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ABSTRACT The evidence base for the most effective and an efficient approach to organising the delivery of more complex care for people with type 2 diabetes is weak. This paper reviews some principles of care delivery, some observational studies of care delivery systems and some national audit data of comparative performance. It concludes that important characteristics of better systems are: structured patient education; reliable identification whether during routine ongoing care or at the time of an intercurrent event of people who could benefit from treatment escalation followed by prompt appropriate interventions; recognition, understanding and application of evidence-based glucose control treatment guidelines by all diabetes care providers; negotiated care planning between patients and the most appropriate care provider when treatment escalation is required; and an integrated system of care that delivers all of these in a collaborative, co-ordinated way by generalist and specialist nurses and doctors throughout a health economy.

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INTRODUCTION

The lifetime trajectory of 'an episode of diabetes' is concisely but comprehensively illustrated by the 'tadpole diagram' of the English National Service Framework for diabetes (Figure 1). Even cursory review makes it clear that someone with diabetes is likely to need a wide variety of services during their lifetime with the disorder, particularly if they develop it in early or middle life. Indeed, a huge variety of support services for people with diabetes have emerged although, it is firmly acknowledged,² the best outcomes arise when they are combined with good self-management skills.

The resultant multiplicity and diversity of services that have to be navigated by a person with diabetes is often and understandably perplexing (Figure 2). User confusion is intensified by the potential for multiple configurations of these components resulting in the emergence of many different 'models of care', each with their staunch advocates.

In contrast to the solid evidence base for the components of care that should be delivered along the lifetime pathway of care,^{3,4} evidence for the significant superiority of any particular configuration of care providers over alternative arrangements is not strong (see below). Using 'After metformin — what next' as the trigger, this paper will endeavour to explore the complexity of the multiple interrelationships and the consequent impossibility of neatly isolating one component of the lifetime care pathway from the rest; what is known about the effectiveness of different care models; how decision-making might occur within the care models; and the current effectiveness of UK Diabetes Care Systems in respect of achieving target (low risk) glucose control.

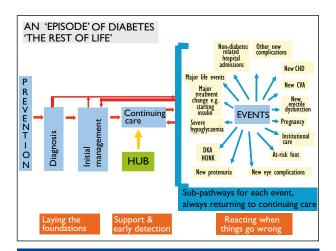


FIGURE I The 'tadpole' diagram.

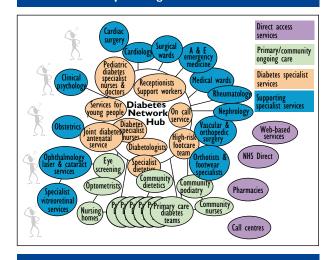


FIGURE 2 Components of an 'integrated' diabetes care service.

B Young

THE COMPLETE CARE PACKAGE: COMPONENTS OF CARE

The topic for one of the strands of this consensus conference is 'After metformin – what next?', implying that it is principally concerned about the approach to the care for people with type 2 diabetes at the point when they have evolved beyond the very earliest stages of their progressive disorder. However, this phase in the progression of diabetes cannot be dissociated from the preceding and potentially succeeding components of the lifetime diabetes care pathway as illustrated by the 'tadpole'.

The first year after diagnosis (tail of the 'tadpole')

This is the period when the foundations of diabetes care need to be laid. The success or failure of treatment for all of the remainder of the course of a person's diabetes is probably predicated on the success of this period. The person with new diabetes needs to be guided through the dismay and the dejection that commonly accompanies diagnosis towards a radical re-evaluation of their lifestyle. They need to be equipped with the knowledge and skills to self-manage their condition effectively in partnership with their professional advisors. Structured education⁴ is now recognised to be essential to the success of this phase of management.

The hub – continuing care (the body of the 'tadpole')

During the first year after diagnosis, in addition to laying the self-care foundations, it is necessary to establish continuing or ongoing care. This is the hub of the lifetime care for everyone with diabetes. It is a regular cycle of recall, review, renegotiation of an agreed care plan and goal setting. As a minimum it comprises the now familiar set of assessments — a review of glucose control, cardiovascular risk and lifestyle as well as screening for early detection of eye, kidney and lower limb complications.

Events – reacting when things go wrong (head of the 'tadpole')

Most people who live for more than a few years with diabetes will encounter events that require additional, usually specialist, management. These 'events' range from physiological changes such as pregnancy through non-diabetes-related hospital admission to acute metabolic decompensation, new long-term complications of diabetes and long-term care for disability. All of these events need to be dealt with competently if the adverse impact of the event itself and its interaction with diabetes is to be minimised so that normal or near-normal function resumed. Once stability has been re-established, continuing care needs to be resumed.

MODELS OF CARE

Recognising the complexity (multiple functions, care providers and care locations) and interdependencies

within the lifetime pathway of diabetes care, groups of providers that share a 'whole systems view' have sought to yield improvements (effectiveness, efficiency, safety, access, equity, satisfaction) by integrating organisational arrangements. The characteristics of these arrangements have been subject to some observational scrutiny.

The evidence for integrated care models

Combined insurer and provider

The NHS combines the roles of insurer and provider, but fragments the provider function. Outside the UK this is the health maintenance organisation (HMO) model, as epitomised by Kaiser Permanente in the USA. Kaiser HMO delivers both inpatient and outpatient care using a multidisciplinary approach across all relevant boundaries. It focuses on chronic disease pathways supporting prevention, self-management, disease management and care management. Key supports of the system include clinical leadership, training and a strong focus on information technology and communication systems.5 Although widely admired, the evidence that such systems deliver healthcare benefits is limited. In summary, they appear to improve partnerships, contribute to increased but unquantified capacity, possibly reduce admissions and lengths of stay and have an uncertain impact on costs.

Integrated providers but separate commissioners

There have been systematic reviews of the effectiveness of care programmes that integrate providers rather than commissioners.⁶ The common elements of the systems evaluated include self-management support and patient education, clinical follow-up, case management, multidisciplinary patient care teams, multidisciplinary care pathways and feedback reminders and education for professionals. In general, the reviews identify improved staff adherence to guidelines, reduced hospitalisation, reduced cost and improved patient health, quality of life and satisfaction. However, evidence for any change in health outcomes is minimal and similarly evidence on patient experience or cost-effectiveness is poorly documented. Things that were key enablers of integration that the reviewers deemed successful included supportive shared clinical information systems, the presence of specialised clinics, agreement about the nature of integration between personnel involved, leaders with a clear vision of integrated care, finance for implementation and maintenance, management commitment and support, a culture of quality improvement and patients capable of and motivated for self-management.

Managed clinical networks

Managed clinical networks aim to provide virtual integration rather than structural integration. An approach in Scotland was evaluated.⁶ It involved patients, sharing information, mapping patient pathways and constructing protocols, standards and guidelines, all of which seem to be viewed positively. A small number of significant improvements in care provision were reported,

but although there were significant set-up and maintenance costs, no benefits could be demonstrated in respect of improved resource use.

On the basis of this rather flimsy evidence but a groundswell of intuitive consensus, borne out of the summative experience of many healthcare professionals and patients, the Royal College of Physicians of London has come down firmly in favour of integrated care in its report *Teams without walls*:

For patients to really benefit from this new approach, hospital and community teams need to merge to ensure that the patient sees the right person, at the right time, in the right setting.⁷

So whereas it is not possible to garner a solid 'evidence base' for virtual or structural provider integration combined with or separated from insurer/commissioner responsibilities, it does seem to this author that the common sense approach to making the elements of a diabetes care service patient friendly and fit to deliver the 'tadpole' care pathway is some sort of formal integrated working arrangements. These include clinical leadership, shared guidelines (between care professionals, across organisational boundaries/care settings), patient engagement, shared clinical information systems and constructive provider/commissioner dialogue. I further suspect that it will never be a case of 'one size fits all', but rather that such principles will always have to be adapted and progressively re-adapted to local geographical, socio-economic and resource (human and financial) constraints.

DECISION-MAKING WITHIN THE 'MODEL OF CARE': MANAGING GLUCOSE CONTROL

The UK Prospective Diabetes Study (UKPDS) confirmed beyond all doubt that type 2 diabetes is a progressive disorder in which if hyperglycaemia is to be minimised, escalating management is required over time. There is now abundant evidence that minimisation of hyperglycaemia reduces the risks of both the specific (microvascular) complications of diabetes and also the enhanced risk of macrovascular disease. Accordingly, effective glucose control in type 2 diabetes confers substantial healthcare and cost benefits. The question 'After metformin – what next?' implies that following lifestyle optimisation, training in self-care and initiation of the foundation pharmacological intervention, metformin, there are more difficult choices about how to manage the remaining course of type 2 diabetes.

I would argue that unless at that point there has already been investment in 'the first year after diagnosis', particularly psychological support and structured education, then the game may already be at least partly lost because the opportunity to intervene at a time of maximum

'readiness to change'9 (i.e. immediately after diagnosis) will have passed. For any intervention to be successful the person with diabetes needs to understand the need for and be ready to engage with one of the next possible steps. The need to consider the next step will often be identified during a routine continuing care review, when the success of the subsequent decision-making will be heavily dependent on the enabling preparation of information and education. Ideally this will have established a framework of understanding about type 2 diabetes progression, the stepwise evolution of care interventions and so on. Alternatively, the need to escalate care might be identified during an 'event' ('head of the 'tadpole') when the psychological impact of an unwelcome change in health circumstances may facilitate a new period of 'readiness to change'.

Among the approaches to consider 'after metformin' is a plethora of potential pharmacological interventions. Various agencies such as the National Institute for Health and Clinical Excellence (NICE) and the Scottish Intercollegiate Network (SIGN) have endeavoured to summarise the evidence for each and they have put recommended sequences of drug use into algorithms,^{2,3} which can be customised by local services (Figure 3). Such algorithms help summarise the evidence and the options, but ultimately patients and their healthcare advisors need to agree a treatment goal, an approach to achieving the goal, responsibilities for the actions that comprise the approach and a time within which the approach will be deemed effective (to be continued) or ineffective (to be discontinued and another plan devised). This is the essence of 'care planning'10 or an 'N of I' trial".

So to optimise the management of glucose control in a person with type 2 diabetes who no longer has low-risk glucose control on treatment with lifestyle optimisation and metformin one needs, as a minimum:

- I. Educated, informed and engaged patients;
- Effective continuing care in which people needing treatment escalation are promptly and accurately identified;
- Recognition at the time of diabetes 'events' of patients with high-risk glucose control;
- 4. Recognition and understanding of evidence-based glucose control treatment guidelines by all diabetes care providers;
- Care planning between patients and the most appropriate care provider (General practitioner? Practice nurse? Diabetes specialist nurse? Diabetologist?) when treatment escalation is required;
- 6. An integrated system of care that ensures I-5 above are delivered in a collaborative, co-ordinated way across a health economy.

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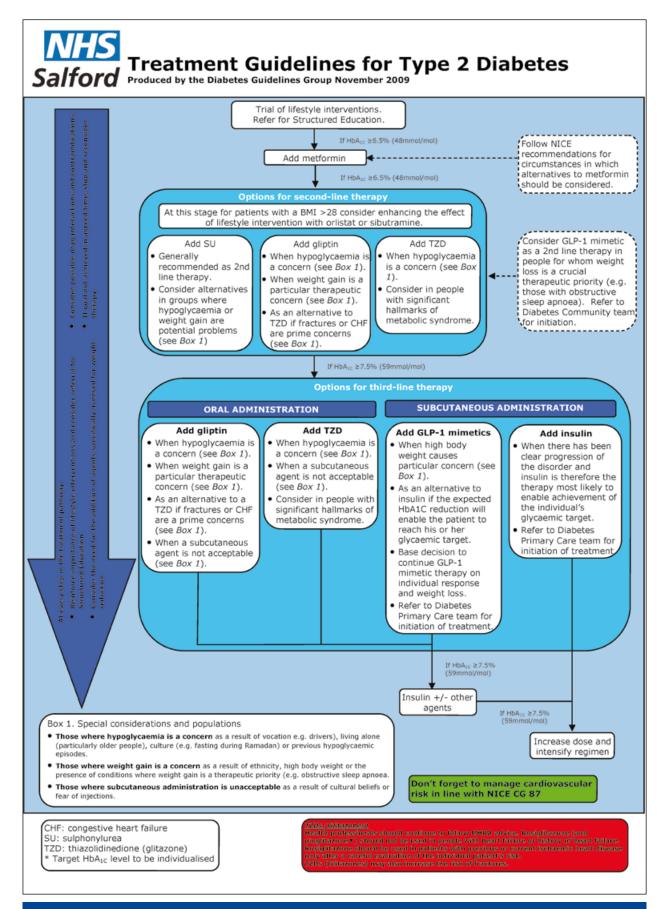
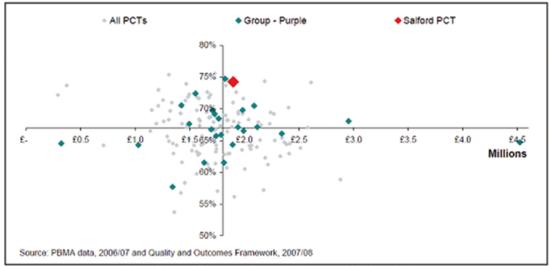


FIGURE 3 NICE guidance for the management of hyperglycaemia in type 2 diabetes summarised into a local algorithm for one health economy.

Programme Budgeting Data and HbA1c Outcomes

The chart below shows total spending on diabetes care based on Programme Budgeting data against the proportion of people with a HbA1c measurement of 7.5% or less.



Spending on Diabetes Prescriptions and HbA1c Outcomes

The chart below shows the Net Ingredient Cost (NIC) of all prescriptions for items to treat and monitor diabetes per patient diagnosed with diabetes between April and June 2008 against the proportion of people with a HbA1c measurement of 7.5% or less.

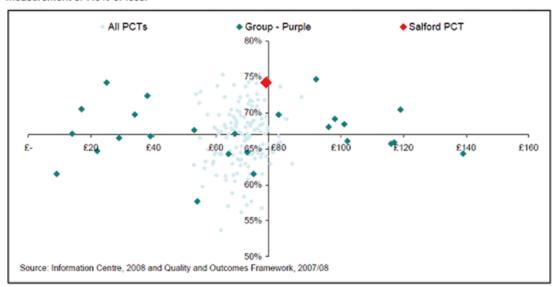


FIGURE 4 Diabetes programme budgeting and spending in NHS Salford.

WHAT ARE CURRENT 'MODELS OF CARE' ACHIEVING?

Since the inception of the Diabetes National Service Framework more than five years of national audit data in England testify both to improvements overall and to considerable residual variation. It is clear that, in England at least, the question 'After metformin, what next?' seems to be answered more often correctly but still very inconsistently.

Cost-effectiveness

Across health economies the cost-effectiveness of deploying the numerous alternative treatments for type

2 diabetes varies widely as shown in data from the Yorkshire & Humber Public Health Organisation Diabetes Health Intelligence Unit (Figure 4). The data highlight the performance of Salford as compared with all English health economies (the 'group – purple' are those in the same Diabetes Area Classification as Salford in respect of age distribution, ethnic mix, obesity and socioeconomic deprivation).

Organisational effectiveness – National Diabetes Audit

If one looks at achievement of the NICE guideline 2 in terms of haemoglobin $A_{\rm lc}$ less than 7.5%, or indeed less than 6.5% or 10%, there have been steady improvements

B Young

Title: Target achieved (%) timetrend by Registered GP (SHA) ®								
Vhere:	Registrations From: Results From: Targets from:	NICE HBAIc <= 7.5%						
L Chart	■ Table	Information Que	ry					
		Target achieved % 2003/4	Target achieved % 2004/5	Target achieved % 2005/6	Target achieved % 2006/7	Target achieved % 2007/8	Target achieved % 2008/9	
East Mi	idlands SHA	19.69	48.81	42.58	60.33	61.23	61.1	
East of England SHA		29.52	44.52	47.49	58.80	59.56	58.8	
London SHA		20.41	42.10	47.72	55.21	56.18	57.0	
North East SHA		48.88	51.79	59.03	65.06	66.75	65.2	
North West SHA		46.05	42.91	56.51	62.64	65.14	64.4	
South Central SHA		34.92	44.69	52.04	57.59	58.80	59.24	
South East Coast SHA		41.99	51.27	53.82	62.96	64.24	63.63	
South West SHA		44.31	28.21	34.77	60.52	60.29	60.40	
West Midlands SHA		36.67	48.50	58.13	56.46	61.39	62.13	
Yorkshire & The Humber SHA		35.59	34.61	49.40	62.19	63.56	62.40	
Selection Total		35.93	44.73	51.71	59.82	61.35	61.20	

FIGURE 5 English National Diabetes Audit (NDA): % HbA_{1c} <7.5%, regions 2004-09, mean 61.3%, range 58.9-65.3%.

here:	Target achieved (%) timetrend by Registered GP (SHA) for SHA (North West) Example: NICE HbA1c <= 7.5%							
Chart	■ Table	Information Query						
		Target achieved % 2003/4	Target achieved % 2004/5	Target achieved % 2005/6	Target achieved % 2006/7	Target achieved % 2007/8	Target achieved % 2008/9	
Ashton Leigh & Wigan PCT		26.15	30.74	24.45	63.97	66.82	63.13	
Blackburn with Darwen PCT		0.00	16.67	52.82	53.17	60.05	62.25	
Blackpoo	PCT	0.00	0.00	63.28	65.35	63.91	57.86	
Bolton PCT		20.78	21.74	22.73	64.79	62.16	64.48	
Bury PCT		52.96	52.11	47.83	58.36	64.14	64.95	
Central 8	& Eastern Cheshire PCT	23.08	33.33	12.57	58.69	61.00	68.24	
Central L	Lancashire PCT	40.00	13.67	57.15	62.85	62.90	63.41	
Cumbria Teaching PCT		11.11	9.09	57.43	63.84	64.56	61.91	
East Lancashire Teaching PCT		31,25	37.50	52.72	56.99	63.04	63.28	
Halton & St Helens PCT		0.00	31.31	62.37	67.64	66.40	66.84	
Heywood	Middleton & Rochdale Po	T 50.15	43.12	53.25	57.33	61.44	59.17	
Knowslev PCT		0.00	50.00	67.83	67.78	68.65	68.75	
Liverpoo	I PCT	53.55	50.00	12.50	68.33	69.91	65.42	
Manches	Manchester PCT		39.56	48.00	45.39	54.80	50.30	
North Lancashire Teaching PCT		0.00	65.10	66.73	69.34	69.10	68.40	
Oldham	PCT	47.23	53.19	61.98	59.90	61.12	58.85	
Salford PCT 46.0		46.03	51.20	63.60	67.38	68.67	65.12	
Sefton PCT 0.00		7.69	0.00	67.13	63.91	66.40		
Stockport PCT		42.68	35.22	55.75	67.12	68.10	67.12	
Tameside & Glossop PCT 41.		41.45	42.76	40.41	67.74	69.77	69.34	
Trafford PCT 40.00		31.10	30.66	69.37	70.87	67.91		
Warrington PCT 41.18		12.50	57.15	64.55	65.21	66,30		
Western Cheshire PCT -		45.58	55.20	60.00	66.90	62.68		
Wirral PCT		0.00	33.33	67.91	65.55	71.06	72.05	

FIGURE 6 English NDA: % HbA_{1c} <7.5%, north-west PCTs 2004–2009, number of people recorded with type 2 diabetes 191,494, mean 64.5%, range 50.3–72.1%.

during the six years of the National Diabetes Audit when judged at regional level (Figure 5). Improvement has occurred generally across all primary care trusts as well (Figure 6), but at this level of organisation more variability is apparent as shown for the north-west region. The pattern among health boards in Scotland is similar (Figure 7). When one gets down to individual general practices, yet again the overall trend is towards improvement, but variation is much more pronounced.

Although it is known that age, duration of diabetes, ethnicity and deprivation all influence overall target achievement rates, and this is reconfirmed in the National Diabetes Audit data, the Yorkshire and Humber Public Health Observatory Diabetes Health Intelligence

reports, which allow comparison of health economies that have similar population characteristics (diabetes area classification), make clear that that these factors alone do not account for the residual variation. So at local health economy and individual general practice levels there is good evidence that the amalgam of factors thought to characterise optimal diabetes care delivery is not being deployed consistently.

CONCLUSIONS

What we are left with, then, is a strong evidence base for effective glucose control interventions in diabetes care; a general acceptance that the totality of these interventions is only practicable as a result of successful collaboration

NHS Board	HbA1c < 7.5		
Ayrshire & Arran	9,655	66.6%	
Borders	2,724	63.0%	
Dumfries & Galloway	3,936	65.9%	
Fife	9,386	69.3%	
Forth Valley	6,771	63.5%	
Grampian	10,722	59.4%	
Greater Glasgow & Clyde	23,756	61.2%	
Highland	6,296	60.2%	
Lanark	13,551	64.8%	
Lothian	16,139	66.8%	
Orkney	474	66.3%	
Shetland	512	70.8%	
Tayside	9,805	64.0%	
Western Isles	553	61.0%	
Scotland	114,280	63.8%	

FIGURE 7 Scottish Diabetes Survey 2009: % HbA_{1c} <7.5% NHS Boards, number of people recorded with type 2 diabetes 199,262, mean 63.8%, range 59.4–70.8%.

between multiple care providers; good evidence that in many health economies and certainly at national level there has been significant overall improvement in the attainment of evidence-based glucose control goals; but balancing evidence that this overall improvement conceals appreciable

variations in performance at the health economy and even more at the primary care organisation level.

Perhaps it is time to investigate the provenance of these variations. Do they reflect failures to adhere to the principles of effective integrated care identified by observational studies to date? Or are there as yet unrecognised factors that determine whether people with type 2 diabetes and their care providers will more consistently be able to answer the question 'After metformin—what next?' in ways that improve achievement of low-risk glucose control?

Almost certainly, when looking to improve treatment target achievement rates, there is a need to review critically the local organisation of care arrangements as rigorously as adherence to treatment guidelines or algorithms. Systems of diabetes care are inherently complex so that the classical randomised controlled trial is unlikely ever to be a practicable mechanism with which to improve the evidence base for the effectiveness and efficiency of the different care models. But as outlined above, health service researchers have identified key characteristics of the prevalent care models. So, now that there are large-scale annual audits throughout the UK, if each health economy added some of these characteristics to their submissions an observational study would instantly be established.

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