

BUILDING BETTER SYSTEMS FOR PEDIATRIC FORMULATION DEVELOPMENT

When Caregivers Bridge the Gap

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Shaping the Future of Pediatric Formulation Development
Session 1A: Patient-Centricity | Pediatric Caregiver Perspective
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ABOUT US

The perspective we bring



MAMA

Parent of a child
with complex
medical needs



ENGINEER

Finding solutions
to real-world
problems



ADVOCATE

Translating lived
experience into
action

Medical training: **NONE**

Caregiver expertise: **EXTENSIVE**



ROADMAP

1

WHEN CAREGIVERS BECOME PHARMACISTS

Medication management in our home

2

BRIDGING THE GAP

Case studies in formulation, access and safety

3

THE STATUS QUO

Insights from the community

4

BUILDING BETTER SYSTEMS

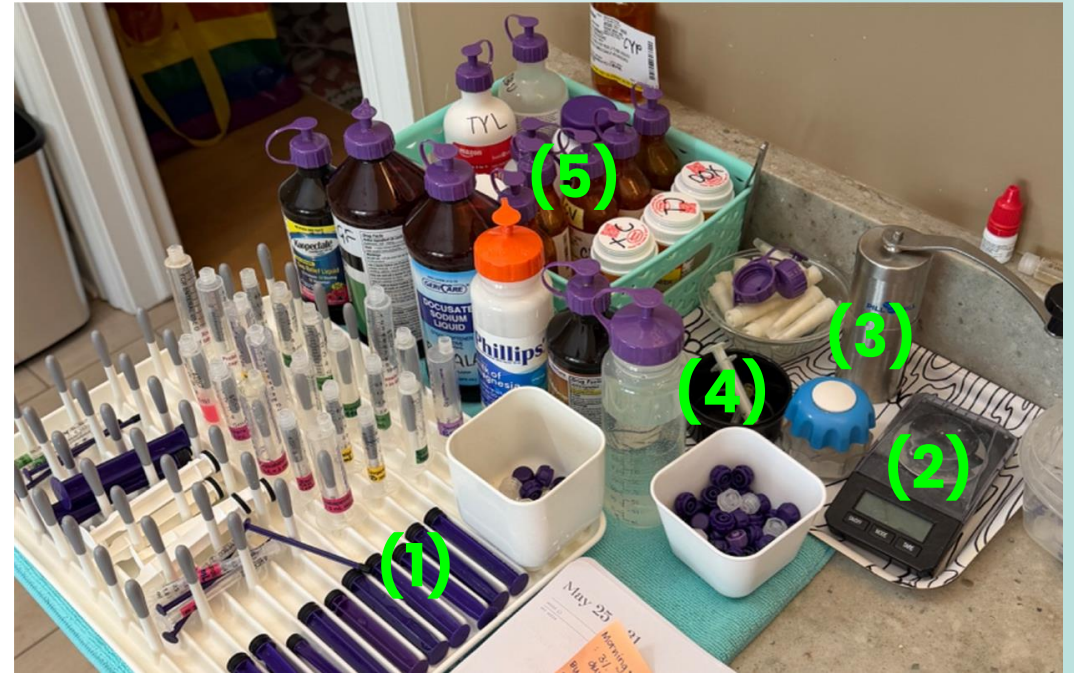
Designing for reality

WHEN CAREGIVERS BECOME PHARMACISTS

Bathroom compounding

Our **medication preparation and storage** area features:

- 1) labeled, color-coded **syringes**
- 2) a digital milligram **scale**
- 3) heavy-duty pill **pulverizers**
- 4) extraction **needles**
- 5) medication storage **bottles**
- 6) a **refrigerator**
- 7) backup and **PRN meds**



WHEN CAREGIVERS BECOME PHARMACISTS

The reality of daily medication management

30

Unique medications

56

Daily administrations



4

INHALED
SOLUTIONS

15

LIQUID
FORMULATIONS

1

PHARMACY
COMPOUNDED

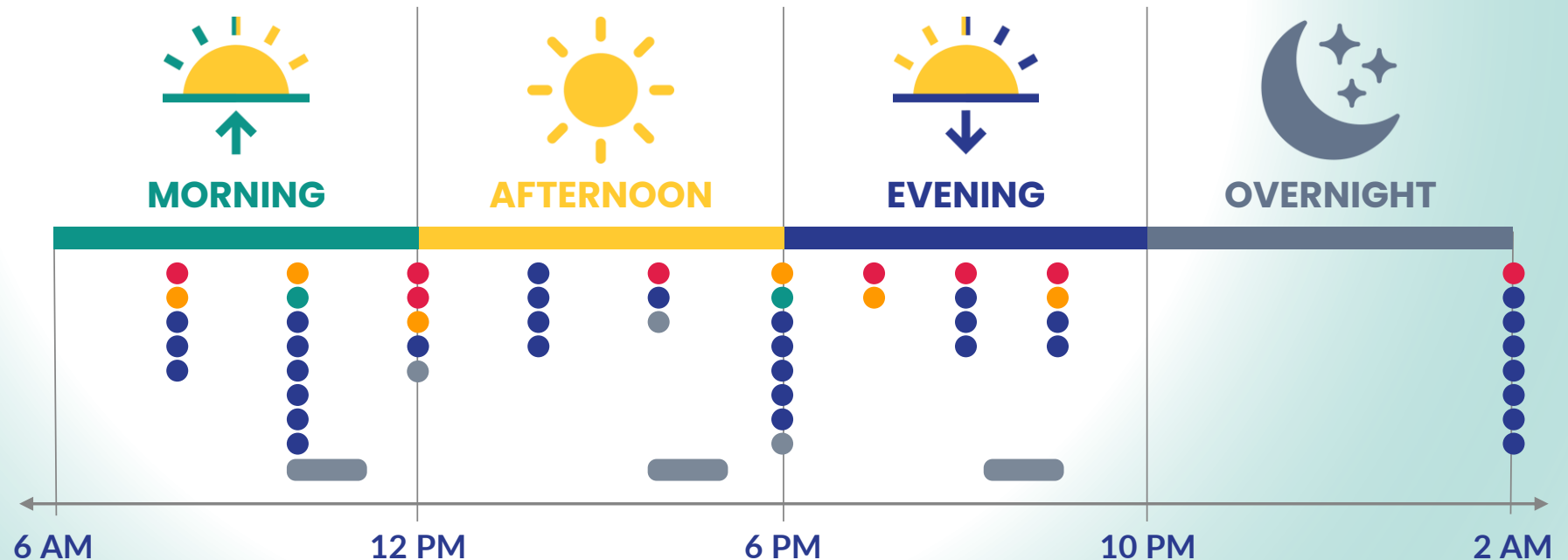
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SOLID
FORMS

4

MODIFIED
FORMS

Medications are needed **every 2 hours** throughout the day – **and overnight.**



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CASE STUDY 1: FORMULATION AVAILABILITY GAP

When the right dose doesn't exist

COMMERCIAL FORMULARY

Transdermal clonidine patches are available in 0.1/0.2/0.3 mg/day for 7 day application.

CLINICAL REALITY

A 0.1 mg/day dose is **sub-therapeutic**.

A 0.2 mg/day dose causes **floppiness and lethargy**.

CONSTRAINT

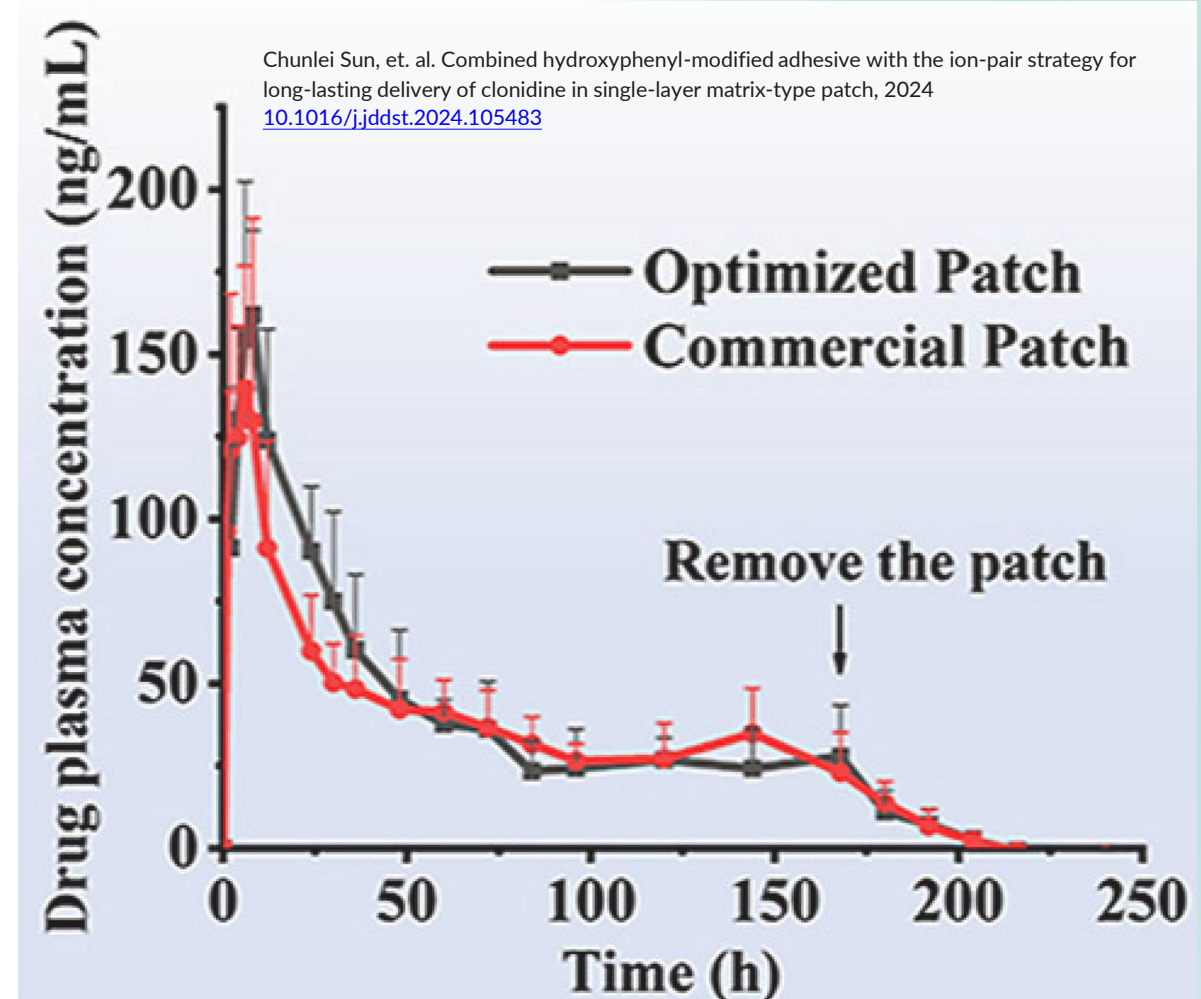
Patches **cannot** be cut.

ADDITIONAL COMPLICATION

Therapeutic effect **declines** before Day 7.

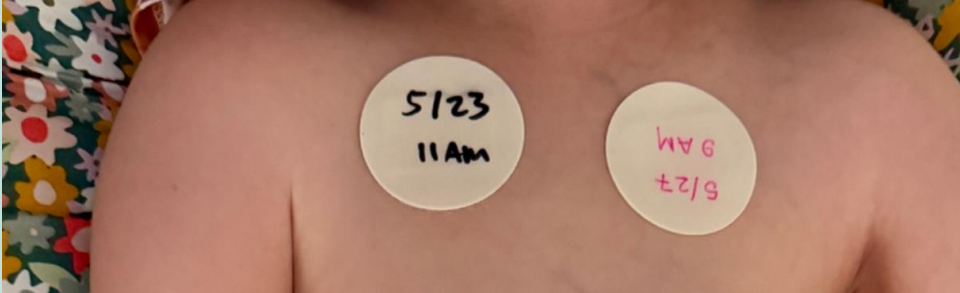
The dose we need doesn't exist.

SO I ENGINEERED ONE.



CASE STUDY 1: FORMULATION AVAILABILITY GAP

Caregiver-engineered solution



ON DAY 0: Apply 1st partially exposed patch.

ON DAY 2: Increase exposure.

ON DAY 4: Introduce 2nd partially exposed patch.

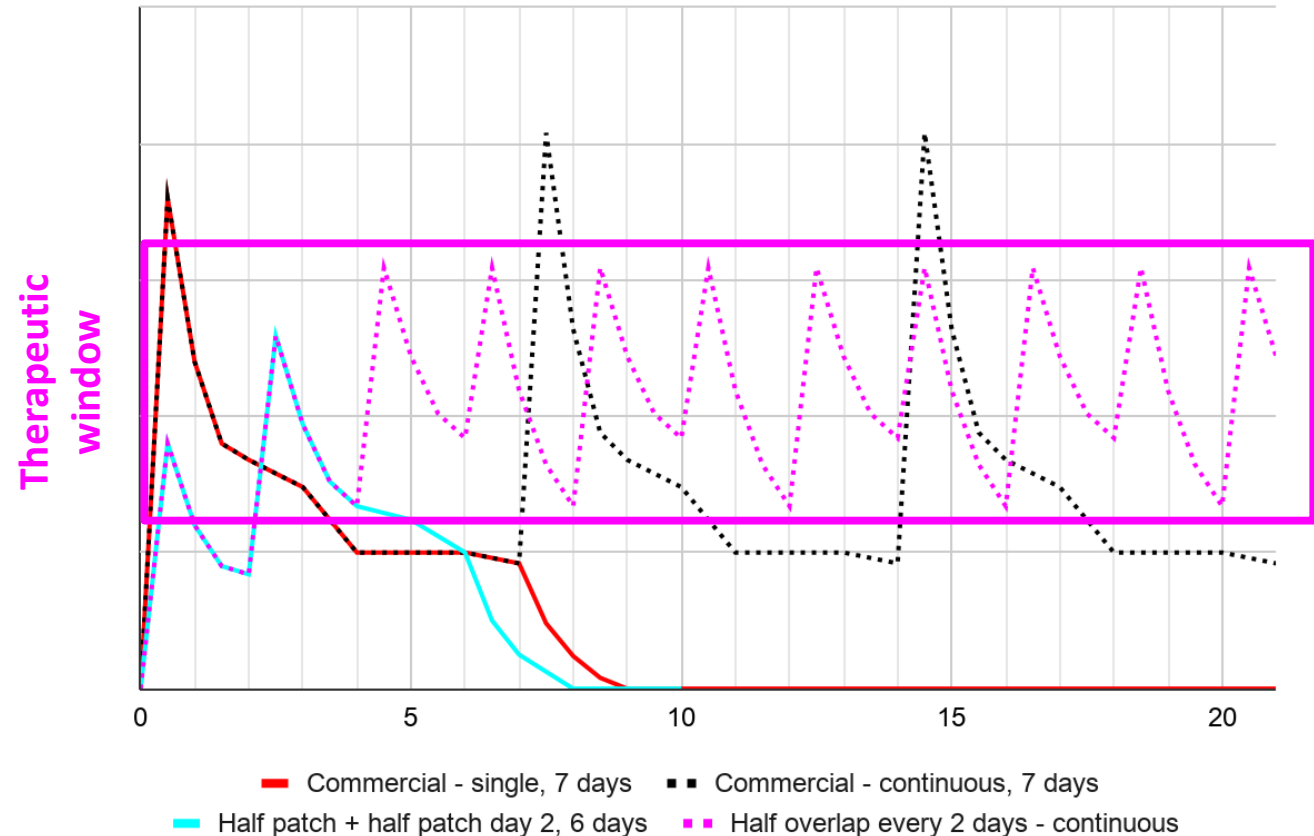
ON DAY 6: Increase exposure of 2nd patch, remove 1st patch.

CONTINUE: Stagger overlap cycle.

By **overlapping patch exposure**, we flatten the pharmacokinetic curves and **maintain the therapeutic window**.

When the right dose doesn't exist,
CAREGIVERS BRIDGE THE GAP.

Clonidine plasma concentration



CASE STUDY 2: ACCESS FAILURE

When the right formulation isn't accessible

APPROPRIATE FORMULATIONS EXIST

In Germany, we used a liquid Dronabinol formulation compatible with a feeding tube.

In the US, we transitioned to Syndros, the only FDA-approved liquid formulation.

ACCESS LOSS

Manufacturer went bankrupt,
Syndros no longer available.

REMAINING OPTIONS

- Gel capsules incompatible with feeding tubes.
- Recreational tinctures lacking FDA oversight.

The formulation we need exists.

WE JUST CAN'T ACCESS IT.



CASE STUDY 2: ACCESS FAILURE

Caregiver-engineered solution

THE PROCESS

1. **Soak** gel capsules to soften shell.
2. **Extract** oil using large-bore needle.
3. **Consolidate** into a single stock preparation.
4. **Suspend** oil in food for J-tube administration.

THE PARADOX

- A **physician** prescribed the medication.
- A **pharmacist** dispensed the medication.
- No **instructions** provided.
- A **caregiver** engineered the solution.

When the right formulation isn't accessible,
CAREGIVERS BRIDGE THE GAP.



CASE STUDY 3: SYSTEM FAILURE

When caregivers must rely on the system...

MEET EVELYN

THE INCIDENT

Received nightly clonidine to induce sleep.

Somnolent, agitated with **nystagmus**.

Seizure suspected, gave emergency **diazepam**.

EMS called. En route to ED, became **apneic and bradycardic, requiring bagging and chest compressions**.

Intubated and **admitted** to PICU.

Sometimes there is no gap to bridge.
CAREGIVERS MUST RELY ON THE SYSTEM.



**Note: I have written consent to share Evelyn's story and photos*

CASE STUDY 3: SYSTEM FAILURE

... the system must be reliable

MOTHER'S INTUITION Mom brought compounded clonidine, noting it looked **different** from previous bottle.

CRITICAL OBSERVATION Based on mom's **suspicion** of clonidine overdose, Naloxene (Narcan) administered in ED.

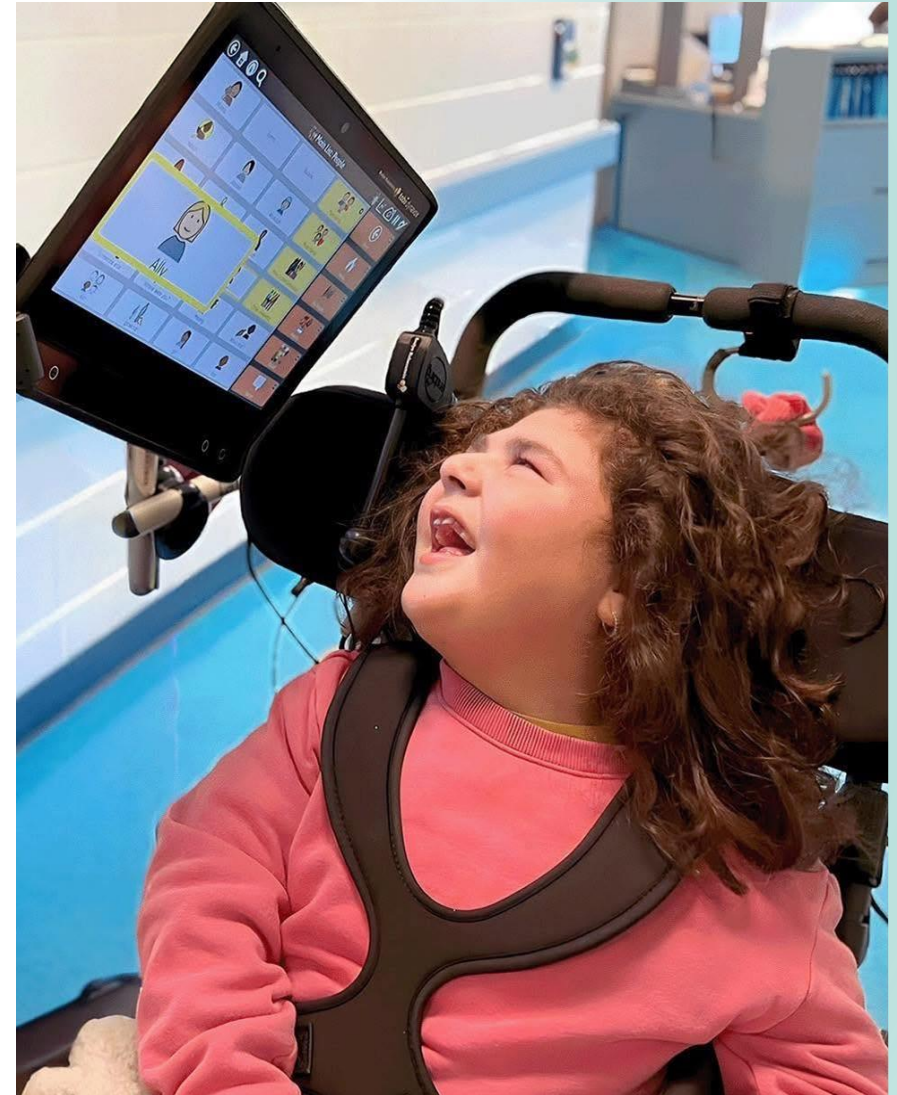
DENIAL FROM PHARMACY Mom was reassured multiple times that **all protocols had been followed** and concentration was correct.

DISMISSAL Mom asked bottle to be **tested**, was told **"This isn't an episode of HOUSE"**.

INDEPENDENT LAB VERIFICATION Revealed that bottle contained approx. **2000X** prescribed concentration.

OUTCOME Spent 8 days in hospital before being discharged to home.

Systems must be resilient enough to respond to inevitable gaps.



**Note: I have written consent to share Evelyn's story and photos*

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Designing for reality

THE STATUS QUO

Insights from the community

Survey asked how caregivers obtain, prepare and administer prescription medications.



50+

caregivers of
children with
medical
complexities

across the US and
internationally



In addition to **quantitative** (multiple-choice) questions, respondents were invited to provide **narrative descriptions**.

CAREGIVERS EXPLORED



Medication
modification



Access
barriers



Caregiver
burden



Stakeholder
responsibility

THE STATUS QUO

Modification is the norm

TYPES OF MODIFICATIONS



Splitting



Crushing



Weighing



Mixing



Extracting



Dissolving

"Multiple portions of my day go to mixing, dividing, and portioning medication and cleaning dosage cups, syringes, pill crushers, and bottles." - Caregiver

For most families, medication modification is **not an exception**, it is part of their **every day**.



82%

Modify medications **at least daily**



67%

Modify medications **multiple times per day**

THE STATUS QUO

Responsibility shifts to caregivers



47%

Little or
no guidance



37%

Oral
instructions



14%

Written
instructions

Medication preparation **responsibilities**
are frequently **transferred to caregivers**
without **standardized guidance**.

*"...caregivers must wade through the swamp of **conflicting and vague information** to arrive at **safe, consistent preparation and dosing information**; often with **no prior medical experience or training**." - Sylvia C., California*



**Medication
safety**



**Dosing
accuracy**



**Caregiver
training**



**Standardization
of care**

THE STATUS QUO

Availability does not guarantee accessibility

WHAT THE SYSTEM SEES



The medication exists.

WHAT CAREGIVERS SEE

-  Insurance denials
-  Prior authorization requirements
-  Drug shortages and backorders
-  Limited compounding access
-  Out-of-pocket costs

A medication that cannot be **accessed** is **functionally unavailable**.

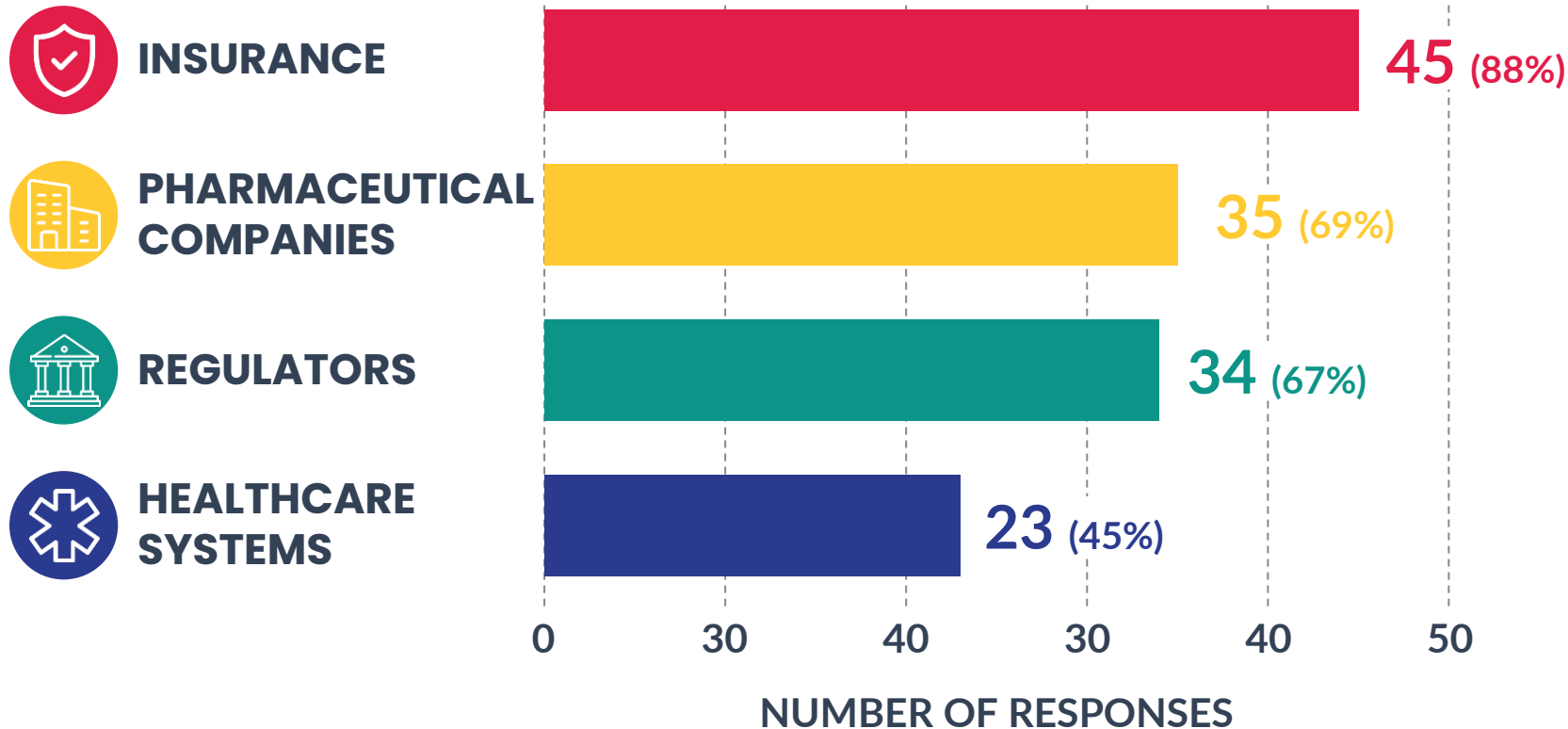
"Every refill, denial, delay, or shortage has real consequences.

It's not paperwork—it's protecting his stability, safety, and dignity." - Kristen M., Florida

THE STATUS QUO

Who is responsible?

Out of 51 responses:



No single stakeholder is responsible

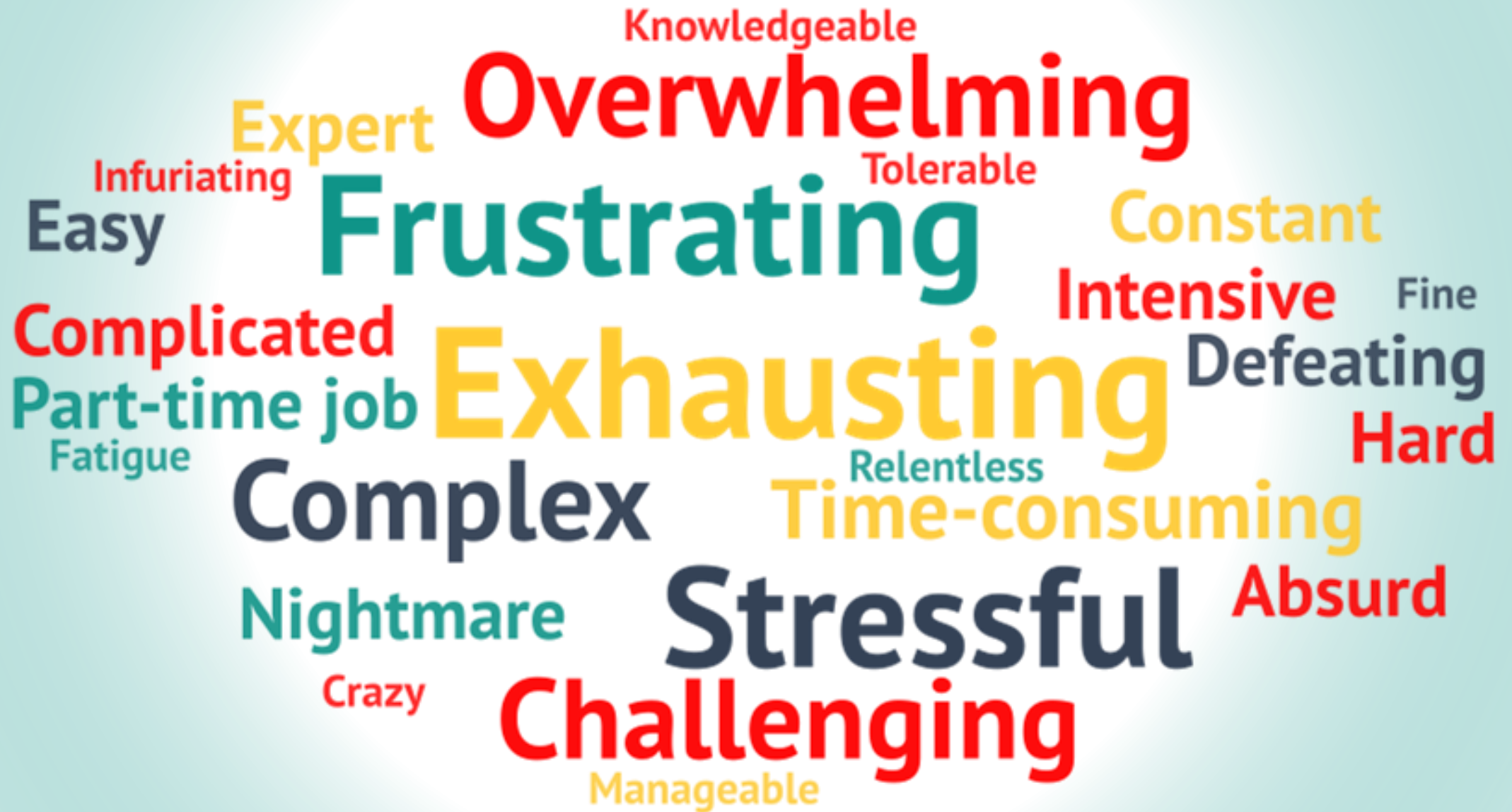


No single stakeholder can close the gaps

"Managing my child's medications requires the skills of a benefits coordinator, pharmacist, registered nurse, and sometimes even EMS." - Mary O., Chicago

THE STATUS QUO

One word to describe it all



WHAT WE LEARNED

Key insights



Medication modification is the norm, not the exception.



Caregivers develop solutions that systems do not provide.



Availability does not guarantee **accessibility**.



Responsibility for bridging gaps frequently **shifts to families**.



These **challenges** are **systemic**.

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BUILDING BETTER SYSTEMS

So caregivers don't have to bridge gaps alone

The question is not whether
caregivers **can** bridge the gap.

WE ALREADY DO. "

The question is how we build better systems
so that when gaps inevitably arise,
caregivers are not left to bridge them alone.

BUILDING BETTER SYSTEMS

What does “better” mean?

- Better does not mean **PERFECT**.
- Gaps will **ALWAYS** exist.
- Off-label use and medication modification are **REALITIES** of pediatric care.
- Better means **RESILIENT** systems **DESIGNED** for the real-world.
- Better systems respond **SAFELY** and **SUPPORT** families when gaps arise.



BUILDING BETTER SYSTEMS

Hope on the horizon

Caregivers of children with medical complexity often feel **unseen** and **unsupported**.

RECOGNITION

of our experiences and expertise.

VALIDATION

of our roles as partners in care.

SHARED COMMITMENT

to building better systems.

The goal isn't perfect systems.

It is resilient systems built with caregivers and designed for reality.



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Thank you for **WELCOMING CAREGIVERS** into this space.