Skills and Knowledge Requirements for the Provision of Quality Care of Adult Type 1Diabetes Patients in Preparation for, or Managed with Insulin Pump Therapy (IPT)

The Australian National Adult Insulin Pump Therapy Working Group

BACKGROUND

The specific skills and knowledge required by the health professional team for the optimal care of Type 1 Diabetes patients managed with insulin pump therapy (IPT) forms part of a broader knowledge-base required for the comprehensive care of this group of patients. While it is recognised that other health professionals may be involved in the provision of care, the core members of the team usually consist of a specialist physician (an endocrinologist or general physician), a RN-CDE and a Dietitian all of whom should possess an appropriate level of expertise required for the safe and effective care of IPT patients. The specific knowledge and skills required to implement this level of care have not yet been rigorously defined. The following document details these.

Recommendations:

1. It is recommended that the RACP Advanced training program for Endocrinology, ADEA and the DAA develop education programs and related certification processes dependent upon a formal assessment of skills and knowledge relevant to the safe and effective care of patients managed with IPT.

2. It is recommended that ongoing renewal of IPT certification be undertaken at appropriate intervals by the health professional. This may consist of either evidence demonstrating involvement in the care of IPT patients at a level sufficient to maintain skills and / or of repeat participation in approved education program.

Health professionals must understand the National Health and Medical Research Council National 'Evidence-Based Clinical Care Guidelines for Type 1 Diabetes for Children, Adolescents and Adults' (1). The following requirements with a focus on IPT have been based on the guidelines published by the Victorian CSII Group (2) as well as original work on the part of the Australian National Adult IPT Working Group.

(A) All members (Specialist Physician, RN-CDE, APD, Dietitian-CDE)

(I) <u>General</u>

- Have a detailed understanding of the pathophysiology associated with an absolute deficiency of insulin.
- Understand their own role as part of the health professional team as well as the roles and responsibilities of other team members with respect to initiation, stabilisation, on-going review and after hours support of patients managed with IPT.
- Possess a general understanding of the common and unique features of the insulin pump models available in Australia.
- Be able to provide an unbiased assessment of those features offered by insulin pump models available in Australia and to be able to assist in an appropriate choice of a pump based upon the individual's requirements and preferences while recognizing that the ultimate decision resides with the patient.
- Understand the limitations and risks associated with IPT.
- Understand the financial considerations enabling access of IPT. Have a working knowledge of differences between individual health funds for pump initiation and replacement. Understand the pre-requisite for NDSS support for disposables. Understand potential options available to the patient for Loan Pumps while waiting for insurance support to become active.
- Accurately assess a patient's suitability for IPT following:
  a) The provision of general information about the nature / benefits and risks of pump therapy to the patient.
  b) An explanation of the patient's responsibilities, the fulfillment of which will maximize positive outcomes while on IPT.
  c) An assessment of the individual's record of contact with the diabetes team and their record of self care.
  d) A review of the patient's commitment, motivation and capacity to self-manage their care while on an insulin pump.
  e) A review of the resources available to the patient enabling access to IPT.
  f) Ensuring registration with NDSS as an insulin pump user

(II) <u>Insulin Delivery and Insulin Dose Determination</u>

- Understand the pharmacokinetics and pharmaco-dynamics of short acting insulin analogues. In particular an understanding of the delay between changes in the time of subcutaneous insulin delivery and the subsequent changes in insulin action is required.
- Understand the two main modes of insulin delivery via IPT and the associated terminology including:

a) Basal insulin; temporary basal rate; basal patterns and profiles.

b) Bolus insulin, meal bolus; correction bolus; standard bolus; square wave/extended wave, dual wave/combination bolus, bolus calculator; insulin to carbohydrate ratio; estimated insulin sensitivity; insulin action time; glucose target range.

a) Basal Insulin

- Understand how basal rates are calculated.
- Understand the principles of basal rate testing.

- Understand the effect of circadian rhythm on insulin requirements in post adolescent / adult patients.
- Be able to understand the rationale for the use of temporary basal rates - increase (e.g. in sick day management) and decrease (e.g. for physical activity or for alcohol).
- Be able to understand the impact of exercise upon blood glucose and be able to suggest strategies aimed at the prevention of hypoglycemia and post exercise hyperglycemia with insulin pump therapy.

b) Bolus Insulin

- Understand how bolus insulin is calculated for food (carbohydrate ratios) and differences between grams of carbohydrate/unit of insulin and units of insulin/ carbohydrate exchange.
- Understand different bolus delivery methods – standard, extended and combination. Understand the dangers of "insulin stacking" with repeated boluses.
- Understand insulin action time and how this impacts bolus delivery
- Understand how correction boluses, target glucose range, insulin action time, calculated "insulin on board" and insulin sensitivity are used to correct hyperglycaemia and bring levels into a desired range.
- Understand how bolus delivery can be modified in patients with delayed gastric emptying.

c) Other Matters Related to Insulin Dosing and Delivery

- Be able to advise the patient on IPT about managing hypoglycaemia and reducing risk of hypoglycemia.
- Have knowledge of the differences in the acute management of hypoglycemia on IPT as compared with MDI.
- Have the knowledge to ensure documentation of pump settings and therapy changes at each clinical review point.
- Have knowledge of the broad categories of insulin infusion sets.
- To be knowledgeable of optimal intervals between catheter replacement

(III) Ongoing Support for Patients on IPT

- The ability to provide information (phone; email; face-to-face) regarding contacts available to the IPT patient in case of urgent or semi-urgent issues which may arise.
- The ability to determine the optimum interval between review appointments with members of the diabetes team once the patient has been established on IPT.
- The ability to assess at each follow up visit the patient's understanding of how to manage diabetes using their pump, eating patterns and physical activity and the skill to help improve their understanding where appropriate.

- The ability to assess and to provide strategies to prospectively reduce hypoglycemia frequency and severity and maladaptive fear of hypoglycemia.
- To be able to determine which IPT insulin delivery parameters (basal rates, insulin to carbohydrate ratios, insulin sensitivity, target ranges, insulin action time) are contributing to recurrent hypoglycemia.
- To be able to assess the patient's understanding of diabetic ketoacidosis occurrence and understanding of sick day management and provide additional information if required to ensure a satisfactory level of knowledge.
- To have a level of experience sufficient to ensure that suggestions relating to changes in insulin dosing are both effective and safe and have been communicated to the patient in a clear manner.
- To be able to provide advice (time zone, back up insulin/pump) for the patient on IPT who is travelling.
- To have sufficient knowledge to advise patients regarding the effect of electromagnetic fields upon the function of pumps.
- To be able to direct patients managed with IPT to local and national support groups.

(IV) Associated Software Review

- To be able to review and interpret information available on Carelink personal and Carelink Pro (Medtronic), Diasend reports (Animas/ Roche) and Roche Accucheck 360 software(Combo pump) reporting systems and assess information contained within the various reporting formats
- To have the ability to recognise limitations in the information that has been uploaded from a pump e.g. situations where only selected glucose readings have been entered into the pump by the patient.
- To have an understanding of the effect of insulin resistance on insulin delivery requirements
- To be able to understand that the patient may find review of the data on their pump confronting. A level of sensitivity on the part of the health professional is required
- To be able to encourage and provide ongoing education of the patient on IPT to enhance self-management/ safety and to maximize independence and self esteem.

(V) Continuous Glucose Monitoring (CGM*)*

- To have an understanding of the principles upon which CGM is based.
- To understand the differences and roles for 'retrospective CGM vs. Real Time-(Patient centered) CGM.
- To appreciate the delay in time between measurement of blood glucose with glucose-meter versus measurement of interstitial glucose by CGM.
- Be able to assess the information contained within a CGM report
- To have an understanding of the direct costs associated with CGM.

(B) The Specialist Physician in addition to (A) should:

- Have the knowledge, experience and be prepared to take ultimate responsibility for the diabetes management of the patient treated with IPT
- Be able to coordinate the care of the patient managed with IPT with other members of the diabetes team and to ensure that all aspects of the patient's diabetes management (inclusive of complication screening) are addressed
- Be knowledgeable about the requirements of private health insurance providers for the support of IPT to a patient and be able to compose a letter of application to an individual's health fund for pump commencement or replacement.
- Be able to determine an individual's pump settings at the time of initiation of IPT and at ongoing follow up including:

a) Basal rates

(1) Be able to assess the optimum number of basal rates required for a patient and determine if the number of basal rates employed is appropriate to the needs of the patient concerned.

(2) Assess the requirement for different basal profiles / patterns e.g. sleep in days/shift work/sedentary work.

b) Insulin-Carbohydrate ratios
c) Sensitivity settings (correction bolus)
d) Target blood glucose levels
e) Duration of insulin action

- To either, be able to directly modify insulin delivery settings on a pump and suggest strategies with the aim of optimising the patient's glucose levels or delegate this task (with documentation) to another member of the insulin pump team (Advanced Trainee Endocrinology, RN-CDE or Dietitian-CDE) while retaining ultimate responsibility for the care of the patient.
- To review if total daily insulin delivery distribution i.e. basal vs bolus is appropriate for patient's activity/weight/carbohydrate intake.
- Be able to advise different management approaches to prevent peri-exercise hypo- and hyperglycemia with specific advice as to how to modify either bolus and/ or basal insulin delivery and strategies to prevent nocturnal hypoglycemia.
- Be able to assess data uploaded from a pump in a report and to utilise the information to modify the patient's pump settings, diet, lifestyle and operation of the pump with the aim of optimizing glycaemic control and reduce hyper and hypo-glycemic events.
- Ensure the pump user has a back-up plan with doses to use for MDI in the event of pump failure and has been supplied a long acting insulin pen.
- Ensure the pump user has a sick day management plan and appropriate basal delivery limits are set to allow delivery of 200% of maximal basal rate if required.
- Ensure that the patient has a prescription for glucagon and relevant others have been educated in its administration.

- With respect to Continuous glucose Monitoring
    - o Be able to assess a CGM report and to utilise the information to optimize the patient's pump settings, diet and lifestyle.
    - o To be able to communicate at an appropriate level with the patient informing them of the patterns of glycaemia observed on CGM and based upon this information, advice on changes to insulin delivery, diet and lifestyle required to optimize glycaemia.

(C) The RN –CDE in addition to (A) should:

- Be able to provide education to the patient regarding general aspects of management of diabetes.
- Be able to provide detailed information to the patient treated with IPT regarding sick day management.
- Be able to provide detailed information to the patient regarding hypoglycemia management
- Have a detailed knowledge of pump operation including:
    a) Programming of settings and pump alerts.
    b) Differences between infusion sets for each of the available pumps.
    c) Manage lifestyle issues- pump detachment and reattachment.
    d) Troubleshooting pump problems.
    e) Transfer this knowledge to patient education either on a group or individual basis as appropriate.
- Have a detailed knowledge of insertion sets, inserters and insulin delivery lines so as to be able to advise the patients as to which is compatible with their pump and is best suited to their needs
- Be able to instruct the patient regarding the insertion of infusion sets, the importance of asepsis, location of the insertion site and how they connect to insulin delivery catheters, frequency of site changes and the need for increased site change frequency in response to circumstances such as pregnancy.
- Be able to instruct the patient on how to fill insulin reservoir and prime insulin delivery lines
- Understand management of complications of infusion sets- e.g. recurrent infection, allergy to site adhesive, recurrent line occlusion, lipohypertrophy. Instruct the patient in management of blood sugars when a line occlusion is suspected.
- Be able to provide general advice to the patient on IPT with regard to sick day management.
- Be able to provide general advice to the patient in the setting of pump failure or loss of a pump.
- Be proficient at uploading data from available insulin pumps and glucose meters.
- Be proficient at uploading data from glucose-meters Be proficient at generating and interpreting reports from each of the data uploads.
- Be proficient at inserting electrodes for purpose of CGM, training patients in use of real time CGM, data upload and interpret data from CGM

- Should have a detailed knowledge of the processes and logistics required to commence an individual on an insulin pump including:

a) Registration with NDSS as a pump user

b) Informing the patient as to how they order infusion sets depending on pump choice and ensure that this is implemented prior to initiation of IPT.

c) Obtain copy of the approval of the health fund from the patient in order to arrange insulin pump purchase.

d) Arrange purchase of the insulin pump.

e) Coordinate and organize the pump start date.

f) Inform the patient what they should bring to their appointment.

g) Ensure that all required documentation is completed including receipt of written copy of pump settings to be used at pump initiation as prescribed by Specialist Physician (detailed under specialist requirements A-E).

(D) The Dietitian/Dietitian-CDE in addition to (A) should:

- To be able to provide both general nutrition advice and medical nutrition therapy for all people with diabetes, appropriate for age and stage in life.
- Have a detailed knowledge of carbohydrate counting and be proficient in the education of the patient or their career on this subject
- Be able to determine that the individual or their career understands the skills required to estimate their carbohydrate intake accurately and provide further education where required.
- Have a detailed knowledge of appropriate resources for carbohydrate counting and GI assessment to provide guidance to the patient in assimilating and understanding of relevant facts.
- Have the ability to teach the patient or career how to calculate the carbohydrate content of a recipe and convert to individual servings.
- Be able to instruct the patient or the career in label reading for packaged foods.
- Be able to provide guidance to the patient or career on carbohydrate counting resources available to assist when eating out.
- Understand the impact of other dietary factors impacting on blood glucose levels i.e. low GI, high-fat meals and be able to apply to the advanced features of the pump.
- Have a detailed knowledge regarding the impact of and dietary management of coexisting co-morbities i.e. coeliac disease, gastroparesis
- To be able to provide advice regarding the impact of alcohol on blood glucose levels and how to prevent hypoglycemia.

References

(1) Craig ME TS, Donaghue KC, Cheung NW, Cameron FJ, Conn J, Jenkins AJ, Silink M, for the Australian Type 1 Diabetes Guidelines Expert Advisory Group. National evidence-based clinical care guidelines for type 1 diabetes in children, adolescents and adults. Australian Government Department of Health and Ageing, Canberra. 2011.

(2) Victorian Insulin Pump Guidelines.https://tools.skillsforhealth.org.uk

Systematic Review of Evidence to inform guidelines for the management of insulin pump therapy in adults with Type 1 Diabetes

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Adult Insulin Pump Therapy Working Group

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COSTS AND COST EFFECTIVENESS

	Clinical question
	1. What is the cost (upfront plus ongoing) and cost-effectiveness of treatment with CSI pumps versus MDI? 1. 2 What is the cost of upgrading a patient on the pump?

Current Guidelines

National evidence based clinical care guidelines for type 1 diabetes in children, adolescents and adults (1*)*

The cost (upfront and ongoing) and cost-effectiveness of treatment with CSII pumps versus MDI was systematically reviewed for these guidelines.

Nice Guidance (2)

The costs and costs effectiveness of treatment with CSII pumps versus MDI was systematically reviewed for the NICE Guidance. A joint economic evaluation was also provided by the pump manufacturers and the Health Technology Assessment group conducted an economic analysis. The NICE committee agreed that at very high baseline HbA1c levels the expected decrease in HbA1c could make CSII cost effective due to avoidance of long term complications. At baseline HbA1c levels less than 9.0% CSII would only be cost effective if an additional quality of life benefit was assumed. The NICE committee accepted episodes of severe hypoglycaemia can be significantly decreased with CSII therapy, and although economic modeling of reduction in rate of severe hypoglycaemia did not have a pronounced effect on ICER's the Committee considered that there would be a greater quality of life benefit due to the avoidance of the fear of hypoglycaemia by the use of CSII.

Systematic Review

This systematic review includes a search date from 2010 in order to identify any evidence post that reported in the National evidence-based clinical care guidelines for type 1 diabetes in children adolescents and adults. Studies were eligible for inclusion if they were a HTA report or economic evaluation, in adults with type 1 diabetes, reporting the cost and cost effectiveness of CSII versus MDI or the costs of upgrading pump therapy, post 2010.

Criteria for determining study eligibility: Clinical question

Study design	Existing HTA reports, published economic evaluations
Population	Adults with type 1 diabetes
Intervention	CSII- modern pumps
Comparator	MDI- at least 3 injections
Outcomes	Cost and cost-effectiveness

Assessment of study eligibility

A total of 34 publications were identified in the literature search. The title and abstract of citations identified were reviewed and the exclusion criteria applied hierarchically. Publications were excluded if they were the wrong study type, if they were in the wrong population (not in adults with type 1 diabetes) or evaluated the wrong intervention (not CSII versus MDI) or reported the wrong outcomes. Only English language publications were eligible for inclusion.

1 publications met the inclusion criteria.(3)

Literature Search summary

Stage	Notes	Number
Search summary	Medline Embase Total	1 34 35
Duplicates identified		0
Total identified		34
Exclusion Criteria	wrong study type (not HTA report, published economic evaluation) wrong population (not type 1 diabetes in adults) wrong intervention (not CSII) wrong comparator (not MDI) wrong outcome Not English Total excluded	13 4 12 1 3 33
Meeting Criteria		1
Included		1

Included Studies

Study ID	Citation
Cummins, E., P. Royle, et al. (2010)	"Clinical effectiveness and cost-effectiveness of continuous subcutaneous insulin infusion for diabetes: Systematic review and economic evaluation." Health Technology Assessment **14**(11): 1-208.

Characteristics and Results of included studies.

Cummins 2010.

This HTA report informed the current NICE Guidance on insulin pump therapy. It consisted of a systematic review for current evidence with search date to June 2007. It also included an economic evaluation provided by the insulin pump manufacturers and an economic evaluation carried out by HTA. As a systematic review of evidence with search date to 2010 is included in the National evidence- based clinical care guidelines for type 1 diabetes in children, adolescents and adults(1) the systematic review component of this paper will not be discussed further here.

The economic evaluation provided by the manufacturers was based on a patient cohort characteristics of 300 adults followed up over a period of 9 years with average age 37.8 years. A baseline HbA1c of 9.4 % was applied for three decreases in HbA1c, 0.62%, 0.95% and the greatest decrease being 1.29%. The rate of severe hypoglycaemia was assumed to be reduced by 75%. A gain in QALYs was seen in all three analyses at an increased cost.

HbA1c reduction	ICER per QALY (pounds)
0.62%	34,330
0.95%	22,897
1.29%	16,842

The model did not consider the psychological benefits of CSII eg avoidance of fear of hypoglycaemia.

The economic evaluation by the HTA simulated a cohort with average age 40years and baseline Hba1c of 8.8%, with reduction of 0.9% HbA1c with CSII. The effect of a 50% and 75% reduction in HbA1c were modelled. A cohort of people with HbA1c of 7.5% and high rates of severe hypoglycaemia was also modelled. The costs included the capital costs, which were outlay for the pump every 4 years (430-720 pounds per year) and a one-off education cost of around 240 pounds(based on cost of DAFNE course), and the cost of consumables (1800-2000 pounds per year).

Cohort with baseline HbA1c 8.8% and severe hypoglycaemia rate 18.7 per 100 person years

HbA1c reduction	Hypoglycaemia Reduction	ICER per QALY (pounds)
0.9%	50%	37,712
0.9%	75%	36,373
0.9%	0%	39,586

Cohort with baseline HbA1c 7.5% and severe hypoglycaemia rate 134 per 100 person years

HbA1c reduction	Hypoglycaemia Reduction	ICER per QALY (pounds)
0%	50%	273,992
0%	75%	152,058
with annual quality of life increment of 0.05		
0%	50%	28,600
with annual quality of life increment of 0.04		
0%	75%	31,300

Conclusion

The systematic review for evidence regarding the costs and cost-effectiveness of CSII versus MDI is based on one HTA report which was undertaken to inform the current NICE Guidance on insulin pump therapy. This HTA report included a systematic review, an economic evaluation prepared by the pump manufacturers, and an economic evaluation by HTA. The costs associated with upgrading a pump were not reported.

Literature Search Strategies

Searches were conducted in EMBASE and Medline. Searches were restricted to studies published after 2010. The search was conducted on 5th July 2012.

Medline

	1	exp Diabetes Mellitus, Type 1/	56784
	2	(continuous subcutaneous insulin infusion or CSII or (insulin pump therapy or IPT).mp.[mp=title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept,unique identifier)	2574
	3	cost-benefit analysis/ or cost effectiveness analysis.mp.[mp=title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept,unique identifier)	55028
	4	(economic evaluation of health economics or cost minimisation analysis or cost utility analysis).mp.[mp=title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept,unique identifier)	90
	5	Quality adjusted life years/ or quality adjusted life year.mp or qaly.mp or life year saved.mp.[mp=title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept,unique identifier)	7682
	6	3 or 4 or 5	57262
	7	1 and 2 and 6	23
	8	limit 16 to (english language and yr =2010 to current)	1

	Citations
Embase	34

HOSPITAL VERSUS AMBULATORY CARE

	Clinical question
	2. What is the effectiveness and cost-effectiveness of hospital versus ambulatory care for initiation of pump-therapy? 2.1 What is the effectiveness and cost-effectiveness of hospital versus ambulatory care for upgrading of pump-therapy?

Current Guidelines

National evidence based clinical care guidelines for type 1 diabetes in children, adolescents and adults (1)

There are no recommendations in these guidelines on the effectiveness of ambulatory versus hospital care for initiation of insulin pump therapy

Nice Guidance (2)

There are no recommendations in these guidelines on the effectiveness of ambulatory versus hospital care for initiation of insulin pump therapy

American Association of Diabetes Educators 2008 Consensus Summit (4)

There are no recommendations in these guidelines on the effectiveness of ambulatory versus hospital care for initiation of insulin pump therapy

Systematic Review

Studies were eligible for inclusion if they were of any comparative design, were in adults with type 1 diabetes having initiation of pump therapy in the hospital or ambulatory setting, or an upgrade of pump therapy in the hospital or ambulatory setting.

Inclusion criteria

Study design	Any comparative study
Population	Adults with type 1 diabetes
Intervention	CSII- modern pumps in hospital setting
Comparator	CSII- modern pumps in in ambulatory setting
Outcomes	HbA1c, DKA, Hypoglycaemia, QoL,

Assessment of study eligibility

A total of 50 publications were identified in the literature search. The title and abstract of citations identified were reviewed and the exclusion criteria applied hierarchically. Publications were excluded if they were the wrong study type, if they were in the wrong population (not in adults with type 1 diabetes) or evaluated the wrong intervention (not inpatient versus ambulatory pump start) or reported the wrong outcomes . Only English language publications were eligible for inclusion.

No publications met the inclusion criteria.

Literature Search summary

Stage	Notes	Number
Search summary	Medline Embase Inahta Cochrane Total	18 12 24 0 54
Duplicates identified		4
Total identified		50
Exclusion Criteria	wrong study type (non comparative study) wrong population (not type 1 diabetes in adults) wrong intervention (not ambulatory or in-patient insulin pump start) wrong outcome Total excluded	17 13 20 50
Meeting Criteria		0
Included		0

Conclusion

There were no publications identified in the literature search which met the inclusion criteria. There is insufficient evidence to address the questions on the effectiveness and cost-effectiveness of in-patient versus ambulatory care for initiation of insulin pump therapy or for upgrading insulin pump therapy.

Literature Search Strategies

Searches were conducted in EMBASE, Medline, Cochrane and INAHTA. Searches were restricted to studies published after 2000. Search terms were searched for as keywords, exploded where possible, and as free text within the title or abstract in the EMBASE and Medline databases. Variations on these terms were used for the Cochrane and INAHTA databases, modified to suit their keywords and descriptors.

The search was conducted on 5th July 2012.

Medline

	1	exp Diabetes Mellitus, Type 1/	56555
	2	(continuous subcutaneous insulin infusion or CSII or (insulin pump therapy or IPT).mp.[mp=title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept,unique identifier)	2543

	3	(in-patient* or inpatient* or in-hospital*).mp.	1044009
	4	(out-patient* or out-patient* or home* or ambulatory*).mp.	516645
	5	1 and 2 and 3 and 4	29
	15	limit 16 to (english language and year 2000 to current)	18

	Citations
INAHTA	24
Cochrane	0
Embase	12

DIABETES EDUCATION AND TIMING OF REVIEW

	Clinical question
	3. What is the effectiveness and cost-effectiveness of individual vs group education for initiation of pump therapy? 3.1 What is the effectiveness and cost-effectiveness of individual vs group education for upgrading of pump therapy?

	Clinical question
	4. What is the optimal timing of review after initial pump start? 4.1 What is the optimal timing of review after upgrading of pump therapy? 4.2What is the optimal timing of review for achieving HbA1c targets and minimising DKA?

	Clinical question
	5. What are the key components of education at pump initiation? 5.1 What are the key components of education at pump upgrade?

	Clinical question
	6. Is structured education effective?

Current Guidelines

National evidence based clinical care guidelines for type 1 diabetes in children, adolescents and adults(1)

There are no recommendations in these guidelines on the effectiveness of individual versus group education for insulin pump users, optimal timing of review, key components of education at pump initiation and upgrade, or the effectiveness of structured education for insulin pump therapy.

Nice Guidance(2)

'It is recommended that CSII therapy be initiated only by a trained specialist team, which should normally comprise a physician with a specialist interest in insulin pump therapy, a diabetes specialist nurse and a dietitian. Specialist teams should provide structured education programmes and advice on diet, lifestyle and exercise appropriate for people using CSII.'

American Association of Diabetes Educators (AADE) 2008 Consensus Summit(4)

The AADE convened an expert panel to discuss guidelines for achieving optimal outcomes in patients using insulin pumps. The panel agreed that achieving the goals of CSII therapy requires diabetes self-management with topics to include infusion site management, fine-tuning basal rates and bolus ratio, minimizing the risk of ketoacidosis, exercising effectively, and the role of record keeping by the patient in optimizing therapy. Diabetes educators are essential for providing ongoing education and training. The panel reported that patients who succeed on CSII therapy are treated with a team approach to training. Follow-up after initiation of CSII therapy should include daily contact with a diabetes educator for the first few weeks and then at least weekly for the first month to 6 weeks of insulin pump therapy.

Systematic Review

For these questions one broad literature search, initially limited to level 1 studies, was undertaken in EMBASE, Medline, Cinahl, INAHTA and the Cochrane database. Search terms were searched for as keywords, exploded where possible, and as free text within the title or abstract in the EMBASE and Medline databases. Variations on these terms were used for the Cinahl, Cochrane and INAHTA databases, modified to suit their keywords and descriptors. The initial search was limited to publications since 2000 and in English language and conducted between 5th July and 7 the July 2012. A second search for primary studies, limited to publications since 2008 and the English language was undertaken on 8th July. A total of 12 publications were retrieved for full review.

Inclusion criteria

Study design	Any descriptive or comparative study
Population	Adults with type 1 diabetes
Intervention	Education or review at pump initiation and follow-up
Comparator	any
Outcomes	HbA1c, DKA, Hypoglycaemia, QoL, knowledge, self care behaviours

Assessment of study eligibility

A total of 258 publications were identified in the literature search. The title and abstract of citations identified were reviewed and the exclusion criteria applied hierarchically. Publications were excluded if they were the wrong study type (review, editorials), if they were in the wrong population (not in adults with type 1 diabetes) or evaluated the wrong intervention (not diabetes education or timing of review) or reported the wrong outcomes . Only English language publications were eligible for inclusion. Of these 12 publications, 2 were excluded as they were only available in abstract, 4 were excluded as wrong study, and 1 was excluded as wrong intervention. A total of 5 publications met the inclusion criteria.

Literature Search summary

Stage	Notes	Number
Search summary	Medline Embase Cinahl Inahta Cochrane Total	61 198 7 24 4 293
Duplicates identified		36

Stage	Notes	Number
Total identified		257
Exclusion Criteria	wrong study type (letter to editor, case report) wrong population (not type 1 diabetes in adults) wrong intervention (not diabetes education/ review at pump initiation or follow-up) wrong outcome (not HbA1c, hypoglycaemia, rate of DKA, QoL, knowledge, self care behaviour) Total excluded	44 102 99 245
Papers retrieved for full review		12
Exclusion criteria	wrong study type (letter to editor, case report) wrong population (not type 1 diabetes in adults) wrong intervention (not diabetes education/ review at pump initiation or follow-up) wrong outcome (not HbA1c, hypoglycaemia, rate of DKA, QoL, knowledge, self care behaviour) Total excluded	6 1 7
Meeting Criteria		5
Included		5

Included Studies

Level 1

Study ID	Citation
Jayasekara, R. S., Z. Munn, et al. (2011).	"Effect of educational components and strategies associated with insulin pump therapy: a systematic review." International Journal of Evidence-Based Healthcare **9**(4): 346-361.

Primary studies

Study ID	Citation
Chellamuthu, P., I. G. Lawrence, et al. (2009)	"Continuous subcutaneous insulin infusion: experience from a large specialist service: are we following NICE guidance and what is the added benefit of the DAFNE programme?" Practical Diabetes International **26**(2): 60-64
Clark, L. F., J. C. Bilbie, et al. (2011).	"What do patients prefer: insulin pumps or multiple daily injections and structured education? A retrospective audit and patient questionnaire." Practical Diabetes International **28**(2): 73-75.

Fish, L. H., H. P. Wetzler, et al. (2008).	"Advanced Insulin Management program reduces A1C levels and regimen-related distress without weight gain in patients with type 1 diabetes mellitus." Insulin **3**(2): 59-66.
Kerr, D., H. Nicholls, et al. (2008)	"Continuous subcutaneous insulin infusion (CSII insulin pump therapy) for type 1 diabetes: a Bournemouth perspective." Practical Diabetes International **25**(3): 114-117.

Characteristics and Results of included studies.

Jayasekara 2011

This systematic review was undertaken to establish the effectiveness of approaches to the provision of education for adults with type 1 diabetes using or initiating an insulin pump and to identify evidence on the association between intervals and duration of follow-up and stated outcome criteria.(5) Study inclusion criteria were clearly stated, with all studies and papers that involved adults using insulin pump therapy who had participated in education or training, being eligible for inclusion. A comprehensive search of the literature for both published and unpublished data was undertaken from 1998 to February 2008. The literature search identified 5 descriptive studies, of which 3 had a pre and post test design. The included studies are summarised in the table below. The authors reviewed the studies for methodological quality but did not report the quality ratings given for each study. The country of origin was not reported for one study.

Included Studies

Referencecountry	Level and type of study, and N	Intervention	Outcomes	Results
Hunger-Dath 2003 Germany (1999-2000)	Descriptive Study N=250	structured 7-day treatment and teaching program (TTP) content: technical instruction about the insulin pump, catheter and tape, adjustment of insulin dose, daily living instructions, prevention and management of ketoacidosis and severe hypoglycaemia, blood glucose self-monitoring and documentation.	HbA1c, severe hypoglycaemia, DKA with hospital admission and hospitalisation days	1 year post TTP, the mean relative HbA1c (Relative HbA1c = HbA1c/Mean HbA1c of a normal control group) decreased from 1.51 (0.9–3.2) to 1.44 (0.9–3.6) afterwards (P < 0.0001). Severe hypoglycaemia decreased from 0.46 to 0.12/patient/year (P < 0.001), DKA from 0.08 to 0.05/ patient/year (P = 0.003) and hospitalisation from 5.2 to 3.1 days/patient/year (P = 0.002).1

Referencecountry	Level and type of study, and N	Intervention	Outcomes	Results
Oswald 2004, country not reported	N=12 prospective study	N=70 participants underwent intensified conventional therapy (ICT) that included a skills training program. The duration of the skills program was not described. The training program was conducted in three phases. In the first phase, patients and partners were involved in 45 min training on carbohydrate counting. the next step was one-on-one instruction on insulin dosage, carbohydrate portions and the use of correction boluses for glycaemic excursions. The third phase involved a short-term follow-up program in a multi-disciplinary clinic for analysing patients' dairies that incorporated food records, blood glucose records and insulin dosages to ensure appropriate use of insulin dosage and adjustments. N=12 of these participants went on to start insulin pump therapy	HbA1c Participant satisfaction	pre-ICT HbA1c 9.6 +- 1.5%, post- ICT HbA1c 8.3 +- 1.4%, *t* = 2.9, *P* < 0.02), but no further improvement was seen after a further year of IPT (HbA1c 8.4 +- 0.8%, *n* = 9). The study also found that patient satisfaction with both ICT and IPT was very high according to a questionnaire. The study concluded that IPT did not appear to offer significant glycaemic control advantages over ICT in this program. The authors recommend that ICT including a training program can be used to initiate IPT successfully.
Rizvi 2001, USA	Observational retrospective study N=5, older adults with suboptimal glycaemic control(HbA1c > 8.0%), microvascular complications and frequent hypoglycaemia).	Before initiation of IPT, 8-h outpatient intensive insulin pump training and training on carbohydrate counting . The teaching method was conducted in groups .Follow-up training programs were conducted by a diabetes nurse educator and a registered dietician at biweekly visits (1 h) during the following period of 2–4months. Components covered in this program included self-monitoring BGL, carbohydrate counting f, calculation of insulin requirements and practical aspects of insulin pump use (e.g. insulin replacement, care of needle insertion sites, and pump malfunction).	HbA1c,	individual and mean HbA1c values showed no significant improvement after intensive training but decreased considerably only after initiation of IPT (HbA1c pre-IPT 9.16%, post-IPT 7.6%, *P* < 0.0025).The study concluded that initiation of IPT was the major factor contributing to the observed favourable outcomes.

Referencecountry	Level and type of study, and N	Intervention	Outcomes	Results
Voevodin 2003 Australia	Survey- self administered questionnaire sent to N=25, with N=16 respondents	A diabetes educator conducted one-and-a-half-day training for patients commencing IPT. The program provided information and training to operate the pump and to set the initial basal rates and premeal boluses. The nutrition session was held at the end of the second half-day and lasted for 45–60 min. In addition, written nutritional information on carbohydrate exchanges and glycaemic index and several other learning aids (e.g. 'Facts on fat', 'Sugar update') were used as teaching materials.	Knowledge, food choice, satisfaction	the most useful information provided (as rated by four patients) was the information on carbohydrate counting and glycaemic index. Of 11 participants who answered this specific question, eight participants were able to recall a message from the session consistent with the information provided and five participants actively made dietary changes following the session.
Morrison 2003 UK	Descriptive study, questionnaire and interview Sample size not reported	2 x group sessions During the first session, basic pump programming and operation skills were taught. The participants were allowed to take the pump home as this enabled them to become more familiar with the pump. In the second session, IPT commenced The training included practical components including having lunch with dietitian, and discussion about dietary, lifestyle and pump management issues. The day after initiation of IPT, the group met again for information on adjusting the basal rate and also to discuss knowledge gaps and problems. Subsequent follow up was arranged according to specific needs until glycaemic control was optimised.	Participant satisfaction	all participants were very positive about the group program. Furthermore, the study found that group participation saved approximately 10–27 h of professional time compared to individual training. The study concluded that the group approach for IPT training allows the development of peer support, strengthens the learning process and avoids isolation.

The authors commented on the difficulty in drawing strong conclusions due to the lack of high-quality comparative studies, small sample sizes and the variability of reported methods in the included studies. They concluded that a mix of group and individual teaching, multidisciplinary teams as educators, educational materials, long-term training with multiple sessions and a variety of educational contents may all be effective for delivering IPT education and training.

Primary Studies

Chellamuthu 2009

This study reports a retrospective clinical audit of 85 adults attending a UK tertiary diabetes service with a mean follow-up time of 19 months.(6) Of the 85 adults the results of a subgroup of 35 participants who had undergone a Dose Adjustment For Normal Eating, DAFNE course prior to commencing CSII were reported.

RESULTS				
	Before DAFNE	After DAFNE and before pump	After pump (latest) (p value as compared to after DAFNE	
Average HbA1c (SD)	9.2(1.6)	8.9(1.3)(p<0.05)	8.5(1.3) (p<0.05)	
severe hypoglycaemia (episodes/patient year)	0.2	0.03	0.04	
diabetic ketoacidosis (episodes/patient year)	0.03	0.03	0.04	

The authors concluded that glycaemic control improves in DAFNE graduates without an increase in severe hypoglycaemia.

Clark 2011

Clark et al report the results of a retrospective audit in a group of 21 adults attending a UK diabetes service.(7) The participants had transitioned from MDI to CSII following completion of the DAFNE course. Outcome measures included HbA1c, hypoglycaemia, admissions to hospital (measured in the last year), hyperglycaemia admissions to hospital (measured in the last year), hypoglycaemia severity and hypoglycaemia awareness. The number of outpatient visits was also ascertained (measured in the last year). Patients also completed three questionnaires: the Problem Areas In Diabetes (PAID) questionnaire, Symptoms Awareness of Hypoglycaemia questionnaire, and a questionnaire designed by JCB, relating to satisfaction and clinical contact time (not validated)

RESULTS			
	MDI	**Post-DAFNE**	**Post-CSII**
Average HbA1c(range)	9.02 (7.3–12.2)	8.59 (7.0–11.3)	8.02 (6.2–9.3)
Episodes of severe hypoglycaemia	1	1	1
Length of time managing diabetes/day In first 3 months After first 3 months	 30-60mins 30-60mins	 30-60mins 30-60mins	 30-60mins 30-60mins
No. of contacts with health care team In first 3 months After first 3 months	 5–10 <5 5-10	 5-10 <5 5-10	 5-10 5-10

RESULTS			
Satisfaction with treatment (scale 0–8, 8 being very satisfied	5	6	7
Would recommend treatment (scale 0–8, 8 being 'Yes, definitely';	5	6	8
Admissions to hospital were low with no admissions for hypoglycaemia in any group and three admissions for hyperglycaemia (one in the MDI group and two on CSII). There were no episodes of diabetic ketoacidosis in any group. All patients had hypoglycaemia awareness before and after commencing CSII therapy.			
Thirteen patients completed the PAID questionnaire before and after starting CSII therapy. The mean pre-CSII score was 20.3 (range 3–67) with 10 patients showing an improved score (mean 17.6; range 2–62) with one unchanged and two showing a small deterioration (reduction in quality of life of 2 and 3).			

The authors concluded with three key messages. Firstly that CSII is associated with better glycaemic control than MDI ± structured education. CSII is preferred by patients and they are more likely to recommend this therapy modality to others despite the higher intensity of therapy and CSII is associated with higher input of health care professionals even after the initial period of time on the new modality.

Fish 2008

This prospective pre-test post-test designed study includes n=113 participants who completed the Advanced Insulin Management (AIM) program at a US diabetes centre.(8) Of the total number of participants, n=20 were currently using an insulin pump at commencement of the study, and n=46 transitioned from MDI to CSII following completion of the program. The program was delivered by a multidisciplanary diabetes team including a psychologist, diabetes educator, dietitian and endocrinologist. Participants attended 3 x weekly group education sessions of 3 hours duration to learn about flexible insulin dosing. The program included home work as well as real-time feedback on blood glucose results. Following this program participants who opted to change from MDI to CSII attended 3 x weekly sessions of 2 hours duration to initiate insulin pump therapy. Primary outcomes included change in Hba1c and weight from baseline to 12 months post AIM and a secondary outcome was diabetes distress as measured by the PAID-2 scale. HbA1c(SD) for the entire group fell from 7.73(1.1) to 7.28 (1.0) P<0.001. For the three individual groups drop in Hba1c were reported graphically as below.

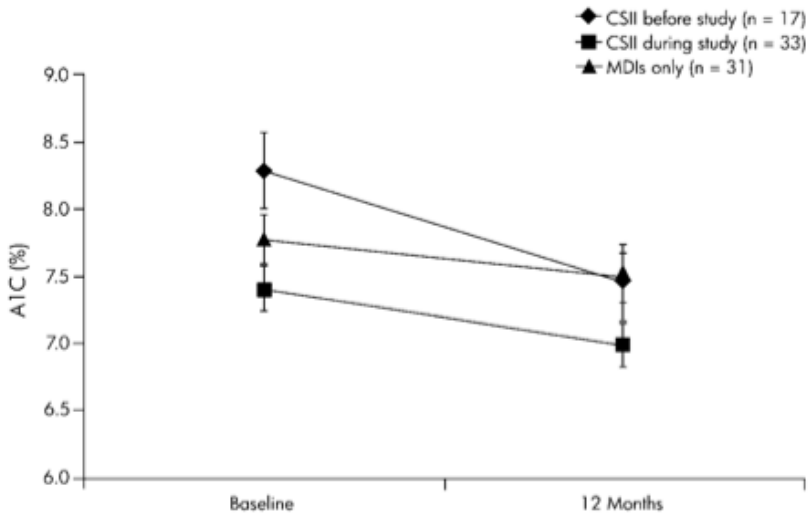

Figure. Changes in mean A1C levels by continuous subcutaneous insulin infusion (CSII) status (n = 81). MDIs = multiple daily injections.

There was no significant change in weight for the entire group from baseline to 12months. Results for those using CSII were not reported separately. The Paid score improved significantly in the group who were already using CSII at beginning of study (19.6 to (15.9; p =0.028)

The authors concluded that intensive approaches like the AIM program are needed to achieve better glycemic control, even in moderately well-controlled populations.

Kerr 2008

Kerr and colleagues report the results of a retrospective audit of 112 adults initiated on CSII at a UK diabetes service.**(9)** The completion of a structured and quality assured group education programme, based around MDI's, which meets criteria as laid down by NICE, is a prerequisite for insulin pump therapy at this diabetes service. Once this course has been completed the following steps are taken to initiate CSII- 1. Initial assessment visit with the diabetes consultant and Diabetes Educator, 2. A 2 hour carb counting session 3. A 2 day group education session for initiation of pump, 4. Individual follow-up according to a structured pathway of care. Follow-up reviews occur in a formal pump clinic and cover key areas of safety education and clinical effectiveness, with the facility for computer pump download available. Outcomes included HbA1c and change in weight, with length of follow-up up to 3 years.

	HbA1c(%)	weight (kgs)
commencing pump	8.73(1.41) n=105	73.25(12.35) n =96
1 year	8.01(1.21) n=76	72.87(12.74) n=69
2 years	8.05(1.10) n=73	74.45(13.59) n=62
3 years	7.96(1.19) n=54	74.16(11.61) n=51
mean change after 1 year (95% CI)	-0.66(0.38;0.93) p<0.001 n=71	+1.05(-0/17;2.27) p=0.093 n=60
mean change after 2 years (95% CI)	-0.60(0.30;0.89) p<0.001 n=68	+1.96(0.61;3.31) p<0.01 n=57
mean change after 3 years (95% CI)	-0.46(0.14;0.78) p<0.005 n=52	+1.31(-0.86;-3.49) p=0.229 n=48

The authors concluded that Before commencing CSII adult patients should have participated in a structured group education program focusing on the nuances of intensive insulin therapy.

Discussion

This systematic review aimed to identify published studies concerning the effectiveness of education, training and the optimal timing of review of adults managed on insulin pump therapy. A broad search strategy was undertaken with one level 1 study and 4 primary studies identified. The 5 studies included in the level 1 study and the 4 primary studies were all descriptive studies involving a small number of study participants. Outcomes measured included HbA1c, rates of severe hypoglycaemia,DKA, and hospital admissions, patient satisfaction, weight, hypoglycaemia awareness, diabetes distress, patient knowledge and behaviours relating to diet. There were no measures reported in the included studies of patient knowledge and skills relating insulin pump therapy and intensive diabetes management, or self-care behaviours specific to insulin pump therapy.

Q3 and 3.1-Group versus individual Education. There were no comparative studies testing the effectiveness of group versus individual education programmes for insulin pump therapy identified for this review. Of the

studies included in the review, all reported on group educational programs with four of the studies reporting individual education in conjunction with the group program.

Q 4 and 4.1- Optimal timing of Review. There were no studies reporting the optimal timing of review at either insulin pump initiation or at insulin pump upgrade.

Q 5 and 5.1- Key Component of Education and Initiation and Upgrade. Of the studies included in the level 1 study, one involved a course aimed at transitioning participants from conventional to flexible MDI prior to pump start. All four of the primary studies described a similar process. One of the primary studies also included participants who were currently on insulin pump therapy prior to attending an advanced insulin management course.(8) Two of the primary studies involved participants completing the DAFNE course.(6, 7) Critical components of the DAFNE course and the AIM course include, carbohydrate counting,blood glucose monitoring, and calculation of insulin requirements. Of the studies which described the components of education at insulin pump initiation, they included technical instruction, setting basal rates and delivering bolus insulin doses, care of needle insertion sites, pump malfunction, catheter and tape, adjustment of insulin dose, daily living instructions, prevention and management of ketoacidosis and severe hypoglycaemia, blood glucose self-monitoring and documentation.

Q6. Effectiveness of Structured Education. Three of the studies included in the level 1 study measured the impact on HbA1c of structured education. The largest of these studies reported a significant drop in mean relative HbA1c one year post a 7 day structured education program. A significant reduction in the rate of Severe Hypoglycaemia, DKA and number of days of hospitalisations was also reported in this study.(5) One study reported a drop in HbA1c following structured education for flexible MDI with no further improvement following initiation of insulin pump therapy.(5) One study reported no significant drop in HbA1c following structured education.(5) Of the primary studies all four reported decreases in HbA1c following structured education and one reported a reduction in rate of severe hypoglycaemia(6), with another reporting no change.(7) One study reported changes in level of diabetes distress as measured by the PAID-2 score following initiation of CSII, with 10 participants showing an improved score, 2 unchanged and one showing a slight deterioration.

Conclusion

This systematic review of evidence concerning the effectiveness of education at insulin pump start and upgrade and the optimal timing of review is based on one level 1 study of low risk of bias and 4 primary studies of high risk of bias, involving n= 526 adults with type 1 diabetes. One of the studies was carried out in Australia, with the other studies carried out in the UK, Germany and US. Reported study exclusions were pregnancy and non-English speaking background. There were no comparative studies included in this review.

Search Strategy

Medline- 5th July 2012

	1	exp Diabetes Mellitus, Type 1/	56851
	2	Education/ or eduction mp.	686352
	3	patient education.mp. or exp Patient Education as Topic/	72451
	4	health education.mp. or exp Health Education/	134979

	5	(((diabet$ or lifestyle or education$) and intervention$) or program$).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	601537
	6	(continuous subcutaneous insulin infusion or csii or insulin pump therapy or ipt).mp.[mp=title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept,unique identifier)	2572
	7	meta-analysis.mp. or exp Meta-Analysis/	53844
	8	systematic review.mp.	27854
	9	pooled analysis.mp.	2512
	10	(review and medline).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	36535
	11	(systematic* and (review* or overview*)).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	59217
	12	7 or 8 or 9 or 10	119829
	13	2 or 3 or 4 or 5	1128846
	14	1 and 6 and 12 and 13	13
	15	limit 16 to (english language and humans)	10

	Citations
EMBASE	7
Cinahl	0
INAHTA	24
Cochrane	4

Medline search for Primary studies- 8th July

	1	exp Diabetes Mellitus, Type 1/	56851
	2	Education/ or eduction mp.	686352

	3	patient education.mp. or exp Patient Education as Topic/	72451
	4	health education.mp. or exp Health Education/	134979
	5	(((diabet$ or lifestyle or education$) and intervention$) or program$).mp. [mp=title, original title, abstract, name of substance word, subject heading word, unique identifier]	601537
	6	(continuous subcutaneous insulin infusion or csii or insulin pump therapy or ipt).mp.[mp=title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept,unique identifier)	2572
	13	2 or 3 or 4 or 5	1128846
	14	1 and 6 and 7	183
	15	limit 16 to (english language and year=2008 to current)	51

Primary studies

	Citations
EMBASE	191
Cinahl	7
INAHTA	24
Cochrane	4

TELEMEDICINE

	Clinical question
	8. What is the effectiveness of telemedicine and other technology-based delivery methods for ongoing management on HbA1c targets and patient satisfaction/quality of life?

Current Guidelines

National evidence based clinical care guidelines for type 1 diabetes in children, adolescents and adults(1)

A systematic review was undertaken to assess the effectiveness of telemedicine and technology based delivery methods for people with type 1 diabetes in rural and remote locations. There was insufficient evidence found to formulate a recommendation.

Nice Guidance(2)

There are no recommendations in these guidelines on the effectiveness of telemedicine and other technology based delivery methods for people using CSII therapy.

American Association of Diabetes Educators 2008 Consensus Summit(4)

There are no recommendations in these guidelines on the effectiveness of telemedicine and other technology based delivery methods for people using CSII therapy.

Systematic Review

A literature search was undertaken in EMBASE, Medline,Cinahl, INAHTA and the Cochrane database. Search terms were searched for as keywords, exploded where possible, and as free text within the title or abstract in the EMBASE and Medline databases. Variations on these terms were used for the Cinahl, Cochrane and INAHTA databases, modified to suit their keywords and descriptors.The initial search was limited to publications since 2000 and in English language and conducted between 5th July and 7 the July 2012. Studies were eligible for inclusion according to inclusion criteria in the table below. A total of 3 publications met the inclusion criteria and were retrieved for full review.

Inclusion criteria

Study design	Any descriptive or comparative study
Population	Adults with type 1 diabetes
Intervention	telemedicine or other technology based delivery methods in management of CSII
Comparator	any
Outcomes	HbA1c, patient satisfaction, QoL

Assessment of study eligibility

A total of 58 publications were identified in the literature search. The title and abstract of citations identified were reviewed and the exclusion criteria applied hierarchically. Publications were excluded if they were the wrong study type (narrative review, editorials), if they were in the wrong population (not in adults with type 1 diabetes) or evaluated the wrong intervention (not telemedicine or technology based delivery method in management of CSII) or reported the wrong outcomes . Only English language publications were eligible for inclusion. Of these 3 publications, 2 were excluded as they were only available in abstract, 4

were excluded as wrong study, and 1 was excluded as wrong intervention. A total of 5 publications met the inclusion criteria.

Literature Search summary

Stage	Notes	Number
Search summary	Medline Embase Cinahl Inahta Cochrane Total	11 20 2 24 6 63
Duplicates identified		5
Total identified		58
Exclusion Criteria	wrong study type (letter to editor, case report) wrong population (not type 1 diabetes in adults) wrong intervention (not telemedicine/ technology and insulin pump) wrong comparator wrong outcome (not HbA1c, patient satisfaction QoL) Total excluded	5 19 27 4 55
Papers retrieved for full review		3
Exclusion criteria	wrong study type (letter to editor, case report) wrong population (not type 1 diabetes in adults) wrong intervention (not diabetes education/ review at pump initiation or follow-up) wrong outcome (not HbA1c, hypoglycaemia, rate of DKA, QoL, knowledge, self care behaviour) Total excluded	0
Meeting Criteria		3
Included		3

Included Studies

Study ID	Citation
Benhamou 2007	Benhamou, P.Y., et al., One-year efficacy and safety of Web-based follow-up using cellular phone in type 1 diabetic patients under insulin pump therapy: the PumpNet study. Diabetes & Metabolism, 2007. 33(3): p. 220-226.

Everett 2010.	Everett, J. and D. Kerr, Telehealth as adjunctive therapy in insulin pump treated patients: a pilot study. Practical Diabetes International, 2010. 27(1): p. 9-10.
Jennings 2009	Jennings, A., et al., A virtual clinic for diabetes self-management: pilot study. Journal of medical Internet research, 2009. 11(1): p. e10.

Characteristics and Results of included studies.

Benhamou 2007

In this randomised cross-over, bi-centre study in France, 31 adults with suboptimal glycaemic control (HbA1c 7.5% to 10%) were randomised to either remotely download their blood glucose results once per week and receive advice from health care professionals via SMS messaging for a period of 6 months followed by 6 months of conventional follow-up or the reverse order. Exclusions included pregnancy, retinopathy, no access to cellular network, not able to perform at least 4 BGLs per day. Participants were taught to use a cellular phone and a personal digital assistant device (PDA). Participants attended routine clinic visits every 3 months. This was a treat to target study with glycaemic targets of 70 to 120 mg/dl pre- prandial and 100 to 160 mg/dl post-prandial. Of the 31 adults enrolled one was later found to have not fulfilled to inclusion criteria due to Hba1c level. Cumulative connection time of the investigators to the server was measured in one centre at 3341 minutes throughout the whole trial duration leading authors to to extrapolate that each investigator required 4.5 minutes per week to monitor each of the 15 patients. The difference in Hba1c between the SMS versus the non-SMS period were not significant. Global scores for Diabetes Quality of Life increased significantly during the SMS period as did satisfaction with life.

treatment sequence	n	HbA1c at baseline	HbA1c at 6 month	difference [95%CI]	p
SMS	30	8.31+-0.65	8.18+-0.59	-0.14[-0.13-0.06]	0.166
No-SMS	30	8.22+-0.72	8.34+-0.67	0.12[-0.13-0.36]	0.333
Paired difference between the treatment sequecnes	30	-0.14+-0.53	0.12+-0.65	0.25[-0.10-0.60]	0.097

Quality of life and Satisfaction

treatment sequence	n	DQoL at baseline	DQoL at 6 month	p
SMS	17	65.6+-6.4	69.3+-9.4	0.05
No-SMS	22	68.8+-8.4	68.8+-9.3	NS
treatment sequence	**n**	**Satisfaction at baseline**	**Satisfaction at 6 month**	**p**
SMS	17	64.8+-11.2	72.9+- 13.4	p=0.01
NO-SMS	22	72.6+-14.7	72.5+-14.4	p= ns

The authors concluded that teletransmission of glucose values using a cellular phone combined with SMS feedback is safe, does not alter quality of life and tends to improve metabolic control non significantly without requiring excessive connection time.

Everett 2010

This UK based pilot project aimed to determine the feasibility of a telehealth system in improving metabolic control in patients with suboptimal glycaemic control using CSII. 16 adults were identified and invited to participate in a trial of a system which allowed wireless download of pump and or glucose meter at home and transmission of this data to a secure file server with data entering the medical teams patient record. Patients could also send or receive messages or video conference with their health provider. Each person was visited at home and the system demonstrated. They were asked to use the system as much as they liked but preferably every few days. Outcomes were measured at baseline, 3 and 12 months and included HbA1c, awareness of hypoglycaemia and problem areas in diabetes
(PAID) score. Of the 16 participants only 12 used the system, one changed to MDI, one had computer problems and two declined to use the system.

Mean HbA1c baseline (range)	Mean HbA1c 3mths (range)	Mean HbA1c 12 months (range)
9.3 (7.6 to 12.5)	8.4(7.6 to 8.7)	8.2(7.1 to 9.6)
significance levels not reported.		

There was no change in hypoglycaemia awareness or the PAID scores. The actual scores were not reported.

The authors reported that the intervention is now offered as part of clinical care and now included educational material, frequently asked questions and a discussion forum.

Jennings 2009

In this before and after study a virtual clinic prototype system was tested for feasibility acceptability and effectiveness. The intervention included six online ‘ask an expert’ sessions with diabetes specialists not directly involved in patients care. These sessions were asynchronous and open to all participants. Participants could also confidentially email their own health care professional at any time and were told to expect a reply within 2 days. Access to a discussion board with synchronous chat allowed for communication with peers, the virtual clinic included access to diabetes information as well as web links to further sources of diabetes related information. 18 adults were recruited from three UK diabetes centres and asked to log on once per week. Outcome measures included Hba1c self efficacy with measured with the Confidence in Self Care Scale(CICS)and quality of life as measured by the Audit of Diabetes Dependent Quality of Life (ADDQoL). The reported baseline characteristics of participants included all white and of British ancestry, 47% educated to undergraduate level or above, and all were regular internet users with an average of 8.9hours per week internet usage. Of the 17 who were enrolled in the study, 4 failed to complete the post test questionaires and follow-up HbA1c values were only available for 6 people. 58% rated the system positively for ease of use and 42% were neutral for ease of use. The intervention was generally well accepted by users who found the online peer support most valuable. There was no significant difference in the HbA1c level pre and post intervention, however follow-up HbA1c only available in 6 of the participants. There was no significant difference in mean ADDQoL scores of pre-test compared with post-test. (-2.1(sd 1.1 range -3.4 to -0.5) compared to -2.0(sd 1.2, range -4.6 to -0.4) post test ; P=6.2 n=12). Confidence was reduced significantly from baseline however authors report that this result was possibly due to an outlier in post test scores in a small sample

size. (89.3(sd 6.64 range 79.8 to 98.8) compared to 83.6(sd 14.4 range 47.6 to 98.8)). The Authors concluded that a virtual clinic appears to be a feasible and acceptable way to provide patients with peer support and information necessary to aid self management.

Discussion

This systematic review was undertaken to identify published studies concerning the effectiveness of telemedicine and other technology based delivery methods for ongoing management of adults on insulin pump therapy. Two descriptive studies of high risk of bias were eligible for inclusion,(10, 11) along with one randomised controlled trial of low risk of bias(12). Two of the studies had an inclusion criteria of 'sub-optimal glycaemic control'(10, 12). Two studies involved the remote download of blood glucose levels with advice on insulin adjustment delivered by health care professionals via SMS text messaging (10)(12). Both of these studies reported a reduction from baseline in HbA1c, this was reported as statistically non-significant in one study(12) with significance levels not reported in the second study(10). One study involved an on-line educational forum as well, a peer-to-peer discussion board and access to advice from healthcare professionals via email.(11) Psychological outcomes were reported in all three of the studies. In one study global scores on the DQOL measure and satisfaction with life increased significantly during the intervention phase.(12) in a second study there were no effects on the PAID score post intervention(10) and in the third study there was no effect on quality of life as measured by ADDQoL scores post intervention, with confidence significantly decreased.(11)

Conclusion

This systematic review is based on three studies, two of high risk of bias, and one of low risk of bias, including a total of N=65 adults. Two of the studies were descriptive with a pre-test post-test design and one study was a randomised controlled trial. Reported exclusions included pregnancy, retinopathy, unable to use hardware, no access to cellular network, not willing to perform 4 BGLs per day.

Search Strategy

Medline- 10th July 2012

	1	exp Diabetes Mellitus, Type 1/	56851
	2	telemedicine.mp or exp Telemedicine/	13855
	3	telehealth.mp	1115
	4	telemonitoring.mp	418
	5	telecommunications.mp. or exp Telecommunications/	53763
	6	(diabetes and internet). mp.[mp= title, abstract original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	912
	7	web-based.mp	9712

	8	(diabetes management and internet).mp [mp= title, abstract original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	0
	9	telecare.mp	277
	10	telephone.mp or Telephone/	36848
	11	2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10	90886
	12	(continuous subcutaneous insulin infusion or csii).mp [mp= title, abstract original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	1296
	13	(insulin pump therapy or IPT).mp [mp= title, abstract original title, name of substance word, subject heading word, protocol supplementary concept, rare disease supplementary concept, unique identifier]	1432
	14	12 or 13	2572
	15	1 and 11 and 14	13
	16	limit 16 to (english language and humans)	11

	Citations
EMBASE	20
Cinahl	2
INAHTA	24
Cochrane	6

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1. Craig ME TS, Donaghue KC, Cheung NW, Cameron FJ, Conn J, Jenkins AJ, Silink M, for the Australian Type 1 Diabetes Guidelines Expert Advisory Group. . National evidence- based clinical care guidelines for type 1 diabetes in children, adolescents and adults. Australian Government Department of Health and Ageing, Canberra. 2011.
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