Diabetes in care homes

Special emphasis on medicines and blood glucose measurements

Lillan Mo Andreassen

Thesis for the degree of Philosophiae Doctor (PhD)
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Bergen, May 2019 Lillan Mo Andreassen

Foreword

'It was like a new world opened to me, the world of science, which I was at last permitted to know in all liberty.'

~ Marie Curie, physicist, a pioneer in the research of radioactivity, discovering the elements of polonium and radium, and twice winner of the Nobel Prize (Physics in 1903, Chemistry in 1911)

My interest in elderly and nursing home medicine was sparked during writing my master thesis on as needed medication in nursing homes. In addition to gaining knowledge of the complexities and challenges in tailoring pharmacotherapy for these patients, I also got a better understanding of how research could help improve the care for this vulnerable population. The research environment I was lucky to be part of, taught me to keep asking questions and being curious, to be both creative and critical (although preferably not at the same time), and the importance of communicating your findings as broadly as possible for them to have an impact.

Diabetes became my field of research by chance rather than by choice, and this PhD journey has been far from a straight road. More than once, I have had doubts about the project. However, the vulnerability of older patients with diabetes and the potential impact focusing on them could have, won over any doubts I might have had. Meetings with patients, health care personnel and other researchers in the field have served as encouragement along the way. Watching my grandparents becoming frail and experiencing both good and poor sides of the medical system, reminded me of why I am doing this and the importance of following through to communicate the findings.

In the end, being pushed into the field of diabetes has expanded rather than narrowed my fondness and advocacy for elderly medicine. It may have taken over eight years, but I am glad that diabetes has become part of my professional identity.

Abbreviations

ADA	American Diabetes Association
ATC	Anatomical Therapeutic Chemical
BP	Blood pressure
CBGM	Capillary blood glucose measurements
CGM	Continuous glucose monitoring
CI	Confidence interval
CKD	Chronic kidney disease
DKA	Diabetic ketoacidosis
DM	Diabetes mellitus
DPP-4	Dipeptidyl peptidase-4
EDWPOP	European Diabetes Working Party for Older People
eGFR	Estimated glomerular filtration rate
FGM	Flash glucose monitoring
FPG	Fasting plasma glucose
FFA	Free fatty acids
GI	Gastrointestinal
GIP	Gastric inhibitory peptide
GLP-1	Glucagon-like peptide-1
Hb	Haemoglobin
HbA1c	Glycated haemoglobin
HHS	Hyperglycaemic hyperosmolar state
IAGG	International Association of Gerontology and Geriatrics
IDF	International Diabetes Foundation
NHS	National Health Service
OAD	Oral antidiabetic drug
OGTT	Oral glucose tolerance test
OSAMU	Optimising Safe and Appropriate Medicines Use
PG	Plasma glucose
PIM	Potentially inappropriate medicine
RBC	Red blood cell
SGLT2	Sodium glucose-linked transporter 2
STC	Systematic text condensation
SU	Sulfonylurea
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
UK	United Kingdom
US	United States

Abstract

Diabetes mellitus (DM) is prevalent among older adults and leads to disability, frailty, and dependency. In care homes, multimorbidity and polypharmacy may further complicate the management of DM and increase the risk of adverse events. This thesis aims to investigate the prevalence and management of DM in care homes, with special emphasis on medicines and blood glucose measurements.

Paper I was a cross-sectional study of 742 residents from 19 Norwegian nursing homes (NHs). We found a DM prevalence of 16 % (n=116), and that 74 % of residents with DM used blood glucose-lowering medicines. CBGM the last four weeks was registered for 73 % of the residents, frequency varied from daily to monthly. Six out of ten residents had at least one blood glucose reading <6.0 mmol/L. An HbA1c value the last twelve months was recorded for 77 % of residents, with a mean of 57 mmol/mol (7.3 %) and a range of 28-112 mmol/mol (4.7-12.4 %).

Paper II was a retrospective study of 826 residents from 30 English care homes, using baseline data from the CAREMED study. For residents with type 2 DM (T2DM), we described comorbidities and prescriptions, and identified potentially inappropriate medicines (PIMs). Of the 106 residents with T2DM, 76 % used blood glucose-lowering medicines. The number of comorbidities, prescriptions, and residents using ≥5 medicines was higher among residents with T2DM compared to residents without DM. We identified 346 PIMs, and nine out of ten residents with T2DM had at least one PIM. Of the 67 PIMs in the 20 % resident sample for validation, a care home physician agreed that 26 and 40 of them could be directly discontinued or considered discontinued, respectively.

Paper III was a qualitative study exploring the perspectives of NH staff on the use and usefulness, procedures, and potential challenges of CBGM in Norwegian NHs. We conducted three profession-specific focus groups, including five physicians, four registered nurses, and three auxiliary nurses, using a semi-structured interview guide. All professional groups found CBGM necessary when caring for residents with DM,

but tried to minimise its use to ease the strain on the residents. The participants mentioned access to and familiarity with procedures, equivalent practice, explicit documentation routines, and sufficient training in DM and its symptoms as means by which to promote the appropriate use of CBGM and ensure patient safety. Currently, one or several of these factors were lacking.

In conclusion, the research in this thesis shows that care home residents with DM suffer a high burden of medicines in general and use of DM medicines in particular. Patient safety may be further compromised by the lack of training and procedures in regard to CBGM and recognising deviant blood glucose concentrations. Thus, the potential to optimise medicine use and improve blood glucose-monitoring practices should be investigated further.

List of publications

Paper I Andreassen LM, Sandberg S, Kristensen GBB, Solvik UO, Kjome RLS. Nursing home patients with diabetes: Prevalence, drug treatment and glycemic control. Diabetes Res Clin Pract 2014; 105(1):102-9.

Paper II Andreassen LM, Kjome RLS, Solvik UO, Houghton J, Desborough JA. The potential for deprescribing in care home residents with Type 2 diabetes. Int J Clin Pharm 2016; 38(4): 977-84.

Paper III Andreassen LM, Granas AG, Solvik UO, Kjome RLS. 'I try not to bother the residents too much' – the use of capillary blood glucose measurements in nursing homes. BMC Nurs 2016; 15: 7.

Contents

1. Introduction

'So you're diabetic?'

'I prefer pancreatically challenged'.

~ Internet meme

1.1 Diabetes mellitus – a rising challenge

1.1.1 Classification and diagnosis

Diabetes mellitus (DM) is not one disease, but rather a group of complex metabolic diseases characterised by hyperglycaemia, which results from deficiencies in insulin secretion and/or response to insulin action. The specific aetiologies of DM have yet to be elucidated, but experts agree that a progressive loss or dysfunction of pancreatic β-cells responsible for producing insulin is the principal component. Disease mechanisms and progression, as well as clinical presentation, may vary from person to person, but broadly speaking, there are two major categories of DM: type 1 diabetes mellitus (T1DM) and type 2 diabetes mellitus (T2DM). The latter accounts for approximately 90 % of all cases of DM. Gestational diabetes and other specific types of diabetes (e.g. monogenic diabetes) are not discussed in this thesis. The risk of developing DM is associated with a strong genetic predisposition, but various environmental factors may also contribute to onset and progression of the disease (1, 2).

Both DM types can become manifest over a wide range of age groups, but T1DM typically presents itself in childhood or early adulthood, while T2DM often becomes manifest later in life. In T1DM, the pancreatic β-cells are destroyed through autoimmune processes, which ultimately lead to absolute insulin deficiency. In the more prevalent T2DM, the mechanisms for disease are more complex, mainly involving different degrees of reduced insulin sensitivity and deficient insulin secretion. These effects have long been attributed to an age-related decline in β-cell function together with an increase in adipose tissue, resulting in increased hepatic

glucose production and impaired glucose uptake in muscle (3, 4). However, during the last decade, the following have been recognised as contributing factors to the hyperglycaemia of T2DM (5, 6):

- increased glucagon secretion due to pancreatic α-cell dysfunction;
- deficiency and resistance to gut hormones (incretins glucagon-like peptide-1 (GLP-1) and gastric inhibitory polypeptide (GIP)) responsible for glucose-dependent insulin secretion and slowing down gastric emptying;
- impaired glucose reabsorption in the renal tubuli, due to upregulation of transport proteins (sodium glucose-linked transporter 2 (SGLT2));
- increased appetite, due to neurotransmitter dysfunction in the brain.

Recently, systemic low-grade inflammation and changes to the microbiota have also been suggested as parts of the pathogenesis picture. Although adding to the complexity of the pathophysiology of T2DM, these insights have resulted in new targets for medicines and warrant greater individualisation of therapy.

DM can be diagnosed based on either the measurement of plasma glucose or glycated haemoglobin (HbA1c) (2, 7). When measuring plasma glucose, venous sampling of the fasting plasma glucose (FPG) or the two-hour plasma glucose (2h PG) after an oral glucose tolerance test (OGTT) can be applied. HbA1c is a measure of the proportion of haemoglobin (Hb) in the red blood cells that is glycated, i.e. bound to glucose. The build-up of glycated haemoglobin reflects the average level of glucose to which the red blood cell (RBC) has been exposed during its life span (7). The average RBC life span is approximately 120 days; however, an HbA1c change toward treatment goal value takes between 25 and 30 days to reach 50 %, and 50 to 70 days to reach 80 % (8). HbA1c is expressed as the ratio of glycated Hb to total Hb in a unit of mmol/mol, which has recently replaced percent as the commonly used unit in Norway (7).

The hyperglycaemia limits that make up the criteria for diagnosis are listed in Table 1. If classic symptoms of hyperglycaemia are present, one affirmative test result or a random plasma glucose measurement ≥11.0 mmol/L is sufficient. If the patient displays no clinical symptoms of hyperglycaemia, two affirmative tests of the FPG, 2h

PG, or the HbA1c are required to confirm the diagnosis (Table 1) (2, 7). In the clinical practice recommendations issued by the American Diabetes Association (ADA), it is stated that the two tests can either come from the same sample or from two separate samples. If using separate samples, it is recommended that the second test be performed without delay (2). Norwegian guidelines, however, state that the diagnosis is confirmed if the patient presents with any of the first three values in Table 1 in two separate samples, taken on two separate days, within a period of two weeks (7).

For the FPG, the patient should have had no caloric intake and avoid smoking for at least eight hours prior to measurement. In the OGTT, the patient fasts for 8-14 hours before drinking 75 g of glucose dissolved in water. The plasma glucose is measured two hours thereafter (7). Compared to the FPG and the 2h PG, the HbA1c measurement is more convenient as it does not require fasting. In addition, it has better pre-analytical stability and is relatively robust regardless of acute changes in glucose levels (2, 9). Thus, HbA1c testing was recommended by the World Health Organization (WHO) as the preferred method of diagnosing DM in 2011 (9). Shortly thereafter, in 2012, HbA1c became the primary diagnostic criteria in the Norwegian guidelines as well (10).

Table 1. Criteria for diagnosing diabetes mellitus (2, 7)

FPG (no caloric intake for ≥8 h)*	≥7.0 mmol/L
OR	
2h PG following OGTT (intake of 75 g anhydrous glucose dissolved in water)*	≥11.1 mmol/L
OR	
HbA1c performed in a laboratory using a NGSP-certified method standardised or traceable to the results in the DCCT*	48 mmol/mol (≥6.5 %)
OR	
Random PG in a patient presenting with classic hyperglycaemia symptoms or a hyperglycaemic crisis	≥11.1 mmol/L

*If there is no display of hyperglycaemia symptoms, diagnosis should be confirmed by additional testing.

2h PG = two-hour plasma glucose, DCCT = Diabetes Control and Complications Trial, FPG = fasting plasma glucose, HbA1c = glycated haemoglobin, NGSP = National Glycohemoglobin Standardization Program, OGTT = oral glucose tolerance test, PG = plasma glucose

1.1.2 Hyperglycaemia and its consequences

If not treated, hyperglycaemia will have several negative impacts on the body. Early on, symptoms such as polyuria, polydipsia, fatigue, blurred vision, and frequent infections can occur (1). In the long term, uncontrolled hyperglycaemia may result in macrovascular and microvascular complications. More specifically, high levels of circulating glucose will over time cause damage to blood vessels, affecting the heart, kidneys (nephropathy), eyes (retinopathy), and nerves (neuropathy) (11). This could in turn lead to complications such as hypertension, stroke, renal failure, impaired vision, sexual dysfunction, foot ulcers and amputation. DM is also associated with a higher risk of developing or exacerbating other diseases, such as thyroid disease, coeliac disease, cancer, fractures, dementia, mental health disorders and various infectious diseases (12).

The high disease burden that accompanies DM is in fact responsible for the greater proportion of the direct medical costs attributed to DM, according to a 2017 population-based analysis from the United States (US) (13). It was estimated that people with DM incur one in four of all healthcare dollars and that they have more than twice the healthcare expenditures compared to people without DM. When adjusted for inflation and diabetes prevalence, the average cost of diabetes had increased by 13 % since 2012 (13). Updated cost numbers from Norway are scarce, but an assessment from 2011 estimated that the total medical costs attributable to DM ranged from €516-589 million (14). The majority part of these costs was related to prevention of microvascular and macrovascular complications, rather than to treatment of complications. In terms of medicine use and medical supply materials, a person with DM was found to have an annual average excess cost of €2730 compared to a person without DM. However, the total national expenses attributable to DM had not risen since 2005, when the cost was estimated at €535 million. (14).

In the US, the annual cost of resources spent on DM increases by age, and 61 % of all healthcare expenditures attributed to DM are utilised by those ≥65 years of age (13). Likewise, the DM prevalence is highest among older age groups. On a global level it

was estimated that in 2017, DM affected 451 million people between the ages of 18-99 years, where those aged ≥65 years accounted for 123 million (27 %). The total figure is expected to increase to 693 million by 2045, and the highest increase is expected among those aged ≥65 years, increasing to 253 million (36 %) (1).

1.2 Diabetes in old age

1.2.1 Pathogenesis

In developed countries, 65 years is generally used as the conventional cut-off to define old age. This is most likely a social construct that corresponds roughly to the retirement age in many countries. Although there is broad agreement that the biological processes which increase the susceptibility to disease and death are not connected to a specific chronological age, this definition of old age is also applied in health research, as exemplified in the two previous paragraphs.

There are several reasons why DM, and primarily T2DM, is prevalent in the older population. Advanced age is associated with sarcopenic obesity, including deteriorating functional ability due to loss of muscle mass and strength, as well as with increased adiposity resulting from changes in fat distribution and physical inactivity (15). Depletion of skeletal muscle, which is mainly responsible for insulin-mediated glucose disposal, greatly influences insulin sensitivity (15), while excess adipose tissue leads to elevated levels of free fatty acids (FFAs) (16). FFAs impair insulin-mediated vasodilation of endothelial tissue and stimulate inflammatory pathways, both of which contribute to increased insulin resistance and thereby reduced glucose disposal (15-17). Furthermore, subcellular defects, such as a reduced mitochondrial oxidative capacity and insulin receptor deficiency, have been suggested as contributing factors to insulin resistance in advanced age (15, 17).

In younger adults, an increased insulin resistance prompts the β-cells to increase the insulin response in order to restore normoglycaemia. However, due to the progressive β-cell failure with age, β-cell function is impaired and compensatory hyperinsulinaemia does not occur (3). In addition, β-cell sensitivity to incretin

hormones may be reduced, further compromising insulin secretion (3). Other co-existing diseases and a number of medicines, commonly presented in the older population, could also have a negative impact on both glucose metabolism and insulin secretion (3, 15, 17). This interplay between altered insulin action and reduced insulin secretion could trigger an already genetic predisposition for the disease, causing diabetes to manifest (Figure 1).

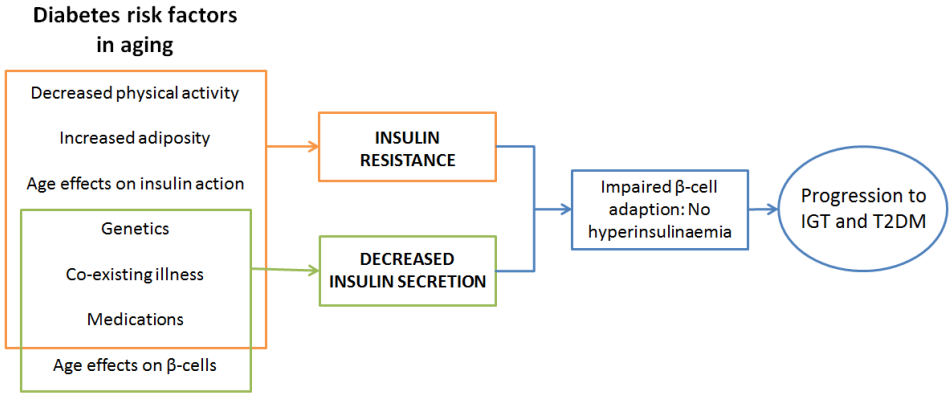

Figure 1. Age-related risk factors contributing to insulin resistance (orange) and decreased insulin secretion (green), which together with impaired β-cell function leads to development of impaired glucose tolerance (IGT) and type 2 diabetes mellitus (T2DM). Adapted with permission from Chang AM, Halter JB. Aging and insulin secretion. Am J Physiol Endocrinol Metab 2003; 284(1): E7-12.

There is evidence that lean older persons with DM have a relatively preserved insulin sensitivity, and that the main metabolic deficiency is a reduced insulin secretion (18). In contrast, obese older persons with DM have a relatively preserved insulin secretion, presenting with insulin resistance as the principal defect (19). This is different from middle-aged persons with DM, where both obese and lean persons present with relative deficiencies in both insulin secretion and insulin sensitivity (18, 19).

1.2.2 Clinical features and complications

Hyperglycaemia

The renal threshold for glucose increases with age, so despite hyperglycaemia, glycosuria seldom occurs. Polydipsia is also uncommon, due to decreased thirst

perception (20). Thus, symptoms of DM may be absent, unspecific, or confused with common age-related symptoms such as confusion and incontinence (20, 21). This may lead to a failure in the detection and treatment of hyperglycaemia.

Furthermore, several medicines commonly used in advanced age may worsen symptoms of pre-existing hyperglycaemia or induce it. For example, it is well known that statins have a diabetogenic effect, although this effect may differ with the type and dose of the statin. Thiazide diuretics, beta blockers, glucocorticoids, and some antidepressants are also associated with an increased risk of hyperglycaemia. The main mechanisms of medicine-induced hyperglycaemia are diminution of insulin secretion and/or production, peripheral insulin sensitivity and/or promotion of weight gain, promotion of hepatic gluconeogenesis and/or glycogenolysis, or direct cytotoxic effects on pancreatic cells (22).

Persistent and untreated hyperglycaemia in the older person carries an additional risk compared to the general risk attributed to this in the younger person with DM. For instance, dehydration and electrolyte disturbances pose serious risks to the older person, and also contribute to dizziness and a greater probability of falling in addition to increasing the risk of hyperglycaemic emergencies, such as diabetic ketoacidosis (DKA) or hyperosmolar hyperglycaemic states (HHS). Infections, oral health problems and urinary incontinence may also result from persistent hyperglycaemia, further deteriorating health and quality of life (21, 23, 24).

Hypoglycaemia

The risk of hypoglycaemia is also increased in old and frail individuals with DM (25, 26). Hypoglycaemia is associated with a range of diverse symptoms that occur at an abnormally low plasma glucose concentration, usually below 4.0 mmol/L (Table 2) (27-30).

Although all of the symptoms in Table 2 are associated with hypoglycaemia, their presentation, pattern, and intensity generally vary between individuals (29, 30). Moreover, hypoglycaemia may have unusual symptom presentation in older patients compared to younger patients (30-33), and could therefore be misinterpreted, for

instance as cerebrovascular or cardiovascular events (30, 33, 34). Examples of unusual symptoms are dilated pupils, abnormal movements, and sudden mood changes (35).

Table 2. Symptoms of hypoglycaemia (27-30)

Autonomic symptoms (first warning signs)	Neuroglycopenic symptoms
Sweating	Warmth
Shaking / Trembling	Weakness
Palpitations	Loss of concentration / Difficulty thinking
Anxiety	Lightheadedness / Dizziness
Hunger	Unsteadiness
Paresthesias / Tingling / Numbness (lips)	Tiredness / Drowsiness
Pallor	Difficulty speaking
	Visual disturbances
(Headache)	Abnormal behaviour (agitation, aggressiveness)
(Nausea)	Confusion
	Coma

Symptoms in parentheses are not considered autonomic, but are often listed amongst the first warnings signs of hypoglycaemia

Age-related declines in renal function, hepatic metabolism, and blood flow (36) may be contributing factors to the increased hypoglycaemia risk seen in this population. As a result of the renal and hepatic dysfunction, medicines will accumulate in the body, increasing the risk of adverse effects. In addition, DM in itself can also compromise renal function over time, further increasing hypoglycaemia risk.

Moreover, the ability to hear, remember, and understand instructions, as well as vision and dexterity, are fundamental for management of a sometimes complex diabetes medicine regime and capillary blood glucose measurements (CBGM). As one or several of these abilities diminish with age, so will the individual's capacity to identify, treat, and report hypoglycaemia (36). In addition, hypoglycaemia unawareness, meaning that the patient is unable to detect the first warning signs of hypoglycaemia (Table 2), is more prevalent in old age (28, 37). This symptom alteration of hypoglycaemia is commonly attributed to a long duration of diabetes, antecedent hypoglycaemia and metabolic changes (28, 30). For instance, older adults have a decreased secretion of one or more counter-regulatory hormones for neutralising hypoglycaemia (28, 38).

Physical and cognitive deterioration from hypoglycaemia are not only apparent in the actual emergency. Studies have shown that repeated episodes of hypoglycaemia are associated with several cardiovascular events (30) and moderate to severe impairment of a patient's general health status (26). Especially severe hypoglycaemia may exacerbate cognitive function (27, 29, 39), increase the risk of falls and fractures (29), hospitalisation and premature death, as well as other adverse events (40, 41).

Comorbidities and clinical complexity

Studies have found that older persons with DM have a median of five comorbid conditions (interquartile range (IQR) 3-8) and that they also are more likely to experience physical symptoms, such as acute pain and shortness of breath (42, 43). Some of the comorbidities contributing to this, such as ischaemic heart disease, hypertension, and peripheral neuropathy are directly related to DM. However, gastro-oesophageal reflux disease, depression, chronic airway disease, chronic pain, and inflammation are also among the common comorbidities in these patients (42).

The metabolic disturbances, complications, and symptom burden following DM contribute to high clinical complexity, disability, ill health, and reduced quality of life in older people (15, 44-47). For instance, an acceleration or increased risk of cognitive decline or dementia in older patients with DM has been reported (48-51), although the link between the two has not been fully established. Other geriatric syndromes such as depression, urinary incontinence, and falls are also more frequent in those with DM compared to those without DM (52, 53). Several studies link an increased risk of falls to diabetes complications such as retinopathy and neuropathy (54-56). In addition, muscle strength and quality also deteriorate faster in older persons with DM compared to older persons without DM (42, 57).

In summary, DM, its complications, and its treatment are all associated with a progressive decline in both physical and cognitive function, resulting in a deterioration of the capacity for self-care. Thus, DM is a common cause of the utilisation of nursing and residential care services (13, 58, 59), mediated by clinical, cognitive, and functional impairment (58, 59).

1.3 Diabetes in care homes

1.3.1 Definition of care homes

The provision and regulation of care-home services vary across countries. We define care homes as institutions that are staffed 24 hours a day and offer accommodation and care to older people who are unable to live at home, for shorter or longer periods. Care homes include both nursing homes and residential homes. Nursing homes provide nursing care in addition to personal care, and hence should always have qualified nursing staff on site. The research in this thesis was carried out in Norway and the United Kingdom (UK), where the organisation of care-home services differs. In Norway, residential and nursing homes are normally separated from each other, with some exceptions. In the UK, it is more common that the two exist within the same care home. The term care home is mainly used throughout this thesis, except for when it is relevant to distinguish nursing homes from residential homes.

1.3.2 Prevalence and burden of DM in care homes

In the last two decades, multiple studies have investigated DM prevalence in care homes across Europe (60-79). The latest studies (data from 2011-2014) indicate a DM prevalence in care homes of 14-22 % (72-79). In high-income countries outside Europe, the most recent prevalence numbers vary from 18 % in Australia (80) to 24 % in Canada (81), whilst in the US numbers as high as 35 % have been reported (82). For additional details of studies reporting DM prevalence in care homes across Europe and outside Europe, please see Appendix 1 and Appendix 2, respectively.

The UK has been among the leading countries describing the DM field in care homes, reporting prevalence, clinical characteristics, and current level of care for residents with DM (60, 63, 64, 68, 69, 73, 83-87). Recently-reported prevalence numbers for diagnosed DM in UK care homes were 16-22 % (68, 69, 73). In contrast, exploration of DM prevalence and management in Norwegian care homes has been scarce. A study from the Tromsø area in 2006 reported that 20 % of older people aged >69 years who received nursing care within an institution or in their own homes had a DM

diagnosis (88). However, this study excluded those with severe illness or dementia, and did not report which patients lived in a nursing home or which patients lived at home. Three newer studies, the first investigating characteristics of cancer patients in cognitively-intact nursing home residents, the second the characteristics of nursing home residents with dementia, and the third investigating whether management of DM in nursing homes was in accordance with guideline recommendations, found a DM prevalence of 16.7 %, 15.3 %, and 15.2 %, respectively (77, 89, 90).

Advanced age, dementia, cognitive impairment, functional impairment, and increased number of prescriptions are all major reasons for care-home residency (91). As such, care home residents have a high burden of disability, comorbidity, and polypharmacy, and are frequent users of healthcare resources (92). For residents with DM, the burden may be greater than for non-DM residents. Most studies comparing the two groups report that residents with DM are younger (73, 79, 93-96), have more comorbidities (73, 93, 96-98) and prescriptions (73, 79, 93-96), and experience more emergency department visits or hospitalisations (72, 73, 95-97), than do residents without DM. Experience of daily or persistent pain is also common (73, 93, 99, 100); however, there are conflicting results as to whether pain is more frequent in residents with DM compared to residents without DM (73, 79, 99, 100).

1.4 Clinical practice recommendations for DM management

The increasing prevalence and metabolic distinction of DM in old age have prompted the development of several guidelines, consensuses, and reviews specifically targeting older adults, including care home residents (Table 3). The recommendations have been, and still are, pragmatic and based on the best available evidence and clinical expertise, reflecting the lack of robust studies including older adults and the heterogeneity of this patient group. As the majority of patients have T2DM and the evidence for management of T1DM in older adults is especially limited, most recommendations apply to the former. However, recommendations for T1DM are included where appropriate.

Table 3. Overview of recommendations for DM management in older adults and care home residents (excl. specific end-of-life care guidelines)

Title	Last updated	Comment
American Diabetes Association (ADA)		
Standards of medical care in diabetes: 12. Older adults (101)	2019	Consensus report 2012 (23), included in standards 2015
Management of diabetes in long-term care and skilled nursing facilities: A position statement of the American Diabetes Association (24)	2016	
American Geriatrics Society (AGS)		
Guidelines abstracted from the American Geriatrics Society Guidelines for improving the care of older adults with diabetes mellitus: 2013 update (102)	2013	First published 2003
Diabetes UK		
Good clinical practice guidelines for care home residents with diabetes (103)	2010	Building on document published 1997
Diabetes Canada		
Diabetes in older people (104)	2018	
European Diabetes Working Party for Older People (EDWPOP)		
An international position statement on the management of frailty in diabetes mellitus (105)	2017	
Diabetes mellitus in older people: position statement on behalf of the International Association of Gerontology and Geriatrics (IAGG), the European Diabetes Working Party for Older People (EDWPOP), and the International Task Force of Experts in Diabetes (106)	2012	
European Diabetes Working Party for Older People 2011 clinical guidelines for type 2 diabetes mellitus. Executive summary (107)	2011	First published 2004
International Diabetes Foundation (IDF)		
IDF Global guideline for managing older people with type 2 diabetes (108)	2013	
Other		
McKellar guidelines for managing older people with diabetes in residential and other care settings (109)	2014	
Pragmatic diabetes management in nursing homes: individual care plan (France) (35)	2013	Expert committees including general and specialist healthcare professionals
Evidence-informed guidelines for treating frail older adults with type 2 diabetes: from the Diabetes Care Program of Nova Scotia (DCPNS) and the Palliative and Therapeutic Harmonization (PATH) program (Canada) (110)	2013	

The newest recommendations compile and highlight key aspects of the earlier recommendations, but also incorporate new insights from the ever-growing body of DM research. There has also been a development towards including topics that are recognised as increasingly important in the care of older adults, such as deprescribing and inter-professionalism.

In Norway, national guidelines for diabetes only recently included recommendations for older adults and care home residents with DM (7). However, the information is limited to targets for glycaemic control and blood pressure. A general clinical procedure for diabetes care in nursing homes, primarily meant to aid registered nurses, was developed and published in 2011 (111). This procedure covers eight areas of care: diagnosis, assessment on admission, treatment goals and algorithms, care planning, injection techniques and blood glucose measurements, preventing and treating complications, hyperglycaemia, and hypoglycaemia. Additionally, clinical procedures for nursing home physicians were published in 2015, and revised in 2018. These include recommendations for management of DM treatment, hypoglycaemic and hyperglycaemic emergencies (112).

Due to close agreement between the recommendations listed in Table 3, the documents from the ADA (24, 101) and the International Diabetes Foundation (IDF) (108) will serve in the following as the main resources to sum up the recommendations. Other recommendation documents will be cited when relevant.

1.4.1 Approach to care guided by health characteristics

Rather than distinguish by age group, the recommendations highlight comorbidity, cognitive and physical function, and life expectancy as important when making care decisions. Despite slight differences in how the recommendations group the patients, three major classes of older patients with DM can be identified and serve as a framework for considering treatment goals and care requirements: 1) patients who are relatively healthy and/or functionally independent; 2) patients with one or more medical, cognitive and/or functional problems, which can make self-care difficult; and 3) those with significant comorbidity, cognitive and/or functional impairment, and/or

who reside in a long-term care facility (24, 101, 108). Distinct recommendations have also been developed for end-of-life patients/palliative patients with DM (24, 101, 103, 108, 109), but these are not the focus of this thesis and thus will not be discussed further.

When consulting frameworks such as these, one should bear in mind that the resident's health status may change over time, and also that not all care home residents necessarily fall into the third group. Consequently, recommendations encourage care homes to develop their own policies for diabetes care, and make use of individual care planning on admission, following care transitions and during annual reviews (24, 101, 103, 107-109).

Various assessment tools and procedures can aid determination of the patient's requirements and help organise the care plan. There is no consensus on which data should be collected; however, information about functional and cognitive capacity should be included as a minimum. Additional measures can be applied to gain information about other factors that are relevant to determine the resident's health status. Frailty is amongst the more commonly suggested measures, as it increases the risk of sarcopenia, falls, complications, and death in these patients. By some, the degree of frailty is specifically used as a defining feature to guide correct placement of the patient into the care classes outlined above (104, 108). There is no one definition of frailty, but there is broad agreement that it occurs due to a combination of decline in physical function (e.g. restriction in mobility and strength), and reduced ability to resist to clinical, functional, or psychosocial stressors (101, 104, 105, 108). Weight loss or inadequate nutritional intake are thought to increase the risk of frailty, and are sometimes included as part of the definition (101, 104, 108). The Clinical Frailty Scale, a 9-point scale, is one way to determine the degree of frailty (104, 108).

1.4.2 Treatment rationale and targets

Table 4 gives an overview of the general recommendations made for treatment rationale and targets for HbA1c, blood pressure, and lipids in the three patient categories defined above, based on several sources (24, 35, 101, 102, 104, 107-109).

The targets provided in Table 4 serve as broad guidelines and should be individualised according to each patient's specific requirements and disease features. A high degree of frailty and short expected life span entail that strict treatment targets and rigid recommendations may have limited benefit (45, 46), and thus, more relaxed goals are recommended for care home residents compared to those recommended for healthier older adults and younger adults (23, 35, 108).

Table 4. Objectives and recommended treatment goals for older adults with diabetes grouped by health characteristics

Patient characteristics	Objectives	Reasonable goal for HbA1c	Blood pressure (mmHg)	LDL-C (mmol/L)
Group 1 Relatively healthy and independent	Treatment and care should consider a longer remaining life expectancy and thus prevent cognitive and functional decline, falls and long-term complications from DM	≤58 mmol/mol (7.5 %)*	<140/90	<2.0 or >50% reduction from baseline (adjusted based on CV risk) Statin unless contraindicated or otherwise clinically inappropriate
Group 2 Complex medical, cognitive and/or functional problems making self-management difficult	Treatment and care should consider an intermediate remaining life expectancy, high treatment burden, risk of hypoglycaemia and falls Focus should be on preserving functional status and prevent complications (within reason)	≤64 mmol/mol (8.0 %)	<140/90	Individualise based on goal for group 1
Group 3 Frail, significant burden of comorbidities, cognitive and/or functional impairment, and/or residing in nursing care	Treatment and care should consider a limited remaining life expectancy and thus risk-benefit evaluations should be made Focus should be on quality of life, monitoring and preventing dehydration, malnutrition, hypoglycaemia, HHS and DKA. Minimal treatment for palliative patients	≤69 mmol/mol (8.5 %)	<150/90	Individualise based on goal for group 1

CV=cardiovascular, DKA=diabetic ketoacidosis, DM=diabetes mellitus, HHS=hyperosmolar hyperglycaemic state, LDL-C=Low density lipoprotein cholesterol

*Lower targets may be appropriate if patient is healthy and has low risk of hypoglycaemia
The table is developed based on frameworks and recommendations issued by the American Diabetes Association (24, 101), the American Geriatrics Society (102), the European Diabetes Working Party for Older People (107), the International Diabetes Federation (108), Benetos et al. (35), and Dunning et al. (109)

Ismail-Beigi et al. (113) were the first to propose a framework for which factors to consider when individualising patients' glycaemic treatment targets. This framework was later adapted by the ADA and the European Association for the Study of Diabetes (EASD) (114). The ADA adaption of this framework is presented in Figure 2 (with permission from the ADA).

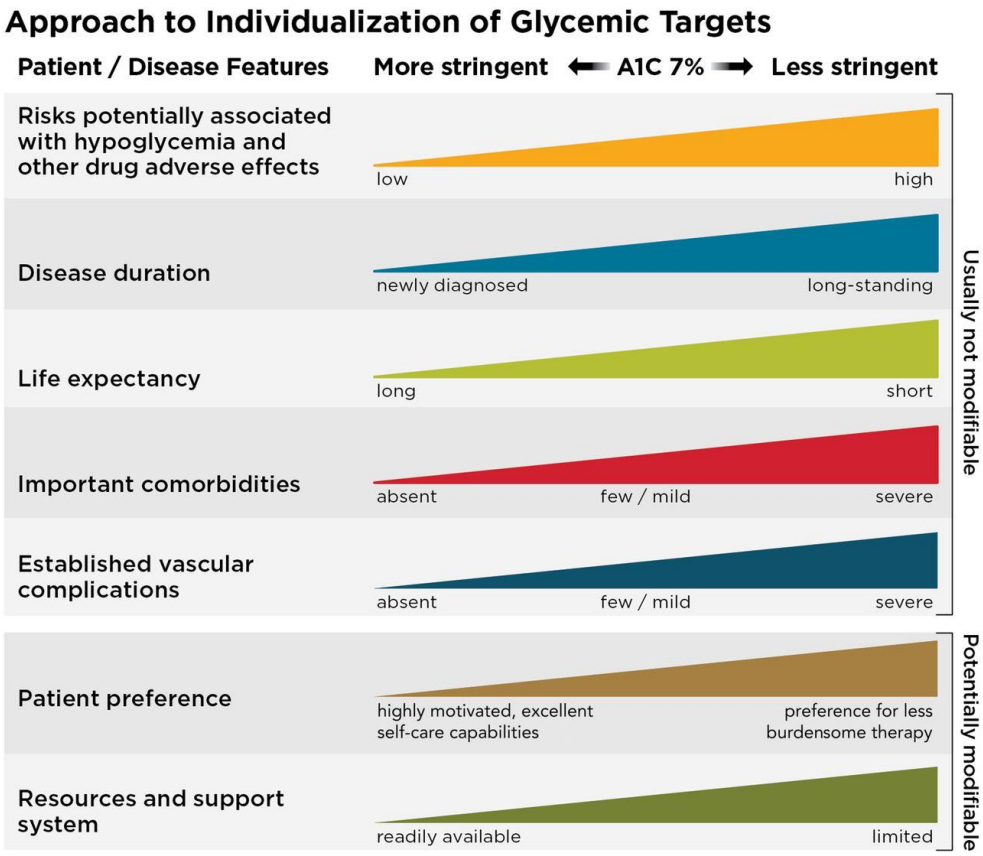

Figure 2. Factors to consider when individualising glycaemic target. Reprint from the American Diabetes Association, 6. Glycemic targets: *Standards of Medical Care in Diabetes*—2019, American Diabetes Association, 2019. Copyright and all rights reserved. Material from this publication has been used with the permission of the American Diabetes Association.

Beyond the fact that the potential advantages of tight glycaemic control are of less importance in older patients with a limited life span, evidence exists that stringent HbA1c goals may even be harmful in this population. Firstly, incidence of hypoglycaemia increases substantially with age in patients with HbA1c <53 mmol/mol

(7.0 %) (115). Secondly, prevalence of falls is also the highest in patients with HbA1c <53 mmol/mol (7.0 %), with the exception of those aged ≥85 years, where an HbA1c >75 mmol/mol (9.0 %) is associated with the highest fall prevalence (115). Finally, the risks of a major cardiovascular event and all-cause mortality are the highest in patients with a median HbA1c level 46 mmol/mol [range 13-50] (6.4 % [range 3.3-6.7]) and 86 mmol/mol [range 85-154] (10.5 % [range 9.9-16.2]) (116). In general, an HbA1c level <53 mmol/mol (7.0 %) is discouraged in frail, older patients, and should be viewed as an alert to overtreatment (35, 108). A group of Canadian experts encourages an even more relaxed line in regard to glycaemic targets, stressing that values below 64 mmol/mol (8.0 %) warrant decreasing or discontinuing antidiabetic pharmacotherapy in these patients. They further endorse HbA1c values up to 108 mmol/mol (12.0 %) as acceptable if the patient is otherwise asymptomatic (110).

Beyond glycaemic control, recommendations also emphasise the value of treating hypertension in older adults, as there is strong clinical evidence that this results in a reduction in cardiovascular morbidity and mortality (101, 108). Choice of antihypertensive therapy follows the same principles as for younger adults, but treatment targets should be individualised and special consideration given to potential detrimental side effects and interactions with other medicines and/or diseases (104, 108, 117). There is limited evidence to support blood pressure (BP) targets <140/90 mmHg (Table 4), and systolic BP <130 mmHg and diastolic BP <67 mmHg may increase mortality in older adults with diabetes (104).

There is less evidence of the benefits of lipid-lowering therapy, especially in patients aged >80 years. Statins, especially in high doses or with higher potency, hold a greater risk of adverse effects such as myopathy and cognitive impairment, which may outweigh potential benefits (108, 118). There seems to be an agreement that statins (or other lipid-lowering therapy where appropriate) could be indicated when clinically relevant, i.e. where life expectancy of the resident at least equals the time frame for expected benefit (101, 108). For primary prevention, the benefit of statins on CVD in older people is somewhat uncertain, but some have shown an increase in effect after five years of therapy. The benefit of statins has been shown for prevention of new

cardiovascular events in people with established CVD (secondary prevention). However, those aged >80 years, those with severe physical or cognitive impairment, or those with a life expectancy <12 months, are unlikely to benefit from statins (108). There is also less agreement on setting specific goals for lipids, as no optimal level of cholesterol has been established for octogenarians with diabetes (118). Thus, lipid targets are generally extrapolated from those given for the younger population, but with the suggestion that they can be relaxed in the more functionally dependent groups (104, 108).

Overall, the aims for care home residents are to avoid hypoglycaemia and symptomatic hyperglycaemia, minimise complications that can deteriorate function, and enhance quality of life. Hence, the care plan should consider all aspects of care, not just clinical targets for glycaemic control, blood pressure, and lipids. For instance, it is encouraged to include management plans for fluid intake, hypoglycaemia, hyperglycaemia, diabetes complications, physical activity, and medicine regimen with review dates. Assessments of and strategies to improve comorbidities or geriatric syndromes closely associated with DM, e.g. cognitive dysfunction, depression, malnutrition, urinary incontinence, falls, skin problems, and oral health problems, are also emphasised (24, 101-104, 108, 109, 111).

1.4.3 Blood glucose monitoring and glucose levels

There is broad agreement that an adequate overview and handling of glycaemic control will improve care for care home residents with DM and prevent acute events such as hypo- and hyperglycaemia (24, 35, 101-104, 108-111). Unfortunately, studies have reported findings that indicate that glucose monitoring may do more harm than good. Incorrect sampling leading to pathogen transmission is probably the most serious shortcoming (119-121). Lack of protocols and agreement on when to perform CBGM (122-127) may be the reason CBGM fails to be performed based on individual needs (87, 128, 129), and uncertainty of how to make use of the results (65) may explain why blood glucose logs are sometimes incomplete (122, 130). For glucose monitoring to be of value, it should have a clear purpose, resident and/or staff should be trained in

appropriate sampling and be able to review and act upon the results, and an analytical quality assurance system should be in place.

A few of the recommendations state that all residents with DM have an HbA1c measurement taken a minimum of every six months, and more often if needed or indicated (102, 103, 111). However, HbA1c may not always be a reliable measurement for glycaemic control in this population. Conditions or treatments affecting the life span of the erythrocytes are not uncommon in older adults with DM and may give false readings of HbA1c (2, 101, 109). For instance, anaemias of chronic disease, iron deficiency, or other nutritional deficiencies increase with age and are especially common in care home residents (131). Depending on the cause of the anaemia, the HbA1c value could be either falsely low or high (132). Furthermore, evidence exists that HbA1c readings are significantly lower in patients with advanced chronic kidney disease (CKD) compared to those without CKD, at comparable levels of blood glucose measured by continuous glucose monitoring (CGM) (133). Lastly, while HbA1c reflects the resident's average level of glycaemic control, the glycaemic variability may be much wider in an older person compared to a younger person, especially if the patient's condition is unstable, or acute illness or dehydration occur (24, 101, 104, 134). Thus, CBGM should be used to complement or substitute HbA1c measurements when appropriate (24, 101, 104).

CBGM is commonly applied to monitor day-to-day fluctuations in blood glucose. CBGM can alert nursing staff to detrimental fluctuations in blood glucose levels that may require action in the form of adjustment of therapy, intake of fluids or food, or closer follow-up for a period. CBGM is especially important in detecting and treating hypoglycaemia. The threshold for hypoglycaemia is defined as a blood glucose level <4.0 mmol/L by most recommendations (24, 101, 106, 108, 111), with the exception of the Australian McKellar guidelines, which define hypoglycaemia as a blood glucose level <6.0 mmol/L (109). However, the recommended ideal glucose range for frail patients, in order to minimise risk of hypoglycaemia and avoid symptoms of hyperglycaemia, varies between sources. Most agree that avoiding glucose levels <6.0 mmol/L is necessary to prevent hypoglycaemia (101, 103, 106, 108, 109, 111), whilst

there is generally a wider interval for what is an acceptable upper limit to minimise the risk of dehydration, electrolyte imbalance, urinary incontinence, dizziness, falls, and hyperglycaemic emergencies. The International Association of Gerontology and Geriatrics (IAGG) and the European Diabetes Working Party for Older People (EDWPOP) advocate keeping glucose levels below the renal threshold for glycosuria (~11.0 mmol/L) (106), but the majority accept that random glucose levels between 12-14 mmol/L generally do not cause symptomatic hyperglycaemia (24, 101, 110, 112). The McKellar guidelines state that a blood glucose level >15 mmol/L should be considered hyperglycaemia, which can turn into a medical emergency if consistently elevated and the resident is feeling unwell (109). A Canadian expert committee support glucose levels up to 20 mmol/L, if these are not associated with bothersome hyperglycaemic symptoms and the patient has a short life expectancy (110).

For residents with T2DM, there is no consensus regarding which residents should receive CBGM and the appropriate frequency of measurement, but there exists an awareness to avoid unnecessary monitoring. Most recommendations thus do not discourage CBGM in any resident; they state that it should be decided on a case-to-case basis founded on the goals for care, complexity of treatment regimen and risk of hypoglycaemia. They put special emphasis on that residents using pharmacotherapy with high hypoglycaemia-risk, such as insulin, sulfonylureas (SU) or meglitinides, should have a management plan that includes a schedule for CBGM (24, 102-104, 108, 111, 112). The ADA proposes block testing: fasting/pre-prandial glucose measurements on some days, postprandial and bedtime glucose measurements on other days as a means to provide a pattern for glycaemic variability without multiple daily measurements (24). Less invasive procedures, such as flash glucose monitoring (FGM), has been investigated in older long-term care residents, but inaccuracy in detecting lower glucose values currently limits its use in this population (135).

In contrast, guidelines from France, Canada and Australia are more specific regarding which residents should receive CBGM, and how often (35, 109, 110). The French and Australian recommendations state that CBGM should be performed at reasonable intervals during the day (e.g. fasting, postprandial and 4 pm), daily to monthly

depending on residents' stability and risk of hypoglycaemia, at least for those using insulin or SU (35, 109). For residents with stable blood glucose levels using other treatment, the Australian recommendations still advocate for CBGM (109), whilst the French recommendations state that the monitoring of HbA1c is sufficient (35). In contrast, the Canadian recommendations argue that even for residents who are stable on basal insulin alone, there is no need for routine CBGM. Furthermore, they conclude that residents who receive both basal and mealtime insulin should have CBGM performed once daily, at alternate times, if they have remained stable on this regimen (110). All three advocate for more frequent CBGM if the resident is unstable, has acute illness or dehydration, or if his or her behaviour and/or cognition changes (35, 109, 110). The Canadian recommendations propose the following situations where CBGM should be performed more frequently: when the resident experiences 1) acute illness; 2) a major change in health status (e.g. substantial functional or cognitive decline); 3) significant change in oral intake; when there is 4) a suspicion of detrimental glucose levels (high or low); 5) an adjustment of treatment for DM; 6) an initiation of or change in oral steroid use (110).

Equally important as monitoring schedules and detailed instructions for management of hyper- and hypoglycaemia, is the appropriate documentation of CBGM readings and other changes in treatment, food and fluid intake, and behaviour that could have consequences for, or be related to, blood glucose levels (35, 103, 108). This information is essential as a reference for everyone who cares for the resident, especially staff that is unfamiliar with the resident (35). Diabetes UK recommends that the care home should define those responsible for CBGM and that no member of staff without training in CBGM and adequate knowledge of diabetes, its symptoms, and how to act on deviant readings, perform CBGM. Whilst they specifically state that the resident should be involved in decisions on monitoring frequency and glycaemic targets, they advise that preferably only registered nurses should undertake the task of performing CBGM (103). On another note, the IDF and the McKellar guidelines encourage care homes to provide adequate support for the resident to self-manage blood glucose monitoring where appropriate (108, 109). Subsequently, the physician should have the main responsibility in supervising and following up any deviations or

other concerns (35) and review at least annually the need and frequency for CBGM (109). As care homes may use the same meter for several residents, procedures for hygiene and correct sampling should also be in place, together with protocols for maintenance and external quality assurance of equipment (103, 109).

1.4.4 Pharmacologic management of diabetes

The overall aims for managing care home residents with DM should also be normative when choosing medicines. Thus, focus is put on avoiding hypoglycaemia and overtreatment together with maintaining quality of life. One should consider the potential for medicine-disease interactions, medicine-medicine interactions, impact on weight, other adverse events, the need to involve care givers, and other patient-related factors that may influence choice of therapy (101, 103, 108, 109).

Metformin is considered the first-line therapy in residents with T2DM, unless the estimated glomerular filtration rate (eGFR) is below 30 ml/min/1.73 m^2, due to the risk of lactic acidosis (101, 108, 136). When the eGFR is between 30 and 60 ml/min/1.73 m^2, metformin is still considered safe with dose reduction and closer monitoring of renal function and adverse events (23, 102, 108, 136). Caution should also be exercised in patients with impaired hepatic function or heart failure, and temporarily discontinuing metformin should be considered during acute illness, dehydration, or other conditions that may compromise renal or hepatic function (101, 136).

With newer medicines and insights into the pathophysiology of T2DM, the potential for individualising therapy has increased. If metformin is contraindicated or not tolerated, there is no defined alternative option. Likewise, the options for second- and third-line therapies are not clearly stated, but should be chosen based on patient- and medicine-specific factors (101, 104, 136). Thus, providing guidance based on factors such as cardiovascular disease (CVD), CKD, promoting weight loss, avoiding hypoglycaemia, and minimising medication costs have replaced fixed algorithms for treatment selection in T2DM (136).

For individualisation to be beneficial, sound knowledge of the advantageous and disadvantageous properties of the various antidiabetic medicines is crucial (24, 35, 101, 104, 136). For instance, several of the recommendations advise caution when prescribing SU due to the increased risk of hypoglycaemia with age (24, 101, 102, 104, 108). Other therapies could also be disadvantageous for certain patients. An overview of properties for each type of medicine, as well as the precautions when prescribing these for care home residents, are listed in Table 5 (pages 36-38). The McKellar guidelines present a glucose-lowering medicine (GLM)-related adverse event risk assessment tool, which they recommend be used together with other quality indicators for use of medicines, to minimise risk and increase benefit (109).

Regarding insulin therapy, simplification of the insulin regimen is promoted (24, 35, 101, 104, 108). A regimen with basal insulin once daily, preferably in the morning rather than at bedtime, is considered effective and safe in terms of hypoglycaemia risk and resident comfort (24, 101, 106). Insulin analogs, such as detemir and glargine, may provide a more predictable and consistent glycaemic effect compared to human insulin (104). Mealtime insulin may still be necessary for some residents, especially those with T1DM, but sliding-scale insulin is discouraged (24, 35, 101, 108).

Table 5. Properties, advantages and precautions to guide the prescribing of blood glucose-lowering therapy in older people (24, 35, 101, 104, 136)

Type of medicine	Mechanism of action	Advantages	Hypo-glycaemia	Weight	Side effects	Precautions	Cost
Insulin	Mimics pattern of normal insulin secretion: increases glucose disposal and reduce hepatic glucose production	No ceiling effect Wide range of options (analogs considered safer than human insulin)	High risk	Gain	Hypoglycaemia	Assess and monitor risk of hypoglycaemia and weight gain. Variable appetite warrants proper matching of prandial insulin dose	Variable
Metformin	Inhibits hepatic glucose production and secretion Increases peripheral insulin sensitivity (especially muscle tissue) Delays and reduces glucose uptake from GI tract	Low hypoglycaemia risk High efficacy Established safety profile, well tolerated Low cost	Low risk	Neutral/ possible loss if patient is frail	GI discomfort, diarrhoea, nausea (mitigated by start low, go slow) May result in lower B_{12} Lactic acidosis (rare)	GI intolerance may exacerbate malnutrition and dehydration Consider periodic monitoring of B_{12} levels Reduce dose if eGFR 30-60 ml/min/1.73 m^2, avoid if eGFR <30 ml/min/1.73 m^2 Temporarily discontinue if acute illness, dehydration, vomiting, or compromised renal function Use with caution if heart failure or hepatic dysfunction	Low
Sulfonylureas	Increases insulin secretion (~12 h) by stimulating β-cells in the pancreas Extrapancreatic effects: reduction of basal hepatic glucose production and increased insulin sensitivity	High efficacy Low cost	Moderate to high risk	Moderate gain	Hypoglycaemia	High risk of hypoglycaemia in older people and CKD, use short-duration SU and low dose Avoid if irregular eating pattern or eGFR <30 ml/min/1.73 m^2 Acute illness or weight loss may require additional CBGM Use with caution if impaired heart or hepatic function	Low

Table 5 continued. Properties, advantages and precautions to guide the prescribing of blood glucose-lowering therapy in older people

Type of medicine	Mechanism of action	Advantages	Hypo-glycaemia	Weight	Side effects	Precautions	Cost
Meglitinides	Increase insulin secretion (2-4 h) by stimulating β-cells in the pancreas	Short half-life, dosing flexibility May be considered if irregular eating pattern	Moderate risk	Moderate gain	Hypoglycaemia Uncertain cardiovascular safety	Some risk of hypoglycaemia Increased regimen complexity Use with caution if impaired heart or hepatic function	Moderate to high
Thiazolidinediones	Increase peripheral insulin sensitivity by lowering FFA levels and increase fat storage	Low hypoglycaemia risk Can be used in renal impairment	Low	Gain (higher doses)	Fluid retention Heart failure Fractures Inconclusive risk of bladder cancer	Avoid in patients with heart failure, hepatic dysfunction or high risk of falls and fractures, and assess risks before initiating and during therapy Less concern for bladder cancer if short remaining life expectancy	Moderate to high
Acarbose	Slows intestinal carbohydrate digestion/absorption	Low hypoglycaemia risk Non-systemic mechanism of action	Low risk	Neutral	Gas, bloating, diarrhoea	GI intolerance may exacerbate malnutrition and dehydration Avoid if intestinal disorders or eGFR <25 ml/min/1.73 m^2	Low to moderate
GLP-1 agonists	Direct increase in incretin effect by mimicking endogenous GLP-1: results in increased insulin secretion, reduced glucagon secretion, slowed gastric emptying and decreased appetite	Low hypoglycaemia risk (but not with SU or insulin) Once-daily and once-weekly formulations Improves cardiovascular risk factors	Low risk	Loss	GI discomfort, nausea, vomiting (upon initiation) Gallbladder disease Modest increase in heart rate	Consider dose adjustment when eGFR <60 ml/min/ 1.73 m^2 and avoid when eGFR <30 ml/min/ 1.73 m^2 (excl. liraglutide) Injection therapy, requires training Monitor for anorexia and weight loss	High

Table 5 continued. Properties, advantages and precautions to guide the prescribing of blood glucose-lowering therapy in older people

Type of medicine	Mechanism of action	Advantages	Hypo-glycaemia	Weight	Side effects	Precautions	Cost
DPP-4 inhibitors	Indirect increase in incretin effect by inhibiting DPP-4 and thus enhancing circulating concentrations GLP-1 and GIP: results in increased insulin secretion and reduced glucagon secretion	Low hypoglycaemia risk (but not with SU) Once-daily oral formulation Well tolerated Combined with basal insulin for low complexity regimen	Low risk	Neutral	Headache, increased URI Musculo-skeletal pain Urticaria/angio-oedema (rare) Saxagliptin: Increased HF hospitalisation	Dose reduction recommended if eGFR <60 ml/min/1.73 m^2 for all but linagliptin Use with caution if impaired hepatic function	High
SGLT2 inhibitors	Inhibits renal glucose reabsorption	Low hypoglycaemia risk Improves cardiovascular risk factors	Low risk	Loss	Genital infections, UTI Hypotension, dizziness DKA (rare) Canagliflozin: Amputation and fracture risk	Efficacy and safety based on reasonable renal function Limited evidence in frail older patients, but increased risk of incontinence, hypotension, dehydration, genital infections Dose adjustment or avoid when eGFR <60 ml/min/ 1.73 m^2	High

CBGM=capillary blood glucose measurements, CKD=chronic kidney disease, DKA=diabetic ketoacidosis, DPP-4=dipeptidyl peptidase 4, eGFR=estimated glomerular filtration rate, FFA=free fatty acids, GI=gastrointestinal, GIP=gastric inhibitory peptide, GLP-1=glucagon-like peptide-1, HF=heart failure, SGLT2=sodium glucose-linked transporter 2, SU=sulfonylurea, URI=upper respiratory infection, UTI=urinary tract infection

1.4.5 Optimising medicines through deprescribing

Optimisation and simplification of therapy should not only be considered when first prescribing, but also in the subsequent monitoring of the therapy (137). Deprescribing, defined as '*the process of withdrawal of an inappropriate medication, supervised by a health care professional with the goal of managing polypharmacy and improving outcomes'* (138), is crucial in this process. The goal of deprescribing is to avoid unnecessary treatment with unlikely benefits and potential harmful effects (139).

Different frameworks for optimising prescribing and aiding deprescribing in patients aged ≥65 years have existed for some time. These are sometimes referred to as prescribing quality indicators (PQI). Well-known examples include the US Beers criteria for Potentially Inappropriate Medication Use in Older Adults (140); Screening Tool to Alert doctors to the Right Treatment (START) and Screening Tool of Older Persons' potentially inappropriate Prescriptions (STOPP), both developed in Ireland (141); and the Norwegian General Practice (NorGeP) criteria (142). These criteria have been formed as explicit standard indicators, based on expert consensus, following examination of available evidence on recommended and problematic medicines in older people. Still, the degree to which they incorporate other clinical information, such as comorbidities and functional dependency, is low. It has therefore been argued that these criteria may not be appropriate for use in care-home settings, where patients have multiple illnesses and/or disabilities, and a limited life expectancy (143, 144).

More recently, updates have been done to make the aforementioned criteria more applicable to care-home settings, exemplified by STOPPFrail (144) in 2017 and NorGeP-NursingHomes (NorGeP-NH) in 2015 (145). At the time of our research, these were not available. However, the UK's National Health Service (NHS) PrescQIPP programme had developed the pragmatic, evidence-based decision aid Optimising Safe and Appropriate Medicine Use (OSAMU) (146), which was updated in 2016 to Improving Medicines and Polypharmacy Appropriateness Clinical Tool

(IMPACT) (147). Sectioned into drug classes as presented in the British National Formulary (BNF) chapters, OSAMU sought to stop or continue therapy based on whether the therapy had a valid indication, and was safe and beneficial for the individual considering comorbidities and remaining life expectancy. Using OSAMU and similar pragmatic approaches demonstrated that deprescribing in general was safe in care home residents and seldom led to reactions that required medicines to be restarted (148-150). In addition, deprescribing contributed to a decrease in medicine cost and administration time (148-150).

Increased awareness of the high risk and detrimental impact of potential medicine-medicine interactions, medicine-disease interactions, hypoglycaemia, and other adverse events care home residents with DM face, has resulted in recommendations urging clinicians to regularly review the complexity of the resident's medicine regime and reduce or stop medicines when appropriate (101, 103, 104, 108, 109). Currently, several of the recommendations for DM management in older people and care home residents also provide practical guidance to aid prescribing decisions, including the deprescribing of blood glucose-lowering therapy (101, 104, 106, 110). For instance, EDWPOP and IAGG recommend not starting blood glucose-lowering medicines until fasting blood glucose is consistently ≥7.0 mmol/L (106), whilst a Canadian expert committee advise that a random glucose reading <7.0 mmol/L should trigger a reduction in blood glucose lowering therapy, and glucose readings frequently >20.0 mmol/L call for an increase in treatment (110). Both the ADA and Diabetes Canada promote ways to simplify an insulin regimen or switch medicines to avoid hypoglycaemia (101, 104). The ADA also highlights specific situations where the simplification, deintensification or deprescribing of antidiabetic therapy may be required (101).

A recent review exploring patient characteristics of those for whom deintensification or deprescribing of blood glucose-lowering therapy is appropriate, identified among other things dementia, old age, impaired renal function, multiple comorbidities, significant weight loss, tight glycemic control, and frequent hypoglycaemia (151). Several studies have in fact shown that blood glucose-lowering treatment can safely

be simplified, reduced, or withdrawn in frail older patients with DM, including care home residents, without causing adverse events or leading to poor glycaemic control (66, 152, 153). One study that switched multiple-dose insulin regimens to once daily insulin glargine with or without non-insulin agents in 65 T2DM patients aged ≥65 years, also found that the simplification resulted in significantly less hypoglycaemia and improvement in DM-related distress score (153). In addition, a particularly telling case from the US has been described by Lekarcyk et al. (31):

An 88-year old woman with T2DM, dementia, and CKD was transferred from one care home to another. The woman had a history of aggressive behaviour, delirium, and hypoglycaemia unawareness, and experienced extreme variations in her pre-breakfast blood glucose levels (from 2.3 mmol/L to 17.3 mmol/L). Upon transfer, her DM therapy were 68 units of insulin glargine at bedtime in addition to 5-12 units of sliding-scale insulin lispro before meals. Her weight was 63 kg and her most recent HbA1c was 54 mmol/mol (7.1 %). She refused CBGM the first days following transfer. Her aggressive behaviour was initially attributed to her progressing dementia, but a diabetes care provider suspected that it could be caused by hypoglycaemia due to the mismatch between the insulin dose, the resident's weight, and her HbA1c value. To verify this, her insulin glargine dose was gradually reduced. At 38 units, they noticed an improvement in her mental status, a decrease in hyperglycaemia, and the woman also became less combative towards CBGM. CBGM showed an association between hypoglycaemia and escalating aggressive behaviour, and her insulin dose was further reduced. At seven units insulin glargine in the morning, she no longer experienced hypoglycaemia and had no need for correction doses using insulin lispro. Further, her aggressive episodes were significantly decreased and she was able to interact socially with staff and other residents (31).

This case report not only exemplifies how harmful overtreatment can be, and the benefits of deprescribing, but also highlights the challenges and complexity entailed in treating frail older patients with DM. The case report also highlights the importance of increasing the knowledge of and focus on blood glucose-lowering therapy, glycaemic control, and blood glucose measurements in this population.

2. Research aims

'My name is Sherlock Holmes. It is my business to know what other people do not know.'

~ Arthur Conan Doyle, from *The Adventure of the Blue Carbuncle*

The overall aim of this research was to investigate the prevalence and management of DM in care homes for older people, with an emphasis on medicines and blood glucose measurements. To explore this, three studies with the following objectives were undertaken:

Study I

The purpose of this study was to determine the prevalence of DM; and investigate the use of blood glucose-lowering medicines, frequency of CBGM and HbA1c measurements, and level of glycaemic control in Norwegian nursing homes.

Study II

The purpose of this study was to describe the comorbidities and medicine use in UK care home residents with T2DM and the number of potentially inappropriate medicines (PIMs) in these residents using a medicines optimisation tool. An additional objective was to describe the clinical applicability of the medicines optimisation tool used.

Study III

The purpose of this study was to explore the perspectives of physicians, registered nurses and auxiliary nurses on the use, usefulness, procedures, and potential challenges related to CBGM in Norwegian nursing homes.

3. Subjects and methods

'I like to envision the whole world as a jigsaw puzzle … If you look at the whole picture, it is overwhelming and terrifying, but if you work on your little part of the jigsaw and know that people all over the world are working on their little bits, that's what will give you hope.'

~ Jane Goodall, ethologist, known for her close and lengthy study of wild chimpanzees in Tanzania

The research in this thesis is based on three studies with different study populations, examined through different methodological approaches. An overview for each of the studies is given in Table 6.

Table 6. Methodological overview of the three studies included in the thesis

Study	Design	Study population	Data collection and analysis
I	Descriptive, observational, cross-sectional study	742 long-term care nursing home residents 19 nursing homes Western Norway	Age, gender, diabetes (yes/no) collected for all residents Details of current blood glucose-lowering medicines, capillary blood glucose measurements the last four weeks and HbA1c measurements the last twelve months collected from the medical records of all residents with a diagnosis of diabetes 35 CBGM observations followed by external quality control Descriptive statistics applied
II	Descriptive, cross-sectional study	826 older care home residents 30 care homes East Anglia UK	Details of active medical problems and current prescriptions collected from the medical records of all residents Potentially inappropriate medicines identified for residents with T2DM using the tool 'Optimising Safe and Appropriate Medicine Use' Applicability of tool evaluated by experienced care home physician Descriptive statistics applied
III	Qualitative study	3 auxiliary nurses 4 registered nurses 5 physicians Employees of nursing homes Western Norway	Three profession-specific focus group interviews regarding capillary blood glucose measurements in nursing homes Analysed in accordance with Malterud's principles of systematic text condensation (154)

CBGM = capillary blood glucose measurements, T2DM = type 2 diabetes mellitus

3.1 Study I

3.1.1 Study population and data collection

In the first study, we wanted to examine the prevalence and medical management of DM in Norwegian nursing homes. Based on what we knew about DM prevalence in nursing homes from other European countries, we aimed to include a total population of a thousand residents to ensure a representative sample of approximately 100 residents with DM. To meet this requirement, and yet keep the data collection within a reasonable limit in regard to time and travel, we drew a random sample of 20 nursing homes from a geographical area that was well-defined, but also diverse in population density and composition, namely the geographical area of the Western Norway Regional Health Authority (counties Rogaland, Hordaland, and Sogn og Fjordane). The number of nursing homes that was invited from each county differed due to population density and the total number of nursing homes within each county. To reach our goal of 20 nursing homes, we randomly selected and invited another nursing home from the same county in cases where one of the nursing homes first approached rejected our invitation. In total, we invited 26 nursing homes: nine from Rogaland, eleven from Hordaland, and six from Sogn og Fjordane. Of the 20 nursing homes that agreed to participate, one later withdrew from the study due to time constraints. The final sample consisted of six nursing homes from Rogaland, nine from Hordaland, and four from Sogn og Fjordane.

Prior to the candidate visiting the nursing homes to collect data, nursing home staff was asked to register year of birth, gender, and whether or not the resident had a registered diagnosis of DM, for all long-term care residents (Appendix 3). Furthermore, they assessed the capacity of the residents with DM to consent, before distributing information and collecting written consent to participate in the study from the residents or their families (Appendix 4). For consenting residents, the candidate was given access to collect information from residents' medical records about blood glucose-lowering treatment, CBGM the last four weeks, and HbA1c

measurements the last twelve months (Appendix 5). Data collection took place between February and August 2012.

Observations of any scheduled CBGM at the nursing homes while visiting, with the intention to assess the quality of the nursing home procedure of CBGM, was originally part of the study. Due to the limited number of observations available, we chose not to pursue this objective further. However, these observations brought up questions about the benefits and appropriateness of CBGM in nursing homes, which provided the basis for Study III.

3.1.2 Analysis

Considerations for analysis

All blood glucose-lowering medicines were sorted according to A10 – 'Drugs used in diabetes' in the Anatomical Therapeutic Chemical (ATC) classification system (155). Hypoglycaemia was defined as any blood glucose concentration <4.0 mmol/L, and a risk for hypoglycaemia as a fasting blood glucose concentration <6.0 mmol/L. Hyperglycaemia was defined as any blood glucose concentration >11.0 mmol/L.

Statistical analysis

To compare means for the normally distributed continuous variables, 95 % confidence intervals (CIs) were estimated. Pearson's chi-squared test was applied to compare dichotomous categorical variables (gender, capacity to consent), whilst categorical data with three or more variables (e.g. blood glucose-lowering medicine regime) were compared by estimating 95 % CIs for the percentages. The 95 % CIs for the percentages were estimated by a bootstrapping method, simulating 10,000 datasets for each CI. Non-overlapping CIs and p-values <0.05 were considered statistically significant. The statistical software IBM SPSS Statistics 20.0 (IBM, Armonk, NY) and Microsoft Excel 2010 (Microsoft, Redmond, WA, USA) were used for data analysis.

3.1.3 Ethics

The study was presented for ethical approval by the Norwegian Regional Committee for Medical and Health Research Ethics serving the geographical region of Rogaland, Hordaland, and Sogn og Fjordane (REC West), which did not have any objections or remarks to the study protocol. As nursing home staff collected resident information and consent forms from the participating residents before the candidate came to visit, the confidentiality of each resident was guaranteed. To avoid exposing frail patients to unnecessary testing, we chose only to observe scheduled CBGM, rather than ask all nursing homes to perform glucose measurements during our visit.

3.2 Study II

3.2.1 Study population and data collection

The study population for this study was the baseline population from a cluster randomised controlled trial named CAREMED, conducted between March 2011 and March 2013. A UK study set in 30 care homes across East Anglia (counties Norfolk and Cambridgeshire), CAREMED aimed to investigate the impact of a multi-professional medication review service (156). At the time of the study, the School of Pharmacy at the University of East Anglia (UEA) and the Centre for Pharmacy at the University of Bergen (UIB) had a teaching collaboration, with an ambition to develop this connection to include joint research projects. Therefore, a research project with a DM-related focus based on the CAREMED data was agreed on. The candidate gained access to the CAREMED database through a one-month overseas exchange to the UEA.

We extracted data on demographics, active medical problems, and name, strength, dosage, and duration of current prescriptions registered at baseline for all the 826 residents included in the CAREMED study. Baseline data for the CAREMED study was collected between April 2011 and January 2012. The baseline data also included information on laboratory tests for blood pressure and eGFR. However, as these

variables were incomplete for some residents, we decided not to include them in further analysis.

3.2.2 Analysis

Considerations for analysis

Extracting only baseline data for the 826 residents included, we performed a cross-sectional sub-analysis, using information about their current conditions and prescriptions. All conditions had been classified into the main chapters (level 1) of the International Statistical Classification of Diseases and Related Health Problems 10th revision (ICD-10) Version 2010 (157) by the technical staff on the CAREMED study. Many, but not all, were also classified further into the major blocks under each chapter (level 2), and some were classified down to single disease codes (level 3). In addition to the recorded diagnosis, we made use of the first level classifications. All prescriptions were classified according to the ATC classification system (155) for the purpose of this study by the candidate.

Residents with T2DM were identified by having T2DM as a recorded diagnosis in the medical records. Residents with other DM diagnoses were excluded from the study population and further analysis. Polypharmacy was defined as having registered ≥five unique medicines, i.e. ATC codes.

In addition, we performed a theoretical medicines optimisation review for all residents with T2DM, using the NHS PrescQIPP document OSAMU (146) as a decision aid. Based on the limited information from the residents' medical records, we identified that 35 out of the 46 areas or drug classes in the OSAMU document were applicable to our population. To allow for a descriptive analysis, the document's stated considerations to optimise medicines use were conveyed into explicit criteria (score 0 = negative or 1 = positive) by the candidate (appendices 6 and 7). In total, 50 explicit criteria were formulated. The candidate used a mix of statistical and visual analysis to review the residents' medicines. A score of 1 was defined as the medicine being potentially inappropriate and therefore eligible for deprescribing. The identified

PIMs were validated and reviewed for deprescribing for a random sample of 20 % of the residents, by a physician with clinical and research expertise on medicines optimisation from Norwegian nursing homes.

Statistical analysis

Due to small numbers and skewed distributions, continuous variables were only calculated as medians with range. To compare medians for the continuous data and percentages for the categorical data, 95 % CIs were estimated. The CIs were estimated by a simple bootstrap, simulating 10,000 datasets for each CI. Non-overlapping CIs were considered statistically significant. IBM SPSS Statistics 22.0 (IBM, Armonk, NY) was used for statistical analysis, apart from bootstrapping, where Python 2.7 was used to aid analysis.

3.2.3 Ethics

The CAREMED study received ethical approval by the NHS Norfolk Research Ethics Committee within the UK Health Departments' Research Ethics Service. All data extracted for the purposes of this study was depersonalised when the candidate received it.

3.3 Study III

3.3.1 Study population and data collection

The observations of CBGM in Study I revealed that the procedure itself, who was allowed to perform it, and when it was performed varied from nursing home to nursing home. Furthermore, nursing home staff often posed questions about the appropriateness of this procedure to the candidate upon visit. It was this that prompted the candidate to explore these concerns by interviewing physicians, registered nurses, and auxiliary nurses working in nursing homes, about their perspectives regarding this commonly used procedure.

Focus group interviews use the interaction between the participants to investigate their common experiences, priorities, and attitudes (158), making this approach suitable to answer our research questions. To gain a credible response to the question in hand, we aimed to explore the perspectives of all professional groups involved in the procedure, in profession-specific interviews. Therefore, we set out to include:

- Physicians with a licence to practice and a full-time or part-time engagement working in a nursing home, as well as experience in managing CBGM in nursing homes.
- Registered nurses with a licence to practice and a full-time or part-time engagement in a nursing home, as well as experience in performing CBGM in nursing homes.
- Auxiliary nurses with a licence to practice and a full-time or part-time engagement in a nursing home, as well as experience in performing CBGM in nursing homes.

To recruit auxiliary nurses and registered nurses, we contacted managers in three nursing homes in proximity of our institution that were also in geographical proximity of each other. The reason for this was that we had planned to chair the interviews at one of the nursing homes, to reduce travel time and expenses for the participants. The nursing home managers helped with recruitment and distributing information, and reported back to us how many had agreed to participate. For one of the three nursing homes, none of the nurses had volunteered for participation.

To recruit physicians, we contacted the local organising committee of a continuing professional education meeting for nursing home physicians that took place approximately once a month. Verbal and written information about the study was given by the candidate at one of the meetings, whilst recruitment of participants was done at the following meeting.

Originally, five auxiliary nurses and four registered nurses, all women, had agreed to participate. However, two of the auxiliary nurses failed to show up to the interview, without informing us in advance that they were unable to attend. From the

physicians' continuing education meeting, five participants were recruited, three women and two men. The interviews with the nurses took place on two dates in June 2014, whilst the physician interview took place in September 2014. Each interview was moderated by the candidate in addition to one or two of her supervisors, following a semi-structured interview guide (Appendix 8). The interviews were audiotaped, lasted between 60 and 75 minutes, and the themes discussed covered perspectives on the use, documentation, interpretation, consequences, and challenges of CBGM in nursing homes (see Table 1 in Paper III).

3.3.2 Analysis

Qualitative analysis was used to categorise the data into patterns following a systematic method. We applied Malterud's principles of systematic text condensation (STC) to our data (154). STC is divided into four steps, which are presented below as defined by Malterud (154) together with an account of how we applied them to our data:

1) From chaos to themes – all authors read all the transcripts to obtain an overview and then agreed on initial themes to aid coding.
2) From themes to codes – the candidate searched the transcripts iteratively to identify units of meaning and sort or code these according to the initial themes.
3) From code to meaning – all authors evaluated the content in each code group and identified sub themes or sub groups. The candidate thereafter condensed the content of each sub group into an artificial quote.
4) From condensation to descriptions and concepts – the candidate collected and transformed the artificial quotes within each code group to an analytical text with illustrative quotes. All authors compared the final text against the original transcripts to validate the findings, and finally agreed on categories for presenting the results.

The text analysis software NVivo version 10 (QSR International Pty Ltd) facilitated the analysis.

3.3.3 Ethics

Volunteering for the focus groups was understood as consent, and all participants also received an information leaflet describing details of the study, and that consent could be withdrawn at any time up until participating in the interviews (Appendix 9). To protect the privacy of the participants and throughout the study process, no names of either participants or nursing homes were linked to the interview data or identified in the transcripts. Audio recordings were deleted as soon as the transcripts were completed. The confidentiality of their colleagues, and patients or family, as well as the importance of professional confidentiality were emphasised both in the information leaflet and by the moderator before the interviews.

The Norwegian Social Science Data Services (NSD) was consulted about the study, but advised that the study was not subject to notification, as no personal data from the participants were registered or stored during data collection. The guidelines for notification have later changed, so that today studies where interviews are audiotaped will generally be subject to notification.

4. Summary of results

'The reward of the young scientist is the emotional thrill of being the first person in the history of the world to see something or to understand something. Nothing can compare with that experience.'

~ Cecilia Payne-Gaposchkin, astronomer, astrophysicist, and the first to describe that stars were composed primarily of hydrogen and helium

4.1 Study I

Paper I

Andreassen LM, Sandberg S, Kristensen GBB, Solvik UO, Kjome RLS. Nursing home patients with diabetes: Prevalence, drug treatment and glycemic control. Diabetes Res Clin Pract 2014, 105(1):102-109.

This cross-sectional study examined the known prevalence of DM in long-term care in Norwegian nursing homes, as well as medicines and glycaemic control among residents with a DM diagnosis.

Within the total study population of 742 nursing home residents from 19 nursing homes in the western part of Norway, 116 residents (15.6 %) had registered a known DM diagnosis. The residents with DM were on average 85.2 years [95 % CI: 83.8, 86.6] and the majority were women (male:female ratio 0.49). Of the 100 residents who consented to further participation in the study, 52 could give informed consent themselves. Blood glucose-lowering medicines were prescribed for 74 residents, 47 of these received insulin. The probability of being prescribed medicines for DM was significantly higher for residents with the capacity to consent ($p = 0.04$).

CBGM and HbA1c records existed for 73 and 77 residents, respectively. CBGM readings from the last four weeks showed that 60 % of the residents had documented at least one episode of hypoglycaemia (<4.0 mmol/L) or risk of hypoglycaemia (<6.0 mmol/L fasting). Risk of hypoglycaemia was recorded for all residents using insulin, 48 % of those only using oral antidiabetic drugs (OADs), and for none of those

without medical treatment for DM. Frequency of CBGM was also treatment-related; residents using insulin had significantly more frequent measurements than residents who did not ($p < 0.01$). The latest HbA1c values ranged from 28 mmol/mol (4.7 %) to 112 mmol/mol (12.4 %), with a mean of 57 mmol/mol [95 % CI: 53, 60] (7.3 % [95 % CI: 7.0, 7.7]). The average HbA1c value was significantly higher for residents on insulin (64 mmol/mol [95 % CI: 58, 70] (8.0 % [95 % CI: 7.4, 8.6])) compared to residents using only OADs (52 mmol/mol [95 % CI: 46, 57] (6.7 % [95 % CI: 6.4, 7.4])) and residents not on blood glucose-lowering medicines (46 mmol/mol [95 % CI: 40, 53] (6.4 % [95 % CI: 5.8, 7.0])). Distribution of HbA1c values according to treatment is depicted in Figure 3. A total of 35 residents (45 %) had an HbA1c <53 mmol/mol (7.0 %).

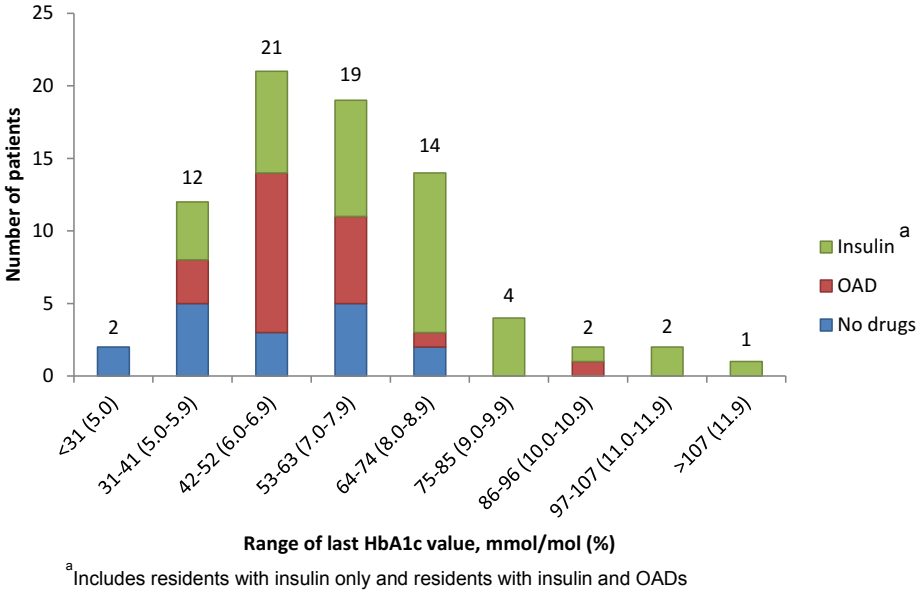

Figure 3. Distribution of last recorded HbA1c value in mmol/mol (%) from 77 residents with DM, according to treatment

4.2 Study II

Paper II

Andreassen LM, Kjome RLS, Solvik UO, Houghton J, Desborough JA. The potential for deprescribing in care home residents with Type 2 diabetes. Int J Clin Pharm 2016; 38(4): 977-84.

This cross-sectional study examined the comorbidities and prescriptions in UK care home residents with T2DM, in addition to the number of potentially inappropriate medicines and the proportion of these eligible for deprescribing.

The study population of 823 residents from 30 care homes included 106 residents (13 %) with T2DM. The residents with T2DM differed from the residents without DM in that they were younger and had a greater number of active medical problems and prescriptions. In addition, a larger proportion of residents with T2DM experienced polypharmacy (≥5 unique medicine substances). The most common diabetes treatment was OADs alone (n = 56), whilst only 14 residents (13 %) were prescribed insulin. The remaining 36 residents did not receive blood glucose-lowering medicines.

Using the tool Optimising Safe and Appropriate Medicines Use, we identified a total of 346 PIMs for 96 of the residents with T2DM (90.6 %). Among these, the number of PIMs ranged from one to nine, and 70 % had ≥3 PIMs. Four out of the five most frequent PIMs concerned absence of a valid indication, including statins, laxatives, antidepressants, and H2 blockers / proton pump inhibitors. The remaining PIM was potentially excessive prescribing of antihypertensives.

A total of 67 PIMs were available for validation in the 20 % random sample of residents. The care home physician agreed that 26 of these (39 %) could be discontinued without further question, and that a further forty medicines (60 %) could potentially be discontinued, but additional clinical data would be needed to confirm or refute this. A change of medicines was recommended for the final PIM.

4.3 Study III

Paper III

Andreassen LM, Granas AG, Solvik UO, Kjome RLS. 'I try not to bother the residents too much' – the use of capillary blood glucose measurements in nursing homes. BMC Nurs 2016, 15:7.

This qualitative study explored the perspectives of physicians, registered nurses and auxiliary nurses in regard to the use, usefulness, procedures, and challenges of CBGM in Norwegian nursing homes. The main findings are summarised in Table 8.

Table 8. Main findings from Study III

Main category with subcategories	Findings
Premises for CBGM *Frequency and benefits of CBGM* *Avoiding discomfort* *The resident perspective*	All groups considered CBGM useful: the physicians for following up and adjusting treatment, and the nurses for confirming or disproving whether a clinical change could be attributed to fluctuations in blood glucose. *'If a resident with diabetes falls ill in any way whatsoever, our first thought is, okay, we should at least check the blood sugar level, to rule it out, you know. (…) We always check it, because it is such an easy and quick thing to do.' RN2.* To promote the well-being and safety of the residents, all groups agreed that CBGM should be kept to a minimum, special diets should be avoided and blood glucose levels should be relaxed. However, residents were seldom allowed to perform CBGM themselves.
Professional competence and understanding of roles *Training and responsibility* *Awareness and assessment of symptoms*	The nurses knew which symptoms would call for additional CBGM or notification of the physician, and the physicians confirmed that hypoglycaemia generally was appropriately managed. However, managing borderline low or high blood glucose values was associated with more uncertainty. The nurses stated that little or no training had been given in diabetes care and that they were expected to acquire and maintain the necessary knowledge themselves. The physicians confirmed this. All groups wished for inter-professional courses to ensure that everyone has the same information and follows the same guidelines. *'In my experience, it is often very useful to attend [the nurses'] training. (…) There are often totally different approaches for the nurses compared to the physicians, you know. And they often benefit from seeing it from both angles.' P3.*

Table 8 continued. Main findings from Study III

Record keeping	Some of the nurses said that they kept a paper record of the residents' CBGM readings readily available at the ward, in addition to registering them in the electronic patient records system. The physicians viewed this as unnecessary, but to the nurses the paper records were essential for easily spotting deviations in readings and documentation.
Single or double documentation? A two-sided argument	*'(…) We do also have a paper form where we register [the values]; it's kept in the resident's kardex. But we also register it in the electronic patient records system that we use. (…) We do register it both places, and that's also because we need it to be available on the ward, easily accessible, you know? To look back at how [the blood glucose levels] have been earlier.' RN3.*
Official guidelines or common procedures?	None of the participating nurses was familiar with any written template or procedure for how to carry out a CBGM or manage acute glycaemic events. This surprised the physicians, who believed the local authority guidelines to be well-known. Still, the nurses said that a common understanding for how to manage unexpected symptoms, deviations or acute events existed among them.

CBGM = Capillary blood glucose monitoring, RN = registered nurse, P = physician

5. Discussion

5.1 Methodological considerations

'The world is noisy and messy. You need to deal with the noise and uncertainty.'

~Daphne Koller, professor in computer science, researching the application of artificial intelligence in biomedical science

The studies in this thesis make use of both quantitative and qualitative methods. These two approaches complement each other and are more and more often used alongside each other in health services research (159). Quantitative methods take a positivist, or objective, approach, where the goal is to describe one or several measurable phenomena or a cause-effect relationship between them. Core questions for this type of research are 'what', 'how many' and 'why'. Qualitative methods belong in the post-positivist tradition, where observations are considered fallible and biased by cultural, social, historical, and individual backgrounds. This approach is referred to as constructivism, the belief that we construct our view of reality based on our perceptions of it. The goal of qualitative methods is to provide a wider explanation or understanding of a phenomenon, using questions such as 'why' and 'how' (159).

As the framework and applicability differ between the two methodologies, different criteria have been developed to assess their scientific rigour (159-162). Where quantitative researchers refer to internal validity – how accurately the findings reflect the phenomena of study, or how confident we and the readers of our research can be of our conclusions – the equivalent are referred to as trustworthiness or credibility by qualitative researchers. The quantitative criteria of external validity and reliability – the generalisability of the findings and replicability of the methods used – relate to the qualitative criteria of transferability and dependability (159, 160). Furthermore, reflexivity is another aspect that may affect qualitative research (159, 161, 162). In contrast to quantitative research, the researcher cannot detach herself from the

process, and must account for her preconceptions of the area studied and how these influence the research process, in order to ensure objectivity. This approach acknowledges that there may be different, but equally valid, versions of knowledge. To account for one's motives, background and beliefs in advance of the study and make use of cross-checks for different explanations and participant validation (member checking) of data, or interpretations of data, are techniques to enhance reflexivity (159, 161).

5.1.1 Study I

Internal validity

Long-term care residents are the largest group of patients within Norwegian nursing homes, comprising 80 % of the total patient population (163). In addition to being a more consistent population than the residents in intermediate care in regard to age, gender distribution, and burden of comorbidities and medicines, they are also the most vulnerable patients. Hence we decided to exclude residents other than those in long-term care. Although we specified this condition to the nursing home staff that recorded birth year, gender, DM diagnosis and capacity to consent, there is a possibility that some have recorded residents outside our inclusion criteria. Still, the chance that this has happened is considered small. In addition, the impact of accidental inclusion of residents outside our inclusion criteria on the results will also be small, as the majority of residents will be in long-term care, and because a DM diagnosis generally implies a high burden of comorbidity and dependency.

As we decided to collect information only on treatment specific to DM, we lack information on possible confounders for CBGM and HbA1c readings. Several clinical factors, such as renal disease, blood diseases, infections, and nutritional disturbances may influence the reliability of these readings. Likewise, information about renal function and other diseases and disorders could have contributed to a wider understanding of the blood glucose-lowering treatment given. Furthermore, we lack information about whether the high and low blood glucose values we registered resulted in clinical symptoms for the residents. Hence the interpretations and

conclusions we draw based on the limited information we included, may have explanations other than the ones suggested.

External validity and reliability

Being an understudied area, we wanted to examine the prevalence and medical management of diabetes in Norwegian nursing homes. Therefore, ensuring the generalisability of the findings is of special importance. The randomised approach, and the diversity of ownership, location, and number of beds in the nursing homes included, increase the external validity, making our results generalisable to the Norwegian nursing home population overall.

However, as the study was cross-sectional, the generalisability across time may diminish due to changes in population and immigration patterns, the increases in both the older population and the number of people developing DM, new developments in pharmacotherapy, and changes in guidelines and healthcare provision for these patients. Heterogeneity of the study population in regard to types of comorbidities, functional and cognitive abilities, and remaining life expectancy may have an influence on choice of treatment and blood glucose readings.

The cross-sectional nature of the study will influence reliability and objectivity in the same way as it does the generalisability. The method section of the study provides sufficient information to repeat the measurement and findings elsewhere, but the heterogeneity of the population and possible confounding factors to use of medicines, CBGM, and HbA1c measurements may produce different data if repeated at a different point in time.

Our use of both CBGM and HbA1c readings to assess glycaemic control contributes to better construct validity than if we used only one. In addition, we used evidence-based guidelines to define cut-offs for hypoglycaemia, hyperglycaemia, and HbA1c values that may be detrimental to quality of life in these patients (35, 101, 103, 106, 108, 111). However, as the study was cross-sectional, this information was not complete for all residents, nor was it collected at specific points in time, e.g. at admission and after three months. Although CBGM and HbA1c readings give an

estimate of the glycaemic control in nursing homes, a longitudinal study could say more about how it changes from admission and during the stay.

5.1.2 Study II

Internal validity

This was a data-driven research approach using baseline data from the CAREMED study – a randomised controlled trial with a different purpose to the one we wanted to focus on. This was disadvantageous because information that could have been of particular interest when investigating the subpopulation of residents with DM, e.g. HbA1c values, was not available. However, the researcher got access to the trial protocol (156) and documents displaying the structure of the database, before the objectives were finally decided. This included careful mapping of the variables available, and identifying any missing information that could potentially be of importance to our research questions and further analysis. Certain variables required recoding to ensure proper statistical analysis due to missing values. In addition, the researcher created an additional variable for analysis purposes, by sorting all medicines according to the ATC system (155). Based on this work, we could define some objectives that would be achievable and also provide information that would complement the other studies in this thesis. In this process, the researcher collaborated closely with both the lead researcher and the main research technician for the original study to ensure that the data used in this study was suitable for its objectives and interpreted correctly.

The tool we used to identify PIMs was developed for use in clinical settings (146). As we applied it to an already existing data set with limited information of laboratory values, medical history, and prescribing history, we could only evaluate certain types of therapy in a theoretical manner. This puts a restriction on the conclusions we can draw from our results. However, by involving a physician with clinical and research expertise in medicines optimisation for care home residents when validating our findings, our results can give an indication of the deprescribing tool's clinical applicability.

External validity and reliability

The CAREMED data gave us an opportunity to get a broader picture of the comorbidity and medicine burden of residents with DM, a useful supplement to the results in our first study. This was a randomised controlled trial of 30 care homes in a well-defined geographical area of the UK, with demographics similar to that of the overall UK care-home population (92). Hence, the results should be transferable to similar care-home settings across the UK. However, as the data was originally collected for a different purpose and in a different country from the two other studies, there are some issues to address as to whether the results are transferable to a Norwegian setting.

Firstly, the UK care-home sample consisted of both residential homes and nursing homes, and the proportion of nursing home residents was less than a fourth. In Norway, nursing home residents make up close to 98 % of the total care home population (164). This is due to differences in organisation of the care sector, where Norwegian residential homes have largely been replaced with people receiving home-care services (164). Secondly, differences may exist based on which resources have been available in the two countries, as the initiatives towards improvement of DM care in this population has been evident in the UK (165, 166), but less so in Norway. Finally, treatment traditions and the availability of blood glucose-lowering medicines may be different in the two countries. Still, the prevalence of DM and the age and gender distribution of the residents in this study are comparable to what we found in the Norwegian study. Furthermore, international guidelines and consensuses for care of older patients with DM form the basis on which Norwegian guidelines are built, and the results from this study could serve as a useful supplement to the two Norwegian studies, giving an idea of the comorbidities and medicine burden faced by care home residents with DM.

5.1.3 Study III

Credibility (internal validity) and reflexivity

Searching for different explanations for the data, looking for cases that do not fit the pattern, and participant validation (member checking) are all techniques to enhance credibility (160-162). The method of STC ensures the former, in that the researcher searches iteratively for subjects of meaning (154). The latter was partly accommodated in that a brief account of the main points discussed by the participants was given by the moderators at the end of each interview. The participants were then asked to give feedback on these preliminary interpretations, correct any misinterpretation or give additional information if they found it appropriate. This aspect could have been strengthened by letting one or several participants from each interview group read through and give feedback on the transcripts and/or the manuscript. However, to ensure participant confidentiality and privacy, we did not register or store personal information, such as names and email addresses, as part of the data collection. Participant validation is also limited in that participants have an individual role in the research process, whilst the researcher's goal is to give an interpretation for a wider audience (162). Thus, participant validation is a way to reduce error, but may also generate more data, which in turn require interpretation (162).

Theoretical frameworks are sometimes used by qualitative researchers as a way to illustrate how interpretations relate to, or are constructed based on, individual, social, or historical contexts (159, 161). However, in qualitative research in medical sciences, a theoretical framework is not always applied. Reflexivity, i.e. providing a frame of reference, or a thorough account of personal and intellectual biases, attends to the construction of knowledge in a similar way and enhances credibility of the findings (161, 162). As previously mentioned, the CBGM observations and additional measurements originally investigated as a part of Study I were too few to give any robust results for the quality of CBGM in nursing homes. However, the observations provided the springboard for the research questions in Study III. The thoughts that emerged from the observations and visits were documented in a field journal by the

candidate. These notes were used to write a document of her preconceptions of the field, including hypotheses of what the study would find (Appendix 10). This helps maintain reflexivity by distinguishing which experiences and opinions were brought into the field in advance by the researcher. Designing, analysing, and interpreting data may also result in different, but equally valid, presentations of the area studied, depending on a researcher's personal and professional background. In this study, additional researchers (AGG, GBBK, RLSK, and UØS) took part in both the design and analysis of data, providing several opportunities to both supplement and challenge the beliefs of the candidate.

Transferability and dependability (external validity and reliability)

The inclusion of several professions to share their perspectives on CBGM in care homes was a strength in this study. This purposeful sampling is a technique to develop a theory or explanation of a subject, which includes a range of factors that might affect variability of behaviour and may enhance transferability (159, 160). However, as stated in Paper III, we experienced difficulty in recruiting nurses, which resulted in limited sample sizes in these two focus groups. Nor did we make use of saturation, where data are analysed concurrently with data collection, and where saturation is reached and data collection can cease when no new themes emerge (159). However, the dynamic in all three groups was good, and the participants did not seem to be reluctant to disclose opposing views. Although additional perspectives on the subject could have emerged from a wider sample, our findings still present some important and relevant aspects regarding the use and usefulness of CBGM in care homes from the perspective of healthcare personnel.

A clear account of preconceptions, and how data was collected and analysed will increase the dependability and confirmability of a qualitative study, in addition to enabling readers to assess the applicability of the findings to their setting (159, 160, 162). We gave an account of the premises for the study and a brief overview of each author's background in the paper. Furthermore, STC facilitates dependability and confirmability through its systematic approach that allows for transparency, inter-subjectivity, and reflexivity throughout the process (154, 161).

In this study, three additional researchers with varying professional backgrounds (UØS, GBBK, and RLSK) gave input on development on the interview guide and co-moderated the interviews together with the candidate. All authors (LMA, AGG, UØS, and RLSK) contributed to the first step of analysis, and the candidate discussed with several of the authors during the other steps of analysis as well. This provides a form of critical appraisal throughout the process, which could help uncover whether the interpretations are applicable to a broader audience, i.e. increase transferability, and also helps to enhance dependability and confirmability (160).

5.2 Discussion of findings

'All sorts of things can happen when you're open to new ideas and playing around with things.'

~ Stephanie Kwolek, the chemist who invented Kevlar

5.2.1 Care home residents with DM – undervalued and overtreated?

Our findings of a total DM prevalence of 16 % in Norwegian nursing homes in 2012 and a T2DM prevalence of 13 % in UK care homes in 2011-12, correspond to the DM prevalence numbers of 14-22 % for care homes across Europe during the same time period (69, 71-77, 90). The age and gender distribution of the study population, and the proportion of pharmacologically-treated residents, are also comparable (67-69, 71-75).

While large cohort studies have found that the incidence of T2DM has declined in all age groups between 2009 and 2014 in Norway (167), and that it has remained relatively stable in the UK population between 2005 and 2013 (168), the prevalence has increased in both countries in this time period, especially in the oldest age groups (167, 168). The prevalence of DM found in Study I and Study II shows that DM is a common diagnosis among care home residents in both Norway and the UK, affecting approximately every sixth resident. These findings alone illustrate that care home residents with DM should be considered an area of priority. Unfortunately, several of

our research findings point towards suboptimal care on the topics of medicine use and blood glucose measurements.

Study I found a high number of residents with low HbA1c values and CBGM readings consistent with hypoglycaemia, and nine out of ten residents in Study II were prescribed at least one PIM. Medicines for prevention of cardiovascular disease were among the top five PIMs in this population, which a physician agreed could be directly discontinued or considered discontinued. Thus, Study I and II demonstrate that care home residents have a high burden of medicines in general and of DM-related medicines in particular, and reveal a major potential for optimising DM treatment. In Study III we further explored the findings from Study I. This study uncovered that the challenges of optimising DM treatment and avoiding hypoglycaemia go beyond correct use of CBGM, in that participants identified a lack of training and procedures for DM care in general. Participants also spoke of the struggle to provide patient-centred care and enhance patient participation.

5.2.2 Targeting hypoglycaemia through HbA1c goals

The ADA and IDF guidelines emphasise care home residents' vulnerability to hypoglycaemia (24, 101, 108). Previous studies have found that between 10 % and 69 % of care home residents experience hypoglycaemia (61, 62, 66, 68, 75, 78, 80, 87, 96, 127, 169-171). This is in line with the results in Study I, where six out of ten residents had at least one recorded blood glucose concentration consistent with hypoglycaemia or high risk of hypoglycaemia. All of the residents prescribed insulin had at least one such recording. Whilst we did not have information about glycaemic control in Study II, we found that nine out of ten residents with T2DM were prescribed five or more medicines. This is defined as polypharmacy and is considered an independent risk factor for hypoglycaemia (172). Register-based studies from the UK found that between 1998 and 2014, the number of hospital admissions for hypoglycaemia increased and remains high, especially in the oldest age groups (173, 174). For adults with T2DM ≥65 years of age, the incidence of hospitalisations for

hypoglycaemia increased from 1.12 to 3.52 per 1000 person-years between 1998 and 2013 (173).

As an HbA1c level <53 mmol/mol (7.0 %) has been shown to increase the risk of hypoglycaemia and other unfavourable events in older patients (115, 116), this has been proposed as a threshold measure of possible overtreatment (35, 108). Following this, deintensification or deprescribing of diabetes treatment could be considered for 45 % of the residents in Study I. HbA1c levels <53 mmol/mol (7.0 %) are generally common in the care-home population, reported for between 36 % and 89 % of residents (62, 65-67, 71, 74, 80, 96, 115, 169, 175-178), indicating that overtreatment is prevalent.

The need for alleviating HbA1c goals to target hypoglycaemia in very old care home residents is supported by the findings in an observational study of 583 residents ≥65 years of age in 117 US nursing homes (115). The researchers found that in residents ≥85 years with an HbA1c value <53 mmol/mol (7.0 %), the incidence of hypoglycaemia was close to twice as high compared to that of those with higher HbA1c levels. This trend was not found in the younger age groups (115), and also stands in contrast to other studies that have not found significant differences in risk and duration of hypoglycaemia between patients grouped by different HbA1c levels (78, 179, 180). CGM has also revealed that nocturnal hypoglycaemia, registered between 10 pm and 6 am, was frequent regardless of different HbA1c levels (180).

In addition, using CGM data from 90 patients ≥70 years to investigate the relationship between HbA1c values and blood glucose levels raised the concern that HbA1c values may not accurately reflect glycaemic variability in these patients (134). The linear correlation between blood glucose levels and the HbA1c values that has been established for adults aged <70 years, sometimes referred to as estimated average glucose (eAG), is also less evident for older adults, according to the same study. Thus, the authors conclude that HbA1c should be interpreted with caution in regard to treatment changes, and fluctuations in blood glucose should always be taken into account (134).

Nonetheless, simplification of insulin treatment has shown to significantly reduce hypoglycaemia duration and hypoglycaemia excursions (153, 180). Additionally, high clinical complexity, defined as an age of ≥75 years, dementia, or end-stage renal disease, or ≥3 serious chronic conditions, has also been found to increase the risk of severe hypoglycaemia in patients with an HbA1c <53 mmol/mol (7.0 %) treated with one or more blood glucose-lowering medicines (181). Thus, one can advocate that the HbA1c value gives some indication of hypoglycaemia risk, but it cannot and should not be used as the sole measure of whether a resident is prone to overtreatment.

5.2.3 Recognising hypoglycaemia – easier said than done

In DM, point-of-care testing (POCT) is widely available for monitoring and optimising treatment. Study III found that the focus group participants appreciated CBGM as a tool to guide both on-site clinical decisions and follow-up of care home residents with DM. Still, the findings from Study I suggest suboptimal use of CBGM.

In detail, findings in our studies raise the concern that not all hypoglycaemia is detected by CBGM alone. For instance, 15 % of the total CBGM readings in Study I were <6.0 mmol/L and only 3 % were defined as hypoglycaemia (<4.0 mmol/L). This may suggest that CBGM is generally done as a routine, and that clinical circumstances and events that may warrant additional CBGM are few or not as easily picked up on by the care home staff. The nurses participating in Study III stated that they were attentive towards symptoms that would require additional measurements, but also expressed uncertainty about how to appropriately act upon readings of 'borderline low' values. These findings agree with what was described in focus group interviews with home care nurses in Norway, who cared for elderly people with DM (126). They also expressed a wish for more guidance in the signs and symptoms to look for, in order to tailor the care to the individual patient: 'I would like to have [the specialists] come [to the users] and see how their blood glucose is and be guided exactly in relation to each user' (126).

According to the physicians participating in Study III, they tried to support proper management of DM by setting a treatment target and giving precise orders for

CBGM. However, a cross-sectional study of 16 nursing homes in Norway and Iceland found that an individual treatment goal (HbA1c) or individual routines for CBGM were registered in very few patient records (77). In the UK, a national audit of diabetes care in care homes undertaken in 2012-13 revealed that 56 % of the care homes either did not keep or did not know if they kept documentation of the HbA1c value for residents with DM (165). Furthermore, assessment for hypoglycaemia and written policies for management of hypoglycaemia were lacking in over a third of the care homes (165).

Recognising hypoglycaemia in care home residents is challenging, as cited and exemplified by Lekarcyk et al. (31) in the introduction of this thesis. Clinical complexity and dementia contributes to an unusual presentation of hypoglycaemia symptoms, as the resident is unable to act or report on the detrimental events she is experiencing, and staff experience confusion around the cause of these symptoms (31). Although most guidelines acknowledge this and thus recommend assessment of a resident's risk of hypoglycaemia as a prevention measure, the McKellar guidelines for managing older people with diabetes in residential and other care settings in Australia is the only one to give specific guidance on how and when to assess hypoglycaemia risk (109). In addition to presenting a risk assessment tool, they list medicines other than blood glucose-lowering ones that could increase the risk of hypoglycaemia, outline the symptoms that mild and severe hypoglycaemia can present with in this population, and provide specific protocols on how to manage them. They recommend using risk assessment tools in care planning and stress the importance of involving the resident as much as possible (109).

The importance of involving the resident in risk assessment and care planning, rather than simply relying on set limits for hypoglycaemia, is illustrated by a quote from one of the physicians participating in Study III, who stated that 'it's a surprisingly wide spectrum for […] when [the residents] experience hypoglycaemia'. A study interviewing 61 DM patients aged >75 years about the lowest tolerable blood glucose level they felt well at and below which symptoms of hypoglycaemia developed, found this to be >4 mmol/L in all patients (mean 6.7 mmol/L (standard deviation

(SD) 1.3)) (182). The study found no significant differences in age, gender, number of comorbidities or medication, insulin therapy, living status, or caring provision between patients that experienced hypoglycaemia at a lower level (≤6.0 mmol/L) compared to a higher level (>6.0 mmol/L) (182). The mean HbA1c value of 60 mmol/mol (7.6 %), and range 29-107 mmol/mol (4.8-11.9 %), were comparable to what we reported for the residents in Study I. Even though we did not investigate whether the CBGM readings <6.0 mmol/L in Study I were accompanied by clinical symptoms of hypoglycaemia for the residents, many of them will likely have experienced discomfort without necessarily presenting with textbook hypoglycaemia symptoms.

5.2.4 From 'what's the matter?' to 'what matters to you?'

There has been a development of clinical guidelines and a steady increase of research and improvement initiatives for care home residents with DM over the last two decades. Despite this, a recent review found that access to guidelines, availability of protocols, monitoring of DM and its complications, staff training and knowledge of DM, and involvement of residents in DM management are still suboptimal (166). The balance between providing high quality care, as stated by the guidelines, whilst considering the complexity of the resident and the wish to allow for the resident to have a personal choice, was identified as challenging by UK care home staff in a focus group study (84).

In an attempt to correct this, new management approaches that shift the focus from a disease-specific approach to that of a holistic, multidisciplinary, and patient-centred approach have emerged (183, 184). Moving the focus from 'what's the matter?' to 'what matters to you?' entails uncovering the patients' individual goals and including patients in treatment decisions (185). In addition to empowering patients by recognising their wishes and enhancing the quality of life through improving functional status, these approaches also warrant close collaboration and communication between several professional disciplines. In Scotland, 'what matters to you?' is used as a key question in the healthcare sector to help staff shift from a

paternalistic ‘we know best’ culture towards more person-centred care, enabling the patient to have a meaningful life (185).

A study investigating 62 care home residents’ quality of life and satisfaction with care found that dignity, spiritual well-being, and food enjoyment were significant predictors of overall satisfaction with the nursing home (186). Experiencing a higher level of dignity was also a significant predictor of residents’ satisfaction with the staff. Within the study population, 37 % of the residents had a DM diagnosis. The authors discuss that enhancement of dignity can be done through daily life interactions; one example being that staff members explain to residents what they are doing in different situations of care. This agrees with what nurses participating in Study III reported regarding talking the resident through the CBGM process as they were performing it.

In a review of DM in older people from 2015, the authors argue that the interplay between DM, frailty, and disability underpin the need to put function first when assessing, planning, and managing DM (183). With similar reasoning, a 2019 consensus opinion from primary care clinicians and diabetes specialists presents recommendations for holistic assessment and management of older people with T2DM (184). In addition to advocating shared decision making and identifying and prioritising clinically-dominant conditions, they particularly emphasise targeting therapeutic inertia, i.e. failure to intensify or de-intensify treatment as appropriate, to avoid overtreatment and adverse events.

The findings from Study I and Study II suggest a major potential for the deprescribing of DM-related treatment, and others have demonstrated that deprescribing both blood glucose-lowering medicines (66, 152) and antihypertensives (187) is safely obtainable in care home residents. In general, using evidence-based decision aids that consider the clinical complexity of care home residents has demonstrated that deprescribing in this population seldom leads to reactions that require medicines to be re-initiated and contributes to a decrease in medicine cost and administration time (148-150).

Sometimes deintensification, simplification, or temporarily pausing medication may be more appropriate than deprescribing directly, and be a way to ease into deprescribing. As the name of the tool we used to guide deprescribing in Study II (OSAMU) indicates, the overall focus should be on optimising or improving treatment (146, 147). Considering the limited amount of historic and clinical data available to us in Study II, it was difficult to approach optimisation of therapy in any other respect than identifying inappropriate treatment in regard to the resident's age, current diagnoses, and concurrent therapy.

There are still questions on how best to arrange for optimisation of medicines in regard to which approach produces the most favourable effects on outcomes such as adverse events and hospitalisations (188). Also, among the barriers to optimising medicines revealed in qualitative studies are fragmented care, incomplete information, and uncertainty about which benefits or harms continuing or discontinuing specific medicines will produce (188). Some patients or their carers may think that fewer medicines equal poorer quality of care, and good communication skills are vital when introducing the patient and their relatives to the idea of deprescribing. In addition, it is important to remember that other therapies, such as analgesics, may be underused in care home residents with DM (99).

The previously-mentioned 2019 consensus opinion suggests an algorithm for how to carry out a holistic review of DM management in the older person, incorporating two pragmatic mnemonics; NEWMEDS for the initiation or change of any medication and DEINTENSIFY for when, how, and for whom deintensification or simplification of blood glucose-lowering medicines may be warranted (184). The DEINTENSIFY mnemonic has been directly adapted from Abdelhafiz and Sinclair (151). The Australian Deprescribing Network (ADeN), comprising a wide range of healthcare professionals and researchers interested in promoting deprescribing, has developed a general deprescribing protocol and algorithm (188). The ADeN underlines that the deprescribing process is about more than just discontinuing inappropriate medicines, including close agreement between the patient, clinician, and pharmacist when

reviewing medicine lists, and training initiatives for healthcare personnel involved in prescribing, dispensing, administering, and monitoring medicine use (188).

6. Conclusions

'I once wrote a lecture for Manchester University called « Moments of Discovery » in which I said that there are two moments that are important. There's the moment when you know you can find out the answer and that's the period you are sleepless before you know what it is. When you've got it and know what it is, then you can rest easy.'

~ Dorothy Crowfoot Hodgkin, chemist and winner of the 1964 Nobel Prize for Chemistry, who determined the structure of vitamin B12 and insulin through her work with X-ray crystallography

The prevalence of DM in Norwegian nursing homes was found to be 16 % and the majority of these residents used blood glucose-lowering medicines. Close to half of the residents were prescribed insulin and all of these residents had at least one recorded episode of a blood glucose level <6.0 mmol/L during the last four weeks, considered to be at a high risk of hypoglycaemia. Frequency of CBGM varied greatly, but residents using insulin had CBGM performed significantly more often. Regardless of treatment, six out of ten residents with DM had registered blood glucose levels <6.0 mmol/L. Three-quarters of the residents had measured HbA1c in the last twelve months. Mean HbA1c was 57 mmol/mol (7.3 %), and 45% had an HbA1c below 53 mmol/mol (7 %) (Study I).

UK care home residents with T2DM had a significantly higher number of comorbidities and prescriptions compared to residents without DM. Additionally, a higher percentage of residents with T2DM were treated with five or more medicines. Among the 106 residents with T2DM we identified 346 PIMs. Nine out of ten residents with T2DM had at least one PIM. The medicines optimisation tool used in this study was well suited to identify PIMs in this population (Study II).

Physicians, registered nurses, and auxiliary nurses working in Norwegian nursing homes regarded CBGM as necessary in the management of DM. The participants in our study tried to limit the strain they associated with frequent CBGM in this population and emphasised the importance of quality of life. However, the participants also acknowledged the challenges in recognising and evaluating deviant

blood glucose concentrations and pointed to deficiencies in training and procedures limiting the usefulness of CBGM (Study III).

In summary, the research in this thesis shows that there is a major potential for deprescribing or optimisation of medicines in care home residents with DM, as evident by both medication lists and blood glucose data. Although the staff seem to be aware of the needs and challenges of this group of patients, the complexities of the disease and treatment make management difficult, and the insufficiency of guidelines and training fosters uncertainty and may lead to unfavourable treatment.

7. Implications and further research

'I don't know where I'm going from here, but I promise it won't be boring.'

~ David Bowie

This thesis investigates a part of DM management in care homes, where we mainly applied a descriptive and explorative approach. Through this, we uncovered that medicine use in general and use of DM medicines in particular could pose a risk to patient safety. We also found that there is room for improvement of the rationale for and use of CBGM in nursing homes.

Due to the time constraints of a PhD project and the limitations of the data collected, there were several questions regarding DM management that we were unable to answer in this thesis. The explorative nature of our studies also resulted in findings that warrant follow up and new questions that emerged during the research process. Future studies should look into interventions to optimise medicine use, including deprescribing, as an attempt to lessen the polypharmacy burden and risk of hypoglycaemia, and promote evidence-based and rational prescribing for this vulnerable group of patients.

An especially important topic to explore further is how to include the patient perspective. Around 80 % of residents in Norwegian care homes are afflicted with cognitive impairment, which can make it challenging to involve them in decision making. Thus, future research should focus on the best ways to identify what matters most to the resident. This will point towards a reasonable and valuable place to start improving care, and should form the basis for treatment choices and care planning, rather than an HbA1c value that is considered appropriate. As noted in an interview study of older home-dwelling people with T2DM, the participants expressed healthcare goals in social and functional terms, rather than biomedical terms (189).

The future also holds great potential when it comes to improved ways of monitoring the disease. New blood glucose-monitoring technologies such as CGM and FGM may currently not be readily available for use in the care-home population, both due to

cost and lack of sufficient studies documenting the value in older people with DM. Research and development in this field is therefore necessary. The new technologies can possibly alleviate the invasiveness blood glucose monitoring can entail, which could ease the strain on both the resident and the healthcare personnel responsible for the measurements. Further, they can provide a better overview of the diurnal blood glucose variability and the factors that influence this in care home residents with DM. Also, CGM or FGM could possibly provide better opportunities to alert caregivers of deviant blood glucose levels. This information can in turn help tailor treatment and aid nursing home staff in gaining a better understanding of when a particular resident is prone to hypo- and hyperglycaemia.

Finally, CGM and FGM can enable patients to become more independent, in that these technologies could make it easier to monitor their disease. Maintaining independence and the ability to carry out activities were among the main self-reported healthcare goals of home-dwelling people with T2DM (189) and are also stated governmental goals in Norway regarding caring for the older population (190). For many people, this entails being able to live at home for as long as possible (190, 191). Thus, the research focus on frail, older people with DM should be expanded to include home-dwelling people with DM, and the possibilities various types of assistive technology could provide for these patients. In these matters, it is also of great importance to discuss ethical considerations, including privacy, autonomy, stigmatisation, individualisation, human contact, and affordability (191).

Source of data

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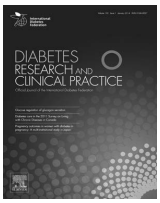

Nursing home patients with diabetes: Prevalence, drug treatment and glycemic control

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ABSTRACT

Aims: Determine prevalence of diabetes, and describe use of blood glucose lowering (BGL) drugs and glycemic control in Norwegian nursing homes.

Methods: In this cross-sectional study we collected details of BGL drugs, capillary blood glucose measurements (CBGM) in the last four weeks and HbA1c measurements in the last 12 months from the medical records of patients with diabetes, within a population of 742 long-term care patients from 19 randomly selected nursing homes in Western Norway. Descriptive statistics were applied, and Pearson's chi-squared ($P \leq 0.05$) or non-overlapping 95% confidence intervals were interpreted as significant effects.

Results: 116 patients (16%) had diabetes, 100 of these gave informed consent and medical data were available. BGL treatment was as follows: (1) insulin only (32%), (2) insulin and oral antidiabetics (OADs) (15%), (3) OADs only (27%) and (4) no drugs (26%). Patients with cognitive impairment were less likely to receive medical treatment ($P = 0.04$). CBGM and HbA1c measurements were performed for 73% and 77% of patients, respectively. Mean HbA1c was 7.3% (57 mmol/mol), 46% of patients had an HbA1c <7.0% (53 mmol/mol), and CBGM consistent with risk of hypoglycemia was found for 60% of these patients.

Conclusions: Prevalence of diabetes and BGL treatment in Norwegian nursing homes is comparable to other European countries. Although special care seems to be taken when choosing treatment for patients with cognitive impairment, there are signs of overtreatment in the population as a whole. The strict glycemic control unveiled may negatively affect these frail patients' quality of life and increase the risk of early death.

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1. Introduction

The prevalence of diabetes is increasing worldwide, with the highest rise in the population ≥60 years of age [1]. Diabetes in the elderly is metabolically distinct from younger patients [2], associated with an accelerated progression of both functional and cognitive decline [3–5] and is a common cause of nursing home admissions [6]. The reported prevalence of diabetes in nursing homes varies from 11 to 36% around the world [7–13].

The majority of nursing home patients receive multiple drug therapy and drug-related problems (DRPs) are common [14]. Patients with diabetes have a higher burden of comorbidities compared to patients without diabetes [10,15], further complicating management of care. Hypoglycemic episodes occur frequently, due to both an overly intensive drug regime [7,11,16] and concurrent diseases [17,18]. Symptoms of hypoglycemia in the elderly are often unspecific and less marked compared to in younger patients [19,20] and may be mistaken for symptoms of their cognitive or functional impairment, or even stroke [20,21]. Hypoglycemia is associated with an increased risk of adverse clinical outcomes, such as cardiovascular disease, dementia and death [22,23]. Lack of guidelines for blood glucose monitoring [7,24], poor recognition of clinical symptoms that may call for unscheduled measurements [9], and unclear limits of blood glucose concentrations where the physician should be notified [24], may further increase the risk and impact of hypoglycemia.

Guidelines for treatment have, until recently, been sparse for frail, older patients. However, the new recommendations concerning treatment of diabetes in this population have a strong focus on reducing the risk of hypoglycemia in addition to limiting hyperglycemia, both through reducing excessive medical treatment and providing appropriate and sufficient blood glucose monitoring. [25,26].

In Norway, a study from the Tromsø area that examined subjects >69 years of age either receiving nursing care at home or in an institution found a known diabetes prevalence of 20% [27]. However, this study did not discriminate between patients that received nursing care at home and patients who were staying in an institution; neither did they include patients with severe illness or dementia. Hence, diabetes prevalence in Norwegian nursing homes has not been studied exclusively, and the quality of diabetes care has not previously been investigated for these patients. This study aims to determine the prevalence of diabetes in Norwegian nursing homes, and investigate the use of blood glucose lowering drugs, frequency of capillary blood glucose measurements (CBGM) and HbA1c measurements, and glycemic control in this population. In addition, these aspects of diabetes care are compared with the newer recommendations for diabetes treatment and follow-up.

2. Subjects, materials and methods

2.1. Study design and participants

This cross-sectional study was performed within a population of long-term care patients in nursing homes between February and August 2012. Long-term care patients were defined as patients admitted for a stay of ≥3 months. We drew a random sample from all nursing homes (n = 180) within the geographical area of the Western Norway Regional Health Authority. A total of 26 nursing homes were invited to participate and 20 of these accepted, of which one withdrew after data collection had begun. The 19 nursing homes were located in both rural and urban areas, with a median long-term care population of 29 patients (range 8–136). Sixteen of the nursing homes were owned by the municipality, whereas three were owned by private foundations.

To ensure patients' confidentiality nursing home staff collected depersonalized data about year of birth, sex, and which patients had a diagnosis of diabetes. Nursing home staff also assessed diabetes patients' capacity to give consent and collected written, informed consent from patients. In cases where patients themselves lacked capacity to consent, their next of kin was asked to give consent on their behalf. The study was approved by a regional committee for medical research ethics (REK Vest).

The researcher (LMA) examined the nursing home medical records of all consenting diabetes patients and registered any blood glucose lowering drugs. They were defined as all drugs within code A10 –"Drugs used in diabetes" in the Anatomical Therapeutic Chemical (ATC) classification system [28]. The researcher also collected information on number of measurements and concentrations of capillary blood glucose and HbA1c within the last four weeks and twelve months, respectively. In this population, we define hypoglycemia as a blood glucose concentration <4.0 mmol/L and risk of hypoglycemia as a fasting blood glucose concentration <6.0 mmol/L [26]. Hyperglycemia is defined as a blood glucose concentration >11.0 mmol/L [26].

2.2. Statistical analyses

Descriptive statistics for normally distributed continuous variables are expressed as means with 95% confidence intervals (CI). Non-overlapping confidence intervals are interpreted as significant effects. Continuous variables with a skewed distribution are presented as median with range. Categorical variables are presented as frequencies and percentages. The 95% CI for the percentages were estimated by the 2.5 and 97.5 percentiles from non-parametric bootstrapped data (10,000 datasets were simulated for each CI). Pearson's chi-squared were used to test for significant effects. P-values ≤ 0.05 were considered statistically significant. Statistical analyses were carried out using IBM SPSS Statistics 20.0 (IBM, Armonk, NY) and Microsoft Excel 2010 (Microsoft, Redmond, WA, USA).

3. Results

3.1. Demographics

A total of 742 long-term care patients lived within the 19 participating nursing homes. Of these, 116 had a diagnosis of diabetes (16%). Patients with diabetes did not differ from the patients without diabetes in mean age (85.2 y [CI: 83.8, 86.6] vs.

Table 1 – Overview of drugs prescribed for regulating blood glucose (ATC-code: A10) divided into insulin injections and oral antidiabetics (OADs) (*n* = 74).

	ATC-code	Substance	Number of patients with prescription[a]	Number of regular prescriptions	Number of prn[b] prescriptions
Insulins A10A	A10AB05	Insulin aspart	31	3	31
	A10AC01	Insulin isophane	25	25	0
	A10AD05	Insulin aspart	9	9	1
	A10AB01	Insulin isophane	7	0	7
	A10AB04	Insulin lispro	3	1	2
	A10AE05	Insulin detemir	3	3	0
	A10AE04	Insulin glargine	1	1	0
	A10AD04	Insulin lispro	1	1	0
Other antidiabetics A10B	A10BA02	Metformin	27	27	0
	A10BB12	Glimepiride	18	18	0
	A10BB07	Glipizide	1	1	0

[a] As some patients are prescribed the drug both regular and prn, this number will not always add up to the sum of regular prescriptions + prn prescriptions.
[b] Prn = pro re nata/as needed medication.

86.0 y [CI: 85.3, 86.7]) or in male to female ratio (0.49 vs. 0.37, $P = 0.22$).

The study population consisted of 100 consenting patients with diabetes, of which 52 were able to give informed consent themselves. The 16 patients not consenting did not differ from the consenting patients in age, in male to female ratio, or in capacity to consent.

Seventy-five patients were registered with type 2 diabetes, five with type 1 diabetes, and for twenty patients information about type of diabetes was not given in the nursing home medical records.

3.2. *Drug regime*

Nearly half of the patients ($n = 47$) were prescribed insulin, 32 of which were prescribed insulin only and 15 of which were prescribed insulin and oral antidiabetics (OADs). Of the patients with only a prn (*pro re nata*–as needed) prescription for insulin ($n = 11$), eight were in the insulin + OAD group. Patients were prescribed a range of eleven different drugs for lowering blood glucose (Table 1). Insulins most frequently prescribed were insulin aspart ($n = 44$) and insulin isophane ($n = 32$). Metformin ($n = 27$) and glimepiride ($n = 18$) were the most commonly prescribed OADs.

A quarter of the patients ($n = 26$) received no blood glucose lowering drugs (Table 2). These did not differ from other patients in mean age, male to female ratio or type of diabetes registered in their medical records. However, the percentage of patients being prescribed blood glucose lowering drugs was significantly higher for patients with capacity to consent compared to patients without capacity to consent (82.7% vs. 64.6%, $P = 0.04$). The patients who received medical treatment for their diabetes had an average of 1.8 [CI: 1.6, 1.9] prescribed drugs for lowering blood glucose (range 1–3). Two of the patients registered with type 1 diabetes were prescribed an OAD (metformin) in addition to insulin.

3.3. *Glycemic control*

Seventy-three of 100 patients had one or more capillary blood glucose measurements (CBGM) in the last four weeks. Median number of CBGM was significantly higher for patients receiving regular insulin injections compared to the other treatment groups ($P < 0.01$) (Table 2). Thirteen patients had daily CBGM, twelve of which received regular insulin injections and one patient who received sulfonylurea as a regular medication.

Of the patients who had a record of CBGM in the last four weeks, 60% had recorded one or more measurements of blood glucose concentrations in the range of hypoglycemia (<4.0 mmol/L) and/or risk of hypoglycemia (fasting blood glucose <6.0 mmol/L). Fifteen percent of all recorded CBGM were in the range of hypoglycemia or risk of hypoglycemia (Table 3).

All patients who were prescribed insulin had at least one recorded episode of a CBGM <6.0 mmol/L (fasting), and 62% of these patients also had a record of CBGM >11.0 mmol/L. For the ''OAD group'' the numbers were 48% and 11%, respectively. None of the patients in the ''No drugs group'' had a record of CBGM <6.0 mmol/L, whilst 8% had a record of CBGM >11.0 mmol/L. A record of CBGM <6.0 mmol/L was significantly associated with higher mean HbA1c value (7.8% [CI: 7.3, 8.3] (61 mmol/mol [CI: 56, 67]) vs. 6.5% [CI: 6.1, 6.9] (48 mmol/mol [CI: 44, 52])). Patients with a record of CBGM >11.0 mmol/L also had a significantly higher mean HbA1c value compared to those with no recordings >11.0 mmol/L (8.3% [CI: 7.7, 8.9] (67 mmol/mol [CI: 60, 74]) vs. 6.8% [CI: 6.4, 7.2] (51 mmol/mol [CI: 46, 55])). We did not find significant differences in mean HbA1c value between patients with a record of CBGM <4.0 mmol/L and patients with no recordings <4.0 mmol/L (8.0% [CI: 7.1, 9.0] (64 mmol/mol [CI: 53, 75]) vs. 7.2% [CI: 6.8, 7.6] (56 mmol/mol [CI: 51, 60])), or between patients with a record of CBGM compared to those with no recordings of CBGM the last four weeks (7.5% [CI: 7.0, 7.9] (58 mmol/mol [CI: 53, 62]) vs. 6.9% [CI: 6.1, 7.8] (52 mmol/mol [CI: 43, 61])). Neither did we find an association between number of CBGM and last recorded HbA1c value (data not shown).

Twenty-three patients had no record of HbA1c measurements during the last 12 months, 14 of which were prescribed blood glucose lowering drugs. Forty patients had one recorded HbA1c value, and in 37 patients the number of measurements

Table 2 – Frequency of capillary blood glucose measurements (CBGM) by drug treatment.

	Insulin						OADs only		No drugs		Total	
	Regular (*n* = 36)			Prn (*n* = 11)			(*n* = 27)		(*n* = 26)		(*n* = 100)	
Frequency of CBGM last four weeks, median (range)	10	(0–121)		3	(0–23)		1	(0–32)	1	(0–12)	3	(0–121)
	n	(%)	[95% CI]	*n*	(%)	[95% CI]	*n*	(%)	*n*	(%)	[95% CI]	*n*	(%)	[95% CI]
Number of patients with a record of CBGM last four weeks	33	(91.7)	[80.6,100]	9	(81.8)	[54.5,100]	16	(59.3)	[40.7,77.8]	15	(57.7)	[38.5,76.9]	73	(73.0)	[64.0,81.0]
≥1 CBGM/day	12	(33.3)	[19.4,50.0]	0	–	–	1	(3.7)	[0.0,11.1]	0	–	–	13	(13.0)	[7.0,20.0]
≥1 CBGM/week, but <1 CBGM/day	18	(50.0)	[33.3,66.7]	4	(36.4)	[9.1,63.6]	2	(7.4)	[0.0,18.5]	7	(26.9)	[11.5,46.2]	31	(31.0)	[22.0,40.0]
≥1 CBGM/month, but <1 CBGM/week	3	(8.3)	[0.0,19.4]	5	(45.5)	[18.2,72.7]	13	(48.1)	[29.6,66.7]	8	(30.8)	[15.4,50.0]	29	(29.0)	[20.0,38.0]
<1 CBGM/month	3	(8.3)	[0.0,19.4]	2	(18.2)	[0.0,45.5]	11	(40.7)	[22.2,59.3]	11	(42.3)	[23.1,61.5]	27	(27.0)	[19.0, 36.0]

Table 3 – Results of capillary blood glucose measurements (CBGM) the last four weeks from 73 patients.

	Number of patients		Number of CBGM	
	(*n* = 73)		(*n* = 1006)	
Blood glucose concentration	*n*	(%)	*n*	(%)
<4.0 mmol/L[a]	10	(13.7)	31	(3.1)
<6.0 mmol/L[b]	35	(47.9)	122	(12.1)
>11.0 mmol/L[a]	34	(46.6)	367	(36.5)

[a] Random blood glucose concentration, not necessarily fasting.
[b] Fasting blood glucose concentration.

ranged from two to six. Last recorded value of HbA1c ranged from 4.7% (28 mmol/mol) to 12.4% (112 mmol/mol), with an average of 7.3% [CI: 7.0, 7.7] (57 mmol/mol [CI: 53, 60]). Distribution of HbA1c values by treatment is shown in Fig. 1. Mean value of HbA1c was significantly higher when prescribed insulin (8.0% [CI: 7.4, 8.6] (64 mmol/mol [CI: 58, 70])) compared to patients prescribed only OADs (6.7% [CI: 6.4, 7.4] (52 mmol/mol [CI: 46, 57])) or patients who did not receive blood glucose lowering drugs (6.4% [CI: 5.8, 7.0] (46 mmol/mol [CI: 40, 53])).

Seven patients neither received CBGM in the last four weeks nor HbA1c measurements in the last 12 months. Four of these patients were prescribed blood glucose lowering drugs; three patients with a prescription for OADs only, and one patient with a prescription for a regular OAD and insulin prn.

Capacity to consent was not associated with a record of CBGM (58% vs. 37%, $P = 0.08$). Neither did we find an association between capacity to consent and having HbA1c measured the last twelve months (53% vs. 48% [$P = 0.81$]), nor last recorded value of HbA1c (7.4% [CI: 6.9, 7.9] (57 mmol/mol [CI: 51, 63]) vs. 7.3% [CI: 6.7, 7.8] (56 mmol/mol [CI: 50, 62])).

Figure 1 – Distribution of last recorded HbA1c value (%, mmol/mol) from 77 patients, sectioned into treatment categories "Insulin", "OADs" and "No drugs".

4. Discussion

Our results show that 16% of long-term care patients in Norwegian nursing homes have a known diagnosis of diabetes. This is consistent with findings from other European countries [7,11–13], and also comparable with the prevalence previously reported for the elderly population receiving nursing care either at home or in an institution in the Tromsø area in Norway [27]. The majority of the patients in our study (71%) receive blood glucose regulating drugs regularly, but frequency and level of glycemic control vary greatly among the patients.

Patients with diabetes were prescribed a variety of blood glucose lowering drugs (Table 1), and choice of drugs, average number of prescribed drugs, and proportion of patients in the different treatment groups are comparable to what are reported in other nursing home studies [7,11,29].

Metformin was the drug of choice for patients prescribed OADs, whilst a basal regime with NPH-insulin was common in insulin-treated patients (Table 1). This is consistent with current recommendations for older people with diabetes, although these also state that newer therapies may benefit selected patients [26]. Insulin detemir and insulin glargine have shown to be more beneficial than NPH-insulin for patients at higher risk of hypoglycemia [30]. The same is true for incretin mimetics in obese patients and DPP-4 inhibitors in malnourished patients [31]. However, limited knowledge of effect and safety of the newer therapies in the population aged ≥75 years, and higher costs may be an explanation for why these drugs are seldom or never prescribed [30,31].

On average, the patients who received medical treatment for their diabetes were prescribed more than one drug for lowering their blood glucose, and almost half of them receive regular insulin injections. The reason for this may be that advanced age is associated with a decline in glucose tolerance and β-cell function, leading to increased insulin resistance and impaired insulin secretion [32]. Progressive loss of glycemic control in type 2 diabetes with time, requiring several OADs and ultimately insulin to achieve appropriate treatment, is also well-known [33]. Although we do not have information about duration of diabetes in these patients, it is reasonable to believe that a number of them have had the disease for some time. Jorde and Hagen reported the average duration of diabetes to be 11.2 ± 8.2 years [27]. They found that 46% of the patients were treated with insulin compared to 47% of the patients in our study. However, the majority of the Tromsø patients received insulin together with OADs (35%), whilst in our population patients mostly used insulin alone (32%). This may be due to some demographic differences in our populations.

Low concentrations of fasting blood glucose (<6.0 mmol/L) and/or hypoglycemic episodes (<4.0 mmol/L) were found for 60% of the patients with a record of CBGM (Table 3), which may indicate overtreatment in these patients, but we do not know if these patients experienced clinical symptoms of hypoglycemia in these cases. However, as hypoglycemia is often overlooked in these patients [20,21] and also associated with an increased risk of cardiovascular events, dementia and death [22,23], this number is worrying. Furthermore, number of hypoglycemic episodes may be underestimated in our study, as only one third of patients receiving regular insulin have daily CBGM (Table 2). Frequent hypoglycemic episodes among nursing home patients using insulin have also been reported in other studies [9,11,34,35]. However, increased CBGM may not be the solution for all patients to solve the problem with hypoglycemia. Studies have shown that even with regular CBGM in these patients, recommended glucose targets were not met [36] and patients not at risk of hypoglycemia experienced unnecessary measurements [35]. Furthermore, clinical symptoms that called for unscheduled CBGM were overlooked [9], and the risk of hypoglycemic episodes still was a considerable issue [9,35,36]. Shorter periods, e.g. 24–72 h, with more frequent measurements, or even continuous glucose monitoring, may give a better understanding of the patient's diurnal variation in blood glucose than regular daily measurements.

Our study also showed that many patients who had experienced low concentrations of blood glucose also had a record of hyperglycemic episodes (>11.0 mmol/L). This glucose variability suggests that management of nursing home patients using insulin is challenging, and that hypoglycemic episodes might be a problem even with higher levels of HbA1c. It has been suggested that too much focus on treating a high HbA1c, rather than individualizing the care for the patient is the reason for this [21,37]. Guidelines recommend that HbA1c should be taken at least every six months, regardless of treatment and even if the patient's glycemic control is stable [25,38]. Over 60% of the patients in this study do not meet this recommendation, possibly compromising initiation and follow-up of treatment. Another worrying finding was that the medical records of 26 patients receiving blood glucose lowering drugs lacked information about level of glycemic control, either in form of a CBGM record, an HbA1c value, or both. Patients who receive medical treatment for their diabetes should receive some sort of measurement to decide their level of glycemic control, to make sure they receive the appropriate treatment.

The newer guidelines have advocated less stringent HbA1c goals (7.0–8.0% (53-64 mmol/mol)) for patients with advanced age, one or several comorbidities and/or an increased risk of hypoglycemia [25,26,38,39]. In our study, the levels of HbA1c were not as low as reported in similar studies [11,12,34], especially not for patients using insulin. Still, for 46% of the patients with a record of HbA1c measurement the last 12 months, the last HbA1c value was below the recommended limit of 7.0% (53 mmol/mol), whilst only a quarter of these patients were within the recommended interval of 7.0–8.0% (53–64 mmol/mol) (Fig. 1). Similar numbers were reported by Jorde and Hagen [27]. Too tight glycemic control in aging patients has been associated with adverse clinical outcomes [40,41]. The Action to Control Cardiovascular Risk in Diabetes (ACCORD) study reported significantly higher frequency of hypoglycemia requiring assistance, and also a significantly higher risk of death in patients receiving an intensive drug regime (mean HbA1c at study end 6.4% (46 mmol/mol)) compared with patients receiving standard therapy (mean HbA1c at study end 7.5% (58 mmol/mol)) [40]. Currie et al. showed that HbA1c values in the lower range (<7.5% (58 mmol/mol)) were significantly associated with an

increased risk of mortality in patients using insulin, compared to HbA1c values between 7.5% and 9.0% (58 and 75 mmol/mol) [41]. Furthermore, a more intensive glycemic control requires more drugs or more frequent dosing of drugs, and it also increases the risk of drug–drug or drug–disease interactions and adverse drug events. Norwegian nursing homes should to a greater extent adjust their HbA1c treatment goals according to the new recommendations, as many of the patients in our study had an HbA1c in the lower range. The high number of patients with a record of low blood glucose concentrations in our study further demonstrates the importance of less stringent HbA1c treatment goals for these patients, especially if they have a limited life expectancy and several comorbidities.

An interesting finding in our study was that lack of capacity to consent was significantly associated with not receiving blood glucose lowering drugs. However, we did not find any significant differences in receiving CBGM or HbA1c measurements, or average HbA1c results based on decisional capacity. A lack of decisional capacity is associated with impaired cognitive function [42], and differences in diabetes management due to impaired cognitive function have been reported [43–45]. However, in contrast to our findings, McNabney et al. report no difference in choice of oral agents between nursing home patients with different levels of both functional and cognitive impairment, and do find lower intensity of both CBGM and HbA1c measurements [45]. Less frequent HbA1c measurements for patients with dementia is also reported by Quinn et al. and Thorpe et al. [43,44]. None of these studies investigated differences in HbA1c results. While it is difficult to point out reasons for these differences, part of the explanation may be that a recent patient safety campaign in Norway has focused on minimizing drug treatment in nursing home patients, especially those with dementia [46]. Restrictions in both drug therapy and monitoring practices may be beneficial for patients with cognitive impairment. A recent study reported worsened cognitive performance for patients using metformin compared to those who were not [47], suggesting that excessive drug treatment may do more harm than good. According to our study, glycemic control of patients without capacity to consent is as good as that of patients with capacity to consent, even if they do receive less blood glucose lowering drugs.

To our knowledge, this is the first descriptive study of Norwegian nursing home patients with diabetes residing in long-term care. We included different sized nursing homes from three counties, located in both urban and rural areas. This should make the results representative for the general nursing home population in Norway. Our results also support findings in similar studies from other European countries, strengthening the knowledge basis for this population. As we did not collect information about length of stay, our results of the HbA1c measurements may be biased. Patients with a stay less than 12 months may have received HbA1c measurements that are not documented in the nursing home medical records. Transfer of medical information between care levels have been shown to sometimes be inadequate [48], which also raises concern about the validity of the treatment foundation. However, three out of four patients did have at least one record of an HbA1c result the last 12 months, giving a reasonable estimate of glycemic control in this population. We did not collect information about duration of diabetes, nutrition/diet, weight/BMI, other diagnoses, drugs or laboratory values from these patients, and hence could not investigate how these aspects may have influenced blood glucose lowering treatment and glycemic control. A more comprehensive diagnosis and medication review for these patients should be included in future studies, to gain a better understanding of the medical challenges and needs for these patients. Future research should also include a more thorough investigation of glycemic control in these patients, as well as CBGM and HbA1c measurement practices in nursing homes, as these aspects of care are essential for initiation and follow-up of treatment.

In conclusion, the prevalence and blood glucose lowering treatment of diabetes in Norwegian nursing homes is comparable to other European countries. Special care seems to be taken when choosing blood glucose lowering treatment for patients with cognitive impairment. However, the high number of insulin treated patients, together with several recordings of low blood glucose concentrations and low HbA1c values suggest that some patients are subject to overtreatment. This may result in lower quality of life and increase the risk of early death. Newer guidelines recommend less stringent HbA1c limits for older patients [25,26,38,39] and Norwegian nursing homes should adjust their treatment targets for patients with diabetes accordingly. Individual care planning should also be applied, especially for patients with high variability in glucose concentrations.

Conflict of interest statement

None

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Paper II

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RESEARCH ARTICLE

The potential for deprescribing in care home residents with Type 2 diabetes

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Abstract *Background* Type 2 diabetes is a common diagnosis in care home residents that is associated with potentially inappropriate prescribing and thus risk of additional suffering. Previous studies found that diabetes medicines can be safely withdrawn in care home residents, encouraging further investigation of the potential for deprescribing amongst these patients. *Objectives* Describe comorbidities and medicine use in care home residents with Type 2 diabetes; identify number of potentially inappropriate medicines prescribed for these residents using a medicines optimisation tool; assess clinical applicability of the tool. *Setting* Thirty care homes for older people, East Anglia, UK. *Method* Data on diagnoses and medicines were extracted from medical records of 826 residents. Potentially inappropriate medicines were identified using the tool 'Optimising Safe and Appropriate Medicines Use'. Twenty percent of results were validated by a care home physician. *Main outcome measure* Number of potentially inappropriate medicines. *Results* The 106 residents with Type 2 diabetes had more comorbidities and prescriptions than those without. Over 90 % of residents with Type 2 diabetes had at least one potentially inappropriate medication. The most common was absence of valid indication. The physician unreservedly endorsed 39 % of the suggested deprescribing, and would consider discontinuing all but one of the remaining medicines following access to additional information. *Conclusion* UK care home residents with Type 2 diabetes had an increased burden of comorbidities and prescriptions. The majority of these patients were prescribed potentially inappropriate medicines. Validation by a care home physician supported the clinical applicability of the medicines optimisation tool.

Keywords Care homes · Deprescribing · Medicines optimisation tool · Pharmacists · Potentially inappropriate medicines · Type 2 diabetes mellitus

Impacts of practice

- The results from this study suggest that care home residents with Type 2 diabetes have a higher burden of comorbidities and polypharmacy than residents without diabetes, thereby having increased risk for potentially inappropriate prescribing.
- The evidence-based, pragmatic medicines optimisation tool used in this study allows pharmacists to identify medicines eligible for deprescribing for care home residents with Type 2 diabetes, thus reducing polypharmacy and potentially adverse events following from it.

Introduction

In the UK, care homes for older people provide accommodation and nursing or personal care to those who need it. These institutions are staffed 24 h a day, with or without

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qualified nursing staff, and are referred to as nursing homes and residential homes respectively. Care home residents generally have a limited life expectancy [1] and experience high levels of disability, comorbidity and polypharmacy [2]. Non-insulin-dependent diabetes, also known as Type 2 diabetes mellitus (T2DM), is reported to be among the ten most common diagnoses, affecting 15 % of the care home population [2].

T2DM is associated with a range of comorbidities and complications [3, 4], deteriorating health and reducing quality of life. In the general older population, diabetes has been identified as a predictor of multiple medicine use [5] and an independent risk factor for being prescribed potentially inappropriate medicines or combinations of these [6, 7]. Unnecessary or inappropriate medicines can cause adverse events and additional suffering in this already vulnerable group of patients. It is argued that people with diabetes who suffer from multiple comorbidities, cognitive impairment or reside in a long-term nursing facility may experience limited or uncertain benefit from diabetes treatment [8, 9]. Concerns about overtreatment with blood glucose lowering medicines have been reported [10, 11] and a Swedish study suggests that diabetes medicines can be safely reduced or withdrawn in the majority of these residents [11]. These findings indicate that the potential for deprescribing should be investigated to a greater extent in this population.

Deprescribing is defined by Reeve et al. [12] as «the process of withdrawal of an inappropriate medication, supervised by a health care professional with the goal of managing polypharmacy and improving outcomes». Deprescribing is increasingly acknowledged as an important part of prescribing when managing patients with multiple conditions and limited life expectancy [13–15]. Several tools exist to help determine medication appropriateness in older persons, the STOPP/START criteria [16] perhaps being the most commonly used in UK settings. However, it has been argued that whilst these criteria are useful in aiding prescribing for healthier older persons, they may be less suitable for use in settings where the patients are frail, late in life, and suffer from multiple illnesses [13]. Hence, there is a requirement for clearer practical guidance that directly addresses appropriate removal of medicines in these patients [13], that should be founded on questions about whether the medicine is currently indicated, safe and beneficial considering comorbidities [17, 18]. The NHS PrescQIPP document 'Optimising Safe and Appropriate Medicine Use' (OSAMU), a pragmatic, evidence-based tool, developed to allow for appropriately stopping or continuing medicines in end of life, uses such an approach [19]. When used as a resource in a care home setting, it has been shown to safely contribute to a reduction in polypharmacy, inappropriate medicines and potential adverse effects [20, 21]. In addition it contributed to a reduction in administration time, waste and costs of medicines.

Aim of the study

This study aimed to investigate the potential for deprescribing in UK care home residents with T2DM. The objectives set were (1) to describe the comorbidities and medicine use in the residents with T2DM; (2) to describe the number of potentially inappropriate medicines in these residents using an evidence-based, pragmatic medicines optimisation tool; and (3) to describe the clinical applicability of the medicines optimisation tool used.

This study is a retrospective sub-analysis of data from the CAREMED study, a cluster randomised controlled trial investigating the impact of a multi-professional medication review service (MMRS) within 30 care homes for older people across East Anglia, UK between March 2011 and March 2013 [22].

Details of inclusion and exclusion criteria, outcome measures, data collection and ethical approval have been described in a previous publication. Findings from the main study have yet to be published.

Ethics approval

The CAREMED study was approved by the National Health Service (NHS) Norfolk Research Ethics Committee (REC reference 09/H0310/96).

Methods

Data extraction and analysis

CAREMED baseline data was extracted for all 826 residents living in the 30 care homes. Data included information about the residents' current medicines and active medical problems, derived from their medical records at the general practitioner's (GP's) surgery.

Demographics

Diabetes prevalence was determined by evidence of T2DM documented as an active medical problem. Residents with other types of diabetes were excluded from the study population and further analysis. Comorbidity burden was determined from the resident's number of active medical problems. All active medical problems in the dataset were classified according to the 22 chapters of the International

Table 1 Demographics, burden of comorbidities and prescriptions in care home residents with and without diabetes mellitus

		Type 2 DM n = 106			No DM n = 717		
		Median	Range	[95 % CI][a]	Median	Range	[95 % CI][a]
Age, years		86	56–98	[84.5, 87.5]	88	39–104	[88.0, 89.0]
Age at admission, years		84	54–98	[81.0, 85.0]	86	36–103	[85.0, 86.0]
Number of active medical problems		6.5	2–16	[6.0, 7.0]	5	1–14	[4.0, 5.0]
Number of prescriptions		9	1–20	[8.5, 10.0]	7	0–27	[7.0, 7.0]
	n	%		[95 % CI][b]	n	%	[95 % CI][b]
Polypharmacy[c]	98	92.5		[86.7, 96.9]	534	74.5	[70.7, 78.1]
Nursing home residents	24	22.6		[8.3, 41.7]	170	23.7	[17.6, 30.0]
Women	70	66.0		[54.3, 77.1]	555	77.4	[73.9, 80.9]

DM diabetes mellitus

[a] Confidence intervals for median values. Non-overlapping confidence intervals are interpreted as statistically significant differences

[b] Confidence intervals for percentages. Non-overlapping confidence intervals are interpreted as statistically significant differences

[c] Polypharmacy is defined as prescription of ≥5 unique drug substances

Statistical Classification of Diseases and Related Health Problems 10th Revision (ICD-10) Version: 2010 [23]. Number of prescriptions was determined from the number of unique medicines prescribed. Polypharmacy was defined as prescription of ≥5 unique medicines. All medicines were coded according to the Anatomical Therapeutic Chemical (ATC) classification system [24].

Potential for deprescribing

The NHS PrescQIPP document OSAMU consists of 46 areas for medicine optimisation based on the drug classes in the British National Formulary (BNF) chapters [19]. Based on the available CAREMED data, we identified that 35 of these areas were applicable to our population. For counting purposes, one or several explicit criteria were identified for each area by LMA in agreement with RLSK (Online Resource 1). LMA and RLSK are pharmacists with experience of clinical work and research in both community pharmacies and care homes, with particular focus on diabetes. Potentially inappropriate medicines (PIMs) were identified by LMA based on the criteria derived from the recommendations given in the OSAMU document (Online Resource 2).

As a further validation of clinical applicability of the OSAMU document a physician (CG) with clinical background from care homes, currently in involved in a large multicentre-study on medicines optimisation in care homes [25], assessed the identified PIMs for discontinuation for a random sample of 20 % of the residents. Based on the information available, the physician evaluated whether (1) the medicine could be discontinued without further question; (2) the medicine should potentially be discontinued, but not before checking other parameters of importance, e.g. laboratory values; (3) the medicine should be changed to a more appropriate choice; or (4) the medicine should be continued.

Statistical analysis

Descriptive statistics were applied. Continuous variables are presented as medians with range and/or 95 % confidence intervals (CI), and categorical variables are presented as frequencies with percentages and/or 95 % CI. The 95 % CI for the medians and percentages were estimated by the 2.5 and 97.5 percentiles from a simple bootstrap (10.000 datasets were randomly generated for each CI). Non-overlapping CI was interpreted as significant effects. The RAND function in Microsoft Excel 2010 (Microsoft, Redmond, WA, USA) was used to create the random 20 % sample for validation. IBM SPSS Statistics 22.0 (IBM, Armonk, NY, USA) was used for all statistical analysis, apart from bootstrapping, which was performed using Python 2.7.

Results

Demographics, therapy and comorbidity burden

Of 826 residents, 109 had a registered diagnosis of DM. Two residents with Type 1 DM and one resident with steroid-induced diabetes were excluded, resulting in a total study population of 823 residents, where 106 residents had

Table 2 The most frequently prescribed drug groups in care home residents with Type 2 diabetes mellitus (n = 106)

ATC code	Therapeutic group/substance	Residents receiving therapy	
		N	%
A10	Drugs used in diabetes	70	66.0
A10A	Insulins and analogues	14	13.2
A10B	Blood glucose lowering drugs, excl. insulins	60	56.6
A10BA02	Metformin	45	42.5
A10BB09	Gliclazide	26	24.5
N02	Analgesics	65	61.3
C10	Lipid modifying agents	61	57.5
B01	Antithrombotic agents	60	56.6
A06	Drugs for constipation	48	45.3
C03	Diuretics	46	43.4
D02	Emollients and protectives	45	42.5
N06	Psychoanaleptics	43	40.6
A02	Drugs for acid related disorders	41	38.7
C09	Agents acting on the renin-angiotensin system	38	35.8
B03	Antianaemic preparations	29	27.4
C01	Cardiac therapy	26	24.5
N05	Psycholeptics	26	24.5
C07	Beta blocking agents	25	23.6
A12	Mineral supplements	24	22.6
H03	Thyroid therapy	24	22.6

diagnosed T2DM (13 %). Table 1 compares residents with T2DM to residents without DM. Residents with T2DM were significantly younger and had a higher burden of both comorbidities and prescriptions than residents without DM.

The top five ICD-10 classifications for residents with T2DM, excluding diabetes, were I00-I99: circulatory diseases (n = 82, 77.4 %), F00-F99: mental and behavioural disorders (n = 52, 49.1 %), M00-M99: musculoskeletal and connective tissue diseases (n = 43, 40.6 %), H00-H59: eye diseases (n = 40, 37.7 %), and N00-N99: genitourinary diseases (n = 37, 34.9 %). They were treated with the following blood glucose lowering therapy: insulin only (n = 10), insulin and oral antidiabetic drugs (OADs) (n = 4), OADs only (n = 56), and no blood glucose lowering drugs (n = 36). The other most commonly prescribed groups of medicines among these residents are listed in Table 2.

Table 3 Total frequency of potentially inappropriate medicines in care home residents with Type 2 diabetes mellitus (n = 106)

PIMs	Residents	
n	n	%
0	10	9.4
1	17	16.0
2	12	11.3
3	21	19.8
4	18	17.0
5	13	12.3
6	6	5.7
7	4	3.8
8	4	3.8
9	1	0.9

PIMs potentially inappropriate medicines

Potential for deprescribing

Among the residents with T2DM, a total of 346 PIMs were identified. The residents had from none to nine PIMs (Table 3), with a median number of three PIMs. In total, 96 residents (90.6 %) were prescribed at least one PIM. Frequency of PIMs by BNF classification is presented in Table 4. The most frequent PIMs were (1) statins prescribed without a valid indication (n = 50, 47.2 %); (2) more than one antihypertensive prescribed (n = 43, 40.6 %); (3) laxatives prescribed without a valid indication (n = 32, 30.2 %); (4) antidepressant prescribed without a valid indication (n = 32, 30.2 %); and (5) H2 blockers/proton pump inhibitors (PPI) prescribed without a valid indication (n = 27, 26.5 %).

Within the 20 % random sample chosen for validation by physician CG, a total of 67 PIMs were identified and 35 of these belonged to the top five frequent PIMs (Table 5).

Table 4 Frequency of potentially inappropriate medicines by classification of the British National Formulary, in residents with Type 2 diabetes mellitus (n = 106)

BNF chapter[a]	Number of criteria in chapter	Residents	
		n	%
Chapter 1—gastrointestinal system	4	70	20.2
Chapter 2—cardiovascular system	10	111	32.1
Chapter 3—respiratory system	3	1	0.3
Chapter 4—central nervous system	15	89	25.7
Chapter 5—infections	3	10	2.9
Chapter 6—bisphosphonates	1	9	2.6
Chapter 7—obstetrics, gynaecology and urinary tract disorders	5	7	2.0
Chapter 9—nutrition and blood	2	24	6.9
Chapter 10—musculoskeletal and joint diseases	4	13	3.8
Chapter 11—eye	1	0	0.0
Chapter 12—ear, nose and oropharynx	1	1	0.3
Chapter 13—skin	1	11	3.2
Total	50	346	100.0

BNF British National Formulary

[a] Chapters omitted indicated that these were not applicable to our population

Table 5 Validation of deprescribing potential for the top five frequently prescribed potentially inappropriate medicines

Description of PIM	Total population n	Sample for validation n	Validation category			
			Discontinue	Need more information	Change	Keep unchanged
Statin, no valid indication (107)[a]	50	12	12	0	0	0
Antihypertensive, more than one (105)[a]	43	7	0	7	0	0
Laxative, no valid indication (103b)[a]	32	7	0	7	0	0
Antidepressant, no valid indication (120a)[a]	32	4	0	4	0	0
H2 blocker/PPI, no valid indication (102)[a]	27	5	4	0	1	0
Total	184	35	16	18	1	0

PIM potentially inappropriate medicine, *PPI* proton pump inhibitor

[a] Numbers in parentheses indicate the assigned criteria number (Online resource 1)

Out of the total of 67 PIMs the physician agreed that 26 of these could be discontinued without further question (38.8 %). A common example of this was statins without a valid indication. In the case of a further 40 PIMs (59.7 %) the physician indicated that medicine discontinuation should be considered, following access to other clinical data. An example here was to check blood pressure before deciding whether or not to discontinue excess antihypertensives. The physician recommended that one PIM (1.5 %) be changed to a different medicine. In this particular case, the combination of an SSRI with low-dose aspirin gave the resident an increased risk of gastrointestinal bleeding and hence the physician recommended keeping the ulcer prophylaxis, but replacing the H2 blocker with a proton pump inhibitor. None of the PIMs were considered for direct continuation.

Discussion

This study found that UK care home residents with T2DM were younger and had a greater burden of active medical problems, prescriptions and polypharmacy than residents without diabetes. Using the NHS PrescQIPP document OSAMU, PIMs were identified for nine out of ten residents with T2DM, with the absence of a valid indication as the most common reason. Based on the available data, a physician with experience of care homes and medicines

optimisation confirmed that 39 % of the PIMs could be directly discontinued, and acknowledged a potential for deprescribing in all but one of the remaining cases.

Our findings concur with previous studies showing that older persons with diabetes have higher rates of comorbidities [26] and prescriptions [5, 27, 28] compared to the general older population, thereby having increased risk for potentially inappropriate prescribing. The proportion of residents with at least one PIM is similar to that found for the general UK care home population when using a similar pragmatic approach for medicines review. The Northumbria Shine 2012 project, a prospective medicines optimisation study involving both clinicians and residents, used OSAMU as a resource in the shared decision making process [21]. When performing an extensive medicine review for 422 residents in 20 care homes in North Tyneside, UK, they found that 90.5 % of the residents required an intervention to their medicines [17, 21]. Stopping medicines was the most common intervention, required for seven out of ten residents [17, 21].

Failure to integrate comorbidities into clinical practice guidelines, and limited guidance on treatment for frail older patients are presented as leading reasons for the prescribing cascade so often seen in this population [29, 30]. Furthermore, frail elderly are normally excluded from randomised controlled trials and other robust studies that guidelines are built upon. Consequently, practitioners have little or no evidence-based guidance for how to prescribe for this vulnerable group of patients, and sometimes feel pressured to follow guidelines not developed based on the needs of these patients [30, 31].

It has been demonstrated that many medicines can be safely discontinued in older patients without causing adverse effects [11, 14, 17]. Still, concerns about withdrawal effects and lack of guidance on how and when to discontinue a medication discourage clinicians from attempting to do so [31, 32]. Several healthcare practitioners have expressed a need for deprescribing guidelines, especially for prevention-oriented medicines, as they may be less appropriate in the care home population [32]. In particular, statins have even been considered harmful in older patients, as low total cholesterol (<5.5 mmol/l) is associated with increased total mortality in those aged ≥80 years [18]. GPs sometimes choose not to follow recommended guidelines and refrain from prescribing statins in patients with T2DM. Questions about whether statins lead to improved quality of life, and concerns regarding frailty, multimorbidity and short life expectancy, are listed as the main reasons for this [33]. In our study, the physician who evaluated the PIMs agreed to stop all statins in the sample cases examined, for the same reasons.

In addition to evaluation of risk versus benefit of continued use of a medicine, the existence of a current indication is of particular concern for healthcare practitioners when considering deprescribing [32]. Four out of the five most common PIMs in our population involved medicines not having a valid indication. Similarly, no current indication was reported as the top reason for stopping medicines in the Northumbria Shine 2012 project [17], and according to Barber et al. [34] incomplete information in medical records is the prescribing error most frequently occurring in UK care homes. Many care homes receive prescribing services from multiple GPs, making clear and complete information crucial for adequate follow-up of the residents. A lack of information on indication may increase the potential for medication errors, and may also hamper deprescribing, as it adds to the uncertainty of whether the medicine is appropriate or not, especially if it is prescribed by a GP different to the one reviewing it. GPs often feel reluctant to change or stop medicines prescribed by colleagues, and also report to lack knowledge of geriatric pharmacotherapy [31].

In general, a lack of communication and team work between the GP practice, the pharmacy and the care home, and hence no integrated system for medicines management, is the reality for many UK care homes [34]. Appointing a lead GP for each care home and involving a pharmacist overseeing and regularly reviewing medicines use, are recommended to improve this [34]. Pharmacist involvement is valued by both GPs and care home staff [17] and can contribute to increased knowledge and awareness around medicines, as well as improve quality of medicine use [35]. The Northumbria Shine 2012 project demonstrated that a review process led by a prescribing pharmacist, where interventions were made available in the electronic medical notes for the GPs to challenge afterwards, was a cost-efficient approach. However, they debated that involving the GP during rather than after the review may result in even more interventions and greater savings [17]. This may be difficult to achieve at all care homes, and several clinical studies have shown that the GPs' acceptance rate for medicine interventions suggested by pharmacists is generally high [17, 36, 37]. Although our approach was theoretical rather than clinical, the physician who evaluated the PIMs fully agreed with the pharmacist's suggestions for deprescribing in 39 % of the cases, and acknowledged a potential for deprescribing in all but one of the remaining cases.

As this study was a cross-sectional and retrospective review of a selection of resident data from an RCT dataset, it has its limitations. For instance, we did not have information about the sequence of prescribing, information about duration of active medical problems, or previous medical problems and prescriptions. Neither did we have access to clinical data, such as blood pressure, lipids, weight and fluid intake. These data could have shed light

on the appropriateness of even more therapies than we included as part of our analysis, and thus have facilitated a consideration of optimisation of therapy, not just the potential for deprescribing. We know from previous studies that blood glucose lowering therapy is not always optimal in the care home population [10, 11]. Additional clinical data could also have provided a better foundation for assessing the applicability of the criteria, and thus have given room for involving a more extensive team of clinicians to validate them. With a limited set of medical information, we identified 346 medicines as potentially inappropriate, where in a random sample a large proportion was directly endorsed for discontinuation by an experienced care home physician. If applied by clinical pharmacists or GPs with full access to all necessary medical information, maybe an even greater number of PIMs could have been identified and discontinued, and other therapies could also have been considered for optimisation.

We used a relatively new tool for evaluating appropriateness of medicines in the care home population. As such, comparison with other studies using other tools should be done with care. However, we have only compared our results to studies using similar, pragmatic approaches. In addition, more well-known tools, such as the STOPP/START criteria, have been considered less suitable when seeking to optimise drug therapy in the very frail old [13]. The tool used in this study is evidence-based, takes into account the complexity of care home residents and has proven to be efficient in this population [20]. Even though the sample size is small and performed in a limited geographical area, the resident population is comparable to that of other studies investigating different aspects of health status of care home residents both with and without DM in other parts of the UK [2, 38]. Hence, there is no reason to believe that the residents in this study are significantly different from the overall UK care home population.

The results of this study indicate that there is an unfulfilled potential for deprescribing in care home residents with T2DM. A more clinical approach with complete access to all relevant information and involvement of a team of clinicians, assessing relevant outcomes such as impact on glycaemic control and quality of life, should be the goal for future studies. It would be interesting to see if such a study gives similar results to those reported here. As a final note, when targeting care home medicines management, involvement of the resident should also be considered. Together with the best current research evidence and clinical expertise, the patient's values and preferences make up the triad for evidence-based medicine [39].

Conclusion

UK care home residents with T2DM have an increased burden of comorbidities, prescriptions and polypharmacy. Using an evidence-based, pragmatic medicines optimisation tool, we identified that the majority of these residents were prescribed at least one PIM. Validation of the PIMs by an experienced care home physician supports the clinical applicability of the 'Optimising Safe and Appropriate Medicines Use' document.

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Conflicts of interest None.

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Paper III

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'I try not to bother the residents too much' – the use of capillary blood glucose measurements in nursing homes

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Abstract

Background: Capillary blood glucose measurements are regularly used for nursing home residents with diabetes. The usefulness of these measurements relies on clear indications for use, correct measurement techniques, proper documentation and clinical use of the resulting blood glucose values. The use of a regular, invasive procedure may also entail additional challenges in a population of older, multimorbid patients who often suffer from cognitive impairment or dementia. The aim of this study was to explore the perspectives of physicians, registered nurses and auxiliary nurses on the use, usefulness and potential challenges of using capillary blood glucose measurements in nursing homes, and the procedures for doing so.

Methods: This was a qualitative study that used three profession-specific focus group interviews. Interviews were transcribed in modified verbatim form and analysed in accordance with Malterud's principles of systematic text condensation. Five physicians, four registered nurses and three auxiliary nurses participated in the focus groups.

Results: All professional groups regarded capillary blood glucose measurements as a necessity in the management of diabetes, the physicians to ensure that the treatment is appropriate, and the nurses to be certain and assured about their caring decisions. Strict glycaemic control and excessive measurements were avoided in order to promote the well-being and safety of the residents. Sufficient knowledge of diabetes symptoms, equivalent practices for glucose measurement, and unambiguous documentation and communication of results were determined to be most helpful. However, all professional groups seldom involved the residents in managing their own measurements and stated that guidelines and training had been inconsistent or lacking.

Conclusion: Inadequate procedures and training in diabetes care may compromise the rationale for capillary blood glucose measurements in nursing homes, and hence the residents' safety. These concerns should be addressed together with the possibility of involving and empowering residents by exploring their ability and wish to manage their own disease.

Keywords: Diabetes mellitus, Capillary blood glucose measurements, Nursing homes, Healthcare professionals, Chronic disease management, Clinical guidelines, Nursing practice

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Background

Nursing home residents with diabetes are medically complex, with a high level of disability, many complications and medicines [1–3]. Feeding or swallowing difficulties, acute illnesses or infections, or use of insulin and other hypoglycaemic medicines can cause detrimental fluctuations in blood glucose levels. Symptoms are sometimes confused with other age-related changes or are less marked compared to symptoms in younger adults [4, 5]. Regular capillary blood glucose measurements (CBGM) are therefore recommended for these patients [6–8].

For CBGM to be useful, it requires a clear purpose, correct sampling and good analytical performance of the device used, as well as appropriate documentation, interpretation and use of the result. However, studies have reported findings such as: that CBGM is not always performed according to individual needs [9–11]; pathogen transmission due to incorrect sampling [12–14]; insufficient blood glucose logs [15, 16]; uncertainty concerning physician involvement [15] and actual use of test results [17]; lack of procedures and inconsistent instructions [15, 18, 19]. In addition, training and guidance about symptoms requiring additional measurements are not always adequate [19, 20].

Incorrect sampling or unnecessary use of CBGM puts residents at risk, adds costs and is associated with a higher burden of depression, distress and worries [21, 22]. In Norway, CBGM is the standard method for day-to-day monitoring of diabetes in nursing homes, and three quarters of nursing home residents with diabetes regularly receive CBGM [23]. Clinical procedures recommend that an individual plan for CBGM should be decided in collaboration between the physician, nursing staff and the resident [7]. However, two recent focus group studies among nurses in Norwegian nursing homes, revealed deficiencies in work procedures for diabetes care, differences of opinions about who should decide the frequency of CBGM, and poor inter-professional collaboration [24, 25].

This study is part of LMA's PhD project on diabetes in nursing homes. In a previous study we investigated diabetes therapy and glycaemic control. One of our findings was that 60 % of the nursing home residents had at least one CBGM reading that was consistent with risk of hypoglycaemia [23]. Together with observations during data collection indicating that CBGM was an area of concern to the healthcare professionals, this led us to question whether the practices relating to CBGM were adequate to ensure the residents' safety and well-being. This study therefore seeks to gain a better understanding of CBGM practices by exploring the perspectives of physicians, registered nurses and auxiliary nurses on the use, usefulness and potential challenges of using CBGM in nursing homes, and the procedures for doing so.

Methods

Design of the study

We conducted profession-specific focus group interviews with physicians, registered nurses and auxiliary nurses employed in nursing homes. Through a series of open ended-questions, focus groups interviews use the interaction between the participants to investigate their common experiences, priorities and attitudes [26].

Participants

Three focus groups with a total of 12 participants were held in June and September 2014. Nurses were recruited in May and June 2014 through nursing home managers at two different, but geographically adjacent nursing homes. The managers received written information about the study and predetermined dates for the interviews, which they distributed to eligible employees. They then informed us how many of each professional group had agreed to participate. Physicians were recruited by visiting continuing professional education meetings for nursing home physicians in June and September 2014.

In Norway, registered nurses have a bachelor's degree in nursing, which requires a minimum of three years education and practical training at a university college. Auxiliary nurses are licensed practical nurses, who have two years of vocational education followed by a two-year apprenticeship. Auxiliary nurses work under the guidance of registered nurses. They are also known as healthcare assistants or nursing assistants. The nursing home physicians are either full-time employed or part-time contracted general practitioners working at a nursing home once or twice a week.

For all professional groups, men and women with a licence to practice and with work experience from a nursing home were invited. No limits were set as regards the length of work experience, but it was specified in the invitation that the participants should have experience of performing or managing CBGM in a nursing home setting.

Three auxiliary nurses (AN) and four registered nurses (RN), all women from two geographically adjacent nursing homes, participated in two separate focus groups. Another two auxiliary nurses were originally recruited, but failed to show up. Five physicians (P) participated in the final focus group, two men and three women. They were employed at different nursing homes, but knew each other from regular continuing professional education meetings.

Setting

The focus group interviews with the nurses were conducted in a meeting room at one of the nursing homes after the participants' working hours. The focus group interview with the physicians was conducted after a

continuing professional education meeting, in an adjacent meeting room. Each interview lasted between 60 and 75 min and was audiotaped. Researcher LMA moderated all interviews, and UØS, GBBK and RLSK took turns as co-moderators. The interview guide was semi-structured with open-ended questions about experience of the use, documentation, interpretation and consequences of CBGM in a nursing home setting, as well as potential challenges for patients or personnel (Table 1). Participants received a complimentary gift voucher worth EUR 45.

Analysis

All interviews were transcribed in modified verbatim form by LMA. The analysis followed the principles for systematic text condensation (STC) [27]. We did not use a theoretical framework for this study, as we emphasised a more descriptive approach. Even though a theoretical framework can support STC analysis, STC is also often used without additional theory. STC is founded on phenomenology and the theory that knowledge is constructed through joint understandings of the world. STC offers a pragmatic, but systematic approach that safeguards transparency, inter-subjectivity, reflexivity and the feasibility of the study [27].

Table 1 Themes and key questions serving as guidance during data collection

Reasons for CBGM	
	Nurses Tell us about what triggered measurement the last time you performed CBGM.
	Physicians Tell us about your approach for deciding if and when a resident with diabetes should receive CBGM
Quality, documentation and communication of CBGM readings	
	Nurses/Physicians Please describe what happens with the CBGM readings at your place of work
Acute events	
	Nurses Tell us about an episode where you experienced either a high or a low blood glucose reading in a resident with diabetes.
	Physicians Tell us about an episode where you experienced or were called upon for either a high or a low blood glucose reading in a resident with diabetes.
Education and training	
	Nurses Tell us about the training you have received on diabetes care and CBGM.
	Physicians Please describe what type of training or education initiatives that exist/are given at your place of work on diabetes care and CBGM.

In this table "Nurses" refer to both registered nurses and auxiliary nurses; the key questions were identical for these two professional groups
CBGM = capillary blood glucose measurements

STC is a four-step process, defined by Malterud as 1) from chaos to themes – obtaining an overview of initial themes; 2) from themes to codes – identifying and sorting units of meaning; 3) from code to meaning – condensation of the meaning units into an abstracted text; and 4) from condensation to descriptions and concepts – synthesising the contents of the condensates. In detail, all authors first read all the transcripts in order to identify initial themes, which were used as starting categories for coding. The four themes agreed on were: needs and benefits of CBGM; glycaemic control – target values, purpose and challenges; professional knowledge, clinical skills and understanding of roles; and documentation and interaction. Secondly, LMA analysed the material iteratively based on these initial themes, searching for units of meaning. Related units were grouped under the same code heading, which was developed from the initial theme and adjusted during analysis. A fifth code group emerged during analysis: the patient perspective. In the third step, all the authors came together to sort the content of the five code groups into subgroups. LMA then condensed and abstracted the content of each subgroup into an artificial quote. In the final step, the artificial quotes within each code group were transformed by LMA into an analytical text accompanied by authentic illustrative quotes. Comparing these analytical texts to the original material, all authors searched for additional perspectives and, lastly, defined the following categories for presenting the results: 1) Premises for CBGM, 2) Professional competence and understanding of roles, 3) Record keeping. The analysis process was facilitated by the text analysis software NVivo version 10 (QSR International Pty Ltd).

Literature search

A systematic literature search was conducted to obtain an overview of existing literature on capillary blood glucose measurements in nursing homes. The databases PubMed (EMBASE), CINAHL and MEDLINE (Ovid) were searched for relevant publications. The following search terms were used in different combinations: diabetes mellitus; nursing homes; homes for the aged; long-term care; health knowledge, attitudes, practice; attitude of health personnel; employee attitudes; professional practice; quality of health care; blood glucose; blood glucose measurement; blood glucose monitoring.

Ethical considerations

The Norwegian Social Science Data Services (NSD) is the advisory body on privacy and research ethics for research involving healthcare professionals. NSD was consulted, but, since no personal data were registered or stored as part of the data collection, the study was not subject to notification. However, the study complied with ethical principles for research in order to protect

the privacy of the participants. Specifically, the names of the participants or their workplace were not linked to the interview data, and audio recordings of the interviews were deleted once the transcripts were completed. No individual participant or nursing home could be identified in the transcripts or the finalised study results. Furthermore, all participants were given an information leaflet prior to the focus group interviews. It described the study aims, what participation entailed and the storage of data, and stated that participants could withdraw their consent at any time up until after participation without providing any reason. The leaflet also stressed the importance of professional confidentiality, reminding the participants not to identify names of patients, their families or colleagues during the interviews. This information was repeated before the interviews. Volunteering for and participation in the focus group interviews was understood as entailing consent.

Results

Premises for CBGM

Frequency and benefit of measurements

All groups expressed the view that measurements should be kept to a minimum in order to ease the strain of blood sampling (finger pricking) on the residents. The participants explained that most residents had established a relaxed and consistent CBGM regime, based on drug treatment and previous recordings of glucose levels. Physicians and registered nurses stressed the HbA1c value as central when deciding on the frequency, a decision that was made jointly according to the nurses.

> *'It varies a lot depending on [the resident's] condition and treatment target. I try not to bother the residents too much, you know. Not to bother them more than necessary to achieve whatever treatment target I've set.' P3.*

The registered nurses emphasised that a change in the resident's situation, such as an infection, decreased food intake or exhibiting unusual symptoms, usually led them to perform more frequent measurements for a period. Both groups of nurses regarded CBGM as an easy and accessible way of confirming or disproving that a change in the residents' cognitive or physical behaviour was due to fluctuations in their blood glucose. They trusted the readings from the CBGM devices, as the nursing homes were enrolled in an external quality assurance programme.

> *'Well, in any case, if a resident with diabetes falls ill in any way whatsoever, our first thought is, okay, we should at least check the blood sugar level, to rule it out, you know. Even if we suspect that it may be due to something completely different, we always check it, because it is such an easy and quick thing to do.' RN2.*

All participants, but especially the physicians, regarded the measurements as essential for following up and adjusting diabetes treatment, but they admitted that they were most useful for residents with unstable blood glucose levels, or for residents in need of rapid-acting insulin.

Avoiding discomfort

The physicians stressed that maintaining quality of life for the residents and avoiding hypoglycaemia were the main aims when deciding the level of glycaemic control. All groups perceived the risk of long-term complications as low due to short remaining life expectancy for most residents. Hence the blood glucose levels were permitted to lie around 10 mmol/l. In their experience, this did not result in discomfort for the residents, and the registered nurses stated that a higher rather than lower blood glucose level made them feel safer as well.

> *'I'm used to them being a bit liberal, that around 10 [mmol/l] is appropriate for older persons, since they do not have that risk of long-term complications, if they're ninety years old, you know? (…) It is safer and the residents feel fine, so if they're in good shape and all that… But, otherwise, somewhere between 5 and 10 [mmol/l].' RN2.*

The nurses explained that most residents achieved better glycaemic control after admission to the nursing home, probably due to regular meals and physical activity. They sometimes worried about the residents' nocturnal blood glucose, due to the long time that elapsed between the evening meal (~7 p.m.) and breakfast (~9 a.m.). In contrast, all groups said that treats from visiting relatives often explained deviant CBGM results. However, they were ambivalent about food restrictions or preventing residents from eating what they wanted. Especially the physicians were sceptical about diets, as different-looking food made some residents feel insecure.

> *'We do not know what they eat at any given time. The wife shows up with grapes and chocolate and sugary yoghurts, and you know. That's a bit of a challenge, to be honest.' AN1.*
>
> *'In residents with dementia, I often observe that when they're given different-looking food at mealtimes, they feel insecure and start wondering what's wrong with them.' P3.*

The resident perspective

Residents rarely measured blood glucose themselves. According to the physicians, many residents would have been able to do so, but the task was assigned to the nurses. The auxiliary nurses said that they involved the residents in the measurements to some extent, either by assisting those able to do it themselves, or by talking the residents through the process.

'Yes, [we'll say] "this might be a bit sharp", "ok, now you will feel a little prick", like that, but then we're allowed to do the measurement, as some of the residents don't perform the measurement themselves. Some are allowed to measure themselves, those who are able to of course, yes. They perform the measurement themselves, and they adjust [the insulin] themselves, but you're with them, observing and double-checking.' AN3.

The nurses were concerned that the CBGM sometimes bothered the residents. They nonetheless stated that the residents, even those with dementia, seldom or never expressed concern or objected to measurement. The physicians shared the same experience, reflecting that most residents were used to the routine after living with diabetes for years.

Professional competence and understanding of roles

Training and responsibility

The auxiliary nurses were given CBGM training by the registered nurses, but did not experience this as entirely appropriate. In their experience, the registered nurses had no consistent method of performing CBGM and very seldom received further training after graduating from nursing college. The registered nurses said that training in performing correct CBGM had been given by an external quality improvement programme managed by Norwegian Quality Improvement of Primary Health Care Laboratories (Noklus) [28], but they confirmed that few courses were provided after graduation. They stated that they were expected to acquire and maintain the necessary knowledge about caring for residents with diabetes. The physicians confirmed this. They expected the registered nurses to be able to differentiate between high, normal and low levels of blood glucose, to be knowledgeable about different insulins and antidiabetic medicines and to provide appropriate management of hypoglycaemia. The nurses followed up this responsibility by engaging in self-study and discussing experiences and questions with colleagues.

'You look it up if you encounter a challenge while at work. You will go home, look into it, then discuss it with the physician, and then you gain knowledge in that way. Discussing with colleagues, your experiences. That is something you learn from all the time.' RN3.

The nurses expressed a wish for mandatory, interprofessional courses to ensure that everyone has the same information and follows the same guidelines. The physicians supported this, and felt that they had a great responsibility to monitor and tailor the training, as it was often them who discovered that it was inadequate. However, they also emphasised the nurses' responsibility for giving feedback on lacking procedures or insufficient courses, and that responsibility ultimately rested with the employer.

'In my experience, it is often very useful to attend [the nurses'] training. (…) There are often totally different approaches for the nurses compared to the physicians, you know. And they often benefit from seeing it from both angles. And my opinion is that it is a joint responsibility, that you as a physician have a great responsibility to oversee the training given at the nursing home, because you work so closely with the staff and the others involved in the training programme.' P3.

Awareness and assessment of symptoms

The nurses knew which symptoms would call for an additional measurement or would require notification of the physician, also among residents not diagnosed with diabetes. The registered nurses said that they found it easier to spot hypoglycaemia than hyperglycaemia, while the auxiliary nurses admitted that they sometimes found it difficult to distinguish between the symptoms of these conditions. Physicians thought that registered nurses interpreted diabetes symptoms appropriately, but found that they deviated from their set orders for CBGM and insulin injections due to concerns about potential hypoglycaemia. The registered nurses admitted a tendency to perform CBGM more often than the physician had recommended, and that borderline low or high values made them feel uncertain. However, the physicians emphasised that diabetes is a complicated disease and that residents' symptoms of hypoglycaemia could cover a surprisingly wide spectrum. They further underlined that proper management depended a lot on precise orders and the opportunity to get regular practice or training in these matters.

'Maybe if a resident's blood glucose is low in the morning, but not very low, more borderline low, somewhat under what's normal for that resident, you start to think "should I inject insulin, should I not inject insulin?", because that's not specified anywhere,

you know? (…) And most times they need [insulin] anyway. When they have eaten, [the blood glucose level] will become too high if they don't get [insulin]. But then, OK, you will still stand there assessing these things, so…' RN2.

'It's not a diagnosis that's based on a blood test, it's a diagnosis based on a clinical assessment. And it's a surprisingly wide spectrum for, you know, what is the lower [limit], or when do they experience hypoglycaemia? Some will not experience it before their value is around 2 [mmol/l], while others may experience it around 4 [mmol/l], you know?' P2.

Record keeping

Single or double documentation? A two-sided argument

The responsible nurse logged all information about the CBGM, e.g. the time, value, site of pricking, units of insulin given, or food intake, in the resident's records. Some would record the information on paper in the resident's medical records, then later, preferably the same day, transfer it to the electronic patient records system, where the physician could examine it at any time. The physicians regarded this as unnecessary double documentation. However, to the nurses, the paper sheets, which were easily accessible in the medicine room or trolley on the ward, made it easier to keep an eye out for deviations, both in the residents' blood glucose levels and each other's documentation routines.

'Strictly speaking, it is double documentation, but we do also have a paper form where we register [the values]; it's kept in the resident's kardex. But we also register it in the electronic patient records system that we use. (…) It makes it easier on the physician's round to be able to access the results from there, but we do register it both places, and that's also because we need it to be available on the ward, easily accessible, you know? To look back at how [the blood glucose levels] have been earlier.' RN3.

Official guidelines or common procedures?

None of the participating nurses was aware of any written template or procedure for how to carry out a CBGM. While the auxiliary nurses expressed concern that this led to staff performing CBGM in many different ways, the registered nurses seemed less concerned about this because they felt that they had a good understanding of the practical aspects of CBGM. The nurses were not familiar with any written procedures for how to manage acute glycaemic events. This surprised the physicians, who stated that local authority guidelines for managing hypo- and hyperglycaemia existed and should be well-known.

'I believe that they have been given some written guidelines, or teaching or, but yes. That they have them available and can look it up somewhere, but I'd better look into it again.' P2.

Despite differences in familiarity with guidelines, common procedures did exist. The registered nurses used the individually set blood glucose limits for residents who needed rapid-acting insulin as guidance, where these existed. However, they stated that orders given by a physician familiar with the resident made them feel much safer than instructions given by an ambulatory physician. In a serious acute event, the physician was always called upon, while smaller deviations in blood glucose and how they had been handled were communicated between shifts and during the physician's round. The physicians were dependent on this, since no warning would pop up in the electronic system if a resident's values were deviant. A possible cause was always sought when unexpected symptoms or CBGM results occurred, and the action taken was based on the information available.

'Yes, if we've taken a blood glucose [measurement] in the morning, you know, then we almost always inform the afternoon shift nurse about the result. Especially if it's an unusual one, if it's a low or a high. So that's part of the verbal report, in addition to it being registered in the medical records.' RN3.

Discussion

Principal findings

The results from this study indicate that the healthcare professionals tried to provide patient-centred care by minimising strict glycaemic control and excessive CBGM. However, the rationale for CBGM in these nursing homes may be somewhat expanded due to inadequacies in formal policies and training in diabetes care. Hence, the basis for how the healthcare professionals make decisions about care could be skewed towards blood glucose testing rather than clinical assessment. In addition, few opportunities existed for resident empowerment, since residents seldom took part in decisions concerning the management of their own care.

CBGM – a safety measure or a source of additional worry?

The participants in our study revealed that training in diabetes management was sparse and inconsistent, and the nurses also felt that clear instructions and written procedures were lacking. This sometimes contributed to

a feeling of uncertainty and created fear of inducing hypoglycaemia in residents. Hence, CBGM was used to reassure both staff and residents. The participants had also created systems for preventing and managing acute events, including good communication and thorough documentation procedures.

In a focus group study from the UK addressing healthcare professionals' concerns about diabetes care in care homes and domiciliary care, the participants stated that, even though regular CBGM and detailed communication between shifts are helpful, knowing your patients well is the key to preventing hypoglycaemia [29]. And, as the physicians in our study pointed out, even though the range of values where residents experience hypoglycaemia can be extremely wide, the registered nurses managed acute situations well. This could be due to good knowledge of signs and symptoms and the fact that they were constantly attentive to their patients. However, the nurses would still confirm their suspicions using CBGM.

Similar findings have been reported by Graue et al., who found that nurses working in nursing homes lacked confidence when interpreting and managing changes in residents with diabetes. Here, the authors point to little time to keep up-to-date about diabetes, few resources that could be consulted, and limited support within and between professions as sources of uncertainty [24]. In our study, the nurses did not seem to lack support from their peers or the physician, but there was a lack of systematic training and common procedures. Performing CBGM not ordered by the physician and keeping glucose logs on paper sheets in the residents' medical records were therefore used to support their clinical assessments. However, borderline glucose values contributed to further uncertainty about how to handle the situation. Even though the physicians stressed that clinical competence is more important than CBGM, they admitted that inadequate instructions and training probably contributed to this practice.

Several studies have observed inappropriate care to be a consequence of deficiencies in guidelines [15, 19, 30] or formal training in diabetes care for healthcare professionals working in long-term care [25, 29]. Accordingly, a need for training in diabetes care has also been pointed out [10, 24, 25, 29, 31], highlighting areas such as which signs and symptoms to look for, recognising when to perform a CBGM and managing hypoglycaemia. Others have emphasised how continued education in diabetes care could enhance the nursing staff's knowledge, confidence and professional competence, and lead to improved patient outcomes [11, 31–33]. These findings seem to be transferable to our study population.

The resident – the centre of attention but not part of the team?

Even though the residents' quality of life was the participants' main concern, they seldom or never talked about including the resident in decisions about their diabetes care or CBGM. The registered nurses stated that decisions about CBGM were made jointly between them and the physicians, but they never mentioned the resident as part of the team. This was also reflected in the fact that very few residents performed CBGM themselves.

Two recent studies found that, even though healthcare professionals wanted to provide patient-centred care, several barriers existed that made them take a more traditional approach and carry out activities on behalf of the patient [33, 34]. In Huber et al., the nurses described how complications and comorbidities limited older patients' ability to manage their diabetes care [33]. Asimakopoulou et al. reported that healthcare professionals had the impression that the concept of empowerment was unfamiliar to older patients, and that they regarded making decisions about treatment as the healthcare professionals' job [34]. This could perhaps explain the situation our participants find themselves in: wanting to empower the residents, but finding that they are neither willing nor able to take this responsibility.

Asimakopoulou et al.'s study also revealed that most healthcare professionals interpreted the term empowerment to mean giving the patients informed choice about their treatment and that meeting biochemical targets was an indicator of successful empowerment [34]. This stands in contrast to the findings of Huang et al., who reported that community-dwelling older adults with diabetes described their goals in global, functional terms, instead of focusing on biomedical goals [35]. This pragmatic view seems to be mirrored by statements made by the healthcare professionals in our study, as they strive to ensure minimal discomfort for the residents, for instance by accepting a slightly raised blood glucose level and attempting to avoid excessive measurements. This sober-minded approach to care could also be part of the reason why the residents seldom or never protested about nursing staff performing CBGM or managing their treatment. However, in a previous study, we found that 60 % of nursing home residents with diabetes had experienced one or several worryingly low CBGM readings, and 46 % had an HbA1c under 7.0 % (53 mmol/mol) [23]. This discrepancy could reflect the possibility that the healthcare professionals in our focus groups are particularly up-to-date about current recommendations for diabetes management. It is also likely, however, that what one strives for in theory may not be so easy to achieve in practice. This could also be true as regards including the resident as part of the team. While the healthcare professionals we interviewed individualised

management as best as they could, they did it based on their own preconceptions of what was considered appropriate and seldom seemed to involve the resident. Huang et al. argue that providers' awareness of how older people define their goals for managing their diabetes should be improved in order to enable better and more individualised plans to be developed [35]. "Patient-centeredness", placing the patient or the resident at the centre of the consultation, is the very foundation for achieving empowerment, Asimakopoulou et al. states [36]. Identification of the resident's wishes and capacities for self-care, as well as any concerns and issues related to their diabetes care, should be done on admission to the nursing home and the care plan should be revised on a regular basis [37]. Often residents are hesitant or anxious to express their wishes or needs to nursing staff, as they fear it will be perceived as conflict behaviour and ultimately will have a negative effect on the care they receive. Hence, it is important to ensure the residents that their opinion matters and that conveying your wishes to the nursing home staff will improve rather than reduce quality of care [37]. To offer the resident to take an active role in their own care, through discussing their views on measurement frequency and CBGM results, as well as providing training or guidance in performing CBGM, may be ways to empowerment. Education and empowerment of nursing staff is also vital to further facilitate resident autonomy [37, 38]. Building professional competence and a healthy and positive work culture among nursing staff will help the staff to be more aware of the residents' needs and enhance nursing care [37, 38]. This requires access to guidelines, opportunity to attend courses and seminars, as well as an open and positive work environment where discussion of care situations is encouraged.

Strengths and limitations of the study

Keeping the focus groups profession-specific was both a strength and a necessity. The professional hierarchy could have proved limiting for group dynamics in a mixed group, and the different professionals might have felt that they were not given an opportunity to stress what was important to them. Profession-specific groups and the use of open-ended questions help the participants to share what they see as important, in their own language, concepts and framework for understanding the topic [26]. Even though the researchers belong to different professional groups than those interviewed, the systematic analysis method stays true to the participants' perspectives and phrasing by creating a condensate in the form of an artificial quote. It also validates the findings and interpretations against the original transcripts, and thus helps to preserve the individual context [27].

The greatest limitation of the study is the difficulty we experienced in recruiting nurses. This resulted in a limited sample size in these two focus groups. The goal was to recruit five to eight participants in each group, as recommended by Malterud [39], but this was only achieved for the physician group. We could have attempted to organise additional focus groups to obtain more material, but we found the interaction between participants to be adequate to elucidate our objectives. Our ambition was not to provide an extensive description of every aspect of CBGM practices in nursing homes, but to explore the breadth of experiences and opinions of the different healthcare professionals involved in this aspect of diabetes care. It is likely, however, that we have included healthcare professionals who are most receptive to the topic. According to Malterud, this may not be a disadvantage, since, with respect to external validity, the number of relevant episodes presented in the focus groups is more important than the number of groups or participants [39].

Conclusion

We found that the aim of protecting the residents' safety and well-being may be compromised by systematic inadequacies in procedures and training. The participants in our study focused more on the residents' quality of life than on glycaemic goals and individualised management as best they could. In nursing homes, it may not always be possible or reasonable to let the residents manage their own treatment, but it is still important to evaluate whether they are able to, and wish to, manage their own disease.

As a follow-up of this study, it would be interesting to use quantitative methods to explore what guidelines, procedures and training opportunities exist for diabetes care in Norwegian nursing homes, and how they are being used. Future studies should also investigate the residents' perspective on self-care in diabetes management, and efforts should be made to include the residents' wishes and needs in their care plans.

Competing interests

The authors declare that they have no competing interests.

Authors' contributions

RLSK, MPharm, PhD; and UØS, MSc, PhD are supervisors for MPharm LMA's PhD project, while AGG, MPharm, PhD, has co-supervised this particular paper. LMA, RLSK and AGG have previous experience of qualitative research in nursing home settings, and RLSK and UØS have experience of procedures for, training in and quality assurance of CBGM in primary care. LMA has contributed to the study conception and design, has had chief responsibility for data collection and analysis, has written the first draft of the paper and contributed to subsequent critical revisions of it. AGG has contributed to the study conception and design, data analysis, drafting and critically revising the manuscript. UØS and RLSK have both contributed to the study conception and design, data collection and analysis, drafting and critically revising the manuscript. All authors have read and approved the final manuscript.

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Appendices

Appendix 1. Studies of DM prevalence and management in care homes, data collected 1999-2014, Europe.

Appendix 2. Studies of DM prevalence and management in care homes, data collected 2002-2013, North America, Australia and New Zealand.

Appendix 3. Sheet for registering residents with DM diagnosis, Study I.

Appendix 4. Consent form, Study I (in Norwegian).

Appendix 5. Sheet for registering DM medicines, CBGM and HbA1c measurements for consenting residents, Study I.

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II.

Appendix 7. Codebook deprescribing criteria + attachments, Study II.

Appendix 8. Interview guide, Study III (in Norwegian).

Appendix 9. Information leaflet for focus group participants, Study III (in Norwegian).

Appendix 10. The candidate's preconceptions, Study III (in Norwegian).

Appendix 1. Studies of DM prevalence and management in care homes, data collected 1999-2014, Europe

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Sinclair et al, 2001 (60)	UK (Birmingham)	Not stated*	Cross-sectional, 30 CHs. Medical records review for 636 residents Screen undiagnosed DM: OGTT for 274 residents, FPG (≥7.0 mmol/l) or 2h PPG (≥12.2 mmol/l)	12.0 % (n=76) Calculated prevalence OGTT: New: 14.8 % Total: 26.7 %	OGTT subjects: Median age 83 y (range 45-101), 179 female residents (65 %)
Pham et al, 2003 (61)	France (Bordeaux)	November 1, 1999 – April 30, 2001	Prospective survey (18 months), 2 NHs + 2 RHs. Medical records review for 494 residents DM management (medicines, monitoring of blood glucose, hypoglycaemia, complications, effects on functional dependency and mortality) Comparison with non-DM residents	14.8 % (n=73) NH: 14.4 % RH: 15.9 %	Mean age 76.0±7.9 y. DM treatment T0 and T18months, respectively: None (25 % vs 30 %), OAD (40 % vs 33 %), insulin (26 % vs 37 %) HbA1c never performed: 26 % Treatment-related frequency of HbA1c and CBGM. Hypoglycaemia 33 % Complications: Macrovascular 74 %, microvascular 11-30 %, dementia 34 %, depression 40 %, pain 60 % High level of functional dependency and mortality, but not different from non-DM
Löfgren et al, 2004 (62)	Sweden (Linköping)	Not stated*	Cross-sectional, 7 NHs. Medical records review for 351 residents BGM in 45 pharmacologically treated residents for 3 consecutive days: fasting, 2 h after breakfast, evening, at night	17.0 % (n=59)	Of total population: 34 % insulin only, 32 % OAD monotherapy, 10 % combination. Pharmacologically-treated residents: Mean age 84 y (range 61-96) Mean HbA1c 41 mmol/mol (5.9 %), range 16-70 mmol/mol (3.6-8.6 %), 82 % HbA1c <53 mmol/mol (7 %), 18 % hypoglycaemia

Appendix 1 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Aspray et al, 2006 (63)	UK (Newcastle upon Tyne)	Not stated*	Cross-sectional, 68 CHs (RHs, EMI-RHs, NHs and EMI-NHs). Medical records for 1630 residents Screen undiagnosed DM: OGTT for 1275 residents (169 excluded), FPG (≥6.1 mmol/l) or 2h PPG (≥11.1 mmol/l)	11.4 % (n=186) Calculated prevalence OGTT: New: 8.2 % (n=105/1275) Total: 19.9 % (n=291/1461)	OGTT: Higher DM prevalence for EMI-residents (patients with dementia). Mean age (range) 82.2-85.3 y Residents with DM 3.7 kg (95 % CI: 0.4-7.0, *p*=0.03) heavier than non-DM residents, but still lean (mean range 60.3-64.5 kg)
Shah et al, 2006 (64)	UK (East Elmbridge and Mid Surrey)	2005	Cross-sectional, 61 CHs (16 NHs, 19 RHs, 5 dual CHs, 19 CHs for people with learning difficulties) Postal survey to care home managers requesting known DM from a total of 1486 residents DM management (medicines, monitoring of complications)	9.6 % (n=142) NH: 11.2 % RH: 9.2 % Dual CH: 8.7 Learning difficulties CH: 5.9 %	Of 138 residents: 33 % diet alone, 46 % diet+OAD, 21 % insulin Assessment tool to plan, deliver and monitor system of diabetes care used by 21 % of CHs Annual GP review 94 %, annual foot assessment 77 %, annual optometrist assessment 85 %, annual retinal screening 46 %
Coll-Planas et al, 2007 (65)	Germany (Dresden)	January – July 2003	Cross-sectional, retrospective, 7 NHs. Postal survey to nursing home managers requesting known DM from a total of 810 residents Interviews and geriatric assessment of a random sample of 46 residents with T2DM	36.1 % (n=292)	Mean age 84.0±7.3 y, 91 % female, 52 % insulin Median: Diagnoses 7.0±2.5, medicines 6.5±2.5, HbA1c 6.95±1.22 % (52 mmol/mol) Last 12 months: Severe hypoglycaemia 10 %, hospitalisation 47 %, hospitalisation due to DM 7 % Personnel: Worries of inadequate documentation (especially HbA1c values). Residents: Concerns about food and frequency of CBGM

Appendix 1 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Sjöblom et al, 2008 (66)	Sweden (Östergötland and Jönköping)	2006	Cross-sectional, interventional, 17 NHs. Medical records review for 658 residents Medication withdrawal/reduction for 32 residents with T2DM, HbA1c ≤6 % (42 mmol/mol), treated with OADs, insulin or both. PG measured 3 days before withdrawal, at day 2, 4 and 28 after withdrawal, HbA1c measured at 3 and 6 months	15.0 % (n=98) (T1DM+T2DM)	Mean age 84.1±8.8 y (range 58-100), 58 % female. Pharmacologically-treated residents: 44 % insulin only, 28 % OADs, 16 % combination Mean HbA1c 48 mmol/mol (6.5±1.6 %), range 25-102 mmol/mol (4.4-11-5 %), 48 % HbA1c ≤42 mmol/mol (6 %) Intervention: 69 % ≥1 episode of hypoglycaemia (range 2.4-4.4 mmol/l). Successful withdrawal in 75 % HbA1c change: Insulin reduction group 33 mmol/mol (5.2 %) to 46 mmol/mol (6.4 %), complete withdrawal 33 mmol/mol (5.2 %) to 38 mmol/mol (5.6 %)
Bouillet et al 2010 (67)	France (Côte d'Or)	May 2008 – January 2009	Cross-sectional, retrospective, 7 NHs. Medical records review for 647 residents DM management (medicines, monitoring of blood glucose, HbA1c, complications, functional dependency) Adherence to guidelines for diabetes in the elderly	15.5±4.9 % (n=100) Range 11.5-23.8 %	Mean age 81.9±11.9 y (range 65-104), 67 % female Pharmacologically treated residents 84 %: OADs only (n=42), insulin only (n=25), combination (n=17). SU>metformin HbA1c measured in 88 %. Mean HbA1c 55 mmol/mol (7.2±2.6 %), 36 % HbA1c <48 mmol/mol (6.5 %), 61 % HbA1c ≤58 mmol/mol (7.5 %) Treatment-related frequency of CBGM Complications: Hypertension 75 %, IHD 14 %, HF 41 %, stroke 21 %, retinopathy 6 %, micoalbuminuria 6 %. Except for creatinine, monitoring for complications was poor

Appendix 1 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Kirkland et al, 2010 (68)	UK (South Staffordshire)	Not stated*	Prospective audit to address hypoglycaemia, 28 CHs. Medical records review for 476 residents CBGM four times daily for five days Chronic hypoglycaemia: BG <4.0 mmol/l for ≥3 consecutive days	22 % (n=105) (T1DM+T2DM)	Pharmacologically-treated residents 60 %: insulin (n=22), SU (n=28), metformin monotherapy (n=13) Of insulin/SU-treated residents (n=50), 27 ≥1 episode of hypoglycaemia (range 1-8) Chronic hypoglycaemia: 7.6 % (n=8) 33 % HbA1c <48 mmol/mol (6.5 %)
Gadsby et al, 2011 (69)	UK (Coventry)	February-April 2010	Cross-sectional, 11 NHs. Medical records review for 472 residents Review of comorbidities and disabilities.	16 % (n=75)	Mean age 80.6 y (range 55-102) Mean comorbidities excl. DM: 4 (range 1-8), dementia (56 %), stroke (47 %) and hypertension (27 %) most prevalent High level of disability (incontinence, help feeding, swallowing difficulty, low mobility, speech problems)
Grzywa et al, 2011 (70)	Poland (Rzeszow)	Not stated*	Cross-sectional, 4 CHs. Medical records review for 478 residents Screen undiagnosed DM: OGTT for 191 residents (221 excluded), FPG (≥7.0 mmol/l) or 2h PPG (≥11.1 mmol/l) at day 7 and 28	13.8 % (n=66) Calculated prevalence OGTT: New: 5.2 % (n=10)	Impaired fasting glucose: 13.6 % (n=26) Impaired glucose tolerance: 13.1 % (n=25)
Basso et al, 2012 (71)	Italy (Vicenza)	November 2009 – January 2010	Cross sectional, 3 NHs. Medical records review of 570 residents (pharmacologically-treated DM)	16.5 % (n=94)	88 pharmacologically-treated residents: Mean/median age 83.5 y/85 y, 73 % female, 41 % insulin, 59 % OADs. Mean HbA1c 48 mmol/mol (6.5 %), HbA1c <42 mmol/mol (6 %), 48 mmol/mol (6.5 %), 53 mmol/mol (7 %) and 58 mmol/mol (7.5 %) were 30 %, 51 %, 74 %, 86 %

Appendix 1 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
De Souto Barreto et al, 2014 (72)	France (Midi-Pyrénées)	May – July 2011	Cross-sectional, 175 NHs. Medical records review for 6275 residents DM management (medicines, comorbidities, emergency department (ED) visits, falls, history of fractures and functional disability (ADL score)). Compare across different treatment groups and to non-DM residents	17.1 % (n=1076)	Median age 86 y (IQR 81-90) Non-drug treatment (n=222), hypoglycaemic (insulin+SU+repaglinide) group (n=722), non-hypoglycaemic (other ADs) group (n=132). Hypoglycaemic group more frequent ED visits vs non-hypoglycaemic (p=0.014) and non-DM group (p=0.007), and higher ADL scores than non-hypoglycaemic group (p=0.024)
Szcerbinska et al, 2015 (73)	Czech republic England Finland France Germany Israel Italy Netherlands	2009-2011	Descriptive analysis of prospective cohort, 59 NHs. Medical records review for 4037 residents Clinical characteristics (comorbidities, polypharmacy, physical/cognitive status, pain) Comparison with non-DM residents	21.8 % (n=879)	Mean age 82.3±7.7 y (younger than non-DM, p<.001), 74 % female DM vs non-DM: Worse self-perceived health, more comorbidities (IHD, HF, hypertension, stroke, UI), more medicines High levels of functional and cognitive disability, not different between groups DM higher risk of pressure ulcers
Neumark et al, 2015 (74)	Sweden (Kalmar)	June 2011 – May 2013	Cross-sectional, 23 NHs. Medical records review for 224 residents Clinical characteristics and DM management across three different levels of care (at home-independent, at home-home care, nursing home) Adherence to national guidelines for diabetes	17.4 % (n=39)	Mean age 87±5.85 y, 75 % female. Hypertension, IHD, stroke and dementia prevalent comorbidities Pharmacologically treated residents 77 %: insulin alone 54 %, OADs alone 21 %, combination 2 %. Metformin>SU HbA1c <12 months 72 %. Mean HbA1c 56.9±19.7 mmol/mol, 48 % HbA1c ≤52mmol/mol (6.9 %). Lower frequency of monitoring and screening tests for NH residents compared to the other groups

Appendix 1 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Haugstvedt et al, 2016 (77)	Norway (Hordaland and Nordland) Iceland	2011-2014	Cross-sectional, 12 NHs (8 in Norway, 4 in Iceland). Medical records review for 1121 residents Documentation of DM diagnosis, treatment goal (HbA1c), CBGM routine, DM medicines	Total: 14.5 % (n=162) Norway: Hordaland 14.9 % Nordland 16.5 % Iceland: 13.7 %	Most residents (53 %) were ≥85 y, 67 % female. DM diagnosis documented for all Icelandic residents, versus 81 % in Hordaland and 55 % in Nordland Mean HbA1c 58.5 mmol/mol (7.5 %), HbA1c <6 months 37 %, treatment goal 3 %, individualised CBGM routine 48 % DM drugs 78 %, insulin 32 %, only OADs 45 %. Insulin more common in Norway than in Iceland
Walfridsson et al, 2016 (75)	Sweden (Uppsala)	2012	Cross-sectional, 30 NHs. Medical records review for 1350 residents DM management (medicines, HbA1c, hypoglycaemia, complications). Stratified according to HbA1c-level	16.1 % (n=218) (T1DM+T2DM) T1DM: n=7	Mean age 84.6±8 y, 63 % female. Pharmacologically-treated residents 60 %: insulin alone 21 %, OADs alone 28 %, combination 12 %. HbA1c data for 92 %. Mean HbA1c 56.0±1.2 mmol/mol (7.3 %) Hypoglycaemia: 24 %, more frequent with HbA1c ≥52 mmol/mol (6.9 %) Complications: Microvascular 21 %, macrovascular 34 %, both 23 %
Hurley et al, 2017 (76)	Ireland (Galway)	February 2013	Cross-sectional, 33 NHs. Postal survey to nursing home managers requesting known DM from a total of 1260 residents Focus group or telephone interviews to assess current level of diabetes care	14 % (n=171) Range 4-25 %	DM residents: Insulin 33 %, DM care plan 97 %, but level of detail and reviews vary 19 % NHs report frequent hypoglycaemia NHs: 36 % of staff additional DM training, identified as main area for improvement Varying access to guidelines and blood test results. Nurses' needs reassurance for titrating insulin

Appendix 1 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Retornaz et al, 2017 (78)	France (Marseilles)	January – April 2014	Observational, unknown number of NHs. Medical records review of 1694 residents Patient characteristics, geriatric assessment, DM management (medicines, average BG values, HbA1c, quality of glycaemic control), hypoglycaemia	14.5 % (n=247)	Of 236 residents: Mean age 82.7±9.5 y, 66.5 % female, 55.5 % heavy dependence, 28.8 % severe cognitive impairment Polypharmacy (>4 drugs) 85.4 %. Insulin 47.5 %, OAD 41.9 %, no treatment 10.6 %. Glycaemic control: Tight 59.3 %, fair/acceptable 19.1 %, moderate chronic hyperglycaemia 11.9 %, severe chronic hyperglycaemia 9.7 %. Hypoglycaemia 17.8 %, across all HbA1c levels, but more frequent in insulin users, and higher RR for residents with chronic moderate hyperglycaemia
Sigurdardottir et al, 2018 (79)	Iceland	2003-2014	Retrospective, descriptive study of all admitted residents to NHs in Iceland 2003-2014, using MDS data. Review of 5242 resident records MDS scales, comorbidities Comparison with non-DM residents	Full period: 13.9 % (n=730) 2003: 9.4 % 2014: 15.0 % 2013 (peak): 19.1 %	Mean age 81.0±8.2 y (younger than non-DM, p<.001), 50.8 % female DM vs non-DM: More medicines, higher BMI, more unstable health status, more cardiovascular disease, less cognitive impairment

*Studies not stating study period, we assume that data collection occurred within 24 months of publishing the results
Abbreviations: 2-h PPG=2-hours postprandial plasma glucose, AD=antidiabetic drug, ADL=activities of daily living, BG=blood glucose, BGM=blood glucose measurement, BMI=body mass index, CBGM=capillary blood glucose measurement, CH=care home, DM=diabetes mellitus, EMI=elderly mentally infirm, FPG=fasting plasma glucose, GP=general practitioner, HF=heart failure, IHD=ischaemic heart disease, MDS=Minimum Data Set, NH=nursing home, OAD=oral antidiabetic drug, OGTT=oral glucose tolerance test, PG=plasma glucose, RH=residential home, RR=relative risk, SU=sulfonylurea, T1DM=type 1 diabetes mellitus, T2DM=type 2 diabetes mellitus, UI=urinary incontinence, y=years
Reference numbers in this table refer to those in the reference list in the main text of the thesis

Appendix 2. Studies of DM prevalence and management in care homes, data collected 2002-2013, North America, Australia and New Zealand

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Travis et al, 2004 (93)	USA (national)	2002	Retrospective, descriptive study of all admitted residents to NHs in USA 2002, using MDS data Review of 548,572 resident records MDS scales, comorbidities Comparison with non-DM residents	26.4 % (n=144,969)	Mean age 72.8±13.6 y, 59.8 % female Comorbidities: Hypertension 69 %, depression 30 %, HF 26 % Mean of 10.9 medicines DM vs non-DM: Younger, more comorbidity, more pain, higher levels of disability and dependence, less cognitive impairment
Maurer et al, 2005 (94)	USA (New York)	Not stated*	Prospective cohort study, 1 NH Medical records review and registering time to fall for 139 residents Comparison with non-DM residents	13 % (n=18)	Mean age 84±6 y, 83 % female. DM vs non-DM: Younger, more medicines, more obesity, higher incidence of falls (78 % vs 30 %). DM independent risk factor for falling
Gill et al, 2006 (127)	New Zealand (Christchurch)	January – November 2002	Cross-sectional, 54 CHs. Medical records review for 1,587 residents DM management (medicines, CBGM, HbA1c, complication screening) Interviews with 110 residents	11.7 % (n=183)	Mean age 81.8±8.3 y, 65 % female Diet only 28 %, insulin 27 %, OADs alone 45 %. HbA1c <12 months 88 %. Mean HbA1c 56 mmol/mol (7.3±1.4 %), 13 % do CBGM themselves 60 % influenza vaccination, 28 % eye examination, 43 % podiatry visit Hypoglycaemia: 160 suspected episodes in 56 residents treated with insulin or SU, CBGM taken in 53 % of episodes, 15 % of these were low (<4 mmol/l) 54 % and 75 % of residents did not know when their BG was low and high, respectively

Appendix 2 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Mader et al, 2006 (123)	USA (Portland)	July – December 2002	Descriptive study + intervention with a standardized CBGM protocol, 1 CH (nursing + rehabilitation). Study population of 191 residents admitted within a 6-month period DM medicines and use of protocol	53 % (n=101) NH: n=50 Rehabilitation: n=51	Mean age 71.1 y, 98 % male No treatment/diet 27 %, insulin alone 45 %, OADs alone 24 %, insulin+OAD 4 % Intervention: 72 % received orders for management goal, moderate control for 96 % of these. 69 % received orders to use CBGM protocol, BID order for 88 %, adjusted frequency for 54 % of residents as appropriately, regarding protocol
Meyers et al, 2007 (175)	USA (Minnesota)	May 2005	Cross-sectional, 12-month retrospective, 20 NHs. Medical records review for 778 residents DM management (medicines, HbA1c, health status) Survey of physicians and nursing practitioners providing for these residents	21.6 % (n=168)	Mean age 63 y HbA1c <12 months 80 %, mean HbA1c 54 mmol/mol (7.1±1.2 %), mean HbA1c ≥65 y 50 mmol/mol (6.7±1.0 %) (significantly lower than for <65 y). Higher HbA1c values associated with insulin use, more frequent CBGM, no association with health status or life expectancy Percentage of providers identifying HbA1c of 53 mmol/mol (7 %), 64 mmol/mol (8 %) or 75 mmol/mol (9 %) as appropriate target, respectively: 56 %, 22 % and 22 %
Resnick et al, 2008 (95)	USA (national)	2004	Cross-sectional, 1174 NHs. Medical records review for 11,939 residents Medicines, ADL, pressure ulcers, ED visits Comparison with non-DM residents	24.6 %	Mean age 81.7 y, significantly younger than non-DM residents (mean 84.9 y) DM vs non-DM: More medicines, more circulatory problems, higher risk of pressure ulcer, more ED visits, lower LOS, lower risk of falls and fractures

Appendix 2 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Joseph et al, 2008 (178)	USA (New York)	Not stated*	Cross-sectional, 1 NH. Medical records review of 202 residents (excluding those with terminal illness/life expectancy <6 months) DM management (medicines, HbA1c, BP, LDL-C, complications)	31 % (n=62)	Mean age 73±9 y, 53 % female Diet alone 6 %, insulin 58 %, metformin 18 %, SU 18 % Statins 55 %, ACEI/A2RB in hypertension 89 %, ACEI/A2RB in CKD 87 % Complications: Hypertension 76 %, moderate/severe CKD 48 %, CVD 63 % HbA1c <53 mmol/mol (7 %) 89 %, HbA1c <42 mmol/mol (6 %) 77 %, BP<130/80 mmHg 84 %, LDL-C <2.6 mmol/l 89 %
Clement & Leung, 2009 (176)	Canada (Toronto + Vernon)	December 2005 – August 2006 (pilot) January – February 2007 (survey)	Prospective pilot study, 1 NH, 254 residents + survey, 5 NHs, 358 residents Medical records review, DM management (medicines, HbA1c, CBGM), identifying barriers to care	Pilot: 29 % (n = 75) Survey: 17 % (n = 60) Range 12-20 % between the 5 NHs in the survey.	Pilot and survey, respectively: Diet alone 19 % and 25 %, OADs 37 % and 3 0%, insulin 44 % and 45 %, HbA1c <6 months 68 % and 90 %, mean HbA1c 60 mmol/mol (7.6 %) and 48 mmol/mol (6.5 %) Barriers to care, pilot project: High resident-to-staff ratio, practices not in agreement with recommendations, knowledge deficiencies nurses and physicians
Zhang et al, 2010 (98)	USA (national)	2004	Cross-sectional, random sample from 12,786 residents Estimation of DM prevalence and comorbidities	23.4 %	Comorbidities DM vs non-DM: CVD male 74.1 % vs 67.8 %, CVD female 78.9 % vs 68.3 %. Renal symptoms male 19.1 % vs 13.7 %, renal symptom female 14.7 % vs 10.3 %

Appendix 2 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Dybicz et al, 2011 (97)	USA (4 geographic regions)	June 2006 – March 2007	Retrospective, 12-month observational study, 23 NHs Medical records review of 2317 residents. Comorbidities, cognition, physical activity, utilization of health services, and medicines Comparison with non-DM residents	32.8 % (n = 761)	DM vs non-DM: Higher burden of CKD dyslipidaemia, skin conditions, cerebrovascular incident, and infection, higher use of ACEI/A2RB, statins, antiplatelets/antithrombotics, higher risk of hospitalization
Newton et al, 2013 (96)	USA (Georgia)	January – December 2008	Cross-sectional, 3 NHs. Medical records review for 1,409 residents DM management (medicines, HbA1c, hypoglycaemia, ED visits, hospitalisations) Comparison with non-DM residents	34.2 % (n = 482) T1DM 2.1 % (n=10) T2DM 97.9 % (n=472)	Mean age 77.4±12.0 y, 50 % female Hypertension, hyperlipidaemia and CVD prevalent comorbidities No pharmacological DM treatment: 45.6 % upon admission, during stay 10 %, prescriptions for insulin increased most Mean HbA1c (admission) 50 mmol/mol (6.7±1.1 %), 42 % experienced ≥1 mild hypoglycaemic episode (<3.9 mmol/l) and 7 % severe hypoglycaemia (<2.2 mmol/l) DM vs non-DM: Younger, higher BMI, more medicines, more comorbidities, less dementia, more ED visits and hospitalisations
Hager et al, 2013 (170)	USA (Kentucky)	2009-2011	Retrospective, 3-year chart review, 1 NH with a dedicated DM focus Medical records review for 126 residents staying >6 months DM management (medicines, HbA1c, BP, eGFR, complications)	38 % (n=126)	Insulin 28 %, metformin 11 %, no restricted diets. HbA1c <6 months 98 %, HbA1c <64 mmol/mol (8 %) 88 % Hypoglycaemia (<3.9 mmol/l) recorded for 17 % Monthly BP readings, 48 % BP<130/80 mmHg. 45 % CKD stage 4

Appendix 2 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Alsabbagh et al, 2015 (81)	Canada (Saskatchewan)	2003-2011	Retrospective cohort study. All admissions (n=14,624) with >6 months stay and >60 y between 2003-2011 Medical records review, investigating DM medicines	23.5 % (n=3,436), stable over the years studied.	Mean age 82.1 y, 57.5 % female 68 % received AD within 6 months of admission, 88 % had received AD before admission OAD 64.9 %, insulin alone 20.4 %, OAD+insulin 14.7 %
Lee et al, 2015 (171)	USA (national)	January 2005 – September 2011	Retrospective, descriptive study of all admitted residents >65 y to 123 NHs for long term stay Review of 40,025 resident records DM medicines, comorbidities, hypoglycaemia, weight loss	23.6 % (n=9,431)	Mean age 78 y, 98 % male OADs 23 %, insulin 31 % Hypertension 68 %, CVD 54 % Hypoglycaemia diagnosis 26 % HbA1c <53 mmol/mol (7 %) 60 %
Zarowitz et al, 2015 (82)	USA (national)	May 2011 – September 2012	Retrospective, 17-month review study Medical records review for 229,283 residents Cognitive and physical function, comorbidities, prescriptions	35.4 % (n=81,087)	Mean age 75.7±12.3 y, 57.6 % female, 41 % obese (BMI≥30 kg/m^2) Moderate cognitive function, highly dependent in ADL. Falls common (28 %) Hypertension 85.8 %, hyperlipidaemia 53.4 %, depression 44.9 % Of 44,665 residents with prescription data: 79.9 % AD prescription OADs only 18.2 %, metformin and SU most common. Injectable therapy 81.8 %, basal insulin and rapid-acting insulin most common, GLP-1 agonist only 0.5 % Statins (53.2 %), antidepressants (52.4 %), ACEI/A2RB (51.3 %) common prescriptions

Appendix 2 continued

Authors, year	Country	Study period	Method and subjects	Prevalence	Other major findings
Haines et al, 2016 (80)	Australia (Victoria)	2013	Cross-sectional, 10 CHs Medical records review of 593 residents DM management (medicines, HbA1c, CBGM, hypoglycaemia, hyperglycaemia, DM-related hospitalisations)	18.2 % (n=108) T1DM (n=1)	Mean age 85±7.3 y, 68 % female Diet only 44.4 %, insulin 21.3 %, OADs 34.3 % HbA1c recorded 52 %, mean HbA1c total 51 mmol/mol (6.81±1.44 %), mean HbA1c active treatment 55 mmol/mol (7.16±1.42 %), HbA1c ≤53 mmol/mol (7 %) 69.6 % Hyperglycaemic event (10 mmol/l) 69.4 %, hypoglycaemic event (<4 mmol/l) 10.2 % DM-related hopsitalisations 6.5 %, acute GP visits 23.1 %

*Studies not stating study period, we assume that data collection occurred within 24 months of publishing the results
Abbreviations: ACEI=angiotensin converting enzyme inhibitors, AD=antidiabetic drug, ADL=activities of daily living, A2RB=angiotensin-2 receptor blockers, BG=blood glucose, BID=twice daily, BMI=body mass index, BP=blood pressure, CBGM=capillary blood glucose measurement, CH=care home, CKD=chronic kidney disease, CVD=cardiovascular disease, DM=diabetes mellitus, ED=emergency department, GP=general practitioner, HF=heart failure, LDL-C=low-density lipoprotein cholesterol, LOS=length of stay, MDS=Minimum Data Set, NH=nursing home, OAD=oral antidiabetic drug, SU=sulfonylurea. T1DM=type 1 diabetes mellitus, T2DM=type 2 diabetes mellitus, y=years
Reference numbers in this table refer to those in the reference list in the main text of the thesis

Appendix 3. Sheet for registering residents with DM diagnosis, Study I.

Name	Number	Year of birth	Gender (M/F)		Diagnosis of DM (Y/N)	Able to give consent (Y/N)	Consent given (Y/N)
	1						
	2						
	3						
	4						
	5						
	6						
	7						
	8						
	9						
	10						
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	23						
	24						

Appendix 4. Consent form, Study I

Forespørsel om deltakelse i forskningsprosjektet

"Diabetespasienter i norske sykehjem og deres behandling"

Bakgrunn og hensikt
Dette er et spørsmål til deg om å delta i en forskningsstudie for å kartlegge behandlingen av diabetes hos beboere på norske sykehjem. Vi kjenner per i dag ikke til hvor mange beboere i norske sykehjem som har diagnosen diabetes, og hvilken behandling og oppfølging de får. For å kunne tilby diabetespasienter i sykehjem best mulig pleie og behandling, er det nødvendig å først kartlegge omfanget av diabetes i norske sykehjem og hvilken behandling diabetespasientene får.

Pleiepersonell ved sykehjemmet du bor på har blitt bedt om å spørre alle beboere på langtidsopphold (3 måneder eller lengre) som har en diabetesdiagnose om å delta i studien.

Forskningsprosjektet utføres av forskere fra Universitetet i Bergen.

Hva innebærer studien?
For å få tilgang til informasjonen beskrevet ovenfor, trenger vi å hente ut opplysninger fra journalen din om eventuelle medisiner du bruker for regulering av ditt blodsukker, om du måler blodsukker og eventuelt hvor ofte blodsukkeret ditt er blitt målt de siste 4 uker. Vi ønsker også å hente ut opplysninger om ditt langtidsblodsukker (HbA1c-verdi) de siste 12 måneder. Vi kommer ikke til å registrere personlige opplysninger, som fødselsnummer, navn eller bosted om deg. Informasjonen vi ønsker å hente ut vil dermed ikke kunne spores direkte tilbake til deg.

Pleiepersonellet har også på forhånd blitt spurt om å registrere om du har en demensdiagnose – dette er for å vurdere om informasjon om deltagelse i studien også skal gis til dine pårørende. Dette er viktig for å ivareta personvernet ditt, slik at du kan få hjelp til å vurdere hva studien innebærer og om det vil være av interesse for deg/dine pårørende å la deg delta.

Studien vil også undersøke hvordan blodsukkermåling foregår ved sykehjemmet der du er beboer. Dersom blodsukkeret ditt blir målt med jevne mellomrom, kan du komme til å bli spurt om forskeren kan observere en av disse målingene. Om du samtykker til dette, vil det for deg innebære et ekstra stikk i fingeren, til en kontrollmåling på et annet instrument.

Mulige fordeler og ulemper
Ved å undersøke hvilken behandling diabetespasienter får i norske sykehjem, vil en få et grunnlag for å vurdere hva som er den beste pleien og behandlingen for denne gruppen. Studien vil således være fordelaktig for pasienter med diabetes i norske sykehjem.

Studien bruker kun opplysninger om deg som er samlet inn fra før, og du vil ikke måtte gjennomgå nye undersøkelser. Det vil ikke bli notert ned navn eller fødselsnummer, men journalen din vil ikke være anonym når forskeren ser den.

Dersom du samtykker til at en av dine blodsukkermålinger blir observert, vil dette innebære ett ekstra stikk i fingeren, til en kontrollmåling. Samtykke til deltakelse i prosjektet vil ikke innebære ekstra målinger av ditt blodsukker, utover dette.

Appendix 4. Consent form, Study I

Hva skjer med informasjonen om deg?
Informasjonen som registreres om deg fra journalen skal kun brukes slik som beskrevet i hensikten med studien. Alle opplysningene vil bli behandlet uten navn og fødselsnummer eller andre direkte gjenkjennende opplysninger. En kode knytter deg til dine opplysninger gjennom en navneliste.

Det er kun autorisert personell knyttet til prosjektet som har adgang til navnelisten og som kan finne tilbake til deg. Opplysningene vil bli slettet når prosjektet er ferdig (senest desember 2014).

Det vil ikke være mulig å identifisere deg i resultatene av studien når disse publiseres.

Hvis en av dine blodsukkermålinger blir observert, vil ingen av opplysningene som samles inn kunne spores tilbake til deg som pasient.

Frivillig deltakelse
Det er frivillig å delta i studien. Du kan når som helst og uten å oppgi noen grunn trekke ditt samtykke til å delta i studien. Dette vil ikke få konsekvenser for din videre behandling. Dersom du ønsker å delta, undertegner du samtykkeerklæringen på siste side. Om du nå sier ja til å delta, kan du senere trekke tilbake ditt samtykke uten at det påvirker din øvrige behandling. Dersom du senere ønsker å trekke deg eller har spørsmål til studien, kan du kontakte

Lillan Mo Andreassen (prosjektleder)
Telefon: 55 58 61 62
Mobil: 993 86 849

Ytterligere informasjon om studien finnes i kapittel *A* – *utdypende forklaring av hva studien innebærer.*

Ytterligere informasjon om biobank, personvern og forsikring finnes i kapittel B – *Personvern, biobank, økonomi og forsikring.*

Samtykkeerklæring følger etter kapittel B.

Appendix 4. Consent form, Study I

Kapittel A- utdypende forklaring av hva studien innebærer

Antall mennesker med diabetes er stadig økende, særlig i den eldre delen av befolkningen, noe som gjør at en antar at stadig flere pasienter i sykehjem vil være diagnostisert med denne sykdommen. Det er ikke tidligere gjort forskning på beboere med diabetes i sykehjem, og vi vet derfor ikke hvor mange sykehjemsbeboere som har denne diagnosen, eller hvilken oppfølging de får for sykdommen. For å kunne tilby deg som diabetespasient i sykehjem best mulig pleie og behandling, er det nødvendig å først kartlegge omfanget av diabetes i norske sykehjem og hvordan diabeteskontrollen, herunder legemiddelbehandling og blodsukkermåling, fungerer.

Kriteriene for deltakelse i studien er at du er en sykehjemsbeboer på langtidsopphold (3 måneder eller lengre), som har diagnosen diabetes. Det blir lettere å planlegge tiltak for å forbedre behandlingen av pasienter med diabetes på sykehjem hvis vi vet hvor mange dette gjelder og hvilken behandling de får i dag. Studien er del av et doktorgradsprosjekt ved Universitetet i Bergen som løper ut 2014. Registrering av opplysninger til denne studien vil skje fra høsten 2011 og fremover. Analyser og publisering av resultater vil skje fortløpende etter dette. Alle opplysninger som samles inn til denne studien vil kun være tilgjengelig for forskergruppen og personidentifiserbare opplysninger slettes når prosjektet er ferdig – senest i desember 2014.

Skulle det fremkomme ny informasjon under studieforløpet som kan tenkes å påvirke din villighet til å delta i studien, vil du eller din verge bli orientert om dette så raskt som mulig. Du kan, som tidligere nevnt, når som helst velge å trekke tilbake ditt samtykke. Allerede registrerte opplysninger om deg vil da umiddelbart bli slettet.

Appendix 4. Consent form, Study I

Kapittel B - Personvern og finansiering

Personvern
Opplysninger som registreres om deg er:

- Fødselsår.
- Kjønn.
- Type diabetes (type 1, type 2, annen).
- Hvilke legemidler du eventuelt bruker for regulering av ditt blodsukker.
- Hvor ofte blodsukkeret ditt er målt innenfor de siste 4 ukene.
- Hvor ofte langtidsblodsukkeret (HbA1c-verdi) ditt er målt innenfor de siste 12 måneder og eventuelle registrerte verdier av denne.
- Om du har en demensdiagnose og i så fall hvilken grad (mild, moderat, alvorlig).

Hvis en av dine blodsukkermålinger blir observert, vil ingen av opplysningene som samles inn kunne spores tilbake til deg som pasient. Kontrollprøven vil analyseres umiddelbart etterpå og vil deretter destrueres.

Universitetet i Bergen ved administrerende direktør er databehandlingsansvarlig.

Rett til innsyn og sletting av opplysninger om deg og sletting av prøver
Hvis du sier ja til å delta i studien, har du rett til å få innsyn i hvilke opplysninger som er registrert om deg. Du har videre rett til å få korrigert eventuelle feil i de opplysningene vi har registrert. Dersom du trekker deg fra studien, kan du kreve å få slettet innsamlede prøver og opplysninger, med mindre opplysningene allerede er inngått i analyser eller brukt i vitenskapelige publikasjoner.

Økonomi
Forskningprosjektet er finansiert av Norges forskningsråd.

Appendix 4. Consent form, Study I

Samtykke til deltakelse i studien

Jeg er villig til å delta i studien

(Signert av prosjektdeltaker, dato)

Stedfortredende samtykke når berettiget, enten i tillegg til personen selv eller istedenfor

---

(Signert av nærstående, dato)

Jeg bekrefter å ha gitt informasjon om studien

(Signert, rolle i studien, dato)

Appendix 5. Sheet for registering DM medicines, CBGM and HbA1c measurements for consenting residents, Study I.

ID:_____

1. **Gender** ☐ Female ☐ Male
2. **Year of birth** 19_____
3. **Diagnosis of DM** ☐ Yes ☐ No
4. **Able to consent** ☐ Yes ☐ No

---

5. **Type of DM**

☐ Type 1 DM ☐ Type 2 DM ☐ Not registered ☐ Other _____

6. **Treatment with glucose lowering medicines**

NAME AND STRENGTH OF DRUG	ADMINISTRATION TIMES (+DOSE)				COMMENTS
Regular	KL.	KL.	KL.	KL.	

As needed	COMMENTS

7. CBGM last 4 weeks

DATE	TIME	VALUE	COMMENT

DATE	TIME	VALUE	COMMENT

8. HbA1c measurements last 12 months

DATE	VALUE	DATE	VALUE

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

Deprescribing criteria based on Ipswich MI document (OSAMU)	
BNF Chapter 1 – Gastrointestinal system	
Antispasmodics: How long have they been prescribed? Avoid long term use, highly anticholinergic preparations, uncertain effectiveness.	Criteria 101
H2 blockers / PPI: Check if there is a valid indication for prescribing e.g. is an NSAID still being taken? There has been no proven peptic ulcer, GI bleeding or dyspepsia for 1 year. Continued use may contribute to C. difficile infection.	Criteria 102
Laxatives: Previous use of opioid analgesics has reduced or stopped. Regular bowel movements occur without difficulty. Patient is eating and drinking and has an adequate fluid intake. If >1 laxatives are used, reduce and stop one at a time slowly. Do not stop treatment abruptly. Reduce stimulant laxative first, increase the dose of the osmotic laxative if necessary. Restart laxative if relapse occurs.	Criteria 103b Criteria 103a
BNF Chapter 2 – Cardiovascular system	
Spironolactone: If dose >25 mg/day, the risk of hyperkalaemia is higher in older adults with heart failure, especially if taking an NSAID, ACE inhibitor, angiotensin II receptor blocker or potassium supplement.	Criteria 201
Antiarrhytmics: Rate control has better balance of benefits and harms than rhythm control for most older adults. Amiodarone is associated with multiple toxicities (thyroid, pulmonary, QT prolongation). Check all monitoring is being done.	Criteria 104

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

Antihypertensives – ACE inhibitors, beta blockers, angiotensin II receptor blockers, diuretics, calcium channel blockers: Check if there is a valid indication for prescribing, is the BP at a normal level or too low?	N/A
Do the known possible adverse drug reactions outweigh the possible benefits e.g. orthostatic hypotension, CNS effects, risk of falls; loop diuretic for ankle oedema – would compression hosiery be more appropriate?	N/A
If >1 antihypertensives are used, stop 1 at a time, maintaining the dose of the others without change. Restart antihypertensives if BP increases above 90 mmHg diastolic and/or 150 mmHg systolic (160 mmHg if no organ damage). Withdraw alpha agonist gradually to avoid severe rebound hypertension.	Criteria 105
Nitrates: The patient has not had chest pain for 6 months. The patient has reduced mobility.	Criteria 106
Statins / lipid lowering drugs: Re-evaluate the patients risk profile for primary and secondary prevention of cardiovascular disease – is there a valid indication for prescribing?	Criteria 107
Stop in metastatic disease.	N/A
Aspirin: Check if there is a valid indication for prescribing (e.g. re-evaluate the patients risk profile for primary prevention). Do the known possible adverse drug reactions outweigh the possible benefits?	Criteria 108
Is a dose of >150 mg/day being used for a cardiovascular indication? Is aspirin being used for dizziness which is not clearly attributable to cerebrovascular disease?	Criteria 202

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

Dipyridamole: Clopidogrel is now preferred over dipyridamole as more clinically and cost effective.	Criteria 109
Anticoagulants – oral and injected: Are LMWHs/oral anticoagulants prescribed following hip/knee replacement surgery still required? Stop warfarin if the risk of falls outweighs the benefits. Long term warfarin use (>6 months) is not recommended when the VTE was provoked by surgery, non-surgical trigger factors or the VTE occurred in the calf only.	N/A
Peripheral vasodilators: Check if there is a valid indication for prescribing. Clinical effectiveness often not established. Do the known possible adverse drug reactions outweigh the possible benefits?	N/A
Digoxin: Check if there is a valid indication for prescribing. Do the known possible adverse drug reactions outweigh the possible benefits? E.g. if there is an increase in toxicity, decrease oral fluid intake. Long term digoxin at >125 mcg/day in patient with impaired renal function can lead to an increased risk of toxicity.	Criteria 110 Criteria 203
BNF Chapter 3 – Respiratory system	
Theophylline: Monotherapy in COPD is not appropriate – safer, more effective alternatives are available.	Criteria 111
Oral corticosteroids: Prednisolone maintenance in COPD is not usually recommended. The magnitude and speed of dose reduction and withdrawal should be determined on a case by case basis. Gradual withdrawal should be considered for those who have received more than 3 weeks treatment, those who have received more than 40 mg prednisolone daily (or equivalent) or have other possible causes of adrenal suppression.	Criteria 112

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

Inhaled corticosteroids: In asthma – review every 3 months, has control been achieved, if yes; reduce dose slowly (by 50% every 3 months). In COPD – if an inhaled corticosteroid is not appropriate, a long acting abtimuscarinic bronchodilator can be used with a long acting beta2 agonist.	N/A
Antihistamines (first generation): Highly anticholinergic, clearance is reduced with advanced age, tolerance develops when used as a hypnotic, greater risk of confusion, dry mouth, constipation.	Criteria 113
BNF Chapter 4 – Central nervous system	
Chloral hydrate: Tolerance occurs within 10 days, risk outweighs benefits as overdose is only 3 times the recommended dose; avoid use, avoid prolonged use (and abrupt withdrawal thereafter).	Criteria 114
Meprobamate: High rate of physical dependence, very sedating, avoid use, avoid prolonged use, abrupt withdrawal may precipitate convulsions. EMEA recommended the suspensions of marketing authorisations in Jan 2012 as the risks of serious CNS side effects outweigh the benefits.	Criteria 115
Barbiturates: Intermediate acting preparations should only be used in severe intractable insomnia, avoid use in the elderly. High rate of physical dependence, tolerance to sleep benefits, risk of overdose at low doses.	Criteria 116
Benzodiazepines (including 'Z' drugs): Is use required if physical and psychological health and personal circumstances are stable? If the patient is willing, committed and compliant, and has adequate social support refer to a withdrawal clinic. Withdrawal should be gradual to avoid confusion, toxic psychosis and convulsions. With long term use, risk of adverse effects including falls, exceeds therapeutic benefit of continued use.	N/A Criteria 117a + 117b

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

Drugs for dementia: If MMSE <10, medicines may be continued if they help with behavior. NICE recommends memantine if MMSE <10. Review benefit, use should only continue if the MMSE score is ≥10 and treatment has an effect on the global, functional or behavioural symptoms.	N/A
Levodopa – carbidopa: Check if there is a valid indication for prescribing. Do the known possible adverse drug reactions outweigh the possible benefits?	Criteria 118
Antipsychotics: Check if there is a valid indication for prescribing. Do the known possible adverse drug reactions outweigh the possible benefits? In dementia patients with behavioural and psychological symptoms, review and discontinue, particularly if there has been no response and symptoms are mild, unless there is extreme risk or distress for the patient. Standardized symptom evaluations and drug cessation attempts should be undertaken at regular intervals. Are chlorpromazine or trifluoperazine being taken with other medicines that have anticholinergic activity and can increase risk of cognitive impairment e.g. TCADs, oxybutynin, chlorphenamine?	Criteria 119 Criteria 301
Antidepressants – Selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCADs), others e.g. MAOIs, agomelatine, duloxetine, reboxetine, venlafaxine, mirtazapine: Check if there is a valid indication for prescribing. For a single episode of depression treat for 6-9 months; for multiple episodes, treat for at least 2 years, no upper duration of treatment has been identified. Dosulepin should not be prescribed. Do the known possible adverse drug reactions outweigh the possible benefits? E.g. TCADs can worsen dementia, glaucoma, constipation, urinary retention; SSRIs may induce clinically significant hyponatremia.	Criteria 120a Criteria 120b Criteria 302

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

Are TCADs being taken with other medicines that have anticholinergic activity and can increase risk of cognitive impairment e.g. chlorpromazine, oxybutynin, chlorphenamine? Reduce dose of antidepressants gradually to avoid withdrawal effects.	Criteria 401
Opioid analgesics: Is a regular opioid still required? The risk of falls/constipation can outweigh the benefits. Consider non-drug options, switch to regular paracetamol. Review laxatives.	Criteria 121a Criteria 121b
Metoclopramide: Check if there is a valid indication for prescribing. How long has it been prescribed? Can cause extrapyramidal effects including tardive dyskinesia, risk greater in frail older adults.	Criteria 122
BNF Chapter 5 – Infections	
Antibacterials: Check if there is a valid indication for prescribing. Inappropriate uses – a bacterial infection has resolved; a viral infection has been diagnosed; prophylactic treatment prescribed but no pathogen isolated. Treatment of asymptomatic bacteriuria (ASB) in older patients and diabetes patients has no beneficial effects. There is a lack of evidence to evaluate the effect of preventing cathether associated ASB with antibiotics. Is fluid intake adequate? Nitrofurantoin has potential for pulmonary toxicity, lack of efficacy in patients with CrCL <60ml/min due to inadequate drug concentration in the urine; avoid long term use.	Criteria 123a Criteria 123b + N/A
Antifungals: Skin scrapings should be taken if systematic therapy is being considered or if there is doubt about the diagnosis. When a course of treatment of appropriate length has been finished, do not continue indefinitely e.g. oral and topical nystatin. For finger and toe nail infections, cure is achieved in only a minority of patients, the relapse rate is high.	Criteria 124

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

BNF Chapter 6 – Endocrine system	
Oestrogens ± progestogens: There is no mandatory limitation on the duration of HRT. Whether or not to continue therapy is dependent on an objective estimation on ongoing benefits and risks. Evidence of carcinogenic potential in breast and endometrium, lack of cardioprotective effect and cognitive protection in older women. Topical low dose oestrogen intravaginal cream safe and effective for dyspareunia and other vaginal symptoms.	N/A
Bisphosphonates: Check if there is a valid indication for prescribing. Has treatment been taken for 5 years or more? Do the known possible adverse drug reactions outweigh the possible benefits? If the patient is at low risk of falls, are these still needed? Prolonged immobility is a risk factor for low BMD.	Criteria 125 N/A
BNF Chapter 7 – Obstetrics, gynaecology and urinary tract disorders	
Alpha blockers: Check if there is a valid indication for prescribing. Use is generally not indicated if a patient has a long term (>2 months) catheter in situ.	Criteria 126 N/A
Antimuscarinics (for bladder/urinary tract symptoms): Check if there is a valid indication for prescribing. Review effectiveness after 3-6 months. Check if continence pads are also used, is concomitant use necessary? Do the known possible adverse drug reactions outweigh the possible benefits? E.g. postural hypotension, urinary retention, constipation. Oxybutynin will decrease MMSE score in patients with dementia.	Criteria 127 N/A Criteria 402a Criteria 402b

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

Are antimuscarinics being taken with other medicines that have anticholinergic activity and can increase risk of cognitive impairment e.g. chlorpromazine, TCADs, chlorphenamine?	Criteria 303
BNF Chapter 8 – Malignant disease and immunosuppression	
Cytotoxics, immunosuppressants: What outcome is expected, do the known possible adverse drug reactions outweigh the possible benefits? Refer to doctor who initiated treatment.	N/A
BNF Chapter 9 – Nutrition and blood	
Sodium, potassium & iron supplements: Check if there is a valid indication for prescribing, do the known possible adverse drug reactions outweigh the possible benefits.	Criteria 130
Vitamins: Check if there is a valid indication for prescribing, e.g. does the patient have a disorder which requires vitamin & mineral supplements.	Criteria 131
Calcium + vitamin D: Does the patient have adequate levels through diet/sunlight exposure? If the patient is not mobile, is this still needed?	N/A
Sip feeds: Check if there is a valid indication for prescribing. Has a dietician recently reviewed the patient; is the patient able to prepare, or have someone else prepare fortified food and therefore does not need sip feeds.	N/A
BNF Chapter 10 – Musculoskeletal and joint diseases	
NSAIDs: Check if there is a valid indication for prescribing. Is an NSAID still needed/appropriate e.g. long term treatment of gout but no prophylaxis prescribed?	Criteria 128a

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

Do the known possible adverse drug reactions outweigh the possible benefits e.g. >3months use for symptom relief in mild osteoarthritis, use in patients with severe hypertension/heart failure/chronic renal failure. If topical NSAIDs are continued indefinitely, review the need for use; short courses are generally advised.	Criteria 403 Criteria 128b
DMARDs: Discontinue penicillamine if there is no improvement within 1 year. Consider withdrawal of azathioprine and ciclosporin if there is no improvement within 3 months of use. Refer to doctor who initiated treatment.	N/A
Skeletal muscle relaxants: Often poorly tolerated because of anticholinergic adverse effects, sedation, risk of fracture, avoid use.	Criteria 129
TNF inhibitors: Psoriatic arthritis/Ankylosing spondylitis – discontinue adalimumab, etanercept and infliximab if there is inadequate response after 12 weeks. Rheumatoid arthritis/Juvenile idiopathic arthritis – withdraw adalimumab, etanercept and infliximab if response is not adequate within 6 months.	N/A
BNF Chapter 11 – Eye	
Eye drops/ointments: Review need for preservative free eye drops – is there a valid indication for prescribing (e.g. previous preservative toxicity), are eye drops instilled more than 4 times per day? Have antibiotic preparations been continued without a review or stop date?	N/A Criteria 132
BNF Chapter 12 – Ear, nose and oropharynx	
Drops, sprays, solutions etc.: Is the medicine still required? Have antibiotic / steroid / sympathomimetic preparations been continued without a review or stop date?	Criteria 133

Appendix 6. Deprescribing criteria derived from OSAMU document, Study II

BNF Chapter 13 – Skin	
Creams, ointments: Has the condition resolved and continued use may cause adverse effects or exacerbate the condition e.g. preparations containing antibacterials or corticosteroids?	Criteria 134
Is the patient using sufficient emollient to avoid use of steroids or development of ulcers?	N/A
Appendix 5 – Wound management products and elasticated garments	
Dressings: Wounds should be reviewed before prescribing to ensure correct dressing chosen. Chronic wounds change over time – refer difficult to treat wounds to a tissue viability nurse. Wounds should reduce in size over time. Address underlying problems e.g. soiling from incontinence, wrong choice of dressing etc. Larger dressings are more expensive than the smaller sizes. Query large size dressings on repeat prescriptions. Query quantities over 10 units per month, most dressings can stay in place for 3-5 days except on infected wounds, although some patients may have multiple wound sites. Avoid waste – prescribe the actual number of dressings needed rather than "1OP".	N/A

CODEBOOK PAPER II 05.10.2015

Additional material to codebook:

Attachment 1: Generic names of medicines prescribed in our population. Each generic medicine has an assigned number.

Attachment 2: Anticholinergic medicines UK. All medicines with anticholinergic properties that are licensed in the UK. Classified into high-potency anticholinergics and low-potency anticholinergics.

Attachment 3: List of anticholinergic medicines prescribed in our population. All medicines with anticholinergic properties prescribed in our population.

Attachment 4: Classified conditions, numbers and ICD. Excel spreadsheet with overview of all classified conditions, their assigned numbers and ICD codes.

Deprescribing criteria based on Ipswich MI document.docx

The following SPSS-files are used for analysis of this codebook:

Datasets:

Dataset aiding deprescribing analysis T2DM 2015-10-05.sav

Dataset aiding deprescribing analysis T2DM POST ANALYSIS 2015-10-05.sav

Deprescribing T2DM 2015-10-05.sav

Syntax:

Syntax recode medicine variables 2015-10-05.sps

Syntax analysis category 1 2015-10-05.sps

Syntax analysis category 2 2015-10-05.sps

Syntax analysis category 3 2015-10-05.sps

Syntax analysis category 4 2015-10-05.sps

Syntax deprescribing analysis 2015-10-07.sps

Category 1: Inappropriate choice of drug

101: Antispasmodics: Avoid long-term use, highly anticholinergic preparations, uncertain effectiveness.

Check antispasmodics use, Yes = 1, No = 0.

Make variable (Antispasmodics) in SPSS by counting the numbers 6, 93, 124 and 149 in 'Medicine_1new … Medicine_20new' in SPSS. The following drugs are listed as antispasmodics in BNF:

Alverine citrate (6)
Atropine sulphate (not prescribed)
Dicycloverine hydrochloride (not prescribed)
Hyoscine butylbromide (93)
Mebeverine hydrochloride (124)
Peppermint oil (149)
Propantheline bromide (not prescribed)

102: H2 blockers / PPI: Check if there is a valid indication for prescribing e.g. NSAID still being taken, diagnosis of peptic ulcer, GI bleeding or dyspepsia. Continued use may contribute to C. difficile infection.

Check for valid indication for use of H2 blockers / PPI; No valid indication = 1, Valid indication = 0.

Make variable for H2 blockers / PPI (A02BA + A02BC) in SPSS. For residents receiving these, check for evidence of prescribed NSAID by making variable (M01 + N02BA01) in SPSS OR diagnoses that can justify use by counting the numbers 20, 70, 73, 88, 98 and 134 in 'Condition1-16' in SPSS. The following diagnoses have by the researchers been identified as valid indications:

Barrett's oesophagus (20)
Gastric haemorrhage (70)
Gastro-oesophagal reflux (73)
Hiatus hernia (88)
Indigestion (dyspepsia) (98)
Oesophagitis (134)

103: Laxatives: Check if there is a valid indication for prescribing e.g. opioid analgesics still being taken, diagnosis of constipation. Also check if >1 laxative is being used.

103a: *Check if there is more than one laxative being prescribed; Yes = 1, No = 0.*

Make variable for laxatives (A06A) in SPSS. Run frequency analysis.

103b: *Check for valid indication for use of laxatives; No valid indication = 1, Valid indication = 0.*

For residents receiving laxatives, visually check for evidence of prescribed opioid analgesic (N02A) OR the diagnosis of constipation or other diagnosis that could justify use in medical records. Disorders affecting colon, like diverticular disease, cancer, hernia of colon etc. have by the researchers been identified as valid indications.

104: Antiarrhytmics: Amiodarone is associated with multiple toxicities (thyroid, pulmonary, QT prolongation), should not be prescribed.

Check for use of amiodarone; Yes = 1, No = 0.

Make variable (Amiodarone) in SPSS by counting the number 8 in 'Medicine_1new … Medicine_20new' in SPSS.

105: Antihypertensives - ACE inhibitors, beta blockers, A2RB, diuretics, calcium channel blockers: Check if >1 antihypertensive is being used.

Check if there is more than one antihypertensive agent being prescribed; Yes = 1, No = 0.

Make variable for antihypertensives (C03: diuretics, C07: beta blockers, C08: calcium channel blockers, C09: ACEI + A2RB) in SPSS. Run frequency analysis.

106: Nitrates: Check if there is a valid indication for prescribing e.g. chest pain/angina.

Check for valid indication for use of nitrates; No valid indication = 1, Valid indication = 0.

Make variable for nitrates (C01DA) in SPSS. For residents receiving these, check for diagnosis of angina or other diagnoses that can justify use in medical records. The following diagnoses have by the researchers been identified as valid indications:

Angina pectoris
Heart failure
Ischaemic heart disease (IHD)
Myocardial infarction

107: Statins / lipid lowering drugs: Re-evaluate the patients risk profile for primary and secondary prevention of cardiovascular disease – is there a valid indication for prescribing? Not sufficient data to recommend in the population aged 80+, with or without CVD (Petersen et al 2010).

Check for valid indication for use of statins; No valid indication = 1, Valid indication = 0.

Make variable (80+ yes/no) in SPSS. Using this as an 'if'-condition (=1), check how many receive prescription for lipid lowering drugs (C10), using already available variable for this.

108: Aspirin: Check if there is a valid indication for prescribing e.g. re-evaluate the patients risk profile for primary prevention. Do the known possible adverse drug

reactions (risk of bleeding) outweigh the possible benefits (cardiovascular endpoints)? Recent studies on patients with high baseline risk, such as those with T2DM, have not found the expected benefits of aspirin on cardiovascular endpoint, and elderly patients are also more vulnerable to major haemorrhage.

Check for valid indication for use of aspirin; No valid indication = 1, Valid indication = 0.

Check which residents are prescribed aspirin by making variable (B01AC06) in SPSS. Then visually check each of these resident's diagnoses to see if use can be justified (sign of secondary prevention). The following diagnoses have by the researchers been identified as valid indications for secondary prevention:

Angina pectoris
Atrial fibrillation and flutter
Aortic valve disorder
Cerebrovascular disease
DVT
Heart failure
Ischaemic heart diseases (IHD)
Myocardial infarction
Stroke
Transient cerebral ischaemic attack

109: Dipyridamole: Clopidogrel is now preferred over dipyridamole as more clinically and cost effective.

Check for use of dipyridamole; Yes = 1, No = 0.

Make variable (Dipyridamole) by counting the number 61 in 'Medicine_1new … Medicine_20new' in SPSS.

110: Digoxin: Check if there is a valid indication for prescribing, e.g. heart failure or arrhythmias.

Check for valid indication for use of digoxin; No valid indication = 1, Valid indication = 0.

Make variable for digoxin (C01AA05) in SPSS. For residents receiving this, check for diagnosis of heart failure or atrial fibrillation/flutter or other diagnoses that can justify use in medical records. The following diagnoses have by the researchers been identified as valid indications:

Atrial fibrillation/flutter
Heart failure
Pulmonary embolism
Pulmonary oedema

111: Theophylline: monotherapy in COPD is not appropriate – safer, more effective alternatives available.

Check for theophylline as monotherapy in COPD; Yes = 1, No = 0.

Make variable for COPD, counting the number 45 in 'Classified condition 1-16' in SPSS. For residents with this diagnosis, visually check for evidence of theophylline as monotherapy in medical records.

112: Oral corticosteroids: Prednisolone maintenance in COPD is not usually recommended. Gradual withdrawal should be considered for those who have received more than 3 weeks treatment, those who have received more than 40 mg prednisolone daily (or equivalent) or have other possible causes of adrenal suppression.

Check for prednisolone as long term therapy (>3 weeks) in COPD; Yes = 1, No = 0.

For residents with COPD diagnosis (use SPSS-variable from 111), visually check for evidence of long term use (>3 weeks) of prednisolone (or daily prednisolone doses >40 mg daily) in medical records.

113: Antihistamines (first generation): Highly anticholinergic, clearance is reduced with advanced age, tolerance develops when used as a hypnotic, greater risk of confusion, dry mouth, constipation.

Check for use of first generation antihistamines; Yes = 1, No = 0.

Visually check for use of first generation antihistamines in the medical records. The following drugs are listed as antihistamines (first generation) in BNF:

Alimemazine tartrate
Chlorphenamine maleate
Cinnarizine
Clemastine
Cyclizine
Cyproheptadine hydrochloride
Hydroxyzine hydrochloride
Ketotifen
Perphenazine
Prochlorperazine
Promethazine hydrochloride/promethazine teoclate
Trifluoperazine

114: Chloral hydrate: Tolerance occurs within 10 days, risk outweighs benefits as overdose is only 3 times the recommended dose; avoid use, avoid prolonged use (and abrupt withdrawal thereafter).

Check for use of chloral hydrate; Yes = 1, No = 0.

Make variable for chloral hydrate (N05CC01) in SPSS.

115: Meprobamate: High rate of physical dependence, very sedating, avoid use, avoid prolonged use, abrupt withdrawal may precipitate convulsions. EMEA recommended the suspensions of marketing authorisations in Jan 2012 as the risks of serious CNS side effects outweigh the benefits.

Check for use of chloral hydrate; Yes = 1, No = 0.

Make variable for meprobamate (N05BC01) in SPSS.

116: Barbiturates: Intermediate acting preparations should only be used in severe intractable insomnia, avoid use in the elderly. High rate of physical dependence, tolerance to sleep benefits, risk of overdose at low doses.

Check for use of intermediate acting barbiturates; Yes = 1, No = 0.

Make variable for barbiturates (N05CA) in SPSS.

117: Benzodiazepines (including 'Z' drugs): With long term use, risk of adverse effects including falls, exceeds therapeutic benefit of continued use.

117a: *Check for benzodiazepines as long term therapy (>3 months); Yes = 1, No = 0.*

Make variable for benzodiazepines (N05CD) in SPSS. For residents using these, visually check for evidence of long term use in medical records.

117b: *Check for benzodiazepines as long term therapy (>3 months); Yes = 1, No = 0.*

Make variable for 'Z' drugs (N05CF) in SPSS. For residents using these, check for evidence of long term use in medical records.

118: Levodopa – carbidopa: Check if there is a valid indication for prescribing, i.e. Parkinson's disease.

Check for valid indication for use of digoxin; No valid indication = 1, Valid indication = 0.

Make variable for levodopa/carbidopa (N04BA) in SPSS. For residents receiving these, check for diagnosis of Parkinson's disease in medical records by counting the number 141 in 'Condition1-16' in SPSS.

119: Antipsychotics: Check if there is a valid indication for prescribing. Do the known possible adverse drug reactions outweigh the possible benefits? In dementia patients with behavioural and psychological symptoms, review and discontinue, particularly if there has been no response and symptoms are mild, unless there is extreme risk or distress for the patient. Standardized symptom evaluations and drug cessation attempts should be undertaken at regular intervals.

Check for antipsychotics by making variable (N05A) in SPSS. For residents using these, check for evidence of schizophrenia or other diagnoses that can justify use (e.g. delirium,

agitation, hallucination, dementia). For other diagnoses than schizophrenia, the prescription should be PRN/short term to be justified!

120: Antidepressants – Selective serotonin reuptake inhibitors (SSRIs), tricyclic antidepressants (TCADs), others e.g. MAOIs, agomelatine, duloxetine, reboxetine, venlafaxine, mirtazapine: Check if there is a valid indication for prescribing, e.g. depression. Dosulepin should not be prescribed.

120a: *Check for valid indication for use of antidepressants; No valid indication = 1, Valid indication = 0.*

Make variable for for antidepressants (N06A) in SPSS. For residents using these, check for evidence of depression in medical records.

120b: *Check for use of dosulepin; Yes = 1, No = 0.*

Check for dosulepin by visually looking through medical records.

121: Opioid analgesics: Is a regular opioid still required? The risk of falls/constipation can outweigh the benefits. Consider non-drug options, switch to regular paracetamol. Review laxatives.

121a: *Check for justified use of regular opioids; No diagnosis justifying use = 1, Diagnosis justifying use = 0.*

Check for opioid analgesics by making variable (N02A) in SPSS. For residents using these, visually check for regular use in medical records. Where regular use is documented, check if use may be justified AND if paracetamol is also prescribed. The following diagnoses have by the researchers been identified (in this population) as valid indications of regular opioid use:

Gout
Osteoarthritis
Osteoporosis / Paget's disease
Sudek's atrophy

121b: *Check for prescription of laxative in residents prescribed regular opioids, No laxative) 1, Laxative = 0.*

For residents using regular opioids, visually check for prescription of laxative in medical records.

122: Metoclopramide: Check if there is a valid indication for prescribing. How long has it been prescribed? Can cause extrapyramidal effects including tardive dyskinesia, risk greater in frail older adults.

Check for valid indication for use of metoclopramide; No valid indication = 1, Valid indication = 0.

Make variable for metoclopramide (A03FA01) in SPSS. For residents using this, check for evidence of diagnoses that can justify use in medical records. The following diagnoses have by the researchers been identified as valid indications:

Cancer
GI disorders (not specified)
Migraine

123: Antibacterials: Check if there is a valid indication for prescribing. Inappropriate uses – a bacterial infection has resolved; a viral infection has been diagnosed; prophylactic treatment prescribed but no pathogen isolated. Treatment of asymptomatic bacteriuria (ASB) in older patients and diabetes patients has no beneficial effects. Nitrofurantoin has potential for pulmonary toxicity; avoid long term use.

123a: *Check for valid indication for use of antibacterials; No valid indication = 1, Valid indication = 0.*

Check for antibacterials (systemic) by making variable (J01) in SPSS. For residents using these, visually check for diagnoses that can justify use, e.g. bacterial infections, or conditions putting resident at risk of bacterial infection.

123b: *Check for long term use (>3 weeks) of nitrofurantoin; Over 3 weeks = 1, Under 3 weeks = 0.*

Make variable for nitrofurantoin by counting the number 138 in 'Medicine_1new … Medicine_20new' in SPSS. For residents using these, check for evidence of long term use in medical records.

124: Antifungals: When a course of treatment of appropriate length has been finished, do not continue indefinitely e.g. oral and topical nystatin.

Check for long term use (>3 weeks) of antifungals with no valid indication; No valid indication = 1, Valid indication = 0.

Make variable for antifungals (oral + topical) by counting the numbers 52, 90, 91, 106, 130 and 139 in 'Medicine_1new … Medicine_20new' in SPSS. For residents using these, visually check for evidence of long term use (>3 weeks) and no valid indication in medical records. The following drugs are listed as antifungals in BNF:

Amorolfine
Amphotericin
Benzoic acid
Caspofungin
Clotrimazole (52 + 90)
Econazole nitrate
Fluconazole
Flucytosine

Griseofulvin
Itrakonazole
Ketoconazole (106)
Miconazole nitrate (130 + 91)
Nystatin (139)
Posaconazole
Salicylic acid
Suloconazole nitrate
Terbinafine
Tioconazole
Undecenoates
Voriconazole

125: Bisphosphonates: Check if there is a valid indication for prescribing.

Check for valid indication for use of bisphosphonates; No valid indication = 1, Valid indication = 0.

Make variable for bisphosphonates (M05BA) in SPSS. For residents using these, visually check for diagnoses that can justify use in medical records. The following diagnoses have by the researchers been identified as valid indications:

Osteoporosis
Paget's disease of bone

126: Alpha blockers: Check if there is a valid indication for prescribing.

Check for valid indication for use of alpha blockers; No valid indication = 1, Valid indication = 0.

Make variable for alpha blockers (G04CA + C02CA) in SPSS. For residents using these, visually check for diagnoses that can justify use in medical records. The following diagnoses have by the researchers been identified as valid indications:

Hyperplasia of prostate
Overactive bladder

127: Antimuscarinics (for bladder/urinary tract symptoms): Check if there is a valid indication for prescribing.

Check for valid indication for use of antimuscarinics for bladder/urinary tract symptoms; No valid indication = 1, Valid indication = 0.

Make variable for antimuscarinics (G04BD) in SPSS (no one in our population uses propantheline). For residents using these, visually check for a diagnosis that can justify use in

their medical records. The following diagnoses have by the researchers been identified as valid indications:

Incontinence
Overactive bladder

128: NSAIDs: Check if there is a valid indication for prescribing. Is an NSAID still needed/appropriate e.g. long term treatment of gout but no prophylaxis prescribed? If topical NSAIDs are continued indefinitely, review the need for use; short courses are generally advised.

128a: *Check for valid indication for use of oral NSAIDs; No valid indication = 1, Valid indication = 0.*

Check for NSAIDs (oral only) by using variable from 102 (M01A + N02BA) in SPSS. For residents receiving these, visually check for a diagnosis that can justify use in their medical records. NB! If used for long-term treatment, GI prophylaxis should also be prescribed! The following diagnoses have by the researchers been identified as valid indications:

Gout
Musculoskeletal diseases (not specified)

128b: *Check for topical NSAIDs as long term therapy (>3 months); Yes = 1, No = 0.*

Make variable for NSAIDs (topical only) (M02AA) in SPSS. For residents receiving these, visually check for long term use (>3 months) in their medical records (preparations prescribed prn are considered short term use).

129: Skeletal muscle relaxants: Often poorly tolerated because of anticholinergic adverse effects, sedation, risk of fracture, avoid use.

Check use of skeletal muscle relaxants; Yes = 1, No = 0. (even if valid indication!)

Make variable (SMR) in SPSS by counting the numbers 19 and 164 in 'Medicine_1new … Medicine_20new' in SPSS. The following drugs are listed as skeletal muscle relaxants in BNF:

Baclofen (19)
Carisoprodol (not prescribed)
Dantrolene (not prescribed)
Diazepam (not prescribed)
Methacarbamol (not prescribed)
Quinine (164)
Tizanidine (not prescribed)

130: Sodium, potassium & iron supplements: Check if there is a valid indication for prescribing.

Check for valid indication for use of sodium, potassium & iron supplements; No valid indication = 1, Valid indication = 0.

Make variable (Na_K_Fe) by counting the numbers 71, 72, 73 and 157 in 'Medicine_1new … Medicine_20new' in SPSS. For residents receiving these, visually check for valid indication in their medical records. The following diagnoses have by the researchers been identified as valid indications. The following diagnoses have by the researchers been identified as valid indications:

Anaemia
Vitamin B12 deficiency

131: Vitamins: Check if there is a valid indication for prescribing, e.g. does the patient have a disorder which requires vitamin & mineral supplements.

Check for valid indication for use of vitamins; No valid indication = 1, Valid indication = 0.

Make variable (Vitamins) by counting the numbers 15, 79, 92, 134 and 191 in 'Medicine_1new … Medicine_20new' in SPSS. For residents receiving these, visually check for valid indication in their medical records, e.g. 'vitamin/mineral deficiency' or use of methotrexate if receiving folic acid.

132: Eye drops/ointments: Have antibiotic preparations been continued without a review or stop date?

Check for long term use of antibiotic preparations without valid indication; No valid indication = 1, Valid indication = 0.

Visually check for antibiotic preparations for eye. If found, check for evidence of valid diagnosis, e.g. bacterial infections.

133: Ear, nose and oropharynx: Drops, sprays, solutions etc.: Have antibiotic / steroid / sympathomimetic preparations been continued without a review or stop date?

Check for long term use of antibiotic / steroid / sympathomimetic preparations without valid indication; No valid indication = 1, Valid indication = 0.

Visually check for antibiotic / steroid / sympathomimetic preparations for ear, nose and oropharynx. If found, check for evidence of valid diagnosis, e.g. bacterial infections etc.

134: Skin: Creams, ointments: Has the condition resolved and continued use may cause adverse effects or exacerbate the condition e.g. preparations containing antibacterials or corticosteroids?

Appendix 7. Codebook deprescribing criteria + attachments, Study II

Check for antibiotic / steroid preparations without valid indication; No valid indication = 1, Valid indication = 0.

Visually check for antibiotic / steroid preparations for skin. If found, check for evidence of valid diagnosis, e.g. bacterial infections, skin disorders.

Category 2: Inappropriate dosage of drugs

201: Spironolactone: If dose >25 mg/day, the risk of hyperkalaemia is higher in older adults with heart failure.

Check for dose of spironolactone >25mg/day in residents with heart failure; Yes = 1, No = 0.

In SPSS make variable for spironolactone (C03DA01), and check for heart failure by making variable for heart failure, counting the number 84 in 'Classified condition 1-16' in SPSS. Combine these two to check if any residents with heart failure receive spironolactone. For residents with this combination, visually check for doses >25mg/day in medical records.

202: Aspirin: Is a dose of >150 mg/day being used for a cardiovascular indication?

Check for dose of aspirin >150mg/day; Yes = 1, No = 0.

Check which residents are prescribed aspirin (B01AC06) in SPSS. Then visually check each of these resident's dose of aspirin in the medical records.

203: Digoxin: Long-term digoxin at >125 mcg/day in patient with impaired renal function can lead to an increased risk of toxicity.

Check for dose of digoxin >125mcg/day in residents with renal failure; Yes = 1, No = 0.

Check for digoxin by making variable (C01AA05) in SPSS. For residents receiving this, visually check for diagnosis of renal failure in medical records. If combination is found, check dose visually.

Category 3: Inappropriate drug-drug combinations

301: Antipsychotics: Are chlorpromazine or trifluoperazine being taken with other medicines that have anticholinergic activity and can increase risk of cognitive impairment e.g. TCADs, oxybutynin, chlorphenamine?

Check for combination of antipsychotics (on anticholinergic list) with other anticholinergic drugs; Yes = 1, No = 0.

Make variable (N05A_anticholinergic) by counting the numbers 140, 163 and 167 in 'Medicine_1new … Medicine_20new' in SPSS. Make variable for anticholinergic drugs in general according to list (see other document). Combine the two variables, and visually check for duplicates in medical records. Antipsychotics with anticholinergic effect according to list:

Chlorpromazine
Clozapine
Fluphenazine
Haloperidol
Levomepromazine
Lithium
Olanzapine (140)
Pimozide
Prochlorperazine
Promazine
Quetiapine (163)
Risperidone (167)

302: Antidepressants: Are TCADs being taken with other medicines that have anticholinergic activity and can increase risk of cognitive impairment e.g. chlorpromazine, oxybutynin, chlorphenamine? Reduce dose of antidepressants gradually to avoid withdrawal effects.

Check for combination of antidepressants (on anticholinergic list) with other anticholinergic drugs; Yes = 1, No = 0.

Make variable (N06A_anticholinergic) by counting the numbers 10, 46, 65, 78, 131, 148 and 186 in 'Medicine_1new … Medicine_20new' in SPSS. Combine with variable for anticholinergic drugs in general according to list (see other document), and visually check for duplicates in medical records. Antidepressants with anticholinergic effect according to list:

Amitriptyline (10)
Citalopram (46)
Clomipramine
Dosulepin (65)
Doxepin
Fluoxetine (78)
Fluvoxamine

Imipramine
Mirtazapine (131)
Nortriptyline
Paroxetine (148)
Phenelzine
Trazodone (186)
Trimipramine

303: Antimuscarinics (for bladder/urinary tract symptoms): Are antimuscarinics being taken with other medicines that have anticholinergic activity and can increase risk of cognitive impairment e.g. chlorpromazine, TCADs, chlorphenamine?

Check for combination of antimuscarinics for bladder/urinary tract symptoms (on anticholinergic list) with other anticholinergic drugs; Yes = 1, No = 0.

Make variable (G04BD_anticholinergic) by counting the numbers 144 and 184 in 'Medicine_1new … Medicine_20new' in SPSS. Combine with variable for anticholinergic drugs in general according to list (see other document), and visually check for duplicates in medical records. Antimuscarinics with anticholinergic effect according to list:

Darifenacin
Flavoxate
Oxybutynin (144)
Tolterodine (184)

Category 4: Inappropriate drug-disease combinations

401: Antidepressants: Do the known possible adverse drug reactions outweigh the possible benefits? E.g. TCADs can worsen dementia, glaucoma, constipation, urinary retention; SSRIs may induce clinically significant hyponatremia.

Check for use of TCADs in residents with diagnoses of dementia, glaucoma, constipation or urinary retention; Yes = 1, No = 0.

Make variable for TCADs (N06AA) in SPSS. Also check for drugs related to TCADs (mianserin, trazodone) (N06AX03 + N06AX05). For residents using these, visually check for evidence of diagnoses that could worsen from use. The following diagnoses have by the researchers been visually searched for:

Constipation
Dementia
Glaucoma
Urinary retention (or related diagnoses, e.g. BPH)

402: Antimuscarinics (for bladder/urinary tract symptoms): Do the known possible adverse drug reactions outweigh the possible benefits? E.g. postural hypotension, urinary retention, constipation. Oxybutynin will decrease MMSE score in patients with dementia.

402a: *Check for use of antimuscarinics for bladder/urinary tract symptoms in residents with diagnoses of hypotension, urinary retention or constipation; Yes = 1, No = 0.*

Visually check if any resident receiving antimuscarinics for bladder/urinary tract symptoms have diagnoses that could worsen from use. The following diagnoses have by the researchers been visually searched for:

Constipation
Hypotension
Urinary retention (or related diagnoses, e.g. BPH)

402b: *Check for use of oxybutynin in residents with dementia; Yes = 1, No = 0.*

Visually check if any resident receiving oxybutynin have a diagnosis of dementia in their medical records.

403: NSAIDs: Do the known possible adverse drug reactions outweigh the possible benefits e.g. use in patients with severe hypertension/heart failure/chronic renal failure.

Check for use of oral NSAIDs in residents with heart failure or chronic renal failure; Yes = 1, No = 0.

Appendix 7. Codebook deprescribing criteria + attachments, Study II

Check which residents use oral NSAIDs (M01A + N02BA) in SPSS. For residents receiving these, visually check for a diagnosis that may contra-indicate use in their medical records, e.g. heart failure or chronic renal failure.

OSAMU criteria not applied

Antihypertensives - ACE inhibitors, beta blockers, A2RB, diuretics, calcium channel blockers: Check if there is a valid indication for prescribing, is the BP at a normal level or too low? Do the known possible adverse drug reactions outweigh the possible benefits e.g. orthostatic hypotension, CNS effects, risk of falls, loop diuretic for ancle oedema – would compression hosiery be more appropriate?

Limited access to clinical data, need to make too many assumptions to evaluate.

Statins: Stop in metastatic disease.

Do not have access to data that can tell whether resident has metastatic disease.

Anticoagulants – oral and injected: Are LMWHs/oral anticoagulants prescribed following hip/knee replacement surgery still required? Stop warfarin if the risk of falls outweighs the benefits. Long term warfarin use (>6 months) is not recommended when the VTE was provoked by surgery, non-surgical trigger factors or the VTE occurred in the calf only.

Limited access to clinical data, unable to evaluate.

Peripheral vasodilators: Check if there is a valid indication for prescribing. Clinical effectiveness often not established. Do the known possible adverse drug reactions outweigh the possible benefits?

Peripheral vasodilators are not prescribed in our population.

Inhaled corticosteroids: In asthma – review every 3 months, has control been achieved, if yes; reduce dose slowly (by 50% every 3 months). In COPD – if an inhaled corticosteroid is not appropriate, a long acting abtimuscarinic bronchodilator can be used with a long acting beta2 agonist.

No access to clinical data that is needed to evaluate this.

Benzodiazepines (including 'Z' drugs): Is use required if physical and psychological health and personal circumstances are stable? If the patient is willing, committed and compliant, and has adequate social support, refer to a withdrawal clinic.

No access to the information necessary to evaluate this.

Drugs for dementia: If MMSE <10, medicines may be continued if they help with behavior. NICE recommends memantine if MMSE <10. Review benefit, use should only continue if the MMSE score is ≥10 and treatment has an effect on the global, functional or behavioural symptoms.

No access to MMSE scores.

Appendix 7. Codebook deprescribing criteria + attachments, Study II

Antibacterials: Nitrofurantoin, lack of efficacy in patients with CrCl <60 ml/min due to inadequate drug concentration in the urine.

No access to clinical data that is needed to evaluate this.

Oestrogens ± progestogens: There is no mandatory limitation on the duration of HRT. Whether or not to continue therapy is dependent on an objective estimation on ongoing benefits and risks. Evidence of carcinogenic potential in breast and endometrium, lack of cardioprotective effect and cognitive protection in older women. Topical low dose oestrogen intravaginal cream safe and effective for dyspareunia and other vaginal symptoms.

Not complete access to all information needed to make this evaluation.

Bisphosphonates: Has treatment been taken for 5 years or more? Do the known possible adverse drug reactions outweigh the possible benefits? If the patient is at low risk of falls, are these still needed? Prolonged immobility is a risk factor for BMD.

Do not have access to information necessary to evaluate this.

Alpha blockers: Use is generally not indicated if a patient has a long term (>2 months) catheter in situ.

Do not have access to information necessary to evaluate this.

Antimuscarinics (for bladder/urinary tract symptoms): Check if continence pads are also used, is concomitant use necessary?

Do not have access to information necessary to evaluate this.

Cytotoxics, immunosuppressants: What outcome is expected, do the known possible adverse drug reactions outweigh the possible benefits? Refer to doctor who initiated treatment.

Do not have access to information necessary to evaluate this.

Calcium + vitamin D: Does the patient have adequate levels through diet/sunlight exposure? If the patient is not mobile, is this still needed?

Do not have access to information necessary to evaluate this.

Sip feeds: Check if there is a valid indication for prescribing. Has a dietician recently reviewed the patient; is the patient able to prepare, or have someone else prepare fortified food and therefore does not need sip feeds.

Do not have access to information necessary to evaluate this.

DMARDs: Discontinue penicillamine if there is no improvement within 1 year. Consider withdrawal of azathioprine and ciclosporin if there is no improvement within 3 months of use. Refer to doctor who initiated treatment.

Do not have access to information necessary to evaluate this.

TNF inhibitors: Psoriatic arthritis/Ankylosing spondylitis – discontinue adalimumab, etanercept and infliximab if there is inadequate response after 12 weeks. Rheumatoid arthritis/Juvenile idiopathic arthritis – withdraw adalimumab, etanercept and infliximab if response is not adequate within 6 months.

Do not have access to information necessary to evaluate this.

Eye drops/ointments: Review need for preservative free eye drops – is there a valid indication for prescribing (e.g. previous preservative toxicity), are eye drops instilled more than 4 times per day?

Do not have access to information necessary to evaluate this.

Creams, ointments: Is the patient using sufficient emollient to avoid use of steroids or development of ulcers?

Do not have access to information necessary to evaluate this.

Dressings: Wounds should be reviewed before prescribing to ensure correct dressing chosen. Chronic wounds change over time – refer difficult to treat wounds to a tissue viability nurse. Wounds should reduce in size over time. Address underlying problems e.g. soiling from incontinence, wrong choice of dressing etc. Larger dressings are more expensive than the smaller sizes. Query large size dressings on repeat prescriptions. Query quantities over 10 units per month, most dressings can stay in place for 3-5 days except on infected wounds, although some patients may have multiple wound sites. Avoid waste – prescribe the actual number of dressings needed rather than "1OP".

Not relevant.

Appendix 7. Codebook deprescribing criteria + attachments, Study II

Attachment 1. Generic names of medicines prescribed in our population

1 Alendronic acid
2 Alfuzosin hydrochloride
3 Alginate
4 Aliskiren
5 Allopurinol
6 Alverine citrate
7 Amiloride + furosemide
8 Amiodarone
9 Amisulpride
10 Amitriptyline
11 Amlodipine
12 Amoxicillin
13 Amoxicillin + clavulanic acid
14 Anastrozole
15 Ascorbic acid (vit C)
16 Aspirin
17 Atenolol
18 Atorvastatin
19 Baclofen
20 Barrier preparation
21 Beclomethasone dipropionate
22 Beclomethasone + formoterol
23 Bendroflumethiazide
24 Benzerazide hydrochloride + levodopa
25 Betamethasone dipropionate
26 Betamethasone valerate
27 Betamethasone valerate + fusidic acid
28 Bimatoprost
29 Bisoprolol
30 Brimonidine
31 Budesonide
32 Bumetanide
33 Buprenorphine
34 Calcium+vitD
35 Calcipotriol + betamethasone
36 Candesartan
37 Carbidopa + levodopa
38 Carbimazole
39 Carbomer 980 (eye lubricant)
40 Carmellose sodium (eye lubricant)
41 Carvedilol
42 Cefradine
43 Cetirizine
44 Cinchocaine hydrochloride + fluocortolone

45 Cinchocaine hydrochloride + prednisolone
46 Citalopram
47 Clobetasol propionate
48 Clobetasone butyrate
49 Clonazepam
50 Clopidogrel
51 Cloral betaine
52 Clotrimazole
53 Coal tar
54 Codeine + paracetamol
55 Codeine
56 Crotamiton
57 Diclofenac
58 Digoxin
59 Dihydrocodeine tartrate
60 Diltiazem
61 Dipyridamole
62 Disodium etidronate
63 Domperidone
64 Donepezil
65 Dosulepin hydrochloride
66 Doxazosin
67 Emollient
68 Enalapril maleate
69 Felbinac
70 Fentanyl
71 Ferrous fumarate
72 Ferrous gluconate
73 Ferrous sulphate
74 Fexofenadine
75 Finasteride
76 Flecainide
77 Fluticasone propionate
78 Fluoxetine
79 Folic acid
80 Foods
81 Furosemide
82 Gabapentin
83 Galantamine
84 Gliclazide
85 Glimepiride
86 Glipizide
87 Glucose
88 Glyceryl trinitrate
89 Hydrocortisone topical
90 Hydrocortisone + clotrimazole topical

91 Hydrocortisone + miconazole topical
92 Hydroxocobalamin (vit B12)
93 Hyoscine
94 Hypromellose (eye lubricant)
95 Ibuprofen
96 Indoramin
97 Insulin (human)
98 Insulin aspart
99 Insulin detemir
100 Insulin glargine
101 Insulin lispro
102 Ipratropiumbromid
103 Isosorbide dinitrate
104 Isosorbide mononitrate
105 Isphagula husk
106 Ketokonazole (coal tar) shampoo
107 Ketoprofen
108 Lactulose
109 Lansoprazole
110 Latanoprost
111 Latanoprost + timolol
112 Lercanidipine
113 Leuprorelin
114 Levetiracetam
115 Levothyroxine
116 Liquid paraffin
117 Liquid paraffin (eye lubricant)
118 Lisinopril
119 Loperamide
120 Loratadine
121 Lorazepam
122 Macrogol
123 Magnesium salt + liquid paraffin
124 Mebeverine hydrochloride
125 Meptazinol
126 Metformin
127 Methotrexate
128 Metoclopramide
129 Metoprolol tartrate
130 Miconazole
131 Mirtazapine
132 Mometasone furoate
133 Morphine
134 Multivitamin
135 Nicorandil
136 Nifedipine

137 Nitrazepam
138 Nitrofurantoin
139 Nystatin
140 Olanzapine
141 Olive oil
142 Olmesartan
143 Omeprazole
144 Oxybutynin
145 Oxycodone
146 Pantoprazole
147 Paracetamol
148 Paroxetine
149 Peppermint oil
150 Pericyazine
151 Perindopril
152 Permethrin
153 Phenytoin
154 Pioglitazone
155 Piroxicam topical
156 Polyvinyl alcohol (eye lubricant)
157 Potassium chloride
158 Pravastatin
159 Prednisolone
160 Procyclidine
161 Propranolol
162 Propylthiouracil
163 Quetiapine
164 Quinine
165 Ramipril
166 Ranitidine
167 Risperidone
168 Salbutamol
169 Salmeterol
170 Senna
171 Silver sulfadiazine
172 Simvastatin
173 Sodium chloride topical
174 Sodium citrate rectal
175 Sodium valproate
176 Sotalol
177 Spironolactone
178 Sterculia
179 Tamsulosin
180 Temazepam
181 Theophylline
182 Tiotropium

183 Tolbutamide
184 Tolterodine
185 Tramadol hydrochloride
186 Trazodone
187 Trimethoprim
188 Venlafaxine
189 Warfarin sodium
190 Zuclopenthixol
191 Zinc sulphate
192 Zolpidem
193 Zopiclone
194 Missing

Attachment 2. Anticholinergic medicines UK.

High-potency anticholinergics

Generic name	ATC code
Amitriptyline	N06AA09
Atropine	A03BA01
Belladonna alkaloids	A03BA04
Benzatropine	N04AC01
Chlorphenamine	R06AB04
Chlorpromazine	N05AA01
Clemastine	R06AA04
Clomipramine	N06AA04
Clozapine	N05AH02
Cyproheptadine	R06AX02
Darifenacin	G04BD10
Dicyclomine/Dicycloverine	A03AA07
Diphenhydramine	R06AA02
Doxepin	N06AA12
Flavoxate	G04BD02
Fluphenazine	N05AB02
Homatropine	S01FA05
Hydroxyzine	N05BB01
Imipramine	N06AA02
Ipratropium	R03BB01
Levomepromazine	N05AA02
Nortriptyline	N06AA10
Orphenadrine	N04AB02
Oxybutynin	G04BD07
Procyclidine	N04AA04
Promethazine	R06AD02
Propantheline	A03AB05
Scopolamine (Hyoscine)	A04AD01
Tizanidine	M03BX02
Tolterodine	G04BD07
Trihexylphenidyl	N04AA01
Trimipramine	N06AA06

Both lists based on Duran CE et al (2013). "Systematic review of anticholinergic risk scales in older adults." Eur J Clin Pharmacol 69(7): 1485-1496.

Low-potency anticholinergics

Generic name	ATC code
Alimemazine	R06AD01
Amantadine	N04BB01
Baclofen	M03BX01
Bromocriptine	N04BC01
Carbamazepine	N03AF01
Cetirizine	R06AE07
Chlordiazepoxide	N05BA02
Cimetidine	A02BA01
Citalopram	N06AB04
Clonazepam	N03AE01
Codeine	R05DA04
Diazepam	N05BA01
Digitoxin	C01AA04
Disopyramide	C01BA03
Domperidone	A03FA03
Dosulepin	N06AA16
Entacapone	N04BX02
Fentanyl	N02AB03
Fexofenadine	R06AX26
Fluoxetine	N06AB03
Fluvoxamine	N06AB08
Haloperidol	N05AD01
Ketorolac	M01AB15
Lithium	N05AN01
Loperamide	A07DA03
Loratadine	R06AX13
Methadone	N07BC02
Methocarbamol	M03BA03
Mirtazapine	N06AX11
Morphine	N02AA01
Olanzapine	N05AH03
Oxcarbazepine	N03AF02
Oxycodone	N02AA05
Paroxetine	N06AB05
Phenelzine	N06AF03
Pimozide	N05AG02
Prochlorperazine	N05AB04
Promazine	N05AA03
Quetiapine (fumarate)	N05AH04
Ranitidine	A02BA02
Risperidone	N05AX08
Temazepam	N05CD07
Theophylline	R03DA04
Tramadol	N02AX02
Trazodone	N06AX05

Attachment 3. List of anticholinergic medicines prescribed in our population

No	Generic name	Potency
10	Amitriptyline	H
19	Baclofen	L
43	Cetirizine	L
46	Citalopram	L
49	Clonazepam	L
54	Codeine + paracetamol	L
55	Codeine	L
63	Domperidone	L
65	Dosulepin hydrochloride	L
70	Fentanyl	L
74	Fexofenadine	L
78	Fluoxetine	L
93	Hyoscine	H
102	Ipratropiumbromid	H
119	Loperamide	L
120	Loratadine	L
131	Mirtazapine	L
133	Morphine	L
140	Olanzapine	L
144	Oxybutynin	H
145	Oxycodone	L
148	Paroxetine	L
160	Procyclidine	H
163	Quetiapine	L
166	Ranitidine	L
167	Risperidone	L
180	Temazepam	L
181	Theophylline	L
184	Tolterodine	H
185	Tramadol hydrochloride	L
186	Trazodone	L

Appendix 7. Codebook deprescribing criteria + attachments, Study II

Attachment 4. Classified conditions, numbers and ICD.

No	Name	ICD 1	ICD 2	ICD 3
1	Cancer (neoplasms - other)			
2	Abnormal weight loss	R00-R99		
3	Acute bronchitis			
4	Aggressive personality			
5	Alcohol misuse			
6	Allergic rhinitis			
7	Alzheimer's disease	G00-G99	G30-G32	G30
8	Anaemia	D50-D89		
9	Angina	I00-I99	I20-I25	I20
10	Anxiety	F00-F99	F40-F48	
11	Anxiety with depression	F00-F99	F40-F48	
12	Aortic aneurysm	I00-I99	I70-I79	I71
13	Aortic valve disorder	I00-I99	I30-I52	
14	Apnoea	G00-G99	G40-G47	
15	Arteritis			
16	Arthropathy	M00-M99	M00-M25	
17	Asthma	J00-J99	J40-J47	J45
18	Atrial fibrillation and flutter	I00-I99	I30-I52	I48
19	Back pain (dorsalgia)	M00-M99	M40-M54	M54
20	Barrett's oesophagus	K00-K93	K20-K31	K22
21	Behavioural management			
22	Bone pain			
23	Bronchiectasis			
24	Bronchitis (recurrent)			
25	Cancer (neoplasms - benign)			
26	Cancer (neoplasms - in situ)			
27	Cancer (neoplasms - malignant)	C00-D48	C00-C97	
28	Cancer (neoplasms - unknown behaviour)	C00-D48	D37-D48	
29	Candidal intertrigo	A00-B99	B35-B49	
30	Candidal vulvovaginitis	A00-B99	B35-B49	
31	Cardiac enlargement	I00-I99	I30-I52	I51
32	Cardiac pacemaker	Z00-Z99	Z80-Z99	Z95
33	Carpal tunnel syndrome			
34	Cellulitis	L00-L99	L00-L08	L03
35	Cerebral atrophy			
36	Cerebrovascular disease	I00-I99	I60-I69	
37	Cervical myelopathy & cord compression			
38	Chest infection			
39	Cholesterol	E00-E90	E70-E90	E78
40	Chondrocalcinosis			

41	Cirrhosis of liver	K00-K93	K70-K77	
42	Coeliac disease	K99-K93	K90-K93	
43	Congenital malformations			
44	Constipation	K00-K93	K59	K59.0
45	COPD	J00-J99	J40-J47	J44
46	Coronary artery disease			
47	Cryptogenic fibrosing alveolities			
48	Cystitis			
49	Degeneration of lumbar spine			
50	Dementia	F00-F99	F00-F09	
51	Depression	F00-F99	F30-F39	
52	Depression (recurrent)			
53	Dermatitis	L00-L99	L20-L30	
54	Diabetes Mellitus (Type 1)	E00-E99	E10-E-14	E10
55	Diabetes Mellitus (Type 2)	E00-E90	E10-E14	E11
56	Diplegia/Hemiplegia			
57	Diverticular disease	K00-K93	K55-K63	K57
58	Duodenal ulcer			
59	DVT	I00-I99	I80-I89	
60	Ear problems	H60-H95		
61	Eczema	L00-L99	L20-L30	L20
62	Electrolyte disorders (eg sodium, potassium)	E00-E90	E70-E90	E87
63	Emphysema	J00-J99	J40-J47	J43
64	Endocrine disorders (other)	E00-E90	E20-E35	
65	Epilepsy	G00-G99	G40-G47	G40
66	Excessive salivation			
67	Factor VIII inhibtor activity			
68	Fractures	S00-T98		
69	Gall bladder, biliary tract and pancreas	K00-K93	K80-K87	
70	Gastric haemorrhage	K00-K93	K90-K93	
71	Gastric ulcer			
72	Gastritis and duodenitis			
73	Gastro-oesophageal reflux	K00-K93	K20-K31	K21
74	Giant cell arteritis	M00-M99	M30-M36	
75	Gout	M00-M99	M05-M14	M10
76	Haematemesis			
77	Haematoma			
78	Haematuria (recurrent & persistent)	N00-N99	N00-N08	
79	Haemopericardium			
80	Haemorrhoids	I00-I99	I80-I89	I84
81	Hay fever	J00-J99	J30-J39	J30
82	Heart block			
83	Heart defect (electrical)			

84	Heart failure	I00-I99	I30-I52	I50
85	Hemiplegia			
86	Hernia	K00-K93	K40-K46	
87	Herpes zoster			
88	Hiatus hernia	K00-K93	K40-K46	
89	Hydrocele			
90	Hydrocephalus			
91	Hyperplasia of prostate	N00-N99	N40-N51	N40
92	Hypertension	I00-I99	I10-I15	I10
93	Hypertensive heart disease	I00-I99	I10-I15	I11
94	Hyperthyroidism	E00-E90	E00-E07	
95	Hypopituitarism			
96	Hypotension	I00-I99	I95-I99	I95
97	Hypothyroidism	E00-E90	E00-E07	
98	Indigestion (dyspepsia)	K00-K93	K20-K31	K30
99	Inflammatory arthritis	M00-M99	M00-M25	
100	Injury and poisoning			
101	Insomnia	G00-G99	G40-G47	G47
102	Intentional self harm			
103	Interstitial lung disease			
104	Intestinal obstruction			
105	Intracerebral haemorrhage			
106	Intracranial haemmorrhage			
107	Irritable bladder			
108	Irritable bowel			
109	Ischaemic colitis			
110	Ischaemic heart diseases (IHD)	I00-I99	I20-I25	
111	Joint pain			
112	Kyphosis			
113	Lacerations			
114	Learning difficulties	F00-F99		
115	Lewy body dementia			
116	Lymphoedema (chronic)			
117	Metabolic disorders	E00-E90	E70-E90	
118	Microalbuminuria	R00-R99		
119	Migraine	G00-G99	G40-G47	G43
120	Mild cognitive disorder			
121	Mood (affective) disorders	F00-F99	F30-F39	
122	MRSA	L00-L99		
123	Multiple sclerosis			
124	Muscle contracture	M00-M99	M60-M63	
125	Myocardial infarction	I00-I99	I20-I25	I21
126	Nail disorders			

127	Nasal polyp	J00-J99	J30-J39	J33
128	Neuralgia			
129	Neutropenia			
130	Non-compliance			
131	Not specified			
132	Nutritional deficiencies	E00-E90	E50-E64	
133	Obesity	E00-E90	E64-E68	
134	Oesophagitis	K00-K93	K20-K31	K20
135	Oral thrush	A00-B99	B35-B49	
136	Organic amnesiac syndrome			
137	Osteoarthritis	M00-M99	M15-M19	M15
138	Osteoporosis	M00-M99	M80-M85	
139	Overactive bladder	N00-N99	N30-N39	
140	Paget's disease of bone	M00-M99	M80-M94	
141	Parkinson's disease	G00-G99	G20-G26	
142	Patulous oesophagus			
143	Pericardial effusion			
144	Peripheral vascular disease	I00-I99	I70-I79	I73
145	Personality disorder			
146	Phemphigoid			
147	Phimosis			
148	Phlebitis			
149	Pleural effusion			
150	Pleural plaque			
151	Pneumonia			
152	Polycythaemia			
153	Polymyalgia rheumatica	M00-M99	M30-M36	
154	Psychosis			
155	Pulmonary heart disease	I00-I99	I26-I28	
156	Rectal bleeding			
157	Rectal prolapse			
158	Recurrent UTIs	N00-N99	N30-N39	
159	Renal failure	N00-N99	N17-N19	N18
160	Respiratory failure			
161	Rheumatoid arthritis	M00-M99	M05-M14	
162	Schizophrenia	F00-F99		
163	Scoliosis			
164	Seizures	G00-G99	G40-G47	
165	Sepsis			
166	Shy drager syndromes			
167	Skin conditions	L00-L99		

168	Solar keratosis			
169	Spinal stenonsis			
170	Spinocerebellar disease	G00-G99	G10-G14	
171	Spondylosis	M00-M99	M40-M54	M45-M49
172	Stroke	I00-I99	I60-I69	
173	Sudek's atrophy	M00-M99	M80-M94	
174	Symptoms and signs not elsewhere classified	R0-R99		
175	Tachycardia			
176	Transient cerebral ischaemic attack	G00-G99	G40-G47	G45
177	Tricuspid regurgitation			
178	Ulcerative colitis	K00-K93	K50-K52	
179	Upper respiratory traction infection			
180	Urinary incontinence	R00-R99		
181	Urinary reflux			
182	Urinary tract infection	N00-N99	N30-N39	
183	Urosepsis			
184	Uterine prolapse			
185	Vaginal prolapse			
186	Varicose veins	I00-I99	I80-I89	I83
187	Vascular dementia	F00-F99	F00-F09	F01
188	Vasomotor rhinitis			
189	Venous insufficiency	I00-I99	I80-I89	
190	Vision impairment/eye conditions	H00-H59		
191	Missing			

Appendix 8. Interview guide, Study III.

Intervjuguide sjukepleiarar/helsefagarbeidarar

Introduksjonsspørsmål

Kva forbinder du med ordet blodsukkermåling?

Korleis føregår blodsukkermåling ved sjukeheimen du arbeidar?
Kven måler, har de mange pasientar som får målt blodsukker, er det pasientar som måler sjølve, kor ofte blir blodsukker målt

Nøkkelspørsmål 1: Årsak til måling

Fortel om sist gong du utførte ei blodsukkermåling – kva utløyste målinga?

Kva avgjer om måling skal gjerast (årsaker til måling: legemiddel, HbA1c-verdien, økonomi, ernæring, infeksjon, innkomst-målingar, screening)?

Kven og kva bestemmer hyppigheit av målingar? Når/kor ofte måler de?

Er det enkelte pasientar med diabetes som får ekstra oppfølging / ein tar ekstra omsyn til (i høve til legemiddelbruk (insulin, OAD), hjartesvikt, nyresvikt, KOLS, demens, smerte)? Korleis følgjer ein opp desse?

Finst individuelle planar for kvar enkelt pasient?

Nøkkelspørsmål 2: Kvalitet, dokumentasjon og kommunikasjon av resultat

Fortel kva som skjer med resultata av blodsukkermålingane?

Korleis dokumenterast målingane og resultatet og kor god er praksis for dette?

Korleis og med kven samhandlar/kommuniserer dykk om resultata (tilsette, pasientar, legen)? Kor ofte?

Kva blir konsekvensane av målingane? Kor ofte får målinga konsekvensar for pasientane / justering av behandling (også kost/mosjon, ikkje berre legemiddel)? Kva verdiar krev ikkje tiltak?

Kva rutinar eksisterer for når ein skal setje i verk tiltak / når ein skal kontakte lege? Settast eigne «grenser» for blodsukkerverdiar for når ein skal gjere dette?

Korleis vurderer de nytteverdien av målingane?

Er de trygg på resultata de får? Kvifor/kvifor ikkje? Korleis sikrar dei kvaliteten på målingane?

Appendix 8. Interview guide, Study III.

Nøkkelspørsmål 3: Akuttsituasjonar

Fortel om ein gong du opplevde ein akuttsituasjon med høgt eller lågt blodsukker hjå ein pasient med diabetes.

Korleis kjenner de att ein akuttsituasjon? Pasientar som har høg risiko for føling eller høgt blodsukker?

Kva trening har de i å kjenne att hyperglykemi og hypoglykemi?

Korleis skil de mellom forventa høge verdiar (ein pasient som har blitt dårlegare), og uventa høge verdiar?

Kor ofte opplev de akuttsituasjonar?

Kva retningslinjer brukast i akuttsituasjonar? Er desse skriftlege og generelle, eller pasientspesifikke?

Kva tiltak finst for akuttsituasjonar, både på kort og lang sikt (særskilt om det er for høgt)? Er desse godt kjent? Er desse skriftlege og generelle, eller pasientspesifikke? Kven har utarbeida tiltak?

Kva blir gjort for å finne årsaka til akuttsituasjonen? Kva retningslinjer finst for dette?

Kva gjer de for å unngå akuttsituasjonar?

Kva andre problematiske situasjonar kan oppstå i samband med blodsukkermåling (t.d. pasientnekt)?

Nøkkelspørsmål 4: Opplæring

Fortel om kva opplæring du har fått innanfor diabetes og blodsukkermåling?

Kva opplæring har blitt gitt – om blodsukkermåling, om diabetes, om akuttsituasjonar? Når? Kor ofte? Kor mykje? Av kven?

Kven kan måle blodsukker og kva opplæring krevjast?

Kva ressursar eksisterer – diabetessjukepleiar, Noklus-kontakt, farmasøyt? Er det nokon hos dykk som er spesielt god på dette? Kven kan du spørje om du er usikker eller lurer på noko i samband med måling av blodsukker eller diabetes?

Kva opplæring er ønskja? Kven ønskjer de at skal gi denne?

Kva forventningar har de til legane?

Er sjukeheimen med i Noklus? Kva ønskjast frå Noklus?

Avslutning/Oppsummering

Alt i alt, føler de at vi har oppsummert dei viktigaste punkta i diskusjonen? Er det noko vi ikkje har fått drøfta, andre ting de har tenkt på?

Appendix 8. Interview guide, Study III.

Intervjuguide legar

Introduksjonsspørsmål

Kva forbinder du med ordet blodsukkermåling?

Korleis føregår blodsukkermåling ved sjukeheimen du arbeidar?
Kven måler, har de mange pasientar som får målt blodsukker, er det pasientar som måler sjølve, kor ofte blir blodsukker målt

Nøkkelspørsmål 1: Årsak til måling

Fortel om kva vurderingar du gjer i høve til om og når ein pasient med diabetes skal få målt blodsukker?

I kva situasjonar og på kva for nokre pasientar måler de blodsukker? Kvifor (legemiddel, økonomi, ernæring, infeksjon, innkomst-målingar, screening)?

Korleis speler HbA1c-verdien inn, og kor viktig opplev dykk blodsukkerverdiane i høve til HbA1c?

Pleiarane spør gjerne om det skal målast før eller etter alle måltid eller insulindosar – kva tenkjer de om dette? Er det tvil om når det skal målast?

Fortel om korleis de går fram når de lagar planar/ordinasjonar for måling av blodsukker. Finst individuelle planar for kvar enkelt pasient?

Korleis og kor ofte følgjer de opp planen/ordinasjonen for blodsukkermålingar? Blir denne følgt (hyppigheit av målingar? Når / kor ofte måler dei?)

Korleis følgjer de opp pasientane med diabetes som er eldre og skrøpelege (har tilleggsutfordringar som til dømes demens, hjartesvikt, nyresvikt, KOLS, smerte) i høve til behandlingsmål og målehyppigheit? Tenkjer over konsekvensar?

Kor strenge er de i høve til ernæring med tanke på målehyppigheit?

I kva grad opplev de at blodsukkermåling er ei belastning? For dykk sjølve, pleiarane og pasientane?

Nøkkelspørsmål 2: Kvalitet, dokumentasjon og kommunikasjon av resultat

Fortel kva som skjer med resultata av blodsukkermålingane?

Korleis dokumenterer de målingane og resultatet og kor god er praksis hos dykk for dette? (Pleiarane seier at dei passar på kvarandre slik at det blir dokumentert «før eller seinare» - kva er dykkar erfaring?)

Kva med pasientar som måler sjølve – kva skjer med desse målingane?

Korleis og med kven samhandlar/kommuniserer dykk om resultata? Kor ofte?

Fortel om kva konsekvensar resultata av målingane får hoss dykk? Kor ofte får målinga konsekvensar for pasientane / justering av behandling (også kost/mosjon, ikkje berre legemiddel)?

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Fortel om kva rutinar som eksisterer hos dykk for når ein skal setje i verk tiltak / når ein skal kontakte lege? Settast eigne «grenser» for blodsukkerverdiar for når ein skal gjere dette (individuelt eller generelt)? Kva verdiar krev ikkje tiltak?

Korleis vurderer de nytteverdien av målingane?

Er de trygg på resultata de får? Kvifor/kvifor ikkje? Korleis sikrar de kvaliteten på målingane?

Nøkkelspørsmål 3: Akuttsituasjonar

Fortel om ein gong du opplevde eller blei kontakta om ein akuttsituasjon med høgt eller lågt blodsukker hjå ein pasient med diabetes.

Kor ofte opplev de (å bli kontakta om) akuttsituasjonar på dykkar sjukeheim?

Kva opplev de oppstår oftast, hypoglykemi eller hyperglykemi? Korleis vurderer de dei ulike situasjonane?

Kva inntrykk har dykk av kva trening / erfaring pleiarane har i å kjenne att hyperglykemi og hypoglykemi?

Korleis skil de / pleiarane mellom forventa høge verdiar (pasient har blitt dårlegare), og uventa høge verdiar?

Fortel om kva retningslinjer dykkar sjukeheim brukar i akuttsituasjonar? Kven har utarbeida desse? Er desse skriftlege og generelle, eller pasientspesifikke? Er dei godt kjent? (pleiarane kjenner ikkje til slike).

Fortel om kva tiltak de gjer ved akuttsitasjonar, både på kort og lang sikt (særskilt om de er for høgt)?

Kva gjer de som legar for å finne årsaka til akuttsituasjonen? Har de retningslinjer for dette?

Kva strategiar har de eller sjukeheimen dykkar for å unngå akuttsituasjonar?

Fortel om de har opplevd å bli kontakta om andre problematiske situasjonar i samband med blodsukkermålingar?

Nøkkelspørsmål 4: Opplæring

Fortel om kva opplæring som finst og blir gitt innanfor diabetes og blodsukkermåling, ved din sjukeheim?

Kva opplæring har blitt gitt – om blodsukkermåling, om diabetes, om akuttsituasjonar? Når? Kor ofte? Kor mykje? Av kven?(Pleiarane fortalte at denne var usystematisk – kva er dykkar inntrykk?)

Kven kan måle blodsukker hos dykk og kva opplæring krevjast?

Kva ressursar eksisterer hos dykk – diabetessjukepleiar, Noklus-kontakt, farmasøyt? Er det nokon hos dykk som er spesielt god på dette? Kjenner de til fagprosedyren for diabetes i sjukeheimar og brukast denne?

Kva forventningar har de til pleiarane?

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Appendix 8. Interview guide, Study III.

Kva opplæring ønskjer de at pleiarane skal ha? Kven ønskjer de at skal gi denne? Kven skal ha ansvar for at denne blir gitt?Kva opplæring har de behov for sjølve??

Er sjukeheimen med i Noklus? Kva ønskjast frå Noklus?

Avslutning/Oppsummering

Alt i alt, føler de at vi har oppsummert dei viktigaste punkta i diskusjonen? Er det noko vi ikkje har fått drøfta, andre ting de har tenkt på?

Appendix 9. Information leaflet for focus group participants, Study III

Førespurnad om deltaking i prosjektet

Helsepersonell sine erfaringar, tankar og haldningar til blodsukkermålingspraksisar i sjukeheimar – ein kvalitativ studie

Bakgrunn og formål

Blodsukkermåling er eit verktøy innanfor diabetesomsorga som brukt riktig kan bidra til å gi informasjon om kor godt pasienten sin diabetes er kontrollert og på bakgrunn av dette optimalisere behandlinga. Det er gjort lite forsking blodsukkermålingspraksisar i sjukeheimar, og meir kunnskap trengs for å kunne vere trygg på at denne delen av diabetesomsorga møter behova til både pasientar og sjukeheimspersonell.

Formålet med denne studien er å undersøke erfaringar, tankar og haldningar til blodsukkermåling i sjukeheimar gjennom profesjonsspesifikke gruppeintervju med tilsette legar, sjukepleiarar og hjelpepleiarar/helsfagarbeidarar. Det er viktig at vi får ei betre forståing av dei ulike profesjonsgruppene sine perspektiv på blodsukkermålingspraksisar, då dei er involvert på ulike måtar i handteringa av og ansvaret for desse praksisane.

Kva inneber deltaking i studien?

Dersom du seier deg villig til å delta i studien vil dette innebere at du deltar på eit gruppeintervju saman med 4-7 andre helsearbeidarar frå same yrkesgruppe. Gruppeintervjua vil vare i 60-75 minutt [tidspunkt og stad]. Vi ha lett servering ved intervjuet og deltakarane vil òg motta eit gåvekort på 400 kr som takk for innsatsen.

Spørsmåla vil omhandle erfaring med og praktisk handtering av blodsukkermålingar, dokumentasjon, tolking og konsekvensar av resultat, og potensielle utfordringar for pasientar og/eller personalet. Vi vil ikkje stille spørsmål om eller be deg uttale deg om enkeltpasientar.

Stipendiaten og ein eller fleire av rettleiarane vil leie intervjuet. Intervjuet vil bli tatt opp på lydband, og forskarane vil òg ta støttenotater undervegs. Dette utgjer grunnlaget for seinare omsetjing av lydmaterialet til tekst. Opplysningane som kjem fram vil bli anonymisert, og opptaka vil bli sletta når studien er ferdig, seinast desember 2014. Ingen enkeltpersonar vil kunne kjenne seg igjen i den ferdige artikkelen, som vil bli publisert i eit internasjonalt helsetidsskrift.

Kva skjer med informasjonen om deg?

Opplysningar om namn, stilling, arbeidsstad og kontaktinformasjon vil bli behandla konfidensielt og ikkje bli kopla opp mot intervjumaterialet. Denne informasjonen vil vere

papirbasert, oppbevarast i ein låst skuff, berre vere tilgjengeleg for stipendiaten, og vil bli sletta straks etter intervjuet er ferdig.

Lydopptaka vil bli overførte til og krypterte på ein pc og ein ekstern harddisk direkte etter intervjuet er avslutta. Lydfilene på minnekorta i opptakarane vil deretter slettast, så snart vi har forsikra oss om at overføringa til pc og ekstern harddisk har vore vellukka. Vi må høyre gjennom lydopptaka for å sjekke dette. Lydopptaka vil berre vere tilgjengeleg for dei involverte forskarane i studien.

Frivillig deltaking

Deltakinga er frivillig og du kan trekkje deg når som helst undervegs, utan å måtte grunngje dette nærare.

Meir om studien

Studien er del av eit doktorgradsprosjekt om diabetesomsorg i sjukeheimar, som utførast ved Universitetet i Bergen (UiB). I tillegg til stipendiaten, Lillan Mo Andreassen, er følgjande personar involvert i prosjektet: Førsteamanuensis Reidun Kjome (hovudrettleiar, UiB), professor Sverre Sandberg (birettleiar, UiB og Noklus), førsteamanuensis Una Sølvik (birettleiar, UiB og Noklus), Gunn Kristensen (birettleiar, Noklus og NKK), og professor Anne Gerd Granås (ressursperson kvalitativ metode, Høgskolen i Oslo og Akershus).

Studien er ikkje søknadspliktig hjå Regional komité for medisinsk forskingsetikk (REK) eller hjå Norsk samfunnsvitskapleg datateneste (NSD), då vi ikkje samlar inn korkje helseopplysningar eller personopplysningar.

Dersom du ønskjer å delta, eller har spørsmål til studien, ta kontakt med Lillan Mo Andreassen på telefon 55 58 61 62, mobil 993 86 849, eller epost lan049@uib.no.

Appendix 10. The candidate's preconceptions, Study III

Bakgrunn for prosjekt og litt om eiga førforståing

Torsdag 09-01-2014:

I løpet av datainnsamlinga til Paper I, kor eg reiste rundt til ulike sjukeheimar på Vestlandet for å samle inn data om medisinsk behandling av diabetespasientar, skreiv eg ein feltlogg. Eg skreiv blant anna korleis eg opplevde besøket på sjukeheimen, og i samtalar med kontaktpersonane mine ved sjukeheimen og dei andre tilsette, kom det også fram ein del generelle opplysningar om diabetesomsorga ved kvar enkelt sjukeheim. Enkelte var veldig opptatt av å fortelje om kva dei hadde av retningslinjer og kunnskap, og kor opptatt dei var av dette området etc., medan andre fokuserte meir på kva som ikkje fungerte og uttrykte ønske om meir kunnskap, betre tilrettelegging, betre forståing av feltet etc. Sidan ein del av datainnsamlinga involverte deltakande observasjon av blodsukkermålingar ved sjukeheimen, blei sjølvsagt fokuset i feltloggen mykje retta mot dette (kva fungerte, kva var vanskeleg, korleis opplevdes det eigentleg), for å kunne ha eit tillegg til å supplere dei meir standardiserte skjema som eg brukte under observasjonen.

Eg fann eigentleg informasjonen om HbA1c-målingar mest interessant til å byrje med, fordi det verka som om praksisen for dette var den som var minst standardisert, og det var mulegvis på bakgrunn av dette at ideen om vidare utforsking av blodsukkermålingspraksis gjennom kvalitativ forskingsmetode kom i stand. På bakgrunn av det eg hadde sett, høyrt og blitt fortalt ila. feltarbeidet, i tillegg til kva eg hadde lest frå tidlegare i artiklar om blodsukkermålingspraksisar i sjukeheimar, satt eg igjen med inntrykket av at dette var eit område som hadde betra seg dei siste åra, særskilt i høve til førebuing og gjennomføring av målingane av pleiepersonalet (sjukepleiarar og hjelpepleiarar/helsefagarbeidarar). Samstundes fekk eg inntrykk av at det var lite refleksjon rundt kvifor enkelte pasientar fekk målt/ikkje målt, kor ofte dei fekk målt og kvifor ein gjorde det på dei tidspunkta ein gjorde det (for den enkelte pasient). Det verka meir som at blodsukkermåling var noko som var bestemt på avdelingsnivå heller enn på pasientnivå. Og det verka òg som om det var ein del av den daglege/vekevise rutina (på same måte som stell, frukost etc.), heller enn ei bevisst handling som hadde tydning for pasientens helse og sjukdomsoppfølging (med mindre verdien var svært unormal, og pasienten svært ustabil). Somme stader avdekka eg også brist i rutinane for dokumentasjon av resultata, og somme gonger blei resultata lagt inn i det elektroniske systemet når ein fekk tid seinare på dagen, men utan å korrigere tidspunktet i loggen. Somme stader var det også brist i rutinane for å innhente informasjon om HbA1c-verdien. Ein tok gjerne å kryssa av for HbA1c når ein likevel skulle ta blodprøver, men gløymde gjerne å få den tilbake frå legekontoret slik at den kunne leggast inn i journalen. No skal det seiast at eg ytterst sjeldan snakka med legen på staden, så det kan vere at HbA1c-verdiane blir sendt direkte til ho/han, men det mangla gjerne informasjon om dette i sjukeheimen/sjukepleiejournalen. Somme gonger verka det som om HbA1c-målingane var ei "legesak", medan dei vanlege kapillære blodsukkermålingane var ei "sjukepleiesak" fram til det eventuelt skjedde noko uvanleg.

Eg tar derfor meg sjølv i å lure, og dette er ein frykteleg fordom mot pleiepersonalet/sjukepleiarane, om desse verdiane berre blir rapportert om det skulle "vere noko", om legen faktisk får sjå sjølve målingane/verdiane, eller om det blir rapportert i ord som "stabilt", "inga endring", "jamnt nivå" etc.? Kor trygge er dei på dei verdiane dei får i målingane, og kor trygg er legen på at desse er riktige? Og er legen sjølv aktiv med å spørje etter verdiane, setje eigne mål for kvar enkelt pasient og gjere vurderingar utifrå funksjonsnivå, samtidig sjukdom, behandling (både diabetes og anna), ikkje berre når

pasienten kjem inn på sjukeheimen, men også undervegs? Og blir dette reflektert over blant pleiepersonalet, altså at "måleregime" til pasienten trengs å tilpassast både frå starten og undervegs? Og gir dei isåfall tilbakemelding til legen om dette? Mykje spørsmål rundt interaksjonen mellom lege-pleiepersonell når det gjeld oppfølging av pasienten altså. Kor ligg ansvaret, og kven kjenner på dette? Kunne det òg ha vore aktuelt å spørje om korleis dei vurderer måling/medisinsk behandling versus matrestriksjonar (som ikkje er anbefalt)? Blir dette for mykje? Kor mykje er det greit å inkludere, og kor like skal intervjuguidane til dei ulike helsepersonellgruppene vere?

Om eg skulle formulere kva eg trur på førehand, må det bli at ein har ei haldning om at sjukeheimspasientar med diabetes for det meste er stabile, og at bestemming av måling blir gjort på "systemnivå", altså generelt for avdelinga, med 1-2 dagar i veka/månaden "for syns skuld", og at ein er mindre bevisst på kliniske symptom som kan medføre at ein må måle oftare (i alle fall på pleienivå - særskilt hjelpepleiarar/helsefagarbeidarar). Eg trur ikkje pleiarane rapporterer nok særleg tilbake til legane om kor ofte ein bør måle/kva som er best for pasienten, eller kanskje berre dette ikkje er eit samtale-emne? Eg trur at det som regel eksisterer retningslinjer for sjølve målinga (teknisk sett), men at retningslinjer for kva for nokre pasientar, kor ofte, og vidare dokumentasjon av resultata (til dømes når ein skal varsle lege) finst i mindre grad/ er i mindre grad kjent/utarbeida. Eg trur også det er for stort fokus på hyperglykemi istadenfor hypoglykemi, og at ein i mindre grad reagerer på om blodsukkeret er litt lågt, men dette er mest i høve til HbA1c. Spørsmålet er om dette skal med i intervjuguiden til legane - altså spørsmål om vurdering av HbA1c-målingar (kva? kvifor? kor ofte? tolking/vurdering? kva er for høgt/for lågt?). Eg trur også at det ikkje reflekterast så mykje rundt kvifor ein gjer målingane og kva ein faktisk bruker resultata til. Når det gjeld belastning for pasientane trur eg pleiepersonalet er meir obs på dette enn legane. Eg trur også legane har ei haldning til at pasientane i hovudsak er stabile og at dei får tilbakemelding frå sjukepleiarane skulle det skje endringar, men kor bevisst er sjukepleiarane dette ansvaret? Eg trur sjukepleiarane og også hjelpepleiarane/helsefagarbeidarane tenkjer at dei får beskjed av legen dersom ein skal måle oftare. Eg trur somme sjukepleiarar har reflektert over kvalitetsbiten av sjølve målinga, men ikkje nødvendigvis at dei elles betraktar denne som problematisk. Legane vil gjerne ikkje betrakte kvaliteten på målingane som problematisk.

Errata for
Diabetes in care homes

Special emphasis on medicines and blood glucose measurements

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Thesis for the degree philosophiae doctor (PhD)
at the University of Bergen

26/8-19 Lillan Mo Andreas — (date and sign. of candidate)

02.09.2019 — (date and sign. of faculty)

Errata

Page 8 Numeric character replaced with numeral: "An HbA1c value the last 12 months was recorded for 77 % of residents, with a mean of 57 mmol/mol (7.3 %) and a range of 28-112 mmol/mol (4.7-12.4 %)." – corrected to "An HbA1c value the last twelve months was recorded for 77 % of residents, with a mean of 57 mmol/mol (7.3 %) and a range of 28-112 mmol/mol (4.7-12.4 %)."

Space missing: "Of the 67 PIMs in the 20% resident sample for validation" – corrected to "Of the 67 PIMs in the 20 % resident sample for validation".

Page 10 Page missing: A technical error resulted in the page containing the list of publications missing. This has been corrected.

Page 18 Information about permission missing in Figure 1: "Adapted from Chang AM, Halter JB. Aging and insulin secretion. Am J Physiol Endocrinol Metab 2003; 284(1): E7-12." – corrected to "Adapted with permission from Chang AM, Halter JB. Aging and insulin secretion. Am J Physiol Endocrinol Metab 2003; 284(1): E7-12."

Page 30 Wrong symbol used: "However, those aged <80 years, those with severe physical or cognitive impairment, or those with a life expectancy <12 months, are unlikely to benefit from statins (108)." – corrected to "However, those aged >80 years, those with severe physical or cognitive impairment, or those with life expectancy <12 months, are unlikely to benefit from statins (108)."

Page 32 Redundant character: "The ADA proposes block testing: - fasting/pre-prandial glucose measurements on some days, postprandial and bedtime glucose measurements on other days as a means to provide a pattern for glycaemic variability without multiple daily measurements (24)." – corrected to "The ADA proposes block testing: fasting/pre-prandial glucose measurements on some days, postprandial and bedtime glucose measurements on other days as a means to provide a pattern for glycaemic variability without multiple daily measurements (24)."

Page 36-8 Wrong formatting of page numbers: The layout of these three pages is in landscape orientation, thus the page numbers should be on the short side

Page 37 Redundant word and misspelling of a sentence in Table 5: "Avoid in if intestinal disorders and eGFR <25 ml/min/1.73 m^{2}" – corrected to "Avoid if intestinal disorders or eGFR<25 ml/min/1.73 m^{2}".

Page 44 Word missing: "Based on what we knew about DM prevalence in nursing homes from other European countries, we aimed to include a total population of a thousand residents to ensure a representative sample approximately 100 residents with DM." – corrected to "Based on what we knew about DM prevalence in nursing homes from other European countries, we aimed to include a total population of a thousand residents to ensure a representative sample of approximately 100 residents with DM."

Page 54 Space missing: "The most common diabetes treatment was OADs alone (n = 56), whilst only 14 residents (13%) were prescribed insulin." – corrected to "The most common diabetes treatment was OADs alone (n = 56), whilst only 14 residents (13 %) were prescribed insulin."

Page 56 Text missing from Table 8: "Table 8 continued" – corrected to "Table 8 continued. Main findings from Study III".

Page 65 Word missing: "ADA and IDF guidelines emphasise care home residents' vulnerability to hypoglycaemia (24, 101, 108)." – corrected to "The ADA and IDF guidelines emphasise care home residents' vulnerability to hypoglycaemia (24, 101, 108)."

Page 66 Misspelling: "As an HbA1c level <53 mmol/mol (7.0 %) has been shown to increase the risk of hypoglycaemia and other unfavourable events in older patients (115, 116), this has been proprosed as a threshold measure of possible overtreatment (35, 108)." – corrected to "As an HbA1c level <53 mmol/mol (7.0 %) has been shown to increase the risk of hypoglycaemia and other unfavourable events in older patients (115, 116), this has been proposed as a threshold measure of possible overtreatment (35, 108)."

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