

Shared care plan: an extraordinary tool for the personalization of medicine and respect for self determination

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Abstract

Background: On 22 December 2017, Law No. 219 was approved in Italy. This law provides citizens with effective tools with which to express healthcare decisions, namely, advance treatment directives (ATD) and shared care plans (SCP). **Methods:** This article presents an analysis of 70 SCP cases carried out in a tertiary hospital in Italy during the period between 01.02.2018 and 29.02.2020 inclusive. **Results:** In 90% of cases, the objective of the plan pertained to situations regarding patients' refusal of transfusions of blood components, the majority (97%) due to their belonging to the religious movement of Jehovah's Witnesses. 46% of the sample had drafted ATDs. The course of treatment recommended by the attending physicians was confirmed in 93% of the SCP cases. Trustees were appointed in 96% of cases. In 55% of cases, patients assigned trustees with attestative functions and the remaining 45% with creative functions. The results demonstrate that each patient personally dictates his or her wishes and the role assigned to the trustee. SCP meetings serve as a useful tool for providing the patient and his or her relatives with information, and for appointing a trustee. However, it has never been necessary to solicit the intervention of the trustee following a surgical operation. **Conclusions:** The SCP has proven to be an essential tool in achieving the objective of personalized medicine. However, there is still notable passivity in its application. Further effort is required in order for it to become a common asset in clinical practice.

Keywords: informed consent, patient self-determination, shared care plan, advance treatment directive, blood refusal.

Introduction

On 22 December 2017, Law No. 219 - "Provisions for informed consent and advance treatment directives" - was approved in Italy [1-9]. This is the result of a long debate in Italian society as regards the option to refuse potentially lifesaving healthcare treatments not only in a current situation but also in advance, in view of a potential pathological condition that renders the person incapable of making conscious decisions [10-13].

The law, composed of eight articles, focuses on the care relationship, analyzing various topics relating to the expression of the person's current wishes regarding care choices. In addition, it regulates for the first time the advance expression of wishes by a person who has become incapable of self-determination at the time a healthcare decision needs to be made. This advance expression is facilitated by advance treatment directives (ATD) and shared care plans (SCP) [14-17].

ATDs are regulated by article 4, clause 1, which states: "In preparation for a potential, future incapacity

to self-determine and on receipt of adequate medical information regarding the consequences of his or her decisions, every adult of sound mind may express his or her wishes in matters of healthcare treatments by means of an ATD. Consent to or refusal of diagnostic tests or treatments and individual healthcare treatments may also be included in said ATD". The ATD provides for the appointment of a trustee who acts on behalf of the person, representing him or her in dealings with doctors and the healthcare facility. The trustee is also in possession of a copy of the ATD. Doctors are required to respect the ATD, with certain exceptions and in agreement with the trustee. Furthermore, the ATD must be drafted as a public deed or an authenticated private deed, i.e. a private deed filed in person with the registry office of the relevant municipality.

SCPs are provided for in article 5, clause 1, which states: "A shared care plan between the patient and the doctor may be drawn up as part of the patient-doctor relationship (...) as regards the development of the effects of a chronic and debilitating illness or one characterized by inexorable progression with an unfortunate prognosis. The doctor and healthcare team are required to adhere to said plan in the event the patient can no longer express consent or becomes incapacitated".

There are differences between the two institutions – ATDs and SCPs – although both serve as vehicles for self-determination in healthcare matters. ATDs refer to "treatment" and SCPs to "care". ATDs are an expression of the unilateral initiative of the person concerned, separate from any care relationship with the doctor; SCPs represent a process that begins and is developed "within the patient-doctor relationship". ATDs pertain to the "person", SCPs to the "patient". The patient is the person with the illness; patients are included in the term persons; patients represent only one part of those persons. Consequently, any person may draft an ATD but only patients can participate in an SCP. Individual patients, those suffering from the illness, may decide to express their wishes by means of an ATD or an SCP or both as regards future treatment options that they may become incapable of deciding.

Therefore, SCPs concern "the development of the effects of a chronic and debilitating illness or one

characterized by inexorable progression with an unfortunate prognosis". The two conditions described lend themselves to numerous interpretations, since the term chronic illness may refer to multiple degrees of invalidity and the term unfortunate prognosis to the quality of life, to the duration of the illness, both accelerated or protracted over time, or to death. Thus, an SCP can be drafted for any pathology and without specific time constraints. In any case, the SCP may be updated in line with the progressive development of the illness. SCPs represent, therefore, a complex institution wherein the doctor provides the patient with technical-scientific expertise, ensuring full comprehension. The doctor then has to decide whether to accept the patient's choice, which is the result of a complete and fully informed communication and decision-making process, and assess whether that choice implicates risks for the patient that are not commensurate with the treatment objective. The doctor and healthcare team must adhere to the plan in the event the patient can no longer express his or her wishes.

Art. 5, clause 2, naturally subject to patient consent, provides for family members, a civil union partner, a cohabitant and a trusted person to participate in SCPs. It specifies that all participants shall be informed regarding "the potential development of the pathology, what the patient can realistically expect in terms of quality of life, clinical intervention options and palliative care". Clause 3 sets out the role of the trustee, without describing his or her functions in detail. However, the trustee's role is evidently to represent the patient by ensuring his or her wishes are respected in situations where the clinical conditions envisaged in the SCP arise and by bringing this document to the attention of professionals who were not part of the planning process [18-20]. Additionally, the trustee can and must intervene should the contents of the SCP appear unclear and ambiguous, making suggestions as to the appropriate interpretation in accordance with his or her knowledge of the patient's aspirations and conception of life. It follows that the trustee would participate in the SCP meeting, during which the patient can explicate the trustee's role in accord with his or her needs. Trustees may be assigned a merely "attestative" role (i.e. to confirm the patient's wishes in regards to the course he or she has already

fully charted), an “integrative” role (i.e. to deviate from or supplement the plan in the event of specific circumstances) or a completely “creative” role (i.e. the ability to make decisions on behalf of the patient).

Art. 5, clause 4, specifies that “patient consent and the prospective designation of a trustee” be confirmed in writing and that the SCP may be “updated in line with the progressive development of the illness at the patient’s request or on the doctor’s recommendation”.

Materials and Methods

This article presents an analysis of the SCPs drafted in a hospital in Italy which conducted a study sponsored by some medicolegal experts engaged in clinical consultant activities in various departments in that hospital [21-22]. These experts work to promote the implementation of SCPs and adapted the legal provision to the local situation, specifically integrating the following in order to structure the SCP procedure:

1. request for a medicolegal consultation and intervention
2. identifying the specific team who will be bound by the care choices
3. a meeting during which the team members provide information to the patient, family members and trustee regarding the pathology and care plan, acknowledging and taking into consideration the patient’s observations
4. development of a shared plan, recorded by the medicolegal expert in a report and signed by the patient, the team of healthcare professionals, the trustee and any family members present
5. insertion of the report into the clinical file.

The study analyzed the SCPs drafted, in line with the procedure previously described, in a tertiary hospital in Italy in the two-year period between 01.02.2018 and 29.02.2020 inclusive. All 70 of the reports drafted in that period were considered and details regarding the patient, care departments, the objective of the clinical procedure in relation to the plan’s contents, the trustee’s role as defined by the patient and the

subsequent repercussions on the relative clinical activities were recorded. This analysis has also brought some qualitative aspects to light.

Results

The sample analyzed shows a preponderance of females (63% F vs 37% M). The average age is 59 years old. The age bracket most represented is between 31 and 74 years old with 81% of patients, followed by the over-75 bracket with 13%, and finally the 18-30 bracket with 6%. As for the type of departments which have promoted SCPs by means of medicolegal consultations, 84% of cases came from departments in the surgical field and the remaining 16% from the medical field.

The macro-units of pathologies, whose clinical procedures specifically pertained to the SCP, were represented as follows: oncologic pathology 30%, cardiac pathology 23%, gastro-enteric pathology 14%, endocrine-metabolic pathology 13%, urologic pathology 10%, vascular pathology 3%, and neurological pathology 3%. The remaining 4% concerned complex situations that cannot be categorized in one single area.

In 90% of the cases, the objective of the plan pertained to situations regarding patient refusal of blood transfusions. The majority of these (97%) were cases of refusal due to belonging to the religious movement of Jehovah’s Witnesses and to the consequent need to adapt intra- and post-surgical procedures to that instruction. The remaining 10% of the SCPs pertained to: 2 cases of patient refusal to undergo tracheostomy and intubation, resulting in palliative care for a neurodegenerative disease; 5 cases of oncology patients evaluating future treatment choices, without specific preliminary conditioning requests.

46% of patients in the sample had drafted an ATD prior to the SCP expressing refusal of blood transfusions. Each case presented with a similar document, not compliant with the requirements in article 4 of Law No. 219, composed of a pre-printed form containing the mandatory direction not to receive blood transfusions, even if healthcare providers believe that such are necessary to preserve life. The patient’s wishes expressed at the beginning of the SCP corresponded

to the those of the ATD, confirming the refusal of transfusions. In the majority of cases, the consultation contributed to a care plan that was more articulate and in harmony with the sick person's feelings.

As regards the overall number of people involved in the development of the SCP, in 79% of the sample between 3 and 5 people participated, whereas in the remaining 21% more than 5 people (up to a maximum of 9) were present. Those always present were the patient, attending physician and medicolegal expert. In the cases of surgical operations, the most prevalent, the surgical specialist and the specialist in anesthesiology and resuscitation were also always present. In cases with more numerous participants, family members and/or the trustee and other professional figures such as doctors in specialist training were also present. In one particular case of a deaf patient, an Italian sign language interpreter was present. In one of the first cases, a bioethicist also participated.

In 93% of the sample, the SCP confirmed the treatment plan recommended by the attending physicians. The remaining 7% showed a change of strategy: 4 cases where an alternative surgical procedure was implemented and 1 case transitioned from surgical to pharmacological treatment.

Trustees were appointed in 96% of cases. In 30% of cases, the appointment was made at the start of the SCP. In cases where the patient arrived with a trustee already appointed, care was taken to conduct a preliminary conversation (which always took place) with the patient to confirm his or her decision without the trustee present. In the other cases, the patient was always informed of the right to designate a trustee. In 48% of the cases where a trustee was appointed, the trustee did attend the meeting to devise the SCP. In the remaining cases, the appointed trustee was not present and would be advised of the role by the patient. The trustee would then have to sign the report and be available throughout the hospital stay/operation.

In cases where patients arrived with an ATD (46% of the sample), we noted that the relative document almost always required the intervention of two trustees. However, at no time was the appointment of more than one trustee permitted in an SCP because, although not in contrast with Law No. 219, it could create unresolvable conflicts in the event their opinions

differed. On completing the SCP, 52% of cases with ATDs, the ATD and SCP were found to differ in 16 cases: in 14 of them, the patient appointed a trustee with a creative role, free to deviate from what was previously stated in the ATD. In one case, the patient decided not to appoint a trustee despite having designated one in the ATD. In another case, during the SCP meeting, the patient appointed a different trustee from the one named in the ATD.

91% of the trustees were members of the family unit. Of the remaining 9%, in 5 cases, a fellow member of the same religion (Jehovah's Witnesses) was nominated as trustee. In 55% of cases, the trustee was assigned an attestative role (the trustee serves as a mere spokesperson for the patient's wishes with the sole prerogative to confirm at a future time what has already been outlined in the SCP). In 45% of cases, the trustee was assigned a creative role (on first receiving an explicit, specific and unequivocal mandate from the patient, the trustee has the right to make autonomous decisions on the patient's behalf). No trustees were assigned an integrative role. In one case of a mandate with a creative role, the trustee accepted that role only after a long discussion with the patient, having initially expressed unease at being called upon to decide in matters that could affect the patient's health and life.

Using the clinical records to check the development of the cases, we confirmed that no intervention by the trustee was ever necessary.

The duration of the consultations varied between 15 and 60 minutes, with nearly all consultations completed in one session. However, two sessions were required in four cases where the patients needed to compare and choose between two surgical options requiring complex understanding and evaluation.

Direct analysis of the reports shows that the SCP: a) implies that doctors first need to provide the patient with information, and ensure he or she has understood, regarding the disease from which he or she is suffering or that needs to be diagnosed, the objectives set by the doctor in opting for any given procedure and what can realistically be expected in terms of quality of life. Additionally, patients are informed regarding the limitations and risks associated with that procedure and with a failure to perform or partially performing said procedure, as well as regarding potential treatment or

diagnostic alternatives, even if less effective at times; b) enables patients to explain their needs and aspirations to doctors and to verify, during the meeting, that they have understood. In the context of shared evaluation, patients are also made aware of additional considerations proffered by attending physicians. Ultimately, the SCP reports document the essential process of sharing and interaction between all interested parties, in full respect and recognition of their specific expertise and autonomy, both personal and professional, which form the basis for the development of the care relationship.

The analysis of the SCP reports brings to light the contribution made by other healthcare professionals to facilitating the care relationship. The twofold objective is to safeguard the patients' wishes and to promote awareness of the clinical pathways ensured by the various professions in relation to the doctor's recommended plan. When present, even family members have contributed to the care relationship, proving to be of assistance to patients in comprehending and processing the information received, including on an emotional level.

In cases where the patient attended the consultation without a family member and/or without a trustee, the patient was always informed of his or her prerogative to take advantage of the support that one or more of these can provide. When present, the trustee was always apprised of the content of the report and asked to sign the final declaration as follows: "I, (name), the undersigned, having read this report, accept the role of trustee on behalf of (name) and confirm that I will be present and at the doctors' disposal throughout the duration of the surgical operation and for the time necessary to be able to intervene and liaise with the doctors should the situation warrant it." A similar note was included in the clinical record in cases where the trustee arrived after the completion of the SCP.

Discussion

The concept of an SCP arises from the need doctors have to organise a care pathway that the patient approves of in the event of discord between the patient's wishes and the doctor's initial proposal.

The hospital in question conducted and continues to conduct this study with the difference that it deviates from the regulatory provision to include certain aspects, which, however, are not in conflict with the law, namely: 1) the presence of a medicolegal expert who not only participates in the SCP but in fact coordinates it, and 2) the participation not only of the attending physician but also other healthcare professionals involved, either currently or potentially, in the prospective care plan. It is evident that the presence of several healthcare professionals, each time varying in number and relative discipline, is indispensable for drafting an SCP.

At least on initial assessment, it may seem anomalous that the SCP meeting be set up in the context of a medicolegal consultation and that the medicolegal expert be one of the participants. In reality, though, the inclusion of a medicolegal expert proves beneficial in the development stage of the study where a person in a coordinator-organizer capacity performs the role of facilitator in meetings between the parties. Nevertheless, it would be ill-advised for such a procedure to continue in the future. Physicians and patients must acquire the ability to discuss and reach an agreed decision without the need for the intervention of a third party, i.e. a medicolegal expert. The accumulation of experience with SCPs may facilitate doctors in the progressive acquisition of this ability. In like manner, medicolegal experts will need to adapt their approach so as to foster patient and doctor autonomy in this reciprocal relationship, in addition to preparing those doctors to take the lead in arranging SCP meetings. This underlines the importance of training activities organized to enable doctors to assimilate the input received during those meetings.

In the context of the SCP, it is a fact that a meeting between all participants proves particularly advantageous not so much because of the united outcome but because of the development of the relationship. Not only is there an exchange of respective viewpoints and needs but, inevitably, each party is put in a position that necessitates careful listening. A positive contribution to the enhancement of the care relationship is made by family members, when present, and healthcare professionals other than the doctor that explained the management aspects of procedures, especially

surgical. In the course of the meeting, trustees, when present, resist significant interventions in the patient's decisions.

As noted above, the great majority of requests were submitted by departments in the surgical field, and of those, the majority of cases concerned patients who, on religious grounds, would not accept the administration of blood components. In these cases, drafting the SCP made for particularly interesting dynamics.

In the case of transfusion refusals, the various participants constantly look into the options for implementing multidiscipline strategies in order to minimize the need for blood. The surgeon always explains the stages of the plan, from the preoperative preparation to the postoperative period, taking time to describe the operation procedures and the options for managing the risk of potential acute anemia due to intra- or postoperative hemorrhaging. The fact that patients are informed of the strict adherence to the indications provided in the Patient Blood Management (PBM) program regarding the potential for surgical operations to be performed without the use of blood transfusions enables patients to express their wishes in correlation with a precise program [23-27]. PBM is explained, in more or less detail depending on the patient's knowledge, in accord with the SIAARTI (Italian Society of Anesthesia, Analgesia, Resuscitation and Intensive Therapy) definition: "a multidiscipline, multimodal and personalized approach to reduce or eliminate the need for transfusions of allogenic blood through management based on the signs of anemia, reducing blood loss and optimizing blood salvage strategies". The specific technical information has always provided patients with the opportunity to express their wishes in a more conscious, articulate and detailed manner as opposed to a generic refusal expressed in a pre-printed ATD form.

The fact that the SCP, in the great majority of cases, confirmed the course of treatment recommended by the physician should be understood in light of the fact that, during the meeting, the team devised the plan and demonstrated they had understood the patient's aspirations, considering them viable. This leads to the conclusion that the initial discord, manifested between the patient and doctor, in relation to the care plan, was due to a lack of understanding rather than an objective

disagreement with the approach. The SCP meeting has therefore proven to be the perfect opportunity to pause for reflection and discussion in a precise rather than generic manner. In that sense, the SCP is to be considered as a process of information-consent not unlike the representative process of "informed consent" in its contents. Participation by several healthcare professionals, which is the nature of SCPs in the hospital in consideration, allows for a broader transmission of information and a more in-depth evaluation of the person's needs. The person can then make a decision in connection with a global project and not focused reductively on a single medical procedure without considering the care context.

The duration of the meetings and the very rare need for a second session, which occurred in just four considerably complex cases, lead us to believe that, with good general organization, the likelihood is negligible that the participation of multiple professionals in the SCP will create human resources issues in the operational facility's overall activities. In any case, it must be taken into account that, without the SCP, time would still have to be dedicated to explaining and clarifying information to patients and listening to them in return. Ultimately, the SCP is a formal, organized method for handling issues that are routinely considered in clinical practice in a disorganized manner (meetings between professionals, with limited and varied representatives, without the patient) or organized by the team (e.g. for the purpose of an individual treatment/rehabilitation plan), often without being recorded in the clinical file.

Conclusion

On initial assessment, SCPs involve a seemingly complex procedure that requires a disproportionate organizational capacity and commitment of personnel in comparison with the advantages it offers. In reality, however, the effort required is modest, essentially linked to the organization and convening of the discussion group and to drawing up the final summary report. Even if the commitment of personnel required in the SCP were to be considered significant, the positive aspects nevertheless prevail: it serves as a tool, implemented to safeguard health, that enables patients and

family members to acquire a greater awareness of the care plan from both a global and detailed perspective.

Moreover, the SCP has proven to be a flexible and high-performing tool in achieving the objective of personalized medicine, simultaneously protecting the patient's right to self-determination and the doctor's autonomy and responsibilities.

This procedure unleashes potentiality to the advantage of sick people, their loved ones and health-care professionals. However, we have observed passivity in its use and application, often relegated to specific clinical contexts. Further effort is required, therefore, in order for it to become, in conjunction with the entire contents of Law No. 219/2017, a common asset and daily practice both for medical teams and citizens, who are now presented with the opportunity to fully exercise this right.

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