

## TOWARDS A MINIMUM DATA SET FOR INTERVENTION STUDIES IN TYPE 2 DIABETES IN OLDER PEOPLE

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### Introduction and setting the scene

Type 2 diabetes mellitus is a common disabling chronic medical disorder which has a tremendous health, social and economic burden (1), and has a high prevalence across Europe of 10-30% of subjects above 65 years of age (2). Diabetes in the elderly is now seen conceptually as a preventable condition, a syndrome of insulin resistance, with more than two thirds of subjects having features of the metabolic syndrome at the time of diagnosis, and as a cardiovascular disorder (3). Acute care hospitalisations account for about 60% of the total expenditure on this special group (4) and compared with non-diabetic counterparts, the relative risk for admission to hospital is 5.0.

It is projected that by 2010, the number of diabetic individuals in the world will reach the number of 221 million, compared with 151 million in 2000 (5). This increase in prevalence will be attributed to several important risk factors such as advancing age of the population, greater numbers of people from ethnic minority backgrounds adopting a 'transitional' lifestyle, greater levels of overweight and obesity, and more sedentary lifestyles. From an epidemiological perspective, ageing is an important factor: in the United States, the number of people with diabetes aged 75 years and over doubled between 1980-1987.

Diabetes is associated with both functional impairment and disability (6). The wide spectrum of vascular complications, acute metabolic de-compensation, adverse effects of medication, and the effects of the condition on nutrition and lifestyle behaviour, may all create varying levels of impairment and/or disability. These changes may have adverse rebound effects on vulnerability to other co-morbidities, independence, and quality of life (7). It is also important to identify patients who would appropriately be labeled as frail because the aims of care are modified for such patients. Frailty, in this context, represents a vulnerability to a wide range of adverse outcomes secondary to the effects of aging, long-term vascular complications of diabetes, physical and cognitive decline, and the presence of other medical co-morbidities.

Several diabetes datasets have previously been developed and published. The European Commission were recently involved in the design of the DIABCARD which consists of diabetes-related data and administrative data (8) and forms part of an initiative towards having European healthcards (EU/G7 Healthcards). It has the advantage of being compatible with

other datasets being developed such as the German Diabetes Passport, V8. The Australian government have produced a summary core dataset for diabetes which is primarily clinically-orientated (9). It has 37 items for collection ranging from demographics through to procedure coding, and is designed to bring about a degree of national consistency in recording information about people with diabetes. In 2003, a Scottish Diabetes Core Dataset was prepared for the collection of data about people with diabetes in primary care (10). This is a very comprehensive dataset (over 50 separate items many of which have sub-categories) but already requires an extension of the dataset due to new clinical contract arrangements for general practitioners (UK government initiated GMS contract).

### First Stage is Using a Minimum Data Set for Assessment in the Clinic

In the frailty model of diabetes (11) a framework is developed that provides further assistance with clinical decisions, and allows the scope for establishing minimum core assessment criteria (these will contribute to the proposed minimum data set (MDS) for Geronto-Net). With this in mind, it has previously been recommended that the annual review process should now include an assessment of basic measures of ADL function, such as a Barthel test; tests of cognitive function, such as the Mini-Mental State Examination (MMSE) or Clock Test; a screen for depression, such as the Geriatric Depression Score; and an assessment of gait and balance, which can be simply estimated by the timed "Get Up and Go" test (6). This integrated process of comprehensive geriatric assessment is therefore suitably applied to diabetes, and we begin to create the culture of defining criteria in not only academic scenarios but also in clinical settings. From this perspective, additional criteria relating to laboratory/metabolic parameters would need to be included in this Clinical MDS.

### First Stage is Using a Minimum Data Set for Assessment in the Clinic

Several clinical intervention models have been proposed (6) which might also serve as a template for determining the items of a diabetes MDS for intervention research. These were developed for frail subjects with diabetes and were designed to detect early vascular complications, optimize functional status,

## TOWARDS A MINIMUM DATA SET FOR INTERVENTION STUDIES IN TYPE 2 DIABETES IN OLDER PEOPLE

and improve well-being: these are the very hallmarks of assessing diabetes interventions. The models proposed were the metabolic model, vascular model, and the rehabilitation model. The latter two require a major input from multi-disciplinary (MD) staff and it could be argued that when we finalise our MDS, we must not fail to include the perspective of the MD team.

Both assessment and outcome criteria have previously been published for diabetic residents of care homes in the United Kingdom (12, 13). In the British Diabetic Association Report (13), at assessment, 11 items were recommended comprising clinical data and medication list, BMI, blood pressure (BP), fundoscopy, feet examination, urine/blood tests, and dietary plan. Outcome data related to HbA1c, lipids, and BP, nutritional status, frequency and severity of hypoglycaemia, frequency and outcome of hospital admissions, vascular complication rate, change in level of dependency and mental function, and QOL/mobility measures. These can be extrapolated easily to intervention studies in older people with Type 2 diabetes depending on the nature of the intervention, for example, a drug intervention or care model approach. The Minimum Data Set/Resident Assessment Instrument (MDS/RAI) was developed in response to a series of scandals relating to quality of care in long term facilities in the United States (14). This is a computerized system designed to be used by nursing staff in the development of care plans. It has 17 domains in the assessment phase and 18 separate resident assessment protocols dealing with issues such as acute confusional states, visual function, mood, falls, nutritional status, and so on. While not directly categorizing by disease, these items have direct relevance to residents with diabetes.

Clinical Guidelines produced by the European Diabetes Working Party for Older People (15) indicated assessment tools which could form part of the basis of defining a MDS based on functional status (Table 1). This latter item is one of the principal assessment/outcome criteria for interventional studies in older people with diabetes. The others relate to assessment of subjects at the time of clinical trial entry, outcome data relating to quality of life, health economic data, and metabolic control, with the other dimensions of the MDS relating to the organization and delivery of care and patient-centred outcomes/informal carer issues. In some cases, these might also be used as prospective/longitudinal outcome data.

By a strict appraisal of the evidence-base for studies in geriatric diabetes, the European Guidelines (15) was also able to define up to 30 new research areas for future study: these areas naturally influence the components of a minimum data set thus emphasising the need for flexibility and adaptation as a key property of a modern research MDS. With this background, multiple potential areas for research by a randomized controlled design (RCT) in geriatric diabetes begin to emerge. For example, a priority list of research trials in older subjects with type 2 diabetes might include:

- Benefits of lifestyle intervention and/or therapeutic approaches (e.g. ACE inhibitor, insulin sensitizer, etc) in reducing the incidence of type 2 diabetes in hypertension or other cardiovascular risk factors
- Outcome of intensive treatment with oral agents and/or insulin in reducing primary macrovascular and microvascular outcomes, and mortality
- Benefits (vascular/mortality outcome data; cost-effectiveness) of statin and/or fibrate therapy in proven cardiovascular disease
- Benefits of prolonged comprehensive geriatric assessment programmes (CGA) (>12 months) in determining clinical outcomes and longevity
- Does lowering blood pressure reduce the risk of dementia in type 2 diabetes and hypertension?
- Value of educational approaches in the prevention of diabetic foot disease in terms of behaviour and knowledge, frequency of ulceration and amputation, quality of life, and patient satisfaction
- Value of both clinical and educational approaches in reducing the severity of hospital admission and metabolic decompensation, infections, and pain outcomes in diabetic residents of care homes

### **A Minimum Data Set for Intervention Trials in Type 2 Diabetes – defining the purpose and content**

An important objective of the international conference, Geronto-Net, set for late November, 2006 in Toulouse, France, is to develop a consensus statement about the most suitable MDS for intervention studies in older people. This 'generic' set of items will require harmonization with additional items selected in the differing research fields. In the field of type 2 diabetes, we will arbitrarily design a 20-item minimum data set which will serve four primary purposes:

- (1) Provide a standardized method of assessment and outcome measures for conducting large scale intervention studies with a randomized controlled design;
- (2) Enable valid comparisons of research findings in different populations of patients
- (3) Allow a more detailed analysis of the validity, reliability and sensitivity of existing measures and promote the development of new measures suitable for studies in older people
- (4) By systematic review procedures and meta-analyses of studies using a recognized minimum data set, there will be an increased likelihood of demonstrating both clinical and cost-effectiveness of a range of interventions

The MDS chosen will ideally need to satisfy four principal criteria:

- (1) Each item should be directly applicable and have clinically relevance to the patient with type 2 diabetes
- (2) As far as possible all functional, quality of life, and patient-centred outcomes should have been validated in

**Table 1**  
 Methods of Functional Assessment in Diabetes. Reproduced from and based on reference (15) with kind permission

Item	Method	Reference
<i>Global/Physical Function</i>		
BADL	Barthel or Katz Index	Mahoney FI & Barthel DW,1965 Katz S et al, 1963
IADL	Extended ADL or Lawton and Brody Index	Nouri FM & Lincoln NB,1987 Lawton MP &Brody EM,1969
Tasks/Mobility	'Get up and Go Test' or Lower extremity function	Mathias S et al,1986 Guralnik JM et al,1995
<i>Cognitive Function</i>		
With memory complaints	MMSE	Folstein MF et al, 1975
	Clock Test	Shulman KI,1985
Without memory complaints	SPMSQ	Pfeiffer E,1975
<i>Affective Function</i>	GDS (15 items)	Burke WJ et al, 1991
<i>Co-morbidities</i>	Charlson Index	Charlson ME et al, 1987
<i>Falls</i>	Fall calendar	Tinetti M et al, 1993
	Gait&balance test	Tinetti M, et al, 1994
<i>Nutritional Status</i>		
Non-frail elderly	PAC or suitable local method	Posner BM et al, 1993
Frail/hospitalized	MNA	Guigoz Y et al,1994
<i>Social Networks/support</i>	3 questions	Kane RA,1995

BADL: Basic Activities of Daily Living; IADL: Instrumental Activities of Daily Living; SPMSQ: Short Portable Mental Status Questionnaire; MMSE: Mini Mental State Examination; PAC: Public Awareness Checklist; refer to (15) for full list of references in Table 1

- older populations
- (3) Each item should retain validity over time making it suitable for prospective study designs
- (4) Each item within the dataset should be precise, unambiguous, and acceptable to all major research stakeholders

The eventual 20-item MDS-Diabetes will be considered as the minimum dataset that research organisations (whether public or private) should use to collect consistent, and standardised (unified) information about the value of interventions. In addition, a Clinical MDS-Diabetes (mentioned earlier) can be established from this so that healthcare organisations can adopt these items for benchmarking and quality assurance purposes. It can also be used by healthcare staff as part of the clinical audit process. By providing this standardised framework, clinical services and networks providing diabetes care to older people can be evaluated critically from a quality perspective, and modifications of the dataset can be used for Commissioning purposes both in primary care and secondary settings. Future evidenced-based decision making will also be enhanced as we see these datasets uniformly employed.

Analysis of studies involving older subjects with diabetes from the electronic databases of Medline, EMBASE and CINAHL suggest that the spectrum on outcome measurement is often not extensive with common repeating sequences such as body weight, HbA1c, stroke rate, cardiovascular event rate, and adverse event rate. However, many studies lack depth of enquiry by restricting the number of variables examined; this combined with the recruitment of poorly documented subjects can limit the effectiveness of any well-designed minimum data

set. This must be borne in mind in our collaborative efforts when developing the final MDS.

For studies in diabetes, the following extensive list of items must be considered as important elements of this disorder (disease)-specific MDS but further selection will be necessary:

*Metabolic and Laboratory*

- Waist-Hip ratio and waist circumference/BMI
- Glycosylated haemoglobin, HbA1c
- Fasting glucose
- Post-prandial glucose

*Fasting insulin*

- Full lipid profile including LDL-C and HDL-C
- Blood pressure
- Creatinine
- Microalbuminuria
- Uric acid, CRP and IL-6, TNF- $\alpha$

*Quality of life*

- Euro-QOL
- ADDQOL Senior

*Patient-centred outcomes*

- Hypoglycaemia rate
- Hospital admission rate
- Satisfaction with Treatment: DSTQ
- Self-rated health and Health status: SF-36
- Pain control
- Carer Strain Index

*Other Diabetes-Specific data items*

- Cardiovascular event rate, stroke rate, fatal- and non-fatal MI for macrovascular and hypertension intervention studies.
- Any diabetes-related end-point including erectile dysfunction.

*Cost-Effectiveness/Health Economics*

- No diabetes-specific data sets identified.

## TOWARDS A MINIMUM DATA SET FOR INTERVENTION STUDIES IN TYPE 2 DIABETES IN OLDER PEOPLE

Outcome variables which measure the effectiveness of differing models of care are not generally available for studies in diabetes. They are likely to require items relating to mortality, inpatient care, quality of life and health economic analysis.

It is also anticipated that data collection will need to include guidance on minimum criteria for enrolment in the clinical trial relating to referral criteria, demographics, and precise assessment of diabetes-related complications and current treatments. This may require additional effort to define minimum datasets for patient demographics, patient categories by diagnosis including patients in hospital, outpatient clinics, and those in care homes, treatment categories, and vascular complications at entry to the trial.

### Conclusions

In order for progress to be made we require international agreement to collect this specified minimum dataset in future clinical trials – this must be regarded as part of Policy for the Geronto-Net organisation. We have a unique opportunity within this newly-created research organisation to take a major step forward on enhancing European collaboration which can only be seen positively.

Our intention is to establish a European Expert Group on Diabetes in Older People via Geronto-Net which is linked to the European Diabetes Working Party for Older People to take this programme of work further. A consensus on the final list of items and format of the dataset is now required.

### COMMENTARY: TOWARDS A MINIMUM DATA SET FOR INTERVENTION STUDIES IN TYPE 2 DIABETES IN OLDER PEOPLE (1)

*Members of the Expert Group: I. Bourdel-Marchasson, L.M. Donini, F. Nourhashémi, P. Ritz, L. Rodriguez Manas, and A.J. Sinclair (Chair). Toulouse, 29th November 2006.*

Diabetes mellitus in older subjects is the commonest metabolic disorder that geriatricians encounter in every day clinical practice and can have devastating consequences if left unsupervised or monitored. Apart from the management of vascular complications, diabetes in the elderly requires attention to recognising the often insidious onset of clinical depression, cognitive impairment, and the need to avoid where possible care home admission and debilitating metabolic decompensation. Specialist care for the vulnerable older adult with diabetes mellitus needs to be enhanced rather than sidelined into generalist care, and requires coordination and integration of diabetes care between health and social services teams. Agreement on the goals of care is mandatory and should involve the patient and carer where appropriate. Geriatric diabetes is an exciting and challenging clinical discipline.

It is therefore not surprising that the Geronto-Net Expert Group on Diabetes in Older People created in November 2006 in Toulouse, France shares the view that developing a diabetes minimum dataset (MDS) is an absolute necessity before we can embark on large well-designed randomised controlled trials (RCTs). The paper by Professor Alan Sinclair (1) which was a detailed account of the rationale and content of a diabetes MDS was endorsed by the Expert Group but the following items stimulated discussion:

- Acceptance of a general principle that a Diabetes MDS should complement a 'general' or 'generic' MDS for studies in older people
- Ideally, the MDS must be valid in different research areas/scenarios, e.g. clinical research or health services research
- The MDS should ideally be easily translatable into different languages and laboratory units (e.g. mmol/l) must also be

### References

1. Sinclair AJ. Diabetes in the elderly: a perspective from the United Kingdom. *Clinics in Geriatric Medicine (USA)* 1999; 15:225-237
2. Finucane P, Popplewell P. Diabetes mellitus and impaired glucose regulation on old age: the scale of the problem. In : Sinclair AJ, Finucane P, Diabetes in Old Age, 2nd Edition, Chichester: John Wiley & Sons Ltd, 2001: 3-16
3. Sinclair AJ. Diabetes mellitus in senior citizens – a major threat to personal independence. *Br J Diab Vasc Disease* 2005; 5 (1): 1-3
4. Krop JS, Shaffer TJ, Powe NR, Saudek CD, Anderson GF. Patterns of expenditures and use of services among older adults with diabetes. *Diabetes Care* 1998; 21:747-751
5. Qiao Q, Williams DE, Imperatore G, Narayan KMV, Tuomilehto J. Epidemiology and Geography of Type 2 Diabetes Mellitus. In: DeFronzo R, Ferrannini E, Keen H, Zimmet P (eds), *International Textbook of Diabetes Mellitus*, 3rd edition, 2004: 33-56
6. Sinclair AJ. Diabetes in old age –changing concepts in the secondary care arena. *J Roy Coll Phys (Lond)* 2000; 34 (3): 240-244
7. Gregg EW, Engelgau MM, Narayan V. Complications of diabetes in elderly people. *BMJ* 2002; 325: 916-7
8. The DIACARD Data Set. Version 4.0 EU/G7 Administrative and Emergency Data. Contact: diabcad@gsf.de
9. National Health Data Committee (now HDSC), Australian Institute of Health and Welfare. *The Diabetes (clinical) Data Set Specifications 2003*. ISBN 1 74024 287 4
10. Scottish Executive, Edinburgh. *Scottish Diabetes Core Dataset December 2003*. SCDiabetes Collaboration and SCIMP. See: [www.diabetesinscotland.org](http://www.diabetesinscotland.org) and [www.ceppc.org/scimp](http://www.ceppc.org/scimp)
11. Sinclair AJ. Aging and diabetes. In *International Textbook of Diabetes Mellitus*, 3rd ed. De Fronzo RA, Ferrannini E, Keen H, Zimmet P, Eds. Chichester, U.K., John Wiley & Sons, 2004 p. 1579-1597
12. BDA (British Diabetic Association). *Guidelines of practice for residents with diabetes in care homes*. London, BDA, 1999
13. Sinclair AJ, Turnbull CJ, Croxson SCM. Document of care for older people with diabetes. *Postgrad Med J* 1996; 72:334-338
14. Hawes C, Morris J, Phillips C, Fries B, Murphy K, Mor V. Development of the nursing home Residents Assessment Instrument in the USA. *Age Ageing* 1997; 27: (Suppl 2):19-25
15. European Diabetes Working Party for Older People 2001–2004: Clinical guidelines for type 2 diabetes mellitus [article online]. Available from [www.eugms.org](http://www.eugms.org)

standardised.

- At a later stage we must consider obesity, the metabolic syndrome, and nutritional impairment with sarcopaenia
- It was agreed that a Level 1 MDS for Diabetes should be created from the original Table 1 in the definitive paper (1) based on additional input from the Expert Group. The purpose was to summarise into a 20-item set those parameters that are considered of primary importance in intervention studies. This is presented as Appendix A.

Further work by the Expert Group in 2007 is anticipated and will include defining an a priori list of research studies for older people with diabetes which can be incorporated in the overall research strategy of Geronto-Net.

**Members of the Expert Group:** I.Bourdel-Marchasson, LM Donini, F Nourhashémi, P Ritz, L Rodriguez Manas, and A J Sinclair (Chair). *Toulouse, 29th November 2006*

## Appendix A

### Towards a Diabetes MDS – proposed Level 1 MDS (20 items)

#### *Functional Measures*

- Basic ADL – Barthel or Katz Index
- Instrumental ADL – Extended ADL (Nouri & Lincoln) or Lawton & Brody Index
- ‘Get Up and Go test’ – Mathias S et al
- MiniMental State Examination – Folstein et al
- Geriatric Depression Score – Burke et al
- Mini Nutritional assessment (MNA) – Guigoz et al

#### *Metabolic and Laboratory*

- HbA1c
- Fasting glucose
- Lipid profile
- Estimated creatinine clearance (eGFR) – Modified Diet in Renal Disease formula (MDRD) - British Renal Association (available on <http://www.renal.org/eGFR/stage3.html>)
- Liver function tests
- CRP
- Albumin/creatinine ratio
- Waist circumference/body mass index (BMI)
- Blood pressure – lying/standing

#### *Quality of Life*

- ADDQOL (Audit of Diabetes Dependent Quality of Life ) Senior – diabetes-specific - Bradley C et al

#### *Patient-centred outcomes*

- Hospital admission rate
- Self-rated health – the 4-question approach – Bourdel-Marchasson I, et al

#### *Diabetes-specific measures*

- Cardiovascular event rate
- Visual function – Glasgow Acuity card method – van der Pols et al

*References:* A full list of references for measures denoted in the Level 1 Diabetes MDS is given in (1):

1. Sinclair AJ. Towards a minimum data set for intervention studies in Type 2 diabetes in older people. *Jour Nutr Health & Aging*, 2007, vol. 11, n°3, 289-293

*Additional references for Commentary are:*

- Bradley C, Sinclair AJ, et al 2007. The development of a new measure of quality of life for older people with diabetes mellitus: the ADDQoL- Senior (For publication in 2007)
- Bourdel-Marchasson I, Dubroca B, Manciet G, et al. Prevalence of diabetes and effect on quality of life in older French living in the community: the PAQUID Epidemiological Survey. *JAGS* 1997; 45: 295-301
- Van der Pols JC, bates CJ, McGraw PV, et al. Visual acuity measurements in a national sample of British elderly people. *Br J ophthalmol* 2000; 84: 165-70