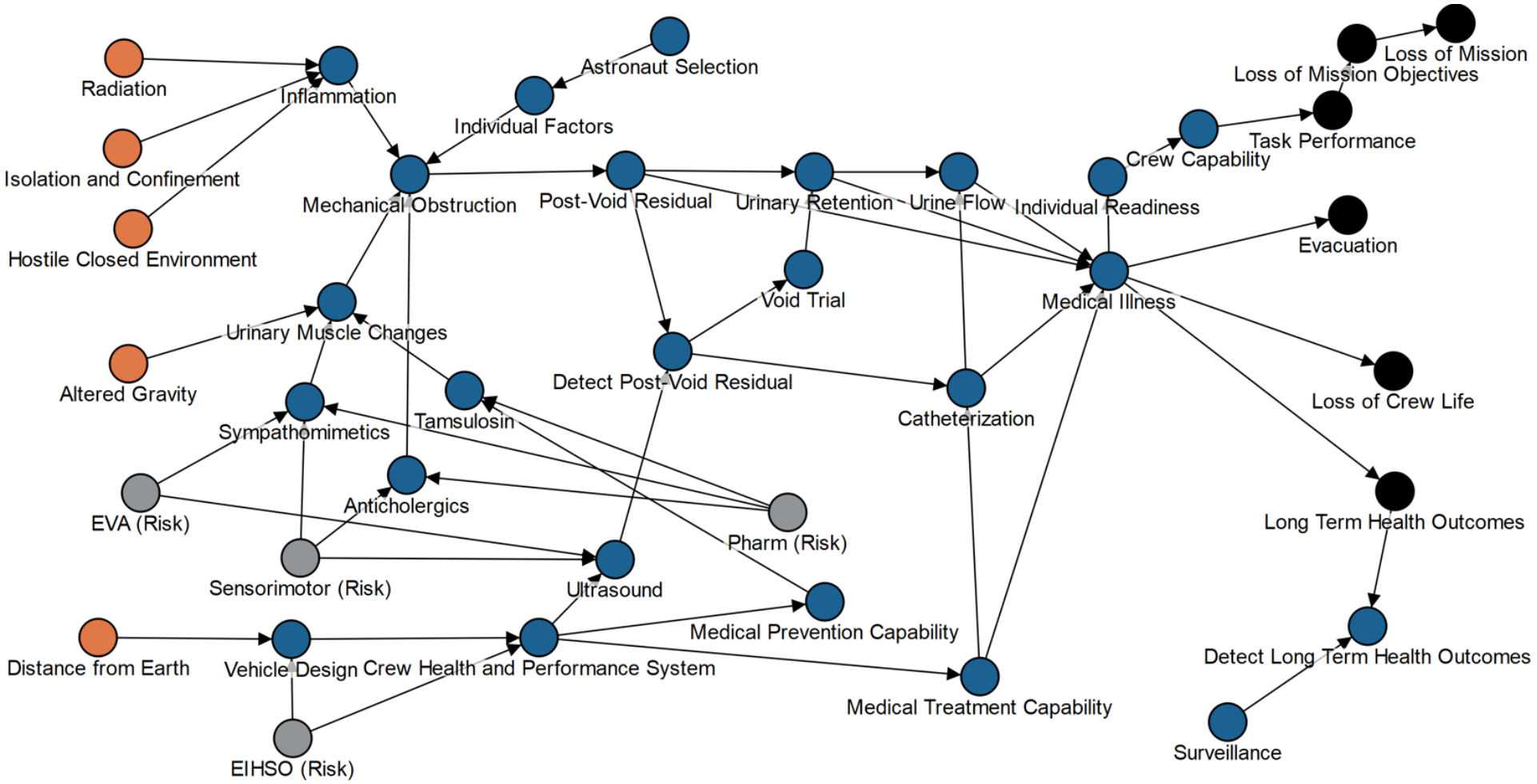
Some basic context

- Symptomatic urinary retention happens in flight and on landing day
- It happens more than we would expect for our populations
- It has a lot of contributing factors that we do not fully understand yet
- It is related to Urinary Tract Infections (UTIs) that can lead to urosepsis
- There are complex causal relationships we should be trying to understand that will be revisited at the end of the presentation

The following are the findings based on the newest evidence:

- Cause of urinary retention is multifactorial
  - Prevalence of each factor may be different inflight vs terrestrial
  - Sex based difference inflight compared to terrestrial
    - Inflight retention rate is higher in females (4.5:1) while terrestrial rate is higher in males (39:1)
  - Promethazine use increases (3X) the risk of developing urinary retention in spaceflight
  - Urinary retention and urinary tract infection (UTI) are highly associated
    - Both, with or without bladder catheterization, but catheterization further increases risk of infection
    - Asymptomatic crewmembers may have increased post void residual that could increase the risk of urinary infection
    - MOG was given catheter recommendations that may reduce infection rate
- Retention risk on postflight day 1, could impact planetary missions upon landing on target celestial body

4. Directed Acyclic Graph (DAG)



Directed Acyclic Graph (DAG) (Narrative)

- The central focus of the Urinary Retention DAG begins with the **Urinary Retention** node which is the point at which the retention of urine in an astronaut reaches a clinically significant level. **Inflammation** can result from the hazards of **Radiation, Hostile Closed Environment, and Isolation and Confinement**. Prior to that, astronauts may retain urine that they are not aware of, and this is called **Post-Void Residual**. Retention may be intentional in some situations. When retained urine begins to affect **Urine Flow**, this can lead to several Medical Illnesses that can affect **Individual Readiness** and **Crew Capability** including:
  - Infectious processes like **Urinary Tract Infections**, **Pyelonephritis** (kidney infection) and potentially **Sepsis** if untreated, can result from **Urinary Retention**.
  - **Renal Colic**, **Retention Pain**, and **Hydronephrosis** can result from **Urinary Retention** or **Urine Flow** disruption.
  - All of these if untreated can potentially lead to **Renal Failure** which has implications for **Evacuation**, **Loss of Crew Life** and **Long-Term Health Outcomes**.
  - Retention of urine can be cause by **Mechanical Obstruction** at the level of the urinary bladder or prostate (in men). Retention may also be intentional in some situations (e.g., not wanting to use MAG). Retention is affected by **Individual Factors** like age, sex, and genetic predispositions and can be caused by
    - **Urinary Muscle Changes** that occur in **Altered Gravity** environments or due to Side Effects of certain medication classes including **Sympathomimetics** and **Anticholinergics** used for **EVA (Risk)** mitigation, **Sensorimotor (Risk)** mitigation, Space Motion Sickness, and congestion.
    - **Inflammation** in the bladder or prostate
- Countermeasures must be designed into the mass and volume allocations for the **Vehicle Design** and **Crew Health and Performance System** to effect risk mitigation. These are affected by the **EIHSO (Risk)** and include:
  - **Ultrasound Monitoring** is used to **Detect Post-Void Residual** when increased, and if severe can inform the use of countermeasures such as a **Void Trial**.
  - **Medical Prevention Capability** such as **Tamsulosin** can help to relax **Urinary Muscle Changes**.
  - **Medical Treatment Capability** such as **Catheterization** may be needed to relieve **Urinary Retention** and prevent the development of other **Medical Illnesses**. Other medical treatments may be needed if **Medical Illness** progresses (i.e., UTI -> Pyelonephritis -> Sepsis).
  - Effectiveness of the **Medical Prevention Capability** and the **Medical Treatment Capability** is dependent on the **Pharm (Risk)**.
- **Long Term Health Outcomes** may occur, and **Surveillance** is needed post-flight and post- mission to help **Detect Long Term Health Outcomes** and characterize the magnitude of the Long-Term Health risk contribution.

5. Risk Summary

Primary Hazard:
Altered gravity (hypo)

Secondary Hazard(s):
Closed environment (spacecraft/spacesuit design)

Countermeasures in use:
Prevention
Ground tests of pharmaceutical side-effects, education of crew on causes of urinary retention and on treatment protocols, preflight training on proper sterile technique for catheterization, and inflight ultrasound evaluation

Monitoring
Ultrasound (PVR and Prostate Size), Dipstick

Intervention
Pharmaceuticals, urinary catheters, ultrasound as adjunct for invasive treatment

Contributing Factors
Obstructive (anatomical), pharmacologic, neurogenic (SAS-Related), psychosocial, myopathic, infectious, gravitational vector (e.g., time on back during launch), increased post void residual, and cohort (primarily sex) factors.

State of Knowledge
Urinary retention (UR) is multifactorial: 1. Sex-based difference in mission compared to terrestrial – males have a higher retention rate on Earth and females have higher ones on orbit. 2. UR appears to be associated with medication use, occurring at any time during a mission whenever medications are in use, including in mission (EVA) and on R+0 (landing day) possibly impacting planetary missions. For example, PMZ increases the likelihood of developing UR threefold. 3. There is also a high association of UR with UTI (UR can cause UTI and vice versa). 4. Holding to urinate on orbit to finish tasks, are contributors to UR.

General Assumptions
- Assume that NASA Standards 3001 have been met
- Countermeasures equivalent to current ISS countermeasures are in use
- Based on the HSRB LxC Matrix and the HSRB DRM Categories

6. LxC Quick look

Current (approved September 2019) 3x4 Matrix

DRM Categories	Mission Type and Duration	LxC Ops	Risk Disposition	LxC LTH	Risk Disposition
Low Earth Orbit (LEO)	Short (<30 days)	3x2	Accepted	1x1	Accepted
	Long (30 d - 1 yr.)	3x2	Accepted	1x1	Accepted
Lunar Orbital (LO)	Short (<30 days)	3x2	Accepted	1x1	Accepted
	Long (30 d - 1 yr.)	3x2	Accepted	1x1	Accepted
Lunar Orbital + Surface (LOS)	Short (<30 days)	3x2	Accepted	1x1	Accepted
	Long (30 d - 1 yr.)	3x2	Accepted	1x1	Accepted
Mars	Preparatory (<1 year)	3x2	Accepted	1x1	Accepted
	Planetary (730-1224 days)	3x2	Accepted	1x1	Accepted

Current (approved February 2023) 5x5 Matrix

DRM Categories	Mission Type and Duration	LxC Ops	Risk Disposition	LxC LTH	Risk Disposition
Low Earth Orbit (LEO)	Short (<30 days)	4x2	Accepted	1x1	Accepted
	Long (30 d - 1 yr.)	4x2	Accepted	1x1	Accepted
Lunar Orbital (LO)	Short (<30 days)	4x2	Accepted	1x1	Accepted
	Long (30 d - 1 yr.)	4x2	Accepted	1x1	Accepted
Lunar Orbital + Surface (LOS)	Short (<30 days)	4x2	Accepted	1x1	Accepted
	Long (30 d - 1 yr.)	4x2	Accepted	1x1	Accepted
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7. HSRB Risk Likelihood x Consequence Matrix

LIKELIHOOD RATING	In-Mission	Flight Recertification	Long Term Health
5 Very High	More likely to happen than not during the mission or probability (P) >10%	Very likely to happen. Controls are insufficient or P> 10%	Likelihood is very high OR >10% excess risk **4x2 Ops:** All
4 High	Likelihood is high during the mission or 1%<P≤10%	Likely to happen. Controls have significant limitations or uncertainties or 1%<P≤ 10%	Likelihood is high OR 6-10% excess risk
3 Moderate	May happen during the mission or 0.1%<P≤1%	Not likely to happen. Controls exist with some limitations or uncertainties or 0.1%<P≤1%	Likelihood is moderate OR 3-6% excess risk
2 Low	Unlikely to happen during the mission or .01%<P≤0.1%	Not expected to happen. Controls have minor limitations or uncertainties or 0.01%<P≤0.1%	Likelihood is low OR 1-6% excess risk **1x1 LTH:** All
1 Very Low	Nearly certain to not occur in-mission or P≤0.01%	Extremely remote possibility that it will happen. Strong controls in place or P≤0.01%	Likelihood is very low OR < 1% excess risk

L x C Matrix

LIKELIHOOD	1	2	3	4	5
5	10	16	20	23	25
4	7	13	18	22	24
3	4	9	15	19	21
2	2	6	11	14	17
1	1	3	5	8	12

CONSEQUENCE

Time frame
Expected Need for Mitigation

Near	0 < 2 Years
Mid	2-7 Years
Far	> 7 Years

Risk Score Card values are constant across all risks and prioritize consequence over likelihood.

CONSEQUENCES		1	2	3	4	5
IN MISSION	Crew Health Impact OR Mission Objectives Impact	Temporary discomfort / Insignificant impact to crew performance and operations – no additional resources required	Minor injury/illness that can be dealt with by crew without ground support, minor crew discomfort / Minor impact to crew performance and operations – requires additional resources (time, consumables)	Significant injury/illness or incapacitation that requires diagnosis and/or treatment support from ground, may affect personal safety / Significant reduction in crew performance, threatens loss of a mission objective	Critical injury/illness of one crew member requiring extended medical intervention and support, may result in temporary disability / Severe reduction of crew performance that results in loss of multiple mission objectives	Death or permanently disabling injury/illness affecting one or more crewmember (LOCL/LOC) / Loss of mission due to crew performance reductions or loss of crew
FLIGHT RECERT	Crew Flight Recertification Status	Immediate flight recertification status	Flight recertification status within 3 months with limited intervention	Flight recertification status within 1 year with nominal intervention or restricted flight status	Flight recertification status requires extended medical intervention and takes > 1 year	Unable to be Recertified for Flight Status, premature career end
LONG TERM HEALTH	Health Outcomes OR Quality of Life	Career related short term self-resolving medical conditions / No impact on quality of life OR independence in activities of daily living	Career related medical conditions manageable with outpatient medical treatments / Minor, short-term impact on quality of life OR rare support required for activities of daily living	Treatable career related medical condition that requires hospitalization for management / Moderate long-term impact on quality of life OR may require some time-limited support for activities of daily living	Chronic career related medical condition requiring intermittent hospitalization or nursing care / Major long-term impact on quality of life OR requires intermittent support for activities of daily living	Career related premature death or permanent disability requiring institutionalization / Chronic debilitating impact on quality of life OR requires continuous support for activities of daily living

Assumptions for Long Term Health Risk Matrix:

- *Long Term Health extends from the end of the post mission time period and covers an astronaut's lifetime.*
- *Conditions considered within the LTH Risk Matrix are those that 1) are related to the astronaut career, 2) are beyond those expected as part of natural aging, and 3) include acute, chronic and latent conditions.*
- *Quality of Life is defined as impact on day-to-day physical and mental functional capability and/or lifetime loss of years*

8. Risk Postures

All DRMs
Operations

4x2	Accepted

- **LxC Drivers for Likelihood**: >1% likelihood based on historical data collected via LSAH query (2014). Incidence includes cases that required catheterization and cases that resolved spontaneously (16 cases/908 person-fights). Regardless of whether catheterization is required, urinary retention can cause significant crew discomfort that impacts performance and require mission resources (e.g., unscheduled PMCs, deferring certain crew activities maybe even EVA). Even a case that resolves "spontaneously" may have benefited from catheterization.

- **LxC Drivers for Consequence**: : It is driven by effects on performance – minor impact to performance requiring additional resources. Even for deep space missions where remote guidance for ultrasound is not available, Crew Medical Officer (CMO) training should include urinary retention diagnosis and treatment using ultrasound and suprapubic bladder aspiration; this countermeasure will maintain the consequence as "low" for these DRM categories.

- **Rationale for Risk Disposition:** Accepted for OPS regarding all DRMs based on the onset timeline combined with the available treatment options.

All DRMs
LTH

1x1	Accepted

- **LxC Drivers for Likelihood:** $\leq$ 0.1% likelihood of chronic consequences

- **LxC Drivers for Consequence:** Severity of consequence is directly tied to the successful treatment of urinary retention regardless of the mission duration; therefore, there are no impacts to quality of life.

- **Rationale for Risk Disposition:** Accepted for LTH regarding all DRMs as inflight episodes will have no impact on the quality of life.

9. Overall Assessment of the Evidence

❖ **Cause of urinary retention is multifactorial**

- Prevalence of each factor may be different inflight vs terrestrial
- Sex based difference inflight compared to terrestrial
  - Inflight retention rate higher in females (4.5:1) while terrestrial rate higher in males (39:1)
  - Several cases of UTI in males have occurred in spaceflight. Matching terrestrial cohorts are almost exclusively females.
- Promethazine use increases (3X) the risk of developing urinary retention in spaceflight
- Urinary retention and urinary tract infection (UTI) are highly associated
  - Both with or without bladder catheterization, but catheterization further increases risk of infection
  - Asymptomatic crewmembers may have increased post void residual that could increase the risk of urinary infection
  - Catheter recommendations that may reduce infection rate were approved by the MOG and provided to HMS for implementation

❖ **Retention risk on postflight day 1, could impact planetary missions upon landing on target celestial body**

10. State of Knowledge – New Evidence

❖ **What is Urinary Retention (UR)?**

- For the purpose of this discussion, urinary retention is the inability, hesitancy, or difficulty to initiate urination. For spaceflight, there are several predisposing factors identified that may lead to urinary retention.

❖ **Urinary Retention Predisposing Factors**

- Obstructive (anatomical) ex. enlarged prostate
- Psychosocial
- Infectious [urinary tract infection (UTI)]
- Cohort
- Gravity Vector
- Pharmacologic
- Neurogenic [space adaptation syndrome (SAS) – Related]
- Myopathic

Incidence Rates (Shuttle vs ISS)

Urinary Ret	Incidence Rates*
Shuttle:	**0.016** events/person flight
ISS:	**0.019** events/person flight

	Shuttle	ISS	Catheter Required	EVA Related	SAS Med Usage
Symptomatic Urinary Retention	**8**	**1**	4	1	7
Bladder fullness/pressure	**2**	**0**	0	0	1
Difficulty initiating/hesitancy	**5**	**0**	0	1	4
TOTAL	**15**	**1**	4	2	12

(*) Data as of February 2018

Sex Differences – Terrestrial vs Spaceflight

- The odds of developing urinary retention inflight are 4.5 times higher among female astronauts.

P<0.01	Retention Rate	95% Confidence Limits	
Female	**0.0510**	*0.0217*	*0.1151*
Male	**0.0111**	*0.0053*	*0.0230*

- Terrestrially urinary retention Male: Female ratio 39:1

Ugare UG, Bassey IA, Udosen EJ, Essiet A, Bassey OO. Management of lower urinary retention in a limited resource setting. Ethiopia Journal of Health Science. 2014 Oct,24(4):329-36.

Promethazine Use

❖ Promethazine (Phenergan)

- The odds of developing urinary retention are **3 times** higher among astronauts who take promethazine.
  - –**2.6% urinary retention rate** if take promethazine

P<0.01	Retention Rate	95% Confidence Limits	
Promethazine	**0.0262**	*0.0139*	*0.0490*
None	**0.0088**	*0.0038*	*0.0197*

Based on US only ISS and all Shuttle crew

Urinary Tract Infection and Catheterization

❖ An astronaut with urinary retention is 25 times more likely to have a UTI

- **14% Infection Rate**
- Urinary retention vs UTI - which is the chicken, and which is the egg?

P<0.0001	Infection Rate	95% Confidence Limits	
Retention	**0.1419**	*0.0498*	*0.3426*
No Retention	**0.0056**	*0.0024*	*0.0129*

Based on all Crew

P=0.4412	Infection Rate	95% Confidence Limits	
Cath	**0.4218**	*0.0178*	*0.9670*
No Cath	**0.1746**	*0.0149*	*0.7472*

❖ An astronaut with a bladder catheter is 2.5 times more likely to have a UTI (not statistically significant; not enough cases to have adequate power)

- **42% Infection Rate**
- Includes cases that prophylaxed with antibiotics

Urinary Tract Infection and Catheterization- cont'd

❖ Taking catheterization out of the picture…

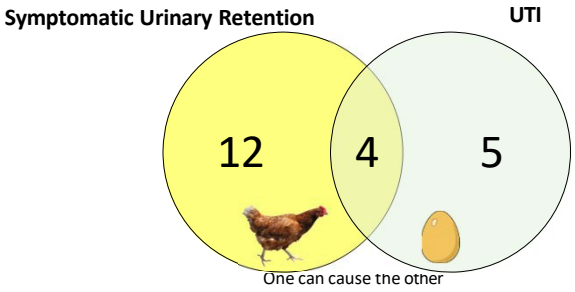
❖ General astronaut population who did NOT get a bladder catheterization

- Those who had urinary retention were **22 times** more likely to have a UTI
- **13% Infection Rate**

P<0.0001	Infection Rate	95% Confidence Limits	
Retention	**0.1299**	*0.0320*	*0.4030*
No Retention	**0.0058**	*0.0024*	*0.0136*

Based on non-Cath Crew

Inflight Summary Numbers (UR+UTI)



	Mission Events (Subjects)
Symptomatic Urinary Retention	12 (10)
Urinary Tract Infection	5 (5)
Symptomatic Urinary Retention + Urinary Tract Infection	4 (3)
Total Events	21 (15)
Total	843 person missions

Missions Included: *STS 1-135 and Expedition 1-52.*

Male UTIs

- **STS (1)**
  - +Urine Dipstick
  - Treated with Cipro
  - Associated with Urinary Retention
- **Apollo (1)#**
  - Cultured- Pseudomonas aeruginosa
- **Early Russian Space Station (1)***
- **USOS ISS Crewmembers (2)***
  - +Dipstick

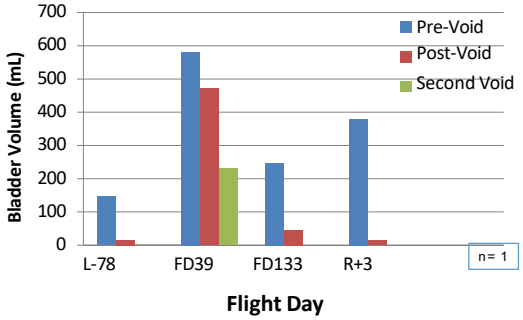
No ultrasound data available to rule out increased PVR

not included due to paper records

* Not in data set due to non-NASA crewmember

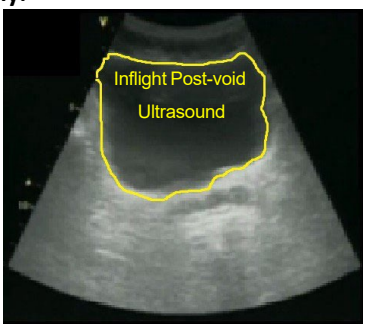
Spaceflight Characterization of Post Void Residual (PVR)

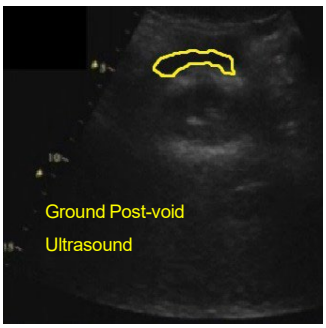
- **ISS Crew Choice Activity - Descriptive Data: (<u>not</u> counted as an episode of <u>Urinary Retention</u> during spaceflight as it was conducted deliberately)**
  - Post-Void Residual (PVR) during Mission – asymptomatic
  - Residual urine after void inflight (<u>471 ml</u> on **FD39** & <u>45 ml</u> on **FD133**) as opposed to (<u>15 ml</u> on ground) Pre/Post
  - No current plan to collect data on other subjects



Spaceflight Characterization of Post Void Residual (PVR) – cont'd

❖ **Ultrasound scans of urinary bladder to characterize PVR in mission and on the ground respectively:**





- Potential decreased sensation to void due to lack of gravity vector may manifest as a subclinical increase in PVR
- Terrestrial UTI risk starts as low as 50 ml PVR

Kelly, C.E. Evaluation of Voiding Dysfunction and Measurement of Bladder Volume. Reviews in Urology. 2004. 6 (suppl. 1), S32-S37. Retrieved from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1472847/pdf/RIU006001_0S32.pdf

Post-flight Urinary Retention (New Evidence)

P<0.001	Retention Rate	95% Confidence Limits	
ISS	**0.0667**	*0.0253*	*0.1644*
Shuttle	**0.0026**	*0.0006*	*0.101*

❖ **ISS**

- 4 events/ 60 person*missions=6.67%
  - –3 of 4 crewmembers attempted to resolve by position adjustment (sitting up or standing). Did not resolve issue.
  - –3 resolved by single use catheterization
  - –1 resolved by sound of running water

❖ **Shuttle**

- 2 events/783 person*missions=0.26%
  - –These events might have been a continuation of inflight event
  - –Both events resolved by catheterization (Inflight onset – Stepaniak et al)

Data Limitations

- **Expeditions 1-52**
- **10 crewmembers with no record of office visit in the EMR within 2 weeks of landing**

Urinary Infection Mission Impact

- **IMM Emergent medical evacuation***
  1. Kidney Stone
  2. Sepsis
  3. Smoke Inhalation
  4. Stroke

- **UTI/Prostatitis**
  - 1 of 3 Russian medical evacuations

    Barratt M. R. & Pool S. L. (Eds.), Principles of Clinical Medicine for Space Flight. 2008. (First Ed., pp. 141). New York, NY: Springer. doi:10.1007/978-0-387-68164-1

- **Apollo case**
  - Symptoms of urosepsis
  - Antibiotic resistance

(*) From IMM Service Request # S-20151123-341, Medical Updates to the ISS PRA Using the IMM

Urinary Catheter and UTI (Systematic Literature Review)

- **Systematic literature review**
  - 80 studies
  - Intermittent and indwelling catheters evaluated separately
  - Compared various catheters infection or bacterial loads
    - No-touch catheter
    - Various catheter tip coatings
      - Silver
      - Antibiotic
      - Hydrophilic
    - Reuse
  - Level of evidence and applicability scored by adding scores from each study and dividing by total possible score

UTI and Catheter Type
(Results of Systematic Literature Review)

Intermittent Catheters (31 studies)

	Hydrophilic	**No-touch**	Reuse
Lower Infection Rate (Improvement)			
No Change in Infection Rate			
Higher Infection Rate (Worsening)			

Reviews: Prieto, 2014: evidence quality too low to draw conclusion

Shamout, 2017: evidence quality low, but likely lower for hydrophilic and aseptic technique

	Hydrophilic	Antibiotic	Silver
Lower Infection Rate (Improvement)			
No Change in Infection Rate			
Higher Infection Rate (Worsening)			

Reviews: Cohen, 1985: infection rate decreased with iodine lubricant

Brosnahan, 2004: combined silver and antibiotic coated may yield small clinical benefit, but further research needed Schumm, 2008: both silver & antibiotic catheters decrease asymptomatic bacteria

Jahn, 2012 & Lam, 2014: Not enough evidence for strong conclusion of catheter type. Silver and antibiotic coated may decrease infections in short durations, but difference is small and questioned clinical significance

Urinary Catheter and UTI
(Limitations of Systematic Literature Review)

- Most studies compared bacteriuria (presence of bacteria in urine) and not actual urinary infections
- Studies centered around unhealthy population
  - Susceptible to infection
    - –Catheterizing multiple times a day
    - –Host factors from reason needing catheter (abnormal anatomy/ spinal cord injury)
- Studies did not include training techniques
- Most reuse catheter studies compare sterilization technique and not to single disposable catheter as gold standard
- Hudson, 2005
  - No-touch study (1 of 2)
    - –Sponsored by manufacturer
    - –Compared no-touch catheter to intentionally placed bacteria load on gloved hand

Urinary Catheter
(Recommendations based on Systematic Literature Review)

- **Recommendations – endorsed by MOG**
  - Catheter coating (silver-alloy, hydrophilic, antibiotic)
    - –Recommend non-urgent incorporation into med kit
  - No-touch intermittent catheters
    - –Recommend non-urgent incorporation into med kit
  - Reusable catheters
    - –Promising for exploration, **not** recommended for current med kits

Risk Mitigation Framework

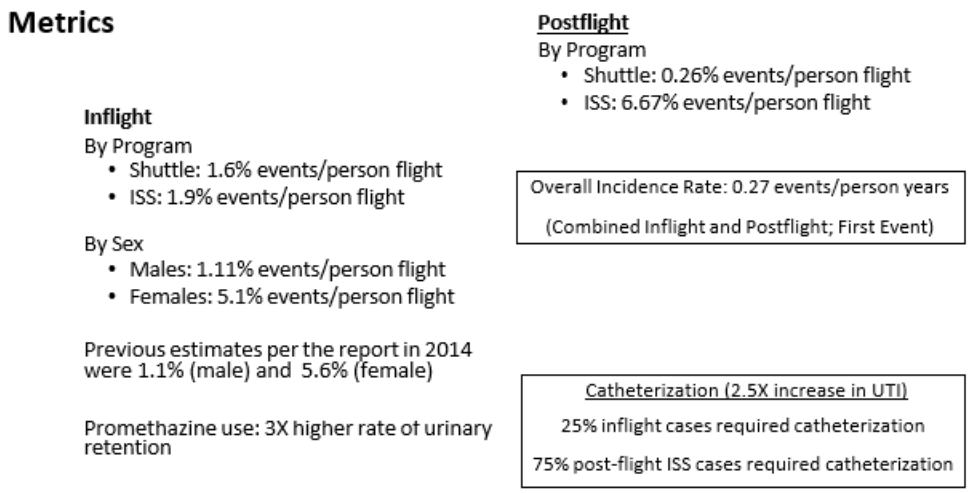
- Tamsulosin (Flomax) available in med kit to improve urination
- Urinary Retention during a mission is generally treated successfully with urinary catheters (straight or indwelling) from medical kit
- Important to ensure adequate resources to support all urinary retention episodes throughout a mission
  - Medication supplies can become depleted
  - Exploration mission shelf-life issues
- Report of two Shuttle flights of a crewmember with positive urine culture for *Escherichia coli* at landing
  - Both cases had bladder catheterizations inflight
  - Both cases resistance to prophylactic antibiotic given at time of bladder catheter placement

Stepaniak PC, Ramchandani, SR, Jones, JA. Acute Urinary Retention Among Astronauts. Aviation, Space, and Environmental Medicine. April 2007;78,4: A5-8

11. Metrics

❖ **2014 LSAH** query found 16 events

- 4 of the 16 cases required catheterization (25%)
- 2 of the 16 cases were related to EVA (12.5%)
- USOS only data
- Among 908 person flights = 0.0176 events/person flight
  - Males: 9 events in 783 person flights = 1.1%
  - Females: 7 events in 125 person flights = 5.6%
  - Previous estimates per the report in 2011 were 0.8% (male) and 6.6% (female)
- Among 17,252.69-person mission days = 0.000927 events/person mission days



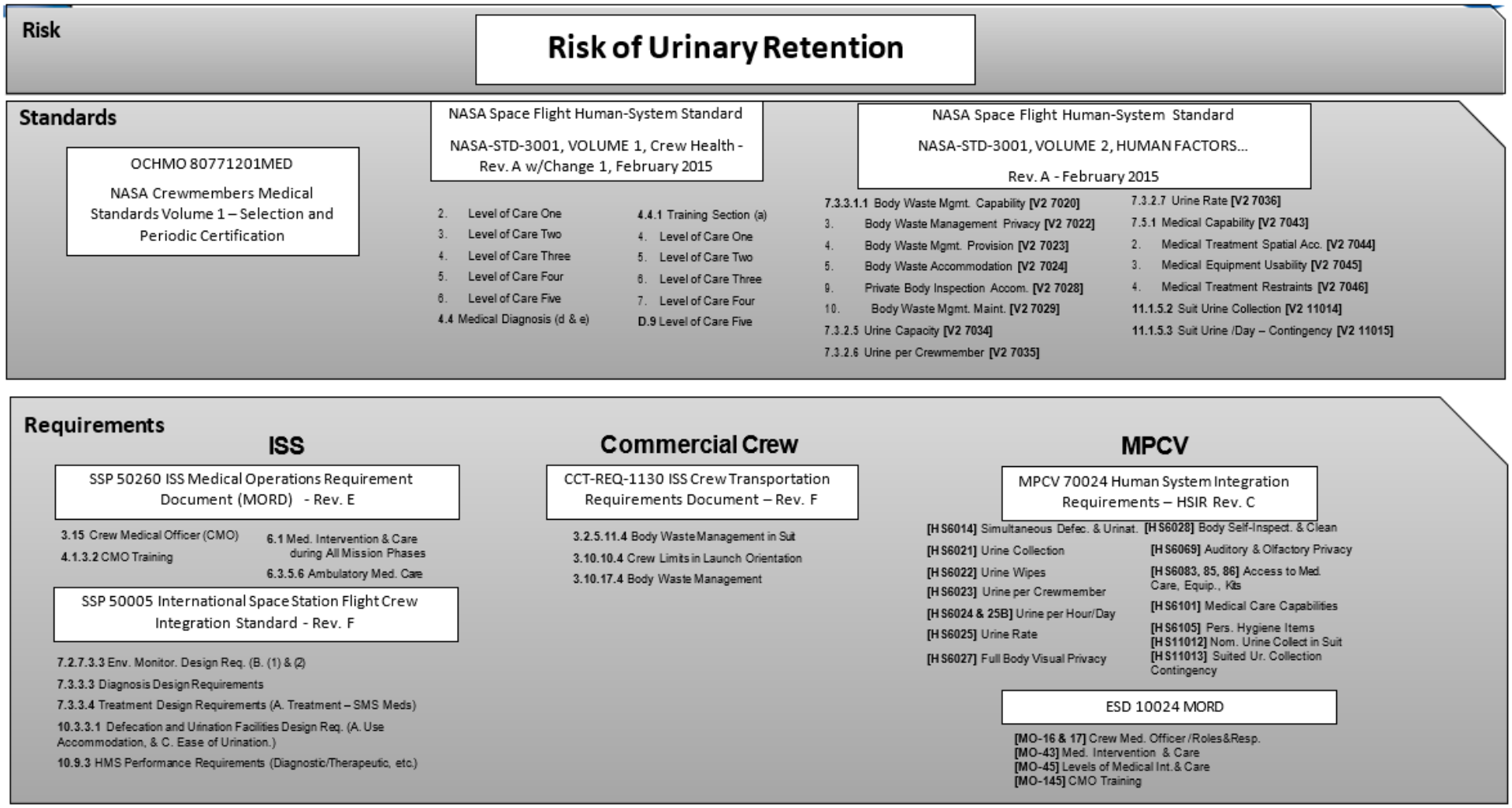
No terrestrial evidence of acute urinary retention has been determined based on promethazine use; but antihistamines and antiarrhythmic drugs increase the odds of developing acute urinary retention (1.11.3.30 Wuerstle et al 2011, Meigs et al., 1999)

12. Risk Mitigation Framework – Color Changes

Yellow -> Green will be achieved when:

- Medical capabilities are identified and fielded/utilized that enable prevention of urinary retention and sufficient intervention to prevent impact to mission objectives while also preventing infection and infection progression.

13. Risk → Standards → Requirements Flow



14. Proposed Standard Updates

None

15. High Value Risk Mitigation Targets

Need to understand:

- The likelihood and consequence of urinary tract infection as related to urinary retention in spaceflight considering contributions of:
  - Medication usage
  - Catheterization techniques
  - Incidence of asymptomatic urinary retention (Post Void Residual)
  - Pre-flight time on back
- The relationship between symptomatic/asymptomatic Urinary Retention and UTI in spaceflight and at landing
- The medical capabilities needed to prevent urinary retention leading to UTI and Urosepsis, especially for exploration missions

Outstanding Questions:

- **Urinary retention risk appears multifactorial, what is the role of:**
  - Preflight urinary diagnoses?
  - Reduced gravity?
  - Medications commonly used in space flight? (Answered for promethazine)
  - Intentionally "holding" urine secondary to operational concerns (ex. EVA, launch pad)?

- **What is the risk over time?**
  - Previously thought to occur early in flight and associated with Space Adaptation Syndrome
  - New evidence points to risk beyond first few days
  - New evidence points to increased probability of UR immediately after landing

- **Is UTI and/or urinary retention risk related to increased Post Void Residual (PVR) during spaceflight?**
  - What is the updated risk of UTI's during space flight? (done)

16. Conclusions

- **Cause of urinary retention is multifactorial**

- **Retention risk on postflight day 1, could impact planetary missions upon landing on target celestial body**

17. Recommendations

Revise Risk Postures from the 3x4 format to the 5x5 format for Likelihood x Consequence.

18. Reference Materials

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Materials Research. Part B, Applied Biomaterials 83, no. 2 (November 2007): 304–13. https://doi.org/10.1002/jbm.b.30796.

19. Acronyms and Abbreviations

CCT	Commercial Crew Transportation
CMO	Crew Medical Officer
CR	Change Request
DAG	Directed Acyclic Graph
ESD	Exploration Systems Directorate
EVA	Extravehicular Activity
HSIR	Human System Integration Requirements
IMM	Integrated Medical Model
ISS	International Space Station
LSAH	Longitudinal Surveillance of Astronaut Health
LxC	Likelihood x Consequence
MOG	Medical Operations Group
MORD	Medical Operations Requirements Document
MPCV	Multi-Purpose Crew Vehicle
Pharm Risk	Risk of Ineffective or Toxic Medications During Long-Duration Exploration Spaceflight
PRA	Probable Risk Assessment
PVR	Post Void Residual
SAS	Space Adaptation Syndrome
SSP	Space Shuttle Program
UTI	Urinary Tract Infection

Appendix - Existing Evidence Base

Existing Evidence — Baseline

Background

- **Male Urinary Tract Infection (UTI)**
  - Extremely rare for healthy males to get UTI
  - Seen in spaceflight
- **Chicken vs Egg**
  - Urinary Tract Infection (UTI) is a cause of urinary retention
    - Terrestrial population: UTI risk with increased post void residual (PVR)
    - Reported risk starts at > 50 ml (PVR)

      Kelly, C.E. Evaluation of Voiding Dysfunction and Measurement of Bladder Volume. *Reviews in Urology*. 2004. 6 (suppl 1), S32-S37. Retrieved from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1472847/pdf/RIU006001_0S32.pdf
    - Increased probability of UTI at 79 ml (PVR)

      Takahashi S, et al., Do patients who complain of lower urinary tract symptoms frequently have clinically significant pyuria?, J Infect Chemother (2014), http://dx.doi.org/10.1016/j.jiac.2014.08.022
- **Bladder catheterization is a cause of UTI**
  - Terrestrial population: once a catheter is placed, the daily incidence of bacteriuria is 3-10%

    Brusch J. L. (Author) Bronze M.S. (Ed.). Catheter-Related Urinary Tract Infection. MedEscape. Jan (2013). Retrieved from: http://emedicine.medscape.com/article/2040035-overview

Evidence

- **Report of two shuttle flights of crew member with positive urine culture for *Escherichia coli* at landing**
  - Both cases had bladder catheterization in-flight
  - First case prophylaxed with antibiotics at time of bladder cath
    - Switched to TMP/SMX (Bactrim) DS after exhausted supply of nitrofurantoin
    - Ground culture was resistant to TMP/SMX (Bactrim) DS while taking this med
  - Second case received antibiotic prophylaxis and still had bacteriuria at landing

Stepaniak PC, Ramchandani, SR, Jones, JA. Acute Urinary Retention Among Astronauts. *Aviation, Space, and Environmental Medicine*. April 2007;78,4: A5-8

Urinary Retention in Limited Resource Setting

Developing Asia and Africa countries

- **Male: Female ratio 39:1**
  - Age 4 to 94
    - –48% in 6th and 7th decade of life
- **Common causes**
  - Prostatic diseases 77%
  - Infections 76%
  - Trauma 12%
  - Congenital 12%
- **Bladder catheterization 76%**
- **Complication**
  - Pyuria 18%
  - Sepsis 18%
  - Hemorrhage from catheter 17%

Ugare UG, Bassey IA, Udosen EJ, Essiet A, Bassey OO. Management of lower urinary retention in a limited resource setting. Ethiopia Journal of Health Science. 2014 Oct,24(4):329-36.

Increased Post Void Residual Management and UTI Risk

- **Catheterization: No current guidelines**
  - <200 Trial without catheterization
  - >400: Catheter in place
- **Pharmacologic management: alpha blocker**
  - Tamsulosin (Flomax) available on ISS
- **Terrestrial UTI from PVR**
  - Reported UTI risk starts at > 50 ml (PVR)

    Kelly, C.E. Evaluation of Voiding Dysfunction and Measurement of Bladder Volume. Reviews in Urology. 2004. 6 (suppl 1), S32-S37. Retrieved from: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1472847/pdf/RIU006001_0S32.pdf
  - Increased probability of UTI at 79 ml (PVR)

    Takahashi S, et al., Do patients who complain of lower urinary tract symptoms frequently have clinically significant pyuria?, J Infect Chemother (2014), http://dx.doi.org/10.1016/j.jiac.2014.08.022
  - Terrestrial UTI correlated with two or more ultrasound readings of 150 ml (PVR)

    May, M., Brookman-Amissah, S., Hoschke, B., Gilfrich, C., Braun, K.-P., & Kendel, F. (2009, June). Post-Void Residual Urine as a Predictor of Urinary Tract Infection—Is There a Cutoff Value in Asymptomatic Men? Journal of Urology, 181, 2540-2544.

Bladder Catheterizations and UTI

- **Terrestrial data**
  - Once a catheter is placed, the daily incidence of bacteriuria is 3-10%

    Brusch J. L. (Author) Bronze M.S. (Ed.). Catheter-Related Urinary Tract Infection. Medscape. Jan (2013). Retrieved from: http://emedicine.medscape.com/article/2040035-overview

Implications

- **Could asymptomatic astronauts be at higher risk for UTIs from increased PVR?**
  - Terrestrial UTI from PVR
    - –Reported UTI risk starts at > 50 ml (PVR)
      Kelly, C.E. Evaluation of Voiding Dysfunction and Measurement of Bladder Volume. Reviews in Urology. 2004. 6 (suppl 1), S32-S37.
      Retrieved from:
      http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1472847/pdf/RIU006001_0S32.pdf
    - –Increased probability of UTI at 79 ml (PVR)
      Takahashi S, et al., Do patients who complain of lower urinary tract symptoms frequently have clinically significant pyuria?, J Infect Chemother (2014), http://dx.doi.org/10.1016/j.jiac.2014.08.022
    - –Terrestrial UTI correlated with two or more ultrasound readings of 150 ml (PVR)
      May, M., Brookman-Amissah, S., Hoschke, B., Gilfrich, C., Braun, K.-P., & Kendel, F. (2009, June). Post-Void Residual Urine as a Predictor of Urinary Tract Infection—Is There a Cutoff Value in Asymptomatic Men? Journal of Urology, 181, 2540-2544.

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Other Background

The content in this presentation has been extensively discussed in the following venues:

Board/Meeting	Date	Focus
MOG Brief	02/13/2018	Introducing better catheters to lower the incidence of UTIs further – *HMS to implement on ISS whenever possible*
SMOCB	02/26/2018	New risk package information including catheter information – *Approved to proceed to HSRB*
HSRB CR Kick-Off Risk Package	03/01/2018	**Informational** – Risk scheduled "yearly" updates to include new evidence – *Approved to release CR*
Risk Package Evaluated via HSRB CR	03/12/2018 (Released)	**Decisional** – *To update risk with new evidence*. Received **evaluations against the Forward Plan** from CH&S on 03/29/2018 and 04/26/2018 regarding proposed on-orbit activity to measure Post Void Residuals (PVR) on healthy asymptomatic individuals
AOHMG – UR Forward Plan Pre-AOHMG Meeting with CMO 08/16/2018 Pre-AOHMG Meeting with HRP 09/13/2018	09/27/2018	[*A new package focusing on the forward plan was developed throughout July and Aug for a meeting in late Aug. Due to AOHMG schedule conflicts, meeting postponed to Sept.*] Based on the evidence presented, *the AOHMG was not convinced that the proposed forward plan fell under Occ. Surveillance*, as interventions stemming from this work were unclear
Post-AOHMG Path Forward	11/07/2018	Initial meeting with HRP, CH&S, and CMO in an attempt to define what research and occupational surveillance activities are needed – work suspended

- Due to open questions from the CR review (From-To Matrix) which remain unresolved regarding a forward plan that involves HRP and CH&S, the team requests to bring a mitigation plan at a later date.

Post Void Residual Crew Time

- **KU coverage required.**
- **Self-scan**
- **Worst case scenario per session**
  - Ultrasound is unstowed and will be restowed at completion.
    - –70 min setup/power on/crew prep/data downlink/power off/stow
    - –10 min scan time
- **Best case scenario per session**
  - Ultrasound is already deployed and will remain partially deployed at completion.
    - –35 min setup/power on//crew prep/data downlink/power off/stow
    - –10 min scan time
- **Pharmacokinetic Study**
  - Two inflight ultrasound sessions (promethazine and placebo)
  - Ultrasound activity 2.5 hours after medication ingestion
- **Standalone study**
  - One inflight session at any time

Addition of USOS Data to Urinary Retention Incidence

- **Available sources of USOS data**
  - MSMB database-does not contain inflight medical events.
  - SMOT notes- significant reporting bias especially if no operational impact; manual review
  - Request data directly from partners.
- **Given overwhelming new evidence, will this data add much?**
- **Analysis would take time to complete; should we pursue USOS data in the future?**

Methods Urinary Catheter and UTI

- **Systematic literature review**
  - Ovid
  - PubMed
  - Defense Technical Information Center
  - Institute for Scientific Information Web of Science
  - Google Scholar
- **80 studies identified**
  - In vitro / model
  - Animal
  - Human observational trials
  - Randomized controlled clinical trials
- **Level of evidence**
  - 1= Survey
  - 2 = Randomized Control Trial
  - 3= Review
  - 0= Other
- **Applicability**
  - 1= In vitro
  - 2= Human proxy measure
  - 3= Human direct measure
- **Level of evidence and applicability scored by adding scores from each study and dividing by total possible score**

Infection vs Catheter Type Compared to Standard Catheter

Intermittent Catheters (31 studies)

	Hydrophilic	No-touch	Reuse
Lower Infection Rate (Improvement)			
No Change in Infection Rate			
Higher Infection Rate (Worsening)			

- Hydrophilic coatings (17 studies)
  - 35.5% level of evidence, 44.1% applicability
- Reuse (10 studies)
  - 60.0% level of evidence, 66.7% applicability
- No-touch technique (2 studies)
  - 66.7% level of evidence, 66.7% applicability

- Reviews (2 papers)
  - Prieto, 2014: evidence quality too low to draw conclusion
  - Shamout, 2017: evidence quality low, but likely lower for hydrophilic and aseptic technique

Infection vs Catheter Coating Compared to Standard Catheter

Indwelling Catheters (49 studies)

	Hydrophilic	Antibiotic	Silver
Lower Infection Rate (Improvement)			
No Change in Infection Rate			
Higher Infection Rate (Worsening)			

- Hydrophilic coatings (13 studies)
  - 66.7% level of evidence, 74.4% applicability
- Antibiotic coatings (9 studies)
  - 58.3% level of evidence, 63.9% applicability
- Silver-coatings (19 studies)
  - 66.7% level of evidence, 78.9% applicability
- Reviews or other techniques (5 papers)
  - Cohen, 1985: infection rate decreased with iodine lubricant
  - Brosnahan, 2004: combined silver and antibiotic coated may yield small clinical benefit, but further research needed
  - Schumm, 2008: both silver & antibiotic catheters decrease asymptomatic bacteria
  - Jahn, 2012 & Lam, 2014: Not enough evidence for strong conclusion of catheter type. Silver and antibiotic coated may decrease infections in short durations, but difference is small and questioned clinical significance

Results
Urinary Catheter vs UTI

- **Intermittent catheterization (31 studies)**
  - Hydrophilic coatings (17 studies)
    - 25.8% reported lower "infection" rates
    - 19.4% reported lower complication rates
    - 35.5% level of evidence, 44.1% applicability
  - Reuse (10 studies)
    - 88.9% reported no difference or decreased "infection" rates
- **Indwelling catheters (49 studies)**
  - Hydrophilic coatings (13 studies)
    - 30.8% reported lower "infection" rates
    - 66.7% level of evidence, 74.4% applicability
    - 22.2% reported no difference in complications
    - 60.0% level of evidence, 66.7% applicability
  - No-touch technique (2 studies)
    - 100% reported no difference or decreased

"infection" rates
  - 66.7% level of evidence, 66.7% applicability
- 2 general reviews and combination (3 papers)
  - Prieto, 2014: evidence quality too low to draw conclusion
  - Shamout, 2017: evidence quality low, but likely lower for hydrophilic and aseptic technique

- Antibiotic coatings (9 studies)
  - 100% reported decreased "infection" rates
  - 58.3% level of evidence, 63.9% applicability
- Silver-coatings (19 studies)
  - 78.9% reported lower "infection" rates
  - 66.7% level of evidence, 78.9% applicability
  - Silver oxide no longer available in US used in many negative trials
  - Silver alloy showed decreased infection rate in almost all related studies
- Reviews or other techniques (5 papers)
  - Cohen, 1985: infection rate decreased with iodine lubricant
  - Brosnahan, 2004: combined silver and antibiotic coated may yield small clinical benefit, but further research needed
  - Schumm, 2008: both silver & antibiotic catheters decrease asymptomatic bacteria
  - Jahn, 2012 & Lam, 2014: Not enough evidence for strong conclusion of catheter type. Silver and antibiotic coated may decrease infections in short durations, but difference is small and questioned clinical significance

Results Summary Urinary Catheter vs UTI

- **Catheter coating (silver-alloy, hydrophilic, antibiotic)**
  - No difference to lower “infection” rates compared to controls
  - Weak evidence of clinical benefit
  - Recommend incorporation into med kit when convenient for HMS
- **Reusable catheters**
  - No difference to higher “infection” rate
  - Not recommended for current med kits, promising for exploration
- **No touch intermittent catheters**
  - Lower “infection” rates compared to controls
  - Weak evidence of clinical benefit
  - Recommend incorporation into med kit when convenient for HMS