

Health technology assessment of utilization, practice and ethical issues of self-pay services in the German ambulatory health care setting

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Abstract

Objectives The provision of self-pay medical services is common across health care systems, but understudied. According to the German Medical Association, such services should be medically necessary, recommended or at least justifiable, and requested by the patient. We investigated the empirical evidence regarding frequency and practice of self-pay services as well as related ethical, social, and legal issues (ELSI).

Methods A systematic literature search in electronic databases and a structured internet search on stakeholder websites with qualitative and quantitative information synthesis.

Results Of 1,345 references, we included 64 articles. Between 19 and 53 % of insured persons received self-pay

service offers from their physician; 16–19 % actively requested such services. Intraocular pressure measurement was the most common service, followed by ultrasound investigations. There is a major discussion about ELSI in the context of individual health services.

Conclusions Self-pay services are common medical procedures in Germany. However, the empirical evidence is limited in quality and extent, even for the most frequently provided services. Transparency of their provision should be increased and independent evidence-based patient information should be supplied.

Keywords IGeL · Individual health services · Self-pay services · German Statutory Health Insurance · Health care quality, access, and evaluation · Cost sharing

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Introduction

Coverage limits in publicly financed health care schemes

Service coverage in publicly financed health care schemes is limited in virtually all European and international health care systems, no matter whether they are financed insurance or tax based (Espin and Rovira 2007; Tambor et al. 2011; Schreyogg et al. 2005). Reasons can be resource constraints, but also the fact that some treatments might be judged as not medically necessary or not effective. Beyond their entitled benefits, insured persons can acquire different kinds of medical services via supplemental insurance or on their own expense, in Germany as in other countries. The majority of EU countries have—though heterogeneous—cost-sharing schemes for physician and outpatient services or hospital stays that include co-payments, co-insurance and deductibles (Tambor et al. 2011).

Individual health services in Germany

So-called individual health services (Individuelle Gesundheitsleistungen, hereafter “IGeL”) are medical self-pay services that are not covered by the German Statutory Health Insurance (SHI). According to the German Medical Association (Bundesärztekammer, BÄK), they should be medically necessary, recommended or at least justifiable, and explicitly requested by the patient (Bundesärztekammer 2006). The term covers as diverse treatments, such as tattoo removal, travel vaccines or different cancer screenings. In contrast to interventions according to the SHI catalogue, a previous written agreement and an explanation of the costs for the individual are obligatory for IGeL (Kassenärztliche Bundesvereinigung 2009, 2011, 2013).

There have been isolated efforts to establish a consistent, systemized definition of IGeL services (Windeler 2006). The only common feature in the range of definitions is the specification of IGeL as non-SHI-services. Even though some authors also refer to additional hospital services as IGeL (Kersting and Pillokat 2006), the term IGeL is predominantly related to outpatient services and we therefore investigated only the ambulatory setting. Finally, no claims data are collected about these services. Thus, their frequency and importance is largely unknown.

Regulation of the Benefit Package in the German Statutory Health Insurance

The Social Code Book V (http://www.gesetze-im-internet.de/sgb_5/) constitutes the legal framework for health benefits under the SHI. It defines which services can and must

be provided by physicians and funded by the SHI. Insured persons are entitled to benefits for prevention, (early-) detection, treatment of disease and rehabilitation services, provided that they are sufficient, appropriate, efficient and do not exceed what is deemed necessary. Furthermore, medical care must reflect the current state of science.

The specification of claims and limits of benefits is at the discretion of the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA), which is the decision-making body of the joint self-government of physicians, dentists, hospitals, and health insurance funds. G-BA issues guidelines which list services that have been evaluated and approved for reimbursement and those that are excluded from SHI health care (Anonymous 2009e).

Physicians who are licensed by the SHI may treat also privately insured persons and offer self-pay services to SHI members without reporting this to their governing body, the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung, KVB) or the insurers.

The provision of self-pay services beyond the SHI benefits catalogue as well as the question which services should be covered by the SHI is object of major discussions in Germany.

Objective

The German Agency for Health Technology Assessment at the German Institute of Medical Documentation and Information (DAHTA@DIMDI), a body of the German Federal Ministry of Health commissioned a health technology assessment (HTA) of IGeL (Schnell-Inderst et al. 2011). Here, we report (1) the empirical evidence regarding offers coming from physicians, utilization, practice, acceptance, and economic relevance of IGeL and (2) their effect on the relationship between physicians and citizens and other relevant ethical, social, and legal issues that are discussed in the context of IGeL.

Methods

Literature search

We performed a systematic literature research in the electronic DIMDI meta-database (35 databases including EMBASE, MEDLINE, Social Science Search, Springer Publishing Database and others) from 1998 through October 2009.

Our search code combined the German keywords for “IGeL”, “individual health service” and “self-pay service” with terms for study type (e.g. “survey”), topical

terms such as “economics”, “costs” and “benefits”, as well as terms related to the ethical, social, and legal issues surrounding IGeL. The full search syntax is listed in the supplement.

We performed an additional internet search. For this purpose, we identified 54 potentially relevant stakeholders (sickness funds, physicians’ associations, customer advice centres, etc.) in the field and systematically inspected their websites either with the keywords, if a search function was available, or by hand search.

Literature selection, quality assessment and data extraction

For the first research question, we included cross-sectional and longitudinal surveys among the German general population, special populations or stakeholders within the health care system that assessed empirical data on physician offers, patient requests, utilization, practice, acceptance, and economic relevance of IGeL.

For the second question regarding social, ethical and legal issues, we included essays, reviews, position papers, statements, guidelines, conference and symposia proceedings that contained detailed descriptions of particular topics. We excluded letters to the editor, short comments, notes and summaries of original contributions that are available in full text. Two independent reviewers (T.H. and either P.S.I., K.H. or R.S.) pre-selected the references on the basis of title and abstract, applying inclusion and exclusion criteria. We ordered full text versions of the included references and again, two reviewers (T.H. and either P.S.I., K.H. or R.S.) independently screened the texts according to specified criteria and documented reasons for exclusion. Articles from the internet search were screened and downloaded by one author (T.H. or K.H.) and reviewed by a second author (P.S.I. or K.H.). We assessed the quality of the studies using a systematic checklist (see supplement).

Relevant characteristics and results of the IGeL studies were extracted from the texts in summary evidence tables (extraction by T.H., verification by K.H.). The extraction sheet collected information on in-/exclusion criteria, study population, sampling procedure, study design and period, endpoints, and main results.

We performed a qualitative content analysis of the literature on ethical, social, and legal issues to allow for a categorization and summary of different aspects. Therefore, we extracted the issues that each text addressed and summarized the identified issues into main topics across the included texts. All reasoning and contributions to the main topics were summarized in a narrative way and different opinions regarding one topic were contrasted.

Results

Results of the literature search

The literature search yielded 1,345 references. After the exclusion of duplicates, 1,221 references remained. Among these, 629 were excluded on the basis of title and/or abstract and 592 were ordered in full text or downloaded from the internet. Twenty-one full-text articles were unavailable, and 507 texts did not meet the inclusion criteria. Finally, this review included 64 full-text articles (Fig. 1). Thirty-one publications reported 29 original studies and 33 publications discussed the ethical, social, and legal issues related to IGeL. A complete list of screened and excluded publications with reasons for exclusion can be obtained from the published HTA report (Schnell-Inderst et al. 2011). Among all original studies included, 19 were cross-sectional studies that involved (computer assisted) telephone interviews, written or online-questionnaires of the insured, patients, or medical practitioners, respectively. Two studies originated from a pilot project about patient counselling and evaluated the topics of patients’ requests. Another eight studies analysed the economic profitability of IGeL for the physician practices and assessed single IGeL services on the basis of yield return scores and ranking lists.

Study characteristics and quality

We found a periodically repeated survey of the Scientific Institute of the Local Health Fund (Wissenschaftliches Institut der Allgemeinen Ortskrankenkasse, WIdO) starting in 2004 (Zok 2004; Wissenschaftliches Institut der AOK (WIdO) 2007, 2008; Zok and Schuldzinski 2005). In addition, the KBV and Bertelsmann “Health Monitor” have repeatedly collected data on IGeL (Forschungsgruppe Wahlen Telefonfeld 2006, 2008; Braun et al. 2006; Schuldzinski and Vogel 2007). A scientific investigation by the University of Lübeck provided valid data from a representative sample with defined inclusion criteria in 2007 (Richter et al. 2009). Other one-time surveys were published by consumer advice centres, a government department (Anonymous 2009f), and an industry association (VDGH 2008). Several Internet surveys among physicians intended to represent the perspective of the service providers. However, they are susceptible to selection bias. An overview of the design of all included studies is provided in Table 1.

Not all studies met the established scientific standards with regard to study design, performance, and quality of reporting (see supplement). Approximately half of the publications were not available as a study report or journal

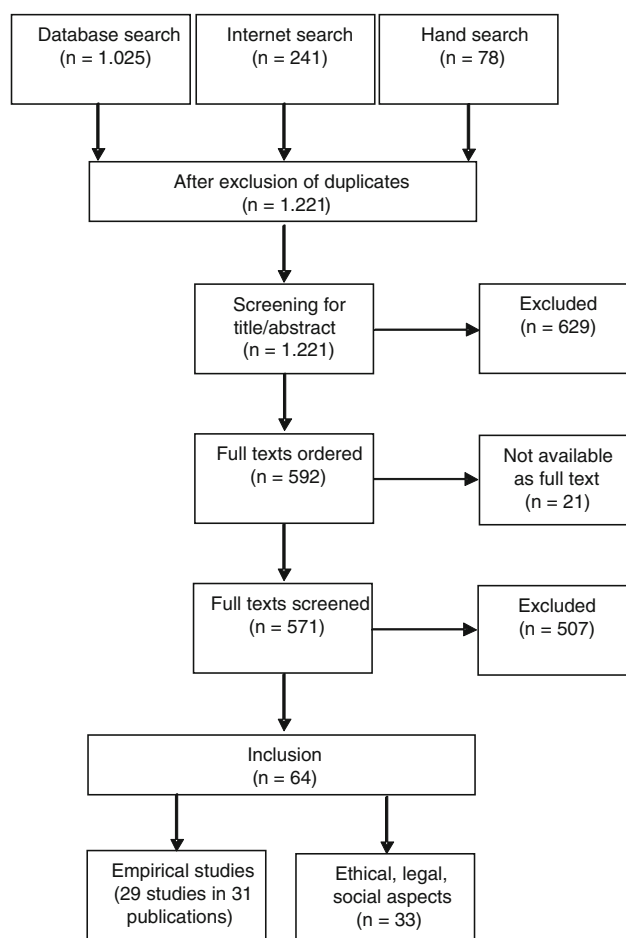


Fig. 1 Literature selection flow chart

article, but only in the form of a press release or presentation slides. Two-thirds of the studies were based on representative random samples; however, only two reported response rates. Direct comparability of the studies was limited since they differed in their definitions of IGeL, in the choice of IGeL services and categories, and in the definition and assessment of outcomes. The articles relating to ethical, social and legal issues had various formats: two-thirds (19) of the texts are articles in (professional) journals, but only five are peer-reviewed. Others were statements published on organization websites and a presentation slide deck. Only few provided reasoning and or examined both positive and negative attributes of the subject. In particular, several advocates of IGeL provided only simple, subjective statements, opinions and examples.

Frequency of IGeL utilization

Empirical data show that IGeL are widely used in outpatient care. Between 19 and 53 % ($n = 6$ studies, median 39 %) of insured persons have received IGeL offers from physicians (Kassenärztliche Bundesvereinigung 2006,

2008; Zok 2004; Zok and Schuldzinski 2005; Anonymous 2009f), of which 77–80 % ($n = 2$ studies) were actually provided (Fig. 2) (VDGH 2008; Anonymous 2009f). Sixteen to 19 % ($n = 2$ studies) of insured persons actively requested IGeL (Forschungsgruppe Wahlen Telefonfeld 2006, 2008). The results from different studies vary due to diverse methodological approaches, but serial investigations as the WIdO monitor show consistency.

Intraocular pressure measurement was the most frequent single service and represented up to 40 % ($n = 7$ studies, median 15.3 %) of all offers (Richter et al. 2009; Forschungsgruppe Wahlen Telefonfeld 2006; Wissenschaftliches Institut der AOK (WIdO) 2007, 2008; Zok 2004; Zok and Schuldzinski 2005), followed by the cluster category “ultrasound scanning”, accounting for up to 25 % ($n = 7$ studies, median 19 %) of the IGeL services (Fig. 3) (Richter et al. 2009; Gerlof 2007; Forschungsgruppe Wahlen Telefonfeld 2006; Wissenschaftliches Institut der AOK (WIdO) 2007, 2008; Zok 2004; Zok and Schuldzinski 2005). Moreover, cancer screening and blood/laboratory tests were frequent offers, representing a major proportion of the demand ($n = 4$ and 8 studies, median 14.8 and 9.7 %, respectively) (Forschungsgruppe Wahlen Telefonfeld 2006; Richter et al. 2009; Wissenschaftliches Institut der AOK (WIdO) 2007, 2008; Zok 2004; Zok and Schuldzinski 2005; Gerlof 2007).

Six studies including a total of 6,983 patients have investigated the influence of IGeL on the doctor–patient relationship (Table 2) (Forschungsgruppe Wahlen Telefonfeld 2006, 2008; Wissenschaftliches Institut der AOK (WIdO) 2007, 2008; Zok and Schuldzinski 2005; Zok 2004). Despite the heterogeneity between the results from two studies by a major health insurance and one by the physicians association, they demonstrate that the majority of patients (51, 58, and 84 %, respectively) do not consider their relationship to the physician to be altered by IGeL. However, most people who do experience changes ($n = 3,308$) report a deterioration in the relationship (Table 1).

IGeL practice

Information about costs and benefits of IGeL for the patient was rated as sufficient by more than 80 % of patients in two studies (Anonymous 2009f; Richter et al. 2009). The time allotted for deciding about a particular offer was rated as sufficient in three studies (Richter et al. 2009; Kassenärztliche Bundesvereinigung 2006, 2008). One study investigated the education on risks associated with IGeL services and found that it was explained in 45 % of cases (Richter et al. 2009). Written agreement and invoice are mandatory but were only provided in 36.1 % (median: range 20.6–39.4 %) and 80.3 % (79.9–85.2 %) of cases, respectively (Richter et al. 2009; Wissenschaftliches

Table 1 Design of included studies

Study	Reference	Objective	Main endpoints	Study population	Survey period	Elicitation method	Sampling procedure	Subjects included
Ärzte Zeitung (2007)	Gerlof (2007)	Requests of IGeL offers	Which of your IGeL offers do patients request?	Readers of the journals „Ärzte Zeitung“, „IGeL plus“ and „WirtschaftsTipp“	Feb 2007	Questionnaire	Survey among readers	$N = 1.614$ ($n = 623$ general practitioners; $n = 187$ internists)
Ärzte Zeitung, PVS (2003, 2005)	Anonymous (2005c)	Practitioners attitudes towards and experiences with IGeL	IGeL offered in the office Information about IGeL Initiation of IGeL IGeL prices Patients' and fee agreements	Practitioners	2003/2005	Online questionnaire	n.r.	2003: $N = 917$; 2005: o. A.
Ärzte Zeitung, PVS (2009)	Anonymous (2009d)	Practitioners elf-pay service offers	Trends in IGeL development Office turnover with IGeL	Practitioners	Nov–Dec 2009	Online questionnaire	n.r.	$N > 1.450$
Bertelsmann Foundation (2006)	Braun et al. (2006)	Effects of incentives for behavioural control in beneficiaries and health care providers	IGeL frequency Information channels Payment IGeL offers and utilization	German speaking resident population, 18–79 years, SHI members	Mar–Apr, Oct–Nov 2004; Oct–Nov 2005	Written questionnaire	Stratified sample from the TNS-Access-Panel	2004: $N = 2.418$; 2005: $N = 1.232$
Bertelsmann Foundation (2007)	Schulzinski and Vogel (2007)	Health politics	IGeL offers and utilization	German resident population, 18–79 years, SHI members	Spring 2004 to fall 2006	Written questionnaire	Representative population sample	$N = 9.000$
http://www.igelarzt.de (2004)	Anonymous (2004)	Legal certainty of practitioners providing IGeL	Demarcation SHI and IGeL services	Practitioners	03.02.2004	Online questionnaire	n.r.	$N = 254$
KBV (2006)	Kassenärztliche Bundesvereinigung (2006)	IGeL offers and requests	IGeL requests, utilization and offers Transformation of the doctor-patient relationship by IGeL	German resident population, 18–79 years	May–June 2006	Telephone interview	Random sample	$N = 4.315$
KBV (2008)	Kassenärztliche Bundesvereinigung (2008)	Patients satisfaction with SHI	IGeL requests, utilization and offers Transformation of the doctor-patient relationship by IGeL	German resident population, 18–79 years	May–June 2008	Telephone interview	Random sample	$N = 6.114$

Table 1 continued

Study	Reference	Objective	Main endpoints	Study population	Survey period	Elicitation method	Sampling procedure	Subjects included
Richter et al. (2009)	Richter et al. (2009)	Frequency of IGeL and patients' judgments	IGeL requests, utilization and offers	Germans registered in Lübeck or Freiburg, 20–79 years	Feb 2007	Tao phase survey (screening and detailed questionnaire)	Systematic random sample from registration offices	Screening questionnaire: $N = 2,606$; detailed questionnaire to persons with IGeL experience: $N = 690$
Stiftung Gesundheit, GfK (2005)	Anonymous (2005b)	Consequences of technical, organizational and economic changes	Transformation of the doctor-patient relationship by IGeL Rating of IGeL services IGeL offers Knowledge about legal norms regarding invoicing for SHI patients Economic need for IGeL	Practitioners	Aug–Oct 2004	n.r.	Representative Sample	$N = 8,000$
VDGH (2008)	VDGH (2008)	Population's valuation and experiences with health market and IGeL	Patients' valuation of IGeL offers Reasons for IGeL offers	German resident population, 14 years or older	Oct 21–22 2008	CATI	Representative population sample	$N = 1,002$
Consumer survey BW (2009)	Anonymous (2009f)	Consumers interests and experiences	Willingness to pay for IGeL Frequency of IGeL offers (Non-) utilization of IGeL and reasons for this	German speaking persons in Baden Württemberg, 15 years or older	Sep 7–20 2009	CATI	Representative random sample	$N = 1,100$
Consumer advice center BW (2006)	Anonymous (2006)	Practitioners duties and patients rights concerning IGeL	IGeL frequency Prices Compliance with formalities	Patients	2006	n.r.	n.r.	$N > 200$
Warnebler (2006)	Warnebler (2006)	Economic relevance of IGeL	Turnover with IGeL IGeL frequency	Medical practices that are member of a clearing center (PVS-Nord)	n.r.	Mail questionnaire	All members of a clearing center (PVS-Nord)	$N = 186$
WIdO-Monitor (2004)	Zok (2004)	Utilization of IGeL	Frequency of IGeL offers and utilization	SHI members, 18 years or older	May 2004	CATI	Representative random sample	$N = 3,000$

Table 1 continued

Study	Reference	Objective	Main endpoints	Study population	Survey period	Elicitation method	Sampling procedure	Subjects included
WIdO/Consumer advice center NRW (2004)	Zok and Schuldzinski (2005)	Consumers experiences with IGeL	Frequency of IGeL offers and utilization Information about IGeL Valuation of IGeL Reasons for IGeL Compliance with formalities Transformation of the doctor-patient relationship by IGeL	Consulters of the consumer advice centers in Bonn, Düsseldorf and Münster	2004	Questionnaire	Non-representative sample	$N = 891$
WIdO-Monitor (2005)	Zok and Schuldzinski (2005)	Utilization of IGeL	Frequency of IGeL offers and utilization Market volume estimate for IGeL	SHI members, 18 years or older	2005	Telephone interview	Representative random sample	$N = 3.000$
WIdO-Monitor (2007)	Wissenschaftliches Institut der AOK (2007)	Utilization of IGeL	Frequency of IGeL offers and utilization Compliance with formalities Transformation of the doctor-patient relationship by IGeL	SHI members, 18 years or older	2007	Telephone interview	Representative random sample	$N = 3.005$
WIdO-Monitor (2008)	Wissenschaftliches Institut der AOK (2008)	Utilization of IGeL	Frequency of IGeL offers and utilization Compliance with formalities Transformation of the doctor-patient relationship by IGeL Annual sales estimate	SHI members, 18 years or older	2008	Telephone interview	Representative random sample	$N = 3.006$

BW Baden-Württemberg, CATI computer-assisted telephone interview, GfK Gesellschaft für Konsumforschung (consumer research institute), HTA Health Technology Assessment, IGeL Individuelle Gesundheitsleistung (individual health service), KBV Kassenärztliche Bundesvereinigung (Association of Statutory Health Insurance Physicians), N number, $n.r.$ not reported, NRW North Rhine-Westphalia, PVS Privatärztliche Verrechnungsstellen (clearing centre for private physicians invoicing), SHI statutory health insurance, VdGH Verband der Diagnostica-Industrie (Association of the German Diagnostics Industry), WIdO Wissenschaftliches Institut der Allgemeinen Ortskrankenkasse (Research Institute of the Local Health Fund)

Fig. 2 Relative frequency of individual health services in Germany (2004–2009). Insured persons in the German Statutory Health Insurance who received practitioners' offers, requested or utilized individual health services *KBV* Association of Statutory Health Insurance Physicians, *BW* Baden-Württemberg, *SIH* statutory Health Insurance, *VDGH* Association of the German Diagnostics Industry, *WIdO* Research Institute of the Local Health Care Fund, *VZ NRW* Consumer Advice Centre North Rhine-Westphalia (colour figure online)

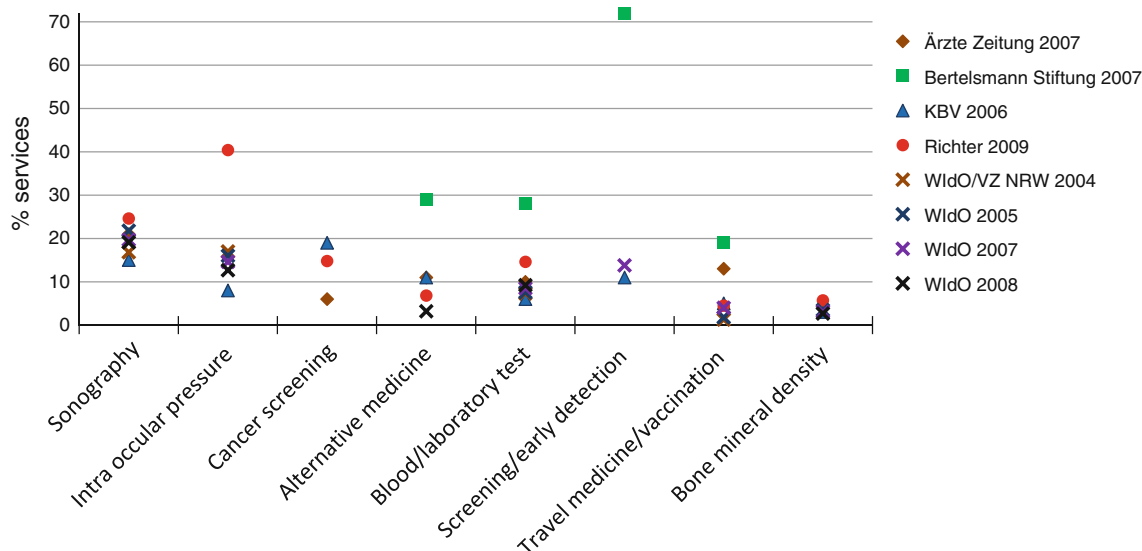
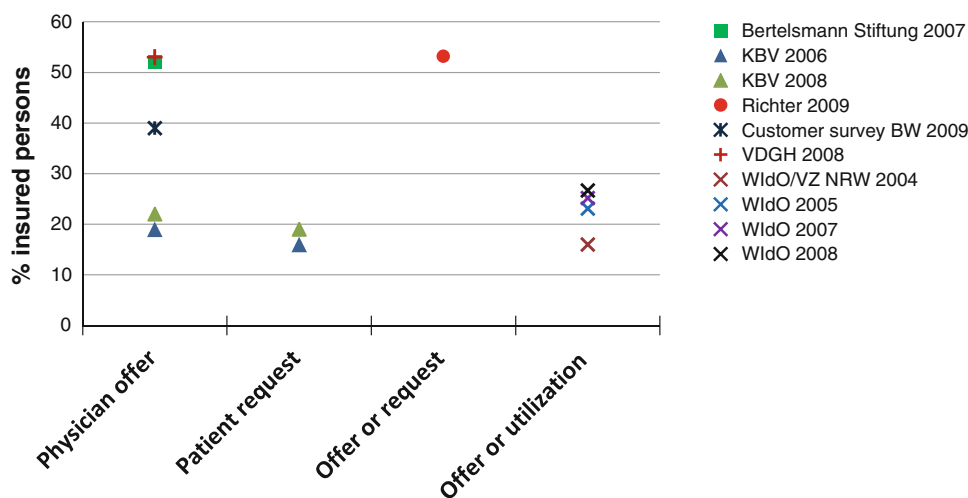


Fig. 3 Relative frequency of selected individual health services in Germany (2004–2009). Services that were offered, requested or utilized by individuals multiple answers possible, therefore, figures do not add up to 100 % (colour figure online)

Institut der AOK (WIdO) 2007, 2008; Zok 2004; Zok and Schuldzinski 2005). Moreover, there were single reports of intimidation and confusion of patients, commercial activities, excessively positive presentation of the IGeL method, and degradation of the SHI services (Anonymous 2009f; Zok and Schuldzinski 2005).

Economic significance of IGeL

Surveys among physicians demonstrate that the trade volume a practice generates with IGeL is <5 % of the total trade volume in almost half of practices (48 %), and only 8 % of practices earn more than 20 % with IGeL (Anonymous 2009f). The profitability rankings show that procedures with intensive use of technical devices offer the

greatest financial return for the physician's practice (Anonymous 2005a, 2009c).

The willingness to pay for one single IGeL is ≤ 50 Euro at an average for one-third of patients (VDGH 2008). Only 6 % of them are willing to pay 500 Euro or more. On the basis of data on offers, requests and utilization, WIdO calculated the total volume of the German IGeL market to be almost one billion Euro in 2005 (Zok and Schuldzinski 2005). According to recent data this increased to 1.5 billion Euro in 2010 (Zok 2010).

Ethical, legal and social issues

The ELSI discussed in relation to IGeL were extracted from 33 publications and focus on eight topics:

Table 2 Influence of individual health services on the physician–patient relationship

Study	No. (%)	Yes (%)	Improved (%)	Deteriorated (%)
WIdO 2004–2008	51–58	38–42	6 (15–20 of “yes”)	21 (76–82 of “yes”)
KBV 2006/2008	84	12–14	4–5	8–9

KBV Association of Statutory Health Insurance Physicians, WIdO Research Institute of the Local Health Care Fund

1. Sovereign patient decision versus induced demand
IGeL advocates are of the opinion that patient demand is responsible for their existence (Krimmel 1998, 2001). In their view, the sovereign patient chooses to receive medical services beyond the SHI health care. Opponents counter that the desire for more and more services is a result of the marketing activities of the physicians, thus induced demand (Nuschler and Thomasius 2006; Schuldzinski 2000; Schmacke 2002).
2. Commercialization of medicine
Critiques complain that IGeL are purely economically motivated (Bilger and Rüter 2005; Windeler 2006). The notion of medicine as a source for services that are not grounded in objective needs but rather in individual desires moves it close to a commercial sector (Kettner 2006). Some maintain that physicians must have additional income sources and that patients need to pay for special service (Krimmel 2001; Kruse-Keirath 2010).
3. Physician’s duty to inform patients
A fundamental obligation of the physician is the informing the patient (Windeler 2006; Anonymous 2009d). Without information, it is impossible to effectively obtain consent (Raspe 2007; Bergmann 2000). However, there are fears that conflicting financial interests might lead to insufficient information being provided to the patient (Windeler 2006; Schuldzinski 2000, 2007; Schmacke 2002; Egidi 2008).
4. Evidence requirements, patient benefit and (quality-) control of IGeL
A major point of critique of IGeL is that the benefits and harms of most IGeL services are not investigated (Schuldzinski 2007). In contrast to SHI services, there is no control of how and by whom they are delivered. There are claims that proponents of a particular health service should prove its effectiveness according to evidence-based medicine criteria (Raspe 2007; Anonymous 2006). The application of technologies that were excluded by the G-BA after review is even deemed to be unethical (Bilger and

Rüter 2005; Windeler 2006). In contrast, it is argued that many SHI services have also never been subject to an assessment (Kruse-Keirath 2010).

5. Role and relationship of physician and patient
IGeL opponents fear that the model of the physician as a care provider to a patient in need is disrupted and replaced by a merchant and customer relationship (Egidi 2008; Raspe 2007; Thanner and Nagel 2009). Others emphasize the individual responsibility of the patient and compare the relational asymmetry with that of other market settings (Krimmel 2001; Kruse-Keirath 2010).
6. Relationship of IGeL to the SHI
Critics see the SHI as being discredited by doctors telling their patients that IGeL are necessary complements to SHI health care (Raspe 2007; Schmacke 2002). Proponents argue that IGeL help to financially relieve and even stabilize the SHI (Krimmel 1998); however, there are also many costs induced by IGeL that the SHI must then pay, e.g. workup of positive test results (Verbraucherzentrale Bundesverband 2008).
7. Social inequality
Some view IGeL as promoting social inequality and stimulating feelings of deprivation by those who cannot afford such services (Egidi 2008; Raspe 2007; Schuldzinski 2007). This is contrary to the efforts of the Bismarckian statutory health insurance to guarantee equal access to medical care independent of social position (Schmacke 2002). IGeL advocates counter that this inequality of resources remains a social reality (Krimmel 2001).
8. Formally correct performance
Common and relatively undisputed formal requirements exist for the administration of IGeL. The German Medical Association issued ten rules for their performance that include correct and reliable patient information, time for consideration and seeking a second opinion, written agreement and invoice (Bundesärztekammer 2006). However, evidence indicates that providers do not adhere sufficiently to these requirements (Schuldzinski 2000). Physician representatives have asked whether they are liable when they do not offer an IGeL even if they think that the SHI service is not state of the art (Anonymous 2009a, b), while lawyers specializing in this area agree that the liability law cannot require higher medical standards than the social law does for the SHI (Laum 2001).

Discussion

In our systematic literature review, we identified 29 studies on IGeL frequency and practice as well as 33 publications

on the ethical, social, and legal considerations surrounding IGeL. Reconciliation with a previous unsystematic overview of IGeL surveys (Rehder 2008) indicates that our review is comprehensive, as we found all the empirical studies listed there. Additionally, we included further and more recent studies and also considered texts on ethical and other issues. Thus, to our best knowledge, this is the first systematic review of IGeL that reflects empirical, ethical, legal and social issues and synthesizes the existing data also in a quantitative way.

Our analysis has severe limitations. Our research on IGeL is limited by the quality of evidence and reporting and by the heterogeneous data obtained from these sources. Limitations of our literature search are inconsistent indexing in literature databases and the constraints of internet researches. The empirical investigations included have partly methodological limitations regarding the study design (e.g. insufficient definition of the study population). The texts on ethical and social concerns are not always of high scientific rigour, but reflect the spectrum of current viewpoints and arguments. The relatively wide distribution of IGeL is largely owed to physicians' offers of services and there are indications for induced demand. The IGeL offers cannot generally be regarded as medically necessary or recommended services, as claimed by the Medical Association. Instead, even IGeL that failed to demonstrate effectiveness in rigorous evaluations are offered. The lack of an evidence base is a major point of critique of IGeL (Egidi 2008; Raspe 2007; Schmacke 2002; Windeler 2006). However, it is true that also many SHI services have not been subject to assessments according to strict criteria of evidence-based medicine, since this would just not be feasible for the G-BA.

In our HTA for DIMDI, we assessed the clinical effectiveness and risks of two frequent IGeL services—ovarian cancer screening with vaginal ultrasound and glaucoma screening for asymptomatic individuals without extra risk (Schnell-Inderst et al. 2011). We found that good evidence on patient relevant outcomes is lacking for both examinations (Schnell-Inderst et al. 2011). For ovarian cancer screening, two randomized controlled trials are ongoing (Buys et al. 2005; Menon et al. 2009). Their interim results indicate a high degree of over-diagnosis resulting in patient harm due to invasive procedures performed on the basis of positive screening results, while cancer mortality was not reduced (Buys et al. 2011). Coverage of both screening tests is restricted in other health care schemes as well, for example, in the US Medicare program (<http://www.medicare.gov/coverage/preventive-and-screening-services.html>).

Most IGeL are screening tests, a fact that reflects the patients' interest in prevention. However, the necessity, the success, potential risks and the benefit–harm balance of

such tests and their consequences are difficult for patients to judge. Studies show that also for physicians, test results are challenging to interpret and communicate (Gigerenzer et al. 2008). This raises the question to what extent practitioners are able to inform their patients about the benefits and risks of IGeL and whether they actually do so. First, basic understanding of statistical or decision-analytic methods is needed (Siebert 2003), in addition to clinical knowledge in order to assess and interpret risk. Secondly, risk communication to the patient is challenging, especially for diagnostic examinations, such as screening. There remains an ongoing dispute about adequate training of physicians who offer IGeL. For several services, evidence-based patient information is available from the German Institute for Quality and Efficiency in Healthcare (<http://www.gesundheitsinformation.de>), the Medical Review Board of the Statutory Health Insurance Funds (<http://www.igel-monitor.de>) and the physicians associations BÄK and KBV (<http://www.patienten-information.de>).

In many cases, the rejection of IGeL is based on critique of the “IGeL industry”, including its promotional magazines, congresses, and internet platforms, more than a single IGeL service itself. This also raises concerns about the commercialization of medicine, which is reinforced by indications that IGeL are preferentially offered to members of higher social classes. On the other hand, organized promotions do not necessarily mean that there is no net benefit of a service. However, the point that IGeL are a necessary economic source for physicians must be rejected as long as there is consensus that financial interests must not be the impetus for offering health services of unknown medical justification. The classification of IGeL as proposed by Windeler (2006) in those that have been excluded from the SHI catalogue after assessment (e.g. glaucoma screening) versus those that have not yet been assessed or that are by nature not part of a publicly financed health scheme (e.g. cosmetic treatments) might help individuals to better judge offers and make rational decisions.

A comparison of the definition of health baskets of EU countries concludes that the ways in which benefit catalogues are framed and the ways in which they shape the actually provided care, differs considerably between countries and health care sectors (Schreyogg et al. 2005). However, they found that most European health care systems implicitly or explicitly exclude services which concern similar areas: cosmetic treatments, certain vaccinations, and alternative medicine.

Individual data from other European countries, for example Austria, suggest that the volume of self-pay medical services is comparable to the German market (Hofmarcher and Rack 2006). A review of patient cost-sharing schemes in EU countries concludes that “underlying cultural values [...] determine whether free access to

health care services is seen as a patient right [...] and how acceptable patient cost-sharing is” (Tambor et al. 2011). This adds to our view, that the question of regulating IGeL is a highly political subject and must reflect societal values regarding the transformation of the individual into an active consumer in the health care market.

Our work portrays the current status of IGeL services in Germany. To give evidence-based recommendations on possible regulation and quality assurance of the self-pay market, detailed health systems and policy research is needed.

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