

IMPACT REAL WORLD SYSTEM VALIDATION

Human Research Program Exploration Medical Capability Element

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“Expanding the Boundaries of Space Medicine and Technology”



Disclosure Information

94th Annual Scientific Meeting

We have no financial relationships to disclose.

We will not discuss off-label use and/or investigational use in my presentation

- Objectives
- Methods
- Outputs
- Challenges and Limitations
- Conclusions
- Future Work
- Questions

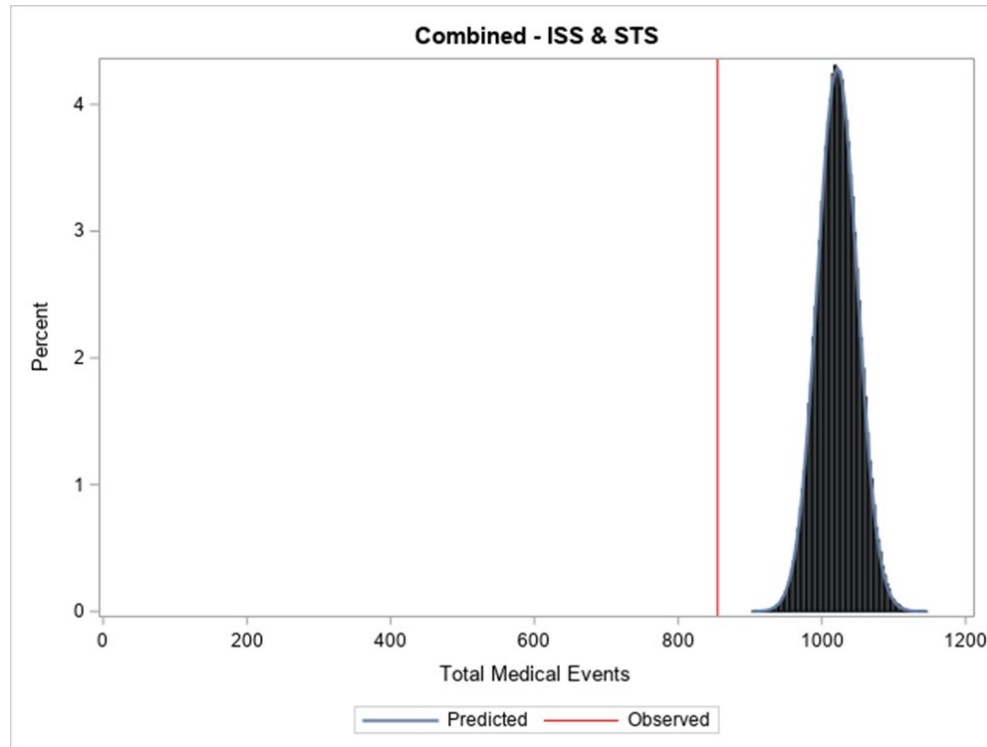
- Analyze IMPACT predicted outcomes in comparison to Real World Systems (RWS) referent data
 - Includes mission analysis and condition-by-condition analysis
 - Predicted total medical events and condition occurrences compared to RWS
 - Predicted Loss of Crew Life (LOCL) compared to the RWS LOCL
- Understand the limitations of the validation of IMPACT using RWS
- Utilize these results to refine and improve IMPACT

Mission Parameters

ISS	Number of Missions	31 ISS Missions
	Flight Years	13.91 person flight-years
	Contact Lens	14 crew wearing contact lenses
	Dental Crowns	15 crew with dental crowns
	EVAs	47 person-EVAs
STS	Number of Missions	21 STS Missions
	Flight Years	4.21 person flight-years
	Contact Lens	30 crew wearing contact lenses
	Dental Crowns	44 crew with dental crowns
	EVAs	120 person-EVAs

Parameter		
Total Medical Events (TME)	Whisker chart comparing observed vs predicted counts for each mission	Observed number of events should be within the 90% simulation distribution
	Scatter plot of observed vs predicted TME (observations for each mission)	Regression with intercept. Intercept should be 0 and slope should be 1.
	Histogram of total simulated events across all missions with the observed count marked	Observed counts should fall within the 90% simulation intervals for each mission type (ISS and STS) as well as combined across all missions.
Loss of Crew Life (LOCL)	Histograms of total simulated LOCLs across the entire set of missions	Results should not be inconsistent with zero.
Individual Medical Conditions	Scatter plot of observed counts vs predicted counts (observations for each condition)	Regression with intercept. Intercept should be 0 and slope should be 1.
	Whisker chart comparing observed vs predicted counts (observations for each condition)	Observed number of events should be within the 90% simulation distribution.
	Scatter plot of observed vs predicted counts (observations for each condition)	Regression with intercept. Intercept should be 0 and slope should be 1.

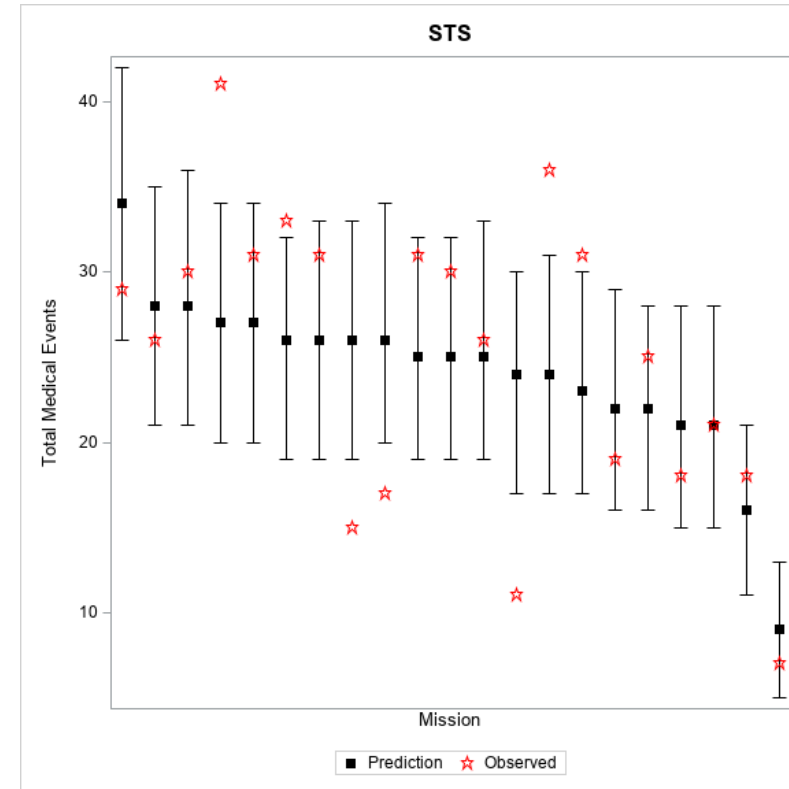
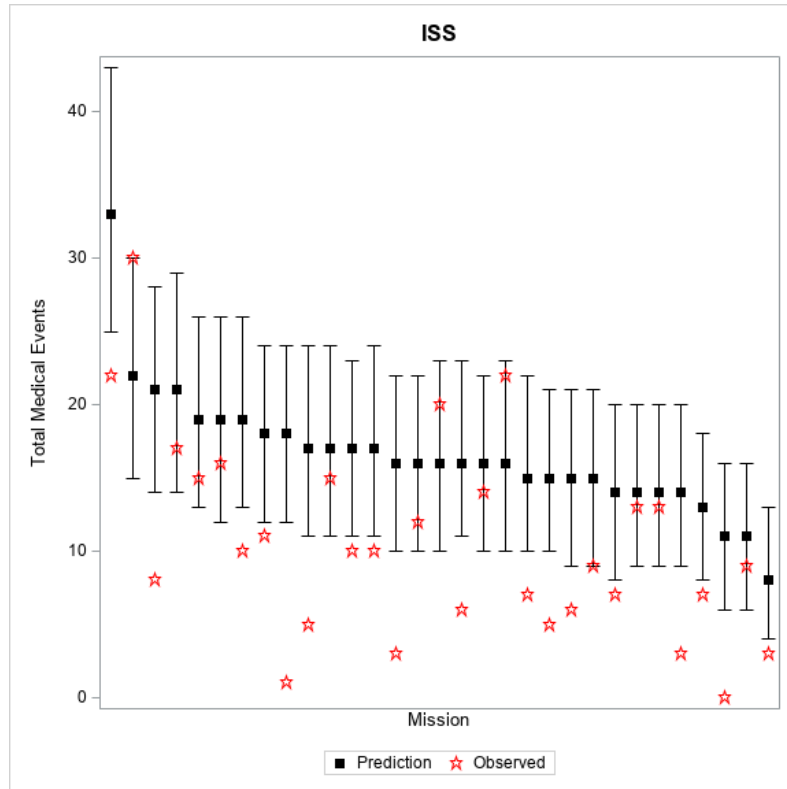
Total medical events (TME) observed and predicted



- Mission simulations generated using IMPACT for each individual ISS and STS mission in the RWS dataset
- Data from individual mission simulations combined to generate combined ISS and STS outcome predictions for the complete set of missions
- Graph shows the distribution of the predicted Total Medical Events (TME) and the observed total RWS medical events identified in the medical records
- IMPACT overpredicted TME for combined ISS and STS missions
- Predicted TME was in range for STS missions (fell within the 90% confidence interval of the predicted number of TME)

Missions	Observed	Predicted	90% Confidence Limits	
ISS	329	505	482	551
STS	526	516	476	536
Combined ISS & STS	855	1021	976	1068

TME Predictions by Mission



<i>Mission</i>	ISS	STS	Combined
<i>Predictions</i>			
<i>In Range</i>	13	14	27
<i>Over Predicted</i>	18	3	21
<i>Under Predicted</i>	0	4	4

IMPACT overpredicts TME for ISS missions and for combined ISS & STS missions

Loss of Crew Life (LOCL)

Combined ISS & STS Missions

- 1.9% probability of at least one LOCL event

ISS Missions

- 1.5% probability of at least one LOCL event

STS Missions

- 0.41% probability of at least one LOCL event

RWS

- No LOCL events

Predictions by Condition

Mission	In Range	Overpredicted	Underpredicted	Underpowered	Percentage Out of Range
ISS	16	15	5	83	56%
STS	17	9	11	82	54%
Combined ISS and STS	17	17	8	77	60%

Prediction of Medical Events (ISS and Combined ISS & STS)

- IMPACT overpredicted medical events
 - Exploration missions are more dangerous than LEO missions
 - Increased behavioral health conditions expected on exploration missions
 - IMPACT includes rare medical events that have not occurred in RWS
 - Under reporting of medical events in ISS RWS

Prediction of Medical Events (STS)

- IMPACT prediction of medical events was in range (90% CI of RWS)
 - More thorough records of medical events in STS RWS (medical debrief forms)

Example of Overprediction

- EVA related Decompression Sickness (DCS) was overpredicted (STS and combined ISS & STS missions)
 - IMPACT incidence based on a conservative NASA model
 - No RWS DCS events in the medical record

Example of Underprediction

- Herpes Zoster Reactivation (STS missions)
 - IMPACT incidence based on analog population which included vaccinated subjects
 - 3 cases of herpes zoster reactivation during RWS STS missions.

Challenges and Limitations

- Limited exploration-class mission data makes it difficult to validate IMPACT using the spaceflight environment for which it was developed
- IMPACT validation used RWS data from LEO missions (ISS and STS)
- Small sample size of RWS missions
- Majority of IMPACT conditions were statistically underpowered due to relatively low incidence rates being compared against limited flight-years (not included in the analysis)
- IMPACT expected to overpredict LEO mission medical events as compared to exploration class missions

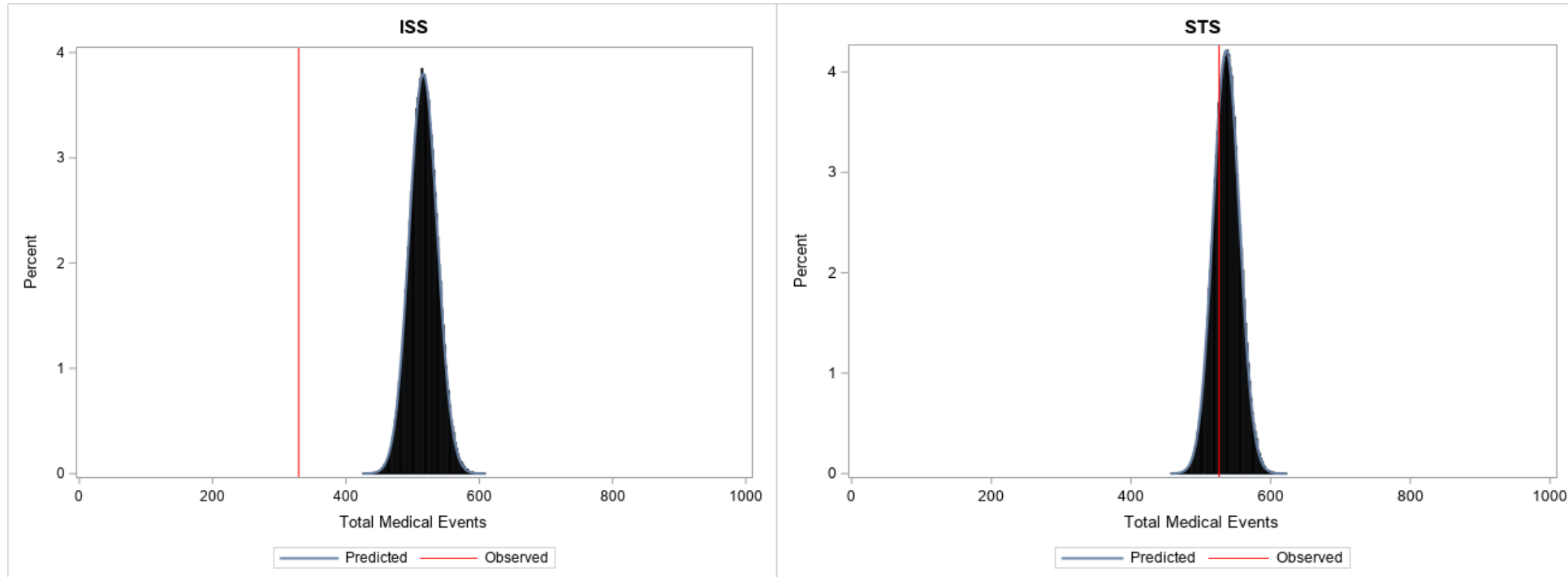
- There is no “gold standard” observed set to compare IMPACT outputs due to limited exploration mission data
- IMPACT outputs were assessed in the context of limited RWS data
- Overprediction of RWS medical events was expected
- Results of IMPACT validation should not be considered as a “pass/fail” test
- IMPACT should only be used as a decision support tool in consultation with subject matter experts

- Continuous revision of data and validation of IMPACT outputs as more spaceflight data becomes available from Artemis missions
- Modify incidence rates based on possible condition recurrence to increase model fidelity
- Add mission segment-specific condition occurrences and incidence rates
- Add conditions to increase model fidelity
- Add evidence base parameters to improve prediction of Clinical Phase durations

Questions?

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