

Inhaler Technique Assessment Service - ITAS - from research to implementation

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Framework for trials of complex interventions

(British medical research council, 2000)

| | |
|--------------|--------------------------|
| | |
| Pre-clinical | Theory |
| Phase 1 | Modelling |
| Phase 2 | Exploratory trial |
| Phase 3 | Definitive RCT |
| Phase 4 | Long-term implementation |

Different research types I

- Descriptive studies:
 - Medication errors, Drug Related Problems (DRPs), risk, consumer needs, cost, qualitative studies
- Development and demonstration projects:
 - Formative evaluation, action research, pilot studies, limited effect studies
- Randomised controlled trials (RCTs) and cost-effect analyses

Different research types II

- Evidence:
 - Reviews, meta-analyses, “Danish Community Pharmacy Evidence Database”
- Implementation research:
 - Documentation of activity and quality, study implementation process, optimisation of services, leadership
- Comparative research:
 - Health Technology Assessment (HTA), comparison of alternative models of care ?

Service development ITAS

1995

- Improving Drug Therapy for Patients with Asthma (Asthma-TOM)

2001

- ITAS is developed (instruction and implementation-support)

2004

- Small scale test project carried out to document feasibility of ITAS

2005

- Implementation support is developed and made available to pharmacies

2005

- First publicly-funded cognitive service in Danish pharmacies

2005+

- Ongoing development of educational package and follow up on implementation

2009

- PhD Kaa,S on the implementation og ITAS



Improving Drug Therapy for Patients with Asthma— Part 1: Patient Outcomes

Hanne Herborg, Birthe Soendergaard, Bente Froekjaer, Lotte Fønnesbaek, Tove Jørgensen, Charles D. Hepler, Timothy-John Grainger-Rousseau, and Bjarne Kjaer Ersboell

Objective: To evaluate the effects of a therapeutic outcomes monitoring (TOM) program on selected process and outcome measures. **Design:** Prospective, controlled, multicenter study. **Setting:** Community pharmacies throughout Denmark (16 intervention, 15 control). **Patients:** Five hundred patients with asthma aged 16 to 60 years and treated in primary care. **Intervention:** TOM is a community-based program for pharmaceutical care. Using a structured, seven-step, cyclical outcome improvement process, TOM pharmacists identify and resolve (or refer) problems with drug therapy that, if not addressed, might result in therapeutic failure or adverse effects. Equal emphasis is placed on the patient's perspective (e.g., coping, control, and empowerment) and the professional's perspective (e.g., adherence, patient knowledge, and therapeutic problems). TOM requires cooperation among pharmacists, patients, and physicians. **Main Outcome Measures:** Asthma symptom status, days of sickness, health-related and asthma-specific quality of life, use of health care services and resources, and satisfaction with health care and pharmacy. **Intermediate Outcome and Process Measures:** Peak expiratory flow rate (PEFR), knowledge of asthma and asthma medications, inhalation errors, and drug therapy problems in the TOM group. **Results:** The mean individual differences for TOM and control patients were tested. Beneficial effects were found for the following outcome measures: asthma symptom status, days of sickness, and health-related and asthma-related quality of life. Satisfaction with health care and pharmacy varied throughout the course of the project, with no significant difference between groups at the final evaluation. Although not statistically significant, differences in use of services were considered to be clinically significant and encouraging. Beneficial effects were found for knowledge of asthma and medications, inhalation errors, drug use and drug therapy problems. No significant differences were found for PEFR. **Conclusion:** The project demonstrated that therapeutic outcomes monitoring by community pharmacists is an effective strategy for improving the quality of drug therapy for asthma patients in primary health care.

Evidence from Asthma-TOM study

Inhalation errors per patient:

| | Baseline mean | 12 months mean | Individual difference | P- value Nested ANOVA |
|--------------------|---------------|----------------|-----------------------|--------------------------|
| TOM (n=207) | 1,71 | 0,17 | - 1,54 | 0,001 |
| Control (n=190) | 1,21 | 0,75 | -0,46 | |

TOM patients improved 90 %
Controls improved 30%

Small scale test at three pharmacies

Research questions:

- Can the service be implemented according to the instruction?
- Can the service be delivered in the estimated time?
- Are there shortcomings in the instruction, which should then be revised?

Results from test pharmacies

- 60% of patients, who received ITAS, made an inhalation error
- The service was realistic and relatively easy to integrate into the pharmacy's daily routine
- The service could easily be carried out at the counter – no consultation room was needed
- The pharmacies found no crucial shortcomings in the instruction
 - Important to provide simple forms for documentation of the service for the government
- The service can be carried out according to the instruction in the estimated time (10 minutes)
- High satisfaction from patients, doctors and pharmacies.

Aim of the service

- To contribute to optimal use of inhalation medicines by asthma and COPD patients in order to ensure that patients can achieve effect from their treatment.

Defined service

- ITAS is a defined and quality assured service
 - Defined – because the government has agreed to pay for a specific service, which is described in the manual
 - Quality assured – because ITAS is delivered according to an instruction, and the service delivery and process must be documented.

Who is the service for?

1. First times users of inhalation medicines
2. Experienced users, when the pharmacy estimates a patient need, e.g.:
 - Big consumption of beta 2-agonists
 - Use of different devices
 - Children
 - Elderly

No need of physician reference!

ITAS elements

- The pharmacy staff member gives instruction and demonstrates the technique (first time users)
- The pharmacy staff member assesses the patient's inhaler technique
 - The patient demonstrates use of inhaler
 - The pharmacy staff member evaluates the technique by use of a checklist
- Counselling according to observed errors and patient needs, e.g. cleaning advice
- Visitation when needed
- Documentation of delivered service

Reimbursement

- The pharmacy can offer 1 service per patient per year
- The pharmacy is paid 10 Euro per service provided the service is documented

| | Numbers of ITAS /Quarter | Numbers of ITAS / year |
|--------------------|--------------------------|------------------------|
| 1. kv. 2011 | 15.037 | |
| 2. kv. 2011 | 16.461 | |
| 3. kv. 2011 | 12.825 | |
| 4. kv. 2011 | 16.943 | 61.266 |
| 1. kv. 2012 | 15.259 | |
| 2. kv. 2012 | 13.881 | |
| 3. kv. 2012 | 12.022 | |
| 4. kv. 2012 | 17.755 | 58.917 |
| 1. kv. 2013 | 13.495 | |
| 2. kv. 2013 | 13.615 | |
| 3. kv. 2013 | 11.083 | |
| 4. kv. 2013 | 13.653 | 51.846 |

Facilitating implementation

- The ITAS instruction
- Catalogue of Implementation Ideas
- FAQ (Frequent asked questions)
- Information Material:
 - Illustrated brochure for patients
 - Letter introducing the service to local physicians
 - Local press release
- Protocols for all devices
- Consultants employed by the Danish Association of Pharmacies provide assistance
- Pharmakon offers courses and consultancy

Quality control and documentation

- **Continuous publication of statistics** on pharmacy uptake and on number of services delivered
 - -> *Slow beginning*
- **Benchmarking** between pharmacies locally, in districts, in the country as a whole
- **Contact to all pharmacies** which had not provided the service
 - -> *Good uptake; anecdotal reports about quality problems*
- **Pseudo-patient** visits
 - Pilot (75 pharmacies – one visit)
 - -> *Confirmed quality problems*
 - Full scale (251 pharmacies – five visits)

The relationship between leadership style and provision of the first Danish publicly reimbursed cognitive pharmaceutical service--a qualitative multicase study.

[Kaae S¹](#), [Søndergaard B](#), [Hauqbølle LS](#), [Traulsen JM](#).

Author information

Abstract

BACKGROUND: Evidence suggests that leadership style is important to the sustainability of cognitive pharmaceutical services, yet only scarce literature on the relationship exists.

OBJECTIVES: Support of the sustainability of the first publicly reimbursed cognitive service in Denmark, the Inhaler Technique Assessment Service (ITAS), was ascertained through a qualitative study to explore how leadership style shapes the implementation process of the service. Sustainability in this project was defined as the state where those asthma patients whose symptom status is negatively clinically affected (as defined by Global Initiative for Asthma guidelines) by inappropriate inhalation technique are identified and offered the service by pharmacy staff.

METHODS: The study was an exploratory qualitative multicase study that used triangulation of both data sources and methods. A theoretical framework of Bolman and Deal inspired the analysis of how leadership style influenced the local process of implementation of the ITAS. Four pharmacies were selected for the analysis because they differed in terms of leadership actions in their implementation process and achievement of ITAS sustainability. The analysis was inductive and linked factors that influence ITAS provision as perceived by employees with the interpreted leadership style of the owner.

RESULTS: Three main themes emerged: (1) the alignment of the owner and staff values, (2) whether owners perceived ITAS development as being under their own control, and (3) whether owners explicated the responsibilities of employees in the implementation process. The themes were interrelated.

CONCLUSIONS: Pharmacy owner's leadership style was significant to sustainability of the ITAS. A strong wish by the owner to have ITAS implemented was important, followed by aligning the owner's values and visions with those of the employees. The widespread perception by owners that experienced users are not interested in the ITAS needs to be addressed to achieve sustainability.

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Accreditation of ITAS

- Test of knowledge
- Professional assessment in the delivery of ITAS
 - Documented
- Delivery of 5 services
 - Documented
- Reaccreditation after 3 years

Conclusion

- Evidence helped
 - In the negotiation of the reimbursement
 - In the development of instructions and implementation tools
 - The implementation support needs different research focus
- The implementation process has been successful, but is still ongoing at the pharmacies
- Continued focus on the quality of the delivered services
- It is a challenge to get all the pharmacies fully involved

We need research to

