

AGENDA

Thursday, December 7, 2023 12:30 PM

CONSENT AGENDA: ALL ITEMS MARKED WITH A SINGLE ASTERICK (*) ARE PART OF THE CONSENT AGENDA AND REQUIRE NO DELIBERATION BY THE GOVERNING BOARD. ANY BOARD MEMBER MAY REMOVE AN ITEM FROM THIS AGENDA TO BE CONSIDERED SEPARATELY.

PROCEED TO BOTTOM OF THIS DOCUMENT FOR APPEARANCE & EXECUTIVE SESSION GUIDELINES

In accordance with the provisions of the Americans with Disabilities Act (ADA), persons in need of a special accommodation in order to participate in this proceeding should, within two (2) days prior to the proceeding, request necessary accommodations by contacting CHW's Executive Assistants at 409-949-3406, or via email at trollins@gchd.org or ahernandez@gchd.org

ANY MEMBERS NEEDING TO BE REACHED DURING THE MEETING MAY BE CONTACTED AT 409-938-2288

REGULARLY SCHEDULED MEETING

Meeting Called to Order Pledge of Allegiance

- Item #1 Comments from the Public
- *Item #2**ACTION**..... Excused Absence(s)
- *Item #3**ACTION**..... Consider for Approval Minutes from November 9, 2023 Governing Board Meeting
- *Item #4**ACTION** Consider for Approval Culture of Safety Survey
- *Item #5**ACTION** Consider for Approval School Based Health Clinic TCISD and HRSA CIS Submission
- *Item #6**ACTION**..... Consider for Approval Revisions to the Coastal Health & Wellness 340B Policy and Procedures
- *Item #7**ACTION**..... Informational Report
 - a) Proposed 2024 Board Meeting Dates
- *Item #8**ACTION**..... Informational Report: Credentialing & Privileging Committee Reviewed and Approved the Following Providers Privileging Rights
 - a) Shady Bishai, DDS
 - b) John Walsh, NP
 - c) Laura Porterfield, MD
- Item #9**ACTION**..... Consider for Approval October 2023 Financial Report Submitted by Kenna Pruitt
- Item #10..... Coastal Health & Wellness Updates
 - a) Organizational Updates Submitted by Executive Director
 - b) Operational Updates/Coastal Wave Submitted by Chief Operating Officer
 - c) Dental Updates Submitted by Dental Director
 - d) Medical Updates Submitted by Medical Director

Item #11.....Comments from Board Members

Adjournment

Next Regular Scheduled Meeting: January 25, 2024

Appearances before the Coastal Health & Wellness Governing Board

A speaker whose subject matter as submitted relates to an identifiable item of business on this agenda will be requested by the presiding officer to come to the podium where they will be limited to three minutes (3). A speaker whose subject matter as submitted does not relate to an identifiable item of business on this agenda will be limited to three minutes (3) and will be allowed to speak before the meeting is adjourned. Please arrive prior to the meeting and sign in with Galveston County Health District staff.

Executive Sessions

When listed, an Executive Session may be held by the Governing Board in accordance with the Texas Open Meetings Act. An Executive Session is authorized under the Open Meetings Act pursuant to one or more the following exceptions: Tex. Gov't Code §§ 551.071 (consultation with attorney), 551.072 (deliberation regarding real property), 551.073 (deliberation regarding a prospective gift or donation), 551.074 (personnel matters), 551.0745 (personnel matters affecting Coastal Health & Wellness advisory body), 551.076 (deliberation regarding security devices or security audits), and/or 551.087 (deliberations regarding economic development negotiations). The Presiding Officer of the Governing Board shall announce the basis for the Executive Session prior to recessing into Executive Session. The Governing Board may only enter into Executive Session if such action is specifically noted on the posted agenda.

**Coastal Health & Wellness
Governing Board
November 9, 2023**

Board Members:

Samantha Robinson
Sergio Cruz
Rev. Walter Jones
Flecia Charles
Donnie VanAckeren
Sharon Hall
Clay Burton
Cynthia Darby

Staff:

Philip Keiser, Executive Director
Ami Cotharn, Chief Operating Officer
Maryann Choi, Chief Medical Officer
Hanna Lindskog, Dental Director
William Lewis, Chief Operating Officer
Jennifer Koch, Director of Operations
John Bearden

Christina Bates
Latoiah Williams
Joshua Williams
Debra Howey
Tikeshia Thompson-Rollins
Anthony Hernandez

Excused Absence: Dr. Tello, Elizabeth Williams, Kevin Avery, Dr. Thompson

Unexcused Absence: Victoria Dougharty, and Ivelissa Caban

Items#1 Comments from the Public

There were no comments from the public.

Items#2-5 Consent Agenda

A motion was made by Sergio Cruz to approve the consent agenda items two through five. Donnie VanAckeren seconded the motion, and the Board unanimously approved the consent agenda.

Item#6 Consider for Approval Coastal Health & Wellness HRSA Non-Competing Continuation (NCC) Progress Report for 2024-2025 Budget Period Submitted Kenna Pruitt

Ami Cotharn, Chief Operating Officer, asked the Board to consider for approval the Coastal Health & Wellness HRSA non-competing continuation progress report for 2024-2025 budget period. A motion to accept the report as presented was made by Donnie VanAckeren. Clay Burton seconded the motion and the Board unanimously approved.

Item#7 Consider for Approval to Pay LabCorp an Amount not to Exceed \$56,500 From Fund Balance for Outstanding Account Balances Through Bill Dates Prior to May 2023 Submitted by Kenna Pruitt

Christina Bates, EHR System Administrator, asked the Board to consider for approval to pay LabCorp an amount not to exceed \$56,500 from fund balance for outstanding account balances through bill dates prior to May 2023. A motion to pay LabCorp an amount not to exceed \$56,500 from fund balance was made by Rev. Jones. Flecia Charles seconded the motion and the Board unanimously approved.

Item#8 Consider for Approval Subcommittee to Discuss the Governing Board Formal Committees

- a) Samantha Robinson
- b) Dr. Hall
- c) Sergio Cruz

Samantha Robinson, Board Chair, asked the Board to consider for approval a subcommittee to discuss the Governing Board formal committees. A motion to accept the subcommittee members was made by Flecia Charles. Clay Burton seconded the motion and the Board unanimously approved.

Item#9 Coastal Health & Wellness Updates

- a) Organizational Updates Submitted by Executive Director
- d) Operational Updates/Coastal Wave Submitted by Chief Operating Officer
- e) Dental Updates Submitted by Dental Director

f) Medical Updates Submitted by Medical Director

Dr. Philip Keiser, Executive Director, updated the Board on organizational updates.

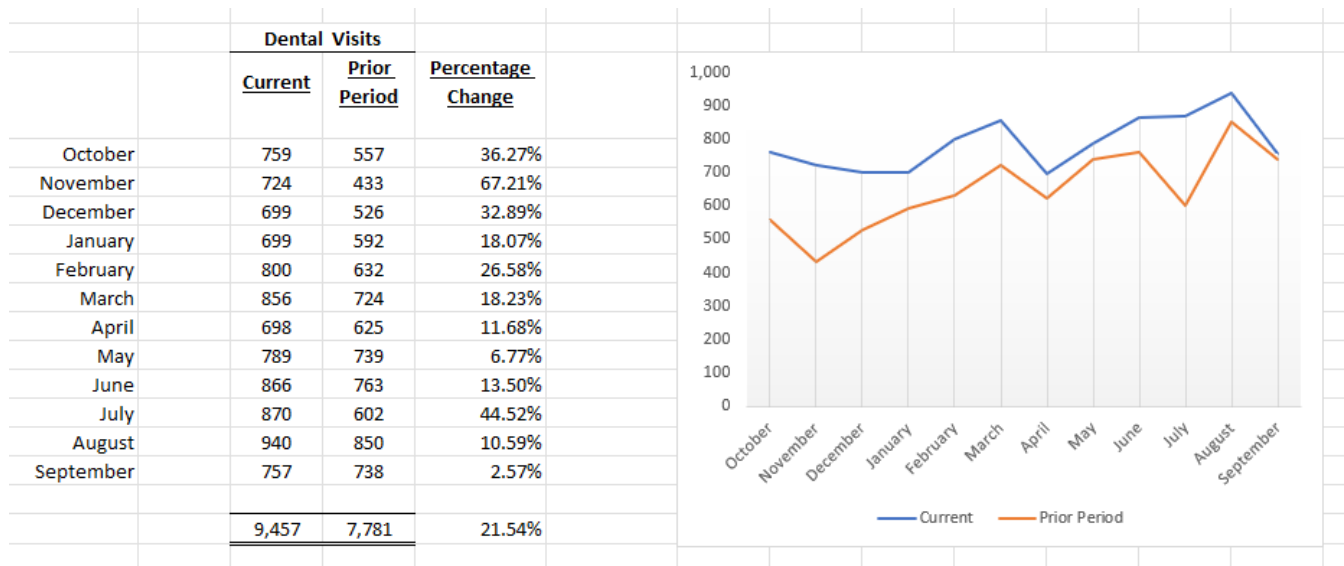
- Dr. Keiser, Ami Cotharn and William Lewis will review candidates for the CFO position and will keep the Board updated.
- Dr. Keiser updated the Board on the Pharmacy buildout and will keep the Board updated as things progress.

Ami Cotharn, Chief Operating Officer, updated the Board on clinical operations.

- Dr. Hall requested a graph that shows the rate of the clinical and support staff increases.

Hanna Lindskog, DDS, updated the Board on Dental services in the Coastal Health & Wellness Clinic:

- Visit Numbers – Based on “FQHC Qual Enc” in NextGen –
 - We are currently reviewing criteria for “FQHC Qual Enc” to make sure all eligible visits are captured as encounters.
 - We continue to see walk in patients in pain as we can fit them into our schedule.
 - We will start releasing comprehensive exams on the 15th of every month



- Current projects, plans, department overview for dental
 - Sterilization Renovation – Cabinets ordered – No update
 - Dr. Lindskog continues to serve on the COM Hygiene School Advisory Board. There are not any updates regarding this program.
- Provider Education Opportunities
 - All providers continue to select and participate in continuing education of their choice. They also share knowledge from these courses with the other providers during monthly meetings.
- Barriers or Needs (if applicable)
 - Staffing
 - The new dental hygienist and dental assistant are scheduled to start on November 9th.

Maryann Choi, Medical Director, updated the Board on Medical services in the Coastal Health & Wellness Clinic.

1. Provider productivity:

- October provider visits:
Scheduled 3345, No show 844, Total visits 2501, Total charges \$699,567
(lower charges are due to posting; RCM will have those after the 10th of the month)
- September provider visits
Scheduled 3217, No show 779, Total visits 2438, Total charges \$832,940

2. Software utilization:

- Telemedicine platform:

- Doxy.me: 178 visits in Sept (total 967 visits since June)
- E-consult platform:
 - ConferMed: 76 (e-consult), we are considered one of the highest utilizers for the time we have been using this service)
- 3. School-based program: Walk-in clinic combined with telemedicine
 - Providers onsite for two full days weekly
 - Oct: 51 visits (33 CHW existing patients, 9 student visits, 9 TCISD staff)
 - Sept: 74 visits (42 CHW existing patients, 23 students, 9 TCISD staff)
- 4. Provider Lead Program: collaborate with public health services (HIV/STI, WIC)
 - ID care: Jacklyn Morgan, PA-C, Maria Culangan (HIV PrEP, HepC, STD)
 - Total revenue (PrEP and HepC meds): \$383,000
 - HIV screening, HepC screening
- 5. Home-based care:
 - House call program for home-bound patients
 - October 78 visits (Dr. Grumbles:38 visits, Pam Cable: 40 visits)
 - September 60 visits (Dr. Grumbles: 30 visits, Pam: 30 visits)
- 6. Remote care management (Patient engagement center/care coordination)
 - Patient engagement and promoting self-care
 - CCM (chronic care management), TCM(transitional care management), AWV (annual wellness visits)
- 7. BHI (behavioral health integration)
- Level 4 Behavioral health /primary care integration with GCC: (level 6 by the end of 2023)
 - CHW/GCC workshop- planning session (10/17): Felicia Jeffery, CEO and GCC team
 - Discussed strategic planning on the BH integration project with one care team model
 - Shared services and resources, expansion of services, provider recruitment
 - (GCC hired Dr. Valdez as Chief Medical Officer and the project team leader as care coordinator)
- 8. 340B program: PPT (John Bearden)

“Strive to deliver high-quality, culturally competent, equitable, and comprehensive primary care with a focus on clinical quality, patient-centered care, and provider and staff well-being.”

Item #10 Comments from Board Members

No Comments

The meeting was adjourned at 1:34p.m.

Chair

Secretary/Treasurer

Date

Date

[**Back to Agenda**](#)

Culture of Safety Survey



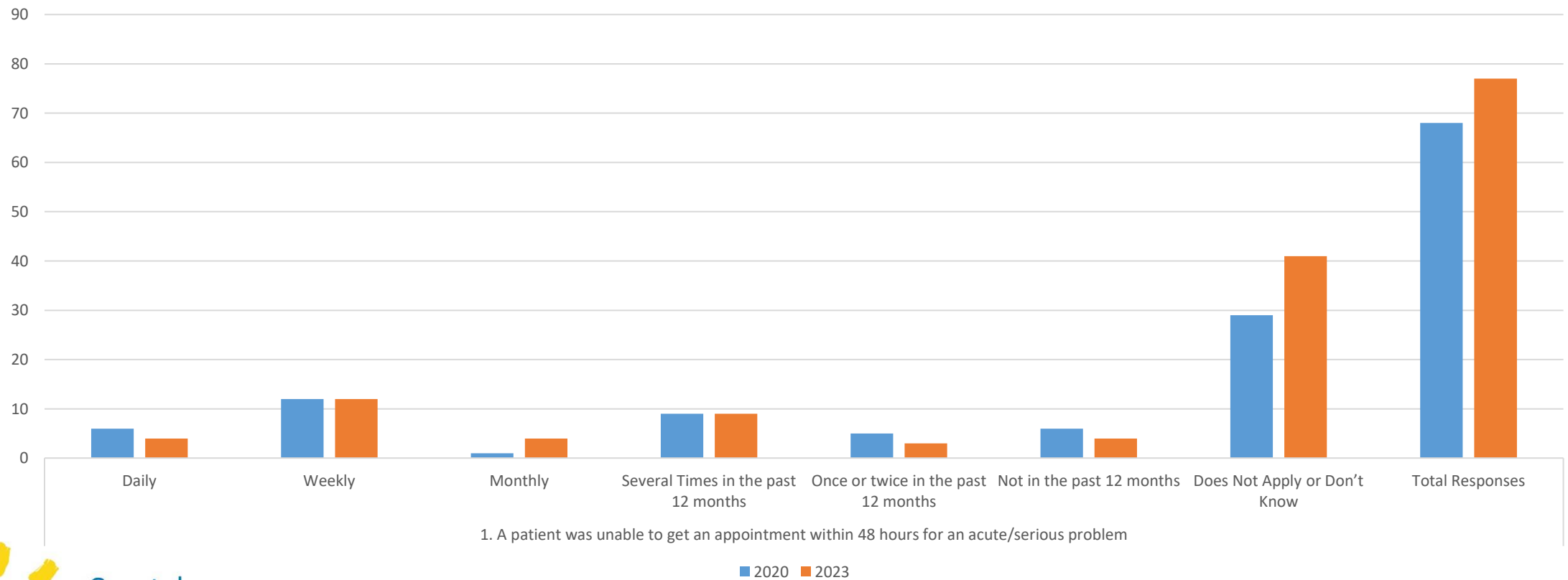
Why have a Culture of Safety

- Establish a safety culture that fosters trust in reporting unsafe conditions to ensure high-quality patient care.
- The Joint Commission defines safety culture as the “product of individual and group beliefs, values, attitudes, perceptions, competencies, and patterns of behavior that determine the organization’s commitment to quality and patient safety.”

Question 1

A patient was unable to get an appointment within 48 hours for an acute/serious problem

Section A: List of patient safety and Quality Issues

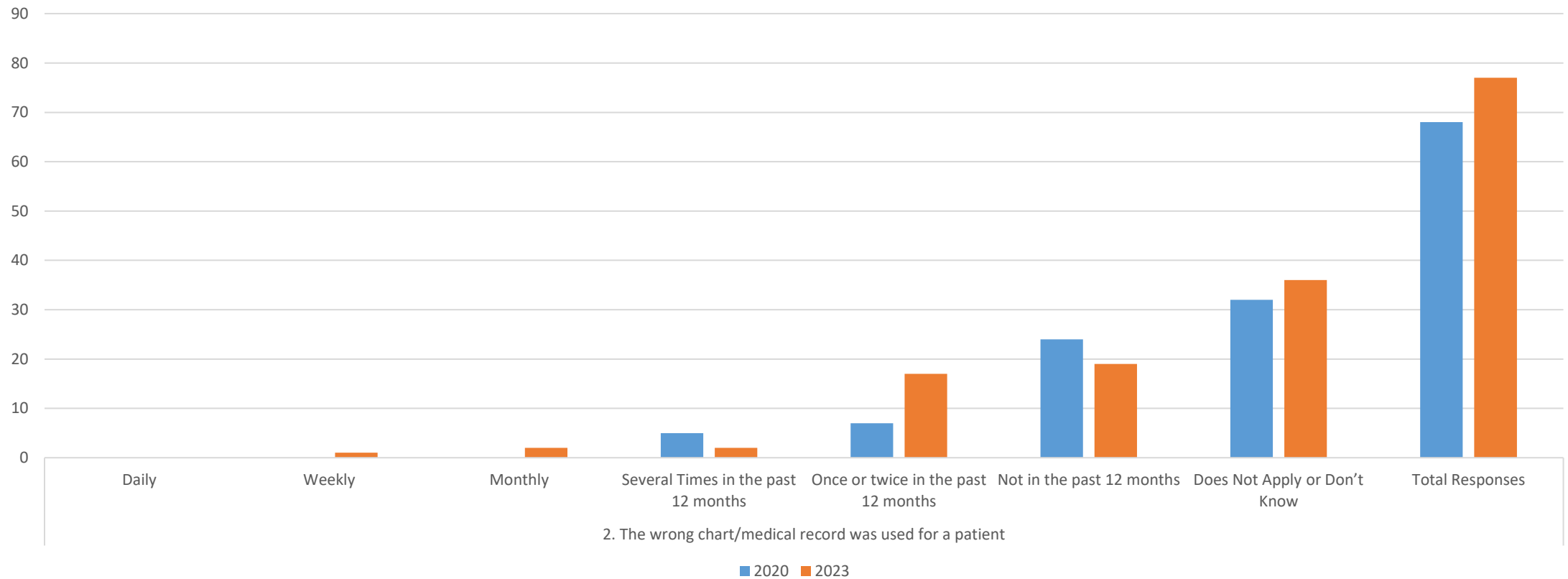


1. A patient was unable to get an appointment within 48 hours for an acute/serious problem

Question 2

The wrong chart/medical record was used for a patient.

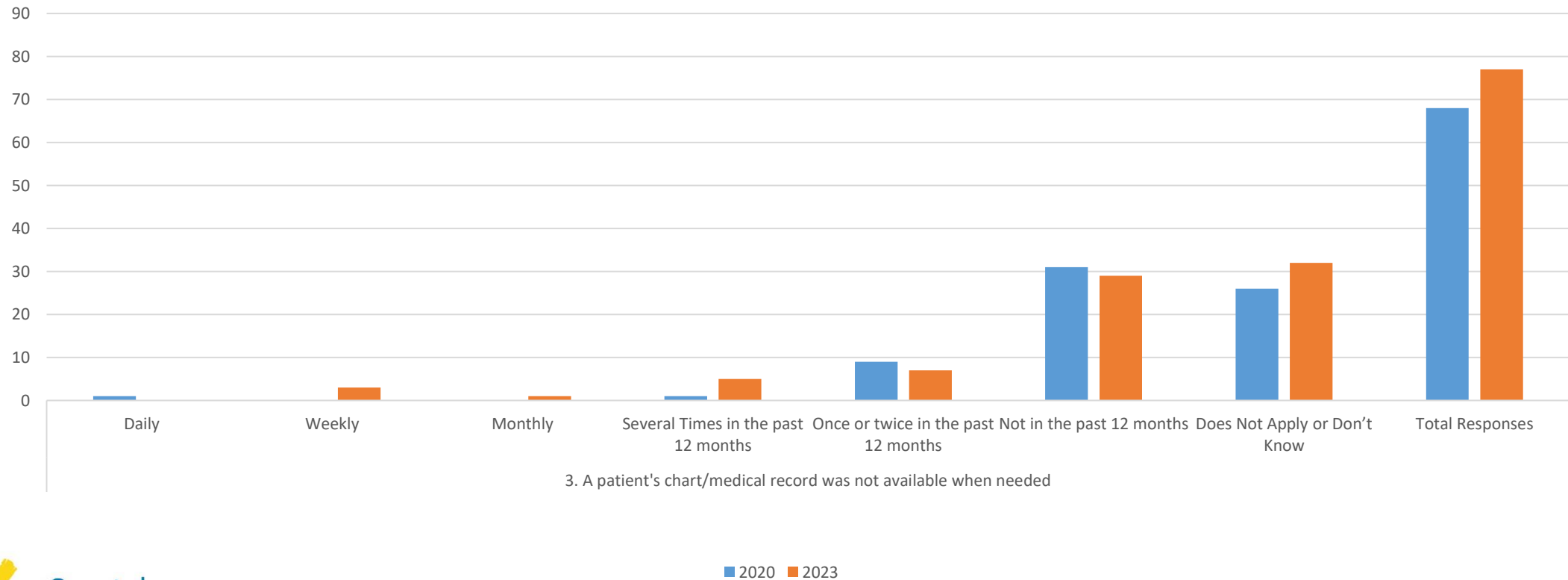
Section A: List of Patient Safety and Quality Issues



Question 3

A patient's chart/medical record was not available when needed

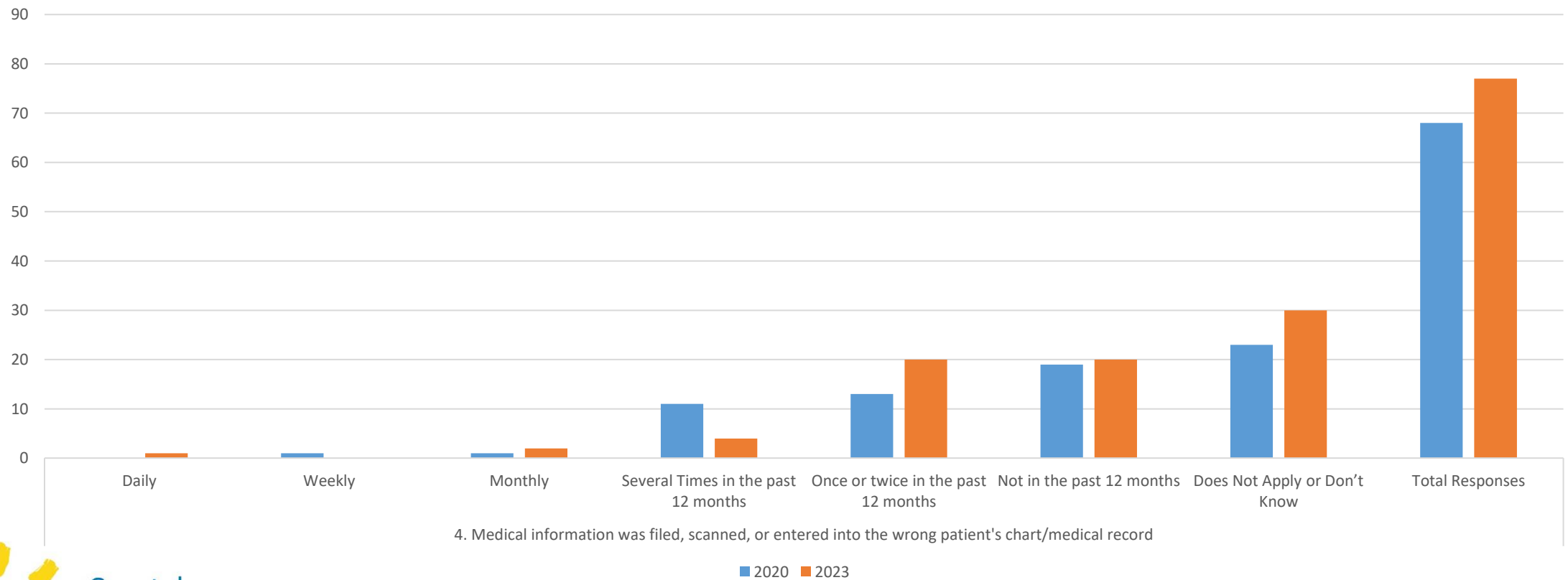
Section A: List of Patient Safety and Quality Issues



Question 4

Medical information was filed, scanned, or entered into the wrong patient's chart/medical record

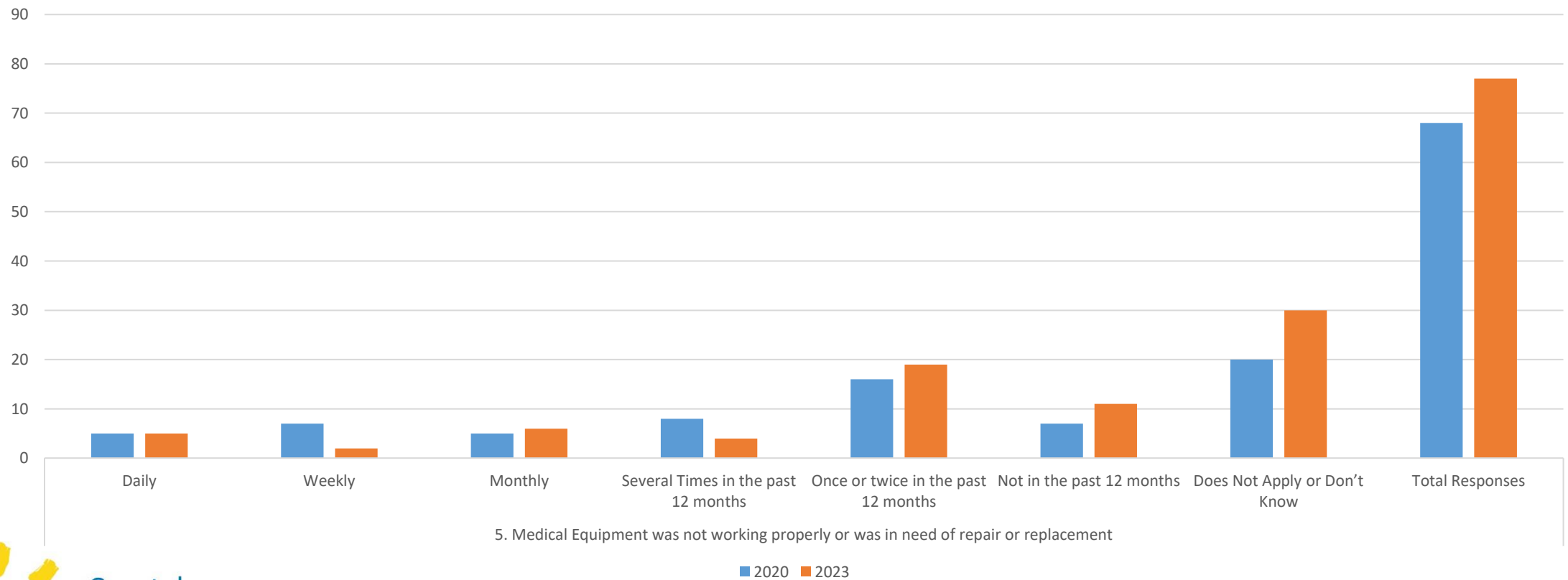
Section A: List of Patient Safety and Quality Issues



Question 5

Medical Equipment was not working properly or was in need of repair or replacement

Section A: List of Patient Safety and Quality Issues

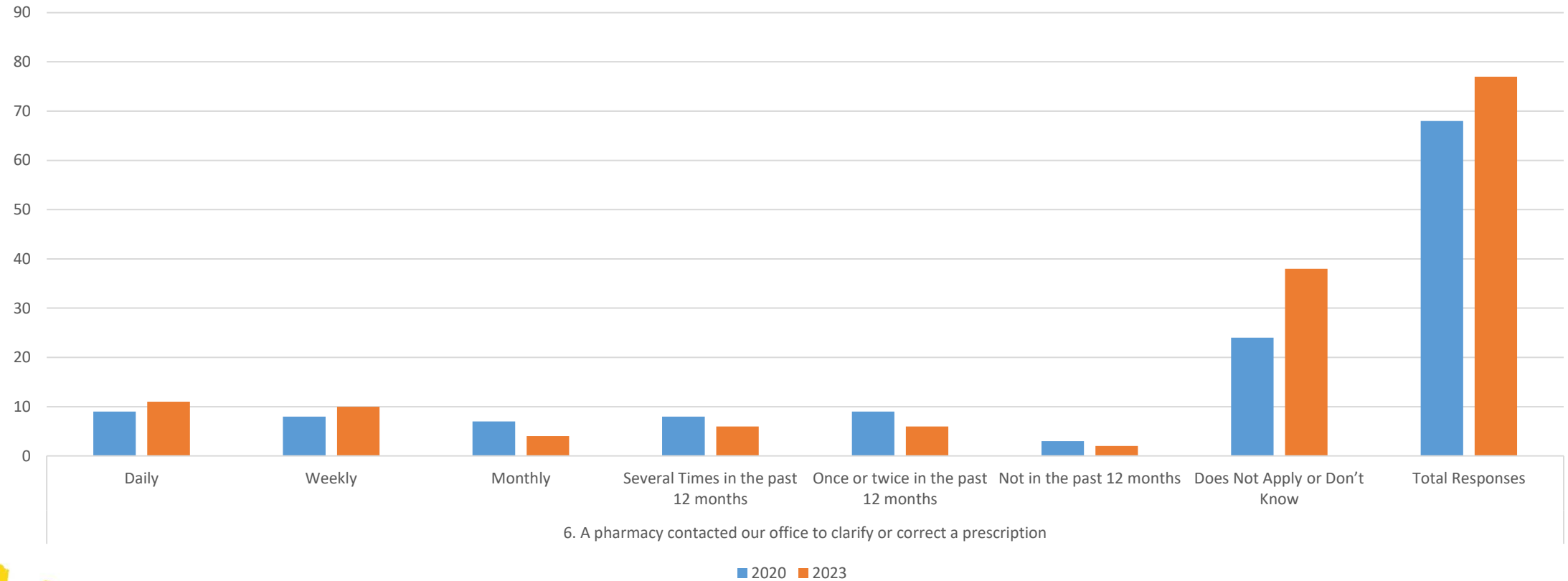


5. Medical Equipment was not working properly or was in need of repair or replacement

Question 6

A pharmacy contacted our office to clarify or correct a prescription

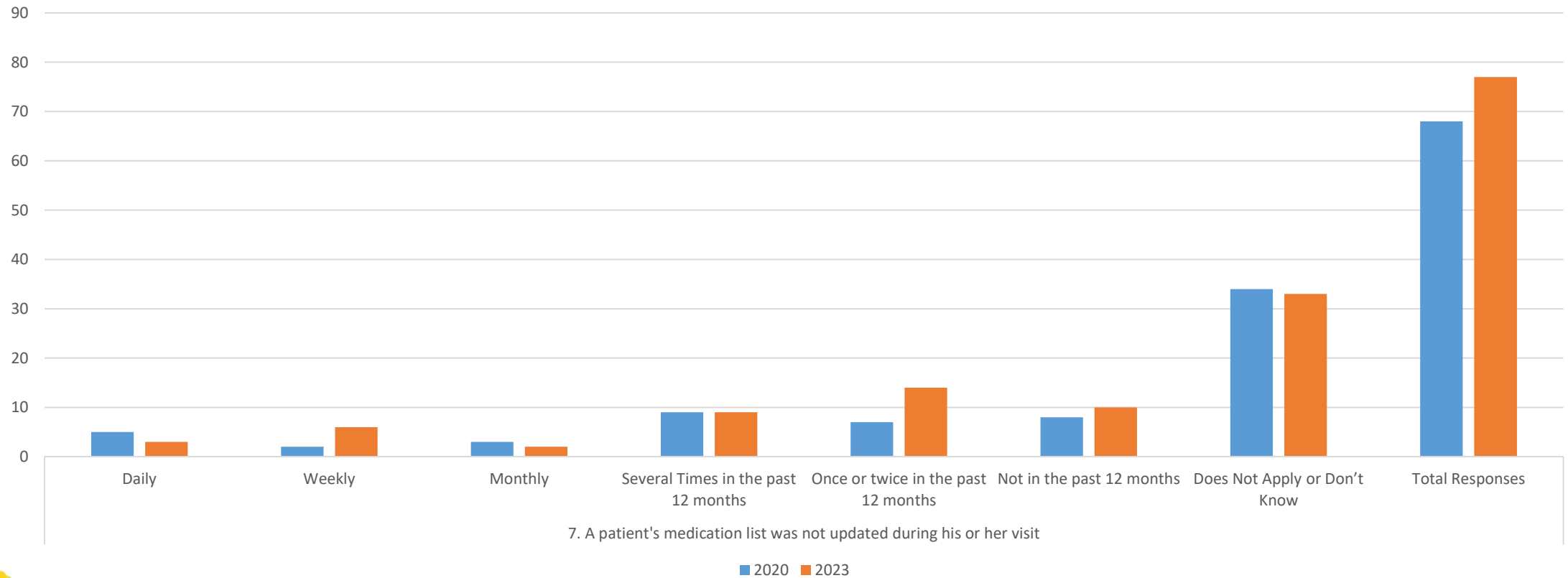
Section A: List of Patient Safety and Quality Issues



Question 7

A patient's medication list was not updated during his or her visit

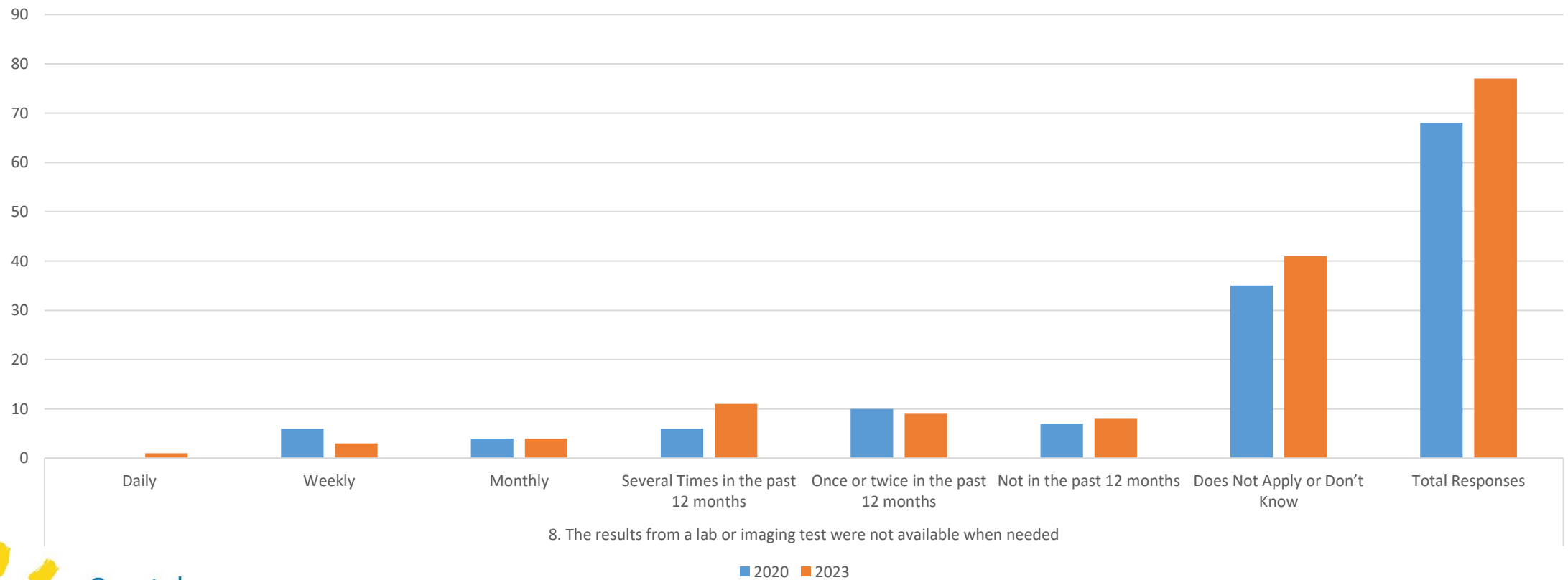
Section A: List of Patient Safety and Quality Issues



Question 8

The results from a lab or imaging test were not available when needed

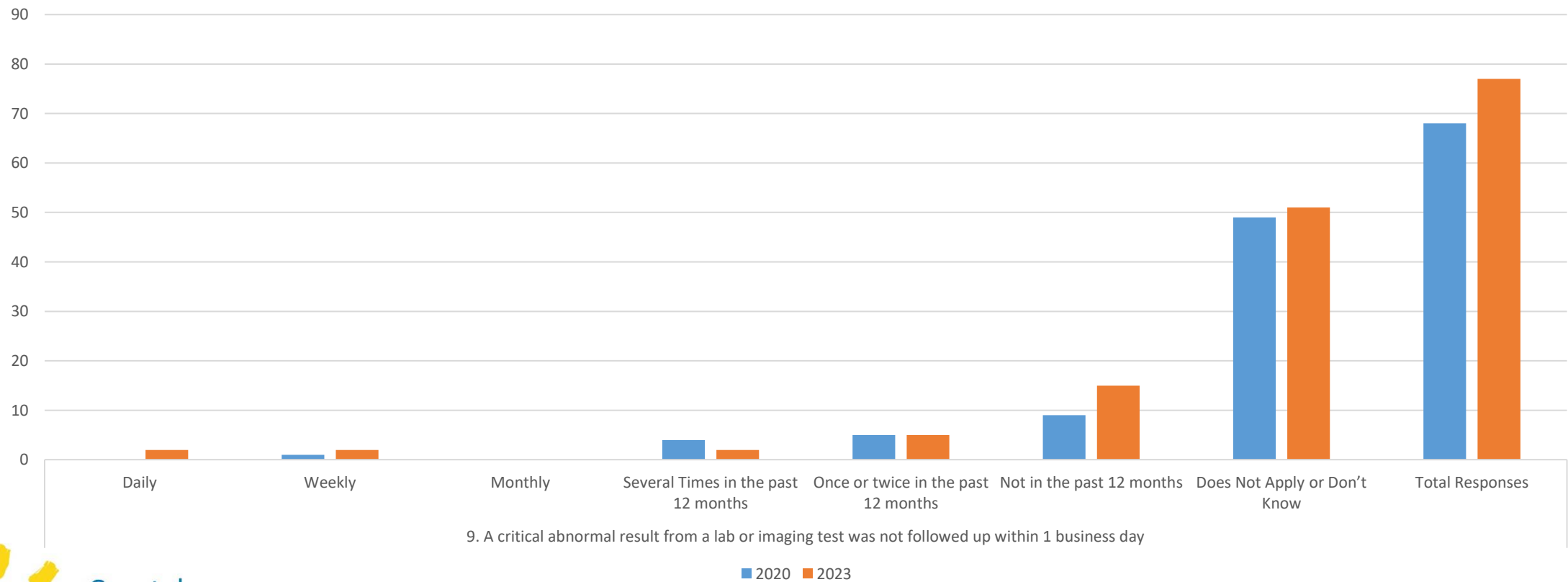
Section A: List of Patient Safety and Quality Issues



Question 9

A critical abnormal result from a lab or imaging test was not followed up within 1 business day

Section A: List of Patient Safety and Quality Issues

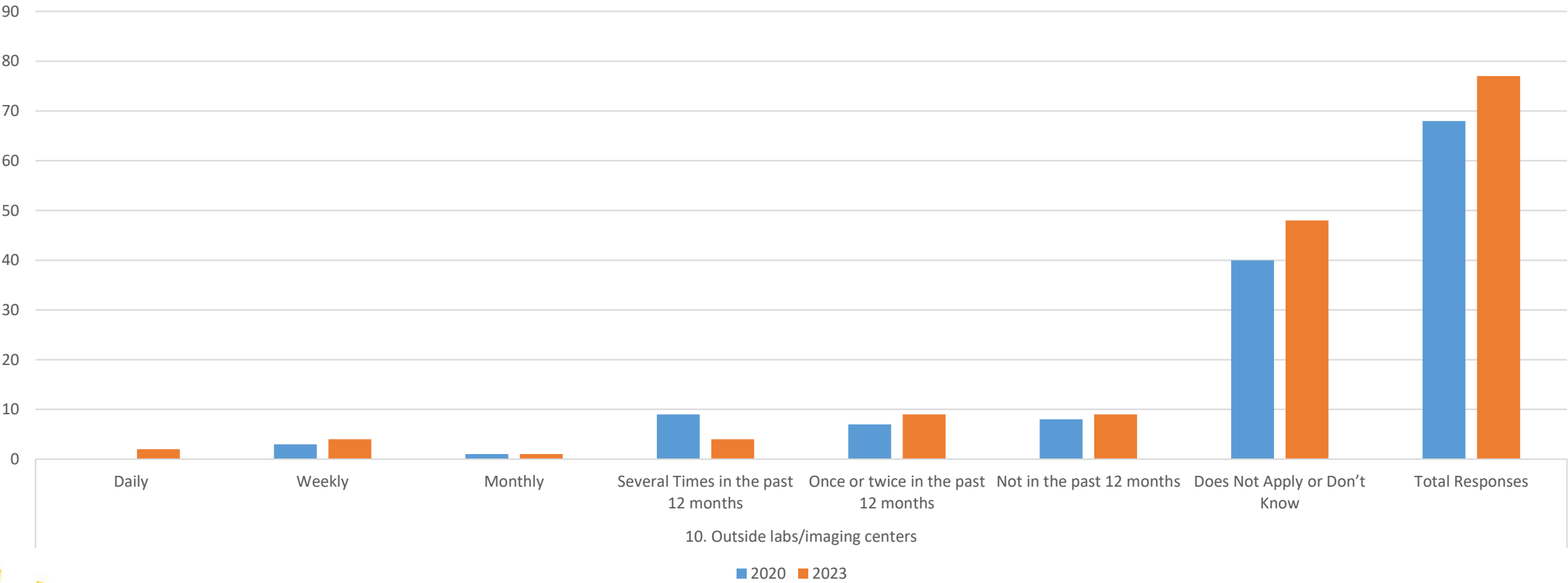


9. A critical abnormal result from a lab or imaging test was not followed up within 1 business day

Question 10

Outside labs/imaging centers

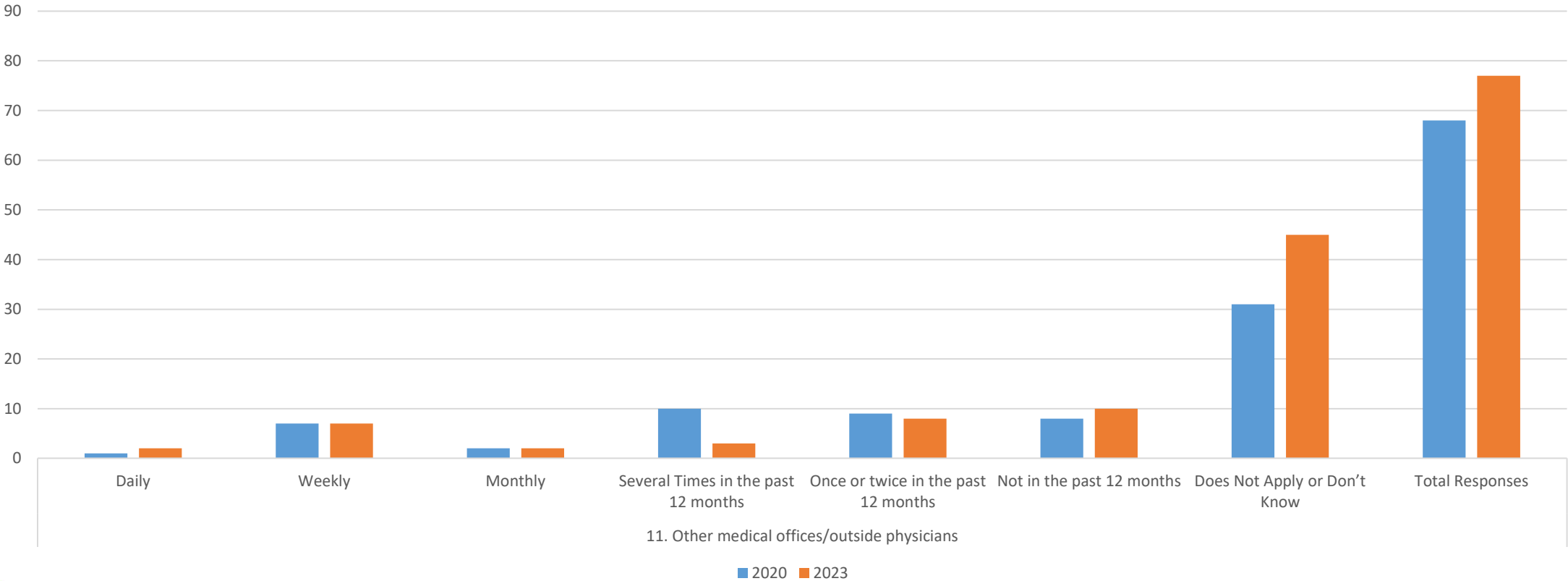
Section B: Information Exchange with Other Settings



Question 11

Other medical offices/outside physicians

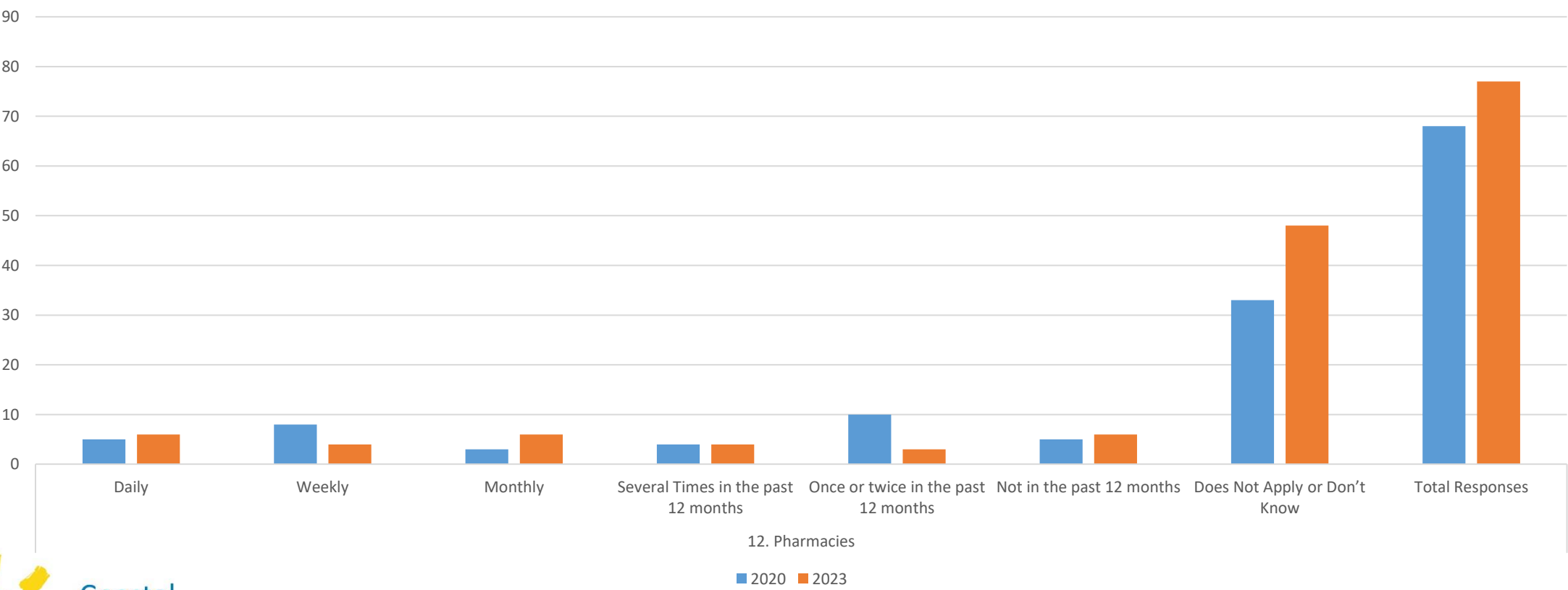
Section B: Information Exchange with Other Settings



Question 12

Pharmacies

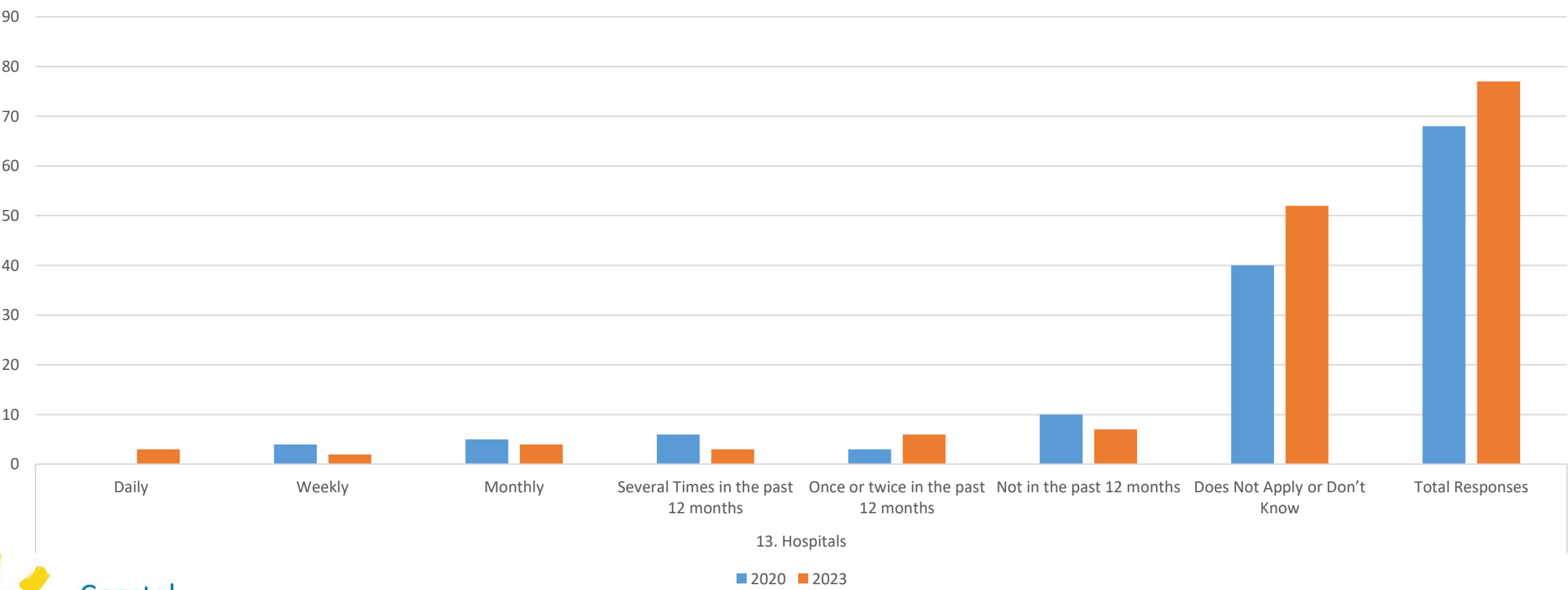
Section B: Information Exchange with Other Settings



Question 13

Hospitals

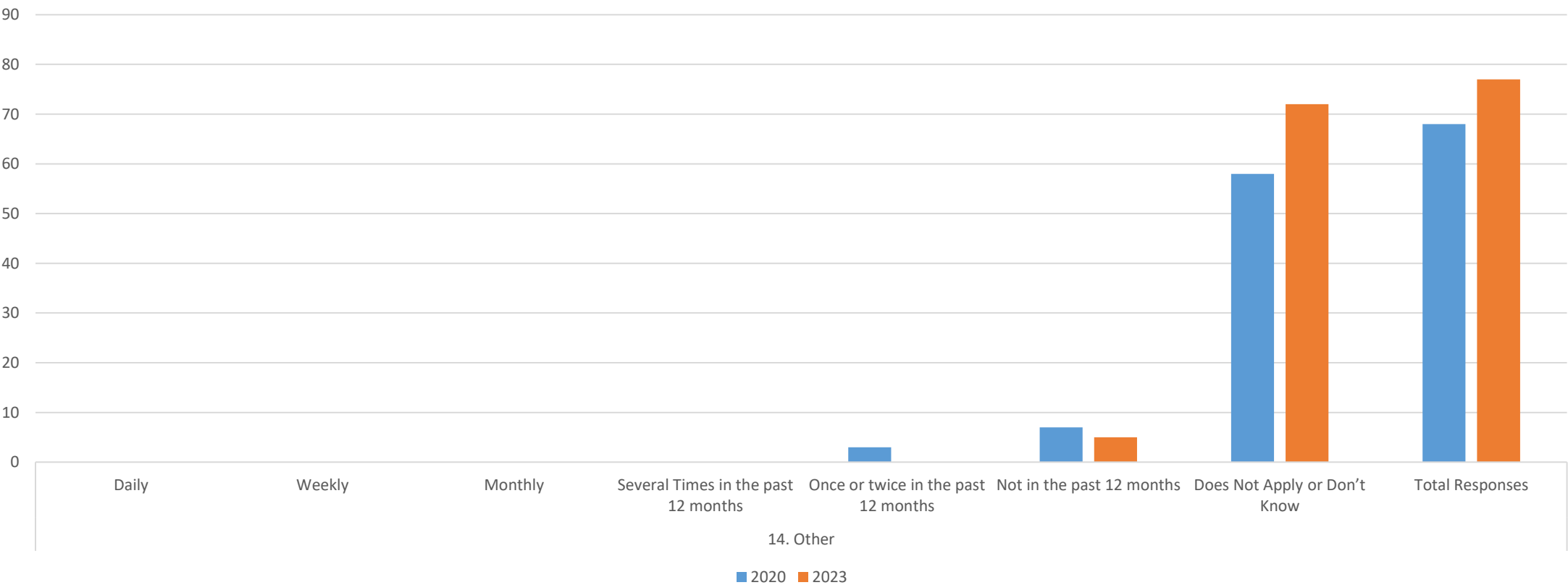
Section B: Information Exchange with Other Settings



Question 14

Other

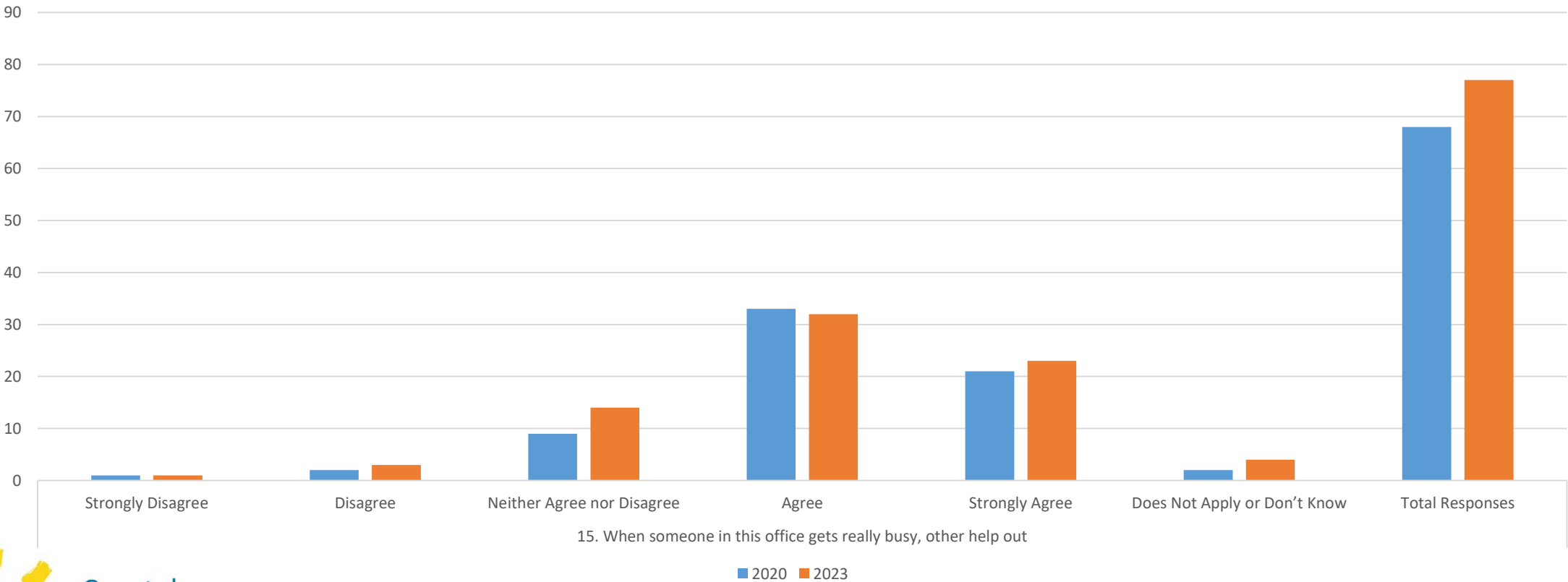
Section B: Information Exchange with Other Settings



Question 15

When someone in this office gets really busy, other help out.

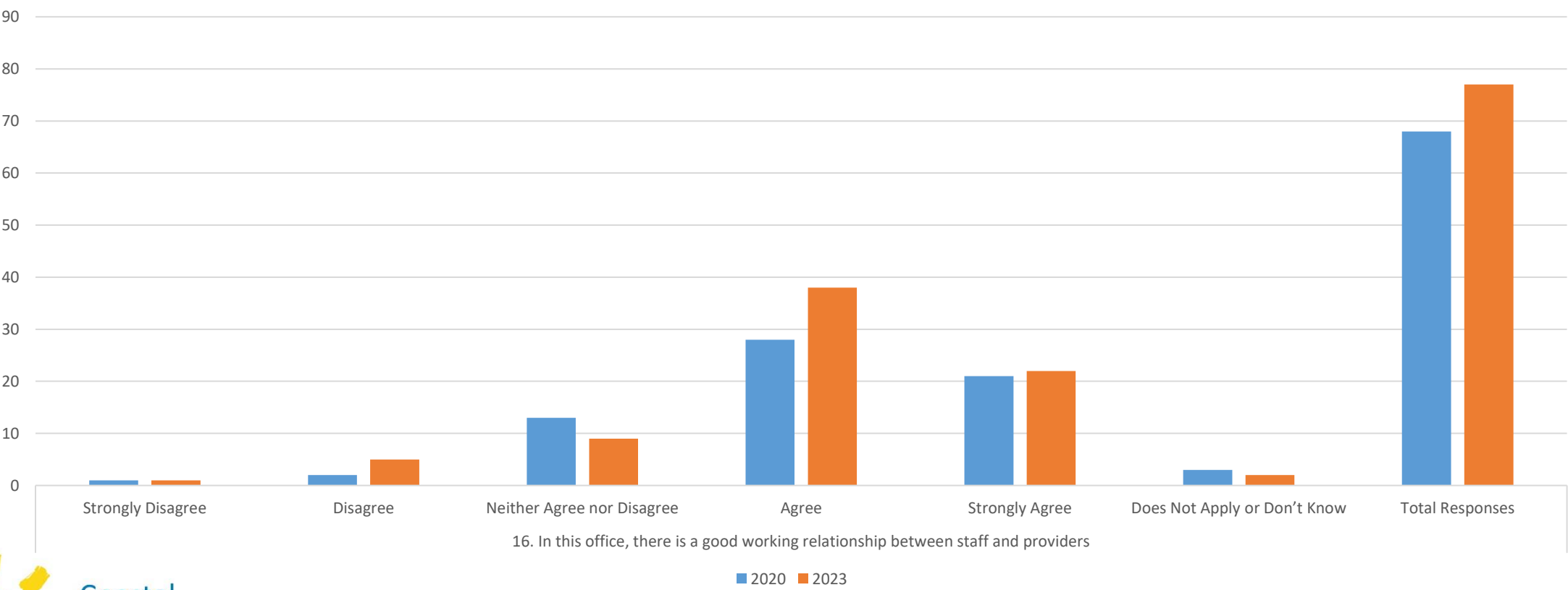
Section C: Working in Your Medical Office



Question 16

In this office, there is a good working relationship between staff and providers.

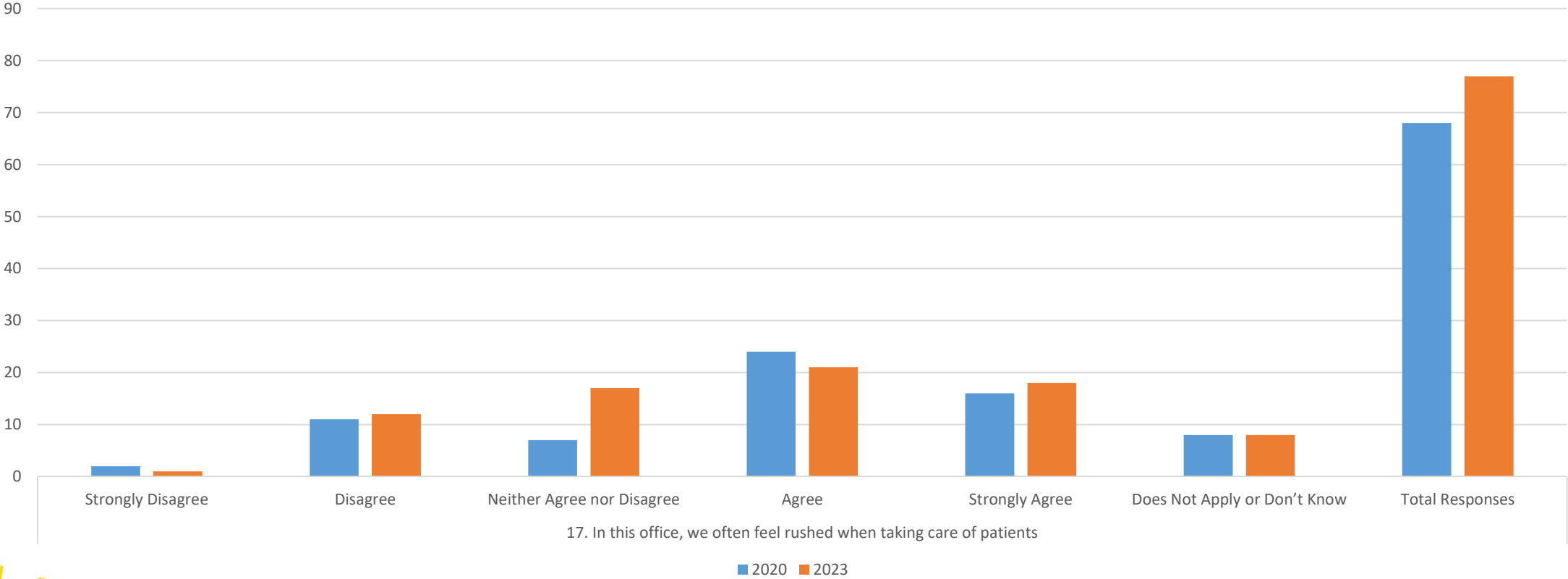
Section C: Working in Your Medical Office



Question 17

In this office, we often feel rushed when taking care of patients.

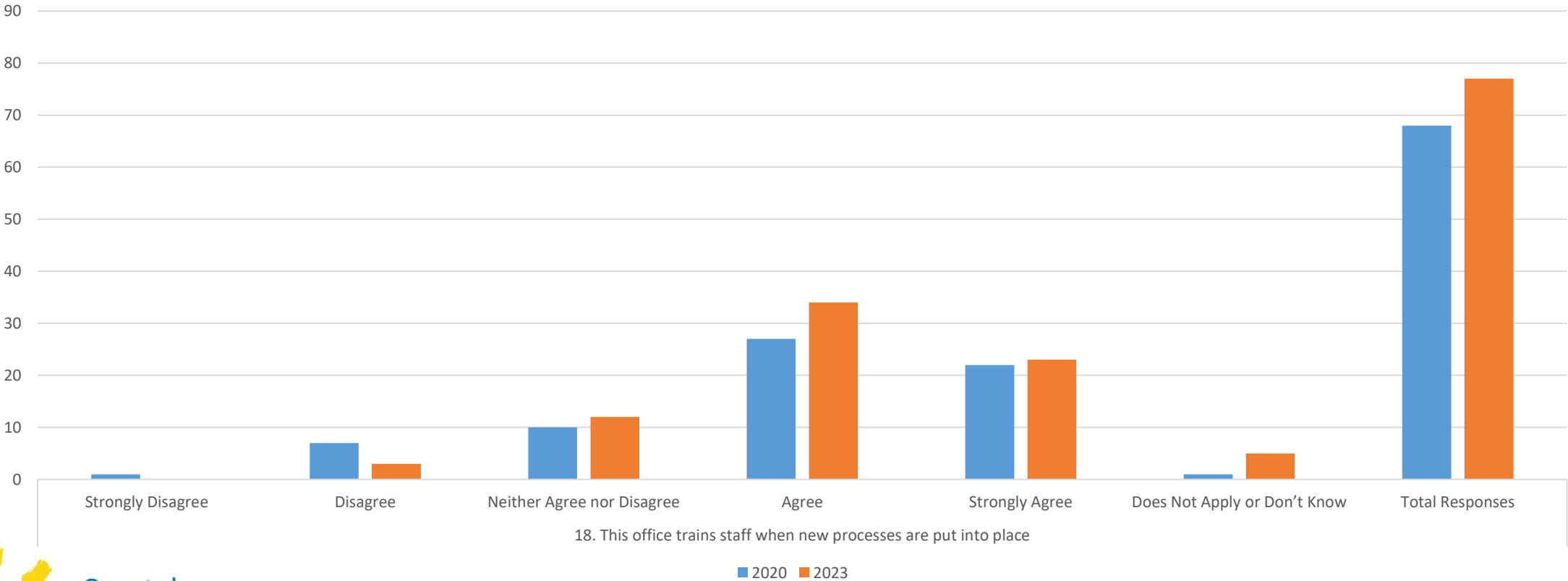
Section C: Working in Your Medical Office



Question 18

This office trains staff when new processes are put into place.

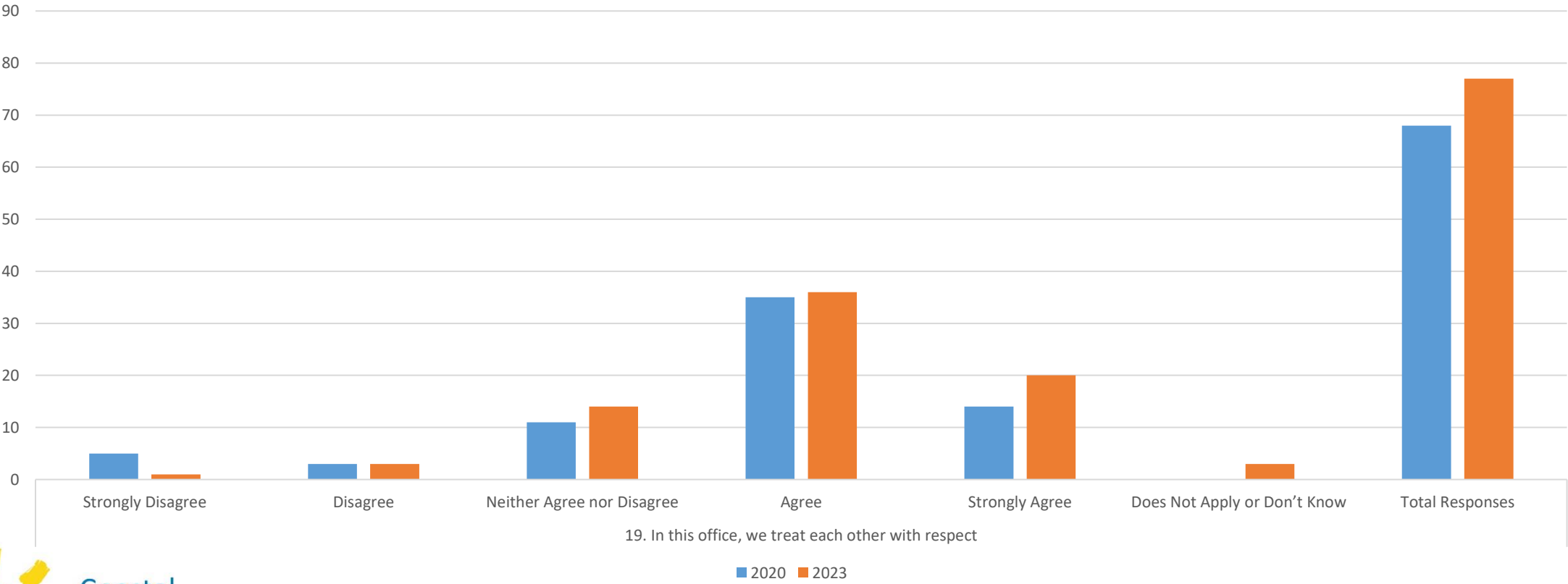
Section C: Working in Your Medical Office



Question 19

In this office, we treat each other with respect.

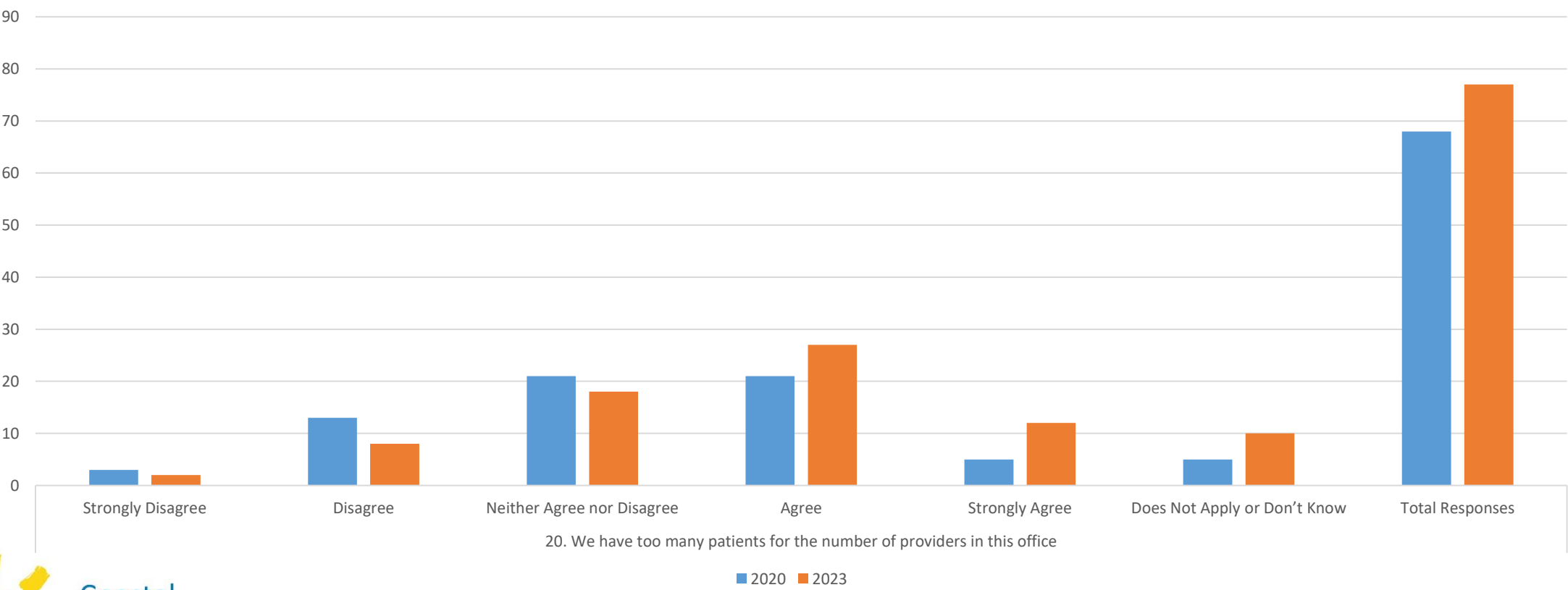
Section C: Working in Your Medical Office



Question 20

We have too many patients for the number of providers in this office.

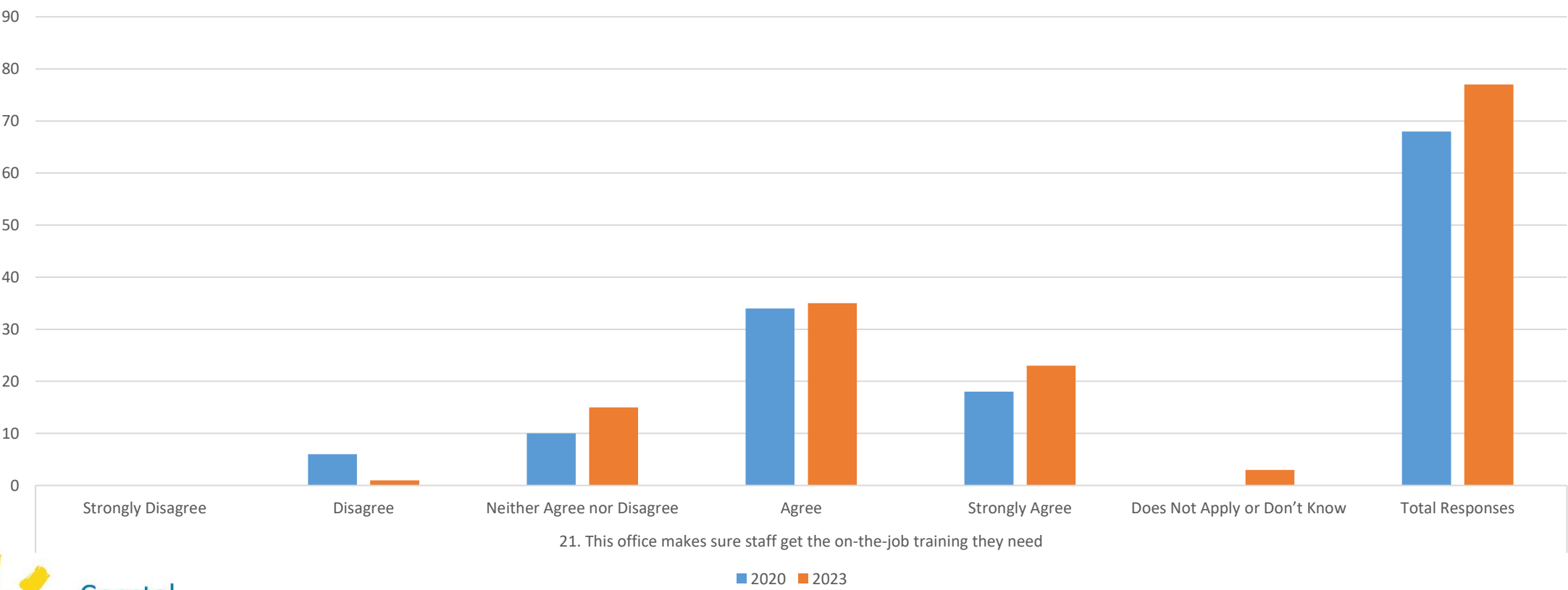
Section C: Working in Your Medical Office



Question 21

This office makes sure staff get the on-the-job training they need.

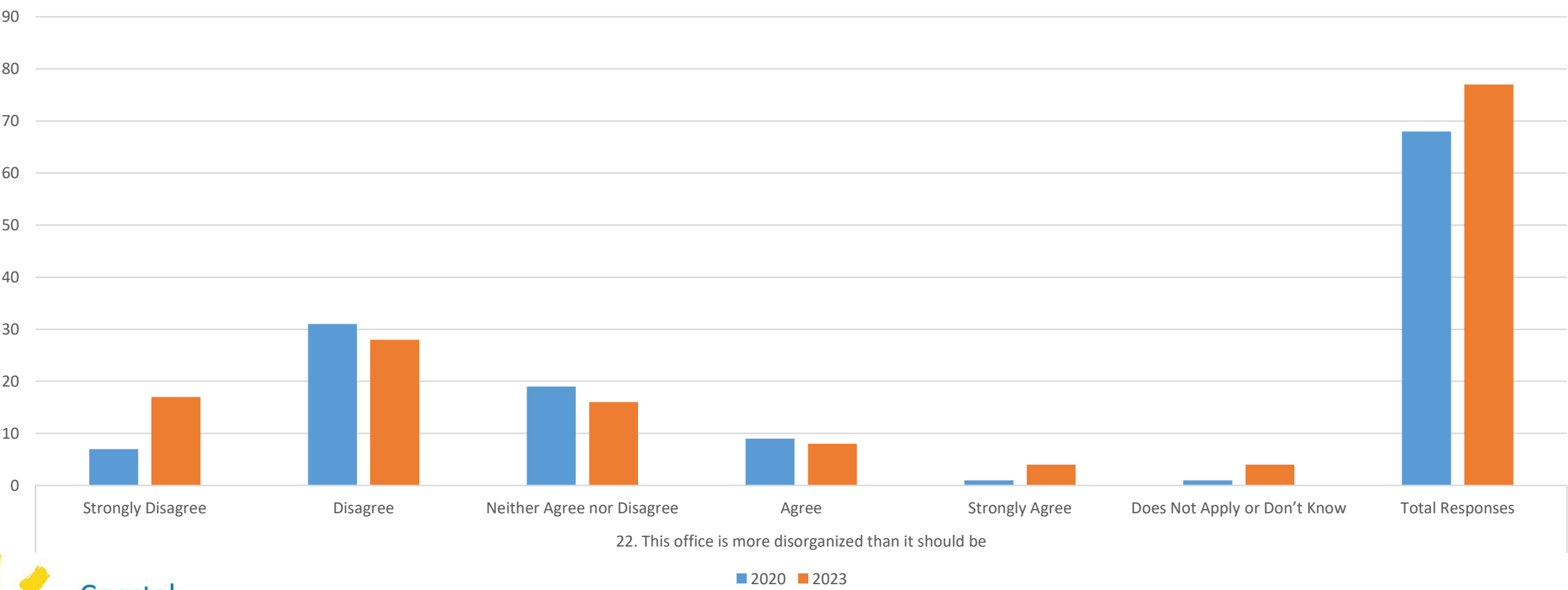
Section C: Working in Your Medical Office



Question 22

This office is more disorganized than it should be.

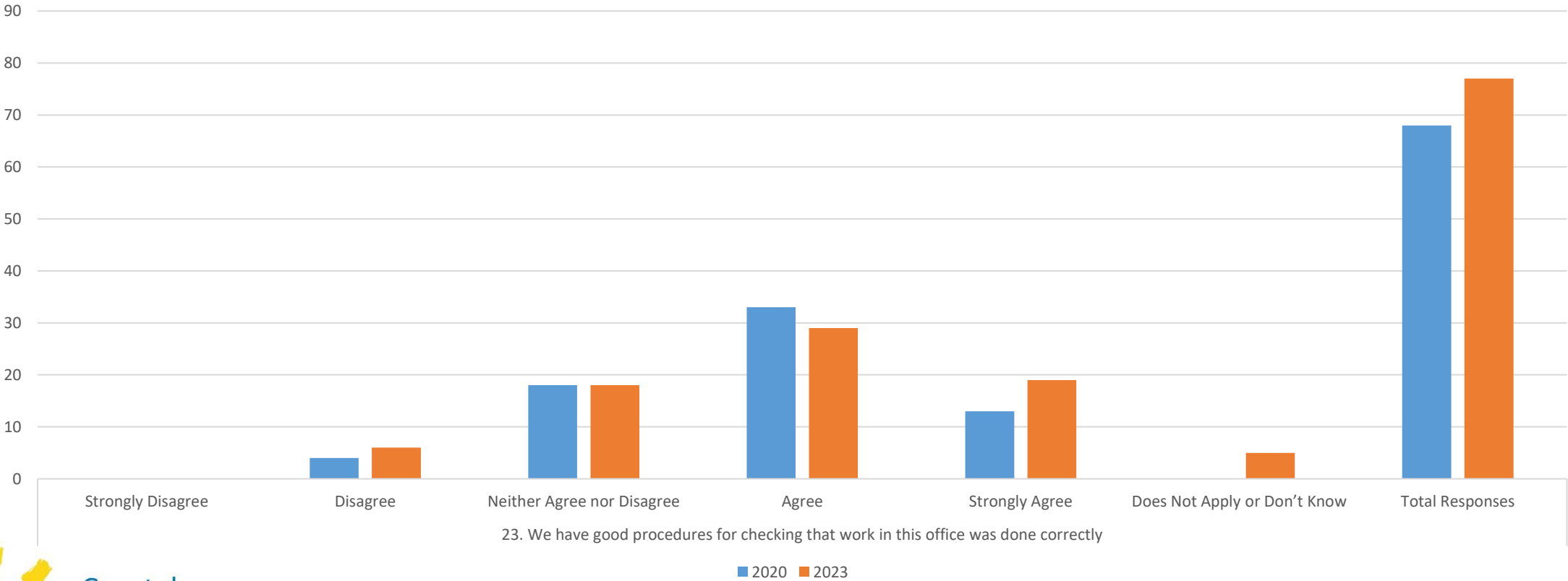
Section C: Working in Your Medical Office



Question 23

We have good procedures for checking that work in this office was done correctly.

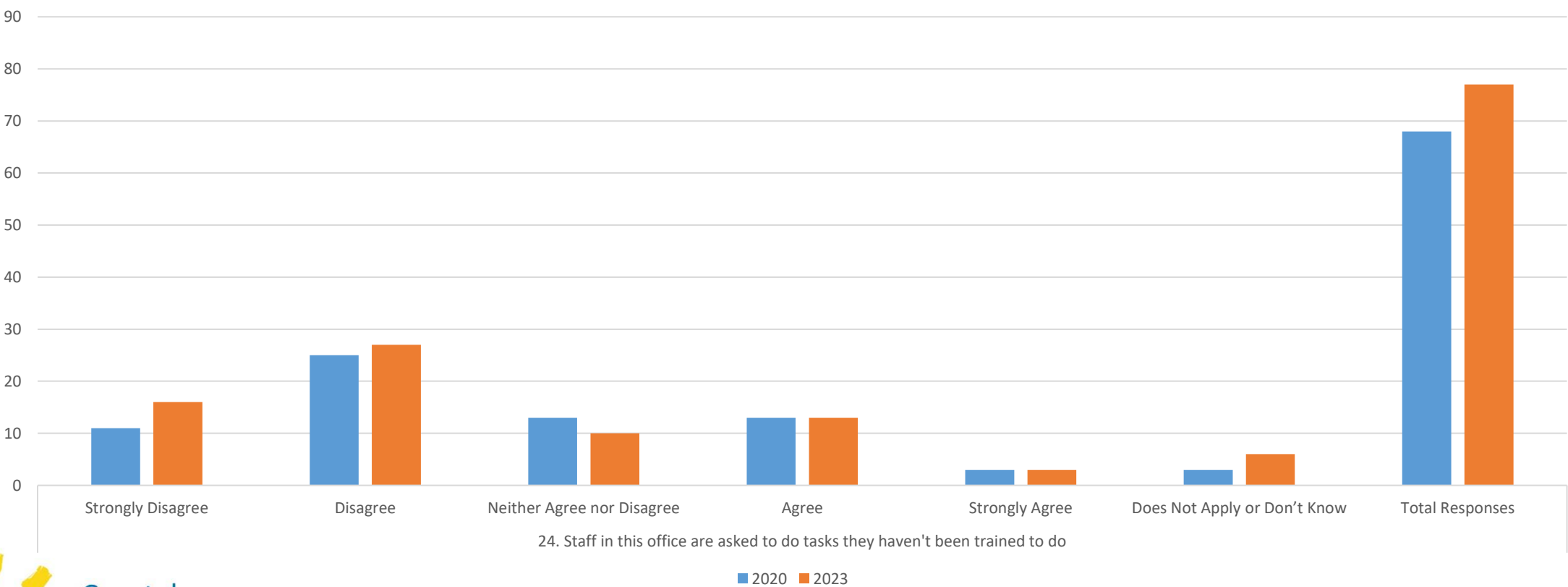
Section C: Working in Your Medical Office



Questions 24

Staff in this office are asked to do tasks they haven't been trained to do.

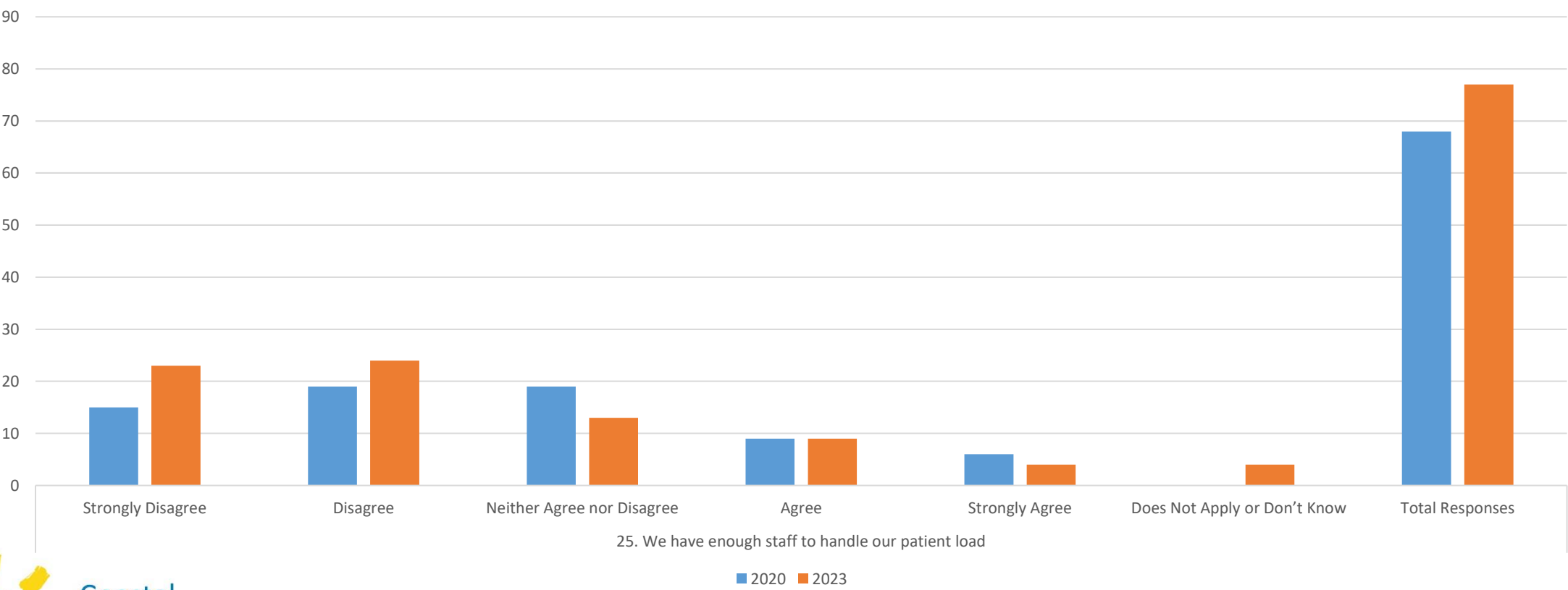
Section C: Working in Your Medical Office



Question 25

We have enough staff to handle our patient load.

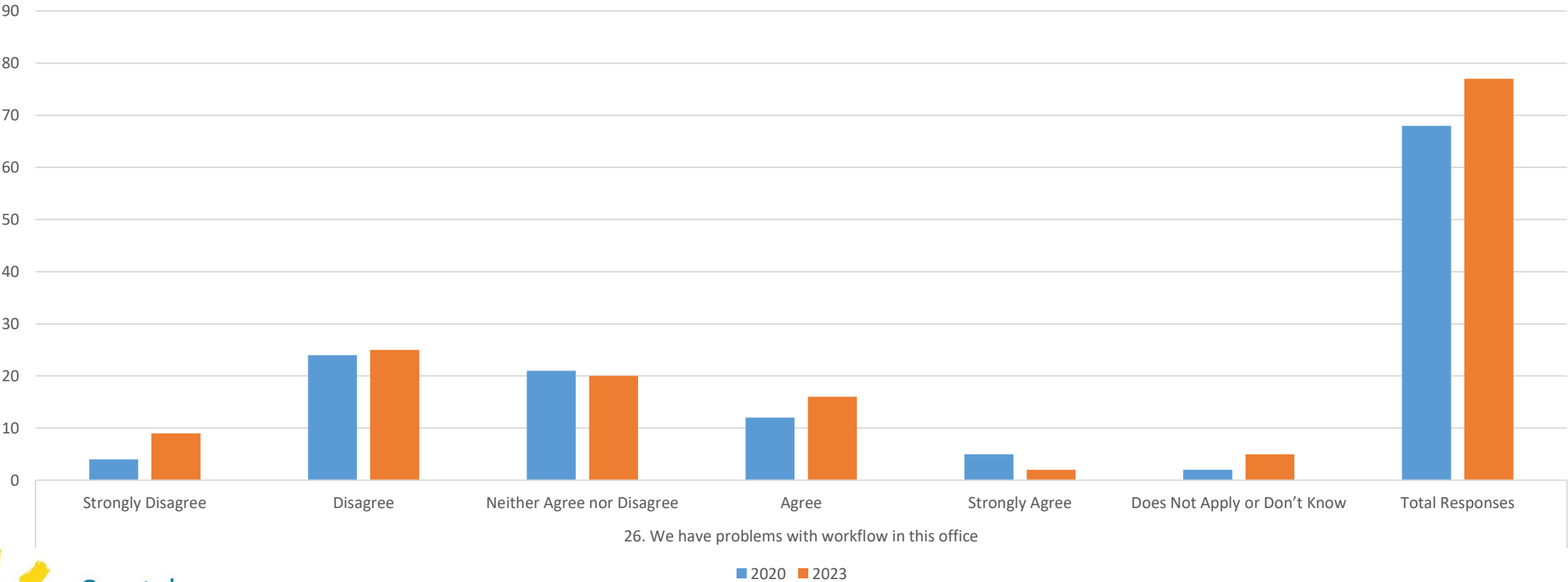
Section C: Working in Your Medical Office



Question 26

We have problems with workflow in this office.

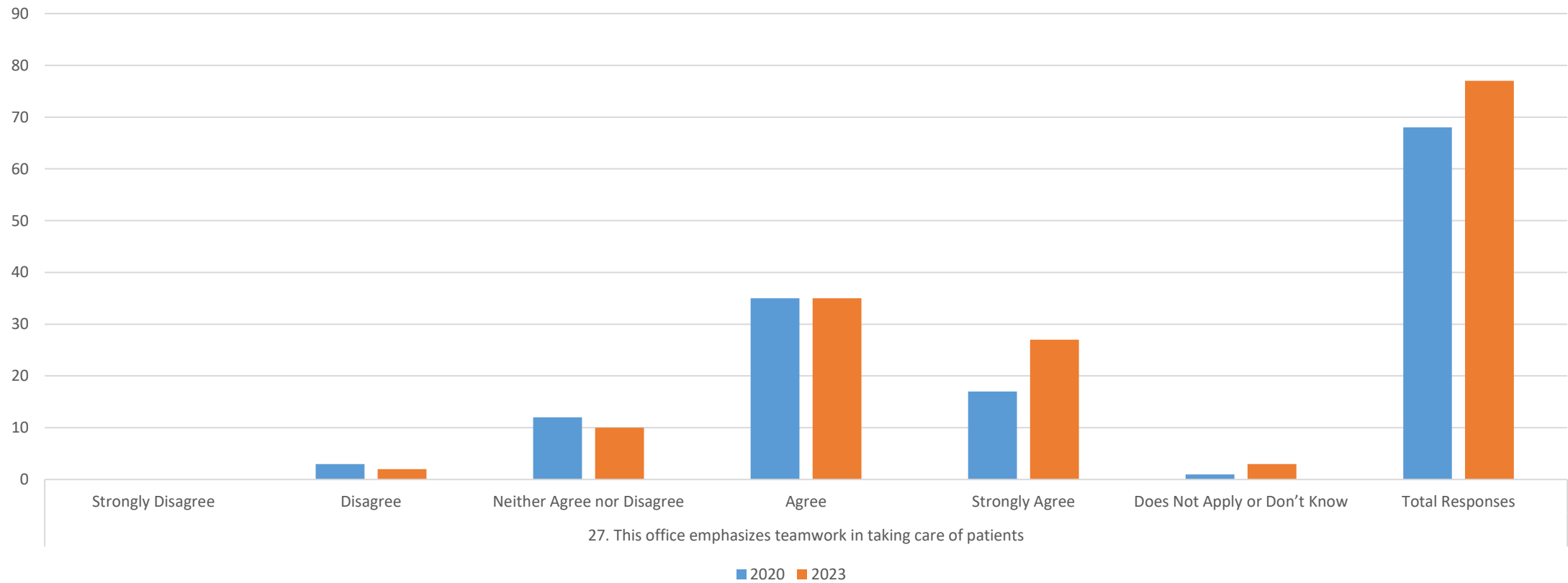
Section C: Working in Your Medical Office



Question 27

This office emphasizes teamwork in taking care of patients

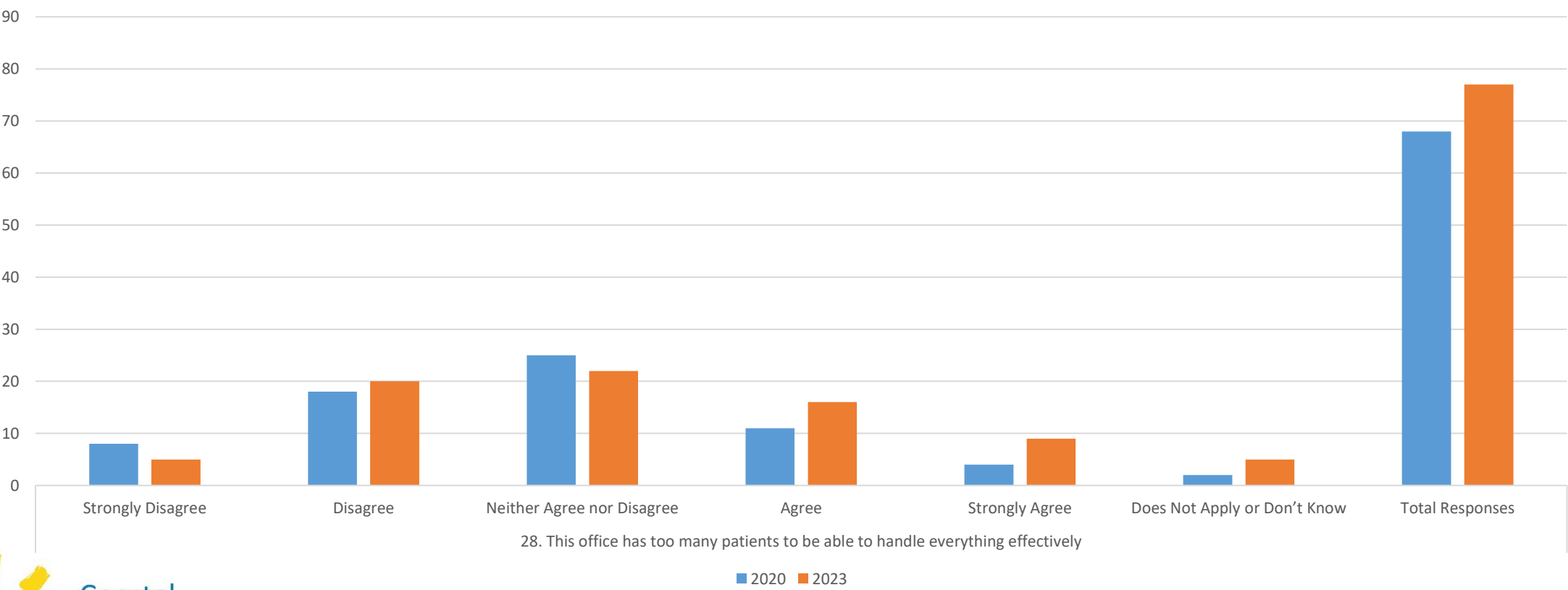
Section C: Working in Your Medical Office



Question 28

This office has too many patients to be able to handle everything effectively

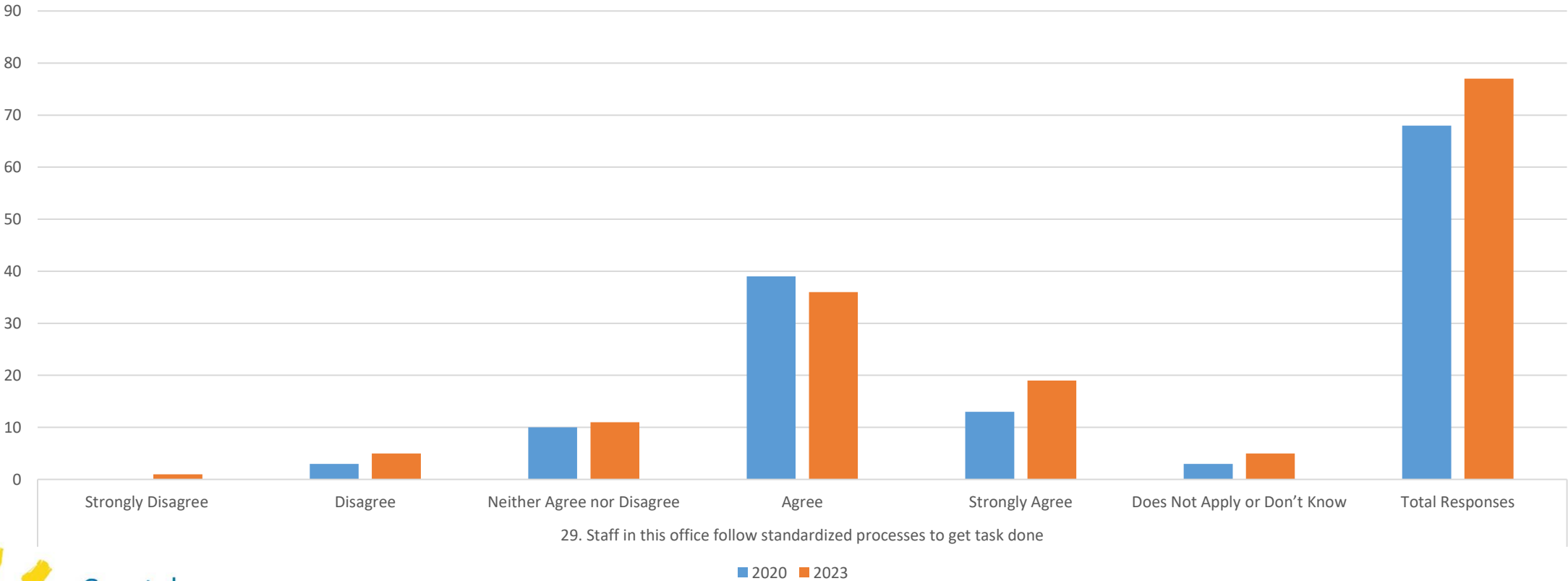
Section C: Working in Your Medical Office



Question 29

Staff in this office follow standardized processes to get task done

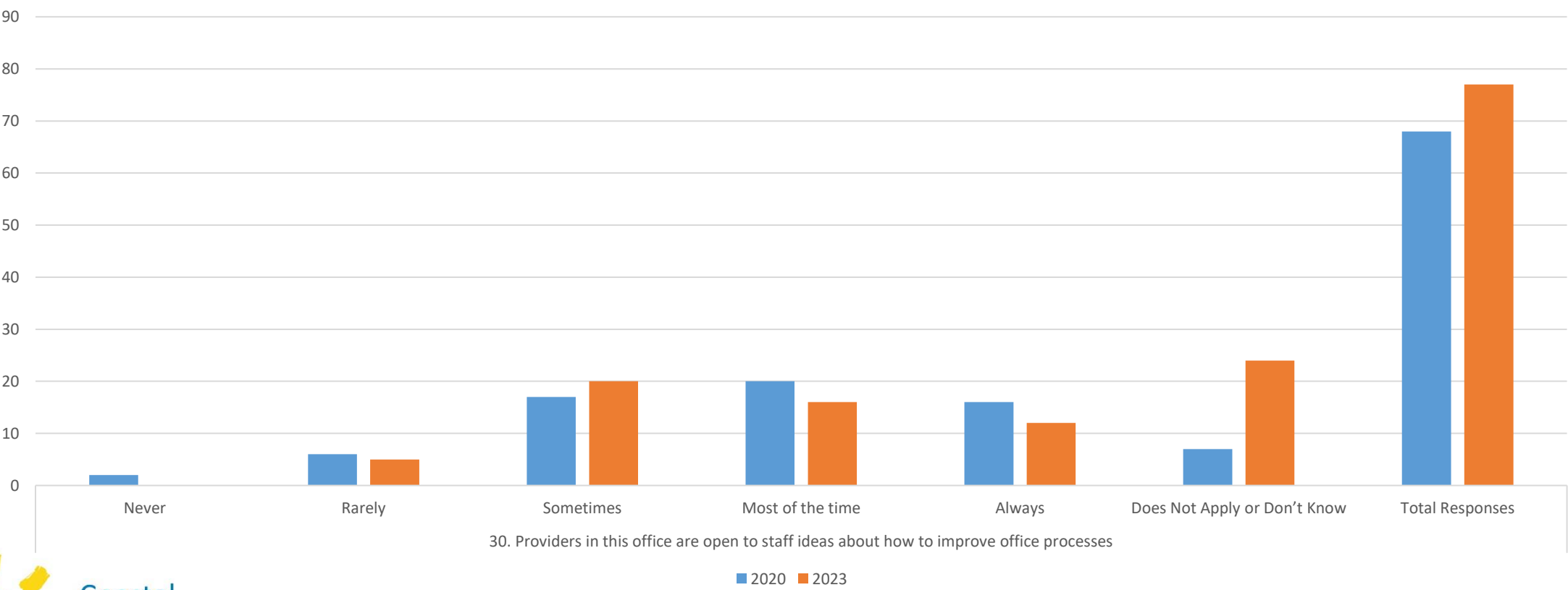
Section C: Working in Your Medical Office



Question 30

Providers in this office are open to staff ideas about how to improve office processes.

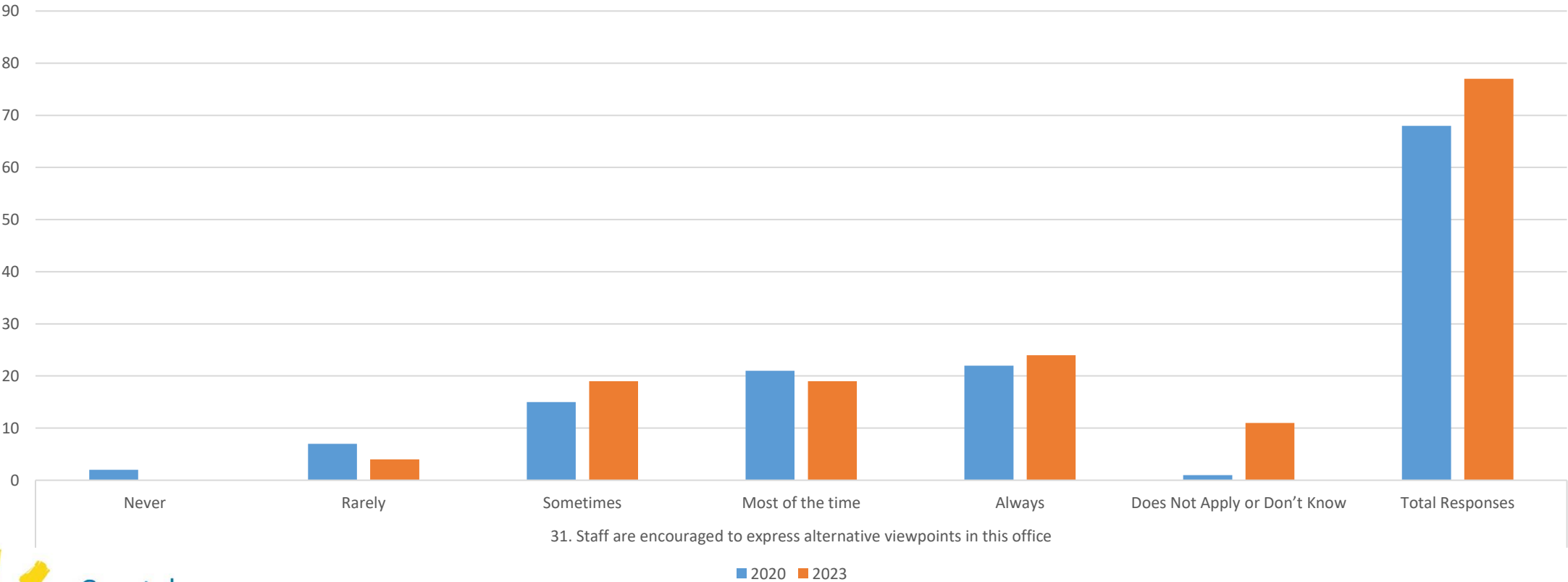
Section D: Communication and Follow Up



Question 31

Staff are encouraged to express alternative viewpoints in this office.

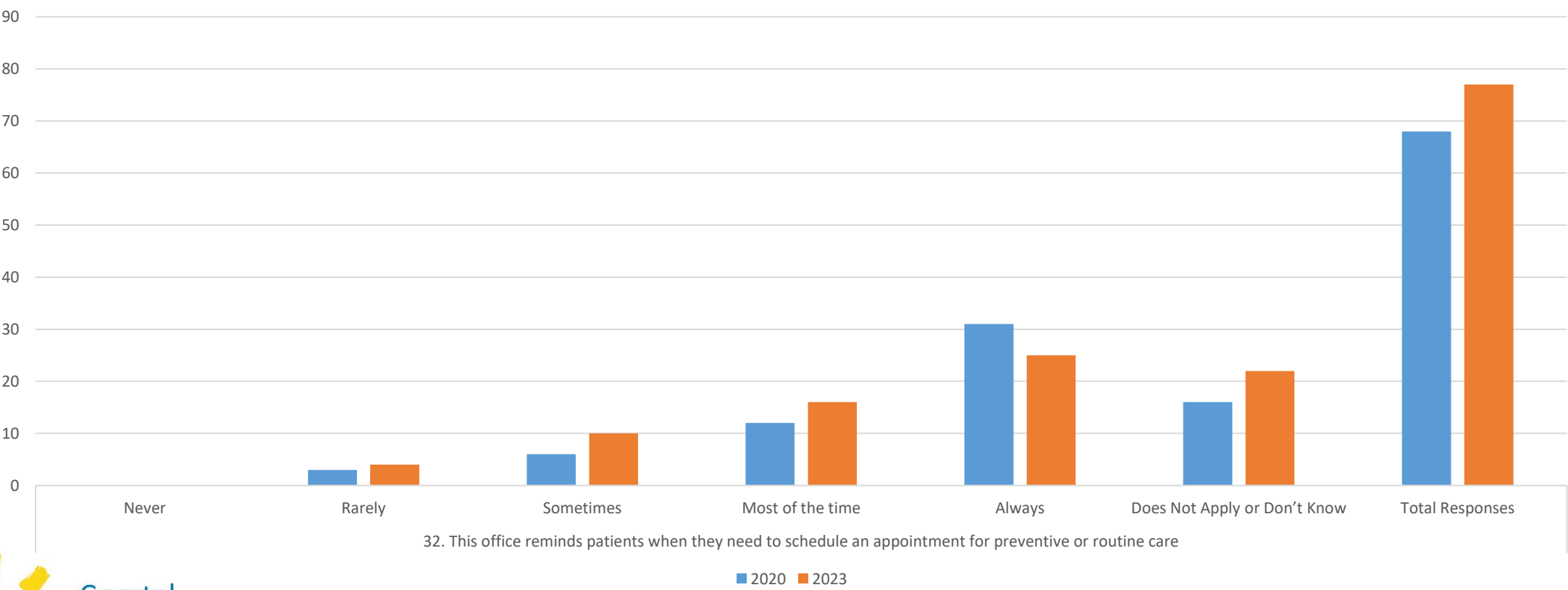
Section D: Communication and Follow Up



Question 32

This office reminds patients when they need to schedule an appointment for preventive or routine care.

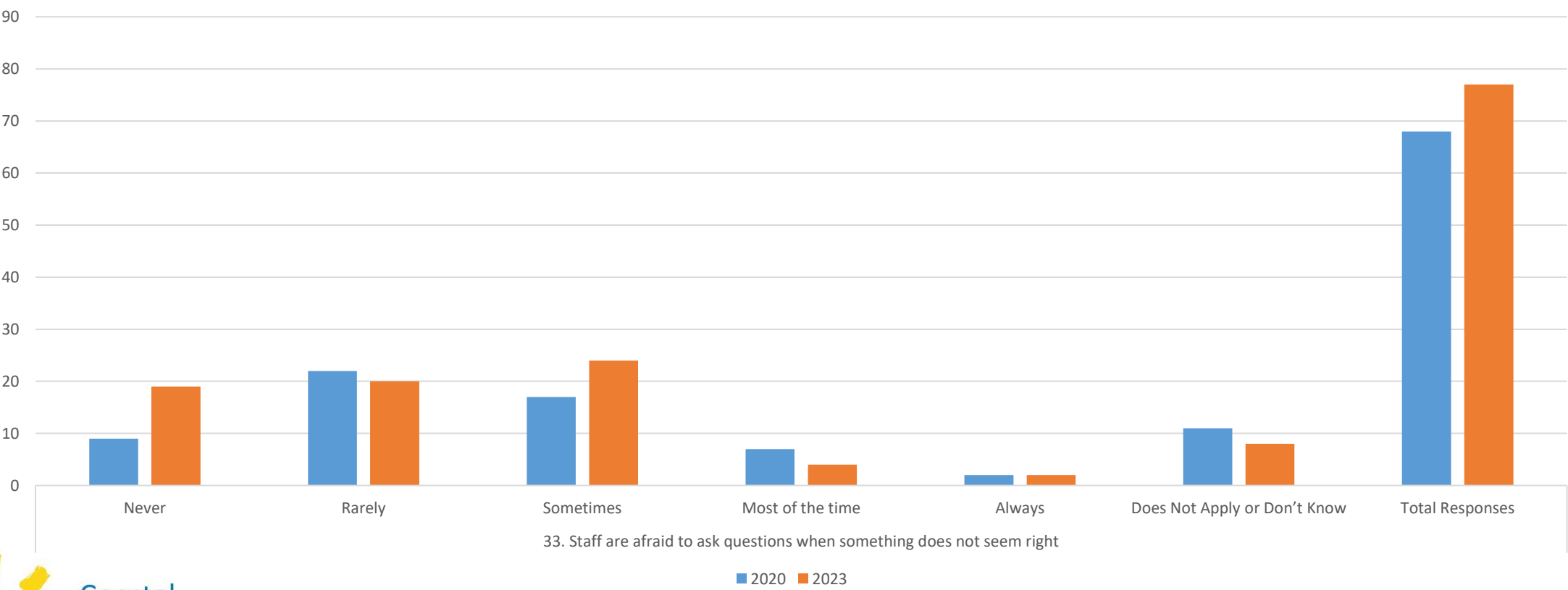
Section D: Communication and Follow Up



Question 33

Staff are afraid to ask questions when something does not seem right.

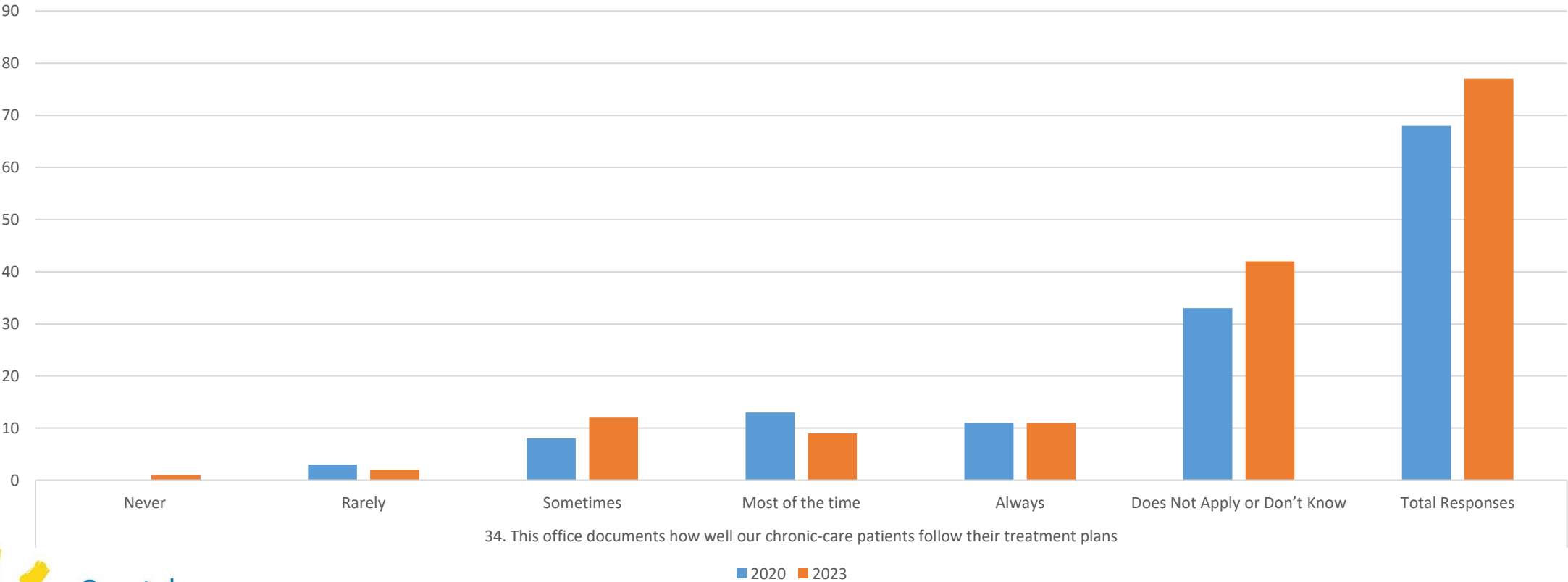
Section D: Communication and Follow Up



Question 34

This office documents how well our chronic-care patients follow their treatment plans.

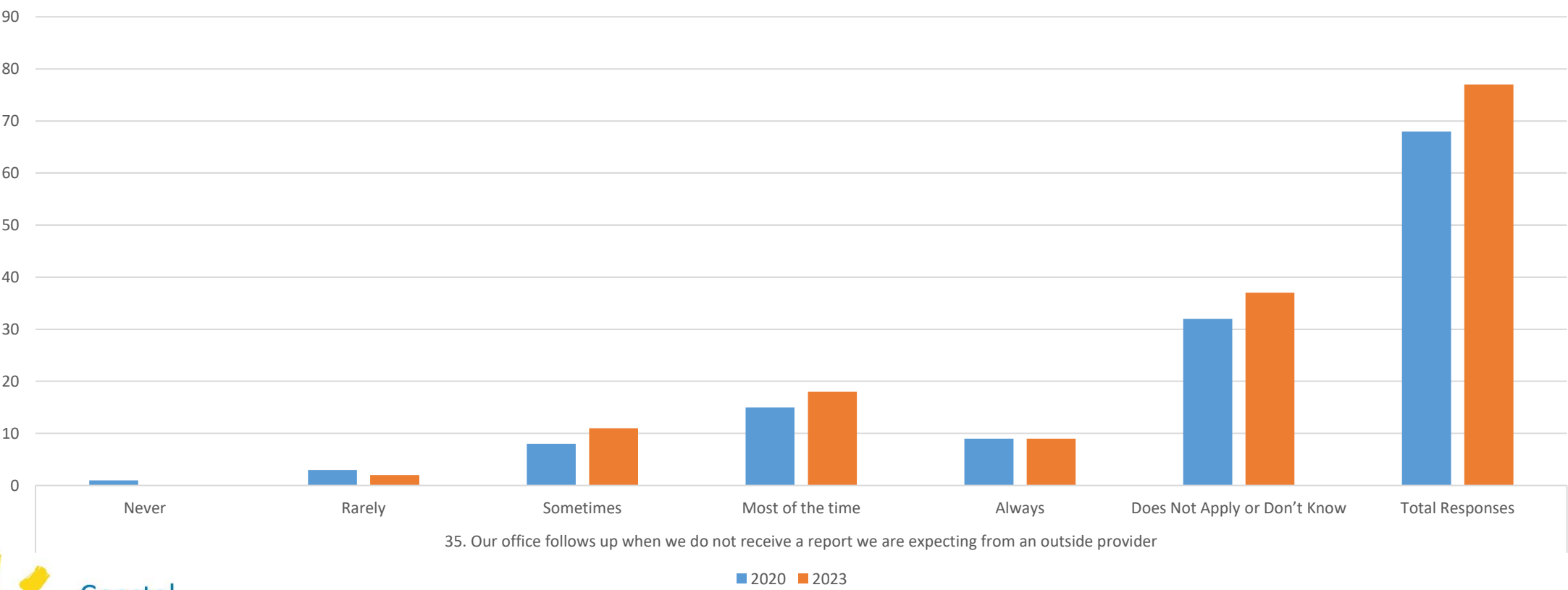
Section D: Communication and Follow Up



Question 35

Our office follows up when we do not receive a report we are expecting from an outside provider.

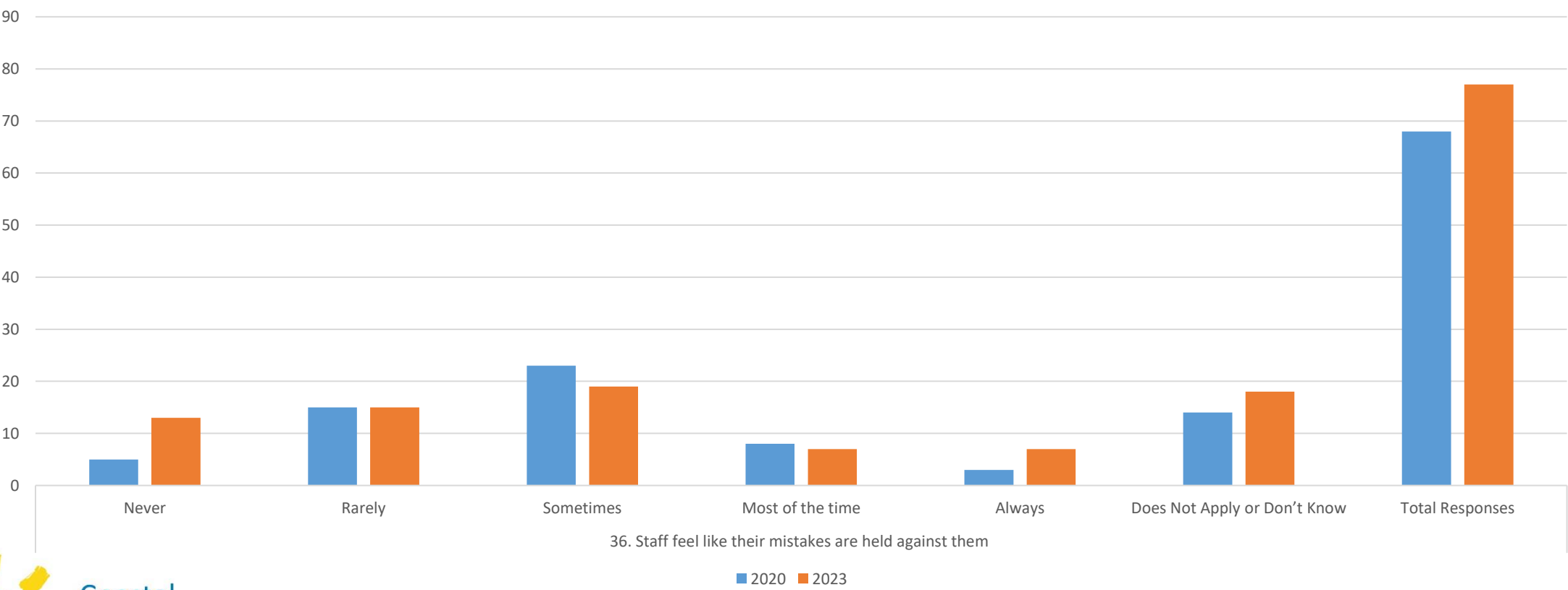
Section D: Communication and Follow Up



Question 36

Staff feel like their mistakes are held against them.

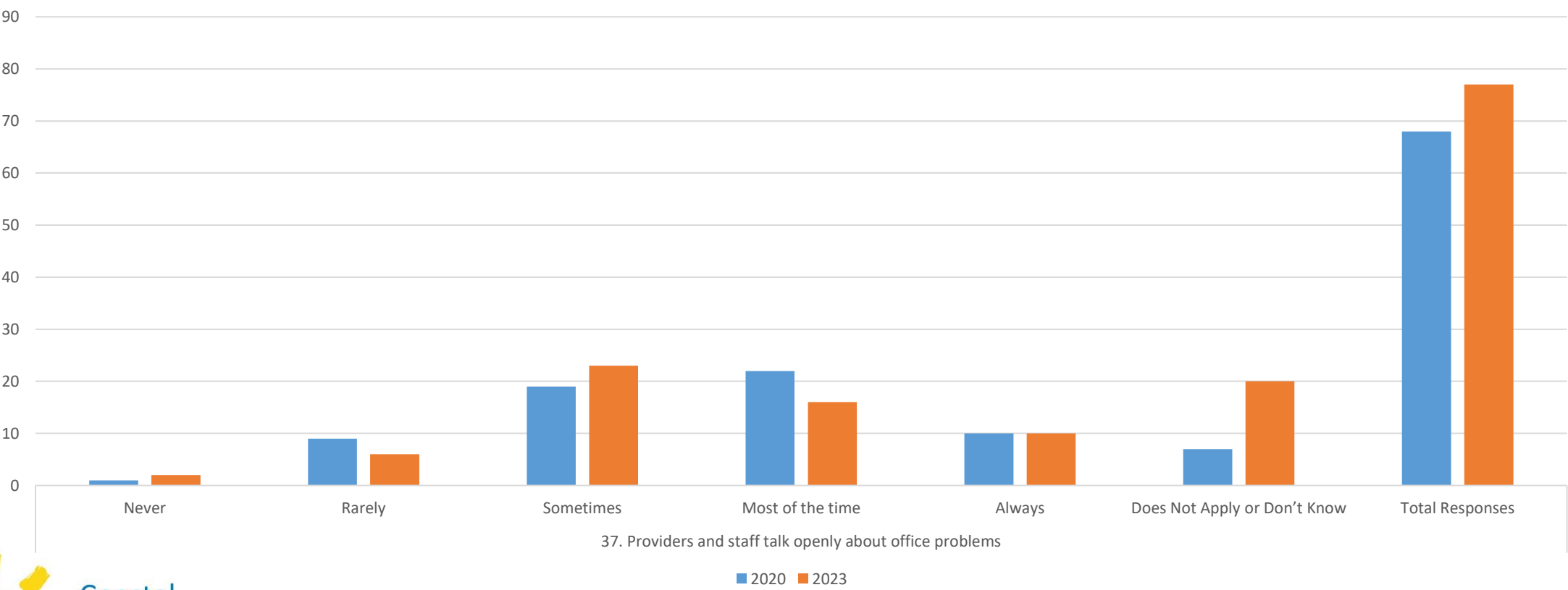
Section D: Communication and Follow Up



Question 37

Providers and staff talk openly about office problems.

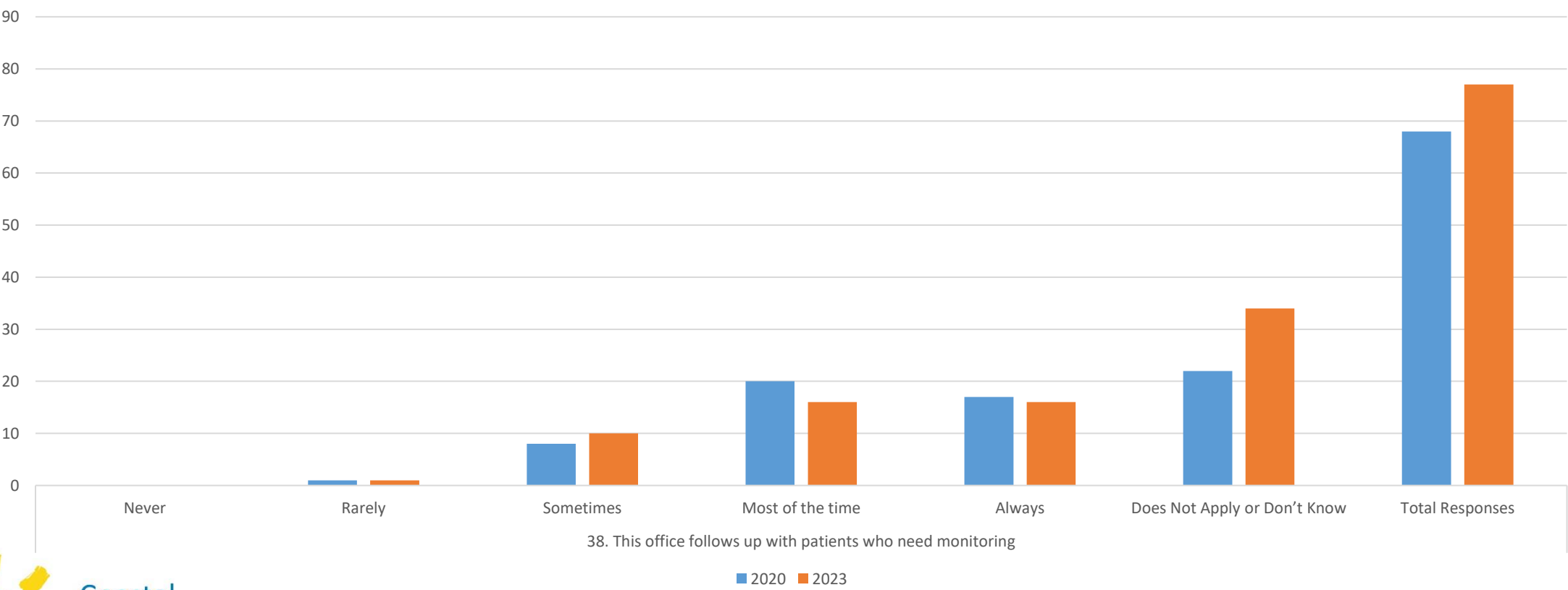
Section D: Communication and Follow Up



Question 38

This office follows up with patients who need monitoring.

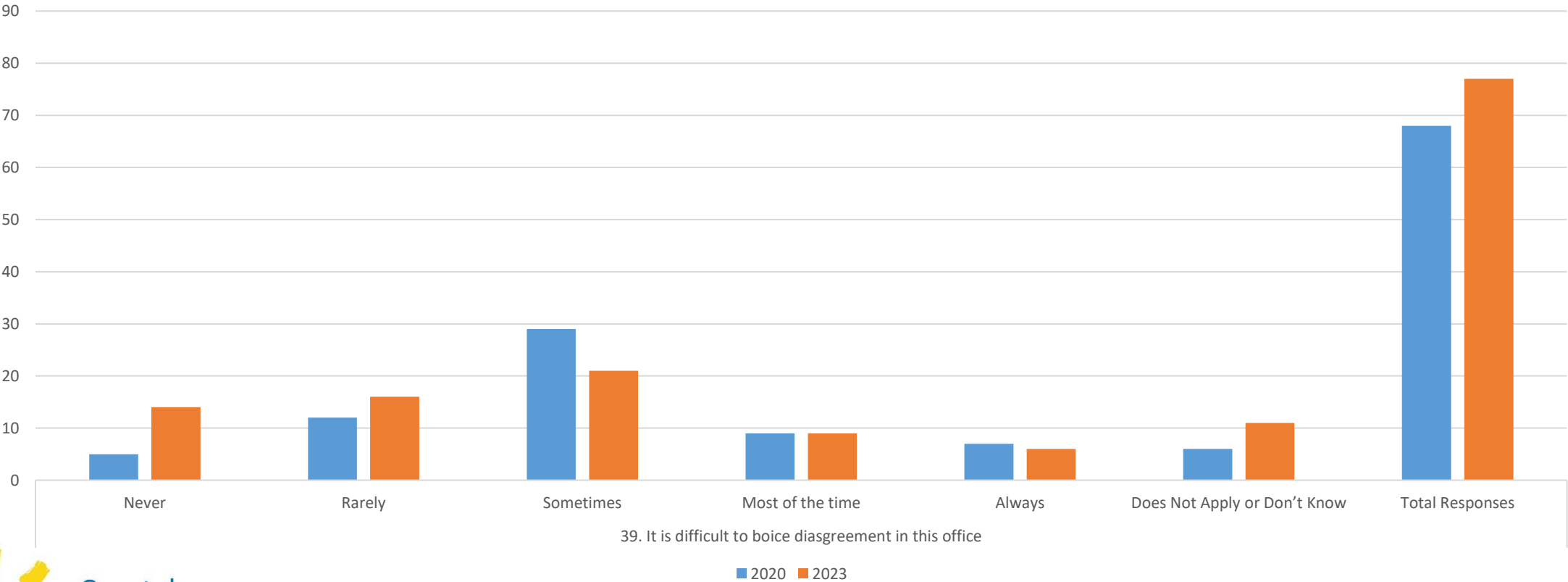
Section D: Communication and Follow Up



Question 39

It is difficult to voice disagreement in this office.

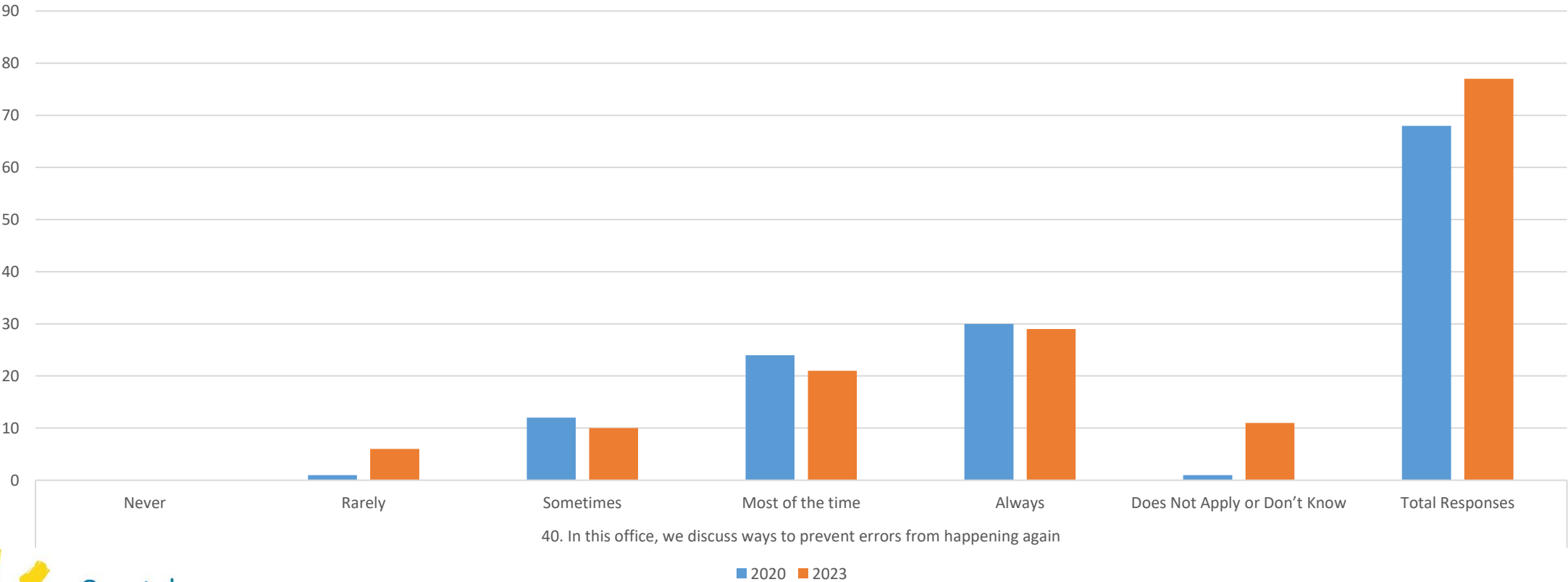
Section D: Communication and Follow Up



Question 40

In this office, we discuss ways to prevent errors from happening again.

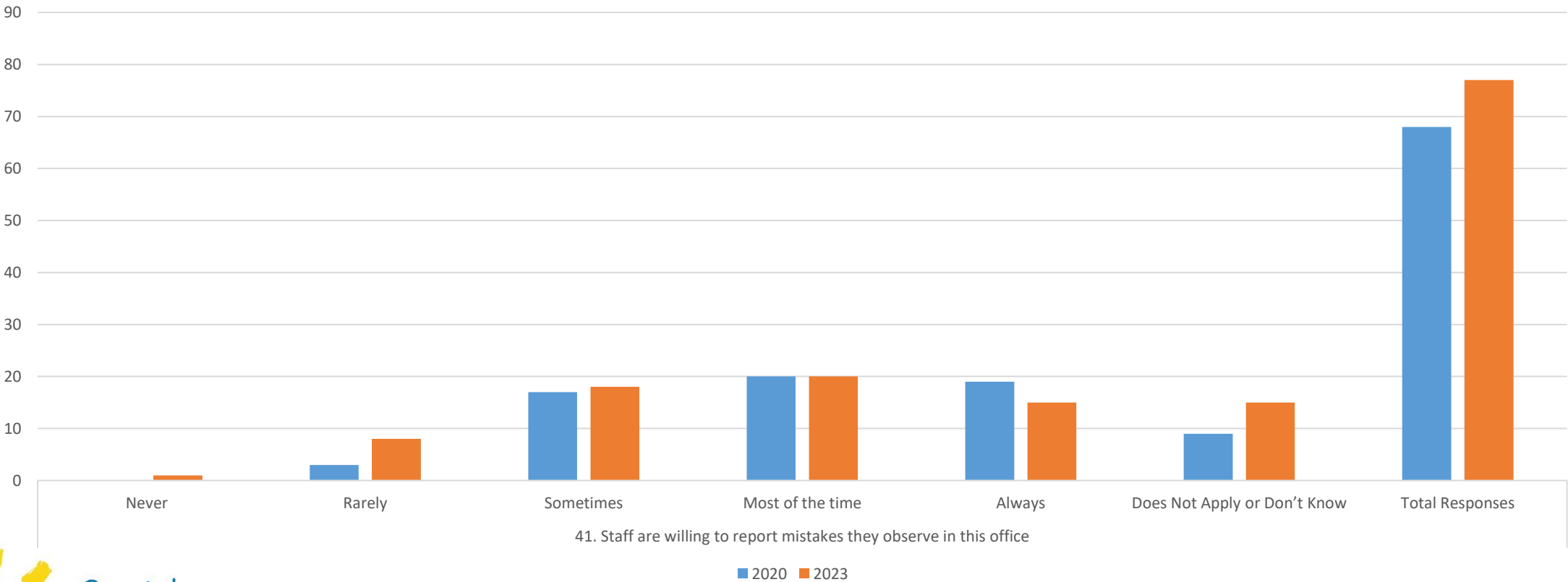
Section D: Communication and Follow Up



Question 41

Staff are willing to report mistakes they observe in this office.

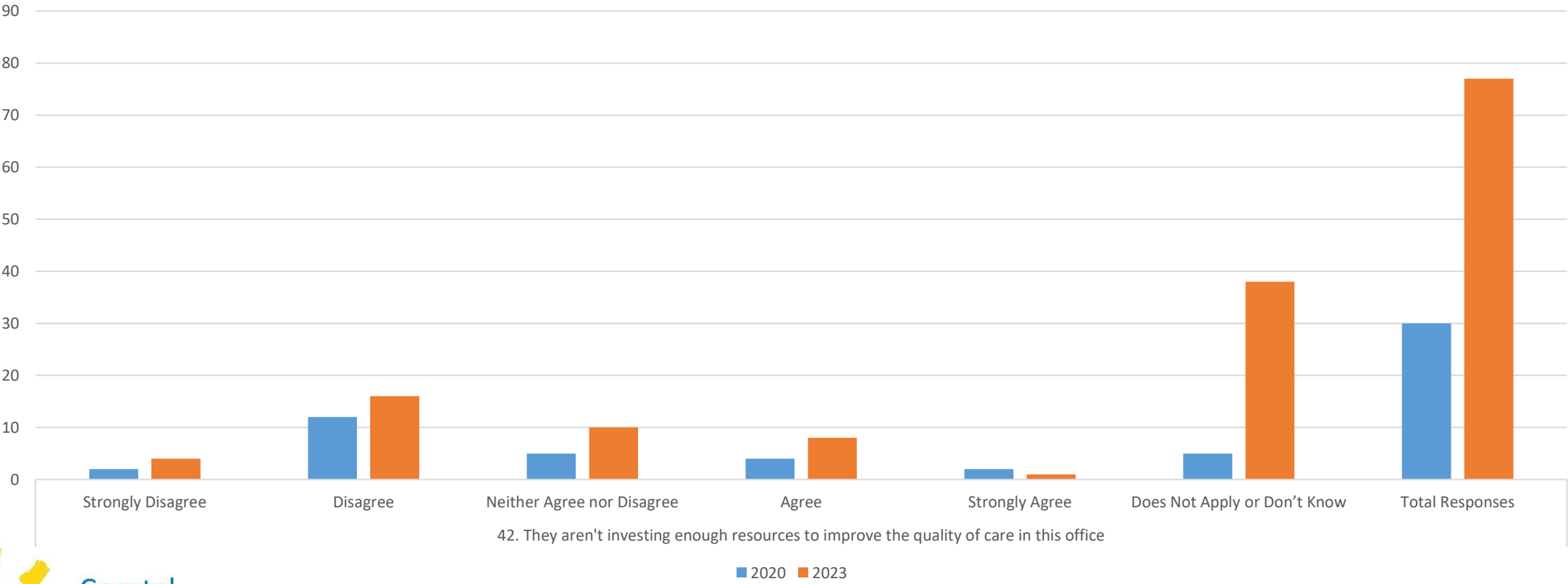
Section D: Communication and Follow Up



Question 42

They aren't investing enough resources to improve the quality of care in this office

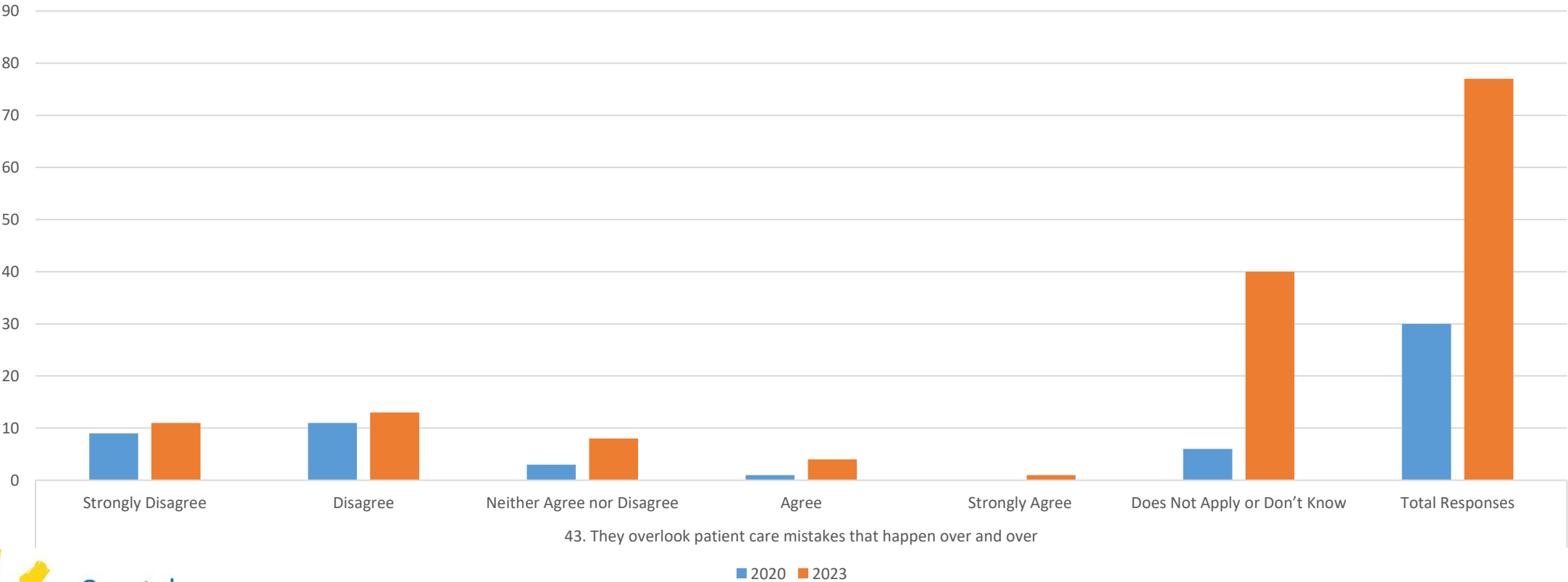
Section E: Owner/Managing Partner/Leadership Support



Question 43

They overlook patient care mistakes that happen over and over

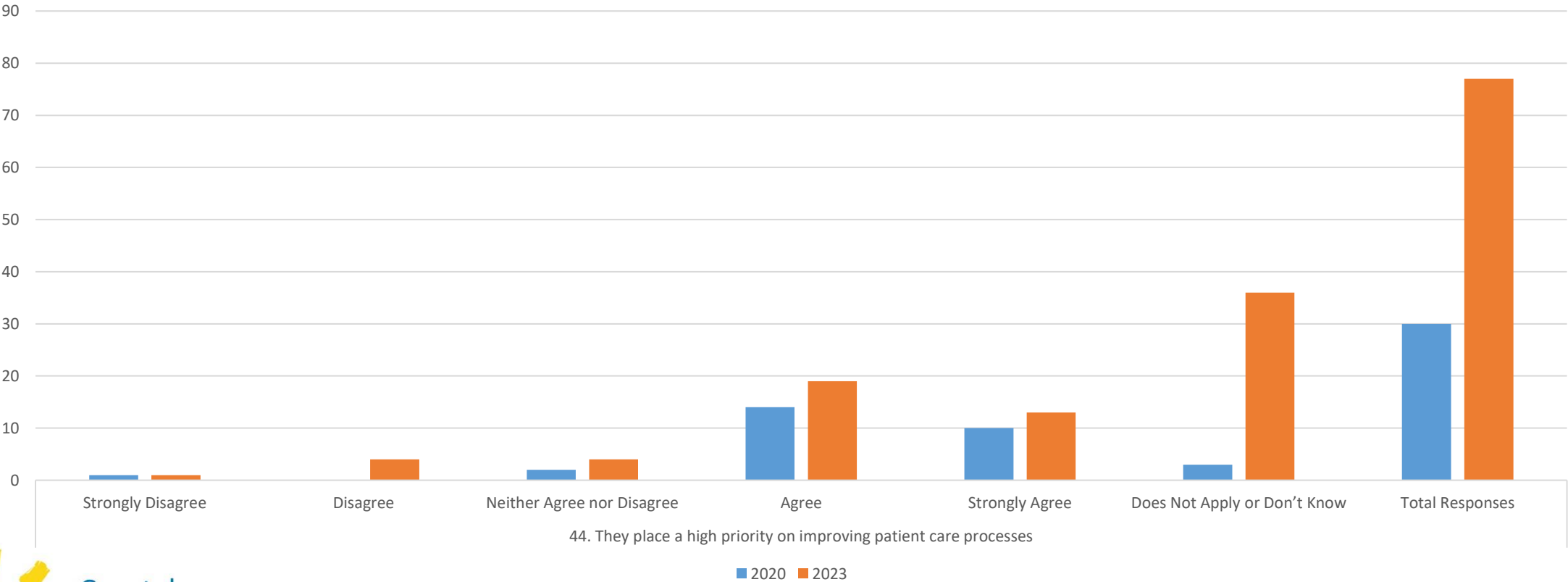
Section E: Owner/Managing Partner/Leadership Support



Question 44

They place a high priority on improving patient care processes

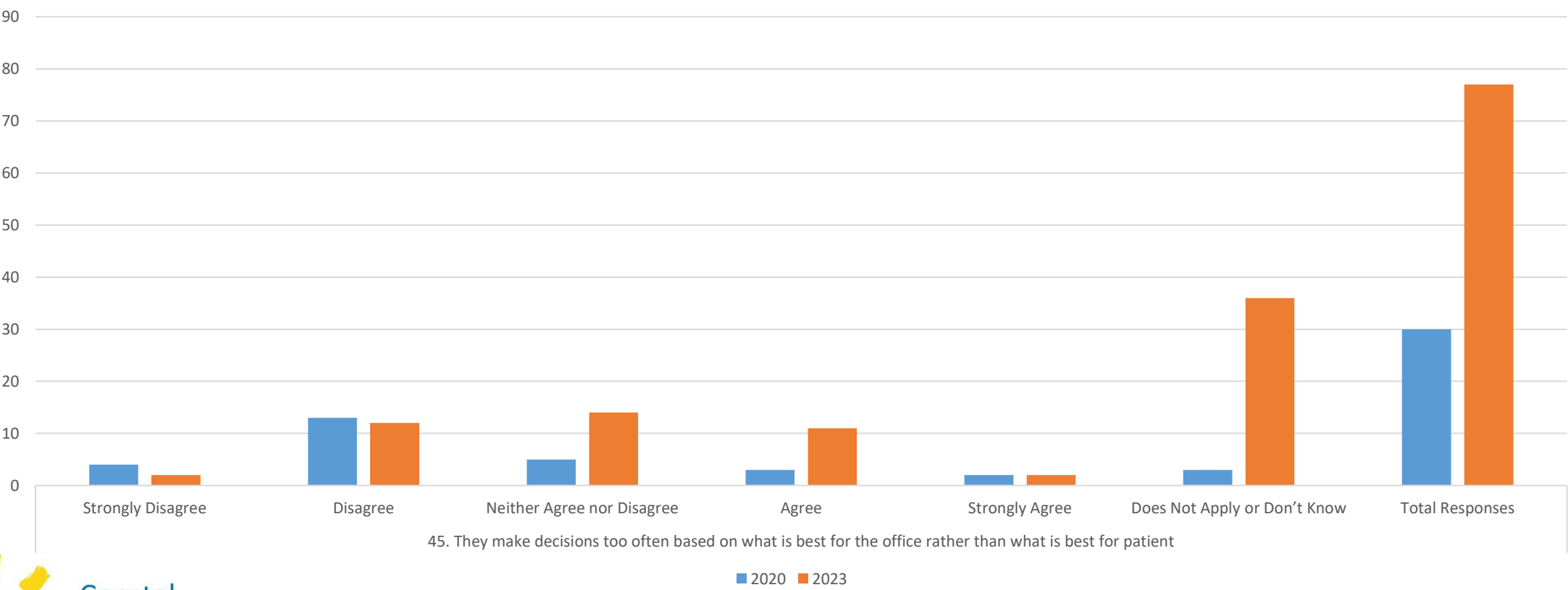
Section E: Owner/Managing Partner/Leadership Support



Question 45

They make decisions too often based on what is best for the office rather than what is best for patient

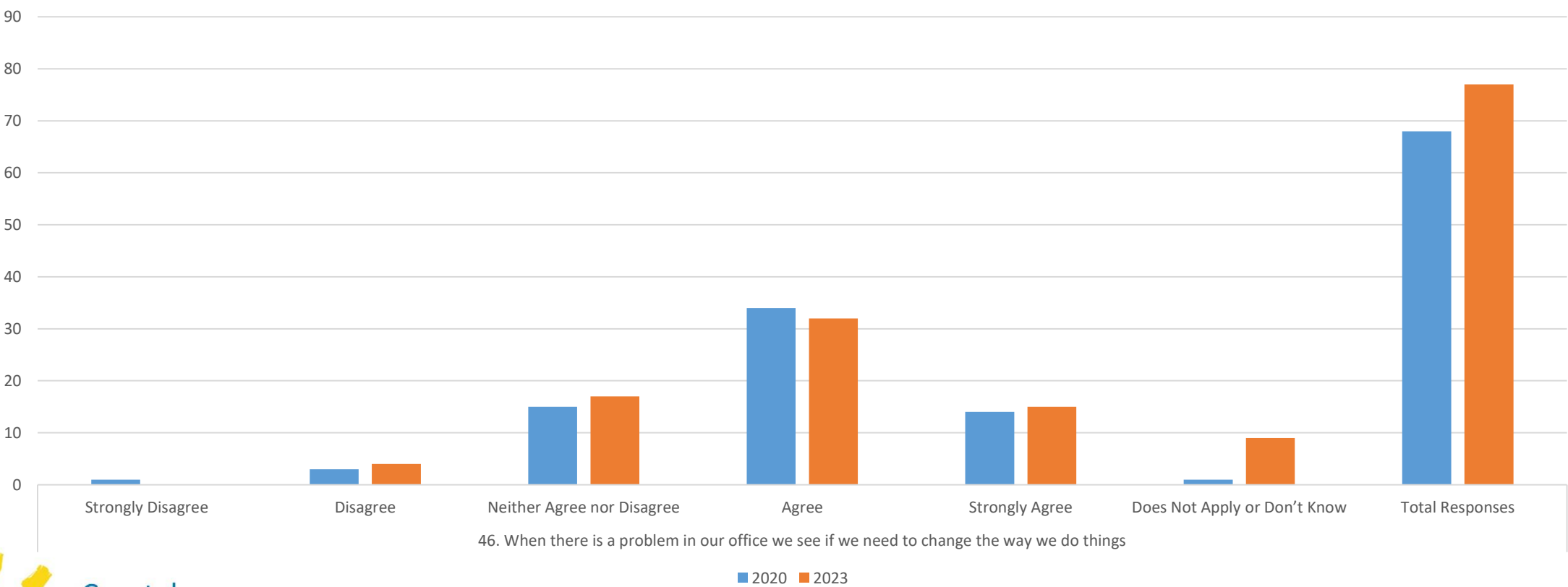
Section E: Owner/Managing Partner/Leadership Support



Question 46

When there is a problem in our office we see if we need to change the way we do things

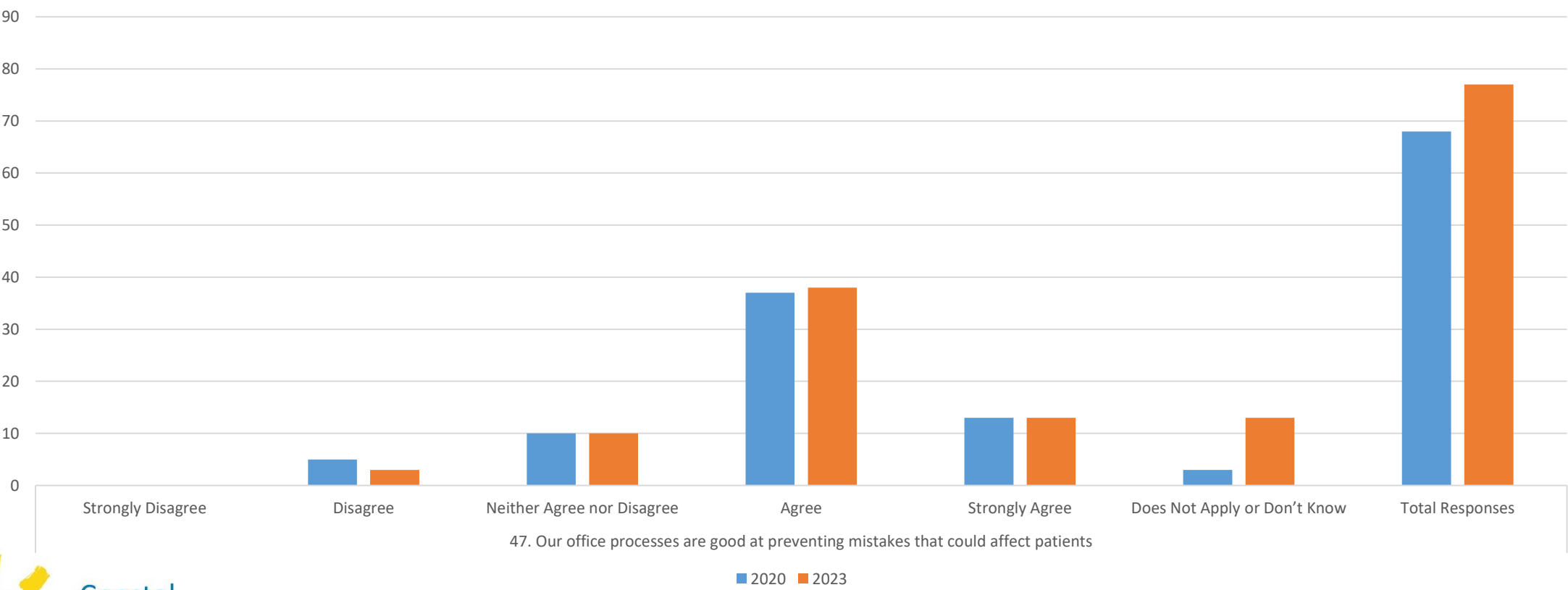
Section F: Your Medical Office



Question 47

Our office processes are good at preventing mistakes that could affect patients

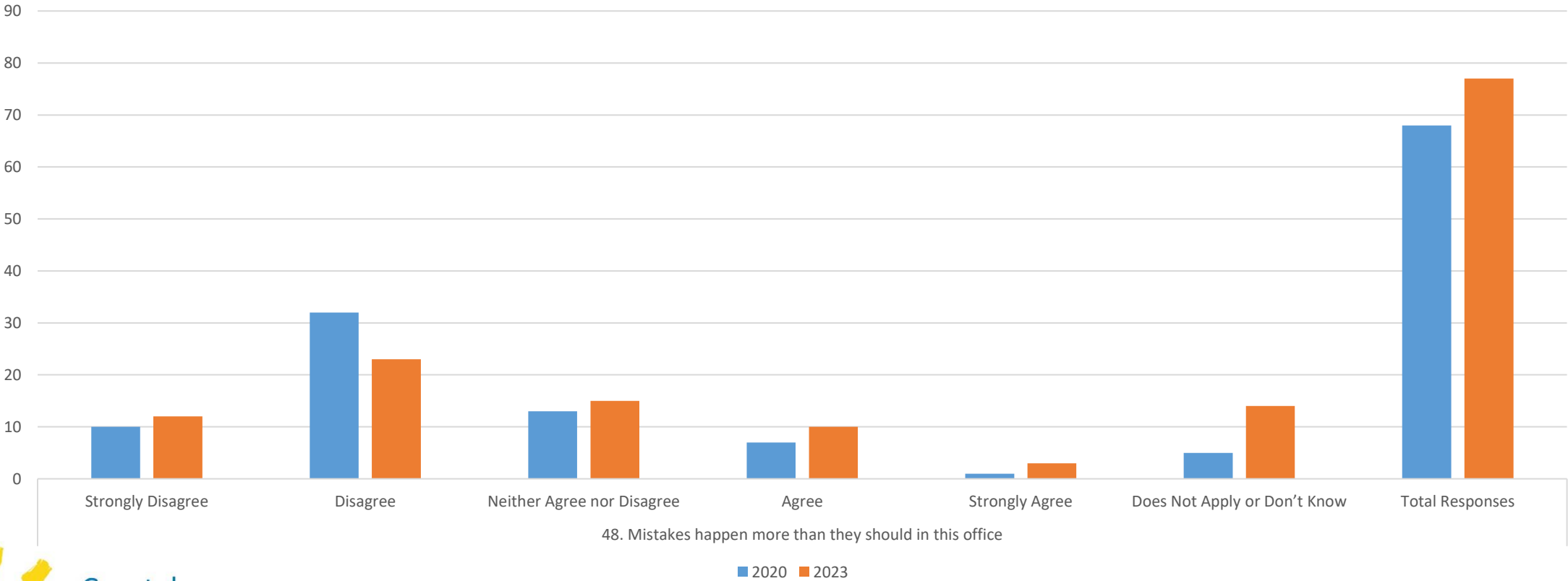
Section F: Your Medical Office



Question 48

Mistakes happen more than they should in this office

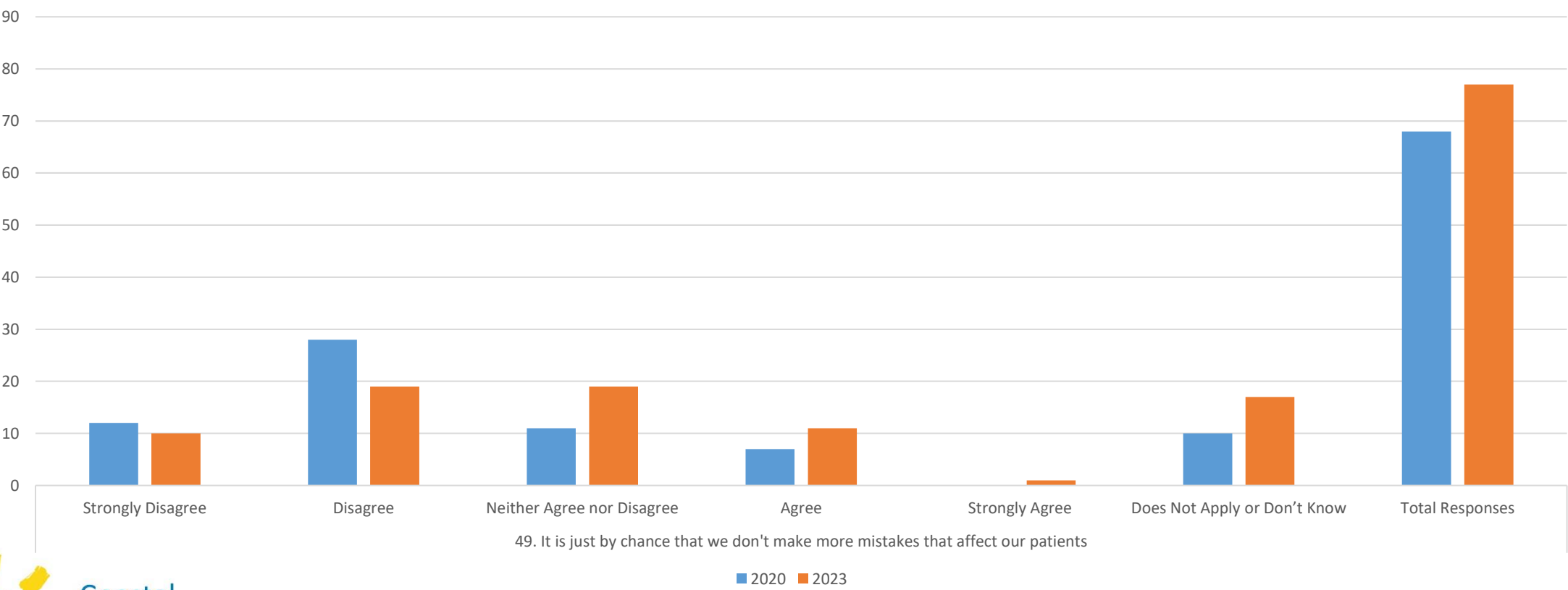
Section F: Your Medical Office



Question 49

It is just by chance that we don't make more mistakes that affect our patients

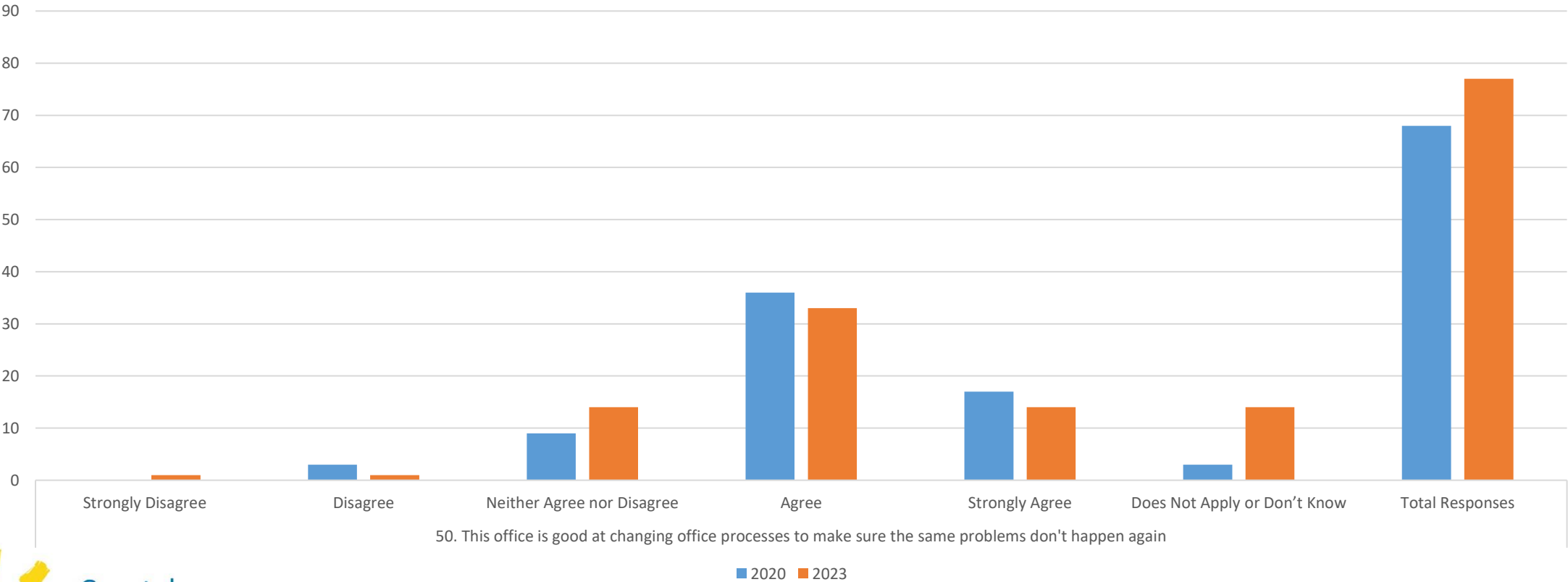
Section F: Your Medical Office



Question 50

This office is good at changing office processes to make sure the same problems don't happen again

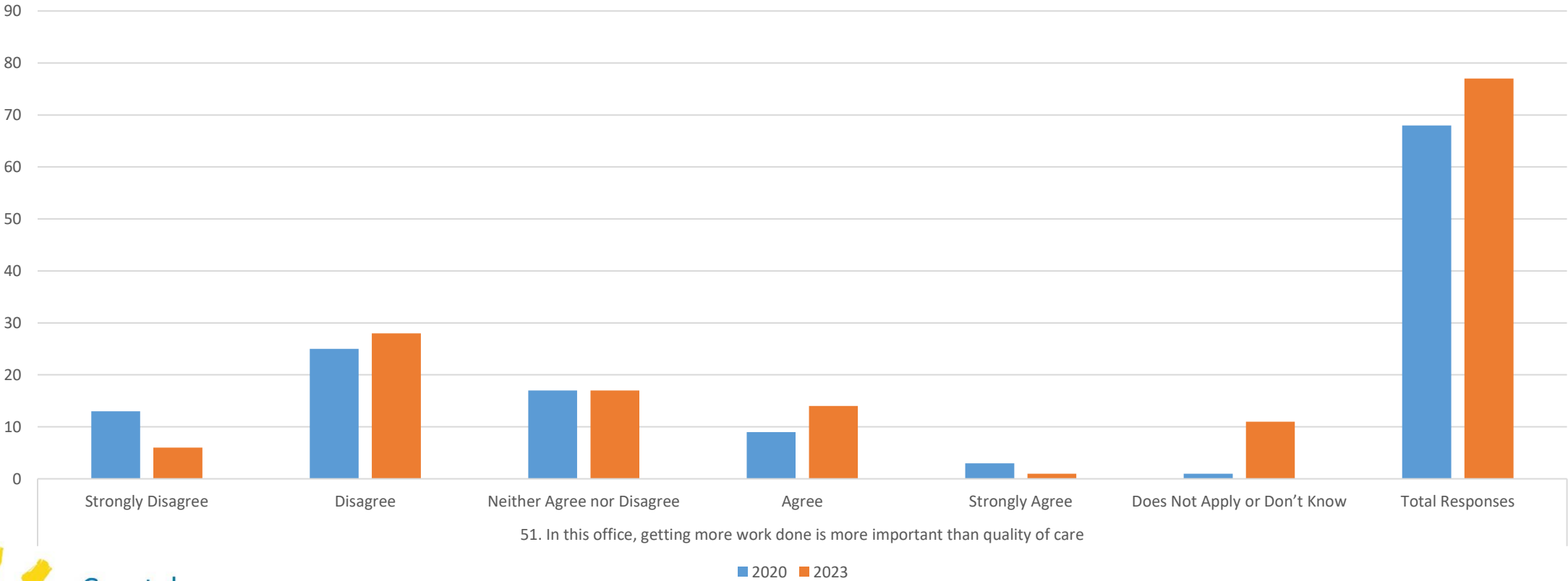
Section F: Your Medical Office



Question 51

In this office, getting more work done is more important than quality of care

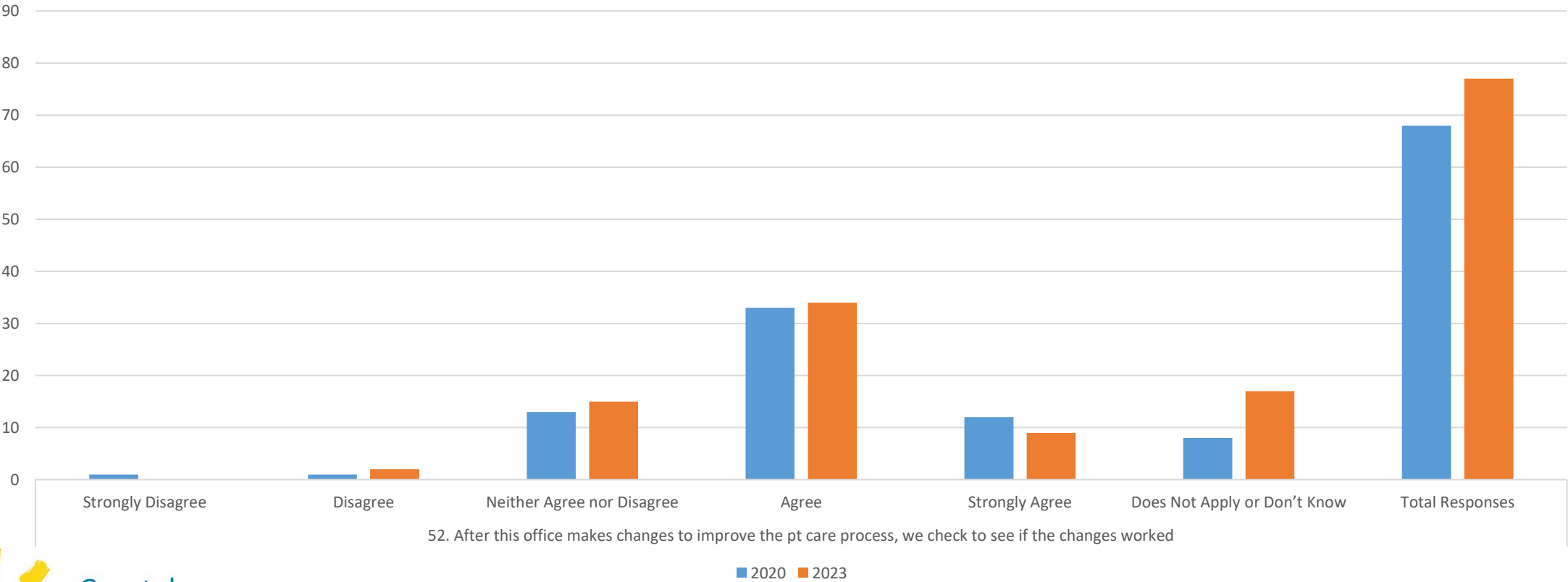
Section F: Your Medical Office



Question 52

After this office makes changes to improve the pt care process, we check to see if the changes worked

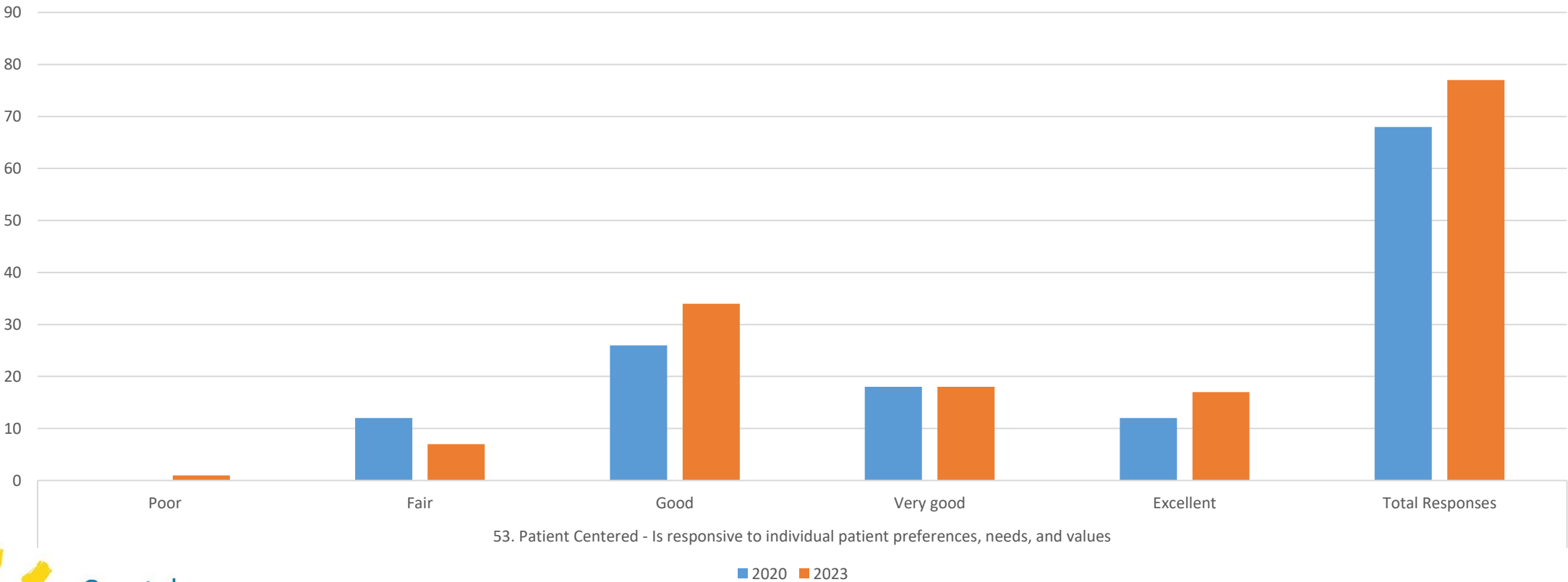
Section F: Your Medical Office



Question 53

Patient Centered - Is responsive to individual patient preferences, needs, and values

Section G: Overall Ratings

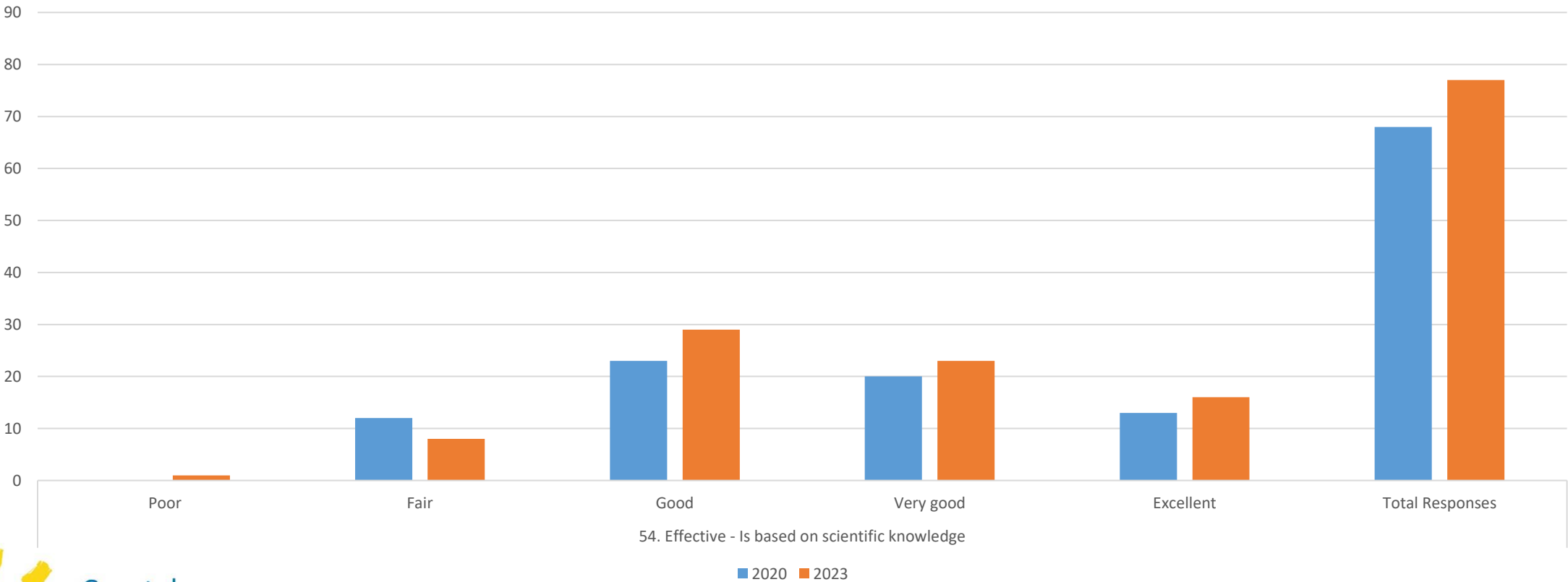


53. Patient Centered - Is responsive to individual patient preferences, needs, and values

Question 54

Effective - Is based on scientific knowledge

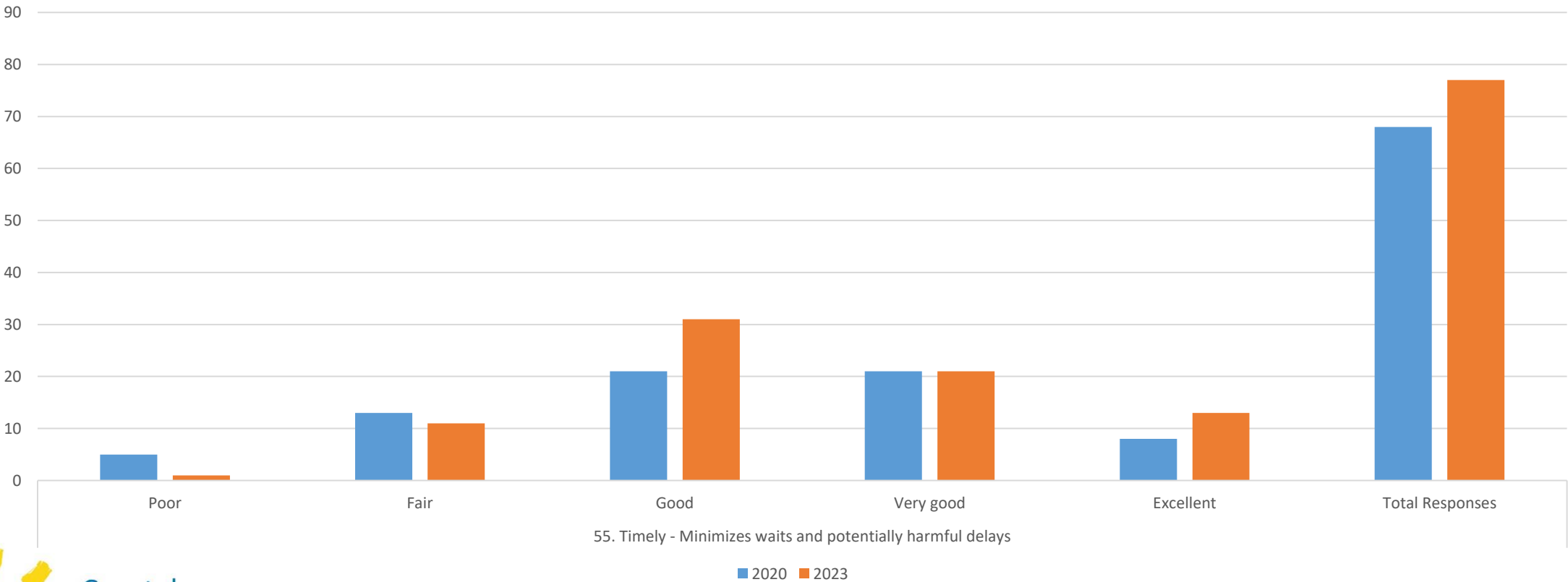
Section G: Overall Ratings



Question 55

Timely - Minimizes waits and potentially harmful delays

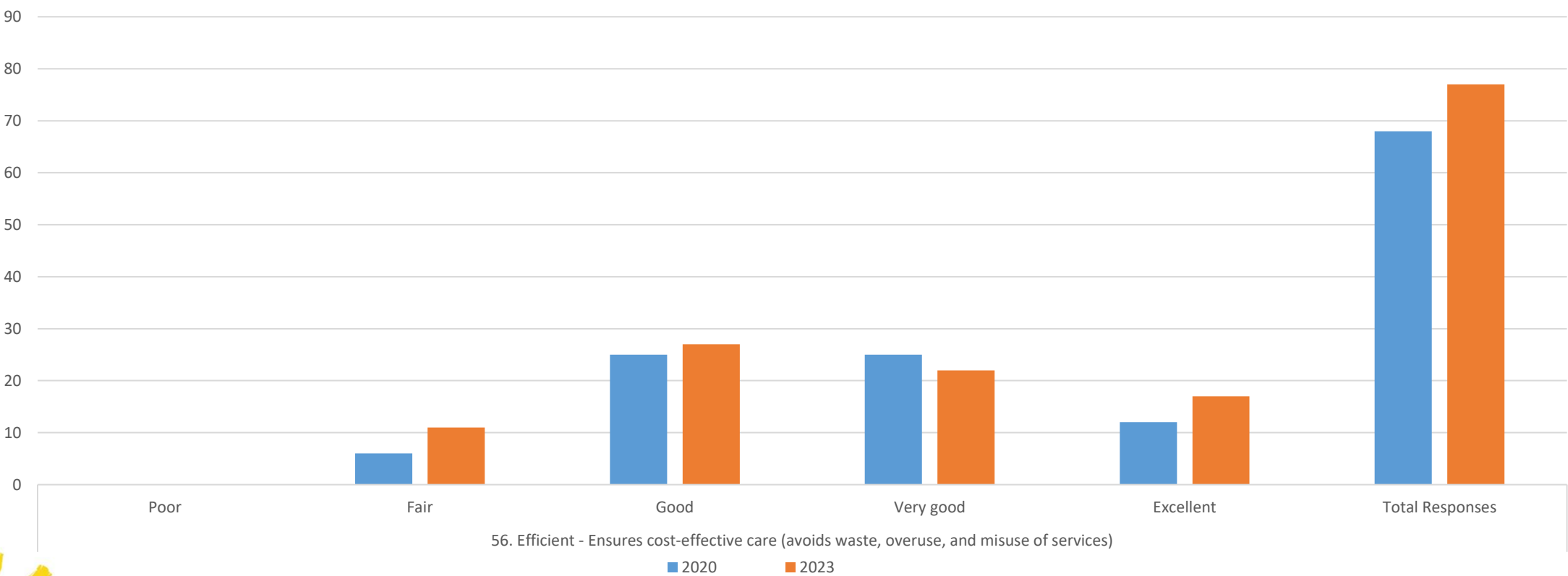
Section G: Overall Ratings



Question 56

Efficient - Ensures cost-effective care (avoids waste, overuse, and misuse of services)

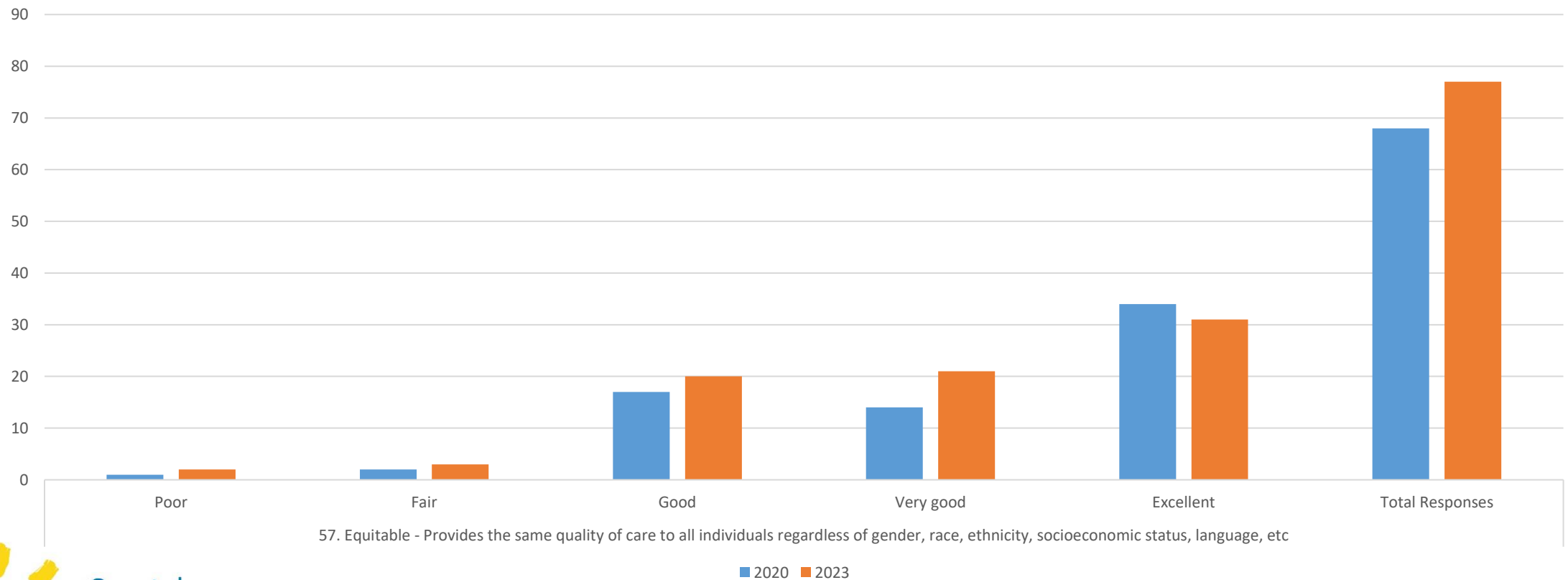
Section G: Overall Ratings



Question 57

Equitable - Provides the same quality of care to all individuals regardless of gender, race, ethnicity, socioeconomic status, language, etc

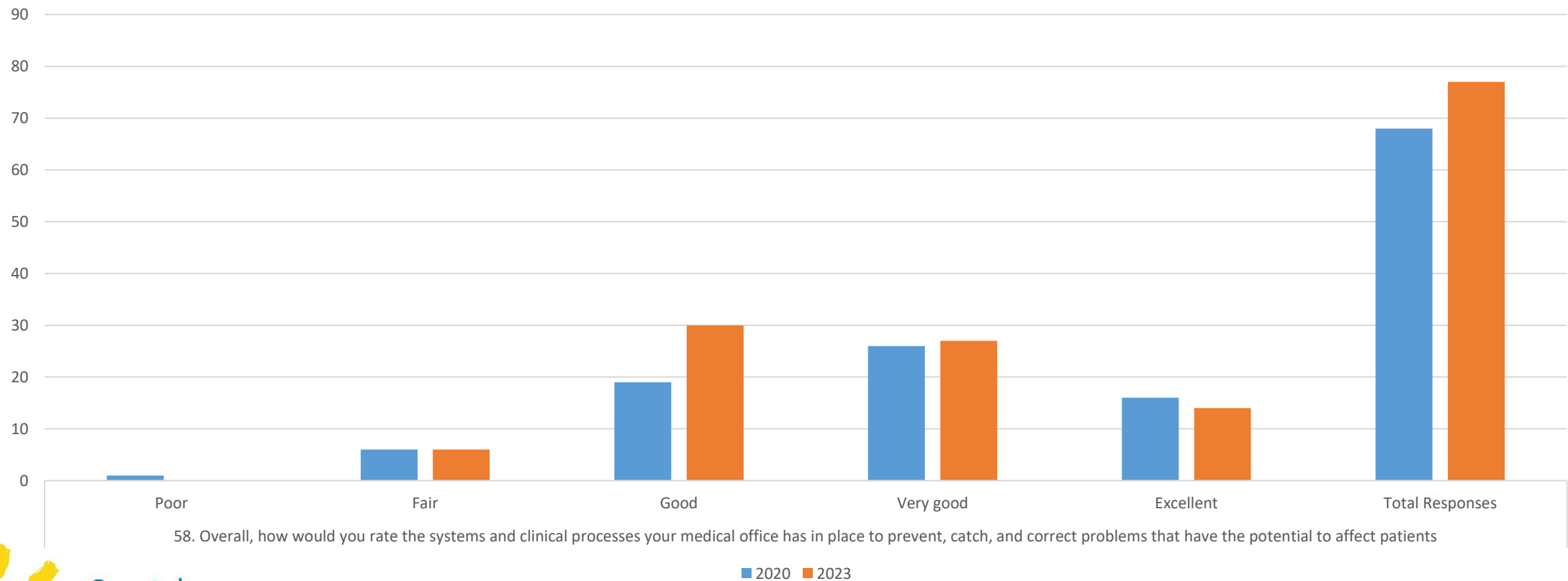
Section G: Overall Ratings



Question 58

Overall, how would you rate the systems and clinical processes your medical office has in place to prevent, catch, and correct problems that have the potential to affect patients

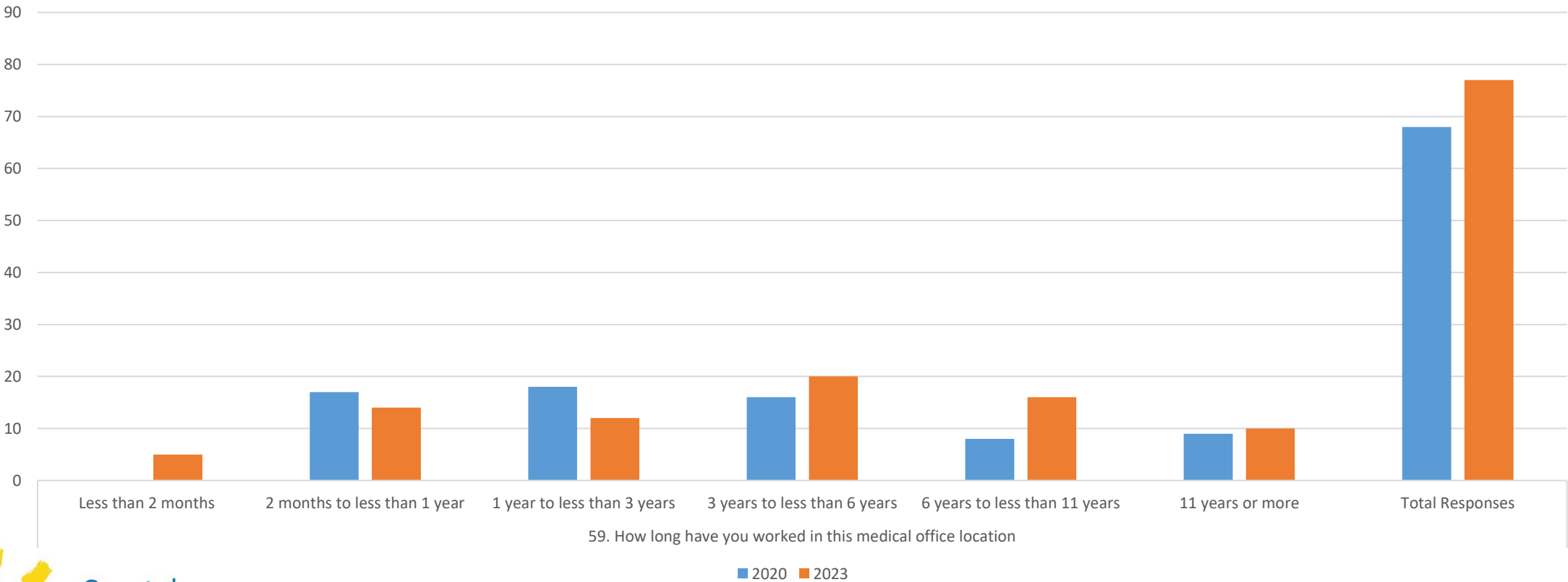
Section G: Overall Ratings



Question 59

How long have you worked in this medical office location

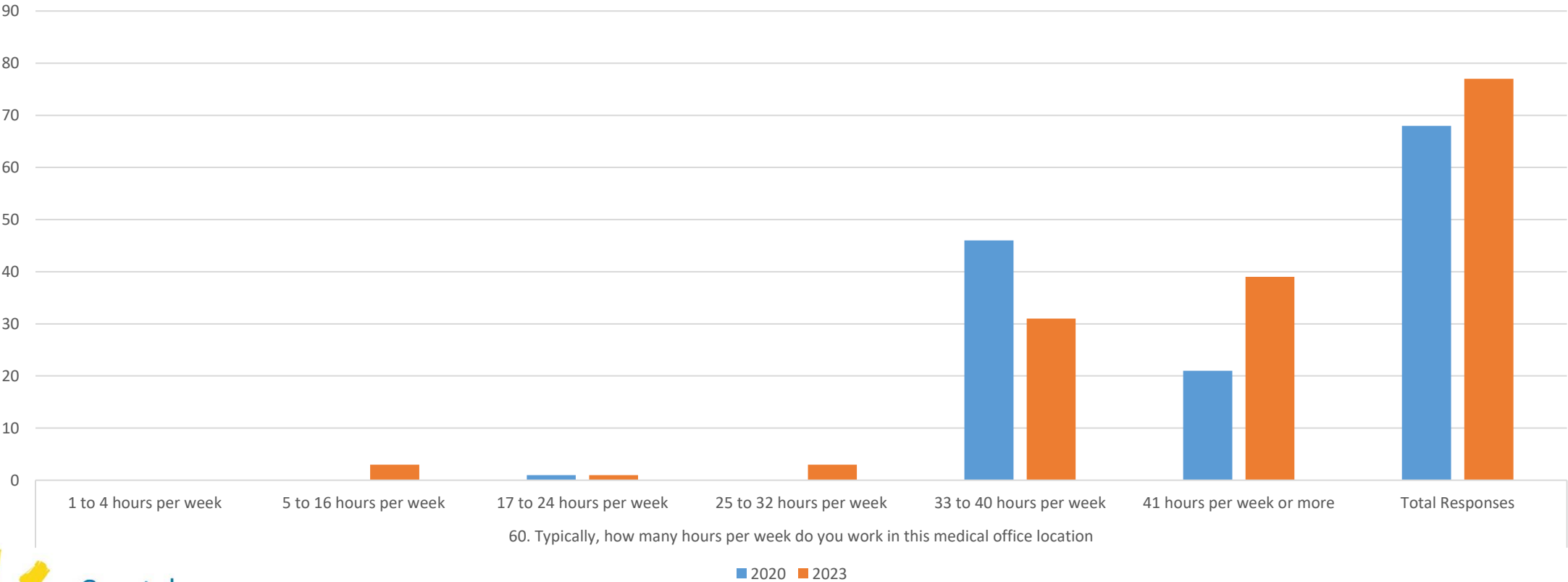
Background Questions



Question 60

Typically, how many hours per week do you work in this medical office location

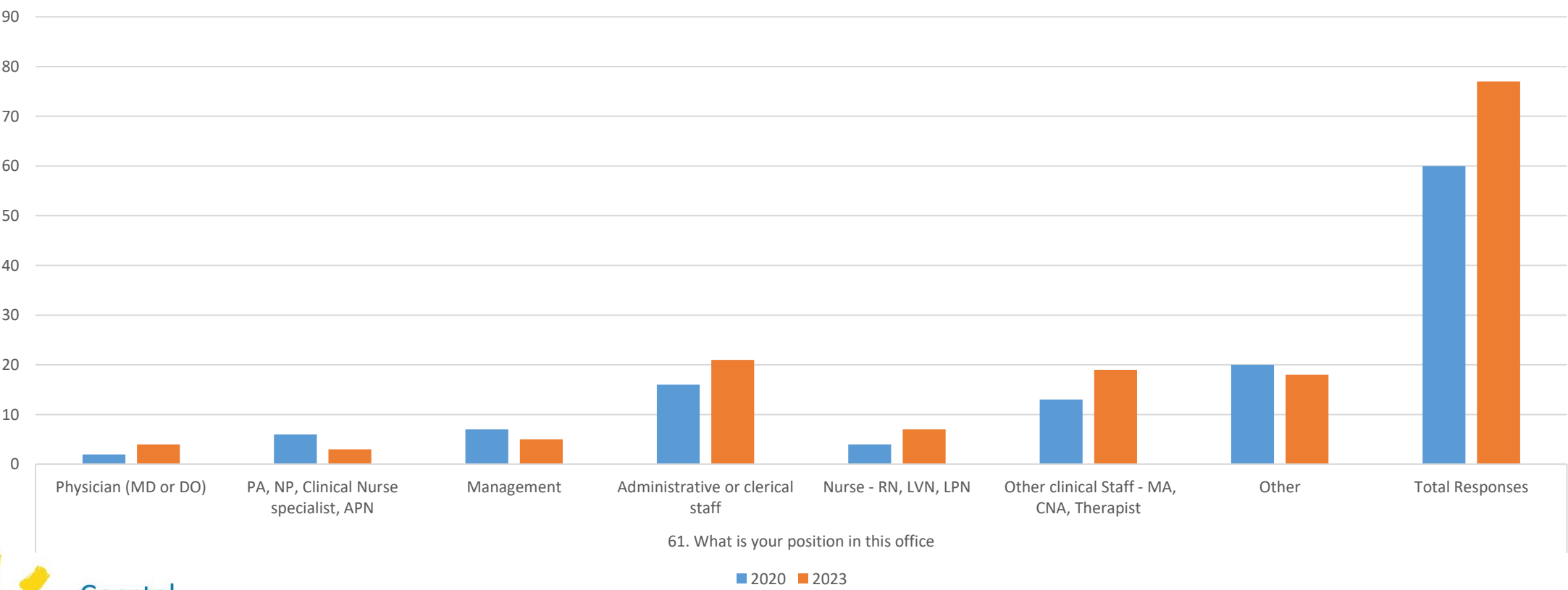
Background Questions



Question 61

What is your position in this office

Background Questions



Top 5 Areas for Improvement

(Developed and planned by all CHW Staff participation)

Question	Improvement Response	Updates
In this office we often feel rushed when taking care of patients.	<ul style="list-style-type: none"> Make sure patient information is correct such as name, date of birth, insurance status, phone number and address. (Help Desk Ticket already been completed - Waiting on Resolution) Find ways to be more efficient in each step of the process through OSIS and Phreesia. Patient must have an active discount and/or CHW is PCP on insurance before appointment will be scheduled (currently doing as of June). Assisting patients to change PCP can take up to 1 hour. Find dental portal for insurance verification (currently calling). 	<ul style="list-style-type: none"> Resolved 10/2023 Continuous work with OSIS Completed 09/2023 Pending
Patient Centered – is responsive to individual patient preferences, needs, and values.	<ul style="list-style-type: none"> Don't ask the patient to call again if they choose the wrong option on the phone tree, transfer (not blindly) but instruct the patient of the proper option. Improve website. 	<ul style="list-style-type: none"> Implemented 08/2023 Pending Communication
Staff in this office are asked to do tasks they haven't been trained to do.	<ul style="list-style-type: none"> Staff feel empowered to ask questions, also supported to express their feelings. Have regular staff trainings and check offs. Perform chart audits to ensure things are being done correctly. 	<ul style="list-style-type: none"> Completed Safet Culture Training 7/2023 Monthly Inservice Each Department Responsibility
Staff are afraid to ask questions when something does not seem right.	<ul style="list-style-type: none"> Anonymous question/comment box, one in each department and one general box. 	<ul style="list-style-type: none"> General comment box placed in big breakroom Completed 08/2023
It is just by chance that we don't make more mistakes	<ul style="list-style-type: none"> Make sure staff are trained and competent to do the job and ask for help if not sure. Encourage staff to not rush through task to ensure all task are done accurately. Slow down, focus on one task, proofread before sending. Use code word to communicate with each other when someone sees something where they might make a mistake. 	<ul style="list-style-type: none"> Department Competencies – department responsibility Remind staff patient safety comes first. Per Department

Federally Qualified Health Center Affiliation Affidavit

Organization: _____

Doing Business As: _____

Federally Qualified Health Center (FQHC) Site / National Provider Identifier (NPI): _____
(where applicable)

Definitions

Affiliation agreement is defined as an agreement that establishes a relationship between an FQHC and a health-care provider under which the affiliate agrees to provide health-care services within the FQHC's scope of services on behalf of the FQHC and to be reimbursed by the FQHC for such services. The term does not include an employment agreement or an agreement formalizing an arrangement in which an individual physician either temporarily substitutes for a member of the FQHC's staff of physicians or temporarily fills a vacancy in the FQHC's staff of physicians.

Health-care provider is defined as a physician, physician assistant, advanced practice registered nurse (except certified registered nurse anesthetist), visiting nurse, a qualified clinical psychologist, clinical social worker, or other health professional for mental health services, dentist, dental hygienist, or an optometrist.

Affiliation

The FQHC has an Affiliation Agreement at the site. Yes___ No___

If Yes, please answer the following:

Does the affiliation governed by the agreement increase access to care? Yes___ No___

Does the affiliation governed by the agreement:

- Add services to the FQHC's scope of services? Yes___ No___
- Enable the FQHC to maintain access to care or the services currently within the FQHC's scope of services?
Yes___ No___

Would a health-care provider employed by the FQHC be less expensive than the affiliation governed by the agreement? Yes___ No___

Name and Type of proposed Affiliate Organization(s) or provider: _____

Affiliate Provider NPI: _____
(where applicable)

Signature of Governing Board Chairperson

Date

PRINT, SIGN, AND MAIL TO:

Texas Medicaid & Healthcare Partnership
ATTN: Provider Enrollment
PO Box 200795
Austin, TX 78720-0795



340B Program Policies and Procedures

Updated June 2023

I. COASTAL HEALTH & WELLNESS MISSION, VISION, & VALUES

Our Mission

Providing high quality healthcare to all

Our Vision

Healthy people in healthy communities

Our Values

I CARE

Integrity- We are honest, trustworthy and transparent in all we do.

Customer Service- We are committed to providing exceptional customer service.

Accountability- We hold ourselves to high standards and take responsibility for our actions.

Respect- We uphold a standard of conduct that recognizes and values the contributions of all.

Equality- We equally value and serve all members of the community.

Coastal Health & Wellness does not discriminate any person based on race, color, national origin, sex, age, religion, or disability in our programs, services, or employment.

CHW 340B Policies and Procedures



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Purpose: This document contains the written policies and procedures that Coastal Health & Wellness (CHW) uses to oversee 340B Program operations, provide oversight of contract pharmacies, and maintain a compliant 340B Program.

Background: [Section 340B of the Public Health Service Act \(1992\)](#) requires drug manufacturers participating in the Medicaid Drug Rebate Program to sign a pharmaceutical pricing agreement (PPA) with the Secretary of Health and Human Services.

- a. This agreement limits the price that manufacturers June charge certain covered entities for covered outpatient drugs.

The 340B Program is administered by the federal Health Resources and Services Administration (HRSA) in the Department of Health and Human Services (DHHS).

Upon registration on 340B OPAIS (Office of Pharmacy Affairs Information System), CHW:

- a. Agrees to abide by specific statutory requirements and prohibitions.
- b. June access 340B drugs.

340B Policy Statements

1. CHW complies with all requirements and restrictions of Section 340B of the Public Health Service Act including, but not limited to, the prohibition against duplicate discounts/rebates under Medicaid, and the prohibition against transferring drugs purchased under 340B to anyone other than a patient of the entity. (REFERENCE: [Public Law 102-585, Section 602, 340B Guidelines, 340B Policy Releases](#)).
2. CHW uses any savings generated from 340B in accordance with 340B Program intent.
3. CHW has systems/mechanisms and internal controls in place to reasonably ensure ongoing compliance with all 340B requirements.
4. CHW maintains auditable records demonstrating compliance with the 340B Program.
 - a. These reports are reviewed by CHW annually as part of its 340B oversight and compliance program.

Definitions: Definitions of terms June be found in (Appendix: [340B Glossary of Terms](#))

References: Each section includes other references to P&Ps, 340B Glossary of Terms, HRSA website, etc.

Policy Review, Updates, and Approval: These written policies and procedures will be updated and approved by CHW staff/committee, and Governing Board whenever there is a clarification or change to the 340B Program requirements. Otherwise, the policy will be reviewed and approved annually.

	Covered Entity Eligibility		
		<i>Revision History</i>	
		<i>Effective Date:</i>	August 2023
Departments Affected:		<i>Original Issue Date:</i>	August 2023
		<i>Last Reviewed:</i>	June 2023
		<i>Last Revision:</i>	June 2023

Policy: CHW must meet the requirements of 42 USC §256b(a)(4)(A) to be eligible for enrollment in, and the purchase of drugs through, the 340B Program.

Purpose: To ensure CHW’s eligibility to participate in the 340B Program.

Definitions: Covered outpatient drug: Defined in Section 1927(k) of the Social Security Act (https://www.ssa.gov/OP_Home/ssact/title19/1927.htm).

Procedure:

1. CHW’s basis for 340B eligibility is determined by meeting the definition of “federally-qualified health center” in [section 1905\(l\)\(2\)\(B\) of the Social Security Act](#).
 - a. The term “Federally-qualified health center” means an entity which—
 - i. Is receiving a grant under section 330 of the Public Health Service Act,
 - ii. Is receiving funding from such a grant under a contract with the recipient of such a grant, and meets the requirements to receive a grant under section 330 of such Act,
 - b. Based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant, including requirements of the Secretary that an entity June not be owned, controlled, or operated by another entity, or
 - c. Was treated by the Secretary, for purposes of part B of title XVIII, as a comprehensive Federally funded health center as of January 1, 1990; and includes an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law 93-638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services. In applying clause (ii), the Secretary June waive any requirement referred to in such clause for up to 2 years for good cause shown.
2. CHW has identified locations where it dispenses or prescribes 340B drugs including:

The main health center site and associated sites included in the scope of grant or FQHC-LA designation. These sites are operational in the HRSA Electronic Handbook (EHB) and registered on 340B OPAIS.

- a. Covered entities should maintain auditable records, policies, and procedures related to the definition of covered outpatient drug that is consistent with the 340B statute and Social Security Act.
- b. Define covered outpatient drugs based on section 1927(k) of the Social Security Act. CHW interprets the definition of covered outpatient drugs to include: An FDA-approved

prescription drug, an over the counter (OTC) drug that is written on a prescription, a biological product that can be dispensed only by a prescription (other than a vaccine), or FDA approved insulin.

3. CHW ensures that 340B OPAIS is complete, accurate, and correct for all 340B eligible locations (main and associated sites, and contract pharmacy(ies)). [Refer to CHW’s Policy and Procedure “340B Program Enrollment, Recertification, and Change Request”]
 - a. All off-site locations that use 340B drugs are registered on CHW’s 340B OPAIS record.
 - b. All main/associated site addresses, billing and shipping addresses, the authorizing official, and the primary contact information are correct and up to date.
 - c. CHW regularly reviews its 340B OPAIS records quarterly.
 - d. CHW informs HRSA immediately of any changes to its Medicaid information by updating the 340B OPAIS Medicaid Exclusion File as soon as the change is identified. The data included in the Medicaid Exclusion File is provided by covered entities for drugs billed under Medicaid fee-for-service and does not apply to Medicaid managed care organizations.

4. CHW annually recertifies CHW’s information on 340B OPAIS. [Refer to CHW’s Policy and Procedure “340B Program Enrollment, Recertification, and Change Request”]

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

	340B Program Enrollment Recertification, and Change Requests		
		<i>Revision History</i>	
		<i>Effective Date:</i>	August 2023
Department s Affected:		<i>Original Issue Date:</i>	August 2023
		<i>Last Reviewed:</i>	June 2023
		<i>Last Revision:</i>	June 2023

Policy: Eligible entities must maintain the accuracy of 340B OPAIS and be actively registered to participate in the 340B Program.

Purpose: To ensure that CHW is registered appropriately on 340B OPAIS and maintains accurate records.

References: 340B Drug Pricing Program: Grantee Registration Instructions
<https://www.hrsa.gov/opa/registration/index.html>

Registration dates:

- January 1–January 15 for an effective start date of April 1
- April 1–April 15 for an effective start date of July 1
- July 1–July 15 for an effective start date of October 1
- October 1–October 15 for an effective start date of January 1

340B Contract Pharmacy Guidelines (<https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>).

Procedures:

Enrollment

1. CHW is eligible to participate in the 340B Program [Refer to CHW’s Policy and Procedure “Covered Entity Eligibility.”]
2. CHW identifies upcoming registration dates and deadlines.
3. CHW identifies CHW’s authorizing official and primary contact.
4. CHW has available the [required documents/contracts](#).
 - a. Include federal grant number (e.g. “H8oCS-----” for CHCs or “LALCS-----” for FQHCLAs)
 - b. Include all Site ID’s (if associated sites are applicable)
5. CHW completes registration on 340B OPAIS (<https://340bopais.hrsa.gov/>).

Recertification Procedure

1. CHW annually recertifies CHW’s information on 340B OPAIS.
 - a. CHW’s Chief Operating Officer or designate completes the annual recertification by following the directions in the recertification email sent from HRSA to CHW’s Chief Operating Officer prior to the stated deadline.
 - i. CHW submits specific recertification questions to 340b.recertification@hrsa.gov.

Enrollment Procedure: New Associated Sites

1. CHW determines that a new service site or facility is eligible to participate in the 340B Program (e.g. due to a change in grant scope).
 - a. The criteria used include that the service site is identified in the scope of grant, has outpatient drug use, and has patients who meet the 340B patient definition (including provision of services consistent with funding and/or designation status).
2. CHW updates the HRSA Electronic Handbook (EHB) to correctly reflect the new service site/facility.
3. Once the site/facility is appropriately listed on the EHB and operational, CHW's authorizing official completes the online registration process in 340B OPAIS during the registration window.

Enrollment Procedure: New Contract Pharmacy(ies)

1. CHW has a signed contract pharmacy services agreement between the entity and contract pharmacy prior to registration on 340B OPAIS.
<https://www.govinfo.gov/content/pkg/FR-2010-03-05/pdf/2010-4755.pdf>
 - a. CHW's legal counsel has reviewed the contract and verified that all federal, state, and local requirements have been met.
2. CHW has contract pharmacy oversight and monitoring policy and procedure developed, approved, and implemented. [Refer to CHW's Policy and Procedure "Contract Pharmacy Oversight Management".]
3. CHW's authorizing official or designee completes the online registration during one of four registration windows.
 - a. Within 15 days from the date of the online registration, the authorizing official certifies online that the contract pharmacy registration request was completed.
4. CHW begins using the contract pharmacy services arrangement only on or after the effective date shown on 340B OPAIS.

Procedure for Changes to CHW's Information in 340B OPAIS

1. CHW notifies HRSA immediately of any changes to CHW's grant status or other such changes within the CHW.
 - a. CHW will stop the purchase of 340B drugs as soon as CHW loses 340B Program eligibility (i.e. through a grant status change)
 - b. CHW's authorizing official will complete the online change request as soon as a change in eligibility is identified.
 - i. CHW will expect changes to be reflected within two weeks of submission of the changes/requests.
2. CHW will notify HRSA immediately of any changes to CHW's information on 340B OPAIS. [Refer to CHW's Policy and Procedure "Covered Entity Eligibility".]
3. CHW's authorizing official will complete the online change request as soon as a change in eligibility is identified.
 - a. CHW will expect changes to be reflected within about 2 weeks of submission of the changes/requests.

Note: 340B OPAIS records should be consistent with EHB records (e.g. site names/addresses). Discrepancies between EHB and OPAIS could result in wholesaler account setup or delivery issues.

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

	Patient Eligibility/Definition		
		Revision History	
		Effective Date:	August 2023
Departments Affected:		Original Issue Date:	August 2023
		Last Reviewed:	June 2023
		Last Revision:	June 2023

Policy: Per the Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 340B drugs are to be provided only to individuals eligible to receive 340B drugs from covered entities.

Purpose: CHW ensures that 340B drugs are dispensed/administered/prescribed only to eligible patients.

Definitions:

Administer: Give a medication to an individual, typically in a clinic, based on a health care provider's order.

Dispense: Provide a medication, typically in clinic, based on a health care provider's order to be administered to a patient.

Prescribe: Provide a prescription for a medication to an individual to be filled at an outpatient pharmacy.

Procedure:

Note: Covered entities need to ensure that the following 340B eligibility determination filters are implemented:

1. CHW validates site/service eligibility.
2. Refer to CHW's Policy and Procedure "Covered Entity Eligibility"
 - a. Patient is outpatient status at the time the medication is dispensed/administered (depending on the outpatient status definition in CHW's policies and procedures.

3. CHW maintains records of individual's health care.
4. CHW determines provider eligibility.
 - a. Provider is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity.
5. The covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care.
6. The individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with the covered entity; and
7. The individual receives a health care service or range of services from the covered entity that is consistent with the service or range of services for which grant funding or federally qualified health center lookalike status has been provided to the entity.
8. A patient is considered active so long as they have had one provider encounter within three calendar years.

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

Departments Affected:	Prevention of Duplicate Discounts		
		Revision History	
		Effective Date:	August 2023
		Original Issue Date:	August 2023
		Last Reviewed:	June 2023
		Last Revision:	June 2023

Policy: 42 USC §256b(a)(5)(A)(i) prohibits duplicate discounts; that is, manufacturers are not required to provide a discounted 340B price and a Medicaid drug rebate for the same drug. Covered entities must have mechanisms in place to prevent duplicate discounts.

Purpose: To ensure that CHW is preventing duplicate discounts.

References:

Procedure: CHW has elected to purchase drugs for its Medicaid patients through other mechanisms (carve out).

Medicaid Carve-Out (FFS)

1. CHW does not dispense or administer 340B purchased drugs to Medicaid patients AND CHW provides non-340B drugs instead and subsequently bills Medicaid for those non-340B drugs (carve out).
 - a. CHW has answered “no” to the question, “Will the covered entity dispense 340B purchased drugs to Medicaid patients AND subsequently bill Medicaid for those dispensed 340B drugs?” on 340B OPAIS.

Medicaid Managed Care (MCO)

Covered entities are required to ensure that drugs purchased under the 340B Program are not subject to a rebate claim by the state Medicaid agency. Covered entities are encouraged to work closely with their State to prevent duplicate discounts for Medicaid Managed Care claims.

Contract Pharmacies

1. CHW’s understands the HRSA guidance and elects to Carve-out Medicaid Fee for Service claims from the 340B program.
2. To ensure compliance with this requirement CHW has requested 340B Administrators block the capture of 340B claims for all Medicaid Fee for Service BIN/PCN in the 340B Administrator’s system.
3. CHW has verified that 340B Administrators have appropriately blocked from 340B capture and validates during the self-audit process.
4. CHW will review and notify 340B Administrators of any changes to Medicaid.
5. CHW does not participate in billing out-of-state Medicaid.

Clinic Administered Drugs

1. CHW’s will not use 340B drugs for any Medicaid Fee for Service for clinic administered drugs.

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

	340B Program Roles and Responsibilities		
		<i>Revision History</i>	
		<i>Effective Date:</i>	August 2023
Department s Affected:		<i>Original Issue Date:</i>	August 2023
		<i>Last Reviewed:</i>	June 2023
		<i>Last Revision:</i>	June 2023

Policy: Covered entities participating in the 340B Program must ensure program integrity and compliance with 340B Program requirements.

Purpose: To identify CHW’s key stakeholders and determine their roles and responsibilities in maintaining 340B Program integrity and compliance.

Procedure:

1. CHW’s key stakeholders involved with CHW’s 340B Program are.
 - a. Executive Director
 - b. Chief Operating Officer (or designee)
 - c. Medical Director (or designee)
 - d. Nursing Director (or designee)
 - e. Director of Quality (or designee)
2. CHW has established a 340B Oversight Committee that is responsible for the oversight of the 340B Program, or other similar oversight process.
3. CHW’s 340B Oversight Committee:
 - a. Meets on a regular basis annually.
 - b. Reviews 340B rules/regulations/guidelines to ensure consistent policies/procedures/oversight throughout the entity.
 - c. Identifies activities necessary to conduct comprehensive reviews of 340B compliance.
 - i. Ensure that the organization meets compliance requirements of program eligibility, patient definition, 340B drug diversion, and duplicate discounts via ongoing multidisciplinary teamwork.
 - ii. Integrate departments such as information technology, legal, pharmacy, compliance, and patient financial services to develop standard processes for contract/data review to ensure program compliance.
 - d. Oversees the review process of compliance activities, as well as taking corrective actions based on findings.
 - i. 340B Oversight Committee assesses if the results are indicative of a material breach (Refer to CHW’s Policy and Procedure “340B Non-Compliance/Material Breach”.
 - e. Reviews and approves work group recommendations (process changes, self-monitoring outcomes and resolutions).

The following CHW staff are potential key players in the 340B Program, including governance and compliance, and should be standing members of the 340B Oversight Committee. CHW will identify who serves as the entity's authorizing official and primary contact for the 340B Program. These individuals should be the sponsors of the 340B Oversight Committee.

Note: The following roles and responsibilities are not specific for all entities and are not all-inclusive.

1. Executive Director
 - Responsible as the OPAIS Authorizing Official charged with oversight and administration of the program; and
 - Responsible for attesting to the compliance of the program in the form of recertification.
2. Chief Operating Officer (COO)(or designee)
 - Responsible for the above in case the Executive Director cannot perform oversight duties;
 - Oversees the CHW Controller or Designee ensure his/her 340B functions are being appropriately carried out; Accounts for savings and use of funds to provide care for the indigent.
3. CHW Controller (or designee)
 - Accountable agent for oversight of 340B related financial affairs.
 - i. For clinic administered drugs:
 1. Ensures compliance with 340B program requirements of qualified patients, drugs, providers, vendors, payers, and locations; and
 2. Monitors and reviews pricing and modifies fees accordingly.
 - ii. Communicates with Contract Pharmacies
 1. Coordinates with representatives for Contract Pharmacies and third-part administrators to ensure responsibilities as outlined in agreement are being followed including, but not limited to:
 - a. Routine maintenance and testing of tracking and auditing software;
 - b. Continuous monitoring of product minimum/maximum levels to effectively balance product availability and cost-effective inventory control;
 - c. Reviewing 340B orders, reconciliations and financial statements;
 - d. Reviewing, refining and providing 340B cost savings reports detailing purchasing and replacement practices as well as dispensing patterns;
 - e. Maintaining system databases to reflect changes in the drug formulary or product specifications; and
 - f. Reconciles monthly pharmacy contractor dispense reports with the amount billed by supplier, and notifying contractors of any discovered discrepancies.
4. 340B Program Coordinator (or designee)
 - Designs and maintains an internal audit plan of compliance with the 340B program'
 - Ensures audit plan is being adhered to;
 - Designs the annual plan to cover all changes in the program from the prior year;
 - Serves as the entity's OPAIS 340B Primary Contact; and
 - Tracks and implements updated 340B laws and regulations.
5. Medical Director (or designee)
 - Remains aware of products covered by 340B and Prime Vendor Program pricing; and
 - Works with the medical staff to provide medications that optimize savings with good clinical outcomes.

6. Nursing Director (or designee)
 - For clinical administered 340B drugs (not requiring prescriptive authority);
 - i. Works with Procurement Officer and Medical Director to ensure sufficient volume and types of 340B administered drugs are ordered and stocked;
 - ii. Responsible for organizing first-in first-out (“FIFO”) and look-alike sound-alike processes for clinic administered 340B medications; and
 - iii. Manually audits logging procedures for ten internally administered 340B medications each quarter.
7. **Procurement Manager** (or designee)
 - Responsible for ordering non-pharmaceutical drugs retained and distributed directly by the Coast Health & Wellness clinic and charging said drugs to the proper distribution accounts;
 - Managing purchasing, receiving, and inventorying control processes;
 - Responsible for receiving medications to be administered at Coastal Health & Wellness, as well as entering purchasing requisitions for monthly invoice for medications purchased by Contracted Pharmacies affiliated with the Coastal Health & Wellness 340B agreement; and
 - Monitoring ordering processes and integrating most current pricing from wholesalers.

***Indicates personnel required to complete Apexus 340B University modules*

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

	340B Program Education and Competency		
		Revision History	
		Effective Date:	August 2023
	Departments Affected:	Original Issue Date:	August 2023
		Last Reviewed:	June 2023
		Last Revision:	June 2023

Policy: Program integrity and compliance are the responsibility of all 340B key stakeholders. Ongoing education and training are needed to ensure that these 340B key stakeholders have the knowledge to guarantee compliant 340B operations.

Purpose: To establish 340B education and competency requirements for CHW’s 340B key stakeholders based on their roles and responsibilities in the 340B Program.

Procedure:

1. CHW determines the knowledge and educational requirements for each 340B Program role (Refer to CHW's Policy and Procedure "340B Program Roles and Responsibilities")
2. 340B key stakeholders complete initial basic training upon hire.
 - a. Watch '[Introduction to the 340B Drug Pricing Program](#)'
 - b. Complete OnDemand modules on the PVP website
 - c. Attend 340B University.
3. 340B key stakeholders complete additional training as identified in #1 above.
4. CHW provides educational updates and training, as needed [Insert entity-specific examples here (e.g. 340B policy changes, updates in HRSA guidance)].
5. CHW conducts annual verification of 340B Program competency through Apexus 340B University.
6. Training and education records are maintained per organizational policy and available for review.

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

	Contract Pharmacy Operations and Inventory Management		
		Revision History	
		Effective Date:	August 2023
Departments Affected:		Original Issue Date:	August 2023
		Last Reviewed:	June 2023
		Last Revision:	June 2023

Policy: Covered entity remains responsible for ensuring that its contract pharmacy operations comply with all 340B Program requirements, such that the covered entity remains responsible for the 340B drugs it purchases and dispenses through a contract pharmacy.

Purpose: To ensure that CHW remains responsible for all 340B drugs used by its contract pharmacy(s).

Reference:

Federal Register / Vol. 61, No. 165 / Friday, August 23, 1996 / Notices
<https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

Background:

340B inventory is procured and managed in the following settings:

- Clinic site administration
- Contract pharmacy

Inventory methods for each of the above areas within the entity shall be described within the inventory management policy and procedure.

CHW uses one of the following inventory methods:

- a. Hybrid (physical and virtual) approach, stocking physically identifiable 340B inventory for clinic administered drugs and maintaining a virtual replenishment system for contract pharmacy(s).

Pharmacists, technicians, and clinicians dispense 340B drugs only to patients meeting all the criteria in [Refer to CHW's Policy and Procedure "Patient Eligibility/Definition"].

Procedure:

1. Physical inventory (both 340B and non-340B drugs) is maintained at clinic administered sites and contract pharmacy(s).
 - a. CHW identifies all 340B and non-340B accounts used for purchasing drugs in each practice setting.
 - b. CHW separates 340B inventory from non-340B inventory.
 - c. CHW performs inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels to determine daily purchase order.
 - d. CHW places 340B and non-340B drug orders.
 - e. CHW receives shipment.
 - f. CHW verifies quantity received with quantity ordered.
 - i. Identifies any inaccuracies.
 - ii. Resolves inaccuracies.
 - iii. Documents resolution of inaccuracies.
 - g. CHW maintains records of 340B-related transactions for 7 years in a readily retrievable and auditable format located [insert entity specifics here].
 - i. These reports are reviewed by CHW as part of its 340B oversight and compliance program.
2. Physical inventory (340B-only) is maintained at clinic administered drugs sites and contract pharmacy(s).
 - a. CHW identifies all accounts used for purchasing drugs in each practice setting.
 - b. CHW maintains inventory.
 - c. CHW performs inventory reviews and shelf inspections of periodic automatic replenishment (PAR) levels to determine daily purchase order.
 - d. CHW places 340B drug orders.
 - e. CHW receives shipment.
 - f. CHW verifies quantity received with quantity ordered.
 - i. Identifies inaccuracies.
 - ii. Resolves inaccuracies.
 - iii. Documents resolution of inaccuracies.
 - g. CHW maintains records of 340B related transactions for a period of 7 years in a readily retrievable and auditable format located. [Insert entity specifics here].

- i. These reports are reviewed by CHW as part of its 340B oversight and compliance program.

Wasted 340B medication

1. CHW pharmacy/clinician staff documents destroyed or wasted drug not administered to the patient.
2. CHW pharmacy/clinician staff communicates wastage to the 340B coordinator.
3. CHW pharmacy staff adjusts 340B accumulator and documents adjustment with reason (if applicable).
4. CHW replaces medication through appropriate purchasing account.

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

Departments Affected:	340B Noncompliance/ Material Breach		
		Revision History	
		Effective Date:	August 2023
		Original Issue Date:	August 2023
		Last Reviewed:	June 2023
		Last Revision:	June 2023

Policy: Covered entities are responsible for contacting HRSA as soon as reasonably possible if there is any material breach by the covered entity or any instance of noncompliance with any of the 340B Program requirements.

Purpose: To define CHW's material breach of 340B compliance and self-disclosure process.

Definitions:

Materiality: A convention within auditing/accounting pertaining to the importance/significance of an amount, transaction, and/or discrepancy.

Threshold: The point that must be exceeded, as defined by the covered entity, resulting in a material breach. Examples of thresholds include:

- a. 5% of total pharmacy spend in a fiscal year.

Reference:

340B PVP Education Tool: [Establishing Material Breach Threshold](#)

340B PVP Education Tool: [Self-Disclosure to HRSA and Manufacturer Template](#)

Procedure:

1. CHW's established threshold of what constitutes a material breach of 340B Program compliance is a discrepancy that results in a negative impact of more than 5% of the total pharmacy spend in a fiscal year and does not self-correct within 6 months].
 - a. If a violation above 5% is noted on an internal or contract pharmacy audit, the auditor will pull another full random sample of claims and re-audit. If after the second sample is analyzed and the total pharmacy spend is above 5%, a material breach will be noted. If after the second sample is analyzed and the total percentage of non-compliance does not exceed the 5%, the auditor will attempt to determine and correct the root cause of the non-compliance.
 - b. If a material breach is identified in an audit, there will be an immediate attempt to retroactively correct the breach and reassess. Upon reassessment, if the material breach falls below the threshold, CHW will attempt to identify the cause and work to correct the non-compliance and will create an internal corrective action plan.
2. A non-correctable violation exceeding the threshold requires self-disclosure. Violations identified through internal self-audits or independent external audits, that meet or exceed the threshold will be immediately reported to HRSA.
 - a. CHW will email HRSA at 340Bselfdisclosure@hrsa.gov and will report to applicable manufacturers using the following self-disclosure template:
https://docs.340bpvp.com/documents/public/resourcecenter/ALL_Entities_Self_Reporting_340B_Non_Compliance.docx
 - b. CHW acknowledges it June be held liable by the manufacturer and June be subject to repayment to the manufacturer.
3. Any corrective action plan or self-disclosure will be reviewed and approved by the 340B Committee.
 - a. Maintain records of material breach violations, including manufacturer resolution correspondence, as determined by organization policy.

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

	340B Program Compliance Monitoring/Reporting		
		<i>Revision History</i>	
		<i>Effective Date:</i>	August 2023
Department s Affected:		<i>Original Issue Date:</i>	August 2023
		<i>Last Reviewed:</i>	June 2023
		<i>Last Revision:</i>	June 2023

Policy: Covered entities are required to maintain auditable records demonstrating compliance with the 340B Program requirements.

Purpose: To provide an internal monitoring program to ensure comprehensive compliance with the 340B Program.

Procedure:

1. CHW develops an annual internal audit plan approved by the internal compliance officer or as determined by organizational policy.
2. CHW reviews 340B OPAIS to ensure the accuracy of the information for all site locations and contract pharmacies (if applicable).
3. CHW reviews the Medicaid Exclusion File (MEF) to ensure the accuracy of the information for the site locations and contract pharmacies (if applicable).
4. CHW reconciles purchasing records and dispensing records to ensure that covered outpatient drugs purchased through the 340B Program are dispensed or administered only to patients eligible to receive 340B drugs and that any variances are not the result of diversion.
5. CHW reconciles dispensing records to patients' health care records to ensure that all medications dispensed were provided to patients eligible to receive 340B drugs. CHW will select 45 records from a drug utilization file and perform the audit monthly.
6. CHW reconciles dispensing records and Medicaid billing practices to demonstrate that CHW's practice is following the Medicaid billing question on 340B OPAIS.
7. CHW's 340B Oversight Committee reviews the internal audit results.
 - a. Assess whether audit results are indicative of a material breach [Refer to CHW's Policy and Procedure "340B Non-Compliance/Material Breach".
8. CHW maintains records of 340B-related transactions for a period of 7 years in a readily retrievable and auditable format located [reference].

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

Departments Affected:	Contract Pharmacy Oversight and Monitoring		
		Revision History	
		Effective Date:	August 2023
		Original Issue Date:	August 2023
		Last Reviewed:	June 2023
		Last Revision:	June 2023

Policy: Covered entities are required to provide oversight of their contract pharmacy arrangements to ensure ongoing compliance. The covered entity has full accountability for compliance with all requirements to ensure eligibility and to prevent diversion and duplicate discounts. Auditable records must be maintained to demonstrate compliance with those requirements.

Purpose: To ensure that CHW maintains 340B Program integrity and compliance at its contract pharmacy(s).

Reference:

Federal Register / Vol. 75, No. 43 / Friday, March 5, 2010 / Notices
<https://www.gpo.gov/fdsys/pkg/FR-2010-03-05/pdf/2010-4755.pdf>

Procedure:

1. CHW conducts internal reviews monthly of each registered contract pharmacy for compliance with 340B Program requirements. The following elements will be included when conducting self-audits of contract pharmacies to ensure program compliance:
 - a. Prescription is written from a 340B eligible site of care that provides healthcare services.
 - b. Patient eligibility: The episode of care that resulted in the 340B prescription is supported in the patient's medical record and the service provided is consistent with the grant funding scope of services provided to the entity.
 - c. Provider eligibility: The prescribing provider is employed, contracted, or under another arrangement with the entity at the time of writing the prescription so that the entity maintains responsibility for the care.
 - d. The 11-digit NDC level is documented for accumulation and/or replenishment of a 340B dispensation or administration (if a virtual inventory is used).

- e. CHW can document that no prescriptions were billed to Medicaid unless the contract pharmacy is listed as a carve-in contract pharmacy on 340B OPAIS.
2. CHW conducts independent audits every 2 years of each registered contract pharmacy for compliance with the 340B Program requirements.
 - a. Independent audits will include reviews of:
 - i. 340B eligibility.
 - ii. 340B registration.
 - iii. Documented policies and procedures.
 - iv. Inventory, ordering, and record keeping practices for all 340B accounts.
 - v. Review of the listing in the Medicaid Exclusion File and its reflection in actual practices.
 - vi. Testing of claims sample to determine any instance of diversion or duplicate discounts over a set period of time.
3. CHW has mechanisms in place to demonstrate compliance with all state Medicaid billing requirements to prevent duplicate discounts at all sites, including off-site outpatient facilities.
4. CHW's 340B Oversight Committee reviews audit results.
 - a. Assess if audit results are indicative of a material breach [Refer to CHW's Policy and Procedure "340B Noncompliance/Material Breach".
5. CHW maintains records of 340B-related transactions for a period of 7 years in a readily retrievable and auditable format located.

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

Departments Affected:	Prime Vendor Program (PVP) Enrollment and Updates		
		<i>Revision History</i>	
		<i>Effective Date:</i>	August 2023
		<i>Original Issue Date:</i>	August 2023
		<i>Last Reviewed:</i>	June 2023
		<i>Last Revision:</i>	June 2023

Policy: The purpose of the Prime Vendor Program (PVP) is to improve access to affordable medications for covered entities and their patients.

Purpose: Support CHW's participation in the PVP to receive the best 340B product pricing, information, and value-added products.

Procedure:

Enrollment in PVP:

1. CHW completes online 340B Program registration with HRSA.
2. CHW completes online PVP registration (<https://www.340bpvp.com/register/apply-to-participate-for-340b/>).
3. PVP staff validates information and sends confirmation email to CHW.
4. CHW logs in to www.340bpvp.com, selects user name/password.

Update PVP Profile:

1. CHW accesses www.340bpvp.com.
2. CHW clicks Login in the upper right corner.
3. CHW inputs PVP log-in credentials.
 - a. In the upper right corner:
 - i. Click “My Profile” to access page.
<https://members.340bpvp.com/webMemberProfileInstructions.aspx>.
4. CHW clicks “Continue to My Profile” to access page
<https://members.340bpvp.com/webMemberProfile.aspx>.
 - a. Find a list of your facilities.
 - i. Click on the 340B ID number hyperlink to view or change profile information for that facility.
 - b. Update HRSA Information:
 - i. Complete the 340B Change Form as detailed above.
 - a) After 340B OPAIS has been updated, the PVP database will be updated during the nightly synchronization.
5. CHW updates the 340B Prime Vendor Program (PVP) Participation Information:
 - a. Edit CHW’s DEA number, distributor and/or contacts.
 - b. Click submit.

Approvals (per organizational policy):

Executive /Authorizing Official Approval:		Date:	
Governing Board Approval:		Date:	
Compliance/Risk Management Approval:		Date:	
Health Information Management Approval:		Date:	
Pharmacy/Primary Contact Approval:		Date:	

Suggested Appendices

340B Operational SOP

PROCEDURE:

Annually:

- Recertify clinic with the HRSA website.
- Verification of approved sites with 340Basics, Walgreens and Apexus
- Review state and federal requirements of the 340b program to confirm the entity is continually meeting all applicable regulations.
- Review McKesson and Cardinal accounts for all 340b contracted pharmacies.
- Review Policy and Procedure for 340b program
- Re-evaluate workflow for 340b program.
- Review list of carved-in payers from 340Basics and Walgreens

Quarterly:

- Review of quarterly contract price load.
- Verify that an updated patient list is sent to 340Basics.
- Review all information is correct and up to date on HRSA/OPAIS website.
- Review of Medicaid Exclusion File
- Verify prices on Prime Vendor with Wholesaler invoices.

Monthly:

- Ensure Prescriber Information is up to date.
- Review prescriptions from non-CHW providers to determine if eligible for 340b discount.
- Audit and Financial reporting to 340b Committee
- Verify that an updated patient list is sent to 340Basics.
- Audit a sample of approved prescriptions from TPA and contract pharmacy to verify the prescription meets the following criteria.
 - Patient seen in last 36 months.
 - Rx written by eligible provider.
 - Rx written at eligible location.

- Claim has appropriate modifier to prevent duplicate discount.
- Payer is carved-in to 340b program.
- Audit a sample of replenishment inventory orders from TPA to ensure drugs were used for legitimate 340b claims.

SOP for 340B Program

Internal Auditing Procedure

1. Download claims details from the TPA.
2. Fill in the columns on the Internal Auditing template:
 - a. Patient First, Last Name
 - b. DOB
 - c. RX Number
 - d. Drug Name
 - e. NDC
 - f. Date Written
 - g. Date Filled
 - h. Name and Store # of contract pharmacy
 - i. Provider First and Last name
 - j. Insurance information
3. Look up patient in EMR.
4. Find the corresponding encounter that goes with the medication and verify it qualifies.
 - a. Check to make sure the medication is mentioned.
 - b. Make sure the Assessments falls within scope.
 - c. Verify the location patient is seen at is 340B eligible (fill in 340B ID on the audit template)
5. Locate prescription.
 - a. Verify written date matches claim.
 - b. Verify prescriber matches claim/confirm eligible provider.
 - c. Fill in Provider NPI
6. In Comments if everything checks off fill in with “Pass” if any section doesn’t qualify Put in “Fail” and then the reason why.

This tool is written to align with Health Resources and Services Administration (HRSA) policy and is provided only as an example for the purpose of encouraging 340B Program integrity. This information has not been endorsed by HRSA and is not dispositive in determining compliance with or participatory status in the 340B Drug Pricing Program. 340B stakeholders are ultimately responsible for 340B Program compliance and compliance with all other applicable laws and regulations. Apexus encourages each stakeholder to include legal counsel as part of its program integrity efforts.

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	Referral Policy & Procedure		
		Revision History	
		Effective Date:	XX-XX-XX
		Original Issue Date:	XX-XX-XX
Departments Affected:		Last Reviewed:	XX-XX-XX
		Last Revision:	XX-XX-XX

Policy: Coastal Health & Wellness will remain compliant with meeting 340B eligibility requirements related to 340B Referral Prescriptions.

Definition

Eligible Patient

- The patient has an established relationship with CHW, such that the organization maintains records of the individual's healthcare and the patient has been seen by a CHW provider in the last 36 months.
- The individual receives healthcare services from a health care professional who is either employed by CHW or provides healthcare under contractual or other arrangements (e.g. referral for consultation) such that responsibility for the care provided remains with CHW.

Procedure:

1. Referrals are considered a part of CHW's 340B Contract Pharmacy Program.
2. CHW and/or authorized Third-party will verify the eligibility of a prescription to be filled using 340B drugs. This determination will be made through the use of the CHW's electronic health record system.
3. A prescription is deemed eligible if an Outbound Referral **OR** a Consult Note is located in the EMR. If there is *not* a Consult Note in the patient's chart, the internal auditor or designated CHW and/or Third-party will try to locate the Consult note by contacting the referral specialist.
4. A documented outbound referral **OR** a Consult note is required in CHW's electronic health record, for the resulting referral prescription to be deemed eligible for 340B.
5. If there is *not* a Consult note in the patient's chart, the internal auditor or designated CHW and/or authorized Third-party will consult the referral specialist to try and obtain the consult note/clinical summary. The attempt to obtain the note/summary will be documented in the patient's chart with specific date(s) and the number of attempts made. If a note/summary is obtained, it will be scanned into a patient's chart.
6. The presence of a documented referral (either outbound referral or consult note), and an active patient status are the required elements to demonstrate responsibility of care as defined by CHW.

7. The documented “Referral” given to the patient is valid indefinitely and does not require a renewal by CHW.

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Governing Board 2024 Meeting Dates

January 25, 2024

February 22, 2024

March 28, 2024

April 25, 2024

May 23, 2024

June 27, 2024

July 25, 2024

August 22, 2024

September 26, 2024

October 24, 2024

November 7, 2024

December 5, 2024

[**Back to Agenda**](#)

Governing Board

December 2023

Item#8

**Informational Report: Credentialing & Privileging Committee
Reviewed and Approved the Following Providers Privileging Rights**

- a) Shady Bishai, DDS
- b) John Walsh, NP
- c) Laura Porterfield, MD

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COASTAL HEALTH & WELLNESS

Governing Board



FINANCIAL SUMMARY

For the Period Ending

October 31, 2023

GCHD Board Room | 9850-A Emmett F. Lowry Expy. | Texas City, TX 77591

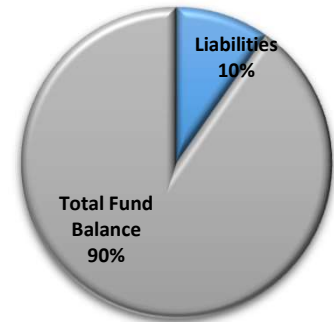
December 7, 2023

CHW - BALANCE SHEET

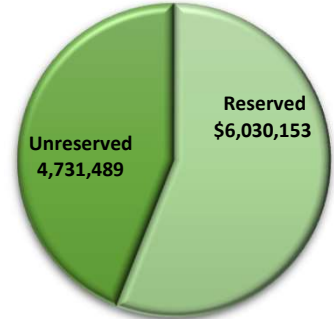
as of October 31, 2023

	Current Month Oct-23	Prior Month Sep-23	Increase (Decrease)
ASSETS			
Cash & Cash Equivalents	\$5,858,751	\$5,548,111	\$310,640
Accounts Receivable	6,868,260	6,337,092	531,168
Allowance For Bad Debt	(933,397)	(889,988)	(43,409)
Pre-Paid Expenses	(13,037)	69,728	(82,765)
Due To / From	141,452	10,318	131,133
Total Assets	\$11,922,028	\$11,075,262	\$846,767
LIABILITIES			
Accounts Payable	\$294,629	\$226,739	\$67,889
Accrued Expenses	352,005	465,589	(113,584)
Deferred Revenues	513,753	24,642	489,111
Total Liabilities	\$1,160,386	716,970	\$443,416
FUND BALANCE			
Fund Balance	\$9,562,869	\$9,562,869	\$0
Current Change	1,198,772	795,422	403,351
Total Fund Balance	\$10,761,642	\$10,358,291	\$403,351
TOTAL LIABILITIES & FUND BALANCE	\$11,922,028	\$11,075,262	\$846,767

Current Period Assets



Total Fund Balance

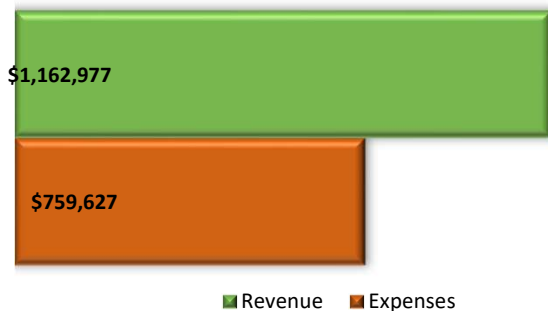


CHW - REVENUE & EXPENSES

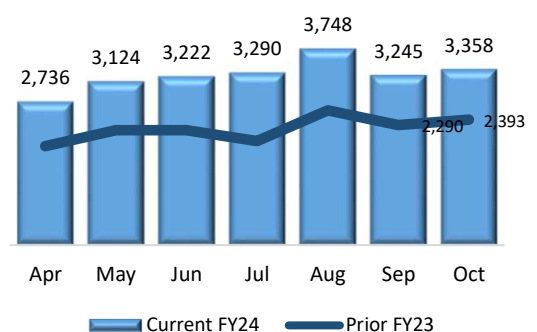
as of October 31, 2023

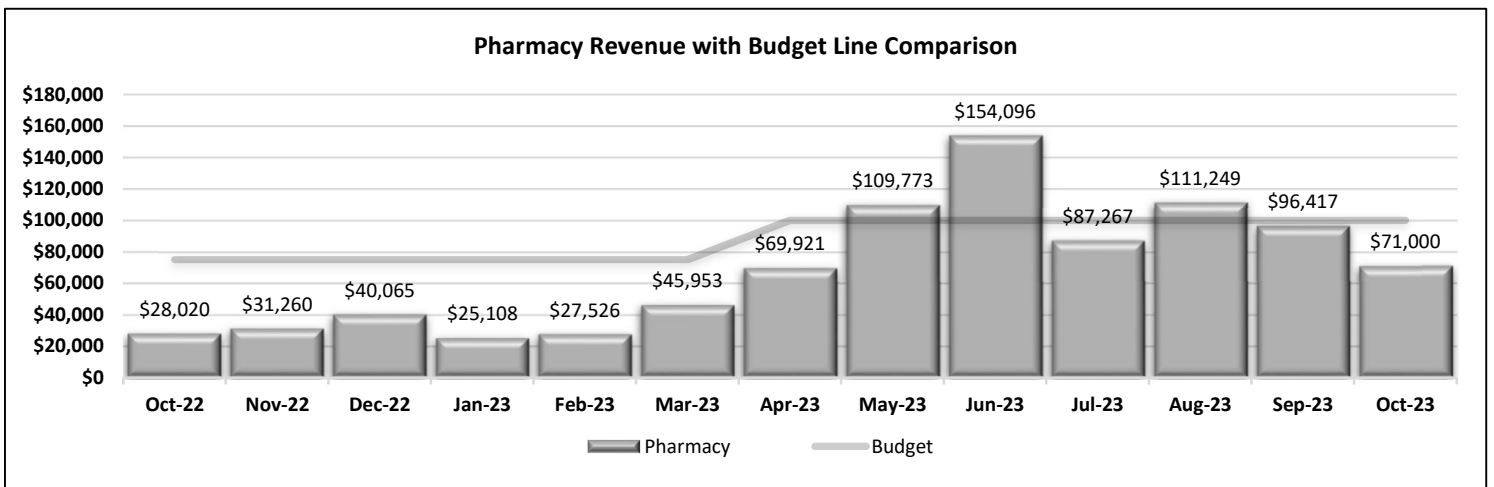
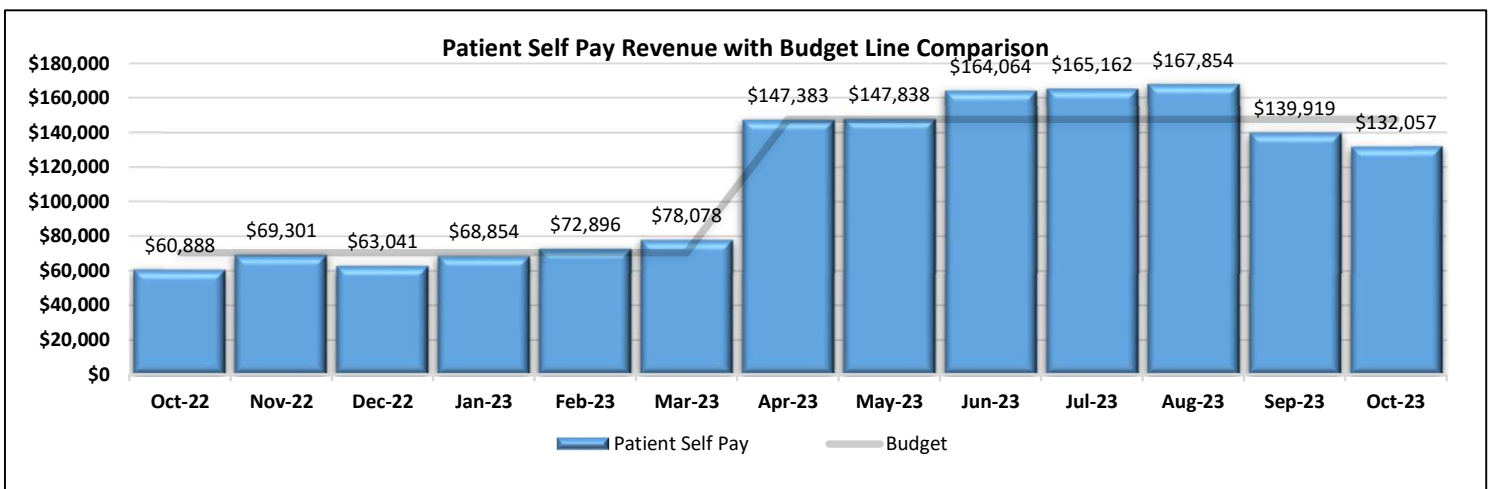
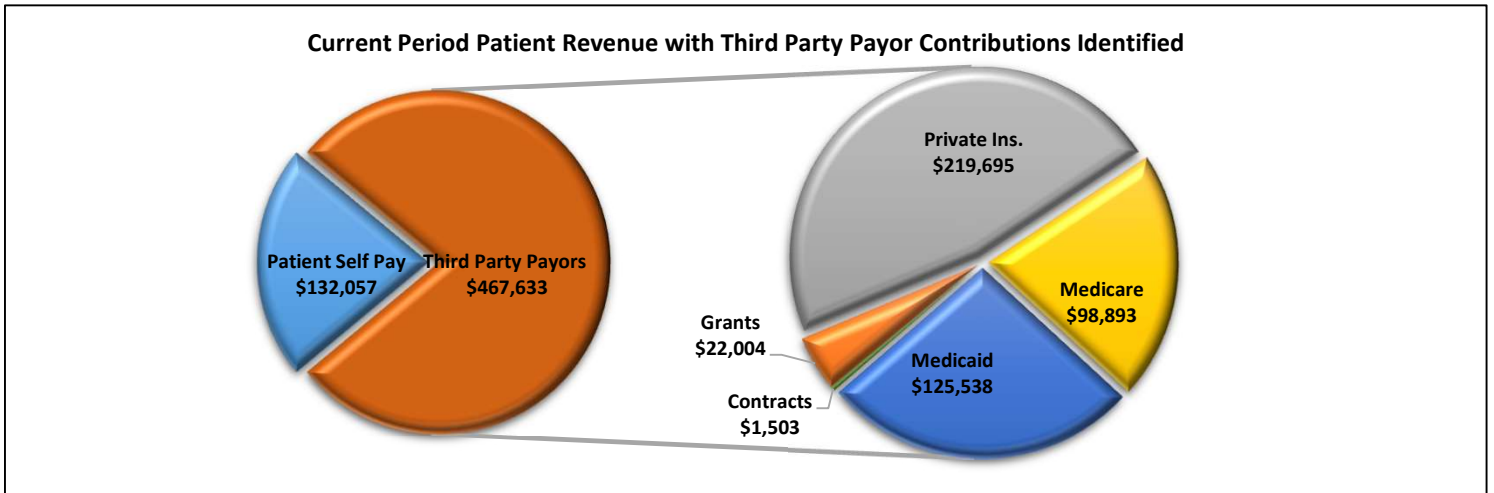
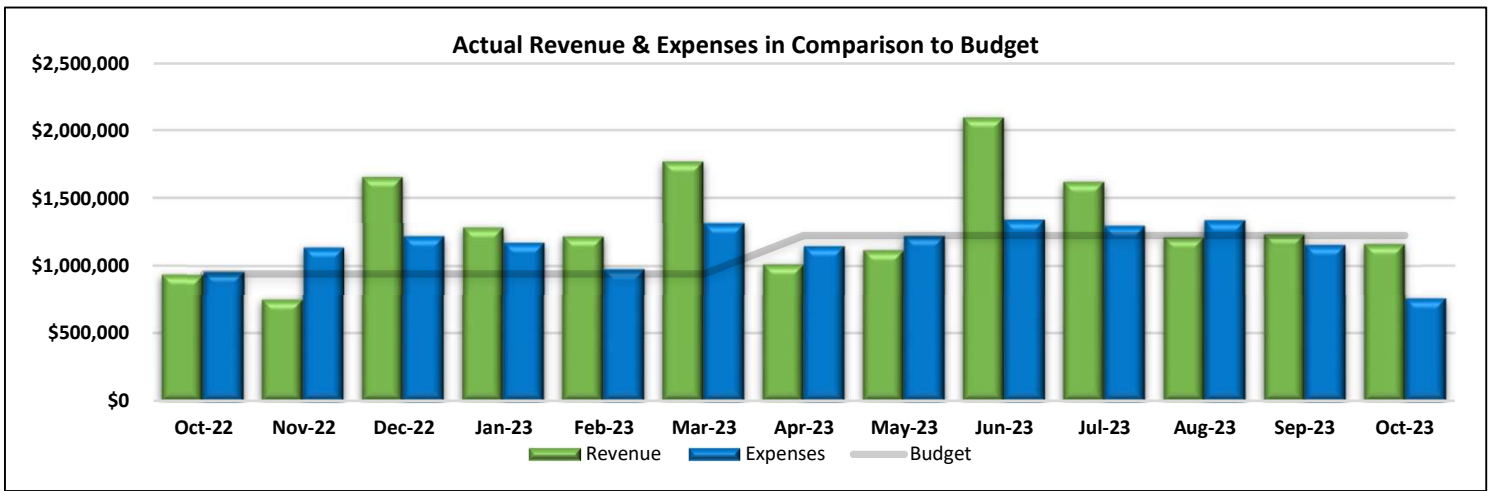
	MTD Actual Oct-23	MTD Budget Oct-23	MTD Budget Variance	YTD Actual thru Oct-23	YTD Budget thru Oct-23	YTD Budget Variance
REVENUE						
County Revenue	\$244,556	\$261,222	(\$16,667)	\$1,911,889	\$1,828,556	\$83,333
HHS Grant Revenue	227,591	358,564	(130,973)	2,857,968	2,509,946	348,023
Patient Revenue	670,689	592,843	77,846	4,554,695	4,149,903	404,791
Other Revenue	20,142	12,833	7,309	137,598	89,833	47,765
Total Revenue	\$1,162,977	\$1,225,463	(\$62,485)	\$9,462,151	\$8,578,238	\$883,913
EXPENSES						
Personnel	\$365,622	\$952,944	\$587,321	\$5,198,812	\$6,670,606	\$1,471,794
Contractual	130,314	114,626	(15,688)	873,477	802,381	(71,095)
Supplies	102,918	117,985	15,068	964,237	825,898	(138,339)
Travel	6,389	1,433	(4,955)	28,495	10,033	(18,462)
Bad Debt Expense	43,409	38,318	(5,091)	329,829	268,226	(61,603)
Other	105,857	136,959	31,102	868,529	958,711	90,182
Total Expenses	\$759,627	\$1,362,265	\$602,638	\$8,263,378	\$9,535,856	\$1,272,477
CHANGE IN NET ASSETS	\$403,351	(\$136,803)	\$540,153	\$1,198,772	(\$957,617)	\$2,156,390

Current Month Actuals

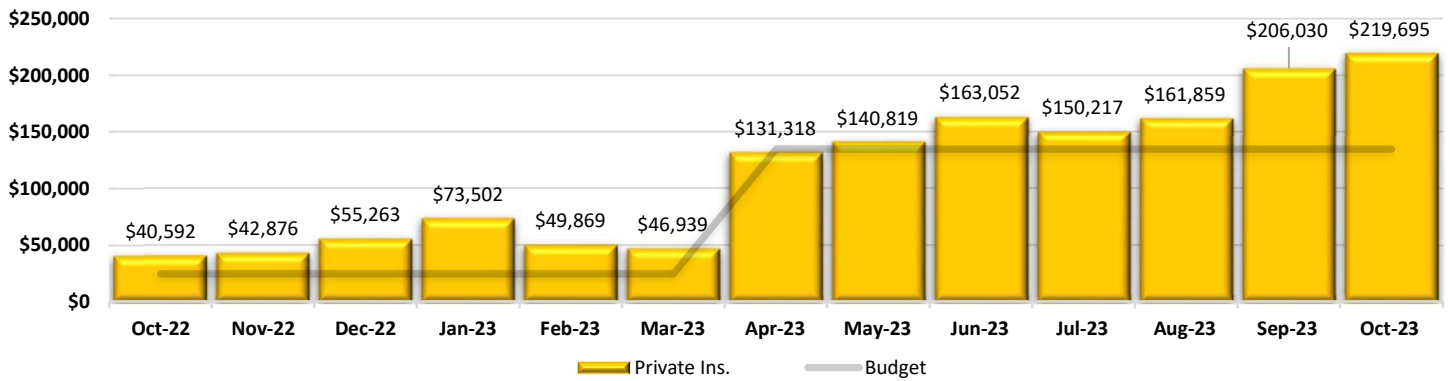


Visits

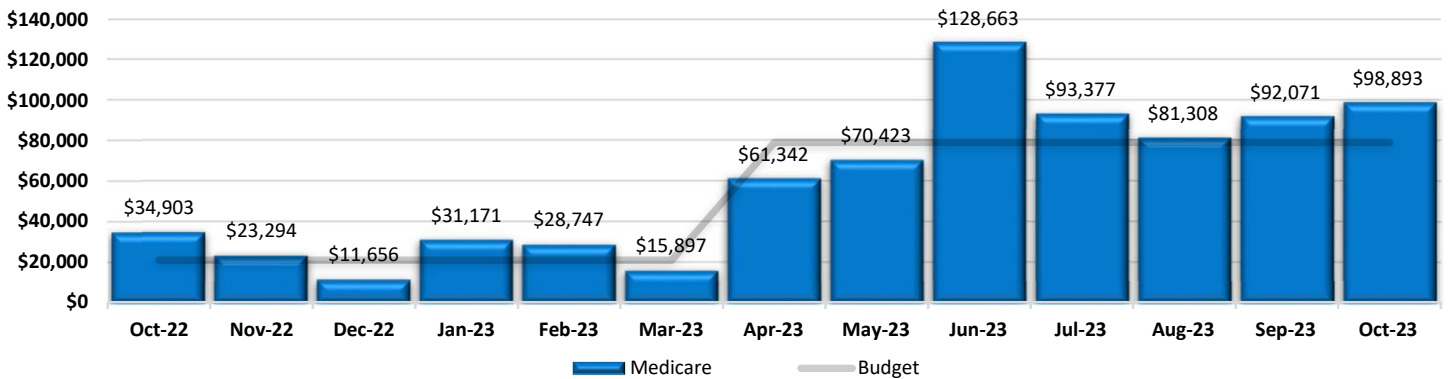




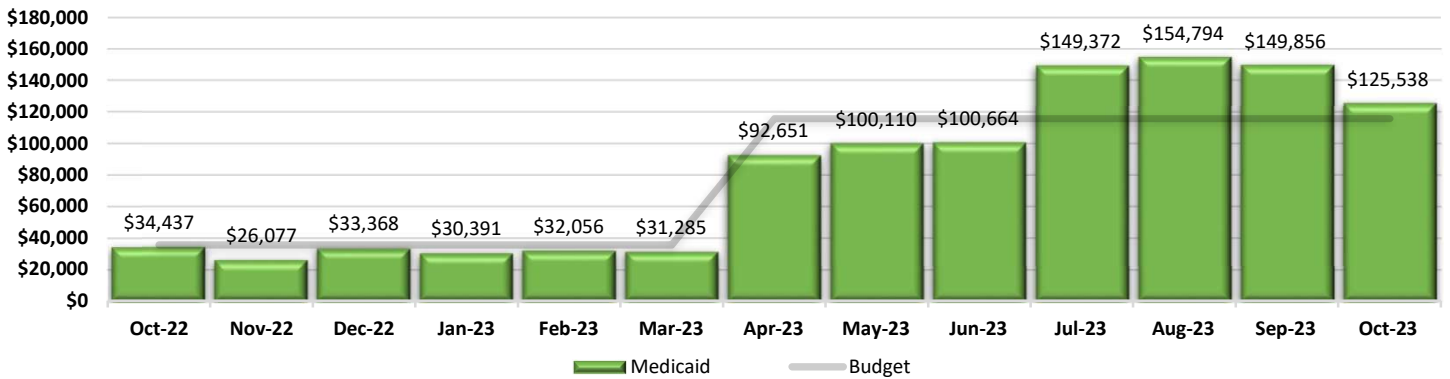
Private Insurance Revenue with Budget Line Comparison



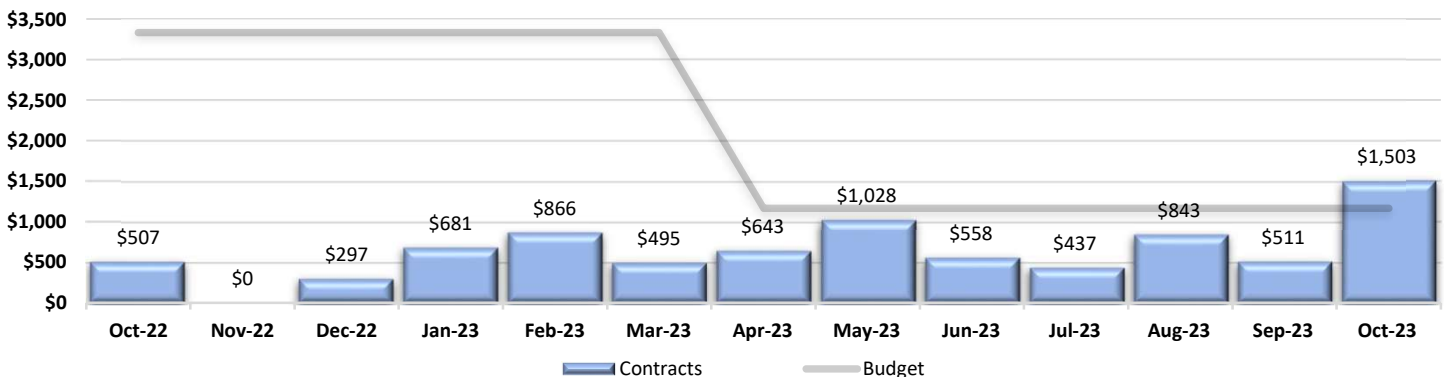
Medicare Revenue with Budget Line Comparison



Medicaid Revenue with Budget Line Comparison



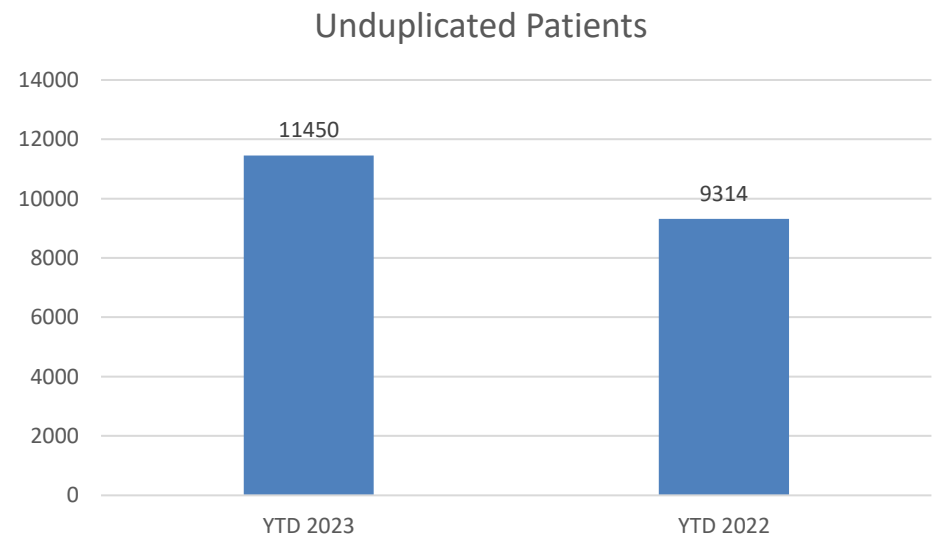
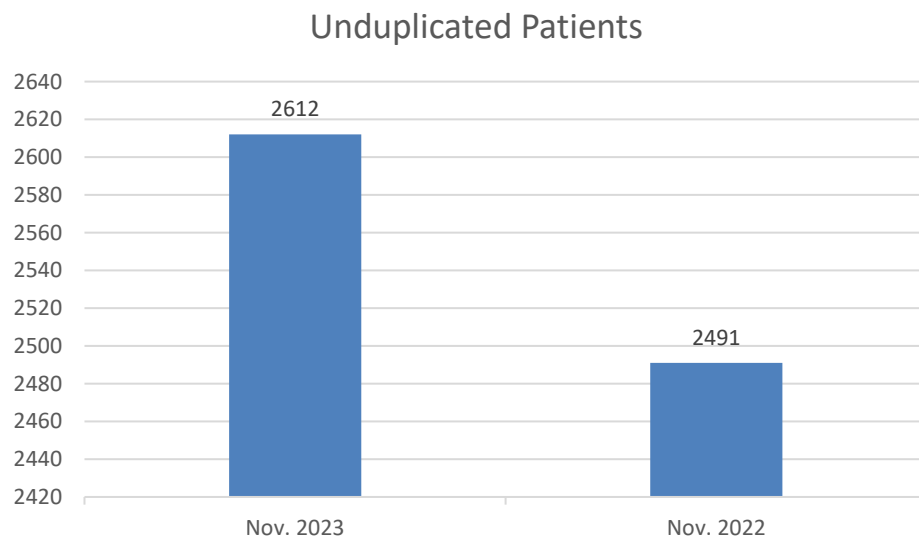
Contract Revenue with Budget Line Comparison



Coastal Health & Wellness *December* 2023 Health Center Update

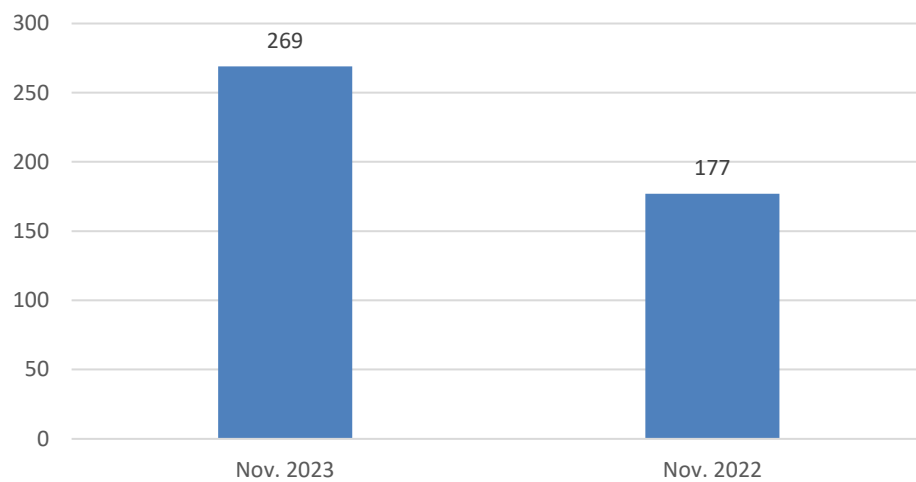


November 2023 Operational Report –Unduplicated Patients

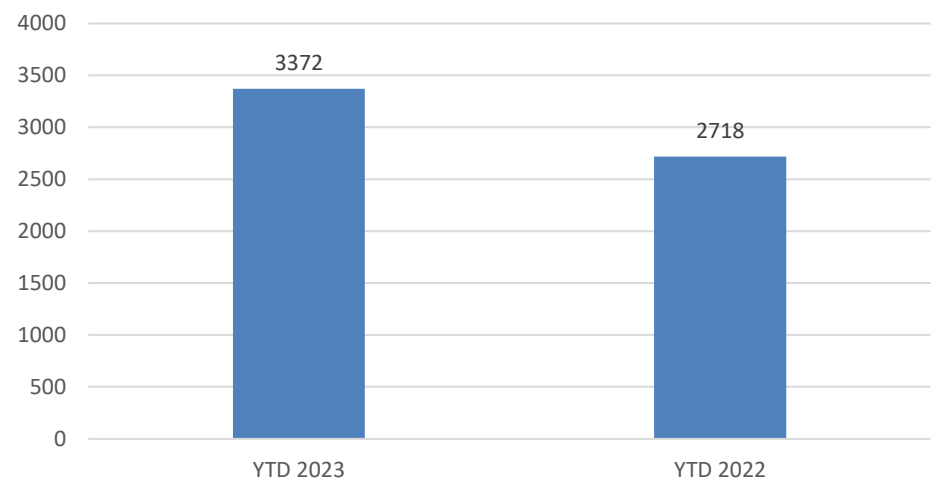


November 2023 Operational Report – New Patients Medical/Dental

New Patients



New Patients



2023 Project Updates

Pharmacy In-house
Texas City –
In progress

NextGen Optimization–
In progress

Joint Commission
Survey –
Nailed It!!!

Joint Commission Survey Preliminary Report

**The Joint Commission
SAFER™ Matrix**
Program: Ambulatory

Likelihood to harm a Patient / Visitor / Staff

ITHS			
High			
Moderate	EC.02.01.01 EP 6 EC.02.01.01 EP 8 EC.02.04.03 EP 3 MM.03.01.01 EP 6	MM.01.02.01 EP 2	
Low	LD.04.01.07 EP 1	EC.02.01.01 EP 3 EC.02.03.01 EP 1	EC.02.03.05 EP 15 HR.01.04.01 EP 3 PC.01.03.01 EP 44 RC.02.01.01 EP 26 RI.01.04.03 EP 6
	Limited	Pattern	Widespread
	Scope		

Out of over 700 elements of performance, there were only 13 findings.

There are more than 250 standards but only 6 were cited.
No Infection Control findings!

Standards:

EC – Environments of care
MM – Medication Management
LD – Leadership
HR – Human Resources
PC – Provision of Care
RI – Rights & Responsibilities

Joint Commission Survey Preliminary Report

Likelihood to harm a Patient / Visitor / Staff

The Joint Commission SAFER™ Matrix Program: Behavioral Health Care and Human Services			
ITHS			
High	NPSG.15.01.01 EP 5		
Moderate	NPSG.15.01.01 EP 1		CTS.02.02.05 EP 2
Low	LD.04.01.07 EP 1 PI.01.01.01 EP 14	CTS.03.01.01 EP 4	CTS.02.01.03 EP 3 CTS.02.01.05 EP 4 CTS.02.01.09 EP 1 CTS.02.01.11 EP 1 CTS.02.03.07 EP 1 CTS.02.03.07 EP 2 CTS.02.03.07 EP 7 CTS.03.01.03 EP 2 CTS.03.01.09 EP 2 HRM.01.06.03 EP 1
	Limited	Pattern	Widespread
	Scope		

We are currently building our Behavioral Health Program.

We just hired a new Counselor to start in January.

The finding in the high category was due to needing a policy/guideline on how to address suicide but will be developed prior to our program start.

Standards:

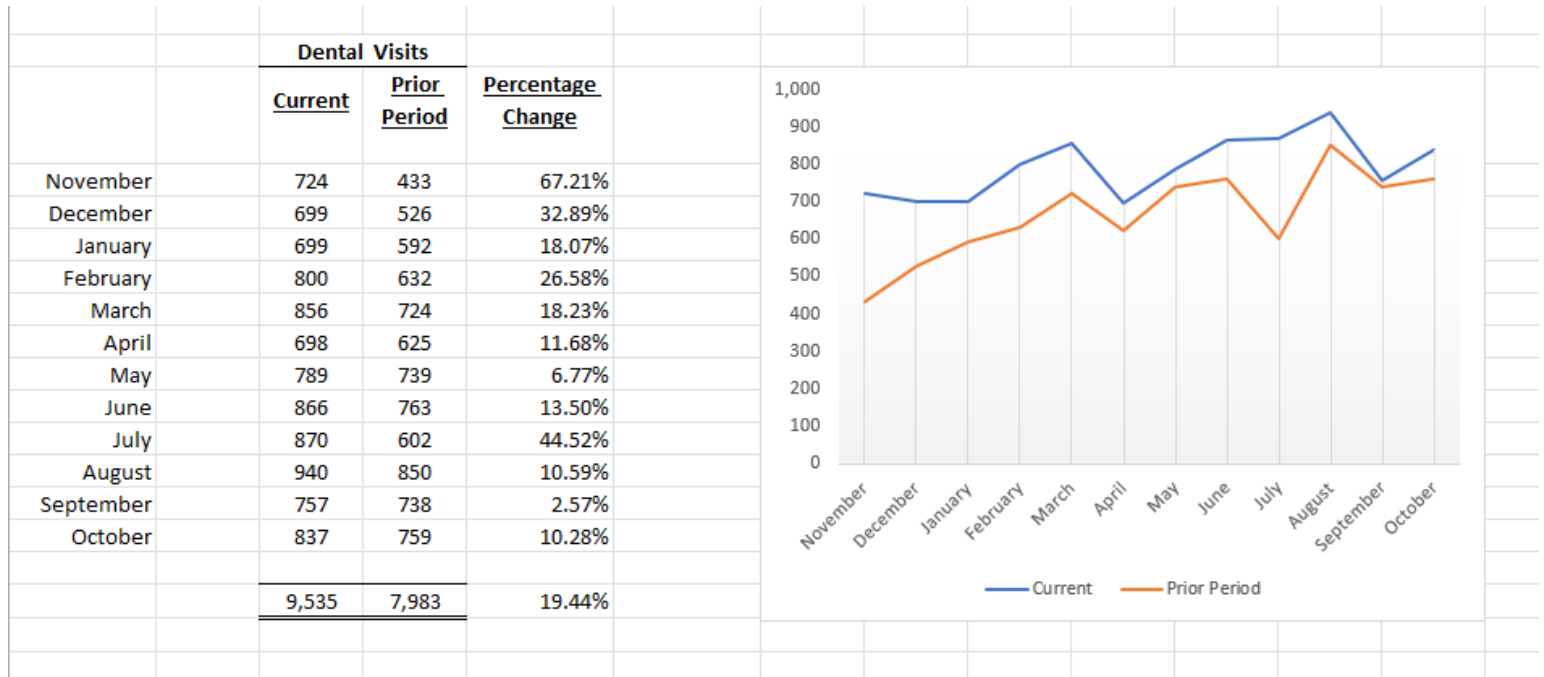
NPSG – Nat’l. Pt. Safety Goal
 CTS – Care, Treatment & Service
 LD – Leadership
 PI – Performance Improvement
 HRM – Human Resource Mgmt.

Thank you!!!



Dental Clinic Board Update 12/07/2023

- Visit Numbers – Based on “FQHC Qual Enc” in NextGen –
 - We reviewed the criteria for “FQHC Qual Enc” to make sure all eligible visits are captured as encounters and now have monthly reports set up for the Dental Office Manager to review any visits that were not captured as qualifying encounters.
 - We continue to see walk in patients in pain as we can fit them into our schedule.
 - This month, we will start releasing comprehensive exams on the 15th of every month. The text message went out on November 28th to inform all current patients on the wait list of the new process. We are also posting the information on our website.



- Current projects, plans, department overview for dental
 - Sterilization Renovation – Cabinets are no longer being manufactured, but we are looking into other options
 - Dr. Lindskog continues to serve on the COM Hygiene School Advisory Board. There are not any updates regarding this program.
- Provider Education Opportunities
 - All providers continue to select and participate in continuing education of their choice. They also share knowledge from these courses with the other providers during monthly meetings.
- Barriers or Needs (if applicable)
 - Staffing
 - The new dental hygienist and dental assistant started on November 9th. They are both doing well. The dental hygienist began seeing her own patients on December 1st.

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December 7, 2023

Governing Board Meeting

1. Provider productivity:
 - October provider visits:
Scheduled 3345, No show 844, Total visits 2501, Total charges \$731,299
 - November provider visits
Scheduled 2859, No show 938, Total visits 1921, Total charges \$473,650
(lower charges are due to posting; RCM will have those after the 10th of the month, number of providers were out on vacation and holiday)
2. Software utilization:
 - Telemedicine platform:
Doxy.me: 178 visits in Oct (total 1071 visits since June)
 - E-consult platform:
ConferMed: 84 (e-consult), we are considered one of the highest utilizers for the time we have been using this service)
2. School-based program: Walk-in clinic combined with telemedicine
 - Providers onsite for two full days weekly
Oct: 51 visits (33 CHW existing patients, 9 student visits, 9 TCISD staff)
Nov: 60 visits (52 CHW existing patients, 5 students, 3 TCISD staff)
4. Provider Lead Program: collaborate with public health services (HIV/STI, WIC)
 - ID care: Jacklyn Morgan, PA-C, Maria Culangan (HIV PrEP, HepC, STD)
 - Women's health: Lisa Cashiola
5. Home-based care:
 - House call program for home-bound patients
October 78 visits (Dr. Grumbles:38 visits, Pam Cable: 40 visits)
6. Remote care management (Patient engagement center/care coordination lead by Teresa Garcia)
 - Patient engagement and promoting self-care
 - CCM (chronic care management), TCM(transitional care management), AWW
7. BHI (behavioral health integration)
 - Level 4 Behavioral health /primary care integration with GCC: (level 6 by the end of 2023)
 - One Care Team steering committee meeting 12/5/2023

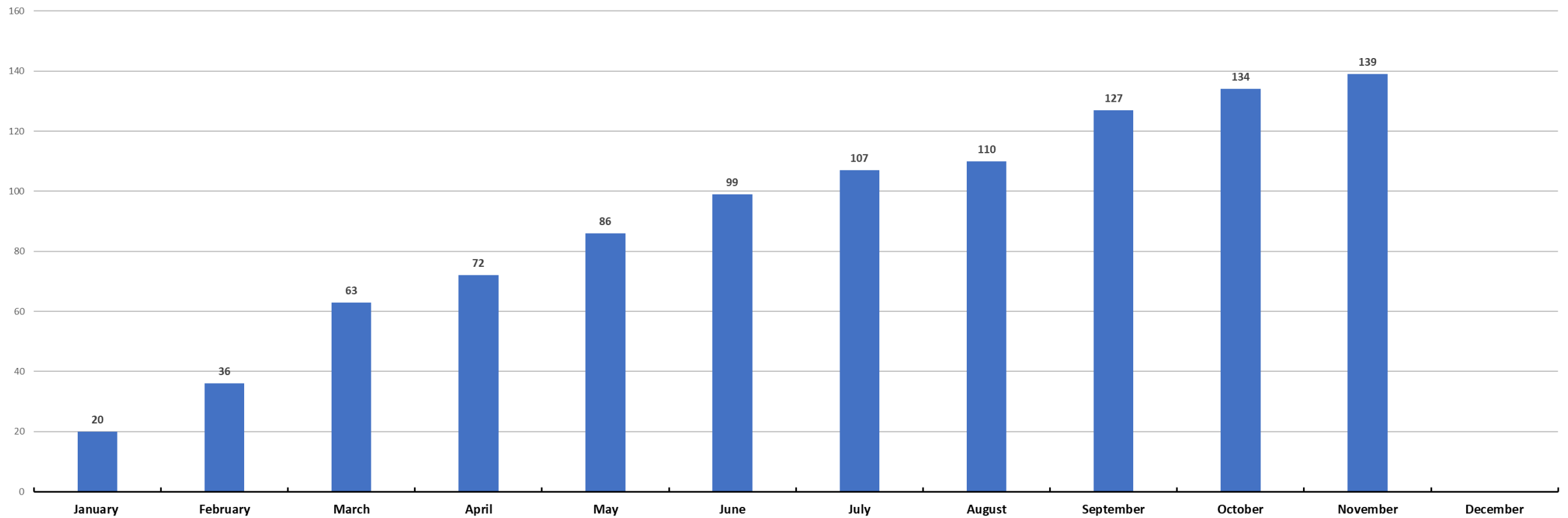
“Strive to deliver high-quality, culturally competent, equitable, and comprehensive primary care with a focus on clinical quality, patient-centered care, and provider and staff well-being.”

CCM/TCM STATS

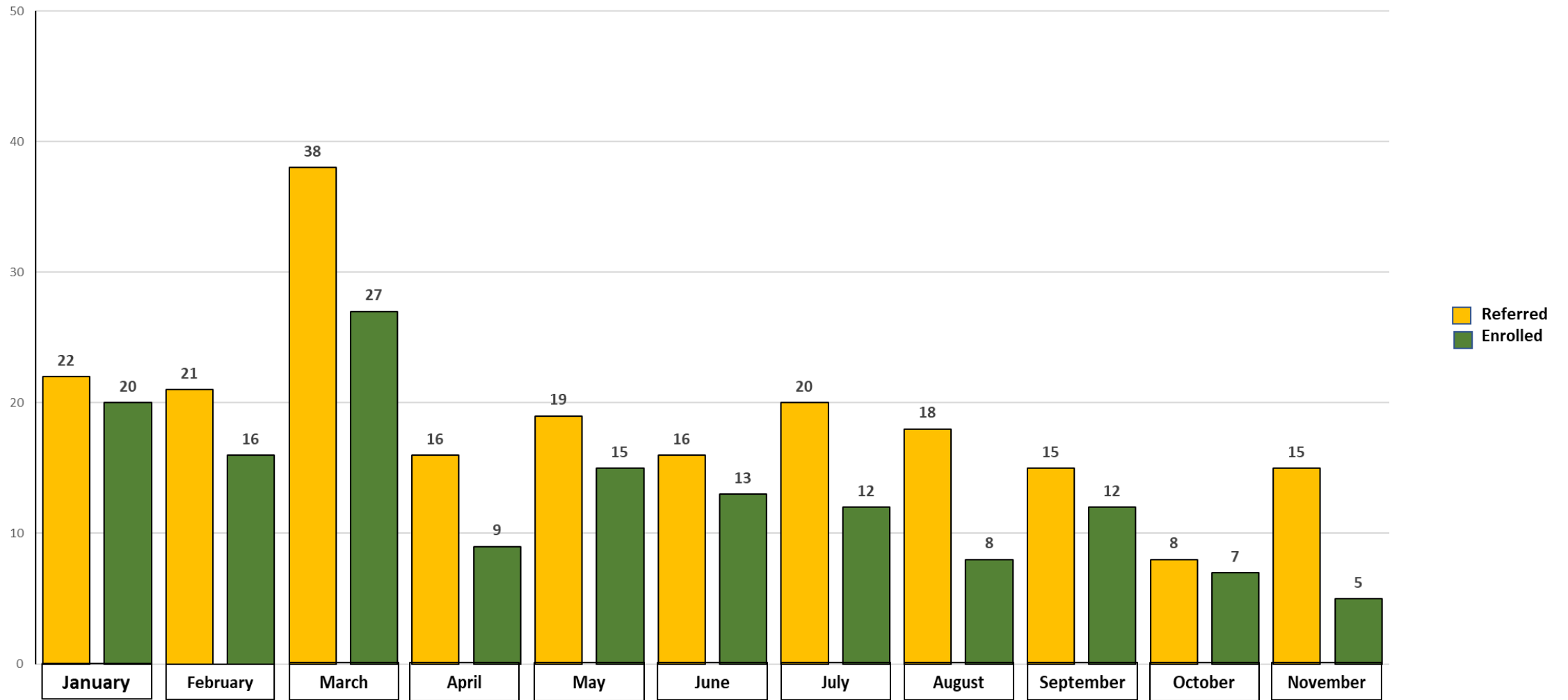
Maryann Choi, MD, MPH, MS, CMD



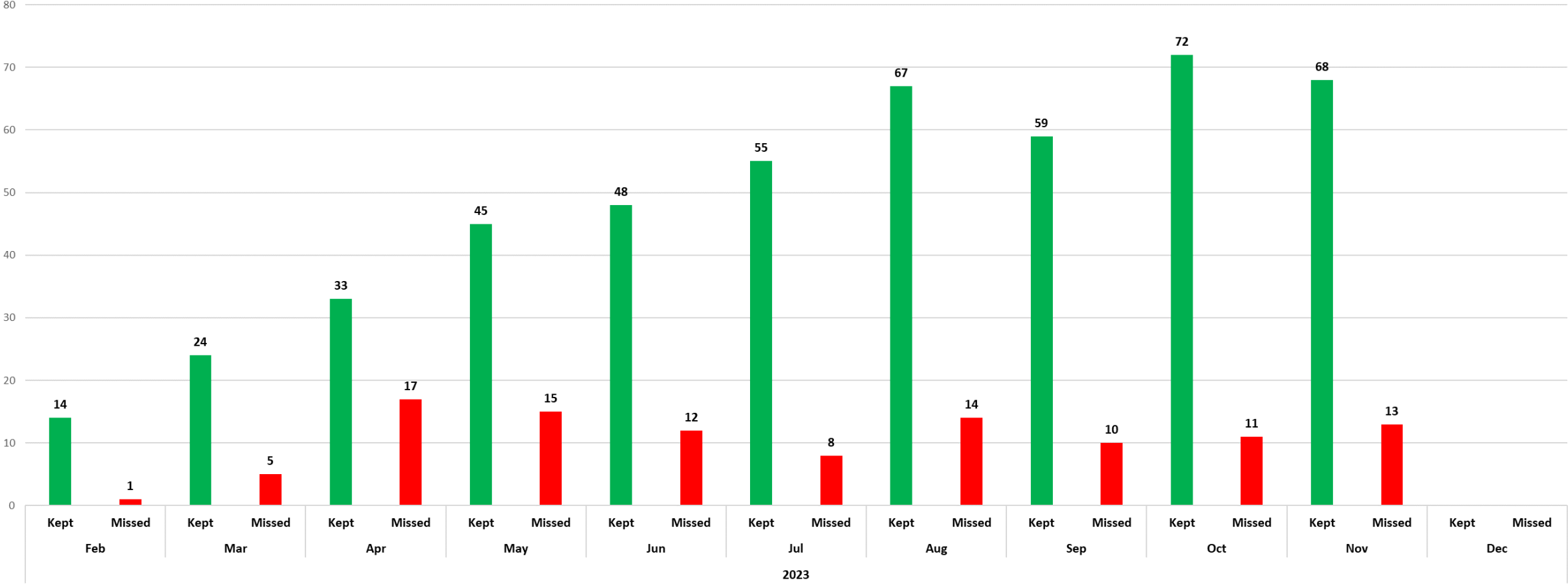
Total CCM Patients - 2023



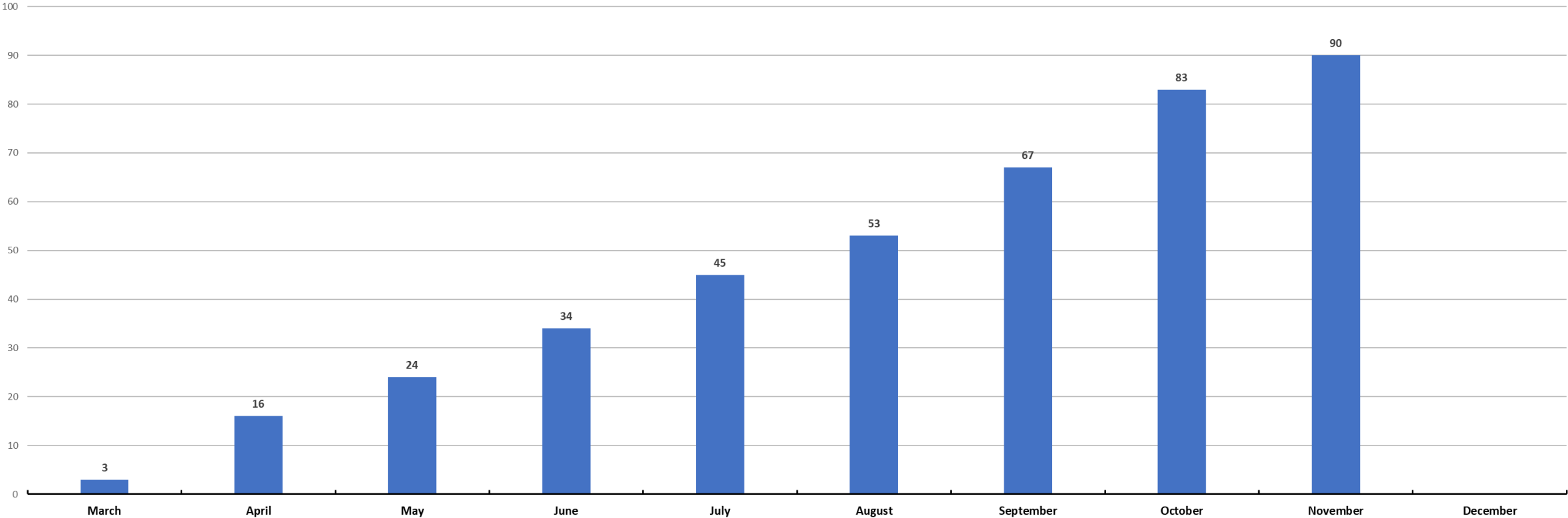
CCM Patients: Referred -vs- Enrolled (2023)



Total CCM Appointments: Kept -vs- Missed



Total TCM Patients - 2023



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**Governing Board
December 2023
Item#11
Comments from Board Members**

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