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An Analysis of Clinical Documentation Submitted with Diagnostic Exome Sequencing Orders and the Added Burden or Benefit of Insurance Billing

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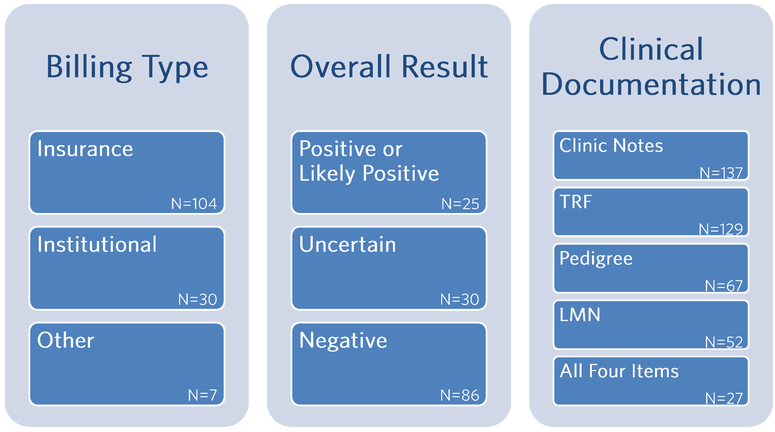
BACKGROUND

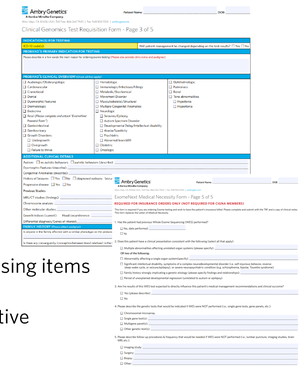
- Comprehensive clinical history is important for accurate interpretation of diagnostic exome sequencing (DES) results[1] and securing insurance preauthorization.
- Required or recommended documentation for DES testing includes a test requisition form (TRF), clinic notes, letter of medical necessity (LMN) and pedigree.
- Follow-up may be needed by laboratory personnel to request this documentation if not provided at time of order.
- This project explores the practices, variables, and impact of submitting clinical documentation for DES. Research questions include:
  - Does the quantity and/or quality of clinical documentation influence the overall diagnostic rate and/or reimbursement of DES?
  - What factors increase submission of required or recommended clinical documentation for DES orders?
  - What is the burden of missing clinical documentation on laboratory operations?

DATA COLLECTED FOR 141 PROBAND-ONLY DES CASES



METHODS

- 141 unselected proband-only DES cases ordered between April 20, 2018 and November 13, 2018 were retrospectively reviewed for:
  - Billing type
    - Insurance
    - Institutional
    - Other
  - Clinical documentation
    - Clinic notes
    - TRF clinical page
    - Internal LMN form
    - Pedigree
  - Need to follow-up for missing items
  - Overall results reported
    - Positive or Likely Positive
    - Uncertain
    - Negative
- Variables were compared and analyzed to determine trends



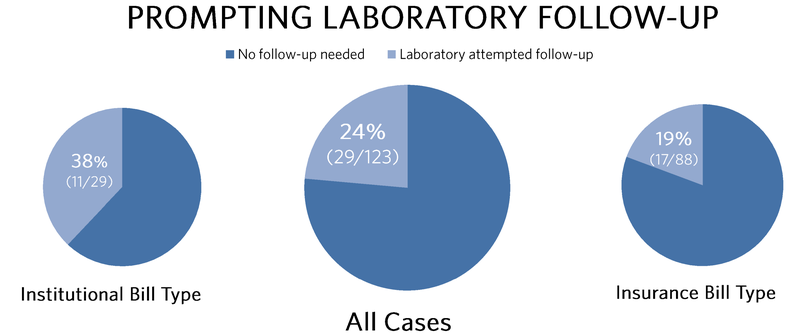
SUMMARY OF CLINICAL DOCUMENTATION SUBMITTED BY BILL TYPE AND OVERALL RESULT CATEGORY

	INSURANCE n	%bill	%result	INSTITUTIONAL n	%bill	%result	OTHER n	%bill	%result	TOTALS n	%all
POSITIVE OR LIKELY POSITIVE	19	18%	76%	3	10%	12%	3	43%	12%	25	18%
Clinic Notes	100%			100%			100%			100%	
TRF Clinical Page	95%			100%			100%			96%	
Pedigree	63%			33%			33%			56%	
LMN Form	42%			33%			33%			40%	
All Four Items	26%			0%			33%			24%	
UNCERTAIN	23	22%	77%	5	17%	17%	2	29%	7%	30	21%
Clinic Notes	100%			80%			100%			97%	
TRF Clinical Page	100%			100%			100%			100%	
Pedigree	43%			40%			50%			43%	
LMN Form	57%			0%			50%			47%	
All Four Items	26%			0%			0%			20%	
NEGATIVE	62	60%	72%	22	73%	26%	2	29%	2%	86	61%
Clinic Notes	97%			95%			100%			97%	
TRF Clinical Page	90%			77%			100%			87%	
Pedigree	48%			41%			50%			47%	
LMN Form	40%			9%			50%			33%	
All Four Items	24%			0%			0%			17%	
TOTALS (n, %all)	104		74%	30		21%	7		5%	141	
Clinic Notes	98%			93%			100%			97%	
TRF Clinical Page	93%			83%			100%			91%	
Pedigree	50%			40%			43%			48%	
LMN Form	44%			10%			43%			37%	
All Four Items	25%			0%			14%			19%	

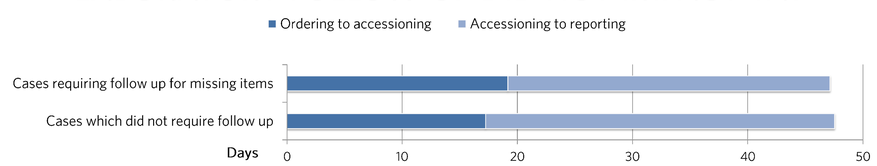
RESULTS

- 39% of all cases had a relevant finding reported (P/LP or uncertain)
  - 40% of insurance versus 27% of institutional cases
- 19% of all cases had all four required and recommended clinical items
  - 25% of insurance versus 0% of institutional cases
  - Lower submission rates observed across all items measured for institutional compared to insurance, with largest difference in LMN
- 97% of all cases had clinic notes; 48% of cases had a pedigree
  - The only 4 DES cases without clinic notes were all adult patients
  - All cases with a positive or likely positive result had clinic notes
- 24% of straight DES orders (excluding reflex or add-ons) required follow-up to request missing clinical items prior to DES analysis
  - 19% of insurance versus 38% of institutional cases
  - 1-3 attempts were made to retrieve these items and this did not impact turn-around-time (TAT)
  - The majority of requests were for clinic notes
- There were no statistically significant differences in the distribution of billing type according to results (%result), or in the distribution of results according to billing type (%bill)
- Future directions include:
  - Cohort expansion
  - Quality assessment
  - Measures of reimbursement

DES ORDERS* WITH MISSING CLINICAL DOCUMENTATION PROMPTING LABORATORY FOLLOW-UP



LABORATORY FOLLOW-UP DID NOT IMPACT TAT*



*This data excluding reflex, add-on, and rapid DES orders

TAKE-HOME POINTS

- Cases with insurance bill type may be more likely to have the required and recommended clinical documentation for DES testing:
  - Are ordering providers more likely to submit this documentation due to preauthorization requirements?
  - Are laboratories more likely to request additional documentation in efforts to improve reimbursement?
- Insurance cases may be more likely to have a relevant finding reported on DES compared to institutional cases:
  - Is this a reflection of better DES interpretation due to more clinical documentation submitted in this group?
  - Could this be a consequence of stricter insurance criteria for DES creating a selection bias?

REFERENCES

1. Bush L, et al. *Genet Med* 2018;20:169-71