2 Design and implementation of the study

2.1 Introduction

In this chapter we shall deal in greater detail with the study design, with the definition of the term ‘second opinion’ in this study, and with the method of data collection. We shall also discuss the questionnaire, the measuring instruments used in it and the method of analysing the data.

2.2 The study design

In this study we opted for a longitudinal observational cohort study with ambispective timing (partly in the past, partly in the future). Apart from empirical investigations, we used existing literature.

2.3 Definition of the term ‘second opinion’

What, actually, is a second opinion? Second opinions, in the broadest sense of the term, are constantly being given during clinical discussions with colleagues one’s own specialism or other disciplines. These ‘internal’ second opinions contribute in the first place to the forming of a personal view, and getting and giving them is for physicians often a daily routine.

An ‘external’ second opinion, on the other hand, focuses on the testing of that view. One example are the SSOPs in the USA where second opinions are reduced to consultations within strictly formulated programmes, intended as a check on the indication as defined by the treating physician/specialist regarding elective operations. These programmes are not intended to support the decision strategy of the treating physician. In the SSOPs, the second opinion consultant is not necessarily of the same level of expertise as the first one, and the former should never take over treatment.

Thus, in the American literature on SSOPs the second opinion is a clearly defined concept, exclusively intended to test the ‘correctness’ of the indication for surgical intervention. Other second opinions, not initiated by the insurers but by the patients, undoubtedly occur in the USA as well, but there is only one study on this subject. In this study it was found that most health care insurers did not use a clear-cut definition for second opinions.

The Dutch situation is essentially different from the American SSOPs. In our country, second opinions are requested not only after an advice to operate, but often also when a conservative or expectative treatment has been proposed. Consequently, the concept of second opinion in the Netherlands has a wider range than in America.

To arrive at a generally valid and clear definition of the concept of second opinion, we need an answer to the following basic questions:

1 precisely what problem does the inquirer want to be solved; is there a clear demarcation line between a tertiary referral and a second opinion?
2 just who can request a second opinion (do requests by specialists, and particularly specialists from other disciplines also count as second opinions?)
3 what is the maximal time interval between the consultation or treatment of the first opinion consultant and the consultation of the second specialist, if the consultation is still to be classified as a second opinion?
**Sub 1: Is there a clear demarcation line between a tertiary referral and a second opinion?**

When the GP or the patient has taken the initiative to seek a second opinion about a disputed first opinion, it will usually be clear that the request is for a second opinion. If the first opinion specialist has taken the initiative to have the patient seen by another physician, it is often unclear whether a referral or a second opinion is intended. The referral letter often does not explicitly request either a second opinion or a referral. Our study shows that patients, first opinion consultants and second opinion consultants often disagree about whether a second opinion or a referral is involved. Cases in which the first opinion consultant is unable or unwilling to treat the patient’s disorder are in this study regarded as referrals. Referrals mostly result from non-orthopaedic specialists sending patients on with the question if an orthopaedic treatment is indicated (which they cannot perform themselves) or because orthopaedists in district hospitals refer patients with disorders requiring treatment in a university hospital (the so-called top reference care).

**Sub 2: Who can request a second opinion?**

Non-orthopaedic specialists may in certain subjects have the same level of expertise as orthopaedic specialists, such as back surgery, knee arthroscopies, surgery of the hand or conservative treatment of foot and back disorders. For this reason, not all patients whose primary consultant was not an orthopaedic surgeon may be regarded as tertiary referrals. Therefore, distinguishing between a tertiary referral and a second opinion is generally difficult and depends on the patient’s disorder or complaint, the first opinion specialism where he was seen and the level of expertise of the specialist.

**Sub 3: What is the maximal time interval between the consultations?**

Most insurance companies impose a period of one year between the first and second opinion for all specialists. This period appears to be on the short side. If patients were treated by their first opinion consultant, they will in general wait for the effect of his/her treatment. In addition to this, some hospitals have long waiting lists for first outpatient visits in orthopaedics, further lengthening the time interval between the first and the second opinion.

Van de Lande et al. (1999) define a second opinion as: an independent opinion from a second consultant (from the same discipline as the first one) concerning the diagnosis and/or therapeutic proposal of the first consultant.

We think this definition has certain shortcomings. First, it states no time limit between the first and the second opinion. Should a patient who five years after the last contact with the first consultant visits another specialist be regarded as a second opinion patient? There may be many reasons to consult another physician after such a long period, and wanting a second opinion is only one of them. Also, second opinions may be requested by physicians from some other specialism than the first opinion consultant since in certain fields of medicine specialisms overlap. A few examples in orthopaedics are: traumatology, hernia surgery and surgery of the hand.

Since in our view no definition of ‘second opinion’ has been described that applies adequately to the Dutch situation, for the purposes of this study we have devised our own definition for second opinions.

*In this study a second opinion is defined as a consultation at which a patient within two years after the first consultation is seen for the same complaints by a second specialist of at least the same level of expertise in order to obtain an independent opinion about the diagnosis or therapeutic proposal of the first consultant. The second opinion specialist should have personally interviewed and examined the patient.*

Since a second opinion is sought in the first place to test the first opinion, a second opinion can only
be given when there exists a complete first opinion. Therefore, in this study we distinguish between a second opinion and a tertiary referral. A tertiary referral does not necessarily need a definite diagnosis or therapeutic plan. A tertiary referral is always meant as a transfer of further examination or further treatment. The main reason for tertiary referrals is that orthopaedists from non-university hospitals refer patients with difficult treatable diseases who according to the current agreements in the professional group should be treated in a university hospital. Another form of referrals occur when specialists without orthopaedic training refer patients with the question whether orthopaedic treatment is indicated; example: the rheumatologist who refers a patient with the question whether there is an indication for a total knee arthroplasty. Both types of referral are often also called second opinions, but in this study they are considered referrals.

Van de Lande et al. also distinguish between tertiary referrals and second opinions. The authors define a tertiary referral as ‘a consultation for which the initiative has always been taken by the first opinion consultant’.

However, it will not always be simple to establish who has taken the initiative, the patient, the GP or the first consultant. On this, patient and physician often disagree. The GP, who in the Dutch system always is the one who refers patients to a specialist, may have been pressed by the patient to do so. Who, in that case, has taken the initiative? It is also possible for the first opinion specialist to be pressed by the patient to refer him for a second opinion. Besides, the first specialist may feel the need to have his/her own opinion tested by a colleague, without wishing to hand over the treatment. In such a case, the first opinion consultant takes the initiative for a second opinion, and there is no question of a tertiary referral. It is tricky to appoint an initiator in the individual patient. Since the initiative to seek a second opinion may be taken by various groups, a completely homogeneous study population probably does not exist. For this reason, in this study the patient/GP-initiated second opinions are compared with the specialist-initiated second opinions. It proved even trickier to distinguish between a tertiary referral and a second opinion at group level, since there lies a grey area between the two. For instance, the provincial orthopaedic practice A will be able to administer the same care for a specific disorder as a university hospital, while provincial practice B cannot do so. This means that practice B will always refer a patient with this disorder, while practice A in such cases may generate either a tertiary referral or a second opinion. One more problem in distinguishing between second opinions and tertiary referrals is that in our study the patient, the first opinion consultant and the second opinion consultant frequently disagree on this matter. The first opinion and the second opinion consultants do not always have the same objective: sometimes the first opinion consultant wants to continue the treatment himself, while according to the second opinion physician the treatment should be taken over. The converse is also frequently encountered: the first opinion consultant wants to refer the patient for further treatment, but the second opinion consultant sends the patient back to the former. Referral letters are not always clear enough about who should continue the treatment.

Since at the start of the study it was expected to be difficult to distinguish sharply between tertiary referrals and second opinions, we have in the first phase included all patients who in the two years prior to the consultation had seen another specialist for the same complaints. The distinction at the individual level between the true second opinions and tertiary referrals according to our definition was made later.

An important criterion for this selection was the taker of the initiative. This initiative may have been taken by the patient, the GP, the specialist in charge or an insurance company. When the initiative (according to the patient) is taken by the patient or the GP, there is always a second opinion according to our definition. When the consultation is initiated by a (different) physician or specialist, distinguishing between a second opinion and a tertiary referral is often somewhat more complicated. Often it cannot be unequivocally established who has taken the initiative, and the referral letter often does not ask explicitly for either a second opinion or a tertiary referral. The influence of the patient on the taker of the initiative (e.g. by putting pressure on the physician) has not been further investigated in this study. In cases where the distinction between tertiary referral and second opinion could not be made beforehand, the outpatient diagnosis (the ICD-
9 code) and the answer of the first consultant to the question who is to continue the treatment have been taken into account (see flow diagram).

Below a list of diagnoses of which in our view the surgical treatment should as a rule be carried out in a university hospital:

- neoplasms
- operative treatment of scoliosis (together with some specialised bigger district hospitals)
- rare or severe congenital anomalies
- relatively new or experimental techniques, (e.g. patello-femoral prostheses)
- various, mostly rare interventions such as leg lengthening, etc.

(*) depends on the first specialist's hospital

Fig. 1: Decision tree on which distinction between second opinions and tertiary referrals is based.
Whatever method is used to distinguish between second opinions and tertiary referrals, it will
never be possible to draw a sharp dividing line between the two. What to think, for instance, about a
referral initiated by the treating specialist with the purpose that the treatment will be taken over,
whereas the diagnosis/treatment would not need to take place in a university hospital? In our study
this occurred quite frequently, for instance with patello-femoral complaints. And where do we place
patients whose diagnosis or treatment according to our definition would require a university hospital,
but whose first specialist wants to continue as the main therapist himself? Here, namely, according
to the first consultant, no (tertiary) referral is involved. By adhering strictly to the flow diagram, the
two examples are classified as referrals. The second opinions/referrals in this grey area have been
classified in this study as tertiary referrals.

In a number of cases third, fourth and further opinions are sought. These ‘doctor shoppers’ may make
up a group apart, but in this study they are classified as ‘second opinions’. This group will be
compared, however, with the group receiving a second opinion for the first time.
The first and/or second specialist is not always aware of the fact that a patient seeks a second
opinion, for instance because the patient fails to mention it, and/or because the GP does not mention
it in the accompanying letter. Such cases are called silent (second) opinions. When a patient met
our definition of second opinion on the basis of the questionnaire on $T_0$, but did not mention this to
the second opinion consultant, this patient was still counted as a second opinion in our study.

2.4 The collection of data

The study was carried out in Groningen University Hospital. From 1 August 1996 to 1 August
1997 all new patients attending the outpatient clinic for Orthopaedics of this hospital were asked to
participate in our study. In the group ‘new patients’ we included all patients visiting the outpatient
clinic for the first time, as well as those already on record there with some other symptom not
related to the current complaint.
Written information about the study was handed out, and the patients willing to participate signed an
informed consent form.
All new patients were given the same questionnaire, they were asked to complete it prior to the
consultation. If it turned out the patient came for a second opinion, a few additional questions were
asked. These questionnaires afforded insight into a number of personal characteristics of the patient
population and duration and nature of the symptoms. New patients who had never before consulted a
specialist for their complaints were classified as first opinion patients. The first opinion patients
served as a reference group in this study. Some of these patients may also seek a second opinion in
the future. Therefore this group cannot be regarded as a control group but only as a group for
comparison.
The physicians in the AZG outpatient department completed a questionnaire for all second opinion
patients concerning the diagnosis and treatment of the primary consultant and the changes, if any, at
second opinion. This questionnaire was only filled out after completion of the second opinion. In case
the patient consented, the first opinion consultant was sent a questionnaire as well.
The second opinion patients were sent a continuation questionnaire four weeks after the completion
of the consultation. The continuation questionnaire after one month gave insight into the patient’s
degree of satisfaction about the second opinion. If the questionnaire had not been returned within a
month after mailing, one reminder was sent. One year after the outpatient visit a second continuation
questionnaire was sent, to find out what therapy ultimately had been effectuated, and if the patient
was satisfied with the result of the treatment. If the patient failed to respond within one month, one
reminder was again sent.
In order to determine if the proportion of second opinion patients in the outpatient clinic for Orthopaedics of the AZG was representative of a Dutch university hospital, all second opinion patients were also counted in the outpatient clinic of the Free University Hospital (VU ziekenhuis) in Amsterdam over a period of three months (1 April 1997 - 1 July 1997). The department of Orthopaedics in this hospital has a preclinical registration system, for which the patients are asked if they have been treated earlier for the present complaints by a specialist, and if so in what year. As a consequence, second opinions and tertiary referrals could not be adequately distinguished from each other.

2.5 The questionnaires

The questionnaires that were used have been devised by ourselves, because validated questionnaires on this subject do not yet exist. A number of existing measuring instruments is incorporated in our questionnaires. The questionnaires appear in Appendices 1, 2, 3, 4 and 5.

2.5.1 The questionnaire for all new patients at \( T_0 \) (Appendix 1)

The questionnaire at \( T_0 \) contained 40 closed multiple choice questions for all new patients and 9 additional closed multiple choice questions for the second opinion patients among them. The questionnaire comprised the following subjects:

- Personal background data: age, education, profession, civil state, insurance form.
- Health as experienced: RAND 36, and any other physical complaints.
- Functional complaints: VOEG 13 item list (Sikkel 1980) \(^6\).
- Medical consumption: frequency of contacts with various GPs or specialists, duration of hospital stays in the preceding 12 months.
- Information about type, duration, severity, course and exact localization of the symptoms. There was also a question about absenteeism.
- The supplementary questionnaire for the second opinion patients contained questions about confidence in the first consultant with regard to the diagnosis and treatment, and the degree of satisfaction about the communication with the latter. The patients were also asked about their motives to seek a second opinion.

The RAND 36-item list

The RAND 36-item Health Survey is a measuring instrument for the patient’s general physical condition. Like many other measuring instruments this questionnaire is capable of discriminating between patients with very limited health problems \(^7\). The RAND 36 is not aimed at specific diseases, 

<table>
<thead>
<tr>
<th></th>
<th>( T_0 ): first outpatient visit</th>
<th>( T_1 ): 1 month after completion consultation</th>
<th>( T_2 ): 1 year after completion consultation</th>
</tr>
</thead>
<tbody>
<tr>
<td>First opinion patient</td>
<td>yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Second opinion patient</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>First opinion consultant</td>
<td>yes</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Second opinion consultant</td>
<td>yes</td>
<td></td>
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</tr>
</tbody>
</table>

Table 1: Selection of measuring times
but is a reliable, valid and sensitive measure of the health in general. The list can be used to determine the effect of a treatment. Furthermore, the RAND 36 is easy to handle and takes little time to complete.

The list contains eight scales: physical functioning, social functioning, role limitations due to a physical problem, role limitation due to an emotional problem, mental health, pain, general experience of health and changes of health in the past year.

In this study use was made of a version of the NCG translated from the American into Dutch.\(^7\)

**The VOEG list**

The VOEG (Vragenlijst Over Ervaren Gezondheid = Questionnaire about Experienced Health) of Dirken (1969) comprises a number of diverse questions about symptoms with a general and aspecific character.\(^8\) The questionnaire was developed by Dirken to measure the degree to which the patient is inclined to transfer stress into physical problems. The list intends to be an indicator of the subjectively experienced physical condition, of misgivings regarding the subject’s health. The question whether this concerns only the physical aspects or also the psychic and social aspects of health is still controversial. Some authors think that a high score indicates a tendency to transform psychic and social complaints into (for physicians) vague physical complaints.\(^8\) The list is also believed to measure the tendency to complain.\(^5\) Patients with a high VOEG score on the whole judge their general health more negatively, and have more physical restrictions and chronic disorders. There also proves to exist a strong link with absenteeism, use of medication and number of contacts with GP or specialist.\(^9\) However, the VOEG list is subject to some critical remarks. The list is somewhat ambiguous, emphasizing, on the one hand, general and aspecific symptoms as manifestations of psycho biological stress, while on the other hand the VOEG list covers a number of more or less recognizable somatic complaints often corresponding to age-linked symptoms. The VOEG score does not correct for a worse state of health (due e.g. to advanced age).

For this study we used an abbreviated version (13 items) devised by Sikkel (1980).\(^8\) This abbreviated VOEG list allegedly shows a strong link with neuroticism scales, but it is not clear if it measures actual neuroticism or a psychic background of physical complaints.\(^11\) It is also possible that the VOEG list measures psychic reactions to (protracted) physical disorders. The question about the psychic or somatic background of the complaints was not further investigated in this study, we only looked for possible differences in VOEG scores between the second opinion patients and the reference group. Earlier studies have shown that persons with higher education and males on average report fewer VOEG complaints, while older persons, on the contrary, report more VOEG complaints.

In our study correction for these variables has been carried out.

### 2.5.2 The Questionnaire for Second Opinion Patients on T\(_1\) (Appendix 2)

The enquiry on T\(_1\) comprised 7 closed multiple choice questions about the assessment of the second opinion and the degree of satisfaction with it. Also, a few questions were asked about the reason to opt for one particular treatment.

### 2.5.3 The Questionnaire for Second Opinion Patients on T\(_2\) (Appendix 3)

The questionnaire on T\(_2\) contained 25 closed multiple choice questions. They asked if the second opinion had met the expectations and if the patient was ultimately satisfied with the second opinion. Information was gained about the course of the complaints and absenteeism, if any. It was also asked what therapy had ultimately been carried out, the reason why that therapy had been chosen and the result of the treatment. To make it possible to measure the changes in general health after one year, this questionnaire again included a RAND 36.
2.5.4 THE QUESTIONNAIRE FOR THE SECOND OPINION PHYSICIANS (APPENDIX 4)

This enquired about the diagnostic examinations performed earlier, asked if the second opinion consultant agreed with the diagnosis and/or therapy (advice) of the primary consultant and about the results of earlier treatments, if any. Another question was if this second opinion had been useful in the view of the second opinion consultant, and who should take charge of the continued treatment.

2.5.5 THE QUESTIONNAIRE FOR THE FIRST OPINION CONSULTANTS (APPENDIX 5)

The orthopaedic surgeons in the region were sent an information letter prior to this study. It was sent only to orthopaedic surgeons, not to other specialists. The first opinion consultant (i.e.: orthopaedic surgeon) was asked about the diagnosis, and the (proposed) treatment, and whether he/she knew about the second opinion, and what reasons had led to seeking it.

2.6 The data analysis

The composition of the patient group was analysed for various socio-economic features. The group was also evaluated for differences in afflictions and medical consumption, with correction for differences in the patients’ socio-economic background. The analyses were performed using SPSS (version 8).

In each of chapters 4, 5 and 6 a statistic model was developed allowing the analysis of the relevant study questions. For the analyses, it is desirable to take into account a number of aspects of the study design and study data. One of the main aspects is the fact that at the first as well as at the second opinion clustering of consultants occurs; each consultant evaluates another group of patients. Furthermore, not all second opinion consultants evaluated the same numbers of patients, which resulted in an unbalanced data set. Finally, an incomplete data set is concerned, data are not completed for all co-variates at every measuring moment (we assumed that these missing values had come about coincidentally). To make it possible to take into account all the above-named three aspects, the analyses were designed as a multi-level model. This resulted in a statistically adequate consideration of these data features (clustering of physicians, repeated measurements, and missing data). The analyses were carried out using MLWIN (version 1).

2.7 The response/non-response

During the enrollment period from August 1996 to August 1997, all 2880 new patients attending the Orthopaedic out clinic of the AZG were invited to participate in the study. Of this group, 801 patients did not take part, mainly because of unwillingness and/or language problems. Further data about this group of refusers are unknown, including the proportion of second opinions in this group.

At T0 a total of 715 usable questionnaires were completed by patients who during the preceding two years had already consulted a specialist for the same complaints. Of these, 625 (87%) were second opinions according to our definition, while the remaining 90 were classified as tertiary referrals.

The 625 second opinion patients were sent a questionnaire on T1. The 163 (26%) patients who one month after the mailing of the first continuation questionnaire had not yet responded, were sent a reminder. Of this group, 47 patients (29%) then returned the first continuation questionnaire.
Twenty-two (3.5%) questionnaires were returned unmarked, to show that the patient wanted to
discontinue his participation. These patients were not sent a further questionnaire on T₂. The first
continuation questionnaire at T₁ was returned by a total of 509 (82%) second opinion patients.
On T₂, 603 patients were sent a continuation questionnaire. The 247 patients (41%) who one month
later had not yet responded were sent a reminder. Of this group, 119 patients (48%) then returned
the second continuation questionnaire. In all, 484 patients (80% of those who wanted to continue
participating in the study at T₁, 77% of the total study group) returned the second continuation
questionnaire. The groups of non-responders and stoppers were not included in the analyses of T₁
and T₂, although a number of known (clinical) data were compared with the responder group to check
for selective dropouts. It was found that younger patients dropped out relatively more often than older
ones, and patients with patello-femoral complaints more often than patients with other diagnoses.
Since patients with patello-femoral complaints are often young, we checked if they might be the
same group. This proved not to be the case. There was, however, some selection in the non-
response.
The response of the second opinion consultants was 100%, that of the first opinion consultants
68.8%.

2.8 Comments on the design and execution of the study

Problems concerning the nature of this study are:
1) the study design is not optimal
2) not all relevant data could be collected
3) some of the measuring instruments were developed by ourselves and consequently not validated.

Sub 1) Study design:
The chosen study design has strong and weak points. A strong point of the design is that it is
capable of measuring relevant features at the individual level. Also, the sequence of measurements
followed the natural time table and the results studied had not yet been obtained at the time of
enrollment.
Drawbacks of this study design are the lack of placebo exposure and randomization, blinding study
subjects was not well feasible, and the comparability of the different cohorts is inadequate.
If we had wanted mainly to answer the question who takes the initiative to the second opinion and
what factors are involved there, a prospective cohort study of the at-risk population would be a better
type of study. In such a study, a large group of new outpatients from a number of non-university
hospitals should be followed over time. This is difficult to realise because a very large group of
patients would have to be enrolled and followed.
If we wanted especially to answer the question whether second opinions yield a health gain for the
patient, a study design with an equivalent control group would be required. The control group should
ideally be selected at random from the population seeking a second opinion, and subsequently, a
second opinion should be withheld from this group. Although such a study design is usual for drug
trials, it is impossible for a study about second opinions; refusing a second opinion to patients who
want it is unacceptable.
Furthermore, the internal validity of the study may be adversely affected by a non-respondents bias
and a withdrawal bias. In addition, in spite of the fact that the subdivision into the various patient
studies was done extremely carefully, some misclassifications may have occurred (patients who
came for a second opinion but were classified as first opinions or tertiary referrals, or vice versa).

Sub 2) The data collection
In the studying about second opinions we should have preferred to collect data or to form a
picture of the following areas:
- the case history, physical and radiological examination of the patient
the original motivation of patient or consultant to seek a second opinion
the diagnosis of the first opinion specialist, the proposed and/or administered treatment
the characteristics of the relationship between the first opinion specialist and the patient
the professional backgrounds of the first opinion as well as of the second opinion consultant
the ideas of the second opinion consultant about the diagnosis and therapeutic proposals of the
first opinion consultant
the effect of the recommendations of the second opinion on the patient’s perception of his/her
symptom pattern, and the degree of satisfaction with the consultation
the negative effects, if any, of the second opinion, concern or confusion about what decision to
take
the decision ultimately made by the patient, and its grounds
the effects of the decision taken (e.g. expenses, taking up public health care time, incapacity for
work)
changes in the health condition observed since the second opinion.

Had all these data been known, we could have described the entire process. Unfortunately, within the
setting of the study collection of all the above data was impossible. First opinion consultants
sometimes did not supply all necessary medial information, therefore diagnosis and the proposed
and/or administered treatment are not always known. Especially when patients have already had
several opinions, the data from all further consultants cannot always be retrieved. In this study, the
professional background of the first opinion consultant has not been investigated further, since the
number of second opinion patients per first opinion consultant on the whole was too small to allow
conclusions.

A study of the effects of the decision ultimately made and of the changes in the health condition after
the second opinion would constitute a large scale investigation in itself.

Sub 3) Measuring instruments
No measuring instruments have so far been devised to study what patients actually obtain a
second opinion and for what reason. For this purpose, questionnaires have been elaborated, some of
them by ourselves.
The ‘communication score’ is a composite score of 10 separate questions. These questions were
devised by us, so they have not been validated. Questions about reasons to seek a second opinion
have also been made up by ourselves.
The scepticism score was copied from another study, but it proved not very useful, because of the
lack of cohesion of the various items.5
2.9 Bibliography