genomDE

Chancen einer besseren Diagnostik Seltener Erkrankungen
im Rahmen der genomDE-Initiative:

Erfahrungen aus dem Innovationsfond-Projekt „Translate-NAMSE“

H. Krude
für die Vertreter des Themas Seltene Erkrankungen in genomDE:
Ch. Mundlos, M. Nöthen, O. Riess,H. Krude

heiko.krude@charite.de

TRANSLATE NAMSE

Berliner Centrum für Seltene Erkrankungen

CHARITÉ UNIVERSITÄTSMEDIZIN BERLIN

Definition der Seltenen Erkrankung in der EU: Prävalenz von < 1 in 2000

REGULATION (EC) No 141/2000 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 December 1999
on orphan medicinal products

Article 3

Criteria for designation

1. A medicinal product shall be designated as an orphan medicinal product if its sponsor can establish:

(a) that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons in the Community when the application is made, or

Country / Continent	RD Prevalence definition per 100 000
Korea [10]	5
Australia [11]	10
Taiwan [12]	10
Japan [13]	40
EU [4]	50
China [14]	76
USA [9]	80

European Journal of Human Genetics (2020) 28:165–173
https://doi.org/10.1038/s41431-019-0508-0

ESHG

ARTICLE

Estimating cumulative point prevalence of rare diseases: analysis of the Orphanet database

Stéphanie Nguengang Wakap[1] · Deborah M. Lambert[2] · Annie Olry[1] · Charlotte Rodwell[1] · Charlotte Gueydan[1] · Valérie Lanneau[1] · Daniel Murphy[1] · Yann Le Cam[3] · Ana Rath[1]

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Insgesamt > 4500 verschiedenen Erkrankungen

Min 3% der Bevölkerung betroffen

75% genetische Ursache

80% Manifestation im Kindesalter

European Journal of Human Genetics (2020) 28:165–173
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Das gemeinsame der Seltenen Erkrankungen: Problem-Trias

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Seltenen Erkrankung: Gemeinsame Problem“Trias“

1. Späte Diagnose (Diagnose-Odyssee)
2. Fehlende Behandlungsexpertise
3. Fehlende Medikamentenentwicklung

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3.7.2009 EN Official Journal of the European Union C 151/7

COUNCIL RECOMMENDATION
of 8 June 2009
on an action in the field of rare diseases
(2009/C 151/02)

Strukturen für die Seltenen Erkrankungen: NAMSE

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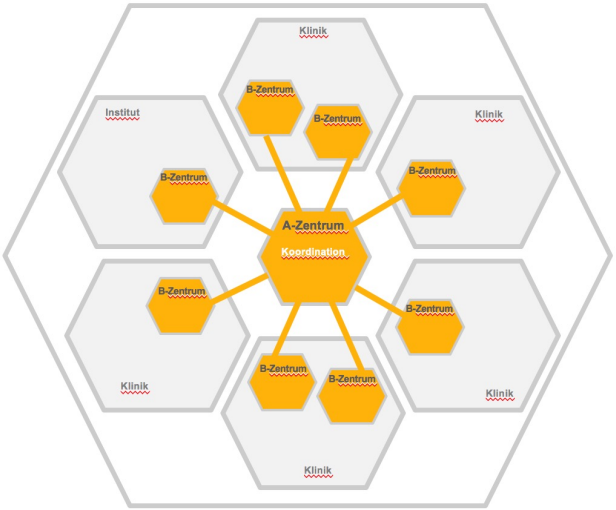

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NAMSE
Nationales Aktionsbündnis für Menschen mit Seltenen Erkrankungen

AAA | Impressum | Sitemap | English | Suche:

NAMSE
Nationales Aktionsbündnis für Menschen
mit Seltenen Erkrankungen

Nationaler Aktionsplan
für Menschen mit Seltenen Erkrankungen
Handlungsfelder, Empfehlungen und Maßnahmenvorschläge

2013

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genomDE

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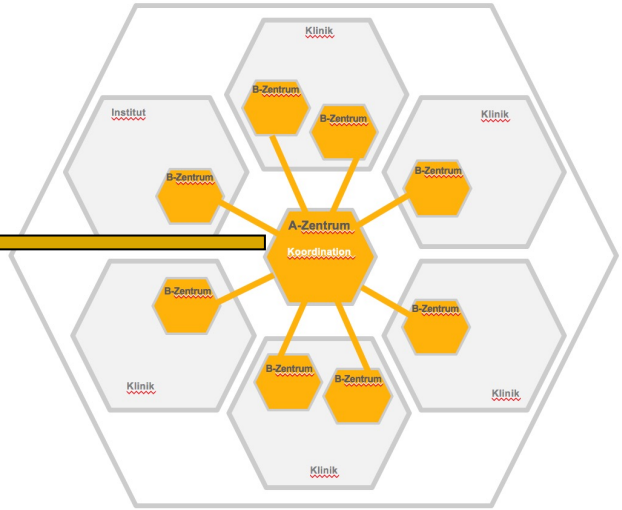

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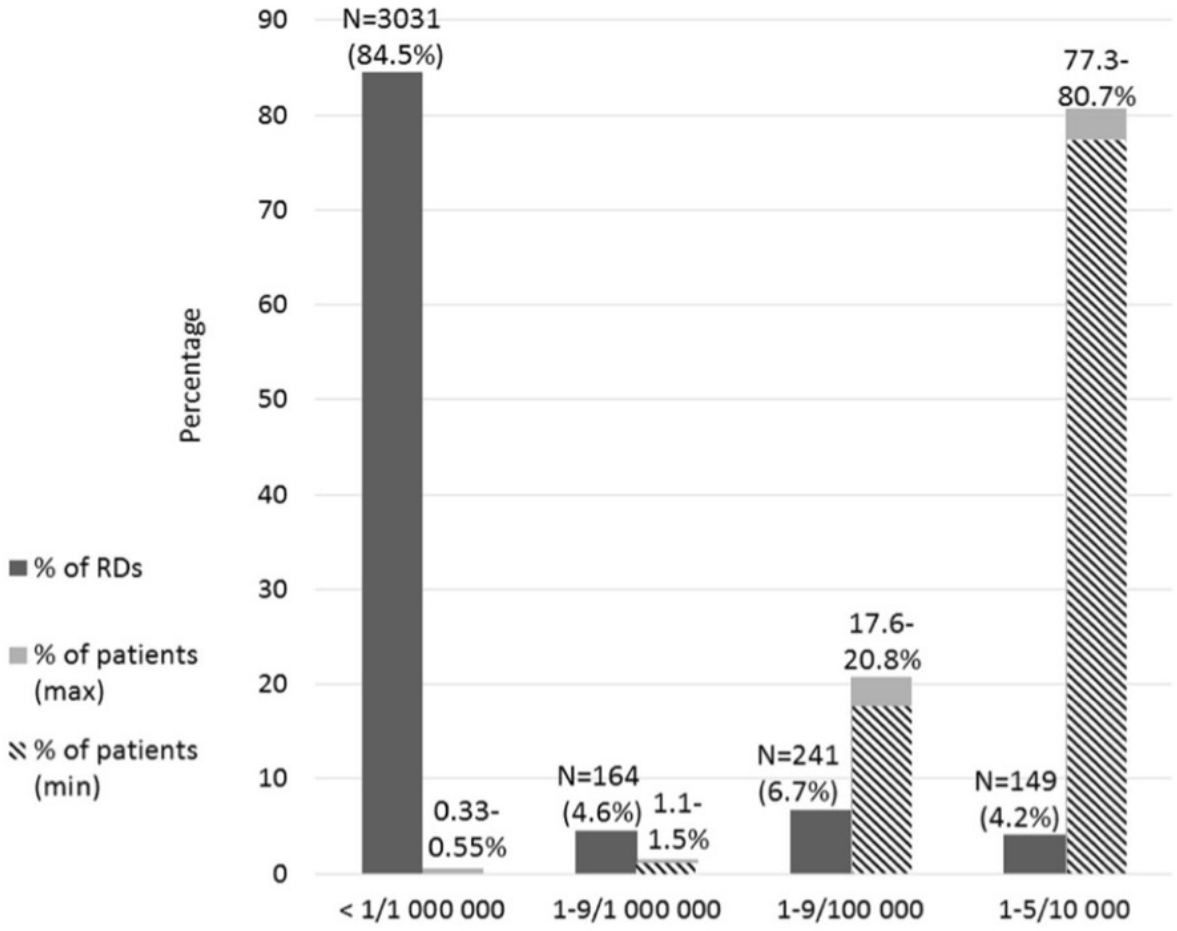
Spektrum der Seltenen Erkrankung: common-rare / extremely rare

>80% Manifestation im Kindesalter

>75% genetische Erkrankungen



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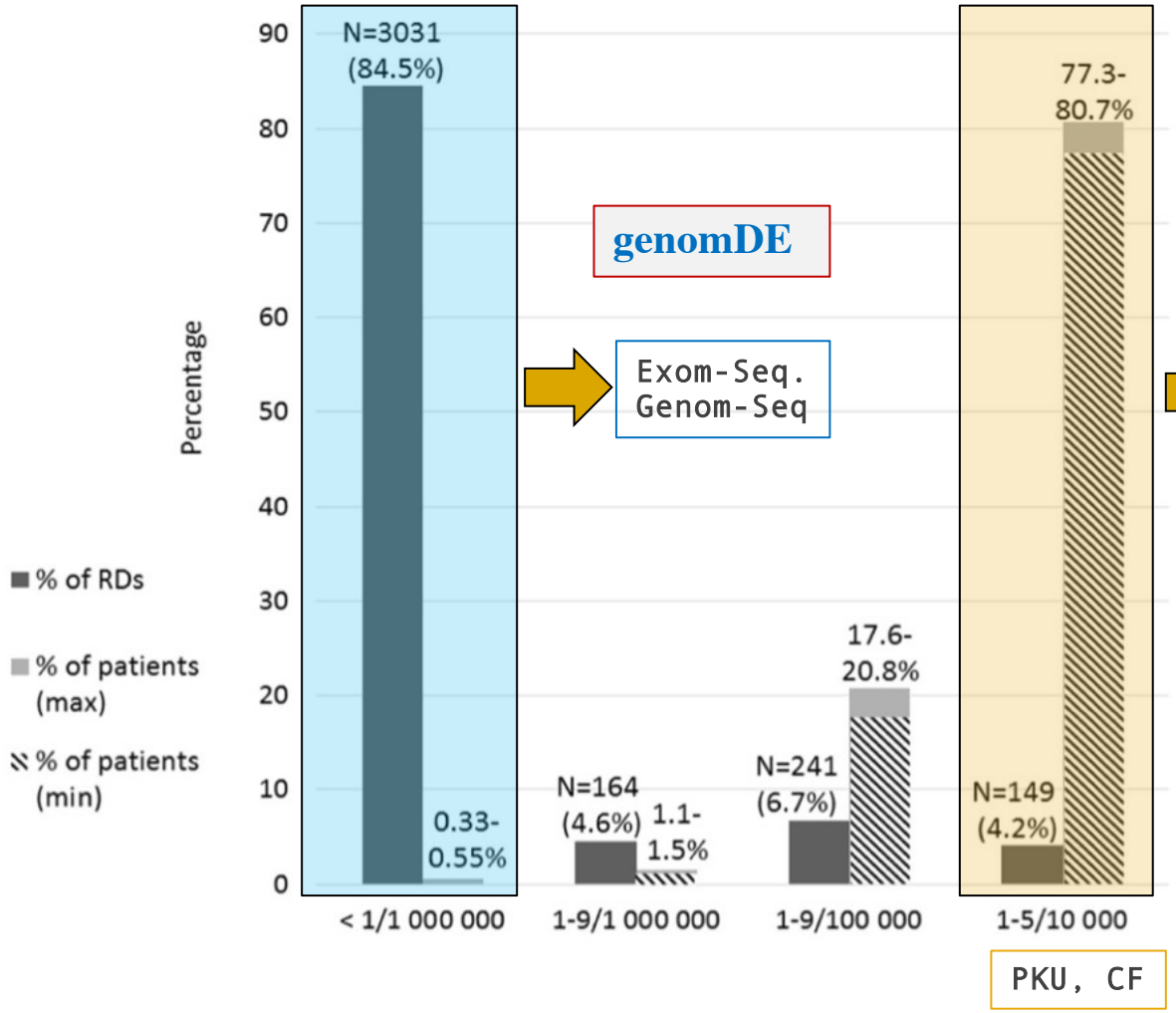

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Erfahrung aus „Translate-NAMSE“ zur Diagnostik Seltener Erkrankungen:

TRANSLATE NAMSE

Kooperation:
NAMSE-A-Zentren
Klinker:innen
Humangenetik

Pressemitteilung

Gemeinsamer Bundesausschuss Innovationsausschuss

Innovationsausschuss beim Gemeinsamen Bundesausschuss gemäß § 92b SGB V

Nr. 07 / 2016

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Telefon: 030 275838-811
Fax: 030 275838-805
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www.g-ba.de/presse-rss

Innovationsausschuss

Förderentscheidungen über innovative Projekte zu neuen Versorgungsformen in der GKV getroffen

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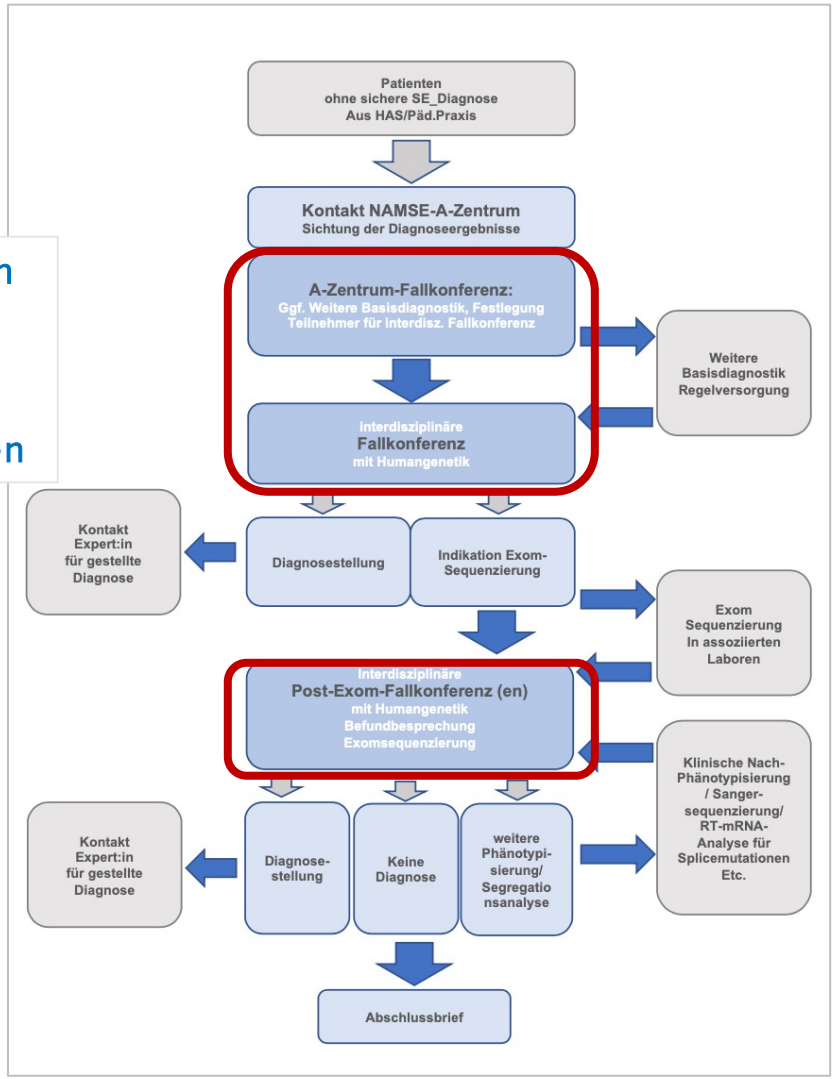
Exom-Indikation und Bewertung in Fallkonferenzen



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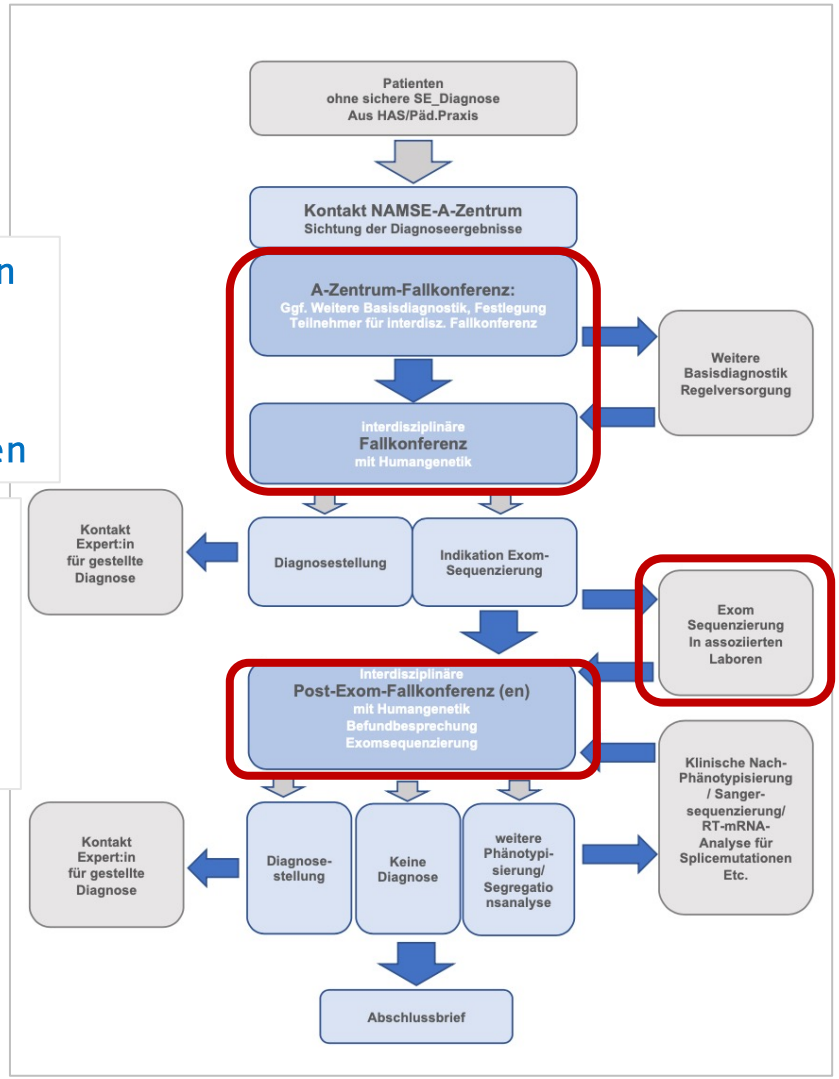
Exom-Indikation und Bewertung in Fallkonferenzen

Exom-Diagnostik:
Prof. Nöthe
Prof. Riess
Prof. Mundlos
Prof. Meitinger



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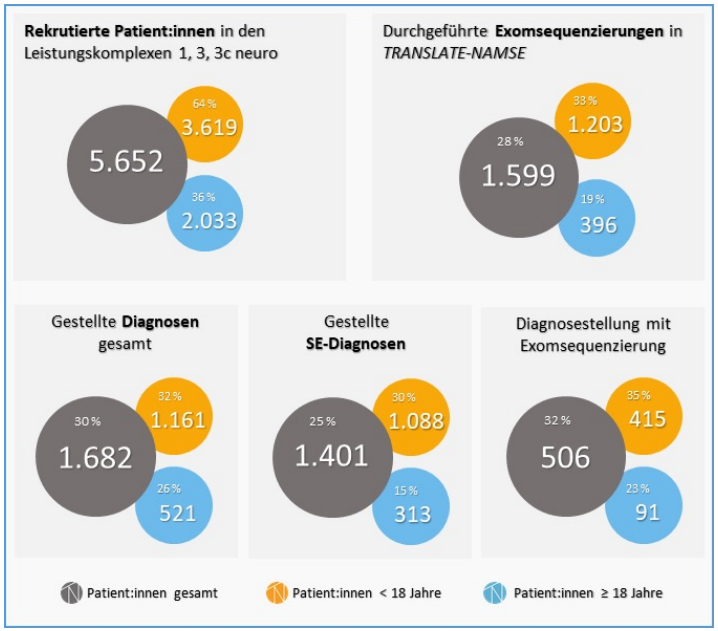

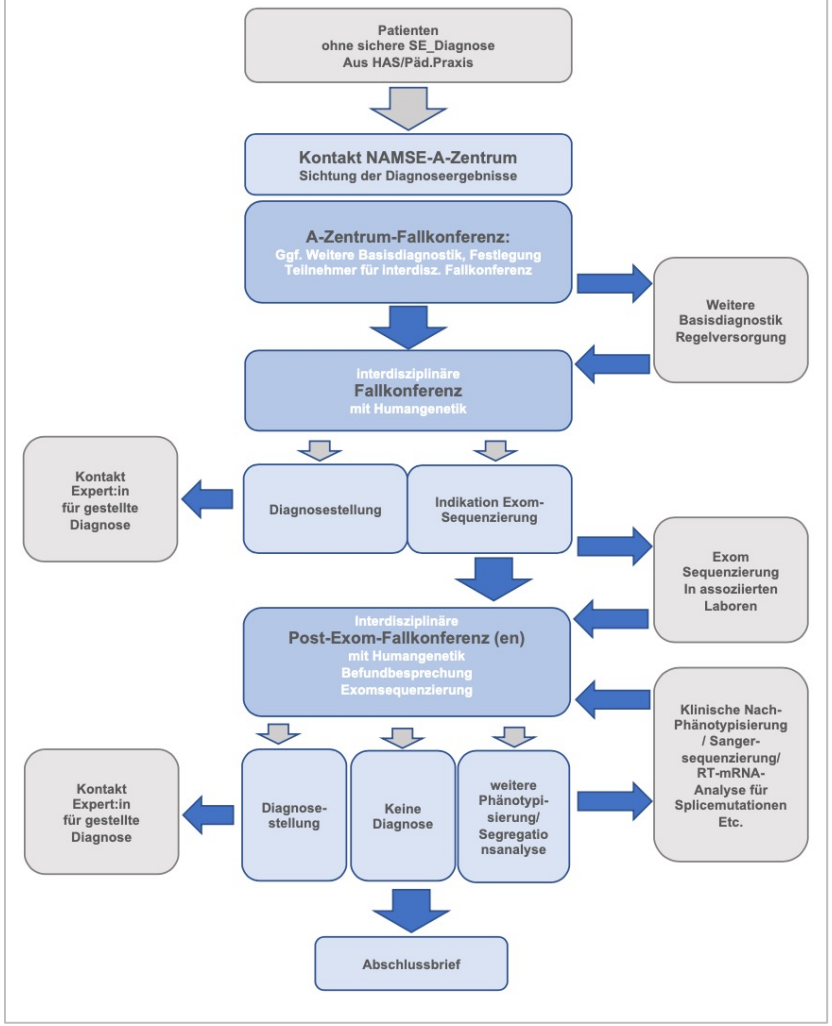

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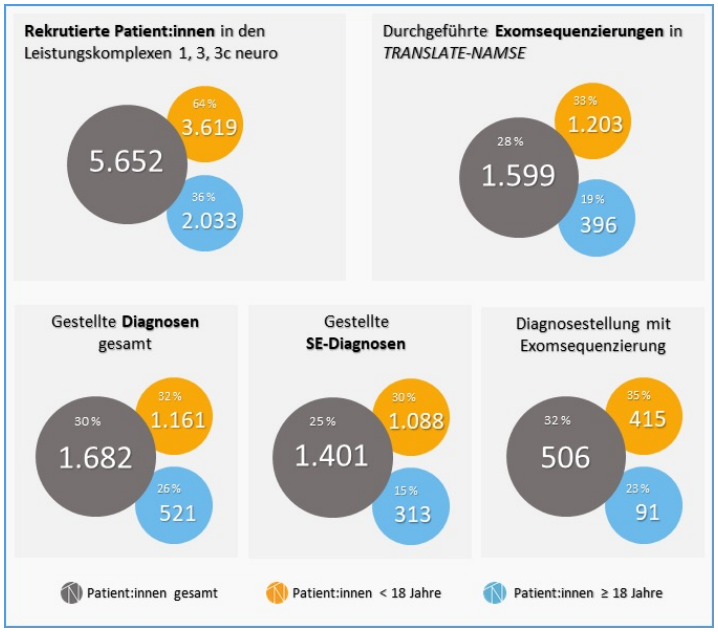

ACOX1	CA2	CTNND1	FOXP2	KCND3	MUT	POLR3A	SETD1A	TRAPPC2
ACTA2	CACNA1A	CUBN	FRMPD4	KCNH1	MUTYH	POLR3B	SETD1B	TREX1
ACTB	CACNA1E	CXorf56	FRRS1L	KCNJ10	MVK	POMGNT1/PPF	SETD2	TRIO
ADAR	CACNA1G	CYFIP2	FZD4	KCNJ2	NAA15	POU3F3	SETD5	TRPM6
ADAT3 / TSPAN	CACNA1S	CYHR1	G6PD	KCNN2	NALCN	PPM1D	SHANK3	TRPV4
ADCY5	CACNA2D2	DCLREC1/EOM	GABRA1	KCNQ5	NEFH	PPP1R12A	SHH	TRRAP
AFF3	CAMK2A	DDX23	GABRA2	KCNT1	NF1	PPP2CA	SLC20A2	TSHZ3
AGO1	CAMK2B / CDH	DDX3X	GATAD2B	KDM3B	NFIA	PPP2R5D	SLC2A1	TTC21B
AGT	CAMTA1	Deletion 15q13	GBA2	KDM5C	NFIX	PQBP1	SLC34A3	TTI1
AHDC1	CAPN3	Deletion 8p21..	GDAP2	KDM6A	NFKB2	PRF1	SLC35C1	TUBB2A
AHI1	CARD11	Deletion Chr17	GHR	KIAA0586	NIPA1	PRPS1	SLC6A8	TUBB3
AIFM1	CASKIN2	DEPDC5	GM2A	KIF2A	NOTCH1	PSMD12	SMARCA5	TUSC3
AKT3	CAV3	DHX30	GNAS	KIF5A	NOTCH2	PTCH1	SMARCC2	UBE3A
ANK2	CD40LG	DLG3	GNB1	KLHL15	NOTCH3	PTEN	SMC1A	UPF1
ANKRD11	CELSR3	DMD	GNB2	KMT2A	NPC1	PTPN11	SMS	USP9X
ANP32A	CHAMP1	DMRT1	GNRHR	KMT2B	NPHS2	PTS	SNX14	VPS13B
AP4M1	CHD1, GNB1, P	DNAAF4	GRIA2	KMT2D	NR2E1	PUF60	SON	VWF
APOB	CHD2	DNAJC2	GRIN2B	KMT5B	NR2F1	PURA	SOS1	WARS2
ARF1	CHD3	DNAJC30	GUCA1A	KY	NRXN1	PYCR1	SOX4	WASHC5/ TGFE
ARID1A	CHD4	DNM1	HBB	LAMA1	NRXN2	RAB3GAP1	SOX5	WDR4
ARID1B	CHD7	DNMT3A	HESX1	LARGE1	NSD1	RAD21	SOX9	WDR45
ARID2	CHD8	DYNC1H1	HEXA	LARS1	NSDHL / AARS1	RAF1	SPATA5L1	WDR73
ARNT2	CHEK2	DYRK1A	HIST1H4C	LAS1L	NUP37	RAI1	SPG7	WRN
ARS/	CHKB	EBF3	HIVEP2	LDHA	NUS1	RARB	SPTAN1	WWOX
ASH:	Chr11	EFTUD2	HK1	LGI3	OGT	RASA1	SSR4	ZBTB18
ASN:								ZBTB24
ASXL								ZMYND11
ATAC								ZNF148
ATM	Chromosom 5	ERF	HSD3B2	MAPK8IP3	PAX2	RORA	SYP	ZNF246
ATP1A3	CLPX	ERI1	HUWE1	MBOAT7	PCDH19	RORB	TAB2	ZNF292
ATP7A	CLTC	ETV6	IDUA	MBTPS1	PDHA1	RSPH1	TALDO1	
AUTS2	CNNM2	EXT2	IFIH1	MDH2	PEPD	RUNX1	TATDN2	
BBS2 / T								
BCL11A								
BCL11B								
BCS1L								
BDNF								
BICD2								
BRAT1								
BRCA2								
BRD4	COL6A2	FKBP14	ITGA8	MT-ATP6	PLAA	SCN8A	SELENON	TGM6
BRIP1	COMP	FLG	ITPR1	MT-ND1	PLCB4	SELENOO	SEMA6B	THOC2
BRWD3	CPT2	FLNB	KANSL1	MT-ND4	PLS3	SEMA6B	SEPN1	THOC6
BTK	CRLF1	FOXC1	KAT6A	MT-ND5	PLXNB3	SEPN1	SERPINA1	THSD1
C10orf118	CSNK2A1	FOXF1	KAT6B	MT-TL1	PMM2	SERPINA1	TMEM67	
C19orf12	CSPP1	FOXG1	KAT6B / FBXO1	mtDNA	POGZ	TMEM70		
	CTNNB1	FOXP1	KCNB1	MTO1	POLD1	SETD1A	TP63	

> 350 verschiedene Gene

>50 Erkrankungen Erstbeschreibung erst während der Projektlaufzeit

Koordination-Exom-Ergebnisse: Prof. P. Krawitz

Erfahrung aus „Translate-NAMSE“ zur Diagnostik Seltener Erkrankungen:

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Kooperation:
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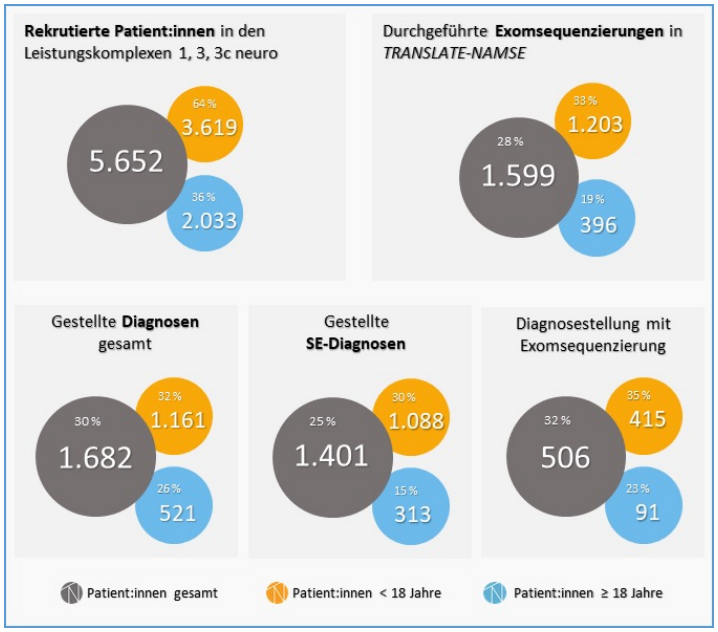
Klinker:innen
Humangenetik



30% Fälle gelöst
(Varianten Kategorie IV/V)

10% Fälle unklar
(Varianten Kategorie III)

60% Fälle ungelöst

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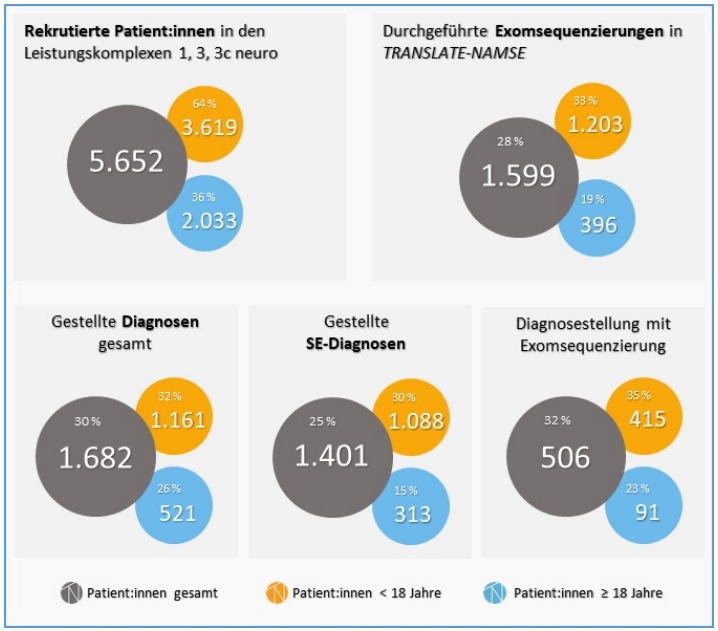

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Genom-Sequenzierung

genomDE

Ziele in genomDE für Seltene Erkrankungen:

Implementierung der Genom-Sequenzierung in den Diagnose-Algorithmus von Patienten mit ungeklärter Seltener Erkrankung

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

100,000 Genomes Pilot on Rare-Disease Diagnosis in Health Care — Preliminary Report

The 100,000 Genomes Project Pilot Investigators

ABSTRACT

BACKGROUND

The U.K. 100,000 Genomes Project is in the process of investigating the role of genome sequencing in patients with undiagnosed rare diseases after usual care and the alignment of this research with health care implementation in the U.K. National Health Service. Other parts of this project focus on patients with cancer and infection.

METHODS

We conducted a pilot study involving 4660 participants from 2183 families, among whom 161 disorders covering a broad spectrum of rare diseases were present. We collected data on clinical features with the use of Human Phenotype Ontology terms, undertook genome sequencing, applied automated variant prioritization on the basis of applied virtual gene panels and phenotypes, and identified novel pathogenic variants through research analysis.

RESULTS

Diagnostic yields varied among family structures and were highest in family trios (both parents and a proband) and families with larger pedigrees. Diagnostic yields were much higher for disorders likely to have a monogenic cause (35%) than for disorders likely to have a complex cause (11%). Diagnostic yields for intellectual disability, hearing disorders, and vision disorders ranged from 40 to 55%. We made genetic diagnoses in 25% of the probands. A total of 14% of the diagnoses were made by means of the combination of research and automated approaches, which was critical for cases in which we found etiologic noncoding, structural, and mitochondrial genome variants and coding variants poorly covered by exome sequencing. Cohortwide burden testing across 57,000 genomes enabled the discovery of three new disease genes and 19 new associations. Of the genetic diagnoses that we made, 25% had immediate ramifications for clinical decision making for the patients or their relatives.

CONCLUSIONS

Our pilot study of genome sequencing in a national health care system showed an increase in diagnostic yield across a range of rare diseases. (Funded by the National Institute for Health Research and others.)

The authors' full names, academic degrees, and affiliations are listed in the Appendix. Dr. Caulfield can be contacted at m.j.caulfield@qmul.ac.uk or at Genomics England, William Harvey Research Institute, Queen Mary University of London, London EC1M 6BQ, United Kingdom.

Drs. Smedley and Smith, Mr. Martin, and Drs. E.A. Thomas, McDonagh, Cipriani, Ellingford, Arno, Tucci, Vandrovcova, Chan, and H.J. Williams and Drs. Scott, Fowler, Rendon, and Caulfield contributed equally to this article.

N Engl J Med 2021;385:1868-80.
DOI: 10.1056/NEJMoa2035790

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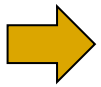

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Prognose-Abschätzung

Patienten-Gewissheit

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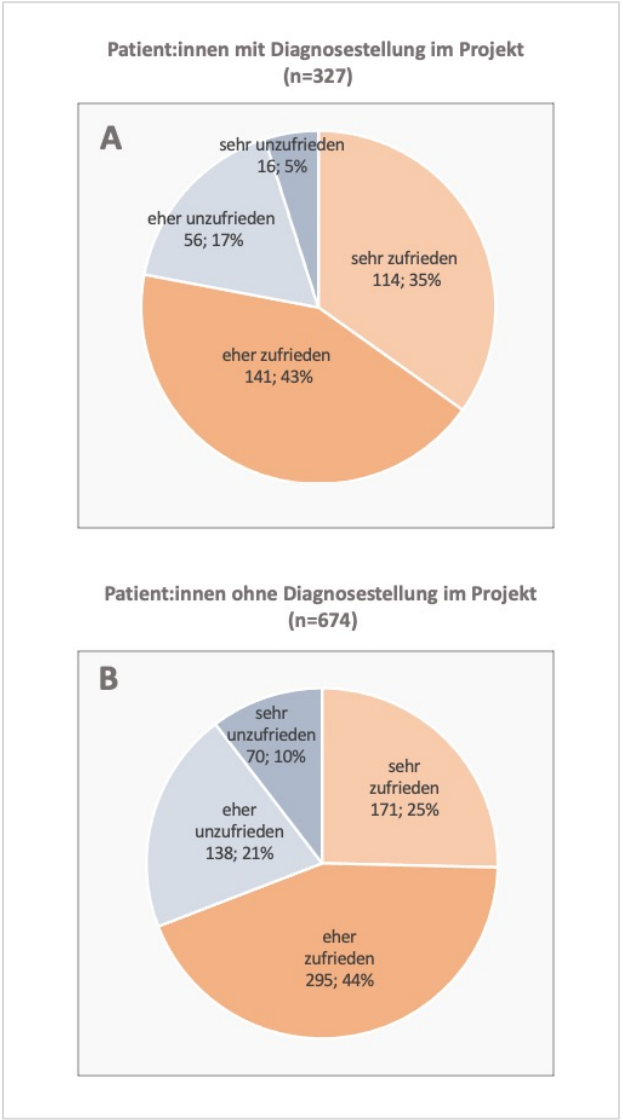

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(Ende der Odyssee)

Therapie-Indikation

Prognose-Abschätzung

Patienten-Gewissheit

TRANSLATE
NAMSE

Danke:

Mitarbeiter:innen

In den klinischen Standorten:

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