HTA Austria
Austrian Institute for
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GmbH

Quality Registries in Dementia Care

Mapping of Registries to improve Quality and Service Delivery

Final report

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List of abbreviations

ACE ..... Addenbrooke's cognitive examination

ACSQHC ..... Australian Commission on Safety and Quality in Health Care

AD ..... Alzheimer's dementia/ Alzheimer's disease

AD-5D ..... Alzheimer's Disease Five Dimensions

ADAScog ..... Alzheimer's Disease Assessment Scale-Cognitive Subscale

ADL ..... activities of daily living

ADNeT ..... the Australian Dementia Network Registry

AHRQ ..... Agency for Healthcare Research and Quality

AIHTA ..... Austrian Institute for Health Technology Assessment

ASCS-ADL ..... Alzheimer's Disease Cooperative Study

AU ..... Australia

BPSD ..... behavioural and psychological symptoms of dementia

BPSDR ..... the Swedish Behavioural and Psychological Symptoms of Dementia Registry

ChEIs ..... cholinesterase inhibitors

CI ..... confidence interval

CPR ..... Central Person Registry

CRO/CRE ..... carer-reported outcome and experience

CSF ..... cerebrospinal fluid

CT ..... computed tomography scan

DAD ..... disability assessment for dementia

DanDem ..... the Danish Quality Database for Dementia

DK ..... Denmark

DLB ..... dementia with Lewy bodies

DNA ..... deoxyribonucleic acid

DNPR ..... Danish National Prescription Registry

DOH ..... Department of Health

DSQIID/ Trindvold ..... Dementia Screening Questionnaire for Individuals with Intellectual Disabilities

EBP ..... evidence-based practice

EDTA ..... ethylenediaminetetraacetic acid

EUnetHTA ..... European Network for Health Technology Assessment

FAQ-IADL ..... Functional Activities Questionnaire Instrumental Activities of Daily Life

FTD ..... frontotemporal dementia

GDPR ..... General Data Protection Regulation

GP ..... general practicioner

HC ..... home care

HDD ..... Huntington's disease dementia

HRQoL ..... health-related quality of life

HSE ..... Health Service Executive

HTA ..... health technology assessment

ICD ..... International Statistical Classification of Diseases

ICPOP ..... Integrated Care Programme for Older People

IE ..... Ireland

IOM ..... Institute of Medicine

IQR ..... interquartile range

IT ..... information technology

IT ..... information technology

KICA ..... Kimberley Indigenous Cognitive Assessment

KMS ..... Danish clinical measurement system

KVALAP ..... quality register for geriatric psychiatry/kvalitets- og forskningsregister i Alderspsykiatrien

LIS ..... Ledelses Informations System/ Management Information System

LMED ..... Swedish Prescribed Medicines Registry

LPR ..... Landspatientregisteret/National patient register

MAD ..... mixed AD/dementia

MCI ..... mild cognitive impairment

MDD ..... major depressive disorder

MDS ..... minimal data set

MMSE ..... Mini-Mental Status Examination

MMSE-NR ..... Mini-Mental Status Examination-Norwegian revision

MoCA.....Montreal cognitive assessment
MR(I) .....magnetic resonance (imaging)
MR.....magnetic resonance
MRS .....Medical Registration System
NA .....not available
NDO.....National Dementia Office
NDRI .....the National Dementia Registry Ireland
NH.....nursing homes
NHN.....Norwegian Health Network
Nivel.....National Dementia Care and Support Register in the Netherlands
NMDA .....N-methyl-d-aspartate
NO.....Norway
NorKog.....Norwegian Registry for Persons with Cognitive Symptoms
NPR.....Norwegian Patient Register
NQF .....National Quality Forum
OUS.....Oslo University Hospital
PCRS.....Primary Care Reimbursement Scheme
PCU.....primary care unit
PDD .....Parkinson's disease dementia
PET .....positron emission tomography
PICo .....population, interest, and context
PROM/PREM...patient-reported outcome and experience measures
QA .....quality assurance
QI.....quality indicator
QR .....quality registry
RC .....Registercentrum
RCT.....randomised controlled trial
REQueST.....Registry Evaluation and Quality Standards Tool
RKKP.....Danish Regions Clinical Quality Program
RNA .....ribonucleic acid
ROSA ..... Registry of Senior Australians
RQ .....research question
RUDAS-S .....Rowland Universal Dementia Assessment Scale-Sweden
RWD .....real-world data
RWE.....real-world evidence
SC/MC.....specialist/memory clinic
SCI .....subjective cognitive impairment
SE .....Sweden
SG.....steering group
SHR.....Standard Health Record
SITHS .....Secure IT in Health and Medical Care
SKR.....Swedish Association of Local Authorities and Regions
SKS.....Sundhedsvæsenets Klassifikations System
SNOMED CT ...Systematised Nomenclature of Medicine Clinical Terms
SOP .....Standard Operating Procedure
SR.....systematic review
SveDem.....Swedish Registry for Cognitive and Dementia Disorders
USD .....unspecified dementia
VAD ..... vascular dementia
WHO.....World Health Organisation

Executive Summary

Background

Quality registries (QRs) in dementia care are seen as a system of ongoing registration of care data to better support decision-makers and healthcare planners in developing optimal dementia care pathways. Developing and monitoring quality indicators (QIs) should ensure the quality and efficiency of dementia care by highlighting care processes and outcome variations while guaranteeing equitable access to dementia care services. QR aspects and QIs need to be based on scientific evidence, patient and caregiver experience, and clinicians' perspectives across the continuum of care from diagnosis to end-of-life.

QRs = systems to monitor & evaluate health care data for decision-support

QR should reflect evidence-based practice

This report addresses aspects and objectives of existing and planned dementia QRs in selected countries. The focus is on identifying key factors in planning, designing, implementing, and operating dementia QRs. In addition, the report intends to present good practice strategies for working with such registries.

report aims: depict characteristics of existing dementia QR & derive good practice strategies

Methods

The present study contains an overview of countries considering dementia QRs integral to their health and social care strategy. We conducted a comprehensive, structured hand search in different databases and on websites of national dementia QRs. The identified information important for planning, designing, and operating a QR, including information on quality indicators from six identified registries, was extracted, summarised, and analysed according to the Registry Evaluation and Quality Standards Tool (REQueST). Finally, a good practice framework was established to provide 'lessons learned' that can be used for future and existing QRs in dementia care.

structured hand search

overview & analysis of identified information with REQueST

good practice framework

Results

Overview of the quality registries

In the course of the search, six national QRs from five countries were identified: Australia (ADNeT), Denmark (DanDem), Ireland (NDRI), Norway (NorKog), and Sweden (SveDem and BPSDR). The registries share aspects or show differences in the following categories:

6 national dementia QRs from 5 countries

- **General and methodological information:** The dementia types and categories that are covered by the registries overlap by and large. A majority of the identified QRs include only patients with a confirmed or new dementia diagnosis in the registry database. Participation from clinical sites and care homes such as specialist and memory clinics or dementia care homes is voluntary in all registries, and willingness to participate in the QR on the part of the clinical sites is very high. All registries have a continuous follow-up system for patients. An important and common secondary aim of all six QRs is that the registry should be capable of supporting research – so-called research readiness.

QRs cover a wide range of dementia forms & causes

voluntary participation from clinical and care sites

research is a common secondary aim

- **Governance and funding:** A clear governance pattern cannot be identified as responsibilities are assigned to different authorities in the five countries, and tasks take place at different levels, but multi-professional steering groups govern all active registries. The state mainly funds

steering group & secondary care sector play an essential role

all QRs. In all six QRs, the secondary healthcare sector is essential in diagnosing dementia and/or managing dementia-related symptoms. SveDem is the only QR that incorporates the primary care sector in collecting data.

data management tasks distributed on different levels

web-based data input

many measures for quality assurance & reporting

- **Data management, quality assurance, and safeguards:** Data management tasks within the QRs are divided between separate organisational units, and data input works via web-based solutions. The registries employ common data elements in their minimum data set, but the number of data elements varies considerably. Besides direct data input, the QRs can link the registry data with administrative data and data from other health-care-related databases. The registries have extensive measures for quality assurance and validation of data. Across the QRs, protection and security measures are homogenous. The registries use a variety of reporting instruments, as the results of the data analysis are of different relevance to the various groups involved in dementia care.

data are pseudonymised & QRs use different consent models

- **Privacy, consent, and ethics:** In most of the identified QRs, data are pseudonymised in alignment with the country's data and patient protection act and the General Data Protection Regulation for countries in the European Union. Across the registries, all three common consent models (opt-in, opt-out, no consent required) are used concerning patient recruitment and participation.

registry data used for research purposes in all six QRs

- **Register-based research:** The registries share some aspects regarding data use for external research purposes, but considerations for using registry data and handling research outcomes differ to some extent from registry to registry.

Quality indicators

QIs are key instruments and should reflect evidence-based practice

Quality indicators are the key instruments measuring quality. All six registries emphasise that QIs should reflect evidence-based practice, underlying recommendations, and standards of the respective healthcare system and dementia care strategy. Each registry uses its mixture of foundations and approaches to arrive at the individual indicator set. Forty-six individual indicators are used across the registries. The indicator landscape in the QRs is heterogeneous. In total, 35 of the 46 indicators are used in only one register each. For eleven QIs, there are overlaps between the QRs. Of the 46 QIs, 40 indicators are process QIs. Five QIs can be assigned to outcome quality and one to structural quality.

46 individual QIs across the six QRs

Good practice framework

interdisciplinary view is essential

Various interdisciplinary aspects need to be considered in the different phases of setting up a QR, operating it and deriving conclusions for improving dementia care.

good practice framework covers important thematic blocks and phases of QRs

Good practice strategies were derived for the following thematic blocks and registry phases:

- Planning,
- Design,
- Governance,
- Recruitment of patients and participating sites,
- Data management:
  - Data elements, the minimum data set, and quality indicators,
  - Data sources and interoperability,

  - Data collection and quality assurance,
  - Registration, processing, and reporting of adverse events,
  - Analysis, interpretation, and reporting.
- Privacy, consent, and ethics,
- Other relevant domains, e.g. change management and knowledge gaps,
- Evaluation of the registry's quality.

identified QRs implement strategies for good registry practice

The embedding of the six identified registries in the formulated good practice framework has shown that existing QRs strive to implement an extensive set of good practice strategies to make dementia care visible and to identify the potential for quality improvement.

Conclusion

numerous aspects must be considered to collect robust data for quality improvement

The increasing availability of digitised health (care) data and the need to coordinate the care of dementia patients on several care levels require the cooperation of all stakeholders concerned. Collecting robust data on the quality of care is important to stimulate continuous and structured quality improvement. One way to manage these tasks is through QRs. Numerous aspects have to be taken into account for efficient functioning.

Zusammenfassung

Hintergrund

Demenz ist ein vielschichtiges Krankheitsbild (Syndrom)

Demenz ist ein Krankheitsbild (Syndrom), das hauptsächlich durch chronische oder fortschreitende Funktionsverluste von Nervenzellen (Neurodegeneration) in und unterhalb der Großhirnrinde entsteht. Mit dem Fortschreiten des Syndroms wird die Bewältigung des Alltags der Betroffenen immer schwieriger. Es treten Probleme mit der Merkfähigkeit, Sprache und der räumlichen und zeitlichen Orientierung auf. Die Komplexität und die (derzeitige) Unheilbarkeit erfordern einen sorgfältigen und evidenzbasierten Umgang mit den Patient*innen durch alle beteiligten Akteur*innen.

QR = organisiertes System zur Datensammlung, Monitoring & Evaluation von demenzspezifischer Versorgungsdaten zur Qualitätsverbesserung & Entscheidungsunterstützung

Ein Qualitätsregister (QR) – ein Subtyp von Patient*innenregistern – soll dabei helfen, qualitativ hochwertige Versorgungspfade sicherzustellen. Ein Demenz-QR ist ein System und gleichzeitig eine Organisation mithilfe nicht nur Patient*innendaten gesammelt, sondern auch im Zeitverlauf beobachtet und analysiert werden. Die Verbesserung der Qualität der Demenzversorgung und der Patient*innenergebnisse ist das primäre Ziel eines Demenz-QR. Zu den erhobenen Daten zählen beispielsweise Patient*inneninformationen, aber auch Informationen über spezifische Behandlungen, Unterstützungsmaßnahmen oder diagnostische Untersuchungen. Mithilfe dieser Daten können sogenannte Qualitätsindikatoren (QI) gebildet werden. Das sind Messinstrumente, die in erster Linie Elemente des gewünschten Standards der Demenzversorgung erheben sollen. Auf Basis der QI kann überprüft werden, ob messbare Ziele oder Qualitätsverbesserungen erreicht wurden. Die Dokumentation und das Monitoren der Daten und Indikatoren sollen Entscheidungsträger*innen im Gesundheitswesen bei der Entwicklung optimaler Demenzversorgungpfade unterstützen, um die Qualität der Demenzversorgung zu verbessern.

Demenz-QR können RCTs ergänzen & neue Erkenntnisse bringen

Zusätzlich ergänzen Demenz-QR (randomisierte) kontrollierte Studien (RCTs), indem sie neue Zusammenhänge aufzeigen oder dabei helfen Hypothesen für künftige Studien aufzustellen. Allerdings müssen für ein optimales Funktionieren eines Demenz-QR zahlreiche Aspekte bei der Umsetzung und in der Anwendung berücksichtigt werden.

Ziele des Berichts

Berichtsfokus:

QR aus ausgewählten Ländern und Schlüsselfaktoren für Planung, Gestaltung & Betrieb eines Demenz-QRs

Im Zuge der Berichtserstellung befassten wir uns mit bestehenden und geplanten Demenz-QRs in ausgewählten Ländern. Der Schwerpunkt lag auf Schlüsselfaktoren, welche bei der Planung, Gestaltung, Umsetzung und dem Betrieb eines Demenz-QR wesentlich sind. Der Bericht soll Gemeinsamkeiten und wesentliche Unterschiede der QR in ausgewählten Ländern, aber auch im Vergleich zu anderen Formen der Evidenzgenerierung wie (R)CTs aufzeigen. Darüber hinaus formulierten wir „Good-Practice-Strategien“ für den Umgang mit Demenz-QRs, um Entscheidungsträger*innen eine praxisrelevante Informationsbasis zu liefern.

Folgende Forschungsfragen (FF) werden im Bericht adressiert:

Welche Länder haben ein Demenz-QR?

FF1. Welche Länder haben Demenz-QR umgesetzt oder geplant, und welche gemeinsamen Merkmale und Unterschiede gibt es bei der derzeitigen Nutzung, Organisation, Umsetzung und den technischen Aspekten?

FF2. Welche Daten werden in Demenz-QRs erhoben, und welche Qualitätsindikatoren oder Parameter zur Struktur-, Prozess- und Ergebnisqualität werden aus den Daten abgeleitet?

Welche QI werden aus den gesammelten Daten gebildet?

FF3. Welche „Good-Practice-Strategien" sind hilfreich für die Implementierung und den Betrieb eines Demenz-QR und unterstützen den Planungsprozess, den Gestaltungsprozess, die Evaluation und die Berichterstattung der Ergebnisse, um die Qualität der Demenzversorgung zu verbessern?

Was kann aus den Informationen für die Praxis abgeleitet werden?

Methoden

Wir haben anhand vordefinierter Kriterien in gesundheitswissenschaftlichen Datenbanken und auf Webseiten nach Demenz-QR, und Informationen, gesucht (umfassende strukturierte Handsuche). Zur Identifizierung und Auswahl geeigneter Demenz-QR und Länder nutzten wir eine bestehende systematische Übersichtsarbeit. Im Zuge der Suche konnten wir sechs nationale Demenz-QR aus fünf Ländern identifizieren und in unsere Analyse einbeziehen. Informationen zu den folgenden Kategorien basierend auf dem Registry Evaluation and Quality Standards Tool (REQueST) wurden für jedes QR extrahiert, dargestellt und analysiert:

umfassende strukturierte Handsuche auf Webseiten zu Demenz-QR & in Fachdatenbanken

- Allgemeine und methodische Informationen des Demenz-QRs,
- Governance des Demenz-QR (Steuerung),
- Datenmanagement inklusive Datensammlung, Datenquellen, Verknüpfung und Austausch von Daten (Interoperabilität), Qualitätssicherung und Sicherheit,
- Zusätzliche Aspekte wie Art der Einwilligungserklärung zur Nutzung der Daten, ethische Aspekte, und Berichterstattung.

Informationen zu 4 Domänen extrahiert basierend auf REQueST

Im zweiten Schritt extrahierten wir Informationen zu den in den Registern eingesetzten QI inklusive der Evidenzgrundlagen. Evidenzgrundlagen umfassen Empfehlungen aus Demenzleitlinien, konsensbasierte Empfehlungen und Demenzversorgungsstandards und -ziele des jeweiligen Gesundheitssystems. Um die Verbindung zwischen den Evidenzgrundlagen der Demenzversorgung in den einzelnen Ländern und den verwendeten QI herzustellen, erstellten wir QI-Vignetten. Zur besseren Übersicht wurden die QI nach Kategorien eines Demenzversorgungspfads thematisch eingeteilt. Zusätzlich stellten wir die QI-Zielwerte und Ergebnisse aus den Jahresberichten der sechs ausgewählten QR in Tabellen dar.

Analyse der QI & zugrundeliegenden Evidenz aus den 6 Demenz-QR

Im letzten Schritt erarbeiteten wir aus den Informationen der identifizierten QR und der Registerliteratur Good-Practice-Strategien, Empfehlungen und Registerpraktiken, die für die Planung, Gestaltung und die Operationalisierung eines QR essentiell sind.

Ausarbeitung von Good Practice-Strategien & Empfehlungen

Ergebnisse: Übersicht der Qualitätsregister aus anderen Ländern

Allgemeine Informationen

Insgesamt wurden sechs nationale QR aus fünf Ländern identifiziert, die Demenz-QR als integralen Bestandteil ihrer Gesundheitsversorgungs- und Sozialfürsorgestrategie betrachten:

6 nationale Demenz-QR in 5 Ländern:

Australien (ADNeT), Dänemark (DanDem), …

- *Australien:* Das Register des australischen Demenznetzwerks (ADNeT),
- *Dänemark:* Die dänische Qualitätsdatenbank für Demenz (DanDem),

… Irland (NDRI), Norwegen (NorKog), Schweden (SveDem, BPSDR)

- *Irland:* Das nationale Demenzregister Irland (NDRI),
- *Norwegen:* Das norwegische Register für Personen mit kognitiven Symptomen (NorKog),
- *Schweden:*
  - Das schwedische Register für kognitive und demenzielle Störungen (SveDem),
  - Das schwedische Register für verhaltensbezogene und psychologische Symptome bei Demenz (BPSDR).

BPSDR mit Fokus auf Verhaltensstörungen bei Demenz

SveDem mit längster Laufzeit und meisten registrierten Patient*innen (Pat.)

Die skandinavischen Länder betreiben ihre Demenz-QR seit mehreren Jahren, wobei SveDem die längste Laufzeit hat (seit 2007). Das jüngste Register ist das australische Demenz-QR (seit 2020) und das nationale Demenzregister in Irland befindet sich in Umsetzung. Aufgrund des längeren Bestehens im Vergleich zu den nicht-skandinavischen QR ist die Anzahl der registrierten Patient*innen in skandinavischen Demenz-QR größer, wobei auch hier SveDem mit ca. 100.000 registrierten Demenzpatient*innen hervorzuheben ist.

Einschlusskriterien: in 5 von 6 QR werden nur (neu)diagnostizierte Pat. registriert

Alle sechs QR decken ein breites Spektrum von Demenzformen ab und überschneiden sich weitgehend. Fünf der sechs QR schließen nur Patient*innen mit einer bestätigten bzw. neuen Demenzdiagnose ein. Die einzige Ausnahme ist das norwegische Demenz-QR. Es erfasst alle Personen, die auf kognitive Symptome oder Demenz untersucht wurden, unabhängig vom Alter.

Teilnahme der datenmeldenden Zentren ist freiwillig & Teilnahmebereitschaft ist hoch

Die Teilnahme seitens (klinischer) Einrichtungen wie Gedächtnisambulanzen (Memory-Kliniken) oder Demenzpflegeheimen ist in allen QR freiwillig. Allerdings werden bei den beiden schwedischen QR Gebühren für die Teilnahme am Demenz-QR eingezogen. Die Bereitschaft zur Teilnahme am Demenz-QR von Seiten der teilnehmenden Einrichtungen ist hoch. Beispielsweise partizipieren in Schweden 78 % der Primärversorgungseinheiten und 100 % der Spezial- und Memory-Kliniken am SveDem.

Demenz-QR verfolgen noch weitere Ziele

Neben dem Hauptziel der Qualitätsverbesserung der Demenzversorgung verfolgen die sechs identifizierten QR noch weitere Ziele. Zu den Zielen zählen beispielsweise die Bereitstellung der Daten für die Forschung oder die Erleichterung der Rekrutierung von Personen mit Demenz für klinische Studien.

Governance (Steuerung)

unterschiedliche Governance-Strukturen mit Überschneidungen

Die Demenz-QRs sind in Bezug auf die Governance-Struktur heterogen. Die Zuständigkeiten in den fünf Ländern sind unterschiedlichen Organen zugewiesen und die Aufgaben finden auf verschiedenen Ebenen statt. Nichtsdestotrotz teilen die QR gleichzeitig einzelne wichtige Governance-Merkmale.

Steuerungsgruppe (SG) ist ein Kernelement in den Demenz-QR

SG sind multiprofessionell und beziehen Betroffene mit ein

Die Demenz-QRs wurden in allen fünf Ländern eingeführt, nachdem nationale Demenzstrategien Maßnahmen zur Verbesserung der Qualität der Demenzversorgung anhand von Registerdaten empfohlen hatten. Eine multiprofessionelle Steuerungsgruppe bildet eines der Kernelemente der Demenz-QRs. Sie überwacht die administrativen, rechtlichen/ethischen und wissenschaftlichen Entscheidungen und übernimmt teilweise die Verantwortung dafür. Diese Expert*innengruppen setzen sich aus Vertreter*innen der Demenzversorgung („Praktiker*innen“) und der Forschung zusammen, aber auch betroffene Patient*innen und Betreuungspersonen sind vertreten. Die Größe der Steuerungsgruppe variiert von zehn bis 21 Expert*innen in den identifizierten QR. Der Schwerpunkt der Expertise liegt auf der Gerontologie. Die Allgemein- und „Community“-Medizin nehmen auch eine wesentliche Rolle ein.

SveDem ist das einzige QR, das die Primärversorgung in die Datenerfassung einbezieht. Hausärzt*innen oder Primärversorgungseinheiten können Daten in die Registerdatenbank einpflegen, nachdem sie Demenzpatient*innen diagnostiziert haben. In allen sechs QR ist der sekundäre Gesundheitssektor von wesentlicher Bedeutung für die Diagnose von Demenz und/oder Behandlung von demenzbezogenen Symptomen. Spezialisierte Kliniken wie neurologische, geriatrische und psychiatrische Kliniken und/oder Gedächtniskliniken führen demenzbezogene Untersuchungen und Behandlungen durch und melden die gesammelten Patient*innendaten an das Register. Die schwedischen QR sind die einzigen Register, die es Demenzpflegeeinrichtungen ermöglichen, teilzunehmen.

Primärversorgung explizit nur in SveDem eingebunden

sekundärer Versorgungssektor ist von wesentlicher Bedeutung in allen Demenz-QR

Alle identifizierten QR sind staatlich finanziert, da nationale Demenz-Aktionspläne oder -Strategien in allen fünf Ländern die Grundlage für die Verbesserung der Qualität in der Demenzversorgung anhand von Registerdaten bilden.

staatliche Finanzierung

Datenmanagement

Das Datenmanagement innerhalb der Registerorganisationen wird zwischen verschiedenen Organisationseinheiten aufgeteilt. Alle QR unterstreichen, dass das Datenmanagement im Einklang mit aktuellen Datenbankstandards und den Datenschutzbestimmungen und -gesetzen wie der Datenschutzgrundverordnung (DSGVO) stehen müssen.

Datenmanagement muss im Einklang mit Datenschutz & Standards stehen

Die Dateneingabe in allen sechs QR erfolgt über webbasierte Lösungen und wird durch Kliniker*innen oder klinisches Pflegepersonal aus den teilnehmenden Einrichtungen durchgeführt. Einige QR erheben neben der Patient*innendaten auch Daten von Pflegepersonen und/oder Angehörigen. Die Daten werden an einen zentralen Server übertragen, der von der jeweiligen Organisation oder einem beauftragten IT-Dienstleister betrieben wird, wo sie weiterverarbeitet werden.

Dateneingabe erfolgt webbasiert durch (klinisches) Fachpersonal

Damit ein Demenz-QR effizient funktioniert, ist ein definierter Mindestdatensatz (MDS) erforderlich. Ein MDS ist ein Mindestsatz gemeinsamer Datenelemente, die alle teilnehmenden Einrichtungen verwenden sollten, um eine standardisierte Datenerfassung in der Sekundär- und Primärversorgung zu gewährleisten. Alle sechs QR weisen einen MDS vor. Die QRs überschneiden sich teilweise hinsichtlich der Datenelemente des MDS, aber die Anzahl der Datenelemente variiert beträchtlich. Das irische Register hat 56 und das schwedische BPSDR hat zehn Datenelemente. Die gesammelten Datenelemente lassen sich in fünf Kategorien unterteilen:

Mindestdatensatz (MDS) ist essentiell

MDS überschneiden sich teilweise, aber Anzahl der Elemente variiert stark

- Patient*innendaten wie Geschlecht, Alter, Bildungsstatus etc.
- Daten des Gesundheitsdienstleisters wie Klinik/Zentrum, Aufnahmedatum etc.
- Diagnosedaten wie Demenzanamnese, Demenztyp, durchgeführte Tests etc.
- Behandlungsdaten wie pharmakologische Behandlung, psychosoziale Interventionen etc.
- Weitere registrierte Variablen, die nicht Teil des MDS sind.

Neben der direkten Dateneingabe nutzen die QR auch Daten aus administrativen und anderen gesundheitsbezogenen Datenbanken. Die QR betonen die Bedeutung der Interoperabilität. Die Verwendung von eindeutigen Patient*innen-Identifikationsnummern in allen sechs Demenz-QR ermöglicht die Erhebung von Längsschnittdaten und die Verknüpfung mit den jeweiligen Datenquellen.

direkte Dateneingabe aber auch Daten aus anderen Quellen

umfangreiche Maßnahmen zur Qualitätssicherung und Validierung der Daten

Alle Register führen umfangreiche Maßnahmen zur Qualitätssicherung und Validierung der Daten durch. Maßnahmen umfassen sowohl personelle Maßnahmen wie Registerschulungen, Workshops oder telefonische Unterstützung, als auch technische Maßnahmen zur Datenbereinigung, Behandlung fehlender Daten oder softwaregestützte Maßnahmen zur Validierung. Die technischen Maßnahmen zur Qualitätssicherung werden hauptsächlich im Rahmen der Validierungsstrategien der sechs Demenz-QR operationalisiert. Beispielsweise erkennt die Software Fehler während der Dateneingabe und weist automatisiert darauf hin. Weitere Validierungsstrategien umfassen:

routinemäßig durchgeführte aber auch Maßnahmen im Zuge des Jahresberichts

- Routinemäßig durchgeführte Maßnahmen zur Prüfung der Konsistenz und Genauigkeit gemäß einem Datenvalidierungsplan,
- Die Standardisierung von Datenstrukturen,
- Die Beseitigung von Doppeleinträgen,
- Den Abgleich der erhobenen Daten mit anderen Datenbanken,
- Prüfung der Daten im Zuge der Erstellung des Jahresberichts.

teilweise externe Audits

Manche QR setzen auch externe oder interne Überprüfungsmaßnahmen (Audits) zur Validierung ein. Das dänische Demenz-QR muss beispielsweise alle drei Jahre eine Bewertung durch die nationale Gesundheitsbehörde bestehen.

Schutz- und Sicherheitsmaßnahmen sind in den Demenz-QR ähnlich

Die Schutz- und Sicherheitsmaßnahmen sind in allen QR zu einem großen Teil einheitlich. Die primäre Schutzmaßnahme in den QR umfasst eine Firewall für den Server, auf dem die Datenbank gehostet wird, und/oder Firewalls an den teilnehmenden (klinischen) Einrichtungen. Die Anmeldung und persönliche Authentifizierung für die Eingabe oder das Lesen von Daten erfolgt über einen Benutzernamen und ein Passwort oder in manchen Registern über Hardware-Lösungen wie Smartcards (Chipkarten). Die Informationen werden in allen QR sicher gespeichert und vertraulich behandelt.

Interpretation der Daten und Berichterstattung

kontinuierliche & regelmäßige Berichterstattung

Die Register verwenden eine Vielzahl von Berichtsinstrumenten, da die Ergebnisse der Datenanalyse für die verschiedenen an der Demenzversorgung beteiligten Gruppen von unterschiedlicher Bedeutung sind. Grundsätzlich wird bei den QR zwischen den folgenden Arten und Unterarten der Berichterstattung unterschieden:

bspw. Ad-hoc-Berichte für verschiedene Interessengruppen

- *Kontinuierliche Berichterstattung:* Echtzeit-/Ad-hoc-Berichte für teilnehmende Einrichtungen und Entscheidungsträger*innen, um Erkenntnisse über die Demenzversorgung zu gewinnen, oder Berichte für Patient*innen und deren Betreuungspersonen, um Informationen über den Gesundheitszustand der betroffenen Person zu erhalten.

Jahresberichte für die breite Öffentlichkeit

- *Regelmäßige Berichterstattung:* Jahresberichte für die breite Öffentlichkeit, regelmäßige Berichte für Entscheidungsträger zur Konzipierung der Demenzversorgungspolitik oder halbjährliche Berichte für teilnehmende und datenliefernde Einrichtungen.

Datenschutz, Einwilligung und ethische Aspekte

EU-Länder unterliegen der DSGVO

Die identifizierten Demenz-QR, welche in EU-Ländern betrieben werden, unterliegen der DSGVO und den darin enthaltenen Datenschutzbestimmungen. Während die DSGVO in allen EU-Mitgliedsstaaten direkt als Gesetz gilt, haben EU-Länder auch ihre eigenen Regelungen mit den jeweiligen nationalen Datenschutzgesetzen. Das norwegische Register hält sich an die von der norwegischen Datenschutzbehörde erlassenen Vorschriften und das australische Demenz-QR hält sich an die australischen Datenschutzbestimmungen.

verschiedene Einverständnismodelle kommen zum Einsatz

Die eingeschlossenen QR verwenden verschiedene Einverständnismodelle zur Datensammlung, wobei die schwedischen Demenz-QR ein Opt-out-Modell und das norwegische QR ein Opt-in-Modell verwenden. Für die Datensammlung im dänischen Register ist keine Einwilligung der Patient*innen oder Betreuungsperson notwendig. Das australische Register verwendet ein modifiziertes Opt-out-Modell und für das irische Demenz-QR steht das Einwilligungsmodell noch nicht fest.

Register-basierte Forschung

Datennutzung für Forschungszwecke ist gemeinsames sekundäres Ziel

Ein gemeinsames sekundäres Ziel oder Zweck der sechs QR ist die Verwendung der Daten für die Forschung abseits der Qualitätsverbesserung. Alle sechs QR betonen, dass die Daten „forschungsreif" sein sollten. Deshalb müssen gewisse Aspekte für die Verwendung der Daten für Forschungszwecke mitgedacht werden:

- Erfassung von demografischen und anderen patient*innenrelevanten Daten,
- Erfassung von Störfaktoren und Möglichkeiten der Risikoadjustierung der Datenauswertung,
- Verknüpfung der Daten mit anderen Datenbanken,
- Genehmigung der Datennutzung durch ein Ethik-Board und Zustimmung der Patient*innen zur Datennutzung für Forschungszwecke,
- Zugang der Daten über eine Forschungsplattform,
- Etwaige Kosten und Gebühren für den Zugang zu den Daten.

Ergebnisse: Qualitätsindikatoren

MDS bildet die Basis für QI

Auf der Grundlage des MDS entwickelt jedes QR sogenannte Qualitätsindikatoren (QI). QIs sind die Basis, um ein Bild der Versorgungsqualität zu bekommen und Qualitätsverbesserungen herbeizuführen. QI und deren Zielwerte sollen in erster Linie den gewünschten Standard der Demenzversorgung in den drei Qualitätsdimensionen (Prozess-, Struktur- und Ergebnisqualität) abbilden.

QI sind meist Proportionskennzahlen

In den meisten Fällen stellen die QI die Qualität in Proportionen oder Prozentsätzen dar. Ein typischer QI ist eine Kennzahl, die aus einem Nenner (betrachtete Population) und einem Zähler (Anzahl der Personen aus der betrachteten Population, die ein bestimmtes Kriterium erfüllen) besteht.

Auswahl der QI-Sets größtenteils konsensbasiert

Bei einem Großteil der Register basiert keiner der QI ausdrücklich auf nationalen Leitlinien oder spezifischen systematischen Evidenzsynthesen. Die QI-Sets wurden größtenteils von den Expert*innen aus der jeweiligen Steuerungsgruppen beschlossen. Teilweise kamen Delphi-Verfahren bei der Entwicklung zum Einsatz. Im Prozess der Entwicklung des endgültigen QI-Sets folgte jedoch zumeist noch eine Ergänzung mit Evidenz aus Leitlinien oder aus einer Literaturübersicht.

schwedische Register gehen explizit von Leitlinien aus

Ausschließlich die beiden schwedischen Demenz-QR gingen explizit von der schwedischen Nationalen Leitlinie für die Versorgung von Demenzbetroffenen aus, um das Indikatoren-Set zu definieren. In diesen beiden QR wurden die QIs inklusive Zielwerte in Zusammenarbeit einer nationalen Behörde ausgearbeitet.

pro QR zwischen 5 und maximal 10 QI

in Summe 46 individuelle QI

In Summe setzen die sechs QR 64 QI ein. Das schließt auch Unterindikatoren ein, welche im Zuge der Hauptindikatoren erhoben werden. Über die QR hinweg, werden mindestens fünf und maximal zehn Hauptindikatoren eingesetzt. Werden die Überschneidungen der QI in den QR berücksichtigt, bleiben 46 individuelle Indikatoren übrig. Die QI können folgenden Kategorien eines Demenzversorgungspfades zugeordnet werden:

Prädiagnose-QI fokussieren auf Überweisungsprozess

- **Prädiagnose** (5 Indikatoren): Diese Indikatoren konzentrieren sich auf den Überweisungsprozess und spiegeln hauptsächlich die zeitliche Komponente der Versorgungsqualität wider, wie z. B. Wartezeiten von den ersten Demenzanzeichen bis zur Überweisung oder Zeit vom Erstkontakt bis zur Diagnosestellung.

Diagnose-QI fokussieren auf Diagnosephase, angewendete Verfahren & Tests

- **Diagnose und diagnostische Abklärung** (16 Indikatoren): Diese Indikatoren sollen die Qualität der Diagnosephase inklusive der angewendeten Verfahren und Tests erfassen, wie z. B. der Anteil der Patient*innen, die eine Basisdemenzuntersuchung komplett durchliefen oder Anteil der Patient*innen mit einer ätiologischen Diagnose.

QI zur Erfassung der Qualität von Behandlungs- & Unterstützungsmaßnahmen

- **Behandlung, Unterstützungsmaßnahmen und Nachsorge** (18 Indikatoren): Diese Indikatoren sollen die Qualität der Behandlungs- sowie Unterstützungsmaßnahmen abbilden, wie z. B. der Anteil der mit Demenzmedikamenten behandelten Patient*innen, Anteil der Patient*innen, die mit antipsychotischen Medikamenten behandelt werden oder Wartezeit bis häusliche Unterstützungsdienste initiiert werden.

QI zu ergebnisbezogenen (Pat.)Informationen

- **Ergebnisbezogene Indikatoren** (5 Indikatoren): Mit diesen Indikatoren werden ergebnisbezogene Informationen der Patient*innen und Betreuer*innen erfasst, wie z. B. die Lebensqualität der Patient*innen oder Informationen über andere ergebnisbezogene Aspekte wie Schmerzfreiheit oder Krankheitsverlauf.

QI zur registerspezifischen Qualität

- **Meta-Indikatoren und andere QI** (2 Indikatoren): Diese Indikatoren sollen die registerspezifische Qualität erfassen, wie z. B. Abdeckungsgrad.

QI-Landschaft heterogen aber mit Überschneidungen

Die Indikatoren-Landschaft in den Registern ist heterogen. Insgesamt werden 35 der 46 Indikatoren in nur jeweils einem Register verwendet. Bei elf QI gibt es Überschneidungen zwischen den QR. Beispielsweise wird der Anteil der Patient*innen, welche mit Demenzmedikamenten behandelt wird in fünf der sechs QR beobachtet. Für 31 der 46 QI liegen Ergebnisse vor. Die Erklärung für die Indikatoren-Auswahl und die Evidenzbasis, d.h. Demenzleitlinien, konsensbasierte Praxis und Empfehlungen und definierte Ziele in der Demenzstrategie, sind für alle 46 QI verfügbar.

Großteil sind QI für Prozessqualität

Von den 46 QI sind 40 Prozess-QI (87 %). Fünf QI (11 %) lassen sich der Ergebnisqualität und einer lässt sich der Strukturqualität zuordnen. QR mit ergebnisbezogenen QI betonen, dass die Förderung der Bedeutung von patient*innenorienierten Ergebnisparametern und Ergebnisparametern mit Fokus auf die Betreuungsperson eine wichtige Priorität darstellen.

Good-Practice-Framework: Strategien, Empfehlungen und praktische Umsetzung

QR haben spezifische Eigenschaften

Die meisten Schritte bei der Planung, der Implementierung und dem Betrieb eines Demenz-QR weisen Ähnlichkeiten zu anderen Arten von Patient*innenregistern auf. Nichtsdestotrotz hat ein Demenz-QR spezifische Eigenschaften, welche es zu beachten gilt:

- **Planung:** Zu der wesentlichsten Aufgabe bei der Planung gehört die kritische Überlegung, ob ein Demenz-QR überhaupt das geeignete Instrument ist, die Qualität der Demenzversorgung im spezifischen Kontext zu verbessern. Darüber hinaus sollte ein Governance-Plan erstellt werden, der die Haupt- und Nebenziele, den Datenumgang, -zugang und Sicherheitsaspekte, sowie allgemeine Managementzuständigkeiten und das Registerteam definiert.

  Planungsphase: Demenz-QR = richtiges Tool für Ziele?

  Governance-Plan ist essentiell

  Ein zusätzliches Hauptaugenmerk sollte auf der Finanzierung liegen. Dabei müssen alle erforderlichen QR-Phasen berücksichtigt werden. In der Planungsphase sollten alle Interessengruppen miteingebunden werden, da die Interessengruppen eine der wichtigsten Säulen für den Erfolg eines QR ist. Ein QR ist kein einfaches Feedback-Instrument. Es zielt darauf ab, das Verhalten von Patient*innen und Leistungserbringer*innen oder die Versorgungspraxis auf breiter Ebene zu verändern.

  Finanzierung abklären

  alle Interessengruppen aktiv einbinden

- **Design:** Wenn möglich, sollte ein Demenz-QR nach Grundsätzen konzipiert werden, die mit den Grundsätzen eines wissenschaftlichen Studiendesigns vergleichbar sind. Elemente eines wissenschaftlichen Studiendesigns sind die Formulierung einer wissenschaftlichen Fragestellung, die Auswahl des Studiendesigns, die Übersetzung der wissenschaftlichen Fragestellung in messbare Ergebnisparameter (MDS und QI), die Auswahl der Patient*innen, die Berücksichtigung von Kontrollvariablen, die Spezifikation der Datenquellen, die Festlegung der Patient*innenzahlen, des Beobachtungszeitraums und die Analyse von Störvariablen.

  Grundsätze eines wissenschaftlichen Studiendesigns berücksichtigen

- **Governance (Steuerung):** Ein formeller Governance-Plan, der den QR-Akteur*innen Verantwortlichkeiten zuweist, einschließlich aller Aspekte des Datenmanagements, gewährleistet den reibungslosen Betrieb über den gesamten QR-Lebenszyklus hinweg. Zentrale Aspekte der Governance, wie Finanzierung, Rechte und Pflichten, sollten schriftlich festgelegt werden und im Laufe der Zeit überprüft und verfeinert werden. Ein schriftlicher Plan gewährleistet zusätzlich Transparenz in Bezug auf vermeintliche oder tatsächliche Interessenkonflikte. Stakeholder, wie z. B. datenerfassende Leistungserbringer*innen, sollten bei der Formulierung des Plans einbezogen werden, um das Engagement zu stärken. Zudem ist eine starke Führung durch eine Steuerungsgruppe unabdingbar. Gleichzeitig sollte aber der gegenseitige Respekt zwischen allen Interessengruppen sichergestellt werden.

  Verantwortlichkeiten klar zuweisen

  Governance-Aufgaben, Rechte & Pflichten verschriftlichen → schafft Transparenz und Klarheit

- **Rekrutierung von Patient*innen und Leistungserbringer*innen:** Die Rekrutierung und das Engagement („Commitment“) von teilnehmenden Leistungserbringer*innen („Datensammler*innen“) und Patient*innen ist für den Erfolg eines QR unerlässlich. Zu den motivierenden Faktoren für die Teilnahme gehören die wahrgenommene Relevanz, Wichtigkeit oder wissenschaftliche Glaubwürdigkeit des Demenz-QRs, die Risiken der und etwaige Anreize für die Teilnahme. Da die Rekrutierung und das Commitment von Leistungserbringer*innen und Pa-

  teilnehmende Zentren & Einrichtungen sowie Pat. motivieren → Engagement der Interessengruppen von zentraler Bedeutung

tient*innen für die Repräsentativität der Zielpopulation von entscheidender Bedeutung sind, sind gut geplante Strategien für die Rekrutierung entscheidend.

MDS & QI sollten evidenzbasierte Praxis widerspiegeln

notwendige Datenelemente haben Vorrang

- **Datenelemente, Minimaldatensatz und Qualitätsindikatoren:** Datenelemente, MDS und QI sollten auf der Grundlage etablierter evidenzbasierter Grundlagen, bereits etablierter (klinischer) Qualitätsstandards und der jeweiligen Praxis des Gesundheitssystems ausgewählt und entwickelt werden. Die absolut notwendigen Datenelemente haben Vorrang vor den wünschenswerten Datenelementen. Die notwendigen Datenelemente bilden das MDS und sollten von allen teilnehmenden Einrichtungen direkt bei den Patient*innen und/oder den entsprechenden Pflegepersonen erhoben werden.

große QI-Sets sind nicht empfehlenswert

Qualität > Quantität

Pat.-Sicht berücksichtigen und Pat. einbinden

Die Nutzung von zu großen QI-Sets ist nicht empfehlenswert. Die Praxis zeigt, dass sich die Demenz-QR auf eine überschaubare Anzahl (~5-10 Stück) von QI festlegen. Der Schwerpunkt sollte auf evidenz- und konsensbasierter Qualität und nicht auf Quantität liegen. Sorgfältig validierte Skalen sollten verwendet werden, um patient*innenbezogene Endpunkte und darauf aufbauende QI zu messen. Die Berücksichtigung der Stimme und der Erfahrungen von Patient*innen und Betreuungspersonen vervollständigt eine partizipative Demenzversorgung.

Pilotierung des MDS & der QI

Machbarkeit & Flaschenhälse können identifiziert werden

Der MDS, die QIs und andere Datenstrukturen sollten in einem Pilotversuch getestet werden. In der Pilotphase werden die einzelnen Schritte der Datenerhebung und -speicherung probeweise durchlaufen. Datenelemente des MDS und weitere wünschenswerte, aber nicht notwendige Datenelemente sollten bei ausgewählten Leistungserbringer*innen erhoben und in die Datenbank eingepflegt werden. Der Pilotversuch soll technische Aspekte erfassen und Rückmeldung über die Verständlichkeit und Bedienbarkeit des Systems geben. So können beispielsweise unzureichende Erläuterungstexte, unverständliche Fragen oder fehlende Informationen für die abschließende Auswertung identifiziert werden.

MDS & QI evaluieren & gegebenenfalls anpassen

Der MDS und das QI-Set sollten nicht statisch bleiben. Nach einer adäquaten Überprüfung können der MDS und das QI-Set im Laufe der Zeit reduziert oder erweitert werden, um den Bedürfnissen aller Beteiligten gerecht zu werden.

andere Datenquellen nutzbar machen

- **Datenquellen:** Ein Demenz-QR sollte in der Lage sein, neben der direkten Dateneingabe auch Daten aus verschiedenen weiteren Quellen zu integrieren. Hierfür sollten einheitliche Patient*innenidentifikatoren eingesetzt werden. Zusätzlich sollte vordefiniert werden, wie mit Problemen bei der Datenverknüpfung umgegangen wird. Mögliche Fehler bei der Verknüpfung sind die Verknüpfung von nicht identischen Fällen oder die Nichtverknüpfung von identischen Fällen.

integriertes Software-System um Daten zu erfassen, bereinigen, analysieren & für die Berichterstattung

- **Datensammlung und Qualitätssicherung:** Ein integriertes (Software)-System zur Erfassung, Bereinigung, Monitoring, Validierung und Berichterstattung der QR-Daten bestimmt die Nutzbarkeit für die Qualitätsverbesserung. Bei der Datenerhebung ist die Einheitlichkeit der Datenerfassung eine wesentliche Voraussetzung. Eine webbasierte Datenerfassung macht das Register lebendig, erhöht die Motivation der Nutzer*innen und gewährleistet eine standardisierte Datenerfassung. Darüber hinaus ermöglichen webbasierte Lösungen eine schnelle Datenverarbeitung und den sofortigen Zugriff auf vorhandene Datenbestände.

Schulungen rund um den Datenumgang

Für die Nutzung der Dateneingabesoftware sind Offline- und Online-Schulungen, wie z. B. Registerseminare, Webinare, Lehrvideos oder zugängliche interaktive Anleitungen, wichtige Säulen.

Qualitätssicherung der Daten vor QR-Umsetzung festlegen

Die Qualitätssicherung (QS) sollte sicherstellen, dass die Daten gemäß den festgelegten Datenqualitätsstandards erhoben und validiert werden. Die Anforderungen an die QS sollten während der Planungsphase des QR definiert werden, indem ein QS-Plan erstellt wird. Der QS-Plan sollte alle Formen der Datenvalidierung definieren und beschreiben. Zusätzlich ist die Durchführung von externen Audits und Plausibilitätskontrollen empfehlenswert.

- **Registrierung, Verarbeitung und Meldung von unerwünschten Ereignissen in Qualitätsregistern:** Es ist empfehlenswert, unerwünschte Ereignisse im Zusammenhang mit allen Maßnahmen der Demenzversorgung zu dokumentieren. Eine Qualitätsverbesserung auf dem gesamten Demenzversorgungspfad kann nur durch eine geplante und systematische Dokumentation im Vergleich zu einer spontanen Dokumentation erreicht werden.

alle unerwünschten Ereignisse dokumentieren

- **Analyse, Interpretation und Berichterstattung:** QR-Operatoren und Datenanalyst*innen sollten sich der Limitationen des Datentyps (Beobachtungsdaten), der Datenstrukturen, möglicher Störfaktoren, fehlender Daten sowie räumlicher und zeitlicher Variation der Daten bewusst sein. Verschiedene analytische Ansätze machen jedoch den Umgang mit Beobachtungsdaten möglich. Ein statistischer Analyseplan sollte das Analysedesign und die verwendeten statistischen Techniken festlegen.

QR-Daten = Beobachtungsdaten

statistischer Analyseplan essentiell

Berichterstattung und Interpretation der Daten ermöglichen Reflexion über Stärken & Schwächen des Demenz-QR

Die Interpretation und Berichterstattung der Resultate bilden den zweiten Schritt hin zur Qualitätsverbesserung. Die Interpretation der Daten ermöglicht eine Reflexion über die Stärken und Schwächen eines Demenz-QR. Vergleiche mit Ergebnissen von qualitativ hochwertigeren Studien oder anderen nationalen Demenz-QR können angestellt werden. Damit kann überprüft werden, ob das QR „gute“ Belege für die Qualitätsverbesserung liefert oder ob die Analysemethoden angemessen waren. Zudem sollte die Interpretation der Ergebnisse und Schlussfolgerungen die Sichtweise aller Interessengruppen berücksichtigen.

Nachvollziehbarkeit der Ergebnisse wichtig für Transparenz

Die Nachvollziehbarkeit der Ergebnisse ist von entscheidender Bedeutung, um Lehren für Entscheidungsträger*innen, Gesundheitsversorgungsplaner*innen, teilnehmende Gesundheitseinrichtungen, Patient*innen und Pflegekräfte abzuleiten. Transparenz und Verfügbarkeit der Ergebnisse sind Mindestanforderungen, um die Ergebnisse für Patient*innen und die Qualität zu verbessern.

- **Datenschutz, Einwilligung und ethische Aspekte:** Die Datenschutzgrundverordnung sollte Überlegungen zum Datenschutz leiten, da sie festlegt was Mitgliedstaaten der Europäischen Union in ihren Datenschutzgesetzen berücksichtigen müssen. Die Orientierung an der Datenschutzgrundverordnung kann als eine langfristige Maßnahme zum Schutz vor Verletzungen der persönlichen Integrität angesehen werden.

DSVGO gibt datenschutzrechtlichen Rahmen vor

Einwilligungsmodalitäten in der Planungsphase mitdenken

Fragen zur Einwilligung seitens der Patient*innen sollten im Laufe der Planung und Entwicklung des Demenz-QR beantwortet werden. Im Falle von Demenz ist es wichtig, bei der erstmaligen Registrierung mögliche Einschränkung der betroffenen Person zu berücksichtigen. Es müssen Anweisungen für Verfahren ausgearbeitet werden, mit denen die Teilnahme jederzeit widerrufen werden kann, es sei denn, für das QR gilt ein Verzicht auf die Einwilligung.

„forschungsreifes" Register

- **Weitere Aspekte:** Daten aus einem Demenz-QR sollten „forschungsreif" sein, d. h. Fragen zu den Zustimmungsformalitäten für Forschungszwecke seitens der Patient*innen und Modalitäten des Datenzugangs sowie zur ethischen Genehmigung sollten geklärt werden.

kontinuierliche Evaluation essentiell

Die Wirksamkeit und Effizienz eines QR muss bewertet werden. Daher sollte eine kontinuierliche Evaluation der Wirksamkeit und Kostenwirksamkeit die Datenerhebungen und -auswertungen begleiten.

„Change Management" mitbedenken

Veränderungsmanagement („Change Management") ist ein wichtiger Aspekt bei der Planung und in der Designphase eines Demenz-QR. Demenz-QR müssen an Veränderungen angepasst werden können.

Conclusio

QR erfahren mehr Bedeutung

QR = komplexe Systeme in komplexer Umgebung

In den letzten Jahren kommen Qualitätsregister vermehrt zum Einsatz, um Qualitätsverbesserungen in verschiedenen Versorgungsbereichen herbeizuführen. Der Bericht zeigt, dass Demenz-QRs komplexe Systeme sind, die in dem komplexen Umfeld des Gesundheitssystems mit unterschiedlichen Gesundheitsdienstleistern für Patient*innen mit einem komplexen Krankheitsbild angesiedelt sind. Verschiedene interdisziplinäre Aspekte aus der Organisations-, Evaluations- und Outcome-Forschung müssen in den verschiedenen Phasen des Aufbaus eines QR und der Operationalisierung berücksichtigt werden. Die zunehmende Verfügbarkeit digitalisierter Daten und die Notwendigkeit, die Versorgung von Demenzpatient*innen auf mehreren Versorgungsebenen zu koordinieren, erfordern die Zusammenarbeit aller betroffenen Akteur*innen. Die Verknüpfung der Demenz-QR-Daten mit verschiedenen anderen Gesundheitsdatenbanken und administrativen Daten über Patient*innenidentifikatoren ist ein wesentlicher Aspekt, um die Interoperabilität zu gewährleisten. Für ein effizientes Funktionieren des Demenz-QRs und robuste Versorgungsdaten müssen allerdings zahlreiche Aspekte berücksichtigt sowie die Anwender*innen in jeder Phase eingebunden werden.

Berücksichtigung zahlreicher Aspekte, um aussagekräftige Daten für eine Qualitätsverbesserung der Demenzversorgung zu erhalten

1 Background

1.1 Introduction

randomisierte kontrollierte Studie (RCT) = Goldstandard zur Belegung kausaler Evidenz

Qualitätsregister (QR) = System zur Sicherung & Verbesserung der Versorgungsqualität

In order to review and legitimise the use of health care interventions, various evaluation measures are necessary. The gold standard to generate causal evidence concerning effectiveness and safety is a randomised controlled trial (RCT). In most RCTs, very restrictive inclusion criteria are chosen, so only a specific subpopulation is investigated. Quality assurance (QA), monitoring, and quality improvement in healthcare systems require complementary measures. In recent years, quality registries (QRs) have emerged to serve this gap. Quality registries are a subset of patient registries that aim to improve the quality of health care services on the local, regional, or national level by collecting and monitoring crucial clinical information [1]. Several countries utilise such registries in different disease areas [2-4] to routinely collect real-world data (RWD) and generate evidence under real-world conditions, so-called real-world evidence (RWE), of current treatment approaches [5].

Ergebnisse von QR sollen Entscheidungsträger*innen unterstützen

QR sollten evidenzbasiert sein & alle Interessengruppen einbinden

QRs in dementia care are seen as a system of ongoing registration of care data to better support decision-makers and healthcare planners in developing optimal dementia care pathways while improving patient care and outcomes. Developing and monitoring of quality indicators (QIs) should ensure the quality and efficiency of dementia care by highlighting clinical processes and outcome variations while guaranteeing equitable access to dementia care services. QRs and QIs need to be based on scientific evidence, patient and caregiver experience, and clinicians' perspectives across the continuum of care from diagnosis to end-of-life. Then, QRs may benefit people directly affected by dementia and their caregivers and relatives [6].

Aufbau & Fokus des vorliegenden Berichts

Our report addresses aspects and objectives of existing and planned dementia QRs in selected countries. The focus is on identifying key factors in planning, designing, implementing, and operating a dementia QR. In addition, the report intends to present good practice strategies for working with dementia QRs. Sections 1.2 and 1.3 provide a brief introductory summary of general aspects relevant to dementia and dementia QRs to provide the knowledge required for the implementation of such registries and to point out characteristics, commonalities, and essential differences between dementia QRs to other forms of evidence-generating frameworks. Section 1.4 describes the project report's aims and research questions. In section 2, the methods used to compile this report are presented. In section 3, specific elements of existing national dementia QRs are elaborated. The focus is on methodological characteristics, governance, data management, privacy and ethical aspects, reporting, and other essential elements to consider when planning and designing a dementia QR. Section 4 gives an overview of key measures of QRs to assess quality improvement: Quality indicators. A good practice framework, including good practice strategies, recommendations, and QR practices, is discussed in section 0, and the final section 6 concludes.

1.2 Dementia

Demenz ist ein vielschichtiges Krankheitsbild (Syndrom)

Dementia is a syndrome mainly resulting from chronic or progressive cortical and subcortical neurodegeneration. Dementias are characterised by cognitive impairment, impaired emotional control and limited daily living skills [7]. The 10th revision of the International Statistical Classification of Diseases (ICD-10) defines dementia as follows:

Definition von Demenz nach ICD-10

> *'Dementia (F00-F03) is a syndrome due to disease of the brain, usually of a chronic or progressive nature, in which there is disturbance of multiple higher cortical functions, including memory, thinking, orientation, comprehension, calculation, learning capacity, language, and judgement. Consciousness is not clouded. The impairments of cognitive function are commonly accompanied, and occasionally preceded, by deterioration in emotional control, social behaviour, or motivation. This syndrome occurs in Alzheimer disease, in cerebrovascular disease, and in other conditions primarily or secondarily affecting the brain.' [8]*

steigende Anzahl an direkten & indirekten Betroffenen erfordert gezielte Public Health-Strategien

The 2017 World Health Organization (WHO) report on the '*Global Action Plan on the Public Health Response to Dementia'* emphasised that more and more people are affected, directly or indirectly, and that the complexity of this condition requires public health action involving multiple stakeholders [9, 10]. Also, in Austria in 2015, the necessity for joint action concerning dementia was acknowledged by the Ministry of Health, leading to the commissioning of a dementia strategy (*'Living Well with Dementia'*) that lays the foundations on how to best support people affected by dementia, their families and friends [11].

einschränkende Vergesslichkeit als erstes Symptom

The most common first symptom of dementia is forgetfulness to such an extent that the person's social and/or professional functioning is impaired. As the syndrome progresses, coping with everyday life becomes increasingly difficult, and problems with language and spatial and (daily) temporal orientation occur. Other common symptoms include impaired judgement, difficulties with abstract thinking, or misplacing things. Loss of initiative and personality changes may occur. Finally, the simplest activities of daily life become impossible [12, 13].

verschiedene Demenzformen & -ursachen

The common causes and forms of dementia [12-14] are:

- Alzheimer's disease (AD)
- Vascular dementia (VAD)
- Lewy body dementia (DLB)
- Mixed dementia (MD)

Demenz begleitet von neuropsychiatrischen Erkrankungen

Frontotemporal dementia (FTD), Huntington's disease dementia (HDD), and Parkinson's disease dementia (PDD) are other forms of dementia but are relatively less common [14]. The various dementia forms are often accompanied by neuropsychiatric diseases and other neurodegenerative changes [12, 13].

unterschiedliche Risikofaktoren: Alter, körperliche Aktivitäten, Rauchen, psychische Erkrankungen etc.

In addition to the heterogeneous nature and forms of dementia, risk factors can also vary. There is a distinction between unmodifiable risk factors, such as age, and modifiable risk factors, such as education status, wages, physical activities, smoking, mental health issues, or other non-communicable diseases. Public health measures or public policies can prevent modifiable risk factors. Although preventive measures provide the potential to lower risk factors, not all dementia is preventable [14, 15].

Demenz ist (aktuell) nicht heilbar

Dementia is (currently) not curable as no effective pharmacological treatment option to cure or delay the onset of cognitive decline is available [15]. A pharmacological approach aims to slow cognitive deterioration and reduce non-cognitive symptoms such as neuropsychiatric symptoms [14]. Despite considerable research, the optimal use of a single anti-dementia drug for all dementia forms remains unclear. Systematic reviews of cholinesterase inhibitors (ChEIs) (donepezil, rivastigmine, galantamine) or memantine [16] showed only modest benefits [17]. However, the effectiveness of ChEIs is deemed sufficiently effective [18], having a minimum clinically important benefit [19]. Nevertheless, most placebo-controlled ChEI studies have only a six-month follow-up and partially lack methodological rigour [14].

Behandlung zielt auf Verlangsamung des Verlusts kognitiver Funktionen ab

medikamentöse Behandlungen sollten leitliniengerecht, bedarfs- & patient*innenorientiert sein

Because dementia manifestation is clinically heterogeneous, it is unlikely that any single drug will have a large effect. This finding means that optimal medical treatment may include multiple medications, each of which may have an effect less than the minimum clinically significant difference [16]. Furthermore, the use of antipsychotics remains still controversial as this treatment form is associated with non-negligible adverse effects [20, 21]. Pharmacological treatment must be generally adjusted to the individual and her*his needs, including monitoring adverse effects [20]. A guideline-based use of anti-dementia drugs and other medications is vital.

"gute" & patient*innenorientierte Demenzversorgung berücksichtigt den ganzen Versorgungspfad

Although no clear evidence exists that multi-domain interventions can prevent incident dementia [15], many dementia forms and accompanied non-cognitive symptoms are manageable by adequate dementia care on top of pharmacological treatment once the dementia diagnosis is established [14, 21]. Good and person-centred dementia care does not rely on a single intervention, but targets the whole dementia care pathway. Adequate care includes diagnosing dementia at the right time and guideline-based treatment, support, and follow-up measures with adequate staffing levels initiated after a diagnosis [14, 22, 23]. Early syndromal and aetiological diagnosis is the basis for treating and caring for patients with dementia and should therefore be made possible for all those affected [22, 23].

Demenz-QR unterstützen Entscheidungsträger*innen & Gesundheitsplaner*innen

A dementia QR can support every single step in the dementia care pathway. It can help choose the right interventions and be used to monitor and evaluate them. Significantly, the latter is essential to support dementia care planning at the healthcare level so that quality improvements materialise.

1.3 Quality registries

1.3.1 Definitions and terminology

Patient*innenregister = organisiertes System zur Datensammlung, Monitoring & Evaluation von Patient*innendaten

In health sciences, the term patient registry is used to distinguish registries focusing on health information from other registry databases. Gliklich et al. use the following terminology for registry and register (registry database):

- *'A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more stated scientific, clinical, or policy purposes.'*
- *'The patient registry database describes a file (or files) derived from the registry.'* – [1, p. 13]

Register ≠ Registerdatenbank

The terms registry and register are often used interchangeably. However, there is a distinction between the two terms in the literature [24, 25]. For this report, the following terminology is used:

- Register refers to a file of documents containing uniform information about individual patients, collected systematically and comprehensively with a focus on a specific health or disease area, e.g. patient record database [24].
- A registry is the act of recording or registering and the record or entry itself [1]. It pertains to the organisation, which systematically monitors the quality of the specific healthcare domain and the processes associated with the register [25].

Arten von Registern:

Patient registries are roughly distinguished between their' purposes and aims. The following types of registries can be roughly distinguished [1, 26, 27]:

epidemiologische Register

- **Epidemiological and surveillance registries:** The primary purpose of these registries is to collect details on patients with specific diseases or conditions. The focus is on the prevalence and incidence of diseases, the spread, the course of diseases, associations of risk factors, the impact of environmental influences, and regional differences.

(präklinische) Forschungs- & Freiwilligenregister

- **Research, pre-clinical research, and volunteer registries:** These registries are essential in fostering research. This type of registry partly overlaps with epidemiological and surveillance registries, but the focus is not on a population but on the (clinical) patient level. The collected data provide information on the aetiology of the respective disease and its natural history, including determinants of progression and their implications for clinical practice. Preclinical research and volunteer registries are a subcategory of research registries. They aim to create a cohort suitable for trials and optimise clinical trials' conduct for interventions.

Medizinprodukte- & Medikamentenregister

- **Medical device and drug registries:** Such registries intend to monitor the medium to long-term safety of medical devices or drugs. Examples include registries tracking the safety of non-invasive devices such as wearable cardioverter defibrillators or implantable devices such as pacemakers.

Qualitätsregister

- **Quality registries:** QRs aim to improve the quality of patient health care services by collecting and monitoring crucial health care information. They are primarily implemented to improve health care at a systemic level and are used by decision-makers and policy-makers to support healthcare planning and evaluation. QRs are an organisational and methodological measure within the evaluation framework under real-world conditions in different disease areas and health care contexts.

Überlappungen von Registern

In reality, registry types can overlap, and patients may be enrolled in many registries.

1.3.2 Quality registries in dementia care

Demenz-QR können RCTs ergänzen & neue Erkenntnisse bringen

Dementia quality registries systematically monitor the quality of dementia care, within a specific care setting, by routinely collecting, analysing, validating, and reporting dementia care-related information [1, 28]. Quality registries can complement (R)CTs by validating study results in underrepresented groups, highlighting new associations and generating hypotheses for future studies [29]. However, the main objective of QRs goes beyond the goals of (R)CTs, evaluating solely single interventions.

Hauptziele:

systematisches Monitoring & Auswertung demenzspezifischer Versorgungsdaten zur Qualitätsverbesserung & Entscheidungs-unterstützung

The primary aims of a dementia QR are [28]:

- To systematically collect and monitor longitudinal data about dementia diagnosis, assessments, tests and examination procedures, treatment, and outcome data for dementia patients and their caregivers to improve the quality of dementia care along the care pathway.
- To generate risk-adjusted reports with validated and quality-assured data to inform decision-makers, dementia care planners, the public, patients, and caregivers about the adequacy, effectiveness, and efficiency of dementia care.

ursprünglich für Forschungszwecke entwickelt

Originally, QRs have been developed, implemented, and operationalised by physicians for research purposes. Improving health care quality was thus achieved through a research approach, while these quality registries were initially used only to a small extent for process improvement [29]. Thus, in addition to the main common goals, dementia QRs have served and continue to serve other purposes, such as building a resource available for research on dementia topics or facilitating the recruitment of participants for studies.

skandinavische Länder als Pioniere bei Nutzung von QR zur Verbesserung der Gesundheitsversorgung

Quality registries were only later used for improvement at a national healthcare system level. For example, Scandinavian countries have adopted quality registries as an integral part of an overall strategic healthcare approach. Sweden is a pioneer in QR development and operates 108 registries, of which some have been operating for more than 20 years [30]. Fifty-four national medical quality registries exist in Norway today [31], and Denmark has 69 National Clinical Quality Databases managed by the Danish Regions Clinical Quality Program (RKKP). All three countries were also among the first to introduce a dementia QR. In recent years, other countries have also tried to move towards quality improvement in dementia care [32].

Aufgaben der QR-Operator*innen betreffen hauptsächlich Datenmanagement-Aktivitäten

Continuous improvement activities by QR operators pertain mainly to data management activities. Tasks are [29]:

- To centrally collect data on clinical processes and patient outcomes.
- To clean data and ensure the quality of the data, i.e. quality assurance.
- To validate, benchmark, and review collected national, regional, or unit-level data.
- To systematically report data and actionable information in different types of reports, e.g. annual reports, for quality improvement and transparency reasons.
- To take appropriate action based on this data, e.g. informing decision-makers, feeding back patient- and clinical-specific data to service and dementia care providers (hospitals, clinicians, caregivers etc.).

Umsetzung von Verbesserungsmaßnahmen auf anderen Ebenen angesiedelt

The responsibility for implementing quality improvement measures resulting from the registry's data depends on the distribution of roles. The organisation running the dementia QR does not necessarily have to take responsibility for implementing quality improvement measures. Responsibility may lie with governmental authorities or the individual dementia care provider in the primary or secondary care sector.

Evidenz für Verbesserung der Versorgungswirksamkeit, -sicherheit & -effizienz durch QR

Independent of the tasks of a QR and responsibilities in the quality improvement circle of dementia care, there is evidence that for some disease areas, QRs can improve the safety of care and quality of patient outcomes and care in general [2-4]. Moreover, at the same time, there is cumulative evidence that QRs are cost-effective and have a significant return on investment [2, 26, 33, 34].

Einsatz empfohlen bei kostenintensiven & hochvolumigen Gesundheits- & Pflegeleistungen

Quality registries should be used for costly, high-volume care measures with variations in care practice and when changes in care can improve outcomes [29]. Many planning, design, implementation, and operational factors need to be considered for a QR to achieve effective and efficient changes in dementia care. One crucial aspect is defining an appropriate quality indicator set [35].

1.3.3 Quality indicators in dementia care

General issues

Qualitätsindikatoren (QI) sind Messinstrumente & dienen dem Monitoring & der Qualitätsverbesserung

Besides fundamental data management tasks, the key aspect of a QR is measuring and monitoring actionable information by so-called quality indicators or quality outcome measures. Quality indicators primarily define elements of the desired standard of health care and are a measurable target for ongoing monitoring, benchmarking, and improvement. Measurement, monitoring, and improvement are closely linked, as no improvements are possible without measurement and monitoring [29, 36].

Definition von QI der Canadian Medical Association

Several definitions of quality indicators exist. Lawrence and Olesen [37] provide an apt definition based on the working definition of the Canadian Medical Association (CMA). A quality indicator is:

> *'A measurable element of practice performance for which there is evidence or consensus that it can be used to assess the quality, and hence change in the quality, of care provided'* – [37, p.104]

ein QI muss „messbar" sein

According to this definition, a QI must be measurable. For an indicator to be measurable, it must be quantitative. E.g. in dementia care, the Mini-Mental State Examination (MMSE) score is a quantitative element of care which can be mapped into a QI (e.g. 'Proportion of patients with a cognitive assessment').

QI müssen evidenzbasierte Praxis widerspiegeln & auf einem Mindestdatensatz (MDS) basieren

In addition, dementia QIs should reflect evidence-based practice[1] (EBP). Therefore, the starting point for a QI is an evidence base such as a systematic review [39] or guidelines on QI or consensus [40] for specific relevant elements of practice, such as the results of a particular dementia assessment, relevant patient information or risk factors [37]. The complete set of practice elements is combined and forms the minimum data set (MDS). An MDS is a minimum set of common data elements that all QRs should consistently utilise. It ensures a standardised data collection process across secondary and primary care and further integrated dementia care providers [32]. As the name suggests, an MDS is the lower limit of data required specific to each QR.

wichtig: Nutzung eines "QI-Sets"

The selection of a subsequent quality indicator based on elements of the MDS requires balancing the aims of the registry with the desire to meet other needs of providers and patients. Moreover, since a single QI can only refer to individual aspects, several should be combined into an indicator set. There is no single variable of quality from which alone reliable conclusions can be drawn about the quality of care [35, 37, 41].

[1] EBP in dementia care is a process used to review, analyse, and translate the latest scientific evidence [38], which includes evidence-based foundations of dementia care (guidelines), consensus-based practicalities, standards, and aims of the respective healthcare system (national dementia strategy) including patient preferences.

Schwellenwerte definieren den Mindeststandard

Target values must be defined to assess whether a certain standard of quality is achieved with the particular QI. Target values are generally accepted (consensus) and/or evidence-based ideas of 'good quality'. Comparing the actual values with the target values indicates whether the level of 'good quality' was reached and, in the case of undercutting, where measures for quality improvement are necessary [37, 41].

QI ist meist eine Verhältniszahl, gibt aber auch QI mit einer zeitlichen Struktur

In a majority of cases, QIs depict quality in proportions or percentages. However, there are also QIs with a temporal dimension. A typical indicator is a ratio consisting of a denominator, i.e. the population under consideration, and a numerator, i.e. the proportion of persons from the population under consideration who have received the respective dementia care service or fulfil a specific criterion [32, 37, 41].

Prozess zur Festlegung eines Qualitätsstandards & Verortung des QIs

Figure 1-1 shows the process of establishing (genealogy) a certain quality of care (standards of care) and the location of QIs in the process.

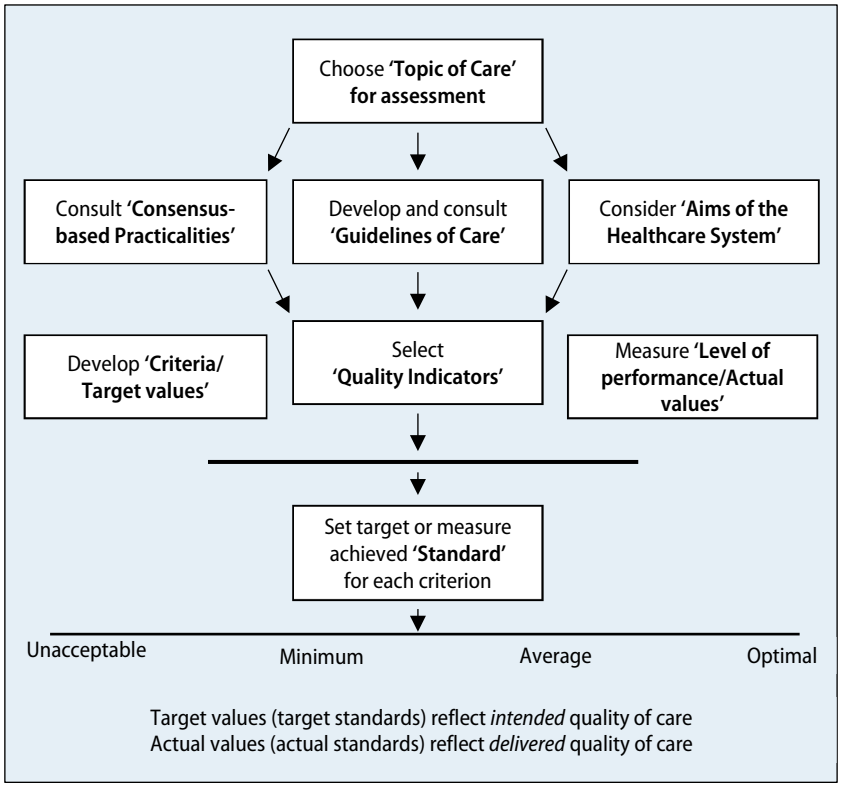


Figure 1-1: Setting a standard of care according to Lawrence and Olesen [37] (adapted, own depiction)

Ausgangspunkte sind der jeweilige Versorgungskontext & die dazugehörige verfügbare Evidenz

The process begins with setting the topic, i.e. dementia care, to consulting guidelines [39], consensus-based dementia care practices [40], and national dementia strategies (aims) to selecting the quality indicator set and evaluating whether QI target values were achieved. In addition, patients' and formal and informal carers' perspectives are also important components when setting a standard of care to create a participatory process. These perspectives are mostly considered and mapped in national dementia strategies or guidelines.

QI zur Prozess-, Struktur- & Ergebnisqualität in der Demenzversorgung

Quality indicators can take the form of process, structural or outcome measures [42]. In the dementia care context, benefits and changes may be realised from tracking QIs, including [32]:

- Time from first indications or symptom onset to referral to a memory clinic to diagnosis (Process quality)
- Proportion of patients for whom a reduction in time was realised (Process quality)
- Proportion of patients with a specific diagnosis of dementia (aetiological diagnosis) to initiate adequate treatment and support measures (Process quality)
- Reduction in the use of antipsychotic drugs (Process quality)
- Neuropsychiatric Inventory (NPI) scores over time (Outcome quality)
- Better support infrastructure for both the person living with dementia and the carer (Structure quality)

patient*innenberichtete Ergebnisse haben eine bedeutende Rolle bei der Erstellung von QI zur Ergebnisqualität

Self-reported health-related Quality of Life (HRQoL) outcomes play a special role in outcome quality indicators as they reflect outcomes from the perspective of patient-centred dementia care. In recent years, there has been growing recognition of the importance of self-reported HRQoL outcomes, including patient- and carer-centred outcome and expectation measures (PROMs/PREMS and CROs/CREs). PROMs and other self-reported outcomes are increasingly incorporated into QRs for other chronic and progressive diseases. Examples of patient-centred outcome quality indicators in dementia care are:

- Overall QoL of the patient with dementia or the carer
- Proportion of patients who reported on patient-related outcome measures

zahlreiche Aspekte müssen berücksichtigt werden

However, the selection of valid and reliable dementia-specific HRQoL measures considering the stage and severity of the dementia type are deemed significant as the pathology possibly influences an individual's ability to engage in such efforts [43]. In addition, the choice of the person providing the information (self, proxy by a caregiver, or a combination) must be considered.

Indicator requirements

Fragen bei der Auswahl: ist der QI ein „gutes" Maß & „zielgruppengerecht"?

The Agency for Healthcare Research and Quality (AHRQ) [1] emphasises that two issues need to be considered when selecting quality indicators:

- Is the quality indicator a 'good' (outcome) measure?
- Are the quality indicators 'suitable' for the target audience (e.g. decision-makers, healthcare planners etc.)?

Grundvoraussetzungen für "gute" QI:

A QI must fulfil specific properties such as validity or reliability for the first question to be satisfied. The AHRQ catalogue [44] gives an appropriate overview of basic requirements[2] based on principles of measurement endorsed by the National Quality Forum (NQF) [46]:

einheitlich einsetzbar?

- **Standardisation:** The QIs are standardised at the national level, which means that all health care providers will be reporting the same kind of data in the same way.

[2] There are further catalogues of requirements for quality indicators. An extensive overview is given by Reiter et al. (2008) [45].

- **Comparability:** If appropriate, the results of the QIs are adjusted for confounders to be comparable across different health care providers in various care settings (Confounders: external factors that could bias the outcome; factors include age, education, gender, income, and health status). — **Vergleichbarkeit gegeben?**
- **Availability:** Data and results from QIs are available for most relevant stakeholders. — **verfügbar für alle Interessengruppen?**
- **Timeliness:** The results of QIs are available in time for you to produce and distribute a report when it is most needed. — **zeitliche Verfügbarkeit?**
- **Relevance:** The QI reflects essential aspects of care quality, relates to national quality objectives, and is helpful for decision-makers or the general targeted audience. — **relevant für alle Zielgruppen?**
- **Validity:** The QI reflects what it intends to measure. For example, does the QI underlying cognitive assessment scale accurately and consistently measure signs and symptoms of dementia? Validity must be tested empirically. — **Gültigkeit: „misst der QI was er messen sollte?"**
- **Reliability:** The QI needs to give repeatedly and reproducibly the same value. For example, different assessors use a test for neuropsychiatric symptoms twice in short intervals and should give identical scores. — **Zuverlässigkeit bei mehrmaliger Messung?**
- **Experience (Feasibility):** Health care providers have experience with all outcome measures and QIs, so they can be confident that the measure reflects actual performance and not shortcomings in information systems. — **Realisierbarkeit gegeben?**
- **Stability:** The QIs are not scheduled to be 'retired', e.g. removed from a measurement data or QI set to make room for better measures. — **Beständigkeit?**
- **Evaluability:** The results of the QIs can be evaluated as either better or worse than other results, in contrast to descriptive information that merely shows how health care providers may differ. — **Evaluierbarkeit gegeben?**
- **Distinguishable:** The QIs reveal significant differences among health care providers. — **Unterscheidbarkeit der Ergebnisse?**
- **Credibility:** The QIs are either audited or do not require an audit. — **vertrauenswürdig?**

If a QI or QI set satisfies all these requirements and is, therefore, a scientifically 'good' measure, one needs to consider whether the QI is also appropriate for decision-makers or healthcare planners. To prove whether the intended or used QI is suitable, one has to ensure that the following three points are met [44]: — **alle Kriterien erfüllt = wissenschaftlich "guter" QI**

- *Do the QIs support quality improvement and improved decision-making or healthcare planning?*
  The use of a 'good' QI set may not only lead to quality improvement in dementia care and dementia outcomes due to better and informed decision-making. Good QIs can raise awareness among providers, patients, and the general public about important aspects of care but perhaps not as visible or well-known to them [44]. — **zielgruppengerechter QI: Unterstützung der Entscheidungsträger*innen bei der Qualitäts-verbesserung**
- *Do decision-makers or healthcare planners view the QIs as important?*
  QIs must capture aspects of health care services decision-makers view as important or whose importance can be easily demonstrated. Decision-makers are very unlikely to look at the QR output, such as annual reports or use the information in it if they do not understand or care about the QI used [44]. — **wird der QI als wichtig erachtet & deckt relevante Aspekte ab?**

QI relevant für Pat., Angehörige und Leistungserbringer*innen?

- *Are the QIs relevant to dementia patients, caregivers, and dementia care providers?*
  A dementia QI must also be important to the dementia-related 'target group'. For example, the QIs should match the needs and interests of dementia patients and their caregivers [44].

1.3.4 Excursus: Quality of care and evaluation research

Was ist Qualität in der Gesundheitsversorgung?

A universal definition of health care quality is as difficult as the definition of health itself. According to Lawrence and Olesen [37], the Institute of Medicine (IOM) [47] has defined quality as:

> *'Quality is the extent to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge'. [37, p.104]*

qualitativ hochwertige Gesundheitsversorgung sollte …

This definition mainly pertains to patients and outcomes and is deemed imprecise for implementation [37]. Therefore, the IOM extended the original definition with six aims in their analytic framework for quality assessment [48]. The framework provides a broader definition of quality, including several healthcare domains. Quality health care and services should be:

effektiv,
- **Effective:** Providing evidence-based health care services to those who need them.

sicher,
- **Safe:** Avoiding harm to people for whom the care is intended.

patient*innenzentriert,
- **Patient-centred:** Providing care that responds to individual preferences, needs, and values.

zeitgerecht,
- **Timely:** Reducing waiting times and sometimes harmful delays.

fair,
- **Equitable:** Providing care that does not vary in quality on account of gender, ethnicity, geographic location, and socio-economic status.

effizient,
- **Efficient:** Maximising the benefit of available resources and avoiding waste.

& über das ganze Leben lang verfügbar sein

The WHO [49] complements the IOM framework with a seventh aim. Quality health services should also be:

- **Integrated:** Providing care that makes the full range of health services available throughout life.

Evaluationsforschung überprüft diese Kriterien & unterscheidet dabei …

Evaluation research in the health sciences concerns whether these quality improvement aims and domains have been achieved. It examines, for example, whether health interventions, programmes, and processes are effective and efficient [1, 50].

… 3 Dimensionen der Qualität

In the context of quality improvement and evaluation of QIs, a distinction can be made between the following criteria – just as in other areas of quality measurement [42, 51]:

Strukturqualität: bezieht sich auf Ressourcen & Personal
- **Structural quality** comprises the evaluation of existing structures or assessments of a specific need for persons, capacities, and resources (e.g. the number of nursing staff per patient; level of training of medical staff; adequate maintenance of technical equipment). It is the sum of material and personal equipment in quantitative and qualitative terms [51, 52].

- **Process quality** comprises the assessment of workflows and procedures that are systematised according to comprehensible and verifiable rules. Process quality corresponds to the state of professional knowledge, which is regularly evaluated and continuously improved [51, 52].
- **Outcome quality** reflects the impact of health care services or interventions on the professionally assessed health status of patients, QoL or satisfaction of individual patients or a population group as a result of certain framework conditions and measures. Patient-reported outcomes play a unique role [51, 52].

Prozessqualität bezieht sich auf verschiedenartige Arbeitsabläufe

Ergebnisqualität bezieht sich auf Patient*innenergebnisse

The different criteria are assessed based on measurable quality indicators (endpoints, outcome measures), which enable the observation, comparison and evaluation of the quality of the respective health care service or pathway [52].

Overall, evaluation research aims to make visible any effect of an intervention on care in (complex) systems. Quality registries can be seen as complex systems to improve the whole dementia care pathway. However, it should be noted that in complex interventions or systems, there is a trade-off between precise, unbiased answers to narrow questions and uncertain answers to broader, more complex questions. Researchers should answer the most valuable questions to decision-makers rather than those that can be answered with greater certainty [53].

QR & Evaluationsforschung hängen zusammen

1.4 Project aims and research questions

The project report aims:

Berichtsziele:

- To give an overview of existing and planned[3] dementia QRs with the main focus on registries intended to be used for monitoring outcomes and improving the quality of dementia care.

Übersicht bestehender Demenz-QR

- To compile commonalities and differences of identified QRs in terms of the current use of such registries, organisational, implementation, and technical aspects, including aims of the registry, governance structure, healthcare setting, funding, target population or types of dementia considered, data management characteristics or type of consent.

Identifikation von organisatorischen, umsetzungsrelevanten & technischen Aspekten

- To identify collected data and the minimum data set (MDS), including data on patient characteristics, dementia care providers, diagnostic workup, treatment, support, and care.
- To identify QIs and outcome measures used to monitor and evaluate the structural, process and outcome quality of the dementia care pathway.

Identifikation von erhobenen Datenstrukturen & eingesetzten QI

- To serve as a basis for decision-makers to implement an Austria-wide QR for dementia care planning and quality control, consistent with and complementing the Austrian dementia strategy.

Basis für Entscheidungsträger*innen bereitstellen

[3] With planned QRs, we refer to registries for which elaborated concepts and models are available.

Nicht-Ziele:

Fokus auf andere Demenzregister, systematische Bewertung von & Entwicklung eines Demenz-QR

The report does not:

- Cover other types of dementia registries such as epidemiological registries, (preclinical) research registries, medical device and drug registries, and research volunteer registries.
- Systematically assess the effectiveness or evaluate the quality of identified QRs, results, and outcome measures.
- Develop an Austrian-wide dementia QR, provide a concrete concept on the implementation process, or develop specific QIs.

3 Forschungsfragen:

Welche Länder haben ein Demenz-QR?

Welche QI werden aus den gesammelten Daten gebildet?

Was kann aus den Informationen für die Praxis abgeleitet werden?

We will answer the following research questions (RQ):

- **RQ1:** Which countries have a dementia quality registry, and what are common characteristics and differences in the current use of such registries, in their organisational, implementation, and technical aspects?
- **RQ2:** What data are collected in dementia quality registries, and which quality indicators or outcome parameters regarding the structural, process, and outcome quality of dementia care are derived from the data?
- **RQ3:** Which good practice strategies need to be considered for implementing and operating a dementia quality registry and support the planning process, design process, evaluation, and reporting of results to improve the quality of dementia care?

2 Methods

Zielgruppe, Interesse & Kontext

The following Population, Interest, and Context (PICo) scheme (see Table 2-1) guided the report, from literature search to registry selection to elaborating all three research questions.

Table 2-1: PICo scheme

Population	Patients with dementia according to ICD-10 [8]: (F00-F03)
Interest	The report is interested in dementia quality registries with a focus on the following aspects: ■ Commonalities and differences of existing and planned QRs in terms of the current use as well as organisational, implementation, and technical aspects ■ Data collected by QR operators derived implications and quality indicators to monitor and evaluate the structural, process, and outcome quality of dementia care ■ Good practice strategies and recommendations for implementing and operating a dementia QR *Non-interests: Other types of dementia registries and registries with restricted local coverage (hospital/clinic-based registries), systematically evaluate/appraise effectiveness or quality of QRs, give instructions on the implementation process or develop QIs*
Context	Countries with upper to high incomes and a comparable healthcare system to Austria
Language	English/German or translation of reports in other languages
Type	Any publication
Period	Update of previous and existing systematic reviews and reports beginning from 2016

Abbreviations: ICD … International Statistical Classification of Diseases, QI … quality indicator, QR … quality registry

2.1 Search for dementia quality registries

umfassende strukturierte Handsuche auf Webseiten zu Demenz-QR & in Fachdatenbanken

To answer research questions 1 and 2, we mapped national and subnational quality registries and quality indicators, which are intended to monitor outcomes and improve the quality of dementia care. In May and June 2022, we conducted an extensive structured hand search for countries that consider dementia QRs as an integral part of their health and social care strategy by using the following resources and databases:

- Websites of national ministries of health and public health institutions,
- Websites of identified registry operators and related annual reports,
- Google (Scholar),
- PubMed,
- TRIP database,
- Alzheimer Europe website,
- WHO website,
- OECD website.

systematische Übersichtsarbeiten als Ausgangsbasis für die QR- & Länderauswahl

As a starting point, we used a systematic review (SR) by Krysinska et al. [26] that reviewed 31 dementia registries in 14 countries worldwide operating on an international, national or local level between 1986 and 2016. In addition, we used two more SRs [54, 55] to identify countries and possible national registries. The scope of all three systematic reviews was beyond dementia quality registries. The reviews also covered epidemiological registries, dementia

research and pre-clinical dementia research registries, and dementia research volunteer registries. Nevertheless, the countries and registries served as a first reference point. As a second starting point for our search for eligible countries and registries, we searched through the national dementia strategies listed for 39 countries on the Alzheimer Europe [56] website.

Suchstrategie Handsuche

We used the following search strategy (see Table 2-2) during our searches in the databases and national dementia strategy documents:

Table 2-2: Search strategy for the structured hand search

Search term	linked with	Suchbegriff	verknüpft mit
English terms		Deutsche Begriffe (German terms)	
quality registry* quality register* quality database* (national) registry* (national) register*	clinical dementia dementia care quality of care	Qualitätsregister* (Nationales) Register* Qualitätsdatenbank*	klinisches Demenz Demenzversorgung Versorgungsqualität

* *indicates that also the plural was used in the search*

2.2 Selection of countries and quality registries

45 Demenzregister in 43 Ländern

The search resulted in 45 dementia registries in 43 countries. Table A-1 in the Appendix gives an overview of the identified countries and dementia registries. In addition, this table provides the source from which the QRs were identified. The inclusion of countries and registries was discussed based on the country list and based on the identified literature and sources by two persons (CS, LG). Differences were resolved through discussion and consensus or the involvement of a third person. Figure 2-1 shows the selection process.

38 der 45 Länder haben (noch) kein Demenz-QR oder eine andere Art von Demenzregister

Of the 43 countries, 38 countries either:

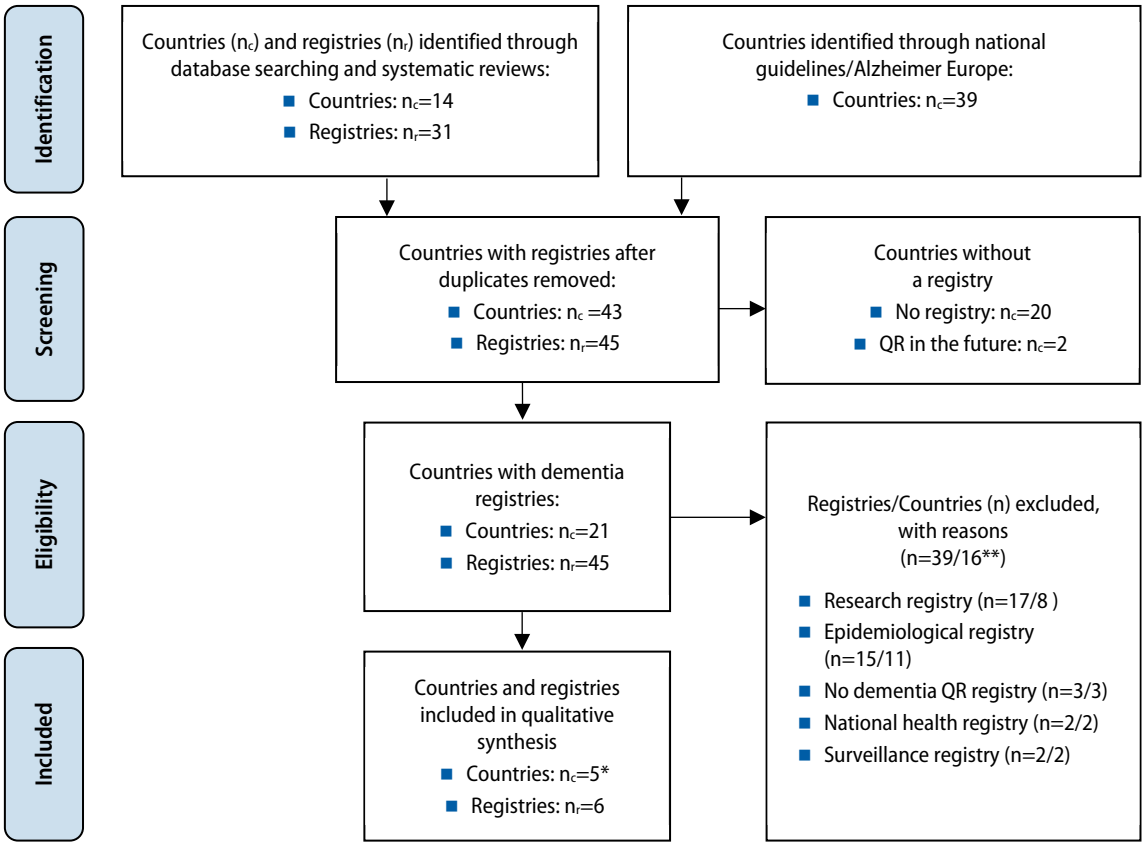
- Do not have a quality registry, nor is information available according to the identified national dementia strategies, systematic reviews and other sources (20 countries).
- Implement a quality registry in the future according to the national dementia strategy (e.g. two countries).
- Have a dementia registry other than a quality registry or do not satisfy the characteristics of a quality registry (16 countries).

Slovenia [57] and Spain [58] do not have a QR but will implement one in the future according to their national dementia strategy. The registry of dementias of Girona (ReDeGi) in Spain is currently epidemiological but will change towards a more quality-oriented focus in the future [32]. The Registry of Senior Australians (ROSA) is not a dementia-specific quality registry. The Dutch Dementia Care and Support Register by the National Dementia Care and Support Register in the Netherlands (Nivel) does not qualify as a quality registry. Nivel's approach is not systematic enough and does not satisfy the methodological foundations of a quality registry.

Of the 45 identified dementia registries across 43 countries, 39 registries in 16 countries do not qualify as quality registries or serve another purpose. Seventeen (44%) of the 39 excluded registries were research registries, 15 registries (38%) were epidemiological registries, two (5%) were national health registries, and a further two (5%) were surveillance registries. Finland has quality registries, but not for dementia [59]. The ROSA [60] and Nivel by the Netherlands Institute for Health Services Research [61] were also excluded.

Six national quality registries from five countries (Australia, Denmark, Ireland, Norway, Sweden), considering dementia QRs as an integral part of their health and social care strategy, were identified and included in our analysis.

in Summe 6 nationale Demenz-QR in 5 Ländern identifiziert



* *Australia, Denmark, Ireland, Norway, Sweden*

** *Countries can have more than one type of (excluded) registry*

Figure 2-1: Flow chart of registry selection (PRISMA Flow Diagram)

2.3 Data extraction and analysis of the dementia registries

Datenextraktion & Übersetzung von nicht-englischer- oder -deutschsprachiger Information

We prepared data extraction tables for each selected country – so-called country and quality indicator profiles. Non-English language sources were translated using DeepL (www.deepl.com). The translations and the extraction tables were checked for consistency by two researchers (CS, LG). We set the extraction categories according to the Registry Evaluation and Quality Standards Tool (REQueST) [62, 63] by the European Network for Health Technology Assessment (EUnetHTA). The REQueST was initially developed to evaluate clinical registries and aims to support HTA organisations and other actors in guiding and assessing registry data for effective usage in HTA. The tool uses an iterative and collaborative methodology with registry holders. We did not assess the registries according to the tool's domains but used the evaluation categories for data extraction to descriptively present important registry characteristics.

Charakteristika nach EUnetHTA REQueST

REQueST: 3 Domänen & 23 Interessenkategorien

The tool has three domains covering 23 areas of interest:

- Methodological information: Geographical and organisational setting, inclusion and exclusion criteria, follow-up etc.
- Essential standards: Registry aims and methodology, governance, minimum data set etc.
- Additional requirements: Interoperability and linkage, data sources, ethics.

Anpassung der Interessenkategorien

We adjusted the domains for our purposes and covered four domains with 32 categories according to the following scheme (see Table 2-3):

Table 2-3: Extraction categories

General and methodological information	Governance and management	Data management	Additional aspects
General information: ■ Registry name ■ Number of inhabitants ■ Dementia prevalence ■ Database completeness (coverage) ■ First launch and duration ■ First annual report and frequency ■ Size/Number of registered patients *Methodological information:* ■ Dementia type ■ Diagnosis system ■ Inclusion and exclusion criteria ■ Follow-up ■ Registry aims and methodology ■ Use for register-based research ■ Confounders	■ Governance ■ Geographical setting/ Participating sites ■ Daily management ■ Technical management ■ Funding/Financing	*General data management:* ■ Data collection and registry maintenance ■ Data dictionary ■ Standard, definitions, and specifications ■ Minimum data set and variables *Interoperability and data sources:* ■ Interoperability and readiness for data linkage ■ Data sources *Quality assurance and safety:* ■ Quality assurance and validation ■ Data cleaning ■ Missing data ■ Protection, security, and safeguards	■ Informed consent/ Participation ■ Ethics ■ Reporting

We summarised and analysed the extracted information of the included quality registries in section 3 according to the extraction categories. We refrained from citing the sources directly in the text in section 3 due to the multitudes of different sources, websites in different languages, and readability. The data extraction tables, including the sources of information for each country, can be found in the Appendix (Table A-2-Table A-13).

genaue Quellen & umfassende Tabellen im Anhang

2.4 Analysis of the quality indicators

We extracted information on the QIs and the underlying evidence foundations (recommendations from guidelines or consensus-based recommendations), including QI target values and results from the annual reports of the six selected registries. Following the registry synthesis, we summarised and analysed the extracted information on the included quality indicators in section 4. With our approach, we wanted to show the genealogy of the respective QI as depicted in Figure 1-1).

Analyse der QI & zugrundeliegenden Evidenz aus den 6 Demenz-QR

As the first step, we described information and sources on the foundations of the QI, such as guidelines, consensus-based recommendations, or dementia care aims defined by national dementia strategies.

1. **Schritt: Übersicht der QI-Grundlagen**

In a second step, we gave an overview of all identified quality indicators and assigned the QIs to categories of a typical dementia care pathway [6, 55]:

2. Schritt: Übersicht aller identifizierten QI & Einteilung nach Kategorien eines Demenzversorgungspfads

- Pre-diagnosis indicators, such as time from first contact to diagnosis
- Diagnosis and diagnostic workup indicators, such as the proportion of patients undergoing basic dementia workup
- Treatment, support, and follow-up indicators, such as the proportion of patients treated with dementia drugs
- Outcome-related indicators, such as Quality of Life (QoL) measures
- Meta indicators and other quality indicators, such as coverage

We clustered the indicators into subgroups in the third step and merged registry-overlapping QIs. We numbered the indicators from QI1 to QI46 and listed the indicators which overlap across registries. The following taxonomy (see Table 2-4) was used to cluster identified indicators thematically:

weitere Gruppierung der QI

Table 2-4: Taxonomy of quality indicator categories and clusters

Category	Clusters
Pre-diagnosis	■ Referral process and waiting times
Diagnosis and diagnostic workup	■ Basic dementia assessment/workup ■ Cognitive assessment and neuropsychiatric assessment ■ Imaging via CT/MR (neuroimaging) ■ Functionality/Activities of daily living assessment ■ Specific dementia diagnosis (aetiological diagnosis) ■ Other tests and diagnosis-related quality indicators

Category	Clusters
Treatment, support, and follow-up	■ Pharmacological treatment (dementia medication) ■ Pharmacological treatment (other medication) ■ Psychosocial treatment and support ■ Other treatment-, support-, and follow-up-related quality indicators
Outcome-related quality indicators	■ Cognitive and neuropsychiatric outcomes ■ QoL of the patient/PROMs/PREMs ■ QoL of the carer/CROs/CREs ■ Other outcome-related quality indicators
Meta indicators and other quality indicators	■ No clusters specified

Abbreviations: CT/MR … computer tomography/magnetic resonance, CRO/CRE … carer-reported outcomes and expectations, PROM/PREM … patient-reported outcome and expectation measure, QoL … quality of life

3. Schritt: Link zwischen QI, Evidenzbasis & Beschreibung der Ergebnisse

As a final step, we have created short vignettes to establish the link between the evidence foundations of dementia care in each country and the quality indicators used. The indicators' results from each registry's last annual report are presented after each vignette.

2.5 Elaboration of good-practice strategies, recommendations, and practicalities

Ausarbeitung von Good Practice-Strategien & Empfehlungen …

To answer research question 3, we elaborated good practice strategies, recommendations, and practicalities important for planning, designing, and operating a QR from the identified QRs and the information from the so-called 'registry science' literature [36, 64-66]. We proceeded as follows:

… basierend auf User Guide für Patient*innenregister der Agency for Healthcare Research and Quality (AHRQ)

Good Practice-Framework mit 12 relevanten Kategorien

In the first step, we consulted the good practice strategies for patient registries elaborated in a report by Mathis and Wild [27]. The report summarises essential pillars of registry work presented in the manual *Registries for Evaluating Patient Outcomes: A User's Guide* by the AHRQ User's Guide[4] (3rd edition) [36]. We have updated the good practice strategies and added contents of the two new categories of the 4th edition of the AHRQ User's guide [1] ('Governance' and 'Selecting and Defining Outcome Measures for Registries'). The good practice strategies on 'Data Elements' and 'Selecting and Defining Outcome Measures for Registries' are discussed in one common section, because the MDS is the basis for the QI set. Figure 2-2 shows the categories for which good practice strategies and recommendations were elaborated (good practice framework).

Ergebnisse der Demenz-QR wurde in das Framework eingebettet & diskutiert → „Lessons learned"

In the second step, we derived conclusions from the empirical findings of the identified QRs and integrated them within the good practice framework elaborated in the first step. The discussed findings in this section can be interpreted as lessons learned from existing dementia QRs.

[4] The manual, now in the 4th edition, is of particular importance when implementing a registry [1]. It is intended as a guide for all phases of registry work from planning to designing to evaluating registries.

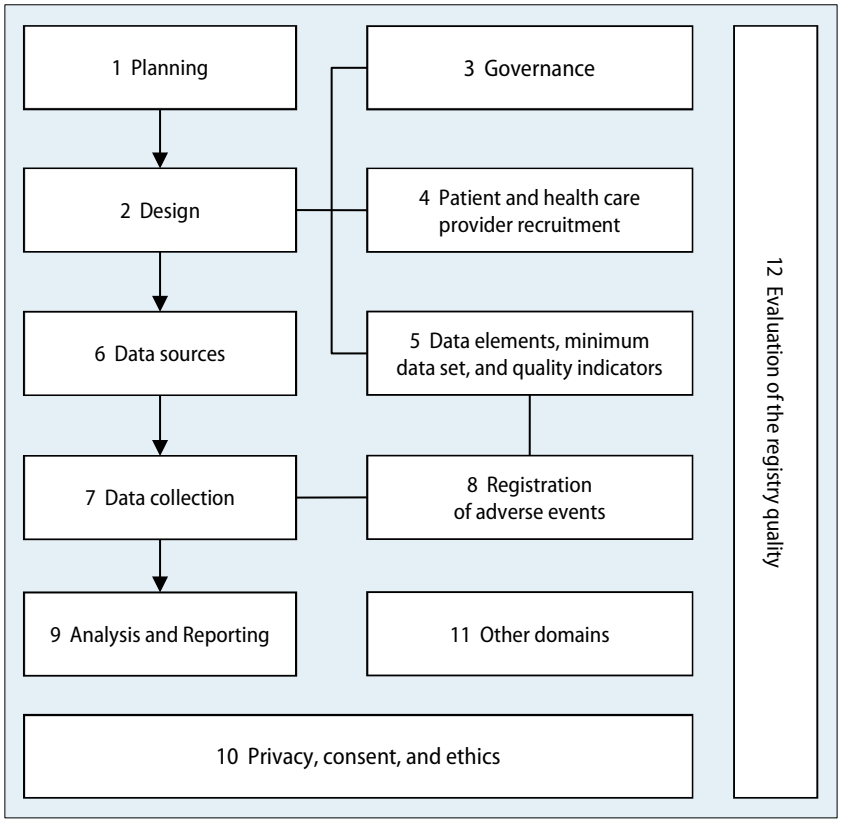


Figure 2-2: Good practice framework and categories by Mathis and Wild [27] and AHRQ [1] (adapted, own depiction)

2.6 Quality assurance of the report

Begutachtung durch 1 interne Reviewerin & 1 externen Reviewer

As part of quality assurance, the report was reviewed by an internal reviewer (CW) and an external person (SM-E). The external reviewers were primarily asked to assess the following quality criteria:

- **Technical correctness:** Is the report technically correct (evidence and information used)?
- Does the report **consider the latest findings** in the research area?
- **Adequacy and transparency of method:** Is the method chosen adequate for addressing the research question, and are the methods applied transparently?
- **Logical structure and consistency of the report:** Is the report's structure consistent and comprehensible?
- **Formal features:** Does the report fulfil formal criteria of scientific writing (e.g. correct citations)?

The AIHTA considers the external peer review by scientific experts from different disciplines as a quality assurance method of scientific work. The responsibility for the report content lies with the AIHTA.

3 Results: Mapping of countries with quality registries

3.1 Included countries and general information

In the course of the search, six national quality registries (QRs) from five countries, which consider dementia QRs as an integral part of their health and social care strategy, were identified:

- *Australia (AU):* The Australian Dementia Network Registry (ADNeT)
- *Denmark (DK):* The Danish Quality Database for Dementia (DanDem)
- *Ireland (IE):* The National Dementia Registry Ireland (NDRI)
- *Norway (NO):* The Norwegian Registry for Persons with Cognitive Symptoms (NorKog)
- *Sweden (SE):*
  - The Swedish Registry for Cognitive and Dementia Disorders (SveDem)
  - The Swedish Behavioural and Psychological Symptoms of Dementia Registry (BPSDR)

6 nationale Demenz-QR in 5 Ländern:

Australien (ADNeT), Dänemark (DanDem), Irland (NDRI), Norwegen (NorKog), Schweden (SveDem, BPSDR) BPSDR mit Fokus auf Verhaltensstörungen bei Demenz

Denmark, Norway, and Sweden have been operating their dementia registries for several years, with SveDem being the longest-running (since 2007). BPSDR, focusing on BPSD in all dementia disorders, was established in 2010. Sweden is the only country amongst the six identified countries which operates two quality registries. NorKog and DanDem were established in 2013 and 2016, respectively. The launch of the Australian registry (ADNeT) was in 2020. A national dementia registry model for Ireland (NDRI) was developed in 2020 as part of a research project. The NDRI is not yet implemented but will be introduced in the next few years.

SveDem läuft seit 2007 & BPSDR seit 2010, DanDem & NorKog seit 2013 bzw. 2016

ADNeT ist seit 2020 aktiv und NDRI noch nicht umgesetzt

The four Scandinavian QRs (DanDem, NorKog, SveDem, BPSDR) have a relatively longer duration than the two non-Scandinavian QRs (ADNeT, NDRI), and thus, the number of registered patients is more extensive within the Scandinavian QRs. SveDem has by far the largest number of registered dementia patients, with 107,099 as of 2022, followed by BPSDR with 82,810, NorKog with 18,229 dementia patients, and DanDem with 9,282 patients. ADNeT started data collection in 2020 and included 1,000 registered patients with dementia disorders until 2022. NDRI commenced in mid to late February 2020 with a data prototype to test the preliminary national QR model on 40 registered patients with dementia.

SveDem mit meisten registrierten Pat. (~107.100) gefolgt von BPSDR (~82.800) und NorKog (~18.200)

3.2 Design and methodological information

3.2.1 Dementia types and diagnosis system

alle 6 QR decken eine breite Palette an Demenzformen & -ursachen ab

Dementia is not a specific disease but a syndrome with a wide range of symptoms. There are many different types and causes of dementia. All six QRs cover a wide range of dementia disorders. Table 3-1 shows dementia types and categories that are covered by each registry:

Table 3-1: Covered dementia types and categories of each quality registry

	Registry					
Dementia types and categories	**ADNeT (AU)**	**DanDem (DK)**	**NDRI (IE)**	**NorKog (NK)**	**SveDem (SE)**	**BPSDR (SE)**
AD	✓	✓	✓	✓	✓	✓
MAD	✓	✓	✓		✓	✓
VAD	✓	✓	✓	✓	✓	✓
DLB	✓	✓	✓	✓	✓	✓
FTD	✓	✓	✓		✓	✓
PDD		✓		✓	✓	✓
HDD		✓				
USD	✓	✓	✓	✓	✓	✓
other and unknown types	✓	✓	✓	✓	✓	✓
MCI	✓	✓	✓	✓	✓	
SCI				✓		

Abbreviations: AD … Alzheimer's disease/dementia, DLB … dementia with Lewy bodies, FTD … frontotemporal dementia, HDD … Huntington's disease dementia, MAD … mixed AD, MCI … mild cognitive impairment, PDD … Parkinson's disease dementia, SCI … subjective cognitive impairment, USD … unspecified dementia, VAD … vascular dementia

größtenteils überlappen die abgebildeten Demenzformen

5 der 6 QR registrieren auch Pat. mit leichten kognitiven Störungen

The dementia types and categories that are covered by the registries overlap by and large. Only DanDem explicitly covers Huntington's disease dementia (HDD). Parkinson's disease dementia (PDD) is covered in four of six QRs (DanDem, NorKog, SveDem, BPSDR). Whether these two specific dementia types are included in the category 'unspecified dementia' or 'other and unknown types' in the other registries is unclear. Five of the six QRs (ADNeT, DanDem, NDRI, NorKog, SveDem) also explicitly cover mild cognitive impairment (MCI). The only QR that covers patients with subjective cognitive impairment (SCI[5]) is NorKog.

[5] SCI is a self-experienced persistent decline in cognitive capacity in comparison with a previously perceived normal cognitive status. SCI is unrelated to an acute event. SCI affected persons have a normal performance on standardised cognitive tests used to classify MCI, adjusted for age, sex, and education. SCI is not a diagnostic category of the International Statistical Classification of Diseases-10 [67].

ICD-10 als Basis für die Diagnoseklassifizierung in allen 6 QR

All registries use the 10th revision of the International Statistical Classification of Diseases (ICD-10) for classifying dementia diagnoses. Three QRs (DanDem, ADNeT, SveDem) use further diagnosis systems:

- *ADNeT (IE):* ICD-10 and Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT[6])
- *Dandem (DK):* Sundhedsvæsenets Klassifikations System (SKS[7])
- *SveDem (SE):* McKeith criteria for dementia with Lewy bodies (DLB) [69], Lund-Manchester criteria for frontotemporal dementia (FTD) [70], and Movement Disorder Society Task Force criteria for PDD [71]

3.2.2 Inclusion and exclusion criteria and follow-up

Einschlusskriterien: in 5 von 6 QR werden nur (neu)diagnostizierte Pat. registriert

Five of the six QRs (ADNeT, NDRI, DanDem, SveDem, BPSDR) include patients only with confirmed or new dementia diagnoses in the registry database. The only exception is NorKog. NorKog covers any patient who was examined for cognitive symptoms or dementia regardless of age. ADNeT and DanDem explicitly only cover patients ≥18 years of age. The other three QRs (NDRI, SveDem, BPSDR) are not explicit about the inclusion age. For patients with a linguistic or cultural background other than Norwegian or indigenous people in Australia and Norway (Sámi) [72], different assessment tools considering different education, cultural, and language background are used in the inclusion process, such as the Kimberley Indigenous Cognitive Assessment (KICA) [73].

Teilnahme der datenmeldenden Zentren ist freiwillig

Participation from clinical and care sites such as specialist and memory clinics (SCs/MCs) is voluntary for all registries. BPSDR and SveDem charge costs from the municipalities' participation in national QRs (since 2019). A one-off fee is charged for the administrator and the certification training [SEK 350 (~€ 32) and SEK 2,500 (~€ 230)]. No other costs are added regarding the use of the registry, regardless of how much it is used. For the other QRs, no information on charged costs was available.

Teilnahmebereitschaft ist generell hoch

Willingness to participate in the QR on the part of the clinical sites is very high, e.g. in Norway, 98% of all outpatient SCs/MCs and nursing homes (NH) participate in NorKog. In Sweden, 78% of primary care units (PCUs) and 100% of SCs/MCs participate in SveDem. Table 3-2 gives an overview of the commonalities and differences concerning the inclusion and exclusion criteria for patients and participating clinical sites:

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[6] SNOMED CT is a systematically organised machine-readable collection of medical terms with codes, terms, synonyms and definitions used in clinical documentation and reporting. The system is used for electronic exchange of clinical health information and constitutes a standard in interoperability [68].

[7] The SKS is a system designed for classification within the hospital system and the primary care sector. The system has been created to ensure clear communication between all groups and actors within the health care system, as well as the electronic information systems in the health care system. The ICD is embedded in the SKS.

Table 3-2: Inclusion and exclusion criteria in each quality registry

Registry	Inclusion and exclusion criteria for patients and participating sites
ADNeT (AU)	All patients ≥18 years of age who attend a participating site receive a new diagnosis of either dementia or MCI, and permanent residents of Australia are included. Site participation is voluntary. The registry team, promotional activities, and word of mouth identify potential sites.
DanDem (DK)	All patients ≥18 years of age who have had an outpatient dementia assessment in a dementia specialist clinic[8]/memory clinic (SC/MC) in the secondary care sector (public as well as private) and whose patient registration in the clinical measurement system (KMS[9]) has been submitted. Site participation is voluntary. General practitioners or other hospital departments typically refer patients to SCs/MCs.
NDRI (IE)	All patients with a confirmed diagnosis of dementia or MCI are included. Site participation is not specified in the model for the national dementia registry. General practitioners or other hospital departments typically refer patients to SCs/MCs.
NorKog (NK)	All patients (also younger patients) who are examined for cognitive symptoms or dementia in outpatient clinics, including primary care, SCs/MCs, or geriatric psychiatric outpatient clinics/NHs[10]. For patients with a linguistic or cultural background other than Norwegian, the privacy ombudsman of the QR has approved several assessment tools considering different education, cultural, and language background.
SveDem (SE)	All patients with a confirmed diagnosis of dementia or MCI are included. Physicians in SCs/MCs, primary care units (PCUs), general practitioners (GPs) or geriatricians in NH can diagnose and register patients.
BPSDR (SE)	All patients with a confirmed diagnosis of dementia experiencing BPSD living in a nursing home/dementia care home (NH/DCH) can participate. People living in-home care (HC) or dementia patients using daycare (DC) or short-term care can also be registered. Still, caregivers/relatives (reference persons) need to ensure that specific criteria are met (e.g. sufficient supervision by a home care team) and have contact with health care providers. Some daycare centres are also taking part.

Abbreviations: NH … nursing home, DCH … dementia care home, PCU … primary care unit, KMS … clinical measurement system, MCI … mild cognitive impairment, SC/MC … specialist clinic/memory clinic

laufende Datenerhebung in allen 6 QR

In general, all six QRs have a continuous follow-up system for patients. The modalities of follow-up differ, albeit slightly, as does the level of detail in reporting on the follow-up period. Table 3-3 lists the specific characteristics of each QR.

Table 3-3: Follow-up modalities in each quality registry

Registry	Follow-up
ADNeT (AU)	Continuous follow-up and data linkage; the collection of patient-reported outcome and experience measures (PROMs/PREMs) and carer-reported outcomes and experiences (CROs/CREs) is done annually. MCI patients are recommended to have a re-assessment of cognition within 18 months post-diagnosis to monitor changes in cognitive functioning.
DanDem (DK)	Continuous follow-up, but no unambiguous follow-up definition exists.
NDRI (IE)	Continuous follow-up of the patient with dementia starting at initial diagnosis and subsequently through regular follow-up.
NorKog (NK)	Continuous follow-up: data is collected from standard outpatient examinations.
SveDem (SE)	Continuous and annual follow-up for the report/quality indicators (QIs): the QI 'Proportion of patients with a regular follow-up' is used to monitor follow-up rates to ensure that the patient's needs are met.
BPSDR (SE)	Continuous follow-up: BPSD registry recommends every 4-6 weeks after first registration, and the National Board of Health and Welfare (Socialstyrelsen) requires follow-up at least once every year.

Abbreviations: CROs/CREs … carer-reported outcomes and experiences, QI … quality indicators, PROMs/PREMs … patient-reported outcome and experience measures

[8] In Denmark, these specialist clinics are called dementia examination units and consist of neurological, geriatric, and psychiatric clinics in the secondary care sector.

[9] The Klinisk Målesystem (KMS) is an online information technology (IT) system where data can be entered into clinical databases via web forms. KMS is a core tool for manual reporting and is used by 26 QRs including DanDem [74].

[10] Clinicians in geriatric psychiatric health services (outpatient clinics/nursing homes) are also obliged to register data into KVALAP, a national geriatric psychiatry QR to improve the assessment and treatment of mental illness among the elderly.

3.2.3 Registry aims

The primary aim of a dementia QR is to systematically monitor the quality of dementia care within a specific care setting. Tasks include routinely collecting, analysing, validating, and reporting data to increase knowledge about dementia diagnosis, assessment tools and examination procedures and to improve patient and caregiver outcomes. All identified dementia QR consider a QR as an integral part of their national dementia care strategy. Besides the common primary aim, the six identified QRs follow further aims.

Hauptziel in allen 6 QR: höhere Qualität der Versorgung → QR integraler Bestandteil

These aims are:

weitere Ziele:

- To establish a resource available for research to study dementia topics such as the risk factors for and trajectory of dementia and MCI (ADNeT, DanDem, NDRI, NorKog, SveDem, BPSDR).

Datenquelle für weitere Forschung,

- To facilitate the recruitment of participants into research (ADNeT, NDRI).

Rekrutierung für Studien,

- To expand the population in dementia assessments in primary care (DanDem).

zielgerichtete Diagnose von Pat. &

- To assist with dementia care planning and policy in general (NDRI, NorKog).

Entscheidungsgrundlage für Gesundheitspolitik

- To reduce BPSD through multi-professional care interventions, thereby reducing suffering and increasing QoL for the person with dementia (BPSDR).

An important and common secondary aim of all six QRs is that the registry should be capable of supporting research – so-called research readiness. In each QR, dementia data is not automatically available for research purposes. Still, interested researchers can apply for data access (Section 3.7 discusses specific topics of register-based research in more detail).

3.3 Governance and funding

3.3.1 Governance

The identified QRs are heterogeneous in terms of the governance structure but simultaneously share important governance characteristics. A clear governance pattern cannot be identified as responsibilities are assigned to different authorities in the five countries, and tasks take place at different levels. However, the organisational entities embedded in the governance structure can be divided into three levels:

unterschiedliche Governance-Strukturen mit Überschneidungen

- **The macro level** relates to the national healthcare system and national policy and regulatory systems, i.e. health authorities issuing the order to establish a QR or bringing QR on the agenda via national dementia action plans and strategies.

Makroebene bzw. Systemebene: Gesundheitsbehörden

- **The meso level** pertains to the registries, i.e. national, regional and local operators, administrators, coordinators, technical management and information technology (IT) tasks.

Mesoebene: Registerorganisation

- **The micro level** relates to day-to-day practice, i.e. the stakeholders in charge of collecting and entering the data (SCs/MCs, PCUs or NHs) and having direct contact with patients.

Mikroebene: datenmeldende Einrichtungen

Macro level: Initiation within healthcare system

Demenz-QR wurden ausgehend von Demenzstrategien initiiert

Gesundheitsbehörden sind zuständig für die „Zulassung"

The QRs in all five countries were introduced after national dementia action plans or strategies recommended taking action to improve the quality of dementia care using registry data. In four of these countries (DK, NO, SE, AU), superordinate authorities are in charge of approving new registries. In Denmark, the Danish Health Data Authority (Sundhedsdatastyrelsen) is responsible for approving new QRs. In Norway, approval is carried out by the National Service Environment for Medical Quality Registries (Nasjonalt servicemiljø for medisinske kvalitetsregistre), a national health competence centre for QRs that belongs to Helse Nord[11]. The competence centre offers assistance in the creation and operation of all 51 Norwegian QRs, including NorKog. In Sweden, an expert group of the National Quality Registries Sweden (Nationella Kvalitetsregister), in cooperation with the Swedish Association of Local Authorities and Regions (SKR), is responsible for approving new QRs based on existing criteria and guidelines. In Australia, the Australian Commission on Safety and Quality in Health Care (ACSQHC), established by the Australian state and territory governments, is responsible for creating a prioritised list of clinical domains for the potential development of national clinical quality registries. The ADNeT registry has been developed and implemented based on this list and the ACSQHC Framework for Australian Clinical Quality Registries [28].

Irland: Register „organisch" aufgebaut & unterschiedliche Strukturen

NDRI was commissioned by the National Dementia Office (NDO) of the Health Service Executive (HSE), the Irish healthcare system, but no specific information on approval is available. However, the authors of the NDRI model state that

> *'registries in Ireland have been set up somewhat organically and governed under different structures traditionally linked to their ownership and funding source'* – [32, p.31].

sehr heterogen auf Registerebene

Meso level: Organisation and administration of the quality registry

At the meso level, the registries are heterogeneously organised:

Australien: ADNeT, öffentliches Non-Profit-Unternehmen

- In Australia, the ADNeT Initiative is a not-for-profit public company with three key components: ADNeT Registry, ADNeT Screening and Trials, and ADNeT Memory Clinics Initiative. The Initiative has a management committee, a chair, and a central governance team at the University of Melbourne.

Dänemark: RKKP = überregionale Netzwerkorganisation der 5 dänischen Gesundheits- und Verwaltungsregionen

- In Denmark, the Regions Clinical Quality Program, RKKP, with its board of directors (five regional health directors), representatives of the national board of health data, national board of health, Danish regions, and the national association of local authorities, are responsible for the operation and development of approximately 85 nationwide clinical quality databases, including DanDem. The RKKP's professional commission has an advisory function to the board and provides professional input to the strategic development of the RKKP. The council consists of representatives of Danish patients, medical societies, other authorised health professional societies, general practitioners, cancer groups, hospital managers with a health professional background, the region's bio- and genome bank, and

[11] Norway has four health regions/authorities: Helse Sør-Øst, Helse Vest, Helse Midt-Norge, and Helse Nord. Each regional health authority is a state enterprise responsible for specialist health care.

the National Board of Health. A registry administrator is appointed at the national level to oversee/coordinate the functions within the registry.

- In Ireland, the National Dementia Office (NDO) typically supports the implementation of dementia care pathways, dementia care policy, and the development of services at an operational level. Therefore, the NDO will also provide support to NDRI. Data monitors at the registry level and data managers at the database level will manage data. The Office of the Chief Information Officer in the HSE will support data management processes. There will also be audit, finance, and risk management tasks, but no specific unit has been assigned yet. An external advisory board consisting of experts and representatives from the Department of Health (DOH), the health and social care field, academia, patient representative groups, HSE NDO, HSE IT, HSE Health Intelligence Unit (HIU), and Integrated Care Programme for Older People (ICPOP) will support the registry on subject-specific questions.

Irland: Zusammenarbeit des nationalen Demenzbüros & Gesundheitsministeriums

- In the case of NorKog, the Oslo University Hospital (OUS) is the QR owner and is responsible for ensuring information security, internal control, compliance with regulation and its documentation, and providing information to the public about data processing. The National Centre for Ageing and Health (Aldring og helse – Nasjonalt senter) has the day-to-day operational responsibility for data processing in the registry. A project manager is responsible for fulfilling obligations given by the data controller and represents the registry externally to the media and other national, Nordic or international QRs. A general manager is responsible for the daily operation of the QR. Further tasks include the preparation of annual reports and decision reports in cooperation with the SG. An administrative manager oversees the budget, accounting tasks, and personnel responsibilities.

Norwegen: Universitätsklinik Oslo ist QR-Eigentümerin

Nationales Zentrum für Älterwerden & Gesundheit verantwortlich für „Tagesgeschäft"

- For SveDem, a QR holder (chair) and a coordinator are responsible for the operability on a national level. The chair is also the QR owner. The Karolinska University Hospital is responsible for the data, and the Competence Centre of the Uppsala Clinical Research (UCR) centre is responsible for developing the database and its support. A regional coordinator is responsible for the operability on a regional level. A large part of the administrative tasks is organised decentrally at the micro level, e.g. each participating SC/MC, PCU, and municipal NH/DCH has a responsible local administrator.

Schweden: SveDem-Vorsitz ist Eigentümer, Karolinska Universitätsklinik verantwortlich für Daten & Uppsala Forschungszentrum für Supportfragen

- The BPSD registry was developed at the Knowledge Centre for dementia, Skåne University Hospital in Malmö. Since 2022, the QR has been further developed at the Cognitive Medicine Unit at Ängelholm Hospital. A secretariat and a steering group of people from different health professions govern the BPSD registry.

Schweden: BPSDR-Sekretariat und SG hat Verantwortlichkeit

Five QRs (ADNeT, DanDem, NorKog, SveDem, BPSDR) are governed by a multi-professional steering group (SG). The SG ensures that the QR runs according to its aims while respecting patients' rights. In addition, the SG oversees and partly takes responsibility for administrative, legal/ethical, and scientific decisions that guide the direction of the registry. Currently, in the implementation phase, NDRI will appoint an external advisory board consisting of experts from the DOH, academia, patient representative groups, and other health and social care representatives. In addition, NDRI will involve the Irish NDO to support the implementation of dementia pathways, dementia policy, and strategy. A typical SG comprises representatives from key stakeholders, including clinicians with specific knowledge of dementia

SG "lenkt" das Demenz-QR: verantwortlich für administrative, rechtliche, ethische & wissenschaftliche Fragestellungen

SG sind multiprofessionell & binden Betroffene mit ein

disorders, people with lived experience, carers[12], patient representatives, and researchers. Table 3-4 presents an overview of represented experts and professionals forming the SG in the respective QR.

Table 3-4: Fields of expertise of the steering group members

Registry	Steering group expertise	
ADNeT (AU)	21 experts with academic/research experience and practical experience in the following fields:	
	■ Geriatrics (specialists in dementia, ageing etc.) ■ Neurology and neuroscience ■ Neuropsychiatry and old age psychiatry/mental health ■ Neuropsychology ■ Nuclear medicine	■ Epidemiology ■ Nursing and aged care ■ Family and community medicine/general practice ■ Persons living with dementia ■ Carers of a person living with dementia ■ Clinical and academic management
DanDem (DK)	13 experts with academic/research experience and practical experience in the following fields:	
	■ Geriatrics ■ Psychiatry/Geriatric psychiatry ■ Neurology ■ Epidemiology (clinical epidemiology)	■ Family and community medicine/general practice ■ Dementia patients, carers and professionals representative (Alzheimer Association Denmark) ■ Contact person of the RKKP[13]
NDRI (IE)	NA[14]	
NorKog (NK)	Ten experts with academic/research experience and practical experience in the following fields:	
	■ Geriatrics ■ Psychiatry ■ Clinical Psychology	■ Nursing and experts from other geriatric services ■ Public health ■ Dementia patients representatives
SveDem (SE)	12 experts with academic/research experience and practical experience in the following fields:	
	■ Geriatrics (specialists in dementia, ageing, public health and caring sciences, community medicine and rehabilitation) ■ Occupational therapy ■ Family and community medicine/general practice	■ Nursing and aged care (activity development and medical nursing) ■ Neuropsychiatry ■ Carer representative
BPSDR (SE)	13 experts with academic/research experience and practical experience in the following fields:	
	■ Geriatrics (specialists in dementia, cognitive medicine, ageing, rehabilitation, community medicine, etc.) ■ Neurology/Neuroradiology ■ Psychotherapy ■ Social care/Community care	■ Nursing ■ Physiotherapy ■ Occupational therapy ■ Representative of NH/DCH ■ Carer representative

Abbreviations: DCH … dementia care homes, NH … nursing homes, RKKP … Danish Regions Clinical Quality Program

SG überschneiden sich in Expertise

10 bis 21 Expert*innen in den jeweiligen SG

The registries overlap to a large extent in terms of the expertise they use. The SGs are composed of representatives from clinical practice and academic research but also affected patients, and carers are represented. ADNeT has the largest SG with 21 experts. The other four QRs (DanDem, NorKog, SveDem, BPSDR) deploy ten to 13 experts and representatives from dementia-related health care fields. The focus of expertise is self-evidently on geriatric medicine. Further expertise includes knowledge in ageing, neurology, public health,

[12] Care persons can be professional caregivers or caregiving relatives/reference persons.

[13] RKKP is responsible for the operation and development of the 85 national QRs.

[14] An SG was part of conceptualising the NDRI model and an external advisory board will support the registry on subject-specific questions when NDRI is implemented.

caring science, cognitive medicine, nursing, physiotherapy, and rehabilitation. Family and community medicine plays an essential role in all of the five QRs with an SG. Patient representatives and/or carer representatives have a seat in all SGs. People living with dementia are also directly represented in ADNeT. BPSDR's SG also provides a seat for an NH/DCH manager to represent the participating NHs/DCH.

Community- & Allgemeinmedizin mit spezieller Rolle

Micro level: Day-to-day handling and data collection

At the micro level, participating sites cooperating with the QR are responsible for the day-to-day operation. Everyday management tasks include:

- Enrolment of registry patients and data collection
- Updating patient details
- Answering queries from the QR operator

"Tagesgeschäft" durch teilnehmende Einrichtungen: Pat.-Registrierung & Datenpflege

Table 3-5 overviews the geographical and healthcare setting and the number of participating sites.

Table 3-5: Healthcare setting

Healthcare setting						
Registry	Primary care sector	Secondary care sector			Public/ private	# of sites
	GP/PCU	SC/MC	NH/DCH	HC		
ADNeT (AU)		✓[15]			Y/Y	46[16] specialist/memory clinics and other dementia/MCI diagnosis services
DanDem (DK)		✓			Y/Y	37 neurological, geriatric, and psychiatric clinics
NDRI (IE)		✓			Y/Y	5 memory clinics
NorKog (NK)		✓[17]	✓		Y/NA[18]	45 outpatient specialist and memory clinics, including geriatric clinics and nursing homes
SveDem (SE)	✓	✓	✓	✓	Y/Y[19]	PCU: 918; SC/MC: 57; NH/DCH/HC[20]: 1,460
BPSDR (SE)			✓	✓	Y/Y	NH/DCH/HC in 288 of 290 municipalities

Abbreviations: DCH … dementia care home, GP … general practitioner, HC … home care, MC … memory clinic, MCI … mild cognitive impairment, NH … nursing home, PCU … primary care unit, SC … specialist clinic, Y … Yes, # … number

[15] Dementia diagnosis also takes place in general practice, hospital inpatient wards, nursing homes, and relevant community services. However, recruiting from these settings is currently not realised, but ADNeT explores the feasibility via sub-studies.

[16] In 2021, 29 sites in major cities and 11 sites in regional areas contributed data to the registry (n=40).

[17] For the future, an extension of the geographical scope beyond secondary health care to the area of primary care (GPs) and nursing homes is being considered.

[18] Information whether SCs/MCs of the private health care sector are integrated is not available. Most hospitals/hospital outpatient clinics in Norway are public hospitals, funded and owned by the state. A small number of hospitals are privately owned [75].

[19] There must be an agreement between SveDem and private health care providers for patient data to be included.

[20] In Sweden, a distinction can be made between normal and special forms of housing (SABÖ). Municipalities are obliged to provide special forms of housing for services and care for older people who need special support, including dementia [76].

Primärversorgung nur in SveDem als "Datensammler"

SveDem is the only QR which incorporates the primary care sector in collecting data from patients with dementia. GPs or PCUs can enter data into the QR after diagnosing patients with dementia.

Sekundär- und Spezialversorgung zentral in allen QR

In all six QRs, the secondary healthcare sector is essential in diagnosing dementia and/or managing dementia-related symptoms. In the case of ADNeT, DanDem, NDRI, NorKog, and SveDem, specialised clinics such as neurological, geriatric, and psychiatric clinics and/or memory clinics carry out dementia examinations and report collected patient data to the registry. The only two QRs that allow NHs/DCUs to participate and report patient data are BPSDR and SveDem. As the BPSDR specialises in treating BPSD, primarily treated in NHs/DCHs or sometimes at home (HC), only NHs/DCHs can participate.

schwedische QR: Pflegeeinrichtungen können auch Daten registrieren

öffentlich & privat finanzierte Kliniken und Einrichtungen können teilnehmen

Participation in almost all QRs is open to the public and private health care providers. For Norway, no information was available, but in Norway, most hospitals/hospital outpatient clinics are public, funded and owned by the state [75].

3.3.2 Funding

Finanzierung: meist staatliche Mittel

As national dementia action plans or strategies build the basis for improving the quality of dementia care using register data in all five countries, funding for all QRs mainly comes from the state.

Australien: Rat für nationale Gesundheit & medizinische Forschung

- *ADNeT (AU):* Funding comes from the National Health and Medical Research Council (NHMRC), National Institute for Dementia Research (NNIDR) programme, and philanthropic organisations. Between 2018 and 2023, the NHMRC has committed $ 18 million (~€ 18.05 million) in funding to establish the ADNeT Initiative.

Dänemark: regionale Regierungsbezirke

- *DanDem (DK):* Funding DanDem and all other Danish QRs works through a national initiative, the RKKP, mandated by law and regulated by the national government but financed and owned by regional governments. The exact funding contribution is not publicly available.

Irland: Gesundheitsministerium

- *NDRI (IE):* Funding of NDRI is intended to be carried out by the Irish DOH. The estimated costs for the first year (development phase) are € 355,253 (value-added tax included), and the annual running costs amount to € 284,836 (value-added tax included).

Norwegen: Helse Sør-Øst (regionale Gesundheitsbehörde)

- *NorKog (NE):* NorKog is funded by the Helse Sør-Øst health authority and the National Centre for Ageing and Health. The exact funding contribution is not publicly available.

Schweden: schwedische Vereinigung der Kommunen & Regionen (SKR)

- *SveDem (SE):* SveDem is funded by the Swedish Association of Local Authorities and Regions (SKR). The annual funding is € 300,000. In 2021, the Swedish government provided € 250,000 in extra funding for improvement work.
- *BPSDR (SE):* BPSDR is funded by the SKR. The annual funding is not publicly available, but in 2021, the Swedish government provided € 250,000 in extra funding for improvement work.

3.4 Data management

3.4.1 General information on data management

Essential tasks of registry management are data governance and data management, i.e. the technical implementation of data governance. Data governance is the foundation of efficient data quality improvements and is also part of the overall QR governance structure [77]. Besides defining data collection roles and the setting, two functions need to be defined within a QR governance structure to be in line with database standards and data protection regulation and privacy laws such as the General Data Protection Regulation (GDPR) [78]:

Daten-Governance & Management sind essentielle Aufgaben

- *Data controller*[21]*:* The natural or legal person, public authority, agency, or other body which, alone or jointly with others, determines the purposes for which and the means by which personal data is processed [79]. **Data Controller = Datenverantwortlicher (Auftragsverarbeiter)**
- *Data processor*[22]*:* A natural or legal person, public authority, agency or other body which processes personal data only on behalf of the controller [79]. **Datenverarbeiter*in**

Data management includes activities to ensure that data is used according to (pre)defined aims in a valuable manner. Data management consists of the following main tasks and processes [1]: **Datenmanagement:**

- Data collection (includes specification of the selection process, recruitment, minimum data set and data sources)
- Data storage
- Managing interoperability and readiness for data linkage
- Quality assurance and data validation (data cleaning and handling of missing data)
- Data analysis
- Reporting
- IT, protection and security responsibilities

Daten sammeln, eingeben, speichern, "verbinden", qualitätssichern, aufbereiten, berichten, sichern & schützen

In reality, a clear temporal demarcation and allocation of data management tasks are impossible because the transitions of tasks are fluid. In most cases, the data processor also performs data management tasks. Data management tasks within a QR can also be divided between separate organisational units. Table 3-6 shows the division of roles and functions[23]. **Datenmanagement-Aufgaben sind unterschiedlich verteilt**

[21] In most of the cases, the data controller is the registry owner/data custodian when a separately defined data custodian does not exist.

[22] There are situations where an entity can be a data controller, or a data processor, or both.

[23] Daily tasks of data collection are excluded in the table, as mentioned above, participating health care sites such as SCs/MCs are responsible for the daily management including data collection (see Table 3-5).

Table 3-6: Data governance and data management responsibilities

Registry	Data controller	Data processor	Data management	IT responsibilities
ADNeT (AU)	ADNet Initiative	Monash University	SG with Monash University (lead) and ADNeT management committee	The University of Newcastle for the whole ADNeT Initiative and Monash University for ADNeT Registry
DanDem (DK)	Midtjylland Region	RKKP's Knowledge Centre database department 'Psychiatry, Gynaecology/Obstetrics and chronic diseases'		
NDRI (IE)	HSE Ireland		Data management at the registry level Data monitoring at SC/MC level	HSE Ireland IT Development/Support
NorKog (NK)	Oslo University Hospital Ullevål (formal QR owner)	National Centre for Ageing and Health with its project manager, general manager, and administrative manager		
SveDem (SE)	Karolinska University Hospital has the overall responsibility for the data, and the registry holder is the owner of the QR and data custodian			Competence centre Uppsala Clinical Research[24]
BPSDR (SE)	Region Skåne	Region Skåne and NH/DCH	Region Skåne	Registercentrum Syd (RC Syd)[24]

Abbreviations: HSE … Health Service Executive, IT … information technology, NH/DCH … nursing homes/dementia care home, RKKP … Regions Clinical Quality Program, SC/MC … specialist/memory clinic, SG … steering group

Dateneingabe funktioniert über webbasierte Lösungen

The data input in all six registries works via web-based solutions[25]. Clinicians or clinical nurse specialists from participating units from affected patients enter the data from their computer into a database via a web-based user interface (see section 3.3.1). Some QRs collect characteristics from carers and/or the patient's relatives[26] (ADNeT, DanDem, NDRI, NorKog, SveDem). The data is transferred to a central server run by respective organisational bodies or commissioned IT service providers, where it is further processed. In DanDem, NDRI, NorKog, SveDem, BPSDR, data are pseudonymised in alignment with the country's data and patient protection act and the GDPR (see Table 3-12). Information on the exact data processing measures, such as pseudonymisation or anonymisation, is unclear for ADNeT.

Datenwörterbuch nur für 2 Demenz-QR verfügbar

Two QRs (ADNeT, NDRI) explicitly provide a data dictionary that establishes common data standards assuring interoperability (see section 0). All identified QRs apply data cleaning and missing data handling measures. The specific steps are discussed below in section 3.4.4, as these measures pertain to data quality and validation.

[24] All QR in Sweden receive IT support by a registry centre. The centre provides support during the start, development, and operation of registers. Furthermore, data is stored at each registry centre.

[25] Before March 2022, registration in NorKog has been paper-based.

[26] The survey of carers' or relatives' characteristics should not be confused with the diagnosis questionnaires such as the Mini-Mental State Examination (MMSE), in which carers/relatives are interviewed about the patients' health status.

3.4.2 Data collection and the minimum data set

MDS essentiell für effiziente Registerpraxis

A minimum data set (MDS) is essential for a dementia QR to work efficiently. The MDS builds the basis for the formation of QIs. An MDS is a minimum set of common data elements that all participating units should consistently utilise to ensure a standardised data collection across secondary and primary care. In addition, national or international comparisons across participating units, geographical regions, dementia types and other variables are possible when deploying a common MDS [32]. A small MDS does not mean that a QR neglects data elements necessary for dementia care. As the name suggests, an MDS is the lower limit of data required specific to each QR. All QRs indicate that further data, such as diagnosis or treatment data, will be collected over time during follow-up to enhance the patient record of each person with dementia. Other QRs such as DanDem, derive other data elements not included in the MDS from other registries and databases via the Central Person Registry (CPR) number.

kleines MDS ≠ "unzureichender" Datensatz

MDS hat 4 Typen von Datenelementen:

For the classification of the collected data into the respective minimum dataset (MDS) of the six QRs, we follow a similar scheme as the Irish registry model and the publication by Sarsarshahi et al. [32, 55]. The following five data categories are used for the classification of the data elements [32, 55]:

Daten von/über …

Main care data categories

Patient*innen, Leistungserbringer*in, Diagnose & Behandlung

- Patient data (e.g. age, gender, educational status etc.)
- Health care and service provider data (e.g. centre, date of admission etc.)
- Diagnosis data (e.g. dementia history, dementia type, conducted tests)
- Treatment data (e.g. pharmacological treatment, psychosocial interventions)
- Further registered variables not part of the MDS

alle QR verwenden einen Pat.-Identifikator

All six QRs have an MDS. Only DanDem and NDRI, explicitly include the patient identifier/patient identification number (patient ID) in their publicly available information on their MDS. However, all QRs automatically assign an ID to every registered patient. For standardisation reasons, we include the patient identifier in the patient data category of the registries MDSs.

MDS überschneiden sich teilweise, aber Anzahl der Elemente variiert stark

Table 3-9 at the end of this section gives an overview of the collected data and the registry's minimum datasets. The QRs employ common data elements[27], but the number of data elements varies considerably. E.g. NDRI collects 56, and BPSDR collects ten data elements.

nicht alle QR sammeln Datenelemente in allen 4 Kategorien

Four of the six QR (ADNeT, DanDem, NDRI, SveDem) have data elements in all four main care categories. NDRI collects the most data elements about patient data (26 data elements), health care and service provider data (5 data elements), and treatment data (14 data elements). ADNeT collects 16 dementia-related diagnosis data elements. NorKog only collects two diagnosis data elements and no treatment data elements for their MDS. Three QRs (DanDem, SveDem, BPSDR) provide a complete list of variables beyond the MDS [80-82].

[27] Common data elements are highlighted in blue in Table 3-9. Common data elements refer to elements, which can be found in at least three QRs.

Patient data

Pat.-Daten: sozio-demografische & gesundheitliche Informationen

Collected patient data relates to personal and socio-demographic information and information about the general health state. Information about the health state provides a broader picture of individual disease risk factors, associated prevention measures, and, if depicted on an aggregate level, information about the public health state. These kinds of data elements vary considerably across QRs. Some QRs derive data elements from other registries and databases or only collect them during follow-up evaluations. Common patient data elements in the MDSs comprise:

bspw. biologisches Geschlecht, Gender, Geburtsdatum, Bildungsabschluss, Arbeitsverhältnis etc.

- Patient ID (ADNeT, DanDem, NDRI, NorKog, SveDem, BPSDR)
- Sex and/or gender (ADNeT, NDRI, NorKog, SveDem, BPSDR)
- Date of birth/death (ADNeT, NDRI, NorKog) or age (NorKog, SveDem, BPSDR)
- Education: Level of education (ADNeT, NDRI) and formal schooling years (NorKog)
- Work relationship: Labour force status (ADNeT), employment status and position (NDRI), and education profession and working (NorKog)
- Living arrangement/environment: Residential setting (ADNeT), living condition/arrangement such as living alone or in NH (ADNeT, DanDem), living status (NDRI), type of lodging (NorKog)

Provider data

Daten der Leistungserbringer*innen meist zeitliche Informationen: Datum der Diagnose, Erstkonsultation etc.

Provider details usually comprise time data, such as specific dates. This data is crucial for QIs, which should reflect the temporal component of quality of care. Specific provider details in the QRs pertain to data elements such as:

- Date of initial appointment
- Date of diagnosis
- Date of referral to an SCs/MCs

Diagnosis data

Daten zur Diagnose umfassen durchgeführte Tests oder Krankheitsgeschichte der Familie

All QRs state that collected diagnosis data elements in the MDS should be in line with national clinical guidelines. Not all QRs have explicit national guidelines for the diagnosis of dementia. NDRI bases its MDS on guidelines from the National Institute for Health and Care Excellence (NICE) in the United Kingdom [23]. Some QRs with available national guidelines for the diagnosis of dementia additionally set the MDS in an iterative process. The process involves the SG, government agencies linked to the healthcare system (DanDem, NorKog, SveDem), and/or patient organisations (NorKog) to take into account the whole process of dementia care. Table 3-7 gives an overview of diagnosis-related data elements and information on all assessments and tests[28] used for the diagnosis of dementia.

[28] There is no single (diagnostic) test for dementia as dementia is a syndrome with different forms. A diagnosis is based on a combination of assessments and tests.

Table 3-7: Common diagnosis-related data elements and assessment tools

Registry	Data elements			
	Cognitive and neuro-psychiatric assessment	Functionality and activities of daily living	Further tests	Other diagnosis-related data elements[29]
ADNeT (AU)	■ MMSE, RUDAS, MoCA, KICA	■ Functional measures (not specified) ■ Independence in ADL	■ 'Core' blood tests ■ Structural and functional neuroimaging ■ Lumbar puncture	■ Past diagnosis of MCI ■ REM sleep behaviour disorder ■ Fall history ■ Continence
DanDem (DK)	■ MMSE	■ FAQ-IADL	■ Blood tests ■ Brain scan via CT and MRI	-
NDRI (IE)	■ MMSE, MoCA, CDRS ■ Comprehensive neuropsychological evaluation	■ IADL	■ Neuroimaging via CT and MRI ■ Bio-markers	-
NorKog (NK)	-	-	-	■ History from relatives related to mental function
SveDem (SE)	■ MMSE ■ Advanced cognitive testing	■ Assessment by an occupational therapist, physiotherapist, and speech therapist	■ Blood test ■ Clock-drawing test ■ Neuroimaging via CT and MRI ■ PET/SPECT ■ Lumbar puncture	■ Family history of dementia: First and second degree relatives
BPSDR (SE)	■ NPI-NH[30]	-	-	-

Abbreviations: ADL … activities in daily living, CDRS … Clinical Dementia Rating Scale, CT … computer tomography, FAQ-IADL … Functional Activities Questionnaire Instrumental Activities of Daily Life, KICA … Kimberley Indigenous Cognitive Assessment, MMSE … Mini-Mental State Examination, MoCA … Montreal Cognitive Assessment, MRI … magnetic resonance imaging, PET … positron emission tomography, RUDAS … Rowland universal dementia scale, SPECT … single photon emission computed tomography

MMSE, RUDAS, MoCA, CDRS kommen zum Einsatz

Data on the Mini-Mental State Examination (MMSE) questionnaire [83] are collected in four out of six QRs (ADNeT, DanDem, NDRI, SveDem) as part of the MDS. Further collected data on cognitive tests comprise data on the Rowland universal dementia scale (RUDAS) [84] and KICA [73], the Montreal Cognitive Assessment (MoCA) [85] and the Clinical Dementia Rating Scale (CDRS). Four QRs (ADNeT, DanDem, NDRI, SveDem) collect diagnosis data on the functional activity of dementia patients. DanDem uses the Functional Activities Questionnaire-Instrumental Activities of Daily Life (FAQ-IADL) [86]. The specific functional tests of the other registries used to collect data on activities of daily living (ADL) are largely unclear from the available data.

Daten über funktionelle Aktivitäten und Aktivitäten des täglichen Lebens werden erhoben

Ergebnisse aus Bluttests, Neurobildgebung (CT/MR)

Other common diagnosis elements are data from blood tests and structural and functional neuroimaging via computed tomography (CT) and/or magnetic resonance (MR) imaging. Other data elements for the MDS vary from

[29] Data on alcohol and/or tobacco use, drug consumption, social activity and other data elements in the patient data category are also relevant for diagnosis, as they are part of the patients (medical) history. For methodological reasons these data elements are assigned to the category 'Patient Data'.

[30] The NPI-NH is also used for follow-up evaluation.

QR to QR. They include, for example, data and results of Neuropsychiatric Inventory Nursing Homes Version[31] (NPI-NH) scores [87], lumbar puncture, clock tearing test, biomarker tests, positron emission tomography (PET), single photon emission computed tomography (SPECT), or family history of dementia.

Treatment data

Daten über pharmakologische & psychosoziale Behandlungen sowie Unterstützungsmaßnahmen werden erhoben

As with diagnostic data, the appropriateness of collecting treatment data and including it in the MDS should be consistent with national clinical guidelines for dementia care. In principle, collected treatment data for the MDSs can be divided into three groups [32]:

- Pharmacological treatment data such as dementia medication with ChEIs or N-methyl-d-aspartate (NMDA) receptor antagonists
- Psychosocial treatment/intervention and support measures data such as health and social care services carried out in NHs/DCHs
- Consideration of carers and relatives

fast alle QR erheben Daten über Medikation → angemessene Medikation monitoren

Almost all QRs include data on used medications in their MDS. The main reason to collect medication data is to monitor appropriate prescriptions and consumption of medicines by a respective quality indicator. Seven different drugs are included in the MDSs across the six QRs (see Table 3-8).

Table 3-8: Data elements concerning medication in the minimum dataset

	Registry					
Medication	**ADNeT (AU)**	**DanDem (DK)**	**NDRI (IE)**	**NorKog (NK)**	**SveDem (SE)**	**BPSDR (SE)**
Dementia medication	✓	✓	✓		✓	✓
Anti-depressants		✓	✓		✓	
Anti-psychotic medication		✓	✓		✓	✓
Anxiolytic			✓		✓	✓
Sedative			✓			✓
Hypnotic			✓		✓	✓
Analgesic						✓

QR erheben pharmakologische Daten zu unterschiedlichen Medikamenten

NDRI, SveDem, and BPSDR collect data on six of the seven drugs in their MDS. Medication data seem not to be part of NorKog's MDS. ADNeT collects only data on dementia medication, and DanDem collects data on three of the seven drug classes for their MDS. Data on psychosocial treatment as part of the MDS is absent in four of the six QRs. Data collection on psychosocial interventions or other care measures as part of the MDS is only conducted in two QRs (NDRI, BPSDR). Only the MDS of NDRI captures data on considerations of carers and/or relatives.

[31] The NPI is a semi structured clinician interview of caregivers in which the severity and frequency of disturbance in 12 symptom domains are measured (hallucinations, delusions, agitation/agitation, depression/depressed mood, anxiety, irritability/laziness, loss of inhibitions, elation/euphoria, apathy/indifference, motor restlessness, sleep disturbances, and appetite and eating disorders). The lower the score, the better the quality of life of patients.

Overview of the collected data and minimum datasets

Table 3-9: Overview of the collected data and minimum datasets

Registry and number of data elements in the minimum data set						
Data category	**ADNeT (AU)**	**DanDem (DK)**	**NDRI (IE)**	**NorKog (NK)**	**SveDem (SE)**	**BPSDR (SE)**
	44 data elements	**21 data elements**	**56 data elements**	**27 data elements**	**21 data elements**	**10 data elements**
Patient data	23 data elements: ■ Patient ID ■ Name ■ Date of birth ■ Date of death ■ Sex ■ Capacity to be involved in the opt-out process ■ Communication of diagnosis ■ Contact details ■ Person responsible name preferred spoken language and contact details ■ Carer name, preferred spoken language and contact details ■ Aboriginal and/or Torres Strait Islander ■ Country of birth ■ Preferred spoken language ■ Level of education ■ Labour force status ■ Residential setting ■ Living arrangement ■ Interest in participation in research ■ Number of strokes ■ Hypertension ■ Diabetes ■ Cardiovascular disease ■ Cancer	4 data elements: ■ Patient ID (Personal identification number) ■ Central person registry (CPR) number ■ Carer/Relative present ■ Living condition (patient lives alone, in NH etc.)	26 data elements: ■ Patient ID (Registry ID) ■ Patient individual health identifier (IHI) number ■ Patient General Medical Services Scheme (GMS) number/Medical council number (MCN) ■ First name ■ Family name ■ Date of birth ■ Date of death ■ Sex at birth ■ Address ■ Postal address/Eircode ■ Marital status ■ Living status ■ Socially active ■ Physically active ■ Hearing impairment ■ Vision impairment ■ Driving ■ Education ■ Employment status ■ Employment position ■ Intellectual disability ■ Weight in kg ■ Height in m^2 ■ Body mass index ■ Alcohol status ■ Smoking status	21 data elements: ■ Patient ID (auto-generated Personal ID) ■ Sex ■ Date of Birth/Age ■ Marital status ■ Children ■ Formal schooling years ■ Education profession ■ Working ■ Patient lives alone ■ Contact with relatives ■ Relation to patient ■ Frequency of relative contact with the patient ■ Type of lodging ■ Social activity ■ Cultural activity ■ Safety – Motoring – Weapons – Falls ■ Tobacco ■ Alcohol Use ■ Drugs other than alcohol ■ The patient has consented to be part of the registry/to be contacted again ■ Relatives have agreed to be contacted again	8 data elements: ■ Patient ID ■ Social security number ■ Sex ■ Age ■ BMI (Height, weight) ■ Possession of a driving license ■ Possession of weapon license ■ Death, time to death (months)	5 data elements: ■ Patient ID ■ Social security number, ■ Age ■ Sex

Registry and number of data elements in the minimum data set						
Data category	**ADNeT (AU)**	**DanDem (DK)**	**NDRI (IE)**	**NorKog (NK)**	**SveDem (SE)**	**BPSDR (SE)**
	44 data elements	**21 data elements**	**56 data elements**	**27 data elements**	**21 data elements**	**10 data elements**
Health care and service provider data	3 data elements: ■ Date of referral ■ Date of initial appointment ■ Date of diagnosis	4 data elements ■ Type of referral/evaluation (e.g. second opinion or primary dementia investigation) ■ Date of first visit ■ Date for information visit ■ Is the patient discharged at this visit?	5 data elements: ■ Clinic ID ■ Referral form ■ Date of receipt of referral ■ Date of initial assessment for dementia ■ Date of dementia diagnosis	4 data elements ■ Referral receive date ■ Date investigation first begins ■ Reason for delay ■ Type of outpatient clinic	2 data elements ■ Date of registration ■ The time needed for diagnosis (in days)	NA
Diagnosis data	16 data elements: ■ Past diagnosis of MCI ■ Diagnosis ■ Mode of service delivery ■ Dementia/MCI subtype ■ Number of prescribed medications ■ Rapid eye movement (REM) sleep behaviour disorder ■ Falls history in the past 12 months ■ Functional measure/s completed ■ Cognitive assessment/s completed ■ Mini-Mental Status Examination (MMSE)/Rowland universal dementia scale (RUDAS)/Montreal Cognitive Assessment (MoCA)/Kimberley Indigenous Cognitive Assessment (KICA) scores ■ Independence in activities of daily living ■ Continence ■ Core blood tests undertaken as part of the diagnostic workup ■ Structural neuroimaging completed as part of the diagnostic workup ■ Functional neuroimaging completed as part of the diagnostic workup ■ Lumbar puncture completed as part of the diagnostic workup	10 data elements: ■ MMSE done? ■ MMSE score ■ IADL-FAQ done? ■ IADL-FAQ score ■ Blood tests ■ CT brain scan ■ MRI brain scan ■ If no brain scan (contra-indication/not relevant/patient cannot cooperate) ■ Dementia (general cognitive status) ■ Diagnosis	11 data elements: ■ Dementia diagnosis ■ Has the person been told about their diagnosis ■ Translation to other disease classifications ■ Diagnosis made by ■ Brief cognitive test (MMSE, MoCA, Clinical Dementia Rating Scale) ■ Comprehensive neuropsychological evaluation ■ Neuroimaging testing (computer tomography [CT]/ magnetic resonance [MR] scan/MR scan dementia protocol) ■ Bio-markers ■ Functional evaluation (IADL) ■ Dementia syndrome/Disease progression measure ■ Dementia syndrome/Disease stage	2 data elements: ■ History from relatives related to mental function ■ Diagnosis according to ICD-10	8 data elements: ■ Living condition ■ Day care ■ Home care ■ Family history of dementia: First-degree, second-degree ■ Type of dementia ■ Diagnostic workup: Blood test, clock-drawing test, CT, MRI, LP, PET/SPECT, EEG, advanced cognitive testing, assessment by an occupational therapist, assessment by a physiotherapist, assessment by a speech therapist? ■ Total number of diagnostic tests ■ MMSE Score	3 data elements: ■ Dementia diagnosis ■ Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores ■ NPI-NH sub-scores

Registry and number of data elements in the minimum data set						
Data category	**ADNeT (AU)**	**DanDem (DK)**	**NDRI (IE)**	**NorKog (NK)**	**SveDem (SE)**	**BPSDR (SE)**
	44 data elements	**21 data elements**	**56 data elements**	**27 data elements**	**21 data elements**	**10 data elements**
Treatment data	2 data elements: ■ Cholinesterase inhibitor (ChEI) recommended or prescribed ■ Follow-up appointment offered	3 data elements: ■ Dementia medication ■ Anti-depressive treatment ■ Anti-psychotic treatment	14 data elements: ■ Dementia medication ■ Anti-depressant medication ■ Anti-psychotic medication ■ Benzodiazepines ■ Total number of medications the person is taking ■ Has a personalised care plan been created ■ Who created the care/support plan ■ Current supports ■ Psychosocial interventions/ Post-diagnostics support ■ Advanced care planning ■ Has this person a dedicated single point of contact within the health service? ■ Has this person a case manager? ■ QoL in Alzheimer's Disease (QoL-AD) carried out with the patient ■ World Health Organisation QoL scale (WHOQOL) carried out with carer	NA	2 data elements: ■ Medication: ChEI, NMDA-antagonist, anti-depressants, anti-psychotics, anxiolytics, hypnotics, cardio-vascular medication ■ Total number of drugs	2 data elements: ■ Care measures taken ■ Medication prescribed (cholinesterase inhibitors, NMDA-antagonists, anti-psychotic drugs, nonbenzodia-zepine, benzodiazepine and other anxiety medications, analgesic)
Further registered variables not part of the MDS	NA	Complete DanDem variable list [80] and variables used for formation of QIs: Table A-4	NA	NA	Complete SveDem variable list [81] and variables collected for referred patients: Table A-12	Complete BPSDR variable list [82]

3.4.3 Data sources and interoperability

Data sources

direkte Dateneingabe aber auch zahlreiche andere Datenquellen

In all identified QRs, only eligible health care facilities can collect data elements for the MDS. Dementia-related and other health care data are collected in several healthcare settings. Besides direct data input for the MDS, QRs also use administrative data and data from other health-care related databases for quality improvement and research purposes. Table 3-10 gives an overview of each registry's data sources.

Table 3-10: Data sources of each quality registry

Registry	Data sources	
ADNeT (AU)	■ Direct data entries by participating sites ■ Data from 'ADNeT Screening and Trials' and 'ADNeT Memory Clinics'	■ Administrative databases (routinely collected data on mortality, hospitalisation, prescribed medication, and care service utilisation) ■ Registry of Senior Australians (ROSA[32])
DanDem (DK)	■ Direct data entries in the QR system (KMS) ■ Landspatientregisteret (LPR)/National patient registry	■ Civil Registration System (CPR) ■ Danish National Prescription Registry (DNPR)
NDRI (IE)	■ Direct data entries in the QR system[33] ■ Primary Care Reimbursement Scheme (PCRS)	■ Other HSE/Irish health system datasets
NorKog (NK)	■ Direct data entries in the QR system (MRS) ■ National Population Registry ■ Norwegian Cause of Death Registry ■ Norwegian Prescription Database ■ Norwegian Patient Registry (NPR)	■ Norwegian Registry for Primary Health Care (KPR) ■ Norwegian Cardiovascular Disease Registry ■ National and regional health surveys ■ Data from Statistics Norway
SveDem (SE)	■ Direct data entries in the QR system ■ Swedish National Patient Registry ■ Prescribed Medicines Registry (LMED)	■ Gothenburg Cerebrospinal Fluid Biomarkers (CSF) Registry ■ Dental registers ■ Data from the other ~100 QRs (e.g. BPSD registry)
BPSDR (SE)	■ Direct data entry ■ LMED	■ Data from the other ~100 QRs (e.g. BPSD registry) ■ Other patient records

Interoperability and data linkage

QR betonen die Wichtigkeit der Datenverknüpfung

All QRs utilise multiple data sources. For this reason, using data from different sources that can communicate with each other is crucial. The QRs emphasise the importance of interoperability. Interoperability should ensure the connectivity of multiple data sources. The employment of unique patient IDs in all QRs enables longitudinal data collection and linkage with the respective data sources. In ADNeT, data linkage is conducted periodically. The linked data build the basis of the annual registry reports. For the other QRs,

[32] ADNeT has a collaboration with the ROSA, which recruits persons at the time of an aged care assessment in South Australia to monitor the health service utilisation, medication use, and other outcomes of senior Australians.

[33] Authors state that SCs/MCs are the logical starting point for data collection. Dementia-related data is collected and captured in multiple locations in the primary and secondary care sector of the health care system (Health Service Executive) in Ireland. The electronic mining of dementia registry data from other sources is difficult as of now, but sources such as electronic health records and general practitioner systems will be further investigated for the purpose of data collection.

the frequency of data linkage is unclear, but linked data are also analysed in the annual reports (see section 3.5 "Interpretation and Reporting" for details). In addition to using the data for quality improvement, the data is linked and used for internal and external research purposes in all QRs (see section 3.7 "Register-based research and confounders" for details).

Datenwörterbücher werden in allen QR als wichtig erachtet

ADNeT and NDRI explicitly provide data dictionaries that establish common data standards assuring interoperability. As part of the model design for the Irish dementia registry, the authors initiated a dataset specification process based on a specific National Data Dictionary and a Standard Health Record (SHR), which have been developed and established in the past. Authors of NDRI emphasise that a data dictionary toolkit and standardised metadata, such as the Book of OHDSI: Observational Health Data Sciences and Informatics [88], are essential to exchange and use information between different software systems. Furthermore, a Standard Operating Procedure (SOP) will need to be developed to support data sharing and international data linkage with organisations such as the WHO. NDRI and the Irish healthcare system focus on standardising the health record rather than exchange standards because exchanging and aggregating patient data are technically more convenient.

Datenverknüpfung setzt Datenwörterbuch voraus

The information on data dictionaries from available sources is unclear for the other four QRs (DanDem, NorKog, SveDem, BPSDR). Since linkage to other registries and databases in these four QRs is possible, they must employ a certain data standard.

3.4.4 Quality assurance, validation strategies, and safeguards

Quality assurance

umfangreiche personelle & technische Maßnahmen zur Qualitätssicherung

All QRs conduct extensive measures for quality assurance (QA) and validation of data. Two types of QA measures exist:

- Personnel measures such as training, workshops, telephone support and further education
- Technical measures such as data cleaning, handling missing data, or software-based measures for validation

Depending on the specific measure, an apparent distinction is sometimes not possible, as personnel and technical measures are connected. A guidance document, for example, is a technological measure used for personnel training purposes.

Angebot an Fortbildungen & weitere Maßnahmen für qualitativ hochwertige & einheitliche Dateneingabe & -sammlung

All QRs offer initial and ongoing training and education for participating site staff to standardise data collection and interpretation. Modes of delivery vary and cover:

- Offline and online training such as in-person registry seminars (all six QRs) or webinars (NDRI, SveDem)
- Instructional videos about login, registration, data input, and general QR topics (ADNeT, NorKog)
- Information disseminated via the QR website (ADNeT, DanDem, NorKog, SveDem, BPSDR) or e-mail correspondence to communicate new registry features (NorKog)
- Telephone or online support (all six QRs)

BPSDR: zertifizierte Trainer*innen führen Schulungen durch

To ensure that data are entered correctly in the BPSDR, multi-professional teams from the NH/DCH undergo administrator training before they start working with the registry data. The training is carried out with the help of certified trainers (~350 trainers certified for BPSDR across Sweden). The certified trainers provide support via follow-up of the registry work (monitoring) and implementation through regular network meetings. In addition, certified trainers inform about how data can be used in improvement work.

Benutzer*innen-Feedback explizit in 2 QR berücksichtigt

User feedback is/will be explicitly implemented as a part of the QRs' quality assurance strategies in two QRs (NDRI, BPSDR). NDRI will implement a mechanism to gather user feedback and periodic questionnaires on training, usability, usefulness, and satisfaction. BPSDR makes use of certified trainers to fulfil this task. According to the available material, the other four rely on their telephone and online support.

Dänemark & Schweden: öffentlich zugängliche Manuale

DanDem and SveDem provide guidance documents, which are publicly available:

- Danish Handbook of Clinical Quality Improvement and the Implementation Handbook supplied by the RKKP and Danish Health Authority [89, 90]
- The National Quality Registries in Sweden at the SKR offer guidance for data validation in their validation handbook [91].

As mentioned above, ADNeT provides a comprehensive data dictionary containing data elements, formats, ranges, and definitions to guide data entry and information on validation rules. This document is publicly not available.

Validation strategies

umfangreiche Datenvalidierungs-maßnahmen auf mehreren Ebenen

The technical measures for QA are mainly operationalised in the course of the registry's validation strategies. Identified QRs commonly carry out the following four different validation approaches:

- Validation in the course of data collection, either by built-in logical checks or manual checks
- Validation by routinely conducted measures (handling missing data, data cleaning)
- Validation by external or internal review (e.g. by a superordinate health authority or by internal or external adjudication)
- Validation in connection with reporting (e.g. annual report)

automatisierte logische Kontrollmechanismen → wurden die Daten richtig/vollständig eingegeben?

Automated logical checks are the most common validation approaches performed by QRs (except NorKog). This validation approach is implemented by making MDS mandatory input variables data elements. If a required data element is not entered, the person entering the date, such as a clinician, receives an alert message or cannot proceed to the next input mask. Furthermore, some QRs (ADNeT, DanDem, NDRI, SveDem) employ further logical checks, such as limiting the range of the variable or other validity checks, such as whether a valid date has been entered.

routinemäßig durchgeführte Prüfung auf Konsistenz & Genauigkeit

All QRs carry out routinely conducted measures for validation. Tasks comprise a manual validation for consistency and accuracy according to a data validation plan, standardisation of data structures, elimination of double entries across further QRs, or cross-checking the collected data with other databases and registries.

Dänemark: Prüfung auf Vollständigkeit

For example, in DanDem, database completeness (coverage) is calculated as follows:

$$Coverage = \frac{cases\ only\ in\ KMS + cases\ in\ KMS + cases\ in\ LPR}{cases\ only\ in\ KMS\ + cases\ in\ KMS\ + cases\ in\ LPR\ +\ cases\ only\ in\ LPR}$$

Cases in KMS are the direct data entries in the registry, and cases in LPR are the registered patients in the Danish National Patient Registry.

externe & interne Reviews (Audits) in 3 QR

Three QRs (DanDem, SveDem, BPSDR) employ external or internal review activities for validation. For Example, in Denmark, each Danish QR has to pass an appraisal by the National Health Authority every three years. Three QRs explicitly report that they carry out validation measures while writing the annual report. Table 3-11 gives an overview of the specific validation approaches of each QR.

Table 3-11: Overview of validation approaches

	Registry					
	ADNeT (AU)	**DanDem (DK)**	**NDRI (IE)**	**NorKog (NK)**	**SveDem (SE)**	**BPSDR (SE)**
Logical checks or manual checks	Logical checks and variable limits are active to reduce missing data and to ensure the proper data format. Data elements of the MDS are mandatory variables. Clinicians are advised to select the "Not stated" response for patients with missing information.	Logical checks: the clinician entering the data receives alerts if not all data elements of the MDS are submitted or in case of wrong entries.	Logical checks, other validity checks[34], and mandatory data fields for MDS elements: data with unresolved queries will be marked with warning flags.	NA	Logical checks (at entry and after entry): limiting values that can be entered, using predefined ranges, and printing a warning for unusual values.	Logical checks are built into the register to prevent incorrect data.
Routinely conducted measures	The data is routinely checked and cleaned for consistency before it is finally entered into the ADNeT registry database.	Standardisation of data structures, elimination of double entries across registers, automation of reporting, information security measures, cooperation between the registry and stakeholders across the healthcare system (transparency).	A person at a participating site verifies the collected source data with the QR's data validation plan. At the QR level, a data manager is responsible for data accuracy and quality and verifies collected data with patient records to check whether recruitment goals are met (cross-check).	During data collection: Verification and data cleaning before data transfer and individual clarification with SCs/MCs. After data collection: Review of variables and quality indicators, elimination of redundant variables in cooperation with clinicians, completeness checks with patient's birth date in NorKog and NPR, and check for reliability with data of outpatient clinics (cross-check).	Cross-checking the collected data with the National Board of Health and Welfare's (Socialstyrelsen) patient register and/or the LMED.	Cross-checking of the collected data with data in the LMED.
External or internal review	NA	External review: each Danish QR, including DanDem, has to pass an appraisal by the National Health Authority every three years to see whether it fulfils national criteria for functionality, data security, and methodology.	NA	NA	Internal reviews: Adjudication and evaluation of variables' quality with a diagnostician's help[35]. Research nurses visit units all over the country and verify if the data in SveDem corresponds to data in patients´ medical records[36].	External review by certified trainers: Cross-checking whether collected data corresponds to data in medical records.
In connection with reporting	NA	The validity of entries in the QR system and the data from the LPR are assessed at least once a year (annual report). Cases in the registry are matched with data from the LPR.	NA	The results of the annual reports are presented to the individual specialist clinic annually and discussed.	Sorting out duplicates during annual reporting and contacting units when anomalous data were entered.	NA

Abbreviations: LMED … Prescribed Medicines Registry, LPR … National Patient Registry, MDS … minimum data set, NA … not available, OUS … Oslo University Hospital, NPR … Norwegian Patient Registry, QR … quality registry

[34] Presence checks (mandatory, expected, optional), business rules checks (date of diagnosis cannot be prior to date of assessment), and validity check (has a valid date been entered)

[35] Diagnosis code in the register is reviewed with the help of a diagnostician to check consistency of the patient case via a questionnaire on diagnostic criteria (gold standard).

[36] 10 baseline and five follow-up registrations are randomly selected per SC/MC, and from these, all recorded variables are reviewed (PCU: half of the variables in the basic registrations are reviewed).

Safeguards

Protection and security[37] measures are homogenous across QRs. The primary protection measure in the QRs includes a firewall for the server hosting the database and/or firewalls at the participating clinical sites. Login and personal authentication to enter or read data works through a username and password or hardware solutions such as smart cards (chip cards). The information is stored securely and treated confidentially in all QRs. For example, in Denmark, the Danish Health and Medicines Authority pseudonymises data immediately after receipt so that data is not stored in direct, personally identifiable form. Table 3-12 gives an overview of the specific safety strategies.

ähnliche Schutz- & Sicherheitsmaßnahmen in allen 6 QR: Firewall, passwortgeschützte Authentifizierung, pseudonymisierte Daten, Verschlüsselung etc.

Table 3-12: Protection and security measures in each quality registry

Registry	Protection and security
ADNeT (AU)	Login to the registry interface works via a pre-configured username and password controlled by system administrators. A Firewall assures monitoring and protection against malicious software. All collected data is pseudonymised (ISO 25237:2008 Pseudonymisation). Compliance with Australian privacy legislation informed by the National eHealth Security and Access Framework and ISO/IEC 27002 assures the protection of privacy. Australian QR need to comply with the Security Compliance Guideline for Quality Registries [92].
DanDem (DK)	Access to the data is restricted using a confidential password (replaced once a year). When personal data are transmitted via the Internet or other external networks, encryption and other appropriate security measures are active to prevent unauthorised access to such data. The Danish Health and Medicines Authority pseudonymises data immediately after receipt so that information is not stored in a directly personally identifiable form. The basis for health privacy is the European Union's (EU) GDPR. All participating sites have a firewall. Other safety measures include the assurance of authenticity (identity of the sender and receiver) and integrity (authenticity of the transmitted data).
NDRI (IE)	Only authorised users with a username and password will be able to access data. Personal identifiable information (e.g. patient name, address, date of birth, etc.) will be encrypted and pseudonymised. Data is encrypted at both rest and when data is in transit. Changes and deletions will be tracked. All system servers will have a firewall, and the registry will be available on an agreed time basis. Data protection and privacy are the Data Protection Act 2018, the Irish Health Research Regulations, and the EU's GDPR.
NorKog (NK)	The login to the registry database works via a smart card/chip card. There are different schemes for each clinic and health region. All collected information is treated confidentially, and staff who work with information from the registry have a duty of confidentiality. Data in NorKog is stored on a secure server in the Norwegian Health Network (Norsk Helsenett). Only the registry data management staff has access to all data and the master file. Personal data is either pseudonymised or anonymised. NorKog has a licence from the Norwegian Data Protection Authority and follows the legal basis of the EU's GDPR.
SveDem (SE)	Following the National Board of Health and Welfare's regulations 2008: 14 chap. 5, access to patient data is preceded by strong authentication and requires authorisation with an e-service card[38]. Data is pseudonymised. The use of national QR data is regulated by the Patient Data Act (2008:355) and the EU's GDPR.
BPSDR (SE)	The use of national QRs is regulated by the Patient Data Act (2008:355) and the EU's GDPR. Data is pseudonymised and can be disclosed for quality improvement and research purposes. Access to patient data is preceded by strong authentication. Hence, access to the results and data input in the registry database requires authorisation with an e-service card and/or login via a username and password. Only authorised users can view all data entered into the BPSD Registry and track results.

Abbreviations: EU … European Union, GDPR … General Data Protection Regulation, ISO … International Organisation for Standardisation, IEC … International Electrotechnical Commission

[37] Protection and security measures are different matters. For example, a protective measure is a firewall, security measures are access rules or encryption techniques.

[38] The Secure IT in Health and Medical Care (SITHS) card is an electronic identity document for the secure identification within regions, municipalities, private health care providers and government authorities. SITHS is used when logging into services, for electronic signing and for secure communication between systems.

3.5 Interpretation and Reporting

Berichterstattung ein wichtiger QR-Grundpfeiler

gewährleistet Informationsaustausch & Transparenz

In addition to collecting dementia-related data and analysing QIs, an essential task of the QRs is to report on the results. Reporting and interpretation of the results build the second step towards quality improvement. Furthermore, reporting assures transparency of the whole dementia health care process. The registries use a variety of reporting instruments, as the results of the data analysis are of different relevance to the various groups involved in dementia care. Furthermore, reports serve other purposes: Quality improvement on a clinical unit level and a system level, benchmarking between participating sites, and informing the patients, carers, decision-makers, and the public about dementia care outcomes (transparency). In principle, QRs differentiate between the following types and subtypes of reporting:

kontinuierliche & regelmäßige Berichterstattung durch Ad-hoc-Berichte & Jahresberichte

- *Continuous reporting:* real-time/ad hoc reports for participating sites and decision makers to gain knowledge of dementia care or reports for patients and carers to have information on their dementia health status
- *Periodic reporting:* annual reports for the broad public, periodic reports for decision makers to conceptualise dementia care policy, or bi-annual reports for participating and data-providing sites

Table 3-13: Types of reporting in each quality registry

Registry	Types of reporting
ADNeT (AU)	■ *Continuous reporting:* built-in ad hoc export function to enable data extraction by SCs/MCs and clinicians to drive service improvements. ■ *Periodic reporting:* 1.) bi-annual site reports with a benchmark system (comparison of reporting of opt-out rates, cumulative recruitment of participating sites, and patient response rates across SCs/MCs) and 2.) public accessible annual reports (analyses of the data by descriptive statistics, aggregate summary information on cohort characteristics, QIs, PROMs/PREMs and CROs/CREs). Clinicians use reports to inform continuous quality improvement, and providers and the government use reports to inform services & policy. The annual reports are published on www.australiandementianetwork.org.au/initiatives/clinical-quality-registry/.
DanDem (DK)	■ *Continuous reporting:* SCs/MCs can view data on their own patients, including QIs, in their regional Management Information System (LIS) (data/QI results are updated monthly). Viewing the aggregated data of other units/ regions is also possible, but for data protection reasons only to a limited extent and only via the regions' intranet. ■ *Periodic reporting:* Results from the registry are published in an annual report. The annual report contains statements of QIs at the departmental, regional, and national levels, which have been professionally assessed and commented on. The annual reports are published on www.sundhed.dk.
NDRI (IE)	■ *Continuous reporting:* interactive dynamic real-time reports via an end-user and data interface (dashboards). These real-time reports allow for real-time filtering of required data fields and graphical visualisation of data online or as printed reports. The data analysed in these reports can also be downloaded (.csv-format), subject to user permissions. Comparisons between SCs/MCs are also possible. ■ *Periodic reporting:* Provision of public reports on a regular basis without user intervention comprising of the standardised registry and stakeholder reports (e.g. patient feedback reports, monthly operational reports, annual reports).
NorKog (NK)	■ *Continuous reporting:* QIs and associated data are presented continuously on www.kvalitetsregistre.no. ■ *Periodic reporting:* 1.) NorKog holds an annual registry seminar where results and data of an annual report for participating SCs/MCs are presented (the basis for benchmarking data between the participating SCs/MCs). 2.) An interactive results report is updated twice a year, giving the SCs/MCs access to their own data. 3.) An annual (public) report from NorKog is distributed by e-mail to each SCs/MCs, with a request to distribute it to relevant colleagues. Annual reports are published on the website of the Norwegian National Centre for Ageing and Health (www.aldringoghelse.no/forskning/norkog/) and contain statements of QIs at the departmental, regional, and national level.

Registry	Types of reporting
SveDem (SE)	■ *Continuous reporting:* 1.) Exportable spreadsheets contain results from each SC/MC during a period of time. 2.) Status report shows the SC's/MC's results for selected QIs and offers benchmarking. 3.) Investigation and follow-up reports for SCs/MCs and PCUs show the unit's investigation, follow-up and intervention results. 4.) Nursing and interventions report for nursing homes and home health care shows results for nursing and dementia/health care. Access to these reports works over the SveDem platform. ■ *Periodic reporting:* Annual (public) report with information on QI and other descriptive statistics on baseline and follow-up registrations. Annual reports are published on www.ucr.uu.se/svedem/.
BPSDR (SE)	■ *Continuous reporting:* 1.) publicly available data on quality indicators, 2.) reports and digital spreadsheets available for the public on request to compare automated results and statistics at the municipal, county, and national level, 3.) each NH/DCH can print their data/results and compare them with national average data (NH/DCH reports). The data can be requested/retrieved on pharos.skane.se/bpsddataportal. ■ *Periodic reporting:* Annual public reports published on bpsd.se.

Abbreviations: NH/DCH … nursing home/dementia care home, SC/MC … specialist clinic/memory clinic

Ergebnisse der QR werden in jährlichen Berichten publiziert (öffentlich zugänglich)

All QRs publish the results of their annual analyses in annual reports publicly available on each QR's website. NorKog also distributes the report via e-mail to each SCs/MCs with a request to distribute it to relevant colleagues. Further periodic reporting approaches include bi-annual site reports (ADNeT) or annual site reports, including a registry seminar for data-providing SCs/MCs (NorKog). These specific site reports are intended for benchmarking data between SCs/MCs. Other QRs (DanDem, NDRI, SveDem, BPSDR) benchmark via specific digital platforms for SCs/MCs, but for data protection reasons only to a limited extent.

unterschiedliche Tools für kontinuierliche Berichterstattung kommen zum Einsatz

Continuous reporting and access to data work through the digital platform solutions of the QRs. ADNeT provides a built-in ad hoc export function to enable data extraction by SCs/MCs and clinicians to drive service improvements. SveDem and BPSDR follow similar approaches. In DanDem, SCs/MCs can view data on their patients, including QIs, in their regional Management Information System (LIS) (data/QI results are updated monthly). In NorKog, a digital interactive results report is updated twice a year, giving the SCs/MCs access to their data.

3.6 Privacy, consent, and ethics

3.6.1 Privacy

DSVGO & eigene nationale Datenschutzbestimmung in EU-Ländern

NorKog orientiert sich an DSVGO

ADNeT mit eigener Datenschutzbestimmung

Security measures are closely linked to patient and health privacy. All EU member states are subject to the GDPR and the privacy regulations therein [93]. While GDPR directly applies as a law in all member states, EU countries also have their own regulations with the respective national privacy laws (see Table 3-12). For example, the basis for data protection and privacy in Ireland is the Data Protection Act 2018 and the Irish Health Research Regulations. The latter gives effect to the GDPR and the Data Protection Act in the context of health research. NorKog complies with the regulations issued by Norwegian Data Protection Authority but also takes the EU's GDPR as a basis for privacy regulations. ADNeT complies with Australian privacy legislation informed by the National eHealth Security and Access Framework. As described above, pseudonymisation is applied in all QRs.

3.6.2 Consent and ethics

unterschiedliche Konsentierungsmodelle kommen zum Einsatz

An important part of a QR is the consent process. The consent process is related to ethical considerations and directly affects recruitment and participation rates [32, 94]. In the QR context, consent has multiple components: consent for the sole purpose of collecting patient information, consent for the purpose of quality improvement, and consent for the subsequent use of the data for research purposes [36]. Table 3-14 shows the consent models for each QR that applies for the primary purpose of quality improvement. Consent with regard to the further use of data for research underlies other consent conditions compared to quality improvement and is discussed in section 3.7 on "Register-based research and confounders".

Table 3-14: Overview of the consent model used in each quality registry

Opt-out	Opt-in	No consent required	Mixed model/Not clear
■ SveDem (SE) ■ BPSDR (SE)	■ NorKog (NK)	■ DanDem (DK)	■ ADNeT (AU) ■ NDRI (IE)

3 geläufige Modelle:

In general, there are three consent models commonly used with regard to patient recruitment and participation:

Opt-out-Modell: Pat. muss informiert werden & kann verneinen

- *Opt-out model:* The patient must be informed of registration and that they have the right to decline participation. In SveDem and BPSDR, patients are entitled to a free extract from the QR per year. In addition, patients have the right to request a withdrawal and the right to have the data removed from the registry. All three requests must be made in written form.

Opt-in-Modell: Pat. kann einer QR-Aufnahme zustimmen

- *Opt-in model:* In NorKog, signed consent on the first visit is required for participating in the QR. If the patient is able to consent, only the patient must consent. Relatives can consent on behalf of patients with a lack of consent competence. Patients can withdraw their consent at any time without giving any reason.

keine Konsentierung notwendig

- *No consent model:* In DanDem, patient consent is not required for data collection, as for all health data in Denmark, according to the Danish Health Data Authority.

für irisches QR unklar

ADNeT and NDRI deviate from the standard models of consent. The consent model for NDRI is unclear as it is not implemented yet. Usually, managing clinical care and measuring quality outcomes do not require an individual's consent in Ireland. ADNeT follows a mixed consent approach:

australisches QR: Kombination aus Opt-out-Modell & spezieller Verzichtserklärung

- Opt-out: Patients' data are entered into the registry once a four-week withdrawal period has expired after the diagnosis has been communicated either to the patient or the carer/relative.
- Waiver of consent: if the diagnosis has not been communicated, no consent is obtained, and the patient is automatically registered.

The following Figure 3-1 presents the ADNeT consent model.

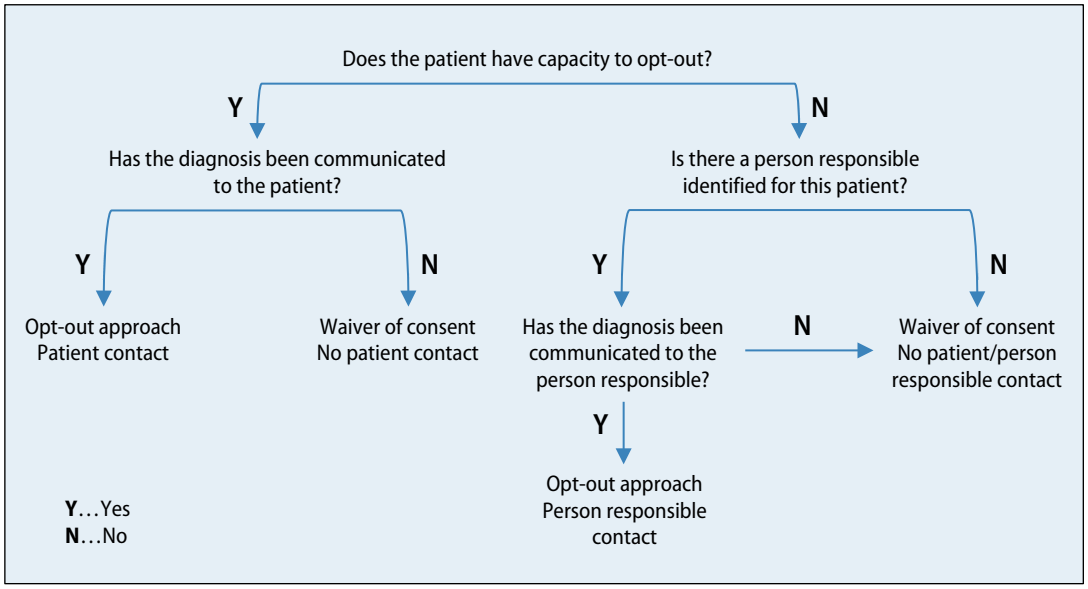

Figure 3-1: ADNeT consent model according to Ward et al [95] (own depiction)

When patients are recruited using a waiver of consent, no patient contact is made, and data are automatically included in the registry. Most ethical guidelines recommend disclosure of diagnosis, but some clinicians might choose not to inform patients for specific reasons. Reasons include patients requesting not to be informed of the diagnosis, concerns about impaired insight among patients, concerns about the risk to the patient's psychological wellbeing or requests from family. Hence, compared to other national dementia QRs, which typically use only one consent method, the ADNeT registry includes a larger group of people with dementia and MCI and maximises the registry coverage and inclusiveness. Patients and/or their families can also choose to withdraw from the registry at any time. Registered patients and carers can apply to access the stored information at any time by contacting the registry coordinator via email or phone.

Verzichtserklärung → kein Pat.-Kontakt & Pat. automatisch registriert

No ethical approval or formal authorisation is required for the primary purpose of quality improvement at the national level, in hospital dementia units, or in NH/DCH in all QRs. The respective consent model only limits the use of data in each QR.

keine Prüfung durch Ethik-Komitee für Maßnahmen zur Qualitätsverbesserung

3.7 Register-based research and confounders

weiteres zentrales Ziel der Demenz-QR: (externe) Forschung;

zu berücksichtigende Aspekte für Forschungszwecke

A common secondary objective or purpose of the six QRs is the use of data for research purposes. Registry data should be 'research ready', and the QR should also fulfil other aspects, e.g. collection of confounders, to be appropriate for research. The QRs share some of these aspects, but considerations for using registry data and handling research outcomes differ to some extent from registry to registry. The following modalities are considered to be necessary by the QRs concerning register-based research:

Erfassung von weiteren Pat.-Daten (bspw. demografische Daten)

- **Collection of demographic and other patient-related variables**: in the course of data collection, all QR collect further essential variables such as demographic and other patient variables (see section 3.4.2). The data are collected to improve dementia care quality and promote and advance dementia research. For example, NorKog's steering group has approved 57 studies (110 publications).

Risikoadjustierung & Störfaktoren berücksichtigen

- **Possibility of risk adjustment and controlling for confounders**: The collection of these other patient-related variables not only allows for the use within the purpose of the QR, such as risk-adjustment of data output and QIs but also makes it possible to control for confounders in other research projects in ADNeT and DanDem.

Verknüpfung mit anderen Datenquellen

- **Linkage to other databases (interoperability):** Possibility to link the data to other databases such as national health care registries or other QRs (see section 0 for information about data sources and linkage).

Antrag auf Datenzugang & -nutzung durch Forscher*innen

unterschiedliche Modalitäten in den QR

- **Application for research use:** If researchers have an interest in using data for research, they need to apply for data access in all six QRs. ADNeT and NorKog explicitly provide an expression of interest form, and NDRI will offer a research application module. DanDem, SveDem, and BPSDR must be contacted directly via e-mail or telephone if researchers want to access the data. The request in NDRI should be based on a clear set of inclusion and exclusion criteria and contain sufficient details to enable subsequent review and acceptance/rejection by the registry team. For NorKog and SveDem, researchers must carry out a similar process. They need to send an application form, including a protocol, to the SG (NorKog) or data controller (SveDem) to be eligible to use the data. The application must contain specific information about which data and variables are used, responsibility for data processing, storage/research server, time limit, return of data/deletion, and who will have access to data. In the BPSDR, a researcher must either get written approval from each NHs/DCHs manager or the head of the social services (Socialförvaltningen) for the concerned municipality. Whereas no registry data will be made available to insurance companies, employers, driving authorities, and other similar bodies in NDRI, biotech companies, pharmaceutical companies, and start-ups can apply for data access in ADNeT. All QRs require direct reference to the registry if the research is published.

Forschungsplattformen für Datenzugang (Software)

- **Platforms for research access and guidance for conducting research:** DanDem offers a separate data portal for research access: https://rkkp-forskningsadgang.dk/. In addition, some QRs offer (quick) guidances, which provide explanations on requesting and handling data, and specific questions regarding the research process and disclosure (ADNeT, DanDem, NorKog, SveDem, BPSDR). For example, Big Data, Machine Learning, or Artificial Intelligence projects must transparently document concrete data needs in NorKog.

- **Ethical approval and consent for research purposes:** No ethical approval or formal authorisation is required to use the data for quality improvement purposes at the national level, in hospital dementia units or in NH/DCH. But for research purposes, ethical approval is necessary for all QRs. For example, the Irish Data Protection Act 2018 and the Irish Health Research Regulations require ethical approval if data from the NDRI is used for research purposes. The NDRI model makes it clear that it is not appropriate to discuss consent for data use in research at the time of diagnosis, as the person and their family have enough to deal with at that point. The same approval procedure applies to SveDem. Ethical approval from the Swedish Ethics Review Authority for each research project where SveDem data will be used is needed.

Genehmigung durch ein Ethik-Komitee für „externe" Forschungszwecke

- **Consent from patients for research (opt-in for research):** If patients have not been informed that their data were collected for research purposes, the patient and/or an independent authority (ethics committee) need to be consulted before data can be handled. Four QRs (ADNeT, DanDem, NDRI, SveDem) require the patient's consent before data is used for research. In DanDem, for example, direct inquiries of patients presuppose that permission has been given by the person responsible for the treatment or the management at the treatment site. NDRI will implement an online mechanism for capturing, viewing, and updating registry participant's informed consent (the person with dementia and/or carer).

Genehmigung durch Pat. der Datennutzung für „externe" Forschungszwecke

- **Costs and fees for data access:** In the two Swedish QRs (SveDem, BPSDR), fees are charged for data access. No fees are charged in the four other QRs, or specific information is not available. Table 3-15 overviews the fee modalities of the six QRs.

schwedische Demenz-QR erheben Gebühren für Zugang

Table 3-15: Costs and fees for the data access (research purposes)

Registry	Costs and fees for data access
ADNeT (AU)	■ No costs or fees/No concrete information available ■ Access to ADNeT data is made available to researchers if certain conditions are met.
DanDem (DK)	■ No costs or fees/No concrete information available ■ Access to DanDem data is made available to researchers if certain conditions are met.
NDRI (IE)	■ Not defined yet
NorKog (NK)	■ No costs or fees/No concrete information available ■ Access to NorKog data is made available to researchers if certain conditions are met.
SveDem (SE)	Fees for data extraction: ■ Fees for 'simple' extractions: SEK 3,000 (€ 274) ■ Fees for 'more elaborate' extractions: SEK 5,000 (€ 457) ■ SEK 1,200 (€ 109) per hour for data extraction itself Furthermore, access is permitted only under specific regulations.
BPSDR (SE)	■ Fees for data access exist but are not publicly available ■ Furthermore, access is permitted only under specific regulations.

Abbreviations: SEK … Swedish krona

4 Results: Quality indicators and outcome parameters

4.1 Evidence foundations of the quality indicators

Qualitätsindikatoren (QI) zentral für Qualitätsverbesserung

Quality indicators are the key instruments measuring the quality of QRs. Based on the MDS, each registry develops indicators to assess dementia care processes, structures, and outcomes to improve care quality. The improvement will be achieved by monitoring, evaluating, and benchmarking these indicators. Section 4.2 gives an overview of the identified QIs.

QI basieren auf MDS

evidenz-basierte Praxis als Basis für QI

All six registries emphasise that QIs should reflect evidence-based practices, underlying recommendations, and standards of the respective healthcare system and dementia care strategy. Each registry uses its mixture of foundations and approaches to arrive at the individual indicator set. Table 4-1 provides an overview of the evidence foundations of the indicator sets, whether the indicators have specific target values[39] for quality improvement, the underlying sources, and other essential aspects regarding QIs.

Table 4-1: Overview of the foundations of the quality indicators

Registry	Evidence foundations	Target values	Sources	Other aspects
ADNeT (AU)	■ Consensus (Delphi study, SG) ■ Guideline (ADNeT GL)	No	■ Annual report (2021) [95] ■ Delphi study [6] ■ Guideline [96]	■ Collection but no monitoring of PROMs/PREMs and CROs/CREs
DanDem (DK)	■ Consensus (SG) ■ Guideline	Yes	■ Annual report (2021) [97] ■ Guideline [98] ■ Handbook quality improvement [90]	■ SG defined QIs primarily based on knowledge of good quality in practice
NDRI (IE)	■ Consensus (stakeholder workshops) ■ Literature review (the basis for the stakeholder workshops)	No	■ NDRI model (2021) [32]	■ No national GLs on dementia care ■ Priority on five QIs
NorKog (NK)	■ Consensus (SG, NorKog's secretariat, National Service Environment for Medical Quality Registries, patients representatives) ■ Guideline (national dementia plan and associated national GLs)	Yes	■ Annual report (2021) [99] ■ National dementia plan [100] ■ Ad-hoc results [101]	■ Five of the 12 QIs are analysed and reported in the annual report
SveDem (SE)	■ Guideline (QI elaboration was cooperation between SveDem's SG and the National Board of Health and Welfare)	Yes	■ Annual report (2020) [102] ■ Guideline [30]	■ Target values for some QIs are partly different for PCUs and SCs/MCs
BPSDR (SE)	■ Guideline (QI elaboration was cooperation between BPSDR and Knowledge Centre for dementia at the Skåne University Hospital Malmö)	Partially used	■ Annual report (2020) [103] ■ Guideline [30] ■ Ad-hoc results [104]	■ Priority #1: patient-reported outcomes and experiences (PROMs/PREMs)

Abbreviations: CRO/CRE … carer-reported outcomes/expectations, GL … guideline, PCU … primary care unit, PROM/PREM … patient-reported outcome and expectation measure, QI … quality indicator, SG … steering group

[39] Target values are thresholds that the registry aims to achieve, exceed, or undercut within a defined period.

Auswahl der QI-Sets größtenteils konsensbasiert

In four registries (ADNeT, DanDem, NDRI, NorKog), none of the indicators is explicitly based on national guidelines or specific evidence syntheses. These four QRs started with a consensus-based approach emanating from the respective SG[40]. The consensus-based approach was complemented by consultation of guidelines in three QRs (ADNeT, DanDem, NorKog) [96, 98, 100] or a literature review in one QR (NDRI) [32] in the process of developing the final QI set. For example, ADNeT's QI set was developed in the course of a modified Delphi study [6], operationalised by Monash University, before establishing the QR. The QI set was later adopted as a part of the National Service guidelines for Specialised Dementia and Cognitive Decline Assessment Services in Australia [96].

schwedische Register gehen explizit von Leitlinien aus

SveDem and BPSDR, on the other hand, explicitly started from the Swedish National Guideline for Care of Dementia [30] to arrive at the indicator set. In these two QRs, QIs were elaborated as a cooperation between the registry's responsible group and an external authority. In SveDem's case, the National Board of Health and Welfare (Socialstyrelsen) has developed and set measurable target values after assessing compliance with the National Guideline for Care of Dementia. The authority has developed target values and identified areas for improvement for both regions and municipalities. The staff of SveDem participated in the development of these target values.

Schwellenwerte nur in 3 Demenz-QR

Three QRs (DanDem, NorKog, SveDem) have explicitly set target values for some key indicators to improve the quality of dementia care. BPSDR has a target value only for one QI.

4.2 Overview of the quality indicators

4.2.1 Quality indicator categories and clusters

64 QI insgesamt über die QR hinweg

A total of 64 indicators across the six QRs were identified [32, 95, 97, 99, 102, 103]. The total number of indicators used for quality improvement for each registry ranges from six in the BPSDR to 15 in DanDem. The number

pro QR zwischen 5 & maximal 10 Haupt-QI

of key QIs ranges from five indicators in NDRI and NorKog to ten QIs in DanDem and SveDem. In total, 36 indicators across the registries have target values. Not all QRs have defined target values (yet). Results are available for 38 of the 64 indicators across the six registries. The QIs are assigned to the following categories of a dementia care pathway:

QI zur Prädiagnose-,

- Pre-diagnosis (PD) indicators, such as time from first contact to diagnosis

Diagnose-,

- Diagnosis and diagnostic workup (DDW) indicators, such as the proportion of patients undergoing basic dementia workup

Behandlungs- & Follow-Up-Phase,

- Treatment, support, and follow-up (TSF) indicators, such as the proportion of patients treated with dementia drugs

ergebnisorientierte QI

- Outcome-related (OUR) indicators, such as QoL measures

& „Meta-QI"

- Meta indicators and other quality indicators (MET), such as coverage

[40] In the course of creating the NDRI concept, a steering group for indicator creation was specially set up. Not to be confused with the typical steering group of a registry.

Table 4-2: Overview of the quality indicators in the care pathway

Number of quality indicators						
Registry	QIs in total	Key QIs	Sub-QIs	QIs with target values	QIs with results	QIs in each category in the care pathway: PD/DDW/TSF/OUR/MET
ADNeT (AU)	7	7	-	-	7	1/5/1/–/-
DanDem (DK)	15	10	5	13	12	3/7/3/–/2
NDRI (IE)	14	5	9[41]	-	-	1/3/8/2/-
NorKog (NK)	12	5	7	12	5	1/9/1/1/-
SveDem (SE)	10	10	-	10	8	-/2/8/–/-
BPSDR (SE)	6	6	-	1	6	-/–/4/2/-
Σ Sum	**64**	**43**	**21**	**36**	**38**	**6/26/25/5/2**

Abbreviations: DDW … diagnosis and diagnostic workup, MET … meta indicators and other quality indicators, OUR … outcome-related, PD … pre-diagnosis, QI … quality indicator, TSF … treatment, support, and follow-up

26 Diagnose- & 25 Behandlungs-QI

SveDem hat Fokus auf Behandlungs-QI & ADNeT, DanDem & NorKog mit Fokus auf Diagnose-QI

The category in the dementia care pathway with the most indicators is DDW, with 26 out of 64 indicators (41%), followed by TSF, with 25 indicators (39%). Six (9%), five (8%), and two (3%) indicators are PD, OUR, and MET indicators, respectively. SveDem has a focus on TSF indicators with eight out of ten indicators. ADNeT, DanDem, and NorKog focus on DDW indicators: 71%, 47%, and 75% of each registry's indicator set are DDW indicators. Four of the six registries (ADNeT, DanDem, NDRI, NorKog) utilise PD indicators to monitor the quality of care, with DanDem having the most (3 PD indicators). DanDem is the only QR that provides MET indicators.

in Summe 46 individuelle QI

für 31 sind Ergebnisse verfügbar

The 64 QIs across the six QRs can be further clustered into subgroups. For example, QIs for TSF can be subdivided into QIs for pharmacological or psychosocial treatment and supportive measures. In addition, some QRs have the same QI and can be combined into one indicator (see 4.2.3 for overlapping indicators). Forty-six individual QIs across all six QRs remain after clustering according to the proposed taxonomy presented in section 2.4 and merging overlapping QIs. Results are available for 31 of the 46 individual QIs. Table 4-3 gives an overview of the type of quality indicator and category affiliation of the care pathway and cluster categories.

Table 4-3: Type of quality indicator and category affiliation

Type of quality indicators				
Category of the care pathway and cluster	Structure quality	Process quality	Outcome quality	Σ Sum
Pre-diagnosis	-	5	-	5
Diagnosis and diagnostic workup	-	15	1	16
Treatment, support, and follow-up	1	17	-	18
Outcome-related quality indicators	0	0	5+1[42]	5+1[42]
Meta indicators and other quality indicators	-	2	-	2
Σ Sum	**1**	**40**	**5+1[42]**	**46+1[42]**

Abbreviations: CRO/CRE … carer-reported outcomes/expectations, CT/MR … computer tomography/magnetic resonance, QI … quality indicator, PROM/PREM … patient-reported outcome and expectation measure, QoL … quality of life,

[41] QIs not covered in phase 1 of implementation.

[42] Q11. Neuropsychiatric Inventory Nursing Homes Version scores assessment is also conducted in the follow-up examination. This QI is only counted once to avoid double counting.

87 % der QI zu Prozessqualität

Of the 46 QIs, 40 (87%) are process quality indicators. Five indicators (11%) can be assigned to outcome quality and one to structural quality. Table A-14 in the Appendix gives a more detailed breakdown of the indicator types for each cluster in the dementia care pathway.

4.2.2 Quality indicators

Pre-diagnosis

Prädiagnose: 5 QI mit Fokus auf Qualität des Überweisungsprozesses

A total of five indicators were identified that could be assigned to the PD category of the dementia care pathway. The indicators focus on the referral process and cover mainly the temporal component of care quality, such as waiting times from first dementia indications to referral to diagnosis. All five indicators target the process quality of dementia care. QI2 is part of two registries, and three registries cover QI5. QI1, QI3, and QI4 are only used in individual registries. The following Table 4-4 gives an overview of pre-diagnosis quality indicators.

Table 4-4: Overview of quality indicators: Pre-diagnosis

Quality indicators: Pre-diagnosis	Registries	Type[43]
Referral process and waiting times		
QI1. Proportion of patients who had the first appointment to referral to an SC/MC <90 days (ADNeT)	ADNeT	P
QI2. Time from referral to first contact (waiting time) (ADNeT[44], DanDem[45],)	ADNeT, DanDem	P
QI3. Proportion of patients who have follow-up or referral after the initial assessments (NDRI[46])	NDRI	P
QI4. Proportion of patients with a definitive diagnosis of dementia <90 days of first visit or first dementia indications (DanDem)	DanDem	P
QI5. Time from start of investigation (1st contact) to time point of diagnosis (1st report) (DanDem, NDRI[46], NorKog)	DanDem, NDRI, NorKog	P

Diagnosis and diagnostic workup

Diagnose: 16 QI mit Fokus auf durchgeführte diagnostische Evaluationen & Tests

A total of 16 indicators were identified that could be assigned to the DDW category of the dementia care pathway. The indicators try to capture the quality component of evaluations and tests conducted during the diagnosis and diagnostic workup phase. One indicator, QI11, is an indicator to monitor the outcome quality and 15 of 16 indicators target the process quality of dementia care. Two registries each use QI6. QI7, QI8, and QI15. QI12 and QI16 are monitored in three registries. QI6 is used in four QRs. QI17-QI21 are only used in individual registries. Table 4-5 overviews the quality indicators of the diagnosis and diagnostic workup phase.

[43] The type specifies whether the quality indicator target structure quality (S), process quality (P), or outcome quality (O) of dementia care.

[44] No main or sub-QI in ADNeT, but derived in the course of 'QI1 Proportion of patients who had the first appointment to referral to a SC/MC <90 days'.

[45] Sub-indicator in the registry.

[46] QI is not part of the prioritised indicator set in phase 1 of implementation of NDRI.

Table 4-5: Overview of quality indicators: Diagnosis and diagnostic workup

Quality indicators: Diagnosis and diagnostic workup	Registries	Type
Basic dementia assessment/workup		
QI6. Proportion of patients undergoing basic dementia workup/assessment (NDRI, SveDem)	NDRI, SveDem	P
Cognitive assessment and neuropsychiatric assessment		
QI7. Proportion of patients who had an assessment of multiple cognitive domains as part of the diagnostic workup (ADNeT) Proportion of patients who had a cognitive test in the SC/MC (DanDem)	ADNeT, DanDem	P
QI8. Proportion of patients who had an extended cognitive test (DanDem[45], NorKog)	DanDem, NorKog	P
QI9. Proportion of patients whose cognition was re-assessed within 18 months of an MCI diagnosis (ADNeT)	ADNeT	P
QI10. Proportion of patients of whom information is collected about neuropsychiatric symptoms via NPI (NorKog)	NorKog	P
QI11. Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores over time (BPSDR)	BPSDR	O
Imaging via CT/MR (Neuroimaging)		
QI12. Proportion of patients who have had a CT/MR scan of the brain (ADNeT, DanDem[47], NorKog)	ADNeT, DanDem, NorKog	P
QI13. Proportion of patients with mild-moderate vascular dementia who have had an MR scan of the brain in the last 24 months (DanDem[45])	DanDem	P
Functionality/Activities of daily living (ADL) assessment		
QI14. Proportion of patients who had an assessment of the capacity to undertake personal and instrumental activities of daily living as part of the diagnostic workup (ADNeT) Proportion of patients evaluated who have had an ADL assessment using the FAQ/IADL scale, DAD, ADCS-ADL or Trindvold/DSQIID (DanDem) Proportion of patients for whom functionality in daily life is mapped (NorKog) Proportion of patients who have undergone a structured functional and activity assessment (SveDem)	ADNeT, DanDem, NorKog, SveDem	P
QI15. Proportion of patients whose health requirements for driving licenses have been assessed (NDRI[46], NorKog)	NDRI, NorKog	P
Specific dementia diagnosis		
QI16. Proportion of patients with a specific diagnosis of dementia (aetiological diagnosis) (DanDem, NDRI, NorKog)	DanDem, NDRI, NorKog	P
Other assessment tests and diagnosis-related QIs		
QI17. Proportion of patients who undertook core blood tests as part of the diagnostic workup (ADNeT)	ADNeT	P
QI18. Proportion of patients with AD and mild dementia who have had a lumbar puncture in the diagnostic workup or PET scan within 24 months before the date of referral (Alzheimer's biomarker) (DanDem)	DanDem	P
QI19. Proportion of patients assessed for depressive symptoms (NorKog)	NorKog	P
QI20. Proportion of patients from whom information was collected from relatives (NorKog)	NorKog	P
QI21. Proportion of patients who had an assessment for a somatic symptom disorder (NorKog)	NorKog	P

[47] CT/MR scan in the last 24 months in the case of DanDem.

Treatment, support, and follow-up

Behandlung, Unterstützung & Follow-Up: 18 QI

A total of 18 indicators, of which 17 are indicators for monitoring process quality and one is an indicator for capturing structural quality (QI28), were identified that could be assigned to the TSF category of the dementia care pathway. QI22 is monitored in five QRs. An intersection in the use of indicators arises for QI24 in two registries. The rest of the QIs are used in individual registries. Table 4-6 gives an overview of treatment, support, and follow-up quality indicators.

Table 4-6: Overview of quality indicators: Treatment, support, and follow-up

Quality indicators: Treatment, support, and follow-up	Registries	Type
Pharmacological treatment (dementia medication)		
QI22. Proportion of patients with a diagnosis of mild to moderate Alzheimer's disease and a prescription/recommendation of acetylcholinesterase inhibitors (ADNeT) Proportion of patients who are treated with anti-dementia medication (DanDem[48], NDRI[46]) Proportion of patients with Alzheimer's disease treated with dementia drugs (SveDem) Proportion of people with Alzheimer's disease who receive symptom-relieving dementia drugs (BPSDR)	ADNeT, DanDem, NDRI, SveDem, BPSDR	P
QI23. Proportion of patients with a prescription for dementia medication who have filled a prescription up to three months after the diagnosis interview (DanDem[45])	DanDem	P
Pharmacological treatment (other medication such as anti-psychotic drugs etc.)		
QI24. Proportion of patients treated with anti-psychotic drugs (NDRI, SveDem)	NDRI, SveDem	P
QI25. Proportion of people treated with either haloperidol, risperidone, zopiclone, hydroxyzine, oxazepam, or paracetamol and average daily dose per patient per year (BPSDR)	BPSDR	P
Psychosocial treatment and support		
QI26. Proportion of patients with dementia who have received a psychosocial offer in connection with information about the diagnosis (psychosocial offer) (DanDem)	DanDem	P
QI27. Time waiting for home support services (NDRI[46])	NDRI	P
QI28. Proportion of patients with dementia who have day-care/home care support (NDRI[46])	NDRI	S
QI29. Proportion of patients whose life story is the basis for the design of care (SveDem)	SveDem	P
QI30. Proportion of patients with individual environmental adaptations in the implementation plan (SveDem)	SveDem	P
QI31. Proportion of patients with coping/care strategies described in the individual implementation plan (SveDem)	SveDem	P
QI32. Proportion of patients with access to person-centred activities and (sense) stimulation (SveDem)	SveDem	P
QI33. Proportion of participating sites initiating support measures (Initiatives to support relatives and patients in connection with the diagnosis of dementia)	SveDem	P
QI34. Purpose and nature of patient activities undertaken and/or measures implemented for patients by health care professionals during the year (percentage of all registrations) (BPSDR)	BPSDR	P
Other treatment-, support-, and follow-up-related QIs		
QI35. Proportion of patients who have a standard care plan (NDRI[46])	NDRI	P
QI36. Time from diagnosis of dementia to permanent residential care (NDRI[46])	NDRI	P
QI37. Proportion of patients with MCI or dementia who were referred to health service after the assessment (NorKog)	NorKog	P
QI38. Proportion of patients with a regular follow-up (SveDem)	SveDem	P
QI39. Proportion of patients for whom a multi-professional team[49] has been deployed (teamwork) (BPSDR)	BPSDR	P

[48] In DanDem, QI22. is restricted to patients with AD, PDD, DLB, and mixed dementia

Outcome-related quality indicators

5 ergebnisorientierte QI

There are no overlaps of indicators with regard to outcome-related QIs. All five QIs in this cluster are covered by individual registries and target the outcome quality of dementia care. The following Table 4-7 gives an overview of outcome-related quality indicators.

Table 4-7: Overview of quality indicators: outcome-related quality indicators

Quality indicators: outcome-related (QoL, PROMs/PREMs etc.)	Registries	Type
Cognitive and neuropsychiatric outcomes		
QI11. Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores over time (BPSDR)	BPSDR	O
QoL of the patient/PROMs/PREMs		
QI40. Overall QoL of the patient with dementia (NDRI)	NDRI	O
QI41. Proportion of patients who reported on patient-related outcome measures (NorKog)	NorKog	O
QoL of the carer/CROs/CREs		
QI42. Overall QoL and well-being of carer (NDRI)	NDRI	O
Other outcome-related QIs		
QI43. Dementia syndrome/Disease progression (NDRI[46])	NDRI	O
QI44. Proportion of patients who were assessed as pain-free and for whom a pain assessment scale was used (BPSDR)	BPSDR	O

Meta indicators and other quality indicators

2 "Metaindikatoren" (nur in DanDem)

DanDem is the only registry that covers Meta indicators. Both of these indicators are indicators regarding process quality. Table 4-8 presents an overview of the meta and other quality indicators.

Table 4-8: Overview of Meta indicators and other quality indicators

Quality indicators: Meta indicators and other quality indicators	Registries	Type
QI45. Coverage (DanDem)	DanDem	P
QI46. Degree of concordance (DanDem)	DanDem	P

[49] A multi-professional dementia team in Sweden often includes nurses, occupational therapists and medical doctors. Some teams also include physiotherapists, speech language pathologists, psychologists and social workers. Neuropsychologists are only very rarely involved in diagnostic assessment in primary health care, and only a minority of patients in SCs/MCs are seen by a neuropsychologist [105].

4.2.3 Overlapping indicators

35 QI werden nur in jeweils einem Demenz-QR & 11 QI in mehreren QR angewendet

The previous subsection (see 4.2.2) has shown that the indicator landscape is considerable heterogeneous across the registries. In total, 35 of the 46 indicators are used in only one registry each for the purpose of quality improvement. In the remaining 11 QIs, there is overlap across the QRs. The following section briefly presents the overlaps in QIs across the registries.

In two registries

6 QI kommen in 2 QR zum Einsatz

Six QIs are used in two registries. Three of the six are diagnosis-related indicators (QI6, QI7, QI8)

- QI2. Time from referral to first contact (waiting time)[44].
- QI6. Proportion of patients undergoing basic dementia workup/assessment.
- QI7. Proportion of patients who had a cognitive test.
- QI8. Proportion of patients who had an extended cognitive test.
- QI15. Proportion of patients whose health requirements for driving licenses have been assessed.
- QI24. Proportion of patients treated with antipsychotic drugs.

In three registries

3 QI kommen in 3 QR zum Einsatz

Three QIs are used in three registries. Two (QI12, QI16) of the three are TSF indicators.

- QI5. Time from start of investigation (1st contact) to time point of diagnosis (1st report).
- QI12. Proportion of patients who have had a CT/MR scan of the brain.
- QI16. Proportion of patients with a specific diagnosis of dementia (Aetiological diagnosis).

In four registries

1 QI kommt in 4 QR zum Einsatz

One indicator, which regards mapping the functionality and activities of daily living, is used by four registries.

- QI14. Proportion of patients for whom functionality in daily life and activities of daily living are assessed.

In five registries

1 QI kommt in 5 QR zum Einsatz

Monitoring the proportion of patients treated with dementia drugs has the most overlaps. The indicator is monitored in five registries.

- QI22. Proportion of patients who are treated with anti-dementia medication.

4.3 Quality indicator vignettes and results

Evidenzbasis der QI: Leitlinien, konsensbasierte Praktiken, Demenzstrategien

Vignetten (Übersicht): Darstellung des Zusammenhangs zwischen Evidenzgrundlage & QI

Ergebnisse der QI diskutiert

The following section contains the evidence foundations (dementia care guidelines, consensus-based practicalities, and aims of the respective healthcare system defined in national dementia strategies) and results of the identified quality indicators. This section's presentation shows the genealogy of the respective QIs (Figure 1-1). For that purpose:

- Short vignettes were created to establish the relationship between the evidence foundations of dementia care in each country and the QI used.
- The registries from which the respective evidence foundation originates are listed in parentheses.
- The respective QI number to which the evidence foundation refers is also listed in parentheses (in blue), as some foundations may refer to several QIs.
- Results of each QI from each QR's last annual report are presented after each vignette.

Table 4-9 provides an overview of each QI's target and actual values. This table indicates whether the target value was met and lists how many of the registries use the respective QI (a detailed overview can be found in the Appendix: Table A-2-Table A-13).

4.3.1 Pre-diagnosis

Referral process and waiting times

Überweisungsprozess & Wartezeiten

The following indicators capture temporal information on the quality of care from first contact to referral to the final diagnosis. A short waiting time for an initial appointment, including an assessment and minimisation of time to diagnosis, are deemed necessary across QRs monitoring these QIs.

Vignette: Referral process and waiting times
QI1. Proportion of patients who had the first appointment to referral to an SC/MC <90 days (ADNeT)
QI2. Time from referral to first contact (waiting time) (ADNeT[44], DanDem[45])
QI3. Proportion of patients who have a follow-up or referral after the initial assessments (NDRI[46])
QI4. Proportion of patients with a definitive diagnosis of dementia <90 days of first visit or first dementia indications (DanDem)
QI5. Time from start of investigation (1st contact) to time point of diagnosis (1st report) (DanDem, NDRI[46], NorKog)
■ Initial assessment for dementia should be conducted within 90 days for normal-priority clients (ideally, within 45 days) and within 30 days for high-priority clients after referral (ADNeT; QI1). ■ Waiting time should be as short as possible as the risk of forgetting the appointment increases with longer waiting times. However, a very short investigation time does not necessarily indicate good quality and may reflect different working practices in the individual investigation units (DanDem; QI2, QI5). ■ The focus should be on ensuring patients are not waiting too long for their initial appointment, but for some patients, a longer time to diagnosis may be better (NDRI; QI3). ■ The patient should receive feedback on the diagnosis as quickly and precisely as possible after the examination has been completed so treatment and support measures can be planned (NorKog; QI5) ■ Total time until diagnosis depends on the extent to which additional tests, such as neuropsychological testing or CT/MR scanning, are performed to make a disease-specific dementia diagnosis (DanDem, NDRI; QI5). ■ Assessment after referral should be arranged with the relatives/carer, and close relatives/carer should accompany patients for dementia assessment (DanDem; QI5). ■ SCs/MCs may choose to decline a referral if the cognitive problems are clearly within the context of a psychiatric disorder, non-progressive brain disease with no evidence of decline, traumatic brain injury, and/or alcohol dependence (ADNeT; QI5).

ADNeT: ~60 % der Pat. Überweisung innerhalb 90 Tage

QI1: In ADNeT, ~60% of patients who had their first appointment with a GP or other primary care professional for first signs of dementia were referred to an SC/MC within 90 days in 2021. As there is no defined target value and no data from previous years, no comparison can be made. However, an initial assessment should be conducted within no more than 90 days for routine-priority clients (ideally, within 45 days of referral) and 30 days of receipt of the referral for high-priority clients [95, 96].

QI2, QI3: NA

DanDem: konstanter Anteil an Pat. mit Diagnoseabklärung <90 Tage

QI4: In Denmark, at the national level, the proportion of patients who completed their assessment within 90 days of referral for the year 2021 and 2020 were constant (42%). But compared to 2019, there is a decrease of 10% points at a national level (42% in 2021 vs 52% in 2019)[50]. In 2021, no region met the target value (>80%), and there is significant variation between all five regions (16-58%) and SCs/MCs. The SG also notes a considerable variation in the number of dementia assessments performed in each unit[51]. DanDem's SG recommends identifying possible bottlenecks and capacity challenges in outpatient services, including access to additional examinations and neuropsychologists [97].

DanDem: für ~25 % der Pat. ist Zeitpunkt der Diagnose = Zeitpunkt des Erstgesprächs

SG zweifelt ob Pat. leitliniengerecht untersucht werden

QI5: In 2021, the time point of diagnosis (1st report) coincided with the date of the diagnostic interview, i.e. start of the investigation, for at least 25% of the patients on a national level in DanDem [97]. The median time from the beginning of the investigation to the time point of diagnosis was 49 days. Some SCs/MCs have a median time of 0 days, i.e. at least 50% of patients receive a diagnosis – and according to the SG, too many receive a disease-specific dementia diagnosis at the first visit. Based on the data, the SG raises some doubts about whether patients are adequately examined according to guidelines, as a rapid assessment cannot be necessarily equated with good quality. DanDem's SG encourages SCs/MCs with short assessment times to comment on this in the annual report consultation response. A very long investigation time can partly be an expression of a long wait for the use of additional examination tools. Also, for QI5, the SG encourages units with very long waiting times to look at whether areas for action can be identified by

- Optimisation of workflows and identification of bottlenecks
- Capacity challenges in the outpatient unit with regard to the staff who have to discharge the patient

DanDem ohne Zielwert

NorKog mit Zielwert aber ohne Ergebnis

DanDem has no set standard for QI5, but the improvement direction is downwards [97]. NorKog does not report a value QI5 for 2021. Still, the target is that within 60 days, 80% of the registered patients should have a definite diagnosis. In NorKog, the patient should receive feedback on the diagnosis as quickly and precisely as possible after completing the examination so treatment and support measures can be planned [99].

[50] 2021, like 2020, has been characterised by COVID-19, which has at times meant cancellations of planned activities in most places, partly due to COVID preparedness, but the SG noted that cancellations have been caught up.

[51] Results from SCs/MCs with small patient numbers should be interpreted with caution, as a single or few patients can have a large impact on the units.

4.3.2 Diagnosis and diagnostic workup

Basic dementia assessment and workup

Abklärungsgespräch & Basisuntersuchung

The following QI captures information on how many registered patients completed a particular set of basic dementia workup procedures. This indicator is used in two of the six registries (NDRI, SveDem). QI6 is only fulfilled in both registries if all defined workup procedures are completed.

Vignette: Basic dementia assessment and workup
QI6. Proportion of patients undergoing basic dementia workup and assessment (NDRI [32], SveDem [30, 102])
Conducted tests and procedures during the basic dementia workup: ■ Blood tests (ADNeT[52], NDRI, SveDem) ■ Cognitive tests: MMSE [83] and MoCA [85] (NDRI, SveDem) ■ Comprehensive neuropsychological evaluation (NDRI) ■ Neuroimaging testing (e.g. computer tomography (CT)/magnetic resonance (MR) scan/MR scan dementia protocol) (NDRI, SveDem) ■ Bio-markers (NDRI) ■ Functional evaluation (instrumental activities of daily living – IADL) (NDRI) ■ Clock-drawing test (SveDem) ■ Other tests: CDRS (NDRI)

SveDem: 81 % der registrierten Pat. mit kompletter Basisuntersuchung in der Primärversorgung & 96 % in der Sekundärversorgung

QI6: In Sweden, 81% of patients registered in PCUs participating in SveDem completed the full basic dementia workup and assessment in 2020. SveDem's target value (≥90%) was not achieved in primary care. In turn, the target value was achieved in specialist care (96%). There are considerable differences in the number of patients diagnosed in specialist and primary care between counties. According to SveDem's SG, CT/MR is performed significantly less in PCUs than SCs/MCs. Still, PCUs increased the proportion of completed basic dementia workups by almost 40% points from 2011 to 2020 (2011: 46%, 2020: 81%) [102].

Cognitive assessment

Anteil Pat. mit durchgeführten kognitiven Tests (MMSE & MoCA)

The following QIs capture the proportion of registered patients assessed with a cognitive test or other cognitive assessment-related tasks. MMSE and MoCA are used in the basic workup of SveDem and NDRI. Still, they are not listed in the following vignette, as both registries and aspects have already been described in the previous vignette.

kognitive Tests sind essentiell

Cognitive testing is essential to the diagnosis process and must be tailored to the client's needs. MMSE [83] and MoCA [85] are typically used to assess cognitive status. Still, for some patients, an MMSE or MoCA test will not be sufficient to determine whether they have mild dementia or MCI or are cognitively intact.

[52] In ADNeT, blood tests as part of the diagnostic workup are independently mapped in QI17. 'Proportion of patients who undertook core blood tests as part of the diagnostic workup'.

Vignette: Cognitive assessment
QI7. Proportion of patients who had an assessment of multiple cognitive domains (cognitive test) as part of the diagnostic workup[53] (ADNeT [95, 96], DanDem [97, 98])
QI8. Proportion of patients who had an extended cognitive test (DanDem[45] [97, 98], NorKog [99, 100])
QI9. Proportion of patients whose cognition was re-assessed within 18 months of an MCI diagnosis (ADNeT [95, 96])

■ Cognitive testing is essential for investigating suspected dementia and a prerequisite for assessing cognitive function (ADNeT, DanDem, NorKog; QI7, QI8).
■ Cognitive testing must be tailored to the client's cultural and educational backgrounds and presenting symptoms (ADNeT; QI7).
■ Recommended tests:
  ■ MMSE [83] (ADNeT, DanDem, NorKog; QI7, QI8)
  ■ MoCA [85] (ADNeT, NorKog; QI7, QI8)
■ For some patients, an MMSE or MoCA test will not be sufficient to determine whether they have mild dementia or MCI or are cognitively intact. These patients will be assessed by Addenbrooke's cognitive examination (ACE) [106], Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAScog) [107], Cambridge cognition examination (CAMcog) [108] or neuropsychology tests (DanDem, NorKog; QI7, QI8).
■ Other assessment tools: KICA [73], RUDAS [84] (ADNeT; QI7)
■ SC/MCs should follow up with all clients with a diagnosis of MCI at least once every 12-18 months based on the clinical judgement and on the client's need for review (ADNeT; QI9).

Anteil Pat. mit kognitiven Test:

99 % in DanDem & ADNeT

QI7: Concerning the proportion of patients who have undergone a cognitive test in Denmark, the target value (>90%) was reached in 2021 at a national level (99%). Although ADNeT does not have a target value, it achieved a similar result (99%) to DanDem in 2021 [95]. All Danish regions and almost all SCs/MCs (except two of 37) met the target value. The region-level trend graph showed that indicator compliance has been high since the database's inception in 2016, but that region results have gradually improved and become more consistent over the life of the database [97].

Anteil Pat. mit erweitertem kognitiven Test:

94 % in DanDem

Norkog ohne Ergebnisse aber Zielwert von ≥95 %

QI8: In Denmark, the proportion of patients registered in DanDem who had an extended cognitive assessment was 94% in 2021. The target value of >80% was achieved at national and regional levels. Three SCs/MCs participating in DanDem did not meet the target value. The variation between regions (88% to 98%) and SCs/MCs is wide due to capacity challenges and/or the impossibility of conducting neuropsychological examinations in all SCs/MCs. DanDem's SG considers this to be worrying for patients who are told they do not have dementia and for patients who have MCI or mild dementia based only on basic cognitive tests. The considerable variation between clinical sites means some patients did not receive the recommended or adequate follow-up treatment. The SG questions whether it is feasible to have an SC/MC for dementia without access to neuropsychological testing. The causes of capacity challenges or implementation problems should be investigated [97]. NorKog has defined a target value (≥95%), but QI8 was not evaluated or reported in the 2021 report. Comparisons over time were also not available for both QRs.

ADNeT: 88 % der reg. Pat. mit milden kognitiven Einschränkungen nach 18 Monaten erneut getestet

QI9: In ADNeT, ~88% of registered patients with an initial MCI diagnosis were re-assessed within 18 months in 2021. As there is no defined target value and no data from previous years, no comparison can be made. Still, ADNeT's SG recommends a re-assessment for a potential dementia diagnosis at least once every 12-18 months based on the clinical judgement and the client's need for review [95].

[53] The indicators with different formulations are combined under one formulation in the vignettes. For the exact wording of each indicator, see Table 4-4-Table 4-8 "Quality indicators".

Neuropsychiatric assessment

neuropsychiatrische Tests

The following QIs capture the proportion of registered patients assessed with neuropsychiatric tests. Neuropsychiatric symptoms in dementia patients include anxiety, depression, hallucinations, restlessness, or delusions.

Vignette: Neuropsychiatric assessment
QI10. Proportion of patients where information is collected about neuropsychiatric symptoms via NPI (NorKog [99, 100])
QI11. Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores over time (BPSDR [30, 103, 104])
■ Common neuropsychiatric symptoms of cognitive impairment, such as anxiety, depression, hallucinations, restlessness, and delusions, should be assessed and mapped via NPI [109] (NorKog; QI10).
■ Structured monitoring and evaluation of BPSD via NPI-NH [87] should be provided to patients at least annually as it positively influences key outcome measures such as BPSD, functionality, and QoL. It also contributes to a reduction in the need for care by the person with dementia, reduced perceived burden and less depression and anxiety or worry for carers (BPSDR; QI11).

NorKog: Anteil Pat. mit neuropsychiatrischem Test ~87 %

Zielwert ≥80 %

QI10: In NorKog, at the national level, the proportion of patients for whom information was collected about neuropsychiatric symptoms for the year 2021 was 87%. NorKog achieved the target level of ≥80%. The QI10 score varied between 81% (Helse Nord) and 89% (Helse Midt-Norge) at the regional level and between 46% and 100% at the SC/MC level, which means that in some SC/MCs only every second registered patient was screened for neuropsychiatric symptoms. Seven of the 45 clinics did not reach the target value of ≥80%. Between 2020 and 2022, NorKog carried out a quality improvement project. The aim was to increase the use of the NPI [109] due to the variation in results in 2019.

BPSDR: kein Zielwert bei neuropsychiatrischem Test-Score

fallende Tendenz des Scores für schwerwiegende BPSD-Fälle (Verbesserung der Lebensqualität)

QI11: BPSDR has no target value for QI11 (NPI-NH scores over time). The mean NPI-NH [87] score, considering all patients, decreased to 20.15 points in 2020 compared to the years 2019 (20.74) and 2017 (21.11). In 2022, the mean NPI-NH score increased to 20.5 compared to 2020, which is an increase of about 0.4 points. The mean NPI-NH scores in 2022 for people with low, medium and severe BPSD[54] for the first three registrations[55], considering the last four years, were 74.5, 49.5, 43.1 for patients with low BPSD, 37.8, 31.4, 29.5 for patients with medium BPSD, and 8.8. 13.5, 15.1 for people with severe BPSD. For previous years, no data were reported in the 2020 annual report for QI11 [103]. Regardless of the year, individuals with a high prevalence and severity of BPSD with at least three registrations scored an average of 74 on the NPI scale at the first registration. This value dropped to 46 at the third registration. Regardless of the year, individuals with no or low prevalence of BPSD with at least three registrations had an average score of 11 at the first registration, which increased to 16 at the third registration. BPSDR's SG expected this development: as dementia progresses, the risk of BPSD increases. Overall, the mean NPI-NH score for people with severe BPSD decreased between 2016 and 2020, meaning an increased QoL for the average patient [103].

[54] Low or no BPSD (NPI-NH score <30), medium BPSD (NPI-NH score 30-60), high/severe BPSD (NPI-NH score >60)

[55] The NPI is continuously applied on BPSD patients dependent on their individual need. The BPSD registry recommends every 4-6 weeks after first registration and the National Board of Health and Welfare requires follow up at least once every year.

Imaging

bildgebende Verfahren

The following QIs capture the proportion of patients referred for investigation of dementia who have had a computer tomography/magnetic resonance (CT/MR) scan. Structural imaging is deemed an important and basic element in assessing dementia by three QRs (ADNeT, DanDem, NorKog) to rule out other causes of cognitive symptoms than dementia. However, for some patient groups, a scan will not be practical (e.g. patients with Down's syndrome or severe behavioural disorders)

Vignette: Imaging
QI12. Proportion of patients who have had a CT/MR scan of the brain (ADNeT [95, 96], DanDem[47] [97, 98], NorKog [99, 100])
QI13. Proportion of patients with mild to moderate vascular dementia and MDD who have had an MR scan of the brain in the last 24 months (DanDem[45] [97, 98])
■ Structural imaging is an important and basic element in assessing dementia to rule out causes of cognitive symptoms other than dementia (ADNeT, DanDem, NorKog; QI12).
■ Structural neuroimaging is completed ideally within three months or within a maximum of 12 months prior to referral or at the time of the diagnosis (ADNeT; QI12)
■ For some patients with severe dementia, AD with Down's syndrome or patients with severe behavioural disorders, it will sometimes not be practical to carry out a scan. (DanDem; QI13)
■ Conduct an MR scan if a vascular contribution to cognitive complaints is suspected in patients with mild to moderate dementia and MDD to increase the quality of the evaluation (NorKog; QI12).

Anteil Pat. mit bildgebenden Verfahren: >90 % in ADNeT & DanDem

DanDem hat Zielwert (>80 %) erreicht

QI12: In ADNeT and DanDem [95, 97], the proportion of patients who have had a CT/MR scan of the brain in the course of the diagnosis pathway was over 90% (ADNeT: ~93%, DanDem: 98%). DanDem complied with the set target value (>80%) nationally in 2021. ADNeT has no defined target value for QI12. For NorKog, no data on QI12 were reported in the annual report, but NorKog defined a target value (≥90%) [99]. In Denmark, all five regions and all units with more than ten patients also met the target value. The trend shows that all regions have been consistent in the indicator performance, meeting the target value over the lifetime of the database.

Anteil Pat. mit Bildgebung bei vaskulärer Demenz innerhalb letzter 24 Monate (DanDem): 51 %

Zielwert nicht erreicht

QI13: 51% of registered patients with mild to moderate vascular dementia had an MR scan of the brain in the last 24 months in DanDem. The defined target value of >80% was not achieved. In addition, none of the regions reached the target value, and only four participating SCs/MCs in the regions met the target value (in 2020: no SC/MC met the target value). DanDem's SG infers that examination units are recommended to conduct audits reviewing relevant patients who have not had an MR scan. There may be patients who have not had a scan because of claustrophobia, metal in the body or who refused the examination to be carried out [97].

Functionality and activities of daily living

Erhebung Funktionsfähigkeit & Aktivitäten des täglichen Lebens

The following QIs capture the proportion of all patients whose functionality and ADL were examined during the diagnostic workup. The assessment of a person's ability to undertake personal and instrumental ADL is strongly recommended by four registries (ADNeT, DanDem, NorKog, SveDem) as part of the diagnostic process to establish a definite dementia diagnosis and to initiate adequate follow-up. Different assessment tools to assess functionality and activities of daily living are used, such as FAQ-IADL [86], Disability Assessment for Dementia (DAD) [110], or Alzheimer's Disease Cooperative Study ADL Scale (ADCS-ADL) [111] or the DSQIID/Trindvold functional test [112].

Vignette: Functionality and activities of daily living
QI14. Proportion of patients who had an assessment of the functionality in daily life and activities of daily life[53] (ADNeT [95, 96], DanDem [97, 98], NorKog [99, 100], SveDem [30, 102])
QI15. Proportion of patients whose health requirements for driving licenses have been assessed (NDRI[46] [32], NorKog [99, 100])
■ Assessment of a person's ability to undertake personal and IADL is strongly recommended as part of the diagnostic process to establish a definite dementia diagnosis (ADNeT, DanDem, NorKog, SveDem; QI14)
■ FAQ-IADL [86], Disability Assessment for Dementia (DAD) [110], or Alzheimer's Disease Cooperative Study ADL Scale (ADCS-ADL) [111] or the DSQIID/Trindvold functional test [112] (DanDem; QI14)
■ In some circumstances, such as mild functional impairment and good cognitive test scores (or when reliable information on a patient's IADL is not available), an occupational therapist with expertise in dementia is consulted to conduct a standardised performance-based assessment (ADNeT; QI14)
■ When the occupational therapist enters the basic dementia assessment after the first meetings, there is already a lot of anamnestic information, as well as the family interview, to be taken into account in the medical record (SveDem; QI14).
■ Cognitive impairment can affect health requirements for driving. Driving can be considered part of QoL. It is recommended that driving ability should be tracked (NDRI, NorKog; QI15).

QI14: Three of four registries using the indicator 'Proportion of patients for whom functionality in daily life and ADL are assessed' have a target value (DanDem: >80%, NorKog: 100%, SveDem: ≥90%). In ADNeT, ~98% of registered patients received an assessment of functionality in daily life and ADL [95]. In DanDem, the actual value for QI14 was comparable (94%) [97]. While DanDem has reached the target value, ADNeT has no set target value. For NorKog, no actual value was reported [99]. In DanDem [97], all regions have improved since the start of the database in 2016. All regions met the target value over the past three years. Only three of 37 SCs/MCs with relatively few patients did not meet the target value. In SveDem the collection of this QI started in 2021 and was not reported until now.

Anteil Pat. mit Erhebung Funktionalität: ADNeT 98 % & DanDem 94 %

kein Wert für NorKog & SveDem

QI15: Results for the indicator 'Proportion of patients whose health conditions for a driving licence were checked' were not reported by NorKog in the annual report [99]. The target value is 100%.

NorKog: kein Wert für Anteil der Pat. mit Gesundheitstest Führerschein

Specific dementia diagnosis

The following QI captures the proportion of patients who received an aetiological diagnosis. Three registries (DanDem, NDRI, NorKog) recommend monitoring this indicator as a specific diagnosis is vital for adequate follow-up treatment and care.

ätiologische Diagnose

Vignette: Specific diagnosis
QI16. Proportion of patients with a specific diagnosis of dementia (aetiological diagnosis) (DanDem [97, 98], NDRI [32], NorKog [99, 100])
■ A higher proportion of receiving a disease-specific dementia diagnosis is recommended, but fulfilment does not provide information on the quality of the examination that has taken place (e.g. diagnostic criteria or adequate additional diagnostic instruments) (DanDem, NDRI, NorKog; QI16)
■ A specific dementia diagnosis is important to be able to offer the right treatment and follow-up (NorKog; QI16).

QI16: The proportion of patients with an aetiological diagnosis of dementia was 84% in NorKog [99] and 93% in DanDem [97]. Both QRs exceeded the target value of >80% by 4% points (NorKog) and 13% points (DanDem). The target value in DanDem has been met on a national, regional, and almost clinical level (except for four SCs/MCs) since the database started in 2016. In NorKog, the variation of the indicator at the clinical level was between

Anteil Pat. mit ätiologischer Diagnose: NorKog 84 % & DanDem 93 %

Zielwerte erreicht

60% and 100% (nine of 45 clinics did not reach the target value), and the range across the four health regions goes from 80% (Helse Sør-Øst) to ~89% (Helse Midt-Norge).

krankheitsspezifische Demenzdiagnose muss auf angemessener Grundlage gemacht werden

Compared to 2020, the value of QI16 in NorKog decreased by about 2% points from 86% at the national level. DanDem's SG is concerned about whether disease-specific dementia diagnosis is made on an adequate basis and whether there is a uniform offer for dementia assessment regardless of where one lives. The SG recommended that SCs/MCs with either high shares of patients with unspecified dementia diagnoses or high percentages of patients with specific dementia diagnoses should review patients and clarify the basis of the dementia diagnosis.

Other assessment tests and diagnosis-related quality indicators

weitere Diagnose-QI & QI zu durchgeführten Tests

The following QIs capture information about patients with tests and evaluations other than those listed above. These include indicators related to blood tests (QI17), PET scans, lumbar puncture (AD biomarkers) (QI18), tests for depressive symptoms (QI19), gathering information from relatives or caregivers (QI20), or assessment of somatic symptom disorders (QI21).

Vignette: Other assessment tests and diagnosis-related quality indicators
QI17. Proportion of patients who undertook core blood tests as part of the diagnostic workup (ADNeT [95, 96]
■ Core blood tests are undertaken ideally within three months or within a maximum of 12 months prior to referral or at the time of the diagnosis. (ADNeT; QI17)

ADNeT: 99 % der reg. Pat. mit Blutbild im Zuge der diagnostischen Abklärung

QI17: In ADNeT, ~99% of registered patients undertook a core blood test as part of the diagnostic workup in 2021 [95]. As there is no defined target value and no data from previous years, no comparison can be made. Still, core blood tests should be undertaken ideally within three months or a maximum of 12 months before referral or at the time of the diagnosis [95].

Vignette: Other assessment tests and diagnosis-related quality indicators
QI18. Proportion of patients with AD and mild dementia who have had a lumbar puncture in the diagnostic workup or PET scan within 24 months before the date of referral (Alzheimer's biomarker) (DanDem [97, 98])
■ For mild to moderate dementia cases, additional diagnostic approaches are potentially needed in the form of targeted and individualised utilisation of Alzheimer's biomarkers according to guidelines to complement results of QI16 (fulfilment of the target value does not provide information on the quality of the assessment) (DanDem; QI18)

DanDem: Anteil Pat. mit PET-Scan innerhalb 24 Monate ~57 %

QI18: In DanDem, the proportion of patients with AD and mild dementia who have had a lumbar puncture in the diagnostic workup or a PET scan within 24 months before the date of referral (Alzheimer's biomarker) in the year 2021 undercut the target value of >80% by 23% points [97].

Anteil variiert zwischen den dänischen Regionen & sollte überprüft werden

The proportion varied widely between regions (36-74%) and SCs/MCs. The SG observed a correlation between short investigation time (QI5), high degree of specific diagnosis (QI16) and low use of lumbar puncture and/or PET scans (QI18). The SG recommends internal audits:

- For SCs/MCs where the proportion of patients with mild to moderate dementia who receive additional investigations beyond the basic investigation is low to clarify whether patients are sufficiently investigated for disease-specific dementia

- For SCs/MCs with low use of further investigations to determine whether it is a capacity challenge
- For SCs/MCs with a high proportion of non-specific dementia diagnoses, investigate whether additional investigations could have been performed to get closer to a disease-specific dementia diagnosis.

The SG considers that QI18, which in 2021 is a newly calculated indicator, should be further analysed. Continuous re-assessment of the indicator's use to prove whether it is optimal is deemed essential by DanDem's SG [97].

Vignette: Other assessment tests and diagnosis-related quality indicators
QI19. Proportion of patients assessed for depressive symptoms (NorKog [99, 100])
■ Surveying depressive symptoms is important to distinguish between depression and dementia. Two depression-specific mapping tools are used in NorKog: the Montgomery and Åsberg Depression Rating Scale (MADRS) [113] and the Cornell Scale for Depression in Dementia (CSDD) [114] (NorKog; QI19)

QI19: In NorKog, at a national level, the proportion of patients assessed for depressive symptoms was 74% in 2021, against 80% in 2020, with a wide variation on a clinical level from 5% to 100%. Nine of 45 clinics did not reach the target value of ≥70%. The range across the four health regions goes from 52% (Helse Vest) to 86% (Helse Midt-Norge). NorKog's SG states that QI19 will be prioritised for the quality improvement project in 2022-2023 due to the observed variations [99].

NorKog: Anteil Pat. getestet auf depressive Symptome ~74 %; QI hat Priorität im nächsten Berichtsjahr

Vignette: Other assessment tests and diagnosis-related quality indicators
QI20. Proportion of patients from whom information was collected from relatives (NorKog [99, 100])
■ Information from a relative is central to getting a picture of symptoms at the onset of dementia, development, challenges, functionality in daily life and safety (NorKog; QI20)

QI20: NorKog's target value for the indicator 'Proportion of patients from whom information was collected from relatives' is ≥95%. As there is no actual value and no data from previous years available, no comparisons can be made [99].

NorKog: Familieninformationen erhoben ~95 %

Vignette: Other assessment tests and diagnosis-related quality indicators
QI21. Proportion of patients who had an assessment for a somatic symptom disorder (NorKog [99, 100])
■ A somatic examination should be carried out to rule out other conditions that can cause cognitive impairment. It can increase the precision of aetiological dementia diagnosis. (NorKog; QI21)

QI21: 'Proportion of patients who had an assessment for a somatic symptom disorder in NorKog defined a target value (100%), but no actual value and no data from previous years are also available [99].

Zielwert Anteil Pat. somatoforme Störung: 100 %

4.3.3 Treatment, support, and follow-up

Pharmacological treatment (dementia medication)

Einsatz von Demenzmedikamenten

The following QIs capture information about patients who receive dementia medication. The underlying foundations recommend that appropriate dementia medication is offered to the target group (DanDem, NDRI, SveDem, BPSDR). Treatment with anti-dementia medication should be initiated as early in the course of the disease as possible (SveDem, BPSDR). However, some patients with relevant diagnoses are likely to have contraindications to dementia medication.

Vignette: Pharmacological treatment (dementia medication)

QI22. Proportion of patients with a diagnosis of mild to moderate Alzheimer's disease and either a prescription/recommendation of or treatment with dementia medication[53] (ADNeT [95, 96], DanDem [97, 98], NDRI[46], SveDem [30, 102], BPSDR [30, 103])

QI23. Proportion of patients with a prescription for dementia medication who have filled a prescription up to three months after the diagnosis interview (DanDem[45] [97, 98])

- It is recommended that the target group (patients with AD, PDD, DLB, and mixed dementia) is offered relevant dementia medication, but some patients with relevant diagnoses are likely to have contraindications to dementia medication (DanDem, NDRI, SveDem, BPSDR; QI22)
- Treatment with anti-dementia medication should be initiated as early in the course of the disease as possible (prescription at the time of the patient's diagnosis) (SveDem, BPSDR; QI22).
- Acetylcholinesterase inhibitors are indicated for cognitive enhancement in people with mild to moderate AD (in SE also AD with vascular features) but are not recommended solely for treating non-cognitive symptoms in a person with AD (NDRI, SveDem; QI22).
- Rivastigmine or donepezil may be considered for non-cognitive symptoms causing severe distress when non-pharmacological interventions have proved ineffective (NDRI; QI22).
- People with vascular dementia or frontotemporal dementia who develop non-cognitive symptoms should not be prescribed acetylcholinesterase inhibitors (NDRI; QI22).
- Memantine is indicated as a cognitive enhancer in people with moderate to severe ADD (in IE also PDD and DLB), but it is not recommended to be prescribed solely for the treatment of non-cognitive symptoms in a person with dementia (NDRI, SveDem; QI22).
- Combination treatment with memantine and ChEIs in moderate to severe Alzheimer's disease patients (SveDem; QI22)

Zielwert von Anteil Pat. mit Demenzmedikation wurde in DanDem & SveDem (teilweise) erreicht

QI22: Three of the five registries (DanDem, SveDem, BPSDR) have a target value for QI22. 'Proportion of patients who are treated with anti-dementia medication'. DanDem's target value for QI22 is >80% [97], SveDem's target values are ≥75% for the primary care setting and ≥80% for specialist care setting (SCs/MCs) [102], and BPSDR's target value is >75% [103]. DanDem (95%) and SveDem for SCs/MCs (83%) exceeded their target values in 2021 and 2020 respectively. This is not the case for SveDem's primary care setting (72%) and for BPSDR (57.2%), as indicated in the 2020 reports. By comparison, in 2022, 60.8% of people registered in the BPSD registry were treated with medicines for dementia. ADNeT [95] and DanDem [97] do not apply target values for QI22. The actual values reported in the 2021 reports were 75.3% (ADNeT) and 58.5% (DanDem). In Denmark, all five regions and all SCs/MCs except one met the target value. All regions have been well above the target value throughout the lifetime of the database, with a general upward trend since the start.

SveDem: Verschreibung von ChEI konstant in letzten 10 Jahren, aber ungleich verteilt in den Regionen

SveDem's SG stated that the prescription of ChEIs has remained constant over the last ten years. The prescription of memantine has more than tripled in that time. More than one in ten patients treated received combination therapy, according to data from the Swedish Medical Products Registry. However, the SG observed a sizeable regional variation (PCUs: 55%-100%, SCs/MCs: 72%-100%). The National Board of Health and Welfare raised the is-

sue of more equitable pharmacotherapy as a priority area for improvement since patients with low levels of education and those born outside the Nordic counties still receive treatment to a lesser extent [102].

93 % der Pat. lösten ihr verschriebenes Rezept bis zu 3 Monate nach dem Diagnosegespräch ein

QI23: In DanDem, 93% of registered patients with a prescription for dementia medication filled their prescriptions up to three months after the diagnosis interview. This value is 13% points more than the minimum target value of 80%. All five regions (91-96%) and almost all SCs/MCs except three of 37 met the target value. The SG recommended that SCs/MCs with low compliance rates should review their own data to identify if there are reasons for non-compliance, e.g. the procedure for writing and filling prescriptions or follow-up after prescribed treatment [97].

Pharmacological treatment with other medication

weitere medikamentöse Behandlungen

The following QIs capture information about patients who receive other medications, such as antipsychotic drugs. All medication-related indicators are formulated against the background that it is important to continuously develop knowledge for dementia patients' medication treatment to avoid unnecessary medication and side effects. BPSD should be prevented and treated primarily through person-centred care and other non-pharmacological interventions, and individual antipsychotic medication should be based on the person's risks and symptoms (NDRI, SveDem, BPSDR).

Vignette: Pharmacological treatment (other medication such as anti-psychotic drugs etc.)
QI24. Proportion of patients treated with anti-psychotic drugs (NDRI [32], SveDem [30, 102])
QI25. Proportion of people treated with either haloperidol, risperidone, zopiclone, hydroxyzine, oxazepam, or paracetamol and average daily dose per patient per year (BPSDR [30, 103])
■ It is important to continuously develop knowledge for treating people with medication in order to avoid unnecessary medication and side effects (NDRI, SveDem, BPSDR; QI24, QI25).
■ Anti-psychotic medications should be used with caution (as low as possible) given the severe associated adverse events and should not be the first line of treatment in non-cognitive symptoms (NDRI, SveDem; QI24).
■ BPSD should primarily be prevented and treated with person-centred care, and other non-pharmacological measures and individual anti-psychotic medication should be based on the particular person's risks and her/his symptoms (i.e. aggression, severe agitation, and psychosis) via a targeted approach NDRI, SveDem, BPSDR; QI24).
■ The effects of the medication on symptom improvement or worsening should be regularly reviewed, monitored, and recorded. The antipsychotic medication should be stopped if symptoms do not improve after a reasonable period (NDRI, SveDem, BPSDR; QI24).
■ BPSD can vary and be triggered by different factors. Besides unmet needs, communication problems, the patient's difficulties interpreting or orienting in the environment, and brain damage, a common underlying cause of BPSD can be a too-high drug dose or inappropriate medication. Reasonable monitoring of medication use is required (e.g. monitoring is a prerequisite for the use of clometiazole) (BPSDR; QI25)

Zielwert Einsatz von Neuroleptika wurde teilweise erreicht

QI24: The proportion of patients treated with antipsychotic drugs in SveDem amounts to 15% in the special housing setting (SABÖ) and 4.5% in the ordinary housing setting and own housing, respectively. The target value of ≤10% in the special housing setting was not undercut, whereas the proportion for the ordinary housing and own housing, setting fell below the target value of ≤5% [102]. There was an increase in the value of QI24 by about 1% point in 2020 compared to 2019 and 2016 (both 14%) in the special housing setting. For the ordinary housing and own housing setting, there was a decrease in the value of QI24 by about 1.5% point in 2020 compared to 2009.

Einsatz von Neuroleptika in Spezial-Wohnheimen höher als in normalen Pflegewohnheimen

SveDem's SG stated that patients with BPSD symptoms registered in SveDem are rare as most people in SveDem are in a relatively early stage of dementia at baseline registration. Treatment with medication for BPSD is, therefore, higher in special housing than in ordinary housing and own housing, as people living in special housing are usually further along in their dementia and disease development.

Aussage über Zielwerterreichung in BPSDR nicht möglich

QI25: In BPSDR, which explicitly covers BPSD patients, including patients at a later stage, the proportion of patients treated with anti-psychotic medication is reflected in the QI25. In 2022, 2.7% (2018) and 21.4% of patients registered in BPSDR were treated with haloperidol and risperidone, compared to 2.7% and 19.7% in 2018. As there is no target value for the QI25 in the BPSDR, no statement can be made about target achievement.

SveDem: vergleichbar geringer Gebrauch von Neuroleptika

Overall, SveDem's SG commented that there was low use of anti-psychotics at baseline (3.3%), which increased to 5.9% at the four-year follow-up. This increase likely reflects the transition to a more advanced dementia phase with BPSD. Nevertheless, international comparisons show that treatment with antipsychotic drugs occurs much less in Sweden, according to the SG [102].

BPSDR beobachtet Medikation von 6 Medikamenten

BPSDR also monitors the proportion of patients consuming medicines other than either haloperidol or risperidone. QI25 is monitored for the following medicines:

- Haloperidol: 2.7% (2018), 2.4% (2022)
- Risperidone: 19.7% (2018), 21.4% (2022)
- Zopiclone: 21.1% (2018), 20.2% (2022)
- Hydroxyzine: 1.6% (2018), 0.9% (2022)
- Oxazepam: 32.1% (2018), 32.6% (2022)
- Paracetamol: 70% (2018), 72% (2022)

Verschreibung in BPSDR: Antidepressiva Frauen > Antidepressiva Männer

Neuroleptika Frauen < Neuroleptika Männer

From 2018 to 2022, there was a decrease in the proportion of patients consuming three different medicines (Risperidone, Zopiclone, and Hydroxyzine). BPSDR's SG reported that registered women are more often prescribed antidepressants than men (almost 50% of women), as well as analgesics (paracetamol) and sedatives (Zopiclone, Oxazepam and Hydroxyzine). Men are more often prescribed sleeping pills and antipsychotics than women. The prescription of antipsychotic and sedative medicines to men has declined slightly in recent years [103].

Psychosocial treatment and support

psychosoziale Interventionen & Unterstützungsmaßnahmen

The following QIs capture information about patients who receive psychosocial and/or other support measures in their treatment pathway and follow-up. The underlying recommendations of the indicators stress the fact that a systematic treatment approach includes providing patients with psychosocial services (QI26), consideration of the patient perspective (QI29, QI30, QI31), and offering support that considers other patient-relevant factors (QI32, QI33, QI34). Furthermore, capturing time waiting for support services facilitates the improvement of dementia care quality (QI27, QI28).

Vignette: Psychosocial treatment and support
QI26. Proportion of patients with dementia who have received a psychosocial offer in connection with information about the diagnosis (psychosocial offer) (DanDem [97, 98])
■ A systematic treatment approach, including providing patients with psychosocial services, is deemed essential for both patients and carers/relatives (DanDem; QI26).

QI26: In DanDem, the proportion of patients with dementia who have received a psychosocial offer in connection with information about the diagnosis amounted to 94%, which was about 14% points greater than the target value (>80%). All five regions and all SCs/MCs met the target value, and compliance with the standard has generally been stable and high in recent years on all levels [97].

Anteil Pat. mit psychosozialem Angebot ~94 %

Vignette: Psychosocial treatment and support
QI27. Time waiting for home support services (NDRI[46] [32]) **QI28.** Proportion of patients with dementia who have day-care/home care support (NDRI[46] [32])
■ Capturing data on referral to day-care/home care support, including associated referral and assessment times, facilitates the calculation and tracking of waiting times for each person in the registry (NDRI; QI27, QI28).

QI27, QI28: NA

Vignette: Psychosocial treatment and support
QI29. Proportion of patients whose life story is the basis for the design of care (SveDem [30, 102])
■ A person-centred approach based on a person's life patterns, values and preferences is essential. This means carers need to see the patient's perspective and understand how they experience the world and the specific situation (SveDem; QI29).

QI29: Since 2015, the proportion of patients whose life history is the basis for designing individualised dementia care has increased from 63% (2015) to 72% (2020) in SveDem, not exceeding the target of ≥90%. There is a variation between 44% and 97% by county [102].

Lebensgeschichte als Basis für Pflegeplanung

Vignette: Psychosocial treatment and support
QI30. Proportion of patients with individual environmental adaptations in the dementia care implementation plan (SveDem [30, 102])
■ Individual environmental adaptations based on preferences, habits and routines are needed as they can help to interpret and understand the environment and thus have an impact on the person's well-being (SveDem; QI30)

QI30: The proportion of patients with individual environmental adaptations in the individual implementation plan for dementia care increased from 42% in 2015 to 70% in 2020. The value varies between the counties for 2020 (54-87%). The target values of ≥98% were not achieved [102].

individuelle Anpassungen des Umfelds

Vignette: Psychosocial treatment and support
QI31. Proportion of patients with coping/care strategies described in the individual implementation plan (SveDem [30, 102]) **QI32.** Proportion of patients with access to person-centred activities and (sense) stimulation (SveDem [30, 102])
■ Dementia care must be based on a person-centred approach, and each person must be treated as unique. The implementation plan documents how the person is to be treated to receive support for daily activities and self-determination (SveDem; QI31). ■ Meaningful activities or stimulation, such as physical activities and social interactions for people with dementia, are important. Such activities should be documented in the implementation plan (SveDem; QI32).

Beschreibung Bewältigungs-/ Betreuungsstrategien im Pflegeplan

QI31: The proportion of patients with coping and care strategies described in the individual dementia care implementation plan has increased from 59% (2015) to 83% (2020) in SveDem (only results from the SÄBO module are available). The target value (≥98%) was not reached. Between counties, values of QI31 vary for the year 2020 (58-100%) [102].

Zugang zu personenzentrierten Aktivitäten

QI32: The actual value for SveDem's indicator 'Proportion of patients with access to person-centred activities and (sense) stimulation' remained at a high and relatively constant level from 2015 until 2020 (84%), but between counties, values varied for 2020 (63-100%), and on a national level the target value (≥98%) was not met [102].

Vignette: Psychosocial treatment and support
QI33. Proportion of participating sites initiating support measures (Initiatives to support relatives and patients in connection with the diagnosis of dementia) (SveDem [30, 102])
■ When a person is diagnosed with dementia, family members are also affected, and this can lead to changes in life situations. Family members of younger people with dementia and relatives regardless of age, carers of people with dementia, or people with dementia combined with other linguistic and cultural backgrounds should be offered individually/specially tailored support during the disease process (Example of an affected family group: a child living at home whose parents are diagnosed with dementia at a young age) (SveDem; QI33)

Anteil der teilnehmenden Einrichtungen, die Unterstützungsmaßnahmen einleiten ist sehr hoch in der Sekundärversorgung

QI33: Support measures to support relatives and patients were initiated by 63% of participating PCUs and 89% of SCs/MCs in SveDem. Generally, SCs/MCs initiated more family support measures than sites in the primary care setting. SveDem's SG noted that patients being investigated in an SC/MC have a more complex clinical picture to diagnose, leading to an increased need for family support. The SG further remarked that the frequency of family support was not dependent on the age of the dementia patients in the specialist setting. Still, in the primary care setting, a higher proportion of family members received support when the person with dementia was >65 years old [102].

Vignette: Psychosocial treatment and support
QI34. Purpose and nature of patient activities undertaken and/or measures implemented for patients by health care professionals during the year (percentage of all registrations) (BPSDR [30, 103])
■ It is vital to gain knowledge about how to prevent behavioural and psychological symptoms. This task may include allowing health professionals to reflect on and practice different ways of dealing with their patients. The following type of patient activities undertaken and/or measures implemented for patients by healthcare professionals should be monitored and evaluated during the year (BPSDR; QI34): ■ Basic needs ■ Affirmation/Reassurance ■ Physical activity ■ Improve communication ■ Cognitive support ■ Environmental adaptation ■ Mind stimulation ■ Social activity

BPSDR erhebt Zweck & Art der durchgeführten Patient*innenaktivitäten

QI34: BPSDR also collects and reviews data on the purpose and nature of patient activities undertaken and measures implemented by health care professionals during the year. In QI34, shares of each bundle of measures and activities in all registrations are evaluated [103].

- Basic needs: 9.4% (2018), 10.6% (2020), 11.2% (2022)
- Affirmation/Reassurance: 19.6% (2018), 24.2% (2020), 26.3% (2022)
- Physical activity: 14.6% (2018), 14.5% (2020), 14.3% (2022)
- Improve communication: 4.9% (2018), 4.0% (2020), 4.1% (2022)
- Cognitive support: 3.6% (2018), 4.3% (2020), 4.8% (2022)
- Environmental adaptation: 4.7% (2018), 5.1% (2020), 5.1% (2022)
- Mind stimulation: 21.6% (2018), 19.3% (2020), 17.6% (2022)
- Social activity: 21.5% (2018), 17.9% (2020), 16.6% (2022)

klarer Zweck der ergriffenen Maßnahmen & Aktivitäten

Although social activities and mental stimulation measures decreased to a non-negligible extent from 2018 to 2022, the most common measures and activities were still concerning mental stimulation, social activity and affirmation. BPSDR's SG stated in the annual report that the review predominantly showed a clear purpose for measures and activities taken [103].

Other treatment-, support-, and follow-up-related quality indicators

weitere Behandlungs- & Unterstützungsmaßnahmen

The following QIs capture information about patients who receive further treatment and support services, such as indicators, which capture data on referral and assessment times (QI36) and information on general treatment aspects (QI35) on the treatment path. Registries state that monitoring follow-up-related elements such as the proportion of patients with a regular follow-up (QI38) or referral to health services after diagnosing cognitive impairment or dementia (QI37, QI39) are essential (NDRI, SveDem, NorKog).

Vignette: Other treatment-, support-, and follow-up-related quality indicators
QI35. Proportion of patients who have a standard care plan (NDRI[46] [32]) **QI36.** Time from diagnosis of dementia to permanent residential care (NDRI[46] [32])
■ Capturing data on referral and assessment times facilitates the calculation and tracking of waiting times for each person in the registry (NDRI; QI36).

QI35, QI36: NA

Vignette: Other treatment-, support-, and follow-up-related quality indicators
QI37. Proportion of patients with MCI or dementia who were referred to health services after the assessment (NorKog [99, 100])
■ Follow-up, including referral to health services after diagnosing cognitive impairment or dementia, is recommended (NorKog, QI37).

Überweisungsquote von Pat. mit milden kognitiven Einschränkungen sehr hoch

QI37: In NorKog, 97% of patients with dementia or MCI were referred to follow-up health services after assessment, exceeding the target value (≥90%). The range across the four health regions goes from 95% (Helse Vest/Nord) to 98% (Helse Midt-Nord/Sør-Øst). NorKog records what the SCs/MCs recommended as measures for discharge, but what the patient received from municipal services is not registered. NorKog's SG reported that interconnectivity with data from Norwegian Registry for Primary Health Care (KPR) would be able to shed light on this in the future [99].

Vignette: Other treatment-, support-, and follow-up-related quality indicators
QI38. Proportion of patients with a regular follow-up (SveDem [30, 102])
■ It is recommended to follow up at least once a year to identify changes in the person's needs for action quickly. Regular and structured follow-ups should assess the dementia symptoms, consequences, and the person's medical and social needs. At the same time, these needs must be met. Depending on the person's needs, more frequent follow-ups may be required (SveDem; QI38).

Anteil der Pat. mit regelmäßiger Nachsorge verbesserungswürdig

QI38: Clear results on QI38 were not reported in SveDem's 2020 report, but the defined target value amounts to >90% [102]. Nevertheless, SveDem's SG said that almost half of the patients had been followed up in the first year, while about 19% of those could have been followed up after four years. The SG noted considerable room for improvement, but the follow-up indicator should be interpreted cautiously because:

- There may be persons who have been followed up by a clinical site that is not registered in SveDem.
- Follow-up may have taken place within the time interval and was just not documented.
- Moving to a specialised home may also result in the person's follow-up not being recorded.

Vignette: Other treatment-, support-, and follow-up-related quality indicators
QI39. Proportion of patients for whom a multi-professional team has been deployed (teamwork) (BPSDR [30, 103])
■ The QI shows the proportion of patients cared for by a multi-professional team[49]. The guidelines state that person-centred care also means that care is multi-professional and team-based. In the early stages of dementia, the focus is on medical assessment and diagnosis. However, as dementia progresses, the person's need for care increases and interventions from other (health) professions are often required. Using a multi-professional team contributes to a holistic approach to the care offered and focuses on the person with dementia, not the diagnosis. Multi-professional care can improve the QoL and function of people with dementia and the QoL of their relatives compared to those who have not received the measure (BPSDR; QI39).

Anteil Pat. für die ein multiprofessionelles Team eingesetzt wurde

QI39: The proportion of patients for whom a multi-professional team has been deployed (teamwork) monitored by BPSDR was at 63.5% in 2020. No target value was defined for this indicator. Since 2018, there has been an increase in QI39 from 32.5% to 40.9%. In 2022, the proportion of patients for whom a multi-professional team was used was 63.5%, almost twice as high as in 2018 [102].

4.3.4 Outcome-related quality indicators

ergebnisbezogene Informationen über Pat. & Betreuungsperson (bspw. Lebensqualität)

The following QIs capture outcome-related information about patients and carers, such as QoL of the patient (QI11, QI40, QI41) and carer (QI42), or information on other outcome-related aspects, such as freedom of pain or disease progression (QI43, QI44). Registries using outcome-related quality indicators note that a key priority lies in promoting the importance of PROMs and CROs. The underlying rationale is that the patient's response to questions about perceived health and experience of reduced memory is vital for successful dementia care (QI40, QI41).

Vignette: Cognitive and neuropsychiatric outcomes
QI11. Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores over time (BPSDR [30, 103])
■ See **QI11** for foundations.

See QI10 and QI11 for results.

Vignette: Quality of life of the patient/PROMs/PREMs
QI40. Overall QoL of the patient with dementia (NDRI [32]) **QI41.** Proportion of patients who reported on patient-related outcome measures (NorKog [99, 100])
■ The use of measures such as QoL-AD [115], the Quality of Well-Being Scale (QWB) [116-118], and EuroQol EQ-5D [119] is a key priority in promoting the importance of PROMs (NDRI; QI40). ■ Priority is given to the patient's own response to questions about perceived health, the experience of reduced memory and whether this causes concerns, using the MMSE [83] and the Alzheimer's Disease Five Dimensions (AD-5D) [120] tool (NorKog, QI41). ■ Information from carers/relatives is an essential component. Recommended tools include NPI [109], ADL via the Personal and instrumental activities in daily life (P-ADL and I-ADL) form by Lawton and Brody [121], Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) [122] for changes in cognitive function answered by relatives (NorKog, QI41).

QI40: NA

QI41: The proportion of patients who reported on patient-related outcome measures nationally in NorKog amounted to 91% in 2021 compared to 92% in 2020. The actual value exceeded the target (≥80%) by 11%. The range across the four health regions for 2021 was 86% (Helse Vest) to 92% (Helse Nord). There was a significant variation between the centres (48-100%). Four of the 45 clinics did not reach the target value.

Anteil Pat. mit patient*innenenbezogenen Ergebnismessungen

Vignette: Quality of life of the carer/CROs/CREs
QI42. Overall QoL and well-being of carer (NDRI)
■ The use of measures such as QoL-AD [115], QWB [116-118], and EuroQol EQ-5D [119] is a key priority in promoting the importance of CROs. This QI is the carer equivalent to **QI40** (NDRI; QI42)

QI42: NA

Vignette: Other outcome-related quality indicators
QI43. Dementia syndrome/Disease progression (NDRI[46] [32]) **QI44.** Proportion of patients who were assessed as pain-free and for whom a pain assessment scale was used (BPSDR [30, 103])
■ Currently, very few QRs and SCs/MCs collect data on dementia syndrome/disease progression, and there is no existing standard regarding which measure to use. The NDRI model recommends that SCs/MCs capture this data in the future. (NDRI; QI43) ■ It is essential to gain knowledge about how to prevent BPSD and the underlying causes, such as the patient's pain, to enable proper treatment. Assessing any pain patients may be experiencing is one component. To some extent, interpreting signs of pain in people with dementia is the task of carers. Rating scales should be used to clarify the assessment and evaluate the effects of interventions because pain assessment is complex (BPSDR; QI44).

QI43: NA

QI44: The value of QI44 in BPSDR amounted to 72% in 2022. No target value for QI44 exists. No statement on target achievement can be made. However, according to the data, pain was the most common possible cause of BPSD, accompanied by sleep disturbance in 2020 and 2022. BPSDR's SG notes that pain can contribute to sleep disturbance. QI44 has been steadily improving over the last five years. This development is considered a 'very good' result by the SG. In 2020, pain rating scales were reported to have been used in 25% of registrations. No value on pain rating scales for 2022 was available [103].

Anteil Pat. schmerzfrei beurteilt ~72 %

kein Zielwert (jedoch Verbesserung zum Vorjahr)

4.3.5 Meta indicators and other quality indicators

"Metaqualitäts-indikatoren"

The following QIs are meta-indicators of the registries and capture registry-specific information. DanDem is the only QR that uses such indicators.

Meta indicators and other quality indicators
QI45. Coverage (DanDem, [97, 98]) **QI46.** Degree of concordance (DanDem, [97, 98])
■ It is recommended that cases in the QR's database are matched with data from the Danish National Health Registry (LPR[56]) to assure database completeness (DanDem; QI45, QI46). ■ Patients in the indicator population registered in the DanDem with a diagnosis date in the current year are contrasted with all patients registered in the Danish National Health Register (LPR) with procedure code ZZ1500/ZZ1500A (dementia assessment/ examination for dementia) (DanDem; QI45) ■ Patients in the indicator population registered in LPR with procedure code ZZ1500/ZZ1500A (dementia assessment/examination for dementia) in the current year are matched to all patients registered in the DanDem with a diagnosis date in the current year (DanDem; QI46).

Abdeckung & Grad der Konkordanz sehr hoch

QI45, QI46: Although DanDem defined target values for QI45 (Coverage: >90%) and QI46 (Degree of concordance: >90%), results on the coverage and degree of concordance were not available [97].

[56] All Danish in- and out-patients who have had contact with a Danish health care facility are registered in the LPR, the Danish national health register, with basic information, such as diagnostic codes and procedures. Regarding dementia care, all patients that had a dementia assessment (procedure code ZZ1500/ZZ1500A) are registered in the LPR. This number is used in the calculation for database completeness in DanDem.

4.3.6 Overview of the target values and actual values

Table 4-9: Target values and actual values of the quality indicators

Quality indicator	Target values/Actual values						Number of registries
	ADNeT	DanDem	NDRI	NorKog	SveDem	BPSDR	
QI1. Proportion of patients who had the first appointment to referral to an SC/MC <90 days (ADNeT)	NA/59.5%	-	-	-	-	-	1/6 QRs
QI2. Time from referral to first contact (waiting time) (ADNeT[44], DanDem[45])	NA/NA	NA/NA	-	-	-	-	2/6 QRs
QI3. Proportion of patients who have follow-up or referral after the initial assessments (NDRI[46])	-	-	NA/NA	-	-	-	1/6 QRs
QI4. Proportion of patients with a definitive diagnosis of dementia <90 days of first visit or first dementia indications (DanDem)		>80%/42%	-	-	-	-	1/6 QRs
QI5. Time from start of investigation (1st contact) to time point of diagnosis (1st report) (DanDem, NDRI[46], NorKog)	-	NA/49 days	NA/NA	80% within 6 months/NA	-	-	3/6 QRs
QI6. Proportion of patients undergoing basic dementia workup and assessment (NDRI, SveDem)	-	-	NA/NA	-	PCUs: ≥90%/81% SCs/MCs: ≥90%/96%	-	2/6 QRs
QI7. Proportion of patients who had a cognitive test (ADNeT, DanDem)	NA/99.1%	>90%/99%	-	-	-	-	2/6 QRs
QI8. Proportion of patients who had an extended cognitive test (DanDem[45], NorKog)	-	>80%/94%	-	≥95%/NA	-	-	2/6 QRs
QI9. Proportion of patients whose cognition was re-assessed within 18 months of an MCI diagnosis (ADNeT)	NA/88.3%	-	-	-	-	-	1/6 QRs
QI10. Proportion of patients of whom information is collected about neuropsychiatric symptoms (NorKog)	-	-	-	≥80%/87%	-	-	1/6 QRs
QI11. Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores over time (BPSDR)	-	-	-	-	-	NA/20.5[57]	1/6 QRs
QI12. Proportion of patients who have had a CT/MR scan of the brain (ADNeT, DanDem[47], NorKog)	NA/92.6%	>80%/98%		≥90%/NA	-	-	3/6 QRs
QI13. Proportion of patients with mild-moderate vascular dementia who have had an MR scan of the brain in the last 24 months (DanDem[45])	-	>80%/51%	-	-	-	-	1/6 QRs
QI14. Proportion of patients for whom functionality in daily life and activities of daily living are assessed (ADNeT, DanDem, NorKog, SveDem)	NA/97.8%	>80%/94%	-	100%/NA	≥90%/NA	-	4/6 QRs
QI15. Proportion of patients whose health requirements for driving licenses have been assessed (NDRI[46], NorKog)	-	-	NA/NA	100%/NA	-	-	2/6 QRs
QI16. Proportion of patients with a specific diagnosis of dementia (Aetiological diagnosis) (DanDem, NDRI, NorKog)		80%/93%	NA/NA	≥80%/84%	-	-	3/6 QRs
QI17. Proportion of patients who undertook core blood tests as part of the diagnostic workup (ADNeT)	NA/99.1%	-	-	-	-	-	1/6 QRs

[57] Mean NPI-NH score for all registered patients in 2022. Table A-13 in the Appendix provides further results for subgroups such as people with high BPSD with at least three registrations regardless of year.

Quality indicator	Target values/Actual values						Number of registries
	ADNeT	DanDem	NDRI	NorKog	SveDem	BPSDR	
QI18. Proportion of patients with AD and mild dementia who have had a lumbar puncture in the diagnostic workup or PET scan within 24 months before the date of referral (Alzheimer's biomarker) (DanDem)	-	>80%/57%	-	-	-	-	1/6 QRs
QI19. Proportion of patients assessed for depressive symptoms (NorKog)	-	-	-	≥70%/74%	-	-	1/6 QRs
QI20. Proportion of patients from whom information was collected from relatives (NorKog)	-	-	-	≥95%/NA	-	-	1/6 QRs
QI21. Proportion of patients who had an assessment for a somatic symptom disorder (NorKog)	-	-	-	100%/NA	-	-	1/6 QRs
QI22. Proportion of patients who are treated with anti-dementia medication (ADNeT, DanDem, NDRI[46], SveDem, BPSDR)	NA/75.3%[58] NA/58.5%	>80%/95%	NA/NA	-	PCUs: ≥75%/72% SCs/MCs: ≥80%/83%	>75%/60.8%	5/6 QRs
QI23. Proportion of patients with a prescription for dementia medication who have filled a prescription up to three months after the diagnosis interview (DanDem)	-	>80%/93%	-	-	-	-	1/6 QRs
QI24. Proportion of patients treated with anti-psychotic drugs (NDRI, SveDem)	-	-	NA/NA	-	SABÖ[59]: ≤10%/15% Ordinary/Own housing: ≤5%/4.5%[60]	-	2/6 QRs
QI25. Proportion of people treated with either haloperidol, risperidone, zopiclone, hydroxyzine, oxazepam, or paracetamol and average daily dose per patient per year (BPSDR)	-	-	-	-	-	NA/see Table A-13	1/6 QRs
QI26. Proportion of patients with dementia who have received a psychosocial offer in connection with information about the diagnosis (psychosocial offer) (DanDem)	-	>80%/94%	-	-	-	-	1/6 QRs
QI27. Time waiting for home support services (NDRI[46])	-	-	NA/NA	-	-	-	1/6 QRs
QI28. Proportion of patients with dementia who have day-care/home care support (NDRI[46])	-	-	NA/NA	-	-	-	1/6 QRs
QI29. Proportion of patients whose life story is the basis for the design of care (SveDem)	-	-	-	-	≥90%/72%	-	1/6 QRs
QI30. Proportion of patients with individual environmental adaptations in the implementation plan (SveDem)	-	-	-	-	≥98%/72%	-	1/6 QRs
QI31. Proportion of patients with coping/care strategies described in the individual implementation plan (SveDem)	-	-	-	-	≥98%/83%	-	1/6 QRs
QI32. Proportion of patients with access to person-centred activities and (sense) stimulation (SveDem)	-	-	-	-	≥98%/84%	-	1/6 QRs

[58] <85 years and ≥85 years

[59] Municipalities are obliged to provide special forms of housing for services and care for the elderly who need special support that includes dementia [76].

[60] The figures of ordinary/own housing differ depending on where the respective data was checked/registered: PCUs: 6% (not fulfilled) SCs/MCs: 3% (fulfilled).

Quality indicator	Target values/Actual values						Number of registries
	ADNeT	DanDem	NDRI	NorKog	SveDem	BPSDR	
QI33. Proportion of participating sites initiating support measures (Initiatives to support relatives and patients in connection with the diagnosis of dementia) (SveDem)	-	-	-	-	PCUs: ≥95%/63% SCs/MCs: ≥95%/89%	-	1/6 QRs
QI34. Purpose and nature of patient activities undertaken and/or measures implemented for patients by health care professionals during the year (percentage of all registrations) (BPSDR)	-	-	-	-	-	NA/see Table A-13	1/6 QRs
QI35. Proportion of patients who have a standard care plan (NDRI[46])	-	-	NA/NA	-	-	-	1/6 QRs
QI36. Time from diagnosis of dementia to permanent residential care (NDRI[46])	-	-	NA/NA	-	-	-	1/6 QRs
QI37. Proportion of patients with MCI or dementia who were referred to health service after the assessment (NorKog)	-	-	-	≥90%/97%	-	-	1/6 QRs
QI38. Proportion of patients with a regular follow-up (SveDem)	-	-	-	-	>90%/NA	-	1/6 QRs
QI39. Proportion of patients for whom a multi-professional team has been deployed (teamwork) (BPSDR)	-	-	-	-	-	NA/63.5%	1/6 QRs
QI40. Overall QoL of the patient with dementia (NDRI)	-	-	NA/NA	-	-	-	1/6 QRs
QI41. Proportion of patients who reported on patient-related outcome measures (NorKog)	-	-	-	≥80%/91%	-	-	1/6 QRs
QI42. Overall QoL and well-being of carer (NDRI)	-	-	NA/NA	-	-	-	1/6 QRs
QI43. Dementia syndrome/Disease progression (NDRI[46])	-	-	NA/NA	-	-	-	1/6 QRs
QI44. Proportion of patients who were assessed as pain-free and for whom a pain assessment scale was used (BPSDR)	-	-	-	-	-	NA/72%	1/6 QRs
QI45. Coverage (DanDem)	-	>90%/NA	-	-	-	-	1/6 QRs
QI46. Degree of concordance (DanDem)	-	>90%/NA	-	-	-	-	1/6 QRs

fulfilled	
not fulfilled	
no target value defined, no actual value reported, or both	
QI not part of the QR	–

Abbreviations: NA … not available, PCU … primary care unit, QoL … quality of life, SABÖ … special housing setting, SC/MC … specialist clinic/memory clinic

5 Good practice framework: strategies, recommendations, and practicalities

5.1 Phases and domains of a dementia quality registry

Planung, Umsetzung & Betrieb von QR ähnlich zu anderen Pat.-Registern aber auch spezifische Eigenschaften

Although most steps in planning, implementing, and operating a QR registry are similar to steps in other types of registries, they face unique challenges. QRs differ in important aspects of planning, design, reporting, and evaluation [1, 36]. For this reason, the empirical findings from the identified QRs are integrated and discussed within a good practice framework based on the manual 'Registries for Evaluating Patient Outcomes: A User's Guide in the 4th edition by the AHRQ with a particular focus on dementia QRs. In addition, theoretical pillars of good registry practice from the so-called 'registry science' literature are referenced if necessary. The results from the identified QRs and QIs are discussed and contrasted. The following figure (Figure 5-1) gives an overview of the section's structure:

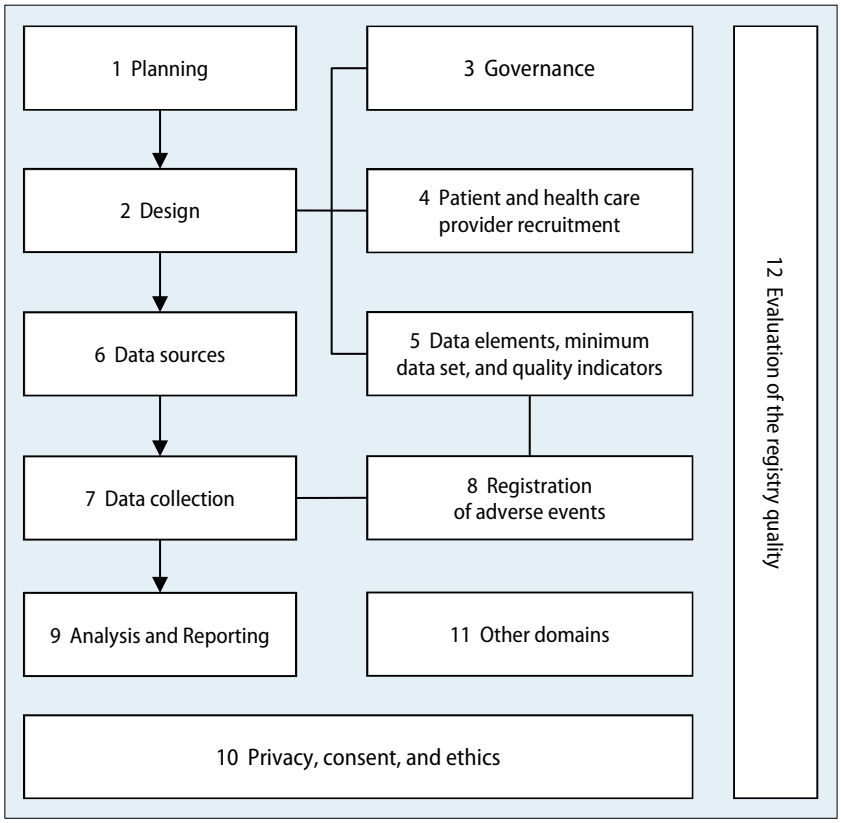

Figure 5-1: Good practice framework and categories by Mathis and Wild [27] and AHRQ [1] (adapted, own depiction)

5.2 Overview of the good practice strategies, recommendations, and practicalities

5.2.1 Planning a dementia quality registry

Planungsphase:

Demenz-QR = richtiges Tool für Ziele? Finanzierung für die ganze Register-Lebensdauer abklären; Governance-Plan ist essentiell

The essential tasks in planning a dementia QR include considering whether a dementia QR is adequate for improving the quality of dementia care in the specific context, identifying key stakeholders, and selecting a registry team based on their expertise and experience. Assessing feasibility, defining the scope and the target population, and securing funding are other substantial pillars in the planning phase. Planning for the entire life span and transitions is also crucial. In addition, a governance plan should be conceptualised that addresses the following issues [1, 36]:

- Overall management, data governance, and operation
- Scientific content
- Ethical principles
- Data security aspects and access rights to data
- Handling of publications
- Change management

The primary purpose of a dementia QR is clear. Nevertheless, secondary goals, such as using data for external research, should be defined in the planning phase.

alle Interessengruppen aktiv einbinden

Special consideration in the planning phase should be given to all stakeholders as it is one of the main pillars for the success of quality improvement in QRs. The engagement of dementia care providers is essential. They should be actively involved. In the QR context, active providers are called 'champions'. A QR is not a simple feedback function. A QR's focus is to change the behaviour of patients and providers or change care practicalities on a broader level [1, 36].

Selected good practice strategies for planning

Check whether a QR is the appropriate methodological tool

QR das geeignete methodische Instrument?

It should be considered to what extent existing dementia and other databases (e.g. electronic patient records, administrative data) and healthcare structures can contribute to the QR (linkage and interoperability) [1]. RCTs or cohort studies can be an alternative to QRs [1, 36].

Define all objectives

alle Ziele des QRs definieren

When planning the registry, all purposes should be clearly formulated by the funding entity in consultation with other members of the governance board [1, 36]. Cameron et al. recommend that objectives should be written into the funding agreement [123].

Clarify the interests of stakeholders

Interessen der Beteiligten klären

The stakeholders determine the benefit or value of the QR through their interests. The stakeholder's intended use of the results should determine the planning of the scope and depth of the QR (patient numbers, care setting, lifespan, level of aggregation) [1, 36].

Adjust the width and depth of included dementia care topics according to the accuracy of the results

Zielgruppe, Setting, Laufzeit, MDS & QI definieren & präzisieren

The scope of the QR should include general topics of dementia care (scope, target population, setting, duration, funding possibilities, and information content of data), the set of dementia-specific core data, the choice of an evidence-based MDS, outcomes, and quality indicators [1, 36]. This scope should not be broader than necessary to achieve a better quality of dementia care.

Funding should take into account all necessary QR phases

Finanzierung für alle QR-Phasen abklären

A major difference between a QR and other registries is the funding scheme. Funding models for QR vary and depend primarily on the aims and the stakeholders involved. Government funds or expenditures by social security institutions can finance a national dementia QR, as is the case for all six identified QRs. A second funding option may be fees paid by participating providers, hospitals, professional associations, societies, the industry, foundations or researchers requesting data access. Some regional or local QRs apply for research grants [36]. Generally, funding should be established for the entire planned QR duration. In many registries, funding is often lacking at the end because the costs for statistical evaluations and reporting are underestimated [1, 36].

Data collection can be linked to the reimbursement of certain services

finanzielle Anreize an Leistungsdokumentation koppeln

A financial incentive linking performance documentation and service can significantly improve the response rate, but it should be evaluated whether this linkage does not provoke the risk of bias [1, 27, 36].

5.2.2 Design of a dementia quality registry

Hauptzweck sollte das QR-Design anleiten

Generally, the primary purpose should always guide the design of a registry [1, 36]. Table 5-1 gives an overview of general key points when designing a patient registry.

Table 5-1: Key points in quality registry design according to Gliklich et al. [1]

Key point	Relevant question
1. Research question/aim:	What are the clinical and/or public health questions of interest?
2. Resources:	What resources, in terms of funding, sites, clinicians, experts, and patients, are available for the study?
3. Exposures and outcomes:	How do the clinical questions of interest translate into measurable exposures and outcomes?
4. Data sources:	Where can the necessary data elements be obtained?
5. Study design:	What types of design can be used to answer the questions or fulfil the purpose?
6. Study population:	What types of patients are needed for study? Is a comparison group needed? How should patients be selected for study?
7. Site and patient recruitment:	How should the study population be recruited, taking into account the target population(s), types of healthcare providers of interest and study design?
8. Study size and duration:	For how long should data be collected, and for how many patients?
9. Internal and external validity:	What are the potential sources of bias, and how much could they distort the study findings (e.g. rate or effect estimates)? What are the concerns about the generalisability of the results (external validity)?

Grundsätze eines wissenschaftlichen Studiendesigns berücksichtigen

Key point 1 is predetermined for a dementia QR. The primary aim is to improve health care service quality and patient outcomes along the whole dementia care pathway. Dementia exposures and outcomes (prevalence, incidence, risk factors etc.) in the specific healthcare system drive the specific dementia patient population selection. Further key points to clarify comprise whether to include a control group, determining where the data will come from (data source), and deciding how many patients are needed for the QR and for how long. The registry population should match the characteristics of a representative dementia target population. The determinants of study size are practicality, cost, and whether the QR is designed to support decision-making and healthcare planning.

QR-Daten = Beobachtungsdaten

QR-"Studiendesign" = Kohortenstudie

The study design (key point 5) does not allow for a degree of freedom in the dementia QR case. In contrast to RCTs, registries have an observational study design. QRs are a special case as they typically use a cohort design[61]. Keeping inclusion and exclusion criteria to a minimum is essential. The intention is to study a broad range of patients and to make the results more generalisable. Patients in the dementia QR context are usually observed in an everyday dementia care setting. The data collected usually reflects measures that health care providers typically use.

Versorgungsdaten außerhalb der teilnehmenden Einrichtungen nicht erfasst

One main limitation of a cohort design is that it may exclude data on dementia care provided outside the participating sites (e.g., private SCs/MCs or NHs not participating in the dementia QR). Underreporting of outcomes if a patient is not adequately followed-up or treated by the respective health care provider (adherence), does not comply with the care plan (compliance), or is leaving the registry can impact results. Furthermore, cohort designs are typically constrained in their statistical power (even when the population size is large).

zuverlässige & gültige Messinstrumente & Ergebnisse

Another key consideration for designing a dementia QR includes translating the purpose and research question into measurable variables and outcomes. This task contains conceptualising reliable and valid dementia QIs and is of utter importance in a QR.

interne und externe Validität überprüfen

Once all key considerations have been made, the QR design should be reviewed to assess potential sources of bias (systematic errors). Potential confounders should be specified and monitored to a reasonable and realisable extent to minimise potential sources of these systematic errors. The information value of a QR is enhanced by its ability to assess the potential for bias, including quantifying how this bias could affect the study results. This observation applies especially in the case of dementia. In addition, internal, external, or historical comparisons with populations with cognitive impairments may help understand whether the observed effects are realistic and differ from the outcome under other conditions [1, 36].

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[61] *'Cohort studies follow over time a group of people who possess a characteristic, to see if individuals in the group develop a particular endpoint or outcome. The cohort design is used for descriptive studies as well as for studies seeking to evaluate comparative effectiveness and/or safety or* ***quality of care****'* [1, p. 66]

Selected good practice strategies for the design

If possible, a dementia QR should be designed by applying principles comparable to principles of a scientific study design

wissenschaftliche Frage(n), Zielgruppe, MDS & QI definiert & formuliert?

Elements of a scientific study design are the formulation of a scientific question, the selection of the study design, the translation of the scientific question into measurable outcome parameters (MDS and QIs), the selection of patients, consideration of control variables, the specification of the data sources, the determination of the patient numbers, the observation period, and the analysis of confounding variables [1, 36].

A dementia QR and clinical studies should be related to each other and, if possible, even planned, conducted and evaluated in an interlocking manner

QR & klinische Studien sollten in Verbindung stehen

The background to this strategy is that both QRs and dementia studies occupy the same field of research. Although they differ in their perspective, they complement each other with fundamental prerequisites or results. For example, RCT participants can be recruited from the population of a QR (and vice versa). Conversely, RCTs or other non-observational studies provide the benchmark against which observations in QRs can be measured [1, 36].

An ethics committee should review the design of the QR and must approve external research

Überprüfung des QR-Designs durch ein Ethik-Komitee empfohlen

Approval from an Ethics Committee is mandatory for clinical (interventional) studies. However, the involvement of an ethics committee in observational study designs is recommended, especially before implementing a dementia QR. An Ethics Committee has approved ADNeT and NorKog before implementation. All research studies not intended for quality improvement and dealing with sensitive data must be approved by an Ethics Committee in the six identified QRs.

When using secondary data sources, systematic errors are very likely and must be reviewed

Störfaktoren mitdenken

An example of a secondary data source is administrative data or data documented for billing purposes. Biases are to be expected and eventual systematic errors within these data sources need to be reviewed, especially in the case of dementia diagnoses [65].

5.2.3 Governance

Governance-Verantwortlichkeiten klar zuweisen (bereits in der Planungsphase)

A clearly defined governance structure is an important tenet to manage the complexities in a dynamic environment consisting of different stakeholders shaped by economic, political, and cultural relationships. A formal governance plan that assigns responsibilities to QR stakeholders, including all aspects of data management, assures the smooth operation of this environment across the QR lifecycle from the beginning (planning phase) through disseminating information and results [1, 36, 64].

Governance-Aufgaben, Rechte & Pflichten verschriftlichen → schafft Transparenz & Klarheit

Central aspects of governance, such as funding, rights, and obligations, should be codified in a written format that can be reviewed, shared, and refined over time. A written plan that includes all expectations of each governance member in a delineated and pragmatic form assures transparency regarding any perceived or actual conflicts of interest (COIs). Stakeholders such as partici-

pating sites should be involved in the process to support stakeholder engagement, and rights, duties, and tasks should be clearly formulated and assigned to ensure transparency [1, 36, 64].

aber gleichzeitig pragmatische Governance → klare Bürokratie

The six identified QRs are heterogeneous in the governance structure but share important governance characteristics. A unified governance board structure across included QRs cannot be identified. Similar responsibilities and tasks are assigned to different authorities at different levels in the five countries. Nevertheless, governance is formalised in all six QR but in a pragmatic manner (see 3.3.1 Governance).

SG zentraler Baustein

The SG is one of the essential building blocks in QR governance. In practice, it comprises a multi-professional team (see Table 3-4). Family and community medicine play a central role in all of the five QRs with an SG. An SG governs the QR and ensures that the QR runs according to its aims while respecting patients' rights. In addition, the SG oversees and partly takes responsibility for administrative, legal/ethical, and scientific decisions that guide the direction of the QR.

Overall, best practice suggests that a QR should be independent of the healthcare system. However, legislation and health regulations often make it problematic [25, 32].

Selected good practice strategies for governance

Formalisation of all aspects of QR governance is important

Governance-Struktur formalisieren → Transparenz

A written format ensures smooth operation and transparency as it can be reviewed, shared, and refined over time [1, 36].

Strong leadership by an SG is essential while ensuring mutual respect among all governance members and stakeholders

starke Führung durch eine SG ist unerlässlich

Leadership by a multi-professional SG with sufficient time capacities and skills to manage the operational and scientific aspects of the QR is a crucial factor for quality improvement. Mutual respect among the governance members and stakeholders is necessary for a constructive working environment [1, 36].

Transparency regarding any perceived or actual COIs of QR stakeholders is a basic requirement

Transparenz hinsichtlich Interessenkonflikte der QR-Akteur*innen

Developing a concept for identifying and managing actual and perceived financial or intangible COIs is recommended (already in the planning phase). Disclosure of COIs is essential for effective governance. COIs, in general, and non-disclosure may influence patients and compromise voluntary participation [1, 36].

Expectations of stakeholders and QR governance members should be explicitly delineated, pragmatic, and transparent

Erwartungen der Governance-Mitglieder & Interessengruppen sollten explizit beschrieben & transparent sein

Stakeholder involvement in the planning phase and governance processes assures further transparency and gives them a voice in all steps of registry work. Rights, duties, and tasks can be clearly defined and mutually agreed upon to benefit all stakeholders equally. In addition, they can provide valuable guidance as they are in charge of the day-to-day management of the dementia QR, including data collection [1, 36].

Data governance (definition of data custodianship, data access rights, the data controller, processor, and manager) should be formalised by partnership agreements and legal contracts in addition to the general governance agreements

Daten-Governance sollte formalisiert werden

In many QRs, the funding body is the data custodian, and governance rights and duties are assigned to different governance members. Establishing clarity concerning data governance and management supports optimal data use and external access to data [1, 36].

5.2.4 Patient and health care provider recruitment

Engagement (Committment) aller QR-Teilnehmer*innen essentiell

Recruitment and retention of participating dementia care providers (data collectors), patients, and other operators are essential for the success of a QR. Recruitment typically occurs at several healthcare system levels:

- Inpatient setting: Hospital SCs/MCs,
- Outpatient setting: outpatient SCs/MCs, NHs/DCHs, GPs
- Patients, carers, and relatives

The motivating factors for participation, as well as the factors for continued participation (retention), differ at each level [1, 36].

alle Interessengruppen sollten motiviert werden

Motivating factors for participation include the perceived relevance, importance, or scientific credibility of the dementia QR, the risks and constraints of involvement and any incentives for participation. Because recruitment and retention of providers and patients are essential for the representativeness of the target population, well-planned strategies for enrolment and retention are crucial. Defining recruitment, retention, and follow-up targets in the planning phase is part of such a strategy. Any deviations during the operation of the QR can be continuously evaluated to minimise the risk of bias [1, 36].

Teilnahme in allen bestehenden Demenz-QR ist freiwillig → Teilnahmebereitschaft sehr hoch

In all six identified QRs, participation from clinical sites is voluntary. Willingness to participate in the QR on the part of the clinical sites is very high, e.g. in Norway, 98% of all outpatient SCs/MCs and nursing homes participate in NorKog. In Sweden, 78% of PCUs and 100% of SCs/MCs participate in SveDem.

Selected good practice strategies for recruitment

The relevance, importance, and reliability of the QR should be made known to all participants

Relevanz & Ziele klar formulieren

The participants' motivation can be increased by making the goal and procedure transparent. Transparent and open communication is necessary for a high response rate and the correct collection of data [1, 36].

Measures for participation, recruitment and securing long-term participation should already be considered in the planning phase

Sicherung der langfristigen Beteiligung bereits in der Planungsphase mitdenken

The implementation of various measures is necessary for recruiting and maintaining continuous participation. The needs of the participants, as well as possible risks, play a central role. For long-term participation, possibilities such as websites, newsletters or information brochures, information dissemination by telephone, workshops, and presentations should be used [1, 36].

Allow all participants and stakeholders to benefit

alle Interessengruppen sollen profitieren

An important aspect of recruiting (both the registry team and the participating dementia care providers) is returning the QR's benefits. The scientists and the institutions involved should benefit directly from the knowledge gained [1, 36].

5.2.5 Data elements, the minimum data set, and quality indicators

Data elements and the minimum data set

MDS: Fokus auf notwendige & relevante Datenelemente

nicht notwendige, aber wünschenswerte Elemente aus anderen Datenbanken ableiten

The selection of data elements begins with identifying the relevant dementia care domains, considering established dementia care guidelines, consensus-based clinical practicalities, aims of the respective healthcare system defined in national dementia strategies, and data standards such as using unique patient identifiers. It is crucial to determine which elements are necessary and desirable but not essential for the overall healthcare context. Non-necessary but desirable data elements may be derived from other databases. Some data elements for QRs are often collected for other purposes (e.g. medical records, billing data and claims, and other health-related registries). The absolutely necessary elements have a priority. These data elements form the MDS and should be collected directly from patients and/or relevant caregivers by all participating units [1, 36].

validierte Skalen für patient*innenberichtete & -generierte Endpunkte wie PROMs oder PREMs

When using measurement scales to capture patient-generated outcomes and data elements (PROMs/PREMs) such as HRQoL or proxy-generated outcomes (CROs/CREs), carefully validated scales should be used [43]. Valid and reliable scales are not the only issues concerning such outcomes. Feasibility is also an essential factor. Although including multiple PROMs or CROs can be tempting, it may discourage patients and caregivers from participating if the effort is unreasonable [1]. Two sources which provide existing PROMs are:

Quellen für valide PROMs

- The Core Outcome Measures in Effectiveness Trials (COMET) Initiative (https://www.comet-initiative.org/)
- The Patient-Reported Outcomes Measurement Information System® (PROMIS®) Initiative by the U.S. National Institutes of Health (https://www.promishealth.org/)

entweder „Core Outcome Set" oder klassische Literatursuche heranziehen

Both initiatives provide publicly available PROM sets. The COMET Initiative promotes the development and application of agreed standardised outcome sets – so-called 'core outcome sets' (COS). COS represent the minimum that should be measured and reported in all clinical trials of a specific condition. Still, COS are suitable for routine care and research other than RCTs, including QRs. The PROMIS® is a set of person-centred measures that evaluates and monitors physical, mental, and social health in adults and children. The PROMIS® specialises in PROMs and provides a guideline for using PROMs in performance measurement [124]. However, a traditional literature search can yield similar results instead of using existing PROM sets, although this can be time-consuming.

Quality indicators

Einigung auf QI & dazugehörige Zielwerte

mehrere Möglichkeiten um QI zu erhalten

If dementia QR operators and stakeholders agree on a joint MDS, they must also agree on the key (outcome) measures of a QR: a QI set with defined standards and target values. Generally, standardised QI sets should be prioritised [1, 32, 35, 41]. However, as with the MDS, there is no 'core QI set' for dementia [32]. Possible solutions are using existing QI sets from other national dementia QR, creating one's own QI set, or a combination of the two (see section 4.2 Quality indicators for existing dementia QIs in other countries).

QI & QI-Sets von anderen Ländern oder Evidenzsynthesen übernehmen → Übertragbarkeit gegeben?

If whole QI sets from other national QRs or from existing evidence synthesis [39, 40] are adapted, one has to consider whether the set is transferable. For example, SveDem and BPSDR focus on treatment, support, and follow-up QIs (see Table 4-2). A closer look reveals a clearer picture. The focus on TSF indicators in Sweden may be because a large number of dementia patients have already been identified, diagnosed, and registered. National estimates for 2018 have shown that approximately 130,000 to 150,000 people are affected by dementia in Sweden [30, 125]. In SveDem, as of 4/2022, about 107,000 people are registered [126].

Stadium der nationalen Demenzversorgung bei der Wahl von QI berücksichtigen

Across the six QRs, most indicators are diagnosis and diagnostic workup QIs, with 26 out of 64 indicators (41%), followed by TSF with 25 indicators (39%). ADNeT, DanDem, and NorKog focus on DDW QIs (71%, 47%, and 75% are DDW indicators). This observation may reflect the importance of DDW QIs in the dementia care pathway of these three countries, as they did not diagnose the intended number of persons with dementia. For this reason, considering the stage of national dementia care when forming and selecting QIs is of utter importance.

aus dem MDS werden QI & dazugehörige Zielwerte abgeleitet

The second option is creating a custom or context-dependent QI set. The selection of a QI set and the underlying MDS have parallels and are both crucial steps in the design of the QR. The development of QIs should follow a stringent process. Mainz [127, 128] provides an overview of the different phases of QI development. The stages essentially correspond to the process of setting a standard of care by Lawrence and Olesen [37] (see Figure 1-1). Mainz defines the following phases and tasks:

QI-Entwicklung sollte nach einem stringenten Prozess erfolgen

- **Planning phase:** The clinical area is chosen, and the measurement team is selected and organised.
- **Development phase:**
  - QIs are prioritised and selected by the measurement team based on documentation and knowledge from the scientific literature and consensus (evidence foundation).
  - Selection of QIs and standards and identification of prognostic factors
  - Specific measures are designed, including inclusion and exclusion criteria for the target population, a description of a risk adjustment strategy, data sources, data collection procedures, and an analytical plan for data analyses.
  - Before QI implementation, testing for reliability and validity is recommended. Preliminary tests may identify areas requiring further modifications and specifications of the indicators.

solide Evidenz für QI entscheidend

Pilotierung

erneute Bewertung der QI & anderen Datenelemente

The first point in the development phase repeatedly stresses that solid evidence is substantial for formulating QIs and associated target values. Once the QIs are selected, the MDS and QIs should be pilot-tested. Testing allows for identifying facilitators and barriers to collecting the necessary and desired data elements [36]. Furthermore, a pilot phase helps to identify areas where data are still missing. Overall, the choice of dementia-related data elements and QIs should be guided by parsimony, validity and a focus on quality improvement [32, 36]. Re-examination of the MDS, QIs, and target values is vital. For example, as with diagnosis data, treatment data are usually only available after a certain period. Therefore, a re-assessment of whether the data elements or the initially formed QIs are appropriate for capturing quality changes is essential [32, 36].

kritische Reflexion warum Großteil nur QI zur Prozessqualität

Qualität von Gesundheitsleistungen am besten durch Pat.-Ergebnisse definiert

Most identified QIs in section 4.2 are indicators targeting process quality (87%). Only five indicators directly concern the outcome quality, and only one QI involves the structural quality of dementia care. This observation is striking and requires critical reflection. Theoretically, the assumption of a causal linear relationship between the three quality dimensions applies [42], meaning an improvement in structural and process quality would automatically lead to an improvement in outcome quality. However, evidence from cardiovascular research shows that this relationship does not necessarily exist [1, 36, 129, 130]. For dementia, it is even unclear as no evidence of the quality relation could be identified. A further argument against focusing on process measures alone is that healthcare value is best defined by patient outcomes, not by processes of care [36, 131].

Überschuss Prozess-QI = fehlendes Wissen über Versorgungsprozesse?

One possible explanation for the excess of process quality indicators in dementia QRs is that there is still a lack of process knowledge due to the complexity of the dementia syndrome and the lack of clarity about optimal treatment approaches.

QR zu engen Fokus bei QI?

breitere Perspektive → breiteres QI-Set und Fokus auf patient*innenzentrierte QI

Another explanation for the underrepresentation of QIs targeting the structure and outcome quality may be that 'real-world' QRs have a too narrow focus: a clinical focus. Dementia care, which is simultaneously long-term care, integrated care, geriatric care, and end-of-life care particularly requires consideration of patient-centred QIs and outcomes. Recent systematic reviews come to a similar diagnosis [39, 40]. A broader perspective in dementia care, i.e. not only targeting care providers but patients, their relatives, and payers as well, results in more diverse QI sets with a focus on patient and caregiver well-being. Examples of such outcome-related QI include whether the caregiver or patient feels supported or the patient is involved in their own care [40].

Selected good practice strategies on data elements

Definition of necessary data elements and an MDS is vital for quality improvement and a prerequisite for the development of QIs

Definition eines MDS & der Datenelemente unerlässlich

The collection of an evidence-based MDS increases the chance of complete data sets. Nevertheless, it is possible to collect additional data elements in individual areas where more (collection) capacity is available. When defining dementia-related data elements, factors such as their relevance to achieving quality improvement goals, reliability, the overall burden on respondents, and the cost-effectiveness of their collection are crucial to consider (see section 1.3.3 Quality indicators in dementia care) [1, 36].

Data elements, MDS, and QIs should be selected and developed according to established evidence-based foundations, already established clinical quality standards, and respective healthcare system practicalities

MDS & QI sollten nach bewährten evidenzbasierten Grundlagen ausgewählt & entwickelt werden

In dementia care, no internationally recognised standards on the MDS and QIs exist compared to other health branches such as cardiology [32]. This observation is verified by the heterogeneity of the collected data elements and QIs in all six identified QRs. Overlaps in QI and data elements exist, but the lack of established standards makes international comparisons problematic. A possible explanation for the heterogeneity may be the complexity of the dementia syndrome and the different dementia care practicalities in countries.

No numerically excessive QI sets should be defined

keine allzu großen QI-Sets definieren

Practice shows that registries commit to a manageable number of QIs. The number of key QIs ranges from five indicators in NDRI and NorKog to ten QIs in DanDem and SveDem. The focus is on evidence-based and consensus-based quality and not quantity.

Carefully validated scales should be used to measure patient-related outcomes and proxy-reported HRQoL of dementia patients

validierte Skalen für Messung patient*innenbezogener Ergebnisse

The measurement scales used should also be based on internationally recognised recommendations. For dementia care, several dementia-specific PROMs exist but are implemented only by some dementia QRs. The selection of valid and reliable dementia-specific HRQoL measures considering the stage and severity of the dementia type are deemed significant as the pathology possibly influences an individual's ability to engage in such measures. In addition, the choice of the person providing the information (self, proxy by a caregiver, or a combination) needs to be considered. Taking into account the voice and experiences of patients and carers completes the picture of what constitutes good dementia care. The use of PROMs/PREMs or CROs/CREs in dementia QRs requires further investigation [43].

The MDS, QIs, and other data structures should be tested in a pilot test

Pilotierung des MDS, der QI & anderer Datenstrukturen

In the pilot phase, the individual data collection and storage steps are run through on a trial basis. Data elements of the MDS and further desirable but not necessary data elements should be collected and entered into the database in selected participating units. The functionality of the input and processing systems should become apparent. The pilot test is intended to record technical aspects and provide feedback on the comprehensibility and usability of the system. For example, insufficient explanatory texts, incomprehensible questions, or missing information for the final evaluation can be identified [1, 36].

NDRI führte einen Proof-of-Concept durch, um die Wirksamkeit & Effizienz zu überprüfen

An example of a pilot test phase is the one proposed by NDRI, which has not yet been fully implemented [32]. NDRI carried out a small-scale registry data proof of concept (prototype) to investigate the effectiveness and efficiency of the recommended data collection model for end users. The specific objectives in the pilot test phase were to:

- Explore the availability of dementia data in participating memory clinics
- Check the usefulness and clarity of the MDS fields
- Test the usability of the QR through the input of case data into the database in MCs and qualitative analysis of memory clinic feedback

The MDS and QI set should not remain static

MDS & QI-Set sollten dynamisch sein

Following appropriate review, the MDS and QI set can be reduced or extended over time to meet the needs of all stakeholders [32].

5.2.6 Data sources of a dementia quality registry

Einbindung von sekundären Daten essentiell

A dementia QR should be able to integrate data from different sources in addition to direct data entries. Data sources can be primary or secondary [1, 36]. Primary data (raw data) are directly collected to fulfil the purpose of the dementia QR. Secondary data carry the information collected for a different purpose, e.g. other research purposes.

Grundvoraussetzung: Pat.-Identifikatoren

Sufficient patient identifiers are needed to match patients in the QR to secondary data sources. It is also essential to have a solid understanding of the original purpose of the secondary data and how it was collected because the way it was collected and validated or verified provides important background information. Secondary data sources comprise patient records, databases from institutions or organisations, administrative data from health insurance companies, birth and death registers, census databases and other existing registry databases [1, 36]. Table 3-10 provides an overview of the different data sources utilised by the six identified QRs.

Selected good practice strategies on data sources

Extensive knowledge of the circumstances and the original purpose of the secondary data

Wissen über Qualität der sekundären Datenquellen?

Secondary data sources (existing data collections created for a different purpose) can be of very heterogeneous quality. The data may have been entered by untrained staff or missed QA (validation for plausibility and accuracy). In addition, the definitions and standards of the data elements may have changed during the collection.

There should be a predefined way to deal with data linkage problems

Pat.-Identifikator

Possible errors in linking are the linking of non-identical cases or the non-linking of identical cases. A uniform patient identifier is decisive.

Defined collaboration between QRs and other registries, such as epidemiological registries

Kooperation mit anderen Registern?

For example, a collaboration between the dementia QR and a death registry allows deaths to be reported.

5.2.7 Data collection and quality assurance

integriertes (Software)System bestimmt die Verwendbarkeit & Qualität der Daten

The integrated system for collecting, cleaning, monitoring, validating, and reporting on the dementia QR data determines the usability of the data for quality improvement [1, 36]. QA should ensure that data are collected and validated according to established data quality standards. QA requirements should be defined optimally during the QR's planning phase by elaborating a QA plan.

weitere wichtige Faktoren zur Qualitätssicherung (QS): einheitliche Datenstruktur, Schulung des Personals & technische Maßnahmen für die Datenerfassung

Decisive data quality factors are a unified data structure and collection, the training of collecting health care staff, and handling data problems (missing data, out-of-range, logically inconsistent values) [1, 36]. The identified QRs use multiple measures to assure data quality (see section 3.4.4 for all concrete measures). The standardised data input in all six registries works via web-based solutions. Other examples of quality assurance measures comprise:

- Personnel measures include training, workshops, telephone support, and ongoing staff training.
- Technical measures include data cleaning, handling missing data, data dictionaries, guidance documents, or software-based approaches for validation.

zahlreiche Validierungsansätze in der Praxis

The identified QRs operationalise technical measures for QA in the course of the QRs validation strategies. Automated logical checks are the most common validation approaches, e.g. if a required data element is not entered by a clinician, he/she/* receives an alert. Other common strategies are cross-checking with other databases and routine checks of consistency and accuracy according to the data validation plan. Some QRs also use external audits. Table 3-11 in Section 3.4.4 overviews all identified validation strategies.

QS auch verbunden mit Kosten

QA measures have a different impact on costs. Therefore, a risk-based approach should be taken when developing the QA plan. This approach aims to identify important and likely sources of errors that may affect the quality of the registry [1, 36].

Selected good practice strategies for data collection and quality assurance

The characteristics of data quality must be defined

Datenqualität anhand Datenstandards definieren

Data quality must be defined using appropriate data standards and data dictionaries. Only then longitudinal comparisons are possible [132]. A systematic collection of data quality indicators can be found in the guideline 'Data quality in medical research' [133].

The integrated software system for the QR should cover the areas of collection, cleaning, monitoring, validating, and reporting capabilities

umfassendes (Software)System wichtig

An integrated software system well adapted to the QR requirements is a prerequisite for the usefulness and usability of the collected data in terms of quality improvement [27].

Standardised data collection via web-based solutions across participating units

standardisierte Datenerfassung über webbasierte Lösungen in allen teilnehmenden Einrichtungen

When collecting data, uniformity of data collection is an essential requirement. Collection protocols can be formulated to ensure valid and trustworthy data collection [65]. In certain situations, it may be necessary to check the inter-rater and/or intra-rater reliability (e.g. Cohen's kappa statistic [134]) [1, 36, 65]. Web-based data collection makes the registry lively, increases users' motivation, and ensures a standardised data collection [65]. In addition, web-based solutions enable fast data processing and immediate access to existing data stock.

Develop a uniform, carefully planned software system that can be used in all participating centres, including support and feedback mechanisms

(Software)System sollte eine Feedback- & Support-Funktion haben

A global software system can avoid allocating too many resources for recurring problems. The QR software should be set up so that inflexibilities due to bureaucracy, imprecise definitions of responsibility, and other organisational obstacles can be avoided [27]. Since many questions can arise during data entry, easily accessible support should be available by telephone and/or e-mail during working hours [27]. The possibility of user feedback is also essential. E.g. NDRI will implement a mechanism to gather user feedback and periodic questionnaires on training, usability, usefulness, and satisfaction. BPSDR makes use of certified trainers to fulfil this task.

Training for people who enter data

Schulung des Personals ist essentiell

Appropriate training, e.g. ongoing training and workshops, is needed to use the data entry software [65]. Training includes ensuring that those involved have a clear understanding of the information that is being collected [27]. Offline and online training such as in-person registry seminars, webinars, instructional videos, or instruction published on the QR's website are possible ways to organise training.

Make use of patient questionnaires

eventuell Pat. bei der Datenerfassung miteinbinden

Using questionnaires filled out directly by patients means that resources (survey staff) can be used for other tasks. In addition, many patients interpret follow-up questionnaires as an indication that their concerns are being addressed [27]. E.g. ADNeT collects patient- and carer-reported outcomes via surveys annually directly from patients, relatives, and carers. Another aspect is that direct patient interviews often reflect the information regarding the objective of the registry better than a further interpretation step by the treatment staff [1, 36].

The dementia QR software should have logical check and cross-check mechanisms

logische Kontrollmechanismen in der QR-Software nutzen

Electronic forms allow it to directly check simple and complex plausibility or validity conditions during data input (valid dates, data out of range, missing entries etc.). In the case of unsuitable entries, warnings are displayed, or the person entering the data cannot proceed to the next input mask. By applying these checks, errors can be avoided [27].

Documentation should be carried out as close to all dementia care services as possible without delay

Datendokumentation

Data documentation should be carried out as early as possible and not retrospectively by integrating data documentation and collection into the routine [27].

Carrying out audits, data monitoring and plausibility checks

Audits & Datenmonitoring veranlassen

Audits, data monitoring and plausibility checks should be carried out for a dementia QR, similarly to clinical trials [27]. In Denmark and Sweden, external or internal review activities for QR validation are employed. For example, in Denmark, each Danish QR has to pass an appraisal by the National Health Authority every three years.

5.2.8 Registration, processing and reporting of adverse events in dementia quality registries

Definition eines unerwarteten Ereignisses (UE) laut EMA

The European Medicines Agency (EMA) defines an adverse event (AE) in the context of pharmacovigilance and outside a clinical trial as:

> *'An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to this medicinal product'* [135, p.7].

UE → berichten, wenn aufgetreten

AEs are categorised by severity and (for medicines) by the degree of expectation of the event [1, 36]. Usually, reporting AEs for medical devices and medicines on the market follows the principle of perception (reporting when perceived).

The collection of adverse events falls into two categories:

- Events that are collected as part of planned documentation
- Events that are collected voluntarily or unplanned

Notwendigkeit der Erfassung von UE abhängig von der wissenschaftlichen Frage

Deciding whether a QR should maintain its own case report form depends on the scientific importance attached to this information (quality improvement) and on legal and regulatory obligations [1, 36]. For example, § 75g of the Austrian Medicines Law (AMG) stipulates that health professionals must report suspected AEs to the Federal Bureau of Safety in Healthcare (BASG) without delay[62] [136].

UE können in QI abgebildet werden

On the other hand, QRs additionally map AEs into QIs. Some QRs use the QI 'Proportion of patients treated with antipsychotic drugs' as an instrument to track AEs. Anti-psychotic medications should be used with caution given the severe associated adverse events [30, 102].

QR-Personal sollte in der Erkennung von UE geschult sein

Regardless of whether AEs are tracked via QIs or regard primarily pharmacological treatments, it is crucial to have an awareness plan to report all occurring AEs of treatment and support measures directly involving the patient. Therefore, QR staff should be trained in identifying AEs and to whom the AEs should be reported [1, 36].

Selected good practice strategies for the registration, processing and reporting of adverse events

A system for documenting observed AEs should/must be established

ein System zur Dokumentation der beobachteten UE sollte eingerichtet werden

In many countries and the EU, reporting adverse medicinal product reactions and pharmacovigilance are mandatory and must take place in a form prescribed by law [1, 36, 137, 138]. General registry guidelines on reporting AEs focus on AEs related to pharmacological products or medical devices. However, documentation of AEs concerning any dementia care-related measure is recommended. Quality improvement on the whole dementia care pathway can only be achieved with planned and systematic documentation compared to spontaneous documentation [1, 27, 36].

[62] Patients can and should also report suspected AEs to the BASG according to § 75h AMG.

5.2.9 Analysis, interpretation, and reporting

Analysis

mehrere Fragen müssen bei der Analyse, Interpretation & Berichterstattung der Daten beantwortet werden …

The analysis, interpretation, and reporting of the QR data begins with answering several key questions [1, 36]:

- Were the objectives defined in advance or retrospectively?
- Who was studied?
- How was the data collected, edited, validated, and missing data dealt with?
- How was the data analysis conducted?

… am besten bereits in der Planungsphase

Ideally, all four questions were already considered in the planning and design phase of the dementia QR. It is self-evident that the primary goal, the improvement of dementia care quality, is already determined in advance or at the time of the intention to implement a QR.

relevante Pat.-Population

Four populations are of interest when describing who was analysed:

- The target population
- The available population
- The intended population
- The population that was actually studied

untersuchte Population = Zielpopulation → Verallgemeinerbarkeit

The representativeness of the studied population to the target population is referred to as generalisability. The analysis in a dementia QR should therefore use the relevant information about the characteristics of the patient population, what interventions were of interest, and what the quality indicators and outcome measures for the relevant population were.

relevante Population klar, dann Datenvollständigkeit überprüfen

When the population of interest is clear, checking data completeness is the next step. Considerations include checking the entirety of the essential cofactors and how missing data were handled and documented. For example, data coverage in DanDem is calculated by matching data in the QR with data from the Danish National Patient Registry (see section 3.4.4 Quality assurance, validation strategies, and safeguards).

Spezifität der QR-Daten besonders berücksichtigen

In addition, the specificity of QR data needs special consideration, primarily when QRs are used to assess an intervention effect to adapt care practice and improve care. QRs have an observational design limiting causal inferences [36]. Observational data and RWD provide potential sources of bias due to the non-randomisation of treatments compared to RCTs. Within an RCT, different treatment options have an equal chance of being assigned, and patients have an even chance of receiving treatment. In addition, consecutive treatments form a care cluster, which makes inference of the treatment effect of a single care component quite difficult. Certainly, multilevel analysis or matching techniques such as propensity score matching adjusting for cofactors and confounders provide a possible solution. Statistical expertise is necessary to conduct such analysis methods [36].

Konzept der Datenvariation muss verstanden werden

Another essential point when analysing (and interpreting) QR outcome data is understanding variation [29, 139], especially for process quality measures. Variation has different meanings for different stakeholders:

Variation unterschiedliche Bedeutung für Forscher*innen, Leistungserbringer*innen & Entscheidungsträger*innen

- For researchers, the focus lies in understanding variation when testing causality (optimally) using RCTs [139].
- For health care professionals such as physicians, controlling variation is often met with scepticism as it may be perceived as an attempt to restrict freedom of treatment (clinical autonomy) [139].
- Healthcare planners or clinical facility managers focus on the quality of care processes and outcomes for groups of patients. Controlling and understanding variation for them means creating stable processes and improving the quality of care [139].

Verständnis der räumlichen & zeitlichen Variation

In the dementia QR context, especially the third point is of interest as there could be variations in outcomes across time or participating care units. Therefore, to understand spatial and temporal variation, both location and spread measures should be used when analysing QR data [29].

Limitationen des Datentyps beachten

QR operators and corresponding data analysts should be aware of all limitations regarding the observational design, data structures, possible confounders, missing data, and spatial and temporal variation. Fortunately, various analytical approaches exist to deal with observational data [36]. A statistical analysis plan should describe the analysis design and statistical techniques used.

Interpretation and Reporting

Berichterstattung & Interpretation der Daten ermöglichen Reflexion über Stärken & Schwächen des Demenz-QR

Interpretation and reporting of the results build the second step towards quality improvement. The interpretation of the data allows for reflecting on the QR's strengths and limitations. Tasks may involve comparisons with results of higher quality studies or other national dementia QRs to confirm or refute whether the QR provides 'good' evidence for quality improvement or whether the analysis methods were adequate. When interpreting the outcomes, confidence intervals are important for interpreting regional variations across participating dementia care units [1, 36]. Considerations should also be given to the clinical significance of the effect estimates and potential biases. If appropriate methods were used to reduce biases, then the interpretation of the QR data should allow a realistic picture of the quality of dementia care.

Standpunkte aller Interessengruppen berücksichtigen

The interpretation of results and conclusions should consider the viewpoint of all stakeholders. The traceability of results is vital to derive lessons learned from the QR analysis for decision-makers, healthcare planners, participating units, patients, and caregivers. Transparency and availability of results are minimum requirements to improve patient and dementia care outcomes, although not sufficient, as the effect of public reporting on general health quality is uncertain [140]. As a general rule, the potential benefit of public reporting must be balanced against the potential harm [1, 36]. Nevertheless, public reporting is deemed a fundamental ethical obligation. Public reporting addresses the patient's right to autonomy, self-determination, and informed consent, including the right to know the comparative evidence of dementia care providers [36].

Nachvollziehbarkeit der Ergebnisse wichtig für Transparenz

in der Praxis sind Berichte der Demenz-QR öffentlich zugänglich

All of the identified QRs annually report on the main results of the quality indicators and further outcome measures. The reports are publicly available on each QR's website. Some QRs also provide insights into ad-hoc results for participating SCs/MCs on specific digital platforms, but for data protection

reasons only to a certain extent. E.g. NDRI will provide interactive dynamic real-time reports via an end-user and data interface (dashboards) once implemented. These reports allow for real-time filtering of required data fields and graphical visualisation of data online or as printed reports. The data analysed in these reports can also be downloaded, subject to user permissions (for a complete overview of all types of reporting, see Section 3.5 Interpretation and Reporting).

Selected good practice strategies for analysis, interpretation, and reporting

Use of a statistical analysis plan

Nutzung eines statistischen Analyseplans

A statistical analysis plan for the main aspects of quality improvement and supplementary statistical analysis plans should be used to deal with all questions regarding the quality of dementia care [1, 36].

An experienced statistician should be employed for the evaluation

erfahrene Statistiker*innen einsetzen

The scope of statistical evaluation in QR is often underestimated and often more complex than, for example, in RCTs [1, 36].

Consideration of the relevant co-factors and confounders in the set of collected elements

Störfaktoren & andere Kofaktoren berücksichtigen

Primarily when registry data are used for different purposes, such as further research projects outside the quality improvement domain, it is crucial to have all the necessary information to detect biases and to be able to adjust for them [1, 36].

Results should act as feedback

(öffentliche) Berichte als Feedback-Funktion

Analysis and reporting should be embedded as a feedback component in a QR [65, 133]. Transparency of results can educate participating dementia care providers and the public about scientific processes. Transparency also contributes to public and professional confidence in the scientific integrity and validity of the QR. Publicly available information may also increase awareness of the scientific utility of QR data by promoting inquiries from interested scientists [1, 36].

The type and frequency of reporting should be clearly defined

Berichterstattung sollte klar definiert sein

Reports on registry evaluations should be published in a defined format on a regular basis (e.g. annually or semi-annually). E.g. all identified QRs publish at least one annual report (see section 3.5 Interpretation and Reporting).

Implement conditional access to data and/or a payment system for research data access

bedingter Zugriff/Zugang auf Daten für Forschungszwecke

Fulfilment of specific conditions and/or fees could be used to control data access and limit 'unnecessary' ad hoc data demands [27]. To access data in all six QRs, researchers must meet certain conditions. Some QRs require that researchers send an application form, including a protocol, to be eligible to use the data. The application must contain specific information about which data and variables are used, responsibility for data processing, storage/research server, time limit, return of data/deletion, and who will have access to data. SveDem and BPSDR also charge fees for data access (see section 3.7 Register-based research and confounders)

5.2.10 Privacy, consent, and ethics

Berücksichtigung ethischer & rechtlicher Aspekte essentiell

A critical review of the ethical and legal aspects of a dementia QR should accompany the development and maintenance of the dementia QR. Considering ethical aspects is not only stipulated by fundamental principles of conducting (human) research but also by the European Commission (EC) and the GDPR:

> *'Data protection is both a central issue for research ethics in Europe and a fundamental human right. It is intimately linked to autonomy and human dignity, and the principle that everyone should be valued and respected. For this principle to guide the development of today's information society, data protection must be rigorously applied by the research community.'* [141, p.4]

DSVGO gibt datenschutzrechtlichen Rahmen vor

All EU member states are subject to the GDPR and the privacy regulations therein [93]. While GDPR directly applies as a law in all member states, EU countries also have their own regulations with the respective national privacy laws, for example, in Sweden and Denmark through the Personal Data Act [142, 143]. Ireland's data protection and privacy are regulated by the Data Protection Act 2018 and the Irish Health Research Regulations. The latter gives effect to the GDPR and the Data Protection Act in the context of health research. NorKog complies with the regulations issued by Norwegian Data Protection Authority but also takes the EU's GDPR as a basis for privacy regulations.

„Datenverwahrer*in" ≠ Dateneigentümer*in

QR custodianship is often mixed with data ownership. Data is the property[63] of the patient. Accessing and using that data beyond quality improvement purposes requires patient consent [144, 145]. In reality, several stakeholders claim ownership of health information, but no universal and unambiguous legal basis for assertions of ownership of health information or raw data elements exists [1, 144]. E.g. the GDPR specifies the terms data controller and data processor but does not specify data ownership [93, 144]. QR custodianship regards operational control of the collected dementia care data and publication rights, which are covered in copyright protections (copyright law). Property rights related to health information are usually negotiated under the terms and conditions of formal agreements between QR developers, healthcare planners, funders, and participating health care providers [1].

3 ethische Grundprinzipien

Three basic principles build the foundation for the ethical analysis of human subject research, including the research of health information in QRs [1]:

Achtung der Person (Selbstbestimmung)

- **Respect for persons (self-determination)**: The principle of respect for persons when using health information pertains to ethical concerns about preserving the privacy and dignity of patients, protecting the confidentiality of health information, and minimising potential harm. Respect for persons supports the practice of obtaining individuals' consent to use their health information for research [1].

[63] Whether health information is property and propertisation (financialisation) enhances patient self-determination, increases market efficiency due to clear property rights (Coase theorem), offers patients a foothold in the data economy, clarifies legal uses of health information, or encourages data-driven innovation is extensively discussed in Liddell et al. [144].

Benefizienz & Schadensvermeidung (Gutes tun, keinen Schaden anrichten, vor Schaden schützen)

- **Beneficence and avoidance of harm (do good, do no harm, protect from harm):** The intention behind this principle is to minimise potential harm to registered individuals or groups (positive benefit-harm ratio). Any research involving human subjects that is unlikely to produce valid scientific information or benefits to human subjects is generally deemed unethical. Minimising harm, therefore, involves identifying (a priori) the information necessary for the QR's objective and purposes. In addition, the risks of unauthorised access and inappropriate use of QR data must be minimised [1].

Gerechtigkeit (Fairness & Gleichbehandlung)

- **Justice (fairness, equitable distribution of burdens and benefits, equal treatment):** Unequal distribution of benefits and harms reinforces the need for risk minimisation concerning QR data use, as the burden may be unevenly and unfairly distributed across individuals [1].

Zustimmung zur Datennutzung & zur Teilnahme am Register sollte freiwillig sein

A general requirement derived from the ethical principle of respect for persons is consent to data use and registry participation. Generally, the permission to use health information for research purposes must be voluntary unless a specific exception to voluntary participation applies. In the case of a QR, the matter is not entirely clear. In principle, QR data are usually used by the same team of investigators and not disclosed. All research activities have the same scientific purpose – improving the quality of dementia care nationally. High-quality and transparent QR work may include (confidential) feedback to healthcare planners and decision-makers, participating health care providers, and public reporting of provider performance. These activities may or may not constitute research. However, using data for external scientific purposes constitutes research in the true sense of the term requiring consent from patients.

Zustimmungsprozess bestimmt Teilnahmequoten

The consent process is not only related to ethical considerations but directly affects recruitment and participation rates [32, 94]. QRs commonly use three consent models: The Opt-in-model, the opt-out-model, and the no-consent-model (see Section 3.6.2 for a detailed description). The choice of the appropriate model should be made in the course of developing a dementia QR [1].

Bedenken hinsichtlich Vertraulichkeit & Eigentumsrechte sind zentrale ethische & rechtliche Aspekte

Confidentiality and proprietary concerns about the identity of participating dementia care providers or social security institutions are essential issues to consider, as specific patient populations or even individual patients [1].

Selected good practice strategies on ethics, privacy, data protection and informed consent

The EU GDPR should guide data protection considerations

DSGVO sollte Überlegungen zum Datenschutz leiten

The EU GDPR specifies what EU member states must consider in their data protection legislation. All European registries have already implemented the directive. The orientation towards the EU GDPR can be seen as a long-term measure to protect against breaches of personal integrity.

Consideration of the three fundamental principles in the context of human subject research is essential for running a QR

Berücksichtigung der 3 ethischen Grundprinzipien wichtig

Protection of confidentiality, privacy, patient dignity, and minimisation of data misuse reflect the ethical principles of respect for persons, beneficence, and justice. QR operators should acknowledge public expectations of protection for patient privacy and dignity with clear and consistent communication [1].

Questions about consensus should be answered in the course of planning and developing the dementia QR

Fragen zum Konsensmodell bereits in der Planungsphase beantworten

In the case of dementia, it is essential to consider any limitation in a person's ability to withdraw information from the QR at the initial registration. Instructions on procedures for withdrawing from participation at any time, unless a waiver of consent applies to the QR, need to be worked out [1].

5.2.11 Other domains

'Research readiness'

Demenz-QR-Daten sollten „forschungsreif" sein

A common secondary objective of QRs is using data for research purposes. Registry data should be 'research-ready'. Questions on the consent formalities, research application and data access modalities, and ethical approval should be clarified (see section 3.7 Register-based research and confounders) [1].

Close knowledge gaps

alle Wissenslücken schließen

There are some knowledge gaps concerning QRs. Existing evidence shows that using QRs in other disease areas improves quality and delivers significant value for money when correctly implemented [2, 26, 33, 34]. For dementia QRs, the results are not so evident. Individual QIs show quality improvements in individual care areas (see section 4.3 Quality indicator vignettes and results). However, the effectiveness and efficiency of a QR must be evaluated at the whole registry level. Therefore, a continuous assessment of effectiveness and cost-effectiveness should accompany the general evaluation of the QR.

Change management: QRs need to be adaptive

Demenz-QR sollte anpassungsfähig sein

Change management is an important consideration when planning and designing a dementia QR. Dementia QRs need to be adaptive to change. For one, there may be new (disruptive) evidence in dementia care that changes how care should be managed. For example, a new, highly effective drug for dementia prevention or treatment of cognitive change may make the original interpretation of quality of care obsolete. On the other hand, even small changes in dementia care guidelines or dementia care practice can make adjustments in the quality focus necessary. For example, shifting from process QIs to outcome QIs may be required. This change can lead to changes in the participating dementia care providers since they may have to acquire new care infrastructure or retrain staff. From a planning perspective, QI registries should anticipate ongoing changes to the registry and plan for the resources needed to support the changes [1, 36].

5.2.12 Evaluation and assessing the quality registry's quality

QR können auch hinsichtlich ihrer Qualität evaluiert werden

While registries can provide valuable data, their validity and reliability can be pursued with varying degrees of rigour so that some registries offer better information for decision support than others. The term 'quality' can be applied to dementia care services and QRs themselves. Hence, QRs themselves can be evaluated to determine whether they meet a certain level of quality. Quality in the QR context means how well it can demonstrate that bias and errors have not affected the findings based on their design, inferential nature, and approach [1, 36].

Evaluations-Checkliste auf Basis des AHRQ User's Guide

A component-based quality checklist was established based on Mathis and Wild [27] and the AHRQ User's guide [1, 36] to define fundamental factors that can influence the QR's results (see p.129, Checklist of essential elements of good practice,).

2 "Qualitätsformen":

The checklist differentiates between two 'quality forms' having different quality domains:

Qualität der Forschungsmethode (Qualität des wissenschaftlichen Prozesses)

- Research method quality (quality of the scientific process):
  - Registry design[64]: Goals, target population, observation period, QR size, data, exposure, outcomes, effect modifiers and confounders, safety, analysis plan
  - Framework design: Ethics and data protection, governance, transparency, change process

Qualität der Evidenz (Qualität der Daten & Ergebnisse)

- Evidence quality (quality of the data and results stemming from the scientific process and analysis of the dementia QR).
  - Methods: Data collection, site and patient recruitment and follow-up, data collection guidance, quality assurance
  - Reporting: overall reporting, analytics, and comparisons

Domänen in der Checkliste = „wesentliche Elemente einer guten QR-Praxis" bzw. "Verbesserungspotenziale"

The quality domains in the checklists, e.g. goals or data collection, can be seen as the 'essential elements of good practice' or as 'potentials for improvement of good practice' [1, 36]. These potentials can reinforce the information value in certain situations. In addition, fulfilment of all quality domains guarantees a certain 'basic' quality standard. The results of using the checklist to evaluate a QR should always be considered in the whole dementia care context. In addition, feasibility, affordability, and the primary purpose of quality improvement should also be kept in mind [1].

[64] Design domains should already have been considered and clarified in the planning phase of the dementia QR.

Checklist of essential elements of good practice

Research method quality: *Planning of the design* [1, 36]

Goals:

☐ A registry plan has been formulated, including the aims, purposes of the QR and/or potential future research questions (optionally with the support of external stakeholders such as decision-makers, healthcare planners, patient representatives etc.).

Target population:

☐ The target population is described, including eligibility criteria (inclusion and exclusion criteria).

Observation period:

☐ Define the follow-up time required to detect events of interest, e.g. decline of cognitive capacities or functionality/ADL, and consider whether long-term follow-up is compatible with other databases and registries.

Size:

☐ Specify the desired and feasible number of included patients necessary to detect potential health (care) effects considering budgetary constraints (formal statistical power calculations are not required for RCTs).

Data:

☐ Determine the critical data elements in the MDS, QIs, and other desirable but not essential variables of outcome (confounders and co-factors).

☐ Use existing data standards and data dictionaries when appropriate

☐ Check whether data from other sources have sufficient quality to achieve the QRs purpose and make use of interoperability with other databases and registries (minimises efforts and costs of data collection).

Exposure:

☐ Collect information on the start and stop of all dementia-related health care services and treatments (e.g. cognitive assessments, neuropsychiatric tests, the dose of cholinesterase inhibitors, antidepressants, antipsychotics etc.).

Outcomes:

☐ Choose MDS, quality indicators and outcomes which have an evidence foundation and are clinically reasonable and relevant for patients and dementia care providers.

☐ Consider international standards for dementia care-related data elements for the MDS, quality indicators, and other standardised outcome measures (core sets).

☐ Use validated tests and scales for diagnosing dementia (e.g. MMSE, MoCA) and assessing dementia-relevant health domains (e.g. NPI), including measures for patient- and carer-reported outcomes (e.g. HRQoL).

☐ Consider the setting where the data and outcomes are collected, e.g. in the primary care setting and/or the specialist care setting (memory clinics), as the setting may influence the accuracy and specificity of the data.

☐ Potential sources of errors relating to accuracy and specificity should be evaluated and quantified through database and/or site reviews.

Effect modifiers:

☐ Identify important factors or characteristics that can impact the relevant outcome, such as exposures (treatment), medical history, risk and resilience factors (consider feasibility and efficiency of data collection and reporting burden).

Safety:

☐ Specify and report dementia care-related safety events (satisfying regulatory requirements).

Analysis plan:

☐ Develop a high-level data analysis plan to address quality improvement-related research questions and handle missing data.

Research method quality: *Framework design* [1, 36]

Ethics and data protection:

- ☐ Specify ethic- and privacy-relevant issues such as mode of consent and data security and match solutions with regulations
- ☐ Obtain review and approval by an ethics, data protection, or review committee before implementing the QR, and clarify any issues concerning the further use of the data outside the quality improvement domain.
- ☐ Determine adequate personnel and infrastructure, including data storage and protection capacities (e.g. firewalls, encryption methods etc.).
- ☐ Specify adequate methods for data linkage, e.g. use a patient identifier and use pseudonymisation or anonymisation strategies.

Governance:

- ☐ Devise a clear governance structure plan that assigns rights, duties, and tasks such as data access and uses to particular entities and describe each role clearly, including the role of external institutions and organisations.
- ☐ Consider employing a steering group comprising dementia care-related experts such as geriatricians, nursing experts, and patient and carer representatives as complementing the expertise from participating dementia care units (see Table 3-4: Fields of expertise of the steering group members). A steering group can provide added value for scientific and methodological purposes and ensure that independent checks and balances are in place.
- ☐ Consider how decisions or recommendations will be agreed on (consensus or voting) if a steering group is employed.

Transparency:

- ☐ If data is made available for research purposes, consider how to allow researchers access to the data and ensure accurate and secure data transfers. Define a process and means for the data access (e.g. expression of interest forms, data access forms specifying information on the research topic, purpose, publication policy, and other research protocol information).
- ☐ Define how results of quality improvement analysis and 'external' research are communicated to the public (website of the dementia QR, newsletter etc.).

Change process/management:

- ☐ Formulate a change management strategy as aims, purposes, or outcome measures can change, e.g. sometimes it can be necessary to change a diagnosis-centred QI set to more treatment and support-focused QI set.
- ☐ Develop a plan for periodic review and stopping or transitioning the dementia QR if necessary.

Evidence quality: *Methods* [1, 36]

Data collection:

- ☐ Consider that an efficient, reliable, feasible, and consistent approach to collecting data is essential. Priority should be given to simplicity and accuracy. Using validation tools such as logical checks in the input software can support consistent data collection (see further examples of validation tools in section 3.4.4 Quality assurance, validation strategies, and safeguards).

Site and patient recruitment and follow-up:

- ☐ Develop plans and materials for participating sites on how to collect initial data and follow-up data of all patients in a consistent way. A systematic follow-up can minimise loss to follow-up. Any loss to follow-up should be documented and evaluated.
- ☐ Consider a small-scale registry data proof of concept (prototype) to investigate the effectiveness and efficiency of the recommended before finally implementing the dementia QR.

Data collection guidance:

- ☐ Consider documentation of data collection methods, including the use of data standards, elaboration of a data dictionary, use of coding that is consistent with an internationally approved coding system.

Quality assurance:

- ☐ Devise a data handling and analysis plan, formulating quality assurance activities.
- ☐ Data checks and validation strategies when entering data, such as logical and range checks, should be implemented in all participating sites.
- ☐ Monitoring and other data validation strategies (see section 3.4.4 Quality assurance, validation strategies, and safeguards), such as external and internal audits, are recommended.

Evidence quality: *Reporting* [1, 36]

Overall reporting:

- ☐ Consider that reports, such as annual reports, should always describe methods used, analysed dementia population, reporting period, care setting and participating sites, data collection, reported QIs and outcome measures, quality control methods, statistical methods, and compliance with regulatory rules ('External' research should at least meet these requirements, but there are guidelines for observational/cohort studies, e.g. STROBE checklist for cohort studies [146]).

Analytics:

- ☐ Consider that results should be reported for the whole specified QI set, including confidence intervals if a cross-sectional analysis of participating sites or regions is conducted.
- ☐ Any impact of missing data or potential confounding variables should be considered.

Comparisons:

- ☐ For comparisons, the comparator is a medical practice for the appropriate reference time period. If such comparative data are not available, then historical data should be used with proper justification.

6 Conclusion

Zunahme an Nutzung von QR

In recent years, the use of quality registries (QR) – a subset of patient registries – has become more common. QRs are systems of ongoing registration of care data to better support decision-makers and healthcare planners in developing optimal dementia care pathways while improving the quality of health care services and patient outcomes.

Bericht als Entscheidungsunterstützung für Implementierung eines Demenz-QR bzw. zur Verbesserung bestehender QR-Praktiken

This report aims to provide decision support for implementing an Austria-wide dementia QR, building on international evidence of QRs and the so-called 'registry science' literature. In the first part of the report (section 3), a review of international dementia QRs was conducted. The first part's primary focus was identifying relevant planning, designing, implementation, and operational aspects of the six identified dementia QRs. The second part of the report (section 4) aimed to give an overview of quality indicators (QIs) used by the identified QRs to monitor, benchmark, and improve dementia care quality. In the final part of the report (section 0), the empirical results, in combination with good registry practice from the literature, were embedded into a good practice framework.

QR = komplexes System in einem komplexen Umfeld

The structured hand search and the embedding of the empirical results into the good practice framework revealed that dementia QRs are complex systems operating in a complex environment – the healthcare system and all its stakeholders. Various interdisciplinary aspects from organisational theory, data management and information theory, health sciences and evaluation and outcome research need to be considered in the different phases of setting up a QR, operating it and deriving conclusions for improving dementia care.

alle relevanten Aspekte in der Planungs-, Design- sowie Umsetzungsphase benötigen große Aufmerksamkeit

Aspects of the following thematic blocks essential for a QR have emerged:

- Planning, design and methodological information,
- Governance and funding, including recruitment of patients and participating sites,
- Data management:
  - Data elements, the minimum data set, and quality indicators,
  - Data sources and interoperability,
  - Data collection and quality assurance,
  - Analysis, interpretation, and reporting.
- Privacy, consent, and ethics,
- Other relevant domains, e.g. change management,
- Evaluation of the registry's quality.

bestehende Demenz-QR weisen Ähnlichkeiten auf …

The identified QRs share similarities with respect to the thematic blocks but also have health system-specific characteristics. For example, a clear identification of a governance pattern was not possible. However, they overlap regarding their expertise within the steering group (SG) or the possibility of linking data to other databases and registries.

… aber auch Unterschiede

Heterogeneity became most evident when looking at the minimum data sets (MDS) and QI sets (section 4). Indicators overlap slightly across registries (section 4.2.3), but most of the identified QIs are used in only individual registries. Nevertheless, practice shows that each QR commits to a manageable number of QIs. The focus is on evidence-based and/or consensus-based quality and not quantity. Another notable observation was that most indicators

target the process quality of dementia care. Outcome QIs form only a minority. This observation applies specifically to patient-oriented outcome indicators. Patient-oriented outcome measures require further investigation in the dementia QR context. In general, the consideration of the patient's and caregiver's perspective is essential in all phases of planning and setting up a dementia QR.

bestehende Demenz-QR versuchen Good Practice-Strategien umzusetzen

The embedding of the six identified registries in the formulated good practice framework has shown that existing QRs strive to implement an extensive set of good practice strategies to make dementia care visible and to identify the potential for quality improvement. The inferred good practice strategies provide 'lessons learned' that can be used for future QRs in dementia care and for existing QRs.

Kooperation aller Interessengruppen ist essentiell

The increasing availability of digitised health (care) data and the need to coordinate the care of dementia patients on several care levels require the cooperation of all stakeholders concerned. In addition, the identified dementia QRs showed that not only the cooperation of stakeholders is necessary. Linking the dementia QR database with various other health (care) data systems through patient identifiers is an essential aspect to ensure interoperability.

es gilt zahlreiche Aspekte zu berücksichtigen

Collecting robust data on the quality of care is important to stimulate continuous and structured quality improvement. One way to manage these tasks is through quality registries. Numerous aspects have to be taken into account for efficient functioning.

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Appendix

Identified countries and registries

Table A-1: Identified countries and registries including sources

Country	Registry name	Coverage	QR dementia	Purpose	Source
Argentina	Cognitive Impairment Centralized Case Registry in Argentina (ReDeCAr)	National	N	EP	[26]
Australia	Australian Dementia Network Clinical Quality (ADNeT) Registry	National	Y	QR	[147]
Australia	Registry for Senior Australians (ROSA)	National	N	QR*	[60]
Austria	Prospective Dementia Registry Austria (PRODEM)	National	N	RES	[148]
Belgium	No registry/information NA	-	N	-	[56]
Bosnia and Herzegovina	No registry/information NA	-	N	-	[56]
Bulgaria	No registry/information NA	-	N	-	[56]
Canada	the IMAGE Project Population – Based Registry of AD	Local (Quebec)	N	EP	[26]
Canada	Canadian Primary Care Sentinel Surveillance Network (CPCSSN)	National	N	SURV	[149]
Colombia	Alzheimer's Prevention Initiative (API) Colombian Registry	Local (Antioquia)	N	RES	[26]
Croatia	No registry/information NA	-	N	-	[56]
Cyprus	No registry/information NA	-	N	-	[56]
Czech Republic	No registry/information NA	-	N	-	[56]
Denmark	Danish Dementia Registry (DanDem)	National	Y	QR	[150]
Denmark	Denmark: National health registers (The National Patient Registry, The Psychiatric Central Registry, The Danish National Prescription Registry)	National	N	NHR	[26]
Estonia	No registry/information NA	-	N	-	[56]
Finland	No registry/information NA, but other QR	-	N	Other**	[56]
France	French National Alzheimer Database	National	N	EP	[26]
Germany	digiDem (former Bavarian Dementia Survey (BayDem)/Erlangen Dementia Registry)	Local (Bavaria)	N	RES	[151]
Gibraltar	No registry/information NA	-	N	-	[56]
Greece	No registry/information NA	-	N	-	[56]
Hungary	NEUROHUN	National	N	EP	[152]
Iceland	No registry/information NA	-	N	-	[56]

Country	Registry name	Coverage	QR dementia	Purpose	Source
Ireland	National Dementia Registry Ireland	National	Y	QR	[32]
Israel	Israel Registry for Alzheimer's Prevention (IRAP)	National	N	EP	[56]
Italy	Experimental Registry for AD/other Dementias	Local (Tuscany)	N	EP	[26]
Japan	Organised Registration for the Assessment of dementia on Nation-wide General consortium toward effective treatment in Japan (ORANGE)	National	N	EP	[153]
Latvia	No registry/information NA	-	N	-	[56]
Lithuania	No registry/information NA	-	N	-	[56]
Luxembourg	No registry/information NA	-	N	-	[56]
Malta	Epidemiological registry	National	N	EP	[154]
Montenegro	No registry/information NA	-	N	-	[56]
Netherlands	Register Dementiezorg en Ondersteuning/Register for Dementia Care and Support (Nivel)	National	Y	QR*	[61]
Netherlands	Hersen ondersoek nl	National	N	RES	[155]
North Macedonia	No registry/information NA	-	N	-	[56]
Norway	Health and Memory Study of Nord- Trøndelag	Local (Nord- Trøndelag)	N	RES	[26]
Norway	Norwegian Dementia Registry (NorKog)	National	Y	QR	[156]
Poland	No registry/information NA	National	N	-	[56]
Portugal	No registry/information NA	National	N	-	[56]
Romania	No registry/information NA	National	N	-	[56]
South Korea	Clinical Research Center for Dementia of South Korea (CREDOS) Study	National	N	RES	[157]
Slovakia	No registry/information NA	National	N	-	[56]
Slovenia	No registry/information NA but will implement according to national strategy	National	N	-	[57]
Spain	No registry/information NA but will implement according to national strategy	National	N	-	[58]
Spain	Registry of Dementia of Girona (ReDeGi)	Local (Girona)	N	EP	[26]
Sweden	Swedish Dementia Registry (SveDem)	National	Y	QR	[126]
Sweden	Swedish Behavioural and Psychological Symptoms of Dementia (BPSD) Registry	National	Y	QR	[158]
Switzerland	Register für Gehirngesundheit Schweiz (Brain health register)	National	N	RES	[26]
UK – England	see UK	see UK	see UK	-	
UK – Northern Ireland	see UK	see UK	see UK	-	
UK – Scotland	see UK	see UK	see UK	-	
UK – Wales	see UK	see UK	see UK	-	

Country	Registry name	Coverage	QR dementia	Purpose	Source
UK	Join Dementia Research (JDR)	National	N	RES	[26]
UK	NHS digital/GP dementia registration	National	N	SURV	[159]
UK	Camberwell Dementia Case Register	Local (Camberwell)	N	EP	[26]
UK	CHARIOT (Cognitive Health in Ageing Register: Investigational, Observational and Trial studies in dementia research)	Local (London)	N	RES	[26]
UK	Dementia Register (DemReg) – Dementia Research Registry North Thames DeNDRoN and EVIDEM (Evidence-based Interventions in Dementia) programme	Local (North Thames)	N	RES	[26]
UK	Scottish Dementia Research Interest Register (SDRIR)	Local (Scotland)	N	RES	[26]
USA	Consortium to Establish a Registry for Alzheimer's Disease (CERAD)	National	N	NHR	[26]
USA	National Alzheimer's Coordinating Center (NACC) Database	National	N	RES	[26]
USA	Alzheimer's Prevention Registry (APR)	National	N	RES	[26]
USA	Global Alzheimer Platform (GAP) Trial Ready Cohort for Preclinical/Prodromal Alzheimer's Disease (TRC PAD)	National	N	RES	[26]
USA	Alzheimer's Prevention Registry/Arizona Alzheimer Registry	National/State-wide (Arizona)	N	RES	[26]
USA	Brain Health Registry	National	N	RES	[26]
USA	Alzheimer Disease Patient Registry (ADPR) of the University of Washington/Alzheimer Disease Research Center (ADRC) registry	State-wide (Washington)/National	N	RES	[26]
USA	AD/Related Dementia State Registry, will implement some type of CQR	State-wide (Georgia)	N	EP	[26]
USA	New York State Department of Health AD/Other Dementias Registry	State-wide (New York)	N	EP	[26]
USA	South Carolina AD Registry	State-wide (South Carolina)	N	EP	[26]
USA	West Virginia AD Registry	State-wide (West Virginia)	N	EP	[26]
USA	Wisconsin Registry for Alzheimer Prevention (WRAP)	Local (Wisconsin)	N	EP	[26]

Abbreviations: EP … epidemiological registry, N … no, NA … not available, NHS … national health register, QR … quality registry, RES … research registry, SURV … surveillance registry, UK … United Kingdom, USA … United States of America, Y … yes

**does not qualify as a dementia quality registry*

*** has various other disease QRs*

Extraction tables: Quality registry profile and quality indicators

Australia: The Australian Dementia Network Registry (ADNeT)

Table A-2: Quality registry profile: Australian Dementia Network Registry (ADNeT)

Country: Australia		Sources
General and methodological information		
General information		
Registry name	The Australian Dementia Network (ADNeT) Registry	
No. of inhabitants	25,698,093	[160]
Dementia prevalence	National estimates (2018): ~386,000 (1.5% of population[65])	[161]
Coverage	National	[95]
First launched and duration	2020-ongoing	[95]
First annual report and frequency	2022[66], yearly published	[95]
No. of patients registered/ Size of the register (most recent)	Registered patients in total: 866 (12/2021) Registered patients in total: ~1,000 (05/2022)	[95]
Methodological information		
Dementia type	Wide range of dementia disorders and mild cognitive impairment (MCI): Alzheimer's disease/dementia (AD), mixed AD (MAD), vascular dementia (VAD), dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), unspecified dementia (USD), other types	[95, 147]
Diagnosis system	ICD-10	[162]
Inclusion and exclusion criteria	■ All patients ≥18 years of age who attend a participating site, receive a new diagnosis of either dementia or MCI, and permanent residents of Australia are included. ■ Site participation in the ADNeT registry is voluntary. The registry team, registry promotional activities, and word of mouth identify potential sites.	[95, 147]
Follow-up	■ Continuous follow-up and data linkage; the collection of patient-reported outcomes and experiences (PROMs/PREMs) and carer-reported outcomes and experiences (CROs/CREs) is done annually. ■ MCI patients are recommended to have a re-assessment of cognition within 18 months post diagnosis to monitor changes in cognitive functioning.	[6, 95]
Registry aims and methodology	The aims are: ■ To collect and analyse data to monitor and enhance the quality of care and patient outcomes and their carers (primary aim). ■ To facilitate the recruitment of participants into research and establish a resource available to study the risk factors for, and trajectory of, dementia and MCI (secondary aim).	[95]

[65] Own calculation

[66] The report was published in July 2022 and covers data collected between 10th of March 2020 to 31st December 2021.

Country: Australia		Sources
Use for register-based research	In the course of data collection, the ADNeT registry collects demographic variables and other patient-related data. If the patient volume is sufficient, data to build the quality indicators (QIs) will be risk-adjusted and benchmarked. Researchers interested in accessing data or collaborating on research projects have to complete an expression of interest form and return it to ADNeT. In addition, biotech or pharmaceutical companies and start-ups can apply. Furthermore, linkage to other databases and registers makes it possible to control for potential confounders in studies (see Minimum data set/Variables and Interoperability and readiness for data linkage). Guidance on requesting and handling data is available (https://www.australiandementianetwork.org.au/clinician/resources/). List of publications	[95, 163]
Confounders	The ADNeT Initiative has three key components: ADNeT Registry, ADNeT Screening and Trials, and ADNeT Memory Clinics. The three components, including the registry, are understood as a synergistic, comprehensive, integrated, and coordinated approach to dementia research and clinical practice improvement. The ADNeT registry also connects interested patients to research. List of publications: annual report [95]	[95]
Governance and Management		
Governance	■ Macro level: The Australian Commission on Safety and Quality in Health Care (ACSQHC), established by the Australian state and territory governments is responsible to create a prioritised list of clinical domains for potential development of national clinical quality registries. The ADNeT registry has been developed and implemented relying on the ACSQHC framework for Australian clinical quality registries. ■ Meso level: the ADNeT Initiative is a not-for-profit public company and has three key components: ADNeT Registry, ADNeT Screening and Trials, and ADNeT Memory Clinics Initiative. The Initiative has a management committee with a chair and a central governance team located at the University of Melbourne. The Monash University manages the ADNeT registry and its data (data controller). A steering group (SG) consisting of representatives from key stakeholders, including clinicians, people with lived experience, carers, peak bodies, and researchers, governs the registry. The SG determines the legal entity (custodian), provides governance oversight and strategic direction, and ensures that key deliverables are met on time and within budget. Specific tasks include the development of a strategic plan for registry sustainability, the mechanisms for monitoring registry operational performance and accountability, and assuring those responsible entities carry out certain aspects of the registry such as data housing, registry coordination, data management and reporting. The SG meets formally on a quarterly basis and reports to the ADNeT Management Committee as part of the ADNeT governance structure. Under the direction of the ADNeT registry SG, a management committee comprising of the clinical lead, the academic lead, and Monash University staff, meets regularly to oversee day-to-day operation of the ADNeT registry. ■ Micro level: public and private SCs/MCs carry out dementia examinations and report patient data into the register.	[28, 95]
Geographical setting/Participating sites and No. of participating sites	40 public and private specialist/memory clinics[67] (SCs/MCs) and other dementia and MCI diagnostic services across five states[68]: 29 sites in major cities and 11 sites in regional areas according to the annual report of 2021 (46 clinics are contributing data as of 05/2022)	[95, 147, 164]
Daily management	See Governance and Geographical setting	
Technical management	■ Data controller: ADNeT Initiative ■ Data processor: Monash University ■ Data management: SG with Monash University (lead) and ADNeT Management Committee ■ Information technology (IT) responsibility: University of Newcastle (Prof Michael Breakspear) for the whole ADNeT Initiative and the Monash University for the ADNeT Registry	[95, 147, 164]
Funding/Financing	The National Health and Medical Research Council (NHMRC), National Institute for Dementia Research (NNIDR) programme, and philanthropic organisations fund the ADNeT Initiative, including the registry. Between 2018 and 2023, the NHMRC has committed $ 18 million in funding to establish the ADNeT Initiative.	[95]

[67] Dementia diagnosis also takes place in general practice, hospital inpatient wards, nursing homes, and relevant community services. However, recruiting from these settings is not realised, but ADNeT explores the feasibility via sub-studies.

[68] New South Wales, Queensland, South Australia, Tasmania, Victoria

Country: Australia			Sources
Data management			
General data management			
Data collection and registry maintenance (method of data collection/input)	Web-based data collection by the ADNeT registry based on data input by participating SCs/MCs. The registry development and maintenance are in alignment with the Framework for Australian clinical quality registries[69] [28].		[95, 147]
Data dictionary	ADNeT developed and provides a data dictionary.		[147]
Standard definitions, terminology, and specifications (e.g. ICD-10, ISO etc.)	Dementia disorders are clinically diagnosed according to ICD-10, International Organization for Standardization (ISO) 27001 (information security) and ISO 27002 (information security, cybersecurity and privacy protection – information security controls), ISO 21090:2011 (Health Informatics – Harmonised data types for information exchange)		
Minimum data set and variables	■ Patient data: ■ Name ■ Date of birth ■ Sex ■ Date of death ■ Capacity to be involved in the opt-out process ■ Communication of diagnosis ■ Contact details ■ Person responsible name, preferred spoken language and contact details ■ Carer name, preferred spoken language and contact details ■ Aboriginal and/or Torres Strait Islander ■ Country of birth ■ Preferred spoken language ■ Level of education ■ Labour force status ■ Residential setting ■ Living arrangement ■ Interest in participation in research ■ Service provider data ■ Date of referral ■ Date of initial appointment ■ Date of diagnosis	■ Diagnosis data ■ Past diagnosis of MCI ■ Diagnosis ■ Mode of service delivery ■ Dementia/MCI subtype ■ Number of prescribed medications ■ Number of strokes ■ Hypertension ■ Diabetes ■ Cardiovascular disease ■ Cancer ■ Rapid eye movement (REM) sleep behaviour disorder ■ Falls history in past 12 months ■ Functional measure/s completed ■ Cognitive assessment/s completed ■ Mini-mental status examination (MMSE)/Rowland universal dementia scale (RUDAS)/Montreal Cognitive Assessment (MoCA)/Kimberley Indigenous Cognitive Assessment (KICA) scores ■ Independence in activities of daily living ■ Continence ■ Core blood tests undertaken as part of diagnostic work-up ■ Structural neuroimaging completed as part of diagnostic work-up ■ Functional neuroimaging completed as part of diagnostic work-up ■ Lumbar puncture completed as part of diagnostic work-up ■ Treatment data ■ Acetyl cholinesterase inhibitor recommended or prescribed ■ Follow-up appointment offered	[95]

[69] Currently, the Australian Commission on Safety and Quality in Health Care (ACSQHC) is revising the current version of the framework.

Country: Australia		Sources
Interoperability and data sources		
Interoperability and readiness for data linkage	Linkage of the data from the three key components (ADNeT Registry, Screening and Trials, and Memory Clinics) is possible in order to conduct research. Furthermore, patient identifiers are collected to enable longitudinal data collection via data linkage with data routinely collected by various government bodies (mortality, hospitalisation, prescribed medication, care service utilisation). Data linkage is conducted periodically. The results of the analyses will be undertaken to provide a comprehensive and longitudinal picture of patient outcomes and build the basis of the registry reports. Furthermore, a collaboration with the Registry of Senior Australians (ROSA) has been established, which recruits persons at the time of an aged care assessment in South Australia to monitor the health, service utilisation, medication use and other outcomes of senior Australians.	[95, 147]
Data sources	Direct data entries by participating sites, data from ADNeT Screening and Trials and Memory Clinics, data from other databases, including administrative databases and routinely collected data (mortality, hospitalisation, prescribed medication, care service utilisation).	[95, 147]
Quality assurance and safety		
Quality assurance and validation	The ADNeT registry provides a comprehensive data dictionary containing data elements, formats, ranges, validation rules and definitions to guide data entry. Training, education and ongoing liaison for participating sites to standardise data collection and interpretation are also conducted. Information and introductory videos are available on the website. The ADNeT registry conducts the following validation strategies to ensure the quality, consistency and interpretability of the data: ■ Validation by built-in logical checks: Data elements of the MDS are mandatory variables and variable limits are active to reduce missing data and to ensure data meets formatting and value requirements. For patients with missing information, clinicians are advised to select the "Not stated" response. ■ Validation by routinely conducted measures: Routine cleaning and quality checks of data before entry into the ADNeT registry databases to ensure improved data consistency and quality.	[95, 147]
Data cleaning	See Quality assurance and validation	
Missing data	See Quality assurance and validation	
Protection, security, and safeguards	Login to the registry interface works via a pre-configured username and password controlled by administrators of the system. Databases are housed and managed in an ISO 27001 certified environment Monitoring and protection against malicious software is assured by a Firewall. All information collected is stored securely and treated confidentially (ISO/TS 25237:2008 Pseudonymisation). Compliance with Australian privacy legislation informed by the National eHealth Security and Access Framework and ISO/IEC 27002 assures protection of privacy. Australian QR need to comply with the Security Compliance Guideline for Quality Registries [92].	[95, 147]
Additional aspects		

Informed consent/Participation	■ Opt-out: Patients data are entered into the register once the four-week withdrawal period has expired
	■ Waiver of consent for four patients groups:
	  ■ Patients who have capacity but the diagnosis has not been communicated to the patients
	  ■ Patients who do not have capacity to opt out nor an identified person responsible
	  ■ Patients who do not have capacity and the diagnosis has not been communicated to the person responsible
	  ■ Patients who die prior to the recruitment period.
	When patients are recruited using waiver of consent, no patient contact is made, and data are automatically included in the register. Most ethical guidelines recommend disclosure of diagnosis, but some clinicians might choose not to inform patients for reasons such as patients requesting not to be informed of the diagnosis, concerns about impaired insight among patients, concerns about risk to patients' psychological well-being or requests from family. Hence, compared to other national dementia QRs, which typically use only one consent method, the ADNeT registry includes a larger group of people with dementia and MCI and maximises the registry coverage and inclusiveness. Patients and/or their families can also choose to withdraw from the register at any time. Registered patients and carers can apply to access the stored information at any time by contacting the registry coordinator via email or by phone.
		[95, 147]

Ethics	The ADNeT registry has received approval from the Alfred Hospital Human Research Ethics Committee under the National Mutual Acceptance Scheme (Project Number: 44037, Approval date: 27/08/2018)	[95]

Country: Australia		Sources
Reporting	■ Continuous reporting: in-built ad hoc exporting function to enable data extraction by participating sites and clinicians. ■ Periodic reporting: 1.) bi-annual site reports with a benchmark system (comparison of reporting of opt-out rates, cumulative recruitment of participating sites, and patient response rates across SCs/MCs) and 2.) public accessible annual reports. In the course of preparing the annual report, analyses of the data by descriptive statistics are conducted to provide aggregate summary information regarding cohort characteristics, QIs, PROMs/PREMs and CROs/CREs. Clinicians use reports to inform continuous quality improvement, and providers and government use reports to inform services & policy. The annual reports are published on https://www.australiandementianetwork.org.au/initiatives/clinical-quality-registry/.	[95, 147]
Quality indicators		
Quality indicators, standards of care, and outcome parameters	1. Proportion of patients who had the first appointment within 90 days of referral 2. Proportion of patients who undertook core blood tests as part of the diagnostic work-up (prior to referral) 3. Proportion of patients who had an assessment of multiple cognitive domains as part of the diagnostic work-up 4. Proportion of patients who completed structural neuroimaging as part of the diagnostic work-up 5. Proportion of patients who had an assessment of the capacity to undertake personal and instrumental activities of daily living as part of the diagnostic work-up 6. Proportion of patients whose cognition was re-assessed within 18 months of a MCI diagnosis 7. Proportion of patients with a diagnosis of mild to moderate Alzheimer's disease and a prescription/recommendation of acetyl cholinesterase inhibitors a. patients <85 years b. patients ≥85 years	[95]

Abbreviations: ACSQHC … Australian Commission on Safety and Quality in Health Care, AD … Alzheimer's dementia/Alzheimer's disease, ADNeT … Australian Dementia Network, DLB … dementia with Lewy bodies, FTD … frontotemporal dementia, ISO … International Organisation for Standardisation, KICA … Kimberley Indigenous Cognitive Assessment, MCI … mild cognitive impairment, MMSE … Mini-mental status examination, MoCA … Montreal Cognitive Assessment, PREM … patient-reported experience measure, PROM … patient-reported outcome measure, QI … quality indicator, QR … quality registry, RUDAS … Rowland universal dementia scale, SC/MC … specialist/memory clinic, USD … unspecified dementia, USD … unspecified dementia, VAD … vascular dementia

Table A-3: Quality Indicators: Australian Dementia Network Registry (ADNeT)

Country/Registry: Australia/The Australian Dementia Network (ADNet) Registry						
General information						
The Australian National Health and Medical Research Council funded a modified Delphi study to inform the development of the quality indicators (QIs) for the Australian Dementia Network (ADNeT) Registry before establishing the registry. The Monash University conducted this study in the course of assessing the feasibility of a quality registry (QR) for dementia. The modified Delphi study proposed a set of 18 QIs, which capture quality of care and patient outcomes across the trajectory of care for people with dementia and mild cognitive impairment (MCI). The 18 QIs were presented to the registry steering group (SG) in 2019. Of these 18 QIs, seven have been approved to be included in the registry. Six of the seven QI capture elements of practice considered best standard. The seventh QI, on acetyl cholinesterase inhibitor prescription, was added to examine variations and to facilitate benchmarking. The QIs are regularly reviewed to ensure that they are relevant and meaningful to clinicians and patients. The national service guidelines for specialised dementia and cognitive decline assessment services in Australia for SCs/MCs prepared by the ADNeT initiative also covers the QIs. To date, the registry does not provide any target values. Besides the QIs, the registry collects also data on patient- and carer-reported outcome and experience measures (PROMs/PREMs and CRO/CRE) of clinical care at the point of diagnosis via self-completed postal surveys. Outcomes and experiences categories are adequate information about diagnosis, involved in decision making, opportunity to ask questions, views and concerns were listened to, treated with dignity and respect, given advice about information and help, overall experience with service, meeting expectations. Although PROMs/PREMs and CROs/CREs are seen as "integral parts of a movement towards patient-centred systems of structuring, monitoring, delivering and financing health care", no QI is explicitly based on these measures.						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
1. **Proportion of patients who had the first appointment within 90 days of referral**	Process quality: pre-diagnosis	According to the national/ADNeT guidelines for dementia care, referral from a GP or other health professional is strongly recommended[70], and prioritisation of referral is encouraged. An initial assessment should be conducted within no more than 90 days for routine-priority clients (ideally, within 45 days of referral) and 30 days of receipt of the referral for high-priority clients. SCs/MCs may choose to decline a referral if the cognitive problems are clearly within the context of a psychiatric disorder, non-progressive brain disease with no evidence of decline, traumatic brain injury and/or alcohol dependence, etc.	not specified	59.5%	NA	[6, 95, 96]
2. **Proportion of patients who undertook core blood tests as part of the diagnostic work-up (prior to referral)**	Process quality: diagnosis and diagnostic work-up	The guidelines recommend[71] that core blood tests are undertaken ideally within 3 months or within a maximum of 12 months prior to referral or at the time of the diagnosis.	not specified	95.4%	NA	[6, 95, 96]
3. **Proportion of patients who had an assessment of multiple cognitive domains as part of the diagnostic work-up**	Process quality: diagnosis and diagnostic work-up	The guidelines for dementia care strongly recommend that cognitive testing needs to be tailored to the client's cultural and educational backgrounds and to their presenting symptoms. Assessments by a neuropsychologist should be considered as required in case of: ■ Diagnostic uncertainty/for the purpose of differential diagnosis ■ Complex or unusual symptom patterns ■ Functional decline (especially if the patient has a high level of education) ■ Pronounced speech and language difficulties ■ young onset of dementia (<65 years) ■ understanding the cognitive profile for treatment purposes ■ Pronounced behavioural changes	not specified	99.1%	NA	[6, 95, 96]

[70] Strong recommendation: This standard received the highest level of agreement from health professionals and people with lived experience during the development of the underlying clinical guidelines (>70% of responses were within the high agreement rating on the Likert Scale). The utilisation of this standard represents the fundamentals of a good SC/MC.

[71] Recommendation: This QI received a high level of agreement (>70% of responses were between medium and high agreement ratings on the Likert Scale) from health professionals and lived experience experts during the development of the underlying clinical guidelines. The utilisation of this standard further increases the quality of care.

Country/Registry: Australia/The Australian Dementia Network (ADNet) Registry						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
3. Proportion of patients who had an assessment of multiple cognitive domains as part of the diagnostic work-up *(continuation)*		■ The need for a specific capacity assessment (e.g. for informed decisions on finances, placements into residential aged care etc.) ■ Subtle cognitive changes Assessments by additional allied health professionals (e.g., speech pathologists) should be considered as required.				
4. Proportion of patients who completed structural neuroimaging as part of the diagnostic work-up	Process quality: diagnosis and diagnostic work-up	The guideline recommends that structural neuroimaging is completed ideally within 3 months or within a maximum of 12 months prior to referral or at the time of the diagnosis.	not specified	92.6%	NA	[6, 95, 96]
5. Proportion of patients who had an assessment of the capacity to undertake personal and instrumental activities of daily living (IADL) as part of the diagnostic work-up	Process quality: diagnosis and diagnostic work-up	The guidelines strongly recommend the assessment of a person's ability to undertake personal and IADL. Under some circumstances, an occupational therapist with expertise in dementia is consulted to conduct a standardised performance-based assessment to clarify domains and extent of functional impairment. These circumstances include but are not limited to 1) a client presenting with mild functional impairment and good cognitive test scores; 2) reliable information on the client's IADL not being available.	not specified	97.8%	NA	[6, 95, 96]
6. Proportion of patients whose cognition was re-assessed within 18 months of a MCI diagnosis	Process quality: diagnosis and diagnostic work-up	The national guidelines recommend that SC/MCs follow up all clients with a diagnosis of MCI at least once every 12-18 months based on the clinical judgement and thereafter based on the client's need for review.	not specified	88.3%	NA	[6, 95, 96]
7. Proportion of patients with a diagnosis of mild to moderate Alzheimer's disease and a prescription/recommendation of acetyl cholinesterase inhibitors **a. patients <85 years** **b. patients ≥85 years**	Process quality: treatment, support, and follow-up	NA	not specified	75.3% 58.5%	NA	[6, 95, 96]

Abbreviations: ACSQHC … Australian Commission on Safety and Quality in Health Care, AD … Alzheimer's dementia/Alzheimer's disease, ADNeT … Australian Dementia Network, DLB … dementia with Lewy bodies, FTD … frontotemporal dementia, ISO … International Organisation for Standardisation, KICA … Kimberley Indigenous Cognitive Assessment, MCI … mild cognitive impairment, MMSE … Mini-mental status examination, MoCA … Montreal Cognitive Assessment, PREM … patient-reported experience measure, PROM … patient-reported outcome measure, QI … quality indicator, QR … quality registry, RUDAS … Rowland universal dementia scale, SC/MC … specialist/memory clinic, USD … unspecified dementia, USD … unspecified dementia, VAD … vascular dementia

Denmark: The Danish Quality Database for Dementia (DanDem)

Table A-4: Quality registry profile: Danish Quality Database for Dementia (DanDem)

Country: Denmark		Source
General and methodological information		
General information		
Registry name	Dansk klinisk kvalitetsdatabase for demens/The Danish Quality Database for Dementia (DanDem)	
No. of inhabitants	5,825,337	[160]
Dementia prevalence	National estimates (2022): ~42,150 (0.72% of population[72]) Alzheimer Europe (2018): 87,377 (1.51% of population)	[165-167]
Coverage	National	[80, 168]
First launched and duration	2014/2016[73]-ongoing	[168, 170]
First annual report and frequency	2017, yearly published	[97]
No. of patients registered/Size of the register (most recent)	Examined patients in DanDem in total: 9,282 (2021)[74] Landspatientregisteret (LPR)/National patient registry: 40,000 patients ≥65 years registered with a dementia diagnosis.	[97]
Methodological information		
Dementia type	All dementia disorders and mild cognitive impairment (MCI): Alzheimer's disease/dementia (AD), mixed AD (MAD), vascular dementia (VAD), dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), Parkinson's disease dementia (PDD), Huntington's disease dementia (HDD), unspecified dementia (USD), other and unknown types	[170]
Diagnosis system	ICD-10 and Sundhedsvæsenets Klassifikations System (SKS[75])	[80, 171]
Inclusion and exclusion criteria	All patients ≥18 years of age: ■ Who have had an outpatient dementia examination in a dementia specialist clinic[76]/memory clinic (SC/MC) in the secondary care sector (neurological, geriatric, and psychiatric units in public as well as private dementia examination clinics), and ■ Whose patient registration in the clinical measurement system (KMS[77]) has been submitted Site participation is voluntary. General practitioners or another hospital department typically refer patients to SCs/MCs.	[80, 172]
Follow-up	Continuous follow-up/Currently, no unambiguous "follow-up" definition exists.	[80, 171]

[72] Own calculation

[73] In 2006, the Capital Region of Denmark established a quality registry for the diagnostic evaluation of dementia. In 2014, the registry was approved for the first time and was adjusted to accommodate QIs from the national database and in 2016 the national quality registry for dementia was launched, based partly on the previous regional version from 2006 [169].

[74] DanDem's steering group notes that the total number of patients treated in 2021 (9,282) shows only a slight decrease compared to 2020 (9,625) and 2019 (9,754).

[75] The SKS is a system designed for classification within the hospital system and the primary care sector. The system has been created to ensure clear communication between all groups and actors within the healthcare system, as well as the electronic information systems in the healthcare system. The ICD is embedded in the SKS.

[76] In Denmark, these specialist clinics are called dementia examination units and consist of neurological, geriatric, and psychiatric clinics in the secondary care sector.

[77] The Klinisk Målesystem (KMS)/Clinical measurement system is an online IT system where data can be entered into clinical databases via web forms. KMS is a core tool for manual reporting and is used by 26 registries including DanDem. The current supplier of KMS terminated the agreement with the Regions' Clinical Quality Program (RKKP). A new solution is on the way [74].

Country: Denmark		Source
Registry aims and methodology	The aims are: ■ To improve the quality of the clinical assessment and treatment of patients referred for elective dementia assessment, and ■ To expand the population to include in dementia assessments in primary care.	[80]
Use for register-based research	Access to the nationwide health care registers and registers from other quality registries (QRs) with the possibility of linking makes it possible to carry out large population-based reports and studies. Use of data for quality improvement purposes by dementia care departments/hospitals as well as use of results from other departments/counties for pure quality purposes can be done without protocol and specific application as long as the general guidelines cover the use of clinical quality data. If results are requested for other departments that are not included in the normal reporting of the register, a protocol must be submitted to the Regions' Clinical Quality Program (RKKP), i.e. the operator of the registry, following the same guidelines as for scientific studies. The RKKP provides a data portal for research access (https://rkkp-forskningsadgang.dk/) and guidelines (https://www.rkkp.dk/siteassets/forskning/kontakt-til-patienten-til-forskningsformal/retningslinjer_forskning_version6_2.pdf) on requesting data for research purposes in accordance with the data protection act §10 [143, 173]. Big Data/Machine Learning/Artificial Intelligence projects must be able to document concrete data needs in relation to the implementation of the research project or use of data needs to be made transparent. List of publications [174]	[169, 174, 175]
Confounders	In the course of data collection, DanDem collects demographic variables and other patient-related data. In the annual reports, all analyses are unadjusted. This means that when comparing departmental results, different patient compositions (age, gender, competing diseases, etc.) of specialist/memory clincs (SCs/MCs) and nursing homes are not taken into account. In some cases, unadjusted analyses may contain relevant information, but in other cases, the differences between quality indicator (QI) measurements in the nursing homes are, to some extent, due to differences in patient composition. Furthermore, linkage to other databases and registers makes it possible to control for potential confounders in studies (see Minimum data set/Variables and Interoperability and readiness for data linkage)	[97, 174]
Governance and Management		
Governance	In 2010, the Danish national action plan dementia recommended that actions should be taken to implement a database to improve the dementia care quality. ■ Macro level: the Danish Health Data Authority (Sundhedsdatastyrelsen) is responsible for approving a quality registry. ■ Meso level: The RKKP, with its board of directors (five regional health directors), representatives of the national board of health data, national board of health, Danish regions, and the national association of local authorities, are responsible for the operation and development of approx. 85 nationwide clinical quality databases, including DanDem. The RKKP's professional council has an advisory function in relation to the board and provides professional input to the strategic development of the RKKP. The council consists of representatives of Danish patients, medical societies, other authorised health professional societies, general practitioners, cancer groups, hospital managements with a health professional background, the regions bio- and genome bank, and the National Board of Health. The RKKP's knowledge centre ensures operation, maintenance and development of the clinical quality databases. The RKKP's database department 3 (Psychiatry, gynaecology/obstetrics, and chronic diseases) is responsible for data processing, analyses and epidemiological comments and assists the steering group with epidemiological, biostatistical and informational technology (IT) expertise as well as knowledge about quality development. A steering group consisting of people from different health professions (physicians, nurses, therapists and other professionals from hospitals/nursing homes) governs and monitors the DanDem register. The steering group is responsible for translating the research findings into quality improvements in the health care system. Municipal representatives are being appointed, and the Alzheimer's Association has been invited to participate in the steering group's work as well. The Midtjylland region is the data responsible authority and the data controller for all approved nationwide QRs. The data controller is obliged to ensure that tasks carried out in the course of QRs (ongoing reporting, publication of annual reports, online documentation etc.) are complied with. Furthermore, Midtjylland region is responsible for technical and organisational security measures (see Protection, security, and safeguards). ■ Micro level: SCs/MCs in public hospitals as well as private SCs/MCs carry out dementia examinations and report patient data into the register.	[97, 150, 176, 177]
Geographical setting/Participating sites and No. of participating sites	37 public and private SCs/MCs (neurological, geriatric, and psychiatric) in the secondary care sector.	[97]
Daily management	See governance and geographical setting	
Technical management	■ Data controller: Midtjylland Region ■ Data management (operation, maintenance, and quality development), data processor and IT responsibility: The RKKP's Knowledge Centre with its three database departments (1. Cardiovasculary, surgery, and emergency area, 2. Cancer/cancer screening, and 3. Psychiatry, Gynaecology/obstetrics and chronic diseases–the departments consist of database-specific teams with a quality consultant, a data manager and an epidemiologist), digitisation and informatics department (KMS account administration, system management, system development of data entry systems and stable operational settlement of the databases), and resources and innovation department (coordination, portfolio management, HR and administration)	[176]

Country: Denmark			Source
Funding/Financing	The funding of DanDem and all other quality registries works through a national initiative, mandated by law and regulated by national government, but financed and owned by regional governments.		[178]
Data management			
General data management			
Data collection and registry maintenance (method of data collection/input)	Web-based data collection of patient data and data of next of kin by SCs/MCs in public hospitals, as well as private dementia examination clinics. The data is transmitted to a central database server. The data from the clinical quality database is passed on to the Danish Health and Medicines Authority. The Danish Health and Medicines Authority pseudonymises data immediately after receipt so that data is not stored in directly personally identifiable form.		[80, 179]
Data dictionary	NA		
Standard definitions, terminology, and specifications (e.g. ICD-10, ISO etc.)	Dementia disorders are clinically diagnosed according to ICD-10. The Danish Medical Classification System – Sundhedsvæsenets Klassifikations System (SKS) based on ICD-10 is used as a basis for information about tests, treatments and diagnoses, ISO 27001 standard for Information technology – Security techniques – Information security management systems – Requirements		[171, 180]
Minimum data set and Variables	■ Patient data: ■ Central person registry (CPR) number ■ Carer/Relative present ■ Living condition ■ Service provider data: ■ Type of referral/evaluation ■ Date of first visit ■ Date for information visit ■ Is the patient discharged at this visit? ■ Diagnosis data: ■ MMSE done? ■ MMSE score ■ IADL-FAQ done? ■ IADL-FAQ score ■ Blood tests ■ CT brain scan ■ MRI brain scan ■ If no brain scan (contraindication/not relevant/patient cannot cooperate) ■ Dementia (general cognitive status) ■ Diagnosis ■ Treatment and care data: ■ Dementia medication ■ Anti-depressive treatment ■ Anti-psychotic treatment ■ Variables for QI formation (QI): ■ CPR status, e.g. active, residence in the Danish civil register (1, 1a, 1b, 30, 31) ■ CPR date of status (1, 1a, 1b, 9, 10) ■ Patient type in KMS, genetic counselling examination, or clinical examination (1, 1a, 1b, 2, 2a, 3)	■ Investigation time (QI 1) ■ Referral type, e.g. primary dementia investigation, second opinion etc. (1, 1a, 1b, 2, 2a, 3, 6a, 7) ■ Date of diagnostic interview (1, 1a, 9, 10) ■ Informant/Relative present (3) ■ CAMcog done (2a) ■ RUDAS done (2a) ■ DSQIID – Trindvold done (2) ■ Neuropsychologist test done (2a) ■ Cognitive test performed (2) ■ ADL performed (3) ■ CT scan (4) ■ MR scan (4, 4a) ■ Degree of cognitive impact (2, 2a, 3, 4, 4a, 5, 6, 6a, 7, 8) ■ Aetiological diagnosis (5, 6, 6a, 8) ■ Medication (6, 6a) ■ Psychosocial offer (7) ■ Number of days from start of treatment in LPR to diagnosis interview date (1a) ■ Prescription redeemed from 1 month before and up to 3 months after the diagnosis interview date (6a) ■ Referral date (1, 1b) ■ First contact (1a, 1b) ■ Process start in registry/diagnosis date (9,10) ■ End of process (9, 10) ■ Waiting time/Time from referral to 1st contact (1b) ■ Pacemaker present (4a) For a more comprehensive list of registered variables, see the DanDem variable list [80]	[80, 181]

Country: Denmark		Source
Interoperability and data sources		
Interoperability and readiness for data linkage	In Denmark, registered patients receive a personal identification number (patient identifier). The Danish personal identification numbers make it possible to link data across national health registers – and all other health data in Denmark. The IT system, reporting and feedback to the database of DanDem, is based on KMS.	[80, 150, 171]
Data sources	Direct data entries in the KMS, LPR, Civil Registration System (CPR), National Prescription Registry (NPR)	[80]
Quality assurance and safety		
Quality assurance and validation	In addition to building the skills and abilities of staff working with DanDem to meet the challenges of digitisation, the RKKP provides guidance for working with its databases (data input/management). RKKP also provides a Handbook of clinical quality improvement [90] in Danish for clinicians and persons who work with database improvement of clinical services. Furthermore, the RKKP provides telephone support for all KMS registers, and every region has a separate contact person for questions about data input. The RKKP undertakes various quality assurance and validation measures: ■ Validation by built-in logical checks: It is not possible to submit the form without all data being entered. Furthermore, the clinician entering the data receives alerts/can correct wrong entries immediately. ■ Validation by routinely conducted measures (for all RKKP registries): Tasks include standardisation of data structures, elimination of double entries across registers, automation of reporting, information security measures, cooperation between RKKP databases and stakeholders across the health care system (create greater transparency), and staff and skills development (capacity and skills building for challenges of digitalisation). ■ Validation by (external) appraisal: every Danish QR, including DanDem, has to pass an appraisal every three years by the National Board of Health to see if it meets the national criteria for functionality, data security and methodology. ■ Validation in connection with the annual report: The validity of entries in the KMS as well as the data from LPR is assessed at least once a year with the preparation of the annual report.	[74, 80, 178, 182, 183]
Data cleaning	See Quality assurance and validation	
Missing data	The database entry form will be constructed so that it is impossible to submit the form without all data being entered. This means that there should be no missing data for those patients who are entered immediately. Furthermore, cases in the register are matched with data from Landspatientregisteret/National patient registry (LPR[78]). Database completeness is then calculated as follows $$Coverage = \frac{only\ in\ KMS + in\ KMS + in\ LPR}{only\ in\ KMS\ + in\ KMS\ +\ LPR\ +\ only\ in\ LPR}$$	[80, 179]
Protection, security, and safeguards	Midtjylland region and the RKKP management are responsible for ensuring that the necessary technical and organisational security measures for all nationwide clinical quality databases are in place. These tasks include that processing personal data follows the terms approved by the Danish Health Data Authority (prevent data from being accidentally or unlawfully destroyed or lost). When using internal networks within the RKKP environment, it must be ensured that unauthorised persons cannot access the information. Access to the data is restricted by means of a confidential password. Password is replaced at least once a year and when otherwise necessary for security processing of the data. When personal data are transmitted (input via KMS and output vis LIS) via the Internet or other external networks, appropriate security measures shall be taken to prevent unauthorised access to such data. This includes the use of encryption where sensitive personal data are transmitted over the Internet (or other open networks), the assurance of authenticity (identity of the sender and receiver) and integrity (authenticity of the transmitted data), as appropriate, through the use of appropriate security measures. All participating sites have a firewall, as the data is online accessible from all computers within the respective facility.	[180, 184]

[78] All Danish in- and out-patients who have had contact with a Danish health care facility are registered in the LPR, the Danish national health register, with basic information, such as diagnostic codes and procedures. Regarding dementia care, all patients that had a dementia assessment/screening examination for dementia (procedure code ZZ1500/ZZ1500A) are registered in the LPR. This number is used in the calculation for database completeness in DanDem.

Country: Denmark		Source
Additional aspects		
Informed consent/Participation	Patient consent is not required for data collection for DanDem, as for all health data in Denmark, according to the Danish Health Data Authority.	[178]
Ethics	For research, patients may not be contacted directly based on extracts from the databases unless there is a separate legal basis (e.g. in the form of approval from a scientific ethics committee, the regional council or consent from the patients obtained by the therapist). Direct inquiries to patients presuppose that permission has been given by the person responsible for treatment or the management at the treatment site (section 46 (6) of the Health Act).	[173, 185]
Reporting	■ Continuous reporting: Units can view data on their own patients including QIs in their regional Management Information System (LIS). Data and QI results have to be updated monthly by the data controller (Midtjylland Region). Viewing the aggregated data of other units/regions by each SCs/MCs is also possible, but for data protection reasons only to a limited extent and only via the regions' intranet. ■ Periodic reporting: Results from the register are published in an annual report. The annual report contains statements of QIs at departmental, regional, and national level, which have been professionally assessed and commented on. The annual reports are published on www.sundhed.dk.	[97, 186]
Quality indicators		
Quality indicators, standards of care, and outcome parameters	1. Proportion of patients with a definitive diagnosis of dementia <90 days of first visit/first dementia indications a. Time from start of investigation (1st contact) to time point of diagnosis (1st report) b. Time from referral to first contact (waiting time) 2. Proportion of patients who had a cognitive test in the specialist clinic/memory clinic (dementia assessment unit) a. Proportion of all patients who had an extended cognitive test in the specialist clinic/memory clinic (dementia assessment) 3. Proportion of patients evaluated who have had an ADL assessment using the FAQ/IADL scale, DAD, ADCS-ADL or Trindvold/DSQIID 4. Proportion of patients who had a CT/MR scan of the brain within the past 24 months (structural imaging procedure) a. Proportion of patients with mild-moderate vascular dementia who had an MRI scan of the brain in the last 24 months 5. Proportion of patients with a specific diagnosis of dementia (Aetiological diagnosis) 6. Proportion of patients with AD, PDD, DLB, and mixed dementia who are treated with anti-dementia medication a. Proportion of patients with a prescription for dementia medication who have filled a prescription up to three months after the diagnosis interview 7. Proportion of patients with dementia who have received a psychosocial offer in connection with information about the diagnosis (psychosocial offer) 8. Proportion of patients with AD and mild dementia who have had a lumbar puncture in the diagnostic workup or PET scan within 24 months before the date of referral (Alzheimer's biomarker) 9. Coverage 10. Degree of concordance	[80, 97, 187]

Abbreviations: ACE … Addenbrooke's cognitive examination, AD … Alzheimer's dementia/Alzheimer's disease, ADAScog … Alzheimer's Disease Assessment Scale-Cognitive Subscale, ADL … activities of daily living, ASCS-ADL … Alzheimer's Disease Cooperative Study, BPSD … behavioural and psychological symptoms of dementia, CI … confidence interval, CPR … civil registration system, CSF … cerebrospinal fluid, CT … computed tomography scan, DAD … disability assessment for dementia, DLB … dementia with Lewy bodies, DSQIID/Trindvold … Dementia Screening Questionnaire for Individuals with Intellectual Disabilities, FAQ-IADL … Functional Activities Questionnaire Instrumental Activities of Daily Life, FTD … frontotemporal dementia, HDD … Huntington's disease dementia, ICD … International Classification of Diseases, IQR … interquartile range, IT … information technology, KMS … clinical measurement system, LIS … Ledelses Informations System/Management Information System, LPR … Landspatientregisteret/National patient registry, MAD … mixed AD/dementia, MCI … mild cognitive impairment, MDD … major depressive disorder, MMSE-SR … Mini-Mental Status Examination-Swedish revision, MoCA … Montreal cognitive assessment, MR(I) … magnetic resonance (imaging), MR … magnetic resonance, NA … not available, PCU … primary care unit, PDD … Parkinson's disease dementia, PET … positron emission tomography, QI … quality indicator, RKKP … Regional Clinical Quality Program, RUDAS-S … Rowland Universal Dementia Assessment Scale-Sweden, SC/MC … specialist/memory clinic, SG … steering group, SKS … Sundhedsvæsenets Klassifikations System, USD … unspecified dementia, VAD … vascular dementia

Table A-5: Quality indicators: Danish Quality Database for Dementia (DanDem)

Country/registry: Denmark/Dansk klinisk kvalitetsdatabase for demens/Danish quality database for dementia (DanDem)						
General information						
In total, DanDem has 15 quality indicators (QIs), of which eight QIs are analysed and reported in an annual report. Four QIs have sub-indicators (1a, 2a, 4a and 6a) [97]. All QIs target the process quality of dementia care. None of the QIs are explicitly based on national guidelines or specific evidence syntheses, but consensus-based on the decision of the steering group (SG). Nonetheless, the SG defines the QIs based on clinical guidelines and knowledge of good quality in practice. Collected data are analysed and interpreted on an ongoing basis. Information technology (IT) expert opinions are consulted on whether adjustments to QIs are needed [186]. QIs 1 to 7 describe basic aspects of the examination process of suspected dementia. There has been a desire to include focus areas clarified by the recent national clinical guidelines, including knowledge when additional diagnostic examinations are advised to support a disease-specific dementia diagnosis in mild to moderate dementia. Therefore, QI 8 considers the use of additional diagnostic and screening approaches to support disease-specific dementia diagnosis. QI 8 is considered for the first time in the annual report for 2021. The Regions' Clinical Quality Program (RKKP) provides guidance for working with its databases (data input/management), an Evidence report for working with the QIs, and a Handbook of clinical quality improvement [90] in Danish for clinicians and persons who work with database improvement of clinical services. Practical information on implementation, dissemination and maintenance of achieved clinical improvements can be found in the Implementation handbook [89] on the Danish Health and Medicines Authority's website.						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value[79]**	**Results, data and conclusions**	**Source**
1. Proportion of patients with a definitive diagnosis of dementia <90 days of first visit/ first dementia indications	Process quality: pre-diagnosis	The QI shows the waiting time from referral to first visit. ■ Indicator population (denominator): All patients referred for medical advice, not referred with a definite diagnosis, found to be matched with a care sequence in the Landspatientregisteret/National patient register (LPR) and date of diagnostic interview recorded in the clinical measurement system (KMS). Patients who died before the diagnostic interview are excluded. ■ Numerator: Patients with a follow-up time of <90 days follow-up time is calculated as time from referral to diagnostic interview. Cases not matched with cases in LPR are recorded as unresolved The SG recommends that close relatives/caregivers accompany referred patients for dementia assessment. The assessment should be arranged with the close relative/caregiver, and waiting time for the appointment should be as short as possible (risk of patients and/or relatives forgetting the appointment increases with longer waiting times). However, the SG states that a very short investigation time does not necessarily indicate good quality and may reflect different working practices in the individual investigation units. The total time will also depend on the extent to which additional tests such as neuropsychological testing, magnetic resonance (MR) scanning, positron emission tomography (PET) scanning and, for example, spinal fluid testing are performed to make a disease-specific dementia diagnosis.	>80%	42% (95% confidence interval [CI]: 41-43%) (not fulfilled)	At national level, the trend graph for 2021 showed no fluctuation compared to 2020 in the proportion of patients who completed their assessment within 90 days of referral Compared to 2019, there was a decrease of 10% at national level (42% in 2021 vs 52% in 2019)[80]. No region met the standard, and there was great variation between all five regions (16-58%) and special/memory clinics (SCs/MCs). The SG noted a large variation in the number of dementia assessments performed in each unit[81]. The SG recommended identifying possible bottlenecks and capacity challenges in the outpatient services, including access to additional examinations and neuropsychologists.	[80, 97, 187]

[79] Actual values consider reported values of the latest annual report (2021) on a national level.

[80] 2021, like 2020, has been characterised by COVID-19, which has at times meant cancellations of planned activities in most places, partly due to COVID preparedness, but the SG noted that cancellations have been caught up.

[81] Results from SCs/MCs with small patient numbers should be interpreted with caution, as a single or few patients can have a large impact on the units.

Country/registry: Denmark/Dansk klinisk kvalitetsdatabase for demens/Danish quality database for dementia (DanDem)						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value[79]**	**Results, data and conclusions**	**Source**
a. Time from start of investigation (1st contact) to time point of diagnosis (1st report)	Process quality: pre-diagnosis	The QI shows the time from the patient's 1st contact to the time point of diagnosis (examination report) ■ Indicator population (denominator): All patients referred for medical advice, not referred with a definite diagnosis, found to have a match in the LPR and a date of diagnosis recorded in the KMS. Patients who died before the diagnostic interview are excluded. Median time from start of investigation (1st contact in the care sequence) to date of diagnostic interview is calculated. Cases where no match with case in LPR is found are recorded as unresolved	No set standard, but improvement direction is downwards	Median: 49 days (interquartile range [IQR]: 0-102 days)	On a national level, the date of the first contact coincided with the date of the diagnostic interview for at least 25% of the patients. Some SCs/MCs had a median time of 0 days, i.e. at least 50% of patients received a diagnosis – and according to the SG, too many received a disease-specific dementia diagnosis at the first visit. The SG raised some doubts as to whether patients are adequately examined according to guidelines (neuropsychological testing, functional scans such as positron emission tomography and/or spinal fluid testing with biomarker). Rapid assessment cannot necessarily be equated with good quality. The SG encourages SCs/MCs with short screening times to comment on this in the annual report consultation response. A very long investigation time can partly be an expression of a long wait for the use of additional examination tools. The SG encourages units with very long waiting times to look at whether areas for action can be identified: ■ Optimisation of workflows and identification of bottlenecks ■ Capacity challenges in the outpatient unit with regard to the staff who have to discharge the patient	[80, 97, 187]
b. Time from referral to first contact (waiting time)	Process quality: pre-diagnosis	The QI shows the waiting time: ■ Indicator population (denominator): All patients referred for medical advice, not referred with a definite diagnosis, found to have a match in the LPR and a date of diagnosis recorded in the KMS. Patients who died before the diagnostic interview are excluded. The median time from referral to the start of the investigation (1st contact in the care sequence) is calculated. Cases where no match with case in LPR is found are recorded as unresolved	No set standard, but improvement direction is downwards	Not reported in the annual report	-	[80, 97, 187]
2. Proportion of patients who had a cognitive test in the specialist clinic/ memory clinic (dementia assessment unit)	Process quality: diagnosis and diagnostic work-up	The QI shows the proportion of patients who have been assessed and who have had a cognitive test in a dementia unit: ■ Indicator population (denominator): All patients referred for medical advice and not re-referred with a definite diagnosis ■ Numerator: Patients who had a cognitive test performed in a dementia SCs/MCs during the assessment Cognitive testing is an essential test in investigating suspected dementia and a prerequisite for assessing cognitive function.	>90%	99% (95 % CI: 98-99 %) (fulfilled)	All regions and almost all SCs/MCs (except two of 37) met the target value in 2021. The region-level trend graph showed that indicator compliance has been high since the database's inception in 2016, but that region results have gradually improved and become more consistent over the life of the database.	[80, 97, 187]

Country/registry: Denmark/Dansk klinisk kvalitetsdatabase for demens/Danish quality database for dementia (DanDem)						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value[79]**	**Results, data and conclusions**	**Source**
a. Proportion of patients who had an extended cognitive test in the specialist clinic/memory clinic (dementia assessment unit)	Process quality: diagnosis and diagnostic work-up	The QI shows the proportion of patients who have been assessed and who have had additional cognitive testing in an SC/MC: ■ Indicator population (denominator): All healthy patients, patients with mild cognitive impairment (MCI), or mild dementia patients (i.e. patients with no definite dementia diagnosis) who were referred for medical advice and had a cognitive test other than Mini-Mental Status Examination (MMSE) or Montreal cognitive assessment (MoCA). Patients who have had Rowland Universal Dementia Assessment Scale (RUDAS) or Dementia Screening Questionnaire for Individuals with Intellectual Disabilities (DSQIID/Trindvold) tests performed are excluded ■ Numerator: Patients in the indicator population who have had at least one of the following tests are in the numerator: Addenbrooke's cognitive examination (ACE), Alzheimer's Disease Assessment Scale-Cognitive Subscale (ADAScog), Cambridge cognition examination (CAMcog) or neuropsychology test For a number of patients, an MMSE or MoCA test will not be sufficient to determine whether they have mild dementia, MCI or are cognitively intact. A neuropsychological examination will often be needed to clarify the cognitive state and is strongly recommended by the SG in cases of continuing doubt about the diagnosis of dementia after a basic dementia assessment.	>80%	94% (95% CI: 94-95%) (fulfilled)	All regions met the target value. Three SCs/MCs do not meet the threshold. Variation between regions (88% to 98%) and SCs/MCs is wide due to capacity challenges or the impossibility of conducting neuropsychological examinations. The SG considered this to be worrying for patients who are told they do not have dementia and for patients who have MCI or mild dementia. This may mean that some patients do not receive the recommended follow-up treatment. The SG questioned whether it is feasible to have a SC/MC for dementia without access to neuropsychological testing and recommends that causes of capacity challenges or impossibility of application should be investigated.	[80, 97, 187]
3. Proportion of patients evaluated who had an ADL assessment using the FAQ/IADL scale, DAD, ADCS-ADL or Trindvold/DSQIID tests	Process quality: diagnosis and diagnostic work-up	The QI shows the proportion of all patients of whose activities of daily living (ADL) using the Functional Activities Questionnaire Instrumental Activities of Daily Life (FAQ-IADL), disability assessment for dementia (DAD), or Alzheimer's Disease Cooperative Study ADL Scale (ADCS-ADL) or the DSQIID/Trindvold functional test are assessed: ■ Indicator population (denominator): All patients referred for medical advice without a clear diagnosis and with a relative present at the examination. ■ Numerator: Patients of the indicator population who have had an ADL assessment using the FAQ-IADL, DAD or ADCS-ADL scale or by the Trindvold/DSQIID functional test in a SC/MC during the assessment As ADL assessment is part of the diagnostic criteria for dementia, the SG recommends an ongoing focus on formal and systematic ADL assessment.	>80%	94% (95% CI: 93-94%) (fulfilled)	All five regions met the target value. All regions have improved since the start of the database in 2016 and have met the target value over the past three years. Only three of 37 SCs/MCs with relatively few patients did not meet the target value in 2021.	[80, 97, 187]
4. Proportion of patients who had a CT/MR scan of the brain within the past 24 months (structural imaging procedure)	Process quality: diagnosis and diagnostic work-up	The QI shows the proportion of patients referred for investigation of dementia who have had a computer tomography/magnetic resonance (CT/MR) scan of the brain within the past 24 months: ■ Indicator population (denominator): All patients referred for medical advice, not referred with a definite diagnosis ■ Numerator: Patients of the indicator population who had a CT/MR scan of the brain within the last 24 months before the date of diagnosis	>80%	98% (95% CI: 98-98%) (fulfilled)	All five regions and all units with more than ten patients meet the target value. The trend shows that all regions have been consistently high in indicator performance and met the standard over the lifetime of the database.	[80, 97, 187]

Country/registry: Denmark/Dansk klinisk kvalitetsdatabase for demens/Danish quality database for dementia (DanDem)						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value[79]**	**Results, data and conclusions**	**Source**
4. Proportion of patients who had a CT/MR scan of the brain within the past 24 months (structural imaging procedure) *(continuation)*		Structural scanning is an important and basic element in assessing dementia according to the clinical guidelines. The inclusion criteria have been changed for the QI from this annual report onwards, following the recommendation of the SG. Before, patients in the indicator population additionally had to meet dementia criteria. Now, patients referred with a definite diagnosis are thus the only ones excluded. For some patients with severe dementia, AD with Down's syndrome or patients with severe behavioural disorders, it will sometimes not be practical to carry out a scan.				
a. Proportion of patients with mild to moderate vascular dementia who had an MR scan of the brain in the last 24 months	Process quality: and diagnostic work-up	The QI shows the proportion of patients with vascular dementia (VAD) and major depressive disorder (MDD) with mild or moderate dementia who have had an MR scan of the brain in the last 24 months: ■ Indicator population (denominator): All patients referred for medical advice and not referred with a definite diagnosis before or with a mild to moderate VAD after the examination. Patients who have a pacemaker are excluded. ■ Numerator: Patients in the indicator population who have had MR scan of the cerebrum The SG recommends MR scan if a vascular contribution to the cognitive complaints is suspected to increase the quality of the evaluation.	>80%	51% (95% CI: 48-53%) '(not fulfilled)	No region meets the target value. Only four SCs/MCs meet the target value (in 2020: no unit met the target value). Examinations units are recommended to conduct audits reviewing relevant patients who have not had an MR scan. There may be patients who have not had a scan because of claustrophobia, metal in the body or who refused the examination to be carried out.	[80, 97, 187]
5. Proportion of patients with a specific diagnosis of dementia (aetiological diagnosis)	Process quality: diagnosis and diagnostic work-up	The QI shows the proportion of patients with specific dementia diagnoses: ■ Indicator population (denominator): All patients referred for medical advice. Patients who do not meet the dementia criteria or who are referred with a definite dementia diagnosis are excluded. ■ Numerator: Patients of the indicator population with a specific diagnosis of dementia A higher proportion of receiving a disease-specific dementia diagnosis is one of the objectives of the Danish Health Authority's action plan 2025. Still, the QI and fulfilment do not provide information on the quality of the examination that has taken place (e.g. diagnostic criteria or adequate additional diagnostic instruments).	>80%	93% (95% CI: 92-94%) (fulfilled)	All five regions and almost all SCs/MCs (except four) meet the target value. The target value has been convincingly met since the database started in 2016. However, the SG is concerned about whether disease-specific dementia diagnosis is made on an adequate basis and whether there is a uniform offer for dementia assessment regardless of where one lives. The SG recommends that SCs/MCs with high rates of patients with unspecified dementia diagnoses and high rates of patients with specific dementia diagnoses should review patients and clarify the basis of the dementia diagnosis.	[80, 97, 187]
6. Proportion of patients with AD, PDD, DLB, and mixed dementia who are treated with anti-dementia medication	Process quality: treatment, support, and follow-up	■ Indicator population (denominator): All patients referred for medical advice, not referred with certain diagnosis, where dementia criteria are met, and the aetiological diagnosis is relevant (Alzheimer's disease/ dementia [AD], Parkinson's disease dementia [PDD], dementia with Lewy bodies [DLB], and mixed dementia) ■ Numerator: Patients in the indicator population who are treated with anti-dementia drugs Some patients with the relevant diagnoses are likely to have contraindications to dementia medication, but the SG recommends that the target group is offered relevant dementia medication.	>80%	95% (95% CI: 95-96%) (fulfilled)	All five regions and all SCs/MCs except one meet the target value. All regions have been well above the target value throughout the lifetime of the database, with a general upward trend since the start.	[80, 97, 187]

Country/registry: Denmark/Dansk klinisk kvalitetsdatabase for demens/Danish quality database for dementia (DanDem)						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value[79]**	**Results, data and conclusions**	**Source**
a. Proportion of patients with a prescription for dementia medication who have filled a prescription up to three months after the diagnosis interview	Process quality: treatment, support, and follow-up	■ Indicator population (denominator): All patients referred for clinical advice, not referred with certain diagnosis, where dementia criteria are met, the aetiological diagnosis is relevant (AD, PDD, DLB, and mixed dementia), and who are receiving dementia medication ■ Numerator: Patients in the indicator population who have filled a prescription for dementia medication in the period 30 days before to 90 days after the date of diagnosis	>80%	93% (95% CI: 92-94%) (fulfilled)	All five regions (91-96%) and almost all SCs/MCs except three of 37 meet the target value. SCs/MCs with low compliance rates are recommended to review their own data to identify if there are demonstrable reasons for non-compliance, e.g. the procedure for prescription redemption or follow-up after prescribed treatment.	[80, 97, 187]
7. Proportion of patients who received a psychosocial offer in connection with information about the diagnosis (psychosocial offer)	Process quality: treatment, support, and follow-up	The QI shows the proportion of patients with dementia who have received a psychosocial offer in connection with information about the diagnosis (including referral to dementia coordinator/dementia consultant, family group, referral to home care and/or patient/family education): ■ Indicator population (denominator): All patients referred for medical advice, not re-referred with a definite diagnosis and where dementia criteria are met ■ Numerator: Patients in the indicator population who have received a psychosocial offer in connection with information about the diagnosis (including referral to dementia coordinator/dementia consultant, relatives group, referral to home care, and/or patient/relative education) The SG recommends a continued systematic approach and attention to providing patients with psychosocial services that are deemed important for both patients and relatives.	>80%	94% (95% CI: 94-95%) (fulfilled)	All five regions and all SCs/MCs meet the target value. Compliance with the standard has generally been stable and high in recent years.	[80, 97, 187]
8. Proportion of patients with AD and mild dementia who had a lumbar puncture in the diagnostic workup or PET scan within 24 months before the date of referral (Alzheimer's biomarker)	Process quality: diagnosis and diagnostic work-up	The QI shows the proportion of patients with mild to moderate dementia who had a spinal fluid examination up to 12 months before the diagnostic interview or a PET scan (PET-FDG, PET-Amyloid, PET-PE2I/SPECT-DAT) up to 24 months before the diagnostic interview and who could be identified in the LPR: ■ Indicator population (denominator): All patients referred for medical advice, not referred with definite diagnosis, match found with diagnostic workup in LPR, degree of cognitive impairment categorised as mild dementia and aetiological diagnosis is Alzheimer's or mixed dementia ■ Numerator: Patients in the indicator population who have had lumbar puncture in diagnostics workup or PET scan within24 months prior to referral date. Diagnostic workups where no match has been found with workups in LPR are registered as undisclosed The SG doubts whether a disease-specific diagnosis of dementia in mild to moderate cases (QI5) can be made without additional diagnostic approaches. A targeted and individualised utilisation of biomarkers according to guidelines should complement the results of QI5 because the fulfilment of the target value does not provide information on the quality of the assessment that has taken place and do not include the basis on which a specific diagnosis of the disease has been made.	>80%	57% (95% CI: 55-58%) (not fulfilled)	Proportion varied widely between regions (36-74%) and SCs/MCs. The SG observes a correlation between short investigation time (QI 1), high degree of specific diagnosis (QI 5) and low use of additional lumbar puncture/ PET scan (QI 8). The SG recommends that internal audits be carried out in SCs/MCs: ■ Where the proportion of patients with mild to moderate dementia who receive additional investigations beyond the basic investigation is low, in order to clarify whether patients are sufficiently investigated for disease-specific dementia ■ With low use of additional investigations, the explanation should be investigated to determine whether it is a capacity challenge	[80, 97, 187]

Country/registry: Denmark/Dansk klinisk kvalitetsdatabase for demens/Danish quality database for dementia (DanDem)						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value[79]**	**Results, data and conclusions**	**Source**
8. Proportion of patients with AD and mild dementia who had a lumbar puncture in the diagnostic workup or PET scan within 24 months before the date of referral (Alzheimer's biomarker) *(continuation)*					■ With a high proportion of non-specific dementia diagnoses, it is recommended to investigate whether additional investigations could have been performed in order to get closer to a disease-specific dementia diagnosis. The SG considers that this QI, which in 2021 is a newly calculated indicator, should be further analysed. Continuous re-assessment of the indicator's use to prove whether it is optimal is essential.	
9. Coverage	Process quality: other	■ Indicator population (denominator): All patients registered in LPR with procedure code ZZ1500/ZZ1500A (dementia assessment/screening examination for dementia) ■ Numerator: Patients in the indicator population registered in the KMS/DanDem with a diagnosis date in current year	>90%	Not reported in the annual report	-	[80, 97, 187]
10. Degree of concordance	Process quality: other	■ Indicator population (denominator): All patients registered in the KMS/DanDem with a diagnosis date in current year ■ Numerator: Patients in the indicator population registered in LPR with procedure code ZZ1500/ZZ1500A (dementia assessment/screening examination for dementia) in current year	>90%	Not reported in the annual report	-	[80, 97, 187]

Abbreviations: ACE … Addenbrooke's cognitive examination, AD … Alzheimer's dementia/Alzheimer's disease, ADAScog … Alzheimer's Disease Assessment Scale-Cognitive Subscale, ADL … activities of daily living, ASCS-ADL … Alzheimer's Disease Cooperative Study, BPSD … behavioural and psychological symptoms of dementia, CAMcog … Cambridge cognition examination, CI … confidence interval, CT … computed tomography scan, DAD … disability assessment for dementia, DLB … dementia with Lewy bodies, DSQIID/Trindvold … Dementia Screening Questionnaire for Individuals with Intellectual Disabilities, FAQ-IADL … Functional Activities Questionnaire Instrumental Activities of Daily Life, FTD … frontotemporal dementia, IQR … interquartile range, IT … information technology, KMS … clinical measurement system, LPR … Landspatientregisteret/National patient register, MCI … mild cognitive impairment, MDD … major depressive disorder, MMSE-SR … Mini-Mental Status Examination-Swedish Revision, MoCA … Montreal cognitive assessment, MR(I) … magnetic resonance (imaging), MR … magnetic resonance, PCU … primary care unit, PDD … Parkinson's disease dementia, PET … positron emission tomography, QI … quality indicator, RKKP … Regional Clinical Quality Program, RUDAS-S … Rowland Universal Dementia Assessment Scale-Sweden, SC/MC … specialist/memory clinic, SG … steering group, VAD … vascular dementia

Ireland: The National Dementia Registry Ireland (NDRI)

Table A-6: Quality registry profile: The National Dementia Registry Ireland (NDRI)

Country: Ireland		Source
General and methodological information		
General information		
Registry name	The National Dementia Registry Ireland (NDRI)	
No. of inhabitants	4,977,443	[160]
Dementia prevalence	National estimates (2020): ~64,000 Alzheimer Europe (2018): 52,736 (1.09% of population)	[32, 167]
Coverage	National	[32]
First launched and duration	Not fully launched yet[82], five specialist/memory clinics (SCs/MCs) commenced in mid to late February 2020 with a data prototype	[32]
First annual report and frequency	NA, considered to be yearly published but also monthly operational reports	[32]
No. of patients registered/Size of the register (most recent)	Registered patients in the data prototype in total: 40 (2020)	[32]
Methodological information		
Dementia type	Wide range of dementia disorders and mild cognitive impairment (MC): Alzheimer's disease/dementia (AD), mixed AD (MAD), vascular dementia (VAD), dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), Parkinson's disease dementia (PDD), unspecified dementia (USD), other types	[32]
Diagnosis system	ICD-10 and Systematised Nomenclature of Medicine Clinical Terms (SNOMED CT[83])	[32]
Inclusion and exclusion criteria	All patients with a confirmed diagnosis of dementia.	[32]
Follow-up	Continuous follow-up of the patient with dementia starting at initial diagnosis and subsequently through regular follow-ups.	[32]
Registry aims and methodology	The aims are: ■ To improve patient care and outcomes for the person with dementia, provide quality assurance and quality indicators (QI), ■ To assist with dementia planning and policy, and research.	[32]
Use for register-based research	The registry will be developed such that it is 'research ready'. The Data Protection Act 2018 and the Irish Health Research Regulations require explicit consent from patients and ethical approval if data is used for research purposes[84]. The registry will require a research data access request to be made formally. The request should be based on a clear set of inclusion and exclusion criteria and contain sufficient detail to enable subsequent review and acceptance/rejection by the registry team. For the purpose of clinical improvement, collected data can be used without requiring an individual's consent. Linkage to other databases and registers makes it possible to control for potential confounders in studies (see Minimum data set/Variables and Interoperability and readiness for data linkage).	[32]
Confounders	In the course of data collection, the NDRI collects demographic variables and other patient-related data. Furthermore, linkage to other databases and registers should make it possible to control for potential confounders in studies (see Minimum data set/Variables and Interoperability and readiness for data linkage).	[32]

[82] As the registry is not yet fully implemented and the extracted data is based on the preliminary model, the characteristics and data in the final registry may still change.

[83] SNOMED CT is a systematically organised machine-readable collection of medical terms with codes, terms, synonyms and definitions used in clinical documentation and reporting. The system is used for electronic exchange of clinical health information and constitutes a standard in interoperability [68].

[84] No registry data should be made available to insurance companies, employers, driving authorities and other similar bodies.

Country: Ireland		Source
Governance and Management		
Governance	In 2014, the Irish national dementia strategy recommended that the Health Service Executive (HSE) should take measures to implement a registry to improve the dementia care quality. ■ Macro level: The NDRI model recommends that the registry is owned by the HSE, the Irish health system. ■ Meso level: a registry administrator will be appointed at the national level to oversee/coordinate the functions within the registry. The registry system administrators will have superior levels of access to the registry. The administrators have access to all aspects of the registry system needed to support the operation of the registry. The administrators can manage users, centres and general registry functions, and are typically the first port of call should any questions or issues arise. The National Dementia Office (NDO) supports the implementation of dementia pathways, dementia policy and development of services at operational level. Data monitors at a provider level and data managers at a database level will conduct data management. The Office of the Chief Information Officer in the HSE will support data management processes. The information technology (IT) tasks will be located at the HSE IT Development/Support department lead by a technical officer. There will also be audit, finance and risk management tasks, but no specific unit has been assigned yet. An external advisory board consisting of experts and representatives from the Department of Health (DOH), the health and social care field, academia, patient representative groups, HSE NDO, HSE IT, HSE Health Intelligence Unit (HIU), Integrated Care Programme for Older People (ICPOP) will support the registry on subject-specific questions. ■ Micro level: SCs/MCs carry out dementia examinations and report patient data into the register.	[32, 188]
Geographical setting/ Participating sites and No. of participating sites	Five small to large SCs/MCs from urban as well as rural areas[85] provided data for the data prototype. Three were hospital-based outpatient SCs/MCs and two were non-hospital-based SCs/MCs. Of the five memory clinics, three were psychiatrist-led and two were geriatrician-led.	[32]
Daily management	Data collection is conducted in SCs/MCs[86].	[32]
Technical management	■ Data controller and processor: registry owner/HSE ■ Data management: General management at registry level and data monitoring at SCs/MCs level: tasks include data collection, storage, data quality and usability (see Quality assurance and validation) ■ IT responsibility: HSE IT Development/Support department	[32]
Funding/Financing	State funding by the DOH is the only option. Estimated costs: ■ 1st year/Development phase: € 355,253 (value added tax included) ■ Annual running cost: € 284,836 (value added tax included)	[32]
Data management		
General data management		
Data collection and registry maintenance (method of data collection/input)	Web-based data collection by SCs/MCs (clinicians or clinical nurse specialists). The registry system will be platform independent: any device with Internet access and a browser should be able to be used to interact with the registry via an end-user and data interface. Implementing a patient interface is also being considered in the long-run for managing informed consent for research activities, collecting optional registry data and potentially facilitating point-in-time surveys of registry participants.	[32]
Data dictionary	In Ireland, a National Data Dictionary and a Standard Health Record (SHR) has been established. The focus is on standardising the health record rather than exchange standards.	[32]
Standard definitions, terminology, and specifications (e.g. ICD-10, ISO etc.)	Dementia disorders are clinically diagnosed according to ICD-10, SNOMED	[32]

[85] For the future, an extension of the geographical scope beyond secondary health care to the area of primary care by including GPs and nursing homes is being considered.

[86] NDRI states that effective engagement with the private health care sector will be required in order to ensure a comprehensive registry.

Country: Ireland			Source
Minimum data set and Variables	■ Patient data: ■ Registry ID ■ Patient individual health identifier (IHI) number ■ Patient General Medical Services Scheme (GMS) number/ Medical council number (MCN) ■ First name ■ Family name ■ Date of birth ■ Sex at birth ■ Address ■ Postal address/Eircode ■ Marital status ■ Living status ■ Socially active ■ Physically active ■ Hearing impairment ■ Vision impairment ■ Driving ■ Education ■ Employment status ■ Employment position ■ Intellectual disability ■ Weight in kg ■ Height in m2 ■ Body mass index ■ Alcohol status ■ Smoking status ■ Service provider data: ■ Clinic ID ■ Referral form ■ Date of receipt of referral	■ Date of initial assessment for dementia ■ Date of dementia diagnosis ■ Diagnosis data: ■ Dementia diagnosis ■ Has the person been told about their diagnosis ■ Translation to other disease classifications ■ Diagnosis made by ■ Brief cognitive test (MMSE, MoCA, Clinical Dementia Rating Scale) ■ Comprehensive neuropsychological evaluation ■ Neuroimaging testing (computer tomography [CT]/ magnetic resonance [MR] scan/MR scan dementia protocol) ■ Bio-markers ■ Functional evaluation (IADL) ■ Disease progression measure ■ Disease stage ■ Treatment and care data: ■ Dementia medication ■ Anti-depressant medication ■ Antipsychotic medication ■ Benzodiazepines ■ Total number of medications the person is taking ■ Has a personalised care plan been created ■ Who created the care/support planCurrent supports ■ Psychosocial interventions/Post-diagnostics support ■ Advanced care planning ■ Has this person a dedicated single point of contact within the health service? ■ Has this person a case manager? ■ Quality of Life in Alzheimer's Disease (QoL-AD) carried out with patient ■ World Health Organisation Quality of Life scale (WHOQOL) carried out with carer ■ Date of death	[32]
Interoperability and data sources			
Interoperability and readiness for data linkage	Up to now, patient registries in Ireland have paid little attention to data interoperability or to the standardised collection of common data fields. A pseudonymous registry patient identifier (RPID) will be created by the system to facilitate matching patient data across sources. Furthermore, as part of the model design for the dementia registry, authors of the model initiated the dataset specification process (DSMP) for the National Dementia Registry Minimum Data Set (MDS). This included consideration of a data dictionary toolkit and standardised metadata (The Book of OHDSI: Observational Health Data Sciences and Informatics). The registry should be able to exchange and use information between different software systems, thus aligning with the Sláintecare implementation plan (Houses of the Oireachtas Committee on the Future of Health care, 2017). A Standard Operating Procedure (SOP) will need to be developed to support data sharing with organisations such as the World Health Organisation (WHO).		[32]

Country: Ireland		Source
Data sources	Direct data entries by participating SCs/MCs[87]; interoperability and connectivity ensure connectivity to the data from the Primary Care Reimbursement Scheme (PCRS) and other HSE/Irish health system datasets	[32]
Quality assurance and safety		
Quality assurance and validation	Core registry staff and all centres providing data will be offered a training process (online and/or in person). This process should be developed in line with HSE training guidelines for introducing new systems. Training manuals and/or online manuals/videos, online support, a help function and dynamic assistance, a mechanism to gather user feedback, periodic questionnaires on training, usability, usefulness and satisfaction should also be part of the registries' quality assurance strategies. The following validation strategies are conducted by the registry: ■ Validation by built-in logical checks and mandatory data fields: data with unresolved queries (for example, as a result of the data matching process) will be marked with warning flags. Presence checks (mandatory, expected, optional), business rules (date of diagnosis cannot be prior to date of assessment), validation messages (text to display if rule not met), and validity check (has a valid date been entered) are further measures. ■ Validation by routinely conducted measures: a person at data provider level, i.e. the data monitor at a participating site, ensures data accuracy and quality at a data. This person will verify source data according to the registry's data validation plan. At a superordinate level, a "data manager" is responsible for the data accuracy and quality across the entire database. Tasks include ensuring that the recruitment goals are being met by verifying data and patient records. The Data Manager can lock the entire database preventing any editing or queries from being raised against the data.	[32]
Data cleaning	See Quality assurance and validation	
Missing data	A data matching process across different (HSE) data sources assures that missing or incorrect data is found	[32]
Protection, security, and safeguards	System security and data privacy are managed by tiered access roles and segregation of identifiable and pseudonymised data, respectively. The basis for data protection and privacy is the Data Protection Act 2018 and the Irish Health Research Regulations. Complete anonymisation of data is impossible for Irish data as identifiable information is required in order to match data coming from different sources. The following security aspects will be implemented: ■ Only authorised users will be able to access data: access control will consist of a username and password ■ Role-based user access/End-users will have different levels of access ■ Data is encrypted at both rest and when data is in transit ■ Personal identifiable information (e.g. patient name, address, date of birth, IHI, MCN) will be encrypted and pseudonymised ■ Changes and deletions will be tracked ■ System servers will have a firewall, and the registry will be available on an agreed time basis	[32]
Additional aspects		
Informed consent/Participation	■ Participation scheme of patients is not clear yet, but managing clinical care and measuring quality outcomes do not require an individual's consent in Ireland. ■ Opt-in for data use in research purposes: the current General Data Protection Regulation (GDPR) and Irish health regulation requirements require opt-in informed consent for data being used for research purposes ■ Further considerations: no consent for fully anonymised data and informed consent for pseudonymised and identifiable data. An online mechanism for capturing, viewing and updating registry participants (person with dementia and carer) informed consent will be included in the registry design.	[32]
Ethics	The Data Protection Act 2018 and the Irish Health Research Regulations require explicit consent from patients and ethical approval if data is used for research purposes[88]. The NDRI model makes it clear that it is not appropriate to discuss consent for data use in research at the time of diagnosis, as the person and their family have enough to deal with at that point.	[32]

[87] The authors state that SCs/MCs are the logical starting point for data collection. Dementia-related data is collected and captured in multiple locations in the primary and secondary care sector of the health care system (Health Service Executive) in Ireland. The electronic mining of dementia registry data from other sources is difficult as of now, but sources such as electronic health records and general practitioner systems will be further investigated for the purpose of data collection.

[88] No registry data should be made available to insurance companies, employers, driving authorities and other similar bodies.

Country: Ireland		Source
Reporting	■ Continuous reporting: interactive dynamic real-time reports via an end-user and data interface (dashboards). These real-time reports allow for real-time filtering of required data fields and graphical visualisation of data online or as printed reports. The data analysed in these reports can also be downloaded (.csv-format), subject to user permissions. ■ Periodic reporting: public reports on a periodic basis without user intervention comprising of standardised registry and stakeholder reports (e.g. patient feedback reports, monthly operational reports, annual reports).	[32]
Quality indicators		
Quality indicators, standards of care, and outcome parameters	1. Proportion of patients undergoing basic dementia work-up 2. Overall quality of life of person with dementia 3. Proportion of patients with dementia who receive a specific dementia diagnosis (aetiological diagnosis) 4. Overall quality of life and wellbeing of carer 5. Proportion of patients treated with antipsychotic drugs 6. Time waiting for home support services 7. Proportion of patients treated with anti-dementia drugs 8. Proportion of patients who have follow-up or referral after the initial assessments 9. Time from start of investigation (1st contact with person) to diagnosis (number of days) 10. Disease progression 11. Proportion of patients who have a standard care plan 12. Proportion of patients in which the ability to continue driving has been assessed 13. Proportion of persons with dementia who have day-care/home care support 14. Time from diagnosis of dementia to permanent residential care	[32]

Abbreviations: AD … Alzheimer's dementia/Alzheimer´s disease, DLB … dementia with Lewy bodies, DOH … Department of Health, DSMP … Dataset Specification Process, FTD … frontotemporal dementia, GDPR … General Data Protection Regulation, GMS … General Medical Services Scheme, HIU … Health Intelligence Unit (HIU), ICPOP … Integrated Care Programme for Older People, MCN … Medical Council Number, MDS … Minimum Data Set, NA … not available, NDRI … National Dementia Registry Ireland, PCRS … Primary Care Reimbursement Scheme, PDD … Parkinson's disease dementia, PREM … patient-reported experience measure, PROM … patient-reported outcome measure, QI … quality indicator, QoL-AD … Quality of Life in Alzheimer's Disease, QR … quality register, SC/MC … specialist/memory clinic, SNOMED CT … Systematised Nomenclature of Medicine Clinical Terms, SOP … Operating Procedure, USD … unspecified dementia, USD … unspecified dementia, VAD … vascular dementia, WHOQOL … World Health Organisation Quality of Life scale

Table A-7: Quality indicators: The National Dementia Registry Ireland (NDRI)

Country/registry: Ireland/National Dementia Registry Ireland (NDRI)						
General information						
As no national clinical guidelines for the diagnosis of dementia in Ireland exist, authors of the model for a National Dementia Registry in Ireland (NDRI) gathered quality indicators (QIs) identified from a literature review of key outcome measures relating to Alzheimer's disease/dementia (AD), and QIs used by existing dementia registries. Outcomes that matter most to people with dementia, their families, health and social care professionals, service providers and policy makers were discussed in stakeholder workshops. The QIs were prioritised. The final list consists of 14 QIs, of which five received the highest priority. The five most high-priority QIs will be monitored by the National Dementia Registry. The authors state that the final list of indicators is not set in stone; existing dementia registries have advised to start small and be realistic with what can be collected initially. Further indicators can be developed over time as data becomes available and in accordance with strategic focus and priority. The authors of the NDRI model especially promote incorporating relevant PROMS/PREMS for diagnostic and post-diagnostic dementia care.						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
1. **Percentage of patients undergoing basic dementia work-up**	Process quality: diagnosis and diagnostic workup	The QI provides the percentage of persons who had the following evaluations completed: ■ Brief cognitive tests such as Mini-Mental State Examination (MMSE) or Montreal Cognitive Assessment (MoCA) ■ Comprehensive neuropsychological evaluation ■ Neuroimaging testing (e.g. computer tomography (CT)/magnetic resonance (MR) scan/ MR scan dementia protocol) ■ Bio-markers ■ Functional evaluation (instrumental activities of daily living – IADL) Since no national clinical guidelines for the diagnosis of dementia in Ireland exist, further guidance will be needed to define basic dementia work up before this can be measured.	not specified[89]	NA	NA	[32]
2. **Overall quality of life of person with dementia**	Qutcome quality: Outcome-related	The QI captures whether Quality of life (QoL) measure was carried out with the person who has dementia. The model recommends[90] that the inclusion of standardised QoL measures, such as Quality of Life in Alzheimer's Disease (QoL-AD), the Quality of Well-Being Scale (QWB), or EuroQol EQ-5D outcome measure, in the registry is an attempt to meet a key priority while promoting the importance of PROMs.	not specified	NA	NA	[32]
3. **Percentage of patients with dementia who receive a specific dementia diagnosis (aetiological diagnosis)**	Process quality: diagnosis and diagnostic workup	The QI captures whether a patient received a specific dementia diagnosis: ■ Vascular dementia (VAD) ■ Alzheimer's disease/dementia (AD) ■ Mixed Alzheimer's/Vascular (MAD) ■ Frontotemporal dementia (FTD) ■ Parkinson's disease dementia (PDD) ■ Dementia with Lewy bodies (DLB) ■ Other ■ Unknown	not specified	NA	NA	[32]

[89] Target values are typically based on national guidelines, but as of now, no national guidelines for dementia care in Ireland exist. Target values should be re-examined in light of forthcoming diagnostic and post-diagnostic path updates from the National Dementia Office.

[90] Recommendation: This QI received a high level of agreement (>70% of responses were between medium and high agreement ratings on the Likert Scale) from health professionals and lived experience experts during the development of the underlying clinical guidelines. The utilisation of this standard further increases the quality of care.

Country/registry: Ireland/National Dementia Registry Ireland (NDRI)						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
4. Overall quality of life and wellbeing of carer	Qutcome quality: Outcome-related	The QI captures whether QoL measure was carried out with the carer. This QI is the carer equivalent to the dementia QoL measure of the patient. Measurement should be carried out via Quality of Life in Alzheimer's Disease (QoL-AD), the Quality of Well-Being Scale (QWB), or EuroQol EQ-5D outcomes.	not specified	NA	NA	[32]
5. Percentage of patients treated with antipsychotic drugs	Process quality: treatment, support, and follow-up	Antipsychotic medications should be used with caution given the severe associated adverse events and should not be the first line of treatment in non-cognitive symptoms. Individual antipsychotic medication should be based on the particular person's risks and her/his symptoms (i.e. aggression, severe agitation, and psychosis) via a targeted approach. The effects of the medication on symptom improvement or worsening should be regularly reviewed, monitored and recorded. The antipsychotic medication should be stopped if not improving symptoms after a reasonable period.	not specified	NA	NA	[32, 189]
6. Time waiting for home support services	Process quality: treatment, support and follow-up	This QI captures the proportion of patients who have follow-up or referral after the initial assessments. Capturing data on referral and assessment times facilitates the calculation and tracking of waiting times for each person in the register. Currently, it is not possible to integrate this data into the registry as there is no standardised way of tracking the provision of home care support across community health care organisations.	not specified	NA	NA	[32]
7. Proportion of patients treated with anti-dementia drugs	Process quality: treatment, support and follow-up	■ Acetylcholinesterase inhibitors are indicated for cognitive enhancement in people with mild to moderate AD but are not recommended solely for treating non-cognitive symptoms in a person with AD. ■ Rivastigmine or donepezil may be considered for non-cognitive symptoms causing severe distress when non-pharmacological interventions have proved ineffective. ■ People with vascular dementia or frontotemporal dementia who develop non-cognitive symptoms should not be prescribed acetylcholinesterase inhibitors. ■ Memantine is indicated as a cognitive enhancer in people with moderate to severe ADD, PDD and DLB, but it is not recommended to be prescribed solely for the treatment of non-cognitive symptoms in a person with dementia. ■ The reviewed evidence of memantine indicates a small benefit for non-cognitive symptoms in AD, which may not be clinically significant. The evidence to support the use of memantine in the treatment of non-cognitive symptoms in other dementias remains very limited and insufficient to generate specific recommendations with regard to its use.	not specified	NA	NA	[32, 189]
8. Proportion of patients who have follow-up or referral after the initial assessments	Process quality: diagnosis and diagnostic workup	Capturing data on referral and assessment times facilitates the calculation and tracking of waiting times for each person in the register. Knowing the rate of referral to post-diagnostic supports would enable the National Dementia Office (NDO) to monitor the rollout of the post-diagnostic pathways for people with dementia. In combination with the specific quality of life data fields, this referral data can also support the monitoring of a person with dementia and carer wellbeing.	not specified	NA	NA	[32]
9. Time from start of investigation (1st contact with person) to diagnosis (number of days)	Process quality: pre-diagnosis	Capturing data on referral and assessment times facilitates the calculation and tracking of waiting times for each person in the register. CT/MR scans can sometimes cause delays. Longer time to diagnosis may be better for some patients. The focus should be on ensuring patients are not waiting too long for their initial appointment.	not specified	NA	NA	[32]

Country/registry: Ireland/National Dementia Registry Ireland (NDRI)						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
10. Disease progression	Process quality: treatment, support and follow-up	Currently, very few SCs/MCs collect data on disease progression, and there is no existing standard regarding which measure to use. The NDRI model recommends that SCs/MCs capture this data in the future	not specified	NA	NA	[32]
11. Proportion of patients who have a standard care plan	Process quality: treatment, support and follow-up	This QI captures whether a personalised care plan has been created.	not specified	NA	NA	[32]
12. Proportion of patients in which the ability to continue driving has been assessed	Process quality: treatment, support, and follow-up	Driving can be considered being part of QoL. The NDRI model recommends that driving is something the registry should track.	not specified	NA	NA	[32]
13. Proportion of persons with dementia who have day-care/ home care support	Process quality: treatment, support and follow-up	Currently, SCs/MCs do not capture data on the provision of day-care/home care support. If the registry is extended to cover GP and/or nursing home data, collection of this data should be possible.	not specified	NA	NA	[32]
14. Time from diagnosis of dementia to permanent residential care	Process quality: treatment, support and follow-up	Currently, SCs/MCs do not capture data on permanent residential care. If the registry is extended to cover GP and/or nursing home data, collection of this data should be possible.	not specified	NA	NA	[32]

Abbreviations: AD … Alzheimer's dementia/Alzheimer's disease, AD … Alzheimer's disease/dementia, DLB … dementia with Lewy bodies, DLB … Dementia with Lewy bodies, FTD … frontotemporal dementia, FTD … Frontotemporal dementia, IADL … Instrumental activities of daily living, ISO … International Organisation for Standardisation, MAD … Mixed Alzheimer's/Vascular, MMSE … Mini-mental status examination, MoCA … Montreal Cognitive Assessment, NA … not available, NDO … National Dementia Office, NDRI … National Dementia Registry in Ireland, PDD … Parkinson's disease dementia, PREM … patient-reported experience measure, PROM … patient-reported outcome measure, QI … quality indicator, QoL … Quality of Life, QoL-AD … Quality of Life in Alzheimer's Disease, QR … quality register, QWB … Quality of Well-Being Scale, SC/MC … specialist/memory clinic, USD … unspecified dementia, VAD … vascular dementia, VAD … Vascular dementia

Norway: The Norwegian Registry for Persons with Cognitive Symptoms (NorKog)

Table A-8: Quality registry profile: The Norwegian Registry for Persons with Cognitive Symptoms (NorKog)

Country: Norway		Source
General and methodological information		
General information		
Registry name	Norsk register for personer som utredes for kognitive symptomer i spesialisthelsetjenesten/The Norwegian Registry for Persons with Cognitive Symptoms (NorKog)	
No. of inhabitants	5,379,472	[160]
Dementia prevalence	National estimates (2020): ~101,000 (all age classes) Alzheimer Europe (2018): 74,821 (1.41% of population)	[167, 190]
Coverage	National	[156]
First launched and duration	2013[91] – ongoing[92]	[156, 191]
First annual report and frequency	2013, yearly published	[101]
No. of patients registered/Size of the register (most recent)	Registered patients in total: 18,229 (2021) Registered patients included in 2021: 2,637	[156]
Methodological information		
Dementia type	All dementia disorders, mild cognitive impairment (MCI), and subjective cognitive impairment (SCI): Alzheimer's disease/dementia (AD), vascular dementia (VAD), dementia with Lewy bodies (DLB), Parkinson's disease dementia (PDD), unspecified dementia (USD), other and unknown types	[99, 156]
Diagnosis system	ICD-10	[99, 156]
Inclusion and exclusion criteria	■ All patients (also younger patients) who are examined for cognitive symptoms or dementia in outpatient clinics, including primary care, specialist clinics/memory clinics (SCs/MCs), or geriatric psychiatric outpatient clinics/nursing homes[93] ■ For patients with a linguistic or cultural background other than Norwegian, the privacy ombudsman of the QR has approved several assessment tools considering different education, cultural, and language background. ■ Site participation is voluntary.	[72, 192, 193]
Follow-up	Continuous follow-up: data is collected from standard outpatient examination	[99, 156]
Registry aims and methodology	The aims are: ■ to improve the knowledge about diagnostics, assessment and treatment for people with cognitive symptoms and dementia who are examined in the specialist clinics ■ to collect data for quality improvement, planning of health care services, and research	[100, 192]

[91] The Norwegian National Centre for Ageing and Health and the Ageing Psychiatric Professional and Research Network Telemark Vestfold (TeVe) took the initiative in 2007 to establish a register for patients who were studied at outpatient clinics in the specialist health service in health South East. In April 2013, the register received status as a national quality registry (QR) for dementia and in 2019, hospitals from all regions will participate in collecting data.

[92] The register has a license for running the register from the Norwegian Data Protection Authority until 31.12.2029.

[93] Clinicians in geriatric psychiatric specialist health service (outpatient clinics/nursing homes) have to register also data into the QR for geriatric psychiatry/kvalitets- og forskningsregister i Alderspsykiatrien (KVALAP), a national QR to improve the assessment and treatment of mental illness among the elderly.

Country: Norway		Source
Use for register-based research	By the end of 2021, the steering group (SG), the so-called fagråd (professional council), has approved 57 studies. Most studies have a clinical approach where the results will have the potential to influence the quality of the patient service. Data and results are used for the development of national guidelines and national dementia strategies. Furthermore, at the end of 2021, 110 research articles had been published using data from the register. Researchers need to send an application form (https://www.aldringoghelse.no/wp-content/uploads/2020/09/soknad-om-utlevering-av-registerdata-fra-norkog.docx) including a protocol to the SG in order to be eligible to use the data. Application must contain specific information about which data/variables, responsibility for data processing, storage/research server, time limit, return of data/deletion, and who will have access to data. List of publications [194]	[99, 156]
Confounders	In the course of data collection, NorKog collects demographic variables and other patient-related data such as use of medicines or other diseases. Demographic information is broken down by region, specialist clinic, and gender and analysed by means of descriptive statistics and frequency analysis in the annual report. Furthermore, linkage to other databases and registers makes it possible to control for potential confounders in studies (see Minimum data set/Variables and Interoperability and readiness for data linkage).	[99]
Governance and Management		
Governance	In 2015, the Norwegian national dementia strategy issues by the Norwegian Ministry for Health and Social Services recommended an implementation of a registry to monitor and improve municipal health and care services. ■ Macro level: The National Service Environment for Medical Quality Registries (Nasjonalt servicemiljø for medisinske kvalitetsregistre) is a competence centre that offers assistance in the creation and operation of all 51 Norwegian medical quality registries (QRs), including NorKog. The four regional health authorities[94], on behalf of the Ministry of Health and Care run the National Service Environment for Medical Quality Registries. ■ Meso level: the Oslo University Hospital (OUS) is the data controller and registry owner, and responsible for ensuring information security, internal control, compliance with regulation and its documentation, and providing information to the public about data processing. Furthermore, the data controller takes care of the composition of the SG (professional representation from each of the health regions in Norway, including a representative of relevant patient organisations, the national association for public health, and The National Center for Ageing and Health). The SG has members from all four health regions. Interdisciplinarity, managerial experience, clinical experience and research expertise. The representatives come from memory clinics, geriatric and geriatric specialist health services. The SG is responsible for setting guidelines and making decisions for the operation and management of the registry, including decisions on the publication of information and the approval of an annual professional report. Furthermore, the SG ensures that the register data is used for quality improvement and sets research priorities accordingly. The SG serves as an advisor to the general manager, project manager, and administrative manager of the National Centre for Ageing and Health. The National Centre for Ageing and Health has the day-to-day operational responsibility for data processing in the registry. A project manager is responsible for fulfilling obligations given by the data controller and represents the registry externally to the media, and other national, Nordic or international QRs. A general manager has the overall responsibility for the daily operation of the registry and the SG. Further tasks include the preparation of annual reports and decision reports in cooperation with the SG. An administrative manager is in charge of the budget, accounting tasks, and personnel responsibilities. ■ Micro level: SCs/MCs carry out dementia examinations and report patient data into the register.	[191, 195]
Geographical setting/ Participating sites and No. of participating sites	45 outpatient SCs/MCs, including geriatric clinics and nursing homes (98% of all outpatient SCs/MCs and nursing homes)	[156, 196]
Daily management	See governance and geographical setting	
Technical management	■ Data controller: Oslo University Hospital Ullevål (formal owner) ■ Data processor, data management (operation, maintenance, and quality development), and information technology (IT) responsibility: The National Centre for Ageing and Health with its project manager, general manager, and administrative manager. Further positions comprise a coordinator, persons responsible for the biobank, analysis, reporting, research support, analysis, technical report, and register logistics.	[191]
Funding/Financing	**NorKog is funded by the Helse Sør-Øst health authority and the National Centre for Ageing and Health**	**[197]**

[94] Norway has four health regions: Helse Sør-Øst, Helse Vest, Helse Midt-Norge, and Helse Nord. Each regional health authority is a state enterprise responsible for specialist health care.

Country: Norway			Source
Data management			
General data management			
Data collection and registry maintenance (method of data collection/input)	Web-based data collection[95] (https://mrs.nhn.no/norkogregister) of patient data by clinicians via SC/MC computers and information from next of kin (relatives/others who know the patient/patient functions in everyday life well) are obtained. The Norwegian Health Network (NHN) has agreed on a data processing agreement. The Medical Registration System (MRS) software, developed by Helse Midt-Norge IT (HEMIT) is used for data collection. Filled patient-reported outcome measures (PROMs) forms are sent by post to a scanning company (Andvord, a subcontractor of HEMIT) and then uploaded to the electronic MRS. Personal data provided for research purposes is either pseudonymised or anonymised. A serial number ensures that individuals can be followed in the data material.		[99, 198]
Data dictionary	NA		
Standard definitions, terminology, and specifications (e.g. ICD-10, ISO etc.)	Dementia disorders are clinically diagnosed according to ICD-10		
Minimum data set and Variables	■ Patient data: ▪ Sex ▪ Date of Birth/Age ▪ Marital status ▪ Children ▪ Formal schooling years ▪ Education profession ▪ Working ▪ Patient lives alone ▪ Contact with relatives ▪ Relation to patient ▪ Frequency of relative contact with patient ▪ Type of lodging ▪ Social activity ▪ Cultural activity ▪ Safety – Motoring –Weapons – Falls	▪ Tobacco ▪ Alcohol Use ▪ Drugs other than alcohol ▪ The patient has consented to be part of the register/to be contacted again ▪ Relatives have agreed to be contacted again ■ Service provider data: ▪ Referral receive date ▪ Date investigation first begins ▪ Reason for delay ▪ Type of outpatient clinic ■ Diagnosis data: ▪ History from relatives related to mental function ▪ Diagnosis according to ICD-10 ■ Treatment and care data: ▪ NA	[32]
Interoperability and data sources			
Interoperability and readiness for data linkage	Registered patients receive a unique (auto-generated) personal identification number (patient identifier) in the MRS system. Hence, the data can be linked with data from hospital records and other public registers such as the National Population Registry, the Norwegian Cause of Death Registry, the Norwegian Prescription Database, the NPR, the Norwegian Registry for Primary Health Care, Norwegian Cardiovascular Disease Registry, Municipal Patient and User Registry (KPR), national and regional health surveys and Statistics Norway.		[191]
Data sources	Direct data entries in the MRS system and other public national registers (National Population Registry, the Norwegian Cause of Death Registry, the Norwegian Prescription Database, the NPR, the Norwegian Registry for Primary Health Care, Norwegian Cardiovascular Disease Registry, National and regional health surveys and Statistics Norway)		

[95] Before March 2022, registration in NorKog has been paper-based.

Country: Norway		Source
Quality assurance and safety		
Quality assurance and validation	Guidance on data input is available in form of instructional videos (https://www.aldringoghelse.no/forskning/norkog/registrering-av-data/). The Norwegian centre for Ageing and Health offers instructional videos about login, registration of patients and patient data, and allocation of access rights. Changes in the register systematic are provided in register seminars, on the website, in e-mail correspondence, and in information materials. Furthermore, a local access allocator who is responsible for giving you access to your department can be contacted if problems with access occur. The OUS undertakes various quality assurance and validation measures: ■ Validation by routinely conducted measures in the course of data collection: Verification and data cleaning before data transfer to the data processing manager, individual clarification with specialist clinics ■ Validation by routinely conducted measures after data collection: master file is stored on a research server at OUS and updated four times a year, review of variables and elimination of superfluous variables in cooperation with clinicians, check for completeness of all five quality indicators (QIs), check for correctness by a comparison of patients birth date in NorKog and NPR, and check for reliability by a comparison of diagnosis/measurements in NorKog with data of outpatient clinics ■ Validation in connection with the annual report: Results of the annual reports are presented to the individual SCs/MCs annually and discussed.	[198]
Data cleaning	Verification and data cleaning is conducted based on internal audits from the data protection ombudsman before data transfer to the data processing manager, individual clarification with specialist clinics (see Quality assurance and validation)	[99]
Missing data	There are two approaches for a coverage analysis: ■ External analysis: an individual-based coverage analysis based on patients who have received a diagnosis of dementia against the Norwegian Patient Registry (NPR)[96]. The analysis is based on defined diagnosis and procedure codes. Only outpatient contacts are included.[97] ■ Internal analysis: the analysis is based on the number of included participants per clinic in NorKog with the number of patients in outpatient clinics who are eligible for inclusion but who, for various reasons, are not included.	[99]
Protection, security and safeguards	The login to the register database works via a smart card/chip card. There are different schemes for each clinic and health region. All collected information is treated confidentially, and staff who work with information from the registry have a duty of confidentiality. Data in NorKog is stored on a secure server in the Norwegian Health Network (Norsk Helsenett). Only the registry data management staff has access to all data and the master file. Personal data is either pseudonymised or anonymised. It will not be possible to identify patients in the results of the studies which are published.	[197, 198]
Additional aspects		
Informed consent/Participation	■ Opt-in: signed consent in the first visit is required for participating in the register. If the patient is able to consent, only the patient must consent. Relatives can consent on behalf of patients with a lack of consent competence. Patients can withdraw their consent at any time without giving any reason.	[198, 199]
Ethics	For research, patients can be contacted again for participation. Patients can also reserve the right to have the data used in specific research projects. Some clinics also collect biological material in an associated research biobank, provided that the patient gives specific consent. The research biobank in NorKog has been approved by the Regional Ethics Committee (REK no. 2009/1953) and is located at the OUS.	[191]
Reporting	■ Continuous reporting: QIs and associated data are presented continuously on www.kvalitetsregister.no ■ Periodic reporting: 1.) NorKog holds an annual registry seminar where results and data of an annual report for participating SCs/MCs are presented. This report and seminar is the basis for benchmarking data between the participating SCs/MCs. 2.) Furthermore, an interactive results report is updated twice a year and gives the SCs/MCs access to their own data. 3.) An annual (public) report from NorKog is distributed by e-mail to the contact person and professional manager at each SCs/MCs, with a request to distribute it to relevant colleagues locally. Annual reports are published on the registry website (https://www.aldringoghelse.no/forskning/norkog/) and contains statements of QIs at departmental, regional and national level.	[99]

[96] The external analyses for the years 2020 and 2021 are not completed yet.

[97] Reasons for discrepancies: lack of consent competence, patients refuse to participate, ethical reasons etc.

Country: Norway		Source
Quality indicators		
Quality indicators, standards of care, and outcome parameters	1. Proportion of patients who have reported on patient-related outcome measures (PROMs) 2. Proportion of patients of whom information about neuropsychiatric symptoms is collected 3. Proportion of patients assessed for depressive symptoms 4. Proportion of patients with dementia with a specific diagnosis of dementia (Aetiological diagnosis) 5. Proportion of patients with mild cognitive impairment or dementia who were referred to health service after the examination 6. Proportion of patients from whom information was collected from relatives 7. Proportion of patients for whom functionality in daily life is mapped 8. Proportion of patients with extended cognitive testing 9. Proportion of patients who have had a CT/MR scan of the brain 10. Proportion of patients whose health requirements for driving licenses have been assessed 11. Time from start of investigation (1st contact) to time point of diagnosis (1st report) and proportion of patients 12. Proportion of patients who had an examination for a somatic symptom disorder	[99, 200]

Abbreviations: AD … Alzheimer's disease, DLB … dementia with Lewy bodies, HHC … home health care, KPR … municipal patient and user registry, KVALAP … Quality Registry for Geriatric Psychiatry/kvalitets- og forskningsregister i Alderspsykiatrien, MCI … mild cognitive impairment, NH … nursing home, NPR … Norwegian Patient Registry, MRS … Medical Registration System, PDD … Parkinson´s disease dementia, NHN … Norwegian Health Network, PROMs … patient-related outcome measures, QI … quality indicator, IT … information technology, SC/MC … specialist/memory clinic, USD … unspecified, OUS … Oslo University HEMIT … Hospital, Helse Midt-Norge IT, SG … steering group, ICD … International Classification of Diseases, NorKog … Norwegian Registry for Persons with Cognitive Symptoms

Table A-9: Quality indicators: The Norwegian registry for persons with cognitive symptoms (NorKog)

Country/registry: Norway/Norsk register for personer som utredes for kognitive symptomer i spesialisthelsetjenesten/The Norwegian registry for persons with cognitive symptoms (NorKog)						
General information						
In total, NorKog has 12 quality indicators (QIs), of which five QIs are analysed and reported in an annual report. The QIs have been prepared by NorKog's secretariat, in collaboration with the steering group and the National Service Environment for Medical Quality Registries/South-Eastern Health Authority. The QIs are based on recommendations in the Norwegian dementia Plan 2020, national professional guidelines, and recommendations from the patients' organisation for people with dementia and their relatives in the National Association for Public Health. Collected data are analysed from year to year and presented at outpatient clinic level, regional, and national level. For outpatient clinics that have fewer than 20 included patients, results are not presented at centre level, but participants from these outpatient clinics are included in the analyses for the whole of NorKog [99].						
Quality indicator (QI)	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value[98]**	**Results, data and conclusions**	**Source**
1. **Proportion of patients who have reported on patient-related outcome measures (PROMs)**	Process quality: outcome-related	This QI shows the proportion of patients who have answered PROM questions. PROMs are obtained from patients and relatives via the following tools and questionnaires: ■ Patients: Norwegian Revised Mini Mental Status Evaluation (MMSE-NR3) and the Alzheimer's Disease Five Dimensions (AD-5D) tool (since 2021 pilot tested) ■ Relatives: Neuropsychiatric interview questionnaire (NPI-Q), activities of daily (ADL) living via the Personal and instrumental activities in daily life (P-ADL and I-ADL) form by Lawton and Brody, Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) for changes in cognitive function answered by the relative Priority is given to information from the patient, who herself/himself answers questions about perceived health, experience of reduced memory and whether this causes concerns.	≥80%	91% (fulfilled)	At national level, the proportion of patients who have answered PROM questions in 2021 is a total of 91%, compared to 92% in 2020. The range across the four health regions goes from 86% (Helse Vest) to 92% (Helse Nord). There is a great variation between the centres (48-100%). Four of 45 clinics did not reach the target value.	[99, 200]
2. **Proportion of patients for whom information is collected about neuropsychiatric symptoms**	Process quality: diagnosis and diagnostic work-up	The QI shows the proportion of patients where neuropsychiatric symptoms have been mapped using the Neuropsychiatric Inventory Questionnaire (NPI-Q) mapping tool. Examples of neuropsychiatric symptoms are anxiety, depression, hallucinations, restlessness, and delusions, which are common symptoms of cognitive impairment.	≥80%	87% (fulfilled)	At national level, the proportion for the year 2021 is 87% for the whole country, with a variation on a regional level from 81% (Helse Nord) to 89% (Helse Midt-Norge), and on a clinical level from 46% to 100%. Between 2020 and 2022, NorKog has carried out a quality improvement project to increase the use of NPI-Q, based on variation in results in 2019. Seven of 45 clinics did not reach the target value.	[99, 200]
3. **Proportion of patients screened for depressive symptoms**	Process quality: diagnosis and diagnostic work-up	The QI shows the proportion of patients who are surveyed for depressive symptoms. Surveying depressive symptoms is important to distinguish between depression and dementia. Two depression-specific mapping tools are used in NorKog: the Montgomery and Åsberg Depression Rating Scale (MADRS) and the Cornell Scale for Depression in Dementia (CSDD).	≥70%	74% (fulfilled)	At a national level, the proportion was 74% in 2021, against 80% in 2020, with a wide variation on a clinical level from 5% to 100%. Nine of 45 clinics did not reach the target value. The range across the four health regions goes from 52% (Helse Vest) to 86% (Helse Midt-Norge). These variations mean that this QI will be prioritised for the quality improvement project in 2022-2023.	[99, 200]

[98] Actual values consider reported values of the latest annual report (2021) on a national level.

Country/registry: Norway/Norsk register for personer som utredes for kognitive symptomer i spesialisthelsetjenesten/The Norwegian registry for persons with cognitive symptoms (NorKog)						
Quality indicator (QI)	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value[98]**	**Results, data and conclusions**	**Source**
4. Proportion of patients with dementia with a specific diagnosis of dementia (aetiological diagnosis)	Process quality: diagnosis and diagnostic work-up	This indicator shows the proportion of patients with dementia where a specific aetiological diagnosis has been made. A specific aetiological dementia diagnosis should be based on diagnostic criteria. Dementia diagnoses include, for example, Alzheimer's disease or dementia with Lewy bodies (DLB). A specific dementia diagnosis is important to be able to offer the right treatment and follow-up.	≥80%	84% (fulfilled)	The proportion of patients with a specific aetiological diagnosis of dementia was 84% in 2021, compared to 86% in 2020. The variation at clinical level was between 60% and 100%. Nine of 45 clinics did not reach the target value. The range across the four health regions goes from 80% (Helse Sør-Øst) to 89.3% (Helse Midt-Norge).	[99, 200]
5. Proportion of patients with mild cognitive impairment or dementia referred to health service after the examination	Process quality: treatment, support, and follow-up	This QI shows the proportion of patients diagnosed with dementia or MCI who are referred to follow-up for adequate health care services after assessment. National guidelines on dementia and the national dementia plan 2025 emphasise the importance of follow-up after diagnosing cognitive impairment or dementia.	≥90%	97% (fulfilled)	The result shows that a high proportion of patients in 2021 (97%) will be referred for follow-up. The range across the four health regions goes from 95% (Helse Vest/Nord) to 98% (Helse Midt-Nord/Sør-Øst). NorKog records what the special clinics recommend as measures for discharge. What the patient actually receives from municipal services is not registered. Data from the Municipal Patient and User Registry (KPR) will be able to shed light on this.	[99, 200]
6. Proportion of patients from whom information was collected from relatives	Process quality: diagnosis and diagnostic work-up	Information from a relative is central to getting a picture of symptoms at onset of dementia, development, challenges, functionality in daily life and safety.	≥95%	Not reported in the annual report	NA	
7. Proportion of patients for whom functionality in daily life is mapped	Process quality: diagnosis and diagnostic work-up	In order to be able to make a diagnosis of dementia, the cognitive impairment must affect the ability to manage activities in daily life.	100%	not reported in the annual report	NA	
8. Proportion of patients with extended cognitive testing	Process quality: diagnosis and diagnostic work-up	National professional guidelines on dementia recommend an extended assessment in the specialist health service when the basic assessment is not sufficient to make a diagnosis.	≥95%	not reported in the annual report	NA	
9. Proportion of patients who have had a CT/MR scan of the brain	Process quality: diagnosis and diagnostic work-up	Examination of the brain using computed tomography (CT) or magnetic resonance (MR) imaging is one of the diagnostic criteria for dementia to rule out causes of cognitive symptoms other than dementia.	≥90%	not reported in the annual report	NA	
10. Proportion of patients whose health requirements for driving licenses have been assessed	Process quality: diagnosis and diagnostic work-up	Cognitive impairment can affect whether a person meets the health requirements for driving. For safety reasons, it is important that further driving is considered.	100%	not reported in the annual report	NA	
11. Time from start of investigation (1st contact) to time point of diagnosis (1st report) and proportion of patients	Process quality: pre-diagnosis	It is desirable that the patient receives feedback on the diagnosis as quickly and precisely as possible after the examination has been completed so treatment and support measures can be planned. The aim is for over 80% of patients to receive a diagnosis within six months.	80% of patients within 6 months	not reported in the annual report	NA	
12. Proportion of patients who had an examination for a somatic symptom disorder	Process quality: diagnosis and diagnostic work-up	A somatic examination is carried out to rule out other conditions that can cause cognitive impairment. It can increase the precision of aetiological dementia diagnosis.	100%	not reported in the annual report	NA	

Abbreviations: AD … Alzheimer's disease/dementia, AD-5D … Alzheimer's Disease Five Dimensions, ADL … activities of daily living, CSDD … Cornell Scale for Depression in Dementia, CT … computer tomography, DLB … dementia with Lewy bodies, IADL … instrumental activities in daily life, IQCODE … Informant Questionnaire on Cognitive Decline in the Elderly, KPR … Municipal Patient and User Registry, MADRS … Montgomery and Åsberg Depression Rating Scale, MMSE-NR3 … Norwegian Revised Mini Mental Status Evaluation, MR … magnetic resonance, NA … not available, NorKog … Norwegian Register for Persons with Cognitive Symptoms, NPI-Q … Neuropsychiatric Inventory Questionnaire, P-ADL … Personal ADL, QI … quality indicator, SC/MC … specialist/memory clinic

Sweden: The Swedish Registry for Cognitive/Dementia Disorders (SveDem)

Table A-10: Quality registry profile: The Swedish Registry for Cognitive/Dementia Disorders (SveDem)

Country: Sweden		Source
General and methodological information		
General information		
Registry name	Svenska registret för kognitiva sjukdomar/demenssjukdomar/The Swedish Registry for Cognitive/Dementia Disorders (SveDem)	
No. of inhabitants	10,353,444	[160]
Dementia prevalence	National estimates (2018): 130,000-150,000 (all age classes) Alzheimer Europe (2018): 168,243 (1.66% of population)	[30, 125, 167, 201]
Coverage	National	[125]
First launched and duration	2007-ongoing	[125]
First annual report and frequency	2007, yearly published	[125]
No. of patients registered/Size of the register (most recent)	Registered patients in total: 107,099 (04/2022) Baseline-registrations: 104,231 (04/2022) Follow-ups: 103,137 (04/2022)	[126]
Methodological information		
Dementia type	All dementia disorders and mild cognitive impairment (MCI): Alzheimer's disease (AD), mixed AD (MAD), vascular dementia (VAD), dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), Parkinson's disease dementia (PDD), unspecified dementia (USD), other types	[201]
Diagnosis system	ICD-10, McKeith criteria for DLB [69], Lund-Manchester criteria for FTD [70] and Movement Disorder Society Task Force criteria for PDD [71]	[201]
Inclusion and exclusion criteria	■ All patients with a confirmed diagnosis of dementia. Physicians in specialist/memory clinics (SCs/MCs), primary care units (PCUs), and general practitioners or geriatricians in nursing homes (NH) can diagnose and register patients with dementia disorders. ■ Since 04/2021, SCs/MCs are able to register patients with MCI and since 10/2021, affiliated PCUs can register the diagnosis of MCI in case of suspicion of dementia.	[201, 202]
Follow-up	Continuous and annual follow-up for the report/quality indicators (QIs): the QI 'Proportion of patients with a regular follow-up' is used to monitor follow-up rates in order to ensure that the patients' needs are met.	[102, 125, 201]
Registry aims and methodology	The aim is to improve the quality of diagnostic work-up, treatment and care of patients with dementia disorders for the whole country.	[125, 126, 201]
Use for register-based research	Data can be used for development of national guidelines and to generate new research hypotheses. The disclosure of data for research purposes requires a special assessment (confidentiality assessment) by the data controller. If patients have not been informed that their data were collected for research purposes, the patient's consent is required. Ethical approval from the Swedish Ethics Review Authority for each research project where SveDem data will be used is needed. Guidance and quick guides on requesting and handling data, and research disclosure are available (https://www.ucr.uu.se/svedem/2014-09-10-11-50-24/riktlinjer-foer-utlaemning-av-data). List of publications 2009-2020 [203]	[201, 203]
Confounders	In the course of data collection, SveDem collects demographic variables and other patient-related data. Furthermore, linkage to other databases and registers makes it possible to control for potential confounders in studies (see Minimum data set/Variables and Interoperability and readiness for data linkage)	[81, 201, 204]

Country: Sweden		Source
Governance and Management		
Governance	■ Macro level: Generally, an expert group of the National Quality Registries Sweden (Nationella Kvalitetsregister) in cooperation with the Swedish Association of Local Authorities and Regions (SKR) are responsible for approving a new quality registry based on existing criteria and guidelines. ■ Meso level: A steering group (SG) consisting of people from different health professions (physicians specialised in geriatric medicine, family medicine or psychiatry; nurses, occupational therapists and researchers) governs the SveDem. On a national level, a registry holder (chair) and a national coordinator are responsible for the operability on a national level. A regional coordinator is responsible for the operability on a regional level. ■ Micro level: Each participating specialist/memory clinic (SC/MC), primary care unit (PCU), and municipal nursing homes/dementia care homes (NH/DCH) have a responsible local administrator, respectively[99]. Local coordinators and local users are in charge of data collection and input. Physicians in SCs/MCs, PCUs, and general practitioners or geriatricians in NHs can diagnose and register patients with dementia disorders. Since 04/2021, SCs/MCs have been able to register patients with MCI and since 10/2021, affiliated PCUs can register the diagnosis of MCI in case of suspicion of dementia	[201, 205, 206]
Geographical setting/ Participating sites and No. of participating sites	918 primary care units (78%) 57 SCs/MCs (100%) 1,460 municipal health and social care units in 102 municipalities, e.g. NH and home care (HC)	[125, 204]
Daily management	See governance and geographical setting	
Technical management	■ Data controller: Karolinska University Hospital ■ Registry/data custodian: Chair of SveDem ■ Information technology (IT) responsibility: Competence centre Uppsala Clinical Research (UCR) centre is responsible for the development of the database online and its support	[125, 201]
Funding/Financing	Swedish Association of Local Authorities and Regions (SKR) provides annual funding of € 300,000. In 2021, the Swedish government provided € 250,000 in extra funding for improvement work.	[32, 125, 201, 207]
Data management		
General data management		
Data collection and registry maintenance (method of data collection/input)	Web-based data collection of newly diagnosed patients by local coordinators and local users of SCs/MCs, PCUs, and NHs are in charge of data collection and input. Data is pseudonymised.	
Data dictionary	NA	
Standard definitions, terminology, and specifications (e.g. ICD-10, ISO etc.)	Dementia disorders are clinically diagnosed according to ICD-10	

[99] Before 2021, one full-time administrator was in charge of the everyday functioning on a national level [201].

Country: Sweden				Source
Minimum data set and Variables	■ Patient data: ■ Social security number ■ Sex ■ Age ■ BMI (Height, weight) ■ Possession of driving license ■ Possession of weapon license ■ Service provider data: ■ Date of registration ■ Time needed for diagnosis (in days) ■ Diagnosis data: ■ Living condition ■ Day care ■ Home care ■ Family history of dementia: First degree, second, degree ■ Type of dementia ■ Diagnostic work-up: Blood test, clock-drawing test, CT, MRI, LP, PET/SPECT, EEG, advanced cognitive testing, assessment by occupational therapist, assessment by physiotherapist, assessment by speech therapist? ■ Total number of diagnostic tests ■ MMSE Score	■ Treatment and care data: ■ Medication: ChEI, NMDA-antagonist, antidepressants, antipsychotics, anxiolytics, hypnotics, cardiovascular medicationTotal number of drugs ■ Death, time to death (months) ■ Additional variables collected for patients forwarded to a NH: ■ General (Social security number, Type of dementia, Date of diagnosis, Date of follow-up, Date of moving to nursing home, Type of nursing home, Weight, Mini Mental State Exam score) ■ Diagnosis (Change of diagnosis) ■ Medications at follow-up (Number of drugs patient continuously treated with at diagnosis, Cholinesterase inhibitors, N-methyl-D-aspartate receptor antagonists, Cardiovascular medication, Antidepressants, Neuroleptics, Anxiolytics, Hypnotics, Additional medication for dementia, Structured medication follow up),	■ Function Assessment Measures: Alzheimer's Disease Co-operative Study Activities of Daily Living Inventory (Regarding eating, Regarding walking, Regarding bowel and bladder function at the toilet, Regarding bathing, Regarding grooming, Regarding dressing) ■ Care interventions (Structured screening for: Fall, Decubitus ulcers, Malnutrition, Oral health,; Structured intervention for: Fall, Decubitus ulcers, Malnutrition, Oral health) ■ Person-centred care (Patient's narrative, Mutual care plan and documentation, Individual attitude, Individual protection measures) ■ Quality of life via Quality of life in severe dementia Points (Qalid) For a more comprehensive list of registered variables see the SveDem variable list[100] [81]	[81, 201]

[100] Additional variables are collected if a patient is forwarded to a nursing home: General (Social security number, Type of dementia, Date of diagnosis, Date of follow-up, Date of moving to nursing home, Type of nursing home, Weight, Mini Mental State Exam score), Diagnosis (Change of diagnosis), Medications at follow-up (Number of drugs patient continuously treated with at diagnosis, Cholinesterase inhibitors, N-methyl-D-aspartate receptor antagonists, Cardiovascular medication, Antidepressants, Neuroleptics, Anxiolytics, Hypnotics, Additional medication for dementia, Structured medication follow up), Function Assessment Measures: Alzheimer's Disease Co-operative Study Activities of Daily Living Inventory (Regarding eating, Regarding walking, Regarding bowel and bladder function at the toilet, Regarding bathing, Regarding grooming, Regarding dressing), Care interventions (Structured screening for: Fall, Decubitus ulcers, Malnutrition, Oral health, Structured intervention for: Fall, Decubitus ulcers, Malnutrition, Oral health), Person-centred care (Patient's narrative, Mutual care plan and documentation, Individual attitude, Individual protection measures), Quality of life via Quality of life in severe dementia Points (Qalid)

Country: Sweden		Source
Interoperability and data sources		
Interoperability and readiness for data linkage	SveDem registry data can be merged with data from other national registries: Swedish National Patient Registry, LMED, Gothenburg Cerebrospinal Fluid Biomarkers (CSF) Registry, dental registers, and other QRs (e.g. BPSD registry). The data is recorded based on each individual´s social security number. A unique number is assigned to all patients. A file linking the personal number, name and patient identifier is safely stored and managed by the UCR centre.	[201, 204]
Data sources	Swedish National Patient Registry, Prescribed Medicines Registry (LMED), Gothenburg Cerebrospinal Fluid Biomarkers (CSF) Registry, dental registers, and other QRs (e.g. BPSD registry)	
Quality assurance and safety		
Quality assurance and validation	In order to ensure that data are entered correctly, user training on-site and via telephone, the development of manuals and templates and the development of help texts in the register are ongoing activities. Since 2020, user training and communication of updates are increasingly undertaken digitally via webinars. For questions, telephone support is available on weekdays between 8 am and 5 pm, and 24-hour technical support. The Office for National Quality Registries at the SKR describes types of validation methods in the validation handbook: ■ Validation by means of logical checks: Limiting values that can be entered, using predefined ranges, and printing a warning for unusual values (at entry and after entry) ■ Validation by routinely conducted measures: Cross-check with the National Board of Health and Welfare's (Socialstyrelsen) patient register and/or the LMED ■ Validation by internal appraisal: Adjudication and evaluating the quality of variables with a clinician, e.g. diagnosis code in the register is reviewed with the help of a diagnostician to check consistency of the patient case via a questionnaire on diagnostic criteria (gold standard) Research nurses are responsible for monitoring data by visiting units all over the country and verify if the data in SveDem corresponds to the original data in patients´ medical records, i.e. ten baseline and five follow-up registrations are randomly selected per SC/MC, and from these, all recorded variables are reviewed (PCU: half of the variables in the basic registrations are reviewed)[101] ■ Validation in connection with reporting: Sorting out duplicates by the UCR centre during annual reporting and contacting units that potentially entered anomalous data	[91, 102, 201]
Data cleaning	See Quality assurance and validation	
Missing data	See Quality assurance and validation	
Protection, security and safeguards	UCR is also responsible for data safety. In accordance with the National Board of Health and Welfare's regulations (SOSFS) 2008: 14 chap. 5 access to patient data is preceded by strong authentication and requires authorisation with an e-service card[102]. Data is pseudonymised. The use of national QR data is regulated in the Patient Data Act (2008:355).	[142]

[101] In 2020, monitoring has been put on hold due to intensive work on the platform change and due to the corona pandemic. Since then, monitoring was carried out via telephone calls. However, SveDem's operators still deem physical visits as the best monitoring option [102].

[102] The Secure IT in Health and Medical Care (SITHS) card is an electronic identity document that is used for the secure identification of both people and systems within regions, municipalities, private health care providers and government authorities. SITHS is used, for example, when logging into services, for electronic signing and for secure communication between systems.

Country: Sweden		Source
Additional aspects		
Informed consent/Participation	Opt-out: ■ The patient must be informed of registration and that they have the right to decline participation ■ The patient is entitled to a free extract from the register per year (must be made in written form) ■ The patient has the right to request withdrawal (must be done in written form) and the right to have the data removed from the registry.	[201]
Ethics	Ethical approval from the Swedish Ethics Review Authority for each research project where SveDem data will be used is needed, e.g. ethical permission for Religa et al. (2015) was obtained from the former regional human ethics committee of Stockholm (#2009/209–31).	[201]
Reporting	■ Continuous reporting: 1.) Excel export contains results from each SC/MC during a period of time. 2.) Status report shows the SC's/MC's results for selected QIs and offers benchmarking. 3.) Investigation and follow-up reports for SCs/MCs and PCUs show the unit's results for investigation, follow-up and interventions. 4.) Nursing and interventions report for nursing homes and home health care shows results for nursing and dementia/health care ■ Periodic reporting: Annual (public) report with information on QI and other descriptive statistics on baseline and follow-up registrations. Annual reports are published on https://www.ucr.uu.se/svedem/.	[208]
Quality indicators		
Quality indicators, standards of care, and outcome parameters	1. Proportion of patients who have undergone basic dementia screening 2. Proportion of patients who have undergone a structured functional and activity assessment 3. Proportion of patients with Alzheimer's disease treated with dementia drugs 4. Proportion of patients with a regular follow-up 5. Proportion of patients who receive treatment with antipsychotic drugs 6. Proportion of patients whose life story is the basis for the design of care 7. Proportion of patients with individual environmental adaptations in the implementation plan 8. Proportion of patients with coping/care strategies described in the individual implementation plan 9. Proportion of patients with access to person-centred activities and (sense) stimulation 10. Initiatives to support relatives in connection with diagnosis of dementia (Proportion of investigating units initiating support measures)	[201]

Abbreviations: AD … Alzheimer's disease, BMI … body mass index, ChEI … cholinesterase inhibitors, CSF … cerebrospinal fluid biomarkers, CT … computed tomography, DCH … dementia care home, DLB … dementia with Lewy bodies, EEG … electroencephalography, EOAD … early onset Alzheimer´s disease, FTD … frontotemporal dementia, HC … home health care, NH … nursing home, LMED … Medicines Registry, LOAD … late-onset Alzheimer's disease, LP … lumbar puncture, MMSE … mini mental state examination, MRI … magnetic resonance imaging, NA … not available, NMDA … N-methyl-D-aspartate, PCU … primary care unit, PDD … Parkinson's disease dementia, PET … positron emission tomography, QI … quality indicator, QR … quality registry, SC/MC … specialist/memory clinic, SG … steering group, SKR … Swedish Association of Local Authorities and Regions, SOFS … National Board of Health and Welfare's regulations, SPECT … single photon emission computed tomography, UCR … Uppsala clinical research, USD … unspecified

Table A-11: Quality indicators: The Swedish Registry for Cognitive/Dementia Disorders (SveDem)

Country/registry: Sweden/Svenska registret för kognitiva sjukdomar/demenssjukdomar/The Swedish Registry for Cognitive/Dementia Disorders (SveDem)						
General information						
The National Board of Health and Welfare (Socialstyrelsen) has developed and set measurable target values after assessing compliance with the national dementia care guidelines for the first time in 2018. The authority has developed target values as it has identified areas for improvement for both regions and municipalities. SveDem staff participated in the development of these target values. Before the current target values were applied, SveDem had its own. The target values of some quality indicators (QIs) may be different for primary care units (PCUs) and specialist/health clinics (SCs/MCs).						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
1. Proportion of patients who have undergone basic dementia screening	Process quality: diagnosis and diagnostic work-up	According to the national guidelines for dementia care, basic dementia assessment includes assessing the medical history of the patient and relatives, medical examination, and cognitive assessments. The target is fulfilled if MMSE-SR, clock-drawing test/RUDAS-S/MoCA, blood tests and CT and/or MRI are completed.	≥90%	PCUs: 81% (not fulfilled) SCs/MCs: 96% (fulfilled)	Main difference between PCUs and SCs/MCs: CT/MR is performed to a significantly lesser extent in PCUs, but PCUs had an increase in the proportion of completed basic assessments from 46% in 2011 to 81% in 2020. There are large differences in the number of patients diagnosed in specialist and primary care between counties.	[30, 102]
2. Proportion of patients who have undergone a structured functional and activity assessment	Process quality: diagnosis and diagnostic work-up	The assessment, according to the national guidelines for dementia care (national guidelines), consists of a short interview and is part of the diagnostic process to assess whether ADL is affected, i.e. whether there is an activity limitation and what kind. The assessor records the patient's own perception of ADL and evaluates everyday activities of the patient. The complexity of the activity depends on the age and state of the patient. When the occupational therapist enters the basic dementia assessment after the first meetings, there is already a lot of anamnestic information as well as the family interview to be taken into account in the medical record.	≥90%	The value's collection started from April 2021 onwards and will only be available in the next annual report.	-	[30, 102]
3. Proportion of patients with Alzheimer's disease treated with dementia drugs	Process quality: treatment, support, and follow-up	The national guidelines for dementia care provide the following recommendations with regard to medical/drug treatment: ■ Priority 1: Provision of cholinesterase inhibitors in mild[103] to moderate dementia in Alzheimer's disease and Alzheimer's disease with vascular features ■ Priority 2: Treatment with memantine in moderate to severe Alzheimer's disease ■ Priority 3: Combination treatment with memantine and cholinesterase inhibitors in moderate to severe Alzheimer's disease patients ■ Some individuals are not suitable for treatment with cholinesterase inhibitors and/or memantine drugs due to side effects, contraindications, or the person's own wish to defer medication (~20%).	PCUs: ≥75% SCs/MCs: ≥80%	PCUs: 72% (not fulfilled) SCs/MCs: 83% (fulfilled)	The prescription of cholinesterase inhibitors has remained constant over the last ten years. The prescription of memantine has more than tripled in that time, and more than one in ten patients treated receive combination therapy, according to data from the Swedish Medical Products Registry. There is a large regional variation (PCUs: 55%-100%, SCs/MCs: 72%-100%) The National Board of Health and Welfare raises the issue of more equitable pharmacotherapy as a priority area for improvement since patients with low levels of education and those born outside the Nordic counties still receive treatment to a lesser extent	[30, 102]

[103] The degree of cognitive impairment of Alzheimer's disease in the Swedish national guideline for dementia care is classified into mild, moderate and severe dementia, respectively, based on the loss of ADL function. In mild dementia, only instrumental ADLs (cooking, cleaning, transportation, laundry, and managing finances) are affected. Moderate dementia involves, for example, the need for assistance with dressing and hygiene. In severe dementia, the person often needs help with transfers and round-the-clock supervision.

Country/registry: Sweden/Svenska registret för kognitiva sjukdomar/demenssjukdomar/The Swedish Registry for Cognitive/Dementia Disorders (SveDem)						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
4. Proportion of patients with a regular follow-up	Process quality: treatment, support, and follow-up	The national guidelines emphasise the importance of follow-up at least once a year in order to quickly identify changes in the person's needs for action. Hence, the goal of SveDem is an annual follow-up of all persons registered with a dementia diagnosis. Regular and structured follow-ups assess dementia symptoms, its consequences and the person's medical and social needs and ensure that these needs are met. Depending on the person's needs, more frequent follow-ups may be required.	≥90%	PCUs: NR (not fulfilled) SCs/MCs: NR (not fulfilled)	Almost half of the patients have been followed up in the first year, while about 19% of those who could have been followed up have been followed up after about four years. There is considerable room for improvement here, but the follow-up indicator should be interpreted with caution because … ■ there may be persons who have been followed up by a unit that is not registered in SveDem ■ follow-up may have taken place within the time interval and was just not registered ■ moving to a specialised home may also result in the person's follow-up not being recorded	[30, 102]
5. Proportion of patients who receive treatment with antipsychotic drugs	Process quality: treatment, support, and follow-up	People with dementia may sometimes need treatment with antipsychotic drugs due to behavioural and psychological symptoms of dementia (BPSD), such as severe hallucinations, paranoid delusions, aggressiveness and severe agitation, which are most common in patients with advanced dementia. BPSD should primarily be prevented and treated with person-centred care and other non-pharmacological measures. But sometimes treatment with antipsychotic drugs is necessary for a short period of time. In cases of concurrent psychiatric illness (psychosis, obsessive-compulsive disorder), long-term treatment may be needed. It is desirable that the use of antipsychotic drugs can be kept as low as possible.	Special housing (SABÖ)[104]: ≤10% Ordinary/ Own housing: ≤5%	SABÖ: 15% (not fulfilled) Ordinary/Own housing: 4.5%[105] (fulfilled)	BPSD symptoms are rare as the majority of people in SveDem are in a relatively early stage of the disease at baseline registration. Treatment with medication for BPSD is, therefore, higher in special housing than in ordinary housing, as people living in special housing are usually further along in their disease development. SABÖ: small increase from 2019 to 2020 (~1%) Ordinary/own housing: Decrease of use from 6% (2009) to 4.5% (2020) Low use of antipsychotics at baseline (3.3%), which increases to 5.9% at four-year follow-up → increase likely reflects the transition to a more advanced disease phase with BPSD International comparison: Treatment with antipsychotic drugs occurs to a much lesser extent in Sweden	[30, 102]
6. Proportion of patients whose life story is the basis for the design of care	Process quality: treatment, support, and follow-up	The national guidelines emphasise the importance of a person-centred approach based on person's life patterns, values and preferences. This means that carers need to see the person's perspective and try to understand how they experience the world and the specific situation.	≥90%	72% (not fulfilled)	Since 2015, the proportion has increased from 63% to 72% in 2020. There is a variation between 44% and 97% by county.	[30, 102]

[104] Municipalities are obliged to provide special forms of housing for services and care for the elderly who need special support that includes dementia [76].

[105] The figures of ordinary/own housing differ depending on where the respective data was checked/registered: PCUs: 6% (not fulfilled) SCs/MCs: 3% (fulfilled).

Country/registry: Sweden/Svenska registret för kognitiva sjukdomar/demenssjukdomar/The Swedish Registry for Cognitive/Dementia Disorders (SveDem)						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
7. Proportion of patients with individual environmental adaptations in the implementation plan	Process quality: treatment, support, and follow-up	In addition to general environmental adaptations based on research, individual environmental adaptations based on preferences, habits and routines are needed. Dementia can make it more difficult to interpret surroundings. To facilitate this, a well-designed environment can help to interpret and understand the environment and thus have an impact on the person's well-being.	≥98%	72% (not fulfilled)	Percentage increased 42% in 2015 to 70% in 2020. The value varies between the counties for 2020 (54-87%)	[30, 102]
8. Proportion of patients with coping/care strategies described in the individual implementation plan	Process quality: treatment, support, and follow-up	The national guidelines emphasise that dementia care must be based on a person-centred approach. This means, among other things, that each person must be treated as a unique individual. The implementation plan documents how the person is to be treated in order to receive support for daily activities and self-determination.	≥98%	83% (not fulfilled)	Percentage has increased from 59% (2015) to 83% (2020) (only results from the SÄBO module are available). Between counties, values vary for 2020 (58-100%)	[30, 102]
9. Proportion of patients with access to person-centred activities and (sense) stimulation	Process quality: treatment, support, and follow-up	The national guidelines stress the importance of providing meaningful activities or stimulation for people with dementia. This includes both physical activities and social interaction, which are individually tailored. To ensure this, they should be documented in the implementation plan. This QI shows the proportion of people with dementia who have been offered person-centred activities or other stimulation, in whole or in part, in the last week based on the implementation plan.	≥98%	84% (not fulfilled)	Value remained at a high and relatively constant level from 2015 until 2020. Between counties, values vary for 2020 (63-100%)	[30, 102]
10. Proportion of participating sites initiating support measures (Initiatives to support relatives in connection with diagnosis of dementia)	Structur quality: treatment, support, and follow-up	When a person has dementia and is diagnosed with dementia, family members are also affected, and this can lead to changes in life situations. The national guidelines recommend that: ■ family members of younger people with dementia and relatives regardless of age, ■ carers of people with dementia and intellectual disability, or ■ people with dementia combined with other linguistic and cultural backgrounds should be offered individually/specially tailored support during the disease process (Example of an affected family group: a child living at home whose parents are diagnosed with dementia at a young age).	≥95%	PCUs: 63% (not fulfilled) SCs/MCs: 89% (not fulfilled)	Generally, SCs/MCs initiate more family support (89%) than PCUs (63%) → A patient being investigated in an SC/MC has a more difficult to diagnose disease, which may lead to an increased need for family support. SCs/MCs: Frequency of family support is not dependent on the age of the person with dementia PCUs: A higher proportion of family members receive support when the person with dementia is >65 years old	[30, 102]

Abbreviations: ADL … activities of daily living, BPSD … behavioural and psychological symptoms of dementia, CT … computed tomography scan, MMSE-SR … Mini Mental Status Examination-Swedish revision, MoCA … Montreal cognitive assessment, MRI … magnetic resonance imaging, PCU … primary care unit, QI … quality indicator, RUDAS-S … Rowland Universal Dementia Assessment Scale-Sweden, SABÖ … special housing/särskilt boende, SC/MC … specialist/memory clinic

Sweden: The Swedish Behavioural and Psychological Symptoms of Dementia Registry (BPSDR)

Table A-12: Quality Registry profile: The Swedish Behavioural and Psychological Symptoms of Dementia Registry (BPSDR)

Country: Sweden		Source
General and methodological information		
General information		
Registry name	Svenskt Register för Beteendemässiga och Psykiska Symtom vid Demens/The Swedish Behavioural and Psychological Symptoms of Dementia (BPSD) Registry	
No. of inhabitants	10,353,444	[160]
Dementia prevalence	National estimates (2018): 130,000-150,000 (all age classes) Alzheimer Europe (2018): 168,243 (1.66% of population)	[30, 167]
Coverage	National	[158]
First launched and duration	2010-ongoing	[158]
First annual report and frequency	2011, yearly published	[158]
No. of patients registered/Size of the register (most recent)	Registered patients in total: 82,810 (2020) Registered patients in 2020: 22,365	[103]
Methodological information		
Dementia type	Behavioural and psychological symptoms of dementia[106] (BPSD) in all dementia disorders: Alzheimer's disease/dementia (AD), mixed AD (MAD), vascular dementia (VAD), dementia with Lewy bodies (DLB), frontotemporal dementia (FTD), Parkinson's disease dementia (PDD), unspecified dementia (USD), other types	[158]
Diagnosis system	ICD-10	[158]
Inclusion and exclusion criteria	All patients with a confirmed diagnosis of dementia experiencing BPSD living in a nursing home/dementia care home (NH/DCH)[107]	
Follow-up	Follow-up: ■ BPSD registry recommends every 4-6 weeks after first registration ■ National Board of Health and Welfare (Socialstyrelsen) requires to follow-up at least once every year	[209]
Registry aims and methodology	The aims are: ■ To enable systematic improvement and development of the quality of dementia health care. ■ To reduce BPSD through multi-professional care interventions, thereby reducing suffering and increasing quality of life for the person with dementia. ■ To enable research and comparison within health care at national or regional level.	[158]
Use for register-based research	The data can be used for research purposes. A researcher must either get written approval from each NHs/DCHs manager or from the head of the social services (Socialförvaltningen) for the municipality in concern. Ethical approval from a regional ethics committee for each research project where BPSD registry data will be used and with intention of scientific publication is needed. Guidance on handling and requesting data is available (https://bpsd.se/fouu/). List of publications, see [210].	[209, 210]

[106] The behavioural domains are: hallucinations, delusions, agitation/agitation, depression/depressed mood, anxiety, irritability/laziness, loss of inhibitions (being rude, saying inappropriate things), elation/euphoria, apathy/indifference, motor restlessness, sleep disturbances, and appetite and eating disorders.

[107] People living in home care (HC) or dementia patients making use of day care (DC) or short-term care can also be registered, but carers need to make sure that certain criteria are met (e.g. sufficient supervision by a home care team) and have contact with health care providers. Some day care centres are also taking part.

Country: Sweden		Source
Confounders	In the course of data collection, the BPSD registry collects demographic variables and other patient-related data. (see Minimum data set/Variables and Interoperability and readiness for data linkage)	[82] [103]
Governance and Management		
Governance	■ Macro level: Generally, an expert group of the National Quality Registries Sweden (Nationella Kvalitetsregister) in cooperation with the Swedish Association of Local Authorities and Regions (SKR) are responsible for approving a new quality registry based on existing criteria and guidelines. ■ Meso level: The BPSD registry was developed at the Knowledge Centre for dementia, Skåne University Hospital in Malmö. Since 2022, the registry is further developed at the Cognitive Medicine Unit at Ängelholm Hospital. A secretariat and a steering group (SG) consisting of people from different health professions (physicians specialised in geriatric medicine, family medicine, psychiatry; physiotherapy and nurses, occupational therapists and researchers) governs the BPSD registry. ■ Micro level: A nurse, the local NH/DCH manager, an occupational therapist, a physiotherapist, a doctor and at least one assistant nurse receive an administrator training[108] (2.5 days) before the respective NH/DCH participates in the registry. The local NH/DCH manager is responsible for data collection and input and coordinates the registry tasks within the multi-professional NH/DCH team.	[158]
Geographical setting/ Participating sites and No. of participating sites	Private and municipal nursing homes/dementia care homes (NH/DCH) in either ordinary housing or special housing (SABÖ)[109] in 288 of 290 municipalities in Sweden HC is, in exceptions, also possible.	[103]
Daily management	Data collection is conducted in NHs/DCHs	[103]
Technical management	■ Data controller and management: Region Skåne ■ Data processor: Region Skåne and NH/DCH ■ Information technology (IT) responsibility and support/Data storage: central server at Registercentrum Syd[110] (RC Syd), which has many years of experience in running quality registries (QRs). RC Syd has helped in constructing of the registry and guarantees the safe handling of data.	[103, 158]
Funding/Financing	■ Swedish Association of Local Authorities and Regions (SKR) ■ In 2021, the Swedish government provided € 250,000 in extra funding for improvement work.	[207]
Data management		
General data management		
Data collection and registry maintenance (method of data collection/input)	Web-based data collection of newly diagnosed patients by local NH/DCH managers and the multi-professional team[111]	[103, 158]
Data dictionary	NA	
Standard definitions, terminology, and specifications (e.g. ICD-10, ISO etc.)	ICD-10	[158]

[108] The team should always consist of at least one assistant nurses, a nurse and a NH/DCH manager.

[109] Municipalities are obliged to provide special forms of housing for services and care for the elderly who need special support that includes dementia [76].

[110] All QR receive support by a registry centre. The centre provides support during the start, development and operation of registers.

[111] A multi-professional dementia team in Sweden often includes nurses, occupational therapists and medical doctors. Some teams also include physiotherapists, speech language pathologists, psychologists and social workers. Neuropsychologists are only very rarely involved in diagnostic assessment in primary health care, and only a minority of patients in SCs/MCs are seen by a neuropsychologist [105].

Country: Sweden		Source

Minimum data set and Variables	■ Patient data[112]
	  ■ Person's social security number,
	  ■ Age
	  ■ Sex
	■ Service provider characteristics
	  ■ NA
	■ Diagnosis characteristics
	  ■ Dementia diagnosis
	  ■ Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores
	  ■ NPI-NH sub-scores
	■ Treatment and care characteristics:
	  ■ Care measures taken
	  ■ Medication prescribed
	For the comprehensive list of registered variables, see the BPSD registry variable list [82]
		[82]

Interoperability and data sources		
Interoperability and readiness for data linkage	A unique number is assigned to all patients (patient identifier). BPSD registry data can be merged with data from other national registries: Swedish National Patient Registry, LMED, Gothenburg Cerebrospinal Fluid Biomarkers (CSF) Registry, dental registers, and other QRs (e.g. SveDem registry).	
Data sources	Direct data entry, Medicines Register (LMED), and other patient records.	
Quality assurance and safety		
Quality assurance and validation	In order to ensure that data are entered correctly, multi-professional teams from the NH/DCH undergo administrator training before they start working with the registry data. The training is carried out with the help of certified trainers (~350 certified trainers across Sweden). The certified trainers provide support via follow-up of the register work (monitoring) and implementation through regular network meetings. Furthermore, certified trainers inform about how output data can be used in improvement work. ■ Validation by built-in logical checks: logic controls are built into the register to prevent incorrect data ■ Validation by routinely conducted measures: Cross-checking of collected data with data in the LMED ■ Validation by (external) review: certified trainers review whether the information entered in the BPSD register corresponds to the information entered in the medical records or obtain information about where the information in the BPSD register was obtained.	
Data cleaning	NA	
Missing data	NA	

[112] Full list of variables: Registration date, all NPI-NH domains, Is the person getting enough food?, Does the person get enough to drink?, Does the person get enough sleep?, Normal urine?, Normal vision?, Normal hearing?, No skin problems?, Without oral problems?, Ability to change body position?, Has an environmental audit been carried out?, Does the person seem pain free?, Has any pain assessment scale been used?, Is there daily positive interaction?, Person's temperature?, Person's pulse?, Person's blood pressure?, Person's breathing?, Person's blood sugar?, Person's urine?, Medication review completed?, Person's stool?, Date of next assessment/registration, Nurse, Nursing Assistant, Nurse, Physician, Occupational therapist, Physiotherapist, Manager, Related persons, Other, Behaviour plan and communication plan, Is the registration/assessment signed?, Date signed, Vitamins and minerals, Analgesics, Antiepileptic drugs, Parkinson medication, Neuroleptics, Sedatives, Sleeping pills, Antidepressants, Cholinesterase inhibitors, N-Methyl-D-Aspartat (NMDA) antagonist, Other medicines

Country: Sweden		Source
Protection, security and safeguards	The use of national QRs is regulated in the Patient Data Act (2008:355). Data that is pseudomysed can be disclosed for quality improvement and research purposes. Access to patient data is preceded by strong authentication. Hence, access to the results and data input in the register requires authorisation with an e-service card and/or login via a username and password[113]. Only authorised users can view all data entered into the BPSD Registry and track results.	[158]
Additional aspects		
Informed consent/Participation	Opt-out: ■ Patient participation is voluntary ■ The patient is entitled to a free extract from the register per year (must be made in written form) ■ The patient has the right to request withdrawal (must be done in written form) and the right to have the data removed from the registry.	[211]
Ethics	Ethical approval from a regional ethics committee (Swedish Ethics Review Authority) for each research project where BPSD registry data will be used is needed.	[209, 210]
Reporting	■ Continuous reporting: 1.) public available data on quality indicators, 2.) reports and excel sheets available for the public on request to compare automated results and statistics at municipal, county, and national level, 3.) each NH/DCH can print their own data/results and compare them with national average data (NH/DCH reports). The data can be requested/retrieved on https://pharos.skane.se/bpsddataportal/ ■ Periodic reporting: Annual public reports published on https://bpsd.se/	[103, 212]
Quality indicators		
Quality indicators, standards of care, and outcome parameters	1. Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores over time for people in the register 2. Proportion of people with Alzheimer's disease who receive symptom-relieving antidementia drugs 3. Proportion of patients for whom a multi-professional team has been deployed (teamwork) 4. Proportion of patients who were assessed as pain-free and for whom a pain assessment scale was used 5. Purpose and nature of patient activities undertaken during the year and/or measures implemented for patients by health care professionals (percentage of all registrations) 6. Proportion of people treated with either haloperidol, risperidone, zopiclone, hydroxyzine, oxazepam, or paracetamol and average daily dose per person per year	

Abbreviations: AD … Alzheimer's disease, BPSD … behavioural and psychological symptoms of dementia, CSF … cerebrospinal fluid biomarkers, DC … day care, DCH … dementia care home, DLB … dementia with Lewy bodies, FTD … frontotemporal dementia, HC … home care, IT … information technology, LMED … Medicines Registry, MAD … mixed AD, NA … not available, NH … nursing home, NMDA … N-Methyl-D-Aspartat, NPI-NH … Neuropsychiatric Inventory Nursing Homes Version, QR … quality registry, PDD … Parkinson's disease dementia, QI … quality indicator, RC … Registercentrum, SC/MC … specialist/memory clinic, SG … steering group, SKR … Swedish Association of Local Authorities and Regions, USD … unspecified dementia, VAD … vascular dementia

[113] The Secure IT in Health and Medical Care (SITHS) card is an electronic identity document that is used for the secure identification of both people and systems within regions, municipalities, private health care providers and government authorities. SITHS is used, for example, when logging into services, for electronic signing and for secure communication between systems.

Table A-13: Quality indicators: The Swedish Behavioural and Psychological Symptoms of Dementia Registry (BPSDR)

Country/registry: Sweden/Svenskt Register för Beteendemässiga och Psykiska Symtom vid Demens/Swedish Behavioural and Psychological Symptoms of Dementia (BPSD) Registry						
General information						
The BPSD registry has six quality indicators (QIs). The BPSD registry, in cooperation with the Knowledge Centre for dementia at the Skåne University Hospital in Malmö, developed these QIs on the basis of the national guidelines for dementia care provided by the National Board of Health and Welfare (Socialstyrelsen). The guidelines and the BPSD registry highlight that person-centred care for people with dementia, especially in nursing homes/dementia care homes (NHs/DCHs) or in residential care, is given priority one. The primary goal of dementia monitoring, according to guidelines, is to create the conditions for the best possible quality of life for the person with dementia. Therefore, the registry also includes QIs, which capture patient-reported outcome and experience measures (PROMs/PREMs). Follow-up in BPSD usually includes the following four measures: ■ Monitoring of the person with dementia and his/her environment by a multi-professional care team. ■ Analysis of underlying causes, including triggers and relievers, and of basic needs such as food, drink, sleep and pain. ■ Medical assessment of the physical and mental status via the Neuropsychiatric Inventory Nursing Homes Version[114] (NPI-NH) [87]. ■ Planning of individualised treatment measures with a clear communication strategy and medication review [30].						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
1. **Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores over time for people in the register**	Outcome quality: outcome-related	The QI shows the development of the neuropsychiatric status assessed by the NPI-NH. The following scores are formed and reported: ■ Mean NPI-NH score for all registered patients (NPI 1) ■ Mean NPI-NH score for people with low, medium and s evere BPSD[115] with the first three registrations[116] in the last four years (NPI 2) ■ Mean NPI-NH score for people with low, medium and severe BPSD with at least three registrations regardless of year (NPI 3) ■ Mean NPI-NH score for people with severe BPSD with at least three registrations regardless of year (NPI 4) The national guidelines recommend that structured monitoring and evaluation of BPSD via NPI-NH should be provided to patients. People with dementia should undergo at least one assessment of the prevalence and severity of BPSD annually. The measure is recommended as it positively influences key outcome measures such as BPSD, function and quality of life. It also contributes to a reduction in the need for care by the person with dementia, reduced perceived burden and less depression and anxiety or worry for carers.	not specified	See Results and data	NPI 1 score: the mean NPI-NH 1 score was 20.15 in 2020, which is a decrease from 2019. In 2022, the mean NPI-NH 1 score was 20.5, which is an increase from 2020. NPI 2 score in 2020: NA NPI 2 score in 2022: (1st/2nd/3rd registration) Low BPSD: 74.5/49.5/43.1 Medium BPSD: 37.8/31.4/29.5 Severe BPSD: 8.8/13.5/15.1 NPI 3 score in 2020: individuals with a high prevalence and severity of BPSD scored an average of 74 on the NPI scale at the first registration. This value dropped to 46 at the third registration. Individuals with no or low prevalence of BPSD had an average score of 11 at the first registration, which increased to 16 at the third registration, as expected (as dementia progresses, the risk of BPSD increases). NPI 3 score in 2022: (1st/2nd/3rd registration) Low BPSD: 73.2/46.6/35.0 Medium BPSD: 41.6/34.9/33.4 Severe BPSD: 10.7/15.0/14.8	[30, 103, 104]

[114] The NPI is a semi structured clinician interview of caregivers in which the severity and frequency of disturbance in 12 symptom domains (hallucinations, delusions, agitation/agitation, depression/depressed mood, anxiety, irritability/laziness, loss of inhibitions, elation/euphoria, apathy/indifference, motor restlessness, sleep disturbances, and appetite and eating disorders). The lower the score, the better the quality of life of patients.

[115] Low or no BPSD (NPI-NH score <30), medium BPSD (NPI-NH score 30-60), high/severe BPSD (NPI-NH score >60)

[116] The NPI is continuously applied on BPSD patients dependent on their individual need. The BPSD registry recommends every 4-6 weeks after first registration and the National Board of Health and Welfare requires follow up at least once every year.

Country/registry: Sweden/Svenskt Register för Beteendemässiga och Psykiska Symtom vid Demens/Swedish Behavioural and Psychological Symptoms of Dementia (BPSD) Registry						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
1. Neuropsychiatric Inventory Nursing Homes Version (NPI-NH) scores over time for people in the register *(continuation)*					NPI 4 score in 2020: the proportion of people with severe BPSD has decreased for all symptoms between 2016 and 2020, meaning an increased quality of life. NPI 4 score in 2022: (1st/2nd/3rd registration) Severe: 62.0/42.0/36.0	
2. Proportion of people with Alzheimer's disease who receive symptom-relieving anti-dementia drugs	Process quality: treatment, support, and follow-up	This QI shows the proportion of people who receive anti-dementia medicines (cholinesterase inhibitors and N-methyl D-aspartate antagonists). The national guidelines recommend that treatment with dementia medicines should be initiated as early in the course of the disease as possible, which means that the medicines should be prescribed at the time of the patient's diagnosis.	>75%	See Results and data (not fulfilled)	In 2020, 57.2% of people registered in the BPSD registry were on treatment with dementia medicines. In 2022, this QI was 60.8%. There has been an increase in the proportion since 2018 (51%). For the anti-dementia drug acetylcholinesterase inhibitor, the gender distribution is even, while memantine is more often prescribed to men than women. The use of acetylcholinesterase inhibitors is most common in patients with Lewy body dementia (DLB) (24%) and memantine in early-onset AD (20%).	[30, 103, 104]
3. Proportion of patients for whom a multi-professional team has been deployed (teamwork)	Process quality: treatment, support, and follow-up	The QI shows the proportion of patients cared for by a multi-professional team[117]. The guidelines state that person-centred care also means that care is multi-professional and team-based. In the early stages of the disease, the focus is on medical assessment and diagnosis. However, as the disease progresses, the person's need for care increases, and interventions from other (health) professions are often required. The use of a multi-professional team contributes to a holistic approach to the care offered and focuses on the person with dementia, not the diagnosis. Multi-professional care can improve the quality of life and function of people with dementia and the quality of life of their relatives compared to those who have not received the measure. The National Board of Health and Welfare considers that the number of multi-professional teams needs to be increased.	not specified	See Results and data	Since 2018, there has been an increase in the QI from 32.5% to 40.9%. In 2022, the proportion of patients for whom a multi-professional team was used was 63.5%, almost twice as high as in 2018.	[30, 103, 104]

[117] A multiprofessional dementia team in Sweden often includes nurses, occupational therapists and medical doctors. Some teams also include physiotherapists, speech language pathologists, psychologists and social workers. Neuropsychologists are only very rarely involved in diagnostic assessment in primary health care, and only a minority of patients in SCs/MCs are seen by a neuropsychologist [105].

Country/registry: Sweden/Svenskt Register för Beteendemässiga och Psykiska Symtom vid Demens/Swedish Behavioural and Psychological Symptoms of Dementia (BPSD) Registry						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
4. Proportion of patients who were assessed as pain-free and for whom a pain assessment scale was used	Outcome quality: outcome-related	The QI shows the proportion of patients assessed with a pain assessment scale. The national guidelines emphasise the importance to gain knowledge about how to prevent BPSD and the underlying causes such as the patient's pain in order to enable proper treatment. This may involve assessing any pain patients may be experiencing. Interpreting signs of pain in people with dementia, is to some extent, the task of carers but it can be complex. Rating scales should be used to clarify the assessment and evaluate the effects of interventions.	not specified	See Results and data	According to the data, pain is the most common possible cause of BPSD accompanied by sleep disturbance, and it is known that pain can contribute to sleep disturbance. This QI has been steadily improving over the last five years, and in 2020, 72% of registered people were reported to be pain-free. This may be considered a very good result. In 2020, pain rating scales were reported to have been used in 25% of registrations. In 2022, the proportion of pain-free patients was still at 72%	[30, 103, 104]
5. Purpose and nature of patient activities undertaken during the year and/or measures implemented for patients by healthcare professionals (percentage of all registrations)	Process quality: treatment, support, and follow-up	The QI breaks down the type of patient activities undertaken and/or measures implemented for patients by healthcare professionals during the year. The QI contains the following measures/activities: ■ Basic needs ■ Affirmation/Reassurance ■ Physical activity ■ Improve communication ■ Cognitive support ■ Environmental adaptation ■ Mind stimulation ■ Social activity The guidelines emphasise that it is important to gain knowledge about how to prevent behavioural and psychological symptoms. This task may include giving health professionals the opportunity to reflect on and practice different ways of dealing with their patients. In the curse of evaluation and monitoring of this QI, measures/activities are linked to symptoms and treatment aims of the initiated measures/activities. A three-step review of the linked data is conducted to check whether care interventions are specific, feasible and person-centred.	not specified	See Results and data	After the first review, approved measures[118] were estimated at 57% of the registered measures. At the time of the second review, it had decreased marginally to 56%, and in the third and final review round, the number had increased to 67% of the registered measures. The annual report states that the review predominantly shows a clear purpose for the measure/activity. The most common measures/activities were with regard to mind stimulation, social activity and affirmation. Basic needs: 9.4% (2018)/10.6% (2020)/11.2% (2022) Affirmation/Reassurance: 19.6% (2018)/24.2% (2020)/26.3% (2022) Physical activity: 14.6% (2018)/14.5% (2020)/14.3% (2022) Improve communication: 4.9% (2018)/4.0% (2020)/4.1% (2022) Cognitive support: 3.6% (2018)/4.3% (2020)/4.8% (2022) Environmental adaptation: 4.7% (2018)/5.1% (2020)/5.1% (2022) Mind stimulation: 21.6% (2018)/19.3% (2020)/17.6% (2022) Social activity: 21.5% (2018)/17.9% (2020)/16.6% (2022)	[30, 103, 104]

[118] Approved measures = measures that correspond to the desired treatment aims and are specific, feasible, and person-centred.

Country/registry: Sweden/Svenskt Register för Beteendemässiga och Psykiska Symtom vid Demens/Swedish Behavioural and Psychological Symptoms of Dementia (BPSD) Registry						
Quality indicator	**Classification and type of QI**	**Description of QI and relation to national guidelines**	**Target value**	**Actual value**	**Results and data**	**Source**
6. Proportion of patients treated with either haloperidol, risperidone, zopiclone, hydroxyzine, oxazepam, or paracetamol and average daily dose per person per year	Process quality: treatment, support, and follow-up	The QI captures the average daily dose of six different drugs per person and year and the proportion of people treated with each of the following six medicines: ■ Haloperidol, ■ Risperidone ■ Zopiclone ■ Hydroxyzine ■ Oxazepam ■ Paracetamol[119] The national guidelines consider that it is important to continuously develop knowledge for treating people with BPSD and to avoid unnecessary medication use. BPSD can vary and be triggered by different factors. Besides unmet needs, communication problems, the patients' difficulties interpreting or orienting in the environment, and brain damage, a common underlying cause of BPSD can be a too high dose of a drug or inappropriate medication. Although the use of one of the medications or a combination is indicated, the medications may have (very) severe side effects or be unsuitable for some forms of dementia. Therefore, good monitoring of medication use is required (e.g. monitoring is a prerequisite for the use of clometiazole). The guideline recommends that NH/DCH should provide opportunities for monitoring.	not specified	See Results and data	Regarding drug treatment for the different diagnoses, treatment with antipsychotic drugs [haloperidol or risperiodone is most common in frontotemporal dementia (20%) and antidepressants most common in people with vascular dementia (35%)]. Registered women are more often prescribed antidepressants than men (almost 50% of women), as well as analgesics (paracetamol) and sedatives (zopiclone, oxazepam and hydroxyzine). Men are more often prescribed sleeping pills and antipsychotics than women. The prescription of antipsychotic and sedative medicines to men has declined slightly in recent years. ■ Haloperidol: 2.7% (2018)/2.4% (2022) ■ Risperidone: 19.7% (2018)/21.4% (2022) ■ Zopiclone: 21.1% (2018)/20.2% (2022) ■ Hydroxyzine: 1.6% (2018)/0.9% (2022) ■ Oxazepam: 32.1% (2018)/32.6% (2022) ■ Paracetamol: 70% (2018)/72% (2022)	[30, 103, 104]

Abbreviations: BPSD … behavioural and psychological symptoms of dementia, NA … not available, NHs/DCHs … nursing homes/dementia care homes, NPI-NH … Neuropsychiatric Inventory Nursing Homes Version, PROMs/PREMs … patient-reported outcome and experience measures, QI … quality indicator

[119] Haloperidol and risperidone are antipsychotic drugs, zopiclone is a nonbenzodiazepine used to treat difficulty sleeping, hydroxyzine is an antihistamine used for the treatment of anxiety and nausea, oxazepam is a short-to-intermediate-acting benzodiazepine used for the treatment of anxiety, and paracetamol is an analgesic used to treat mild to moderate pain.

Further tables

Table A-14: Type of quality indicator and cluster affiliation

Type of quality indicators				
Category of the care pathway and cluster	**Structure quality**	**Process quality**	**Outcome quality**	**∑ Sum**
Pre-diagnosis	-	5	-	**5**
Referral process and waiting times	-	5	-	5
Diagnosis and diagnostic workup	-	15	1	**16**
Basic dementia assessment/workup	-	1	-	1
Cognitive assessment and neuropsychiatric assessment	-	4	1	5
Imaging via CT/MR (Neuroimaging)	-	2	-	2
Functionality/Activities of daily living assessment	-	2	-	2
Specific dementia diagnosis	-	1	-	1
Other assessment tests and diagnosis-related QIs	-	5	-	5
Treatment, support, and follow-up	1	17	-	**18**
Pharmacological treatment (dementia medication)	-	2	-	2
Pharmacological treatment (other medication)	-	2	-	2
Psychosocial treatment and support	1	8	-	8
Other treatment-, support-, and follow-up-related QIs	-	5	-	5
Outcome-related quality indicators	0	0	5+1[120]	**5+1**[120]
Cognitive and neuropsychiatric outcomes	-	-	1	1
QoL of the patient/PROMs/PREMs	-	-	2	2
QoL of the carer/CROs/CREs	-	-	1	1
Other outcome-related QIs	-	-	1	1
Meta indicators and other quality indicators	-	2	-	2
∑ Sum	**1**	**40**	**5+1**[120]	**46+1**[120]

[120] Q11. Neuropsychiatric Inventory Nursing Homes Version scores assessment is also conducted in the follow-up examination. This QI is only counted once to avoid double counting.

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