# Algorithm models for extended genotyping applications in high-risk HPV screening and persistence tracking

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ASCCP Improving Lives Through the Prevention & Treatment of Anogenital & HPV-Related Diseases

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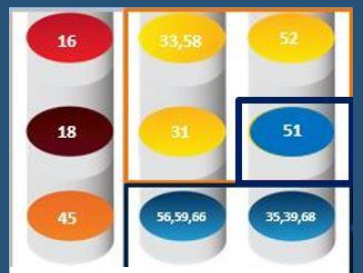
# Disclosures

- Full-time employee of BD

# Methods

- Two principles for cervical cancer screening and management were accepted: programs will be risk-based & similar management for similar risk
- The prevailing USA action thresholds for retesting in 12 months and referral to colposcopy were accepted.
- The current best evidence for risk of CIN3+ by genotype and cytology results was applied under 3 screening paradigms: cytology with HPV triage, cotesting, and primary HPV with cytology triage.
- The hierarchical method for assigning mixed infections to the genotype with highest positive predictive value was accepted.
- The discriminated risks were applied against the accepted action thresholds to generate algorithmic decision trees.

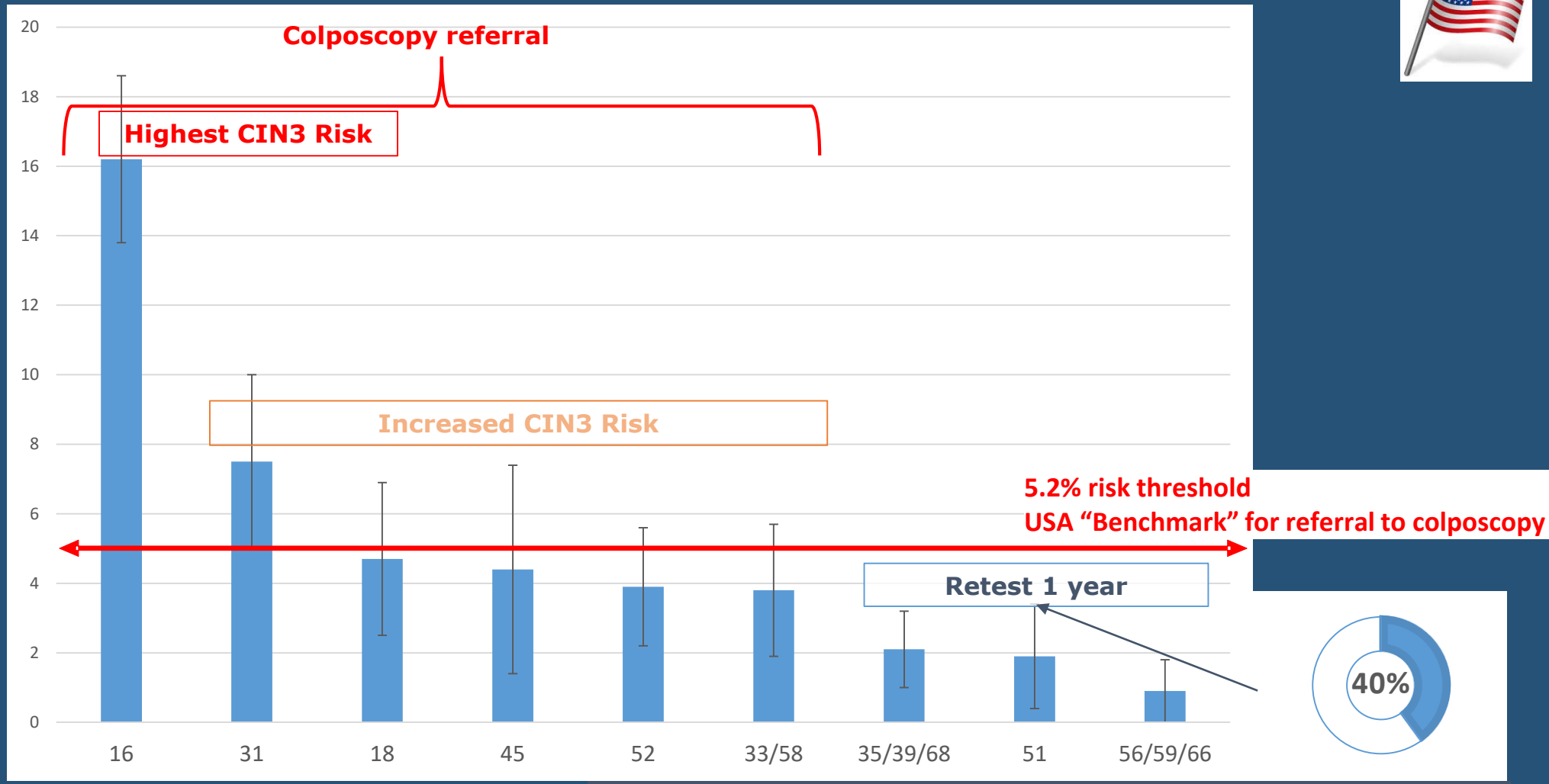
# ASC-US, risk-based management with extended genotyping




**HPV assay**

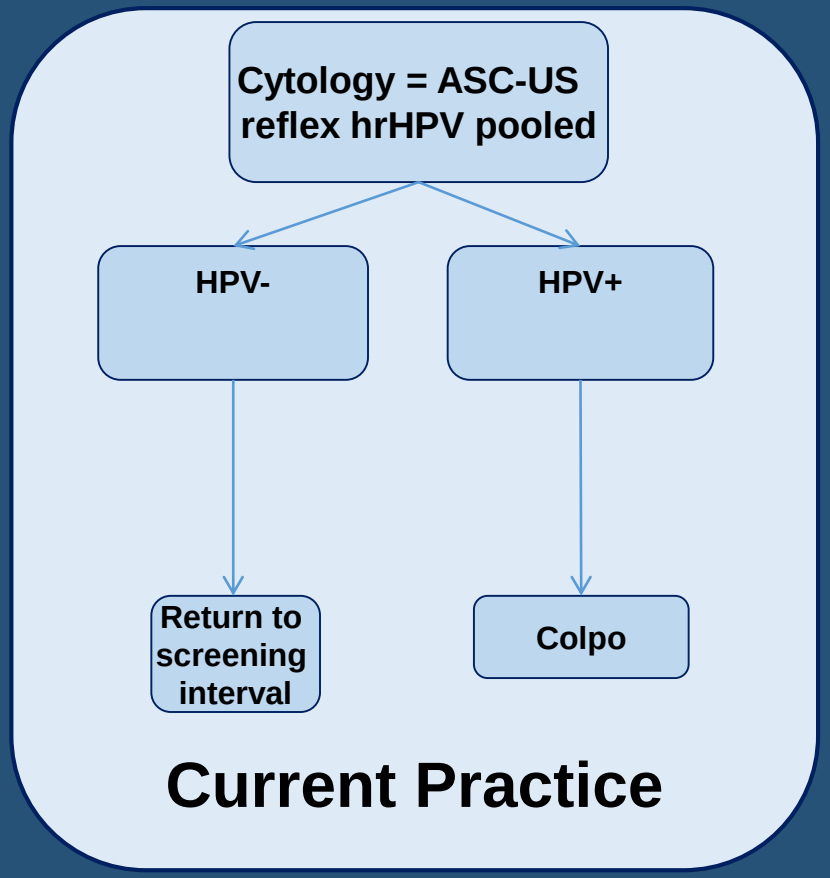
**Total ASC-US+ women = 6,125**
(N=937,922)

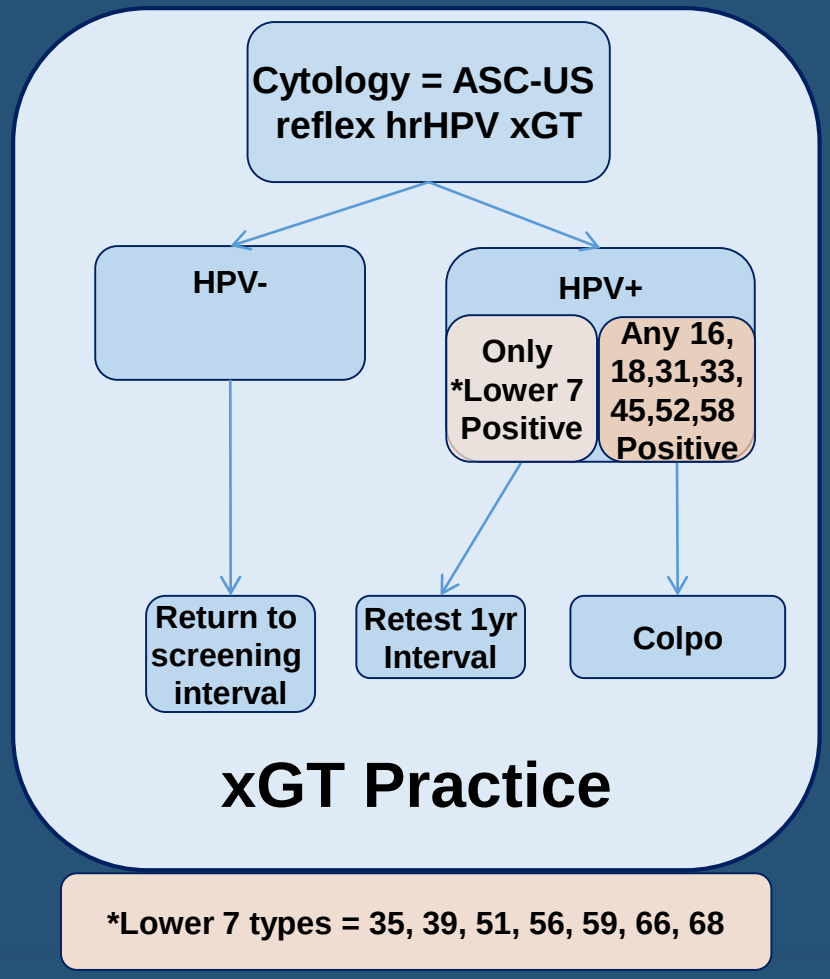
**Composite from:**
Onclarity 2018,
Wheeler 2014 IJC,
Monsonego 2015 GO,
Schiffman 2015 GO




**40% of all HPV+ ASC-US cases fall into the lower risk category. Half of these would retest negative at the 1-year follow-up**

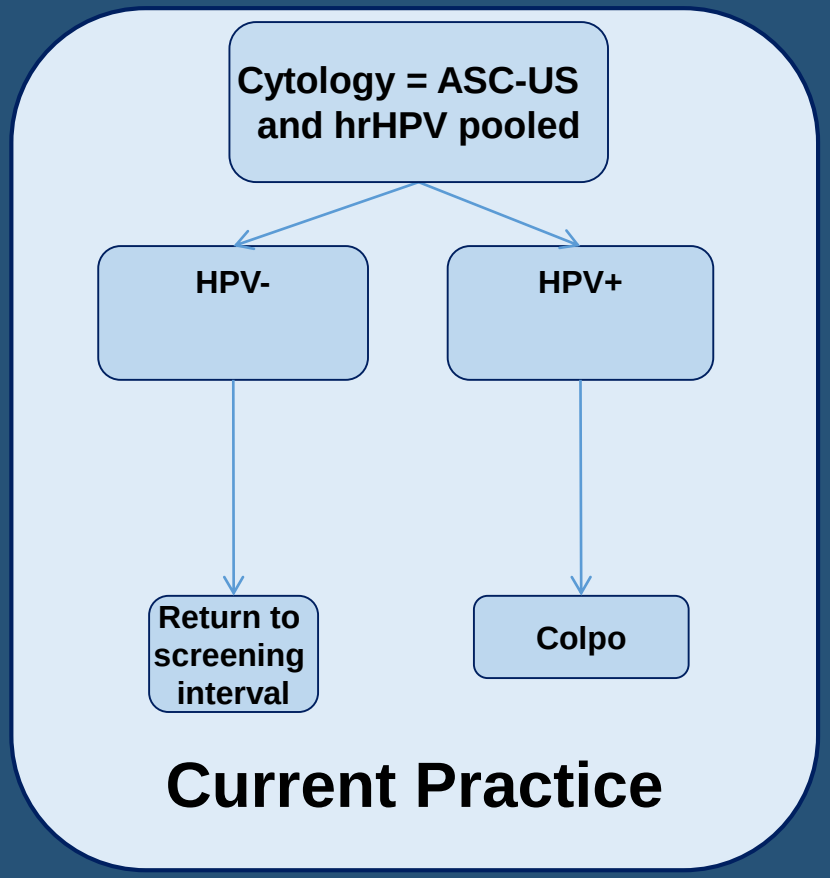
# Cytology with ASC-US Reflex – Current vs xGT option

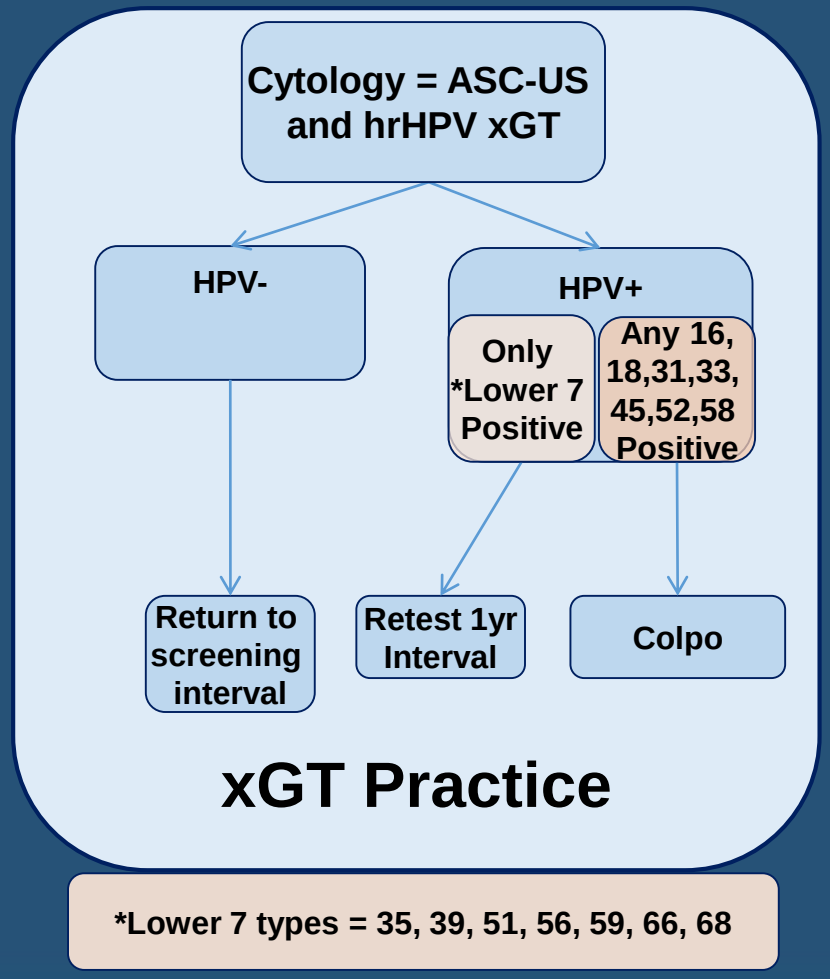



*Lower 7 types = 35, 39, 51, 56, 59, 66, 68

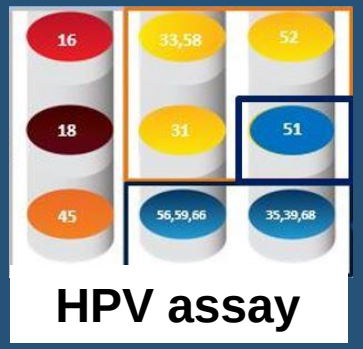
# Co-Testing with ASC-US result– Current vs xGT option




*Lower 7 types = 35, 39, 51, 56, 59, 66, 68

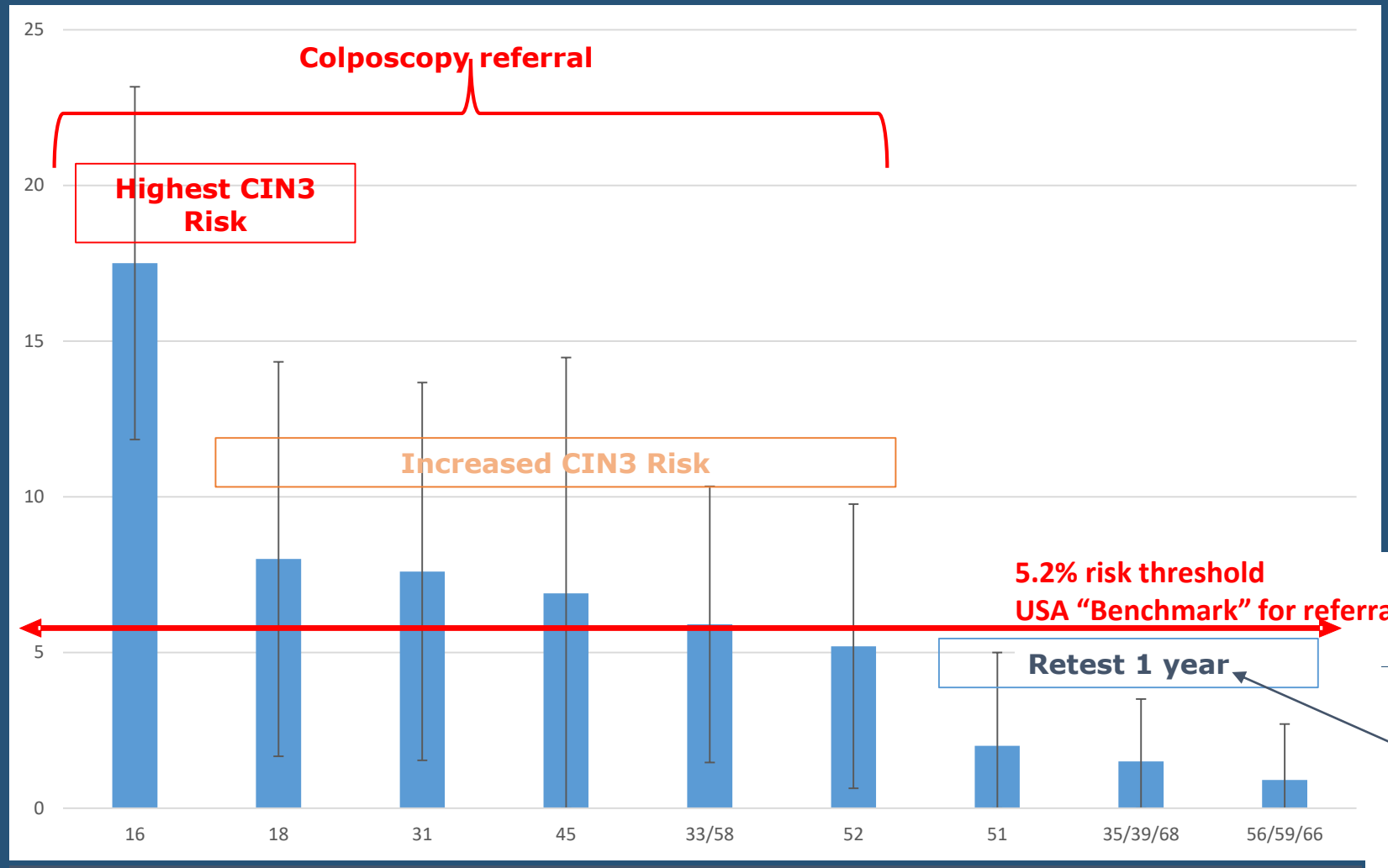
# LSIL, risk-based management with extended genotyping

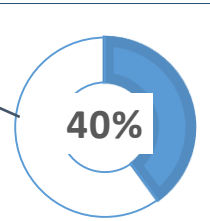



**HPV assay**

**Total LSIL+ women = 1275**
(N=81,399)

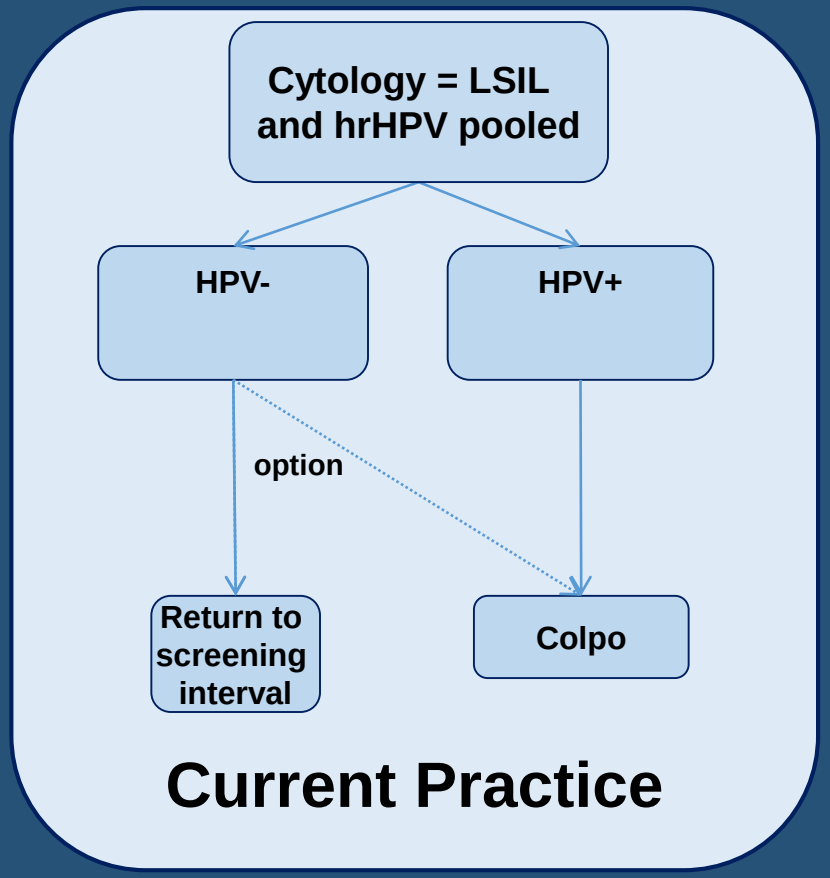
**Composite from:**
Onclarity 2018,
Wheeler 2014 IJC

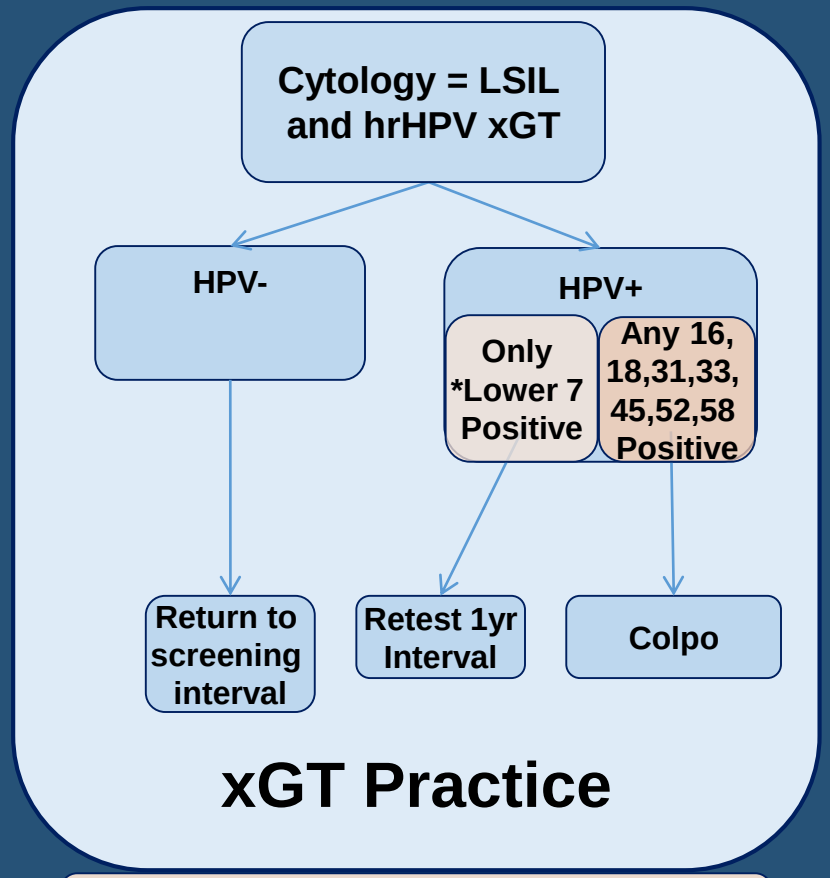



**40% of all HPV+ LSIL cases fall into the lower risk category.**
**Half of these would retest negative at the 1-year follow-up**

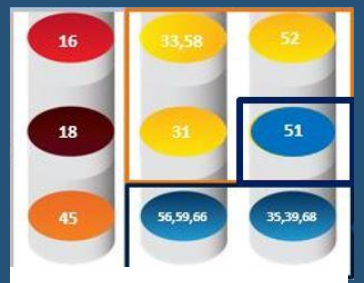
# Co-Testing with LSIL result– Current vs xGT option




*Lower 7 types = 35, 39, 51, 56, 59, 66, 68

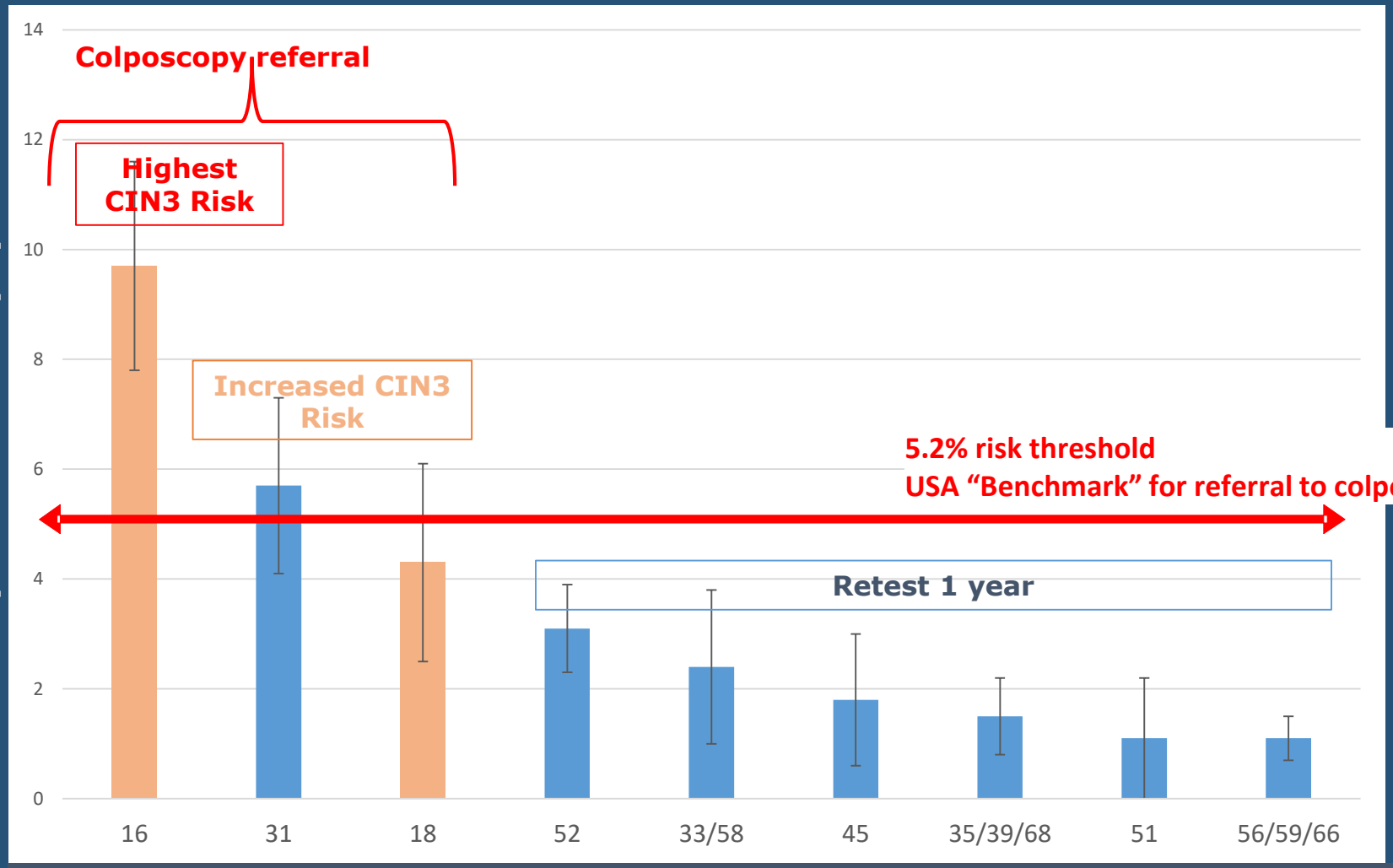
# NILM, risk-based management with extended genotyping




**HPV assay**

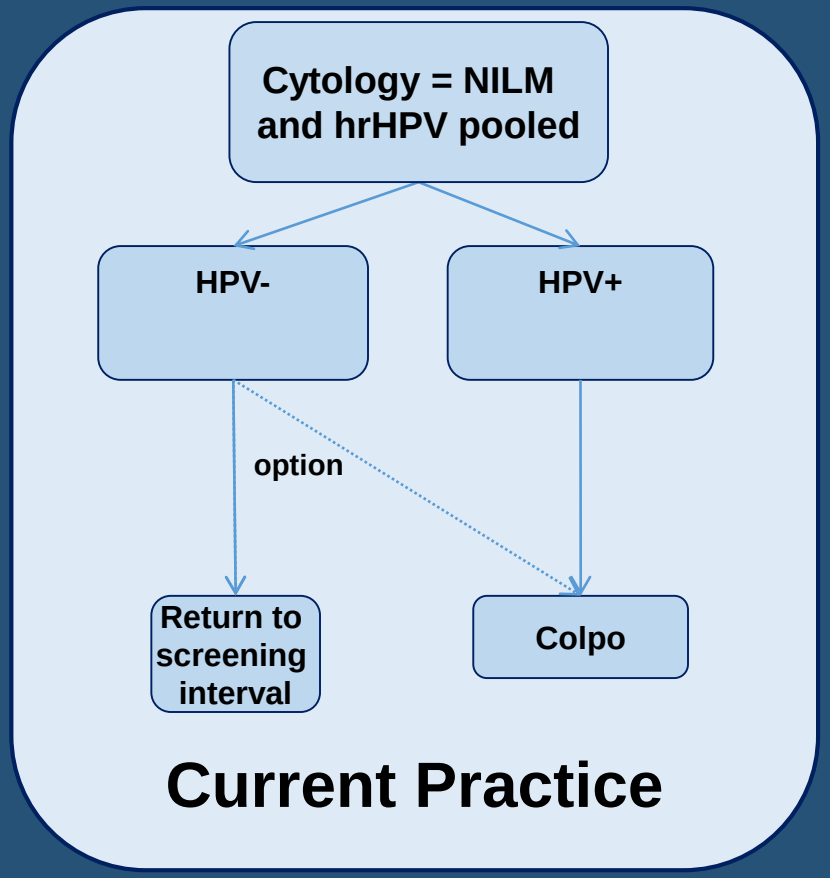
**Total NILM+ women = 16,801**
(N=840,380)

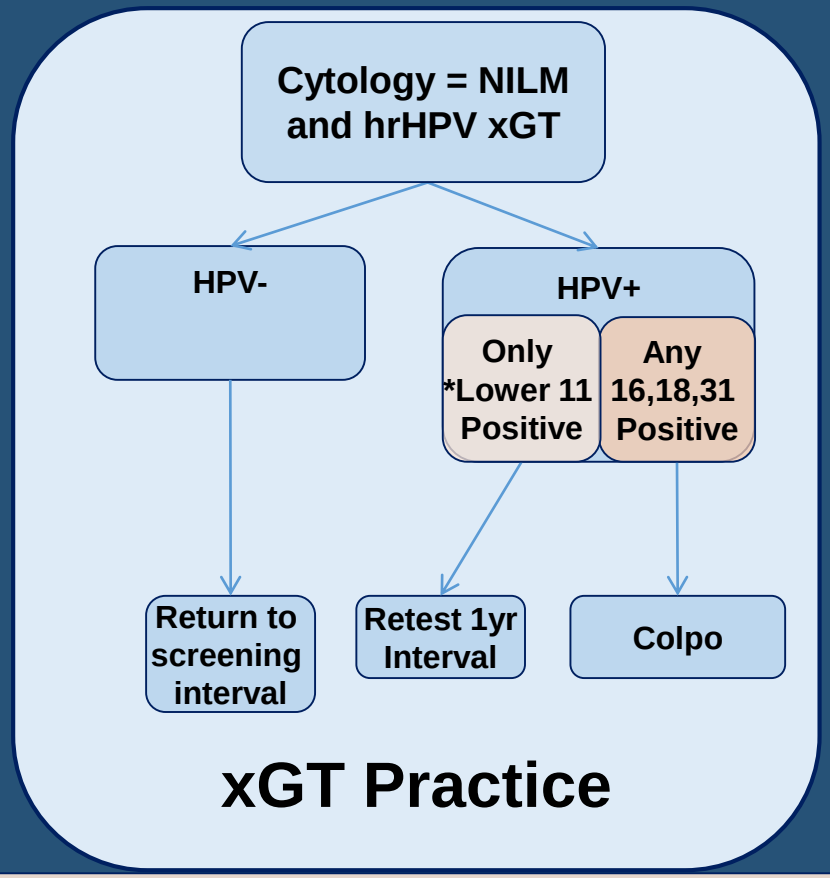
**Composite from:**
Onclarity 2018,
Schiffman 2015 JCM,
Wheeler 2014 IJC,
Monsonego 2015 GO,
Schiffman 2016 IJC




**Under the principle of equal management for equal risk, HPV31+ should be managed like HPV18+**

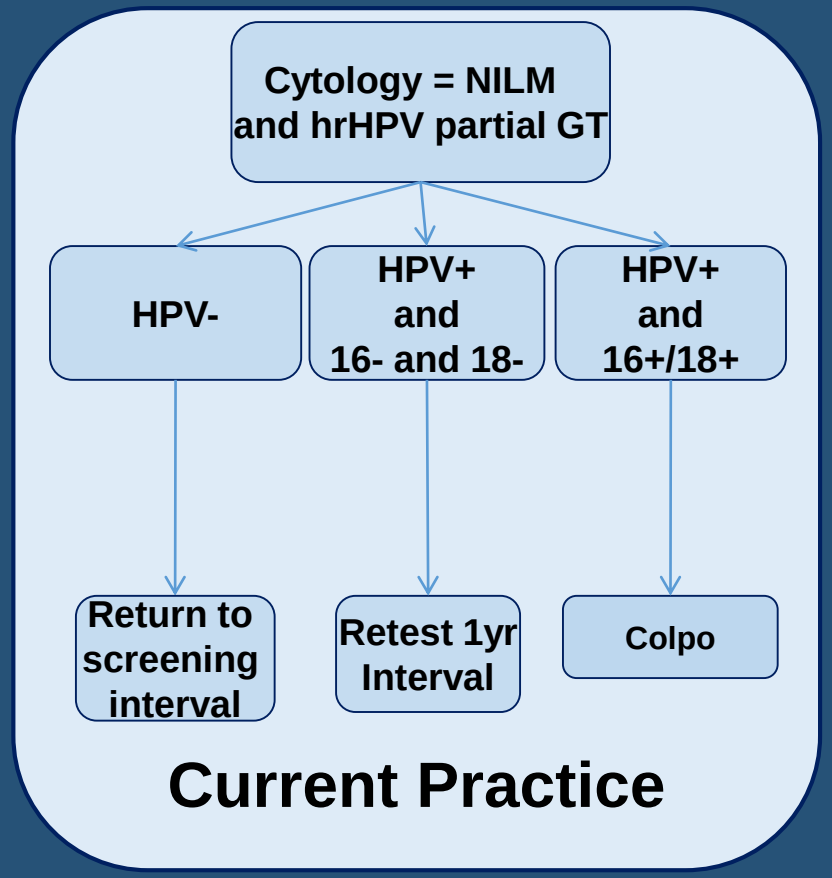
# Co-Testing with NILM result– Current pooled vs xGT option

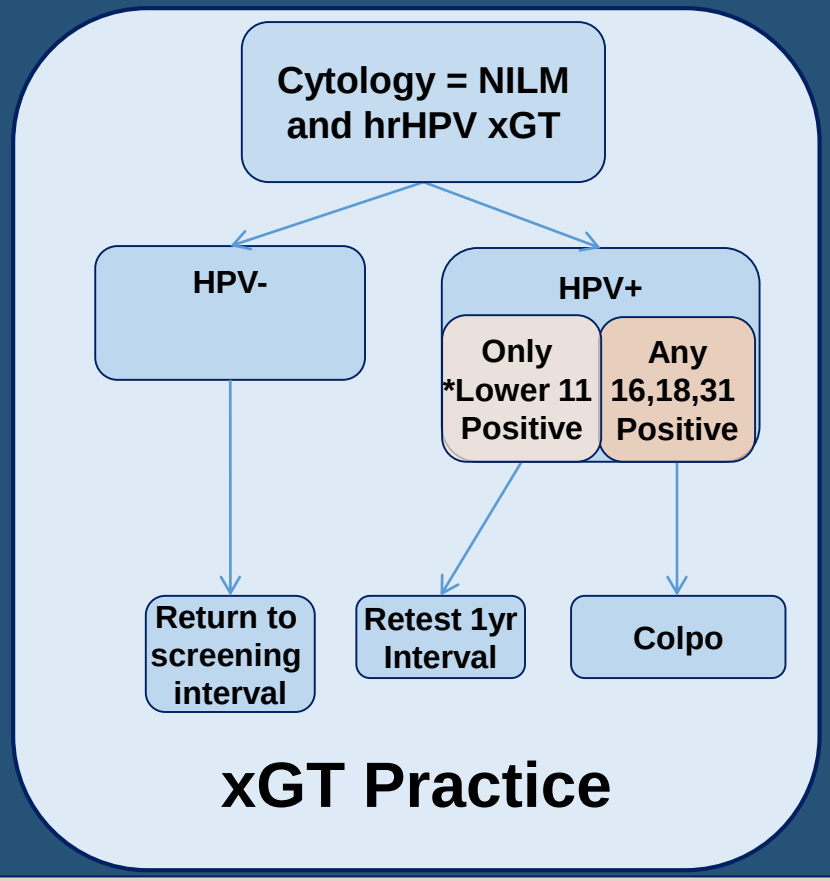



*Lower 11 types = 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68

# Co-Testing with NILM result– Current partial vs xGT

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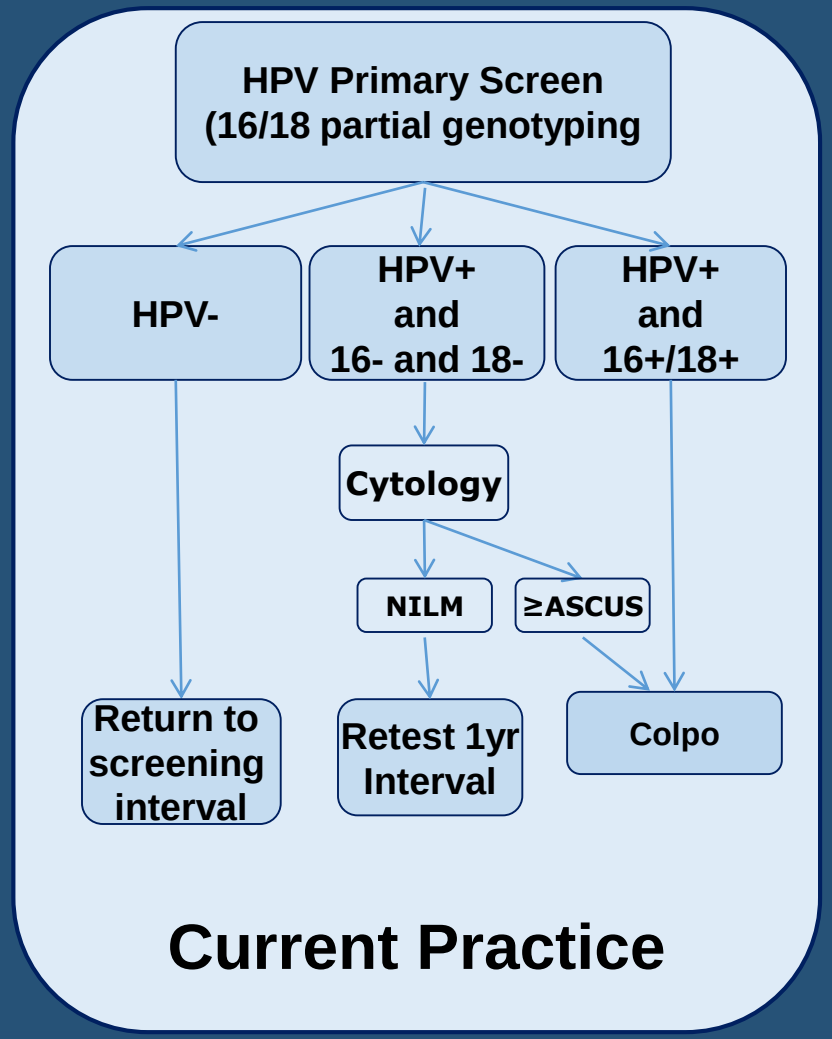
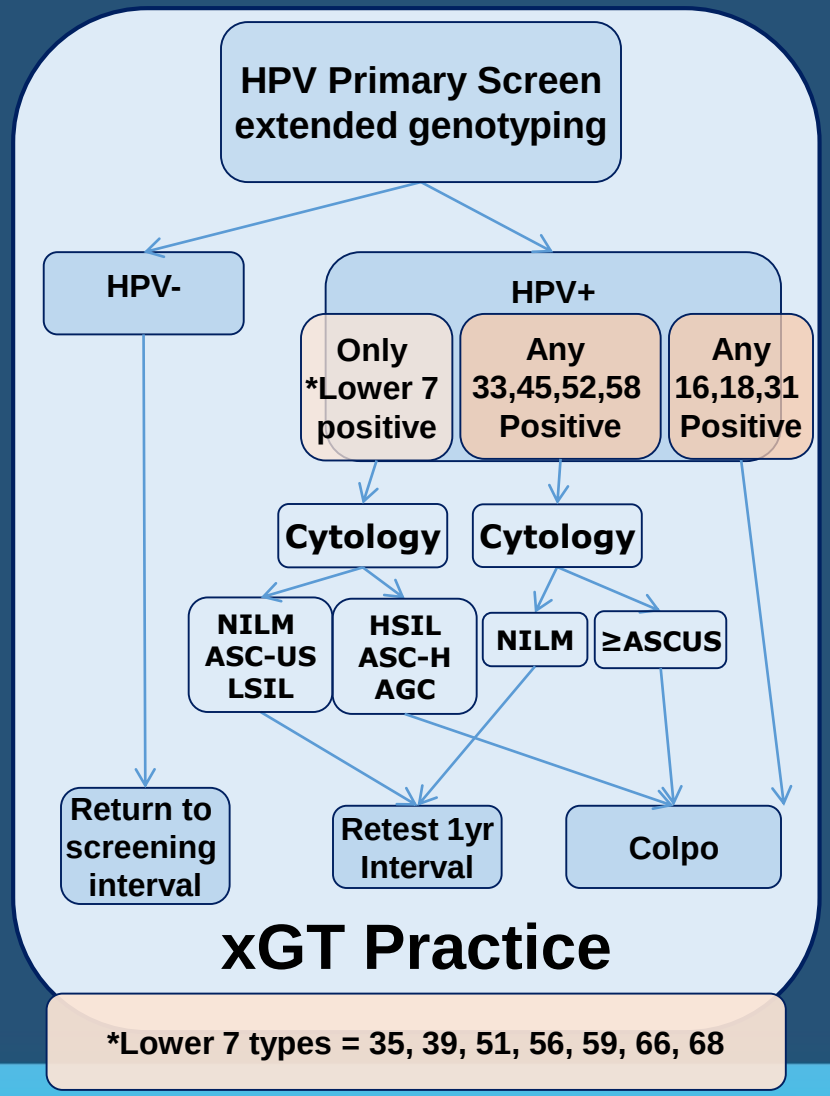
# Primary Screen - Current partial vs xGT option (apply equal management for equal risk)




*Lower 7 types = 35, 39, 51, 56, 59, 66, 68

# Conclusions

- Current ASCCP and SGO guidelines include recommendations for positive results of limited genotyping (16/18).
- Meijer criteria and VALGENT validation of HPV extended genotype (xGT) assays testing have been met by four assays.
- xGT for all hrHPV genotypes may be included by future guideline panels.
- The NCI and ASCCP have published collaborative plans to develop new decision support tools that utilize big data and mobile applications.
- Static decision tree algorithms may be replaced by these new modalities; in the interim, algorithms can support modeling and inform debate.

# Thank you

BD Associates: Charles Cooper, Salma Kodsi, Karen Eckert, Karen Yanson, Devin Gary, Edith Torres-Chavolla, Larry Vaughan, Paul Holt, Doug Malinowski, Meredith Seagraves, Giselle Bonet, Tracy Gambrell