Ethics of Returning Children's Individual Research Findings: from Principles to Practice.

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Abstract

Little ethical recommendations on returning children's individual research findings are available for researchers in behavioral sciences, especially when compared to genetic research. Anecdotic evidence suggests that since parents are often interested in their child's individual research findings, researchers tend to offer this information as a form of compensation for research participation. Despite good intentions, these practices are not without potential harmful consequences for children. We were confronted with these difficulties and with the paucity of available guidance on this topic, being involved in a longitudinal, infant development study, i.e. Tracking Infants At Risk for Autism (TIARA).

Firstly, we review current ethical recommendations and discuss their limitations in the light of the TIARA study. Secondly, we will suggest to revise these recommendations, by identifying and applying the relevant bioethical principles and concepts at hand. Thirdly, as an example of practical implementation, the adopted 'return of research findings'-policy for the TIARA-study is presented.

The principles and concepts we engage with are the *ancillary care responsibilities* of the researcher, *non-maleficence and beneficence*, the *right to an open future of the child*, and the *avoidance of therapeutic misconception*.

Ultimately, we present the concrete return of research findings policy implemented in the TIARA-study. Here, we suggest restricting systematic return of children's individual research findings to cases where findings are considered *clinically significant and actionable for the child*. We discuss the broader implications for designing and conducting research in behavioral sciences with children.

Introduction

Much has been written regarding the ethics of returning individual research findings to study participants and their relatives with regards to biomedical research, and especially genetic findings [1]. However, significantly less has been published about communicating individual findings in behavioral sciences, e.g. in the fields of psychological, educational and developmental research, particularly when minors are concerned. While it is not our aim to frame parents as potential liabilities to their children, we believe that particular attention and care towards children in research settings is relevant, as their interests do not always converge entirely with those of their parents. Below, we will highlight some of these diverging interests between children and their parents, as we believe that these are often interpreted as one and the same.

To our knowledge, very little recommendations are available for researchers in this field with regards to the duties they owe their underage research participants and their parents [2]. In contrast to genetic research where researchers previously tended not to inform their participants about individual research findings [3], anecdotal evidence from the field of behavioral sciences suggests that these researchers do often return children's individual research findings to parents. Such results may range from a description of how well a child has performed on a certain psychological task, visual material of brain imaging or the results of an intelligence test conducted as part of a research protocol. It is often assumed that parents have a right to this information about their child, and thus, that it is the duty of researchers to return these results. Previous empirical work showed that parents value receiving such individual feedback [4]. As such, both parents and researchers might consider this information a kind of compensation for research participation. To our knowledge, often, researchers already make a nuancing distinction between returning findings based on standardized instruments for which norm or cut-off scores are available, as compared to findings from experimental instruments for which

interpretation of the results is less straightforward. However, despite this valuable distinction, we will argue below that more criteria need to be fulfilled in order to justify returning children's individual research findings in behavioral research. As such, our position is that returning information from the child that is being collected during research should rather be the exception than the rule, especially when young children are involved.

Before outlining the set-up of this argument, some conceptual clarifications with regards to terminology seem to be relevant at this point. The concept 'return of research findings' might refer both to communicating the *general* findings of a study (or 'aggregate findings') to all participants, as to providing individual participants and their caretakers with personal feedback on the outcome of the instruments that were administered. It has been argued before extensively, that the return of general research findings to all participants willing to receive them, should be common practice acknowledging that participants do not merely act as a mean to a scientific end, but should be respected in their dignity as person as such [5, 6]. Additionally, empirical studies repeatedly highlighted participants' interest to be informed of these general findings [7].

Here, we focus on the ethics of returning *individual* research findings, in the case of underage research participants. Individual research findings are the *interpreted* outcomes of a given assessment of a single participant obtained within a research study setting. These may be *intended* results (results that straightforwardly come out of the instruments administered) or *incidental* findings (results that come out of an instrument but where not intended, think for example about the detection of a tumor during brain imaging research). For the purpose of this paper, we will not make the distinction, since our argumentation and conclusions apply to a same extent to both intended and incidental findings.

Firstly, we will review existing ethical recommendations on this topic. Secondly, we will introduce the TIARA study (Tracking Infants At Risk[1] for Autism), a longitudinal infant development study in which we are involved concerning the research ethics. We will describe the limitations we were confronted with when applying the existent recommendations in practice. Thirdly, we will attempt to revise existent recommendations, building on the principles and concepts that have been successfully applied to the question of returning individual findings in the case of genetic research on minors. These principles and concepts include the *ancillary care responsibilities* of the researcher, *non-maleficence* and *beneficence,* the *right to an open future of the child,* and the avoidance of *therapeutic misconception*. Lastly, we will describe the practical implementation of these revised recommendations in the TIARA study.

[1] Although the phrase 'at-risk for autism' is widely used in research settings, we understand that the use of the word 'risk' when referring to autism is controversial. At-risk language frames autism as a threat, as a medical condition to be prevented as such. More neutral use of language replacing 'risk' by 'likelihood' or 'chance' could function as a less pejorative alternative [20].

Existing ethical recommendations on returning children's research findings

To our knowledge, only Lefaivre, Chambers and Fernandez [2] examined, from a theoretical perspective, the ethics of returning children's individual research findings in the field of psychology[2]. Before providing a set of recommendations, the authors highlight several relevant issues to be taken into account, both in favor as opposed to returning children's individual research findings. Here we give an overview of those issues as formulated by Lefaivre et al., which we have categorized as related to:

(a) the impact on participants and their parents;

(b) the impact on the research project; and

(c) the qualitative aspects of the research findings.

(a) With regard to issues impacting underage participants and their parents, Lefaivre et al. [2] argue, in line with arguments on returning general research findings, that "one of the strongest arguments in favor of offering individualized feedback is that this procedure obligates researchers to treat each of their participants primarily as persons or an end in themselves rather than a means to an end" (p.245). Adding up to this, "the opportunity to gain knowledge[3]" (p.245) is presented as a benefit of research participation for both the child and the parent. They also present caveats regarding individualized feedback, such as the child's right to privacy, the

[2] In order to identify earlier ethical recommendations on returning children's individual research findings, we carried out a literature review. Papers were included for review if they (a) prescribed ethical recommendations on whether and how (b) individual research results of (c) minors (<18y) should be (d) returned to parents (e) within the field of psychological and pychiatric sciences. Papers were excluded if they merely (a) empirically researched the effects of returning such findings or stakeholder preferences on the topic, or (b) when they only addressed genetic or biological findings. To this extent we searched Web of Science using the following search terms (ethic* OR recommendation*) *AND* (result* OR finding*) AND (return OR feedback OR communication OR disclosure) *AND* (psycholog* OR psychiatr*) *AND* (child* OR infant OR youth OR adolescen* OR parent*). This search yielded 379 results. Based on title and abstract, 6 results were selected for full-text review. Three papers were excluded for only adressing genetics or neuroimaging findings. One paper did not discuss individual research findings, while one did engage with our precise research question, but addressed the issue in an empirical-descriptive way [4][4][4][4][4][4]. Ultimately, one paper could be included, i.e. Lefaivre et al. [2].

[3] Lefaivre et al. refer here to the potential benefits of gaining *individual* knowledge

potential of disagreement between the minor and the parent on whether and how the research results should be dealt with, the risk for the child of being labeled unwantedly and for installing a self-fulfilling prophecy. For example, merely returning research results of a child scoring below average on a test measuring receptive language skills, might, hypothetically, incite parents to simplify their language or read less to their child, as they might believe is best. In result, the amount of language on offer reduces and the child's receptive language competences are granted less opportunities to develop. This way, the prophecy fulfils itself.

(b) From the perspective of the researchers and their study, Lefaivre et al. suggest that returning individual findings to participants as compensation for their efforts may encourage participants to take part in research in the first place, and may keep participants involved when longitudinal research is concerned (2007). However, the authors equally mention concerns on how the promise of individual results as recruitment strategy in some cases can be considered an "excessive enticement for research participation" (p.246). Especially in healthcare contexts where clinical access to the assessments in case might be limited, e.g. due to financial limitations or waiting lists, research participation carries the risk of compromising the autonomous consent procedure of participants to take part in the study without any form of coercion. This way, the authors argue, theoretically, a sample bias could be introduced 'limiting the generalizability of the study's results' when "parents and youths falsely report difficulties or signs of psychopathology simply to meet the eligibility criteria" (p.246). Furthermore, and especially when results are returned during ongoing longitudinal research, "the timing of the feedback and subsequent need for additional assessment could compromise the integrity of the research design" (p.248).

(c) As a third category of issues, Lefaivre and colleagues [2] highlight the point that instruments that are administered in research settings regularly differ from those used in clinical

circumstances in terms of "reliability, validity and clinical utility" (p. 247), qualities on which the justification of returning individual research findings depend. If the instruments at hand lack good psychometric properties, or if the findings do not evidently correlate to diagnostic or therapeutic practice, returning findings based on those instruments is of limited value.

In an effort to translate these theoretical issues into practical guidance for researchers in psychology and related fields, Lefaivre and colleagues listed a set of ethical recommendations. In these recommendations, the authors define *which* kind of individual findings could be returned, and *when* and *how* this could be done.

In practical terms, the authors recommend returning individual findings if these rely on "well-validated psychological measures" and if they include "normative data or empirically-derived cut-offs" (p.248-249). Furthermore, the authors formulate extensive recommendations on how to approach this individual feedback. They suggest explaining the opportunity for returning findings during the consent procedure, to engage underage participants in the choice to obtain the findings and to provide written feedback in lay-language combined with percentile ranks or a description comparing the results with the average outcome range. The authors advise to have a face-to-face conversation led by a clinically experienced professional when complex, ambiguous or impactful findings need to be communicated.

Taken together, these suggested practical recommendations focus firstly on the principle of *beneficence* by providing valid and reliable individual research findings to participants that are considered of interest to them and their parents. Secondly, the recommendations highlight the underage participant and parents' *autonomy* in having their voice heard on whether or not individual feedback is to be welcomed.

However, it is remarkable that these practical recommendations do not integrate all the theoretical reflections the authors raised before. Most prominently, attention to *prevention of harm* to both the participant and the study itself, and to the aspect of *clinical utility* appears to be left out in the recommendations. Furthermore, while the authors stress parents' autonomy on whether they want to be informed on the research findings of their child, the recommendations seem to imply that parents can opt-out of all findings. While this is a valuable position in many cases, it can be problematic when the findings indicate a severe or life-threatening condition. A critical appraisal of parents' apparent right of not knowing certain findings seems to be lacking.

In what follows, we will illustrate how we were confronted with these gaps in the practical recommendations when reflecting on the return of individual findings during the TIARA-study in which we are involved. We start by describing the goals and methods of TIARA as such, moving over to the relevant ethical principles and concepts to consider and finalize by giving insight in the return of research findings policy that we eventually adopted.

From ethical principles to practice: the case of TIARA (Tracking Infants At-Risk for Autism)

TIARA is a multi-center, longitudinal cohort study on infant development between the age of 5 and 36 months, co-led by two Belgian universities, Ghent University and KU Leuven. (http://tiara-onderzoek.be/). TIARA aims to identify and understand the interplay and the predictive value of a wide range of parameters in the early development of autism spectrum disorder (ASD, or shortly autism). Children participating in TIARA belong to one of three groups, each with a suspected increased chance for developing ASD, i.e. siblings of children with an established ASD diagnosis [8], infants born prematurely under 30 weeks of gestation [9] and infants with persistent, medically insufficiently explained feeding problems [10]. These

children are being assessed at 5, 10, 14, 24 and 36 months of age. At these ages, children are assessed in a variety of ways including via developmental (e.g. Bayley Scales of Infant Development (BSID-III)) and behavioral assessments (e.g. Autism Diagnostic Observation Scale (ADOS-2), mother-child interaction, eye-tracking), and genetic, metabolic and neurophysiological tests (e.g. EEG). At the age of 36 months, a best-estimate categorical research diagnosis of ASD, non-ASD or atypical development is established.

Within the TIARA study, parents prove to be particularly interested in the individual research findings of their young child, a dynamic which has equally been reported in a similar Swedish study [11]. This should not be a surprise knowing that the participating child has been described as 'being at-risk for autism' even before the first study assessment took place. Additionally, parents are in some cases confronted with the fact that their child has difficulties with specific tasks since they are present at the research assessments. As such, it can be understood that parents have a particular interest to be informed of the findings of their child. Another factor is that over the course of the different assessments a more familiar bond is established between parents and researchers, leading parents to ask more questions and researchers to intuitively lean towards discussing more individual findings. Most of the TIARA researchers have clinical degrees in psychiatry, psychology and educational sciences, and because of this clinical training, they also may be more inclined to discuss results with parents, as they would do in a clinical setting. This reciprocal give-and-take dynamic where borders between research and care are partly blurred, has been described in ethnographic research before as a noteworthy characteristic of performing early autism studies [12].

However, TIARA is a research protocol, not clinical care. Therefore, the TIARA team developed a return of research findings policy, which, in our view, respects the principles and concepts of *ancillary care responsibilities of the researcher*, *non-maleficence* and *beneficence*,

the right to an open future of the child, and the avoidance of *therapeutic misconception*. We are convinced that these principles and concepts can help guiding similar policies in other studies too. However, their application will necessarily depend on the concrete circumstances at hand.

Implementing researchers' ancillary care responsibilities

To start with, one can ask if researchers do have any responsibility at all to be occupied with returning individual research findings and if so, how far such responsibility would reach. In this respect Richardson and Belsky helpfully conceptualized the *ancillary care responsibilities* for researchers [13]. These authors argue that there is indeed a minimal set of responsibilities for researchers to care for their participants, be it only if two criteria are fulfilled based on the scope and strength of the findings. Ancillary care is defined here as care "which goes beyond the requirements of scientific validity, safety, keeping promises, or rectifying injuries" (p. 26). Ancillary care can thus entail returning individual research findings and providing –directly or indirectly via a referral- clinical care, if needed.

Hereby Richardson and Belsky find a middle ground between two polar positions, i.e. the researcher as personal physician for the participant as patient on the one hand versus the researcher as pure scientist and the participant as mere volunteer on the other. Research participants do not hand over permission to researchers to promote their health in the same way as in a clinical patient-physician relationship. However by taking part in research, participants (or when minors are concerned: their parents) do give limited authorizations to the researchers to collect health information about them or to conduct a certain intervention. This happens however within a pre-defined scope. As such, a certain vulnerability is generated between participant and researcher in which the participant's well-being is partly dependent on the researcher's decision-making. Together, this is what Richardson and Belsky describe as the *partial entrustment model* of the researcher-subject relationship.

From this model, two criteria come forth that justify and limit ancillary care responsibilities. Firstly, the care should fit within the health *scope* of what participants have entrusted the researchers. Clearly, this means that there are significant differences in scope between studies relying on a simple once-only online questionnaire versus those using a longitudinal approach with many different contacts between participant and researcher and using a variety of instruments. Secondly, based on the participant's vulnerability in the concrete case, the rationale to provide care should be sufficiently *strong.* To this extent, Richardson and Belsky, point to the following three elements: How much difference would the provided care make (i.e. clinical significance of the finding and the associated act), how much risk did the participant take to participate and how dependent is the participant to the researcher to provide the care needed [13]? For example, the authors argue that in brain imaging studies, researchers have a responsibility to undertake a diagnostic reading of the brain scans to screen for tumors and aneurisms. These findings are clearly within the scope of the brain imaging research and their potential life-threatening character makes participants strongly vulnerable to the researcher acting upon the findings.

This concept of ancillary care offers some guidance on whether researchers should consider providing care, such as returning individual findings and referring to clinical care. Besides the *scope* and *strength* criteria, we also believe the consequences of returning individual research findings are to be considered. Below we outline the consequential principles of non-maleficence and beneficence.

Considering non-maleficence and beneficence

The principles of non-maleficence and beneficence are two of the four basic principles of biomedical ethics, as laid down by Beauchamp and Childress [14]. Both of them point to the consequences of a given act to judge whether this act can be justified. Non-maleficence refers to the duty of medical personnel and biomedical researchers to avoid harm from happening to

their patients and participants, either by the professionals' interventions or by negligence. Beneficence on the other hand refers to the duty to be of a benefit for patients and participants by taking active steps to promote health or to prevent and remove harm. Clearly, these two principles are partly entangled. Furthermore, absolute interpretations of either of them set a practically unfeasible standard. Therefore, the application of these principles often comes down to finding a reasonable balance between minimizing harms and maximizing benefits. We believe this also applies to psychological, educational and developmental research, although the possible 'harm' and 'benefit' may be not so straightforward here. Importantly to note here is that definition of benefits and harms are often not merely objective facts. Making up the balance depends on whom the consequences of an act occur to and how these consequences are interpreted. In other words, the principles of non-maleficence and beneficence are value-laden.

The recommendations by Lefaivre et al. would support returning all findings based on standardized instruments for which norm or cut-off scores are available, suggesting that they consider these findings as neutral or not harmful. In the case of TIARA, this would imply for example returning findings regarding the child's cognitive development obtained via the BSID-III, or the results on the ADOS-2. Parents might be interested to know at which percentile their child situates herself, or whether she scores above, below or on average for these measures. We believe however that giving parents systematically access to all of this information, even if this relies on a standardized instrument, entails a couple of risks. In our view, Lefaivre et al.'s practical recommendations do not sufficiently take into account potential negative implications for the child, i.e. the principle of non-maleficence. Such potentially negative implications for the child, as exemplified below, may trump the benefits that these findings may have in satisfying parental interest. Indeed, as we are dealing with

research on minors, it is important to keep in mind that, strictly speaking, the child is a participant, and not her parents.

Potential negative implications of returning any and all findings may imply unasked for and potentially unnecessary labeling, i.e. applying classificatory terms associated with sticky stereotypes or a self-fulfilling prophecy. For example, returning findings of a child scoring above the clinical cut-off on the ADOS, an observation schedule of autism characteristics, might lead the child's environment to start seeing the child as 'a little autistic', even when in se, this result by itself does not imply that a clinical diagnosis of ASD could nor should be established. Another example, this time not drawn from the TIARA study, could be returning an average result on an intelligence test (e.g. IQ 100). Especially when interpreted statically, as in the implicit entity theory of intelligence (Dweck, 1999), the perspective of parents on their child and possibly the expectations they hold for her may be altered (e.g. "an average intelligent child shouldn't strive for going to university"), all while there might be no clear clinical argument that this practice would benefit the child[4]. As mentioned before, applying non-maleficence and beneficence involves finding a balance between potential harms and benefits. In research settings the primary goal, and thus benefit, is a scientific one, i.e. to gather generalizable knowledge. Individual benefits for participants are definitely not excluded, but are not on the forefront. This is a sharp difference compared to clinical care. Therefore, we believe that minimizing harm warrants a stringent interpretation in research settings. We understand that this is an ideal that is hard to attain and that in one way or another, participation in research may alter the child's life course. The aim of policies is

[4] User guidelines of instruments like the ADOS-2 and BSID-III highlight these risks of overinterpreting results of a single test at one point in time as a definite diagnostic assessment, especially during early development. The ADOS-2 for example, does not use clinical cut-offs in the toddler version of the instrument, while BSID-III mobilizes the terminology of *developmental index* and acknowledges limitations to its stability over time, when compared to intelligence tests administered at school age or later in life. We are however concerned that such strong interpretations might still take place when feeding back findings to parents in a research context, despite efforts of the developers of these instruments to apply the necessary nuances.

however to avoid that such alteration is actively enabled if it potentially implies harm to the child. When it comes the consequences of returning individual findings, we believe that the child in case should clearly benefit from this act to justify it. This judgement on the beneficial consequences of feeding back certain findings should be based on the best available clinical evidence. At this point in our argumentation, we feel however that it is important to stress that this a clinical judgement specific to the given case and its context, including parents' view on the matter. Therefore, the decision-makers at hand will often need to deal with various layers of uncertainty. Examples of such uncertainty are the notion that findings often only capture a snapshot of a child's development, which is a dynamic process; and that often evidence-based clinical interventions are not directly applicable to the particular, individual case at hand. As such, researchers in this field of inquiry will benefit from having close ties with clinicians experienced in working with the relevant instruments and research population.

As is often the case in bioethical analyses, this interpretation of the principles of non-maleficence and beneficence heavily relies on professional judgement. Defining what is beneficial or harmful undeniably depends on who is judging and what their priorities and values are [16]. Respecting autonomy rights of the participant, i.e. the child, is therefore a key element, besides respecting the views of parents who are the primary caregivers of the child. In our practical implementation below, we will discuss how this approach differs from full-fledged shared decision-making processes in clinical care.

Respecting the right of the child to an open future

In bioethics, making a decision autonomously refers to judging a situation voluntarily, i.e. without external pressure, and in an informed way. Since this capacity for autonomy develops over time, parents initially make decisions for their children, granting them more voice when they grow older. When doing research with young children, such as in the TIARA study, respecting autonomy does however not merely boils down to acquiring parents' informed

consent. Here, the *right of the child to an open future* provides useful guidance. Legal scholar Joel Feinberg defined this as a right, derived from adults' rights on autonomy, which protects the child against having important life choices determined by others before she has the ability to make them for herself (Feinberg, 1980). In the context of genetic research, this *right to an open future* has been taken to imply that unless a result of a genetic test is clinically actionable while the child is still underage, the choice to undergo such an action should be left to the child. The rationale behind this right is that she may have or develop a different opinion about what she wants to be known about her genes [18]. Although results of psychological, behavioral and developmental assessments usually contain information that will change throughout a lifetime, unlike genetic information, we believe that some analogy can be drawn here. This is particularly the case when the research involves e.g. intelligence correlates or an assessment of autistic characteristics that are frequently interpreted as being stable over the lifetime. In other words, the application of long-lasting diagnostic labels or the use of interventions with long-term effects pose a potential threat for the future autonomy of the child. However, such actions can be justified when weighed against the other principles here at stake, namely the ancillary care responsibilities of the researcher, beneficence and non-maleficence. The added value of considering the child's right to an open future is rather that actions with long-term effects for the child, should not be undertaken lightly as if there were no autonomy rights of the child in case at stake.

Avoiding therapeutic misconception

Returning individual findings to parents of participating infants may be considered as a form of compensation for research participation, especially in cases where such compensation is otherwise not foreseen. Apart from the above mentioned reasons, such situations must be avoided since it increases the risk of *therapeutic misconception* [19]. Especially in research studies where the instruments administered are similar or identical to those taken in the context

of a clinical assessment, there is a risk that participants or, in the case of TIARA, their parents, mistake the research for clinical care or for research that is primarily oriented towards the care of their child, rather than to generate new knowledge about child development in general. For example, they may interpret early findings as a definite diagnosis of autism or of another developmental condition. As in Belgium the waiting lists for a clinical assessment are long, they may have the expectation that by participating in the research an earlier diagnosis can be obtained, even if this cannot be guaranteed. Such misconceptions about the aim of the study may also include a sample bias: those participating may not be representative for the population of parents of a child at increased chance of a developmental condition, but rather be a subgroup of parents with a certain vigilance toward possibly deviant behavior of their child or who are already actively looking for clinical care for their child. Although we feel it is important to make clear from the outset to participating families that they engage in a research, and not a clinical trajectory, this does not mean that when beneficial clinical consequences can be obtained from research participation this should be blocked off. This might be especially beneficial for less privileged families who face on average more obstacles in obtaining access to clinical care. This notion of therapeutic misconception is further developed below when describing the concrete policy that we have adopted.

Practical implementation

Clinical significance and actionability

We consider the above-mentioned principles and concepts as building blocks for designing a respectful return of findings policy when doing research with children in our field of inquiry. The concrete application of these theoretical considerations depends however on the particularities of the research setting at hand. With regards to the TIARA study, the following particular elements shaped the design of the policy. This study has a longitudinal design, with

five daylong contacts during which a wide variety of developmental, behavioral and biological parameters are assessed. When reflecting on ancillary care responsibilities, these aspects result in a fairly wide scope of well-being domains entrusted to the researchers, i.e. the physical, social and emotional development of the child. Furthermore, there is a significant vulnerability in the relationship with participants since this kind of in-depth assessment with clinically relevant instruments is not easily available in clinical settings at such a young age, and since it is generally accepted that infancy is a critical period for development. Following the concept of ancillary care, these two elements make that in the setting of TIARA there is a significant responsibility for researchers to provide care beyond what is merely necessary to keep the study running. However, as we have discussed returning individual research findings might also have potential harmful effects for the child and can thwart their future autonomy especially when long-term labels are considered. When reflecting on whether or not individual research findings should be returned to parents, we believe a case-by-case analysis should be made defining if the beneficial consequences outweigh the potential harms and limits to future autonomy. In the context of TIARA, we practically translated these theoretical considerations into the following baseline of our return of research findings policy. We have chosen to limit the systematic return of individual findings to *clinically significant and actionable findings*. As laid out below, we refer here to significantly deviating findings that stem from validated instruments within the behavioral, developmental and biological scope of the research and for which the estimated benefits of clinical action (such as clinical follow-up, further diagnostic assessment or therapy) are considered to outweigh potential harmful effects to the child in its particular context.

Return of research findings policy in TIARA

As an element in the informed consent procedure, parents can indicate if they want to obtain individualized feedback. If parents give their consent, they receive a feedback report in

understandable lay language after each round of testing in this longitudinal protocol. This report either states that the child's performance on the administrated instruments warrants no clinical follow-up at that stage or either that it does.

Findings based on validated instruments, such as well-established questionnaires and observation scales can be communicated to parents if a multidisciplinary team of researchers supplemented with experienced clinicians agrees that the findings are both clinically relevant and actionable from a professional perspective, as defined above. If this is the case, a concrete referral towards a clinical practitioner is proposed to parents, depending on the developmental domain concerned. For example, when a child scores significantly low on gross motor skills, we suggest the parents to consult a pediatrician for follow-up of this developmental domain. Due to the longitudinal design, researchers often have come to know parents' views on their child's development. As such, it is possible for the multidisciplinary team to consider this input when making the decision on returning individual findings and on the concrete referral that is proposed. In principle when such contextual factors differ considerably, a similar finding can result in a different decision on whether to return it or not.

When clinical follow-up is advised, parents receive information on the research findings that are relevant for this follow-up. As such, parents only receive the concrete, individual findings of their child if these findings are considered clinically significant and actionable. If not, we aim to reassure parents that based on the administered instruments and to the best of the team's knowledge, no clinical guidance is warranted for their child. We consider it our responsibility as researcher to deliver this minimal, reassuring feedback as a form of ancillary care towards parents. This policy rules out returning findings based on instruments for which at the point of data collection in this study, no validated norms or cut-off values are available, such as for eye-tracking and explorative EEG paradigms. These findings offer too limited

guidance in terms of clinical significance and actionability, while they might have harmful effects when interpreted as deviant.

For a child with feeding problems or a child in follow-up due to prematurity, with permission of the parents, findings may be communicated to the clinical team in order to offer clinical guidance directly, or to avoid unnecessary duplication of an assessment, which in itself may be burdensome for the child.

In case no consent is given by parents to receive individualized feedback, this position is evidently respected, except when findings are obtained where the parents' choice not to know would very significantly harm the child, such as in case of detection of a life-threatening condition. It is clear that the bar for returning findings in this case is set higher compared to the standard of mere clinical significance and actionability discussed above.

Early on, during the design of the TIARA research protocol, different clinical referral pathways were reflected upon and discussed with clinical practitioners in the surroundings of the study centers, in order to make sure that children in need would have effective access to clinical follow-up. In order to set the right expectations from the start, this policy is communicated to parents during the informed consent procedure. Additionally, to avoid therapeutic misconception, during promotion of study participation, arguments that stress clinical benefits are avoided (e.g. 'Is your child autistic? Know it early on by participating in this study!'). When parents explicitly express their worries about their child's development during the study, despite findings that are not clinically significant, we offer parents a discussion with a senior researcher with clinical experience. In this conversation, we discuss the rationale behind this policy and we consider whether parents should be oriented to a clinical setting to explore their concerns further.

We believe that this policy which restricts systematic return of individual research findings but explicitly argues in favor of returning clinically relevant and actionable findings, is respectful for the infants in the study, and ultimately also their parents. Even though this policy does not eliminate parents' interest in the individual findings, we can reassure them that they will have access to this information, if clinical action is needed. As such, we believe that we have centered the fact that at its heart, TIARA is a research protocol and not clinical care, while also not forgetting that vulnerable research participants such as infants need specific care.

Strengths, Limitations and Future Research

Ethical guidance on returning individual research findings of children in the field of behavioral sciences is scarce. As we have pointed out, in our view earlier recommendations lacked a critical approach to possible harmful effects of returning findings for the child, including thwarting of their future autonomy. By discussing the different ethical principles and concepts, we aimed to fill this gap and provide the theoretical building blocks that can inspire other return of research findings policies in our field. The novelty of this work lies in the unique collaboration of researchers from the fields of child psychology and psychiatry, educational sciences and ethics. Hereby, we have been able to ground our recommendations both firmly in ethical theory as in the daily experiences of conducting clinical research with children.

We acknowledge however that a different research setting would have led to a different integration of the principles and concepts discussed. For example, when research participants are adolescents, the autonomy principle might play a larger role in deciding which findings are returned to them and beneficial outcomes might also entail satisfying personal interest of the adolescent, going beyond the more restrictive approach of only returning findings that are clinically actionable. We did not argue however for a case-by-case full-fledged shared

decision- making process (with parents) on deciding which findings are to be returned, as is this is typically the case in clinical settings. As discussed for the TIARA study, parental views are taken into account, but we believe that –at least in settings like ours- individual discussions at the time of giving consent would stretch beyond the ancillary care responsibilities of the researchers. Instead, we have opted to install and communicate clearly a policy to which parents can agree if they want to join the study, thereby entrusting the researchers in making a justifiable decision on returning individual findings of their child.

Furthermore, as we touched upon, clinical significance and actionability might be less straightforward concepts than they appear to be. Despite the weight of evidence-based medicine and best practices, there will be differences in judgements between centers regarding the conditions that require or are amenable to clinical action. Although we argued for having close ties to experienced clinical practitioners when deciding on this aspect, we understand that this is not self-evident for all research groups.

Lastly, it should be mentioned that besides a discussion based on ethical principles and concepts, also from a legal perspective arguments can be drawn. Most importantly, we can think of the child's right to privacy as defined in Article 16 of the United Nations Convention on the Rights of the Child (UNCRC), protecting children's personal information, even from caretakers. On the other hand, data protection regulations such as the EU's GDPR could, arguably, also provide parents with a right to access and verify data from their children that have been collected, processed and stored within research contexts. Exemptions to this right however exist; therefore, we consider the interpretation of the GDPR in light of the right of parents to access their children's data and the rights of children to be protected from such access to be valuable matters for future legal research.

Conclusion

Deciding on the returning individual research findings of children is a point of ethical discussion, also in the behavioral sciences. We introduced a set of principles and concepts that can inspire a concrete return of research findings policy. As a matter of example, we presented the practical implementation of such a policy in the longitudinal child development study TIARA. Here we decided to restrict systematic return of individual findings to those considered clinically significant and actionable. Hereby, we refer here to significantly deviating findings that stem from validated instruments within the scope of the research and for which the estimated benefits of clinical action are considered to outweigh potential harmful effects for the child in its particular context.

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Competing interests

On behalf of all authors, the corresponding author states that there is no conflict of interest.

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