



# Battery-Powered Medical Devices: Challenges & Opportunities

## Closing Remarks



# Action plan presentations

1. Batt-Maxx Challenge
2. Breakout Pink
3. Intelligent Battery Systems - Alligators
4. HitchHiker's Guide to the Battery Universe
5. BPMD-RMDG
6. Isosmart
7. Battery is a Critical Component
8. Got Battery!?

# Team 1: Batt-Maxx Challenge

Session 1 - Green\*

## BATT-MAXX CHALLENGE



MANUFACTURERS, FDA, UL, FCRI, PATIENTS, HOSPITALS

BETTER / SAFER BATTERIES + DEVICES  
FLEXIBLE FRAMEWORK TO WORK WITH

Session 1  
Green:  
Shane Adams

SET GUIDELINES WHICH RESULT IN IMPROVED PATIENT CARE WITH TECHNOLOGY + MINIMIZED USE ERRORS

Batt. mg. will have a set level of quality they must achieve.

effects manufacturing, raw materials performance requirements

Define SPECIFIC LABELING AND DO INDICATORS OF BATTERY RUN TIME + USABLE LIFE TIME

Guidelines for User Interface Design

→ Design to meet Users' Expectations so that Users don't make errors

→ Design sim such a way that users need minimum instructions and training Use the Final Product.

Design with Visual Indicators

→ Design with "Clear" Labelling

COST: WORTH EVERY PENNY / SAVE A LIFE

TIME: GET STOCKHOLDERS TO DEVELOPE PLAN BY JUNE 2014

Safe operating parameters for Battery Packs

- Voltage (over-voltage)
- Current (over current charge + dischg)
- Temperature (over/under Temperature of cells under charge + dis charge)
- Safety devices (PTC, TCO C.ID, vents)

Hazards to mitigate for specific devices e.g. venting a bat powered toothbrush

Unlimited cost = other opportunities missed

# Team 2: Breakout Pink

Concept/Value Statement  
Develop battery  
related risk  
checklists to be  
considered by medical  
Device/Battery Manf.

Responsible Stakeholders  
Med. Dev. Manufacturers  
Battery Manufacturers  
Regulators  
Health Tech. Managers

- Features/Benefits
- Better met user needs
  - More consistent battery/BPMD development
  - Improved management of battery-related risks
  - More consistent submission review for Manf. & Regulator

unmet needs  
lack of clarity  
in user needs  
& development requirements

Team  
#1 3  
Session #2

★  
Breakout  
PINK

Concept Description

stake holder  
workshop

Identify battery/BPMD  
design, usage, testing & implementation  
concerns

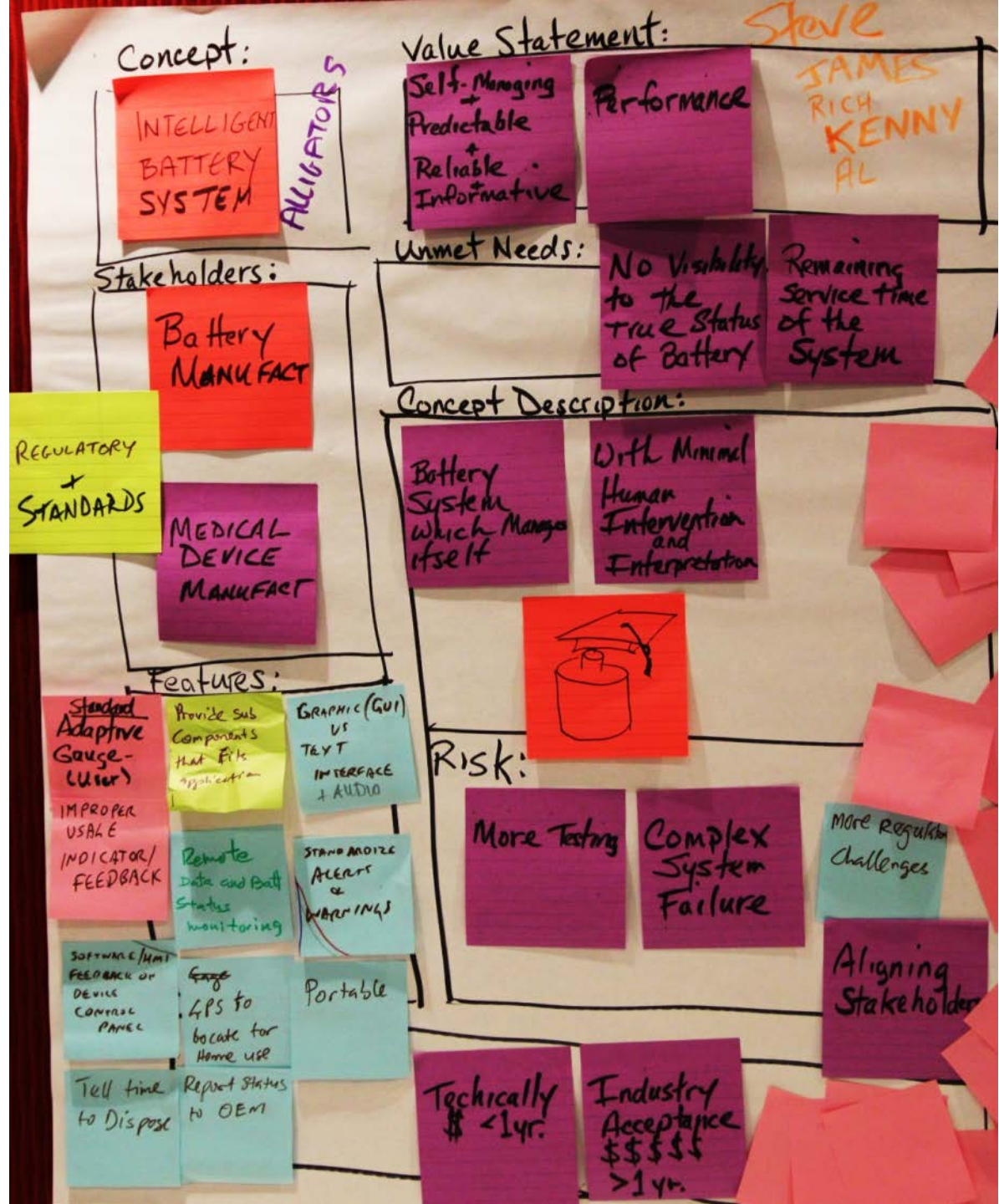
Manufacturer/Regulator  
working group

Categorize  
concerns  
based on  
device type  
& application

Develop  
guideline  
presenting  
check lists  
for concerns to be  
addressed during  
Battery/BPMD development



# Team 3: Intelligent Battery System- Alligators



# Team 4: HitchHiker's Guide to the Battery Universe

Name: **Team 4** ★  
HitchHiker's Guide to  
the Battery Universe

Value Statement: Inform users & providers of  
BPMD of expectations, operation & maintenance

Stakeholders:

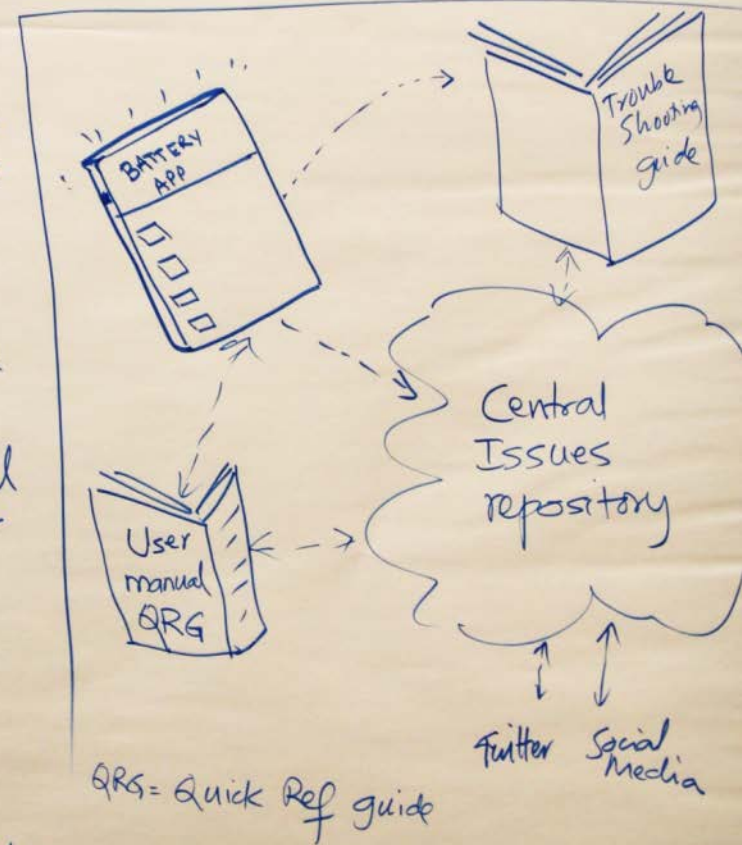
- Home Users
- Biomed
- Clinicians
- BPMD providers

Unmet Needs: ~~gap~~ Bridging gaps in the  
Universe of battery use.

Features & Benefits

- Rapid trouble shooting guides  
- via electronic media, apps
- User education
 

	<u>Delivery</u>
- Home users	- web
- Clinicians	- apps
- Device Provider	- on device
- Biomed	- print
- Central Repository of all  
battery issues - web &  
APP
- Safety
- Reduced downtime
- clear performance expectations
- Increased reporting & feedback



Cost: CAN BPMD & Industry fund = \$200k & 18 months  
Associations



# Team 5: BPMD-RMDG

**Concept name:**  
BPMD-RMDG  
Battery Powered Medical Device  
Regulation Manual + Design Guidance

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**Value Stmt.**  
"To create a Manu.-based templated  
design & guidance for Battery Powered Medical  
Devices - based on risk."

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**Responsible Stakeholders**

- FDA - Regulatory Bodies
- OEM
- Batt manufacturers
- End User

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**Unmet Needs:**  
Specificity of common battery characteristics  
User  
Common regulatory standards by:

- device type
- battery type / Chemistry
- battery size
- application of Device
  - Ambulatory
  - Home care

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**FEATURES / BENEFITS**

- Reduction in Ambiguity
- Flexible Test Stds

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**EMT**

class 1      class 2      class 3

Environment

USERS

Device Use

OEM

User (Devices)

Regulatory

CONCEPT DESCRIPTION RISK

# Team 6: Isosmart

CONCEPT POSTER

Group #6 ■ Team #1

**Isolette Isosmart**



## Value Statement

Smart Technology  
Value Statement  
Improve safety, reliability  
enhance use of BP and  
more implementation of  
smart technology within  
warranty systems



RELIABLE  
METHOD TO  
COMMUNICATE  
BATTERY LIFE  
LEFT ON DEVICE



## Stakeholders

Stakeholder  
User  
- engineer  
- clinician  
- regulatory  
- FDA

Smart Technology  
Stakeholders  
- Battery mfg  
- Device mfg  
- Tooling mfg  
- Clinical user / caregiver  
Regulatory  
- Including their group  
- FDA/EMA

DEVICE  
MANUFACTURERS  
Stakeholders  
Users  
Finance  
Brand  
Engineering  
Sales  
Marketing

Hospitals  
BPIES  
Clinics  
- users  
- people who maintain  
equipment  
- battery suppliers  
- designers of equipment  
- regulatory people

Battery Co.  
Device mfg.  
Waste disposal

## Unmet Needs

Smart Technology  
Unmet need  
Clear, easy to understand  
battery charge indicator  
and data (battery level)  
- smart capability

Reduced  
Cost, better  
we're expensive!

Outcomes, stress  
etc.  
w/ home user

- HIGH + LOW  
TEMP. USE  
- CLEAR  
INDICATION  
OF TIME LEFT  
IN BATTERY

- Clear  
of battery status  
- less errors  
when battery dies

- slow cost

\* DESIGN CHANGE  
CONFORMANCE WITH  
FEDERAL CARE  
\* CHINA REGULATIONS  
\* S.O.C.

## Description

Indicator will  
provide early &  
accurate warning  
of battery low left  
- user would be  
aware when they  
start using device  
whether battery will  
last time enough

Visual  
indication  
of SOC  
- green  
- yellow  
- red

Smart indicator of  
run time to  
battery depletion  
at end of device  
function.  
Visual represent-  
ation of minutes  
of run time  
remaining.



PROVIDE  
EFFECTIVE  
TIME OF USE  
LEFT

## Benefits & Features

- DEVICE MFG  
- USERS  
- FDA-REGUL  
- MILITARY

- more predictable  
results  
- clear indication  
when new battery  
is needed  
- early warning of  
through life to  
replace

Benefits  
Reduced Down Time  
Reduced replacement  
cost

\* BENEFITS/VALUES  
- Evaluate w/ NEEDS  
- PERFORMANCE DESIGN  
- SECURITY DESIGN  
- PROTECT FROM BOMB  
- VULNERABLE USE

Visual  
indication  
of SOC  
- green  
- yellow  
- red

Audible  
status  
indicator

(PHASE 1)  
\$200k  
COST  
\$400K

## Goals & Timelines

Charge status  
Life status  
Data support  
Compatible non compatible  
Power systems  
Reduce down-time costs  
maintainance costs  
Reduce critical events due  
to battery used

Timing  
for  
Recharge  
VOLTAGE -  
Ah -  
TIME LEFT

PHASE 1  
Understand  
user  
application  
hu factors

PHASE 2  
Cost  
analysis

PHASE 3  
Research  
Available  
technology  
Critical  
to  
Quality

PHASE 4  
Develop  
prototype  
User  
input  
Verify &  
Confirm

PHASE 4  
Validate  
Design  
transfer

Understand  
display  
limitations  
What is  
risk/benefit  
for device?

Define  
specs  
Ensure  
correct  
users  
Business  
case



# Team 7: Battery is a Critical Component

John Dumas

BATTERY IS A CRITICAL COMPONENT (QSR)

## CONCEPT PAPER - GROUP #7

### Value Statement

Ensures all batteries power devices appropriately -  
Battery Quality is clear

### Stakeholders

Manufacturer  
FDA  
3rd Party  
Standard Orgs.  
Customer

### Unmet Need

All suppliers (3rd Party included) are subjected to the same controls as original equipment/approved device

### Concept Description

#### ① Enforcement:

- require serial #/lot codes
- FDA
- Clear description of specs/IFU (enforce these)

- Clear labeling

#### ② Education:

- Who is a MDM??
- What is a critical component
- What is a patient "critical" device?
- Disposal - Clear labeling

### Features & Benefits

Level "playing field"

Clear expectations: performance, reliability  
Traceability of 3rd party batteries  
Increase Quality

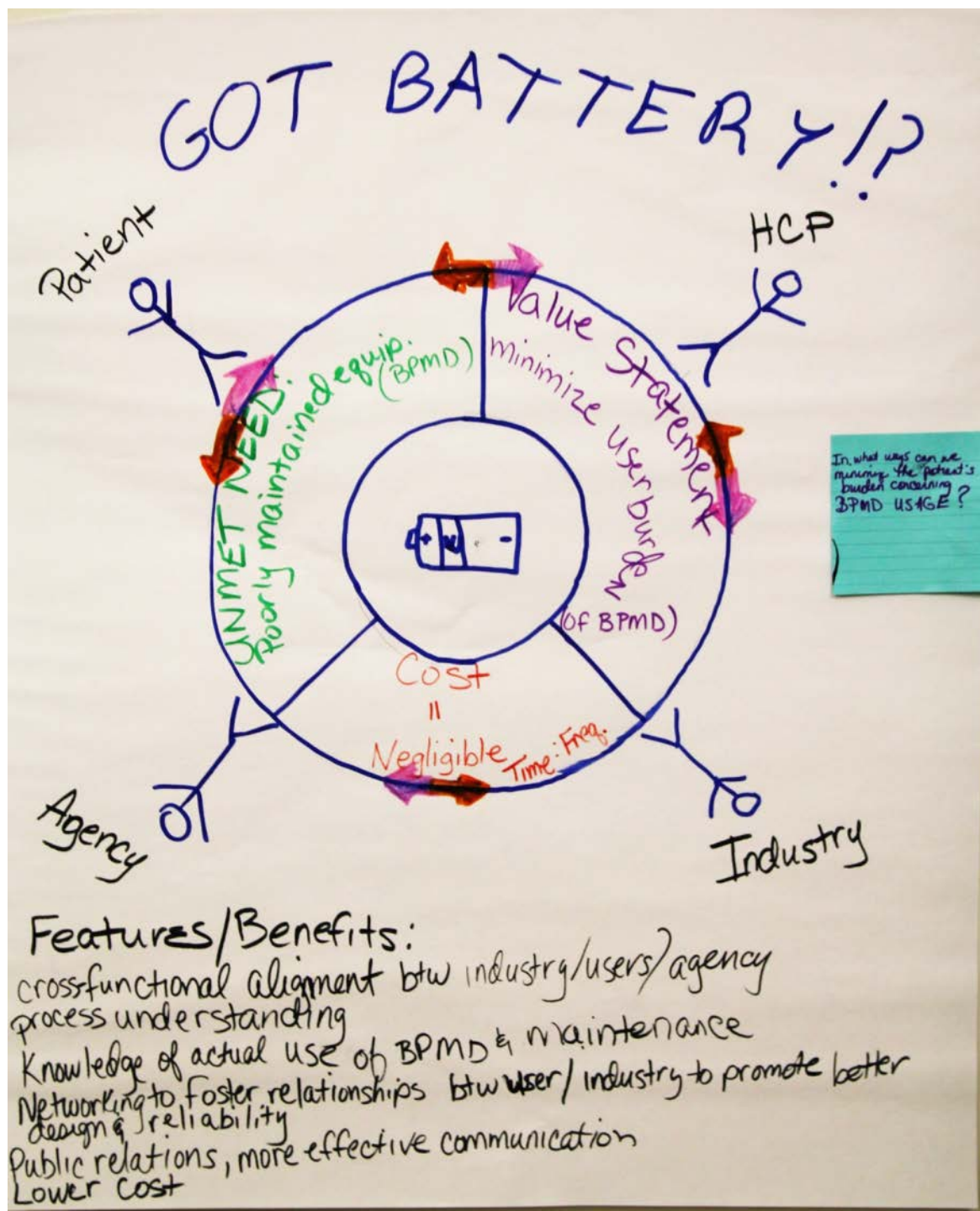
### COS'S

Volume matters

If ↑ demand ⇒ ↓ cost

Initial increase cost for replacement batteries but potential for lower owners hip cost

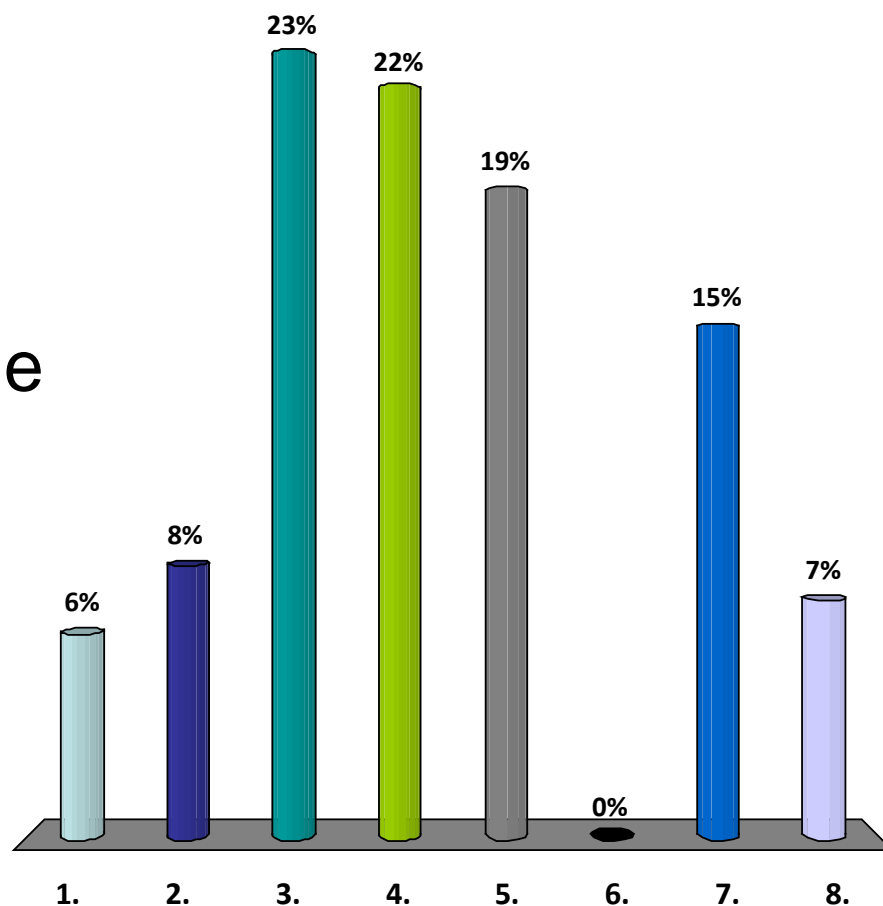
# Team 8: Got Battery!?



# Which concept will have the most significant impact?

Response Counter

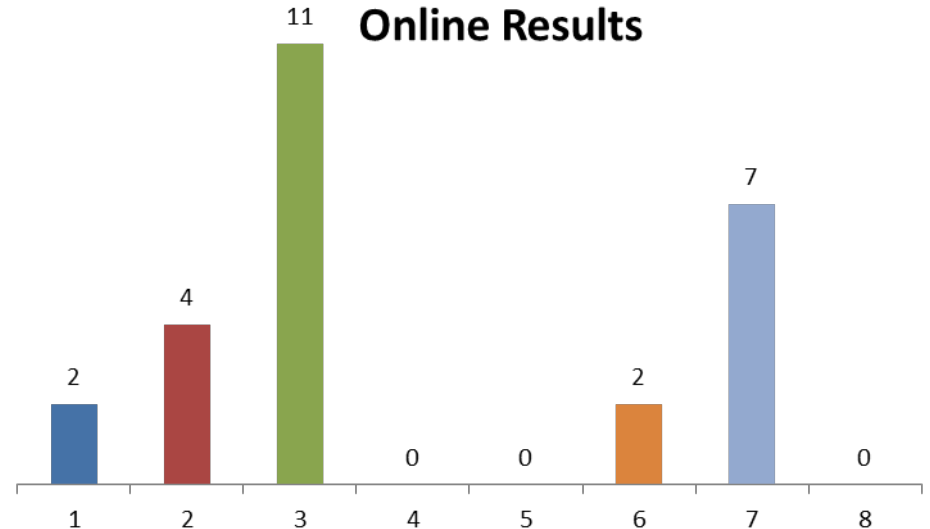
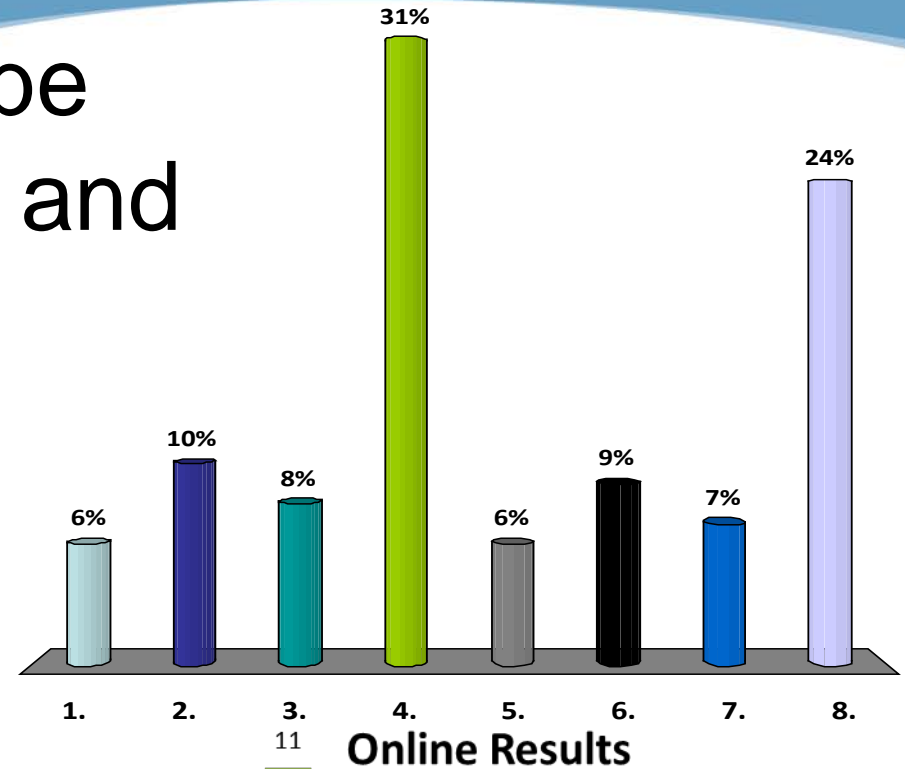
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# Which concept can be implemented quickly and easily?

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# Which concept would you be willing to support, based on your expertise?

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