

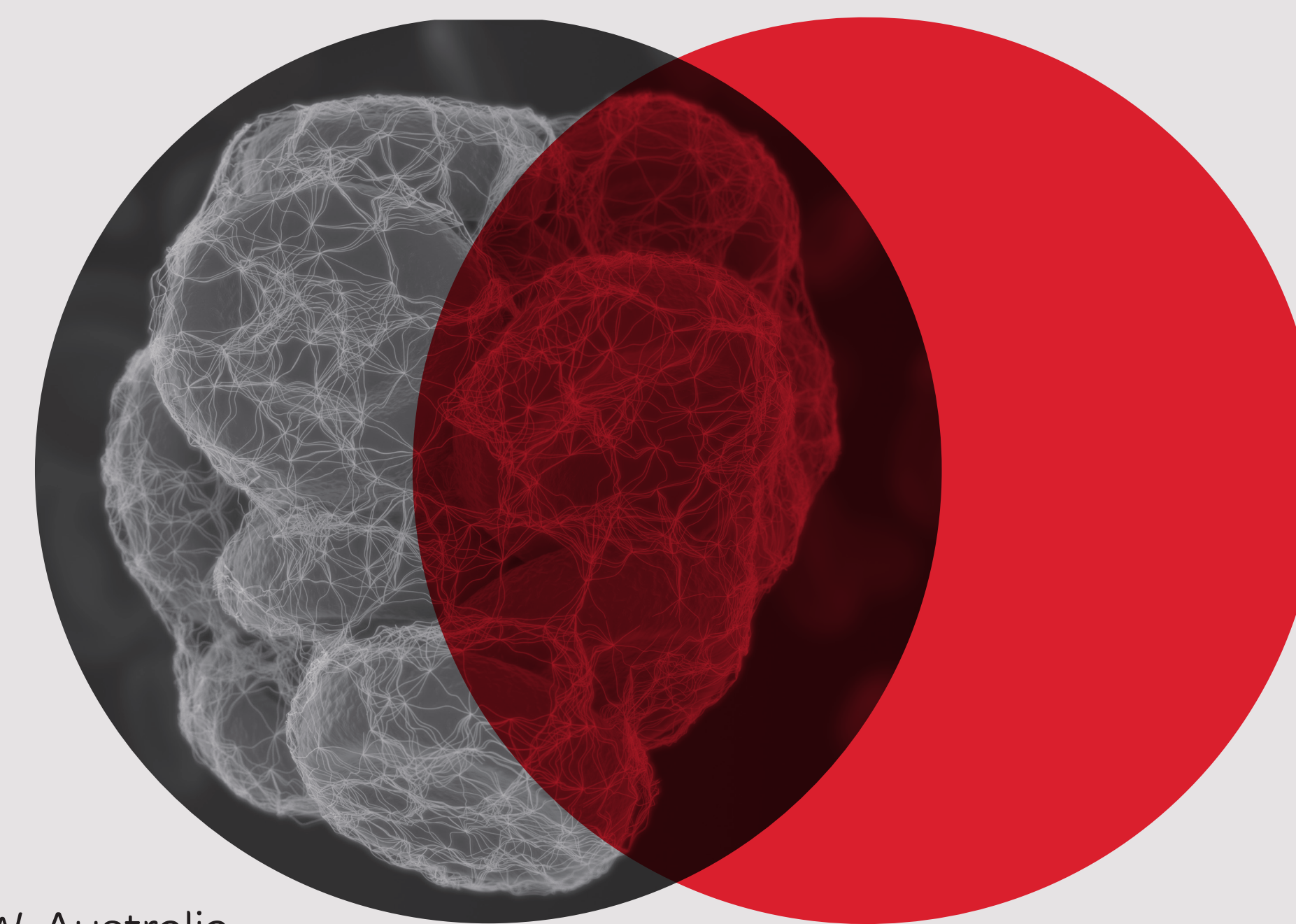
Ongoing improvements in laboratory performance of coagulation factors VIII and IX: Recent experience from the RCPAQAP

Sandya Arunachalam¹, Emmanuel J Favaloro^{2,3}

¹ RCPAQAP Haematology, Suite 201, Level 2, 8 Herbert St, St Leonards, Sydney, Australia

² Haematology, Institute of Clinical Pathology and Medical Research (ICPMR), NSW Health Pathology, Westmead Hospital, Westmead, NSW, Australia

³ Sydney Centres for Thrombosis and Haemostasis, Westmead, NSW, Australia



Background

The Royal College of Pathologists Australasia Quality Assurance Programs (RCPAQAP) is an international QAP with over 100 participants enrolled in the Coagulation Factors Program. Coagulation factors VIII (FVIII) and IX (FIX) are most commonly tested in Haemostasis laboratories and used to screen and monitor Haemophilia A and B respectively. Data presented here is from an evaluation of the assessment criteria for FVIII and FIX over a six-year period. The aim of this evaluation was to identify areas of benefit and weakness resulting from a recent (2016) change in criteria from assessment against factor deficient plasma 'reagent' to plasma 'calibrator', as this was felt to be more relevant for determination of factor level.

Methods

Data from 2013 to 2018 was reviewed, with 2013–2015 reflecting assessment against factor deficient plasma 'reagent' and data from 2016–2018 based on 'calibrator'. Six surveys were distributed in each year, with each comprising two samples. Assessment based on reagent/calibrator was performed when there were ten or more users in a reagent/calibrator group. Here, the laboratory result is compared against the median of all users of the same reagent/calibrator. For reagent/calibrator groups with less than ten users, assessment is based on the overall median. Numbers of participants identified as outliers from each assessment criteria and Coefficients of Variation (CVs) were also compared.

Results

Reagent and calibrator assessment each included 36 survey samples for total 72 samples over six-years. As represented in Figures 1 and 2, we identified an ongoing improvement in participant performance, as reflected by reduction in numbers of participants outside the RCPAQAP Analytical Performance Specifications (APS) for both FVIII and FIX. The APS during this assessment period (2013–2018) did not change. FVIII outliers almost halved from 43 to 23 participants, and FIX outliers reduced by over 60% from 36 to 14 participants. Figures 3 and 4 represent the percentage of outliers when assessment was based on reagent (between 2013 and 2015) compared to when assessment was based on calibrator (between 2016 and 2018). The CV for FVIII assessment against reagent ranged from 6.8–20.3% (2013–2015) and against calibrator ranged from 3.6–17.3% (2016–2018). The corresponding CVs for FIX were 2.9–26.2% (2013–2015) and from 5.5–17.8% (2016–2018).

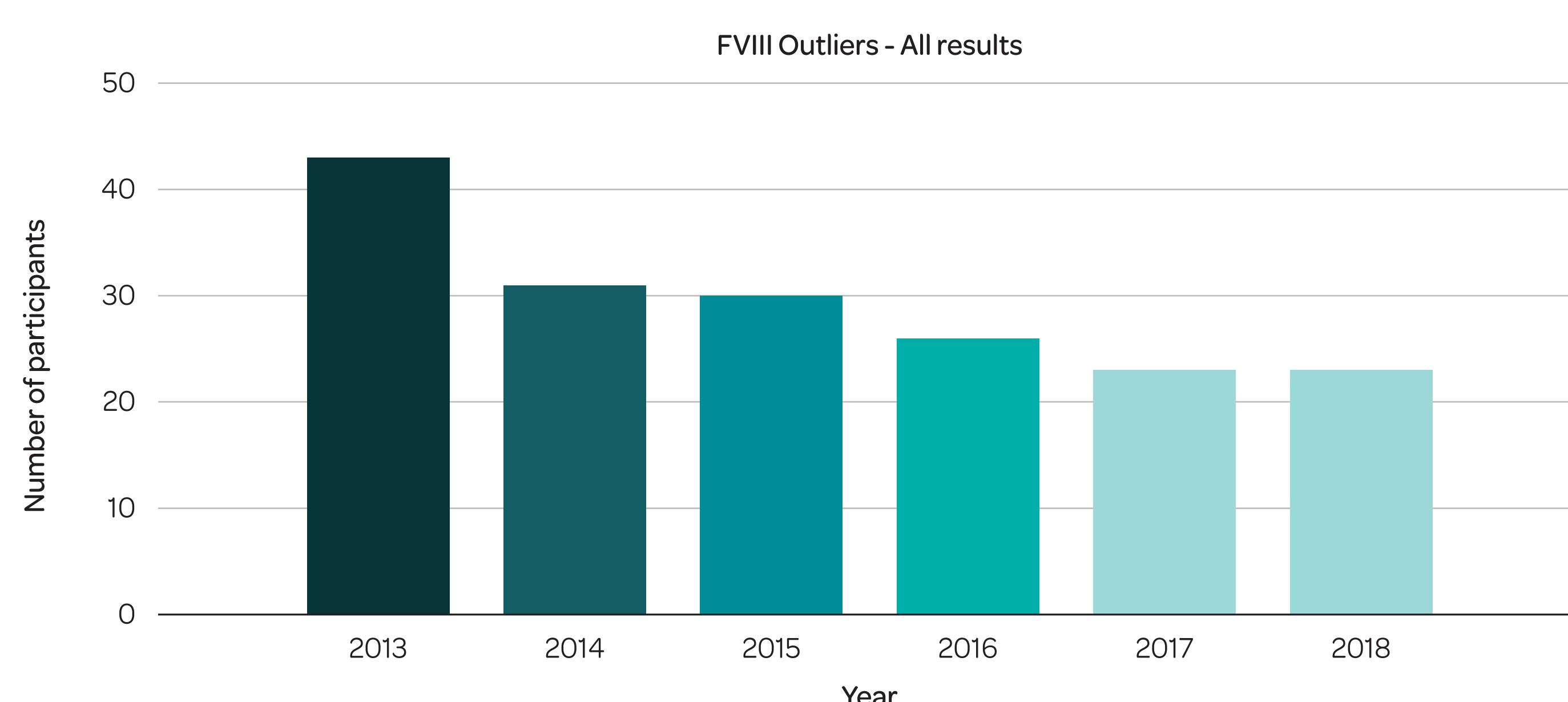


Figure 1. Number of Factor VIII participants identified as outliers in the RCPAQAP Coagulation Factors Program between 2013 to 2018.

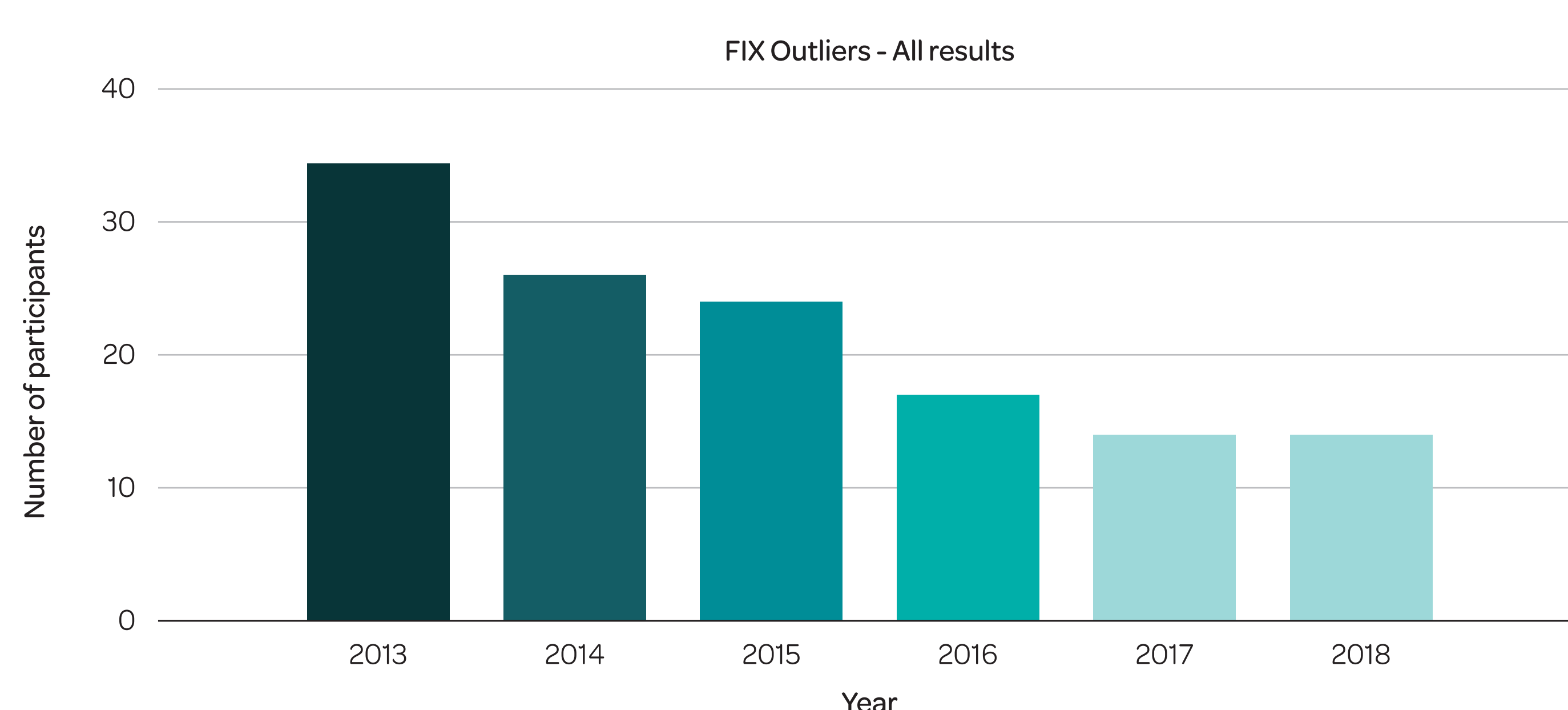


Figure 2. Number of Factor IX participants identified as outliers in the RCPAQAP Coagulation Factors Program between 2013 to 2018.

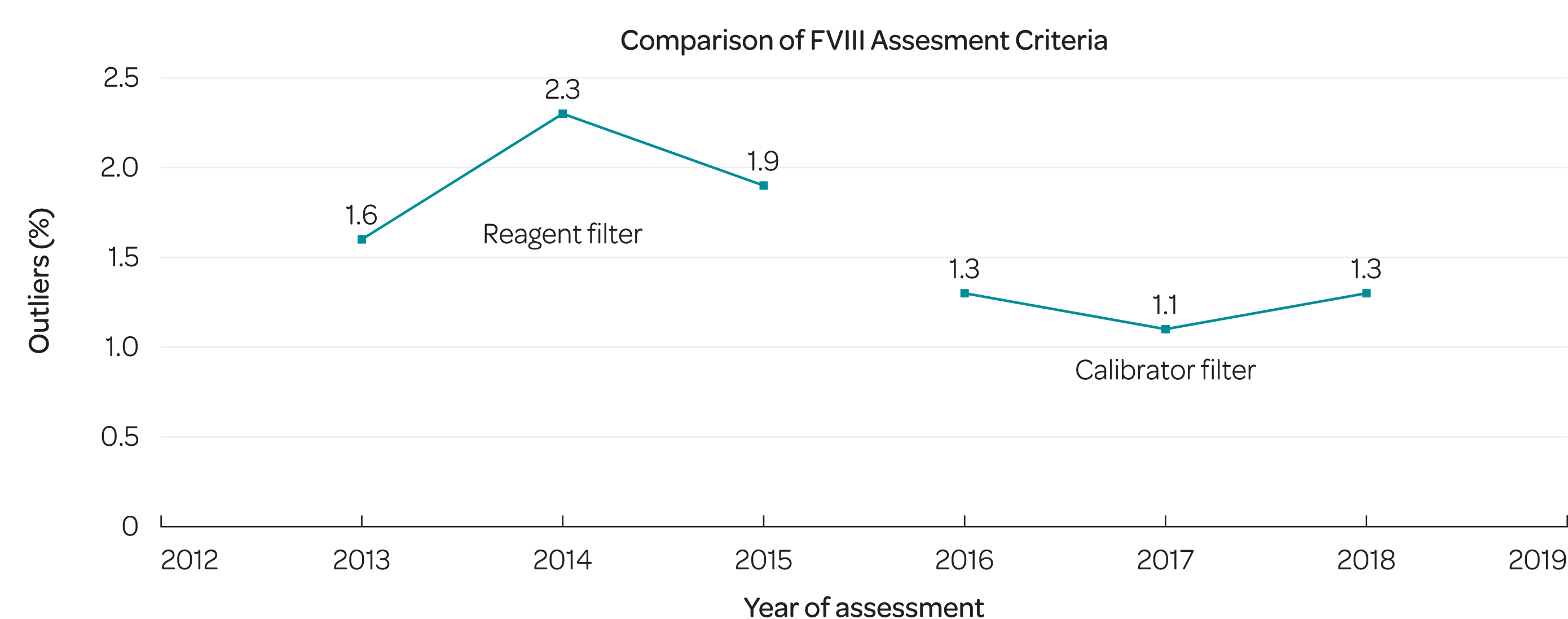


Figure 3. Comparison of Factor VIII assessment criteria performance in the RCPAQAP Coagulation factors program

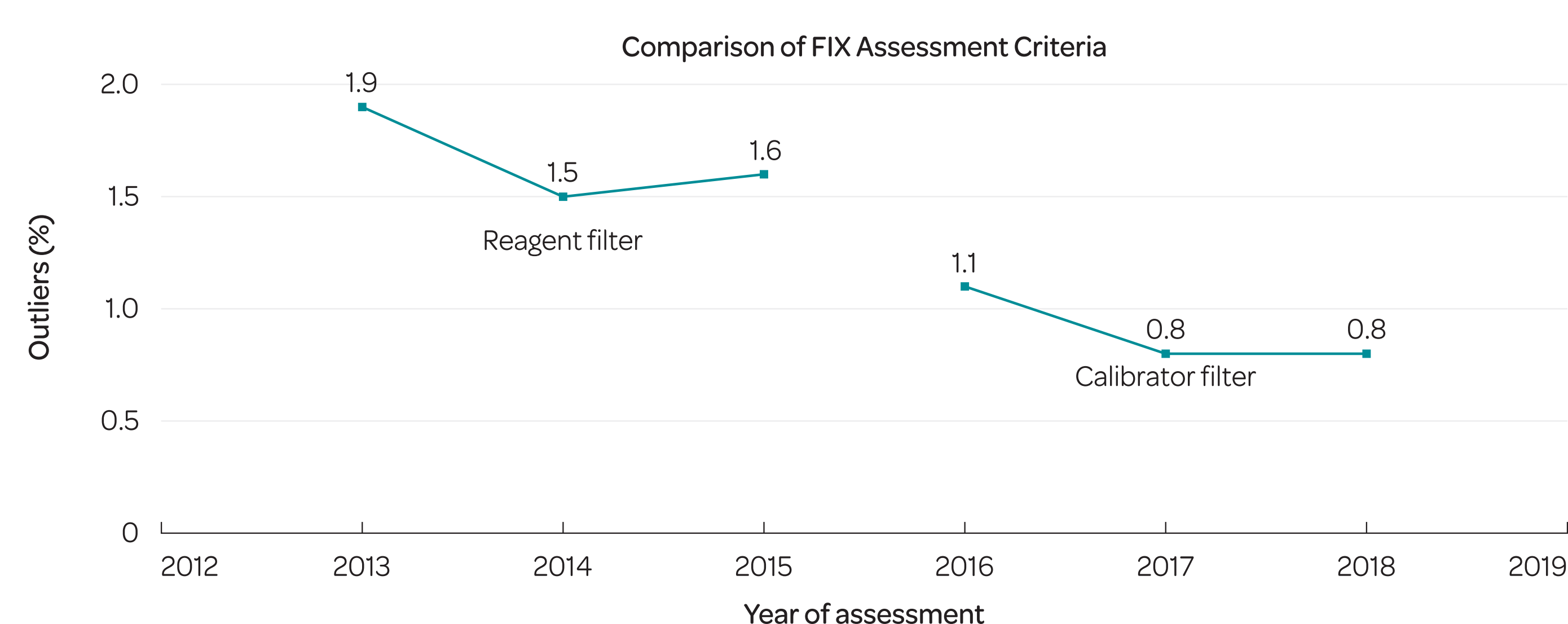


Figure 4. Comparison of Factor IX assessment criteria performance in the RCPAQAP Coagulation factors program

Discussion

A change to the RCPAQAP assessment criteria of the coagulation factors program from reagent to calibrator was made from 2016 to enable the assessment criteria to be more relevant. The aim of this review was to determine if this change in assessment criteria has had a positive impact on the assessment of participants. As shown in Figures 1 and 2, there was overall reduction in the number of outliers for FVIII and FIX results reported by participants from 2013 to 2018. This seems to reflect a year by year improvement. The percentage of outliers is higher for both FVIII and FIX (Figures 3 and 4) when assessment was against reagent, than when assessment was on calibrator. This indicates the performance of participants in the RCPAQAP coagulation factors programs has improved over the years as well providing support to the hypothesis that the change in assessment criteria from reagent to calibrator was at least partially responsible. Looking at the CV's of both reagent and calibrator allows for evaluating the performance of both assessment criteria. The FVIII and FIX survey results' CV's for reagent assessment indicates more variation than that of calibrator assessment, thus further supporting the change to calibrator assessment being more relevant.

Conclusion

Laboratory performance of FVIII and FIX testing has improved over the past six years. Assessments based against calibrator rather than reagent showed reduction in the numbers of outliers in each peer group and provided improved comparability of results with reduced CVs. The decreasing trend in outliers also supports the retention of the assessment criteria being based on calibrator.

References

- Duncan, E., & Rodgers, S. (2017). One-stage Factor VIII Assays. In Favaloro, E. J & Lippi, G (Eds.), *Haemostasis and Thrombosis Methods and Protocols* (pp. 247–263). New York, United States on America: Humana Press.

