

Welcome to Today's Webinar

We will begin at 1:02 p.m. ET

Organ Procurement Organization National Safety and Quality Standards Development



This webinar is interactive with polls used throughout the presentation. A yellow icon in the bottom-right corner of a slide indicates that a poll is active.



All attendees are muted.



Please enter brief comments in the chat. Messages are only visible to the host. You may send longer comments to <https://www.hrsa.gov/optn-modernization/contact>



This webinar will be recorded for internal use.

Contact Us





Organ Procurement Organization (OPO) National Safety and Quality Standards Development

March 3, 2026 (updated March 9, 2026 with poll results)

Health Systems Bureau (HSB), Division of Transplantation (DOT)
Health Federally Funded Research Development Center (FFRDC)*

Vision: Healthy Communities, Healthy People

*The Health FFRDC is operated by the MITRE Corporation.



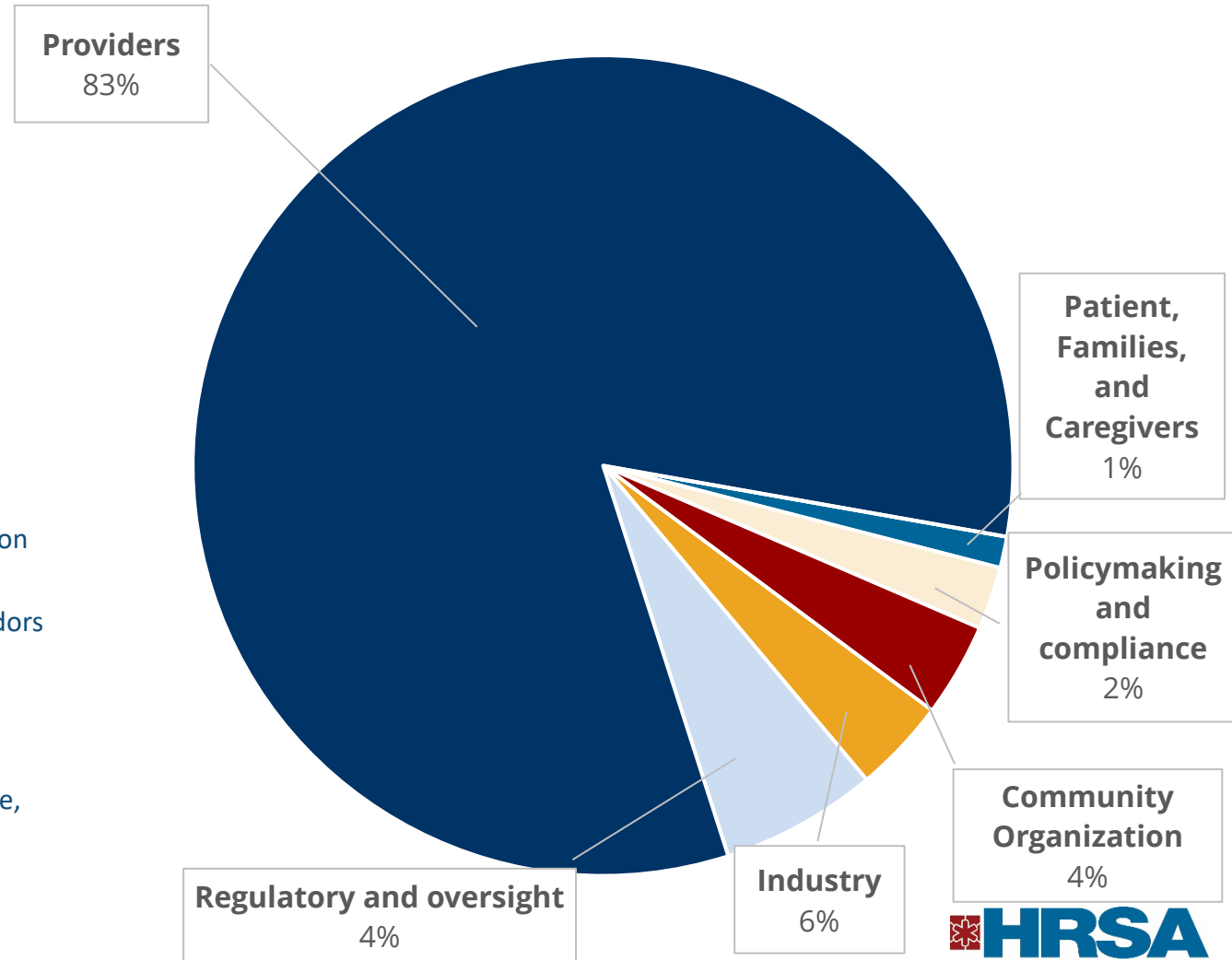


Audience Poll Results

Which group best describes your connection to the organ donation, procurement and transplant community?

(81 responses)

- Community organization: Peer support, patient advocacy, organ donation registries, living donor services
- Industry: Healthcare products and services, professional societies, vendors
- Patients, families, and caregivers
- Policymaking and compliance: OPTN board of directors, committee members
- Providers: OPOs, transplant centers, histocompatibility labs, clinical care, allied professionals
- Regulatory and oversight: HRSA, CMS, FDA, HHS, OIG, GAO



Agenda

Organ Procurement and Transplantation Network (OPTN) Modernization Initiative

- Patient safety at the heart of modernization
- Ongoing efforts
- Strengthening through standards

OPO National Safety and Quality Standards

- Development approach and inputs
- Topic areas under development
- Audience polls

Closing and Next Steps



Today's Goals

At the conclusion of this webinar, participants will be able to:

1

Explain the importance of **patient safety** in HRSA's OPTN Modernization Initiative

2

Describe the **OPO National Safety and Quality Standards'** topic areas

3

Provide **real-time input** to shape practical and relevant OPO standards



Organ Procurement and Transplantation Network (OPTN) Modernization Initiative



Organ Procurement and Transplant System

The growth in organ procurement and transplant and increasing complexity of medicine, technology, and safety required a new approach.



More than **100,000 people** are on the transplant waitlist



Rapid rise in patients entering the **donation after circulatory death** pathway



Someone is added to the waitlist every **8 minutes**



Organ transplants are rising, reaching a **record high** in 2025



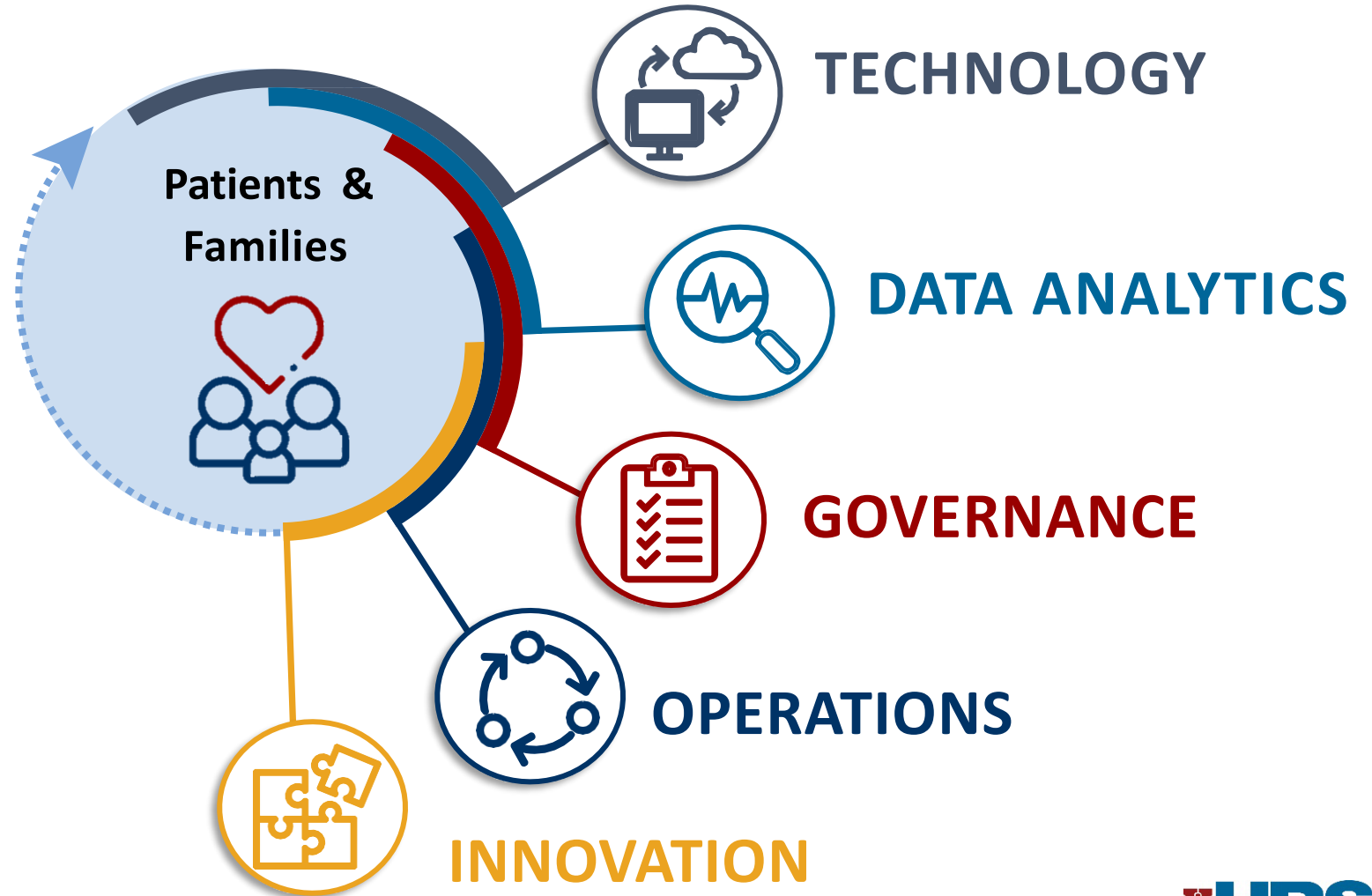
Patients and families rely on the national system **24/7**



1+ million patients a year are evaluated by OPOs to donate organs

HRSA OPTN Modernization Initiative

Patient safety is at the heart of modernization.



HRSA's Commitment to Patient Safety

HRSA's recent actions advancing patient safety:

- Directed the OPTN to require every OPO have a **patient safety officer**
- Instituted a process for anyone to **report allegations of misconduct** directly to HRSA for triage, with findings informing policy and oversight changes
- Provided critical comments to the OPTN and continue to collaborate to strengthen key policy & patient safety issues such as **NRP, DCD, transmissible diseases, and AOOS**



Partnering to safeguard every patient, family, and caregiver

Strengthen Patient Safety with National Standards



Strengthening oversight for a more patient-centered, safe, transparent, and accountable national system.

Evidence-based standards are used in healthcare to improve patient safety and quality of care by:

- Setting **consistent** performance expectations
- Focusing on systematic **continuous** quality improvement
- Promoting **best** practices
- Fostering **trust** with patients, families, caregivers, and the community

HRSA launched an effort with the Health Federally Funded Research & Development Center to develop safety and quality standards for OPTN members, **starting with OPOs.**

Organ Procurement Organization (OPO) National Safety and Quality Standards

Dr. Rakhee Palekar and Dr. Shauna St.Clair Flemming, MITRE



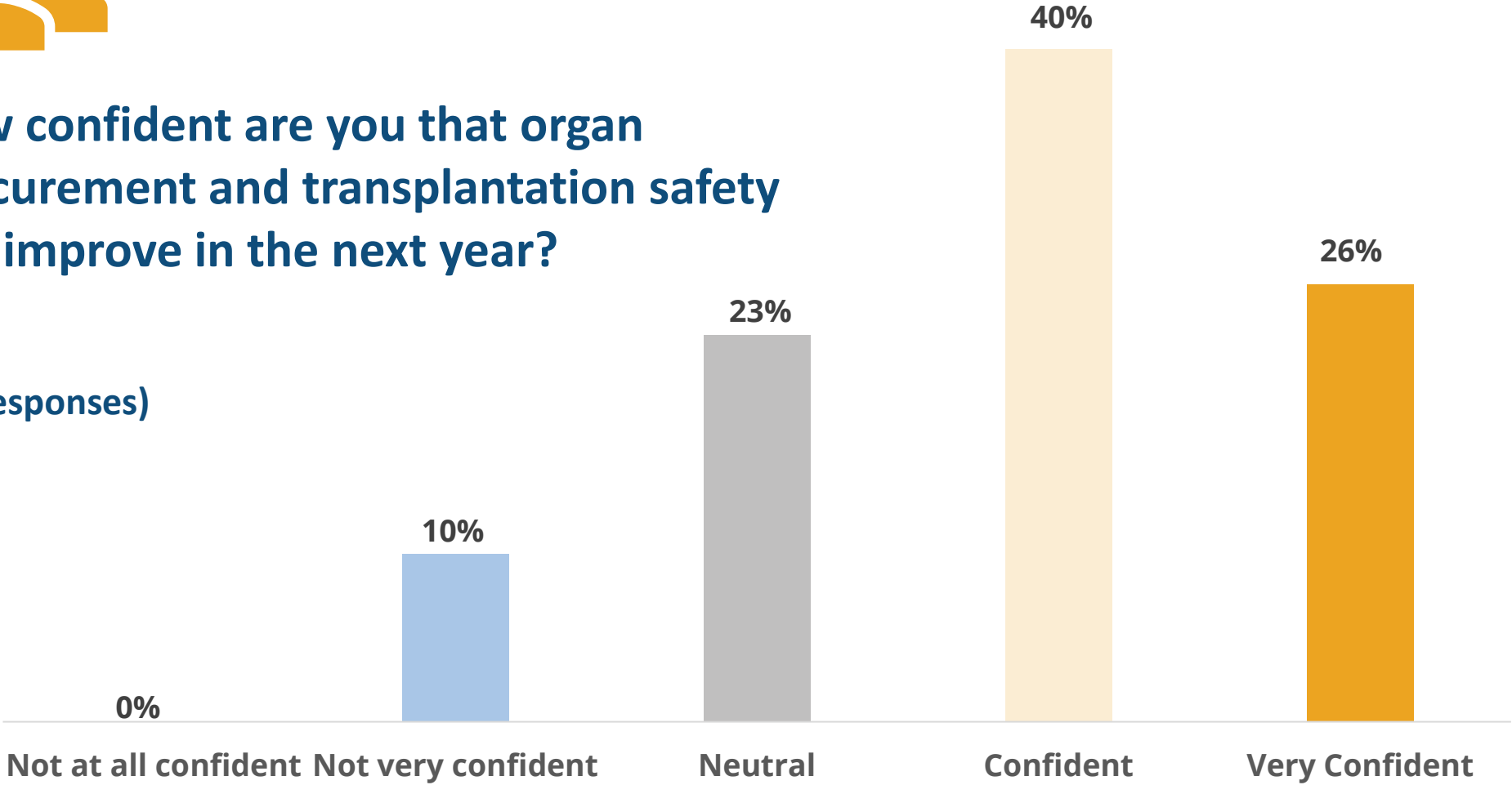


Audience Poll Results



How confident are you that organ procurement and transplantation safety will improve in the next year?

(77 responses)



Developing Evidence-Based OPO Standards



Standard Topic Areas Under Discussion

For each of the 9 topic areas we will present:

- Topic area scope and priorities
- Polling question

**Governing
Body and
Leadership**

**Provision of
Care and
Services**

**Respect for
Individual
Rights**

**Quality and
Performance
Improvement**

**Organ
Transport**

**Information
Management**

**Emergency
Management**

**Physical
Environment**

**Human
Resources**



Governing Body and Leadership



Sets the strategic organizational priorities, drives continuous improvement, and builds a culture of safety and high-quality care.



The governing body has the ultimate responsibility for the OPO's provision of safe and high-quality patient services and care.

Standards will address:

- Mission, vision, and values
- Executive leadership and governance practices
- Ethical conduct and conflict of interest
- Law, regulation, and policy compliance
- Fiduciary responsibility and adequacy of resources
- Quality and safety, accountability, and culture
- Operational excellence and risk management
- Contracts and hospital agreements management
- Public accountability and information dissemination

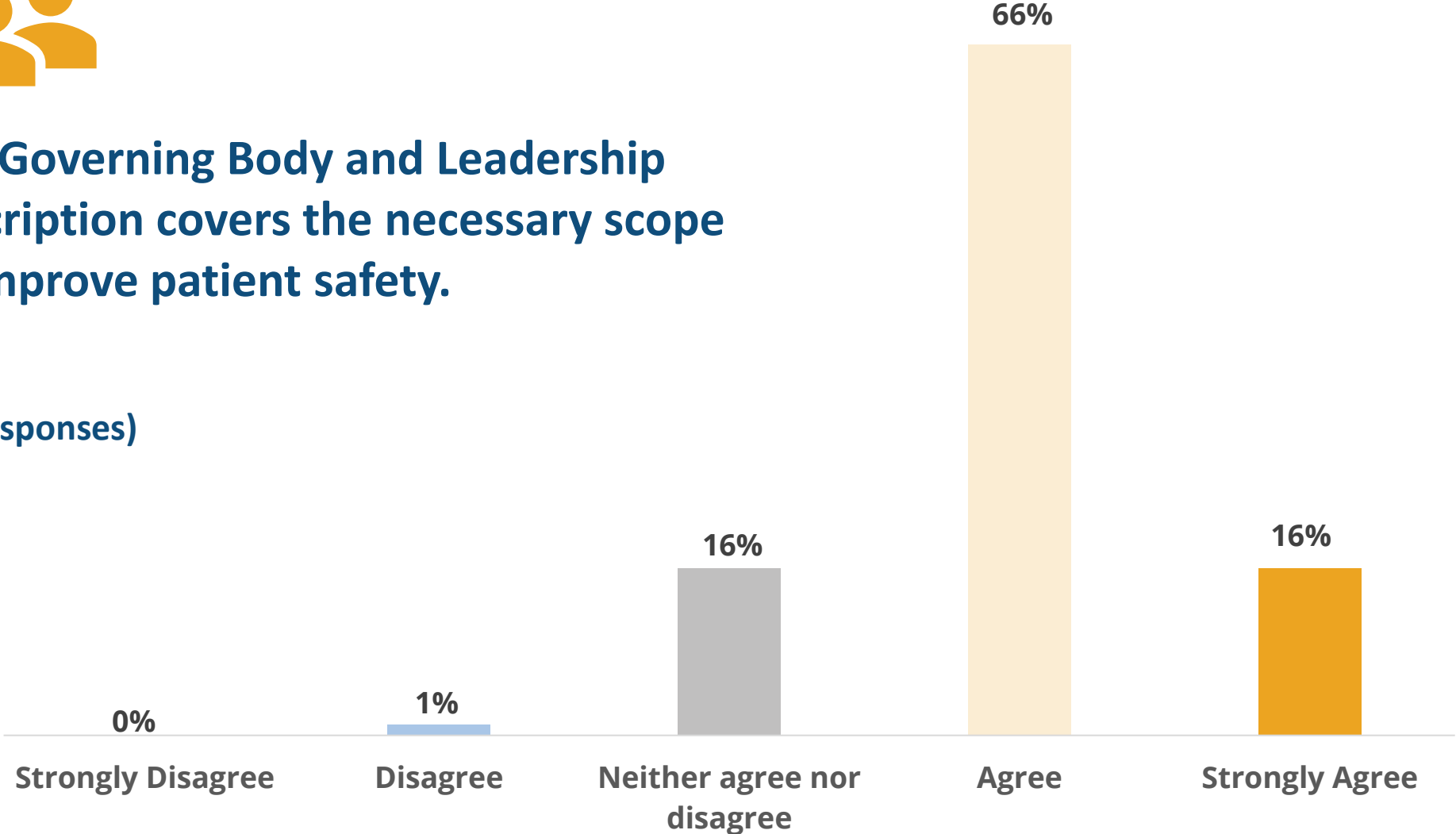


Audience Poll Results



The Governing Body and Leadership description covers the necessary scope to improve patient safety.

(73 responses)



Provision of Care and Services



Sets expectations for the OPOs from the point of patient referral through procurement and packaging of organs, in alignment with the highest professional, ethical, and clinical guidelines.



Adherence to these standards supports patient and staff well-being and delivery of patient-centered care.

Standards will address:

- Coordination of patient referrals and procurement services
- Verification of patient death
- Patient clinical management
- Infection prevention and control
- Organ utility maximization
- Organ allocation
- Organ procurement and packaging
- Risk assessment

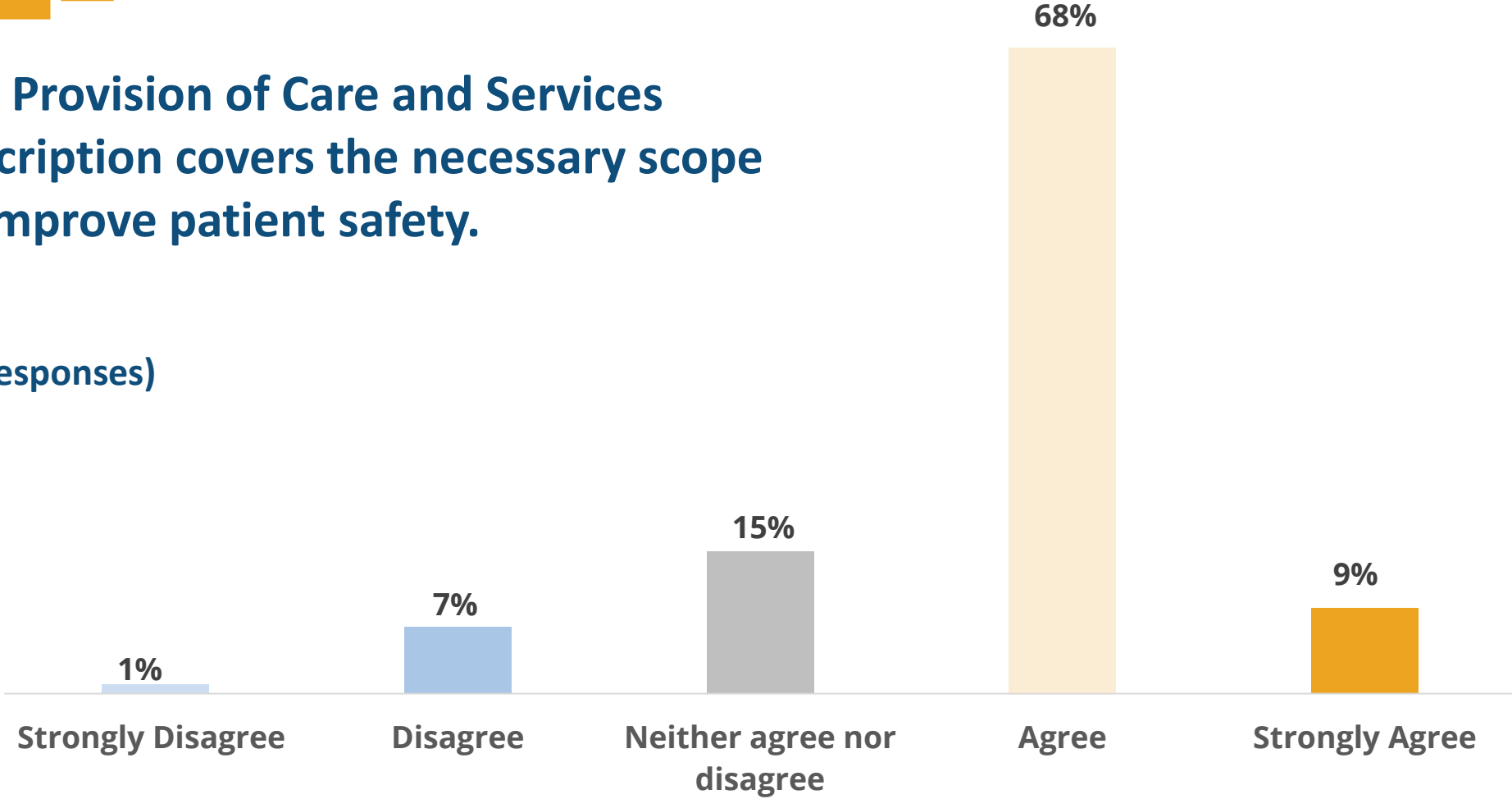


Audience Poll Results



The Provision of Care and Services description covers the necessary scope to improve patient safety.

(75 responses)



Respect for Individual Rights



Describes expectations for OPOs to deliver person-centered care and services that supports optimal patient care, honors patients' autonomy in end-of-life choices, protects confidentiality, and informs and helps patients, families, and caregivers understand and exercise their rights.



Respect for individual rights promotes a culture of respect, quality care, improves patient safety, and strengthens confidence in the organ procurement and transplantation system.

Standards will address:

- Culturally responsive communication
- Informed consent
- Patient, family, and caregiver information privacy and access
- Patient, family, and caregiver rights
- Patient, family, and caregiver services and support
- Research and clinical trials protections

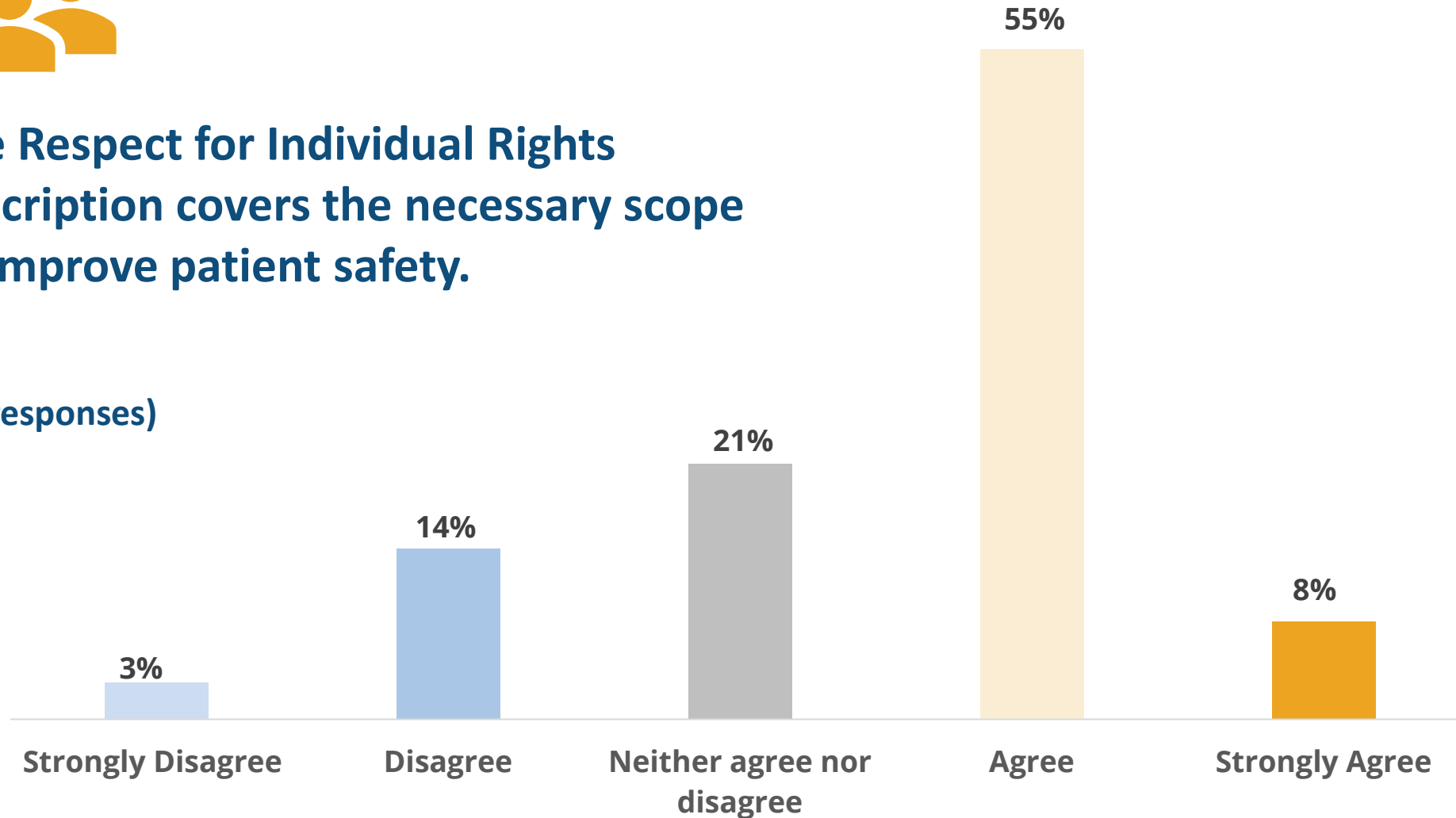


Audience Poll Results



**The Respect for Individual Rights
description covers the necessary scope
to improve patient safety.**

(80 responses)



First Check In: Standard Topic Areas Under Discussion

For each of the 9 topic areas we will present:

- Topic area scope and priorities
- Polling question

**Governing
Body and
Leadership** ✓

**Provision of
Care and
Services** ✓

**Respect for
Individual
Rights** ✓

**Quality and
Performance
Improvement**

**Organ
Transport**

**Information
Management**

**Emergency
Management**

**Physical
Environment**

**Human
Resources**



Quality and Performance Improvement



Focuses on the implementation of organization-wide, comprehensive, evidence-based, and data-driven processes reflecting the complexity of procurement and transplant services and the need to respond to adverse events.



Implementation of these actions will result in measurable, continuous improvement in safety, quality, and outcomes for all patients.

Standards will address:

- Organizational QAPI approach
- Performance improvement implementation
- Continuous improvement evaluation
- Internal compliance monitoring
- Quality and safety data collection, analysis, dissemination, and use
- Response to adverse events and complaints

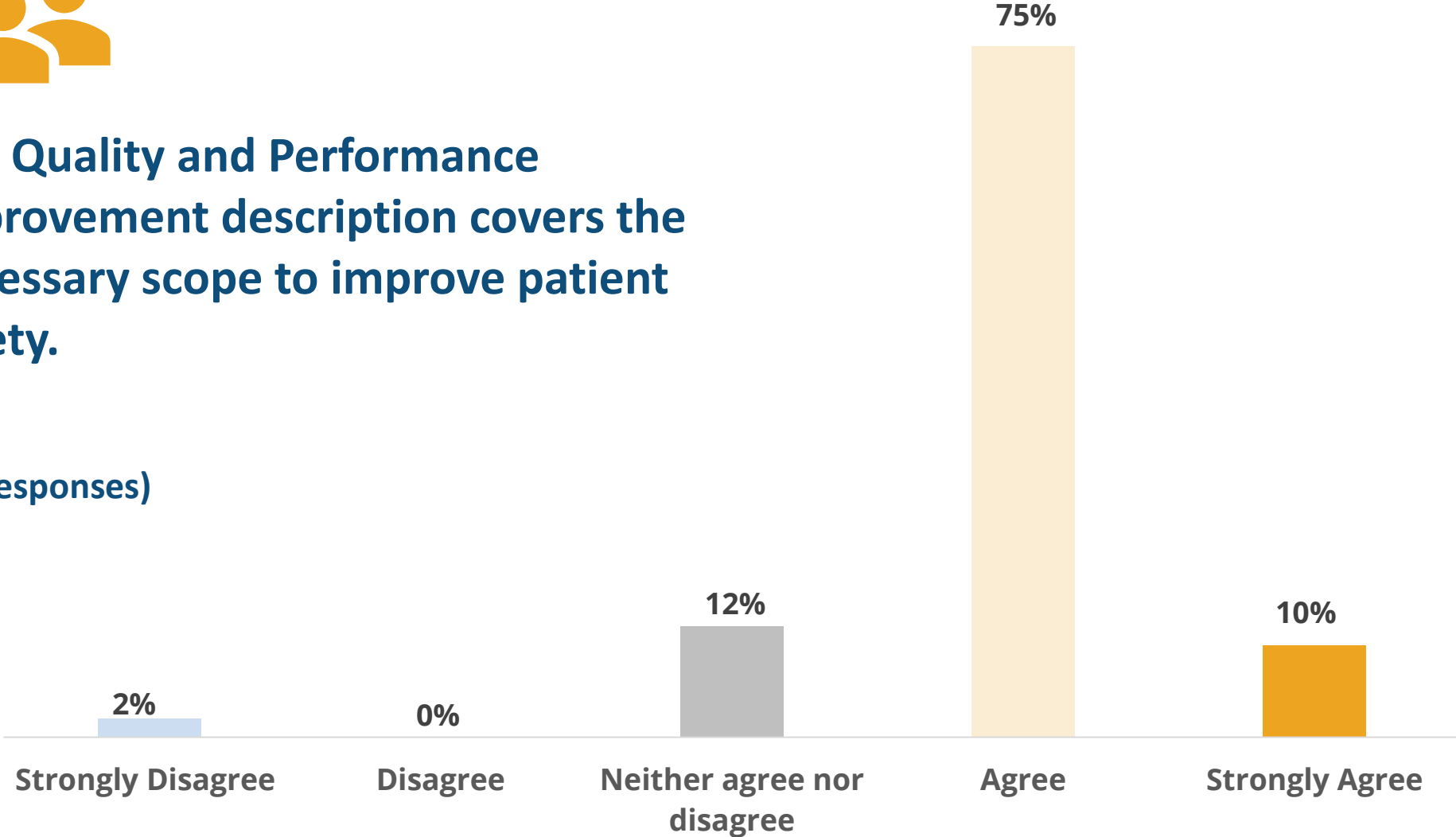


Audience Poll Results



The Quality and Performance Improvement description covers the necessary scope to improve patient safety.

(81 responses)



Organ Transport



Addresses expectations that OPOs plan and execute, the safe, efficient, and accurate transportation of organs.



Following these standards helps mitigate delivery delays and organ damage, increasing the number of organs available for transplant.

Standards will address:

- Transport policies and protocols
- Chain of custody and location tracking
- Communication with relevant parties during organ transport
- Condition tracking
- Contracted services and 3rd party logistics provider oversight
- Preservation policies and management

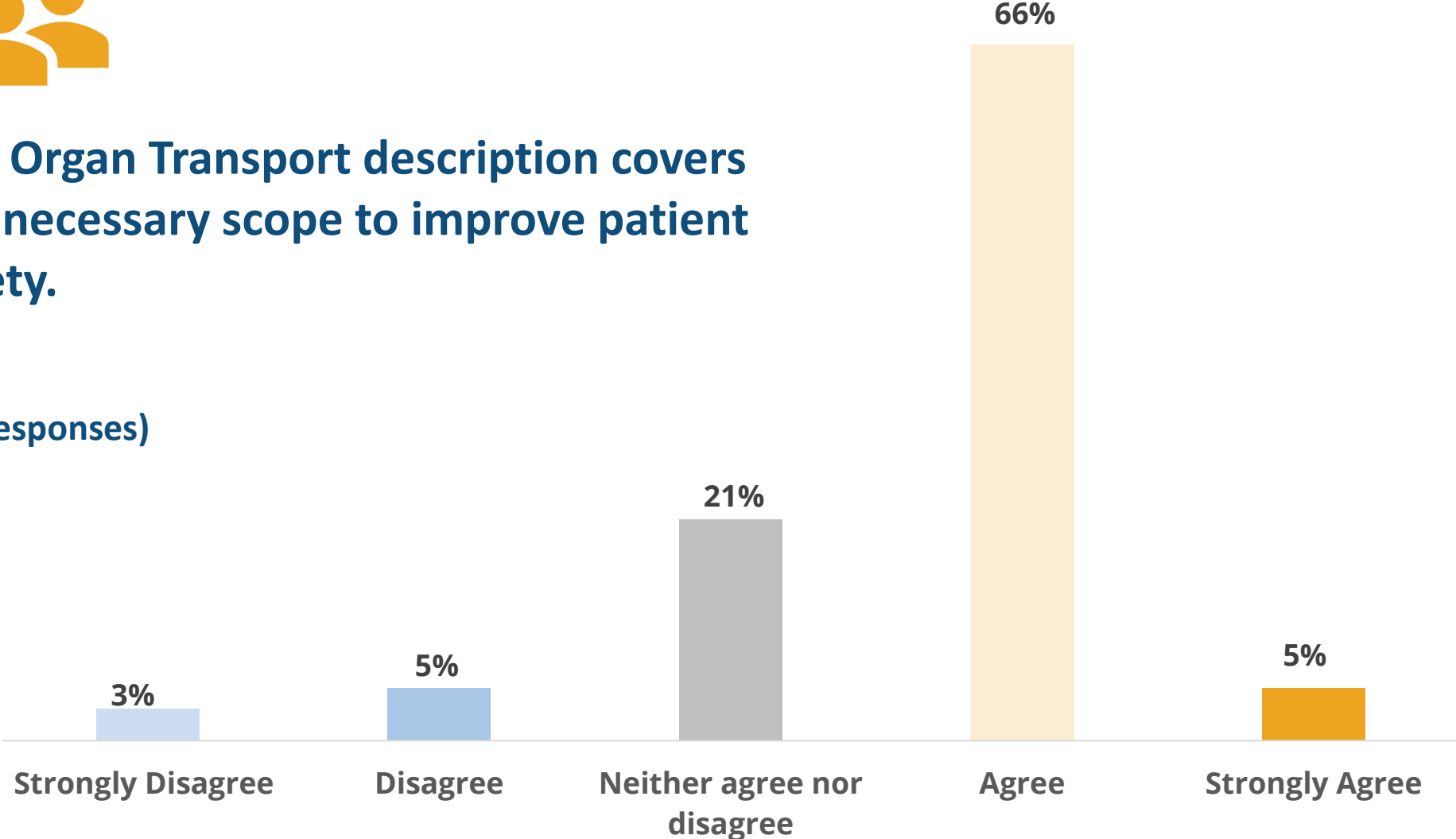


Audience Poll Results



The Organ Transport description covers the necessary scope to improve patient safety.

(76 responses)



Information Management



Includes collecting, sharing, analyzing, storing, exchanging, and protecting data.



These standards promote accuracy, security, and accessibility of patient information critical to efficient clinical decision-making and compliant operations across OPOs and partner organizations.

Standards will address:

- Data and technology
- Information management system
- Infrastructure maintenance
- Operational tools
- Systems and data security
- Systems integration and support

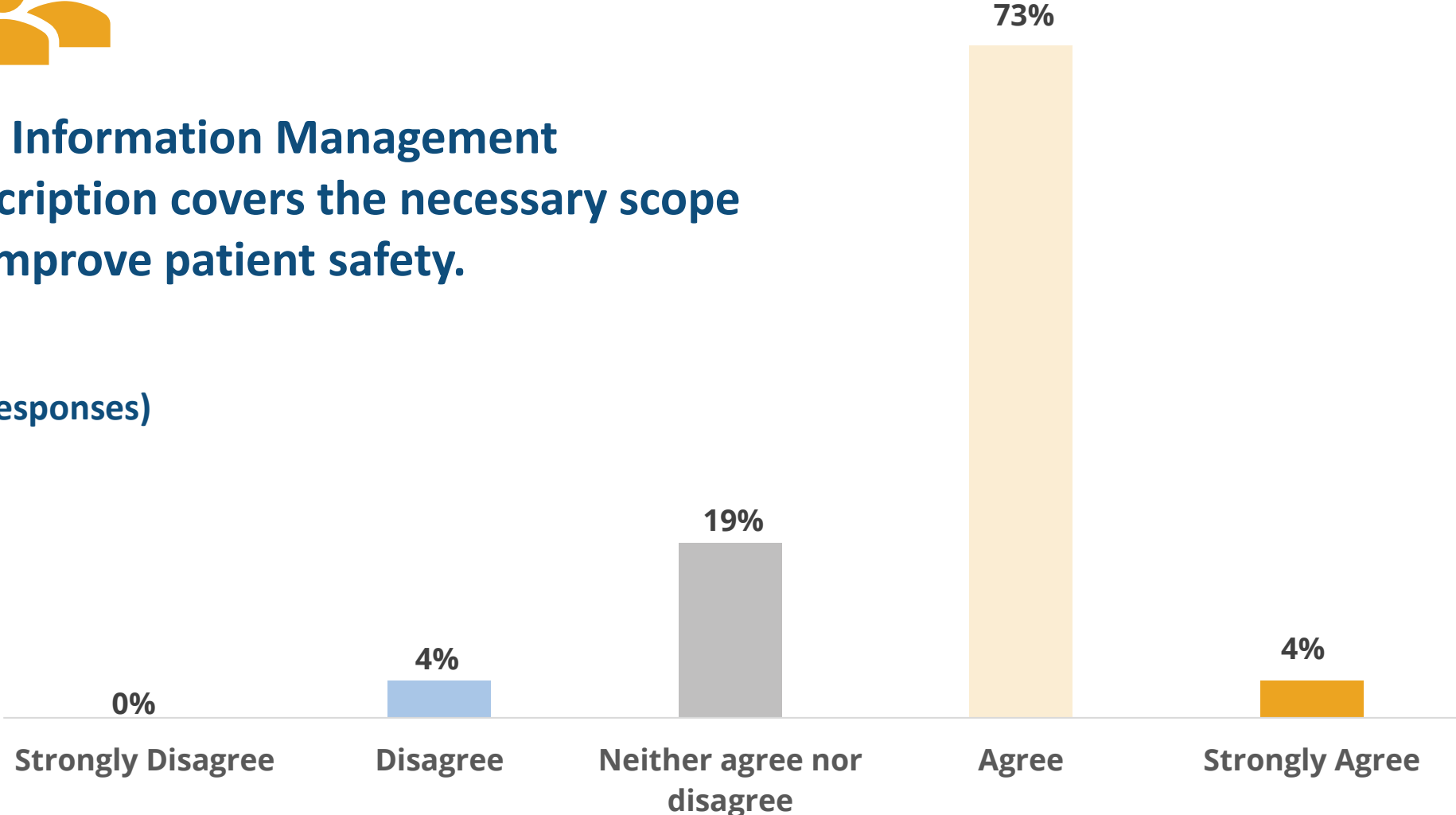


Audience Poll Results



The Information Management description covers the necessary scope to improve patient safety.

(75 responses)



Second Check In: Standard Topic Areas Under Discussion

For each of the 9 topic areas we will present:

- Topic area scope and priorities
- Polling question

Governing
Body and
Leadership ✓

Provision of
Care and
Services ✓

Respect for
Individual
Rights ✓

Quality and
Performance
Improvement ✓

Organ
Transport ✓

Information
Management ✓

Emergency
Management

Physical
Environment

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Resources



Emergency Management



Centers on implementing an all-hazards approach to OPO, mitigation, preparation, response, and recovery from any potential emergency that could disrupt organ procurement and transplantation.



Implementation of these standards will ensure organizational resilience, protect patient safety, and prevent disruption of life saving services.

Standards will address:

- Hazard vulnerability analysis
- Emergency operations plan
- Continuity of operations plan
- Testing and evaluation of the plan

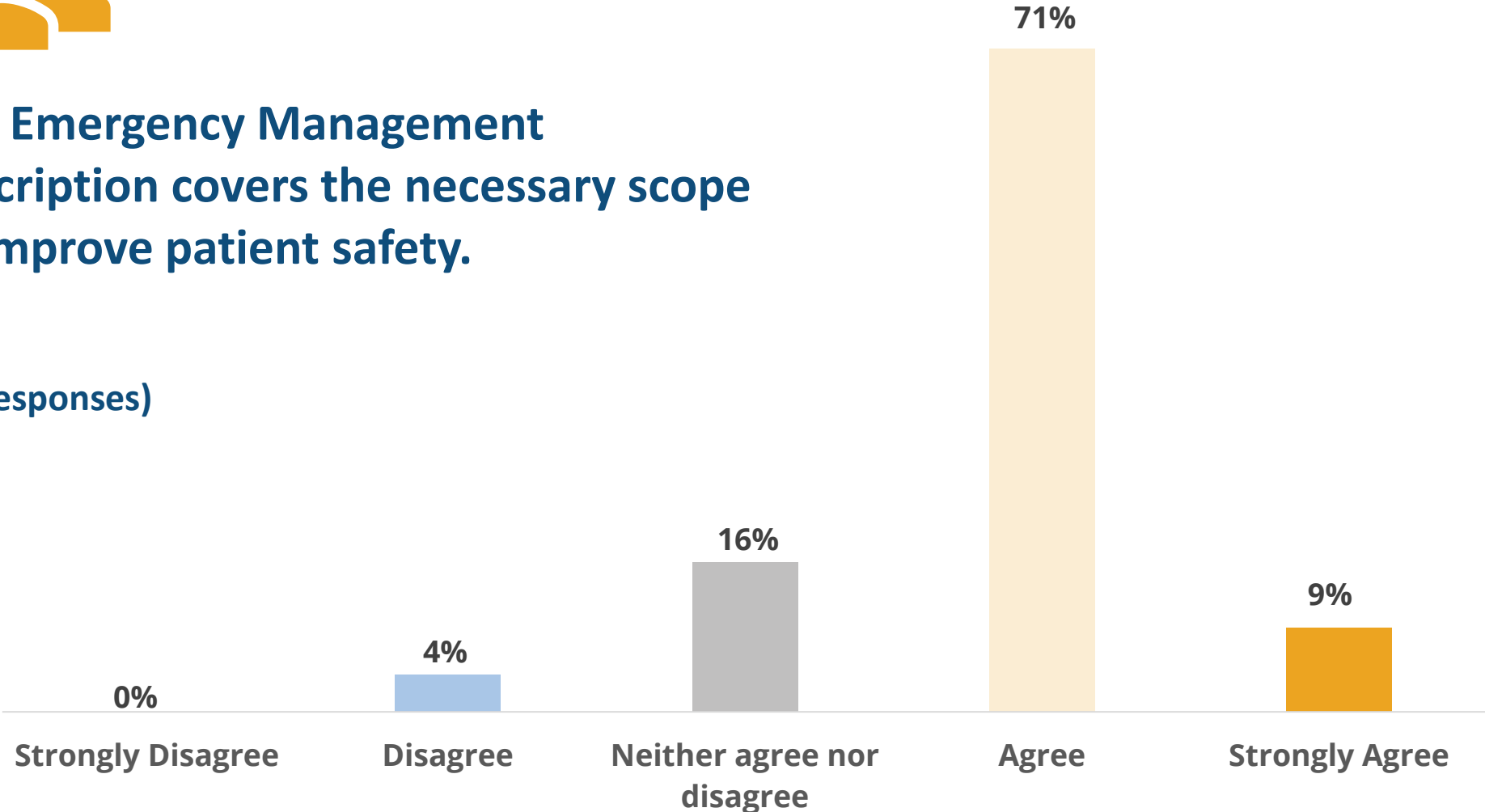


Audience Poll Results



The Emergency Management description covers the necessary scope to improve patient safety.

(70 responses)



Physical Environment



Establishes life safety and building management expectations for OPOs handling organs and tissues at their facilities.



Adherence to these standards will ensure that the facility is safe and well maintained, thereby allowing for delivery of safe and high-quality patient care.

Standards will address:

- Building and life safety codes
- Hazardous materials and waste handling
- Security
- Building utilities and equipment

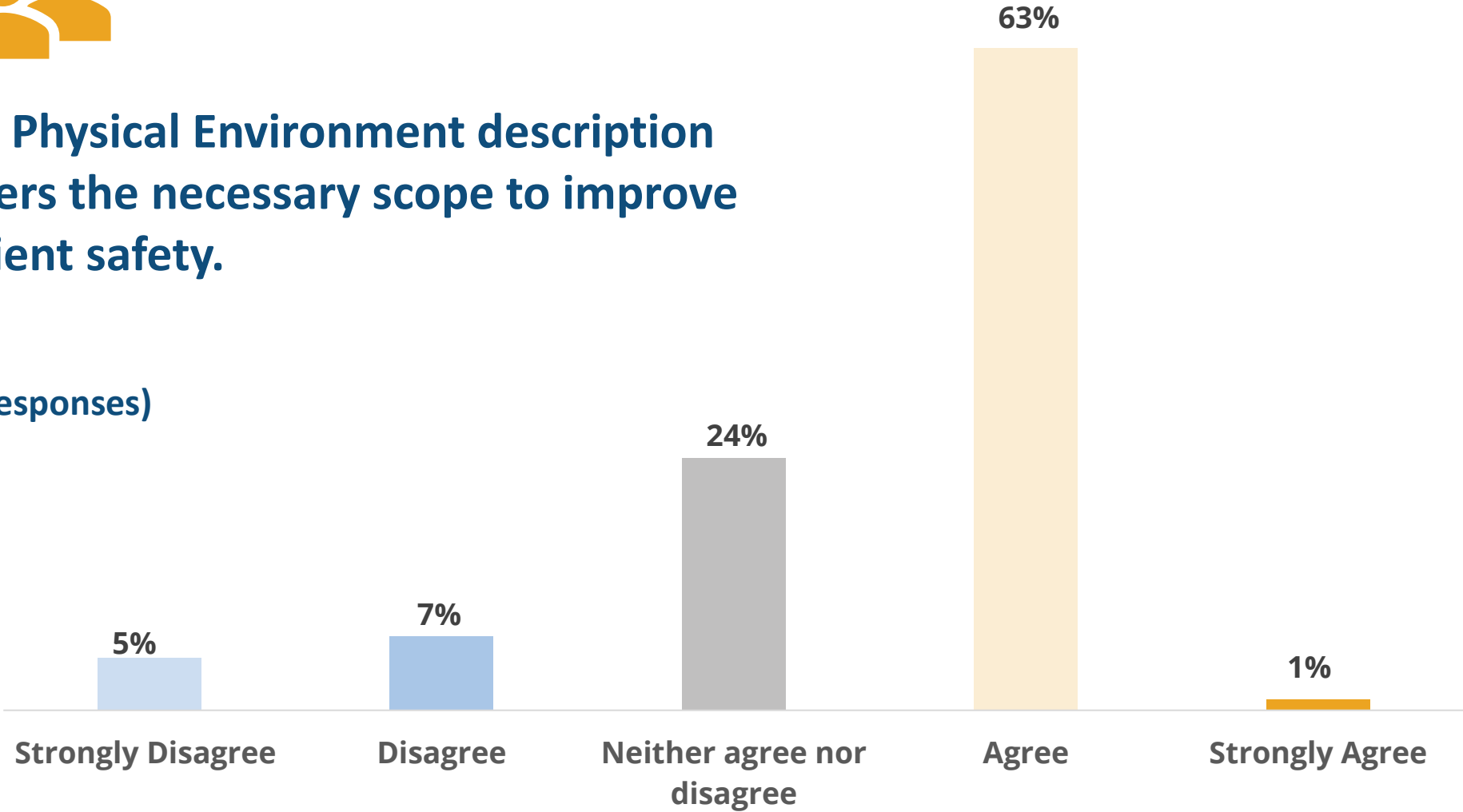


Audience Poll Results



The Physical Environment description covers the necessary scope to improve patient safety.

(76 responses)



Human Resources



Sets expectations for OPOs to recruit, develop, support, and retain a competent, ethical, and engaged workforce capable of delivering safe, high-quality care.



A human resources infrastructure emphasizes accountability, fairness, and continuous improvement, aligning its practices with organizational mission, values, and strategic objectives to strengthen operational effectiveness and service outcomes.

Standards will address:

- Continuous training, education, and upskilling
- Human resources management system
- Performance management
- Recruiting and credentialing
- Workforce planning
- Workforce well-being

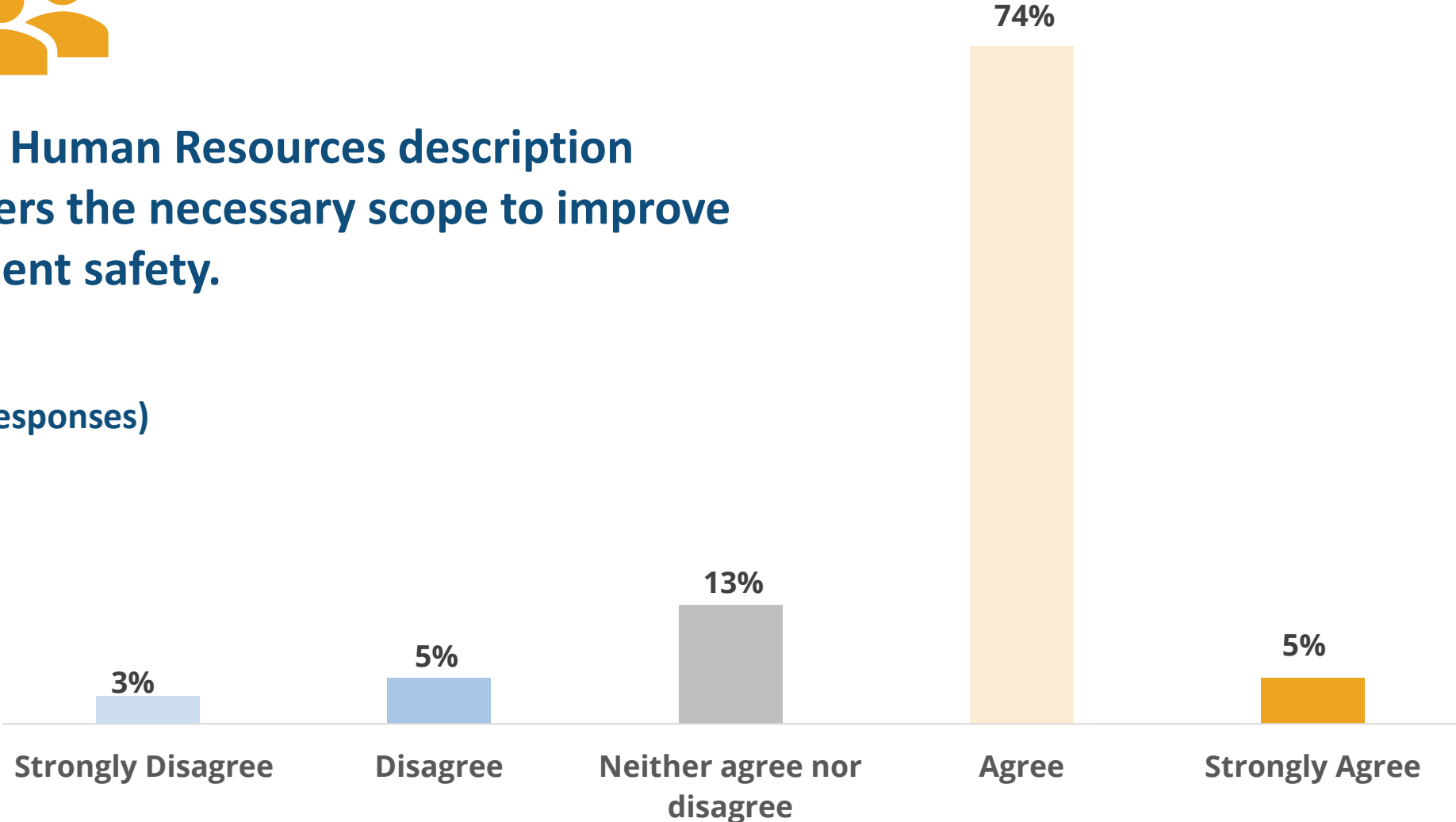


Audience Poll Results



The Human Resources description covers the necessary scope to improve patient safety.

(76 responses)



Recap: Standard Topic Areas Under Discussion

**Governing
Body and
Leadership**

**Provision of
Care and
Services**

**Respect for
Individual
Rights**

**Quality and
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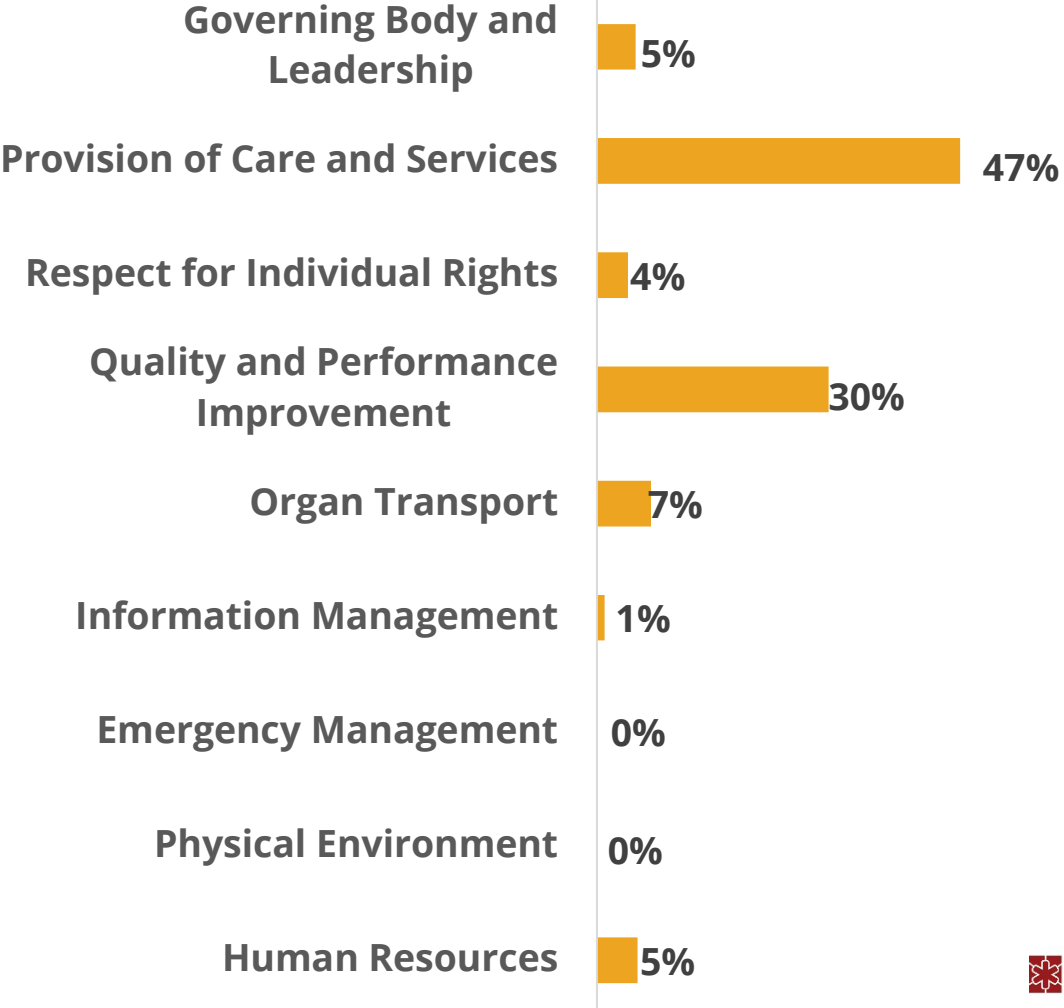


Audience Poll Results



In which area do you think standards will have the most impact on patient safety?

(76 responses)



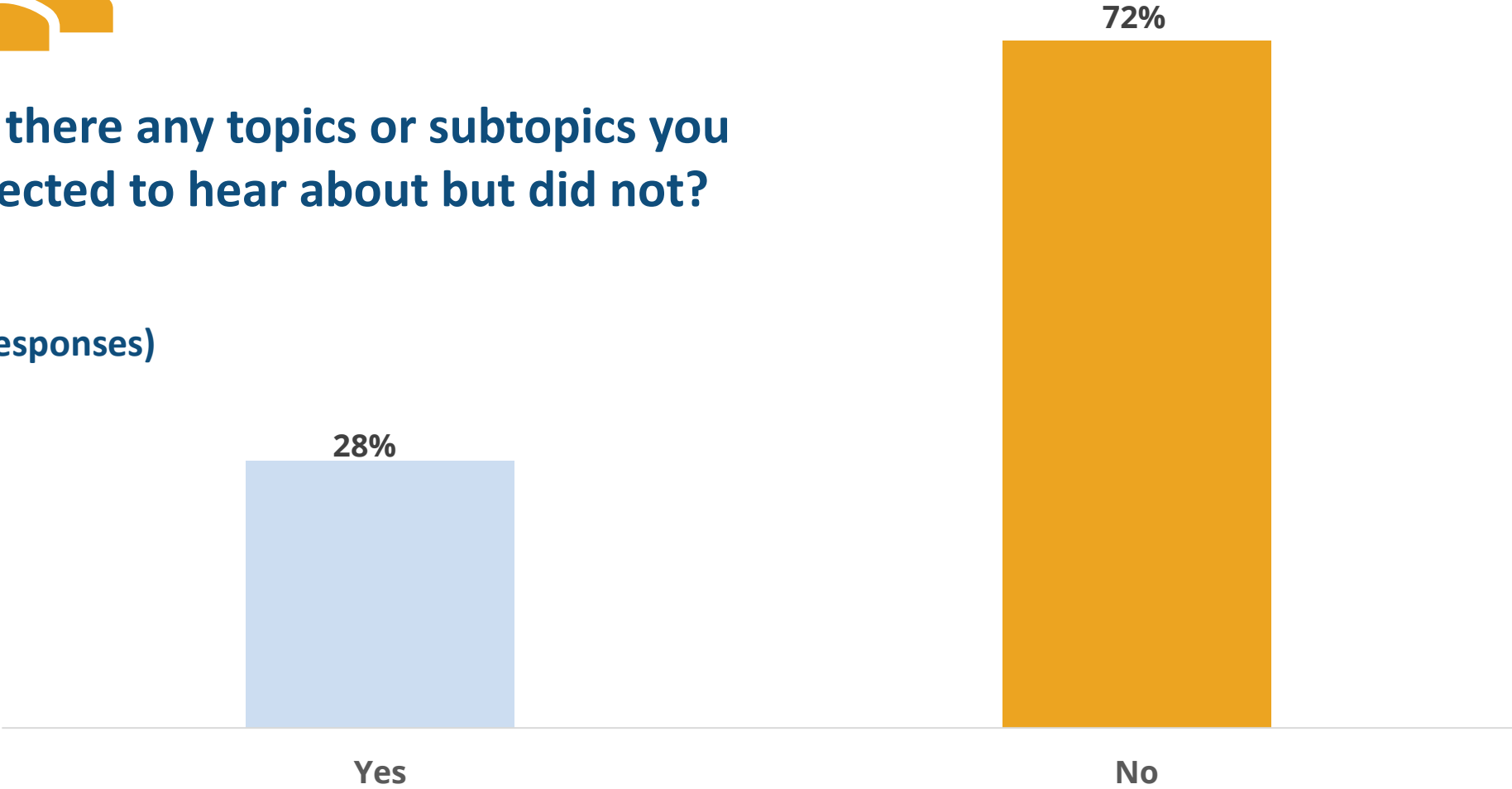


Audience Poll Results



Are there any topics or subtopics you expected to hear about but did not?

(58 responses)



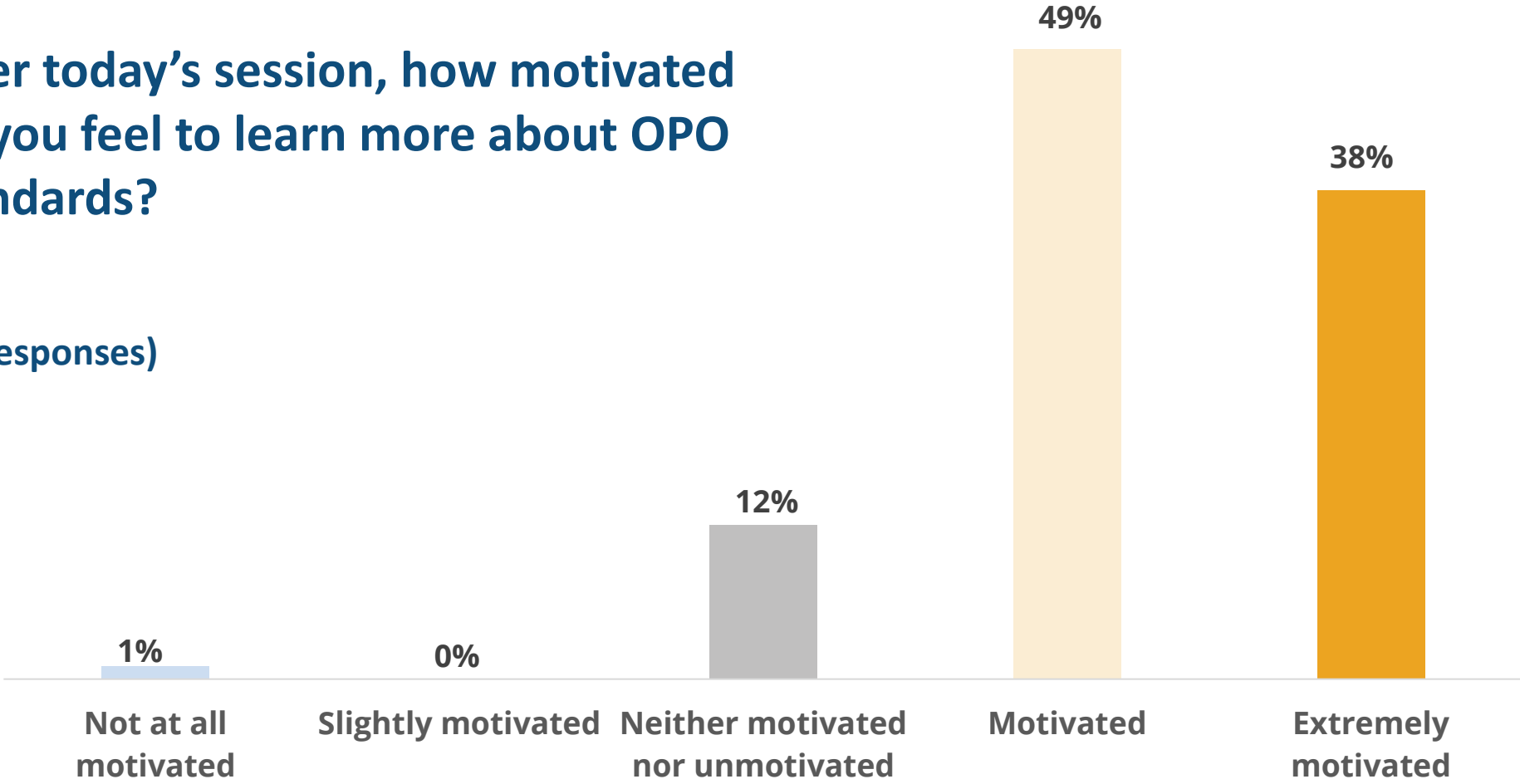


Audience Poll Results



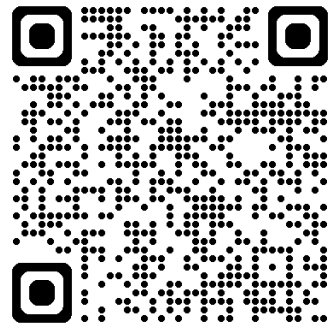
After today's session, how motivated do you feel to learn more about OPO standards?

(76 responses)



Thank you!

If you have additional comments for our consideration, please send them through <https://www.hrsa.gov/optn-modernization/contact>.



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