PATHWAYS TO MBS FUNDING FOR IN-VITRO DIAGNOSTICS: TIMELINES AND SUCCESS RATES IN AUSTRALIA

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Background

- In-vitro diagnostics (IVD) are tests on human tissue or blood used for diagnosis, monitoring, and precision medicine.
- In Australia, the Medical Services Advisory Committee (MSAC) assesses IVD funding applications and provides recommendations for reimbursement on the Medicaress Benefits Schedule (MBS).
- The MSAC health technology assessment process has multiple stages (Fig. 1).
- Assessments can be developed by the applicant (ADAR) or contracted to an assessment group by the Department of Health (DCAR).
- IVD tests linked to drug eligibility require parallel evaluation of both drug and test (co-dependent submission).
- This study analysed timelines and outcomes of IVD submissions to MSAC to identify factors influencing the listing process.

Objectives

- Analyse the total time taken for IVD MSAC applications to be listed on the MBS.
- Identify factors that may influence the total time taken for applications to be listed on the MBS.

Methods

Data Collection

- Collected from MSAC public summary documents and the MBS website.
- Included IVD applications with ≥1 MSAC meeting between 2016 and 2023.
- Captured variables included: Number of meetings, reason for resubmission, economic evaluation type (cost-effectiveness analysis [CEA], cost-utility analysis [CUA], cost-minimisation analysis [CMA] or other), disease, co-dependency, application date, MSAC outcome, submission and meeting dates, MBS listing date.

Primary outcome

- Time from PASC Application Cut-off to MBS Listing: The time between the application cut-off date to the date of listing (or amendment) of the item on the MBS. If there was no PASC meeting (i.e., PASC was bypassed due to streamlined or expedited submission), the assessment report lodgment deadline was used.
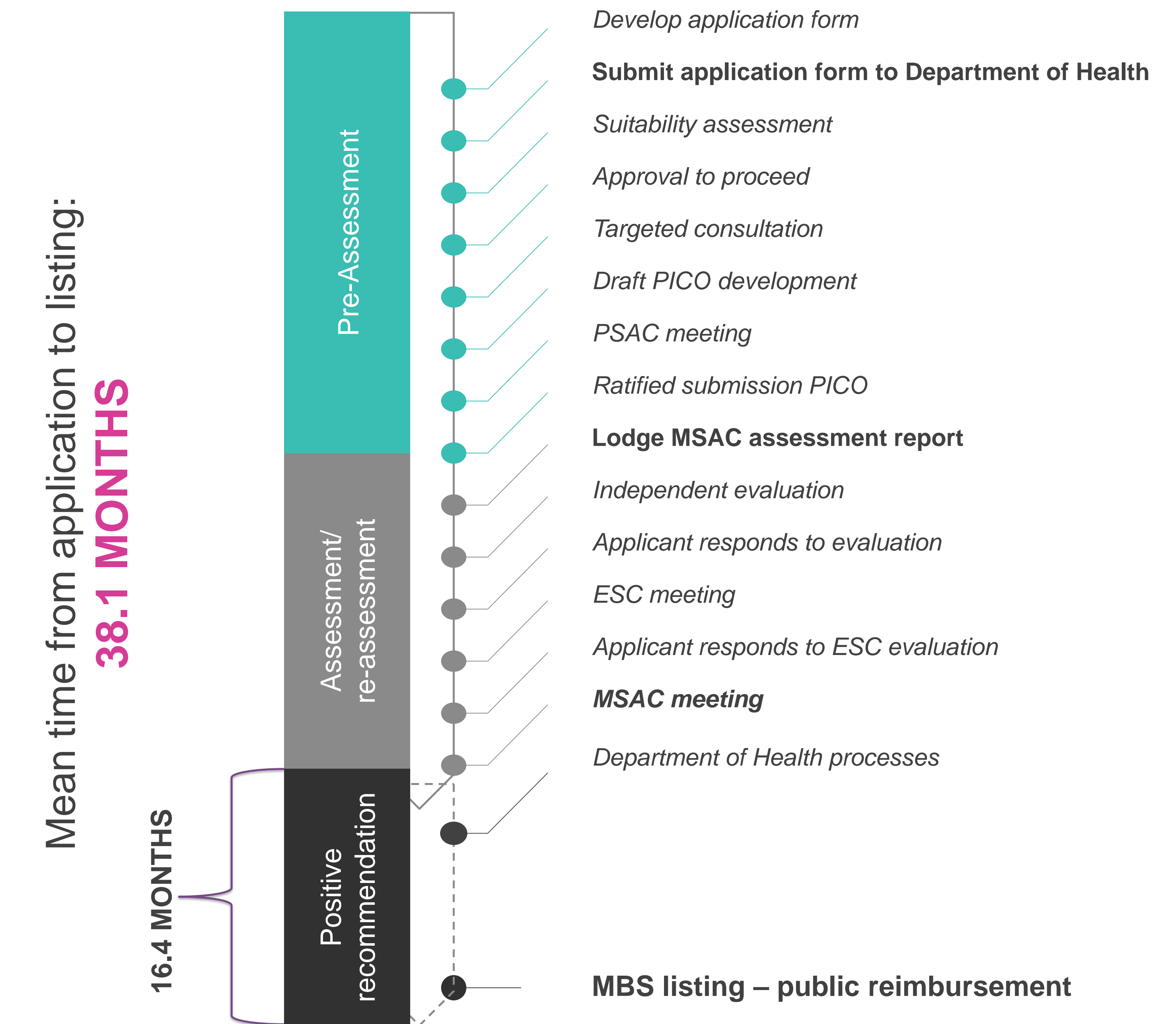
Secondary Outcomes

- Time from Last MSAC Meeting to MBS Listing: The time between the date of the last MSAC meeting when a positive recommendation was received and the date of listing (or amendment) of the item on the MBS.
- Positive Recommendation Rate.
- Resubmissions Required.

Analysis

- Outcomes were analysed descriptively in Microsoft Excel.
- Mean, median, standard deviation and range were calculated.
- Applications with multiple meetings/resubmissions were considered over a continuous timeframe from the first application to MBS listing.
- Time-based endpoints were reported in months.
- Subgroup analyses were conducted based on data contained in each assessment report.

FIG 1. STANDARD MSAC SUBMISSION PROCESS – MEAN TIME TO MBS LISTING

Mean time from application to listing: **38.1 MONTHS**

16.4 MONTHS

Pre-Assessment:
- Develop application form
- **Submit application form to Department of Health**
- Suitability assessment
- Approval to proceed
- Targeted consultation
- Draft PICO development
- PSAC meeting
- Ratified submission PICO

Assessment/re-assessment:
- **Lodge MSAC assessment report**
- Independent evaluation
- Applicant responds to evaluation
- ESC meeting
- Applicant responds to ESC evaluation
- *MSAC meeting*
- Department of Health processes

Positive recommendation:
- **MBS listing – public reimbursement**

Results

MSAC Meetings and Outcomes

- Eighty consolidated applications (considered at 120 meetings) met the inclusion criteria.
- Sixty-two (78%) had a positive final recommendation (38 first-time recommendations) and were listed on the MBS (Table 2).

Time From Application To MBS listing

- Mean time from application to listing was 38.1 months (SD = 21.8; Table 1).
- Submissions with drug co-dependency had a mean time of 35.7 months (n=21, SD=23.7) versus 39.3 months (n=41, SD=20.6) for those not linked to a medicine listing.
- Resubmissions due to limitations in clinical evidence caused the greatest delay to MBS listing (n=5, 70.2 months, SD=28.7), followed by uncertain cost-effectiveness (n=3, 56.7 months, SD=30.6).
- ADARs (n=30, 35.4 months, SD=21.2) were on average faster to gain MBS listing than DCARs (n=32, 40.7 months, SD=22.1).
- The median time from application to MBS listing was 31.0 months. Approximately 42% of applications took 2-3 years to gain MBS listing (Fig. 2).
- Time to MBS listing decreased from an average of 47.1 months (SD=25.2) between 2016-2019 to 32.0 months (SD=16.5) between 2020-2023 (Fig. 3).

Time From MSAC meeting To MBS listing

- Mean time from last MSAC meeting to MBS listing was 16.4 months (SD = 12.1).
- Co-dependent submissions (mean=14.9 months, SD=16.1) were faster to list than others (mean = 17.2, SD = 9.4), but had more variation.

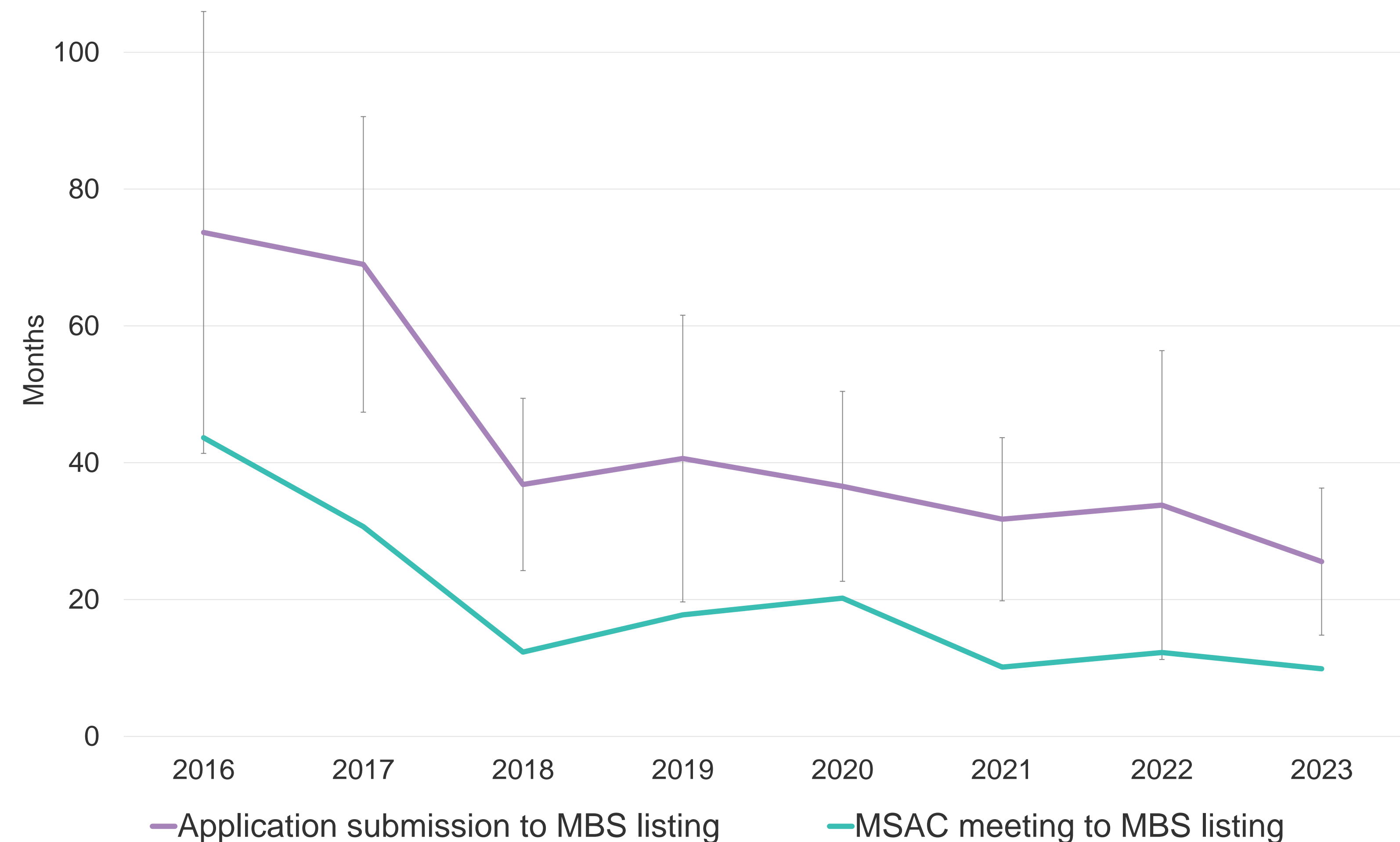## FIG 3. MEAN TIME TO MBS LISTING FROM APPLICATION SUBMISSION AND FINAL MSAC MEETING

— Application submission to MBS listing   — MSAC meeting to MBS listing

TABLE 1. TIME FROM APPLICATION TO MBS LISTING

Variable	n	Mean (months)	SD
Overall	62	38.1	21.8
Date of last MSAC meeting			
2016-2019	25	47.1	25.2
2020-2023	37	32.0	16.5
Co-dependent application			
Yes	21	35.7	23.7
No	41	39.3	20.6
Application developer			
ADAR	30	35.4	21.2
DCAR	32	40.7	22.1
Rare disease			
Yes	34	35.4	14.8
No	28	41.4	27.6
Economic evaluation			
CEA	15	36.6	20.8
CUA	25	39.5	21.5
CMA	9	34.8	13.2
Other	13	39.4	27.3
Reason for resubmission			
No resubmission	37	28.4	9.7
Clinical evidence	5	70.2	28.7
Economic	3	56.7	30.6
Clinical setting	4	48.3	9.4
Drug re-evaluation	11	47.6	26.2

FIG 2. TIME FROM APPLICATION TO MBS LISTING

■ < 1 year ■ 1-2 years ■ 2-3 years ■ 3-4 years ■ 4 years +
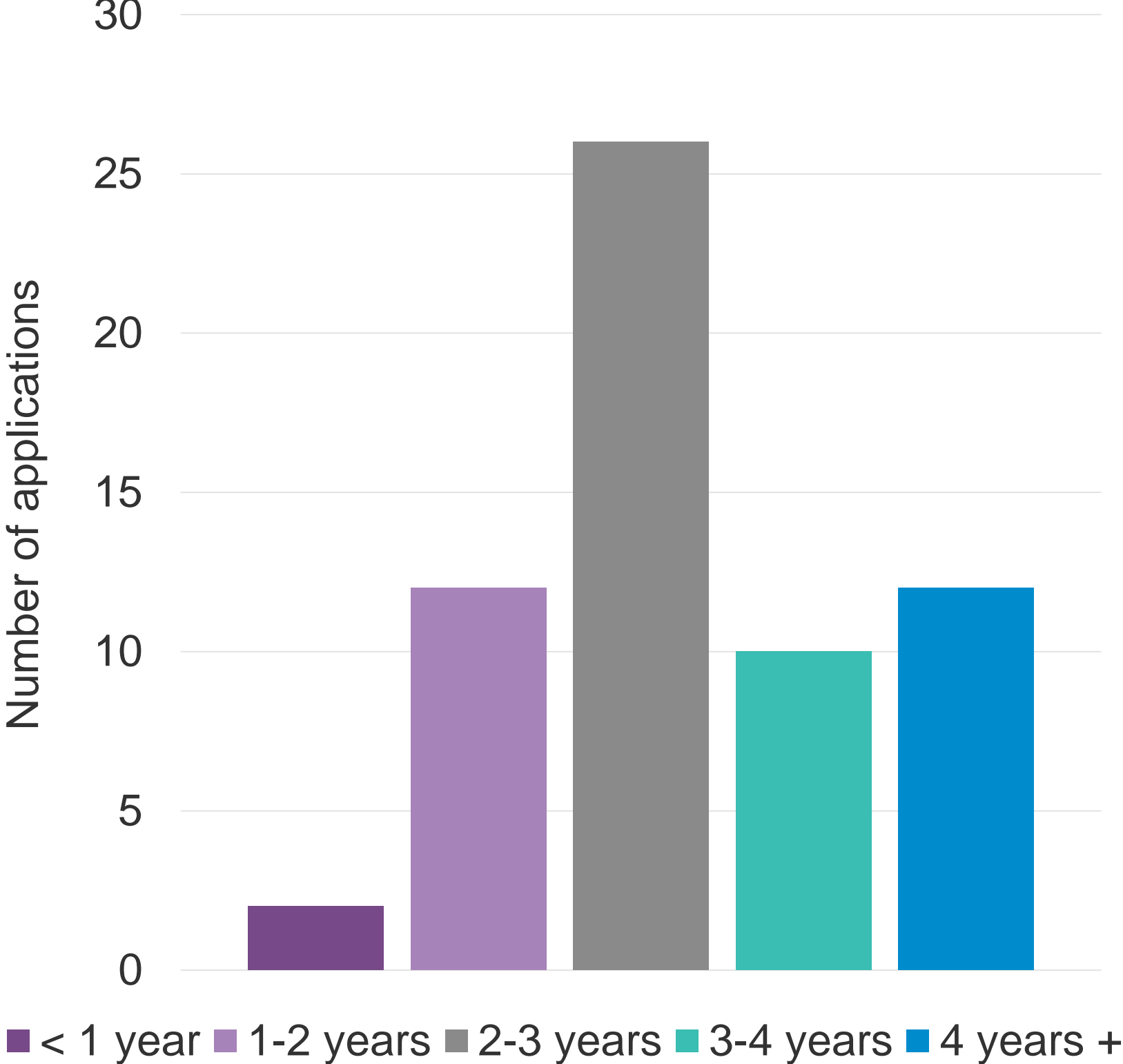
TABLE 2. RECOMMENDATION RATE AND RESUBMISSIONS

Variable	n	%
Overall recommendation		
Positive	62	78%
Negative	18	23%
First meeting recommendation		
Positive	38	48%
Negative	22	28%
Deferred	20	25%
Resubmissions		
Applications with ≥1 resubmission	29/80	36%
Number of resubmissions	69/120	58%

Conclusions

- Time to MBS listing has improved since 2016, however significant delays remain.
- There is substantial variation in listing times. Future research should consider regression analysis to understand the impact of submission characteristics on listing timelines.
- The post-MSAC process lacks transparency. Reasons for delay warrant further investigation.

Acknowledgements