MEDIZINISCHE UNIVERSITÄT INNSBRUCK

Compliance (Adhärenz) bei onkologischen Behandlungen – gut oder Pillen für die Tonne?

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Abgebrochene Aidsstudie
Pillen für die Tonne

Eine große Studie zur Prävention einer HIV-Infektion scheitert an unwilligen Probanden:

Zwei Drittel der teilnehmenden afrikanischen Frauen verweigerten heimlich die Einnahme der Medikamente.

Medikamente Viele möchten kürzer leben statt Pillen schlucken

Täglich Pillen und Kapseln einnehmen zu müssen, reduziert die Lebensqualität. Viele Menschen würden bei dieser Aussicht sogar ein paar Jahre Lebenszeit opfern. Spielt die Angst vor Nebenwirkungen eine Rolle?

Compliance

Mit Compliance wird das Aus-maß bezeichnet, mit dem ein tatsächlicher Behandlungs-vollzug mit dem optimalen Behandlungsvollzug überein-stimmt.

Compliance

Therapeutische Compliance:
Grad der Übereinstimmung zwischen dem Patientenverhalten und den vom Arzt vorgegebenen Behandlungsrichtlinien.

Compliance

Therapeutencompliance:
Grad der Übereinstimmung zwischen den durchgeführten ärztlichen Maßnahmen und den geltenden medizinisch-wissen-schaftlichen Standards.

Adhärenz (Adherence)

beschreibt das Ausmaß indem das Verhalten einer Person therapeutischen gemeinsamen Vereinbarungen (u.a. Medikation, Diät, Lebensstiländerungen) folgt. Adhärenz wird zunehmend bevorzugt gegenüber Compliance (passives Befolgen des medizinischer Vorschriften) und setzt voraus die therapeutische Allianz und einen Behandlungsvertrag.

→ Shared decision making, Partizipative Gesprächsführung:

The extent to which a person‘s behaviour – taking medication, following a diet, and /or executing lifestyle changes, corresponds with agreed recommendations from a health care provider.

Haynes 1979

Table 1. Methods of Measuring Adherence.

Test	Advantages	Disadvantages
Direct methods		
Directly observed therapy	Most accurate	Patients can hide pills in the mouth and then discard them; impractical for routine use
Measurement of the level of medicine or metabolite in blood	Objective	Variations in metabolism and "white-coat adherence" can give a false impression of adherence; expensive
Measurement of the biologic marker in blood	Objective; in clinical trials, can also be used to measure placebo	Requires expensive quantitative assays and collection of bodily fluids
Indirect methods		
Patient questionnaires, patient self-reports	Simple; inexpensive; the most useful method in the clinical setting	Susceptible to error with increases in time between visits; results are easily distorted by the patient
Pill counts	Objective, quantifiable, and easy to perform	Data easily altered by the patient (e.g., pill dumping)
Rates of prescription refills	Objective; easy to obtain data	A prescription refill is not equivalent to ingestion of medication; requires a closed pharmacy system
Assessment of the patient's clinical response	Simple; generally easy to perform	Factors other than medication adherence can affect clinical response
Electronic medication monitors	Precise; results are easily quantified; tracks patterns of taking medication	Expensive; requires return visits and downloading data from medication vials
Measurement of physiologic markers (e.g., heart rate in patients taking beta-blockers)	Often easy to perform	Marker may be absent for other reasons (e.g., increased metabolism, poor absorption, lack of response)
Patient diaries	Help to correct for poor recall	Easily altered by the patient
When the patient is a child, questionnaire for caregiver or teacher	Simple; objective	Susceptible to distortion

Osterberg L, Blaschke T. N Engl J Med 2005;353:487-497.

Adhärenz

- In der **AKUT BEHANDLUNG** und **klinischen Studien** höhere Adhärenz
- In der **Langzeitbehandlung** niedrige Adhärenzraten insbesondere nach 6 Monaten
- Chronische Erkrankungen (auch in Studien nur 43-78% Adhärenz)
- „White coat adherence“: 5 Tage vor und nach einem Termin verbessert sich die Adhärenz

„ I know it must be difficult to take all your medications regularly. How often do you miss taking them?” This approach makes most patients feel comfortable in telling the truth and facilitates the identification of poor adherence. A patient who admits to poor adherence is generally being candid. Patients should also be asked whether they are having any side effects of their medications, whether they know why they are taking their medications, and what the benefits of taking them are”.

(Osterberg und Blaschke 2005)

KOSTEN der NON ADHÄRENZ

Hundert Milliarden $ in der USA (DI Matteo 2004)

durch Medikamtenvergeudung

fehlende Wirkung

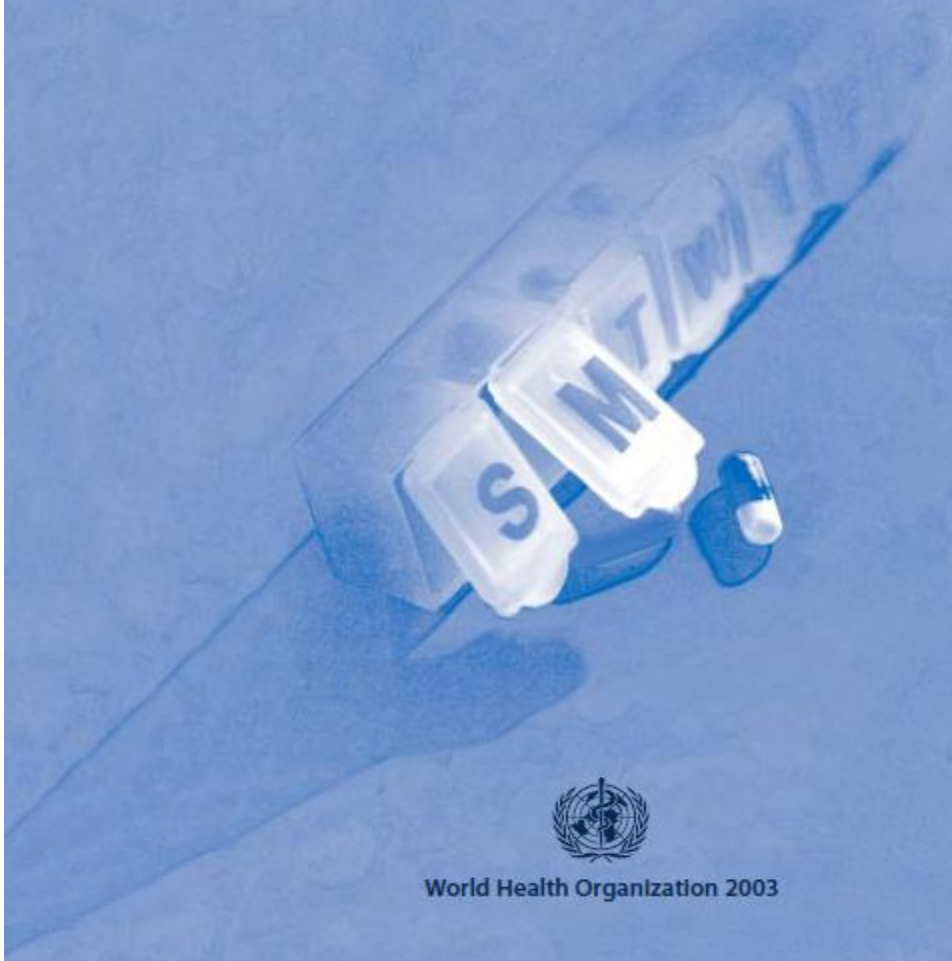
falsche Wirkung

„Adherence rates have been found to be nearly 3 times higher in primary care relationships characteriezd by very high levels of trust coupled with physicians' knowledge of the patient as a whole person. In fact, patients' trust in their physician has been found to far exceed many other variables when it comes to promoting patients' satisfaction with their care (*Safran et al 1998).*

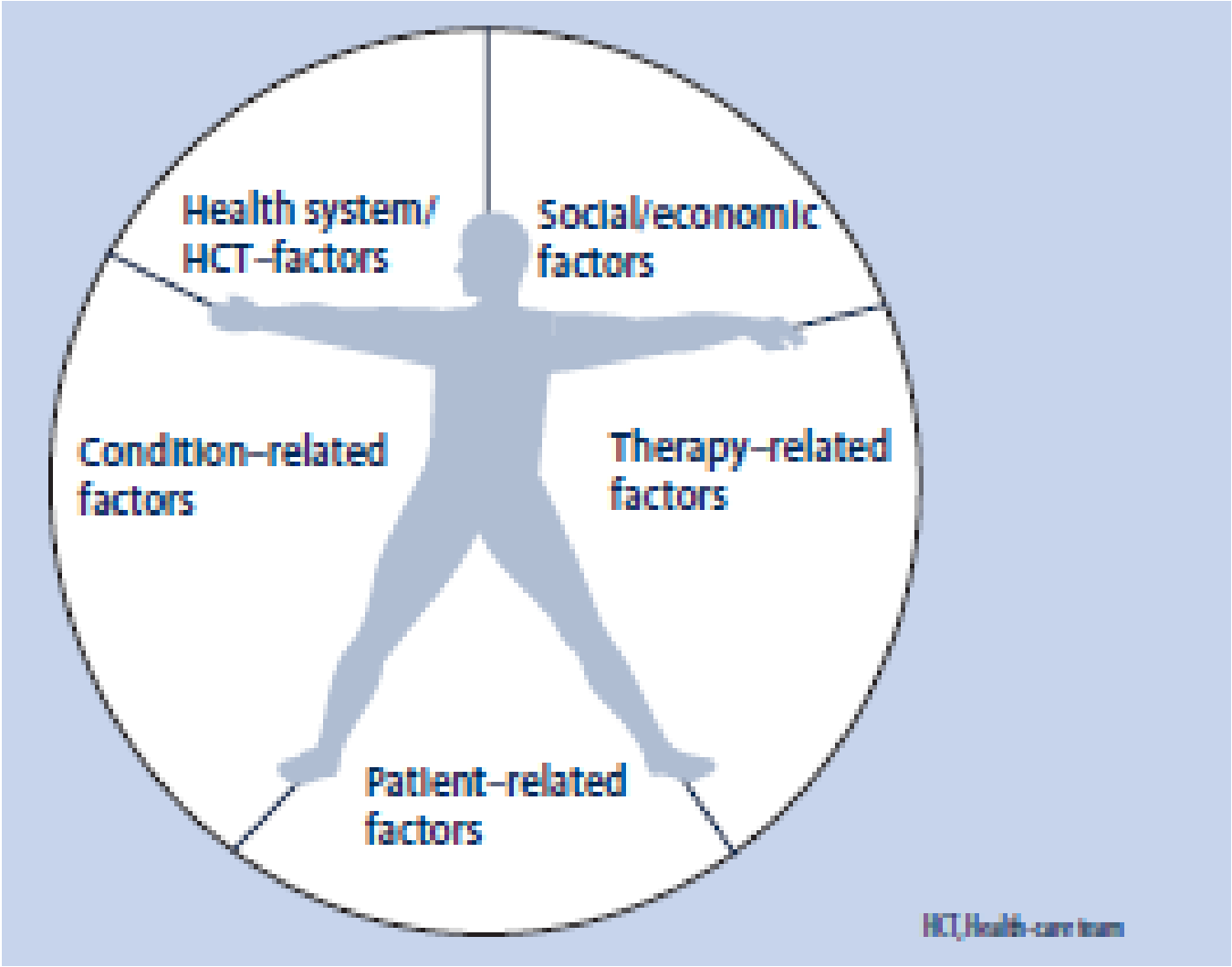
Ärzte sind in der Regel nicht gut informiert über die Adhärenz der Patienten.

ADHERENCE TO LONG-TERM THERAPIES

Evidence for action



World Health Organization 2003


Health system/
HCT-factors
Social/economic
factors
Condition-related
factors
Therapy-related
factors
Patient-related
factors
HCT, Health-care team

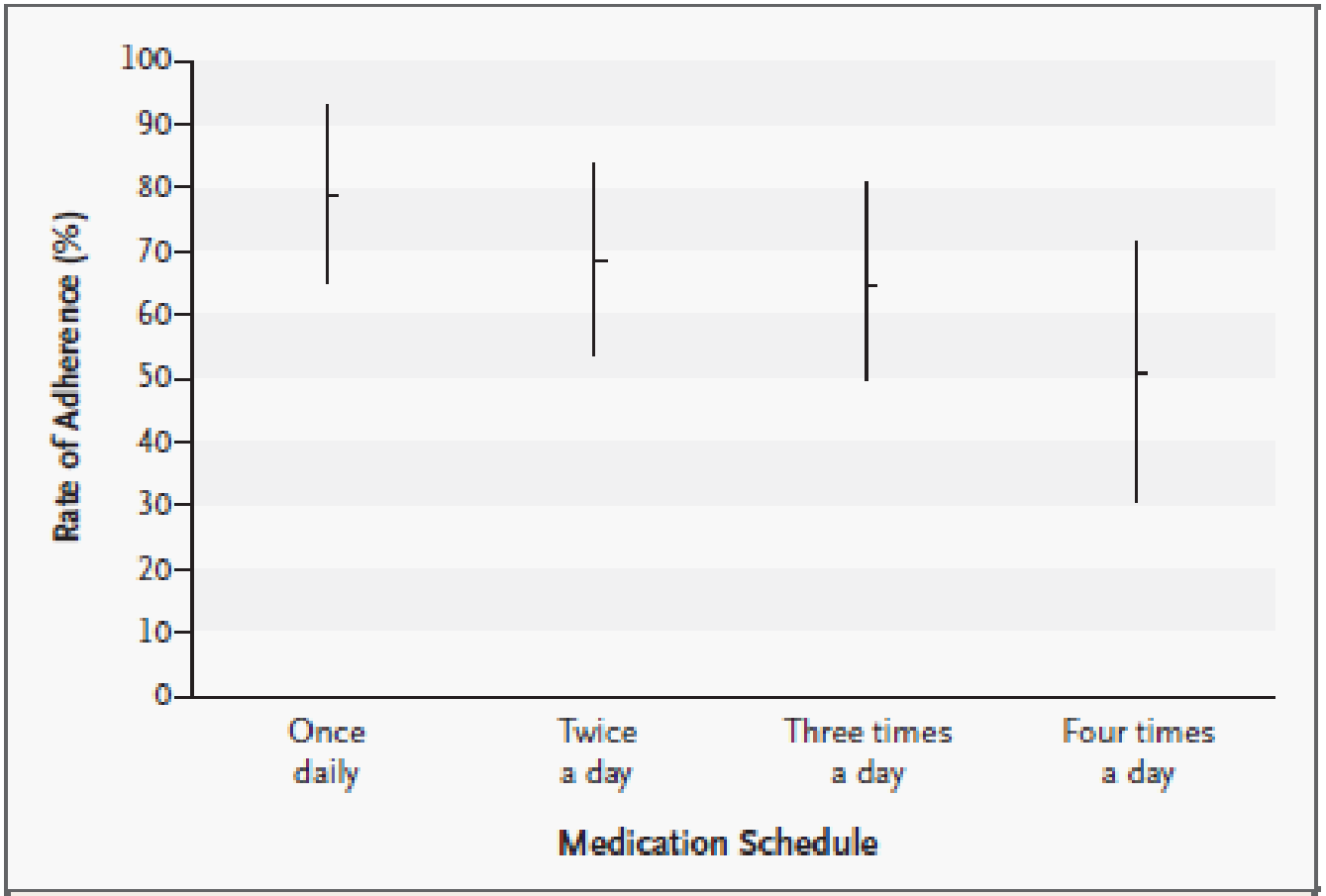


Figure 1. Adherence to Medication According to Frequency of Doses.
Vertical lines represent 1 SD on either side of the mean rate of adherence (horizontal bars). Data are from Claxton et al.[7]

Osterberg L, Blaschke T. N Engl J Med 2005;353:487-497.

Therapie Faktoren

Folgende Faktoren sind von besonderer Bedeutung:

- Nebenwirkungen der Therapiewirkung
- Langsames Einsetzen der positiven Therapiewirkung (z.B. bei Antidepressiva erst nach 10 – 14 Tagen)
- Langsames Einsetzen negativer Folgen bei Absetzen der Therapie
- Komplizierte Behandlungen erschweren die Compliance
- Aufsplitterung der ärztlichen Verantwortung
- Problem in der Arzt-Patient-Beziehung

Compliance erhöhen	Compliance vermindern
• Zufriedenheit des Patienten mit der Arzt-Patient-Beziehung • Gute Information und Überwachung des Patienten • Krankheitskonzepte des Patienten (Krankheit wird als ernst, aber therapierbar angesehen) • Behandlung lässt sich in das Leben integrieren • Stabile Familiensituation, Familie ist an der Therapie interessiert	• Gestörte Arzt-Patient-Beziehung • Unzureichende Information und zu hohe Komplexität der Anweisungen • Krankheitskonzepte des Patienten (Krankheit ist asymptomatisch oder wird als nicht therapierbar angesehen) • Behandlung erfordert eine erhebliche Lebensveränderung • Nebenwirkungen • Dauer der Behandlung • Persönlichkeit des Patienten (Angststörungen, Alkohol/Medikamentenmissbrauch, soziale Isolation, Gedächtnisstörungen u.a.)

Tab. Diese Faktoren verändern die Compliance positiv oder negativ.

Table 2. Major Predictors of Poor Adherence to Medication, According to Studies of Predictors.

Predictor	Study
Presence of psychological problems, particularly depression	van Servellen et al.,[51] Ammassari et al.,[52] Stilley et al.[53]
Presence of cognitive impairment	Stilley et al.,[53] Okuno et al.[54]
Treatment of asymptomatic disease	Sewitch et al.,[55]
Inadequate follow-up or discharge planning	Sewitch et al.,[55] Lacro et al.[56]
Side effects of medication	van Servellen et al.[51]
Patient's lack of belief in benefit of treatment	Okuno et al.,[54] Lacro et al.[56]
Patient's lack of insight into the illness	Lacro et al.,[56] Perkins[57]
Poor provider–patient relationship	Okuno et al.,[54] Lacro et al.[56]
Presence of barriers to care or medications	van Servellen et al.,[51] Perkins[57]
Missed appointments	van Servellen et al.,[51] Farley et al.[58]
Complexity of treatment	Ammassari et al.[52]
Cost of medication, copayment, or both	Balkrishnan,[59] Ellis et al.[60]

Osterberg L, Blaschke T. N Engl J Med 2005;353:487-497.

Soziale und ökonomische Faktoren beeinflussen die Adhärenz

- Armut
- Kultureller Hintergrund – fehlende Bildung
- Alter und Geschlecht: Jugendliche als Problemfeld mit Adhärenz < 50 %
  Alter mit kognitiven Einschränkungen
- Gesundheitssystem – Bezahlung
- Erkrankungsfaktoren
  Depression mindert Adhärenz
- Therapiebezogene Faktoren
- Patientenbezogene Faktoren

↓

<u>WICHTIGSTER FAKTOR</u>

Arzt-Patient-Kommunikation

Arzt-Patient-Beziehung

Zolnierek, Di Matteo, Med Care. 2009; 826-834.
Physician communication and patient adherence to treatment: a meta-analysis

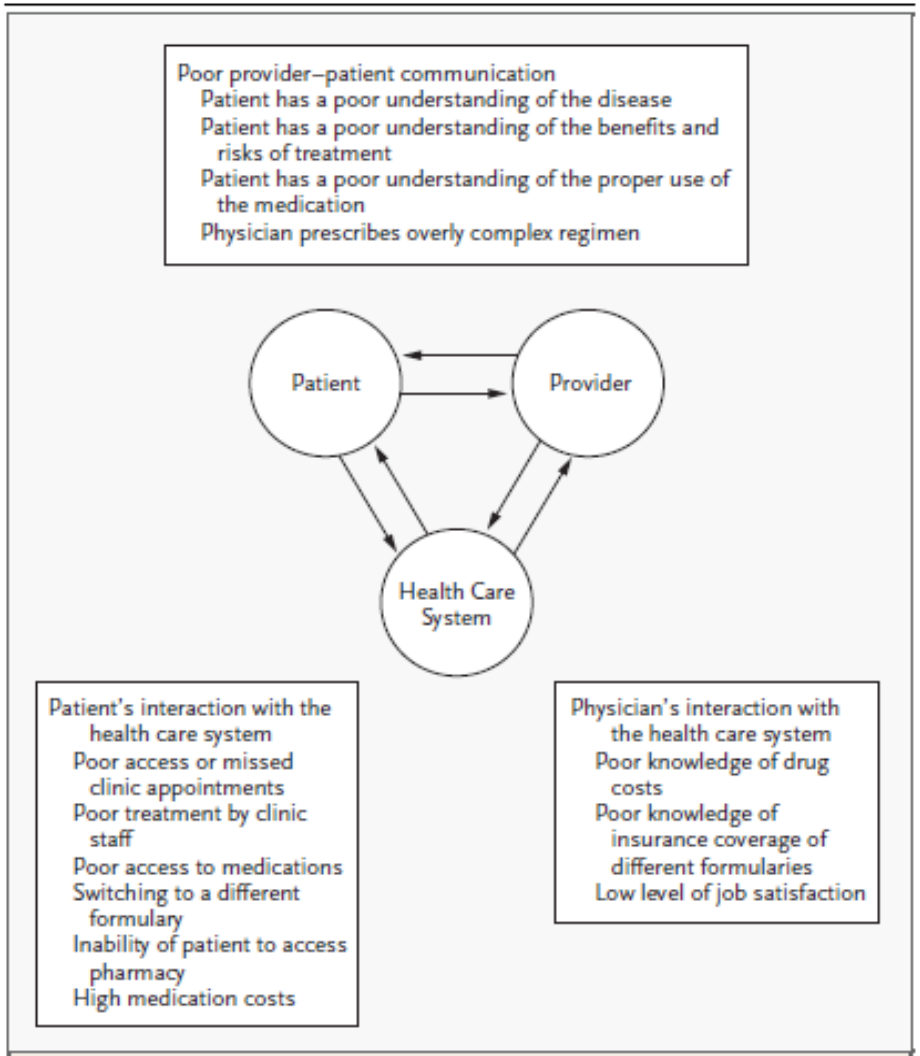


Figure 2. Barriers to Adherence.

The interactions among the patient, health care provider, and health care system depicted are those that can have a negative effect on the patient's ability to follow a medication regimen.

Osterberg L, Blaschke T. N Engl J Med 2005;353:487-497.

Folgen

- verringerte klinische Wirksamkeit der Behandlung
- Entstehung von Therapieresistenz (u.a. Antibiotika)
- Erkrankungsrückfälle, Abhängigkeit, Toxizität

↓

Increasing the effectiveness of adherence interventions might have a far greater impact on the health of the population than any improvement in specific medical treatments.

Veränderung des Gesundheitssystems

- • Systems direct appointment length, and providers report that their schedules do not allow time to
- adequately address adherence behaviour.
- • Systems determine fee structures, and in many systems (e.g. fee-for-service) the lack of financial reimbursement
- for patient counselling and education seriously threatens adherence-focused interventions.
- • Systems allocate resources in a way that may result in high stress and increased demands upon
- providers which, in turn, have been associated with decreased adherence in their patients.
- • Systems determine continuity of care. Patients demonstrate better adherence behaviour when they
- receive care from the same provider over time.
- • Systems direct information sharing.The ability of clinics and pharmacies to share information on
- patients' behaviour regarding prescription refills has the potential to improve adherence.
- • Systems determine the level of communication with patients.Ongoing communication efforts (e.g.
- telephone contacts) that keep the patient engaged in health care may be the simplest and most
- cost-effective strategy for improving adherence.

Diabetes

Patientenschulung verbessert die Adhärenz und die glykämischen Werte – nach 3 Monaten reduzieren sich die Verbesserungen → Kontinuität

Hypertonie

In einem mehrjährigen Projekt zeigte sich die verbesserte Adhärenz mit besseren Werten (Gewicht – RR) und einer deutlichen Mortalitätsreduktion (Morisky et al 1983)

Asthma

„Nur“ Patientenschulung führte zu keinen Verbesserungen, Schulung und Selbst-Management führte zu Adhärenz-, Kosten- und Gesundheitsverbesserung

NIH Antiretroviral Guidelines

Inform patient, anticipate, and treat side-effects.

- Simplify food requirements.
- Avoid adverse drug interactions.
- If possible, reduce dose frequency and number of pills.
- Negotiate a treatment plan, which the patient understands and to which he or she is committed.
- Take time, and use several encounters, to educate the patient and explain the goals of therapy and the need for adherence.
- Establish the patient's readiness to take medication before the first prescription is written.
- Recruit family and friends to support the treatment plan.
- Develop a concrete plan for a specific regimen including dealing with side-effects and relate it to meals and the patient's daily schedule.
- Provide a written schedule with pictures of medications, daily or weekly pill boxes, alarm clocks, pagers or other mechanical aids to adherence.
- Set up adherence support groups, or add adherence issues to the regular agenda of support groups.
- Develop links with local community-based organizations to help explain the need for adherence using educational sessions and practical strategies.
- Consider "pill trials"with jelly beans.

Confusion and forgetfulness are major obstacles

NIH Antiretroviral Guidelines

- Establish trust.
- Serve as educator, source of information, continuous support and monitoring.
- Provide access between visits for questions or problems by giving the patient a pager number, and arranging for coverage during vacation periods and conferences.
- Monitor adherence; intensify management during periods of low adherence (e.g. by means of more frequent visits, recruitment of family and friends, deployment of other team members, referral for mental health or chemical-dependency services).
- Utilize health team for all patients, for difficult patients and for those with special needs (e.g. peer educators for adolescents or for intravenous drug users).
- Consider the impact of new diagnoses (e.g. depression, liver disease,wasting, recurrent chemical dependency), on adherence and include adherence intervention in their management.
- Enlist nurses, pharmacists, peer educators, volunteers, case managers, drug counsellors, physician’s assistants, nurse practitioners and research nurses to reinforce the message of adherence.
- Provide training on antiretroviral therapy and adherence to the support team.
- Add adherence interventions to the job descriptions of HIV support-team members; add continuity-of-care role to improve patient access.

Je besser ein Patient aufgeklärt und informiert ist, je aktiver und selbstverantwortlicher er die Therapie durchführt, umso besser ist die Compliance (siehe Tabelle).

Ein Problem ist die häufige Verschreibung von mehreren Medikamenten gleichzeitig. Die Compliance fällt ab drei Medikamenten gleichzeitig drastisch ab. Die pharmakologischen Wechselwirkungen potenzieren sich, ebenso die UAW (unerwünschte Arzneimittelwirkdung).

- Bei 2 Medikamenten – 1 Wechselwirkung
- Bei 3 Medikamenten – 3 Wechselwirkungen
- Bei 4 Medikamenten – 6 Wechselwirkungen
- Bei 5 Medikamenten – 10 Wechselwirkungen

Patienten mit 2 Medikamenten gleichzeitig zeigten 0,17% schwere und 0,67 moderate Interaktionen, Patienten mit 8 Medikamenten gleichzeitig 3,58% schwere und 21,5 % moderate Wechselwirkungen (Halkin et al. 2001).

Passiver Patient	Aufklärung und Information	• Klare und einfache Sprache, Patient wird aufgefordert, Fragen zu stellen und geben, am Ende die Information zu weiderholen
∑	Verbesserung der therapeutischen Maßnahmen	• Schriftliche Informationshilfen • Minimierung der Nebenwirkungen • Therapie sollte auf die Lebensart des Patienten zugeschnitten werden
Aktiver Patient	Dialog Arzt-Patient	• Patient als Selbstverantwortlicher, Patient, der alle Maßnahmen selbst entscheidet und durchführt

Tab. Ziel aller ärztlichen Bemühungen ist zwangsläufig die Verbesserung der Compliance.

2. Factors and interventions affecting adherence

Table 2 **Factors affecting adherence to palliative care for cancer and interventions for improving it, listed by the five dimensions and the interventions used to improve adherence**

Cancer	Factors affecting adherence	Interventions to improve adherence
Socioeconomic-related factors	(–) Long distance from treatment setting	Optimizing the cooperation between services; assessment of social needs *(3)*; family preparedness *(3)*; mobilization of community-based organizations
Health care team/health system-related factors	(–) Lack of knowledge of health professionals about pain management; inadequate understanding of drug dependence by health professionals *(5)*; health professionals' fears of investigation or sanction *(19)*; poor delivery of care education to the patient *(20)*; poor delivery of care education to family and caregivers *(20)*; reluctance of health professionals to prescribe opioids for use at home *(20)* (+) Good relationship between patient and physician *(14)*	Training of health professionals on adherence *(20)*; pain education component in training programmes *(13)*; support to caregivers; multidisciplinary care; follow-up consultation by community nurses *(20)*; supervision in home pain management *(20)*; identification of the treatment goals and development of strategies to meet them
Condition-related factors	(–) Nature of the patient's illness; poor understanding of the disease and its symptoms	Education on use of medicine *(11)*
Therapy-related factors	(–) Complex treatment regimens; taking too many tablets *(9)*; frequency of dose; having no treatment instructions *(9)*; misunderstanding instructions about how to take the drugs *(9)*; bad tasting medication; adverse effects of treatment *(9)*; inadequate treatment doses; perceived ineffectiveness *(9)* unnecessary duplicate prescribing *(9)* (+) Monotherapy with simple dosing schedules *(9)*	Simplification of regimens *(15)*; education on use of medications *(9)*; giving clear instructions *(9)*; clarifying misunderstandings about the recommendation of opioids; patient-tailored prescriptions *(9,15)*; continuous monitoring and reassessment of treatment; assessment and management of side-effects; coordination of prescribing *(9)*
Patient-related factors	(–) Forgetfulness *(9)*; misconceptions about pain *(11,12)*; difficulty in taking the preparation as prescribed *(9)*; fear of injections *(11)*; anxieties about possible adverse effects *(12)*; no self-perceived need for treatment *(9,21)*; feeling that it is not important to take medications *(9,21)*; undue anxiety about medication dependence *(11)*; fear of dependence *(14)*; psychological stress	Interventions to redress misconceptions about pain treatment and to encourage dialogue about pain control between patient and oncologist *(9,11)*; exploration of fears (e.g. about dependence) *(9,11)*; assessment of psychological needs *(3)*; education on use of medications *(11)*; behavioural and motivational intervention *(11)*; good patient–provider relationship *(14)*; self-management of disease and treatment *(11,16–18)*; self-management of side-effects *(16–18)*

Physician Communication and Patient Adherence to Treatment: A Meta-analysis

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Abstract

Background—Numerous empirical studies from various populations and settings link patient treatment adherence to physician-patient communication. Meta-analysis allows estimates of the overall effects both in correlational research and in experimental interventions involving the training of physicians' communication skills.

Objectives—Calculation and analysis of "*r* effect sizes" and moderators of the relationship between physician's communication and patient adherence, and the effects of communication training on adherence to treatment regimens for varying medical conditions.

Methods—Thorough search of published literature (1949 - August 2008) producing separate effects from 106 correlational studies and 21 experimental interventions. Determination of random effects model statistics and the detailed examination of study variability using moderator analyses.

Results—Physician communication is significantly positively correlated with patient adherence; there is a 19% higher risk of nonadherence among patients whose physician communicates poorly than among patients whose physician communicates well. Training physicians in communication skills results in substantial and significant improvements in patient adherence such that with physician communication training, the odds of patient adherence are 1.62 times higher than when a physician receives no training.

Conclusion—Communication in medical care is highly correlated with better patient adherence, and training physicians to communicate better enhances their patients' adherence. Findings can contribute to medical education and to interventions to improve adherence, supporting arguments that communication is important and resources devoted to improving it are worth investing in. Communication is thus an important factor over which physicians have some control in helping their patients to adhere.

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Table 3. Strategies for Improving Adherence to a Medication Regimen.*

- Identify poor adherence
  - Look for markers of nonadherence: missed appointments ("no-shows"), lack of response to medication, missed refills
  - Ask about barriers to adherence without being confrontational
- Emphasize the value of the regimen and the effect of adherence
- Elicit patient's feelings about his or her ability to follow the regimen, and if necessary, design supports to promote adherence
- Provide simple, clear instructions and simplify the regimen as much as possible
- Encourage the use of a medication-taking system
- Listen to the patient, and customize the regimen in accordance with the patient's wishes
- Obtain the help from family members, friends, and community services when needed
- Reinforce desirable behavior and results when appropriate
- Consider more "forgiving" medications when adherence appears unlikely†
  - Medications with long half-lives
  - Depot (extended-release) medications
  - Transdermal medications

* Information in this table was adapted from Osterberg and Rudd.[83]

† Forgiving medications are drugs whose efficacy will not be affected by delayed or missed doses.

Osterberg L, Blaschke T. N Engl J Med 2005;353:487-497.

Gelten für Krebserkrankung andere Faktoren für Adhärenz/Nonadhärenz

Im vergleich zu chronischen Erkrankungen weniger Studien die Ergebnisse sind jedoch völlig vergleichbar

Puts et al 2013

Adhärenz bei Krebserkrankung

- Lange kein Thema: systemische Therapien i.V.
  Patienten bevorzugen jedoch orale Therapie (Twelves et al 2006)
- Heute >20 orale Onkologia mit oft langandauernder Einnahme (zB: 3-5 Jahre) als initiale oder adjuvante Behandlung
- Untersuchungen zu vielen Tumoren, vor allem MammaCa, Kolorektal Tumor, LungenCa u.a.
- Adhärenzraten von 15 – 97 %,
  30 – 50 % unvollständige Chemotherapie
  ~40 % vollständige Adhärenz
  Zur Übersicht Stingler et al 2014, Hansen 2015, Puts et al 2013

- bei adjuvanter Hormontherapie 41-72% (Murphy et al 2012)
- Besondere Risikogruppe: Adoleszente – auch in der Akutbehandlung sind > 50 % nonadhärent
- Strahlenheilkunde: Bei HNO-Ca Erkrankungen erhielten 59 % weniger als die effektive Dosis von 65 Gy (Patel et al 2008)

Table 2
Factors associated with poor adherence and strategies for improvement [10,12,52].

	Factor/predictor	Recommendations for improved adherence
Therapy-related	Adverse effects Complexity of treatment Cost of medication	Consulting patient preferences Improved patient education Communication with health care provider Switching Vitamin D/calcium/bisphosphonates
Patient-related	Lack of belief in treatment Psychological problems (especially depression) Forgetting to take drug Poor awareness of therapeutic benefit or recurrence risk Age	Improved patient education and counseling Established routine
Health care provider-related	Poor patient–health care provider relationship Lack of discussion of possible adherence problems Lack of discussion of possible adverse effects Lack of time to discuss patient problems/questions	Improved provider–patient relationship Improved patient education and counseling
Predictors of poor adherence	Missed appointments Inadequate follow-up Unfilled prescriptions	Reminder services supplied by health care provider Ancillary care Convenient appointment scheduling

Identifying cancer patients at risk for nonadherence

- Adverse events
- Forgetfulness
- Missed appointments
- Competing priorities (medical and/or social)
- Lack of information
- Higher out-of-pocket costs
- Longer duration of treatment
- Poor relationship with healthcare provider
- Higher levels of comorbidity
- Regimens with high dosing frequency
- History of low out-of-pocket pharmacy costs in the year prior to cancer diagnosis
- Belief that patient has little influence over his or her own health
- Belief that no benefit is to be gained from medication
- Families in conflict
- Age (conflicting data)
- Missed appointments

http://www.valuebasedcancer.com/articles/1822-vbcc-1822

Table 1. Factors often associated with nonadherence to prescribed oral medication regimens*

Complex treatment regimen
Substantial behavioral change required
Inconvenient or inefficient clinics
Inadequate supervision
Poor communication with health care providers
Patient dissatisfaction with care
Patient health beliefs in favor of nonadherence
Inadequate social support
History of nonadherence
History of mental illness

Journal of the National Cancer Institute, Vol. 94, No. 9, May 1, 2002

Table. Factors Related to Nonadherence and Strategies for Improvement[9,10,12,30,31]

Factor	Recommendation for Improved Adherence
Adverse effects	Use questionnaires or quality-of-life scales to elicit overall symptom burden; consult with patient for preferences on management
Complexity of treatment	Improve patient education; simplify the regimen as much as possible: provide simple, clear instructions and encourage use of a medication-taking system; involve social support system when possible
Cost of medication	Improve communication; switch medication; explore alternative sources of medication
Lack of belief in treatment	Emphasize the value of the regimen and the effect of adherence; involve social support system when possible; obtain commitment to appropriate medication use
Poor awareness of therapeutic benefit	Provide improved education and counseling; involve the patient in setting goals for adherence
Psychological problems	Provide improved counseling; elicit patient's feelings about his or her ability to follow the regimen; treat depression or anxiety when appropriate
Poor patient-HCP relationship	Develop improved relationship; listen to the patient and customize the regimen in accordance with the patient's wishes; reinforce desirable behavior and results
Missed appointments	Use reminder services; create convenient appointment schedule; discuss barriers with patient

Abbreviation: HCP, healthcare provider.

http://www.valuebasedcancer.com/articles/1822-vbcc-1822

Lessons learned

1. Patients need to be supported, not blamed 19

2. The consequences of poor adherence to long-term therapies are poor health outcomes and increased health care costs 20

3. Improving adherence also enhances patient safety 21

4. Adherence is an important modifier of health system effectiveness 22

5. Improving adherence might be the best investment for tackling chronic conditions effectively 22

6. Health systems must evolve to meet new challenges 23

7. A multidisciplinary approach towards adherence is needed 24

Verbesserung der Adhärenz

- Schlechte Adhärenz identifizieren
- Bedeutung der Therapie und der Adhärenz klären
- Dem Patienten zuhören, seine Vorstellungen klären
- Wirkungen/Nebenwirkungen klären
- Wie geht es dem Patienten, was macht es schwer, Unterstützungsmöglichkeiten
- Einfache Anweisungen, einfache Verordnungen, Verständnis klären
- Hilfe von Familie - Freunde – sozialen Netzwerken in Anspruch nehmen
- Psychische Probleme identifizieren