

# Introduction of a Point of Care Ketones EQA

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## Introduction

Point of Care Ketone meters are in routine use for detecting and monitoring diabetic ketoacidosis (DKA). The RCPAQAP introduced a Point of Care (PoC) EQA for Ketone meters in 2019 following requests from customers in hospital settings. The material is customised for specific meters and initially offered for StatStrip® and Optium Neo® meters, but to date, the main interest has been from StatStrip® users. We reviewed the performance of StatStrip® meters enrolled in our 2020/21 program as a potential indicator of the 'fitness for purpose' of the device and their PoC operators in hospital settings.

## Method

Results from six bi-monthly (two sample) surveys from June 2020 to April 2021 were analysed using RCPAQAP inhouse software. Participant/meter performance is reported using a "traffic light" assessment where Green is within 1 Analytical Performance Specification (APS), Orange between 1 and 2 APS and Red > 2 APS. The APS is based on clinical utility (as no published Biological Variation data was found) and defined as +/-0.5 mmol/L up to 5 mmol/L then +/- 10%. The samples are aqueous liquid samples supplemented with ketone, provided in six linearly related concentrations designed to cover the accepted medical decision limit (>3 mmol/L).

## Results and Discussion

Eight sites with a total of 1,148 meters participated in the program. The medians of the six sample levels ranged from 1.2 mmol/L to 6.4 mmol/L indicating the material performed to specifications.

Participation rates were site dependent and appear to correlate with the oversight. Those with laboratory supervision were more likely to participate and review performance. The incentive to participate may also be less as ward based ketone meters don't normally appear on the scope of NATA accredited laboratories.

While participation varied over the course of the cycle, most sites averaged good (green) performance for 75% of their results, acceptable (orange) 15% and poor (red) 10% indicating overall clinically acceptable performance for the detection and monitoring of DKA. One site (No 8) clearly underperformed compared to others. It should be noted that results flagging red at the 3.0 decision limit are outside 3.0 +/- 1.0 mmol/L indicating the potential to miss a DKA or incorrectly diagnose DKA.

## Conclusion

While the data from the RCPAQAP Ketones program demonstrates that well trained competent PoC operators can achieve satisfactory performance in keeping with good clinical practice, the lack of participation and poor performance in some sites indicates follow up is required. Laboratory involvement in review and feedback is an important component of PoC and shouldn't rely on accreditation requirements as the motivator.

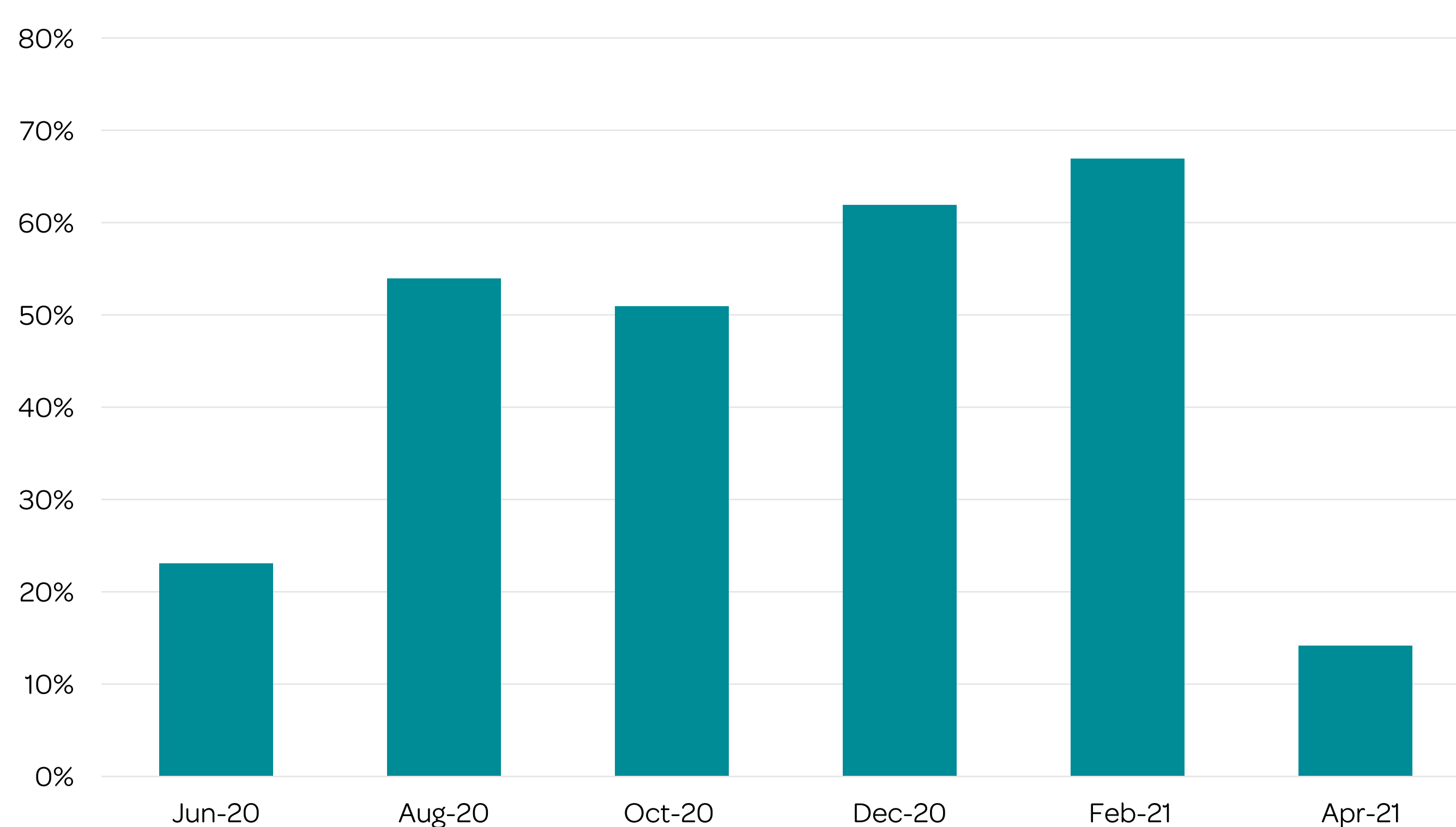
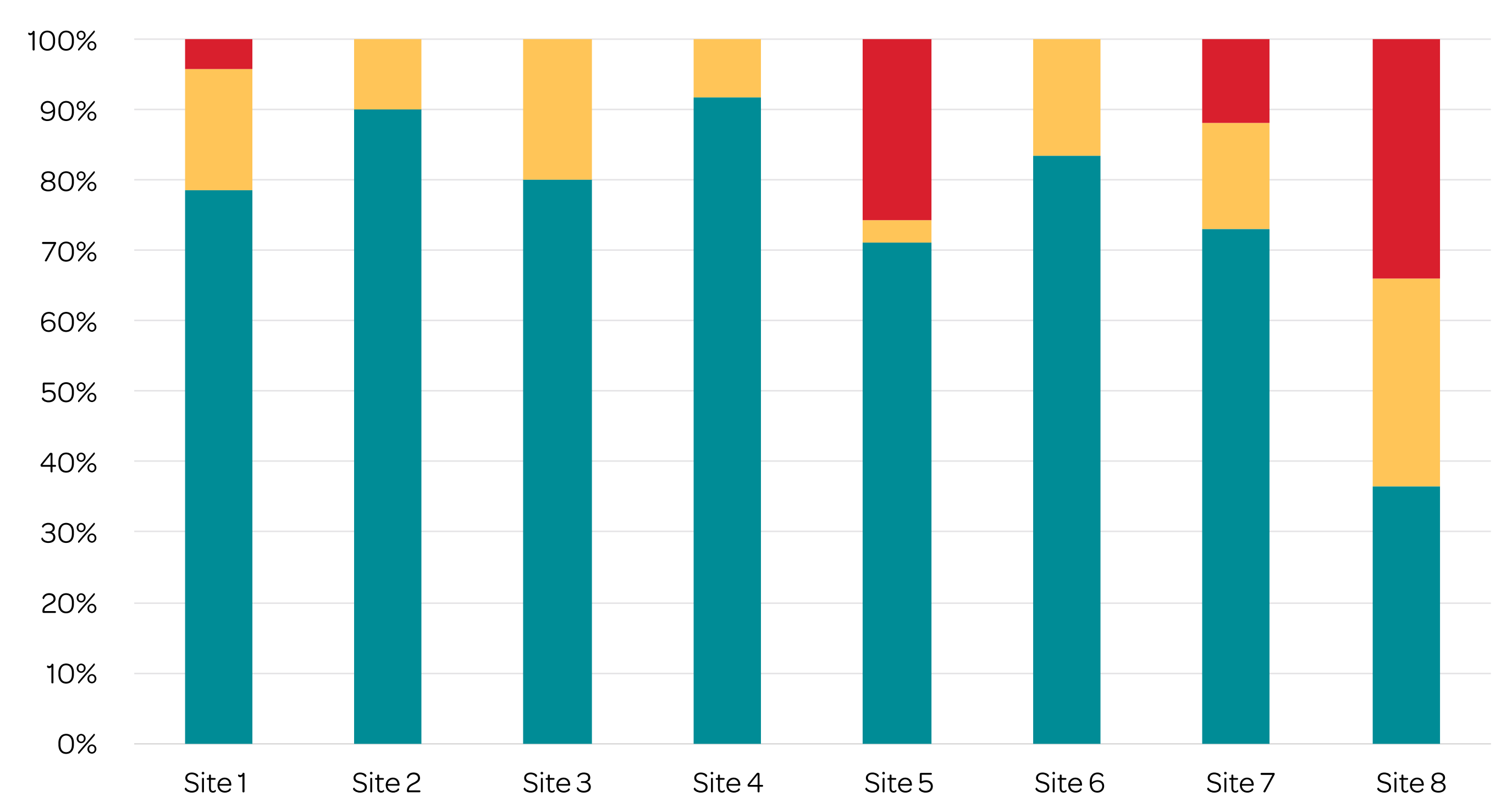


Figure 1. Survey Participation



	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6	Site 7	Site 8
Red	4	0	0	0	26	0	12	34
Orange	17	10	20	8	3	17	15	30
Green	79	90	80	92	71	83	73	36

Figure 2. Performance per site, green = good, orange = acceptable, red = poor