

An Evidence-Based, Systematic, and Repeatable Method to Determine Candidate Clinical Capabilities and Resources for Exploration Missions

Dana R. Levin,^{1,2} Ariana Nelson,^{2,3} Chris Zahner,² Emily Stratton,^{1,2} Arian Anderson,⁴
Jon G. Steller^{2,3}

¹*Baylor College of Medicine*

²*University of Texas Medical Branch*

³*University of California Irvine*

⁴*University of Colorado Anschutz School of Medicine*

Correspondent:

Dana Levin, MD MPH

Department of Emergency Medicine

Baylor College of Medicine

1504 Lamar Flemming Street

Houston Texas, 77030

Dana.Levin@bcm.edu

Tele: 917-941-8813

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INTRODUCTION: This paper describes the method for assigning medical diagnostic and treatment capabilities and resources to the database informing an updated probabilistic risk analysis (PRA) tool for exploration class medical system planning. NASA has used PRA since 2011 to inform mission medical system design, but existing tools are designed only for low Earth orbit. An updated PRA tool was needed to inform exploration class missions.

METHODS: A team of medical experts with a wide range of expertise and experience including Space Medicine was assembled to build capability and resource tables for the new PRA tool. This team met over 8 months and used practice guidelines, literature, and experience to build capability and resource tables (CRTs) for each condition in the new PRA tool database.

RESULTS: This process led to CRTs for each condition and a total of 617 distinct capabilities and 839 discrete resources.

CONCLUSION: The CRT method is an effective way to translate medical practice guidelines into capabilities and resources usable by PRA tools for exploration class medical system planning. This same method may be utilized in commercial space ventures and in other applications in which medical predictive analytics are informative.

Key Words: Crew Medical Officer (CMO); Training; Space; System Design; Capabilities and Resources; ExMC; HRP.

Introduction

Historically, medical resources for space missions were selected heuristically as part of a highly successful risk mitigation strategy with an impressive safety record. [1], [2], [3] However, every mission to date, with the exception of the Apollo program, benefited from access to readily available resupply and evacuation, which helped mitigate the consequences of manifesting inadequate or excessive medical supplies. [4], [5] With missions farther from Earth, resupply, evacuation, and real-time communication become far more challenging or impossible, substantially increasing the consequences of mission/system resource mismatching.[4], [6]

To address this, NASA augments the heuristic approach with probabilistic risk assessment (PRA). [2], [7] PRA uses mission duration, crew size, medical equipment mass and volume allocation, and other mission parameters to estimate medical risk based on a list of anticipated medical conditions associated with incidence and outcomes data.[8], [9] Conditions can either be treated or untreated based on the availability of necessary resources, and each resource carries a mass and volume cost. An optimization algorithm compares treated vs. untreated outcomes across the various system configurations that fit within the vehicle mass and volume constraints to determine the configuration most likely to reduce mission relevant risks, such as loss of crew life (LOCL), crew task time lost to disability (TTL), and the risk of a return to definitive care (RTDC).[10]–[12] This provides mission planners with an evidence-based, data-driven tool to inform medical system planning and mission operations. PRA is now the standard for NASA medical planning, providing a ‘first draft’ of the medical system that can be augmented with heuristic expertise and will be increasingly more important as missions venture farther from Earth.[2], [4], [7]

Current medical PRA tools, like the Integrated Medical Model (IMM), were designed for low Earth orbit. Since PRA requires a dataset relevant to each potential mission profile and the operations of future missions are not presently known, exploration-class medical planning requires a standardized, reproducible method for building this dataset and defining medical management in terms of clinical capabilities and resources.[4], [11]

For the purposes of this paper ‘capability’ refers to sets, of tasks, skills, and/or actions (e.g., ‘obtain intravenous access’ or ‘perform ultrasound’) while ‘resource’ refers to a single piece of equipment, pharmaceutical, or a discrete skill (e.g., 20-gauge vascular catheter’ or ‘interpret cardiac ultrasound’). This paper describes the method used to systematically define and structure capabilities and resources for NASA’s Informing Mission Planning through Analysis of Complex Tradespaces (IMPACT) deep space medical PRA tool.

Methods

Step 1: Defining Conditions

Identifying medical conditions relevant to the desired mission profiles is a complex task described by Kreykes et. al. through the creation of the IMPACT 1.0 Medical Condition List (ICL 1.0). [4] These 120 carefully defined conditions, were selected to inform IMPACT’s computational engine, the Medical Extensible Database Probabilistic Risk Analysis Tool (MEDPRAT). [13], [14].

Step 2: Assemble a Team of Subject Matter Experts

A team of physicians with expertise in Aerospace Medicine, Anesthesiology, Emergency Medicine, Family Medicine, Hyperbaric Medicine, Internal Medicine, Obstetrics and Gynecology, Pain Medicine, Pathology, Psychiatry, Sports Medicine, Space Medicine, Wilderness Medicine, Physical Medicine and Rehabilitation, and Women's Health was assembled. All clinicians were board certified in their respective specialties, actively practicing, and familiar with current standards of care. The team also included a former NASA astronaut, a former ISS flight controller, and systems engineers. This team operated under NASA's Human Research Program. Representatives from NASA Medical Operations Division were involved as consultants on an as needed basis. Additional expertise was sought as needed.

Step 3: Assign Capabilities to Conditions

Each ICL 1.0 condition requires a capability and resource table (CRT) to describe the equipment and skillsets needed to manage it. The CRTs use MEDPRAT's 3 clinical phase structure.

Clinical phase 1 (CP1) includes diagnostic capabilities and resources, clinical phase 2 (CP2) includes treatment and monitoring capabilities and resources, and clinical phase 3 (CP3) represents the end state of each condition (e.g., full recovery, partial recovery, evacuation, or death).[14] No resources are assigned to CP3 though some CP2 resources may continue until the end of the mission which may include CP3.

To avoid overcounting, each capability and resource was assigned only once per condition, even if used in multiple phases (e.g., a cardiac monitor/defibrillator) or given a distinct name for each phase (e.g., CP1-laboratory-BMP for diagnosis and CP2-laboratory-BMP for monitoring).

Capabilities serve as a method for summarizing practice guidelines and standardizing resources across conditions. Each physician was assigned a subset of conditions relevant to their specialty, e.g., an emergency medicine physician was assigned “sepsis” while a sports medicine physician was assigned “upper extremity strain/sprain”. The assigned physician reviewed practice guidelines, medical literature, and their own experience to develop a list of clinical and nonclinical capabilities required to diagnose and treat the condition. Terrestrial practice standards were modified to accommodate the limitations of spaceflight based on present day technology, e.g., no large diagnostic equipment, and limited surgical abilities (Figure 2). Capabilities were assigned a standardized name to ensure the same resources would be allocated across all conditions using that capability.

Step 4: Assign Resources to Capabilities

The assigned physician for each medical condition also assigned resources to each new capability before presenting their work to the CRT working group meeting. Once approved resource sets would not change to enable capabilities to be standardized between conditions.

Step 5: Alternate and Non-alternate Clusters

Resources could be individual or grouped "clusters" of items. Clusters could be either alternate or non-alternate clusters. A non-alternate cluster requires all assigned resources to be present for the condition to be “treated.” For instance, intravenous antibiotics may require both lyophilized powder and a diluent. If only the diluent is present, the infection cannot be treated. Alternate clusters allow capabilities to be fulfilled in multiple ways using equivalent resources, e.g., a wrist splint may be fabricated from plaster, fiberglass, or a rigid object with tape. As long as one of the

alternatives is present, the condition can still be treated. Alternates can be either individual resources or clusters themselves, such as those required for an intravenous line versus an intraosseous line.

This structure preserves essential capabilities even when the primary resource is unavailable. It also allows MEDPRAT to model some improvised solutions, such as using an elastic rehabilitation exercise band as a tourniquet. Each alternate was assigned a primacy number to instruct MEDPRAT which alternate to use if more than one equivalent resource is available. MEDPRAT parameters can be set to include resources with higher or lower efficacy but due to difficulty in standardizing measures of efficacy with parameter was not used.

Step 6: SME Consensus

The assigned physicians presented their work to the CRT working group. A minimum of three SMEs from the CRT working group, including at least one Space Medicine expert, would discuss the condition, modify the capabilities and resources, and seek additional input as needed.

Step 7: Assigning Model Parameters

Model parameters instruct MEDPRAT how to use each capability and resource during the simulation. Model parameters associated with capabilities include, a Scope of Practice Code (SoP), Contribution, Necessity, Equivalence, Primacy, and Efficacy. Resources use two additional parameters, dose, and dose type (Table 2). These parameters were assigned using the same consensus structure described above. An in-depth discussion of these parameters is beyond the scope of this paper and better addressed in the MEDPRAT documentation.[13], [14]

Step 8: Medication Dosing and Pharmaceutical Review

Dose is defined as the amount of a resource consumed per occurrence (e.g., the number of pills, gauze pads, or ultrasound probes). *Dose type* instructs IMPACT how to apply the dose. It is coded ‘per event,’ ‘per day,’ or ‘end of mission.’ Per event medications are a fixed amount allocated whenever the condition occurs irrespective of condition duration, e.g., antibiotics for an infection. Per day is best used for medications that will be given for the duration of a condition’s treatment period (e.g., pain medication). Paradoxically, this is also a fixed amount despite CP2 being a range of time defined by medical literature. Since CP2 duration will trend towards the mean of its range over the hundreds of thousands of simulation runs used for MEDPRAT’s PRA, MEDPRAT uses the mean CP2 value for per day dosing. End of mission medications represent medications that must continue for remainder of the mission, e.g., cholesterol medications after a heart attack. MEDPRAT calculates the amount based on how many mission days remain when the condition occurs. Some medications are optimally administered in multiple forms, such as intravenous antibiotics later converted to an oral form. The CRT working group used the rubric in Appendix A as the basis for assigning parameters to these medications.

After physician consensus, the medication doses, and routes (e.g., oral, intramuscular, intravenous) were reviewed by Space pharmacists to ensure appropriate dilution, storage, pharmacodynamics, and pharmacokinetics were considered. Conflicts between the pharmacy and clinician team were resolved by discussion.

Step 9: Clinical Phase I Duration

While the duration of CP2 was defined by evidence from medical literature, CP1 was defined by consensus estimation of the time required for each individual CP1 capability added together. CP1 duration was necessary for MEDPRAT's calculation of affected crewmember disability (task time lost) and typically lasted only a few minutes to a few hours.[12], [13]

Step 10: Capability and Resource Table and Written Summary

The condition's physician incorporated all SME feedback to finalize the CRT outline and draft a text summary of the practice capabilities including literature references. The finalized documents were handed off to a reviewer who generated a CRT in Microsoft Excel™ including all model parameters and the appropriate database structure. The CRT team would work with the database and modeling teams to ensure correct data and formatting. Any errors or changes were incorporated into all other CRTs to ensure consistency.

Step 11: Assignment of Mass and Volume to Resources

The Excel™ file was then passed to the systems engineering team to assign the relevant figures of merit (mass and volume) and to import the CRT information into a database readable by the MEDPRAT engine. Values were obtained from published data and/or direct measurement of representative items.

Step 12: Peer Review, Verification, and Validation

Verification and validation occurred in three stages. First, an independent reviewer familiar with the CRTs evaluated the text summary. This reviewer also evaluated a random sample of completed CRTs. In the second stage the CRT spreadsheets were imported into a database. Software validation tools were used to detect errors in parameters, titles, and data structure which

were corrected. Finally, two clinician scientists reviewed MEDPRAT outputs with the engineering and computational modeling teams, making adjustments and seeking additional team input as needed.

Step 13: Updating the CRT based on new research, capabilities, or mission needs

This process produces modular capabilities with resources standardized across conditions. As technology and treatment standards develop, the CRTs can be updated by modifying capabilities, adjusting parameters, or adding capabilities within and across conditions.

It is also possible to modify individual parameters to increase model fidelity as new features are added. For example, the efficacy parameter can be used to reflect “probability of success” for a given resource or capability e.g., a new drug that is 98.5% effective. As efficacy data is collected for more capabilities this parameter could be updated to better reflect the effect of treatment on condition outcomes.

Results

This method generated 617 capabilities and 839 resources for the Evidence Library database. When resources are assigned to capabilities, this yields 2,293 items available for MEDPRAT to select in varied quantities for the mission simulation. Skin Abrasion is used as an illustrative example of the process.

The best case definition for this condition on the ICL 1.0 list is “*Mild abrasion(s) resolving spontaneously or requiring minimal intervention.*” The worst case definition is “*Moderate to severe abrasion(s) requiring additional intervention. (Note this is exclusive of "Cellulitis").*”

Assigned Capabilities

The following capabilities were assigned for the best case:

1. CP1 - Patient Encounter and Equipment Setup Time
2. CP1 - Software - Clinical Records and Decision Support
3. CP1 - History - Collect History of Present Illness
4. CP1 - Physical Exam - Primary Assessment (ABCs)
5. CP1 - Hygiene - Hand
6. CP1 - Physical Exam - Skin
7. CP1 - PPE - Nitrile Gloves
8. CP1 - Physical Exam - Wound
9. CP1 - Interpretation - Physical Exam
10. CP2 - Acute - Software - Clinical Records and Decision Support
11. CP2 - Acute - Management Decisions - Skin Abrasion
12. CP2 - Procedure - Wound Dressing
13. CP2 - Assessment - Fitness for Duty

And for the worst case:

1. CP1 - Patient Encounter and Equipment Setup Time
2. CP1 - Software - Clinical Records and Decision Support
3. CP1 - History - Collect History of Present Illness
4. CP1 - Physical Exam - Primary Assessment (ABCs)
5. CP1 - Hygiene - Hand
6. CP1 - Physical Exam - Skin
7. CP1 - PPE - Nitrile Gloves
8. CP1 - Physical Exam - Wound
9. CP1 - Interpretation - Physical Exam
10. CP2 - Acute - Software - Clinical Records and Decision Support
11. CP2 - Acute - Management Decisions - Skin Abrasion
12. CP2 - Standing - Pharmacy - Topical Antibiotic
13. CP2 - Procedure - Wound Dressing
14. CP2 - Standing - Pharmacy - Antipyretics/Mild Pain Management
15. CP2 - Assessment - Fitness for Duty
16. CP2 - Physical Exam - Focused Reassessments

For illustrative purposes, CP2 - Procedure - Wound Dressing is an example of a non-alternate cluster with nested alternate clusters. The capability requires each of the following nested resource clusters:

1. *“Bundle - Wound Care – Dressing”*
AND

2. *“Wound Care - Bandage - 4 Inch Rolled Gauze”*
AND

3. *“Bundle – Tape”*

Two of these, in turn, are non-alternate clusters:

1. *“Bundle - Wound Care – Dressing”*
 - a. *“Bundle - Wound Care – Gauze”*
 - i. *“Wound Care - Dressing - 2x2 Gauze Square”*
OR
 - ii. *“Wound Care - Dressing - 4x4 Gauze Square”*
OR

- b. *“Hygiene - Feminine – Pads”*
- AND

2. *“Wound Care - Bandage - 4 Inch Rolled Gauze”*
AND

3. *“Bundle – Tape”*
 - a. *“General Supply - Paper Tape”* OR *“General Supply - Grey Tape”*

CP1 resources were assigned a duration of 0.53 hours for the best case and 0.7 hours for the worst case. This time encompasses the maximum time required to move both provider and patient to a private area, obtain any necessary resources, conduct the exam, and discuss the findings. Table 1 provides an example of the parameters assigned to each capability.

Discussion

The CRTs translate medical practice guidelines into the mass and volume necessary for diagnosis and treatment. The described structure is a standardized and reproducible approach to generate the necessary data for medical PRA. Taken together, the CRTs for the IMPACT conditions list are also an outline of the medical knowledge, skills, and abilities required to

manage the medical conditions most likely to affect a deep space mission. This information may help develop mission class specific training programs for medical officers and crew or assist with mission crew selection based on how prior training impacts risk outcomes. The flexibility of the structure enables rapid updates and additions as new clinical standards are developed or new mission profiles are added.

This method may also be useful beyond spaceflight since PRA is a predictive analytics tool for quantifying risk and matching resource needs to minimize them. Using the methods outlined in the paper CRTs can be built to support PRA tools for a variety of scenarios such as disaster planning, event medicine, expedition medicine, public health, or even hospital supply needs.

PRA and the CRT method are powerful tools but there are opportunities for improvement. For example, the CRTs do not account for variability in resource necessity (e.g., a defibrillator is more critical for advanced cardiac life support than the tape to secure an intravenous line).

Relatedly, the dose structure may overcount certain items, especially those present in multiple conditions or with prolonged treatment times. Finally, the current model only accounts for the presence of resources and does not account for variation in task success by provider expertise nor the presence of the physical volume in the spacecraft needed to perform each task. [15], [16]

The CRT development process also included important lessons on process and project management. There is strong interdependency between the conditions chosen, the definitions used, the incidence and outcomes data, and the assigned resources/capabilities. Ideally, the data collection processes for each should be done in concert, however, due to project constraints,

these tasks had to be performed asynchronously. This limited the information available to each team, increasing the risk for errors, and often leading to significant additional time spent on corrections as definitions were revised and assumptions made without knowledge of the work done by other teams. As a result, the CRT lists presented in this paper should be interpreted as a starting point for medical resources to be used on exploration class missions. If possible, future efforts should avoid asynchronous development.

It is also worth noting the CRTs are based primarily on terrestrial guidelines adapted to the limitations of spaceflight. While this is currently the best information available, it is by no means ideal. The CRT team accounted for this by relying on Space Medicine experts, consultation with astronauts, and constraining resources to only those possible within the limits of present-day spaceflight technology (e.g., limited invasive surgical capabilities and no large diagnostic equipment). However, the CRTs would undoubtedly benefit from additional scrutiny by care providers with spaceflight experience, particularly as we gain experience beyond low earth orbit.

Conclusion

Limitations notwithstanding the CRT is a powerful, expandable, and reproducible method for translating medical practice guidelines into system resources and, ultimately, mass, volume, and other figures of merit. In the context of IMPACT, CRTs enable a flexible and widely applicable tool for predicting spaceflight medical risk and informing system design. The method may also be useful for any scenario where predictive analytics overlaps with limited data availability in a high consequence setting.

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Figures and Tables

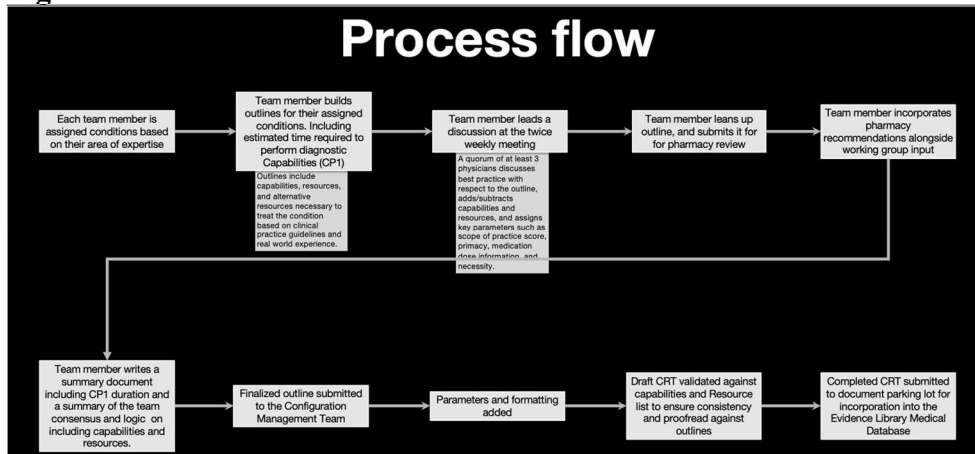


Figure 1: Process of capability and resources table (CRT) construction

ICL - ##, <<NAME>>	BEST CASE			
Definition:				
CAPABILITIES	ESTIMATED TIME FOR CP1 (in hours)	RESOURCES	NOTES	NOTES FOR PHARMACY
CP1				
CP1 - Patient Encounter/Equipments Setup Time	0.333			
CP1 - Software - Clinical Records and Decision Support	0			
CP1 - History - Collect History of Present Illness				
CP1 - Physiole - Hand Hygiene	0.0833			
CP2 - Fitness/Emergency Assessment				
CP1 - Physical Exam - ***				
CP1 - Skillset - Interpret Physical Exam	0			
TOTAL TIME	0.4163			
CP2				
CP2 - Acute - Software - Clinical Records and Decision Support				
CP2 - Standing - Management Decisions - ***				
CP2 - Standing - Pharmacy - ***				
CP2 - Convalescent - Assessment - Fitness for Duty Assessment				

Figure 2: CRT outline

CAPABILITY	SCOPE OF PRACTICE	CAPABILITY CONTRIBUTION	CAPABILITY NECESSITY	CAPABILITY EQUIVALENCE	CAPABILITY PRIMACY	CAPABILITY EFFICACY	
CP1 - PPE - NITRILE GLOVES	1	1	1	0	0	1	
RESOURCE PHASE	RESOURCE CONTRIBUTION	RESOURCE NECESSITY	RESOURCE EQUIVALENCE	RESOURCE PRIMACY	RESOURCE EFFICACY	RESOURCE DOSE PER DAY	RESOURCE DOSE TYPE
Hygiene - PPE - nonsterile gloves	1	1	0	0	1	2	Event

Table 1: Example of Parameters Assigned to a resource

Parameter	Description	Capability or Resource Phase
<i>Scope of Practice Code</i>	Training level required to perform this capability 1 - First responder/EMT-Basic 2 - Paramedic/Military medic 3 - Experienced ED/ICU Nurse, 4 - Intern/PA/NP 5 - Attending Physician	Capability Phase only
<i>Contribution</i>	Relative importance of item within the capability	Both
<i>Necessity</i>	Essentialness of the item to the capability	Both
<i>Equivalence</i>	How much of this item equals other items in the capability	Both
<i>Primacy</i>	For alternative resources, MEDPRAT will select 1 This determines the ranking order of Preference for selecting Items if multiple alternates Still exist in the system e.g., the alternates were not Weeded out by mass/volume	Both
<i>Efficacy</i>	Percentage of items' effect relative to other items in the capability	Both
<i>Resource Dose Per Day</i>	Number of items needed, e.g., number of Pills or number of IV catheters, per 24-hour period	Resource Only
<i>Resource Dose Type</i>	Per day Per event Until the end of the mission	Resource Only

Table 2: Description of Parameters

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Appendix A: Rubric for Considering Assignment of Doses

Option 1: no dose form change.

	Primacy	Dose amount	Dose Type	CP2 average duration	Total included per occurrence
IV Levofloxacin	N/A	1	Per day	5 days	5

- Benefits: simple clear, tied to CP2
- Limitations: no ability to change dose forms

Option 1a: full course of two dose forms included from the beginning to allow for changes.

	Primacy	Dose amount	Dose Type	CP2 average duration	Total included per occurrence
Levofloxacin IV	N/A	1	Per day	5 days	5 IV doses
Levofloxacin PO	N/A	1	Per day	5 days	5 PO doses
Total Doses in Kit					10 doses total

- Benefits: allows both dose forms for full duration based on CP2 average
- Limitations: adds extra meds/mass/volume

Option 2: Fixed dosing with a switch

	Primacy	Dose amount	Dose Type	CP2 average duration	Total included per occurrence
Initial Levofloxacin IV	1	2	Event	5 days	2 IV doses
Initial Levofloxacin PO	2	2	Event	5 days	2 PO doses
	Primacy	Dose amount	Dose Type	CP2 average duration	Total included per occurrence
Final Levofloxacin IV	2	3	Event	5 days	3 IV doses
Final Levofloxacin PO	1	3	Event	5 days	3 PO doses
Total Doses in Kit					5 total doses

- Benefits: allows for dose route to switch, limits to only necessary meds, ensures complete course should one dose form not be available
- Limitation: not tied to CP2, may undertreat or over treat, unclear when switch should occur, no flexibility

Option 3: Fixed initial IV dose, variable PO dose

	Primacy	Dose amount	Dose Type	CP2 average duration	Total included per occurrence
Initial Levofloxacin IV	N/A	2	Event	5 days	2 IV doses
	Primacy	Dose amount	Dose Type	CP2 average duration	Total included per occurrence
Final Levofloxacin PO	N/A	1	Per Day	5 days	5 PO doses
					7 total doses

- Benefits: allows for dose to switch, limits to only necessary meds, ensures complete course even if IV is excluded, tied to CP2, allows for flexibility
- Limitation: always includes additional doses of IV med will increase mass/volume, but not as much as option 1, may be more or less than option 2

Suggested application:

- Option 1 is ideal for most meds that do not change route.
- Option 1a is overly conservative from a mass/volume perspective.
- Option 2 may be useful for some courses of antibiotics or complex dose changing medications where a fixed duration is known and dose changes (e.g., PO azithromycin 500mg initial and 250mg for 4 days thereafter in nearly all conditions)
- Option 3 will often be better in cases where dose needs to switch but total care duration is not fixed (e.g., pneumonia)